

ISOPYRAZAM (249)

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EXPLANATION

Isopyrazam is a broad-spectrum foliar fungicide belonging to the chemical class of ortho-substituted phenyl amides. It controls a wide range of fungal pathogens. Isopyrazam was first evaluated by the JMPR as a new compound in 2 ± 11. An ADI of 0–0.06 mg/kg bw/day and an ARfD of 0.3 mg/kg bw were established.

The residue definitions were established: for compliance with MRL for plant commodities: *Isopyrazam (sum of syn-isomer and anti-isomer)*; for risk assessment for plant commodities: *Sum of isopyrazam and 3-difluoromethyl-1-methyl-1H-pyrazole-4-carboxylic acid [9-(1-hydroxyl-1-methylethyl)-(1RS, 4RS, 9RS)-1,2,3,4-tetrahydro-1,4-methanonaphthalen-5-yl] amide (CSCD459488) expressed as isopyrazam*; for animal commodities (enforcement and risk assessment): *Isopyrazam (sum of syn-isomer and anti-isomer)*. The residue is fat-soluble.

Isopyrazam was scheduled by the 48th Session of the CCPR as additional MRLs for consideration by the 2017 JMPR. The Meeting received information on registered labels and supporting residue trials data for pome fruit, stone fruit, cucurbits, pepper, tomato, carrot, barley, wheat, oilseed rape and peanut, as well as storage stability of isopyrazam and CSCD459488 during processing.

Storage stability under frozen conditions

The Meeting received a study report on storage stability of metabolite CSCD459488 Residues in Crops stored deep frozen for up to 28 Months (Gemrot, F., 2010, Report No. T007495-05-REG). The stability of CSCD459488 residues was tested between 2007 and 2010 in wheat grain and straw, oilseed rape (seed), apple fruit, lentils seed, orange fruit, spinach leaves and carrot root, covering representatives of all five crop types i.e. predominantly high water, acid, oil, protein and starch containing materials.

10 g crop samples were fortified with a known amount of CSCD459488 in acetonitrile at a rate of 0.5 mg/kg. The solvent was allowed to evaporate and the samples sealed and stored in a freezer at a nominal temperature of -200 ± 5 °C. The initial concentration was determined by analysis of three freshly-prepared fortified samples. At subsequent storage intervals of approximately 3, 6, 11, 23 and 28 months a sample set of each substrate, consisting of a control sample, two freshly fortified samples and two freezer-stored fortified samples, were analysed for residues of CSCD459488 using method GRM006.03A. The test results are shown in table 1. There was no significant change in the residue level of CSCD459488 in any commodity during the 28 month storage period. Therefore, residues of CSCD459488 are expected to be stable in all crop commodities when stored at -200 ± 5 °C for at least 28 months.

Table 1 Stability of CSCD459488 residues in various crops following frozen storage

Commodity	Storage Period (months)	CSCD459488 Concentration – Uncorrected (mg/kg) ^a	Mean Procedural Recovery (%) ^b	CSCD459488 Concentration – Corrected (mg/kg) ^c	Percentage Recovery ^d
Wheat (grain)	0	0.40	81	0.49	100
	3	0.52	103	0.51	103
	6	0.37	80	0.47	94
	11	0.40	98	0.41	83
	23	0.38	80	0.48	97
	28	0.54	97	0.56	113
Wheat (straw)	0	0.44	88	0.50	100
	3	0.47	84	0.56	111

Commodity	Storage Period (months)	CSCD459488 Concentration – Uncorrected (mg/kg) ^a	Mean Procedural Recovery (%) ^b	CSCD459488 Concentration – Corrected (mg/kg) ^c	Percentage Recovery ^d
	6	0.43	83	0.52	103
	11	0.41	87	0.48	95
	23	0.39	80	0.50	99
	28	0.46	98	0.47	93
Oilseed rape (seed)	0	0.37	77	0.48	100
	3	0.47	87	0.54	111
	6	0.41	83	0.49	101
	11	0.47	90	0.52	108
	23	0.47	85	0.55	115
	28	0.44	98	0.45	94
Apple (fruit)	0	0.40	81	0.49	100
	3	0.53	100	0.53	108
	6	0.44	83	0.53	109
	11	0.49	101	0.49	100
	23	0.43	83	0.52	106
	28	0.57	99	0.57	117
Lentils (seed)	0	0.38	74	0.52	100
	3	0.43	93	0.47	90
	6	0.45	87	0.52	100
	11	0.43	87	0.50	97
	23	0.40	85	0.47	91
	28	0.42	87	0.49	94
Orange (fruit)	0	0.43	85	0.50	100
	3	0.46	98	0.47	94
	6	0.39	92	0.42	84
	11	0.40	86	0.46	92
	23	0.44	79	0.56	111
	28	0.45	92	0.48	96
Spinach (leaves)	0	0.40	78	0.51	100
	3	0.45	88	0.51	101
	6	0.43	78	0.55	108
	11	0.45	82	0.54	107
	23	0.48	93	0.52	102
	28	0.47	98	0.48	94
Carrot (roots)	0	0.40	81	0.49	100
	3	0.52	98	0.53	107
	6	0.46	89	0.52	105
	11	0.48	85	0.56	114
	23	0.39	78	0.50	101
	28	0.47	90	0.53	106

^a Mean of two samples (three at 0 months), not corrected for procedural recovery

^b Mean of two recoveries

^c Mean of two samples (three at 0 months), corrected for procedural recovery

^d Percentage of 0 day = (residue concentration / initial residue concentration using corrected residues) x 100

USE PATTERNS

The registered GAP information is summarised in following table.

Table 2 Use pattern (GAP) for isopyrazam

Crop	Country or region	Method	Max No of Apps	App Interval (days)	App Rate (g ai/ha)	Min PHI (days)
Pome fruit (outdoor)	Chile	Foliar spray	2	7	150	21

Crop	Country or region	Method	Max No of Apps	App Interval (days)	App Rate (g ai/ha)	Min PHI (days)
Apricot and peach (outdoor)	Turkey	Foliar spray	2	10-14	150	7 (peach) 21 (apricot)
Cucumber and courgette (protected)	Europe (UK)	Foliar spray	2	7	125 g ai/ha	1
Melon and watermelon (protected)	Europe (UK)	Foliar spray	2	7	125	7
Pepper, sweet and chili (protected)	Europe (UK)	Foliar spray	2	7	125	3
Tomato and aubergine (protected)	Europe (UK)	Foliar spray	2	7	125	1
Carrot (outdoor)	Europe (UK)	Foliar spray	2	14	125	14
Barley, wheat, rye and triticale (outdoor)	Europe (UK)	Foliar spray	2	14	125	n/a ^a
Oilseed rape (outdoor)	Europe (UK)	Foliar spray	1	n/a	125	n/a ^a
Peanut (outdoor)	Latin America (Nicaragua)	Foliar spray	2 per crop cycle† (4 per year)	14	100 - 125 (max. 500 g ai/ha per year)	7

^a Not applicable - defined by the vegetation period from application until harvest. **N.B.** Latest time of application is BBCH 61 - 69 (end of flowering).

(†): **N.B.** The crop cycle for peanut (i.e. planting to harvest) takes *ca.* 4-5 months.

RESIDUES FROM SUPERVISED FIELD TRIALS ON CROPS

Apple

A total of sixteen supervised trials were conducted on apple in Europe (France, Germany, Greece, Hungary, Italy, Poland, Portugal and Spain) in 2013. The trials support the registered GAP for pome fruit in Chile. Samples of apple whole fruits were collected on the same day of application immediately after the spray deposit had dried and approximately 7, 10, 14 and 21 days after the final application. Samples were immediately frozen and maintained in frozen storage for periods of up to 7 months prior to extraction. Residues of isopyrazam (both isomers) in apple were determined using analytical method GRM006.01B with an LOQ of 0.005 mg/kg for each isomer (0.01 mg/kg for the sum of both isomers). Residues of CSCD459488 in apple were determined using analytical method GRM006.03A with an LOQ of 0.005 mg/kg. The results of the trials are summarised in table 3, where residues relevant to risk assessment and the setting of an MRL for pome fruit are underlined

Table 3 Residues in **apple (outdoor)** from supervised trials in **Europe** involving **foliar applications** of Isopyrazam (**100 g/L SC** formulation)

Apple Trial Location Country, year (Variety)	Application			DALA (days)	Commodity	Residues (mg/kg)			Reference & Comments
	Rate (g ai/ha)	Water (L/ha) (GPA)	No.			Isopyrazam ^a	CSCD 459488	Total ^b	
Trial: S13-03423-01 Barnim, Brandenburg, Germany, 2013 (Idared)	146 + 152 7 day interval	1217 1265	2	0	Fruit	0.065	< 0.005	0.070	Report: S13-03423 Study: S13-03423 (SC)
				7	Fruit	0.059	< 0.005	0.064	
				10	Fruit	0.047	< 0.005	0.052	
				14	Fruit	0.047	< 0.005	0.052	
				20	Fruit	0.026	< 0.005	0.031	
Trial: S13-03423-02 Stade, Niedersachsen, Germany, 2013 (Elstar)	160 + 151 7 day interval	1336 1263	2	0	Fruit	0.150	< 0.005	0.155	Report: S13-03423 Study: S13-03423 (SC)
				7	Fruit	0.219	< 0.005	0.224	
				10	Fruit	0.142	< 0.005	0.147	
				14	Fruit	0.201	< 0.005	0.206	
				21	Fruit	0.189	< 0.005	0.194	

Apple Trial Location Country, year (Variety)	Application			DALA (days)	Commodity	Residues (mg/kg)			Reference & Comments
	Rate (g ai/ha)	Water (L/ha) (GPA)	No.			Isopyrazam ^a	CSCD 459488	Total ^b	
Trial: S13-03423-03 Frankfurt, Brandenburg,Germany, 2013 (Shampion)	150 + 145 7 day interval	1248 1207	2	0	Fruit	0.209	< 0.005	0.214	Report: S13-03423 Study: S13-03423 (SC)
				8	Fruit	0.202	< 0.005	0.207	
				10	Fruit	0.157	< 0.005	0.162	
				15	Fruit	0.151	< 0.005	0.156	
				22	Fruit	0.200	< 0.005	0.205	
Trial: S13-03423-04 Stade, Niedersachsen Germany, 2013 (Elstar)	162 + 152 7 day interval	1350 1268	2	0	Fruit	0.204	< 0.005	0.209	Report: S13-03423 Study: S13-03423 (SC)
				7	Fruit	0.197	< 0.005	0.202	
				10	Fruit	0.194	< 0.005	0.199	
				14	Fruit	0.155	< 0.005	0.160	
				21	Fruit	0.122	< 0.005	0.127	
Trial: S13-03423-05 Szamotulski, Wielkopolskie, Poland, 2013 (Szampion)	141 + 149 7 day interval	1173 1243	2	0	Fruit	0.076	< 0.005	0.081	Report: S13-03423 Study: S13-03423 (SC)
				7	Fruit	0.102	< 0.005	0.107	
				10	Fruit	0.042	< 0.005	0.047	
				14	Fruit	0.033	< 0.005	0.038	
				21	Fruit	0.031	< 0.005	0.036	
Trial: S13-03423-06 Obornicki, Wielkopolskie, Poland, 2013 (Golden Delicious)	143 + 141 7 day interval	1194 1176	2	0	Fruit	0.083	< 0.005	0.088	Report: S13-03423 Study: S13-03423 (SC)
				7	Fruit	0.093	< 0.005	0.098	
				11	Fruit	0.104	< 0.005	0.109	
				14	Fruit	0.073	< 0.005	0.078	
				21	Fruit	0.117	< 0.005	0.122	
Trial: S13-03423-07 Fejer, Kozep-Dunantul, Hungary, 2013 (Idared)	147+ 151 7 day interval	1228 1258	2	0	Fruit	0.168	< 0.005	0.173	Report: S13-03423 Study: S13-03423 (SC)
				7	Fruit	0.146	< 0.005	0.151	
				11	Fruit	0.127	< 0.005	0.132	
				14	Fruit	0.157	< 0.005	0.162	
				21	Fruit	0.092	< 0.005	0.097	
Trial: S13-03423-08 Tolna, Del- Dunantul,Hungary, 2013 (Jonagold)	158+ 158 7 day interval	1314 1315	2	0	Fruit	0.153	< 0.005	0.158	Report: S13-03423 Study: S13-03423 (SC)
				7	Fruit	0.130	< 0.005	0.135	
				10	Fruit	0.114	< 0.005	0.119	
				14	Fruit	0.070	< 0.005	0.075	
				21	Fruit	0.093	< 0.005	0.098	
Trial: S13-03424-01 Pella, Kentriki Makedonia, Greece, 2013 (Granny Smith)	152+ 153 7 day interval	1365 1376	2	0	Fruit	0.115	< 0.005	0.120	Report: S13-03424 Study: S13-03424 (SC)
				6	Fruit	0.081	< 0.005	0.086	
				10	Fruit	0.086	< 0.005	0.091	
				13	Fruit	0.078	< 0.005	0.083	
				21	Fruit	0.050	< 0.005	0.055	
Trial: S13-03424-02 Gard, Languedoc- Roussillon, France,2013 (Gala)	153+ 148 7 day interval	1365 1376	2	0	Fruit	0.211	< 0.005	0.216	Report: S13-03424 Study: S13-03424 (SC)
				6	Fruit	0.174	< 0.005	0.179	
				14	Fruit	0.092	< 0.005	0.097	
				21	Fruit	0.111	< 0.005	0.116	
					Fruit	0.111	< 0.005	0.116	
Trial: S13-03424-03 Aragon, Zaragoza, Spain,2013 (Golden Delicious)	163+ 143 7 day interval	1527 1340	2	0	Fruit	0.118	< 0.005	0.123	Report: S13-03424 Study: S13-03424 (SC)
				7	Fruit	0.096	< 0.005	0.101	
				10	Fruit	0.141	< 0.005	0.146	
				14	Fruit	0.172	< 0.005	0.177	
				21	Fruit	0.140	< 0.005	0.145	
Trial: S13-03424-04 Zaragoza, Aragon, Spain, 2013 (Verde Doncella)	156+ 141 7 day interval	1350 1225	2	0	Fruit	0.187	< 0.005	0.192	Report: S13-03424 Study: S13-03424 (SC)
				7	Fruit	0.093	< 0.005	0.098	
				10	Fruit	0.100	< 0.005	0.105	
				14	Fruit	0.090	< 0.005	0.095	
				20	Fruit	0.153	< 0.005	0.158	
Trial: S13-03424-05 Caracedo, Entre Douro Minho, Portugal, 2013 (Golden Delicious)	153+ 147 7 day interval	1367 1354	2	0	Fruit	0.315	< 0.005	0.320	Report: S13-03424 Study: S13-03424 (SC)
				6	Fruit	0.450	< 0.005	0.455	
				9	Fruit	0.344	< 0.005	0.349	
				13	Fruit	0.327	< 0.005	0.332	
				20	Fruit	0.235	< 0.005	0.240	

Apple Trial Location Country, year (Variety)	Application			DALA (days)	Commodity	Residues (mg/kg)			Reference & Comments
	Rate (g ai/ha)	Water (L/ha) (GPA)	No.			Isopyrazam ^a	CSCD 459488	Total ^b	
Trial: S13-03424-06 Ferrara, Emilia Romagna, Italy, 2013 (Imperatore Dallago)	158+ 151 7 day interval	1371 1309	2	0	Fruit	0.136	< 0.005	0.141	Report: S13-03424 Study: S13-03424 (SC)
				7	Fruit	0.056	< 0.005	0.061	
				10	Fruit	0.071	< 0.005	0.076	
				14	Fruit	0.042	< 0.005	0.047	
				21	Fruit	0.062	< 0.005	0.067	
Trial: S13-03424-07 Ferrara, Emilia Romagna, Italy, 2013 (Fujiko)	151+ 164 7 day interval	1313 1421	2	0	Fruit	0.259	< 0.005	0.264	Report: S13-03424 Study: S13-03424 (SC)
				7	Fruit	0.229	< 0.005	0.234	
				10	Fruit	0.126	< 0.005	0.131	
				14	Fruit	0.110	< 0.005	0.115	
				21	Fruit	0.173	< 0.005	0.178	
Trial: S13-03424-08 Pella, Kentriki Makedonia, Greec, 2013 (Granny Smith)	152+ 152 7 day interval	1322 1320	2	0	Fruit	0.119	< 0.005	0.124	Report: S13-03424 Study: S13-03424 (SC)
				6	Fruit	0.078	< 0.005	0.083	
				10	Fruit	0.042	< 0.005	0.047	
				13	Fruit	0.084	< 0.005	0.089	
				21	Fruit	0.047	< 0.005	0.052	

^a Sum of syn- and anti-isomer (i.e. residue definition for enforcement)

^b Sum of isopyrazam and CSCD459488 expressed as isopyrazam (i.e. residue definition for risk assessment)

Stone fruit

Apricot and peach

A total of eight supervised trials were conducted on apricot (4 trials) and peach (4 trials) in Europe (France, Italy and Spain) in 2013. The peach trials support the registered cGAP in Turkey (i.e. 2 × 10 g ai/hL; 7 day PHI for peach). Samples of peach and apricot whole fruits were collected on the same day of application immediately after the spray deposit had dried and approximately 1, 3 and 7 days after the final application. Samples were immediately frozen and maintained in frozen storage for periods of up to 4 months prior to extraction. Residues of isopyrazam (both isomers) in stone fruit were determined using analytical method GRM006.01B with an LOQ of 0.005 mg/kg for each isomer (0.01 mg/kg for the sum of both isomers). Residues of CSCD459488 in stone fruit were determined using analytical method GRM006.03A with an LOQ of 0.005 mg/kg. The results of the trials are summarised in Tables 4 and 5.

Table 4 Residues in **peach (outdoor)** from supervised trials in Europe involving foliar applications of Isopyrazam (100 g/L SC formulation).

Peach Trial Location Country, Year (Variety)	Application			DALA (days)	Commodity	Residues (mg/kg)			Reference & Comments	
	Rate (g ai/ha)	Water (L/ha) (GPA)	No.			Isopyrazam ^a	CSCD 459488	Total ^b		
Trial: S13-02498-01 Longuedoc-Roussillin, Pyrenees-Orientales, France, 2013 (Maillardiva)	158 + 151 7 day interval	1579 1521	2	0	Fruit w/o stone	0.163	< 0.005	0.168	Report: S13- 02498 Study: S13- 02498 (SC)	
				1	Fruit w/o stone	0.200	0.123	< 0.005		0.205
				3	Fruit w/o stone	0.084	0.152	< 0.005		0.128
				6	Fruit w/o stone	0.186	< 0.005	0.089		
				0	Whole fruit ^c	0.116	< 0.005	0.157		
				1	Whole fruit ^c	<u>0.080</u>	< 0.005	0.191		
				3	Whole fruit ^c	< 0.005	< 0.005	0.121		
				6	Whole fruit ^c	< 0.005	< 0.005	<u>0.085</u>		

Peach Trial Location Country, Year (Variety)	Application			DALA (days)	Commodity	Residues (mg/kg)			Reference & Comments
	Rate (g ai/ha)	Water (L/ha) (GPA)	No.			Isopyrazam ^a	CSCD 459488	Total ^b	
Trial: S13-02498-02 Zaragoza, Spain, 2013 (Carlson)	140 + 164 7 day interval	1399 1642	2	0	Fruit w/o stone	1.057	< 0.005	1.062	Report: S13- 02498 Study: S13- 02498 (SC)
				1	Fruit w/o stone	0.606 0.520	< 0.005	0.611	
				3	Fruit w/o stone	0.411	< 0.005	0.525	
				7	Fruit w/o stone	0.985	< 0.005	0.416	
				0	Whole fruit ^c	0.557	< 0.005	0.990	
				1	Whole fruit ^c	0.478	< 0.005	0.562	
				3	Whole fruit ^c	<u>0.390</u>	< 0.005	0.483	
				7	Whole fruit ^c		< 0.005	<u>0.395</u>	
Trial: S13-02498-03 Zaragoza, Spain, 2013 (Catherine)	150 + 160 7 day interval	1505 1600	2	0	Fruit w/o stone	0.356	< 0.005	0.361	Report: S13- 02498 Study: S13- 02498 (SC)
				1	Fruit w/o stone	0.171 0.170	< 0.005	0.176	
				3	Fruit w/o stone	0.184 0.334	< 0.005	0.175	
				7	Fruit w/o stone	0.160	< 0.005	0.189	
				0	Whole fruit ^c	0.162	< 0.005	0.339	
				1	Whole fruit ^c	<u>0.176</u>	< 0.005	0.165	
				3	Whole fruit ^c		< 0.005	0.167	
				7	Whole fruit ^c		< 0.005	<u>0.181</u>	
Trial: S13-02498-04 Bologna, Italy, 2013 (P2)	154 + 151 7 day interval	1544 1511	2	0	Fruit w/o stone	0.476	< 0.005	0.481	Report: S13- 02498 Study: S13- 02498 (SC)
				1	Fruit w/o stone	0.336 0.430	< 0.005	0.341	
				3	Fruit w/o stone	0.266 0.432	< 0.005	0.435	
				7	Fruit w/o stone	0.309	< 0.005	0.271	
				0	Whole fruit ^c	0.398	< 0.005	0.437	
				1	Whole fruit ^c	<u>0.251</u>	< 0.005	0.314	
				3	Whole fruit ^c		< 0.005	0.403	
				7	Whole fruit ^c		< 0.005	<u>0.256</u>	

^a Sum of syn- and anti-isomer (i.e. residue definition for enforcement)

^b Sum of isopyrazam and CSCD459488 expressed as isopyrazam (i.e. residue definition for risk assessment)

^c Residues calculated using the peel/pulp ratio

Table 5 Residues in **apricot** (outdoor) from supervised trials in **Europe** involving **foliar applications** of Isopyrazam (**100 g/L SC** formulation).

Apricot Trial Location Country, year (Variety)	Application			DALA (days)	Commodity	Residues (mg/kg)			Reference & Comments
	Rate (g ai/ha)	Water (L/ha) (GPA)	No.			Isopyrazam ^a	CSCD 459488	Total ^b	
Trial: S13- 02499-01 Valencia, Valencia, Spain, 2013 (Mítixer de Castelló)	154 + 141 7 day interval	1441 1321	2	0	Fruit w/o stone	0.453	< 0.005	0.458	Report: S13- 02499 Study: S13- 02499 (SC)
				1	Fruit w/o stone	0.348 0.413	< 0.005	0.353	
				3	Fruit w/o stone	0.346 0.434	< 0.005	0.418	
				7	Fruit w/o stone	0.334	< 0.005	0.351	
				0	Whole fruit ^c	0.397	< 0.005	0.439	
				1	Whole fruit ^c	0.334	< 0.005	0.339	
				3	Whole fruit ^c		< 0.005	0.402	
				7	Whole fruit ^c		< 0.005	0.339	
Trial: S13- 02499-02 Valencia, Valencia, Spain, 2013 (Tadeo)	147 + 154 7 day interval	1376 1439	2	0	Fruit w/o stone	0.347	< 0.005	0.352	Report: S13- 02499 Study: S13- 02499 (SC)
				1	Fruit w/o stone	0.359 0.293	0.006	0.365	
				3	Fruit w/o stone	0.184 0.325	0.006	0.299	
				7	Fruit w/o stone	0.337	0.006	0.190	
				0	Whole fruit ^c	0.274	< 0.005	0.330	
				1	Whole fruit ^c	0.172	0.006	0.343	
				3	Whole fruit ^c		0.005	0.279	
				7	Whole fruit ^c		0.006	0.178	

Apricot	Application			DALA	Commodity	Residues (mg/kg)			Reference & Comments
Trial Location Country, year (Variety)	Rate (g ai/ha)	Water (L/ha) (GPA)	No.	(days)		Isopyrazam ^a	CSCD 459488	Total ^b	
Trial: S13-02499-03 Ferrara, Emilia Romagna, Italy, 2013 (Portici)	155+ 152 7 day interval	1449 1418	2	0	Fruit w/o stone	0.203	< 0.005	0.208	Report: S13-02499 Study: S13-02499 (SC)
				1	Fruit w/o stone	0.180 0.153	0.005	0.185	
				3	Fruit w/o stone	0.129 0.182	0.006	0.159	
				7	Fruit w/o stone	0.163	0.005	0.134	
				0	Whole fruit ^c	0.139	< 0.005	0.187	
				1	Whole fruit ^c	0.118	< 0.005	0.168	
				3	Whole fruit ^c		0.005	0.144	
7	Whole fruit ^c		< 0.005	0.123					
Trial: S13-02499-04 Bologna, Emilia Romagna, Italy, 2013 (Precoce D'Imola)	152+ 157 7 day interval	1419 1467	2	0	Fruit w/o stone	0.324	0.006	0.330	Report: S13-02499 Study: S13-02499 (SC)
				1	Fruit w/o stone	0.297 0.201	0.008	0.305	
				3	Fruit w/o stone	0.119 0.288	0.010	0.211	
				7	Fruit w/o stone	0.265	0.008	0.127	
				0	Whole fruit ^c	0.180	0.006	0.294	
				1	Whole fruit ^c	0.111	0.007	0.272	
				3	Whole fruit ^c		0.009	0.189	
7	Whole fruit ^c		0.008	0.119					

^a Sum of syn- and anti-isomer (i.e. residue definition for enforcement)

^b Sum of isopyrazam and CSCD459488 expressed as isopyrazam (i.e. residue definition for risk assessment)

^c Residues calculated using the peel/pulp ratio

Fruiting vegetables, cucurbits - edible peel

Cucumber and courgette (summer squash)

A total of eight supervised trials were conducted on protected cucumber in Europe (France, Germany, Italy, Spain and the UK) in 2010 and 2011. These trials support the registered indoor GAP in the UK (i.e. 2×125 g ai/ha; 1 day PHI). Samples of cucumber fruits were collected on the same day of application immediately after the spray deposit had dried and approximately 1, 3 and 7 days after the final application. Samples were immediately frozen and maintained in frozen storage for periods of up to 7 months prior to extraction. Residues of isopyrazam (both isomers) in cucumber were determined using analytical method GRM006.01B with an LOQ of 0.005 mg/kg for each isomer (0.01 mg/kg for the sum of both isomers). Residues of CSCD459488 in cucumber were determined using analytical method GRM006.03A with an LOQ of 0.005 mg/kg. The results of the trials are summarised in Table 6

Table 6 Residues in **Cucumber** (indoor trails) from supervised trials in Europe involving foliar applications of isopyrazam (125 g/L EC formulation)

Cucumber	Application			DALA	Commodity	Residues (mg/kg)			Reference & Comments
Trial Location Country, year (Variety)	Rate (g ai/ha)	Water (L/ha) (GPA)	No.	(days)		Isopyrazam ^a	CSCD 459488	Total ^b	
Trial: S10-01551-01 Regine Kuchly, France, 2010 (Verdon)	127 + 132 7 day interval	1013 1055	2	0	Fruit	0.046	< 0.005	0.051	Report : S10-01551 Study : S10-01551
				1	Fruit	0.025	< 0.005	0.030	
				3	Fruit	0.025	< 0.005	0.030	
				7	Fruit	0.015	< 0.005	0.020	
Trial: S10-01552-01 Sanlúcar de Barrameda, Spain, 2010 (Llano Verde)	119 + 119 7 day interval	1146 1144	2	0	Fruit	0.032	< 0.005	0.037	Report : S10-01552 Study: S10-01552
				1	Fruit	0.036	< 0.005	0.041	
				3	Fruit	0.018	< 0.005	0.023	
				7	Fruit	< 0.005	< 0.005	< 0.015	

Cucumber Trial Location Country, year (Variety)	Application			DALA (days)	Commodity	Residues (mg/kg)			Reference & Comments
	Rate (g ai/ha)	Water (L/ha) (GPA)	No.			Isopyrazam ^a	CSCD 459488	Total ^b	
Trial: S11-00645-01 Cottingham, UK, 2011 (Bon Bon)	126 + 132 7 day interval	303 477	2	0	Fruit	0.012	< 0.005	0.017	Report : S11-00645 Study : S11-00645
				1	Fruit	< 0.010	0.008	0.018	
				3	Fruit	< 0.010	0.014	<u>0.023</u>	
				7	Fruit	< 0.010	< 0.005	< 0.015	
Trial: S11-00645-02 Vetschau, Brandenburg, Germany, 2011 (Indira)	129 + 131 7 day interval	1030 1048	2	0	Fruit	0.010	0.006	0.016	Report :S11-00645 Study :11-00645
				1	Fruit	<u>0.012</u>	0.009	0.021	
				3	Fruit	0.010	0.014	<u>0.023</u>	
				7	Fruit	< 0.005	0.008	0.018	
Trial: S11-00645-03 Longué-Jumelles, France, 2011 (Verdon)	135 + 120 7 day interval	975 864	2	0	Fruit	0.015	< 0.005	0.020	Report : S11-00645 Study: 11-00645
				1	Fruit	<u>0.015</u>	0.007	<u>0.022</u>	
				3	Fruit	0.013	< 0.005	0.018	
				7	Fruit	< 0.010	< 0.005	< 0.015	
Trial: S11-00646-01 Fondi, Italy, 2011 (Ekron)	126 + 115 7 day interval	1009 922	2	0	Fruit	0.018	0.008	0.026	Report : S11-00646 Study : S11-00646
				1	Fruit	<u>0.010</u>	0.011	<u>0.021</u>	
				3	Fruit	< 0.010	0.006	0.016	
				8	Fruit	< 0.010	< 0.005	< 0.015	
Trial: S11-00646-02 Andalucía, Spain, 2011 (Alanis)	124 + 124 7 day interval	990 990	2	0	Fruit	0.013	0.008	0.021	Report : S11-00646 Study : S11-0064
				1	Fruit	<u>0.013</u>	0.011	<u>0.024</u>	
				3	Fruit	< 0.010	0.006	0.016	
				7	Fruit	< 0.010	< 0.005	< 0.015	
Trial: S11-00646-03 Andalucía, Spain, 2011 (Llanero)	129 + 127 7 day interval	1036 1019	2	0	Fruit	0.017	0.008	0.025	Report : S11-00646 Study : S11-00646
				1	Fruit	<u>0.017</u>	0.007	<u>0.024</u>	
				3	Fruit	< 0.010	0.007	0.017	
				7	Fruit	< 0.010	< 0.005	< 0.015	

^a Sum of syn- and anti-isomer (i.e. residue definition for enforcement)

^b Sum of isopyrazam and CSCD459488 expressed as isopyrazam (i.e. residue definition for risk assessment)

Fruiting vegetables, cucurbits - inedible peel

Melon and watermelon

A total of eight supervised trials were conducted on protected melon in Europe (France, Spain and Italy) in 2010 and 2011. These trials support the registered indoor GAP in the UK (i.e. 2 × 125 g ai/ha; 7 day PHI). Samples of melon whole fruits were collected on the same day of application immediately after the spray deposit had dried and approximately 1, 3 and 7 days after the final application. Samples were immediately frozen and maintained in frozen storage for periods of up to 5 months prior to extraction. Residues of isopyrazam (both isomers) in melon were determined using analytical method GRM006.01B with an LOQ of 0.005 mg/kg for each isomer (0.01 mg/kg for the sum of both isomers). Residues of CSCD459488 in melon were determined using analytical method GRM006.03A with an LOQ of 0.005 mg/kg. The results of the trials are summarised in Table 8.

Table 8 Residues in **melon** (indoor) from supervised trials in Europe involving foliar applications of Isopyrazam (62.5 g/L or 125 g/L EC formulation)

Melon Trial Location Country, year (Variety)	Application			DALA (days)	Commodity	Residues (mg/kg)			Reference & Comments
	Rate (g ai/ha)	Water (L/ha) (GPA)	No.			Isopyrazam ^a	CSCD 459488	Total ^b	
Trial: S10-01553-01 Epieds, France,2010 (Ugo)	129 + 124 7 days interval	1031 994	2	0	Peel	0.650	< 0.005	0.655	Report: S10-01553 Study: S10-01553
				0	Pulp	< 0.010	< 0.005	< 0.015	
				0	Whole fruit ^c	0.137	< 0.005	0.142	
				1	Peel	0.901	0.006	0.907	
				1	Pulp	< 0.010	< 0.005	< 0.015	
				1	Whole fruit ^c	0.216	< 0.005	0.221	
				3	Peel	0.560	< 0.005	0.565	
				3	Pulp	< 0.010	< 0.005	< 0.015	
				3	Whole fruit ^c	0.139	< 0.005	0.144	
				7	Peel	0.350	< 0.005	0.355	
7	Pulp	< 0.010	< 0.005	< 0.015					
7	Whole fruit ^c	0.101	< 0.005	0.106					
Trial: S11-00647-01 Stotzheim, France,2011 (Santon)	121 + 126 7 days interval	485 506	2	0	Peel	0.075	0.006	0.081	Report: S11-00647 Study: S11-00647
				0	Pulp	< 0.010	< 0.005	< 0.015	
				0	Whole fruit ^c	0.021	0.005	0.026	
				1	Peel	0.077	0.010	0.087	
				1	Pulp	< 0.010	< 0.005	< 0.015	
				1	Whole fruit ^c	0.025	0.006	0.031	
				3	Peel	0.043	0.005	0.048	
				3	Pulp	< 0.010	< 0.005	< 0.015	
				3	Whole fruit ^c	0.019	0.005	0.024	
				7	Peel	0.072	0.009	0.081	
7	Pulp	< 0.010	< 0.005	< 0.015					
7	Whole fruit ^c	0.022	0.006	0.028					
Trial: S11-00647-02 Orgerus, France, 2011 (Edgar)	127 + 124 7 days interval	508 495	2	0	Peel	0.035	< 0.005	0.040	Report: S11-00647 Study: S11-00647
				0	Pulp	< 0.010	< 0.005	< 0.015	
				0	Whole fruit ^c	0.015	< 0.005	0.020	
				1	Peel	0.038	< 0.005	0.043	
				1	Pulp	< 0.010	< 0.005	< 0.015	
				1	Whole fruit ^c	0.016	< 0.005	0.021	
				3	Peel	0.024	< 0.005	0.029	
				3	Pulp	< 0.010	< 0.005	< 0.015	
				3	Whole fruit ^c	0.013	< 0.005	0.018	
				7	Peel	0.019	< 0.005	0.024	
7	Pulp	< 0.010	< 0.005	< 0.015					
7	Whole fruit ^c	0.012	< 0.005	0.017					
Trial: S11-00647-03 Epieds, France, 2011 (Hugo)	124 + 114 7 days interval	897 824	2	0	Peel	0.040	< 0.005	0.045	Report: S11-00647 Study: S11-00647
				0	Pulp	< 0.010	< 0.005	< 0.015	
				0	Whole fruit ^c	0.014	< 0.005	0.019	
				1	Peel	0.043	< 0.005	0.048	
				1	Pulp	< 0.010	< 0.005	< 0.015	
				1	Whole fruit ^c	0.017	< 0.005	0.022	
				3	Peel	0.024	< 0.005	0.029	
				3	Pulp	< 0.010	< 0.005	< 0.015	
				3	Whole fruit ^c	0.012	< 0.005	0.017	
				7	Peel	0.027	< 0.005	0.032	
7	Pulp	< 0.010	< 0.005	< 0.015					
7	Whole fruit ^c	0.014	< 0.005	0.019					

Melon	Application			DALA	Commodity	Residues (mg/kg)			Reference & Comments
Trial Location Country, year (Variety)	Rate (g ai/ha)	Water (L/ha) (GPA)	No.	(days)		Isopyrazam ^a	CSCD 459488	Total ^b	
Trial: S10-01554-01 Sanlúcar de Barrameda, Spain, 2010 (Prima)	127 + 133 7 days interval	1217 1281	2	0	Peel	0.267	< 0.005	0.272	Report: S10-01554 Study: S10-01554
				0	Pulp	< 0.010	< 0.005	< 0.015	
				0	Whole fruit ^c	0.063	< 0.005	0.068	
				1	Peel	0.245	< 0.005	0.250	
				1	Pulp	< 0.010	< 0.005	< 0.015	
				1	Whole fruit ^c	0.051	< 0.005	0.056	
				3	Peel	0.258	< 0.005	0.263	
				3	Pulp	< 0.010	< 0.005	< 0.015	
				3	Whole fruit ^c	0.041	< 0.005	0.046	
				7	Peel	0.056	< 0.005	0.061	
				7	Pulp	< 0.010	< 0.005	< 0.015	
7	Whole fruit ^c	0.017	< 0.005	0.022					
Trial: S11-00648-01 Castelsarrasin, France, 2011 (Hugo)	125 + 125 7 days interval	999 998	2	0	Peel	0.082	< 0.005	0.087	Report: S11-00648 Study: S11-00648
				0	Pulp	< 0.010	< 0.005	< 0.015	
				0	Whole fruit ^c	0.020	< 0.005	0.025	
				1	Peel	0.076	< 0.005	0.081	
				1	Pulp	< 0.010	< 0.005	< 0.015	
				1	Whole fruit ^c	0.021	< 0.005	0.026	
				3	Peel	0.034	< 0.005	0.039	
				3	Pulp	< 0.010	< 0.005	< 0.015	
				3	Whole fruit ^c	0.015	< 0.005	0.020	
				7	Peel	0.029	< 0.005	0.034	
				7	Pulp	< 0.010	< 0.005	< 0.015	
7	Whole fruit ^c	0.013	< 0.005	0.018					
Trial: S11-00648-02 Mudaison, France, 2011 (Cisco)	125 + 121 7 days interval	1002 972	2	0	Peel	0.146	< 0.005	0.151	Report: S11-00648 Study: S11-00648
				0	Pulp	< 0.010	< 0.005	< 0.015	
				0	Whole fruit ^c	0.046	< 0.005	0.051	
				1	Peel	0.174	0.007	0.181	
				1	Pulp	< 0.010	< 0.005	< 0.015	
				1	Whole fruit ^c	0.049	0.006	0.055	
				3	Peel	0.177	0.008	0.185	
				3	Pulp	< 0.010	< 0.005	< 0.015	
				3	Whole fruit ^c	0.046	0.006	0.052	
				7	Peel	0.105	0.007	0.112	
				7	Pulp	< 0.010	< 0.005	< 0.015	
7	Whole fruit ^c	0.031	0.006	0.037					
Trial: S11-00648-03 Sermide, Italy, 2011 (Honey Moon)	125 + 127 7 days interval	702 715	2	0	Peel	0.049	< 0.005	0.054	Report: S11-00648 Study: S11-00648
				0	Pulp	< 0.010	< 0.005	< 0.015	
				0	Whole fruit ^c	0.019	< 0.005	0.024	
				1	Peel	0.048	< 0.005	0.053	
				1	Pulp	< 0.010	< 0.005	< 0.015	
				1	Whole fruit ^c	0.019	< 0.005	0.024	
				3	Peel	0.036	< 0.005	0.041	
				3	Pulp	< 0.010	< 0.005	< 0.015	
				3	Whole fruit ^c	0.016	< 0.005	0.021	
				7	Peel	0.058	< 0.005	0.063	
				7	Pulp	< 0.010	< 0.005	< 0.015	
7	Whole fruit ^c	0.017	< 0.005	0.022					

^a Sum of syn- and anti-isomer (i.e. residue definition for enforcement)

^b Sum of isopyrazam and CSCD459488 expressed as isopyrazam (i.e. residue definition for risk assessment)

^c Residues calculated using the peel/pulp ratio

Fruiting vegetables, other than Cucurbits

Pepper (sweet and chili)

A total of eight supervised trials were conducted on protected pepper in Europe (UK, France, Italy and Spain) in 2010 and 2011. These trials support the registered indoor GAP in the UK (i.e. 2 × 125 g ai/ha; 3 day PHI). Samples of pepper fruits were collected on the same day of application immediately after the spray deposit had dried and approximately 1, 3 and 7 days after the final application. Samples were immediately frozen and maintained in frozen storage for periods of up to 6 months prior to extraction. Residues of isopyrazam (both isomers) have been found to be stable during frozen storage in a wide range of crops stored at about -18 °C, during storage periods over 24 months. Residues of isopyrazam (both isomers) in pepper were determined using analytical method GRM006.01B with an LOQ of 0.005 mg/kg for each isomer (0.01 mg/kg for the sum of both isomers). Residues of CSCD459488 in pepper were determined using analytical method GRM006.03A with an LOQ of 0.005 mg/kg. The results of the trials are summarised in Table 9.

Table 9 Residues in **pepper** (indoor) from supervised trials in **Europe** involving **foliar applications** of Isopyrazam (**125 g/L or 62.5 g/L EC** formulation)

Pepper Trial Location Country, year (Variety)	Application			DALA (days)	Commodity	Residues (mg/kg)			Reference & Comments
	Rate (g ai/ha)	Water (L/ha) (GPA)	No.			Isopyrazam ^a	CSCD 459488	Total ^b	
Trial: S11-00649-01 Waltham Abbey, UK, 2011 (Soprano)	126 + 125 7 day interval	809 798	2	0	Fruit	0.033	< 0.005	0.038	Report: S11-00649 Study: S11-00649
				1	Fruit	0.034	< 0.005	0.039	
				3	Fruit	<u>0.036</u>	< 0.005	<u>0.041</u>	
				8	Fruit	0.034	< 0.005	0.039	
Trial: S11-00649-02 St Pryvé St Mesmin, France, 2011 (Spartakus)	123 + 130 7 day interval	989 1040	2	0	Fruit	0.030	< 0.005	0.035	Report: S11-00649 Study: S11-00649
				1	Fruit	0.033	< 0.005	0.038	
				3	Fruit	<u>0.023</u>	< 0.005	<u>0.028</u>	
				7	Fruit	0.019	< 0.005	0.024	
Trial: S11-00649-03 Orgerus, France, 2011 (Lipari)	127 + 123 7 day interval	810 790	2	0	Fruit	0.013	< 0.005	0.018	Report: S11-00649 Study: S11-00649
				1	Fruit	< 0.010	< 0.005	< 0.015	
				3	Fruit	<u>< 0.010</u>	< 0.005	<u>< 0.015</u>	
				7	Fruit	< 0.010	< 0.005	< 0.015	
Trial: S11-00649-04 Varennes Sur Loire, France, 2011 (Denver)	127 + 122 7 day interval	711 685	2	0	Fruit	0.047	< 0.005	0.052	Report: S11-00649 Study: S11-00649
				1	Fruit	0.045	< 0.005	0.050	
				3	Fruit	0.041	< 0.005	0.046	
				7	Fruit	<u>0.045</u>	< 0.005	<u>0.050</u>	
Trial: S10-01558-02 Fondi, Italy, 2010 (Peppone)	127 + 138 7 day interval	1017 1107	2	0	Fruit	0.015	< 0.005	0.020	Report: S10-01558 Study: S10-01558
				1	Fruit	0.018	< 0.005	0.023	
				3	Fruit	<u>0.028</u>	< 0.005	<u>0.033</u>	
				7	Fruit	0.017	< 0.005	0.022	
Trial: S11-00650-01 Fondi, Italy, 2011 (Corrado)	132 + 123 7 day interval	1055 988	2	0	Fruit	0.015	< 0.005	0.020	Report: S11-00650 Study: S11-00650
				1	Fruit	0.013	< 0.005	0.018	
				3	Fruit	<u>0.019</u>	< 0.005	<u>0.024</u>	
				7	Fruit	0.014	< 0.005	0.019	
Trial: S11-00650-02 Vallemarina, Italy, 2011 (Senior)	136 + 146 7 day interval	1093 1167	2	0	Fruit	0.029	< 0.005	0.034	Report: S11-00650 Study: S11-00650
				1	Fruit	0.029	< 0.005	0.034	
				3	Fruit	<u>0.021</u>	< 0.005	<u>0.026</u>	
				7	Fruit	0.020	< 0.005	0.025	
Trial: S11-00650-03 Igea Marina, Italy, 2011 (Roni)	124 + 122 7 day interval	991 976	2	0	Fruit	0.050	< 0.005	0.055	Report: S11-00650 Study: S11-00650
				1	Fruit	0.049	< 0.005	0.054	
				3	Fruit	<u>0.039</u>	< 0.005	<u>0.044</u>	
				7	Fruit	0.031	< 0.005	0.036	

^a Sum of syn- and anti-isomer (i.e. residue definition for enforcement)

^b Sum of isopyrazam and CSCD459488 expressed as isopyrazam (i.e. residue definition for risk assessment)

Tomato and aubergine (egg plant)

A total of eight supervised trials were conducted on protected tomato in Europe (France, Spain, UK and Italy) in 2010, 2011 and 2013. These trials support the registered indoor GAP in the UK (i.e. 2×125 g ai/ha; 1 day PHI). Samples of tomato fruits were collected on the same day of application immediately after the spray deposit had dried and approximately 1, 3 and 7 days after the final application. Samples were immediately frozen and maintained in frozen storage for periods of up to 4 months prior to extraction. Residues of isopyrazam (both isomers) in tomato were determined using analytical method GRM006.01B with an LOQ of 0.005 mg/kg for each isomer (0.01 mg/kg for the sum of both isomers). Residues of CSCD459488 in tomato were determined using analytical method GRM006.03A with an LOQ of 0.005 mg/kg. The results of the trials are summarised in Table 10.

Table 10 Residues in **tomato (indoor)** from supervised trials in Europe involving **foliar applications** of Isopyrazam (**125g/L EC** formulation).

Tomato Trial Location Country, year (Variety)	Application			DALA (days)	Commodity	Residues (mg/kg)			Reference & Comments
	Rate (g ai/ha)	Water (L/ha) (GPA)	No.			Isopyrazam ^a	CSCD 459488	Total ^b	
Trial: S10-01555-01 Dampierre en burly Loiret, France, 2010 (Lucinda)	126 + 131 7 days interval	807 836	2	0	Fruit	0.276	< 0.005	0.281	Report: S10-01555 Study: S10-01555
				1	Fruit	<u>0.191</u>	< 0.005	<u>0.196</u>	
				3	Fruit	0.183	< 0.005	0.188	
				7	Fruit	0.154	< 0.005	0.159	
Trial: S10-01556-01 Canals, Valencia Spain, 2010 (Granillon)	135 + 128 7 days interval	1081 1029	2	0	Fruit	0.229	< 0.005	0.234	Report: S10-01556 Study: S10-01556
				1	Fruit	0.134	< 0.005	0.139	
				3	Fruit	0.148	< 0.005	0.153	
				7	Fruit	<u>0.228</u>	< 0.005	<u>0.233</u>	
Trial: S11-00651-03 Dampierre en burly, Loiret, France, 2011 (Lucinda)	124 + 126 7 days interval	598 607	2	0	Fruit	0.026	< 0.005	0.031	Report: S11-00651 Study: S11-00651
				1	Fruit	<u>0.025</u>	< 0.005	<u>0.030</u>	
				3	Fruit	0.017	< 0.005	0.022	
				7	Fruit	0.019	< 0.005	0.024	
Trial: S11-00651-04 Newbourne, Suffolk, UK, 2011 (Conchita)	129 + 127 7 days interval	620 612	2	0	Fruit	0.021	< 0.005	0.026	Report: S11-00651 Study: S11-00651
				1	Fruit	0.021	< 0.005	0.026	
				3	Fruit	<u>0.049</u>	< 0.005	<u>0.054</u>	
				7	Fruit	< 0.010	< 0.005	< 0.015	
Trial: S11-00652-01 Elne, Pyrenees-Orientales, Languedoc-Roussillon, France, 2011 (Sweet)	132 + 127 7 days interval	738 712	2	0	Fruit	0.058	< 0.005	0.063	Report: S11-00652 Study: S11-00652
				1	Fruit	<u>0.048</u>	< 0.005	<u>0.053</u>	
				3	Fruit	0.044	< 0.005	0.049	
				7	Fruit	0.023	< 0.005	0.028	
Trial: S11-00652-02 Vallemarina, Latina, Lazio, Italy, 2011 (Tropical)	125 + 127 7 days interval	1000 1020	2	0	Fruit	0.025	< 0.005	0.030	Report: S11-00652 Study: S11-00652
				1	Fruit	<u>0.017</u>	< 0.005	<u>0.022</u>	
				3	Fruit	0.010	< 0.005	0.015	
				7	Fruit	0.012	< 0.005	0.017	
Trial: S11-00652-03 Conil de la Frontera, Cadiz, Andalucia, Spain, 2011 (Lupita)	128 + 135 7 days interval	818 866	2	0	Fruit	0.016	< 0.005	0.021	Report: S11-00652 Study: S11-00652
				1	Fruit	0.017	< 0.005	0.022	
				3	Fruit	<u>0.018</u>	< 0.005	<u>0.023</u>	
				7	Fruit	0.015	< 0.005	0.020	
Trial: S13-02543-01 Latina Italy, 2013 (Tropical)	120 + 130 7 days interval	962 1040	2	1	Fruit	<u>0.134</u>	< 0.005	<u>0.139</u>	Report: S13-02543 Study: S13-02543

^a Sum of syn- and anti-isomer (i.e. residue definition for enforcement)

^b Sum of isopyrazam and CSCD459488 expressed as isopyrazam (i.e. residue definition for risk assessment)

Root and tuber vegetables

Carrot

A total of sixteen supervised trials were conducted on carrot in Europe (UK, Germany, France, Spain and Italy) in 2010 and 2011. These trials support the registered GAP in the UK (i.e. 2 ×125 g ai/ha; 14 day PHI). Samples of carrot roots were collected on the same day of application immediately after the spray deposit had dried and approximately 3, 7, 10 and 14 days after the final application. Samples were immediately frozen and maintained in frozen storage for periods of up to 6 months prior to extraction. Residues of isopyrazam (both isomers) in carrot were determined using analytical method GRM006.01B with an LOQ of 0.005 mg/kg for each isomer (0.01 mg/kg for the sum of both isomers). Residues of CSCD459488 in carrot were determined using analytical method GRM006.03A with an LOQ of 0.005 mg/kg. The results of the trials are summarised in Table 11.

Table 11 Residues in carrots (**outdoor**) from supervised trials in **Europe** involving **foliar applications** of Isopyrazam (**62.5 g/L or 125 g/L EC** formulation).

Carrots Trial Location Country, year (Variety)	Application			DALA (days)	Commodity	Residues (mg/kg)			Reference & Comments
	Rate (g ai/ha)	Water (L/ha) (GPA)	No.			Isopyrazam ^a	CSCD 459488	Total ^b	
Trial: S10-01549-01 Rainford Lancashire, UK, 2010 (Artist)	124 + 125 14 day interval	398 400	2	0	Root	0.015	< 0.005	0.020	Report: S10- 01549 Study: S10- 01549
				3	Root	0.038	< 0.005	0.043	
				7	Root	0.026	< 0.005	0.031	
				10	Root	0.018	< 0.005	0.023	
				14	Root	<u>0.019</u>	< 0.005	<u>0.024</u>	
Trial: S10-01549-03 Kutenholz Niedersachsen, Germany, 2010 (Vito)	128 + 127 14 day interval	412 408	2	0	Root	0.093	< 0.005	0.098	Report: S10- 01549 Study: S10- 01549
				3	Root	0.165	< 0.005	0.170	
				7	Root	0.100	< 0.005	0.105	
				10	Root	0.091	< 0.005	0.096	
				14	Root	<u>0.055</u>	< 0.005	<u>0.060</u>	
Trial: S11-00643-01 Shenton, Staffordshire, UK, 2011 (Nairobi)	128 + 125 14 day interval	255 252	2	0	Root	0.021	< 0.005	0.026	Report: S11- 00643 Study: S11- 00643
				3	Root	0.015	< 0.005	0.020	
				7	Root	0.010	< 0.005	0.015	
				10	Root	0.022	< 0.005	0.027	
				14	Root	<u>0.015</u>	< 0.005	<u>0.020</u>	
Trial: S11-00643-02 Rainford, Lancashire, North West, UK, 2011 (Nigel)	122+ 128 14 day interval	390 410	2	0	Root	0.013	< 0.005	0.018	Report: S11- 00643 Study: S11- 00643
				3	Root	0.018	< 0.005	0.023	
				7	Root	0.014	< 0.005	0.019	
				10	Root	0.015	< 0.005	0.020	
				14	Root	<u>0.010</u>	< 0.005	<u>0.015</u>	
Trial: S11-00643-03 Dreetz, Brandenburg, Germany, 2011 (Joba)	135+ 129 13 day interval	270 258	2	0	Root	0.014	< 0.005	0.019	Report: S11- 00643 Study: S11- 00643
				3	Root	0.015	< 0.005	0.020	
				7	Root	< 0.010	< 0.005	< 0.015	
				10	Root	< 0.010	< 0.005	< 0.015	
				14	Root	<u>0.011</u>	< 0.005	<u>0.016</u>	
Trial: S11-00643-04 Kutenholz, Niedersachsen, Germany, 2011 (Nantaise DP44)	129+ 126 14 day interval	413 405	2	0	Root	0.050	< 0.005	0.055	Report: S11- 00643 Study: S11- 00643
				3	Root	0.028	< 0.005	0.033	
				7	Root	0.069	< 0.005	0.074	
				10	Root	0.028	< 0.005	0.033	
				14	Root	<u>0.054</u>	< 0.005	<u>0.059</u>	
Trial: S11-00643-05 Niedernai, Alsace, France, 2011 (Texto)	134+ 136 14 day interval	323 327	2	0	Root	0.013	< 0.005	0.018	Report: S11- 00643 Study: S11- 00643
				3	Root	0.014	< 0.005	0.019	
				7	Root	0.013	< 0.005	0.018	
				10	Root	0.011	< 0.005	0.016	
				14	Root	<u>< 0.010</u>	< 0.005	<u>< 0.015</u>	

Carrots	Application			DALA	Commodity	Residues (mg/kg)			Reference & Comments
	Rate (g ai/ha)	Water (L/ha) (GPA)	No.			(days)	Isopyrazam ^a	CSCD 459488	
Trial: S11-00643-06 Allonnes, Anjou, Pays de loire, France, 2011 (Mondibel F1)	134+ 120 14 day interval	323 288	2	0 3 7 10 14	Root Root Root Root Root	0.014 0.026 0.019 0.017 <u>< 0.010</u>	< 0.005 < 0.005 < 0.005 < 0.005 < 0.005	0.019 0.031 0.024 0.022 <u>< 0.015</u>	Report: S11-00643 Study: S11-00643
Trial: S10-01550-01 Argeles surmer, Pyrenees-Orientala, Languedoc-Roussillon, France, 2011 (Chambord)	127+ 129 14 day interval	611 621	2	0 3 7 10 14	Root Root Root Root Root	0.030 0.080 0.079 0.031 <u>0.075</u>	< 0.005 < 0.005 < 0.005 < 0.005 < 0.005	0.035 0.085 0.084 0.036 <u>0.080</u>	Report: S10-01550 Study: S10-01550
Trial: S10-01550-02 Conil de la Frontera, Cadiz, Andalucia, Spain, 2010 (Nevi)	122+ 127 14 day interval	488 507	2	0 3 7 10 14	Root Root Root Root Root	< 0.010 < 0.010 < 0.010 0.011 <u>< 0.010</u>	< 0.005 < 0.005 < 0.005 < 0.005 < 0.005	< 0.015 < 0.015 < 0.015 0.016 <u>< 0.015</u>	Report: S10-01550 Study: S10-01550
Trial: S11-00644-01 Blagnac, Midi Pyrenees, France, 2011 (Maestro)	122+ 128 14 day interval	585 617	2	0 3 7 10 14	Root Root Root Root Root	0.014 0.013 0.015 0.013 <u>< 0.010</u>	< 0.005 < 0.005 < 0.005 < 0.005 < 0.005	0.019 0.018 0.020 0.018 <u>< 0.015</u>	Report: S11-00644 Study: S11-00644
Trial: S11-00644-02 Argeles sur Mer, Pyrenees-Orientales, France, 2011 (Chambord)	123+ 116 14 day interval	396 373	2	0 3 7 10 14	Root Root Root Root Root	< 0.010 0.017 0.016 0.013 <u>0.010</u>	< 0.005 < 0.005 < 0.005 < 0.005 < 0.005	< 0.015 0.022 0.021 0.018 <u>0.015</u>	Report: S11-00644 Study: S11-00644
Trial: S11-00644-03 Ferrara, Emilia Romagna, Italy, 2011 (Romance)	125+ 119 14 day interval	400 383	2	0 3 7 10 14	Root Root Root Root Root	< 0.010 0.021 0.013 0.017 <u>0.025</u>	< 0.005 < 0.005 < 0.005 < 0.005 < 0.005	< 0.015 0.026 0.018 0.022 <u>0.030</u>	Report: S11-00644 Study: S11-00644
Trial: S11-00644-04 Rovigo, Veneto, Italy, 2011 (Bolero)	124+ 130 14 day interval	397 417	2	0 3 7 10 14	Root Root Root Root Root	0.018 0.025 0.019 < 0.010 <u>0.099</u>	< 0.005 < 0.005 < 0.005 < 0.005 < 0.005	0.023 0.030 0.024 < 0.015 <u>0.104</u>	Report: S11-00644 Study: S11-00644
Trial: S11-00644-05 Andalucia, Cadiz, Spain, 2011 (Nevir)	128+ 121 14 day interval	411 583	2	0 3 7 10 14	Root Root Root Root Root	0.019 0.047 0.035 0.035 <u>0.029</u>	< 0.005 < 0.005 < 0.005 < 0.005 < 0.005	0.024 0.052 0.040 0.040 <u>0.034</u>	Report: S11-00644 Study: S11-00644
Trial: S11-00644-06 Andalucia, Cadiz, Spain, 2011 (Nevir F1)	128+ 134 14 day interval	615 647	2	0 3 7 10 14	Root Root Root Root Root	0.063 0.105 0.095 0.071 <u>0.037</u>	< 0.005 < 0.005 < 0.005 < 0.005 < 0.005	0.068 0.110 0.100 0.076 <u>0.042</u>	Report: S11-00644 Study: S11-00644

^a Sum of syn- and anti-isomer (i.e. residue definition for enforcement)

^b Sum of isopyrazam and CSCD459488 expressed as isopyrazam (i.e. residue definition for risk assessment)

Cereal grains

Barley

A total of eighteen supervised trials were conducted on barley in Europe (France, Germany, Italy, Spain, Switzerland and the UK) in 2006 and 2007. These trials support the registered GAP in the UK

(i.e. 2×125 g ai/ha; BBCH < 61). Samples of barley whole plants were collected on the day of application immediately after the spray deposit had dried and also at further immature stages. Immediately before maturity in some trials, plants were sampled and separated into immature grain and the remaining plant. Finally, samples of grain and straw were taken at maturity. Samples were immediately frozen and maintained in frozen storage for periods of up to 23 months prior to extraction. Residues of isopyrazam (both isomers) in barley were determined using analytical method GRM006.01B with an LOQ of 0.005 mg/kg for each isomer (0.01 mg/kg for the sum of both isomers). Residues of CSCD459488 in barley were determined using analytical method GRM006.03A with an LOQ of 0.005 mg/kg. The results of the trials are summarised in Table 12 **Error! Reference source not found.**, where residues relevant to risk assessment and the setting of MRLs for barley commodities are underlined.

Table 12 Residues in **barley (outdoor trials)** from supervised trials in **Northern Europe** involving **foliar applications** of Isopyrazam (125g/L EC formulation)

Barley Trial Location Country, year (Variety)	Application				DALA	Commodity	Residues (mg/kg)			Reference & Comments
	Rate (g ai/ha)	Water (L/ha) (GPA)	No.	(days)			Isopyrazam ^a	CSCD 459488	Total ^b	
Trial: CH-FR-06-0023 CH-1896 Vouvry, Switzerland, 2006 (Bologna)	127 + 126 37days interval	304 302	2	54	Grain	< 0.010	< 0.005	< 0.015	Report: CEMR-3393-REG Study: T000674-06	
	127 + 126 43days interval	304 301	2	48	Grain	<u>0.024</u>	0.019	<u>0.042</u>		
	126 + 126 43days interval	302 303	2	48	Grain	0.015	0.011	0.026		
Trial: CH-FR-06-0024 CH-1880 Bex, Switzerland, 2006 (Merlot)	126 + 127 37days interval	302 304	2	54	Grain	< 0.010	< 0.005	< 0.015	Report: CEMR-3393-REG Study: T000674-06	
	126 + 125 43days interval	302 300	2	48	Grain	0.014	0.006	0.020		
	125 + 128 43days interval	299 307	2	48	Grain	<u>0.014</u>	0.006	<u>0.020</u>		
Trial: FR-FR-06-0026 51490 BEINE NAUROY, France, 2006 (Esterel)	127 + 129 14days interval	300 300	2	60	Grain	< 0.010	< 0.005	< 0.015	Report: CEMR- 3393-REG Study: T000674-06	
	124 + 126 20days interval	300 300	2	54	Grain	0.028	0.020	0.047		
	124 + 131 43days interval	300 300	2	54	Grain	<u>0.035</u>	0.023	<u>0.057</u>		
Trial: IT-FR-06-0027 Rubano, Italy, 2006 (Boreale)	130 + 125 15days interval	311 299	2	53	Grain	< 0.010	< 0.005	< 0.015	Report: CEMR-3394-REG Study: T000675-06	

Barley Trial Location Country, year (Variety)	Application				DALA	Commodity	Residues (mg/kg)			Reference & Comments
	Rate (g ai/ha)	Water (L/ha) (GPA)	No.	(days)			Isopyrazam ^a	CSCD 459488	Total ^b	
	133 + 132 23days interval	319 318	2	31 45	Grain Grain	0.012 <u>0.016</u>	< 0.005 0.016	0.017 <u>0.031</u>		
Trial: ES-FR-06-0028 La Overuela, Spain, 2006 (Verticale)	124 + 131 14 days interval	198 317	2	57	Grain	0.014	< 0.005	0.019	Report: CEMR-3394-REG Study: T000675-06	
	127 + 133 21days interval	203 320	2	42 50	Grain Grain	0.170 <u>0.145</u>	0.041 0.052	0.209 <u>0.195</u>		
Trial: FR-FR-06-0029 84370 BEDARRIDES "Les Taillades", France, 2006 (Baraka)	131 + 129 21days interval	300 300	2	52	Grain	0.011	< 0.005	0.016	Report: CEMR-3393-REG Study: T000674-06	
	130 + 131 32days interval	300 300	2	41	Grain	<u>0.173</u>	0.046	<u>0.217</u>		
Trial: FR-FR-06-0030 82170 GRISOLLES "Les crespys, France, 2006 (Nevada)	126 + 127 25days interval	200 200	2	56	Grain	<u>0.015</u>	< 0.005	<u>0.020</u>	Report: CEMR-3393-REG Study: T000674-06	
	127 + 127 31days interval	200 200	2	42 50	Immature Grain Grain	< 0.010< 0.010	< 0.005 0.006	< 0.015 0.016		
Trial: DE-FR-06-4422 Stephansposching, Germany, 2006 (Carat)	124+ 124 21days interval	300 300	2	52	Grain	< 0.010	< 0.005	< 0.015	Report: T001788-06-REG Study: T001788-06	
	124 + 124 28days interval	300 300	2	45	Grain	<u>0.026</u>	0.022	<u>0.047</u>		
	124 + 124 28days interval	300 300	2	45	Grain	0.022	0.020	0.041		
Trial: AF/11519/SY/1 Alpera, Spain, 2007 (Chamorro)	130 + 125 35days interval	208 201	2	30 42	Grain Grain	0.504 <u>0.408</u>	0.030 0.023	0.533 0.430	Report: CEMR-3365 - REG	
Trial: AF/11519/SY/2 Pilastrí,, Spain, 2007 (Sonora)	126 + 122 39days interval	202 196	2	42	Grain	<u>0.270</u>	0.090	<u>0.356</u>	Report: CEMR-3365 - REG	
Trial: AF/11519/SY/3 St Etienne sur Reyssouze, France, 2007 (Scarlett)	124 + 124 33days interva	200 200	2	30 43	Immature grain Grain	0.021 <u>0.046</u>	0.008 0.016	0.029 <u>0.061</u>	Report: CEMR-3365 - REG Version 2	
Trial: AF/11519/SY/4 Cordes France, 2007 (Prestige)	122 + 124 27days interva	195 200	2	45	Grain	<u>0.024</u>	0.028	<u>0.051</u>	Report: CEMR-3365 - REG Version 2	

Barley Trial Location Country, year (Variety)	Application				DALA	Commodity	Residues (mg/kg)			Reference & Comments
	Rate (g ai/ha)	Water (L/ha) (GPA)	No.	(days)			Isopyrazam ^a	CSCD 459488	Total ^b	
Trial: AF/11519/SY/5 Vazerac, France, 2007 (Platine)	118 + 124 35days interva	189 199	2	63	Grain	<u>< 0.010</u>	0.008	<u>0.018</u>	Report: CEMR-3365 - REG Version 2	
Trial: AF/11518/SY/1 Perouse, Germany, 2007 (Braemar)	193 200		2	45	Grain	0.020	0.012	0.031	Report: CEMR-3367 -REG Version 2	
Trial: AF/11518/SY/2 Heidelberg, Germany, 2007 (Braemar)	200 200		2	30 38	Immature Grain Grain	0.053 0.016	.049 0.013	0.100 0.028	Report: CEMR-3367 – REG Version 2	
Trial: AF/11518/SY/3 Arnold, UK, 2007 Westminster)	199 198		2	42	Grain	0.016	0.006	0.022	Report: CEMR-3367 – REG Version 2	
Trial: AF/11518/SY/4 Loiret, France, 2007 (Colibri)	199 199		2	44 61	Immature Grain Grain	0.019 0.017	0.015 0.012	0.033 0.028	Report: CEMR-3367 – REG Version 2	
Trial: AF/11518/SY/5 Saone et Loire, France, 2007 (Platine)	199 193		2	30 42	Immature Grain Grain	0.041 0.026	0.026 0.020	0.066 0.045	Report: CEMR-3367 – REG Version 2	

^a Sum of syn- and anti-isomer (i.e. residue definition for enforcement)

^b Sum of isopyrazam and CSCD459488 expressed as isopyrazam (i.e. residue definition for risk assessment)

Wheat, rye and triticale

A total of eighteen supervised trials were conducted on wheat in Europe (France, Germany, Italy, Spain and the UK) in 2006 and 2007. These trials support the registered GAP/label ($\pm 25\%$) in the UK (i.e. 2×125 g ai/ha; BBCH < 71). Samples of wheat whole plants were collected on the same day of application immediately after the spray deposit had dried and also at further immature stages. Immediately before maturity in some trials plants were sampled and separated into immature grain and the remaining plant. Finally, samples of grain and straw were taken at maturity. Samples were immediately frozen and maintained in frozen storage for periods of up to 25 months prior to extraction. Residues of isopyrazam (both isomers) in wheat were determined using analytical methods GRM006.01A and GRM006.01B with an LOQ of 0.005 mg/kg for each isomer (0.01 mg/kg for the sum of both isomers). Residues of CSCD459488 in wheat were determined using analytical method GRM006.03A with an LOQ of 0.005 mg/kg. The results of the trials are summarised in Table 13, where residues relevant to risk assessment and the setting of MRLs for wheat commodities are underlined.

Table 13 Residues in wheat (outdoor trails) from supervised trials in Spain, Italy and Southern France involving foliar applications of Isopyrazam (125g/L EC formulation)

Wheat Trial Location Country, year (Variety)	Application				DALA	Commodity	Residues (mg/kg)			Reference & Comments
	Rate (g ai/ha)	Water (L/ha) (GPA)	No.	(days)			Isopyrazam a	CSCD 459488	Total b	
Trial: FR-FR-06-0032, 80250 MALPART "La Pointe", France,2006 (Limonera)	127 + 121 43days interval	300 300	2	61	Grain	< 0.010	< 0.005	< 0.015	Report: CEMR-3391- REG	
	129 + 125 + 127 33days+20days interval	300 300 300	3	31 51	Immature grain Grain	0.374 0.012	0.254 0.006	0.617 0.018	Report: CEMR-3391- REG	
	121 + 130 + 126 20days+20days interval	300 300 300	3	31 51	Immature grain Grain	0.117 0.012	0.070 0.007	0.184 0.019	Report: CEMR-3391- REG	
Trial: FR-FR-06-0033, 80250 GRIVESNES "Le Moulin", France,2006 (Limes)	124 + 122 44days interval	300 300	2	62	Grain	0.013	0.005	0.018	Report: CEMR-3391- REG	
	125 + 124 + 128 33days+ 20days interval	300 300 300	3	51	Grain	0.017	0.009	0.026	Report: CEMR-3391- REG	
	122+ 125+ 125 20days+ 20days interval	300 300 300	3	51	Grain	0.013	0.006	0.019	Report: CEMR-3391- REG	
Trial: FR-FR-06-0034, 51490 BEINE NAUROY "Menu Dime 1" , France,2006 (Charger)	131+ 124 23days interval	300 300	2	61	Grain	< 0.010	< 0.005	< 0.015	Report: CEMR-3391- REG	
	120+ 120+ 125 17days+ 26days interval	300 300 300	3	41	Grain	< 0.010	< 0.005	< 0.015	Report: CEMR-3391- REG	
	119+ 123+ 129 20days+ 20days interval	300 300 300	3	41	Grain	< 0.010	< 0.005	< 0.015	Report: CEMR-3391- REG	
Trial: ES-FR-06-0035, La Overuela, Spain,2006 (Fiufa)	134+ 133 24days interval	215 320	2	52	Grain	0.014	< 0.005	0.019	Report: CEMR-3392- REG	
	120+ 133+ 133 14days+ 21days interval	192 320 320	3	30 41	Immature grain Grain	0.026 0.030	0.017 0.006	0.042 0.036	Report: CEMR-3392- REG	
Trial: ES-FR-06-0036, Wamba, Spain,2006 (Soissons)	133+ 135 26days interval	213 323	2	51	Grain	< 0.010	< 0.005	< 0.015	Report: CEMR-3392- REG	

Wheat	Application			DALA	Commodity	Residues (mg/kg)			Reference & Comments
Trial Location Country, year (Variety)	Rate (g ai/ha)	Water (L/ha) (GPA)	No.	(days)		Isopyrazam a	CSCD 459488	Total b	
	135+ 128+ 124 18days+ 24days interval	217 307 297	3	29 35	Grain Grain	0.023 0.028	< 0.005 0.008	0.028 0.036	Report: CEMR-3392- REG
Trial: FR-FR-06-0037, 82170 GRISOLLES "Mistral" S29, France,2006 (Aztec)	129+ 127 25days interval	200 200	2	67	Grain	< 0.010	< 0.005	< 0.015	Report: CEMR-3392- REG
	131+ 117+ 128 21days+ 28ays interval	200 200 200	3	43	Grain	0.019	0.006	0.025	Report: CEMR-3392- REG
Trial: FR-FR-06-0038, 34590 MARSILLARGUES "Sole 1" , France,2006 (Aztec)	123+ 127 37days interval	250 250	2	55	Grain	0.010	< 0.005	0.015	Report: CEMR-3392- REG
	123+ 126+ 124 30days+ 16days interval	250 250 250	3	46	Grain	0.018	< 0.005	0.023	Report: CEMR-3392- REG
Trial: DE-FR-06-4421, Stetten, Germany,2006 (Dekan)	124+ 124 28days interval	300 300	2	51	Grain	< 0.010	< 0.005	< 0.015	Report: T001787-06- REG
	124+ 124+ 124 15days+ 29days interval	300 300 300	3	29 35	Grain Grain	0.010 < 0.010	< 0.005 < 0.005	0.015 < 0.015	Report: T001787-06- REG
	124+ 124+ 124 15days+ 29days interval	300 300 300	3	29 35	Grain Grain	0.011 < 0.010	< 0.005 < 0.005	0.016 < 0.015	Report: T001787-06- REG
Trial: AF/11521/SY/1, Ayora, Spain, 2007 (Oтира)	123+ 128+ 124 16days+ 28days interval	197 206 200	3	30 42	Grain Grain	0.086 0.050	0.005 < 0.005	0.091 0.055	Report : CEMR-3364- REG Version 2
Trial: AF/11521/SY/2, Castagnolino, Italy, 2007 (Bologna)	129+ 124+ 126 12days+ 36days interval	207 199 202	3	42	Grain	0.116	0.038	0.152	Report : CEMR-3364- REG Version 2
Trial: AF/11521/SY/3, Budrio, Italy,2007 (Duilio)	127+ 125+ 127 12days+ 33days interval	204 200 204	3	41 53	Grain Grain	0.021 0.041	0.007 0.021	0.028 0.061	Report : CEMR-3364- REG Version 2
Trial: AF/11521/SY/4, Barry d'Islemade, France,2007 (Quality)	120+ 122+ 120 27days+ 22days interval	193 196 193	3	41	Grain	< 0.010	< 0.005	< 0.015	Report : CEMR-336- REG Version 2

Wheat	Application			DALA	Commodity	Residues (mg/kg)			Reference & Comments
Trial Location Country, year (Variety)	Rate (g ai/ha)	Water (L/ha) (GPA)	No.	(days)		Isopyrazam a	CSCD 459488	Total b	
Trial: AF/11521/SY/5, Verdun sur Garonne, France,2007 (Pr22r58)	125+ 126+ 123 27days+ 18days interval	200 201 197	3	45 60	Immature grain Grain	0.041 < 0.010	0.056 < 0.005	0.095 < 0.015	Report :CEMR- 336-REG Version 2
Trial: AF/11520/SY/1, Dollern Lower Saxony, Germany,2007 (Herman)	122+ 125+ 127 41days+ 21days interval	196 201 204	3	43	Grain	< 0.010	< 0.005	< 0.015	Report: CEMR-3366 - REG Version 2
Trial: AF/11520/SY/2, Burweg, Lower Saxony, Germany,2007 (Atlantis)	125+ 126+ 125 37days+ 25days interval	202 203 201	3	43	Grain	< 0.010	< 0.005	< 0.015	Report: CEMR-3366 - REG Version 2
Trial: AF/11520/SY/3, Measham, UK, 2007 (Malacca)	125+ 125+ 123 17days+ 32days interval	201 201 198	3	42	Grain	0.014	< 0.005	0.019	Report: CEMR-3366 - REG Version 2
Trial: AF/11520/SY/4, Rouvres Saint Jean, France, 2007 (Courtot)	127+ 127+ 129 25days+ 22days interval	204 204 208	3	30 44 57	Immature Grain Immature Grain Grain	< 0.010 < 0.010 < 0.010	< 0.005 < 0.005 < 0.005	< 0.015 < 0.015 < 0.015	Report: CEMR-3366 - REG Version 2
Trial: AF/11520/SY/5, Martailly les Brancion, France, 2007 (Soissons)	123+ 124+ 125 25days+ 22days interval	198 200 201	3	30 44	Immature Grain Grain	< 0.010 < 0.010	< 0.005 < 0.005	< 0.015 < 0.015	Report: CEMR-3366 - REG Version 2

^a Sum of syn- and anti-isomer (i.e. residue definition for enforcement)

^b Sum of isopyrazam and CSCD459488 expressed as isopyrazam (i.e. residue definition for risk assessment)

Oilseeds

Rape seed (canola)

A total of twenty supervised trials were conducted on oilseed rape in Europe (France, Germany, Spain, Italy and the UK) in 2009, 2010, 2014 and 2016. Eight trials were conducted at 1×125 g ai/ha or at an exaggerated rate of 2×125 g ai/ha at BBCH 61–69. Samples of oilseed rape whole plants were collected on the same day of application immediately after the spray deposit had dried and approximately 7, 14, 28 and 42 days after the final application for 2010, 2011 and 2014 trials, and approximately 0, 10, 20, 30 and 40 days after the final application for 2016 trials. Samples of oilseed rape seeds were collected at normal commercial harvest (34–70 days after the final application). Samples were immediately frozen and maintained in frozen storage for periods of up to 11 months prior to extraction. Residues of isopyrazam (both isomers) in oilseed rape (whole plants and seeds) were determined using analytical method GRM006.01B with an LOQ of 0.005 mg/kg for each isomer (0.01 mg/kg for the sum of both isomers). Residues of CSCD459488 in oilseed rape (whole plants and seeds) were determined using analytical method GRM006.03A with an LOQ of 0.005 mg/kg. The results of the trials are summarised in Table 14, where residues relevant to risk assessment and the setting of an MRL for oilseed rape are underlined

Table 14 Residues in Oilseed rape (outdoor) from supervised trials in Europe involving foliar applications of Isopyrazam (125 g/L SC formulation)

Oilseed rape Trial Location Country, year (Variety)	Application			DALA (days)	Commodity	Residues (mg/kg)			Reference & Comments
	Rate (g ai/ha)	Water (L/ha) (GPA)	No.			Isopyrazam ^a	CSCD 459488	Total ^b	
Trial: S09-01529-01 Drusenheim, Alsace, France, 2009 (Ability)	123 + 126 18 day interval	296 303	2	0	Whole plant	3.383	0.016	3.398	Report: S09- 01529-REG Study: S09- 01529
				7	Whole plant	1.444	0.013	1.456	
				14	Whole plant	1.191	0.010	1.201	
				27	Whole plant	0.612	0.011	0.623	
				42	Whole plant	0.331	< 0.005	0.336	
				48	Seed	<u>0.035</u>	< 0.005	<u>0.040</u>	
Trial: S09-01529-02 Knottingley Yorkshire UK WF11 0DQ, UK, 2009 (Morley)	128 + 130 34 day interval	206 208	2	0	Whole plant	0.881	< 0.005	0.886	Report: S09- 01529-REG Study: S09- 01529
				7	Whole plant	0.757	< 0.005	0.762	
				14	Whole plant	0.428	0.005	0.433	
				28	Whole plant	0.534	0.012	0.545	
				42	Seed	<u>0.033</u>	< 0.005	<u>0.038</u>	
				Trial: S09-01529-03 Broadstone Lane Ticknall, Derbyshire DE73 8LD, UK, 2009 (Heros)	128 + 121 36 day interval	205 193	2	0	
7	Whole plant	0.230	< 0.005					0.235	
14	Whole plant	0.197	< 0.005					0.202	
28	Whole plant	0.268	0.009					0.277	
42	Seed	<u>0.055</u>	< 0.005					<u>0.060</u>	
Trial: S09-01529-04 Helmster Weg 2, Dollern, Lower Saxony, Germany,2009 (Ability)	123 + 135 24 day interval	395 433	2					0	Whole plant
				7	Whole plant	1.162	0.007	1.169	
				14	Whole plant	1.111	0.013	1.123	
				29	Whole plant	0.491	0.009	0.500	
				42	Whole plant	0.271	0.009	0.280	
				58	Seed	<u>0.068</u>	< 0.005	<u>0.073</u>	
Trial: S10-00962-01 Normanton On Soar, Leicestershire, UK, 2010 (Excalibur)	126 + 126 54 day interval	304 303	2	0	Whole plant	1.240	< 0.005	1.245	Report: S10- 00962-REG Study: S10- 00962
				7	Whole plant	0.880	< 0.005	0.885	
				14	Whole plant	1.037	0.010	1.047	
				28	Whole plant	0.919	0.016	0.934	
				56	Seed	<u>0.086</u>	< 0.005	<u>0.091</u>	
				Trial: S10-00962-02 Upton Warwickshire, UK, 2010 (dk cabernet)	126 + 124 55 day interval	304 298	2	0	
7	Whole plant	0.911	0.005					0.916	
14	Whole plant	1.211	0.010					1.221	
28	Whole plant	0.686	0.008					0.694	
42	Whole plant	0.487	0.015					0.501	
50	Seed	<u>0.038</u>	< 0.005					<u>0.043</u>	
Trial: S10-00962-03 Blumberg, Barnim, Brandenburg, Germany,2010 (Titan Raw)	132 + 131 36 day interval	213 211	2	0	Whole plant	1.608	< 0.005	1.613	Report: S10- 00962-REG Study: S10- 00962
				7	Whole plant	0.797	0.010	0.807	
				24	Whole plant	0.819	0.013	0.831	
				28	Whole plant	0.446	0.008	0.454	
				42	Whole plant	0.233	0.009	0.242	
				62	Seed	<u>0.068</u>	< 0.005	<u>0.073</u>	
Trial: S10-00962-04 Leouville, Loiret, France, 2010 (Safran)	126 + 129 32 day interval	203 208	2	0	Whole plant	2.408	0.011	2.419	Report: S10- 00962-REG Study: S10- 00962
				7	Whole plant	1.553	0.017	1.569	
				14	Whole plant	1.226	0.016	1.241	
				28	Whole plant	0.330	0.008	0.338	
				42	Whole plant	0.281	0.011	0.292	
				51	Seed	<u>0.090</u>	< 0.005	<u>0.095</u>	
Trial: S13-01042-01 Tarn et Garonne, Midi Pyrennees, France, 2014 (Chrome)	136 + 134 30 day interval	219 215	2	55	Seed	< 0.010	0.014	<u>0.023</u>	Report: S13- 01042 Study: S13- 01042

Oilseed rape	Application			DALA	Commodity	Residues (mg/kg)			Reference & Comments
Trial Location Country, year (Variety)	Rate (g ai/ha)	Water (L/ha) (GPA)	No.	(days)		Isopyrazam ^a	CSCD 459488	Total ^b	
Trial: S13-01042-02 Tarn et Garonne, Midi Pyrennees, France, 2014 (Batzz)	137 + 132 18 day interval	220 212	2	64	Seed	<u>0.012</u>	0.027	<u>0.038</u>	Report: S13-01042 Study: S13-01042
Trial: S13-01042-03 Aragon, Zaragoza, Spain, 2014 (Fricola)	125 + 118 19 day interval	402 377	2	52	Seed	<u>< 0.010</u>	0.008	<u>0.018</u>	Report: S13-01042 Study: S13-01042
Trial: S13-01042-04 Bologna, Italy, 2014 (Primus)	131 + 137 17 day interval	419 439	2	43	Seed	<u>0.052</u>	0.251	<u>0.292</u>	Report: S13-01042 Study: S13-01042
Trial: S15-01942-01 North Yorkshire, Yorkshire, UK, 2015 (Compass)	131	313	1	0 11 20 29 44 69	Whole plant Whole plant Whole plant Whole plant Whole plant Seed	1.456 0.266 0.191 0.086 0.064 <u>0.010</u>	< 0.005 < 0.005 < 0.005 < 0.005 < 0.005 < 0.005	1.461 0.271 0.196 0.091 0.069 <u>0.015</u>	Report: S15-01942 Study: S15-01942
Trial: S15-01942-02 Leicestershire, Leicestershire, UK, 2015 (DK Cabernet)	132	211	1	0 11 20 29 40 61	Whole plant Whole plant Whole plant Whole plant Whole plant Seed	0.856 0.428 0.341 0.358 0.271 <u>0.013</u>	< 0.005 0.006 0.008 0.017 0.020 < 0.005	0.861 0.434 0.349 0.374 0.290 <u>0.018</u>	Report: S15-01942 Study: S15-01942
Trial: S15-01942-03 Leicestershire, Leicestershire, UK, 2015 (DK Camelot)	131	209	1	0 10 21 30 39 70	Whole plant Whole plant Whole plant Whole plant Whole plant Seed	3.168 1.247 0.419 0.302 0.159 <u>0.016</u>	< 0.005 0.018 0.014 0.015 0.010 < 0.005	3.173 1.264 0.432 0.316 0.169 <u>0.021</u>	Report: S15-01942 Study: S15-01942
Trial: S15-01942-04 Barnim, Brandenburg, Germany, 2015 (Flyer)	132	265	1	0 11 21 31 40 66	Whole plant Whole plant Whole plant Whole plant Whole plant Seed	1.377 0.330 0.272 0.112 0.090 <u>< 0.010</u>	< 0.005 < 0.005 < 0.005 < 0.005 < 0.005 < 0.005	1.382 0.335 0.277 0.117 0.095 <u>< 0.015</u>	Report: S15-01942 Study: S15-01942
Trial: S15-01943-01 Bologna, Emilia Romagna, Italy, 2015 (Excalibur)	135	434	1	0 11 20 29 34 34	Whole plant Whole plant Whole plant Whole plant Seed Remaining plant	0.900 0.542 0.422 0.359 <u>0.068</u> 0.918	< 0.005 0.009 0.017 0.017 0.007 0.054	0.905 0.551 0.438 0.375 <u>0.075</u> 0.970	Report: S15-01943 Study: S15-01943
Trial: S15-01943-02 Herault, Languedoc- Roussillon, France, 2015 (Attletick)	118	237	1	0 11 21 32 41 50	Whole plant Whole plant Whole plant Whole plant Whole plant Seed	0.970 0.488 0.394 0.505 0.413 <u>0.058</u>	< 0.005 0.007 0.009 0.018 0.026 < 0.005	0.975 0.495 0.403 0.522 0.438 <u>0.063</u>	Report: S15-01943 Study: S15-01943
Trial: S15-01943-03 Tarn Et Garonne, Midi Pyrenees, France, 2015 (Expertise)	124	298	1	0 11 20 29 34 34	Whole plant Whole plant Whole plant Whole plant Whole plant Seed	1.163 0.423 0.326 0.297 0.332 <u>0.094</u>	< 0.005 0.011 0.011 0.013 0.023 < 0.005	1.168 0.434 0.337 0.309 0.354 <u>0.099</u>	Report: S15-01943 Study: S15-01943

Oilseed rape	Application			DALA	Commodity	Residues (mg/kg)			Reference & Comments
Trial Location Country, year (Variety)	Rate (g ai/ha)	Water (L/ha) (GPA)	No.	(days)		Isopyrazam ^a	CSCD 459488	Total ^b	
Trial: S15-01943-04 Huesca, Aragon, Spain, 2015 (Expertise)	125	301	1	0 11 21 32 41 50	Whole plant Whole plant Whole plant Whole plant Seed Remaining plant	0.810 0.282 0.306 0.304 <u>0.013</u> 0.537	0.005 < 0.005 < 0.005 < 0.005 < 0.005 0.051	0.815 0.287 0.311 0.309 <u>0.018</u> 0.586	Report: S15- 01943 Study: S15- 01943

^a Sum of syn- and anti-isomer (i.e. residue definition for enforcement)

^b Sum of isopyrazam and CSCD459488 expressed as isopyrazam (i.e. residue definition for risk assessment)

Peanut

A total of four supervised trials were conducted on peanut in Latin America (Nicaragua) in 2010. Trials were conducted at an exaggerated/overdosed rate (3×125 g ai/ha per crop cycle) compared to the registered critical GAP/label rate (2×125 g ai/ha per crop cycle). Samples of peanut (nutmeat) were collected on the same day of application immediately after the spray deposit had dried and approximately 3, 7, 10 and 14 days after the final application. Samples were immediately frozen and maintained in frozen storage for periods of up to 3 months prior to extraction. Residues of isopyrazam (both isomers) in peanut were determined using analytical method GRM006.01B with an LOQ of 0.005 mg/kg for each isomer (0.01 mg/kg for the sum of both isomers). Residues of CSCD459488 in peanut were determined using analytical method GRM006.03A with an LOQ of 0.005 mg/kg. The results of the trials are summarised in Table 15, where residues relevant to risk assessment and the setting of an MRL for peanut are underlined

Table 15 Residues in **Peanut** (outdoor trails) from supervised trials in Nicaragua involving foliar applications of Isopyrazam (125 g/L EC formulation)

Peanut	Application			DALA	Commodity	Residues (mg/kg)			Reference & Comments
Trial Location Country, year (Variety)	Rate (g ai/ha)	Water (L/ha) (GPA)	No.	(days)		Isopyrazam ^a	CSCD 459488	Total ^b	
Trial: TK0040606-02 Cofradia, Nicaragua, 2010 (Georgia Green)	132.0 + 127.9 + 127.6 14 day interval	469 455 454	3	7	Nutmeat	<u>< 0.010</u>	< 0.005	<u>< 0.015</u>	Report: TK0040606 Study: TK0040606
Trial: TK0040606-03 Cofradia, Nicaragua, 2010 (Georgia Green)	130.6 + 135.5 + 132.4 14 day interval	464 482 471	3	0 3 7 10 14	Nutmeat Nutmeat Nutmeat Nutmeat	< 0.010 < 0.010 <u>< 0.010</u> < 0.010 < 0.010	< 0.005 < 0.005 < 0.005 < 0.005 < 0.005	< 0.015 < 0.015 <u>< 0.015</u> < 0.015 < 0.015	Report: TK0040606 Study: TK0040606
Trial: TK0040606-04 Cofradia, Nicaragua, 2010 (Georgia Green)	133.5 + 120.7 + 132.7 14 day interval	475 429 472	3	0 3 7 10 14	Nutmeat Nutmeat Nutmeat Nutmeat	< 0.010 < 0.010 <u>< 0.010</u> < 0.010 < 0.010	< 0.005 < 0.005 < 0.005 < 0.005 < 0.005	< 0.015 < 0.015 <u>< 0.015</u> < 0.015 < 0.015	Report: TK0040606 Study: TK0040606
Trial: TK0040606-05 Cofradia, Nicaragua, 2010 (Georgia Green)	127.2 + 128.0 + 130.6 14 day interval	452 455 464	3	7	Nutmeat	<u>< 0.010</u>	< 0.005	<u>< 0.015</u>	Report: TK0040606 Study: TK0040606

^a Sum of syn- and anti-isomer (i.e. residue definition for enforcement)

^b Sum of isopyrazam and CSCD459488 expressed as isopyrazam (i.e. residue definition for risk assessment)

Primary animal feed commodities*Forage, Straw and fodder (dry) of cereals***Table 16 Residues in barley plant and straw (outdoor trials) from supervised trials in Northern Europe involving foliar applications of Isopyrazam (125g/L EC formulation)**

Barley Trial Location Country, year (Variety)	Application			DALA (days)	Commodity	Residues (mg/kg)			Reference & Comments
	Rate (g ai/ha)	Water (L/ha) (GPA)	No.			Isopyrazam ^a	CSCD 459488	Total ^b	
Trial: CH-FR-06-0023 CH-1896 Vouvry, Switzerland, 2006 (Bologna)	127 + 126 37days interval	304 302	2	-0	Whole plant	0.038	< 0.005	0.043	Report: CEMR-3393-REG Study: T000674-06
				0	Whole plant	2.016	0.007	2.023	
				7	Whole plant	0.807	0.067	0.871	
				13	Whole plant	0.253	0.058	0.309	
				21	Whole plant	0.127	0.053	0.178	
				34	Whole plant	0.236	0.089	0.321	
	54	Straw	0.957	0.111	1.063				
	127 + 126 43days interval	304 301	2	-0	Whole plant	0.051	< 0.005	0.056	Report: CEMR-3393-REG Study: T000674-06
				0	Whole plant	<u>2.143</u>	0.007	2.150	
10				Whole plant	0.316	0.040	0.354		
20				Whole plant	0.176	0.032	0.207		
30				Whole plant	0.353	0.049	0.400		
42	Whole plant	0.400	0.053	0.451					
48	Straw	<u>1.056</u>	0.073	1.126					
126 + 126 43days interval	302 303	2	-0	Whole plant	0.032	< 0.005	0.037	Report: CEMR-3393-REG Study: T000674-06	
			0	Whole plant	1.705	< 0.005	1.710		
			10	Whole plant	0.401	0.032	0.432		
			20	Whole plant	0.236	0.030	0.265		
			30	Whole plant	0.247	0.040	0.285		
			42	Whole plant	0.673	0.052	0.723		
48	Straw	0.526	0.066	0.589					
Trial: CH-FR-06-0024 CH-1880 Bex, Switzerland, 2006 (Merlot)	126 + 127 37days interval	302 304	2	-0	Whole plant	0.037	< 0.005	0.042	Report: CEMR-3393-REG Study: T000674-06
				0	Whole plant	<u>2.280</u>	0.006	2.286	
				7	Whole plant	1.008	0.041	1.047	
				13	Whole plant	0.518	0.043	0.559	
				21	Whole plant	0.364	0.064	0.425	
				34	Whole plant	0.252	0.052	0.302	
	54	Straw	<u>0.349</u>	0.140	0.483				
	126 + 125 43days interval	302 300	2	-0	Whole plant	0.027	< 0.005	0.032	Report: CEMR-3393-REG Study: T000674-06
				0	Whole plant	1.713	0.005	1.718	
				10	Whole plant	0.239	0.034	0.272	
				20	Whole plant	0.143	0.039	0.180	
				30	Whole plant	0.253	0.058	0.309	
42	Whole plant	0.176	0.040	0.214					
48	Straw	0.176	0.078	0.251					
125 + 128 43days interval	299 307	2	-0	Whole plant	0.020	< 0.005	0.025	Report: CEMR-3393-REG Study: T000674-06	
			0	Whole plant	2.264	< 0.005	2.269		
			10	Whole plant	0.361	0.030	0.390		
			20	Whole plant	0.161	0.026	0.186		
			30	Whole plant	0.233	0.039	0.270		
			42	Whole plant	0.317	0.043	0.358		
48	Straw	0.331	0.081	0.409					
Trial: FR-FR-06-0026 51490 BEINE NAUROY, France, 2006	127 + 129 14days interval	300 300	2	60	Straw	0.391	0.540	0.908	Report: CEMR- 3393-REG Study: T000674-06

Barley Trial Location Country, year (Variety)	Application			DALA (days)	Commodity	Residues (mg/kg)			Reference & Comments
	Rate (g ai/ha)	Water (L/ha) (GPA)	No.			Isopyrazam ^a	CSCD 459488	Total ^b	
(Esterel)	124 + 126 20days interval	300 300	2	43 43 54	Ear Immature Straw Straw	0.030 0.239 <u>0.838</u>	0.046 0.238 0.470	0.074 0.467 1.288	Report: CEMR-3393-REG Study: T000674-06
	124 + 131 43days interval	300 300	2	43 43 54	Ear Immature Straw Straw	0.053 0.578 0.723	0.068 0.259 0.419	0.118 0.826 1.124	Report: CEMR-3393-REG Study: T000674-06
Trial: IT-FR-06-0027 Rubano, Italy, 2006(Boreale)	130 + 125 15days interval	311 299	2	-0 0 7 14 21 35 53	Whole plant Whole plant Whole plant Whole plant Whole plant Straw	1.292 1.574 0.555 0.241 0.120 0.092 0.120	0.049 0.044 0.058 0.051 0.050 0.034 0.190	1.339 1.616 0.611 0.290 0.168 0.125 0.302	Report: CEMR-3394-REG Study: T000675-06
	133 + 132 23days interval	319 318	2	-0 0 10 20 31 45	Whole plant Whole plant Whole plant Remaining plant Straw	0.166 <u>2.944</u> 0.311 0.154 0.016 <u>0.145</u>	0.026 0.037 0.069 0.073 0.016 0.188	0.191 2.979 0.377 0.224 0.031 0.325	Report: CEMR-3394-REG Study: T000675-06
Trial: ES-FR-06-0028 La Overuela, Spain, 2006(Verticale)	124 + 131 14 days interval	198 317	2	-0 0 7 14 21 35 57	Whole plant Whole plant Whole plant Whole plant Whole plant Straw	0.819 3.339 1.237 1.186 0.939 0.894 2.512	0.046 0.044 0.077 0.127 0.121 0.105 1.159	0.863 3.381 1.311 1.308 1.055 0.995 3.622	Report: CEMR-3394-REG Study: T000675-06
	127 + 133 21days interval	203 320	2	-0 0 10 20 30 42 50	Whole plant Whole plant Whole plant Remaining plant Straw Straw	1.069 <u>3.494</u> 2.441 1.653 3.113 0.145 <u>3.495</u>	0.063 0.069 0.142 0.128 0.250 0.052 0.538	1.129 3.560 2.577 1.776 3.352 0.195 4.010	Report: CEMR-3394-REG Study: T000675-06
Trial: FR-FR-06-0029 84370 BEDARRIDES "Les Taillades", France, 2006 (Baraka)	131 + 129 21days interval	300 300	2	52	Straw	1.835	0.520	2.333	Report: CEMR-3393-REG Study: T000674-06
	130 + 131 32days interval	300 300	2	41	Straw	<u>5.862</u>	0.874	6.699	Report: CEMR-3393-REG Study: T000674-06
Trial: FR-FR-06-0030 82170 GRISOLLES "Les crespys, France, 2006 (Nevada)	126 + 127 25days interval	200 200	2	56	Straw	<u>1.423</u>	0.551	1.951	Report: CEMR-3393-REG Study: T000674-06
	127 + 127 31days interval	200 200	2	42 42 50	Immature Straw Straw	1.356 1.109	0.409 0.644	1.748 1.726	Report: CEMR-3393-REG Study: T000674-06
Trial: DE-FR-06- 4422 Stephansposching, Germany, 2006	124+ 124 21days interval	300 300	2	52	Straw	0.117	0.146	0.257	Report: T001788-06-REG Study: T001788-06

Barley Trial Location Country, year (Variety)	Application			DALA (days)	Commodity	Residues (mg/kg)			Reference & Comments
	Rate (g ai/ha)	Water (L/ha) (GPA)	No.			Isopyrazam ^a	CSCD 459488	Total ^b	
(Carat)	124 + 124 28days interval	300 300	2	45	Straw	0.115	0.194	0.301	Report: T001788-06-REG Study: T001788-06
	124 + 124 28days interval	300 300	2	45	Straw	<u>0.129</u>	0.126	0.250	Report: T001788-06-REG Study: T001788-06
Trial: AF/11519/SY/1 Alpera, Spain, 2007 (Chamorro)	130 + 125 35days interval	208 201	2	-0 0 10 20 30 42	Whole plant Whole plant Whole plant Whole plant Straw Straw	0.256 4.730 4.188 <u>5.494</u> 0.408 <u>6.900</u>	0.046 0.031 0.086 0.110 0.023 0.256	0.300 4.760 4.270 5.599 0.430 7.145	Report: CEMR-3365 - REG Version 2 Study :CEMS-3365
Trial: AF/11519/SY/2 Pilastrí,, Spain, 2007 (Sonora)	126 + 122 39days interval	202 196	2	-0 0 10 20 30 42	Whole plant Whole plant Whole plant Whole plant Whole plant Straw	0.019 <u>5.027</u> 1.637 3.296 1.437 <u>2.492</u>	< 0.005 < 0.005 0.078 0.274 0.148 0.483	0.024 5.032 1.712 3.558 1.579 2.954	Report: CEMR-3365 - REG Version 2 Study: CEMS-3365
Trial: AF/11519/SY/3 St Etienne sur Reyssouze, France, 2007(Scarlett)	124 + 124 33days interval	200 200	2	-0 0 10 20 30 43	Whole plant Whole plant Whole plant Whole plant Remaining plant Straw	0.013 <u>3.521</u> 0.563 0.509 0.489 <u>0.262</u>	0.009 0.016 0.065 0.083 0.065 0.047	0.022 3.536 0.625 0.588 0.551 0.307	Report: CEMR-3365 - REG Version 2 Study: CEMS-3365
Trial: AF/11519/SY/4 Cordes France, 2007(Prestige)	122 + 124 27days interval	195 200	2	-0 0 10 20 30 45	Whole plant Whole plant Whole plant Whole plant Whole plant Straw	0.160 <u>3.937</u> 0.409 0.200 0.173 <u>0.446</u>	0.014 0.013 0.051 0.043 0.045 0.145	0.173 3.949 0.458 0.241 0.216 0.585	Report: CEMR-3365 - REG Version 2 Study: CEMS-3365
Trial: AF/11519/SY/5 Vazerac, France, 2007 (Platine)	118 + 124 35days interval	189 199	2	-0 0 10 20 30 45 45 63	Whole plant Whole plant Whole plant Whole plant Whole plant Ear Remaining plant Straw	0.073 <u>3.126</u> 0.427 0.183 0.174 < 0.010 0.076 <u>0.125</u>	0.014 0.009 0.033 0.038 0.040 0.017 0.035 0.066	0.086 3.135 0.459 0.219 0.212 0.026 0.110 0.188	Report: CEMR-3365 - REG Version 2 Study: CEMS-3365
Trial: AF/11518/SY/1 Perouse, Germany, 2007(Braemar)	193 200		2	-0 0 10 20 30 45	Whole plant Whole plant Whole plant Whole plant Whole plant Straw	0.096 3.259 0.444 0.379 0.334 0.466	0.051 0.056 0.072 0.089 0.079 0.133	0.145 3.313 0.513 0.464 0.410 0.593	Report: CEMR-3367 -REG Version 2 Study: CEMS-3367
Trial: AF/11518/SY/2 Heidelberg, Germany, 2007(Braemar)	200 200		2	-0 0 10 20 30 38	Whole plant Whole plant Whole plant Whole plant Remaining Plant Straw	0.391 3.627 0.502 0.124 0.117 0.206	0.097 0.098 0.126 0.092 0.120 0.110	0.484 3.721 0.623 0.212 0.232 0.311	Report: CEMR-3367 - REG Version 2 Study: CEMS-3367

Barley	Application			DALA	Commodity	Residues (mg/kg)			Reference & Comments
Trial Location Country, year (Variety)	Rate (g ai/ha)	Water (L/ha) (GPA)	No.	(days)		Isopyrazam ^a	CSCD 459488	Total ^b	
Trial: AF/11518/SY/3 Arnold, UK, 2007 (Westminster)	199 198		2	0	Whole plant	0.119	0.052	0.169	Report: CEMR-3367 – REG Version 2 Study: CEMS-3367
				0	Whole plant	2.925	0.057	2.980	
				10	Whole plant	0.194	0.055	0.247	
				20	Whole plant	0.155	0.057	0.210	
				30	Whole plant	0.090	0.032	0.121	
				42	Straw	0.076	0.021	0.096	
Trial: AF/11518/SY/4 Loiret, France, 2007 (Colibri)	199 199		2	0	Whole plant	2.303	0.031	2.333	Report: CEMR-3367 – REG Version 2 Study: CEMS-3367
				10	Whole plant	1.107	0.049	1.154	
				20	Whole plant	0.409	0.043	0.450	
				30	Whole plant	0.326	0.033	0.358	
				44	Remaining Plant	0.662	0.073	0.732	
61	Straw	0.679	0.033	0.711					
Trial: AF/11518/SY/5 Saone et Loire, France, 2007 (Platine)	199 193		2	-0	Whole plant	0.137	0.024	0.160	Report: CEMR-3367 – REG Version 2 Study: CEMS-3367
				0	Whole plant	2.448	0.029	2.476	
				10	Whole plant	1.321	0.073	1.391	
				20	Whole plant	0.359	0.061	0.417	
				30	Remaining Plant	0.814	0.120	0.929	
42	Straw	0.495	0.096	0.587					

^a Sum of syn- and anti-isomer (i.e. residue definition for enforcement)

^b Sum of isopyrazam and CSCD459488 expressed as isopyrazam (i.e. residue definition for risk assessment)

Table 17 Residues in wheat plant and straw (outdoor trials) from supervised trials in Spain, Italy and Southern France involving foliar applications of Isopyrazam (125g/L EC formulation).

Wheat	Application			DALA	Commodity	Residues (mg/kg)			Reference & Comments
Trial Location Country, year (Variety)	Rate (g ai/ha)	Water (L/ha) (GPA)	No.	(days)		Isopyrazam ^a	CSCD 459488	Total ^b	
Trial: FR-FR-06-0032, 80250 MALPART "La Pointe", France, 2006 (Limonera)	127 + 121 43days interval	300 300	2	-0	Whole plant	0.074	0.023	0.096	Report: CEMR-3391- REG Study: T000672-06 (EC)
				0	Whole plant	<u>2.057</u>	0.027	2.083	
				7	Whole plant	1.763	0.103	1.862	
				14	Whole plant	1.081	0.154	1.228	
				21	Whole plant	0.880	0.182	1.054	
				35	Whole plant	0.385	0.165	0.543	
				61	Straw	<u>0.965</u>	1.521	2.421	
	129 + 125 + 127 33days+20days interval	300 300 300	3	-0	Whole plant	0.561	0.105	0.662	Report: CEMR-3391- REG Study: T000672-06
				0	Whole plant	2.224	0.102	2.322	
				11	Whole plant	1.066	0.236	1.292	
				21	Whole plant	0.509	0.194	0.695	
				31	Immature Grain	0.374	0.254	0.617	
				31	Remaining Plant	1.137	0.459	1.576	
				51	Straw	0.921	1.647	2.498	

Wheat	Application			DALA	Commodity	Residues (mg/kg)			Reference & Comments								
Trial Location Country, year (Variety)	Rate (g ai/ha)	Water (L/ha) (GPA)	No.	(days)		Isopyrazam ^a	CSCD 459488	Total ^b									
	121 + 130 + 126 20days+20days interval	300 300 300	3	-0	Whole plant	0.700	0.096	0.792	Report: CEMR-3391- REG Study: T000672-06								
				0	Whole plant	2.947	0.100	3.043									
				11	Whole plant	1.291	0.211	1.493									
				21	Whole plant	0.858	0.180	1.030									
				31	Immature Grain	0.117	0.070	0.184									
				31	Remaining Plant	1.202	0.385	1.571									
				51	Straw	0.977	1.360	2.279									
Trial: FR-FR-06-0033, 80250 GRIVESNES "Le Moulin", France,2006 (Limes)	124 + 122 44days interval	300 300	2	62	Straw	<u>0.750</u>	1.185	1.884	Report: CEMR-3391- REG Study: T000672-06								
									125 + 124 + 128 33days+ 20days interval	300 300 300	3	51	Straw	0.831	1.307	2.082	Report: CEMR-3391- REG Study: T000672-06
									122+ 125+ 125 20days+ 20days interval	300 300 300							3
Trial: FR-FR-06-0034, 51490 BEINE NAUROY "Menu Dime 1", France,2006 (Charger)	131+ 124 23days interval	300 300	2	61	Straw	<u>0.0510</u>	0.262	0.302	Report: CEMR-3391- REG Study: T000672-06								
									120+ 120+ 125 17days+ 26days interval	300 300 300	3	41	Straw	0.260	0.586	0.821	Report: CEMR-3391- REG Study: T000672-06
									119+ 123+ 129 20days+ 20days interval	300 300 300							3
Trial: ES-FR-06-0035, La Overuela, Spain,2006 (Fiufa)	134+ 133 24days interval	215 320	2	-0	Whole plant	0.452	0.053	0.503	Report: CEMR-3392- REG Study: T000673-06								
				0	Whole plant	1.920	0.044	1.962									
				7	Whole plant	<u>2.326</u>	0.127	2.448									
				14	Whole plant	1.676	0.121	1.792									
				21	Whole plant	1.450	0.118	1.563									
	35	Whole plant	2.174	0.245	2.409												
	52	Straw	<u>5.508</u>	0.513	5.999												
	120+ 133+ 133 14days+ 21days interval	192 320 320	3	-0	Whole plant	0.903	0.122	1.020	Report: CEMR-3392- REG Study: T000673-06								
				0	Whole plant	4.963	0.170	5.126									
				10	Whole plant	2.230	0.129	2.354									
23				Whole plant	2.145	0.318	2.449										
30				Remaining plant	4.266	0.641	4.880										
41	plant																
41	Straw	8.366	0.889	9.217													

Wheat	Application			DALA	Commodity	Residues (mg/kg)			Reference & Comments
Trial Location Country, year (Variety)	Rate (g ai/ha)	Water (L/ha) (GPA)	No.	(days)		Isoprazam ^a	CSCD 459488	Total ^b	
Trial: ES-FR-06-0036, Wamba, Spain,2006 (Soissons)	133+ 135 26days interval	213 323	2	-0 0 7 14 21 35 51	Whole plant Whole plant Whole plant Whole plant Whole plant Whole plant Straw	0.117 <u>2.100</u> 1.623 1.759 1.815 1.520 <u>3.613</u>	0.030 0.041 0.081 0.129 0.145 0.206 0.378	0.146 2.139 1.701 1.883 1.954 1.717 3.975	Report: CEMR-3392- REG Study: T000673-06
	135+ 128+ 124 18days+ 24days interval	217 307 297	3	-0 0 11 20 29 35	Whole plant Whole plant Whole plant Remaining Plant Straw	< 0.010 4.080 2.797 3.100 3.683 7.077	0.115 0.118 0.224 0.230 0.400 0.500	0.120 4.193 3.011 3.320 4.066 7.556	Report: CEMR-3392- REG Study: T000673-06
Trial: FR-FR-06-0037, 82170 GRISOLLES "Mistral" S29, France,2006 (Aztec)	129+ 127 25days interval	200 200	2	67	Straw	<u>0.620</u>	0.778	1.365	Report: CEMR-3392- REG Study: T000673-06
	131+ 117+ 128 21days+ 28days interval	200 200 200	3	43	Straw	5.138	2.056	7.106	Report: CEMR-3392- REG Study: T00(EC)0673- 06
Trial: FR-FR-06-0038, 34590 MARSILLARGUES "Sole 1", France,2006 (Aztec)	123+ 127 37days interval	250 250	2	55	Straw	<u>4.160</u>	1.527	5.622	Report: CEMR-3392- REG Study: T000673-06
	123+ 126+ 124 30days+ 16days interval	250 250 250	3	46	Straw	3.616	1.449	5.003	Report: CEMR-3392- REG Study: T000673-06
Trial: DE-FR-06- 4421, Stetten, Germany,2006 (Dekan)	124+ 124 28days interval	300 300	2	-0 0 6 13 22 34 51	Whole plant Whole plant Whole plant Whole plant Whole plant Whole plant Straw	0.091 <u>1.880</u> 1.202 0.691 0.401 0.164 <u>0.293</u>	0.039 0.041 0.071 0.122 0.134 0.100 0.703	0.128 1.919 1.270 0.808 0.529 0.260 0.966	Report: T001787-06- REG Study: T001787-06
	124+ 124+ 124 15days+ 29days interval	300 300 300	3	-0 0 10 18 29 35	Whole plant Whole plant Whole plant Remaining Plant Straw	0.081 2.245 0.571 0.433 0.888 1.514	0.061 0.064 0.133 0.149 0.406 0.877	0.139 2.306 0.698 0.576 1.277 2.354	Report: T001787-06- REG Study: T001787-06
	124+ 124+ 124 15days+ 29days interval	300 300 300	3	-0 0 10 18 29 35	Whole plant Whole plant Whole plant Remaining Plant Straw	0.090 2.095 0.889 0.679 0.786 1.062	0.420 0.055 0.128 0.152 0.473 0.709	0.492 2.148 1.012 0.825 1.239 1.741	Report: T001787-06- REG Study: T001787-06

Wheat	Application			DALA	Commodity	Residues (mg/kg)			Reference & Comments
Trial Location Country, year (Variety)	Rate (g ai/ha)	Water (L/ha) (GPA)	No.	(days)		Isopyrazam ^a	CSCD 459488	Total ^b	
Trial: AF/11521/SY/1, Ayora, Spain, 2007 (Otira)	123+ 128+ 124 16days+ 28days interval	197 206 200	3	-0 0 10 20 30 42	Whole plant Whole plant Whole plant Whole plant Straw Straw	1.780 5.042 7.402 3.982 6.676 5.642	0.210 0.186 0.347 0.387 0.520 0.469	1.981 5.220 7.734 4.353 7.174 6.091	Report : CEMR-3364- REG Version 2 Study: CEMS-3364
Trial: AF/11521/SY/2, Castagnolino, Italy, 2007 (Bologna)	129+ 124+ 126 12days+ 36days interval	207 199 202	3	-0 0 20 30 42	Whole plant Whole plant Whole plant Whole plant Straw	0.064 3.539 2.365 1.449 2.832	0.035 0.031 0.136 0.214 0.791	0.098 3.569 2.495 1.654 3.589	Report : CEMR-3364- REG Version 2 Study: CEMS-3364
Trial: AF/11521/SY/3, Budrio, Italy,2007 (Duilio)	127+ 125+ 127 12days+ 33days interval	204 200 204	3	-0 0 10 20 30 41 53	Whole plant Whole plant Whole plant Whole plant Whole plant Straw Straw	0.070 3.699 1.788 0.526 0.796 1.318 1.195	0.033 0.031 0.123 0.108 0.193 0.408 0.511	0.102 3.729 1.906 0.629 0.981 1.709 1.684	Report : CEMR-3364- REG Version 2 Study: CEMS-3364
Trial: AF/11521/SY/4, Barry d'Islemade, France,2007 (Quality)	120+ 122+ 120 27days+ 22days interval	193 196 193	3	-0 0 10 20 30 41	Whole plant Whole plant Whole plant Whole plant Whole plant Straw	0.425 2.534 0.519 0.464 0.326 0.199	0.061 0.055 0.052 0.050 0.078 0.234	0.483 2.587 0.569 0.512 0.401 0.423	Report : CEMR-336- REG Version 2 Study: CEMS-3364
Trial: AF/11521/SY/5, Verdun sur Garonne, France,2007 (Pr22r58)	125+ 126+ 123 27days+ 18days interval	200 201 197	3	-0 0 10 20 30 45 60	Whole plant Whole plant Whole plant Whole plant Whole plant Remaining Plant Straw	0.303 3.356 0.734 0.570 0.295 0.414 < 0.010	0.043 0.046 0.062 0.078 0.057 0.164 < 0.005	0.344 3.400 0.793 0.645 0.350 0.571 < 0.015	Report :CEMR-336- REG Version 2 Study:CEMS- 3364
Trial: AF/11520/SY/1, Dollern Lower Saxony, Germany,2007 (Herman)	122+ 125+ 127 41days+ 21days interval	196 201 204	3	-0 0 10 20 30 43	Whole plant Whole plant Whole plant Whole plant Whole plant Straw	0.248 1.174 0.446 0.269 0.143 0.288	0.038 0.052 0.062 0.043 0.033 0.037	0.284 1.224 0.505 0.310 0.175 0.323	Report: CEMR-3366 - REG Version 2 Study: CEMS-3366
Trial: AF/11520/SY/2, Burweg, Lower Saxony, Germany,2007 (Atlantis)	125+ 126+ 125 37days+ 25days interval	202 203 201	3	-0 0 10 20 30 43	Whole plant Whole plant Whole plant Whole plant Whole plant Straw	0.204 1.529 0.258 0.215 0.075 0.113	0.067 0.071 0.075 0.071 0.049 0.059	0.268 1.597 0.330 0.283 0.122 0.169	Report: CEMR-3366 - REG Version 2 Study: CEMS-3366
Trial: AF/11520/SY/3, Measham, UK, 2007 (Malacca)	125+ 125+ 123 17days+ 32days interval	201 201 198	3	-0 0 10 20 30 42	Whole plant Whole plant Whole plant Whole plant Whole plant Straw	0.251 1.334 0.416 0.299 0.321 1.108	0.131 0.181 0.116 0.189 0.117 0.110	0.376 1.507 0.527 0.480 0.433 1.213	Report: CEMR-3366 - REG Version 2 Study: CEMS-3366

Wheat	Application			DALA	Commodity	Residues (mg/kg)			Reference & Comments
Trial Location Country, year (Variety)	Rate (g ai/ha)	Water (L/ha) (GPA)	No.	(days)		Isopyrazam ^a	CSCD 459488	Total ^b	
Trial: AF/11520/SY/4, Rouvres Saint Jean, France, 2007 (Courtot)	127+ 127+ 129 25days+ 22days interval	204 204 208	3	-0	Whole plant	0.342	0.065	0.404	Report: CEMR-3366 - REG Version 2 Study: CEMS-3366
				0	Whole plant	2.455	0.110	2.560	
				10	Whole plant	0.758	0.086	0.840	
				20	Whole plant	0.583	0.097	0.676	
				30	Remaining Plant	0.734	0.090	0.820	
				44	Remaining Plant	1.084	0.081	1.162	
				57	Straw	0.947	0.036	0.981	
Trial: AF/11520/SY/5, Martailly les Brancion, France, 2007 (Soissons)	123+ 124+ 125 25days+ 22days interval	198 200 201	3	-0	Whole plant	0.370	0.087	0.453	Report: CEMR-3366 - REG Version 2 Study: CEMS-3366
				0	Whole plant	0.360	0.100	0.456	
				10	Whole plant	1.039	0.126	1.160	
				20	Whole plant	0.501	0.135	0.630	
				30	Remaining Plant	1.764	0.249	2.002	
				44	Straw	1.405	0.178	1.575	

^a Sum of syn- and anti-isomer (i.e. residue definition for enforcement)

^b Sum of isopyrazam and CSCD459488 expressed as isopyrazam (i.e. residue definition for risk assessment)

RESIDUES IN PROCESSED FOODS

Isopyrazam was evaluated by the JMPR in 2011 where the processing of residues in barley and wheat was evaluated and where applicable processing factors were established. A high-temperature hydrolysis study to investigate the nature of residues in processed commodities was also evaluated by the 2011 JMPR. Isopyrazam was concluded to be hydrolytically stable under conditions representative of pasteurisation, baking/brewing/boiling and sterilisation.

The Meeting received information on processing studies on carrot, tomato, apple, oilseed rape have been conducted.

Processing of apples

The effect of processing on residues of isopyrazam in apples was studied (Oppiliart, S., 2009, Report No. T009264-07-REG). Two residue field trials were conducted in southern France during 2008. The apples were treated with 3 applications of 125 g/L isopyrazam EC at rate of 300 g ai/ha with seven-day intervals. Seven days after the final application, samples (~90 kg) of treated and untreated fruit were harvested from each trial and transported at ambient temperature to the processing facility. In addition, fruit (~3 kg) were frozen for residue analysis. Apple fruit was processed into sauce, juice, canned fruit and dried fruit.

Sauce

Approximately 16 kg of treated fruit was used for processing to sauce: Fruit was thoroughly washed with water and strained. Washed fruit was blanched in boiling water for 2 minutes to avoid enzymatic browning. Blanched fruit was crushed with an electric crusher and sieved to separate the puree from the peel and pips. The Brix degree of the raw puree was measured, sugar added and the puree was reduced by heating in a double jacket saucepan to obtain a Brix degree of 24%. The pH of the sauce was measured, the sauce was packaged into glass jars, sterilised at 115/120 °C for 10 minutes and cooled.

Juice:

Approximately 35 kg of treated fruit was used for processing to juice: Fruit was thoroughly washed with water and strained. Washed fruit was crushed with an electric crusher, pressed and the juice

separated from the pomace. The wet pomace was dried in an oven at 60 °C for two days. Pectolytic enzymes (0.02 mL/L) were added to the juice which was left to settle for at least 12 hours. The juice was racked from the deposits, filtered over trimming plates using a filtration unit under nitrogen pressure. The pH of the juice was measured and the juice was pasteurised at 85 °C for at least 1 minute and cooled.

Canned fruit:

Approximately 13 kg of treated fruit was used for processing to canned fruit. Fruit was thoroughly washed with water and strained. Washed fruit was peeled and the peeled fruit blanched in boiling water for approximately two minutes. The blanched fruit was cored and cut into pieces. Saccharose syrup (20% sugar, pH ~3.5) was added to the cored fruits at one third syrup to two thirds fruit, and the mixture sealed in cans.

Dried fruit:

Approximately 17 kg of treated fruit was used for processing to dried fruit. Fruit was thoroughly washed with water and strained. Washed fruit was cored and cut into parts, then sliced into 3 mm thick pieces with a mandolin. Apple slices were placed on siliconised paper in an oven at 60 °C until fully dried and turned over daily.

Two balance studies and two follow-up studies were carried out on each process. At each processing step sub-samples of the treated and untreated processed commodities, including waste products, were taken and frozen. Samples were analysed for isopyrazam (as SYN534969 and SYN534968) using method GRM006.01B and for CSCD459488 and CSCD459489 using method GRM006.03A. Mass balances for isopyrazam residues were calculated for each process. Processing factors were calculated for isopyrazam and for the sum of isopyrazam and CSCD459488. The isopyrazam residues in apple fruit prior to processing and sauce, juice, canned fruit and dried fruit, as well as in the intermediate processed fractions and the processing by-products from the two balance studies are presented below.

Table 18 Isopyrazam residues in apple and processed commodities during processing of fruit into sauce – Balance 1

S08-00691-01 - Sauce processing specimen	Isopyrazam (SYN534968 + SYN534969)		
	Sample Residue (mg/kg)	Total Residue (mg)	% Recovered as a Proportion of Initial Residue
Whole apple fruit prior to processing *	0.491	4.963	100.00
Whole fruit sub-specimen *	0.491	1.541	31.0
Wash water	0.063	0.212	4.3
Washed fruit	0.347	0.386	7.8
Blanching water	0.015	0.118 #	2.4
Blanched fruit	0.457	0.502	10.1
Raw sauce	0.098	0.098	2.0
Waste	0.996	1.525	30.7
Reduced fruit	0.101	0.061	1.2
Sauce	0.086	0.060	1.2
Balance (whole fruit + wash water + washed fruit + blanching water + blanched fruit + raw sauce + waste + reduced fruit + sauce)			91

* - Mean of two samples for SYN534968 and SYN534969.

- SYN534969 only; SYN534968 residues <LOQ.

Table 19 Isopyrazam residues in apple and processed commodities during processing of fruit into sauce – Balance 2

S08-00691-01 - Sauce processing specimen	Isopyrazam (SYN534968 + SYN534969)		
	Sample Residue (mg/kg)	Total Residue (mg)	% Recovered as a Proportion of Initial Residue
Whole apple fruit prior to processing *	0.563	5.079	100
Whole fruit sub-specimen *	0.563	1.800	35.4
Wash water	0.201	0.542	10.7
Washed fruit	0.478	0.492	9.7
Blanching water	0.024	0.217	4.3
Blanched fruit	0.526	0.562	11.1
Raw sauce	0.027	0.027	0.5
Waste	1.107	1.366	26.9
Reduced fruit	0.040	0.012	0.2
Sauce	0.054	0.034	0.7
Balance (whole fruit + wash water + washed fruit + blanching water + blanched fruit + raw sauce + waste + reduced fruit + sauce)			100

* - Mean of two samples for SYN534968 and SYN534969.

Table 20 Isopyrazam residues in apple and processed commodities during processing of fruit into juice – Balance 1

S08-00691-01 - Sauce processing specimen	Isopyrazam (SYN534968 + SYN534969)		
	Sample Residue (mg/kg)	Total Residue (mg)	% Recovered as a Proportion of Initial Residue
Whole apple fruit prior to processing *	0.436	8.297	100
Whole fruit sub-specimen *	0.436	1.366	16.5
Wash water	0.090	0.685	8.3
Washed fruit	0.340	0.385	4.6
Raw juice	0.036	0.036	0.4
Wet pomace	0.876	4.438	53.5
Dry pomace	2.447	(1.923)**	--**
Waste	0.359	0.166	2.0
Filtered juice	0.014	0.009 #	0.1
Filter plate	0.105	0.002	0.0
Juice	< 0.010	-- ##	0.0
Balance (whole fruit + wash water + washed fruit + raw juice + wet pomace + waste + filtered juice + filter plate + juice)			85

* - Mean of two samples for SYN534968 and SYN534969.

** - Dry pomace is formed directly from drying wet pomace and is not included in the balance calculations.

- SYN534969 only; SYN534968 residues <LOQ.

- Not calculated: SYN534968 and SYN534969 residues <LOQ.

Table 21 Isopyrazam residues in apple and processed commodities during processing of fruit into juice – Balance 2

S08-00691-01 - Sauce processing specimen	Isopyrazam (SYN534968 + SYN534969)		
	Sample Residue (mg/kg)	Total Residue (mg)	% Recovered as a Proportion of Initial Residue
Whole apple fruit prior to processing *	0.636	11.46	100
Whole fruit sub-specimen *	0.636	2.034	17.7
Wash water	0.203	1.456	12.7
Washed fruit	0.459	0.499	4.4
Raw juice	0.052	0.052	0.5
Wet pomace	1.378	5.498	48.0
Dry pomace	2.695	(1.554)**	--**
Waste	0.420	0.247	2.2
Filtered juice	0.020	0.020	0.2
Filter plate	0.107	0.002	0.0

S08-00691-01 - Sauce processing specimen	Isopyrazam (SYN534968 + SYN534969)		
	Sample Residue (mg/kg)	Total Residue (mg)	% Recovered as a Proportion of Initial Residue
Juice	0.012	0.046 #	0.4
Balance (whole fruit + wash water + washed fruit + raw juice + wet pomace + waste + filtered juice + filter plate + juice)			86

* - Mean of two samples for SYN534968 and SYN534969.

** - Dry pomace is formed directly from drying wet pomace and is not included in the balance calculations.

- SYN534969 only; SYN534968 residues <LOQ

Table 22 Isopyrazam residues in apple and processed commodities during processing of fruit into canned fruit – Balance 1

S08-00691-01 - Sauce processing specimen	Isopyrazam (SYN534968 + SYN534969)		
	Sample Residue (mg/kg)	Total Residue (mg)	% Recovered as a Proportion of Initial Residue
Whole apple fruit prior to processing *	0.402	3.661	100
Whole fruit sub-specimen *	0.402	1.253	34.2
Wash water	0.074	0.214	5.8
Washed fruit	0.228	0.267	7.3
Peeled fruit	0.076	0.084	2.3
Peels	1.861	1.280	35.0
Blanching water	< 0.010	-- ##	0.0
Blanched fruit	0.105	0.108	3.0
Cored fruit	0.013	0.006 #	0.2
Cores	0.512	0.134	3.7
Canned fruit	0.010	0.008 #	0.2
Balance (peeled fruit + peels + blanching water + cored fruit + cores + canned fruit)			92

* - Mean of two samples for SYN534968 and SYN534969.

- SYN534969 only; SYN534968 residues <LOQ.

- Not calculated: SYN534968 and SYN534969 residues <LOQ.

Table 23 Isopyrazam residues in apple and processed commodities during processing of fruit into canned fruit – Balance 2

S08-00691-01 - Sauce processing specimen	Isopyrazam (SYN534968 + SYN534969)		
	Sample Residue (mg/kg)	Total Residue (mg)	% Recovered as a Proportion of Initial Residue
Whole apple fruit prior to processing *	0.494	4.029	100
Whole fruit sub-specimen *	0.494	1.523	37.8
Wash water	0.166	0.383	9.5
Washed fruit	0.626	0.652	16.2
Peeled fruit	0.280	0.302	7.5
Peels	2.769	1.423	35.3
Blanching water	0.013	0.034 #	0.8
Blanched fruit	0.057	0.041	1.0
Cored fruit	0.032	0.022	0.5
Cores	0.660	0.133	3.3
Canned fruit	0.013	0.010 #	0.3
Balance (peeled fruit + peels + blanching water + cored fruit + cores + canned fruit)			112

* - Mean of two samples for SYN534968 and SYN534969.

- SYN534969 only; SYN534968 residues <LOQ.

Table 24 Isopyrazam residues in apple and processed commodities during processing of fruit into dried fruit – Balance 1

S08-00691-01 - Sauce processing specimen	Isopyrazam (SYN534968 + SYN534969)		
	Sample Residue (mg/kg)	Total Residue (mg)	% Recovered as a Proportion of Initial Residue
Whole apple fruit prior to processing *	0.324	3.276	100
Whole fruit sub-specimen *	0.324	1.061	32.4
Wash water	0.056	0.181	5.5
Washed fruit	0.281	0.340	10.4
Cored fruit	0.326	0.342	10.4
Cores	0.629	0.430	13.1
Dried fruit	2.248	1.263	38.6
Balance (cored fruit + cores + dried fruit)			110

* - Mean of two samples for SYN534968 and SYN534969.

Table 25 Isopyrazam residues in apple and processed commodities during processing of fruit into dried fruit – Balance 2

S08-00691-01 - Sauce processing specimen	Isopyrazam (SYN534968 + SYN534969)		
	Sample Residue (mg/kg)	Total Residue (mg)	% Recovered as a Proportion of Initial Residue
Whole apple fruit prior to processing *	0.460	4.161	100
Whole fruit sub-specimen *	0.460	1.444	34.7
Wash water	0.175	0.481	11.6
Washed apple	0.452	0.509	12.2
Cored fruit	0.437	0.498	12.0
Cores	1.290	0.459	11.0
Dried fruit	1.992	0.936	22.5
Balance (cored fruit + cores + dried fruit)			104

* - Mean of two samples for SYN534968 and SYN534969.

Residues of isopyrazam in the apple fruit prior to processing ranged from 0.324 to 0.636 mg/kg. Mass balances were good with a total of 91–100%, 85–86%, 92–112% and 104–110% of the isopyrazam residues on the apple fruit accounted for in the sauce, juice, canned fruit and dried fruit (plus processing by-products), respectively. Residues of CSCD459488 in the apple fruit prior to processing were less than the LOQ (< 0.005 mg/kg); therefore no calculations of mass balance were possible. CSCD459488 residues above the LOQ were measured in dry pomace, peels and dried fruit. Isopyrazam residues in washed fruit, sauce, juice and canned fruit were lower than in the corresponding fruit prior to processing with mean processing factors of 0.77, 0.18, 0.02 and 0.05, respectively. Isopyrazam residues in wet pomace, dry pomace and dried fruit were higher than in the corresponding fruit prior to processing with mean processing factors of 2.49, 5.51 and 6.03, respectively.

Total residues of isopyrazam and CSCD459488 in washed fruit, sauce, juice and canned fruit were lower than in the corresponding fruit prior to processing with mean processing factors of 0.77, 0.19, 0.03 and 0.06, respectively. Total residues of isopyrazam and CSCD459488 in wet pomace, dry pomace and dried fruit were higher than in the corresponding fruit prior to processing with mean processing factors of 2.48, 5.55 and 5.95, respectively. Residues of isopyrazam and total residues of isopyrazam and CSCD459488 in the apple fruit prior to processing and in processed commodities together with the calculated processing factors are presented below.

Table 26 Isopyrazam residues in apple sauce, juice, canned fruit and dried fruit, intermediates and by-products

Process		Isopyrazam residue in fruit before processing* (mg/kg)	Isopyrazam residue in processed commodity (mg/kg)	Processing factor
Sauce processing				
Balance 1	Washed fruit	0.491	0.347	0.71
	Sauce	0.491	0.086	0.17
Balance 2	Washed fruit	0.563	0.478	0.85
	Sauce	0.563	0.054	0.10
Follow-up 1	Washed fruit	0.300	0.085	0.28
	Sauce	0.300	0.074	0.25
Follow-up 2	Washed fruit	0.613	0.386	0.63
	Sauce	0.613	0.135	0.22
Juice processing				
Balance 1	Washed fruit	0.436	0.341	0.78
	Wet pomace	0.436	0.876	2.01
	Dry pomace	0.436	2.446	5.61
	Juice	0.436	< 0.010**	< 0.02
Balance 2	Washed fruit	0.636	0.459	0.72
	Wet pomace	0.636	1.378	2.17
	Dry pomace	0.636	2.695	4.24
	Juice	0.636	0.012	0.02
Follow-up 1	Wet pomace	0.309	0.774	2.50
	Dry pomace	0.310	1.945	6.28
	Juice	0.310	< 0.010**	< 0.03
Follow-up 2	Wet pomace	0.500	1.648	3.30
	Dry pomace	0.500	2.957	5.91
	Juice	0.500	0.011	0.02
Canned fruit processing				
Balance 1	Washed fruit	0.402	0.228	0.57
	Canned fruit	0.402	0.010	0.02
Balance 2	Washed fruit	0.494	0.626	1.27
	Canned fruit	0.494	0.013	0.03
Follow-up 1	Canned fruit	0.333	0.019	0.06
Follow-up 2	Canned fruit	0.448	0.034	0.08
Dried fruit processing				
Balance 1	Washed fruit	0.324	0.281	0.87
	Dried fruit	0.324	2.248	6.95
Balance 2	Washed fruit	0.460	0.452	0.98
	Dried fruit	0.460	1.992	4.33
Follow-up 1	Dried fruit	0.188	1.691	8.98
Follow-up 2	Dried fruit	0.680	2.616	3.85
Mean Processing factors				
Washed fruit (n = 10)				0.77
Sauce (n = 4)				0.18
Wet pomace (n = 4)				2.49
Dry pomace (n = 4)				5.51
Juice (n = 4)				0.02
Canned fruit (n = 4)				0.05
Dried fruit (n = 4)				6.03

* - Total of the mean residue of two samples for each isomer

** - In cases where both the individual isomer residues were below the LOQ, the total residue is expressed as being less than twice the LOQ (i.e. < 0.010 mg/kg).

Table 27 Total isopyrazam and CSCD459488 residues in apple sauce, juice, canned fruit and dried fruit, intermediates and by-products

Process		Isopyrazam* + CSCD459488 residue in fruit before processing (mg/kg)	Isopyrazam + CSCD459488 residue in processed commodity (mg/kg)	Processing factor
Sauce processing				
Balance 1	Washed fruit	0.496	0.352	0.71
	Sauce	0.496	0.091	0.18
Balance 2	Washed fruit	0.568	0.483	0.85
	Sauce	0.568	0.059	0.10
Follow-up 1	Washed fruit	0.305	0.090	0.30
	Sauce	0.305	0.079	0.26
Follow-up 2	Washed fruit	0.618	0.391	0.63
	Sauce	0.618	0.140	0.23
Juice processing				
Balance 1	Washed fruit	0.441	0.346	0.78
	Wet pomace	0.441	0.881	2.00
	Dry pomace	0.441	2.490	5.64
	Juice	0.441	< 0.015**	< 0.03
Balance 2	Washed fruit	0.641	0.464	0.72
	Wet pomace	0.641	1.383	2.16
	Dry pomace	0.641	2.741	4.27
	Juice	0.641	0.017	0.04
Follow-up 1	Wet pomace	0.309	0.779	2.47
	Dry pomace	0.315	1.990	6.32
	Juice	0.315	< 0.015**	< 0.05
Follow-up 2	Wet pomace	0.505	1.653	3.27
	Dry pomace	0.505	3.012	5.96
	Juice	0.505	0.016	0.03
Canned fruit processing				
Balance 1	Washed fruit	0.407	0.233	0.57
	Canned fruit	0.407	0.015	0.04
Balance 2	Washed fruit	0.499	0.631	1.27
	Canned fruit	0.499	0.018	0.04
Follow-up 1	Canned fruit	0.338	0.024	0.07
Follow-up 2	Canned fruit	0.453	0.039	0.09
Dried fruit processing				
Balance 1	Washed fruit	0.329	0.286	0.87
	Dried fruit	0.329	2.259	6.88
Balance 2	Washed fruit	0.465	0.457	0.98
	Dried fruit	0.465	1.997	4.29
Follow-up 1	Dried fruit	0.193	1.699	8.79
Follow-up 2	Dried fruit	0.685	2.624	3.83
Mean Processing factors				
Washed fruit (n = 10)				0.77
Sauce (n = 4)				0.19
Wet pomace (n = 4)				2.48
Dry pomace (n = 4)				5.55
Juice (n = 4)				0.03
Canned fruit (n = 4)				0.06
Dried fruit (n = 4)				5.95

* - Total of the mean residue of two samples for each isomer

** - In cases where both the individual isomer residues were below the LOQ, the total residue is expressed as being less than twice the LOQ (i.e. < 0.010 mg/kg).

Processing of Tomatoes

A tomato processing study (Gemrot, F., 2012, Report No. S09-00358) was conducted in France (South) in 2009. Two residue field trials were conducted in southern France during 2009. Tomatoes were treated

with 3 applications of isopyrazam EC containing 62.5g isopyrazam and 150 g cyprodinil per litre at rate of 250 g isopyrazam/ha with 7-day intervals. One day after the final application, samples (40–68 kg) of treated and untreated tomatoes were harvested from each trial and transported to the processing facility. In addition, tomato fruits (approximately 2 kg) were frozen for residue analysis. Tomato fruits were processed into tomato juice, tomato puree/paste, canned tomatoes, ketchup and sun-dried tomatoes and into the processing by-products wet and dry pomace. Two balance studies and two follow-up studies were carried out on each process.

Samples were analysed for isopyrazam (as SYN534969 and SYN534968) using method GRM006.01B and for CSCD459488 and CSCD459489 using method GRM006.03A. Mass balances for isopyrazam residues were calculated for each process. Processing factors were calculated for the sum of both isopyrazam isomers.

Residues of isopyrazam in tomato fruits in the two balance and two follow-up studies prior to processing ranged from 0.084 to 0.225 mg/kg. Mass balances were variable with a total of 55–62%, 60–117%, 55–121%, 57–103, 55–114% and 21–61% of the isopyrazam residues in the tomato fruits accounted for in the juice, canned tomato, tomato puree, tomato paste, ketchup and sun-dried tomato (plus processing by-products), respectively.

Isopyrazam residues in washed tomato, tomato juice and canned tomatoes were lower than the corresponding residue in tomato prior to processing with mean processing factors of 0.98, 0.50 and 0.19, respectively. Isopyrazam residues in wet and dry pomace, tomato puree/paste, ketchup and dried tomatoes were higher than the corresponding residue in tomato prior to processing with mean processing factors of 3.1–8.8 (depending on process), 32, 5.1, 6.4, 4.2 and 11, respectively. Residues of CSCD459488 in the tomato fruit prior to processing were less than the LOQ (< 0.005 mg/kg); therefore no calculations of processing factors were possible.

Juice

Approximately 12 kg of treated tomato fruits were used for processing to juice. The unwashed tomatoes were weighed and crushed. The crushed tomatoes were sieved. Raw juice and wet pomace were sub-sampled and analysed. Remaining wet pomace was dried at 60 °C. Dry pomace was sub-sampled and analysed. The Brix degree of juice was measured and cooking salt was added to juice at a level of 7 g/kg. The pH of the juice was adjusted to approximately 3.5 with citric acid. An aliquot was taken and used for the canning process. The juice was pasteurised for 1 minute at 82–85 °C, packaged in plastic bottles and frozen (below -18 °C).

Canned tomato:

Approximately 6 kg of treated tomato fruits were used for canning. Unwashed tomatoes were blanched by plunging into boiling water (≤ 1 minute) then immediately followed by plunging into cold water to crack the peels. Blanched tomatoes were peeled. Peels and peeled tomatoes were sub-sampled and analysed. Cans with peeled tomatoes were filled up with juice (see production of juice above) at a ratio of $\frac{1}{3}$ to $\frac{2}{3}$ (approximately 250 g juice to 500 g tomato). The cans were sterilised at 115–120 °C for 10 minutes. Sub-samples were labelled and frozen (below -18 °C).

Puree and paste processing:

Approximately 10 kg of treated tomato fruits were used for puree and paste processing. Unwashed tomatoes were weighed and crushed, aliquots were sub-sampled and analysed. Crushed tomatoes were reduced in a double jacketed saucepan until the Brix degree reached 12–13%. Samples were separated into two parts, one for processing of puree, one for processing of paste.

a) Puree: The reduced tomatoes were put into an automatic sieve to remove peels and seeds (wet pomace). Sieved tomatoes and wet pomace were sub-sampled and analysed. Cooking salt was added to puree at 4 g/kg and the pH was adjusted to approximately 3.5 with citric acid. Puree sub-samples were packaged in glass bottles, sterilised at 115–120 °C for 10 minutes, labelled and frozen (below -18 °C).

b) Paste: Reduced tomatoes were further reduced in a double jacketed saucepan until the Brix degree reached 24–26%. Reduced tomatoes were sub-sampled and analysed. The reduced tomatoes were put into an automatic siever to remove peels and seeds (wet pomace). Sieved tomatoes and wet pomace were sub-sampled and analysed. Cooking salt was added to the puree at 4 g/kg and the pH was adjusted to approximately 3.5 with citric acid. Paste sub-samples were packaged in glass bottles, sterilised at 115–120 °C for 10 minutes, labelled and frozen (below -18 °C).

Ketchup:

Approximately 6 kg of treated tomato fruits were used for processing of ketchup. Unwashed tomatoes were weighed and crushed, aliquots were sub-sampled and analysed. Crushed tomatoes were reduced in a double jacketed saucepan until the Brix degree reached 14–15%. Sub-samples were taken and analysed. The reduced tomatoes were put into an automatic siever to remove peels and seeds (wet pomace). Sieved tomatoes and wet pomace were sub-sampled and analysed. Ketchup was prepared in the following composition: 72% tomato puree, 19% brown sugar, 7% cider vinegar and 2% salt. Ketchup sub-samples were packaged in glass bottles, sterilised at 115–120 °C for 10 minutes, labelled and frozen (below -18 °C).

Dried tomatoes:

Approximately 21 kg of treated tomato fruits were used for processing of dried tomatoes. Unwashed tomatoes were cut in quarters. Quarters were pressed to remove as much water as possible before drying. The weight of the tomatoes following pressing was recorded. The water produced during pressing from each sample was collect and weighed.

a) Sun-drying: One part of the pressed tomatoes were placed on plates and exposed to sunlight for drying (storage in a glasshouse during night, bad weather and weekend). Samples were collected when visually dry after 4–7 days of sun-drying, labelled and frozen (below -18 °C).

b) Oven-drying: A second part of the pressed tomatoes were placed in an oven at 60 °C, on shelves or drawers covered with siliconised baking paper to dry. Samples were collected when visually dry after 2–3 days of drying. Samples of oven-dried tomatoes were not analysed.

At each processing step sub-samples of the treated and untreated processed commodities, including waste products, were taken and frozen. The isopyrazam residues in tomato fruits prior to processing and tomato juice, tomato puree/paste, canned tomatoes, ketchup and dried tomatoes, as well as in the intermediate processed fractions and the processing by-products from the two balance studies are presented below.

Table 28 Isopyrazam residues in tomato and processed commodities during processing into juice - Balance calculations

Commodity	Isopyrazam (SYN534968 + SYN534969)		
	Sample Residue (mg/kg)	Total Residue (mg)	% Recovered as a Proportion of Initial Residue
Balance study 1 - S09-00358-01			
Whole tomato prior to processing *	0.242	2.804	100
Whole tomato sub-specimen *	0.242	0.369	13.2
Crushed tomato sub-specimen	0.034	0.034	1.2
Crushed tomato lost on crush	0.034	0.003	0.1
Raw juice sub-specimen	0.072	0.072	2.6
Wet pomace	0.342	0.962	34.3
Wet pomace lost on sieving (calculated)	0.342	0.086	3.1
Tomato juice	0.043	0.147	5.2
Tomato juice kept for canning	0.043	0.062	2.2
Balance (whole tomatoes + crushed tomatoes + raw juice + wet pomace + finished juice)			61.9
Balance study 2 - S09-00358-02			
Whole tomato prior to processing *	0.399	4.604	100

Commodity	Isopyrazam (SYN534968 + SYN534969)		
	Sample Residue (mg/kg)	Total Residue (mg)	% Recovered as a Proportion of Initial Residue
Whole tomato sub-specimen *	0.399	0.659	14.3
Crushed tomato sub-specimen	0.031	0.031	0.7
Crushed tomato lost on crush	0.031	0.005	0.1
Raw juice sub-specimen	0.071	0.073	1.6
Wet pomace	0.379	1.549	33.7
Wet pomace lost on sieving (calculated)	0.379	0.017	0.4
Tomato juice	0.054	0.102	2.2
Tomato juice kept for canning	0.054	0.083	1.8
Balance (whole tomatoes + crushed tomatoes + raw juice + wet pomace + finished juice)			54.7

* - Mean of two samples for SYN534968 and SYN534969.

Table 29 Isopyrazam residues in tomato and processed commodities during processing into canned tomato - Balance calculations

Commodity	Isopyrazam (SYN534968 + SYN534969)		
	Sample Residue (mg/kg)	Total Residue (mg)	% Recovered as a Proportion of Initial Residue
Balance study 1 - S09-00358-01			
Whole tomato prior to processing *	0.242	1.457	100
Whole tomato sub-specimen *	0.242	0.372	25.5
Recovered water from blanching	0.044	0.169	11.6
Water lost (calculated)	0.044	0.029	2.0
Recovered water from cooling	0.010	0.045	3.1
Water lost (calculated)	0.010	0.000	0.0
Blanched tomato sub-specimen	0.168	0.170	11.7
Peeled tomato sub-specimen	0.010	0.010	0.7
Peels	2.203	0.811	55.6
Peeled tomato not used for canning (calculated)	0.010	0.000	0.0
Canned tomato sub-specimen	0.017	0.025	1.7
Canned tomato after sterilisation sub-specimen	0.049	0.074	5.1
Balance (whole tomatoes + blanching water + cooling water + blanched tomatoes + peeled tomatoes + peels + canned tomatoes)			117.1
Balance study 2 - S09-00358-02			
Whole tomato prior to processing *	0.399	2.404	100
Whole tomato sub-specimen *	0.399	0.600	25.0
Recovered water from blanching	0.044	0.194	8.0
Water lost (calculated)	0.044	0.008	0.3
Recovered water from cooling	0.010	0.046	1.9
Water lost (calculated)	0.010	0.001	0.0
Blanched tomato sub-specimen	0.090	0.094	3.9
Peeled tomato sub-specimen	0.010	0.011	0.5
Peels	1.062	0.430	17.9
Peeled tomato not used for canning (calculated)	0.010	0.000	0.0
Canned tomato sub-specimen	0.019	0.029	1.2
Canned tomato after sterilisation sub-specimen	0.022	0.031	1.3
Balance (whole tomatoes + blanching water + cooling water + blanched tomatoes + peeled tomatoes + peels + canned tomatoes)			60.0

* - Mean of two samples for SYN534968 and SYN534969.

Table 30 Isopyrazam residues in tomato and processed commodities during processing into tomato puree - Balance calculations

Commodity	Isopyrazam (SYN534968 + SYN534969)		
	Sample Residue (mg/kg)	Total Residue (mg)	% Recovered as a Proportion of Initial Residue
Balance study 1 - S09-00358-01			
Whole tomato prior to processing *	0.242	2.307	100
Whole tomato sub-specimen *	0.242	0.365	15.8
Crushed tomato sub-specimen	0.022	0.022	1.0
Crushed tomato lost on crush (calculated)	0.022	0.003	0.1
Reduced tomato sub-specimen	0.752	0.053	2.3
Reduced tomato not used for puree (calculated)	0.752	1.808	78.4
Wet pomace	1.234	0.051	2.2
Sieved tomato sub-specimen	0.670	0.047	2.0
Lost on sieving (calculated)	0.670	0.144	6.2
Puree	0.949	0.301	13.0
Balance (whole tomatoes + crushed tomatoes + reduced tomatoes + wet pomace + sieved tomatoes + puree)			121.1
Balance study 2 - S09-00358-02			
Whole tomato prior to processing *	0.399	3.805	100
Whole tomato sub-specimen *	0.399	0.614	16.1
Crushed tomato sub-specimen	0.101	0.101	2.7
Crushed tomato lost on crush (calculated)	0.101	0.015	0.4
Reduced tomato sub-specimen	0.650	0.046	1.2
Reduced tomato not used for puree (calculated)	0.650	0.967	25.4
Wet pomace	0.606	0.107	2.8
Sieved tomato sub-specimen	0.388	0.023	0.6
Lost on sieving (calculated)	0.388	0.128	3.4
Puree	0.439	0.095	2.5
Balance (whole tomatoes + crushed tomatoes + reduced tomatoes + wet pomace + sieved tomatoes + puree)			55.1

* - Mean of two samples for SYN534968 and SYN534969.

Table 31 Isopyrazam residues in tomato and processed commodities during processing into tomato paste - Balance calculations

Commodity	Isopyrazam (SYN534968 + SYN534969)		
	Sample Residue (mg/kg)	Total Residue (mg)	% Recovered as a Proportion of Initial Residue
Balance study 1 - S09-00358-01			
Whole tomato prior to processing *	0.242	2.307	100
Whole tomato sub-specimen *	0.242	0.365	15.8
Crushed tomato sub-specimen	0.022	0.022	1.0
Crushed tomato lost on crush (calculated)	0.022	0.003	0.1
Reduced tomato sub-specimen	0.752	0.053	2.3
Reduced tomato not used for concentration	0.557	0.333	14.4
Reduced tomato sub-specimen	1.414	0.099	4.3
Wet pomace	1.735	0.763	33.1
Sieved tomato sub-specimen	0.670	0.047	2.0
Lost on sieving (calculated)	0.949	0.518	22.5
Paste	0.997	0.170	7.4
Balance (whole tomatoes + crushed tomatoes + reduced tomatoes + wet pomace + sieved tomatoes + paste)			102.9
Balance study 2 - S09-00358-02			
Whole tomato prior to processing *	0.399	3.805	100
Whole tomato sub-specimen *	0.399	0.614	16.1
Crushed tomato sub-specimen	0.101	0.101	2.7
Crushed tomato lost on crush (calculated)	0.101	0.015	0.4

Commodity	Isopyrazam (SYN534968 + SYN534969)		
	Sample Residue (mg/kg)	Total Residue (mg)	% Recovered as a Proportion of Initial Residue
Reduced tomato sub-specimen	0.650	0.046	1.2
Reduced tomato not used for concentration	0.650	0.390	10.3
Reduced tomato sub-specimen	1.003	0.071	1.9
Wet pomace	1.016	0.366	9.6
Sieved tomato sub-specimen	0.799	0.048	1.3
Lost on sieving (calculated)	0.799	0.419	11.0
Paste	0.552	0.095	2.5
Balance (whole tomatoes + crushed tomatoes + reduced tomatoes + wet pomace + sieved tomatoes + paste)			56.9

* - Mean of two samples for SYN534968 and SYN534969.

Table 32 Isopyrazam residues in tomato and processed commodities during processing into ketchup - Balance calculations

Commodity	Isopyrazam (SYN534968 + SYN534969)		
	Sample Residue (mg/kg)	Total Residue (mg)	% Recovered as a Proportion of Initial Residue
Balance study 1 - S09-00358-01			
Whole tomato prior to processing *	0.242	1.360	100
Whole tomato sub-specimen *	0.242	0.368	27.1
Crushed tomato sub-specimen	0.188	0.188	13.8
Crushed tomato lost on crush (calculated)	0.188	0.017	1.2
Reduced tomato sub-specimen	1.083	0.076	5.6
Wet pomace	1.675	0.233	17.1
Sieved tomato sub-specimen	0.449	0.031	2.3
Lost on sieving (calculated)	0.449	0.130	9.5
Ketchup	0.578	0.502	36.9
Balance (whole tomatoes + crushed tomatoes + reduced tomatoes + wet pomace + sieved tomatoes + ketchup)			113.6
Balance study 2 - S09-00358-02			
Whole tomato prior to processing *	0.399	2.216	100
Whole tomato sub-specimen *	0.399	0.620	28.0
Crushed tomato sub-specimen	0.020	0.020	0.9
Crushed tomato lost on crush (calculated)	0.020	0.002	0.1
Reduced tomato sub-specimen	0.626	0.044	2.0
Wet pomace	0.579	0.087	3.9
Sieved tomato sub-specimen	0.481	0.034	1.5
Lost on sieving (calculated)	0.481	0.201	9.1
Ketchup	0.575	0.217	9.8
Balance (whole tomatoes + crushed tomatoes + reduced tomatoes + wet pomace + sieved tomatoes + ketchup)			55.3

* - Mean of two samples for SYN534968 and SYN534969.

Table 33 Isopyrazam residues in tomato and processed commodities during processing into sun-dried tomato - Balance calculations

Commodity	Isopyrazam (SYN534968 + SYN534969)		
	Sample Residue (mg/kg)	Total Residue (mg)	% Recovered as a Proportion of Initial Residue
Balance study 1 - S09-00358-01			
Whole tomato prior to processing *	0.242	4.977	100
Whole tomato sub-specimen *	0.242	0.371	7.5
Tomato quarters not collected (calculated)	0.242	0.099	2.0
Pressed tomatoes sub-specimen	0.101	0.101	2.0
Tomato water from pressing	0.173	0.204	4.1
Pressed tomatoes not used for drying	0.101	0.930	18.7
Dried tomatoes	1.284	1.332	26.8

Commodity	Isopyrazam (SYN534968 + SYN534969)		
	Sample Residue (mg/kg)	Total Residue (mg)	% Recovered as a Proportion of Initial Residue
Balance (whole tomatoes + quarters + pressed tomatoes + tomato water from pressing + dried tomatoes)			61.0
Balance study 2 - S09-00358-02			
Whole tomato prior to processing *	0.399	8.191	100
Whole tomato sub-specimen *	0.399	0.621	7.6
Tomato quarters not collected (calculated)	0.399	0.054	0.7
Pressed tomatoes sub-specimen	0.045	0.046	0.6
Tomato water from pressing	0.202	0.161	2.0
Pressed tomatoes not used for drying	0.045	0.429	5.2
Dried tomatoes	1.405	0.438	5.4
Balance (whole tomatoes + quarters + pressed tomatoes + tomato water from pressing + dried tomatoes)			21.4

* - Mean of two samples for SYN534968 and SYN534969.

Residues of isopyrazam in tomato fruits in the two balance and two follow-up studies prior to processing ranged from 0.084 to 0.225 mg/kg. Isopyrazam residues in washed tomato, tomato juice and canned tomatoes were lower than the corresponding residue in tomato prior to processing with mean processing factors of 0.98, 0.50 and 0.19, respectively. Isopyrazam residues in wet and dry pomace, tomato puree/paste, ketchup and dried tomatoes were higher than the corresponding residue in tomato prior to processing with mean processing factors of 3.1–8.8 (depending on process), 32, 5.1, 6.4, 4.2 and 11, respectively.

Residues of isopyrazam in tomato fruit prior to processing and in processed commodities together with the calculated processing factors are presented below.

Table 34 Isopyrazam residues in washed tomato, tomato juice, tomato puree/paste, canned tomatoes, ketchup, dried tomatoes intermediates and by-products

Process		Isopyrazam residue in crop before processing* (mg/kg)	Isopyrazam residue in processed commodity (mg/kg)	Processing factor
Washing				
Balance 1	Wash water	0.211	0.052	0.25
	Washed tomato	0.211	0.214	1.01
Balance 2	Wash water	0.109	0.046	0.42
	Washed tomato	0.109	0.099	0.91
Follow-up 1	Washed tomato	0.145	0.212	1.46
Follow-up 2	Washed tomato	0.119	0.063	0.53
Juice processing				
Balance 1	Crushed tomato	0.165	0.034	0.21
	Wet pomace	0.165	0.342	2.07
	Dry pomace	0.165	6.118	37.08
	Raw juice	0.165	0.072	0.44
	Juice	0.165	0.043	0.26
Balance 2	Crushed tomato	0.084	0.031	0.37
	Wet pomace	0.084	0.379	4.54
	Dry pomace	0.084	2.061	24.68
	Raw juice	0.084	0.071	0.85
	Juice	0.084	0.054	0.65
Follow-up 1	Wet pomace	0.122	0.438	3.60
	Dry pomace	0.122	4.893	40.27
	Juice	0.122	0.028	0.23
Follow-up 2	Wet pomace	0.093	0.206	2.22
	Dry pomace	0.093	2.238	24.06
	Juice	0.093	0.080	0.86
Tomato puree / paste processing				
Balance 1	Crushed tomato	0.121	0.022	0.18
	Reduced tomato	0.121	0.752	6.24

Process		Isopyrazam residue in crop before processing* (mg/kg)	Isopyrazam residue in processed commodity (mg/kg)	Processing factor
	Sieved tomato	0.121	0.447	3.71
	Wet pomace	0.121	1.234	10.24
	Puree	0.121	0.949	7.88
	Reduced tomato	0.121	1.671	13.87
	Sieved tomato	0.121	1.224	10.16
	Wet pomace	0.121	1.862	15.45
	Paste	0.121	0.997	8.27
Balance 2	Crushed tomato	0.169	0.101	0.60
	Reduced tomato	0.169	0.650	3.86
	Sieved tomato	0.169	0.388	2.30
	Wet pomace	0.169	0.606	3.60
	Puree	0.169	0.439	2.61
	Reduced tomato	0.169	1.003	5.95
	Sieved tomato	0.169	0.799	4.74
	Wet pomace	0.169	1.016	6.03
Follow-up 1	Puree	0.122	0.623	5.13
	Paste	0.122	0.781	6.43
Follow-up 2	Puree	0.100	0.489	4.89
	Paste	0.100	0.756	7.56
Canned tomato processing				
Balance 1	Blanched tomato	0.141	0.168	1.20
	Blanching water	0.141	0.044	0.31
	Cooling water	0.141	0.010	0.07
	Peels	0.141	2.203	15.68
	Peeled tomato	0.141	0.010 **	0.07
	Canned tomato ***	0.141	0.033	0.23
Balance 2	Blanched tomato	0.100	0.090	0.90
	Blanching water	0.100	0.044	0.44
	Cooling water	0.100	0.010	0.10
	Peels	0.100	1.062	10.67
	Peeled tomato	0.100	0.010 **	0.10
	Canned tomato ***	0.100	0.021	0.21
Follow-up 1	Peeled tomato	0.138	0.010 **	0.07
	Canned tomato	0.138	0.010	0.07
Follow-up 2	Peeled tomato	0.084	0.020	0.24
	Canned tomato	0.084	0.021	0.25
Ketchup processing				
Balance 1	Crushed tomato	0.163	0.188	1.16
	Reduced tomato	0.163	1.083	6.66
	Sieved tomato	0.163	0.449	2.76
	Wet pomace	0.163	1.675	10.31
	Ketchup	0.163	0.578	3.56
Balance 2	Crushed tomato	0.094	0.020	0.21
	Reduced tomato	0.094	0.626	6.66
	Sieved tomato	0.094	0.481	5.12
	Wet pomace	0.094	0.579	6.16
	Ketchup	0.094	0.575	6.12
Follow-up 1	Ketchup	0.160	0.580	3.63
Follow-up 2	Ketchup	0.161	0.578	3.60
Sun-dried tomatoes				
Balance 1	Pressed tomato	0.225	0.101	0.45
	Tomato water	0.225	0.173	0.77
	Sun-dried tomato	0.225	1.284	5.71
Balance 2	Pressed tomato	0.135	0.045	0.33
	Tomato water	0.135	0.202	1.50
	Sun-dried tomato	0.135	1.405	10.45
Follow-up 1	Sun-dried tomato	0.170	2.011	11.83
Follow-up 2	Sun-dried tomato	0.096	1.376	14.33

Process	Isopyrazam residue in crop before processing* (mg/kg)	Isopyrazam residue in processed commodity (mg/kg)	Processing factor
Mean Processing factors			
Washed tomatoes (n = 4)			0.98
Wet pomace juice production (n = 4)			3.11
Dry pomace juice production (n = 4)			31.52
Juice (n = 4)			0.50
Wet pomace puree / paste production (n = 4)			8.83
Puree (n = 4)			5.12
Paste (n = 4)			6.38
Canned (n = 4)			0.19
Wet pomace ketchup production (n = 2)			8.23
Ketchup (n = 4)			4.23
Sun-dried (n = 4)			10.58

* - Total of the mean residue of two samples for each isomer.

** - In cases where both the individual isomer residues were below the LOQ, the total residue is expressed as being less than twice the LOQ (i.e. < 0.010 mg/kg).

*** - Mean of a double determination.

Table 35 Isopyrazam processing factors in processed tomato commodities

Commodity	Measured processing factors				Mean processing factor
	Balance study 1	Balance study 2	Follow-up study 1	Follow-up study 2	
Wet pomace*	2.1	4.5	3.6	2.2	3.1
Dry pomace*	37	25	40	24	32
Juice	0.26	0.65	0.23	0.86	0.5
Puree	7.9	2.6	5.1	4.9	5.1
Paste	8.3	5.1	6.4	7.6	6.4
Canned tomato	0.23	0.21	0.07	0.25	0.19
Ketchup	3.6	6.1	3.6	3.6	4.2
Sun-dried tomato	5.7	10	12	14	11

* - Pomace from the production of juice. So-called "pomace" from the production of other tomato commodities (puree/paste and ketchup) does not from part of animal diets and is more generally regarded as waste so is not include here.

Isopyrazam residues in wet and dry pomace, tomato puree/paste, ketchup and dried tomatoes were higher than the corresponding residue in tomato prior to processing with mean processing factors of 3.1–8.8 (depending on process), 32, 5.1, 6.4, 4.2 and 11, respectively.

Processing of carrots

A carrot processing study (Gemrot, F., 2012, Report No. S09-01531) was conducted in Southern France in 2009. Carrots were treated with 3 applications of isopyrazam EC containing 62.5g isopyrazam and 150 g cyprodinil per litre at rate of 250 g isopyrazam/ha, with 14-day intervals. Seven days after the final application, samples (21–33 kg) of treated and untreated roots were harvested from each trial and transported refrigerated to the processing facility. In addition, roots (2–3 kg) were frozen for residue analysis. Carrot roots were processed into carrot juice, canned carrot and carrot puree and into the processing by-products wet and dry pomace. Two balance studies and two follow-up studies were carried out on each process. Samples were analysed for isopyrazam (as SYN534969 and SYN534968) using method GRM006.01B and for CSCD459488 and CSCD459489 using method GRM006.03A. Mass balances for isopyrazam residues were calculated for each process. Processing factors were calculated for the sum of both isopyrazam isomers.

Residues of isopyrazam in carrot roots in the two balance and two follow-up studies prior to processing ranged from 0.139 to 0.253 mg/kg. Mass balances were good with a total of 81–88%, 80–104% and 82–93% of the isopyrazam residues in the carrot roots accounted for in the juice, canned

carrot and carrot puree (plus processing by-products), respectively. Isopyrazam residues in washed carrot, juice, canned carrot and carrot puree were lower than the corresponding residue in carrot prior to processing with mean processing factors of 0.68, 0.21, 0.06 and 0.13, respectively. Isopyrazam residues in wet pomace and dry pomace were higher than the corresponding residue in carrot prior to processing with mean processing factors of 1.18 and 8.28, respectively. Residues of CSCD459488 in the carrot root prior to processing were less than the LOQ (< 0.005 mg/kg); therefore no calculations of mass balance or processing factors were possible. CSCD459488 residues above the LOQ were measured in dry pomace only.

Carrot roots were processed into carrot juice, canned carrot and carrot puree and into the processing by-products wet and dry pomace. The production of puree equates to the process of cooking vegetables in water, as required by EU guidance (7035/VI/95 rev.5). The only additional step in the production of puree from cooked carrots is mechanical sieving which will have no effect on residue levels. Two balance studies and two follow-up studies were carried out on each process.

Juice

Approximately 10 kg of treated carrot roots were used for processing to juice. Carrot roots were thoroughly washed with water and strained. Washed carrots were introduced into the upper part of the juice extractor to separate the juice from the pulp. The carrot pieces struck the spinning sieve at high speed and the juice and pulp were separated, the juice passed through the sieve into a plastic container and the pulp was expelled into a plastic tub. Raw juice and wet pomace were sub-sampled and analysed. Remaining wet pomace was dried for 1.75 hours at 60 °C. Dry pomace was sub-sampled and analysed. The pH of the juice was adjusted to approximately 3.5 with citric acid. The juice was pasteurised for about 1 minute at approximately 85 °C, packaged in plastic bottles and stored frozen (below -18 °C).

Canned carrot

Approximately 7 kg of treated carrot roots were used for canning. Carrot roots were peeled by abrasion and washed with an automatic peeler with a water flow regulated at 10–12 L/min. Peels were recovered by a filter basket and washing water in a plastic container. Peels and peeled carrots were sub-sampled and analysed. The washed and peeled carrots were blanched in boiling water (1 L of water per kg of carrot) for approximately 1 minute. For the balance studies blanching water and blanched carrots were sub-sampled and analysed. An aqueous brine containing salt 30 g/L and adjusted to a pH 3.5 with citric acid was prepared and added to blanched carrots with a relation of $\frac{1}{3}$ to $\frac{2}{3}$ (approximately 250 g brine to 500 g carrot). The cans were sealed with a cover and sterilised at 115–120 °C for 10 minutes. Sub-samples were labelled and frozen (below -18 °C).

Puree processing

Approximately 10 kg of treated carrot roots were used for puree processing. Carrot roots were trimmed at both ends and peeled with a knife. Peels and peeled carrots were sub-sampled and analysed. Peeled carrots were cooked in boiling water (1 L of tap water per 1 kg of trimmed carrots). The duration of cooking was a function of the diameter of carrots. The carrot cooking was verified with a knife. In the balance studies cooking water and cooked carrots were sub-sampled and analysed. Remaining cooked carrots were sieved to be processed into puree. In the balance studies raw puree and waste were sub-sampled and analysed. Remaining puree was packaged in glass bottles, sterilised at 115–120 °C for 10 minutes, labelled and frozen (below -18 °C).

At each processing step sub-samples of the treated and untreated processed commodities, including waste products, were taken and frozen. The results of two balance studies and two follow-up studies, and the isopyrazam residues in carrot roots prior to processing and in finished juice, canned carrot and carrot puree in Southern France in 2009, as well as in the intermediate processed fractions and the processing by-products from the two balance studies are presented below.

Table 36 Isopyrazam residues in carrot roots and processed commodities during processing into juice - Balance calculations

Commodity	Isopyrazam (SYN534968 + SYN534969)		
	Sample Residue (mg/kg)	Total Residue (mg)	% Recovered as a Proportion of Initial Residue
Balance study 1 - S09-01531-01			
Carrot roots prior to processing *	0.252	2.404	100
Carrot roots sub-specimen *	0.252	0.387	16.1
Wash water	0.037	0.229	9.5
Washed carrot sub-specimen	0.171	0.173	7.2
Raw juice sub-specimen	0.061	0.061	2.5
Wet pomace	0.289	1.033	43.0
Carrot juice	0.034	0.069	2.9
Balance (carrot roots + wash water + washed carrots + raw juice + wet pomace + carrot juice)			81.2
Balance study 2 - S09-01531-02			
Carrot roots prior to processing *	0.154	1.480	100
Carrot roots sub-specimen *	0.154	0.237	16.0
Wash water	0.035	0.210	14.2
Washed carrot sub-specimen	0.093	0.094	6.3
Raw juice sub-specimen	0.072	0.072	4.9
Wet pomace	0.150	0.587	39.7
Carrot juice	0.052	0.099	6.7
Balance (carrot roots + wash water + washed carrots + raw juice + wet pomace + carrot juice)			87.7

* - Mean of two samples for SYN534968 and SYN534969.

Table 37 Isopyrazam residues in carrot roots and processed commodities during processing into canned carrot – Balance calculations

Commodity	Isopyrazam (SYN534968 + SYN534969)		
	Sample Residue (mg/kg)	Total Residue (mg)	% Recovered as a Proportion of Initial Residue
Balance study 1 - S09-01531-01			
Carrot roots prior to processing *	0.158	1.029	100
Carrot roots sub-specimen *	0.158	0.241	23.4
Wash water	0.028	0.302	29.3
Peeled carrot sub-specimen	0.007 **	0.007 **	0.7
Peels	0.461	0.420	40.8
Peels lost on peeling (calculated)	0.461	0.097	9.5
Blanched carrot sub-specimen	NC	NC	NC
Blanched carrot not used for canning (calculated)	NC	NC	NC
Canned carrot sub-specimen	NC	NC	NC
Canned carrot after sterilisation sub-specimen	NC	NC	NC
Balance (carrot roots + wash water + peeled carrots + peels + lost peels + blanched carrot + blanched carrot used for canning + canned carrot + canned carrot after sterilisation)			103.7
Balance study 2 - S09-01531-02			
Carrot roots prior to processing *	0.165	1.242	100
Carrot roots sub-specimen *	0.165	0.259	20.9
Wash water	0.016	0.249	20.1
Peeled carrot sub-specimen	0.008 **	0.008 **	0.7
Peels	0.390	0.420	33.8
Peels lost on peeling (calculated)	0.390	0.053	4.2

Commodity	Isopyrazam (SYN534968 + SYN534969)		
	Sample Residue (mg/kg)	Total Residue (mg)	% Recovered as a Proportion of Initial Residue
Blanched carrot sub-specimen	NC	NC	NC
Blanched carrot not used for canning (calculated)	NC	NC	NC
Canned carrot sub-specimen	NC	NC	NC
Canned carrot after sterilisation sub-specimen	NC	NC	NC
Balance (carrot roots + wash water + peeled carrots + peels + lost peels + blanched carrot + blanched carrot used for canning + canned carrot + canned carrot after sterilisation)			79.6

* - Mean of two samples for SYN534968 and SYN534969.

** - SYN534969 only; SYN534968 residues <LOQ.

NC - Not calculated as residue was less than the LOQ.

Table 38 Isopyrazam residues in carrot roots and processed commodities during processing into puree - Balance calculations

Commodity	Isopyrazam (SYN534968 + SYN534969)		
	Sample Residue (mg/kg)	Total Residue (mg)	% Recovered as a Proportion of Initial Residue
Balance study 1 - S09-01531-01			
Carrot roots prior to processing *	0.202	1.922	100
Carrot roots sub-specimen *	0.202	0.309	16.1
Peeled carrot	0.023	0.146	7.6
Peels	0.751	1.154	60.1
Peels lost on peeling (calculated)	0.751	0.088	4.6
Recovered water from cooking	NC	NC	NC
Cooked carrot sub-specimen	NC	NC	NC
Puree loss on sieving (calculated)	0.025	0.033	1.7
Raw puree sub-specimen	0.025	0.013	0.7
Waste	0.007 **	0.007 **	0.4
Puree sub-specimen	0.034	0.034	1.8
Balance (carrot roots + peeled carrots + peels + lost peels + cooking water + cooked carrots + puree (lost and recovered) + waste)			92.8
Balance study 2 - S09-01531-02			
Carrot roots prior to processing *	0.173	1.652	100
Carrot roots sub-specimen *	0.173	0.280	16.9
Peeled carrot	0.029	0.030	1.8
Peels	0.915	0.972	58.8
Peels lost on peeling (calculated)	0.915	0.044	2.7
Recovered water from cooking	NC	NC	NC
Cooked carrot sub-specimen	0.007 **	0.007 **	0.4
Puree loss on sieving (calculated)	NC	NC	NC
Raw puree sub-specimen	NC	NC	NC
Waste	NC	NC	NC
Puree sub-specimen	0.018	0.018	1.1
Balance (carrot roots + peeled carrots + peels + lost peels + cooking water + cooked carrots + puree (lost and recovered) + waste)			81.7

* - Mean of two samples for SYN534968 and SYN534969.

** - SYN534969 only; SYN534968 residues <LOQ.

NC - Not calculated as residue was less than the LOQ.

Residues of isopyrazam in carrot root prior to processing and in processed commodities together with the calculated processing factors are presented below.

Table 39 Isopyrazam residues in carrot juice, canned carrot and carrot puree, intermediates and by-products

Process		Isopyrazam residue in crop before processing* (mg/kg)	Isopyrazam residue in processed commodity (mg/kg)	Processing factor
Washing				
Balance 1	Wash water	0.178	0.041	0.23
	Washed carrot	0.178	0.132	0.74
Balance 2	Wash water	0.139	0.026	0.19
	Washed carrot	0.139	0.106	0.77
Follow-up 1	Washed carrot	0.217	0.161	0.74
Follow-up 2	Washed carrot	0.147	0.081	0.55
Juice processing				
Balance 1	Washed carrot	0.253	0.171	0.68
	Raw juice	0.253	0.061	0.24
	Wet pomace	0.253	0.289	1.14
	Dry pomace	0.253	1.669	6.61
	Juice	0.253	0.034	0.13
Balance 2	Washed carrot	0.155	0.093	0.60
	Raw juice	0.155	0.072	0.47
	Wet pomace	0.155	0.150	0.97
	Dry pomace	0.155	1.062	6.87
	Juice	0.155	0.052	0.34
Follow-up 1	Wet pomace	0.190	0.298	1.57
	Dry pomace	0.190	2.330	12.30
	Juice	0.190	0.029	0.15
Follow-up 2	Wet pomace	0.151	0.153	1.01
	Dry pomace	0.151	1.111	7.36
	Juice	0.151	0.033	0.22
Canned carrot processing				
Balance 1	Peels	0.159	0.461	2.91
	Peeled carrot	0.159	0.012	0.08
	Blanched carrot	0.159	0.010 **	0.06
	Canned carrot	0.159	0.010 **	0.06
	Canned carrot after sterilisation	0.159	0.010 **	0.06
Balance 2	Peels	0.165	0.390	2.36
	Peeled carrot	0.165	0.013	0.08
	Blanched carrot	0.165	0.010 **	0.06
	Canned carrot	0.165	0.010 **	0.06
	Canned carrot after sterilisation	0.165	0.010 **	0.06
Follow-up 1	Peeled carrot	0.201	0.010 **	0.05
	Canned carrot after sterilisation	0.201	0.010 **	0.05
Follow-up 2	Peeled carrot	0.146	0.010 **	0.07
	Canned carrot after sterilisation	0.146	0.010 **	0.07
Carrot puree processing				
Balance 1	Peels	0.201	0.751	3.74
	Peeled carrot	0.201	0.023	0.11
	Cooked carrot	0.201	0.010	0.05
	Raw puree	0.201	0.025	0.12
	Puree	0.201	0.034	0.17
Balance 2	Peels	0.174	0.915	5.27
	Peeled carrot	0.174	0.029	0.17
	Cooked carrot	0.174	0.012	0.07
	Raw puree	0.174	0.010 **	0.06
	Puree	0.174	0.018	0.10
Follow-up 1	Puree	0.141	0.021	0.15
Follow-up 2	Puree	0.169	0.019	0.11
Mean Processing factors				
Washed carrots (n = 6)				0.68
Wet pomace (n = 4)				1.18
Dry pomace (n = 4)				8.28

Process	Isopyrazam residue in crop before processing* (mg/kg)	Isopyrazam residue in processed commodity (mg/kg)	Processing factor
Juice (n = 4)			0.21
Canned carrots (n = 4)			0.06
Carrot puree (n = 4)			0.13

* - Total of the mean residue of two samples for each isomer

** - In cases where both the individual isomer residues were below the LOQ, the total residue is expressed as being less than twice the LOQ (i.e. < 0.010 mg/kg).

Table 40 Isopyrazam processing factors in processed carrot commodities

Commodity	Measured processing factors				Mean processing factor
	Balance study 1	Balance study 2	Follow-up study 1	Follow-up study 2	
Wet pomace	1.1	0.97	1.6	1.0	1.2
Dry pomace	6.6	6.9	12.3	7.4	8.3
Juice	0.13	0.34	0.15	0.22	0.21
Canned carrots*	0.06	0.06	0.05	0.07	0.06
Carrot puree	0.17	0.10	0.15	0.11	0.13

* - After sterilisation

Processing of oilseed rape

The processing of rape seed from a field trial into rapeseed oil and intermediate products was studied (Tessier, V., 2015, Report No. S11-01425). Two residue field trials on oil seed rape were conducted in northern France and the UK during 2011. Isopyrazam containing 125 g of isopyrazam per litre EC was applied to oil seed rape twice at rate of 500 g ai/ha. Following the final application treated and untreated samples were collected at harvest.

Oil seed rape seed was processed to oil, presscake and refined oil. One balance study and one follow-up study were carried out for each field trial. The following fractions were produced for analysis; oil seed rape cleaned seed, heated seeds, pressed crude oil, extracted crude oil, combined crude oil, waste and waste (soap). Field samples and processing samples were analysed for isopyrazam (SYN520453 as SYN534968 and SYN534969) using analytical method GRM006.01B and CSCD459488 and CSCD459489 using analytical method GRM006.03A. Mass balances and processing factors for isopyrazam (SYN520453 as SYN534968 and SYN534969), CSCD459488 and CSCD459489 were calculated.

Residues of SYN534969 in the pre-processing seeds samples were in the range 0.006 to 0.007 mg/kg. Residues of SYN534968 in the pre-processing seeds samples were in the range below the limit of quantification (0.005 mg/kg) to 0.008 mg/kg. Residues of CSCD459488 in the pre-processing seeds samples were in the range 0.012 to 0.018 mg/kg. No residues of CSCD459489 were detected at or above the limit of quantification (0.005 mg/kg) in the pre-processing seeds samples.

Residues of SYN534969 in oil seed rape refined oil ranged from 0.008 to 0.020 mg/kg. Residues of SYN534968 in oil seed rape refined oil ranged below the limit of quantification (0.005 mg/kg) to 0.026 mg/kg. No residues of CSCD459488 and CSCD459489 in oil seed rape refined oil were determined at or above the LOQ (0.005 mg/kg).

Relevant industrial practices and standardized procedures were applied to simulate the common processes used by industry for production of presscake and refined oil. The processing procedures followed industrial and domestic food processing technologies adapted to residue studies in smaller volumes.

Oil seed rape preparation

The oil seed rape seed samples were prepared on 06 July and 08 August 2011. The oil seed rape seed specimens were prepared using a single grading unit. The cleaned seed was dried in an oven set at 60 °C for at least 12 hours before pressing. For the mass balance trials, oil seed rape waste, cleaned seeds and heated seeds were sub-sampled and retained for analysis.

Oil seed rape pressed crude oil processing

The prepared seed was placed into the press. The presscake was collected in a plastic container placed at the press head exit and the crude oil was collected in a plastic bucket placed under the press head. For the mass balance trials, presscake was sub-sampled and retained for analysis.

Oil seed rape extracted crude oil processing

The presscake was further extracted for crude oil. The presscake was extracted on 22–25 August 2011 by the CREOL laboratory located in Pessac (France). The presscake specimens were removed from the freezer on 21 August 2011 and transported at ambient temperature by a car to Pessac. After receipt on 22 August 2011 at the CREOL laboratory, presscake specimens were placed in a cold room prior to extraction.

The extraction of the oil from presscake was performed in an extractor using hexane as a solvent. Hexane was injected through the presscake six times and collected. The presscake after extraction was kept at ambient for minimum 12 hours to permit the evaporation of the remaining hexane. The crude oil/solvent mixture (miscella) was heated to distil off the hexane, leaving the crude oil. The crude oil obtained after extraction was taken in plastic bottle and stored in a cold room. The unused presscake, crude oil and the extracted presscake were transported back to the Staphy processing laboratory (Marsillargues) on 25 August 2011 and stored in a cold room. At this time the pressed crude oil was removed from the freezer and placed into a cold room.

Oil seed rape refined oil processing

The crude oil was processed into refined oil on 29 August to 01 September, 02, 05, 06, 07, 08 and 12 to 16 September 2011. Prior to refining process, the pressed crude oil was combined with the solvent extracted crude oil. Soda was added to the combined crude oil and was mixed for a minimum of 30 minutes in an oven (80–90 °C). The mixture was allowed to settle for approximately 30 minutes after which the oil was centrifuged. The centrifuged oil was placed into a reactor and heated to approximately 240 °C for approximately 1 hour. The refined oil was allowed to cool and was filtered.

For the mass balance trials combined crude oil, waste (soap) and cooled waste were sub-sampled and retained for analysis. For all trials, refined oil sub-specimens were retained for analysis.

Material mass balances of 98% and 90% were obtained for isopyrazam through the processes investigated in oil processing. Recoveries of the initial residues are summarised below.

Table 41 Processing factors in processed rape seed commodities

Process	Residues mg/kg					
	Trial S11-01425-SRFR11-006-37FRb			Trial S11-01425-SRUK11-002-37FRb		
	Pre-processing	Pressed crude oil	Refined oil	Pre-processing	Pressed crude oil	Refined oil
Balance						
SYN534968	0.0045	0.0045	0.007	0.0085	0.018	0.014
SYN534969	0.007	0.009	0.014	0.0075	0.014	0.012
CSCD459488	0.0185	< 0.005	< 0.005	0.02	< 0.005	< 0.005
SYN534968+ SYN534969	0.0115	0.0135	0.021	0.016	0.032	0.026
Processing factor of isopyrazam		1.17	1.83		2	1.33
SYN534968+ SYN534969+	0.03	0.014	0.026	0.036	0.037	0.031

Process	Residues mg/kg					
	Trial S11-01425-SRFR11-006-37FRb			Trial S11-01425-SRUK11-002-37FRb		
	Pre-processing	Pressed crude oil	Refined oil	Pre-processing	Pressed crude oil	Refined oil
CSCD459488						
Processing factor		0.47	0.87		1.03	0.86
Follow up						
SYN534968	0.004		< 0.005	0.009		0.026
SYN534969	0.006		0.008	0.0075		0.020
CSCD459488	0.02		< 0.05	0.024		< 0.005
SYN534968+ SYN534969	0.01		0.013	0.0165		0.046
Processing factor of isopyrazam			1.3			2.79
SYN534968+ SYN534969+ CSCD459488	0.03		0.018	0.0405		0.051
Processing factor			0.6			1.26

The processing factors of isopyrazam from rape seed to pressed crude oil were 1.17 and 2 (mean 1.59), from rape seed to refined oil were 1.83, 1.33, 1.3, 2.79 (mean 1.81). The processing factors of isopyrazam and CSCD459488 from rape seed to pressed crude oil were 0.47 and 1.03 (mean 0.75), from rape seed to refined oil were 0.87, 0.86, 0.6, 1.26 (mean 0.90). Residues of CSCD459489 were not found at or above the LOQ (0.005 mg/kg). The processing factors were not calculated.

Processing of cereals

The processing of barley for brewing and production of pot barley and the processing of wheat to produce flour type 550, wholemeal flour, wholemeal bread, and wheat germ were previously evaluated by the 2011 JMPR. Processing factors are summarised below.

Table 42 Processing factors for Isopyrazam in cereals

Crop	Commodity	Median processing factors	
		Isopyrazam*	Isopyrazam and CSCD459488**
Barley	Malt	0.50	0.59
	Spent grain	0.82	0.54
	Spent yeast	< 0.13	0.13
	Beer	< 0.13	< 0.12
	Pot barley	0.37	0.33
Wheat	Middlings	1.46	1.99
	Bran (total)	4.07	4.39
	Toppings	1.53	1.62
	Type 550 flour	0.20	0.23
	Wholemeal flour	0.73	0.81
	Wholemeal bread	0.50	0.55
	Wheat germ	0.19	0.25

* - According to the residue definition for enforcement (*anti*-isomer + *syn*-isomer)

** - According to the residue definition for risk assessment (*anti*-isomer + *syn*-isomer + CSCD459488)

A summary of all available processing factors is provided below.

Table 43 Overall summary of processing factors

Crop	Commodity	Mean/Median Processing factor	
		Isopyrazam*	Isopyrazam and CSCD459488**
Apple	Washed fruit	0.77	0.77
	Sauce	0.18	0.19
	Wet pomace	2.49	2.48
	Dry pomace	5.51	5.55
	Juice	0.02	0.03
	Canned fruit	0.05	0.06
	Dried fruit	6.03	5.95
Tomato	Wet pomace	3.1	NC
	Dry pomace	32	NC
	Juice	0.5	NC
	Puree	5.1	NC
	Paste	6.4	NC
	Canned tomato	0.19	NC
	Ketchup	4.2	NC
	Sun-dried tomato	11	NC
Carrot	Wet pomace	1.2	NC
	Dry pomace	8.3	NC
	Juice	0.21	NC
	Canned carrots	0.06	NC
	Carrot puree	0.13	NC
Oilseed rape	Pressed crude oil	1.59***	0.75**
	Refined oil	1.81***	0.9***
Barley	Malt	0.50	0.59
	Spent grain	0.82	0.54
	Spent yeast	<0.13	0.13
	Beer	<0.13	<0.12
	Pot barley	0.37	0.33
Wheat	Middlings	1.46	1.99
	Bran (total)	4.07	4.39
	Toppings	1.53	1.62
	Type 550 flour	0.20	0.23
	Wholemeal flour	0.73	0.81
	Wholemeal bread	0.50	0.55
	Wheat germ	0.19	0.25

* - According to the residue definition for enforcement (anti-isomer + syn-isomer).

** - According to the residue definition for risk assessment (anti-isomer + syn-isomer + CSCD459488).

*** - Sum of individual processing factors (anti-isomer + syn-isomer) or (anti-isomer + syn-isomer + CSCD459488).

NC - Not calculable.

APPRAISAL

Isopyrazam is a broad-spectrum foliar fungicide belonging to the chemical class of ortho-substituted phenyl amides. It controls a wide range of fungal pathogens. Isopyrazam was first evaluated by the JMPR as a new compound in 2011. An ADI of 0–0.06 mg/kg bw/day and an ARfD of 0.3 mg/kg bw were established. The residue definitions were established: for compliance with MRLs for plant commodities: *Isopyrazam (sum of syn-isomer and anti-isomer)*; for risk assessment for plant commodities: *Sum of isopyrazam and 3-difluoromethyl-1-methyl-1H-pyrazole-4-carboxylic acid [9-(1-hydroxyl-1-methylethyl)-(1RS, 4RS, 9RS)-1,2,3,4-tetrahydro-1,4-methanonaphthalen-5-yl] amide(CSCD459488)*, expressed as isopyrazam; for animal commodities (enforcement and risk assessment): *Isopyrazam (sum of syn-isomer and anti-isomer)*. The residue is fat-soluble.

Isopyrazam was scheduled by the 48th Session of the CCPR for evaluation by the 2017 JMPR for additional MRLs. The Meeting received information on registered labels and supporting residue trials data for pome fruits, stone fruits, cucurbits, peppers, tomato, carrot, barley, wheat, rape seed and peanut as well as studies on the storage stability of CSCD459488 and processing studies.

Methods of analysis

The analytical methods used in the trials (GRM006.01B, GRM006.03A) were reviewed by the 2011 JMPR and considered suitable as data collection methods. In general, the methods employ extraction by homogenization with a mixture of acetonitrile and water (mostly 80:20 v/v), clean-up with solid phase extraction or a process of centrifugation and dilution, and determination of analytes using LC-MS/MS or GC-MS/MS.

Stability of residues in stored analytical samples

The stability of residues of isopyrazam (both isomers) and metabolites CSCD459488, CSCD 459489, CSCD465008, and CSAA 798670 during frozen storage (-15 to -20 °C) was evaluated by the 2011 JMPR. The stability of residues of each analyte spiked at 0.5 mg/kg was investigated in tomato, oilseed rape seeds, lentil seeds, potato tubers, barley grain and straw, ryegrass forage and spinach leaves and the animal commodities milk, eggs, liver, kidney, muscle and fat. Isopyrazam (both isomers) was stable for at least 24 months in all plant matrices. CSCD459488 and other metabolites were stable for at least 11 months during frozen storage. Both isomers of isopyrazam were stable for at least 14 months in animal commodities, the metabolites hydrolysable to CSAA798670 were stable for at least 12 months.

The current Meeting received information on the stability of metabolite CSCD459488 in wheat grain and straw, rape seed, apple fruit, lentils, orange fruit, spinach and carrot stored at a temperature of -200 ± 5 °C. The residues of CSCD459488 spiked at a level of 0.5 mg/kg were stable in all tested commodities in storage for at least 28 months. The tested commodities covered representatives of all five crop sample types i.e. high water, high acid, high oil, high protein and high starch containing materials. Therefore, residues of CSCD459488 are expected to be stable in all crop commodities, when stored at -200 ± 5 °C, for at least 28 months.

Results of supervised residue trials on crops

The Meeting received supervised trial data for isopyrazam on apple, apricot, peach, cucumber and summer squash, melon, peppers (sweet), cherry tomato, carrot, barley, wheat, rape seed (canola) and peanut.

Pome fruits

Apple

The GAP for on pome fruit in Chile is 2 foliar applications of 150 g ai/ha with a PHI of 21 days. In trials conducted in Europe matching the Chilean GAP, residues of isopyrazam in apples were (n=16): 0.026, 0.031, 0.047, 0.050, 0.062, 0.092, 0.093, 0.11, 0.12, 0.12, 0.14, 0.15, 0.17, 0.19, 0.20 and 0.24 mg/kg. For dietary assessment, total residues (isopyrazam plus CSCD459488, expressed as isopyrazam) were (n=16): 0.031, 0.036, 0.052, 0.055, 0.067, 0.097, 0.098, 0.12, 0.12, 0.13, 0.15, 0.16, 0.18, 0.19, 0.21 and 0.24 mg/kg.

The Meeting estimated a maximum residue level of 0.4 mg/kg based on residues of isopyrazam, estimated an STMR of 0.12 mg/kg and an HR of 0.24 mg/kg based on total residues. The Meeting estimated a median residue for animal burden calculations of 0.115 mg/kg based on residues of parent. As the Chile GAP is for pome fruit, the Meeting agreed to extrapolate the maximum residue level, STMR and HR of apples to pome fruits.

*Stone fruits**Apricot and Peach*

The GAP for apricot and peach in Turkey is 2 foliar applications of 10 g ai/hL with a PHI of 7 days for peach and 21 days for apricot. In trials conducted in France, Italy and Spain matching the Turkish GAP, the residues of isopyrazam in peach fruit were (n=4): 0.080, 0.18, 0.25 and 0.39 mg/kg, the total residues were (n=4): 0.085, 0.18, 0.26 and 0.40 mg/kg. The Meeting concluded that four trials were insufficient for the estimation of a maximum residue level.

*Fruiting vegetables, Cucurbits**Cucumber*

The GAP for cucumber and summer squash (protected) in the UK is 2 foliar applications at a rate of 12.5 g ai/hL, up to 1000 L/ha (maximum of 125 g ai/ha) with a PHI of 1 day. In trials conducted in Europe matching the UK GAP, the residues of isopyrazam in protected cucumber were (n=8): < 0.010, 0.010, 0.012, 0.013, 0.015, 0.017, 0.025 and 0.036 mg/kg. The total residues in cucumber were (n=8): 0.021, 0.022, 0.023(2), 0.024(2), 0.030 and 0.041 mg/kg.

The Meeting estimated the maximum residue level of 0.06 mg/kg, STMR of 0.0235 mg/kg and HR of 0.041 mg/kg for cucumber.

Melons

The GAP for melon and watermelon (protected) in the UK is 2 foliar applications at rate of 12.5 g ai/hL, up to 1000 L/ha (maximum of 125 g ai/ha) with a PHI of 7 days. In trials conducted in Europe matching the UK GAP, the residues of isopyrazam in protected melon (whole fruit) were (n=8): 0.012, 0.013, 0.014, 0.017(2), 0.022, 0.031 and 0.10 mg/kg, the total residues in melon flesh were (n=8): < 0.015(8) mg/kg.

The Meeting estimated the maximum residue level of 0.15 mg/kg for melons except watermelon, STMR of 0.015 mg/kg and HR of 0.015 mg/kg for melon flesh.

*Fruit vegetable, other than Cucurbits**Peppers*

The GAP for on protected sweet peppers and chili peppers in the UK is 2 foliar applications at rate of 12.5 g ai/hL, up to 1000 L/ha (maximum of 125 g ai/ha) with a PHI of 3 days. In trials conducted in Europe matching the UK GAP, the residues of isopyrazam in sweet peppers were (n=8): < 0.010, 0.019, 0.021, 0.023, 0.039, 0.028, 0.036 and 0.045mg/kg, the total residues in sweet peppers were (n=8): < 0.015, 0.024, 0.026, 0.028, 0.033, 0.041, 0.044 and 0.050 mg/kg.

The Meeting agreed to recommend the maximum residue level of 0.09 mg/kg, STMR of 0.0305mg/kg and HR of 0.050 mg/kg for sweet peppers.

Tomato

The GAP for tomato and eggplant (protected) in the UK allows 2 foliar applications at rate of 12.5 g ai/hL, up to 1000 L/ha (maximum of 125 g ai/ha) with a PHI of 1 day. In trials conducted in Europe matching the UK GAP, the residues of isopyrazam in cherry tomato were (n=8): 0.017, 0.018, 0.025, 0.048, 0.049, 0.13, 0.19 and 0.23 mg/kg, and the total residues in cherry tomato were (n=8): 0.022, 0.023, 0.030, 0.053, 0.054, 0.14, 0.20 and 0.23 mg/kg.

The Meeting estimated the maximum residue level of 0.4 mg/kg, STMR of 0.0535 mg/kg and HR of 0.23 mg/kg for cherry tomato. The Meeting estimated a median residue of 0.0485 mg/kg for animal burden calculation. The Meeting noted residues in cherry tomato are normally higher than tomato, and agreed to extrapolate the MRL, STMR and HR to tomato and to the subgroup of eggplants.

*Root and tuber vegetables**Carrot*

The GAP for carrot in the UK is 2 foliar applications at rate of 125 g ai/ha with a PHI of 14 days. In trials conducted in Europe matching the UK GAP, the residues of isopyrazam in carrot root were (n=16): < 0.010(4), 0.010(2), 0.011, 0.015, 0.019, 0.025, 0.029, 0.037, 0.054, 0.055, 0.075 and 0.099 mg/kg, and the total residues in carrot root were (n=16): < 0.015(4), 0.015(2), 0.016, 0.020, 0.024, 0.030, 0.034, 0.042, 0.059, 0.060, 0.080 and 0.10 mg/kg.

The Meeting estimated the maximum residue level of 0.15 mg/kg, STMR of 0.022 mg/kg and HR of 0.10 mg/kg for carrot.

*Cereal grains**Barley*

The GAP for barley in the UK is 2 foliar applications at rate of 125 g ai/ha before beginning of flowering (first anthers visible, BBCH 61). In trials conducted in Europe matching the UK GAP, the residues of isopyrazam in barley grains were (n=13): < 0.010, 0.014, 0.015, 0.016, 0.024(2), 0.026, 0.035, 0.046, 0.15, 0.17, 0.27 and 0.41 mg/kg, and the total residues in barley grains were (n=13): 0.018, 0.020(2), 0.031, 0.042, 0.047, 0.051, 0.057, 0.061, 0.20, 0.22, 0.36 and 0.43 mg/kg.

The Meeting estimated a maximum residue level of 0.6 mg/kg to replace the previous recommendation of 0.07 mg/kg, an STMR of 0.051 mg/kg, and a median residue of 0.026 mg/kg for the calculation of animal burden for barley.

Wheat

The GAP for wheat, rye and triticale in the UK is 2 foliar applications at a rate of 125 g ai/ha before grain watery ripe stage (BBCH 71). In trials conducted in Europe matching the UK GAP, the residues of isopyrazam in wheat grain were (n=8): < 0.010(5), 0.010, 0.013, 0.014 mg/kg, the total residues were < 0.015(5), 0.015, 0.018 and 0.019 mg/kg.

The Meeting confirmed the previous maximum residue level recommendation of 0.03 mg/kg, STMR of 0.015 mg/kg and median residues of 0.01 mg/kg for wheat, triticale and rye.

*Oil seeds**Rape seed (canola)*

The GAP for oilseed rape in the UK allows 1 foliar application at rate of 125 g ai/ha up to the end of flowering (BBCH 71). In trials conducted in Europe matching the UK GAP, the residues of isopyrazam in rape seed were (n=20): < 0.010(3), 0.010, 0.012, 0.013(2), 0.016, 0.033, 0.035, 0.038, 0.052, 0.055, 0.058, 0.068(3), 0.086, 0.090 and 0.094 mg/kg, the total residues in rape seed were (n=20): < 0.015, 0.015, 0.018(3), 0.021, 0.023, 0.038(2), 0.040, 0.043, 0.060, 0.063, 0.073(2), 0.075, 0.091, 0.095, 0.099 and 0.292 mg/kg.

The Meeting estimated a maximum residue level of 0.2 mg/kg and an STMR of 0.0415 mg/kg mg/kg for rape seed.

Peanut

The GAP for peanut in Nicaragua allows 2 foliar application at rate of 100–125 g ai/ha with PHI of 7 days. In trials conducted in Nicaragua (3 application at 125 g ai/ha), the residues of isopyrazam in peanuts were (n=4): < 0.010(4) mg/kg, and the total residues in peanut seeds were (n=4): < 0.015(4) mg/kg.

The Meeting estimated a maximum residue level of 0.01* mg/kg and an STMR of 0.015 mg/kg mg/kg for peanut.

Animal feedstuffs*Cereal forage*

The GAP for barley (up to BBCH 61), wheat, rye and triticale (up to BBCH 71) in UK allows 2 foliar applications at rate of 125 g ai/ha. As no livestock feeding withholding periods are specified. The Meeting used the residue values from 0-day whole plant samples to estimate median and highest residues. In trials conducted in Europe matching the UK GAP, the residues of isopyrazam in barley forages were (n=9): 2.1, 2.3, 2.9, 3.1, 3.5, 3.5, 3.9, 5.0 and 5.5 mg/kg. Residues of isopyrazam in wheat forages were (n=4): 1.9, 2.1, 2.1, 2.3 mg/kg.

Based on the combined data sets for the wheat and barley forage (1.9, 2.1, 2.1, 2.1, 2.3, 2.3, 2.9, 3.1, 3.5, 3.5, 3.9, 5.0 and 5.5 mg/kg), the Meeting estimated a median residues of 2.9 mg/kg and highest residues of 5.5 mg/kg for wheat and barley forage, and agreed to extrapolate these estimates to rye, and triticale forage, and to replace previous recommendation.

Cereal straw and fodder, dry

The GAP for barley (application up to BBCH 61), wheat, rye and triticale (application up to BBCH 71) in the UK allows for 2 foliar applications at a rate of 125 g ai/ha. No livestock feeding withholding periods are specified. In trials conducted in Europe matching the UK GAP, the residues of isopyrazam in barley straw were (n=13): 0.13, 0.13, 0.15, 0.26, 0.35, 0.45, 0.84, 1.1, 1.4, 2.5, 3.5, 5.9 and 6.9 mg/kg. Residues of isopyrazam in wheat straw were (n=8): 0.051, 0.29, 0.62, 0.75, 0.97, 3.6, 4.2 and 5.5 mg/kg.

Based on the combined data sets for the wheat and barley straw (0.051, 0.13, 0.13, 0.15, 0.26, 0.29, 0.35, 0.45, 0.62, 0.75, 0.84, 0.97, 1.1, 1.4, 2.5, 3.5, 3.6, 4.2, 5.5, 5.9, 6.9 mg/kg), the Meeting estimated a maximum residue level of 15 mg/kg dw), median residues of 0.84 mg/kg and highest residues of 6.9 mg/kg for wheat and barley straw, and agreed to extrapolate these estimates to rye and triticale straw, and to replace previous recommendation of 3 mg/kg.

Fate of residues during processing

The Meeting received information on processing of apple, tomato, carrot and rape seed. Processing factors were calculated for the corresponding processed food commodities and are shown in the table below, together with those calculated by the 2011 JMPR for the commodities considered at this Meeting. STMR-Ps or HR-Ps were calculated for the processed corresponding commodities which are consumed as foods.

Crop	Commodity	Mean/Median Processing factor		STMR or STMR-P*** mg/kg	HP or HR-P mg/kg
		Isopyrazam*	Isopyrazam and CSCD459488**		
Barley (2011 JMPR)	RAC			0.051	
	Malt	0.55	0.59	0.03	
	Beer	< 0.13	< 0.12	0.061	
	Pot barley	0.37	0.33	0.17	
Wheat (2011 JMPR)				0.015	
	Bran (unprocessed)	4.07	4.39	0.066	
	White flour	0.20	0.23	0.0035	
	Whole meal flour	0.73	0.81	0.012	
	Whole meal bread	0.50	0.55	0.0083	
	Wheat germ	0.19	0.25	0.0038	
Apple	RAC			0.12	0.24
	Washed fruit	0.77	0.77	0.092	0.18
	Sauce	0.18	0.19	0.023	
	Juice	0.02	0.03	0.0036	
	Canned fruit	0.05	0.06	0.0071	0.014
	Dried fruit	6.03	5.95	0.71	1.4

Crop	Commodity	Mean/Median Processing factor		STMR or STMR-P*** mg/kg	HP or HR-P mg/kg
		Isopyrazam*	Isopyrazam and CSCD459488**		
Tomato	RAC			0.0535	0.23
	Juice	0.5	NC		
	Puree	5.1	NC		
	Paste	6.4	NC		
	Canned tomato	0.19	NC		
	Ketchup	4.2	NC		
	Sun-dried tomato	11	NC		
Rape seed	RAC			0.042	
	Pressed crude oil	1.59	0.75	0.032	
	Refined oil	1.81	0.9	0.038	

* - According to the residue definition for enforcement (anti-isomer + syn-isomer).

** - According to the residue definition for risk assessment (anti-isomer + syn-isomer + CSCD459488).

***STMR-P is calculated with processing factor of isopyrazam and CSCD459488.

NC - Not calculable.

Processing factors were calculated for the corresponding processed commodities used for feed and are shown in the table below for the commodities considered at this Meeting. Processed Median Residue or Highest residue were calculated for the processed corresponding commodities which were used for the calculation of animal burdens.

Crop	Commodity	Mean/Median Processing factor		Median Residue -P** mg/kg
		Isopyrazam*		
Apple	RAC			0.115
	Wet pomace	2.49		0.28
	Dry pomace	5.51		0.63
Tomato	RAC			0.0485
	Wet pomace	3.1		0.15
	Dry pomace	32		1.6

* - According to the residue definition for animal commodities (anti-isomer + syn-isomer).

** Processed Median Residues and highest Residues are calculated with processing factor of isopyrazam.

As residues in apple dried fruit are higher than residues in apple fruit, the Meeting estimated a maximum residue level of 3 mg/kg for apple, dried by multiplying the maximum residue level for apple fruit (0.4 mg/kg) by 6.03.

As residues in sun-dry tomato are higher than residues in tomato fruit, the Meeting estimated a maximum residue level of 5 mg/kg for dry tomato by multiplying the maximum residue level for tomato fruit (0.4 mg/kg) by 11.

Residues in animal commodities

Farm animal dietary burden

Potential cattle feed items include: grain, straw and forage of barley, wheat, rye and triticale, apple pomace, tomato pomace and carrot culls that may be fed to dairy cattle, beef cattle, broilers and layers. The maximum and mean dietary burden were calculated using the highest residues or median residue of isopyrazam estimated using the OECD diets listed in Appendix IX of the 2016 edition of the FAO Manual.

Summary of livestock dietary burden (ppm isopyrazam equivalents of dry matter diet)

	US-Canada		EU		Australia		Japan	
	Max	Mean	Max	mean	max	Mean	max	Mean
Beef cattle	0.80	0.11	6.52	3.47	22 ^a	11.6 ^c	0.021	0.021
Dairy cattle	4.57	2.42	6.44	3.40	14.09 ^b	7.14 ^c	0.012	0.012
Broilers	0.022	0.022	0.103	0.035	0.004	0.004	0.003	0.003
Layers	0.022	0.022	2.307 ^{ef}	1.202 ^{ef}	0.004	0.004	-	-

^A Highest maximum beef or dairy cattle dietary burden suitable for MRL estimates for mammalian meat

^B Highest maximum dairy cattle dietary burden suitable for MRL estimates for mammalian milk

^C Highest mean beef or dairy cattle dietary burden suitable for STMR estimates for mammalian meat.

^D Highest mean dairy cattle dietary burden suitable for STMR estimates for milk.

^E Highest maximum poultry dietary burden suitable for MRL estimates for poultry meat and eggs

^F Highest mean poultry dietary burden suitable for STMR estimates for poultry meat and eggs

Residues in milk and cattle tissues

Feeding study on lactating dairy cow were evaluated by 2011 JMPR, the residues of isopyrazam in milk from all dose group (15, 42 and 137 ppm in diet) were less than 0.01 mg/kg. The residues in low and median dose groups were: < 0.01–0.01 for muscle, 0.01–0.036 for liver, < 0.01–0.012 for kidney, < 0.01–0.053 for fat.

The calculation used to estimate highest total residues for use in estimating maximum residue levels, STMR and HR values for cattle matrices is shown below.

	Feed level ppm for milk residues	Residues (mg/kg) in milk	Residues (mg/kg) in cream	Feed level (ppm) for tissue residues	Residue (mg/kg)			
					Muscle	liver	Kidney	Fat
MRL (mg/kg); beef or dairy cattle								
Feeding study	15	< 0.01	0.01	15	< 0.01	0.01	< 0.01	< 0.01
				42	0.01	0.036	0.012	0.053
Dietary burden and high residue estimation	14.09	< 0.01	< 0.01	22	< 0.01	0.017	0.0106	0.0211
STMR (mg/kg). beef or dairy cattle								
Feeding study	15	< 0.01	0.01	15	< 0.01	0.01	< 0.01	< 0.01
Dietary burden and median residue estimated	7.14	< 0.01	< 0.01	11.63	< 0.01	< 0.01	< 0.01	< 0.01

The Meeting estimated a maximum residue level of 0.03 mg/kg for mammalian fat, a maximum residue level of 0.03 mg/kg (fat) for mammalian meat, to replace the previous recommendation (0.01* mg/kg for fat, 0.01* mg/kg for meat), and confirmed a maximum residue level of 0.02 mg/kg for edible offal (mammalian) and milk fat, and a maximum residue level of 0.01* mg/kg for isopyrazam in milk. The Meeting estimated an STMR of 0.01 mg/kg respectively for milk, mammalian meat, edible offal (mammalian) and mammalian fat and milk fat.

Residues in eggs and poultry tissues

No feeding study on laying hens was available. In a hen metabolism study conducted at a dose of 11 ppm dry matter in feed, the residues in extracts of egg white, egg yolk, meat, liver, skin and attached fat, and peritoneal fat were less than 0.004 mg/kg. The calculated maximum and mean dietary burdens for poultry were 2.31 and 1.20 ppm, significantly higher than the burdens calculated by the 2011 JMPR, but significantly lower than 11ppm, the Meeting confirmed the maximum residue levels of

0.01*mg/kg and STMRs of 0.01 mg/kg for isopyrazam in eggs, poultry meat, edible offal of poultry and fat.

RECOMMENDATION

On the basis of the data from supervised trials the Meeting concluded that the residue levels listed below are suitable for establishing maximum residue limits and for IEDI/IESTI assessment.

The definition of the residue (for compliance with MRLs) for plant commodities: *Isopyrazam (sum of syn-isomer and anti-isomer)*.

The definition of the residue (for estimation of dietary intake) for plant commodities: *Sum of isopyrazam and 3-difluoromethyl-1-methyl-1H-pyrazole-4-carboxylic acid [9-(1-hydroxyl-1-methylethyl)-(1RS, 4RS, 9RS)-1,2,3,4-tetrahydro-1,4-methanonaphthalen-5-yl] amide(CSCD459488), expressed as isopyrazam;*

The definition of the residue (for compliance with the MRLs and estimation of dietary intake) for animal commodities: *Isopyrazam (sum of syn-isomer and anti-isomer)*.

The residue is fat-soluble.

Table of MRL recommendations.

Commodity		Recommended MRL (mg/kg)		STMR or STMR-P (mg/kg)	HR, HR-P, highest residue (mg/kg)
CCN	Name	New	Previous		
FP 0009	Group of pome fruits	0.4		0.12	0.24
VC 0424	Cucumber	0.06		0.0235	0.041
VC 0046	Melon, except watermelon	0.15		0.015	0.015
VO 0445	Sweet peppers	0.09		0.0305	0.050
VO 2700	Cherry tomato	0.4		0.0535	0.23
VO 0448	Tomato	0.4		0.0535	0.23
VO 2046	Subgroup of eggplants	0.4		0.0535	0.23
VR 0577	Carrot	0.15		0.022	0.10
GC 0640	Barley	0.6	0.07	0.051	
GC 0654	Wheat	0.03	0.03	0.015	
GC 0650	Rye	0.03	0.03	0.015	
GC 0653	Triticale	0.03	0.03	0.015	
SO 0495	Rape seed	0.2		0.0415	
SO 0697	Peanut	0.01		0.015	
DF0226	Apple, dried	3		0.71	1.4
DV0448	Tomato, dried	5		0.5885	2.53
AS 0640	Barley straw and fodder, dry	15 (dw)	3		
AS 0650	Rye straw and fodder, dry	15 (dw)	3		
AS 0653	Triticale straw and fodder, dry	15 (dw)	3		
AS 0654	Wheat straw and fodder, dry	15 (dw)	3		
MF 0100	Mammalian fat except milk fat	0.03	0.01*	0.01	
MM 0095	Mammalian meat, other than marine mammalian	0.03(fat)	0.01*	0.01	
MO 0105	Edible offal, mammalian	0.02	0.02	0.01	
ML 0106	Milks	0.01*	0.01*	0.01	
FM 0183	Milk fats	0.02	0.02	0.01	

Table of additional STMR and HR values for use in dietary intake estimation.

Commodity		STMR or STMR-P (mg/kg)	HR, HR-P, highest residue (mg/kg)
CCN	Name		
JF 0226	Apple juice	0.0036	
FP 0226	Canned apple	0.0071	0.014
	Apple paste	0.023	-
FP 0226	Apple sauce/puree	0.023	
GC 0640	Barley malt	0.03	

GC 0640	Barley beer	0.061	
GC 0640	Pot barley	0.17	
OC 0495	Refined oil of rape seed	0.038	

Table of median and highest residue values for use in livestock dietary burden estimation.

Commodity CCN	Name	median residue (mg/kg)	HR, HR-P, highest residue (mg/kg)
GC 0640	Barley	0.026	
	Wheat	0.01	
	Forage of barley	2.9	5.5
	Forage of wheat	2.9	5.5
	Forage of rye	2.9	5.5
	Forage of triticale	2.9	5.5
AS 0640	Barley straw and fodder, dry	0.84	6.9
AS 0650	Rye straw and fodder, dry	0.84	6.9
AS 0653	Triticale straw and fodder, dry	0.84	6.9
AS 0654	Wheat straw and fodder, dry	0.84	6.9
AB 0226	Apple pomace, dry	0.66	1.3
	Apple pomace, wet	0.3	
	Tomato pomace, wet	0.15	
	Carrot	0.017	0.099

DIETARY RISK ASSESSMENT

Long-term dietary exposure

The IEDI of isopyrazam based on the STMRs estimated by this and previous Meetings for the 17 GEMS/Food regional diets were 0–1% of the maximum ADI of 0.06 mg/kg bw. The Meeting concluded that the long-term dietary exposure to residues of isopyrazam is unlikely to present a public health concern.

Short-term dietary exposure

The ARfD for isopyrazam is 0.3 mg/kg bw. The Meeting estimated the International Estimated Short-Term Intake (IESTI) of isopyrazam for commodities for which STMR, HR and maximum residue levels were estimated by the current Meeting. The IESTI represented a maximum of 6–10% of the ARfD. The Meeting concluded that the short-term dietary exposure to isopyrazam residues from uses considered by the current Meeting is unlikely to present a public health concern.

REFERENCE

Report No.	Author	Year	Title
T007495-05-REG	Gemrot, F.	2010	SYN520453 – Storage Stability of Metabolite CSCD459488 Residues in Crops Stored Deep Frozen for up to 28 Months Report No. T007495-05-REG, GLP, Unpublished Syngenta File No. SYN545364_11235
S13-03423	Dorange, J.B.	2014	Isopyrazam – Residue Study on Apple in Germany, Poland and Hungary in 2013. Report No. S13-03423, GLP, Unpublished Syngenta File No. A16524AA_10401
S13-03424	Dorange, J.B.	2014	Isopyrazam – Residue Study on Apple in Southern France, Spain, Portugal, Italy and Greece in 2013. Report No. S13-03424, GLP, Unpublished Syngenta File No. A16524AA_10402
S13-02498	Gemrot, F.	2014	Isopyrazam - Residue Study on Peach in Southern France, Spain and Italy in 2013.

Report No.	Author	Year	Title
S13-02499	Gemrot, F.	2014	Report No. S13-02498, GLP, Unpublished Syngenta File No. A16524AA_10399 Isopyrazam - Residue Study on Apricot in Spain and Italy in 2013.
S10-01551	Gemrot, F.	2011	Report No. S13-02499, GLP, Unpublished Syngenta File No. A16524AA_10400 Isopyrazam - Residue Study on Protected Cucumber in Northern France in 2010.
S10-01552	Gemrot, F.	2011	Report No. S10-01551, GLP, Unpublished Syngenta File No. A16934C_10009 Isopyrazam - Residue Study on Protected Cucumber in Southern Spain in 2010.
S11-00645	Tessier, V.	2012	Report No. S10-01552, GLP, Unpublished Syngenta File No. A16934C_10010 Isopyrazam - Residue Study on Protected Cucumber in the United Kingdom, Germany and Northern France in 2011.
S11-00646	Tessier, V.	2012	Report No. S11-00645, GLP, Unpublished Syngenta File No. A15149AC_11362 Isopyrazam - Residue Study on Protected Cucumber in Italy and Spain in 2011.
S10-01553	Gemrot, F.	2011	Report No. S11-00646, GLP, Unpublished Syngenta File No. A15149AC_11363 Isopyrazam - Residue Study on Protected Melon in Northern France in 2010.
S11-00647	Tessier, V.	2012	Report No. S10-01553, GLP, Unpublished Syngenta File No. A16934C_10019 Isopyrazam - Residue Study on Protected Melon in Northern France in 2011.
S10-01554	Gemrot, F.	2011	Report No. S11-00647, GLP, Unpublished Syngenta File No. A15149AC_11359 Isopyrazam - Residue Study on Protected Melon in Spain in 2010.
S11-00648	Tessier, V.	2012	Report No. S10-01554, GLP, Unpublished Syngenta File No. A16934C_10011 Isopyrazam - Residue Study on Protected Melon in Southern France and Italy in 2011.
S11-00649	Tessier, V.	2012	Report No. S11-00648, GLP, Unpublished Syngenta File No. A15149AC_11364 Isopyrazam - Residue Study on Protected Pepper in the United Kingdom and Northern France in 2011.
S10-01558-REG	Tessier, V.	2011	Report No. S11-00649, GLP, Unpublished Syngenta File No. A15149AC_11366 Isopyrazam - Residue Study on Protected Pepper in Italy in 2010.
S11-00650	Tessier, V.	2012	Report No. S10-01558-REG, GLP, Unpublished Syngenta File No. A16934C_10012 Isopyrazam - Residue Study on Protected Pepper in Italy and Spain in 2011.
S10-01555	Tessier, V.	2011	Report No. S11-00650, GLP, Unpublished Syngenta File No. A15149AC_11365 Isopyrazam - Residue Study on Protected Cherry Tomatoes in Northern France in 2010.
S10-01556	Tessier, V.	2011	Report No. S10-01555, GLP, Unpublished Syngenta File No. A16934C_10017 Isopyrazam - Residue Study on Protected Cherry Tomatoes in Spain in 2010.
S11-00651	Tessier, V.	2012	Report No. S10-01556, GLP, Unpublished Syngenta File No. A16934C_10018 Isopyrazam - Residue Study on Protected Cherry Tomato in the United Kingdom and Northern France in 2011.
S11-00652	Tessier, V.	2012	Report No. S11-00651 GLP, Unpublished Syngenta File No. A15149AC_11370 Isopyrazam - Residue Study on Protected Cherry Tomato in Southern France, Spain and Italy in 2011.
S13-02543	Bernal, J.	2013	Report No. S11-00652, GLP, Unpublished Syngenta File No. A15149AC_11371 Isopyrazam - Residue Study on Protected Cherry Tomato in Italy in 2013. Report No. S13-02543, GLP, Unpublished

Report No.	Author	Year	Title
S10-01549	Tessier, V.	2011	Syngenta File No. A15149W_11773 Isopyrazam - Residue Study on Carrots in Germany and the United Kingdom in 2010. Report No. S10-01549, GLP, Unpublished
S11-00643	Tessier, V.	2012	Syngenta File No. A16934C_10013 Isopyrazam - Residue Study on Carrot in the United Kingdom, Germany and Northern France in 2011. Report No. S11-00643, GLP, Unpublished
S10-01550	Tessier, V.	2011	Syngenta File No. A15149AC_11361 Isopyrazam - Residue Study on Carrots in Southern France and Spain in 2010. Report No. S10-01550, GLP, Unpublished
S11-00644	Tessier, V.	2012	Syngenta File No. A16934C_10016 Isopyrazam - Residue Study on Carrot in Southern France, Italy and Spain in 2011. Report No. S11-00644, GLP, Unpublished
CEMR-3393-REG	Marshall, L.	2008	Syngenta File No. A15149AC_11373 SYN520453 - Residue Study on Barley in Switzerland and Northern France in 2006. Report No. CEMR-3393-REG, GLP, Unpublished
CEMR-3394-REG	Oliver-Kang, J.	2008	Syngenta File No. A15149K_11192 SYN520453 - Residue Study on Barley in Italy, Spain and Southern France in 2006. Report No. CEMR-3394-REG, GLP, Unpublished
T001788-06-REG	Bell, A.	2008	Syngenta File No. A15149K_11030 SYN520453 - Residue Study in or on Barley in Germany in 2006. Report No. T001788-06-REG, GLP, Unpublished
CEMR-3365-REG	Bell, A.	2008	Syngenta File No. A15149G_10000 SYN520453 - Residue Study on Barley in Spain, Italy and Southern France in 2007. Report No. CEMR-3365-REG. Version 2, GLP, Unpublished
CEMR-3367-REG	Bell, A.	2008	Syngenta File No. A15149K_10524 SYN520453 - Residue Study on Barley in Germany, The United Kingdom and Northern France in 2007. Report No. CEMR-3367-REG. Version 2, GLP, Unpublished
CEMR-3391-REG	Oliver-Kang, J.	2008	Syngenta File No. A15149K_10525 SYN520453 - Residue Study on Wheat in Northern France in 2006. Report No. CEMR-3391-REG, GLP, Unpublished
CEMR-3392-REG	Marshall, L.	2008	Syngenta File No. A15149K_11031 SYN520453 - Residue Study on Wheat in Spain and Southern France in 2006. Report No. CEMR-3392-REG, GLP, Unpublished
T001787-06-REG	Simon, P.	2008	Syngenta File No. A15149K_11279 SYN520453 - Residue Study in or on Wheat in Germany in 2006. Report No. T001787-06-REG, GLP, Unpublished
CEMR-3364-REG	Bell, A.	2008	Syngenta File No. A15149G_10001 SYN520453 - Residue Study on Wheat in Spain, Italy and Southern France in 2007. Report No. CEMR-3364-REG. Version 2, GLP, Unpublished
CEMR-3366-REG	Bell, A.	2008	Syngenta File No. A15149K_10529 SYN520453 - Residue Study on Wheat in Germany, the United Kingdom and Northern France in 2007. Report No. CEMR-3366-REG. Version 2, GLP, Unpublished
S09-01529-REG	Tessier, V.	2010	Syngenta File No. A15149K_10595 SYN520453/Azoxystrobin - Residue Study on Spring Oilseed Rape in Northern France, the United Kingdom and Germany in 2009. Report No. S09-01529-REG, GLP, Unpublished
S10-00962	Tessier, V.	2011	Syngenta File No. A16609E_10017 Isopyrazam/Azoxystrobin - Residue Study on Oilseed Rape in Northern France, Germany and the United Kingdom in 2010. Report No. S10-00962, GLP, Unpublished
S13-01042	Gemrot, F.	2014	Syngenta File No. A16609E_10015 Isopyrazam - Residue Study on Oilseed Rape in Southern France, Spain and Italy in 2013. Report No. S13-01042, GLP, Unpublished
			Syngenta File No. A16609L_10008

Report No.	Author	Year	Title
S15-01942	Bernal, J.	2016	Isopyrazam - Residue study on Oilseed Rape in the United Kingdom and Germany in 2015. Report No. S15-01942, GLP, Unpublished Syngenta File No. A16609L_10205
S15-01943	Bernal, J.	2016	Isopyrazam - Residue study on Oilseed Rape in Italy, Southern France and Spain in 2015. Report No. S15-01943, GLP, Unpublished Syngenta File No. A16609L_10200
TK0040606	Willard, T.R.	2011	Isopyrazam (A15149AC) – Magnitude of the Residues in or on Peanuts in Nicaragua. Report No. TK0040606, GLP, Unpublished Syngenta File No. A15149AC_50002
T009264-07-REG	Oppilliart, S.	2009	SYN520453 - Residue Study on Apple and Processed Products in France (South) in 2008. Report No. T009264-07-REG, GLP, Unpublished Syngenta File No. A15149AC_11318
S09-00358	Gemrot, F.	2012	Isopyrazam and Cyprodinil - Residue Study on Tomatoes and Processed Products in France (South) in 2009. Report No. S09-00358, GLP, Unpublished Syngenta File No. A16934C_10026
S09-01531	Gemrot, F.	2012	Isopyrazam and Cyprodinil - Residue Study on Carrots and Processed Products in Southern France in 2009. Report No. S09-01531, GLP, Unpublished Syngenta File No. A16934C_10025
S11-01425	Tessier, V.	2015	Isopyrazam – Residue Study on Oil seed Rape and Processed Products in Northern France and the United Kingdom in 2011. Report No. S11-01425, GLP, Unpublished Syngenta File No. A15149AC_11392