HSE

Draft Assessment Report

Evaluation of Active Substances

Plant Protection Products

Prepared according to **Retained Regulation (EC) 1107/2009** as it applies in Great Britain

Prosulfuron

Volume 3 – B.7 (AS)

Residue Data

GB Article 7 Amendment

Great Britain

September 2023

Version History

When	What
September 2023	HSE Initial Assessment

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B.7. RESIDUE DATA

This evaluation represents an assessment of new information submitted as part of an Article 7 amendment application in GB to remove the following restriction on the use of prosulfuron:-

> *Use shall be limited to one application every three years on the same field at a maximum dose of 20 g active substance per hectare.*

Prosulfuron went through the EU renewal of approval process with France as RMS and was re-approved on the 01 May 2017, Implementing Regulation (EU) 2017/375[1] containing the above restriction – the restriction relates to groundwater metabolites. At EU exit the approval was sustained in GB, details of the GB approval can be found on the GB active substance approvals register[2]. The expiry date for Prosulfuron in GB is 31 July 2028.

An identical Article 7 amendment application was made in the EU in 2016 and was fully considered by the original EU RMS France. The French assessment was completed in 2018, and revised in 2019 in light of additional data requested by EFSA during the EU peer review process. An updated EFSA Conclusion was published in 2020[3]. The implementing regulation amending the approval conditions of prosulfuron (removing the above restriction) can be found in Implementing Regulation (EU) 2021/574[4]. However the amended implementing regulation was not published until

[1] Commission Implementing Regulation (EU) 2017/375 of 2 March 2017 renewing the approval of the active substance prosulfuron, as a candidate for substitution, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011 (OJ L 58, 4.3.2017, p. 3–7).
[2] Active substances approved for use in pesticides - HSE (no date). Available at: https://www.hse.gov.uk/pesticides/pesticides-registration/active-substances/register.htm. (Accessed 20 September 2022).
[3] EFSA (European Food Safety Authority), Anastassiadou, M, Arena, M, Auteri, D, Brancato, A, Bura, L, Carrasco Cabrera, L, Chaideftou, E, Chiusolo, A, Crivellente, F, De Lentdecker, C, Egsmose, M, Fait, G, Greco, L, Ippolito, A, Istace, F, Jarrah, S, Kardassi, D, Leuschner, R, Lostia, A, Lythgo, C, Magrans, O, Mangas, I, Miron, I, Molnar, T, Padovani, L, Parra Morte, JM, Pedersen, R, Reich, H, Santos, M, Sharp, R, Stanek, A, Sturma, J, Szentes, C, Terron, A, Tiramani, M, Vagenende, B and Villamar-Bouza, L, 2020. Conclusion on the peer review of the pesticide risk assessment of the active substance prosulfuron. EFSA Journal 2020;18(7):6181, 20 pp.
[4] Commission Implementing Regulation (EU) 2021/574 of 30 March 2021 amending Implementing Regulations (EU) 2017/375 and (EU) No 540/2011 as regards the conditions of approval of the active substance prosulfuron (OJ L 120, 8.4.2021, p. 9–12).

30 March 2021, after the end of the EU Exit transition period, and this therefore does not apply in GB.

Since a full assessment including the EFSA peer review stage and publication of the EFSA conclusion was completed before the end of the EU Exit transition period, and this assessment would have applied the same guidance and assessment standards as applicable in GB, HSE has considered the assessment documents supporting the EU Article 7 amendment application. These documents were provided by the applicant as part of the GB Article 7 amendment application.

B.7.1. METABOLISM, DISTRIBUTION AND EXPRESSION OF RESIDUES IN PLANTS (ANNEX IIA 6.1 AND ANNEX IIIA 8.1)

Metabolism in primary crops was investigated following either foliar spray application, cell suspension and callus culture or stem injection on outdoor and indoor cereals (maize), using ^{14}C-triazine and ^{14}C-phenyl labelled prosulfuron for the approval of the active substance, the available data was summarised in the article 12 MRL review (EFSA, 2012[5]).

A summary of the available primary crop metabolism data is presented below (EFSA, 2012).

Crop group	Crop	Label position	Application and sampling details			
			Method, F or G [(a)]	Rate (kg a.s./ha)	Number	DAT[(b)] (days)
Cereals /grass crops	Maize	4,6-^{14}C triazine U-^{14}C phenyl	Cell suspension and callus culture, G	-	1	7
			Stem injection, G	0.5 mg per plant at 64 and 84 days post-planting	2	77 after the first injection (foliage, stalks, cobs and grain)

[5] European Food Safety Authority; Reasoned opinion on the review of the existing maximum residue levels (MRLs) for prosulfuron according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2012;10(12):3013. [31 pp.] doi:10.2903/j.efsa.2012.3013.

			Foliar spray, G	0.04	1	0 (whole plant), 1 (whole plant), 30 (whole plant), 45 (whole plant), 69 (stalks)
			Foliar spray, F	0.04	1	0 (leaves), 30 (forage), 46 (silage), 93 (harvest of stalks, cob and grain)

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

(b) DAT: Days after treatment where identification/characterisation of the residues has been investigated (interim samplings with information limited to TRR levels only, can be omitted)

According to the EFSA 2012 MRL review the results of the metabolism study showed that "*after 93 days at harvest, residues were low in stalks (0.009-0.05 mg eq/kg), and at levels too low for further characterisation or identification in cobs and grain (<0.003 mg eq/kg)*". Whilst residues were considered "*less readily extractable in the mature stalks sampled at harvest (36-43 %)*", the following was observed:

"*The metabolism studies in maize indicate that the parent compound is rapidly degraded and that there are no metabolites at significant amounts in the studies of relevance to the GAP. In mature stalks, the triazine metabolites CGA188838 and G28533 were the most prevalent metabolites found together at 23 % TRR and 0.002 mg/kg mg eq/kg. In maize forage, the same metabolites were the most prevalent found together at a level of 30 % TRR and 0.009 mg/kg mg eq/kg. Other metabolites found above 10 % TRR (total of free and conjugated form) were CGA300408 and CGA304060. Due to the low levels at which they were found, none of the metabolites are expected to contribute significantly to the toxicological burden.*

Based on the identified metabolites, it was concluded in the DAR that metabolism of prosulfuron proceeds via the following steps: hydroxylation of the phenyl ring to form the 5-hydroxy-phenyl derivative (CGA 300408), mainly present as the sugar conjugate; methoxy ether cleavage to form the 5-hydroxy-phenyl-4-hydroxy-triazine derivative; hydrolytic cleavage of the urea bridge to form CGA159902, CGA 304060, and various triazine metabolites following reactions including deamination and

oxidation of the triazine ring methyl group. Conjugation of CGA 304060 to a polyamine derivative and sugar conjugation of the various hydroxy metabolites, also occurs.

Based on the extensive metabolism of prosulfuron and low level of individual residues in the various plant parts at harvest, the residue for enforcement and risk assessment following a broadcast spray application in cereals at the requested application rates is defined as prosulfuron only".

The data obtained for plants following foliar spray was considered suitable to support the crops under consideration at the approved rates (maize and sweetcorn). Therefore, no additional consideration of plant metabolism is required.

For the renewal of the approval of prosulfuron, the residue definition for risk assessment (RD-RA) and enforcement (RD- Enf) in plants were proposed as:

- Prosulfuron (Draft subject to the data gap on the genotoxicity of CGA150829)

However, the RD-Enf currently in force is:

- Prosulfuron

The residue definition for enforcement and risk assessment was considered provisional, pending the addressment of the following data gap on the genotoxicity of CGA150829 (EFSA conclusion, 2014):

'The further assessment of the toxicological relevance of the plant and groundwater metabolite CGA150829, for which a genotoxic potential cannot be ruled out based on the available data. For this reason the consumer risk assessment cannot be finalised. Groundwater exposure to this metabolite is predicted to be above the drinking water limit of 0.1 µg/L in 6 out of 8 relevant FOCUS groundwater scenarios for acidic and alkaline soils'

The residue definitions for enforcement and risk assessment in plant commodities remained as provisional in EFSA peer review (2020) – these residue definition proposals are not directly relevant to GB.

Within the current assessment, the genotoxic potential of the metabolite CGA150829 was excluded (See B.6.8.1), therefore the data gap above has been addressed.

The genotoxic potential of CGA150829 has been addressed; in order to remove this metabolite from the provisional residue definition a conservative risk has been undertaken. Consumer risk assessments to address possible exposure to CGA150829 through diet were performed using a highly conservative approach (see tables B.7.11 3 - 5 and 7 - 9). The TRR value for maize grain in the metabolism study of 0.003 mg/kg was used as the STMR to assess exposure to maize and sweetcorn (representative uses) against the ADI value derived for CGA150829 in the current assessment. This approach is considered worst case, as it uses the observed TRR value from an overdosed metabolism study; a value which accounts for all possible plant metabolites of prosulfuron rather than just CGA150829. The resultant exposure is significantly below the ADI of 0.0007 mg/kg bw per day with a NEDI of 2% and an IEDI of 3%. The acute exposure was 18.6% of the ARfD for the UK model and 19% for the PRIMo model (ADI of 0.0007 mg/kg bw per day used as the ARfD in place of a metabolite specific acute TRV). This shows the low potential exposure to the metabolite, using a highly conservative approach in place of a %TRR value.

The residue definitions for risk assessment and enforcement are no longer considered draft.

The residue definition for risk assessment (RD-RA) in plant commodities is therefore proposed as:

- Prosulfuron

The residue definition for enforcement (RD-Enf) in plant commodities is proposed as:

- Prosulfuron

This conclusion is based on the current intended uses for prosulfuron (see table B.7.4-1). If in future the uses are changed and a more critical GAP is considered, the metabolism of prosulfuron and the subsequent residue

definition for risk assessment will need to be re-considered. The residue definitions will also be re-considered at the next renewal of the active.

There were additional data gaps relating to the metabolites CGA159902, CGA349707, CGA325025 and SYN547308 and the need for further toxicological assessment to review the potential for consumer risk assessments. Additional toxicological data has been submitted; toxicological reference values (TRVs) have been established for all relevant metabolites and chronic exposure assessments have been undertaken. The data gaps relating to exposure from these metabolites has been addressed.

It is further noted that data is only available on maize; for the setting of a general residue definition for risk assessment, additional data on a wider range of crops is required.

As all MRLs are currently set at LOQ, it is appropriate to maintain the residue definition for enforcement as prosulfuron only. If in future, substantive MRLs are required, this may require further consideration.

B.7.2. METABOLISM, DISTRIBUTION AND EXPRESSION OF RESIDUES IN LIVESTOCK (ANNEX IIA 6.2 AND ANNEX IIIA 8.1)

See previous DAR under point B.7.2.

Moreover, the applicant submitted an addendum which provides information on the stability of the [triazine-^{14}C] metabolites observed in the hen metabolism study. This addendum is summarised below.

Report:	KIIA 6.2.2/01, [redacted], 1994
Title:	Metabolism of [Triazine-^{14}C]CGA-152005 in the Chicken-Addendum 1.
Document No:	[redacted] – addendum 1
Guidelines:	EPA guideline 171-4 (a)
GLP	Yes

Acceptability	**Deviations**
Yes	None

Materials and method

The purpose of the Addendum is to demonstrate the stability of [triazine-^{14}C]CGA-152005 (prosulfuron) metabolites observed in the metabolism of hens.

The in-life phase of this study was conducted between 11 Feb 91 and 18 Feb 91 at the [redacted]. All hens were sacrificed on 18 Feb 91. Excreta were stored frozen immediately after collection. Eggs were separated into whites and yolks and stored frozen. Tissues (liver, kidney, lean meat and fat) were stored frozen immediately after sacrifice. The tissues, egg whites and yolks, and excreta were sent to [redacted] packed on dry ice on April 91 and were received in frozen condition. All specimens were immediately stored at -20°C.

Samples were periodically removed from storage for processing and analysis. Processed tissues, eggs and excreta were kept at -20°C between bench work-ups and analysis.

The analytical method is described in detail in the report [redacted]. Extractable ^{14}C-residues in liver, lean meat, egg whites and egg yolks were analysed using two reversed-phase HPLC systems based on H_2O/acetonitrile and H_2O/methanol.

Results

During storage at -20°C for up to 297 days (lean meat), 300 days (liver and egg whites), 353 days (fat) and 618 days (egg yolks), no significant changes were observed in the HPLC profiles of the extractable ^{14}C-residues.

Conclusion

Residues of [triazine-^{14}C]CGA-152005 (prosulfuron) in all tissues were considered stable under the storage conditions used in the study.

B.7.3. DEFINITION OF THE RESIDUE (ANNEX IIA 6.7, ANNEX IIIA 8.6)

In the initial list of endpoints, it was proposed to define the residue in plant and animal commodities as prosulfuron only for both enforcement and risk assessment.

For the residue definition the following facts from the metabolism studies in plant and animal were decisive:

- Parent, although efficiently degraded, is detectable in the plant over a prolonged period following application. It is still detectable in leaves and stalks with analytical techniques used for radiolabelled compounds.
- Not all the metabolites exceed currently proposed trigger values of 0.01 mg/kg in edible parts of plant and animal origin under practical condition.
- Parent is quantitatively the major portion of the residues in animal tissues and excreta.
- The metabolic pathways in plant and animal are qualitatively comparable.
- Some plant metabolites (CGA 300408, CGA 159902 and CGA 150829) were also discovered in the animal metabolism (see Volume 3 B6) and are thus toxicologically covered.
- Most other plant metabolites give evidence for their possible occurrence in animals based on their chemical structures and the same degradation steps.
- There is no evidence for any other plant metabolite with a toxicological relevance which would need further investigation or to be monitored by routine residue determination.
- In case of misuse (e.g. high overdose or application too close to harvest) parent prosulfuron is the appropriate compound for analytical monitoring.

On the basis of these facts parent prosulfuron is still considered to be the relevant residue in plant and animal commodities. It is concluded indeed that determination of

this compound will allow with sufficient accuracy to assess the potential exposure of consumers to residues and to control the proper use of the herbicide.

B.7.4. USE PATTERN

See **Error! Reference source not found.**.

Table B. 7.4-1 Intended uses for prosulfuron

Crop and/or situation (a)	Product Name	F, G or I (b)	Pests or group of pests controlled (c)	Formulation		Application				Application per treatment			PHI (days) (l)	Remarks (m)
				type (d-f)	Conc of a.i. g/kg (i)	method kind (f-h)	growth stage & season (j)	number min-max (k)	interval between applications (days)	g a.i./hl min-max	water l/ha; min-max	g a.i./ha min-max		
Maize and sweet corn	PEAK® 75 WG	F	Broad leaved weeds as cited on label	WG	750	Broadcast foliar application	BBCH 12-18 corresponding to 2-8 leaves	1	-	5-25	80-400	20	90 (grain) 60 (silage)	In combination with a nonionic surfactant at 0.1% to 0.25% of application volume
Maize and sweet corn	PEAK® 75 WG	F	Broad leaved weeds as cited on label	WG	750	Broadcast foliar application	BBCH 12-18 corresponding to 2-8 leaves	1	-	3.75-18.75	80-400	15	90 (grain) 60 (silage)	In combination with a nonionic surfactant at 0.1% to 0.25% of application volume
Maize and sweet corn	PEAK® 75 WG	F	Broad leaved weeds as cited on label	WG	750	Broadcast foliar application	BBCH 12-19 corresponding to 2-9 leaves	1 (or split application) *	-	3.75-18.75	80-400	15 (total)	90 (grain) 60 (silage)	In combination with a nonionic surfactant at 0.1% to 0.25% of application volume [split app. is 2 apps to a total of 15g within BBCH 19]

(a) For crops, the EU and Codex classification (both) should be taken into account ; where relevant, the use situation should be described (e.g. fumigation of a structure)
(b) Outdoor or field use (F), greenhouse application (G) or indoor application (I)
(c) *e.g.* biting and suckling insects, soil born insects, foliar fungi, weeds
(d) *e.g.* wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(e) GCPF Codes – GIFAP Technical Monograph N° 2, 1989
(f) All abbreviations used must be explained
(g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench
(h) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plant – type of equipment used must be indicated (i) Concentration in g ai/kg of g ai/L.
(i) g/kg or g/L. Normally the rate should be given for the active substance (according to ISO) and not for the variant in order to compare the rate for same active substances used in different variants (e.g. fluoroxypyr). **In certain cases, where only one variant synthesised, it is more appropriate to give the rate for the variant (e.g. benthiavalicarb-isopropyl).**
(j) Growth stage at last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
(k) Indicate the minimum and maximum number of application possible under practical conditions of use
(l) PHI - minimum pre-harvest interval
(m) Remarks may include: extent of use / economic importance / restrictions

*split application is 2 applications to a total of 15 g/ha within BBCH 19

B.7.5. IDENTIFICATION OF CRITICAL GAPS

The use for one application at a rate of 20 g a.i./ha at latest stage 18 (BBCH scale) (approximately 90 - 120 days before harvest, depending on variety) represents the critical GAP, i.e. the worst case use conditions.

An additional use has been included which allows a later treatment at BBCH 19 corresponding to 9 or more leaves unfolded and split application of a total of 15 g as/ha within this time. It is considered that an application at a slightly later growth stage will not have an impact on the residue level at maturity (applications still made before the consumable parts of the crop have started to form).

B.7.6. RESIDUES RESULTING FROM SUPERVISED TRIALS (ANNEX IIA 6.3, ANNEX IIIA 8.2)

B.7.6.1. Sample storage stability for analysis (annex IIA 6.0)

In the framework of the peer review under Directive 91/414 CE, residues of prosulfuron in frozen raw agricultural (sweet corn, maize) and processed (maize oil) commodities have been shown to be stable through storage for at least 12 months. Residues of prosulfuron in frozen animal products have been shown to be stable through storage for at least 10 months in milk and beef meat and for at least 16 months in eggs and beef liver.

The final reports, showing storage stability for up to 25 months, are now available and new data are summarised below.

Report:	KIIA 6.1.1/01, [redacted], 1994
Title:	Storage stability of in field- incurred residues of CGA-152005 in corn (whole plant) under freezer storage conditions
Document No:	ABR-94046
Guidelines:	EPA guideline 171-4 (e)
GLP	Yes

Acceptability	**Deviations**

Yes	None

Materials and method

The objective of this study was to determine the stability of field-incurred residues of CGA-152005 (prosulfuron) in representative sweet and field corn (whole plant) stored under freezer storage conditions (approximately -20°C). The storage conditions were chosen to represent the actual storage conditions under which field trial samples were stored prior to assay.

This report presents the results of the analysis of CGA-152005 in field-treated samples through 24 months of freezer storage. An earlier interim report, ABR-93038, and summarized in the initial DAR, presented the results through 12 months of freezer storage.

The test commodities used were sweet corn and field maize (whole plant, ~10 cm seedlings) obtained from field trials carried out in Sanger, CA, USA and Dewey, IL, USA.

CGA152005 (prosulfuron) formulated as 50 WG was applied early post-emergence on sweet corn (1X treatment and 2X treatment) and field maize (1X treatment). Untreated and field-incurred residue whole plant samples were collected and stored deep frozen at approximately -20°C until being analysed. At the desired storage intervals of approximately 0, 0.5, 1.5, 3.5, 7.5, 12, 18, and 24 months a sample set of one control sample, freshly fortified samples (with 1 mg/kg CGA-152005) and two or three freezer stored field-incurred samples were analysed for residues of CGA152005 (prosulfuron).

Method AG-590 was used to determine the residues of CGA152005 (prosulfuron) in sweet corn and field maize and sufficiently validated. This method comprised the extraction of crop samples (6 g) with acetonitrile/aqueous sodium bicarbonate, partitioning of the extracts with 1:1 methyl tert-butyl ether/hexane, and the cleanup using an Extrelut QE column. CGA152005 (prosulfuron) was measured by HPLC-UV. The limit of determination was 0.01 mg/kg.

Results

Only new results obtained in the final report are presented in Table B.7.6-1.

Percentage recoveries were calculated using the mean uncorrected prosulfuron concentrations presented in the reports and the residue levels measured at 0 days.

No residues of prosulfuron were present in control samples.

Table B.7.6-1 Stability of CGA 152005 (prosulfuron) residues in sweet corn and field maize following storage at -20°C

Commodity	Storage period (months)	Mean uncorrected residue (mg/kg)	Mean recovered uncorrected residue (%)	Mean procedural recovery (%)
Sweet corn (whole plant)	18.1	1.14[a]	121	86
		3.34[b]	124	
	24.1	1.15[a]	122	87
		3.06[b]	114	
Field maize (whole plant)	17.8	5.24	109	93
	24.2	5.62	117	89

[a] 1X treatment
[b] 2X treatment

Conclusion

Residues of CGA-152005 are stable in sweet and field corn stored under freezer conditions (-20°C) for a minimum of 24 months.

Report:	KIIA 6.1.1/02, [redacted], 1994
Title:	Stability of CGA-152005 fortified into corn substrates under freezer storage conditions
Document No:	ABR-94051
Guidelines:	EPA guideline 171-4 (e)
GLP	Yes

Acceptability	**Deviations**
Yes	None

Materials and method

The objective of this study was to determine the stability of residues of CGA-152005 in corn forage, grain, and oil samples stored under freezer storage conditions (approximately -20°C).

The storage conditions were chosen to represent the actual storage conditions under which field trial samples were stored prior to assay.

This report presents the results of the analyses of CGA-152005 in laboratory-fortified samples through 25 months of freezer storage. An earlier interim report, ABR-93054, and summarized in the initial DAR, presented results through 12 months of freezer storage.

Field maize was grown under normal agricultural conditions. Maize forage (whole plant) was sampled six weeks after planting (or < 51 cm height). Maize grain was sampled at normal harvest. Untreated maize forage and grain samples and purchased maize oil samples were fortified with CGA152005 (prosulfuron) at the following concentrations: maize forage (1.0 mg/kg), maize grain (0.1 mg/kg), maize oil (0.1 mg/kg). Fortified samples were stored deep frozen at approximately -20°C until being analysed. At the desired storage intervals of approximately 0, 1, 2, 6, 12, 18, and 25 months a sample set for each interval and substrate of a control sample, two freshly fortified samples, and two freezer stored fortified samples were analysed for residues of CGA152005 (prosulfuron).

Method AG-590 was used to determine the residues of CGA152005 (prosulfuron) in maize forage, grain, and oil and sufficiently validated. See study IIA 6.1.1/01 for a short description of the method. Maize oil samples were dissolved in hexane and partitioned with sodium carbonate solution prior to cleanup. CGA152005 (prosulfuron) was measured by HPLC-UV. The limit of determination was 0.01 mg/kg.

Results

Only new results obtained in the final report are presented in Table B.7.6-2.

Percentage recoveries were calculated using the mean uncorrected prosulfuron concentrations presented in the reports and the theoretical fortification level (1 mg/kg for maize forage and 0.1 mg/kg for maize grain and oil).

No residues of prosulfuron were present in control samples.

Table B.7.6-2 Stability of CGA 152005 (prosulfuron) residues in maize forage, grain and oil following storage at -20°C

Commodity	Storage period (months)	Mean uncorrected residue (mg/kg)	Mean recovered uncorrected residue (%)	Mean procedural recovery (%)
Maize forage	19	0.90	90	88
	25	0.85	85	95
Maize grain	19	0.09	90	79
	25	0.09	90	87
Maize oil	19	0.06	60	80
	25	0.05	50	59
	25.6	0.05	50	66

Conclusion

Residues of CGA-152005 are stable for a minimum of 25 months in maize forage and grain stored under freezer storage conditions (-20°C).

For maize oil, residue levels measured after 19, 25 and 25.6 months are below 70%. Therefore it can be concluded that prosulfuron is stable in maize oil during 12 months (results of the study, see previous DAR) but not further.

Report:	KIIA 6.1.1/03, [redacted], 1997
Title:	Stability of CGA-152005 fortified into meat, milk and eggs under freezer storage conditions
Document No:	ABR-97044
Guidelines:	Part 860.1380 of the Office of Prevention, Pesticide, and Toxic Substances (OPPTS)
GLP	Yes

Acceptability	Deviations
Yes	None

Materials and method

The objective of this study was to determine the stability of residues for CGA-152005 in meat, milk and egg samples stored under freezer storage conditions (approximately -20°C).

The storage conditions were chosen to represent the actual storage conditions under which residue samples from animal feeding studies are stored prior to assay.

An earlier report, ABR-93055, presented interim results of beef muscle and milk samples stored for 16 months (see previous DAR). This report presents stability data from ABR-93055 as well as additional results from analyses of beef muscle, beef liver, and milk samples stored for up to 25 months of freezer storage.

For each interval and substrate, subsamples of 10 g (50 g for milk) were fortified with CGA152005 (prosulfuron) at 0.1 mg/kg. Fortified samples were stored deep frozen at approximately -20°C until being analysed. At several intervals up to 25 months (16 months for eggs) a sample set for each interval and substrate of a control sample, two freshly fortified samples, and two freezer stored fortified samples were analysed for residues of CGA152005 (prosulfuron).

Method AG-592 was used to determine the residues of CGA152005 (prosulfuron) in meat, liver, milk, and egg substrates and was sufficiently validated. This method comprised the extraction with acetonitrile: 0.1% aqueous sodium bicarbonate (9:1), partitioning with methyl-tert-butyl ether:hexane (1:1), extraction of the acidified extract with dichloromethane:hexane (1:1), and cleanup using an alumina-A Sep-Pak column. CGA152005 (prosulfuron) was measured by HPLC-UV. The limit of determination was 0.05 mg/kg for meat, liver and eggs and 0.01 mg/kg for milk.

Results

Only new results obtained in the final report are presented in Table B.7.6-3. For eggs, no new data were available.

Percentage recoveries were calculated using the mean uncorrected prosulfuron concentrations presented in the reports and the theoretical fortification level (0.1 mg/kg).

No residues of prosulfuron were present in control samples.

Table B.7.6-3 Stability of CGA 152005 (prosulfuron) residues in beef muscle, beef liver and milk following storage at -20°C

Commodity	Storage period (days)	Mean uncorrected residue (mg/kg)	Mean recovered uncorrected residue (%)	Mean procedural recovery (%)
Beef muscle	21.6	0.09	90	81
	24.4	0.09	90	81
Beef liver	25.4	0.08	80	77
Milk	18.5	0.08	80	87
	25	0.08	80	76

Conclusion

Residues of CGA 152005 are stable for a minimum of 25 months in beef muscle, beef liver, and milk and for a minimum of 16 months in egg samples stored under freezer storage conditions (-20°C).

B.7.6.2. Supervised trials

See previous DAR under point B.7.6.

Number of submitted trials relevant to intended GAP on maize and sweet corn as well as summary of selected residue levels analysed in these trials are presented in Table B.7.6-4.

Table B.7.6-4 Summary of residue results on maize and sweet corn

Zone	Number of trials supporting the GAP	Residues (mg/kg)		STMR	HR	Comments
Enforcement and risk assessment residue definition : prosulfuron						
maize : foliar treatment, 20 g/ha, PHI 90 (grain)						
Northern EU	12	Grain	8x<0.01; 4x<0.02	<0.01	<0.02	Sufficient data are available to support the intended use and derive risk assessment data and a MRL.
Southern EU	7	Grain	4x<0.01; 3x<0.02	<0.01	<0.02	
Sweet corn : foliar treatment, 20 g/ha, PHI 90 (grain)						
Northern EU	11	Grain	11x<0.01	<0.01	<0.01	Sufficient data are available to support the intended use and derive risk assessment data and a MRL.
Southern EU	4	Grain	4x<0.01	<0.01	<0.01	

Remark : an analytical method for enforcement in plant is available with a LOQ of 0.01 mg/kg. Therefore, the proposed MRL from the trials of 0.02*mg/kg in maize and sweet corn has been set at 0.01* mg/kg.

B.7.7. EFFECTS OF INDUSTRIAL PROCESSING AND/OR HOUSEHOLD PREPARATION (ANNEX IIA 6.5, ANNEX IIIA 8.4)

See previous DAR under point B.7.7.

B.7.8. LIVESTOCK FEEDING STUDIES (ANNEX IIA 6.4, ANNEX IIIA 8.3)

See previous DAR under point B.7.8.

B.7.9. RESIDUES IN SUCCEEDING OR ROTATIONAL CROPS (ANNEX IIA 6.6, ANNEX IIIA 8.5)

See previous DAR under point B.7.9.

B.7.10. PROPOSED PRE-HARVEST INTERVALS FOR ENVISAGED USES, OR WITH HOLDING PERIODS, IN THE CASE OF POST-HARVEST USES (ANNEX IIA 6.8, ANNEX IIIA 8.7)

See previous DAR under point B.7.10.

B.7.11. ESTIMATES OF POTENTIAL AND ACTUAL DIETARY EXPOSURE THROUGH DIET AND OTHER MEANS (ANNEX IIA 6.9, ANNEX IIIA 8.8)

Consumer intake calculations have been performed using the UK chronic and acute dietary exposure models and the EFSA PRIMo model.

UK NEDI and NESTI

The UK NEDI and NESTI have been calculated based only on the supported uses of representative formulated product for the evaluation, 'A8714C (PEAK 75 WG)' (DAR, 2014).

The UK NEDIs and NESTIs for the active and commodities listed below have been calculated for ten consumer groups as detailed in the Regulatory Update 21/2005. The following assumptions have been made:

1) For the NESTIs, upper range of normal (97.5th percentile) consumption of each individual crop which may have been treated.
2) For the NEDIs, the 'Rees-Day' approach is taken which sums the two highest 97.5th percentile intakes and the mean intakes for all remaining commodities.
3) All produce eaten which may have been treated has been treated and contains residues at the STMR (NEDI) / HR (NESTI) found in the trials

considered to support GAP, as given below.

4) There is no loss of residue during transport or storage, or processing of foods prior to consumption.

Input values for the UK consumer risk assessment are given in Table 7.11-1**.**

Model outputs for the UK acute and chronic models (version 1.2 and 1.1 respectively) for prosulfuron run by HSE are presented in Tables 7.11-8 and 7.11-4 respectively.

The maximum NEDI for prosulfuron was <1% of the ADI. Chronic intakes for all consumer groups are below the ADI of 0.02 mg/kg bw/day therefore no health effects are expected.

The maximum contribution of a commodity to the ARfD was sweetcorn at 0.4% for the consumer group of toddler. Acute intakes for all consumer groups are below the ARfD of 0.1 mg/kg bw therefore no health effects are expected to arise for the parent compound.

PRIMo

The PRIMo IESTIs and PRIMo IEDIs for prosulfuron and commodities listed below have been calculated using PRIMo v3.1 – Pesticide Residues Intake Model. As the application was received by the RMS after 1st February 2018, PRIMo 3.1 has been used.

A full description of PRIMo and the underlying assumptions is in the document: 'Use of EFSA pesticide residues intake model 'EFSA PRIMo revision 3.1'[6]. Information is also included in the PRIMo model in the tab 'background information'.

Within the context of this assessment for the supported uses of the representative product 'A8714C (PEAK 75 WG)', a PRIMo consumer risk assessment has been undertaken, which includes only UK uses.

[6] European Food Safety Authority (no date) "Pesticide evaluation: Tools," European Food Safety Authority [Preprint]. Available at: https://www.efsa.europa.eu/en/applications/pesticides/tools (Accessed January 2023).

The risk assessment is undertaken using STMR and HRs determined for all plant products based on the supported uses of the representative product 'A8714C (PEAK 75 WG)', which are adequately supported by data (EU RAR 2013 (applicable to GB)).

The following assumptions have been made:

1) All produce eaten which may have been treated, has been treated and contains residues at the MRL as given below.

2) There is no loss of residue during transport or storage, or processing of foods prior to consumption.

Input values for the PRIMo consumer risk assessment are given in Table 7.11-1.

Model outputs for EFSA PRIMO Rev 3.1 for prosulfuron run by HSE are presented in Tables 7.11-2 and 7.11-6.

The maximum IEDI was 0.4% of the ADI. As chronic intakes for all consumer groups are below the ADI of 0.02 mg/kg bw/day therefore no health effects are expected.

The maximum contribution of a commodity to ARfD was sweetcorn at 0.4% for children. Acute intakes for all consumer groups are below the ARfD of 0.1 mg/kg bw therefore no health effects are expected.

Table B.7.11-1 Input values for the consumer risk assessment

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Prosulfuron				
Maize (grain)	0.01	Median residue (RAR, 2014)	0.01	Median residue (RAR, 2014)
Sweetcorn	0.01	Median residue (RAR, 2014)	0.01	Highest residue (RAR, 2014)

B.7.11.1. Chronic risk assessment output

Table B.7.11-2 EFSA model (PRIMo) for chronic risk assessment - rev. 3.1 for prosulfuron

Chronic risk assessment: JMPR methodology (IEDI/TMDI)											
				No of diets exceeding the ADI :	---					Exposure resulting from	
	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	MRLs set at the LOQ (in % of ADI)	commodities not under assessment (in % of ADI)
TMDI/NEDI/IEDI calculation (based on average food consumption)	0.4%	NL toddler	0.07	0.4%	Maize/corn	0.0%	Sweet corn				
	0.1%	GEMS/Food G06	0.01	0.1%	Maize/corn	0.0%	Sweet corn				
	0.1%	UK infant	0.01	0.1%	Maize/corn	0.0%	Sweet corn				
	0.0%	RO general	0.01	0.0%	Maize/corn		FRUIT AND TREE NUTS				
	0.0%	GEMS/Food G10	0.01	0.0%	Maize/corn	0.0%	Sweet corn				
	0.0%	GEMS/Food G15	0.01	0.0%	Maize/corn	0.0%	Sweet corn				
	0.0%	FR child 3 15 yr	0.01	0.0%	Maize/corn	0.0%	Sweet corn				
	0.0%	GEMS/Food G07	0.00	0.0%	Maize/corn	0.0%	Sweet corn				
	0.0%	GEMS/Food G08	0.00	0.0%	Maize/corn	0.0%	Sweet corn				
	0.0%	PT general	0.00	0.0%	Maize/corn		FRUIT AND TREE NUTS				
	0.0%	IE adult	0.00	0.0%	Maize/corn	0.0%	Sweet corn				
	0.0%	NL child	0.00	0.0%	Maize/corn	0.0%	Sweet corn				
	0.0%	ES child	0.00	0.0%	Maize/corn		FRUIT AND TREE NUTS				
	0.0%	DE child	0.00	0.0%	Maize/corn	0.0%	Sweet corn				
	0.0%	GEMS/Food G11	0.00	0.0%	Maize/corn	0.0%	Sweet corn				
	0.0%	FR toddler 2 3 yr	0.00	0.0%	Maize/corn	0.0%	Sweet corn				
	0.0%	NL general	0.00	0.0%	Maize/corn	0.0%	Sweet corn				
	0.0%	DE women 14-50 yr	0.00	0.0%	Maize/corn	0.0%	Sweet corn				
	0.0%	SE general	0.00	0.0%	Sweet corn		FRUIT AND TREE NUTS				
	0.0%	ES adult	0.00	0.0%	Maize/corn		FRUIT AND TREE NUTS				
	0.0%	FR adult	0.00	0.0%	Maize/corn	0.0%	Sweet corn				
	0.0%	UK vegetarian	0.00	0.0%	Sweet corn	0.0%	Maize/corn				
	0.0%	FI 3 yr	0.00	0.0%	Sweet corn	0.0%	Maize/corn				
	0.0%	DE general	0.00	0.0%	Maize/corn	0.0%	Sweet corn				
	0.0%	UK toddler	0.00	0.0%	Sweet corn	0.0%	Maize/corn				
	0.0%	DK child	0.00	0.0%	Sweet corn	0.0%	Maize/corn				
	0.0%	IT toddler	0.00	0.0%	Maize/corn	0.0%	Sweet corn				
	0.0%	FI 6 yr	0.00	0.0%	Maize/corn	0.0%	Sweet corn				
	0.0%	IE child	0.00	0.0%	Sweet corn	0.0%	Maize/corn				
	0.0%	UK adult	0.00	0.0%	Sweet corn	0.0%	Maize/corn				
	0.0%	IT adult	0.00	0.0%	Maize/corn	0.0%	Sweet corn				
	0.0%	FR infant	0.00	0.0%	Maize/corn	0.0%	Sweet corn				
	0.0%	FI adult	0.00	0.0%	Sweet corn	0.0%	Maize/corn				
	0.0%	LT adult	0.00	0.0%	Maize/corn	0.0%	Sweet corn				
	0.0%	PL general	0.00	0.0%	Maize/corn		FRUIT AND TREE NUTS				
	0.0%	DK adult	0.00	0.0%	Sweet corn		FRUIT AND TREE NUTS				
	Conclusion: The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI. The long-term intake of residues of Prosulfuron is unlikely to present a public health concern.										

Table B.7.11-3 EFSA model (PRIMo) for chronic risk assessment - rev. 3.1 for metabolite CGA150829

Chronic risk assessment: JMPR methodology (IEDI/TMDI)											
				No of diets exceeding the ADI :	---					Exposure resulting from	
	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	MRLs set at the LOQ (in % of ADI)	commodities not under assessment (in % of ADI)
TMDI/NEDI/IEDI calculation (based on average food consumption)	3%	NL toddler	0.02	3%	Maize/corn	0.0%	Sweet corn				
	0.5%	GEMS/Food G06	0.00	0.5%	Maize/corn	0.0%	Sweet corn				
	0.4%	UK infant	0.00	0.4%	Maize/corn	0.0%	Sweet corn				
	0.4%	RO general	0.00	0.4%	Maize/corn		FRUIT AND TREE NUTS				
	0.4%	GEMS/Food G10	0.00	0.3%	Maize/corn	0.1%	Sweet corn				
	0.3%	GEMS/Food G15	0.00	0.3%	Maize/corn	0.1%	Sweet corn				
	0.2%	FR child 3 15 yr	0.00	0.2%	Maize/corn	0.0%	Sweet corn				
	0.2%	GEMS/Food G07	0.00	0.1%	Maize/corn	0.1%	Sweet corn				
	0.2%	GEMS/Food G08	0.00	0.2%	Maize/corn	0.0%	Sweet corn				
	0.2%	PT general	0.00	0.2%	Maize/corn		FRUIT AND TREE NUTS				
	0.2%	IE adult	0.00	0.1%	Maize/corn	0.1%	Sweet corn				
	0.1%	NL child	0.00	0.1%	Maize/corn	0.0%	Sweet corn				
	0.1%	ES child	0.00	0.1%	Maize/corn		FRUIT AND TREE NUTS				
	0.1%	DE child	0.00	0.1%	Maize/corn	0.0%	Sweet corn				
	0.1%	GEMS/Food G11	0.00	0.1%	Maize/corn	0.0%	Sweet corn				
	0.0%	FR toddler 2 3 yr	0.00	0.0%	Maize/corn	0.0%	Sweet corn				
	0.0%	NL general	0.00	0.0%	Maize/corn	0.0%	Sweet corn				
	0.0%	DE women 14-50 yr	0.00	0.0%	Maize/corn	0.0%	Sweet corn				
	0.0%	SE general	0.00	0.0%	Sweet corn		FRUIT AND TREE NUTS				
	0.0%	ES adult	0.00	0.0%	Maize/corn		FRUIT AND TREE NUTS				
	0.0%	FR adult	0.00	0.0%	Maize/corn	0.0%	Sweet corn				
	0.0%	UK vegetarian	0.00	0.0%	Sweet corn	0.0%	Maize/corn				
	0.0%	FI 3 yr	0.00	0.0%	Sweet corn	0.0%	Maize/corn				
	0.0%	DE general	0.00	0.0%	Maize/corn	0.0%	Sweet corn				
	0.0%	UK toddler	0.00	0.0%	Sweet corn	0.0%	Maize/corn				
	0.0%	DK child	0.00	0.0%	Sweet corn	0.0%	Maize/corn				
	0.0%	IT toddler	0.00	0.0%	Maize/corn	0.0%	Sweet corn				
	0.0%	FI 6 yr	0.00	0.0%	Maize/corn	0.0%	Sweet corn				
	0.0%	IE child	0.00	0.0%	Sweet corn	0.0%	Maize/corn				
	0.0%	UK adult	0.00	0.0%	Sweet corn	0.0%	Maize/corn				
	0.0%	IT adult	0.00	0.0%	Maize/corn	0.0%	Sweet corn				
	0.0%	FR infant	0.00	0.0%	Maize/corn	0.0%	Sweet corn				
	0.0%	FI adult	0.00	0.0%	Sweet corn	0.0%	Maize/corn				
	0.0%	LT adult	0.00	0.0%	Maize/corn	0.0%	Sweet corn				
	0.0%	PL general	0.00	0.0%	Maize/corn		FRUIT AND TREE NUTS				
	0.0%	DK adult	0.00	0.0%	Sweet corn		FRUIT AND TREE NUTS				
	Conclusion: The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI. The long-term intake of residues of CGA150829 is unlikely to present a public health concern.										

Table B.7.11-4 UK NEDIs for 10 consumer groups (calculated using chronic consumer version 1.1) for prosulfuron

Active substance:	Prosulfuron		ADI:	0.02	mg/kg bw/day		Source:					
			TOTAL INTAKE based on 97.5th percentile									
			ADULT	INFANT	TODDLER	4-6 YEARS	7-10 YEARS	11-14 YEARS	15-18 YEARS	VEGETARIAN	ELDERLY (OWN HOME)	ELDERLY (RESIDENTIAL)
	mg/kg bw/day		0.00001	0.00006	0.000030	0.000016	0.00001	0.00001	0.00001	0.00001	0.00001	0.00000
	% of ADI		<1%	<1%	<1%	<1%	<1%	<1%	<1%	<1%	<1%	<1%
	STMR	P	COMMODITY INTAKES									
Commodity	(mg/kg)		(mg/kg bw/day)									
Sweet corn	0.01		0.00001	0.00001	0.00002	0.00001	0.00001	0.00000	0.00001	0.00001	0.00001	0.00000
Maize	0.01		0.00000	0.00005	0.00001	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000
* 0.00000 corresponds to <0.000005 mg/kg bw/day (any value ≥0.000005 is rounded to 0.00001												
L/C Low consumption (<0.1 g/day) or low number of consumers (<4)												

Table B.7.11-5 UK NEDIs for 10 consumer groups (calculated using chronic consumer version 1.1) for metabolite CGA150829

Active substance:	CGA150829		ADI:	0.0007	mg/kg bw/day		Source:					
			TOTAL INTAKE based on 97.5th percentile									
			ADULT	INFANT	TODDLER	4-6 YEARS	7-10 YEARS	11-14 YEARS	15-18 YEARS	VEGETARIAN	ELDERLY (OWN HOME)	ELDERLY (RESIDENTIAL)
	mg/kg bw/day		0.00000	0.00002	0.000009	0.000005	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000
	% of ADI		<1%	2%	1%	<1%	<1%	<1%	<1%	<1%	<1%	<1%
	STMR	P	COMMODITY INTAKES									
Commodity	(mg/kg)		(mg/kg bw/day)									
Sweet corn	0.003		0.00000	0.00000	0.00001	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000
Maize	0.003		0.00000	0.00001	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000
* 0.00000 corresponds to <0.000005 mg/kg bw/day (any value ≥0.000005 is rounded to 0.00001												
L/C Low consumption (<0.1 g/day) or low number of consumers (<4)												

B.7.11.2. Acute risk assessment output

Table B.7.11-6 EFSA model (PRIMo) for acute risk assessment - rev. 3.1 for prosulfuron

Show results for all crops

Unprocessed commodities

Results for children No. of commodities for which ARfD/ADI is exceeded (IESTI): ---				**Results for adults** No. of commodities for which ARfD/ADI is exceeded (IESTI): ---			
IESTI				**IESTI**			
Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
0.4%	Sweet corn	0 / 0.01	0.43	0.2%	Sweet corn	0 / 0.01	0.16
0.07%	Maize/corn	0 / 0.01	0.07	0.02%	Maize/corn	0 / 0.01	0.02
Expand/collapse list							
Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation)							

Table B.7.11-7 EFSA model (PRIMo) for acute risk assessment - rev. 3.1 for metabolite CGA150829

Show results for all crops

Unprocessed commodities

Results for children No. of commodities for which ARfD/ADI is exceeded (IESTI): ---				**Results for adults** No. of commodities for which ARfD/ADI is exceeded (IESTI): ---			
IESTI				**IESTI**			
Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
19%	Sweet corn	0 / 0	0.13	7%	Sweet corn	0 / 0	0.05
3%	Maize/corn	0 / 0	0.02	0.9%	Maize/corn	0 / 0	0.01
Expand/collapse list							
Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation)							

Table B.7.11-8 UK NESTIs for 10 consumer groups (calculated using acute consumer version 1.2) for prosulfuron

Acute Intakes (97.5th percentiles) **Goto Inputs**

			adult		infant		toddler		4-6 year old child		7-10 year old child	
commodity	HR	P	NESTI	%ARfD	NESTI	%ARfD	NESTI	%ARfD	NESTI	%ARfD	NESTI	%ARfD
Sweet corn	0.01		0.00018	0.2	0.00030	0.3	0.00043	0.4	0.00035	0.4	0.00042	0.4
Maize	0.01		0.00000	0.0	0.00007	0.1	0.00004	0.0	0.00002	0.0	0.00001	0.0

			11-14 year old child		15-18 year old child		vegetarian		Elderly - own home		Elderly - residential	
commodity	HR	P	NESTI	%ARfD	NESTI	%ARfD	NESTI	%ARfD	NESTI	%ARfD	NESTI	%ARfD
Sweet corn	0.01		0.00018	0.2	0.00024	0.2	0.00022	0.2	0.00014	0.1	0.00010	0.1
Maize	0.01		0.00001	0.0	0.00001	0.0	0.00002	0.0	0.00000	0.0	0.00000	0.0

Pesticide	Prosulfuron	
ARfD	0.100	mg/Kg bw/day
Source		

* 0.00000 corresponds to <0.000005 mg/kg bw/day (any value ≥0.000005 is rounded to 0.00001

Table B.7.11-9 UK NESTIs for 10 consumer groups (calculated using acute consumer version 1.2) for metabolite CGA150829

Goto Inputs

Acute Intakes (97.5th percentiles)

			adult		infant		toddler		4-6 year old child		7-10 year old child	
commodity	HR	P	NESTI	%ARfD	NESTI	%ARfD	NESTI	%ARfD	NESTI	%ARfD	NESTI	%ARfD
Sweet corn	0.00		0.00005	7.7	0.00009	12.8	0.00013	18.6	0.00011	15.0	0.00013	18.1
Maize	0.00		0.00000	0.2	0.00002	2.9	0.00001	1.6	0.00000	0.7	0.00000	0.3

			11-14 year old child		15-18 year old child		vegetarian		Elderly - own home		Elderly - residential	
commodity	HR	P	NESTI	%ARfD	NESTI	%ARfD	NESTI	%ARfD	NESTI	%ARfD	NESTI	%ARfD
Sweet corn	0.00		0.00006	7.9	0.00007	10.5	0.00007	9.4	0.00004	6.1	0.00003	4.1
Maize	0.00		0.00000	0.3	0.00000	0.5	0.00001	0.9	0.00000	0.2	0.00000	0.1

Pesticide	CGA150829		
ARfD	0.001	mg/Kg bw/day	
Source			

* 0.00000 corresponds to <0.000005 mg/kg bw/day (any value ≥0.000005 is rounded to 0.00001

B.7.11.3. Drinking water assessment

Individual drinking water assessments for each metabolite are given in Tables 7.11-10 – 14.

TTC chronic exposure - drinking water assessment

Estimated chronic exposure assessments have been undertaken following conclusions from new toxicological data that metabolites CGA150829 and CGA325025 are not genotoxic. Toxicology colleagues recommended the following values to be used in the chronic exposure assessment:

- **CGA150829:** ADI value of 0.0007 mg/kg bw/day
- **CGA159902:** ADI value of 0.0013 mg/kg bw/day
- **CGA349707:** ADI value of 0.001 mg/kg bw/day
- **CGA325025:** Cramer Class III TTC value of 0.0015 mg/kg bw/day
- **SYN547308:** Cramer Class III TTC value of 0.0015 mg/kg bw/day

The above metabolites could be present in groundwater at levels requiring further consideration. Based upon worst case modelling conducted in the assessment for the representative uses, taking account of annual use, the resulting worst case PEC_{gw} estimation indicates that all metabolites above may be present above the trigger value of 0.1 µg/L in groundwater.

None of the metabolites detailed above are included in the plant or animal residue definition for risk assessment. In relation to the drinking water contribution, the highest intake is expected for infants (< 4 months). EFSA Guidance on pesticides in foods for infants and young children estimates the water consumption of bottle-fed infants as 1.135 L/day, equating to 227 ml/kg bw/day (EFSA 2018). Estimated intakes of all metabolites potentially found drinking water for the critical consumer group infants are detailed in the table below.

Metabolite	80th Percentile PECgw (µg/L)	Chronic drinking water exposure (for critical consumer group) mg/kg bw/day [Percentage of ADI/CCIII TTC value]	ADI or CCIII TTC value exceeded?
CGA150829	0.234	0.00005 (infant (EFSA Journal 2018;16(6):5286)) **[7.6%]**	No
CGA159902	0.370	0.00008 (infant (EFSA Journal 2018;16(6):5286)) **[6.5%]**	No
CGA349707	0.962	0.00022 (infant (EFSA Journal 2018;16(6):5286)) **[21.8%]**	No
CGA325025	0.123	0.00003 (infant (EFSA Journal 2018;16(6):5286)) **[1.9%]**	No
SYN547308	0.220	0.00005 (infant (EFSA Journal 2018;16(6):5286)) **[3.3%]**	No

Conclusion

As the estimated intake from drinking water, for each individual metabolite, is ≤ 100 % of the established ADI for CGA150829, CGA159902 and CGA349707; and ≤ 100 % of the TTC CCIII threshold value for CGA325025 and SYN547308, and dietary intakes from other sources is not expected, no further consideration of these metabolites is required. As the estimated intakes for all metabolites from the

representative use of prosulfuron are below the respective ADI/TRV; no harmful effect on human health is expected.

Table B.7.11-10 Drinking water assessment using model V1.1 - CGA150829

Insert level in B7 (µg/l)	0.234	
ADI (mg/kg bw/day)	0.0007	
	Water consumption (litres/kg bw)	
Adult (WHO)	0.033	2 litres 60 kg bw
Child (WHO)	0.100	1 litre 10 kg bw
Infant (WHO)	0.150	0.75 litre 5 kg bw
Infant (EFSA Journal 2018;16(6):5286)	0.227	260 g/kg bw/day formula based on 33 g/kg bw powder and 227 ml/kg bw/day
UK Infant (historic)	0.250	2 litres 8 kg bw
	Results (intake in µg/kg bw/day)	
Adult (WHO)	0.01	
Child (WHO)	0.02	
Infant (WHO)	0.04	
Infant (EFSA Journal 2018;16(6):5286)	0.05	
UK Infant (historic)	0.06	
	Results (intake in mg/kg bw/day)	
Adult (WHO)	0.00001	
Child (WHO)	0.00002	
Infant (WHO)	0.00004	
Infant (EFSA Journal 2018;16(6):5286)	0.00005	
UK Infant (historic)	0.00006	
	Results (%ADI)	
Adult (WHO)	1.1	
Child (WHO)	3.3	
Infant (WHO)	5.0	
Infant (EFSA Journal 2018;16(6):5286)	7.6	
UK Infant (historic)	8.4	

Table B.7.11-11 Drinking water assessment using model V1.1 – CGA159902

Insert level in B7 (µg/l)	0.37	
ADI (mg/kg bw/day)	0.0013	
	Water consumption (litres/kg bw)	
Adult (WHO)	0.033	2 litres 60 kg bw
Child (WHO)	0.100	1 litre 10 kg bw
Infant (WHO)	0.150	0.75 litre 5 kg bw
Infant (EFSA Journal 2018;16(6):5286)	0.227	260 g/kg bw/day formula based on 33 g/kg bw powder and 227 ml/kg bw/day
UK Infant (historic)	0.250	2 litres 8 kg bw
	Results (intake in µg/kg bw/day)	
Adult (WHO)	0.01	
Child (WHO)	0.04	
Infant (WHO)	0.06	
Infant (EFSA Journal 2018;16(6):5286)	0.08	
UK Infant (historic)	0.09	
	Results (intake in mg/kg bw/day)	
Adult (WHO)	0.00001	
Child (WHO)	0.00004	
Infant (WHO)	0.00006	
Infant (EFSA Journal 2018;16(6):5286)	0.00008	
UK Infant (historic)	0.00009	
	Results (%ADI)	
Adult (WHO)	0.9	
Child (WHO)	2.8	
Infant (WHO)	4.3	
Infant (EFSA Journal 2018;16(6):5286)	6.5	
UK Infant (historic)	7.1	

Table B.7.11-12 Drinking water assessment using model V1.1 - CGA349707

Insert level in B7 (µg/l)	0.962	
ADI (mg/kg bw/day)	0.001	
	Water consumption (litres/kg bw)	
Adult (WHO)	0.033	2 litres 60 kg bw
Child (WHO)	0.100	1 litre 10 kg bw
Infant (WHO)	0.150	0.75 litre 5 kg bw
Infant (EFSA Journal 2018;16(6):5286)	0.227	260 g/kg bw/day formula based on 33 g/kg bw powder and 227 ml/kg bw/day
UK Infant (historic)	0.250	2 litres 8 kg bw
	Results (intake in µg/kg bw/day)	
Adult (WHO)	0.03	
Child (WHO)	0.10	
Infant (WHO)	0.14	
Infant (EFSA Journal 2018;16(6):5286)	0.22	
UK Infant (historic)	0.24	
	Results (intake in mg/kg bw/day)	
Adult (WHO)	0.00003	
Child (WHO)	0.00010	
Infant (WHO)	0.00014	
Infant (EFSA Journal 2018;16(6):5286)	0.00022	
UK Infant (historic)	0.00024	
	Results (%ADI)	
Adult (WHO)	3.2	
Child (WHO)	9.6	
Infant (WHO)	14.4	
Infant (EFSA Journal 2018;16(6):5286)	21.8	
UK Infant (historic)	24.1	

Table B.7.11-13 Drinking water assessment using model V1.1 - CGA325025

Insert level in B7 (µg/l)	0.123	
ADI (mg/kg bw/day)	0.0015	
	Water consumption (litres/kg bw)	
Adult (WHO)	0.033	2 litres 60 kg bw
Child (WHO)	0.100	1 litre 10 kg bw
Infant (WHO)	0.150	0.75 litre 5 kg bw
Infant (EFSA Journal 2018;16(6):5286)	0.227	260 g/kg bw/day formula based on 33 g/kg bw powder and 227 ml/kg bw/day
UK Infant (historic)	0.250	2 litres 8 kg bw
	Results (intake in µg/kg bw/day)	
Adult (WHO)	0.00	
Child (WHO)	0.01	
Infant (WHO)	0.02	
Infant (EFSA Journal 2018;16(6):5286)	0.03	
UK Infant (historic)	0.03	
	Results (intake in mg/kg bw/day)	
Adult (WHO)	0.00000	
Child (WHO)	0.00001	
Infant (WHO)	0.00002	
Infant (EFSA Journal 2018;16(6):5286)	0.00003	
UK Infant (historic)	0.00003	
	Results (%ADI)	
Adult (WHO)	0.3	
Child (WHO)	0.8	
Infant (WHO)	1.2	
Infant (EFSA Journal 2018;16(6):5286)	1.9	
UK Infant (historic)	2.1	

Table B.7.11-14 Drinking water assessment using model V1.1 - SYN547308

Insert level in B7 (µg/l)	0.22	
ADI (mg/kg bw/day)	0.0015	
	Water consumption (litres/kg bw)	
Adult (WHO)	0.033	2 litres 60 kg bw
Child (WHO)	0.100	1 litre 10 kg bw
Infant (WHO)	0.150	0.75 litre 5 kg bw
Infant (EFSA Journal 2018;16(6):5286)	0.227	260 g/kg bw/day formula based on 33 g/kg bw powder and 227 ml/kg bw/day
UK Infant (historic)	0.250	2 litres 8 kg bw
	Results (intake in µg/kg bw/day)	
Adult (WHO)	0.01	
Child (WHO)	0.02	
Infant (WHO)	0.03	
Infant (EFSA Journal 2018;16(6):5286)	0.05	
UK Infant (historic)	0.06	
	Results (intake in mg/kg bw/day)	
Adult (WHO)	0.00001	
Child (WHO)	0.00002	
Infant (WHO)	0.00003	
Infant (EFSA Journal 2018;16(6):5286)	0.00005	
UK Infant (historic)	0.00006	
	Results (%ADI)	
Adult (WHO)	0.5	
Child (WHO)	1.5	
Infant (WHO)	2.2	
Infant (EFSA Journal 2018;16(6):5286)	3.3	
UK Infant (historic)	3.7	

B.7.11.4. Combined chronic risk from diet and drinking water

All individual contributions of the metabolites CGA150829, CGA159902, CGA349707, CGA325025 and SYN547308 to their respective ADIs/TRVs from drinking water are ≤ 100 %. The maximum NEDI for prosulfuron was <1% of the ADI and the maximum IEDI was 0.4% of the ADI from dietary intakes (maize and sweetcorn).

As a first step, combined exposure, assuming combined toxicity, has been considered. The combined chronic risk from exposure to prosulfuron, CGA150829, CGA159902, CGA349707, CGA325025 and SYN547308 through either diet or drinking water is <42.1% of the respective ADIs/TRVs.

As the combined estimated intakes of prosulfuron and all metabolites from the representative uses of prosulfuron are below the respective ADI/TRV; no harmful effect on human health is expected.

B.7.12. SUMMARY AND EVALUATION OF RESIDUE BEHAVIOUR (ANNEX IIA 6.10, ANNEX IIIA 8.9)

B.7.12.1. Metabolism, distribution and expression of residues in plants

See previous RAR.

B.7.12.2. Metabolism, distribution and expression of residues in livestock

See previous RAR.

B.7.12.3. Definition of the residue

See previous RAR.

B.7.12.4. Residues resulting from supervised trials

See previous RAR.

B.7.12.5. Storage stability

See previous RAR.

B.7.12.6. Effects of industrial processing and/or household preparation

See previous RAR.

B.7.12.7. Livestock feeding studies

See previous RAR.

B.7.12.8. Residues in succeeding or rotational crops

See previous RAR.

B.7.12.9. Proposed EU MRLs

See previous RAR.

B.7.13. REFERENCES RELIED ON

Annex point	Author	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or Unpublished	Data protection claimed Y/N	Owner
IIA 6.1.1/01	[redacted]	1994	**Title :** Storage stability of in field-incurred residues of CGA-152005 in corn (whole plant) under freezer storage conditions. **Source :** Ciba-Geigy Corporation, Ciba Crop Protection, Greensboro, NC, USA. **Company :** Syngenta **Report N°:** ABR-94046 **GLP compliance :** Yes **Unpublished**	Y	SYN
IIA 6.1.1/02	[redacted]	1994	**Title :** Stability of CGA-152005 fortified into corn substrates under freezer storage conditions. **Source :** Ciba-Geigy Corporation, Ciba Crop Protection, Greensboro, NC, USA. **Company :** Syngenta **Report N°:** ABR-94051 **GLP compliance :** Yes **Unpublished**	Y	SYN
IIA 6.1.1/03	[redacted]	1997	**Title :** Stability of CGA-152005 fortified into meat, milk and eggs under freezer storage conditions. **Source :** Ciba-Geigy Corporation, Ciba Crop Protection, Greensboro, NC, USA. **Company :** Syngenta **Report N°:** ABR-97044 **GLP compliance :** Yes **Unpublished**	Y	SYN
IIA 6.2.2/01	[redacted]	1994	**Title :** Metabolism of [Triazine-^{14}C]CGA-152005 in the Chicken-Addendum 1. **Source :** [redacted]. **Company :** Syngenta **Report N°:** [redacted] **GLP compliance :** Yes **Unpublished**	Y	SYN