REGISTRATION REPORT

Part B

Section 7

Metabolism and Residues

Detailed summary of the risk assessment

Product code: GLOB2112dH

Product name: Walkover Trio

Chemical active substances:

Thiencarbazone-methyl, 75 g/L
Mesotrione, 375 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(authorization)

Applicant: Globachem NV

Submission date: September 2024

zRMS Assessment : 31/03/2025

Version after commenting: 03/07/2025

List of references update: 10/07/2025

Version history

When	What
September 2024	Initial dossier submission by applicant for approval of new product.
March 2025	zRMS assessment
July 2025	After commenting round
July 2025	List of references update

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7 Metabolism and residue data (KCA section 6)

7.1 Summary and zRMS Conclusion

Mesotrione

Storage stability

No new study on stability was submitted. Residues of mesotrione were stable at -18°C for 42 months in maize grain (high starch content) and for 31 months in maize forage (high water content). Residues of its metabolite MNBA were found to be stable at -18°C for 42 months in maize grain and forage.

Metabolism

Metabolism in primary and rotational crops was found to be similar. The residue definition for enforcement and risk assessment is proposed as mesotrione.
The available animal metabolism study is acceptable to derive a residue definition for enforcement and risk assessment in ruminant. AMBA is expected to be the predominant compound of the total residues in the major feed item (maize silage and grass) to which ruminants are expected to be exposed to. At the estimated dietary burden, the transfer of AMBA residues in all matrices was shown to be negligible and residue definitions for animal commodities are provisionally not required for the representative use (EFSA, 2016).

Processing

As the residues in maize grain are <0.01 mg/kg, processing studies are not necessary.

Magnitude of residues in plants

Maize

Type of GAP	Method	Number of applications	Max. application rate per treatment (kg as/ha)	Interval between application (days)	Growth stage at last application	PHI (days)
GAP EU (EFSA, 2015)	Foliar spray	1	0.15	-	BBCH 12 – 19	-
Intended GAP	Foliar spray	1	0.04875-0.075	-	BBCH 10 – 18	-

Maize is a major crop in Northern Europe. The applicant relied upon 15 NEU trials that have been previously evaluated at EU level, with application rates higher than those proposed GAP. The proposed use is within the EU GAP. Available results show that the current MRL of 0.01 mg/kg (Reg. (EU) 2024/1077) will not be exceeded. Therefore the proposed uses of the product can be considered as supported on maize in Central Europe.
The magnitude of residues in rotational crops is not expected to exceed 0.01 mg/kg.

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

Consumer exposure

The calculation of the TMDI led to an utilisation of the ADI of 12.0 % based on NL toddler being the population group with the highest value. For this diet, the highest contributor is milk with 6% of the ADI. The highest International Estimated Short-Term Intake (IESTI) is at 6.0% and 3.0% of the ARfD for the consumption of milk by children and boiled pumpkin by adults (processed commodities) and at 8.0% and 2% of ADI for the consumption of potatoes by childen and cabbages by adults (raw commodities). The

proposed use of mesotrione in the product Walkover Trio does not represent unacceptable chronic and acute risks for the consumers.

Thiencarbazone-methyl

Storage stability

No new studies submitted. The available studies demonstrated that thiencarbazone-methyl, BYH 18636-N-desmethyl and BYH 18636-MMT-glucoside were stable in high water, high oil content commodities and dry commodities for 26 months when stored at -18°C.

Meatbolism

Metabolism and distribution of thiencarbazone-methyl in rotational crops is similar to the metabolic pathway observed in primary crops. The residue definition for enforcement is proposed as thiencarbazone-methyl only. 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. The metabolism of thiencarbazone-methyl residues in livestock indicated similar pathway in lactating goats and laying hens. The residue definition for monitoring and risk assessment was proposed as the sum of thiencarbazone-methyl and BYH 18636-MMT expressed as thiencarbazone-methyl.

Processing

Processing studies are not necessary - the residues in maize grain are <0.01 mg/kg.

Magnitude of residues in plants

Maize

Type of GAP	Method	Number of applications	Max. application rate per treatment (kg as/ha)	Interval between application (days)	Growth stage at last application	PHI (days)
GAP EU (EFSA, 2013)	Foliar spray	1	0.04-0.054	-	BBCH 13 – 18	-
Intended GAP	Foliar spray	1	0.00975-0.015	-	BBCH 10 – 18	-

The applicant relied upon 12 NEU trials that have been previously evaluated at EU level, with application rates higher than those proposed GAP. The required use is within the EU GAP. Available results show that the current MRL of 0.01 mg/kg (Reg. (EU) 2021/1110) will not be exceeded. Therefore the proposed uses of the product can be considered as supported on maize in Central Europe.
Residues in rotational crops following use the product according to the proposed GAP are unlikely to exceed 0.01 mg/kg.

Consumer exposure

The calculation of the TMDI led to an utilisation of the ADI of 0.5 % based on NL toddler being the population group with the highest value. For this diet, the highest contributor is milk with 0.3% of the ADI. As no ARfD was established, no acute risk assessment was performed. The proposed use of thiencarbazone-methyl in the product Walkover Trio does not represent unacceptable chronic and acute risks for the consumers.

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 GLOB2112dH are presented in Table 7.1-1. They have been selected from the individual GAPs in the central zone for maize. A list of all intended uses within the central zone is given in Part B, Section 0.

Overall conclusion

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

Data gaps

Noticed data gaps are: none

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

1	2	3	4	5	6	7		8				9			10	11
GAP number (see part B.0)*	**Crop and/ or situation ****	**Zone**	**Product code**	**F, Fn, Fpn G, Gn, Gpn or I*****	**Pests or Group of pests controlled**	**Formulation**		**Application**				**Application rate per treatment**			**PHI (days)**	**Conclusion**
						Type	**Conc. of as**	**method kind**	**growth stage & season**	**number min max**	**interval between applications (min)**	**kg as/hL min max**	**water L/ha min max**	**kg as/ha min max**		
1	Maize (ZEAMX)	Central	GLOB2112dH	F	*Annual dicotyle-donous weed plants* (3ANDIT) *Annual grasses* (3ANMNT)	SC	Mesotrione: 375 g/L Thiencarbazone-methyl: 75 g/L	Downwards spraying – Broadcast application	BBCH 10-18	1	NA	Mesotrione: 0.025-0.075 Thiencarbazone-methyl: 0.005-0.015	100-300	Mesotrione: 0.075 Thiencarbazone-methyl: 0.015	NA	A
2	Maize (ZEAMX)	Central	GLOB2112dH	F	*Annual dicotyle-donous weed plants* (3ANDIT) *Annual grasses* (3ANMNT)	SC	Mesotrione: 375 g/L Thiencarbazone-methyl: 75 g/L	Downwards spraying – Broadcast application	BBCH 10-18	1	NA	Mesotrione: 0.01625-0.04875 Thiencarbazone-methyl: 0.00325-0.00975	100-300	Mesotrione: 0.04875 Thiencarbazone-methyl: 0.00975	NA	A

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

Explanation for Column 11 "Conclusion"

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

7.1.2 Summary of the evaluation

The preparation GLOB2112dH is composed of mesotrione and thiencarbazone-methyl.

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

Reference value	Source	Year	Value	Study relied upon	Safety factor
Mesotrione					
ADI	EFSA conclusions	2016	0.01 mg/kg bw/d	Mouse multi-generation	200
ARfD	EFSA conclusions	2016	0.02 mg/kg bw/d	Mouse multi-generation	100
Thiencarbazone-methyl					
ADI	EFSA	2013	0.23 mg/kg bw/d	Rat chronic study, ~~12 month dog and 90 day rat study~~	100
ARfD	EFSA	2013	Not required		

7.1.2.1 Summary for mesotrione

Table 7.1-3: Summary for mesotrione

Use-No.*	Crop	Plant metabolism covered?	Sufficient residue trials?	PHI sufficiently supported?	Sample storage covered by stability data?	MRL compliance	Chronic risk for consumers identified?	Acute risk for consumers identified?
1, 2	Maize	Yes	Yes (34, NEU:15, SEU: 19)	Yes	Yes	Yes	No	No

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

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

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

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

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?
1, 2	Maize	Yes	Yes (25, NEU:12, SEU: 13)	Yes	Yes	Yes	No	No

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

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 MRLs in commodities of animal origin is therefore not necessary.

7.1.2.3 Summary for GLOB2112dH

Table 7.1-5: Information on GLOB2112dH (KCA 6.8)

Crop	PHI for GLOB2112dH proposed by applicant	PHI/ Withholding period* sufficiently supported for		PHI for GLOB2112dH proposed by zRMS	zRMS Comments (if different PHI proposed)
		Mesotrione	Thiencarbazone-methyl		
Maize	NR	NR	NR		

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

Table 7.1-6: Waiting periods before planting succeeding crops

Waiting period before planting succeeding crops			Overall waiting period proposed by zRMS for GLOB2112dH
Crop group	Led by mesotrione	Led by thiencarbazone-emthyl	
Maize	NR	NR	

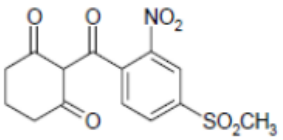
NR: not relevant

Assessment

7.2 Mesotrione

General data on mesotrione are summarized in the table below (last updated 2024/04/25)

Table 7.2-1: General information on mesotrione

Active substance (ISO Common Name)	Mesotrione
IUPAC	2-(4-mesyl-2-nitrobenzoyl) cyclohexane -1,3-dione
Chemical structure	
Molecular formula	$C_{14}H_{13}NO_7S$
Molar mass	339.3 g/mol
Chemical group	Benzoylcyclohexanedione herbicides
Mode of action (if available)	Competitive inhibition of the enzyme 4-hydroxyphenylpyruvate dioxygenase, a component of the biochemical pathway that converts tyrosine to plastiquinone and alphatocopherol preventing chlorophyll destruction by sunlight
Systemic	Yes
Company (ies)	Syngenta Crop Protection AG*
Rapporteur Member State (RMS)	UK
Approval status	Approved 01/10/2003 COMMISSION DIRECTIVE 2003/68/EC - REGULATION (EU) No 540/2011 – REGULATION (EU) 2017/725
Restriction	-
Review Report	SANTE/11654/2016 – 23 March 2017
Current MRL regulation	~~Regulation (EC) No 2017/626~~ Reg.(EU)2024/1077
Peer review of MRLs according to Article 12 of Reg No 396/2005 EC performed	Yes
EFSA Journal : Conclusion on the peer review	Yes; EFSA, 2016**
EFSA Journal: conclusion on article 12	Yes; EFSA, 2015**
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

7.2.1 Stability of Residues (KCA 6.1)

7.2.1.1 Stability of residues during storage of samples

Available data

No new data submitted in the framework of this application.

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

Matrix	Characteristics of the matrix	Acceptable Maximum Storage duration	Reference
Data relied on in EU			
Plant products			
Maize forage	High water content	31 months (mesotrione) 42 months (MNBA)	UK, 1999, 2015 EFSA, 2016 Wiebe L.A., 1997 RR-97-042B-INT
Maize grain	High starch content	42 months (mesotrione) 42 months (MNBA)	

Conclusion on stability of residues during storage

The potential for degradation of residues during storage has been previously assessed in the framework of the peer review for mesotrione. Storage stability of mesotrione for high water, starch and protein oil commodities when frozen (approximately -18°C) was demonstrated as listed in the table above.

According to UK, 2015: "Mesotrione is considered to be stable under freezer storage (at -18°C ±5°C) for at least 42 months in corn grain and fodder and for 31 months in corn forage. Frozen storage stability (at -18°C ±5°C) of metabolite MNBA in corn grain, forage and fodder was demonstrated for at least 42 months. Residues of mesotrione and MNBA were also stable for a period of 40 months in soy bean seed and 44 months in radish root under freezer storage at -18°C, although the method of analysis was not fully validated for these crops."

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

7.2.1.2 Stability of residues in sample extracts (KCA 6.1)

In residue trials, concurrent recovery experiments were performed and confirmed the stability of mesotrione in sample extracts.

RMS comment: No new study on stability was submitted. Regarding the intended use, mesotrione and its metabolite MNBA was stable in maize grain and maize forage. Residues of mesotrione were stable at -18°C for 42 months in maize grain (high starch content) and for 31 months in maize forage (high water content). Residues of its metabolite MNBA were found to be stable at -18°C for 42 months in maize grain and forage. This data was considered acceptable and no further data is required.

7.2.2 Nature of residues in plants, livestock and processed commodities

7.2.2.1 Nature of residue in primary crops (KCA 6.2.1)

Available data

No new data submitted in the framework of this application.

Table 7.2-3: Summary of plant metabolism studies

Crop Group	Crop	Label position	Application and sampling details					Reference
			Method, F or G (a)	Rate (g a.s./ha)	No	Sampling (DAT)	Remarks	
EU data								
Cereals/grass crops	Maize	2-^{14}C- cyclohexane	Soil application, F	140	2	28[(b)], 125[(c)], 125[(d)]	2 pre-emergence applications	UK, 1999, 2015 EFSA, 2016 Wei Y., *et al*., 1997 RR 96-026B Tarr J.B., *et al*., 1997
		U-^{14}C-phenyl	Soil application, F					
		2-^{14}C- cyclohexane	Foliar application, F	140	1	28[(b)], 125[(c)], 125[(d)]	1 post-emergence application 27 days after planting	
		U-^{14}C-phenyl	Foliar application, F					

zRMS correction according to EFSA (2016)

Crop Group	Crop	Label position	Application and sampling details			
			Method, F or G[(a)]	Rate	No	Sampling (DAT)
Cereals/grass	Maize	phenyl-(U)-14C	Pre-emergence, F	280 g a.s./ha	1 (at planting)	Forage: 27 Grain, fodder: 153
			Pre-emergence, F	164 g a.s./ha	1 (28 d after planting)	Forage: 28 Grain, fodder: 125
		cyclohexane-(U)-14C	Pre-emergence, F	307 g a.s./ha	1 (at planting)	Forage: 27 Grain, fodder: 153
			Pre-emergence, F	161 g a.s./ha	1 (28 d after planting)	Forage: 28 Grain, fodder: 153

Summary of plant metabolism studies reported in the EU

EFSA conclusion on pesticides peer review 2016
Metabolism studies were conducted with crops representative of cereal/grass (maize) and based on the commercially recommended use pattern, i.e. pre- or post- and pre- and post-emergence foliar applications.

In maize following pre- and post-emergence applications respectively with the cyclohexane and phenyl labelling forms, the total radioactive residues ranged between 0.19-0.23 mg eq/kg in forage leaves, 0.011-0.014 mg eq/kg in grain and 0.65-0.97 mg eq/kg in fodder leaves. For the cyclohexane label in forage leaves, parent mesotrione was extensively degraded (1.1 % TRR – 0.002 mg/kg) and the 4-OH-mesotrione12 was recovered at a level of 5.8 % TRR (0.012 mg eq/kg). Up to 74 % of total residues were shown to be incorporated into natural plant constituents (sugars). For the phenyl label in maize forage and fodder leaves, an extensive degradation of the parent compound was also observed with residue levels <1 % TRR (<0.01 mg/kg). Cleavage of the parent molecule at the linkage between the phenyl and the cyclohexane rings constituted the predominant route of degradation of mesotrione with the subsequent formation of MNBA (up to 3.4 % TRR; 0.019 mg eq/kg) followed by a reduction into AMBA recovered mainly under its glycoside conjugated form in forage and fodder (25.7 % TRR-0.07 mg eq/kg and 19.7 % TRR-0.211 mg eq/kg, respectively). Unconjugated AMBA occurred at a minor level (5.1% TRR-0.013 mg eq/kg and 7.8 % TRR-0.083 mg eq/kg, respectively). Additional characterization of the radioactive residues showed also the presence of a polar conjugated fraction (7.6 % TRR – 0.019 mg eq/kg). Furthermore, a minor route of degradation involved hydroxylation of the parent compound with subsequent glucoside conjugation (up to 3.6 % TRR-0.009 mg eq/kg). The total rate of identification in maize forage and fodder accounted for 50 and 30.5 % TRR, respectively.

Regardless of the radioactive label, attempt to identify metabolites in maize grain was not made due to the low levels of recovered radioactivity (0.01-0.014 mg eq/kg). Only the metabolite AMBA was tentatively characterized and recovered at a low proportion (<5 % TRR).

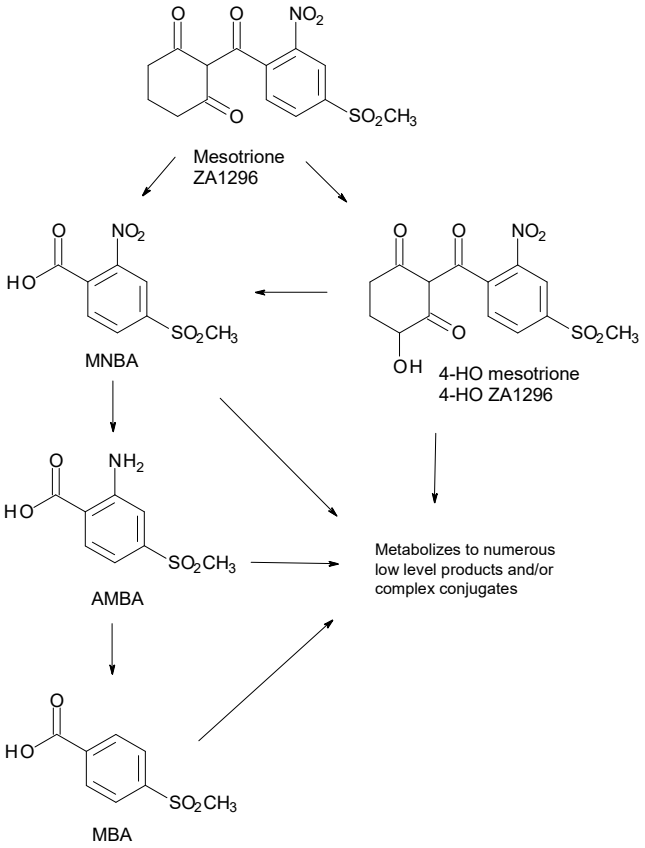
EFSA conclusion on pesticides peer review
Since the absolute concentration of all metabolites was below 0.01 mg/kg in the seeds, the residue definition for enforcement and risk assessment was set as mesotrione only for food commodities. For feed commodities, the potential inclusion of the predominant metabolites MNBA and AMBA (free and conjugated) besides mesotrione in the residue definition for risk assessment was intended. MNBA was characterized as non genotoxic and of lower toxicity compared to the parent compound and was never detected in the GAP-compliant residue trials on maize (<0.01 mg/kg). In contrast, a genotoxic potential in vivo could not be excluded for AMBA and repeated dose toxicity profile needs to be addressed. For risk assessment in feed commodities and pending on the toxicological profile of AMBA conjugates, the residue definition is provisionally proposed as mesotrione and AMBA (including its conjugates). If it can be demonstrated that the conjugates of AMBA are not genotoxic and of no toxicological relevance, additional residue trials on maize where AMBA is analysed for are not needed and only mesotrione has to be included in the residue definition. These residue definitions are valid for conventional crops (cereals) only.

According to the outcome of the consultation with Member States, the applicant and EFSA on the pesticide risk assessment for mesotrione in light of confirmatory data (EFSA, 2018)[1] there is sufficient evidence of lack of genotoxic potential of the metabolite AMBA. The relative toxicity of the metabolite compared with mesotrione has not been addressed and needs to be further discussed.

The proposed metabolic pathway in maize is given in the figure below.

[1] EFSA (European Food Safety Authority), 2018. Technical report on the outcome of the consultation with Member States, the applicant and EFSA on the pesticide risk assessment for mesotrione in light of confirmatory data. EFSA supporting publication 2018:EN-1527. 22pp. doi:10.2903/sp.efsa.2018.EN-1527.

Proposed metabolic pathway for mesotrione in maize



Conclusion on metabolism in primary crops

The available data are sufficient to support the intended use of GLOB2112dH.

zRMS comment: The metabolism of mesotrione was considered as sufficiently investigated in cereals (maize) thus it covers the intended GAP. The residue definition for enforcement and risk assessment is proposed as mesotrione.

7.2.2.2 Nature of residue in rotational crops (KCA 6.6.1)

Available data

No new data submitted in the framework of this application.

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

Crop group	Crop	Label position	Application and sampling details				Report reference	Source
			Method, F or G[(a)]	Rate (g a.s./ha)	Sowing intervals (DAT)	Harvest Intervals (DAT)		
EU reviewed data								
Leafy vegetables	Endive	phenyl-(U)-^{14}C	Soil application, G	164	120, 300[(b)]	Maturity: 198	Gorder *et al.*, 1997. RR 96-	UK, 1999, 2015 EFSA,

							084B	2016
		cyclohexane-(U)- ^{14}C	Soil application, G	164	120, 300[(b)]	Maturity: 198	Spillner *et al.*, 1997 RR 95-042B	
Root and tuber vegetables	Radish	phenyl-(U)- ^{14}C	Soil application, G	164	120, 300[(b)]	Maturity (tops and roots): 176	Gorder *et al.*, 1997. RR 96-084B	
		cyclohexane-(U)- ^{14}C	Soil application, G	164	120, 300[(b)]	Maturity (tops and roots): 176	Spillner *et al.*, 1997 RR 95-042B	
Cereals	Wheat	phenyl-(U)- ^{14}C	Soil application, G	164	120, 300[(b)]	Forage: 142 Hay: 177 Grain, straw: 254	Gorder *et al.*, 1997. RR 96-084B	
		cyclohexane-(U)- ^{14}C	Soil application, G	164	120, 300[(b)]	Forage: 142 Hay: 177 Grain, straw: 254	Spillner *et al.*, 1997 RR 95-042B	

~~* Outdoor/field application (F) or glasshouse/protected/indoor application (G)~~
(a) Outdoor/field application (F) or glasshouse/protected/indoor application (G)
(b) Crops sown 300 DAT were not harvested due to the low level of radioactive residues in the 120 DAT crops.

Summary of plant metabolism studies reported in the EU

UK 2015
The metabolism and distribution of mesotrione was investigated in the rotational crops wheat, endive and radish planted 120 and 300 days following soil application of [^{14}C] mesotrione to soil in pots at approximately 164 g a.s./ha. Low levels of radioactivity were detected in the 120 DAT crops (< 0.001 – 0.033 mg/kg). MNBA, AMBA sulphate and AMBA conjugate were present in all extracts of wheat forage, hay and straw, the only significant component was MNBA at 0.011 mg/kg in wheat forage (33% TRR).

EFSA conclusion on pesticides peer review 2016
The metabolism of mesotrione in rotational crops was found to be similar to the primary crops.

Conclusion on metabolism in rotational crops

The data evaluated are sufficient to support the intended use of GLOB2112dH.
Metabolism in primary and rotational crops was found to be similar and a specific residue definition for rotational crops is not deemed necessary.

zRMS comment: Metabolism in primary and rotational crops was found to be similar and a specific residue definition for rotational crops is not deemed necessary. The magnitude of residues in rotational crops is not expected to exceed 0.01 mg/kg, provided that mesotrione is applied in compliance with the authorized European uses (EFSA, 2015).

7.2.2.3 Nature of residues in processed commodities (KCA 6.5.1)

No data were submitted. All samples at harvest contained no residues of mesotrione or MNBA, with a limit of quantification of 0.01 mg/kg. In addition, consumer intakes accounted for less than 1% of the ADI. Therefore it is considered that processing studies are not required.

zRMS comment: as the residues in maize grain are <0.01 mg/kg, processing studies are not necessary.

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

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

Endpoints	
Plant groups covered	Foliar and soil application : Cereals (maize)
Rotational crops covered	Leafy crops (endive), root vegetables (radish) and cereals (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	Mesotrione (Regulation n° ~~2017/626~~ 2024/1077) Mesotrione (cereals grain) (EFSA 2016)
Plant residue definition for risk assessment	Final Review Report, 2017 (SANTE/11654/2016): **Food commodities:** Mesotrione **Feed commodities:** Mesotrione and AMBA - provisional (inclusion of AMBA pending due to missing genotoxicity conclusions; submission of confirmatory data concerning the toxicological profile of AMBA is required) EFSA, 2018 AMBA : no genotoxic potential. The relative toxicity of the metabolite compared with mesotrione has not been addressed and needs to be further discussed. EFSA, 2016: **Food commodities:** Mesotrione (cereals and pulses/oilseeds only) **Feed commodities:** Mesotrione and AMBA (including its conjugates) (cereals, pulses and oilseeds only – conventional crops) – provisional
Conversion factor from enforcement to RA	Not applicable

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

7.2.2.5 Nature of residues in livestock (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

Specie	Label position	Number of specimen	Application details		Sampling		Reference
			Duration	Rate (mg/kg bw/d)	Commodity	Time	
Dairy Cow	[phenyl-U-^{14}C] AMBA	Single cow treated Control: n.r.	7 days	~~200~~ 0.4 ~~(12.2 mg/kg diet, once a day (at morning milking))~~	Milk	Twice daily: prior to the dosing and during the dosing phase	UK, 1999, 2015 EFSA, 2016 [redacted] 1997
					Urine, faeces	n.r.	
					Liver, kidney, forequarter and hindquarter meat, fat (subcutaneous, omental, perirenal)	After sacrifice (23 hours after the final dose)	

Summary of plant metabolism studies reported in the EU

In the Monograph (United Kingdom, 1999), one metabolism study in ruminants is presented. No new studies were conducted for the renewal.

EFSA conclusion on pesticides peer review 2016
The livestock dietary burden was tentatively estimated using the highest magnitude of AMBA conjugates residues in maize forage, fodder from the metabolism study and the total residues in maize grain. In this case, livestock metabolism studies are not triggered. A ruminant metabolism study was however conducted with phenyl-U-14C AMBA. The total residues were below 0.01 mg/kg in all matrices except in kidney (0.053 mg/kg) and fat (0.018 mg/kg) with AMBA being the predominant compound that accounted for 79% TRR and 62% TRR, respectively. At the estimated dietary burden, the transfer of AMBA residues in all matrices was shown to be negligible and residue definitions for animal commodities are provisionally not required for the representative use. This assessment has however to be reconsidered pending the outcome of AMBA toxicity. Furthermore, the setting of residue definitions for products of animal origin will also have to be assessed with regard to the authorized European uses for mesotrione (maize forage, grass) (EFSA, 2015), and in the case animals are fed with genetically modified soya bean seed (meal) where mesotrione can be find at significant proportions.

According to the outcome of the consultation with Member States, the applicant and EFSA on the pesticide risk assessment for mesotrione in light of confirmatory data (EFSA, 2018) there is sufficient evidence of lack of genotoxic potential of the metabolite AMBA. The relative toxicity of the metabolite compared with mesotrione has not been addressed and needs to be further discussed.

Conclusion on metabolism in livestock

The data evaluated are sufficient to support the intended use of GLOB2112dH.

zRMS comment: EFSA is of the opinion that the available metabolism study is acceptable to derive a residue definition for enforcement and risk assessment in ruminant. AMBA is expected to be the predominant compound of the total residues in the major feed item (maize silage and grass) to which ruminants are expected to be exposed to. At the estimated dietary burden, the transfer of AMBA residues in all matrices was shown to be negligible and residue definitions for animal commodities are provisionally not required for the representative use (EFSA, 2016).

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

Table 7.2-7: Summary on the nature of residues in commodities of animal origin

	Endpoints
Animals covered	Lactating goat~~/~~cows
Time needed to reach a plateau concentration	5 days in milk
Animal residue definition for monitoring	Regulation ~~(EU) No 2017/626~~ (EU) 2024/1077: Mesotrione EFSA, 2016: Not required for the representative use (provisional)
Animal residue definition for risk assessment	EFSA, 2016; Final Review Report, 2017 (SANTE/11654/2016): Not required for the representative use (provisional)
Conversion factor	Not applicable
Metabolism in rat and ruminant similar	Yes
Fat soluble residue	AMBA residues in muscle (<0.01 mg/kg) and in fat free muscle (0.003-0.018 mg/kg). AMBA is not expected to be fat soluble. (EFSA 2016)

7.2.3 Magnitude of residues in plants (KCA 6.3)

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

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

Table 7.2-8: Summary of EU reported and new data supporting the intended uses of GLOB2112dH and conformity to existing MRL

Commodity	Source	Residue zone (N-EU, S-EU, EU, outside EU)	Evaluation GAP Residue levels (mg/kg)	STMR (mg/kg)	HR (mg/kg)	Unrounded OECD calculator MRL (mg/kg)	Current EU MRL (mg/kg) *	MRL compliance
Maize	UK, 1999, 2015 EFSA, 2016 Barnes J.P., *et al*., 1997 RR 96-071B RR 97-045B RR 96-078B RR 97-048B RR 96-077B RR 97-049B	N-EU	GAP on which MRL is based: 1 x 0.14-0.20 kg as/ha, BBCH 15-18, PHI 12-15d, outdoor All < 0.01	N/A				
		S-EU	GAP on which MRL is based: 1 x 0.14-0.20 kg as/ha, BBCH 13-18, PHI 12-15d, outdoor All < 0.01					
	Overall supporting data for cGAP	N-EU	Forage: 13 x < 0.01 Silage: 13 x < 0.01 Grain: 15 x < 0.01	0.01	0.01	0.01	0.01	Yes
		S-EU	Forage: 15 x < 0.01 Silage: 19 x < 0.01 Grain: 19 x < 0.01	0.01	0.01	0.01	0.01	Yes

* Source of EU MRL: Reg. (EC) No ~~2017/626~~ 2024/1077

Conclusion on the magnitude of residues in plants
According to the available data, the intended uses on maize are considered acceptable, for outdoor uses.

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

zRMS comment: Comparison of EU and intended GAP in maize:

Type of GAP	Method	Number of applications	Max. application rate per treatment (kg as/ha)	Interval between application (days)	Growth stage at last application	PHI (days)
GAP EU (EFSA, 2015)	Foliar spray	1	0.15	-	BBCH 12 – 19	-
Intended GAP	Foliar spray	1	0.075	-	BBCH 10 – 18	-

Maize is a major crop in Northern Europe. The applicant relied upon 15 NEU trials that have been previously evaluated at EU level, with application rates higher than those proposed GAP. The proposed use is within the EU GAP. Available results show that the current MRL of 0.01 mg/kg (Reg. (EU) 2024/1077) will not be exceeded. Therefore the proposed uses of the product can be considered as supported on maize in Central Europe.

7.2.4 Magnitude of residues in livestock

7.2.4.1 Dietary burden calculation

Mesotrione is authorised for use on several crops that might be fed to livestock. A review of all existing MRLs has been conducted by EFSA in the framework of Article 12 of Regulation (EC) No 396/2005.

Regarding the residue definition, the dietary burden calculation for mesotrione was performed in the same way as in the EFSA conclusion of mesotrione (EFSA Journal 2016;14(3):4419).

The processing factors for all by-products were set to 1 because mesotrione is applied early in the growing season and residues are expected to be below the LOQ.

Table 7.2-9: Input values for the dietary burden calculation (considering the uses evaluated in the Art. 12 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: mesotrione				
Corn, Field, Forage/Silage	0.01	Median residue	0.01	Highest residue
Corn, Field, Stover (fodder)	0.01	Median residue	0.01	Highest residue
Corn, Pop, Stover (fodder)	0.01	Median residue	0.01	Highest residue
Corn, Field (Maize), Grain	0.01	Median residue	-	-
Corn, Pop, Grain	0.01	Median residue	-	-
Corn, Field, Milled by-pdts	0.01	Median residue	-	-

Feed Commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Corn, Field, Hominy Meal	0.01	Median residue	-	-
Corn, Field, Gluten Feed	0.01	Median residue	-	-
Corn, Field, Gluten Meal	0.01	Median residue	-	-
Distiller's grain, Dried	0.01	Median residue	-	-
Flaxseed/Linseed, Meal	0.01	Median residue	-	-
Canola (Rape seed), Meal	0.01	Median residue	-	-
Rape, Meal	0.01	Median residue	-	-
Risk assessment residue definition: AMBA (including its conjugates)				
Corn, Field, Forage/Silage	0.043 (provisional)	Maximum residue levels of total AMBA (including its conjugates) recovered from the metabolism data. Pending clarification of the genotoxic potential of AMBA and of its toxicological profile GAP-compliant residue trials for the determination of AMBA conjugates residues in maize fodder, forage may be needed and the livestock dietary burden to be revised accordingly.*	0.043 (provisional)	Maximum residue levels of total AMBA (including its conjugates) recovered from the metabolism data. Pending clarification of the genotoxic potential of AMBA and of its toxicological profile GAP-compliant residue trials for the determination of AMBA conjugates residues in maize fodder, forage may be needed and the livestock dietary burden to be revised accordingly.*
Corn, Field, Stover (fodder)	0.301 (provisional)		0.301 (provisional)	
Corn, Pop, Stover (fodder)	0.301 (provisional)		0.301 (provisional)	
Corn, Field, Grain	0.014	Total residues from the metabolism data.	-	-
Corn, Field, Milled By-pdts	0.014	Total residues from the metabolism data.	-	-
Corn, Field, Hominy Meal	0.014	Total residues from the metabolism data.	-	-
Corn, Field, Gluten Feed	0.014	Total residues from the metabolism data.	-	-
Corn, Field, Gluten Meal	0.014	Total residues from the metabolism data.	-	-
Distiller's grain, Dried	0.014	Total residues from the metabolism data.	-	-

* Based on the confirmatory data of mesotrione (EFSA Supporting publication 2018: EN-1527), it was agreed that the metabolite AMBA is unlikely to be genotoxic, however it was proposed to further discuss its toxicological profile in an experts' consultation

since the metabolite is relevant to consumer exposure.

Table 7.2-10: Results of the dietary burden calculation

Animal species	Median dietary burden (mg/kg bw/d)	Maximum dietary burden (mg/kg bw/d)	Highest contributing commodity	Max dietary burden (mg/kg DM)	Trigger exceeded (Y/N)
Risk assessment residue definition: mesotrione					
Beef cattle*	0.0006	0.001	Corn, Field, Forage/Silage	Not calculated	N
Dairy cattle*	0.0009	0.001	Corn, Field, Forage/Silage	Not calculated	N
Ram/ewe	0.0004	0.0004	Corn, Field, Gluten meal	Not calculated	N
Lamb	0.0005	0.0005	Corn, Field, Gluten meal	Not calculated	N
Breeding swine	0.0003	0.0003	Corn, Field, Forage/Silage	Not calculated	N
Finishing swine*	0.0003	0.0003	Corn, Field, Milled by-pdts	Not calculated	N
Broiler poultry	0.001	0.001	Corn, Field, Milled by-pdts	Not calculated	N
Layer poultry*	0.001	0.001	Corn, Field, Forage/Silage	Not calculated	N
Turkey	0.001	0.001	Corn, Field, Milled by-pdts	Not calculated	N
Fish	-	-	-	> 0.1 mg/kg	N
Risk assessment residue definition: AMBA (including its conjugates)					
Beef cattle*	0.003	0.003	Corn, Field, Stover	Not calculated	N
Dairy cattle*	0.004	0.004	Corn, Field, Stover	Not calculated	N
Ram/ewe	0.001	0.001	Corn, Field, Gluten feed	Not calculated	N
Lamb	0.001	0.001	Corn, Field, Gluten feed	Not calculated	N
Breeding swine	0.002	0.002	Corn, Field, Stover	Not calculated	N
Finishing swine*	0.001	0.001	Corn, Field, Gluten feed	Not calculated	N
Broiler poultry	0.001	0.001	Corn, Field, Milled by-pdts	Not calculated	N
Layer poultry*	0.003	0.003	Corn, Field, Forage/Silage	Not calculated	N
Turkey	0.002	0.002	Corn, Field, Hominy meal	Not calculated	N

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

Calculation performed according to Animal model 2017:

New data requirements	Regulation (EU) No 283/2013)							
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)	0,001	0,001	0,02	0,02	Dairy cattle	Corn, field	forage/silage	No
Cattle (dairy only)	0,001	0,001	0,02	0,02	Dairy cattle	Corn, field	forage/silage	No
Sheep (all diets)								No
Sheep (ewe only)								No
Swine (all diets)	0,000	0,000	0,01	0,01	Swine (breeding)	Corn, field	forage/silage	No
Poultry (all diets)	0,000	0,000	0,00	0,00	Poultry layer	Corn, field	forage/silage	No
Poultry (layer only)	0,000	0,000	0,00	0,00	Poultry layer	Corn, field	forage/silage	No

7.2.4.2 Livestock feeding studies (KCA 6.4.1-6.4.3)

No new data were submitted in the framework of this application. Livestock animals are not exposed via feed above the trigger value established in Reg. (EC) No 1107/2009. Feeding studies are therefore not required.

zRMS comment: The calculated dietary burdens were found to be below the trigger value of 0.004 mg/kg bw hence no livestock feeding studies are required.

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

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

zRMS comment: Residues of mesotrione do not exceed the trigger values defined in Regulation (EU) No 283/2013, therefore there is no need to investigate the effect of industrial and/or household processing.

7.2.6 Magnitude of residues in representative succeeding crops

The crops under consideration can be grown in rotation.

Considering available data dealing with nature of residues (see 7.2.2.2) and considering also the low to moderate persistence of mesotrione, MNBA and AMBA, no study dealing with magnitude of residues in succeeding crops is needed.

7.2.6.1 Field rotational crop studies (KCA 6.6.2)

Available data

No new data submitted in the framework of this application.

Table 7.2-11: Summary of available studies in field rotational crops

Primary crop	Rate (kg a.s./ha) (GS at application or PHI)	Residue levels in succeeding crops			
		Succeeding crop group	Succeeding crop	Sowing intervals (DAT)	Reference / Remarks
EU data					
Maize	0.34 (soil application)	Pulses/ oilseeds	Soya bean	29	UK, 1999, 2015 Barnes J.P., Wiebe L.A., 1997 RR 97-044B
	0.34 (soil application) + 0.22 (post-emergence; plants up to 24-36 inches tall)	Leafy vegetables	Endive	98	
	0.34 (soil application) 0.34 (soil application) + 0.22 (post-emergence; plants up to 24-36 inches tall)	Root vegetables	Radish tops Radish root	29 98 29 98	
	0.34 (soil application)	Cereals	Millet	29	
	0.34 (soil application) + 0.22 (post-emergence; plants up to 24-36 inches tall)		Wheat	98	
	0.34 (soil application)		Sorghum	29	

US rotational crop field trials were conducted on pulses/oilseeds (soya bean), leafy vegetables (endive), root vegetables (radish) and cereals (small grains (wheat)) after bare soil application at 0.34 kg a.s./ha or after bare soil application (0.34 kg a.s./ha) followed by a post-emergence application (0.22 kg a.s./ha). Residues of mesotrione and of MNBA were < 0.01 mg/kg in all crop parts.

Conclusion on rotational crops studies

For the intended uses of GLOB2112dH on maize, no residues are expected in rotational crops.

According to the soil degradation studies evaluated in the framework of the peer review, DT_{90} field values of mesotrione are expected to range between 36 - 78 days which is far below the trigger value of 100 days. Furthermore, the major soil metabolites MNBA and AMBA were also demonstrated to be of low persistence (DT_{50} lab values of 7.5 and 3.2 days, respectively). Further investigation of residues in rotational crops is not required (EFSA, 2015).

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

Additional residue trials

Additional residue trials were conducted to determine the residue levels of mesotrione and its metabolite

MNBA in maize raw agricultural commodity after one foliar application of the formulated product Mesotrione 100 g/L SC on the crop. The data from this study can be used to determine the DT_{50} of mesotrione in maize. Full details of this study can be found in Appendix 2.
~~Additional residue trials were also conducted to determine the residue levels of mesotrione in oilseed rape raw agricultural commodity after one foliar application of the formulated product Mesotrione 100 SC on the crop. Full details of this study can be found in Appendix 2.~~

Residue level in pollen and bee products

In Regulation (EU) No. 283/2013 for active substances, the residue level in pollen and bee products for human consumption resulting from residues taken up by honeybees need to be determined. Although that this determination of residues level in pollen and bee products is an active substance requirement rather than a plant protection product requirement and therefore such active substance studies should be addressed during the annex I renewal of the active substance, based on the argumentation below, the residue level of mesotrione in pollen and bee products can be considered as negligible.

The uses of GLOB2112dH are on maize which is not considered to be a melliferous crop. Mesotrione is not considered as a systemic compound. Therefore, exposure via succeeding crops is not relevant. Only the exposure of non-target plants (in-field weeds and adjacent plants) is relevant.

In-field weeds:
Based on the metabolism studies, the parent mesotrione was hardly recovered in maize (3% TRR in maize forage only) whilst the most pertinent metabolites identified in the feed items were MNBA (up to 20% TRR in maize forage leaves) and AMBA, free and conjugated (13% and 28% TRR respectively in maize forage leaves and fodder). However, AMBA and MNBA are not included in the residues definition for food of plant origin. Therefore, the contribution of in-field weeds to residues in honey is considered negligible.
In addition, to prevent yield losses, farmers protect the maize 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 max. 4 leave stage, dicots max. 7 leave stage). Therefore, there is a very low probability that at the time of application weeds have already reached the flowering stage. After application, maize growth suppresses the further development of potential surviving weeds. In summary, there is a very low probability that in-field weeds reach the flowering stage. As bees are attracted by large areas of flowering plants, it is very unlikely that they would collect pollen and nectar from flowering weeds in a maize field – a crop that does not produce nectar and is only a pollen resource. Thus, it is not expected that in-field weeds could be a source for residues in honey.

Off-field flowering weeds and plants:

According to the recent technical guidance on honey MRL (11956), if the highest residue (HR) found in aerial parts are below 0.05 mg/kg, no further residue studies in honey are necessary and the default MRL of 0.05 mg/kg can be set. If the HR value is found to be above 0.05 mg/kg but below 0.5 mg/kg in the aerial parts, the MRL could be based on the HR value considering a transfer factor of 1 from aerial parts to honey. If the HR value is found to be above 0.5 mg/kg in the aerial parts, further specific data would be needed to set the MRL.
To estimate the residue level in aerial parts, reference is made to Appendix F of the EFSA bee guidance from 2013 which mentions RUD values in pollen/nectar for approx. 35 substances based on HR values analysed after spray applications during flowering. For pollen, the **95th percentile** and the highest RUD are given at **82.1** and 149.8 mg a.s./kg respectively. For nectar, the 95th percentile and the highest RUD are given at 12.0 and 20.7 mg a.s./kg respectively. Considering the 95th percentile RUD for aerial parts (i.e. pollen) of 82.1 mg a.s./kg, such an RUD would cover a MRL setting without the need of specific additional data up to a dose rate of 6.09 g a.s./ha (with such an application rate, the calculated MRL would be 82.1*0.00609 = 0.499 mg as/kg pollen, thus below the threshold value of 0.5 mg/kg). On the other hand, the default MRL of 0.05 mg/kg would be supported for dose rate < 0.6 g a.s./ha. In case the

dose rate is higher than 6.09 g a.s./ha, further residue studies would be necessary.
Since off-field flowering weeds and plants are only exposed to the drift rate (2.77% of the full rate), the dose rate to be taken into account for 1 application of GLOB2112dH would be 2.08 g mesotrione/ha. This is below 6.09 g a.s./ha and thus no further studies are needed.

In conclusion, no exceedance of the default MRL in honey is expected based on the intended uses.

zRMS comment: According to Technical Guidelines SANTE/11956/2016 rev. 9 14 September 2018, maize is not considered as melliferous plant.

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

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

7.2.8.1 Input values for the consumer risk assessment

Consumer risk assessment calculations were performed taking into account all the crops for which an MRL has been set for mesotrione under EU Regulation 2017/626. Where the MRL for a particular crop is below the LOQ, calculations have been made with the LOQ for that crop.

Table 7.2-12: Input values for the consumer risk assessment

Commodity	Input value (mg/kg)	Comment
Risk assessment residue definition: mesotrione		
Maize	0.01*	EU MRL (Reg. (EU) ~~No 2017/626)~~ 2024/1077
All other commodities	EU MRLs	Reg. (EU) ~~No 2017/626~~ 2024/1077

*Indicates that the input value is proposed at the LOQ

7.2.8.2 Conclusion on consumer risk assessment

Chronic and acute exposure calculations for all crops were performed using revision 3.1 of the EFSA Pesticide Residues Intake Model (PRIMo) (EFSA, 2007). The calculated exposures were compared with the toxicological reference values derived for mesotrione (see 7.1.2). Extensive calculation sheets are presented in Appendix 3.

Table 7.2-13: Consumer risk assessment

TMDI (% ADI) according to EFSA PRIMo	12% (based on NL toddler)
IEDI (% ADI) according to EFSA PRIMo	No IEDI calculations were performed as the TMDI calculations using the MRLs were already acceptable. No refinement of the chronic risk assessment is required.
IESTI (% ARfD) according to EFSA PRIMo*	Potatoes: 8% (based on children) Sugar beets (root)/sugar: 6% (based on children)
NTMDI (% ADI) **	-
NEDI (% ADI)**	-
NESTI (% ARfD) **	-

* ~~include raw and processed commodities if both values are required for PRIMo~~

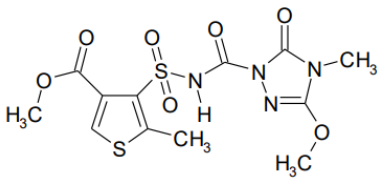
The proposed uses of mesotrione in the formulation GLOB2112dH do not represent unacceptable acute and chronic risks for the consumer.

zRMS comment: The calculation of the TMDI led to an utilisation of the ADI of 12.0 % based on NL toddler being the population group with the highest value. For this diet, the highest contributor is milk with 6% of the ADI. The highest International Estimated Short-Term Intake (IESTI) is at 6.0% and 3.0% of the ARfD for the consumption of milk by children and boiled pumpkin by adults (processed commodities) and at 8.0% and 2% of ADI for the consumption of potatoes by childen and cabbages by adults (raw commodities). The proposed use of mesotrione in the product Walkover Trio does not represent unacceptable chronic and acute risks for the consumers.

7.3 Thiencarbazone-methyl

General data on thiencarbazone-methyl are summarized in the table below (last updated 2024/04/25)

Table 7.3-1: General information on thiencarbazone-methyl

Active substance (ISO Common Name)	Thiencarbazone-methyl
IUPAC	Methyl 4-({[(3-methoxy-4-methyl-5-oxo-4,5- dihydro-1H-1,2,4-triazol-1- yl)carbonyl]amino}sulfonyl)-5-methylthiophene-3- carboxylate
Chemical structure	
Molecular formula	$C_{12}H_{14}N_4O_7S_2$
Molar mass	390.4 g/mol
Chemical group	Triazolone herbicides
Mode of action (if available)	ALS inhibitor, absorbed by roots and leaves, contact and residual action
Systemic	No
Company (ies)	Bayer CropScience*
Rapporteur Member State (RMS)	UK
Approval status	Approved Date of 01/07/2014 and reference to decision COMMISSION REGULATION (EU) No 145/2014
Restriction	-
Review Report	SANCO/12602/2013 – rev. 2 23/03/2018
Current MRL regulation	Regulation (EU) 2021/1110
Peer review of MRLs according to Article 12 of Reg No 396/2005 EC performed	Yes
EFSA Journal : Conclusion on the peer review	Yes, EFSA, 2013**
EFSA Journal: conclusion on article 12	Yes, EFSA, 2020**
Current MRL applications on intended uses	None

* Notifier in the EU process to whom the a.s. belong(s)
** See list of references

7.3.1 Stability of Residues (KCA 6.1)

7.3.1.1 Stability of residues during storage of samples

Available data

No new data submitted in the framework of this application.

Table 7.3-2: Summary of stability data achieved at ≤ - 18°C (unless stated otherwise)

Matrix	Characteristics of the matrix	Acceptable Maximum Storage duration	Reference
Data relied on in EU			
Plant products (BYH18636 and its metabolites BYH18636-N-desmethyl and BYH18636-MMT-glucoside)			
Maize forage, lettuce, tomato, potato	High water content	26 months	EFSA, 2013 Storage up to 12 months: Brumhard B, Wolters A., 2007 MR-186/05 Storage up to 24 months (nominal): Brumhard B, Wolters A., 2008 MR-07/229
Soybean	High lipid content	26 months	
Maize grain and stover	Dry	26 months	
Animal Products (BYH18636-sulfonamide)			
Ruminant	Fat	2 months	EFSA, 2013 [redacted] MR06/095
Ruminant	Milk	2 months	

Conclusion on stability of residues during storage

The available studies demonstrated that thiencarbazone-methyl, BYH18636-N-desmethyl and BYH18636-MMT-glucoside were stable in plant matrices for a period of 26 months when stored at -18°C.

The available data are sufficient to support the intended uses of GLOB2112dH.

7.3.1.2 Stability of residues in sample extracts (KCA 6.1)

The storage stability of pesticide residues in sample extracts is generally checked during the development of the applicable analytical residue methods. Moreover, the relevant information on the stability in the final or any intermediate step can be derived from the fortification experiments performed during method validation. If the recoveries in the fortified samples are within the acceptable range of 70 - 110%, stability is considered as sufficiently proven. Additionally every analytical batch does contain at least one concurrent recovery which is handled and stored in parallel to the residue samples. So the acceptability of the concurrent recoveries demonstrates the stability of the samples during the work up procedure.

zRMS comment: The storage stability of thiencarbazone-methyl and its metabolites BYH18636-N-

desmethyl and BYH18636-MMT-glucoside was assessed in the framework of the peer review. The available studies demonstrated that thiencarbazone-methyl, BYH 18636-N-desmethyl and BYH 18636-MMT-glucoside were stable in high water, high oil content commodities and dry commodities for 26 months when stored at -18°C.

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

No new data submitted in the framework of this application.

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	
EU data							
Cereals	Maize	[dihydrotriazole-3-^{14}C]BYH18636	G	0.045	1	Forage: BBCH 83 Stover and grains: BBCH 99	EFSA, 2013 Bongartz R., 2005 MEF-05/004
	Maize	[thiophene-4-^{14}C]BYH18636	G	0.045	1	Forage: BBCH 83 Stover and grains: BBCH 99	EFSA, 2013 Bongartz R., 2005 MEF-05/003
	Maize	[dihydrotriazole-3-^{14}C]BYH18636	G	0.015 (4 plants) 0.030 (2 plants) 0.075 (1 plant)	1	Forage: BBCH 83 Stover and grains: BBCH 99	EFSA, 2013 Bongartz R., 2005 MEF-04/182
	Maize	[thiophene-4-^{14}C]BYH18636	G	0.0119 or 0.0199 or 0.0346	1	Forage: BBCH 83 Stover and grains: BBCH 99	EFSA, 2013 Bongartz R., 2005 MEF-04/181
	Maize	[dihydrotriazole-3-^{14}C]BYH18636		0.030 (foliar) 0.015 (soil)	1	Forage: BBCH 83 Stover and grains: BBCH 99	EFSA, 2013 Bongartz R., 2005 MEF-05/006
	Maize	[thiophene-4-^{14}C]BYH18636	G	0.030 (foliar)	1	Forage: BBCH 83 Stover and grains:	EFSA, 2013 Bongartz

				0.015 (soil)		BBCH 99	R., 2006 MEF-05/005
	Wheat	[dihydrotriazole-3-^{14}C]BYH18636	G	0.015	1	Forage: GS not precised Hay: forage dry for 4 d at ambient temp. Straw and grain: at maturity	EFSA, 2013 Sur R., 2005 MEF-05/041
	Wheat	[thiophene-4-^{14}C]BYH18636	G	0.015	1	Forage: GS not precised Hay: forage dry for 4 d at ambient temp. Straw and grain: at maturity	EFSA, 2013 Sur R., 2005 MEF-05/042

Summary of plant metabolism studies reported in the EU

The metabolism of thiencarbazone-methyl was investigated after foliar and soil treatment in cereals (maize and wheat). In all studies thiencarbazone-methyl was radiolabelled either in the dihydrotriazole or the thiophene ring of the molecule.

In maize, three different application patterns were investigated which cover possible routes of uptake, i.e. via soil and leaves, namely: a single pre-emergence application, an early post-emergence application, and a split-application with a post-emergence foliar treatment followed by a soil treatment.

The studies performed with these three different patterns showed similar results and similar metabolic profile. In general, very low total radioactive residues (TRR) levels were detected (0.001–0.083 mg eq/kg); therefore, in all maize matrices, many metabolites were identified but all at very low levels below the limit of quantification (LOQ) (≤ 0.01 mg/kg). BYH18636-MMT-glucoside was always found to be the major metabolite in the dihydrotriazole label, while parent thiencarbazone-methyl was a very minor residue detected only in maize forage and stover at a maximum level of 0.007 mg eq/kg.

Following the pre-emergence application pattern (48 g a.s./ha), BYH18636-MMT-glucoside represented up to 65% TRR in maize forage and stover (0.003–0.01 mg eq/kg) in the dihydrotriazole label. In the thiophene label, the significant metabolites were BYH18636-hydroxy-sulfonamidecarboxylic acid and conjugates present at 23% TRR (0.003 mg eq/kg) in maize stover, and BYH18636-hydroxy-sulfonamide-carboxylic acid and BYH 18636-hydroxy-thienosaccharine and their conjugates accounting together for 32% TRR (0.001 mg eq/kg) in maize forage. After the early post-emergence application pattern (12 g a.s./ha at stage BBCH 13-16, equivalent to a field treatment at 48 g a.s./ha), BYH18636-MMT-glucoside was still the major metabolite in maize forage and stover (up to 17% TRR; 0.009 mg eq/kg). BYH18636-N-desmethyl-hydroxy was also significant, representing up to 12.5% TRR (0.006 mg eq/kg) in maize forage. Finally, in the split-application pattern (post-emergence application of 32 g a.s./ha at BBCH 16 and an additional soil treatment of 16 g a.s./ha at BBCH 19), the main metabolite BYH18636-MMT-glucoside accounted for up to 63% TRR in maize forage and stover. Other metabolites just above 10% TRR were identified but at very low absolute levels.

In wheat, a single early post-emergence application of 16–17 g a.s./ha at stage BBCH 13–15 was studied. Following this application, higher TRR levels were observed in wheat, up to 0.014 mg eq/kg in grain and 0.39 mg eq/kg in the other matrices. Parent thiencarbazone-methyl was detected in significant proportions and levels (up to 17% TRR; 0.05 mg eq/kg) only in forage samples with both labels. Metabolite BYH18636-N-desmethyl was the major component in all matrices and for both labels, representing up to 47% TRR (0.17 mg eq/kg) in forage, 14% TRR (0.06 mg eq/kg) in straw and 31% TRR (0.003 mg eq/kg) in grain, while BYH18636-MMT-glucoside was present at up to 22% TRR (0.06 mg eq/kg) in straw. Other metabolites were found above 10% TRR, however absolute levels were always below 0.05 mg eq/kg in feed items and below 0.01 mg eq/kg in grain.

A similar metabolic profile was observed in maize and wheat, noting that in maize, metabolites result from the cleavage of the parent molecule, whereas in wheat the metabolism is dominated by the compounds (specially BYH18636-N-desmethyl) containing the entire structure of the parent.

Conclusion on metabolism in primary crops

Considering that BYH18636-N-desmethyl and BYH18636-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, BYH18636-N-desmethyl and BYH18636-MMT-glucoside expressed as thiencarbazone-methyl. For monitoring, the residue definition was limited to the parent compound only.

The available data are sufficient to support the intended uses of GLOB2112dH.

zRMS comment: The metabolism of thiencarbazone-methyl was investigated after foliar and soil treatment in cereals (maize and wheat) and assessed in the framework of the peer review.
The studies performed with three different patterns showed similar metabolic pathway.
The residue definition for enforcement is proposed as thiencarbazone-methyl only. 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 (EFSA, 2020).

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)	
EU data						
Root and tuber vegetables	Turnip	Dihydrotriazole or thiophene ^{14}C-thiencarbazone-methyl	G	0.045 0.030 0.015	180, 270 180, 269 29, 118, 247	EFSA, 2013 Justus K., 2006 MEF-06/215 MEF-05/297 MEF-06/258 MEF-05/539 Reiner H., 2005 MEF-05/023 MEF-05/024
Leafy vegetables	Swiss chard		G	0.015	29, 118, 247	EFSA, 2013 Reiner H., 2005 MEF-05/023 MEF-05/024
Cereals	Wheat		G	0.045 0.030 0.015	90, 270 90, 269 29, 118, 247	EFSA, 2013 Justus K., 2006 MEF-06/215 MEF-05/297 MEF-06/258 MEF-05/539 Reiner H., 2005 MEF-05/023 MEF-05/024
Pulses and	Soybean		G	0.045	90, 270	EFSA, 2013

oilseeds				0.030	90, 269	Justus K., 2006 MEF-06/215 MEF-05/297 MEF-06/258 MEF-05/539

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

Summary of plant metabolism studies reported in the EU

Confined rotational crop studies with thiencarbazone-methyl radiolabelled on the dihydrotriazole or thiophene ring of the molecule are available. The uptake of thiencarbazone-methyl residues by the rotational crops was investigated at different application rates on bare soil.
In the studies where thiencarbazone-methyl was applied at 45 g a.s./ha, root and tuber vegetables (turnip), cereals (wheat) and pulses and oilseeds (soybean) were planted at nominal plantback intervals (PBIs) of 90 and 270 days after treatment (DAT). Turnips were planted again at 180 DAT because of crop damages. Parent thiencarbazone-methyl remained a major compound only in soybean matrices (up to 27% TRR; 0.004 mg/kg). The major metabolite identified was BYH18636-MMT-glucoside either at 90 or 270 DAT, with highest levels observed in soybean hay (45–49% TRR; 0.012–0.017 mg eq/kg), wheat hay (43–58% TRR; 0.007–0.018 mg eq/kg) and wheat straw (55–56% TRR; 0.013–0.035 mg eq/kg). Three metabolites were also significant: BYH18636-N-desmethylhydroxy accounting for up to 16% TRR (0.006 mg eq/kg) in wheat matrices, BYH18636-MMT (33% TRR; 0.004 mg eq/kg) in soybean forage, and BYH18636-carboxylic acid (20% TRR; 0.006 mg eq/kg) in soybean hay.
A similar metabolic pathway was observed with thiencarbazone-methyl applied at a lower rate of 30 g a.s./ha to investigate residues in the same crops. The same metabolites were identified and again, the dihydrotriazole labelled-specific metabolite BYH18636-MMT-glucoside was a major compound observed in proportions up to 61% TRR (0.014 mg eq/kg) in soybean hay, 69% TRR (0.013 mg eq/kg) in wheat hay and 67% TRR (0.021 mg eq/kg) in wheat straw.
The third study performed at an underdosed rate of 15 g a.s./ha and investigating residues in Swiss chards (leafy crops), wheat and turnips, showed similar results as the studies performed with higher application rates. The major metabolite identified was still BYH18636-MMT-glucoside, accounting for a maximum of 64% TRR (0.043 mg eq/kg) observed in wheat matrices. In Swiss chards, the parent compound and BYH18636-MMT were significant representing respectively up to 30% TRR and 22% TRR, however, with low absolute levels (< 0.001 mg eq/kg).
For all application rates of 15, 30 and 45 g a.s./ha, residues were generally decreasing over time in all raw agricultural commodities and no individual compound exceeded the LOQ of 0.01 mg/kg in edible parts of the crops for both labels, nor 0.05 mg/kg in feed commodities.

Conclusion on metabolism in rotational crops

The metabolic pathway as observed in primary crops and in rotational crops consists in the N-desmethylation of the parent compound and several hydrolysis steps. It can be concluded that the metabolism and distribution of thiencarbazone-methyl in rotational crops is similar to the metabolic pathway observed in primary crops.

The available data are sufficient to support the intended uses of GLOB2112dH.

zRMS comment: The metabolism of thiencarbazone-methyl in rotational crops was and in the framework of the peer review. It is concluded that the metabolism and distribution of thiencarbazone-methyl in rotational crops is similar to the metabolic pathway observed in primary crops.

7.3.2.3 Nature of residues in processed commodities (KCA 6.5.1)

Available data

No new data submitted in the framework of this application.

In all commodities residues were below 0.1 mg/kg and the total theoretical maximum daily intake is below 10% of the acceptable daily intake (ADI). Therefore, the investigation of the nature of residues in processed commodities is not required.

Conclusion on nature of residues in processed commodities

The investigation of the nature of residues in processed commodities is not required.

The available data are sufficient to support the intended uses of GLOB2112dH.

zRMS comment: As no residues above 0.1 mg/kg were in all commodities and the TMDI was below 10% of the ADI, the investigation of the nature of residues in processed commodities is 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	Cereals (Maize and wheat)
Rotational crops covered	Wheat, soybean, turnip, swiss chard
Metabolism in rotational crops similar to metabolism in primary crops?	Yes
Processed commodities	Not required
Plant residue definition for monitoring	Thiencarbazone-methyl (Reg. (EU) 2021/1110)
Plant residue definition for risk assessment	Sum of thiencarbazone-methyl, BYH 18636- N-desmethyl and BYH 18636-MMT-glucoside, expressed as thiencarbazone-methyl (EFSA, 2013)
Conversion factor from enforcement to RA	No conversion factor necessary for cereals as all residue values < LOQ

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 or thiophene ^{14}C-thiencarbazone-methyl	1	2	5	Milk	twice daily	EFSA, 2013 Schmeer K, Koester J. MEF-05/261 MEF-05/307
						Urine and faeces	daily	
						Tissues	at sacrifice	
Laying poultry	Hens		6	2	14	Eggs	daily	EFSA, 2013 Schmeer K, Koester J. MEF-05/259 MEF-05/260
						Excreta	Daily	
						Tissues	At sacrifice	

Summary of plant metabolism studies reported in the EU

Although not required, metabolism studies were available and assessed in the framework of the peer review (UK, 2012; EFSA, 2013).
The metabolism of thiencarbazone-methyl residues in livestock was investigated in lactating goats and laying hens at a dose rate of 2 mg/kg body weight (bw) per day, covering largely the calculated maximum dietary burdens.
In both studies, thiencarbazone-methyl was radiolabelled in the dihydrotriazole or thiophene ring of the molecule. The studies performed with the dihydrotriazole label showed that the parent is extensively metabolised in all livestock matrices and, when detected, present in low proportions (≤ 8% TRR; 0.06 mg eq/kg). Whereas with the thiophene label, parent thiencarbazone-methyl accounted for 83% TRR (0.004 mg eq/kg) in eggs and 80% TRR (0.102 mg eq/kg) in milk. The main metabolites identified in all matrices were BYH18636-MMT (49–70% TRR in poultry; 23-49% TRR in goat) and methyl carbamate (13–23% TRR in poultry; 27–54% TRR in goat). In lactating goats, significant levels of BYH18636-sulfonamide were found up to 85% TRR (3.1 mg eq/kg) in liver, as well as BYH18636-sulfonamide carboxylic acid up to 52% TRR (0.35 mg eq/kg) in fat.

Conclusion on metabolism in livestock

The metabolism in lactating goats and laying hens is very similar and residues result from the cleavage of the parent compound, oxidative N-demethylation and hydrolysis steps. Parent thiencarbazone-methyl and BYH18636-MMT were found to be the most relevant compounds in livestock commodities. Therefore, a residue definition for enforcement and for risk assessment was proposed as thiencarbazone-methyl and BYH18636-MMT, expressed as thiencarbazone-methyl.

The available data are sufficient to support the intended uses of GLOB2112dH.

zRMS comment: The metabolism studies were assessed in the framework of the peer review. The metabolism of thiencarbazone-methyl residues in livestock indicated similar pathway in lactating goats and laying hens. The residue definition for monitoring and risk assessment was proposed as the sum of thiencarbazone-methyl and BYH 18636-MMT expressed as thiencarbazone-methyl.

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	Thiencarbazone-methyl and BYH18636-MMT, expressed as thiencarbazone-methyl (Reg. (EU) 2021/1110)
Animal residue definition for risk assessment	Thiencarbazone-methyl and BYH18636-MMT, expressed as thiencarbazone-methyl (EFSA, 2013)
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)

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

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

Table 7.3-8: Summary of EU reported and new data supporting the intended uses of GLOB2112dH and conformity to existing MRL

Commodity	Source	Residue zone (N-EU, S-EU, EU, outside EU)	Evaluation GAP Residue levels (mg/kg) E = according to enforcement residue definition RA = according to risk assessment residue definition	STMR (mg/kg)	HR (mg/kg)	Unrounded OECD calculator MRL (mg/kg)	Current EU MRL (mg/kg) *	MRL compliance
Maize grain	EFSA, 2013 Billian P., Wolters A., 2006 RA-2583/05	N-EU	Trials GAP: 1 x 0.04-0.045 kg as/ha, BBCH 13-14, outdoor 7 x < 0.01	N/A				
	EFSA, 2013 Wolters A., 2007 RA-2615/06	N-EU	Trials GAP: 1 x 0.054 kg as/ha, BBCH 18, outdoor 5 x < 0.01					
	EFSA, 2013 Zimmer D., 2007 RA-2584/05	S-EU	Trials GAP: 1 x 0.04-0.045 kg as/ha, BBCH 13-14, outdoor 8 x < 0.01					
	EFSA, 2013 Wolters A., 2007 RA-2616/06	S-EU	Trials GAP: 1 x 0.054 kg as/ha, BBCH 18, outdoor 5 x < 0.01					
	Overall supporting data for cGAP	N-EU & S-EU	25 x < 0.01	0.01	0.01	0.01	0.01	Yes
Maize green	EFSA, 2013	N-EU	Trials GAP: 1 x 0.04-0.045 kg as/ha, BBCH 13-14, outdoor	N/A				

material	Billian P., Wolters A., 2006 RA-2583/05		7 x < 0.01			
	EFSA, 2013 Wolters A., 2007 RA-2615/06	N-EU	Trials GAP: 1 x 0.054 kg as/ha, BBCH 18, outdoor 5 x < 0.01			
	EFSA, 2013 Zimmer D., 2007 RA-2584/05	S-EU	Trials GAP: 1 x 0.04-0.045 kg as/ha, BBCH 13-14, outdoor 8 x < 0.01			
	EFSA, 2013 Wolters A., 2007 RA-2616/06	S-EU	Trials GAP: 1 x 0.054 kg as/ha, BBCH 18, outdoor 5 x < 0.01			
	Overall supporting data for cGAP	N-EU & S-EU	25 x < 0.01	0.01	0.01	N/A

* Source of EU MRL: Reg. (EU) 2021/1110

7.3.3.2 Conclusion on the magnitude of residues in plants

Maize is considered a major crop in Southern and Northern Europe. Therefore, trials from both regions are required. Since a no residue situation is expected based on the metabolism study, 4 Southern trials and 4 Northern trials are sufficient to cover the maize use of GLOB2112dH.
12 NEU and 13 SEU trials are available all showing that residues are below the LOQ. The data confirm the no residue situation.

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

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

zRMS comment: Comparison of EU and intended GAP in maize:

Type of GAP	Method	Number of applications	Max. application rate per treatment (kg as/ha)	Interval between application (days)	Growth stage at last application	PHI (days)
GAP EU (EFSA, 2013)	Foliar spray	1	0.04-0.054	-	BBCH 13 – 18	-
Intended GAP	Foliar spray	1	0.015-0.00975	-	BBCH 10 – 18	-

Maize is a major crop in Northern Europe. The applicant relied upon 12 NEU trials that have been previously evaluated at EU level, with application rates higher than those proposed GAP. The required use is within the EU GAP. Available results show that the current MRL of 0.01 mg/kg (Reg. (EU) 2021/1110) will not be exceeded. Therefore the proposed uses of the product can be considered as supported on maize in Central Europe.

7.3.4 Magnitude of residues in livestock

7.3.4.1 Dietary burden calculation

Table 7.3-9: Input values for the dietary burden calculation (considering the uses 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: sum of thiencarbazone-methyl, BYH 18636-N-desmethyl and BYH 18636-MMT-glucoside, expressed as thiencarbazone-methyl				
Barley, grain	0.01*	STMR	-	-
Brewer's grain, dried	0.01*	STMR**	-	-
Corn, field (Maize), grain	0.01*	STMR	-	-
Corn, pop, grain	0.01*	STMR	-	-
Corn, field, milled by-pdts	0.01*	STMR**	-	-

Feed Commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Corn, field, hominy meal	0.01*	STMR**	-	-
Corn, field, distiller's grain (dry)	0.01*	STMR**	-	-
Corn, field, gluten feed	0.01*	STMR**	-	-
Corn, field, gluten, meal	0.01*	STMR	-	-
Millet, grain	0.01*	STMR	-	-
Rye, grain	0.01*	STMR	-	-
Sorghum, grain	0.01*	STMR	-	-
Triticale, grain	0.01*	STMR	-	-
Wheat, grain	0.01*	STMR	-	-
Wheat, distiller's grain (dry)	0.01*	STMR**	-	-
Wheat, gluten, meal	0.01*	STMR**	-	-
Wheat, milled by-pdts	0.01*	STMR**	-	-
Beet, sugar, dried pulp	0.01*	STMR**	-	-
Beet, sugar, ensiled pulp	0.01*	STMR**	-	-
Beet, sugar, molasses	0.01*	STMR**	-	-
Corn, field, forage/silage	0.01*	STMR	0.01*	HR
Barley, straw	0.01*	STMR	0.01*	HR
Millet, straw (fodder, dry)	0.01*	STMR	0.01*	HR
Corn, field, stover (fodder)	0.01*	STMR	0.01*	HR
Corn, pop, stover	0.01*	STMR	0.01*	HR
Rye, straw	0.01*	STMR	0.02	HR
Sorghum, grain, stover	0.01*	STMR	0.01*	HR
Triticale, straw	0.01*	STMR	0.02	HR
Wheat, straw	0.01*	STMR	0.02	HR
Beet, mangel, fodder	0.01*	STMR	0.01*	HR
Beet, sugar, tops	0.01*	STMR	0.01*	HR

*Indicates that the input value is proposed at the LOQ
**For brewer's grain, processed commodities of corn, wheat and sugar beet, no default processing factor was applied because thiencarbazone-methyl is applied early in the growing season and residues are expected to be below the LOQ. Concentration of residues in these commodities is therefore not expected.

Table 7.3-10: Results of the dietary burden calculation

Animal species	Median dietary burden (mg/kg bw/d)	Maximum dietary burden (mg/kg bw/d)	Highest contributing commodity	Max dietary burden (mg/kg DM)	Trigger exceeded (Y/N)
Risk assessment residue definition: sum of thiencarbazone-methyl, BYH 18636-N-desmethyl and BYH 18636-MMT-glucoside, expressed as thiencarbazone-methyl					
Beef cattle*	0.0010	0.001	Beet, sugar, ensiled pulp	0.04	N
Dairy cattle*	0.0018	0.002	Beet, mangel, fodder	0.05	N
Ram/ewe	0.0007	0.001	Corn, field, gluten feed	0.02	N
Lamb	0.0009	0.001	Corn, field, gluten feed	0.02	N
Breeding swine	0.0005	0.0005	Beet, mangel, fodder	0.02	N
Finishing swine*	0.0004	0.0004	Corn, field, milled by-pdts	0.01	N
Broiler poultry	0.0008	0.001	Corn, field, milled by-pdts	0.01	N
Layer poultry*	0.0009	0.001	Corn, field, forage/silage	0.01	N
Turkey	0.0008	0.001	Corn, field, milled by-pdts	0.01	N

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

7.3.4.2 Livestock feeding studies (KCA 6.4.1-6.4.3)

Dietary burden intakes are all below 0.004 mg/kg bw/d, so no livestock feeding studies are required.

zRMS comment: The calculated dietary burdens were found to be below the trigger value of 0.004 mg/kg bw hence no livestock feeding studies are required.

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

As residues in the RAC at harvest are less than the 0.1 mg/kg trigger value, studies on the effects of industrial processing and household preparations on the nature and levels of the residue are not required.

zRMS comment: Residues of thiencarbazone-methyl do not exceed the trigger values defined in Regulation (EU) No 283/2013, therefore there is no need to investigate the effect of industrial and/or household processing.

7.3.6 Magnitude of residues in representative succeeding crops

The crops under consideration can be grown in rotation.

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

summarized hereafter.

7.3.6.1 Field rotational crop studies (KCA 6.6.2)

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

zRMS comment: Residues in rotational crops following use the product according to the proposed GAP are unlikely to exceed 0.01 mg/kg (the available field high-dose study (45 g/as/ha) was assessed during peer review and indicated that in samples of soyabean and wheat grown in rotation residues of thiencarbazone-methyl were found to be lower than 0.01 mg/kg).

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 GLOB2112dH. Therefore, other special studies are not needed.

In Regulation (EU) No. 283/2013 for active substances, the residue level in pollen and bee products for human consumption resulting from residues taken up by honeybees need to be determined. Although that this determination of residues level in pollen and bee products is an active substance requirement rather than a plant protection product requirement and therefore such active substance studies should be addressed during the annex I renewal of the active substance, based on the argumentation below, the residue level of thiencarbazone-methyl in pollen and bee products can be considered as negligible. Indeed, as detailed in the EU report on pesticide residues in food (EFSA journal 2021;19(4):6491), the European monitoring program showed that active substance residues were always below the LOQ (0.01 mg/kg).

The uses of GLOB2112dH are on maize which is not considered to be a melliferous crop. Thiencarbazone-methyl is not considered as a systemic compound. Therefore, exposure via succeeding crops is not relevant. Only the exposure of non-target plants (in-field weeds and adjacent plants) is relevant.

<u>In-field weeds:</u>
In the metabolism study in maize (pre- and post-emergence), in general very low total radioactive residues (TRR) levels were detected. Parent thiencarbazone-methyl was a very minor residue detected only in maize forage and stover at a maximum level of 0.007 mg eq/kg. Therefore, the contribution of in-field weeds to residues in honey is considered negligible.
In addition, to prevent yield losses, farmers protect the maize 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 max. 4 leave stage, dicots max. 7 leave stage). Therefore, there is a very low probability that at the time of application weeds have already reached the flowering stage. After application, maize growth suppresses the further development of potential surviving weeds. In summary, there is a very low probability that in-field weeds reach the flowering stage. As bees are attracted by large areas of flowering plants, it is very unlikely that they would collect pollen and nectar from flowering weeds in a maize field – a crop that does not produce nectar and is only a pollen resource. Thus, it is not expected that in-field weeds could be a source for residues in honey.

<u>Off-field flowering weeds and plants:</u>
According to the recent technical guidance on honey MRL (11956), if the highest residue (HR) found in aerial parts are below 0.05 mg/kg, no further residue studies in honey are necessary and the default MRL of 0.05 mg/kg can be set. If the HR value is found to be above 0.05 mg/kg but below 0.5 mg/kg in the aerial parts, the MRL could be based on the HR value considering a transfer factor of 1 from aerial parts to honey. If the HR value is found to be above 0.5 mg/kg in the aerial parts, further specific data would be needed to set the MRL.
To estimate the residue level in aerial parts, reference is made to Appendix F of the EFSA bee guidance

from 2013 which mentions RUD values in pollen/nectar for approx. 35 substances based on HR values analysed after spray applications during flowering. For pollen, the **95th percentile** and the highest RUD are given at **82.1** and 149.8 mg a.s./kg respectively. For nectar, the 95th percentile and the highest RUD are given at 12.0 and 20.7 mg a.s./kg respectively. Considering the 95th percentile RUD for aerial parts (i.e. pollen) of 82.1 mg a.s./kg, such an RUD would cover a MRL setting without the need of specific additional data up to a dose rate of 6.09 g a.s./ha (with such an application rate, the calculated MRL would be 82.1*0.00609 = 0.499 mg as/kg pollen, thus below the threshold value of 0.5 mg/kg). On the other hand, the default MRL of 0.05 mg/kg would be supported for dose rate < 0.6 g a.s./ha. In case the dose rate is higher than 6.09 g a.s./ha, further residue studies would be necessary.
Since off-field flowering weeds and plants are only exposed to the drift rate (2.77% of the full rate), the dose rate to be taken into account for 1 application of GLOB2112dH would be 0.416 g thiencarbazone-methyl/ha. This is below 6.09 g a.s./ha and thus no further studies are needed.

This together with the results from the EU monitoring program (EFSA journal 2021;19(4):6491) let us conclude that no exceedance of the default MRL in honey is expected based on the intended uses.

Reference is also made to the waiver presented by Bayer (Hoffmann M. & Barrière I., 2020) confirming that no exceedance of the default MRL in honey is expected.

zRMS comment: According to Technical Guidelines SANTE/11956/2016 rev. 9 14 September 2018, maize is not considered as melliferous plant.

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

7.3.8.1 Input values for the consumer risk assessment

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

Commodity	Chronic risk assessment	
	Input value (mg/kg)	Comment
Risk assessment residue definition: sum of thiencarbazone-methyl, BYH 18636-N-desmethyl and BYH 18636-MMT-glucoside, expressed as thiencarbazone-methyl		
Herbs and edible flowers	0.02*	MRL (Reg. (EU) 2021/1110)
Teas, coffee, herbal infusions, cocoa and carobs	0.05*	MRL (Reg. (EU) 2021/1110)
Hops	0.05*	MRL (Reg. (EU) 2021/1110)
Spices	0.05*	MRL (Reg. (EU) 2021/1110)
All other plant commodities	0.01*	MRL (Reg. (EU) 2021/1110)
Risk assessment residue definition: sum of thiencarbazone-methyl and BYH 18636- MMT, expressed as thiencarbazone-methyl		

Commodity	Chronic risk assessment	
	Input value (mg/kg)	Comment
Honey and other apiculture products	0.05*	MRL (Reg. (EU) 2021/1110)
All other animal commodities	0.01*	MRL (Reg. (EU) 2021/1110)

* Indicates that the input value is proposed at the limit of quantification

7.3.8.2 Conclusion on consumer risk assessment

Extensive calculation sheets are presented in Appendix 3.

Table 7.3-12: Consumer risk assessment

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

The proposed uses of thiencarbazone-methyl in the formulation GLOB2112dH 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

Not required.

7.4.2 Chronic consumer risk assessment from combined exposure

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

zRMS comment: The calculation of the TMDI led to an utilisation of the ADI of 0.5 % based on NL toddler being the population group with the highest value. For this diet, the highest contributor is milk with 0.3% of the ADI. As no ARfD was established, no acute risk assessment was performed. The proposed use of thiencarbazone-methyl in the product Walkover Trio does not represent unacceptable chronic and acute risks for the consumers.

7.5 References

EC (European Commission), 2003. Review report for the active substance mesotrione. Finalised in the Standing Committee on the Food Chain and Animal Health at its meeting on 11 April 2003 in view of the inclusion of mesotrione in Annex I of Council Directive 91/414/EEC. SANCO/1416/2001 –Final 14 April 2003. Available online:
http://ec.europa.eu/sanco_pesticides/public/index.cfm?event=activesubstance.selection

United Kingdom, 1999. Draft assessment report on the active substance mesotrione prepared by the rapporteur Member State United Kingdom in the framework of Council Directive 91/414/EEC, December 1999.

United Kingdom, 2001a. Addendum 1 to the draft assessment report on the active substance mesotrione prepared by the rapporteur Member State United Kingdom in the framework of Council Directive 91/414/EEC, May 2001.

United Kingdom, 2001b. Addendum 2 to the draft assessment report on the active substance mesotrione prepared by the rapporteur Member State United Kingdom in the framework of Council Directive 91/414/EEC, September 2001

United Kingdom, 2003. Addendum 3 to the draft assessment report on the active substance mesotrione prepared by the rapporteur Member State United Kingdom in the framework of Council Directive 91/414/EEC, January 2003

EFSA (European Food Safety Authority), 2015. Reasoned opinion on the review of the existing maximum residue levels (MRLs) for mesotrione according to Article 12 of Regulation EC No 396/2005. EFSA Journal (2015) 13(1), 3976.

EFSA (European Food Safety Authority), 2016. Peer review of the pesticide risk of the active substance mesotrione. EFSA Journal (2016) 14(3): 4419.

EFSA (European Food Safety Authority), 2018. Technical report on the outcome of the consultation with Member States, the applicant and EFSA on the pesticide risk assessment for mesotrione in light of confirmatory data. EFSA supporting publication 2018:EN-1527. 22pp. doi:10.2903/sp.efsa.2018.EN-1527

UK, 2012. Draft assessment report on the active substance thiencarbazone prepared by the rapporteur Member State UK in the framework of Council Directive 91/414/EEC, April.

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.

EFSA (European Food Safety Authority), 2020. 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.

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 (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 6.10	Schneider E.	2016	Determination of mesotrione and its metabolite (MNBA) residues in maize following treatment with Mesotrione 100 SC under field conditions in northern and southern France in 2015. Study No B5116 Anadiag GLP Unpublished	N	Globachem NV
KCA 6.10	Ertus C.	2020	Determination of mesotrione residues in oilseed rape following treatment with Mesotrione 100 g/L SC under field conditions in northern and southern Europe in 2018 and 2019. Study No B7314 Anadiag GLP Unpublished	N	Globachem NV

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

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 6.1	Wiebe, L.A.	1997	ZA 1296: Stability of ZA 1296 and the Metabolite MNBA in Frozen Crops (Interim Report) Zeneca Report No: RR 97-042B INT DPDB Ref. 59800 GLP unpublished	N	Syngenta *Data out of protection*
KCA 6.1	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 MR186/05 GLP Unpublished	N	Bayer CropScience *Data out of protection*
KCA 6.1	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 MR-07/229 GLP Unpublished	N	Bayer CropScience *Data out of protection*
KCA 6.1	Brumhard B., Auer S., Eberhardt R.	2007	BYH 18636: Dairy Cattle Feeding Study MR-06/095 GLP Unpublished	N	Bayer CropScience *Data out of protection*
KCA 6.2.1	Wei, Y. *et al.*	1997	[Cyclohexane-2-^{14}C]ZA 1296: Nature of the Residues in Corn (Zea mays) Zeneca Report No: RR 96-026B DPDB Ref. 59801 GLP unpublished	N	Syngenta *Data out of protection*

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 6.2.1	Tarr, J.B. *et al.*	1997	[Phenyl-U-^{14}C]ZA 1296: nature of the residues in corn Report No: not given DPDB Ref. 59802 GLP unpublished	N	Syngenta *Data out of protection*
KCA 6.2.1	Bongartz R.	2005	Metabolism of [dihydrotriazole-3-^{14}C]BYH18636 in Corn in Combination with the Safener AE 0001789 as a Pre-emergence Application MEF-05/004 GLP Unpublished	N	Bayer CropScience *Data out of protection*
KCA 6.2.1	Bongartz R.	2005	Metabolism of [thiophene-4-^{14}C]BYH18636 in Corn in Combination with the Safener AE 0001789 as a Pre-emergence Application MEF-05/003 GLP Unpublished	N	Bayer CropScience *Data out of protection*
KCA 6.2.1	Bongartz R.	2005	Metabolism of [dihydrotriazole-3-^{14}C]BYH18636 in Corn MEF-04/182 GLP Unpublished	N	Bayer CropScience *Data out of protection*
KCA 6.2.1	Bongartz R.	2005	Metabolism of [thiophene-4-^{14}C]BYH18636 in Corn MEF-04/181 GLP Unpublished	N	Bayer CropScience *Data out of protection*
KCA 6.2.1	Bongartz R.	2005	Metabolism of [dihydrotriazole-3-^{14}C]BYH18636 in Corn in Combination with the Safener Isoxadifen-ethyl following two Post-emergence Applications at Growth Stages V6 and V12	N	Bayer CropScience

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
			MEF-05/006 GLP Unpublished		*Data out of protection*
KCA 6.2.1	Bongartz R.	2006	Metabolism of [thiophene-4-^{14}C]BYH18636 in Corn in Combination with the Safener Isoxadifen-ethyl following two Post-emergence Applications at Growth Stages V6 and V12 MEF-05/005 GLP Unpublished	N	Bayer CropScience *Data out of protection*
KCA 6.2.1	Sur R.	2005	Metabolism of [dihydrotriazole-3-^{14}C]BYH18636 in Wheat MEF-05/041 GLP Unpublished	N	Bayer CropScience *Data out of protection*
KCA 6.2.1	Sur R.	2005	Metabolism of [thiophene-4-^{14}C]BYH18636 in Wheat MEF-05/042 GLP Unpublished	N	Bayer CropScience *Data out of protection*
KCA 6.2.2	[redacted]	1997	AMBA: Metabolism of Orally Administrated Multiple doses in Lactating Cow Report No: not given [redacted] GLP unpublished	Y	Syngenta *Data out of protection*
KCA 6.2.2	[redacted]	2006	Metabolism of [Thiophene-4- 14C]BYH18636 in the Laying Hen [redacted] GLP Unpublished	Y	Bayer CropScience *Data out of*

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
					protection
KCA 6.2.2	[redacted]	2006	Metabolism of [Dihydrotriazole-3-^{14}C]BYH18636 in the Laying Hen [redacted] GLP Unpublished	Y	Bayer CropScience *Data out of protection*
KCA 6.2.3	[redacted]	2006	[Thiophene-4-^{14}C]BYH18636: Absorption, Distribution, Excretion and Metabolism in the Lactating Goat [redacted] GLP Unpublished	Y	Bayer CropScience *Data out of protection*
KCA 6.2.3	[redacted]	2006	[Dihydrotriazole-3-^{14}C]BYH18636: Absorption, Distribution, Excretion, and Metabolism in the Lactating Goat [redacted] GLP Unpublished	Y	Bayer CropScience *Data out of protection*
KCA 6.3	Barnes, J.P. *et al.*	1997a	ZA 1296: Residue Levels in Maize from Trials Carried Out in France during 1995 Zeneca Agrochemicals Report No: RR 96-071B DPDB Ref. 59806 GLP unpublished	N	Syngenta *Data out of protection*
KCA 6.3	Barnes, J.P. *et al.*	1997b	ZA 1296: Residue Levels in Maize from Trials Carried Out in France during 1996 Zeneca Agrochemicals Report No: RR 97-045B DPDB Ref. 59808 GLP unpublished	N	Syngenta *Data out of protection*

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 6.3	Barnes, J.P. *et al.*	1997c	ZA 1296: Residue Levels in Maize from Trials Carried Out in Germany during 1995 Zeneca Agrochemicals Report No: RR 96-078B DPDB Ref. 59810 GLP unpublished	N	Syngenta *Data out of protection*
KCA 6.3	Barnes, J.P. *et al.*	1997d	ZA 1296: Residue Levels in Maize from Trials Carried Out in Germany during 1995 Zeneca Agrochemicals Report No: RR 97-048B DPDB Ref. 59812 GLP unpublished	N	Syngenta *Data out of protection*
KCA 6.3	Barnes, J.P. *et al.*	1997e	ZA 1296: Residue Levels in Maize from Trials Carried Out in Italy during 1995. Zeneca Agrochemicals Report No: RR 96-077B DPDB Ref. 59813 GLP unpublished	N	Syngenta *Data out of protection*
KCA 6.3	Barnes, J.P. *et al.*	1997f	ZA 1296: Residue Levels in Maize from Trials Carried Out in Italy during 1995. Zeneca Agrochemicals Report No: RR 97-049B DPDB Ref. 59815 GLP unpublished	N	Syngenta *Data out of protection*
KCA 6.3	Billian P., Wolters A.	2006	Determination of the residues of AE 0001789 and BYH 18636 in/on corn after spraying of AE 1162464 02 SC39 A4 (450 SC) in the field in Germany, northern France, United Kingdom and Belgium RA-2583/05 GLP	N	Bayer CropScience *Data out of protection*

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**
			Unpublished		
KCA 6.3	Zimmer D.	2007	Determination of the residues of AE 0001789 and BYH 18636 in/on corn after spraying of AE 1162464 02 SC39 A4 (450 SC) in the field in southern France, Spain, Italy, Greece and Portugal RA-2584/05 GLP Unpublished	N	Bayer CropScience *Data out of protection*
KCA 6.3	Wolters A.	2007	Determination of the residues of AE 0001789, Isoxaflutole, and BYH 18636 in/on corn after spraying of AE 0001789 & Isoxaflutole (480 SC) and AE 0001789 & BYH 18636 (450 SC) in the field in northern France, United Kingdom and Germany RA-2615/06 GLP Unpublished	N	Bayer CropScience *Data out of protection*
KCA 6.3	Wolters A.	2007	Determination of the residues of AE 0001789, Isoxaflutole, and BYH 18636 in/on corn after spraying of AE 0001789 & Isoxaflutole (480 SC) and AE 0001789 & BYH 18636 (450 SC) in the field in southern France, Spain and Italy RA-2616/06 GLP Unpublished	N	Bayer CropScience *Data out of protection*
KCA 6.6.1	Spillner, C. *et. al*	1997	[Cyclohexane-2-14C]ZA 1296: confined accumulation studies on rotational crops – low rate Report No.: not given DPDB Ref. 59812 GLP unpublished	N	Syngenta *Data out of protection*
KCA 6.6.1	Gorder, G.W. *et al.*	1997	[Phenyl-U-^{14}C]ZA 1296: confined accumulation studies on rotational crops – low rate Report No: not given	N	Syngenta *Data out of*

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
			DPDB Ref. 59818 GLP unpublished		*protection*
KCA 6.6.1	Justus K.	2006	Metabolism of [dihydrotriazole-3- 14C]BYH18636 in Confined Rotational Crops following co-application with Safener AE 0001789 MEF-06/215 GLP Unpublished	N	Bayer CropScience *Data out of protection*
KCA 6.6.1	Justus K.	2006	Metabolism of [thiophene-4-^{14}C]BYH18636 in Confined Rotational Crops following coapplication with Safener AE 0001789 MEF-05/297 GLP Unpublished	N	Bayer CropScience *Data out of protection*
KCA 6.6.1	Justus K.	2006	Metabolism of [dihydrotriazole-3-^{14}C]BYH18636 in Confined Rotational Crops after an application rate of 30 g/ha in the presence of safener AE 0001789 MEF-06/258 GLP Unpublished	N	Bayer CropScience *Data out of protection*
KCA 6.6.1	Justus K.	2006	Metabolism of [thiophene-4-^{14}C]BYH18636 in Confined Rotational Crops after an application rate of 30 g/ha in the presence of safener AE 0001789 MEF-05/539 GLP Unpublished	N	Bayer CropScience *Data out of protection*
KCA 6.6.1	Reiner H.	2005	Metabolism of [dihydrotriazole-3-^{14}C]BYH18636 in Confined Rotational Crops MEF-05/023 GLP Unpublished	N	Bayer CropScience *Data out of*

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**
					protection
KCA 6.6.1	Reiner H.	2005	Metabolism of [thiophene-4-^{14}C]BYH18636 in Confined Rotational Crops MEF-05/024 GLP Unpublished	N	Bayer CropScience *Data out of protection*
KCA 6.6.2	Barnes, J.P., Wiebe, L.A.	1997	ZA 1296: Residue Levels on Rotated Crops from Trials Carried Out in the United States During 1995-1996. Zeneca Report No: RR 97-044B DPDB Ref. 59819 GLP unpublished	N	Syngenta *Data out of protection*
KCA 6.10.1	Hoffmann M., Barrière I.	2020	EU approval renewal of the active substance thiencarbazone-methyl – Waiver for studies investigating residues in honey Bayer AG Not GLP Unpublished	N	Bayer CropScience *Not GLP, not protected*

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 Mesotrione

A 2.1.1 Stability of residues

A 2.1.1.1 Stability of residues during storage of samples

A 2.1.1.1.1 Storage stability of residues in plant products

No new studies were submitted.

A 2.1.1.1.2 Storage stability of residues in animal products

No new studies were submitted.

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

A 2.1.2.1 Nature of residue in plants

A 2.1.2.1.1 Nature of residue in primary crops

No new studies were submitted.

A 2.1.2.1.2 Nature of residue in rotational crops

No new studies were submitted.

A 2.1.2.1.3 Nature of residues in processed commodities

No new studies were submitted.

A 2.1.2.2 Nature of residues in livestock

No new studies were submitted.

A 2.1.3 Magnitude of residues in plants

No new studies were submitted.

A 2.1.4 Magnitude of residues in livestock

A 2.1.4.1 Livestock feeding studies

No new studies were submitted.

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

No new studies were submitted.

A 2.1.6 Magnitude of residues in representative succeeding crops

No new studies were submitted.

A 2.1.7 Other/Special Studies

A 2.1.7.1 Study 1

Comments of zRMS:	Study conducted according to relevant guidelines and GLP requirements. Study is acceptable. The results of the study were used in calculation of DT_{50} in Part B9 of the registration report, point 9.3.2.2 (Refinement of DT_{50}).
Reference:	KCA 6.10
Report	Determination of mesotrione and its metabolite (MNBA) residues in maize following treatment with Mesotrione 100 SC under field conditions in Northern and Southern France in 2015. Schneider, E., 2016, Study No B5116
Guideline(s):	Yes, OECD 509, SANCO 7525/VI/95 rev. 10.3, SANCO/825/00 rev.9.1, SANCO/3029/99 rev.4
Deviations:	Yes, the weight of 1 analytical sample and 7 spare samples was below 0.4 kg as required by the study plan. The deviation has no impact on the study as more as 12 plants were collected for each sample. Moreover the weight of the analytical sample is close to 0.4 kg and spare samples should not be analysed.
GLP:	Yes
Acceptability:	Yes

Materials and methods

Field phase:
4 residue trials were carried out in Northern Europe (Northern France) and 1 residue trial was carried out in Southern Europe (Southern France). In each trial, one plot was treated once with Mesotrione 100 g/L SC at the application rate of 1.5 L/ha (150 g/ha mesotrione). The growth stage of the maize at application was BBCH 14-16. The application volume was 200-400 L/ha. A second plot remained untreated. Only at 1 trial site minimal rainfall occurred during the study, while no rainfall was recorded at the other 4 trial sites for the duration of the study.

Trial	Site	European area	Crop, variety	Trial type
B5116 AN1	Seebach, Alsace, France	North	Maize, Karedas	Decline curve
B5116 MA1	Donnelay, Lorraine, France	North	Maize, P3184	Decline curve
B5116 BM1	Thorée les Pins, Pays de la Loire, France	North	Maize, P9074	Decline curve
B5116 ND1	Hérin, Nord Pas de Calais, France	North	Maize, Ramses	Decline curve
B5116 EF1	Saint-Livrade, Aquitaine, France	South	Maize, Roberi	Decline curve

Maize samples (whole plants without roots; min. 0.4 kg and 12 plants) were taken at 0, 1, 2, 4, 7, 21, 28, and 49 hours after the application and a last sampling was done 3 days after application. Samples were dispatched to the laboratory under deep frozen conditions.

Analytical phase:
The residue analytical method validated in the study No. B5117 (please refer to section B5) was used.

Samples are homogenized and residues are extracted with acetonitrile in acidic conditions in the presence of magnesium sulphate and sodium chloride. The extract obtained after centrifugation is then analysed by LC-MS/MS.

The limit of quantification was set at 0.01 mg/kg for both mesotrione and AMBA.

Results and discussions

Residues in control samples were non-detectable or below the limit of quantification. The residue results in whole plant for mesotrione and MNBA in the treated specimens are summarized below:

		Residues (mg/kg)								
Trial No.	Analyte	0 HAA	1 HAA	2 HAA	4 HAA	7 HAA	21 HAA	28 HAA	49 HAA	3 DAA
B5116 AN1	Mesotrione	27.08 * 34.46 **	35.04	28.97	22.43	18.38	10.87	5.67	2.90	1.13
	MNBA	0.06* 0.06**	0.21	0.37	0.63	0.82	0.81	0.51	0.44	0.22
B5116 MA1	Mesotrione	20.21* 30.17**	21.25	20.12	18.97	19.32	13.56	7.96	4.27	1.15
	MNBA	0.02* 0.02**	0.09	0.09	0.19	0.42	0.64	0.43	0.27	0.11
B5116 BM1	Mesotrione	32.17* 30.06**	35.60	25.08	23.37	18.11	11.20	4.32	0.76	0.39
	MNBA	0.04* 0.03**	0.23	0.29	0.79	0.82	1.27	0.62	0.31	0.25
B5116 ND1	Mesotrione	16.42* 19.16**	15.41	13.14	11.85	8.17	5.13	3.07	1.71	0.38
	MNBA	0.02* 0.02**	0.07	0.17	0.42	0.58	0.45	0.54	0.50	0.21
B5116 EF1	Mesotrione	24.31* 34.02**	27.85	25.42	18.05	10.02	7.81	6.55	2.57	1.03
	MNBA	0.03* 0.03**	0.26	0.45	0.54	0.60	0.61	0.51	0.37	0.22

* Analytical sample, the results of these samples were not used to calculate the mesotrione half-life.
** Retain sample, the results of these samples were not used to calculate the mesotrione half-life.
HAA: Hour after application
DAA: Days after application
LOQ = 0.01 mg/kg

The tier 1 tables are given on the following pages.

Conclusion

The data from the residue trials can be used to determine the DT_{50} of mesotrione in maize (see KCP 10.1.2.2 in section B9).

RESIDUES DATA SUMMARY FROM SUPERVISED TRIALS (SUMMARY)
(Application on agricultural and horticultural crops)

Active ingredient:	**Mesotrione**	Producer of commercial product:	GLOBACHEM NV
Crop/crop group:	Maize/Maize		
Responsible body for reporting:	ANADIAG, 16 rue Ampère		
(name, address):	67500 HAGUENAU, France		
Country:	Northern France	Indoor/Glasshouse/Outdoor:	Outdoor
Content of active substance (g/kg or g/L):	100 g/L	Other a.s. in formulation:	-
Formulation (e.g. WP):	SC	(common name and content):	
Commercial product (name):	**Mesotrione 100 SC**	Residues calculated as:	mg/kg mesotrione and MNBA

1	2	3	4	5			6	7	8	9	10	11	12
Report-No ; Location including Postal Code	**Commodity /Variety** (a)	**Date of 1) Planting 2) Flowering 3) Harvest** (b)	**Method of treatment** (c)	**Application rate per treatment (actual)** g a.s./ha	Water (L/ha)	g a.s./hL	**Dates of treatment(s) or No. of treatment(s) and last date** (d)	**Growth stage at last treatment or date** (e)	**Portion analysed** (a)	**Mesotrione residues (mg/kg)**	**MNBA residues (mg/kg)**	**PHI** (f)	**Remarks** (g)
B5116 AN1 Seebach 67160 Northern France	Maize / Karedas	1) 16/04/2015 2) n.r. 3) not recorded	Medium volume spraying Overall spraying	159.0	318	50.0	03/06/2015	14-16	Whole plants Whole plants Whole plants Whole plants Whole plants Whole plants Whole plants Whole plants	35.04 28.97 22.43 18.38 10.87 5.67 2.90 1.13	0.21 0.37 0.63 0.82 0.81 0.51 0.44 0.22	1 hour 2 hours 4 hours 7 hours 21 hours 28 hours 49 hours 3 days	LOQ = 0.01 mg/kg

Remarks:

(a) According to EEC and Codex Classification (both) should be used
(b) Only if relevant
(c) High or low volume spraying, spreading, dusting etc
(d) Year must be indicated
(e) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4
(f) Minimum number of days after last application (Label pre-harvest interval, PHI, underline)
(g) Remarks may include: Climatic conditions; Reference to analytical method and information on which metabolites are included
n.r.: not recorded

RESIDUES DATA SUMMARY FROM SUPERVISED TRIALS (SUMMARY)
(Application on agricultural and horticultural crops)

Active ingredient:	**Mesotrione**	Producer of commercial product:	GLOBACHEM NV
Crop/crop group:	Maize/Maize		
Responsible body for reporting:	ANADIAG, 16 rue Ampère		
(name, address):	67500 HAGUENAU, France		
Country:	Northern France	Indoor/Glasshouse/Outdoor:	Outdoor
Content of active substance (g/kg or g/L):	100 g/L	Other a.s. in formulation:	-
Formulation (e.g. WP):	SC	(common name and content):	
Commercial product (name):	**Mesotrione 100 SC**	Residues calculated as:	mg/kg mesotrione and MNBA

1	2	3	4	5			6	7	8	9	10	11	12
Report-No ; Location including Postal Code	**Commodity /Variety**	**Date of 1) Planting 2) Flowering 3) Harvest**	**Method of treatment**	**Application rate per treatment (actual)**			**Dates of treatment(s) or No. of treatment(s) and last date**	**Growth stage at last treatment or date**	**Portion analysed**	**Mesotrione residues (mg/kg)**	**MNBA residues (mg/kg)**	**PHI**	**Remarks**
				g a.s./ha	**Water (L/ha)**	**g a.s./hL**							
	(a)	(b)	(c)				(d)	(e)	(a)			(f)	(g)
B5116 MA1 Donnelay 57810 Northern France	Maize / P3184	1) 13/04/2015 2) 10/07/2015 to 15/07/2015 3) 26/08/2015	Medium volume spraying Overall spraying	142.5	285	50.0	02/06/2015	16	Whole plants Whole plants Whole plants Whole plants Whole plants Whole plants Whole plants Whole plants	21.25 20.12 18.97 19.32 13.56 7.96 4.27 1.15	0.09 0.09 0.19 0.42 0.64 0.43 0.27 0.11	1 hour 2 hours 4 hours 7 hours 21 hours 28 hours 49 hours 3 days	LOQ = 0.01 mg/kg

Remarks:
(a) According to EEC and Codex Classification (both) should be used
(b) Only if relevant
(c) High or low volume spraying, spreading, dusting etc
(d) Year must be indicated
(e) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4
(f) Minimum number of days after last application (Label pre-harvest interval, PHI, underline)
(g) Remarks may include: Climatic conditions; Reference to analytical method and information on which metabolites are included
n.r.: not recorded

RESIDUES DATA SUMMARY FROM SUPERVISED TRIALS (SUMMARY)
(Application on agricultural and horticultural crops)

Active ingredient:	**Mesotrione**	Producer of commercial product:	GLOBACHEM NV
Crop/crop group:	Maize/Maize		
Responsible body for reporting:	ANADIAG, 16 rue Ampère		
(name, address):	67500 HAGUENAU, France		
Country:	Northern France	Indoor/Glasshouse/Outdoor:	Outdoor
Content of active substance (g/kg or g/L):	100 g/L	Other a.s. in formulation:	-
Formulation (e.g. WP):	SC	(common name and content):	
Commercial product (name):	**Mesotrione 100 SC**	Residues calculated as:	mg/kg mesotrione and MNBA

1	2	3	4	5			6	7	8	9	10	11	12
Report-No ; Location including Postal Code	**Commodity /Variety** (a)	**Date of 1) Planting 2) Flowering 3) Harvest** (b)	**Method of treatment** (c)	**Application rate per treatment (actual)**			**Dates of treatment(s) or No. of treatment(s) and last date** (d)	**Growth stage at last treatment or date** (e)	**Portion analysed** (a)	**Mesotrione residues (mg/kg)**	**MNBA residues (mg/kg)**	**PHI** (f)	**Remarks** (g)
				g a.s./ha	**Water (L/ha)**	**g a.s./hL**							
B5116 BM1 Thorée les Pins 72800 Northern France	Maize / P9074	1) 20/04/2015 2) n.r. 3) n.r.	Medium volume spraying Overall spraying	142.8	238	60.0	30/05/2015	15-16	Whole plants Whole plants Whole plants Whole plants Whole plants Whole plants Whole plants Whole plants	35.60 25.08 23.37 18.11 11.20 4.32 0.76 0.39	0.23 0.29 0.79 0.82 1.27 0.62 0.31 0.25	1 hour 2 hours 4 hours 7 hours 21 hours 28 hours 49 hours 3 days	LOQ = 0.01 mg/kg

Remarks:
(a) According to EEC and Codex Classification (both) should be used
(b) Only if relevant
(c) High or low volume spraying, spreading, dusting etc
(d) Year must be indicated
(e) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4
(f) Minimum number of days after last application (Label pre-harvest interval, PHI, underline)
(g) Remarks may include: Climatic conditions; Reference to analytical method and information on which metabolites are included
n.r.: not recorded

RESIDUES DATA SUMMARY FROM SUPERVISED TRIALS (SUMMARY)
(Application on agricultural and horticultural crops)

Active ingredient:	**Mesotrione**	Producer of commercial product:	GLOBACHEM NV
Crop/crop group:	Maize/Maize		
Responsible body for reporting:	ANADIAG, 16 rue Ampère		
(name, address):	67500 HAGUENAU, France		
Country:	Northern France	Indoor/Glasshouse/Outdoor:	Outdoor
Content of active substance (g/kg or g/L):	100 g/L	Other a.s. in formulation:	-
Formulation (e.g. WP):	SC	(common name and content):	
Commercial product (name):	**Mesotrione 100 SC**	Residues calculated as:	mg/kg mesotrione and MNBA

1	2	3	4	5			6	7	8	9	10	11	12
Report-No ; Location including Postal Code	**Commodity /Variety**	**Date of 1) Planting 2) Flowering 3) Harvest**	**Method of treatment**	**Application rate per treatment (actual)**			**Dates of treatment(s) or No. of treatment(s) and last date**	**Growth stage at last treatment or date**	**Portion analysed**	**Mesotrione residues (mg/kg)**	**MNBA residues (mg/kg)**	**PHI**	**Remarks**
				g a.s./ha	**Water (L/ha)**	**g a.s./hL**							
	(a)	(b)	(c)				(d)	(e)	(a)			(f)	(g)
B5116 ND1 Hérin 59195 Northern France	Maize / Ramses	1) 12/04/2015 2) n.r. 3) n.r.	Medium volume spraying Overall spraying	149.3	199	75.0	24/06/2015	16	Whole plants Whole plants Whole plants Whole plants Whole plants Whole plants Whole plants Whole plants	15.41 13.14 11.85 8.17 5.13 3.07 1.71 0.38	0.07 0.17 0.42 0.58 0.45 0.54 0.50 0.2'	1 hour 2 hours 4 hours 7 hours 21 hours 28 hours 49 hours 3 days	LOQ = 0.01 mg/kg

Remarks:
(a) According to EEC and Codex Classification (both) should be used
(b) Only if relevant
(c) High or low volume spraying, spreading, dusting etc
(d) Year must be indicated
(e) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4
(f) Minimum number of days after last application (Label pre-harvest interval, PHI, underline)
(g) Remarks may include: Climatic conditions; Reference to analytical method and information on which metabolites are included
n.r.: not recorded

RESIDUES DATA SUMMARY FROM SUPERVISED TRIALS (SUMMARY)
(Application on agricultural and horticultural crops)

Active ingredient:	**Mesotrione**	Producer of commercial product:	GLOBACHEM NV
Crop/crop group:	Maize/Maize		
Responsible body for reporting:	ANADIAG, 16 rue Ampère		
(name, address):	67500 HAGUENAU, France		
Country:	Southern France	Indoor/Glasshouse/Outdoor:	Outdoor
Content of active substance (g/kg or g/L):	100 g/L	Other a.s. in formulation:	-
Formulation (e.g. WP):	SC	(common name and content):	
Commercial product (name):	**Mesotrione 100 SC**	Residues calculated as:	mg/kg mesotrione and MNBA

1	2	3	4	5			6	7	8	9	10	11	12
Report-No ; Location including Postal Code	**Commodity /Variety**	**Date of 1) Planting 2) Flowering 3) Harvest**	**Method of treatment**	**Application rate per treatment (actual)**			**Dates of treatment(s) or No. of treatment(s) and last date**	**Growth stage at last treatment or date**	**Portion analysed**	**Mesotrione residues (mg/kg)**	**MNBA residues (mg/kg)**	**PHI**	**Remarks**
				g a.s./ha	**Water (L/ha)**	**g a.s./hL**							
	(a)	(b)	(c)				(d)	(e)	(a)			(f)	(g)
B5116 EF1 Sainte-Livrade 47110 Southern France	Maize / Roberi	1) 14/04/2015 2) n.r. 3) n.r.	Medium volume spraying Overall spraying	150.0	300	50.0	26/05/2015	16	Whole plants Whole plants Whole plants Whole plants Whole plants Whole plants Whole plants Whole plants	27.85 25.42 18.05 10.02 7.81 6.55 2.57 1.03	0.26 0.45 0.54 0.60 0.61 0.51 0.37 0.22	1 hour 2 hours 4 hours 7 hours 21 hours 28 hours 49 hours 3 days	LOQ = 0.01 mg/kg

Remarks:
(a) According to EEC and Codex Classification (both) should be used
(b) Only if relevant
(c) High or low volume spraying, spreading, dusting etc
(d) Year must be indicated
(e) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4
(f) Minimum number of days after last application (Label pre-harvest interval, PHI, underline)
(g) Remarks may include: Climatic conditions; Reference to analytical method and information on which metabolites are included
n.r.: not recorded

A 2.1.7.2 Study 2

Comments of zRMS:	Study conducted according to relevant guidelines and GLP requirements. Study is acceptable. The data from the residue trials can be used to determine the DT50 of mesotrione in oilseed rape (see KCP 10.1.2.2 in section B9).

Reference:	KCA 6.10
Report	Determination of mesotrione residues in oilseed rape following treatment with Mesotrione 100 g/L SC under field conditions in Northern and Southern Europe in 2018 and 2019. Ertus, C., 2019, Study No B7314
Guideline(s):	Yes, OECD 509, SANCO 7525/VI/95 rev. 10.3, SANCO/3029/99 rev.4, OECD72 and 39
Deviations:	In trial PL1 and ES1, the interval between sampling of some of the untreated samples and freezing was above maximum. No impact. In trial EF1, the growth stage at application was BBCH 14-18 instead of 14. At sampling No. 10 leaves were damp. No impact. In trial ND1, wind speed was not recorded at application. No impact. No deviation was recorded during the analytical phase of the study.
GLP:	Yes
Acceptability:	-

Materials and methods

Field phase:
4 residue trials were carried out in Northern Europe and 2 residue trial were carried out in Southern Europe. The trials were sampled frequently to monitor the decline of residues shortly after the treatment. In each trial, one plot was treated once with Mesotrione 100 g/L SC at the application rate of 1.5 L/ha (150 g mesotrione/ha) when the crop reached BBCH 14. One plot remained untreated.

Trial	Site	European area	Crop	Trial type
B7314 HU1	Central Transdanubia, Hungary	North	Oilseed rape	Decline curve
B7314 MA1	Grand Est, France	North	Oilseed rape	Decline curve
B7314 ND1	Hauts-de-France, France	North	Oilseed rape	Decline curve
B7314 PL1	Lodzkie, Poland	North	Oilseed rape	Decline curve
B7314 EF1	Nouvelle-Aquitaine, France	South	Oilseed rape	Decline curve
B7314 ES1	Catalonia, Spain	South	Oilseed rape	Decline curve

Sampling was performed just after application at 0, then 1, 2, 4, 7, 21 (±1), 28 (±3) and 49 (±5) hours after the application and at 3, 5, 7 (±1) and 10 (±1) days after the application.

Analytical phase:
The residue analytical method validated in the study No. B7315 (submitted in section B5) was used.

Samples are homogenized and residues are extracted with acetonitrile in acidic conditions in the presence of magnesium sulphate and sodium chloride. The extract obtained after centrifugation is then analysed by LC-MS/MS.

The limit of quantification was set at 0.01 mg/kg.

Results and discussions

Residues in control samples were non-detectable or below the limit of quantification. The residue results for mesotrione in the treated specimens are summarized below:

		Mesotrione residues (mg/kg)					
Sampling event	**Matrix**	**B7314 HU1**	**B7314 MA1**	**B7314 ND1**	**B7314 PL1**	**B7314 EF1**	**B7314 ES1**
0 HAA	Whole plants (without roots)	8.13	3.49	3.10	7.91	7.03	4.10
1 HAA	Whole plants (without roots)	8.94	3.74	4.89	5.60	4.99	3.15
2 HAA	Whole plants (without roots)	6.51	4.24	4.65	5.24	5.66	3.89
4 HAA	Whole plants (without roots)	7.40	2.79	3.49	3.70	4.38	3.66
7 HAA	Whole plants (without roots)	7.18	2.72	3.10	2.19	5.40	2.60
21 (±1) HAA	Whole plants (without roots)	4.44	1.35	1.70	2.07	4.16	1.09
28 (±3) HAA	Whole plants (without roots)	3.78	1.28	1.41	1.92	2.93	1.13
49 (±5) HAA	Whole plants (without roots)	2.04	0.62	0.99	1.20	1.76	0.54
3 DAA	Whole plants (without roots)	1.57	0.39	0.56	0.68	0.86	0.16
5 DAA	Whole plants (without roots)	0.92	0.20	0.21	0.40	0.26	0.05
7 (±1) DAA	Whole plants (without roots)	0.54	0.14	0.12	0.32	0.16	0.05
10 (±1) DAA	Whole plants (without roots)	0.21	0.05	0.07	0.25	0.11	0.04

HAA: Hour(s) After Application
DAA: Days After Application
LOD = 0.003 mg/kg
LOQ = 0.01 mg/kg

The tier 1 tables are given on the following pages.

Conclusion

The data from the residue trials can be used to determine the DT_{50} of mesotrione in oilseed rape (see KCP 10.1.2.2 in section B9).

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or planting 2.Flowering 3. Harvest	Application rate per treatment			Dates of treatment or no. of treatments and last date	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)	PHI	Details on trial
			g a.s./ ha	Water (l/ha)	g a.s./hl				Mesotrione		
	(a)	(b)				(c)				(d)	(e)
B7314 HU1/2921 Komárom, Central Transdanubia, Hungary/north/2018	Oilseed rape/ACHAT	1.13/04/2018 2.n.r. 3.n.r.	152.0	304	50	17/05/2018	BBCH 14	Whole plants (without roots)	8.13 8.94 6.51 7.40 7.18 4.44 3.78 2.04 1.59 0.92 0.54 0.21	0 HAA 1 HAA 2 HAA 4 HAA 7 HAA 22 HAA 28 HAA 51 HAA 3 DAA 5 DAA 7 DAA 10 DAA	LOQ = 0.01 mg/kg
B7314 MA1/57810 Donnelay, Grand Est, France/north/2018	Oilseed rape/MOSAIK	1.20/04/2018 2.n.r. 3.n.r.	144.0	288	50	25/05/2018	BBCH 14	Whole plants (without roots)	3.49 3.74 4.24 2.79 2.72 1.35 1.28 0.62 0.39 0.20 0.14 0.05	0 HAA 1 HAA 2 HAA 4 HAA 7 HAA 21 HAA 28 HAA 45 HAA 3 DAA 5 DAA 7 DAA 10 DAA	LOQ = 0.01 mg/kg
B7314 ND1/59189 Steenbecque, Hauts-de-France, France/north/2018	Oilseed rape/GAZZETTA	1.03/05/2018 2.n.r. 3.n.r.	153.0	204	75	20/06/2018	BBCH 14	Whole plants (without roots)	3.10 4.89 4.65 3.49 3.10 1.70 1.41 0.99 0.56 0.21 0.12 0.07	0 HAA 1 HAA 2 HAA 4 HAA 7 HAA 22 HAA 28 HAA 47 HAA 3 DAA 5 DAA 7 DAA 9 DAA	LOQ = 0.01 mg/kg

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or planting 2.Flowering 3. Harvest	Application rate per treatment			Dates of treatment or no. of treatments and last date	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)	PHI	Details on trial
			g a.s./ ha	Water (l/ha)	g a.s./hl				Mesotrione		
	(a)	(b)				(c)				(d)	(e)
B7314 PL1/99122 Góra Swietej Malgorzaty, Lodzkie, Poland/north/2018	Oilseed rape/MARKUS	1.20/04/2018 2.n.r. 3.n.r.	149.4	249	60	21/05/2018	BBCH 14	Whole plants (without roots)	7.91 5.60 5.24 3.70 2.19 2.07 1.92 1.20 0.68 0.40 0.32 0.25	0 HAA 1 HAA 2 HAA 4 HAA 7 HAA 22 HAA 26 HAA 52 HAA 3 DAA 5 DAA 7 DAA 9 DAA	LOQ = 0.01 mg/kg
B7314 EF1/47110 Sainte-Livrade-sur-Lot, Nouvelle-Aquitaine, France/south/2019	Oilseed rape/ MOSAIK	1.27/02/2019 2.n.r. 3.n.r.	159.0	212	75	13/05/2019	BBCH 14-18	Whole plants (without roots)	7.03 4.99 5.66 4.38 5.40 4.16 2.93 1.76 0.86 0.26 0.16 0.11	0 HAA 1 HAA 2 HAA 4 HAA 7 HAA 21 HAA 28 HAA 49 HAA 3 DAA 5 DAA 7 DAA 10 DAA	LOQ = 0.01 mg/kg
B7314 ES1/17257 LLabia, Catalonia, Spain/south/2018	Oilseed rape/ MOSAIK	1.23/05/2018 2.n.r. 3.n.r.	144.0	384	37.5	23/05/2018	BBCH 14	Whole plants (without roots)	4.10 3.15 3.89 3.66 2.60 1.09 1.13 0.54 0.16 0.05 0.05 0.04	0 HAA 1 HAA 2 HAA 4 HAA 7 HAA 22 HAA 29 HAA 52 HAA 3 DAA 5 DAA 7 DAA 9 DAA	LOQ = 0.01 mg/kg

A 2.2 Thiencarbazone-methyl

A 2.2.1 Stability of residues

A 2.2.1.1 Stability of residues during storage of samples

A 2.2.1.1.1 Storage stability of residues in plant products

No new studies submitted.

A 2.2.1.1.2 Storage stability of residues in animal products

No new studies submitted.

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

A 2.2.2.1 Nature of residue in plants

A 2.2.2.1.1 Nature of residue in primary crops

No new studies submitted.

A 2.2.2.1.2 Nature of residue in rotational crops

No new studies submitted.

A 2.2.2.1.3 Nature of residues in processed commodities

No new studies submitted.

A 2.2.2.2 Nature of residues in livestock

No new studies submitted.

A 2.2.3 Magnitude of residues in plants

No new studies submitted.

A 2.2.4 Magnitude of residues in livestock

A 2.2.4.1 Livestock feeding studies

No new studies submitted.

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

A 2.2.5.1 Distribution of the residue in peel/pulp

No new studies submitted.

A 2.2.5.2 Processing studies on a core set of representative processes

No new studies submitted.

A 2.2.5.3 Magnitude of residues in representative succeeding crops

No new studies submitted.

A 2.2.6 Other/Special Studies

No new studies submitted.

Appendix 3 Pesticide Residue Intake Model (PRIMo)

A 3.1 TMDI calculations

Mesotrione

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

Mesotrione

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

Toxicological reference values

ADI (mg/kg bw/day):	0.01	ARfD (mg/kg bw):	0.02
Source of ADI:		Source of ARfD:	
Year of evaluation:		Year of evaluation:	

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

Comments:

Normal mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI: ---

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

Calculated exposure (% of ADI)	MS Diet	Expsoure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	Exposure resulting from MRLs set at the LOQ (in % of ADI)	Exposure resulting from commodities not under assessment (in % of ADI)
12%	NL toddler	1.24	6%	Milk: Cattle	1%	Apples	0.7%	Maize/corn	12%	
7%	NL child	0.67	2%	Milk: Cattle	0.8%	Sugar beet roots	0.6%	Apples	7%	
6%	DE child	0.64	2%	Milk: Cattle	1%	Apples	0.4%	Wheat	6%	
6%	UK infant	0.61	4%	Milk: Cattle	0.3%	Potatoes	0.3%	Wheat	6%	
6%	FR toddler 2 3 yr	0.56	3%	Milk: Cattle	0.3%	Apples	0.3%	Wheat	6%	
6%	FR child 3 15 yr	0.55	2%	Milk: Cattle	0.5%	Wheat	0.4%	Sugar beet roots	6%	
5%	GEMS/Food G11	0.49	1%	Soyabeans	0.8%	Milk: Cattle	0.4%	Potatoes	4%	
4%	UK toddler	0.45	2%	Milk: Cattle	0.4%	Wheat	0.3%	Potatoes	4%	
4%	GEMS/Food G10	0.43	1.0%	Soyabeans	0.5%	Milk: Cattle	0.4%	Wheat	3%	
4%	GEMS/Food G07	0.42	0.6%	Milk: Cattle	0.5%	Soyabeans	0.4%	Wheat	4%	
4%	GEMS/Food G08	0.42	0.6%	Soyabeans	0.6%	Milk: Cattle	0.4%	Wheat	4%	
4%	GEMS/Food G15	0.42	0.7%	Milk: Cattle	0.5%	Soyabeans	0.5%	Wheat	4%	
4%	DK child	0.41	1%	Milk: Cattle	0.6%	Rye	0.4%	Wheat	4%	
4%	GEMS/Food G06	0.41	0.7%	Wheat	0.4%	Soyabeans	0.4%	Tomatoes	4%	
4%	RO general	0.38	1%	Milk: Cattle	0.5%	Wheat	0.4%	Potatoes	4%	
4%	ES child	0.38	1%	Milk: Cattle	0.4%	Wheat	0.3%	Cocoa beans	4%	
4%	SE general	0.37	1%	Milk: Cattle	0.4%	Bovine: Muscle/meat	0.4%	Potatoes	4%	
4%	DE women 14-50 yr	0.37	1%	Milk: Cattle	0.5%	Sugar beet roots	0.3%	Apples	4%	
4%	DE general	0.36	1%	Milk: Cattle	0.4%	Sugar beet roots	0.2%	Apples	4%	
4%	FI adult	0.35	3%	Coffee beans	0.1%	Potatoes	0.1%	Rye	4%	
3%	IE adult	0.33	0.4%	Milk: Cattle	0.4%	Sweet potatoes	0.2%	Wheat	3%	
3%	NL general	0.30	0.8%	Milk: Cattle	0.3%	Sugar beet roots	0.2%	Potatoes	3%	
3%	FR infant	0.29	2%	Milk: Cattle	0.2%	Potatoes	0.2%	Apples	3%	
2%	FR adult	0.22	0.4%	Milk: Cattle	0.2%	Wine grapes	0.2%	Wheat	2%	
2%	PT general	0.21	0.5%	Potatoes	0.4%	Wheat	0.2%	Wine grapes	2%	
2%	ES adult	0.21	0.5%	Milk: Cattle	0.2%	Wheat	0.1%	Oranges	2%	
2%	FI 3 yr	0.18	0.5%	Potatoes	0.1%	Bananas	0.1%	Wheat	2%	
2%	IT toddler	0.16	0.7%	Wheat	0.2%	Other cereals	0.1%	Tomatoes	2%	
2%	DK adult	0.16	0.5%	Milk: Cattle	0.1%	Potatoes	0.1%	Wheat	2%	
2%	LT adult	0.16	0.4%	Milk: Cattle	0.3%	Potatoes	0.2%	Apples	2%	
1%	UK vegetarian	0.15	0.3%	Milk: Cattle	0.2%	Wheat	0.1%	Potatoes	1%	
1%	FI 6 yr	0.14	0.4%	Potatoes	0.1%	Cocoa beans	0.1%	Wheat	1%	
1%	UK adult	0.14	0.3%	Milk: Cattle	0.2%	Wheat	0.1%	Potatoes	1%	
1%	IT adult	0.12	0.4%	Wheat	0.1%	Tomatoes	0.1%	Apples	1%	
1.0%	PL general	0.10	0.3%	Potatoes	0.2%	Apples	0.1%	Tomatoes	1.0%	
0.8%	IE child	0.08	0.4%	Milk: Cattle	0.1%	Wheat	0.1%	Potatoes	0.8%	

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

Thiencarbazone-methyl

European Food Safety Authority
EFSA PRIMo revision 3.1; 2021/01/06

Thiencarbazone-methyl

LOQs (mg/kg) range from: 0.01 to: 0.07

Toxicological reference values

ADI (mg/kg bw/day):	0.23	ARfD (mg/kg bw):	insert valid entry
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%	NL child	0.66	0.1%	Milk: Cattle	0.0%	Sugar beet roots	0.0%	Apples	0.3%	
0.3%	DE child	0.63	0.1%	Milk: Cattle	0.1%	Apples	0.0%	Wheat	0.3%	
0.3%	UK infant	0.61	0.2%	Milk: Cattle	0.0%	Potatoes	0.0%	Wheat	0.3%	
0.2%	FR toddler 2 3 yr	0.56	0.1%	Milk: Cattle	0.0%	Apples	0.0%	Wheat	0.2%	
0.2%	FR child 3 15 yr	0.55	0.1%	Milk: Cattle	0.0%	Wheat	0.0%	Sugar beet roots	0.2%	
0.2%	UK toddler	0.45	0.1%	Milk: Cattle	0.0%	Wheat	0.0%	Potatoes	0.2%	
0.2%	GEMS/Food G11	0.42	0.0%	Milk: Cattle	0.0%	Potatoes	0.0%	Soyabeans	0.2%	
0.2%	DK child	0.41	0.1%	Milk: Cattle	0.0%	Rye	0.0%	Wheat	0.2%	
0.2%	GEMS/Food G07	0.38	0.0%	Milk: Cattle	0.0%	Wheat	0.0%	Potatoes	0.2%	
0.2%	GEMS/Food G06	0.38	0.0%	Wheat	0.0%	Tomatoes	0.0%	Milk: Cattle	0.2%	
0.2%	GEMS/Food G15	0.38	0.0%	Milk: Cattle	0.0%	Wheat	0.0%	Potatoes	0.2%	
0.2%	GEMS/Food G08	0.38	0.0%	Milk: Cattle	0.0%	Wheat	0.0%	Potatoes	0.2%	
0.2%	RO general	0.38	0.1%	Milk: Cattle	0.0%	Wheat	0.0%	Potatoes	0.2%	
0.2%	ES child	0.38	0.1%	Milk: Cattle	0.0%	Wheat	0.0%	Cocoa beans	0.2%	
0.2%	SE general	0.37	0.1%	Milk: Cattle	0.0%	Bovine: Muscle/meat	0.0%	Potatoes	0.2%	
0.2%	DE women 14-50 yr	0.37	0.1%	Milk: Cattle	0.0%	Sugar beet roots	0.0%	Apples	0.2%	
0.2%	GEMS/Food G10	0.37	0.0%	Milk: Cattle	0.0%	Wheat	0.0%	Soyabeans	0.2%	
0.2%	DE general	0.36	0.1%	Milk: Cattle	0.0%	Sugar beet roots	0.0%	Apples	0.2%	
0.2%	FI adult	0.35	0.1%	Coffee beans	0.0%	Potatoes	0.0%	Rye	0.2%	
0.1%	IE adult	0.33	0.0%	Milk: Cattle	0.0%	Sweet potatoes	0.0%	Wheat	0.1%	
0.1%	NL general	0.30	0.0%	Milk: Cattle	0.0%	Sugar beet roots	0.0%	Potatoes	0.1%	
0.1%	FR infant	0.29	0.1%	Milk: Cattle	0.0%	Potatoes	0.0%	Apples	0.1%	
0.1%	FR adult	0.22	0.0%	Milk: Cattle	0.0%	Wine grapes	0.0%	Wheat	0.1%	
0.1%	PT general	0.21	0.0%	Potatoes	0.0%	Wheat	0.0%	Wine grapes	0.1%	
0.1%	ES adult	0.21	0.0%	Milk: Cattle	0.0%	Wheat	0.0%	Oranges	0.1%	
0.1%	FI 3 yr	0.18	0.0%	Potatoes	0.0%	Bananas	0.0%	Wheat	0.1%	
0.1%	IT toddler	0.16	0.0%	Wheat	0.0%	Other cereals	0.0%	Tomatoes	0.1%	
0.1%	DK adult	0.16	0.0%	Milk: Cattle	0.0%	Potatoes	0.0%	Wheat	0.1%	
0.1%	LT adult	0.16	0.0%	Milk: Cattle	0.0%	Potatoes	0.0%	Apples	0.1%	
0.1%	UK vegetarian	0.15	0.0%	Milk: Cattle	0.0%	Wheat	0.0%	Potatoes	0.1%	
0.1%	FI 6 yr	0.14	0.0%	Potatoes	0.0%	Cocoa beans	0.0%	Wheat	0.1%	
0.1%	UK adult	0.14	0.0%	Milk: Cattle	0.0%	Wheat	0.0%	Potatoes	0.1%	
0.1%	IT adult	0.12	0.0%	Wheat	0.0%	Tomatoes	0.0%	Apples	0.1%	
0.0%	PL general	0.10	0.0%	Potatoes	0.0%	Apples	0.0%	Tomatoes	0.0%	
0.0%	IE child	0.08	0.0%	Milk: Cattle	0.0%	Wheat	0.0%	Potatoes	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.
DISCLAIMER: Dietary data from the UK were included in PRIMO when the UK was a member of the European Union.

A 3.2 IEDI calculations

Not required as TMDI does not exceed ADI.

A 3.3 IESTI calculations - Raw commodities

Mesotrione

Show results for all crops

Unprocessed commodities

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

IESTI

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
8%	Potatoes	0.01 / 0.01	1.5
8%	Melons	0.01 / 0.01	1.5
7%	Pears	0.01 / 0.01	1.4
7%	Oranges	0.01 / 0.01	1.3
6%	Milk: Cattle	0.01 / 0.01	1.2
6%	Watermelons	0.01 / 0.01	1.2
5%	Apples	0.01 / 0.01	1.1
5%	Pineapples	0.01 / 0.01	1.0
5%	Bananas	0.01 / 0.01	0.97
5%	Peaches	0.01 / 0.01	0.95
4%	Mangoes	0.01 / 0.01	0.79
4%	Grapefruits	0.01 / 0.01	0.79
4%	Table grapes	0.01 / 0.01	0.73
3%	Cucumbers	0.01 / 0.01	0.66
3%	Carrots	0.01 / 0.01	0.63

Expand/collapse list

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

IESTI

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
2%	Head cabbages	0.01 / 0.01	0.42
2%	Watermelons	0.01 / 0.01	0.41
2%	Melons	0.01 / 0.01	0.39
2%	Milk: Cattle	0.01 / 0.01	0.39
2%	Swedes/rutabagas	0.01 / 0.01	0.34
2%	Table grapes	0.01 / 0.01	0.34
2%	Oranges	0.01 / 0.01	0.31
2%	Pears	0.01 / 0.01	0.31
1%	Potatoes	0.01 / 0.01	0.30
1%	Pineapples	0.01 / 0.01	0.30
1%	Yams	0.01 / 0.01	0.28
1%	Apples	0.01 / 0.01	0.28
1%	Cucumbers	0.01 / 0.01	0.28
1%	Aubergines/egg plants	0.01 / 0.01	0.27
1%	Mangoes	0.01 / 0.01	0.26

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

A 3.4 IESTI calculations - Processed commodities

Mesotrione

Processed commodities

Results for children				Results for adults			
No of processed commodities for which ARfD/ADI is exceeded (IESTI):			---	No of processed commodities for which ARfD/ADI is exceeded (IESTI):			---
IESTI				**IESTI**			
Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
6%	Sugar beets (root) / sugar	0.01 / 0.12	1.1	3%	Pumpkins / boiled	0.01 / 0.01	0.55
5%	Potatoes / fried	0.01 / 0.01	0.93	2%	Sugar beets (root) / sugar	0.01 / 0.12	0.44
4%	Pumpkins / boiled	0.01 / 0.01	0.89	2%	Cauliflowers / boiled	0.01 / 0.01	0.42
4%	Witloofs / boiled	0.01 / 0.01	0.89	2%	Beetroots / boiled	0.01 / 0.01	0.39
4%	Broccoli / boiled	0.01 / 0.01	0.79	2%	Celeries / boiled	0.01 / 0.01	0.34
3%	Cauliflowers / boiled	0.01 / 0.01	0.70	2%	Apples / juice	0.01 / 0.01	0.33
3%	Escaroles/broad-leaved er	0.01 / 0.01	0.66	1%	Broccoli / boiled	0.01 / 0.01	0.24
3%	Potatoes / dried (flakes)	0.01 / 0.05	0.59	1%	Coffee beans / extraction	0.05 / 0.01	0.24
3%	Leeks / boiled	0.01 / 0.01	0.57	1%	Courgettes / boiled	0.01 / 0.01	0.23
3%	Apples / juice	0.01 / 0.01	0.54	1%	Parsnips / boiled	0.01 / 0.01	0.21
3%	Oranges / juice	0.01 / 0.01	0.53	1%	Kohlrabies / boiled	0.01 / 0.01	0.21
3%	Turnips / boiled	0.01 / 0.01	0.51	1%	Wine grapes / juice	0.01 / 0.01	0.21
3%	Parsnips / boiled	0.01 / 0.01	0.51	1%	Escaroles/broad-leaved	0.01 / 0.01	0.20
3%	Sweet potatoes / boiled	0.01 / 0.01	0.50	1.0%	Florence fennels / boiled	0.01 / 0.01	0.19
2%	Florence fennels / boiled	0.01 / 0.01	0.45	1.0%	Turnips / boiled	0.01 / 0.01	0.19
Expand/collapse list							

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