REGISTRATION REPORT

Part B

Section 7

Metabolism and Residues

Detailed summary of the risk assessment

Product code: ADM.09050.H.1.A

Product name(s): **STEMPER**

Chemical active substance:

Trinexapac-ethyl, 175 g/L

Central

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(authorization)

Applicant: **ADAMA**

Submission date: May 2022, updated November 2022

Evaluation date: March 2023

Revision date: June 2023

Version history

When	What
May 2022	dRR version 1 submitted by applicant
November 2022	updated
March 2023	Initial RR after zRMS evaluation
June 2023	RR B7 after comments

DATA PROTECTION CLAIM

Under Article 59, Regulation 1107/2009/EC, on behalf of the Sponsor Company the applicant claims data protection for these studies. The data protection status and corresponding justification as valid for the respective country will be confirmed in the respective PART A

STATEMENT FOR OWNERSHIP

The summaries and evaluations contained in this document may be based on unpublished proprietary data submitted for the purpose of the assessment undertaken by the regulatory authority that prepared it. Other registration authorities should not grant, amend, or renew a registration on the basis of the summaries and evaluation of unpublished proprietary data contained in this document unless they have received the data on which the summaries and evaluation are based, either –

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7 Metabolism and residue data (KCA section 6)

7.1 Summary and zRMS Conclusion

It should be noted that the applicant's dRR was not rewritten by the ZRMS and the RR resulted from the evaluation was prepared by an insertion into the dRR by the zRMS' comments/corrections on the grey background. Original PRIMo reports of the applicant were replaced by the zRMS' calculations for the reason described within the present section of the RR (7.2.8.2).

7.1.1 Critical GAP(s) and overall conclusion

Selection of critical uses and justification

The critical GAPs for barley, wheat, triticale, spelt, oat, rye and grass (for seed production) with respect to consumer intake and risk assessment for the preparation ADM.09050.H.1.A are presented in Table 7.1-1. They have been selected from the individual GAPs in the central zone for cereals. A list of all intended uses within the Central zone is given in Part B, Section 0.

Justification for the selection of the critical GAP

The critical GAP uses concern

- the highest single and yearly application rates (highest single application rate of 1.2 L prod./ha in cereals and grass),
- the maximum number of applications, (1/2) and
- the latest application growth stage in the crop (BBCH 39 in cereals, BBCH 37 in grass[1]).

In addition, residue from wheat and barley can be used to support the intended uses on cereals since according to SANTE/2019/12752, when the application is before forming of the edible part (in the case of cereals before stage BBCH 51), it is possible to extrapolate from barley to oat, rye and wheat and vice-versa. Therefore, data obtained from barley and/or wheat can be used to support the intended uses on cereals (wheat, barley, oats, rye, spelt and triticale).
Grass for seed production will not be consumed by humans or livestock. Residue trials for MRL setting or for consumer risk assessment are therefore not needed.

However, a list of all intended uses within the Central zone given in Part B Section 0 includes the table for CEU with use numbers 1-34, and the GAP table for PL taken from national part A with use numbers 1-7. All these uses can be accepted.
Moreover, Part B Section 0 also includes a table titled “critical GAPs” highlighted in blue including uses for EU with numbers of 1-3 taken from the 2018 RAR and consistent with 2018 RAR residue trials, but slightly different from the described above by the applicant intended GAP (rates within 25%, BBCH up to 49). The purpose of this RAR GAP in B0 is not clear, however for CEU these uses obviously also are already accepted.
Since there are more than one table in B0, they are numbered for clarity (see B0).
No new studies have been submitted by the applicant in the framework of this application[2]. New studies were submitted for Annex I Renewal of trinexapac-ethyl; they have been evaluated by the RMS Lithuania (RAR, 2018) and by EFSA (2018). Syngenta Crop Protection AG submitted a dossier, on behalf of the Trinexapac Task Force of which Adama Company (the applicant) was also a member and thus, zRMS

[1] With the smaller rate than for BBCH 33 in table 7.1-1, therefore in the table 7.1-1 BBCH 33 is presented.
[2] Except one study on residues stability. See Appendix 2.

believes, has the right to use already approved residue data presented in this report for registration purposes. The applicant originally included these studies in wheat and barley assessed in the 2018 RAR in Appendix 2 as the studies for evaluation but he was asked to remove them from there for clarity (the contents yellowed and crossed out by the applicant).

Finally concluding, the intended GAP from table 7.1-1 and the intended PL GAP from part A (both included in B 0) can be transformed for clarity into the acceptable intended GAP in table below where all uses except for wheat, barley, and grass (i.e. 6, 17, 18, 24) are less critical "sub-uses" of no 19.

No (from B 0)	Crop	Timing / Growth stage of crop & season	Max. number a) per use b) perseason	kg or L prdct / ha a) max. rate per appl. b) max. total rate	g or kg as/ha a) max. rate per appl. b) max. total rate	Water L/ha min / max	PHI
3 (1, 2, 25)	**Grass** (not for consumption)	BBCH 31-33	a) 1 b) 1	a) 1,2 L/ha b) 1,2 L/ha	a) 210 b) 210	200-400	na
14 (10, 16, 20, 32, 21, 7, 13, 29)	**Barley**	BBCH 31-35	a) 1 b) 1	a) 1,2 L/ha b) 1,2 L/ha	a) 210 b) 210	200-400	na
19 (8, 11,12,15,30, 33, 34, 24, 4, 26, 17, 5, 23, 27, 6, 28, 18, 9, 22, 31)	**Wheat**, oat, rye, spelt, triticale	BBCH 31-39	a) 1 b) 1	a) 0,6 L/ha b) 0,6 L/ha	a) 105 b) 105	250-400	na

Overall conclusion

The data available are considered sufficient for risk assessment. An exceedance of the current MRLs of 3.0 mg/kg for trinexapac-ethyl in barley, wheat (including triticale and spelt) and oat and of 0.5 mg/kg in rye as laid down in Regulation (EU) 2017/1016 (of Reg. (EU) 396/2005) is not expected.
Although the MRLs of wheat and rye differ, rye can be extrapolated from wheat according to the intended GAPs consistency.
The chronic ~~and the short-term~~ intakes of trinexapac-ethyl residues are unlikely to present a public health concern.
As far as consumer health protection is concerned, the zRMS agrees with the authorization of the intended uses.
According to available data, no specific mitigation measures should apply.

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	12	13	14
					Application				Application rate				
GAP number (see part B.0)*	**Member state(s)**	**Crop and/ or situation**** (crop destination / purpose of crop)	**F, Fn, Fpn G, Gn, Gpn or I*****	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L ADM.09050.H.1.A / ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max	**PHI** (days)	**Conclusion**
3	CEU	Grass for seed: timothy (PHLPR)	F	Growth regulator (YHALM) lodging control (YELDU)	foliar, spraying, overall	-/ BBCH 31-33	a) 1 b) 1		a) 1.2 L/ha b) 1.2 L/ha	a) 210 b) 210	200-400	na	
6		Spelt (TRZSP)	F	Growth regulator (YHALM) lodging control (YELDU)	foliar, spraying, overall	-/ BBCH31-32	a) 1 b) 1		a) 0.5 L/ha b) 0.5 L/ha	a) 87.5 b) 87.5	200-400	na	
14		Winter barley (HORVW)	F	Growth regulator (YHALM)	foliar, spraying, overall	-/ BBCH 31-35	a) 1 b) 1		a) 1.2 L/ha b) 1.2 L/ha	a) 210 b) 210	200-400	na	
17		Rye (SECCW)	F	Growth regulator (YHALM)	foliar, spraying, overall	-/ BBCH 31-39	a) 1 b) 1		a) 0.6 L/ha b) 0.6 L/ha	a) 105 b) 105	200-400	na	
18		Triticale (TTLSS)	F	Growth regulator (YHALM)	foliar, spraying, overall	-/ BBCH 31-39	a) 1 b) 1		a) 0.6 L/ha b) 0.6 L/ha	a) 105 b) 105	200-400	na	
19		Winter wheat (TRZAW)	F	Growth regulator (YHALM) lodging control (YELDU)	foliar, spraying, overall	-/ BBCH 37-39	a) 1 b) 1		a) 0.6 L/ha b) 0.6 L/ha	a) 105 b) 105	250-400	na	
24		Oats (AVESS)	F	Growth regulator (YHALM) lodging control (YELDU)	foliar, spraying, overall	-/ BBCH 32	a) 1 b) 1		a) 0.6 L/ha b) 0.6 L/ha	a) 105 b) 105	250-400	na	PL: up to BBCH 33

* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 are given in column 1 (the table for PL in B0 with use numbers 1-7 can be considered as acceptable derivative of the uses 3, 6, 14, 17, 18, 19, 24 – the table for PL is covered by the GAP here).
** 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

7.1.2 Summary of the evaluation

The preparation ADM.09050.H.1.A is composed of trinexapac-ethyl.

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

Reference value	Source	Year	Value	Study relied upon	Safety factor
Trinexapac-ethyl - Parent compound					
ADI	EFSA	2018	0.32	Dog, 1-year	100
~~ARfD~~	~~EFSA~~	~~2018~~	~~0.34~~	~~Rat, 90-day~~	~~100~~
ARfD	Not applicable (An acute reference dose (ARfD) is not needed for the substance. The systemic acceptable operator exposure level (AOEL) is 0.34 mg/kg bw per day)				

7.1.2.1 Summary for trinexapac-ethyl

Table 7.1-3: Summary for trinexapac-ethyl

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?
14	Barley	Yes	Yes (18 trials including scaled wheat data)	N/A (determined by growth stage at last application)	Yes	Yes	No	No
19	Wheat	Yes	Yes (11 trials)	N/A (determined by growth stage at last application)	Yes	Yes		No
6	Spelt	Yes	Yes (extrapolation from wheat)	N/A (determined by growth stage at last application)	Yes	Yes		No
18	Triticale	Yes	Yes (extrapolation from wheat)	N/A (determined by growth stage at	Yes	Yes		No

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?
				last application)				
24	Oats	Yes	Yes (extrapolation from wheat)	N/A (determined by growth stage at last application)	Yes	Yes		No
17	Rye	Yes	Yes (extrapolation from wheat)	N/A (determined by growth stage at last application)	Yes	Yes		No
3	Grass (seed production)	Yes	Not required as not intended as a food/feed item and therefore not relevant for human consumption	N/A (determined by growth stage at last application)	N/A	N/A	N/A	N/A

N/A: Not applicable
* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1

The effects of processing on the nature of trinexapac-ethyl residues have been investigated. Data on effects of processing on the amount of residue have been submitted.
These data were not considered for risk assessment.

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.
Based on the metabolism results, residues of trinexapac are not expected in ruminant tissues and milk. Significant residues are not expected in poultry commodities as well considering the outcome of the metabolism study. Recalculation of the livestock dietary burden is pending the finalisation of the residue definition for the risk assessment for feed items and in animal products and information on the transfer of residues of CGA300405 and SYN548584 in animal matrices (EFSA Journal 2018;16(4):5229). Thus, dietary burden was not calculated according to the newest ~~methodology~~ data, and it should be formally updated when it will be possible as post registration issue. It does not affect the registration of the product.
Residues in pollen and bee products for human consumption are no of concern here because the GAP is intended before flowering.
No acute risk has been identified for any of the crops considered in this submission. The use of ADM.09050.H.1.A on barley, wheat, triticale, spelt, oat and rye is therefore acceptable.
Grass is intended for seed production only and therefore has no relevance to human consumption.

7.1.2.2 Summary for ADM.09050.H.1.A

Table 7.1-4: Information on ADM.09050.H.1.A (KCA 6.8)

Crop	PHI for ADM.09050.H.1.A proposed by applicant	PHI/ Withholding period* sufficiently supported for	PHI for ADM.09050.H.1.A proposed by zRMS	zRMS Comments (if different PHI proposed)
		Trinexapac-ethyl		
Barley	F**	NR		
Wheat	F**	NR		
Spelt	F**	NR		
Triticale	F**	NR		
Oats	F**	NR		
Rye	F**	NR		
Grass (seed production)	F**	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 ADM.09050.H.1.A
Crop group	Lead by trinexapac-ethyl	
Leafy vegetables	None	None
Root vegetables	None	None
Cereals	None	None

NR: not relevant

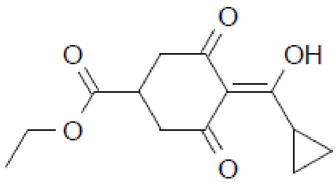
In accordance with the EFSA Scientific Report (2018) (trinexapac-ethyl), no particular restriction related to rotational crops is needed.

Assessment

7.2 Trinexapac-ethyl

General data on trinexapac-ethyl are summarized in the table below (last updated 2020/11/05)

Table 7.2-1: General information on trinexapac-ethyl

Active substance (ISO Common Name)	Trinexapac-ethyl
IUPAC	Ethyl (1*RS*,4*EZ*)-4-cyclopropyl(hydroxy)methylene-3,5-dioxocyclohexanecarboxylate
Chemical structure	
Molecular formula	$C_{13}H_{16}O_5$
Molar mass	252.3g/mol
Chemical group	Cyclohexanediones
Mode of action	Plant growth regulator that inhibits the later stages in the synthetic pathway for Gibberellin, inhibiting internode elongation
Systemic	Yes
Companies	Task Force members Syngenta Crop Protection AG, Adama Agriculture BV, Cheminova A/S and Helm AG*
Rapporteur Member State (RMS)	Lithuania
Approval status	Approved (01/05/2007) (Regulation (EU) No 2020/421)
Restriction	Only uses as plant growth regulator may be authorised
Review Report	SANCO/10011/06 final 04/042006
Current MRL regulation	Regulation (EC) No 2017/1016 of 14/06/2017
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, 2018
EFSA Journal: conclusion on article 12	Yes. EFSA, 2012
Current MRL applications on intended uses	None

* Notifier in the EU process to whom the a.s. belong(s)

7.2.1 Stability of Residues (KCA 6.1)

7.2.1.1 Stability of residues during storage of samples

Available data

Reference: RMS The Netherlands (DAR, 2003; DAR, 2005 – addendum to DAR, 2003);RMS Lithuania

(RAR, 2018); EFSA, 2018

One new storage stability study has been submitted by the applicant in the framework of this application. New studies were submitted for Annex I Renewal of trinexapac-ethyl; they have been evaluated by RMS Lithuania (RAR, 2018) and by EFSA (2018). All studies are summarized in the table below.

Table 7.2-2: Summary of stability data achieved at ≤ - 18°C (unless stated otherwise)

Matrix	Characteristics of the matrix	Acceptable Maximum Storage duration (months)				Source
		Trinexapac	CGA 313458	CGA 113745	CGA 224439	
Data relied on in EU						
Plant products						
Oilseed rape seeds	High lipid content	24				RAR, 2018; EFSA, 2018
Wheat grain	High starch content	24	12	1(1)	12	RAR, 2018; EFSA, 2018
Wheat straw	No group	12 (24)(2)				RAR, 2018; EFSA, 2018, (DAR, 2003)
Beer	Processed product		12	1(1)	12	RAR, 2018; EFSA, 2018
Bran			6	1(1)	12	RAR, 2018; EFSA, 2018
Flour			3	1(1)	12	RAR, 2018; EFSA, 2018
Bread			6	1(1)	12	RAR, 2018; EFSA, 2018
Animal Products						
Dairy cow	Muscle	3				DAR, 2003
Dairy cow	Liver	3				DAR, 2003
Dairy cow	Kidney	3				DAR, 2003
Dairy cow	Fat, omental	3				DAR, 2003
Dairy cow	Milk	4				DAR, 2003
Dairy cow	Blood	3				DAR, 2003
New data						
Plant products						
Oilseed rape seeds	High lipid content	26				Brown, D., 2020 Report No.: 227361
Lettuce	High water content	18				
Cereal grain	High starch content	26				
Broad bean	High protein content	26				
Citrus	High acid content	26				

(1) CGA113475 was unstable in the presence of crop matrices - degrading to only 20% of the initial amount over 30 days.
(2) Mean storage stability of trinexapac in straw after 24 months was 75% (61.8% uncorrected for procedural recoveries).

Accordingly, straw may be considered sufficiently stable for a period of 24 months, as according to the DAR, 2003 and in devitation from RAR, 2018 (see below).

Conclusion on stability of residues during storage

"Residues of trinexapac acid (CGA 179500) in cereal grain as well as in rapeseed can be considered as stable for at least 24 months when stored at -18°C. Residues of trinexapac acid (CGA 179500) in wheat straw can be considered as stable for at least 12 months when stored at -18°C. Some cereal samples from the residue trials were stored up to 25.5 months. As the degradation of trinexapac acid is slow (in grain, 90% (79.4 % uncorrected) of trinexapac acid was recovered after 24 months), the applicant considers that there is no impact on the levels of trinexapac acid in the samples. RMS agrees with EFSA that trials not adequately supported by storage stability shall be excluded from the assessment."(*RAR, 2018*)

"Residues of trinexapac acid (CGA 179500) in muscle, liver, kidney, fat and blood can be considered as stable for at least 3 months and in milk for at least 4 months when stored at -18°C. Storage stability in animal matrices was tested as part of the feeding study. This study was performed prior to the adoption of the OECD guideline 506 for stability of pesticide residues in stored commodities. Ten fortified specimens were prepared for each matrix and stored at or below -18°C. Five sub-specimens were used for analysis, the other five served as reserve. Each series of analyses was accompanied by two freshly fortified specimens to check the procedural recoveries. The average recovery for muscle is below the 70 % (67 %), the range of measurements is around 70% (three values >70 and two values <70%). It is explained by the applicant that recoveries for both stored commodities and procedural recoveries are similar and both low, which suggests that there may not be a decline on storage. The corrected recovery for muscle is above 70%; this indicates that the "low" uncorrected recovery is due to the analytical method and is not a decline on storage. Despite the minor deficiencies the RMS considers the stability study as sufficient to cover the proposed uses of this application." (*RAR, 2018*)

Summary of new storage stability data

Residues of trinexapac acid (CGA 179500) in dried broad bean, cereal grain, oilseed rape seed can be considered stable for at least 26 months when stored at -20°C.

Residues of trinexapac acid (CGA 179500) in lettuce can be considered stable for 18 months when stored at -20°C.

7.2.1.2 Stability of residues in sample extracts (KCA 6.1)

The relevant information on the stability in the final or any intermediate step can be derived from the fortification experiments performed during method validation. If the recoveries in the fortified samples are within the acceptable range of 70 - 120%, stability is sufficiently demonstrated.
The procedural recoveries obtained fully support the residue data presented in this submission.

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

Reference: RMS The Netherlands (DAR, 2003; DAR, 2005 – addendum to DAR, 2003); RMS Lithuania (RAR, 2018); EFSA, 2018

No new metabolism studies on primary crops have been submitted by the applicant in the framework of this application. New studies were submitted for Annex I Renewal of trinexapac-ethyl; they have been evaluated by RMS Lithuania (RAR, 2018) and by EFSA (2018). All studies are summarized in the table below.

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	
Data relied on in EU								
Pulses and oilseeds	Spring oilseed rape	^{14}C-cyclohexyl	Foliar, G	0.40	1	0, 14, 65	Nicollier, G., 1991 Report 4/91 Nicollier, G., 1993 Report 7/93 (supplementary)	DAR, 2003, RAR, 2018, EFSA, 2018
Cereals	Spring wheat	^{14}C-cyclohexyl	Foliar, G	0.15	1	0, 1, 2, 7, 14, 21	Krauss, J.H., 1990 Report 20/90	DAR, 2003, RAR, 2018, EFSA, 2018
	Spring wheat	^{14}C-cyclohexyl	Foliar, F	0.15	1	0, 25, 48, 71	Krauss, J.H., 1993 Report 6/93 (supplementary)	DAR, 2003, RAR, 2018, EFSA, 2018
	Paddy rice	^{14}C-cyclohexyl	Foliar, G	Scenario 1: 0.04 Scenario 2: 0.16	1	Scenario 1: Foliage 0, 7, 21 Grain, husks, straw: 82 Scenario 2: Grain, straw: 60	Gross, D., 1996 Report 11/96	DAR, 2003, RAR, 2018, EFSA, 2018
	Grass	^{14}C-cyclohexyl	Foliar, F	0.56	1	22, 46, 102	Ray, W.J., May-Hertl, U., 2003 Report 623-00	DAR, 2003, RAR, 2018, EFSA, 2018
Pulses and oilseeds	Spring oilseed rape	^{14}C-cyclohexyl	Foliar, G	0.394	1	Foliage(c): 21 Whole plant(c):	Piskorski, R., 2015a Report	RAR, 2018 EFSA, 2018 2018

Crop Group	Crop	Label position	Application and sampling details					Reference
			Method, F or G (a)	Rate (kg a.s./ha)	No	Sampling (DAT)	Remarks	
						67-91	20120173	
Cereals	Spring wheat	^{14}C-cyclohexyl	Foliar, F	0.211	1	Forage: 7 Hay: 34 Grain, straw: 62	Piskorski, R., 2015b Report 20120098	RAR, 2018 EFSA, 2018

Summary of plant metabolism studies

"All studies were performed using a cyclohexane ring radiolabelled form of trinexapac-ethyl ([^{14}C]-trinexapac-ethyl). No study was conducted using cyclopropane ring radiolabelled form of trinexapac-ethyl ([^{14}C]-trinexapac-ethyl).In one trial on spring wheat (new data), the application rate was 1.69 times higher than the critical GAP proposed for wheat in Southern and Northern Europe (0.211 vs 0.125 kg a.s./ha) and 1.06 times higher than the critical GAP proposed for barley in Southern and Northern Europe (0.211 vs 0.200 kg a.s./ha). In remaining wheat and oilseed rape trials the application rate was in line with the critical GAP proposed for wheat and oilseed rape in Southern and Northern Europe.

Trinexapac-ethyl (CGA163935) is extensively degraded in wheat, oilseed rape, rice and grass by very similar biotransformation pathways. It should be noted, that original metabolism studies (from the DAR, 2003) on oilseed rape and wheat (Nicollier, 1991 and Krauss, 1993) are considered supplementary due to deviations from OECD 501. Trinexapac-ethyl was only detected at trace levels in wheat forage and all parts of rice. Metabolism proceeded via hydrolysis to the major metabolite trinexapac acid (CGA179500) up to 0.577 mg/kg 40 % TRR in wheat grain, followed by hydroxylation (forming hydroxylated CGA179500; 0.175 mg/kg representing 12.1 % TRR) and subsequent ring opening of the cyclohexane ring. Stepwise oxidation/decarboxylation yielded saturated and unsaturated tricarboxylated acids such as CGA275537 (tricarballylic acid; up to 0.91 mg/kg representing 17 % TRR in grass seeds), CGA312753 (aconitic acid; 0.058 mg/kg representing 35 % TRR in rice husks) and citric acid, all precursors to incorporation into the biosynthetic pool of natural products.

A secondary pathway proceeded via ring opening of the cyclohexane ring of parent leading to formation of CGA300405 (0.374 mg/kg representing 20.7 % TRR in wheat forage) and the mono ethyl esters of CGA275537 (tricarballylic acid; up to 0.206 representing 10.3 % TRR in wheat hay and 0.37 representing 17 % TRR in rice husks), CGA312753 (aconitic acid; up to 0.058 mg/kg representing 35 % TRR in rice husks). Further steps observed were aromatisation of the 6-membered ring of trinexapac acid and keto-enol tautomerism to 4-cyclopropanecarbonyl-3,5-dihydroxobenzoic acid CGA329773 (up to 0.03 representing 2.5 % TRR in rice grain and 11 % TRR in wheat grain – supplementary study) and NOA433257 (terephthalic acid; found only in grass up to 3.5 mg/kg representing 12 % TRR in seed screenings of grass) and reduction of CGA179500 to yield CGA351210 (found only in supplementary study of oilseed rape in oil, pods and stalks up to 28 % TRR).

In the new metabolism studies provided for renewal, the following metabolites – trinexapac acid (CGA179500), CGA300405, tricarballylic acid (CGA275537) and hydroxylated trinexapac acid (SYN548584) – were found in amounts more than 10 %TRR. In EU reviewed metabolism studies, the following metabolites – CGA329773, transaconitic acid CGA312753, metabolite A (SYN540405) and terephthalic acid NOA433257 – were found in amounts more than 10 %TRR.

Although not all metabolites were found in every plant species, all observed degradation and transformation steps (oxidation, decarboxylation, ring cleavage, conjugation) occurred in all crops. Therefore, the metabolic pathways are considered comparable in all crops." (*RAR, 2018*)

"All the metabolism studies were conducted exclusively with trinexapac-ethyl radiolabelled in the cyclohexyl ring and not in the cyclopropyl moiety. Cleavage of the molecule was observed and confirmed in the hydrolysis study with formation of the compound CGA224439. There are indications that CGA224439 may be more toxic than parent […]. *A data gap is identified to address the nature of residues in primary and rotational crops and livestock with regard to the cyclopropyl moiety*. Primary plant metabolism was investigated on cereal/grass (wheat, rice, grass) and pulse/ oilseed (rape seeds). In grains and seeds, trinexapac, free and in the conjugated form, was the main component of the total residues followed by its hydroxylated form (12% total radioactive residue (TRR), 0.17 mg/kg). The Task Force communicated that this metabolite (SYN548584) is unstable outside plant matrix and is not possible to be analysed. Therefore, the Task Force proposed to estimate its amounts in cereals using a conversion factor derived from the metabolism study in wheat. *Overall, further data to elucidate the structure and amounts of SYN548584 in cereals grain and straw are required (data gap).*

In the plant parts intended for animal feed, metabolism was more extensive. Trinexapac and the metabolite CGA300405 were both present at comparable levels (max. 22% and 21% TRR, respectively) in forage and straw. Tricarballylic acid (CGA275537) was identified in wheat, rice and grass at varied proportions and levels (19% TRR, 0.03 mg/kg, rice straw; 14% TRR, 0.28 mg/ kg, grass forage) whereas aconitic acid (CGA312753) was only identified in rice husk (35% TRR, 0.06 mg eq/kg). As they are also naturally occurring compounds in plants and, moreover, tricarballylic acid seems to be produced by rumen microorganisms, they were not proposed for inclusion in the residue definition for feed items. *In grass, unique metabolites were observed compared to the other cereal crops, and a data gap is identified to address their relevance for the entire category of cereal/ grass crops.*

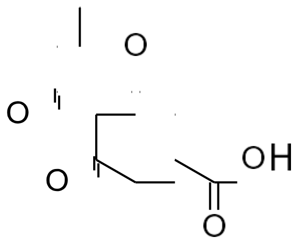
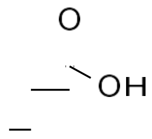
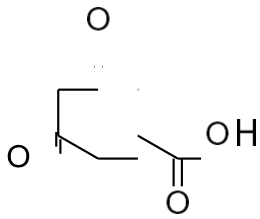
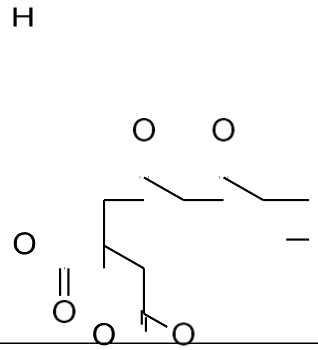
For the cereal/grass crops category group, the residue definition for monitoring is trinexapac and its salts, expressed as trinexapac (current residue definition). For risk assessment, the residue definition shall be regarded as provisional and it is proposed as trinexapac, free and conjugated for grains and trinexapac, free and conjugated plus CGA300405 for cereal fodder items/grass. *Whether the consumer risk assessment for CGA300405 is to be conducted combined or separately is pending assessment of its toxicological relevance [...] and investigation to address the relevance in feed items and the potential carry-over of residues in animal commodities (data gap)*. For the pulse and oilseed group, the residue definition could not be finalised." (*EFSA, 2018*)

Applicant response to data gaps stated by EFSA (2018)

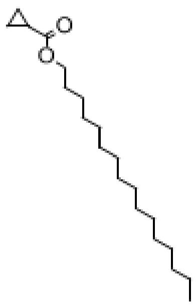
(1) **Regarding „*to address the nature of residues in primary and rotational crops and livestock with regard to the cyclopropyl moiety*":**

The TRINEXAPAC task force believes that based on the literature evidence shown below no additional metabolites other than CPCA (cyclopropanecarboxylic acid or CGA224439) and its' conjugates will be formed from the plant and livestock metabolism of cyclopropyl labelled trinexapac-ethyl. Therefore, the TRINEXAPAC task force believes that additional plant and livestock metabolism studies to quantify levels of CPCA and its' conjugates are unnecessary.

The TRINEXAPAC task force has demonstrated that trinexapac acid forms CPCA (CGA224439), CGA313458 and CGA113745 (see structures below) under processing conditions (baking, boiling, brewing, sterilisation and pasteurisation) and has quantified low levels of these metabolites in processed commodities in both wheat and barley processing studies.

CGA179500	**CGA224439 (CPCA)**	**CGA113745**	**CGA313458**
			

With regard to the cyclopropyl moiety of trinexapac, further literature searches on CPCA were conducted and papers outside of the ten year remit for the literature review were found. The metabolic fate of CPCA in mammals and plants is well understood and reported in a series of papers published in 1978, which are all publicly available.
In a plant metabolism study with apple and orange trees (Quistad *et al*., 1978a[3]) treated with Cycloprate (see structure below), the single major metabolite found in both fruit and foliage was CPCA (CGA224439) (present mainly as conjugates) and omega-cyclopropyl fatty acids.
The bioavailability of the CPCA polar conjugates in rats was also examined. Administration of the conjugates derived from apple fruit to rats provided a similar metabolic profile of CPCA metabolites (CPCA-glycine, CPCA-carnitine and omega-cyclopropyl fatty acids).
Taking into consideration the published data from these plant studies, the TRINEXAPAC task force considers plant metabolism studies to study the fate of CPCA (CGA224439) to be unwarranted.


Cycloprate

In livestock treated with cycloprate (hexadecyl cyclopropanecarboxylate) (Quistad *et al*., 1978b-d[4]), CPCA was eliminated in urine mainly as the glycine conjugate with a smaller proportion as free CPCA. The majority of the residue in milk was characterized as cyclopropane fatty acids (abundant in bacteria of ruminants and to a lesser extent in the intestinal flora of monogastric animals thus representing a natural exposure to these fatty acids) or CPCA carnitine conjugate.
Given the publication of this data from cow, rat and dog, the applicant considers the use of further animals to study the fate of CPCA to be unwarranted and unethical with respect to animal welfare.
The TRINEXAPAC task force considers that the relevant published literature existing on plant and animal metabolism is sufficient to address the concern on CPCA (CGA224439) and that the risk assessment can

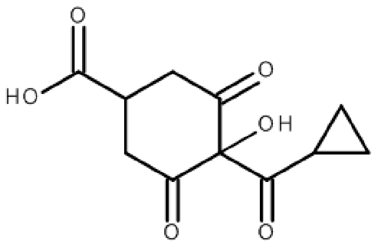
[3] Quistad GB, Staiger LE and Schooley DA (1978a) Environmental Degradation of the Miticide Cycloprate (Hexadecyl Cyclopropanecarboxylate). 2. By Apples and Oranges. J. Agric. FoodChem., 26, 76-80
[4] Quistad GB, Staiger LE and Schooley DA (1978b) Environmental Degradation of the Miticide Cycloprate (Hexadecyl Cyclopropanecarboxylate). 3. Bovine Metabolism. J. Agric. FoodChem., 26, 71-75
Quistad GB, Staiger LE and Schooley DA (1978c) Environmental Degradation of the Miticide Cycloprate (Hexadecyl Cyclopropanecarboxylate). 1. Rat Metabolism. J. Agric. FoodChem., 26, 60-66
Quistad GB, Staiger LE and Schooley DA (1978d) Environmental Degradation of the Miticide Cycloprate (Hexadecyl Cyclopropanecarboxylate). 4. Beagle Dog Metabolism. J. Agric. FoodChem., 26, 76-80

be adequately addressed and finalized.

(2) Regarding „*further data to elucidate the structure and amounts of SYN548584 in cereals grain and straw*":

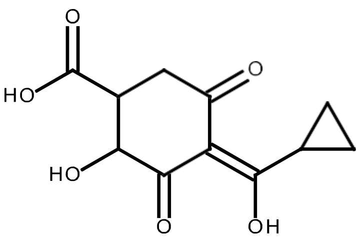
Results from the wheat metabolism study (Piskorski, R., 2015b; Report 20120098) identified the presence of a hydroxylated form of trinexapac acid (SYN548584) in grain. The identity of the metabolite was based on the following data:

- LC/MS analysis was conducted in both positive and negative mode and the elemental formula was determined as a hydroxylated form of trinexapac acid (based on molecular ion and $^{14}C/^{14}C_2$ isotopic pattern). Fragmentation data was consistent with no modification in the cyclopropane group.
- Deuterium exchange experiments were conducted in negative mode on trinexapac acid, the component of interest and CGA329773. The number of exchangeable protons present in each component was 2, 3 and 3 respectively. These data indicate that the site of hydroxylation is not on the acidic carbon between the three carbonyl groups (see structure of 4-hydroxy moiety below).

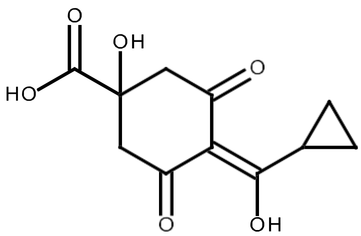


4-hydroxy

Based on these data the oxidation was proposed to take place in the cyclohexanedione portion of the molecule to form either the 2-hydroxy or 1-hydroxy moiety (see structures below).



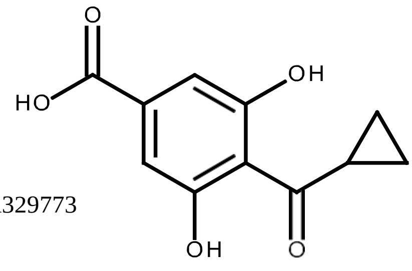
2-hydroxy



1-hydroxy

In addition, to the LC/MS analysis, hydrolysis experiments were conducted on the component of interest. Under acid hydrolysis conditions (0.1M HCl, 40°C, 3 hours) it was observed that approximately 25% of the component of interest was converted to a known metabolite CGA329773 (see structure below). Both structures proposed by LC-MS are consistent with such a transformation.

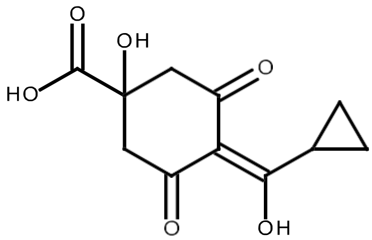
CGA329773



Following conduct of the GLP study, non-GLP work was initiated to attempt to determine the position of hydroxylation. This was carried out by isolation of the component of interest from the grain commodity to produce a sample of sufficient purity for analysis by NMR. This has been unsuccessful due to large amounts of endogenous material co-eluting with the component of interest. In addition, there has been consistent losses of the component of interest during work up to form CGA329773 (based on chromatographic retention time) consistent with the hydrolysis experiment described above.

In parallel to this work, attempts to synthesis the two proposed hydroxylated trinexapac acid components have been ongoing for two years. To date, the diastereoisomer pairs of the 2-hydroxy metabolite have been synthesised (SYN549426 and SYN549427). Analysis by two dissimilar chromatographic systems (HPLC and 2D-TLC) both indicate that they do not match the component of interest in grain. Attempts to synthesise the tertiary alcohol have to date been unsuccessful, as it appears to be unstable outside of the plant matrix.

Based on the data provided above and confirmation that the 2-hydroxy component is not present, the grain metabolite is tentatively identified as the 1-hydroxy metabolite, SYN548584 (structure below).



1-hydroxy (SYN548584)

This structure is consistent with the known metabolic pathway of trinexapac-ethyl in wheat based on the 2 available trinexapac-ethyl wheat metabolism studies.

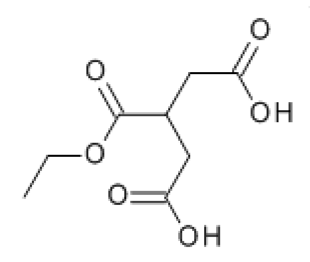
- Citric acid was observed in the wheat metabolism study (Piskorski, 2015b, Report 20120098) which indicates hydroxylation does occur adjacent to the carboxylic acid.

Additionally, the mono ethyl ester of CGA312753 was observed in the Krauss (1993; Report 6/93) study indicative of activation of the 1-position on the cyclohexanedione ring.
The applicant believes that this evidence shows that exhaustive attempts have already been made to elucidate and confirm the structure of the metabolite SYN548584.

As this molecule SYN548584 is unstable outside the plant matrix estimates of residue levels in all the representative uses could be calculated from the wheat metabolism study.

(3) Regarding "*Whether the consumer risk assessment for CGA300405 is to be conducted combined or separately is pending assessment of its toxicological relevance [...] and investigation to address the relevance in feed items and the potential carry-over of residues in animal commodities*":

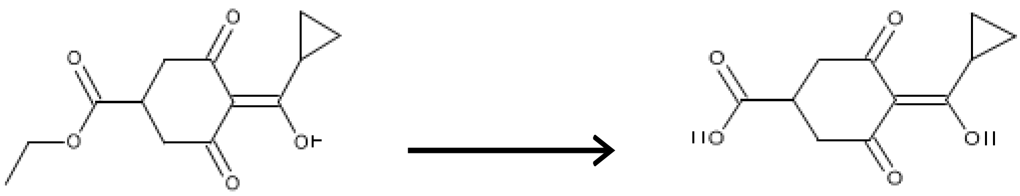
Due to the evidence shown below, the TRINEXAPAC task force believes that CGA300405 should not be included in the definition of residue for straw.
Relevance of CGA300405 in feed items and potential carry over into animal commodities (structure shown



below):

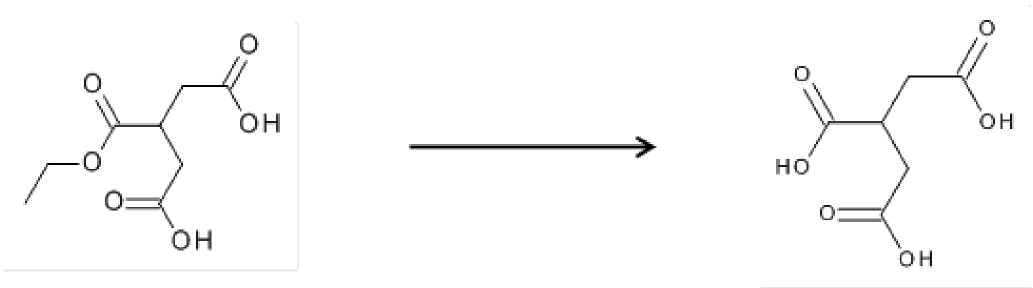
CGA300405

From the wheat metabolism study - CGA300405 is found in forage, hay and straw. Trinexapac-ethyl is only registered for use on cereals intended for grain production and therefore CGA300405 is only relevant in straw for feeding purposes.
In the metabolism study the contribution of CGA300405 to the residue in straw was 9.6% TRR (0.13 mg/kg) in addition to the residue of trinexapac acid 5.5% TRR (0.075 mg/kg). The metabolic pathway in cereals shows CGA300405 is likely to hydrolyse rapidly to CGA275537 (tricarballylic acid), so CGA300405 present in straw and fed to animals is also likely to break down in the animal.
In the existing parent trinexapac-ethyl goat and hen metabolism studies, parent is rapidly metabolized by hydrolysis of the ester group (no parent remains in any ruminant commodities and only 0.005 mg/kg in poultry) to produce trinexapac acid, as shown below.



Trinexapac-ethyl Trinexapac acid

It is therefore postulated that CGA300405 would undergo the same rapid ester hydrolysis to the tricarballylic acid (CGA275537), as shown below.



CGA300405 CGA275537

The total calculated residue in straw (from the metabolism study) is 0.13 + 0.075 mg/kg = 0.205 mg/kg. Residues in straw are used in the dietary burden calculations and the calculated burden (0.59 mg/kg DM (sheep)) compared with the feeding study data to show whether there is any transfer from feed into animal tissues. From the trinexapac feeding study -the only animal tissue which would contain any residue at this dietary burden is ruminant kidney (0.01 mg/kg) and residue levels are below MRL of 0.05 mg/kg. Therefore, although CGA300405 is observed in cereals, the levels found have no significant impact on the level of the terminal residue in animal commodities even before rapid hydrolysis is taken into consideration.
CGA300405 is non-genotoxic and considered to be of low toxicological concern due to the expected rapid hydrolysis to CGA275537.
The TRINEXAPAC task force believes that according to the evidence shown above, CGA300405 should not be included in the Definition of residue (DoR) for straw.

Conclusion on metabolism in primary crops

The metabolism of trinexapac-ethyl in plants following foliar application is sufficiently addressed to support the proposed uses of the product ADM.09050.H.1.A. It is concluded that metabolite CGA300405 does not need to be included in the risk assessment residue definition for cereal fodder.

7.2.2.2 Nature of residue in rotational crops (KCA 6.6.1)

Available data

Reference: RMS The Netherlands (DAR, 2003; DAR, 2005 – addendum to DAR, 2003); RMS Lithuania (RAR, 2018); EFSA, 2018

No new nature of residue studies on rotational crops have been submitted by the applicant in the framework of this application. New studies were submitted for Annex I Renewal of trinexapac-ethyl; they have been evaluated by RMS Lithuania (RAR, 2018) and by EFSA (2018). All studies are summarized in the table below.

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	
Data relied on in EU								
Leafy vegetables	Lettuce	^{14}C-cyclohexyl	Bare soil, F	0.150	99, 119	129, 169	Krauss, J.H., 1992. Report 23/92	DAR, 2003 EFSA, 2018
Root and tuber vegetables	Sugar beet	^{14}C-cyclohexyl	Bare soil, F	0.150	343, 407, 496	387, 515, 693	Krauss, J.H., 1992. Report 23/92	DAR, 2003 EFSA, 2018
Cereals	Wheat	^{14}C-cyclohexyl	Bare soil, F	0.150	173, 299, 343, 407	227, 479, 567, 695	Krauss, J.H., 1992. Report 23/92	DAR, 2003 EFSA, 2018
	Maize	^{14}C-cyclohexyl	Bare soil, F	0.150	369, 407, 496	400, 476, 654	Krauss, J.H., 1992. Report 23/92	DAR, 2003 EFSA, 2018
Leafy vegetables	Lettuce	^{14}C-cyclohexyl	Bare soil, F	0.330	30, 120, 270	Immature: 86, 183, 290 Mature: 113, 198, 309	Quistad, G.B., Kovatchev, A., 2010. Report 1802W	RAR, 2018 EFSA, 2018
Root and tuber vegetables	Radish	^{14}C-cyclohexyl	Bare soil, F	0.330	30, 120, 309	83, 183, 350	Quistad, G.B., Kovatchev, A., 2010. Report 1802W	RAR, 2018 EFSA, 2018
Cereals	Wheat	^{14}C-cyclohexyl	Bare soil, F	0.330	30, 120, 270	Forage: 83, 168, 296 Hay: 168, 209, 315 Grain, straw: 231, 251, 352	Quistad, G.B., Kovatchev, A., 2010. Report 1802W	RAR, 2018 EFSA, 2018

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

Summary of metabolism studies on rotational crops

"The uptake of CGA 163935 in rotational crops, as analysed in lettuce, winter wheat, sugar beets and corn after direct application of 0.15 kg as/ha radio-labelled compound to the soil, is very low (<0.01 mg/kg). The application rate of CGA 163935 was 25% below the proposed GAP for barley (150 g instead of 200 g as/ha). The study is considered suitable for evaluation. (*DAR, 2003*)

After one application of trinexapac-ethyl applied to bare ground at a rate of 0.3 kg a.s./ha (1.5N (300 g/ha instead of 200 g/ha) the maximum rate of the representative crops (barley), the total radioactive residues in all RACs were very low <0.01 mg/kg, except for some 30 day PBI foliage RACs (lettuce and wheat) were slightly above 0.01 mg/kg. However, no individual extractable ^{14}C-residue was found to be >0.01 mg/kg for any RAC at any PBI. No extractable residue match parent. These finding suggest extensive and rapid soil degradation of parent and likely mineralization to CO_2, since little ^{14}C was take-up into any rotational crop." (*RAR, 2018*)

"All the metabolism studies were conducted exclusively with trinexapac-ethyl radiolabelled in the cyclohexyl ring and not in the cyclopropyl moiety. Cleavage of the molecule was observed and confirmed in the hydrolysis study with formation of the compound CGA224439. There are indications that CGA224439 may be more toxic than parent […]. *A data gap is identified to address the nature of residues in primary and rotational crops and livestock with regard to the cyclopropyl moiety*. […] In the rotational crop, metabolism studies residues were too low (total residues quantifiable only in wheat foliage and lettuces at 30-day plant-back interval) to define the metabolic pathway of trinexapac." (*EFSA, 2018*)

Applicant response to data gaps stated by EFSA (2018)

(1) Regarding „*to address the nature of residues in primary and rotational crops and livestock with regard to the cyclopropyl moiety*":

This issue has been discussed in detail in Point 7.2.2.1 above.

Conclusion on metabolism in rotational crops

Metabolism in primary and rotational crops was found to be similar and a specific residue definition for rotational crops is not deemed necessary.

7.2.2.3 Nature of residues in processed commodities (KCA 6.5.1)

Available data

Reference: RMS The Netherlands (DAR, 2003; DAR, 2005 – addendum to DAR, 2003), RMS Lithuania (RAR, 2018), EFSA, 2006; EFSA, 2018

No new nature of residue studies in processed commodities have been submitted by the applicant in the framework of this application. New studies were submitted for Annex I Renewal of trinexapac-ethyl; they have been evaluated by RMS Lithuania (RAR, 2018) and by EFSA (2018). All studies are summarized in the table below.

Table 7.2-5: Nature of the residues in processed commodities

Conditions (Duration, Temperature, pH)	Identified compound(s) (%)					Remarks	Reference
	Trinexapac-ethyl	CGA 179500	CGA 313458	CGA 224439	CGA 113745		
Data relied on in EU							

Conditions (Duration, Temperature, pH)	Identified compound(s) (%)					Remarks	Reference
	Trinexapac-ethyl	CGA 179500	CGA 313458	CGA 224439	CGA 113745		
^{14}C-cyclohexyl-trinexapac-ethyl							
Pasteurisation (20 minutes, 90°C, pH 4)	99%					Cadalbert, R., Buckel, T., 2001. Report 01RC02	DAR, 2003 EFSA, 2006, 2018
Baking, boiling, brewing (60 minutes, 100°C, pH 5)	99%						
Sterilisation (20 minutes, 120°C, pH 6)	99%						
^{14}C-cyclohexyl-trinexapac acid							
Pasteurisation (20 minutes, 90°C, pH 4)	N/A	52.5%	19.7%		9.6%	Mound, E.L., 2004. Report RJ3480B	DAR, 2005
Baking, boiling, brewing (60 minutes, 100°C, pH 5)	N/A	58.8%	16.1%		10.5%		
Sterilisation (20 minutes, 120°C, pH 6)	N/A	50.9%	21.0%		11.6%		
^{14}C-cyclohexyl-trinexapac acid							
Pasteurisation (20 minutes, 90°C, pH 4)	N/A	95.2%	2.7%		2.2%	Flörchinger, M., 2008. Report S08-03106	RAR, 2018 EFSA, 2018
Baking, boiling, brewing (60 minutes, 100°C, pH 5)	N/A	93.1%	3.5%		3.4%		
Sterilisation (20 minutes, 120°C, pH 6)	N/A	97.7%	2.3%				
^{14}C-cyclopropyl-trinexapac							
Pasteurisation (20 minutes, 90°C, pH 4)	N/A	85.8%	4.7%	5.4%		Scullion, P., 2012. Report C93481	RAR, 2018 EFSA, 2018
Baking, boiling, brewing (60 minutes, 100°C, pH 5)	N/A	63.2%	17.7%	16.3%			
Sterilisation (20 minutes, 120°C, pH 6)	N/A	82.1%	8.4%	3.8%			

Summary of nature of residues in processed commodities studies

"The effect of processing on the nature of trinexapac-ethyl and trinexapac acid was investigated in the framework of the peer review. Studies were conducted by Syngenta simulating representative hydrolytic conditions for pasteurisation (20 minutes at 90°C, pH 4), boiling/brewing/baking (60 minutes at 100°C, pH 5) and sterilisation (20 minutes at 120°C, pH 6). Two other studies were conducted by the members of the Task Force and are therefore submitted. Results of all these studies are presented in the table B.7.5.1-8.
In the studies conducted by Syngenta and Cheminova, trinexapac acid was radiolabelled in the cyclohexane ring while the Adama study has been conducted with a different radiolabelled position (cyclopropane ring). The Syngenta and Adama studies show that trinexapac acid degrades under elevated temperatures conditions, but represents the major part of the residue (~51-86% TRR). Degradation products identified are CGA313458 (~4-21% TRR), CGA113745 (~10-12% TRR) and cyclopropane carboxylic acid (CGA224439) (~5-18% TRR), which haven't been found in the rat metabolism.

The Cheminova study shows that trinexapac acid remains stable under pasteurisation, baking/boiling/brewing and sterilisation conditions – which is different from the Syngenta and Adama studies.
It can be concluded that the nature of residues in processed commodities is different to the one in raw agricultural commodities." (*RAR, 2018*)

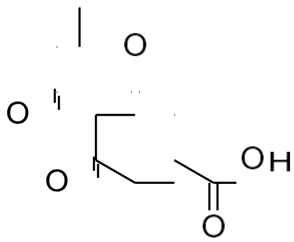
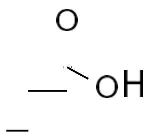
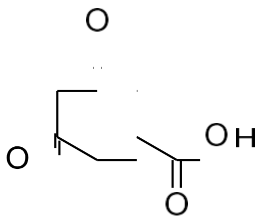
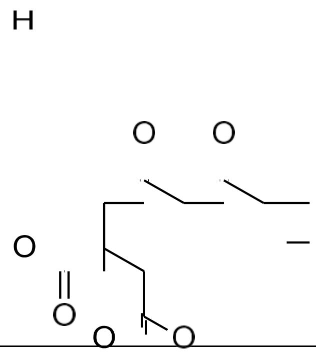
"A residue definition for processed products could not be set due to the contradictory outcome of the standard hydrolysis studies. *These experiments showed the compound to be either stable or to degrade forming CGA113745, CGA313458 and CGA224439, leading to a* <u>*data gap*</u> *for further clarifications*." (*EFSA; 2018*)

Applicant response to data gaps stated by EFSA (2018)

(1) Regarding „experiments showed the compound to be either stable or to degrade forming CGA113745, CGA313458 and CGA224439, leading to a data gap for further clarification":

Due to the evidence shown below, the TRINEXAPAC task force believes that qualitatively only three breakdown products (CGA113745, CGA313458 and CGA224439 (CPCA)) from processed crops which contain trinexapac acid (CGA179500) residues are possible and that the residue definition for processed products can be set and finalized.

The TRINEXAPAC task force has shown that under the conditions for baking, boiling, brewing, sterilization and pasteurisation trinexapac-ethyl is stable. However, the three studies submitted carried out by different TRINEXAPAC task force members with trinexapac acid – CGA179500 – as the test item, showed qualitatively that this molecule is unstable under the conditions stipulated in the guidance and breaks down to CGA313458, CGA224439 (CPCA) and CGA113745.

CGA179500	CGA224439 (CPCA)	CGA113745	CGA313458
			

Two studies were carried out with the same radioactive label (^{14}C-cyclohexyl) and both showed some degradation to CGA313458 and CGA113745 although quantification was different.

The third study was carried out with a different radio-label (^{14}C- cyclopropane carbonyl) and therefore only degradation molecules containing the ^{14}C-cyclopropane carbonyl were observed - CGA313458 and CGA224439.

It is scientifically reasonable to assume that if CGA113745 is formed by cleaving trinexapac acid next to the cyclohexyl ring, CGA224439 might be produced under the same conditions.

TRINEXAPAC task force believes that the hydrolysis studies show qualitatively that three breakdown products (CGA113745, CGA313458 and CGA224439 (CPCA)) are possible in the processing of crops which contain trinexapac acid (CGA179500) residues. Therefore, the residue definition for processed products can be set and finalized.

In light of the quantitative differences in the studies, the TRINEXAPAC task force decided to analyse for all three degradation compounds observed in the hydrolysis studies (CPCA, CGA113745 and CGA313458) in the processing studies. Analytical methods were developed for each of the metabolites and validated in the processing studies.

Processing studies were carried out on wheat and barley to quantify the levels of these breakdown products and were reported in MCA section 6. Additionally, a storage stability study on all the processed commodities was reported. It was found during these studies that CGA113745 was unstable in plant matrices - despite being seen in the pH controlled high temperature hydrolysis studies. Hence consumer exposure to CGA113745 from cereal commodities and processed cereal products is highly unlikely.

Conclusion on nature of residues in processed commodities

The nature of residues in processed commodities has been sufficiently addressed to support the proposed uses of the product ADM.09050.H.1.A. It is concluded that exposure from processing metabolites it unlikely and metabolites do not need to be included in the residue definition.

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

Table 7.2-6: Summary of the nature of residues in commodities of plant origin

Endpoints	
Plant groups covered	Cereals (wheat, rice, grass) Pulses/oilseeds (oilseed rape)
Rotational crops covered	Root/tuber crops (sugar beet, radish) Leafy crops (lettuce) Cereal (small grain) (wheat, maize)
Metabolism in rotational crops similar to metabolism in primary crops?	Yes
Processed commodities	Trinexapac-ethyl is not stable under standard hydrolysis conditions
Residue pattern in processed commodities similar to pattern in raw commodities?	No Residue definition in processed commodities is open[(a)] (EFSA, 2018)
Plant residue definition for monitoring	- Trinexapac (sum of trinexapac (acid) and its salts, expressed as trinexapac (Regulation n°2017/1016)
Plant residue definition for risk assessment	- Trinexapac, free and conjugated (cereal grain) (provisional) - Trinexapac, free and conjugated plus CGA300405 (cereal fodder items/grass) (expressed as trinexapac or separate, pending its toxicological relevance) (provisional) [(b)] (EFSA 2018)
Conversion factor from enforcement to RA	Cereal grain 1.8 (median) (EFSA, 2018) Cereal straw: open[(b)] (EFSA, 2018)

(a) See applicant response under Point 7.2.2.3 above
(b) See applicant response under Point 7.2.2.1 above. CF (median) for straw calculated as 4.38 (see Table 7.2-12)

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

Available data

Reference: RMS The Netherlands (DAR, 2003; DAR, 2005 – addendum to DAR, 2003); RMS Lithuania (RAR, 2018); EFSA, 2018

No new livestock metabolism studies have been submitted by the applicant in the framework of this application. New studies were submitted for Annex I Renewal of trinexapac-ethyl; they have been evaluated by the RMS Lithuania (RAR, 2018) and by EFSA (2018). All studies are summarized in the table below.

Table 7.2-7: Summary of animal metabolism studies

Group	Species	Label position	No of animal	Application details		Sample details		Remarks	Reference
				Rate (mg/kg bw/d)	Duration (days)	Commodity	Time of sampling		
Data relied on in EU									
Lactating ruminants	Goat	^{14}C-cyclohexyl	1	0.2	4	Milk	Twice daily	xxxx, 1992b Report 141782	DAR, 2003 EFSA, 2018
						Urine and faeces	Daily		
						Tissues	At sacrifice (4h)		
Lactating ruminants	Goat	^{14}C-cyclohexyl	1	20	4	Milk	Twice daily	xxxx 1993b Report 5/93 (supplementary)	DAR, 2003 EFSA, 2018
						Urine and faeces	Daily		
						Tissues	At sacrifice (4h)		
Lactating ruminants	Goat	^{14}C-cyclohexyl	2	3	4	Milk	Twice daily	xxxx 2002 Report 624-00	DAR, 2005 EFSA, 2018
						Urine and faeces	Daily		
						Tissues	At sacrifice (6h)		
Laying poultry	Hens	^{14}C-cyclohexyl	2	0.4	4	Eggs	Daily	xxxx 1992a Report 141798	DAR, 2003 EFSA, 2018
						Excreta	Daily		
						Tissues	At sacrifice (4h)		
Laying poultry	Hens	^{14}C-cyclohexyl	4	20	4	Eggs	Daily	xxxx, 1993b Report 6/93	DAR, 2003 EFSA, 2018
						Excreta	Daily		
						Tissues	At sacrifice (4h)		
Laying poultry	Hens	^{14}C-cyclohexyl	5	0.85	10	Eggs	Daily	xxxx 2006 Report RJ3678	RAR, 2018 EFSA, 2018
						Excreta	Daily		
						Tissues	At sacrifice (22h)		

Summary of animal metabolism studies

“Five hens were dosed for 10 consecutive days with ^{14}C-cyclohexadione labelled CGA163935 at a rate of 8.1 – 10.4 mg/kg in the diet, the hens were sacrificed approximately 22 hours after the final dose and necropsy of tissues of human dietary significance undertaken. Eggs were also collected during the dosing period. All tissue, eggs and excreta samples (also collected during the dosing period) were radioassayed to determine the radioactive residue (mg CGA163935 equivalents /kg sample) and the balance of dosed radioactivity recovered. Radioactivity extracted from egg white were fractionated and analysed by chromatography. The results of the analysis demonstrate that:

- [^{14}C]-trinexapac-ethyl and/or its hens biotransformation products are readily excreted as more than 87% of the dose was accounted for in the excreta.
- Total radioactive residues in egg yolk and egg white reached a maximum level of 0.009 mg/kg and 0.031 mg/kg after 8 days of dosing, respectively.
- Egg white was the only sample found to contain residues >0.01 mg/kg.
- Parent and trinexapac acid (CGA179500) were found in egg white at 0.005 mg/kg and 0.003 mg/kg respectively.

The predominant biotransformation pathway for trinexapac-ethyl in the hen is the hydrolysis of parent to the corresponding carboxylic acid, CGA179500. It is difficult to establish a plateau from the available studies. Although max values are reached 3 to 10 days in each animal, the mean concentration curve is quite stable during the experiment. RMS agrees with the applicant that plateau is reached rapidly as quite high values is observed at 1 day in 3 of 5 hens.
Study was performed prior to adoption of OECD guidelines 503." (*RAR, 2018*)

"After oral dosing with highly exaggerated doses of trinexapac-ethyl, the highest total radioactivity residues were found in kidneys (0.50-42 mg eq/kg). Relatively low residue levels were observed in milk (0.008-0.83 mg eq/kg). Residue concentrations reached plateau levels in milk after about 2 or 3 days. Trinexapac acid was the major residue component identified in milk, meat and offal, accounting for about 66-97% TRR. In one of the goat studies, metabolite CGA113745 was also found in the liver, kidney and fat (6-16% TRR), but at low absolute levels (<0.4 mg/kg) particularly when considering the exaggerated dose rate administered to the animals, anticipated residue levels would be negligible at the estimated maximum dietary burden of pesticide residues in the diet. The metabolism studies on lactating goats were reviewed within the framework of Directive 91/414/EEC and were considered to be acceptable; the notifier considers that no further metabolism study in ruminant is required to support trinexapac-ethyl." (*RAR, 2018*)

"All the metabolism studies were conducted exclusively with trinexapac-ethyl radiolabelled in the cyclohexyl ring and not in the cyclopropyl moiety. Cleavage of the molecule was observed and confirmed in the hydrolysis study with formation of the compound CGA224439. There are indications that CGA224439 may be more toxic than parent […]. *A data gap is identified to address the nature of residues in primary and rotational crops and livestock with regard to the cyclopropyl moiety*. […]
Metabolism studies with trinexapac-ethyl in lactating goats and laying hens showed that trinexapac is the main component of total residues. The only major metabolite identified is CGA113745 in goat liver (16.3% TRR, 0.35 mg/kg). For monitoring, the residue definition is proposed as trinexapac and its salts, expressed as trinexapac. Meanwhile, for risk assessment the residue definition is provisionally set in poultry as trinexapac and in ruminants as trinexapac plus the metabolite CGA 113745, expressed as trinexapac. In the feeding study in lactating cows, the metabolite CGA 113745 has not been analysed for.
Based on the results, residues of trinexapac are not expected in ruminant tissues and milk. Significant residues are not expected in poultry commodities as well considering the outcome of the metabolism study." (*EFSA, 2018*)

Applicant response to data gaps stated by EFSA (2018)

(1) Regarding „*to address the nature of residues in primary and rotational crops and livestock with regard to the cyclopropyl moiety*":

This issue has been discussed in detail in Point 7.2.2.1 above.

Conclusion on metabolism in livestock

The metabolism of trinexapac-ethyl in livestock has been sufficiently addressed to support the proposed uses of the product ADM.09050.H.1.A.

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

Table 7.2-8: 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	2-3 days in milk
	2-8 days in eggs
Animal residue definition for monitoring	Trinexapac (sum of trinexapac (acid) and its salts), expressed as trinexapac (Regulation n°2017/1016)
Animal residue definition for risk assessment	Poultry : trinexapac Ruminant: trinexapac + metabolite CGA 113745, expressed as trinexapac (Provisional, pending the outcome of the cyclopropyl label metabolism study proposed in the expert meeting)[(a)] (EFSA, 2018)
Conversion factor	Ruminants: provisional (based on the metabolism study): 1.25 (liver), 1.07 (kidney), 1.03 (muscle), 1.13 (fat), 1 (milk) Poultry: n.a. (EFSA, 2018)
Metabolism in rat and ruminant similar	Yes
Fat soluble residue	No

(a) See applicant response under Point 7.2.2.1 above

zRMS:
All issues considered in the present report on nature of the residues in plants and livestock has been accepted. They were considered within the RAR.

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

Reference: RMS Lithuania (RAR, 2018); EFSA, 2012 (Art. 12); EFSA, 2018

The intended cGAP for ADM-09050.H.1.A in barley in the Central Zone corresponds to or is less critical than the EU cGAP as shown in the table below. The intended cGAP for ADM-09050.H.1.A in wheat and rye is less critical than the EU cGAP as shown in the table below.

Studies were submitted for Annex I Renewal of trinexapac-ethyl, which have been evaluated by RMS Lithuania (RAR, 2018) and by EFSA (2018). No new studies on the magnitude of residues in plants have been submitted by the applicant in the framework of this application.

All studies are summarized Table 7.2-10 below and full study summaries are presented in the Appendix for ease of reference (see A 2.1.3).

Table 7.2-9: Comparison of intended and critical EU GAPs

Type of GAP	Region	Crop	Number of applications	Application rate per treatment (kg a.s./ha)	Interval between applications [min. days]	Growth stage at last application	PHI (days)	Remark
cGAP EU (RAR, 2018; EFSA, 2018)	EU	Barley	1	0.200	-	49	n.a.	
	EU	Wheat	1	0.125	-	49	n.a.	
	EU	Rye	1	0.125	-	49	n.a.	
cGAP EU (Art. 12, EFSA, 2012)	EU	Barley	1	0.180	-	49	n.a.	
	EU	Wheat	1	0.130	-	49	n.a.	
	EU	Rye	1	0.130	-	39	n.a.	
	EU	Oats	1	0.130	-	37	n.a.	
Intended cGAP (number 14)	C-EU	Barley	1	0.210	-	35	n.a.	
Intended cGAP (number 19)	C-EU	Wheat	1	0.105	-	39	n.a.	
Intended cGAP (number 6, 28)	C-EU	Spelt	1	87.5	-	32	n.a.	
Intended cGAP (number 18)	C-EU	Triticale	1	0.105	-	39	n.a.	
Intended cGAP (number 24)	C-EU	Oats	1	0.105	-	32	n.a.	
Intended cGAP (number 17)	C-EU	Rye	1	0.105	-	39	n.a.	

n.a.: not applicable, the PHI is covered by the time remaining between application and harvest

Table 7.2-10: Summary of EU reported and new data supporting the intended uses of ADM.09050.H.1.A and conformity to existing MRL

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)	Un-rounded OECD calculator MRL (mg/kg)	Current EU MRL (mg/kg) *	MRL compliance
Plant residue definition for monitoring: Trinexapac (sum of trinexapac (acid) and its salts, expressed as trinexapac Plant residue definition for risk assessment: Trinexapac, free and conjugated (cereal grain) (provisional); Trinexapac, free and conjugated plus CGA300405 (cereal fodder items/grass) (provisional)[a]								
Barley grain	RAR, 2018; EFSA, 2018	N-EU	GAP on which EU a.s. assessment is based: 1 x 0.200 kg as/ha, BBCH 49, outdoor E: 2 x<0.01, 2 x 0.03, 0.04, 2 x 0.12 RA: 0.01, 0.02, 0.05, 0.07, 0.13, 0.26, 0.27	E: 0.03 RA: 0.07	E: 0.12 RA: 0.27	0.244	3	Yes
	RAR, 2018; EFSA, 2018	S-EU	GAP on which EU a.s. assessment is based: 1 x 0.200 kg as/ha, BBCH 49, outdoor E: <0.01, 0.01, 0.03, 0.06[d], 0.14, 0.16[d], 2 x 0.47 RA: <0.01, 0.02, 0.06, 0.14, 0.17[d], 0.38[d], 0.69, 0.90	E: 0.10 RA: 0.16	E: 0.47 RA: 0.90	0.945	3	Yes
Wheat grain (Scaled data extrapolated to barley)	RAR, 2018; EFSA, 2018	N-EU	GAP on which EU a.s. assessment is based: 1 x 0.210 kg as/ha, BBCH 49, outdoor[c] E: 0.05, 2 x 0.08, 0.10, 0.11, 0.14, 0.15, 0.19, 0.37, 0.39, 0.66 RA: 0.02, 0.07, 4 x 0.10, 0.11, 0.18, 0.30, 0.39, 0.59	E: 0.14 RA: 0.10	E: 0.66 RA: 0.59	0.961	3	Yes
Barley grain (including extrapolated wheat data)	**Overall data supporting cGAP**	N-EU	E: 2 x <0.01, 2 x 0.03, 0.04, 0.05[c], 2 x 0.08[c], 0.10[c], 0.11[c], 2 x 0.12, 0.13[c], 0.14[c], 0.19[c], 0.35[c], 0.37[c], 0.63[c] RA: 0.01, 0.02, 0.02[c], 0.05, 0.06[c], 0.07, 0.09[c], 3 x 0.10[c], 0.11[c], 0.13, 0.17[c], 0.26, 0.27, 0.29[c], 0.37[c], 0.56[c]	E: 0.11 RA: 0.10	E: 0.63 RA: 0.56	0.777	3	Yes
Wheat grain (including spelt, triticale)	RAR, 2018; EFSA, 2018	N-EU	GAP on which EU a.s. assessment is based: 1 x 0.125 kg as/ha, BBCH 49, outdoor E: 0.03, 2 x 0.05, 0.06, 0.07, 0.08, 0.09, 0.11, 0.22, 0.24, 0.37 RA: 0.01, 0.04, 4 x 0.06, 0.07, 0.10, 0.17, 0.23, 0.36	E: 0.08 RA: 0.06	E: 0.37 RA: 0.36	0.550	3	Yes
	RAR, 2018; EFSA, 2018	S-EU	GAP on which EU a.s. assessment is based: 1 x 0.125 kg as/ha, BBCH 49, outdoor[c]	E: 0.06 RA: 0.09	E: 0.27 RA: 0.43	0.382	3	Yes

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)	Un-rounded OECD calculator MRL (mg/kg)	Current EU MRL (mg/kg) *	MRL compliance
Plant residue definition for monitoring: Trinexapac (sum of trinexapac (acid) and its salts, expressed as trinexapac Plant residue definition for risk assessment: Trinexapac, free and conjugated (cereal grain) (provisional); Trinexapac, free and conjugated plus CGA300405 (cereal fodder items/grass) (provisional)[(a)]								
			Mo: 3 x 0.03, 2 x 0.05, 2 x 0.06, 0.08, 0.15[(d)], 0.27[(d)] RA: 0.03, 0.04, 3 x 0.08, 0.09, 0.11, 0.12, 0.19[(d)], 0.43[(d)]					
	Overall data supporting cGAP	N-EU+S-EU	GAP on which EU a.s. assessment is based: 1 x 0.125 kg as/ha, BBCH 49, outdoor E: 4 x 0.03, 4 x 0.05, 3 x 0.06, 0.07, 2 x 0.08, 0.09, 0.11, 0.15[(d)], 0.22, 0.23, 0.27[(d)], 0.37 RA: 0.01, 0.03, 2 x 0.04, 4 x 0.06, 0.07, 3 x 0.08, 0.09, 0.11, 0.11, 0.12, 0.17, 0.19, 0.23, 0.36, 0.43	E: 0.06 RA: 0.08	E: 0.37 RA: 0.43	0.477	3	Yes
Oat grain (extrapolated from wheat grain)	**Overall data supporting cGAP**	N-EU+S-EU	GAP on which EU a.s. assessment is based: 1 x 0.125 kg as/ha, BBCH 49, outdoor E: 4 x 0.03, 4 x 0.05, 3 x 0.06, 0.07, 2 x 0.08, 0.09, 0.11, 0.15[(d)], 0.22, 0.23, 0.27[(d)], 0.37 RA: 0.01, 0.03, 2 x 0.04, 4 x 0.06, 0.07, 3 x 0.08, 0.09, 0.11, 0.11, 0.12, 0.17, 0.19, 0.23, 0.36, 0.43	E: 0.06 RA: 0.08	E: 0.37 RA: 0.43	0.477	3	Yes
Rye grain (extrapolated from wheat grain)	**Overall data supporting cGAP**	N-EU+S-EU	GAP on which EU a.s. assessment is based: 1 x 0.125 kg as/ha, BBCH 49, outdoor E: 4 x 0.03, 4 x 0.05, 3 x 0.06, 0.07, 2 x 0.08, 0.09, 0.11, 0.15[(d)], 0.22, 0.23, 0.27[(d)], 0.37 RA: 0.01, 0.03, 2 x 0.04, 4 x 0.06, 0.07, 3 x 0.08, 0.09, 0.11, 0.11, 0.12, 0.17, 0.19, 0.23, 0.36, 0.43	E: 0.06 RA: 0.08	E: 0.37 RA: 0.43	0.477	0.5	Yes
Barley straw	RAR, 2018; EFSA, 2018	N-EU	GAP on which EU a.s. assessment is based: 1 x 0.200 kg as/ha, BBCH 49, outdoor E: <0.01, 0.01, 0.02, 2 x 0.04 RA: *3 x <0.05*[(b)], *0.07*[(b)], 0.09	E: 0.02 RA: <0.05	E: 0.04 RA: 0.09	N/A		
	RAR, 2018;	S-EU	GAP on which EU a.s. assessment is based: 1 x 0.200 kg as/ha,	E: 0.03	E: 0.32	N/A		

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)	Un-rounded OECD calculator MRL (mg/kg)	Current EU MRL (mg/kg) *	MRL compliance
Plant residue definition for monitoring: Trinexapac (sum of trinexapac (acid) and its salts, expressed as trinexapac Plant residue definition for risk assessment: Trinexapac, free and conjugated (cereal grain) (provisional); Trinexapac, free and conjugated plus CGA300405 (cereal fodder items/grass) (provisional)[a]								
	EFSA, 2018		BBCH 49, outdoor[c] E: 2 x <0.01, 0.02, 0.03[d], 0.05[d], 0.13, 0.32 RA: *2 x 0.05*[b], *0.07*[b], 0.07[d], 0.18, 0.25[d], *0.28*[b]	RA: 0.07	RA: 0.28			
Wheat straw (Scaled data extrapolated to barley)	RAR, 2018	N-EU	GAP on which EU a.s. assessment is based: 1 x 0.210 kg as/ha, BBCH 49, outdoor[c] E: 2 x 0.02, 0.03, 0.04, 0.05, 0.11 RA: -	E: 0.035 RA: -	E: 0.11 RA: -	N/A		
Barley straw (including extrapolated wheat data)	**Overall data supporting cGAP**	N-EU	E: <0.01, 0.01, 0.02, 2 x 0.02[c], 2 x 0.03[c], 2 x 0.04, 0.05[c],0.11[c] RA: *3 x <0.05*[b], *0.07*[b], 0.09	E: 0.03 RA: <0.05	E: 0.11 RA: 0.09	N/A		
Wheat straw (including spelt, triticale)	RAR, 2018; EFSA, 2018	N-EU	GAP on which EU a.s. assessment is based: 1 x 0.125 kg as/ha, BBCH 49, outdoor E: 5 x <0.01, 2 x 0.01, 2 x 0.02, 0.03, 0.07 RA: 4 x <0.05; *7 x <0.05*[b]	E: 0.01 RA: 0.05	E: 0.07 RA: 0.05	N/A		
	RAR, 2018; EFSA, 2018	S-EU	GAP on which EU a.s. assessment is based: 1 x 0.125 kg as/ha, BBCH 49, outdoor[c] E: 5 x <0.01, 0.01, 0.03, 0.05[d], 0.08, 0.09[d] RA: *6 x <0.05*[b], *0.05*[b], 0.03[d], 0.09[d], 0.17[d]	E: 0.01 RA: 0.05	E: 0.09 RA: 0.17			
	Overall data supporting cGAP	N-EU + S-EU	GAP on which EU a.s. assessment is based: 1 x 0.125 kg as/ha, BBCH 49, outdoor E: 10 x <0.01, 3 x 0.01, 2 x 0.02, 2 x 0.03, 0.05, 0.07, 0.08, 0.09 RA: 4 x<0.05, *13 x <0.05*[b], 0.05[b], 0.03[d], 0.09[d], 0.17[d]	E: 0.01 RA: 0.05	E: 0.09 RA: 0.17	N/A		
Oat straw	**Overall data**	N-EU + S-EU	GAP on which EU a.s. assessment is based: 1 x 0.125 kg as/ha,	E: 0.01	E: 0.09	N/A		

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)	Un-rounded OECD calculator MRL (mg/kg)	Current EU MRL (mg/kg) *	MRL compliance
Plant residue definition for monitoring: Trinexapac (sum of trinexapac (acid) and its salts, expressed as trinexapac Plant residue definition for risk assessment: Trinexapac, free and conjugated (cereal grain) (provisional); Trinexapac, free and conjugated plus CGA300405 (cereal fodder items/grass) (provisional)[a]								
(extrapolated from wheat grain)	**supporting cGAP**		BBCH 49, outdoor E: 10 x <0.01, 3 x 0.01, 2 x 0.02, 2 x 0.03, 0.05, 0.07, 0.08, 0.09 RA: 4 x<0.05, *13 x <0.05*[b], 0.05[b], 0.03[d], 0.09[d], 0.17[d]	RA: 0.05	RA: 0.17			
Rye straw (extrapolated from wheat grain)	**Overall data supporting cGAP**	N-EU + S-EU	GAP on which EU a.s. assessment is based: 1 x 0.125 kg as/ha, BBCH 49, outdoor E: 10 x <0.01, 3 x 0.01, 2 x 0.02, 2 x 0.03, 0.05, 0.07, 0.08, 0.09 RA: 4 x<0.05, *13 x <0.05*[b], 0.05[b], 0.03[d], 0.09[d], 0.17[d]	E: 0.01 RA: 0.05	E: 0.09 RA: 0.17	N/A		

* Source of EU MRL: Regulation (EC) No 2017/1016
(a) EFSA, 2018. Regarding the inlusion of metabolite CGA300405 in cereal fodder see applicant response in Point 7.2.2.1 above. CGA300405 was not analysed in any of the samples.
(b) In italics: Storage stability > 12 months not demonstrated acc. to EFSA (2018). However, previously evaluated study (RMS The Netherlands, DAR, 2003; RMS Lithuania, RAR, 2018) demonstrated storage stability of trinexapac-ethyl in straw for 24 months (see also Table 7.2-2). The data are therefore considered valid.
(c) Actual application rate 125 g as/ha . Data have been upscaled to intended rate of 210 g as/ha (see Table 7.2-11below)
(d) Down-scaled values according to EFSA (2018)

zRMS for convenience highlighted in the table in grey NEU data for grain.

7.2.3.2 Conclusion on the magnitude of residues in plants

Barley

Barley is a major crop in Central/Northern Europe and 8 trials are required. Five valid trials have been evaluated by Lithuania (RAR, 2018) and EFSA (2018) that correspond to the intended GAP for ADM.09050.H.1.A in Central Europe. Two further trials (study TK0178789) that had been excluded from evaluation due to lack of storage stability data have now been included as storage stability in grain over a period of 26 months has been shown (see point 7.2.1).

As the last application according to the intended GAP for ADM.09050.H.1.A is done before edible parts are formed (i.e. before BBCH 51), data on wheat can be extrapolated to barley (SANTE/2019/12752). Furthermore, the proportionality concept can be applied for plant growth regulators such as trinexapac-ethyl to between x0.3 and x4 of the GAP dose rate where quantifiable residues occur[1].

Residue data for wheat grain and straw were scaled up to the maximum GAP rate for barley and extrapolated to barley (see Table 7.2-11). When including the scaled wheat data, there is a total of 18 trials data available for barley grain and 11 trials data for barley straw that comply with the residue definition for enforcement.

It is concluded that sufficient data are available to support the intended uses on barley. The data show that no exceedance of the current MRL will occur.

Wheat, spelt, triticale

Wheat is a major crop in Central/Northern Europe and 8 trials are required. Eleven valid trials have been evaluated by Lithuania (RAR, 2018) and EFSA (2018) that correspond to the intended GAP for ADM.09050.H.1.A in Central Europe.

It is concluded that sufficient data are available to support the intended uses on wheat, spelt and triticale. The data show that no exceedance of the current MRL will occur.

Oat, rye

According to SANTE/2019/12752 for applications before BBCH 51 (i.e. before edible parts are formed), data for wheat can be extrapolated to oat and rye as the GAPs for these crops are comparable to or less critical than the GAP for wheat. In line with the EFSA (2018) assessment, where data from N-EU/C-EU and S-EU regions were combined for rye, combined N-EU/S-EU data were used here for extrapolation to both, oat and rye.

Sufficient data are therefore available to extrapolate the existing data to oat and rye. The data show that no exceedance of the current MRLs for oat and rye will occur.

Grass (seed production)

Grass for seed production will not be consumed by humans or livestock. Residue trials for MRL setting or for consumer risk assessment are therefore not needed.

zRMS: the applicant’s considerations and conclusions has been accepted.

Table 7.2-11: Residues of trinexapac-ethyl in wheat scaled up to intended cGAP rate of 210 g as/ha

Report/ trial	Trial application rate (g as/ha)	Portion analysed	Residue$_{Mo}$ (mg/kg)[(a)]	Residue$_{RA}$ (mg/kg)[(b)]	Scaling factor[(c)]	Scaled residue$_{Mo}$ (mg/kg)[(a)]	Scaled residue$_{RA}$ (mg/kg)[(b)]
36094 Trial 1	125.6	Whole plant	0.04	0.04	1.67	0.07	0.07

[1] EFSA (European Food Safety Authority), 2018. Recommendations on the use of the proportionality approach in the framework of risk assessment for pesticide residues. EFSA supporting publication 2017:EN-1503. 18 pp. doi:10.2903/sp.efsa.2017.EN-1503

Report/ trial	Trial application rate (g as/ha)	Portion analysed	Residue$_{Mo}$ (mg/kg)(a)	Residue$_{RA}$ (mg/kg)(b)	Scaling factor(c)	Scaled residue$_{Mo}$ (mg/kg) (a)	Scaled residue$_{RA}$ (mg/kg) (b)
		Grain	0.09	0.06	1.67	0.15	0.10
		Straw	0.02	<0.05	1.67	0.03	n.a.(d)
36094 Trial 2	124.3	Whole plant	0.07	0.13	1.69	0.12	0.22
		Grain	0.22	0.23	1.69	0.37	0.39
		Straw	0.03	<0.05	1.69	0.05	n.a.(d)
36094 Trial 3	125.4	Whole plant	0.04	0.05	1.67	0.07	0.08
		Grain	0.05	0.04	1.67	0.08	0.07
		Straw	<0.01	<0.05	1.67	n.a.(d)	n.a.(d)
36094 Trial 4	128.6	Whole	0.23	0.24	1.63	0.38	0.39
		Grain	0.24	0.36	1.63	0.39	0.59
		Straw	0.07	<0.05	1.63	0.11	n.a.(d)
36094 Trial 5	120.6	Whole plant	0.05	0.06	1.74	0.09	0.10
		Grain	0.08	0.06	1.74	0.14	0.10
		Straw	<0.01	<0.05	1.74	n.a.(d)	n.a.(d)
36094 Trial 6	117.8	Whole plant	0.03	0.1	1.78	0.05	0.18
		Grain	0.37	0.17	1.78	0.66	0.30
		Straw	0.02	<0.05	1.78	0.04	n.a.(d)
36094 Trial 7	118.7	Whole plant	0.1	0.11	1.77	0.18	0.19
		Grain	0.11	0.1	1.77	0.19	0.18
		Straw	<0.01	<0.05	1.77	n.a.(d)	n.a.(d)
37231 Trial 1	128.8	Grain	0.07	0.06	1.63	0.11	0.10
		Straw	0.01	<0.05	1.63	0.02	n.a.(d)
37231 Trial 2	125.9	Grain	0.06	0.06	1.67	0.10	0.10
		Straw	<0.01	<0.05	1.67	n.a.(d)	n.a.(d)
37231 Trial 3	133.1	Grain	0.05	0.07	1.58	0.08	0.11
		Straw	0.01	<0.05	1.58	0.02	n.a.(d)
37231 Trial 4	127.3	Grain	0.03	0.01	1.65	0.05	0.02
		Straw	<0.01	0.05	1.65	n.a.(d)	0.08

(a) Residue according to residue definition for Monitoring: Trinexapac free
(b) Residue according to residue definition for Risk Assessment: Trinexapac free and conjugated (excluding CGA 300405 for straw)
(c) Scaling factor obtained by dividing intended application rate (210 g a.s./ha) by trial application rate
(d) Scaling not possible because residue in trial is below LOQ

Table 7.2-12: Median conversion factors for cereals for monitoring to risk assessment residue definitions

Crop	Conversion factor monitoring to risk assessment (median)		Overall (median)	Comment
	N-EU	S-EU		
Barley grain	2.00	2.00	1.80	EFSA, 2018
Wheat grain	0.86	1.60		
Barley straw	3.75	3.50	4.38	Calculated, see Table 7.2-13
Wheat straw	5.00	5.00		Calculated, see Table 7.2-14

Table 7.2-13: Conversion factors in barley straw for monitoring to risk assessment residue definitions

Study	Trial no.	$Residue_{Mo}$ (mg/kg)[(a)]	$Residue_{RA}$ (mg/kg) [(b)]	CF monitoring to risk assessment
N-EU				
36129	1	0.01	0.05	5.00
36129	2	0.01	0.05	5.00
36129	3	0.01	0.05	5.00
36129	5	0.02	0.05	2.50
36129	7	0.04	0.07	1.75
37124	1	0.04	0.09	2.25
			Median	**3.75**
S-EU				
36190	1	0.01	0.05	5.00
36190	2	0.02	0.07	3.50
36190	3	0.13	0.18	1.38
36190	4	0.32	0.28	0.88
36190	5	0.01	0.05	5.00
37194	1	0.05	0.07	1.40
37194	2	0.03	0.25	8.33
			Median	**3.50**

(a) Residue according to residue definition for Monitoring: Trinexapac free
(b) Residue according to residue definition for Risk Assessment: Trinexapac free and conjugated (excluding CGA 300405 for straw)

Table 7.2-14: Conversion factors in wheat straw for monitoring to risk assessment residue definitions

Study	Trial no.	$Residue_{Mo}$ (mg/kg)[(a)]	$Residue_{RA}$ (mg/kg) [(b)]	CF monitoring to risk assessment
N-EU				
36094	1	0.02	0.05	2.50
36094	2	0.03	0.05	1.67
36094	3	0.01	0.05	5.00
36094	4	0.07	0.05	0.71
36094	5	0.01	0.05	5.00

Study	Trial no.	Residue$_{Mo}$ (mg/kg)[(a)]	Residue$_{RA}$ (mg/kg) [(b)]	CF monitoring to risk assessment
36094	6	0.02	0.05	2.50
36094	7	0.01	0.05	5.00
37231	1	0.01	0.05	5.00
37231	2	0.01	0.05	5.00
37231	3	0.01	0.05	5.00
37231	4	0.01	0.05	5.00
			Median	**5.00**
S-EU				
36220	1	0.01	0.05	5.00
36220	2	0.01	0.05	5.00
36220	3	0.03	0.05	1.67
36220	4	0.08	0.18	2.25
36220	5	0.01	0.05	5.00
36220	6	0.01	0.05	5.00
36220	7	0.01	0.05	5.00
36220	8	0.01	0.05	5.00
37278	1	0.28	0.1	0.36
37278	2	0.17	0.3	1.76
			Median	**5.00**

(a) Residue according to residue definition for Monitoring: Trinexapac free
(b) Residue according to residue definition for Risk Assessment: Trinexapac free and conjugated (excluding CGA 300405 for straw)

zRMS: the most critical rate for wheat is 125g/ha in critical GAP (blue in B0)

7.2.4 Magnitude of residues in livestock

7.2.4.1 Dietary burden calculation

According to the OECD guidance document on residues in livestock (ENV/JM/MONO(2013)8), envisaged uses of ADM.09050.H.1.A on cereal crops may lead to residues in livestock, therefore the possible transfer of residues into animal commodities should be considered. Previously registered uses were also considered, using the residue values as listed in the EFSA (2012) Art. 12 evaluation.
The dietary burdens were calculated for different groups of livestock using the EFSA calculator[1]. Livestock intake calculations are provided below.

[1] ~~https://ec.europa.eu/food/plant/docs/pesticides_mrl_guidelines_animal_model_2016.xls~~
https://food.ec.europa.eu/document/download/8a840d8f-b419-4755-9f22-158f0d344d8a_en?filename=pesticides_mrl_guidelines_animal_model_2017.xls

Table 7.2-15: Input values for the dietary burden calculation (considering the uses authorized evaluated in Art. 12 procedure and the uses under consideration)

Feed Commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Plant residue definition for risk assessment: Trinexapac, free and conjugated (cereal grain) (provisional) [(a)]; Trinexapac, free and conjugated plus CGA300405 (cereal fodder items/grass) (provisional)[(a)]				
Barley, straw	0.05	Median residue primary crop (see Table 7.2-10)	0.09	Highest residue primary crop (see Table 7.2-10)
Oat, straw	0.05	Median residue primary crop (see Table 7.2-10)	0.17	Highest residue primary crop (see Table 7.2-10)
Rye, straw	0.05	Median residue primary crop (see Table 7.2-10)	0.17	Highest residue primary crop (see Table 7.2-10)
Triticale, straw	0.05	Median residue primary crop (see Table 7.2-10)	0.17	Highest residue primary crop (see Table 7.2-10)
Wheat, straw	0.05	Median residue primary crop (see Table 7.2-10)	0.17	Highest residue primary crop (see Table 7.2-10)
Barley, grain	0.10	Median residue primary crop (see Table 7.2-10)	0.10	Median residue primary crop (see Table 7.2-10)
Bean, seed (dry)	4.11	Median residue N-EU (EFSA, 2018)	4.11	Median residue N-EU (EFSA, 2018)
Oat, grain	0.08	Median residue primary crop (see Table 7.2-10)	0.08	Median residue primary crop (see Table 7.2-10)
Rye, grain	0.08	Median residue primary crop (see Table 7.2-10)	0.08	Median residue primary crop (see Table 7.2-10)
Triticale, grain	0.08	Median residue primary crop (see Table 7.2-10)	0.08	Median residue primary crop (see Table 7.2-10)
Wheat, grain	0.08	Median residue primary crop (see Table 7.2-10)	0.08	Median residue primary crop (see Table 7.2-10)
Brewer’s grain, dried	0.33	Median residue barley grain x default PF (0.10 mg/kg x 3.3)	0.33	Median residue barley grain x default PF (0.10 mg/kg x 3.3)
Canola (Rape seed), meal	0.53	Median residue rape seed x PF (EFSA, 2012)	0.53	Median residue rape seed x PF (EFSA, 2012)
Distiller’s grain, dried	0.26	Median residue wheat grain x default PF (0.08 mg/kg x 3.3)	0.26	Median residue wheat grain x default PF (0.08 mg/kg x 3.3)
Rape meal	0.53	Median residue rape seed x PF (EFSA, 2012)	0.53	Median residue rape seed x PF (EFSA, 2012)
Wheat gluten, meal	0.02	Median residue wheat grain x PF (see Table 7.2-18) (0.08 mg/kg x 0.2)	0.02	Median residue wheat grain x PF (see Table 7.2-18) (0.08 mg/kg x 0.2)
Wheat, milled by-products	0.08	Median residue wheat grain x PF (see Table 7.2-18) (0.08 mg/kg x 1.0)	0.08	Median residue wheat grain x PF (see Table 7.2-18) (0.08 mg/kg x 1.0)

(a) EFSA, 2018. Regarding the inlusion of metabolite CGA300405 in cereal fodder see applicant response in Point 7.2.2.1 above. CGA300405 was not analysed in any of the samples.

The results of the calculations are reported in Table 7.2-16. The calculated dietary burdens for cattle, sheep, swine and poultry were found to exceed the trigger value of 0.004 mg/kg bw per day. Further investigation of residues is therefore required for all groups of livestock.

Table 7.2-16: 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)
Plant residue definition for risk assessment: Trinexapac, free and conjugated (cereal grain) (provisional) [(a)]; Trinexapac, free and conjugated plus CGA300405 (cereal fodder items/grass) (provisional)[(a)]					
Beef cattle*	0.0257	0.026	Bean, seed	1.09	Y
Dairy cattle*	0.0389	0.040	Bean, seed	1.03	Y
Ram/ewe	0.0353	0.037	Bean, seed	1.10	Y
Lamb	0.0450	0.047	Bean, seed	1.10	Y
Breeding swine	0.024	0.024	Bean, seed	1.05	Y
Finishing swine*	0.032	0.032	Bean, seed	1.05	Y
Broiler poultry	0.074	0.074	Bean, seed	1.04	Y
Layer poultry*	0.068	0.068	Bean, seed	1.00	Y
Turkey	0.075	0.075	Bean, seed	1.05	Y

* These categories correspond to those (formerly) assessed at EU level.
(a) EFSA, 2018. Regarding the inlusion of metabolite CGA300405 in cereal fodder see applicant response in Point 7.2.2.1 above. CGA300405 was not analysed in any of the samples.

7.2.4.2 Livestock feeding studies (KCA 6.4.1-6.4.3)

Available data

Reference: RMS The Netherlands (DAR, 2003); RMS Lithuania (RAR, 2018); EFSA, 2012; EFSA, 2018

No new livestock feeding studies have been submitted by the applicant in the framework of this application. A feeding study on cows (Anon, 2000; report 330/99) and a metabolism study on hens (Anon, 2006; report RJ3678) have been evaluated (DAR, 2003, RAR, 2018). The studies were re-submitted for Annex I Renewal of trinexapac-ethyl. These study results are summarized in the table below.

Table 7.2-17: Overview of the values derived from livestock feeding studies

Commodity	Dietary burden		Results of the livestock feeding study[(a)]						Median residue at 1N (mg/kg)[(c)]	Highest residue at 1N (mg/kg)[(d)]	Calculated MRL (mg/kg)	CF for RA[(e)]
	Med. (mg/kg bw/d)	Max. (mg/kg bw/d)	Dose Level (mg/kg bw/d)	No	Result for enforcement		Result for RA[(b)]					
					Mean (mg/kg)	Max. (mg/kg)	Mean (mg/kg)	Max. (mg/kg)				
EU data (DAR, 2003; RAR, 2018; EFSA, 2012; 2018)												
Enforcement residue definition: Trinexapac (sum of trinexapac (acid) and its salts), expressed as trinexapac Risk assessment residue definition: Poultry: trinexapac; Ruminant: trinexapac + metabolite CGA 113745, expressed as trinexapac [(b)]												
Pig meat	0.032 (finishing)	0.032 (finishing)	0.068	3	<0.02	<0.02	<0.02	<0.02	0.01	0.01	0.01*	-
			0.21	3	<0.02	<0.02	<0.02	<0.02				
			0.71	3	<0.02	<0.02	<0.02	<0.02				
Pig fat	0.032 (finishing)	0.032 (finishing)	0.068	3	<0.02	<0.02	<0.02	<0.02	0.01	0.01	0.01*	-
			0.21	3	<0.02	<0.02	<0.02	<0.02				
			0.71	3	<0.02	<0.02	<0.02	<0.02				
Pig liver	0.032 (finishing)	0.032 (finishing)	0.068	3	<0.02	<0.02	<0.02	<0.02	0.01	0.01	0.01*	-
			0.21	3	<0.02	<0.02	<0.02	<0.02				
			0.71	3	0.03	0.03	0.03	0.03				
Pig kidney	0.032 (finishing)	0.032 (finishing)	0.068	3	0.03	0.03	0.03	0.03	0.02	0.02	0.05	-
			0.21	3	0.05	0.05	0.05	0.05				
			0.71	3	0.17	0.29	0.17	0.29				
Ruminant meat	0.0450 (lamb)	0.0470 (lamb)	0.068	3	<0.02	<0.02	<0.02	<0.02	0.01	0.01	0.01*	-
			0.21	3	<0.02	<0.02	<0.02	<0.02				
			0.71	3	<0.02	<0.02	<0.02	<0.02				
Ruminant fat	0.0450	0.0470	0.068	3	<0.02	<0.02	<0.02	<0.02	0.01	0.01	0.01*	-

Commodity	Dietary burden		Results of the livestock feeding study[(a)]						Median residue at 1N (mg/kg)[(c)]	Highest residue at 1N (mg/kg)[(d)]	Calculated MRL (mg/kg)	CF for RA[(e)]
	Med. (mg/kg bw/d)	Max. (mg/kg bw/d)	Dose Level (mg/kg bw/d)	No	Result for enforcement		Result for RA[(b)]					
					Mean (mg/kg)	Max. (mg/kg)	Mean (mg/kg)	Max. (mg/kg)				
	(lamb)	(lamb)	0.21	3	<0.02	<0.02	<0.02	<0.02				
			0.71	3	<0.02	<0.02	<0.02	<0.02				
Ruminant liver	0.0450 (lamb)	0.0470 (lamb)	0.068	3	<0.02	<0.02	<0.02	<0.02	0.01	0.01	0.01*	-
			0.21	3	<0.02	<0.02	<0.02	<0.02				
			0.71	3	0.03	0.03	0.03	0.03				
Ruminant kidney	0.0450 (lamb)	0.0470 (lamb)	0.068	3	0.03	0.03	0.03	0.03	0.03	0.03	0.05	-
			0.21	3	0.05	0.05	0.05	0.05				
			0.71	3	0.17	0.29	0.17	0.29				
Poultry meat	0.075 (layer)	0.075 (layer)	0.85	5	<0.01	<0.01	<0.01	<0.01	0.01	0.01	0.01*	-
Poultry fat	0.075 (layer)	0.075 (layer)	0.85	5	<0.01	<0.01	<0.01	<0.01	0.01	0.01	0.01*	-
Poultry liver	0.075 (layer)	0.075 (layer)	0.85	5	<0.01	<0.01	<0.01	<0.01	0.01	0.01	0.05	-
Milk	0.0389 (dairy)	0.040 (dairy)	0.068	3	<0.01	n.a.	<0.02	n.a.	0.01	0.01	0.01*	-
			0.21	3	<0.01	n.a.	<0.01	n.a.				
			0.71	3	<0.01	n.a.	<0.01	n.a.				
Eggs	0.068 (layer)	0.068 (layer)	0.85	5	0.01	0.02	0.01	0.02	0.01	0.01	0.01*	-

(*): Indicates that the MRL is set at the limit of analytical quantification.
(a): Data from cow feeding study (330/99) and hen metabolism study (RJ3678).
(b): Residues were not analysed for CGA 113745, according to proposed residue definition for risk assessment (ruminant: trinexapac + metabolite CGA300405, expressed as trinexapac)
(c): Median residue value according to the enforcement residue definition, derived by interpolation/extrapolation from the feeding study for the median dietary burden (FAO, 2009).
(d): 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).
(e): The median conversion factor for enforcement to risk assessment.

Summary of animal feeding studies

"The transfer of residues from cattle into tissues and milk was assessed in the framework of the first Annex I inclusion.[…] The kidney was the only tissue of all samples analysed where a clear dose dependent increase of CGA 179500 residues was found. The residues in muscle and fat were below or around the LOQ of 0.02 mg/kg. In the liver the residue level was just above the LOQ only in the highest dose group. Residues in milk samples were only found in the highest dosed group, reaching 0.011 mg/kg. No detectable residues are expected in ruminant products at a nominal intake of CGA 179500 via feed (0.30-0.40 mg/kg feed). The storage stability data provided in this study show that CGA 179500 is stable during storage at -18°C for at least three months. RMS LT agrees with the above conclusions." (*RAR, 2018*)

"In the feeding study in lactating cows, the metabolite CGA 113745 has not been analysed for. Based on the results, residues of trinexapac are not expected in ruminant tissues and milk. Significant residues are not expected in poultry commodities as well considering the outcome of the metabolism study. Recalculation of the livestock dietary burden is pending the finalisation of the residue definition for the risk assessment for feed items and in animal products and information on the transfer of residues of CGA300405 and SYN548584 in animal matrices. Feeding studies analysing for CGA113745 in tissues and milk of ruminants may be required." (*EFSA, 2018*)

Conclusion on feeding studies

The new mode of calculation modifies the theoretical maximum daily intake for animals, but regarding available feeding data, there is no risk for animal MRLs to be exceeded. Considering the proposed uses of the product ADM.09050.H.1.A, residues of trinexapac-ethyl are not expected in commodities of animal origin.

zRMS: The applicant's conclusions are acceptable.

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

7.2.5.1 Available data for all crops under consideration

Reference: RMS The Netherlands (DAR, 2003); RMS Lithuania (RAR, 2018); EFSA, 2018

No new studies on the magnitude of residues in processed commodities have been submitted by the applicant in the framework of this application. New studies were submitted for Annex I Renewal of trinexapac-ethyl; they have been evaluated by RMS Lithuania (RAR, 2018) and by EFSA (2018).
EFSA (2018) concluded that processing factors could not be determined as "a residue definition for processed products could not be set due to the contradictory outcome of the standard hydrolysis studies."
However, the applicant argued in its response as detailed in Point 7.2.2.3, that no separate residue definition needs to be set for processed commodities, i.e. that the residue definition for RAC and processed commodities can be the same. Based on the applicant's conclusion, processing results from all studies are summarized in the table below.

Table 7.2-18: Overview of the available processing studies

Processed commodity	Number of studies[(a)]	Median PF (Mo) [(b)]	Median PF (RA) [(c)]	Median CF [(d)]	Comments	Report references	Source
EU reviewed data							

Processed commodity	Number of studies[(a)]	Median PF (Mo) [(b)]	Median PF (RA) [(c)]	Median CF [(d)]	Comments	Report references	Source
Enforcement residue definition: Trinexapac (sum of trinexapac (acid) and its salts), expressed as trinexapac; Residue definition for risk assessment: Trinexapac (sum of trinexapac (acid) and its salts), free and conjugated [(e)]							
Barley, pot	2/2	0.65	0.20	0.32	No comments - -	T003422-07 37194 CEMR-7354	RAR, 2018
Barley, pearl	2/6	0.60	1.01	0.30[(f)]			
Barley, bran	2/6	1.28	1.70	0.21[(f)]			
Barley, flour	2/6	0.85	0.44	0.51[(f)]			
Barley, brewing malt	2/2	0.75	0.51	0.69[(f)]			
Barley, malt sprouts	2/2	0.87	0.10	0.11			
Barley, brewer's grain (dried)	2/2	0.37	0.12	0.33			
Barley, brewer's yeast	2/2	1.69	0.17	0.10			
Barley, beer	2/2	0.15	0.06	0.42			
Wheat, waste (offal)	2/2	0.81	0.96	1.29		3011/00	DAR, 2003
Wheat, white flour	7/6	0.32	0.43	0.75[(f)]			
Wheat, total bran	7/6	2.20	1.56	0.79[(f)]			RAR, 2018
Wheat, shorts	6/6	0.91	0.59	0.60[(f)]		T003605-07 T002695-03 37278	
Wheat, middlings	6/6	0.47	0.51	0.91[(f)]			
Wheat, wholemeal flour	3/2	1.00	0.78	0.78[(f)]			
Wheat, wholemeal bread	3/2	0.81	0.66	0.77[(f)]			
Wheat, germ	6/6	0.93	0.92	0.35[(f)]			
Wheat, dry gluten	2/2	0.30	0.25	0.81			
Wheat, dry starch	2/2	0.09	0.08	0.89			
Wheat, gluten feed meal	2/2	0.20	0.18	0.88			

Mo: monitoring, RA: risk assessment

(a) All available processing studies have been considered, i.e. even those where trinexapac acid (free) or trinexapac acid (free and conjugated) were not measured. In such cases, two numbers are displayed - e.g., 4/8 means that 4 studies measured trinexapac acid (free) and 8 studies measured total trinexapac acid (free and conjugated).

(b) The median processing factor is obtained by calculating the median of the individual processing factors of each processing study. Those processing factors are based on residue levels of trinexapac acid (free) and therefore derived for monitoring purposes.

(c) The median processing factor is obtained by calculating the median of the individual processing factors of each processing study. Those processing factors are based on residue levels of total trinexapac acid (free and conjugated) and therefore are the ones used for the risk assessment calculations.

(d) The median conversion factor for enforcement to risk assessment is obtained by calculating the median of the individual conversion factors of each processing study. They are derived for monitoring purposes.

(e) Open according to EFSA (2018). According to applicant's response under Point 7.2.2.3, residue definition for RAC and processed commodities should be the same.

(f) Conversion factor derived based on the studies where both trinexapac acid (free) and total trinexapac acid (free and conjugated) were measured.

Conclusion on processing studies

Considering the applicant response as detailed in Point 7.2.2.3, the residue definition for RAC and processing commodities should be identical. Based on this reasoning, robust processing factors for monitoring and for risk assessment can be derived for processed commodities of wheat and barley.

zRMS: The applicant’s conclusions are acceptable.

7.2.6 Magnitude of residues in representative succeeding crops

The crops under consideration can be grown in rotation.

zRMS: The applicant’s conclusions are acceptable.

7.2.6.1 Field rotational crop studies (KCA 6.6.2)

“Studies on the magnitude of trinexapac-ethyl residues in rotational crops are not required. Considering that the above rotational crop metabolism study was carried out on a bare soil with 0.75N to 1.65N application rate, it can be concluded that trinexapac-ethyl residue levels in rotational commodities are not expected to exceed 0.01 mg/kg, provided that trinexapac-ethyl is applied in compliance with the representative GAP.” (*RAR, 2018*)

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

The available data for the active substance sufficiently address aspects of the residue situation that might arise from the use of ADM-09050.H.1.A. Therefore, other special studies are not needed.

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

The input values for the consumer risk assessment (TMDI calculation) are given in Table 7.2-19. Current EU MRLs (Reg. (EU) 2017/1016) were used for all commodities.

Table 7.2-19: Input values for the consumer risk assessment

Code	Commodity	Chronic risk assessment		~~Acute risk assessment~~	
		Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Risk assessment residue definition: Trinexapac, free and conjugated (expressed as trinexapac)					
300010	Beans	10.0	MRL (Regulation (EU) 2017/1016)	~~-~~	~~Not relevant for this submission~~
401030	Poppy seeds	7.0	MRL (Regulation (EU) 2017/1016)	~~-~~	~~Not relevant for this submission~~

Code	Commodity	Chronic risk assessment		~~Acute risk assessment~~	
		Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
401060	Rapeseeds	2.0	MRL (Regulation (EU) 2017/1016)	~~-~~	~~Not relevant for this submission~~
500010	Barley	3.0	MRL (Regulation (EU) 2017/1016)	~~3.0~~	~~MRL (Regulation (EU) 2017/1016)~~
500050	Oat	3.0	MRL (Regulation (EU) 2017/1016)	~~3.0~~	~~MRL (Regulation (EU) 2017/1016)~~
500070	Rye	0.5	MRL (Regulation (EU) 2017/1016)	~~0.5~~	~~MRL (Regulation (EU) 2017/1016)~~
500090	Wheat	3.0	MRL (Regulation (EU) 2017/1016	~~3.0~~	~~MRL (Regulation (EU) 2017/1016)~~
840040	Horseradish	0.07	MRL (Regulation (EU) 2017/1016)	~~-~~	~~Not relevant for this submission~~
900020	Sugar canes	0.5	MRL (Regulation (EU) 2017/1016)	~~-~~	~~Not relevant for this submission~~
All other crops and animal commodities		0.01-0.05	All MRLs at LOQ (Regulation (EU) 2017/1016)	~~-~~	~~Not relevant for this submission~~

7.2.8.2 Conclusion on consumer risk assessment

Extensive calculation sheets are presented in Appendix 3.

Table 7.2-20: Consumer risk assessment

The applicant mistakenly used AOEL instead ARfD.
Therefore, TMDI was recalculated in normal mode by zRMS and resulted report replaced the applicant's PRIMo in Appendix 3. Current EU MRLs (Reg. (EU) 2017/1016) were used as input data.

TMDI (% ADI) according to EFSA PRIMo 3.1	~~8 % (based on GEMS/Food G06)~~ 2,6% based on UK toddler
IEDI (% ADI) according to EFSA PRIMo	-
~~IESTI (% ARfD) according to EFSA PRIMo 3.1*~~ No ARfD is set. The applicant	~~Wheat: 13 % (based on UK 4-6 year old child)~~ ~~Barley: 5% (based on DE child)~~ ~~Oat: 1.0% (based on DE child)~~ ~~Rye: 0.9% (based on UK infant)~~
NTMDI (% ADI) **	--
NEDI (% ADI)**	--

* include raw and processed commodities if both values are required for PRIMo
** if national model is available

The proposed uses of trinexapac-ethyl in the formulation ADM.09050.H.1.A do not represent unacceptable acute or chronic risks for the consumer.

7.3 Combined exposure and risk assessment

Not relevant. The product contains only one active substance.

7.4 References

The Netherlands, 2005. Final addendum to the draft assessment report on the active substance trinexapac prepared by the rapporteur Member State The Netherlands in the framework of Council Directive 91/414/EEC, compiled by EFSA, September 2005.

The Netherlands, 2003. Draft assessment report on the active substance trinexapac prepared by the rapporteur Member State The Netherlands in the framework of Council Directive 91/414/EEC, October 2003.

EFSA (European Food Safety Authority), 2012. Review of the existing maximum residue levels (MRLs) for trinexapac according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2012;10(1):2511. [38 pp.] doi:10.2903/j.efsa.2012.2511.

EFSA (European Food Safety Authority), 2014. Scientific support for preparing an EU position in the 46th Session of the Codex Committee on Pesticide Residues (CCPR). EFSA Journal 2014;12(7):3737, 182 pp. doi:10.2903/j.efsa.2014.3737

EFSA (European Food Safety Authority), 2016. Reasoned opinion on the setting of import tolerance for trinexapac in poppy seed. EFSA Journal 2016;14(11):4636, 15 pp. doi:10.2903/ j.efsa.2016.4636

EFSA (European Food Safety Authority), 2018. Conclusion on the peer review of the pesticide risk assessment of the active substance trinexapac (variant evaluated trinexapac-ethyl). EFSA Journal 2018;16(4):5229, 25 pp. https://doi.org/10.2903/j.efsa.2018.5229

FAO/WHO, 2013. Pesticide residues in food - 2013: evaluations / Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Core Assessment Group on Pesticide Residues. Geneva, Switzerland, 17–26 September 2013. Paper 220. Part 1, Residues, pp 1595 – 1716.

Lithuania, 2017. Renewal assessment report under Regulation (EC) 1107/2009. Trinexapac-ethyl, March 2017.

Lithuania, 2018. Renewal assessment report under Regulation (EC) 1107/2009. Revised version. Trinexapac-ethyl, February. 2018

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
KCA 6.1/01	Brown, D.	2020	Trinexapac-ethyl (CGA163935) - storage stability of residues of trinexapac acid (CGA179500) in crop matrices stored frozen for up to 26 months Charles River Laboratories, Edinburgh, United Kingdom, 227361 GLP not published	N	Trinexapac Task Force

List of data submitted or referred to by the applicant and relied on, but already evaluated at EU peer review (or New Data already reviewed by RMS Lithuania (RAR, 2018) and EFSA, 2018)

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	Previous evaluation (DAR) or New Data (RAR, 2018)
CA 6.1	Sack St.	1998	Stability of residues of CGA 179500 (metabolite of Trinexapac-ethyl, CGA 163935) in deep freeze stored analytical specimens of wheat (grain and straw) and rapeseed Novartis Crop Protection AG, Basel, Switzerland Novartis Crop Protection AG, Basel, Switzerland, 105/95 GLP not published Syngenta File No CGA163935/0562	N	Trinexapac Task Force	DAR KIIA 6.3.2.1/01
CA 6.1	Anon	2000	Residues of CGA 179500 in milk, blood and tissues (muscle, fat, liver,	N	Trinexapac	DAR

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	Previous evaluation (DAR) or New Data (RAR, 2018)
			kidney) of dairy cattle resulting from feeding of CGA 179500 (metabolite of trinexapac-ethyl, CGA 163935) at three dose levels Novartis Crop Protection AG, Basel, Switzerland 330/99 GLP not published Syngenta File No CGA179500/0030		Task Force	KIIA 6.3.2.2 / 01 & KIIA 6.4.2 / 01
CA 6.1	Watson G.	2017	Trinexapac-ethyl: Storage Stability of Residues of metabolite CGA224439 (CPCA) in Crop Matrices Stored Frozen for up to Twelve Months. Final Report and Final Report Amendment 1 Syngenta ResChem Analytical Limited Unit 27 Derwent Business Centre, Clarke Street, Derby, DE1 2BU, UK, RES-00030 GLP not published Syngenta File No CA876_10009	N	Trinexapac Task Force	RAR KCA 6.1 / 01
CA 6.1	Langridge G.	2017	Trinexapac-ethyl – Storage Stability of Residues of Metabolites CGA113745 and CGA313458 in Crop Matrices Stored Frozen for up to Twelve Months. CEM Analytical Services Ltd (CEMAS) Berkshire, UK, CEMR-7358 GLP not published Syngenta File No. CGA113745_10003	N	Trinexapac Task Force	RAR KCA 6.1 / 02
CA 6.2.1	Nicollier G.	1991	Distribution and degradation of ^{14}C-cyclohexyl-CGA 163935 in green-house grown spring rape Novartis Crop Protection AG, Basel, Switzerland Ciba-Geigy Ltd., Basel, Switzerland, 4/91 GLP not published Syngenta File No CGA163935/0209	N	Trinexapac Task Force	DAR KIIA 6.1.3.2 / 01
CA 6.2.1	Nicollier G.	1993	Metabolism of [^{14}C-cyclohexyl]-CGA 163935 in greenhouse grown	N	Trinexapac	DAR

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	Previous evaluation (DAR) or New Data (RAR, 2018)
			spring rape 90GN15BPR2 (7/93) 90GN15B GLP not published		Task Force	KIIA 6.1.3.2 / 02
CA 6.2.1	Krauss J. H.	1990	Uptake, distribution and degradation of ^{14}C-cyclohexyl CGA 163935 in field grown spring wheat Novartis Crop Protection AG, Basel, Switzerland Ciba-Geigy Ltd., Basel, Switzerland, 20/90 GLP not published Syngenta File No CGA163935/0086	N	Trinexapac Task Force	DAR KIIA 6.1.3.1 / 01
CA 6.2.1	Krauss J. H.	1993	Metabolism of [^{14}C-Cyclohexyl]-CGA 163935 in Field Grown Spring Wheat Novartis Crop Protection AG, Basel, Switzerland Ciba-Geigy Ltd., Basel, Switzerland, 6/93 GLP not published Syngenta File No CGA163935/0303	N	Trinexapac Task Force	DAR KIIA 6.1.3.1 / 02
CA 6.2.1	Gross D.	1996	Behaviour and metabolism of CGA 163935 in greenhouse grown paddy rice after application of (3,5- cyclohexadion-1,2,6-^{14}C)labelled material Novartis Crop Protection AG, Basel, Switzerland Ciba-Geigy Ltd., Basel, Switzerland, 11/96 GLP not published Syngenta File No CGA163935/0482	N	Trinexapac Task Force	DAR KIIA 6.1.3.3 / 01
CA 6.2.1	Ray W. J., May-Hertl U.	2003	[1,2,6-^{14}C] Cyclohexyl-CGA-163935 : Nature of the Residue in Field Grown Grass Syngenta Crop Protection AG, Basel, Switzerland Syngenta Crop Protection, Inc., Greensboro, USA,	N	Trinexapac Task Force	DAR KIIA 6.1.3.4 / 01

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	Previous evaluation (DAR) or New Data (RAR, 2018)
			623- 00 GLP not published Syngenta File No CGA163935/0862			
CA 6.2.1	Piskorski R.	2015a	Trinexapac-ethyl - Metabolism of [^{14}C]-Trinexapac-ethyl in Oilseed Rape Syngenta Innovative Environmental Services, Witterswil, Switzerland, 20120173 GLP not published Syngenta File No CGA163935_10561	N	Trinexapac Task Force	RAR KCA 6.2.1 / 01
CA 6.2.1	Piskorski R.	2015b	Trinexapac-ethyl - Metabolism of [^{14}C]-Trinexapac-ethyl in Spring Wheat Syngenta Innovative Environmental Services, Witterswil, Switzerland, 20120098 GLP not published Syngenta File No CGA163935_10644	N	Trinexapac Task Force	RAR KCA 6.2.1 / 02
CA 6.2.2	xxxxxxxx	1992a	Distribution and excretion of (1,2 - ^{14}C) - cyclohexyl CGA 163935 after multiple oral administration to laying hens. xxxxxxxxxxxxxxxx 141798 GLP not published Syngenta File No CGA163935/0277	Y	Trinexapac Task Force	DAR KIIA 6.2.2.2 / 01
CA 6.2.2	xxxxxx	1993a	The Nature of Metabolites in Eggs, Tissues, and Excreta of Laying Hen after Multiple Oral Administration of [1,2-^{14}C]Cyclohexyl CGA 163935 xxxxxxxxxxxxxxxxxxxxxx 6/93 GLP not published Syngenta File No CGA163935/0306	Y	Trinexapac Task Force	DAR KIIA 6.2.2.2 / 02

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	Previous evaluation (DAR) or New Data (RAR, 2018)
CA 6.2.2	xxxxxxx	2006	[3,5-Cyclohexadione-1,2,6-^{14}C] - labelled Trinexapac-ethyl (CGA163935) - Metabolism in Laying Hens xxxxxxxxxxxxxxxxxxxxxxx 04JH011, RJ3678B GLP not published Syngenta File No CGA163935/1048	Y	Trinexapac Task Force	RAR KCA 6.2.2 / 03
CA 6.2.3	xxxxxxx	1992b	Absorption, distribution and excretion of (1, 2 - ^{14}C) - cyclohexyl CGA 163935 after multiple oral administration to lactating goats. xxxxxxxxxxxxxxxxxxxx 7478, 141782 GLP not published Syngenta File No CGA163935/0276	Y	Trinexapac Task Force	DAR KIIA 6.2.2.1 / 01
CA 6.2.3	xxxxxx	1993b	The Nature of the Metabolites in Milk, Tissues, and Excreta of Lactating Goat after Multiple Oral Administration of [1,2-^{14}C]Cyclohexyl CGA 163935 xxxxxxxxxxxxxxxxxxxxxxxxx 5/93 GLP not published Syngenta File No CGA163935/0305	Y	Trinexapac Task Force	DAR KIIA 6.2.2.1 / 01
CA 6.2.3	xxxxxxx	2002	[1,2,6-^{14}C] Cyclohexyl-CGA-163935: Nature of the Residue in Lactating Goats xxxxxxxxxxxxxxxxxxxxxxxx 624-00 GLP not published Syngenta File No CGA163935/0944	Y	Trinexapac Task Force	DAR KIIA 6.2.2.1 / 03
CA 6.3.1	Brown D.	2016	Trinexapac-ethyl - Residue Study on Barley in Northern France and the UK in 2014 Syngenta Charles River Laboratories, Edinburgh, United Kingdom,	N	Trinexapac Task Force	RAR KCA 6.3.1 / 02

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	Previous evaluation (DAR) or New Data (RAR, 2018)
			36129 GLP not published Syngenta File No A8587F_10144			
CA 6.3.1	Brown D.	2016a	Trinexapac-ethyl - Residue Study on Barley in Belgium in 2015 Syngenta, CHEMINOVA A/S, Lemvig, Denmark, ADAMA Agriculture B.V., Schaffhausen, Switzerland Charles River Laboratories, Edinburgh, United Kingdom, 37124 GLP not published Syngenta File No A8587F_10525	N	Trinexapac Task Force	RAR KCA 6.3.1 / 03
CA 6.3.1	Andrews G.	2015	Trinexapac-ethyl- Residue Study on Winter Barley in northern France and Germany in 2013 Syngenta Battelle UK Ltd, Chelmsford, Essex, UK, TK0178789 GLP not published Syngenta File No A8587F_10138	N	Trinexapac Task Force	RAR KCA 6.3.1 / 01
CA 6.3.1	Brown D.	2016b	Trinexapac-Ethyl - Residue Study on Barley in Southern France, Italy and Spain in 2014. Syngenta Charles River Laboratories, Edinburgh, United Kingdom, 36190 GLP not published Syngenta File No. A8587F_10135	N	Trinexapac Task Force	RAR KCA 6.3.1 / 05
CA 6.3.1	Mac Dougall J.	2016	Trinexapac-ethyl - Residue Processing Study on Barley in Spain and Italy in 2015 Syngenta, CHEMINOVA A/S, Lemvig, Denmark, ADAMA Agriculture B.V., Schaffhausen, Switzerland Charles River Laboratories, Edinburgh, United Kingdom, 37194	N	Trinexapac Task Force	DAR KIIA 6.3.1 / 06 & 6.5.3 / 04

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	Previous evaluation (DAR) or New Data (RAR, 2018)
			GLP Not published Syngenta File No A8587F_10526			
CA 6.3.1	Andrews G.	2015a	Trinexapac-ethyl - Residue Study on Winter Barley in Italy and Spain 2013 Syngenta Battelle UK Ltd, Chelmsford, Essex, UK, TK0178795 GLP not published Syngenta File No A8587F_10132	N	Trinexapac Task Force	DAR KIIA 6.3.1 / 04
CA 6.3.2	Brown D.	2016c	Trinexapac-ethyl - Residue Study on Wheat in Northern France and the UK in 2014 Syngenta Charles River Laboratories, Edinburgh, United Kingdom, 36094 GLP not published Syngenta File No A8587F_10145	N	Trinexapac Task Force	RAR KCA 6.3.2 / 01
CA 6.3.2	Brown D.	2016d	Trinexapac-ethyl - Residue Study on Wheat in Poland, Czech Republic, Austria and Germany in 2015 Syngenta, CHEMINOVA A/S, Lemvig, Denmark, ADAMA Agriculture B.V., Schaffhausen, Switzerland Charles River Laboratories, Edinburgh, United Kingdom, 37231 GLP not published Syngenta File No A8587F_10527	N	Trinexapac Task Force	RAR KCA 6.3.2 / 02
CA 6.3.2	Brown D.	2016e	Trinexapac-ethyl - Residue Study on Wheat in Southern France, Italy and Spain in 2014 Syngenta Charles River Laboratories, Edinburgh, United Kingdom, 36220	N	Trinexapac Task Force	RAR KCA 6.3.2/03

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	Previous evaluation (DAR) or New Data (RAR, 2018)
			GLP not published Syngenta File No A8587F_10141			
CA 6.3.2	Mac Dougall J.	2016	Trinexapac-ethyl – Residue Processing Study on Wheat in France and Spain in 2015 Syngenta, CHEMINOVA A/S, Lemvig, Denmark, ADAMA Agriculture B.V., Schaffhausen, Switzerland Charles River Laboratories, Edinburgh, United Kingdom, 37278 GLP not published Syngenta File No A8587F_10524	N	Trinexapac Task Force	RAR KCA 6.3.2 / 04 & KCA 6.5.3 / 16
CA 6.4.2	xxxxxxx	2000	Residues of CGA 179500 in milk, blood and tissues (muscle, fat, liver, kidney) of dairy cattle resulting from feeding of CGA 179500 (metabolite of trinexapac-ethyl, CGA 163935) at three dose levels xxxxxxxxxxxxxxxxxxxxxx 330/99 GLP not published Syngenta File No CGA179500/0030	Y	Trinexapac Task Force	DAR KIIA 6.3.2.2 / 01 & KIIA 6.4.2 / 01
CA 6.5.1	Cadalbert R., Buckel T.	2001	Hydrolysis of [1,2,6- ^{14}C]-Cyclohexanedione Labelled CGA 163935 under Processing Conditions Syngenta Crop Protection AG, Basel, Switzerland Syngenta Crop Protection AG, Basel, Switzerland, 01RC02 GLP not published Syngenta File No CGA163935/0733	N	Trinexapac Task Force	DAR KIIA 6.5.1 / 01
CA 6.5.1	Mound E. L.	2004	[^{14}C]Cyclohexyl Trinexapac Acid (CGA179500): Aqueous Hydrolysis at 90, 100 & 120 degrees C Syngenta Crop Protection AG, Basel, Switzerland Syngenta - Jealott's Hill, Bracknell, United Kingdom, RJ3480B	N	Trinexapac Task Force	DAR KIIA 6.5.1 / 02

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	Previous evaluation (DAR) or New Data (RAR, 2018)
			GLP not published Syngenta File No CGA179500/0036			
CA 6.5.1	Scullion P.	2012	[^{14}C]Trinexapac acid: Simulated Processing - Aqueous Hydrolysis at 90, 100 and 120 °C ADAMA Celsius Property B.V., Amsterdam, Netherlands Harlan Laboratories Ltd., Itingen, Switzerland, C93481 GLP not published Syngenta File No CGA179500_11002	N	Adama Celsius	RAR KCA 6.5.1 / 03
CA 6.5.1	Florchinger M.	2008	Abiotic Degradation (Hydrolysis) of ^{14}C-Trinexapac under Typical Conditions (pH, Temperature and Time) of Processing CHEMINOVA A/S, Lemvig, Denmark Eurofins - GAB, Niefern Öschelbronn, Germany, S08-03106 GLP not published Syngenta File No CGA179500_11004	N	Trinexapac Task Force	RAR KCA 6.5.1 / 04
CA 6.5.3	Gasser A.	2001	Residue Study with Trinexapac-Ethyl (CGA 163935) in or on Winter Wheat in France (North) Syngenta Crop Protection AG, Basel, Switzerland Syngenta Crop Protection AG, Basel, Switzerland, 3011/00 GLP not published Syngenta File No CGA163935/0734	N	Trinexapac Task Force	DAR KIIA 6.5.3.1 / 01
CA 6.5.3	Mayer T.	2010	Trinexapac-ethyl – Magnitude of the Residues in or on Barley Syngenta Crop Protection, Inc., Greensboro, USA Syngenta Crop Protection, Inc., Greensboro, USA, T003422-07, ML08-1507-SYN GLP not published	N	Trinexapac Task Force	RAR KCA 6.5.3 / 01

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	Previous evaluation (DAR) or New Data (RAR, 2018)
			Syngenta File No CGA163935_50026			
CA 6.5.3	Mayer T.	2010a	Trinexapac-ethyl - Magnitude of the Residues in or on Wheat Syngenta Syngenta Crop Protection, Inc., Greensboro, USA, T003605-07, ML08-1504-SYN GLP not published Syngenta File No CGA163935_50036	N	Trinexapac Task Force	RAR KCA 6.5.3 / 02
CA 6.5.3	Ediger K.	2006	Trinexapac-ethyl - Magnitude of the Residues in or on Wheat Syngenta Crop Protection AG, Basel, Switzerland Syngenta Crop Protection, Inc., Greensboro, USA, T002695-03 GLP not published Syngenta File No CGA163935/1053	N	Trinexapac Task Force	RAR KCA 6.5.3 / 03
CA 6.5.3	Mac Dougall J.	2016	Trinexapac-ethyl - Residue Processing Study on Barley in Spain and Italy in 2015 Syngenta, CHEMINOVA A/S, Lemvig, Denmark, ADAMA Agriculture B.V., Schaffhausen, Switzerland Charles River Laboratories, Edinburgh, United Kingdom, 37194 GLP Not published Syngenta File No A8587F_10526	N	Trinexapac Task Force	DAR KIIA 6.3.1 / 06 & 6.5.3 / 04
CA 6.5.3	Watson G.	2016	Analysis of Barley Processing Phase Specimens for CPCA from Study 699779 Trinexapac-ethyl - Residue Processing Study on Barley in Spain and Italy in 2015 Syngenta, CHEMINOVA A/S, Lemvig, Denmark, ADAMA Agriculture B.V., Schaffhausen, Switzerland ResChem Analytical Limited, Derby, UK, RES-00027 GLP not published	N	Trinexapac Task Force	RAR KCA 6.5.3 / 05

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	Previous evaluation (DAR) or New Data (RAR, 2018)
			Syngenta File No CA876_10004			
CA 6.5.3	Langridge G.	2016	Trinexapac-ethyl - Determination of Trinexapac-ethyl Metabolites CGA313458 and CGA113745 in Barley Process Fractions Syngenta, ADAMA Agriculture B.V., Schaffhausen, Switzerland, CHEMINOVA A/S, Lemvig, Denmark CEM Analytical Services Ltd (CEMAS) - Berkshire, UK, CEMR-7354 GLP not published Syngenta File No CGA313458_10010	N	Trinexapac Task Force	RAR KCA 6.5.3 / 10
CA 6.5.3	Langridge G.	2016	Trinexapac-ethyl - Determination of Trinexapac-ethyl Metabolites CGA313458 and CGA113745 in Wheat Process Fractions Syngenta CEM Analytical Services Ltd (CEMAS) - Berkshire, UK, CEMR-7355 GLP not published Syngenta File No CGA313458_10011	N	Trinexapac Task Force	RAR KCA 6.5.3 / 11
CA 6.5.3	Mac Dougall J.	2016	Trinexapac-ethyl – Residue Processing Study on Wheat in France and Spain in 2015 Syngenta, CHEMINOVA A/S, Lemvig, Denmark, ADAMA Agriculture B.V., Schaffhausen, Switzerland Charles River Laboratories, Edinburgh, United Kingdom, 37278 GLP not published Syngenta File No A8587F_10524	N	Trinexapac Task Force	RAR KCA 6.3.2 / 04 & KCA 6.5.3 / 16
CA 6.5.3	Watson G.	2016	Analysis of Wheat Processing Phase Specimens for CPCA from Study 699784 Trinexapac-ethyl - Residue Processing Study on Wheat in France and Spain in 2015 Syngenta, CHEMINOVA A/S, Lemvig, Denmark, ADAMA Agriculture B.V., Schaffhausen, Switzerland ResChem Analytical Limited, Derby, UK, RES-00028	N	Trinexapac Task Force	RAR KCA 6.5.3 / 08

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	Previous evaluation (DAR) or New Data (RAR, 2018)
			GLP not published Syngenta File No CA876_10003			
CA 6.6.1	Krauss J. H.	1992	Outdoor confined accumulation study on rotational crops after bare-ground soil application of (^{14}C-cyclohexyl)- CGA 163935 Novartis Crop Protection AG, Basel, Switzerland Ciba-Geigy Ltd., Basel, Switzerland, 23/92 GLP not published Syngenta File No CGA163935/0265	N	Trinexapac Task Force	DAR KIIA 6.6.1 / 01
CA 6.6.1	Quistad G., Kovatchev A.	2010	^{14}C-Trinexapac-ethyl - Uptake and Metabolism in Confined Rotational Crops Syngenta Crop Protection, Inc., Greensboro, USA PTRL West, Inc., Hercules, USA, 1802W GLP not published Syngenta File No CGA163935_50024	N	Trinexapac Task Force	RAR KCA 6.6.1 / 02

zRMS for convenience highlighted above in grey and yellow already evaluated data in Appendix 2.

Appendix 2 Detailed evaluation of the additional studies relied upon

A 2.1 Trinexapac-ethyl

A 2.1.1 Stability of residues

A 2.1.1.1 Stability of residues during storage of samples

A 2.1.1.1.1 Storage stability of residues in plant products

A 2.1.1.1.1.1 Study 227361

Comments of zRMS:	Study has been accepted. This study was designed to evaluate the stability of residues of CGA179500 in various crop matrices when stored under deep frozen conditions (nominal -20°C) for up to 26 Months. The samples were analyzed for CGA179500 using procedures described in residue analytical method GRM020.05A. The analytical method has been shown to be acceptable for analysis of trinexapac acid in crops and is therefore considered to be valid for the analysis of OSR seeds, citrus, cereal grain, lettuce, and dried bean samples. Final determination is by high performance liquid chromatography with triple quadrupole mass spectrometric detection (LC-MS/MS). There was no significant decrease (> 30% as compared to the nominal fortification level) in the observed residue levels of CGA179500 in dried broad beans, lettuce, cereal grain, oilseed rape seed and citrus fruit when stored frozen at -20°C for a period of 26 months except for lettuce where stability was only demonstrated for a period of 18 months. Thus, it can be concluded that residues of CGA179500 have been demonstrated to be stable in dried broad beans, lettuce, cereal grain, oilseed rape seed and citrus when stored deep frozen at -20°C for at least 26 months except for lettuce where stability was only demonstrated for a period of 18 months.

Reference:	KCA 6.1/01
Report	Trinexapac-ethyl (CGA163935) - Storage Stability of Residues of Trinexapac acid (CGA179500) in Crop Matrices Stored Frozen for up to 26 Months., Brown D., 2020, Report no. 227361
Guideline(s):	Commission of the European Communities, Storage Stability of Residue Samples; 7032/VI/95 (Appendix H, rev.5), dated 22/7/97. OECD Guidelines for the Testing of Chemicals 506. Stability of Pesticide Residues in Stored commodities. (16 October 2007). Residue Chemistry Test Guidelines OPPTS 860.1380 Storage Stability Data, EPA 712-C-95-177, August 1996. Regulation (EC) No 1107/2009 of the European Parliament and of the council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC.

	SANCO/3029/99 rev. 4 European Commission Guidance for Generating and Reporting Methods of Analysis in Support of Pre-registration Requirements for Annex II (Part A, Section 4) of Directive 91/414. OECD Guidance Document on Pesticide Residue Analytical Methods, ENV/JM/MONO(2007)17 (Unclassified, 13 Aug 2007).
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Materials and methods

Storage stability of trinexapac acid (CGA179500) was assessed in representative crop matrices (high water content (lettuce), high protein (dried broad beans), high starch (cereal grain), high oil (oilseed rape) and high acid (citrus fruit) for up to 26 months under freezer conditions.
Individual samples (homogenised when relevant) were weighed into polypropylene bottles with screw caps and fortified with a known amount of CGA179500 in acetonitrile at a rate of 0.1 mg/kg. Each sample was fortified before proceeding with the extraction or sealed and stored in a freezer at a nominal temperature of 20°C to simulate conditions under which actual field samples are stored prior to their analysis.
Triplicate samples were analysed for CGA179500 at the zero-time point, and duplicate samples were analysed after 1, 3, 6, 12, 18 and 26 months of storage at a nominal temperature of -20°C.
On each analytical occasion, a control sample and two freshly fortified samples were extracted alongside two stored samples except at study initiation where three replicates were analysed for both the freshly fortified and stored samples.
The samples were analysed for CGA179500 using procedures described in residue analytical method GRM020.05A, with an LOQ of 0.01 mg/kg.

Results and discussions

Residues of trinexapac acid in the various matrices are shown in the table below.

Table A 1: Summary of of residues of trinexapac acid in crop matrices after storage at -20ºC

Interval storage time		Nominal fortification level	Procedural recovery sample (freshly fortified samples)	Mean procedural recovery sample		Uncorrected stored sample residue	Mean uncorrected stored sample residue	Mean corrected stored sample residue	Mean corrected stored sample residue
Months (Nominal)	Days (Actual)	(mg/kg)	(mg/kg)	(mg/kg)	(%)[a]	(mg/kg)	(mg/kg)	(mg/kg) [b]	(% of nominal) [c]
Dried Broad Beans									
0	0	0.1	0.0983	0.105	105	0.0815	0.0831	0.0790	78.8
			0.117			0.0831			
			0.101			0.0847			
1	33	0.1	0.0778	0.0783	78.3	0.0734	0.0806	0.103	103
			0.0788			0.0879			
3	92	0.1	0.0744	0.0741	74.2	0.0766	0.0722	0.0974	97.4
			0.0739			0.0678			
6	184	0.1	0.0869	0.0866	86.6	0.0910	0.0880	0.102	102
			0.0862			0.0849			

Interval storage time		Nominal fortification level	Procedural recovery sample (freshly fortified samples)	Mean procedural recovery sample		Uncorrected stored sample residue	Mean uncorrected stored sample residue	Mean corrected stored sample residue	Mean corrected stored sample residue
Months (Nominal)	Days (Actual)	(mg/kg)	(mg/kg)	(mg/kg)	(%)[(a)]	(mg/kg)	(mg/kg)	(mg/kg) [(b)]	(% of nominal) [(c)]
12	365	0.1	0.0813 0.0822	0.0817	81.8	0.0801 0.0797	0.0799	0.0978	97.7
18	551	0.1	0.0830 0.0859	0.0844	84.5	0.0780 0.0788	0.0784	0.0928	92.8
26	797	0.1	0.0990 0.0990	0.0990	99.0	0.0952 0.0967	0.0959	0.0969	96.9
Lettuce									
0	0	0.1	0.0948 0.0782 0.110	0.0945	94.3	0.129 0.0959 0.0825	0.102	0.108	109
1	32	0.1	0.0769 0.0851	0.0810	81.0	0.0677 0.0790	0.0733	0.0905	90.5
3	95	0.1	0.0900 0.0876	0.0888	88.8	0.0863 0.0846	0.0855	0.0962	96.2
6	186	0.1	0.0727 0.0958	0.0842	84.3	0.0613 0.0642	0.0628	0.0745	74.54
12	365	0.1	0.0738 0.0733	0.0735	73.6	0.0671 0.0642	0.0657	0.0893	89.3
18	550	0.1	0.103 0.103	0.103	103	0.0721 0.0731	0.0726	0.0705	70.54
26	789	0.1	0.0877 0.0864	0.0875	87.6	0.0544 0.0454	0.0499	0.0570	57.0
26 repeat	802	0.1	0.0877	0.0873	87.3	0.0512	0.0456	0.0522	52.2
Cereal grain									
0	0	0.1	0.0907 0.0716 0.0898	0.0840	84.0	0.0847 0.0930 0.0908	0.0895	0.107	107
1	30	0.1	0.0846 0.0921	0.0883	88.4	0.0927 0.0892	0.0910	0.103	103
3	91	0.1	0.0996 0.0903	0.0950	95.0	0.0989 0.0939	0.0964	0.102	102
6	181	0.1	0.0793 0.0807	0.0800	80.0	0.0765 0.0769	0.0767	0.0958	95.9
12	369	0.1	0.0886 0.0923	0.0905	90.5	0.0843 0.0836	0.0840	0.0928	92.8
18	546	0.1	0.101 0.0938	0.0974	97.4	0.0948 0.0920	0.0934	0.0959	95.9

Interval storage time		Nominal fortification level	Procedural recovery sample (freshly fortified samples)	Mean procedural recovery sample		Uncorrected stored sample residue	Mean uncorrected stored sample residue	Mean corrected stored sample residue	Mean corrected stored sample residue
Months (Nominal)	Days (Actual)	(mg/kg)	(mg/kg)	(mg/kg)	(%)[(a)]	(mg/kg)	(mg/kg)	(mg/kg) [(b)]	(% of nominal) [(c)]
26	800	0.1	0.101 0.0929	0.0967	97.0	0.0775 0.0956	0.0865	0.0893	89.3
Oilseed rape seed									
0	0	0.1	0.0773 0.0870 0.0691	0.0778	77.8	0.0831 0.0770 0.0724	0.0775	0.0996	99.6
1	30	0.1	0.0930 0.0958	0.0944	94.4	0.0978 0.0941	0.0960	0.102	102
3	91	0.1	0.0888 0.0991	0.0940	94.0	0.0900 0.0826	0.0863	0.0918	91.8
6	181	0.1	0.0882 0.0880	0.0881	88.1	0.0908 0.0750	0.0829	0.0941	94.1
12	372	0.1	0.103 0.0847	0.0939	93.9	0.0759 0.0646	0.0703	0.0749	74.94
18	546	0.1	0.0971 0.0947	0.0959	95.9	0.0972 0.0993	0.0982	0.102	102
26	805	0.1	0.0947 0.0905	0.0926	92.6	0.0891 0.0787	0.0839	0.0906	90.6
Citrus									
0	0	0.1	0.0954 0.0937 0.102	0.0972	97.0	0.0993 0.105 0.0998	0.101	0.104	104
1	33	0.1	0.0719 0.0773	0.0746	74.6	0.0885 0.0850	0.0867	0.116	116
3	97	0.1	0.0618 0.0755	0.0686	68.7	0.0689 0.0813	0.0751	0.109	109
6	181	0.1	0.0790 0.0828	0.0809	80.9	0.0835 0.0839	0.0837	0.103	103
12	369	0.1	0.0813 0.0804	0.0808	80.9	0.0844 0.0844	0.0844	0.104	104
18	546	0.1	0.101 0.100	0.101	101	0.0944 0.0967	0.0955	0.0951	95.1
26	804	0.1	0.0800 0.0809	0.0805	80.5	0.0783 0.0763	0.0773	0.0961	96.1

(a) [Mean Procedural Recovery Sample Residue (mg/kg) / Nominal Fortification Level (mg/kg)] × 10
(b) [Mean Uncorrected Stored Sample Residue (mg/kg) / Mean Procedural Recovery Sample Residue (mg/kg)] x Nominal Fortification Level (mg/kg)
(c) Based on nominal fortification level = [Mean Corrected Stored Sample Residue (mg/kg) / Nominal Fortification Level (mg/kg)] × 100

Conclusion

Residues of trinexapac acid have been shown to be stable in dried broad beans, lettuce, cereal grain, oilseed rape seed and citrus fruit when stored deep frozen at -20°C for up to 26 months, with the exception of lettuce where stability was only demonstrated for a period of 18 months.

A 2.1.1.1.2 Storage stability of residues in animal products

No new studies have been submitted by the applicant in the framework of this application. New studies were submitted for Annex I Renewal of trinexapac-ethyl; they have been evaluated by RMS Lithuania (RAR, 2018) and by EFSA (2018).

A 2.1.2 Nature of residues in plants, livestock and processed commodities

A 2.1.2.1 Nature of residue in plants

A 2.1.2.1.1 Nature of residue in primary crops

No new studies have been submitted by the applicant in the framework of this application. New studies were submitted for Annex I Renewal of trinexapac-ethyl; they have been evaluated by RMS Lithuania (RAR, 2018) and by EFSA (2018).

A 2.1.2.1.2 Nature of residue in rotational crops

No new studies have been submitted by the applicant in the framework of this application. New studies were submitted for Annex I Renewal of trinexapac-ethyl; they have been evaluated by RMS Lithuania (RAR, 2018) and by EFSA (2018).

A 2.1.2.1.3 Nature of residues in processed commodities

No new studies have been submitted by the applicant in the framework of this application. New studies were submitted for Annex I Renewal of trinexapac-ethyl; they have been evaluated by RMS Lithuania (RAR, 2018) and by EFSA (2018).

A 2.1.2.2 Nature of residues in livestock

No new studies have been submitted by the applicant in the framework of this application. New studies were submitted for Annex I Renewal of trinexapac-ethyl; they have been evaluated by RMS Lithuania (RAR, 2018) and by EFSA (2018).

A 2.1.3 Magnitude of residues in plants

A 2.1.3.1 Barley

No new studies have been submitted by the applicant in the framework of this application. New studies were submitted for Annex I Renewal of trinexapac-ethyl; they have been evaluated by RMS Lithuania (RAR, 2018) and by EFSA (2018).

Studies are presented that were considered by the evaluators (RAR, 2018; EFSA, 2018). Data relevant for risk assessment and MRL calculation are underlined.

Table A 2: Comparison of intended and critical EU GAPs

Crop	Type of GAP	Number of applications	Application rate per treatment (kg a.s./ha)	Interval between applications [min. days]	Growth stage at last application	PHI (days)
Barley, winter	cGAP EU (RAR, Lithuania, 2018; EFSA, 2018)	1	0.20	--	BBCH 25-49	n.a.
	cGAP EU (Art. 12, EFSA, 2012)	1	0.18	-.	BBCH 31-49	n.a.
	Intended cGAP (number 14)	1	0.21	--	BBCH 31-35	n.a.

n.a. = not applicable as PHI is determined by growth stage at last application

~~A 2.1.3.1.1 Study 36129 (Barley, NEU)~~

~~Comments of zRMS:~~	~~Comment on study; acceptable or not; deficiencies, corrections, according to recent guidelines or not, used in evaluation or only as additional information~~

~~Reference:~~	~~CA 6.3.1~~
~~Report~~	~~Trinexapac-Ethyl - Residue Study on Barley in Northern France and the UK in 2014. Syngenta File No. A8587F_10144, Brown D., 2016, Report no. 36129~~
~~Guideline(s):~~	~~Commission of the European Communities, General Recommendations for the Design, Preparation and Realization of Residue Trials; 7029/VI/95 (rev. 5, working document).~~ ~~Guidelines and Criteria for the Preparation and Presentation of Complete Dossiers and of Summary Dossiers for the Inclusion of Active Substances in Regulations (EU) 283/2013 and 284/2013 implementing Regulation (EC) 1107/2009.~~
~~Deviations:~~	~~No~~
~~GLP:~~	~~Yes~~
~~Acceptability:~~	~~Yes~~

Table A 3: Summary of the study 36129 trials

Active substance (common name):	Trinexapac-ethyl	Commercial product (name):	
Crop/crop group:	Barley / cereals	Producer of commercial product:	
Responsible body for reporting (name, address):	Syngenta Ltd.	Indoor/Glasshouse/Outdoor:	Outdoor
Country:	France (North), United Kingdom	Other active substance in the formulation (common name and content):	-
Content of active substance (g/kg or g/L): Formulation:	250 g/L ME	Residues calculated as:	Trinexapac acid, free Trinexapac-acid, free and conjugated

Report No. Trial No. Location (Region) (Postcode)	Commodity/ Variety (a)	Date of 1. Sowing or Planting 2. Flowering 3. Harvest (b)	Method of Treatment	Application rate per treatment			Date of treatment(s) or no of treatment(s) and last date Application Interval (days) (c)	Growth Stage at Treatment	Portion Analyzed	Residue found (Uncorrected) (mg/kg)		PHI (d)	Sample Date (Cut Date) (d)	Trial Details (e)
				kg a.s./hl	Water	Rate (Additive Type, Rate)				Trinexapac acid, free	Trinexapac acid, free and conjugated			
36129 Trial 1 UNITED KINGDOM (Europe North) (YO17 6QA)	Winter barley *(Cassia)*	1.06 Sep 2013 2. - 3. -	Foliar		352 L/ha	200.8 g a.s./ha (-)	05 May 2014 (-)	BBCH 49	Whole plant	0.03	0.04	14	19 May 2014	Method GRM020.05, GRM020.009A SP (max): 19 months
									Grain	<0.01	0.01	71	15 Jul 2014	
									Straw	<0.01	<0.05	71	15 Jul 2014	
36129 Trial 2 UNITED KINGDOM (Europe North) (YO62 7TD)	Winter barley *(Saffron)*	1.30 Sep 2013 2. - 3. -	Foliar		350 L/ha	199 g a.s./ha (-)	06 May 2014 (-)	BBCH 49	Whole plant	0.04	0.04	14	20 May 2014	
									Grain	<0.01(f)	0.01(f)	78	23 Jul 2014	
									Straw	0.01(f)	<0.05(f)	78	23 Jul 2014	
36129 Trial 3 UNITED KINGDOM (Europe North) (YO30 2AY)	Winter barley *(Glacier)*	1.07 Oct 2013 2. - 3. -	Foliar		350 L/ha	200 g a.s./ha (-)	08 May 2014 (-)	BBCH 49	Whole plant	0.04	0.04	14	22 May 2014	
									Grain	<0.01	0.02	74	21 Jul 2014	
									Straw	0.01	<0.05	74	21 Jul 2014	
36129 Trial 5 FRANCE (Europe North)	Spring barley *(Sebastian)*	1.12 Mar 2014 2. - 3. -	Foliar		340 L/ha	194 g a.s./ha (-)	29 May 2014 (-)	BBCH 49	Whole plant	0.20	0.16	14	12 Jun 2014	
									Grain	0.12	0.27	55	23 Jul 2014	

~~**Report No. Trial No. Location (Region) (Postcode)**~~	~~**Commodity/ Variety (a)**~~	~~**Date of 1. Sowing or Planting 2. Flowering 3. Harvest (b)**~~	~~**Method of Treatment**~~	~~**Application rate per treatment**~~			~~**Date of treatment(s) or no of treatment(s) and last date Application Interval (days) (c)**~~	~~**Growth Stage at Treatment**~~	~~**Portion Analyzed**~~	~~**Residue found (Uncorrected) (mg/kg)**~~		~~**PHI (d)**~~	~~**Sample Date (Cut Date) (d)**~~	~~**Trial Details (e)**~~
				~~**kg a.s./hl**~~	~~**Water**~~	~~**Rate (Additive Type, Rate)**~~				~~**Trinexapac acid, free**~~	~~**Trinexapac acid, free and conjugated**~~			
~~(60123)~~									~~Straw~~	~~0.02~~	~~<0.05~~	~~55~~	~~23 Jul 2014~~	
~~36129 Trial 6 FRANCE (Europe North) (60440)~~	~~Spring barley (*Sebastian*)~~	~~1.14 Mar 2014 2.– 3.–~~	~~Foliar~~		~~349 L/ha~~	~~199 g a.s./ha (-)~~	~~29 May 2014 (-)~~	~~BBCH 49~~	~~Whole plant~~	~~0.32(g)~~	~~0.30(g)~~	~~14~~	~~12 Jun 2014~~	
									~~Grain~~	~~0.36(g)~~	~~0.42(g)~~	~~50~~	~~18 Jul 2014~~	
									~~Straw~~	~~0.04(g)~~	~~0.07(g)~~	~~50~~	~~18 Jul 2014~~	
~~36129 Trial 7 FRANCE (Europe North) (62217)~~	~~Spring barley (*Beatrix*)~~	~~1.11 Mar 2014 2.– 3.–~~	~~Foliar~~		~~339 L/ha~~	~~193 g a.s./ha (-)~~	~~03 Jun 2014 (-)~~	~~BBCH 49~~	~~Whole plant~~	~~0.08~~	~~0.10~~	~~14~~	~~17 Jun 2014~~	
									~~Grain~~	~~0.04~~	~~0.13~~	~~52~~	~~25 Jul 2014~~	
									~~Straw~~	~~0.04~~	~~0.07~~	~~52~~	~~25 Jul 2014~~	

~~(a) According to Codex (or other e.g. EU) classification~~
~~(b) Only if relevant~~
~~(c) Year must be indicated~~
~~(d) Minimum number of days after last application (Label pre-harvest interval, PHI, underline)~~
~~(e) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included~~
~~(f) Trials 1 and 2 approx. 10 km apart were considered replicates, therefore only data from one trial considered~~
~~(g) Trial results not considered as residues were found in control samples (0.09 mg/kg in whole plant; 0.06 mg/kg in grain)~~

~~(*) Indicates sample taken prior to application~~
~~(#) Indicates corrected Residue values~~
~~(^) PHI calculated using cut date~~
~~(+) Indicates calculated Residue value~~

~~A 2.1.3.1.2 Study 37124 (Barley, NEU)~~

~~Comments of zRMS:~~	~~Comment on study; acceptable or not; deficiencies, corrections, according to recent guidelines or not, used in evaluation or only as additional information~~

~~Reference:~~	~~CA 6.3.1~~
~~Report~~	~~Trinexapac-Ethyl – Residue Study on Barley in Belgium in 2014. Syngenta File No. A8587F_10525, Brown D., 2016a, Report no. 37124~~
~~Guideline(s):~~	~~Commission of the European Communities, General Recommendations for the Design, Preparation and Realization of Residue Trials; 7029/VI/95 (rev. 5, working document).~~ ~~Guidelines and Criteria for the Preparation and Presentation of Complete Dossiers and of Summary Dossiers for the Inclusion of Active Substances in Regulations (EU) 283/2013 and 284/2013 implementing Regulation (EC) 1107/2009.~~
~~Deviations:~~	~~No~~
~~GLP:~~	~~Yes~~
~~Acceptability:~~	~~Yes~~

Table A 4: Summary of the study 37124 trials

Active substance (common name):	**Trinexapac-ethyl**	Commercial product (name):	
Crop/crop group:	**Barley / cereals**	Producer of commercial product:	
Responsible body for reporting (name, address):	Syngenta Ltd.	Indoor/Glasshouse/Outdoor:	**Outdoor**
Country:	Belgium	Other active substance in the formulation (common name and content):	-
Content of active substance (g/kg or g/L):	**250 g/L**	Residues calculated as:	Trinexapac acid, free Trinexapac-acid, free and conjugated
Formulation:	ME		

Report No. Trial No. Location (Region) (Postcode)	Commodity/ Variety (a)	Date of 1. Sowing or Planting 2. Flowering 3. Harvest (b)	Method of Treatment	Application rate per treatment			Date of treatment(s) or no of treatment(s) and last date Application Interval (days) (c)	Growth Stage at Treatment	Portion Analyzed	Residue found (Uncorrected) (mg/kg)		PHI (d)	Sample Date (Cut Date) (d)	Trial Details (e)
				kg a.s./hl	Water	Rate (Additive Type, Rate)				Trinexapac acid, free	Trinexapac acid, free and conjugated			
37124 Trial 1 BELGIUM (Europe North) (YO17 6QA)	Spring barley (*Shandy*)	1.16 Mar 2015 2. - 3. -	Foliar		356 L/ha	203 g a.s./ha (-)	03 Jun 2015 (-)	BBCH 45-49	Whole plant	0.27	0.37	14	17 Jun 2015	Method: GRM020.05A, GRM020.009A SP (max):
									Grain	0.12	0.26	64	06 Aug 2015	
									Straw	0.04	0.09	64	06 Aug 2015	8 months

(a) According to Codex (or other e.g. EU) classification
(b) Only if relevant
(c) Year must be indicated
(d) Minimum number of days after last application (Label pre-harvest interval, PHI, underline)
(e) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included.

(*) Indicates sample taken prior to application
(#) Indicates corrected Residue values
(^) PHI calculated using cut date
(+) Indicates calculated Residue value

A 2.1.3.2 Wheat

No new studies have been submitted by the applicant in the framework of this application. New studies were submitted for Annex I Renewal of trinexapac-ethyl; they have been evaluated by the RMS Lithuania (RAR, 2018) and by EFSA (2018).
For the sake of clarity all data are presented in detail below that were considered acceptable by the evaluators (RAR, 2018; EFSA, 2018).

Table A 5: Comparison of intended and critical EU GAPs

Crop	Type of GAP	Number of applications	Application rate per treatment (kg a.s./ha)	Interval between applications [min. days]	Growth stage at last application	PHI (days)
Wheat, winter	cGAP EU (RAR, Lithuania, 2018; EFSA, 2018)	1	0.125	--	BBCH 25-49	n.a.*
	cGAP EU (Art. 12, EFSA, 2012)	1	0.13	-.	BBCH 25-49	n.a.*
	Intended cGAP (number 14)	1	0.105	--	BBCH 37-39	n.a.*

n.a. not applicable as PHI is determined by growth stage at last application

~~A 2.1.3.2.1 Study 36094 (Wheat, NEU)~~

~~Comments of zRMS:~~	~~Comment on study; acceptable or not; deficiencies, corrections, according to recent guidelines or not, used in evaluation or only as additional information~~

~~Reference:~~	~~CA 6.3.2~~
~~Report~~	~~Trinexapac-Ethyl - Residue Study on Wheat in Northern France, and the UK in 2014. Syngenta File No. A8587F_10145, Brown D., 2016c, Report no. 36094~~
~~Guideline(s):~~	~~FAO Guidelines on Producing Pesticide Residues Data from Supervised Trials (Rome, 1990).~~ ~~Commission of the European Communities, General Recommendations for the Design, Preparation and Realization of Residue Trials; 7029/VI/95 (rev. 5, working document).~~ ~~Guidelines and Criteria for the Preparation and Presentation of Complete Dossiers and of Summary Dossiers for the Inclusion of Active Substances in Regulations (EU) 283/2013 and 284/2013 implementing Regulation (EC) 1107/2009.~~ ~~Support of Pre-registration Requirements for Annex II (Part A, Section 4) of Directive 91/414, SANCO/3029/99 revision 4 (11 Jul 2000).~~ ~~European Commission Guidance Document on Residue Analytical Method, SANCO/825/00 revision 8.1 (16 Nov 2010).~~ ~~The Application of the OECD Principles of GLP to the Organisation and Management of Multi-Site Studies, ENV/JM/MONO (2002) 9~~
~~Deviations:~~	~~No~~
~~GLP:~~	~~Yes~~
~~Acceptability:~~	~~Yes~~

~~**Table A 6: Summary of the study 36094 trials**~~

~~Active substance (common name):~~	~~**Trinexapac-ethyl**~~	~~Commercial product (name):~~	
~~Crop/crop group:~~	~~**Wheat / cereals**~~	~~Producer of commercial product:~~	
~~Responsible body for reporting (name, address):~~	~~Syngenta Ltd.~~	~~Indoor/Glasshouse/Outdoor:~~	~~**Outdoor**~~
~~Country:~~	~~United Kingdom, France (North)~~	~~Other active substance in the formulation (common name and content):~~	~~-~~
~~Content of active substance (g/kg or g/L):~~	~~**250 g/L**~~	~~Residues calculated as:~~	~~Trinexapac acid, free~~
~~Formulation:~~	~~ME~~		~~Trinexapac-acid, free and conjugated~~

~~**Report No. Trial No. Location (Region) (Post-code)**~~	~~**Commod-ity/ Vari-ety (a)**~~	~~**Date of 1. Sowing or Planting 2. Flowering 3. Harvest (b)**~~	~~**Method of Treatment**~~	~~**Application rate per treat-ment**~~			~~**Date of treat-ment(s) or no of treat-ment(s) and last date Application Interval (days) (c)**~~	~~**Growth Stage at Treatment**~~	~~**Portion Analyzed**~~	~~**Residue found (Uncor-rected) (mg/kg)**~~		~~**PHI (d)**~~	~~**Sample Date (Cut Date) (d)**~~	~~**Trial Details (e)**~~
				~~**kg a.s./hl**~~	~~**Water**~~	~~**Rate (Ad-ditive Type, Rate)**~~				~~**Trinexapac acid, free**~~	~~**Trinexapac acid, free and conju-gated**~~			
~~36094 Trial 1 UNITED KING-DOM (Europe North) (YO25 8JW)~~	~~Winter wheat (*Cordiale*)~~	~~1.15 Sep 2013 2.- 3.-~~	~~Foliar~~		~~352 L/ha~~	~~125.6 g a.s./ha (-)~~	~~26 May 2014 (-)~~	~~BBCH 49~~	~~Whole plant~~	~~0.04~~	~~0.04~~	~~14~~	~~09 Jun 2014~~	~~Method: GRM020.05, GRM020.009A SP (max): 21 months~~
									~~Grain~~	~~0.09~~	~~0.06~~	~~65~~	~~30 Jul 2014~~	
									~~Straw~~	~~0.02~~	~~<0.05~~	~~65~~	~~30 Jul 2014~~	
~~36094 Trial 2 UNITED KING-DOM (Europe North) (YO17 6RY)~~	~~Winter wheat (*Revela-tion*)~~	~~1.30 Sep 2013 2.- 3.-~~	~~Foliar~~		~~348 L/ha~~	~~124.3 g a.s./ha (-)~~	~~30 May 2014 (-)~~	~~BBCH 49~~	~~Whole plant~~	~~0.07~~	~~0.13~~	~~14~~	~~13 Jun 2014~~	
									~~Grain~~	~~0.22~~	~~0.23~~	~~69~~	~~07 Aug 2014~~	
									~~Straw~~	~~0.03~~	~~<0.05~~	~~69~~	~~07 Aug 2014~~	
~~36094 Trial 3 UNITED KING-DOM (Europe North) (YO30 2AY)~~	~~Winter wheat (JB Diego)~~	~~1.31 Oct 2013 2.- 3.-~~	~~Foliar~~		~~351 L/ha~~	~~125.4 g a.s./ha (-)~~	~~03 Jun 2014 (-)~~	~~BBCH 49~~	~~Whole plant~~	~~0.04~~	~~0.05~~	~~14~~	~~17 Jun 2014~~	
									~~Grain~~	~~0.05~~	~~0.04~~	~~71~~	~~13 Aug 2014~~	
									~~Straw~~	~~<0.01~~	~~<0.05~~	~~71~~	~~13 Aug 2014~~	
~~36094 Trial 4 UNITED KING-DOM (Europe North) (YO7 2HA)~~	~~Winter wheat (*Santiago*)~~	~~1.16 Dec 2013 2.- 3.-~~	~~Foliar~~		~~360 L/ha~~	~~128.6 g a.s./ha (-)~~	~~17 Jun 2014 (-)~~	~~BBCH 49~~	~~Whole plant~~	~~0.23~~	~~0.24~~	~~14~~	~~01 Jun 2014~~	
									~~Grain~~	~~0.24~~	~~0.36~~	~~71~~	~~27 Aug 2014~~	
									~~Straw~~	~~0.07~~	~~<0.05~~	~~71~~	~~27 Aug 2014~~	

Report No. Trial No. Location (Region) (Post-code)	Commod-ity/ Vari-ety (a)	Date of 1. Sowing or Planting 2. Flowering 3. Harvest (b)	Method of Treatment	Application rate per treat-ment			Date of treat-ment(s) or no of treat-ment(s) and last date Application Interval (days) (c)	Growth Stage at Treatment	Portion Analyzed	Residue found (Uncor-rected) (mg/kg)		PHI (d)	Sample Date (Cut Date) (d)	Trial Details (e)
				kg a.s./hl	Water	Rate (Ad-ditive Type, Rate)				Trinexapac acid, free	Trinexapac acid, free and conju-gated			
36094 Trial 5 FRANCE (Europe North) (60440)	Winter wheat (*Apache*)	1.25 Oct 2013 2.– 3.–	Foliar		338 L/ha	120.6 g a.s./ha (-)	09 May 2014 (-)	BBCH 49-51	Whole plant	0.05	0.06	14	23 May 2014	
									Grain	0.08	0.06	70	18 Jul 2014	
									Straw	<0.01	<0.05	70	18 Jul 2014	
36094 Trial 6 FRANCE (Europe North) (80300)	Spring wheat (*Lennox*)	1.08 Apr 2014 2.– 3.–	Foliar		330 L/ha	117.8 g a.s./ha (-)	16 Jun 2014 (-)	BBCH 45-49	Whole plant	0.03	0.10	14	30 Jun 2014	
									Grain	0.37	0.17	64	19 Aug 2014	
									Straw	0.02	<0.05	64	19 Aug	
36094 Trial 7 FRANCE (Europe North) (60490)	Winter wheat (*Koreli*)	1.31 Oct 2013 2.– 3.–	Foliar		333 L/ha	118.7 g a.s./ha (-)	16 May 2014 (-)	BBCH 49	Whole plant	0.10	0.11	14	30 May 2014	
									Grain	0.11	0.10	68	23 Jul 2014	
									Straw	<0.01	<0.05	68	23 Jul	
36094 Trial 8 FRANCE (Europe North) (60113)	Winter wheat (*Pakito*)	1.23 Oct 2013 2.– 3.–	Foliar		351 L/ha	125.3 g a.s./ha (-)	16 May 2014 (-)	BBCH 49	Whole plant	0.06	0.09	14	30 May 2014	
									Grain	0.10	0.08	63	18 Jul 2014	
									Straw	<0.01	<0.05	63	18 Jul 2014	

(a) According to Codex (or other e.g. EU) classification
(b) Only if relevant
(c) Year must be indicated
(d) Minimum number of days after last application (Label pre-harvest interval, PHI, underline)
(e) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included.

(*) Indicates sample taken prior to application
(#) Indicates corrected Residue values
(^) PHI calculated using cut date
(+) Indicates calculated Residue value

~~A 2.1.3.2.2 Study 37231 (Wheat, NEU)~~

~~Comments of zRMS:~~	~~Comment on study; acceptable or not; deficiencies, corrections, according to recent guidelines or not, used in evaluation or only as additional information~~

~~Reference:~~	~~CA 6.3.2~~
~~Report~~	~~Trinexapac-Ethyl - Residue Study on Wheat in Poland, Czech Republic, Austria and Germany in 2015. Syngenta File No. A8587F_10527, Brown D., 2016c, Report no. 37231~~
~~Guideline(s):~~	~~Commission of the European Communities, General Recommendations for the Design, Preparation and Realization of Residue Trials; 7029/VI/95 (rev. 5, working document).~~ ~~Guidelines and Criteria for the Preparation and Presentation of Complete Dossiers and of Summary Dossiers for the Inclusion of Active Substances in Regulations (EU) 283/2013 and 284/2013 implementing Regulation (EC) 1107/2009.~~
~~Deviations:~~	~~No~~
~~GLP:~~	~~Yes~~
~~Acceptability:~~	~~Yes~~

~~Table A 7: Summary of the study 37231 trials~~

~~Active substance (common name):~~ ~~**Trinexapac-ethyl**~~
~~Crop/crop group:~~ ~~**Wheat / cereals**~~
~~Responsible body for reporting (name, address):~~ ~~Syngenta Ltd.~~
~~Country:~~ ~~Germany, Poland, Austria, Czech Republic~~
~~Content of active substance (g/kg or g/L):~~ ~~**250 g/L**~~
~~Formulation:~~ ~~ME~~

~~Commercial product (name):~~
~~Producer of commercial product:~~
~~Indoor/Glasshouse/Outdoor:~~ ~~**Outdoor**~~
~~Other active substance in the formulation (common name and content):~~ ~~-~~
~~Residues calculated as:~~ ~~Trinexapac acid, free~~
~~Trinexapac-acid, free and conjugated~~

Report No. Trial No. Location (Region) (Postcode)	Commodity/ Variety (a)	Date of 1. Sowing or Planting 2. Flowering 3. Harvest (b)	Method of Treatment	Application rate per treatment			Date of treatment(s) or no of treatment(s) and last date Application Interval (days) (c)	Growth Stage at Treatment	Portion Analyzed	Residue found (Uncorrected) (mg/kg)		PHI (d)	Sample Date (Cut Date) (d)	Trial Details (e)
				kg a.s./hl	Water	Rate (Additive Type, Rate)				Trinexapac acid, free	Trinexapac acid, free and conjugated			
37231 Trial 1 GERMANY (Europe North)	Winter wheat (*Cubus*)	1.19 Oct 2014 2.- 3.-	Foliar		361 L/ha	128.8 g a.s./ha (-)	28 May 2015 (-)	BBCH 49	Grain	0.07	0.06	57	24 Jul 2015	Method: GRM020.05, GRM020.009A SP (max): 7 months
									Straw	0.01	<0.05	57	24 Jul 2015	
37231 Trial 2 POLAND (Europe North) (47-270)	Winter wheat (*Arkadia*)	1.31 Oct 2014 2.- 3.-	Foliar		353 L/ha	125.9 g a.s./ha (-)	28 May 2015 (-)	BBCH 49	Grain	0.06	0.06	56	23 Jul 2015	
									Straw	<0.01	<0.05	56	23 Jul 2015	
37231 Trial 3 AUSTRIA (Europe North) (4063)	Winter wheat (*Capo*)	1.31 Oct 2014 2. 5-10 Jun 2015 3.-	Foliar		372 L/ha	133.1 g a.s./ha (-)	18 May 2015 (-)	BBCH 49	Grain	0.05	0.07	66	23 Jul	
									Straw	0.01	<0.05	66	23 Jul 2015	
37231 Trial 4 CZECH REPUBLIC (Europe North) (68724)	Winter wheat (*Dagmar*)	1.06 Nov 2014 2.- 3.-	Foliar		356 L/ha	127.3 g a.s./ha (-)	19 May 2015 (-)	BBCH 49	Grain	0.03	0.01	65	23 Jul 2015	
									Straw	<0.01	<0.05	65	23 Jul 2015	

(a) According to Codex (or other e.g. EU) classification
(b) Only if relevant
(c) Year must be indicated
(d) Minimum number of days after last application (Label pre-harvest interval, PHI, underline)
(e) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included.

(*) Indicates sample taken prior to application
(#) Indicates corrected Residue values
(^) PHI calculated using cut date
(+) Indicates calculated Residue value

A 2.1.3.3 Livestock feeding studies

No new studies have been submitted by the applicant in the framework of this application. New studies were submitted for Annex I Renewal of trinexapac-ethyl; they have been evaluated by RMS Lithuania (RAR, 2018) and by EFSA (2018).

A 2.1.4 Magnitude of residues in processed commodities (Industrial Processing and/or Household Preparation)

No new studies have been submitted by the applicant in the framework of this application. Studies that had previously been submitted (DAR, 2003) were evaluated again by RMS Lithuania (RAR, 2018) and by EFSA (2018).

A 2.1.5 Magnitude of residues in representative succeeding crops

No new studies have been submitted by the applicant in the framework of this application.

A 2.1.6 Other/Special Studies

None

Appendix 3 Pesticide Residue Intake Model (PRIMo 3.1)

A 3.1 TMDI calculations (recalculation of zRMS)

European Food Safety Authority
EFSA PRIMo revision 3.1; 2021/01/06

Trinexapac-ethyl

LOQs (mg/kg) range from:	0,01	to:	0,05
Toxicological reference values			
ADI (mg/kg bw/day):	0,32	ARfD (mg/kg bw):	not necessary
Source of ADI:	Dir 06/64	Source of ARfD:	Dir 06/64
Year of evaluation:	2018	Year of evaluation:	2018

Input values
Details - chronic risk assessment
Supplementary results - chronic risk assessment
Details - acute risk assessment/children
Details - acute risk assessment/adults

Comments: Current EU MRLs (Reg. (EU) 2017/1016) were used for all commodities as input data.

Normal mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

TMDI/NEDI/IEDI calculation (based on average food consumption)

Calculated exposure (% of ADI)	MS Diet	Expsoure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	Exposure resulting from MRLs set at the LOQ (in % of ADI)	Exposure resulting from commodities not under assessment (in % of ADI)
3%	UK toddler	8,41	2%	Beans	0,1%	Milk: Cattle	0,0%	Oat	0,0%	
2%	UK infant	6,35	2%	Beans	0,2%	Oat	0,1%	Milk: Cattle	0,0%	
2%	NL toddler	5,83	0,6%	Rapeseeds/canola seeds	0,4%	Beans	0,2%	Milk: Cattle	0,0%	
2%	GEMS/Food G08	5,41	0,8%	Barley	0,2%	Sugar canes	0,2%	Rapeseeds/canola seeds	0,0%	
1%	GEMS/Food G07	4,74	0,6%	Barley	0,3%	Rapeseeds/canola seeds	0,2%	Sugar canes	0,0%	
1%	GEMS/Food G15	4,69	0,7%	Barley	0,2%	Sugar canes	0,2%	Beans	0,0%	
1%	GEMS/Food G10	4,55	0,6%	Barley	0,3%	Beans	0,2%	Sugar canes	0,0%	
1%	DK child	4,31	0,9%	Rye	0,4%	Oat	0,0%	Milk: Cattle	0,0%	
1%	GEMS/Food G11	4,14	0,7%	Barley	0,3%	Sugar canes	0,1%	Beans	0,0%	
1%	UK vegetarian	3,95	1%	Beans	0,0%	Oat	0,0%	Barley	0,0%	
0,9%	GEMS/Food G06	2,99	0,4%	Beans	0,3%	Sugar canes	0,1%	Barley	0,0%	
0,9%	FI 3 yr	2,99	0,5%	Oat	0,1%	Beans	0,1%	Rye	0,0%	
0,9%	DE general	2,72	0,5%	Barley	0,1%	Oat	0,1%	Rye	0,0%	
0,8%	FR child 3 15 yr	2,71	0,6%	Beans	0,1%	Oat	0,1%	Milk: Cattle	0,0%	
0,8%	FI 6 yr	2,59	0,3%	Oat	0,3%	Beans	0,1%	Rye	0,0%	
0,8%	UK adult	2,50	0,7%	Beans	0,0%	Barley	0,0%	Oat	0,0%	
0,7%	NL general	2,26	0,3%	Barley	0,2%	Rapeseeds/canola seeds	0,1%	Beans	0,0%	
0,7%	IE adult	2,24	0,4%	Beans	0,2%	Oat	0,0%	Rye	0,0%	
0,7%	NL child	2,22	0,3%	Rapeseeds/canola seeds	0,1%	Beans	0,1%	Milk: Cattle	0,0%	
0,7%	ES adult	2,21	0,5%	Barley	0,2%	Beans	0,0%	Milk: Cattle	0,0%	
0,7%	PT general	2,19	0,5%	Beans	0,0%	Barley	0,0%	Barley	0,0%	
0,6%	DE child	1,85	0,2%	Oat	0,1%	Rye	0,1%	Milk: Cattle	0,0%	
0,5%	FR toddler 2 3 yr	1,74	0,3%	Beans	0,1%	Milk: Cattle	0,1%	Oat	0,0%	
0,5%	DE women 14-50 yr	1,69	0,2%	Barley	0,1%	Oat	0,1%	Rye	0,0%	
0,5%	ES child	1,68	0,4%	Beans	0,0%	Milk: Cattle	0,0%	Wheat		
0,5%	RO general	1,61	0,4%	Beans	0,0%	Milk: Cattle	0,0%	Wheat	0,0%	
0,5%	FR adult	1,54	0,4%	Beans	0,0%	Oat	0,0%	Milk: Cattle	0,0%	
0,4%	FI adult	1,26	0,1%	Oat	0,1%	Rye	0,1%	Coffee beans	0,0%	
0,4%	LT adult	1,15	0,2%	Rye	0,1%	Oat	0,1%	Barley	0,0%	
0,3%	IT toddler	1,06	0,2%	Beans	0,0%	Wheat	0,0%	Barley	0,0%	
0,2%	IT adult	0,77	0,2%	Beans	0,0%	Wheat	0,0%	Barley	0,0%	
0,2%	SE general	0,56	0,0%	Rye	0,0%	Milk: Cattle	0,0%	Wheat	0,0%	
0,2%	FR infant	0,50	0,1%	Beans	0,1%	Milk: Cattle	0,0%	Potatoes	0,0%	
0,2%	DK adult	0,49	0,1%	Rye	0,0%	Beans	0,0%	Milk: Cattle	0,0%	
0,1%	PL general	0,42	0,1%	Beans	0,0%	Potatoes	0,0%	Apples	0,0%	
0,0%	IE child	0,14	0,0%	Milk: Cattle	0,0%	Oat	0,0%	Wheat	0,0%	

Conclusion:
The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.
The long-term intake of residues of Trinexapac-ethyl is unlikely to present a public health concern.
DISCLAIMER: Dietary data from the UK were included in PRIMO when the UK was a member of the European Union.

A 3.2 IEDI calculations

Not relevant

A 3.3 IESTI calculations - Raw commodities (PRIMo 3.1)

zRMS: No ARfD allocated – no IESTI calculations
The applicant's calculations were removed.

A 3.4 IESTI calculations - Processed commodities (PRIMo 3.1)

zRMS: No ARfD allocated – no IESTI calculations
The applicant's calculations were removed.

Appendix 4 Additional information provided by the applicant

None