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.8 (AS)

Environmental Fate & Behaviour

GB Article 7 amendment application

Great Britain

September 2023

Version History

When	What
September 2023	HSE Initial Assessment

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B.8. ENVIRONMENTAL FATE AND BEHAVIOUR

This evaluation represents an assessment of new information submitted under the retained Regulation (EC) No 1107/2009 as part of an Article 7 amendment to the conditions of approval of prosulfuron in GB to remove the following restriction:-

> *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 Rapporteur Member State (RMS) and was re-approved as a candidate for substitution on 01 May 2017. The implementing Regulation (EU) 2017/375[1] contains the above restriction. 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 within implementing Regulation (EU)

[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.

2021/574[4]. However the amended implementing Regulation was not published until 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.

In order to remove the restriction the applicant submitted new field dissipation studies conducted with prosulfuron in order to revise the groundwater modelling DT_{50}. In addition new laboratory soil degradation and sorption data were provided on the metabolite SYN 547308 to revise groundwater modelling DT_{50}, K_{foc} and 1/n values.

Only new submitted studies have been summarised in this document and reference is made to the original RAR (2014), which is still considered valid, in cases no new data have been submitted.

B.8.1. FATE AND BEHAVIOUR IN SOIL

SUMMARY OF USES AND PROPERTIES

Table B. 8-1: Proposed maximum use of prosulfuron within the European Union

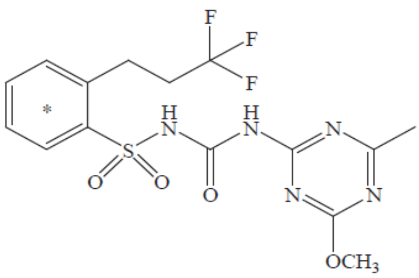
Crop and/or situation	Group of pests controlled	Formulation	Application			Application rate per treatment	
			Method	Growth stage	Number	Water L/ha	kg a.s./ha
Maize/sweetcorn	Broad leaved weeds	PEAK 75 WG	Broadcast foliar application	BBCH 12 to 18 corresponding to 2 to 8	1	80-400	0.020

[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).

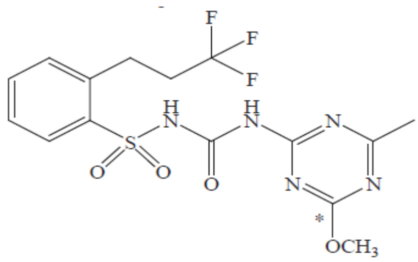
Crop and/or situation	Group of pests controlled	Formulation	Application			Application rate per treatment	
			Method	Growth stage	Number	Water L/ha	kg a.s./ha
				leaves of maize			

Substance name description

The fate and behaviour in soils of prosulfuron (used as a herbicide) were investigated using [phenyl-^{14}C]- and [triazine-^{14}C]- prosulfuron.



[phenyl-^{14}C]- prosulfuron

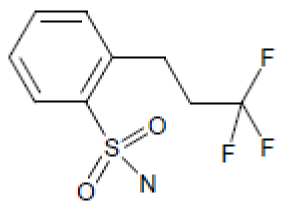


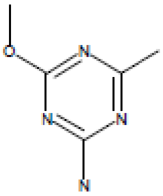
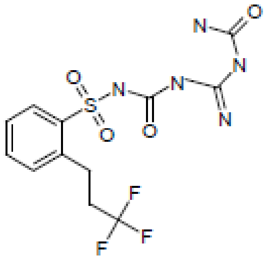
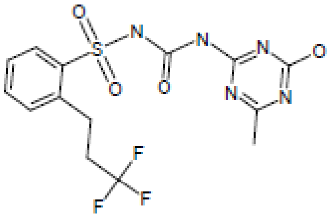
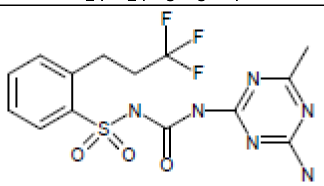
[triazine-^{14}C]- prosulfuron

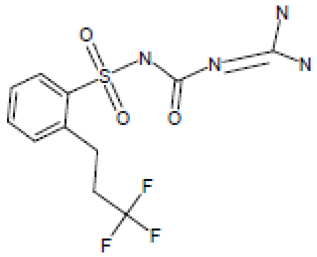
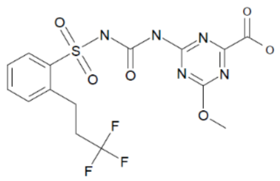
* indicates label position

The code used throughout this document, IUPAC name and synonyms, and chemical structure of prosulfuron metabolites, which have been identified in environmental compartments are summarised in Table B8-2.

Table B. 8-2: Prosulfuron identified metabolites and degradation products

Code	Structure	IUPAC name	Compound found in (report reference)
CGA159902	 Molecular Mass: 253.2 g/mol Empirical Formula: $C_9H_{10}NO_2S$	2-(3,3,3-Trifluoropropyl)-benzenesulfonamide	

Code	Structure	IUPAC name	Compound found in (report reference)
CGA150829 IN-A4098AE F059411	 Molecular Mass: 140.1 g/mol Empirical Formula: $C_5H_8N_4O$	4-methoxy-6-methyl-[1,3,5]triazine-2-ylamine	
SYN542604	 Molecular Mass: 381.3 g/mol Empirical Formula: $C_{12}H_{14}F_3N_5O_4S$	[(N-aminocarbonyl]amino]imino)methyl)amino carbonyl-2-(3,3,3-trifluoropropyl)benzenesulfonamide	
CGA300406	 Molecular Mass: 405.4 g/mol Empirical Formula: $C_{14}H_{14}F_3N_5O_4S$	N-[[(1,4-dihydro-6-methyl-4-oxo-1,3,5-triazin-2-yl)amino]carbonyl]-2-(3,3,3-trifluorpropyl)-benzenesulfonamide	
CGA325025	 Molecular Mass: 404.4 g/mol Empirical Formula: $C_{14}H_{15}F_3N_6O_3S$	N-[[(4-amino-6-methyl-1,3,5-triazin-2-yl)amino]carbonyl]-2-(3,3,3-trifluoropropyl)-benzenesulfonamide	

Code	Structure	IUPAC name	Compound found in (report reference)
CGA349707	 Molecular Mass: 338.3 g/mol Empirical Formula: $C_{11}H_{13}F_3N_4O_3S$	N-Guanidinocarbonyl-2-(3,3,3-trifluor-propyl)-benzenesulfonamide	
SYN547308	 Molecular Mass: 449.4 g/mol Empirical Formula: $C_{15}H_{14}F_3N_5O_6S$	4-methoxy-6-((((2-(3, 3, 3-trifluoropropyl) phenyl) sulfonyl) carbamoyl) amino) -1, 3, 5-triazine-2-carboxylic acid	

B.8.1.1. Laboratory route and rate of degradation in soil

During the aerobic soil degradation studies conducted with prosulfuron, two unknown soil metabolites M17 and M18 were detected, which would trigger a risk assessment for groundwater contamination according to SANCO/221/2000. In the original [redacted] (2011) study, metabolite M17 reached 6.1% of the applied radioactivity (on day 120; study end) in the 18 Acres soil after application of phenyl-labelled prosulfuron. In the [redacted] (2011a) study, metabolite M18 accounted for 9.9% of the applied radioactivity (on day 120; study end) in the Vétroz soil treated with triazine-labelled prosulfuron. After several attempts, the Notifier has been able to identify M18 (designated as SYN547308).

Despite additional analytical work performed by the applicant, identification of M17 has not been possible and therefore no information of its properties or concentrations in the environment is available. HSE accepts the position of the applicant that identification of M17 is not technically feasible as mentioned in SANCO/221/2000 and therefore no further work is necessary.

A new laboratory soil degradation study and separate kinetic modelling report has been provided for the metabolite SYN547308 ([redacted], 2014/study and [redacted], 2014/kinetics). The study summary prepared by the applicant is presented below.

Reference:	KIIA 7.2.3 / 11
Report Title:	Prosulfuron – Rate of Degradation of [^{14}C]-SYN547308. Final Report.
Author(s) & Year:	[redacted]; 2014
Document No, Authority registration No	3200460
Guideline(s):	Yes OECD (307); EPA OPPTS 835.4100
Deviations:	None
GLP or GEP:	Yes
Acceptability:	Yes
Study relied upon:	Yes

Materials and methods:

The rate of degradation of [^{14}C]-SYN547308 (specific activity 2.209 MBq/mg; radiochemical purity prior to definitive test 98.58%), a metabolite of prosulfuron, was investigated in three different soils. The soils had not been treated with pesticides in last five years. Soil characteristics are presented in Table B.8-79.

The freshly collected soils from the top 2 to 20 cm layer were passed through 2 mm sieve prior to use. SYN547308 was applied at a rate of 0.027 mg/kg dry weight soil, equivalent to a single field application rate of 20 g ai/ha (assuming an incorporation depth of 5 cm and a bulk density of 1.5g/cm^3). The soils were incubated under aerobic conditions in the laboratory and maintained at soil moisture of pF2 and dark conditions at 20 ± 2°C for up to 120 days.

For each soil, duplicate samples (100 g dry weight) were taken for analysis up to 120 days after treatment (DAT). At each sampling time, samples were extracted once with acetonitrile, twice with acetonitrile:water (1:1, v/v) and twice with acetonitrile:0.1%

ammonium hydroxide in water (1:1, v/v)). Amount of radioactivity recovered in each extract type was quantified by LSC. All extracts were combined and concentrated prior to analysis by HPLC. Selected samples were analysed by thin layer chromatography (TLC). Any volatile radioactivity was continuously flushed from the vessels and collected in NaOH traps. A mass balance was determined for each sample.

Table B. 8-3: Characteristics of the soils

	Vétroz (Switzerland)	**18 Acres (UK)**	**Krone (Switzerland)**
Soil type (USDA)	Loam	Sandy clay loam	Silt loam
% clay (<0.002 mm)	23	25	16
% silt (0.002-0.05 mm)	44	24	65
% sand (>0.05 mm)	33	51	19
% organic C	2.3	3.0	1.3
pH ($CaCl_2$) (H_2O)	 7.7 8.3	 5.8 6.5	 5.0 6.0
Cation exchange capacity (meq/100g soil)	10.8	18.9	16.6
Microbial biomass (µg org. C/g soil) Start of incubation End of incubation	534.3 658.2	598.1 465.6	335.3 251.3
Moisture at pF2	26.4	29.8	23.7

Findings:

The mean mass balance from all soils was 98.1% (range 91.2 to 103.6%). The amount of extractable radioactivity in all three soils decreased with time from 85.0% to 97.0% at 0 DAT to 29.4 to 68.6% by 120 DAT. Carbon dioxide levels remained low throughout the incubation, reaching a maximum of < 1% by 120 DAT. Unextracted residues increased steadily throughout the incubation, reaching a maximum of 30.5% and 64.5% of AR at the end of the incubation for Vetroz and 18 Acres soils, respectively. For Krone soil, the unextracted residues reached a maximum of 59.2% at 30 DAT before decreasing to 53.4% at 120 DAT. The amount of SYN547308 extracted from the soil decreased over time.

Table B. 8-4: Distribution and recovery of radioactivity: Vetroz soil

[14C]-SYN547308	Replicate	Percent of Applied Radioactivity by Incubation Time (days) 0	3	6	13	30	59	120
Extract 1 (non-harsh)	A	47.3	39.7	40.5	39.0	34.3	32.1	25.9
	B	47.6	40.9	39.7	38.8	34.6	30.2	27.7
	Mean	**47.5**	**40.3**	**40.1**	**38.9**	**34.5**	**31.2**	**26.8**
Extract 2 (non-harsh)	A	42.7	41.9	40.0	38.9	37.0	33.5	32.1
	B	43.2	42.7	40.8	38.3	39.9	34.8	31.8
	Mean	**43.0**	**42.3**	**40.4**	**38.6**	**38.5**	**34.2**	**32.0**
Extract 3 (non-harsh)	A	6.5	9.2	10.6	10.8	10.6	10.2	9.8
	B	6.7	9.7	9.8	10.6	9.8	10.0	9.8
	Mean	**6.6**	**9.5**	**10.2**	**10.7**	**10.2**	**10.1**	**9.8**
Total Extractables (non-harsh)	**Mean**	**97.0**	**92.1**	**90.7**	**88.2**	**83.1**	**75.4**	**68.6**
Unextracted	A	ND	6.3	7.1	13.9	16.7	23.5	30.8
	B	ND	6.8	8.7	13.2	15.6	19.6	30.1
	Mean	**ND**	**6.6**	**7.9**	**13.6**	**16.2**	**21.6**	**30.5**
Alkaline Traps (as $^{14}CO_2$)	A	NA	ND	0.3	0.4	0.6	0.9	1.1
	B	NA	ND	0.3	0.4	0.5	0.7	0.7
	Mean	**NA**	**ND**	**0.3**	**0.4**	**0.6**	**0.8**	**0.9**
Total % recovery	A	96.5	97.1	98.5	103.0	99.2	100.2	99.7
	B	97.5	100.1	99.3	101.3	100.4	95.3	100.1
	Mean	**97.0**	**98.6**	**98.9**	**102.2**	**99.8**	**97.8**	**99.9**
Overall Mean ± SD		**99.2 ± 1.7**						

NA = not applicable
ND = not detected (or < 0.1% AR)
Note: %AR values reported above for extracts are prior to concentrating samples for chromatographic analyses. Procedural recoveries for all concentrated Vetroz samples were ≥ 95% of their initial sample radioactivity.

Table B. 8-5: Distribution and recovery of radioactivity: 18 Acres soil

[14C]-SYN547308	Replicate	Percent of Applied Radioactivity by Incubation Time (days) 0	3	6	13	30	59	120
Extract 1 (non-harsh)	A	37.8	29.3	26.1	18.3	11.5	9.5	12.0
	B	36.2	28.1	25.0	14.3	11.4	8.9	11.3
	Mean	**37.0**	**28.7**	**25.6**	**16.3**	**11.5**	**9.2**	**11.7**
Extract 2 (non-harsh)	A	47.0	41.3	35.3	29.1	20.9	14.0	12.5
	B	45.7	40.8	34.3	31.0	20.1	14.4	12.2
	Mean	**46.4**	**41.1**	**34.8**	**30.1**	**20.5**	**14.2**	**12.4**
Extract 3 (non-harsh)	A	9.5	9.9	13.9	15.0	10.3	7.4	5.4
	B	8.9	10.3	14.3	13.8	9.3	6.7	5.3
	Mean	**9.2**	**10.1**	**14.1**	**14.4**	**9.8**	**7.1**	**5.4**
Total Extractables (non-harsh)	**Mean**	**92.6**	**79.9**	**74.5**	**60.8**	**41.8**	**30.5**	**29.4**
Unextracted	A	4.3	20.5	22.6	35.8	58.1	63.9	64.9
	B	5.6	19.3	25.5	39.7	54.1	60.9	64.1
	Mean	**5.0**	**19.9**	**24.1**	**37.8**	**56.1**	**62.4**	**64.5**
Alkaline Traps (as $^{14}CO_2$)	A	NA	ND	0.2	0.3	0.4	0.4	0.3
	B	NA	ND	0.2	0.3	0.3	0.3	0.4
	Mean	**NA**	**ND**	**0.2**	**0.3**	**0.4**	**0.4**	**0.4**
Total % recovery	A	98.6	101.0	98.1	98.5	101.2	95.2	95.1
	B	96.4	98.5	99.3	99.1	95.2	91.2	93.3
	Mean	**97.5**	**99.8**	**98.7**	**98.8**	**98.2**	**93.2**	**94.2**
Overall Mean ± SD		**97.2 ± 2.5**						

NA = not applicable
ND = not detected (or < 0.1% AR)
Note: %AR values reported above for extracts are prior to concentrating samples for chromatographic analyses. Procedural recoveries for all concentrated 18 Acres samples were ≥ 93% of their initial sample radioactivity.

Table B. 8-6: Distribution and recovery of radioactivity: Krone soil

[^{14}C]-SYN547308	Replicate	Percent of Applied Radioactivity by Incubation Time (days)						
		0	3	6	13	30	59	120
Extract 1 (non-harsh)	A	27.5	22.7	16.1	11.8	10.5	14.2	21.7
	B	28.8	19.6	15.8	12.5	11.3	14.4	21.1
	Mean	**28.2**	**21.2**	**16.0**	**12.2**	**10.9**	**14.3**	**21.4**
Extract 2 (non-harsh)	A	41.2	38.0	26.5	17.8	18.0	15.0	16.6
	B	41.1	37.1	25.9	20.2	16.8	15.4	18.1
	Mean	**41.2**	**37.6**	**26.2**	**19.0**	**17.4**	**15.2**	**17.4**
Extract 3 (non-harsh)	A	15.5	15.4	15.8	16.3	11.2	7.7	5.9
	B	15.9	15.8	15.7	13.8	10.2	7.7	6.3
	Mean	**15.7**	**15.6**	**15.8**	**15.1**	**10.7**	**7.7**	**6.1**
Total Extractables (non-harsh)	**Mean**	**85.0**	**74.3**	**57.9**	**46.2**	**39.0**	**37.2**	**44.9**
Unextracted	A	17.3	27.5	35.7	50.6	59.9	56.6	52.6
	B	14.3	26.2	37.5	48.6	58.5	59.3	54.1
	Mean	**15.8**	**26.9**	**36.6**	**49.6**	**59.2**	**58.0**	**53.4**
Alkaline Traps (as $^{14}CO_2$)	A	NA	ND	ND	0.3	0.3	0.4	0.4
	B	NA	ND	0.2	0.3	0.4	0.5	0.7
	Mean	**NA**	**ND**	**0.1**	**0.3**	**0.4**	**0.5**	**0.6**
Total % recovery	A	101.5	103.6	94.1	96.8	99.9	93.9	97.2
	B	100.1	98.7	95.1	95.4	97.2	97.3	100.3
	Mean	**100.8**	**101.2**	**94.6**	**96.1**	**98.6**	**95.6**	**98.8**
Overall Mean ± SD		**97.9 ± 2.6**						

NA = not applicable
ND = not detected (or < 0.1% AR)
Note: %AR values reported above for extracts are prior to concentrating samples for chromatographic analyses. Procedural recoveries for all concentrated Krone samples were ≥ 90% of their initial sample radioactivity.

Table B. 8-7: Characterisation / identification of radioactive residues in soil extracts: Vetroz soil

[^{14}C]-Residues Soil: Vetroz	Replicate	Percent of Applied Radioactivity by Incubation Time (days)						
		0	3	6	13	30	59	120
Parent (SYN547308)	A	95.5	87.0	88.4	82.8	76.3	68.5	56.8
	B	96.4	89.5	86.3	83.0	78.3	68.2	58.8
	Mean	**95.9**	**88.2**	**87.4**	**82.9**	**77.3**	**68.4**	**57.8**
Unidentified Product(s) (if any)	A	1.0	2.2	2.2	4.2	4.0	7.0	10.7
	B	0.9	2.2	2.8	3.6	5.1	6.3	9.9
	Mean	**0.9**	**2.2**	**2.5**	**3.9**	**4.6**	**6.6**	**10.3**
Unresolved Background	A	0.0	1.6	0.5	1.7	1.6	0.3	0.3
	B	0.3	1.6	1.2	1.1	0.9	0.5	0.6
	Mean	**0.1**	**1.6**	**0.8**	**1.4**	**1.3**	**0.4**	**0.4**
Total Extractables	A	96.5	90.8	91.1	88.7	81.9	75.8	67.8
	B	97.5	93.3	90.3	87.7	84.3	75.0	69.3
	Mean	**97.0**	**92.1**	**90.7**	**88.2**	**83.1**	**75.4**	**68.6**
CO_2	A	NA	ND	0.3	0.4	0.6	0.9	1.1
	B	NA	ND	0.3	0.4	0.5	0.7	0.7
	Mean	**NA**	**ND**	**0.3**	**0.4**	**0.6**	**0.8**	**0.9**

NA = not applicable
ND = not detected (or < 0.1%AR)

Table B. 8-8: Characterisation / identification of radioactive residues in soil extracts: 18 Acres soil

[14C]-Residues Soil: 18 Acres	Replicate	Percent of Applied Radioactivity by Incubation Time (days)						
		0	3	6	13	30	59	120
Parent (SYN547308)	A	92.5	76.0	72.1	58.3	35.3	18.1	9.1
	B	86.0	75.9	70.3	54.4	33.2	18.3	9.1
	Mean	**89.3**	**75.9**	**71.2**	**56.4**	**34.2**	**18.2**	**9.1**
Unidentified Product(s) (if any)	A	0.4	3.4	2.3	3.2	7.3	12.4	20.7
	B	3.8	2.2	2.1	3.6	7.1	11.3	19.6
	Mean	**2.1**	**2.8**	**2.2**	**3.4**	**7.2**	**11.8**	**20.1**
Unresolved Background	A	1.3	1.1	0.9	0.9	0.1	0.5	0.1
	B	1.0	1.1	1.2	1.1	0.5	0.4	0.1
	Mean	**1.2**	**1.1**	**1.1**	**1.0**	**0.3**	**0.4**	**0.1**
Total Extractables	A	94.3	80.5	75.3	62.4	42.7	30.9	29.9
	B	90.8	79.2	73.6	59.1	40.8	30.0	28.8
	Mean	**92.6**	**79.9**	**74.4**	**60.7**	**41.8**	**30.5**	**29.3**
CO_2	A	NA	ND	0.2	0.3	0.4	0.4	0.3
	B	NA	ND	0.2	0.3	0.3	0.3	0.4
	Mean	**NA**	**ND**	**0.2**	**0.3**	**0.4**	**0.4**	**0.4**

NA = not applicable
ND = not detected (or < 0.1%AR)

Table B. 8-9: Characterisation / identification of radioactive residues in soil extracts: Krone soil

[14C]-Residues Soil: Krone	Replicate	Percent of Applied Radioactivity by Incubation Time (days)						
		0	3	6	13	30	59	120
Parent (SYN547308)	A	81.9	71.6	53.8	40.6	27.7	14.8	9.5
	B	80.7	67.5	54.0	39.3	26.6	15.3	9.8
	Mean	**81.3**	**69.5**	**53.9**	**40.0**	**27.1**	**15.0**	**9.6**
Unidentified Product(s) (if any)	A	1.6	3.1	3.5	4.6	11.5	22.1	34.4
	B	4.5	3.7	2.8	6.6	11.3	22.1	35.4
	Mean	**3.1**	**3.4**	**3.1**	**5.6**	**11.4**	**22.1**	**34.9**
Unresolved Background	A	0.8	1.4	1.2	0.7	0.5	0.0	0.4
	B	0.5	1.4	0.6	0.6	0.4	0.1	0.3
	Mean	**0.6**	**1.4**	**0.9**	**0.6**	**0.5**	**0.1**	**0.3**
Total Extractables	A	84.2	76.1	58.4	45.9	39.7	36.9	44.2
	B	85.8	72.5	57.4	46.5	38.3	37.5	45.5
	Mean	**85.0**	**74.3**	**57.9**	**46.2**	**39.0**	**37.2**	**44.9**
CO_2	A	NA	ND	ND	0.3	0.3	0.4	0.4
	B	NA	ND	0.2	0.3	0.4	0.5	0.7
	Mean	**NA**	**ND**	**0.1**	**0.3**	**0.4**	**0.5**	**0.6**

NA = not applicable
ND = not detected (or < 0.1%AR)

Conclusion of the Applicant:

The rate of degradation of [^{14}C]-SYN547308 was investigated in Vetroz, 18 Acres and Krone soils under aerobic conditions. In all soils, carbon dioxide levels remained low (< 1%), whilst unextracted residues increased steadily to a maximum of 64.5% AR.

In 18 Acres and Krone soils, the degradation of SYN547308 was constant with < 10% AR remaining by 120 DAT. In more alkaline Vetroz soil, the degradation was comparatively slower with 57.8% AR remaining at 120 DAT. No other soil parameter appeared to significantly impact the degradation rate.

Conclusion of HSE:

HSE has reviewed the study report and confirmed that the summary represents an accurate record of the experimental work of [redacted], 2014. Minor additional points are noted below.

Table B.8-79 provides details of soil characteristics. HSE confirmed that microbial biomass represented more than 1% organic carbon at both the start and end of the study, demonstrating that soils are likely to have remained microbially viable throughout.

A consideration of possible pH effects on degradation and sorption of metabolite SYN547308 is provided by HSE after the evaluation of the new soil sorption study on this same metabolite (see Section B.8.22).

HSE notes that as the study of [redacted] (2014) is a metabolite dosed rate of degradation study, there is no formal requirement to provide information on formation of metabolites from SYN547308. However, this would have been technically feasible and it could have provided useful further information of the metabolism profile, and ultimately led to the identification of additional metabolites that would trigger inclusion in the exposure assessment. The highest amount of unidentified extractable radioactivity was observed in the 120 d sample from the Krone soil (average of 34.9% AR). Reference to the example chromatograms in the original study report for this sample point suggests that although the total amount of unidentified radioactivity was comprised of 6 separate peaks, one major peak represented 27.9% AR (information available from a single replicate sample only). However, in prosulfuron dosed studies metabolite SYN547308 itself was only observed at a peak of 9.9%. Therefore relating the peak of unidentified material formed from SYN547308 in this study back to levels relative to applied parent prosulfuron would suggest that this peak would not exceed 5% AR relative to parent prosulfuron. It would therefore be unlikely to breach triggers requiring further assessment and HSE is content that no further information is required.

Reference:	KIIA 7.2.3 / 11
Report Title:	Prosulfuron – Laboratory Degradation Kinetics for Modelling Endpoints for the soil metabolite SYN547308. Final Report.
Author(s) & Year:	[redacted]; 2014
Document No, Authority registration No	RAJ1065B
Guideline(s):	Yes FOCUS Kinetics Guidance (2006)
Deviations:	None
GLP or GEP:	No (not applicable modelling study)
Acceptability:	Yes
Study relied upon:	Yes

Materials and methods:

The results of laboratory soil degradation study ([redacted], 2014) on three different soils was used to calculate the rates of degradation of prosulfuron metabolite SYN547308 for use as modelling endpoints according to FOCUS Degradation Kinetics guidance document. The study [redacted] (2014) is summarised above and detections of SYN547308 are presented in Tables B.8-83 to B.8-85. Kinetic modelling was carried out using CAKE v2.0 (2013).

The M0 values for each soil were set to the total recovered amount multiplied by the radiochemical purity. In the first instance, the data was directly fitted un-weighted with the complete data set and unconstrained initial concentration (M0) for parent.

Table B. 8-10: Correction of M0 residue values

Study	Soil	Recovered M0 (%AR)	Purity (%)	Corrected M0 (%AR)
Gilbert 2014	Vetroz	96.5 / 97.5	98.58	95.1 / 96.1
Gilbert 2014	18 Acres	98.6 / 96.4	98.58	97.2 / 95.0
Gilbert 2014	Krone	101.5 / 100.1	98.58	100.1 / 98.7

Confidence in the resulting parameters has been assessed visually and from the confidence intervals for the α and β parameters of the first order multi compartment (FOMC) model or probability values for a t-test of the rate parameters for the single first order (SFO), dual first order in parallel (DFOP) and hockey stick (HS) models. Where the parameters for a particular model are not significantly different from zero at the 95^{th} or 90^{th} significance level, it has been concluded that the model is not appropriate to represent the degradation behaviour of SYN547308 in that soil. The $\chi 2$ error% parameter has been used to determine goodness of fit and where two models are an appropriate to fit the data, the choice of best fit has been based on the lowest value of this parameter.

As the study was conducted at 20ºC and moisture adjusted to 10 kPa, no normalisation of $DegT_{50}$ values was required.

Findings:

The fits were conducted using SFO, FOMC and DFOP kinetics and are summarised in Table B.8-87.

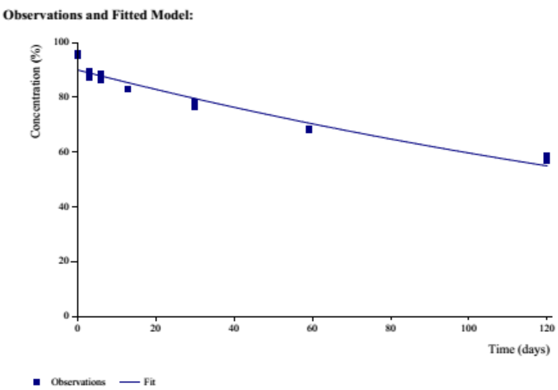
Table B. 8-11: Summary of the results of kinetic fitting of SYN547308

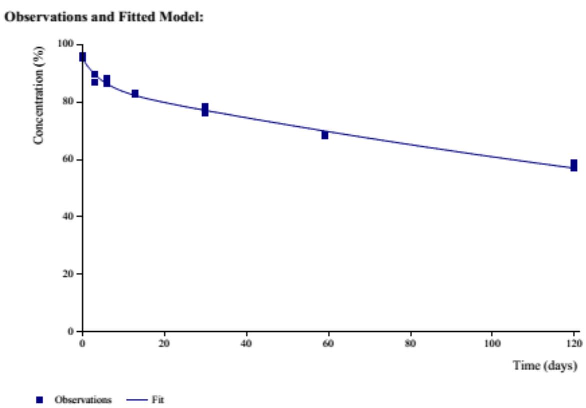
Soil (ref)	Vetroz (Gilbert, 2014)	Vetroz (Gilbert, 2014)	18 Acres (Gilbert, 2014)	18 Acres (Gilbert, 2014)
Model	SFO	DFOP	SFO	FOMC
Visual Fit	Acceptable	Good	Acceptable	Good
Residuals (visual)	Acceptable	Good	Acceptable	Good
χ2 error (%)	2.83	1.18	7.31	3.77
Initial value: estimate / (range) / standard error	Pini: 90 (95.1 - 96.1) σ: 1.166	Pini: 95.2 (95.1 - 100) σ: 1.063	Pini: 88.5 (95 - 97.2) σ: 2.53	Pini: 93.5 (95 - 100) σ: 1.737
Rate Parameters: estimate / standard error / probability (trigger:0.05)	kP: 0.0041 σ: 0.000334 $p < 0.01$	k1: 0.2126 σ: 0.07536 $p < 0.01$	kP: 0.03094 σ: 0.002722 $p < 0.01$	α: 1.32 σ: 0.2395 CI does not contain 0
		k2: 0.003355 σ: 0.000239 $p < 0.01$		β: 25.53 σ: 7.013 CI does not contain 0
		g: 0.1041 σ: 0.01637		
DT_{50} (days)	169	174	22.4	17.6
DT_{90} (days)	562	654	74.4	120
Modelling DT_{50} (days)[a]	169	207	22.4	36.4
Adjusted for 20C and pF2 (days)	169	207	22.4	36.4
FOCUS decision step	10% not reached – Try DFOP	DFOP better and more robust than SFO – Use DFOP k2	10% reached – Try FOMC	FOMC better than SFO and robust – Use FOMC (DT90/ 3.32)

[a] DT50 if SFO, DT90/3.32 if 10% reached during study, otherwise ln(2)/k2

Soil (ref)	Krone (Gilbert, 2014)	Krone (Gilbert, 2014)
Model	SFO	FOMC
Visual Fit	Poor	Good
Residuals (visual)	Poor	Good
χ^2 error (%)	16.10	2.40
Initial value: estimate / (range) / standard error	Pini: 87.6 (98.7 - 100) σ: 5.4	Pini: 99.2 (98.7 - 100) σ: 1.209
Rate Parameters: estimate / standard error / probability (trigger:0.05)	kP: 0.05218 σ: 0.009175 $p < 0.01$	α: 0.6593 σ: 0.03834 CI does not contain 0
		β: 4.186 σ: 0.5029 CI does not contain 0
DT_{50} (days)	13.3	7.79
DT_{90} (days)	44.1	133
Modelling DT_{50} (days)[a]	13.3	40.1
Adjusted for 20C and pF2 (days)	13.3	40.1
FOCUS decision step	10% reached – Try FOMC	FOMC better than SFO – Use FOMC (DT90/ 3.32)

[a] DT50 if SFO, DT90/3.32 if 10% reached during study, otherwise ln(2)/k2





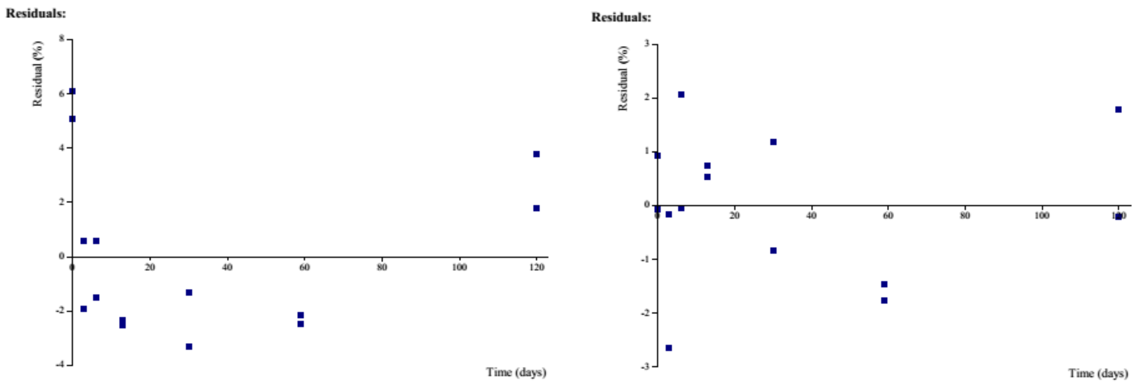


Figure B.8-60: Fitting of data and residual plot for Vetroz soil (SFO on the left; DFOP on the right)

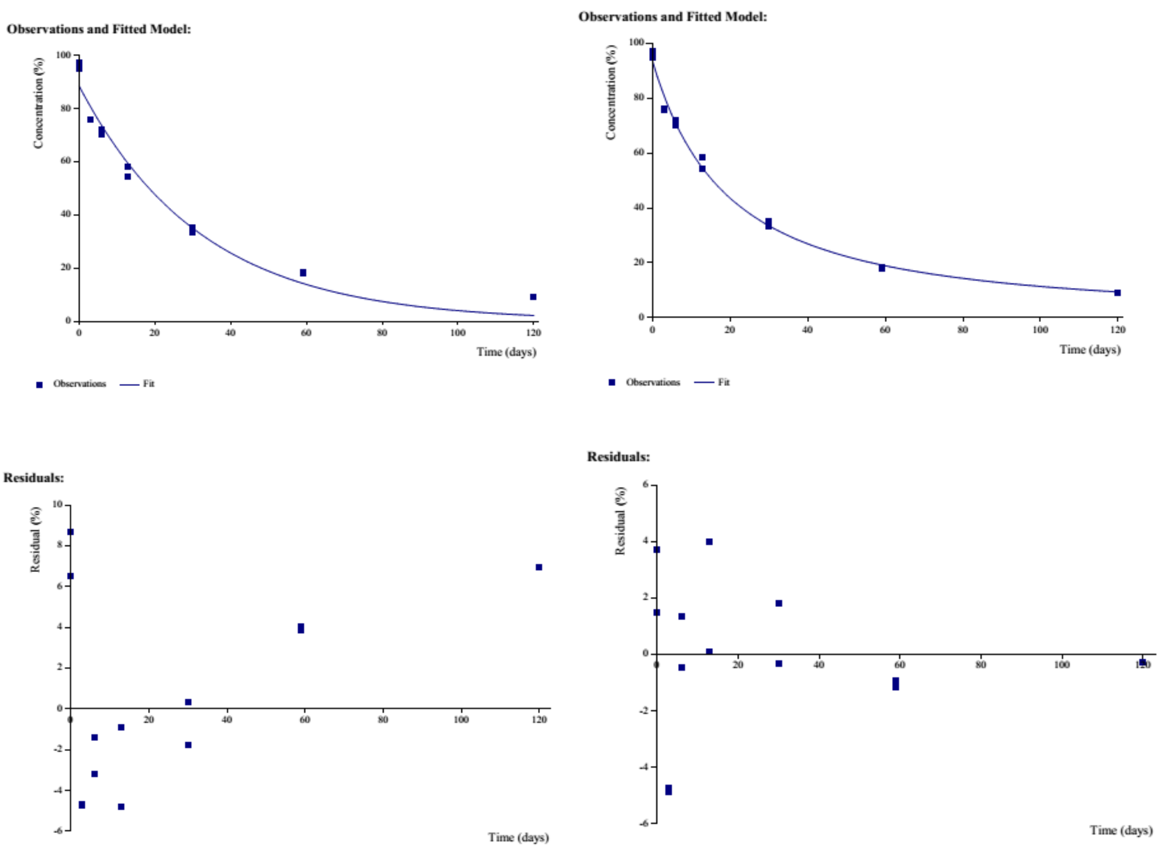


Figure B.8-61: Fitting of data and residual plot for 18 Acres soil (SFO on the left; FOMC on the right)

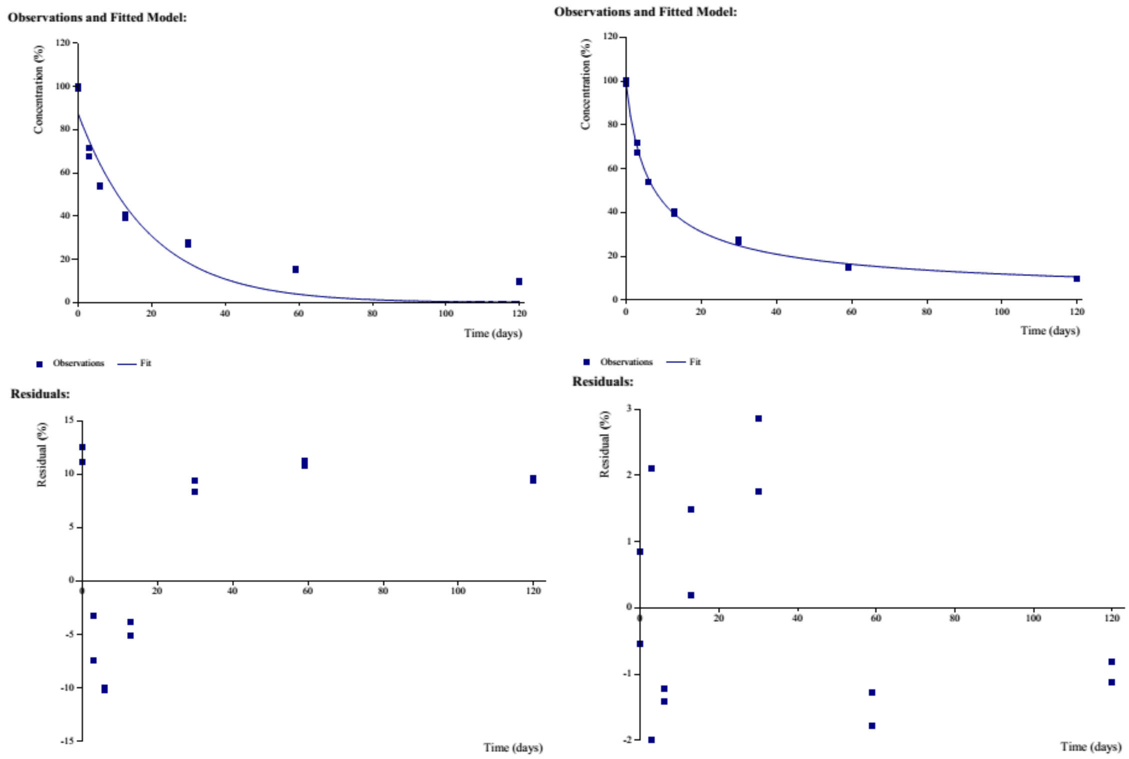


Figure B.8-62: Fitting of data and residual plot for Krone soil (SFO on the left; FOMC on the right)

Table B. 8-12: DT_{50} and DT_{90} values for SYN547308 in aerobic laboratory study (at 20°C and pF2)

Soil	DT_{50} (days)	DT_{90} (days)	Modelling DT_{50} (days)*
Vetroz	174	654	207
18 Acres	17.6	120	36.4
Krone	7.79	133	40.1
Geometric mean (n=3)	**-**	**-**	**67.1**

* DT50 if SFO, DT90/3.32 if 10% reached during study, otherwise ln(2)/k2

Conclusion of the Applicant:

Kinetic modelling analysis of datasets from aerobic degradation study for SYN547308 showed acceptable model fits when determining modelling endpoints. The calculated DT_{50} values (at 20ºC and pF2 soil moisture content) can be used for environmental exposure assessments.

Conclusion of HSE:

HSE considers it to be clear and transparent in terms of visual and statistical goodness of fit measures used in decision making. For the Vetroz soil the decision to reject SFO and rely on a DFOP fit was considered marginal in the opinion of HSE, and it could have been possible to justify acceptance of the SFO fit for modelling. However SYN547308 is a terminal metabolite and therefore the selection of worst case pseudo SFO endpoints from biphasic fits for all soils (i.e. DT_{50} derived from k_2 slow phase rate constant for Vetroz soil, and DT_{50} derived from the FOMC $DT_{90/3.32}$ in the 18 Acres and Krone soils) is accepted by HSE for the purposes of a conservative first tier exposure assessment. HSE has repeated the kinetic fitting for the 18 Acres soil using Cake v3.4 and confirmed that fitted parameters, statistics and endpoints were comparable to those provided by the applicant. The potential for pH dependent degradation has been considered in more detail in Section B.8.22.

B.8.1.1.1. Route of degradation in soil

Six new field soil dissipation studies and separate kinetic modelling reports have been provided for parent prosulfuron ([redacted] and [redacted], 2016a-f/dissipation studies and [redacted] and [redacted], 2016a and [redacted], 2018/kinetics). The study summaries prepared by the applicant are presented below.

Reference:	KIIA 7.2.1 / 06
Report Title:	Prosulfuron – Soil Dissipation Study with Bare Soil Application in Breitenwisch, Germany in 2014-2015. Final Report.
Author(s) & Year:	[redacted] & [redacted]; 2016a
Document No, Authority registration No	S13-05212
Guideline(s):	Yes

	EPA OPPTS 835.6100; SETAC 1995; EFSA Journal 2010;8(12):1936; EFSA Journal 2014;12(5):3662[5]
Deviations:	Deviation to EPA guideline (but in line with EFSA 2014): a single application was applied to a bare soil that was immediately covered with sand. This deviation has no impact on the outcome of the study.
GLP or GEP:	No (not applicable modelling study)
Acceptability:	Yes
Study relied upon:	Yes

Materials and methods:

Field dissipation behaviour of prosulfuron was investigated at Breitenwisch, Germany, during 2014-2015. The plots were located on level ground (0-1 % slope) in an area typical for maize production which was not prone to flooding or erosion. The site had not been cultivated with trees or vines in the past 3 years prior to the study start. The soil characteristics are presented in Table B.8-123.

A single application of A8714C (a 750 g a.i./kg water dispersible granule (WG) formulation) was applied at a nominal rate of 20 g a.i./ha as a broadcast spray application to the bare soil surface on 30 June 2014. Following application, the plot was kept weed free by using glyphosate, diquat or MCPA and dicamba.

No product containing prosulfuron had been used on the test plots in the last three years.

After application of the test item and post deposition tray sampling and before subsequent soil residue sampling, the control plot and the treated plot were immediately covered with a thin layer of untreated sand (particle size of approximately < 2 mm) to remove soil surface processes. The application of sand was conducted by hand using a sand spreader until complete coverage of the soil surface was achieved. The thickness of the sand layer was approximately 0.5 – 0.8 cm over the 3 treated subplots and the untreated control plot and measured at several spots with a ruler. Thickness of the sand cover was controlled and measured at least until 07 July 2014

[5] EFSA (2014) European Food Safety Authority, 2014. EFSA Guidance Document for evaluating laboratory and field dissipation studies to obtain DegT50 values of active substances of plant protection products and transformation products of these active substances in soil. EFSA Journal 2014;12(5):3662, 37 pp., doi:10.2903/j.efsa.2014.3662

(7 days after application, DAA). A renewal of the sand cover was not necessary. Within this time period of 7 days, the field received a total precipitation (rain) of 10.2 mm.

Daily weather data (air temperature, air humidity, precipitation, solar radiation, wind speed, soil temperature (at 10 cm and 30 cm depth) and soil moisture (at 10 cm and 30 cm depth)) were recorded using an on-site weather station located 36.2 metres from the western-corner of subplot 3 of the treated plot. The 30 year (1961 - 1990) long term weather data were taken from the official weather station Bremervörde, located 21 km from the trial site.

The average air temperature during the field phase of the study was very similar to the 29 year long term average. Onsite air temperatures were colder in August 2014, January 2015, February 2015 and May 2015. All other months were slightly warmer, except June 2014 which was the same as the long term. Rainfall was more erratic. From June 2014 to June 2015 monthly rainfall was significantly lower (>20% difference) than the long term average for 5 out of 12 months and significantly higher (>20% difference) than the long term average for 4 out of 12 months. The total rainfall from the date of first sampling until last sampling (26 June 2014 – 25 June 2015) was 763.4 mm which is a little lower than the corrected long term average of 778.9 mm over the same time period. Very high rainfall was observed in August 2014 (109.8 mm) and in December 2014 (126.2 mm). Very low rainfall was observed in September 2014 (29.2 mm), November 2014 (26.0 mm) and April 2015 (13.6 mm). The plot was irrigated on months of lower rainfall to compensate for drier months. A total of 194.6 mm irrigation was applied to account for the monthly deficits.

Untreated soil residue samples (0 – 100 cm depth) were taken at 4 days before application (DBA) from the treated and the untreated plot. Treated soil residue samples (0 – 30 cm cores) were taken after application (0 DAA) and at 1, 3 and 7 DAA. Treated soil residue 0 – 100 cm cores were taken at 15, 21, 30, 59, 91, 116, 183 and 360 DAA. Five soil cores were taken from each subplot, including control plot.

For verification of the application rate, two deposition trays (filled with sieved soil) were placed on the soil surface of each treated subplot during application and then sampled immediately after application.

Upon sample receipt, all samples were stored deep-frozen (≤ - 18 °C). The 0-30 cm soil cores were cut into depths 0 – 10, 10 – 20 and 20 – 30 cm. The 0 – 100 cm soil cores were generally cut into depths 0 – 10, 10 – 20, 20 – 30, 30 – 50, 50 – 70 and 70 – 100 cm. For the 0 – 10, 10 – 20, 20 – 30, 30 - 50, 50 – 70 and 70 – 100 cm depths the core layers coming from the same subplot and the same layer were combined per subplot and homogenised by grinding and sieving in the presence of dry ice. Two aliquots of at least 400 g frozen homogenized soil were taken and stored deep frozen.

Sub-samples from the 0 – 10 cm and 10 – 20 cm soil layers, from each subplot, up to 59 DAA, were then analysed for prosulfuron.

For the extraction of the soil samples, a 10 g aliquot (recovery samples were prepared by fortifying blank soil) was extracted with 20 mL 200 mM ammonium acetate/acetonitrile (20:80, v/v). The extract resulting from shaking was centrifuged before being diluted 1:1 with 200 mM ammonium acetate/methanol (90/10; v/v). Samples were analysed by high performance liquid chromatography with triple quadrupole mass spectrometry determination (LC-MS/MS).

Table B. 8-13: Characteristics of the soils

Soil Depth (cm)	0-10	10-20	20-30	30-50	50-70	70-100
Soil type (USDA)	Clay loam	Clay loam	Clay loam	Loam	Loam	Loam
% clay (<0.002 mm)	32.2	32.5	33.9	23.6	20.8	24.8
% silt (0.002-0.05 mm)	40.5	39.1	41.0	30.5	28.2	34.9
% sand (>0.05 mm)	27.4	28.4	25.1	46.0	51.1	40.4
% organic C	2.7	2.2	1.4	0.38	0.38	1.2
pH Water $CaCl_2$	 4.89 5.32	 4.79 5.00	 4.71 4.74	 4.72 5.04	 4.64 5.44	 4.54 4.98
Cation exchange capacity (meq/100g soil)	19.9	19.1	18.4	10.7	10.2	11.6
Soil bulk density (g/L)	1250	1320	1360	1470	1290	1110
Microbial biomass (mg C/100 g dry soil)	151.2					
Moisture at pF2	31.2 (1-5 cm)					

Findings:

The mean prosulfuron residue in the deposition trays was 17.7 g a.i./ha. This corresponded to an application rate of 89%, based on the target application rate of 20 g a.i./ha. The mean prosulfuron residue in the 0 DAA cores was 14.9 g a.i./ha. This corresponded to an application rate of 73 %, based on the target application rate of 20 g a.i./ha. These values confirm the correct application rate was applied to the trial plot.

The prosulfuron residue at 0 DAA was 14.9 g a.i./ha and declined throughout the study to reach a residue of 0 g a.i./ha (wet weight residue values were < LOQ (0.5 µg/kg)) by 59 DAA. Analysis of subsequent sampling interval cores was not required as prosulfuron had dissipated by >90 % by 59 DAA. Prosulfuron residues were only detected in the 0 – 10 cm soil layer and were not detected in the 10 – 20 cm soil layer throughout the study. Analysis of the soil layers below the 0 – 20 cm soil layer was not necessary. Residues of prosulfuron were not detected in the 4 day before application (DBA) control soil samples.

Table B. 8-14: Summary of the results (Breitenwisch)

Actual sampling interval	Core depth (cm)	Sub plot No.	Prosulfuron residue (g a.i./ha)	Mean prosulfuron residue (g a.i./ha)
0 DAA	0-10	1	15.5	14.9
	0-10	2	15.1	
	0-10	3	14.0	
	10-20	1	0	0
	10-20	2	0	
	10-20	3	0	
1 DAA	0-10	1	14.4	17.5
	0-10	2	16.9	
	0-10	3	21.2	
	10-20	1	0	0
	10-20	2	0	
	10-20	3	0	
3 DAA	0-10	1	15.2	13.6
	0-10	2	13.5	
	0-10	3	12.1	
	10-20	1	0	0
	10-20	2	0	
	10-20	3	0	

7 DAA	0-10	1	13.0	11.6
	0-10	2	10.6	
	0-10	3	11.2	
	10-20	1	0	0
	10-20	2	0	
	10-20	3	0	
15 DAA	0-10	1	4.3	3.6
	0-10	2	3.2	
	0-10	3	3.3	
	10-20	1	0	0
	10-20	2	0	
	10-20	3	0	
21 DAA	0-10	1	3.0	3.3
	0-10	2	3.3	
	0-10	3	3.7	
	10-20	1	0	0
	10-20	2	0	
	10-20	3	0	
30 DAA	0-10	1	1.5	1.5
	0-10	2	1.3	
	0-10	3	1.6	
	10-20	1	0	0
	10-20	2	0	
	10-20	3	0	
59 DAA	0-10	1	0	0
	0-10	2	0	
	0-10	3	0	
	10-20	1	0	0
	10-20	2	0	
	10-20	3	0	

DAA: Days after application;
n. d.: not detected (residues are below the limit of detection (LOD), 0.15 µg/kg wet soil);
Where the wet weight residue was either <LOQ or n.d., the calculated g a.i. residue was set to zero. Residues were calculated using values rounded to 2 decimals.

Conclusion of the Applicant:

Residues of prosulfuron in soil following a bare soil application of prosulfuron as a 75 WG formulation (A8714C) declined to less than 10% of the residue observed at 0 DAA by 59 DAA and hence the time course of prosulfuron residues in soil following application onto bare soil as a broadcast spray could be determined. Residues of prosulfuron dissipated (declined) in soil under field conditions.

Reference:	KIIA 7.2.1 / 07
Report Title:	Prosulfuron – Soil Dissipation Study with Bare Soil Application in Castelsarrasin, France in 2014-2015. Final Report.

Author(s) & Year:	[redacted] & [redacted]; 2016b
Document No, Authority registration No	S13-05218
Guideline(s):	Yes EPA OPPTS 835.6100; SETAC 1995; EFSA Journal 2010;8(12):1936; EFSA Journal 2014;12(5):3662
Deviations:	Deviation to EPA guideline (but in line with EFSA 2014): a single application was applied to a bare soil that was immediately covered with sand. This deviation has no impact on the outcome of the study.
GLP or GEP:	Yes
Acceptability:	Yes
Study relied upon:	Yes

Materials and methods:

Field dissipation behaviour of prosulfuron was investigated at Castelsarrasin, southern France, during 2014-2015. The plots were located on level ground (0 % slope) in an area typical for maize production which was not prone to flooding or erosion. The site had not been cultivated with trees or vines in the past 3 years prior to the study start. The soil characteristics are presented in Table B.8-125.

A single application of A8714C (a 750 g a.i./kg water dispersible granule (WG) formulation) was applied at a nominal rate of 20 g a.i./ha as a broadcast spray application to the bare soil surface on 30 June 2014. Following application, glyphosate was used to keep the plot generally weed free. No product containing prosulfuron had been used on the test plots in the last three years.

After application of the test item and post deposition tray sampling and before subsequent soil residue sampling, the control plot and the treated plot were immediately covered with a thin layer of untreated sand (particle size of approximately 3 mm) to remove soil surface processes. The application of sand was conducted by hand using a spade until complete coverage of the soil surface was achieved. The thickness of the sand layer was approximately 3 – 7 cm over the 3 treated subplots and measured at several spots with a ruler. Thickness of the sand cover was controlled and verified by photos at least until 14 July 2014 (14 days after application, DAA). Within this time period of 14 days, the field received a total precipitation (rain) of 25.0

mm. A renewal of the sand cover was done on 15 July 2014 (15 DAA) with a sand cover thickness of approximately 4-7 mm.

Daily weather data (air temperature, air humidity, precipitation, solar radiation, wind speed, soil temperature (at 10 cm and 30 cm depth) and soil moisture (at 10 cm and 30 cm depth)) were recorded using an on-site weather station located 3.0 metres from the plot. The 12 year (1989 - 2000) long term weather data were taken from the official weather station located 2.0 km from the trial site.

The average air temperature during the field phase of the study was very similar to the 12 year long term average. Onsite air temperatures were colder in July 2014, August 2014 and from December 2014 until March 2015. All other months were slightly warmer. Rainfall was more erratic. From June 2014 to June 2015 monthly rainfall was significantly lower (> 20 % difference) than the long term average for 5 out of 12 months and significantly higher (> 20 % difference) than the long term average for 5 out of 12 months. The total rainfall from first sampling until last sampling (25 June 2014 – 26 June 2015) was 631.0 mm which is slightly lower than the long term average of 703.6 mm over the same time period. Very high rainfall was observed in July 2014 (93.04 mm), in August 2014 (71.6 mm) and in June 2015 (93.4 mm). Very low rainfall was observed in June 2014 (3.6 mm), in September 2014 (13.8 mm), in October 2014 (10.8 mm) and in May 2015 (28.6 mm). The plot was irrigated on months of lower rainfall to compensate for these drier months. A total of 337.7 mm irrigation was applied to account for the monthly deficits.

Untreated soil residue samples (0 – 100 cm depth) were taken at 5 days before application (DBA) from the treated and the untreated plot. Treated soil residue samples (0 – 30 cm cores) were taken after application (0 DAA) and at 1, 3 and 7 DAA. Treated soil residue 0 – 100 cm cores were taken at 15, 21, 28, 58, 93, 119, 173 and 361 DAA. Five soil cores were taken from each subplot, including control plot.

For verification of the application rate, two deposition trays (filled with sieved soil) were placed on the soil surface of each treated subplot during application and then sampled immediately after application.

Upon sample receipt, all samples were stored deep-frozen (≤ - 18 °C). The 0-30 cm soil cores were cut into depths 0 – 10, 10 – 20 and 20 – 30 cm. The 0 – 100 cm soil cores were generally cut into depths 0 – 10, 10 – 20, 20 – 30, 30 – 50, 50 – 70 and 70 – 100 cm. The deep frozen 0-10 cm soil cores required no cutting. For the 0 – 10, 10 – 20, 20 – 30, 30 - 50, 50 – 70 and 70 – 100 cm depths the core layers coming from the same subplot and the same layer were combined per subplot and homogenised by grinding and sieving in the presence of dry ice. Two aliquots of at least 400 g frozen homogenized soil were taken and stored deep frozen.

Sub-samples from the 0 – 10 cm and 10 – 20 cm soil layers, from each subplot, up to 93 DAA, were then analysed for prosulfuron.

For the extraction of the soil samples, a 10 g aliquot (recovery samples were prepared by fortifying blank soil) was extracted with 20 mL 0.2 M ammonium acetate/acetonitrile (20:80, v/v). The extract resulting from shaking was centrifuged before being diluted 1:1 with 0.2 M ammonium acetate/methanol (90/10; v/v). Samples were analysed by high performance liquid chromatography with triple quadrupole mass spectrometry determination (LC-MS/MS).

Table B. 8-15: Characteristics of the soils

Soil Depth (cm)	0-10	10-20	20-30	30-50	50-70	70-100
Soil type (USDA)	Silt loam	Silt loam	Silt loam	Silty clay loam	Silty clay loam	Silty clay
% clay (<0.002 mm)	22.8	21.3	21.1	30.0	38.8	40.7
% silt (0.002-0.05 mm)	54.5	55.5	55.4	51.3	45.3	43.9
% sand (>0.05 mm)	22.8	23.3	23.6	18.8	15.9	15.5
% organic C	0.69	0.67	0.67	0.32	<0.3	<0.3
pH Water $CaCl_2$	 4.94 6.06	 4.80 6.16	 5.54 6.22	 5.58 6.41	 4.50 5.53	 4.18 4.28
Cation exchange capacity (meq/100g soil)	7.3	7.1	6.8	8.3	12.3	12.4
Soil bulk density (g/L)	1160	1240	1330	1400	1390	1400
Microbial biomass (mg C/100 g dry soil)	48.2					
Moisture at pF2	20.4 (1-5 cm)					

Findings:

The mean prosulfuron residue in the deposition trays was 13.8 g a.i./ha. This corresponded to an application rate of 69%, based on the target application rate of 20 g a.i./ha. The mean prosulfuron residue in the 0 DAA cores was 11.1 g a.i./ha. This corresponded to an application rate of 56 %, based on the target application rate of 20 g a.i./ha. These values confirm the correct application rate was applied to the trial plot.

The prosulfuron residue at 0 DAA was 11.1 g a.i./ha and declined throughout the study to reach a residue of 0 g a.i./ha (wet weight residue values were < LOQ (0.5 µg/kg) or were not detected (<0.15 µg/kg)) by 58 and 93 DAA. Analysis of subsequent sampling interval cores was not required as prosulfuron had dissipated by >90 % by 93 DAA. Prosulfuron residues were only detected in the 0 – 10 cm soil layer and were not detected in the 10 – 20 cm soil layer throughout the study. Analysis of the soil layers below the 0 – 20 cm soil layer was not necessary. Residues of prosulfuron were not detected in the 5 day before application (DBA) control soil samples.

Table B. 8-16: Summary of the results (Castelsarrasin)

Actual sampling interval	Core depth (cm)	Sub plot No.	Prosulfuron residue (g a.i./ha)	Mean prosulfuron residue (g a.i./ha)
0 DAA	0-10	1	10.6	11.1
	0-10	2	10.9	
	0-10	3	11.9	
	10-20	1	0	0
	10-20	2	0	
	10-20	3	0	
1 DAA	0-10	1	11.2	7.8
	0-10	2	8.3	
	0-10	3	3.9	
	10-20	1	0	0
	10-20	2	0	
	10-20	3	0	
3 DAA	0-10	1	12.7	8.4
	0-10	2	5.7	
	0-10	3	6.9	
	10-20	1	0	0
	10-20	2	0	
	10-20	3	0	

7 DAA	0-10	1	9.7	7.4
	0-10	2	6.6	
	0-10	3	5.9	
	10-20	1	0	0
	10-20	2	0	
	10-20	3	0	
15 DAA	0-10	1	4.1	4.1
	0-10	2	3.3	
	0-10	3	5.0	
	10-20	1	0	0
	10-20	2	0	
	10-20	3	0	
21 DAA	0-10	1	2.2	2.3
	0-10	2	1.9	
	0-10	3	2.8	
	10-20	1	0	0
	10-20	2	0	
	10-20	3	0	
28 DAA	0-10	1	2.1	1.7
	0-10	2	1.5	
	0-10	3	1.6	
	10-20	1	0	0
	10-20	2	0	
	10-20	3	0	
58 DAA	0-10	1	0	0
	0-10	2	0	
	0-10	3	0	
	10-20	1	0	0
	10-20	2	0	
	10-20	3	0	
93 DAA	0-10	1	0	0
	0-10	2	0	
	0-10	3	0	
	10-20	1	0	0
	10-20	2	0	
	10-20	3	0	

DAA: Days after application;
n. d.: not detected (residues are below the limit of detection (LOD), 0.15 µg/kg wet soil);
Where the wet weight residue was either <LOQ or n.d., the calculated g a.i. residue was set to zero. Residues were calculated using values rounded to 2 decimals.

Conclusion of the Applicant:

Residues of prosulfuron in soil following a bare soil application of prosulfuron as a 75 WG formulation (A8714C) declined to less than 10% of the residue observed at 0 DAA by 93 DAA and hence the time course of prosulfuron residues in soil following application onto bare soil as a broadcast spray could be determined. Residues of prosulfuron dissipated (declined) in soil under field conditions.

Reference:	KIIA 7.2.1 / 08
Report Title:	Prosulfuron – Soil Dissipation Study with Bare Soil Application in Bogense - Nørreby, Denmark in 2014-2015. Final Report.
Author(s) & Year:	[redacted] & [redacted]; 2016c
Document No, Authority registration No	S13-05216
Guideline(s):	Yes EPA OPPTS 835.6100; SETAC 1995; EFSA Journal 2010;8(12):1936; EFSA Journal 2014;12(5):3662
Deviations:	Deviation to EPA guideline (but in line with EFSA 2014): a single application was applied to a bare soil that was immediately covered with sand. This deviation has no impact on the outcome of the study.
GLP or GEP:	Yes
Acceptability:	Yes
Study relied upon:	Yes

Materials and methods:

Field dissipation behaviour of prosulfuron was investigated at Bogense - Nørreby, Denmark, during 2014-2015. The plots were located on level ground (0 % slope) in an area typical for maize production which was not prone to flooding or erosion. The site had not been cultivated with trees or vines in the past 3 years prior to the study start. The soil characteristics are presented in Table B.8-127.

A single application of A8714C (a 750 g a.i./kg water dispersible granule (WG) formulation) was applied at a nominal rate of 20 g a.i./ha as a broadcast spray application to the bare soil surface on 1 July 2014. Following application, glyphosate was used to keep the plot generally weed free. No product containing prosulfuron had been used on the test plots in the last three years.

After application of the test item and collection of the deposition tray samples, the control plot and the respective treated subplot were immediately covered with a thin layer of untreated sand (particle size of approximately 0.5-4 mm) to remove soil surface processes. The application of sand was conducted by hand and using a shovel until complete coverage of the soil surface was achieved. The thickness of the sand layer was approximately 5 – 9 cm over the 3 treated subplots. Thickness of the sand cover was controlled and measured until 16 July 2014 (15 days after application, DAA). A renewal of the sand cover was not necessary. Within this time period of 15 days, the field received a total precipitation (rain and irrigation) of 39.8 mm.

Daily weather data (air temperature, air humidity, precipitation, solar radiation, wind speed, soil temperature (at 10 cm and 30 cm depth) and soil moisture (at 10 cm and 30 cm depth)) were recorded using an on-site weather station located 7 metres from the plot. Due to a malfunction of the on-site weather station in June 2015, the daily rainfall in June 2015 was supplied by weather station Bogense Sejlklub, about 12.6 km away from the trial site. The 30 year (1961 – 1990) long term weather data were taken from regional long term weather data of Fyn.

The average air temperature during the field phase of the study was very similar to the 30 year long term average. Onsite air temperatures were colder in May 2015 and June 2015. All other months were slightly warmer. Rainfall was more erratic. From June 2014 to June 2015 monthly rainfall was significantly lower (>20 % difference) than the long term average for 5 out of 12 months and significantly higher (>20 % difference) than the long term average for 4 out of 12 months. The total rainfall from the date of first sampling until last sampling (30 June 2014 – 24 June 2015) was 612.3 mm which is slightly lower than the long term average of 629.2 mm over the same time period. Very high rainfall was observed in December 2014 (94.6 mm). Very low rainfall was observed in November 2014 (27.8 mm) and June 2015 (21.1 mm). The plot was irrigated on months of lower rainfall to compensate for these drier months. A total of 206.2 mm irrigation was applied to account for the monthly deficits.

Untreated soil residue samples (0 – 100 cm depth) were taken at 1 day before application (DBA) from the treated and the untreated plot. Treated soil residue samples (0 – 30 cm cores) were taken after application (0 DAA) and at 1, 3, 7 and 17 DAA. Treated soil residue 0 – 100 cm cores were taken at 15, 21, 28, 58, 93, 119, 173 and 358 DAA. Five soil cores were taken from each subplot, including control plot.

For verification of the application rate, two deposition trays (filled with sieved soil) were placed on the soil surface of each treated subplot during application and then sampled immediately after application.

Upon sample receipt, all samples were stored deep-frozen (≤ - 18 °C). The 0-30 cm soil cores were cut into depths 0 – 10, 10 – 20 and 20 – 30 cm. The 0 – 100 cm soil cores were generally cut into depths 0 – 10, 10 – 20, 20 – 30, 30 – 50, 50 – 70 and 70 – 100 cm. The deep frozen 0-10 cm soil cores required no cutting. For the 0 – 10, 10 – 20, 20 – 30, 30 - 50, 50 – 70 and 70 – 100 cm depths the core layers coming from the same subplot and the same layer were combined per subplot and homogenised by grinding and sieving in the presence of dry ice. Two aliquots of at least 400 g frozen homogenized soil were taken and stored deep frozen.

The sample cores 50 – 100 cm of 58 DAA sampling event and 30 – 100 cm of 93 DAA sampling were segmented but were neither milled nor analysed.

The sample cores 0 – 100 cm of 119 DAA, 173 DAA and 358 DAA samplings were neither cut, nor milled, nor analysed.

For the extraction of the soil samples, a 10 g aliquot (recovery samples were prepared by fortifying blank soil) was extracted with 20 mL 200 mM ammonium acetate/acetonitrile (20:80, v/v). The extract resulting from shaking was centrifuged before being diluted 1:1 with 200 mM ammonium acetate/methanol (90/10; v/v). Samples were analysed by high performance liquid chromatography with triple quadrupole mass spectrometry determination (LC-MS/MS).

Table B. 8-17: Characteristics of the soils

Soil Depth (cm)	0-10	10-20	20-30	30-50	50-70	70-100
Soil type (USDA)	Sandy loam	Sandy loam	Sandy loam	Sandy loam	Sandy loam	Sandy loam
% clay (<0.002 mm)	11.0	11.2	10.9	15.6	13.0	13.4
% silt (0.002-0.05 mm)	24.5	24.7	24.6	27.1	17.9	21.3
% sand (>0.05 mm)	64.6	64.2	64.6	57.4	69.2	65.4
% organic C	1.2	1.3	1.5	0.71	<0.3	<0.3
pH						
Water	5.07	6.93	5.45	6.03	7.99	7.99
$CaCl_2$	6.48	6.88	6.51	6.51	7.37	7.50

Cation exchange capacity (meq/100g soil)	9.1	9.5	9.5	8.5	6.2	6.4
Soil bulk density (g/L)	1430	1540	1410	1580	1670	1810
Microbial biomass (mg C/100 g dry soil)	37.2					
Moisture at pF2	16.3 (1-4 cm)					

Findings:

The mean prosulfuron residue in the deposition trays was 16.3 g a.i./ha. This corresponded to an application rate of 82%, based on the target application rate of 20 g a.i./ha. The mean prosulfuron residue in the 0 DAA cores was 22.3 g a.i./ha. This corresponded to an application rate of 112 %, based on the target application rate of 20 g a.i./ha. These values confirm the correct application rate was applied to the trial plot.

The prosulfuron residue at 0 DAA was 22.3 g a.i./ha and declined throughout the study to reach a residue of 0.5 g a.i./ha by 93 DAA. Analysis of subsequent sampling interval cores was not required as prosulfuron had dissipated by >90 % by 93 DAA. Prosulfuron residues in the 0 – 10 cm soil layer deceased to 0.5 g a.i./ha by 93 DAA. Prosulfuron residues were first detected in the 10 – 20 cm soil layer at a level of 0.7 g a.i./ha at 15 DAA and increased to a maximum of 1.9 g a.i./ha by 17 DAA. The prosulfuron residues in the 10 – 20 cm soil layer decreased to <LOQ by 93 DAA. Residues of prosulfuron were not detected below the 10 – 20 cm soil layer except for a residue in the 20 – 30 cm soil layer, for one subplot at 58 DAA, at a level of <LOQ. Residues of prosulfuron were not detected in the 1 day before application (DBA) control soil samples.

Table B. 8-18: Summary of the results (Bogense)

Actual sampling interval	Core depth (cm)	Sub plot No.	Prosulfuron residue (g a.i./ha)	Mean prosulfuron residue (g a.i./ha)
0 DAA	0-10	1	23.4	22.3
	0-10	2	19.8	
	0-10	3	23.8	
	10-20	1	0	0
	10-20	2	0	
	10-20	3	0	

1 DAA	0-10	1	13.2	13.0
	0-10	2	12.4	
	0-10	3	13.3	
	10-20	1	0	0
	10-20	2	0	
	10-20	3	0	
3 DAA	0-10	1	13.1	13.3
	0-10	2	12.0	
	0-10	3	14.8	
	10-20	1	0	0
	10-20	2	0	
	10-20	3	0	
7 DAA	0-10	1	9.2	9.1
	0-10	2	9.2	
	0-10	3	8.9	
	10-20	1	0	0
	10-20	2	0	
	10-20	3	0	
15 DAA	0-10	1	7.1	6.5
	0-10	2	4.9	
	0-10	3	7.4	
	10-20	1	1.0	0.3
	10-20	2	0	
	10-20	3	0	
	20-30	1	0	0
	20-30	2	0	
	20-30	3	0	
17 DAA	0-10	1	4.7	5.9
	0-10	2	5.8	
	0-10	3	7.1	
	10-20	1	2.9	1.9
	10-20	2	1.6	
	10-20	3	1.1	
	20-30	1	0	0
	20-30	2	0	
	20-30	3	0	
21 DAA	0-10	1	5.3	5.5
	0-10	2	4.7	
	0-10	3	6.5	
	10-20	1	1.2	0.8
	10-20	2	0	
	10-20	3	1.2	
	20-30	1	0	0
	20-30	2	0	
	20-30	3	0	
28 DAA	0-10	1	3.9	3.9
	0-10	2	3.5	

	0-10	3	4.3	
	10-20	1	0	1.0
	10-20	2	1.7	
	10-20	3	1.4	
	20-30	1	0	0
	20-30	2	0	
	20-30	3	0	
58 DAA	0-10	1	1.5	1.5
	0-10	2	1.2	
	0-10	3	1.7	
	10-20	1	1.2	1.4
	10-20	2	1.2	
	10-20	3	1.9	
	20-30	1	0	0
	20-30	2	0	
	20-30	3	0	
	30-50	1	0	0
93 DAA	0-10	1	0	0.5
	0-10	2	0	
	0-10	3	1.6	
	10-20	1	0	0
	10-20	2	0	
	10-20	3	0	
	20-30	1	0	0
	20-30	2	0	
	20-30	3	0	

DAA: Days after application;
n. d.: not detected (residues are below the limit of detection (LOD), 0.15 µg/kg wet soil);
Where the wet weight residue was either <LOQ or n.d., the calculated g a.i. residue was set to zero. Residues were calculated using values rounded to 2 decimals.

Conclusion of the Applicant:

Residues of prosulfuron in soil following a bare soil application of prosulfuron as a 75 WG formulation (A8714C) declined to less than 10% of the residue observed at 0 DAA by 93 DAA and hence the time course of prosulfuron residues in soil following application onto bare soil as a broadcast spray could be determined. Residues of prosulfuron dissipated (declined) in soil under field conditions.

Reference:	KIIA 7.2.1 / 09
Report Title:	Prosulfuron – Soil Dissipation Study with Bare Soil Application in Wilson, UK in 2014-2015. Final Report.
Author(s) & Year:	[redacted] & [redacted]; 2016d

Document No, Authority registration No	S13-05214
Guideline(s):	Yes EPA OPPTS 835.6100; SETAC 1995; EFSA Journal 2010;8(12):1936; EFSA Journal 2014;12(5):3662
Deviations:	Deviation to EPA guideline (but in line with EFSA 2014): a single application was applied to a bare soil that was immediately covered with sand. This deviation has no impact on the outcome of the study.
GLP or GEP:	Yes
Acceptability:	Yes
Study relied upon:	Yes

Materials and methods:

Field dissipation behaviour of prosulfuron was investigated at Wilson, UK during 2014-2015. The plots were located on level ground (0 % slope) in an area typical for maize production which was not prone to flooding or erosion. The site had not been cultivated with trees or vines in the past 3 years prior to the study start. The soil characteristics are presented in Table B.8-129.

A single application of A8714C (a 750 g a.i./kg water dispersible granule (WG) formulation) was applied at a nominal rate of 20 g a.i./ha as a broadcast spray application to the bare soil surface on 25 June 2014. Following application, glyphosate was used to keep the plot generally weed free. No product containing prosulfuron had been used on the test plots in the last three years.

After application of the test item and post deposition tray sampling and before subsequent soil residue sampling, the control plot and the treated plot were immediately covered with a thin layer of untreated sand (particle size of approximately 0-2 mm) to remove soil surface processes. The application of sand was conducted by hand and using shovels until complete coverage of the soil surface was achieved. The thickness of the sand layer was approximately 3 – 5 cm over the 3 treated subplots. Thickness of the sand cover was controlled and measured at least until 23 July 2014 (28 days after application, DAA). A renewal of the sand cover was not necessary. Within this time period of 28 days, the field received a total precipitation (rain and irrigation) of 100.8 mm.

Daily weather data (air temperature, air humidity, precipitation, solar radiation, wind speed, soil temperature (at 10 cm and 30 cm depth) and soil moisture (at 10 cm and 30 cm depth)) were recorded using a weather station located approximately 20 metres from the plot. The soil data was supplied by weather station located < 10 m away from the treated plots. The 30 year (1971 – 2000) long term weather data were taken from an official weather station (Sotton-Bonington) located 9.0 km from the trial site.

The average air temperature during the field phase of the study was very similar to the 30 year long term average. Onsite air temperatures were colder in August 2014, February 2015 and June 2015. All other months were slightly warmer, except March 2015 which was the same as the long term. Rainfall was not very erratic. From June 2014 to June 2015 monthly rainfall was significantly lower (> 20% difference) than the long term average for 3 out of 12 months and significantly higher (>20% difference) than the long term average for 4 out of 12 months. The total rainfall from the date of first sampling until last sampling (24 June 2014 – 19 June 2015) was 603.0 mm which is a little higher than the long term average of 598.1 mm over the same time period. Very high rainfall was observed in November 2014 (98.8 mm). Very low rainfall was observed in September 2014 (0.4 mm) and April 2015 (19.8 mm). The plot was irrigated on months of lower rainfall to compensate for these drier months. A total of 66.6 mm irrigation was applied to account for the monthly deficits.

Untreated soil residue samples (0 – 100 cm depth) were taken at 1 day before application (DBA) from the treated and the untreated plot. Treated soil residue samples (0 – 30 cm cores) were taken after application (0 DAA) and at 1, 3 and 7 DAA. Treated soil residue 0 – 100 cm cores were taken at 13, 21, 28, 57, 91, 120, 180 and 359 DAA. Five soil cores were taken from each subplot, including control plot.

For verification of the application rate, two deposition trays (filled with sieved soil) were placed on the soil surface of each treated subplot during application and then sampled immediately after application.

Upon sample receipt, all samples were stored deep-frozen (≤ - 18 °C). The 0-30 cm soil cores were cut into depths 0 – 10, 10 – 20 and 20 – 30 cm. The 0 – 100 cm soil cores were generally cut into depths 0 – 10, 10 – 20, 20 – 30, 30 – 50, 50 – 70 and 70 – 100 cm. For the 0 – 10, 10 – 20, 20 – 30, 30 - 50, 50 – 70 and 70 – 100 cm depths the core layers coming from the same subplot and the same layer were combined per subplot and homogenised by grinding and sieving in the presence of dry ice. Generally the 30 – 50, 50 – 70 and 70 – 100 cm soil cores were stored non-milled. An exception were the samples at 57 DAA, where all soil layers were analysed (except for the 30 – 50 cm soil layer). Two aliquots of at least 400 g frozen homogenized soil were taken and stored deep frozen.

For the extraction of the soil samples, a 10 g aliquot (recovery samples were prepared by fortifying blank soil) was extracted with 20 mL 0.2 M ammonium acetate/acetonitrile (20:80, v/v). The extract resulting from shaking was centrifuged before being diluted 1:1 with 0.2 M ammonium acetate/methanol (90/10; v/v). Samples were analysed by high performance liquid chromatography with triple quadrupole mass spectrometry determination (LC-MS/MS).

Table B. 8-19: Characteristics of the soils

Soil Depth (cm)	0-10	10-20	20-30	30-50	50-70	70-100
Soil type (USDA)	Loam	Loam	Loam	Loam	Clay loam	Clay loam
% clay (<0.002 mm)	24.4	25.5	25.0	25.0	29.9	29.3
% silt (0.002-0.05 mm)	43.0	44.8	44.3	43.2	36.7	32.1
% sand (>0.05 mm)	32.6	29.8	30.8	31.8	33.5	38.7
% organic C	2.0	1.8	1.7	0.53	<0.3	<0.3
pH Water $CaCl_2$	 7.16 7.07	 7.21 7.07	 6.91 7.00	 6.96 7.13	 7.31 7.27	 7.55 7.41
Cation exchange capacity (meq/100g soil)	11.9	13.0	12.8	9.4	10.1	10.6
Soil bulk density (g/L)	1560	1720	1750	1800	1810	1780
Microbial biomass (mg C/100 g dry soil)	91.0					
Moisture at pF2	20.4 (1-4 cm)					

Findings:

The mean prosulfuron residue in the deposition trays was 14.1 g a.i./ha. This corresponded to an application rate of 70%, based on the target application rate of 20 g a.i./ha. The mean prosulfuron residue in the 0 DAA cores was 12.2 g a.i./ha. This corresponded to an application rate of 61 %, based on the target application rate of 20 g a.i./ha. These values confirm the correct application rate was applied to the trial plot.

The prosulfuron residue at 0 DAA was 12.2 g a.i./ha and declined throughout the study to reach a residue of 0.9 g a.i./ha by 91 DAA. Analysis of subsequent sampling interval cores was not required as prosulfuron had dissipated by >90 % by 91 DAA. Prosulfuron residues were only detected in the 0 – 10 cm soil layer and were not detected in the 10 – 20 cm soil layer throughout the study. Analysis of the soil layers below the 0 – 20 cm soil layer were not required. The one exception to this was at 57 DAA. The analytical preliminary results of the 0 – 10 cm, 10 – 20 cm and 20 – 30 cm soil horizons from the 57 DAA sampling showed that a prosulfuron residue was not detectable in all three horizons, contrary to the samples of 28 DAA and 91 DAA where the analyte was detected in the 0 – 10 cm horizon. This observation necessitated the additional analysis of the lowest horizons of the 57 DAA samples, namely the 70 – 100 cm and 50 – 70 cm soil horizons to confirm the suspicion that the top and bottom of the cores were erroneously swapped due to switching of the core cap colours compared to that described by the study plan. Analysis of the 70 – 100 cm horizon in all three samples showed prosulfuron residues below the limit of quantification but above the limit of detection – this was the expected residue concentration for the larger 0 – 30 cm horizon, given the residues observed in the 0 – 10 cm horizon at 28 DAA and 91 DAA. Residues of prosulfuron were not detected in the 1 day before application (DBA) control soil samples.

The analytical method was validated with an LOQ = 0.5 µg/kg.

Table B. 8-20: Summary of the results (Wilson)

Actual sampling interval	Core depth (cm)	Sub plot No.	Prosulfuron residue (g a.i./ha)	Mean prosulfuron residue (g a.i./ha)
0 DAA	0-10	1	14.6	12.2
	0-10	2	12.0	
	0-10	3	10.0	
	10-20	1	0	0
	10-20	2	0	

	10-20	3	0	
1 DAA	0-10	1	13.2	12.0
	0-10	2	12.6	
	0-10	3	10.3	
	10-20	1	0	0
	10-20	2	0	
	10-20	3	0	
3 DAA	0-10	1	14.0	15.4
	0-10	2	17.0	
	0-10	3	15.1	
	10-20	1	0	0
	10-20	2	0	
	10-20	3	0	
7 DAA	0-10	1	8.2	9.6
	0-10	2	11.7	
	0-10	3	8.8	
	10-20	1	0	0
	10-20	2	0	
	10-20	3	0	
13 DAA	0-10	1	7.6	7.3
	0-10	2	8.1	
	0-10	3	6.1	
	10-20	1	0	0
	10-20	2	0	
	10-20	3	0	
21 DAA	0-10	1	1.7	2.5
	0-10	2	2.9	
	0-10	3	2.9	
	10-20	1	0	0
	10-20	2	0	
	10-20	3	0	
28 DAA	0-10	1	3.2	2.5
	0-10	2	2.3	
	0-10	3	2.1	
	10-20	1	0	0
	10-20	2	0	
	10-20	3	0	
	20-30	2	0	0
57 DAA	0-30	1	0	0
	0-30	2	0	
	0-30	3	0	
	30-50	1	0	0
	30-50	2	0	
	30-50	3	0	
	70-80	1	0	0
	70-80	2	0	
	70-80	3	0	

	80-90	1	0	0
	80-90	2	0	
	80-90	3	0	
	90-100	1	0	0
	90-100	2	0	
	90-100	3	0	
91 DAA	0-10	1	1.2	0.9
	0-10	2	0.8	
	0-10	3	0.7	
	10-20	1	0	0
	10-20	2	0	
	10-20	3	0	
	20-30	1	0	0
	20-30	2	0	
	20-30	3	0	

DAA: Days after application;
n. d.: not detected (residues are below the limit of detection (LOD), 0.15 µg/kg wet soil);
Where the wet weight residue was either <LOQ or n.d., the calculated g a.i. residue was set to zero. Residues were calculated using values rounded to 2 decimals.

Conclusion of the Applicant:

Residues of prosulfuron in soil following a bare soil application of prosulfuron as a 75 WG formulation (A8714C) declined to less than 10% of the residue observed at 0 DAA by 91 DAA and hence the time course of prosulfuron residues in soil following application onto bare soil as a broadcast spray could be determined. Residues of prosulfuron dissipated (declined) in soil under field conditions.

Reference:	KIIA 7.2.1 / 10
Report Title:	Prosulfuron – Soil Dissipation Study with Bare Soil Application in Saint-Cyprien, France in 2014-2015. Final Report.
Author(s) & Year:	[redacted] & [redacted]; 2016e
Document No, Authority registration No	S13-05219
Guideline(s):	Yes EPA OPPTS 835.6100; SETAC 1995; EFSA Journal 2010;8(12):1936; EFSA Journal 2014;12(5):3662
Deviations:	Deviation to EPA guideline (but in line with EFSA 2014): a single application was applied to a bare soil that was immediately covered with sand. This deviation has no impact on the outcome of the study.
GLP or GEP:	Yes
Acceptability:	Yes
Study relied upon:	Yes

Materials and methods:

Field dissipation behaviour of prosulfuron was investigated at Saint-Cyprien, southern France during 2014-2015. The plots were located on level ground (0 % slope) in an area typical for maize production which was not prone to flooding or erosion. The site had not been cultivated with trees or vines in the past 3 years prior to the study start. The soil characteristics are presented in Table B.8-131.

A single application of A8714C (a 750 g a.i./kg water dispersible granule (WG) formulation) was applied at a nominal rate of 20 g a.i./ha as a broadcast spray application to the bare soil surface on 23 June 2014. Following application, glyphosate was used to keep the plot generally weed free. No product containing prosulfuron had been used on the test plots in the last three years.

After application of the test item and post deposition tray sampling and before subsequent soil residue sampling, the control plot and the treated plot were immediately covered with a thin layer of untreated sand (particle size of approximately 2 mm) to remove soil surface processes. The application of sand was conducted by hand and using a shovel until complete coverage of the soil surface was achieved. The thickness of the sand layer was approximately 5 cm over the 3 treated subplots and the untreated control plot. Thickness of the sand cover was controlled and verified at least until 21 July 2014 (28 days after application, DAA). A renewal of the sand cover was not necessary. Within this time period of 28 days, the field received a total precipitation (rain and irrigation) of 42.4 mm.

Daily weather data (air temperature, air humidity, precipitation, solar radiation, wind speed, soil temperature (at 10 cm and 30 cm depth) and soil moisture (at 10 cm and 30 cm depth)) were recorded using a weather station located approximately 6 metres from subplot 1. The 30 year (1981 – 2010) long term weather data were taken from an official weather station located 20 km from the trial site.

The average air temperature during the field phase of the study was very similar to the 30 year long term average. Onsite air temperatures were colder in July 2014, August 2014 and February 2015. All other months were slightly warmer. Rainfall was more erratic. From June 2014 to June 2015 monthly rainfall was significantly lower (> 20 %

difference) than the long term average for 6 out of 12 months and significantly higher (> 20 % difference) than the long term average for 6 out of 12 months. The total rainfall from one day before application until last sampling (22 June 2014 – 26 June 2015) was 869.8 mm which was much higher than the long term average of 561.8 mm over the same time period. Very high rainfall was observed in September 2014 (162.4 mm), in November 2014 (317.6 mm) and in March 2015 (136.4 mm). Very low rainfall was observed in October 2014 (10.8 mm) and in May 2015 (5.6 mm). The plot was irrigated on months of lower rainfall to compensate for these drier months. A total of 230.2 mm irrigation was applied to account for the monthly deficits.

Untreated soil residue samples (0 – 100 cm depth) were taken at 4 days before application (DBA) from the treated and the untreated plot. Treated soil residue samples (0 – 30 cm cores) were taken after application (0 DAA) and at 1, 3 and 7 DAA. Treated soil residue 0 – 100 cm cores were taken at 14, 22, 28, 57, 87, 113, 175 and 358 DAA. Five soil cores were taken from each subplot, including control plot.

For verification of the application rate, two deposition trays (filled with sieved soil) were placed on the soil surface of each treated subplot during application and then sampled immediately after application.

Upon sample receipt, all samples were stored deep-frozen (≤ - 18 °C). The 0-30 cm soil cores were cut into depths 0 – 10, 10 – 20 and 20 – 30 cm. The 0 – 100 cm soil cores were generally cut into depths 0 – 10, 10 – 20, 20 – 30, 30 – 50, 50 – 70 and 70 – 100 cm. The deep frozen 0-10 cm soil cores required no cutting. For the 0 – 10, 10 – 20, 20 – 30, 30 - 50, 50 – 70 and 70 – 100 cm depths the individual subplot samples were combined and homogenised by grinding and sieving in the presence of dry ice. Two aliquots of at least 400 g frozen homogenized soil were taken and stored deep frozen.

For the extraction of the soil samples, a 10 g aliquot (recovery samples were prepared by fortifying blank soil) was extracted with 20 mL 0.2 M ammonium acetate/acetonitrile (20:80, v/v). The extract resulting from shaking was centrifuged before being diluted 1:1 with 0.2 M ammonium acetate/methanol (90/10; v/v). Samples were analysed by high performance liquid chromatography with triple quadrupole mass spectrometry determination (LC-MS/MS).

Table B. 8-21: Characteristics of the soils

Soil Depth (cm)	0-10	10-20	20-30	30-50	50-70	70-100
Soil type (USDA)	Loam	Loam	Loam	Loam	Sandy loam	Loam
% clay (<0.002 mm)	16.7	14.9	13.7	14.3	9.7	11.2
% silt (0.002-0.05 mm)	39.9	42.3	39.1	40.7	30.8	40.6
% sand (>0.05 mm)	43.5	42.9	47.3	45.1	59.6	48.2
% organic C	1.3	0.95	0.74	0.39	0.34	0.38
pH Water $CaCl_2$	 6.71 7.40	 6.77 7.49	 6.98 7.58	 6.71 7.44	 6.25 7.60	 6.28 7.43
Cation exchange capacity (meq/100g soil)	11.7	11.0	10.2	9.6	9.1	11.6
Soil bulk density (g/L)	1450	1540	1600	1360	1450	1440
Microbial biomass (mg C/100 g dry soil)	208.9					
Moisture at pF2	22.5 (1-4 cm)					

Findings:

The mean prosulfuron residue in the deposition trays was 15.5 g a.i./ha. This corresponded to an application rate of 77%, based on the target application rate of 20 g a.i./ha. The mean prosulfuron residue in the 0 DAA cores was 11.4 g a.i./ha. This corresponded to an application rate of 57 %, based on the target application rate of 20 g a.i./ha. These values confirm the correct application rate was applied to the trial plot.

The prosulfuron residue at 0 DAA was 11.4 g a.i./ha and declined throughout the study to reach a residue of 0.3 g a.i./ha by 175 DAA. Analysis of subsequent sampling interval cores was not required as prosulfuron had dissipated by >90 % by 175 DAA. Prosulfuron residues were only detected in the 0 – 10 cm soil layer and were not detected in the 10 – 20 cm soil layer throughout the study, except for residues between <LOQ and 1.5 g a.i./ha at 0 DAA and 1 DAA. Analysis of the soil layers below the 0 – 20 cm soil layer were not required except for at 0 and 1 DAA, where there was no detection of any prosulfuron residues in the 20-30 cm soil layers. Residues of prosulfuron were not detected in the 4 day before application (DBA) control soil samples.

The analytical method was validated with an LOQ = 0.50 µg/kg.

Table B. 8-22: Summary of the results (Saint-Cyprien)

Actual sampling interval	Core depth (cm)	Sub plot No.	Prosulfuron residue (g a.i./ha)	Mean prosulfuron residue (g a.i./ha)
0 DAA	0-10	1	14.4	11.4
	0-10	2	10.4	
	0-10	3	9.5	
	10-20	1	0	0
	10-20	2	0	
	10-20	3	0	
1 DAA	0-10	1	13.9	11.4
	0-10	2	11.1	
	0-10	3	9.1	
	10-20	1	0	0.5
	10-20	2	1.5	
	10-20	3	0	
	20-30	1	0	0
	20-30	2	0	
	20-30	3	0	
3 DAA	0-10	1	6.9	10.6
	0-10	2	14.8	
	0-10	3	10.2	
	10-20	1	0	0
	10-20	2	0	
	10-20	3	0	
7 DAA	0-10	1	5.9	8.6
	0-10	2	11.5	
	0-10	3	8.4	
	10-20	1	0	0
	10-20	2	0	
	10-20	3	0	
14 DAA	0-10	1	3.8	6.6
	0-10	2	12.3	
	0-10	3	3.7	
	10-20	1	0	0
	10-20	2	0	
	10-20	3	0	
22 DAA	0-10	1	6.4	5.2
	0-10	2	3.7	
	0-10	3	5.6	
	10-20	1	0	0
	10-20	2	0	
	10-20	3	0	
28 DAA	0-10	1	4.9	4.9
	0-10	2	4.3	

	0-10	3	5.4	
	10-20	1	0	0
	10-20	2	0	
	10-20	3	0	
57 DAA	0-10	1	2.3	4.4
	0-10	2	5.4	
	0-10	3	5.5	
	10-20	1	0	0
	10-20	2	0	
	10-20	3	0	
87 DAA	0-10	1	1.4	2.3
	0-10	2	2.9	
	0-10	3	2.7	
	10-20	1	0	0
	10-20	2	0	
	10-20	3	0	
113 DAA	0-10	1	1.4	1.7
	0-10	2	1.7	
	0-10	3	2.1	
	10-20	1	0	0
	10-20	2	0	
	10-20	3	0	
175 DAA	0-10	1	0	0.3
	0-10	2	0	
	0-10	3	0.8	
	10-20	1	0	0
	10-20	2	0	
	10-20	3	0	

DAA: Days after application;
n. d.: not detected (residues are below the limit of detection (LOD), 0.15 µg/kg wet soil);
Where the wet weight residue was either <LOQ or n.d., the calculated g a.i. residue was set to zero. Residues were calculated using values rounded to 2 decimals.

Conclusion of the Applicant:

Residues of prosulfuron in soil following a bare soil application of prosulfuron as a 75 WG formulation (A8714C) declined to less than 10% of the residue observed at 0 DAA by 175 DAA and hence the time course of prosulfuron residues in soil following application onto bare soil as a broadcast spray could be determined. Residues of prosulfuron dissipated (declined) in soil under field conditions.

Reference:	KIIA 7.2.1 / 11
Report Title:	Prosulfuron – Soil Dissipation Study with Bare Soil Application in Canals, Spain in 2014-2015. Final Report.
Author(s) & Year:	[redacted] & [redacted]; 2016f

Document No, Authority registration No	S13-05220
Guideline(s):	Yes EPA OPPTS 835.6100; SETAC 1995; EFSA Journal 2010;8(12):1936; EFSA Journal 2014;12(5):3662
Deviations:	Deviation to EPA guideline (but in line with EFSA 2014): a single application was applied to a bare soil that was immediately covered with sand. This deviation has no impact on the outcome of the study.
GLP or GEP:	Yes
Acceptability:	Yes
Study relied upon:	Yes

Materials and methods:

Field dissipation behaviour of prosulfuron was investigated at Canals, Spain during 2014-2015. The plots were located on level ground (0 % slope) in an area typical for maize production which was not prone to flooding or erosion. The site had not been cultivated with trees or vines in the past 3 years prior to the study start. The soil characteristics are presented in Table B.8-133.

A single application of A8714C (a 750 g a.i./kg water dispersible granule (WG) formulation) was applied at a nominal rate of 20 g a.i./ha as a broadcast spray application to the bare soil surface on 23 June 2014. Following application, glyphosate was used to keep the plot generally weed free. No product containing prosulfuron had been used on the test plots in the last three years

After application of the test item and collection of the deposition tray samples, the control plot and the treated subplots were immediately covered with a thin layer of untreated sand (particle size of approximately ≤ 2 mm) to remove soil surface processes. The application of sand was conducted by hand and using a bucket until complete coverage of the soil surface was achieved. The thickness of the sand layer was approximately 3-8 mm over the 3 treated subplots and 3-7 mm on the untreated control plot. Thickness of the sand cover was only measured on the application day. The homogeneity of the sand cover was checked visually at least until 24 June 2014 (1 day after application, DAA). A renewal of the sand cover was not necessary. Within this time period of 1 day, the field received a total precipitation (rain and irrigation) of 11.6 mm.

Daily weather data (air temperature, air humidity, precipitation, solar radiation, wind speed, soil temperature (at 10 cm and 30 cm depth) and soil moisture (at 10 cm and 30 cm depth)) were recorded using a weather station located approximately 2.5 metres from the treated plot. The 10 year (2002 – 2011) long term weather data were taken from an official weather station located 5.6 km from the trial site.

The average air temperature during the field phase of the study was very similar to the 10 year long term average. Onsite air temperatures were colder in winter /early spring 2015 (December, January, February), June 2015, July 2014 and they were slightly warmer in June 2014, August to November 2014, March, April and May 2015. Rainfall was more erratic. From June 2014 to June 2015 monthly rainfall was significantly lower (> 20% difference) than the long term average for 6 out of 12 months and significantly higher (> 20% difference) than the long term average for 5 out of 12 months. The total rainfall from the date of first sampling until last sampling included in this report (18 June 2014 – 24 June 2015) was 568.8 mm which is a little lower than the long term average of 596.7 mm over the same time period. Very high rainfall was observed in Nov 2014 (103.4 mm) and Mar 2015 (186.4 mm). Very low rainfall was observed in August 2014 (0.6 mm), Oct 2014 (24.0 mm), January 2015 (13.4mm), April 2015 (1.4 mm) and May 2015 (8.8 mm). The plot was irrigated on months of lower rainfall to compensate for these drier months. A total of 456.6 mm irrigation was applied to the treated plot, to account for the monthly deficits.

Untreated soil residue samples (0 – 100 cm depth) were taken at 5 days before application (DBA) from the treated and the untreated plot. Treated soil residue samples (0 – 30 cm cores) were taken after application (0 DAA) and at 1, 3 and 7 DAA. Treated soil residue 0 – 100 cm cores were taken at 14, 21, 29, 58, 91, 116, 184 and 366 DAA. Five soil cores were taken from each subplot, including control plot.

For verification of the application rate, two deposition trays (filled with sieved soil) were placed on the soil surface of each treated subplot prior to application and then sampled immediately after application.

Upon sample receipt, all samples were stored deep-frozen (≤ - 18 °C). The 0-30 cm soil cores were cut into depths 0 – 10, 10 – 20 and 20 – 30 cm. The 0 – 100 cm soil cores were generally cut into depths 0 – 10, 10 – 20, 20 – 30, 30 – 50, 50 – 70 and 70 – 100 cm. For the 0 – 10, 10 – 20, 20 – 30, 30 - 50, 50 – 70 and 70 – 100 cm depths the individual subplot samples were combined and homogenised by grinding and sieving in the presence of dry ice. Two aliquots of at least 400 g frozen homogenized soil were taken and stored deep frozen.

For the extraction of the soil samples, a 10 g aliquot (recovery samples were prepared by fortifying blank soil) was extracted with 20 mL 0.2 M ammonium acetate/acetonitrile (20:80, v/v). The extract resulting from shaking was centrifuged before being diluted 1:1 with 0.2 M ammonium acetate/methanol (90/10; v/v). Samples were analysed by high performance liquid chromatography with triple quadrupole mass spectrometry determination (LC-MS/MS).

Table B. 8-23: Characteristics of the soils

Soil Depth (cm)	0-10	10-20	20-30	30-50	50-70	70-100
Soil type (USDA)	Clay	Clay	Clay	Clay loam	Clay loam	Clay loam
% clay (<0.002 mm)	44.0	44.3	45.3	33.9	31.4	33.2
% silt (0.002-0.05 mm)	32.3	31.7	31.6	45.4	46.4	41.1
% sand (>0.05 mm)	23.7	24.1	23.2	20.8	22.3	25.8
% organic C	0.71	0.64	0.63	0.48	<0.3	<0.3
pH Water $CaCl_2$	 7.75 7.60	 7.67 7.60	 7.91 7.61	 7.83 7.68	 8.06 7.70	 7.99 7.68
Cation exchange capacity (meq/100g soil)	19.5	19.8	20.3	22.0	21.9	22.2
Soil bulk density (g/L)	1400	1310	1200	1480	1550	1630
Microbial biomass (mg C/100 g dry soil)	54.0					
Moisture at pF2	22.6 (1-4 cm)					

Findings:

The mean prosulfuron residue in the deposition trays was 18.0 g a.i./ha. This corresponded to an application rate of 90%, based on the target application rate of 20 g a.i./ha. The mean prosulfuron residue in the 0 DAA cores was 17.4 g a.i./ha. This corresponded to an application rate of 87 %, based on the target application rate of 20 g a.i./ha. These values confirm the correct application rate was applied to the trial plot.

The prosulfuron residue at 0 DAA was 17.4 g a.i./ha and declined throughout the study to reach a residue of 0 g a.i./ha (wet weight residue values were not detected (<0.15 µg/kg)) by 184 DAA. Analysis of subsequent sampling interval cores was not required as prosulfuron had dissipated by >90 % by 184 DAA. Prosulfuron residues were initially detected in the 10 – 20 cm soil layer at 14 DAA at a level of 0.3 g a.i./ha. The prosulfuron residue in the 10 – 20 cm soil layer increased to 1.0 g a.i./ha at 21 DAA before decreasing to be below LOQ (<0.5 µg/kg) by 58 DAA. No prosulfuron residues were detected in the analysed 20-30 cm soil layers. Analysis of the soil layers below the 20 – 30 cm soil layer was not required. Residues of prosulfuron were not detected in the 5 day before application (DBA) control soil samples.

The analytical method was validated with an LOQ = 0.50 µg/kg.

Table B. 8-24: Summary of the results (Canals)

Actual sampling interval	Core depth (cm)	Sub plot No.	Prosulfuron residue (g a.i./ha)	Mean prosulfuron residue (g a.i./ha)
0 DAA	0-10	1	19.5	17.4
	0-10	2	13.3	
	0-10	3	19.4	
	10-20	1	0	0
	10-20	2	0	
	10-20	3	0	
1 DAA	0-10	1	17.5	16.9
	0-10	2	19.9	
	0-10	3	13.2	
	10-20	1	0	0
	10-20	2	0	
	10-20	3	0	
3 DAA	0-10	1	14.1	13.4
	0-10	2	10.8	
	0-10	3	15.4	
	10-20	1	0	0
	10-20	2	0	
	10-20	3	0	
7 DAA	0-10	1	9.0	11.4
	0-10	2	9.3	

	0-10	3	16.0	
	10-20	1	0	0
	10-20	2	0	
	10-20	3	0	
14 DAA	0-10	1	10.1	9.7
	0-10	2	8.4	
	0-10	3	10.7	
	10-20	1	1.0	0.3
	10-20	2	0	
	10-20	3	0	
	20-30	1	0	0
	20-30	2	0	
	20-30	3	0	
21 DAA	0-10	1	10.2	8.7
	0-10	2	7.7	
	0-10	3	8.3	
	10-20	1	0.9	1.0
	10-20	2	1.1	
	10-20	3	1.0	
	20-30	1	0	0
	20-30	2	0	
	20-30	3	0	
29 DAA	0-10	1	6.8	7.0
	0-10	2	5.9	
	0-10	3	8.3	
	10-20	1	1.1	0.4
	10-20	2	0	
	10-20	3	0	
	20-30	1	0	0
	20-30	2	0	
	20-30	3	0	
58 DAA	0-10	1	3.9	2.6
	0-10	2	1.8	
	0-10	3	2.1	
	10-20	1	0	0
	10-20	2	0	
	10-20	3	0	
	20-30	1	0	0
	20-30	2	0	
	20-30	3	0	
91 DAA	0-10	1	2.5	2.1
	0-10	2	1.9	
	0-10	3	2.0	
	10-20	1	0	0
	10-20	2	0	
	10-20	3	0	
	20-30	1	0	0

	20-30	2	0	
	20-30	3	0	
116 DAA	0-10	1	1.5	0.9
	0-10	2	0	
	0-10	3	1.1	
	10-20	1	0	0
	10-20	2	0	
	10-20	3	0	
	20-30	1	0	0
	20-30	2	0	
	20-30	3	0	
184 DAA	0-10	1	0	0
	0-10	2	0	
	0-10	3	0	
	10-20	1	0	0
	10-20	2	0	
	10-20	3	0	
	20-30	1	0	0
	20-30	2	0	
	20-30	3	0	

DAA: Days after application;
n. d.: not detected (residues are below the limit of detection (LOD), 0.15 µg/kg wet soil);
Where the wet weight residue was either <LOQ or n.d., the calculated g a.i. residue was set to zero. Residues were calculated using values rounded to 2 decimals.

Conclusion of the Applicant:

Residues of prosulfuron in soil following a bare soil application of prosulfuron as a 75 WG formulation (A8714C) declined to less than 10% of the residue observed at 0 DAA by 184 DAA and hence the time course of prosulfuron residues in soil following application onto bare soil as a broadcast spray could be determined. Residues of prosulfuron dissipated (declined) in soil under field conditions.

Conclusion of HSE:

Six new field soil dissipation studies and separate kinetic modelling reports have been provided for parent prosulfuron ([redacted] and [redacted], 2016a-f/dissipation studies and [redacted] and [redacted], 2016a and [redacted], 2018/kinetics). The study summaries prepared by the applicant are presented above. HSE considers that the summaries represent an accurate summary of the experimental work of [redacted] and [redacted], 2016a-f. Minor additional points are noted below.

Separate study summaries were provided for each field dissipation study, however, the study conduct was essentially consistent across each site. The analytical method

CIG 152 B ([redacted], 1994) used LC-MS/MS and was reported in the original EU draft assessment report (DAR) and was fully validated for the determination of prosulfuron and metabolites CGA 159902, CGA 300406 and CGA150829 in soil with LOQ = 0.5 µg/kg for each analyte. It has therefore not been further considered as part of this Article 7 amendment application. The application methodology included application of a sand layer after application to minimise surface processes in line with the EFSA $DegT_{50}$ guidance. Although measured residues on day 0 were variable and typically below the intended application rate of 20 g a.s./ha, levels were not outside normal variation for such studies. The LOQ was reported to be 0.5 µg/kg based on wet weight residue values, however, tabulated results were only reported after conversion to a g/ha rate. The conversion to g/ha is an acceptable approach, particularly where low levels of residues were detected in the 10-20 cm soil horizon in some sites and the areic measure of g/ha allowed total residues in both horizons to be more easily summed. But for completeness HSE has used an identical conversion process to convert the LOQ of 0.5 µg/kg to approximately 0.7 g/ha (variable due to different bulk densities at each site). The LOQ was therefore confirmed as appropriate to quantify residues down to at least 10% of initially applied (equivalent to a DT_{90}).

The summary stated that no product containing prosulfuron had been used on test plots in the last three years. HSE has reviewed and subsequently confirmed that as well as no products containing prosulfuron, no products containing sulfonyl urea herbicides, that could be potentially structurally similar to prosulfuron, were used. This is important to reduce analytical interferences and potential microbial adaptations for the test.

As an additional point, whilst it is recognised that the applicant's primary purpose of this study is to obtain $DegT_{50}$ values for exposure modelling, it is still a field dissipation study. The results presented ideally should primarily represent the parameter measured in the study, i.e. mg/kg or µg/kg residues, as well as the g/ha values which have to be calculated from the primary measured parameter. HSE has checked a subset of the calculations where the original concentration values measured in the study were converted to g/ha and is content that the conversion was correctly conducted. Note that within the field dissipation study report values below the LOQ or LOD were set to zero for the calculation of g/ha levels. However in the subsequent kinetic modelling reports (see [redacted] and [redacted], 2016a and b), residues below the LOQ and LOD were handled in accordance with the FOCUS kinetics guidance, for example by setting the first timepoint values less than LOD as ½ LOD and excluding subsequent timepoints also below the LOD etc.

Overall the studies appeared to be well conducted with no significant deviations from accepted guidelines and are therefore appropriate for derivation of modelling endpoints.

Two separate reports have been provided which detail kinetic assessments for modelling endpoint selection from the field dissipation studies of [redacted] and [redacted], 2016a-f. The first report by [redacted] and [redacted], 2016a below was based on time step normalisation using measured daily on-site soil temperature data combined with simulated daily soil moisture contents derived from PEARL v4.4.4 evaluations. The PEARL simulations used site specific soil information and meteorological data from on-site weather stations. The first report also used pF2 values from HYPRES and calculated soil bulk densities rather than the measured pF2 and measured bulk density data that were available for each site. The later study of [redacted], 2018 was provided by the applicant as a result of the EU Article 7 amendment application process which requested the use of measured daily on site soil temperature and measured daily on-site soil moisture data in the time step normalisation process. The study summaries prepared by the applicant are presented below.

Reference:	KIIA 7.2.1 / 12
Report Title:	Prosulfuron – Kinetic Modelling Evaluation of Data from Field Soil Dissipation Studies Normalised to 20°C (Q10 2.58). Final Report.
Author(s) & Year:	[redacted]. & [redacted]; 2016a
Document No, Authority registration No	NC/15/041A
Guideline(s):	Yes FOCUS Kinetics Guidance (2006), EFSA Journal (2014);12(5):3662
Deviations:	None
GLP or GEP:	No (not applicable modelling study)
Acceptability:	Yes

Study relied upon:	Yes

Materials and methods:

Timestep normalisation was used to calculate DegT50 values corrected to the standard conditions of 20ºC and moisture at 10 kPa (pF2), in order to produce values suitable for use in environmental models.

The rate of degradation of prosulfuron applied to bare soil followed by sand coverage has been studied in the field in six studies: [[redacted] & [redacted] (a-f)]. Kinetic modelling following the appropriate FOCUS Kinetics (2006) flowcharts was carried out using CAKE v3.1 (2015).

Measured daily on-site soil temperatures were used, taken directly from the study data. Daily soil moisture contents were derived from PEARL (4.4.4) evaluations with meteorological data from on-site weather stations. Data for a warm-up period prior to the study were taken from MARS database. For temperature correction a Q_{10} factor of 2.58 and a B-factor (moisture exponent) of 0.7 were used.

Using the available daily meteorological measurements, robust estimates for the moisture content along with soil temperature were predicted for a three year period encompassing the study duration. These parameters were estimated with the PEARL 4.4.4 simulation model. PEARL meteorological files were generated from daily weather data (minimum, maximum air temperature, rainfall, humidity, solar radiation and windspeed).

PEARL input files were set up, with the van Geneuchten parameters being estimated with the HYPRES[6] database, using the soil characterisation data obtained for the study. Soil bulk density was not available and was therefore estimated based on the organic matter content (OM) using the following formula:

Bulk density (g/L) = 1800 + 1236*OM – 2910*SQRT(OM)

[6] http://eusoils.jrc.it/ESDB_Archive/ ESDBv2/ popup/hy_param.htm

The PEARL model was run using the site-specific soil properties and meteorological data with the estimated daily soil temperature and volumetric moisture content for each 2.5cm layer stored in an output file. This file was then processed in Excel to calculate the average soil temperature and moisture contents in the top 10cm for each day. For consistency, pF2 values used in the timestep evaluation were estimated with the pedo transfer functions used to parameterise PEARL (Table B.8-135).

The M0 values for each soil were determined through free optimisation of parameters. The first timepoint with residues declining below LOQ was set to ½ (LOQ+LOD), and values less than LOD were set to ½ LOD according to FOCUS Kinetics approaches. Subsequent values below LOD were not included.

Confidence in the resulting parameters was assessed visually and from the confidence intervals for the α and β parameters of the first order multicompartment (FOMC) model or probability values for a t-test of the rate parameters for the single first order (SFO), dual first order in parallel (DFOP) models. Where the parameters for a particular model were not significantly different from zero at the 95^{th} or 90^{th} significance level, it was concluded that the model is not appropriate to represent the degradation behaviour in that soil. The $\chi 2$ error% parameter was used to determine goodness of fit and where two models were appropriate to fit the data, the choice of best fit was based on the lowest value of this parameter.

In the original data for the Spanish trial, erroneous core diameters were given. The recalculated residue data for this trial resulting from that change in core diameter were taken into account for these calculations.

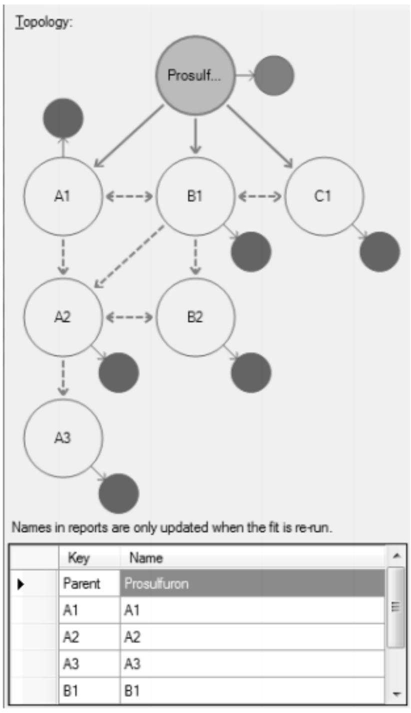


Figure B.8-127: Example kinetic modelling scheme in CAKE 3.1

Table B. 8-25: Estimated pF2 values

Trial	Texture	pF2 (% v/v)
Bogense (DK)	Sandy loam	26.6
Castelsarrasin (FR1)	Silt loam	33.4
St. Cyprien (FR2)	Loam	31.8
Breitenwisch (DE)	Clay loam	40.3
Canals (ES)	Clay	36.2
Wilson (UK)	Loam	36.7

Table B. 8-26: Summary of reported prosulfuron data

Bogense (DK)		Castelsarrasin (FR1)		St. Cyprien (FR2)	
Time (days)	PSF (g ai/ha)	Time (days)	PSF (g ai/ha)	Time (days)	PSF (g ai/ha)
0	23.4	0	10.6	0	14.4
0	19.8	0	10.9	0	11.0
0	23.8	0	11.9	0	10.0
1	13.2	1	11.2	1	14.4
1	12.4	1	8.3	1	12.6
1	13.3	1	3.9	1	9.1
3	13.1	3	12.7	3	6.9
3	12.0	3	5.7	3	14.9
3	14.8	3	6.9	3	10.2
7	9.3	7	9.7	7	5.9
7	9.2	7	6.6	7	11.5
7	8.9	7	5.9	7	8.4
15	8.1	15	4.1	14	3.8
15	5.5	15	3.3	14	12.3
15	8.1	15	5.0	14	3.7
17	7.5	21	2.2	22	6.4
17	7.5	21	1.9	22	3.7
17	8.2	21	2.8	22	5.6
21	6.5	28	2.1	28	4.9
21	5.3	28	1.5	28	4.3
21	7.7	28	1.6	28	5.4
28	4.0	58	0.5	57	2.3
28	5.3	58	0.6	57	5.4
28	5.7	58	0.6	57	5.5
58	3.3	93	0.7	87	1.4
58	2.5	93	0.2	87	2.9
58	3.6	93	0.7	87	2.7
93	1.3	-	-	113	1.4
93	1.3	-	-	113	1.7
93	2.3	-	-	113	2.1
-	-	-	-	175	0.5
-	-	-	-	175	0.5
-	-	-	-	175	0.8

Breitenwisch (DE)		Canals (ES)		Wilson (UK)	
Time (days)	PSF (g ai/ha)	Time (days)	PSF (g ai/ha)	Time (days)	PSF (g ai/ha)
0	15.5	0	19.5	0	14.6
0	15.1	0	13.3	0	12.0
0	14.0	0	19.4	0	10.0
1	14.4	1	17.5	1	13.2
1	16.9	1	19.9	1	12.6
1	21.2	1	13.2	1	10.3
3	15.2	3	14.1	3	14.0
3	13.5	3	10.8	3	17.0
3	12.1	3	15.4	3	15.1
7	13.0	7	9.1	7	8.2
7	10.6	7	9.3	7	11.7
7	11.2	7	16.0	7	8.8
15	4.3	14	11.1	13	7.6
15	3.2	14	8.5	13	8.1
15	3.3	14	11.2	13	6.1
21	3.0	21	11.1	21	1.7
21	3.3	21	8.8	21	2.9
21	3.7	21	9.2	21	2.9
30	1.7	29	7.9	28	3.2
30	1.3	29	6.4	28	2.3
30	1.6	29	8.8	28	2.1
59	0.6	58	3.9	57	1.6
59	0.6	58	1.9	57	1.5
59	0.5	58	2.2	57	1.6
-	-	91	3.0	91	1.2
-	-	91	2.4	91	0.8
-	-	91	2.5	91	0.7
-	-	116	2.1	-	-
-	-	116	1.2	-	-
-	-	116	1.7	-	-
-	-	184	0.1	-	-
-	-	184	0.1	-	-
-	-	184	0.1	-	-

Table B. 8-27: Timestep normalised sampling times

Bogense (DK)		Castelsarrasin (FR1)		St. Cyprien (FR2)	
Time (days)	Time step (days)	Time (days)	Time step (days)	Time (days)	Time step (days)
0	0.0	0	0.0	0	0.0
1	0.8	1	1.1	1	1.4
3	2.3	3	3.6	3	4.2
7	6.3	7	8.5	7	9.5
15	14.6	15	17.3	14	18.8
17	16.6	21	25.9	22	30.2
21	21.6	28	35.3	28	41.5
28	30.9	58	69.9	57	91.0
58	56.9	93	110.7	87	136.4
93	80.6	-	-	113	167.3
-	-	-	-	175	207.7

Breitenwisch (DE)		Canals (ES)		Wilson (UK)	
Time (days)	Time step (days)	Time (days)	Time step (days)	Time (days)	Time step (days)
0	0.0	0	0.0	0	0.0
1	0.8	1	1.7	1	1.1
3	2.3	3	4.7	3	3.1
7	6.8	7	11.9	7	6.3
15	16.7	14	25.8	13	11.9
21	25.3	21	41.4	21	19.7
30	37.6	29	60.3	28	27.8
59	65.0	58	125.8	57	58.0
-	-	91	192.6	91	82.8
-	-	116	224.0	-	-
-	-	184	269.3	-	-

Findings:

The prosulfuron degradation data (Table B.8-136) and timestep data (Table B.8-137) were entered into the CAKE 3.1 scheme. Optimisations with SFO kinetics showed both visually and statistically acceptable fits to the FR1, FR2, DE, ES and UK trials. Optimisation with DFOP kinetics showed both visually and statistically acceptable fits to the DK trial.

Table B. 8-28: DegT50 values for prosulfuron normalised to reference conditions of 20°C and pF2

Soil (code) (ref)	Bogense (DK) [Gezahegne (a)]	Bogense (DK) [Gezahegne (a)]	Bogense (DK) [Gezahegne (a)]
Kinetic Model	SFO	FOMC	DFOP
Cake output location (report page)	36	40	44
Visual Fit	Poor	Poor	Good
Residuals (visual)	Poor	Poor	Good
χ2 error (%)	22.6	12.3	7.65
Initial value: estimate / (range) / standard error	P_{ini}: 16.43 (14.45-18.42) σ: 0.9676	P_{ini}: 22.01 (20.04-23.99) σ: 0.9629	P_{ini}: 22.33 (20.82-23.85) σ: 0.737
Rate Parameters: estimate / standard error / probability (trigger:0.05)	k: 0.04785 σ: 0.007206 p: 1.67×10^{-7}	α: 0.3224 σ: 0.04098 95th %ile CI does not contain 0	k_1: 3.193 σ: 1.544 p: 0.02433
		β: 0.3636 σ: 0.1671 90th %ile CI does not contain 0	k_2: 0.0297 σ: 0.003391 p: 1.56×10^{-9}
			g: 0.4386 σ: 0.03483
$DegT_{50}$ (days)	14.5	138[a]	23.3[b]
$DegT_{90}$ (days)	48.1	459	77.4[c]
FOCUS decision step	SFO unacceptable; 10% of P_{ini} reached within experimental period; fit FOMC	FOMC unacceptable (poor fit around DT90 and the end of the study); expert judgement; fit DFOP	DFOP better than FOMC, acceptable; DFOP selected as best fit. Slow phase k_2 used to calculate DT_{50} as worst case

[a] $DegT_{90}$ / 3.32
[b] k_2 $DegT_{50}$
[c] k_2 $DegT_{90}$

Soil (code) (ref)	Castelsarrasin (FR1) [Gezahegne (b)]	St. Cyprien (FR2) [Gezahegne (c)]
Kinetic Model	SFO	SFO
Cake output location (report page)	48	52
Visual Fit	Good	Good
Residuals (visual)	Good	Good
χ2 error (%)	12.6	14.6
Initial value: estimate / (range) / standard error	P_{ini}: 10.01 (8.601-11.41) σ: 0.6817	P_{ini}: 10.96 (9.44-12.48) σ: 0.746
Rate Parameters: estimate / standard error / probability (trigger:0.05)	k: 0.04975 σ: 0.009049 $p = 5.17 \times 10^{-6}$	k: 0.01603 σ: 0.00339 $p = 2.33 \times 10^{-5}$
$DegT_{50}$ (days)	13.9	43.2
$DegT_{90}$ (days)	46.3	144
FOCUS decision step	SFO acceptable	

Soil (code) (ref)	Breitenwisch (DE) [Gezahegne (d)]	Canals (ES) [Gezahegne (e)]	Wilson (UK) [Gezahegne (f)]
Kinetic Model	SFO	SFO	SFO
CAKE output loation (report page)	56	60	64
Visual Fit	Good	Good	Acceptable
Residuals (visual)	Good	Good	Acceptable
χ2 error (%)	11.3	11.1	18.3
Initial value: estimate / (range) / standard error	P_{ini}: 16.54 (15.18-17.89) σ: 0.6524	P_{ini}: 15.71 (14.31-17.12) σ: 0.6889	P_{ini}: 13.91 (12.34-15.48) σ: 0.7626
Rate Parameters: estimate / standard error / probability / break point (trigger:0.05)	k: 0.06879 σ: 0.00789 $p = 6.87 \times 10^{-9}$	k: 0.01291 σ: 0.001758 $p = 1.45 \times 10^{-8}$	k: 0.0584 σ: 0.008748 $p = 2.70 \times 10^{-7}$
$DegT_{50}$ (days)	10.1	53.7	11.9
$DegT_{90}$ (days)	33.5	178	39.4
FOCUS decision step	SFO acceptable		

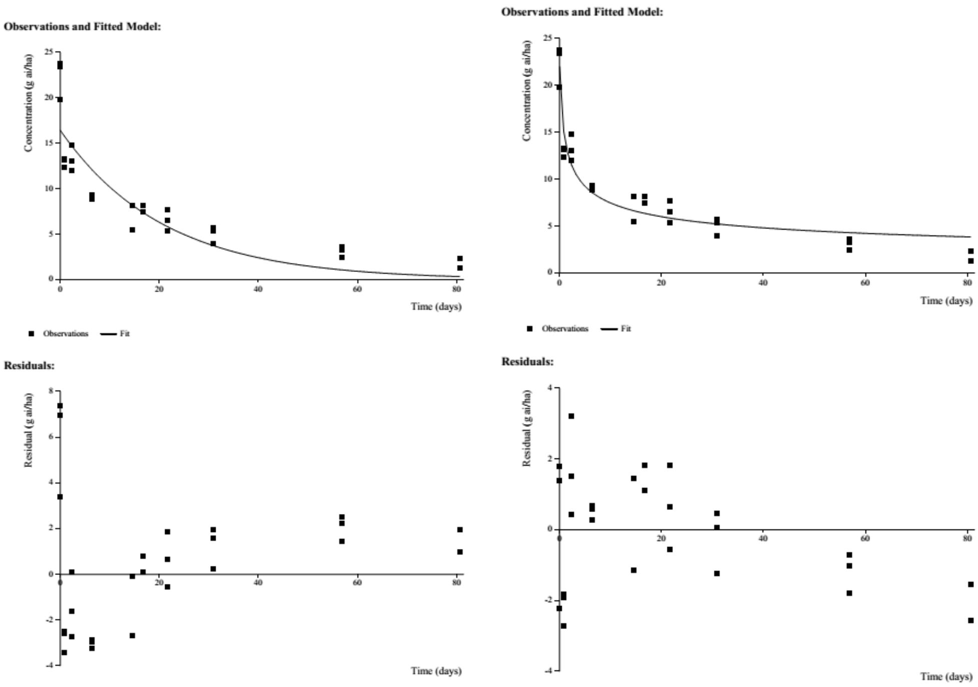


Figure B.8-128: Modelling endpoints; fitting of data and residual plots for Bogense trial; SFO (left), FOMC (right)

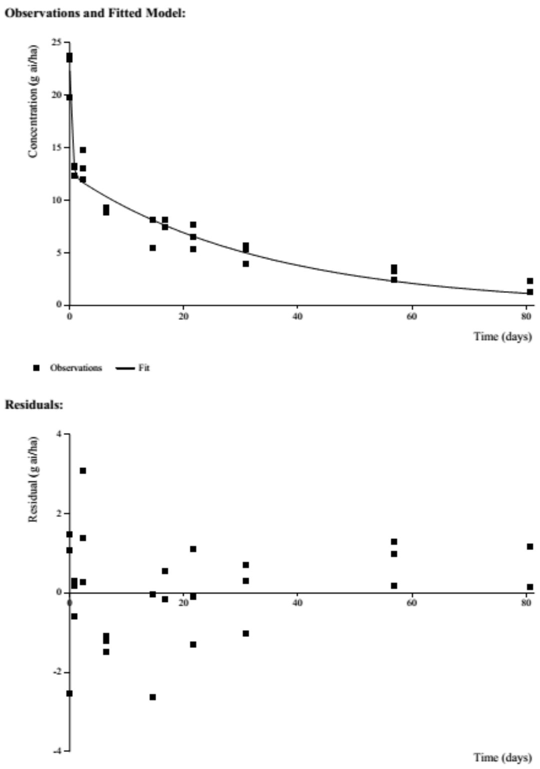


Figure B.8-129: Modelling endpoints; fitting of data and residual plots for Bogense trial; DFOP

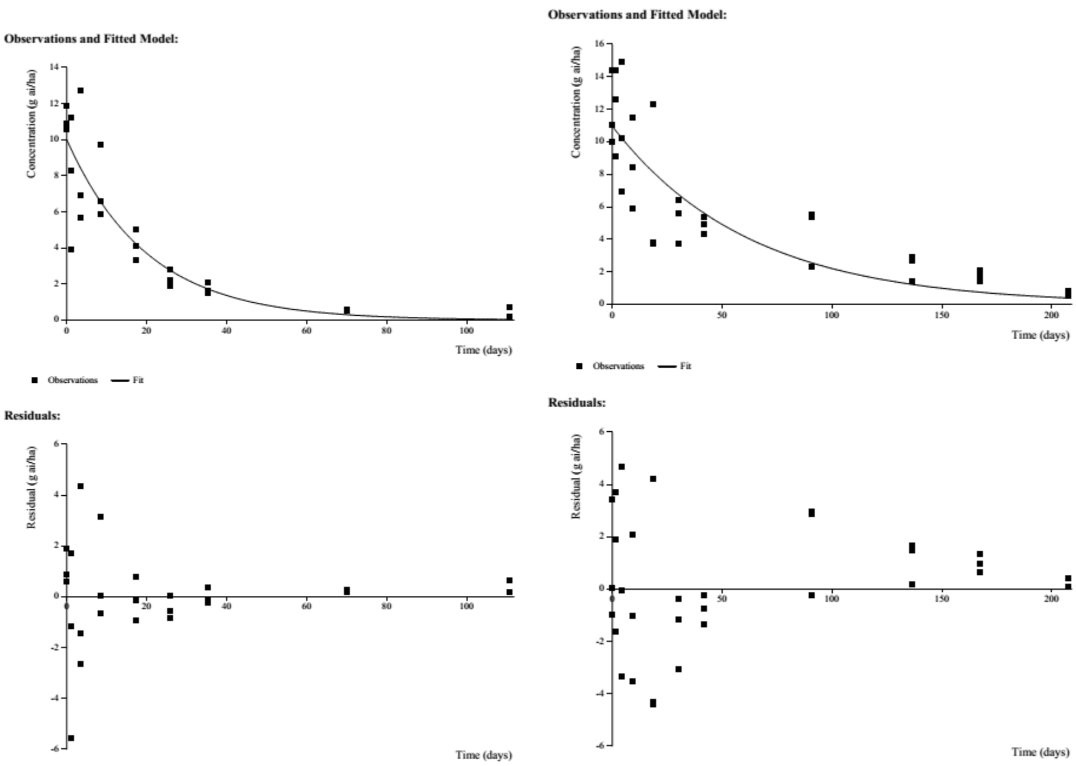


Figure B.8-130: Modelling endpoints; fitting of data and residual plots for Castelsarrasin trial (left; SFO) and for St. Cyprien (right; SFO)

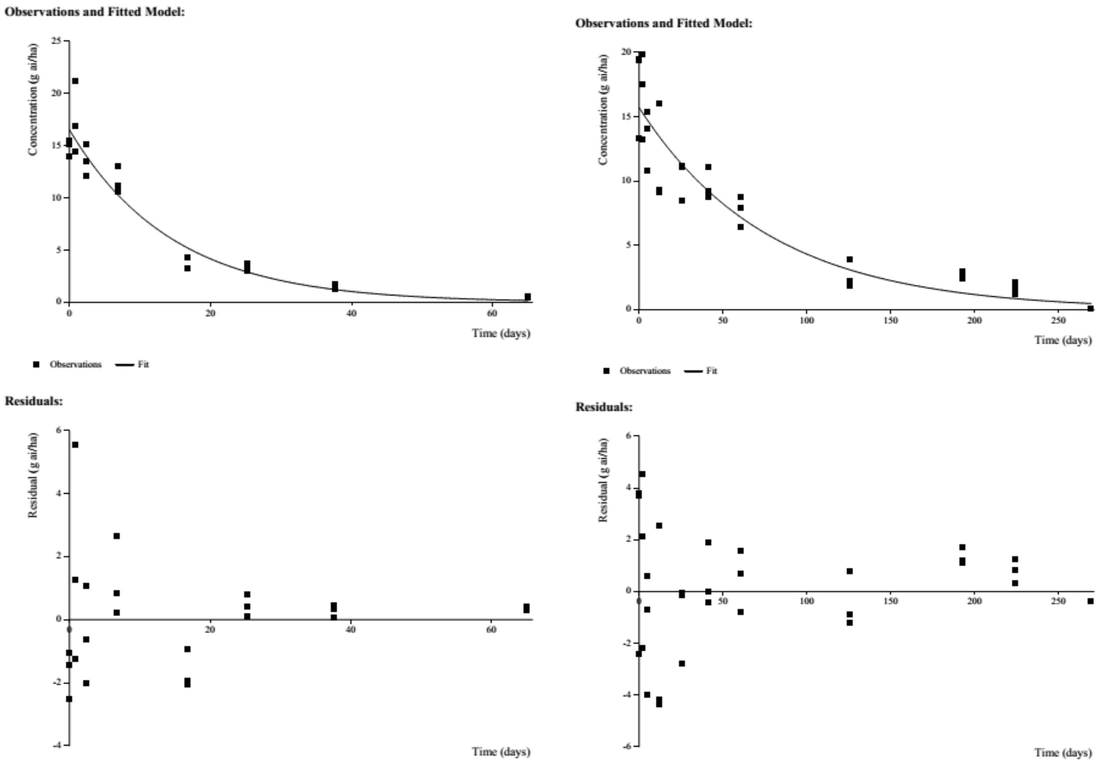


Figure B.8-131: Modelling endpoints; fitting of data and residual plots for Breitenwisch trial (left; SFO) and for Canals (right; SFO)

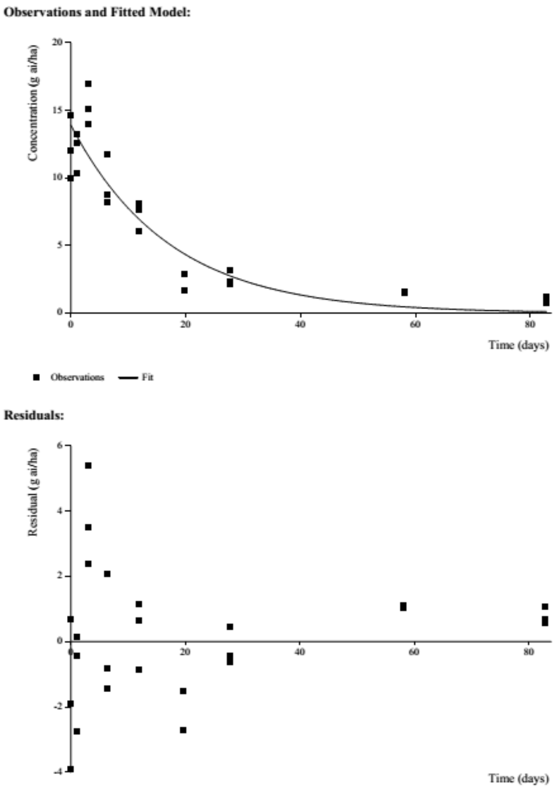


Figure B.8-132: Modelling endpoints; fitting of data and residual plots for Wilson trial (SFO)

Table B. 8-29: Summary of modelling endpoint DegT50 values for prosulfuron

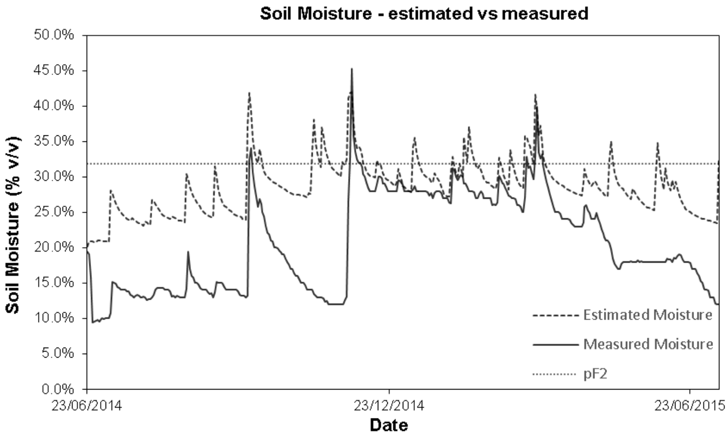
Soil name	Soil texture	Soil pH (water)	DegT50 (days)	Kinetic model	Reference
Bogense (DK)	Sandy loam	5.07	23.3	DFOP k_2	[redacted] & [redacted] (c)
Castelsarrasin (FR1)	Silt loam	4.94	13.9	SFO	[redacted] & [redacted] (b)
St. Cyprien (FR2)	Loam	6.71	43.2	SFO	[redacted] & [redacted] (e)
Breitenwisch (DE)	Clay loam	4.89	10.1	SFO	[redacted] & [redacted] (a)
Canals (ES)	Clay	7.75	53.7	SFO	[redacted] & [redacted] (f)
Wilson (UK)	Loam	7.16	11.9	SFO	[redacted] & [redacted] (d)
Geometric mean (n=6)			**21.2**		

Conclusion of the Applicant:

The kinetic evaluations yielded a total of six $DegT_{50}$ values for prosulfuron which have been used to calculate the geometric mean $DegT_{50}$ of 21.2 days. This value is suitable for use in environmental models.

Conclusion of HSE:

In terms of the approach of using either measured or simulated soil moisture data, HSE notes that there is limited external guidance available. The use of simulated data (via appropriately parameterised PEARL simulations) has been accepted in the past in situations where, for example, measured on-site data is either missing or there is an incomplete record as a result of on-site instrument failure. In this case, the study author provided further information to justify the use of simulated moisture data. With regards to the measured soil moisture data, although a complete record was available for each site, including during winter months, the study author argued that there were inconsistencies in the measured data when compared with simulated data. HSE considers that the term "*inconsistencies in measured data*" could be slightly misleading, and since it is not known which set of data best represents the true value, it might be more appropriate to simply state that there were "differences" between measured and simulated data. An example from one of the French trial sites is shown below, and illustrates that measured values were generally below estimated values. In terms of the normalisation, using measured data would be expected to have the effect of reducing corrected day lengths compared to simulated data (since field conditions would be calculated to deviate further from pF2), ultimately reducing normalised DT_{50}s. The applicant approach based on simulated data would therefore be conservative and result in longer DT_{50} values.



For bulk density, the study author noted that measured data was only available for four designated 0-100cm soil cores from the trial plot boundaries. When these were compared to estimated values, at 4 sites there was no significant difference but at two sites the measured bulk densities were either significantly higher or lower than expected. The study author argued that the use of estimated bulk densities for all 6 sites provided a more consistent approach. A similar argument was made for use of estimated pF2 values, where for a single site there was considered to be a discrepancy between the measured and estimated value and therefore the author proposed using estimated values for all sites, again for consistency.

In the absence of agreed guidance in this area it is not easy to conclude on the most appropriate approach. In general, it is considered preferable to have on-site measured data available rather than to rely on simulated data. Therefore where possible it is considered preferable to make use of that measured data in the time step normalisation work. Although the study author argues that measured data was at times inconsistent (or at least different to) simulated data, this largely ignores the inherent uncertainty associated with the simulated data. In this case, due to relatively rapid dissipation of prosulfuron, the choice of data to use in the time step normalisation is noted to have a relatively small effect on overall modelling endpoints. The geometric mean DT_{50} from [redacted] and [redacted], 2016a (using some simulated data) was reported to be 21.2 days and the updated value from [redacted], 2018 (using measured data) was 19.6 d.

Overall HSE considers that modelling endpoints derived from the later study of [redacted], 2018 should be relied on. Therefore the study of [redacted] and [redacted], 2016a is not reviewed in detail (but is retained since in Table B.8.136 it reports the prosulfuron field residue data used in the later kinetic fitting of [redacted], 2018). Refer to the study summary and evaluation of [redacted] 2018 further below for details of the final modelling endpoint selection from the field dissipation studies.

Reference:	KIIA 7.2.1 / 13
Report Title:	Prosulfuron – Kinetic Modelling Evaluation of Data from Field Soil Dissipation Studies for Trigger Endpoints. Final Report.
Author(s) & Year:	[redacted]. & [redacted]; 2016b
Document No, Authority registration No	NC/15/041B
Guideline(s):	Yes FOCUS Kinetics Guidance (2006)
Deviations:	None
GLP or GEP:	No (not applicable modelling study)
Acceptability:	Yes
Study relied upon:	Yes

Materials and methods:

The unnormalised field DT_{50} and DT_{90} values for the active substance prosulfuron for trigger endpoints were calculated. The rate of degradation of prosulfuron applied to bare soil followed by covering with sand has been studied in the field in six studies: [[redacted] (a-f)].

Kinetic modelling following the appropriate FOCUS Kinetics (2006) flowcharts was carried out using CAKE v3.1 (2015) (see kinetic modelling scheme in Figure B.8-127 above).

The M0 values for each soil were determined through free optimisation of parameters in CAKE v3.1. The first timepoint with residues declining below LOQ was set to ½ (LOQ+LOD), and values less than LOD were set to ½ LOD according to FOCUS Kinetics approaches. Subsequent values below LOD were not included.

Confidence in the resulting parameters has been assessed visually and from the confidence intervals for the α and β parameters of the first order multicompartment (FOMC) model or probability values for a t-test of the rate parameters for the single first order (SFO), dual first order in parallel (DFOP) models. Where the parameters for a particular model are not significantly different from zero at the 95th or 90th significance level, it has been concluded that the model is not appropriate to represent the degradation behaviour in that soil. The χ2 error% parameter has been used to determine goodness of fit and where two models are an appropriate to fit the data, the choice of best fit has been based on the lowest value of this parameter.

In the original data for the Spanish trial, erroneous core diameters were given. The recalculated residue data for this trial resulting from that change in core diameter were taken into account for these calculations.

Summary of the reported prosulfuron data is presented in Table B.8-136 above.

Findings:

Optimisations with SFO kinetics showed both visually and statistically acceptable fits to the FR1, DE, ES and UK trials. Optimisation with DFOP kinetics showed a visually and statistically acceptable fit to the DK and FR2 trials.

Table B. 8-30: DT_{50} values for prosulfuron

Soil (code) (ref)	Bogense (DK) [Gezahegne (a)]	Bogense (DK) [Gezahegne (a)]	Bogense (DK) [Gezahegne (a)]
Kinetic Model	SFO	FOMC	DFOP
CAKE output location (report page)	32	36	40
Visual Fit	Poor	Poor	Acceptable
Residuals (visual)	Poor	Poor	Acceptable
χ^2 error (%)	21.6	12.2	8.23
Initial value: estimate / (range) / standard error	16.95 (14.96-18.95) σ : 0.972	21.94 (19.98-23.89) σ : 0.9515	22.33 (20.77-23.9) σ : 0.7606
Rate Parameters: estimate / standard error / probability (trigger:0.05)	k: 0.05117 σ: 0.007169 $p = 4.55 \times 10^{-8}$	α: 0.3572 σ: 0.04795 95th %ile CI does not contain 0	k_1: 2.989 σ: 2.108 p: 0.08404
		β: 0.5706 σ: 0.255 95th %ile CI does not contain 0	k_2: 0.03143 σ : 0.003858 p: 6.28×10^{-9}
			g: 0.4222 σ: 0.03862
DT_{50} (days)	13.6	3.4	4.6
DT_{90} (days)	45.0	359	55.8
FOCUS decision step	SFO unacceptable, fit FOMC	FOMC unacceptable, fit DFOP	DFOP better than FOMC; DFOP selected as best fit

Soil (code) (ref)	Castelsarrasin (FR1) [Gezahegne (b)]	Castelsarrasin (FR1) [Gezahegne (b)]
Kinetic Model	SFO	FOMC
CAKE output location (report page)	44	48
Visual Fit	Good	Acceptable
Residuals (visual)	Good	Acceptable
$\chi2$ error (%)	12.4	13.2
Initial value: estimate / (range) / standard error	10.05 (8.638-11.46) σ : 0.6843	10.14 (8.696-11.58) σ : 0.6992
Rate Parameters: estimate / standard error / probability (trigger:0.05)	k: 0.06066 σ: 0.01089 p = 4.30 x 10^{-6}	α: 128.2 σ: not calculated 95th %ile CI not calculated
		β: 2.02 x 10^{3} σ: not calculated 90th %ile CI not calculated
DT_{50} (days)	11.4	10.9
DT_{90} (days)	38.0	36.6
FOCUS decision step	SFO acceptable	FOMC statistically unacceptable. SFO selected as best-fit

Soil (code) (ref)	St. Cyprien (FR2) [Gezahegne (c)]	St. Cyprien (FR2) [Gezahegne (c)]	St. Cyprien (FR2) [Gezahegne (c)]
Kinetic Model	SFO	FOMC	DFOP
CAKE output location (report page)	52	56	60
Visual Fit	Acceptable	Acceptable	Acceptable
Residuals (visual)	Acceptable	Acceptable	Acceptable
$\chi2$ error (%)	13.1	6.9	5.5
Initial value: estimate / (range) / standard error	11.14 (9.619-12.66) σ: 0.746	12.22 (10.31-14.12) σ: 0.934	12.33 (10.3-14.35) σ: 0.9911
Rate Parameters: estimate / standard error / probability (trigger:0.05)	k: 0.02454 σ: 0.004938 p = 1.17 x 10^{-5}	α: 0.8669 σ: 0.4471 90th %ile CI does not contain 0	k_1: 0.1201 σ: 0.1106 p: 0.1433
		β: 14.99 σ: 14.13 90th %ile CI contains 0	k_2: 0.01126 σ: 0.0064 p: 0.04458
			g: 0.4615 σ: 0.221
DT_{50} (days)	28.3	18.4	61.6
DT_{90} (days)	93.8	198	150
FOCUS decision step	SFO unacceptable; fit FOMC	FOMC unacceptable; fit DFOP	DFOP better than FOMC; DFOP selected as best fit

Note: DT_{50} for DFOP fitting (61.6 days) erroneously reported by the Applicant. The correct value is 17.4 days.

Soil (code) (ref)	Breitenwisch (DE) [Gezahegne (d)]	Breitenwisch (DE) [Gezahegne (d)]
Kinetic Model	SFO	FOMC
CAKE output location (report page)	64	68
Visual Fit	Good	Poor
Residuals (visual)	Good	Poor
$\chi 2$ error (%)	12.6	13.4
Initial value: estimate / (range) / standard error	16.99 (15.48-18.5) σ: 0.7285	17.86 (16.11-19.6) σ: 0.8387
Rate Parameters: estimate / standard error / probability (trigger:0.05)	k: 0.0769 σ: 0.008694 $p = 5.36 \times 10^{-9}$	α: 313.3 σ: 79.77 95th %ile CI does not contain 0
		β: 3.09×10^{3} σ: 980.7 95th %ile CI does not contain 0
DT_{50} (days)	9.01	6.85
DT_{90} (days)	29.9	22.8
FOCUS decision step	SFO acceptable	SFO better than FOMC. SFO selected as best-fit.

Soil (code) (ref)	Canals (ES) [Gezahegne (e)]	Canals (ES) [Gezahegne (e)]	Canals (ES) [Gezahegne (e)]
Kinetic Model	SFO	FOMC	DFOP
CAKE output location (report page)	72	76	80
Visual Fit	Good	Good	Good
Residuals (visual)	Good	Good	Good
$\chi 2$ error (%)	10.1	9.21	6.83
Initial value: estimate / (range) / standard error	16.01 (14.59-17.44) σ: 0.6983	16.58 (14.93-18.22) σ: 0.807	17.79 (15.53-20.05) σ: 1.106
Rate Parameters: estimate / standard error / probability (trigger:0.05)	k: 0.02707 σ: 0.003552 $p = 6.79 \times 10^{-9}$	α: 2.092 σ: 1.443 90th %ile CI contains 0	k_1: 0.4408 σ: 0.424 p: 0.1536
		β: 55.51 σ: 50.76 90th %ile CI contains 0	k_2: 0.02076 σ: 0.004213 p: 1.55×10^{-5}
			g: 0.2342 σ: 0.09247
DT_{50} (days)	25.6	21.8	20.5
DT_{90} (days)	85.1	111	98.1
FOCUS decision step	SFO acceptable	FOMC shows improvement over SFO; fit DFOP	DFOP better than FOMC; DFOP selected as best fit

Soil (code) (ref)	Wilson (UK) [Gezahegne (f)]	Wilson (UK) [Gezahegne (f)]
Kinetic Model	SFO	FOMC
CAKE output location (report page)	84	88
Visual Fit	Acceptable	Poor
Residuals (visual)	Acceptable	Poor
$\chi2$ error (%)	17.8	18.8
Initial value: estimate / (range) / standard error	13.9 (12.37-15.42) σ: 0.7394	14.54 (12.9-16.17) σ: 0.792
Rate Parameters: estimate / standard error / probability (trigger:0.05)	k: 0.05529 σ: 0.007944 p = 1.35×10^{-7}	α: 528 σ: not calculated 95th %ile CI not calculated
		β: 7.56×10^{3} σ: not calculated 90th %ile CI not calculated
DT_{50} (days)	12.5	9.93
DT_{90} (days)	41.6	33.0
FOCUS decision step	SFO acceptable	FOMC statistically unacceptable. SFO selected as best fit

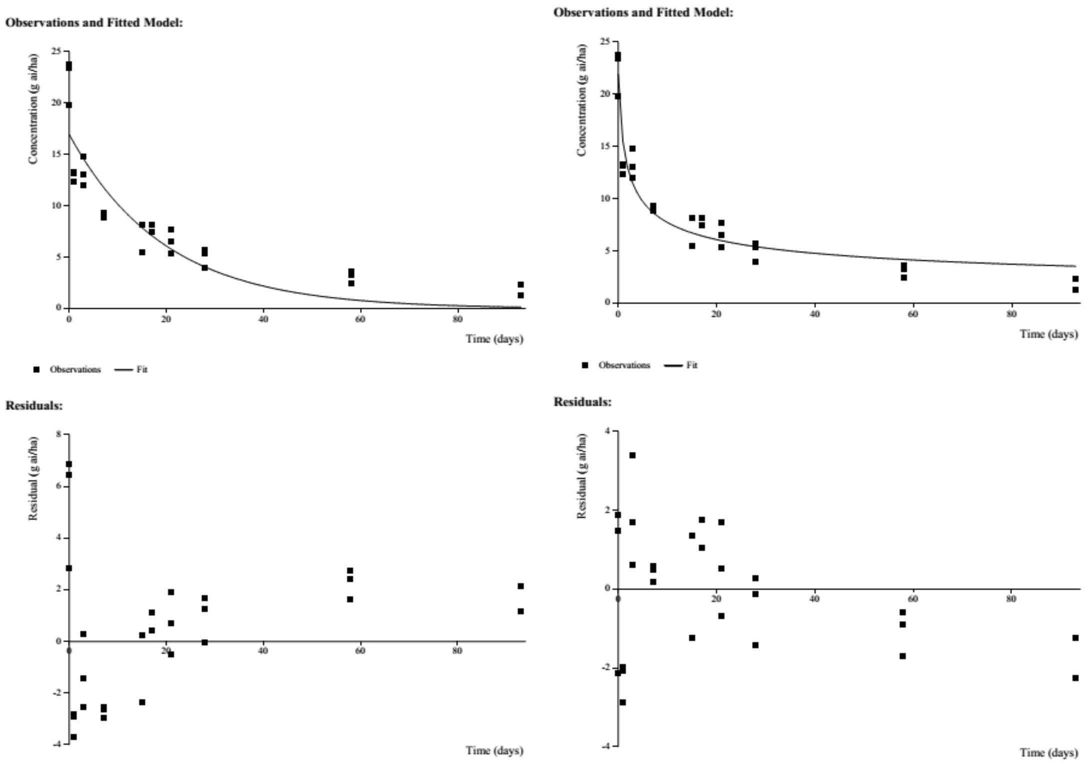


Figure B.8-133: Trigger endpoints; fitting of data and residual plots for Bogense trial; SFO (left), FOMC (right)

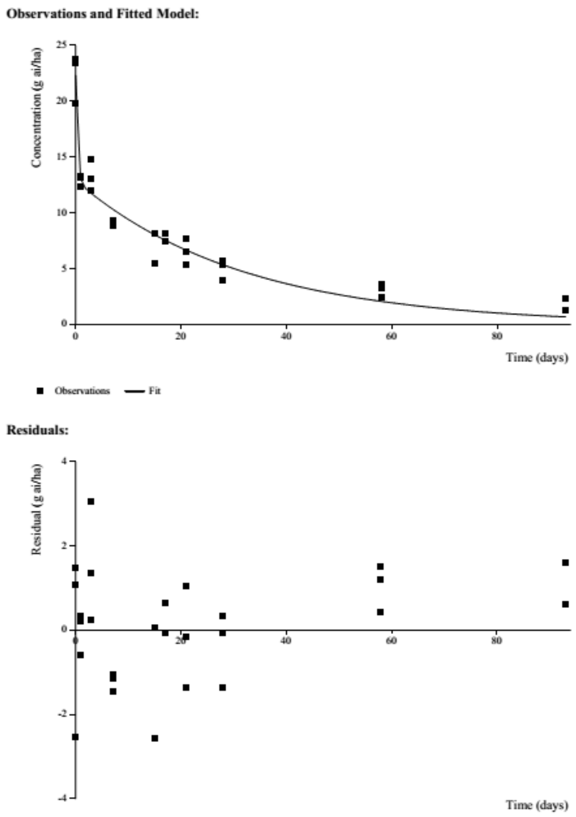


Figure B.8-134: Trigger endpoints; fitting of data and residual plots for Bogense trial; DFOP

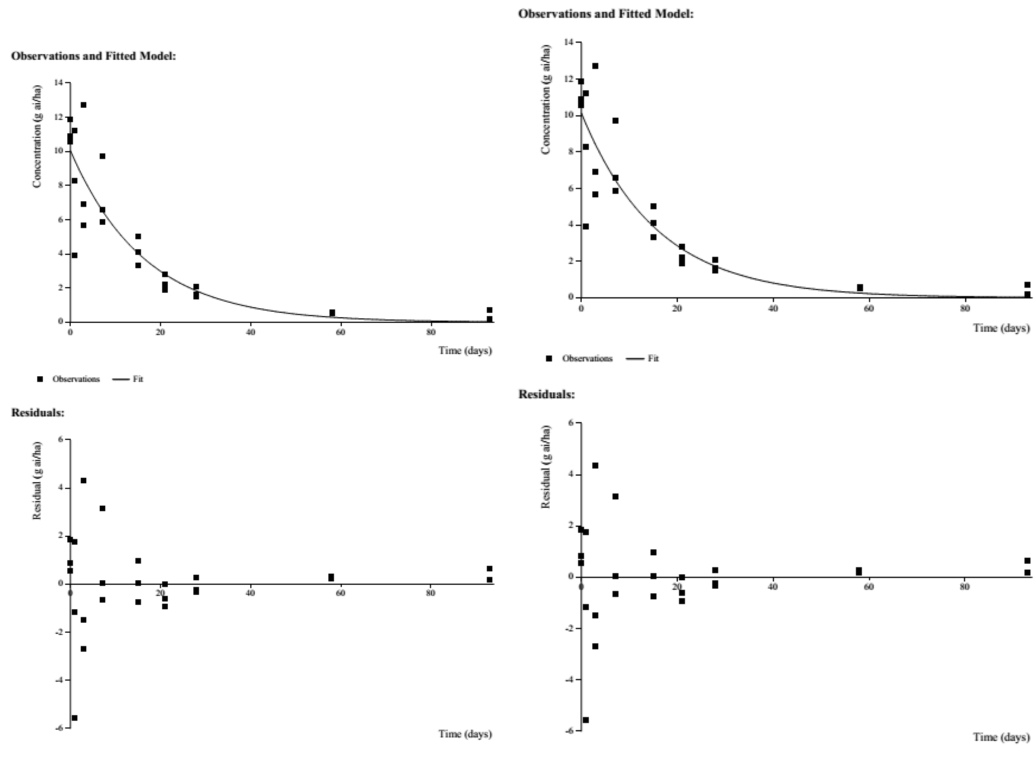


Figure B.8-135: Trigger endpoints; fitting of data and residual plots for Castelsarrasin trial; SFO (left), FOMC (right)

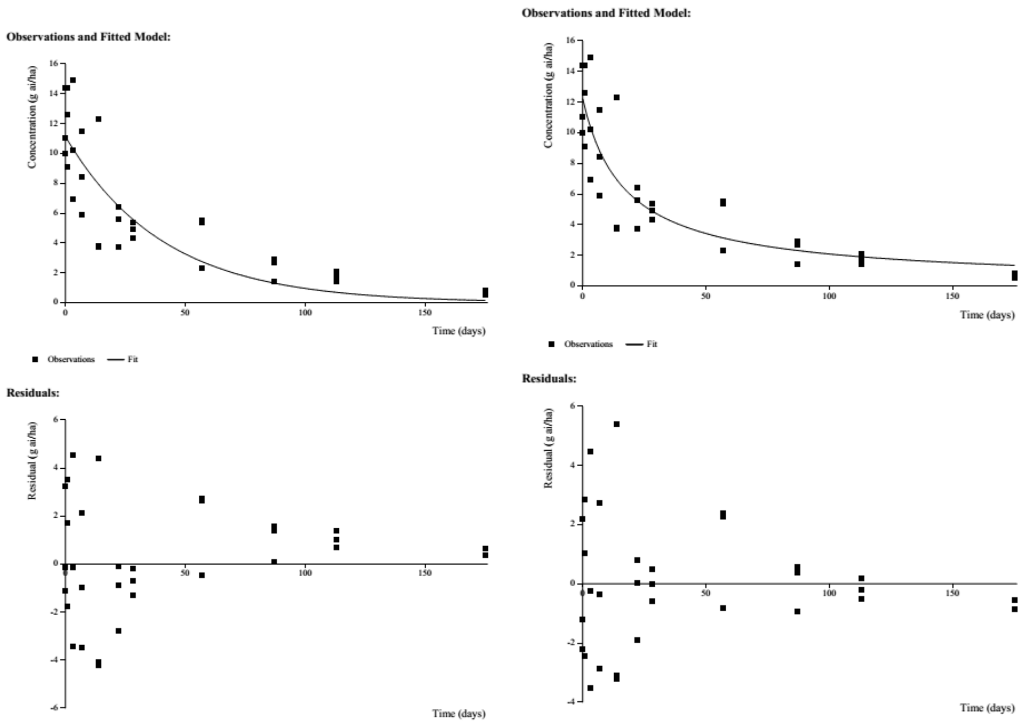


Figure B.8-136: Trigger endpoints; fitting of data and residual plots for St. Cyprien trial; SFO (left), FOMC (right)

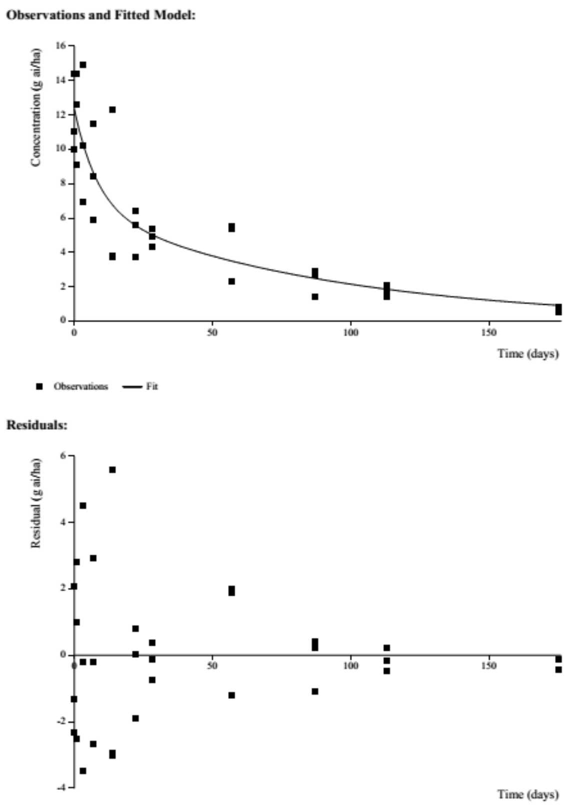


Figure B.8-137: Trigger endpoints; fitting of data and residual plots for St. Cyprien trial; DFOP

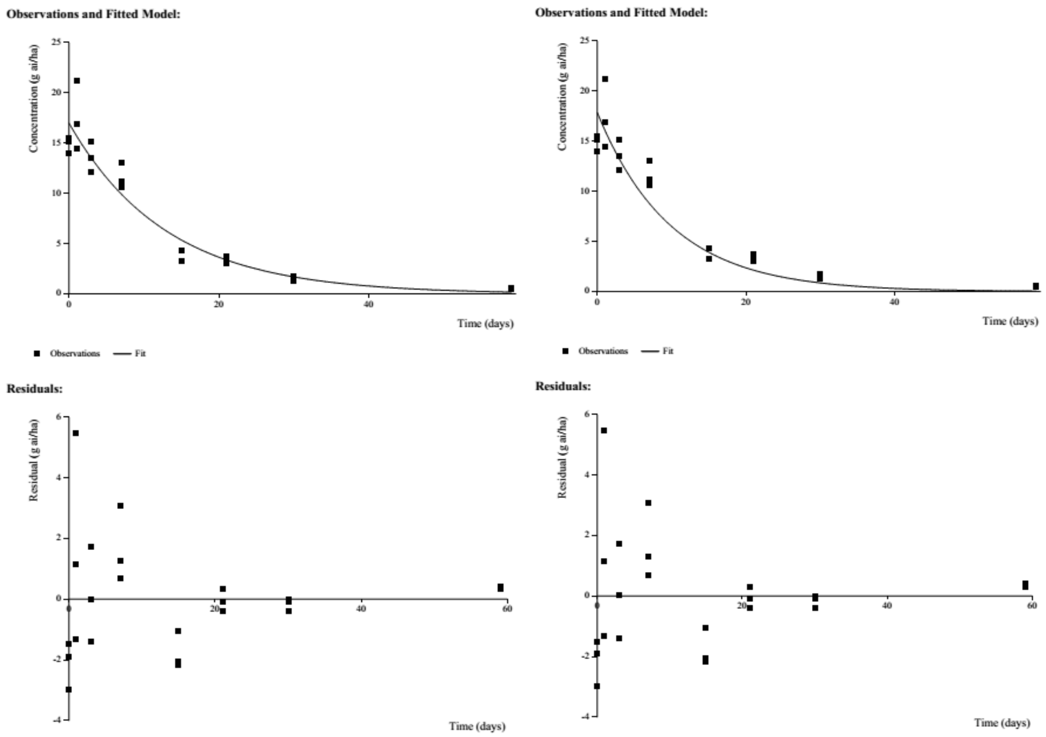


Figure B.8-138: Trigger endpoints; fitting of data and residual plots for Breitenwisch trial; SFO (left), FOMC (right)

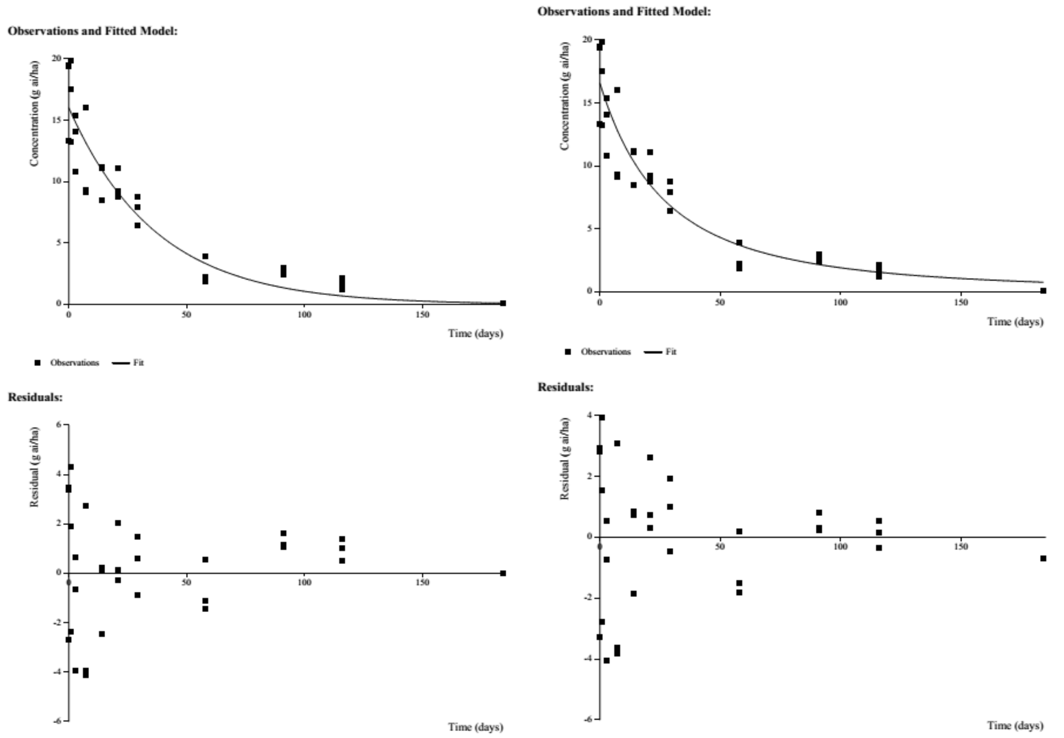


Figure B.8-139: Trigger endpoints; fitting of data and residual plots for Canals trial; SFO (left), FOMC (right)

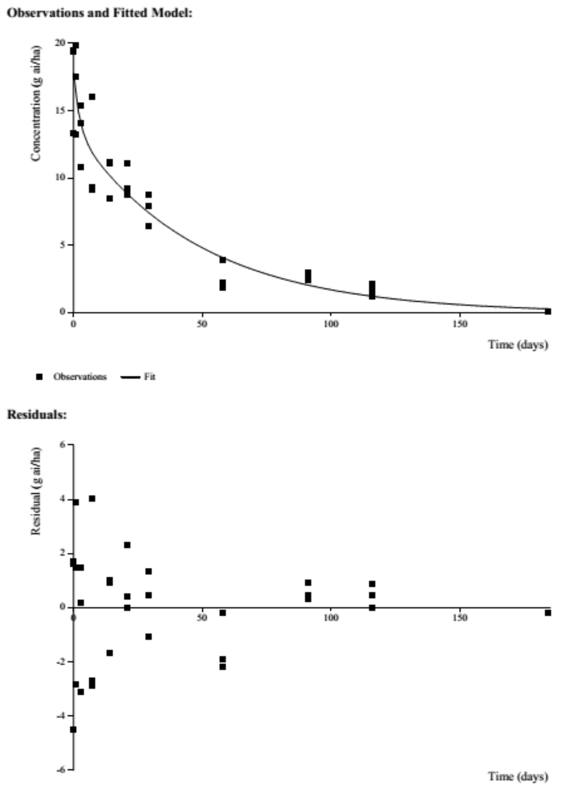


Figure B.8-140: Trigger endpoints; fitting of data and residual plots for Canals trial; DFOP

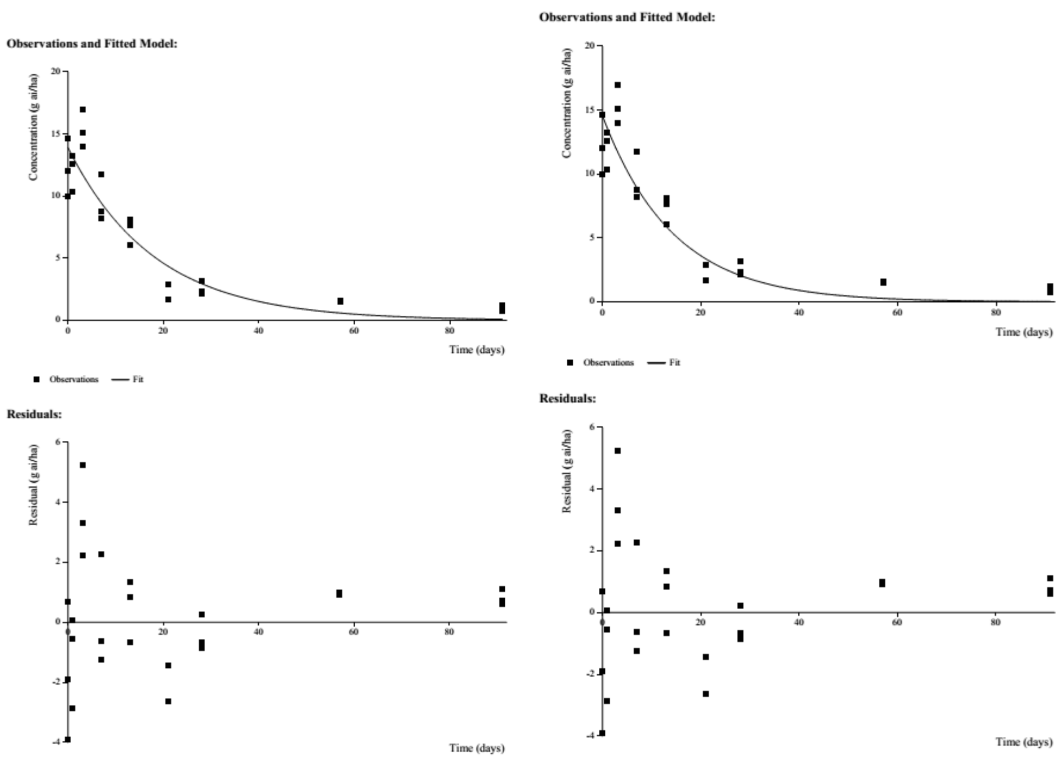


Figure B.8-141: Trigger endpoints; fitting of data and residual plots for Wilson trial; SFO (left), FOMC (right)

Table B. 8-31: Summary of trigger endpoint DT_{50} values for prosulfuron

Trial	Best-fit kinetic	DT_{50} (days)	DT_{90} (days)
Bogense (DK)	DFOP	4.6	55.8
Castelsarrasin (FR1)	SFO	11.4	38.0
St. Cyprien (FR2)	DFOP	17.4	150
Breitenwisch (DE)	SFO	9.01	29.9
Canals (ES)	DFOP	20.5	98.1
Wilson (UK)	SFO	12.5	41.6

Conclusion of the Applicant:

The kinetic evaluations yielded a total of six DT_{50} values for prosulfuron (4.6-20.5 days). These values can be used in subsequent exposure assessment.

Conclusion of HSE:

The study provides kinetic analysis of the new field dissipation studies for the purposes of deriving triggering endpoints ([redacted] and [redacted], 2016b). This study has not been considered in detail by HSE because new trigger endpoints are not required as part of the Article 7 amendment application. The Article 7 amendment application has been made specifically to remove the timing restriction as a result of risk to groundwater which relies on revised modelling endpoints. In addition, the new trigger values do not alter the existing regulatory assessment because a longer worst case soil DT_{50} of 38.9 d has already been used in the soil exposure assessment. The worst case DT_{90} value from the new study of 150 d is also well below 1 year, and further consideration of soil accumulation is therefore not triggered.

Reference:	KIIA 7.2.1 / 14
Report Title:	Prosulfuron – Kinetic Modelling Evaluation of Data from Field Soil Dissipation Studies Normalised to 20°C and pF2. Final Report.
Author(s) & Year:	[redacted]; 2018
Document No, Authority registration No	NC/18/031A

Guideline(s):	Yes FOCUS Kinetics Guidance (2006) EFSA Journal (2014);12(5):3662
Deviations:	None
GLP or GEP:	No (not applicable modelling study)
Acceptability:	Yes
Study relied upon:	Yes

Materials and methods:

Timestep normalisation was used to calculate DegT50 values corrected to the standard conditions of 20ºC and moisture at 10 kPa (pF2), in order to produce values suitable for use in environmental models.

The rate of degradation of prosulfuron applied to bare soil followed by sand coverage has been studied in the field in six studies: [[redacted] & [redacted] (a-f)]. Kinetic modelling following the appropriate FOCUS Kinetics (2006) flowcharts was carried out using CAKE v3.3 (2017).

Measured daily on-site soil temperatures and moisture contents were used, taken directly from the study data. Measured gravimetric (% w/w) soil pF2 values were converted to volumetric (% v/v) using measured soil bulk density values (g/mL) (see Table B.8-142).

Table B. 8-142: Gravimetric and volumetric soil pF2 values

Trial	Gravimetric pF2 (%w/w)	Bulk density (g/mL)	Volumetric pF2 (%v/v)
DK	16.3	1.43	23.3
FR1	20.4	1.16	23.7
FR2	22.5	1.45	32.6
DE	31.2	1.25	39.0
ES	22.6	1.40	31.6
UK	20.4	1.56	31.8

The M0 values for each soil were determined through free optimisation of parameters. The first timepoint with residues declining below LOQ was set to ½ (LOQ+LOD), and values less than LOD were set to ½ LOD according to FOCUS Kinetics approaches. Subsequent values below LOD were not included.

Confidence in the resulting parameters was assessed visually and from the confidence intervals for the α and β parameters of the first order multicompartment (FOMC) model or probability values for a t-test of the rate parameters for the single first order (SFO), dual first order in parallel (DFOP) models. Where the parameters for a particular model were not significantly different from zero at the 95th or 90th significance level, it was concluded that the model is not appropriate to represent the degradation behaviour in that soil. The χ^2 error% parameter was used to determine goodness of fit and where two models were appropriate to fit the data, the choice of best fit was based on the lowest value of this parameter.

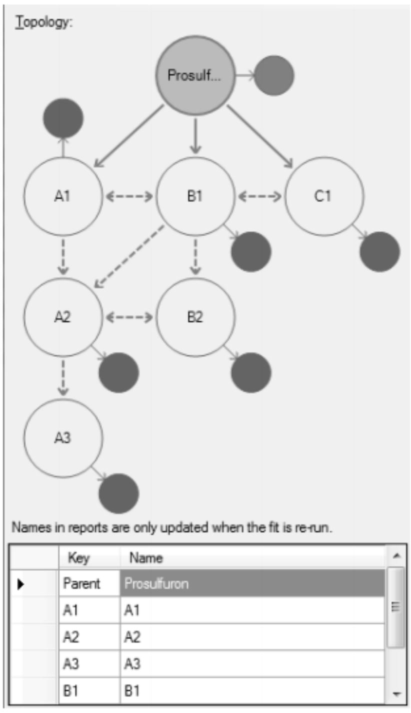


Figure B.8-142: Example kinetic modelling scheme in CAKE 3.3

Table B. 8-143: Timestep normalised sampling times

Bogense (DK)		Castelsarrasin (FR1)		St. Cyprien (FR2)	
Time (days)	Time step (days)	Time (days)	Time step (days)	Time (days)	Time step (days)
0	0.0	0	0.0	0	0.0
1	0.9	1	1.3	1	1.4
3	2.4	3	4.2	3	3.7
7	6.8	7	9.8	7	6.8
15	15.6	15	19.4	14	12.2
17	17.7	21	28.8	22	19.5
21	23.1	28	38.9	28	27.0
28	33.1	58	74.3	57	59.1
58	60.2	93	116.6	87	88.5
93	84.5	-	-	113	112.2
-	-	-	-	175	140.3

Breitenwisch (DE)		Canals (ES)		Wilson (UK)	
Time (days)	Time step (days)	Time (days)	Time step (days)	Time (days)	Time step (days)
0	0.0	0	0.0	0	0.0
1	0.8	1	1.5	1	1.2
3	2.3	3	4.0	3	3.3
7	6.7	7	10.1	7	6.5
15	16.4	14	21.7	13	12.2
21	25.2	21	34.8	21	20.1
30	37.8	29	50.7	28	28.4
59	65.4	58	98.1	57	58.9
-	-	91	148.4	91	84.6
-	-	116	173.9	-	-
-	-	184	212.3	-	-

Findings:

The prosulfuron degradation data (see Table B.8-136) and timestep data (Table B.8-143) were entered into the CAKE 3.3 scheme. Optimisations with SFO kinetics showed both visually and statistically acceptable fits to the FR1, FR2, DE, ES and UK trials. Optimisation with DFOP kinetics showed both visually and statistically acceptable fits to the DK trial.

Table B. 8-144: DegT50 values for prosulfuron normalised to reference conditions of 20°C and pF2

Soil (code) (ref)	Bogense (DK) [Gezahegne (a)]	Bogense (DK) [Gezahegne (a)]	Bogense (DK) [Gezahegne (a)]
Kinetic Model	SFO	FOMC	DFOP
Cake output location (report page)	35	39	43
Visual Fit	Poor	Poor	Good
Residuals (visual)	Poor	Poor	Good
χ2 error (%)	22.6	12.0	7.49
Initial value: estimate / (range) / standard error	P_{ini}: 16.44 (14.47-18.42) σ: 0.9650	P_{ini}: 22.03 (20.09-23.97) σ: 0.9468	P_{ini}: 22.33 (20.83-23.83) σ: 0.7308
Rate Parameters: estimate / standard error / probability (trigger:0.05)	k: 0.04481 σ: 0.006712 p: 1.52×10^{-7}	α: 0.3278 σ: 0.04107 95th %ile CI does not contain 0	k_1: 2.778 σ: 1.296 p: 0.02083
		β: 0.411 σ: 0.1835 95th %ile CI does not contain 0	k_2: 0.02787 σ: 0.003154 p: 1.31×10^{-9}
			g: 0.4385 σ: 0.03475
$DegT_{50}$ (days)	15.5	139[a]	24.9[b]
$DegT_{90}$ (days)	51.4	462	82.6[c]
FOCUS decision step	SFO unacceptable; 10% of P_{ini} reached within experimental period; fit FOMC	FOMC unacceptable (poor fit around DT90 and the end of the study); expert judgement; fit DFOP	DFOP better than FOMC, acceptable; DFOP selected as best fit. Slow phase k_2 used to calculate DT_{50} as worst case

[a] $DegT_{90}$ / 3.32
[b] k_2 $DegT_{50}$
[c] k_2 $DegT_{90}$

Soil (code) (ref)	Castelsarrasin (FR1) [Gezahegne (b)]	St. Cyprien (FR2) [Gezahegne (c)]
Kinetic Model	SFO	SFO
Cake output location (report page)	47	50
Visual Fit	Good	Good
Residuals (visual)	Good	Good
χ2 error (%)	12.6	14.9
Initial value: estimate / (range) / standard error	P_{ini}: 10.05 (8.632-11.46) σ: 0.6873	P_{ini}: 11.07 (9.495-12.65) σ: 0.774
Rate Parameters: estimate / standard error / probability (trigger:0.05)	k: 0.04459 σ: 0.008018 $p = 4.39 \times 10^{-6}$	k: 0.02492 σ: 0.005359 $p = 2.92 \times 10^{-5}$
$DegT_{50}$ (days)	15.5	27.8
$DegT_{90}$ (days)	51.6	92.4
FOCUS decision step	SFO acceptable	

Soil (code) (ref)	Breitenwisch (DE) [Gezahegne (d)]	Canals (ES) [Gezahegne (e)]	Wilson (UK) [Gezahegne (f)]
Kinetic Model	SFO	SFO	SFO
CAKE output loation (report page)	54	57	61
Visual Fit	Good	Good	Acceptable
Residuals (visual)	Good	Good	Acceptable
χ2 error (%)	11.4	10.9	18.5
Initial value: estimate / (range) / standard error	P_{ini}: 16.54 (15.18-17.9) σ: 0.6563	P_{ini}: 15.8 (14.4-17.21) σ: 0.6885	P_{ini}: 13.94 (12.34-15.53) σ: 0.7743
Rate Parameters: estimate / standard error / probability / break point (trigger:0.05)	k: 0.06958 σ: 0.008055 $p = 8.08 \times 10^{-9}$	k: 0.01594 σ: 0.002087 $p = 6.56 \times 10^{-9}$	k: 0.05694 σ: 0.008589 $p = 3.01 \times 10^{-7}$
$DegT_{50}$ (days)	9.96	43.5	12.2
$DegT_{90}$ (days)	33.1	145	40.4
FOCUS decision step	SFO acceptable		

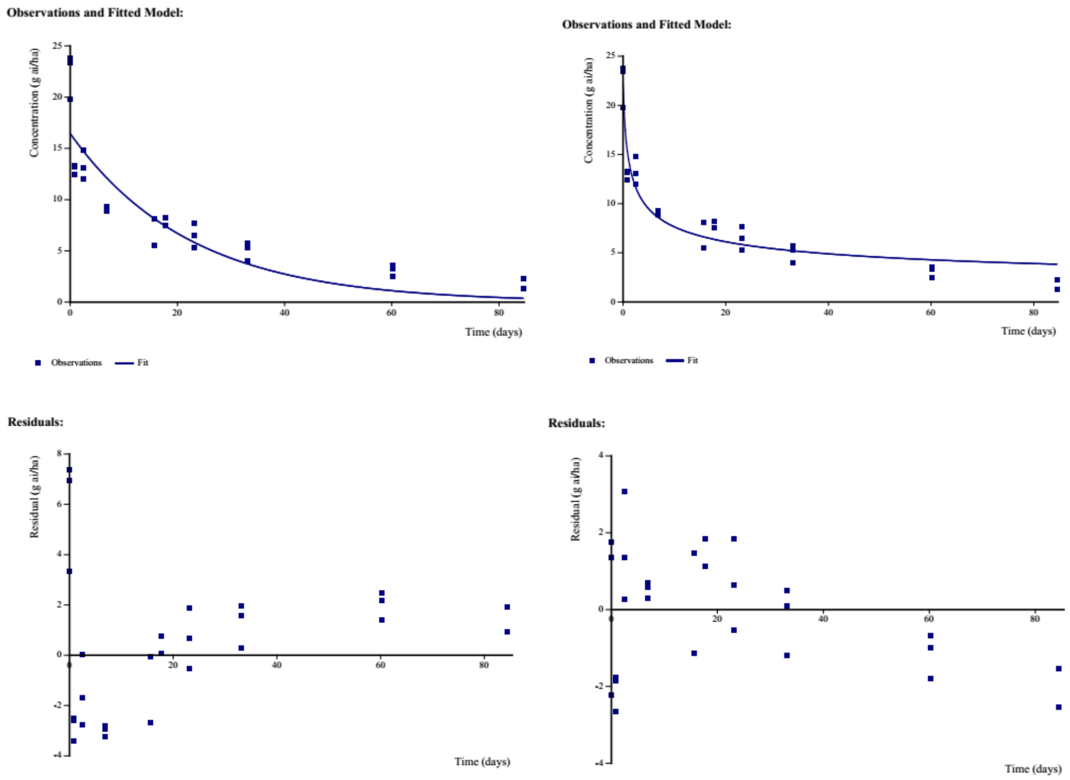


Figure B.8-143: Modelling endpoints; fitting of data and residual plots for Bogense trial; SFO (left), FOMC (right)

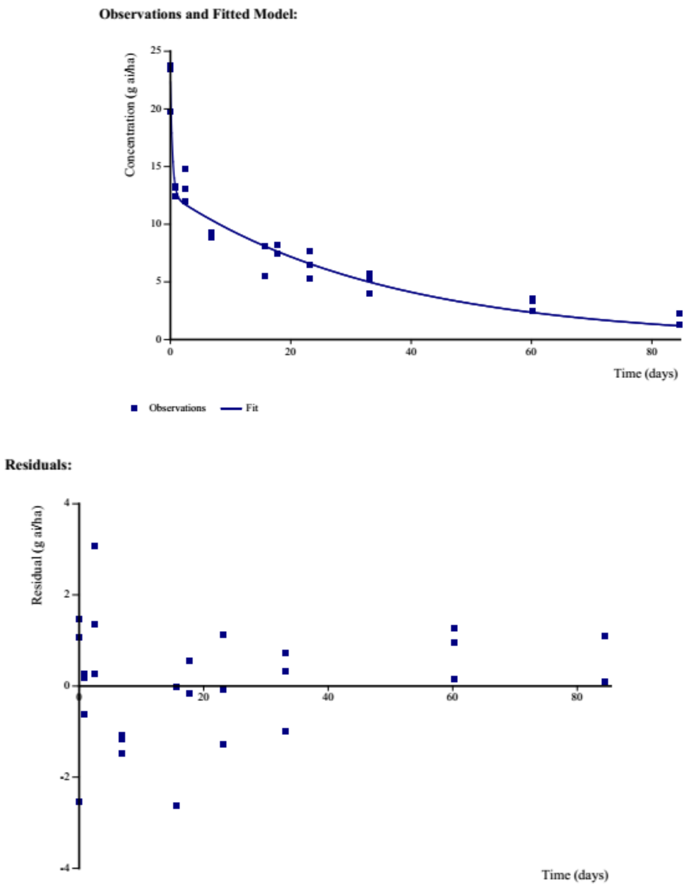


Figure B.8-144: Modelling endpoints; fitting of data and residual plots for Bogense trial; DFOP

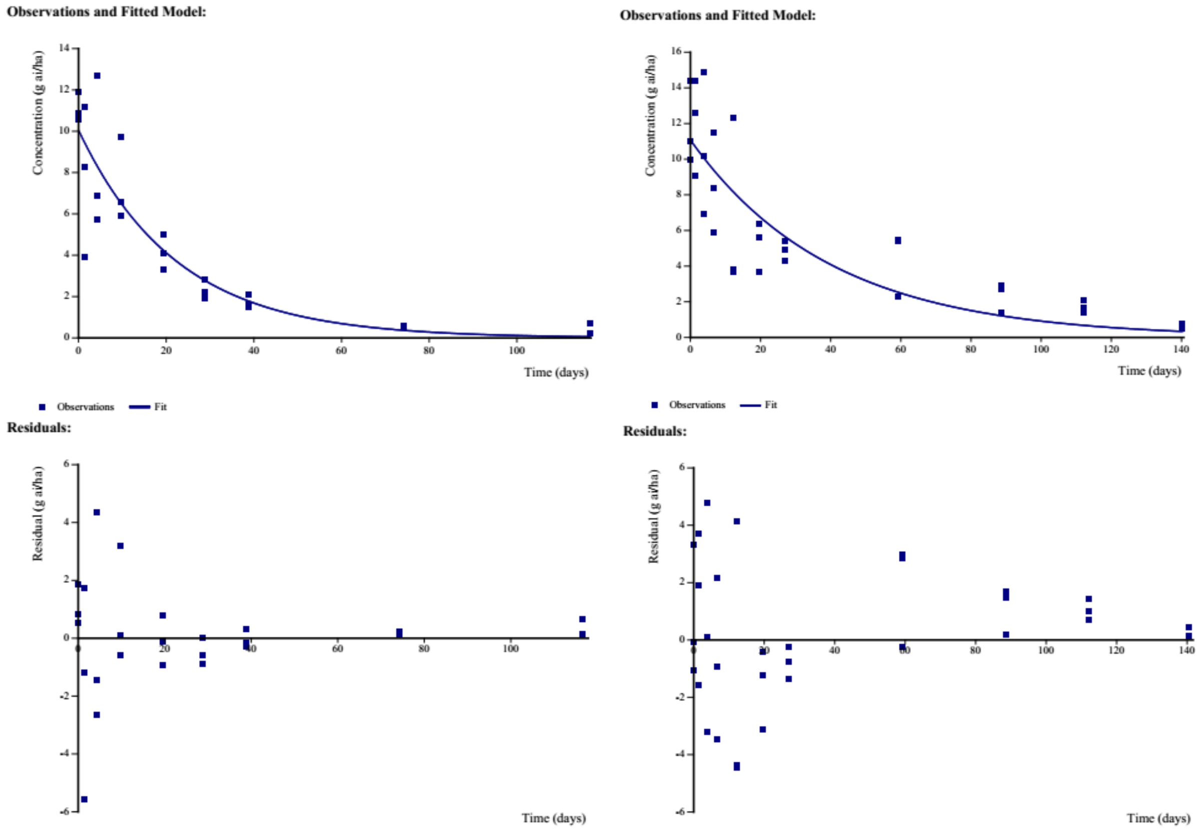
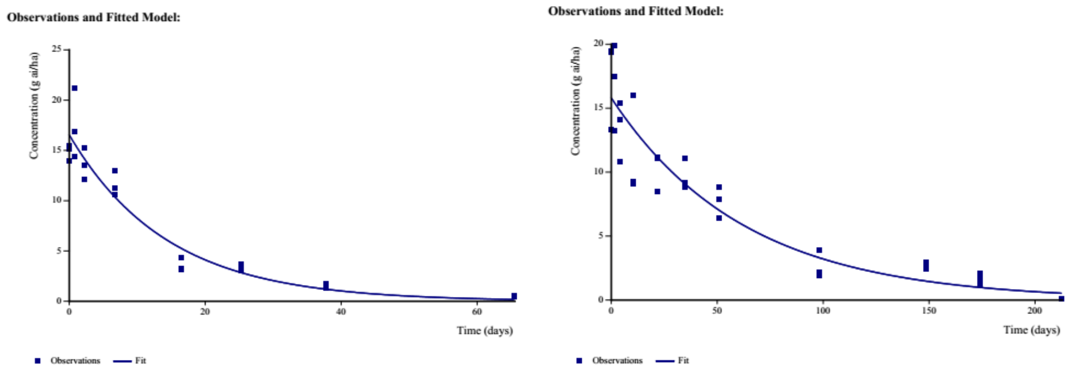


Figure B.8-145: Modelling endpoints; fitting of data and residual plots for Castelsarrasin trial (left; SFO) and for St.Cyprien (right; SFO)



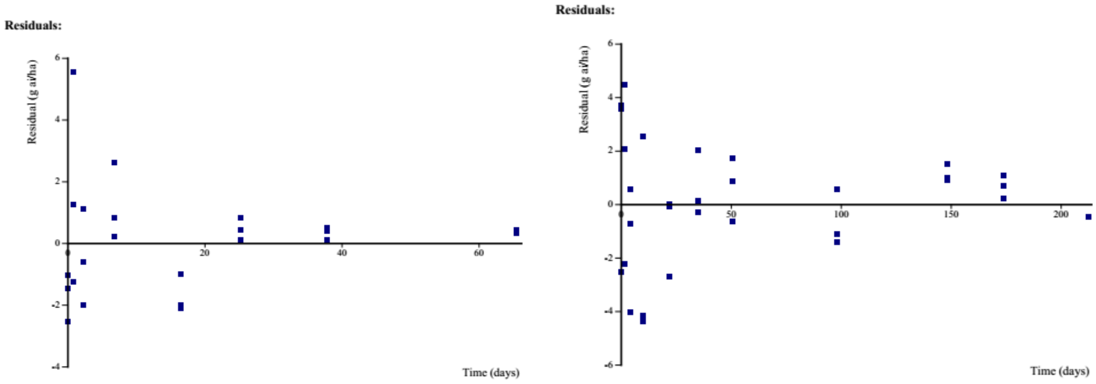


Figure B.8-146: Modelling endpoints; fitting of data and residual plots for Breitenwisch trial (left; SFO) and for Canals (right; SFO)

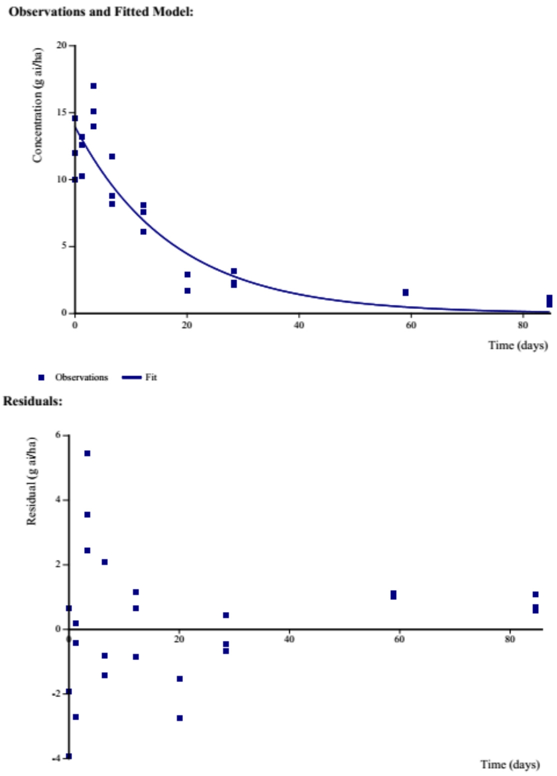


Figure B.8-147: Modelling endpoints; fitting of data and residual plots for Wilson trial (SFO)

Table B. 8-145: Summary of modelling endpoint DegT50 values for prosulfuron

Soil name	Soil texture	Soil pH (water)	DegT50 (days)	Kinetic model	Reference
Bogense (DK)	Sandy loam	5.07	24.9	DFOP k_2	[redacted] & [redacted] (c)
Castelsarrasin (FR1)	Silt loam	4.94	15.5	SFO	[redacted] & [redacted] (b)
St. Cyprien (FR2)	Loam	6.71	27.8	SFO	[redacted] & [redacted] (e)
Breitenwisch (DE)	Clay loam	4.89	9.96	SFO	[redacted] & [redacted] (a)
Canals (ES)	Clay	7.75	43.5	SFO	[redacted] & [redacted] (f)
Wilson (UK)	Loam	7.16	12.2	SFO	[redacted] & [redacted] (d)
Geometric mean (n=6)			**19.6**		

Conclusion of the Applicant:

The kinetic evaluations yielded a total of six $DegT_{50}$ values for prosulfuron which have been used to calculate the geometric mean $DegT_{50}$ of 19.6 days. This value is suitable for use in environmental models.

Conclusion of HSE:

The above study summary reports the kinetic assessment to derive normalised modelling endpoints from the field dissipation studies using all measured data as part of the time step normalisation process. As noted earlier, this approach was agreed by HSE as part of the independent GB evaluation.

HSE has reviewed the study and confirmed that the summary represents an accurate summary of the kinetic modelling of [redacted], 2018. Minor additional points are noted below.

The kinetic modelling report was clearly presented, with full details of statistical and visual measures of goodness of fit. HSE agreed with the choice of kinetic models for modelling endpoint selection (DFOP for the Bogense site where there was a stronger tendency for biphasic decline, SFO for all other sites). HSE consider that the quality of the visual fit at the St. Cyprien trial was likely impacted by the relatively high level of variation within replicate time points, rather than any very clear tendency towards biphasic degradation. For this site, the SFO model was able to provide a reasonable description of the final measured time point, suggesting the SFO model is unlikely to significantly underestimate long term persistence and was therefore accepted by HSE for the purposes of modelling endpoint selection, where SFO is generally favoured.

The geometric mean DT_{50} for modelling was proposed by the study author to be 19.6 d. This was noted to contain one trial site fitted with DFOP kinetics (Bogense) where a pseudo SFO DT_{50} derived from the slow phase k_2 rate constant from the DFOP kinetic was used. The EFSA peer review requested that this value be replaced by a pseudo SFO DT_{50} calculated from the DFOP DT_{90}/3.32 (since the DT_{90} was reached within the study duration). This reduced the geometric mean from 19.6 to 18.7 d.

The exposure modelling for prosulfuron will include linked metabolites in the simulation. Therefore it is not totally appropriate from a technical point of view to use either of the above conservative workaround values. This is because, by slightly overestimating the persistence of the parent, there could be an influence on the simulated formation of subsequent metabolites. However in this case it is noted that only 1 out of 6 sites required a biphasic kinetic model, and the overall average parent behaviour (appropriate for modelling) is likely to be close to single first order kinetics. Therefore the use of a conservative workaround value for the Bogense site is considered reasonable in this case, rather than triggering much more complex groundwater modelling. In addition, in the subsequent groundwater modelling performed by HSE it was found that 5 out of 6 metabolites were predicted to have slightly higher PECgw concentrations when using a longer parent prosulfuron DT_{50} of 19.6 d compared to 18.7 d. Only one metabolite (CGA349707) gave slightly lower PECgw concentrations at two out of four GB relevant scenarios with the longer parent DT_{50}, and this metabolite was already agreed to be non-relevant and present in groundwater in excess of 0.75 µg/l. So in this specific case the use of a conservative workaround DT_{50} in the parent database is unlikely to have any impact on the regulatory decision.

The Applicant found DFOP fit as best fit for Bogense trial. The DegT50 was calculated from slow phase k2. In the EFSA Data requirement 4.1 it was explicitly asked to calculate DegT50 as DT90/3.32 also for DFOP kinetics. The Applicant’s DegT50 for

Bogense trial is 24.9 days, whereas back-calculated DegT50 would be 18.6 days. The overall geometric mean would change from 19.6 days to 18.7 days. HSE accepts the prosulfuron geometric mean DT_{50} of 18.7 d for the purposes of parent and metabolite modelling. The field endpoints were separately demonstrated to be statistically shorter than laboratory values, and therefore in accordance with the EFSA $degT_{50}$ guidance, the use of a geometric mean value from the field for parent prosulfuron is appropriate.

B.8.1.2. Selection of laboratory and field endpoints for modelling purposes

The following study summarises all results obtained under B.8.1.2.1 and B.8.1.2.2 (except study [redacted], 2012b; [redacted] & [redacted] 2016a-f and [redacted] & [redacted] 2016 a-b). No new calculation is provided.

Reference:	KIIA 7.2.3 / 07
Report Title:	Prosulfuron – Overview of FOCUS Kinetic Modelling of Laboratory and Field Soil Studies and Selection of Modelling Endpoints. Final Report.
Author(s) & Year:	[redacted] & [redacted]; 2011c
Document No, Authority registration No	NC/10/031F
Guideline(s):	No (not applicable)
Deviations:	None
GLP or GEP:	No (not applicable modelling study)
Acceptability:	Yes
Study relied upon:	Yes

Materials and methods:

In this summary, data from fifteen laboratory and eleven field degradation datasets were evaluated in order to calculate normalised DT_{50} values for prosulfuron and its metabolites CGA159902, CGA150829, CGA300406, CGA325025, SYN542604 and CGA349707, together with formation fractions, for use as modelling endpoints in risk assessments. Additional datasets were evaluated for the CGA159902, CGA150829, CGA325025, SYN542604 and CGA349707 metabolites from laboratory studies conducted with the metabolite applied as test compound.

Degradation in laboratory soils

The behaviour of soil applied prosulfuron in soil has been investigated in eight soil degradation studies conducted on ten different soils with two ^{14}C labels (phenyl and triazine) under aerobic conditions [[redacted], 2011, 2011a; [redacted], 1993a&b, 1994a&b; [redacted], 1994, 1995]. The data from these studies have been reanalysed [[redacted] and [redacted], 2011, 2011b] according to FOCUS Kinetics guidance in order to derive DT_{50} values and formation fractions for use as modelling endpoints. Metabolite data from the [redacted] [1993a&b, 1994a&b] studies did not provide any robust evaluations and were not used further to derive metabolite formation fractions and DT_{50} values.

The behaviour of the prosulfuron metabolite CGA150829 in soil has been investigated in five soil degradation studies conducted on seven different soils under aerobic conditions [[redacted] & [redacted], 2006; [redacted], 2011, 2011a; [redacted], 2001; [redacted], 2000]. [redacted] [2011] summarised data available within an industry task force for CGA150829 an aminotriazine metabolite common to several sulphonyl urea active ingredients ([redacted], 2001 and [redacted], 2000). The data from [redacted] & [redacted], 2006; [redacted], 2011, 2011a studies have been reanalysed [[redacted] and [redacted], 2011a, 2011b] in order to derive DT_{50} values and formation fractions for use as modelling endpoints.

The behaviour of the prosulfuron metabolite CGA159902 in soil has been investigated in two soil degradation studies conducted on three different soils under aerobic conditions [[redacted] & [redacted], 2006; [redacted], 2011]. The data from these studies have been reanalysed [[redacted] and [redacted], 2011a, 2011b] in order to derive DT_{50} values and formation fractions for use as modelling endpoints.

The behaviour of the prosulfuron metabolite CGA300406 in soil has been investigated in four soil degradation studies conducted on five different soils under aerobic conditions [[redacted], 2011, 2011a; [redacted], 1994, 1995]. The data from these studies have been reanalysed [[redacted] and [redacted], 2011b] in order to derive DT_{50} values and formation fractions for use as modelling endpoints.

The behaviour of the prosulfuron metabolite SYN542604 in soil has been investigated in four soil degradation studies conducted on six different soils under aerobic conditions [[redacted], [redacted] & [redacted], 2011; [redacted], 2011, 2011a; [redacted], 1994, 1995]. The data from these studies have been reanalysed [[redacted] and [redacted], 2011a, 2011b] in order to derive DT_{50} values and formation fractions for use as modelling endpoints.

The behaviour of the prosulfuron metabolite CGA325025 in soil has been investigated in one soil degradation study conducted on three different soils under aerobic conditions [[redacted], [redacted] & [redacted], 2011]. The data from this study have been reanalysed [[redacted] and [redacted], 2011a] in order to derive DT_{50} values for use as modelling endpoints.

The behaviour of the prosulfuron metabolite CGA349707 in soil has been investigated in three soil degradation studies conducted on four different soils under aerobic conditions [[redacted], 2006; [redacted], 1994, 1995]. The data from these studies have been reanalysed [[redacted] and [redacted], 2011a, 2011b] in order to derive DT_{50} values and formation fractions for use as modelling endpoints.

Dissipation in field soils

Eighteen field soil dissipation studies with prosulfuron have been conducted at trial sites across Europe, located in France, Germany, Italy, Austria and Switzerland [[redacted], 1992 a-d; [redacted], 1994 a-f, k, m, n; [redacted], 1995; [redacted], 1997 a&b]. Of these eighteen studies seven were not selected for further kinetic analysis. The data from the remaining eleven studies have been reanalysed [[redacted] and [redacted], 2011c] in order to derive normalised (20°C and pF2) DT_{50} values and formation fractions for use as modelling endpoints.

Findings:

Degradation in laboratory soils

Table B. 8-146: Laboratory SFO DT_{50} values for prosulfuron normalised to 20°C and pF2 (according to [redacted] & [redacted], 2011)

Study	Soil	DT_{50} 20°C, pF2 (days)
[redacted], 2011	18 Acres (phenyl)	22.5

	18 Acres (triazine)	18.9
[redacted], 2011a	18 Acres (triazine)	21.0
	Vétroz (triazine)	41.3
	Krone (triazine)	15.4
	Nebraska (triazine)	61.1
[redacted], 1993a, 1993b	Fayette (phenyl)	106
	Fayette (triazine)	229
[redacted], 1994a, 1994b	Madison (phenyl)	142
	Madison (triazine)	122
[redacted], 1994	Neuhofen (phenyl)	124
	Collombey (phenyl)	98.2*
	Stein (phenyl)	132
	Les Evouettes (phenyl)	47.2
[redacted], 1995	Les Evouettes (phenyl)	21.9
Geometric mean (n=10) **Median (n=10)**		**62.1**** **79.7****

* In this summary study this DT_{50} was reported to be 80.5 days, but the RMS has corrected it to this table (as well as the calculated mean values) according to the new revised study report of [redacted] & [redacted] (2011)).
** Geometric mean of replicate soils calculated first (18 Acres 20.8 days; Fayette 156 days; Madison 131 days; Les Evouettes 32.2 days)

Table B. 8-147: Laboratory SFO DT_{50} values and formation fractions for CGA150829 normalised to 20°C and pF2 (according to [redacted] & [redacted], 2011a & b; [redacted], 2011)

Study	Soil	DT_{50} 20°C, pF2 (days)	ffM (from prosulfuron)
[redacted], 2011	18 Acres (triazine)	295	0.36
[redacted], 2011a	18 Acres (triazine)	228	0.28
	Vétroz (triazine)	61.9	0.11
	Krone (triazine)	1000	0.41
	Nebraska (triazine)	1000	0.21
[redacted] & [redacted], 2006	18 Acres	250	-
	Gartenacker	102	-
	Krone	191	-
[redacted], 2011	Honville	158	-

	Arrow	34.3	-
Geometric mean (n=7)*		**167**	
ffm (n=4)*			**0.26**

* Geometric/arithmetic mean of replicate soils calculated first (18 Acres 256 days / 0.32; Krone 437 days)

Table B. 8-148: Laboratory SFO DT_{50} values and formation fractions for CGA159902 normalised to 20°C and pF2 (according to [redacted] & [redacted], 2011a & b)

Study	Soil	DT_{50} 20°C, pF2 (days)	ffM (from prosulfuron)
[redacted], 2011	18 Acres (phenyl)	90.6	0.36
[redacted] & [redacted], 2006	18 Acres	173*	-
	Gartenacker	169**	-
	Krone	89.7	-
Geometric mean (n=3)***		**124**	
ffm (n=1)			**0.36**

* calculated from DFOP slow phase
** calculated from HS slow phase
*** Geometric mean of replicate soils calculated first (18 Acres 125 days)

Table B. 8-149: Laboratory SFO DT_{50} values and formation fractions for CGA300406 normalised to 20°C and pF2 (according to [redacted] & [redacted], 2011b)

Study	Soil	DT_{50} 20°C, pF2 (days)	ffM (from prosulfuron)
[redacted], 2011	18 Acres (phenyl)	4.3	0.48
	18 Acres (triazine)	4.0	0.40
[redacted], 2011a	18 Acres (triazine)	4.1	0.51
	Vétroz (triazine)	25.4	0.56
	Krone (triazine)	2.6	0.29
	Nebraska (triazine)	14.0	0.25
[redacted], 1994	Les Evouettes (phenyl)	30.2	0.46
[redacted], 1995	Les Evouettes (phenyl)	21.0	0.68
Geometric mean (n=5)*		**9.9**	
ffm (n=5)*			**0.43**

* Geometric/arithmetic mean of replicate soils calculated first (18 Acres 4.1 days / 0.46; Les Evouettes 25.2 days / 0.57).

Table B. 8-150: Laboratory SFO DT_{50} values and formation fractions for CGA325025 normalised to 20°C and pF2 (according to [redacted] & [redacted], 2011a)

Study	Soil	DT_{50} 20°C, pF2 (days)	ffM (from CGA300406)
[redacted], [redacted] & [redacted], 2011	18 Acres	50.1	-
	Gartenacker	102	-
	Krone	47.4	-
Geometric mean (n=3)		**62.4**	
ffm (from CGA300406)			**0.12***

* Assumed ffm from CGA300406, calculated by (1-ffM_SYN542604)

Table B. 8-151: Laboratory SFO DT_{50} values and formation fractions for SYN542604 normalised to 20°C and pF2 (according to [redacted] & [redacted], 2011a & b)

Study	Soil	DT_{50} 20°C, pF2 (days)	ffM (from CGA300406)
[redacted], 2011	18 Acres (phenyl)	150	1.00
	18 Acres (triazine)	142	1.00
[redacted], 2011a	18 Acres (triazine)	184	0.73
	Vétroz (triazine)	61.5	0.87
	Krone (triazine)	125	1.00
	Nebraska (triazine)	118	1.00
[redacted], 1994	Les Evouettes (phenyl)	52.0	0.66
[redacted], 1995	Les Evouettes (phenyl)	51.0	0.54
[redacted], [redacted] & [redacted], 2011	18 Acres	102	-
	Gartenacker	25.0	-
	Krone	140	-
Geometric mean (n=6)*		**74.7**	
ffm (from CGA300406; n=6)*			**0.88**

* Geometric/arithmetic mean of replicate soils calculated first (18 Acres 142 days / 0.91; Krone 132 days; Les Evouettes 51.5 days / 0.60).

Table B. 8-152: Laboratory SFO DT_{50} values and formation fractions for CGA349707 normalised to 20°C and pF2 (according to [redacted] & [redacted], 2011a & b)

Study	Soil	DT_{50} 20°C, pF2 (days)	ffM (from SYN542604)
[redacted], 2006	18 Acres	113	-
	Gartenacker	91.9	-
	Krone	140	-
[redacted], 1994	Les Evouettes (phenyl)	210	1.00
[redacted], 1995	Les Evouettes (phenyl)	663	0.72
Geometric mean (n=4)*		**153**	
ffm (from SYN542604; n=2)			**0.86**

* Geometric mean of replicate soils calculated first (Les Evouettes 373 days).

<u>Dissipation in field soils</u>

Table B. 8-153: Field DT_{50} values for prosulfuron in field studies normalised to 20°C and pF2 (according to [redacted] & [redacted], 2011e)

Soil	Kinetics	DT_{50} (days)
GER1	SFO	24.9
GER2	SFO	3.5
GER3	SFO	8.5
GER4	SFO	10.6
GER5	SFO	3.7
GER6	SFO	6.2
SWZ1	SFO	3.4
SWZ2	SFO	2.3
IT1	DFOP	15.1*
FR1	SFO	12.2
FR2	SFO	4.9
Geometric mean (n=11) **Median (n=11)**		**6.7** **6.2**

* DFOP DT_{90}/3.32

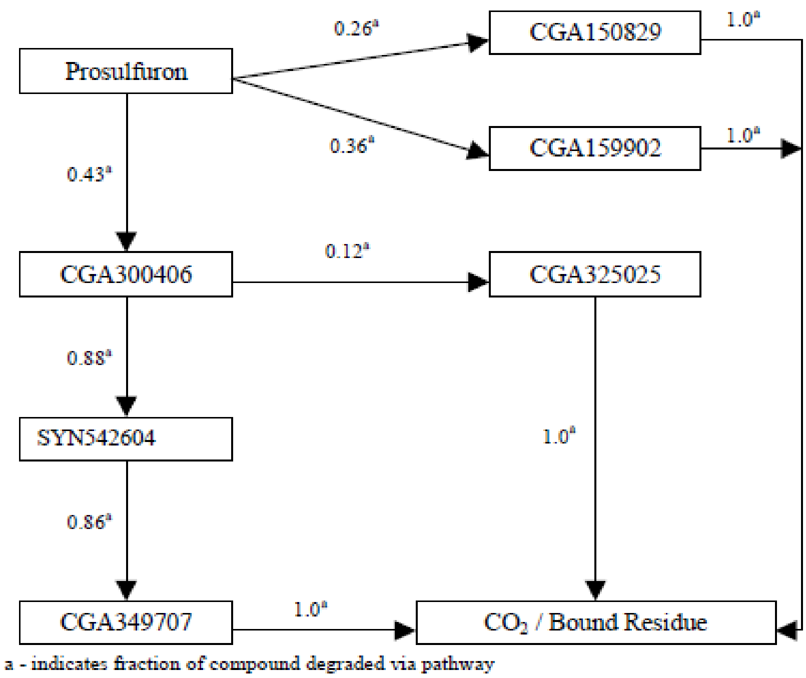


Figure B.8-142: Prosulfuron degradation pathway for model evaluations

Conclusion of the applicant:

Kinetic modelling analysis of datasets from prosulfuron laboratory and field soil dissipation studies showed good model fits when determining endpoints for modelling. The calculated SFO degradation rates normalised to 20ºC and pF2 soil moisture content and formation fractions can be used for environmental exposure assessments.

B.8.1.3. Adsorption and desorption in soil

B.8.1.3.1. Adsorption and desorption in soil

Data are available in the original DAR for CGA159902, CGA300406 and CGA325025 and in the Addendum to the DAR (26 July 2000) for CGA150829 and CGA349707. For the purpose of the renewal of prosulfuron approval, the Applicant submitted several Task Force studies on adsorption of CGA150829 and a new study on adsorption of SYN542604. A study on adsorption of CGA325025 was submitted, which recalculated the Koc values using a correct regression. In a context of request for an amendment of the approval conditions (to remove the restriction to application once every 3 years), the Applicant provided an adsorption/desorption study for metabolite SYN547308.

Reference:	KIIA 7.4.2 / 09
Report Title:	SYN547308 – Adsorption and Desorption Properties of 14C-SYN547308, a Metabolite of Prosulfuron
Author(s) & Year:	[redacted]; 2014
Document No, Authority registration No	3200461
Guideline(s):	Yes OECD 106 (January 2000)
Deviations:	None
GLP or GEP:	Yes
Acceptability:	Yes
Study relied upon:	Yes

Materials and methods:

Adsorption and desorption of SYN547308 (specific activity 2.209 MBq/mg, radiochemical purity 97.6 %) was determined in five soils using the batch equilibrium method. Soil characteristics are presented in Table B.8-166.

The preliminary study used five soils. Adsorption to container was assessed at 0.01 µg/mL. Two soil/solution ratios (1/1 and 1/2) were tested with test item concentration of 0.1 mg/L. Duplicate soil samples (2 mm sieved) of 5 or 10 g (dry weight) were added to the test vessels and were made up to a final volume of 10 ml with 0.01 M calcium chloride solution. Equilibration time determination was up to 48 hours. The samples of supernatant were measured by LSC and HPLC to check the stability of test item.

The definitive study used soil/solution ratio of 1/1 and five test item concentrations (0.01, 0.04, 0.1, 0.4 and 1.0 mg/L) and an adsorption time of 24 hours at 20°C followed by desorption for 24 hours. The aqueous supernatant after adsorption and desorption was separated by centrifugation and the SYN547308 residues in the supernatants were analyzed by liquid scintillation counting (LSC). After the desorption steps, the soil was dried and combusted. The adsorption parameters were calculated using the Freundlich adsorption isotherm. Stability of the test item during the entire test was confirmed by reverse phase HPLC with radio-detection. In addition, adsorption of the test item to tube walls was investigated during the study.

Table B. 8-166: Characteristics of the soils

	Vetroz	18 Acres	Krone	Madera	Sarpy
Soil type (USDA)	Loam	Sandy clay loam	Silt loam	Sandy loam	Silt loam
% clay (<0.002 mm)	23	25	16	11	25
% silt (0.002-0.05 mm)	44	24	65	16	56
% sand (>0.05 mm)	33	51	19	73	19
% organic C	2.3	3.0	1.3	0.5	1.8
pH (H_2O) ($CaCl_2$)	 8.3 7.7	 6.5 5.8	 6.0 5.0	 8.2 7.3	 6.7 6.4
Cation exchange capacity (mmol/kg soil)	108	189	166	96	16.7

Findings:

The test item was relatively stable in the course of the study. Although the amount of radioactivity recovered as ^{14}C-SYN547308 was < 90% in some instances, the proportion of radioactivity in the chromatogram attributed to ^{14}C-SYN547308 ranged from 90.1 to 99.2%. During the preliminary test no adsorption on the surface of the test vials was observed.

The results of desorption step show that in some soils desorption of SYN547308 is possible. There is no significant correlation between pH and adsorption for the investigated soils.

Table B. 8-167: Adsorption and desorption coefficients of SYN547308 in five soils

Soil	Adsorption				Desorption			
	Kf (mL/g)	Kfoc (mL/g)	1/n	r^2	Kdes (mL/g)	Kfoc (mL/g)	1/n	r^2
Vetroz	1.49	65	0.9318	0.9992	1.69	73	0.933	0.9997
18 Acres	2.89	96	0.9527	0.9990	4.18	139	0.996	0.9971
Krone	3.74	288	0.9501	0.9993	4.79	368	0.964	0.9997
Madera	0.42	83	0.9193	0.9982	0.53	105	0.919	0.9986
Sarpy	2.23	124	0.9127	0.9989	2.63	146	0.906	0.9991
Arithmetic mean (n=5) **Arithmetic mean (n=4)*** **Geometric mean (n=5)** **Geometric mean (n=4)***		**131.2** **-** **113.1** **89.5***	**0.9333** **0.929*** **-** **-**	**-** **-** **-** **-**	**-** **-** **-** **-**	**166.2** **-** **-** **-**	**0.945** **-** **-** **-**	**-** **-** **-** **-**

* Since pH dependency cannot be excluded, the RMS proposes leaving out Krone soil to produce a conservative endpoint; see RMS comments below.

Conclusion of the Applicant:

The adsorption Kfoc values for SYN547308 range from 65 mL/g to 288 mL/g and the 1/n values range from 0.9127 to 0.9527 indicating slightly non-linear adsorption. The desorption constants are similar to the adsorption constants, indicating that the test item can be desorbed in some soils.

Conclusion of HSE:

HSE has performed all relevant quality checks as part of confirming the acceptability of the study and of the reported endpoints. Detailed information on test item mass balance was available from the highest concentrations tested in each soil in the definitive test. Since this information was from the definitive test, it included the additional 24 h desorption step prior to solvent extraction of soil sorbed parent material. Therefore the mass balances reported are likely to be conservative compared to the mass balances that would be achieved after the single 24 h adsorption step. These checks confirmed that unextracted residues were generally low (less than 5% in 3 out of 5 soils, ranging from 1.9 to a peak of 8.8% in the 18 Acres soil). The parental mass balance ranged from 87.2 to 95.5% (only less than 90% in the 18 Acres soil, where unextracted radioactivity was highest) and % adsorption of 29.1-79.8% were all considered acceptable. The acceptability of the analytical method was difficult to confirm from the information reported, but it was noted that the LOQ was stated to be 0.1% of applied radioactivity. As a worst case, if this is assumed to apply to the highest test concentration, this should still be acceptable for the lowest concentration (2 orders of magnitude below the highest concentration) and based on maximum adsorbed percentage of around 80%. The use of the indirect method was appropriate based on a Kd * soil/solution ratio > 0.3 in all soils. The graphical fits of the Freundlich equation in the original study report were independently reviewed by the HSE evaluator. The R^2 of the standard linear regressions ranged from 0.9971 to 0.9997 and the visual fits were acceptable.

HSE repeated the sorption calculations using the supporting EFSA OECD 106 Evaluators checklist tool. This enabled calculation of Kd * soil/solution ratios, 95% confidence intervals and K_{fE} / K_f ratios. Note that the independent HSE analysis was unable to replicate the exact values reported in the study, but this is likely due to rounding errors in the HSE calculation where the study report used more accurate concentrations calculated direct from the analytical equipment and used more accurate soil and solution weights and volumes (the HSE calculations assumed 10 g soil and 10 ml solution as exact weights and volumes were only reported in the presentation of a single example calculation in the study report). Overall the HSE results were considered similar enough to the study report values to be able to accept the study report as the definitive values. The HSE values are presented below for information and to confirm the acceptability of the additional checklist criteria.

HSE sorption results based on the EFSA OECD 106 evaluators checklist tool

Parameter	Units	Vetroz	18 Acres	Krone	Madera	Sarpy
Adsorption method	-	indirect	indirect	indirect	indirect	indirect
Soil:solution ratio	g dw / mL	10 / 10	10 / 10	10 / 10	10 / 10	10 / 10
Mass balance of ^{14}C (at top concentration)	%	90.5	87.2	92.2	95.5	91.5
Adsorbed %	%	58.1-67.0	73.2-79.0	78.6-83.0	26.7-37.0	68.9-78.0
Kd x soil/solution ratio	-	1.39-2.03	2.75-3.76	3.67-4.88	0.36-0.59	2.22-3.55
$^{ads}K_f$ (95% confidence interval)	L/kg dw	1.403 (1.289-1.527)	2.788 (2.562-3.034)	3.503 (3.254-3.771)	0.395 (0.354-0.442)	2.175 (1.922-2.462)
$^{ads}1/n$ (95% confidence interval)	-	0.934 (0.911-0.957)	0.952 (0.931-0.973)	0.943 (0.925-0.960)	0.924 (0.888-0.960)	0.913 (0.882-0.944)
$^{ads}R^2$	-	0.999	0.999	0.999	0.998	0.998
$^{ads}K_{f,oc}$	L/kg dw	61.0	92.9	269.4	79.0	120.9
K_{fE} / K_f	-	1.17	1.18	1.08	1.23[1]	1.12

[1]the K_{fE} / K_f only slightly exceeded 1.2 in one replicate in the Madera soil. Since all other quality checks were acceptable, and this was the soil was adsorbed percentage was lowest, the result for this soil was accepted for inclusion in the regulatory database

With regards to possible pH dependence, it should be noted that metabolite SYN547308 contains a carboxylic acid functional group, and therefore there is a mechanistic reason for pH dependence to be observed, with lower sorption expected at higher pH as the acid functional group is dissociated. HSE performed analysis using the Kendall test and linear regression analysis and confirmed that pH dependence could not be excluded and as a result proposed deriving a geometric mean K_{foc} from the 4 soils with neutral and alkaline pH.

Although the p-value (0.086) of the Kendall test of correlation between K_f and pH was slightly higher than the standard 0.05 level of significance, HSE calculated the p-value of the linear regression of K_f versus pH as 0.026. Noting the mechanistic basis for possible pH dependence and the relatively high R^2 and low p-value for the linear regression of K_f versus pH, HSE considered that pH dependence should be considered when selecting modelling endpoints. HSE concludes a geometric mean K_{foc} of 89.5 ml/g and arithmetic mean 1/n of 0.929 for SYN547308 based on results for 4 soils with pH in H_2O > 6.5 (effectively excluding the result from the more acidic Krone soil where sorption was higher since this will result in a more conservative leaching assessment protective of neutral and alkaline soils).

As noted above, pH dependent sorption has been considered relevant for this metabolite, with lower sorption in neutral or alkaline soils. If degradation rates are influenced by the degree of soil sorption, theory would suggest that you would expect slower degradation in soils with more sorption.

In the sorption study of [redacted] (2014) the Vetroz soil was the most alkaline tested, and resulted in the lowest K_{foc}. However from a mechanistic point of view, if pH dependent degradation was linked to the observed pH dependent sorption, it would generally be expected that degradation would be slower in the soils where sorption was strongest (and thus reducing availability for degradation in the liquid phase). Degradation data on only 3 soils was available for SYN547308 and so it is difficult to draw clear conclusions from such a small database. But overall, given no obvious mechanistic reason to suspect pH dependent degradation, this has not been considered further and exposure modelling will rely on the geometric mean DT_{50} from all three tested soils. As noted above, SYN547308 is a non-relevant metabolite present at greater than 0.1µg/l and although taking into account slower degradation in alkaline soils would result in an increase in PECgw, overall HSE is content that the assessment is sufficiently conservative.

Predicted environmental concentrations in ground water and in surface water (PEC_{GW}, PEC_{SW})

Predicted environmental concentrations in ground water

The groundwater modelling report below details updated simulations from the EU Article 7 amendment assessment that were provided by the applicant to support this GB application. It therefore uses endpoints mostly in line with the conclusions of the EU assessment. The GB assessment is provided below.

Reference:	KIIA 9.6.1 / 02
Report Title:	Final Prosulfuron Technical letter. RE: A leaching Assessment for Prosulfuron and its Soil Metabolites CGA150829, CGA159902, CGA300406, SYN542604, CGA349707, CGA325025 and SYN547308 Using the PEARL 4.4.4, PELMO 5.5.3 and MACRO 5.5.4 Groundwater Models Following Spray Application to Various Crops in the EU – Plant uptake of 0.15.
Author(s) & Year:	[redacted]; 2018
Document No, Authority registration No	-
Guideline(s):	Yes FOCUS Groundwater Guidance
Deviations:	None
GLP or GEP:	No (not applicable modelling study)
Acceptability:	Yes
Study relied upon:	Yes

Materials and methods:

The revised modelling used a geomean field soil half-life normalised according to measured soil moisture data rather than modelled. The transpiration stream concentration factor (TSCF) value for prosulfuron was requested to be set at 0.15 (calculated from logPow at pH 6 of -0.21 using the Briggs equation). In addition, the water solubility for prosulfuron was set at 43,000 mg/L. All other input parameters were retained. Summary of the input parameters used in the modelling are presented in Tables B.8-236 and B.8-237.

The modelling was performed using FOCUS-PEARL 4.4.4, FOCUS-PELMO 5.5.3 and MACRO 5.5.4 models for all available FOCUS scenarios for maize.

Table B. 8-234: Agronomic parameters used in the groundwater modelling

Use No.	1	2	3
Crop	Maize / sweetcorn		
Application rate	1 x 15 g as/ha	1 x 16 g as/ha	1 x 20 g as/ha
Crop interception	25% (BBCH 12-18)		
Frequency of application	Annual		

Table B. 8-235: Application dates used in the groundwater modelling

Crop	Scenario	Application dates (absolute)
Maize Use No.1, 2, 3	Châteaudun	4-May
	Hamburg	8-May
	Kremsmünster	8-May
	Okehampton	28-May
	Piacenza	18-May
	Porto	4-May
	Sevilla	10-Mar
	Thiva	23-Apr

Table B. 8-236: Summary of input parameters for prosulfuron, CGA150829, CGA159902 and CGA300406 for PECgw calculations

Compound	Prosulfuron	CGA150829	CGA159902	CGA300406	Value in accordance to EU endpoint / Reference
Molar mass (g/mol)	419.4	140.1	253.2	405.4	Yes, EFSA (2014)
Water solubility (mg/L)	43000 (25°C)	1000 (20°C)	1000 (20°C)	1000 (20°C)	Yes, EFSA (2014); pH 7.7
Saturated vapour pressure (Pa)	0	0	0	0	Loss due to volatilisation was not considered → worst case
DT_{50} in soil (d) lab	62.1 (geomean)	196 (median)	188 (geomean)	2.6 (minimum) 30.2 (maximum)	Yes, EFSA (2014)
DT_{50} in soil (d) field	19.6 (geomean)	-	-	-	No, Hardy (2018) based on measured moisture content
K_{FOC} / K_{FOM} (mL/g)	11.7/ 6.8 (geomean)	45.6 / 26.5 (geomean)	68.0 / 39.4 (geomean)	46.8 / 27.1 (geomean)	Yes EFSA (2014)
1/n	0.869 (arithmetic mean)	0.90 (arithmetic mean)[e]	0.88 (arithmetic mean)	0.90 (arithmetic mean)	Yes EFSA (2014)
Plant uptake factor	0.15	0	0	0	Calculated using Brigg's equation for parent
Formation fraction	-	0.28 (from Prosulfuron)	0.43 (from Prosulfuron)	0.47 (from Prosulfuron)	Yes, EFSA (2014)
Washoff Factor (1/m) (PEARL)	0.0001	0.0001	0.0001	0.0001	Default
Foliar DT_{50} (d)	10	10	10	10	Default

Table B. 8-237: Summary of input parameters for SYN542604, CGA349707, CGA325025 and SYN547308 for PECgw calculations

Compound	SYN542604	CGA349707	CGA325025	SYN547308	Value in accordance to EU endpoint / Reference
Molar mass (g/mol)	381.3	338.3	404.4	449.4	Yes, EFSA (2014)
Water solubility (mg/L)	1000 (20°C)	1000 (20°C)	1000 (20°C)	1000 (20°C)	Yes, EFSA (2014)
Saturated vapour pressure (Pa)	0	0	0	0	Loss due to volatilisation was not considered → worst case
DT_{50} in soil (d) lab	84.6 (geomean)	153 (geomean)	62.4 (geomean)	67.1 (geomean)	Yes, EFSA (2014)
DT_{50} in soil (d) field	-	-	-	-	
K_{FOC} / K_{FOM} (mL/g)	111 / 64.4 (geomean)	44.0 / 25.5 (geomean)	26.2 / 15.2 (geomean)	89.5 / 51.9 (geomean)	Yes EFSA (2014)
1/n	0.850 (arithmetic mean)	0.960 (arithmetic mean)	0.973 (arithmetic mean)	0.929 (arithmetic mean)	Yes EFSA (2014)
Plant uptake factor	0	0	0	0	
Formation fraction	0.88 (from CGA300406)	0.86 (from SYN542604)	0.12 (from CGA300406)	0.5 (from Prosulfuron	Yes, EFSA (2014)
Washoff Factor (1/m) (PEARL)	0.0001	0.0001	0.0001	0.0001	Default
Foliar DT_{50} (d)	10	10	10	10	Default

Findings:

Table B. 8-238: PECgw for prosulfuron, CGA150829, CGA159902, CGA300406, SYN542604, CGA349707, CGA325025 and SYN547308 (with FOCUS PEARL v4.4.4) – using a minimum DT_{50} of 2.6 days for CGA300406

Crop	Scenario	80th Percentile PEC_{gw} at 1 m Soil Depth (µg/L)			
		Prosulfuron	CGA300406	SYN542604	CGA349707
Maize Use No. 1	Chateaudun	0.036	0.001	0.016	0.531
	Hamburg	0.086	0.004	0.031	0.687
	Kremsmunster	0.057	0.002	0.032	0.473
	Okehampton	0.089	0.003	0.039	0.410
	Piacenza	0.018	< 0.001	0.019	0.549
	Porto	0.007	< 0.001	0.004	0.278
	Sevilla	< 0.001	< 0.001	< 0.001	0.261
	Thiva	0.010	< 0.001	0.006	0.702
Maize Use No. 2	Chateaudun	0.039	0.001	0.018	0.568
	Hamburg	0.093	0.004	0.034	0.734
	Kremsmunster	0.061	0.002	0.034	0.505
	Okehampton	0.096	0.003	0.043	0.438
	Piacenza	0.019	< 0.001	0.021	0.587
	Porto	0.008	< 0.001	0.004	0.297
	Sevilla	< 0.001	< 0.001	< 0.001	0.279
	Thiva	0.011	< 0.001	0.006	0.752
Maize Use No. 3	Chateaudun	0.052	0.001	0.025	0.715
	Hamburg	0.124	0.005	0.047	0.924
	Kremsmunster	0.080	0.003	0.046	0.634
	Okehampton	0.125	0.004	0.058	0.548
	Piacenza	0.025	0.001	0.028	0.741
	Porto	0.011	< 0.001	0.006	0.374
	Sevilla	< 0.001	< 0.001	< 0.001	0.353
	Thiva	0.015	< 0.001	0.009	0.953

Crop	Scenario	80th Percentile PEC_{gw} at 1 m Soil Depth (µg/L)			
		CGA150829	CGA159902	SYN547308	CGA325025
Maize Use No. 1	Chateaudun	0.129	0.211	0.100	0.054
	Hamburg	0.158	0.268	0.148	0.080
	Kremsmunster	0.117	0.200	0.131	0.055
	Okehampton	0.112	0.217	0.162	0.051
	Piacenza	0.131	0.198	0.100	0.042
	Porto	0.062	0.100	0.043	0.025
	Sevilla	0.051	0.039	0.006	0.012
	Thiva	0.166	0.237	0.056	0.048
Maize Use No. 2	Chateaudun	0.138	0.228	0.108	0.058
	Hamburg	0.170	0.289	0.159	0.086
	Kremsmunster	0.126	0.215	0.141	0.059
	Okehampton	0.119	0.233	0.174	0.054
	Piacenza	0.141	0.213	0.108	0.045
	Porto	0.066	0.107	0.046	0.027
	Sevilla	0.055	0.043	0.007	0.012
	Thiva	0.178	0.256	0.061	0.052
Maize Use No. 3	Chateaudun	0.176	0.297	0.140	0.073
	Hamburg	0.216	0.373	0.206	0.108
	Kremsmunster	0.160	0.277	0.183	0.074
	Okehampton	0.151	0.299	0.223	0.068
	Piacenza	0.180	0.276	0.138	0.056
	Porto	0.084	0.139	0.060	0.034
	Sevilla	0.071	0.058	0.009	0.016
	Thiva	0.228	0.337	0.080	0.065

Table B. 8-239: PECgw for prosulfuron, CGA150829, CGA159902, CGA300406, SYN542604, CGA349707, CGA325025 and SYN547308 (with FOCUS PEARL v4.4.4) – using a maximum DT_{50} of 30.2 days for CGA300406

Crop	Scenario	80th Percentile PEC_{gw} at 1 m Soil Depth (µg/L)			
		Prosulfuron	CGA300406	SYN542604	CGA349707
Maize Use No. 1	Chateaudun	0.036	0.029	0.039	0.561
	Hamburg	0.086	0.056	0.058	0.715
	Kremsmunster	0.057	0.051	0.053	0.480
	Okehampton	0.090	0.063	0.064	0.405
	Piacenza	0.018	0.029	0.035	0.601
	Porto	0.007	0.009	0.011	0.292
	Sevilla	< 0.001	< 0.001	< 0.001	0.290
	Thiva	0.010	0.012	0.022	0.788
Maize Use No. 2	Chateaudun	0.039	0.031	0.043	0.599
	Hamburg	0.094	0.061	0.063	0.763
	Kremsmunster	0.061	0.055	0.058	0.512
	Okehampton	0.097	0.068	0.069	0.432
	Piacenza	0.019	0.031	0.039	0.643
	Porto	0.008	0.010	0.012	0.312
	Sevilla	< 0.001	< 0.001	< 0.001	0.311
	Thiva	0.011	0.013	0.024	0.844
Maize Use No. 3	Chateaudun	0.052	0.041	0.058	0.754
	Hamburg	0.125	0.080	0.083	0.959
	Kremsmunster	0.081	0.072	0.078	0.642
	Okehampton	0.127	0.088	0.092	0.539
	Piacenza	0.025	0.040	0.052	0.811
	Porto	0.011	0.013	0.017	0.393
	Sevilla	< 0.001	< 0.001	< 0.001	0.393
	Thiva	0.015	0.018	0.033	1.07

Crop	Scenario	80th Percentile PEC_{gw} at 1 m Soil Depth (µg/L)			
		CGA150829	CGA159902	SYN547308	CGA325025
Maize Use No. 1	Chateaudun	0.129	0.211	0.100	0.062
	Hamburg	0.158	0.268	0.148	0.092
	Kremsmunster	0.118	0.200	0.131	0.062
	Okehampton	0.112	0.218	0.162	0.056
	Piacenza	0.132	0.198	0.100	0.053
	Porto	0.062	0.100	0.043	0.033
	Sevilla	0.051	0.039	0.006	0.018
	Thiva	0.166	0.237	0.057	0.060
Maize Use No. 2	Chateaudun	0.139	0.228	0.108	0.067
	Hamburg	0.170	0.289	0.160	0.098
	Kremsmunster	0.126	0.215	0.142	0.067
	Okehampton	0.119	0.234	0.174	0.060
	Piacenza	0.141	0.214	0.108	0.056
	Porto	0.066	0.107	0.046	0.035
	Sevilla	0.055	0.043	0.007	0.019
	Thiva	0.179	0.257	0.061	0.064
Maize Use No. 3	Chateaudun	0.177	0.298	0.140	0.084
	Hamburg	0.216	0.373	0.207	0.124
	Kremsmunster	0.160	0.277	0.183	0.084
	Okehampton	0.151	0.300	0.223	0.075
	Piacenza	0.181	0.277	0.138	0.071
	Porto	0.084	0.139	0.060	0.044
	Sevilla	0.071	0.059	0.009	0.024
	Thiva	0.228	0.339	0.081	0.081

Table B. 8-240: PECgw for prosulfuron, CGA150829, CGA159902, CGA300406, SYN542604, CGA349707, CGA325025 and SYN547308 (with FOCUS PELMO 5.5.3) – using a minimum DT_{50} of 2.6 days for CGA300406

Crop	Scenario	80th Percentile PEC_{gw} at 1 m Soil Depth (µg/L)			
		Prosulfuron	CGA300406	SYN542604	CGA349707
Maize Use No. 1	Chateaudun	0.019	0.001	0.010	0.505
	Hamburg	0.054	0.002	0.020	0.551
	Kremsmunster	0.053	0.002	0.027	0.482
	Okehampton	0.080	0.002	0.031	0.375
	Piacenza	0.027	0.001	0.022	0.371
	Porto	0.007	< 0.001	0.004	0.281
	Sevilla	0.001	< 0.001	< 0.001	0.240
	Thiva	0.005	< 0.001	0.003	0.549
Maize Use No. 2	Chateaudun	0.021	0.001	0.011	0.540
	Hamburg	0.057	0.002	0.022	0.589
	Kremsmunster	0.057	0.002	0.029	0.515
	Okehampton	0.086	0.003	0.033	0.400
	Piacenza	0.029	0.001	0.024	0.396
	Porto	0.008	< 0.001	0.004	0.300
	Sevilla	0.001	< 0.001	< 0.001	0.257
	Thiva	0.006	< 0.001	0.003	0.587
Maize Use No. 3	Chateaudun	0.027	0.001	0.015	0.680
	Hamburg	0.073	0.003	0.029	0.740
	Kremsmunster	0.075	0.002	0.039	0.649
	Okehampton	0.110	0.003	0.045	0.502
	Piacenza	0.038	0.002	0.032	0.498
	Porto	0.010	< 0.001	0.006	0.377
	Sevilla	0.001	< 0.001	< 0.001	0.326
	Thiva	0.008	< 0.001	0.004	0.741

Crop	Scenario	80th Percentile PEC_{gw} at 1 m Soil Depth (µg/L)			
		CGA150829	CGA159902	SYN547308	CGA325025
Maize Use No. 1	Chateaudun	0.119	0.186	0.070	0.045
	Hamburg	0.127	0.214	0.115	0.061
	Kremsmunster	0.115	0.196	0.122	0.051
	Okehampton	0.107	0.206	0.147	0.049
	Piacenza	0.095	0.164	0.108	0.040
	Porto	0.060	0.100	0.043	0.025
	Sevilla	0.043	0.028	0.003	0.012
	Thiva	0.138	0.178	0.035	0.037
Maize Use No. 2	Chateaudun	0.128	0.200	0.075	0.048
	Hamburg	0.137	0.231	0.124	0.065
	Kremsmunster	0.123	0.211	0.131	0.055
	Okehampton	0.115	0.221	0.158	0.052
	Piacenza	0.102	0.176	0.116	0.043
	Porto	0.064	0.108	0.046	0.026
	Sevilla	0.046	0.030	0.003	0.013
	Thiva	0.149	0.193	0.038	0.040
Maize Use No. 3	Chateaudun	0.163	0.260	0.098	0.061
	Hamburg	0.174	0.298	0.160	0.082
	Kremsmunster	0.157	0.270	0.169	0.069
	Okehampton	0.145	0.285	0.203	0.065
	Piacenza	0.130	0.227	0.148	0.054
	Porto	0.081	0.139	0.060	0.033
	Sevilla	0.060	0.042	0.004	0.016
	Thiva	0.190	0.256	0.050	0.050

Table B. 8-241: PECgw for prosulfuron, CGA150829, CGA159902, CGA300406, SYN542604, CGA349707, CGA325025 and SYN547308 (with FOCUS PELMO 5.5.3) – using a maximum DT_{50} of 30.2 days for CGA300406

Crop	Scenario	80th Percentile PEC_{gw} at 1 m Soil Depth (μg/L)			
		Prosulfuron	CGA300406	SYN542604	CGA349707
Maize Use No. 1	Chateaudun	0.019	0.019	0.026	0.539
	Hamburg	0.054	0.032	0.038	0.571
	Kremsmunster	0.053	0.045	0.048	0.496
	Okehampton	0.080	0.055	0.054	0.372
	Piacenza	0.027	0.035	0.038	0.389
	Porto	0.007	0.010	0.011	0.297
	Sevilla	0.001	< 0.001	< 0.001	0.263
	Thiva	0.005	0.006	0.011	0.601
Maize Use No. 2	Chateaudun	0.021	0.020	0.029	0.577
	Hamburg	0.057	0.034	0.041	0.609
	Kremsmunster	0.057	0.049	0.052	0.529
	Okehampton	0.086	0.059	0.059	0.397
	Piacenza	0.029	0.037	0.041	0.416
	Porto	0.008	0.011	0.012	0.317
	Sevilla	0.001	< 0.001	< 0.001	0.282
	Thiva	0.006	0.007	0.012	0.642
Maize Use No. 3	Chateaudun	0.027	0.027	0.039	0.728
	Hamburg	0.073	0.045	0.055	0.764
	Kremsmunster	0.075	0.065	0.069	0.662
	Okehampton	0.110	0.077	0.079	0.497
	Piacenza	0.038	0.048	0.055	0.522
	Porto	0.010	0.015	0.017	0.398
	Sevilla	0.001	0.001	0.001	0.358
	Thiva	0.008	0.009	0.017	0.808

Crop	Scenario	80th Percentile PEC_{gw} at 1 m Soil Depth (μg/L)			
		CGA150829	CGA159902	SYN547308	CGA325025
Maize Use No. 1	Chateaudun	0.119	0.186	0.070	0.055
	Hamburg	0.127	0.214	0.115	0.071
	Kremsmunster	0.115	0.196	0.122	0.057
	Okehampton	0.107	0.206	0.147	0.052
	Piacenza	0.095	0.164	0.108	0.046
	Porto	0.060	0.100	0.043	0.031
	Sevilla	0.043	0.028	0.003	0.017
	Thiva	0.138	0.178	0.035	0.048
Maize Use No. 2	Chateaudun	0.128	0.200	0.075	0.058
	Hamburg	0.137	0.231	0.124	0.076
	Kremsmunster	0.123	0.211	0.131	0.061
	Okehampton	0.115	0.221	0.158	0.056
	Piacenza	0.102	0.176	0.116	0.050
	Porto	0.064	0.108	0.046	0.033
	Sevilla	0.046	0.030	0.003	0.018
	Thiva	0.149	0.193	0.038	0.051
Maize Use No. 3	Chateaudun	0.163	0.260	0.098	0.074
	Hamburg	0.174	0.298	0.160	0.095
	Kremsmunster	0.157	0.270	0.169	0.077
	Okehampton	0.145	0.285	0.203	0.070
	Piacenza	0.130	0.227	0.148	0.062
	Porto	0.081	0.139	0.060	0.042
	Sevilla	0.060	0.042	0.004	0.023
	Thiva	0.190	0.256	0.050	0.064

Table B. 8-242: PECgw for prosulfuron, CGA150829, CGA159902, CGA300406, SYN542604, CGA349707, CGA325025 and SYN547308 (with FOCUS MACRO v5.5.4) – using a minimum DT_{50} of 2.6 days for CGA300406

Crop	Scenario	80th Percentile PEC_{gw} at 1 m Soil Depth (µg/L)			
		Prosulfuron	CGA300406	SYN542604	CGA349707
Maize Use No. 1	Chateaudun	0.015	< 0.001	0.006	0.374
	-				
Maize Use No. 2	Chateaudun	0.016	< 0.001	0.006	0.399
	-				
Maize Use No. 3	Chateaudun	0.022	< 0.001	0.008	0.503
	-				

Crop	Scenario	80th Percentile PEC_{gw} at 1 m Soil Depth (µg/L)			
		CGA150829	CGA159902	SYN547308	CGA325025
Maize Use No. 1	Chateaudun	0.096	0.144	0.051	0.033
	-				
Maize Use No. 2	Chateaudun	0.103	0.156	0.055	0.035
	-				
Maize Use No. 3	Chateaudun	0.132	0.202	0.071	0.044
	-				

Table B. 8-243: PECgw for prosulfuron, CGA150829, CGA159902, CGA300406, SYN542604, CGA349707, CGA325025 and SYN547308 (with FOCUS MACRO v5.5.4) – using a maximum DT_{50} of 30.2 days for CGA300406

Crop	Scenario	80th Percentile PEC_{gw} at 1 m Soil Depth (µg/L)			
		Prosulfuron	CGA300406	SYN542604	CGA349707
Maize Use No. 1	Chateaudun	0.015	0.012	0.006	0.374
	-				
Maize Use No. 2	Chateaudun	0.016	0.013	0.006	0.399
	-				
Maize Use No. 3	Chateaudun	0.022	0.017	0.008	0.503
	-				

Crop	Scenario	80th Percentile PEC_{gw} at 1 m Soil Depth (µg/L)			
		CGA150829	CGA159902	SYN547308	CGA325025
Maize Use No. 1	Chateaudun	0.096	0.144	0.051	0.033
	-				
Maize Use No. 2	Chateaudun	0.103	0.156	0.055	0.035
	-				
Maize Use No. 3	Chateaudun	0.132	0.202	0.071	0.044
	-				

Conclusion of HSE:

HSE has repeated a subset of the calculations using the final agreed prosulfuron DT_{50} of 18.7 d and 216 d for CGA150829 (and all other agreed endpoints as per Tables B.8.236 and 237 – see consolidated summary). Applications dates in Table B.8.235

were noted to be in line with estimates from AppDate for BBCH 12-18 in maize and were also used in the HSE calculations.

Compound	Prosulfuron	CGA150829	CGA159902	CGA300406	Value in accordance with EU endpoint / reference
Molar mass (g/mol)	419.4	140.1	253.2	405.4	Yes, EFSA (2014)
Water solubility (mg/l)	43000 (25°C)	1000 (20°C)	1000 (20°C)	1000 (20°C)	Yes, EFSA (2014)
Saturated vapour pressure (Pa)	0	0	0	0	Worst case
DT_{50} in soil (d) lab	62.1 (geomean)	216 (median)	188 (geomean)	2.6 (minimum) 30.2 (maximum)	Yes, EFSA (2014)
DT_{50} in soil (d) field	18.7 (geomean)	-	-	-	[redacted] (2018)
K_{foc} / K_{fom} (ml/g)	11.7 / 6.8 (geomean)	45.6 / 26.5 (geomean)	68.0 / 39.4 (geomean)	46.8 / 27.1 (geomean)	Yes, EFSA (2014)
1/n	0.869 (arithmetic mean)	0.90 (arithmetic mean)	0.88 (arithmetic mean)	0.90 (arithmetic mean)	Yes, EFSA (2014)
Plant uptake factor	0.15	0	0	0	Based on Briggs equation for parent
Formation fraction	-	0.28 (from prosulfuron)	0.43 (from prosulfuron)	0.47 (from prosulfuron	Yes, EFSA (2014)
Compound	**SYN542604**	**CGA349707**	**CGA325025**	**SYN547308**	**Value in accordance with EU endpoint / reference**
Molar mass (g/mol)	381.3	338.3	404.4	449.4	Yes, EFSA (2014)
Water solubility (mg/l)	1000 (20°C)	1000 (20°C)	1000 (20°C)	1000 (20°C)	Yes, EFSA (2014)

Saturated vapour pressure (Pa)	0	0	0	0	Worst case
DT_{50} in soil (d) lab	84.6 (geomean)	153 (geomean)	62.4 (geomean)	67.1 (geomean)	Yes, EFSA (2014)
K_{foc} / K_{fom} (ml/g)	111 / 64.4 (geomean)	44.0 / 25.5 (geomean)	26.2 / 15.2 (geomean)	89.5 / 51.9 (geomean)	Yes, EFSA (2014)
1/n	0.850 (arithmetic mean)	0.960 (arithmetic mean)	0.973 (arithmetic mean)	0.929 (arithmetic mean)	Yes, EFSA (2014)
Plant uptake factor	0	0	0	0	Default
Formation fraction	0.88 (from CGA300406)	0.86 (from SYN542604)	0.12 (from CGA300406)	0.5 (from prosulfuron	Yes, EFSA (2014)

HSE only repeated modelling using the FOCUS PEARL v4.4.4 model since this resulted in higher predicted concentrations than PELMO or MACRO simulations. In the full report modelling was performed with a fast and slow DT_{50} for metabolite CGA300406. However maximum PECgw values were derived with simulations using the maximum DT_{50} value of 30.2 d, and so only these simulations have been repeated in the HSE assessment. HSE only repeated modelling for the 1 x 20 g a.s./ha GAP since only this GAP is relevant for considering removal of the restriction to 1 application every 3 years at the maximum rate.

The impact of running the simulations with the shorter parent DT_{50} of 18.7 d was to slightly reduce all metabolite PECgw values, except for two scenarios for metabolite CGA349707 where concentrations were slightly higher than calculated with the longer parent DT_{50}. Since this metabolite clearly exceeded the 0.1µg/l limit (and the 0.75µg/l limit) this difference is not considered of significance for the regulatory decision. The impact of running the simulations with the longer DT_{50} for CGA150829 was to slightly increase PECgw values for this metabolite only (noting this is a terminal metabolite in the degradation scheme). HSE results are presented below.

HSE PECgw simulations for prosulfuron, CGA300406, SYN542604, CGA349707, CGA150829, CGA159902, SYN547308 and CGA325025 (with FOCUS PEARL v4.4.4) – using of DT_{50} of 18.7 for prosulfuron, a maximum DT50 of 30.2 d for CGA 300406 and a DT50 of 216 d for CGA 150829. Values above 0.1µg/l in bold.

Crop	Scenario	80th percentile PECgw at 1m depth (µg/l)			
		Prosulfuron	CGA300406	SYN542604	CGA349707
Maize 1 x 20 g a.s./ha Annual	Chateaudun	0.043	0.038	0.056	**0.754**
	Hamburg	**0.106**	0.076	0.081	**0.962**
	Kremsmunster	0.069	0.069	0.076	**0.644**
	Okehampton	**0.111**	0.086	0.090	**0.543**
Maize 1 x 20 g a.s./ha 1 year in 2	Chateaudun	0.024	0.021	0.025	**0.376**
	Hamburg	0.055	0.031	0.036	**0.436**
	Kremsmunster	0.037	0.032	0.032	**0.326**
	Okehampton	0.056	0.046	0.038	**0.263**
Crop	Scenario	80th percentile PECgw at 1m depth (µg/l)			
		CGA150829	CGA159902	SYN547308	CGA325025
Maize 1 x 20 g a.s./ha Annual	Chateaudun	**0.194**	**0.293**	**0.135**	0.083
	Hamburg	**0.234**	**0.370**	**0.200**	**0.123**
	Kremsmunster	**0.174**	**0.274**	**0.177**	0.083
	Okehampton	**0.162**	**0.299**	**0.220**	0.075
Maize 1 x 20 g a.s./ha 1 year in 2	Chateaudun	0.097	**0.139**	0.071	0.043
	Hamburg	**0.107**	**0.163**	0.094	0.059
	Kremsmunster	0.088	**0.131**	0.083	0.041
	Okehampton	0.078	**0.138**	**0.105**	0.039

Using the prosulfuron field DT_{50} value, for annual application at 20 g/ha, the concentrations of prosulfuron were >0.1 µg/L in two out of four GB relevant scenarios with PEARL 4.4.4 (0.106 µg/L in Hamburg and 0.111 µg/L in Okehampton scenario). Concentrations of prosulfuron were <0.1 µg/L in all four GB relevant scenarios when uses were restricted to a 1 in 2 year interval in all GB relevant scenarios.

The current conditions of approval of prosulfuron limit use to one application every three years at a maximum dose of 20 g/ha. The groundwater modelling presented here demonstrates that the current restriction to a 1 in 3 year application interval is no longer required. Since annual applications at a maximum dose of 20 g/ha do result in the identification of safe uses (ie based on 2 out of 4 GB relevant FOCUS scenarios giving rise to concentrations <0.1 µg/L) no restriction on the approval is considered necessary. However the risk to groundwater resources may still need to be mitigated at individual product level.

To protect groundwater resources, products must demonstrate concentrations of prosulfuron <0.1 µg/L in all four GB relevant scenarios. HSE notes that this may result in restriction at product level for product uses at applications of 20 g/ha.

The metabolites CGA150829 and CGA325025 occur up to 0.234 µg/L and 0.123 µg/L respectively following annual applications. For CGA150829 the trigger was still breached in one GB relevant scenario when uses were restricted to a 1 in 2 year application (0.107 µg/L in the Hamburg scenario). For CGA325025 the trigger was not breached in any GB relevant scenario when uses were restricted to 1 year in 2. The metabolites CGA159902 and SYN547308 occur at >0.1 µg/L and CGA349707 occurs at >0.75 µg/L following annual applications of 20 g/ha as shown in the table above.

Since all 5 metabolites included in the residue definition for groundwater assessment are now considered non-relevant according to SANCO/221/2000, no additional restrictions on timing of application of prosulfuron products applied at up to 20 g/ha are required to mitigate risks to groundwater from these metabolites. Further details of the groundwater metabolite relevance assessment is included in Volume 1, Section 2.11, including an assessment up to Step 5 of the SANCO/221/2000 guidance for metabolite CGA349707 which breaches the 0.75 µg/L trigger limit following annual applications.

B.8.2. DEFINITION OF THE RESIDUE

B.8.2.1. Definition of the residue for risk assessment (Data Requirement 7.4.1)

Soil:

Prosulfuron, CGA150829, CGA159902, CGA300406, CGA325025, SYN542604, CGA349707

Groundwater:

Prosulfuron, CGA150829, CGA159902, CGA300406, CGA325025, SYN542604, CGA349707, SYN547308

Surface water:

Prosulfuron, CGA150829, CGA159902, CGA300406, CGA325025, SYN542604, CGA349707

Sediment:

Prosulfuron, CGA159902, CGA300406

Air:

Prosulfuron

B.8.3. References relied on

Annex point	Author (s)	Year	Title Source (were different from company) Company, report No GLP status Published or not	Data protection claimed Y/N	Owner
KIIA 7.2.1 / 06	[redacted]	2016a	Prosulfuron – Soil Dissipation Study with Bare Soil Application in Breitenwisch, Germany in 2014-2015. Final Report. Syngenta Eurofins Agroscience Services GmbH, Germany, S13-05212 GLP, not published	Y	Syngenta
KIIA 7.2.1 / 07	[redacted]	2016b	Prosulfuron – Soil Dissipation Study with Bare Soil Application in Castelsarrasin, France in 2014-2015. Final Report. Syngenta Eurofins Agroscience Services GmbH, Germany, S13-05218 GLP, not published	Y	Syngenta
KIIA 7.2.1 / 08	[redacted]	2016c	Prosulfuron – Soil Dissipation Study with Bare Soil Application in Bogense - Nørreby, Denmark in 2014-2015. Final Report. Syngenta Eurofins Agroscience Services GmbH, Germany, S13-05216 GLP, not published	Y	Syngenta
KIIA 7.2.1 / 09	[redacted]	2016d	Prosulfuron – Soil Dissipation Study with Bare Soil Application in Wilson, UK in 2014-2015. Final Report. Syngenta Eurofins Agroscience Services GmbH, Germany, S13-05214 GLP, not published	Y	Syngenta

Annex point	Author (s)	Year	Title Source (were different from company) Company, report No GLP status Published or not	Data protection claimed Y/N	Owner
KIIA 7.2.1 / 10	[redacted]	2016e	Prosulfuron – Soil Dissipation Study with Bare Soil Application in Saint-Cyprien, France in 2014-2015. Final Report. Syngenta Eurofins Agroscience Services GmbH, Germany, S13-05219 GLP, not published	Y	Syngenta
KIIA 7.2.1 / 11	[redacted]	2016f	Prosulfuron – Soil Dissipation Study with Bare Soil Application in Canals, Spain in 2014-2015. Final Report. Syngenta Eurofins Agroscience Services GmbH, Germany, S13-05220 GLP, not published	Y	Syngenta
KIIA 7.2.1 / 12	[redacted]	2016a	Prosulfuron – Kinetic Modelling Evaluation of Data from Field Soil Dissipation Studies Normalised to 20°C (Q_{10} 2.58). Final report. Syngenta Battelle UK Ltd., NC/15/041A Not GLP, not published	Y	Syngenta
KIIA 7.2.1 / 14	[redacted]	2018	Prosulfuron – Kinetic Modelling Evaluation of Data from Field Soil Dissipation Studies Normalised to 20°C and pF2. Final Report. Syngenta Battelle UK Ltd., NC/18/031A Not GLP, not published	Y	Syngenta
KIIA 7.2.3 / 10	[redacted]	2014	Prosulfuron – Rate of Degradation of [^{14}C]-SYN547308. Final Report.	Y	Syngenta

Annex point	Author (s)	Year	Title Source (were different from company) Company, report No GLP status Published or not	Data protection claimed Y/N	Owner
			Syngenta Smithers Viscient (ESG) Ltd., Harrogate, United Kingdom, 3200460 GLP, not published		
KIIA 7.2.3 /11	[redacted]	2014	Prosulfuron – Laboratory Degradation Kinetics for Modelling Endpoints for the soil metabolite SYN547308. Final Report. Syngenta, RAJ1065B Not GLP, not published	Y	Syngenta
KIIA 7.4.2 / 09	[redacted]	2014	SYN547308 – Adsorption and Desorption Properties of ^{14}C-SYN547308, a Metabolite of Prosulfuron Syngenta Smithers Viscient (ESG) Ltd. Harrogate, UK, 3200461 GLP, Not published	Y	Syngenta
KIIIA 9.6.1/02	[redacted]	2018	Final Prosulfuron Technical letter. RE: A leaching Assessment for Prosulfuron and its Soil Metabolites CGA150829, CGA159902, CGA300406, SYN542604, CGA349707, CGA325025 and SYN547308 Using the PEARL 4.4.4, PELMO 5.5.3 and MACRO 5.5.4 Groundwater Models Following Spray Application to Various Crops in the EU – Plant uptake of 0.15. Syngenta Not GLP, not published	Y	Syngenta