



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY AND
POLLUTION PREVENTION

MEMORANDUM

Date: February 8, 2012

SUBJECT: Fluxapyroxad (BAS 700F) on Small Grains, Oilseeds, Corn, Cotton, Sugar Beet, Tubers & Corm Vegetables, Legumes, Fruiting Vegetables except Cucurbits, Pome Fruits and Stone Fruits. Evaluation of Analytical Methods and Residue Data.

PC Code: 138009

DP Barcode: D390223

Decision No.: 431203

Registration No.: 7969-GRE, 7969-GNA, 7969-GNT, 7969-GNI, 7969-GNO, 7969-GRN, 7969-GRR

Petition No.: 0F7709

Regulatory Action: Section 3 Registration

Risk Assessment Type: Residue
Chemistry Summary Document

Case No.: NA

TXR No.: NA

CAS No.: 907204-31-3

MRID No.: See MRID Reference List

40 CFR: 180.xxx

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BASF has proposed use of the fungicide fluxapyroxad (BAS 700F; 3-(difluoromethyl)-1-methyl-N-(3',4',5'-trifluoro[1,1'-biphenyl]-2-yl)-1H-pyrazole-4-carboxamide) on cereal grains, legume vegetables (succulent and dry), oil seed crops (canola and sunflower), peanuts, pome fruit, stone fruit, root and tuber vegetables (potatoes and sugar beets), fruiting vegetables, and cotton. Fluxapyroxad is a pyrazole fungicide. The technical product to be registered is XEMIUM Technical (EPA File Symbol 7969-GRE). The proposed formulations are BAS 700 01 F

Fungicide (7969-GNA, an emulsifiable concentrate (EC) containing 5.96% fluxapyroxad, 0.52 lb ai/gal); BAS 700 02 F (7969-GNT, for seed treatment, 28.78% ai); BAS 700 03 F (7969-GNI, for seed treatment, 28.70%); BAS 700 04 F (7969-GNO, EC formulation with 26.55% ai, 2.47 lb ai/gal); and two co-active ingredient products with pyraclostrobin: BAS 703 01 F (7969-GRN, with fluxapyroxad at 21.26% (2.09 lb ai/gal) and pyraclostrobin at 21.26 %) and BAS 703 02 F (7969-GRR, with fluxapyroxad at 14.33% (1.39 lb ai/gal) and pyraclostrobin at 28.58%).

Table A. MRID Summary Table For Fluxapyroxad		
MRID No.	Study Type	Monograph Section(s); Comments
47923642	860.1300 MOR Soybean	B.7.1.1
47923641	860.1300 MOR Tomato	B.7.1.2
47923643	860.1300 MOR Wheat	B.7.1.3
47923644	860.1300 Hen	B.7.2.1
47923645	860.1300 Hen	B.7.2.1
47923646	860.1300 Hen	B.7.2.1
47923647	860.1300 Hen	B.7.2.1
47923772	860.1300 Hen	B.7.2.1
47923773	860.1300 Hen	B.7.2.1
47923648	860.1300 Goat	B.7.2.2
47923649	860.1300 Goat	B.7.2.2
47923650	860.1300 Goat	B.7.2.2
47923651	860.1300 Goat	B.7.2.2
47923774	860.1300 Goat	B.7.2.2
47923542	860.1340 Validation of L0076/03 in Plant Matrices	B.5.2.1
47923543	860.1340 Validation of L0137/01 in Plant Matrices	
47923547		
47923544	860.1340 ILV in Plant and Animal Matrices	B.5.2.2
47923545		
47923546		
47923548		
47923549	860.1360 Multiresidue Methods	B.5.2.3
47923637	860.1380 Storage Stability	B.7.6.2
47923638		
47923639		
47923640		
47923666	860.1480 Poultry Tissues and Egg	B.7.8.1
47923667	860.1480 Cattle Tissues and Milk	
47923652	860.1500 Cereal Grains & Forage & Fodder	B.7.6.1
47923653	860.1500 Wheat, Barley US trials	B.7.6.1
47923654	860.1500 Wheat, Triticale – European trials	B.7.6.1
47923655	860.1500 Wheat, Triticale – European trials	B.7.6.1
47923656	860.1500 Barley – European Trials	B.7.6.1
47923657	860.1500 Barley – European Trials	B.7.6.1
47923658	860.1500 Legumes & Foliage of Legumes	B.7.6.1
47923659	860.1500 Oilseeds	B.7.6.1
47923660	860.1500 Peanut	B.7.6.1
47923661	860.1500 Pome Fruit	B.7.6.1
47923662	860.1500 Stone Fruit	B.7.6.1
47923663	860.1500 Potato, Sugarbeets	B.7.6.1
47923664	860.1500 Fruiting Vegetables	B.7.6.1
47923665	860.1500 Cotton	B.7.6.1
	860.1520 Cotton Processed Fractions	B.7.7.1

MRID No.	Study Type	Monograph Section(s); Comments
47923669 47923670 47923671	860.1520 Cereal Grain Processed Fractions	B.7.7.1
47923672	860.1520 Soybean Processed Fractions	B.7.7.1
47923673	860.1520 Oilseed Processed Fractions	B.7.7.1
47923674	860.1520 Peanut Processed Fractions	B.7.7.1
47923675	860.1520 Apple Processed Fractions	B.7.7.1
47923676	860.1520 Plum Processed Fractions	B.7.7.1
47923677	860.1520 Root & Tuber Processed Fractions	B.7.7.1
47923678	860.1520 Tomato Processed Fractions	B.7.7.1
47923679	860.1850 Confined rotational crops	B.7.9.1
47923680	860.1850 Confined rotational crops	B.7.9.1
47923681	860.1900 Rotational Lettuce, Radish, Wheat	B.7.9.2
47923682	860.1900 Rotational Lettuce, Radish, Wheat	B.7.9.2
48580801	860.1380 Storage Stability Data	B.7.6.2
48580802	860.1380 Storage Stability Data	B.7.6.2

Under PP# 0F7709, BASF is proposing the following tolerances for residues of fluxapyroxad, per se.

Table B. Proposed Tolerances for Residues of BAS 700 F in Crop Matrices

Crop / Commodities	Proposed Tolerance (ppm)
Apple, wet pomace	3.5
Barley, bran	6.0
Beet, sugar tops	4.0
Beet, sugar, dried pulp	0.16
Corn, field, grain	0.01
Corn, oil, field refined	0.05
Cotton, gin byproducts	0.01
Cotton, undelinted seed	0.01
Fruit, pome, group 11	0.70
Fruit, stone, group 12	1.4
Grain, aspirated fractions	16.0
Grain, cereal, group 15, except field corn grain	2.5
Grain, cereal, forage, fodder and straw, group 16	25.0
Oilseeds, group 20	0.6
Peanut	0.02
Peanut, meal	0.03
Peanut, refined oil	0.06
Plum, prune	4.0
Potato, wet peel	0.2
Rapeseed (cultivars, varieties and/or hybrids including canola and crambe)	0.60

Crop / Commodities	Proposed Tolerance (ppm)
Rice hulls	10.0
Soybean, hulls	6.5
Soybean, seed	0.20
Sunflower, seed	0.60
Vegetable, foliage of legume, group 7	18.0
Vegetable, fruiting, group 8	0.60
Vegetable, legume, dried shell pea and bean, (except soybean), subgroup 6C	0.35
Vegetable, legume, edible podded, subgroup 6A	1.4
Vegetable, legume, succulent shelled pea and bean, subgroup 6B	0.45
Vegetable, root, subgroup 1A	0.10
Vegetable, tuberous and corm, subgroup 1C	0.04
Vegetable, tuberous and corm (except potato), subgroup 1D	0.04
Wheat, bran	6.0
Wheat, germ	3.0

Table C. Proposed Tolerances for Residues of BAS 700 F in Livestock Matrices

Crop / Commodities or Animal Matrices	Proposed Tolerance (ppm)
Cattle, fat	0.10
Cattle, kidney	0.01
Cattle, liver	0.10
Cattle, meat	0.01
Cattle, meat byproducts	0.10
Egg	0.01
Goat, fat	0.10
Goat, kidney	0.01
Goat, liver	0.10
Goat, meat	0.01
Goat, meat byproducts	0.10
Hog, fat	0.01
Hog, liver	0.01
Hog, meat	0.01
Hog, meat byproducts	0.01
Horse, fat	0.10
Horse, kidney	0.01
Horse, liver	0.10
Horse, meat	0.01
Horse, meat byproducts	0.10

Crop / Commodities or Animal Matrices	Proposed Tolerance (ppm)
Milk	0.02
Milk fat	0.2
Poultry, byproducts	0.01
Poultry, fat	0.01
Poultry, liver	0.01
Poultry, meat	0.01
Poultry, skin	0.01
Sheep, fat	0.10
Sheep, kidney	0.01
Sheep, liver	0.10
Sheep, meat	0.01
Sheep, meat byproducts	0.10

Review of the submitted petition is being conducted as a quadri-lateral review work-share effort which has been carried out in part with Canada (PMRA), Australia (APVMA), and New Zealand (MAF). The EU has recently set MRLs on a number of the same commodities.

Executive Summary

This petition includes the registration and first food uses for the fungicide fluxapyroxad (BAS 700F; 3-(difluoromethyl)-1-methyl-*N*-(3',4',5'-trifluoro[1,1'-biphenyl]-2-yl)-1*H*-pyrazole-4-carboxamide) and includes the first application for registration of fluxapyroxad, in the US, Canada, Australia, and New Zealand. In addition, MRLs have been recently established in the EU.

The nature of the residue in plants is adequately understood based on metabolism studies with fluxapyroxad on wheat, soybean and tomato. The terminal residue of concern for risk assessment in plants is the parent compound, fluxapyroxad and its pyrazole ring hydroxylated metabolite M700F008.

The nature of the residue in livestock animals (ruminants and poultry) is adequately understood. The terminal residue of concern in livestock commodities is the parent compound, fluxapyroxad and its pyrazole ring hydroxylated metabolite M700F008; and includes the desmethyl pyrazole ring hydroxylated metabolite M700F010 in milk only.

The nature of the residue in rotational crops is adequately understood based on confined rotational crop studies with rotated soybean, radish, and wheat. The metabolic pathway of pyroxasulfone is similar in primary and rotational crops. The terminal residue of concern for risk assessment in rotational crops is the parent compound, fluxapyroxad, and its pyrazole ring hydroxylated metabolite M700F008.

Fluxapyroxad is a suitable marker for residues in/on plants, rotational crops and livestock; therefore, the ROCKS committee recommended it as the only residue of concern for tolerance enforcement purposes.

The residue analytical methods available for enforcement of fluxapyroxad tolerances include the LC/MS/MS method used for data gathering and proposed for enforcement. This method uses reversed-phase HPLC with gradient elution, and includes 2 ion transitions to be monitored for the parent and the metabolites M700F008 and M700F048, so the method also serves as the confirmatory method. For M700F002, a second ion transition wasn't sensitive enough, so alternate chromatographic conditions were developed for the confirmatory method.

FDA Multiresidue protocols were tested with fluxapyroxad. Protocols A & B yielded no recovery. GC Characteristics were obtained from Protocol C. Fluxapyroxad did not elute in 15% ethyl ether, nor in the 50% ethyl ether in petroleum ether fractions for Protocol D. Fluxapyroxad was trapped in Florisil, so there was no recovery in Protocol E. Protocol F yielded no peaks. FDA multiresidue methods were not appropriate for detection of fluxapyroxad.

Although not included in the analytical method section of the OECD summary document, a QuEChERS analytical method is available, has been proposed for enforcement use in the EU, and does detect fluxapyroxad.

Adequate storage stability data for fluxapyroxad, per se, are available to support the storage conditions and durations of field trial samples for raw agricultural commodities. The available data indicate that residues of fluxapyroxad are relatively stable for up to 24 months (the length of time the study was conducted) in/on apple (fruit), tomato (fruit), triticale (whole plant), soybean (seed), avocado (fruit), dried pea (seed), cereal (grain), potato (tuber), grape (fruit), lemon (fruit), and wheat (straw) stored at -20 C. The data available on these crops adequately address the OECD guidelines outlined for stored commodities (i.e., representative matrices from five different categories: two high water content, two high oil content, one high protein content, two high starch content and two high acid content commodities). Therefore, frozen storage stability testing on processed commodities are not required.

Some instability was seen for the fluxapyroxad metabolite M700F008, which is to be included in the risk assessment. The instability was seen in oily and starchy commodities. Residues of M700F008 have been corrected for use in the risk assessment to account for this instability.

Based on livestock feedstuffs associated with proposed uses, the dietary burdens of fluxapyroxad and M700F008 to livestock are estimated to be 3.1 ppm for beef cattle, 12.3 ppm for dairy cattle, 0.49 ppm for poultry and 0.44 ppm for swine.

The submitted field trial data for fluxapyroxad on cereal grains, legume vegetables (succulent and dry), oil seed crops (canola and sunflower), peanuts, pome fruit, stone fruit, root and tuber vegetables (potatoes and sugar beets), and fruiting vegetables reflect the use of 2-4 foliar applications of an emulsifiable concentrate formulation. Decline studies were submitted for each commodity, as required. Seed treatment studies for fluxapyroxad on cotton reflect the use of an SC formulation.

Residues of M700F008 (included in the fluxapyroxad risk assessment) are stable for up to four months in soybean seed, 12 months in wheat (grain), and 24 months (the length of time the study was conducted) in wheat straw, lemon, dried pea seed and wheat whole plant. Regarding the crops in the current submission, residues of M700F008 are considered to be stable only up to four months in high oil and high protein matrices (soybean seed, canola seed, sunflower seed, peanut nutmeat, cotton seed, succulent peas and beans), and if samples of these commodities are stored frozen for longer than four months, quantifiable residues of M700F008 need to be corrected for in-storage dissipation using a 57% recovery rate. Similarly, residues of M700F008 are considered to be stable only up to 12 months in high starch matrices (cereal grains, root and tuber crops), and if samples of these commodities are stored frozen for longer than 12 months, quantifiable residues of M700F008 need to be corrected for in-storage dissipation using a 63% recovery rate.

Processing studies were provided for processed commodities associated with cereal grains, oil seed crops (canola and sunflower), peanuts, pome fruit, stone fruit, root and tuber vegetables (potatoes and sugar beets), and fruiting vegetables. Residues of fluxapyroxad concentrated in the following processed commodities and tolerances are needed for: potato wet peel at 0.1 ppm, sugar beet dried pulp at 0.1 ppm, soybean hulls at 0.03 ppm, tomato wet pomace at 1.5 ppm, apple wet pomace at 2 ppm, plum, prune at 3 ppm, barley bran at 3 ppm, wheat bran at 0.6 ppm, corn oil at 0.03 ppm, rice hulls at 8 ppm, rice bran at 5 ppm, peanut oil at 0.02 ppm, and aspirated grain fractions at 6 ppm.

Analytical reference standards are available for fluxapyroxad in the Pesticide Repository.

Confined and Field Rotational Crop data were provided for fluxapyroxad. The field rotational crop studies show finite residues at 30, 60, 90, and 120 day plant back intervals (PBIs). The confined rotational crop studies show no quantifiable residues at a 365 day plant back interval, except in wheat commodities, which is a primary crop. The 365 day plant back interval for all crops not currently on the fluxapyroxad label must remain.

No Codex, or Mexican maximum residue limits (MRLs) have been established for residues of fluxapyroxad on any commodity. Maximum residue limits (MRLs) for the commodities in this petition are being proposed concurrently in Canada, and MRLs on some of the commodities included in this petition are being proposed concurrently in Australia and New Zealand. MRLs have been recently established in the EU for fluxapyroxad on a number of the same commodities for which tolerances are proposed in the US.

Regulatory Recommendations and Residue Chemistry Deficiencies

HED has examined the residue chemistry database for fluxapyroxad. Pending submission of a revised Section B (see requirements under Directions for Use), and a revised Section F (see requirements under Proposed Tolerances), there are no residue chemistry issues that would preclude granting unconditional Section 3 registration for the requested uses of fluxapyroxad, or establishment of tolerances for residues of fluxapyroxad as follows:

Tolerances are established for residues of the fungicide fluxapyroxad, including its metabolites and degradates, in or on the commodities in the table below. Compliance

with the tolerance levels specified below is to be determined by measuring only fluxapyroxad [3-(difluoromethyl)-1-methyl-*N*-(3',4',5'-trifluoro[1,1'-biphenyl]-2-yl)-1*H*-pyrazole-4-carboxamide] in or on the commodity.

The recommended tolerances to be established are listed in Table 49.

860.1200 Directions for Use

- The label must be revised to delete use on root and tuber vegetables, subgroup 1A. Only use on sugar beets from subgroup 1A is allowed.
- The petitioner must clarify the PHI for peanuts.
- The 365 day plant back interval must remain on the label.

860.1340 Residue Analytical Methods

- BASF Methods L0137/01 and L0140/02 will be submitted to ACL/BEAD and to FDA for updating PAM II, and to USDA for enforcement of tolerances in livestock commodities.

860.1500 Crop Field Trials

- Field trials on carrot and radish must be submitted in a future petition in order to allow use on root and tuber vegetables, subgroup 1A.

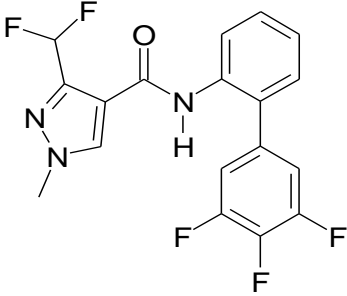
860.1550 Proposed Tolerances

- A revised Section F must be submitted.

Background

Fluxapyroxad (BAS 700 F) is a member of the chemical class pyrazole carboximide and the fungicide group succinate dehydrogenase inhibitors (SDHI). The mode of action of BAS 700 F at the molecular level is the inhibition of the enzyme succinate dehydrogenase (SDH), also known as complex II in the mitochondrial electron transport chain. Through its inhibition of complex II, fluxapyroxad disrupts fungal growth by preventing energy production and by eliminating the availability of the chemical building blocks for the synthesis of other essential cellular components.

The chemical structure and nomenclature of fluxapyroxad and the physicochemical properties are presented in Tables 1 and 2.

Chemical structure	
Common name	Fluxapyroxad (ISO, proposed)
Company experimental name	BAS 700 F
IUPAC name	3-(difluoromethyl)-1-methyl-N-(3',4',5'-trifluorobiphenyl-2-yl)pyrazole-4-carboxamide
CAS name	3-(difluoromethyl)-1-methyl-N-(3',4',5'-trifluoro[1,1'-biphenyl]-2-yl)-1H-pyrazole-4-carboxamide
CAS #	907204-31-3
Molecular Formula	C ₁₈ H ₁₂ F ₅ N ₃ O
End-use product/EP	Xemium Technical, BAS 700 01F, BAS 700 02F, BAS 700 03F, BAS 700 04F

Parameter	Value	Reference
Melting point/range	156.8 °C	Product Chemistry monograph
pH of 1% solution in water	5.8	
Density	1.47	
Water solubility (20°C)	3.88 mg/L at pH 5.8 (not buffered)	
	3.78 mg/L at pH 4 3.44 mg/L at pH 7 3.84 mg/L at pH 9	

Parameter	Value	Reference																								
Solvent solubility (g/L at 20°C)	acetone	>250																								
	acetonitrile	167.6 ± 0.2																								
	dichloromethane	146.1 ± 0.3																								
	ethylacetate	123.3 ± 0.2																								
	methanol	53.4 ± 0.0																								
	toluene	20.0 ± 0.0																								
	n-octanol	4.69 ± 0.01																								
	n-heptane	0.106 ± 0.001																								
Vapor pressure at 25 °C	8.1 x 10 ⁻⁹ Pa																									
Dissociation constant (pK _a)	12.58 (calculated)																									
Octanol/water partition coefficient Log(K _{OW})	3.08 (deionized water)																									
	3.09 at pH 4																									
	3.13 at pH 7																									
	3.09 at pH 9																									
UV/visible absorption spectrum	<table border="1"> <thead> <tr> <th>pH</th> <th>λ_{max}</th> <th>ε</th> </tr> </thead> <tbody> <tr> <td rowspan="3">1.4</td> <td>199</td> <td>35913</td> </tr> <tr> <td>230</td> <td>24137</td> </tr> <tr> <td>290</td> <td>1145</td> </tr> <tr> <td rowspan="3">5.9</td> <td>193</td> <td>44100</td> </tr> <tr> <td>230</td> <td>24010</td> </tr> <tr> <td>290</td> <td>978</td> </tr> <tr> <td rowspan="3">12.2</td> <td>215</td> <td>23227</td> </tr> <tr> <td>229</td> <td>23473</td> </tr> <tr> <td>290</td> <td>2405</td> </tr> </tbody> </table>		pH	λ _{max}	ε	1.4	199	35913	230	24137	290	1145	5.9	193	44100	230	24010	290	978	12.2	215	23227	229	23473	290	2405
	pH	λ _{max}	ε																							
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		290	978																							
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	ε: molar absorption coefficient, [L mol ⁻¹ cm ⁻¹]																									

860.1200 Directions for Use

The petitioner has submitted copies of the proposed labels for XEMIUM Technical (EPA File Symbol 7969-GRE), and the formulations BAS 700 01 F Fungicide (7969-GNA, an emulsifiable concentrate (EC) containing 5.96% fluxapyroxad, 0.52 lb ai/gal); BAS 700 02 F (7969-GNT, for seed treatment, 28.78% ai); BAS 700 03 F (7969-GNI, for seed treatment, 28.70%); BAS 700 04 F (7969-GNO, EC formulation with 26.55% ai, 2.47 lb ai/gal); and two co-active ingredient products with pyraclostrobin: BAS 703 01 F (7969-GRN, with fluxapyroxad at 21.26% (2.09 lb ai/gal) and pyraclostrobin at 21.26 %) and BAS 703 02 F (7969-GRR, with fluxapyroxad at 14.33% (1.39 lb ai/gal) and pyraclostrobin at 28.58%). The proposed use directions are presented in Table 3 below.

Table 3. Summary of Directions for Use of Fluxapyroxad					
Applic. Timing, Type, and Equip.	Formulation	Applic. Rate (lb ai/A)	Max. No. Applic. per Season	Max. Seasonal Applic. Rate (lb ai/A)	PHI (days)
Cereal Grains					
Foliar spray Ground, Aerial or Chemigation	5.96% EC 26.55% EC 21.26% EC 14.33% EC	0.09	2	0.18	21/7*
	Use Directions and Limitations: A minimum 7-day RTI is specified. Applications may be begin at emergence, but typical applications begin as plants touch across rows. *A 7 day PHI is allowed for sweet corn only.				
Seed Treatment	28.7% SC	0.01	Not provided	Not applicable	Not applicable
	Use Directions and Limitations: Rate is expressed in lb ai/100 lb seed. Apply in enough water to ensure adequate coverage, but without damaging the seed. A higher rate of 0.02 lb ai/100 lb seed is allowed on sweet corn and sorghum seed. A higher rate of 0.05 lb ai/100 lb seed is allowed on wheat seed.				
Cotton, Sunflower					
Seed Treatment	28.7% SC	0.02	Not provided	Not applicable	Not applicable
	Use Directions and Limitations: Rate is expressed in lb ai/100 lb seed. Apply in enough water to ensure adequate coverage, but without damaging the seed.				
Oilseeds, Dried Shelled Peas, Soybeans					
Foliar spray Ground, aerial or chemigation	5.96% (0.52 lb/gal) EC 26.55% (2.47 lb/gal) EC 21.26% (2.09 lb/gal) EC 14.33% (1.39 lb/gal) EC	0.09	2	0.18	7 days
	Use Directions and Limitations: A minimum 7-day RTI is specified. Applications may be begin at emergence, but typical applications begin as plants touch across rows. DO NOT harvest for forage, green chop, vines, or hay within 7 days of last application (14 days for 1.39 and 2.09 lb/gal EC). Do not feed soybean hay for 14 days after application (21 days for 2.09 lb/gal EC). No livestock feeding restrictions for oilseeds.				

Table 3. Summary of Directions for Use of Fluxapyroxad					
Applic. Timing, Type, and Equip.	Formulation	Applic. Rate (lb ai/A)	Max. No. Applic. per Season	Max. Seasonal Applic. Rate (lb ai/A)	PHI (days)
Dried Shelled Beans					
Foliar spray Ground, aerial or chemigation	5.96% (0.52 lb/gal) EC 26.55% (2.47 lb/gal) EC 21.26% (2.09 lb/gal) EC 14.33% (1.39 lb/gal) EC	0.18	2	0.36	7 days
Use Directions and Limitations: A minimum 7-day RTI is specified. Applications may be begin at emergence, but typical applications begin as plants touch across rows. DO NOT harvest for forage, green chop, vines, or hay within 7 days of last application (14 days for 1.39 and 2.09 lb/gal EC).					
Dried Shelled Beans and Peas, Soybeans					
Seed Treatment	28.7% SC	0.01	Not provided	Not applicable	Not applicable
Use Directions and Limitations: Rate is expressed in lb ai/100 lb seed. Apply in enough water to ensure adequate coverage, but without damaging the seed.					
Edible Podded Legume Vegetables, Succulent Shelled Beans and Peas					
Foliar spray Ground, aerial or chemigation	5.96% (0.52 lb/gal) EC 26.55% (2.47 lb/gal) EC 21.26% (2.09 lb/gal) EC 14.33% (1.39 lb/gal) EC	0.09	2	0.18	7
Use Directions and Limitations: A minimum 7-day RTI is specified. Applications may be begin at emergence, but typical applications begin as plants touch across rows. DO NOT harvest for forage, green chop, vines, or hay within 7 days of last application (14 days for 1.39 and 2.09 lb/gal EC).					
Fruiting Vegetables Group, Sugar Beets, Tuberos & Corm Vegetables Subgroup					
Foliar spray Ground, aerial or chemigation	5.96% (0.52 lb/gal) EC 26.55% (2.47 lb/gal) EC 21.26% (2.09 lb/gal) EC 14.33% (1.39 lb/gal) EC	0.09	3	0.27	7
Use Directions and Limitations: A minimum 7-day RTI is specified (14 days for sugar beets). Apply a minimum of 20 gallons of spray volume per acre, and increase the spray volume as the plants grow during the season. Spray volume should be proportional to the amount of plant tissue to be covered such that 100 gallons of spray per acre is used on mature plants. DO NOT make more than two (2) consecutive applications of fluxapyroxad before alternating to a labeled fungicide with a different mode of action. Sugar beet leaves, roots and tops may be fed no sooner than 7 days after last application. Use of the 2.09 lb/gal EC on sugar beets is not permitted, due to restrictions on the pyraclostrobin label.					
Peanut					
Foliar spray Ground, aerial or chemigation	5.96% (0.52 lb/gal) EC 26.55% (2.47 lb/gal) EC 14.33% (1.39 lb/gal) EC	0.09	3	0.27	7*
Use Directions and Limitations: A minimum 14-day RTI is specified. DO NOT make more than two (2) consecutive applications of fluxapyroxad before alternating to a labeled fungicide with a different mode of action. Do not graze or harvest for peanut forage. * The 1.39 lb/gal EC label states that a 7 day PHI is required in the crop specific use directions, and 14 days in the overview table.					
Seed Treatment	28.7% SC	0.01	Not provided	Not applicable	Not applicable

Table 3. Summary of Directions for Use of Fluxapyroxad					
Applic. Timing, Type, and Equip.	Formulation	Applic. Rate (lb ai/A)	Max. No. Applic. per Season	Max. Seasonal Applic. Rate (lb ai/A)	PHI (days)
	Use Directions and Limitations: Rate is expressed in lb ai/100 lb seed. Apply in enough water to ensure adequate coverage, but without damaging the seed.				
Pome Fruit Group					
Foliar spray Ground, aerial or chemigation	5.96% (0.52 lb/gal) EC 26.55% (2.47 lb/gal) EC 21.26% (2.09 lb/gal) EC 14.33% (1.39 lb/gal) EC	0.09	4	0.36	0
	Use Directions and Limitations: Do not use less than 10 gallons of spray solution per acre. A minimum 7-day RTI is specified. DO NOT make more than two (2) consecutive applications of fluxapyroxad before alternating to a labeled fungicide with a different mode of action. No restriction on livestock grazing or feeding.				
Stone Fruit Group					
Foliar spray Ground, aerial or chemigation	5.96% (0.52 lb/gal) EC 26.55% (2.47 lb/gal) EC 21.26% (2.09 lb/gal) EC 14.33% (1.39 lb/gal) EC	0.11	3	0.33	0
	Use Directions and Limitations: Do not use less than 10 gallons of spray solution per acre. A minimum 7-day RTI is specified. DO NOT make more than two (2) consecutive applications of fluxapyroxad before alternating to a labeled fungicide with a different mode of action.				

The label permits the use of adjuvants. For aerial application, the label requires a minimum of 2 gallons per acre, and for tree crops, a minimum of 10 gallons per acre. The label contains rotational crop restrictions to plant only crops on the fluxapyroxad label immediately after application. There is a 365 day restriction against planting of crops other than those on the fluxapyroxad label.

On the 1.39 lb/gal EC label, the overview of application restrictions states that for peanuts, a 14 day PHI is required. However, in the use directions by crop, the label states that a 7 day PHI is required.

Conclusions. The proposed use directions are adequate to allow evaluation of the residue data relative to the proposed use. The petitioner must clarify the PHI needed for peanuts on the 1.39 lb/gal EC label.

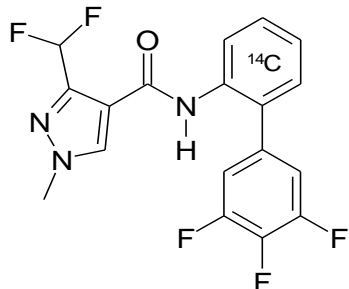
860.1300 Nature of the Residue – Plants

Monograph Section B.7.1

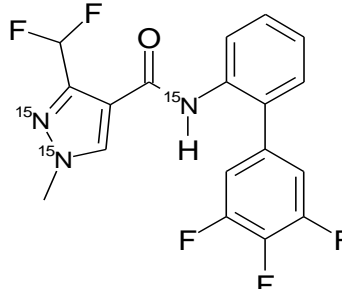
MRIDs 47923641, 47923642, 47923643

The metabolism of fluxapyroxad (BAS 700 F) in soybeans, tomato and wheat was investigated using BAS 700 F radiolabelled in the aniline ring and, in separate studies, the pyrazole ring. For the aniline label studies, the test item was a mixture of aniline-U- C^{14} -BAS 700 F and aniline- N^{15} , pyrazole-1,2- N^{15} -BAS 700 F. For the pyrazole studies, the test item was a mixture of pyrazole-4- C^{14} -BAS 700 F with unlabelled BAS 700 F. The molecular structures and the label positions are shown below:

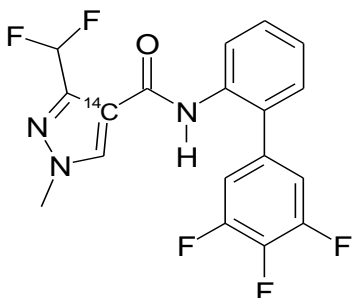
Aniline-U- C^{14}



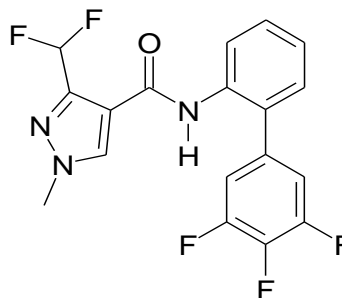
Aniline- N^{15} , Pyrazole-1,2- N^{15} Label



Pyrazole-4- C^{14}



BAS 700 F, unlabelled



Proposed Metabolic pathways are shown in Appendix I. Structures of metabolites are shown in Appendix II.

Metabolism in Soybeans. Foliar applications were made to soybeans with fluxapyroxad labeled in the aniline ring, and in separate study, in the pyrazole ring, at a rate of 3 x 60 g a.i./ha for each label (corresponding to spray volumes of approximately 220 L/ha) at BBCH 16/17, 51–59 and 71–75 using an automatic spray track system. This corresponds to a 0.6x the single application rate and 0.9x the maximum seasonal rate.

Samples of soybean forage were taken after the first application (0 days after treatment; DAT) and immediately before the third application (21 days after the first treatment; 14 days after the second treatment). Soybean hay, straw, hull and seed were harvested at BBCH 89, approximately a month after the third application. Samples were frozen and frozen subsamples of soybean seeds were milled.

Samples of soybean forage were extracted three to five times with methanol, and the extracts combined, and measured by liquid scintillation counting (LSC). The residue was extracted twice with water, extracts combined and measured by LSC. In order to release the residual radioactive residues (RRR), the residues of soybean hull and bean after extraction with methanol and water were subjected to a sequential solubilisation procedure applying treatments with aqueous ammonia, enzymes and hydrochloric acid. Samples were extracted within 97 days (3.2 months).

Following foliar application of aniline- or pyrazole-labeled BAS 700 F to soybeans at a rate of 3 x 60 g a.i./ha, TRRs observed were 61.238 and 54.294 mg/kg in soybean hay, 6.413 and 4.368 mg/kg in forage at 0 DAT, 5.091 and 4.665 in forage at 21 DAT, 2.737 and 2.237 mg/kg in hulls, 1.006 and 0.837 mg/kg in straw and 0.115 and 0.260 mg/kg in seed, for the aniline and pyrazole labels, respectively.

After extraction, analyses were done by radio-HPLC. Three analytical extraction procedures were compared: a three-step extraction method (L0137/01) with methanol/water (1/1, v/v), a three-step extraction method (L0076/03) with methanol/water/2N HCl (70/25/5, v/v/v) and a three-step extraction (Multi-residue method S19) with acetone/water (2/1, v/v). In general, all three extraction methods were comparable to the extraction method used for metabolism investigations in the current study in regards to the amount and composition of residues.

The residues identified are shown in Table 4 below.

Table 4. Metabolites detected in soybean matrices (foliar treatments with BAS 700 F).

Soybean Matrix	BAS 700 F		M700F002 *		M700F048	
	[mg/kg]	[% TRR]	[mg/kg]	[% TRR]	[mg/kg]	[% TRR]
Aniline label						
Forage 0 DAT	6.264	97.7	Not detected		Not detected	
Forage 21 DAT	4.774	93.8			0.032	0.6
Hay	54.259	88.6			0.994	1.6
Straw	0.931	92.5			0.008	0.8
Hull **	1.755	64.1			0.071	2.6
Seed	0.024	21.2			0.023	19.9
Pyrazole label						
Forage 0 DAT	4.264	97.6	Not detected		Not detected	
Forage 21 DAT	4.277	91.7			0.056	1.2
Hay	46.932	86.4			1.188	2.2
Straw	0.749	89.5			Not detected	
Hull	1.207	53.9	0.045 (0.019) ***	2.0	0.071	3.1
Seed	0.019	7.4	0.087 (0.037) ***	33.4	0.023	8.8

* The metabolite M700F002 is only detectable with the pyrazole label.

** In the case of soybean hull, the sum of identified components in the extractable radioactive residues (ERR) and in the residual radioactive residues after solvent extraction (RRR) is given.

*** Values in brackets: re-calculated using the actual molecular weight of the metabolite M700F002

BAS 700 F represented the main component in all soybean matrices (53.9-97.7% of the TRRs) except for seed (7.4-21.2% of the TRRs). The main transformation product in seed was the metabolite M700F002 (33.4% of the TRRs) resulting from cleavage of BAS 700 F and thus only detectable with the pyrazole label. This metabolite was also found in hulls (2.0% of the TRRs). The N-glucoside M700F048 was present in all matrices (8.8-19.9% of the TRRs in seed, 0.6-3.1% in other soybean matrices). Another peak was assigned to metabolite M700F008/M700F006 (0.2-5.4% of the TRRs). In addition, several minor, non-quantifiable metabolites were identified in hay.

The proposed metabolic pathways of BAS 700 F in soybean are mainly by demethylation of the pyrazole moiety, hydroxylation of the biphenyl moiety, and hydroxylation of the methyl group at the pyrazole ring. These derivatives subsequently conjugate with glucose and malonic acid. Furthermore, specifically in seeds, significant amounts of M700F002, a metabolite known to be generated by cleavage of the carboxamide bond of BAS 700 F in the soil, were detected. The absence of any cleavage products carrying the aniline label suggested that M700F002 is generated by cleavage of BAS 700 F in the soil and subsequent uptake into the plant rather than by cleavage in the plant.

Metabolism in Tomato. Tomato plants were treated three times, using a hand-held sprayer, with the EC formulation of BAS 700 F at a rate of 100 g a.i./ha each. This corresponds to a 1x application rate (both single and maximum seasonal rate). The applications took place 17, 10 and 3 days before harvest (55, 62 and 69 days after planting). Tomato plants with ripe fruits were sampled three days after treatment (DAT) with BAS 700 F. Ripe tomato fruits were harvested, weighed and frozen. Other green parts of the plants (stem, panicles and leaves - referred to as "tomato leaves") were sampled, cut with scissors, weighed and frozen. The same extraction scheme was used as had been used for soybean samples.

TRRs of 6.703 mg/kg (aniline label) and 4.456 mg/kg (pyrazole label) were found in tomato leaves, and TRRs of 0.166 mg/kg (aniline label) and 0.112 mg/kg (pyrazole label) were found in tomato fruits.

The extractability of radioactive residues with methanol and water was >98% of the TRRs in tomato leaves and fruits. Thus, the RRRs were low <1.7% of the TRRs for both matrices.

BAS 700 F was the only compound observed at levels >10% of the TRRs in tomato matrices, amounting to >94% of the TRRs in tomato fruits and >90% of the TRRs in tomato leaves. In addition, minor amounts of the desmethyl metabolite M700F008 were identified (1.4% of the TRRs in fruits, aniline label only; 2.7% and 2.8% of the TRRs in leaves, aniline and pyrazole label, respectively). Minor amounts of the N-glucoside M700F048 were detected in leaves (0.8% of the TRRs, aniline label only). In extracts of leaves, two putative metabolite structures were assigned to a further peak (1.4% of the TRRs, 0.097 mg/kg, aniline label and 0.1% of the TRRs, 0.004 mg/kg, pyrazole label): M700F075 representing an O-glucoside and M700F076 representing a cysteine conjugate at the aniline moiety.

The metabolites identified are shown in the Table 5 below.

Table 5. Metabolites detected in tomato leaves and fruits following foliar treatment with BAS 700 F.

Metabolite	Tomato leaves (3 DAT [*])		Tomato fruits (3 DAT [*])	
	[mg/kg]	[% TRR]	[mg/kg]	[% TRR]
Aniline label				
BAS 700 F	6.039	90.1	0.156	94.4
M700F075 / M700F076	0.097	1.4	n.d.**	n.d.
M700F048	0.050	0.8	n.d.	n.d.
M700F008	0.179	2.7	0.002	1.4
Pyrazole label				
BAS 700 F	4.099	92.0	0.111	98.5
M700F075 / M700F076	0.004	0.1	n.d.	n.d.
M700F008	0.123		2.8	

* Days After last Treatment

** Not detected

Metabolism in wheat. Two foliar applications of an EC formulation were made to wheat, using an automatic spray track system, at a rate of 125 g a.i./ha for each label (at BBCH 30/35 and 69). This corresponds to a 1.25x application rate (both single and maximum seasonal rate). Wheat hay was sampled at 4 DALA (BBCH 73-75); straw, chaff and grain samples were collected at 34 and 35 DALA for aniline and pyrazole label, respectively (BBCH 89). Wheat forage samples were collected 36 days after the first application at BBCH 59 (forage samples received one application of 125 g a.i./ha only).

Prior to extraction and determination of the TRRs, subsamples of wheat chaff and grain were homogenised at room temperature using a mill. Frozen subsamples of forage and hay were cut with a porcelain knife to prepare for extraction. The extractions used were similar to those used for soybean commodities. In addition to the methanol and aqueous extracts, for wheat grain and chaff, the RRRs after extraction with methanol and water were subjected to a sequential solubilisation procedure. Subsamples of the dried and homogenised residues after solvent extraction were first treated with appropriate volumes of an aqueous ammonia solution (1%). The dried residues were then subjected to three consecutive solubilisation steps with hydrolyzing enzymes in aqueous buffers, followed by a final treatment with a solution of sodium hydroxide.

The initial extraction and analysis was completed in 77 days (<3 months). Additional analyses were completed within 13-15 months. The metabolite profiles were compared at the beginning and end of the storage period and showed relevant change in the nature of the radioactive residues during frozen storage

In order to classify the metabolites into organo-soluble and water-soluble, the methanol extracts were partitioned between isohexane, dichloromethane, ethyl acetate and water. The identification of the metabolites was based on LC-MS/MS analyses of fractions from the dichloromethane and the ethyl acetate phase of straw (pyrazole label). The metabolites in the other samples were assigned by comparison of the retention times and the elution profiles with those of the extracts investigated by LC-MS and those of reference items.

For identification, the methanol and water extracts were analyzed by radio-HPLC. Three analytical extraction procedures were compared: a three-step extraction method (L0137/01) with methanol/water (1/1, v/v), a three-step extraction method (L0076/03) with methanol/water/2N HCl (70/25/5, v/v/v) and a three-step extraction (Multi-residue method S19) with acetone/water (2/1, v/v). In general, all three extraction methods were comparable to the extraction method used for metabolism investigations in the current study in regards to the amount and composition of residues.

The metabolites identified are shown in Table 6 below.

Table 6. Summary of identified components in wheat matrices after treatment with ¹⁴C-BAS 700 F.

Metabolite	Wheat matrix*									
	Forage **		Hay		Straw		Chaff		Grain	
	[mg/kg]	[% TRR]	[mg/kg]	[% TRR]	[mg/kg]	[% TRR]	[mg/kg]	[% TRR]	[mg/kg]	[% TRR]
Aniline label										
M700F074	0.002	0.3	0.023	0.2	0.060	0.3	0.028	0.4	n.d.	n.d.
M700F058	0.003	0.3	0.021	0.2	0.050	0.3	0.017	0.3	n.d.	n.d.
M700F131/M700F041/ M700F130/M700F058	n.d.	n.d.	n.d.	n.d.	0.041	0.2	n.d.	n.d.	0.000	0.3
M700F048/M700F057	0.005	0.5	0.054	0.5	0.113	0.6	0.042	0.6	n.d.	n.d.
M700F059/M700F060	0.002	0.2	0.014	0.1	0.062	0.3	0.005	0.1	n.d.	n.d.
M700F082	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	0.009	0.1	n.d.	n.d.
M700F042/M700F024/ M700F005	0.002	0.3	0.033	0.3	0.134	0.7	0.041	0.6	n.d.	n.d.
M700F008/M700F043/ M700F041/M700F006	0.037	4.2	0.248	2.4	0.546	2.8	0.421	6.2	0.003	6.5
M700F134/M700F133	n.d.	n.d.	0.026	0.3	0.052	0.3	0.025	0.4	n.d.	n.d.
BAS 700 F	0.808	91.3	9.124	89.4	16.158	83.8	5.517	81.9	0.028	63.0
Pyrazole label										
M700F007/M700F002	0.005	0.5	0.031	0.3	0.084	0.5	0.039	0.5	0.000	0.5
M700F001	n.d.	n.d.	0.001	0.0	0.020	0.1	0.021	0.3	n.d.	n.d.
M700F036/M700F132	0.007	0.6	0.012	0.1	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.
M700F074	0.007	0.6	0.027	0.3	0.059	0.3	0.015	0.2	n.d.	n.d.
M700F058	0.012	1.2	0.042	0.4	0.075	0.4	0.009	0.1	n.d.	n.d.
M700F131/M700F041/ M700F130/M700F058	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	0.000	0.6
M700F048/M700F057	0.011	1.1	0.059	0.6	0.089	0.5	0.035	0.5	n.d.	n.d.
M700F059/M700F060	n.d.	n.d.	0.010	0.1	0.032	0.2	n.d.	n.d.	n.d.	n.d.
M700F082	n.d.	n.d.	0.014	0.1	0.039	0.2	0.016	0.2	n.d.	n.d.
M700F042/M700F024/ M700F005	n.d.	n.d.	0.059	0.6	0.122	0.7	0.050	0.7	n.d.	n.d.
M700F008/M700F043/ M700F041/M700F006	0.061	5.8	0.346	3.3	0.644	3.7	0.427	5.8	0.004	6.5
M700F134/M700F133	0.000	0.0	0.024	0.2	0.070	0.4	0.047	0.6	n.d.	n.d.
BAS 700 F	0.923	87.3	8.937	86.6	14.896	85.6	5.635	76.2	0.034	60.2

* Added from extracted residues (ERR) and the fractions solubilised from the RRR

** Forage was sampled 36 days after 1st application and 13 days prior to second application, i.e. forage samples received only one application

n. d. = not detected

BAS 700 F is present in wheat as the predominant compound while metabolites account for only minor proportion of the residue. Analysis of the metabolite patterns reveals a high number of metabolites. Their structural identification indicates that a few key transformation reactions lead to a range of structurally related metabolites, notably:

- N-demethylation of the pyrazole moiety
- Hydroxylation of the biphenyl moiety.

Both reactions, combinations thereof, and subsequent O- and N-conjugation reactions (glucose and/or malonic acid) result in a range of related compounds. N-demethylation of the pyrazole moiety leads to the metabolite M700F008, a precursor for the N-glycosides M700F048 and M700F060 as well as the hydroxyl metabolite M700F036. Hydroxylation of the biphenyl moiety leads to the metabolite M700F005 (and its isomers M700F006/M700F041/M700F042), precursor for the O-glycosides M700F074, M700F058, M700F130 and M700F131. Finally, the O-glycosides M700F057 and M700F059 can be derived from BAS 700 F via hydroxylation and subsequent conjugation of the methyl group at the pyrazole moiety.

Additional transformation reactions are the removal of a fluorine atom (leading to the metabolites M700F133, M700F134, M700F024, M700F040) and the conversion of the CHF₂ group into a carboxyl group. Additionally, cleavage products were identified resulting from cleavage of the trifluorophenyl ring (M700F082, M700F132). The presence of M700F002 and M700F001, carrying the pyrazole label only, indicates that the carboxamide bond of BAS 700 F can be cleaved. The absence of any cleavage products carrying the aniline label only, can be taken as an indication that M700F002 is generated by cleavage of BAS 700 F in the soil and subsequent uptake into the plant rather than by cleavage in the plant.

Conclusions. Plant metabolism studies were conducted for fluxapyroxad in three diverse crops, soybeans, tomato and wheat, to determine the qualitative metabolic fate of fluxapyroxad. The available metabolism data are sufficient.

Fluxapyroxad is metabolized in soybeans and wheat by N-demethylation of the pyrazole moiety, and hydroxylation of the biphenyl moiety, and conjugation of the metabolites formed. Very little metabolism was seen in tomatoes. The predominant residue found in plants is the parent fluxapyroxad, except for soybean seed. In tomatoes, fluxapyroxad was the only residue found. N-demethylation of the pyrazole moiety produces the metabolite M700F008. Metabolite M700F002 is formed by cleaving the carboxamide bond of fluxapyroxad.

860.1300 Nature of the Residue - Livestock

Monograph Section B.7.2

MRIDs 47923644, 47923645, 47923646, 47923648, 47923649, 47923650, 47923772

The metabolism of fluxapyroxad (BAS 700 F) was investigated in lactating goats using BAS 700 F radiolabelled in the aniline ring and, in separate studies, the pyrazole ring, and in laying hens using BAS 700 F radiolabelled in the aniline ring only. For the aniline label studies, the test item was a mixture of aniline-U-C¹⁴-BAS 700 F and aniline-N¹⁵, pyrazole-1,2-N¹⁵-BAS 700 F. For the

pyrazole studies, the test item was a mixture of pyrazole-4-C¹⁴-BAS 700 F with unlabelled BAS 700 F. The molecular structures and the label positions are shown above in section 860.1300 Nature of the Residue – Plants.

Metabolism in Lactating Goat. Two animals each were treated with fluxapyroxad labelled in the aniline and the pyrazole label. The dose level was 12 mg/kg feed for both labels. Animals were dosed by gavage once daily (in the morning) with 1 g of test substance in aqueous vehicle preparation per 100 g feed consumption for 8 consecutive days. Milk was sampled twice daily (in the morning before administration of the test substance and in the afternoon), pooled and stored in the refrigerator.

Excreta and milk samples were weighed immediately after collection and aliquots were taken for liquid scintillation counting (LSC). Lactating goats were sacrificed within 24 hours of the last dose. Tissues harvested were liver, kidney, leg-chest muscle, fat (kidney fat and intraperitoneal fat) and bile. Matrices sampled for balance analysis were bile, blood, gut/stomach, gut contents, stomach contents and cage wash. Samples were stored frozen at -18 C. Initial analyses of milk, feces and urine samples were completed in nine days. Some analyses continued for 550 days after collection.

Blood, stomach content, gut content, gut/stomach organs, heart, skin and lung were weighed immediately after sacrifice and aliquots were taken for LSC. Samples of bile, kidney, fat and muscle were weighed immediately after sacrifice, pooled for goats 1 and 2, or goats 3 and 4, homogenized as relevant, and aliquots taken for LSC.

Samples were stored frozen prior to transportation to the analytical laboratory. Tissues were shipped out on same day as sacrifice and collection; maximum storage time for milk, feces and urine samples was nine days, with shipment on day of sacrifice following eight treatment days. Samples were transported frozen and stored at -18°C at the analytical laboratory prior to work-up. Analysis was carried out up to 550 days after sample collection.

The radioactivity in urine, feces, blood, stomach content, gut content, gut/stomach and in individual milk samples was determined by LSC. After transport of the samples to the test facility at BASF Agricultural Center (Germany), subsamples of urine, feces and milk of both animals dosed with the aniline label and both animals dosed with the pyrazole label were combined to generate label-specific pooled samples for Day 1 8. Aliquots of the pooled urine and milk samples were measured for radioactivity by LSC. The tissues/organs of both animals (aniline and pyrazole label separately) were combined and homogenized. The radioactive residues in the pooled feces sample and homogenized tissues were determined by oxidative combustion of small aliquots followed by LSC.

No extraction was necessary for urine prior to HPLC analysis. Subsamples of the pooled milk and feces samples, and homogenized tissue samples were extracted with methanol and/or acetonitrile. In addition, the extraction procedure applied in the residue analytical method using acetonitrile/water (8:2) was tested. The results of the methanol extractions and/or the acetonitrile extractions (LSC of the combined extracts) are referred to as extractable radioactive residues (ERR). The residual radioactive residues after solvent extraction (RRR) were determined by combustion analysis. The methanol or acetonitrile extracts with sufficient concentrations of

radioactive residues were concentrated and analyzed by reversed-phase HPLC with gradient elution and radio-detection using two chromatographic methods.

Identification of metabolites was mainly based on LC-MS/MS investigations performed with purified fractions from urine of both labels (isolated using semi-preparative HPLC). In addition, LC-MS/MS investigations were carried out with a concentrated feces extract (aniline label) and isolated HPLC fractions from bile (aniline label). The metabolites in the other samples were assigned by comparison of the retention times and the HPLC profiles with those of urine and of reference items or reference samples from other studies using two different HPLC methods. Further HPLC peaks were characterized by their chromatographic properties.

Residue analytical method L0140/02 was developed for the detection of BAS 700 F and the metabolites M700F002, M700F008 and M700F048 in animal matrices. In this method, a mixture of acetonitrile/water (8:2) was used for extraction. To support the development of the method for residue analysis, the extractability of radioactive residues from matrices of the goat study was tested using the methanol/water (8:2) mixture. It was found that the extraction procedure applied in the residue analytical method released similar amounts of radioactive residues and yielded comparable metabolite patterns in comparison to data obtained with the extraction solvents methanol or acetonitrile used for analysis and metabolite identification in the current study.

The proposed metabolic pathways of BAS 700 F in lactating goats are shown in Figure B.7.2-1. Both labels showed comparable metabolic pathways revealing that BAS 700 F is metabolized by two main transformation reactions in lactating goats:

- Hydroxylation of the biphenyl moiety and
- N-demethylation of the pyrazole moiety.

N-demethylation of the pyrazole moiety leads to the metabolite M700F008, which is a precursor for a range of other metabolites. N-demethylation, hydroxylation, their combination, as well as subsequent conjugation with glucuronic acid, lead to a series of related metabolites. Minor metabolic transformations of the pyrazole moiety are N-glucuronidation, hydroxylation, and conversion of the CHF₂ group into a carboxy group. A minor transformation of the biphenyl moiety is the removal of an aromatic fluorine substituent. Hydrolytic cleavage of the carboxamide bond was not observed.

To demonstrate storage stability in homogenized matrices, extraction patterns and HPLC profiles from fat samples extracted 6-, 10-, 20- and 24-months after sampling were compared. No significant change in the extraction behavior and in the HPLC patterns was observed when the chromatograms were compared, except for one peak in at a retention time of ~60 minutes (in the 10-month sample) which was reported to result from carry-over from the HPLC sample analyzed previously. The comparison indicated that residues in homogenized fat kept in frozen storage are stable over a period of approximately 24 months.

The identification of metabolites in lactating goats and residue levels found are reported in the following table 7, and hens in Table 8

Table 7. Summary of BAS 700 F and metabolites and of characterized fractions in goat milk, liver, kidney, muscle, fat, urine, feces (pyrazole label).

Metabolite/Fraction	Milk		Liver		Kidney		Muscle		Fat		Urine		Feces	
	mg/kg	% TRR	mg/kg	% TRR	mg/kg	% TRR	mg/kg	% TRR	mg/kg	% TRR	mg/kg	% TRR	mg/kg	% TRR
BAS 700 F	0.0033	19.8	0.020	3.7	0.004	5.4	n.d.	n.d.	0.0084	34.1	n.d.	n.d.	0.036	2.0
M700F004	n.d.	n.d.	0.015	2.6	0.010	12.3	n.d.	n.d.	0.0015	6.1	0.054	1.3		
M700F005/M700F024*	n.d.	n.d.	0.046	8.3	0.015	19.2	n.d.	n.d.	0.0034	13.7	1.473	34.4	0.891	50.5
M700F008 **	0.0043	25.4	0.071	12.8	0.017	22.5	0.0078	82.9	0.0064	25.8	0.585	13.7	0.137	7.8
M700F009	0.0010	5.7	0.014	2.5	0.003	3.6	n.d.	n.d.	n.d.	n.d.	0.361	8.4	0.318	18.0
M700F010/M700F040 ***	0.0025	15.0	n.d.	n.d.	0.003	4.0	n.d.	n.d.	0.0009	3.7	0.128	3.0	0.066	3.8
M700F014	n.d.	n.d.	n.d.	n.d.	0.002	3.0	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.
M700F015	n.d.	n.d.	n.d.	n.d.	0.003	4.1	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.
M700F033	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	0.024	1.4
M700F034/M700F036	n.d.	n.d.	n.d.	n.d.	0.004	4.9	n.d.	n.d.	n.d.	n.d.	0.265	6.2	n.d.	n.d.
M700F038/M700F039	n.d.	n.d.	n.d.	n.d.	0.004	5.1	n.d.	n.d.	n.d.	n.d.	0.118	2.8	n.d.	n.d.
M700F041/-042/-043/-044	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	0.151	3.6	n.d.	n.d.
M700F046/M700F047	n.d.	n.d.	n.d.	n.d.	0.003	4.4	n.d.	n.d.	n.d.	n.d.	0.441	10.3	n.d.	n.d.
Total Identified (ERR)	0.0110	66.0	0.166	29.9	0.069	88.7	0.0078	82.9	0.0205	83.5	3.575	83.5	1.471	83.5
Total Characterized by HPLC (ERR)	0.0014	8.2	0.018	3.2	n. a.	n. a.	n. a.	n. a.	0.0057	23.0	0.707	16.5	0.028	1.6
Total Identified and/or Characterized from ERR	0.0124	74.2	0.184	33.2	n. a.	n. a.	n. a.	n. a.	0.0262	106.4	4.282	100.0	1.500	85.1
RRR after solvent extraction	0.0008	4.9	0.380	68.4	0.007	8.5	0.0011	11.5	0.0025	10.1	n. a.	n. a.	0.296	16.8
Total Characterized from RRR	n. a.	n. a.	n. a.	n. a.	n. a.	n. a.	n. a.	n. a.	n. a.	n. a.	n. a.	n. a.	n. a.	n. a.
Total Characterized (ERR + RRR)	n. a.	n. a.	n. a.	n. a.	n. a.	n. a.	n. a.	n. a.	n. a.	n. a.	n. a.	n. a.	n. a.	n. a.
Total Identified and/or Characterized (ERR + RRR)	n. a.	n. a.	n. a.	n. a.	n. a.	n. a.	n. a.	n. a.	n. a.	n. a.	n. a.	n. a.	n. a.	n. a.
Grand total [%]	0.0132	79.0	0.564	101.6	0.075	97.2	0.0089	94.4	0.0287	116.6	4.282	100.0	1.796	101.9

n. d. = not detected

n. a. = not applicable

* Besides M700F005, minor amounts of M700F024 were detected in a range from 0.065 to 0.035 mg/kg (urine, aniline label) to not detectable (liver, aniline label)

** Besides M700F008, metabolite M700F006 was found in urine (aniline label) and was not detected in milk, liver, kidney, muscle, fat

*** Besides M700F010, metabolite M700F040 was only found in minor amounts in urine (aniline label). Minor co-eluting metabolites were not further investigated in tissues from animals treated with pyrazole label.

Table 8. Identified, characterized and final ¹⁴C-residues from hen matrices after 12 daily doses with ¹⁴C-BAS 700 Fat mg/kg feed. (%TRR is not corrected for dimer concentration.)

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Designation	Matrix									
	Excreta		Eggs		Liver		Muscle		Fat	
	mg/kg	% TRR	mg/kg	% TRR	mg/kg	% TRR	mg/kg	% TRR	mg/kg	% TRR
Total Radioactive Residue (TRR)	3.640	100.0	0.077	100.0	0.210	100.0	0.010	100.0	0.059	100.0
Extractable Radioactive Residues (ERR)	3.228	88.7	0.070	91.7	0.143	67.9	0.008	79.3	0.060	102.5
Identified										
BAS 700 F	0.271	7.4	0.009	11.8	0.002	0.9	0.0011	11.7	0.023	38.5
M700F004	–	–	0.003	4.2	–	–	–	–	–	–
M700F005	0.630	17.3	0.005	6.6	0.009	4.1	0.0003	2.1	0.001	1.0
M700F008	0.228 ⁽¹⁾	6.3 ⁽¹⁾	0.033	43.5	0.009 ⁽¹⁾	4.1	0.0016 ⁽²⁾	17.1	0.009	15.4
M700F009 and/or M700F038	0.433	11.9	0.004	5.0	0.011	5.2	–	–	–	–
M700F024	0.392	10.8	–	–	0.014	6.7	–	–	–	–
M700F047	0.134	3.7	–	–	0.003	1.4	–	–	–	–
dimer of parent	0.042	1.1	0.008	10.9	0.007	3.3	0.0020	20.8	0.021	35.7
Total identified	2.130	58.5	0.063	81.9	0.055	26.0	0.005	52.4	0.053	90.7
Total characterized from ERR	1.098	30.2	0.007	9.3	0.083	39.4	0.002	18.6	0.004	6.6
Total identified and/or characterized from ERR	3.228	88.7	0.070	91.3	0.137	65.4	0.007	71.0	0.057	97.2
Residual Radioactive Residues	0.339	9.3	0.007	9.0	0.078	37.2	0.003	27.5	0.000	0.3
Identified in RRR supernatant after Pronase treatment										
M700F063	–	–	–	–	0.010	5.0	–	–	–	–
Total identified from RRR	–	–	–	–	0.010	5.0	–	–	–	–
Total characterized from RRR	–	–	–	–	0.046	21.8	–	–	–	–
Final residue	–	–	–	–	0.010	4.7	–	–	–	–
Grand total	3.567	98.0	0.077	100.3	0.203	96.9	0.009	98.6	0.057	97.5

⁽¹⁾ Includes unknown metabolite and M700F016⁽²⁾ Includes M700F016

Overall, $\geq 80\%$ of the total administered dose was eliminated in excreta. In milk, 0.09-0.10% of the administered dose was detected (0.011-0.017 mg/kg), with a plateau reached within 24 hours after administration. Tissues and organs retained $< 0.4\%$ of the administered dose (0.007-0.009 mg/kg in muscle, 0.021-0.025 mg/kg in fat, 0.036-0.078 mg/kg in kidney and 0.348-0.555 mg/kg in liver). The extractability of the radioactive residues was $\geq 79\%$ for all tissues other than liver. In liver, extractability was 30.3-34.2%. A major proportion of the residual radioactive residues (polar components, probably bound to proteins) was released from extracted liver tissue after incubation with protease.

BAS 700 F represented one of the major residues in milk (13.0-19.8% of the TRRs), muscle (12.0%, aniline label only) and fat (34.1-43.6% of the TRRs), while accounting for minor proportions in liver and kidney (3.2-7.0% of the TRRs). The other predominant compound was the desmethyl metabolite M700F008, representing a main proportion in milk (23.9-25.4% of the TRRs), muscle (54.7-82.9% of the TRRs), fat (25.8-25.9% of the TRRs), liver (12.8-16.7% of the TRRs) and kidney (22.5-25.6% of the TRRs).

Further metabolites at $> 10\%$ of the TRRs were detected in milk, kidney and fat. In milk, the metabolite M700F010 was found at levels of 12.3-15.0% of the TRRs (≤ 0.0025 mg/kg). The metabolite M700F005 was present in fat at 13.7% of the TRRs (0.0034 mg/kg) and in kidney at 19.2% of the TRRs (0.015 mg/kg), with pyrazole label only. The metabolite M700F004 was present in kidney at levels of 12.3-13.1% of the TRRs (≤ 0.010 mg/kg).

In urine and feces, the main portion of the radioactive residue was represented by metabolites derived by N-demethylation (M700F008), hydroxylation (M700F005) or a combination thereof (M700F009).

With both labels, comparable metabolic pathways were observed. Hydrolytic cleavage of BAS 700 F at the carboxamide bond was not seen. BAS 700 F was metabolized via two main transformation reactions, N-demethylation of the pyrazole moiety and hydroxylation of the biphenyl moiety. These reactions, occurring also in combination, followed by conjugation with glucuronic acid, led to the main metabolites. Several minor metabolic routes, i.e. hydroxylation at the pyrazole ring, conversion of the pyrazole CHF₂ group into a carboxy group, N-glucuronidation of the desmethyl metabolite and removal of an aromatic fluorine substituent, led to a range of minor components.

Metabolism in Laying Hens. The metabolism study in laying hens was conducted with the test substance labeled in the aniline ring only. Laying hens (12 per dose group) were dosed with 12 mg/kg feed by oral gavage. Eggs were collected twice daily (in the afternoon after administration of the test substance and in the morning before the subsequent administration, except for weekends when records on egg production were made once per day), and pooled. Excreta was collected once daily and pooled for each day of application. The laying hens were sacrificed about 23 hours after the last dose. Tissues harvested were liver, muscle (leg and breast), fat and bile. All tissues were pooled. Excreta and tissues were stored frozen.

Daily pooled homogenized egg samples, GI tract skin and contents (processed with acetone water, 1:1) and blood samples were directly analysed for radioactivity by LSC. After

homogenization, tissue samples (chest and leg muscle, fat, liver) and pooled 7-12 day egg samples (white and yolk) were analysed for radioactivity by combustion followed by LSC. Extraction and analysis by HPLC was done similarly to that done for lactating goats. For quantitation of radioactive residues, extracts of each matrix were analyzed by reverse-phase radio-HPLC. Extractability was compared to that of the proposed enforcement method, and was found to be similar, although a little less of liver radioactivity was extracted by the proposed enforcement method.

The characterization and identification of residues in the hen matrices is summarized in Table***. In the extracts of several matrices, a dimer of parent was detected that was identified to be a contaminant. This contaminant comprised about 1.17% of the application solution as determined by HPLC analysis. It was not considered to be a metabolite generated by the biotransformation of BAS 700 F in hens.

Radioactive residues in liver were not completely extracted - 0.078 mg/kg or 37.2% of the TRR remained unextracted, and was characterized using a sequential solubilisation procedure. Pronase treatment released considerable quantities from the RRR (24.7% of the TRRs), which had probably been associated with proteins. The protease solubilisates were investigated by HPLC analysis. Among other components, metabolite M700F063 was identified by co-chromatography experiments. The residue obtained after protease treatment (0.025 mg/kg or 12.0% of the TRRs) was further microwave-extracted, releasing 4.7% of the TRRs.

BAS 700 F was metabolized by two main transformation reactions in laying hens:

- Hydroxylation of the biphenyl moiety and
- N-demethylation of the pyrazole moiety

Metabolism studies in goats and hens with M700F002 and M700F048. Additional metabolism studies in lactating goats and laying hens were conducted using metabolite M700F002 and M700F048. M700F002 was not further metabolised in the lactating goat or laying hen. These studies are discussed in the monograph and will not be further discussed here.

Conclusions. The available ruminant and poultry metabolism data are adequate to support the proposed uses.

Overall, $\geq 80\%$ of the total administered dose to lactating goats was eliminated in excreta. In milk, 0.09-0.10% of the administered dose was detected (0.011-0.017 mg/kg), with a plateau reached within 24 hours after administration. Tissues and organs retained $< 0.4\%$ of the administered dose (0.007-0.009 mg/kg in muscle, 0.021-0.025 mg/kg in fat, 0.036-0.078 mg/kg in kidney and 0.348-0.555 mg/kg in liver). The extractability of the radioactive residues was $\geq 79\%$ for all tissues other than liver. In liver, extractability was 30.3-34.2%. A major proportion of the residual radioactive residues (polar components, probably bound to proteins) was released from extracted liver tissue after incubation with protease.

BAS 700 F represented one of the major residues in milk (13.0-19.8% of the TRRs), muscle (12.0%, aniline label only) and fat (34.1-43.6% of the TRRs), while accounting for minor proportions in liver and kidney (3.2-7.0% of the TRRs). The other predominant compound was the desmethyl metabolite M700F008, representing a main proportion in milk (23.9-25.4% of the

TRRs), muscle (54.7-82.9% of the TRRs), fat (25.8-25.9% of the TRRs), liver (12.8-16.7% of the TRRs) and kidney (22.5-25.6% of the TRRs).

Further metabolites at >10% of the TRRs were detected in milk, kidney and fat. In milk, the metabolite M700F010 was found at levels of 12.3-15.0% of the TRRs (≤ 0.0025 mg/kg). The metabolite M700F005 was present in fat at 13.7% of the TRRs (0.0034 mg/kg) and in kidney at 19.2% of the TRRs (0.015 mg/kg), with pyrazole label only. The metabolite M700F004 was present in kidney at levels of 12.3-13.1% of the TRRs (≤ 0.010 mg/kg).

In urine and feces, the main portion of the radioactive residue was represented by metabolites derived by N-demethylation (M700F008), hydroxylation (M700F005) or a combination thereof (M700F009).

Fluxapyroxad is metabolized in ruminants and poultry by N-demethylation of the pyrazole moiety, and hydroxylation of the biphenyl moiety, and combinations thereof, followed by conjugation of the metabolites formed. In poultry, loss of fluorine was also observed. The major (>10%) residues found in livestock tissues and milk and eggs was the parent fluxapyroxad and metabolite M700F008. In milk, the metabolite, M700F010 was also found as a major residue. N-demethylation of the pyrazole moiety produces the metabolite M700F008. Metabolite M700F002 is formed by cleaving the carboxamide bond of fluxapyroxad.

The main biotransformation reactions were deglycosylation of M700F048 and hydroxylation at the biphenyl moiety. Further biotransformation reactions observed were hydroxylation at the pyrazole ring, replacement of an aromatic fluorine atom, presumably by a hydroxy group and oxidation and hydrolysis of the CHF₂ group (forming a carboxy group) with subsequent protein conjugation.

860.1340 Residue Analytical Methods

Monograph Section B.5.2

Method Validation MRIDs 47923641, 47923642, 47923643

ILV MRIDs 47923544, 47923545, 47923546, 47923548

Enforcement and data collection methods:

Fluxapyroxad BASF Methods **L0137/01** (HPLC-MS/MS and UPLC-MS/MS; for plant matrices) and **140/02** (HPLC-MS/MS; for animal matrices) were developed to determine BAS 700 F and the metabolites M700F002, M700F008 and M700F048. The method **L0137/01** was validated in plant materials (wheat grain and straw, tomato, whole lemon, soy bean and onion). The method **140/02** was validated in animal matrices. BASF method L0140/02 was validated in animal matrices (milk, egg, bovine meat and liver) for the determination of **M700F002**.

BASF Method L0137/01: The analyte is extracted from plant material with methanol/water (50/50, v/v). An aliquot of the extract is diluted with saturated sodium chloride solution, acidified with hydrochloric acid and subsequently partitioned with water-saturated ethyl acetate. An aliquot of the organic phase is evaporated to dryness and dissolved in a mixture of

methanol/water (50/50, v/v). The final determination is performed by LC-MS/MS with a C18 column using gradient elution with 0.1% formic acid in water to 0.1% formic acid in acetonitrile as the mobile phase. MS/MS detection in the positive ionization mode was used to monitor ion transitions m/z 382→362 for BAS 700 F, m/z 368→348 for M700F008, and m/z 530→368 for M700F048. MS/MS detection in the negative ionization mode is used to monitor ion transitions 161→141 for M700F002. The LOQ was reported as 0.01 mg/kg. The LOD was not reported with the method validation, but was reported to be 0.002 – 0.003 ppm in the individual field trial reports.

BASF Method 140/02: The analyte is extracted from animal matrices using acetonitrile/water (80/20, v/v). An aliquot of the extract is evaporated to dryness and subsequently dissolved in methanol/water, diluted with saturated sodium chloride solution, acidified with hydrochloric acid and subsequently partitioned with waer-saturated ethyl acetate. An aliquot of the organic phase is evaporated to dryness and dissolved in methanol/water (40/60, v/v). The final determination is performed by HPLC-MS/MS using a T3 column and gradient elution using 0.1% formic acid in water to 0.1% formic acid in methanol as the mobile phase. MS/MS detection in the positive ionization mode was used to monitor ion transitions m/z 382→362 for BAS 700 F, m/z 368→348 for M700F008, and m/z 530→368 for M700F048. MS/MS detection in the negative ionization mode was used to monitor ion transitions 161→141 for M700F002. The LOQ was reported as 0.01 mg/kg for liver and muscle, and 0.001 mg/kg for milk and eggs.

Conclusions. BASF Methods L0137/01 and L0140/02 underwent successful validation by an independent laboratory and were deemed suitable for the determination of fluxapyroxad, and metabolites M700F002, M700F008, and M700F048 in plant and animal matrices, respectively.

The methods were shown to be selective, with accurate and repeatable results. The LOQs were reported as 0.01 mg/kg for plant material bovine meat and liver, and 0.001 mg/kg for milk and egg. The LODs were not reported with the analytical method, but were reported with the field trial reports and the livestock feeding studies as 0.002 to 0.003 for each analyte.

The proposed enforcement method has not been referred to ACL/BEAD for a Petition Method Validation (PMV) because the criteria specified in the Analytical Method PMV SOP have not triggered the requirement of a PMV. 1) The analytical method meets the requirements for an enforcement method in GLN 860.1340. 2) There were no major problems encountered in the ILV. 3) The technology used in the method is not new or novel. 4) This is not the first registration of a pyrazole fungicide. 5) Recovery data were provided at levels at or below the proposed tolerance levels. 6) The analytical method is based on sound scientific principles. 7) Although fluxapyroxad is not recovered by FDA's multiresidue methods, it can be recovered by multiresidue methods commonly used by enforcement agencies. 8) There are no dietary risks of concern. The method is suitable for enforcement purposes.

BASF Methods L0137/01 and L0140/02 will be submitted to ACL/BEAD and to FDA for updating PAM II, and to USDA for enforcement of tolerances in livestock commodities.

860.1360 Multiresidue Methods

Monograph Section B.5.2

MRID 47923549

Multiresidue method data have been submitted in support of the registration of fluxapyroxad. Fluxapyroxad and metabolites M700F002 and M700F008 were tested using the PAM multiresidue method protocols according to the guidance given in the PAM protocols, Volume I: Multiresidue Methods, Protocols A, B, C, D, E and F.

No response to fluxapyroxad or metabolites from the fluorescence detector was seen using Protocol A. No detector response was seen for metabolite M700F002 using Protocol B. Using Protocol C, Fluxapyroxad produced a single peak, with a long retention time. M700F002 produced no response using Module DG13. Fluxapyroxad was not recovered in either petroleum ether fraction for Protocol D. Using Protocols E and F, no peaks were detected, using Clean-up C1 or Clean-up C2.

Additional multiresidue analytical methods. The tissues from the plant metabolism studies were extracted using the extraction scheme from the German multiresidue method, DFG Method S19. Similar amounts were extracted to those extracted with the proposed enforcement method. Additionally, BASF reports that they have tested the QuEChERS extraction scheme, proposed for use as a multiresidue analytical method in the EU, with similar results.

Conclusions. PAM I multiresidue methods are not appropriate for detection of fluxapyroxad, nor metabolites M700F002 and M700F008. However, other multiresidue methods may be appropriate for fluxapyroxad.

860.1380 Storage Stability

Monograph Section B.7.6.2.

MRID 47923637, 47923638, 47923639, 47923640

The freezer storage stability of fluxapyroxad and its metabolites, M700F008, M700F002, and M700F048 in a number of plant matrices were investigated for samples stored at -20°C. The studies were planned for 2 years; interim reports were provided with this petition. Updated reports have since been provided. No processed commodities were studied for all analytes. No storage stability data were provided for livestock commodities.

The freezer storage stability of fluxapyroxad in apple (fruit), tomato (fruit), triticale (whole plant), soybean (seed), avocado (fruit), dried pea (seed), cereal (grain), potato (tuber), grape (fruit), lemon (fruit), wheat (straw) were investigated for samples stored at -20°C.

The freezer storage stability of M700F008 (metabolite of BAS 700 F) was investigated in plant matrices - Wheat (whole plant), wheat (grain), wheat (straw), lemon (fruit), dried pea (seed), soybean (seed); for samples stored at -20°C. The study was planned over a period of two years; interim results after three months (88-91 days) were initially reported, and the remainder of the 24 month study was subsequently submitted.

The freezer storage stability of M700F002 was investigated over a period of 18 months (538 days) in Apple (fruit), tomato (fruit), triticale (whole plant), soybean (seed), avocado (fruit), dried pea (seed), cereal (grain), potato (tuber), grape (fruit), lemon (fruit), and wheat (straw), for samples stored at -20°C. The Day 0 samples in the study were not collected on the day of spiking of stored samples.

The freezer storage stability of M700F048 was investigated over a period of 24 months in Apple (fruit), tomato (fruit), wheat (whole plant), soybean (seed), avocado (fruit), dried pea (seed), cereal (grain), potato (tuber), grape (fruit), lemon (fruit), wheat (straw), apple (juice), soybean (refined oil), potato (crisps), grape (raisins), and barley (beer) for samples stored at -20°C. initial reports included data up to 7 months of storage; the remainder of the study was subsequently submitted.

These data indicate that residues of fluxapyroxad are reasonably stable under frozen storage conditions in/on the above commodities for up to 24 months (the storage time tested) at -20 C. Residues of M700F008 were stable for up to four months in soybean seed, twelve months in wheat grain and 24 months (the storage time tested) in wheat (whole plant and straw), lemon, and dried pea seed, for samples stored at -20 C. Residues of M700F002 were stable for up to 538 days (18 months) in apple, tomato, triticale, soybean seed, avocado, dried pea seed, cereal grain, potato tuber, grape, lemon and wheat straw stored at -20 C. Residues of M700F048 were stable for up to 24 months in apple (fruit and juice), tomato, wheat, soybean (seed and refined oil), avocado, dried pea seed, cereal grain, potato (tuber and crisps), grape (fruit and raisins), lemon, wheat straw and barley (beer).

The storage durations and conditions of samples from the field trials and processing studies submitted to support this petition are presented in Table 4.

TABLE 9. Summary of Storage Conditions.				
Matrix (RAC)	Storage Temperature1 (°C)	Actual Storage Duration2	Extract Storage	Interval of Demonstrated Storage Stability
Legume RACs	<-5 at BASF, NC <-20 at Alliance Pharma, PA	327 days (11 months)	3 days	Fluxapyroxad 24 months at -20C in soybean seed M700F008 4 months at -20 C in soybean seed M700F002- 18 months at -20C in soybean seed M700F048- 24 months at -20C in soybean seed
Corn RACS	<-5	375 days (12.3 months)	7 days	Fluxapyroxad 24 months at -20C in cereal grain M700F008 4 months at -20 C in soybean seed M700F002- 18 months at -20C in cereal grain M700F048- 24 months at -20C in cereal grain
Wheat RACs	<-5	443 days (14.5 months)	7 days	Fluxapyroxad 24 months at -20C in cereal grain M700F008 12 months at -20 C in wheat grain & 24 months in wheat straw M700F002- 18 months at -20C in cereal grain M700F048- 24 months at -20C in cereal grain
Sorghum RACs	<-5	321 days (10.5 months)	7 days	Fluxapyroxad 24 months at -20C in cereal grain M700F008 12 months at -20 C in wheat grain & 24 months in wheat straw M700F002- 18 months at -20C in cereal grain M700F048- 24 months at -20C in cereal grain
Rice RACs	<-5	257 days (8.4 months)	7 days	Fluxapyroxad 24 months at -20C in cereal grain M700F008 12 months at -20 C in wheat grain & straw M700F002- 18 months at -20C in cereal grain M700F048- 24 months at -20C in cereal grain
Oilseeds	<-5 at BASF, NC <-20 at Alliance Pharma, PA	499 days (16.4 mo)	7 days	Fluxapyroxad 24 months at -20C in soybean seed M700F008 4 months at -20 C in soybean seed M700F002- 18 months at -20C in soybean seed M700F048- 24 months at -20C in soybean seed
Cotton seed & Gin Byproducts	<-5	410 days (13.6 mo)	5 days	Fluxapyroxad 24 months at -20C in soybean seed M700F008 4 months at -20 C in soybean seed M700F002- 18 months at -20C in soybean seed M700F048- 24 months at -20C in soybean seed
Sugar beet tops	<-5	380 days (12.5 mo)	5 days	Fluxapyroxad 24 months at -20C in wheat straw M700F008 24 months at -20 C in wheat straw M700F002- 18 months at -20C in wheat straw M700F048- 24 months at -20C in wheat straw
Sugar beet roots	<-5	315 days (10.4 mo)	7 days	Fluxapyroxad 24 months at -20C in potatoes M700F008-24 months at -20 C in wheat plants M700F002- 18 months at -20C in potatoes M700F048- 24 months at -20C in potatoes
Potato tubers	<-5	341 days (11.2 mo)	7 days	Fluxapyroxad 24 months at -20C in potatoes M700F008-12 months at -20 C in wheat plant M700F002- 18 months at -20C in potatoes M700F048- 24 months at -20C in potatoes
Fruiting vegetables	<-5	399 days (13.3 mo)	9 days	Fluxapyroxad 24 months at -20C in tomato M700F008-24 months at -20 C in lemon M700F002- 18 months at -20C in tomato M700F048- 24 months at -20C in tomato

TABLE 9. Summary of Storage Conditions.				
Matrix (RAC)	Storage Temperature ¹ (°C)	Actual Storage Duration ²	Extract Storage	Interval of Demonstrated Storage Stability
Peanuts	<-5	420 days (14 Mo)	16 days	Fluxapyroxad 24 months at -20C in soybean seed M700F008 4 months at -20 C in soybean seed M700F002- 18 months at -20C in soybean seed M700F048- 24 months at -20C in soybean seed
Pome Fruit RACs	<-5 at BASF, NC <-20 at Alliance Pharma, PA	301 days (9.9 mo)	6 days	Fluxapyroxad 24 months at -20 C in apple M700F008- 24 months at -20 C in lemon M700F002- 18 months at -20 C in apple M700F048- 24 months at -20C in apple
Stone Fruit RACs	<-5 at BASF, NC <-20 at Alliance Pharma, PA	611 days (20.1 mo)	6 days	Fluxapyroxad 24 months at -20 C in apple M700F008- 24 months at -20 C in lemon M700F002- 18 months at -20 C in apple M700F048- 24 months at -20C in apple
Cottonseed PACs (oil, meal, hulls)	-10 F (-22 C) at processor <-5 at BASF, NC	410 days (13.6 mo)	5 days	No storage stability data in processed commodities for Fluxapyroxad, M700F008, or M700F002 Fluxapyroxad 24 months at -20C in soybean seed M700F008 4 months at -20 C in soybean seed M700F002- 18 months at -20C in soybean seed M700F048- 24 months at -20C in soybean oil
Apple PACs (wet pomace, juice)	ambient before processing, -17 after processing, <-5 at BASF, NC	371 (12.2 mo)	6 days	No storage stability data in processed commodities for Fluxapyroxad, M700F008, or M700F002 Fluxapyroxad 24 months at -20C in apple M700F008-24 months at -20 C in lemon M700F002- 18 months at -20C in apple M700F048- 24 months at -20 C in apple
Oilseed PACs (oil, meal)	<-10 at processor, <-5 at BASF, NC <-20 at Alliance Pharma, PA	474 days (16 months) for canola, 416 days (14 months) for sunflower	5 days	No storage stability data in processed commodities for Fluxapyroxad, M700F008, or M700F002 Fluxapyroxad 24 months at -20C in soybean seed M700F008 4 months at -20 C in soybean seed M700F002- 18 months at -20C in soybean seed M700F048- 24 months at -20C in soybean oil
Peanut PACs (oil, meal)	< -10 F (-23 C+B26) at processor, <-5 at BASF, NC	391 days (13 mo)	2 days	No storage stability data in processed commodities for Fluxapyroxad, M700F008, or M700F002 Fluxapyroxad 24 months at -20C in soybean seed M700F008 4 months at -20 C in soybean seed M700F002- 18 months at -20C in soybean seed M700F048- 24 months at -20C in soybean oil
Plums	<-10 at processor, <-5 at BASF, NC <-20 at Alliance Pharma, PA	442 days (14.5 mo)	3 days	No storage stability data in processed commodities for Fluxapyroxad, M700F008, or M700F002 Fluxapyroxad 24 months at -20C in apple M700F008- 24 months at -20 C in lemon M700F002- 18 months at -20C in apple M700F048- 24 months at -20 C in apple
Tomato PACs (paste, puree)	refrigerated (≤6.6) before processing, <-10 after processing, <-5 at BASF, NC	104 days (3.4 mo)	7 days	No storage stability data in processed commodities for Fluxapyroxad, M700F008, or M700F002 Fluxapyroxad 24 months at -20 C in tomato M700F008- 24 months at -20 C in lemon 700F002- 18 months at -20C in tomato M700F048- 24 months at -20C in tomato

TABLE 9. Summary of Storage Conditions.				
Matrix (RAC)	Storage Temperature ¹ (°C)	Actual Storage Duration ²	Extract Storage	Interval of Demonstrated Storage Stability
Cereal Grain PACs (bran, flour, middlings, shorts, germ, pearled barley, corn oil)	refrigerated (≤6.6) before processing, <-10 after processing, <-5 at BASF, NC	266 days (8.7 mo), except 182 days (6 mo) barley;	11 days	No storage stability data in processed commodities for Fluxapyroxad, M700F008, or M700F002 Fluxapyroxad 24 months at -20C in cereal grain M700F008- 12 months at -20 C in wheat grain M700F008 4 months at -20 C in soybean seed M700F002- 18 months at -20C in cereal grain M700F048- 24 months at -20C in cereal grain
Potato PACs (granules/flakes, chips, wet peel)	refrigerated (≤6.6) before processing, <-10 after processing, <-5 at BASF, NC	390 days (12.8 mo)	7 days	No storage stability data in processed commodities for Fluxapyroxad, M700F008, or M700F002 Fluxapyroxad 24 months at -20C in potato M700F008- 24 months at -20 C in wheat plants M700F002- 18 months at -20C in potato M700F048- 24 months at -20C in potato and crisps
Sugar Beet PACs (sugar, dried pulp, molasses)	refrigerated (≤6.6) before processing, <-10 after processing, <-5 B31at BASF, NC	232 days (7.6 mo)	7 days	No storage stability data in processed commodities for Fluxapyroxad, M700F008, or M700F002 Fluxapyroxad 24 months at -20C in potato M700F008- 24 months at -20 C in wheat plants M700F002- 18 months at -20C in potato M700F048- 24 months at -20C in potato and crisps
Soybean PACs (oil, meal, hulls)	refrigerated (≤6.6) before processing, <-10 after processing, <-5 at BASF, NC	232 days (7.6 mo)	7 days	No storage stability data in processed commodities for Fluxapyroxad, M700F008, or M700F002 Fluxapyroxad 24 months at -20C in soybean seed M700F008 4 months at -20 C in soybean seed M700F002- 18 months at -20C in soybean seed M700F048- 24 months at -20C in soybean seed and oil
Livestock tissues, milk, eggs	-20	<30 days	NS	No storage stability data in livestock commodities.

¹ Based on the sample storage temperature from sample receipt at the analytical facility through the last extraction.

² Based on number of days between harvest and extraction dates. All samples were analyzed within 4 days of extraction.

Conclusions. These data indicate that residues of fluxapyroxad are stable for up to 24 months (the length of time the study was conducted) in apple, tomato, triticale, soybean seed, avocado, dried pea seed, cereal grain, potato tuber, grape, lemon and wheat straw stored at -20 C. The data available on these crops adequately address the OECD guidelines outlined for stored commodities (i.e., representative matrices from five different categories: two high water content, two high oil content, one high protein content, two high starch content and two high acid content commodities). Therefore, frozen storage stability testing on processed commodities are not required.

Residues of M700F008 are stable for up to four months in soybean seed, 12 months in wheat (grain), and 24 months (the length of time the study was conducted) in wheat straw, lemon, dried pea seed and wheat whole plant. Regarding the crops in the current submission, residues of M700F008 are considered to be stable only up to four months in high oil and high protein matrices (soybean seed, canola seed, sunflower seed, peanut nutmeat, cotton seed, succulent peas and beans), and if samples of these commodities are stored frozen for longer than four months, quantifiable residues of M700F008 need to be corrected for in-storage dissipation using a 57%

recovery rate. Similarly, residues of M700F008 are considered to be stable only up to 12 months in high starch matrices (cereal grains, root and tuber crops), and if samples of these commodities are stored frozen for longer than 12 months, quantifiable residues of M700F008 need to be corrected for in-storage dissipation using a 63% recovery rate.

Residues of M700F002 were stable for up to 538 days (18 months) in apple, tomato, triticale, soybean seed, avocado, dried pea seed, cereal grain, potato tuber, grape, lemon and wheat straw stored at -20 C. Residues of M700F048 were stable for up to 24 months in apple (fruit and juice), tomato, wheat, soybean (seed and refined oil), avocado, dried pea seed, cereal grain, potato (tuber and crisps), grape (fruit and raisins), lemon, wheat straw and barley (beer) stored at -20 C.

Residues of BAS 700 F, M700F002, M700F008 and M700F048 were shown to be stable after storage of the extracts under refrigerated conditions for 3-14 days (Annex B.5.2).

The storage stability studies were conducted at -20 C, but many of the field trial and processing studies were conducted at -5 C. The storage data will be adequate to demonstrate the stability of samples stored at -5 C. However, the petitioner should be reminded that storage stability studies should be conducted at the same conditions as the samples were stored.

The Day 0 samples in the Fluxapyroxad, M700F002, and M700F048 storage stability study were not collected on the day of spiking of stored samples. The purpose of zero-time sampling points is to establish and check the residue levels present at the time samples are placed into storage. As such, the study is considered to have limitations. The petitioner should be reminded that storage stability studies should have day 0 analyses.

No processed commodities were studied for all analytes. We note that the OECD guidelines do not require storage stability data for processed commodities. Considering the availability of storage stability data on representative matrices from five different categories (two high water content, two high oil content, one high protein content, two high starch content and two high acid content commodities), the data available on these crops adequately address the OECD guidelines outlined for stored commodities. Therefore, frozen storage stability testing on processed commodities are not required.

No storage stability data were provided for livestock commodities. The livestock feeding study samples were stored less than 30 days, so no storage stability data for livestock commodities are needed at this time.

860.1400 Water, Fish, and Irrigated Crops

There are no proposed uses that are relevant to this guideline topic.

860.1460 Food Handling

There are no proposed uses that are relevant to this guideline topic.

860.1480 Meat, Milk, Poultry, and Eggs

Monograph Section B.7.8

MRID 47923666, MRID 47923667

There are a number of livestock feedstuffs associated with the proposed uses of fluxapyroxad: apple, pomace, wet; cereal grain, grain, milled byproducts, hay and straw; beet, sugar, dried, and molasses; corn, grain, forage/silage, stover, and milled byproducts; cotton, undelinted seed, meal, hulls, and gin byproducts; foliage of legumes; grain, aspirated fractions; safflower, meal; peanut, meal and hay; and soybean, seed, meal, hulls, forage/silage, and hay.

The dietary burdens of fluxapyroxad to livestock were calculated using the procedures of the most recent guidance developed by OECD (Mar 2011); see Table 6. The estimated dietary burdens are 0.4 ppm for beef cattle, 11.2 ppm for dairy cattle, 0.19 ppm for poultry, and 0.54 ppm for swine. BASF submitted feeding studies with cattle and poultry which are summarized below.

Table 10. Calculation of Dietary Burdens of Fluxapyroxad Residues to Livestock.					
Feedstuff	Type ¹	% Dry Matter ²	% Diet ²	HAFT/Ave (ppm) ³	Dietary Contribution (ppm) ⁴
Beef Cattle					
Canola meal	PC	0.88	5	0.11	0.006
barley straw	R	0.89	10	9.8	1.101
Wheat hay	R	0.88	5	9.71	0.552
Aspirated grain	CC	0.89	5	15.4	0.865
rice grain	CC	0.88	20	0.87	0.198
Barley grain	CC	0.88	50	0.62	0.352
TOTAL BURDEN	--	--	100.00		3.1
Dairy Cattle					
Canola meal	PC	0.88	10	0.11	0.013
peanut hay	R	0.85	5	8.9	0.524
Apple pomace	CC	0.4	10	0.97	0.243
rice grain	CC	0.89	20	0.87	0.196
Barley grain	CC	0.88	15	0.62	0.106
wheat forage	R	0.25	20	9.2	7.360
Soybean Hay	R	0.85	20	16.25	3.824
TOTAL BURDEN	--	--	100		12.3
Poultry					
Canola meal	PC		15	0.11	0.017
Cowpeas	PC		10	0.07	0.007
Barley grain	CC		75	0.62	0.465
TOTAL BURDEN	--	--	100	--	0.49
Swine					
Canola meal	PC	0.88	15	0.11	0.017
rice grain	CC	0.89	20	0.87	0.174
Barley grain	CC	0.88	20	0.62	0.124
Wheat bran	CC	0.88	45	0.28	0.126

TOTAL BURDEN	--	--	100		0.44
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¹ R: Roughage; CC: Carbohydrate concentrate; PC: Protein concentrate.

² OPPTS 860.1000 Table 1 Feedstuffs (June 2008), OECD Guidance Document on Residues in Livestock (Mar 2011)

³ Residue to be input is the highest residue for forages, and the STMR for blended commodities.

⁴ Contribution = ([residue/% DM] X % diet) for beef and dairy cattle; contribution = ([residue] X % diet) for poultry and swine, where residue = HAFT for forages and hays and STMdR for blended feeds

Livestock Feeding Studies

The magnitude of the residue of fluxapyroxad and metabolites M700F002 and M700F008 in dairy cattle tissues and milk, and laying hen tissues and eggs was determined in a feeding study. For 28 consecutive days, lactating dairy cows and laying hens were administered fluxapyroxad and metabolite M700F002 at the target dose levels shown below.

Dairy Cattle Feeding Levels

Group 1, control, 0 mg/kg BAS 700 F and 0 mg/kg M700F002

Group 2, 3.0 mg/kg BAS 700 F and 0 mg/kg M700F002

Group 3, 6.0 mg/kg BAS 700 F and 0.10 mg/kg M700F002

Group 4, 18 mg/kg BAS 700 F and 0.30 mg/kg M700F002

Group 5, 60 mg/kg BAS 700 F and 1.0 mg/kg M700F002

Laying Hen Feeding Levels

Group 1, control, 0 mg/kg BAS 700 F and 0 mg/kg M700F002

Group 2, 0.3 mg/kg BAS 700 F and 0.025 mg/kg M700F002

Group 3, 0.6 mg/kg BAS 700 F and 0.05 mg/kg M700F002

Group 4, 1.8 mg/kg BAS 700 F and 0.15 mg/kg M700F002

Group 5, 6.0 mg/kg BAS 700 F and 0.5 mg/kg M700F002

Group 6, 6.0 mg/kg BAS 700 F and 0.5 mg/kg M700F002

The highest dose level (60 mg/kg fluxapyroxad) is 13x the Beef Cattle dietary burden; 2.8x the Dairy Cattle dietary burden, 27x the swine dietary burden, and 1.6x the Poultry dietary burden).

Dairy Cattle. Dairy cattle were fed for 28 consecutive days at the target dose levels shown above.

The dosing was orally in gelatine capsules filled with feed. Milk samples from each animal were collected twice daily, and combined as one pooled sample per day. On Study Day 21, milk was also separated into cream and skimmed milk. All animals were sacrificed within 22-24 hours after the final dosing, except for three cows in Group 5, which were sacrificed two, five and seven days after the final dose to determine decline of residue levels post-dosing. Tissue samples were taken from muscle (~1 kg consisting of equal portions of loin, hind-leg {round piece} and diaphragm), liver (2 kg sample from distal portions of each lobe), kidney (both entire organs) and fat (~1 kg consisting of equal portions of perirenal, mesenterial and subcutaneous fat). All samples were stored at -20°C and remained frozen until analysis.

In Group 3 (6 mg/kg feed of BAS 700 F + 0.1 mg/kg feed of M700F002), mean residues of BAS 700 F and M700F008 up to 0.0019 mg/kg and 0.0018 mg/kg, respectively, were detected in milk. In meat, no quantifiable residues of BAS 700 F or M700F008 were found. In kidney, no quantifiable residues of BAS 700 F and low residues (0.011 mg/kg) of M700F008 were present. In fat, BAS 700 F was found at a mean residue level of 0.019 mg/kg, and M700F008 residues

were <LOQ. In liver, BAS 700 F was found at a mean residue level of 0.013 mg/kg, and M700F008 was found at mean residue level of 0.038 mg/kg.

In Group 4 (18 mg/kg feed of BAS 700 F + 0.3 mg/kg feed of M700F002), mean residues of BAS 700 F and M700F008 up to 0.0047 mg/kg and 0.0046 mg/kg, respectively, were found in milk. In meat, no residues of BAS 700 F or M700F008 were found above LOQ. In kidney, residues of BAS 700 F were <LOQ, and mean residues of M700F008 were 0.017 mg/kg. In fat, BAS 700 F was found at a mean residue level of 0.045 mg/kg, and M700F008 was found at 0.025 mg/kg. In liver, BAS 700 F was found at a mean level of 0.031 mg/kg, and M700F008 was found at a mean level of 0.088 mg/kg.

At the highest dose level (60 mg/kg feed of BAS 700 F + 1.0 mg/kg feed of M700F002), quantifiable residues of BAS 700 F and M700F008 were found in all matrices. Maximum residues in milk were 0.0154 mg/kg for BAS 700 F and 0.0160 mg/kg for M700F008. In muscle, mean residue levels were 0.011 mg/kg for BAS 700 F, and 0.024 mg/kg for M700F008. In liver, BAS 700 F was present at a mean level of 0.085 mg/kg, and M700F008 was found at a mean level of 0.255 mg/kg. In kidney, BAS 700 F was found at a mean level of 0.014 mg/kg, and M700F008 at a mean level of 0.050 mg/kg. In fat, BAS 700 F was present at a mean level of 0.015 mg/kg, and M700F008 at a mean level of 0.108 mg/kg.

No quantifiable residues of M700F002 were found in any milk, skim milk, cream or tissue sample in any of the treatment groups.

Residues of BAS 700 F and the metabolite M700F008 in milk reached a plateau within five to seven days, and were completely eliminated after four days withdrawal. In tissues, residues of BAS 700 F and M700F008 were non-detectable within two days of withdrawal of the test items.

Laying Hens. Ten laying hens were included in each dose group. The doses were administered in gelatin capsules filled with chicken feed as a carrier. Eggs from each animal were collected twice daily and combined as one pooled sample per day per dose group. Tissues from each bird were pooled per dose group for processing, then stored at -20°C. Eggs and tissue samples were stored frozen at -20°C and analyzed within 30 days of storage.

The residues of fluxapyroxad, M700F008 and M700F002 found in eggs during the treatment and depuration period are summarized in Table 7, for the 6.0 ppm feeding level. Since the dosing levels were so low compared to the dietary burdens, only residues from the highest feeding level are tabulated.

In the 0.3 and 0.6 mg/kg dose groups, no residues of fluxapyroxad were quantifiable with the exceptions of the 0.3 mg/kg dose group at day 23 and the 0.6 mg/kg dose group at days 13 and 23. The residues at these time points were ≤ 0.0031 mg/kg. In the 1.8 mg/kg dose group, mean residues of up to 0.0028 mg/kg were detected (maximum concentration of 0.0045 mg/kg on day 27). In the 6.0 mg/kg dose group, mean residues reached a plateau after five days at levels of up to 0.0065 mg/kg with maximum residues of 0.0124 mg/kg. In the samples of the depuration group (dosed at 6.0 mg/kg), residues were below LOQ after 3 days of depuration and not detectable after 7 days of depuration. In the control group, no residues above LOQ (0.001

mg/kg) were detected. No quantifiable residues of M700F002 (< 0.001 mg/kg) were found in any egg samples from any dose groups. No quantifiable residues of M700F008 (< 0.001 mg/kg) were found in the lowest dose group (fed 0.3 mg/kg). In the 0.6 mg/kg, 1.8 mg/kg, and 6.0 mg/kg dose groups, a plateau was reached after day 5 with maximum concentrations of 0.0021 mg/kg (day 16), 0.0055 mg/kg (day 20) and 0.0184 mg/kg (day 5), respectively. In the depuration group (fed 6.0 mg/kg), residues were non-quantifiable (<0.001 mg/kg) after 7 days of depuration. No quantifiable residues of fluxapyroxad, M700F002, or M700F008 were detected in the control group.

Table 11. Residues of Fluxapyroxad in Poultry Commodities From 6.0 mg/kg Dose Group (12x Feeding Level) and 0.60 mg/kg Dose Group (1.2x Feeding Level)

Tissue	6.0 mg/kg Dose Group		0.60 mg/kg Dose Group	
	Residue Fluxapyroxad (ppm)	Residue M700F008 (ppm)	Residue Fluxapyroxad (ppm)	Residue M700F008 (ppm)
Egg	0.045	0.013	0.0017	0.0017
Poultry liver	<0.01	0.014	<0.01	<0.01
Poultry muscle	<0.01	<0.01	<0.01	<0.01
Poultry fat	0.03	0.01	<0.01	<0.01
Poultry skin with fat	<0.01	<0.01	<0.01	<0.01

No quantifiable residues of M700F002 were found in any tissue or egg sample

Table 12. Residues of BAS 700 F in cattle commodities from 60 mg/kg dosing group (4.9x feeding level for Dairy Cattle, 19x feeding level for Beef Cattle, 140x feeding level for Swine)

Tissue	Residue BAS 700F (ppm)	Residue M700F008 (ppm)
Milk	0.015	0.016
Cattle liver	0.085	0.26
Cattle kidney	0.014	0.050
Cattle muscle	0.011	0.024
Cattle fat	0.15	0.108

Conclusions. The dairy cattle and laying hen feeding studies are acceptable. Tolerances are needed for fluxapyroxad on cattle, goat, horses, sheep, and egg commodities. The calculation is shown in Table 9 and 10 below.

Table 13. Calculation of Fluxapyroxad Tolerances and Residues To Be Used in Risk Assessment for Cattle, Goat, Horse, and Sheep Commodities.

Tissue	Feeding Study Dietary Burden 60 ppm		Tolerance and Residues for Risk Assessment Dietary Burden 12.3 ppm		
	Residue Fluxapyroxad (ppm)	Residue M700F008 (ppm)	Tolerance Needed (ppm)	Metabolites of Concern (ppm)	Residue for Risk Assessment (ppm)
Milk	0.015	0.016	0.003	0.006	0.010
Cattle liver	0.085	0.26	0.017	0.055	0.073
Cattle kidney	0.014	0.05	0.003	0.011	0.014
Cattle muscle	0.011	0.024	0.002	0.005	0.007
Cattle fat	0.15	0.108	0.031	0.023	0.026

Tolerance needed (ppm) = Residue of Fluxapyroxad x 12.3 ppm / 60 ppm

Total residues (ppm) = BAS 700 F (ppm) + [1.038 * M700F008] where,

1.038 = MW BAS 700 F / M700F008 (381.3/367.3)

For milk, M700F010 is included in the risk assessment. Residues of M700F010 were approximately the same as the residues of parent fluxapyroxad (BAS 700F), so it is added in at the same level as BAS 700F.

Table 14. Calculation of Tolerances and Residues To Be Used in Risk Assessment for Poultry Commodities.

Tissue	Feeding Study Dietary Burden 6.0 ppm		Tolerance and Residues for Risk Assessment Dietary Burden 0.49 ppm		
	Residue Fluxapyroxad (ppm)	Residue M700F008 (ppm)	Tolerance Needed (ppm)	Metabolites of Concern (ppm)	Residue for Risk Assessment (ppm)
Egg	0.045	0.013	0.004	0.001	0.005

Tolerance needed (ppm) = Residue of Fluxapyroxad x 12.3 ppm / 60 ppm

Total residues (ppm) = BAS 700 F (ppm) + [1.038 * M700F008] where,

1.038 = MW BAS 700 F / M700F008 (381.3/367.3)

Tolerances for fluxapyroxad will be set as follows:

Milk at 0.003 ppm, with 0.007 ppm to be used for risk assessment.

Cattle*, fat at 0.05 ppm

Cattle, meat at 0.01 ppm

Cattle, meat byproducts** at 0.03 ppm

*tolerances for cattle commodities will also apply to goat, horses, and sheep

**tolerances for meat byproducts cover residues in liver and kidney

Swine and poultry commodities, except eggs, fall under Category 3 of 40 CFR 180.6(a)(3), no expectation of finite residues, based on the new OECD Guidance for livestock commodities.

860.1500 Crop Field Trials

Monograph Section B.7.6.1

47923653 Wheat, Barley US trials
47923654 Wheat, Triticale – European trials
47923655 Wheat, Triticale – European trials
47923656 Barley – European Trials
47923657 Barley – European Trials
47923658 Legumes & Foliage of Legumes
47923659 Oilseeds
47923660 Peanut
47923661 Pome Fruit
47923662 Stone Fruit
47923663 Potato, Sugarbeets
47923664 Fruiting Vegetables
47923665 Cotton

The crop field trials are discussed below in crop group order. All samples were analyzed using BASF Method L0137/01 (HPLC-MS/MS), the data collection method for the determination of BAS 700 F and metabolites in plant commodities, which is described in more detail above under 860.1340 Residue Analytical Methods. Concurrent method recoveries were considered acceptable for all commodities and are included in the field trial monograph. Residues of BAS 700 F and the metabolites were less than the method LOQ (<0.01 ppm each) in/on all untreated control samples. Sample storage times and conditions are summarized above under 860.1380 Storage Stability. The tabular summary of field trial data includes only data at the proposed use pattern (application rate and PHI). Data for other application rates and PHIs are included in the monograph. Field trial locations did not always match the recommendations, but were reasonably close to those recommended.

Root and Tuber Vegetables. Thirty-three field trials were conducted on potatoes and sugar beets during the 2008 growing season. Potato is the representative commodity for crop subgroup 1C. Sugarbeets is one of the three required representative commodities for crop subgroup 1A; the others being carrots and radishes.

Potato. A total of 21 field trials on potatoes were conducted, 5 in NAFTA Region 1, 1 in Region 2, 1 in Region 3, 5 in Region 5, 1 in Region 7A, 1 in Region 9, 1 in Region 10, 4 in Region 11, 1 in Region 12, and 1 in Region 14. The treated potato plots received three broadcast foliar applications of BAS 700 F (formulation code BAS 700 AE F, nominal concentration 62.5 g/L EC), targeting 100 g a.i./ha/application (0.089 lb a.i./A/application). The actual application rates were 91-129 g a.i./ha/application (0.081-0.115 lb a.i./A/application), with a 6-10 day RTI (except 1 trial in WA, which had a 29-day RTI between the 2nd and 3rd applications, due to investigator oversight), for a total rate of 290-326 g a.i./ha/season (0.259-0.291 lb a.i./A/season). Samples of potato roots and sugar beet roots and tops were harvested by hand or mechanical equipment 7-8, 13-15 and 20-22 days after treatment. In addition, at 2 sites, additional samples were collected at 10 and 28 days to evaluate residue decline.

The results from the crop field trials showed that following broadcast foliar applications of BAS 700 F to root and tuber vegetables at a rate of 290-326 g a.i./ha/season (0.26-0.29 lb

a.i./A/season), maximum residues of BAS 700 F were 0.02 ppm in/on potato tubers (n=42; PHI of 7 days). Residues of metabolites M700F002, M700F008 and M700F048 were <0.01 ppm on potato tubers.

Since residues were <0.01 ppm in most potato tuber samples, residue decline could not be evaluated in potatoes.

Sugar beet. A total of 12 field trials on sugar beets were conducted, 4 in NAFTA Region 5, 1 in Region 7, 1 in Region 7A, 1 in Region 8, 1 in Region 9, 1 in Region 10, 2 in Region 11, and 1 in Region 14. The treated sugar beet plots received three broadcast foliar applications of BAS 700 F (formulation code BAS 700 AE F, nominal concentration 62.5 g/L EC), targeting 100 g a.i./ha/application (0.089 lb a.i./A/application). The actual application rates were 91-129 g a.i./ha/application (0.081-0.115 lb a.i./A/application), with a 6-10 day RTI (except trial R080462, which had a 29-day RTI between the 2nd and 3rd applications, due to investigator oversight), for a total rate of 290-326 g a.i./ha/season (0.259-0.291 lb a.i./A/season). Samples of potato roots and sugar beet roots and tops were harvested 7-8, 13-15 and 20-22 days after treatment. In addition, at 2 sites, additional samples were collected at 10 and 28 days to evaluate residue decline.

The results from the crop field trials showed that following broadcast foliar applications of BAS 700 F to sugar beets at a rate of 290-326 g a.i./ha/season (0.26-0.29 lb a.i./A/season), maximum residues of BAS 700 F were 0.07 ppm in/on sugar beet roots (n=24; PHI of 7-8 days), and 4.17 ppm in/on sugar beet tops (leaves) (n=22; PHI of 7-8 days). Residues of metabolites M700F002, M700F008 and M700F048 were <0.01 ppm on sugarbeets, with the exception of M700F008 residues on sugar beet tops (<0.01-0.07 ppm).

The residue decline data indicated that residues of BAS 700 F in sugar beets decrease with increasing PHIs from 7 to 21 days.

Commodity	Appl. Rate g a.i./ha (lb a.i./A)	Analyte	PHI (days)	Residue Levels (ppm)						
				n	Min.	Max.	HAFT	Median (STMDr)	Mean (STMR)	Std. Dev.
Potato, tubers	290-320 (0.26-0.29)	BAS 700 F	7	42	<0.01	0.02	0.02	<0.01	0.01	0.002
		M700F002	7	42	<0.01	<0.01	<0.01	<0.01	<0.01	NA
		M700F008	7	42	<0.01	<0.01	<0.01	<0.01	<0.01	NA
		M700F048	7	42	<0.01	<0.01	<0.01	<0.01	<0.01	NA
		Total residues**	7	42	0.02	0.03	0.03	0.02	0.02	0.002
Sugar beet, roots	290-330 (0.26-0.29)	BAS 700 F	7-8	24	<0.01	0.07	0.06	0.02	0.03	0.02
		M700F002	7-8	24	<0.01	<0.01	<0.01	<0.01	<0.01	NA
		M700F008	7-8	24	<0.01	<0.01	<0.01	<0.01	<0.01	NA
		M700F048	7-8	24	<0.01	<0.01	<0.01	<0.01	<0.01	NA
		Total residues**	7-8	24	0.02	0.08	0.07	0.03	0.04	0.02
Sugar beet, tops (leaves)	290-330 (0.26-0.29)	BAS 700 F	7-8	22	0.70	4.17	3.82	2.44	2.30	1.12
		M700F002	7-8	22	<0.01	<0.01	<0.01	<0.01	<0.01	NA
		M700F008	7-8	22	<0.01	0.07	0.06	0.03	0.03	0.02
		M700F048	7-8	22	<0.01	<0.01	<0.01	<0.01	<0.01	NA
		Total residues**	7-8	22	0.71	4.23	3.88	2.47	2.33	1.14

* Only samples harvested at PHIs corresponding to the proposed GAP were included in the summary table.

** The residue definition in plants is fluxapyroxad and metabolite M700F008. The molecular weight conversion factor for M700F008 is 1.038 (MW BAS 700 F / M700F008 = 381.3 / 367.3). Total residues were calculated in fluxapyroxad equivalents as BAS 700 F + [1.038 x M700F008].

HAFT = Highest Average Field Trial value.
STMdR = Supervised Trial Median Residue.
STMR = Supervised Trial Mean Residue.

Legumes. Crop field trials on legumes (PMRA# 1884448. MRID 47923658) were conducted at thirty-nine sites during the 2008 growing season. The locations of the trials do not completely match the Canadian and US guideline recommendations. The treated sites received two broadcast foliar applications of an emulsifiable concentrate (EC) formulation of BAS 700 F (formulation code BAS 700 AE F, nominal concentration 62.5 g/L) at 93-105 g a.i./ha/application (0.083-0.094 lb a.i./A/application), with a 6-8 day retreatment interval (RTI), for a total rate of 188-207 g a.i./ha/season (0.166-0.185 lb a.i./A/season).

For dry beans, the second treated plot at each location received two broadcast foliar applications at a higher rate, 196-210 g a.i./ha/application (0.175-0.188 lb a.i./A/application), with a 6-9 day RTI, for a total rate of 398-413 g a.i./ha/season (0.355-0.369 lb a.i./A/season). An adjuvant was added to the spray mixture for all legume trials. Samples were harvested targeting 7±1 days after last application (DALA). For two succulent pea and two soybean trials, residue decline samples were taken at PHIs targeting 0, 4 and 14 DALA.

Peas. Following two broadcast foliar applications of BAS 700 F to peas targeting 100 g a.i./ha/application (0.089 lb a.i./A/application), residues were: BAS 700 F, 0.16-0.97 ppm; M700F002, ND-<0.01 ppm; M700F008, ND-0.02 ppm; M700F048, ND-<0.01 ppm in/on 18 treated pea succulent seed with pod samples harvested at a targeted 7±1 day PHI (actual, 6-7 day PHI, except at one site where the samples were taken at 4 DALA because the peas developed more quickly than expected and were collected early). Residues were: BAS 700 F, <0.01-0.05 ppm; M700F002, ND-<0.01 ppm; M700F008, ND; M700F048, ND in/on 18 treated pea succulent seed without pod samples. Residues were: BAS 700 F, 0.55-4.36 ppm; M700F002, ND; M700F008, ND-0.04 ppm; M700F048, ND-0.06 ppm in/on 17 treated pea vine samples, and BAS 700 F, 1.60-13.2 ppm; M700F002, ND-<0.01 ppm; M700F008, 0.02-0.11 ppm; M700F048, ND-0.13 ppm in/on 18 treated pea hay samples. Residues in/on 18 treated pea dried seed samples were: BAS 700 F, <0.01-0.20 ppm; M700F002, ND-<0.01 ppm; M700F008, ND-<0.01 ppm; M700F048, ND.

Dry Beans. Following two broadcast foliar applications of BAS 700 F to dry beans targeting 100 g a.i./ha/application (0.089 lb ai/A/application), residues were: BAS 700 F, ND-0.14 ppm; M700F002, ND; M700F008, ND-0.02 ppm; M700F048, ND-<0.01ppm in/on 22 treated dried seed samples harvested at a 21-22 day PHI. Residues were: BAS 700 F, ND-0.21 ppm; M700F002, ND-<0.01 ppm; M700F008, ND-0.03 ppm; M700F048, ND-0.01ppm in/on 22 treated dried seed samples harvested at a PHI of 21-22 days after the last of two applications at the higher rate targeting 200 g a.i./ha/application (0.18 lb a.i./A/application).

Soybeans. Following two broadcast foliar applications of BAS 700 F to soybean targeting 100 g a.i./ha/application (0.089 lb a.i./A/application), residues were: BAS 700 F, 0.04-0.85 ppm; M700F002, ND-0.02 ppm; M700F008, <0.01-0.06 ppm; M700F048, ND-0.03 ppm in/on 30 treated soybean succulent seed with pod samples harvested at a targeted 7±1 day PHI (actual, 6-8 day PHI, except at one site where the samples were taken at 28 DALA because the soybeans developed more slowly than expected because of weather conditions). Residues were: BAS 700

F, <0.01-0.38 ppm; M700F002, ND-0.01 ppm; M700F008, ND-0.02 ppm; M700F048, ND-0.02 ppm in/on 30 treated soybean succulent seed without pod samples. Residues were: BAS 700 F, 0.77-6.46 ppm; M700F002, ND-<0.01 ppm; M700F008, ND-0.07 ppm; M700F048, ND-0.08 ppm in/on 30 treated soybean forage samples, and BAS 700 F, 0.45-16.8 ppm; M700F002, ND-<0.01 ppm; M700F008, 0.01-0.13 ppm; M700F048, <0.01-0.20 ppm in/on 30 treated soybean hay samples. Residues in/on 29 treated soybean dried seed samples were: BAS 700 F, ND-0.13 ppm; M700F002, ND-<0.01 ppm; M700F008, ND-<0.01 ppm; M700F048, ND-0.01 ppm).

Residue decline studies were conducted at four garden pea and two soybean trial sites. The residue decline data indicate that residues of BAS 700 F and metabolites in legume vegetables decline with increasing PHIs from 0 to 13-15 days.

The results from the legume trials showed that after two foliar applications of BAS 700 F targeting ~100 g a.i./ha/application (~0.09 lb a.i./A/application) with a 6-8 day retreatment interval, totalling 186-207 g a.i./ha/season (0.166-0.185 lb a.i./A/season), maximum residues of BAS 700 F were 0.97 ppm in peas, succulent seed with pods (PHI 4-7 days), 0.04 ppm in peas, succulent seed without pod (PHI 4-7 days), 0.85 ppm in soybeans, succulent seed with pod (PHI 6-8 days), 0.38 ppm in soybeans, succulent seed without pods (PHI 6-8 days), 4.36 ppm in pea vines (PHI 4-7 days), 13.21 ppm in pea hay (PHI 4-7 days), 6.46 ppm in soybean forage (PHI 6-8 days), 16.8 ppm in soybean hay (PHI 6-8 days), 0.20 ppm in peas (dried seed; PHI 21-22 days), 0.14 ppm in dry beans (dried seed; PHI 21-22 days), and 0.13 ppm in soybeans (dried seed; PHI 20-22 days).

After two foliar applications of BAS 700 F (on dry beans only) targeting ~200 g a.i./ha/application (~0.18 lb a.i./A/application), with a 6-8 day retreatment interval, totalling 398-413 g a.i./ha/season (0.355-0.369 lb a.i./A/season), maximum residues of BAS 700 F were 0.21 ppm in/on dry beans (dried seed) at a PHI of 21-22 days.

The residue decline data indicated that residues of BAS 700 F and metabolites in legume vegetables decreased with increasing PHIs from 0 to 13-15 days.

Commodity	Appl. Rate g a.i./ha (lb a.i./A)	Analyte	PHI (days)	Residue Levels (ppm)						
				n	Min.	Max.	HAFT	Median (STMdR)	Mean (STMR)	Std. Dev.
Pea, succulent seed with pod	199-207 (0.178-0.184)	BAS 700 F	4-7**	18	0.16	0.97	0.95	0.63	0.52	0.28
		M700F002	4-7**	18	<0.01	<0.01	<0.01	<0.01	<0.01	0
		M700F008***	4-7**	18	<0.01	0.04	0.04	0.01	0.02	0.01
		M700F048	4-7**	18	<0.01	<0.01	<0.01	<0.01	<0.01	0
		Total residues****	4-7**	18	0.17	0.98	0.96	0.65	0.54	0.27
Soybean, succulent seed with pod	192-204 (0.171-0.182)	BAS 700 F	6-8	28	0.07	0.85	0.69	0.23	0.27	0.21
		M700F002	6-8	28	<0.01	0.02	0.02	<0.01	0.01	0.002
		M700F008***	6-8	28	<0.01	0.10	0.08	0.04	0.04	0.03
		M700F048	6-8	28	<0.01	0.03	0.03	0.01	0.01	0.004
		Total residues****	6-8	28	0.08	0.92	0.76	0.27	0.31	0.22
Pea, succulent seed without pod	199-207 (0.178-0.184)	BAS 700 F	4-7**	18	<0.01	0.05	0.05	0.03	0.03	0.010
		M700F002	4-7**	18	<0.01	<0.01	<0.01	<0.01	<0.01	0
		M700F008	4-7**	18	<0.01	<0.01	<0.01	<0.01	<0.01	0
		M700F048	4-7**	18	<0.01	<0.01	<0.01	<0.01	<0.01	0
		Total residues****	4-7**	18	0.02	0.06	0.06	0.04	0.04	0.01
Soybean, succulent seed	192-204 (0.171-0.182)	BAS 700 F	6-8	28	<0.01	0.38	0.37	<0.01	0.05	0.09
		M700F002	6-8	28	<0.01	0.01	<0.01	<0.01	0.01	0

Commodity	Appl. Rate g a.i./ha (lb a.i./A)	Analyte	PHI (days)	Residue Levels (ppm)						
				n	Min.	Max.	HAFT	Median (STMdR)	Mean (STMR)	Std. Dev.
without pod		M700F008***	6-8	28	<0.01	0.04	0.03	<0.01	0.01	0.01
		M700F048	6-8	28	<0.01	0.02	0.02	<0.01	0.01	0.003
		Total residues****	6-8	28	0.02	0.39	0.38	0.02	0.06	0.09
Pea, vines	199-207 (0.178-0.184)	BAS 700 F	4-7**	17	0.55	4.36	4.11	2.85	2.39	1.19
		M700F002	4-7**	17	<0.01	<0.01	<0.01	<0.01	<0.01	0
		M700F008	4-7**	17	<0.01	0.04	0.04	<0.01	0.01	0.01
		M700F048	4-7**	17	<0.01	0.06	0.05	<0.01	0.02	0.014
		Total residues****	4-7**	17	0.56	4.37	4.12	2.87	2.41	1.19
Pea, hay	199-206 (0.178-0.184)	BAS 700 F	4-7**	18	1.60	13.21	12.12	7.71	7.63	3.18
		M700F002	4-7**	18	<0.01	<0.01	<0.01	<0.01	<0.01	0
		M700F008	4-7**	18	0.02	0.11	0.11	0.04	0.05	0.03
		M700F048	4-7**	18	<0.01	0.13	0.13	0.01	0.03	0.04
		Total residues****	4-7**	18	1.62	13.23	12.14	7.75	7.68	3.18
Soybean, forage	192-204 (0.171-0.182)	BAS 700 F	6-8	28	0.77	6.46	6.43	1.90	2.15	1.44
		M700F002	6-8	28	<0.01	<0.01	<0.01	<0.01	<0.01	0
		M700F008	6-8	28	<0.01	0.07	0.07	0.03	0.03	0.01
		M700F048	6-8	28	<0.01	0.08	0.08	0.03	0.04	0.02
		Total residues****	6-8	28	0.79	6.53	6.50	1.92	2.18	1.45
Soybean, hay	192-204 (0.171-0.182)	BAS 700 F	6-8	28	0.45	16.80	16.25	4.39	4.73	3.78
		M700F002	6-8	28	<0.01	<0.01	<0.01	<0.01	<0.01	0
		M700F008	6-8	28	0.01	0.13	0.13	0.04	0.05	0.03
		M700F048	6-8	28	<0.01	0.20	0.20	0.07	0.08	0.06
		Total residues****	6-8	28	0.46	16.94	16.38	4.45	4.78	3.81
Pea, dried seed	195-207 (0.174-0.185)	BAS 700 F	21-22	18	<0.01	0.20	0.16	0.04	0.07	0.06
		M700F002	21-22	18	<0.01	<0.01	<0.01	<0.01	<0.01	0
		M700F008	21-22	18	<0.01	<0.01	<0.01	<0.01	<0.01	0
		M700F048	21-22	18	<0.01	<0.01	<0.01	<0.01	<0.01	0
		Total residues****	21-22	18	0.02	0.21	0.17	0.05	0.08	0.06
Dried beans, dried seed [low rate]	195-202 (0.174-0.180)	BAS 700 F	21-22	22	<0.01	0.14	0.11	0.01	0.03	0.03
		M700F002	21-22	22	<0.01	<0.01	<0.01	<0.01	<0.01	0
		M700F008	21-22	22	<0.01	0.02	0.02	<0.01	<0.01	0.002
		M700F048	21-22	22	<0.01	<0.01	<0.01	<0.01	<0.01	0
		Total residues****	21-22	22	0.02	0.16	0.12	0.02	0.04	0.03
Soybean, dried seed	186-202 (0.166-0.181)	BAS 700 F	20-22	29	<0.01	0.13	0.10	<0.01	0.02	0.03
		M700F002	20-22	29	<0.01	<0.01	<0.01	<0.01	<0.01	0
		M700F008	20-22	29	<0.01	<0.01	<0.01	<0.01	<0.01	0
		M700F048	20-22	29	<0.01	0.01	<0.01	<0.01	<0.01	0
		Total residues****	20-22	29	0.02	0.14	0.11	0.02	0.03	0.03
Dried beans, dried seed [high rate]	398-413 (0.355-0.369)	BAS 700 F	21-22	22	<0.01	0.21	0.21	0.03	0.05	0.05
		M700F002	21-22	22	<0.01	<0.01	<0.01	<0.01	<0.01	0
		M700F008	21-22	22	<0.01	0.03	0.03	<0.01	0.01	0.01
		M700F048	21-22	22	<0.01	0.01	0.01	<0.01	<0.01	0
		Total residues****	21-22	22	0.02	0.24	0.24	0.04	0.06	0.06

* Only samples harvested at PHIs corresponding to the proposed GAP were included in the summary table.

** Pea samples harvested at 4-day PHI in one trial were included since residues were comparable to those from trials with PHIs of 6-7 days.

*** Quantifiable residues of M700F008 were corrected for in-storage dissipation in samples stored for longer than 4 months (based on soybean seed results in freezer storage stability tests; 57% recovery following 177-day storage and 55% recovery following 2-year storage).

**** The residue definition in plants is fluxapyroxad and metabolite M700F008. The molecular weight conversion factor for M700F008 is 1.038 (MW BAS 700 F / M700F008 = 381.3 / 367.3). Total residues were calculated in fluxapyroxad equivalents as BAS 700 F + [1.038 x M700F008].

HAFT = Highest Average Field Trial value.

STMdR = Supervised Trial Median Residue.

STMR = Supervised Trial Mean Residue.

Fruiting Vegetables. Thirty (30) crop field trials were conducted on fruiting vegetables during the 2008 growing season: 20 on tomato, 8 on bell pepper, and 2 on non-bell pepper. Two of the

tomato trials in CA were conducted on cherry tomatoes. Tomato varieties included large and smaller tomato varieties, including processing varieties.

Tomato. A total of 20 tomato field trials were conducted, 1 in NAFTA Region 1, 1 in Region 2, 1 in Region 3, 6 in Region 5, 3 in Region 5B, and 8 in Region 10. Two of the tomato trials in CA (Region 10) were conducted on cherry tomatoes. Tomato varieties included large and smaller tomato varieties, including processing varieties. At each test location, two or three broadcast foliar applications of BAS 700 F, 62.5 g/L EC Formulation, were made to tomatoes targeting 0.089 lb ai/A/application (0.100 kg ai/ha/application). The actual application rate for BAS 700 F for 2 treatments was 0.086-0.095 lb ai/A/application (0.096-0.106 kg ai/ha/application), for a total rate of 0.174-0.187 lb ai/A/season (0.195-0.209 kg ai/ha/season). The actual application rate for BAS 700 F for 3 treatments was 0.085-0.094 lb ai/A/application (0.095-0.105 kg ai/ha/application), for a total rate of 0.262-0.275 lb ai/A/season (0.293-0.309 kg ai/ha/season). The retreatment interval (RTI) was 6 to 8 days for both treatments. An adjuvant was added to the spray mixture for all applications. The proposed use is 3 treatments.

Following three broadcast foliar applications of BAS 700 F to tomato targeting 100 g ai/A (0.089 lb ai/A/application), with a 6-8 day retreatment interval, totalling ~300 g ai/A/season (0.267 lb ai/A/season), maximum residues of BAS 700 F were 0.46 ppm (7 day PHI), 0.33 ppm (14 day PHI), and 0.22 ppm (21 day PHI) in/on treated tomato fruit samples (n=40 for each sampling interval). Residues of M700F008 were < LOQ (0.01 ppm) in/on all treated tomato fruit samples, across all sampling intervals.

Pepper. A total of 8 field trials were conducted for bell peppers, 1 in NAFTA Region 2, 1 in Region 3, 5 in Region 5, and 1 in Region 10. Additionally, 2 field trials were conducted in Non-bell peppers, 1 in Region 6, and 1 in Region 10. At each test location, two or three broadcast foliar applications of BAS 700 F, 62.5 g/L EC Formulation, were made to tomatoes targeting 0.089 lb ai/A/application (0.100 kg ai/ha/application). The actual application rate for BAS 700 F for 2 treatments was 0.086-0.095 lb ai/A/application (0.096-0.106 kg ai/ha/application), for a total rate of 0.174-0.187 lb ai/A/season (0.195-0.209 kg ai/ha/season). The actual application rate for BAS 700 F for 3 treatments was 0.085-0.094 lb ai/A/application (0.095-0.105 kg ai/ha/application), for a total rate of 0.262-0.275 lb ai/A/season (0.293-0.309 kg ai/ha/season). The retreatment interval (RTI) was 6 to 8 days for both treatments. An adjuvant was added to the spray mixture for all applications. The proposed use is 3 treatments.

Following three broadcast foliar applications of BAS 700 F to pepper targeting 100 g ai/A (0.089 lb ai/A/application), with a 6-8 day retreatment interval, totalling ~300 g ai/A/season (0.267 lb ai/A/season), maximum residues of BAS 700 F were 0.31 ppm (7 day PHI), 0.25 ppm (14 day PHI), and 0.07 ppm (21 day PHI) in/on treated pepper fruit samples (n=20 for each sampling interval). Residues of M700F008 were a maximum of 0.15 ppm.

The residue decline data indicated that residues of BAS 700 F and metabolites in fruiting vegetables decreased with increasing PHIs from 0 to 21 days.

Table 17. Summary of Residue Data from Fruiting Vegetable Field Trials with BAS 700 F*.				
Commodity	Appl. Rate	Analyte	PHI	Residue Levels (ppm)

	g a.i./ha (lb a.i./A)		(days)	n	Min.	Max.	HAFT	Median (STMdR)	Mean (STMR)	Std. Dev.
Tomato, fruit [low rate]	190-200 (0.17-0.18)	BAS 700 F	7	40	<0.01	0.19	0.18	0.04	0.06	0.05
		M700F002	7	40	<0.01	<0.01	<0.01	<0.01	<0.01	0
		M700F008	7	40	<0.01	<0.01	<0.01	<0.01	<0.01	0
		M700F048	7	40	<0.01	<0.01	<0.01	<0.01	<0.01	0
		Total residues**	7	40	0.02	0.20	0.19	0.05	0.07	0.05
Tomato, fruit [high rate]	290-310 (0.26-0.27)	BAS 700 F	7	40	<0.01	0.46	0.44	0.05	0.08	0.10
		M700F002	7	40	<0.01	<0.01	<0.01	<0.01	<0.01	0
		M700F008	7	40	<0.01	<0.01	<0.01	<0.01	<0.01	0
		M700F048	7	40	<0.01	<0.01	<0.01	<0.01	<0.01	0
		Total residues**	7	40	0.02	0.47	0.45	0.06	0.09	0.10
Bell pepper, fruit [low rate]	200-210 (0.18-0.19)	BAS 700 F	7	16	<0.01	0.12	0.10	0.02	0.04	0.04
		M700F002	7	16	<0.01	<0.01	<0.01	<0.01	<0.01	0
		M700F008	7	16	<0.01	0.07	0.06	0.02	0.03	0.02
		M700F048	7	16	<0.01	<0.01	<0.01	<0.01	<0.01	0
		Total residues**	7	16	0.02	0.19	0.16	0.04	0.07	0.06
Bell pepper, fruit [high rate]	290-310 (0.26-0.28)	BAS 700 F	7	16	<0.01	0.29	0.24	0.03	0.06	0.08
		M700F002	7	16	<0.01	<0.01	<0.01	<0.01	<0.01	0
		M700F008	7	16	<0.01	0.15	0.14	0.02	0.04	0.04
		M700F048	7	16	<0.01	<0.01	<0.01	<0.01	<0.01	0
		Total residues**	7	16	0.02	0.45	0.38	0.04	0.10	0.12
Nonbell pepper, fruit [low rate]	200 (0.18)	BAS 700 F	7	4	<0.01	0.19	0.19	0.10	0.10	0.10
		M700F002	7	4	<0.01	<0.01	<0.01	<0.01	<0.01	0
		M700F008	7	4	<0.01	<0.01	<0.01	<0.01	<0.01	0
		M700F048	7	4	<0.01	<0.01	<0.01	<0.01	<0.01	0
		Total residues**	7	4	0.02	0.20	0.20	0.11	0.11	0.10
Nonbell pepper, fruit [high rate]	300 (0.27)	BAS 700 F	7	4	0.01	0.31	0.30	0.15	0.16	0.16
		M700F002	7	4	<0.01	<0.01	<0.01	<0.01	<0.01	0
		M700F008	7	4	0.01	0.02	0.02	0.02	0.18	0.01
		M700F048	7	4	<0.01	<0.01	<0.01	<0.01	<0.01	0
		Total residues**	7	4	0.02	0.33	0.32	0.17	0.17	0.17

* Only samples harvested at PHIs corresponding to the proposed GAP were included in the summary table.

** The residue definition in plants is fluxapyroxad and metabolite M700F008. The molecular weight conversion factor for M700F008 is 1.038 (MW BAS 700 F / M700F008 = 381.3 / 367.3). Total residues were calculated in fluxapyroxad equivalents as BAS 700 F + [1.038 x M700F008].

HAFT = Highest Average Field Trial value.

STMdR = Supervised Trial Median Residue.

STMR = Supervised Trial Mean Residue.

Pome Fruit. Field trial data have been generated for BAS 700 F on the representative crops (apple and pear) of the pome fruit crop group (Crop Group 11) using a 62.5 g/L EC.

Apple. Fourteen trials were conducted on apples in NAFTA Growing Region 1 (NY, three trials), 5 (MI, ON, two trials each; IL, one trial), 9 (UT, one trial), 10 (CA, one trial), and 11 (ID and WA, two trials each). At each test location, four broadcast foliar (airblast) applications of BAS 700 F (formulation code BAS 700 AE F, nominal concentration 62.5 g/L EC) were made to pome fruits targeting 0.089 lb ai/A/application (0.100 kg ai/ha/application). The actual application rate was 0.081-0.099 lb ai/A/application (0.091-0.111 kg ai/ha/application), with a 6-8 day retreatment interval, for a total rate of 0.346-0.370 lb ai/A/season (0.388-0.414 kg ai/ha/season). The applications were made to plots at each site using either concentrate (49-95 gal/A of water, 456-893 L/ha, Treatment 2) or dilute (119-237 gal/A of water, 1113-2214 L/ha, Treatment 3) spray volumes. An adjuvant was added to the spray mixture for all applications. Samples were harvested 0, 1, 7, and 12-14 days after treatment. At three sites, treated samples were also collected at 10 days after the last application to provide additional data points for the examination of residue decline.

The results from the field trials show that after four broadcast (airblast) foliar applications of BAS 700 F to apple targeting 100 g ai/ha/application (0.089 lb ai/A/application), actual application rate of 0.091-0.111 kg ai/ha/application (0.081-0.099 lb ai/A/application), with a 6-8 day retreatment interval, for a total rate of 0.388-0.414 kg ai/ha/season (0.346-0.370 lb ai/A/season), maximum residues of BAS 700 F were 0.37, 0.36, 0.29, and 0.24 ppm in apple fruit samples harvested 0, 1, 7, and 14 days after the last application. Maximum residues of M700F008 were <LOQ (0.01 ppm) at all sampling intervals. The proposed PHI is 0 days.

Pear. Ten trials were conducted on pears in NAFTA Growing Regions 1 (NY, two trials), 5 (MI, two trials; ON, one trial), 10 (CA, two trials), and 11 (OR, one trial; WA, two trials). At each test location, four broadcast foliar (airblast) applications of BAS 700 F (formulation code BAS 700 AE F, nominal concentration 62.5 g/L EC) were made to pome fruits targeting 0.089 lb ai/A/application (0.100 kg ai/ha/application). The actual application rate was 0.081-0.099 lb ai/A/application (0.091-0.111 kg ai/ha/application), with a 6-8 day retreatment interval, for a total rate of 0.346-0.370 lb ai/A/season (0.388-0.414 kg ai/ha/season). The applications were made to plots at each site using either concentrate (49-95 gal/A of water, 456-893 L/ha, Treatment 2) or dilute (119-237 gal/A of water, 1113-2214 L/ha, Treatment 3) spray volumes. An adjuvant was added to the spray mixture for all applications. Samples were harvested 0, 1, 7, and 12-14 days after treatment. At three sites, treated samples were also collected at 10 days after the last application to provide additional data points for the examination of residue decline.

The results from the field trials show that after four broadcast (airblast) foliar applications of BAS 700 F to pear targeting 100 g ai/ha/application (0.089 lb ai/A/application), actual application rate of 0.091-0.111 kg ai/ha/application (0.081-0.099 lb ai/A/application), with a 6-8 day retreatment interval, for a total rate of 0.388-0.414 kg ai/ha/season (0.346-0.370 lb ai/A/season), maximum residues of BAS 700 F were 0.47, 0.42, 0.42, and 0.31 ppm in pome fruit samples harvested 0, 1, 7, and 14 days after the last application. Maximum residues of M700F008 were 0.01 ppm (0 and 1 day PHI), and 0.02 ppm (7 and 14 day PHIs). The proposed PHI is 0 days.

The residue decline data indicate that residues of BAS 700 F in both apples and pears decrease at longer preharvest intervals. No storage stability data were provided for the storage conditions used for sample storage (-5 C).

Commodity	Appl. Rate g a.i./ha (lb a.i./A)	Analyte	PHI (days)	Residue Levels (ppm)						
				n	Min.	Max.	HAFT	Median (STMdR)	Mean (STMR)	Std. Dev.
Apple, fruit	390-410 (0.35-0.36)	BAS 700 F	0	28	0.08	0.37	0.37	0.19	0.20	0.08
		M700F002	0	28	<0.01	<0.01	<0.01	<0.01	<0.01	0
		M700F008	0	28	<0.01	0.08	0.08	0.01	0.01	0.01
		M700F048	0	28	<0.01	<0.01	<0.01	<0.01	<0.01	0
		Total residues**	0	28	0.09	0.38	0.38	0.20	0.21	0.08
Pear, fruit	390-410 (0.35-0.37)	BAS 700 F	0	20	0.10	0.47	0.47	0.22	0.25	0.11
		M700F002	0	20	<0.01	<0.01	<0.01	<0.01	<0.01	0
		M700F008	0	20	<0.01	0.01	0.01	<0.01	<0.01	0
		M700F048	0	20	<0.01	<0.01	<0.01	<0.01	<0.01	0
		Total residues**	0	20	0.11	0.48	0.48	0.23	0.26	0.11

* Only samples harvested at PHIs corresponding to the proposed GAP were included in the summary table.

** The residue definition in plants is fluxapyroxad and metabolite M700F008. The molecular weight conversion factor for M700F008 is 1.038 (MW BAS 700 F / M700F008 = 381.3 / 367.3). Total residues were calculated in fluxapyroxad equivalents as BAS 700 F + [1.038 x M700F008].

HAFT = Highest Average Field Trial value

STMdR = Supervised Trial Median Residue

STMR = Supervised Trial Mean Residue

Stone Fruit. Field trial data have been generated for BAS 700 F on the representative crops (peach, plum, and cherry (both sweet and tart)) of the pome fruit crop group (Crop Group 11) using a 62.5 g/L EC. The proposed PHI is 0 days. Six trials were conducted on cherries in NAFTA Growing Regions 5 (MI, two trials; ON, one trial), 10 (CA, one trial), and 11 (WA and OR, one trial each); twelve trials were conducted on peaches in NAFTA Growing Regions 1 (NY, one trial), 2 (GA, two trials), 5 (MI, two trials; ON and IL, one trial each), 6 (OK, one trial), 10 (CA, three trials), and 11 (WA, one trial); ten trials were conducted on plums in NAFTA Growing Regions 1 (NY, one trial), 5 (MI, two trials; ON, one trial), 10 (CA, four trials), 11 (WA, one trial), and 12 (OR, one trial). At each test location, three broadcast foliar (airblast) applications of BAS 700 F (formulation code BAS 700 AE F, nominal concentration 62.5 g/L EC) were made to stone fruits targeting 0.111 lb ai/A/application (0.125 kg ai/ha/application) of BAS 700 F. The actual application rate for BAS 700 F was 0.105-0.126 lb ai/A/application (0.118-0.141 kg ai/ha/application), with a 6-8 day retreatment interval, for a total rate of 0.325-0.377 lb ai/A/season (0.364-0.423 kg ai/ha/season). The applications were made to plots at each site using either concentrate (49-99 gal/A of water, 463-930 L/ha, Treatment 2) or dilute (119-214 gal/A of water, 1116-2005 L/ha, Treatment 3) spray volumes with ground equipment (air blast sprayers). An adjuvant was added to the spray mixture for all applications. The proposed PHI is 0 days.

Cherry. The results from the field trials show that after three broadcast (airblast) foliar applications of BAS 700 F to sweet and tart cherry targeting 0.125 kg ai/ha/application (0.111 lb ai/A/application), actual application rate of 0.118-0.141 kg ai/ha/application (0.105-0.126 lb ai/A/application), with a 6-8 day retreatment interval, for a total rate of 0.364-0.423 kg ai/ha/season (0.325-0.377 lb ai/A/season), maximum residues of BAS 700 F were 1.05 ppm (0 day PHI), 1.10 ppm (1 day PHI), 0.40 ppm (7 day PHI), and 0.59 ppm (14 day PHI). Maximum residues of M700F008 were 0.30 ppm (0 day PHI), 0.30 ppm (1 day PHI), 0.30 ppm (7 day PHI), and 0.29 ppm (14 day PHI).

Peach. The results from the field trials show that after three broadcast (airblast) foliar applications of BAS 700 F to peach targeting 0.125 kg ai/ha/application (0.111 lb ai/A/application), actual application rate of 0.118-0.141 kg ai/ha/application (0.105-0.126 lb ai/A/application), with a 6-8 day retreatment interval, for a total rate of 0.364-0.423 kg ai/ha/season (0.325-0.377 lb ai/A/season), maximum residues of BAS 700 F were 0.63 ppm (0 day PHI), 0.59 ppm (1 day PHI), 0.57 ppm (7 day PHI), and 0.30 ppm (14 day PHI). Maximum residues of M700F008 were 0.08 ppm (0 day PHI), 0.06 ppm (1 day PHI), 0.10 ppm (7 day PHI), and 0.09 ppm (14 day PHI).

Plum. The results from the field trials show that after three broadcast (airblast) foliar applications of BAS 700 F to plum targeting 0.125 kg ai/ha/application (0.111 lb ai/A/application), actual application rate of 0.118-0.141 kg ai/ha/application (0.105-0.126 lb

ai/A/application), with a 6-8 day retreatment interval, for a total rate of 0.364-0.423 kg ai/ha/season (0.325-0.377 lb ai/A/season), maximum residues of BAS 700 F were 0.95 ppm (0 day PHI), 0.62 ppm (1 day PHI), 0.59 ppm (7 day PHI), and 0.54 ppm (14 day PHI). Maximum residues of M700F008 were <LOQ (0.01 ppm, 0 day PHI), 0.02 ppm (1 day PHI), 0.02 ppm (7 day PHI), and 0.01 ppm (14 day PHI).

The residue decline data indicate that residues of BAS 700 F in stone fruits generally decline at longer preharvest intervals.

Commodity	Appl. Rate g a.i./ha (lb a.i./A)	Analyte	PHI (days)	Residue Levels (ppm)						
				n	Min.	Max.	HAFT	Median (STMdR)	Mean (STMR)	Std. Dev.
Cherry, fruit	370-380 (0.33-0.34)	BAS 700 F	0	12	0.05	1.05	1.05	0.46	0.50	0.29
		M700F002	0	12	<0.01	<0.01	<0.01	<0.01	<0.01	0
		M700F008	0	12	0.13	0.30	0.30	0.18	0.19	0.05
		M700F048	0	12	0.01	0.08	0.08	0.01	0.03	0.02
		Total residues**	0	12	0.23	1.27	1.27	0.64	0.70	0.32
Peach, fruit	370-420 (0.33-0.38)	BAS 700 F	0	24	0.10	0.63	0.63	0.36	0.38	0.15
		M700F002	0	24	<0.01	<0.01	<0.01	<0.01	<0.01	0
		M700F008	0	24	<0.01	0.08	0.08	0.02	0.02	0.02
		M700F048	0	24	0.01	0.08	0.08	0.01	0.03	0.02
		Total residues**	0	24	0.11	0.66	0.66	0.37	0.40	0.16
Plum, fruit	360-420 (0.33-0.37)	BAS 700 F	0	20	0.14	0.95	0.95	0.32	0.39	0.21
		M700F002	0	20	<0.01	<0.01	<0.01	<0.01	<0.01	0
		M700F008	0	20	<0.01	<0.01	<0.01	<0.01	<0.01	0
		M700F048	0	20	<0.01	<0.01	<0.01	<0.01	<0.01	0
		Total residues**	0	20	0.15	0.96	0.96	0.33	0.40	0.21

* Only samples harvested at PHIs corresponding to the proposed GAP were included in the summary table.

** The residue definition in plants is fluxapyroxad and metabolite M700F008. The molecular weight conversion factor for M700F008 is 1.038 (MW BAS 700 F / M700F008 = 381.3 / 367.3). Total residues were calculated in fluxapyroxad equivalents as BAS 700 F + [1.038 x M700F008].

HAFT = Highest Average Field Trial value.

STMdR = Supervised Trial Median Residue.

STMR = Supervised Trial Mean Residue.

Cereal Grains. Seventy-eight cereal field trials were conducted during the 2008 and 2009 growing seasons, 9 trials on sweet corn, 15 trials on field corn, 25 trials on wheat, 9 trials on grain sorghum, 12 trials on rice, and 12 trials on barley (but barley hay and straw were only harvested from the 6 trials in NAFTA Region 14). The treated plots received two broadcast foliar applications of an emulsifiable concentrate (EC) formulation of BAS 700 F (formulation code BAS 700 AE F, nominal concentration 62.5 g/L) at 93-105 g a.i./ha/application (0.083-0.094 lb a.i./A/application), with a 6-10 day retreatment interval, for a total rate of 195-206 g a.i./ha/season (0.174-0.184 lb a.i./A/season). An adjuvant was added to all applications, except for the first applications in two trials on rice and on wheat. At four sites (two wheat, one rice and one barley) additional treated samples were collected to examine residue decline. Wheat samples were collected targeting 0, 7±1, and 10±1 days (Treatment 2, forage and hay) or 7±1, 14±1, 21±1, and 28±1 days (Treatment 3, grain and straw) after the last application. Rice samples (grain and straw) and barley samples (grain, hay and straw) were collected targeting 21±1, 22±1, 24±1, 28±1 and 31±1 days after the last application.

Field and Sweet Corn. Field corn forage samples (whole aerial portion of the plant) were harvested targeting 7 ± 1 DALA (BBCH 85-87). Samples of field corn grain and stover (dried stalks from which the grain or whole ear [cob + grain] has been removed and consisting of ~85% dry matter) were harvested targeting 21 ± 1 DALA (BBCH 99). At field corn/sweet corn (combined) sites, samples of forage and fresh kernels plus cobs with husks removed (K+CWHR) were harvested targeting 7 ± 1 DALA (BBCH 85-87); grain and stover samples were harvested targeting 21 ± 1 DALA (BBCH 99). Field corn grain and stover samples were harvested targeting 21 ± 1 DALA (BBCH 99). At sweet corn only sites, K+CWHR samples were harvested targeting 7 ± 1 DALA (BBCH 85-87).

Barley. Samples of barley grain (kernel plus hull) were harvested targeting 21 ± 1 days after the last application (BBCH 99). Barley hay samples were harvested targeting the milk to soft dough growth stage and field-dried to a moisture content targeting 10-20%. Samples of barley straw were harvested after grain harvest and consisted of dried stalks or stems remaining after grain harvest.

Rice. Samples of rice grain (kernel plus hull) were harvested targeting 21 ± 1 days after the last application (BBCH 99). Samples of straw were harvested after grain harvest and consisted of dried stalks or stems remaining after grain harvest.

Wheat. Samples of wheat forage and hay were harvested targeting 7 ± 1 DALA (BBCH 37-39). Wheat hay was allowed to field-dry to a moisture content targeting 10-20%. Wheat grain and straw were harvested at 21 ± 1 DALA (BBCH 99). Sorghum forage was harvested targeting 7 ± 1 DALA, or soft dough to hard dough growth stage. Samples of sorghum grain and stover (dried stalks from which the grain has been removed, consisting of ~85% dry matter) were harvested targeting 21 ± 1 DALA, or maturity.

Commodity	Appl. Rate g a.i./ha (lb a.i./A)	Analyte	PHI (days)	Residue Levels (ppm)						
				n	Min.	Max.	HAFT	Median (STMdR)	Mean (STMR)	Std. Dev.
Field and sweet corn, K+CWHR**	197-202 (0.175-0.180)	BAS 700 F	5-7	18	<0.01	0.09	0.08	0.01	0.02	0.02
		M700F002	5-7	18	<0.01	<0.01	<0.01	<0.01	<0.01	NA
		M700F008	5-7	18	<0.01	<0.01	<0.01	<0.01	<0.01	NA
		M700F048	5-7	18	<0.01	<0.01	<0.01	<0.01	<0.01	NA
		Total residues***	5-7	18	0.02	0.10	0.09	0.02	0.03	0.02
Field corn, forage	195-206 (0.174-0.184)	BAS 700 F	6-8	30	0.18	1.43	1.33	0.70	0.70	0.30
		M700F002	6-8	30	<0.01	<0.01	<0.01	<0.01	<0.01	NA
		M700F008	6-8	30	<0.01	0.05	0.05	0.04	0.03	0.01
		M700F048	6-8	30	<0.01	0.01	0.01	0.01	0.01	NA
		Total residues***	6-8	30	0.20	1.48	1.38	0.73	0.73	0.31
Field corn, grain	195-206 (0.174-0.184)	BAS 700 F	20-22	30	<0.01	<0.01	<0.01	<0.01	<0.01	NA
		M700F002	20-22	30	<0.01	<0.01	<0.01	<0.01	<0.01	NA
		M700F008	20-22	30	<0.01	<0.01	<0.01	<0.01	<0.01	NA
		M700F048	20-22	30	<0.01	<0.01	<0.01	<0.01	<0.01	NA
		Total residues***	20-22	30	0.02	<0.02	<0.02	<0.02	<0.02	NA
Field corn, stover	195-206 (0.174-0.184)	BAS 700 F	20-22	30	<0.01	3.68	3.57	1.22	1.40	0.90
		M700F002	20-22	30	<0.01	<0.01	<0.01	<0.01	<0.01	NA
		M700F008	20-22	30	<0.01	0.07	0.07	0.04	0.04	0.02
		M700F048	20-22	30	<0.01	0.01	0.01	0.01	0.01	NA
		Total residues***	20-22	30	0.02	3.75	3.63	1.25	1.44	0.91
Wheat,	195-206	BAS 700 F	6-8	50	<0.01	9.44	9.20	0.83	1.47	2.01

Table 20. Summary of Residue Data from Cereal Field Trials (Crop Group 15) with BAS 700 F*										
Commodity	Appl. Rate g a.i./ha (lb a.i./A)	Analyte	PHI (days)	Residue Levels (ppm)						
				n	Min.	Max.	HAFT	Median (STMDR)	Mean (STMR)	Std. Dev.
forage	(0.174-0.184)	M700F002	6-8	50	<0.01	<0.01	<0.01	<0.01	<0.01	NA
		M700F008	6-8	50	<0.01	0.18	0.17	0.04	0.05	0.04
		M700F048	6-8	50	<0.01	0.03	0.03	0.01	0.01	0.01
		Total residues***	6-8	50	0.02	9.51	9.26	0.87	1.52	2.04
Wheat, hay	195-206 (0.174-0.184)	BAS 700 F	6-8	50	<0.01	9.71	9.60	2.60	3.08	2.38
		M700F002	6-8	50	<0.01	<0.01	<0.01	<0.01	<0.01	NA
		M700F008	6-8	50	<0.01	0.31	0.30	0.10	0.12	0.07
		M700F048	6-8	50	<0.01	0.06	0.06	0.02	0.02	0.01
Total residues***	6-8	50	0.02	9.97	9.84	2.73	3.20	2.44		
Wheat, grain	195-205 (0.174-0.183)	BAS 700 F	20-27****	50	<0.01	0.21	0.19	0.07	0.09	0.05
		M700F002	20-27****	50	<0.01	<0.01	<0.01	<0.01	<0.01	NA
		M700F008	20-27****	50	<0.01	0.04	0.03	0.01	0.01	0.01
		M700F048	20-27****	50	<0.01	<0.01	0.01	0.01	0.01	NA
Total residues***	20-27****	50	0.02	0.22	0.20	0.09	0.10	0.05		
Wheat, straw	195-205 (0.174-0.183)	BAS 700 F	20-27****	48	0.17	8.32	7.29	2.04	2.75	2.22
		M700F002	20-27****	48	<0.01	<0.01	<0.01	<0.01	<0.01	NA
		M700F008	20-27****	48	0.01	1.08	1.01	0.22	0.30	0.27
		M700F048	20-27****	48	<0.01	0.02	0.02	0.01	0.01	0.01
Total residues***	20-27****	48	0.25	9.07	7.98	2.32	3.07	2.31		
Grain sorghum, forage	197-203 (0.176-0.181)	BAS 700 F	6-7	18	0.38	2.37	2.30	0.78	0.98	0.58
		M700F002	6-7	18	<0.01	<0.01	<0.01	<0.01	<0.01	NA
		M700F008	6-7	18	0.01	0.06	0.05	0.04	0.03	0.01
		M700F048	6-7	18	<0.01	0.04	0.04	0.01	0.02	0.009
Total residues***	6-7	18	0.42	2.41	2.34	0.80	1.01	0.59		
Grain sorghum, grain	199-201 (0.178-0.179)	BAS 700 F	20-23	18	0.12	0.43	0.40	0.18	0.21	0.10
		M700F002	20-23	18	<0.01	<0.01	<0.01	<0.01	<0.01	NA
		M700F008	20-23	18	<0.01	0.08	0.06	0.01	0.02	0.02
		M700F048	20-23	18	<0.01	<0.01	<0.01	<0.01	<0.01	NA
Total residues***	20-23	18	0.13	0.44	0.41	0.20	0.23	0.10		
Grain sorghum, stover	199-201 (0.177-0.179)	BAS 700 F	20-23	18	0.17	1.17	1.03	0.63	0.61	0.29
		M700F002	20-23	18	<0.01	<0.01	<0.01	<0.01	<0.01	NA
		M700F008	20-23	18	<0.01	0.04	0.04	0.02	0.02	0.01
		M700F048	20-23	18	<0.01	0.04	0.04	0.01	0.02	0.01
Total residues***	20-23	18	0.18	1.20	1.06	0.65	0.64	0.29		
Rice, grain	197-204 (0.176-0.182)	BAS 700 F	20-22	22	0.08	1.96	1.77	0.71	0.87	0.51
		M700F002	20-22	22	<0.01	<0.01	<0.01	<0.01	<0.01	NA
		M700F008	20-22	22	<0.01	0.03	0.03	0.01	0.02	0.01
		M700F048	20-22	22	<0.01	<0.01	<0.01	<0.01	<0.01	NA
Total residues***	20-22	22	0.09	1.97	1.78	0.73	0.88	0.51		
Rice, straw	197-204 (0.176-0.182)	BAS 700 F	20-22	18	0.25	2.25	1.70	0.68	0.83	0.56
		M700F002	20-22	18	<0.01	<0.01	<0.01	<0.01	<0.01	NA
		M700F008	20-22	18	<0.01	0.04	0.04	0.01	0.02	0.01
		M700F048	20-22	18	<0.01	<0.01	<0.01	<0.01	<0.01	NA
Total residues***	20-22	18	0.28	2.26	1.71	0.70	0.85	0.55		
Barley, grain	198-204 (0.177-0.182)	BAS 700 F	20-22	23	<0.01	1.65	1.22	0.53	0.62	0.34
		M700F002	20-22	23	<0.01	<0.01	<0.01	<0.01	<0.01	NA
		M700F008****	20-22	23	<0.01	0.10	0.07	0.02	0.02	0.02
		M700F048	20-22	23	<0.01	<0.01	<0.01	<0.01	<0.01	NA
Total residues***	20-22	23	0.02	1.75	1.29	0.55	0.64	0.35		
Barley, hay	198-204 (0.177-0.182)	BAS 700 F	20-26	12	0.64	8.85	7.80	5.03	4.61	2.47
		M700F002	20-26	12	<0.01	<0.01	<0.01	<0.01	<0.01	NA
		M700F008	20-26	12	0.05	0.24	0.20	0.11	0.12	0.058
		M700F048	20-26	12	<0.01	0.07	0.06	0.01	0.02	0.019
Total residues***	20-26	12	0.70	9.05	7.97	5.13	4.73	2.48		
Barley, straw	198-204 (0.177-0.182)	BAS 700 F	20-22	12	0.67	10.1	9.52	4.03	4.36	2.89
		M700F002	20-22	12	<0.01	<0.01	<0.01	<0.01	<0.01	NA
		M700F008	20-22	12	0.06	0.33	0.27	0.11	0.15	0.10
		M700F048	20-22	12	<0.01	0.05	0.05	0.01	0.02	0.01
Total residues***	20-22	12	0.76	10.4	9.80	4.28	4.51	2.94		

* Only samples harvested at PHIs corresponding to the proposed GAP were included in the summary table.

** Including samples of field corn at the milk stage collected to represent sweet corn K+CWHR.

*** The residue definition in plants is fluxapyroxad and metabolite M700F008. The molecular weight conversion factor for M700F008 is 1.038 (MW BAS 700 F / M700F008 = 381.3 / 367.3). Total residues were calculated in fluxapyroxad equivalents as BAS 700 F + [1.038 x M700F008].

**** Wheat grain and straw samples harvested at 27-day PHI in one trial were included since residues were comparable to those from trials with PHIs of 20-25 days.

***** Quantifiable residues of M700F008 were corrected for in-storage dissipation in samples stored for longer than 4 months (based on wheat grain results in freezer storage stability tests; 63% recovery following 544-day storage and 65% recovery following 2-year storage).

HAFT = Highest Average Field Trial value.

STMdR = Supervised Trial Median Residue.

STMR = Supervised Trial Mean Residue.

Oilseeds. Twenty-four oilseed field trials were conducted during the 2008 growing season, 16 on canola, and 8 on sunflower.

Canola. A total of 16 field trials were conducted on canola, 1 in NAFTA Region 2, 1 in Region 5, 1 in Region 7, 2 in Region 11, and 11 in Region 14. Each treated plot received two broadcast foliar applications of BAS 700 F (formulation code BAS 700 AE F, nominal concentration 62.5 g/L EC) a target rate of 100 g a.i./ha/application (0.089 lb a.i./A/application). Actual application rates were 96-105 g a.i./ha/application (0.086-0.094 lb a.i./A/application), with a 13-15 day retreatment interval, for a total rate of 197-208 g a.i./ha/season (0.176-0.186 lb a.i./A/season). An adjuvant was added to the spray mixture for all applications. Samples were harvested by hand or mechanical equipment 21-22 days after treatment. In addition, at two canola trials (in ID and SK), treated samples were collected at 14, 18, 24 and 27-28 days after the last application to assess residue decline.

The results from the canola crop field trials showed that following broadcast foliar applications of BAS 700 F to canola at a rate of 197-208 g a.i./ha/season (0.176-0.186 lb a.i./A/season), maximum residues of BAS 700 F were 0.81 ppm in/on canola seed samples (n=40; PHI of 18-25 days). Maximum residues were 0.01 ppm for M700F002, 0.10 ppm for M700F008 and 0.12 ppm for M700F048 in canola seed samples.

Sunflower. A total of 16 field trials were conducted on sunflower, 2 in NAFTA Region 5, 3 in Region 7, 1 in Region 8, and 2 in Region 14. Each treated plot received two broadcast foliar applications of BAS 700 F (formulation code BAS 700 AE F, nominal concentration 62.5 g/L EC) a target rate of 100 g a.i./ha/application (0.089 lb a.i./A/application). Actual application rates were 96-105 g a.i./ha/application (0.086-0.094 lb a.i./A/application), with a 13-15 day retreatment interval, for a total rate of 197-208 g a.i./ha/season (0.176-0.186 lb a.i./A/season). An adjuvant was added to the spray mixture for all applications. Samples were harvested by hand or mechanical equipment 21-22 days after treatment. In addition, at one sunflower trials (in KS), treated samples were collected at 14, 18, 24 and 27-28 days after the last application to assess residue decline.

The results from the sunflower crop field trials showed that following broadcast foliar applications of BAS 700 F to sunflower at a rate of 197-208 g a.i./ha/season (0.176-0.186 lb a.i./A/season), maximum residues of BAS 700 F were 0.15 ppm in/on sunflower seed samples

(n=20; PHI of 18-24 days). Maximum residues were <0.01 ppm for M700F002, <0.01 ppm for M700F008 and <0.01 ppm for M700F048 in sunflower seed samples.

The residue decline data indicated that residues of BAS 700 F decreased in canola and sunflower seed samples with increasing PHIs from 14 to 28 days.

Commodity	Appl. Rate g a.i./ha (lb a.i./A)	Analyte	PHI (days)	Residue Levels (ppm)						
				n	Min.	Max.	HAFT	Median (STMdR)	Mean (STMR)	Std. Dev.
Canola, seed	197-208 (0.176-0.186)	BAS 700 F	21-22	32	0.01	0.27	0.23	0.10	0.11	0.08
		M700F002	21-22	32	<0.01	<0.01	<0.01	<0.01	<0.01	NA
		M700F008**	21-22	32	<0.01	0.07	0.07	0.02	0.03	0.02
		M700F048	21-22	32	<0.01	0.03	0.03	0.01	0.01	0.01
		Total residues***	21-22	32	0.02	0.31	0.29	0.11	0.13	0.09
Sunflower, seed	197-204 (0.176-0.182)	BAS 700 F	21	16	<0.01	0.15	0.13	0.04	0.06	0.05
		M700F002	21	16	<0.01	<0.01	<0.01	<0.01	<0.01	NA
		M700F008	21	16	<0.01	<0.01	<0.01	<0.01	<0.01	NA
		M700F048	21	16	<0.01	<0.01	<0.01	<0.01	<0.01	NA
		Total residues***	21	16	0.02	0.16	0.14	0.05	0.07	0.05

* Only samples harvested at PHIs corresponding to the proposed GAP were included in the summary table.

** Quantifiable residues of M700F008 were corrected for in-storage dissipation in samples stored for longer than 4 months (based on soybean seed results in freezer storage stability tests; 57% recovery following 177-day storage and 55% recovery following 2-year storage).

*** The residue definition in plants is fluxapyroxad and metabolite M700F008. The molecular weight conversion factor for M700F008 is 1.038 (MW BAS 700 F / M700F008 = 381.3 / 367.3). Total residues were calculated in fluxapyroxad equivalents as BAS 700 F + [1.038 x M700F008].

HAFT = Highest Average Field Trial value

STMdR = Supervised Trial Median Residue

STMR = Supervised Trial Mean Residue

Peanuts. A total of 12 crop field trials were conducted on peanuts, during the 2008 growing season and; 8 in NAFTA Region 2 (GA – 4 trials, SC – 2 trials, AL - 2 trials), 1 in Region 3 (FL - 1 trial), 2 in Region 6 (OK – 1 trial, TX – 1 trial) and 1 in Region 8 (TX - 1 trial). Three applications of BAS 700 AE F (EC formulation) were made, each targeted at 100 g ai/ha (~0.09 lb ai/A) for a seasonal total of about 300 g ai/ha (0.27 lb ai/A). The actual rate range applied was 0.089 to 0.094 lb ai/A/application (99.7 to 105.3 g ai/ha) with a 13 to 15-day retreatment interval for a total rate of 0.269 – 0.277 lb ai/A/season (301.3 to 310.2 g ai/ha/season). Samples were harvested at 7, 14, and 21-days after last treatment, and 0, 4, 7, 14, and 21-days after last treatment for the decline study.

Maximum residues of BAS 700 F in peanut nutmeat samples were <LOQ (<0.01 ppm) at all intervals. Maximum residues of M700F008 in peanut nutmeat samples were <LOQ (<0.01 ppm) at all intervals. Maximum residues of BAS 700 F in peanut hay samples were 8.89, 4.96, and 2.58 ppm, respectively at 7, 14, and 21-days PHI. Maximum residues of M700F008 in peanut hay samples were 1.44, 1.75, and 0.71 ppm, respectively at 7, 14, and 21-days PHI.

The residue decline data from the one Georgia trial demonstrate that residues of BAS 700 F in peanut hay decline quickly immediately after application and gradually declined from 5.79 to 1.08 ppm over the 21-day post-application interval. Residues of the metabolites M700F008

showed no clear pattern of decline or accumulation, although there is some indication that the levels increased toward 7- and 14-days PHI and decreased by 21-days PHI.

No storage stability data were provided for the storage conditions used for sample storage (-5 C).

Commodity	Appl. Rate g a.i./ha (lb a.i./A)	Analyte	PHI (days)	Residue Levels (ppm)							
				n	Min.	Max.	HAFT	Median (STMdR)	Mean (STMR)	Std. Dev.	
Peanut, nutmeat	301-310 (0.27-0.28)	BAS 700 F	7	22	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	0
		M700F002	7	22	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	0
		M700F008	7	22	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	0
		M700F048	7	22	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	0
		Total residues**	7	22	0.02	0.02	0.02	0.02	0.02	0.02	0
Peanut, hay	301-310 (0.27-0.28)	BAS 700 F	7	22	<0.01	8.89	8.86	2.19	3.24	2.96	
		M700F002	7	22	<0.01	<0.01	<0.01	<0.01	<0.01	0	
		M700F008	7	22	<0.01	1.44	1.40	0.52	0.58	0.48	
		M700F048	7	22	<0.01	3.66	3.16	1.32	1.27	0.99	
		Total residues**	7	22	0.05	10.38	10.31	3.26	3.85	3.40	

* Only samples harvested at PHIs corresponding to the proposed GAP were included in the summary table.

** The residue definition in plants is fluxapyroxad and metabolite M700F008. The molecular weight conversion factor for M700F008 is 1.038 (MW BAS 700 F / M700F008 = 381.3 / 367.3). Total residues were calculated in fluxapyroxad equivalents as BAS 700 F + [1.038 x M700F008].

HAFT = Highest Average Field Trial value
STMdR = Supervised Trial Median Residue
STMR = Supervised Trial Mean Residue

Cottonseed. Twelve (12) field trials were conducted during the 2008 growing season on cotton; in NAFTA Growing Region 2 (GA, one trial), Region 4 (AR, two trials; MS, one trial), Region 6 (TX, one trial), Region 8 (OK, one trial; TX, three trials), and Region 10 (AZ, one trial; CA, two trials). Seed was treated with a suspension concentrate (SC) formulation containing the active ingredient BAS 700 F (formulation code BAS 700 AC F, 300 g/L nominal concentration) prior to planting targeting 20 g ai/100 kg seed. At two of the trial locations (GA and TX), an additional treated plot was planted with cotton seed treated at an exaggerated rate of 100 g ai/100 kg seed (5x rate) to generate additional treated cotton RAC samples and bulk seed cotton for processing. The results from these supervised crop field trials on cotton show that residues of BAS 700 F and its metabolites M700F002, M700F008, and M700F048 were non-quantifiable (<0.01 ppm) in/on all undelinted seed and gin byproducts derived from cotton harvested at maturity and grown from seed treated with BAS 700 F at 20 or 100 g ai/100 kg seed. (1x and 5x rates). Trial locations used matched the requested trial locations. No storage stability data were provided for the storage conditions used for sample storage (-5 C). Residue decline could not be evaluated, since all residues reported were <LOQ (0.01 ppm).

Commodity	Appl. Rate g a.i./ 100 kg seed	Analyte	PHI (days)	Residue Levels (ppm)							
				n	Min.	Max.	HAFT	Median (STMdR)	Mean (STMR)	Std. Dev.	
Cotton, undelinted seed [low rate]	20	BAS 700 F	155-193	24	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	0
		M700F002	155-193	24	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	0
		M700F008	155-193	24	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	0
		M700F048	155-193	24	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	0
		Total residues*	155-193	24	0.02	0.02	0.02	0.02	0.02	0.02	0

Commodity	Appl. Rate g a.i./ 100 kg seed	Analyte	PHI (days)	Residue Levels (ppm)						
				n	Min.	Max.	HAFT	Median (STMdR)	Mean (STMR)	Std. Dev.
Cotton, undelinted seed [high rate]	100	BAS 700 F	162-193	4	<0.01	<0.01	<0.01	<0.01	<0.01	0
		M700F002	162-193	4	<0.01	<0.01	<0.01	<0.01	<0.01	0
		M700F008	162-193	4	<0.01	<0.01	<0.01	<0.01	<0.01	0
		M700F048	162-193	4	<0.01	<0.01	<0.01	<0.01	<0.01	0
		Total residues*	162-193	4	0.02	0.02	0.02	0.02	0.02	0.02
Cotton, gin byproducts [low rate]	20	BAS 700 F	156-193	14	<0.01	<0.01	<0.01	<0.01	<0.01	0
		M700F002	156-193	14	<0.01	<0.01	<0.01	<0.01	<0.01	0
		M700F008	156-193	14	<0.01	<0.01	<0.01	<0.01	<0.01	0
		M700F048	156-193	14	<0.01	<0.01	<0.01	<0.01	<0.01	0
		Total residues*	156-193	14	0.02	0.02	0.02	0.02	0.02	0.02
Cotton, gin byproducts [high rate]	100	BAS 700 F	162-193	4	<0.01	<0.01	<0.01	<0.01	<0.01	0
		M700F002	162-193	4	<0.01	<0.01	<0.01	<0.01	<0.01	0
		M700F008	162-193	4	<0.01	<0.01	<0.01	<0.01	<0.01	0
		M700F048	162-193	4	<0.01	<0.01	<0.01	<0.01	<0.01	0
		Total residues*	162-193	4	0.02	0.02	0.02	0.02	0.02	0.02

* The residue definition in plants is fluxapyroxad and metabolite M700F008. The molecular weight conversion factor for M700F008 is 1.038 (MW BAS 700 F / M700F008 = 381.3 / 367.3). Total residues were calculated in fluxapyroxad equivalents as BAS 700 F + [1.038 x M700F008].

HAFT = Highest Average Field Trial value.

STMdR = Supervised Trial Median Residue.

STMR = Supervised Trial Mean Residue.

Seed Treatment. In addition to foliar uses, BASF has proposed the use of seed treatment on the following commodities: beans and peas, cereal grains, peanuts, soybeans, and sunflower. The field trials conducted did not reflect the use of seed treatment followed by foliar treatment. Historically, EPA had not required field trials for seed treatments when foliar treatments were registered. The seed treatment rate (calculated in terms of ai/A) is compared to the foliar application rate in the table below. The seed treatment rate was less than 20% of the single application rate and less than 10% of the seasonal application rate.

Crop	App Rate (lb ai/100 lb seed)	Planting Rate (lb seed/A)	Equip App Rate (lb ai/A)	Foliar Rate (lb ai/A)	Max Seasonal Rate (lb ai/A)
Barley	0.01	96	0.010	0.09	0.18
Beans/Peas	0.01	60	0.006	0.18	0.36
Corn	0.01	15	0.002	0.09	0.18
Oats	0.01	100	0.010	0.09	0.18
Peanuts	0.01	142	0.014	0.09	0.27
Rice	0.01	150	0.015	0.09	0.18
Rye	0.01	112	0.011	0.09	0.18
Sorghum	0.01	20	0.002	0.09	0.18
Soybeans	0.01	60	0.006	0.09	0.18
Sunflower	0.02	4	0.001	0.09	0.18
Wheat	0.01	150	0.015	0.09	0.18
Planting rates from ExpoSAC SOP 15					
Sunflower planting rates from http://www.jeffersoninstitute.org/pubs/sunflower.shtml					

Conclusions. The submitted field trial data are adequate to support the proposed uses on sugar beets, tuberous & corm vegetables crop subgroup 1C, legumes, fruiting vegetables, pome fruit, stone fruit, cereal grains, oilseeds, peanuts, and cotton. There were some minor differences between the recommended field trial locations and the locations where studies were conducted, but these differences did not affect our conclusions.

The submitted field trial data for sugarbeets are adequate to support a tolerance on sugar beets, but will not support a tolerance for residues of fluxapyroxad on subgroup 1A, because no residue data were submitted for the other two representative commodities – carrots and radishes.

Although seed treatments were proposed on a number of commodities for which foliar treatments were also proposed, no field trials were submitted to support those seed treatments. The application rate for those seed treatments is low enough that the seed treatment is unlikely to affect the residues in the commodities after foliar treatment.

860.1520 Processed Food and Feed

47923665 Cotton Processed Fractions
47923669, 47923670, 47923671 Cereal Grain Processed Fractions
47923672 Soybean Processed Fractions
47923673 Oilseed Processed Fractions
47923674 Peanut Processed Fractions
47923675 Apple Processed Fractions
47923676 Plum Processed Fractions
47923677 Root & Tuber Processed Fractions
47923678 Tomato Processed Fractions

Sample storage conditions and analytical methods used for all processing studies are summarized above in the Storage Stability and Analytical Methods sections. Residues of M700F008, which is to be included in the risk assessment were small enough that they did not affect the calculation for the processing factor, except for canola, and are not included in the discussion below.

Potato and Sugar beet. Trials were conducted in Regions 5 (ND) and 11 (ID). The treated plots received three broadcast foliar applications of BAS 700 F (62.5 g/L EC) at 479-523 g a.i./ha/application (0.427-0.467 lb a.i./A/application), with a 6-8 day RTI, resulting in a total exaggerated rate of 1.493-1.528 kg a.i./ha/season (1.332-1.363 lb a.i./A). An adjuvant was used. Potato and sugar beet bulk tuber and root samples were harvested 6-7 days after the last application (6-7 day PHI), at normal maturity.

Commodities were processed according to simulated commercial procedures into the following samples: granules/flakes, chips, wet peel, peeled potatoes, boiled potatoes, microwave/boiled potatoes (unpeeled), baked potato, fried potato, process waste and dried pulp.

Residues of fluxapyroxad concentrate in wet potato peel (2.0-7.0x, average processing factor 4.7x) and dried potato pulp (5.0-12.0x, average processing factor 8.0x), but do not concentrate in

any of the other processed commodities of potato.

Trial ID	Processed Commodity	Rep.	Processing Factor for BAS 700 F	Av. Processing Factor for BAS 700 F
RCN R080538	Granules/Flakes	A	0.5	0.75x
RCN R080539		A	0.5	
RCN R080538		B	1	
RCN R080538	Chips	A	0.5	0.75x
RCN R080539		A	0.5	
RCN R080538		B	1	
RCN R080538	Peel, wet	A	2	4.7x
RCN R080539		A	5	
RCN R080538		B	7	
RCN R080538	Peeled potatoes	A	0.5	0.75x
RCN R080539		A	0.5	
RCN R080538		B	1	
RCN R080538	Boiled potatoes	A	0.5	0.75x
RCN R080539		A	0.5	
RCN R080538		B	1	
RCN R080538	Microwaved boiled potatoes (unpeeled)	A	0.5	0.75x
RCN R080539		A	0.5	
RCN R080538		B	1	
RCN R080538	Baked potato	A	0.5	<0.75x
RCN R080539		A	0.5	
RCN R080538		B	1	
RCN R080538	Fried potato	A	0.5	0.75x
RCN R080539		A	0.5	
RCN R080538		B	1	
RCN R080538	Process waste	A	0.5	0.75x
RCN R080539		A	0.5	
RCN R080538		B	1	
RCN R080538	Dried pulp	A	7	8.0x
RCN R080539		A	5	
RCN R080538		B	12	

Sugar beet. Trials were conducted in Regions 5 (ND) and 11 (ID). The treated plots received three broadcast foliar applications of BAS 700 F (62.5 g/L EC) at 479-523 g a.i./ha/application (0.427-0.467 lb a.i./A/application), with a 6-8 day RTI, resulting in a total exaggerated rate of 1.493-1.528 kg a.i./ha/season (1.332-1.363 lb a.i./A). An adjuvant was used. Sugar beet bulk

tuber and root samples were harvested 6-7 days after the last application (6-7 day PHI), at normal maturity.

Sugar beet samples were processed using simulated commercial processing procedures into refined sugar, dried sugar beet pulp, and molasses. In addition, raw sugar beet juice, thick sugar beet juice, raw sugar, sugar beet press water, pressed sugar beet pulp and ensiled sugar beet pulp samples were collected.

Residues of BAS 700 F concentrate in sugar beet dried pulp (0.5 and 3.0x, average processing factor 1.8x) but do not concentrate in any of the other processed commodities of sugar beet.

Table 26. Average Processing Factors in Sugar Beet Processed Commodities.				
Trial ID	Processed Commodity	Rep	Processing Factor for BAS 700 F	Av. Processing Factor for BAS 700 F
RCN R080540	Refined sugar	A	0.1	0.2x
RCN R080541		A	0.3	
RCN R080540	Dried pulp	A	0.5	1.8x
RCN R080541		A	3	
RCN R080540	Molasses	A	0.4	0.8x
RCN R080541		A	1.2	
RCN R080540	Raw juice	A	0.1	0.2x
RCN R080541		A	0.3	
RCN R080540	Thick juice	A	0.3	0.75x
RCN R080541		A	1.2	
RCN R080540	Raw sugar	A	0.4	1.0x
RCN R080541		A	1.6	
RCN R080540	Press water	A	0.1	0.15x
RCN R080541		A	0.2	
RCN R080540	Pressed pulp	A	0.1	0.25x
RCN R080541		A	0.4	
RCN R080540	Ensiled pulp	A	0.1	0.25x
RCN R080541		A	0.6	

Soybean. Two field trials were conducted on soybean in NAFTA Growing Region 5 (MB, one trial; ND, one trial). One of the treated plots at each site received two broadcast foliar applications of BAS 700 F (62.5 g/L EC) at 495-511 g a.i./ha/application (0.442-0.456 lb a.i./A/application), with a 7-8 day retreatment interval, resulting in a total exaggerated rate of 1.006-1.010 kg a.i./ha/season (0.898-0.901 lb a.i./A/season; Treatment 2).

The other treated plot at each site was established to generate AGF samples. This plot received two broadcast foliar applications of BAS 700 F at 97-103 g a.i./ha/application (0.086-0.092 lb a.i./A/application), with a 7-8 day retreatment interval, totaling 199-202 g a.i./ha/season (0.178-0.180 lb a.i./A/season; Treatment 3). Soybean bulk seed samples were harvested 21 days after

the last application (21-day PHI), at normal maturity. The bulk soybean seed samples were frozen and shipped to the processing facility.

The soybean seed samples were processed according to simulated commercial procedures into the following samples: AGFs, flour, hulls, meal, miso, refined oil, soymilk, soy sauce and tofu. Residues of BAS 700 F concentrate in hulls (0.2-8.2x, average processing factor of 2.7x), but do not concentrate in flour, meal, miso, refined oil, soy milk, soy sauce or tofu.

Residues of BAS 700 F concentrate in hulls (0.2-8.2x, average processing factor 2.7x), but do not concentrate in any of the other processed commodities of soybean. Maximum residues of BAS 700 F were 1.769 ppm in/on AGF samples derived from seed samples treated with foliar applications of BAS 700 F at a total rate of 200 g a.i./ha/season (0.178 lb a.i./A/season) and harvested at a 21-day PHI. The average processing factor for soybean AGF was 150x.

Table 27. Average Processing Factors in Soybean Processed Commodities.				
Trial ID	Processed Commodity	Rep	Processing Factors for BAS 700 F	Av. Processing Factor for BAS 700 F
RCN R080528	Flour	A	<0.1	<0.52x
RCN R080528		B	<0.1	
RCN R080529		A	0.9	
RCN R080529		B	1	
RCN R080528	Hulls	A	0.7	2.7x
RCN R080528		B	0.2	
RCN R080529		A	1.6	
RCN R080529		B	8.2	
RCN R080528	Meal	A	<0.1	<0.52x
RCN R080528		B	<0.1	
RCN R080529		A	0.9	
RCN R080529		B	1	
RCN R080528	Miso	A	<0.1	<0.52x
RCN R080528		B	<0.1	
RCN R080529		A	0.9	
RCN R080529		B	1	
RCN R080528	Refined Oil	A	0.2	0.75x
RCN R080528		B	0.2	
RCN R080529		A	0.9	
RCN R080529		B	1	
RCN R080528	Soy milk	A	<0.1	<0.52x
RCN R080528		B	<0.1	
RCN R080529		A	0.9	
RCN R080529		B	1	
RCN R080528	Soy sauce	A	<0.1	<0.52x
RCN R080528		B	<0.1	
RCN R080529		A	0.9	
RCN R080529		B	1	
RCN R080528	Tofu	A	<0.1	<0.52x
RCN R080528		B	<0.1	

RCN R080529	A	0.9
RCN R080529	B	1

Tomato. Four field trials were conducted on tomato in NAFTA Growing Region 10 (CA). The treated plots received two foliar broadcast applications of BAS 700 F (62.5 g/liter EC) at 0.432-0.461 lb ai/A/application (0.485-0.516 kg ai/ha/application), with a 6-7 day retreatment interval, resulting in a total exaggerated rate of 0.878-0.909 lb ai/A (0.984-1.019 kg ai/ha/season). An adjuvant was added to the spray mixture. Tomato samples were harvested 7 days after the last application, at normal maturity. The samples were shipped on blue ice, and refrigerated prior to processing.

Trial ID	Processed Commodity	Processing Factor for parent BAS 700 F	Average Processing Factor for parent BAS 700 F
R090402	Canned Tomatoes	0.4	0.22x
R090403		0.1	
R090404		0.2	
R090405		0.2	
R090402	Paste	0.9	0.7x
R090403		0.5	
R090404		1.2	
R090405		0.2	
R090402	Peeled Tomatoes	0.4	0.13x
R090403		0	
R090404		0.1	
R090405		<0.01	
R090402	Puree	0.4	0.45x
R090403		0.3	
R090404		0.4	
R090405		0.7	
R090402	Raw Juice	0.3	0.2x
R090403		0.1	
R090404		0.3	
R090405		0.1	
R090402	Tomato Peel	2.3	3.3x
R090403		1.8	
R090404		2.4	
R090405		6.8	
R090402	Wash Water	0.2	0.16x
R090403		0.4	
R090404		<0.01	
R090405		<0.01	
R090402	Washed Tomatoes	0.6	0.7x

R090403		0.7	
R090404		0.8	
R090405		0.8	
R090402	Wet Pomace	4.6	3.4x
R090403		3.2	
R090404		3.6	
R090405		2.2	

Tomato samples were processed according to simulated commercial procedures into Canned Tomatoes, Paste, Peeled Tomatoes, Puree, Raw Juice, Tomato Peel, Wash Water, Washed Tomatoes, and Wet Pomace.

Residues of BAS 700 F concentrate in tomato peel (1.7-6.8x, average processing factor 3.2x) and wet pomace (2.1-4.6x, average processing factor 3.4x), but do not concentrate in canned tomatoes (0.1-0.4x, average processing factor 0.2x), paste (0.2-1.2x, average processing factor 0.7x), peeled tomatoes (<0.1-0.4x, average processing factor 0.1x), puree (0.3-0.7x, average processing factor 0.4x), raw juice (0.1-0.3x, average processing factor 0.2x), wash water (0.1-0.4x, average processing factor 0.2x), or washed tomatoes (0.6-0.8x, average processing factor 0.7x).

Apple. Two field trials were conducted on apple in NAFTA Growing Region 1 (NY). Four airblast foliar applications of BAS 700 F (62.5 g/liter EC) were made at 0.448-0.455 lb ai/A/application (0.502-0.510 kg ai/ha/application), with a 7 day retreatment interval, resulting in a total exaggerated rate of 1.802-1.808 lb ai/A (2.020-2.027 kg ai/ha/season). Apples were harvested at normal maturity, 0 days after treatment.

Apples were processed according to simulated commercial procedures into apple juice and wet pomace, and additionally into applesauce, canned apple, and dried apple. Residues of BAS 700 F concentrate in wet pomace (4.5-4.7x, average processing factor 4.6x), but do not concentrate in apple juice (0.2x, average processing factor 0.2x), applesauce (0.2-0.3x, average processing factor 0.3x), canned apples (0.2-0.3x, average processing factor 0.3x), or dried apples (0.4-0.7x, average processing factor 0.6x).

Trial ID	Processed Commodity	Rep.	Processing Factor for BAS 700 F	Av. Processing Factor for BAS 700 F
RCN R080180	Juice	A	0.2	0.2x
RCN R080181		A	0.2	
RCN R080180	Wet Pomace	A	4.5	4.6x
RCN R080181		A	4.7	

RCN R080180	Apple Sauce	A	0.2	0.25x
RCN R080181		A	0.3	
RCN R080180	Canned Apples	A	0.2	0.25x
RCN R080181		A	0.3	
RCN R080180	Dried Apples	A	0.7	0.55x
RCN R080181		A	0.4	

Plum. Two field trials were conducted on plums in NAFTA Growing Region 10 (CA). Three broadcast foliar (airblast) applications of BAS 700 F (62.5 g/liter EC) were made at 0.385-0.401 lb ai/A/application (0.432-0.449 kg ai/ha/application), resulting in a total seasonal rate of 1.177-1.189 lb ai/A (1.319-1.333 kg ai/ha/season). This exaggerated application rate corresponds to 5x the maximum proposed label rate for plums. Samples were collected on the day of the last test substance application (0-day PHI), when the plums were at normal maturity. The samples were shipped at ambient temperatures on the day of harvest to the processing facility.

Plums were processed according to simulated commercial procedures into the following fractions: washed plums, plum puree, plum jam, and dried prunes. BAS 700 F residues concentrated in dried prunes (processing factors of 2.7-2.8), and did not concentrate in washed plums, puree, or jam.

Trial ID	Processed Commodity	Rep.	Processing Factor for BAS 700 F	Av. Processing Factor for BAS 700 F
RCN R080552	Washed Plum	A	0.9x	0.75x
RCN R080553		A	0.6x	
RCN R080552	Plum Puree	A	0.8x	0.85x
RCN R080553		A	0.9x	
RCN R080552	Plum Jam	A	0.4x	0.4x
RCN R080553		A	0.4x	
RCN R080552	Dried Prunes	A	2.8x	2.8x
RCN R080538		A	2.8x	

Barley. Four field trials were conducted on barley in NAFTA Growing Regions 5 (ND, one trial) and 11 (WA, one trial; ID, two trials). Two broadcast foliar applications of BAS 700 F (62.5 g/L EC) at 498-533 g a.i./ha/application (0.445-0.476 lb a.i./A/application), with a 7-8 day RTI, resulting in a total exaggerated rate of 1.00-1.03 kg a.i./ha/season (0.89-0.92 lb a.i./A). An adjuvant was used except for one trial. Barley grain samples were harvested 21-23 days after the last application, at normal maturity. Samples were frozen and shipped to the processing facility.

The barley grain samples were processed according to simulated commercial procedures into the following processed barley commodities: pot barley, bran, flour, brewing malt, malt culms (sprouts), spent grain, spent hops (flocs), brewer's (spent) yeast, and beer.

Residues of BAS 700 F concentrate in bran (1.3-2.5x, average processing factor 1.9x), but do not concentrate in any of the other processed commodities of barley.

Table 31. Average Processing Factors in Barley Processed Commodities.				
Trial ID	Processed Commodity	Rep	Processing Factors for BAS 700 F	Av. Processing Factor for BAS 700 F
RCN R080534	Pot barley	A	0.1	0.2x
RCN R080534		B	0.1	
RCN R080535		A	0.1	
RCN R080535		B	0.1	
RCN R080600		A	0.2	
RCN R080600		B	0.2	
RCN R080601		A	0.4	
RCN R080601		B	0.4	
RCN R080534	Bran	A	1.3	1.9x
RCN R080534		B	1.7	
RCN R080535		A	1.9	
RCN R080535		B	1.6	
RCN R080600		A	1.9	
RCN R080600		B	2.2	
RCN R080601		A	2.5	
RCN R080601		B	2.3	
RCN R080534	Flour	A	0.1	0.22x
RCN R080534		B	0.1	
RCN R080535		A	0.1	
RCN R080535		B	0.1	
RCN R080600		A	0.2	
RCN R080600		B	0.3	
RCN R080601		A	0.5	
RCN R080601		B	0.4	
RCN R080534	Brewing malt	A	<0.1	<0.1x
RCN R080534		B	<0.1	
RCN R080535		A	<0.1	
RCN R080535		B	<0.1	
RCN R080600		A	<0.1	
RCN R080600		B	<0.1	
RCN R080601		A	<0.1	
RCN R080601		B	<0.1	
RCN R080534	Malt culms (Sprouts)	A	0.2	0.3x
RCN R080534		B	0.1	
RCN R080535		A	0.3	
RCN R080535		B	0.2	
RCN R080600		A	0.2	
RCN R080600		B	0.4	
RCN R080601		A	0.5	
RCN R080601		B	0.5	
RCN R080534	Spent grain	A	0.3	0.26x
RCN R080534		B	0.2	
		A	0.2	
RCN R080535		B	0.2	

RCN R080600		A	0.2	
RCN R080600		B	0.3	
RCN R080601		A	0.4	
RCN R080601		B	0.3	
RCN R080534	Spent hops (Flocs)	A	0.1	0.2x
RCN R080534		B	0.1	
RCN R080535		A	0.2	
RCN R080535		B	0.1	
RCN R080600		A	0.2	
RCN R080600		B	0.2	
RCN R080601		A	0.5	
RCN R080601		B	0.2	
RCN R080534	Brewer's (spent) yeast	A	0.2	0.3x
RCN R080534		B	<0.1	
RCN R080535		A	0.5	
RCN R080535		B	0.3	
RCN R080600		A	0.3	
RCN R080600		B	0.3	
RCN R080601		A	0.3	
RCN R080601		B	0.4	
RCN R080534	Beer	A	<0.1	<0.1x
RCN R080534		B	<0.1	
RCN R080535		A	<0.1	
RCN R080535		B	<0.1	
RCN R080600		A	<0.1	
RCN R080600		B	<0.1	
RCN R080601		A	<0.1	
RCN R080601		B	<0.1	

Wheat. Four field trials were conducted on wheat in NAFTA Growing Regions 5 (ND, one trial) and 11 (WA, one trial; ID, two trials). Two broadcast foliar applications of BAS 700 F (62.5 g/L EC) at 499-508 g a.i./ha/application (0.446-0.453 lb a.i./A/application), with a 6-7 day RTI, resulting in a total rate of 1.00-1.01 kg a.i./ha/season (0.89-0.91 lb a.i./A). In addition, at the site located in WA, another treated plot was established to generate AGF samples. This plot received two broadcast foliar applications of BAS 700 F at 100 g a.i./ha/application (0.089 lb a.i./A/application), with a 7 day RTI, totaling 200 g a.i./ha/season (0.18 lb a.i./A). Wheat grain samples were harvested at 21-22 day PHI, at normal maturity. At two trials, the samples were frozen and shipped to the processing facility. At the other two trials, the samples were held at ambient temperature and shipped to the processing facility.

The wheat grain samples were processed according to simulated commercial procedures into AGFs, germ, bran, middlings, straight flour shorts or low-grade meal, whole meal flour, whole meal bread and white bread.

Residues of BAS 700 F concentrate in bran (2.4-4.7x, average processing factor 3.1x) and germ (0.6-2.6x, average processing factor 1.5x), but do not concentrate in flour (average processing

factor 0.2x), middlings (average processing factor 0.4x), shorts (average processing factor 0.6x), white bread (average processing factor 0.2x), whole meal flour (average processing factor 1.0x), or whole meal bread (average processing factor 0.7x). The wheat AGF sample concentrated 220x.

Table 32. Average Processing Factors in Wheat Processed Commodities.				
Trial ID	Processed Commodity	Rep	Processing Factors for BAS 700 F	Av. Processing Factor for BAS 700 F
RCN R080536	Bran	A	3.3	3.1x
RCN R080536		B	2.9	
RCN R080537		A	3	
RCN R080537		B	2.4	
RCN R080602		A	2.8	
RCN R080602		B	2.9	
RCN R080603		A	4.7	
RCN R080603		B	2.7	
RCN R080536	Flour	A	0.2	0.23x
RCN R080536		B	<0.1	
RCN R080537		A	0.2	
RCN R080537		B	0.1	
RCN R080602		A	0.1	
RCN R080602		B	0.2	
RCN R080603		A	0.6	
RCN R080603		B	0.4	
RCN R080536	Middlings	A	0.2	0.4x
RCN R080536		B	0.2	
RCN R080537		A	0.4	
RCN R080537		B	0.3	
RCN R080602		A	0.3	
RCN R080602		B	0.4	
RCN R080603		A	0.8	
RCN R080603		B	0.6	
RCN R080536	Shorts	A	0.2	0.56x
RCN R080536		B	0.4	
RCN R080537		A	0.7	
RCN R080537		B	0.6	
RCN R080602		A	0.4	
RCN R080602		B	0.4	
RCN R080603		A	1.1	
RCN R080603		B	0.7	
RCN R080536	Germ	A	1	1.5x
RCN R080536		B	1.3	
RCN R080537		A	0.9	
RCN R080537		B	0.6	
RCN R080602		A	1.2	

RCN R080602		B	1.6			
RCN R080603		A	2.6			
RCN R080603		B	2.5			
RCN R080536	Bread (white)	A	0.1	0.19x		
RCN R080536		B	<0.1			
RCN R080537		A	0.1			
RCN R080537		B	0.1			
RCN R080602		A	0.1			
RCN R080602		B	0.1			
RCN R080603		A	0.5			
RCN R080603		B	0.3			
RCN R080536		Whole meal	A		1.1	1.0x
RCN R080536			B		1	
RCN R080537	A		0.9			
RCN R080537	B		0.7			
RCN R080602	A		0.9			
RCN R080602	B		0.9			
RCN R080603	A		1.8			
RCN R080603	B		1.1			
RCN R080536	Bread (whole meal)	A	0.7	0.71x		
RCN R080536		B	0.7			
RCN R080537		A	0.6			
RCN R080537		B	0.5			
RCN R080602		A	0.6			
RCN R080602		B	0.6			
RCN R080603		A	1.2			
RCN R080603		B	0.8			

Field Corn. Two trials were conducted on field corn in Region 5 (WI) and Region 12 (OR). Plots received two broadcast foliar applications of BAS 700 F (62.5 g/L EC) at 495-514 g a.i./ha/application (0.442-0.458 lb a.i./A/application), with a 7-9 day RTI, resulting in a total exaggerated rate of 992-1010 g a.i./ha/season (0.89-0.90 lb a.i./A). In addition, at one site in WI, plots were treated with two applications of BAS 700 F at 96-101 g a.i./ha/application (0.086-0.090 lb a.i./A/application), with a 7 day RTI, totaling 195-201 g a.i./ha/season (0.17-0.18 lb a.i./A) to generate samples of AGFs. The field corn samples were harvested 19-21 days after the last application, at normal maturity.

The field corn samples were processed using simulated commercial processing procedures into refined oil and starch (from wet milling) and meal, refined oil, grits and flour (from dry milling). Residues of BAS 700 F concentrate in refined oil from wet-milling (1.0-4.0x, average processing factor 2.0x), but do not concentrate in meal (0.7-1.0x, average processing factor 0.9x), refined oil from dry milling (0.5-1.0x, average processing factor 0.8x), flour (0.9-1.0x, average processing factor 1.0x), grits (0.3-1.0x, average processing factor 0.7x), and starch (0.7-1.0x, average processing factor 0.9x). The field corn AGF sample concentrated 7x.

Table 33. Average Processing Factors in Field Corn Processed Commodities.			
Trial ID	Processed Commodity	Processing Factor for BAS 700 F	Av. Processing Factor for BAS 700 F
RCN R080521	Meal	1.0x	0.85x
RCN R080522		0.7x	
RCN R080521	RDB oil (wet-milled)	1.0x	2.6x
RCN R080522		4.1x	
RCN R080521	Flour	1.0x	0.95x
RCN R080522		0.9x	
RCN R080521	Grits	1.0x	0.65x
RCN R080522		0.3x	
RCN R080521	Starch	1.0x	0.55x
RCN R080522		0.1x	
RCN R080521	RDB oil (dry-milled)	1.0x	0.7x
RCN R080522		0.4x	

Grain Sorghum. At one site in IL for grain sorghum, plots were treated with two applications of BAS 700 F at 96-101 g a.i./ha/application (0.086-0.090 lb a.i./A/application), with a 7 day RTI, totaling 195-201 g a.i./ha/season (0.17-0.18 lb a.i./A) to generate samples of AGFs. The grain sorghum samples were harvested 19-21 days after the last application, at normal maturity.

The grain sorghum samples were processed according to simulated commercial procedures into aspirated grain fractions. The grain sorghum AGF sample concentrated 15x.

Sweet Sorghum. Two trials were conducted on sweet sorghum (GA and MI). Plots received two broadcast foliar applications of BAS 700 F (62.5 g/L EC) at 495-514 g a.i./ha/application (0.442-0.458 lb a.i./A/application), with a 7-9 day RTI, resulting in a total exaggerated rate of 992-1010 g a.i./ha/season (0.89-0.90 lb a.i./A). The sweet sorghum samples were harvested 19-21 days after the last application, at normal maturity.

The sweet sorghum grain samples were processed using simulated commercial processing procedures into syrup. Residues of BAS 700 F do not concentrate in sweet sorghum syrup (0.1-0.2x, average processing factor 0.1x).

Trial ID	Processed Commodity	Processing Factor for BAS 700 F	Av. Processing Factor for BAS 700 F
RCN R080524	Syrup	0.1x	0.15x
RCN R080525		0.2x	

Rice. Two trials were conducted on rice (CA and AR). Plots received two broadcast foliar applications of BAS 700 F (62.5 g/L EC) at 495-514 g a.i./ha/application (0.442-0.458 lb a.i./A/application), with a 7-9 day RTI, resulting in a total exaggerated rate of 992-1010 g a.i./ha/season (0.89-0.90 lb a.i./A). The rice samples were harvested 19-21 days after the last application, at normal maturity.

The rice grain samples were processed using simulated commercial processing procedures into polished rice, hulls and bran from normal milling. In addition, glazed rice, brown (husked) rice, and rice flour from normal milling, and cooked rice, hulls, brown rice, and bran from parboiling were collected for analysis. Residues of BAS 700 F concentrate in rice hulls from normal milling (3.9-4.3x, average processing factor 4.1x) and in bran from parboiling (0.9-3.8x, average processing factor 2.3x), but do not concentrate in polished rice (<0.1x), bran from normal milling (0.9x), glazed rice (<0.1x), brown rice from normal milling (<0.1-0.2x, average processing factor 0.1x), cooked (parboiled) rice (0.1-0.5x, average processing factor 0.3x), rice flour (<0.1x), rice hulls from parboiling (0.8-1.6x, average processing factor 1.2x), and brown rice from parboiling (0.2-0.6x, average processing factor 0.4x).

Trial ID	Processed Commodity	Processing Factor for BAS 700 F	Av. Processing Factor for BAS 700 F
RCN R080526	Polished rice/white milled	<0.1x	<0.1x
RCN R080527		<0.1x	
RCN R080526	Rice hulls (normal milling)	4.3x	4.1x
RCN R080527		3.9x	
RCN R080526	Bran (normal milling)	0.9x	0.9x
RCN R080527		0.9x	
RCN R080526	Glazed rice (normal milling)	<0.1x	<0.1x
RCN R080527		<0.1x	
RCN R080526	Husked rice/brown rice (normal milling)	<0.1x	<0.15x
RCN R080527		0.2x	
RCN R080526	Cooked rice/parboiled white milled	0.1x	0.3x
RCN R080527		0.5x	
RCN R080526	Flour (polished rice/white milled)	<0.1x	<0.1x
RCN R080527		<0.1x	
RCN R080526	Rice hulls (parboiling)	0.8x	1.2x
RCN R080527		1.6x	
RCN R080526	Husked rice/brown (parboiling)	0.2x	0.4x

RCN R080527		0.6x	
RCN R080526	Bran (parboiling)	0.9x	2.4x
RCN R080527		3.8x	

Canola. Two field trials were conducted on canola in NAFTA Growing Regions 11 (ID) and 14 (AB). Plots received two broadcast foliar applications of BAS 700 F (62.5 g/L EC) at 288-308 g a.i./ha/application (0.257-0.275 lb a.i./A/application), resulting in a total rate of 577-616 g a.i./ha/season (0.515-0.549 lb a.i./A/season). Canola seed samples were harvested at a PHI of 21 days, at normal maturity.

The canola seed samples were processed according to simulated commercial procedures into meal, crude oil and refined oil. Residues of BAS 700 F do not concentrate in any of the processed commodities of canola.

Trial ID	Processed Commodity	Rep	Processing Factors for BAS 700 F	Av. Processing Factor for BAS 700 F	Processing Factor for Combined Residues (based on RD)	Av. Processing Factor for Combined Residues (based on RD)
RCN R080211	Meal	A	0.7	0.42x	0.7	0.61 x
RCN R080211		B	0.3		0.95	
RCN R080212		A	0.4		0.43	
RCN R080212		B	0.3		0.36	
RCN R080211	Crude Oil	A	1.1	0.8x	2.5	1.4x
RCN R080211		B	0.9		1.8	
RCN R080212		A	0.7		0.67	
RCN R080212		B	0.5		0.52	
RCN R080211	Refined Oil	A	0.4	0.27x	0.32	0.28x
RCN R080211		B	<0.1		0.18	
RCN R080212		A	0.2		0.2	
RCN R080212		B	0.4		0.42	

Sunflower. Two field trials were conducted on sunflowers in NAFTA Growing Regions 7 (SK) and 8 (KS). Plots received two broadcast foliar applications of BAS 700 F (62.5 g/L EC) at 493-516 g a.i./ha/application (0.440-0.461 lb a.i./A/application), resulting in a total rate of 993-1018 g a.i./ha/season (0.886-0.908 lb a.i./A/season). Sunflower seed samples were harvested at a PHI of 21 days, at normal maturity,

The sunflower seed samples were processed according to simulated commercial procedures into meal, crude oil and refined oil. Residues of BAS 700 F do not concentrate in any of the processed commodities of sunflower.

Table 37. Average Processing Factors in Sunflower Processed Commodities.				
Trial ID	Processed Commodity	Rep	Processing Factors for BAS 700 F	Av. Processing Factor for BAS 700 F
RCN R080213	Meal	A	0.3	<0.18x
RCN R080213		B	0.2	
RCN R080214		A	<0.1	
RCN R080214		B	<0.1	
RCN R080213	Crude Oil	A	0.4	0.25
RCN R080213		B	0.3	
RCN R080214		A	0.1	
RCN R080214		B	0.2	
RCN R080213	Refined Oil	A	0.2	<0.12x
RCN R080213		B	<0.1	
RCN R080214		A	<0.1	
RCN R080214		B	<0.1	

Cottonseed. Two trials were conducted (one each in GA and TX), where cottonseed was treated with a suspension concentrate (SC) formulation of BAS 700 F, at an exaggerated rate of 100 g ai/100 kg seed to generate seed cotton for processing. Cotton samples were harvested at normal maturity, 155-193 days after planting, by mechanical picker or stripper-picker. Seed samples were frozen and shipped to the processor.

Undelinted cottonseed was processed according to simulated commercial procedures, into cottonseed hull, meal, and refined oil. Residues of BAS 700 F show no evidence of concentration in cottonseed hull, meal, or refined oil (as residues were non-quantifiable in the undelinted cotton seed and all processed fractions).

Table 38. Average Processing Factors in Cottonseed Processed Commodities.				
Trial ID	Processed Commodity	Rep.	Processing Factor for BAS 700 F	Av. Processing Factor for BAS 700 F
RCN R080304	Cottonseed hull	A	1x	1x
RCN R080309		A	1x	
RCN R080304	Cottonseed meal	A	1x	1x
RCN R080309		A	1x	
RCN R080304	Cottonseed refined oil	A	1x	1x
RCN R080309		A	1x	

Peanuts. Two field trials were conducted during the 2008 growing season in EPA Region 2. Three foliar applications of BAS 700 AE F (62.9 g/L) EC formulation were made, each targeting 100 g ai/ ha (~0.09 lb ai/acre) for a seasonal total of 300 g ai/ha (~0.27 lb ai/A), with a 14-day retreatment interval. Samples were harvested 7 days after the last application. Typical for commercial practice, the peanuts were harvested by digging them from the ground (date of harvest) and then collected 4 or 6 days later (date of collection) after standing in the field. RAC samples of nutmeat were collected as well as unshelled nuts.

The peanut nutmeat samples were processed according to simulated commercial procedures into meal, peanut butter, expeller crude oil, expeller refined oil, solvent-extracted crude oil, and solvent-extracted refined oil.

BAS 700 F concentrated about 3-fold into peanut oil fractions (the potential for concentration was about 10-fold based upon mass-balance data). Residues did not concentrate in peanut meal or peanut butter (which was produced by adding untreated commercial peanut oil).

Table 39. Average Processing Factors in Peanut Processed Commodities.				
Trial ID	Processed Commodity	Rep.	Processing Factor for BAS 700 F	Av. Processing Factor for BAS 700 F
RCN R080552	Peanut Meal	A	1x	1x
RCN R080553		A	1x	
RCN R080552	Peanut Butter	A	1x	1x
RCN R080553		A	1x	
RCN R080552	Crude Oil-Expeller	A	>2.5x	>2.8x
RCN R080553		A	>3x	
RCN R080552	Refined Oil-Expeller	A	>2x	>2x
RCN R080553		A	>2x	
RCN R080552	Crude Oil-Solvent	A	>2.5x	>2.8x
RCN R080553		A	>3x	
RCN R080552	Refined Oil-Solvent	A	>2x	>2x
RCN R080553		A	>2x	

Aspirated Grain Fractions. In the field trials for sorghum, corn, soybean, and wheat, aspirated grain fractions were collected. The trials are discussed in the sections above for each grain crop. The residues for each aspirated grain fraction are calculated below. A tolerance for residues of fluxapyroxad in “grain, aspirated fractions” will be set at the highest residue calculated in the table below.

Table 40. Calculation of Fluxapyroxad Residue in Aspirated Grain Fractions.

Grain	STMdR	Ave. Factor	Residue
soybean	0.01	150	1.5
wheat	0.07	220	15.4
corn, field	0.01	7	0.07
sorghum	0.18	15	2.7

Conclusions. The field trials for processing studies were conducted at approximately 5x exaggerated rates, except for the trials for aspirated grain fractions. The residue data are supported by storage stability studies. Some decline was seen in oily commodities. The analytical methods used are adequate for the analysis of the residues of concern, fluxapyroxad and M700F008.

Tolerances are needed for fluxapyroxad on the following processed commodities: potato wet peel at 0.1 ppm, sugar beet dried pulp at 0.1 ppm, soybean hulls at 0.03 ppm, tomato wet pomace at 1.5 ppm, apple wet pomace at 2 ppm, plum, prune at 3 ppm, barley bran at 3 ppm, wheat bran at 0.6 ppm, corn oil at 0.03 ppm, rice hulls at 8 ppm, rice bran at 5 ppm, peanut oil at 0.02 ppm, and aspirated grain fractions at 6 ppm. The calculation of the needed tolerances on processed commodities is shown in the table below.

The processing studies are adequate to support the proposed uses in this petition.

Table 41. Calculation of Fluxapyroxad tolerances for processed commodities.				
Commodity	HAFT (ppm)	Processing Factor	Calculated Tolerance (ppm)	Rounded Tolerance (ppm)
Potato	0.02			
wet peel		4.7	0.094	0.10
Sugar beet	0.06			
dried pulp		1.8	0.108	0.10
Soybean	0.01			
hulls		2.7	0.027	0.03
Tomato	0.44			
wet pomace		3.4	1.496	1.5
Apple	0.37			
wet pomace		4.6	1.702	2.0
Plum	0.95			
prune		2.8	2.66	3.0
Barley	1.22			
bran		1.9	2.318	2.5*
Wheat	0.19			
bran		3.1	0.589	0.60
Corn	0.01			
oil		2.6	0.026	0.03

Commodity	HAFT (ppm)	Processing Factor	Calculated Tolerance (ppm)	Rounded Tolerance (ppm)
Rice	1.77			
hulls		4.1	7.257	8.0
bran		2.4	4.248	5.0
Peanut	0.01			
oil		2	0.02	0.02
AGF	0.07	220	15.4	20

*Tolerance needed for Barley Bran is lower than the crop group tolerance, so the tolerance will not be set.

The processing factors for all commodities determined in the processing studies are summarized in the table below.

Commodity	Processing factor
Potato	
Granules/Flakes	0.75
Chips	0.75
Peel, wet	4.7
Peeled potatoes	0.75
Boiled potatoes	0.75
Microwaved boiled potatoes (unpeeled)	0.75
Baked potato	<0.75
Fried potato	0.75
Process waste	0.75
Dried pulp	8
Sugar beets	
Refined sugar	0.2
Dried pulp	1.8
Molasses	0.8
Raw juice	0.2
Thick juice	0.75
Raw sugar	1
Press water	0.2
Pressed pulp	0.25
Ensiled pulp	0.25
Soybean	
Flour	<0.52
Hulls	2.7
Meal	<0.52

Table 42. Summary of All Fluxapyroxad Processing Factors.	
Commodity	Processing factor
Miso	<0.52
Refined Oil	0.75
Soy milk	<0.52
Soy sauce	<0.52
Tofu	<0.52
Tomato	
Canned tomatoes	0.22
Paste	0.7
Peeled Tomatoes	0.13
Puree	0.45
Raw Juice	0.2
Tomato Peel	3.3
Wash Water	0.16
Washed Tomatoes	0.7
Wet Pomace	3.4
Apple	
Juice	0.2
Wet Pomace	4.6
Apple Sauce	0.25
Canned Apples	0.25
Dried Apples	0.55
Plum	
Washed Plum	0.75
Plum Puree	0.75
Plum Jam	0.4
Dried Prunes	2.8
Barley	
Pot barley	0.2
Bran	1.9
Flour	0.22
Brewing malt	<0.1
Malt culms (Sprouts)	0.3
Spent grain	0.26
Spent hops	0.8
Brewer's (spent) yeast	0.3
Beer	0.1
Wheat	
Bran	3.1
Flour	0.23

Table 42. Summary of All Fluxapyroxad Processing Factors.	
Commodity	Processing factor
Middlings	0.4
Shorts	0.56
Germ	1.5
White Bread	0.19
Whole meal	1
Bread (whole meal)	0.71
Corn	
Meal	0.85
Refined oil (wet milled)	2.6
Flour	0.95
Grits	0.65
Starch	0.55
Refined oil (dry milled)	0.7
Sweet sorghum	
Syrup	0.15
Rice	
Polished white rice	<0.1
Hulls	4.1
Bran	0.9
Glazed rice	<0.1
Husked brown rice	<0.15
Parboiled white rice	0.3
Flour	<0.1
Hulls (parboiled)	1.2
Husked brown rice (parboiled)	0.4
Bran (parboiled)	2.4
Canola	
Meal	0.61
Crude Oil	1.4
Refined Oil	0.28
Sunflower	
Meal	<0.18
Crude Oil	0.25
Refined Oil	<0.1
Cottonseed	
Meal	1
Hull	1
Refined oil	1
Peanut	

Commodity	Processing factor
Meal	1
Peanut butter	1
Crude oil - expeller	>2.8
Refined oil - expeller	>2
Crude oil - solvent	>2.8
Refined oil - solvent	>2
Grain, aspirated fractions	15.4

1860.1650 Submittal of Analytical Reference Standards

BASF submitted the following analytical reference standards for fluxapyroxad and its metabolites the EPA National Pesticide Standards Repository in June and August of 2010.

fluxapyroxad, expiration date 8/1/2012

fluxapyroxad metabolite M700F002, expiration date 4/1/2012

fluxapyroxad metabolite M700F008, expiration date 3/1/2013

fluxapyroxad metabolite M700F048, expiration date 2/1/2012

860.1850 Confined Accumulation in Rotational Crops

Monograph Section B.7.9.1 Metabolism and distribution studies on representative crops

PMRA# 1884199. MRID 47923680

PMRA# 1884201. MRID 47923679

The metabolism of fluxapyroxad (BAS 700 F) in the rotational crops radish, spinach, and wheat was investigated using BAS 700 F radiolabelled in the aniline ring and, in separate studies, the pyrazole ring. For the aniline label studies, the test item was a mixture of aniline-U-C¹⁴-BAS 700 F and aniline-N¹⁵, pyrazole-1,2-N¹⁵-BAS 700 F. For the pyrazole studies, the test item was a mixture of pyrazole-4-C¹⁴-BAS 700 F with unlabelled BAS 700 F. The molecular structures and the label positions are shown above in section 860.1300 Nature of the Residue – Plants.

A single spray application of 14C-BAS 700 F (as BAS 700 AD F EC formulation) was made to bare soil at a nominal application rate of 250 g a.i./ha (0.28 lb ai/A; 0.78x the maximum seasonal rate on beans) using an automatic spray track system. The treated soil was aged for 30, 120 and 365 days. After the soil aging periods were completed, ploughing was simulated by mixing the treated and untreated soil layers. Directly after these treatments, spinach, white radish, spring wheat were sowed.

Mature (GS 49) and immature spinach leaves were harvested; the roots remained in the soil. Immature white radishes were sampled as whole “white radish plants” (thinning out). Ripe white radishes (GS 49) were pulled from the soil and separated into the edible parts (root) and the remaining green parts (top). Immature green wheat plants (GS 39) were harvested (forage and hay; after drying). Ears of mature wheat (GS 89) were cropped with scissors and separated by threshing into chaff and grain. Mature wheat (GS 89) was harvested by cutting the plants just above the soil line (wheat straw); the roots remained in the soil. Samples were frozen at -18 C until analysis.

The radioactive residues in homogenised plant samples or soil samples were determined by oxidative combustion of small aliquots (LSC measurement). Subsamples were extracted with methanol followed by water. Extractable residues were reported as extractable radioactive residues (ERR). The residue remaining after extraction was reported as residual radioactive residue (RRR). The total radioactive residue (TRR) was the sum of the two (ERR + RRR).

The results of the identification of metabolites are shown in the tables below, for the two studies,

one with aniline label, and a second study with pyrazole label.

Table 43. Summary of identified components in extractable and residual radioactive residues (ERR * + RRR*) from rotational crop matrices of spinach and white radish following cultivation in soil treated with ¹⁴C-BAS 700 F (aniline label) after PBIs of 30, 120 and 365 days.

Metabolite	Crop parts									
	Immature spinach		Mature spinach		White radish plant		White radish top		White radish root	
	[mg/kg]	[% TRR]	[mg/kg]	[% TRR]	[mg/kg]	[% TRR]	[mg/kg]	[% TRR]	[mg/kg]	[% TRR]
Plant back interval: 30 DAT										
BAS 700 F	0.027	30.6	0.022	21.7	0.034	40.7	0.013	18.2	0.008	53.4
M700F008 **	0.008	9.3	0.003	3.1	0.020	24.2	0.018	25.6	0.004	26.1
M700F036	0.003	2.9	0.008	7.8	0.002	1.9	0.006	8.9	n. d.	n. d.
M700F042 ***	0.013	14.7	0.003	3.1	0.001	1.1	0.0005	0.7	n. d.	n. d.
M700F048 / M700F057	0.011	11.8	0.005	4.5	0.008	9.5	0.009	12.8	0.001	4.9
M700F058	0.005	5.5	0.012	11.5	n. d.	n. d.	0.001	0.9	n. d.	n. d.
M700F059 ****	n. d.	n. d.	n. d.	n. d.	0.001	1.0	0.008	11.4	n. d.	n. d.
M700F074	0.006	6.6	0.017	16.4	0.002	2.6	0.002	3.3	n. d.	n. d.
Sum of identified components	0.073	81.5	0.069	68.2	0.068	81.1	0.056	81.7	0.013	84.4
Plant back interval: 120 DAT										
BAS 700 F	0.026	30.9	0.012	16.3	0.022	49.1	0.008	8.5	0.004	42.2
M700F008 **	0.009	10.6	0.002	2.6	0.011	23.9	0.020	22.5	0.004	36.6
M700F036	n. d.	n. d.	0.005	7.5	n. d.	n. d.	0.009	9.8	n. d.	n. d.
M700F042 ***	0.021	25.2	0.003	3.6	0.002	4.3	0.001	1.2	n. d.	n. d.
M700F048 / M700F057	0.009	10.6	0.002	3.3	0.004	8.5	0.027	30.5	0.001	6.8
M700F058	0.001	1.3	0.011	14.8	n. d.	n. d.	0.001	0.6	n. d.	n. d.
M700F059 ****	0.004	5.0	n. d.	n. d.	n. d.	n. d.	0.006	6.7	n. d.	n. d.
M700F074	0.002	2.9	0.009	12.8	n. d.	n. d.	0.003	3.0	n. d.	n. d.
Sum of identified components	0.072	86.4	0.044	61.0	0.038	85.8	0.074	82.7	0.009	85.6
Plant back interval: 365 DAT										
BAS 700 F	0.010	25.2	0.005	17.3	0.008	30.4	0.007	11.5	0.003	37.7
M700F008 **	0.003	7.8	0.001	4.1	0.008	30.4	0.010	15.1	0.003	38.2
M700F036	0.002	5.8	0.002	5.6	0.001	4.6	0.013	19.5	0.00003	0.5
M700F042 ***	0.001	3.4	0.001	2.7	n. d.	n. d.	n. d.	n. d.	n. d.	n. d.
M700F048 / M700F057	0.002	5.2	0.001	4.6	0.003	10.6	0.008	12.7	0.001	10.8
M700F058	0.004	9.6	0.004	14.1	n. d.	n. d.	0.001	1.6	n. d.	n. d.
M700F059 ****	n. d.	n. d.	n. d.	n. d.	0.0005	1.7	0.012	18.2	n. d.	n. d.
M700F074	0.005	13.1	0.005	18.4	0.001	3.0	0.003	4.1	n. d.	n. d.
Sum of identified components	0.029	70.1	0.019	66.9	0.021	80.7	0.053	82.7	0.006	87.2

* ERR = Extractable Radioactive Residues (methanol extract and water extract), RRR = Residual (non-extractable) Radioactive Residues

** M700F008 might also contain minor portions of M700F043 and M700F041

*** M700F042 might also contain minor portions of M700F024 and M700F005

**** M700F059 might also contain minor portions of M700F060

Table 44. Summary of identified components in extractable and residual radioactive residues (ERR * + RRR *) from rotational crop matrices of spring wheat following their cultivation in soil treated with 14C-BAS 700 F (aniline label) after PBIs of 30, 120 and 365 days.

Metabolite	Crop parts									
	Spring wheat forage		Spring wheat hay		Spring wheat straw		Spring wheat chaff		Spring wheat grain	
	[mg/kg]	[% TRR]	[mg/kg]	[% TRR]	[mg/kg]	[% TRR]	[mg/kg]	[% TRR]	[mg/kg]	[% TRR]
Plant back interval: 30 DAT										
BAS 700 F	0.121	84.5	0.876	81.2	1.206	64.3	0.214	53.6	0.006	28.5
M700F008 **	0.008	5.6	0.067	6.2	0.143	7.6	0.018	4.5	0.001	6.4
M700F036	0.001	0.6	n. d.	n. d.	n. d.	n. d.	n. d.	n. d.	n. d.	n. d.
M700F042 ***	n. d.	n. d.	0.007	0.6	0.113	6.0	0.001	0.3	0.0001	0.3
M700F048 / M700F057	0.001	1.0	0.010	0.9	0.036	1.9	n. d.	n. d.	n. d.	n. d.
M700F058	n. d.	n. d.	n. d.	n. d.	n. d.	n. d.	0.007	1.7	n. d.	n. d.
M700F059 ****	n. d.	n. d.	n. d.	n. d.	n. d.	n. d.	n. d.	n. d.	n. d.	n. d.
M700F074	0.001	1.0	n. d.	n. d.	n. d.	n. d.	0.012	3.1	n. d.	n. d.
Sum of identified components	0.133	92.7	0.960	88.9	1.498	79.9	0.252	63.2	0.007	35.2
Plant back interval: 120 DAT										
BAS 700 F	0.131	72.7	0.775	71.2	1.137	72.6	0.432	74.4	0.004	28.2
M700F008 **	0.011	6.3	0.079	7.2	0.096	6.1	0.049	8.5	0.001	7.5
M700F036	0.002	1.4	n. d.	n. d.	n. d.	n. d.	n. d.	n. d.	n. d.	n. d.
M700F042 ***	n. d.	n. d.	0.040	3.7	0.046	2.9	0.006	1.1	n. d.	n. d.
M700F048 / M700F057	0.001	0.6	0.014	1.3	0.023	1.4	0.0002	0.03	0.0001	0.6
M700F058	0.003	1.7	n. d.	n. d.	0.008	0.5	n. d.	n. d.	n. d.	n. d.
M700F059 ****	0.002	1.3	n. d.	n. d.	n. d.	n. d.	n. d.	n. d.	n. d.	n. d.
M700F074	0.006	3.3	0.029	2.6	0.037	2.4	n. d.	n. d.	0.00003	0.2
Sum of identified components	0.157	87.2	0.936	86.0	1.346	86.0	0.488	84.0	0.005	36.5
Plant back interval: 365 DAT										
BAS 700 F	0.110	77.4	0.811	80.1	1.722	64.9	0.329	62.3	0.008	39.8
M700F008 **	0.008	5.5	0.074	7.3	0.273	10.3	0.053	10.0	0.001	6.0
M700F036	n. d.	n. d.	n. d.	n. d.	0.032	1.2	0.003	0.6	n. d.	n. d.
M700F042 ***	n. d.	n. d.	0.001	0.1	0.096	3.6	0.006	1.1	n. d.	n. d.
M700F048 / M700F057	0.001	0.9	0.010	1.0	0.083	3.1	0.002	0.3	n. d.	n. d.
M700F058	0.001	0.8	0.009	0.8	0.052	1.9	n. d.	n. d.	n. d.	n. d.
M700F059 ****	n. d.	n. d.	n. d.	n. d.	n. d.	n. d.	n. d.	n. d.	n. d.	n. d.
M700F074	0.002	1.1	0.010	1.0	0.019	0.7	0.004	0.7	n. d.	n. d.
Sum of identified components	0.122	85.6	0.915	90.4	2.277	85.8	0.396	75.1	0.009	45.9

* ERR = Extractable Radioactive Residues (methanol extract and water extract), RRR = Residual (non-extractable) Radioactive Residues

** M700F008 might also contain minor portions of M700F043 and M700F041

*** M700F042 might also contain minor portions of M700F024 and M700F005

**** M700F059 might also contain minor portions of M700F060

Table 45. Summary of identified components in extractable and residual radioactive residues (ERR * + RRR *) from rotational crop matrices of spinach and white radish following cultivation in soil treated with ¹⁴C-BAS 700 F (pyrazole label) after PBIs of 30, 149 and 365 days.

Metabolite	Crop parts											
	Immature spinach		Mature spinach		White radish plant		White radish top		White radish root			
	[mg/kg]	[% TRR]	[mg/kg]	[% TRR]	[mg/kg]	[% TRR]	[mg/kg]	[% TRR]	[mg/kg]	[% TRR]		
Plant back interval: 30 DAT												
BAS 700 F			0.017	9.6					0.006	42.9		
M700F001			0.002 (0.001) °	1.0					0.000 (0.000) °	1.4		
M700F002			0.086 (0.036) °	48.8					0.000 (0.000) °	1.7		
M700F008 **			0.009	4.9					0.004	29.0		
M700F036			n. d.	n. d.					n. d.	n. d.		
M700F042 ***	no samples taken		0.014	8.1	no samples taken				n. d.	n. d.		
M700F048 / M700F057			0.005	3.1					0.001	5.9		
M700F058			n. d.	n. d.					n. d.	n. d.		
M700F059 ****			n. d.	n. d.					n. d.	n. d.		
M700F074				0.008		4.7				n. d.	n. d.	
Sum of identified components				0.140		80.1					0.011	80.9
Plant back interval: 149 DAT												
BAS 700 F			0.011	12.6	0.009	13.3	0.006	30.7	0.006	68.6		
M700F001			0.005 (0.002) °	5.2	0.001 (0.000) °	1.6	n. d.	n. d.	0.000 (0.000) °	1.3		
M700F002			0.054 (0.023) °	61.9	0.040 (0.017) °	61.1	0.003 (0.001) °	12.5	0.000 (0.000) °	1.9		
M700F008 **			n. d.	n. d.	0.005	7.0	0.004	17.8	0.001	15.2		
M700F036			n. d.	n. d.	n. d.	n. d.	0.001	7.4	n. d.	n. d.		
M700F042 ***	no samples taken		0.010	11.3	0.001	1.3	n. d.	n. d.	n. d.	n. d.		
M700F048 / M700F057			0.002	2.0	0.005	7.7	0.002	11.9	0.000	2.8		
M700F058			n. d.	n. d.	n. d.	n. d.	n. d.	n. d.	n. d.	n. d.		
M700F059 ****			n. d.	n. d.	n. d.	n. d.	0.000	2.1	n. d.	n. d.		
M700F074			n. d.	n. d.	n. d.	n. d.	0.001	2.6	n. d.	n. d.		
Sum of identified components				0.081	93.0	0.060	92.0	0.017	85.0	0.008	89.9	
Plant back interval: 365 DAT												
BAS 700 F	0.010	14.8	0.010	12.9	0.009	30.2	0.007	15.5	0.006	38.9		
M700F001	0.002 (0.001) °	2.9	0.003 (0.002) °	4.3	0.000 (0.000) °	1.0	n. d.	n. d.	n. d.	n. d.		
M700F002	0.022 (0.009) °	31.8	0.017 (0.007) °	22.6	0.007 (0.003) °	24.5	0.005 (0.002) °	10.2	0.000 (0.000) °	1.4		
M700F008 **	0.003	4.6	0.002	3.0	0.006	18.4	0.006	12.9	0.002	12.0		
M700F036	0.002	2.7	0.004	4.6	0.001	3.8	0.002	3.3	n. d.	n. d.		
M700F042 ***	n. d.	n. d.	0.001	1.6	n. d.	n. d.	n. d.	n. d.	n. d.	n. d.		
M700F048 / M700F057	0.002	3.2	0.002	2.8	0.002	7.2	0.004	8.4	0.000	2.6		
M700F058	0.003	4.1	0.004	5.6	n. d.	n. d.	0.001	1.8	n. d.	n. d.		
M700F059 ****	n. d.	n. d.	n. d.	n. d.	0.001	1.7	0.003	7.2	n. d.	n. d.		
M700F074	0.008	11.2	0.007	9.2	0.001	2.2	0.001	1.9	n. d.	n. d.		
Sum of identified components	0.053	75.3	0.051	66.7	0.027	89.0	0.028	61.2	0.008	54.9		

* ERR = Extractable Radioactive Residues (methanol extract and water extract), RRR = Residual (non-extractable) Radioactive Residues

** M700F008 might also contain minor portions of M700F043 and M700F041

*** M700F042 might also contain minor portions of M700F024 and M700F005

**** M700F059 might also contain minor portions of M700F060

° Concentrations [mg/kg] of metabolites M700F001 and M700F002 (given in brackets) were re-calculated using the molecular masses of M700F001 and M700F002, respectively.

Table 46. Summary of identified components in extractable and residual radioactive residues (ERR * + RRR *) from rotational crop matrices of spring wheat following cultivation in soil treated with ¹⁴C-BAS 700 F (pyrazole label) after PBIs of 30, 149 and 365 days.

Metabolite	Crop parts									
	Spring wheat forage		Spring wheat hay		Spring wheat straw		Spring wheat chaff		Spring wheat grain	
	[mg/kg]	[% TRR]	[mg/kg]	[% TRR]	[mg/kg]	[% TRR]	[mg/kg]	[% TRR]	[mg/kg]	[% TRR]
Plant back interval: 30 DAT										
BAS 700 F	0.219	76.0	no samples taken	1.217	54.4	0.530	64.3	0.009	24.1	
M700F001	n. d.	n. d.		0.011 (0.005)°	0.5	0.005 (0.003)°	0.7	n. d.	n. d.	
M700F002	0.012 (0.005)°	4.2		0.046 (0.020)°	2.0	0.049 (0.021)°	5.9	n. d.	n. d.	
M700F008 **	0.017	6.0		0.099	4.4	0.064	7.8	0.002	4.0	
M700F036	n. d.	n. d.		n. d.	n. d.	n. d.	n. d.	n. d.	n. d.	
M700F042 ***	n. d.	n. d.		0.020	0.9	0.004	0.5	n. d.	n. d.	
M700F048 / M700F057	0.003	1.0		0.050	2.2	0.006	0.8	n. d.	n. d.	
M700F058	n. d.	n. d.		0.053	2.4	n. d.	n. d.	n. d.	n. d.	
M700F059 ****	n. d.	n. d.		n. d.	n. d.	n. d.	n. d.	n. d.	n. d.	
M700F074	0.003	1.0		0.054	2.4	n. d.	n. d.	n. d.	n. d.	
Sum of identified components	0.254	88.1		1.550	69.3	0.658	79.9	0.011	28.1	
Plant back interval: 149 DAT										
BAS 700 F	0.119	57.1	no samples taken	0.267	31.9	0.094	42.7	0.004	9.5	
M700F001	0.002 (0.001)°	1.2		0.028 (0.013)°	3.4	0.003 (0.001)°	1.2	0.002 (0.001)°	3.7	
M700F002	0.011 (0.005)°	5.4		0.054 (0.023)°	6.4	0.016 (0.007)°	7.4	0.001 (0.000)°	1.8	
M700F008 **	0.007	3.5		0.045	5.4	0.021	9.3	0.001	2.0	
M700F036	n. d.	n. d.		n. d.	n. d.	n. d.	n. d.	n. d.	n. d.	
M700F042 ***	0.006	3.0		0.061	7.3	0.002	0.9	n. d.	n. d.	
M700F048 / M700F057	n. d.	n. d.		0.001	0.1	0.008	3.7	n. d.	n. d.	
M700F058	0.009	4.5		0.020	2.4	n. d.	n. d.	n. d.	n. d.	
M700F059 ****	n. d.	n. d.		n. d.	n. d.	n. d.	n. d.	n. d.	n. d.	
M700F074	0.044	20.9		0.080	9.5	0.005	2.3	n. d.	n. d.	
Sum of identified components	0.200	95.7		0.557	66.5	0.149	67.6	0.006	14.8	
Plant back interval: 365 DAT										
BAS 700 F	0.083	76.4	no samples taken	1.052	64.3	0.121	40.6	0.002	5.5	
M700F001	n. d.	n. d.		n. d.	n. d.	n. d.	n. d.	0.000 (0.000)°	0.3	
M700F002	0.002 (0.001)°	2.3		0.037 (0.016)°	2.2	0.002 (0.001)°	0.7	0.001 (0.000)°	2.6	
M700F008 **	0.005	4.8		0.117	7.2	0.013	4.4	0.001	1.4	
M700F036	n. d.	n. d.		0.005	0.3	n. d.	n. d.	n. d.	n. d.	
M700F042 ***	n. d.	n. d.		0.019	1.1	0.001	0.3	n. d.	n. d.	
M700F048 / M700F057	0.001	1.2		0.015	0.9	n. d.	n. d.	n. d.	n. d.	
M700F058	n. d.	n. d.		n. d.	n. d.	n. d.	n. d.	n. d.	n. d.	
M700F059 ****	n. d.	n. d.		n. d.	n. d.	n. d.	n. d.	n. d.	n. d.	
M700F074	0.002	1.4		0.017	1.0	0.001	0.3	0.000	0.2	
Sum of identified components	0.093	86.0		1.262	77.1	0.138	46.3	0.003	7.9	

* ERR = Extractable Radioactive Residues (methanol extract and water extract), RRR = Residual (non-extractable) Radioactive Residues

** M700F008 might also contain minor portions of M700F043 and M700F041

*** M700F042 might also contain minor portions of M700F024 and M700F005

**** M700F059 might also contain minor portions of M700F060

° Concentrations [mg/kg] of metabolites M700F001 and M700F002 (given in brackets) were re-calculated using the molecular masses of M700F001 and M700F002, respectively.

At all three plantback intervals, significant translocation of radioactivity from soil into plant was observed, with radioactive residues in wheat straw up to 2.65 mg/kg and in spinach up to 0.10 mg/kg. Lower residues were observed in radish roots (maximum of 0.015 mg/kg) and wheat grain (maximum of 0.020 mg/kg).

The extractability of the radioactive residues with methanol and water was high for all matrices (77-98% of the TRRs), except for spring wheat grain (49-60% of the TRRs). In most cases, the major part of the radioactive residues was extracted with methanol.

The metabolic pathways were seen to be highly comparable in the different succeeding crops investigated. The resulting metabolite pattern was qualitatively similar to the one identified for primary crops, with total residues in rotational crops much lower than in foliar-treated plants. No metabolites specific to rotational crops were found. Similar as in foliar-treated plants, BAS 700F was the main component of the residue.

Conclusions . The confined rotational crop studies are adequate. Fluxapyroxad is taken up from the soil. The residue of concern for tolerance enforcement is fluxapyroxad, per se. The major residue seen was fluxapyroxad, with M700F008, the metabolite N-demethylated in the pyrazole moiety. M700F008 is an intermediate metabolite which further metabolizes. The TRR was adequately characterized. The residue of concern for risk assessment is fluxapyroxad and its metabolite, M700F008.

860.1900 Field Accumulation in Rotational Crops

Monograph Section B.7.9.2 Field trials on representative crops

PMRA# 1884455. MRID 47923681

47923682 – field rotational crop trials in EU (not reviewed)

Rotational field trials on radish, lettuce and wheat were carried out in NAFTA Growing Regions 2 (GA, one site) and 10 (CA, one site). Four plant-back intervals (PBIs) were tested – 30, 60, 90, and 120 days. No 365 day PBI was tested, although a 365 day PBI was included in the Confined Rotational Crop study, and in the European field rotational crop study (MRID 47923682), which has not been reviewed, but show all non-quantifiable residues at the 365 day PBI. The treated plots received two broadcast applications of BAS 700 F (formulation BAS 700 AE F; 62.5 g/L EC) to bare soil at 99-101 g a.i./ha/application, at a 13-15 day retreatment interval, for a total rate of 198-202 g a.i./ha/season (0.177-0.180 lb a.i./A/season). The applications were made in 210-287 L/ha (22-31 gal/A) of water using ground equipment, and an adjuvant (Induce or Helena Crop Oil Concentrate) was added to the spray mixture. The three rotational crops, radish, wheat, and lettuce were all grown in each treated plot.

The rotational wheat samples were harvested at commercial maturity, 129-144 days after planting (DAP) for forage and hay and 217-248 DAP for grain and straw. The forage samples were collected from wheat at a growth stage ranging from BBCH 49 (first awns visible) to BBCH 59 (inflorescence fully emerged) by cutting whole immature green plants above soil surface using a sickle or knife. Hay samples were harvested in the same manner and timing as forage and were allowed to dry under ambient conditions (protected from rain) for 6-20 days prior to sampling. Grain and straw (dried stalks or stems with leaves left after grain harvested) were collected at

crop maturity.

The rotational radish samples (tops and roots) were harvested 57-92 DAP. The samples were collected at commercial maturity, between growth stages BBCH 45 to 49 (50-100% of the expected root diameter reached), before the crop began to go to seed.

The rotational leaf lettuce samples (leaves) were harvested 59-122 DAP. The samples were collected at commercial maturity, between growth stages BBCH 45 to 49 (50-100% of the leaf mass typical for the variety reached), before the crop began to go to seed.

All samples were frozen on the day of collection, transported to the laboratory by freezer truck where they were stored at -5 C for up to 9 months prior to analysis. The analytical method used is described above.

Following two broadcast applications to the soil targeting 100 g a.i./ha/application (0.089 lb a.i./A/application), with a 13-15 day retreatment interval, for a total rate of 200 g a.i./ha (0.18 lb a.i./A), quantifiable residues of BAS 700 F were observed in rotational crops planted up to four months after the last application, with the exception of wheat grain and radish tops. The residues of BAS 700 F and metabolites in/on treated rotational crops grown at PBIs of approximately 1, 2, 3 and 4 months are presented in Table B.7.9-19 and summarized in Table B.7.9-20.

Wheat forage. Maximum BAS 700 F residues were 0.03, 0.08, 0.03, and 0.05 ppm in/on wheat forage from the 1-, 2-, 3- and 4-month PBIs, respectively. Residues of the metabolites M700F002, M700F008 and M700F048 ranged from non-detectable (ND, <0.002 ppm) to <0.01 ppm (for each analyte) in/on all forage samples from the 1-, 2-, 3- and 4-month PBIs.

Wheat hay. Maximum BAS 700 F residues were 0.11, 0.18, 0.09, and 0.14 ppm in/on wheat hay from the 1-, 2-, 3- and 4-month PBIs, respectively. Residues of the metabolites M700F002, M700F008 and M700F048 were ND to <0.01 ppm each in/on all hay samples from the 1-, 2-, 3- and 4-month PBIs, with the following exception: Maximum M700F048 residues were 0.01 ppm in/on wheat hay from the 4-month PBI.

Wheat grain. Residues of BAS 700 F and metabolites were ND-<0.01 ppm (for each analyte) in/on all wheat grain samples collected from the 1-, 2-, 3- and 4-month PBIs.

Wheat straw. Maximum BAS 700 F residues were 0.28, 0.54, 0.16, 0.31 ppm in/on wheat straw from the 1-, 2-, 3-, and 4-month PBIs, respectively, and maximum M700F008 residues were 0.02, 0.03, 0.01, and 0.02 ppm from these PBIs. M700F002 and M700F048 residues were ND to <0.01 ppm each in/on straw samples from the 1-, 2-, 3- and 4-month PBIs.

Radish tops. BAS 700 F and M700F02 residues were ND to <0.01 ppm each in radish tops samples from the 1-, 2-, 3- and 4-month PBIs. Maximum M700F008 residues were 0.01, 0.02, 0.02, and 0.02 ppm from the 1-, 2-, 3- and 4-month PBIs, respectively. Maximum M700F048 residues were <0.01 ppm except for 0.01 ppm at the 3-month PBI.

Radish root. Maximum BAS 700 F residues were 0.02, 0.01, 0.01, and 0.01 ppm in/on radish root samples from the 1-, 2-, 3- and 4-month PBIs, respectively. Residues of the metabolites

M700F002, M700F008 and M700F048 were ND to <0.01 ppm each in/on radish root samples from the 1-, 2-, 3- and 4-month PBIs.

Lettuce leaves. Maximum BAS 700 F residues were <0.01, 0.02, <0.01, and 0.02 ppm in/on lettuce from the 1-, 2-, 3- and 4-month PBIs, respectively. Residues of the metabolites M700F002, M700F008 and M700F048 were ND to <0.01 ppm each in/on lettuce samples from the 1-, 2-, 3- and 4-month PBIs.

All control and replicate treated samples of each rotational crop for each PBI were analyzed. Residues of BAS 700 F and the metabolites M700F002, M700F008 and M700F048 were non-detectable (<0.002 ppm) in/on all untreated rotational crop control samples (n=2 each), with following exceptions: The wheat straw sample from one site in GA had quantifiable BAS 700 F residues at 0.04 ppm, and detectable M700F048 residues at 0.006 ppm (<LOQ). The source of the contamination could not be determined.

The field accumulation studies for fluxapyroxad demonstrate that finite residues of fluxapyroxad were detected at all PHIs tested. No quantifiable residues were found for any of the metabolites analyzed.

Table 47. Residue Data from Rotational Crop Field Trials with BAS 700 F.

Location / (Trial ID) Year	Region	Crop	Matrix	Total Rate (lb a.i./A)	Harvest DAP ¹	PBI ² (days)	Rep	Residues (ppm) ³			
								BAS 700 F	M700 F002	M700 F008	M700 F048
Tift, GA / (R080487) 2008	2	Wheat	Forage	0.179	144	30	A	0.02	<0.01	<0.01	ND
							B	0.02	<0.01	<0.01	ND
				0.179	144	60	A	<0.01	ND	ND	ND
							B	0.01	ND	ND	ND
				0.178	144	91	A	<0.01	ND	ND	ND
							B	<0.01	ND	ND	ND
				0.179	144	120	A	<0.01	ND	ND	ND
							B	<0.01	ND	ND	ND
Tift, GA / (R080487) 2008	2	Wheat	Hay	0.179	144	30	A	0.05	<0.01	<0.01	ND
							B	0.06	<0.01	<0.01	ND
				0.179	144	60	A	0.04	<0.01	<0.01	ND
							B	0.04	<0.01	<0.01	ND
				0.178	144	91	A	0.02	ND	ND	ND
							B	0.04	<0.01	<0.01	ND
				0.179	144	120	A	0.03	ND	ND	ND
							B	0.03	ND	ND	ND
Tift, GA / (R080487) 2008	2	Wheat	Grain	0.179	217	30	A	ND	ND	ND	ND
							B	ND	ND	ND	ND
				0.179	217	60	A	ND	ND	ND	ND
							B	ND	ND	ND	ND
				0.178	217	91	A	ND	ND	ND	ND
							B	ND	ND	ND	ND
				0.179	217	120	A	ND	ND	ND	ND
							B	ND	ND	ND	ND
Tift, GA / (R080487) 2008	2	Wheat	Straw	0.179	217	30	A	0.07	ND	0.02	ND
							B	0.08	ND	0.02	ND
				0.179	217	60	A	0.04	ND	<0.01	ND
							B	0.07	ND	0.02	ND
				0.178	217	91	A	0.05	ND	<0.01	ND
							B	0.04	ND	0.01	ND
				0.179	217	120	A	0.04	ND	0.01	ND
							B	0.04	ND	0.01	ND

Table 47. Residue Data from Rotational Crop Field Trials with BAS 700 F.

Location / (Trial ID) Year	Region	Crop	Matrix	Total Rate (lb a.i./A)	Harvest DAP ¹	PBI ² (days)	Rep	Residues (ppm) ³				
								BAS 700 F	M700 F002	M700 F008	M700 F048	
Fresno, CA / (R080488) 2008	10	Wheat	Forage	0.180	129	29	B	0.05	ND	0.01	ND	
							A	0.03	ND	ND	ND	
				0.179	140	60	A	0.08* (0.08, 0.07)	ND	<0.01	ND	
							B	0.08* (0.08, 0.08)	ND	<0.01	ND	
				0.178	129	90	A	0.03	ND	ND	ND	
							B	0.03	ND	ND	ND	
	0.177	140	121	A	0.05 (0.05, 0.05)	ND	<0.01	ND				
				B	0.05* (0.04, 0.05)	ND	<0.01	ND				
	Fresno, CA / (R080488) 2008	10	Wheat	Hay	0.180	129	29	A	0.11	<0.01	<0.01	ND
								B	0.11	<0.01	<0.01	ND
					0.179	140	60	A	0.18	<0.01	<0.01	<0.01
								B	0.18	<0.01	<0.01	<0.01
0.178					129	90	A	0.09	<0.01	<0.01	ND	
							B	0.09	<0.01	<0.01	ND	
0.177		140	121	A	0.14	ND	<0.01	0.01				
				B	0.09* (0.09, 0.09)	ND	<0.01	ND				
Fresno, CA / (R080488) 2008		10	Wheat	Grain	0.180	248	29	A	ND	ND	ND	ND
								B	ND	ND	ND	ND
					0.179	217	60	A	<0.01	ND	ND	ND
								B	<0.01	ND	ND	ND
	0.178				248	90	A	ND	ND	ND	ND	
							B	ND	ND	ND	ND	
	0.177	217	121	A	<0.01* (ND, <0.01)	ND	ND* (ND, ND)	ND* (ND, ND)				
				B	<0.01* (<0.01, <0.01)	ND	ND* (ND, ND)	ND				
	Fresno, CA / (R080488) 2008	10	Wheat	Straw	0.180	248	29	A	0.28	ND	0.02	ND
								B	0.20	<0.01	0.01	ND
					0.179	217	60	A	0.48	<0.01	0.03	<0.01
								B	0.54	<0.01	0.03	<0.01
0.178					248	90	A	0.14	<0.01	<0.01	ND	
							B	0.16	<0.01	<0.01	ND	
0.177		217	121	A	0.31	<0.01	0.02	ND				
				B	0.25	<0.01	0.01	ND				
Tift, GA / (R080487) 2008		2	Lettuce	Leaves	0.179	73	30	A	<0.01	<0.01	ND	ND
								B	<0.01	<0.01	ND	ND
					0.179	73	60	A	<0.01	<0.01	ND	ND
								B	<0.01	ND	ND	ND
	0.178				73	91	A	<0.01	ND	ND	ND	
							B	<0.01	ND	ND	ND	
	0.179	73	120	A	<0.01	ND	ND	ND				
				B	<0.01	ND	ND	ND				
	Tift, GA / (R080487) 2008	2	Radish	Tops	0.179	70	30	A	<0.01	<0.01	0.01	<0.01
								B	<0.01	ND	<0.01	<0.01
					0.179	70	60	A	<0.01	ND	<0.01	ND
								B	<0.01	ND	<0.01	ND
0.178					70	91	A	<0.01	ND	<0.01	ND	
							B	<0.01	ND	<0.01	<0.01	
0.179		70	120	A	ND	ND	ND	ND				
				B	ND	ND	<0.01	ND				

Table 47. Residue Data from Rotational Crop Field Trials with BAS 700 F.

Location / (Trial ID) Year	Region	Crop	Matrix	Total Rate (lb a.i./A)	Harvest DAP ¹	PBI ² (days)	Rep	Residues (ppm) ³			
								BAS 700 F	M700 F002	M700 F008	M700 F048
Tift, GA / (R080487) 2008	2	Radish	Root	0.179	70	30	A	0.02	ND	<0.01	ND
							B	0.01	ND	<0.01	ND
				0.179	70	60	A	<0.01	ND	<0.01	ND
							B	<0.01	ND	<0.01	ND
				0.178	70	91	A	<0.01	ND	<0.01	ND
							B	<0.01	ND	<0.01	ND
				0.179	70	120	A	<0.01	ND	ND	ND
							B	<0.01	ND	<0.01	ND
Fresno, CA / (R080488) 2008	10	Lettuce	Leaves	0.180	59	29	A	<0.01	<0.01	ND	ND
							B	<0.01	<0.01	ND	ND
				0.179	122	60	A	0.02	<0.01	<0.01	ND
							B	0.02	<0.01	<0.01	ND
				0.178	59	90	A	<0.01* (<0.01, <0.01, <0.01)	<0.01	ND	ND
							B	<0.01* (<0.01, <0.01, <0.01)	<0.01	ND	ND
				0.177	122	121	A	0.02* (0.01, 0.02, 0.02)	<0.01	<0.01	ND
							B	0.02* (0.01, 0.02, 0.02)	<0.01	<0.01	ND
Fresno, CA / (R080488) 2008	10	Radish	Tops	0.180	57	29	A	<0.01	ND	0.01	<0.01
							B	<0.01	<0.01	0.01	<0.01
				0.179	92	60	A	<0.01	ND	0.02	<0.01
							B	<0.01	ND	0.02	<0.01
				0.178	57	90	A	<0.01	ND	0.02	0.01* (0.01, 0.02, 0.01)
							B	<0.01	<0.01	0.02	0.01* (0.01, <0.01, 0.01)
				0.177	92	121	A	<0.01	<0.01	0.02	<0.01
							B	<0.01	ND	0.02	<0.01
Fresno, CA / (R080488) 2008	10	Radish	Root	0.180	57	29	A	0.01	ND	<0.01	ND
							B	<0.01	ND	<0.01	ND
				0.179	92	60	A	0.01	ND	<0.01	ND
							B	0.01	ND	<0.01	ND
				0.178	57	90	A	0.01	ND	<0.01	ND
							B	0.01	ND	<0.01	ND
				0.177	92	121	A	<0.01* (<0.01, <0.01, <0.01)	ND	<0.01	ND
							B	0.01* (0.01, 0.01, 0.01)	ND	<0.01	ND

¹ DAP = Days After Planting² PBI = Plant Back Interval (in days)³ All analytes are reported in terms of themselves. The LOQ is 0.01 ppm each for BAS 700 F and the metabolites M700F008, M700F002 and M700F048 in/on rotational crop samples. The method LOD is set at 20% of the LOQ, or 0.002 ppm each for BAS 700 F and the metabolites M700F008, M700F002 and M700F048.

Commodity	Total Appl. Rate lb a.i./A (kg a.i./ha)	PBI ¹ (days)	Maximum Residues ² (ppm)				
			n	BAS 700 F	M700F002	M700F008	M700F048
Wheat, forage	0.177-0.180 (0.198-0.202)	29-30	4	0.03	<0.01	<0.01	<0.01
		60	4	0.08	<0.01	<0.01	<0.01
		90-91	4	0.03	<0.01	<0.01	<0.01
		120-121	4	0.05	<0.01	<0.01	<0.01
Wheat, hay	0.177-0.180 (0.198-0.202)	29-30	4	0.11	<0.01	<0.01	<0.01
		60	4	0.18	<0.01	<0.01	<0.01
		90-91	4	0.09	<0.01	<0.01	<0.01
		120-121	4	0.14	<0.01	<0.01	0.01
Wheat, grain	0.177-0.180 (0.198-0.202)	29-30	4	<0.01	<0.01	<0.01	<0.01
		60	4	<0.01	<0.01	<0.01	<0.01
		90-91	4	<0.01	<0.01	<0.01	<0.01
		120-121	4	<0.01	<0.01	<0.01	<0.01
Wheat, straw	0.177-0.180 (0.198-0.202)	29-30	4	0.28	<0.01	0.02	<0.01
		60	4	0.54	<0.01	0.03	<0.01
		90-91	4	0.16	<0.01	0.01	<0.01
		120-121	4	0.31	<0.01	0.02	<0.01
Radish, tops	0.177-0.180 (0.198-0.202)	29-30	4	<0.01	<0.01	0.01	<0.01
		60	4	<0.01	<0.01	0.02	<0.01
		90-91	4	<0.01	<0.01	0.02	0.01
		120-121	4	<0.01	<0.01	0.02	<0.01
Radish, root	0.177-0.180 (0.198-0.202)	29-30	4	0.02	<0.01	<0.01	<0.01
		60	4	0.01	<0.01	<0.01	<0.01
		90-91	4	0.01	<0.01	<0.01	<0.01
		120-121	4	0.01	<0.01	<0.01	<0.01
Lettuce, leaves	0.177-0.180 (0.198-0.202)	29-30	4	<0.01	<0.01	<0.01	<0.01
		60	4	0.02	<0.01	<0.01	<0.01
		90-91	4	<0.01	<0.01	<0.01	<0.01
		120-121	4	0.02	<0.01	<0.01	<0.01

¹ Plant Back Interval

² All analytes are reported in terms of themselves. The LOQ is 0.01 ppm each for BAS 700 F and the metabolites M700F008, M700F002 and M700F048 in/on rotational crop samples.

³ The combined residues will be calculated when the RD is determined.

Conclusions. Finite residues of fluxapyroxad are found at all plantback intervals tested (30, 60, 90, and 120 days). Non-quantifiable residues were found in the radish roots and tops, and spinach at the 365 day PBI in the Confined Rotational Crop study. Finite residues were reported in the wheat commodities at the 365 day PBI, but cereal grains are a primary crop. The field rotational crop studies are adequate, provided that a 365 day plant back interval appears on the label.

860.1550 Proposed Tolerances

This petition proposes the first tolerances for the residues of fluxapyroxad. Tolerances are proposed under 40CFR§180.xxx for the combined residues of fluxapyroxad and its metabolites, calculated as fluxapyroxad on the commodities in the table below. The proposed tolerances range from 0.01 ppm on several livestock commodities to 18 ppm on foliage of legume vegetables.

No Codex, Canadian, or Mexican maximum residue limits (MRLs) have been established for residues of fluxapyroxad. However, MRLs are co-pending in Canada, Australia, and New Zealand for some or all of the same commodities, and MRLs have recently been established in the European Union (EU).

Although no CODEX maximum residue levels have been established for residues of fluxapyroxad in root and tuber vegetables (subgroups 1A, 1C, D) legume vegetables including soybean (group 06), foliage of legume vegetables (group 07), fruiting vegetables (group 8), pome fruits (group 11), stone fruits (group 12), cereal grains (group 15), forage, fodder and straw of cereal grains (group 16), canola, sunflower (group 20), peanut, cotton, and livestock commodities, BASF has nominated these crops for inclusion on the 2012 tentative CODEX evaluation schedule.

The tolerance expression for fluxapyroxad should read:

Tolerances are established for residues of the fungicide fluxapyroxad [3-(difluoromethyl)-1-methyl-*N*-(3',4',5'-trifluoro[1,1'-biphenyl]-2-yl)-1*H*-pyrazole-4-carboxamide], including its metabolites and degradates, in or on the commodities in the table below. Compliance with the tolerance levels specified below is to be determined by measuring only fluxapyroxad in or on the commodity.

Table 49. Recommended Tolerances for Fluxapyroxad

Crop Group or Commodity	Proposed Tolerance (ppm)	Recommended Tolerance (ppm)	Comments; <i>Correct Commodity Definition</i>
Apple, wet pomace	3.5	2.0	
Barley, bran	6	--	Calculated tolerance level (3.0 ppm) is the same as the Grain, Cereal, Group 15 tolerance, so it is not needed.
Beet, sugar	-	0.1	A tolerance cannot be set on vegetable, root and tuber, subgroup 1A at this time, so a separate tolerance on beet, sugar will be set.
Beet, sugar, dried pulp	0.16	0.1	
Beet, sugar, tops	4	7.0	
Cattle, fat	0.1	0.05	Rounded to 0.05 ppm.
Cattle, kidney	0.01	--	Covered by tolerance in/on meat byproducts
Cattle, liver	0.1	--	Covered by tolerance in/on meat byproducts
Cattle, meat	0.01	0.01	
Cattle, meat byproducts	0.1	0.03	
Corn, field, grain	0.1	0.01	
Corn, oil, refined	0.05	0.03	<i>Corn, oil</i>
Corn, pop. grain	--	0.01	Separate tolerance is needed because there is more than a 10x difference between the needed tolerance and the crop group tolerance.
Corn, sweet, kernels plus cobs with husks removed	--	0.15	Separate tolerance is needed because there is more than a 10x difference between the needed tolerance and the crop group tolerance.
Cotton, undelinted seed	0.01	0.01	

Crop Group or Commodity	Proposed Tolerance (ppm)	Recommended Tolerance (ppm)	Comments; <i>Correct Commodity Definition</i>
Cotton, gin byproducts	0.01	0.01	
Egg	0.01	0.002	
Fruit, pome, group 11	0.7	0.8	
Fruit, stone, group 12	1.4	2.0	
Goat, fat	0.1	0.05	
Goat, kidney	0.01	--	Covered by tolerance in/on meat byproducts
Goat, liver	0.1	--	Covered by tolerance in/on meat byproducts
Goat, meat	0.01	0.01	
Goat, meat byproducts	0.1	0.03	
Grain, aspirated fractions	16.0	20.0	
Grain, cereal, group 15, except field corn grain	2.5	3.0	<i>Grain, cereal, group 15 (except corn, field, grain; except corn, pop, grain; except corn, kernels plus cobs with husks removed; except wheat)</i> More than 10x difference: wheat 0.3 ppm, sorghum 0.7 ppm, barley 2 ppm, rice 3 ppm, sweet corn 0.15 ppm; wheat will be excluded from crop group as well.
Grain, cereal, forage, fodder and straw, group 16	25	20	More than 10x difference – corn forage 2 ppm, corn stover 5 ppm, wheat forage 10 ppm, wheat hay 15 ppm, wheat straw, 15 ppm, sorghum forage 4 ppm, stover 2 ppm, barley hay 15 ppm, barley straw 20 ppm, rice straw 2 ppm. However, crop group tolerance will be set as is.
Hog, fat	0.01	--	<i>Swine, fat</i> – not needed – Category 3
Hog, liver	0.01	--	<i>Swine, liver</i> – not needed – Category 3
Hog, meat	0.01	--	<i>Swine, meat</i> – not needed – Category 3
Hog, meat byproducts	0.01	--	<i>Swine, meat byproducts</i> – not needed – Category 3
Horse, fat	0.1	0.05	
Horse, kidney	0.01	--	Covered by tolerance in/on meat byproducts
Horse, liver	0.1	--	Covered by tolerance in/on meat byproducts
Horse, meat	0.01	0.01	
Horse, meat byproducts	0.1	0.03	
Milk	0.02	0.002	
Oilseeds, group 20	0.6	0.9	Highest residue in canola was 0.84 ppm, rounded to 0.9 ppm
Peanut	0.02	0.01	
Peanut, refined oil	0.06	0.02	
Peanut, meal	0.03	--	Not needed, only 1.5x concentration
Plum, prune	4	3.0	
Potato, wet peel	0.2	0.1	
Poultry, byproducts	0.01	--	Not needed – estimated residues more than 10x lower than LOQ (Category 3)
Poultry, fat	0.01	--	Not needed – estimated residues more than 10x lower than LOQ (Category 3)
Poultry, liver	0.01	--	Not needed – estimated residues more than 10x lower than LOQ (Category 3)

Crop Group or Commodity	Proposed Tolerance (ppm)	Recommended Tolerance (ppm)	Comments; <i>Correct Commodity Definition</i>
Poultry, meat	0.01	--	Not needed – estimated residues more than 10x lower than LOQ (Category 3)
Poultry, skin	0.01	--	Not needed – estimated residues more than 10x lower than LOQ (Category 3)
Rapeseed, (cultivars/varieties and/or hybrids including canola and crambe)	0.60	--	not needed, included in oilseeds, group 20
Rice, bran	4.5	4.5	
Rice hulls	10	8.0	<i>Rice, hulls</i>
Sheep, fat	0.1	0.05	
Sheep, kidney	0.01	0.01	Covered by tolerance in/on meat byproducts
Sheep, liver	0.1	0.02	Covered by tolerance in/on meat byproducts
Sheep, meat	0.01	0.01	
Sheep, meat byproducts	0.1	0.03	
Soybean, hulls	6.5	0.3	
Soybean, seed	0.2	0.15	
Sunflower, seed	0.60	--	Not needed, included in oilseed, group 20
Vegetable, Foliage of legume, group 7	18	30	
Vegetables, Fruiting, group 8	0.6	0.7	
Vegetable, legume, dried shelled (except soybean) subgroup 6C	0.35	0.4	<i>Pea and bean, dried shelled, except soybean, subgroup 6C</i>
Vegetable, legume, edible podded, subgroup 6A	1.4	2.0	
Vegetable, legume, succulent shelled, subgroup 6B	0.45	0.5	<i>Pea and bean, succulent shelled, subgroup 6B</i>
Vegetable, root, subgroup 1A	0.1	0.1	<i>Beet, sugar.</i> No data were submitted for the other two representative commodities of the crop subgroup (carrot and radish). A crop subgroup tolerance is not possible.
Vegetable, tuberous and corm, subgroup 1C	0.04	0.02	
Vegetable, tuberous and corm, except potato, subgroup 1D	0.04	--	Tolerance on this subgroup is not needed since all commodities are included in subgroup 1C
Wheat, bran	6	0.6	
Wheat, germ	3	--	Not needed, concentration is only 1.5x
Wheat, grain	--	0.3	Tolerance is set separately from crop group tolerance because residues in wheat grain are more than 5x lower than the highest residue.

References

DP#: D390225
Subject: Fluxapyroxad (BAS 700F), Issues for Consideration by Residues of Concern Knowledge-Base Subcommittee. PP# 0F7709
From: S. Hummel
To: ROCKS Chairperson
Date: June 9, 2011
MRID#s:

DP#: D390225
Subject: **Fluxapyroxad (BAS 700F)**. Report of the Residues of Concern Knowledgebase Subcommittee (ROCKS).
From: I. Negrón-Encarnación
To: Fluxapyroxad Risk Assessment Team
Date: June 21, 2011
MRID#s: None.

Attachments:

International Residue Limit Status Sheet
Appendix I: Proposed Metabolic Pathway
Appendix II: Structure of Fluxapyroxad Metabolites
Appendix III: OECD MRL Calculator Spreadsheets

International Residue Limits

Fluxapyroxad (PC Code 138009)

Summary of US and International Tolerances and Maximum Residue Limits				
<i>Residue Definition:</i>				
US	Canada	Mexico ²	Codex	
40 CFR 180.xxx: Plant: Fluxapyroxad Livestock: Fluxapyroxad	Fluxapyroxad		No proposals yet for any commodity.	
<i>Commodity</i> ¹	<i>Tolerance (ppm) /Maximum Residue Limit (mg/kg)</i>			
	US	Canada	Mexico ²	Codex
Apple, wet pomace	2	--		
Barley, bran	--	--		
Beet, sugar	0.1	0.1		
Beet, sugar, dried pulp	0.1	--		
Beet, sugar, tops	7	--		
Cattle, fat	0.05	0.05		
Cattle, kidney	--	0.01		
Cattle, liver	--	0.02		
Cattle, meat	0.01	0.01		
Cattle, meat byproducts	0.03	0.02		
Corn, field, grain	0.01	0.01		
Corn, oil, refined	0.03	0.03		
Corn, pop, grain	0.01	0.01		
Corn, sweet, kernels plus cobs with husks removed	0.15	0.15		
Cotton, undelinted seed	0.01	0.01		
Cotton, gin byproducts	0.01	--		
Egg	0.002	0.002		
Fruit, pome, group 11	0.8	0.8		
Fruit, stone, group 12	2	2		
Goat, fat	0.05	0.05		
Goat, kidney	0.01	0.01		
Goat, liver	0.02	0.02		
Goat, meat	0.01	0.01		
Goat, meat byproducts	0.03	0.03		
Grain, aspirated fractions	6	--		
Grain, cereal, group 15 (except corn, field, grain; except corn, pop, grain; except corn, kernels plus cobs with husks removed; except wheat)	3	3		
Grain, cereal, forage, fodder and straw, group 16	20	--		
Hog, fat	--	--		
Hog, liver	--	--		

Summary of US and International Tolerances and Maximum Residue Limits				
<i>Residue Definition:</i>				
US	Canada	Mexico ²	Codex	
40 CFR 180.xxx: Plant: Fluxapyroxad Livestock: Fluxpyroxad	Fluxapyroxad		No proposals yet for any commodity.	
<i>Commodity</i> ¹	<i>Tolerance (ppm) /Maximum Residue Limit (mg/kg)</i>			
	US	Canada	Mexico ²	Codex
Hog, meat	--	--		
Hog, meat byproducts	--	--		
Horse, fat	0.05	0.05		
Horse, kidney	0.01	0.01		
Horse, liver	0.02	0.02		
Horse, meat	0.01	0.01		
Horse, meat byproducts	0.03	0.03		
Milk	0.005	0.005		
Oilseed, group 20	0.9	0.9		
Peanut	0.02	0.02		
Peanut, refined oil	0.02	0.02		
Peanut, meal	--	--		
Plum, prune	3	3		
Potato, wet peel	0.1	--		
Poultry, byproducts	--	--		
Poultry, fat	--	--		
Poultry, liver	--	--		
Poultry, meat	--	--		
Poultry, skin	--	--		
Rapeseed, (cultivars/varieties and/or hybrids including canola and crambe)	--	--		
Rice, bran	4.5	4.5		
Rice, hulls	8	8		
Sheep, fat	0.05	0.05		
Sheep, kidney	0.01	0.01		
Sheep, liver	0.02	0.02		
Sheep, meat	0.01	0.01		
Sheep, meat byproducts	0.03	0.03		
Soybean, hulls	0.3	--		
Soybean, seed	0.15	0.15		
Sunflower, seed	--	--		
Vegetable, Foliage of legume, group 7	30	--		
Vegetables, Fruiting, group 8	0.7	0.7		
Vegetable, legume, dried shelled (except soybean) subgroup 6C	0.4	0.4		
Vegetable, legume, edible podded, subgroup 6A	2	2		

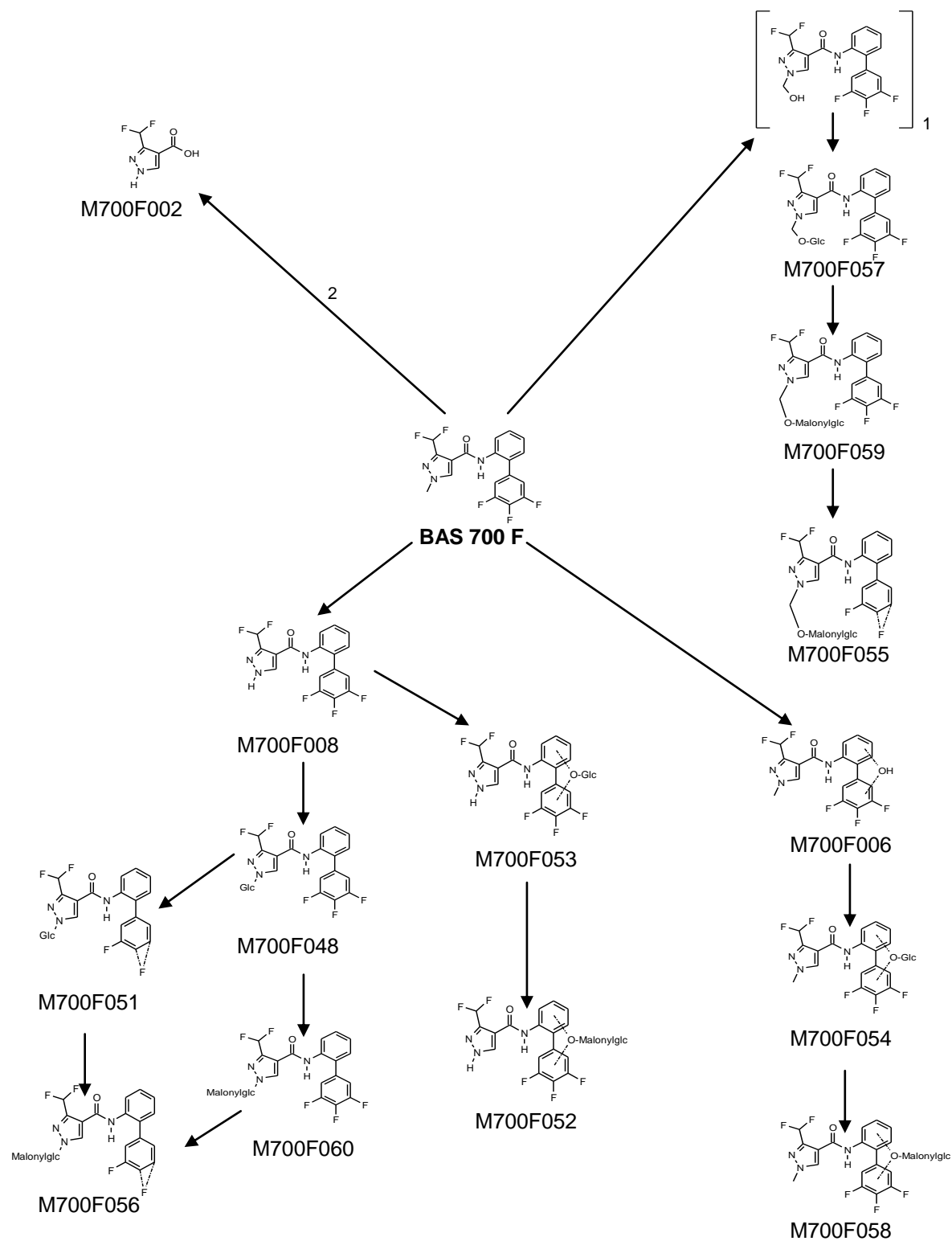
Summary of US and International Tolerances and Maximum Residue Limits				
<i>Residue Definition:</i>				
US	Canada	Mexico ²	Codex	
40 CFR 180.xxx: Plant: Fluxapyroxad Livestock: Fluxpyroxad	Fluxapyroxad		No proposals yet for any commodity.	
<i>Commodity</i> ¹	<i>Tolerance (ppm) /Maximum Residue Limit (mg/kg)</i>			
	US	Canada	Mexico ²	Codex
Vegetable, legume, succulent shelled, subgroup 6B	0.5	0.5		
Vegetable, tuberous and corm, subgroup 1C	0.02	0.02		
Vegetable, tuberous and corm, except potato, subgroup 1D	--	--		
Wheat, bran	0.6	0.6		
Wheat, germ	--	--		
Wheat, grain	0.3	0.3		
Peanut, hay	15	--		
Completed: 11/30/2011				

¹ Includes only commodities of interest for this action. Tolerances should be the HED recommendations and not those proposed by the applicant.

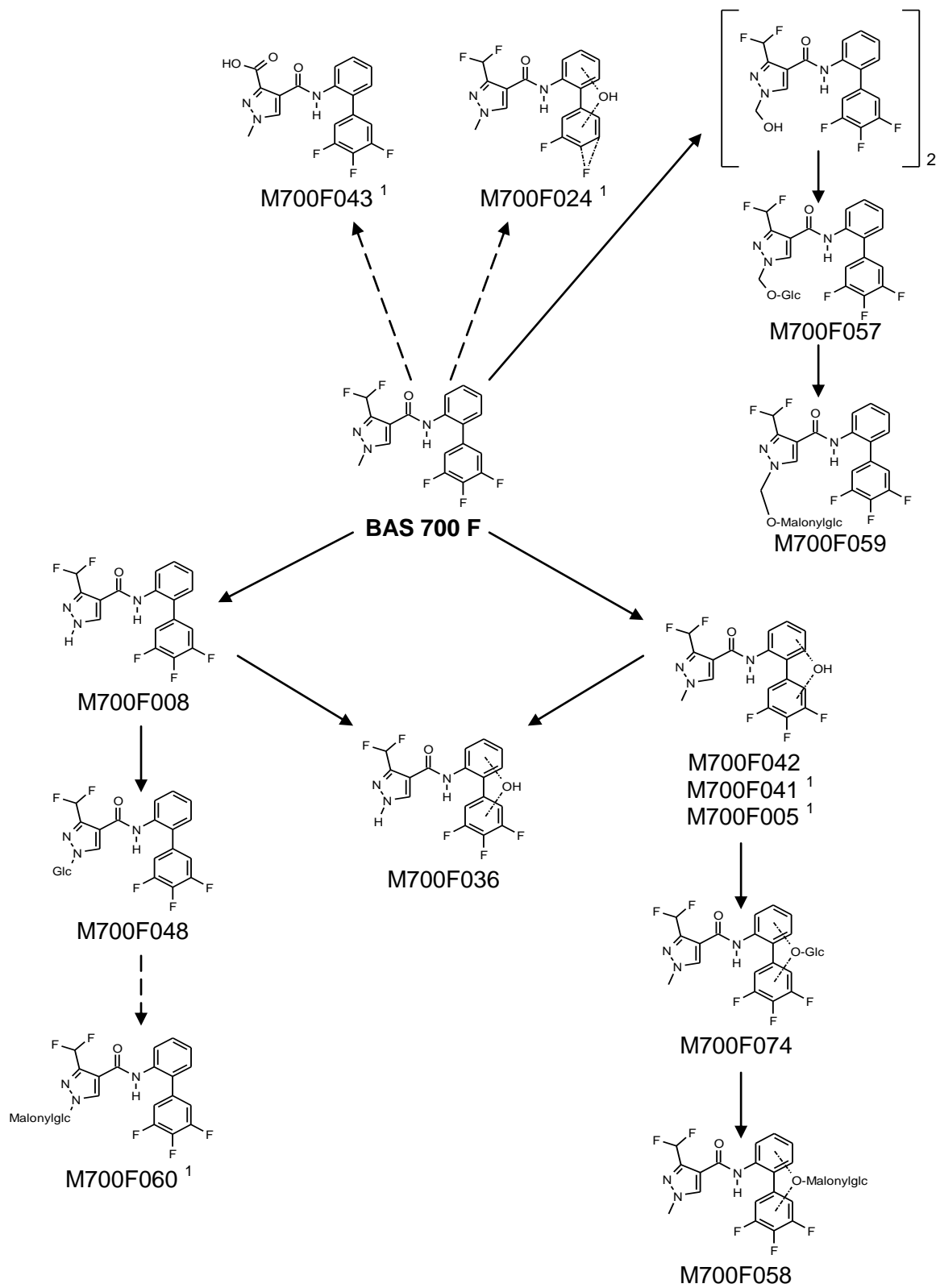
² Mexico adopts US tolerances and/or Codex MRLs for its export purposes.

³ * = absent at the limit of quantitation; Po = postharvest treatment, such as treatment of stored grains. PoP = processed postharvest treated commodity, such as processing of treated stored wheat. (fat) = to be measured on the fat portion of the sample. MRLs indicated as proposed have not been finalized by the CCPR and the CAC.

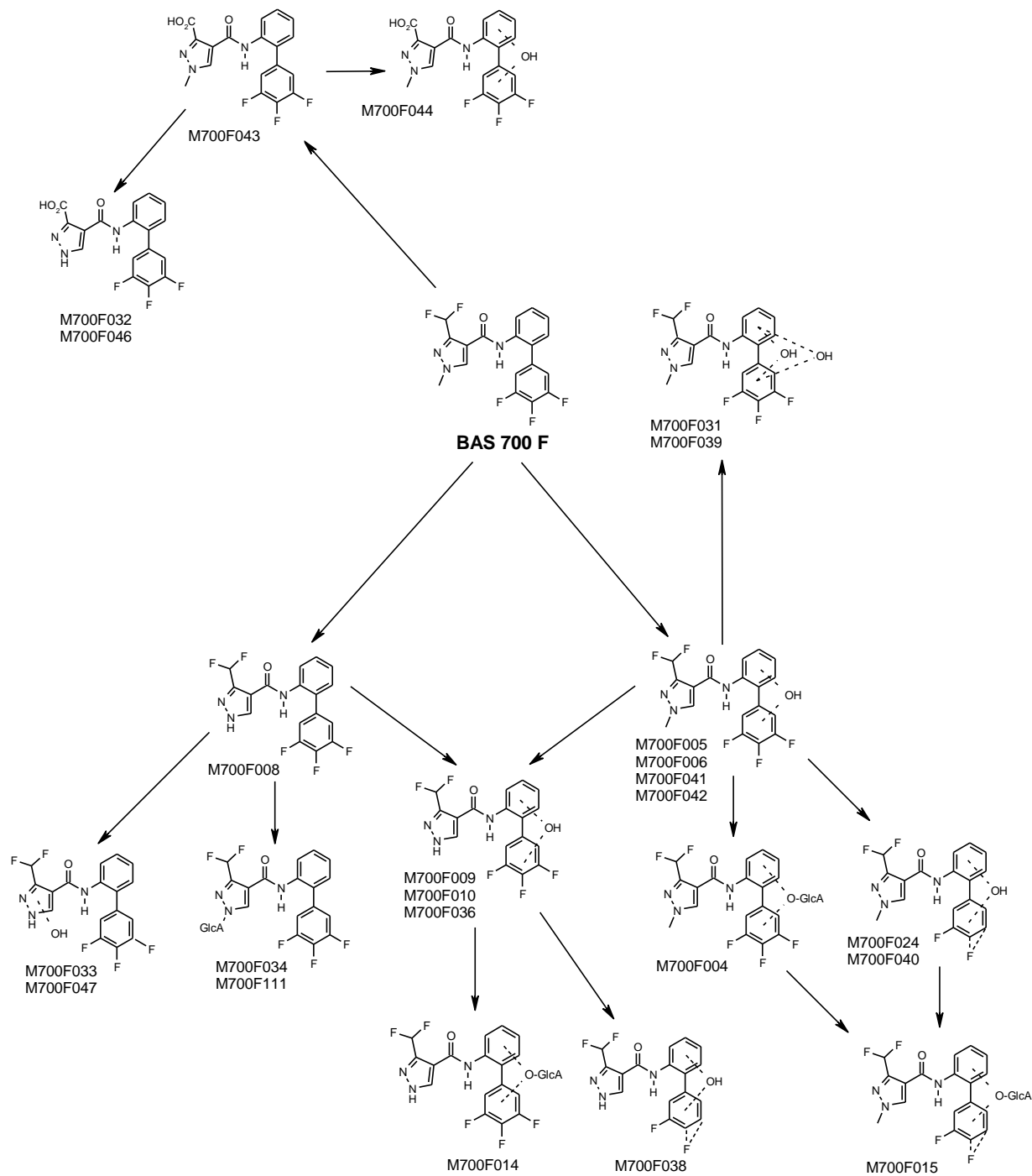
Appendix I. Figure I-1. Proposed metabolic pathways of BAS 700 F (fluxapyroxad) in plants.



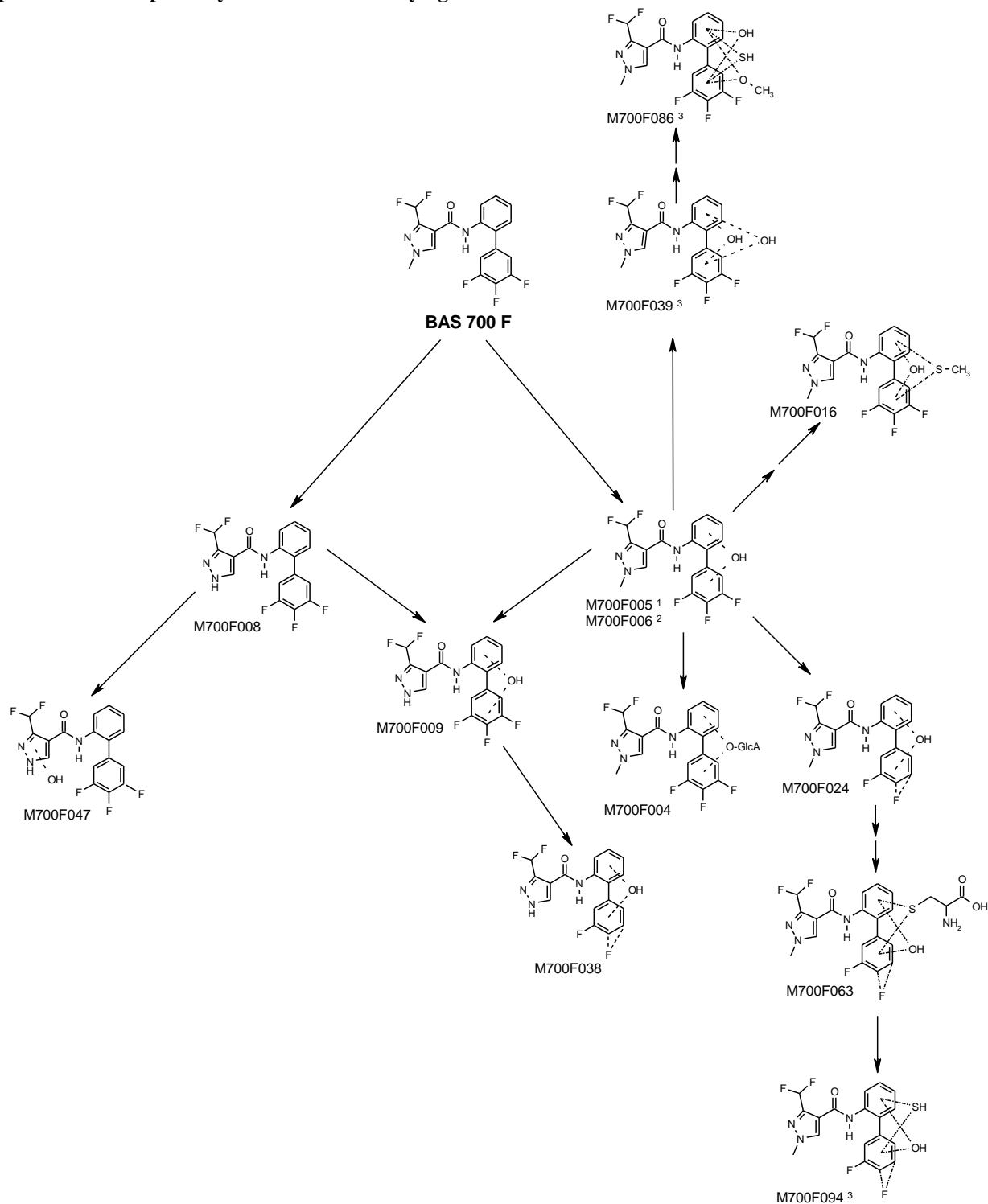
Proposed metabolic pathways of BAS 700 F (fluxapyroxad) in rotational crops (aniline label).



Proposed metabolic pathways for BAS 700 in lactating goats.



Proposed metabolic pathways of BAS 700 F in laying hens.

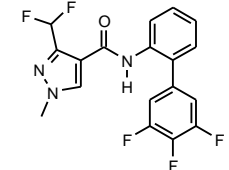
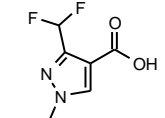
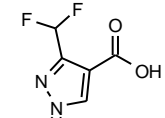
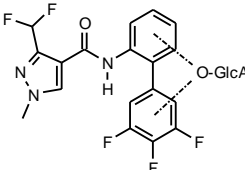
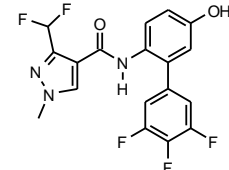
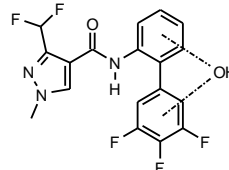
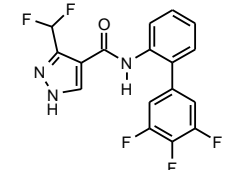
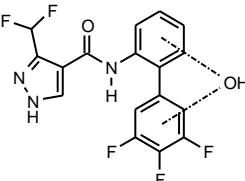


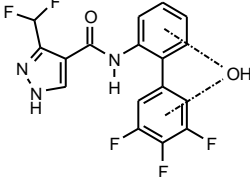
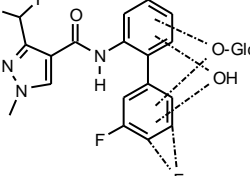
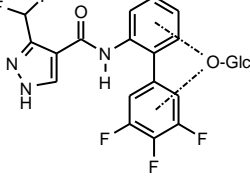
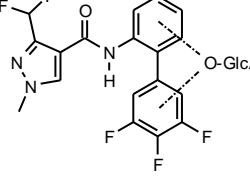
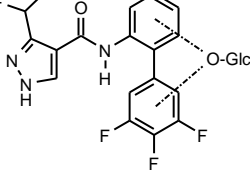
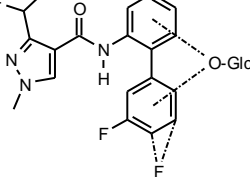
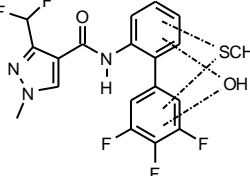
¹ M700F005 is hydroxylated in para-position to the amide group, established by ¹H NMR spectroscopy

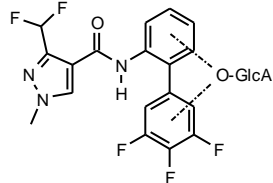
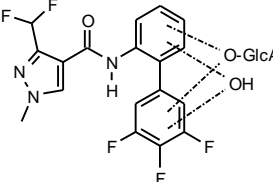
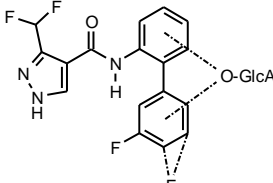
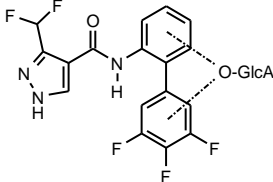
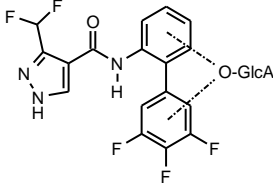
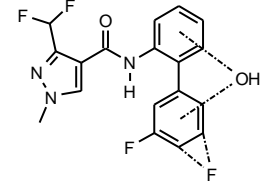
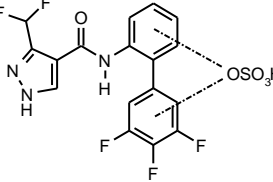
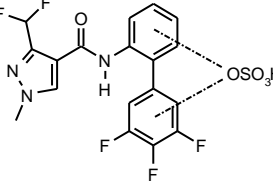
² Proposed intermediate, not identified in the current study

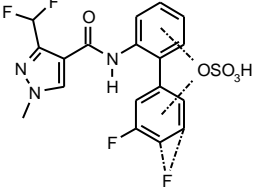
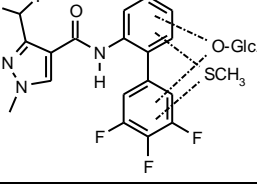
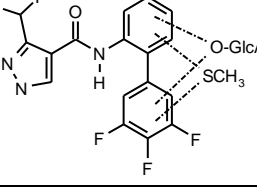
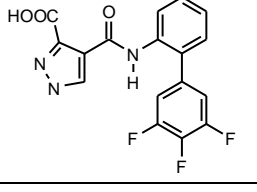
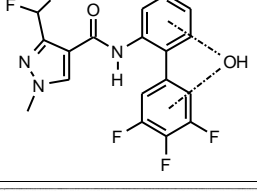
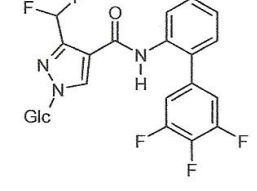
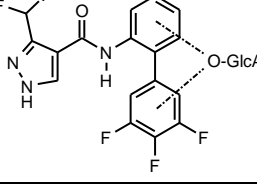
³ These metabolites were identified by LC-MS/MS, but they could not unambiguously be assigned to a distinct HPLC peak. They occurred at minor quantities, but they were not listed in metabolite quantification tables, because the correlation to a distinct HPLC peak was not given.

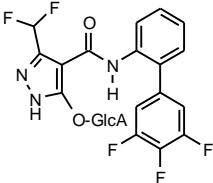
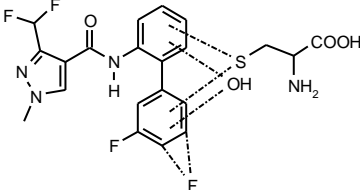
Appendix II. Fluxapyroxad and Metabolite Structures

Metabolite Designation (Code) Chemical Name	Molecular Mass	Structure
BAS 700 F =M700F000 3-(difluoromethyl)-1-methyl-N-(3',4',5'-trifluoro[1,1'-biphenyl]-2-yl)-1Hpyrazole-4-carboxamide	M = 381	
M700F001 3-(difluoromethyl)-1-methyl-1H-pyrazole-4-carboxylic acid	M = 176	
M700F002 3-(difluoromethyl)-1H-pyrazole-4-carboxylic acid	M = 162	
M700F004 3-(difluoromethyl)-1-methyl-N-((1-glucuronyl)oxy-3',4',5'-trifluoro-[1,1'-biphenyl]-2-yl)-1H-pyrazole-4-carboxamide	M = 573	
M700F005 3-(difluoromethyl)-1-methyl-N-(4-hydroxy-3',4',5'-trifluoro[1,1'-biphenyl]-2-yl)-1H-pyrazole-4-carboxamide	M = 397	
M700F006 3-(difluoromethyl)-1-methyl-N-(hydroxy-3',4',5'-trifluoro[1,1'-biphenyl]-2-yl)-1H-pyrazole-4-carboxamide	M = 397	
M700F008 3-(difluoromethyl)-N-(3',4',5'-trifluoro[1,1'-biphenyl]-2-yl)-1H-pyrazole-4-carboxamide	M = 367	
M700F009 3-(difluoromethyl)-N-(hydroxy-3',4',5'-trifluoro[1,1'-biphenyl]-2-yl)-1Hpyrazole-4-carboxamide	M = 383	

Metabolite Designation (Code) Chemical Name	Molecular Mass	Structure
<p>M700F010 3-(difluoromethyl)-N-(hydroxy-3',4',5'-trifluoro[1,1'-biphenyl]-2-yl)-1Hpyrazole-4-carboxamide</p>	M = 383	
<p>M700F011 3-(difluoromethyl)-1-methyl-N-(hydroxy-(1-glucuronyl)oxy-3',[4' or 5']-difluoro-[1,1'-biphenyl]-2-yl)-1H-pyrazole-4-carboxamide</p>	M = 571	
<p>M700F012 3-(difluoromethyl)-N-((1-glucuronyl)oxy-3',4',5'-trifluoro-[1,1'-biphenyl]-2-yl)-1H-pyrazole-4-carboxamide</p>	M = 559	
<p>M700F013 3-(difluoromethyl)-1-methyl-N-((1-glucuronyl)oxy-3',4',5'-trifluoro-[1,1'-biphenyl]-2-yl)-1H-pyrazole-4-carboxamide</p>	M = 573	
<p>M700F014 3-(difluoromethyl)-N-((1-glucuronyl)oxy-3',4',5'-trifluoro-[1,1'-biphenyl]-2-yl)-1H-pyrazole-4-carboxamide</p>	M = 559	
<p>M700F015 3-(difluoromethyl)-1-methyl-N-((1-glucuronyl)oxy-3',[4' or 5']-difluoro-[1,1'-biphenyl]-2-yl)-1H-pyrazole-4-carboxamide</p>	M = 555	
<p>M700F016 3-(difluoromethyl)-1-methyl-N-(methylthio-hydroxy-3',4',5'-trifluoro-[1,1'-biphenyl]-2-yl)-1H-pyrazole-4-carboxamide</p>	M = 443	

Metabolite Designation (Code) Chemical Name	Molecular Mass	Structure
<p>M700F019</p> <p>3-(difluoromethyl)-1-methyl-N-((1-glucuronyl)oxy-3',4',5'-trifluoro-[1,1'-biphenyl]-2-yl)-1H-pyrazole-4-carboxamide</p>	M = 573	
<p>M700F020</p> <p>3-(difluoromethyl)-1-methyl-N-(hydroxy-(1-glucuronyl)oxy-3',4',5'-trifluoro-[1,1'-biphenyl]-2-yl)-1H-pyrazole-4-carboxamide</p>	M = 589	
<p>M700F021</p> <p>3-(difluoromethyl)-N-((1-glucuronyl)oxy-3',[4' or 5']-difluoro-[1,1'-biphenyl]-2-yl)-1H-pyrazole-4-carboxamide</p>	M = 541	
<p>M700F022</p> <p>3-(difluoromethyl)-N-((1-glucuronyl)oxy-3',4',5'-trifluoro-[1,1'-biphenyl]-2-yl)-1H-pyrazole-4-carboxamide</p>	M = 559	
<p>M700F023</p> <p>3-(difluoromethyl)-N-((1-glucuronyl)oxy-3',4',5'-trifluoro[1,1'-biphenyl]-2-yl)-1H-pyrazole-4-carboxamide</p>	M = 559	
<p>M700F024</p> <p>3-(difluoromethyl)-1-methyl-N-(hydroxy-3',[4' or 5']-difluoro[1,1'-biphenyl]-2-yl)-1H-pyrazole-4-carboxamide</p>	M = 379	
<p>M700F025</p> <p>3-(difluoromethyl)-N-((hydroxysulfonyl)oxy-3',4',5'-trifluoro[1,1'-biphenyl]-2-yl)-1H-pyrazole-4-carboxamide</p>	M = 463	
<p>M700F026</p> <p>3-(difluoromethyl)-1-methyl-N-((hydroxysulfonyl)oxy-3',4',5'-trifluoro[1,1'-biphenyl]-2-yl)-1H-pyrazole-4-carboxamide</p>	M = 477	

Metabolite Designation (Code) Chemical Name	Molecular Mass	Structure
<p>M700F027</p> <p>3-(difluoromethyl)-1-methyl-N-((hydroxysulfonyl)oxy-3',[4' or 5']-difluoro[1,1'-biphenyl]-2-yl)-1H-pyrazole-4-carboxamide</p>	M = 459	
<p>M700F028</p> <p>3-(difluoromethyl)-1-methyl-N-(methylthio-(1-glucuronyloxy)-3',4',5'-trifluoro-[1,1'-biphenyl]-2-yl)-1H-pyrazole-4-carboxamide</p>	M = 619	
<p>M700F029</p> <p>3-(difluoromethyl)-N-(methylthio-(1-glucuronyl)oxy-3',4',5'-trifluoro-[1,1'-biphenyl]-2-yl)-1H-pyrazole-4-carboxamide</p>	M = 605	
<p>M700F032</p> <p>3-(hydroxycarbonyl)-N-(hydroxy-3',4',5'-trifluoro[1,1'-biphenyl]-2-yl)-1H-pyrazole-4-carboxamide or tautomer</p>	M = 361	
<p>M700F042</p> <p>3-(difluoromethyl)-1-methyl-N-(hydroxy-3',4',5'-trifluoro[1,1'-biphenyl]-2-yl)-1H-pyrazole-4-carboxamide</p>	M = 397	
<p>M700F048</p> <p>3-(difluoromethyl)-1-(-D-glucopyranosyl)-N-(3',4',5'-trifluoro[1,1'-biphenyl]-2-yl)-1H-pyrazole-4-carboxamide</p>		
<p>M700F050</p> <p>3-(difluoromethyl)-N-((1-glucuronyl)oxy-3',4',5'-trifluoro[1,1'-biphenyl]-2-yl)-1H-pyrazole-4-carboxamide</p>	M = 559	

Metabolite Designation (Code) Chemical Name	Molecular Mass	Structure
M700F061 3-(difluoromethyl)-5-(1-glucuronyl)oxy-N-(3',4',5'-trifluoro[1,1'-biphenyl]-2-yl)-1H-pyrazole-4-carboxamide	M = 559	
M700F063 3-(difluoromethyl)-1-methyl-N-((S-cysteiny)-hydroxy-3',[4' or 5']-difluoro-[1,1'-biphenyl]-2-yl)-1H-pyrazole-4-carboxamide	M = 498	

Appendix III. OECD MRL Calculator

This appendix includes the OECD MRL calculator spreadsheets that show how the tolerances in the US and MRLs in Canada were determined. Except for non-bell peppers, the spreadsheet includes one residue input from each field trial. This residue is the average field trial residue for each trial. For non-bell peppers, since there were only two field trials, all four residues reported in those two trials were input into the calculator. For tree crops which had field trials for dilute and concentrate sprays, the dilute and concentrate spray results were entered separately, and the higher tolerance/MRL chosen.

Compound	Fluxapyroxad	Fluxapyroxad	Fluxapyroxad
Crop	Non-bell Pepper	Bell Pepper	Tomato
Region / Country	US/Canada	US/Canada	US/Canada
GAP	0.2-0.3 kg ai/ha 7d PHI	0.3 kg ai/ha 7d PHI	0.3 kg ai/ha 7d PHI
Total number of data (n)	4	8	20
Percentage of censored data	0%	25%	10%
Number of non-censored data	4	6	18
Lowest residue	0.010	0.010	0.010
Highest residue	0.300	0.240	0.440
Median residue	0.105	0.025	0.060
Mean	0.130	0.063	0.085
Standard deviation (SD)	0.140	0.079	0.098
Correction factor for censoring (CF)	1.000	0.833	0.933
- Mean + 4 SD	0.691	0.380	0.475
- CF x 3 Mean	0.390	0.156	0.237
Unrounded MRL	<u>0.691</u>	<u>0.380</u>	<u>0.475</u>
Rounded MRL	<u>0.7</u>	<u>0.4</u>	<u>0.5</u>
	High uncertainty of MRL estimate due to small dataset.		
	Residues (mg/kg)	Residues (mg/kg)	Residues (mg/kg)
	0.010	0.010	0.05
	0.190	0.090	0.01 *
	0.020	0.020	0.01 *
	0.300	0.030	0.05
		0.010 *	0.06
		0.010 *	0.04
		0.090	0.08
		0.240	0.07
			0.07
			0.02
			0.04
			0.05
			0.06
			0.03
			0.07
			0.44
			0.10
			0.13
			0.24
			0.07

Compound	Fluxapyroxad	Fluxapyroxad	Fluxapyroxad	Fluxapyroxad
Crop	Apple (dilute spray)	Apple (conc spray)	Pear (dilute spray)	Pear (conc spray)
Region / Country	US/Canada	US/Canada	US/Canada	US/Canada
GAP	0.3 kg ai/ha 0d PHI	0.3 kg ai/ha 0d PHI	0.3 kg ai/ha 0d PHI	0.3 kg ai/ha 0d PHI
Total number of data (n)	14	14	10	10
Percentage of censored data	0%	0%	0%	0%
Number of non-censored data	14	14	10	10
Lowest residue	0.080	0.080	0.170	0.100
Highest residue	0.270	0.370	0.450	0.470
Median residue	0.185	0.200	0.225	0.215
Mean	0.176	0.223	0.269	0.230
Standard deviation (SD)	0.059	0.086	0.097	0.117
Correction factor for censoring (CF)	1.000	1.000	1.000	1.000
- Mean + 4 SD	0.413	0.565	0.658	0.698
- CF x 3 Mean	0.527	0.669	0.807	0.690
Unrounded MRL	<u>0.527</u>	<u>0.669</u>	<u>0.807</u>	<u>0.698</u>
Rounded MRL	<u>0.6</u>	<u>0.7</u>	<u>0.8</u>	<u>0.7</u>
	Residues (mg/kg)	Residues (mg/kg)	Residues (mg/kg)	Residues (mg/kg)
	0.15	0.16	0.18	0.21
	0.18	0.28	0.34	0.26
	0.08	0.08	0.21	0.18
	0.15	0.18	0.17	0.13
	0.19	0.21	0.29	0.38
	0.08	0.15	0.22	0.23
	0.14	0.12	0.4	0.47
	0.21	0.27	0.23	0.22
	0.22	0.31	0.45	0.1
	0.24	0.19	0.2	0.12
	0.23	0.3		
	0.21	0.32		
	0.27	0.37		
	0.11	0.18		

Compound	Fluxapyroxad		Fluxapyroxad		Fluxapyroxad	
Crop	Cherry (dilute spray)		Cherry (conc spray)		Peach (dilute spray)	
Region / Country	US/Canada		US/Canada		US/Canada	
GAP	0.3 kg ai/ha 0d PHI		0.3 kg ai/ha 0d PHI		0.3 kg ai/ha 0d PHI	
Total number of data (n)	6		6		12	
Percentage of censored data	0%		0%		0%	
Number of non-censored data	6		6		12	
Lowest residue	0.050		0.190		0.180	
Highest residue	0.860		1.050		0.630	
Median residue	0.365		0.510		0.335	
Mean	0.418		0.585		0.380	
Standard deviation (SD)	0.272		0.304		0.147	
Correction factor for censoring (CF)	1.000		1.000		1.000	
- Mean + 4 SD	1.506		1.803		0.969	
- CF x 3 Mean	1.255		1.755		1.140	
Unrounded MRL	<u>1.506</u>		<u>1.803</u>		<u>1.140</u>	
Rounded MRL	<u>1.5</u>		<u>2</u>		<u>1.5</u>	
	High uncertainty of MRL estimate due to small dataset.		High uncertainty of MRL estimate due to small dataset.			
	Residues (mg/kg)		Residues (mg/kg)		Residues (mg/kg)	
	0.86		1.05		0.43	
	0.05		0.43		0.42	
	0.34		0.53		0.18	
	0.39		0.82		0.33	
	0.56		0.49		0.26	
	0.31		0.19		0.34	
					0.32	
					0.58	
					0.63	
					0.24	
					0.26	
					0.57	

Compound	Fluxapyroxad		Fluxapyroxad		Fluxapyroxad	
Crop	Peach (conc spray)		Plum (dilute spray)		Plum (conc spray)	
Region / Country	US/Canada		US/Canada		US/Canada	
GAP	0.3 kg ai/ha 0d PHI		0.3 kg ai/ha 0d PHI		0.3 kg ai/ha 0d PHI	
Total number of data (n)	12		10		10	
Percentage of censored data	0%		0%		0%	
Number of non-censored data	12		10		10	
Lowest residue	0.100		0.140		0.200	
Highest residue	0.590		0.790		0.950	
Median residue	0.380		0.315		0.335	
Mean	0.376		0.360		0.417	
Standard deviation (SD)	0.152		0.188		0.235	
Correction factor for censoring (CF)	1.000		1.000		1.000	
- Mean + 4 SD	0.985		1.113		1.358	
- CF x 3 Mean	1.128		1.080		1.251	
Unrounded MRL	<u>1.128</u>		<u>1.113</u>		<u>1.358</u>	
Rounded MRL	<u>1.5</u>		<u>1.5</u>		<u>1.5</u>	
	Residues (mg/kg)		Residues (mg/kg)		Residues (mg/kg)	
	0.37		0.79		0.95	
	0.55		0.42		0.49	
	0.55		0.24		0.2	
	0.39		0.44		0.64	
	0.1		0.32		0.37	
	0.29		0.49		0.48	
	0.17		0.18		0.2	
	0.44		0.14		0.24	
	0.59		0.27		0.3	
	0.3		0.31		0.3	
	0.3					
	0.46					

Compound	Fluxapyroxad		Fluxapyroxad	
Crop	Peanut, nutmeat		Peanut, hay	
Region / Country	US		US	
GAP	3x0.09 lb/A 7d PHI		3x0.09 lb/A 7d PHI	
Total number of data (n)	11		11	
Percentage of censored data	100%		18%	
Number of non-censored data	0		9	
Lowest residue	0.010		0.010	
Highest residue	0.010		8.860	
Median residue	0.010		2.185	
Mean	0.010		3.238	
Standard deviation (SD)	0.000		3.026	
Correction factor for censoring (CF)	0.333		0.879	
- Mean + 4 SD	0.010		15.343	
- CF x 3 Mean	0.010		8.537	
Unrounded MRL	<u>0.010</u>		<u>15.343</u>	
Rounded MRL	<u>0.01</u>		<u>15</u>	
	High uncertainty of MRL estimate due to high level of censoring.			
	Residues (mg/kg)		Residues (mg/kg)	
	0.010	*	6.140	
	0.010	*	1.945	
	0.010	*	0.470	
	0.010	*	5.880	
	0.010	*	2.185	
	0.010	*	4.000	
	0.010	*	5.575	
	0.010	*	8.860	
	0.010	*	0.545	
	0.010	*	0.010	*
	0.010	*	0.010	*

Compound	Fluxapyroxad		Fluxapyroxad	
Crop	Cotton, undelinted seed		Cotton, gin byproducts	
Region / Country	US		US	
GAP	Seed trt 0.01 lb/hwt		Seed trt 0.01 lb/hwt	
Total number of data (n)	12		7	
Percentage of censored data	100%		100%	
Number of non-censored data	0		0	
Lowest residue	0.010		0.010	
Highest residue	0.010		0.010	
Median residue	0.010		0.010	
Mean	0.010		0.010	
Standard deviation (SD)	0.000		0.000	
Correction factor for censoring (CF)	0.333		0.333	
- Mean + 4 SD	0.010		0.010	
- CF x 3 Mean	0.010		0.010	
Unrounded MRL	<u>0.010</u>		<u>0.010</u>	
Rounded MRL	<u>0.01</u>		<u>0.01</u>	
	High uncertainty of MRL estimate due to high level of censoring.		High uncertainty of MRL estimate due to small dataset and high level of censoring.	
	Residues (mg/kg)		Residues (mg/kg)	
	0.010	*	0.010	*
	0.010	*	0.010	*
	0.010	*	0.010	*
	0.010	*	0.010	*
	0.010	*	0.010	*
	0.010	*	0.010	*
	0.010	*	0.010	*
	0.010	*		
	0.010	*		
	0.010	*		
	0.010	*		
	0.010	*		

Compound	Fluxapyroxad		Fluxapyroxad	
Crop	Canola, seed		Sunflower, seed	
Region / Country	US/Canada		US/Canada	
GAP	0.2 kg/ha 18-25d PHI		0.2 kg/ha 18-24d PHI	
Total number of data (n)	16		8	
Percentage of censored data	0%		13%	
Number of non-censored data	16		7	
Lowest residue	0.020		0.010	
Highest residue	0.230		0.130	
Median residue	0.090		0.040	
Mean	0.107		0.056	
Standard deviation (SD)	0.076		0.048	
Correction factor for censoring (CF)	1.000		0.917	
- Mean + 4 SD	0.409		0.250	
- CF x 3 Mean	0.321		0.155	
Unrounded MRL	<u>0.409</u>		<u>0.250</u>	
Rounded MRL	<u>0.4</u>		<u>0.3</u>	
	Residues (mg/kg)		Residues (mg/kg)	
	0.09		0.02	
	0.04		0.01	*
	0.16		0.13	
	0.11		0.09	
	0.19		0.06	
	0.02		0.11	
	0.02		0.01	
	0.02		0.02	
	0.23			
	0.22			
	0.22			
	0.09			
	0.08			
	0.05			
	0.05			
	0.12			

Compound	Fluxapyroxad		Fluxapyroxad	
Crop	Canola, seed		Sunflower, seed	
Region / Country	US/Canada		US/Canada	
GAP	0.2 kg/ha 18-25d PHI		0.2 kg/ha 18-24d PHI	
Total number of data (n)	16		8	
Percentage of censored data	0%		13%	
Number of non-censored data	16		7	
Lowest residue	0.020		0.010	
Highest residue	0.230		0.130	
Median residue	0.090		0.040	
Mean	0.107		0.056	
Standard deviation (SD)	0.076		0.048	
Correction factor for censoring (CF)	1.000		0.917	
- Mean + 4 SD	0.409		0.250	
- CF x 3 Mean	0.321		0.155	
Unrounded MRL	<u>0.409</u>		<u>0.250</u>	
Rounded MRL	<u>0.4</u>		<u>0.3</u>	
	Residues (mg/kg)		Residues (mg/kg)	
	0.09		0.02	
	0.04		0.01	*
	0.16		0.13	
	0.11		0.09	
	0.19		0.06	
	0.02		0.11	
	0.02		0.01	
	0.02		0.02	
	0.23			
	0.22			
	0.22			
	0.09			
	0.08			
	0.05			
	0.05			
	0.12			

Compound	Fluxapyroxad		Fluxapyroxad		Fluxapyroxad	
Crop	Sugar beet, top		Sugar beet, root		Potato, tuber	
Region / Country	US/Canada		US/Canada		US/Canada	
GAP	0.3 kg/ha 7-8d PHI		0.3 kg/ha 7-8d PHI		0.3 kg/ha 7d PHI	
Total number of data (n)	11		12		21	
Percentage of censored data	0%		17%		95%	
Number of non-censored data	11		10		1	
Lowest residue	0.750		0.010		0.010	
Highest residue	3.820		0.060		0.020	
Median residue	2.110		0.025		0.010	
Mean	2.301		0.030		0.010	
Standard deviation (SD)	1.116		0.018		0.002	
Correction factor for censoring (CF)	1.000		0.889		0.365	
- Mean + 4 SD	6.766		0.100		0.019	
- CF x 3 Mean	6.903		0.080		0.011	
Unrounded MRL	<u>6.903</u>		<u>0.100</u>		<u>0.020</u>	
Rounded MRL	<u>7</u>		<u>0.1</u>		<u>0.02</u>	
					High uncertainty of MRL estimate due to high level of censoring.	
	Residues (mg/kg)		Residues (mg/kg)		Residues (mg/kg)	
	3.82		0.06		0.01	*
	1.16		0.03		0.01	*
	3.79		0.04		0.01	*
	2.57		0.01		0.01	*
	0.75		0.02		0.01	*
	2.98		0.01	*	0.02	
	1.81		0.02		0.01	*
	2.11		0.01	*	0.01	*
	2.07		0.04		0.01	*
	0.84		0.05		0.01	*
	3.41		0.02		0.01	*
			0.05		0.01	*
					0.01	*
					0.01	*
					0.01	*
					0.01	*
					0.01	*
					0.01	*
					0.01	*
					0.01	*
					0.01	*
					0.01	*
					0.01	*

Compound	Fluxapyroxad		Fluxapyroxad		Fluxapyroxad	
Crop	Pea, succ seed with pod		Pea, succ seed w/o pod		Pea, vines	
Region / Country	US/Canada		US/Canada		US/Canada	
GAP	0.2 kg/ha 4-7d PHI		0.2 kg/ha 4-7d PHI		0.2 kg/ha 4-7d PHI	
Total number of data (n)	9		9		9	
Percentage of censored data	0%		11%		0%	
Number of non-censored data	9		8		9	
Lowest residue	0.170		0.010		0.620	
Highest residue	0.950		0.050		4.110	
Median residue	0.650		0.030		2.780	
Mean	0.527		0.031		2.350	
Standard deviation (SD)	0.280		0.012		1.203	
Correction factor for censoring (CF)	1.000		0.926		1.000	
- Mean + 4 SD	1.646		0.078		7.163	
- CF x 3 Mean	1.580		0.086		7.050	
Unrounded MRL	<u>1.646</u>		<u>0.086</u>		<u>7.163</u>	
Rounded MRL	<u>2</u>		<u>0.09</u>		<u>8</u>	
	Residues (mg/kg)		Residues (mg/kg)		Residues (mg/kg)	
	0.39		0.04		1.76	
	0.74		0.03		3.35	
	0.66		0.04		2.88	
	0.95		0.05		4.11	
	0.73		0.03		2.78	
	0.23		0.03		1.6	
	0.65		0.01	*	3.23	
	0.22		0.03		0.82	
	0.17		0.02		0.62	

Compound	Fluxapyroxad		Fluxapyroxad		Fluxapyroxad	
Crop	Pea, hay		Pea, dried seed		Soybean, succ seed with pod	
Region / Country	US/Canada		US/Canada		US/Canada	
GAP	0.2 kg/ha 4-7d PHI		0.2 kg/ha 21-22d PHI		0.2 kg/ha 6-8d PHI	
Total number of data (n)	9		9		14	
Percentage of censored data	0%		22%		0%	
Number of non-censored data	9		7		14	
Lowest residue	1.650		0.010		0.100	
Highest residue	12.120		0.160		0.690	
Median residue	7.710		0.040		0.205	
Mean	7.632		0.068		0.272	
Standard deviation (SD)	3.245		0.061		0.204	
Correction factor for censoring (CF)	1.000		0.852		1.000	
- Mean + 4 SD	20.614		0.311		1.088	
- CF x 3 Mean	22.897		0.173		0.816	
Unrounded MRL	<u>22.897</u>		<u>0.311</u>		<u>1.088</u>	
Rounded MRL	<u>30</u>		<u>0.4</u>		<u>1.5</u>	
	Residues (mg/kg)		Residues (mg/kg)		Residues (mg/kg)	
	7.2		0.16		0.29	
	10.8		0.02		0.2	
	9.49		0.11		0.69	
	7.71		0.01	*	0.69	
	9.18		0.04		0.29	
	6.01		0.01	*	0.11	
	12.12		0.02		0.18	
	4.53		0.15		0.27	
	1.65		0.09		0.1	
					0.1	
					0.46	
					0.11	
					0.11	
					0.21	

Compound	Fluxapyroxad	Fluxapyroxad	Fluxapyroxad	Fluxapyroxad
Crop	Soybean, forage	Soybean, hay	Soybean, dried seed	Bean, dried seed
Region / Country	US/Canada	US/Canada	US/Canada	US/Canada
GAP	0.2 kg/ha 6-8d PHI	0.2 kg/ha 6-8d PHI	0.2 kg/ha 20-22d PHI	0.4 kg/ha 21-22d PHI
Total number of data (n)	14	14	15	11
Percentage of censored data	0%	0%	80%	18%
Number of non-censored data	14	14	3	9
Lowest residue	0.830	0.480	0.010	0.010
Highest residue	6.430	16.250	0.100	0.210
Median residue	2.050	4.495	0.010	0.040
Mean	2.149	4.731	0.019	0.051
Standard deviation (SD)	1.451	3.846	0.024	0.056
Correction factor for censoring (CF)	1.000	1.000	0.467	0.879
- Highest residue	6.430	16.250	0.100	0.210
- Mean + 4 SD	7.953	20.116	0.116	0.274
- CF x 3 Mean	6.448	14.194	0.027	0.134
Unrounded MRL	<u>7.953</u>	<u>20.116</u>	<u>0.116</u>	<u>0.274</u>
Rounded MRL	<u>8</u>	<u>20</u>	<u>0.15</u>	<u>0.3</u>
			High uncertainty of MRL estimate due to high level of censoring.	
	Residues (mg/kg)	Residues (mg/kg)	Residues (mg/kg)	Residues (mg/kg)
	2.17	6.32	0.01	0.02
	2.9	6.44	0.01	0.01
	1.66	5.2	0.01	0.03
	3.24	4.6	0.1	0.01
	1.16	4.39	0.01	0.21
	1.1	3.6	0.01	0.05
	0.83	1.79	0.03	0.05
	2.42	4.79	0.01	0.07
	2.19	3.64	0.01	0.04
	2.25	2.33	0.01	0.03
	1.93	5.87	0.01	0.04
	0.93	0.48	0.01	
	0.88	0.54	0.01	
	6.43	16.25	0.01	
			0.04	

Compound	Fluxapyroxad		Fluxapyroxad		Fluxapyroxad	
Crop	Sweet corn, K+CWHR		Field corn, forage		Field corn, stover	
Region / Country	US/Canada		US/Canada		US/Canada	
GAP	0.2 kg/ha 5-7d PHI		0.2 kg/ha 6-8d PHI		0.2 kg/ha 20-22d PHI	
Total number of data (n)	9		15		15	
Percentage of censored data	89%		0%		0%	
Number of non-censored data	1		15		15	
Lowest residue	0.010		0.200		0.230	
Highest residue	0.080		1.330		3.570	
Median residue	0.010		0.690		1.130	
Mean	0.018		0.697		1.404	
Standard deviation (SD)	0.023		0.301		0.901	
Correction factor for censoring (CF)	0.407		1.000		1.000	
- Mean + 4 SD	0.111		1.901		5.006	
- CF x 3 Mean	0.022		2.090		4.212	
Unrounded MRL	<u>0.111</u>		<u>2.090</u>		<u>5.006</u>	
Rounded MRL	<u>0.15</u>		<u>2</u>		<u>5</u>	
	High uncertainty of MRL estimate due to high level of censoring.					
	Residues (mg/kg)		Residues (mg/kg)		Residues (mg/kg)	
	0.01	*	0.66		0.23	
	0.08		0.2		0.96	
	0.01	*	1.33		1.1	
	0.01	*	0.64		0.93	
	0.01	*	0.9		1.13	
	0.01	*	0.4		1.43	
	0.01	*	0.87		0.6	
	0.01	*	1.04		2.22	
	0.01	*	0.84		2.12	
			0.44		1.45	
			0.9		2.13	
			0.69		0.59	
			0.78		0.39	
			0.33		2.21	
			0.43		3.57	

Compound	Fluxapyroxad		Fluxapyroxad		Fluxapyroxad	
Crop	Field corn, grain		Wheat, forage		Wheat, hay	
Region / Country	US/Canada		US/Canada		US/Canada	
GAP	0.2 kg/ha 20-22d PHI		0.2 kg/ha 6-8d PHI		0.2 kg/ha 6-8d PHI	
Total number of data (n)	15		25		25	
Percentage of censored data	100%		0%		0%	
Number of non-censored data	0		25		25	
Lowest residue	0.010		0.100		0.270	
Highest residue	0.010		9.200		9.600	
Median residue	0.010		0.830		2.640	
Mean	0.010		1.474		3.080	
Standard deviation (SD)	0.000		2.032		2.405	
Correction factor for censoring (CF)	0.333		1.000		1.000	
- Mean + 4 SD	0.010		9.604		12.699	
- CF x 3 Mean	0.010		4.423		9.240	
Unrounded MRL	<u>0.010</u>		<u>9.604</u>		<u>12.699</u>	
Rounded MRL	<u>0.01</u>		<u>10</u>		<u>15</u>	
	High uncertainty of MRL estimate due to high level of censoring.					
	Residues (mg/kg)		Residues (mg/kg)		Residues (mg/kg)	
	0.01	*	0.17		0.33	
	0.01	*	0.92		2.72	
	0.01	*	1.17		2.86	
	0.01	*	0.6		1.42	
	0.01	*	0.8		1.38	
	0.01	*	4.69		9.6	
	0.01	*	0.1		0.37	
	0.01	*	0.19		0.51	
	0.01	*	0.56		2.24	
	0.01	*	0.13		0.27	
	0.01	*	0.32		2.12	
	0.01	*	1.13		2.74	
	0.01	*	1.36		2.09	
	0.01	*	0.25		0.51	
	0.01	*	9.2		5.75	
			3.51		4.8	
			0.83		2.64	
			0.98		3.37	
			0.91		3.29	
			0.27		7.46	
			0.54		2.87	
			0.5		2.42	
			3.25		6.69	
			0.84		2.58	
			3.64		5.97	

Compound	Fluxapyroxad		Fluxapyroxad	
Crop	Wheat, straw		Wheat, grain	
Region / Country	US/Canada		US/Canada	
GAP	0.2 kg/ha 20-27d PHI		0.2 kg/ha 20-27d PHI	
Total number of data (n)	24		25	
Percentage of censored data	0%		0%	
Number of non-censored data	24		25	
Lowest residue	0.560		0.020	
Highest residue	7.290		0.190	
Median residue	2.060		0.080	
Mean	2.755		0.087	
Standard deviation (SD)	2.223		0.047	
Correction factor for censoring (CF)	1.000		1.000	
- Mean + 4 SD	11.646		0.274	
- CF x 3 Mean	8.266		0.260	
Unrounded MRL	<u>11.646</u>		<u>0.274</u>	
Rounded MRL	<u>15</u>		<u>0.3</u>	
	Residues (mg/kg)		Residues (mg/kg)	
	1.92		0.06	
	0.99		0.12	
	1.07		0.07	
	0.8		0.03	
	0.75		0.05	
	6.39		0.06	
	0.85		0.08	
	2.56		0.11	
	3.4		0.06	
	0.78		0.05	
	0.97		0.05	
	2.63		0.08	
	1.84		0.02	
	5.14		0.13	
	7.29		0.03	
	4.61		0.09	
	1.08		0.05	
	2.2		0.16	
	3.08		0.19	
	1.24		0.05	
	2.29		0.11	
	6.53		0.11	
	0.56		0.12	
	7.16		0.1	
			0.19	

Compound	Fluxapyroxad		Fluxapyroxad		Fluxapyroxad	
Crop	Sorghum, forage		Sorghum, stover		Sorghum, grain	
Region / Country	US		US		US	
GAP	0.2 kg/ha 6-7d PHI		0.2 kg/ha 20-23d PHI		0.2 kg/ha 20-23d PHI	
Total number of data (n)	9		9		9	
Percentage of censored data	0%		0%		0%	
Number of non-censored data	9		9		9	
Lowest residue	0.450		0.200		0.130	
Highest residue	2.300		1.030		0.400	
Median residue	0.790		0.660		0.190	
Mean	0.983		0.612		0.217	
Standard deviation (SD)	0.593		0.281		0.088	
Correction factor for censoring (CF)	1.000		1.000		1.000	
- Mean + 4 SD	3.357		1.735		0.569	
- CF x 3 Mean	2.950		1.837		0.650	
Unrounded MRL	<u>3.357</u>		<u>1.837</u>		<u>0.650</u>	
Rounded MRL	<u>4</u>		<u>2</u>		<u>0.7</u>	
	Residues (mg/kg)		Residues (mg/kg)		Residues (mg/kg)	
	0.72		0.42		0.13	
	1.44		0.83		0.15	
	0.79		0.35		0.15	
	2.3		0.4		0.19	
	1.18		0.75		0.31	
	0.94		1.03		0.4	
	0.45		0.2		0.21	
	0.47		0.66		0.17	
	0.56		0.87		0.24	

Compound	Fluxapyroxad		Fluxapyroxad		Fluxapyroxad	
Crop	Barley, hay		Barley, straw		Barley, grain	
Region / Country	US/Canada		US/Canada		US/Canada	
GAP	0.2 kg/ha 20-26d PHI		0.2 kg/ha 20-22d PHI		0.2 kg/ha 20-22d PHI	
Total number of data (n)	6		6		12	
Percentage of censored data	0%		0%		8%	
Number of non-censored data	6		6		11	
Lowest residue	0.790		0.680		0.010	
Highest residue	7.800		9.520		1.220	
Median residue	4.870		3.670		0.520	
Mean	4.608		4.357		0.593	
Standard deviation (SD)	2.465		2.959		0.333	
Correction factor for censoring (CF)	1.000		1.000		0.944	
- Mean + 4 SD	14.468		16.193		1.927	
- CF x 3 Mean	13.825		13.070		1.681	
Unrounded MRL	<u>14.468</u>		<u>16.193</u>		<u>1.927</u>	
Rounded MRL	<u>15</u>		<u>20</u>		<u>2</u>	
	High uncertainty of MRL estimate due to small dataset.		High uncertainty of MRL estimate due to small dataset.			
	Residues (mg/kg)		Residues (mg/kg)		Residues (mg/kg)	
	6		5.43		0.52	
	5.84		3.89		0.39	
	7.8		9.52		0.01	*
	3.9		3.45		0.54	
	0.79		0.68		0.39	
	3.32		3.17		0.52	
					0.87	
					1.02	
					0.82	
					0.5	
					0.32	
					1.22	

Compound	Fluxapyroxad	
Crop	Rice, straw	Rice, grain
Region / Country	US	US
GAP	0.2 kg/ha 20-22d PHI	0.2 kg/ha 20-22d PHI
Total number of data (n)	9	11
Percentage of censored data	0%	0%
Number of non-censored data	9	11
Lowest residue	0.260	0.080
Highest residue	1.700	1.770
Median residue	0.660	0.710
Mean	0.834	0.867
Standard deviation (SD)	0.491	0.514
Correction factor for censoring (CF)	1.000	1.000
- Mean + 4 SD	2.798	2.923
- CF x 3 Mean	2.503	2.602
Unrounded MRL	<u>2.798</u>	<u>2.923</u>
Rounded MRL	<u>3</u>	<u>3</u>
	Residues (mg/kg)	Residues (mg/kg)
	0.26	0.52
	0.62	0.71
	0.54	0.08
	1.7	0.33
	0.8	0.51
	1.47	1.77
	0.66	1.36
	1.09	1.17
	0.37	1.18
		1.27
		0.64