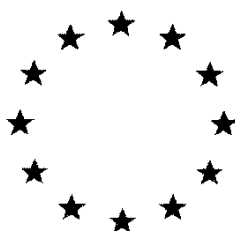


# *European Commission*



**Draft Renewal Assessment Report prepared according to the Commission  
Regulation (EU) N° 1107/2009**

**FLUFENACET**

**Volume 2**

Rapporteur Member State: Poland  
Co-Rapporteur Member State: France

## Version History

When	What
August 1997	Initial assessment. <b>Draft Assessment Report</b> for first inclusion to Annex I. RMS: FR
April 2016	<b>Draft Renewal Assessment Report</b> prepared according to the Commission; Regulation (EU) N° 1107/2009; RMS: PL; Co-RMS: FR
May 2017	Revised after Co-RMS comments

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## A. LIST OF THE TESTS, STUDIES AND INFORMATION SUBMITTED

New studies and information submitted in the framework of the application for renewal of a.s. approval have been highlighted by means of yellow shading.

### A.1. IDENTITY

Please refer to the different Volume 4, confidential parts.

### A.2. PHYSICAL AND CHEMICAL PROPERTIES

References for the active substance: FLUFENACET

Annex point / reference number	Author(s)	Year	Title Source ( <i>where different from company</i> ) Company name, Report No., Date, GLP status ( <i>where relevant</i> ), published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
74	Krohn, J.	1992a	Melting point of FOE 5043 Bayer AG, Leverkusen, Germany Bayer CropScience, Report No.: PC167, Edition Number: M-004726-01-1 Date: 1992-07-31 GLP/GEP: yes, unpublished	N	N	-	Bayer CropScience
KCA 2.1 /02	Eberz, A.; Berg, G.	1993	Thermal stability of the active ingredient FOE 5043 Bayer AG, Leverkusen, Germany Bayer CropScience, Report No.: PC176, Edition Number: M-004753-01-1 Date: 1993-09-01 GLP/GEP: yes, unpublished	N	N	-	Bayer CropScience

Annex point / reference number	Author(s)	Year	Title Source ( <i>where different from company</i> ) Company name, Report No., Date, GLP status ( <i>where relevant</i> ), published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCA 2.2 /01	Krohn, J.	1994a	Vapour pressure curve of FOE 5043 Bayer AG, Leverkusen, Germany Bayer CropScience, Report No.: PC170, Edition Number: M-004730-01-1 Date: 1994-01-25 GLP/GEP: yes, unpublished	N	N	-	Bayer CropScience
KCA 2.2 /02	Krohn, J.	1994b	Calculation of the Henry Law Constant of FOE 5043/FOE 5043-N-isomer Bayer AG, Leverkusen, Germany Bayer CropScience, Report No.: PC185, Edition Number: M-004737-01-1 Date: 1994-03-02 GLP/GEP: no, unpublished	N	N		Bayer CropScience
KCA 2.2 /03	Ziemer, F.	2013	AE 1218900 (FOE5043-N-isomer): Calculation of the Henry's Law constants Bayer CropScience, Report No.: AF13/019, Edition Number: M-461497-01-1 Date: 2013-08-13 GLP/GEP: no, unpublished	N	Y	A new calculation has been performed since the necessary old water solubility study had applied an equilibration time of only 24 h. The new calculation is based on a new water solubility study of the FOE 5043-N-Isomer	Bayer CropScience

Annex point / reference number	Author(s)	Year	Title Source ( <i>where different from company</i> ) Company name, Report No., Date, GLP status ( <i>where relevant</i> ), published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCA 2.3 /01	Leibowitz, S. J.	1994	The physical properties of BAY FOE 5043 technical Miles Inc., Agriculture Division, Kansas City, MO, USA Bayer CropScience, Report No.: 106605, Edition Number: M-004755-01-1 Date: 1994-07-14 GLP/GEP: yes, unpublished	N	N	-	Bayer CropScience
KCA 2.3 /02	Krohn, J.	1995	Appearance and odour of FOE 5043 Bayer AG, Leverkusen, Germany Bayer CropScience, Report No.: PC1071, Edition Number: M-004738-01-1 Date: 1995-11-07 GLP/GEP: no, unpublished	N	N	-	Bayer CropScience
KCA 2.3 /03	Ziemer, F.; Strunk, B.	2012a	Flufenacet (FOE 5043, AE F133402), pure substance: Physical characteristics colour, physical state and odour Bayer CropScience, Report No.: PA12/078, Edition Number: M-438536-01-1 Date: 2012-09-06 GLP/GEP: yes, unpublished	N	Y	A new study has been performed since the old study had not precisely described the testing procedure.	Bayer CropScience
KCA 2.3 /04	Ziemer, F.; Strunk, B.	2012b	Flufenacet (FOE 5043, AE F133402), technical substance: Physical characteristics colour, physical state and odour Bayer CropScience, Report No.: PA12/087, Edition Number: M-441058-01-1 Date: 2012-10-31 GLP/GEP: yes, unpublished	N	Y	A new study has been performed since the old study had not precisely described the testing procedure.	Bayer CropScience

<b>Annex point / reference number</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Source (where different from company) Company name, Report No., Date, GLP status (where relevant), published or not</b>	<b>Vertebrate study Y/N</b>	<b>Data protection claimed Y/N</b>	<b>Justification if data protection is claimed</b>	<b>Owner</b>
KCA 2.4 /01	Stupp, H. P.	1993	Spectra of FOE 5043 - UV spectrum Bayer AG, Leverkusen, Germany Bayer CropScience, Report No.: PC162, Edition Number: M-004721-01-1 Date: 1993-10-12 GLP/GEP: no, unpublished	N	N	-	Bayer CropScience
KCA 2.4 /02	Etzel, W.	1992	Spectroscopic identification of FOE 5043 Bayer AG, Leverkusen, Germany Bayer CropScience, Report No.: PC163, Edition Number: M-004722-01-1 Date: 1992-12-02 GLP/GEP: yes, unpublished	N	N	-	Bayer CropScience
KCA 2.4 /03	Grohs, R.	1993	Spectra of FOE 5043 - infrared spectrum Bayer AG, Leverkusen, Germany Bayer CropScience, Report No.: PC164, Edition Number: M-004723-01-1 Date: 1993-08-31 GLP/GEP: no, unpublished	N	N	-	Bayer CropScience
KCA 2.4 /04	Etzel, W.	1993	Spectra of FOE 5043 - NMR spectrum Bayer AG, Leverkusen, Germany Bayer CropScience, Report No.: PC165, Edition Number: M-004724-01-1 Date: 1993-11-05 GLP/GEP: no, unpublished	N	N	-	Bayer CropScience

Annex point / reference number	Author(s)	Year	Title Source ( <i>where different from company</i> ) Company name, Report No., Date, GLP status ( <i>where relevant</i> ), published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCA 2.4 /05	Thielking, G.	1993	Spectra of FOE 5043 - mass spectrum Bayer AG, Leverkusen, Germany Bayer CropScience, Report No.: PC166, Edition Number: M-004725-01-1 Date: 1993-08-30 GLP/GEP: no, unpublished	N	N	-	Bayer CropScience
KCA 2.4 /06	Ruengeler, W.	2012	Spectral data set of flufenacet a.i. - Reference material Bayer CropScience, Report No.: 15-600-2566, Edition Number: M-431269-01-1 Date: 2012-05-16 GLP/GEP: yes, unpublished	N	Y	A complete new set of spectral data has been prepared due to partly missing information, poor copies or non-GLP in the old studies	Bayer CropScience
KCA 2.5 /01	Krohn, J.	1992b	Water solubility of FOE 5043 Bayer AG, Leverkusen, Germany Bayer CropScience, Report No.: PC173, Edition Number: M-004742-01-1 Date: 1992-07-28 GLP/GEP: yes, unpublished	N	N	-	Bayer CropScience
KCA 2.5 /02	Krohn, J.	1994	Water solubility of FOE 5043-N-Isomer Bayer AG, Leverkusen, Germany Bayer CropScience, Report No.: PC186, Edition Number: M-004756-01-1 Date: 1994-02-22 GLP/GEP: yes, unpublished	N	N	-	Bayer CropScience



Annex point / reference number	Author(s)	Year	Title Source ( <i>where different from company</i> ) Company name, Report No., Date, GLP status ( <i>where relevant</i> ), published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCA 2.5 /03	Krohn, J.	1998	Water solubility, partition coefficient in octanol-water and pKa-value of sulfonic acid - FOE5043 Bayer AG, Leverkusen, Germany Bayer CropScience, Report No.: 141200953, Edition Number: M-005351-01-1 Date: 1998-08-24 GLP/GEP: yes, unpublished ...also filed: KCA 2.7 /02 ...also filed: KCA 2.8 /02	N	N	-	Bayer CropScience
KCA 2.5 /04	Peschke, C.; Ziemer, F.	2012a	Flufenacet (FOE 5043, AE F133402), pure substance: Solubility in distilled water (flask method) Bayer CropScience, Report No.: PA12/059, Edition Number: M-438187-01-1 Date: 2012-09-13 GLP/GEP: yes, unpublished	N	Y	A new study has been performed since the old study had applied an equilibration time of only 24 h.	Bayer CropScience
KCA 2.5 /05	Ziemer, F.; Peschke, C.	2013	AE 1218900 (FOE5043- <i>N</i> -isomer): Water solubility at pH 4, pH 7 and pH 9 (flask method) Bayer CropScience, Report No.: PA13/088, Edition Number: M-461493-01-1 Date: 2013-08-13 GLP/GEP: yes, unpublished	N	Y	A new study has been performed since the old had not precisely described the testing procedure	Bayer CropScience
KCA 2.6 /01	Krohn, J.	1992c	Solubility of FOE 5043 in representative polar and unpolar solvents Bayer AG, Leverkusen, Germany Bayer CropScience, Report No.: PC174, Edition Number: M-004744-01-1 Date: 1992-07-27 GLP/GEP: yes, unpublished	N	N	-	Bayer CropScience

Annex point / reference number	Author(s)	Year	Title Source ( <i>where different from company</i> ) Company name, Report No., Date, GLP status ( <i>where relevant</i> ), published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCA 2.6 /02	Eyrich, U.; Ziemer, F.	2012	Flufenacet (FOE 5043, AE F133402), technical substance: Solubility in organic solvents Bayer CropScience, Report No.: PA12/025, Edition Number: M-429219-01-1 Date: 2012-04-19 GLP/GEP: yes, unpublished	N	Y	A new study has been performed since the old study is missing a complete method validation and a solubility testing in an ester (e.g. ethyl acetate)	Bayer CropScience
KCA 2.7 /01	Krohn, J.	1992d	Partition coefficient of FOE 5043 Bayer AG, Leverkusen, Germany Bayer CropScience, Report No.: PC175, Edition Number: M-004745-01-1 Date: 1992-07-20 GLP/GEP: yes, unpublished <b>...also filed: KCA 8.2.2.3 /02</b>	N	N	-	Bayer CropScience
KCA 2.7 /02	Krohn, J.	1998a	Water solubility, partition coefficient in octanol-water and pKa-value of sulfonic acid - FOE5043 Bayer AG, Leverkusen, Germany Bayer CropScience, Report No.: 141200953, Edition Number: M-005351-01-1 Date: 1998-08-24 GLP/GEP: yes, unpublished <b>...also filed: KCA 2.5 /03</b> <b>...also filed: KCA 2.8 /02</b>	N	N	-	Bayer CropScience

Annex point / reference number	Author(s)	Year	Title Source ( <i>where different from company</i> ) Company name, Report No., Date, GLP status ( <i>where relevant</i> ), published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCA 2.7 /03	Krohn, J.	1998b	Physical and chemical properties of FOE 5043 - Thiadone Bayer AG, Leverkusen, Germany Bayer CropScience, Report No.: 141200948, Edition Number: M-004764-01-1 Date: 1998-06-23 GLP/GEP: yes, unpublished	N	N	-	Bayer CropScience
KCA 2.7 /04	Bogdoll, B.; Peschke, C.	2011a	BCS-CP38571 (Flufenacet-methylsulfide): Partition coefficients 1-octanol / water at pH 5, pH 7 and pH 9 (HPLC method) Bayer CropScience, Report No.: PA11/068, Edition Number: M-420022-01-1 Date: 2011-12-12 GLP/GEP: yes, unpublished	N	Y	Guideline requirement	Bayer CropScience
KCA 2.7 /05	Schneider, S.	2011	Trifluoroacetic acid (AE C502988): Partition coefficients 1-octanol / water at pH 5, pH 7 and pH 9 (shake flask method) Allessa Chemie GmbH, Frankfurt am Main, Germany Bayer CropScience, Report No.: B 027/2010, Edition Number: M-420136-01-1 Date: 2011-12-14 GLP/GEP: yes, unpublished	N	Y	Guideline requirement	Bayer CropScience

Annex point / reference number	Author(s)	Year	Title Source ( <i>where different from company</i> ) Company name, Report No., Date, GLP status ( <i>where relevant</i> ), published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCA 2.7 /06	Bogdoll, B.; Strunk, B.	2011b	BCS-CO62475 (flufenacet-methylsulfone): Partition coefficients 1-octanol / water at pH 5, pH 7 and pH 9 (HPLC method) Bayer CropScience, Report No.: PA11/070, Edition Number: M-420210-01-1 Date: 2011-12-12 GLP/GEP: yes, unpublished	N	Y	Guideline requirement	Bayer CropScience
KCA 2.7 /07	Ziemer, F.; Peschke, C.	2012b	Sodium 2,2,2-trifluoroethanesulfonate (BCS-CU62474): Partition coefficients 1-octanol / water at pH 5, pH 7 and pH 9 (shake flask method) Bayer CropScience, Report No.: PA12/028, Edition Number: M-432717-01-1 Date: 2012-06-15 GLP/GEP: yes, unpublished	N	Y	Guideline requirement	Bayer CropScience

Annex point / reference number	Author(s)	Year	Title Source ( <i>where different from company</i> ) Company name, Report No., Date, GLP status ( <i>where relevant</i> ), published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCA 2.7 /08	Ziemer, F.; Peschke, C.	2012c	BCS-AB16305 (FOE 5043-oxalate): Partition coefficients 1-octanol / water at pH 5, pH 7 and pH 9 (shake flask method) Bayer CropScience, Report No.: PA12/007, Edition Number: M-436227-01-1 Date: 2012-08-01 GLP/GEP: yes, unpublished	N	Y	Guideline requirement	Bayer CropScience
KCA 2.7 /09	Ziemer, F.; Charter, G. E.	2012	Flufenacet (FOE 5043, AE F133402), pure substance: Partition coefficients 1-octanol / water at pH 4, pH 7 and pH 9 (HPLC method) Bayer CropScience, Report No.: PA12/040, Edition Number: M-438516-01-1 Date: 2012-09-06 GLP/GEP: yes, unpublished	N	Y	A new study has been performed since the pH-value of the mobile phase was not defined in the old study.	Bayer CropScience
KCA 2.8 /01	Stupp, H. P.	1992	Dissociation constant and pH value of FOE 5043 Bayer AG, Leverkusen, Germany Bayer CropScience, Report No.: PC172, Edition Number: M-004739-01-1 Date: 1992-12-03 GLP/GEP: yes, unpublished	N	N	-	Bayer CropScience

Annex point / reference number	Author(s)	Year	Title Source ( <i>where different from company</i> ) Company name, Report No., Date, GLP status ( <i>where relevant</i> ), published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCA 2.8 /02	Krohn, J.	1998	Water solubility, partition coefficient in octanol-water and pKa-value of sulfonic acid - FOE5043 Bayer AG, Leverkusen, Germany Bayer CropScience, Report No.: 141200953, Edition Number: M-005351-01-1 Date: 1998-08-24 GLP/GEP: yes, unpublished <b>...also filed: KCA 2.5 /03</b> <b>...also filed: KCA 2.7 /02</b>	N	N	-	Bayer CropScience
KCA 2.8 /03	Zeng, Z.; Wood, S.	1992	Stability of FOE 5043 in sterile aqueous buffer solution Miles Inc., Agriculture Division, Stilwell, KS, USA Bayer CropScience, Report No.: MR102623, Edition Number: M-002203-01-1 Date: 1992-03-12 GLP/GEP: yes, unpublished <b>...also filed: KCA 7.2.1.1 /01</b>	N	N	-	Bayer CropScience
KCA 2.8 /04	Wiche, A.; Ziemer, F.	2012	Flufenacet (FOE 5043, AE F133402), pure substance: Dissociation constant in water Bayer CropScience, Report No.: PA12/080, Edition Number: M-438182-01-1 Date: 2012-09-13 GLP/GEP: yes, unpublished	N	Y	A new study has been performed since the old study has used the titration method which is not suitable for compounds with low water solubility.	Bayer CropScience

Annex point / reference number	Author(s)	Year	Title Source ( <i>where different from company</i> ) Company name, Report No., Date, GLP status ( <i>where relevant</i> ), published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCA 2.9 /01	Mix, K. H.	1995	Determination of safety-relevant parameters of FOE 5043 T Bayer AG, Leverkusen, Germany Bayer CropScience, Report No.: PC859, Edition Number: M-004754-01-1 Date: 1995-06-06 GLP/GEP: yes, unpublished <b>...also filed: KCA 2.10 /01</b> <b>...also filed: KCA 2.11 /01</b>	N	N	-	Bayer CropScience
KCA 2.10 /01	Mix, K. H.	1995	Determination of safety-relevant parameters of FOE 5043 T Bayer AG, Leverkusen, Germany Bayer CropScience, Report No.: PC859, Edition Number: M-004754-01-1 Date: 1995-06-06 GLP/GEP: yes, unpublished <b>...also filed: KCA 2.11 /01</b> <b>...also filed: KCA 2.9 /01</b>	N	N	-	Bayer CropScience
KCA 2.11 /01	Mix, K. H.	1995	Determination of safety-relevant parameters of FOE 5043 T Bayer AG, Leverkusen, Germany Bayer CropScience, Report No.: PC859, Edition Number: M-004754-01-1 Date: 1995-06-06 GLP/GEP: yes, unpublished <b>...also filed: KCA 2.10 /01</b> <b>...also filed: KCA 2.9 /01</b>	N	N	-	Bayer CropScience

Annex point / reference number	Author(s)	Year	Title Source ( <i>where different from company</i> ) Company name, Report No., Date, GLP status ( <i>where relevant</i> ), published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCA 2.12 /01	Krohn, J.	1995a	Surface tension of FOE 5043 Bayer AG, Leverkusen, Germany Bayer CropScience, Report No.: PC894, Edition Number: M-004741-01-1 Date: 1995-04-25 GLP/GEP: yes, unpublished	N	N	-	Bayer CropScience
KCA 2.12 /02	Eyrich, U.; Ziemer, F.	2012	Flufenacet (FOE 5043, AE F133402), technical substance: Determination of the surface tension Bayer CropScience, Report No.: PA12/055, Edition Number: M-439214-01-1 Date: 2012-09-26 GLP/GEP: yes, unpublished	N	Y	A new study has been performed since purified active substance was used in the old study and the test concentration was not correctly adjusted.	Bayer CropScience
KCA 2.13 /01	Smeykal, H.	2012a	Flufenacet (FOE 5043, AE F133402), technical substance: oxidizing properties Siemens AG, Frankfurt am Main, Germany Bayer CropScience, Report No.: 20120116.02, Edition Number: M-434552-01-1 Date: 2012-07-12 GLP/GEP: yes, unpublished	N	Y	Guideline requirement	Bayer CropScience
KCA 2.14 /01	Krohn, J.	1995b	Density of FOE 5043 Bayer AG, Leverkusen, Germany Bayer CropScience, Report No.: PC1037, Edition Number: M-004727-01-1 Date: 1995-09-29 GLP/GEP: yes, unpublished	N	N	-	Bayer CropScience



Annex point / reference number	Author(s)	Year	Title Source ( <i>where different from company</i> ) Company name, Report No., Date, GLP status ( <i>where relevant</i> ), published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCA 2.14 /02	Hellpointner, E.	1995	Assessment of the Henry's law constant of thiadone, 3-trifluoromethyl-1,3,4-thiadiazol-2(3H)one, by the Sar program Henrywin Bayer AG, Leverkusen, Germany Bayer CropScience, Report No.: 107282, Edition Number: M-103764-01-1 Date: 1995-10-23 GLP/GEP: no, unpublished	N	N	-	Bayer CropScience
KCA 2.14 /03	Schmidt, M.	2011	BCS-CO62475 (Flufenacet-methylsulfone): Determination of the dissociation constant in water Bayer CropScience, Report No.: 15-630-2538, Edition Number: M-414377-01-1 Date: 2011-09-13 GLP/GEP: yes, unpublished	N	Y	Guideline requirement	Bayer CropScience

Annex point / reference number	Author(s)	Year	Title Source ( <i>where different from company</i> ) Company name, Report No., Date, GLP status ( <i>where relevant</i> ), published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCA 2.14 /04	Smeykal, H.	2011a	BCS-CO62475 (Flufenacet-methylsulfone): Vapour pressure Siemens AG, Frankfurt am Main, Germany Bayer CropScience, Report No.: 20110244.01, Edition Number: M-411303-01-1 Date: 2011-07-19 GLP/GEP: yes, unpublished	N	Y	Guideline requirement	Bayer CropScience
KCA 2.14 /05	Winkler, S.	2011	Trifluoro acetic acid (AE C502988): Determination of the dissociation constant in water Siemens AG, Frankfurt am Main, Germany Bayer CropScience, Report No.: 20100672.02, Edition Number: M-418628-01-1 Date: 2011-11-18 GLP/GEP: yes, unpublished	N	Y	Guideline requirement	Bayer CropScience
KCA 2.14 /06	Wiche, A.; Bogdoll, B.	2011a	BCS-CP38571 (Flufenacet-methylsulfide): Solubility in distilled water (flask method) Bayer CropScience, Report No.: PA11/067, Edition Number: M-420027-01-1 Date: 2011-12-12 GLP/GEP: yes, unpublished	N	Y	Guideline requirement	Bayer CropScience
KCA 2.14 /07	Wiche, A.; Bogdoll, B.	2011b	BCS-CO62475 (Flufenacet-methylsulfone): Water solubility at pH 7 (flask method) Bayer CropScience, Report No.: PA11/069, Edition Number: M-420028-01-1 Date: 2011-12-12 GLP/GEP: yes, unpublished	N	Y	Guideline requirement	Bayer CropScience

Annex point / reference number	Author(s)	Year	Title Source ( <i>where different from company</i> ) Company name, Report No., Date, GLP status ( <i>where relevant</i> ), published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCA 2.14 /08	Schneider, S.	2011	Trifluoroacetic acid (AE C502988): Miscibility with distilled water and solubility in water in a pH range of 0.4 to 12.6 Allessa Chemie GmbH, Frankfurt am Main, Germany Bayer CropScience, Report No.: B 026/2010, Edition Number: M-420129-01-1 Date: 2011-12-14 GLP/GEP: yes, unpublished	N	Y	Guideline requirement	Bayer CropScience
KCA 2.14 /09	Smeykal, H.	2011b	Sodium trifluoroacetate (AE 1046319): Vapour pressure Siemens AG, Frankfurt am Main, Germany Bayer CropScience, Report No.: 20100681.01, Edition Number: M-420190-01-1 Date: 2011-12-07 GLP/GEP: yes, unpublished	N	Y	Guideline requirement	Bayer CropScience
KCA 2.14 /10	Ziemer, F.; Eyrich, U.	2011	BCS-CO62475 (Flufenacet-methylsulfone): Calculation of the Henry's law constant Bayer CropScience, Report No.: AF11/020, Edition Number: M-420714-01-1 Date: 2011-12-15 GLP/GEP: no, unpublished	N	Y	Guideline requirement	Bayer CropScience
KCA 2.14 /11	Ziemer, F.	2012a	BCS-CP38571 (flufenacet-methylsulfide): Statement on the dissociation constant Bayer CropScience, Report No.: AF12/003, Edition Number: M-423244-01-1 Date: 2012-01-20 GLP/GEP: n.a., unpublished	N	N	-	Bayer CropScience

Annex point / reference number	Author(s)	Year	Title Source ( <i>where different from company</i> ) Company name, Report No., Date, GLP status ( <i>where relevant</i> ), published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCA 2.14 /12	Smeykal, H.	2012b	BCS-AB16305 (FOE 5043-oxalate): Vapour pressure Siemens AG, Frankfurt am Main, Germany Bayer CropScience, Report No.: 20120034.01, Edition Number: M-429179-01-1 Date: 2012-04-16 GLP/GEP: yes, unpublished	N	Y	Guideline requirement	Bayer CropScience
KCA 2.14 /13	Smeykal, H.	2012c	Sodium 2,2,2-trifluoroethanesulfonate (BCS-CU62474): Vapour pressure Siemens AG, Frankfurt am Main, Germany Bayer CropScience, Report No.: 20120063.01, Edition Number: M-429683-01-1 Date: 2012-04-18 GLP/GEP: yes, unpublished	N	Y	Guideline requirement	Bayer CropScience
KCA 2.14 /14	Ziemer, F.; Peschke, C.	2012b	Sodium 2,2,2-trifluoroethanesulfonate (BCS-CU62474): Water solubility at pH 5, pH 7 and pH 9 Bayer CropScience, Report No.: PA12/027, Edition Number: M-432716-01-1 Date: 2012-06-15 GLP/GEP: yes, unpublished	N	Y	Guideline requirement	Bayer CropScience
KCA 2.14 /15	Ziemer, F.; Kloeckner, C.	2012	BCS-AB16305 (FOE 5043-oxalate): Water solubility at pH 5, pH 7 and pH 9 Bayer CropScience, Report No.: PA12/008, Edition Number: M-433165-01-1 Date: 2012-06-21 GLP/GEP: yes, unpublished	N	Y	Guideline requirement	Bayer CropScience

Annex point / reference number	Author(s)	Year	Title Source ( <i>where different from company</i> ) Company name, Report No., Date, GLP status ( <i>where relevant</i> ), published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCA 2.14 /16	Ziemer, F.	2012b	BCS-AB16305 (FOE 5043-oxalate): Calculation of the Henry's law constants Bayer CropScience, Report No.: AF12/020, Edition Number: M-433622-01-1 Date: 2012-07-02 GLP/GEP: no, unpublished	N	Y	Guideline requirement	Bayer CropScience
KCA 2.14 /17	Ziemer, F.	2012c	Sodium 2,2,2-trifluoroethanesulfonate (BCS-CU62474): Calculation of the Henry's law constants Bayer CropScience, Report No.: AF12/025, Edition Number: M-433635-01-1 Date: 2012-07-02 GLP/GEP: no, unpublished	N	Y	Guideline requirement	Bayer CropScience
KCA 2.14 /18	Schmidt, M.	2012	Sodium 2,2,2-trifluoroethanesulfonate (BCS-CU62474) - Determination of the dissociation constant in water Bayer CropScience, Report No.: 15-630-2572, Edition Number: M-434048-01-1 Date: 2012-07-04 GLP/GEP: yes, unpublished	N	Y	Guideline requirement	Bayer CropScience
KCA 2.14 /19	Wiche, A.; Ziemer, F.	2012	BCS-AB16305 (FOE 5043-oxalate): Dissociation constant in water Bayer CropScience, Report No.: PA12/042, Edition Number: M-436674-01-1 Date: 2012-08-17 GLP/GEP: yes, unpublished	N	Y	Guideline requirement	Bayer CropScience

Annex point / reference number	Author(s)	Year	Title Source ( <i>where different from company</i> ) Company name, Report No., Date, GLP status ( <i>where relevant</i> ), published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCA 2.14 /20	Ziemer, F.	2011	Sodium trifluoroacetate (AE 1046319): Calculation of the Henry's Law constant Bayer CropScience, Report No.: AF11/032, Edition Number: M-420526-01-1 Date: 2011-12-22 GLP/GEP: no, unpublished	N	Y	Guideline requirement	Bayer CropScience

## References for the plant protection product: Flufenacet + Diflufenican SC 600

Annex point / reference number	Author(s)	Year	Title Source ( <i>where different from company</i> ) Company name, Report No., Date, GLP status ( <i>where relevant</i> ), published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 2.1 /01	Rexer, K.	2012a	Physical, chemical and technical properties of diflufenican + flufenacet SC 600 (200+400 g/L) Final report Bayer CropScience GmbH, Frankfurt am Main, Germany Bayer CropScience, Report No.: FF0002(PC00)G01, Edition Number: M-431821-01-1 Date: 2012-05-16 GLP/GEP: no, unpublished ...also filed: KCP 2.10 /01 ...also filed: KCP 2.4 /01 ...also filed: KCP 2.5 /01 ...also filed: KCP 2.6 /01 ...also filed: KCP 2.9 /01	N	Y	Guideline requirement	Bayer CropScience
KCP 2.2 /01	Rexer, K.; Zindel, J.	2007	Safety relevant technical properties of diflufenican + flufenacet SC 600 (200 + 400) g/L -Final report- Bayer CropScience, Report No.: FOR0868 (PC) 03, Edition Number: M-295806-01-1 Date: 2007-12-05 GLP/GEP: yes, unpublished	N	Y	Guideline requirement	Bayer CropScience

Annex point / reference number	Author(s)	Year	Title Source (where different from company) Company name, Report No., Date, GLP status (where relevant), published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 2.2 /02	Heitkamp, D.	2002	Determination of Safety-Relevant Data of FOE 5043 400 SC DFF 200 Bayer AG, Leverkusen, Germany Bayer CropScience, Report No.: 01/00493, Edition Number: M-038709-01-1 Date: 2002-02-11 GLP/GEP: yes, unpublished <b>...also filed: KCP 2.3 /01</b>	N	Y	Guideline requirement	Bayer CropScience
KCP 2.3 /01	Heitkamp, D.	2002	Determination of Safety-Relevant Data of FOE 5043 400 SC DFF 200 Bayer AG, Leverkusen, Germany Bayer CropScience, Report No.: 01/00493, Edition Number: M-038709-01-1 Date: 2002-02-11 GLP/GEP: yes, unpublished <b>...also filed: KCP 2.2 /02</b>	N	Y	Guideline requirement	Bayer CropScience
KCP 2.4 /01	Rexer, K.	2012a	Physical, chemical and technical properties of diflufenican + flufenacet SC 600 (200+400 g/L) Final report Bayer CropScience GmbH, Frankfurt am Main, Germany Bayer CropScience, Report No.: FF0002(PC00)G01, Edition Number: M-431821-01-1 Date: 2012-05-16 GLP/GEP: no, unpublished <b>...also filed: KCP 2.1 /01</b> <b>...also filed: KCP 2.10 /01</b> <b>...also filed: KCP 2.5 /01</b> <b>...also filed: KCP 2.6 /01</b> <b>...also filed: KCP 2.9 /01</b>	N	Y	Guideline requirement	Bayer CropScience

Annex point / reference number	Author(s)	Year	Title Source (where different from company) Company name, Report No., Date, GLP status (where relevant), published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 2.5 /01	Rexer, K.	2012a	Physical, chemical and technical properties of diflufenican + flufenacet SC 600 (200+400 g/L) Final report Bayer CropScience GmbH, Frankfurt am Main, Germany Bayer CropScience, Report No.: FF0002(PC00)G01, Edition Number: M-431821-01-1 Date: 2012-05-16 GLP/GEP: no, unpublished ...also filed: KCP 2.1 /01 ...also filed: KCP 2.10 /01 ...also filed: KCP 2.4 /01 ...also filed: KCP 2.6 /01 ...also filed: KCP 2.9 /01	N	Y	Guideline requirement	Bayer CropScience
KCP 2.6 /01	Rexer, K.	2012a	Physical, chemical and technical properties of diflufenican + flufenacet SC 600 (200+400 g/L) Final report Bayer CropScience GmbH, Frankfurt am Main, Germany Bayer CropScience, Report No.: FF0002(PC00)G01, Edition Number: M-431821-01-1 Date: 2012-05-16 GLP/GEP: no, unpublished ...also filed: KCP 2.1 /01 ...also filed: KCP 2.10 /01 ...also filed: KCP 2.4 /01 ...also filed: KCP 2.5 /01 ...also filed: KCP 2.9 /01	N	Y	Guideline requirement	Bayer CropScience
KCP 2.7 /01	Rexer, K.	2012b	Shelf life of diflufenican + flufenacet SC 600 (200+400 g/L) - Packaging material: HDPE (24 months at ambient temperature) - Final report Bayer CropScience, Report No.: FF0002(RA01)N01, Edition Number: M-428039-01-1 Date: 2012-03-23 GLP/GEP: no, unpublished	N	Y	Guideline requirement	Bayer CropScience



Annex point / reference number	Author(s)	Year	Title Source (where different from company) Company name, Report No., Date, GLP status (where relevant), published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 2.7 /02	Rexer, K.	2012c	Storage stability at elevated temperature and cold stability of diflufenican + flufenacet SC 600 (200+400 g/L) Packaging material: HDPE Final report (14 days at 54 degree celsius) Bayer CropScience GmbH, Frankfurt am Main, Germany Bayer CropScience, Report No.: FF0002(AC01)N01, Edition Number: M-431809-01-1 Date: 2012-05-29 GLP/GEP: no, unpublished	N	Y	Guideline requirement	Bayer CropScience
KCP 2.9 /01	Rexer, K.	2012a	Physical, chemical and technical properties of diflufenican + flufenacet SC 600 (200+400 g/L) Final report Bayer CropScience GmbH, Frankfurt am Main, Germany Bayer CropScience, Report No.: FF0002(PC00)G01, Edition Number: M-431821-01-1 Date: 2012-05-16 GLP/GEP: no, unpublished ...also filed: KCP 2.1 /01 ...also filed: KCP 2.10 /01 ...also filed: KCP 2.4 /01 ...also filed: KCP 2.5 /01 ...also filed: KCP 2.6 /01	N	Y	Guideline requirement	Bayer CropScience
KCP 2.10 /01	Rexer, K.	2012a	Physical, chemical and technical properties of diflufenican + flufenacet SC 600 (200+400 g/L) Final report Bayer CropScience GmbH, Frankfurt am Main, Germany Bayer CropScience, Report No.: FF0002(PC00)G01, Edition Number: M-431821-01-1 Date: 2012-05-16 GLP/GEP: no, unpublished ...also filed: KCP 2.1 /01 ...also filed: KCP 2.4 /01 ...also filed: KCP 2.5 /01 ...also filed: KCP 2.6 /01 ...also filed: KCP 2.9 /01	N	Y	Guideline requirement	Bayer CropScience

### A.3. DATA ON APPLICATION AND EFFICACY

References for the active substance: FLUFENACET

Annex point / reference number	Author(s)	Year	Title Source (where different from company) Company name, Report No., Date, GLP status (where relevant), published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCA Section 3 /01	Dahmen, P.	2004	Screening and efficacy data for WAK6222 (metabolite of FOE5043) Bayer AG, Leverkusen, Germany Bayer CropScience, Report No.: PF-F-HB_WAK6222_01, Edition Number: M-089475-01-1 Date: 2004-06-22 GLP/GEP: no, unpublished	N	Y	Required according SANCO/221/2000 rev. 10	Bayer CropScience
KCA Section 3 /02	Hills, M.	2009	Evaluation of the pre-emergence biological activity of FOE 5043-Oxalate (code: BCS-AB16305) a metabolite of fFlufenacet Bayer CropScience, Report No.: PP09022, Edition Number: M-353844-01-1 Date: 2009-06-16 GLP/GEP: no, unpublished	N	Y	Required according SANCO/221/2000 rev. 10	Bayer CropScience
KCA Section 3 /03	Noeding, S.	2012	Evaluation of the pre-emergence biological activity of flufenacet and its metabolite BCS-CO 62475 Bayer CropScience GmbH, Frankfurt am Main, Germany Bayer CropScience, Report No.: FFS125049, Edition Number: M-460326-01-1 Date: 2012-11-22 GLP/GEP: no, unpublished	N	Y	Required according SANCO/221/2000 rev. 10	Bayer CropScience
KCA Section 3 /04	Noeding, S.	2012	Evaluation of the post-emergence biological activity flufenacet and its metabolite BCS-CO 62475 Bayer CropScience, Report No.: FFS125048, Edition Number: M-460332-01-1 Date: 2012-11-15 GLP/GEP: no, unpublished	N	Y	Required according SANCO/221/2000 rev. 10	Bayer CropScience

Annex point / reference number	Author(s)	Year	Title Source (where different from company) Company name, Report No., Date, GLP status (where relevant), published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCA Section 3 /05	Noeding, S.	2012	Evaluation of the pre-emergence biological activity of flufenacet and its metabolite BCS-CO 62474 Bayer CropScience GmbH, Frankfurt am Main, Germany Bayer CropScience, Report No.: M-460336-01-1, Edition Number: M-460336-01-1 Date: 2012-11-22 GLP/GEP: no, unpublished	N	Y	Required according SANCO/221/2000 rev. 10	Bayer CropScience
KCA Section 3 /06	Jans, D.	2013	Evaluation of the post emergence herbicidal activity of trifluoroethansulfonicacid sodium-salt (metabolite of flufenacet) in comparison with flufenacet Bayer CropScience, Report No.: RF13/035, Edition Number: M-460341-01-1 Date: 2013-07-04 GLP/GEP: no, unpublished	N	Y	Required according SANCO/221/2000 rev. 10	Bayer CropScience
KCA Section 3 /07	Noeding, S.	2013	Evaluation of the pre-emergence biological activity of flufenacet and its metabolite BCS-AZ 56567 Bayer CropScience, Report No.: FFS135016, Edition Number: M-461398-01-1 Date: 2013-06-26 GLP/GEP: no, unpublished	N	Y	Required according SANCO/221/2000 rev. 10	Bayer CropScience

#### References for the plant protection product: Flufenacet + Diflufenican SC 600

Not relevant for this section.

## A.4. FURTHER INFORMATION

#### References for the active substance: FLUFENACET

Not relevant for this section.

## References for the plant protection product: Flufenacet + Diflufenican SC 600

Data Point	Author(s)	Year	Title Compagny Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previous evaluation
KCP 4.2/01	Anonymous	2014	Firebird SC600 4X3L BOT GB -public data-, Report No.: M-481757-01-1, Edition Number: M-481757-01-1 Date: 2014-02-03 GLP/GEP: n.a., unpublished	N	N	-	Public data	Submitted for the purpose of renewal

## A.5. METHODS OF ANALYSIS

### References for the active substance: FLUFENACET

Annex point / reference number	Author(s)	Year	Title Source (where different from company) Company name, Report No., Date, GLP status (where relevant), published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCA 4.1. B.4.1.1. CA B.5.1.1.	Mohsin, S.B	1994	HPLC analysis of BAY FOE 5043 TM C-16.01 1994-08-26 Non GLP	N	N	-	
KCA 4.1/01 B.4.1.1. CA B.5.1.1.	Reubke, K. J.	1995	Material accountability of FOE 5043 - Acetone process Bayer AG, Leverkusen, Germany Bayer CropScience, Report No.: PC1102, Edition Number: M-004706-01-1 Date: 1995-12-06 GLP/GEP: yes, unpublished confidential	N	N	-	Bayer CropScience
KCA 4.1.1/01 B.4.1.1. CA B.5.1.1.	Harbin, D. N.	1997	Validation of Test Method C-16.01: Quantitation of BAY FOE 5043 in Technical Material and 60 percent Dry Flowable Formulations Bayer Corporation, Kansas City, MO, USA Bayer CropScience, Report No.: 107584, Edition Number: M-055185-01-1 Date: 1997-04-11 GLP/GEP: no, unpublished	N	N	-	Bayer CropScience
KCA 4.1.1 /09 CA.4.1.1/01 CA B.5.1.1.	Kraemer, F.; Ruengeler, W.	2011a	Flufenacet - Determination of active substance in technical material HPLC - external standard Bayer CropScience, Report No.: AM015811MP1, Edition Number: M-414331-01-1 Date: 2011-07-22 GLP/GEP: no, unpublished confidential	N	Y	Guideline requirement	Bayer CropScience

Annex point / reference number	Author(s)	Year	Title Source (where different from company) Company name, Report No., Date, GLP status (where relevant), published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCA 4.1.1 /10 CA.4.1.1/02 CA B.5.1.1.	Kraemer, F.; Ruengeler, W.	2011b	Validation of HPLC-method AM015811MP1 - Flufenacet - Determination of active substance in technical material HPLC - external standard Bayer CropScience, Report No.: VB1-AM015811MP1, Edition Number: M-414332-01-1 Date: 2011-07-22 GLP/GEP: no, unpublished confidential	N	Y	Guideline requirement	Bayer CropScience
B.4.2.1 CA B.5.1.2.	Seym, M.	1994	Independent laboratory validation of the residue analytical method for FOE 5043 residues in plant. 106907 RA-352-94 1994-06-24 GLP	N	N	-	Bayer CropScience
KCA 4.1.2 /01 CA B.5.1.2.	Seym, M.	1995a	Amendment no 1 to report: MR-981/95 - Analytical method for the determination of the total residue of FOE 5043 in plant materials Bayer AG, Leverkusen, Germany Bayer CropScience, Report No.: 00346, Edition Number: M-018864-02-1 Method Report No.: MR-981/95 Date: 1995-10-20 GLP/GEP: yes, unpublished ...also filed: KCA 4.2 /01	N	N	-	Bayer CropScience
KCA 4.1.2 /02 CA B.5.1.2.	Gould, T. J.; Lemke, V. J.; Zoloty, K. L.	1995	An analytical method for the determination of FOE 5043 residues in animal matrices Bayer Corporation, Kansas City, MO, USA Bayer CropScience, Report No.: 00418, Edition Number: M-019605-01-1 Method Report No.: F3120201 Date: 1995-04-10 GLP/GEP: yes, unpublished ...also filed: KCA 4.2 /02	N	N	-	Bayer CropScience

Annex point / reference number	Author(s)	Year	Title Source (where different from company) Company name, Report No., Date, GLP status (where relevant), published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCA 4.1.2 /03 CA B.5.1.2.	Seym, M.	1995b	Modification M001 of method 00418 for the determination of FOE 5043 residues in animal matrices Bayer AG, Leverkusen, Germany Bayer CropScience, Report No.: 00418/M001, Edition Number: M-019614-01-1 Method Report No.: MR-1118/95 Date: 1995-11-17 GLP/GEP: yes, unpublished ...also filed: <b>KCA 4.2 /03</b>	N	N	-	Bayer CropScience
KCA 4.1.2 /04 CA B.5.1.2.	Gould, T. J.; Lemke, V. J.	1995	An analytical method for the determination of FOE 5043 residues in plant matrices Bayer Corporation, Kansas City, MO, USA Bayer CropScience, Report No.: 106406, Edition Number: M-041601-01-1 EPA MRID No.: 43850079 Date: 1995-05-11 GLP/GEP: yes, unpublished ...also filed: <b>KCA 4.2 /04</b>	N	N	-	Bayer CropScience
KCA 4.1.2 /06 CA B.5.2.3.	Riegner, K.	1995	Methode zur Bestimmung von FOE 5043 in Luft Bayer AG, Leverkusen, Germany Bayer CropScience, Report No.: 00410, Edition Number: M-012833-01-2 Method Report No.: MR-798/95 Date: 1995-07-19 GLP/GEP: yes, unpublished	N	N	-	Bayer CropScience

Annex point / reference number	Author(s)	Year	Title Source (where different from company) Company name, Report No., Date, GLP status (where relevant), published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCA 4.1.2 /07 CA B.5.2.2.	Koenig, T.	1998	Amendment to method 00489, MR-473/97 - Method for the determination of FOE 5043 in drinking water by HPLC with on-line solid phase extraction Bayer AG, Leverkusen, Germany Bayer CropScience, Report No.: 00489, Edition Number: M-020397-03-1 Method Report No.: MR 473/97 Method Report No.: MR-012/98 Date: 1998-03-13 GLP/GEP: no, unpublished	N	N	-	Bayer CropScience
KCA 4.1.2 /12 CA B.5.1.2.1.	Seym, M.	1997	Supplement E001 of method 00346 for the determination of residue of total residue of FOE 5043 in/on potato Bayer AG, Leverkusen, Germany Bayer CropScience, Report No.: 00346/E001, Edition Number: M-018872-01-1 Method Report No.: MR-388/96 Date: 1997-01-16 GLP/GEP: yes, unpublished	N	Y	Completion of data package for data generation methods	Bayer CropScience
KCA 4.1.2 /13 CA B.5.1.2.1.	Seym, M.	1998	Supplement E002 of method 00346 for the determination of FOE 5043 total residue in/on soybean, plant and tomato, fruit Bayer AG, Leverkusen, Germany Bayer CropScience, Report No.: 00346/E002, Edition Number: M-018878-01-1 Method Report No.: MR-400/98 Date: 1998-10-16 GLP/GEP: yes, unpublished ...also filed: KCA 4.2 /23	N	Y	Completion of data package for data generation methods	Bayer CropScience



Annex point / reference number	Author(s)	Year	Title Source (where different from company) Company name, Report No., Date, GLP status (where relevant), published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCA 4.1.2 /14 CA B.5.1.2.1.	Rzepka, S.	2006	Supplement E004 of Method 00346 for the determination of residues of FOE 5043, FOE 5043 Oxalate, FOE 5043 Sulfonic Acid, and FOE 5043 Thioglycolate Sulfoxide in rice (grain) Eurofins Analytik GmbH, Hamburg, Germany Bayer CropScience, Report No.: 00346/E004, Edition Number: M-277805-01-1 Method Report No.: BAY-0610V Date: 2006-09-12 GLP/GEP: yes, unpublished	N	Y	Completion of data package for data generation methods	Bayer CropScience
KCA 4.1.2 /15 CA B.5.1.2.	Stuke, S.; Teubner, L.	2013	Modification M002 of the residue analytical method 01100 for the determination of residues of flufenacet (FOE 5043) in/on cereals (straw, grain, and green material) at a LOQ of 0.01 mg/kg (0.05 mg/kg for straw) by HPLC-MS/MS Bayer CropScience, Report No.: 01100/M002, Edition Number: M-448503-01-1 Date: 2013-03-04 GLP/GEP: yes, unpublished	N	Y	Completion of data package for data generation methods	Bayer CropScience
KCA 4.1.2 /16 CA B.5.1.2.	Stuke, S.; Weile, M.	2011	Position paper: Subject: Flufenacet: Answer to CRD questions related to the authorization of the product Liberator SC 500 (flufenacet + diflufenican 400 g/L + 100 g/L) - Comparison of flufenacet residue analytical method nos. 00346 vs. 01179 Bayer CropScience, Report No.: M-416013-01-1, Edition Number: M-416013-01-1 Date: 2011-10-21 GLP/GEP: n.a., unpublished	N	N	-	Bayer CropScience

Annex point / reference number	Author(s)	Year	Title Source (where different from company) Company name, Report No., Date, GLP status (where relevant), published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCA 4.1.2 /17 CA B.5.1.2.	Stuke, S., Bauer, J.; Ruhl, S.	2012	Modification M001 of the residue analytical method 01100 for the determination of residues of flufenacet (FOE5043) and its metabolites in/on cereals (straw, grain, and green material) at a LOQ of 0.01 mg/kg for grain and green material and at a LOQ of 0.05 mg/kg for straw by HPLC-MS/MS Bayer CropScience, Report No.: 01100/M001, Edition Number: M-433720-01-1 Method Report No.: MR-11/011 Date: 2012-06-13 GLP/GEP: yes, unpublished <b>...also filed: KCA 4.2 /10</b>	N	Y	Completion of data package for data generation methods and enforcement methods	Bayer CropScience
KCA 4.1.2 /18 CA B.5.1.2.	Billian, P.	2010	Analytical method 01100 for the determination of residues of flufenacet (FOE5043) and its metabolites in/on plant material Bayer CropScience, Report No.: 01100, Edition Number: M-362575-02-1 Method Report No.: 01100 Method Report No.: MR-08/060 Date: 2010-01-27 <b>...Amended: 2010-02-04</b> GLP/GEP: yes, unpublished <b>...also filed: KCA 4.2 /11</b>	N	Y	New simplified single method for data generation and monitoring purposes (3 matrix groups)	Bayer CropScience
KCA 4.1.2 /19 CA B.5.1.2.	Class, Th.; Merdian, H.	2010	Validation of BCS analytical method no. 01179 for the determination of residues of flufenacet in/on plant materials by HPLC-MS/MS PTL Europe GmbH, Ulm, Germany Bayer CropScience, Report No.: 01179, Edition Number: M-362716-01-1 Method Report No.: B 1778 G Date: 2010-01-22 GLP/GEP: yes, unpublished <b>...also filed: KCA 4.2 /12</b>	N	Y	New simplified single method for data generation and monitoring purposes (cereal matrices)	Bayer CropScience

Annex point / reference number	Author(s)	Year	Title Source (where different from company) Company name, Report No., Date, GLP status (where relevant), published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCA 4.1.2 /20 CA B.5.1.2.	Gould, T. J.	1995	Extraction efficiency of the analytical method for the determination of FOE 5043 residues in plant matrices Bayer Corporation, Kansas City, MO, USA Bayer CropScience, Report No.: 106927, Edition Number: M-041609-01-1 Date: 1995-06-02 GLP/GEP: yes, unpublished	N	Y	EU data requirement	Bayer CropScience
KCA 4.1.2 /21 CA B.5.1.2.	Beedle, E. C.; Ying, S. L.	2000	The metabolism of [fluorophenyl-UL-14C] Flufenacet in potatoes Bayer Corporation, Stilwell, KS, USA Bayer CropScience, Report No.: 109226, Edition Number: M-020428-01-1 Date: 2000-04-28 GLP/GEP: yes, unpublished	N	Y	Completion of data package, additional crop	Bayer CropScience
KCA 4.1.2 /22 CA B.5.1.2.	Krolski, M. E.; Bosnak, L. L.	1997	The metabolism of [Fluorophenyl-UL-14C] FOE 5043 in wheat after postemergent foliar spray application Bayer Corporation, Stilwell, KS, USA Bayer CropScience, Report No.: 107399, Edition Number: M-002275-01-1 EPA MRID No.: 45012403 Date: 1997-11-04 GLP/GEP: yes, unpublished	N	Y	Completion of data package, post-emergence use on cereals	Bayer CropScience
KCA 4.1.2 /23 CA B.5.1.2.1.	██████████	1995	Extraction efficiency of the analytical method for the determination of FOE5043 residues in animal matrices ██████████ ██████████, Report No.: 106926, Edition Number: M-071501-01-1 Date: 1995-08-16 GLP/GEP: yes, unpublished	Y	Y	EU data requirement	Bayer CropScience

Annex point / reference number	Author(s)	Year	Title Source (where different from company) Company name, Report No., Date, GLP status (where relevant), published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCA 4.2 /01 B.4.2.1. CA B.5.2.1.	Seym, M.	1995a	Amendment no 1 to report: MR-981/95 - Analytical method for the determination of the total residue of FOE 5043 in plant materials Bayer AG, Leverkusen, Germany Bayer CropScience, Report No.: 00346, Edition Number: M-018864-02-1 Method Report No.: MR-981/95 Date: 1995-10-20 GLP/GEP: yes, unpublished ...also filed: KCA 4.1.2 /01	N	N	-	Bayer CropScience
KCA 4.2 /02 B.4.2.1. CA B.5.2.1.	Gould, T. J.; Lemke, V. J.; Zoloty, K. L.	1995	An analytical method for the determination of FOE 5043 residues in animal matrices Bayer Corporation, Kansas City, MO, USA Bayer CropScience, Report No.: 00418, Edition Number: M-019605-01-1 Method Report No.: F3120201 Date: 1995-04-10 GLP/GEP: yes, unpublished ...also filed: KCA 4.1.2 /02	N	N	-	Bayer CropScience
KCA 4.2 /03 B.4.2.1. CA B.5.2.1.	Seym, M.	1995b	Modification M001 of method 00418 for the determination of FOE 5043 residues in animal matrices Bayer AG, Leverkusen, Germany Bayer CropScience, Report No.: 00418/M001, Edition Number: M-019614-01-1 Method Report No.: MR-1118/95 Date: 1995-11-17 GLP/GEP: yes, unpublished ...also filed: KCA 4.1.2 /03	N	N	-	Bayer CropScience

<b>Annex point / reference number</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Source (where different from company) Company name, Report No., Date, GLP status (where relevant), published or not</b>	<b>Vertebrate study Y/N</b>	<b>Data protection claimed Y/N</b>	<b>Justification if data protection is claimed</b>	<b>Owner</b>
KCA 4.2 /04 B.4.2.1. CA B.5.2.1.	Gould, T. J.; Lemke, V. J.	1995	An analytical method for the determination of FOE 5043 residues in plant matrices Bayer Corporation, Kansas City, MO, USA Bayer CropScience, Report No.: 106406, Edition Number: M-041601-01-1 EPA MRID No.: 43850079 Date: 1995-05-11 GLP/GEP: yes, unpublished <b>...also filed: KCA 4.1.2 /04</b>	N	N	-	Bayer CropScience
KCA 4.2 /05 B.4.2.1. CA B.5.2.1.	Seym, M.	1994	Independent laboratory validation of the residue analytical method for FOE 5043 residues in plant Bayer AG, Leverkusen, Germany Bayer CropScience, Report No.: 106907, Edition Number: M-014828-01-1 Date: 1994-06-24 GLP/GEP: yes, unpublished	N	N	-	Bayer CropScience
KCA 4.2 /06 B.4.2.2. CA B.5.2.1.	Bajzik, M. E.	1995	Independent laboratory validation of the analytical method for the determination of FOE 5043 in animal matrices (miles report no.106773) Huntingdon Analytical Services, Middleport, NY, USA Bayer CropScience, Report No.: 106913, Edition Number: M-071918-01-1 Date: 1995-03-22 GLP/GEP: yes, unpublished	N	N	-	Bayer CropScience

<b>Annex point / reference number</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Source</b> <i>(where different from company)</i> <b>Company name, Report No., Date, GLP status</b> <i>(where relevant), published or not</i>	<b>Vertebrate study</b> Y/N	<b>Data protection claimed</b> Y/N	<b>Justification if data protection is claimed</b>	<b>Owner</b>
KCA 4.2 /08 CA B.5.2.2.	Bethem, R. A.; Peterson, R. G.; Leimkuhler, W. A.; Mattern, G. C.	1995	Determination of FOE 5043 and the alcohol, Oxalate, thiadone and sulfonic acid metabolites in groundwater by high performance liquid chromatography electrospray tandem mass spectrometry (LC-ESI/MS/MS) Alta Analytical Laboratory, Inc., El Dorado Hills, CA, USA Bayer CropScience, Report No.: 107138, Edition Number: M-070022-01-2 Date: 1995-06-22 GLP/GEP: no, unpublished	N	N	-	Bayer CropScience
KCA 4.2 /09 CA B.5.2.2.	Allmendinger, H.; Bachlechner, G.	1994	Validated method for the determination of the herbicide FOE 5043 and its metabolites FOE 5043-alcohol, FOE 5043-oxalate and FOE 5043-sulfonic acid in soil using HPLC-MS-MS Bayer AG, Leverkusen, Germany Bayer CropScience, Report No.: 107725, Edition Number: M-019071-01-3 Method Report No.: RA-246/96 Method Report No.: RA-399/94 Date: 1994-07-01 GLP/GEP: yes, unpublished	N	N	-	Bayer CropScience

Annex point / reference number	Author(s)	Year	Title Source (where different from company) Company name, Report No., Date, GLP status (where relevant), published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCA 4.2 /10 CA B.5.2.1.	Stuke, S., Bauer, J.; Ruhl, S.	2012	Modification M001 of the residue analytical method 01100 for the determination of residues of flufenacet (FOE5043) and its metabolites in/on cereals (straw, grain, and green material) at a LOQ of 0.01 mg/kg for grain and green material and at a LOQ of 0.05 mg/kg for straw by HPLC-MS/MS Bayer CropScience, Report No.: 01100/M001, Edition Number: M-433720-01-1 Method Report No.: MR-11/011 Date: 2012-06-13 GLP/GEP: yes, unpublished <b>...also filed: KCA 4.1.2 /17</b>	N	Y	Completion of data package for data generation methods and enforcement methods	Bayer CropScience
KCA 4.2 /11 CA B.5.2.1.	Billian, P.	2010	Analytical method 01100 for the determination of residues of flufenacet (FOE5043) and its metabolites in/on plant material Bayer CropScience, Report No.: 01100, Edition Number: M-362575-02-1 Method Report No.: 01100 Method Report No.: MR-08/060 Date: 2010-01-27 <b>...Amended: 2010-02-04</b> GLP/GEP: yes, unpublished <b>...also filed: KCA 4.1.2 /18</b>	N	Y	New simplified single method for data generation and monitoring purposes (3 matrix groups)	Bayer CropScience
KCA 4.2 /12 CA B.5.2.1.	Class, Th.; Merdian, H.	2010	Validation of BCS analytical method no. 01179 for the determination of residues of flufenacet in/on plant materials by HPLC-MS/MS PTL Europe GmbH, Ulm, Germany Bayer CropScience, Report No.: 01179, Edition Number: M-362716-01-1 Method Report No.: B 1778 G Date: 2010-01-22 GLP/GEP: yes, unpublished <b>...also filed: KCA 4.1.2 /19</b>	N	Y	New simplified single method for data generation and monitoring purposes (cereal matrices)	Bayer CropScience

Annex point / reference number	Author(s)	Year	Title Source (where different from company) Company name, Report No., Date, GLP status (where relevant), published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCA 4.2 /13 CA B.5.2.3.	Hellpointner, E.	2000	Confirmatory method for the determination of FOE 5043 in air (confirmed method: 00410) Bayer AG, Leverkusen, Germany Bayer CropScience, Report No.: 00410C, Edition Number: M-048783-01-1 Method Report No.: MR-469/00 Date: 2000-10-25 GLP/GEP: yes, unpublished	N	Y	EU data requirement - confirmatory method for enforcement method in air	Bayer CropScience
KCA 4.2 /14 CA B.5.2.1.	Class, T.	2004	Independent laboratory validation (ILV) of a common moiety residue method for the determination of Flufenacet (FOE 5043) and 3 metabolites in wheat grain (Bayer CropScience method 00346) PTRL Europe GmbH, Ulm, Germany Bayer CropScience, Report No.: P740G, Edition Number: M-072609-01-1 Method Report No.: P740G Date: 2004-05-13 GLP/GEP: yes, unpublished	N	Y	Completion of data package for enforcement methods	Bayer CropScience
KCA 4.2 /15 CA B.5.2.1.	Klimmek, S.	2005	Enforcement method for the determination of residues of FOE 5043, FOE 5043 Oxalate, FOE 5043 Sulfonic Acid, and FOE 5043 Thioglycolate Sulfoxide in materials of apples Dr. Specht & Partner, Chemische Laboratorien GmbH, Hamburg, Germany Bayer CropScience, Report No.: BAY-0408V, Edition Number: M-088233-02-1 Method Report No.: BAY-0408V Date: 2004-07-29 <b>...Amended: 2005-06-07</b> GLP/GEP: yes, unpublished	N	Y	Completion of data package for enforcement methods	Bayer CropScience



Annex point / reference number	Author(s)	Year	Title Source (where different from company) Company name, Report No., Date, GLP status (where relevant), published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCA 4.2 /16 CA B.5.2.2.	Brumhard , B.	2005	Modification M001 of method 00359 for the determination of the herbicide FOE 5043 and its metabolite FOE 5043-alcohol, FOE 5043-oxalate and FOE 5043-sulfonic acid in soil using HPLC-MS/MS Bayer CropScience, Report No.: 00359/M001, Edition Number: M-248543-01-1 Method Report No.: MR-028/05 Date: 2005-04-01 GLP/GEP: yes, unpublished	N	Y	EU data requirement - Enforcement method in soil	Bayer CropScience
KCA 4.2 /17 CA B.5.2.1.	Meyer, M.	2011	Independent laboratory validation of the Bayer CropScience methods 01100 and 01179 for the determination of residues of Flufenacet (FOE5043) in/on plant materials SGS Institut Fresenius GmbH, Taunusstein, Germany Bayer CropScience, Report No.: P612107502, Edition Number: M-405654-01-1 Method Report No.: IF-10/01717126 Date: 2011-04-14 GLP/GEP: yes, unpublished	N	Y	Data requirement: ILV for new enforcement method	Bayer CropScience
KCA 4.2 /18 CA B.5.2.1.	Klimmek, S.; Goellner, C.; Amann, S.	2013	Validation of the Bayer methods 00418 (M-019605-01-1) and 00418/M001 (M-019614-01-1) for the determination of residues of flufenacet (FOE 5043) and its metabolites in animal tissues and animal products Eurofins Agroscience Services Chem GmbH (EAS Chem), Hamburg, Germany Bayer CropScience, Report No.: S12-00052, Edition Number: M-461242-01-1 Date: 2013-05-13 GLP/GEP: yes, unpublished	N	Y	Data requirement: ILV for residue analytical method on animal matrices including additional validation data	Bayer CropScience

Annex point / reference number	Author(s)	Year	Title Source (where different from company) Company name, Report No., Date, GLP status (where relevant), published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCA 4.2 /19 CA B.5.2.2.	Krebber, R.; Braune, M.	2013	Analytical method 01387 for the determination of various pesticides in drinking and surface water by HPLC-MS/MS Bayer CropScience, Report No.: MR-13/085, Edition Number: M-466732-01-1 Method Report No.: MR-13/085 Date: 2013-10-09 GLP/GEP: yes, unpublished	N	Y	EU data requirement; Data generation method	Bayer CropScience
KCA 4.2 /20 CA B.5.2.1.	Weile, M.	2013	Flufenacet : Evaluation of EFSA's recommendation to develop a multi residue method for enforcement purpose as replacement of the single common moiety method Bayer CropScience, Report No.: M-457898-01-1, Edition Number: M-457898-01-1 Date: 2013-04-16 GLP/GEP: n.a., unpublished	N	N	-	Bayer CropScience
KCA 4.2 /21 CA B.5.2.1.	Dujardin, B.	2013	Potential and possible solutions for simplifying complex residue definitions Publisher:Anon., Location:Anon., Journal:Anon., Pages:1-11, Year:2012, Report No.: M-459903-01-1, Edition Number: M-459903-01-1 GLP/GEP: n.a., published	N	N	-	
KCA 4.2 /22 CA B.5.2.2.	Stanislawski, T.	2013	Independent laboratory validation of BCS analytical methods 01333 and 01387 for determination of various pesticides in surface water by Di-HPLC-MS/MS PTRL Europe, Ulm, Germany Bayer CropScience, Report No.: P3117 G, Edition Number: M-470714-02-1 Date: 2013-12-13 GLP/GEP: yes, unpublished	N	Y	ILV to support new method	Bayer CropScience

Annex point / reference number	Author(s)	Year	Title Source (where different from company) Company name, Report No., Date, GLP status (where relevant), published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCA 4.2 /23 CA B.5.2.1.	Seym, M.	1998	Supplement E002 of method 00346 for the determination of FOE 5043 total residue in/on soybean, plant and tomato, fruit Bayer AG, Leverkusen, Germany Bayer CropScience, Report No.: 00346/E002, Edition Number: M-018878-01-1 Method Report No.: MR-400/98 Date: 1998-10-16 GLP/GEP: yes, unpublished <b>...also filed: KCA 4.1.2 /13</b>	N	Y	Completion of data package for data generation methods	Bayer CropScience
KCA 4.2/13 CA B.5.2.4	Kaussman n, M.	2016	Analytical Method 01486 for the determination of various pesticides and selected pesticide metabolites in plasma by HPLC-MS/MS Bayer CropScience Report No.: P683166504 Edition Number: M-556577-01-1 GLP/GEP: yes, unpublished	N	Y	Supplementary dossier	Bayer CropScience

References for the plant protection product: Flufenacet + Diflufenican SC 600

Annex point / reference number	Author(s)	Year	Title Source ( <i>where different from company</i> ) Company name, Report No., Date, GLP status ( <i>where relevant</i> ), published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 5.1.1 /01	Seidel, E.	1996	Determination of FOE 5043 and Diflufenican in formulations Bayer AG, Leverkusen, Germany Bayer CropScience, Report No.: 2001-0043101-96, Edition Number: <a href="#">M-002450-01-2</a> Date: 1996-05-31 GLP/GEP: no, unpublished	N	Y	Guideline requirement	Bayer CropScience
KCP 5.1.1 /02	Michel, A.	2007	Validation of the analytical method 2001-0043101-96 for the determination of diflufenican (AE F088657) and flufenacet (FOE 5043) in diflufenican+flufenacet SC 600 g/l formulations by liquid chromatography (HPLC) Bayer CropScience, Report No.: FTA07/028, Edition Number: <a href="#">M-294030-01-1</a> Date: 2007-10-29 GLP/GEP: no, unpublished	N	Y	Guideline requirement	Bayer CropScience

## A.6. TOXICOLOGY AND METABOLISM DATA

### References for the active substance: FLUFENACET

Annex point / reference number	Author(s)	Year	Title Source ( <i>where different from company</i> ) Company name, Report No., Date, GLP status ( <i>where relevant</i> ), published or not	Vertebrate study Y/N	Data protection on claimed Y/N	Justification if data protection is claimed	Owner
KCA 5.1 /03	[REDACTED]	2010	The metabolism of FOE 5043 in rats - Amendment no. 1 to final report [REDACTED] Bayer CropScience, Report No.: 106665-1, Edition Number: M-384235-01-1 Date: 2010-06-25 GLP/GEP: yes, unpublished ...also filed: KCA 5.1.1 /02	Y	Y	Evaluation of pharmacokinetic data; new EU data requirement	Bayer CropScience
KCA 5.1 /04	[REDACTED]	2012	[Thiadiazole-5-14C]flufenacet: Supportive experiment for the identification of metabolites in the urine of the rat - Final report Bayer CropScience, Report No.: EnSa-12-0439, Edition Number: M-441499-01-1 Date: 2012-11-07 GLP/GEP: yes, unpublished ...also filed: KCA 5.1.1 /03	Y	Y	Investigation of occurrence in rat of major plant metabolite identified with new label	Bayer CropScience
KCA 5.1.1 /01	[REDACTED]	1995	The metabolism of FOE 5043 in rats [REDACTED] Bayer CropScience, Report No.: MR106665, Edition Number: M-002247-01-1 Date: 1995-02-17 GLP/GEP: yes, unpublished	Y	Y		Bayer CropScience
KCA 5.1.1 /02	[REDACTED]	2010	The metabolism of FOE 5043 in rats - Amendment no. 1 to final report [REDACTED] Bayer CropScience, Report No.: 106665-1, Edition Number: M-384235-01-1 Date: 2010-06-25 GLP/GEP: yes, unpublished ...also filed: KCA 5.1 /03	Y	Y	Evaluation of pharmacokinetic data; new EU data requirement	Bayer CropScience

Annex point / reference number	Author(s)	Year	Title Source (where different from company) Company name, Report No., Date, GLP status (where relevant), published or not	Vertebrate study Y/N	Data protection on claimed Y/N	Justification if data protection is claimed	Owner
KCA 5.1.1 /03	[REDACTED]	2012	[Thiadiazole-5-14C]flufenacet: Supportive experiment for the identification of metabolites in the urine of the rat - Final report Bayer CropScience, Report No.: EnSa-12-0439, Edition Number: M-441499-01-1 Date: 2012-11-07 GLP/GEP: yes, unpublished ...also filed: KCA 5.1 /04	Y	Y	Investigation of occurrence in rat of major plant metabolite identified with new label	Bayer CropScience
KCA 5.1.1 /04	[REDACTED]	2014	[Thiadiazole-5-14C]flufenacet: Metabolic stability and profiling in liver microsomes from rats and humans for inter-species comparison [REDACTED] [REDACTED] Bayer CropScience, Report No.: EnSa-13-0826, Edition Number: M-475336-01-1 Date: 2014-01-22 GLP/GEP: yes, unpublished	Y	Y	New EU-registration requirement	Bayer CropScience
KCA 5.2.1 /01	[REDACTED] [REDACTED] [REDACTED]	1991	Experimental acute oral toxicity study with technical grade FOE 5043 in mice - Supplemental submission to EPA MRID no. 43850010 - Bayer Corporation Agriculture Division report no. 101914 [REDACTED] [REDACTED] [REDACTED] Report No.: BC6013, Edition Number: M-004850-01-1 EPA MRID No.: 43850010 Date: 1991-09-25 GLP/GEP: yes, unpublished	Y	Y		Bayer CropScience

Annex point / reference number	Author(s)	Year	Title Source ( <i>where different from company</i> ) Company name, Report No., Date, GLP status ( <i>where relevant</i> ), published or not	Vertebrate study Y/N	Data protection on claimed Y/N	Justification if data protection is claimed	Owner
KCA 5.2.1 /02	████████	1992a	Acute oral toxicity study with FOE 5043 in nonfasted male rats - Supplemental submission to EPA MRID no. 43850008 - Bayer Corporation Agriculture Division report no. 102671 ██████████ ██████████████████ ██████████ Report No.: BC6686, Edition Number: M-004864-01-1 EPA MRID No.: 43850008 Date: 1992-04-23 GLP/GEP: yes, unpublished	Y	Y		Bayer CropScience
KCA 5.2.1 /03	████████ ██ ████████ ██████	1993	Acute oral toxicity study with technical grade FOE 5043 in rats ██████████████████ ██████████████████ ██████████, Report No.: BC6916, Edition Number: M-004865-02-1 Date: 1993-01-20 ...Amended: 1996-06-11 GLP/GEP: yes, unpublished	Y			Bayer CropScience
KCA 5.2.2 /01	██████ ██████	1992b	Acute dermal toxicity study with technical grade FOE 5043 in rats - Supplemental submission to EPA MRID no. 43441106 - Bayer Corporation Agriculture Division report no. 100656 ██████████████████ ██████████████████ ██████████████████ No.: BC5477, Edition Number: M-004843-01-1 EPA MRID No.: 43441106 Date: 1992-03-31 GLP/GEP: yes, unpublished	Y			Bayer CropScience

Annex point / reference number	Author(s)	Year	Title Source (where different from company) Company name, Report No., Date, GLP status (where relevant), published or not	Vertebrate study Y/N	Data protection on claimed Y/N	Justification if data protection is claimed	Owner
KCA 5.2.3 /01	██████████ ████	1990	Acute four-hour inhalation toxicity study with technical grade FOE 5043 in rats ██████████ ████████████████████ ████ ████████████████████ Report No.: BC5362, Edition Number: M-004844-01-1 Date: 1990-10-26 GLP/GEP: yes, unpublished	Y	Y		Bayer CropScience
KCA 5.2.4 /01	██████ ████ ██████ ████	1992a	Primary dermal irritation study with technical grade FOE 5043 in rabbits ██████████ ████████████████████ ████ ████████████████████ Report No.: BC6350, Edition Number: M-004846-01-1 Date: 1992-01-23 GLP/GEP: yes, unpublished	Y	Y		Bayer CropScience
KCA 5.2.5 /01	██████ ██ ██████ ██	1992b	Primary eye irritation study with technical grade FOE 5043 in rabbits ████████████████████ ████████████████████ ████████████████████ Report No.: BC6349, Edition Number: M-004847-01-1 Date: 1992-01-27 GLP/GEP: yes, unpublished	Y			Bayer CropScience
KCA 5.2.6 /01	██████████	1994	FOE 5043 - Study for the skin sensitization effect in guinea pigs (Maximization test of Magnusson and Kligman) ████████████████████ ██████ ████████████████████ Report No.: 23560, Edition Number: M-004637-01-1 Date: 1994-12-16 GLP/GEP: yes, unpublished	Y	Y		Bayer CropScience



Annex point / reference number	Author(s)	Year	Title Source (where different from company) Company name, Report No., Date, GLP status (where relevant), published or not	Vertebrate study Y/N	Data protection on claimed Y/N	Justification if data protection is claimed	Owner
KCA 5.2.6 /02	██████████ ██████████ ██████████ ██████████	1992c	Dermal sensitization study with technical grade FOE 5043 in guinea pigs ████████████████████ ████████████████████ ████████████████████, Report No.: BC3991, Edition Number: M-004845-01-1 Date: 1992-03-31 GLP/GEP: yes, unpublished	Y	Y		Bayer CropScience
KCA 5.2.6 /03	██████████	1995	FOE 5043 - Study for the skin sensitization effect in guinea pigs (Maximization test Magnusson and Kligman) ████████████████████ ██████████ ████████████████████, Report No.: 23924, Edition Number: M-004677-01-1 Date: 1995-04-11 GLP/GEP: yes, unpublished	Y	Y	Confirmation of end point/study result	Bayer CropScience
KCA 5.2.6 /04	██████████	2004	FOE 5043 - Local lymph node assay in mice (LLNA/IMDS) ████████████████████ ████████████████████ ████████████████████, Report No.: AT01491, Edition Number: M-090513-01-1 Date: 2004-09-21 GLP/GEP: yes, unpublished	Y	Y	Confirmation of end point/study result by a new study type	Bayer CropScience
KCA 5.2.7 /01	Heppenheimer, A.	2013	Flufenacet TC: Cytotoxicity assay in vitro with BALB/c 3T3 cells: Neutral red (NR) test during simultaneous irradiation with artificial sunlight Harlan Cytotest Cell Research GmbH (Harlan CCR), Rossdorf, Germany Bayer CropScience, Report No.: 1561200, Edition Number: M-464615-03-1 Date: 2013-09-12 ... <b>Amended: 2013-12-18</b> GLP/GEP: yes, unpublished	N	Y	New data requirement	Bayer CropScience

Annex point / reference number	Author(s)	Year	Title Source ( <i>where different from company</i> ) Company name, Report No., Date, GLP status ( <i>where relevant</i> ), published or not	Vertebrate study Y/N	Data protection on claimed Y/N	Justification if data protection is claimed	Owner
KCA 5.3.2 /01	██████████ ██████████ ██████████	1995a	FOE 5043: 13-week subchronic feeding study in beagle dogs ████████████████████ ████████████████████ ████████████████████ Report No.: BC7563, Edition Number: M-004977-02-1 Date: 1995-03-28 ...Amended: 1997-07-18 GLP/GEP: yes, unpublished	Y			Bayer CropScience
KCA 5.3.2 /02	██████████ ██████████ ██████████ ██████████	1995a	Technical grade FOE 5043: A 13-week range-finding toxicity study in the mouse ████████████████████ ██████████ ████████████████████ Report No.: BC7720, Edition Number: M-004985-01-1 Date: 1995-07-17 GLP/GEP: yes, unpublished	Y	Y		Bayer CropScience
KCA 5.3.2 /03	██████████ ██████████ ██████████ ██████████	1995b	Technical grade FOE 5043: A subchronic toxicity testing in the rat ████████████████████ ██████████ ████████████████████ Report No.: BC7733, Edition Number: M-004999-01-1 Date: 1995-07-19 GLP/GEP: yes, unpublished	Y	Y		Bayer CropScience
KCA 5.3.2 /04	██████████ ██████████ ██████████	1995b	Technical grade FOE 5043 : A chronic toxicity feeding study in the Beagle dog ████████████████████ ██████████ ████████████████████ Report No.: BC7779, Edition Number: M-005001-02-2 Date: 1995-09-20 ...Amended: 1997-07-18 GLP/GEP: yes, unpublished	Y			Bayer CropScience

Annex point / reference number	Author(s)	Year	Title Source (where different from company) Company name, Report No., Date, GLP status (where relevant), published or not	Vertebrate study Y/N	Data protection on claimed Y/N	Justification if data protection is claimed	Owner
KCA 5.3.2 /05	Bongartz, R.	2012	Expert statement (non GLP) - Flufenacet (FOE 5043): Explanation of the chromatographic behaviour of FOE-thiadone in the extract of brain from dogs of the chronic feeding study Bayer CropScience, Report No.: EnSa-12/0266, Edition Number: M-430840-02-1 Date: 2012-05-08 ...Amended: 2012-07-04 GLP/GEP: no, unpublished	N	Y	Supplementary study information	Bayer CropScience
KCA 5.3.3 /01	██████ ██████ ██████ ██████	1995	Repeated dose 21-day dermal toxicity study with technical grade FOE 5043 in rats ████████████████████ ██████████ ████████████████████, Report No.: BC7682, Edition Number: M-004981-01-1 Date: 1995-09-29 GLP/GEP: yes, unpublished	Y			Bayer CropScience
KCA 5.3.3 /02	████████	2008a	Flufenacet (FOE 5043) - 1-week inhalation pilot study in Wistar rats (exposure 6h/day, 5 days/week) ████████████████████ ████████████████████ ████████████████████, Report No.: AT04505, Edition Number: M-300005-01-1 Date: 2008-04-10 GLP/GEP: no, unpublished	Y	Y	Requested by non-EU authorities, relevant for reference dose derivation	Bayer CropScience

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KCA 5.3.3 /03		2008b	Flufenacet (FOE 5043) - 4-week subacute inhalation study in Wistar rats (exposure 6h/day, 5 days/week on four consecutive weeks) Report No.: AT04589, Edition Number: M-302961-01-2 EPA MRID No.: 47473101 Date: 2008-05-28 GLP/GEP: yes, unpublished	Y	Y	Requested by non-EU authorities, relevant for reference dose derivation	Bayer CropScience
KCA 5.4.1 /01	Brendler-Schwaab, S.	1994	FOE 5043 - Mutagenicity study for the detection of induced forward mutations in the V79-HGPRT assay in vitro Bayer AG, Wuppertal, Germany Bayer CropScience, Report No.: 23538, Edition Number: M-004634-01-1 Date: 1994-12-09 GLP/GEP: yes, unpublished	N	Y	Guide line requirement	Bayer CropScience
KCA 5.4.1 /02	Brendler-Schwaab, S.	1992	FOE 5043 - Test on unscheduled DNA synthesis in rat liver primary cell cultures in vitro Bayer AG, Wuppertal, Germany Bayer CropScience, Report No.: 21885, Edition Number: M-004577-01-1 Date: 1992-12-03 GLP/GEP: yes, unpublished	N	Y		Bayer CropScience
KCA 5.4.1 /03	Herbold, B.	1995	FOE 5043 - Salmonella/microsome test plate incorporation and preincubation method Bayer AG, Wuppertal, Germany Bayer CropScience, Report No.: 23948, Edition Number: M-004696-01-1 Date: 1995-04-24 GLP/GEP: yes, unpublished	N	Y		Bayer CropScience

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KCA 5.4.1 /04	Gahlmann, R.	1995	FOE 5043 - In vitro mammalian chromosome aberration test with Chinese hamster ovary (CHO) cells Bayer AG, Wuppertal, Germany Bayer CropScience, Report No.: 24340, Edition Number: M-004692-01-1 Date: 1995-10-04 GLP/GEP: yes, unpublished	N	Y		Bayer CropScience
KCA 5.4.1 /05	Sokolowski, A.	2010	Salmonella typhimurium reverse mutation assay with flufenacet techn. Harlan Cytotest Cell Research GmbH (Harlan CCR), Rossdorf, Germany Bayer CropScience, Report No.: 1370100, Edition Number: M-395211-01-1 Date: 2010-11-18 GLP/GEP: yes, unpublished	N	Y	Requested by non-EU authorities ; SANCO/105 97/20 03 -rev. 10.1	Bayer CropScience
KCA 5.4.2 /01	■■■■■ ■■	1993	FOE 5043 - Micronucleus test on the mouse ■■■■■ ■■■■■ ■■■■■, Report No.: 22384, Edition Number: M-004588-01-1 Date: 1993-07-14 GLP/GEP: yes, unpublished	Y	Y		Bayer CropScience
KCA 5.5 /01	■■■■■ ■■ ■■■■■ ■■■	1995c	Technical grade of FOE 5043: An oncogenicity toxicity testing study in the mouse ■■■■■ ■■■■■ ■■■■■, Report No.: BC7795, Edition Number: M-005060-02-1 Date: 1995-10-03 ...Amended: 1996-06-14 GLP/GEP: yes, unpublished	Y	Y		Bayer CropScience

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KCA 5.5 /02	[REDACTED]	1995d	Technical Grade FOE 5043: A combined chronic toxicity/oncogenicity testing study in the rat [REDACTED] [REDACTED] [REDACTED] Report No.: BC7798, Edition Number: M-005062-02-1 Date: 1995-10-03 ...Amended: 1997-06-30 GLP/GEP: yes, unpublished				Bayer CropScience
KCA 5.6.1 /01	[REDACTED]	1995	A two-generation dietary reproduction study in rats using technical grade FOE 5043 [REDACTED] [REDACTED] [REDACTED] Report No.: BC7695, Edition Number: M-004984-03-1 Date: 1995-06-19 ...Amended: 1997-07-15 GLP/GEP: yes, unpublished	Y	Y		Bayer CropScience
KCA 5.6.2 /01	[REDACTED]	1995	A developmental toxicity study with orally administered FOE 5043 technical in the rat [REDACTED] [REDACTED] [REDACTED] [REDACTED] [REDACTED] Report No.: BC7471, Edition Number: M-004976-02-1 Date: 1995-01-10 ...Amended: 1997-07-21 GLP/GEP: yes, unpublished	Y	Y		Bayer CropScience
KCA 5.6.2 /02	[REDACTED]	1995	A developmental toxicity study with orally administered FOE 5043 technical in the rabbit [REDACTED] [REDACTED] [REDACTED] [REDACTED] [REDACTED] Report No.: BC7661, Edition Number: M-004979-01-1 Date: 1995-05-22 GLP/GEP: yes, unpublished	Y	Y		Bayer CropScience

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KCA 5.7.1 /01	██████ ██████ ██████ ██████	1995	An acute oral neurotoxicity screening study with technical grade FOE 5043 in Fischer 344 rats ████████████████████ ████████ ████████████████████, Report No.: BC7709, Edition Number: M-004986-02-1 Date: 1995-07-10 ...Amended: 1998-03-18 GLP/GEP: yes, unpublished	Y	Y		Bayer CropScience
KCA 5.7.1 /02	██████ ███ ██████ ██████ ██████ ███	1995	A subchronic dietary neurotoxicity screening study with technical grade Thiafluamide (FOE 5043) in Fischer 344 rats ████████████████████ ████████ ████████████████████, Report No.: BC7796, Edition Number: M-005014-01-2 Date: 1995-10-09 GLP/GEP: yes, unpublished	Y	Y		Bayer CropScience
KCA 5.7.1 /03	████████ ██████	2000	Developmental neurotoxicity study of technical grade Flufenacet administered orally via diet to Crl:CD BR VAF/Plus presumed pregnant rats ████████████████████ ████████████████████ ████████████████████ ████████████████████, Report No.: BC9333, Edition Number: M-026105-01-1 Date: 2000-09-12 GLP/GEP: yes, unpublished ...also filed: KCA 5.8.2 /05	Y	Y	Requested by non-EU authorities	Bayer CropScience

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KCA 5.8.1 /01	██████████	1998	FOE 5043 Sulfonsaeure (plant metabolite of FOE 5043) - Study for acute oral toxicity in rats ██████████ ██████████ ██████████, Report No.: 27317, Edition Number: M-004749-01-1 Date: 1998-03-19 GLP/GEP: yes, unpublished	Y	Y		Bayer CropScience
KCA 5.8.1 /02	Herbold, B. A.	2000a	FOE 5043-sulfonic-acid - Salmonella/microsome test - Plate incorporation and preincubation method Bayer AG, Wuppertal, Germany Bayer CropScience, Report No.: 29473, Edition Number: M-019064-01-1 Date: 2000-01-19 GLP/GEP: yes, unpublished	N	Y		Bayer CropScience
KCA 5.8.1 /03	Herbold, B.	2000b	FOE 5043-Thioglycolate Sulfoxide - Salmonella/microsome test - plate incorporation and preincubation method Bayer AG, Wuppertal, Germany Bayer CropScience, Report No.: 29871, Edition Number: M-032500-01-1 Date: 2000-05-12 GLP/GEP: yes, unpublished	N			Bayer CropScience



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KCA 5.8.1 /04	■■■■■ ■■■■■ ■■■■■ ■■	2000	FOE 5043 Sulfonic acid - Plasmakinetik and excretion in urine in a rat study with single oral versus intravenous administration ■■■■■ ■■■■■ ■■■■■, Report No.: 30052, Edition Number: M-042251-01-1 Date: 2000-07-25 GLP/GEP: yes, unpublished	N	Y		Bayer CropScience
KCA 5.8.1 /05	Heimann, K. G.; Klamroth, E.	2000	Assessment of the toxicological significance of metabolite M4 (thioglycolate sulfoxide) Bayer AG, Leverkusen, Germany Bayer CropScience, Report No.: MO-01-016035, Edition Number: M-069957-01-1 Date: 2000-02-03 GLP/GEP: no, unpublished	N	Y		Bayer CropScience
KCA 5.8.1 /06	■■■■■ ■■ ■■■■■ ■■	1993	Acute oral toxicity study with FOE 6457 (Thiadone, an FOE 5043 metabolite) in rats ■■■■■ ■■■■■ ■■■■■, Report No.: BC6979, Edition Number: M-004951-01-1 Date: 1993-04-27 GLP/GEP: yes, unpublished	Y	Y		Bayer CropScience

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KCA 5.8.1 /07	Herbold, B.	2009	FOE 5043-Oxalate (Project: FOE 5043 (Flufenacet/AE F133402)) - Salmonella/microsome test - Plate incorporation and preincubation method Bayer HealthCare AG, Wuppertal, Germany Bayer CropScience, Report No.: AT05640, Edition Number: M-358953-01-1 Date: 2009-11-11 GLP/GEP: yes, unpublished	N	Y	Completion of metabolite data package	Bayer CropScience
KCA 5.8.1 /08	Wollny, H. E.	2002	FOE 5043-Oxalate - Gene mutation assay in Chinese hamster V79 cells in vitro (V79/HPRT) Harlan Cytotest Cell Research GmbH (Harlan CCR), Rossdorf, Germany Bayer CropScience, Report No.: 1277301, Edition Number: M-361724-01-1 Date: 2002-12-10 GLP/GEP: yes, unpublished	N	Y	Completion of metabolite data package	Bayer CropScience
KCA 5.8.1 /09	Nern, M.	2009	FOE 5043-oxalate (Project: Flufenacet (FOE 5043)) - In vitro chromosome aberration test with Chinese hamster V79 cells Bayer Schering Pharma AG, Wuppertal, Germany Bayer CropScience, Report No.: AT05598, Edition Number: M-358043-01-1 Date: 2009-10-22 GLP/GEP: yes, unpublished	N	Y	Completion of metabolite data package	Bayer CropScience

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KCA 5.8.1 /10	Wollny, H. E.	2009	FOE 5043-Sulfonic acid Na-salt - Gene mutation assay in Chinese hamster V79 cells in vitro (V79/HPRT) Harlan Cytotest Cell Research GmbH (Harlan CCR), Rossdorf, Germany Bayer CropScience, Report No.: 1277302, Edition Number: M-361158-01-1 Date: 2009-12-10 GLP/GEP: yes, unpublished	N	Y	Completion of metabolite data package	Bayer CropScience
KCA 5.8.1 /11	Nern, M.	2010a	FOE 5043-sulfonic acid Na-salt (Project: Flufenacet (FOE 5043)) - In vitro chromosome aberration test with Chinese hamster V79 cells Bayer Schering Pharma AG, Wuppertal, Germany Bayer CropScience, Report No.: AT05870, Edition Number: M-366380-01-1 Date: 2010-03-15 GLP/GEP: yes, unpublished	N	Y	Completion of metabolite data package	Bayer CropScience
KCA 5.8.1 /12	██████████	2010b	FOE 5043-sulfonic acid Na-salt - Project: Flufenacet (FOE 5043) - Micronucleus-test on the male mouse ██████████ ██████████ ██████████, Report No.: AT05913, Edition Number: M-368627-01-1 Date: 2010-05-04 GLP/GEP: yes, unpublished	Y	Y	Completion of metabolite data package	Bayer CropScience

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KCA 5.8.1 /13	[REDACTED]	2010c	FOE 5043-sulfonic acid Na-salt (Project: Flufenacet (FOE 5043)) - Unscheduled DNA synthesis test with male rat liver cells in vivo [REDACTED] [REDACTED] [REDACTED], Report No.: AT06167, Edition Number: M-397810-01-1 Date: 2010-12-07 GLP/GEP: yes, unpublished	Y	Y	Completion of metabolite data package	Bayer CropScience
KCA 5.8.1 /14	Sokolowski, A.	2012	Salmonella typhimurium reverse mutation assay with FOE 5043-methylsulfone Harlan Cytotest Cell Research GmbH (Harlan CCR), Rossdorf, Germany Bayer CropScience, Report No.: 1454201, Edition Number: M-422370-01-1 Date: 2012-01-17 GLP/GEP: yes, unpublished	N	Y	Completion of metabolite data package	Bayer CropScience
KCA 5.8.1 /15	Wollny, H. E.	2012	FOE 5043-methylsulfone - Gene mutation assay in Chinese hamster V79 cells in vitro (V79/HPRT) Harlan Cytotest Cell Research GmbH (Harlan CCR), Rossdorf, Germany Bayer CropScience, Report No.: 1454202, Edition Number: M-430571-01-1 Date: 2012-05-08 GLP/GEP: yes, unpublished	N	Y	Completion of metabolite data package	Bayer CropScience

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KCA 5.8.1 /16	Bohnenberger, S.	2012	In vitro chromosome aberration test in Chinese hamster V79 cells with FOE 5043-methylsulfone Harlan Cytotest Cell Research GmbH (Harlan CCR), Rossdorf, Germany Bayer CropScience, Report No.: 1454203, Edition Number: M-437250-01-1 Date: 2012-08-23 GLP/GEP: yes, unpublished	N	Y	Completion of metabolite data package	Bayer CropScience
KCA 5.8.1 /17	Sokolowski, A.	2011	Salmonella typhimurium reverse mutation assay with FOE 5043-Thiadone Harlan Cytotest Cell Research GmbH (Harlan CCR), Rossdorf, Germany Bayer CropScience, Report No.: 1423000, Edition Number: M-413989-01-1 Date: 2011-09-13 GLP/GEP: yes, unpublished	N	Y	Requested by non-EU authorities	Bayer CropScience
KCA 5.8.1 /18	Sokolowski, A.	2012	Salmonella typhimurium reverse mutation assay with FOE 5043-trifluoroethanesulfonic acid Na-salt Harlan Cytotest Cell Research GmbH (Harlan CCR), Rossdorf, Germany Bayer CropScience, Report No.: 1486601, Edition Number: M-434728-01-1 Date: 2012-07-13 GLP/GEP: yes, unpublished	N	Y	Completion of metabolite data package	Bayer CropScience

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KCA 5.8.1 /19	Wollny, H. E.	2013	FOE 5043-trifluoroethanesulfonic acid Na-salt - Gene mutation assay in Chinese hamster V79 cells in vitro (V79/HPRT) Harlan Cytotest Cell Research GmbH (Harlan CCR), Rossdorf, Germany Bayer CropScience, Report No.: 1486603, Edition Number: M-446033-01-1 Date: 2013-02-01 GLP/GEP: yes, unpublished	N	Y	Completion of metabolite data package	Bayer CropScience
KCA 5.8.1 /20	Bohnenberger, S.	2013	In vitro chromosome aberration test in Chinese hamster V79 cells with FOE 5043-trifluoroethanesulfonic acid Na-salt Harlan Cytotest Cell Research GmbH (Harlan CCR), Rossdorf, Germany Bayer CropScience, Report No.: 1486602, Edition Number: M-447404-01-1 Date: 2013-02-20 GLP/GEP: yes, unpublished	N	Y	Completion of metabolite data package	Bayer CropScience
KCA 5.8.1 /21	Johnson, M.	2005	Trifluoroacetate (TFA): reverse mutation in five histidine-requiring strains of Salmonella typhimurium Covance Laboratories Ltd., Harrogate, North Yorkshire, United Kingdom Bayer CropScience, Report No.: 2014/82, Edition Number: M-256628-01-1 Date: 2005-08-24 GLP/GEP: yes, unpublished	N	Y	Completion of metabolite data package; Required to test the toxicological relevance of groundwater metabolite	Bayer CropScience

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KCA 5.8.1 /22	Ballantyne, M.	2005	Trifluoroacetate (TFA) - Mutation at the thymidine kinase (tk) locus of mouse lymphoma L5178Y cells (MLA) using the Microtitre fluctuation technique Covance Laboratories Ltd., Harrogate, North Yorkshire, United Kingdom Bayer CropScience, Report No.: 2014/84-D6173, Edition Number: M-260699-01-1 Date: 2005-10-17 GLP/GEP: yes, unpublished	N	Y	Completion of metabolite data package; Required to test the toxicological relevance of groundwater metabolite	Bayer CropScience
KCA 5.8.1 /23	Clare, G.	2005	Trifluoroacetate (TFA) - Induction of chromosome aberrations in cultured human peripheral blood lymphocytes Covance Laboratories Ltd., Harrogate, North Yorkshire, United Kingdom Bayer CropScience, Report No.: 2014/83-D6172, Edition Number: M-260807-01-1 Date: 2005-10-12 GLP/GEP: yes, unpublished	N	Y	Completion of metabolite data package; Required to test the toxicological relevance of groundwater metabolite	Bayer CropScience
KCA 5.8.1 /24	██████████ ██████████	2013	Sodium Trifluoroacetate - Acute oral toxicity study in rats ██ ██ ██ Report No.: 12/333-001P, Edition Number: M-444479-01-1 Date: 2013-01-14 GLP/GEP: yes, unpublished	Y	Y	Completion of metabolite data package; Required to test the toxicological relevance of groundwater metabolite	Bayer CropScience

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KCA 5.8.1 /25	[REDACTED]	2001	Trifluoroacetate - Exploratory 14-day toxicity study in the rat by dietary administration [REDACTED] [REDACTED], Report No.: C016316, Report includes Trial Nos.: SA01136 Edition Number: M-202165-01-1 Date: 2001-09-14 GLP/GEP: no, unpublished	Y	Y	Completion of metabolite data package; Required to test the toxicological relevance of groundwater metabolites	Bayer CropScience
KCA 5.8.1 /26	[REDACTED]	2005	Sodium trifluoroacetate (TFA) - 28-day toxicity study in the rat by dietary administration [REDACTED] [REDACTED], Report No.: SA05054, Edition Number: M-259106-01-1 Date: 2005-10-11 GLP/GEP: yes, unpublished	Y	Y	Completion of metabolite data package; Required to test the toxicological relevance of groundwater metabolite	Bayer CropScience
KCA 5.8.1 /27	[REDACTED]	2007	Sodium trifluoroacetate (TFA) 90-day toxicity study in the rat by dietary administration [REDACTED] [REDACTED], Report No.: SA06080, Edition Number: M-283994-01-1 Date: 2007-02-16 GLP/GEP: yes, unpublished	Y	Y	Completion of metabolite data package; Required to test the toxicological relevance of groundwater metabolite	Bayer CropScience
KCA 5.8.1 /28	[REDACTED]	2010	Trifluoroacetic acid: Embryo-fetal oral gavage toxicity study in rats [REDACTED] [REDACTED] [REDACTED] Report No.: 09-4352, Edition Number: M-411209-01-1 Date: 2010-11-08 GLP/GEP: yes, unpublished	Y	Y	Completion of metabolite data package; Required to test the toxicological relevance of groundwater metabolite	Ishihara



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KCA 5.8.1 /29	Buerkle, L.; Hartmann, K.; Weile, M.	2014	Flufenacet - Toxicological profile and exposure assessment of the plant metabolites Bayer CropScience, Report No.: M-476535-01-1, Edition Number: M-476535-01-1 Date: 2014-03-07 GLP/GEP: n.a., unpublished	N	N		Bayer CropScience
KCA 5.8.1 /30	Hartmann, K.; Semino, G.; Hamm, M.	2014	Trifluoroacetate (TFA) - Waiver of an acute reference dose (ARfD) Bayer CropScience, Report No.: M-480037-01-1, Edition Number: M-480037-01-1 Date: 2014-03-12 GLP/GEP: n.a., unpublished	N	N		Bayer CropScience
KCA 5.8.2 /01	Christenson, W. R.; Wahle, B. S.	1995e	Technical grade FOE 5043: Evidence for an extrathyroidal mechanism to explain alterations in circulating thyroid hormone concentration following exposure of the male rat to the experimental acetanilide Bayer Corporation, Stilwell, KS, USA Bayer CropScience, Report No.: BC7685, Edition Number: M-004982-03-1 EPA MRID No.: 43850041 Date: 1995-07-21 ...Amended: 1996-11-19 GLP/GEP: yes, unpublished	N	Y		Bayer CropScience

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KCA 5.8.2 /02	Jones, R. D.; Lake, S. G.	1995	Method development to establish michaelis-menten conditions for the punitive neurotoxin thiadone in the beagle dog Miles Inc., Agriculture Division, Stilwell, KS, USA Bayer CropScience, Report No.: BC7675, Edition Number: M-004978-01-1 Date: 1995-06-07 GLP/GEP: yes, unpublished	N	Y		Bayer CropScience
KCA 5.8.2 /03	Christenson, W. R.; Becker, B. D.; Wahle, B. S.; Moore, K. D.; Dass, P. D.; Lake, S. G.; Stuart, B. P.; Goethem, D. L. van; Sangha, G. K.; Thyssen, J. H.	1996	Evidence of chemical stimulation of hepatic metabolism by an experimental acetanilide (FOE 5043) indirectly mediating reductions in circulating thyroid hormone levels in the male rat Publisher:Society of Toxicology, Location:Dallas, USA, Journal:Fundamental and Applied Toxicology, Volume:29, Pages:251-259, Year:1996, Report No.: M-012231-01-2, Edition Number: M-012231-01-2 GLP/GEP: n.a., published	Y	N		
KCA 5.8.2 /04	Christenson, W. R.; Becker, B. D.; Hoang, H. D.; Wahle, B. S.; Moore, K. D.; Dass, P. D.; Lake, S. G.; Stuart, B. P.; Goethem, D. L. van; Sangha, G. K.; Thyssen, J. H.	1995	Extrathyroidally mediated changes in circulating thyroid hormone concentrations in the male rat following administration of an experimental oxyacetamide (FOE 5043) Publisher:Academic Press, Location:USA, Journal:Toxicology and Applied Pharmacology, Volume:132, Pages:253-262, Year:1995, Report No.: MO-99-006106, Edition Number: M-012226-01-1 GLP/GEP: n.a., published	N			

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KCA 5.8.2 /05	██████████ ██████████	2000	Developmental neurotoxicity study of technical grade Flufenacet administered orally via diet to CrI:CD BR VAF/Plus presumed pregnant rats ██████████ ██████████ ██████████ ██████████, Report No.: BC9333, Edition Number: M-026105-01-1 Date: 2000-09-12 GLP/GEP: yes, unpublished ...also filed: KCA 5.7.1 /03	Y	Y	Requested by non-EU authorities	Bayer CropScience
KCA 5.8.2 /06	██████████ ██████████	2012	FOE 5043 (flufenacet) - A tolerability and pilot study to verify the exposure of offspring during lactation when administered via the diet to Sprague-Dawley rats ██████████ ██████████ ██████████ ██████████, Report No.: SA 10153, Edition Number: M-434509-01-1 EPA MRID No.: 48898901 Date: 2012-07-11 GLP/GEP: no, unpublished	Y	Y	Requested by non-EU authorities, relevant for reference dose derivation	Bayer CropScience
KCA 5.8.2 /07	██████████	2012q	Flufenacet (FOE5043) - Comparative thyroid sensitivity assay in the rat (gestational exposure phase) ██████████ ██████████ ██████████ ██████████, Report No.: SA 10154, Edition Number: M-435619-01-1 EPA MRID No.: 48898902 Date: 2012-07-27 GLP/GEP: yes, unpublished	Y	Y	Requested by non-EU authorities, relevant for reference dose derivation	Bayer CropScience

Annex point / reference number	Author(s)	Year	Title Source ( <i>where different from company</i> ) Company name, Report No., Date, GLP status ( <i>where relevant</i> ), published or not	Vertebrate study Y/N	Data protection on claimed Y/N	Justification if data protection is claimed	Owner
KCA 5.8.2 /08	[REDACTED]	2012b	Flufenacet (FOE5043) - Comparative thyroid sensitivity assay in the rat by dietary exposure (gestational and lactational exposure phase) [REDACTED] [REDACTED] [REDACTED] [REDACTED], Report No.: SA 11052, Edition Number: M-435313-01-1 EPA MRID No.: 48898903 Date: 2012-07-27 GLP/GEP: yes, unpublished	Y	Y	Requested by non-EU authorities, relevant for reference dose derivation	Bayer CropScience
KCA 5.8.2 /09	Brousse, I.; Amir Tahmasseb, L.	2010	Flufenacet - Determination by high performance liquid chromatography analysis in ground rodent diet Bayer S.A.S., Bayer CropScience, Sophia Antipolis, France Bayer CropScience, Report No.: SA 10292, Edition Number: M-393212-01-1 Date: 2010-10-28 GLP/GEP: yes, unpublished	N	Y	Method development	Bayer CropScience
KCA 5.8.2 /10	Amir-Tahmasseb, L.; Gomez, C.	2011	Flufenacet - Determination by high performance liquid chromatography analysis in ground rodent diet Bayer S.A.S., Bayer CropScience, Sophia Antipolis, France Bayer CropScience, Report No.: SA 11357, Edition Number: M-426082-01-1 Date: 2011-12-19 GLP/GEP: yes, unpublished	N	Y	Method development	Bayer CropScience

Annex point / reference number	Author(s)	Year	Title Source ( <i>where different from company</i> ) Company name, Report No., Date, GLP status ( <i>where relevant</i> ), published or not	Vertebrate study Y/N	Data protection on claimed Y/N	Justification if data protection is claimed	Owner
KCA 5.8.2 /11	Amir Tahmasseb, L.	2012	Flufenacet - Stability in ground rodent diet Bayer S.A.S., Bayer CropScience, Sophia Antipolis, France Bayer CropScience, Report No.: SA 11175, Edition Number: M-435625-01-1 Date: 2012-07-24 GLP/GEP: yes, unpublished	N	Y	Method development	Bayer CropScience
KCA 5.8.2 /12	[REDACTED]	2012c	Flufenacet (FOE5043) - Comparative thyroid sensitivity assay in the rat complementary assay (gavage exposure of pups) [REDACTED] [REDACTED] [REDACTED] [REDACTED], Report No.: SA 11167, Edition Number: M-435126-01-1 EPA MRID No.: 48898904 Date: 2012-07-25 GLP/GEP: yes, unpublished	Y	Y	Requested by non-EU authorities, relevant for reference dose derivation	Bayer CropScience
KCA 5.8.2 /13	Brousse, I.; Amir Tahmasseb, L.	2011	Flufenacet - Determination by high performance liquid chromatography analysis in aqueous 0,5 percent methylcellulose 400 Bayer S.A.S., Bayer CropScience, Sophia Antipolis, France Bayer CropScience, Report No.: SA 11176, Edition Number: M-411290-01-1 Date: 2011-07-21 GLP/GEP: yes, unpublished	N	Y	Method development	Bayer CropScience

Annex point / reference number	Author(s)	Year	Title Source (where different from company) Company name, Report No., Date, GLP status (where relevant), published or not	Vertebrate study Y/N	Data protection on claimed Y/N	Justification if data protection is claimed	Owner
KCA 5.8.2 /14	Amir Tahmasseb, L.	2011	Flufenacet - Stability in aqueous 0.5 percent methylcellulose 400 Bayer S.A.S., Bayer CropScience, Sophia Antipolis, France Bayer CropScience, Report No.: SA 11177, Edition Number: M-418123-01-1 Date: 2011-11-09 GLP/GEP: yes, unpublished	N	Y	Method development	Bayer CropScience
KCA 5.8.2 /15	Herbold, B. A.	1993	FOE 5043-Hydroxy - Salmonella/microsome test plate incorporation and preincubation method Bayer AG, Wuppertal, Germany Bayer CropScience, Report No.: 22438, Edition Number: M-004586-01-1 Date: 1993-08-05 GLP/GEP: yes, unpublished	N	Y	Supportive information for justification of the active substance specification	Bayer CropScience
KCA 5.8.2 /16	██████████	1992a	FOE 5043-Hydroxy - Study of the acute oral toxicity to rats ██████████ ██████████ ██████████, Report No.: 21889, Edition Number: M-004579-01-1 Date: 1992-12-03 GLP/GEP: yes, unpublished	Y	Y	Supportive information for justification of the active substance specification	Bayer CropScience

Annex point / reference number	Author(s)	Year	Title Source (where different from company) Company name, Report No., Date, GLP status (where relevant), published or not	Vertebrate study Y/N	Data protection on claimed Y/N	Justification if data protection is claimed	Owner
KCA 5.8.2 /17	[REDACTED]	1993	FOE 5043-Hydroxy (intermediate for the manufacture of FOE 5043 technical) - Study of the acute inhalation toxicity in rats in accordance with OECD guideline no. 403 [REDACTED] [REDACTED], Report No.: 22155, Edition Number: M-004589-01-2 Date: 1993-03-30 GLP/GEP: yes, unpublished	Y	Y	Supportive information for justification of the active substance specification	Bayer CropScience
KCA 5.8.2 /18	[REDACTED]	1992b	FOE 5043-Hydroxy - Study for skin and eye irritation/corrosion in rabbits [REDACTED] [REDACTED], Report No.: 21257, Edition Number: M-004564-01-1 Date: 1992-04-08 GLP/GEP: yes, unpublished	Y	Y	Supportive information for justification of the active substance specification	Bayer CropScience
KCA 5.8.2 /19	[REDACTED]	1994	FOE 5043-Hydroxy - Study of the skin sensitization effect on guinea pigs (Maximization test of Magnusson and Kligman) [REDACTED] [REDACTED], Report No.: 22824, Edition Number: M-004614-01-2 Date: 1994-01-24 GLP/GEP: yes, unpublished	Y	Y	Supportive information for justification of the active substance specification	Bayer CropScience

Annex point / reference number	Author(s)	Year	Title Source (where different from company) Company name, Report No., Date, GLP status (where relevant), published or not	Vertebrate study Y/N	Data protection on claimed Y/N	Justification if data protection is claimed	Owner
KCA 5.8.2 /20	Herbold, B. A.	1993	FOE 5043-Sulfon - Salmonella/microsome test plate incorporation and preincubation method Bayer AG, Wuppertal, Germany Bayer CropScience, Report No.: 22629, Edition Number: M-004606-01-1 Date: 1993-10-22 GLP/GEP: yes, unpublished	N	Y	Supportive information for justification of the active substance specification	Bayer CropScience
KCA 5.8.2 /21	■■■■■ ■	1992c	FOE 5043 Sulfon - Study for acute oral toxicity in rats ■■■■■ ■■■■■ ■■■■■, Report No.: 21893, Edition Number: M-004578-01-1 Date: 1992-12-03 GLP/GEP: yes, unpublished	Y	Y	Supportive information for justification of the active substance specification	Bayer CropScience
KCA 5.8.2 /22	■■■■■	1992a	FOE 5043-Sulfone - Study of the acute inhalation toxicity to rats in accordance with OECD guideline no. 403 ■■■■■ ■■■■■ ■■■■■, Report No.: 21784, Edition Number: M-004576-01-2 Date: 1992-10-21 GLP/GEP: yes, unpublished	Y	Y	Supportive information for justification of the active substance specification	Bayer CropScience
KCA 5.8.2 /23	■■■■■ ■	1992d	FOE 5043-Sulfon - Study for skin and eye irritation/corrosion in rabbits ■■■■■ ■■■■■ ■■■■■, Report No.: 21156, Edition Number: M-004522-01-1 Date: 1992-03-10 GLP/GEP: yes, unpublished	Y	Y	Supportive information for justification of the active substance specification	Bayer CropScience



Annex point / reference number	Author(s)	Year	Title Source (where different from company) Company name, Report No., Date, GLP status (where relevant), published or not	Vertebrate study Y/N	Data protection on claimed Y/N	Justification if data protection is claimed	Owner
KCA 5.8.2 /24	[REDACTED]	1994	FOE 5043-Sulfone - Study of the skin sensitization effect on guinea pigs (Maximization test of Magnusson and Kligman) [REDACTED] [REDACTED], Report No.: 23001, Edition Number: M-004673-01-2 Date: 1994-04-19 GLP/GEP: yes, unpublished	Y	Y	Supportive information for justification of the active substance specification	Bayer CropScience
KCA 5.8.2 /25	[REDACTED]	1993	FOE 5043-Sulfone - Study to assess the sensory irritation potential to mice (RD50 determination) [REDACTED] [REDACTED], Report No.: 22729, Edition Number: M-004601-01-1 Date: 1993-12-03 GLP/GEP: yes, unpublished	Y	Y	Supportive information for justification of the active substance specification	Bayer CropScience
KCA 5.8.2 /26	[REDACTED]	1992a	FOE 5043-Sulfone - Range-finding study of the subacute inhalation toxicity to rats (exposure: 5x6h) [REDACTED] [REDACTED], Report No.: 21390, Edition Number: M-004571-01-2 Date: 1992-05-21 GLP/GEP: yes, unpublished	Y	Y	Supportive information for justification of the active substance specification	Bayer CropScience

Annex point / reference number	Author(s)	Year	Title Source (where different from company) Company name, Report No., Date, GLP status (where relevant), published or not	Vertebrate study Y/N	Data protection on claimed Y/N	Justification if data protection is claimed	Owner
KCA 5.8.2 /27	[REDACTED]	1994	FOE 5043-Sulfone - Study of the subacute inhalation toxicity to rats in according with OECD guideline no. 412 [REDACTED] [REDACTED], Report No.: 22918, Edition Number: M-004779-01-1 Date: 1994-03-01 GLP/GEP: yes, unpublished	Y	Y	Supportive information for justification of the active substance specification	Bayer CropScience
KCA 5.8.2 /28	[REDACTED]	1994	FOE 5043 Acetate - Study for acute oral toxicity in rats [REDACTED] [REDACTED], Report No.: 23279, Edition Number: M-004640-01-1 Date: 1994-08-24 GLP/GEP: yes, unpublished	Y	Y	Supportive information for justification of the active substance specification	Bayer CropScience
KCA 5.8.2 /29	[REDACTED]	1996	FOE 5043 Acetat (intermediate product of FOE 5043) -Study for acute inhalation toxicity in rats according to OECD no. 403 [REDACTED] [REDACTED], Report No.: 25414, Edition Number: M-004734-01-1 Date: 1996-09-09 GLP/GEP: yes, unpublished	Y	Y	Supportive information for justification of the active substance specification	Bayer CropScience
KCA 5.8.2 /30	[REDACTED]	1994	FOE 5043 Acetat - Study for skin and eye irritation/corrosion in rabbits [REDACTED] [REDACTED], Report No.: 23062, Edition Number: M-004662-01-1 Date: 1994-05-31 GLP/GEP: yes, unpublished	Y	Y	Supportive information for justification of the active substance specification	Bayer CropScience

Annex point / reference number	Author(s)	Year	Title Source (where different from company) Company name, Report No., Date, GLP status (where relevant), published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCA 5.9.1 /01	Bloomberg, J. R.	1995	Worker exposure to FOE 5043/Axiom Bayer Corporation, Kansas City, MO, USA Bayer CropScience, Report No.: BC7815, Edition Number: M-005467-01-1 Date: 1995-10-09 GLP/GEP: no, unpublished	N	Y		Bayer CropScience
KCA 5.9.1 /02	Steffens, W.	2014	Occupational medical experiences with flufenacet Bayer CropScience, Report No.: M-475871-01-1, Edition Number: M-475871-01-1 Date: 2014-01-30 GLP/GEP: yes, unpublished	N	Y	Updated information	Bayer CropScience

## References for the plant protection product: Flufenacet + Diflufenican SC 600

Annex point / reference number	Author(s)	Year	Title Source (where different from company) Company name, Report No., Date, GLP status (where relevant), published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 7.1.1 /01	██████████ ██████████	2002a	FOE 5043 400 SC & DFF 200 (c.n.: Flufenacet & Diflufenican) - Study for acute oral toxicity in rats ██████████ B██████████ Report No.: 31921, Edition Number: M-055334-01-1 Date: 2002-04-08 GLP/GEP: yes, unpublished	Y	Y	Acute data package representative formulation	Bayer CropScience

Annex point / reference number	Author(s)	Year	Title Source (where different from company) Company name, Report No., Date, GLP status (where relevant), published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 7.1.2 /01	██████████	2002b	FOE 5043 400 SC & DFF 200 (c.n.: Flufenacet & Diflufenican) - Study for acute dermal toxicity in rats ██████████ Report No.: 31920, Edition Number: M-055277-01-1 Date: 2002-04-08 GLP/GEP: yes, unpublished	Y	Y	Acute data package representative formulation	Bayer CropScience
KCP 7.1.3 /01	██████████	2002	1st revised version of report-no. 31766 as of 2002-02-13 - FOE 5043 400 SC & DFF 200 (c.n.: Flufenacet, Diflufenican) - Study on acute inhalation toxicity in rats according to OECD No. 403 ██████████ Report No.: 32133, Edition Number: M-036417-02-1 Date: 2002-02-13 <b>...Amended: 2002-06-25</b> GLP/GEP: yes, unpublished	Y	Y	Acute data package representative formulation	Bayer CropScience
KCP 7.1.4 /01	██████████	2001a	Acute skin irritation test (patch test) of FOE 5043 400 SC & DFF 200 in rabbits - revised version of report no. 8085 from October 23rd, 2001 - ██████████ Report No.: R8100, Edition Number: M-083086-02-1 Date: 2001-10-23 <b>...Amended: 2001-10-23</b> GLP/GEP: yes, unpublished	Y	Y	Acute data package representative formulation	Bayer CropScience

Annex point / reference number	Author(s)	Year	Title Source (where different from company) Company name, Report No., Date, GLP status (where relevant), published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 7.1.5 /01	[REDACTED]	2001b	Acute eye irritation study of FOE 5043 400 SC & DFF 200 by instillation into the conjunctival sac of rabbits [REDACTED] [REDACTED], Report No.: R8086, Edition Number: M-083083-01-1 Date: 2001-10-25 GLP/GEP: yes, unpublished	Y	Y	Acute data package representative formulation	Bayer CropScience
KCP 7.1.6 /01	[REDACTED]	2002	FOE 5043 400 SC & DFF 200 - Study for the skin sensitization effect in guinea pigs (guinea pig maximization test according to Magnusson and Kligman) [REDACTED] [REDACTED] Report No.: 32190, Edition Number: M-071813-01-1 Date: 2002-07-16 GLP/GEP: yes, unpublished	Y	Y	Acute data package representative formulation	Bayer CropScience
KCP 7.3 /01	[REDACTED]	2009	Herold SC600: [phenyl-UL-14C]-flufenacet (spec number 102000007948) - Comparative in vitro dermal absorption study using human and rat skin [REDACTED] [REDACTED] [REDACTED], Report No.: SA 08326, Edition Number: M-358525-01-1 Date: 2009-11-06 GLP/GEP: yes, unpublished	N	Y	New data requirement	Bayer CropScience

## A.7. RESIDUE DATA

References for the active substance: FLUFENACET

Annex point / reference number	Author(s)	Year	Title Source (where different from company) Company name, Report No., Date, GLP status (where relevant), published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCA 6.1 /01	Bosnak, L. L.	1995	The storage stability of FOE 5043 and metabolites in corn, soybean, and turpin raw agricultural commodities - Addendum 1 - The storage stability of FOE 5043 and metabolites in corn, soybean, and turnip raw agricultural commodities- 20-month and 28-month data Bayer Corporation, Stilwell, KS, USA Bayer CropScience, Report No.: 106971, Edition Number: M-002426-01-1 EPA MRID No.: 44228701 Date: 1995-08-16 GLP/GEP: yes, unpublished	N	N		Bayer CropScience
KCA 6.1 /02	Stuke, S.; Ballmann, C.	2012	Amendment no. 1 to report no: P642100741 - Storage stability of flufenacet and metabolites in/on orange fruit and dry bean seeds for 24 months Bayer CropScience, Report No.: MR-10/006, Edition Number: M-439517-02-1 Date: 2012-10-08 ...Amended: 2013-11-05 GLP/GEP: yes, unpublished	N	Y	Completion of data package on storage stability (additional matrix groups)	Bayer CropScience
KCA 6.1 /03	Klimmek, S.; Gizler, A.	2013	Amendment No. 1 to Final Report - 7 days freezer storage stability study of flufenacet (FOE5043), and its metabolites in tomato and wheat grain Eurofins Agrosience Services Chem GmbH, Hamburg, Germany Bayer CropScience, Report No.: S13-02753, Edition Number: M-467724-02-1 Date: 2013-10-08 ...Amended: 2013-11-19 GLP/GEP: yes, unpublished	N	Y	Short-term storage stability study to address temperature deviations during shipment of field samples	Bayer CropScience

Annex point / reference number	Author(s)	Year	Title Source (where different from company) Company name, Report No., Date, GLP status (where relevant), published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCA 6.1 /04	Bosnak, L. L.	1997	The storage stability of FOE 5043 and metabolites in wheat forage, grain, and straw Bayer Corporation, Stilwell, KS, USA Bayer CropScience, Report No.: 107137, Edition Number: M-002424-01-1 EPA MRID No.: 45012402 Date: 1997-04-22 GLP/GEP: yes, unpublished	N	Y	Data generated for USA	Bayer CropScience
KCA 6.2.1 /01	Baird, J. H.	1994	Metabolism of [fluorophenyl-UL- <sup>14</sup> C] FOE 5043 in corn Miles Inc., Agriculture Division, Stilwell, KS, USA Bayer CropScience, Report No.: MR105027, Edition Number: M0022270-01-1 Date: 1994-12-19 GLP/GEP: yes, unpublished	N	N		Bayer CropScience
KCA 6.2.1 /02	Krolski, M. E.; Bosnak, L. L.	1995 a	The metabolism of FOE 5043 in soybeans Miles Inc., Agriculture Division, Stilwell, KS, USA Bayer CropScience, Report No.: MR105187, Edition Number: M-002278-01-1 Date: 1995-03-07 GLP/GEP: yes, unpublished	Y	N		Bayer CropScience
KCA 6.2.1 /03	Krolski, M. E.; Bosnak, L. L.	1995 b	The metabolism of [Fluorophenyl-UL- <sup>14</sup> C] FOE 5043 in cotton Bayer Corporation, Stilwell, KS, USA Bayer CropScience, Report No.: MR106666, Edition Number: M-002277-01-1 Date: 1995-12-01 GLP/GEP: yes, unpublished	N	N		Bayer CropScience

Annex point / reference number	Author(s)	Year	Title Source (where different from company) Company name, Report No., Date, GLP status (where relevant), published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCA 6.2.1 /04	Koester, J.; Brauner, A.	1995	Degradation of [Fluorophenyl-UL- <sup>14</sup> C]FOE 5043 and [Thiadiazole-2- <sup>14</sup> C]FOE 5043 by heterotrophic plant cell suspension cultures (supplemental study in support of biodegradation in plants) Bayer AG, Leverkusen, Germany Bayer CropScience, Report No.: PF4049, Edition Number: M-002366-01-1 Date: 1995-04-12 GLP/GEP: yes, unpublished	N	N		Bayer CropScience
KCA 6.2.1 /05	Krolski, M. E.; Bosnak, L. L.	1998	The metabolism of [fluorophenyl-UL- <sup>14</sup> C] FOE 5043 in corn after postemergent foliar spray application Bayer Corporation, Stilwell, KS, USA Bayer CropScience, Report No.: 108497, Edition Number: M-005755-01-1 Date: 1998-09-23 GLP/GEP: yes, unpublished	N	Y	Completion of data package, post-emergence use on maize	Bayer CropScience
KCA 6.2.1 /06	Bongartz, R.	2012	Metabolism of [thiadiazole-5- <sup>14</sup> C]flufenacet in potatoes - Final report Bayer CropScience, Report No.: EnSa-12-0537, Edition Number: M-441506-02-1 Date: 2012-11-07 ...Amended: 2012-12-10 GLP/GEP: yes, unpublished	N	Y	Completion of data package, additional crop, new label	Bayer CropScience
KCA 6.2.1 /07	Bongartz, R.; Miebach, D.	2013	Metabolism of [thiadiazole-5- <sup>14</sup> C]flufenacet in wheat Bayer CropScience, Report No.: EnSa-12-0536, Edition Number: M-444475-01-1 Date: 2013-01-07 GLP/GEP: yes, unpublished	N	Y	Completion of data package, new label	Bayer CropScience



Annex point / reference number	Author(s)	Year	Title Source (where different from company) Company name, Report No., Date, GLP status (where relevant), published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCA 6.2.2 /01	[REDACTED]	1995 b	Metabolism of [Fluorophenyl-UL- <sup>14</sup> C] FOE 5043 in laying hens [REDACTED] [REDACTED] [REDACTED], Report No.: MR103946, Edition Number: M-002251-01-1 Date: 1995-03-24 GLP/GEP: yes, unpublished	Y	N		Bayer CropScience
KCA 6.2.2 /02	[REDACTED]	1995 a	Metabolism of [Thiadiazole-2- <sup>14</sup> C] FOE 5043 in laying hens [REDACTED] [REDACTED] [REDACTED], Report No.: MR106785, Edition Number: M-002253-01-1 Date: 1995-03-20 GLP/GEP: yes, unpublished	Y	N		Bayer CropScience
KCA 6.2.2 /03	[REDACTED]	1995 b	Metabolism of [phenyl-UL- <sup>14</sup> C] FOE oxalate in laying hens [REDACTED] [REDACTED] [REDACTED], Report No.: MR106787, Edition Number: M-004474-01-1 Date: 1995-04-11 GLP/GEP: yes, unpublished ...also filed: KCA 5.1 /01	Y	N		Bayer CropScience
KCA 6.2.2 /04	[REDACTED]	2013	[1- <sup>14</sup> C]Trifluoroacetic acid: Metabolism in the laying hen [REDACTED], Report No.: EnSa-12-0648, Edition Number: M-463376-01-1 Date: 2013-09-02 GLP/GEP: yes, unpublished	Y	Y	Data on major metabolite; new information: animal metabolism of TFA metabolite in laying hen	Bayer CropScience

Annex point / reference number	Author(s)	Year	Title Source (where different from company) Company name, Report No., Date, GLP status (where relevant), published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCA 6.2.3 /01	██████████ ██████████ ██████████ ██████████	1995 a	Metabolism of [Fluorophenyl-UL- <sup>14</sup> C] FOE 5043 in a lactating goat ████████████████████ ████████████████████ ████████████████████, Report No.: MR105184, Edition Number: M-002250-01-1 Date: 1995-03-03 GLP/GEP: yes, unpublished	Y	N		Bayer CropScience
KCA 6.2.3 /02	██████████ ██████████ ██████████ ██████████ ██████████	1995	Metabolism of [Thiadiazole-2- <sup>14</sup> C] FOE 5043 in a lactating goat ████████████████████ ██████████ ████████████████████, Report No.: MR106784, Edition Number: M-002248-01-1 Date: 1995-07-11 GLP/GEP: yes, unpublished	Y	N		Bayer CropScience
KCA 6.2.3 /03	██████████ ██████████ ██████████ ██████████ ██████████ ██████████	1995	Metabolism of [phenyl-UL- <sup>14</sup> C] FOE oxalate in a lactating goat ████████████████████ ██████████ ████████████████████, Report No.: MR106786, Edition Number: M-004478-01-1 Date: 1995-03-31 GLP/GEP: yes, unpublished ...also filed: KCA 5.1 /02	Y	N		Bayer CropScience
KCA 6.2.3 /04	██████████ ██████████ ██████████	2002	The metabolism of FOE 5043 thiadone <i>N</i> -glycoside in a lactating goat ████████████████████ ████████████████████ ████████████████████ Report No.: 110998, Edition Number: M-079251-01-1 Date: 2002-05-21 GLP/GEP: yes, unpublished	Y	Y	Study conducted on request of US EPA. No identification of residues in edible tissues and milk.	Bayer CropScience

Annex point / reference number	Author(s)	Year	Title Source (where different from company) Company name, Report No., Date, GLP status (where relevant), published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCA 6.2.3 /05	[REDACTED]	2013	[1- <sup>14</sup> C]Trifluoroacetic acid - Metabolism in the lactating goat [REDACTED], Report No.: EnSa-12-0628, Edition Number: M-444459-01-1 Date: 2013-01-08 GLP/GEP: yes, unpublished	Y	Y	New information: animal metabolism of TFA metabolite in lactating goat; Transfer study on major metabolite	Bayer CropScience
KCA 6.2.5 /01	[REDACTED]	1994	Identification of radioactive residues of Phenyl-( <sup>14</sup> C) FOE 5043 in bluegill sunfish (Lepomis macrochirus) [REDACTED] [REDACTED], Report No.: 106577, Edition Number: M-003804-01-1 EPA MRID No.: 43441139 Date: 1994-07-13 GLP/GEP: yes, unpublished ...also filed: KCA 8.2.1 /04	Y	Y	New data requirement (fish metabolism)	Bayer CropScience
KCA 6.2.5 /02	[REDACTED]	1994	Uptake, depuration and bioconcentration of <sup>14</sup> C-FOE 5043 technical by bluegill (Lepomis macrochirus) under flow-through conditions [REDACTED] [REDACTED], Report No.: 106760, Edition Number: M-003803-01-1 EPA MRID No.: 43441127 Date: 1994-07-08 GLP/GEP: yes, unpublished ...also filed: KCA 8.2.2.3 /01	Y	Y	New data requirement (fish metabolism)	Bayer CropScience

Annex point / reference number	Author(s)	Year	Title Source (where different from company) Company name, Report No., Date, GLP status (where relevant), published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCA 6.3.1 /01	Seym, M.	1996	Determination of residues of FOE 5043 60 WG in/on winter barley, winter rye and winter wheat following early post-emergence spray application in Germany and France Bayer AG, Leverkusen, Germany Bayer CropScience, Report No.: RA-2008/94, Report includes Trial Nos.: 400351 400378 400386 400394 401528 401544 Edition Number: M-002280-01-2 Date: 1996-03-25 GLP/GEP: yes, unpublished	N	N		Bayer CropScience
KCA 6.3.1 /02	Jersch-Schmitz, S.; Seym, M.	1995	Determination of residues of FOE 5043 60 WG in/on winter wheat and winter barley following early post-emergence spray application in Germany, France and the Netherlands Bayer AG, Leverkusen, Germany Bayer CropScience, Report No.: RA-2054/93, Report includes Trial Nos.: 300489 301655 301663 301671 302554 302562 305030 305049 305057 305065 305138 305146 Edition Number: M-002284-01-2 Date: 1995-10-10 GLP/GEP: yes, unpublished	N	N		Bayer CropScience

Annex point / reference number	Author(s)	Year	Title Source (where different from company) Company name, Report No., Date, GLP status (where relevant), published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCA 6.3.1 /03	Seym, M.	1996 b	Determination of residues of FOE 5043 & Diflufenican 60 WG in/on winter barley, winter rye and winter wheat following early post-emergence spray application in Germany Bayer AG, Leverkusen, Germany Bayer CropScience, Report No.: RA-2010/94, Report includes Trial Nos.: 400440 400459 400467 400475 Edition Number: M-004451-01-2 Date: 1996-03-25 GLP/GEP: yes, unpublished	N	Y	Supplementary data on supported crop/product/GAP	Bayer CropScience
KCA 6.3.1 /04	Seym, M.; Deissler, A.	1999	Determination of residues of FOE 5043 & Diflufenican 70 WG in/on winter barley and winter wheat in the field in France Bayer AG, Leverkusen, Germany Bayer CropScience, Report No.: RA-2153/97, Report includes Trial Nos.: 702587 707317 707325 Edition Number: M-012486-02-1 Date: 1999-02-10 ...Amended: 1999-07-29 GLP/GEP: yes, unpublished	N	Y	Supplementary data on supported crop/product/GAP	Bayer CropScience
KCA 6.3.1 /05	Neigl, A.	2000	Determination of residues of FOE 5043 on winter wheat after spray application of FOE 5043 & diflufenican 70 WG in the field in France Bayer AG, Leverkusen, Germany Bayer CropScience, Report No.: RA-2185/98, Report includes Trial Nos.: 817260 817279 Edition Number: M-033163-01-1 Date: 2000-05-12 GLP/GEP: yes, unpublished	N	Y	Supplementary data on supported crop/product/GAP	Bayer CropScience

Annex point / reference number	Author(s)	Year	Title Source (where different from company) Company name, Report No., Date, GLP status (where relevant), published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCA 6.3.1 /06	Hoffmann, M.	2002	Determination of residues of FOE 5043 in/on wheat and barley following spray application of FOE 5043 & Diflufenican (600 SC) to winter wheat and winter barley in the field in Northern and Southern France, Germany and Spain Bayer AG, Leverkusen, Germany Bayer CropScience, Report No.: RA-2144/00, Report includes Trial Nos.: R 2000 0566/0 R 2000 0567/9 R 2000 0568/7 R 2000 0570/9 Edition Number: M-058156-01-1 Date: 2002-04-12 GLP/GEP: yes, unpublished	N	Y	Supplementary data (N-EU) and new (S-EU) on supported crop/GAP	Bayer CropScience
KCA 6.3.1 /07	Billian, P.; Krusell, L.	2010	Determination of the residues of diflufenican and flufenacet in/on winter barley after spraying of Flufenacet & Diflufenican SC 600 in the field in France (South) Bayer CropScience, Report No.: 09-2048, Report includes Trial Nos.: 09-2048-01 09-2048-02 09-2048-03 Edition Number: M-361495-01-1 Date: 2010-01-12 GLP/GEP: yes, unpublished	N	Y	Supplementary data on supported crop/product/GAP	Bayer CropScience

Annex point / reference number	Author(s)	Year	Title Source (where different from company) Company name, Report No., Date, GLP status (where relevant), published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCA 6.3.1 /08	Billian, P.; Reineke, A.; Krusell, L.	2010	Determination of the residues of diflufenican and flufenacet in/on winter wheat after spraying of Flufenacet & Diflufenican SC 600 in the field in France (south) Bayer CropScience, Report No.: 09-2052, Report includes Trial Nos.: 09-2052-01 09-2052-02 09-2052-03 09-2052-04 Edition Number: M-363200-02-1 Date: 2010-02-05 ...Amended: 2010-08-05 GLP/GEP: yes, unpublished	N	Y	Supplementary data on supported crop/product/GAP	Bayer CropScience
KCA 6.3.1 /09	Noss, G.; Diehl, P.	2013	Determination of the residues of diflufenican, flufenacet and flurtamone in/on winter wheat after spray application of DFF & FFA & FLT SC 360 in Germany, the Netherlands, southern France and Spain - Diflufenican + flufenacet + flurtamone SC 360 (120 + 120 + 120 g / L) Bayer CropScience, Report No.: 11-2095, Report includes Trial Nos.: 11-2095-01 11-2095-02 11-2095-03 11-2095-04 Edition Number: M-459755-01-1 Date: 2013-07-10 GLP/GEP: yes, unpublished	N	Y	Supplementary data on supported crop/product/GAP	Bayer CropScience

Annex point / reference number	Author(s)	Year	Title Source (where different from company) Company name, Report No., Date, GLP status (where relevant), published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCA 6.3.1 /10	Stuke, S.; Ballmann, C.	2013	Determination of the residues of flufenacet and flurtamone in/on winter barley and winter wheat after Spraying of DFF & FFA & FLT SC 360 in the field in Germany, Belgium and the Netherlands - DFF+FFA+FLT SC 120+120+120 Bayer CropScience, Report No.: 12-2001, Report includes Trial Nos.: 12-2001-01 12-2001-02 12-2001-03 12-2001-04 Edition Number: M-459795-01-1 Date: 2013-07-09 GLP/GEP: yes, unpublished	N	Y	Supplementary data on supported crop/product/GAP	Bayer CropScience
KCA 6.3.1 /11	Stuke, S.; Teubner, L.; Ballmann, C.	2013	Determination of the residues of flufenacet and flurtamone in/on winter barley and winter wheat after spray application of DFF & FFA & FLT SC 360 in Southern France, Italy, Spain and Portugal - DFF+FFA+FLT SC 120+120+120 G U-EU Bayer CropScience, Report No.: 12-2002, Report includes Trial Nos.: 12-2002-01 12-2002-02 12-2002-03 12-2002-04 Edition Number: M-459799-01-1 Date: 2013-07-09 GLP/GEP: yes, unpublished	N	Y	Supplementary data on supported crop/product/GAP	Bayer CropScience



Annex point / reference number	Author(s)	Year	Title Source (where different from company) Company name, Report No., Date, GLP status (where relevant), published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCA 6.3.1 /12	Noss, G.; van Berkum, S.	2013	Determination of the residues of diflufenican, flufenacet and flurtamone in/on winter barley after spray application of DFF & FFA & FLT SC 360 in Germany, the United Kingdom, southern France and Italy - Diflufenican + flufenacet + flurtamone SC 360 (120 + 120 + 120 g / L) Bayer CropScience, Report No.: 11-2094, Report includes Trial Nos.: 11-2094-01 11-2094-02 11-2094-03 11-2094-04 Edition Number: M-460003-01-1 Date: 2013-07-11 GLP/GEP: yes, unpublished	N	Y	Supplementary data on supported crop/product/GAP	Bayer CropScience
KCA 6.3.1 /13	Weile, M.	2014	Tier 1 summary of the residue data and processing studies for flufenacet and supplementary residue data supporting the representative product flufenacet + diflufenican SC 600 Bayer CropScience, Report No.: M-478066-01-1, Edition Number: M-478066-01-1 Date: 2014-02-10 GLP/GEP: n.a., unpublished	N	N		Bayer CropScience
KCA 6.3.2 /02	Seym, M.	1995	Determination of residues of FOE 5043 60 WG in corn following preemergence spray application in France Bayer AG, Leverkusen, Germany Bayer CropScience, Report No.: RA-2052/93, Report includes Trial Nos.: 302406 302414 302422 302430 Edition Number: M-002304-02-2 Date: 1995-07-20 ...Amended: 1995-10-20 GLP/GEP: yes, unpublished	N	N		Bayer CropScience

Annex point / reference number	Author(s)	Year	Title Source (where different from company) Company name, Report No., Date, GLP status (where relevant), published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCA 6.3.4 /02	Seym, M.	1995 b	Determination of residues of FOE 5043 60 WG following pre-emergent spray application on soybean in Italy Bayer AG, Leverkusen, Germany Bayer CropScience, Report No.: RA-2079/95, Report includes Trial Nos.: 500526 505676 505714 505722 Edition Number: M-002384-01-2 Date: 1997-04-28 GLP/GEP: yes, unpublished	N	N		Bayer CropScience
KCA 6.4.2 /01	██████████	1995	FOE Oxalate - a 29-day dairy cattle feeding study ██████████ ██████████ ██████████, Report No.: MR106945, Edition Number: M-002268-01-1 Date: 1995-09-27 GLP/GEP: yes, unpublished	Y	N		Bayer CropScience
KCA 6.5.1 /01	Buerkle, L.W.	2011	Flufenacet - Waiving of the high temperature hydrolysis study for the determination of the nature of pesticides residues in processed commodities Bayer CropScience, Report No.: MEF-11/482, Edition Number: M-409521-01-1 Date: 2011-06-10 GLP/GEP: no, unpublished	N	Y	Waiver for GL requirement	Bayer CropScience
KCA 6.5.3 /01	Grace, T. J.	1995	FOE 5043 60 DF - Magnitude of the residue in corn processed products Bayer Corporation, Stilwell, KS, USA Bayer CropScience, Report No.: 106659, Edition Number: M-002412-01-1 Date: 1995-08-02 GLP/GEP: yes, unpublished	N	N		Bayer CropScience

Annex point / reference number	Author(s)	Year	Title Source (where different from company) Company name, Report No., Date, GLP status (where relevant), published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCA 6.5.3 /02	Grace, T. J.	1995	FOE 5043 60 DF - Magnitude of the residue in soybean processed products Bayer Corporation, Stilwell, KS, USA Bayer CropScience, Report No.: 106668, Edition Number: M-002420-01-1 Date: 1995-08-02 GLP/GEP: yes, unpublished	N	N		Bayer CropScience
KCA 6.5.3 /03	Krolski, M. E.	1997	FOE 5043 60 DF - Magnitude of the residue in wheat processed commodities and aspirated grain fractions Bayer Corporation, Stilwell, KS, USA Bayer CropScience, Report No.: 107840, Edition Number: M-002403-01-1 EPA MRID No.: 45012408 Date: 1997-12-03 GLP/GEP: yes, unpublished	N	Y	New data requirement	Bayer CropScience
KCA 6.5.3 /04	Noss, G.; Ruhl, S.; Ballmann, C.	2013	Determination of the residues of flufenacet in/on wheat and the processed fractions (white flour, white flour bran, white bread, whole meal, whole meal bread, middlings, shorts, gluten, gluten feed meal, starch) after spraying of Flufenacet WG 60 in the United Kingdom and the Netherlands Bayer CropScience, Report No.: 11-3401, Report includes Trial Nos.: 11-3401-01 11-3401-02 Edition Number: M-457286-01-1 Date: 2013-06-20 GLP/GEP: yes, unpublished	N	Y	New data requirement	Bayer CropScience

Annex point / reference number	Author(s)	Year	Title Source (where different from company) Company name, Report No., Date, GLP status (where relevant), published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCA 6.5.3 /05	Noss, G.	2013	Determination of the residues of flufenacet in/on barley and the processed fractions from pearl barley processing and preparation of alcoholic beverages (malting, brewing, distillation) after spray application of Flufenacet WG 60 in Germany and Belgium Bayer CropScience, Report No.: 11-3400, Report includes Trial Nos.: 11-3400-01 11-3400-02 Edition Number: M-468736-02-1 Date: 2013-01-25 ...Amended: 2014-01-07 GLP/GEP: yes, unpublished	N	Y	based on guideline requirement	Bayer CropScience
KCA 6.6 /01	Krolski, M. E.	1997	FOE 5043 60 DF - Magnitude of the residue in field rotational crops Bayer Corporation, Stilwell, KS, USA Bayer CropScience, Report No.: 107703, Edition Number: M-002371-01-1 EPA MRID No.: 44253103 Date: 1997-03-27 GLP/GEP: yes, unpublished ...also filed: KCA 6.6.2 /03	N	N		Bayer CropScience
KCA 6.6.1 /01	Halarnkar, P. P.; Mennicke, E. J.	1995	Accumulation of [Thiadiazole-2- <sup>14</sup> C]FOE 5043 residues in confined rotational crops Bayer Corporation, Stilwell, KS, USA Bayer CropScience, Report No.: MR106639, Edition Number: M-002368-01-1 Date: 1995-05-26 GLP/GEP: yes, unpublished	N	N		Bayer CropScience

Annex point / reference number	Author(s)	Year	Title Source (where different from company) Company name, Report No., Date, GLP status (where relevant), published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCA 6.6.1 /02	Lenz, M. F.; McKinney, M. K.	1994	Accumulation of [Phenyl- <sup>14</sup> C] FOE 5043 residues in confined rotational crops Miles Inc., Agriculture Division, Stilwell, KS, USA Bayer CropScience, Report No.: MR106768, Edition Number: M-002369-01-1 Date: 1994-10-17 GLP/GEP: yes, unpublished ...also filed: KCA 6.6.2 /01	N	N		Bayer CropScience
KCA 6.6.1 /03	Bongartz, R.; Klankers, M.	2012	Metabolism of [thiadiazole-5- <sup>14</sup> C]Flufenacet in confined rotational crops Bayer CropScience, Report No.: EnSa-12-0535, Edition Number: M-443538-01-1 Date: 2012-11-29 GLP/GEP: yes, unpublished	N	Y	Completion of data package, new label	Bayer CropScience
KCA 6.6.2 /01	Lenz, M. F.; McKinney, M. K.	1994	Accumulation of [Phenyl- <sup>14</sup> C] FOE 5043 residues in confined rotational crops Miles Inc., Agriculture Division, Stilwell, KS, USA Bayer CropScience, Report No.: MR106768, Edition Number: M-002369-01-1 Date: 1994-10-17 GLP/GEP: yes, unpublished ...also filed: KCA 6.6.1 /02	N	N		Bayer CropScience

Annex point / reference number	Author(s)	Year	Title Source (where different from company) Company name, Report No., Date, GLP status (where relevant), published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCA 6.6.2 /04	Melrose, I.; Erler, S.	2004	Determination of the residues of FOE 5043 in/on the rotational crops cereals after spraying of Artist (41.5 WG) and Liberator (500 SC) in the field in the United Kingdom, Germany and Northern France Bayer CropScience S.A., Lyon, France Bayer CropScience, Report No.: RA-2020/06, Report includes Trial Nos.: R2006-0003/8=0003-06 R20060046/1=0046-06 R20060418/1=0418-06 R20060420/3=0420-06 Edition Number: M-306269-01-1 Date: 2004-07-19 GLP/GEP: yes, unpublished	N	Y	New data on rotational crops	Bayer CropScience
KCA 6.9 /01	Anon.	1993	Pruefung des Rueckstandsverhaltens - Abschaetzung der Aufnahme von Pflanzenschutzmittelrueckstaen den ueber die Nahrung Publisher:Saphir Verlag, Location:Ribbesbüttel, Journal:Biologische Bundesanstalt für Land- und Forstwirtschaft, Volume:Teil IV, Pages:1-52, Year:1993, Report No.: MO-98-000905, Edition Number: M-002038-01-1 GLP/GEP: n.a., published	N	N		

Annex point / reference number	Author(s)	Year	Title Source (where different from company) Company name, Report No., Date, GLP status (where relevant), published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCA 6.9 /02	Anon.	1995	Details of theoretical maximum daily intake and estimated maximum daily intake calculations for pesticides evaluated by the 1994 joint FAO/WHO meeting on pesticides residues, including global/cultural diets Publisher:Joint FAO/WHO, Location:Hague, Netherlands, Journal:Conference room document 5, Year:1995, Report No.: MO-98-000907, Edition Number: M-002041-01-1 GLP/GEP: n.a., published	N	N		
KCA 6.9 /03	Anon.	1989	Guidelines for prediciting dietary intake of pesticide residues Publisher:World Health Organization, Location:Geneva/Switzerland, Pages:1-24; +2, Year:1989, Report No.: MO-98-000909, Edition Number: M-002043-01-1 GLP/GEP: n.a., published	N	N		

**References for the plant protection product: Flufenacet + Diflufenican SC 600**

Not relevant for this section.

## A.8. ENVIRONMENTAL FATE AND BEHAVIOUR

Active substance:

a) studies submitted by the Notifier:

Data point (OECD-format)	Author(s)	Year	Title  Company Report No.  Source (where different from company)  GLP or GEP status  Published or not	Vertebrate study	Data protection claimed yes/no	Justification if data protection is claimed	Owner <sup>*)</sup>	Previous evaluation
KCA 7.1.1.1./01;  KCA 7.1.2.1.1.  (OECD Annex points KIIA 7.1.1, KIIA 7.2.1 and KIIA 7.2.3)	Kelley I. V., Wood S., McKinney M.	1995	<p>“Degradation of [Phenyl-UL-<sup>14</sup>C]FOE 5043 in Three Soil Types.”;</p> <p>Bayer Corporation (formerly Miles Inc), Agriculture Division, P. O. Box 4913, Kansas City, Missouri 64120, USA;</p> <p>study No. F3042104; unpublished Bayer Report No. MR 106664;</p> <p>31 August 1995;</p> <p>Study reference number: M-002146-01-1;</p> <p>GLP: yes;</p> <p>Unpublished study</p>	No	Yes	<p>Justification not provided by the Applicant.</p> <p>However apply the provisions of Article 59, § 1, subparagraph 7 of the Regulation (EC) 1107/2009, stating that “A study shall also be protected if it was necessary for renewal or review of authorisation. The period for data protection shall be 30 months. The first to fourth subparagraphs shall apply mutatis mutandis.”</p>	BCS	The study submitted for the purpose of the previous authorisation of flufenacet in the EU.



Data point (OECD-format)	Author(s)	Year	Title  Company Report No.  Source (where different from company)  GLP or GEP status  Published or not	Vertebrate study	Data protection claimed yes/no	Justification if data protection is claimed	Owner <sup>*)</sup>	Previous evaluation
KCA 7.1.1.1./02;  KCA 7.1.2.1.1.1.  (OECD Annex points KIIA 7.1.1, KIIA 7.2.1 and KIIA 7.2.3)	Pangilinan N. C., Smith D. M.,	1994	<p>“Aerobic Soil Metabolism of [Phenyl-U-<sup>14</sup>C] FOE 5043”;</p> <p>Miles Inc., Agriculture Division, Research and Development Department, P. O. Box 4913, Kansas City, Missouri 64120-0013, USA;</p> <p>study No. F3042102; unpublished Miles Report No. MR 106408;</p> <p>12 May 1994;</p> <p>Study reference number: M-002166-10-1;</p> <p>GLP: Yes</p> <p>Unpublished study</p>	No	Yes	Justification not provided by the Applicant. However apply the provisions of Article 59, § 1, subparagraph 7 of the Regulation (EC) 1107/2009, stating that “A study shall also be protected if it was necessary for renewal or review of authorisation. The period for data protection shall be 30 months. The first to fourth subparagraphs shall apply mutatis mutandis.”	BCS	The study submitted for the purpose of the previous authorisation of flufenacet in the EU.

Data point (OECD-format)	Author(s)	Year	Title  Company Report No.  Source (where different from company)  GLP or GEP status  Published or not	Vertebrate study	Data protection claimed yes/no	Justification if data protection is claimed	Owner <sup>*)</sup>	Previous evaluation
KCA 7.1.1.1./03;  (OECD Annex point KIIA 7.1.1)	Hellpointner E.,	1995	<p>“Evolution of the microbial biomass in the biometer flask system (supportive to study no. F3042102, aerobic metabolism of FOE 5043).”;</p> <p>Bayer AG, Agrochemicals Division, Development, Institute for Metabolism Research &amp; Residue Analysis, D51368 Leverkusen; Germany;</p> <p>unpublished Report No. PF 4066;</p> <p>20 June 1995;</p> <p>Study reference number: M-002164-01-1;</p> <p>GLP: Yes;</p> <p>Unpublished study</p>	No	Yes	Justification not provided by the Applicant. However apply the provisions of Article 59, § 1, subparagraph 7 of the Regulation (EC) 1107/2009, stating that “A study shall also be protected if it was necessary for renewal or review of authorisation. The period for data protection shall be 30 months. The first to fourth subparagraphs shall apply mutatis mutandis.”	BCS	The study submitted for the purpose of the previous authorisation of flufenacet in the EU.

Data point (OECD-format)	Author(s)	Year	Title  Company Report No.  Source (where different from company)  GLP or GEP status  Published or not	Vertebrate study	Data protection claimed yes/no	Justification if data protection is claimed	Owner <sup>*)</sup>	Previous evaluation
KCA 7.1.1.1./04;  KCA 7.1.2.1.1  (OECD Annex points KIIA 7.1.1, KIIA 7.2.1 and KIIA 7.2.3)	Pangilinan N. C., Smith D. M.,	1994a	<p>"Aerobic Soil Metabolism of [Thiadiazole -2-<sup>14</sup>C] FOE 5043";</p> <p>Miles Inc., Agriculture Division, Research and Development Department, P. O. Box 4913, Kansas City, Missouri 64120-0013, USA;</p> <p>study No. F3042103; unpublished Miles Report No. MR 106420;</p> <p>30 June 1994;</p> <p>Study reference number: M-002165-01-1</p> <p>GLP: Yes</p> <p>Unpublished study</p>	No	Yes	Justification not provided by the Applicant. However apply the provisions of Article 59, § 1, subparagraph 7 of the Regulation (EC) 1107/2009, stating that "A study shall also be protected if it was necessary for renewal or review of authorisation. The period for data protection shall be 30 months. The first to fourth subparagraphs shall apply mutatis mutandis."	BCS	The study submitted for the purpose of the previous authorisation of flufenacet in the EU.
KCA 7.1.1.1./05;  KCA 7.1.2.1.1./04  (OECD Annex points KIIA 7.1.1, KIIA 7.2.1 and KIIA 7.2.3)	Hein E.-M.	2012	<p>"[Thiadiazole -5-<sup>14</sup>C] Flufenacet: Aerobic Degradation/Metabolism in One European Soil.";</p> <p>Bayer CropScience AG, BCS-D-EnSa-Testing, 40789 Monheim, Germany, Study M1251994-1;</p> <p>unpublished Study Report No. MEF-11/937;</p> <p>2012. 09. 19, amended (Amendment No 1) 2013. 04. 10;</p> <p>Study reference number: M-439105-02-1</p> <p>GLP: Yes;</p> <p>Unpublished study</p>	No	Yes	EU data requirement – further elucidation of the route of degradation of heterocycle	BCS	Study is submitted specifically for this evaluation.

Data point (OECD-format)	Author(s)	Year	Title  Company Report No.  Source (where different from company)  GLP or GEP status  Published or not	Vertebrate study	Data protection claimed yes/no	Justification if data protection is claimed	Owner <sup>*)</sup>	Previous evaluation
KCA 7.1.1.1./06;  KCA 7.1.2.1.1./05  (OECD Annex points KIIA 7.1.1, KIIA 7.2.1 and KIIA 7.2.3)	Hein E.-M.	2012a	<p>“[Thiadiazole -5-<sup>14</sup>C] Flufenacet: Aerobic Degradation/Metabolism in Three European Soils.”;</p> <p>Bayer CropScience AG, BCS-D-EnSa-Testing, 40789 Monheim, Germany, Study M1252037-0;</p> <p>unpublished Study Report No. MEF-11/938;</p> <p>2012. 10. 18, amended (Amendment No 1) 2013. 01. 28;</p> <p>Study reference number: M-440348-02-1</p> <p>GLP: Yes;</p> <p>Unpublished study,</p>	No	Yes	EU data requirement – further elucidation of the route of degradation of heterocycle	BCS	Study is submitted specifically for this evaluation.
KCA 7.1.1.2./01;  KCA 7.1.2.1.2./01  (OECD Annex points KIIA 7.1.2, KIIA 7.2.4 and KIIA 7.2.5,)	Pangilinan N. C., Smith D. M.,	1995	<p>“Anaerobic Soil Metabolism of [Phenyl-U-<sup>14</sup>C] FOE 5043”;</p> <p>Bayer Corporation (formerly Miles Inc.), Agriculture Division, P. O. Box 4913, Kansas City, Missouri 64120-0013, USA;</p> <p>study No. F3042106; unpublished Miles Report No. MR 106645;</p> <p>20 June 1995;</p> <p>Study reference number: M-002162-01-1;</p> <p>GLP: Yes;</p> <p>Unpublished study;</p>	No	Yes	EU data requirement – study originally conducted for US-EPA, so far not evaluated in the EU	BCS	Study is submitted specifically for this evaluation.

Data point (OECD-format)	Author(s)	Year	Title  Company Report No.  Source (where different from company)  GLP or GEP status  Published or not	Vertebrate study	Data protection claimed yes/no	Justification if data protection is claimed	Owner <sup>*)</sup>	Previous evaluation
KCA 7.1.1.2./02;  KCA 7.1.2.1.2./02  (OECD Annex points KIIA 7.1.2, KIIA 7.2.4 and KIIA 7.2.5,)	Heinemann O.	2012	<p>"[Thiadiazole-5-<sup>14</sup>C] FOE 5043: Anaerobic degradation/Metabolism in Two European Soils.";</p> <p>Bayer CropScience AG, Development Environmental Safety-Testing, Alfred-Nobel-Str. 50, D-40789 Monheim am Rhein, Germany;</p> <p>Study M1262057-3; unpublished Study Report No. MEF-11/908;</p> <p>2012. 08. 16; amended by the Amendment No 1 on 2013. 02. 28 and Amendment No 2 on 2013. 11. 27;</p> <p>Study reference number: M-437443-03-1;</p> <p>GLP: Yes;</p> <p>Unpublished study;</p>	No	Yes	EU data requirement	BCS	Study is submitted specifically for this evaluation.

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KCA 7.1.1.3./01;  KCA 7.1.2.1.3.  (OECD Annex points KIIA 7.1.3 and KIIA 7.2)	Kasper A. M., Shadrick B. A.,	1995	<p>“Photolysis of [Phenyl-U-<sup>14</sup>C] FOE 5043 on Sandy Loam.”;</p> <p>Bayer Corporation (formerly Miles Inc.), Agriculture Division, P. O. Box 4913, Kansas City, Missouri 64120-0013, USA;</p> <p>study No. F3082101/F3082102 (Bayer); unpublished Miles Report No. MR 106247;</p> <p>22 June 1995;</p> <p>Study reference number: M-002145-01-1;</p> <p>GLP: Yes;</p> <p>Unpublished study;</p>	No	Yes	Justification not provided by the Applicant. However apply the provisions of Article 59, § 1, subparagraph 7 of the Regulation (EC) 1107/2009, stating that “A study shall also be protected if it was necessary for renewal or review of authorisation. The period for data protection shall be 30 months. The first to fourth subparagraphs shall apply mutatis mutandis.”	BCS	The study submitted for the purpose of the previous authorisation of flufenacet in the EU.

Data point (OECD-format)	Author(s)	Year	Title  Company Report No.  Source (where different from company)  GLP or GEP status  Published or not	Vertebrate study	Data protection claimed yes/no	Justification if data protection is claimed	Owner <sup>*)</sup>	Previous evaluation
KCA 7.1.1.3./02;  KCA 7.1.2.1.3.  (OECD Annex points KIIA 7.1.3 and KIIA 7.2)	Lentz N. R., Bloomberg A. M.,	2001	<p>“Soil Photolysis of Thiadone on Loamy Sand (A Metabolite of FOE 5043).”;</p> <p>Ricerca LLC, Department of Environmental and Metabolic Fate, 7528 Auburn Road, Painesville, Ohio 44077, USA (performing laboratory) for Bayer Corporation, Agriculture Division, P. O. Box 4913, Kansas City, MO 64120, USA;</p> <p>Ricerca document No. 7410-0055-EF-001, study No. F3082103 (Bayer); Bayer Report No. 108721;</p> <p>21 June 2001;</p> <p>Study reference number: M-106297-01-1</p> <p>GLP: Yes;</p> <p>Unpublished study;</p>	No	Yes	Study originally conducted for US-EPA, so far not evaluated in the EU	BCS	Study is submitted specifically for this evaluation.
KCA 7.1.2.1.1./01  (OECD Annex point KIIA 7.2.1)	Hellpointner E.,	1999	<p>“Aerobic Degradation of Flufenacet in Lysimeter Soil Laacherhof AXx.”;</p> <p>Bayer AG, Institute for Metabolism Research and Residue Analysis, D-513468 Leverkusen, Federal Republic of Germany;</p> <p>study No. M1250988-3, unpublished study Report No. MR-388/99;</p> <p>23 July 1999;</p> <p>Study reference number: M-009592-01-1;</p> <p>GLP: Yes;</p> <p>Unpublished study;</p>	No	Yes	Requested by EU-generation of paired data for modeling of lysimeter study	BCS	Study is submitted specifically for this evaluation.

Data point (OECD-format)	Author(s)	Year	Title  Company Report No.  Source (where different from company)  GLP or GEP status  Published or not	Vertebrate study	Data protection claimed yes/no	Justification if data protection is claimed	Owner <sup>*)</sup>	Previous evaluation
KCA 7.1.2.1.1./02  (OECD Annex points KIIA 7.2.1 and KIIA 7.2.3)	Reinken G., Partsch S.,	2014	<p>“Kinetic Evaluation of the Degradation of [phenyl-UL-<sup>14</sup>C] flufenacet and its Degradation Products under Aerobic Soil Conditions in Laboratory According to FOCUS Kinetics Using the KinGUI 2 Tool. Flufenacet (FOE 5043); FOE sulfonic acid; FOE oxalate; FOE methylsulfone.”;</p> <p>Bayer CropScience AG, Environmental Safety, Alfred-Nobel-Straße 50, 40789 Monheim, Germany;</p> <p>Study Report No. EnSa-12-0575;</p> <p>2014. 02. 17;</p> <p>Study reference number: M-477878-01-1;</p> <p>GLP: no, not applicable (modelling study);</p> <p>Unpublished study;</p>	No	Yes	New data/guideline requirement: Kinetic analysis of the degradation of flufenacet and its major degradation products FOE oxalate, FOE sulfonic acid and FOE methylsulfone for modelling purpose.	BCS	Study is submitted specifically for this evaluation.
KCA 7.1.2.1.1./03  (OECD Annex points KIIA 7.2.1 and KIIA 7.2.3)	Reinken G., Maassen K.,	2014a	<p>“Trigger evaluation for the Degradation of Flufenacet Degradation Product FOE oxalate under Aerobic Soil Conditions in Laboratory According to FOCUS Kinetics Using the KinGUI 2 Tool. FOE oxalate.”;</p> <p>Bayer CropScience AG, Environmental Safety, Alfred-Nobel-Strasse 50, 40789 Monheim, Germany;</p> <p>Study Report No. En-Sa-13-1009;</p> <p>2014. 02. 18.;</p> <p>Study reference number: M-478440-01-1;</p> <p>GLP: no, not applicable (modelling study);</p> <p>Unpublished study;</p>	No	Yes	New data/guideline requirement: Kinetic analysis of the degradation of flufenacet to derive half-lives for its major degradation product FOE oxalate for trigger evaluation.	BCS	Study is submitted specifically for this evaluation.



Data point (OECD-format)	Author(s)	Year	Title  Company Report No.  Source (where different from company)  GLP or GEP status  Published or not	Vertebrate study	Data protection claimed yes/no	Justification if data protection is claimed	Owner <sup>*)</sup>	Previous evaluation
KCA 7.1.2.1.1./06  (OECD Annex points KIIA 7.2.1 and KIIA 7.2.3)	Reinken G., Partsch S.,	2014b	<p>“Trigger evaluation for the Degradation of Flufenacet Degradation Product FOE 5043 trifluoroethane-sulfonic acid under Aerobic Conditions in Laboratory According to FOCUS Kinetics Using the KinGUI 2 Tool. FOE 5043-trifluoroethane sulfonic acid, Trifluoroacetic acid.”;</p> <p>Bayer Crop Science AG, Environmental Safety, Alfred-Nobel-Strasse 50, 40789 Monheim, Germany;</p> <p>Study Report No. En-Sa-13-1010;</p> <p>2014. 02. 18.;</p> <p>Study reference number: M-478444-01-1;</p> <p>GLP: no, not applicable (modelling study);</p> <p>Unpublished study;</p>	No	Yes	New data/guideline requirement: Kinetic analysis of the degradation of flufenacet to derive half-lives for its major degradation product FOE 5043-trifluoroethanesulfonic acid for trigger evaluation.	BCS	Study is submitted specifically for this evaluation.

Data point (OECD-format)	Author(s)	Year	Title  Company Report No.  Source (where different from company)  GLP or GEP status  Published or not	Vertebrate study	Data protection claimed yes/no	Justification if data protection is claimed	Owner <sup>*)</sup>	Previous evaluation
KCA 7.1.2.1.1./07  (OECD Annex points KIIA 7.2.1 and KIIA 7.2.3)	Reinken G., Partsch S.,	2014c	<p>“Kinetic Evaluation of [thiadiazole-5-<sup>14</sup>C] flufenacet and its Degradation Products under Aerobic Conditions in Laboratory According to FOCUS Kinetics Using the KinGUI 2 Tool. Flufenacet (FOE 5043), FOE-thiadone, FOE 5043-trifluoroethane sulfonic acid, Trifluoroacetic acid.”;</p> <p>Bayer Crop Science AG, Environmental Safety, Alfred-Nobel-Strasse 50, 40789 Monheim, Germany;</p> <p>Study Report No. En-Sa-12-0577;</p> <p>2014. 02. 17.;</p> <p>Study reference number: M-477835-01-1;</p> <p>GLP: no, not applicable (modelling study);</p> <p>Unpublished study;</p>	No	Yes	New data/guideline requirement: Kinetic analysis of the degradation of flufenacet and its major degradation products FOE-thiadone, FOE 5043-trifluoroethanesulfonic acid and Trifluoroacetic acid for modelling purpose	BCS	Study is submitted specifically for this evaluation.

Data point (OECD-format)	Author(s)	Year	Title  Company Report No.  Source (where different from company)  GLP or GEP status  Published or not	Vertebrate study	Data protection claimed yes/no	Justification if data protection is claimed	Owner <sup>*)</sup>	Previous evaluation
KCA 7.1.2.1.1./08  (OECD Annex points KIIA 7.2.1 and KIIA 7.2.3)	Reinken G., Partsch S.,	2014d	<p>“Kinetic Evaluation of the Degradation of [thiadiazole-2-<sup>14</sup>C] flufenacet and its Degradation Product under Aerobic Soil Conditions in Laboratory According to FOCUS Kinetics using the KinGUI 2 Tool. Flufenacet (FOE 5043); FOE-thiadone.”;</p> <p>Bayer CropScience AG, Environmental Safety, Alfred-Nobel-Strasse 50, 40789 Monheim, Germany;</p> <p>Study Report No. EnSa-12-0576;</p> <p>2014. 02.17;</p> <p>Study reference number: M-477885-01-1;</p> <p>GLP: no, not applicable (modelling study);</p> <p>Unpublished study;</p>	No	Yes	New data/guideline requirement: Kinetic analysis of the degradation of flufenacet and its major degradation product FOE-thiadone for modelling purpose	BCS	Study is submitted specifically for this evaluation.

Data point (OECD-format)	Author(s)	Year	Title  Company Report No.  Source (where different from company)  GLP or GEP status  Published or not	Vertebrate study	Data protection claimed yes/no	Justification if data protection is claimed	Owner <sup>*)</sup>	Previous evaluation
KCA 7.1.2.1.1./09  (OECD Annex point KIIA 7.2.3)	Hellpointner E.,	1996	<p>“Degradation of [Phenyl-UL-<sup>14</sup>C]FOE 5043-Sulfonic Acid in Three Soils.”;</p> <p>Bayer AG, Crop Protection Business Group, Crop-Protection Development, Agrochemicals Division, Development, Institute for Metabolism Research and Residue Analysis, D51368 Leverkusen; Germany for Bayer Corporation, Agriculture Division, P. O. Box 4913, Hawthorne Road, Kansas City, MO 64120-0013, USA; Study Report No. PF 4110 (Bayer Report Number 107515);</p> <p>8 January 1996;</p> <p>Study reference number: M-004098-01-2;</p> <p>GLP: Yes;</p> <p>Unpublished study;</p>	No	Yes	Justification not provided by the Applicant. However apply the provisions of Article 59, § 1, subparagraph 7 of the Regulation (EC) 1107/2009, stating that “A study shall also be protected if it was necessary for renewal or review of authorisation. The period for data protection shall be 30 months. The first to fourth subparagraphs shall apply mutatis mutandis.”	BCS	The study submitted for the purpose of the previous authorisation of flufenacet in the EU.
KCA 7.1.2.1.1./10; 7.1.3.2/01;  (OECD Annex points KIIA, 7.2.3 and KIIA 7.4.2)	Hellpointner E.,	2003	<p>“Time-Dependent Sorption of FOE5043-Sulfonic Acid in Soil.”;</p> <p>Bayer Crop Science AG, Development – Global Regulatory Affairs, D-40789 Monheim, Germany;</p> <p>Study Report No. MEF-229/03;</p> <p>2003-10-13.;</p> <p>Study reference number: M-111445-01-1;</p> <p>GLP: Yes;</p> <p>Unpublished study;</p>	No	Yes	Higher tier study for the refinement of risk assessment	BCS	Study is submitted specifically for this evaluation.

Data point (OECD-format)	Author(s)	Year	Title  Company Report No.  Source (where different from company)  GLP or GEP status  Published or not	Vertebrate study	Data protection claimed yes/no	Justification if data protection is claimed	Owner <sup>*)</sup>	Previous evaluation
KCA 7.1.2.1.1./11;  (OECD Annex point KIIA 7.2.3)	Hein E. M.	2013	<p>“FOE sulfonic acid: Aerobic Degradation in Four European Soils.”;</p> <p>Bayer CropScience AG, BCS-D-EnSa-Testing, 40789 Monheim, Germany;</p> <p>unpublished Study Report No. EnSa-13-0442; 2013. 08. 05, updated by the Amendment No. 1 (Hein E. M. (2013): “Amendment No. 1 to: FOE Sulfonic Acid: Aerobic Degradation in Four European Soils.”; Bayer CropScience AG, BCS-D-EnSa-Testing, 40789 Monheim, Germany;</p> <p>2013. 08. 22.;</p> <p>Study reference number: M-461413-02-1;</p> <p>GLP: Yes;</p> <p>Unpublished study;</p>	No	Yes	EU Data requirement	BCS	Study is submitted specifically for this evaluation.
KCA 7.1.2.1.1./12;  (OECD Annex point KIIA 7.2.3)	Ströck K., Junge T.	2013	<p>„FOE sulfonic acid: Degradation in Four Aerobic Soils.”;</p> <p>Bayer CropScience AG, BCS-D-EnSa-Testing, 40789 Monheim, Germany;</p> <p>unpublished Study Report No. EnSa-13-0618;</p> <p>2013. 10. 24.;</p> <p>Study reference number: M-467862-01-1;</p> <p>GLP: Yes;</p> <p>Unpublished study;</p>	No	Yes	Additional data: Rate of degradation in aerobic soil of major degradation product FOE sulfonic acid	BCS	Study is submitted specifically for this evaluation.

Data point (OECD-format)	Author(s)	Year	Title  Company Report No.  Source (where different from company)  GLP or GEP status  Published or not	Vertebrate study	Data protection claimed yes/no	Justification if data protection is claimed	Owner <sup>*)</sup>	Previous evaluation
KCA 7.1.2.1.1./13;  (OECD Annex point KIIA 7.2.3)	Reinken G., Partsch S.	2014e	<p>“Kinetic Evaluation of the Degradation of Flufenacet Degradation Product FOE sulfonic acid under Aerobic Soil conditions in Laboratory according to FOCUS Kinetics Using the KinGUI 2 Tool. FOE sulfonic acid.”;</p> <p>Bayer CropScience AG, Environmental Safety, Alfred-Nobel-Strasse 50, 40789 Monheim, Germany;</p> <p>unpublished Study Report No. EnSa-12-0580;</p> <p>2014. 02. 17.;</p> <p>Study reference number: M-477844-01-1;</p> <p>GLP: no, not applicable (modelling study);</p> <p>Unpublished study;</p>	No	Yes	New data/guideline requirement: Kinetic analysis of the degradation of FOE sulfonic acid for modelling purpose	BCS	Study is submitted specifically for this evaluation.
KCA 7.1.2.1.1./14;  (OECD Annex point KIIA 7.2.3)	Traub M.	2012	<p>“FOE methylsulfone: Aerobic Degradation in Four European Soils.”;</p> <p>Eurofins Agrosience Services EcoChem GmbH, Eutinger Str. 24, 75223 Niefern-Öschelbronn, Germany, for Bayre Crop Science AG, 40789 Monheim;</p> <p>unpublished study No. S11-03808;</p> <p>2012. 10.18;</p> <p>Study reference number:M-443658-01-1;</p> <p>GLP: Yes;</p> <p>Unpublished study;</p>	No	Yes	EU Data requirement	BCS	Study is submitted specifically for this evaluation.

Data point (OECD-format)	Author(s)	Year	Title  Company Report No.  Source (where different from company)  GLP or GEP status  Published or not	Vertebrate study	Data protection claimed yes/no	Justification if data protection is claimed	Owner <sup>*)</sup>	Previous evaluation
KCA 7.1.2.1.1./15;  (OECD Annex point KIIA 7.2.3)	Ströck K., Junge T.	2013a	„FOE methylsulfone: Degradation in Four Aerobic Soils.“;  Bayer CropScience AG, BCS-D-EnSa-Testing, 40789 Monheim, Germany;  unpublished Study Report No. EnSa-13-0617;  2013. 10. 24.;  Study reference number: M-467858-01-1;  GLP: Yes;  Unpublished study;	No	Yes	New data/guideline requirement: Rate of degradation for the newly identified major degradation product FOE methylsulfone	BCS	Study is submitted specifically for this evaluation.
KCA 7.1.2.1.1./16;  (OECD Annex point KIIA 7.2.3)	Reinken G., Partsch S.	2014f	“Kinetic Evaluation of the Degradation of Flufenacet Degradation Product FOE methylsulfone under Aerobic Soil conditions in Laboratory according to FOCUS Kinetics Using the KinGUI 2 Tool. FOE methylsulfone acid.“;  Bayer CropScience AG, Environmental Safety, Alfred-Nobel-Strasse 50, 40789 Monheim, Germany;  unpublished Study Report No. EnSa-12-0578;  2014. 02. 17.;  Study reference number: M-477839-01-1;  GLP: no, not applicable (modelling study);  Unpublished study;	No	Yes	New data/guideline requirement: Kinetic analysis of the degradation of FOE methylsulfone for modelling purpose	BCS	Study is submitted specifically for this evaluation.

Data point (OECD-format)	Author(s)	Year	Title  Company Report No.  Source (where different from company)  GLP or GEP status  Published or not	Vertebrate study	Data protection claimed yes/no	Justification if data protection is claimed	Owner <sup>*)</sup>	Previous evaluation
KCA 7.1.2.1.1./17;  (OECD Annex point KIA 7.2.3)	Lentz N. R., Bloomberg A. M.	1999	<p>“Rate of Aerobic Soil Degradation for Thiadone (A Metabolite of FOE 5043).”;</p> <p>Ricerca LLC, Department of Environmental and Metabolic Fate, 7528 Auburn Road, Painesville, Ohio 44077, USA (performing laboratory) for Bayer Corporation, Agriculture Division, P. O. Box 4913, Kansas City, MO 64120, USA;</p> <p>Ricerca document No. 7410-0055-EF-001, study No. F3082103 (Bayer); Bayer Report No. 108722;</p> <p>16 February 1999, amended on 24 March 1999;</p> <p>Study reference number: M-009828-01-1;</p> <p>GLP: Yes;</p> <p>Unpublished study;</p>	No	Yes	EU data requirement	BCS	Study is submitted specifically for this evaluation.



Data point (OECD-format)	Author(s)	Year	Title  Company Report No.  Source (where different from company)  GLP or GEP status  Published or not	Vertebrate study	Data protection claimed yes/no	Justification if data protection is claimed	Owner <sup>*)</sup>	Previous evaluation
KCA 7.1.2.1.1./18;  (OECD Annex point KIIA 7.2.3)	Reinken G., Partsch S.	2014g	<p>“Kinetic Evaluation of the Degradation of Flufenacet Degradation Product FOE-thiadone under Aerobic Soil conditions in Laboratory according to FOCUS Kinetics Using the KinGUI 2 Tool. FOE-thiadone.”;</p> <p>Bayer CropScience AG, Environmental Safety, Alfred-Nobel-Strasse 50, 40789 Monheim, Germany;</p> <p>unpublished Study Report No. EnSa-12-0579;</p> <p>2014. 02. 17.;</p> <p>Study reference number: M-477840-01-1;</p> <p>GLP: no, not applicable (modelling study);</p> <p>Unpublished study;</p>	No	Yes	New data/guideline requirement: Kinetic analysis of the degradation of FOE-thiadone for modelling purpose	BCS	Study is submitted specifically for this evaluation.
KCA 7.1.2.1.1./19;  (OECD Annex point KIIA 7.2.3)	Eckermann N.	2012	<p>“[1-<sup>14</sup>C]Trifluoroacetate: Aerobic Degradation in Four European Soils.”;</p> <p>Bayer CropScience AG, BCS-D-EnSa-Testing, 40789 Monheim, Germany;</p> <p>unpublished Study Report No. EnSa-12-0393;</p> <p>2012. 09. 26.;</p> <p>Study reference number: M-439283-01-1;</p> <p>GLP: Yes;</p> <p>Unpublished study;</p>	No	Yes	New data requirements	BCS	Study is submitted specifically for this evaluation.

Data point (OECD-format)	Author(s)	Year	Title  Company Report No.  Source (where different from company)  GLP or GEP status  Published or not	Vertebrate study	Data protection claimed yes/no	Justification if data protection is claimed	Owner <sup>*)</sup>	Previous evaluation
KCA 7.1.2.1.1./20;  (OECD Annex point KIIA 7.2.3)	Eckermann N.	2012a	<p>"[1-<sup>14</sup>C]Trifluoroacetate: Concentration dependent Mineralization under Aerobic Conditions.";</p> <p>Bayer CropScience AG, BCS-D-EnSa-Testing, 40789 Monheim, Germany;</p> <p>unpublished Study Report No. EnSa-12-0445;</p> <p>2012. 10. 11.;</p> <p>Study reference number: M-441101-01-1;</p> <p>GLP: Yes;</p> <p>Unpublished study;</p>	No	Yes	Additional data for refinement of risk assessment	BCS	Study is submitted specifically for this evaluation.
KCA 7.1.2.1.1./21;  (OECD Annex points KIIA 7.2.1 and KIIA 7.2.3)	Reinken G. Porschewski R.,	2014g	<p>"Flufenacet Core PECsoil and Accumulation: Modelling Core Info Document for Soil Exposure Assessment in Europe.";</p> <p>Bayer CropScienceAG, Environmental Safety, Alfred-Nobel-Straße 50, 40789 Monheim, Germany, unpublished Report No. EnSa-13-1007;</p> <p>2014. 02. 25.;</p> <p>Study reference number: M-478418-01-1;</p> <p>GLP: no, not applicable (modelling study);</p> <p>Unpublished study;</p>	No	Yes	<p>Justification not provided by the Applicant, however should apply the provisions of the of Article 59, § 1, subparagraph 7 of the Regulation (EC) 1107/2009, stating that "A study shall also be protected if it was necessary for renewal or review of authorisation.</p> <p>As this is a new study, should apply the rules set for the new/newly submitted studies.</p>	BCS	Study is submitted specifically for this evaluation.

Data point (OECD-format)	Author(s)	Year	Title  Company Report No.  Source (where different from company)  GLP or GEP status  Published or not	Vertebrate study	Data protection claimed yes/no	Justification if data protection is claimed	Owner <sup>*)</sup>	Previous evaluation
KCA 7.1.2.1.1./21;  (OECD Annex points KIIA 7.2.1 and KIIA 7.2.3)	Reinken G. Porschewski R.,	2014h	<p>“Flufenacet Core PECgw FOCUS EU: Modelling Core Info Document for Groundwater Risk Assessment in Europe.”;</p> <p>Bayer CropScienceAG, Environmental Safety, Alfred-Nobel-Straße 50, 40789 Monheim, Germany, unpublished Report No. EnSa-13-1006;</p> <p>2014. 02. 25.;</p> <p>Study reference number: M-478214-01-1;</p> <p>GLP: no, not applicable (modelling study);</p> <p>Unpublished study;</p>	No	Yes	<p>Justification not provided by the Applicant, however should apply the provisions of the of Article 59, § 1, subparagraph 7 of the Regulation (EC) 1107/2009, stating that “A study shall also be protected if it was necessary for renewal or review of authorisation.</p> <p>As this is a new study, should apply the rules set for the new/newly submitted studies.</p>	BCS	Study is submitted specifically for this evaluation.
KCA 7.1.2.1.2./01;  (OECD Annex points KIIA 7.2.4 and KIIA 7.2.5)	Reinken G., Partsch S., Bolekhan A.,	2014	<p>“Kinetic evaluation of the Degradation of Flufenacet and its Degradation Products under Anaerobic Soil Conditions in Laboratory According to FOCUS Kinetics Using the KinGUI 2 Tool.”;</p> <p>Bayer CropScience AG, Environmental Safety, Alfred-Nobel-Strasse 50, 40789 Monheim, Germany;</p> <p>unpublished study Report No. EnSa-13-0971;</p> <p>2014. 02. 28.;</p> <p>Study reference number: M-478213-02-1;</p> <p>GLP: no, not applicable (modelling study);</p> <p>Unpublished study;</p>	No	Yes	<p>New data/guideline requirement: Kinetic analysis of degradation of FOE oxalate, FOE sulfonic acid, FOE-thiadone, FOE 5043-trifluoroethanesulfonic acid and trifluoroacetic acid under anaerobic conditions for modelling purpose and trigger evaluation</p>	BCS	Study is submitted specifically for this evaluation.

Data point (OECD-format)	Author(s)	Year	Title  Company Report No.  Source (where different from company)  GLP or GEP status  Published or not	Vertebrate study	Data protection claimed yes/no	Justification if data protection is claimed	Owner <sup>*)</sup>	Previous evaluation
KCA 7.1.2.2.1./01;  (OECD Annex point KIIA 7.3.1.)	Sommer H.	1995	<p>“Dissipation of FOE 5043 in Soil under Field Conditions (Germany, France).”;</p> <p>Bayer AG, Crop Protection Business Group, Crop Protection-Development, Institute for Metabolism Research &amp; Residue Analysis, D-51368 Leverkusen-Baywerk, Germany (performing laboratory) for Bayer Corporation, Agriculture Division, P. O. Box 4913, Hawthorne Road, Kansas City, MO 64120-0013, USA;</p> <p>Study Report RA-2112/93; Bayer Report No. 107724;</p> <p>1 September 1995;</p> <p>Study reference number: M-002172-01-2;</p> <p>GLP: Yes;</p> <p>Unpublished study;</p>	No	Yes	<p>Justification not provided by the Applicant, however should apply the provisions of the of Article 59, § 1, subparagraph 7 of the Regulation (EC) 1107/2009, stating that “A study shall also be protected if it was necessary for renewal or review of authorisation.</p> <p>As this is a new study, should apply the rules set for the new/newly submitted studies.</p>	BCS	The study submitted for the purpose of the previous authorisation of flufenacet in the EU.

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KCA 7.1.2.2.1./02;  (OECD Annex point KIIA 7.3.1.)	Sommer H.	1995a	<p>“Dissipation of FOE 5043 in Soil under Field Conditions (Germany).”;</p> <p>Bayer AG, Crop Protection Business Group, Crop Protection-Development, Institute for Metabolism Research &amp; Residue Analysis, D-51368 Leverkusen-Baywerk, Germany (performing laboratory) for Bayer Corporation, Agriculture Division, P. O. Box 4913, Hawthorne Road, Kansas City, MO 64120-0013, USA;</p> <p>Study Report RA-2116/93; Bayer Report No. 107722;</p> <p>5 October 1995;</p> <p>Study reference number: M-02171-01-2;</p> <p>GLP: Yes;</p> <p>Unpublished study;</p>	No	Yes	<p>Justification not provided by the Applicant, however should apply the provisions of the of Article 59, § 1, subparagraph 7 of the Regulation (EC) 1107/2009, stating that “A study shall also be protected if it was necessary for renewal or review of authorisation.</p> <p>As this is a new study, should apply the rules set for the new/newly submitted studies.</p>	BCS	The study submitted for the purpose of the previous authorisation of flufenacet in the EU.

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KCA 7.1.2.2.1./03;  (OECD Annex point KIIA 7.3.1.)	Sommer H.	1995b	<p>“Dissipation of FOE 5043 in Soil under Field Conditions (France).”;</p> <p>Bayer AG, Crop Protection Business Group, Crop Protection-Development, Institute for Metabolism Research &amp; Residue Analysis, D-51368 Leverkusen-Baywerk, Germany (performing laboratory) for Bayer Corporation, Agriculture Division, P. O. Box 4913, Hawthorne Road, Kansas City, MO 64120-0013, USA;</p> <p>Study Report RA-2051/93; Bayer Report No. 107723;</p> <p>6 October 1995;</p> <p>Study reference number: M-002169-01-2;</p> <p>GLP: Yes;</p> <p>Unpublished study;</p>	No	Yes	<p>Justification not provided by the Applicant, however should apply the provisions of the of Article 59, § 1, subparagraph 7 of the Regulation (EC) 1107/2009, stating that “A study shall also be protected if it was necessary for renewal or review of authorisation.</p> <p>As this is a new study, should apply the rules set for the new/newly submitted studies.</p>	BCS	The study submitted for the purpose of the previous authorisation of flufenacet in the EU.

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KCA 7.1.2.2.1./04;  (OECD Annex point KIIA 7.3.1.)	Sommer H.,	1995c	<p>“Dissipation of FOE 5043 in Soil under Field Conditions (France, Italy).”;</p> <p>Bayer AG, Crop Protection Business Group, Crop Protection-Development, Institute for Metabolism Research &amp; Residue Analysis, D-51368 Leverkusen-Baywerk, Germany (performing laboratory) for Bayer Corporation, Agriculture Division, P. O. Box 4913, Hawthorne Road, Kansas City, MO 64120-0013, USA;</p> <p>Study Report RA-2019/94; Bayer Report No. 107721;</p> <p>23 November 1995;</p> <p>Study reference number: M-002175-01-2;</p> <p>GLP: Yes;</p> <p>Unpublished study;</p>	No	Yes	<p>Justification not provided by the Applicant, however should apply the provisions of the of Article 59, § 1, subparagraph 7 of the Regulation (EC) 1107/2009, stating that “A study shall also be protected if it was necessary for renewal or review of authorisation.</p> <p>As this is a new study, should apply the rules set for the new/newly submitted studies.</p>	BCS	The study submitted for the purpose of the previous authorisation of flufenacet in the EU.

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KCA 7.1.2.2.1./05;  (OECD Annex point KIIA 7.3.1.)	Lin H, Green D. L., Fig P. S,	1995	<p>“Freezer stability of [Phenyl-UL-<sup>14</sup>C]FOE 5043 in Soil.”;</p> <p>Agriculture Division, Miles Inc., Research and Development Department, P. O. Box 4913, Kansas City, Missouri 64120, USA;</p> <p>Miles Study No. F3132101, Miles Report No. 106231;</p> <p>23 February 1995;</p> <p>Study reference number: M-002201-01-1;</p> <p>GLP: Yes;</p> <p>Unpublished study;</p>	No	Yes	<p>Justification not provided by the Applicant, however should apply the provisions of the of Article 59, § 1, subparagraph 7 of the Regulation (EC) 1107/2009, stating that “A study shall also be protected if it was necessary for renewal or review of authorisation.</p> <p>As this is a new study, should apply the rules set for the new/newly submitted studies.</p>	BCS	The study submitted for the purpose of the previous authorisation of flufenacet in the EU.



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KCA 7.1.2.2.1./06;  (OECD Annex point KIIA 7.3.1.)	Lin H, Green D. L.,	1995	<p>“Freezer stability of seven metabolites of [<sup>14</sup>C]FOE 5043 in Soil.”;</p> <p>Agriculture Division, Miles Inc., Research and Development Department, P. O. Box 4913, Kansas City, Missouri 64120, USA;</p> <p>Miles Study No. F3132102, Miles Report No. 106640;</p> <p>26 June 1995;</p> <p>Study reference number: M-002199-01-1;</p> <p>GLP: Yes;</p> <p>Unpublished study;</p>	No	Yes	<p>Justification not provided by the Applicant, however should apply the provisions of the of Article 59, § 1, subparagraph 7 of the Regulation (EC) 1107/2009, stating that “A study shall also be protected if it was necessary for renewal or review of authorisation.</p> <p>As this is a new study, should apply the rules set for the new/newly submitted studies.</p>	BCS	The study submitted for the purpose of the previous authorisation of flufenacet in the EU.
KCA 7.1.2.2.1./07;  (OECD Annex point KIIA 7.3.1.)	Hammel K.,	2008	<p>“Kinetic Evaluation of the Dissipation of Flufenacet and its Metabolite Flufenacet-sulfonic acid in soil based on Field Studies.”;</p> <p>Bayer CropScience AG, Institute for Metabolism and Environmental Fate, Alfred-Nobel-Strasse 50, 40789 Monheim, Germany;</p> <p>study Report MEF-08/266;</p> <p>2008. 08. 25.;</p> <p>Study reference number: M-306683-01-1;</p> <p>GLP: no, not applicable (modelling study);</p> <p>Unpublished study;</p>	No	Yes	The Applicant provided following justification: “New kinetic evaluation.”	BCS	Study is submitted specifically for this evaluation.

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KCA 7.1.3.1.1./01  (OECD Annex point KIIA 7.4.1)	Kelley I., Wood S.,	1992	<p>“Adsorption/Desorption of FOE 5043 to Soil.”;</p> <p>Miles Inc., Agriculture Division, Research and Development Department, P. O. Box 4913, Kansas City, Missouri 64120, USA;</p> <p>Miles Study No. F3182101, Miles Report No. 103903;</p> <p>30 September 1992; <i>updated by study report:</i> Kelley I., Wood S., (1993): Addendum to Miles Report No. 103903: Adsorption/Desorption of FOE 5043 to Soil.”; Miles Report No.103903-1; 13 September 1993;</p> <p>Study reference number: M-002202-01-1;</p> <p>GLP: Yes;</p> <p>Unpublished study;</p>	No	Yes	<p>Justification not provided by the Applicant, however should apply the provisions of the of Article 59, § 1, subparagraph 7 of the Regulation (EC) 1107/2009, stating that “A study shall also be protected if it was necessary for renewal or review of authorisation.</p> <p>As this is a new study, should apply the rules set for the new/newly submitted studies.</p>	BCS	The study submitted for the purpose of the previous authorisation of flufenacet in the EU.
KCA 7.1.3.1.1./02  (OECD Annex point KIIA 7.4.1)	Hein E.-M.,	2012	<p>“[Thiadiazole-5-<sup>14</sup>C] FOE 5043 (Flufenacet): Adsorption/Desorption on Five Soils.”;</p> <p>Bayer CropScience AG, BCS-D-EnSa-Testing, 40789 Monheim, Germany;</p> <p>study ID M1312069-2, Report No. EnSa-12-0517;</p> <p>01 October 2012;</p> <p>Study reference number: M-439282-01-1;</p> <p>GLP: Yes;</p> <p>Unpublished study;</p>	No	Yes	Additional data for refinement of risk assessment.	BCS	Study is submitted specifically for this evaluation.

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KCA 7.1.3.1.1./03  (OECD Annex point KIIA 7.4.1)	Stupp H. P.	2010	<p>"[Phenyl-UL-<sup>14</sup>C] Flufenacet: Adsorption on Two Japanese Soils.";</p> <p>Bayer CropScience AG – Development, Environmental Safety Metabolism/ADME and Environmental Fate, Alfred-Nobel-Str. 50, D-40789 Monheim am Rhein, Germany (performing laboratory) for Bayer CropScience K. K, 6-5 Marunouchi 1-chome, Chiyoda-ku, 100-8262 Tokyo, Japan;</p> <p>Study No. M1311954-4; Bayer Report MEF-10/534;</p> <p>04. 08. 2010.;</p> <p>Study reference number: M-387572-01-1;</p> <p>GLP: Yes;</p> <p>Unpublished study;</p>	No	Yes	Study originally conducted for FAMIC (Japan) – so far not evaluated in EU.	BCS	Study is submitted specifically for this evaluation.

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KCA 7.1.3.1.2./01  (OECD Annex point KIIA 7.4.2)	Blumhorst M. R., Yen P. Y., Marlow V. A.	1994	<p>“Soil Adsorption/ Desorption of FOE 5043 Degradates: FOE Sulfonic acid, FOE Methyl Sulfoxide, FOE Oxalate, FOE Alcohol and Thiadone.”;</p> <p>EPL Bio-analytical Services, Inc. (EPL-BAS), P. O. Box 109, 395N. Memorial Parkway, Harristown IL 62537, USA (performing laboratory) for Miles Inc., Agriculture Division, Research and Development Department, P. O. Box 4913, Kansas City, MO 64120- 0013, USA;</p> <p>EPL-BAS study No. 122S19, study report (Miles) No. MR 106598;</p> <p>26 September 1994;</p> <p>study reference number: M-002185-01-1;</p> <p>GLP: Yes;</p> <p>Unpublished study;</p>	No	Yes	<p>Justification not provided by the Applicant, however should apply the provisions of the of Article 59, § 1, subparagraph 7 of the Regulation (EC) 1107/2009, stating that “A study shall also be protected if it was necessary for renewal or review of authorisation.</p> <p>As this is a new study, should apply the rules set for the new/newly submitted studies.</p>	BCS	The study submitted for the purpose of the previous authorisation of flufenacet in the EU.

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KCA 7.1.3.1.2./02  (OECD Annex point KIIA 7.4.2)	Hein W.,	2011	<p>"[Phenyl-UL-<sup>14</sup>C] BCS-CO62475: Adsorption/Desorption in Five Different Soils.";</p> <p>RLP AgroScience GmbH, Breitenweg 71, 67435 Neustadt a. d. Weinstrasse, Germany (performing laboratory) for Bayer CropScience Aktiengesellschaft, Development, Environmental Safety Metabolism/ADME and Environmental Fate, Alfred Nobel Str. 50, D-40789 Monheim, Germany;</p> <p>Study number (RLP AgroSciences GmbH) AS158; Bayer Report No. M-411141-01-1;</p> <p>30 June 2011;</p> <p>study reference number:</p> <p>M-411141-01-1.</p> <p>GLP: Yes;</p> <p>Unpublished study;</p>	No	Yes	New data requirements	BCS	Study is submitted specifically for this evaluation.

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KCA 7.1.3.1.2./03  (OECD Annex point KIIA 7.4.2)	Moendel M., Hein W.	2011	<p>"[1-<sup>14</sup>C] BCS-AZ56567: Adsorption/Desorption in Five Different Soils.";</p> <p>RLP AgroScience GmbH, Breitenweg 71, 67435 Neustadt a. d. Weinstrasse, Germany (performing laboratory) for Bayer CropScience Aktiengesellschaft, Development, Environmental Safety Metabolism/ADME and Environmental Fate, Alfred Nobel Str. 50, D-40789 Monheim, Germany;</p> <p>Study number (RLP AgroSciences GmbH) AS155; Bayer Report No. M-406740-01-1;</p> <p>07 April 2011;</p> <p>study reference number: M-406740-01-1.</p> <p>GLP: Yes;</p> <p>Unpublished study;</p>	No	Yes	EU data requirements	BCS	Study is submitted specifically for this evaluation.

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KCA 7.1.3.1.2./04  (OECD Annex point KIIA 7.4.2)	Traub M.,	2013	<p>“Determination of the Adsorption/Desorption behaviour of FOE 5043-trifluoroethanesulfonic acid in five Soils.”;</p> <p>Eurofins Agrosience Services EcoChem GmbH, Eutinger Strasse 24, 75223 Niefern-Öschelbronn, Germany (performing laboratory) for Bayer CropScience AG, 40789 Monheim, Germany;</p> <p>Study number (Eurofins) S11-03923; Report No. MEFOP017;</p> <p>18. 02. 2013;</p> <p>study reference number: M-449893-01-1.</p> <p>GLP: Yes;</p> <p>Unpublished study;</p>	No	Yes	New data requirements	BCS	Study is submitted specifically for this evaluation.
KCA 7.1.4.1.2/01  (OECD Annex point KIIA 7.4.4:)	Hein E. –M.	2014	<p>“[1-<sup>14</sup>C]trifluoroacetate: Soil column Leaching”;</p> <p>Bayer CropScience AG, BCS-D-EnSa Testing, 40789 Monheim, Germany;</p> <p>Study No. M1212045-5; Report No. EnSa-14-0050;</p> <p>2014-02-20;</p> <p>study reference number: M-477737-01-1;</p> <p>GLP: Yes;</p> <p>Unpublished study;</p>	No	Yes	<p>New data requirement; higher tier study for investigation of the soil adsorption behaviour</p> <p>trifluoroacetic acid</p>	BCS	Study is submitted specifically for this evaluation.

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KCA 7.1.4.2/01  (OECD Annex point KIIA 7.4.7.)	Hellpointner E.,	1997	<p>“Lysimeter study on the translocation of <i>FOE 5043</i> into the subsoil after 2-year use as pre-emergence herbicide in corn.”;</p> <p>Bayer AG, Agrochemical Division, Development, Institute for Metabolism Research and Residue analysis; D-51368 Leverkusen, Germany;</p> <p>report No. PF-4188 (MR-074/97);</p> <p>19 September 1997;</p> <p>study reference number: M-002187-01-1;</p> <p>GLP: Yes;</p> <p>Unpublished study;</p>	No	Yes	<p>Justification not provided by the Applicant, however should apply the provisions of the of Article 59, § 1, subparagraph 7 of the Regulation (EC) 1107/2009, stating that “A study shall also be protected if it was necessary for renewal or review of authorisation.</p> <p>As this is a new study, should apply the rules set for the new/newly submitted studies.</p>	BCS	The study submitted for the purpose of the previous authorisation of flufenacet in the EU.



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KCA 7.1.4.2/02  (OECD Annex point KIIA 7.4.7.)	Hellpointner E.,	1996	<p>“Lysimeter study on the translocation of <i>FOE 5043</i> into the subsoil after use as pre-emergence herbicide in a maize/winter wheat crop rotation.”;</p> <p>Bayer AG, Agrochemical Division, Development, Institute for Metabolism Research and Residue analysis; D-51368 Leverkusen, Germany;</p> <p>report No. PF-4184 (107688);</p> <p>18 November 1996;</p> <p>study reference number: M-002190-01-2;</p> <p>GLP: Yes;</p> <p>Unpublished study;</p>	No	Yes	<p>Justification not provided by the Applicant, however should apply the provisions of the of Article 59, § 1, subparagraph 7 of the Regulation (EC) 1107/2009, stating that “A study shall also be protected if it was necessary for renewal or review of authorisation.</p> <p>As this is a new study, should apply the rules set for the new/newly submitted studies.</p>	BCS	The study submitted for the purpose of the previous authorisation of flufenacet in the EU.

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KCA 7.1.4./01  (OECD Annex point not defined)	Schmeling S., Bongartz R.,	2012	<p>“Determination of the Plant Uptake Factor of FOE Methylsulfone, FOE Sulfonic acid and Trifluoroethanesulfonic acid in Wheat.”;</p> <p>Bayer Crop Science AG, Development-Environmental Safety-Metabolism/ADME and Environmental Fate, 40789 Monheim am Rhein, Germany;</p> <p>Study ID: M9992073-9, Report No. EnSa-12-260;</p> <p>2012. 06. 28,</p> <p>updated with Amendment No. 1 on 2013. 02. 19; study reference number: M-434257-02-1;</p> <p>GLP: Yes;</p> <p>Unpublished study;</p>	No	Yes	New data for refinement of risk assessment	BCS	Study is submitted specifically for this evaluation.
KCA 7.1.4./02  (OECD Annex point not defined)	Bongartz R.,	2013	<p>“Determination of the Plant Uptake Factor of Trifluoroacetic acid (TFA) in Wheat.”;</p> <p>Bayer Crop Science AG, BCS-D-EnSA-Testing, Monheim, Germany;</p> <p>Study ID: M9992182-0, Report No. EnSa-13-0357;</p> <p>2013. 06. 05, updated with Amendment No. 1 on 2013. 06. 24 and with Amendment No. 2 on 2013. 07. 25;</p> <p>study reference number: M-456754-03-1;</p> <p>GLP: Yes;</p> <p>Unpublished study;</p>	No	Yes	New data for refinement of risk assessment	BCS	Study is submitted specifically for this evaluation.

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KCA 7.1.4./03  (OECD Annex point not defined)	Bongartz R.,	2013a	<p>“Determination of the Plant Uptake Factor of Trifluoroacetic acid (TFA) in Wheat, Corn and Tomatoes.”;</p> <p>Bayer Crop Science AG, BCS-D-EnSA-Testing, Monheim, Germany;</p> <p>Study ID: M9992182-0, Report No. EnSa-12-0581;</p> <p>2012. 10. 18;</p> <p>study reference number: M-440106-01-1;</p> <p>GLP: Yes;</p> <p>Unpublished study;</p>	No	Yes	New data for refinement of risk assessment	BCS	Study is submitted specifically for this evaluation.
KCA 7.1.4./04  (OECD Annex point not defined)	Roepke B.,	2013	<p>“Determination of a suitable Plant Uptake Factor (PUF) of Trifluoroacetic acid (TFA) for use in Environmental Fate Models in the Target Crop Wheat.”;</p> <p>Bayer Crop Science AG, Environmental Safety, Alfred Nobel Str. 50, D-40789 Monheim am Rhein, Germany;</p> <p>Report No. EnSa-13-0545;</p> <p>24. 10. 2013;</p> <p>study reference number: M-468684-01-1;</p> <p>GLP: No, not applicable – position paper;</p> <p>Unpublished study;</p>	No	No	Not applicable	BCS	Study is submitted specifically for this evaluation.

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KCA 7.2.1.1./01  (OECD Annex point KIIA 2.9.1 and KIIA 7.5.)	Zeng Z., Wood S.,	1992	<p>“Stability of FOE 5043 in Sterile Aqueous Buffer Solution.”;</p> <p>Miles Inc., Agriculture Division, Research and Development Department, P. O. box 4913, Kansas City, MO 64120, USA;</p> <p>study No. F3072401 (Miles Inc.); Report No. 102623 (Miles Inc.);</p> <p>12 March 1992;</p> <p>study reference number: M-002203-01-1;</p> <p>GLP: Yes;</p> <p>Unpublished study;</p>	No	Yes	<p>Justification not provided by the Applicant, however should apply the provisions of the of Article 59, § 1, subparagraph 7 of the Regulation (EC) 1107/2009, stating that “A study shall also be protected if it was necessary for renewal or review of authorisation.</p> <p>As this is a new study, should apply the rules set for the new/newly submitted studies.</p>	BCS	The study submitted for the purpose of the previous authorisation of flufenacet in the EU.

Data point (OECD-format)	Author(s)	Year	Title  Company Report No.  Source (where different from company)  GLP or GEP status  Published or not	Vertebrate study	Data protection claimed yes/no	Justification if data protection is claimed	Owner <sup>*)</sup>	Previous evaluation
KCA 7.2.1.1./02  (OECD Annex point KIIA 2.9.1 and KIIA 7.5.)	Bloomberg A. M., Shah J. F.,	1999	<p>“Hydrolysis study of Thiadone (A Metabolite of FOE 5043).”;</p> <p>Ricerca LLC, Department of Environmental and Metabolic Fate, 7528 Auburn Road, Painesville, Ohio 44077, USA (performing laboratory) for Bayer Corporation, Agriculture Division, P. O. Box 4913, Kansas City, MO 64120, USA;</p> <p>Ricerca document No. 7410-0058-EF-001, study No. F3082402 (Bayer); Bayer Report No. 108719;</p> <p>22 February 1999;</p> <p>study reference number: M-009620-01-1;</p> <p>GLP: Yes;</p> <p>Unpublished study;</p>	No	Yes	Additional data: Requested by the US Environmental Protection Agency (EPA)	BCS	Study is submitted specifically for this evaluation.
KCA 7.2.1.1./03  (OECD Annex point KIIA 2.9.1 and KIIA 7.5.)	Babczinski P., Jantzen T.,	2009	<p>“[Thiadiazole-2-<sup>14</sup>C]FOE5043-Thiadone (BCS-AA41715): Hydrolytic degradation.”;</p> <p>Bayer Crop Science AG, Alfred-Nobel-Str. 50, D-40789 Monheim am Rhein, Germany;</p> <p>study No. M1111833-8, Report No. MEF-009/308;</p> <p>2009. 10. 26;</p> <p>study reference number M-358419-01-1;</p> <p>GLP: Yes;</p> <p>Unpublished study;</p>	No	Yes	Study originally requested by US EPA – so far not evaluated in EU	BCS	Study is submitted specifically for this evaluation.

Data point (OECD-format)	Author(s)	Year	Title  Company Report No.  Source (where different from company)  GLP or GEP status  Published or not	Vertebrate study	Data protection claimed yes/no	Justification if data protection is claimed	Owner <sup>*)</sup>	Previous evaluation
KCA 7.2.1.2/01; KCA 7.2.1.3./01  (OECD Annex points: KIIA 2.9.2. and KIIA 7.6)	Kasper A. M., Shadrick B. A.,	1995	<p>"Aqueous Photolysis of [Phenyl-U-<sup>14</sup>C] FOE 5043.";</p> <p>Bayer Corporation (formerly Miles Inc.), Agriculture Division, P. O. Box 4913, Kansas City, Missouri 64120-0013, USA;</p> <p>study No. F3082401 (Bayer); unpublished Miles Report No. MR 106246;</p> <p>30 May 1995;</p> <p>study reference number: M-002206-01-1;</p> <p>GLP: Yes, but only for the part of the experiment that examined the direct photolysis of Flufenacet;</p> <p>Unpublished study;</p>	No	Yes	<p>Justification not provided by the Applicant, however should apply the provisions of the of Article 59, § 1, subparagraph 7 of the Regulation (EC) 1107/2009, stating that "A study shall also be protected if it was necessary for renewal or review of authorisation.</p> <p>As this is a new study, should apply the rules set for the new/newly submitted studies.</p>	BCS	The study submitted for the purpose of the previous authorisation of flufenacet in the EU.

Data point (OECD-format)	Author(s)	Year	Title  Company Report No.  Source (where different from company)  GLP or GEP status  Published or not	Vertebrate study	Data protection claimed yes/no	Justification if data protection is claimed	Owner <sup>*)</sup>	Previous evaluation
KCA 7.2.1.2/02  (OECD Annex points: KIIA 2.9.2. and KIIA 7.6)	Hellpointner E.,	1993	<p>“Determination of the Quantum Yield and Assessment of the Environmental Half-life of the Direct Photodegradation of FOE 5043 in Water.”;</p> <p>Bayer AG, Crop Protection, Development, Institute for Metabolism Research, 51368 Leverkusen, Germany;</p> <p>Study No. M 112 0566-1, Report No. PF-3919 (HPO-103);</p> <p>27 September 1993;</p> <p>study reference number M-002206-01-1;</p> <p>GLP: Yes;</p> <p>Unpublished study;</p>	No	Yes	<p>Justification not provided by the Applicant, however should apply the provisions of the of Article 59, § 1, subparagraph 7 of the Regulation (EC) 1107/2009, stating that “A study shall also be protected if it was necessary for renewal or review of authorisation.</p> <p>As this is a new study, should apply the rules set for the new/newly submitted studies.</p>	BCS	The study submitted for the purpose of the previous authorisation of flufenacet in the EU.

Data point (OECD-format)	Author(s)	Year	Title  Company Report No.  Source (where different from company)  GLP or GEP status  Published or not	Vertebrate study	Data protection claimed yes/no	Justification if data protection is claimed	Owner <sup>*)</sup>	Previous evaluation
KCA 7.2.1.2/03  (OECD Annex points: KIIA 2.9.2. and KIIA 7.6)	Lentz N. R., Bloomberg A. M.,	1999	<p>“Aqueous Photolysis of Thiadone (A Metabolite of FOE 5043).”;</p> <p>Ricerca Inc., Department of Environmental and Metabolic Fate, 7528 Auburn Road, Painesville, Ohio 44077, USA (performing laboratory) for Bayer Corporation, Agriculture Division, P. O. Box 4913, Kansas City, MO 64120, USA;</p> <p>Ricerca document No. 7410-98-0056-EF-001, study No. F3082402 (Bayer); Bayer Report No. 108720; 1</p> <p>9 August 1999;</p> <p>study reference number: M-017985-01-1;</p> <p>GLP: Yes;</p> <p>Unpublished study;</p>	No	Yes	Study originally requested by US EPA – so far not evaluated in EU	BCS	Study is submitted specifically for this evaluation.
KCA 7.2.1.3/02  (OECD Annex points: KIIA 2.9.2. and KIIA 7.6)	Stupp H.–P., Unold M.,	2011	<p>“[Thiadiazole-2-<sup>14</sup>C] BCS-AA41715 (FOE 5043-thiadone). Phototransformation in Natural Water.”;</p> <p>Bayer CropScience AG, Development, Environmental Safety, Metabolism /ADME and Environmental Fate, BCS-D-EnSDa-MeA/Efate, Alfred-Nobel-Str. 50, D-40789 Monheim am Rhein, Germany; study No. M 1121843-0, Report No. MEF-09/506;</p> <p>21. 03. 2011;</p> <p>study reference number: M404931-01-1;</p> <p>GLP: Yes;</p> <p>Unpublished study;</p>	No	Yes	Study originally requested by US EPA – so far not evaluated in EU	BCS	Study is submitted specifically for this evaluation.



Data point (OECD-format)	Author(s)	Year	Title  Company Report No.  Source (where different from company)  GLP or GEP status  Published or not	Vertebrate study	Data protection claimed yes/no	Justification if data protection is claimed	Owner <sup>*)</sup>	Previous evaluation
KCA 7.2.2.2/01  (OECD Annex point KIIA 7.8.1.)	Schocken M. J., Yen P. Y., Widmer S. L.,	1995	<p>"[Phenyl-U-<sup>14</sup>C]FOE 5043 – Determination of Aerobic Aquatic Biotransformation at 25°C.";</p> <p>Springborn Laboratories Inc., Environmental Sciences Division, 790 Main Street, Wareham, Massachusetts 02571-1075, USA (performing laboratory) for Bayer Corporation (formerly Miles Inc.), Agriculture Division, Research and Development Department, P. O. Box 4913, Kansas City, MO 64120, USA;</p> <p>Springborn Laboratories Report No. 95-4-5785; study No. F3042404 (Bayer); Bayer Report No. BR106961;</p> <p>27 December 1995;</p> <p>study reference number: M 002210-01-1;</p> <p>GLP: Yes;</p> <p>Unpublished study;</p>	No	Yes	Study originally conducted for PMRA – will be used as surrogate for OECD 309 to fulfil current EU data requirements. So far not yet evaluated in EU	BCS	Study is submitted specifically for this evaluation.
KCA 7.2.2.2/02  (OECD Annex point KIIA 7.8.1.)	Hein E. – M.,	2013	<p>"Evaluation of the Study: [Phenyl-U-<sup>14</sup>C] FOE 5043 – Determination of Aerobic Aquatic Biotransformation at 25°C.";</p> <p>Bayer CropScience AG, Environmental Fate, BCS AG – R&amp;D-D-EnSa-Efate, Alfred-Nobel-Str. 50, D-40789 Monheim, Germany;</p> <p>unpublished report No. EnSa-13-0268;</p> <p>03. 04. 2013;</p> <p>study reference number: M-450131-01-1;</p> <p>GLP: No, not applicable – position paper;</p> <p>Unpublished study;</p>	No	No	Not applicable	BCS	Study is submitted specifically for this evaluation.

Data point (OECD-format)	Author(s)	Year	Title  Company Report No.  Source (where different from company)  GLP or GEP status  Published or not	Vertebrate study	Data protection claimed yes/no	Justification if data protection is claimed	Owner <sup>*)</sup>	Previous evaluation
KCA 7.2.2.3/01  (OECD Annex point KIIA 7.8.3.)	Kelley I., Wood S., McKinney M.	1995	<p>“Degradability and Fate of [Phenyl-UL-<sup>14</sup>C]FOE 5043 in Two Sediment/Water Systems.”;</p> <p>Bayer Corporation (formerly Miles Inc), Agriculture Division, Research and Development Department, 17745 S. Metcalf, Stilwell, Kansas 66085, USA (performing laboratory) for Bayer Corporation, Agriculture Division, P. O. Box 4913, Kansas City, Missouri 64120, USA;</p> <p>unpublished study No. F3042405;</p> <p>Report No. MR106928;</p> <p>01 November 1995;</p> <p>study reference number: M002213-01-1;</p> <p>GLP: Yes;</p> <p>Unpublished study;</p>	No	Yes	<p>Justification not provided by the Applicant, however should apply the provisions of the of Article 59, § 1, subparagraph 7 of the Regulation (EC) 1107/2009, stating that “A study shall also be protected if it was necessary for renewal or review of authorisation.</p> <p>As this is a new study, should apply the rules set for the new/newly submitted studies.</p>	BCS	The study submitted for the purpose of the previous authorisation of flufenacet in the EU.

Data point (OECD-format)	Author(s)	Year	Title  Company Report No.  Source (where different from company)  GLP or GEP status  Published or not	Vertebrate study	Data protection claimed yes/no	Justification if data protection is claimed	Owner <sup>*)</sup>	Previous evaluation
KCA 7.2.2.3/02  (OECD Annex point KIIA 7.8.3.)	Halarnakar P. P., Irwin D. W.,	1997	<p>“Degradability and Fate of [Thiadiazole-2-<sup>14</sup>C]FOE 5043 in Two Water/Sediment Systems.”;</p> <p>Bayer Corporation, Agriculture Division, Environmental Research, 17745 S. Metcalf, Stilwell, Kansas 66085, USA (performing laboratory) for Bayer Corporation, Agriculture Division, Research and Development Department, P. O. Box 4913, Kansas City, Missouri 64120, USA;</p> <p>unpublished study No. F3042406;</p> <p>unpublished Report No. 107822;</p> <p>06 October 1997;</p> <p>study reference number: M004595-01-1;</p> <p>GLP: Yes;</p> <p>Unpublished study;</p>	No	Yes	<p>Justification not provided by the Applicant, however should apply the provisions of the of Article 59, § 1, subparagraph 7 of the Regulation (EC) 1107/2009, stating that “A study shall also be protected if it was necessary for renewal or review of authorisation.</p> <p>As this is a new study, should apply the rules set for the new/newly submitted studies.</p>	BCS	The study submitted for the purpose of the previous authorisation of flufenacet in the EU.

Data point (OECD-format)	Author(s)	Year	Title  Company Report No.  Source (where different from company)  GLP or GEP status  Published or not	Vertebrate study	Data protection claimed yes/no	Justification if data protection is claimed	Owner <sup>*)</sup>	Previous evaluation
KCA 7.2.2.3/03  (OECD Annex point KIIA 7.8.3.)	Reinken G., Maassen K.,	2014	<p>“Kinetic Evaluation of Degradation and Dissipation Behaviour of Flufenacet and its Degradation Products in Water/Sediment Systems According to FOCUS Kinetics Using the KinGUI 2 Tool. Flufenacet (FOE 5043); FOE Methylsulfide; FOE-thiadone.”;</p> <p>Bayer CropScience AG, Environmental Safety, Alfred-Nobel-Strasse 50, 40789 Monheim, Germany;</p> <p>unpublished Study report No. En-Sa-13-0973;</p> <p>17. 02. 2014;</p> <p>study reference number: M-477845-01-1.</p> <p>GLP: no, not applicable (modelling study);</p> <p>Unpublished study;</p>	No	Yes	New data/guideline requirement: Kinetic analysis of the degradation of flufenacet and its major degradation products FOE methylsulfide and FOE-thiadone for modelling purpose.	BCS	Study is submitted specifically for this evaluation.

Data point (OECD-format)	Author(s)	Year	Title  Company Report No.  Source (where different from company)  GLP or GEP status  Published or not	Vertebrate study	Data protection claimed yes/no	Justification if data protection is claimed	Owner <sup>*)</sup>	Previous evaluation
KCA 7.3.1/01  (OECD Annex IIA point 7.10)	Hellpointner E.,	1995	<p>"Determination of the Volatilisation Behavior of FOE 5043 (60WG) in a Field Trial.";</p> <p>Bayer AG, Crop Protection-Development, Institute for Metabolism Research and Residue Analysis, D-51368 Leverkusen, Germany (performing laboratory) for Bayer Corporation, Agriculture Division, P. O. Box 4913, Kansas City, MO 64120, USA;</p> <p>Bayer Report No. 107281 (PF-4091);</p> <p>12 September 1995;</p> <p>study reference number: M-002237-01-2.;</p> <p>GLP: Yes;</p> <p>Unpublished study;</p>	No	Yes	<p>Justification not provided by the Applicant, however should apply the provisions of the of Article 59, § 1, subparagraph 7 of the Regulation (EC) 1107/2009, stating that "A study shall also be protected if it was necessary for renewal or review of authorisation.</p> <p>As this is a new study, should apply the rules set for the new/newly submitted studies.</p>	BCS	The study submitted for the purpose of the previous authorisation of flufenacet in the EU.
IIA 7.3.1./02  (OECD Annex IIA point 7.10)	Hellpointner E.,	1995	<p>"Calculation of the Chemical Lifetime of Thiafluamide (FOE 5043) I the Troposphere.";</p> <p>Bayer AG, Crop Protection-Development, Institute for Metabolism Research and Residue Analysis, D-51368 Leverkusen, Germany;</p> <p>Report No. PF-4069 (HPO-123);</p> <p>07 July 1995;</p> <p>study reference number: M-002236-01-1;</p> <p>GLP: no, not applicable (modelling study);</p> <p>Unpublished study;</p>	No	Yes	<p>Justification not provided by the Applicant,</p>	BCS	The study submitted for the purpose of the previous authorisation of flufenacet in the EU.

Data point (OECD-format)	Author(s)	Year	Title  Company Report No.  Source (where different from company)  GLP or GEP status  Published or not	Vertebrate study	Data protection claimed yes/no	Justification if data protection is claimed	Owner*)	Previous evaluation
KCA 9;  (OECD Annex point not defined)	Derpmann J.,  Teubner L.,	2014	“Summary of the literature data for Flufenacet”;  Bayer Crop Science;  BCS report No. M-482180-01-1;  GLP: no, not required;  Unpublished Report;	No	Yes	Justification not provided by the Applicant,	BCS	Report submitted specifically for this evaluation, to meet the requirement set by the Article 8(5) of the EU Regulation 1107/2009

b) Open- source literature used in the evaluation:

Annex point/ reference number	Author(s)	Year	Title of publication;  Reference data (source's name, publication date)	Status of the publication	Submitted by:	Submitted – Original dossier (1 <sup>st</sup> inclusion) / Supplementary dossier (renewal of the inclusion)
KCA 7.1.1.1./07;	Bloomberg A. M., Shadrack B. A., Ellen A. L., Clay V. E.	2002	„Outdoor Soil Metabolism of [Phenyl-U- <sup>14</sup> C] Flufenacet on California Soils.”;  published in: <b>Phelps W. (ed.) “ACS Symposium Series, vol. 813: Pesticide Environmental Fate”, chapter 12, pp 167 – 182;</b> American Chemical Society, Washington, DC, 2002, publication date March 1, 2002;	Study considered as relevant and used to derive regulatory endpoints, because it enabled the identification and quantitation of the degradation products of Flufenacet, in particular FOE alcohol as major metabolite.	Listed by RMS, submitted by Applicant on the request by RMS	Submitted in the supplementary dossier (renewal of the inclusion).

Annex point/ reference number	Author(s)	Year	Title of publication; Reference data (source's name, publication date)	Status of the publication	Submitted by:	Submitted – Original dossier (1 <sup>st</sup> inclusion) / Supplementary dossier (renewal of the inclusion)
KCA 7.1.1.1./08;	Lam C. K., McKinney M. K., Clay V. E.,	2002	“Evaluation of Laboratory and Field Extraction Methods: Extraction of [Phenyl-U- <sup>14</sup> C] Flufenacet from Aged Soils.”;  published in: <b>Phelps W. (ed.) “ACS Symposium Series, vol. 813: Pesticide Environmental Fate”, chapter 11, pp 153 – 166;</b> American Chemical Society, Washington, DC, 2002, publication date March 1, 2002;	Supplementary study, not to be used to derive regulatory endpoints.	Listed by both Applicant and RMS, submitted by Applicant on the request by RMS	Submitted in the supplementary dossier (renewal of the inclusion).
KCA 7.1.2.1.1./26;  KCA 7.1.2.1.2;  KCA 7.1.3.1.1./05;  KCA 7.1.4.1./02	Gupta S., Gajbhiye V. T., Agnihotri N. P.	2001	“Adsorption-Desorption, Persistence, and Leaching Behaviour of Flufenacet in Alluvial Soil of India.”;  published in: <b>Bulletin of Environmental Contamination and Toxicology</b> , 2001, <b>66</b> (1), 9 – 16.	Supplementary study, not to be used to derive regulatory endpoints.	Listed by RMS,	No - the Applicant has not identified the paper as a potentially relevant, most probably because it was beyond the temporal limits set for the literature search (the paper was issued in 2001, a year before the Applicant’s search began).
KCA 7.1.2.1.1./27;  KCA 7.1.2.1.2;	Gupta S., Gajbhiye V. J.,	2002	“Effect of concentration, moisture and soil type on the dissipation of flufenacet from soil.”;  Published in: <b>Chemosphere</b> , 2002, <b>47</b> (9), 901 – 906.	Supplementary study, not to be used to derive regulatory endpoints.	Listed by both Applicant and RMS, submitted by Applicant on the request by RMS	Submitted in the supplementary dossier (renewal of the inclusion).
KCA 7.1.2.2.1./08;	Rouchaud J., Neus O., Cools K., Bulcke R.	1999	“Dissipation and mobility of the oxyacetamide flufenacet herbicide in corn and wheat crops.”;  Published in: <b>Mededlingen – Faculteit Landbouwkundige en Toegepaste Biologische Wetenschappen, Universiteit Gent</b> , 1999, <b>64</b> , (3b), 673 – 677.	Supplementary study, not to be used to derive regulatory endpoints.	Listed by RMS,	No - the Applicant has not identified the paper as a potentially relevant, most probably because it was beyond the temporal limits set for the literature search (the paper was issued in 1999, two years before the Applicant’s search began).

Annex point/ reference number	Author(s)	Year	Title of publication; Reference data (source's name, publication date)	Status of the publication	Submitted by:	Submitted – Original dossier (1 <sup>st</sup> inclusion) / Supplementary dossier (renewal of the inclusion)
KCA 7.1.2.2.1./09;	Rouchaud J., Neus O., Cools K., Bulcke R.	1999	“Flufenacet Soil Persistence and Mobility in Corn and Wheat Crops.”;  Published in: <b>The Bulletin of Environmental Contamination and Toxicology</b> , 1999, <b>63</b> , 460 – 466.	Supplementary study, not to be used to derive regulatory endpoints.	Listed by RMS,	No - the Applicant has not identified the paper as a potentially relevant, most probably because it was beyond the temporal limits set for the literature search (the paper was issued in 1999, two years before the Applicant's search began).
KCA 7.1.2.2.1./10;  KCA 7.1.3.1.1./07	Rouchaud J., Neus O., Eelen H., Bulcke R.	2001	“Persistence, Mobility and Adsorption of the Herbicide Flufenacet in the Soil of Winter Wheat Crops.”;  Published in: <b>“The Bulletin of Environmental Contamination and Toxicology”</b> , 2001, <b>67</b> , 609 – 616.	Supplementary study, not to be used to derive regulatory endpoints.	Listed by both Applicant and RMS, submitted by Applicant on the request by RMS	Submitted in the supplementary dossier (renewal of the inclusion).
KCA 7.1.3.1.1./06	Gajbhiye V. T., Gupta S.	2001	“Adsorption-desorption behaviour of flufenacet in five different soils of India.”;  Published in: <b>Pest Management Science</b> , 2001, <b>57</b> , 633 – 639.	Supplementary study, not to be used to derive regulatory endpoints.	Listed by RMS,	No - the Applicant has not identified the paper as a potentially relevant, most probably because it was beyond the temporal limits set for the literature search (the paper was issued in 2001, a year before the Applicant's search began).
KCA 7.1.4.1./03	Campagna G. Paci F., Fabbi A., Rapparini G.,	2006	“Studio in colonna della percolazione di alcuni diserbanti residuali del mais.” ( <i>title in English: “Percolation of acetochlor, dimethenamid, flufenacet and s-metolachlor applied in columns.”</i> );  Published in: <b>Giornate Fitopatologiche</b> , 2006, <b>I</b> , 591 – 598;	Supplementary study, not to be used to derive regulatory endpoints.	Listed by both Applicant and RMS, submitted by Applicant on the request by RMS	Submitted in the supplementary dossier (renewal of the inclusion).
KCA 7.2.1.1./04	Sunita Rani, Beena Kumari, TS Kathpal,	2006	“Effect of pH on the Dissipation Behaviour of Flufenacet (FOE- 5043) in Water.”;  Published in: <b>Pesticide Research Journal</b> , 2006, <b>18</b> (2), 201 – 204;	Supplementary study, not to be used to derive regulatory endpoints.	Listed by both Applicant and RMS, submitted by Applicant on the request by RMS	Submitted in the supplementary dossier (renewal of the inclusion).



Annex point/ reference number	Author(s)	Year	Title of publication; Reference data (source's name, publication date)	Status of the publication	Submitted by:	Submitted – Original dossier (1 <sup>st</sup> inclusion) / Supplementary dossier (renewal of the inclusion)
KCA 7.2.2.2.3./05	Ellis D. A., Hanson M. L., Sibley P. K., Shahid T., Fineberg N. A., Solomon K. R., Muir D. C. G., Mabury S. A.,	2001	“The fate and persistence of trifluoroacetic and chloroacetic acids in pond water.”;  published in: “ <b>Chemosphere</b> ”, 2001, <b>42</b> , 309-318.	Supplementary study, not to be used to derive regulatory endpoints.	Listed by RMS,	No - the Applicant has not identified the paper as a potentially relevant, most probably because it was beyond the temporal limits set for the literature search (the paper was issued in 2001, a year before the Applicant's search began).
KCA 7.2	Anon.	2013	“Final Report of Project WT1246- Understanding changes in pesticide usage to inform water company risk assessment.”; DEFRA 2013, available on-line: <a href="http://dwi.defra.gov.uk/research/completed-research/2000today.htm">http://dwi.defra.gov.uk/research/ completed- research/2000today.htm</a>	One of the key studies used in the evaluation of the impact on water treatment processes	Listed by RMS,	No - the Applicant has not identified the paper as a potentially relevant, most probably because it was beyond the temporal limits set for the literature search.
KCA 7.2	Dealtry S., Holmsgaard P. N, Dunon V., Jechalke S., Ding G-C. Krögerreckl enfort E., Heuer H., Hansen L. H., Springael D., Zühlke S., Sørensen S., Smalla K.,	2014	“Shifts in abundance and Diversity of Mobile Genetic Elements after the Introduction of Diverse Pesticides into an On- Farm Biopurification System over the Course of a Year.”; Published in: <b>Applied and Environmental Microbiology</b> , 2014, <b>80</b> (13), 4012 – 4020.	One of the key studies used in the evaluation of the impact on water treatment processes	Listed by RMS,	No - the Applicant has not identified the paper as a potentially relevant, most probably because it was beyond the temporal limits set for the literature search.
KCA 7.2	Hollender J., Zimmerman n S. G., Koepke S., Krauss M., McArdell C. S., Ort C., Singer H., von Gunten U., Siegrist H.,	2009	“Elimination of Organic Micropollutants in a Municipal Wastewater Treatment Plant Upgraded with a Full-Scale Post- Ozonation Followed by Sand Filtration.”;  Published in: <b>Environmental Science and Technology</b> , 2009, <b>43</b> (20), 7862 – 7869.	One of the key studies used in the evaluation of the impact on water treatment processes	Listed by RMS,	No - the Applicant has not identified the paper as a potentially relevant.

Annex point/ reference number	Author(s)	Year	Title of publication; Reference data (source's name, publication date)	Status of the publication	Submitted by:	Submitted – Original dossier (1 <sup>st</sup> inclusion) / Supplementary dossier (renewal of the inclusion)
KCA 7.2	Sakkas V. A., Calza P., Vlachou A. D., Medana C., Minero C., Albanis T.,	2011	“Photocatalytic transformation of flufenacet over TiO <sub>2</sub> aqueous suspension: Identification of intermediates and the mechanisms involved.”;  Published in: <b>Applied Catalysis B: Environmental</b> , 2011, <b>110</b> , 238 – 250;	One of the key studies used in the evaluation of the impact on water treatment processes	Listed by both Applicant and RMS, submitted by Applicant on the request by RMS	Submitted in the supplementary dossier (renewal of the inclusion).
KCA 7.2	Sinclair C., van Beinum W., Adams C., Bevan R., Levy L., Parsons S., Goslan E., Baumann G.,	2010	“A Desk Study on Pesticide Metabolites, Degradation and Reaction Products to Inform the Inspectorate’s Position on Monitoring Requirements. Final Report for Drinking Water Inspectorate.”;  The Food and Environment Research Agency (FERA), Sand Hutton, York, UK, FERA Project S3VB, DEFRA Project WT1221, DWI Project 70/2/232, Februray 2010, report available on-line on DEFRA web-site.	One of the key studies used in the evaluation of the impact on water treatment processes	Listed by RMS,	No - the Applicant has not identified the paper as a potentially relevant.
KCA 7.2	Sinclair C. J., Boxall A. B. A., Parsons S. A., Thomas M. R.,	2006	“Prioritization of Pesticide Environmental Transformation Products in Drinking Water Supplies.”;  Published in: <b>Environmental Science and Technology</b> , 2006, <b>40</b> (23), 7283 – 7289;	One of the key studies used in the evaluation of the impact on water treatment processes	Listed by RMS,	No - the Applicant has not identified the paper as a potentially relevant.
KCA 7.2	Verstraeten I. M., Thurman E. M., Lindsey M. E., Lee E. C., Smith R. D.,	2002	“Changes in concentrations of traizine and acetamide herbicides by bank filtration, ozonation and chlorination in a public water supply.”;  Published in: <b>Journal of Hydrology</b> , 2002, <b>266</b> , 190 – 208	One of the key studies used in the evaluation of the impact on water treatment processes	Listed by RMS,	No - the Applicant has not identified the paper as a potentially relevant.
KCA 7.2	Bond T., Tempelton M. R., Graham N.	2012	“Precursors of nitrogenous disinfection byproducts in drinking water – A Critical review and analysis.”;  Published in: <b>Journal of Hazardous Materials</b> , 2012, <b>235- 236</b> , 1 – 16.	Supplementary study used in the evaluation of the impact on water treatment processes	Listed by RMS,	No - the Applicant has not identified the paper as a potentially relevant.

Annex point/ reference number	Author(s)	Year	Title of publication; Reference data (source's name, publication date)	Status of the publication	Submitted by:	Submitted – Original dossier (1 <sup>st</sup> inclusion) / Supplementary dossier (renewal of the inclusion)
KCA 7.2	Anon.	----	“Report on Carcinogens, Thirteen Edition; <i>N</i> - Nitrosamines: 15 Listing.”;  NIH National Toxicology Program, Department of Health and Human Services; document available on-line on: <a href="http://ntp.niehs.nih.gov/go/roc13">http://ntp.niehs.nih.gov/go/roc13</a>	Supplementary study used in the evaluation of the impact on water treatment processes	Listed by RMS,	No - the Applicant has not identified the paper as a potentially relevant.
KCA 7.2	Anon.	----	Toxicological data sheet for TFA published on TOXNET – Toxicology Data Network, site of US NIH National Library of Medicine; available on-line at <a href="http://toxnet.nlm.nih.gov/index.html">http://toxnet.nlm.nih.gov/index.html</a> as a record CASRN: 76-05-1;	Supplementary study used in the evaluation of the impact on water treatment processes	Listed by RMS,	No - the Applicant has not identified the paper as a potentially relevant.
KCA 7.2	Boorman G. A., Dellarco V., Dunnick J. K., Chapin R. E., Hunter S., Hauchman F., Gardner H., Cox M., Sills R. C.,	1999	“Drinking Water Disinfection Byproducts: Review and Approach to Toxicity Evaluation.”;  Published in: <b>Environmental Health Perspectives</b> , 1999, <b>107 Supplement 1</b> , 207 – 217;	Supplementary study used in the evaluation of the impact on water treatment processes	Listed by RMS,	No - the Applicant has not identified the paper as a potentially relevant.
KCA 7.2	Kim J., Clevenger T. E.,	2007	“Prediction of <i>N</i> - nitrosodimethylamine (NDMA) formation as a disinfection by- product.”;  Published in: <b>Journal of Hazardous Materials</b> , 20007, <b>145</b> , 270 – 276;	Supplementary study used in the evaluation of the impact on water treatment processes	Listed by RMS,	No - the Applicant has not identified the paper as a potentially relevant.
KCA 7.2	Krasner S. W., Mitch W. A., McCurry D. L., Hanigan D., Westerhoff P.,	2013	“Formation, precursors, control and occurrence of nitrosoamines in drinking water: a review.”;  Published in: <b>Water Research</b> , 2013, <b>47</b> , 4433 – 4450;	Supplementary study used in the evaluation of the impact on water treatment processes	Listed by RMS,	No - the Applicant has not identified the paper as a potentially relevant.
KCA 7.2	Le Roux J., Gallard H., Croué J.-P.,	2011	“Chloramination of nitrogenous contaminants (pharmaceuticals and pesticides): NDMA and halogenated DBPs formation.”;  Published in: <b>Water Research</b> , 2011, <b>45</b> , 3164 – 3174;	Supplementary study used in the evaluation of the impact on water treatment processes	Listed by RMS,	No - the Applicant has not identified the paper as a potentially relevant.

Annex point/ reference number	Author(s)	Year	Title of publication; Reference data (source's name, publication date)	Status of the publication	Submitted by:	Submitted – Original dossier (1 <sup>st</sup> inclusion) / Supplementary dossier (renewal of the inclusion)
KCA 7.2	Manoj A. Lazar, Shaji Varghese, Santosh S. Nair	2012	“Photocatalytic Water Treatment by Titanium Dioxide: Recent Updates.”;  Published in: <b>Catalyst</b> , 2012, <b>2</b> , 572 – 601	Supplementary study used in the evaluation of the impact on water treatment processes	Listed by RMS,	No - the Applicant has not identified the paper as a potentially relevant.
KCA 7.2	Mitch W. A., Sedlak D. L.,	2002	“Factors controlling nitrosamine formation during wastewater chlorination.”;  Published in: <b>Water Science and Technology: Water Supply</b> , 2002, <b>2</b> (3), 191 – 198;	Supplementary study used in the evaluation of the impact on water treatment processes	Listed by RMS,	No - the Applicant has not identified the paper as a potentially relevant.
KCA 7.2	Nawrocki J., Andrzejew- ski P.,	2011	“Nitrosoamines and water.”;  Published in: <b>Journal of Hazardous Materials</b> , 2011, <b>189</b> , 1 – 18;	Supplementary study used in the evaluation of the impact on water treatment processes	Listed by RMS,	No - the Applicant has not identified the paper as a potentially relevant.
KCA 7.2	Richardson S. D., Postigo C.,	2012	“Drinking Water Disinfection By- products”;  Published in <i>Barcelo D. (ed.) “Emerging Organic Contaminants and Human Health”, “Handbook of Environmental Chemistry”</i> , 2012, Springer Verlag, 93 – 138;	Supplementary study used in the evaluation of the impact on water treatment processes	Listed by RMS,	No - the Applicant has not identified the paper as a potentially relevant.
KCA 7.2	Rostkowska K., Zwierz K., Róžański A., Moniuszko- Jakoniuk J., Roszczenko A.,	1998	“Formation and Metabolism of N-Nitrosamines.”;  Published in: <b>Polish Journal of Environmental Studies</b> , 1998, <b>7</b> (6), 321 – 325;	Supplementary study used in the evaluation of the impact on water treatment processes	Listed by RMS,	No - the Applicant has not identified the paper as a potentially relevant.
KCA 7.3.1.	Hurley M. D., Sulbaek Andersen, M. P., Wallington T. J., Ellis D. A., Martin J. W., Mabury S. A.,	2004	“Atmospheric Chemistry of Perfluorinated Carboxylic Acids: Reaction with OH Radicals and Atmospheric Lifetimes.”;  Published in: <b>Journal of Physical Chemistry, A</b> , 2004, 108 (4), 615 – 620.	Supplementary study, not to be used to derive regulatory endpoints.	Listed by both Applicant and RMS, submitted by Applicant on the request by RMS	Submitted in the supplementary dossier (renewal of the inclusion).

Annex point/ reference number	Author(s)	Year	Title of publication; Reference data (source's name, publication date)	Status of the publication	Submitted by:	Submitted – Original dossier (1 <sup>st</sup> inclusion) / Supplementary dossier (renewal of the inclusion)
KCA 7.3.1.	Oeberg. T.	2005	“A QSAR for the hydroxyl radical reaction rate constant: validation, domain of application, and prediction.”;  Published in: <b>Atmospheric Environment</b> , 2005, 39 (12), 2189 – 2200.	Supplementary study, not to be used to derive regulatory endpoints.	Listed by both Applicant and RMS, submitted by Applicant on the request by RMS	Submitted in the supplementary dossier (renewal of the inclusion).
KCA 7.3.1.	Kutsuna S., Hori H.,	2008	“Experimental determination of Henry's law constants of trifluoroacetic acid at 278-298 K.”;  Published in: <b>Atmospheric Environment</b> , 2008, 42 (7), 1399 – 1412.	Supplementary study, not to be used to derive regulatory endpoints.	Listed by both Applicant and RMS, submitted by Applicant on the request by RMS	Submitted in the supplementary dossier (renewal of the inclusion).
KCA 7.3.1.	Bowden D. J., Clegg S. L., Brimblecombe P.	1996	“The Henry's law constant of Trifluoroacetic acid and its partitioning into liquid water in the atmosphere.”;  Published in: <b>Chemosphere</b> , 1996, 32 (2), 405 – 420;	Supplementary study, not to be used to derive regulatory endpoints.	Listed by RMS,	No - the Applicant has not identified the paper as a potentially relevant, most probably because it was beyond the temporal limits set for the literature search.
KCA 7.3.2.; KCA 7.5;	Capel P. D., McCarthy K. A., Barbash J. E.,	2008	“National, Holistic, Watershed-Scale Approach to Understand the Sources, Transport, and Fate of Agricultural Chemicals.”;  Published in: <b>Journal of Environmental Quality</b> , 2008, 37, 983 – 993.	Supplementary study, not to be used to derive regulatory endpoints.	Listed by RMS,	No - the Applicant has not identified the paper as a potentially relevant.
KCA 7.3.2.; KCA 7.5;	Vogel J. R., Majewski M. S., Capel P. D.,	2008	“Pesticides in Rain in Four Agricultural Watersheds in the United States.”;  Published in: <b>Journal of Environmental Quality</b> , 2008, 37, 1101 – 1115.	Supplementary study, not to be used to derive regulatory endpoints.	Listed by RMS,	No - the Applicant has not identified the paper as a potentially relevant.
KCA 7.3.2.; KCA 7.5;	Henne, S.; Shallcross, D. E.; Reimann, S.; Xiao, P.; Boulos, S.; Gerecke, A. C.; Brunner, D.	2012	“Environmental impacts of HFO-1234yf and other HFOs.”;  Published in : <b>Moving Towards Sustainability, ASHRAE/NIST Refrigerants Conference, Gaithersburg, MD, United States, Oct. 29-30, 2012</b> (2012), 13/1-13/13.	Supplementary study, not to be used to derive regulatory endpoints.	Listed by both Applicant and RMS, submitted by Applicant on the request by RMS	Submitted in the supplementary dossier (renewal of the inclusion).

Annex point/ reference number	Author(s)	Year	Title of publication; Reference data (source's name, publication date)	Status of the publication	Submitted by:	Submitted – Original dossier (1 <sup>st</sup> inclusion) / Supplementary dossier (renewal of the inclusion)
KCA 7.3.2.; KCA 7.5;	Jordan A., Frank H.,	1999	“Trifluoroacetate in the Environment. Evidence for Sources Other Than HFC/HCFCs.”;  Published in: <b>Environmental Science and Technology</b> , 1999, 33 (4), 522 – 527;	Supplementary study, not to be used to derive regulatory endpoints.	Listed by RMS,	No - the Applicant has not identified the paper as a potentially relevant.
KCA 7.3.2.;	Wilson S. R., Solomon K. R., Tang X.,	2007	“Changes in tropospheric composition and air quality due to stratospheric ozone depletion and climate change.”;  Published in: <b>Photochemical and Photobiological Sciences</b> , 2007, 6 (3), 301 – 310.	Supplementary study, not to be used to derive regulatory endpoints.	Listed by both Applicant and RMS, submitted by Applicant on the request by RMS	Submitted in the supplementary dossier (renewal of the inclusion).
KCA 7.5.;	Baker N. T., Stone W. S.,	2015	“Estimated Annual Agricultural Pesticide Use for Counties of the Conterminous United States, 2008 – 12.”;  <b>US Geological Survey Data Series 907</b> , 2015.	Supplementary study, not to be used to derive regulatory endpoints.	Listed by RMS,	No - the Applicant has not identified the paper as a potentially relevant.
KCA 7.5.;	Battaglin W. A., Kolpin D. A., Scribner E. A., Kuivila K. M., Sandstrom M. W.,	2005	“Glyphosate, other herbicides, and transformation products in Midwestern streams, 2002.”;  Published in: <b>JAWRA Journal of the American Water Resources Association</b> , 2005, 41 (2), 323 – 332.	Supplementary study, not to be used to derive regulatory endpoints.	Listed by RMS,	No - the Applicant has not identified the paper as a potentially relevant.
KCA 7.5.;	Berg M., Müller S. R., Mühlemann J., Wiedmer A., Schwarzenbach R. P.,	2000	“Concentrations and Mass Fluxes of Chloroacetic acids and Trifluoroacetic acid in Rain and Natural Waters in Switzerland.”;  Published in: <b>Environmental Science and Technology</b> , 2000, 34 (13), 2675 – 2683;	Supplementary study, not to be used to derive regulatory endpoints.	Listed by RMS,	No - the Applicant has not identified the paper as a potentially relevant.
KCA 7.5.;	Bischoff G., Pestmer W., Rodemann B.;	2003	“Entry of pesticides into surface waters – new results of Lamprunge run-off monitoring project 1999 – 2001.”;  Published in: <b>Pesticide in Air, Plant, Soil and Water System, Proceedings of the Symposium Pesticide Chemistry, 12<sup>th</sup>, Piacenza, Italy</b> , 2003, pp. 849 – 856.	Supplementary study, not to be used to derive regulatory endpoints.	Listed by the Applicant,	Submitted in the supplementary dossier (renewal of the inclusion).

Annex point/ reference number	Author(s)	Year	Title of publication; Reference data (source's name, publication date)	Status of the publication	Submitted by:	Submitted – Original dossier (1 <sup>st</sup> inclusion) / Supplementary dossier (renewal of the inclusion)
KCA 7.5.;	Durham L., Fisk A., Kannan K, Macdonald R. W, Muir D. C. G., Scott B. F., Spencer C., Witter A., Yamashita N.,	2005	“Trifluoroacetate profiles in the Arctic, Atlantic, and Pacific Oceans.”;  Published in: <b>Environmental Science and Technology</b> , 2005, 39 (17), 6555 – 6560.	Supplementary study, not to be used to derive regulatory endpoints.	Listed by the Applicant,	Submitted in the supplementary dossier (renewal of the inclusion).
KCA 7.5.;	Frank H., Christoph E. H., Holm- Hansen O., Bullister J. L.,	2002	“Trifluoroacetate in Ocean Waters.”;  Published in: <b>Environmental Science and Technology</b> , 2002, 36 (1), 12 – 15.	Supplementary study, not to be used to derive regulatory endpoints.	Listed by the Applicant,	Submitted in the supplementary dossier (renewal of the inclusion).
KCA 7.5.;	Kern S., Singer H., Hollender J., Schwarzen- bach R. P., Fenner K.,	2011	“Assessing Exposure to Transformation Products of Soil- Applied Organic Contaminants in Surface Water: Comparison of Model Predictions and Field Data.”;  Published in: <b>Environmental Science and Technology</b> , 2011, 45 (7), 2833 – 2841.	Supplementary study, not to be used to derive regulatory endpoints.	Listed by both Applicant and RMS, submitted by Applicant on the request by RMS	Submitted in the supplementary dossier (renewal of the inclusion).
KCA 7.5.;	Kolpin D. W., Schnoebele n D. J., Thurman M. E.,	2004	“Degradates Provide Insight to Spatial and Temporal Trends of Herbicides in Ground Water.”;  Published in: <b>Groundwater</b> , 2004, 42 (4), 601 – 608.	Supplementary study, not to be used to derive regulatory endpoints.	Listed by RMS,	No - the Applicant has not identified the paper as a potentially relevant.
KCA 7.5.;	Kowal S. Balsaa P., Werres F., Schmidt T. C.,	2013	“Fully automated standard addition method for the quantification of 29 polar pesticide metabolites in different water bodies using LC-MS/MS.”;  Published in: <b>Analytical and Bioanalytical Chemistry</b> , 2013, 405, 6337 – 6351.	Supplementary study, not to be used to derive regulatory endpoints.	Listed by RMS,	No - the Applicant has not identified the paper as a potentially relevant, probably because it was beyond the temporal limits of the literature search.
KCA 7.5.;	Mills P. C., Kolpin D. W., Scribner E. A., Thurman E. M.,	2005	“Herbicides and degradates in shallow aquifers of Illinois: spatial and temporal trends.”;  Published in: <b>JAWRA Journal of the American Water Resources Association</b> , 2005, 41 (3), 537 – 547.	Supplementary study, not to be used to derive regulatory endpoints.	Listed by RMS,	No - the Applicant has not identified the paper as a potentially relevant.

Annex point/ reference number	Author(s)	Year	Title of publication; Reference data (source's name, publication date)	Status of the publication	Submitted by:	Submitted – Original dossier (1 <sup>st</sup> inclusion) / Supplementary dossier (renewal of the inclusion)
KCA 7.5.;	Moschet C., Götz C., Longrée P., Hollender J., Singer H.,	2013	“Multi-Level Approach for the Integrated Assessment of Polar Organic Micropollutants in an International Lake Catchment: The Example of Lake Constance.”;  Published in: <b>Environmental Science and Technology</b> , 2013, 47 (13), 7028 – 7036.	Supplementary study, not to be used to derive regulatory endpoints.	Listed by RMS,	No - the Applicant has not identified the paper as a potentially relevant, probably because it was beyond the temporal limits of the literature search.
KCA 7.5.;	Moschet C., Wittmer I., Simovic J., Junghans M., Piazzoli A., Singer H., Stamm C., Leu C. Hollender J.,	2014	“How a Complete Pesticide Screening Changes the Assessment of Surface Water Quality.”;  Published in: <b>Environmental Science and Technology</b> , 2014, 48 (10), 5423 – 5432.	Supplementary study, not to be used to derive regulatory endpoints.	Listed by RMS,	No - the Applicant has not identified the paper as a potentially relevant, probably because it was beyond the temporal limits of the literature search.
KCA 7.5.;	Moschet C., Vermeirsser E. L. M, Singer H., Stamm C., Hollender J.,	2015	“Evaluation of in-situ calibration of Chemcatcher passive samplers for 322 micropollutants in agricultural and urban affected rivers.”;  Published in: <b>Water Research</b> , 2015, 71, 306 – 317.	Supplementary study, not to be used to derive regulatory endpoints.	Listed by RMS,	No - the Applicant has not identified the paper as a potentially relevant, probably because it was beyond the temporal limits of the literature search.
KCA 7.5.;	Rebich R. A., Coupe R. H, Thurman E. M.,	2004	“Herbicide concentrations in the Mississippi River Basin – the importance of chloroacetanilide herbicide degradates.”;  Published in: <b>Science of the Total Environment</b> , 2004, 321 (1-3), 189 – 199.	Supplementary study, not to be used to derive regulatory endpoints.	Listed by RMS,	No - the Applicant has not identified the paper as a potentially relevant.
KCA 7.5.;	Scott B. F., MacTavish D., Spencer C., Strachan W. M. J., Muir D. C.,	2000	“Haloacetic Acids in Canadian Lake Waters and Precipitation.”;  Published in: <b>Environmental Science and Technology</b> , 2000, 34 (20), 1266 – 4272.	Supplementary study, not to be used to derive regulatory endpoints.	Listed by RMS,	No - the Applicant has not identified the paper as a potentially relevant.
KCA 7.5.;	Scribner E. A., Battaglin W. A., Dieze J. E., Thurman E. M.,	2003	“Reconnaissance Data for Glyphosate, Other Selected Herbicides, Their Degradation Products, and Antibiotics in 51 Streams in Nine Mid-Western States 2002.”;  <b>US Geological Survey Open-File Report 03-217</b> , 2003.	Supplementary study, not to be used to derive regulatory endpoints.	Listed by RMS,	No - the Applicant has not identified the paper as a potentially relevant.



Annex point/ reference number	Author(s)	Year	Title of publication; Reference data (source's name, publication date)	Status of the publication	Submitted by:	Submitted – Original dossier (1 <sup>st</sup> inclusion) / Supplementary dossier (renewal of the inclusion)
KCA 7.5.;	Wujcik C., Cahill T. M., Seiber J. N.,	1999	“Determination of Trifluoroacetic Acid in 1996 – 1997 Precipitation and Surface Waters in California and Nevada.”;  Published in: <b>Environmental Science and Technology</b> , 1999, 33 (10), 1747 – 1751.	Supplementary study, not to be used to derive regulatory endpoints.	Listed by RMS,	No - the Applicant has not identified the paper as a potentially relevant.
KCA 7.5.;	Zimmerman L. R., Schneider R. J., Thurman E. M.,	2002	“Analysis and Detection of the Herbicides Dimethenamid and Flufenacet and Their Sulfonic and Oxalinic Acid Degradates in Natural Degradates in Natural Water.”;  Published in: <b>Journal of Agricultural and Food Chemistry</b> , 2002, 50 (5), 1045 – 1052.	Supplementary study, not to be used to derive regulatory endpoints.	Listed by RMS,	No - the Applicant has not identified the paper as a potentially relevant.

### Formulation:

a) studies submitted by the Notifier:

Data point (OECD- format)	Author(s)	Year	Title  Company Report No.  Source (where different from company)  GLP or GEP status  Published or not	Vertebrate study	Data protection claimed yes/no	Justification if data protection is claimed	Owner*)	Previous evaluation
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Data point (OECD-format)	Author(s)	Year	Title  Company Report No.  Source (where different from company)  GLP or GEP status  Published or not	Vertebrate study	Data protection claimed yes/no	Justification if data protection is claimed	Owner <sup>*)</sup>	Previous evaluation
KCA 7.1.2.1.1./21;  KCP 9.1.3.	Reinken G. Porschewski R.,	2014g	<p>"Flufenacet Core PECsoil and Accumulation: Modelling Core Info Document for Soil Exposure Assessment in Europe."; Bayer CropScienceAG, Environmental Safety, Alfred-Nobel-Straße 50, 40789 Monheim, Germany, unpublished Report No. EnSa-13-1007; 2014. 02. 25.;</p> <p>Study reference number: M-478418-01-1;</p> <p>GLP: no, not applicable (modelling study);</p> <p>Unpublished study;</p>	No	Yes	<p>Justification not provided by the Applicant, however should apply the provisions of the of Article 59, § 1, subparagraph 7 of the Regulation (EC) 1107/2009, stating that "A study shall also be protected if it was necessary for renewal or review of authorisation.</p> <p>As this is a new study, should apply the rules set for the new/newly submitted studies.</p>	BCS	Study is submitted specifically for this evaluation.

Data point (OECD-format)	Author(s)	Year	Title  Company Report No.  Source (where different from company)  GLP or GEP status  Published or not	Vertebrate study	Data protection claimed yes/no	Justification if data protection is claimed	Owner <sup>*)</sup>	Previous evaluation
KCA 7.1.2.1.1./22; KCP 9.2.4.1.	Reinken G. Porschewski R.,	2014h	<p>"Flufenacet Core PECgw FOCUS EU: Modelling Core Info Document for Groundwater Risk Assessment in Europe.";</p> <p>Bayer CropScienceAG, Environmental Safety, Alfred-Nobel-Straße 50, 40789 Monheim, Germany, unpublished Report No. EnSa-13-1006;</p> <p>2014. 02. 25.;</p> <p>Study reference number: M-478214-01-1;</p> <p>GLP: no, not applicable (modelling study);</p> <p>Unpublished study;</p>	No	Yes	<p>Justification not provided by the Applicant, however should apply the provisions of the of Article 59, § 1, subparagraph 7 of the Regulation (EC) 1107/2009, stating that "A study shall also be protected if it was necessary for renewal or review of authorisation.</p> <p>As this is a new study, should apply the rules set for the new/newly submitted studies.</p>	BCS	Study is submitted specifically for this evaluation.

Data point (OECD-format)	Author(s)	Year	Title  Company Report No.  Source (where different from company)  GLP or GEP status  Published or not	Vertebrate study	Data protection claimed yes/no	Justification if data protection is claimed	Owner <sup>*)</sup>	Previous evaluation
KCP 9.2.5.	Reinken G. Porschewski R.,	2014h	<p>"Flufenacet Core PECsw FOCUS EU: Modelling Core Info Document for Standard FOCUS STEP 1-2 and STEP 3-4 Surface Water Exposure Assessment in Europe.";</p> <p>Bayer CropScience AG, Environmental Safety, Alfred-Nobel-Strasse 50, 40789 Monheim, Germany;</p> <p>Study Report No. EnSa-13-1008;</p> <p>25. 02. 2014;</p> <p>study reference number: M478438-01-1;</p> <p>GLP: no, not applicable (modelling study);</p> <p>Unpublished study;</p>	No	Yes	<p>Justification not provided by the Applicant, however should apply the provisions of the of Article 59, § 1, subparagraph 7 of the Regulation (EC) 1107/2009, stating that "A study shall also be protected if it was necessary for renewal or review of authorisation.</p> <p>As this is a new study, should apply the rules set for the new/newly submitted studies.</p>	BCS	Study is submitted specifically for this evaluation.
KCA 9; KCP 11	Derpmann J., Teubner L.,	2014	<p>"Summary of the literature data for Flufenacet";</p> <p>Bayer Crop Science;</p> <p>BCS report No. M-482180-01-1;</p> <p>GLP: no, not required;</p> <p>Unpublished Report;</p>	No	Yes	Justification not provided by the Applicant,	BCS	Report submitted specifically for this evaluation, to meet the requirement set by the Article 8(5) of the EU Regulation 1107/2009

b) Open- source literature used in the evaluation:

None identified.

## A.9. ECOTOXICOLOGY

Active substance:

Annex point / reference number	Author(s)	Year	Title Source (where different from company) Company name, Report No., Date, GLP status (where relevant), published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previous evaluation
KCA 8.1.1 /01	Jans, D.	2010	Determination of residues of Flufenacet SC 500 g/L in <i>Poecilus cupreus</i> L. (Coleoptera, Carabidae) in an extended laboratory test  Bayer CropScience, Report No.: CW09/028,  Edition Number: <u>M-368306-01-1</u>  Date: 2010-05-05  GLP/GEP: yes, unpublished	N	Y	Information needed for risk assessment	Bayer Crop Science	New study submitted for renewal of a.s.
KCA 8.1.1 /02	Noss, G.; Diehl, P.	2012	Determination of the residues of flufenacet in/on winter barley and winter wheat after spray application of flufenacet & diflufenican SC 600 in Germany, the Netherlands and Belgium  Bayer CropScience, Report No.: 11-2950, Report includes Trial Nos.:  11-2950-01 11-2950-02 11-2950-03 11-2950-04  Edition Number: <u>M-443138-01-1</u>  Date: 2012-12-03  GLP/GEP: yes, unpublished	N	Y	Data basis for calculation of DT <sub>50</sub> (for M-451178-01-1)	Bayer Crop Science	New study submitted for renewal of a.s.

KCA 8.1.1 /03	Scherr, F.; Ellerich, C.	2013	Statement on residue dissipation of flufenacet in treated foliage of monocotyledonous plants: kinetic evaluation - Flufenacet (FOE 5043)  Bayer CropScience,  Report No.: EnSa-13-0197,  Edition Number: <u>M-451178-01-1</u>  Date: 2013-04-05  GLP/GEP: no, unpublished	N	Y	Kinetic evaluation to derive DT <sub>50</sub> as refinement for bird and mammals RA	Bayer CropScience	New study submitted for renewal of a.s.
KCA 8.1.1.1 /01	■■■■■ ■	1992	Technical FOE 5043: An acute oral LD50 with bobwhite quail  ■■■■■ ■■■■■  ■■■■■,  Report No.: 102642,  Edition Number: <u>M-003866-01-1</u>  EPA MRID No.: 43441113  Date: 1992-05-12  GLP/GEP: yes, unpublished	Y	Y		Bayer CropScience	The study was evaluated in the DAR (1997)
KCA 8.1.1.1 /02	■■■■■ ■■■■■ ■■■■■	1997	FOE 5043 technical: An acute oral LD50 with mallards  ■■■■■ ■■■■■  ■■■■■  Report No.: 107700,  Edition Number: <u>M-003851-01-1</u>  EPA MRID No.: 44246801  Date: 1997-03-11  GLP/GEP: yes, unpublished	Y	Y	Study needed for risk assessment	Bayer CropScience	New study submitted for renewal of a.s.

KCA 8.1.1.1 /03		2013	<p>Toxicity of flufenacet technical during an acute oral LD50 with the canary (<i>Serinus canaria</i>)</p> <p>Report No.: 07SRLS13C5, Edition Number: <u>M-468210-01-1</u> EPA MRID No.: 49244202 Date: 2013-10-25 GLP/GEP: yes, unpublished</p>	Y	Y	Study required by US EPA on passerine bird. Reveals lowest acute bird endpoint.	Bayer CropScience	New study submitted for renewal of a.s.
KCA 8.1.1.2 /01		1993	<p>FOE 5043 technical: A subacute dietary LC50 with mallard duck</p> <p>Report No.: 103814, Edition Number: <u>M-003864-01-1</u> EPA MRID No.: 43441115 Date: 1993-03-30 GLP/GEP: yes, unpublished</p>	Y	Y		Bayer CropScience	The study was evaluated in the DAR (1997)
KCA 8.1.1.2 /02		1994	<p>FOE 5043 technical: A subacute dietary LC50 with northern bobwhite</p> <p>Report No.: 106583, Edition Number: <u>M-003859-01-1</u> EPA MRID No.: 43441114 Date: 1994-06-08 GLP/GEP: yes, unpublished</p>	Y	Y		Bayer CropScience	The study was evaluated in the DAR (1997)

KCA 8.1.1.3 /01	[REDACTED]	1994	Effect of technical FOE 5043 on mallard reproduction [REDACTED] [REDACTED], Report No.: 106594, Edition Number: <u>M-003858-01-1</u> EPA MRID No.: 43441120 Date: 1994-07-08 GLP/GEP: yes, unpublished	Y	Y		Bayer CropScience	The study was evaluated in the DAR (1997)
KCA 8.1.1.3 /02	[REDACTED]	1994	Effects of a subchronic dietary exposure of FOE 5043 techn. on bobwhite quail including effects on reproduction and health [REDACTED] [REDACTED], Report No.: SXR/REP 03, Edition Number: <u>M-003861-01-1</u> EPA MRID No.: 43441119 Date: 1994-04-30 GLP/GEP: yes, unpublished	Y	Y		Bayer CropScience	The study was evaluated in the DAR (1997)
KCA 8.1.2.2 /01	Diesing, L.	2014	Flufenacet -Toxicity endpoint for the wild mammal reproductive risk assessment Bayer CropScience, Report No.: <u>M-476600-01-1</u> , Edition Number: <u>M-476600-01-1</u> Date: 2014-02-12 GLP/GEP: n.a., unpublished	N	N		Bayer CropScience	-
KCA 8.1.2.2 /02	Diesing, L.	2014	Trifluoroacetate (TFA) - Toxicity endpoints for terrestrial vertebrate risk assessments Bayer CropScience, Report No.: <u>M-477154-01-1</u> , Edition Number: <u>M-477154-01-1</u> Date: 2014-02-18 GLP/GEP: n.a., unpublished	N	N		Bayer CropScience	-



KCA 8.2.1 /01	■■■■■ ■■■■■ ■	1995	Acute Toxicity of FOE 5043 technical to the rainbow trout ( <i>Oncorhynchus mykiss</i> ) under static-renewal conditions  ■■■■■■■■■■■■■■■■■■■■ ■■■■■■■■■■■■■■■■■■■■  ■■■■■■■■■■■■■■■■■■■■, Report No.: 106673, Edition Number: <u>M-002379-01-1</u> EPA MRID No.: 43850007 Date: 1995-01-18 GLP/GEP: yes, unpublished	Y	Y		Bayer CropScience	The study was evaluated in the DAR (1997)
KCA 8.2.1 /02	■■■■■ ■■	1995	Acute toxicity of FOE 5043 technical to the bluegill ( <i>Lepomis macrochirus</i> ) under static-renewal conditions  ■■■■■■■■■■■■■■■■■■■■ ■■■■■■■■■■■■■■■■■■■■  ■■■■■■■■■■■■■■■■■■■■, Report No.: 106674, Edition Number: <u>M-002378-01-1</u> EPA MRID No.: 43595501 Date: 1995-01-20 GLP/GEP: yes, unpublished	Y	Y		Bayer CropScience	The study was evaluated in the DAR (1997)
KCA 8.2.1 /03	■■■■■ ■■	1995	FOE 5043 Sulfonic acid - Acute toxicity (96 hours) to rainbow trout ( <i>Oncorhynchus mykiss</i> ) in a static test  ■■■■■■■■■■■■■■■■■■■■ ■■■■■■■■■■■■■■■■■■■■  ■■■■■■■■■■■■■■■■■■■■, Report No.: DOM 95031, Edition Number: <u>M-004932-01-1</u> Date: 1995-09-28 GLP/GEP: yes, unpublished	Y	Y		Bayer CropScience	The study was evaluated in the DAR (1997)

KCA 8.2.1 /04	████████ ██████ ████████	1994	<p>Identification of radioactive residues of Phenyl-(14C) FOE 5043 in bluegill sunfish (<i>Lepomis macrochirus</i>)</p> <p>████████████████████ ██████████ ████████████████</p> <p>Report No.: 106577, Edition Number: <u>M-003804-01-1</u> EPA MRID No.: 43441139 Date: 1994-07-13 GLP/GEP: yes, unpublished ...also filed: KCA 6.2.5 /01</p>	Y	Y	New data requirement (fish metabolism)	Bayer CropScience	The study was evaluated in the Addendum (2003) to the DAR ( 1997)
KCA 8.2.1 /05	████████ ████████ ██████	1994	<p>Acute toxicity of FOE 5043 to the sheepshead minnow (<i>Cyprinodon variegatus</i>) under static renewal conditions</p> <p>████████████████████ ██████████ ████████████████</p> <p>Report No.: 106421, Edition Number: <u>M-002422-01-1</u> EPA MRID No.: 43441122 Date: 1994-03-10 GLP/GEP: yes, unpublished</p>	Y	Y	US Study, not submitted to EU so far	Bayer CropScience	New study submitted for renewal of a.s.
KCA 8.2.1 /06	████████ ████████ ██	1998	<p>Acute toxicity of Thiadone to the rainbow trout (<i>Oncorhynchus mykiss</i>) under static conditions</p> <p>████████████████████ ██████████ ████████████████</p> <p>Report No.: 108738, Edition Number: <u>M-005388-01-1</u> Date: 1998-12-18 GLP/GEP: yes, unpublished</p>	Y	Y		Bayer CropScience	The study was evaluated in the Addendum (2000 and 2003) to the DAR ( 1997)

KCA 8.2.1 /07	██████ ██████ █	1999	Acute toxicity of thiadone to the sheepshead minnow (Cyprinodon variegatus) under static conditions  ████████████████████ ██████  ██████████, Report No.: 108809, Edition Number: <u>M-009684-01-1</u> Date: 1999-03-08 GLP/GEP: yes, unpublished	Y	Y	US Study, not submitted to EU so far	Bayer CropScience	New study submitted for renewal of a.s.
KCA 8.2.1 /08	██████ ██████	1999	Acute toxicity of Thiadone, a metabolite of FOE 5043, to the bluegill (Lepomis macrochirus)  ████████████████████ ██████  ██████████, Report No.: 108455, Edition Number: <u>M-016583-01-1</u> Date: 1999-03-22 GLP/GEP: yes, unpublished	Y	Y	US Study, not submitted to EU so far	Bayer CropScience	New study submitted for renewal of a.s.
KCA 8.2.1 /09	██████	2010	Acute toxicity of flufenacet (tech.) to fish (Cyprinus carpio) under static-renewal conditions - Amendment 2 from 2012-04-05  ██████████, Report No.: EBFOL149, Edition Number: <u>M-361666-03-1</u> Date: 2010-01-15 <b>...Amended: 2012-04-05</b> GLP/GEP: yes, unpublished	Y	Y		Bayer CropScience	New study submitted for renewal of a.s.

KCA 8.2.1 /10	██████ ██████ ██████ ██████	1992	The acute toxicity of sodium trifluoroacetate to the zebra fish <i>Brachydanio rerio</i>  ████████████████████ ████████████████████  ████████████████████, Report No.: C047202,  Report includes Trial Nos.: C.SOL.51.040  Edition Number: <u>M-247889-01-1</u>  Date: 1992-07-20  GLP/GEP: yes, unpublished	Y	Y	Required study for new soil metabolite	Bayer CropScience	New study submitted for renewal of a.s.
KCA 8.2.2 /01	██████ █	1995	Early life stage toxicity of FOE 5043 technical to the Rainbow Trout ( <i>Oncorhynchus mykiss</i> ) under flow-through conditions  ████████████████████ ████████████████████  ████████████████████, Report No.: 106978,  Edition Number: <u>M-002357-01-1</u>  EPA MRID No.: 43795301  Date: 1995-08-17  GLP/GEP: yes, unpublished	Y	Y		Bayer CropScience	The study was evaluated in the DAR (1997)
KCA 8.2.2.1 /01	Ulhaq, M.; Carlsson, G.; Oern, S.; Norrgrén, L.	2013	Comparison of developmental toxicity of seven perfluoroalkyl acids to zebrafish embryos .  Year:2013,  Report No.: <u>M-462660-01-1</u> ,  Edition Number: <u>M-462660-01-1</u>  GLP/GEP: n.a., published	N	N			New submitted article for renewal of a.s.
KCA 8.2.2.1 /01	Ulhaq, M.; Carlsson, G.; Oern, S.; Norrgrén, L.	2013	Comparison of developmental toxicity of seven perfluoroalkyl acids to zebrafish embryos .  Year:2013,  Report No.: <a href="#">M-462660-01-1</a> ,  Edition Number: <a href="#">M-462660-01-1</a>  GLP/GEP: n.a., published	N	N			New submitted article for renewal of a.s.

KCA 8.2.7 /14	Hanson, M. L.; Solomon, K. R.	2012	Haloacetic acids in the aquatic environment. Part I: macrophyte toxicity  Report No.: <a href="#">M-455787-01-1</a> ,  Edition Number: <a href="#">M-455787-01-1</a>  GLP/GEP: n.a., published	N	N			New submitted article for renewal of a.s.
KCA 8.2.2.1 /02	██████████ ██████████ ██████████ ██████████	2013	Early life stage toxicity of flufenacet technical to the sheepshead minnow ( <i>Cyprinodon variegatus</i> ) under flow-through conditions ██████████ ████████████████████ ██████████ ████████████████████ ██████████, Report No.: EBFOL244, Edition Number: <a href="#">M-464909-01-1</a> EPA MRID No.: 49244201 Date: 2013-08-14 GLP/GEP: yes, unpublished	Y	Y	Study required by US EPA on saltwater fish. Reveals lowest ELS endpoint	Bayer CropScience	New study submitted for renewal of a.s.
KCA 8.2.2.2 /01	██████████ ██████████	2002	Fathead minnow ( <i>Pimephales promelas</i> ) fish life cycle test with flufenacet (FOE 5043 technical)  ████████████████████ ██████████  ██████████, Report No.: 109767,  Edition Number: <a href="#">M-082934-01-1</a>  Date: 2002-10-28  GLP/GEP: yes, unpublished	Y	Y	US Study, not submitted to EU so far	Bayer CropScience	New study submitted for renewal of a.s.
KCA 8.2.2.3 /01	██████████ ██████████	1994	Uptake, depuration and bioconcentration of 14C-FOE 5043 technical by bluegill ( <i>Lepomis macrochirus</i> ) under flow-through conditions  ████████████████████ ██████████ ██████████, Report No.: 106760,  Edition Number: <a href="#">M-003803-01-1</a>  EPA MRID No.: 43441127  Date: 1994-07-08  GLP/GEP: yes, unpublished  ...also filed: KCA 6.2.5 /02	Y	Y	New data requirement (fish metabolism)	Bayer CropScience	The study was evaluated in the the DAR ( 1997)

KCA 8.2.4.1 /01	Bowers, L. M.	1994	<p>Acute toxicity of FOE 5043 technical to the waterflea (<i>Daphnia magna</i>) under static conditions</p> <p>Bayer Corporation, Kansas City, MO, USA</p> <p>Bayer CropScience,</p> <p>Report No.: 106597,</p> <p>Edition Number: <u>M-003805-01-1</u></p> <p>EPA MRID No.: 43441118</p> <p>Date: 1994-06-24</p> <p>GLP/GEP: yes, unpublished</p>	N	Y		Bayer CropScience	The study was evaluated in the DAR (1997)
KCA 8.2.4.1 /02	Heimbach, F.	1995	<p>Acute toxicity of FOE 5043-sulfonic acid to water fleas (<i>Daphnia magna</i>)</p> <p>Bayer AG, Leverkusen, Germany</p> <p>Bayer CropScience,</p> <p>Report No.: HBF/DM 145,</p> <p>Edition Number: <u>M-004930-01-1</u></p> <p>Date: 1995-10-09</p> <p>GLP/GEP: yes, unpublished</p>	N	Y		Bayer CropScience	The study was evaluated in the DAR (1997)
KCA 8.2.4.1 /03	Bowers, L. M.; Lam, C. V.	1998	<p>Acute toxicity of Thiadone (a metabolite of FOE 5043) to the waterflea <i>Daphnia magna</i> under static conditions</p> <p>Bayer Corporation, Stilwell, KS, USA</p> <p>Bayer CropScience,</p> <p>Report No.: 108464,</p> <p>Edition Number: <u>M-005390-01-1</u></p> <p>Date: 1998-12-18</p> <p>GLP/GEP: yes, unpublished</p>	N	Y	US Study, not submitted to EU so far	Bayer CropScience	The study was evaluated in the Addendum (2000 and 2003) to the DAR (1997)

KCA 8.2.4.1 /04	Groenevald, A. H. C.; de Kok, H. A. M.; van den Berg, G.	1992	The acute toxicity of sodium trifluoroacetate to <i>Daphnia magna</i>  Solvay Duphar, Netherlands;  Bayer CropScience,  Report No.: C047203,  Report includes Trial Nos.:  C.SOL.51.039  Edition Number: <u>M-247890-01-1</u>  Date: 1992-07-20  GLP/GEP: yes, unpublished	N	Y	New major metabolite	Bayer CropScience	New study submitted for renewal of a.s.
KCA 8.2.4.2 /01	Bowers, L. M.	1995	Acute toxicity of FOE 5043 (technical) to <i>Hyalella azteca</i> under static conditions  Bayer Corporation, Stilwell, KS, USA  Bayer CropScience,  Report No.: 106908,  Edition Number: <u>M-002374-01-1</u>  EPA MRID No.: 43595503  Date: 1995-03-08  GLP/GEP: yes, unpublished	N	Y		Bayer CropScience	The study was evaluated in the DAR (1997)
KCA 8.2.4.2 /02	Palmer, S. J.; Krueger, H. O.	1998	Thiadone metabolite of FOE 5043: A 96-hour flow-through acute toxicity test with the saltwater mysid ( <i>Mysidopsis bahia</i> )  Wildlife International, Ltd., Easton, MD, USA  Bayer CropScience,  Report No.: 108488,  Edition Number: <u>M-005110-01-1</u>  Date: 1998-08-12  GLP/GEP: yes, unpublished	N	Y	US Study, not submitted to EU so far	Bayer CropScience	New study submitted for renewal of a.s.

KCA 8.2.4.2 /03	Claude,, M. B.; Martin, K. H.; Gallagher, S. P.; Krueger, H.O.	2013	<p>Flufenacet: A 96-hour static acute toxicity test with the saltwater mysid (<i>Americamysis bahia</i>)</p> <p>Wildlife International, Ltd., Easton, MD, USA</p> <p>Bayer CropScience,</p> <p>Report No.: 149A-248,</p> <p>Edition Number: <u>M-452205-01-1</u></p> <p>EPA MRID No.: 49119001</p> <p>Date: 2013-04-26</p> <p>GLP/GEP: yes, unpublished</p>	N	Y	New US study, so far not submitted to EU	Bayer CropScience	New study submitted for renewal of a.s.
KCA 8.2.5 /01	Gagliano, G. G.; Bowers, L. M.	1994	<p>Chronic toxicity of FOE 5043 technical to the waterflea (<i>Daphnia magna</i>) under static renewal conditions</p> <p>Bayer Corporation, Kansas City, MO, USA</p> <p>Bayer CropScience,</p> <p>Report No.: 106762,</p> <p>Edition Number: <u>M-003795-01-1</u></p> <p>EPA MRID No.: 43441126</p> <p>Date: 1994-07-06</p> <p>GLP/GEP: yes, unpublished</p>	N	Y		Bayer CropScience	The study was evaluated in the DAR (1997)
KCA 8.2.5.2 /01	Claude,, M. B.; Martin, K. H.; Gallagher, S. P.; Krueger, H.O.	2013	<p>Flufenacet: A flow-through life-cycle toxicity test with the saltwater mysid (<i>Americamysis bahia</i>)</p> <p>Wildlife International, Ltd., Easton, MD, USA</p> <p>Bayer CropScience,</p> <p>Report No.: 149A-246,</p> <p>Edition Number: <u>M-452207-01-1</u></p> <p>EPA MRID No.: 49119002</p> <p>Date: 2013-04-26</p> <p>GLP/GEP: yes, unpublished</p>	N	Y	New US study, so far not submitted to EU	Bayer CropScience	New study submitted for renewal of a.s.



KCA 8.2.5.3 /01	Bruns, E.	2010	<p>Chironomus riparius 28-day chronic toxicity test with flufenacet (tech.) in a water-sediment system using spiked water</p> <p>Bayer CropScience,</p> <p>Report No.: EBFOL153,</p> <p>Edition Number: <u>M-372857-01-1</u></p> <p>Date: 2010-06-16</p> <p>GLP/GEP: yes, unpublished</p>	N	Y	New data requirement	Bayer CropScience	New study submitted for renewal of a.s.
KCA 8.2.6.1 /01	Bowers, L. M.	1995	<p>Toxicity of 14C-FOE 5043 to the Green Alga Selenastrum capricornutum</p> <p>Bayer Corporation, Stilwell, KS, USA</p> <p>Bayer CropScience,</p> <p>Report No.: 107114,</p> <p>Edition Number: <u>M-002348-02-1</u></p> <p>EPA MRID No.: 438344-02</p> <p>Date: 1995-10-19</p> <p>...Amended: 1998-09-09</p> <p>GLP/GEP: yes, unpublished</p>	N	Y		Bayer CropScience	The study was evaluated in the DAR (1997)
KCA 8.2.6.1 /02	Anderson, J. P. E.	1997	<p>Growth of the Green Alga, Pseudokirchneriella subcapitata (formerly Selenastrum capricornutum), during and after exposure to high concentrations of FOE 5043</p> <p>Bayer AG, Leverkusen, Germany</p> <p>Bayer CropScience,</p> <p>Report No.: AJO/157097,</p> <p>Edition Number: <u>M-002343-01-1</u></p> <p>Date: 1997-07-14</p> <p>GLP/GEP: yes, unpublished</p>	N	Y		Bayer CropScience	The study was evaluated in the DAR (1997)

KCA 8.2.6.1 /03	Dorgerloh, M.	1998	FOE 5043-Methylsulfide - Influence on the Growth of the Green Alga, <i>Pseudokirchneriella subcapitata</i> (formerly <i>Selenastrum capricornutum</i> )  Bayer AG, Leverkusen, Germany  Bayer CropScience,  Report No.: DOM 98011,  Edition Number: <u>M-002341-01-1</u>  Date: 1998-06-16  GLP/GEP: yes, unpublished	N	Y		Bayer CropScience	The study was evaluated in the Addendum (2000 and 2003) to the DAR (1997)
KCA 8.2.6.1 /04	Anderson, J. P. E.	1995	Influence of FOE 5043-sulfonic acid on the growth of the green alga, <i>Scenedesmus subspicatus</i>  Bayer AG, Leverkusen, Germany  Bayer CropScience,  Report No.: AJO/132495,  Edition Number: <u>M-004931-01-1</u>  Date: 1995-10-06  GLP/GEP: yes, unpublished	N	Y		Bayer CropScience	The study was evaluated in the DAR (1997)
KCA 8.2.6.1 /05	Dorgerloh, M.	1998	Toxicity of 14C-FOE 5043 to the green alga <i>Selenastrum capricornutum</i>  Bayer AG, Leverkusen, Germany  Bayer CropScience,  Report No.: DOM 98092,  Edition Number: <u>M-086475-01-1</u>  Date: 1998-09-09  GLP/GEP: no, unpublished	N	Y		Bayer CropScience	The study was evaluated in the DAR (1997)

KCA 8.2.6.1 /06	Hall, A. T.; Lam, C. V.	1999	<p>Toxicity of 14C-Thiadone, a metabolite of FOE 5043, to the green alga <i>Selenastrum capricornum</i></p> <p>Bayer Corporation, Kansas City, MO, USA</p> <p>Bayer CropScience,</p> <p>Report No.: 108823,</p> <p>Edition Number: <a href="#">M-009214-01-1</a></p> <p>EPA MRID No.: 45796115</p> <p>Date: 1999-03-22</p> <p>GLP/GEP: yes, unpublished</p>	N	Y	US Study, not submitted to EU so far	Bayer CropScience	The study was evaluated in the Addendum (2000 and 2003) to the DAR ( 1997)
KCA 8.2.6.1 /07	Berends, A. G.; Molenaar, J. A.	1993	<p>The toxicity of sodium trifluoroacetate to the alga <i>Selenastrum capricornutum</i> at low concentrations</p> <p>Solvay Duphar B.V., Netherlands;</p> <p>Bayer CropScience,</p> <p>Report No.: C047121,</p> <p>Report includes Trial Nos.: C.SOL.51.045</p> <p>Edition Number: <a href="#">M-247818-02-1</a></p> <p>Date: 1993-04-15</p> <p>GLP/GEP: yes, unpublished</p>	N	Y	New major metabolite	Bayer CropScience	New study submitted for renewal of a.s.
KCA 8.2.6.1 /08	Bruns, E.	2009	<p><i>Pseudokirchneriella subcapitata</i> growth inhibition test with flufenacet-oxalate</p> <p>Bayer CropScience,</p> <p>Report No.: EBFOL137,</p> <p>Edition Number: <a href="#">M-358823-01-1</a></p> <p>Date: 2009-11-06</p> <p>GLP/GEP: yes, unpublished</p>	N	Y	Major metabolite; new data requirement	Bayer CropScience	New study submitted for renewal of a.s.

KCA 8.2.6.1 /09	Bruns, E.	2010	Pseudokirchneriella subcapitata growth inhibition test with flufenacet (tech.)  Bayer CropScience,  Report No.: EBFOL150,  Edition Number: <u>M-363891-03-1</u>  Date: 2010-02-19  <b>...Amended: 2011-02-19</b>  GLP/GEP: yes, unpublished	N	Y	Study performed for Japan; necessary for refined risk assessment	Bayer CropScience	New study submitted for renewal of a.s.
KCA 8.2.6.1 /10	Bruns, E.	2010	Pseudokirchneriella subcapitata growth inhibition test with flufenacet-methylsulfone  Bayer CropScience,  Report No.: EBFOL146,  Edition Number: <u>M-364591-01-1</u>  Date: 2010-02-26  GLP/GEP: yes, unpublished	N	Y		Bayer CropScience	New study submitted for renewal of a.s.
KCA 8.2.6.1 /12	Groeneveld, A. H. C.; de Kok, H. A. M.; van den Berg, G.	1992	The toxicity of sodium trifluoroacetate to the alga Selenastrum capricornutum  Solvay Duphar B.V., Netherlands;  Bayer CropScience,  Report No.: C047124,  Report includes Trial Nos.: C.SOL.51.038  Edition Number: <u>M-247820-01-1</u>  Date: 1992-10-15  GLP/GEP: yes, unpublished	N	Y	Major metabolite; new data requirement	Bayer CropScience	New study submitted for renewal of a.s.

KCA 8.2.6.1 /13	Berends, A. G.; Keetelaar-Jansen, W. A. J.; van Dijk, N. R. M.	1995	<p>A comparison of the toxicity of sodium trifluoroacetate, sodium difluoroacetate, sodium monofluoroacetate and sodium fluoride to the alga <i>Scenedesmus supspicatus</i></p> <p>Solvay Duphar B.V., Netherlands;</p> <p>Bayer CropScience,</p> <p>Report No.: C047129,</p> <p>Report includes Trial Nos.: C.SOL.51.074</p> <p>Edition Number: <a href="#">M-247825-01-1</a></p> <p>Date: 1995-02-01</p> <p>GLP/GEP: yes, unpublished</p>	N	Y	required study for new soil metabolite	Bayer CropScience	New study submitted for renewal of a.s.
KCA 8.2.6.1 /14	Berends, A. G.	1996	<p>The toxicity of sodium trifluoroacetate to algae Third Draft</p> <p>Solvay Duphar B.V., Netherlands;</p> <p>Bayer CropScience,</p> <p>Report No.: C047126,</p> <p>Edition Number: <a href="#">M-247822-01-1</a></p> <p>Date: 1996-01-01</p> <p>GLP/GEP: no, unpublished</p>	N	Y	Major metabolite; new data requirement	Bayer CropScience	New study submitted for renewal of a.s.
KCA 8.2.6.1 /15	Bruns, E.	2012	<p><i>Pseudokirchneriella subcapitata</i> growth inhibition test with BCS-CU62474 - limit test</p> <p>Bayer CropScience,</p> <p>Report No.: EBFOP017,</p> <p>Edition Number: <a href="#">M-444217-01-1</a></p> <p>Date: 2012-12-21</p> <p>GLP/GEP: yes, unpublished</p>	N	Y	Major metabolite; new data requirement	Bayer Crop Science	New study submitted for renewal of a.s.
KCA 8.2.6.1 /16	Bruns, E.	2011	<p><i>Desmodesmus subspicatus</i> growth inhibition test with flufenacet (tech.)</p> <p>Bayer CropScience,</p> <p>Report No.: EBFOL114/3,</p> <p>Edition Number: <a href="#">M-415813-01-1</a></p> <p>Date: 2011-10-04</p> <p>GLP/GEP: yes, unpublished</p>	N	Y	Additional algae species needed for refinement of risk assessment	Bayer Crop Science	New study submitted for renewal of a.s.

KCA 8.2.6.2 /01	Bowers, L. M.; Dobbs, M. G.	1995	Acute toxicity of 14C-FOE 5043 to the freshwater diatom ( <i>Navicula pelliculosa</i> )  Bayer Corporation, Stilwell, KS, USA  Bayer CropScience, Report No.: 107113, Edition Number: <a href="#">M-002355-01-1</a>  EPA MRID No.: 43834401  Date: 1995-10-18  GLP/GEP: yes, unpublished	N	Y		Bayer CropScience	The study was evaluated in the DAR (1997)
KCA 8.2.6.2 /02	Hughes, J. S.; Alexander, M. M.	1993	Acute toxicity of FOE 5043 (technical) to <i>Anabaena flos-aquae</i>  Malcolm Pirnie, Tarrytown, NY, USA  Bayer CropScience, Report No.: 105199, Edition Number: <a href="#">M-002423-01-1</a>  EPA MRID No.: 43441131  Date: 1993-12-17  GLP/GEP: yes, unpublished	N	Y		Bayer CropScience	The study was evaluated in the Addendum (2000 and 2003) to the DAR (1997)
KCA 8.2.6.2 /04	Bruns, E.	2011	<i>Synechococcus leopoliensis</i> growth inhibition test with flufenacet (tech.)  Bayer CropScience, Report No.: EBFOL114, Edition Number: <a href="#">M-415814-01-1</a>  Date: 2011-10-07  GLP/GEP: yes, unpublished	N	Y	Additional algae species needed for refinement of risk assessment	Bayer CropScience	New study submitted for renewal of a.s.
KCA 8.2.6.2 /05	Bruns, E.	2011	<i>Chlorella vulgaris</i> growth inhibition test with flufenacet (tech.)  Bayer CropScience, Report No.: EBFOL114/4, Edition Number: <a href="#">M-416169-01-1</a>  Date: 2011-10-17  GLP/GEP: yes, unpublished	N	Y	Additional algae species needed for refinement of risk assessment	Bayer CropScience	New study submitted for renewal of a.s.

KCA 8.2.6.2 /06	Sobczyk, H.	2011	Chlamydomonas terricola growth inhibition test with flufenacet (tech.)  Bayer CropScience,  Report No.: EBFOL114/1,  Edition Number: <u>M-418627-01-1</u>  Date: 2011-11-29  GLP/GEP: yes, unpublished	N	Y	Additional algae species needed for refinement of risk assessment	Bayer CropScience	New study submitted for renewal of a.s.
KCA 8.2.7 /01	Hughes, J. S.; Alexander, M. M.	1994	Acute toxicity of FOE 5043 (technical) to Lemna gibba G3  Malcolm Pirnie, Tarrytown, NY, USA  Bayer CropScience,  Report No.: 105198,  Edition Number: <u>M-002418-02-1</u>  EPA MRID No.: 43441132  Date: 1994-01-04  ...Amended: 1998-09-01  GLP/GEP: yes, unpublished	N	Y	-	Bayer CropScience	The study was evaluated in the DAR (1997)
KCA 8.2.7 /02	Dorgerloh, M.	1995	FOE 5043-Sulfonic acid - Toxicity (14 days) to Lemna gibba G3  Bayer AG, Leverkusen, Germany  Bayer CropScience,  Report No.: DOM 95072,  Edition Number: <a href="#">M-004929-01-1</a>  Date: 1995-11-28  GLP/GEP: yes, unpublished	N	Y		Bayer CropScience	The study was evaluated in the DAR (1997)
KCA 8.2.7 /03	Dorgerloh, M.	1998	Acute toxicity of FOE 5043 (technical) to Lemna gibba G3  Bayer AG, Leverkusen, Germany  Bayer CropScience,  Report No.: DOM 98091,  Edition Number: <u>M-086479-01-1</u>  Date: 1998-09-01  GLP/GEP: no, unpublished	N	Y	According to new guideline	Bayer CropScience	The study was evaluated in the DAR (1997). New recalculation was provided according to new guideline

KCA 8.2.7 /04	Smyth, D. V.; Thompson, R. S.; Gillins, E.	1993	Sodium trifluoroacetate: toxicity to the duckweed (Lemna gibba)  Zeneca Ltd., Brixham Environmental Laboratory, Brixham, United Kingdom  Bayer CropScience, Report No.: C047215, Report includes Trial Nos.:  SP91-18.7 W907/B  Edition Number: <u>M-247900-01-1</u>  Date: 1993-05-12  GLP/GEP: yes, unpublished	N	Y	New major metabolite	Bayer CropScience	New study submitted for renewal of a.s.
KCA 8.2.7 /05	Bruns, E.	2009	Lemna gibba G3 Growth inhibition test with flufenacet-oxalate under static conditions  Bayer CropScience, Report No.: EBFOL138, Edition Number: <u>M-359515-02-1</u>  Date: 2009-11-24  <b>...Amended: 2009-12-08</b>  GLP/GEP: yes, unpublished	N	Y	Major metabolite; new data requirement	Bayer CropScience	New study submitted for renewal of a.s.
KCA 8.2.7 /06	Bruns, E.	2010	Lemna gibba G3 - Growth inhibition test with flufenacet-methylsulfone (BCS-CO62475) under static conditions  Bayer CropScience, Report No.: EBFOL145, Edition Number: <u>M-369703-01-1</u>  Date: 2010-05-21  GLP/GEP: yes, unpublished	N	Y	Major metabolite; new data requirement	Bayer CropScience	New study submitted for renewal of a.s.



KCA 8.2.7 /07	Bruns, E.	2010	Lemna gibba G3 - Growth inhibition test with flufenacet-methylsulfide under static conditions  Bayer CropScience,  Report No.: EBFOL143,  Edition Number: <u>M-393709-01-1</u>  Date: 2010-10-27  GLP/GEP: yes, unpublished	N	Y	Major metabolite; new data requirement	Bayer CropScience	New study submitted for renewal of a.s.
KCA 8.2.7 /08	Bruns, E.	2010	Lemna gibba G3 - Growth inhibition test with flufenacet-thiadone under static conditions  Bayer CropScience,  Report No.: EBFOL144,  Edition Number: <u>M-393718-01-3</u>  Date: 2010-10-27  GLP/GEP: yes, unpublished	N	Y	Major metabolite; new data requirement	Bayer CropScience	New study submitted for renewal of a.s.
KCA 8.2.7 /10	Weyers, A.	2013	Lemna gibba G3 - Growth inhibition test with BCS-CU62474 (potassium salt of trifluoroethanesulfonic acid, metabolite of flufenacet) under static conditions  Bayer CropScience,  Report No.: EBFOP018,  Edition Number: <u>M-445884-01-1</u>  Date: 2013-01-25  GLP/GEP: yes, unpublished	N	Y	Major metabolite; new data requirement	Bayer CropScience	New study submitted for renewal of a.s.
KCA 8.2.7 /11	Bruns, E.	2013	Lemna gibba G3 - Growth inhibition test with flufenacet (technical substance) under static conditions  Bayer CropScience,  Report No.: EBFON004,  Edition Number: <u>M-451198-01-1</u>  Date: 2013-03-13  GLP/GEP: yes, unpublished	N	Y	New 7 day study performed as old US-EPA study was performed over 14 days	Bayer CropScience	New study submitted for renewal of a.s.

KCA 8.2.7 /12	Bruns, E.	2013	Lemna gibba G3 - Growth inhibition test with flufenacet tech. under peak exposure conditions  Bayer CropScience,  Report No.: EBFOL234,  Edition Number: <u>M-452567-01-1</u>  Date: 2013-04-16  GLP/GEP: yes, unpublished	N	Y	Higher tier study, necessary for refinement	Bayer CropScience	New study submitted for renewal of a.s.
KCA 8.2.7 /13	Sowig, P.	2014	Flufenacet rationale for the replacement of the old 14-day Lemna growth inhibition study (Hughes & Alexander 1993; <u>M-002418-02-1</u> ) with the new 7-day Lemna study (Bruns 2013; <u>M-451198-01-1</u> )  Bayer CropScience,  Report No.: <u>M-478762-01-1</u> ,  Edition Number: <u>M-478762-01-1</u>  Date: 2014-02-28  GLP/GEP: n.a., unpublished	N	N		Bayer CropScience	-.
KCA 8.2.7 /14	Hanson, M. L.; Solomon, K. R.	2012	Haloacetic acids in the aquatic environment. Part I: macrophyte toxicity  Report No.: <u>M-455787-01-1</u> ,  Edition Number: <u>M-455787-01-1</u>  GLP/GEP: n.a., published	N	N			New study submitted for renewal of a.s.
KCA 8.2.8 /01	Wheat, J.; Evans, J.	1993	Acute effects of FOE 5043 (technical) on new shell growth of the eastern oyster (Crassostrea virginica)  Toxikon Environmental Sciences, Jupiter, FL, USA  Bayer CropScience,  Report No.: 105181,  Edition Number: <u>M-002427-01-1</u>  EPA MRID No.: 43441123  Date: 1993-09-28  GLP/GEP: yes, unpublished	N	Y	US Study, not submitted to EU so far	Bayer CropScience	New study submitted for renewal of a.s.

KCA 8.2.8 /02	Palmer, S. J.; Krueger, H. O.	1998	Thiadone metabolite of FOE 5043: A 96-hour shell deposition test with the eastern oyster ( <i>Crassostrea virginica</i> )  Wildlife International, Ltd., Easton, MD, USA  Bayer CropScience,  Report No.: 108489,  Edition Number: <u>M-005108-01-1</u>  Date: 1998-08-12  GLP/GEP: yes, unpublished	N	Y	US Study, not submitted to EU so far	Bayer CropScience	New study submitted for renewal of a.s.
KCA 8.2.8 /03	Bruns, E.	2009	Statement on the suitability of the microcosm study "The fate and biological effects of Flufenacet WG 60 in aquatic indoor microcosms" for the use in higher tier risk assessments with special focus on algal species and aquatic macrophytes  Bayer CropScience,  Report No.: <u>M-329959-01-1</u> ,  Edition Number: <u>M-329959-01-1</u>  Date: 2009-02-27  GLP/GEP: n.a., unpublished	N	N		Bayer CropScience	-
KCA 8.2.8 /04	Banman, C. S.; Alexander, T. M.; Moore, S.	2013	Acute toxicity of flufenacet technical to the African clawed frog ( <i>Xenopus laevis</i> ) under static conditions  SynTech Research Laboratory Services, LLC, Stilwell, KS, USA  Bayer CropScience,  Report No.: EBFON083,  Edition Number: <u>M-471899-01-1</u>  Date: 2013-12-04  GLP/GEP: yes, unpublished	N	Y	Study required by US EPA on African clawed frog	Bayer CropScience	New study submitted for renewal of a.s.

KCA 8.3.1.1.1 /01	Nengel, S.	1995	Assessment of side effects of FOE 5043 (tech.) to the honey bee, <i>Apis mellifera</i> L. in the laboratory following the EPPO guideline No. 170  GAB Biotechnologie GmbH, Niefern-Oeschelbronn, Germany  Bayer CropScience,  Report No.: 94137/01-BLEU,  Edition Number: <u>M-004919-01-1</u>  Date: 1995-08-30  GLP/GEP: yes, unpublished  <b>...also filed: KCA 8.3.1.1.2 /02</b>	N	Y		Bayer CropScience	The study was evaluated in the DAR (1997)
KCA 8.3.1.1.1 /02	Tornier, I.	1995	Results of the screening test on the honey bee <i>Apis mellifera</i> L. test substance: FOE 5043 (techn.)  GAB Biotechnologie GmbH, Niefern-Oeschelbronn, Germany  Bayer CropScience,  Report No.: B-958264,  Edition Number: <u>M-004920-01-1</u>  Date: 1995-02-08  GLP/GEP: no, unpublished  <b>...also filed: KCA 8.3.1.1.2 /03</b>	N	Y		Bayer CropScience	The study was evaluated in the DAR (1997)
KCA 8.3.1.1.1 /03	Schmitzer, S.	2011	Effects of flufenacet tech. (acute contact and oral) on honey bees ( <i>Apis mellifera</i> L.) in the laboratory  IBACON GmbH, Rossdorf, Germany  Bayer CropScience,  Report No.: 67681035,  Edition Number: <u>M-421687-01-1</u>  Date: 2011-12-15  GLP/GEP: yes, unpublished	N	Y	Study performed according to most recent guideline	Bayer CropScience	New study submitted for renewal of a.s.

KCA 8.3.1.1.2 /02	Nengel, S.	1995	Assessment of side effects of FOE 5043 (tech.) to the honey bee, <i>Apis mellifera</i> L. in the laboratory following the EPPO guideline No. 170  GAB Biotechnologie GmbH, Niefern-Oeschelbronn, Germany  Bayer CropScience,  Report No.: 94137/01-BLEU,  Edition Number: <u>M-004919-01-1</u>  Date: 1995-08-30  GLP/GEP: yes, unpublished  <b>...also filed: KCA 8.3.1.1.1 /01</b>	N	Y		Bayer CropScience	The study was evaluated in the DAR (1997)
KCA 8.3.1.1.2 /03	Tornier, I.	1995	Results of the screening test on the honey bee <i>Apis mellifera</i> L. test substance: FOE 5043 (techn.)  GAB Biotechnologie GmbH, Niefern-Oeschelbronn, Germany  Bayer CropScience,  Report No.: B-958264,  Edition Number: <u>M-004920-01-1</u>  Date: 1995-02-08  GLP/GEP: no, unpublished  <b>...also filed: KCA 8.3.1.1.1 /02</b>	N	Y		Bayer CropScience	The study was evaluated in the DAR (1997)
KCA 8.3.1.1.2 /04	Vergé, E.	2014	Flufenacet (tech.): Acute contact toxicity to the bumble bee <i>Bombus terrestris</i> L. (Hymenoptera, Apidae) under laboratory conditions  Eurofins-GAB GmbH, Niefern-Oeschelbronn, Germany  Bayer CropScience,  Report No.: S13-01762,  Edition Number: <u>M-478564-01-1</u>  Date: 2014-02-04  GLP/GEP: yes, unpublished	N	Y	Study according to new guideline	Bayer CropScience	New study submitted for renewal of a.s.

KCA 8.3.1.2 /01	Kling, A.	2014	<p>Flufenacet (tech.) - Assessment of chronic effects to the honeybee, <i>Apis mellifera</i> L., in a 10 days continuous laboratory feeding limit test</p> <p>eurofins-GAB GmbH, Niefern-Oeschelbronn, Germany</p> <p>Bayer CropScience,</p> <p>Report No.: S13-00145,</p> <p>Edition Number: <u>M-477339-01-1</u></p> <p>Date: 2014-01-29</p> <p>GLP/GEP: yes, unpublished</p>	N	Y	required to fulfill new data requirements	Bayer CropScience	New study submitted for renewal of a.s.
KCA 8.3.1.3 /01	Hecht-Rost, S.	2012	<p>Flufenacet SC 508.8: A honeybee brood feeding study to evaluate the effects on brood development of the honeybee, <i>Apis mellifera</i> L. (Hymenoptera: Apidae)</p> <p>Innovative Environmental Services (IES) Ltd, Witterswil, Switzerland</p> <p>Bayer CropScience,</p> <p>Report No.: 20110057,</p> <p>Edition Number: <u>M-456504-01-1</u></p> <p>Date: 2012-08-12</p> <p>GLP/GEP: yes, unpublished</p>	N	Y	New data requirement	Bayer CropScience	New study submitted for renewal of a.s.
KCA 8.4.1 /01	Nienstedt, K. M.	1999	<p>FOE 5043-Oxalate: A 14-day acute toxicity test with the earthworm (<i>Eisenia fetida</i>)</p> <p>Springborn Laboratories AG, Horn, Switzerland</p> <p>Bayer CropScience,</p> <p>Report No.: 1022.006.630,</p> <p>Edition Number: <u>M-008793-01-1</u></p> <p>Date: 1999-07-19</p> <p>GLP/GEP: yes, unpublished</p>	N	Y		Bayer Crop Science	The study was evaluated in the DAR (1997)

KCA 8.4.1 /02	Heimbach, F.	1995	<p>Toxicity of FOE 5043 T (tech.) to earthworms</p> <p>Bayer AG, Leverkusen, Germany</p> <p>Bayer CropScience,</p> <p>Report No.: 107310,</p> <p>Edition Number: <u>M-004876-01-2</u></p> <p>Date: 1995-01-05</p> <p>GLP/GEP: yes, unpublished</p>	N	Y		Bayer Crop Science	The study was evaluated in the DAR (1997)
KCA 8.4.1 /03	Nienstedt, K. M.	1999	<p>FOE 5043-Sulfonic acid Na-salt: A 14-day acute toxicity test with the earthworm (<i>Eisenia fetida</i>)</p> <p>Springborn Laboratories AG, Horn, Switzerland</p> <p>Bayer CropScience,</p> <p>Report No.: 99-005-1022,</p> <p>Edition Number: <u>M-008794-01-1</u></p> <p>Date: 1999-07-15</p> <p>GLP/GEP: yes, unpublished</p>	N	Y		Bayer CropScience	The study was evaluated in the DAR (1997)
KCA 8.4.1 /05	Leicher, T.	2009	<p>Flufenacet (FOE 5043)-sulfonic acid Na-salt: Effects on survival, growth and reproduction on the earthworm <i>Eisenia fetida</i> tested in artificial soil with 5% peat</p> <p>Bayer CropScience,</p> <p>Report No.: LRT-RG-R-64/09,</p> <p>Edition Number: <u>M-358264-01-1</u></p> <p>Date: 2009-11-02</p> <p>GLP/GEP: yes, unpublished</p>	N	Y	Major metabolite; new data requirement	Bayer CropScience	New study submitted for renewal of a.s.

KCA 8.4.1 /06	Leicher, T.	2010	<p>Flufenacet (FOE 5043) Methylsulfone: Effects on survival, growth and reproduction on the earthworm <i>Eisenia fetida</i> tested in artificial soil with 5 % peat</p> <p>Bayer CropScience,</p> <p>Report No.: LRT-RG-R-68/09,</p> <p>Edition Number: <u>M-362081-01-1</u></p> <p>Date: 2010-01-21</p> <p>GLP/GEP: yes, unpublished</p>	N	Y	Major metabolite; new data requirement	Bayer CropScience	New study submitted for renewal of a.s.
KCA 8.4.1 /07	Leicher, T.	2010	<p>FOE 5043-oxalate: Effects on survival, growth and reproduction on the earthworm <i>Eisenia fetida</i> tested in artificial soil with 10 % peat</p> <p>Bayer CropScience,</p> <p>Report No.: LRT-RG-R-93/10,</p> <p>Edition Number: <u>M-398163-01-1</u></p> <p>Date: 2010-12-20</p> <p>GLP/GEP: yes, unpublished</p>	N	Y	Major metabolite; new data requirement	Bayer CropScience	New study submitted for renewal of a.s.
KCA 8.4.1 /08	Kratz, M. A.	2012	<p>Flufenacet-thiadone (AE 1258593, BCS-AA 41715): Effects on survival, growth and reproduction on the earthworm <i>Eisenia fetida</i> tested in artificial soil</p> <p>Bayer CropScience,</p> <p>Report No.: KRA-RG-R-136/12,</p> <p>Edition Number: <u>M-442579-01-1</u></p> <p>Date: 2012-11-28</p> <p>GLP/GEP: yes, unpublished</p>	N	Y	Major metabolite; new data requirement	Bayer CropScience	New study submitted for renewal of a.s.



KCA 8.4.1 /09	Luehrs, U.	2005	Effects of AE C502988 00 1B99 0001 on reproduction and growth of earthworms <i>Eisenia fetida</i> in artificial soil  IBACON GmbH, Rossdorf, Germany  Bayer CropScience,  Report No.: C048065,  Edition Number: <u>M-251328-01-1</u>  Date: 2005-05-03  GLP/GEP: yes, unpublished	N	Y	New data requirements; major metabolite	Bayer CropScience	New study submitted for renewal of a.s.
KCA 8.4.1 /10	Kratz, M.A.	2012	Flufenacet-trifluoroethanesulfonic acid Na-salt (BCS-CU62474): Effects on survival, growth and reproduction on the earthworm <i>Eisenia fetida</i> tested in artificial  Bayer CropScience,  Report No.: KRA-RG-R-131/12,  Edition Number: <u>M-436340-01-1</u>  Date: 2012-08-08  GLP/GEP: yes, unpublished	N	Y	Major metabolite; new data requirement	Bayer CropScience	New study submitted for renewal of a.s.
KCA 8.4.1 /11	Leicher, T.	2008	Flufenacet SC 500: effect on the earthworm fauna of a grassland area within one year  Bayer CropScience,  Report No.: LRT/RG-F-4/08,  Edition Number: <u>M-307211-01-1</u>  Date: 2008-09-19  GLP/GEP: yes, unpublished	N	Y	Earthworm field study, needed for refinement	Bayer CropScience	New study submitted for renewal of a.s.
KCA 8.4.2.1 /01	Kratz, M.-A.	2009	Flufenacet-methylsulfone: Influence on mortality and reproduction on the soil mite species <i>Hypoaspis aculeifer</i> tested in artificial soil with 5 % peat  Bayer CropScience,  Report No.: KRA-HR-17/09,  Edition Number: <u>M-357707-01-1</u>  Date: 2009-10-15  GLP/GEP: yes, unpublished	N	Y	Major metabolite; new data requirement	Bayer CropScience	New study submitted for renewal of a.s.

KCA 8.4.2.1 /02	Frommholz, U.	2010	Flufenacet a.s.: Influence on the reproduction of the collembola species Folsomia candida tested in artificial soil with 5 % peat  Bayer CropScience,  Report No.: FRM-COLL-79/10,  Edition Number: <u>M-363896-01-1</u>  Date: 2010-02-23  GLP/GEP: yes, unpublished	N	Y	New data requirement	Bayer CropScience	New study submitted for renewal of a.s.
KCA 8.4.2.1 /03	Kratz, M.-A.	2010	Flufenacet-oxalate: Influence on mortality and reproduction on the soil mite species Hypoaspis aculeifer tested in artificial soil with 5 % peat  Bayer CropScience,  Report No.: KRA-HR-38/10,  Edition Number: <u>M-393634-01-1</u>  Date: 2010-10-26  GLP/GEP: yes, unpublished	N	Y	Major metabolite; new data requirement	Bayer CropScience	New study submitted for renewal of a.s.
KCA 8.4.2.1 /04	Frommholz, U.	2010	Flufenacet-oxalate: Influence on the reproduction of the collembolan species Folsomia candida tested in artificial soil  Bayer CropScience,  Report No.: FRM-COLL-95/10,  Edition Number: <u>M-394712-01-1</u>  Date: 2010-11-15  GLP/GEP: yes, unpublished	N	Y	Major metabolite; new data requirement	Bayer CropScience	New study submitted for renewal of a.s.
KCA 8.4.2.1 /05	Frommholz, U.	2010	Flufenacet-sulfonic acid Na-salt: Influence on the reproduction of the collembolan species Folsomia candida tested in artificial soil.  Bayer CropScience,  Report No.: FRM-COLL-98/10,  Edition Number: <u>M-396039-01-1</u>  Date: 2010-11-29  GLP/GEP: yes, unpublished	N	Y	Major metabolite; new data requirement	Bayer CropScience	New study submitted for renewal of a.s.

KCA 8.4.2.1 /06	Frommholz, U.	2012	Trifluoroacetic acid Na-salt (BCS-AZ56567): Influence on the reproduction of the collembolan species Folsomia candida tested in artificial soil  Bayer CropScience,  Report No.: FRM-COLL-132/12,  Edition Number: <u>M-436127-01-1</u>  Date: 2012-08-02  GLP/GEP: yes, unpublished	N	Y	New data requirements; major metabolite	Bayer CropScience	New study submitted for renewal of a.s.
KCA 8.4.2.1 /07	Frommholz, U.	2012	Flufenacet-trifluoroethanesulfonic acid Na-salt (BCS-CU62474): Influence on the reproduction of the Collembolan species Folsomia candida tested in artificial soil  Bayer CropScience,  Report No.: FRM-COLL-123/12,  Edition Number: <u>M-436128-01-1</u>  Date: 2012-08-02  GLP/GEP: no, unpublished	N	Y	Major metabolite; new data requirement	Bayer CropScience	New study submitted for renewal of a.s.
KCA 8.4.2.1 /08	Kratz, M.A.	2012	Flufenacet-trifluoroethanesulfonic acid Na-salt (BCS-CU62474): Influence on mortality and reproduction on the soil mite species Hypoaspis aculeifer tested in artificial soil  Bayer CropScience,  Report No.: KRA-HR-57/12,  Edition Number: <u>M-436315-01-1</u>  Date: 2012-08-07  GLP/GEP: yes, unpublished	N	Y	Major metabolite; new data requirement	Bayer CropScience	New study submitted for renewal of a.s.

KCA 8.4.2.1 /09	Kratz, M.A.	2012	Trifluoroacetic acid Na-salt (BCS-AZ56567): Influence on mortality and reproduction on the soil mite species Hypoaspis aculeifer tested in artificial soil  Bayer CropScience, Report No.: KRA-HR-58/12, Edition Number: <u>M-436326-01-1</u> Date: 2012-08-07 GLP/GEP: yes, unpublished	N	Y	New data requirements; major metabolite	Bayer CropScience	New study submitted for renewal of a.s.
KCA 8.4.2.1 /10	Frommholz, U.	2012	Flufenacet-thiadone (BCS-AA41715): Influence on the reproduction of the collembolan species Folsomia candida tested in artificial soil  Bayer CropScience, Report No.: FRM-COLL-137/12, Edition Number: <u>M-440372-01-1</u> Date: 2012-10-24 GLP/GEP: yes, unpublished	N	Y	Major metabolite; new data requirement	Bayer CropScience	New study submitted for renewal of a.s.
KCA 8.4.2.1 /11	Kratz, M. A.	2012	Flufenacet-thiadone (BCS-AA41715): Influence on mortality and reproduction on the soil mite species Hypoaspis aculeifer tested in artificial soil  Bayer CropScience, Report No.: KRA-HR-68/12, Edition Number: <u>M-442897-01-1</u> Date: 2012-11-20 GLP/GEP: yes, unpublished	N	Y	Major metabolite; new data requirement	Bayer CropScience	New study submitted for renewal of a.s.
KCA 8.4.2.1 /12	Kratz, M. A.	2013	Flufenacet a.s.: Influence on mortality and reproduction of the soil mite species hypoaspis aculeifer tested in artificial soil  Bayer CropScience, Report No.: kra-HR-83/13, Edition Number: <u>M-455214-01-1</u> Date: 2013-05-31 GLP/GEP: yes, unpublished	N	Y	New data requirement	Bayer CropScience	New study submitted for renewal of a.s.

KCA 8.4.2.1 /13	Kratz, M. A.	2013	<p>Flufenacet-sulfonic acid Na-salt (BCS-AZ23374): Influence on mortality and reproduction of the soil mite species <i>Hypoaspis aculeifer</i> tested in artificial soil</p> <p>Bayer CropScience,</p> <p>Report No.: kra-HR-88/13,</p> <p>Edition Number: <u>M-455654-01-1</u></p> <p>Date: 2013-05-31</p> <p>GLP/GEP: yes, unpublished</p>	N	Y	Major metabolite; new data requirement	Bayer CropScience	New study submitted for renewal of a.s.
KCA 8.4.2.1 /14	Frommholz, U.	2010	<p>Flufenacet-methylsulfone (BCS-CO62475): Influence on the reproduction of the collembolan species <i>Folsomia candida</i> tested in artificial soil</p> <p>Bayer CropScience,</p> <p>Report No.: FRM-COLL-96/10,</p> <p>Edition Number: <u>M-392345-01-1</u></p> <p>Date: 2010-10-19</p> <p>GLP/GEP: yes, unpublished</p>	N	Y	Major metabolite; new data requirement	Bayer CropScience	New study submitted for renewal of a.s.
KCA 8.5 /01	Anderson, J. P. E.	1994	<p>Influence of FOE 5043 on microbial mineralization of nitrogen in soils</p> <p>Bayer AG, Leverkusen, Germany</p> <p>Bayer CropScience,</p> <p>Report No.: AJO/124594,</p> <p>Edition Number: <u>M-003871-01-2</u></p> <p><u>Amedmend (recalculation)</u></p> <p><u>Ernst G., CroderS., 2016</u></p> <p>Date: 1994-11-08</p> <p>GLP/GEP: yes, unpublished</p>	N	Y		Bayer CropScience	The study was evaluated in the DAR (1997)

KCA 8.5 /02	Anderson, J. P. E.	1994	Influence of FOE 5043 on glucose stimulated respiration in soil  Bayer AG, Leverkusen, Germany  Bayer CropScience, Report No.: 107670,  Edition Number: <u>M-003872- 01-2</u>  Date: 1994-11-08  GLP/GEP: yes, unpublished	N	Y		Bayer CropScience	The study was evaluated in the DAR (1997)
KCA 8.5 /03	Lechelt- Kunze, C.	2005	Metabolite Flufenacet- Sulfonic acid Na- salt: Determination of effects on nitrogen transformation in soil  Bayer CropScience, Report No.: LKC-N-41/05,  Edition Number: <u>M-250265- 01-1</u>  Date: 2005-04-25  GLP/GEP: yes, unpublished	N	Y	Major metabolite; new data requirement	Bayer CropScience	New study submitted for renewal of a.s.
KCA 8.5 /04	Lechelt- Kunze, C.	2005	Metabolite flufenacet- oxalate hydrate: determination of effects on nitrogen transformation in soil  Bayer CropScience, Report No.: LKC-N-45/05,  Edition Number: <u>M-250511- 01-1</u>  Date: 2005-05-02  GLP/GEP: yes, unpublished	N	Y	Major metabolite; new data requirement	Bayer CropScience	New study submitted for renewal of a.s.
KCA 8.5 /05	Frommholz, U.	2010	Metabolite flufenacet- methylsulfone (BCS- CO62475): Determination of effects on nitrogen transformation in soil  Bayer CropScience, Report No.: FRM-N-151/10,  Edition Number: <u>M-398568- 01-1</u>  Date: 2010-12-23  GLP/GEP: yes, unpublished	N	Y	Major metabolite; new data requirement	Bayer CropScience	New study submitted for renewal of a.s.

KCA 8.5 /06	Schulz, L.	2013	<p>Trifluoroacetic acid Na-salt (BCS-AZ56567): Effects on the activity of soil microflora (nitrogen transformation test)</p> <p>BioChem agrar GmbH, Gerichshain, Germany</p> <p>Bayer CropScience,</p> <p>Report No.: 12 10 48 080 N,</p> <p>Edition Number: <u>M-444423-01-1</u></p> <p>Date: 2013-01-07</p> <p>GLP/GEP: yes, unpublished</p>	N	Y	New data requirements; major metabolite	Bayer CropScience	New study submitted for renewal of a.s.
KCA 8.5 /07	Schulz, L.	2013	<p>Flufenacet-thiadone (BCS-AA41715): Effects on the activity of soil microflora (nitrogen transformation test)</p> <p>BioChem agrar GmbH, Gerichshain, Germany</p> <p>Bayer CropScience,</p> <p>Report No.: 13 10 48 078 N,</p> <p>Edition Number: <u>M-457326-01-1</u></p> <p>Date: 2013-06-11</p> <p>GLP/GEP: yes, unpublished</p>	N	Y	Major metabolite; new data requirement	Bayer CropScience	New study submitted for renewal of a.s.
KCA 8.5 /08	Schulz, L.	2013	<p>Flufenacet-trifluoroethanesulfonic acid Na-salt (BCS-CU62474): Effects on the activity of soil microflora (nitrogen transformation test)</p> <p>BioChem agrar GmbH, Gerichshain, Germany</p> <p>Bayer CropScience,</p> <p>Report No.: 13 10 48 079 N,</p> <p>Edition Number: <u>M-457331-01-1</u></p> <p>Date: 2013-06-11</p> <p>GLP/GEP: yes, unpublished</p>	N	Y	New metabolite which needs to be addressed; new data requirement	Bayer CropScience	New study submitted for renewal of a.s.
KCA 8.7 /01	Oehrlé, N. W.; Green, L. S.; Karr, D. B.; Emerich, D. W.	2012	<p>The HFC/HCFC breakdown product trifluoroacetic acid (TFA) and its effects on the symbiosis between Bradyrhizobium japonicum and soybean (Glycine max)</p> <p>Report No.: <u>M-455785-01-1</u>,</p> <p>Edition Number: <u>M-455785-01-1</u></p> <p>GLP/GEP: n.a., published</p>	N	N			New study submitted for renewal of a.s.

KCA 8.7 /02	Smit, M.; Van Heerden, P.; Pienaar, J.; Weissflog, L.; Strasser, R.; Kruger, G.	2009	Effect of trifluoroacetate, a persistent degradation product of fluorinated hydrocarbons, on Phaseolus vulgaris and Zea mays  Report No.: <u>M-455801-01-1</u> ,  Edition Number: <u>M-455801- 01-1</u>  Date: 2009-01-01  GLP/GEP: no, published	N	N			New study submitted for renewal of a.s.
KCA 8.7 /03	Benesch, J. A.; Gustin, M. S.; Cramer, G. R.; Cahill, T. M.	2012	Investigation of effects of trifluoroacetate on vernal pool ecosystems  Report No.: <u>M-455780-01-1</u> ,  Edition Number: <u>M-455780- 01-1</u>  GLP/GEP: n.a., published	N	N			New study submitted for renewal of a.s.
KCA 8.8 /01	Kanne, R.	1989	Oxygen consumption test with activated sludge FOE 5043  Bayer AG, Leverkusen, Germany  Bayer CropScience,  Report No.: BA-898271,  Report includes Trial Nos.:  89238067  Edition Number: <u>M-004740- 02-1</u>  Date: 1989-12-08  ...Amended: 2006-03-20  GLP/GEP: no, unpublished	N	Y		Bayer CropScience	The study was evaluated in the DAR (1997)
KCA 8.8 /02	Weyers, A.	2007	Flufenacet TC - Toxicity to bacteria  Bayer Industry Services GmbH, Leverkusen, Germany  Bayer CropScience,  Report No.: 2006/0171/01,  Edition Number: <u>M-283846- 01-1</u>  Date: 2007-02-05  GLP/GEP: yes, unpublished	N	Y	New data requirement	Bayer CropScience	New study submitted for renewal of a.s.



-	Hills, M.	2009	Evaluation of the pre-emergence biological activity of FOE 5043-Oxalate  (code: BCS-AB16305) a metabolite of Flufenacet.  Study No. PP09022, Reference BCS No:M-353844-01-1	N	Y	Additional data	Bayer CropScience	New study submitted for renewal of a.s.
-	Dahmen, P.	2004	Screening and Efficacy Data for WAK6222 (metabolite of FOE5043)  Report No: PF-F-HB-WAK6222-01, Reference BCS No: M-089475-01-1	N	Y	Additional data	Bayer CropScience	New study submitted for renewal of a.s.
	Jans, D.	2013	Evaluation of the post emergence herbicidal activity of trifluoroethansulfonic acid sodium-salt (metabolite of flufenacet) in comparison with flufenacet  Report No: RF13/035, Reference BCS No: M-460341-01-1	N	Y	Additional data	Bayer CropScience	New study submitted for renewal of a.s.
	S. Nöding	2013	Evaluation of the pre-emergence herbicidal activity of flufenacet and its metabolite BCS-AZ 56567  Study No: FFS135016, Reference BCS No: M-461398-01-1	N	Y	Additional data	Bayer CropScience	New study submitted for renewal of a.s.

a) studies submitted by the Notifier:

b) Formulation

Annex pointn / reference number	Author(s)	Year	Title  <i>Source (where different from company)</i>  <b>Company name, Report No., Date, GLP status (where relevant), published or not</b>	Vertebrate study  Y/N	Data protection  claimed  Y/N	Justification  if data protection is claimed	Owner	Previous evaluation
KCP 10.2.1 /01	Dorgerloh, M.; Sommer, H.	2001	FOE 5043 & diflufenican SC 600 - Influence on the growth of the green alga, <i>Selenastrum capricornutum</i>  Bayer AG, Leverkusen, Germany  Bayer CropScience,  Report No.: DOM 20073,  Edition Number: <a href="#">M-073137-01-1</a>  Date: 2001-09-18  GLP/GEP: yes, unpublished	N	Y	Data requirement	Bayer Crop Science	New study submitted for the renewal of a.s.
KCP 10.2.1 /02	Dorgerloh, M.; Sommer, H.	2001	FOE 5043 & diflufenican SC 600 - Toxicity (7 days) to <i>Lemna gibba</i> G3 in a static test  Bayer AG, Leverkusen, Germany  Bayer CropScience,  Report No.: DOM 20074,  Edition Number: <a href="#">M-073160-01-1</a>  Date: 2001-09-18  GLP/GEP: yes, unpublished	N	Y	Data requirement	Bayer Crop Science	New study submitted for the renewal of a.s.
KCP 10.3.1.1.1 /01	Schmitzer, S.; Sekine, T.	2009	Effects of diflufenican + flufenacet SC 600 (200+400) G (acute contact and oral) on honey bees ( <i>Apis mellifera</i> L.) in the laboratory  IBACON GmbH, Rossdorf, Germany  Bayer CropScience,  Report No.: 47501035,  Edition Number: <a href="#">M-356881-01-1</a>  Date: 2009-10-05  GLP/GEP: yes, unpublished  <b>...also filed: KCP 10.3.1.1.2 /01</b>	N	Y	Data requirement	Bayer Crop Science	New study submitted for the renewal of a.s.

Annex pointn / reference number	Author(s)	Year	Title  <i>Source (where different from company)</i>  <b>Company name, Report No., Date, GLP status (where relevant), published or not</b>	Vertebrate study  Y/N	Data protection  claimed  Y/N	Justification  if data protection is claimed	Owner	Previous evaluatio
KCP 10.3.1.1.2 /01	Schmitzer, S.; Sekine, T.	2009	Effects of diflufenican + flufenacet SC 600 (200+400) G (acute contact and oral) on honey bees ( <i>Apis mellifera</i> L.) in the laboratory  IBACON GmbH, Rossdorf, Germany  Bayer CropScience,  Report No.: 47501035,  Edition Number: <a href="#">M-356881-01-1</a>  Date: 2009-10-05  GLP/GEP: yes, unpublished  <b>...also filed: KCP 10.3.1.1.1 /01</b>	N	Y	Data requirement	Bayer Crop Science	New study submmited for the renewal
KCP 10.3.2.1 /01	Gossmann, A.	2001	Effects of flufenacet & diflufenican SC 600 on the predatory mite <i>Typhlodromus pyri</i> Scheuten (Acari, Phytoseiidae) in the laboratory - dose response design -  IBACON GmbH, Rossdorf, Germany  Bayer CropScience,  Report No.: 9352063,  Edition Number: <a href="#">M-058604-01-1</a>  Date: 2001-07-04  GLP/GEP: yes, unpublished	N	Y	Data requirement	Bayer Crop Science	New study submmited for the renewal of a.s.

Annex pointn / reference number	Author(s)	Year	Title  <i>Source (where different from company)</i>  <b>Company name, Report No., Date, GLP status (where relevant), published or not</b>	Vertebrate study  Y/N	Data protection  claimed  Y/N	Justification if data protection is claimed	Owner	Previous evaluatio
KCP 10.3.2.1 /02	Moll, M.; Buetzler, R.	2001	Effects of flufenacet & diflufenican SC 600 on the parasitoid <i>Aphidius rhopalosiphii</i> in the laboratory - limit test -  IBACON GmbH, Rossdorf, Germany  Bayer CropScience,  Report No.: 9351001,  Edition Number: <a href="#">M-058618-01-1</a>  Date: 2001-07-04  GLP/GEP: yes, unpublished	N	Y	Data requirement	Bayer Crop Science	New study submitted for the renewal of a.s.
KCP 10.3.2.2 /01	Chauzat, M. P.	2002	The effects of flufenacet & diflufenican SC 600 on <i>Typhlodromus pyri</i> (Acari: Phytoseiidae) on natural substrate in laboratory (extended laboratory test)  Promo-Vert S.A., Serres Castet, France  Bayer CropScience,  Report No.: 01TYBYL12,  Edition Number: <a href="#">M-034242-01-1</a>  Date: 2002-01-14  GLP/GEP: yes, unpublished	N	Y	Data requirement	Bayer Crop Science	New study submitted for the renewal of a.s.

Annex pointn / reference number	Author(s)	Year	Title  <i>Source (where different from company)</i>  <b>Company name, Report No., Date, GLP status (where relevant), published or not</b>	Vertebrate study  Y/N	Data protection  claimed  Y/N	Justification  if data protection is claimed	Owner	Previous evaluatio
KCP 10.3.2.2 /02	Waibel, J.	2009	Toxicity to the green lacewing Chrysoperla carnea STEPH. (Neuroptera, Chrysopidae) using an extended laboratory test on Zea mays; Flufenacet + Diflufenican SC 400 + 200 g/L  Bayer CropScience,  Report No.: CW09/010,  Edition Number: <a href="#">M-352372-01-1</a>  Date: 2009-07-28  GLP/GEP: yes, unpublished	N	Y	Data requirement	Bayer Crop Science	New study submmited for the renewal of a.s.
KCP 10.3.2.2 /03	Roehlig, U.	2009	Chronic toxicity (ER50) of Diflufenican + Flufenacet SC 600 g/L to the rove beetle Aleochara bilineata GYLL. under extended laboratory conditions  BioChem agrar GmbH, Gerichshain, Germany  Bayer CropScience,  Report No.: 09 10 48 027 A,  Edition Number: <a href="#">M-353760-01-1</a>  Date: 2009-07-28  GLP/GEP: yes, unpublished	N	Y	Data requirement	Bayer Crop Science	New study submmited for the renewal of a.s.

Annex pointn / reference number	Author(s)	Year	Title  <i>Source (where different from company)</i>  <b>Company name, Report No., Date, GLP status (where relevant), published or not</b>	Vertebrate  study  Y/N	Data  protection  claimed  Y/N	Justification  if data protection is  claimed	Owner	Previous evalutio
KCP 10.3.2.2 /04	Jans, D.	2009	Toxicity to the predatory mite Typhlodromus pyri SCHEUTEN (Acari, Phytoseiidae) using an extended laboratory test (under semi-field conditions aged residues on Zea mays), Flufenacet + Diflufenican SC 400 + 200 g/L  Bayer CropScience,  Report No.: CW09/026,  Edition Number: <a href="#">M-355238-01-1</a>  Date: 2009-09-08  GLP/GEP: yes, unpublished	N	Y	Data requirement	Bayer Crop Science	New study submmited for the renewal of a.s.
KCP 10.4.1.1 /01	Leicher, T.	2010	Diflufenican + Flufenacet SC 600 G: Effects on survival, growth and reproduction on the earthworm Eisenia fetida tested in artificial soil with 5 % peat  Bayer CropScience,  Report No.: LRT-RG-R-70/10,  Edition Number: <a href="#">M-362809-01-1</a>  Date: 2010-02-08  GLP/GEP: yes, unpublished	N	Y	New data requirement	Bayer Crop Science	New study submmited for the renewal of a.s.

Annex pointn / reference number	Author(s)	Year	Title  <i>Source (where different from company)</i>  <b>Company name, Report No., Date, GLP status (where relevant), published or not</b>	Vertebrate study  Y/N	Data protection  claimed  Y/N	Justification if data protection is claimed	Owner	Previous evaluatio
KCP 10.4.1.2 /01	Hamberger, A.	2014	DFF+FFA SC 200+400 G - A field study to investigate effects on the earthworm fauna in southern Germany  eurofins-GAB GmbH, Niefern-Oeschelbronn, Germany  Bayer CropScience,  Report No.: S12-03897/EBFON089,  Edition Number: <a href="#">M-478092-01-1</a>  Date: 2014-02-24  GLP/GEP: yes, unpublished	N	Y	Earthworm field study, needed for refinement	Bayer Crop Science	New study submmited for the renewal of a.s.
KCP 10.4.2.1 /01	Feije, R.	2002	Flufenacet & diflufenican SC 600: The effects on survival and reproduction of the predaceous mite Hypoaspis aculeifer Canestrini (Acari: Laelapidae) in standard soil (LUFA 2.1)  MITOX Stichting Bevoordering Duurzame Plaagbestrijding, Amsterdam, Netherlands  Bayer CropScience,  Report No.: B094HAE,  Edition Number: <a href="#">M-061660-01-1</a>  Date: 2002-04-26  GLP/GEP: yes, unpublished	N	Y	Data requirement	Bayer Crop Science	New study submmited for the renewal of a.s.

Annex pointn / reference number	Author(s)	Year	Title  <i>Source (where different from company)</i>  <b>Company name, Report No., Date, GLP status (where relevant), published or not</b>	Vertebrate study  Y/N	Data protection  claimed  Y/N	Justification if data protection is claimed	Owner	Previous evaluatio
KCP 10.4.2.1 /02	Frommholz, U.	2011	<p>Diflufenican + flufenacet SC 600 (200+400) G: Influence on the reproduction of the collembolan species <i>Folsomia candida</i> tested in artificial soil.</p> <p>Bayer CropScience,</p> <p>Report No.: FRM-Coll-125/11,</p> <p>Edition Number: <a href="#">M-415903-01-1</a></p> <p>Date: 2011-10-11</p> <p>GLP/GEP: yes, unpublished</p>	N	Y	New data requirement	Bayer Crop Science	New study submmited for the renewal of a.s.
KCP 10.5 /01	Frommholz, U.	2009	<p>Diflufenican + flufenacet SC 600 (200+400) G: determination of effects on nitrogen transformation in soil</p> <p>Bayer CropScience,</p> <p>Report No.: FRM-N-121/09,</p> <p>Edition Number: <a href="#">M-357934-01-1</a></p> <p>Date: 2009-10-27</p> <p>GLP/GEP: yes, unpublished</p>	N	Y	Data requirement	Bayer Crop Science	New study submmited for the renewal of a.s.
KCP 10.6.2 /01	Kalsch, W.	2002	<p>Flufenacet &amp; diflufenican SC 600: Vegetative vigour test on terrestrial non-target plants of 6 families (2 Monocotyledoneae, 4 Dicotyledoneae)</p> <p>ECT Oekotoxikologie GmbH, Floersheim, Germany</p> <p>Bayer CropScience,</p> <p>Report No.: P3PB,</p> <p>Edition Number: <a href="#">M-071692-01-1</a></p> <p>Date: 2002-07-12</p> <p>GLP/GEP: yes, unpublished</p>	N	Y	Data requirement	Bayer Crop Science	New study submmited for the renewal of a.s.



Annex pointn / reference number	Author(s)	Year	Title  <i>Source (where different from company)</i>  <b>Company name, Report No., Date, GLP status (where relevant), published or not</b>	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previous evaluation
KCP 10.6.2 /02	Kalsch, W.	2002	Flufenacet & diflufenican SC 600: Seedling emergence and seedling growth test on terrestrial non-target plants of 6 families (2 Monocotyledoneae, 4 Dicotyledoneae)  ECT Oekotoxikologie GmbH, Floersheim, Germany  Bayer CropScience,  Report No.: P2PA,  Edition Number: <a href="#">M-072308-01-1</a>  Date: 2002-07-12  GLP/GEP: yes, unpublished	N	Y	Data requirement	Bayer Crop Science	New study submitted for the renewal of a.s.
-	Friedrich, S.	2005	Flufenacet SC 500: Vegetative vigour test on non target terrestrial plants.  Bayer Crop Science  Report/Doc.number: Report No: 041048105,  Edition Number: <a href="#">M-248251-01-1</a>  Date: Data:2005-03-25  GLP: yes, unpublished	N	Y		Bayer Crop Science	New study submitted for the renewal of a.s.
-	Friedrich,S.	2005	Flufenacet 500 S: Seedling emergence and seedling growth test on terrestrial non-target plants. Study Number: 04 10 48 104  Edition Number: <a href="#">M-248251-01-1</a>  Data: 2005-03-25  GLP/GEP: yes, unpublished	N	Y		Bayer Crop Science	New study submitted for the renewal of a.s.

**The additional publications/articles:**

- Maynard et al. “Weeds in the treated field – a realistic scenario for pollinator risk assessment?”  
*Hazards of pesticides to bees - 12th International Symposium of the ICP-PR Bee Protection Group, Ghent (Belgium), September 15-17, 2014, 56 Julius-Kühn-Archiv, 450 (2015),*
- Seitz, B.-J. 1989. *Beziehungen zwischen Vogelwelt und Vegetation im Kulturland - Untersuchungen im südwestdeutschen Hügelland. Beihefte zu den Veröffentlichungen für Naturschutz und Landschaftspflege in Baden-Württemberg 54: 1-236 (cf Appendix 1)*
- Scheffer/Schachtschnabel (1998) *Lehrbuch der Bodenkunde. Stuttgart , Enke Verlag.*
- Edwards CA & Lofty JR (1972) *The biology of earthworms. London, Chapman and Hall.*

*Position Paper :*

- *The risk assessment for Bees for flufenacet Annex I Renewal (11<sup>th</sup> May , 2016), authors: M.Almanza, U.Koelzer*