

REGISTRATION REPORT

Part B

Section 7

Metabolism and Residues

Detailed summary of the risk assessment

Product code: **AMINO 30 SL**

Product name(s): El Camino 30 SL, Ranchero 30 SL

Chemical active substance:

Aminopyralid, 30 g/L

Central Zone

Zonal Rapporteur Member State: PL

CORE ASSESSMENT

(authorization)

Applicant: Innvigo Sp. z o.o.

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April 2025	zRMS Assessment
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7 Metabolism and residue data (KCA section 6)

7.1 Summary and zRMS Conclusion

7.1.1 Critical GAP(s) and overall conclusion

Selection of critical uses and justification

The critical GAPs with respect to consumer intake and risk assessment for the preparation AMINO 30 SL are presented in Table 7.1-1. They have been selected from the individual GAPs in the zone for winter oil seed rape. A list of all intended uses within the zone is given in Part B, Section 0.

Overall conclusion

The data available is considered sufficient for risk assessment. An exceedance of the current MRL of 0.05 mg/kg for aminopyralid as laid down in Reg. (EU) 2021/1841 is not expected.

The chronic and the short-term intakes of aminopyralid residues are unlikely to present a public health concern.

As far as consumer health protection is concerned, zRMS agrees with the authorization of the intended use(s).

According to available data, no specific mitigation measures should apply.

This report has been prepared on the request expressed in letter from the Ministry of Agriculture and Rural Development in Poland dated 28 March 2025 as a result of application of Innvigo Sp. z o.o. authorisation of product Amino 30 SL to rapeseed and grassland. The assessment is based on the available residue information. No new data have been submitted by the Applicant in the framework of this application.

According to the data evaluated at EU level aminopyralid residues were found to be stable at $\leq 20^{\circ}\text{C}$ for at least 16 months in high water content, high starch and dry matrices. In high oil content matrices the studies demonstrated storage stability for a period of 25 months.

The metabolism of aminopyralid investigated in three varieties of grass and in cereals and oilseeds indicated similar pathway. The residue definition for enforcement and risk assessment in cereals/grass and oilseeds is proposed as the sum of aminopyralid and its conjugates, expressed as aminopyralid. The same residue definition is applicable for rotational crops.

The metabolism of aminopyralid residues in livestock resulted in the residue definition for enforcement and risk assessment as aminopyralid only.

Specific studies investigating the magnitude of aminopyralid residues in processed commodities are not required, as the residues expected in primary crops are low and the total theoretical maximum daily intake (TMDI) is below the trigger value of 10 % of the ADI.

The available residue studies show that the current MRL of 0.05 mg/kg for rape (Reg. (EU) 2021/1841) will not be exceeded. Grasslands are not in the scope of residue assessment.

No new studies for residues in succeeding crops have been submitted in the framework of this application. Based on the EFSA opinion, to avoid the presence of aminopyralid residues in succeeding crops, a 90-day PBI is recommended, however according to Efficacy section (B3) for some crops a period of 4 months is indicated, which is included in the product label and Appendix 1 of Section A of registration report.

The dietary burden calculation indicates that the livestock exposure to rape meal is insignificant.

The proposed use of aminopyralid in the formulation Amino 30 SL on rapeseed does not represent unacceptable acute and chronic risks for the consumers when the product is used according to the GAP.

Data gaps

Noticed data gaps are: None

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

1	2	3	4	5	6	7		8				9			10	11
GAP number (see part B.0)*	Crop and/ or situation **	Zone	Product code	F, Fn, Fpn G, Gn, Gpn or I***	Pests or Group of pests controlled	Formulation		Application				Application rate per treatment			PHI (days)	Conclusion
						Type	Conc. of as	method kind	growth stage & season	number min max	interval between applications (min)	kg as/hL min max	water L/ha min max	kg as/ha min max		
1	Winter oilseed rape 401060	NEU	AMINO 30 SL	F	Dicotyledonous weeds	SL	30 g/l ami-nopyralid	Spray, medium spray	Autumn BBCH 10-18	a) 1 per use b) 1 per season	n/a	0.002-0.004	200-300	0.006-0.00801	-	A

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

** Use also code numbers according to Annex I of Regulation (EU) No 396/2005

*** F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application

Explanation for Column 11 “Conclusion”

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

Table 7.1-2: Assessed (critical) uses during approval of aminopyralid

Summary of representative uses evaluated (*aminopyralid*)

Crop and/or situation (a)	Member State or Country	Product Name	F G or I (b)	Pests or Group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (l)	Remarks (m)
					Type (d-f)	Conc. of a.s.g/l (i)	Method Kind (f-h)	Growth stage & season (j)	Number min-max (k)	Interval between apps	g a.s./hL min-max	water (L/ha) min-max	g a.s./ha min-max		
Grassland established and rotational pasture	EU BE, DE, FR, IE NL, LU, UK	GF-839	F	Broad-leaved weeds	EO	Aminopyralid (A): 30 Fluroxypyr (F): 100	Broadcast Foliar Tractor mounted boom sprayer	Established grassland* Spring/ Summer	1 per year	N/A	A: 15-30 F: 50-100	200-400	A: 60 F: 200	7	A gun sprayer or knapsack with hand lance may be used in some countries
Amenity grassland	EU UK, BE, FR, ES, IT, LU	GF-839	F	Broad-leaved weeds	EO	Aminopyralid (A): 30 Fluroxypyr (F): 100	Broadcast Foliar Tractor/van mounted boom or gun sprayer Knapsack with hand lance	Established grassland Spring/ Summer	1 per year	N/A	A: 10-30 F: 33-100	200-600	A: 60 F: 200	7	

* GF-839 may be used on established grassland intended for grazing in the calendar year of application. GF-839 may NOT be used on fields intended for hay, haylage or silage production in the calendar year of application.

<p>* For uses where the column "Remarks" is marked in grey further consideration is necessary. Uses should be crossed out when the notifier no longer supports this use(s).</p> <p>(a) For crops, the EU and Codex classifications (both) should be taken into account; where relevant, the use situation should be described (e.g. fumigation of a structure)</p> <p>(b) Outdoor or field use (F), greenhouse application (G) or indoor application (I)</p> <p>(c) e.g. biting and sucking insects, soil born insects, foliar fungi, weeds</p> <p>(d) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)</p> <p>(e) GCPF Codes - GIFAP Technical Monograph No 2, 1989</p> <p>(f) All abbreviations used must be explained</p> <p>(g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench</p> <p>(h) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plant- type of equipment used must be indicated</p>	<p>(i) g/kg or g/L. Normally the rate should be given for the active substance (according to ISO) and not for the variant in order to compare the rate for same active substances used in different variants (e.g. fluroxypyr). In certain cases, where only one variant is synthesised, it is more appropriate to give the rate for the variant (e.g. benthialvalicarb-isopropyl).</p> <p>(j) Growth stage at last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application</p> <p>(k) Indicate the minimum and maximum number of application possible under practical conditions of use</p> <p>(l) The values should be given in g or kg whatever gives the more manageable number (e.g. 200 kg/ha instead of 200 000 g/ha or 12.5 g/ha instead of 0.0125 kg/ha)</p> <p>(m) PHI - minimum pre-harvest interval</p>
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7.1.2 Summary of the evaluation

The preparation AMINO 30 SL is composed of aminopyralid.

Table 7.1-2: Toxicological reference values for the dietary risk assessment of aminopyralid

Reference value	Source	Year	Value	Study relied upon	Safety factor
Aminopyralid					
ADI	<i>EFSA Journal 2013;11(9):3352</i>	2013	0.26 mg/kg bw per day	Developmental rabbit study (maternal toxicity of aminopyralid TIPA)	100
ARfD	<i>EFSA Journal 2013;11(9):3352</i>	2013	0.26 mg/kg bw	Developmental rabbit study (maternal toxicity of aminopyralid TIPA)	100

7.1.2.1 Summary for aminopyralid

Table 7.1-3: Summary for aminopyralid

Use-No.*	Crop	Plant metabolism covered?	Sufficient residue trials?	PHI sufficiently supported?	Sample storage covered by stability data?	MRL compliance	Chronic risk for consumers identified?	Acute risk for consumers identified?
1	Winter oilseed rape	Yes	Yes	Yes	Yes	Yes	No	No

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

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

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

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

7.1.2.2 Summary for AMINO 30 SL

Table 7.1-4: Information on AMINO 30 SL (KCA 6.8)

Crop	PHI for AMINO 30 SL proposed by applicant	PHI/ Withholding period* sufficiently supported for	PHI for AMINO 30 SL proposed by zRMS	zRMS Comments (if different PHI proposed)
		Aminopyralid		
Winter oilseed rape	NR	NR	NR	NR

NR: not relevant

* Purpose of withholding period to be specified

** F: PHI is defined by the application stage at last treatment (time elapsing between last treatment and harvest of the crop).

Table 7.1-5: Waiting periods before planting succeeding crops

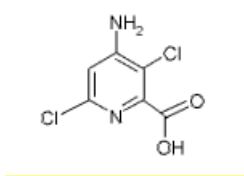
Waiting period before planting succeeding crops		Overall waiting period proposed by zRMS for AMINO 30 SL
Crop group	Led by amino-pyralid	
Leafy vegetables	90	90
Root vegetables	90	90
Cereals	90	90

NR: not relevant

7.2 Aminopyralid

General data on aminopyralid are summarized in the table below (last updated 2024/12/20)

Table 7.2-1: General information on aminopyralid

Active substance (ISO Common Name)	Aminopyralid
IUPAC	4-amino-3,6-dichloropyridine-2-carboxylic acid
Chemical structure	
Molecular formula	C ₆ H ₄ Cl ₂ N ₂ O ₂
Molar mass	207.026 g/mol
Chemical group	Pyridine carboxylic acid group
Mode of action (if available)	Herbicide
Systemic	Yes
Company (ies)	DAS
Rapporteur Member State (RMS)	UK
Approval status	Approved Date of approval (01/01/2015) (COMMISSION IMPLEMENTING REGULATION (EU) No 891/2014 of 14 August 2014)
Restriction (e.g. is restricted to use as "...")	For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on aminopyralid, and in particular Appendices I and II thereof, as finalised in the Standing Committee on Plants, Animals, Food and Feed on 11 July 2014 shall be taken into account. In this overall assessment Member States shall pay particular attention to: (a) the risk to groundwater, if the substance is applied under vulnerable soil or climatic conditions; (b) the risk to aquatic macrophytes and terrestrial non-target plants; (c) chronic risk to fish. Conditions of use shall include risk mitigation measures, where appropriate.
Review Report	SANCO/11423/2014 - rev. 1 11/07/2014
Current MRL regulation	Regulation (EU) 2021/1841
Peer review of MRLs according to Article 12 of Reg No 396/2005 EC performed	Yes
EFSA Journal : Conclusion on the peer review	Yes EFSA Journal 2013;11(9):3352
EFSA Journal: conclusion on article 12	Yes EFSA Journal 2020;18(8):6229

Current MRL applications on intended uses	N/A – MRL already set
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* Notifier in the EU process to whom the a.s. belong(s)

** If yes: EFSA, YYYY - see list of references

7.2.1 Stability of Residues (KCA 6.1)

7.2.1.1 Stability of residues during storage of samples

Available data

No new data submitted in the framework of this application.

The storage stability of residues in plant matrices were presented during Aminopyralid Annex I inclusion (hay, forage grass, wheat grain and wheat straw) and in the Registration Report of Navigator 360 SL - Poland, 2010 (oilseed rape);

We are obliged to rely upon following studies taking account that according to Regulation (EC) No 1107/2009 Article 59 Data protection: The period of data protection is 10 years starting at the date of first authorization in that Member State, except as provided in paragraph 2 of this Article or in Article 62. According to Official Journal of the European Union C 229/2 Period of protection is 10 years from date of first authorization of the product in each Member State (not the date of authorization of the new crop). First registration of the product was in 15.12.2010, therefore data protection was over on 14.12.2020, and other Applicants can refer to studies performed during authorization process.

The storage stability of residues in plant matrices is summarized in Table 7.2-2:

Table 7.2-2: Summary of stability data achieved at $\leq -18^{\circ}\text{C}$ (unless stated otherwise)

Matrix	Characteristics of the matrix	Acceptable Maximum Storage duration	Reference
Data relied on EU			
Plant products (Sum of aminopyralid and its conjugates expressed as aminopyralid)			
Hay (grass)	Dry commodities	187 days	Draft Assessment Report (DAR), Aminopyralid Lindsay, D.A. Frozen <i>Storage Stability of XDE-750 in Range Land and Pasture Grass and Hay and Wheat Straw and Wheat Grain</i> Report No.: 030004.01
Forage (grass)	High water content commodities	187 days	
Wheat grain	Dry commodities	168 days	
Wheat straw	Dry commodities	175 days	
oilseed rape- seeds	High oil content	25 months	Registration Report of Navigator 360 SL - Poland, 2010

Feeding studies: Samples of muscle, liver, fat and kidney were collected and stored frozen until analysis. All samples were analysed within 30 days.

Conclusion on stability of residues during storage

The time in which the initial analyses were conducted was within the acceptable storage range for samples. All samples from feeding studies were analysed within 30 days.

As a result, no additional work is needed to confirm storage stability of residues.

7.2.1.2 Stability of residues in sample extracts (KCA 6.1)

Available data

According to Registration report of Navigator 360 SL- Poland, 2010: the time in which the final HPLC analyses were conducted was within the acceptable storage range for sample extracts. As a result, no additional work is needed to confirm storage stability.

Conclusion on stability of residues in sample extracts

No additional studies are needed to confirm stability of residues in sample extracts.

zRMS comment: No new studies have been submitted in the framework of this application. The Applicant referred to the data evaluated during aminopyralid Annex I inclusion.

According to the EFSA Journal 2013;11(9):3352 – “Peer review of the pesticide risk assessment of the active substance aminopyralid”:

Residues of aminopyralid stable at least 16 months in matrices with:

- high water content: (forage and grass)

- high starch content: (wheat grain) and

- dry matrices: (straw, hay),

when stored at -20°C.

In high oil content matrices the studies demonstrated storage stability for a period of 25 months, thus the storage stability data covers the required use of aminopyralid in rape.

7.2.2 Nature of residues in plants, livestock and processed commodities

7.2.2.1 Nature of residue in primary crops (KCA 6.2.1)

Available data

No new data submitted in the framework of this application.

The metabolism of aminopyralid in primary crop studies (wheat and grass) were evaluated by the United Kingdom in the framework of the peer review under Directive 91/414/EEC (United Kingdom, 2012).

Moreover, the metabolism of aminopyralid in primary crops (oilseed rape) studies were assessed in the Registration report of Navigator 360 SL- Poland, 2010; Linder, S.J. 2007, *A Nature of Residue Study with ¹⁴C Labeled Aminopyralid Applied to Oilseed Rape*; Dow AgroSciences; DAS Report No.: 060011.

We are obliged to rely upon following studies taking account that according to Regulation (EC) No 1107/2009 Article 59 Data protection: The period of data protection is 10 years starting at the date of first authorization in that Member State, except as provided in paragraph 2 of this Article or in Article 62.

According to Official Journal of the European Union C 229/2 Period of protection is 10 years from date of first authorization of the product in each Member State (not the date of authorization of the new crop).

First registration of the product was in 15.12.2010, therefore data protection was over on 14.12.2020, and other Applicants can refer to studies performed during authorization process.

The overview of the study design is presented in the table below.

Table 7.2-3: Summary of plant metabolism studies

Crop Group	Crop	Label position	Application and sampling details					Reference
			Method, F or G (a)	Rate (kg a.s./ha)	No	Sampling (DAT)	Remarks	
EU data								
Pulses and oilseeds	Oilseed rape	2- and 6- ¹⁴ C pyridine ring	F	0.015 kg ai/ha (actual application rate: 0.0136 kg ai/ha)	1	0 (forage), 7 (forage), 14 (forage), 28 (forage), 62 (whole plant, seed) DAT	Treatment at BBCH 51	Registration report of Navigator 360 SL- Poland, 2010; Linder, S.J. 2007, <i>A Nature of Residue Study with 14C Labeled Aminopyralid Applied to Oilseed Rape</i> ; Dow AgroSciences; DAS Report No.: 060011.
Cereals/Grass crops	Grass	2- and 6- ¹⁴ C pyridine ring	F	0.360 kg a.s./ha	1	0, 7, 14, 21, 42 (grass) and 42 (hay, air dried for 1-2 days) DAT	Three varieties of common pasture were treated in the US	Final addendum to the Draft Assessment Report (DAR), Aminopyralid, July 2013; Graper, L.K.; Smith, K.P.; Hilla, S. 2003 <i>A Nature of the Residue Study with 14C-Labeled XDE-750 Applied to Spring Wheat</i> DAS, Indiana, USA & Research for Hire, California, USA Report No.: 020022.
	Spring wheat	2- and 6- ¹⁴ C pyridine ring	F	0.040 and 0.080	1	0, 14 (forage), 35 (hay), 86 (straw) and 86	BBCH 26–28 treatment in the US	Final addendum to the Draft Assessment Report

						(grain) DAT		(DAR), Aminopyralid, July 2013; Graper, L.K.; Smith, K.P.; Hilla, S. 2003 <i>A Nature of the Residue Study with 14C-Labeled XDE-750 Applied to Spring Wheat</i> DAS, Indiana, USA & Research for Hire, California, USA Report No.: 020022.
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Summary of plant metabolism studies reported in the EU

Metabolism in plants was investigated in wheat, three different varieties of grass and in oilseed rape using a single application of ¹⁴C-aminopyralid labelled in the 2 and 6 position of the pyridine ring. Samples were collected just after application and at regular intervals up to 42 for grass, 86 days for wheat and 62 days for rape seed.

The main identified components in grass, wheat and rape seed metabolism studies were the parent aminopyralid and its conjugates which were released as parent aminopyralid upon hydrolytic extraction conditions. At 0 day after application the residue consisted principally of parent aminopyralid but after longer harvest intervals, levels of parent declined while levels of conjugated aminopyralid were increasing.

Conclusion on metabolism in primary crops

The metabolism in primary crops studies assessed in Final addendum to the Draft Assessment Report (DAR), Aminopyralid, July 2013 and Registration report of Navigator 360 SL cover use of AMINO 30 SL on oilseed rape. No new studies are necessary.

zRMS comment: The metabolism of aminopyralid was investigated in three varieties of grass and in cereals and oilseeds. The metabolism of aminopyralid was similar in all crops assessed. the residue definition for enforcement and risk assessment in cereals/grass and oilseeds is proposed as the sum of aminopyralid and its conjugates, expressed as aminopyralid.

7.2.2.2 Nature of residue in rotational crops (KCA 6.6.1)

Available data

No new data submitted in the framework of this application.

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

Crop group	Crop	Label position	Application and sampling details					Reference
			Method, F or G *	Rate (kg a.s./ha)	Sowing intervals (DAT)	Harvest Intervals (DAT)	Remarks	
Aminopyralid								
Leaf vegetables	Lettuce	2- and 6- ¹⁴ C pyridine ring	Applied to the bare ground soil	0.01	90 and 120 DAT	Plants: various growth stages; Soil: 0 DAT and after sowing (90 or 120 DAT)	No residue above 0.01 mg/kg was detected in plant samples	Final addendum to the Draft Assessment Report (DAR), Aminopyralid, July 2013; Magnussen, J. D. 2004b <i>A Confined Rotational Crop Study with ¹⁴C XDE-750</i> . DAS, Indiana, USA & Research for Hire, California, USA; Report No.: 030008.
Root and tuber vegetables	Turnips	2- and 6- ¹⁴ C pyridine ring	Applied to the bare ground soil	0.01	90 and 120 DAT	Plants: various growth stages; Soil: 0 DAT and after sowing (90 or 120 DAT)	Max. residue in turnip top (120 days aged soil) of 0.01 mg/kg)	Final addendum to the Draft Assessment Report (DAR), Aminopyralid, July 2013; Magnussen, J. D. 2004b <i>A Confined Rotational Crop Study with ¹⁴C XDE-750</i> . DAS, Indiana, USA & Research for Hire, California, USA; Report No.: 030008.
Cereals	Sorghum	2- and 6- ¹⁴ C pyridine ring	Applied to the bare ground soil	0.01	90 and 120 DAT	Plants: various growth stages; Soil: 0 DAT and after sowing	Max. residue level in early forage sorghum of 0.027 mg/kg (90-day aged	Final addendum to the Draft Assessment Report (DAR), Aminopyralid, July 2013;

						(90 or 120 DAT)	soil) and 0.017 mg/kg (120-day aged soil)	Magnussen, J. D. 2004b <i>A Confined Rotational Crop Study with ¹⁴C XDE-750</i> . DAS, Indiana, USA & Research for Hire, California, USA; Report No.: 030008.
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* Outdoor/field application (F) or glasshouse /protected/indoor application (G)

Summary of plant metabolism studies reported in the EU

Characterisation of the nature of the residue in sorghum forage and turnip top showed that radioactivity consisted mainly of aminopyralid and its conjugates. The only component that would be taken up from soil is aminopyralid which is further metabolised in aminopyralid conjugates in plants.

The data on metabolism and distribution of aminopyralid in succeeding crops demonstrate that the metabolism of the active substance in rotational crops is similar to the pathway observed in primary crops. Thus, the same residue definition is applicable for rotational crops (United Kingdom, 2012).

Conclusion on metabolism in rotational crops

The metabolism in rotational crops studies assessed in Final addendum to the Draft Assessment Report (DAR), Aminopyralid, July 2013 cover use of AMINO 30 SL on oilseed rape. No new studies are necessary.

zRMS comment: The data on metabolism and distribution of aminopyralid in succeeding crops demonstrate that the metabolism of the active substance in rotational crops is similar to the pathway observed in primary crops. Thus, the same residue definition is applicable for rotational crops.

7.2.2.3 Nature of residues in processed commodities (KCA 6.5.1)

Available data

No new data submitted in the framework of this application.

The applicant makes reference to hydrolysis of aminopyralid in aqueous solution at pH 5, 7 and 9 at 20°C over a period of 31 days and at 50°C over a period of 5 days. Aminopyralid was found to be stable under these conditions. As aminopyralid does not undergo appreciable degradation by hydrolysis, processing of RACs containing residues of aminopyralid is unlikely to result in any significant degradation of aminopyralid and the nature of the residue is not expected to be altered during processing. This study was submitted and evaluated under Fate and Behaviour section B.8.4.1 (Final addendum to the Draft Assessment Report (DAR), Aminopyralid, July 2013; Cook, W.L., 2003a; *Hydrolysis of XDE-750 at pH 5, 7, and 9*. DAS, Indiana, USA, Report No.: 020067)

Conclusion on nature of residues in processed commodities

A study investigating the nature of aminopyralid residues following temperature hydrolysis simulating

industrial processing was conducted (Final addendum to the Draft Assessment Report (DAR), Aminopyralid, July 2013; Fate and Behaviour section B.8.4.1; Cook, W.L., 2003a; *Hydrolysis of XDE-750 at pH 5, 7, and 9*. DAS, Indiana, USA Report No.: 020067). The study demonstrated that aminopyralid was stable at 20 and 50 °C over 31 days at various pHs.

zRMS comment: According to EFSA (2012) specific studies investigating the magnitude of aminopyralid residues in processed commodities are not required, as the residues expected in primary crops are low and the total theoretical maximum daily intake (TMDI) is below the trigger value of 10 % of the ADI. However, studies investigating the nature of aminopyralid residues in processed commodities were assessed in the framework of a previous application to modify MRLs in cereals but not peer reviewed. These studies were conducted with radiolabelled aminopyralid simulating representative hydrolytic conditions for pasteurisation (20 min at 90°C, pH 4), boiling/brewing/baking (60 min at 100°C, pH 5) and sterilization (20 min at 120°C, pH 6). Aminopyralid was stable to hydrolysis under standard conditions of pasteurisation, baking/brewing/boiling and sterilization (EFSA, 2020).

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

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

Endpoints	
Plant groups covered	oilseeds, grass, cereals
Rotational crops covered	Leaf vegetables (Lettuce), Root and tuber vegetables (Turnip), Cereals (Sorghum); 10 g a.s./ha; 90 and 120 DAT
Metabolism in rotational crops similar to metabolism in primary crops?	Yes
Processed commodities	a.s. is stable
Residue pattern in processed commodities similar to pattern in raw commodities?	Yes
Plant residue definition for monitoring	Sum of aminopyralid and its conjugates expressed as aminopyralid. (EFSA Journal 2013;11(9):3352) **
Plant residue definition for risk assessment	Sum of aminopyralid and its conjugates expressed as aminopyralid. (EFSA Journal 2013;11(9):3352) ***
Conversion factor from enforcement to RA	None

* If residue pattern in processed commodities is not similar to that in raw commodities

** A more recent proposal by EFSA may be provided as additional information (EFSA RO XXXX).

*** If no EFSA proposal is available, a proposal should be made by the applicant/zRMS.

7.2.2.5 Nature of residues in livestock (KCA 6.2.2-6.2.5)

Available data

No new data submitted in the framework of this application.

Table 7.2-6: Summary of animal metabolism studies

Group	Species	Label position	No of animal	Application details		Sample details		Reference
				Rate (mg/kg bw/d)	Duration (days)	Commodity	Time of sampling	
EU data								
Lactating ruminants	Goat	¹⁴ C aminopyralid labeled at the 2- and 6-positions of the pyridine ring	1	0.27 mg/kg bw/day	6	Milk	twice daily	Final addendum to the Draft Assessment Report (DAR), Aminopyralid, July 2013; [REDACTED], 2003, <i>The Distribution and Metabolism of [14C]-XDE-750 in the Lactating Goat</i> ; [REDACTED]
						Urine and faeces	daily	
						Tissues	at sacrifice	
Laying poultry	Hens	¹⁴ C aminopyralid labeled at the 2- and 6-positions of the pyridine ring	10	1.01 mg/kg bw/day	7	Eggs	twice daily	Final addendum to the Draft Assessment Report (DAR), Aminopyralid, July 2013; [REDACTED], 2003, <i>The Distribution and Metabolism of [14C]-XDE-750 in the Lactating Goat</i> ; [REDACTED]
						Excreta	daily	
						Tissues	at sacrifice	

Summary of animal metabolism studies reported in the EU

A goat metabolism was conducted at the dose of 17.6 mg/kg DM over 6 consecutive days (*ca* 0.8N). Aminopyralid was intensively excreted in faeces and urine and no more than 0.07% of the administered dose was recovered in milk and edible matrices. TRRs in milk, liver, muscle and fat were below 0.009 mg/kg and the characterisation of residues was therefore only attempted in kidney where 80% TRR was identified as aminopyralid. Moreover, a metabolism study on laying hen was provided, conducted at the dose rate of 11.6 mg/kg DM over 7 consecutive days. As previously for ruminants, aminopyralid was

almost totally excreted, and all TRRs in eggs and tissues were significantly below 0.01 mg/kg, in the range of <0.002 to 0.004 mg/kg. No characterisation of residues was performed in any of these samples. The animal residue definition for monitoring and risk assessment was proposed as aminopyralid.

Conclusion on metabolism in livestock

The animal metabolism studies assessed in Final addendum to the Draft Assessment Report (DAR), Aminopyralid, July 2013 cover use of AMINO 30 SL on oilseed rape. No new studies are necessary.

zRMS comment: The metabolism of aminopyralid residues in livestock was investigated in lactating goats and laying hens. According to the results of these studies, the residue definition for enforcement and risk assessment in livestock commodities was proposed as aminopyralid only.

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

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

	Endpoints
Animals covered	Lactating goats
	Laying hens
Time needed to reach a plateau concentration	2 days in milk
	5-7 days in eggs
Animal residue definition for monitoring	Aminopyralid (<i>EFSA Journal 2013;11(9):3352</i>)*
Animal residue definition for risk assessment	Aminopyralid (<i>EFSA Journal 2013;11(9):3352</i>)**
Conversion factor	None
Metabolism in rat and ruminant similar	Yes
Fat soluble residue	No

* A more recent proposal by EFSA may be provided as additional information (EFSA RO XXXX)

** If no EFSA proposal is available, a proposal should be made by the applicant/zRMS.

*** If metabolism in rat and ruminant are not similar

7.2.3 Magnitude of residues in plants (KCA 6.3)

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

No new data are submitted in the framework of this application. The magnitude of residues in plants was assessed in the Registration report of Navigator 360 SL-Poland, 2010; Devine, H.C. 2006, *Residues of Clopyralid, Picloram and Aminopyralid in Oil seed Rape at Intervals and at Harvest Following a Single Application of GF-1634, Germany, Poland and Hungary – 2005*. CEM Analytical Services Ltd; DAS Report No.: GHE-P-11273.; Devine, H.C. 2007, *Residues of Clopyralid, Picloram and Aminopyralid in Oil Seed Rape at Intervals and at Harvest Following a Single Application of GF-1633 or GF-871. Northern Europe – 2006*, CEM Analytical Services Ltd, DAS Report No.: GHE-P-11493.

We are obliged to rely upon following studies taking account that according to Regulation (EC) No 1107/2009 Article 59 Data protection: The period of data protection is 10 years starting at the date of first authorization in that Member State, except as provided in paragraph 2 of this Article or in Article 62. According to Official Journal of the European Union C 229/2 Period of protection is 10 years from date of first authorization of the product in each Member State (not the date of authorization of the new crop). First registration of the product was in 15.12.2010, therefore data protection was over on 14.12.2020, and other Applicants can refer to studies performed during authorization process.

A summary of the studies is presented below.

Table 7.2-8: Summary of EU reported and new data supporting the intended uses of AMINO 30 SL and conformity to existing MRL

During the authorization of Navigator 360 SL, a total of 10 trials were presented using the GF-1634 (aminopyralid 18 g ae/ha; 50-51 BBCH), GF-1633 (aminopyralid 12 g ae/ha; 50-51 BBCH) and GF-871 (aminopyralid 18 g ae/ha; 50-51 BBCH) formulations.

Commodity	Source	Residue zone (N-EU, S-EU, EU, outside EU)	Evaluation GAP Residue levels (mg/kg) E = according to enforcement residue definition RA = according to risk assessment residue definition	STMR (mg/kg)	HR (mg/kg)	Unrounded OECD calculator MRL (mg/kg)	Current EU MRL (mg/kg) *	MRL compliance
Oilseed rape, seed	Registration report of Navigator 360 SL	NEU	Trials GAP: 1 x 0.018 kg ae/ha, BBCH 50-51, PHI N/A, outdoor <0.01, <0.01, <0.01, <0.01, <0.002, <0.01, <0.01	N/A				

	Registration report of Navigator 360 SL	NEU	Trials GAP: 1 x 0.012 kg ae/ha, BBCH 50-51, PHI N/A, outdoor <0.002, <0.01, <0.01					
	Overall supporting data for cGAP	NEU	<0.01, <0.01, <0.01, <0.01, <0.002, <0.01, <0.01, <0.002, <0.01, <0.01	0.01	0.01	0.01	0.05	yes

* Source of EU MRL: *Regulation (EU) 2021/1841*

7.2.3.2 Conclusion on the magnitude of residues in plants

According to the available data, the intended uses on winter oilseed rape are considered acceptable, for outdoor uses.
The data submitted show that no exceedance of the MRL will occur.
The uses are considered acceptable.

zRMS comment: Comparison of reported and intended GAP in rape:

Type of GAP	Number of applications	Max. application rate per treatment (kg as/ha)	Interval between application (days)	Growth stage at last application	PHI (days)	Residues (mg/kg)
Registration report of Navigator 360 SL	1	0.012-0.018	-	BBCH 50–51	-	8x<0.01 2x<0.002
Authorised outdoor use in NEU (EFSA, 2020)	1	0.012	-	BBCH 12-31	-	11x<0.01 1x<0.002
Intended GAP	1	0.006-0.008	-	BBCH 10 – 18	-	

Rape is a major crop in Northern Europe. The applicant relied upon sufficient number of NEU trials, based on a GAP that is more critical (higher rates and later application timings) than the GAP proposed for the product Amino 30 SL. The available results show that the current MRL of 0.05 mg/kg (Reg. (EU) 2021/1841) will not be exceeded. The proposed use of the product is accepted.

7.2.4 Magnitude of residues in livestock

7.2.4.1 Dietary burden calculation

Table 7.2-9: Input values for the dietary burden calculation (considering the uses authorized within the zone and the uses under consideration)

Feed Commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Aminopyralid				
Canola (Rape seed)	0.02	STMR x PF (2)[a]	-	-
Rape meal	0.02	STMR x PF (2)[a]	-	-

[a] Default PF (Animal Model 2017)

New Dietary Burden calculations were performed, taking into account STMR values from residues trials on AMINO 30 SL. New calculations were presented below in Animal model 2017.

Animal burden calculation

aminopyralid

According to:

"OECD Guidance Document, Series on testing and assessment No 64 and Series on pesticides No 32" and "OECD Guidance Document on Residues in livestock, Series on Pesticides No 73"

Maximum Intake	Cattle						Sheep					
	Beef			Dairy			Ram/Ewe			Lamb		
(mg/kg bw/d)	0.000	500 kg 12 kg	mg/kg bw/d %	0.000	650 kg 25 kg	mg/kg bw/d %	0.000	75 kg 2.5 kg	mg/kg bw/d %	0.000	40 kg 1.7 kg	mg/kg bw/d %
Contributor 1	Rape	meal	20	Canola	meal	10	Rape	meal	15	Rape	meal	15
Contributor 2												
Contributor 3												
Contributor 4												
Median intake	0.0001	mg/kg bw/d		0.0001	mg/kg bw/d		0.0001	mg/kg bw/d		0.0001	mg/kg bw/d	

Maximum Intake

Breeding

260 kg
6 kg

0.000

mg/kg bw/d %

Finishing

100 kg
3 kg

0.000

mg/kg bw/d %

Contributor 1

Canola

meal

20

Canola

meal

20

Contributor 2

Contributor 3

Contributor 4

Median intake

0.000

mg/kg bw/d

0.000

mg/kg bw/d

Maximum Intake

Broiler

1.7 kg
0.12 kg

0.000

mg/kg bw/d %

Layer

1.9 kg
0.13 kg

0.000

mg/kg bw/d %

Turkey

7 kg
0.5 kg

0.000

mg/kg bw/d %

Contributor 1

Canola

meal

18

Canola

meal

10

Canola

meal

20

Contributor 2

Contributor 3

Contributor 4

Median intake

0.000

mg/kg bw

0.000

mg/kg bw

0.000

mg/kg bw

Intakes expressed on the dry mater basis (mg/kg DM)

mg/kg DM	Cattle		Sheep		Swine	
	Beef	Dairy	Ram/Ewe	Lamb	Breeding	Finishing
Maximum	0.00	0.00	0.0	0.00	0.00	0.00
Median	0.00	0.00	0.00	0.00	0.00	0.00

Poultry

Broiler

Layer

Turkey

Maximum

0.00

0.00

0.00

Median

0.00

0.00

0.00

Intake >0.1 mg/kg DM

in red characters

Table 7.2-10: Results of the dietary burden calculation

Animal species	Median dietary burden (mg/kg bw/d)	Maximum dietary burden (mg/kg bw/d)	Highest contributing commodity	Max dietary burden (mg/kg DM)	Trigger exceeded (Y/N)
Aminopyralid					
Beef cattle*	0.0001	0.00	Rape meal	0.00	N
Dairy cattle*	0.0001	0.00	Canola meal	0.00	N
Ram/ewe	0.0001	0.00	Rape meal	0.00	N
Lamb	0.0001	0.00	Rape meal	0.00	N
Breeding swine	0.000	0.00	Canola meal	0.00	N
Finishing swine*	0.000	0.00	Canola meal	0.00	N
Broiler poultry	0.000	0.00	Canola meal	0.00	N
Layer poultry*	0.000	0.00	Canola meal	0.00	N
Turkey	0.000	0.00	Canola meal	0.00	N

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

7.2.4.2 Livestock feeding studies (KCA 6.4.1-6.4.3)

Available data

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

Based on dietary burden assessment, intakes above 0.004 mg/kg bw/d and 0.1 mg/kg DM were not found for any group and no studies are necessary. However, livestock feeding studies are available (Final addendum to the Draft Assessment Report (DAR), Aminopyralid, July 2013; *Magnitude of XDE-750 Residues in Bovine Tissues and Milk from a 28-Day Feeding Study*; Report No.: 030061). A summary of the study is presented below.

In 2004 a GLP feeding study was conducted on Holstein dairy cows (*Bos Taurus*). Animals were dosed with aminopyralid daily at rates on a dry matter basis of 32.8 mg/kg, 64.5 mg/kg, 181.5 mg/kg and 644.7 mg/kg (equivalent to ca 1.5N, 3N, 8.5N and 30N based on the theoretical maximum dietary burden for cattle, see section B.7.16.1) in the cow's diet for 28 consecutive days by capsule using a balling gun. Three cows were assigned to the 1.5N, 3N and 8.5N dose groups, while four cows were assigned to the control group and nine cows assigned to the 30N group. Milk samples were taken daily. Within 24 hours all cows within the 1.5N, 3N and 8.5N groups were slaughtered, whilst the remaining six cows from the 30N group and one cow from the control group were maintained on a withdrawal schedule to evaluate depuration of residues in milk and tissues. Samples of muscle, liver, fat and kidney were collected and stored frozen until analysis. All samples were analysed within 30 days.

Residues from livestock feeding studies (Annex IIA, point 6.4, Annex IIIA, point 8.3)

	Ruminant:	Poultry:	Pig:
Conditions of requirement of feeding studies			
Expected intakes by livestock ≥ 0.1 mg/kg diet (dry weight basis) (yes/no)	Yes (21.3 mg/kg DM)	No	No
Potential for accumulation (yes/no):	No	No	No
Metabolism studies indicate potential level of residues ≥ 0.01 mg/kg in edible tissues	Yes	No	n/a
Aminopyralid residue levels (mg/kg) observed in the feeding study on cattle at the rate of 32.8 mg/kg DM (1.5N):			
Muscle	<0.01	n/a	n/a
Liver	<0.01	n/a	n/a
Kidney	Max: 0.102 Mean: 0.065	n/a	n/a
Fat	<0.01	n/a	n/a
Milk	<0.01		
Eggs		n/a	

Table 7.2-11: Overview of the values derived from livestock feeding studies

Commodity	Dietary burden		Results of the livestock feeding study					Median residue (0.5 N rate) (mg/kg) ^(b)	Highest residue (0.5 N rate) (mg/kg) ^(c)	Calculated MRL (mg/kg)	CF for RA ^(d)	
	Med. (mg/kg bw/d)	Max. (mg/kg bw/d)	Dose Level (mg/kg bw/d) ^(a)	No	Result for enforcement		Result for RA					
					Mean (mg/kg)	Max. (mg/kg)	Mean (mg/kg)					Max. (mg/kg)
EU data (Final addendum to the Draft Assessment Report (DAR), Aminopyralid, July 2013)												
Aminopyralid												
Ruminant meat	0.0001	0.00	1.1 (1.5 N rate)	3	nd	nd	Refer to results for enforcement residue definition	0.01	0.01	0.01*	1	
			2.48 (3 N rate)	3	<0.01	<0.01						
			6.4 (8.5 N rate)	3	0.024	0.046						
			23.27 (30 N rate)	9	0.021	0.029						
Ruminant fat	0.0001	0.00	1.1 (1.5 N rate)	3	<0.01	0.011		0.01	0.011	0.01*	1	
			2.48 (3 N rate)	3	<0.01	<0.01						
			6.4 (8.5 N rate)	3	<0.01	0.013						
			23.27 (30 N rate)	9	0.035	0.042						
Ruminant liver	0.0001	0.00	1.1 (1.5 N rate)	3	<0.01	<0.01	0.01	0.01	0.01*	1		
			2.48 (3 N rate)	3	<0.01	0.014						

			rate)							
			6.4 (8.5 N rate)	3	0.038	0.054				
			23.27 (30 N rate)	9	0.080	0.0116				
Ruminant kidney	0.0001	0.00	1.1 (1.5 N rate)	3	0.065	0.102		0.07	0.102	0.136
			2.48 (3 N rate)	3	0.147	0.202				1
			6.4 (8.5 N rate)	3	0.833	1.537				
			23.27 (30 N rate)	9	1.565	2.549				
Milk	0.0001	0.00	1.1 (1.5 N rate)	3	<0.01 ^(e)	<0.01		0.01	0.01	0.01*
			2.48 (3 N rate)	3	<0.01 ^(e)	0.014				1
			6.4 (8.5 N rate)	3	0.019 ^(e)	0.028				
			23.27 (30 N rate)	9	0.068 ^(e)	0.152				

N/A: Not applicable – only the mean values are considered for calculating MRLs in milk.

n.r.: Not reported

nd: Not detected

(*): Indicates that the MRL is set at the limit of analytical quantification.

(F): MRL is expressed as mg/kg of fat contained in the whole product.

(a): Based on animal consuming 32.8 mg/kg, 64.5 mg/kg, 181.5 mg/kg and 644.7 mg/kg feed DM/day.

(b): Median residue value according to the enforcement residue definition, derived by interpolation/extrapolation from the feeding study for the median dietary burden (FAO, 2009).

(c): Highest residue value (tissues, eggs) or mean residue value (milk) according to the enforcement residue definition, derived by interpolation/extrapolation of the maximum dietary burden between the relevant feeding groups of the study (FAO, 2009).

(d): The median conversion factor for enforcement to risk assessment.

(e): Mean residue level from day 2 until day 28 (7 cows, 28 sampling days).

zRMS comment: dietary burden calculation indicates that the livestock exposure to rape meal is insignificant.

In the framework of the peer review, a feeding study was performed with dairy cows. The results confirmed the intensive excretion of aminopyralid observed in the metabolism study.

The study performed on dairy cows was used to derive MRL and risk assessment values for all commodities of ruminants. Since extrapolation from ruminants to pigs is acceptable, results of the livestock feeding study on ruminants were relied upon to derive the MRL and risk assessment values in pigs. Significant levels of aminopyralid are only expected in kidney, for milk and all other tissues of ruminants, no residues were found above the LOQ at any dosing levels. No study was available for poultry, since poultry are not expected to be exposed to significant levels of aminopyralid residues (EFSA, 2020).

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

Specific studies investigating the magnitude of aminopyralid residues in processed commodities are not required, as the residues expected in primary crops are low (<0.1 mg/kg) and the total theoretical maximum daily intake (TMDI) is below the trigger value of 10 % of the ADI.

zRMS comment: Since no residues of aminopyralid exceeding 0.1 mg/kg are expected in the treated crops and TMDI is below 10% of the ADI, further considerations about the effects of processing are not required.

7.2.6 Magnitude of residues in representative succeeding crops

Data have not been submitted for rotational crops residue field trials. However metabolism data are available for rotational crops (section B.7.2.2) indicating that significant rotational crop residues are not expected to occur.

zRMS comment: According to EFSA (2020) the occurrence of residues in rotational crops above 0.01 mg/kg, could not be fully excluded. Consequently, to avoid the presence of aminopyralid residues in rotational crops, therefore 90-day PBI is recommended.

7.2.6.1 Field rotational crop studies (KCA 6.6.2)

Available data

No new data submitted in the framework of this application.

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

The magnitude of residues in plants studies (7.2.3) (BBCH 50-51; application rate 12-18 g a.s/ha) indicate that the residue levels in the whole plant are very low, therefore residues in honey are not expected above LOQ level in case of earlier application (BBCH 10-18) and lower application rate (8 g a.s/ha).

No further data is required as the risk of exceeding default MRL value in honey is negligible.

zRMS comment: Based on the available residue studies conducted following treatment of rape with higher application rate (12-18 g/ha) and later growth stage (BBCH 50-51), it can be reasonably concluded that the presence of residues in honey when aminopyralid is used according to the proposed GAP is unlikely.

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

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

7.2.8.1 Input values for the consumer risk assessment

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

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Risk assessment residue definition for plants: Sum of aminopyralid and its conjugates expressed as aminopyralid. (<i>EFSA Journal 2013;11(9):3352</i>)				
Risk assessment residue definition for animals: Aminopyralid (<i>EFSA Journal 2013;11(9):3352</i>)				
Tier I				
Rapeseeds/canola seeds	0.05	EU MRL Reg. (EU) 2021/1841	0.05	EU MRL Reg. (EU) 2021/1841
Rapeseeds / oils	0.05	EU MRL Reg. (EU) 2021/1841	0.05	EU MRL Reg. (EU) 2021/1841
Muscle (swine, sheep, goat, equine, other farmed animals)	0.1	EU MRL Reg. (EU) 2021/1841	0.1	EU MRL Reg. (EU) 2021/1841
Muscle (poultry)	0.01	EU MRL Reg. (EU) 2021/1841	0.01	EU MRL Reg. (EU) 2021/1841
Fat (swine, sheep, goat, equine, other farmed animals)	0.1	EU MRL Reg. (EU) 2021/1841	0.1	EU MRL Reg. (EU) 2021/1841
Fat (poultry)	0.01	EU MRL Reg. (EU) 2021/1841	0.01	EU MRL Reg. (EU) 2021/1841
Liver	0.05	EU MRL Reg. (EU) 2021/1841	0.05	EU MRL Reg. (EU) 2021/1841
Kidney (swine, sheep, goat, equine, other farmed animals)	1	EU MRL Reg. (EU) 2021/1841	1	EU MRL Reg. (EU) 2021/1841
Kidney (poultry)	0.01	EU MRL Reg. (EU) 2021/1841	0.01	EU MRL Reg. (EU) 2021/1841
Milk	0.02	EU MRL Reg. (EU) 2021/1841	0.02	EU MRL Reg. (EU) 2021/1841
Honey and other apiculture	0.05	EU MRL Reg. (EU) 2021/1841	0.05	EU MRL Reg. (EU) 2021/1841
Tier II				
Rapeseeds/canola seeds	0.01	STMR	0.01	STMR

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Rapeseeds/oils	0.01	STMTR	0.01	STMTR

7.2.8.2 Conclusion on consumer risk assessment

Extensive calculation sheets are presented in Appendix 2.

Table 7.2-13: Consumer risk assessment

TMDI (% ADI) according to EFSA PRIMo	0.6 % (based on NL toddler diet; Milk: Cattle) 0.0% (based on FI 3 yr, FI 6 yr, FI adult diet; Rape-seeds/canola seeds)
IEDI (% ADI) according to EFSA PRIMo	0.5 % (based on NL toddler diet; Milk: Cattle) 0.0% (based on FI 3 yr, FI 6 yr, FI adult diet; Rape-seeds/canola seeds)
IESTI (% ARfD) according to EFSA PRIMo*	Unprocessed: 1 % (based on children group; Bovine: kidney); 1% (based on children group; Milk: Cattle) Processed: 0 % (based on children group; Rapeseed / oils)
IESTI (% ARfD) according to EFSA PRIMo#	Unprocessed: 0.01 % (children) 0.0% (adults)

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

** if national model is available

IESTI recalculated by the zRMS using only MRL of 0.05 mg/kg for rape

The proposed uses of aminopyralid in the formulation AMINO 30 SL do not represent unacceptable acute and chronic risks for the consumer.

zRMS comment: The consumer risk assessments were performed with of the EFSA Pesticide Residues Intake Model (PRIMo 3.1). The calculation of the TMDI led to an utilisation of the ADI of 0.6% with the NL toddler being the population group with the highest value. For this diet, the highest contributor is cattle milk with 0.5% of the ADI.

The highest International Estimated Short-Term Intake (IESTI) is at very low level for the consumption of rapeseeds by children and by adults.

The proposed use of aminopyralid in the formulation Amino 30 SL does not represent unacceptable chronic and acute risks for the consumers.

7.3 References

- EFSA (European Food Safety Authority), 2013. *Conclusion on the peer review of the pesticide risk assessment of the active substance aminopyralid*; EFSA Journal 2013;11(9):3352,
- Final addendum to the Draft Assessment Report (DAR), Volume 3, Annex B.7 – Aminopyralid; July 2013
- Registration report of Navigator 360 SL (Poland, 2010).
- EFSA (European Food Safety Authority), 2020. Review of the existing maximum residue levels for aminopyralid according to Article 12 of Regulation (EC) No 396/2005; EFSA Journal 2020;18(8):6229.

Appendix 1 Lists of data considered in support of the evaluation

List of data submitted by the applicant and relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
-	-	-	-	-	-

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

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 6.1	Lindsay, D.A.	2004	Frozen Storage Stability of XDE-750 in Range Land and Pasture Grass and Hay and Wheat Straw and Wheat Grain. DAS, Indiana, USA Report No.: 030004.01 GLP/GEP (Y/N): Y Published (Y/N): N	N	DAS
KCP 7.2.2.5	[REDACTED]	2003	The Distribution and Metabolism of [14C]-XDE-750 in the Lactating Goat [REDACTED] GLP/GEP (Y/N): Y Published (Y/N): N	Y	DAS
KCP 7.2.4.2	[REDACTED]	2004	Magnitude of XDE-750 Residues in Bovine Tissues and Milk from 28-Day Feeding Study [REDACTED] GLP/GEP (Y/N): Y	Y	DAS

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			Published (Y/N): N		
KCP 7.2.2.5		2004a	14C XDE-750 Poultry Nature of Residue Study DAS Indiana, USA & Wildlife International, Ltd, Maryland, USA GLP/GEP (Y/N): Y Published (Y/N): N	Y	DAS
KCP 7.2.2.1	Linder, S.J.	2007	A Nature of Residue Study with ¹⁴ C Labeled Aminopyralid Applied to Oilseed Rape Dow AgroSciences DAS Report No.: 060011 GLP/GEP (Y/N): Y Published (Y/N): N	N	DAS
KCP 7.2.2.1	Magnussen, J. D. and Balcer, J. L.	2004	¹⁴ C XDE-750 Grass Nature or Residue Study. DAS, Indiana, USA Report No.: 010071 GLP/GEP (Y/N): Y Published (Y/N): N	N	DAS
KCP 7.2.2.1	Graper, L. K.; Smith, K. P.; Hilla, S.	2003	A Nature of the Residue Study with ¹⁴ C-Labeled XDE-750 Applied to Spring Wheat DAS, Indiana, USA & Research for Hire, California, USA Report No.: 020022 GLP/GEP (Y/N): Y Published (Y/N): N	N	DAS
KCP 7.2.2.2	Magnussen, J.D.	2004b	A Confined Rotational Crop Study with ¹⁴ C XDE-750. DAS, Indiana, USA & Research for Hire, California, USA. Report No.: 030008 GLP/GEP (Y/N): Y Published (Y/N): N	N	DAS
KCP 7.2.3	Devine, H.C.	2006	Residues of Clopyralid, Picloram and Aminopyralid in Oil Seed Rape at Intervals and at Harvest Following a Single Application of GF-1634, Germany, Poland and Hungary – 2005 CEM Analytical Services Ltd	N	DAS

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			DAS Repor No.: GHE-P-11273 GLP/GEP (Y/N): Y Published (Y/N): N		
KCP 7.2.3	Devine, H.C.	2007	Residues of Clopyralid, Picloram and Aminopyralid in Oil Seed Rape at Intervals and at Harvest Following a Single Application of GF-1633 or GF-871, Nothern Europe – 2006 CEM Analytical Services Ltd DAS Report No.: GHE-P-11493 GLP/GEP (Y/N): Y Published (Y/N): N	N	DAS
KCP 7.2.2.3	Cook, W.L.	2003a	Hydrolysis of XDE-750 at pH 5,7, and 9. DAS, Indiana, USA. Report No.: 020067 GLP/GEP (Y/N): Y Published (Y/N): N	N	DAS

List of data submitted by the applicant and not relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
-	-	-	-	-	-

List of data relied on and not submitted by the applicant but necessary for evaluation


Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
-	-	-	-	-	-

Appendix 2 Detailed evaluation of the additional studies relied upon

No new studies submitted.

Appendix 3 Pesticide Residue Intake Model (PRIMo)

A 3.1 TMDI calculations



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

aminopyralid (F)

LOQs (mg/kg) range from:	0.05	to:	0.05
Toxicological reference values			
ADI (mg/kg bw/day):	0.26	ARfD (mg/kg bw):	0.26
Source of ADI:	EFSA Journal	Source of ARfD:	EFSA Journal
Year of evaluation:	2013	Year of evaluation:	2013

Input values

Details - chronic risk

Supplementary results -

Details - acute risk

Details - acute risk

Comments:


Normal mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

Calculated exposure (% of ADI)		Exposure (µg/kg bw per day)	No of diets exceeding the ADI : --		2nd contributor to MS diet (in % of ADI)	3rd contributor to MS diet (in % of ADI)	Exposure resulting from MRLs set at the LOQ (in % of ADI)	commodities not under assessment (in % of ADI)
MS Diet	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities		
0.6% NL toddler	1.48	Milk: Cattle	0.0%	Bovine: Muscle/meat	0.0%	Swine: Muscle/meat	0.0%	
0.4% UK infant	0.93	Milk: Cattle	0.0%	Bovine: Kidney	0.0%	Swine: Muscle/meat	0.0%	
0.3% FR toddler 2-3 yr	0.85	Milk: Cattle	0.0%	Swine: Muscle/meat	0.0%	Swine: Muscle/meat	0.0%	
0.3% FR child 3-15 yr	0.80	Milk: Cattle	0.1%	Bovine: Muscle/meat	0.1%	Swine: Muscle/meat	0.0%	
0.3% NL child	0.75	Milk: Cattle	0.0%	Swine: Muscle/meat	0.0%	Bovine: Muscle/meat	0.0%	
0.3% SE general	0.69	Bovine: Muscle/meat	0.1%	Milk: Cattle	0.0%	Honey and other apiculture products	0.0%	
0.2% DK child	0.63	Milk: Cattle	0.1%	Swine: Muscle/meat	0.1%	Bovine: Muscle/meat	0.0%	
0.2% ES child	0.57	Milk: Cattle	0.1%	Bovine: Muscle/meat	0.0%	Swine: Muscle/meat	0.0%	
0.2% UK toddler	0.57	Milk: Cattle	0.0%	Bovine: Muscle/meat	0.0%	Bovine: Fat tissue	0.0%	
0.2% DE child	0.50	Milk: Cattle	0.0%	Swine: Muscle/meat	0.0%	Bovine: Muscle/meat	0.0%	
0.2% GEMS/Food G07	0.42	Milk: Cattle	0.0%	Swine: Muscle/meat	0.0%	Bovine: Muscle/meat	0.0%	
0.2% DE general	0.42	Milk: Cattle	0.0%	Swine: Muscle/meat	0.0%	Bovine: Muscle/meat	0.0%	
0.2% FR infant	0.42	Milk: Cattle	0.0%	Swine: Muscle/meat	0.0%	Bovine: Muscle/meat	0.0%	
0.2% GEMS/Food G08	0.41	Swine: Muscle/meat	0.0%	Milk: Cattle	0.0%	Bovine: Muscle/meat	0.0%	
0.2% GEMS/Food G15	0.40	Swine: Muscle/meat	0.1%	Milk: Cattle	0.0%	Bovine: Muscle/meat	0.0%	
0.2% GEMS/Food G11	0.40	Milk: Cattle	0.0%	Swine: Muscle/meat	0.0%	Bovine: Muscle/meat	0.0%	
0.2% RO general	0.40	Milk: Cattle	0.0%	Swine: Muscle/meat	0.0%	Bovine: Muscle/meat	0.0%	
0.1% DE women 14-50 yr	0.39	Milk: Cattle	0.0%	Swine: Muscle/meat	0.0%	Bovine: Muscle/meat	0.0%	
0.1% NL general	0.37	Milk: Cattle	0.0%	Swine: Muscle/meat	0.0%	Bovine: Muscle/meat	0.0%	
0.1% GEMS/Food G10	0.34	Milk: Cattle	0.0%	Bovine: Muscle/meat	0.0%	Swine: Muscle/meat	0.0%	
0.1% DK adult	0.29	Milk: Cattle	0.0%	Swine: Muscle/meat	0.0%	Bovine: Muscle/meat	0.0%	
0.1% ES adult	0.28	Milk: Cattle	0.0%	Bovine: Muscle/meat	0.0%	Swine: Muscle/meat	0.0%	
0.1% FR adult	0.25	Milk: Cattle	0.0%	Swine: Muscle/meat	0.0%	Bovine: Muscle/meat	0.0%	
0.1% IE adult	0.25	Milk: Cattle	0.0%	Bovine: Muscle/meat	0.0%	Swine: Muscle/meat	0.0%	
0.1% LT adult	0.22	Swine: Muscle/meat	0.0%	Milk: Cattle	0.0%	Bovine: Muscle/meat	0.0%	
0.1% UK adult	0.14	Bovine: Muscle/meat	0.0%	Milk: Cattle	0.0%	Poultry: Muscle/meat	0.0%	
0.0% GEMS/Food G06	0.12	Milk: Cattle	0.0%	Bovine: Muscle/meat	0.0%	Sheep: Muscle/meat	0.0%	
0.0% IE child	0.11	Milk: Cattle	0.0%	Swine: Muscle/meat	0.0%	Swine: Fat tissue	0.0%	
0.0% UK vegetarian	0.07	Milk: Cattle	0.0%	Bovine: Fat tissue	0.0%	Bovine: Muscle/meat	0.0%	
0.0% FI 3 yr	0.00	Rapeseeds/canola seeds	0.0%	Honey and other apiculture products	0.0%		0.0%	
0.0% FI 6 yr	0.00	Rapeseeds/canola seeds	0.0%	Honey and other apiculture products	0.0%		0.0%	
0.0% FI adult	0.00	Rapeseeds/canola seeds	0.0%	Grapefruits	0.0%		0.0%	
0.0% IT toddler		Grapefruits		Grapefruits				
0.0% IT toddler		Grapefruits		Grapefruits				
0.0% IT toddler		Grapefruits		Grapefruits				
0.0% IT toddler		Grapefruits		Grapefruits				

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

A 3.2 IEDI calculations



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

aminopyralid (F)

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

Toxicological reference values

ADI (mg/kg bw/day): 0.26 ARfD (mg/kg bw): 0.26

Source of ADI: EFSA Journal Source of ARfD: EFSA Journal

Year of evaluation: 2013 Year of evaluation: 2013

Input values

Details - chronic risk

Supplementary results -

Details - acute risk

Details - acute risk

Comments:

Normal mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

			No of diets exceeding the ADI : —						Exposure resulting from		
	Calculated exposure (% of ADI)	MS Diet	Exposure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	MRLs set at the LOQ (in % of ADI)	commodities not under assessment (in % of ADI)
TMDI/NEDI/IEDI calculation (based on average food consumption)	0.5%	NL toddler	1.43	0.5%	Milk: Cattle	0.0%	Bovine: Muscle/meat	0.0%	Swine: Muscle/meat		
	0.4%	UK infant	0.93	0.3%	Milk: Cattle	0.0%	Bovine: Muscle/meat	0.0%	Bovine: Kidney		
	0.3%	FR toddler 2-3 yr	0.85	0.2%	Milk: Cattle	0.0%	Bovine: Muscle/meat	0.0%	Swine: Muscle/meat		
	0.3%	FR child 3-15 yr	0.80	0.2%	Milk: Cattle	0.1%	Bovine: Muscle/meat	0.1%	Swine: Muscle/meat		
	0.3%	NL child	0.73	0.2%	Milk: Cattle	0.0%	Swine: Muscle/meat	0.0%	Bovine: Muscle/meat		
	0.3%	SE general	0.69	0.2%	Bovine: Muscle/meat	0.1%	Milk: Cattle	0.0%	Honey and other apiculture products		
	0.2%	DK child	0.63	0.1%	Milk: Cattle	0.1%	Swine: Muscle/meat	0.1%	Bovine: Muscle/meat		
	0.2%	ES child	0.57	0.1%	Milk: Cattle	0.1%	Bovine: Muscle/meat	0.0%	Swine: Muscle/meat		
	0.2%	UK toddler	0.57	0.2%	Milk: Cattle	0.0%	Bovine: Muscle/meat	0.0%	Bovine: Fat tissue		
	0.2%	DE child	0.50	0.2%	Milk: Cattle	0.0%	Swine: Muscle/meat	0.0%	Bovine: Muscle/meat		
	0.2%	DE general	0.42	0.1%	Milk: Cattle	0.0%	Swine: Muscle/meat	0.0%	Bovine: Muscle/meat		
	0.2%	FR infant	0.42	0.1%	Milk: Cattle	0.0%	Swine: Muscle/meat	0.0%	Bovine: Muscle/meat		
	0.2%	GEMS/Food G07	0.40	0.0%	Milk: Cattle	0.0%	Swine: Muscle/meat	0.0%	Bovine: Muscle/meat		
	0.2%	GEMS/Food G08	0.40	0.1%	Swine: Muscle/meat	0.0%	Milk: Cattle	0.0%	Bovine: Muscle/meat		
	0.2%	GEMS/Food G11	0.40	0.1%	Milk: Cattle	0.0%	Swine: Muscle/meat	0.0%	Bovine: Muscle/meat		
	0.2%	GEMS/Food G15	0.40	0.1%	Swine: Muscle/meat	0.1%	Milk: Cattle	0.0%	Bovine: Muscle/meat		
	0.2%	RO general	0.40	0.1%	Milk: Cattle	0.0%	Swine: Muscle/meat	0.0%	Bovine: Muscle/meat		
	0.1%	DE women 14-50 yr	0.39	0.1%	Milk: Cattle	0.0%	Swine: Muscle/meat	0.0%	Bovine: Muscle/meat		
	0.1%	NL general	0.36	0.1%	Milk: Cattle	0.0%	Swine: Muscle/meat	0.0%	Bovine: Muscle/meat		
	0.1%	GEMS/Food G10	0.33	0.0%	Milk: Cattle	0.0%	Bovine: Muscle/meat	0.0%	Swine: Muscle/meat		
	0.1%	DK adult	0.29	0.0%	Milk: Cattle	0.0%	Swine: Muscle/meat	0.0%	Bovine: Muscle/meat		
	0.1%	ES adult	0.28	0.0%	Milk: Cattle	0.0%	Bovine: Muscle/meat	0.0%	Swine: Muscle/meat		
	0.1%	FR adult	0.25	0.0%	Milk: Cattle	0.0%	Swine: Muscle/meat	0.0%	Bovine: Muscle/meat		
	0.1%	IE adult	0.25	0.0%	Milk: Cattle	0.0%	Bovine: Muscle/meat	0.0%	Swine: Muscle/meat		
	0.1%	LT adult	0.22	0.0%	Swine: Muscle/meat	0.0%	Milk: Cattle	0.0%	Bovine: Muscle/meat		
	0.1%	UK adult	0.14	0.0%	Bovine: Muscle/meat	0.0%	Milk: Cattle	0.0%	Poultry: Muscle/meat		
	0.0%	GEMS/Food G06	0.12	0.0%	Milk: Cattle	0.0%	Bovine: Muscle/meat	0.0%	Sheep: Muscle/meat		
	0.0%	IE child	0.11	0.0%	Milk: Cattle	0.0%	Swine: Muscle/meat	0.0%	Swine: Fat tissue		
	0.0%	UK vegetarian	0.07	0.0%	Milk: Cattle	0.0%	Bovine: Fat tissue	0.0%	Bovine: Muscle/meat		
	0.0%	FI 3 yr	0.00	0.0%	Rapeseeds/canola seeds	0.0%	Honey and other apiculture products				
0.0%	FI 6 yr	0.00	0.0%	Rapeseeds/canola seeds	0.0%	Honey and other apiculture products					
0.0%	FI adult	0.00	0.0%	Rapeseeds/canola seeds	0.0%	Grapefruits					
	IT toddler			Grapefruits		Grapefruits					
	IT toddler			Grapefruits		Grapefruits					
	IT toddler			Grapefruits		Grapefruits					
	IT toddler			Grapefruits		Grapefruits					

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

A 3.3 IESTI calculations - Raw commodities

Acute risk assessment /children				Acute risk assessment / adults / general population				Acute risk assessment /children				Acute risk assessment / adults / general population						
Details - acute risk assessment /children				Details - acute risk assessment/adults				Hide IESTI new calculations				Show IESTI new calculations						
The acute risk assessment is based on the ARfD. The calculation is based on the large portion of the most critical consumer group.								IESTI new calculations: The calculation is performed with the MRL and the peeling/processing factor (PF), taking into account the residue in the edible portion and/or the conversion factor for the residue definition (CF). For case 2a, 2b and 3 calculations a variability factor of 3 is used. Since this methodology is not based on internationally agreed principles, the results are considered as indicative only. Since this methodology is not based on internationally agreed principles, the results are considered as indicative only.										
Show results for all crops																		
Unprocessed commodities	Results for children No. of commodities for which ARfD/ADI is exceeded (IESTI):				Results for adults No. of commodities for which ARfD/ADI is exceeded (IESTI):				IESTI new Results for children No. of commodities for which ARfD/ADI is exceeded (IESTI new):				IESTI new Results for adults No. of commodities for which ARfD/ADI is exceeded (IESTI new):					
	---				---				---				---					
	IESTI				IESTI				IESTI new				IESTI new					
	Highest % of ARfD/ADI		MRL / input for RA (mg/kg)		Exposure (µg/kg bw)		Highest % of ARfD/ADI		MRL / input for RA (mg/kg)		Exposure (µg/kg bw)		Highest % of ARfD/ADI		MRL / input for RA (mg/kg)		Exposure (µg/kg bw)	
	1%	Bovine: Kidney	1 / 1	3.8	0.8%	Swine: Kidney	1 / 1	2.2	1%	Bovine: Kidney	1 / 1	3.8	0.8%	Swine: Kidney	1 / 1	2.2		
	1.0%	Milk: Cattle	0.02 / 0.02	2.5	0.8%	Bovine: Kidney	1 / 1	2.1	1.0%	Milk: Cattle	0.02 / 0.02	2.5	0.8%	Bovine: Kidney	1 / 1	2.1		
	0.5%	Swine: Kidney	1 / 1	1.3	0.3%	Milk: Cattle	0.02 / 0.02	0.77	0.5%	Swine: Kidney	1 / 1	1.3	0.3%	Milk: Cattle	0.02 / 0.02	0.77		
	0.5%	Swine: Muscle/meat	0.1 / 0.1	1.2	0.2%	Bovine: Muscle/meat	0.1 / 0.1	0.57	0.5%	Swine: Muscle/meat	0.1 / 0.1	1.2	0.2%	Bovine: Muscle/meat	0.1 / 0.1	0.57		
	0.3%	Bovine: Muscle/meat	0.1 / 0.1	0.72	0.2%	Other farmed animals: Muscle/meat	0.1 / 0.1	0.56	0.3%	Bovine: Muscle/meat	0.1 / 0.1	0.72	0.2%	Other farmed animals: Muscle/meat	0.1 / 0.1	0.56		
	0.3%	Other farmed animals: Muscle/meat	0.1 / 0.1	0.69	0.2%	Swine: Muscle/meat	0.1 / 0.1	0.48	0.3%	Other farmed animals: Muscle/meat	0.1 / 0.1	0.69	0.2%	Swine: Muscle/meat	0.1 / 0.1	0.48		
0.2%	Equine: Muscle/meat	0.1 / 0.1	0.80	0.2%	Equine: Muscle/meat	0.1 / 0.1	0.48	0.2%	Equine: Muscle/meat	0.1 / 0.1	0.80	0.2%	Equine: Muscle/meat	0.1 / 0.1	0.48			
0.2%	Sheep: Muscle/meat	0.1 / 0.1	0.54	0.2%	Sheep: Muscle/meat	0.1 / 0.1	0.47	0.2%	Sheep: Muscle/meat	0.1 / 0.1	0.54	0.2%	Sheep: Muscle/meat	0.1 / 0.1	0.47			
0.2%	Milk: Goat	0.02 / 0.02	0.48	0.1%	Milk: Goat	0.02 / 0.02	0.37	0.2%	Milk: Goat	0.02 / 0.02	0.48	0.1%	Milk: Goat	0.02 / 0.02	0.37			
0.2%	Bovine: Liver	0.05 / 0.05	0.40	0.1%	Milk: Sheep	0.02 / 0.02	0.30	0.2%	Bovine: Liver	0.05 / 0.05	0.40	0.1%	Milk: Sheep	0.02 / 0.02	0.30			
0.08%	Bovine: Fat tissue	0.1 / 0.1	0.21	0.09%	Poultry: Liver	0.05 / 0.05	0.24	0.08%	Bovine: Fat tissue	0.1 / 0.1	0.21	0.09%	Poultry: Liver	0.05 / 0.05	0.24			
0.07%	Honey and other apiculture	0.05 / 0.05	0.18	0.08%	Swine: Fat tissue	0.1 / 0.1	0.20	0.07%	Honey and other apiculture	0.05 / 0.05	0.18	0.08%	Swine: Fat tissue	0.1 / 0.1	0.20			
0.07%	Swine: Fat tissue	0.1 / 0.1	0.17	0.08%	Bovine: Liver	0.05 / 0.05	0.20	0.07%	Swine: Fat tissue	0.1 / 0.1	0.17	0.08%	Bovine: Liver	0.05 / 0.05	0.20			
0.07%	Poultry: Muscle/meat	0.01 / 0.01	0.17	0.06%	Goat: Muscle	0.1 / 0.1	0.18	0.07%	Poultry: Muscle/meat	0.01 / 0.01	0.17	0.06%	Goat: Muscle	0.1 / 0.1	0.18			
0.03%	Milk: Sheep	0.02 / 0.02	0.07	0.05%	Sheep: Liver	0.05 / 0.05	0.14	0.03%	Milk: Sheep	0.02 / 0.02	0.07	0.05%	Sheep: Liver	0.05 / 0.05	0.14			
Expand/collapse list																		
Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation)								Total number of commodities found exceeding the ARfD/ADI in children and adult diets (IESTI new calculation)										

A 3.4 IESTI calculations - Processed commodities

[illegible]