

FINAL REGISTRATION REPORT

Part B

Section 10

**Assessment of the relevance of metabolites in
groundwater**

Detailed summary of the risk assessment

Product code: A18385B

Product name: SPANDIS

Chemical active substances:

Dicamba, 400 g/kg
Nicosulfuron, 100 g/kg
Prosulfuron, 40 g/kg

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(new authorization)

Applicant: Syngenta

Submission date: xx/11/2020

MS Finalisation date: 11/07/2022

Version history

When	What
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November 2021	Updates based on feedback from zRMS Poland
January 2022	Updates based on feedback from zRMS Poland
April 2022	zRMS evaluation of dRR
July 2022	Final version prepared by zRMS after Commenting period

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zRMS comments:

The text highlighted in grey was provided by the evaluator.

10 Relevance of metabolites in groundwater

zRMS Comments:	<p>The submitted PEC_{gw} values for metabolites of prosulfuron and nicosulfuron were assessed in Section 8.</p> <p>Prosulfuron. All relevant metabolites: CGA 349707, CGA 159902 and CGA 150829 with PEC_{gw} > 0.1 µg/L were taken into consideration. Based on Tier 2 assessment the max PEC_{gw} values are presented in Table 10.1-1.</p> <p>Nicosulfuron. All relevant metabolites: HMUD, AUSN, UCSN, ASDM and MU-466 with PEC_{gw} > 0.1 µg/L were taken into consideration. The max PEC_{gw} values are presented in Table 10.1-2.</p> <p>Dicamba. No metabolites with PEC_{gw} > 0.1 µg/L were identified.</p> <p>Following new groundwater modelling results, further consideration in line with the stepwise procedure of the EC guidance document SANCO/221/2000–rev.10 has been made. Overall, prosulfuron and nicosulfuron groundwater metabolites exceeding the threshold of 0.1µg/L were determined not to be of concern. The assessment of the relevance of prosulfuron metabolites has been previously agreed at an EU level. The previous relevance assessment is applicable as well for the GAP and groundwater scenarios considered in this dRR and has not been re-evaluated for toxicity here. The relevance of the nicosulfuron metabolites has been also previously assessed at EU level and it was concluded that none of the groundwater metabolites were considered to be relevant according to the EU guidance document SANCO/221/2000–rev.10. No dicamba metabolites with PEC > 0.1 µg/L were identified, therefore further assessment of the potential metabolites relevance is not required.</p>
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10.1 General information

Prosulfuron metabolites

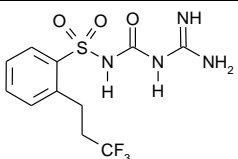
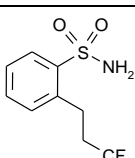
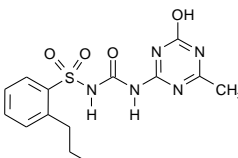
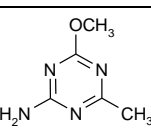
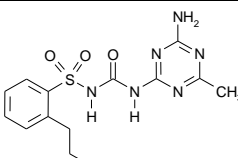
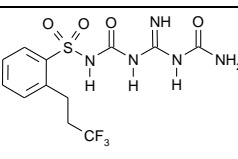
The relevance of the groundwater metabolites of prosulfuron has already been assessed but could not be finalised at EU level (see **Prosulfuron, EFSA Journal 2014; 12(9): 3815; Prosulfuron, EFSA Journal 2020;18(7):6181**). Meanwhile, additional data have been generated and are given in the appropriate **Document N4** (Syngenta File No CGA152005_10566) assessing potential relevance of metabolites in groundwater at EU level. The document was submitted previously for EU review.

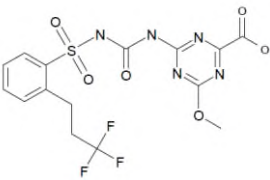
General information on the metabolites is provided in Table 10.1-1 and the assessment on whether a particular GAP use leads to acceptable risk or not is presented in the summary of the cGAP evaluation in chapter 8.1 of the dRR Part B, Section 8 (Environmental Fate).

However, the relevance of the metabolites was already assessed for different application rates of 15, 16 and 20 g a.s./ha on maize and at application rates of 15 g a.s./ha on winter cereals and spring cereals (see **Document N4**, Syngenta File No CGA152005_10566). The relevance assessment is applicable for the GAP and groundwater scenarios considered in this dRR, but there have been some changes in the input parameters for the modelling in groundwater according to the RMS last request (October, 2021). Hence, a complete new assessment according to Step 1-5 of guidance document SANCO/221/2000 –rev.10 is not required, but the Max PEC_{gw} have been updated according to the new results (please see calculations in **A18385B, Part B, Section 8.8.2**). Therefore, a short summary of the outcome of the assessment is considered sufficient.

The PEC_{GW} of the prosulfuron metabolites CGA349707, CGA159902, CGA150829, ~~CGA325025 and SYN547308~~ are predicted to occur in groundwater at concentrations above 0.1 µg/L (see **Document N4**, Syngenta File No CGA152005_10566 please see calculations in **A18385B, Part B, Section 8.8.2**) and the summary of the outcome of the relevance assessment according to the stepwise procedure of the EC guidance document (SANCO/221/2000 –rev.10) is presented hereafter (see Point 10.2 to 10.8)

Table 10.1-1: General information on the metabolites of prosulfuron

Name of active substance	Metabolite name and code	Structural/molecular formula	Trigger for relevance assessment	
CGA152005 Prosulfuron	CGA349707		Max Tier 2eb, PEC _{gw}	0.436 0.887 µg/L FOCUS-PEARL v4.4.4 maize 20g ai/ha, Thiva Hamburg FOCUS scenario
	CGA159902		Max Tier 2eb, PEC _{gw}	0.155 µg/L 0.163 µg/L FOCUS-PEARL v4.4.4 maize 20 g ai/ha, Hamburg FOCUS scenario
	CGA300406		Max Tier 2eb, PEC _{gw}	0.027 µg/L 0.032 µg/L FOCUS-PEARL v4.4.4 winter cereals 20 g ai/ha, Hamburg Kremsmünster FOCUS scenario
	CGA150829		Max Tier 2eb, PEC _{gw}	0.063 µg/L 0.107 µg/L FOCUS-PEARL v4.4.4 maize 20 g ai/ha, Hamburg FOCUS scenario
	CGA325025		Max Tier 2eb, PEC _{gw}	0.059 µg/L FOCUS- PEARL v4.4.4 maize 20 g ai/ha, Hamburg FOCUS scenario
	SYN542604		Max Tier 2eb, PEC _{gw}	0.031 µg/L 0.036 µg/L FOCUS-PEARL v4.4.4 winter cereals maize 20 g ai/ha, Hamburg FOCUS scenario

Name of active substance	Metabolite name and code	Structural/molecular formula	Trigger for relevance assessment	
	SYN547308		Max Tier 2eb, PEC _{gw} Based on:	0.092 µg/L 0.094 µg/L FOCUS-PEARL v4.4.4 winter cereals maize 20 g ai/ha, Hamburg FOCUS scenario

Nicosulfuron metabolites

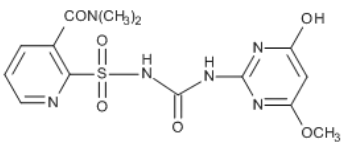
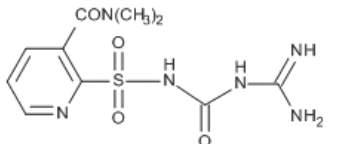
The relevance of the groundwater metabolites of nicosulfuron has previously been assessed at EU level (Nicosulfuron, EFSA Scientific Report (2007); 120, 1-91) and it was concluded that none of the groundwater metabolites were considered to be relevant according to the EU guidance document SANCO/221/2000 –rev.10.

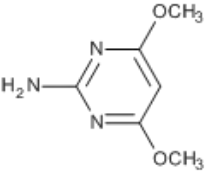
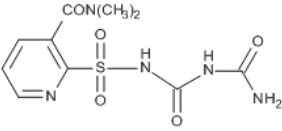
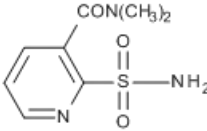
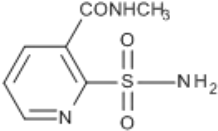
General information on the metabolites is provided in Table 10.1-2 and the assessment on whether a particular GAP use leads to acceptable risk or not is presented in the summary of the cGAP evaluation in chapter 8.1 of the dRR Part B, Section 8 (Environmental Fate).

Groundwater modelled outputs were previously provided in the Draft Assessment Report (Nicosulfuron, EFSA Scientific Report (2007); 120, 1-91). Syngenta has a letter of access to nicosulfuron data but in addition has carried out modelling in support of the proposed product uses assuming triennial use rates of 40 or 50 g a.s/ha (see Part B, Section 8 (Environmental Fate). The relevance of the metabolites was already assessed for the authorization of the product A18385B for the GAP and groundwater scenarios considered in this dRR. Hence, a new assessment according to Step 1-5 of guidance document SANCO/221/2000 –rev.10 is not required. Therefore, a short summary of the outcome of the assessment is considered sufficient.

The metabolite ADMP is predicted to occur in groundwater <0.001µg/L, the metabolite MU-466 <0.1 µg/L and the metabolite HMUD >0.1 µg/L but <0.75 µg/L. The metabolites AUSN, UCSN and ASDM are predicted to occur in groundwater at concentrations >0.75 µg/L but <10 µg/L. The summary of the outcome of the relevance assessment according to the stepwise procedure of the EC guidance document (SANCO/221/2000 –rev.10) is presented hereafter (see Point 10.9 to 10.13).

Table 10.1-2 General information on the metabolites of nicosulfuron

Name of active substance	Metabolite name and code	Structural/molecular formula	Trigger for relevance assessment	
Nicoulfuron	HMUD		Max PEC _{gw} Based on:	0.458 µg/L FOCUS-PEARL v4.4.4 maize 50 g ai/ha, Hamburg FOCUS scenario
	AUSN		Max PEC _{gw} Based on:	1.79 µg/L 1.95 µg/L FOCUS

Name of active substance	Metabolite name and code	Structural/molecular formula	Trigger for relevance assessment	
				PELMO v5.5.3 FOCUS-PEARL v4.4.4 maize 50 g ai/ha, Thiva FOCUS scenario
	ADMP		Max PEC _{gw} Based on:	< 0.001 µg/L FOCUS-PEARL v4.4.4 and FOCUS- PELMO v5.5.3 All models maize 50 g ai/ha, all FOCUS scenarios
	UCSN		Max PEC _{gw} Based on:	1.37 µg/L FOCUS-PEARL v4.4.4 maize 50 g ai/ha, Thiva FOCUS scenario
	ASDM		Max PEC _{gw} Based on:	1.23 µg/L 1.26 µg/L FOCUS-PEARL v4.4.4 maize 50 g ai/ha, Thiva FOCUS scenario
	MU-466		Max PEC _{gw} Based on:	0.085 µg/L 0.113 µg/L FOCUS-PEARL v4.4.4 maize 50 g ai/ha, Thiva FOCUS scenario

Dicamba metabolites

The EFSA report for dicamba (**EFSA Journal 2011; 9(1):1965**), and in particular Appendix A thereof, is considered to provide the relevant review information. The representative formulated product for the evaluation was BANVEL 480 SL (A7254B), a soluble concentrate (SL).

The Commission Implementing Regulation (EU) No. 540/2011 of 25 May 2011 does not stipulate any specific provisions for dicamba which need to be considered by the applicant in the preparation of their submission or by the MS prior to granting an authorization.

General information on the metabolites is provided in Table 10.1-3 and the assessment on whether a particular GAP use leads to acceptable risk or not is presented in the summary of the cGAP evaluation in chapter 8.1 of the dRR Part B, Section 8 (Environmental Fate).

The PEC of **DCSA (NOA414746)**, the dicamba metabolite, in ground water (PEC_{gw}) has been assessed with standard FOCUS scenarios to obtain outputs from the FOCUS PELMO and FOCUS PEARL models and the K_{FOC} values established in the EU review (see Part B, Section 8 (Environmental Fate)).

For the major metabolite **DCSA (NOA414746)**, strong adsorption to soil combined with a fast degradation indicate a low potential for movement to groundwater. The predicted environmental concentrations (PEC_{gw}) at 1 m depth of the use of dicamba on maize at 200 g ai/ha were less than 0.001 µg/L in all scenarios using FOCUS-PELMO and FOCUS-PEARL models.

The models predict that **DCSA (NOA414746)** will not be measured in ground water at concentrations equal to, or greater than 0.1 µg/L. Therefore, further assessment of the potential relevance of **DCSA (NOA414746)** is not required.

Table 10.1-3: General information on the metabolite of dicamba

Name of active substance	Metabolite name and code	Structural/molecular formula	Trigger for relevance assessment	
Dicamba	DCSA (NOA414746)		Max PEC _{gw}	< 0.001 µg/L
			Based on:	FOCUS-PEARL v4.4.4 and FOCUS-PELMO v5.5.3, maize, 1 x 200 g ai/ha, all FOCUS scenarios

10.2 Relevance assessment of prosulfuron metabolite CGA349707

Summary:

The relevance of the groundwater metabolite **CGA349707** has already been assessed and the assessment agreed at EU level (see **Document N4**, Syngenta File No CGA152005_10566), and the relevance assessment is applicable as well for the GAP and groundwater scenarios considered in this dRR (i.e., the conclusions reached at the EU-level are valid ~~also with regard to the PEC_{gw} calculated for the GAP and groundwater scenarios considered in this dRR~~ but the Max PEC_{gw} have been updated according to the new results (please see calculations in **A18385B, Part B, Section 8.8.2**)). **CGA349707** is not considered relevant according to the criteria laid down in the EC guidance document SANCO/221/2000 –rev.10. A summary of the relevance assessment is given in Table 10.2-1.

Table 10.2-1: Summary of the relevance assessment for CGA349707

	Assessment step		Result of assessment	
	STEP 1		Metabolite of no concern?	no
Quantification of groundwater contamination	STEP 2		Max PEC _{gw}	0.887 0.436 µg/L
			Based on	Tier 2eb, FOCUS-PEARL v4.4.4 maize 20 g ai/ha, Hamburg FOCUS scenario
Hazard assessment	STEP 3	Stage 1	Biological activity comparable to the parent?	no
		Stage 2	Genotoxic properties of metabolite	Non-genotoxic
		Stage 3	Toxic properties of metabolite	None
			Classification of parent	Acute Tox. 4; H302
			Classification of metabolite	None

Consumer health risk assessment	STEP 4	Estimated consumer exposure <i>via</i> drinking water and other sources; threshold of concern approach	not acceptable ($\geq < 0.75 \mu\text{g/L}$)
	STEP 5	Refined risk assessment	Acceptable N/A*
		Predicted exposure (% of ADI)	2.8 % of ADI#N/A*
		ADI based on	ADI for CGA349707 can be conservatively derived by multiplying the ADI of prosulfuron by 5%. The ADI value for prosulfuron is 0.02 mg/kg bw/day, based on the 1-year dog and 18 month mouse studies and using a safety factor of 100 for intra and inter species differences. The resulting ADI for CGA349707 is 0.001 mg/kg bw/day. N/A*
$\# \text{ADI utilisation (\%)} = [\text{PEC}_{\text{gw}} (\mu\text{g/L}) \times \text{water consumption (L/day)} \times 100] / [\text{bw (kg)} \times 1000 \times \text{ADI (mg/kg bw/day)}]$ Calculation of risk (% ADI) for 60 kg adult (consuming 2.0 L/day)			
* N/A: not applicable			

10.2.1 STEP 1: Exclusion of degradation products of no concern

The relevance of the groundwater metabolite **CGA349707** has already been assessed and the assessment agreed at EU level. Therefore only summary of the relevance assessment is given in Table 10.2-1.

10.2.2 STEP 2: Quantification of potential groundwater contamination

The relevance of the groundwater metabolite **CGA349707** has already been assessed and the assessment agreed at EU level. Therefore only summary of the relevance assessment is given in Table 10.2-1.

10.2.3 STEP 3: Hazard assessment – identification of relevant metabolites

10.2.3.1 STEP 3, Stage 1: screening for biological activity

The relevance of the groundwater metabolite **CGA349707** has already been assessed and the assessment agreed at EU level. Therefore only summary of the relevance assessment is given in Table 10.2-1.

10.2.3.2 STEP 3, Stage 3: screening for toxicity

The relevance of the groundwater metabolite **CGA349707** has already been assessed and the assessment agreed at EU level. Therefore only summary of the relevance assessment is given in Table 10.2-1.

10.2.4 STEP 4: Exposure assessment – threshold of concern approach

The relevance of the groundwater metabolite **CGA349707** has already been assessed and the assessment agreed at EU level. Therefore only summary of the relevance assessment is given in Table 10.2-1.

10.2.5 STEP 5: Refined risk assessment

The relevance of the groundwater metabolite **CGA349707** has already been assessed and the assessment agreed at EU level. Therefore only summary of the relevance assessment is given in Table 10.2-1.

10.3 Relevance assessment of prosulfuron metabolite CGA159902

Summary:

The relevance of the groundwater metabolite **CGA159902** has already been assessed and the assessment

agreed at EU level (see **Document N4**, Syngenta File No CGA152005_10566), and the relevance assessment is applicable as well for the GAP and groundwater scenarios considered in this dRR (i.e., the conclusions reached at the EU-level are valid also valid ~~also with regard to the PEC_{gw} calculated for the GAP and groundwater scenarios considered in this dRR~~ but the Max PEC_{gw} have been updated according to the new results (please see calculations in **A18385B, Part B, Section 8.8.2**)). **CGA159902** is not considered relevant according to the criteria laid down in the EC guidance document SANCO/221/2000 – rev.10. A summary of the relevance assessment is given in Table 10.3-1.

Table 10.3-1: Summary of the relevance assessment for CGA159902

	Assessment step		Result of assessment	
	STEP 1		Metabolite of no concern?	no
Quantification of groundwater contamination	STEP 2		Max PEC _{gw}	0.155 0.163 µg/L
			Based on	Tier 2eb, FOCUS-PEARL v4.4.4 maize 20 g ai/ha, Hamburg FOCUS scenario
Hazard assessment	STEP 3	Stage 1	Biological activity comparable to the parent?	no
		Stage 2	Genotoxic properties of metabolite	Non-genotoxic
		Stage 3	Toxic properties of metabolite	None
			Classification of parent	Acute Tox. 4; H302
			Classification of metabolite	None
Consumer health risk assessment	STEP 4		Estimated consumer exposure <i>via</i> drinking water and other sources; threshold of concern approach	acceptable (< 0.75µg/L)
	STEP 5		Refined risk assessment	N/A*
			Predicted exposure (% of ADI)	N/A*
			ADI based on	N/A*

* N/A: not applicable

10.3.1 STEP 1: Exclusion of degradation products of no concern

The relevance of the groundwater metabolite **CGA159902** has already been assessed and the assessment agreed at EU level. Therefore only summary of the relevance assessment is given in Table 10.3-1.

10.3.2 STEP 2: Quantification of potential groundwater contamination

The relevance of the groundwater metabolite **CGA159902** has already been assessed and the assessment agreed at EU level. Therefore only summary of the relevance assessment is given in Table 10.3-1.

10.3.3 STEP 3: Hazard assessment – identification of relevant metabolites

10.3.3.1 STEP 3, Stage 1: screening for biological activity

The relevance of the groundwater metabolite **CGA159902** has already been assessed and the assessment agreed at EU level. Therefore only summary of the relevance assessment is given in Table 10.3-1.

10.3.3.2 STEP 3, Stage 2: screening for genotoxicity

The relevance of the groundwater metabolite **CGA159902** has already been assessed and the assessment agreed at EU level. Therefore only summary of the relevance assessment is given in Table 10.3-1.

10.3.3.3 STEP 3, Stage 3: screening for toxicity

The relevance of the groundwater metabolite **CGA159902** has already been assessed and the assessment agreed at EU level. Therefore only summary of the relevance assessment is given in Table 10.3-1.

10.3.4 STEP 4: Exposure assessment – threshold of concern approach

The relevance of the groundwater metabolite **CGA159902** has already been assessed and the assessment

agreed at EU level. Therefore only summary of the relevance assessment is given in Table 10.3-1.

10.3.5 STEP 5: Refined risk assessment

The relevance of the groundwater metabolite **CGA159902** has already been assessed and the assessment agreed at EU level. Therefore only summary of the relevance assessment is given in Table 10.3-1.

10.4 Relevance assessment of prosulfuron metabolite CGA300406

Summary:

The relevance of the groundwater metabolite **CGA300406** has already been assessed and the assessment agreed at EU level (see **Document N4**, Syngenta File No CGA152005_10566), and the relevance assessment is applicable as well for the GAP and groundwater scenarios considered in this dRR (i.e., the conclusions reached at the EU-level are valid ~~also with regard to the PEC_{gw} calculated for the GAP and groundwater scenarios considered in this dRR~~ but the Max PEC_{gw} have been updated according to the new results (please see calculations in **A18385B, Part B, Section 8.8.2**). **CGA300406** is not considered relevant according to the criteria laid down in the EC guidance document SANCO/221/2000 –rev.10. A summary of the relevance assessment is given in Table 10.4-1.

Table 10.4-1: Summary of the relevance assessment for CGA300406

	Assessment step		Result of assessment	
	STEP 1		Metabolite of no concern?	no
Quantification of groundwater contamination	STEP 2		Max PEC _{gw}	0.027 0.032 µg/L
			Based on	Tier 2eb, FOCUS-PEARL v4.4.4 winter cereals maize 20 g ai/ha, Hamburg-Kremsmünster FOCUS scenario
Hazard assessment	STEP 3	Stage 1	Biological activity comparable to the parent?	no
		Stage 2	Genotoxic properties of metabolite	Non-genotoxic
		Stage 3	Toxic properties of metabolite;	None
			Classification of parent	Acute Tox. 4; H302
			Classification of metabolite	None
Consumer health risk assessment	STEP 4		Estimated consumer exposure <i>via</i> drinking water and other sources; threshold of concern approach	acceptable (< 0.75µg/L)
	STEP 5	Refined risk assessment		N/A*
		Predicted exposure (% of ADI)		N/A*
				ADI based on

* N/A: not applicable

10.4.1 STEP 1: Exclusion of degradation products of no concern

The relevance of the groundwater metabolite **CGA300406** has already been assessed and the assessment agreed at EU level. Therefore only summary of the relevance assessment is given in Table 10.4-1.

10.4.2 STEP 2: Quantification of potential groundwater contamination

The relevance of the groundwater metabolite **CGA300406** has already been assessed and the assessment agreed at EU level. Therefore only summary of the relevance assessment is given in Table 10.4-1.

10.4.3 STEP 3: Hazard assessment – identification of relevant metabolites

10.4.3.1 STEP 3, Stage 1: screening for biological activity

The relevance of the groundwater metabolite **CGA300406** has already been assessed and the assessment agreed at EU level. Therefore only summary of the relevance assessment is given in Table 10.4-1.

10.4.3.2 STEP 3, Stage 2: screening for genotoxicity

The relevance of the groundwater metabolite **CGA300406** has already been assessed and the assessment agreed at EU level. Therefore only summary of the relevance assessment is given in Table 10.4-1.

10.4.3.3 STEP 3, Stage 3: screening for toxicity

The relevance of the groundwater metabolite **CGA300406** has already been assessed and the assessment agreed at EU level. Therefore only summary of the relevance assessment is given in Table 10.4-1.

10.4.4 STEP 4: Exposure assessment – threshold of concern approach

The relevance of the groundwater metabolite **CGA300406** has already been assessed and the assessment agreed at EU level. Therefore only summary of the relevance assessment is given in Table 10.4-1.

10.4.5 STEP 5: Refined risk assessment

The relevance of the groundwater metabolite **CGA300406** has already been assessed and the assessment agreed at EU level. Therefore only summary of the relevance assessment is given in Table 10.4-1.

10.5 Relevance assessment of prosulfuron metabolite CGA150829

Summary:

The relevance of the groundwater metabolite **CGA150829** has already been assessed and the assessment agreed at EU level (see **Document N4**, Syngenta File No CGA152005_10566), and the relevance assessment is applicable as well for the GAP and groundwater scenarios considered in this dRR (i.e., the conclusions reached at the EU-level are valid **also with regard to the PEC_{gw} calculated for the GAP and groundwater scenarios considered in this dRR but the Max PEC_{gw} have been updated according to the new results (please see calculations in A18385B, Part B, Section 8.8.2)).** **CGA150829** is not considered relevant according to the criteria laid down in the EC guidance document SANCO/221/2000 –rev.10. A summary of the relevance assessment is given in Table 10.5-1.

Table 10.5-1: Summary of the relevance assessment for CGA150829

	Assessment step		Result of assessment	
	STEP 1		Metabolite of no concern?	no
Quantification of groundwater contamination	STEP 2		Max PEC_{gw}	0.063 0.107 µg/L
			Based on	Tier 2eb, FOCUS-PEARL v4.4.4 maize 20 g ai/ha, Hamburg FOCUS scenario
Hazard assessment	STEP 3	Stage 1	Biological activity comparable to the parent?	no
		Stage 2	Genotoxic properties of metabolite	Non-genotoxic
		Stage 3	Toxic properties of metabolite	None
			Classification of parent	Acute Tox. 4; H302
			Classification of metabolite	None

Consumer health risk assessment	STEP 4	Estimated consumer exposure <i>via</i> drinking water and other sources; threshold of concern approach	acceptable (< 0.75µg/L)
	STEP 5	Refined risk assessment	N/A*
		Predicted exposure (% of ADI)	N/A*
		ADI based on	N/A*

* N/A: not applicable

10.5.1 STEP 1: Exclusion of degradation products of no concern

The relevance of the groundwater metabolite **CGA150829** has already been assessed and the assessment agreed at EU level. Therefore only summary of the relevance assessment is given in Table 10.5-1.

10.5.2 STEP 2: Quantification of potential groundwater contamination

The relevance of the groundwater metabolite **CGA150829** has already been assessed and the assessment agreed at EU level. Therefore only summary of the relevance assessment is given in Table 10.5-1.

10.5.3 STEP 3: Hazard assessment – identification of relevant metabolites

10.5.3.1 STEP 3, Stage 1: screening for biological activity

The relevance of the groundwater metabolite **CGA150829** has already been assessed and the assessment agreed at EU level. Therefore only summary of the relevance assessment is given in Table 10.5-1.

10.5.3.2 STEP 3, Stage 2: screening for genotoxicity

The relevance of the groundwater metabolite **CGA150829** has already been assessed and the assessment agreed at EU level. Therefore only summary of the relevance assessment is given in Table 10.5-1.

10.5.3.3 STEP 3, Stage 3: screening for toxicity

The relevance of the groundwater metabolite **CGA150829** has already been assessed and the assessment agreed at EU level. Therefore only summary of the relevance assessment is given in Table 10.5-1.

10.5.4 STEP 4: Exposure assessment – threshold of concern approach

The relevance of the groundwater metabolite **CGA150829** has already been assessed and the assessment agreed at EU level. Therefore only summary of the relevance assessment is given in Table 10.5-1.

10.5.5 STEP 5: Refined risk assessment

The relevance of the groundwater metabolite **CGA150829** has already been assessed and the assessment agreed at EU level. Therefore only summary of the relevance assessment is given in Table 10.5-1.

10.6 Relevance assessment of prosulfuron metabolite CGA325025

Summary:

The relevance of the groundwater metabolite **CGA325025** has already been assessed and the assessment agreed at EU level (see **Document N4**, Syngenta File No CGA152005_10566), and the relevance assessment is applicable as well for the GAP and groundwater scenarios considered in this dRR (i.e., the conclusions reached at the EU-level are valid also with regard to the PEC_{gw} calculated for the GAP and groundwater scenarios considered in this dRR but the Max PEC_{gw} have been updated according to the new results (please see calculations in **A18385B, Part B, Section 8.8.2**)). **CGA325025** is not considered relevant according to the criteria laid down in the EC guidance document SANCO/221/2000 –rev.10. A summary of the relevance assessment is given in Table 10.6-1.

Table 10.6-1: Summary of the relevance assessment for CGA325025

	Assessment step	Result of assessment
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	STEP 1		Metabolite of no concern?	no
Quantification of groundwater contamination	STEP 2		Max PEC _{gw}	0.059 0.109 µg/L
			Based on	Tier 2eb, FOCUS-PEARL v4.4.4 maize 20 g ai/ha, Hamburg FOCUS scenario
Hazard assessment	STEP 3	Stage 1	Biological activity comparable to the parent?	no
		Stage 2	Genotoxic properties of metabolite	Non-genotoxic
		Stage 3	Toxic properties of metabolite	None
			Classification of parent	Acute Tox. 4; H302
			Classification of metabolite	None
Consumer health risk assessment	STEP 4		Estimated consumer exposure <i>via</i> drinking water and other sources; threshold of concern approach	acceptable (< 0.75µg/L)
	STEP 5		Refined risk assessment	N/A*
			Predicted exposure (% of ADI)	N/A*
				ADI based on

* N/A: not applicable

10.6.1 STEP 1: Exclusion of degradation products of no concern

The relevance of the groundwater metabolite **CGA325025** has already been assessed and the assessment agreed at EU level. Therefore only summary of the relevance assessment is given in Table 10.6-1.

10.6.2 STEP 2: Quantification of potential groundwater contamination

The relevance of the groundwater metabolite **CGA325025** has already been assessed and the assessment agreed at EU level. Therefore only summary of the relevance assessment is given in Table 10.6-1.

10.6.3 STEP 3: Hazard assessment – identification of relevant metabolites

10.6.3.1 STEP 3, Stage 1: screening for biological activity

The relevance of the groundwater metabolite **CGA325025** has already been assessed and the assessment agreed at EU level. Therefore only summary of the relevance assessment is given in Table 10.6-1.

10.6.3.2 STEP 3, Stage 2: screening for genotoxicity

The relevance of the groundwater metabolite **CGA325025** has already been assessed and the assessment agreed at EU level. Therefore only summary of the relevance assessment is given in Table 10.6-1.

10.6.3.3 STEP 3, Stage 3: screening for toxicity

The relevance of the groundwater metabolite **CGA325025** has already been assessed and the assessment agreed at EU level. Therefore only summary of the relevance assessment is given in Table 10.6-1.

10.6.4 STEP 4: Exposure assessment – threshold of concern approach

The relevance of the groundwater metabolite **CGA325025** has already been assessed and the assessment agreed at EU level. Therefore only summary of the relevance assessment is given in Table 10.6-1.

10.6.5 STEP 5: Refined risk assessment

The relevance of the groundwater metabolite **CGA325025** has already been assessed and the assessment agreed at EU level. Therefore only summary of the relevance assessment is given in Table 10.6-1.

10.7 Relevance assessment of prosulfuron metabolite SYN542604

Summary:

The relevance of the groundwater metabolite **SYN542604** has already been assessed and the assessment agreed at EU level (see **Document N4**, Syngenta File No CGA152005_10566), and the relevance assessment is applicable as well for the GAP and groundwater scenarios considered in this dRR (i.e., the conclusions reached at the EU-level are valid **also with regard to the PEC_{gw} calculated for the GAP and groundwater scenarios considered in this dRR but the Max PEC_{gw} have been updated according to the new results (please see calculations in A18385B, Part B, Section 8.8.2).** **SYN542604** is not considered relevant according to the criteria laid down in the EC guidance document SANCO/221/2000 –rev.10. A summary of the relevance assessment is given in Table 10.7-1.

Table 10.7-1: Summary of the relevance assessment for SYN542604

	Assessment step		Result of assessment	
	STEP 1		Metabolite of no concern?	no
Quantification of groundwater contamination	STEP 2		Max PEC _{gw}	0.031-0.036 µg/L
			Based on	Tier 2eb, FOCUS-PEARL v4.4.4 winter cereals maize 20 g ai/ha, Hamburg FOCUS scenario
Hazard assessment	STEP 3	Stage 1	Biological activity comparable to the parent?	no
		Stage 2	Genotoxic properties of metabolite	Non-genotoxic
		Stage 3	Toxic properties of metabolite	None
			Classification of parent	Acute Tox. 4; H302
			Classification of metabolite	None
Consumer health risk assessment	STEP 4		Estimated consumer exposure <i>via</i> drinking water and other sources; threshold of concern approach	acceptable (< 0.75µg/L)
	STEP 5	Refined risk assessment		N/A*
		Predicted exposure (% of ADI)		N/A*
				ADI based on

* N/A: not applicable

10.7.1 STEP 1: Exclusion of degradation products of no concern

The relevance of the groundwater metabolite **SYN542604** has already been assessed and the assessment agreed at EU level. Therefore only summary of the relevance assessment is given in Table 10.7-1.

10.7.2 STEP 2: Quantification of potential groundwater contamination

The relevance of the groundwater metabolite **SYN542604** has already been assessed and the assessment agreed at EU level. Therefore only summary of the relevance assessment is given in Table 10.7-1.

10.7.3 STEP 3: Hazard assessment – identification of relevant metabolites

10.7.3.1 STEP 3, Stage 1: screening for biological activity

The relevance of the groundwater metabolite **SYN542604** has already been assessed and the assessment agreed at EU level. Therefore only summary of the relevance assessment is given in Table 10.7-1.

10.7.3.2 STEP 3, Stage 2: screening for genotoxicity

The relevance of the groundwater metabolite **SYN542604** has already been assessed and the assessment agreed at EU level. Therefore only summary of the relevance assessment is given in Table 10.7-1.

10.7.3.3 STEP 3, Stage 3: screening for toxicity

The relevance of the groundwater metabolite **SYN542604** has already been assessed and the assessment agreed at EU level. Therefore only summary of the relevance assessment is given in Table 10.7-1.

10.7.4 STEP 4: Exposure assessment – threshold of concern approach

The relevance of the groundwater metabolite **SYN542604** has already been assessed and the assessment agreed at EU level. Therefore only summary of the relevance assessment is given in Table 10.7-1.

10.7.5 STEP 5: Refined risk assessment

The relevance of the groundwater metabolite **SYN542604** has already been assessed and the assessment agreed at EU level. Therefore only summary of the relevance assessment is given in Table 10.7-1.

10.8 Relevance assessment of prosulfuron metabolite SYN547308

Summary:

The relevance of the groundwater metabolite **SYN547308** has already been assessed and the assessment agreed at EU level (see **Document N4**, Syngenta File No CGA152005_10566), and the relevance assessment is applicable as well for the GAP and groundwater scenarios considered in this dRR (i.e., the conclusions reached at the EU-level are valid **also with regard to the PEC_{gw} calculated for the GAP and groundwater scenarios considered in this dRR but the Max PEC_{gw} have been updated according to the new results (please see calculations in A18385B, Part B, Section 8.8.2)**). **SYN547308** is not considered relevant according to the criteria laid down in the EC guidance document SANCO/221/2000 –rev.10. A summary of the relevance assessment is given in Table 10.8-1.

Table 10.8-1: Summary of the relevance assessment for SYN547308

	Assessment step		Result of assessment	
	STEP 1		Metabolite of no concern?	no
Quantification of groundwater contamination	STEP 2		Max PEC _{gw}	0.092 0.094 µg/L
			Based on	Tier 2eb, FOCUS-PEARL v4.4.4 winter cereals 20 g ai/ha, Hamburg FOCUS scenario
Hazard assessment	STEP 3	Stage 1	Biological activity comparable to the parent?	no
		Stage 2	Genotoxic properties of metabolite	Non-genotoxic
		Stage 3	Toxic properties of metabolite	None
			Classification of parent	Acute Tox. 4; H302
			Classification of metabolite	None
Consumer health risk assessment	STEP 4		Estimated consumer exposure <i>via</i> drinking water and other sources; threshold of concern approach	acceptable (< 0.75µg/L)
	STEP 5		Refined risk assessment	N/A*
			Predicted exposure (% of ADI)	N/A*
				ADI based on

* N/A: not applicable

10.8.1 STEP 1: Exclusion of degradation products of no concern

The relevance of the groundwater metabolite **SYN547308** has already been assessed and the assessment agreed at EU level. Therefore only summary of the relevance assessment is given in Table 10.8-1.

10.8.2 STEP 2: Quantification of potential groundwater contamination

The relevance of the groundwater metabolite **SYN547308** has already been assessed and the assessment agreed at EU level. Therefore only summary of the relevance assessment is given in Table 10.8-1.

10.8.3 STEP 3: Hazard assessment – identification of relevant metabolites

10.8.3.1 STEP 3, Stage 1: screening for biological activity

The relevance of the groundwater metabolite **SYN547308** has already been assessed and the assessment agreed at EU level. Therefore only summary of the relevance assessment is given in Table 10.8-1.

10.8.3.2 STEP 3, Stage 2: screening for genotoxicity

The relevance of the groundwater metabolite **SYN547308** has already been assessed and the assessment agreed at EU level. Therefore only summary of the relevance assessment is given in Table 10.8-1.

10.8.3.3 STEP 3, Stage 3: screening for toxicity

The relevance of the groundwater metabolite **SYN547308** has already been assessed and the assessment agreed at EU level. Therefore only summary of the relevance assessment is given in Table 10.8-1.

10.8.4 STEP 4: Exposure assessment – threshold of concern approach

The relevance of the groundwater metabolite **SYN547308** has already been assessed and the assessment agreed at EU level. Therefore only summary of the relevance assessment is given in Table 10.8-1.

10.8.5 STEP 5: Refined risk assessment

The relevance of the groundwater metabolite **SYN547308** has already been assessed and the assessment agreed at EU level. Therefore only summary of the relevance assessment is given in Table 10.8-1.

10.9 Relevance assessment of nicosulfuron metabolite HMUD

Summary:

The relevance of the groundwater metabolite **HMUD** has already been assessed and the assessment agreed at EU level for the authorization of the product A18385B, and the relevance assessment is applicable as well for the GAP and groundwater scenarios considered in this dRR (i.e., the conclusions reached at the EU-level are valid also with regard to the PEC_{gw} calculated for the GAP and groundwater scenarios considered in this dRR). **HMUD** is not considered relevant according to the criteria laid down in the EC guidance document SANCO/221/2000 –rev.10. A summary of the relevance assessment is given in Table 10.9-1.

Table 10.9-1: Summary of the relevance assessment for HMUD

	Assessment step		Result of assessment	
	STEP 1		Metabolite of no concern?	no
Quantification of groundwater contamination	STEP 2		Max PEC_{gw}	0.458 µg/L
			Based on	FOCUS-PEARL v4.4.4 maize 50 g ai/ha, Hamburg FOCUS scenario
Hazard assessment	STEP 3	Stage 1	Biological activity comparable to the parent?	no

		Stage 2	Genotoxic properties of metabolite	Non-genotoxic
		Stage 3	Toxic properties of metabolite	None
			Classification of parent	None
			Classification of metabolite	None
Consumer health risk assessment	STEP 4		Estimated consumer exposure <i>via</i> drinking water and other sources; threshold of concern approach	acceptable (< 0.75µg/L)
	STEP 5	Refined risk assessment	N/A*	
		Predicted exposure (% of ADI)	N/A*	
			ADI based on	N/A*
* N/A: not applicable				

10.9.1 STEP 1: Exclusion of degradation products of no concern

The relevance of the groundwater metabolite **HMUD** has already been assessed and the assessment agreed at EU level. Therefore only summary of the relevance assessment is given in Table 10.9-1.

10.9.2 STEP 2: Quantification of potential groundwater contamination

The relevance of the groundwater metabolite **HMUD** has already been assessed and the assessment agreed at EU level. Therefore only summary of the relevance assessment is given in Table 10.9-1.

10.9.3 STEP 3: Hazard assessment – identification of relevant metabolites

10.9.3.1 STEP 3, Stage 1: screening for biological activity

The relevance of the groundwater metabolite **HMUD** has already been assessed and the assessment agreed at EU level. Therefore only summary of the relevance assessment is given in Table 10.9-1.

10.9.3.2 STEP 3, Stage 3: screening for toxicity

The relevance of the groundwater metabolite **HMUD** has already been assessed and the assessment agreed at EU level. Therefore only summary of the relevance assessment is given in Table 10.9-1.

10.9.4 STEP 4: Exposure assessment – threshold of concern approach

The relevance of the groundwater metabolite **HMUD** has already been assessed and the assessment agreed at EU level. Therefore only summary of the relevance assessment is given in Table 10.9-1.

10.9.5 STEP 5: Refined risk assessment

The relevance of the groundwater metabolite **HMUD** has already been assessed and the assessment agreed at EU level. Therefore only summary of the relevance assessment is given in Table 10.9-1.

10.10 Relevance assessment of nicosulfuron metabolite AUSN

Summary:

The relevance of the groundwater metabolite **AUSN** has already been assessed and the assessment agreed at EU level for the authorization of the product A18385B, and the relevance assessment is applicable as well for the GAP and groundwater scenarios considered in this dRR (i.e., the conclusions reached at the EU-level are valid also with regard to the PEC_{gw} calculated for the GAP and groundwater scenarios considered in this dRR). **AUSN** is not considered relevant according to the criteria laid down in the EC guidance document SANCO/221/2000 –rev.10. A summary of the relevance assessment is given in Table 10.10-1.

Table 10.10-1: Summary of the relevance assessment for AUSN

	Assessment step		Result of assessment	
	STEP 1		Metabolite of no concern?	no
Quantification of groundwater contamination	STEP 2		Max PEC _{gw}	1.79 1.95 µg/L
			Based on	FOCUS PELMO v5.5.3 FOCUS-PEARL v4.4.4 maize 50 g ai/ha, Thiva FOCUS scenario
Hazard assessment	STEP 3	Stage 1	Biological activity comparable to the parent?	no
		Stage 2	Genotoxic properties of metabolite	Non-genotoxic
		Stage 3	Toxic properties of metabolite	None
			Classification of parent	None
			Classification of metabolite	None
Consumer health risk assessment	STEP 4		Estimated consumer exposure <i>via</i> drinking water and other sources; threshold of concern approach	not acceptable (> 0.75 µg/L)
	STEP 5	Refined risk assessment		Acceptable
		Predicted exposure (% of ADI)		Adult: < 0.1 % of ADI [#] Child: < 0.1 % of ADI [§] Infant: < 0.1 % of ADI ^{\$}
			ADI based on	In the absence of toxicological information on AUSN the parent (nicosulfuron) acceptable daily intake (ADI) value may be used. The ADI for nicosulfuron was derived from the 28-day, 90-day and 1-year toxicity studies in the dog and the chronic rat study and using a safety factor of 100. The ADI for nicosulfuron is 2.0 mg/kg bw/day.
# ADI utilisation (%) = [PEC _{gw} (µg/L) × water consumption (L/day) × 100] / [bw (kg) × 1000 × ADI (mg/kg bw/day)] Calculation of risk (% ADI) for 60-kg adult (consuming 2.0 L/day) § ADI utilisation (%) = [PEC _{gw} (µg/L) × water consumption (L/day) × 100] / [bw (kg) × 1000 × ADI (mg/kg bw/day)] Calculation of risk (% ADI) for 10-kg adult child (consuming 1.0 L/day) \$ ADI utilisation (%) = [PEC _{gw} (µg/L) × water consumption (L/day) × 100] / [bw (kg) × 1000 × ADI (mg/kg bw/day)] Calculation of risk (% ADI) for 5-kg adult infant (consuming 0.75 L/day)				

10.10.1 STEP 1: Exclusion of degradation products of no concern

The relevance of the groundwater metabolite **AUSN** has already been assessed and the assessment agreed at EU level. Therefore only summary of the relevance assessment is given in Table 10.10-1.

10.10.2 STEP 2: Quantification of potential groundwater contamination

The relevance of the groundwater metabolite **AUSN** has already been assessed and the assessment agreed at EU level. Therefore only summary of the relevance assessment is given in Table 10.10-1.

10.10.3 STEP 3: Hazard assessment – identification of relevant metabolites

10.10.3.1 STEP 3, Stage 1: screening for biological activity

The relevance of the groundwater metabolite **AUSN** has already been assessed and the assessment agreed at EU level. Therefore only summary of the relevance assessment is given in Table 10.10-1.

10.10.3.2 STEP 3, Stage 3: screening for toxicity

The relevance of the groundwater metabolite **AUSN** has already been assessed and the assessment agreed at EU level. Therefore only summary of the relevance assessment is given in Table 10.10-1.

10.10.4 STEP 4: Exposure assessment – threshold of concern approach

The relevance of the groundwater metabolite **AUSN** has already been assessed and the assessment agreed at EU level. Therefore only summary of the relevance assessment is given in Table 10.10-1.

10.10.5 STEP 5: Refined risk assessment

The relevance of the groundwater metabolite **AUSN** has already been assessed and the assessment agreed at EU level. Therefore only summary of the relevance assessment is given in Table 10.10-1.

10.11 Relevance assessment of nicosulfuron metabolite UCSN

Summary:

The relevance of the groundwater metabolite **UCSN** has already been assessed and the assessment agreed at EU level for the authorization of the product A18385B, and the relevance assessment is applicable as well for the GAP and groundwater scenarios considered in this dRR (i.e., the conclusions reached at the EU-level are valid also with regard to the PEC_{gw} calculated for the GAP and groundwater scenarios considered in this dRR). **UCSN** is not considered relevant according to the criteria laid down in the EC guidance document SANCO/221/2000 –rev.10. A summary of the relevance assessment is given in Table 10.11-1.

Table 10.11-1: Summary of the relevance assessment for UCSN

	Assessment step		Result of assessment	
	STEP 1		Metabolite of no concern?	no
Quantification of groundwater contamination	STEP 2		Max PEC _{gw}	1.37 µg/L
			Based on	FOCUS-PEARL v4.4.4 maize 50 g ai/ha, Thiva FOCUS scenario
Hazard assessment	STEP 3	Stage 1	Biological activity comparable to the parent?	no
		Stage 2	Genotoxic properties of metabolite	Non-genotoxic
		Stage 3	Toxic properties of metabolite	None
			Classification of parent	None
			Classification of metabolite	None
Consumer health risk assessment	STEP 4		Estimated consumer exposure <i>via</i> drinking water and other sources; threshold of concern approach	not acceptable (> 0.75 µg/L)
	STEP 5		Refined risk assessment	Acceptable
			Predicted exposure (% of ADI)	Adult: < 0.1 % of ADI [#]

			Child: < 0.1 % of ADI [§] Infant: < 0.1 % of ADI [§]
		ADI based on	In the absence of toxicological information on UCSN the parent (nicosulfuron) acceptable daily intake (ADI) value may be used. The ADI for nicosulfuron was derived from the 28-day, 90-day and 1-year toxicity studies in the dog and the chronic rat study and using a safety factor of 100. The ADI for nicosulfuron is 2.0 mg/kg bw/day.
[#] ADI utilisation (%) = $[\text{PEC}_{\text{gw}} (\mu\text{g/L}) \times \text{water consumption (L/day)} \times 100] / [\text{bw (kg)} \times 1000 \times \text{ADI (mg/kg bw/day)}]$ Calculation of risk (% ADI) for 60-kg adult (consuming 2.0 L/day) [§] ADI utilisation (%) = $[\text{PEC}_{\text{gw}} (\mu\text{g/L}) \times \text{water consumption (L/day)} \times 100] / [\text{bw (kg)} \times 1000 \times \text{ADI (mg/kg bw/day)}]$ Calculation of risk (% ADI) for 10-kg adult child (consuming 1.0 L/day) ^{\$} ADI utilisation (%) = $[\text{PEC}_{\text{gw}} (\mu\text{g/L}) \times \text{water consumption (L/day)} \times 100] / [\text{bw (kg)} \times 1000 \times \text{ADI (mg/kg bw/day)}]$ Calculation of risk (% ADI) for 5-kg adult infant (consuming 0.75 L/day)			

10.11.1 STEP 1: Exclusion of degradation products of no concern

The relevance of the groundwater metabolite UCSN has already been assessed and the assessment agreed at EU level. Therefore only summary of the relevance assessment is given in Table 10.11-1.

10.11.2 STEP 2: Quantification of potential groundwater contamination

The relevance of the groundwater metabolite UCSN has already been assessed and the assessment agreed at EU level. Therefore only summary of the relevance assessment is given in Table 10.11-1.

10.11.3 STEP 3: Hazard assessment – identification of relevant metabolites

10.11.3.1 STEP 3, Stage 1: screening for biological activity

The relevance of the groundwater metabolite UCSN has already been assessed and the assessment agreed at EU level. Therefore only summary of the relevance assessment is given in Table 10.11-1.

10.11.3.2 STEP 3, Stage 3: screening for toxicity

The relevance of the groundwater metabolite UCSN has already been assessed and the assessment agreed at EU level. Therefore only summary of the relevance assessment is given in Table 10.11-1.

10.11.4 STEP 4: Exposure assessment – threshold of concern approach

The relevance of the groundwater metabolite UCSN has already been assessed and the assessment agreed at EU level. Therefore only summary of the relevance assessment is given in Table 10.11-1.

10.11.5 STEP 5: Refined risk assessment

The relevance of the groundwater metabolite UCSN has already been assessed and the assessment agreed at EU level. Therefore only summary of the relevance assessment is given in Table 10.11-1.

10.12 Relevance assessment of nicosulfuron metabolite ASDM

Summary:

The relevance of the groundwater metabolite ASDM has already been assessed and the assessment agreed at EU level for the authorization of the product A18385B, and the relevance assessment is applicable as well for the GAP and groundwater scenarios considered in this dRR (i.e., the conclusions reached at the EU-level are valid also with regard to the PEC_{gw} calculated for the GAP and groundwater scenarios considered in this dRR). ASDM is not considered relevant according to the criteria laid down in the EC guidance document SANCO/221/2000 –rev.10. A summary of the relevance assessment is given in Table 10.12-1.

Table 10.12-1: Summary of the relevance assessment for ASDM

	Assessment step		Result of assessment	
	STEP 1		Metabolite of no concern?	no
Quantification of groundwater contamination	STEP 2		Max PEC _{gw}	1.23 1.26 µg/L
			Based on	FOCUS-PEARL v4.4.4 maize 50 g ai/ha, Thiva FOCUS scenario
Hazard assessment	STEP 3	Stage 1	Biological activity comparable to the parent?	no
		Stage 2	Genotoxic properties of metabolite	Non-genotoxic
		Stage 3	Toxic properties of metabolite	None
			Classification of parent	None
			Classification of metabolite	None
Consumer health risk assessment	STEP 4		Estimated consumer exposure <i>via</i> drinking water and other sources; threshold of concern approach	not acceptable (> 0.75 µg/L)
	STEP 5	Refined risk assessment		Acceptable
		Predicted exposure (% of ADI)		Adult: < 0.1 % of ADI [#] Child: < 0.1 % of ADI [§] Infant: < 0.1 % of ADI ^{\$}
			ADI based on	In the absence of toxicological information on ASDM the parent (nicosulfuron) acceptable daily intake (ADI) value may be used. The ADI for nicosulfuron was derived from the 28-day, 90-day and 1-year toxicity studies in the dog and the chronic rat study and using a safety factor of 100. The ADI for nicosulfuron is 2.0 mg/kg bw/day.
# ADI utilisation (%) = [PEC _{gw} (µg/L) × water consumption (L/day) × 100] / [bw (kg) × 1000 × ADI (mg/kg bw/day)] Calculation of risk (% ADI) for 60-kg adult (consuming 2.0 L/day) § ADI utilisation (%) = [PEC _{gw} (µg/L) × water consumption (L/day) × 100] / [bw (kg) × 1000 × ADI (mg/kg bw/day)] Calculation of risk (% ADI) for 10-kg adult child (consuming 1.0 L/day) \$ ADI utilisation (%) = [PEC _{gw} (µg/L) × water consumption (L/day) × 100] / [bw (kg) × 1000 × ADI (mg/kg bw/day)] Calculation of risk (% ADI) for 5-kg adult infant (consuming 0.75 L/day)				

10.12.1 STEP 1: Exclusion of degradation products of no concern

The relevance of the groundwater metabolite **ASDM** has already been assessed and the assessment agreed at EU level. Therefore only summary of the relevance assessment is given in Table 10.12-1.

10.12.2 STEP 2: Quantification of potential groundwater contamination

The relevance of the groundwater metabolite **ASDM** has already been assessed and the assessment agreed at EU level. Therefore only summary of the relevance assessment is given in Table 10.12-1.

10.12.3 STEP 3: Hazard assessment – identification of relevant metabolites

10.12.3.1 STEP 3, Stage 1: screening for biological activity

The relevance of the groundwater metabolite **ASDM** has already been assessed and the assessment agreed at EU level. Therefore only summary of the relevance assessment is given in Table 10.12-1.

10.12.3.2 STEP 3, Stage 3: screening for toxicity

The relevance of the groundwater metabolite **ASDM** has already been assessed and the assessment agreed at EU level. Therefore only summary of the relevance assessment is given in Table 10.12-1.

10.12.4 STEP 4: Exposure assessment – threshold of concern approach

The relevance of the groundwater metabolite **ASDM** has already been assessed and the assessment agreed at EU level. Therefore only summary of the relevance assessment is given in Table 10.12-1.

10.12.5 STEP 5: Refined risk assessment

The relevance of the groundwater metabolite **ASDM** has already been assessed and the assessment agreed at EU level. Therefore only summary of the relevance assessment is given in Table 10.12-1.

10.13 Relevance assessment of nicosulfuron metabolite MU-466

Summary:

The relevance of the groundwater metabolite **MU-466** has already been assessed and the assessment agreed at EU level for the authorization of the product A18385B, and the relevance assessment is applicable as well for the GAP and groundwater scenarios considered in this dRR (i.e., the conclusions reached at the EU-level are valid also with regard to the PEC_{gw} calculated for the GAP and groundwater scenarios considered in this dRR). **MU-466** is not considered relevant according to the criteria laid down in the EC guidance document SANCO/221/2000 –rev.10. A summary of the relevance assessment is given in Table 10.12-1.

Table 10.13-1: Summary of the relevance assessment for MU-466

	Assessment step		Result of assessment	
	STEP 1		Metabolite of no concern?	no
Quantification of groundwater contamination	STEP 2		Max PEC _{gw}	0.085 0.113 µg/L
			Based on	FOCUS-PEARL v4.4.4 maize 50 g ai/ha, Thiva FOCUS scenario
Hazard assessment	STEP 3	Stage 1	Biological activity comparable to the parent?	no
		Stage 2	Genotoxic properties of metabolite	Non-genotoxic
		Stage 3	Toxic properties of metabolite	None
			Classification of parent	None
			Classification of metabolite	None
Consumer health risk assessment	STEP 4		Estimated consumer exposure <i>via</i> drinking water and other sources; threshold of concern approach	acceptable (< 0.75µg/L)
	STEP 5		Refined risk assessment	N/A*
			Predicted exposure (% of ADI)	N/A*

		ADI based on	N/A*
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* N/A: not applicable

10.13.1 STEP 1: Exclusion of degradation products of no concern

The relevance of the groundwater metabolite **MU-466** has already been assessed and the assessment agreed at EU level. Therefore only summary of the relevance assessment is given in Table 10.12-1.

10.13.2 STEP 2: Quantification of potential groundwater contamination

The relevance of the groundwater metabolite **MU-466** has already been assessed and the assessment agreed at EU level. Therefore only summary of the relevance assessment is given in Table 10.12-1.

10.13.3 STEP 3: Hazard assessment – identification of relevant metabolites

10.13.3.1 STEP 3, Stage 1: screening for biological activity

The relevance of the groundwater metabolite **MU-466** has already been assessed and the assessment agreed at EU level. Therefore only summary of the relevance assessment is given in Table 10.12-1.

10.13.3.2 STEP 3, Stage 3: screening for toxicity

The relevance of the groundwater metabolite **MU-466** has already been assessed and the assessment agreed at EU level. Therefore only summary of the relevance assessment is given in Table 10.12-1.

10.13.4 STEP 4: Exposure assessment – threshold of concern approach

The relevance of the groundwater metabolite **MU-466** has already been assessed and the assessment agreed at EU level. Therefore only summary of the relevance assessment is given in Table 10.12-1.

10.13.5 STEP 5: Refined risk assessment

The relevance of the groundwater metabolite **MU-466** has already been assessed and the assessment agreed at EU level. Therefore only summary of the relevance assessment is given in Table 10.12-1.

Appendix 1 Lists of data considered in support of the evaluation

Appendix 2 Additional information

No new studies are submitted