

**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY**

WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY AND
POLLUTION PREVENTION**MEMORANDUM****Date:** 11/15/2016**Subject:** **Florpyrauxifen-benzyl:** First Food Use. Petition for the Establishment of Permanent Tolerances and Registration for Uses on Rice, Fish, and Shellfish. Summary of Analytical Chemistry and Residue Data.

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62719-TNN, 62719-TNRRegulatory Action: Section 3
Registration

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40 CFR: 180§TBD

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Summary of Submitted Residue Chemistry Studies			
OCSPP 860 Series Guideline	MRID Number	Monograph Annex B Reference	Title
860.1300 Nature of the Residue – Plants, Livestock	49677819	IIA 6.2.1/1	Rotondaro, S. L., Taylor, J. A., Adelfinskaya, Y. A.; 2015; Title; Dow AgroSciences LLC, Indianapolis, Indiana, USA; DAS Study No. 121067; 19 March 2015; Unpublished 223 p.
860.1300 Nature of the Residue – Plants, Livestock	49677820	IIA 6.2.2/1	Taylor, J. A., Brackman, R. M., Adelfinskaya, Y. A.; 2015; A Nature of the Residue Study with [14C]-Florpyrauxifen-benzyl in the Laying Hen; Dow AgroSciences LLC; DAS Study No. 130704; 09 June 2015; Unpublished 154 p.
860.1300 Nature of the Residue – Plants, Livestock	49677821	IIA 6.2.3/1	Blakeslee, B. A., Kish, B. P., Adelfinskaya, Y. A.; 2015; A Nature of the Residue Study in the Ruminant with [14C]-Florpyrauxifen-benzyl; Dow AgroSciences LLC; DAS Study No. 130188; 19 August 2015; Unpublished 273 p.
860.1300 Nature of the Residue – Plants, Livestock	49677749	IIA	Hicks, S.; 2015; 14C-Florpyrauxifen-benzyl: Bioconcentration and Metabolism Study with Bluegill, <i>Lepomis macrochirus</i> ; ABC Laboratories, Inc. Columbia, Missouri 65202, USA; Lab Study No. 69924; DAS Study No. 130986; 30 March 2015; Unpublished 124 p.
860.1340 Analytical Methods	49677823	IIA 4.3/5	Austin, R., Turner, R.; 2015; Independent Laboratory Validation of a Dow AgroSciences Method for the Determination of Florpyrauxifen-benzyl and Three Metabolites (X11438848, X12300837 and X11966341) in Agricultural Commodities; Battelle UK Ltd, Chelmsford, Essex, United Kingdom; Lab Study No. YR/14/028; DAS Study No. 140963; 31 July 2015; Unpublished 129 p.
860.1340 Analytical Methods	49677824	IIA 4.3/6	Rawle, N. W.; 2015; Validation of an Analytical Method for the Determination of Florpyrauxifen-benzyl, its Acid Metabolite (X11438848) and its Hydroxy Acid Metabolite (X11966341) in Animal Matrices; CEM Analytical Services Ltd (CEMAS), Wokingham, Berkshire, UK; Lab Study No. CEMS-6919; DAS Study No. 140961; 27 July 2015; Unpublished 264 p.
860.1340 Analytical Methods	49677825	IIA 4.3/9	Hall, L.; 2015; Radiovalidation of the Extraction Method for XDE-848 BE, XDE-848 Acid, and XDE-848 Taurine Conjugate in Fish; ABC Laboratories, Inc. Columbia, Missouri, USA; Lab Study No. 81942; DAS Study No. 141232; 01 July 2015; Unpublished 55 p. Independent Laboratory Validation (ILV) of the Determination of Residues of Florpyrauxifen-benzyl and Metabolites in Catfish by Liquid Chromatography with Tandem Mass Spectrometry.
860.1340 Analytical Methods	49677826	IIA 4.3/3	Huang, T. Y., Walter, M. J.; 2015; Method Validation of the Determination of Residues of Florpyrauxifen-benzyl and Its Metabolites in Rice Grain and Straw Using Liquid Chromatography with Tandem Mass Spectrometry; Dow AgroSciences LLC, Indianapolis, Indiana, USA; Lab Study No. 1307941; DAS Study No. 130794.01; 06 August 2015; Unpublished 108 p.
860.1340 Analytical Methods	49677827	IIA 4.3/4	Huang, T. Y., Walter, M. J.; 2015; Method Validation of the Determination of Residues of Florpyrauxifen-benzyl and Its Metabolites in Rice Processed Fractions Using Liquid Chromatography with Tandem Mass Spectrometry; Dow AgroSciences LLC, Indianapolis, Indiana, USA; Lab Study No. 130794; DAS Study No. 130794.02; 10 August 2015; Unpublished 218 p.
860.1340 Analytical Methods	49677828	IIA 4.3/7	Senciuc, M.; 2015; Independent Laboratory Validation (ILV) of the Determination of Florpyrauxifen-benzyl and two Metabolites X11438848 and X11966341 in Animal Matrices; PTRL Europe GmbH, D-89081 Ulm, Germany; Lab Study No. P 3523 G; DAS Study No. 140958; 04 August 2015; Unpublished 93 p.
860.1340 Analytical Methods	49677829	IIA 4.3/8	Huang, T. Y.; 2015; Method Validation Study for the Determination of Residues of Florpyrauxifen-benzyl and Metabolites in Crayfish, Catfish, and Clams by Liquid Chromatography with Tandem Mass Spectrometry; Dow AgroSciences LLC, Indianapolis, Indiana, USA; Lab Study No. 140954; DAS Study No. 140954; 12 August 2015;

Summary of Submitted Residue Chemistry Studies			
OCSPP 860 Series Guideline	MRID Number	Monograph Annex B Reference	Title
			Unpublished 129 p.
860.1340 Analytical Methods	49677830	IIA 4.3/1	Lindner, M., Grewe, D.; 2015; Validation of a Multi-Residue Method following the QuEChERS Sample Preparation Technique for the Determination of XDE-848 BE and XDE 848 in Matrices of Plant and Animal Origin; Eurofins Agroscience Services Chem GmbH, Hamburg, Germany; Lab Study No. S14-05077; DAS Study No. 130588; 18 August 2015; Unpublished 176 p.
860.1340 Analytical Methods	49677831	IIA 4.3/2	Austin, R, Turner, R.; 2015; Independent Laboratory Validation of a Multi-residue Method Following the QuEChERS Sample Preparation Technique for the Determination of Florpyrauxifen-benzyl and its Metabolite X11438848 in Matrices of Plant and Animal Origin; Battelle UK Ltd, Chelmsford, Essex, UK; Lab Study No. YR/14/030; DAS Study No. 140899; 31 July 2015; Unpublished 181 p.
860.1380 Storage Stability	49678603	IIA 6.1.1/4	Huang, T. Y., Walter, M. J.; 2016; XDE-848 - Frozen Storage Stability of XDE-848 BE and Major Metabolites in Rice Grain, Straw and Processed Fractions-12 Month; Dow AgroSciences LLC, Indianapolis, Indiana, USA; Lab Study No. 140955; DAS Study No. 140955; 07 January 2016; Unpublished 99 p.
860.1380 Storage Stability	49677834	IIA 6.1.1/4	Huang, T. Y., Walter, M. J.; 2015; XDE-848 - Frozen Storage Stability of XDE-848 BE and Major Metabolites in Rice Grain, Straw and Processed Fractions-6 Month Interim Report; Dow AgroSciences LLC, Indianapolis, Indiana, USA; Lab Study No. 140955; DAS Study No. 140955; 14 August 2015; Unpublished 99 p.
860.1380 Storage Stability	49677835	IIA 6.1.1/1	Commander, R. F.; 2015; XDE-848 - Frozen Storage Stability for the Determination of Florpyrauxifen-benzyl and two Metabolites (X11438848, Acid Metabolite and X11966341, Hydroxyl Acid Metabolite) in Animal Matrices; CEM Analytical Services Ltd (CEMAS); Lab Study No. CEMS-6966; DAS Study No. 140960; 04 August 2015; Unpublished 83 p.
860.1380 Storage Stability	49678603		Frozen Storage Stability of XDE-848 BE and Major Metabolites in Rice Grain, Straw and Processed Fractions (12 months final Report)
860.1400 Water, Fish, and Irrigated Crops	49677836		Smith R. J.; 2015; GF-3301 – Magnitude of Residues Study in an Outdoor, Static Aquatic System Following OCSPP Guideline 860.1400; Smithers Viscient Study No. 14076.6103; 14 April 2015; Unpublished 395 p.
860.1480 Meat/Milk/Poultry/Eggs	49677837	IIA 6.4.2	Rawle, N. W. Summary of XDE-848 Livestock Feeding Study: Magnitude of Residue in Milk, Muscle, Liver, Kidney and Fat of Lactating Dairy Cattle; Dow AgroSciences LLC; DAS Study No. 141270; 2015; Unpublished 821 p.
860.1480 Meat/Milk/Poultry/Eggs	49678604		Philips A. M., Laughlin L. A., Tiu C.; 2015; Waiver Rationale for XDE-848 BE Poultry Feeding Study; Dow AgroSciences, Indianapolis, Indiana, USA; DAS Study No. 151216; 16 December 2015; Unpublished 16 p
860.1500 Crop Field Trials/ 860.1520 Processed Food/Feed	49677816	IIA 6.3.1/1	Korpalski, S. J. (2015). Magnitude of XDE-848 Residues in Raw and Processed Commodities Following Application of GF-3162 or GF-3187 to Rice. Dow Agrosciences DAS Study No.: 130794. Unpublished study 520 p.
860.1500 Crop Field Trials/ 860.1520 Processed Food/Feed	49677817	IIA 6.3.1/8	Cenni M. (2015) Magnitude of XDE-848 BE Residues in Raw and Processed Commodities Following Application of GF-3206 to Rice in China. DAS Report Number: 140722. Unpublished Study 206 p.
860.1500 Crop Field Trials/ 860.1520 Processed Food/Feed	49677818	IIA 6.3.1/2	Korpalski, S. J. (2015). Magnitude of XDE-848 Residues in Raw Commodities Following Application of GF-3162 or GF-3187 to Rice. DAS Study No.140788. Unpublished 782 p.
860.1500 Crop Field Trials	49677838	IIA 6.3.1/3	Addison. S. (2014). Residues of XDE-848 BE in Rice Australia 2013. DOW DAS Study No. 131244. Unpublished 179 p.

Summary of Submitted Residue Chemistry Studies			
OCSPP 860 Series Guideline	MRID Number	Monograph Annex B Reference	Title
860.1500 Crop Field Trials	49677839	IIA 6.3.1/4	Semrau, J. (2015). Determination of Residues of XDE-848 after One and after Two Applications of GF-3206 in rice (outdoor) at 4 sites in Southern Europe. DAS Report Number: 140879. Unpublished 356 p.
860.1500 Crop Field Trials	49677840	IIA 6.3.1/6	Castanho, G. M. (2015). Residues of XDE-848 in rice following applications of GF-3206 - Brazil – 2014/2015. DAS Report Number: 141099. Unpublished 303 p.
860.1500 Crop Field Trials/ 860.1520 Processed Food/Feed	49677841	IIA 6.3.1/5	Castanho, G. M. (2015) Residues of XDE-848 in rice Following Applications of GF-3206 – Argentina – 2014/2016 - INTERIM REPORT 1ST SEASON DAS Report Number: 141145. Unpublished 178 p.
860.1500 Crop Field Trials/ 860.1520 Processed Food/Feed		IIA 4.3/7	Anon. Residues of XDE-848 BE in Rice Following Sequential Applications of DAH-1401-1kg GR and DAH-1403SC (GF-2978) – Japan, 2014. DAS Report Number: 141295
	49678604		Philips A. M., Laughlin L. A., Tiu C.; 2015; Waiver Rationale for XDE-848 BE Poultry Feeding Study; Dow AgroSciences, Indianapolis, Indiana, USA; DAS Study No. 151216; 16 December 2015; Unpublished 16 p
860.1850 Confined Rotational Crops	49677843	IIA 6.6.2/1	Rotondaro, S. L., Croffie, J. W., Adelfinskaya, Y.; 2015; A Confined Rotational Crop Study with 14C-Florpyrauxifen-benzyl; PY, PH and BE Labels; Dow AgroSciences, Indianapolis, Indiana, USA; DAS Study No. 130201; 31 July 2015; Unpublished 156 p
860.1900 Field Accumulation Rotational Crop	49678644	IIA 6.6.3	Tiu C., Breaux N., Laughlin L. A., Papineni S., Weimer M.; 2015; Waiver Rationale for XDE-848 Study on Field Accumulation on Rotational Crops. Dow AgroSciences, Indianapolis, Indiana, USA; DAS Study No. 151083; 28 August 2015; Unpublished 19 p

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1.0 Executive Summary

Florpyrauxifen-benzyl (alternate names: XDE-848 benzyl ester, XDE-848 BE, Rinskor™, and X11959130) (benzyl 4-amino-3-chloro-6-[4-chloro-2-fluoro-3-methoxyphenyl]-5-fluoropyridine-2-carboxylate) is a new arylpicolinate systemic herbicide developed by Dow Agrosciences, LLC (DAS). It controls grasses, broadleaves, and sedges and controls or suppresses most herbicide resistant biotypes in rice. Additionally, it is proposed for use for freshwater aquatic weed control in ponds, lakes, reservoirs, marshes, wetlands, bayous, drainage ditches, canals, and other aquatic use sites. Target plants for the aquatic uses (other than rice) include invasive species such as hydrilla (*Hydrilla verticillata*), Eurasian watermilfoil (*Myriophyllum spicatum*), and crested floating heart (*Nymphaoides cristata*).

In addition to in-water application for control of aquatic weeds, a foliar use has been proposed for nuisance floating and emergent aquatic weed management. Tolerances on rice, freshwater fish, and shellfish (crustacean and mollusk) are being proposed to support these uses.

This is the first registration and tolerance request for florpyrauxifen-benzyl.

There are four end-use products (EPs) relevant to this registration action. The EPs are proposed for a maximum of two foliar spray applications using ground or aerial equipment at a maximum single application rate of 0.027 lb ai/A/Application for rice. The proposed preharvest interval (PHI) is 60 days. One end use product (GF-3301, U.S. only) can be applied directly to water or sprayed onto emergent foliage of aquatic plants. Three applications a year are proposed, with a maximum active ingredient concentration of 50 ppb per application, for a total of 150 ppb per annual growth cycle.

The nature of the residue in rice is adequately understood based on an acceptable study conducted on rice. The study was conducted using three different scenarios: water-injected scenario (W), foliar-flooded scenario (F), and dry-seeded scenario (D). Florpyrauxifen-benzyl, florpyrauxifen (alternate names: XDE-848 acid, X11438848), and XDE-848 hydroxy acid (alternate name: X11966341) and were major components of the residue.

The primary pathway involved cleavage of the benzyl ester to give XDE-848 acid (X11438848) metabolite and benzyl alcohol (theoretical hydrolysis product). The X11438848 was then further modified by demethylation to give XDE-848 hydroxy acid (X11966341). No metabolites were observed that would suggest cleavage of the bond between the phenyl and pyridine rings.

The nature of the residue in rotational crops is adequately understood based on an acceptable confined rotational crop study conducted on wheat (small grain), lettuce or mustard (leafy vegetable), and radish (root vegetable). The metabolism in confined rotational crops was similar to that in primary plants, with similar metabolites.

The nature of the residue in ruminants and poultry is adequately understood based on acceptable studies conducted on lactating goats and laying hens. Additionally, a Bluegill sunfish metabolism study was submitted. The metabolism studies indicate degradation pathways similar to the plant and rat metabolism pathways.

For the purpose of this petition, there is no reasonable expectation of finite florpyrauxifen-benzyl residues of concern in livestock commodities [40 CFR §180.6(a)(3)] as a result of the proposed uses.

Based on these data, the HED Residues of Concern Knowledgebase Subcommittee (ROCKS) concluded that the residues of concern for tolerance enforcement are florpyrauxifen-benzyl + X11438848 (4-Amino-3-chloro-6-(4-chloro-2-fluoro-3-methoxy-phenyl)-5-fluoro-pyridine-2-carboxylic acid), expressed as florpyrauxifen-benzyl.

An adequate residue analytical method for tolerance enforcement and data collection was submitted for plants and livestock. The method monitors two ion transitions.

The available storage stability data are adequate to validate the storage conditions and durations of samples from the crop field trial for rice. The available storage stability data indicate that residues are stable for 12 months (one year). The freezer storage stability data indicate that residues of florpyrauxifen-benzyl and metabolites are stable in livestock commodities for up to 71 days (65 for liver) when stored under frozen conditions.

The submitted magnitude of the residue data for rice are adequate with respect to the number and locations of field trials. The data reflect the proposed application rates and PHIs.

The submitted rice processing study is acceptable. Field trial data with exaggerated application rate (5x) indicated that residues were non-quantifiable for the raw agricultural commodities (RACs) and processed commodities.

An analytical standard for florpyrauxifen-benzyl is currently available at the EPA National Pesticide Standards Repository.

2.0 Regulatory Recommendations

Provided the petitioner submits a revised Section B and Section F, HED concludes there are no residue chemistry issues that would preclude the establishment of the proposed tolerances and uses. A human health risk assessment is forthcoming.

2.1 Data Deficiencies/Data Needs

None

2.2 Tolerance Considerations

2.2.1 Enforcement Analytical Method

An adequate analytical method which uses high-performance liquid chromatography with tandem mass spectrometry (HPLC/MS-MS) to quantitate residues of florpyrauxifen-benzyl and X11438848 in various crops and livestock commodities is available for enforcement.

The method is based on the multiresidue analytical method, QuEChERS (EN 15662) sample preparation technique. Briefly, residues of florpyrauxifen-benzyl and X11438848 are extracted from samples with acetonitrile (ACN). After addition of MgSO₄, NaCl, and buffering citrate salts, the samples are shaken and centrifuged. For fatty samples only, extracts are stored for ≥ 4 hours in a freezer in order to precipitate the majority of fat from the sample. For oilseed rape (seeds) samples only, an additional clean-up step is carried out by transferring an aliquot into a tube containing C18 material and intensively shaking. For all matrices, an aliquot of the CAN phase is evaporated to dryness before reconstitution in methanol/water (1:1) containing 0.1% formic acid. The final sample is analysed for florpyrauxifen-benzyl and X11438848 by LC-MS/MS.

This multiresidue method is applicable for the quantitative determination of residues of florpyrauxifen-benzyl and X11438848 in agricultural commodities, represented by wheat grain (high starch content), lettuce (high water content), lemon (whole fruit) (high acid content) and oilseed rape (seeds) (high oil content) and in livestock commodities (poultry eggs and bovine fat, liver, meat, and whole milk). The method was validated over the concentration range of 0.01-0.1 ppm with a validated limit of quantification of 0.01 ppm for each analyte.

The ion transitions monitored for florpyrauxifen-benzyl are m/z 439 \rightarrow 91 (quantitation) and m/z 441 \rightarrow 65 (confirmation) and for X11438848 are m/z 349 \rightarrow 268 (quantitation) and m/z 349 \rightarrow 270 (confirmation).

Fish

Residues of florpyrauxifen-benzyl, X11438848 and X12482999 were extracted from samples by homogenizing and shaking with ACN/0.1 N HCl (90/10, v/v) (2x). After centrifuging and decanting the supernatant, an aliquot of the sample was diluted with an internal standard diluent solution and centrifuged at a high speed. The sample was analysed for florpyrauxifen-benzyl, X11438848 and X12482999 using LC-MS/MS. The method was validated over the concentration range of 0.01-1.0 ppm with a validated limit of quantification of 0.01 ppm.

The ion transitions monitored for florpyrauxifen-benzyl are m/z 439 \rightarrow 91 (quantitation) and m/z 441 \rightarrow 91 (confirmation) and for X11438848 are m/z 349 \rightarrow 268 (quantitation) and m/z 351 \rightarrow 270 (confirmation).

2.2.2 Recommended Tolerances

HED has reviewed the available residue data and has determined the appropriate tolerance levels for residues of florpyrauxifen-benzyl (Table 2.2.2.). A revised Section F/proposed tolerances is required to correct residue levels and commodity definitions.

The proposed tolerances need to be revised as listed below (Table 2.2.2). The recommended tolerance expression is as follows:

General (a). Tolerances are established for residues of florpyrauxifen-benzyl, 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 the sum of florpyrauxifen-benzyl (phenylmethyl 4-amino-3-chloro-6-(4-chloro-2-fluoro-3-methoxyphenyl)-5-fluoro-2-pyridinecarboxylate) and its acid metabolite (4-amino-3-chloro-6-(4-chloro-2-fluoro-3-methoxyphenyl)-5-fluoropyridine-2-carboxylic acid) calculated as the stoichiometric equivalent of florpyrauxifen-benzyl, in or on the commodity.

Commodity	Proposed Tolerance (ppm)	HED-Recommended Tolerance (ppm)	Comments (correct commodity definition)
Rice, grain, (dehulled)	0.01	None	
Rice, grain	0.2	0.30	
Fish, freshwater	2	2.0	Fish - freshwater finfish
Shellfish, crustacean	0.5	0.50	Fish - shellfish, crustacean
Shellfish, mollusc	9	20	Fish - shellfish, mollusc

2.2.3 Revisions to Petitioned-For Tolerances

HED's recommended tolerances differ from the registrant's proposed tolerances. The Agency is revising the commodity definitions for the requested tolerances (fish and shellfish), to reflect the correct commodity vocabulary currently used by the Agency. Additionally, the Agency is revising the significant figures for the tolerance levels based on current policy. Therefore, a revised Section F needs to be submitted.

The proposed tolerance for residues of florpyrauxifen-benzyl in/on rice, grain is 0.2 ppm. Based on the Organization for Economic Cooperation and Development (OECD) statistical calculation applied to the field trial (U.S.) residue data, a value of 0.30 ppm is recommended.

The recommended tolerances for residues of florpyrauxifen-benzyl in/on freshwater fish, shellfish crustacean and shellfish mollusc are 2.0, 0.50 and 20 ppm, respectively. The recommended tolerance for shellfish mollusc was revised based on the residue data provided which included the 0-day data. It appears that the registrant did not consider the 0-day data. The OECD calculation procedures were not used to estimate these tolerances since only decline data were available.

2.2.4 International Harmonization

There are no Codex/Canadian maximum residue limits (MRLs) established on florpyrauxifen-benzyl; therefore, there are no harmonization issues.

2.3 Label Recommendations

The following restrictions were listed on the proposed labels:

“Do not use water from any treated site for food/feed crop irrigation, other than rice, at concentrations >1 ppb unless a 30-day pre-harvest interval can be observed and authorization is obtained from DAS, or unless concentrations are ≤1 ppb. For food/feed crops and in areas irrigated with GF-3301 at >1 ppb, consult DAS for site-specific risk evaluations before planting rotational crops or other plants unless a 90-day pre-planting interval is observed between end of irrigation with treated water and time of planting.” HED does not consider these proposed restrictions enforceable and these statements do not eliminate the need for Magnitude of the residue data for irrigated crops.

“Do not use water for irrigation of greenhouse or nursery plants unless herbicide concentration is <1 ppb or authorization is received from Dow AgroSciences.”

The registrant can either prohibit applications to water that will be applied to irrigated crops or revise the Section F and propose an exemption from the requirement of tolerances for the indirect or inadvertent residues of florpyrauxifen-benzyl on commodities resulting from treatment of water for irrigation.

3.0 Introduction

Florpyrauxifen-benzyl is a new arylpicolinate systemic herbicide. It is proposed for use on rice and for freshwater aquatic weed control in ponds, lakes, reservoirs, marshes, wetlands, bayous, drainage ditches, canals, and other aquatic use sites (which include both direct in water applications and foliar applications to aquatic vegetation). It controls grasses, broadleaves, and sedges and controls or suppresses most herbicide resistant biotypes in rice. Target plants for the aquatic uses (other than rice) include invasive species such as hydrilla (*Hydrilla verticillata*), Eurasian watermilfoil (*Myriophyllum spicatum* or EWM), and crested floating heart (*Nymphoides cristata*).

3.1 Chemical Identity

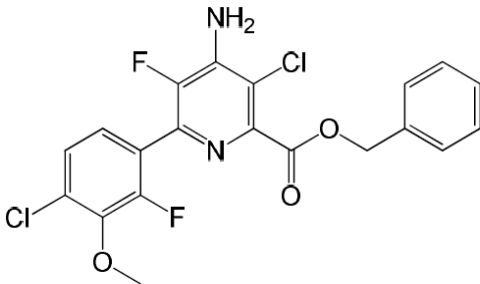
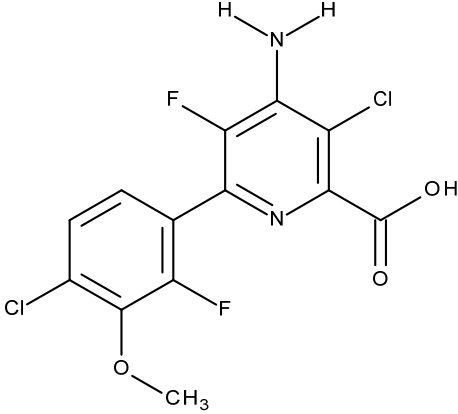
Table 3.1. Florpyrauxifen-benzyl Nomenclature.	
Compound	
Common name	Florpyrauxifen-benzyl
Identity	florpyrauxifen-benzyl (XDE- 848 Benzyl Ester) (benzyl-4-amino-3-chloro-6-(4-chloro-2-fluoro-3-methoxy-phenyl)-5-fluoro-pyridine-2-carboxylate)
Molecular Weight	439.2 g/mole
Chemical Formula	C ₂₀ H ₁₄ Cl ₂ F ₂ N ₂ O ₃
CAS no.	1390661-72-9
Company experimental names	XDE-848 Benzyl Ester, XDE-848 BE, Rinskor™, and X11959130

Table 3.1. Florpyrauxifen-benzyl Nomenclature.	
(Synonyms)	
IUPAC name	benzyl 4-amino-3-chloro-6-(4-chloro-2-fluoro-3-methoxyphenyl)-5-fluoropyridine-2-carboxylate
CAS name	phenylmethyl 4-amino-3-chloro-6-(4-chloro-2-fluoro-3-methoxyphenyl)-5-fluoro-2-pyridinecarboxylate
End-use products (EPs)	GF-3206 (A.I. Florpyrauxifen-benzyl) EPA File Symbol 62719-AOI GF-3301 (A.I. Florpyrauxifen-benzyl) EPA File Symbol 62719- AOO GF-3480 (A.I. Florpyrauxifen-benzyl, cyhalofop-butyl) EPA File Symbol 62719-TNN GF-3565 (A.I. Florpyrauxifen-benzyl, penoxsulam) EPA File Symbol 62719-TNR
Compound (metabolite)	
Common name	Florpyrauxifen
Synonym	X11438848
IUPAC name	4-amino-3-chloro-6-(4-chloro-2-fluoro-3-methoxyphenyl)-5-fluoropyridine-2-carboxylic acid
CAS no.	943832-81-3

3.2 Physical/Chemical Characteristics

Florpyrauxifen-benzyl has a low water solubility (0.015 mg/L in water at 20°C) and has a low vapor pressure (3.2×10^{-5} Pa at 20°C) and therefore is not highly volatile. It has an octanol/water partition coefficient of 5.5.

* PAI = Pure Active Ingredient. TGAI = Technical Grade Active Ingredient.

Table 3.2. Physicochemical Properties of Florpyrauxifen-benzyl.		
Parameter	Value	Reference (MRID or Source)
Physical State	Powder (as manufactured) @ 21.3°C	49677702
Relative Density Bulk Density	Relative density 1.39 Bulk Density 0.202 g/mL at 23.4°C Tap Density 0.320 g/mL at 23.4°C	49677702
Vapor Pressure	4.6×10^{-5} Pa (3.5×10^{-7} mmHg) at 25°C 3.2×10^{-5} Pa (2.4×10^{-7} mmHg) at 20°C Classified as 'Non-volatile under field conditions.' ⁽¹⁾⁽³⁾	49677702
Henry's Law Constant	9.2×10^{-6} atm-m ³ /mole at 20°C 1.3×10^{-5} atm-m ³ /mole, using VP at 25°C and S at 20°C	Estimated from water solubility and vapor pressure

Parameter	Value	Reference (MRID or Source)
Water Solubility	Purified Water: 0.015 mg/L at 20°C pH 5 buffer solution: 0.014 mg/L pH 7 buffer solution: 0.011 mg/L pH 9 buffer solution: 0.012 mg/L	49677702
Solubility in Organic Solvents	All at 20°C: methanol 13 g/L acetone 210 g/L xylene 14 g/L 1,2-dichloroethane 95 g/L ethyl acetate 120 g/L n-heptane 0.053 g/L n-octanol 4.9 g/L	49677702
Octanol – water partition coefficient (K _{ow})	pH 5 (log ₁₀ Pow = 5.4 ± 0.1) at 20°C pH 7 (log ₁₀ Pow = 5.5 ± 0.04) at 20°C pH 9 (log ₁₀ Pow = 5.5 ± 0.1) at 20°C	49677702
Dissociation Constant	Does not dissociate in the environmental pH range (pH 4 to 10)	49677702
pH	6.58 at 23.4 °C (1% dilution in water)	49677702
UV/Visible light absorption	Neutral: λ max at 212, 245 nm Acidic: λ max at 212, 245 nm Alkaline: λ max at 217, 241 nm	49677702

3.3 Pesticide Use Pattern/Directions for Use (860.1200)

There are four end use products proposed for use in the U.S.: GF-3206 an emulsifiable concentrate (EC) formulation containing 25 g ai/L, 0.21 lb ai/gal; GF-3301 a suspension concentrate (SC) formulation containing 300 g ai/L 2.5 lb ai/gal (US only); GF-3480 a multiple active ingredient (MAI) EC formulation containing cyhalofop 20 g ai/L, 0.17 lb ai/gal; GF-3565 MAI EC formulation containing penoxsulam 12.5 g ai/L, 0.10 lb ai/gal.

Applic. Timing, Type, and Equip.	Formulation [EPA File Symbol]	Applic. Rate/Season g/ha (lb ai/A)	Max. No. Applic./Year	Max. Applic. Rate/Year g/ha (lb ai/A)	PHI (days)	Use Directions and Limitations
Rice in the states of Arkansas, Florida, Louisiana, Mississippi, Missouri, South Carolina, Tennessee and Texas						
Broadcast Foliar spray; Aerial or Ground	GF-3206 EC [62719-AOI]	30 (0.027)	2	60 (0.054)	60	GF-3206 can be applied to rice fields used for crayfish production. Use of an agriculturally approved methylated seed oil adjuvant at a rate of 0.5 pints per acre is required. RTI of 14 days or greater is recommended.
Broadcast Foliar spray; Aerial or Ground	GF-3301 SC [62719-AOO]	30 (0.027)	2	60 (0.054)	60	RTI of 14 days or greater is recommended.
Broadcast Foliar spray; Aerial or Ground	GF-3480 EC (MAI) [62719-TNN]	30 (0.027)	1	30 (0.027)	60	Do not fish or commercially grow fish, shellfish or crustaceans on treated acres during the year of treatment.

Applic. Timing, Type, and Equip.	Formulation [EPA File Symbol]	Applic. Rate/Season g/ha (lb ai/A)	Max. No. Applic./Year	Max. Applic. Rate/Year g/ha (lb ai/A)	PHI (days)	Use Directions and Limitations
Broadcast Foliar spray; Aerial or Ground	GF-3565 OD (MAI) [62719-TNR]	24 (0.021)	1	24 (0.021)	60	

* PHI = Pre-Harvest Interval.

Restrictions: Applications are to be made in a minimum of 10 gallons per acre (GPA). Do not rotate treated land to crops other than rice for 3 months following application. Except for crayfish, do not fish or commercially grow fish, shellfish or crustaceans on treated acres during the year of treatment. Do not apply this product through any type of irrigation system. Do not use on wild rice.

Aquatics: Ponds, lakes, reservoirs, marshes, wetlands, bayous, drainage ditches, canals, and other aquatic sites (freshwater aquatic vegetation)					
In-Water Application- Maximum application rate 150 ppb/per annual growth cycle.					
Percent Area of Waterbody Treated* %.	Days of Irrigation Precaution in Treated Area				Use Directions and Limitations
	5 - 10 ppb	10 - 20 ppb	20 - 50 ppb	>50 ppb	
2% or less	5 days	7 days	10 days	**	No restrictions on consumption of treated water for potable water use or by livestock, pets, or other animals. No restrictions on the use of treated water for recreational purposes, including swimming and fishing, or for irrigating established turf. Do not use water from any treated site for food/feed crop irrigation, other than rice, at concentrations >1 ppb unless a 30-day pre-harvest interval can be observed and authorization is obtained from DAS, or unless concentrations are ≤1 ppb. For food/feed crops and in areas irrigated with GF-3301 at >1 ppb, consult DAS for site-specific risk evaluations before planting rotational crops or other plants unless a 90-day pre-planting interval is observed between end of irrigation with treated water and time of planting.
3 - 10%	10 days	21 days	28 days	**	
11 - 20%	21 days	28 days	**	**	
>20%	**	**	**	**	
Foliar Application (emergent foliage)-Maximum application rate 5.4 fl oz/A (0.105 lb ai/A) annual growth cycle.					
	Up to 1.4 fl oz/A (0.027 lb ai/A)		Up to 2.7 fl oz/A (0.0527 lb ai/A)		For post-emergence foliar applications, mix GF-3301 with a surfactant. Use only surfactants approved for aquatic use.
2% or less	3 days		3 days		
3 - 10%	5 days		10 days		
11 - 20%	21 days		28 days		
>20%	**		**		

*Assumes treated area rapidly dilutes with untreated water.

**Contact a Dow Solutions Expert for site-specific plan.

Restrictions: Do not use water-containing GF-3301 for hydroponic farming. Do not use water for irrigation of greenhouse or nursery plants unless herbicide concentration is <1 ppb or authorization is received from Dow AgroSciences. Applications are to be made in a minimum of 15 GPA (air).

Conclusions: Pending submission of a revised label, (as indicated in Section 2.3) the labels are adequate to allow the evaluation of the field trial residue data relative to the proposed uses. An acceptable plant-back interval (PBI) of 3-months is proposed.

4.0 Metabolite/Degradate Residue Profile

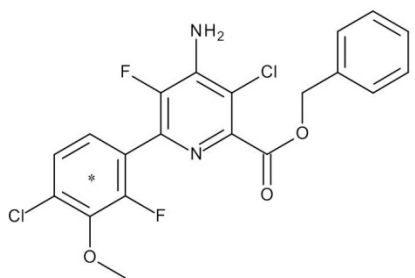
4.1 Nature of the Residue

4.1.1 Summary of Plant Metabolism (860.1300)

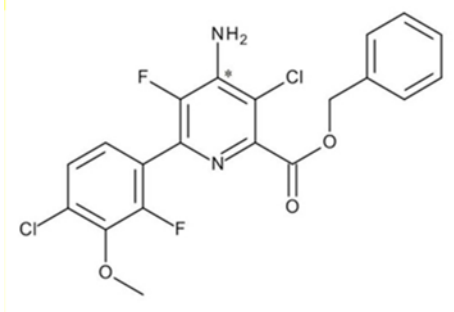
Tier II Summaries 49677883 Ref: IIA 6.2.1/1

The radiolabeled florpyrauxifen-benzyl used in the plant and confined rotational crop studies was labelled in the [¹⁴C]- florpyrauxifen-benzyl, PH (phenyl label), PY (pyridine label), and BE (benzyl ester label) as shown below.

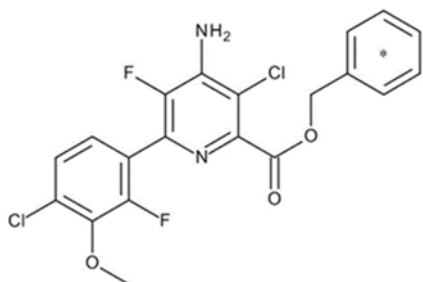
[¹⁴C]- PH- florpyrauxifen-benzyl



[¹⁴C]- PY- florpyrauxifen-benzyl



[¹⁴C]- BE- florpyrauxifen-benzyl



Metabolism studies for florpyrauxifen-benzyl were conducted on the primary crop rice, and on rotational crops (wheat, lettuce, and radish) which were studied at three PBI (30, 90, and 271 days). Lettuce did not germinate at 30- or 90-day PBIs, and was replaced with mustard at the 271-day PBI.

In all tested systems, the benzyl group was quantitatively cleaved from the compound to form benzyl alcohol or benzoic acid. Since the plant and animal metabolism of benzyl alcohol and other benzyl derivatives is well understood and have little to no toxicological concern, only the results from the PH and PY label test materials are presented.

Adequate amounts of radiolabelled residues were extracted and analysed. All samples were stored frozen and were extracted and analysed within 6 months of collection.

Rice: The metabolism of [¹⁴C]- florpyrauxifen-benzyl was investigated in rice following two applications of [¹⁴C]- florpyrauxifen-benzyl PH, PY, and BE, at a rate of approximately 60-200 g ai/ha (0.054-0.178 lb ai/A), for a total rate of 120-400 g ai/ha (0.107- 0.357 lb ai/A, ~7X label rate).

Three typical rice planting/application scenarios were studied: water-injected scenario (W), foliar-flooded scenario (F), and dry-seeded scenario (D). For the water-injected, the [¹⁴C]- florpyrauxifen-benzyl was applied directly to the rice paddy water. For the foliar-flooded and the dry-seeded [¹⁴C]- florpyrauxifen-benzyl was foliarly applied to the rice plants. For the water-injected and foliar-flooded, the rice was planted initially in a greenhouse and later transplanted to outdoor plots and grown to maturity. For the dry-seeded, the rice was directly seeded into outdoor plots and grown to maturity. Immature plants were collected 13 days after the second application (growth stage BBCH-59). Mature white rice, hulls, and straw were harvested 59-70 days after the second application (growth stage BBCH-99). All crop fractions (except PH-label mature grain) were extracted using six individual accelerated solvent extraction (ASE) procedures with 3 different solvents. An aliquot of each of the six neutral organic extracts containing >0.01 ppm were pooled, then purified and concentrated using a Strata-X Solid Phase extraction (SPE) and analysed by HPLC.

Overall, the major residues (>10%) identified in immature rice, mature hulls, and mature straw were parent florpyrauxifen-benzyl, X11438848 and X11966341. Benzoic acid (X194973) was present at >10% in the BE-label of immature samples.

Water injected: For the PH- and PY-labels about 70% and 75% of the TRR was extractable from the immature rice and mature straw, respectively. For the BE-label, about 40% of the TRR was extracted for the immature rice and 30% of the TRR for mature straw. For rice hulls, 60% of the TRR was extracted from the PH-label, and 10% of the TRR was extracted from the PY- and BE-labels. For all radiolabels, 5% of the TRR were extractable from grain. In all samples, low-levels of radioactivity remained unextracted (≤ 0.050 ppm).

For the PH-, PY- and BE- labels, the TRR values in immature rice were 0.046-0.054 ppm; 0.070-0.112 ppm in mature rice straw, 0.015-0.0475 ppm in mature rice hulls, and 0.015-0.061 ppm in mature rice grain.

The major metabolites in water-injected immature rice were X11438848 (PH- and PY-label only, 24.9 and 48.7% TRR) and parent florpyrauxifen-benzyl (9.2-20.3% TRR all labels). The BE-label load/wash contained only polar compounds (6.8% TRR) (early eluting compounds). The major metabolites in mature straw and the PH-label hulls, were X11438848 accounting for approximately 40% of the TRR and parent florpyrauxifen-benzyl remaining at approximately

10% of the TRR. The BE-label straw post-extracted solids remaining after the neutral ASE extractions, were further extracted and hydrolyzed using 1 N HCl. Approximately 2.7% TRR (0.003 ppm) was extracted with the acid hydrolysis. The naturally incorporated or bound residues were evaluated for the BE-labeled straw. The BE-labeled straw contained 14.8, 15.5, and 11.7% of the TRR as pectin, lignin, and hemicelluloses, respectively. Between 48.3% and 57.2% TRR was associated with the starch of the rice grain.

The major residues (>10%) identified in water-injected were immature rice, mature straw and the PH-label hulls were X11438848 and parent, florpyrauxifen-benzyl.

Table 4.1.1-1: Distribution of the Parent and the Metabolites in Water-Injected Scenario (W) Immature Rice when Dosed with ¹⁴C-Labeled Florpyrauxifen-benzyl.

	¹⁴ C-PH		¹⁴ C-PY		¹⁴ C-BE ^a	
	(Elution)		(Elution)		(Elution + Load/Wash)	
	% TRR	ppm ^b	% TRR	ppm	% TRR	Ppm
Total Radioactive Residue (TRR)	100.0	0.046	100.0	0.052	100.0	0.054
Total neutral extractable	67.9	0.031	69.8	0.036	42.2	0.023
Total extractable analysed by HPLC	63.2	0.029	72.7	0.038	39.4	0.021
XR-848-benzyl ester (34min)	20.3	0.009	9.2	0.005	17.6	0.009
Polar (<5min)	Not Detected	Not Detected	Not Detected	Not Detected	6.8	0.004
X11966341 (23min) ^c	3.4	0.002	Not Detected	Not Detected	No ¹⁴ C-Label	No ¹⁴ C-Label
X11438848 (27min) ^c	24.9	0.011	48.7	0.025	No ¹⁴ C-Label	No ¹⁴ C-Label
Total acid extractable	Not Analyzed	Not Analyzed	Not Analyzed	Not Analyzed	Not Analyzed	Not Analyzed
Total Identified ^d	48.6	0.022	57.8	0.030	17.6	0.009
Total extractable, not identified ^e	19.4	0.009	11.9	0.006	42.2	0.023
Total Natural Incorporation ^f	Not Analyzed	Not Analyzed	Not Analyzed	Not Analyzed	Not Analyzed	Not Analyzed
Total characterized ^g	67.9	0.031	69.8	0.036	42.2	0.023
Total unextractable	21.9	0.010	27.3	0.014	63.4	0.034
Accountability ^h	89.8	0.041	97.1	0.050	105.6	0.057

^a More information on benzyl ester metabolites is available in the final report.

^b mg XR-848-benzyl ester eq/kg.

^c Metabolite is not relevant for ¹⁴C-BE labeled samples

^d Total identified = sum known metabolites (not including conjugates or polar)

^e Total extractable, not identified = total extractable - identified

^f Natural incorporation = pectin + lignin + hemicelluloses

^g Total characterized = total identified + total extractable, not identified + natural incorporation

^h Accountability = total extracted (neutral + acid) + natural incorporation + unextractable

Table 4.1.1-2: Distribution of the Parent and the Metabolites in Water-Injected Scenario (W) Mature Rice Straw when Dosed with ¹⁴C-Labeled Florpyrauxifen-benzyl.

	¹⁴ C-PH		¹⁴ C-PY		¹⁴ C-BE ^a	
	(Elution)		(Elution)		(Elution)	
	% TRR	ppm ^b	% TRR	ppm	% TRR	Ppm
Total Radioactive Residue (TRR)	100.0	0.112	100.0	0.070	100.0	0.106
Total neutral extractable	85.3	0.096	71.4	0.050	30.6	0.033
Total extractable analysed by HPLC	65.7	0.074	59.7	0.042	19.7	0.021
XR-848-benzyl ester (34min)	10.1	0.011	8.3	0.006	13.0	0.014
X11966341 (23min) ^c	2.4	0.003	3.3	0.002	No ¹⁴ C-Label	No ¹⁴ C-Label
X11438848 (27min) ^c	47.8	0.054	41.9	0.029	No ¹⁴ C-Label	No ¹⁴ C-Label
Total acid extractable	Not Analyzed	Not Analyzed	Not Analyzed	Not Analyzed	2.7	0.003
Total Identified ^d	60.3	0.068	50.2	0.035	13.0	0.014
Total extractable, not identified ^e	24.9	0.028	21.2	0.015	20.2	0.022
Total Natural Incorporation ^f	Not Analyzed	Not Analyzed	Not Analyzed	Not Analyzed	42.0 ^h	0.045 ^h
Total characterized ^g	85.3	0.096	71.4	0.050	77.9	0.083
Total unextractable	21.3	0.024	36.5	0.025	29.1	0.031
Accountability ⁱ	106.5	0.120	107.8	0.075	104.3	0.111

^a More information on benzyl ester metabolites is available in the final report.

^b mg XR-848-benzyl ester equivalents/kg tissue.

^c Metabolite is not relevant for ¹⁴C-BE labeled samples.

^d Identified = sum known metabolites (not including conjugates or polar).

^e Total extractable, not identified = (total extractable neutral + acid) – identified.

^f Natural incorporation = pectin + lignin + hemicelluloses.

^g Total characterized = amount identified + extractable not identified (neutral + acid) + natural incorporation.

^h In the BE-label straw the following characterizations were made: pectin 14.8% TRR (0.016 mg eq/kg); lignin 15.5% TRR (0.016 mg eq/kg), hemicellulose 11.7% TRR (0.012 mg eq/kg).

ⁱ Accountability = total extracted (neutral + acid) + natural incorporation + unextractable.

Table 4.1.1-3: Distribution of the Parent and the Metabolites in Water-Injected Scenario (W) Mature rice Hulls when Dosed with ¹⁴C-Labeled Florpyrauxifen-benzyl.

	¹⁴ C-PH		¹⁴ C-PY		¹⁴ C-BE ^a	
	(Elution)		(Elution)		(Elution)	
	% TRR	Ppm	% TRR	ppm ^a	% TRR	Ppm
Total Radioactive Residue (TRR)	100.0	0.035	100.0	0.015	100.0	0.047
Total neutral extractable	59.6	0.021	12.3	0.002	8.3	0.004
Total extractable analysed by HPLC	47.8	0.017	Not Analyzed	Not Analyzed	Not Analyzed	Not Analyzed
XR-848-benzyl ester (34min)	7.0	0.002	Not Analyzed		Not Analyzed	
X11966341 (23min) ^b	Not Detected	Not Detected				
X11438848 (27min) ^b	38.6	0.014				
Total acid extractable	Not Analyzed	Not Analyzed	Not Analyzed	Not Analyzed	Not Analyzed	Not Analyzed
Total Identified ^c	45.6	0.016	Not Available	Not Available	Not Available	Not Available
Total extractable, not identified ^d	14.0	0.005	12.3	0.002	8.3	0.004
Total Natural Incorporation ^e	Not Analyzed	Not Analyzed	Not Analyzed	Not Analyzed	Not Analyzed	Not Analyzed
Total characterized ^f	59.6	0.021	12.3	0.002	8.3	0.004
Total unextractable	33.2	0.012	78.2	0.012	96.8	0.045
Accountability ^g	92.8	0.032	90.5	0.014	105.1	0.049

^a mg XR-848-benzyl ester equivalents/kg tissue.

^b metabolite is not relevant for ¹⁴C-BE labeled samples.

^c identified = sum known metabolites (not including conjugates or polar).

^d total extractable, not identified = (total extractable neutral + acid) – identified.

^e natural incorporation = pectin + lignin + hemicelluloses.

^f total characterized = amount identified + extractable not identified (neutral + acid) + natural incorporation.

^g accountability = total extracted (neutral + acid) + natural incorporation + unextractable.

Table 4.1.1-4: Distribution of the Parent and the Metabolites in Water-Injected Scenario (W) Mature Rice Grain when Dosed with ¹⁴C-Labeled Florpyrauxifen-benzyl.

	¹⁴ C-PH		¹⁴ C-PY		¹⁴ C-BE ^a	
	% TRR	ppm	% TRR	ppm ^a	% TRR	ppm
Total Radioactive Residue (TRR)	100.0	0.015	100.0	0.019	100.0	0.061
Total neutral extractable	5.3	0.001	4.4	0.001	4.4	0.003
Total extractable analysed by HPLC	Not Analyzed					
Total acid extractable	Not Analyzed					
Total Identified ^b	Not Available					
Total extractable, not identified ^c	5.3	0.001	4.4	0.001	4.4	0.003
Total Natural Incorporation as Starch ^d	48.3%	0.007	57.2%	0.011	52.6%	0.032

Table 4.1.1-4: Distribution of the Parent and the Metabolites in Water-Injected Scenario (W) Mature Rice Grain when Dosed with ¹⁴C-Labeled Florpyrauxifen-benzyl.

	¹⁴ C-PH		¹⁴ C-PY		¹⁴ C-BE ^a	
	% TRR	ppm	% TRR	ppm ^a	% TRR	ppm
Total characterized ^c	53.6	0.008	61.6	0.011	57.0	0.035
Total unextractable	92.1	0.014	107.2	0.021	91.0	0.056
Accountability ^f	97.4	0.015	111.6	0.022	95.4	0.058

^a mg XR-848-benzyl ester equivalents/kg tissue

^b identified = sum known metabolites (not including conjugates or polar)

^c total extractable, not identified = (total extractable neutral + acid) - identified

^d natural incorporation for grain, starch isolation only, starch isolation was performed using fresh tissue: total accountability for fresh tissue starch isolation was 90.1% for 4C-PH, 98.7% for 14C-PY, and 91.0% for 14C-BE total characterized = amount identified + extractable not identified (neutral + acid) accountability = total extracted (neutral + acid) + natural incorporation + unextractable

Foliar-flooded: For all labels about 85% of the TRR was extracted from immature plants, 75% of from mature rice straw, 70% from mature rice hulls, and 40% from mature rice grain (except BE-label).

The immature plant major residues were florpyrauxifen-benzyl (14.4-35.2% TRR), X11966341 (loss of benzyl and methyl esters, 11.4-14.4% TRR), and X194973 (benzoic acid) from the BE-label. X12131932, the dechlorinated benzyl ester, was observed in all immature samples (3.8-4.4% TRR, 0.011-0.035 ppm). X12131932 is a photolysis product and presumably formed on the surface of the plants.

Residues in mature straw and hulls contained parent florpyrauxifen-benzyl (14.2-38.8% TRR), X11966341 (11-18% TRR in straw and 1.6-1.7% TRR in hulls, indicating limited translocation of X11966341 into untreated parts of the plant), X11438848 (3-5% TRR), and X12131932 (\leq 5.8% TRR). X194973 (benzoic acid) was not present in the BE-label mature samples. Rather, the benzoic acid was further metabolized to form a conjugate (13-16% TRR) that released benzoic acid with both acid and heat. X11966341 was also conjugated with glucose to form X12431091 (2-3% TRR in straw). In addition, X12300837 (loss of methyl ester only) was observed at low levels (\leq 2.6% TRR); however, X12300837 was not confirmed by mass spectrometry. Evidence of the relationship between benzoic acid and the conjugate was through acid hydrolysis of the isolated conjugate.

Residues in mature grain (PH- and PY-labels) contained florpyrauxifen-benzyl (3.9-6% TRR), X11966341 (2.1-3.2% TRR), X11438848 (\leq 4.0% TRR), and X12131932 (\leq 2.6% TRR).

For all immature rice samples, all straw samples, and PH- and PY-label hulls, the post-extracted solids remaining after the neutral ASE extractions were further extracted and hydrolyzed using 1 N HCl. For the immature rice samples 1.3% to 2.5% TRR (0.006-0.010 ppm) was extracted with the acid hydrolysis. For the straw samples 1.1% to 3.3% TRR (0.020-0.035 ppm) was extracted with the acid hydrolysis. For the PH and PY hulls 2.0% to 2.5% TRR (0.008 ppm) was extracted with the acid hydrolysis. Since the level of radioactivity extracted and hydrolyzed by acid was low for all samples, these extracts were not analysed.

For the immature plants and mature straw, (all radiolabels), the naturally incorporated residue were distributed fairly evenly amongst pectin, lignin, and hemicelluloses (1.1-4.0% TRR), totaling 1.1-5.6% of the TRR and (1.2-6.5% TRR), totaling 8.5-16.3% of the TRR, respectively. The PH- and PY-label hulls contained 14.4-18.1% TRR associated with lignin and 6.8-6.9% TRR associated with pectin. For rice grain, 19.7% (PH) and 34.3% TRR (PY) was bound in the starch.

The major residues (>10%) identified in foliar-flooded immature rice and mature straw were parent florpyrauxifen-benzyl and X11966341. Parent florpyrauxifen-benzyl was the major residue in rice hulls. Benzoic acid (X194973) was present at >10% in the BE-label of immature samples.

Table 4.1.1-5: Distribution of the Parent and the Metabolites in Foliar-Flooded Scenario (F) Immature Plants when Dosed with ¹⁴C-Labeled Florpyrauxifen-benzyl.

	¹⁴ C-PH		¹⁴ C-PY		¹⁴ C-BE ^a	
	(Elution)		(Elution)		(Elution)	
	% TRR	ppm ^b	% TRR	ppm	% TRR	ppm
Total Radioactive Residue	100.0	0.322	100.0	0.287	100.0	0.801
Total neutral extractable	83.4	0.268	85.1	0.244	87.0	0.697
Total extractable analysed by HPLC	68.0	0.219	69.1	0.198	73.7	0.591
XR-848-benzyl ester (34.0min)	14.4	0.046	16.0	0.046	35.2	0.282
Unknown (20.7min)	Not Detected		Not Detected		2.0	0.016
X11966341 (21.83-22.80min) ^c	11.4	0.037	14.4	0.041	No ¹⁴ C-Label	
Unknown (21.83-22.80min)	No ¹⁴ C-Label				1.9	0.015
Benzoic Acid (23.5min) ^{d, e}	No ¹⁴ C-Label				12.0	0.096
X11438848 (26.83-27.50min) ^c	3.4	0.011	3.7	0.011	No ¹⁴ C-Label	
Unknown (26.83-27.50min) ^c	No ¹⁴ C-Label				1.2	0.010
Unknown (29.8min)	1.3	0.004	1.7	0.005	1.4	0.011
Unknown (31.2min)	4.0	0.013	2.1	0.006	1.5	0.012
X12131932 (32.5-33.0min)	4.4	0.014	3.8	0.011	4.4	0.035
Unknown (33.0-33.5min)	1.9	0.006	1.9	0.006	1.1	0.009
Total acid extractable	2.5	0.008	2.1	0.006	1.3	0.010
Total Identified ^f	33.6	0.108	37.9	0.109	51.5	0.145
Total extractable, not identified ^g	52.3	0.168	49.3	0.142	36.7	0.294
Pectin	1.6	0.005	1.1	0.003	1.2	0.009
Lignin	4.0	0.013	N/A ^h	N/A	1.2	0.010
Hemicellulose	N/A	N/A	N/A	N/A	2.0	0.016
Total Natural Incorporation ⁱ	5.6	0.018	1.1	0.003	4.4	0.035
Total characterized ^j	94.0	0.303	90.4	0.259	93.9	0.752
Total unextractable	11.8	0.038	12.6	0.036	3.7	0.029
Accountability ^k	100.8	0.324	98.8	0.284	95.1	0.762

^a More information on benzyl ester metabolites is available in the final report.

^b mg XR-848-benzyl ester eq/kg.

^c Metabolite is not relevant for ¹⁴C-BE labeled samples.

^d Metabolite confirmed by LC/MS/MS and HPLC.

^e Metabolite is not relevant for 14C-PH or 14C-PY labeled samples.

^f Identified = sum known metabolites (not including conjugates or polar).

^g Total extractable, not identified = (total extractable neutral + acid) - identified.

^h N/A = not analyzed.

ⁱ Natural incorporation = pectin + lignin + hemicelluloses.

^j Total characterized = amount identified + extractable not identified (neutral + acid) + natural incorporation.

^k Accountability = total extracted (neutral + acid) + natural incorporation + unextractable.

Table 4.1.1-5: Distribution of the Parent and the Metabolites in Foliar-Flooded Scenario (F) Mature Straw when Dosed with ¹⁴C-Labeled Florpyrauxifen-benzyl (metabolites >2.5% TRR shown).

	¹⁴ C-PH		¹⁴ C-PY		¹⁴ C-BE ^a	
	(Elution)		(Elution + Load/Wash)		(Elution)	
	% TRR	ppm ^b	% TRR	ppm	% TRR	ppm
Total Radioactive Residue	100.0	1.005	100.0	1.043	100.0	2.013
Total neutral extractable	75.3	0.777	71.7	0.748	80.8	1.627
Total analysed by HPLC	70.6	0.709	86.9	0.907	81.2	1.635
XR-848-benzyl ester (34.0min) ^c	17.4	0.175	19.1	0.199	38.8	0.781
Polar (<5min)	ND ^b	ND	5.0	0.052	ND	ND
Unknown (16.0min)	ND	ND	ND	ND	2.3	0.045
X12431091 (16.5-17.0min) ^{c,d}	2.6	0.027	2.2	0.023	No ¹⁴ C-Label	
Acid/Heat labile conjugate of benzoic acid (18.0min) ^{e,f}	No ¹⁴ C-Label				13.4	0.270
Unknown (19.7min) ^c	0.26	0.003	ND	ND	2.5	0.050
X11966341 (21.83-22.80min) ^{c,d}	10.8	0.109	17.6	0.183	No ¹⁴ C-Label	
Unknown (21.83-22.80min)	No ¹⁴ C-Label				2.84	0.057
Unknown (23.8min)	3.1	0.031	0.74	0.008	0.8	0.016
X11438848 (26.83-27.50min) ^{c,d}	4.3	0.043	5.4	0.056	No ¹⁴ C-Label	
Unknown (27.50-27.83min)	1.4	0.014	3.2	0.033	0.4	0.008
Unknown (28.2min)	2.6	0.026	1.4	0.015	0.7	0.015
Unknown (30.7min)	3.1	0.031	3.3	0.034	0.5	0.009
Unknown (31.7min)	ND	ND	2.6	0.027	ND	ND
X12300837 (32.0-32.3min)	2.6	0.026	ND	ND	1.4	0.028
X12131932 (32.5-33.0min) ^c	4.0	0.040	3.8	0.040	2.8	0.055
Total acid extractable	2.0	0.020	3.3	0.035	1.1	0.022
Total Identified ^g	36.5	0.366	45.9	0.478	41.5	0.836
Total extractable, not identified ^h	40.8	0.410	29.2	0.304	40.4	0.813
Pectin	3.3	0.033	5.5	0.057	1.2	0.009
Lignin	5.5	0.055	6.5	0.068	1.2	0.010
Hemicellulose	4.7	0.047	4.3	0.045	2.0	0.010
Total Natural Incorporation ⁱ	13.5	0.135	16.3	0.170	8.5	0.171
Total characterized ^j	92.8	0.933	94.7	0.988	91.5	1.843
Total unextractable	4.1	0.041	4.0	0.042	1.9	0.038
Accountability ^k	94.8	0.953	95.4	0.995	92.3	1.859

^a More information on benzyl ester metabolites is available in the final report.

^b mg XR-848-benzyl ester eq. /kg.

^c ND = not detected.

^d Metabolite is not relevant for 14C-BE labeled samples.

^e After hydrolysis, Benzoic acid was confirmed by LC/MS/MS and HPLC.

^f Metabolite is not relevant for 14C-PH or 14C-PY labeled samples.

^g Identified, not identified = sum known metabolites (not including conjugates or polar).

^h Total extractable = (total extractable neutral + acid) – identified.

ⁱ Natural incorporation = pectin + lignin + hemicelluloses.

^j Total characterized = amount identified + extractable not identified (neutral + acid) + natural incorporation.

^k Accountability = total extracted (neutral + acid) + natural incorporation + unextractable.

Table 4.1.1-6: Distribution of the Parent and the Metabolites in Foliar-Flooded Scenario (F) Mature Hulls when Dosed with ¹⁴C-Labeled Florpyrauxifen-benzyl.

	¹⁴ C-PH		¹⁴ C-PY		¹⁴ C-BE ^a	
	(Elution + Load and Wash)		(Elution + Load and Wash)		(Elution + Load and Wash)	
	% TRR	ppm ^b	% TRR	ppm	% TRR	ppm
Total Radioactive Residue (TRR)	100.0	0.392	100.0	0.312	100.0	0.084
Total neutral extractable	67.7	0.266	64.7	0.202	70.8	0.059
Total extractable analysed by HPLC	52.8	0.207	53.3	0.166	52.5	0.044
XR-848-benzyl ester (34.0min)	14.2	0.056	15.7	0.049	19.2	0.016
polar (<5min)	1.3	0.005	3.7	0.012	Not Detected	
Acid/Heat labile conjugate of benzoic acid (18.0min) ^c	No ¹⁴ C-Label				15.9	0.013
X11966341 (21.83-22.80min) ^d	1.6	0.006	1.7	0.005	No ¹⁴ C-Label	
Unknown (23.5min)	0.6	0.002	1.5	0.005	Not Detected	
Unknown (23.8min)	2.4	0.009	0.6	0.002	Not Detected	
X11438848 (26.83-27.50min) ^d	3.4	0.013	3.8	0.012	No ¹⁴ C-Label	
Unknown (27.50-27.83min)	3.2	0.013	0.9	0.003	Not Detected	
X12300837 (32.0-32.3min)	1.3	0.005	Not Detected		Not Detected	
X12131932 (32.5-33.0min)	5.8	0.023	4.2	0.013	Not Detected	
Total acid extractable	2.0	0.008	2.5	0.008	Not Analyzed	
Total Identified ^e	25.0	0.098	25.3	0.079	19.2	0.016
Total extractable, not identified ^f	44.7	0.176	41.8	0.131	51.6	0.043
Pectin	6.8	0.027	6.9	0.022	Not performed	
Lignin	18.1	0.071	14.4	0.045		
Hemicellulose	Not performed		Not performed			
Total Natural Incorporation ^g	25.0	0.098	21.3	0.066	N/A	N/A
Total characterized ^h	96.7	0.379	90.9	0.284	70.8	0.059
Total unextractable	19.1	0.075	18.0	0.056	31.2	0.026
Accountability ⁱ	113.8	0.446	106.5	0.333	102.0	0.086

^a More information on benzyl ester metabolites is available in the final report.

^b mg XR-848-benzyl ester eq/kg.

^c Metabolite is not relevant for ¹⁴C-BE labeled samples.

^d Metabolite confirmed by LC/MS/MS and HPLC.

^e Metabolite is not relevant for ¹⁴C-PH or ¹⁴C-PY labeled samples.

^f Identified = sum known metabolites (not including conjugates or polar).

^g Total extractable, not identified = (total extractable neutral + acid) - identified.

^h N/A = not analyzed.

ⁱ Natural incorporation = pectin + lignin + hemicelluloses.

^j Total characterized = amount identified + extractable not identified (neutral + acid) + natural incorporation.

^k Accountability = total extracted (neutral + acid) + natural incorporation + unextractable.

Table 4.1.1-7: Distribution of the Parent and the Metabolites in Foliar-Flooded Scenario (F) Mature Grain when Dosed with ¹⁴C-Labeled Florpyrauxifen-benzyl.

	¹⁴ C-PH		¹⁴ C-PY		¹⁴ C-BE	
	(Elution + Load and Wash)		(Elution + Load and Wash)			
	% TRR	ppm ^a	% TRR	ppm	% TRR	ppm
Total Radioactive Residue (TRR)	100.0	0.032	100.0	0.024	100.0	0.007
Total neutral extractable	44.0	0.014	36.5	0.009	Not Applicable, TRR less than 0.01 ppm	
Total extractable analysed by HPLC	33.2	0.011	25.1	0.006		
XR-848-benzyl ester (34.0min)	6.0	0.002	3.9	0.001	Not Applicable, TRR less than 0.01 ppm	

Table 4.1.1-7: Distribution of the Parent and the Metabolites in Foliar-Flooded Scenario (F) Mature Grain when Dosed with ¹⁴C-Labeled Florpyrauxifen-benzyl.

	¹⁴ C-PH		¹⁴ C-PY		¹⁴ C-BE	
	(Elution + Load and Wash)		(Elution + Load and Wash)			
	% TRR	ppm ^a	% TRR	ppm	% TRR	ppm
X11966341 (21.83-22.80min)	3.2	0.001	2.1	0.001		
X11438848 (26.83-27.50min)	4.0	0.001	Not Detected			
X12131932 (32.5-33.0min)	2.6	0.001	Not Detected			
Total acid extractable	Not Analyzed		Not Analyzed		Not Applicable, TRR less than 0.01 ppm	
Total Identified ^b	15.8	0.005	6.0	0.001		
Total extractable, not identified ^c	28.2	0.009	30.5	0.007		
Total Natural Incorporation as Starch ^d	19.7	0.006	34.3	0.008		
Total characterized ^e	63.7	0.020	70.8	0.016		
Total unextractable	47.6	0.015	68.0	0.017		
Accountability ^f	91.6	0.029	104.5	0.025		

^a mg XR-848-benzyl ester eq./kg

^b Identified = sum known metabolites (not including conjugates or polar)

^c Total extractable, not identified = (total extractable neutral + acid) - identified

^d Natural incorporation for grain, starch isolation only, starch isolation was performed using fresh tissue: total accountability for fresh tissue starch isolation was 98.7% for ¹⁴C-PH and 97.8% for ¹⁴C-PY.

^e Total characterized = amount identified + extractable not identified (neutral + acid) + natural incorporation.

^f Accountability = total extracted (neutral + acid) + unextractable.

Dry-seeded: for all labels about 60-90% of the TRR was extracted from immature rice, mature rice straw and mature hulls, while 10-20% was extracted from mature rice grain.

The immature plant major residues were florpyrauxifen-benzyl (19.4-25.3% TRR), X11966341 (loss of benzyl and methyl esters, 15.0-18.0% TRR), and from the BE-label, benzoic acid (15.2% TRR). Residues of X11966341 were higher than residues of X11438848 (loss of benzyl ester to form the acid), indicating that initially X11438848 is rapidly metabolized. X12131932, the dechlorinated benzyl ester, was observed in all immature samples (4.2-5.6% TRR, 0.006-0.021 ppm).

Residues in mature straw and hulls contain parent florpyrauxifen-benzyl (13.2-23.0% TRR), X11966341 (11-14% TRR in straw and 1.7-2.9% TRR in hulls, indicating limited translocation of X11966341 into untreated parts of the plant), X11438848 (1.9-6.0% TRR), and X12131932 (4.2-5.5% TRR). Benzoic acid was not present in the BE-label mature samples. The benzoic acid was further metabolized to form a conjugate (18.3 and 13.7% TRR in straw and hulls, respectively) that released benzoic acid with both acid and heat. X11966341 was also conjugated with glucose to form X12431091 (\leq 9.2% TRR). Extractable residues in mature grain were low (< 0.01 ppm) for all labels.

For PH-label immature rice sample, all straw samples, and PH- and PY-label hulls, the post-extracted solids remaining after the neutral ASE extractions were further extracted and hydrolyzed using 1 N HCl. For the PH-label, 1.3% TRR (0.005 ppm) for immature rice and

1.3% to 2.1% TRR (0.006-0.029 ppm) for straw samples was extracted with the acid hydrolysis. For the PH- and PY-label hulls 2.5% to 2.7% TRR (0.003 and 0.005 ppm, respectively) was extracted with the acid hydrolysis.

The PH-label immature rice showed a small amount of naturally incorporated residue as pectin (1% of the TRR). For the straw (all radiolabels), the naturally incorporated residue was distributed evenly amongst pectin, lignin, and hemicelluloses (1.9-6.1% TRR), totalling 6.1-12.3% of the TRR. PY-label hulls contained 12.1% TRR associated with lignin, and 6.5% TRR associated with pectin. In all radiolabels, 31.8%-44.4% TRR was bound in the starch of the rice grain.

Table 4.1.1-8: Distribution of the Parent and the Metabolites in Dry-Seeded Scenario (D) Immature Plants when Dosed with ¹⁴C-Labeled Florpyrauxifen-benzyl.

	¹⁴ C-PH (Elution)		¹⁴ C-PY (Elution)		¹⁴ C-BE ^a (Elution)	
	% TRR	ppm ^b	% TRR	Ppm	% TRR	ppm
	Total Radioactive Residue (TRR)	100.0	0.392	100.0	0.334	100.0
Total extractable	85.7	0.336	95.1	0.318	89.5	0.137
Total extractable analysed by HPLC	77.3	0.303	89.1	0.298	75.7	0.116
XR-848-benzyl ester (34.0min)	19.4	0.076	25.3	0.085	19.4	0.030
X11966341 (22.00-22.83min) ^c	15.0	0.059	18.0	0.060	No ¹⁴ C-Label	
Unknown (22.00-22.83min)	No ¹⁴ C-Label				4.2	0.006
Benzoic Acid (23.67min) ^d	No ¹⁴ C-Label				15.2	0.023
X11438848 (27.00-27.33min) ^c	3.9	0.015	5.4	0.018	No ¹⁴ C-Label	
Unknown (28.50min)	2.9	0.011	1.7	0.006	Not Detected	Not Detected
Unknown (29.00min)	2.9	0.011	1.3	0.004	Not Detected	Not Detected
X12300837 (32.33min)	2.8	0.011	1.9	0.006	Not Detected	Not Detected
X12131932 (32.67-33.00min)	5.3	0.021	5.6	0.019	4.2	0.006
Total acid extractable	1.3	0.005	Not Analyzed	Not Analyzed	Not Analyzed	Not Analyzed
Total Identified ^e	43.6	0.171	54.3	0.181	38.8	0.059
Total extractable, not identified ^f	43.3	0.170	40.8	0.137	50.7	0.078
Total Natural Incorporation ^g (Pectin Only)	1.0 ^j	0.004 ^j	Not Analyzed	Not Analyzed	Not Analyzed	Not Analyzed
Total characterized ^h	89.2	0.350	95.1	0.318	89.5	0.137
Total unextractable	10.8	0.042	13.4	0.045	16.3	0.025
Accountability ⁱ	98.7	0.387	108.5	0.363	105.8	0.162

^a More information on benzyl ester metabolites is available in the final report.

^b mg XR-848-benzyl ester eq./kg.

^c Metabolite is not relevant for ¹⁴C-BE labeled samples.

^d Metabolite is not relevant for ¹⁴C-PH or ¹⁴C-PY labeled samples.

^e Identified = sum known metabolites (not including conjugates or polar).

^f Total extractable, not identified = (total extractable neutral + acid) - identified.

^g Natural incorporation = pectin + lignin + hemicelluloses.

^h Total characterized = amount identified + extractable not identified (neutral + acid) + natural incorporation.

ⁱ Accountability = total extracted (neutral + acid) + natural incorporation + unextractable.

^j PH-label immature rice contained 1.0% TRR (0.004 mg eq./kg) as pectin; no analyses were conducted for lignin or hemicelluloses.

Table 4.1.1-9: Distribution of the Parent and the Metabolites in Dry-Seeded Scenario (D) Mature Straw when Dosed with ¹⁴C-Labeled Florpyrauxifen-benzyl (Metabolites >2.5% shown).

	¹⁴ C-PH		¹⁴ C-PY		¹⁴ C-BE ^a	
	(Elution + Load/Wash)		(Elution + Load/Wash)		(Elution)	
	% TRR	ppm ^b	% TRR	Ppm	% TRR	ppm
TRR	100.0	1.101	100.0	1.699	100.0	0.480
Total extractable	76.7	0.844	81.2	1.379	84.7	0.406
Total analysed by HPLC	77.3	0.851	90.7	1.541	76.2	0.365
XR-848-benzyl ester (34.0min) ^c	20.3	0.223	23.0	0.390	20.5	0.098
Polar (<5.00min)	1.2	0.013	2.9	0.049	ND ^d	ND
X12431091 (16.67min) ^{c, e}	2.9	0.032	9.2	0.157	No ¹⁴ C-Label	
Unknown (16.67min)	No ¹⁴ C-Label				3.7	0.018
Acid/Heat labile conjugate of benzoic acid (18.33-18.67min) ^{c, f}	No ¹⁴ C-Label				18.3	0.088
X12431475 (19.67min)	0.5	0.005	0.8	0.013	No ¹⁴ C-Label	
Unknown (19.67min)	No ¹⁴ C-Label				3.8	0.018
X11966341 (22.00-22.83min) ^{c, e}	11.1	0.123	14.0	0.238	No ¹⁴ C-Label	
Unknown (22.00-22.83min)	No ¹⁴ C-Label				6.9	0.033
X12427971 (26.17-26.33min) ^e	2.3	0.026	2.5	0.042	No ¹⁴ C-Label	
X11438848 (27.00-27.33min) ^{c, e}	4.5	0.050	6.0	0.101	No ¹⁴ C-Label	
Unknown (27.67min)	2.5	0.028	2.9	0.049	0.6	0.003
Unknown (28.50min)	ND	ND	2.5	0.043	0.6	0.003
Unknown (29.00min)	3.1	0.034	1.5	0.025	1.9	0.009
Unknown (29.67min)	3.1	0.034	1.1	0.019	ND	ND
Unknown (30.67min)	2.0	0.022	3.4	0.059	0.8	0.004
X12131932 (32.67-33.00min) ^c	5.5	0.061	4.4	0.074	4.4	0.021
Total acid extractable	2.1	0.023	1.7	0.029	1.3	0.006
Total Identified ^g	43.9	0.483	47.3	0.804	24.9	0.119
Total extractable, not identified ^h	32.7	0.360	33.8	0.575	59.9	0.287
Pectin	2.9	0.032	1.9	0.032	6.1	0.029
Lignin	5.9	0.065	4.4	0.074	Not performed	
Hemicellulose	3.5	0.039	3.7	0.063		
Total Natural Incorporation ⁱ	12.3	0.136	10.0	0.169	6.1	0.029
Total characterized ^j	91.1	1.002	92.8	1.576	92.2	0.442
Total unextractable	4.6	0.051	4.2	0.072	11.1	0.053
Accountability ^k	95.7	1.053	97.0	1.648	103.3	0.495

^a More information on benzyl ester metabolites is available in the final report.

^b Mg XR-848-benzyl ester eq/kg.

^c Metabolite confirmed by LC/MS/MS and HPLC.

^d ND = not detected.

^e Metabolite is not relevant for ¹⁴C-BE labeled samples.

^f Metabolite is not relevant for ¹⁴C-PH or ¹⁴C-PY labeled samples.

^g Identified = sum known metabolites (not including conjugates or polar).

^h Total extractable, not identified = (total extractable neutral + acid) – identified.

ⁱ Natural incorporation = pectin + lignin + hemicelluloses.

^j Total characterized = amount identified + extractable not identified (neutral + acid) + natural incorporation.

^k Accountability = total extracted (neutral + acid) + natural incorporation + unextractable.

Table 4.1.1-10: Distribution of the Parent and the Metabolites in Dry-Seeded Scenario (D) Mature Hulls when Dosed with ¹⁴C-Labeled Florpyrauxifen-benzyl.

	¹⁴ C-PH		¹⁴ C-PY		¹⁴ C-BE ^a	
	(Elution + Load/Wash)		(Elution + Load/Wash)		(Elution)	
	% TRR	ppm ^b	% TRR	Ppm	% TRR	ppm
Total Radioactive Residue	100.0	0.127	100.0	0.178	100.0	0.078
Total extractable	60.4	0.077	63.0	0.112	61.6	0.048
Total extractable analysed by HPLC	56.5	0.072	54.8	0.098	50.5	0.040
XDE-848-benzyl ester (34.0min)	18.4	0.023	13.2	0.023	18.0	0.014
X12431091 (16.67min)	Not Detected	Not Detected	2.0%	0.004	No ¹⁴ C-Label	
Acid/Heat labile conjugate of benzoic acid (18.33-18.67min) ^c	No ¹⁴ C-Label				13.7	0.011
X11966341 (22.00-22.83min) ^d	1.7	0.002	2.9	0.005	No ¹⁴ C-Label	
X11438848 (27.00-27.33min) ^d	1.9	0.002	2.7	0.005	No ¹⁴ C-Label	
X12131932 (32.67-33.00min)	5.4	0.007	4.2	0.007	4.7	0.004
Total acid extractable	2.5	0.003	2.7	0.005	N/A	N/A
Total Identified ^e	27.4	0.035	22.9	0.041	36.4	0.029
Total extractable, not identified ^f	32.9	0.042	31.8	0.057	25.2	0.020
Total Natural Incorporation ^g	Not analysed		18.6 ^j	0.033 ^j	Not analysed	
Total characterized ^h	62.9	0.080	76.0	0.136	61.6	0.048
Total unextractable	35.9	0.046	6.4	0.011	34.4	0.027
Accountability ⁱ	96.3	0.122	90.7	0.162	96.0	0.075

^a More information on benzyl ester metabolites is available in the final report..

^b mg XR-848-benzyl ester eq/kg.

^c Metabolite is not relevant for ¹⁴C-PH or ¹⁴C-PY labeled samples.

^d Metabolite is not relevant for ¹⁴C-BE labeled samples.

^e Identified = sum known metabolites (not including conjugates or polar).

^f Total extractable, not identified = (total extractable neutral + acid) – identified.

^g Natural incorporation = pectin + lignin + hemicelluloses.

^h Total characterized = amount identified + extractable not identified (neutral + acid) + natural incorporation.

ⁱ Accountability = extracted (neutral + acid) + natural incorporation + unextractable.

^j PY-label contained pectin (6.5% TRR, 0.012 mg eq/kg) and lignin (12.1% TRR, 0.022 mg eq/kg); no analyses were performed for hemicelluloses.

Table 4.1.1-11: Distribution of the Parent and the Metabolites in Dry-Seeded Scenario (D) Mature Grain when Dosed with ¹⁴C-Labeled Florpyrauxifen-benzyl.

	¹⁴ C-PH		¹⁴ C-PY		¹⁴ C-BE ^a	
	(Elution + Load/Wash)		(Elution + Load/Wash)		(Elution)	
	% TRR	ppm ^b	% TRR	Ppm	% TRR	ppm
Total Radioactive Residue (TRR)	100.0	0.009	100.0	0.015	100.0	0.011
Total extractable	23.3	0.002	17.5	0.003	10.4	0.001
Total extractable analysed by HPLC	Not analysed, extracted TRR less than 0.01 ppm					
Total acid extractable	Not Analyzed					
Total Identified ^c	Not Analyzed					
Total extractable, not identified ^f	23.3	0.002	17.5	0.003	10.4	0.001
Total Natural Incorporation as Starch ^g	44.4	0.004	41.4	0.006	31.7	0.003
Total characterized ^h	67.7	0.006	58.9	0.009	42.1	0.004
Total unextractable	69.6	0.006	64.3	0.009	69.6	0.007
Accountability ⁱ	92.9	0.009	81.8	0.012	80.0	0.009

^a More information on benzyl ester metabolites is available in the final report.

^b mg XR-848-benzyl ester eq. /kg.

^c Metabolite is not relevant for ¹⁴C-PH or ¹⁴C-PY labeled samples.

^d Metabolite is not relevant for ¹⁴C-BE labeled samples.

^e Identified = sum known metabolites (not including conjugates or polar).

^f Total extractable, not identified = (total extractable neutral + acid) – identified.

^g Natural incorporation for grain, starch isolation only, starch isolation was performed using fresh tissue: total accountability for fresh tissue starch isolation was 109.8% for 4C-PH, 96.7% for 14C-PY, and 107.9% for 14C-BE.

^h Total characterized = amount identified + extractable not identified (neutral + acid) + natural incorporation.

ⁱ Accountability = extracted (neutral + acid) + unextractable.

Table 4.1.1-12: Distribution of the Parent and the Metabolites in Dry-Seeded Scenario (D) Mature Straw when Dosed with ¹⁴C-Labeled Florpyrauxifen-benzyl (Metabolites >2.5% shown).

	¹⁴ C-PH		¹⁴ C-PY		¹⁴ C-BE ^a	
	(Elution + Load/Wash)		(Elution + Load/Wash)		(Elution)	
	% TRR	ppm ^b	% TRR	Ppm	% TRR	ppm
TRR	100.0	1.101	100.0	1.699	100.0	0.480
Total extractable	76.7	0.844	81.2	1.379	84.7	0.406
Total analysed by HPLC	77.3	0.851	90.7	1.541	76.2	0.365
XR-848-benzyl ester (34.0min) ^c	20.3	0.223	23.0	0.390	20.5	0.098
Polar (<5.00min)	1.2	0.013	2.9	0.049	ND ^d	ND
X12431091 (16.67min) ^{c, e}	2.9	0.032	9.2	0.157	No ¹⁴ C-Label	
Unknown (16.67min)	No ¹⁴ C-Label				3.7	0.018
Acid/Heat labile conjugate of benzoic acid (18.33-18.67min) ^{c, f}	No ¹⁴ C-Label				18.3	0.088
X12431475 (19.67min)	0.5	0.005	0.8	0.013	No ¹⁴ C-Label	
Unknown (19.67min)	No ¹⁴ C-Label				3.8	0.018
X11966341 (22.00-22.83min) ^{c, e}	11.1	0.123	14.0	0.238	No ¹⁴ C-Label	
Unknown (22.00-22.83min)	No ¹⁴ C-Label				6.9	0.033
X12427971 (26.17-26.33min) ^e	2.3	0.026	2.5	0.042	No ¹⁴ C-Label	
X11438848 (27.00-27.33min) ^{c, e}	4.5	0.050	6.0	0.101	No ¹⁴ C-Label	
Unknown (27.67min)	2.5	0.028	2.9	0.049	0.6	0.003
Unknown (28.50min)	ND	ND	2.5	0.043	0.6	0.003
Unknown (29.00min)	3.1	0.034	1.5	0.025	1.9	0.009
Unknown (29.67min)	3.1	0.034	1.1	0.019	ND	ND
Unknown (30.67min)	2.0	0.022	3.4	0.059	0.8	0.004
X12131932 (32.67-33.00min) ^c	5.5	0.061	4.4	0.074	4.4	0.021
Total acid extractable	2.1	0.023	1.7	0.029	1.3	0.006
Total Identified ^g	43.9	0.483	47.3	0.804	24.9	0.119
Total extractable, not identified ^h	32.7	0.360	33.8	0.575	59.9	0.287
Pectin	2.9	0.032	1.9	0.032	6.1	0.029
Lignin	5.9	0.065	4.4	0.074	Not performed	
Hemicellulose	3.5	0.039	3.7	0.063		
Total Natural Incorporation ⁱ	12.3	0.136	10.0	0.169	6.1	0.029
Total characterized ^j	91.1	1.002	92.8	1.576	92.2	0.442
Total unextractable	4.6	0.051	4.2	0.072	11.1	0.053
Accountability ^k	95.7	1.053	97.0	1.648	103.3	0.495

Conclusions: The submitted primary metabolism study on rice is acceptable. For future requests with expanded uses, additional metabolism studies may be needed since diverse crops are not represented by the metabolism study.

The metabolism proceeds through cleavage of the benzyl ester from florpyrauxifen-benzyl which yields the acid compound X11438848 (see Appendix B). The acid (X11438848), is then metabolized to X11966341, and X11966341 is conjugated with glucose to form X12431091. Benzoic acid was observed in this study as a metabolite from the benzyl ester labeled XR-848-benzyl ester. In rice, benzoic acid is further conjugated into an acid/heat labile conjugate of benzoic acid. The photolysis product (X12131932), was observed in the foliar applied scenarios (foliar-flooded and dry-seeded). Metabolism proceeds through natural incorporation of the radiolabeled carbon into natural plant constituents, such as starch, pectin, lignin, or hemicellulose.

Overall, the metabolic pathway was similar for all three planting/application scenarios: water-injected scenario, foliar-flooded scenario and dry-seeded scenario. However, since the water-injected scenario was not a direct application to the plants, the incurred residues in commodities other than rice grain, were significantly lower than the foliar-flooded scenario and dry-seeded scenario even though the application rate was higher. The hydrolysis product X11438848 was the most significant metabolite in the water-injected scenario, presumably due to significant hydrolysis of florpyrauxifen-benzyl that occurred in the rice paddy water before plant uptake. For the water-injected scenario, metabolites from the benzyl ester, benzoic acid and the “acid/heat labile conjugate of benzoic acid” were not observed. The photolysis product (X12131932) was not observed in the water-injected scenario rice samples, presumably because hydrolysis of the ester was more significant route of degradation than photolysis. In all cases, X12131932 is not a significant residue in rice plants. Conjugation of X11966341 with glucose to form X12431091 was not observed in the water-injected scenario either, presumably due to the low total radioactive residue levels compared to the foliar-flooded scenario and dry-seeded scenario.

4.1.2 Summary of Livestock (860.1300) and Fish Metabolism

Tier II Summaries 49677883 Ref: IIA 4.3

Metabolism studies were conducted in livestock (lactating goats and laying hens) and bluegill fish.

Ruminants: The goat was orally dosed once daily for seven consecutive days at dose levels equivalent to 11.3, 10.7, and 10.7 ppm in the diet, for the [¹⁴C]-florpyrauxifen-benzyl PH, [¹⁴C]-florpyrauxifen-benzyl PY, and [¹⁴C]-florpyrauxifen-benzyl BE test compound, respectively. This dose level represents an exaggerated rate relative to the estimated maximum possible dietary burden to hens (~2700x). The animals were sacrificed about 6-8.5 hours after the last administration.

Following seven consecutive daily doses of [¹⁴C]-florpyrauxifen-benzyl PH and [¹⁴C]-florpyrauxifen-benzyl PY at 10.7-11.3 ppm dry feed/day in the diet, florpyrauxifen-benzyl was primarily excreted in feces (64-68%), urine (5-8%) and gastrointestinal contents (9-13%). Less than 0.022% of the dose was recovered in the edible tissues.

The TRR in all fat, muscle and milk samples were less than 0.010 ppm (florpyrauxifen-benzyl equivalents) and no further characterization of residues was conducted.

Liver and kidney were the only edible tissues that contained residues greater than 0.01 ppm. The majority of the radioactivity was extracted with neutral organic solvent (66-102%). Analyses of the liver and kidney samples showed that the major metabolites are X11438848, X11966341 (hydroxy acid) and X194907 (conjugated benzoic acid). Parent florpyrauxifen-benzyl was not observed in either the liver or kidney samples.

The majority of the residue recovered in the faeces was unchanged parent, florpyrauxifen-benzyl. Analyses of the urine samples showed primarily X11438848, X11966341 (along with lower

levels of the hydroxy acid conjugates MW414/510) and X194973 (benzoic acid) and benzoic acid conjugate X194907. Parent florpyrauxifen-benzyl was not observed in urine.

Florpyrauxifen-benzyl metabolism in lactating goats (ruminants) mainly proceeds either demethylation of X11438848 or cleavage of the benzyl ester resulted in the metabolite X11966341. Conjugation of X11966341 resulted in the metabolites MW414 and MW510. No metabolites were observed that would suggest cleavage of the bond between the phenyl and pyridine rings. None of the observed residue components appears to accumulate in the milk or edible tissues as the vast majority of the residues (>99%) were excreted. Samples were analysed within 6 months. The results from this study are comparable to those seen in laying hens.

Metabolite Fraction	PH Liver		PY Liver		BE Liver	
	% TRR	Ppm	% TRR	ppm	% TRR	Ppm
TRR ^a	100.00%	0.0076	100.00%	0.0164	100.00%	0.0215
Total Extractable ^b	74.4%	0.006	79.6%	0.013	66.2%	0.014
Total analysed by HPLC ^c	58.7%	0.004	49.7%	0.008	50.2%	0.011
Florpyrauxifen-benzyl (Parent)	ND	ND	ND	ND	ND	ND
X11438848 ^c	6.9%	0.001	6.0%	0.001	--	--
X11966341 ^c	20.8%	0.002	20.8%	0.003	--	--
X194907 ^c	--	--	--	--	13.8%	0.003
Total ID ^c	27.7%	0.002	26.8%	0.004	13.8%	0.003
Total characterized ^d	31.0%	0.002	22.9%	0.004	36.3%	0.008
Unextractable ^e	23.2%	0.002	20.5%	0.003	35.7%	0.008
Accountability ^{f, g}	97.6%	0.007	100.1%	0.0164	101.9%	0.022
Metabolite Fraction	PH Kidney		PY Kidney		BE Kidney	
	% TRR	Ppm	% TRR	ppm	% TRR	Ppm
TRR ^a	100.00%	0.0135	100.00%	0.0220	100.00%	0.0205
Total Extractable ^b	102.2%	0.014	100.6%	0.022	100.3%	0.021
Total analysed by HPLC	68.0%	0.009	79.1%	0.017	99.7%	0.020
Florpyrauxifen-benzyl (Parent)	ND	ND	ND	ND	ND	ND
X11438848 ^c	27.9%	0.004	44.7%	0.010	--	--
X11966341 ^c	24.9%	0.003	24.0%	0.005	--	--
X194907 ^c	--	--	--	--	99.7%	0.022
Total ID ^c	52.8%	0.007	68.7%	0.015	99.7%	0.022
Total characterized ^d	15.2%	0.002	10.4%	0.002	0.0%	0.000
Unextractable ^e	5.6%	0.001	7.5%	0.002	3.8%	0.001
Accountability ^{f, g}	107.8%	0.015	108.1%	0.024	103.9%	0.021

^a Determined by initial combustion.

^b The sum of the residues measured in the 80/20 methanol/water and hexanes (liver only) extractions.

^c Average of duplicate samples, more decimals places than are shown were used in these calculations.

^d Total characterized = total analyzed by HPLC – total identified by HPLC, more decimal places used in calculation than are shown.

^e Determined by oxidative combustion of debris remaining after extractions.

^f Accountability (% TRR) = total extractable % TRR + total unextractable % TRR.

^g Accountability (mg/kg) = (accountability (%TRR)/100) * TRR (mg/kg).

Poultry:

Two groups of ten laying hens were orally dosed with either [¹⁴C]-florpyrauxifen-benzyl PH Label or [¹⁴C]-florpyrauxifen-benzyl PY label, administered in a gelatin capsule, once daily for a total of 14 days. Based on food consumption during the acclimatization period, the average dose level of [¹⁴C]-florpyrauxifen-benzyl PH label was 12 ppm in the diet and [¹⁴C]-florpyrauxifen-benzyl PY label was 11 ppm in the diet. This dose level represents an exaggerated rate relative to the estimated maximum possible dietary burden to hens (~3700x). The hens were sacrificed approximately 9 hours after the final dose. TRR were determined daily in the eggs.

For both the PH and PY Label extracts, no significant differences were seen in the residue profiles. This would suggest that the bond between the phenyl ring and the pyridine ring remained intact.

The majority of the administered dose (89% of phenyl label and 91% of pyridine label) was rapidly eliminated in the excreta. The TRR levels in egg, liver, muscle, skin, and fat were low. The major residues identified were parent florpyrauxifen-benzyl, X11438848 and X11966341. The residue levels in eggs reached a plateau within about 8-12 days during the dosing phase for both [¹⁴C]-florpyrauxifen-benzyl PH label and [¹⁴C]-florpyrauxifen-benzyl PY label. The plateaus for both labels were less than 0.001 ppm. The low TRR levels in both eggs and edible tissues show that residues of florpyrauxifen-benzyl are not readily transferred into poultry meat and eggs following oral consumption. Florpyrauxifen-benzyl is metabolized in laying hens to X11438848 and X11966341. Neither of these two metabolites appeared to be converted to conjugates. None of the observed residue components appear to accumulate in the eggs or edible tissues as they are all rapidly excreted. Samples were analysed within 6 months.

The 1, 7, and day 14 excreta samples were extracted with 80:20 ACN:water and analysed (PH and PY Labels). For all labels residues in excreta were readily extractable with organic solvents 87-108%. Major residues (>10%) identified are florpyrauxifen-benzyl, X11438848, and X11966341.

Table 4.1.2-5: Total radioactive residues (TRRs) of Florpyrauxifen-benzyl in Eggs, Tissue and Excreta.					
Matrix	Collection Timing	¹⁴ C-XDE-848-BE		¹⁴ C-XDE-848-BE	
		PH-Label		PY-Label	
		(% dose)	(ppm) ^a	(% dose)	(ppm)
Whole Eggs	Day 1 to 7	ND ^b	ND	ND	ND
Whole Eggs	Day 8 to 13	(0.0001-0.0002)	(0.0005-0.0007) ^c	ND (0.0002 day 12)	ND (0.0005 day 12)
Whole Eggs	Day 14 ^d	(0.0002)	(0.0009)	ND	ND
Total		0.001	Not applicable	0.000	Not applicable
Excreta	Day 1	5.186	4.936	5.292	5.999
Excreta	Day 2	5.412	6.595	6.039	7.077
Excreta	Day 3	7.336	8.797	6.637	7.552
Excreta	Day 4	6.161	8.430	6.237	8.401
Excreta	Day 5	6.380	8.035	6.351	7.765
Excreta	Day 6	5.992	8.805	6.137	8.680
Excreta	Day 7	6.541	7.951	6.977	8.202
Excreta	Day 8	5.852	7.496	6.451	8.273
Excreta	Day 9	6.667	9.300	6.438	8.407
Excreta	Day 10	7.071	8.366	6.801	9.861

Excreta	Day 11	7.363	9.196	7.065	7.791
Excreta	Day 12	6.673	6.969	7.579	8.032
Excreta	Day 13	7.084	8.509	6.557	8.459
Excreta	Day 14 ^d	5.521	15.905	6.359	15.939
Total		89.238	Not applicable	90.920	Not applicable
Liver	Sacrifice	0.001	0.005	0.0003	(0.0010)
Leg Muscle	Sacrifice	(0.001)	(0.0008)	ND	ND
Breast Muscle	Sacrifice	ND	ND	ND	ND
Fat	Sacrifice	0.001	0.004	(0.0001)	(0.0006)
Skin with Fat	Sacrifice	0.004	0.007	0.002	0.003
Total		0.007	Not applicable	0.002	Not applicable
Cage Rinse	Sacrifice	0.418	1.287	0.347	1.426
Total (Mass Balance)		89.664	Not applicable	91.269	Not applicable

^a Detailed calculations for how concentration (mg eq./kg) was determined can be in the report for this study.

^b ND = non-detect, value was below calculated LOD of 0.00045 mg/kg.

^c Values in parentheses are below LOQ of 0.0017 mg eq./kg, but above the LOD of 0.00045 mg eq./kg.

^d Not a complete sampling day, hens sacrificed with 9 hours of day 14 dose. No a.m. eggs or excreta collect from the following day for day 14 sample. Sample consisted of eggs and excreta from a p.m. collection only.

Conclusions: The submitted livestock metabolism studies are acceptable. Adequate amounts of the administered doses were recovered in all cases. In the poultry metabolism study, residue levels were low in eggs, liver, muscle, skin, and fat. In the goat metabolism study, liver and kidney were the only edible tissues that contained residues ≥ 0.01 ppm. The major metabolites were X11438848, X11966341 and X194907 (conjugated benzoic acid). Parent florpyrauxifen-benzyl was not observed in either the liver or kidney samples. The majority of the residue recovered in the feces was unchanged parent, florpyrauxifen-benzyl. Analyses of the urine samples showed primarily X11438848, X11966341 (along with lower levels of the hydroxy acid conjugates MW414/510), and X194973 (benzoic acid conjugate X194907). Parent, florpyrauxifen-benzyl was not observed in urine.

Metabolism studies in laying hens and lactating goats showed that the metabolic pathways in livestock were similar to that found in the rat.

Fish (Bluegill Sunfish)

Tier II Summaries 49677885

A 30-day (16-day uptake phase followed by a 14-day depuration) aqueous exposure (flow through) study was conducted on bluegill sunfish, (*Lepomis macrochirus*), using [¹⁴C]-florpyrauxifen-benzyl PY label. The objectives of this study were to determine the distribution of test compound between edible and non-edible portions of the organism and characterization/identification of significant metabolites.

The study consisted of a 16-day uptake phase immediately followed by a 14-day depuration phase. Nominal test substance concentrations selected for the uptake phase were 3.0 and 30 μg [¹⁴C]-florpyrauxifen-benzyl/L. A control was also included in the study design. During the depuration phase, the fish were exposed to flowing dilution water, absent of vehicle and test substance. The uptake phase was initiated with 120 fish in the control and each treatment. During the uptake phase, water was sampled at 0, 0.17, 0.33, 1, 3, 7, 9, 11, 14, and 16-days. Fish were sampled at the same times of the uptake phase, with the exception of the 0-day. Following

the collection of all water and fish tissue samples on day 16 of the uptake phase, the depuration phase was initiated by transferring remaining fish in each uptake phase test chamber to the appropriate depuration test chamber. During the depuration phase, water was sampled at 0, 0.17, 1, 3, 7, and 14-days. Fish were sampled on depuration 0.17, 1, 3, 7, and 14-days.

Samples of fish (four/sample day) were impartially sampled in a non-systematic manner. The fish were dissected to yield fillets (edible tissue: body muscle, skin, most of the bones minus the skull) and viscera (non-edible tissue: head, internal organs, fins). Both fillet and viscera tissues were sectioned into small pieces and homogenized. Sub-samples of processed tissues were analysed using LSC.

The samples were blended with ACN and centrifuged. ACN/water (80:20) was added to the acetonitrile extract sample and centrifuged (3x). All extracts (supernatants) were combined and evaporated. The concentrated sample was diluted with water and cleaned up using a pre-conditioned SPE cartridge. All containers were rinsed with water; water/methanol (9:1); ACN/HPLC grade water (9:1; 30 mL) and the rinse was applied to the SPE cartridge. For both the viscera and the fillet extractions, the water/methanol (9:1) rinse from the first SPE was diluted with water, mixed, and applied to a new pre-conditioned SPE cartridge. The SPE was rinsed with water and eluted with ACN/water (9:1) and collected. Each collected SPE rinse fraction was counted by LSC to confirm that the radioactivity was less than 3% of the TRR before proceeding to the next step. The two ACN/water eluents were combined and evaporated. The resulting sample extracts were radioassayed and analysed by HPLC with in-line radiodetector.

Initial metabolite identification was accomplished by using HPLC. Structure confirmation of tentatively identified components as well as the identification of any significant fraction that did not co-elute with a standard was accomplished by HPLC/MS and/or HPLC/MS/MS. Because the residue level was much higher in the viscera, the viscera extract, after SPE and concentration, was directly analysed by HPLC-MS/MS.

The TRR as determined by initial combustion analysis for high dose 16-day fillet and viscera were 1.290 ppm and 14.0 ppm, respectively. The TRR for the fillet and viscera determined by addition of the extracted radioactive residues and the residual radioactivity in the extracted solids were 1.19 ppm and 11.9 ppm, respectively. The percent TRR reported for each residue/fraction during metabolite identification were based on 1.19 ppm and 11.9 ppm for the fillet and viscera, respectively.

Mean measured concentrations of the low and high ¹⁴C-florpyrauxifen-benzyl exposure treatments were 2.59 and 23.2 µg TRR/L, 86.3 and 77.3% of target, respectively. The major residues identified in the fillet were X11438848; 52.6% TRR and florpyrauxifen-benzyl (27.8% TRR). Minor metabolites include a taurine conjugate of X11438848 (6.2% TRR), dechlorinated XDE-848 acid (X12393505; 0.8% TRR). Three additional minor metabolites were detected, but each comprised ≤0.8% of the TRR. Overall, 85.7% of the viscera TRR (10.227 ppm) and 87.4% of the fillet TRR (1.040 ppm) was conclusively identified by LC-MS/MS, and all radioactive residues that comprised >5% TRR in either tissue type were identified. The major residue identified in the viscera is X11438848; 69.1% TRR. Minor metabolites include, a taurine

conjugate of X11438848 (8.0% TRR), florpyrauxifen-benzyl (7.9% TRR), and XDE-848 deschloro-acid (X12393505; 0.8% TRR). Four additional minor metabolites were detected, but each comprised $\leq 1.2\%$ TRR.

Table 4.1.2-6: Summary of Characterization and Identification of Radioactive Residues of ^{14}C -Labeled Florpyrauxifen-benzyl Bluegill Sunfish Tissues of the $30\ \mu\text{g a.i./L}$ Treatment on Day 16 of the Bioconcentration Study.

Compound	Edible portion (fillet) TRR = 1.29 ppm		Non-edible portion (viscera) TRR = 14.0 ppm	
	% TRR	ppm	% TRR	ppm
Florpyrauxifen-benzyl	27.8	0.331	7.9	0.947
X12393505	0.8	0.010	0.8	0.092
X11438848 taurine conjugate	6.2	0.074	8.0	0.952
X11438848	52.6	0.626	69.1	8.237
Total identified	87.4	1.041	85.8	10.228
Total no. of metabolites identified	7		8	
Total no. of metabolites characterized	4		4	
Total extractable	96.9	1.153	98.9	11.792
Unextractable (PES) ¹	3.1	0.037	1.1	0.137
Total recovered ²	100	1.190	100	11.928
Accountability ³	92.2		85.2	

¹ Residues remaining after exhaustive extractions

² Total recovered = total extractable + Unextractable

³ Accountability = (Total recovered)/(TRRs from combustion analysis) * 100

Conclusions:

The bluegill sunfish study is adequate. In bluegill sunfish, (*Lepomis macrochirus*) exposed to [^{14}C]- florpyrauxifen-benzyl PY, under flow-through conditions at 2.59 and 23.2 $\mu\text{g/L}$ (Mean) for 16 days, the major residues identified in the fillet (edible portion) were X11438848 and florpyrauxifen-benzyl. Minor metabolites identified include a taurine conjugate of X11438848 and X12393505.

Metabolism study in bluegill sunfish, showed that the metabolic pathway is similar to laying hens and lactating goats.

4.1.3 Summary of Confined Rotational Crops (860.1850)

Tier II Summaries 49677883 Ref: IIA 6.6.2

The metabolism of florpyrauxifen-benzyl in representative rotational crops (wheat, lettuce or mustard, and radish) from three consecutive rotations was investigated. Phenyl-, pyridine-, and benzyl-labeled ^{14}C -florpyrauxifen-benzyl were each formulated as an EC formulation (GF-3175) and soil applied to confined plots of sandy loam soil at a rate of 120 g a.i./ha (0.107 lb ai/A) which is 2X the current maximum seasonal rate. The crops were each sown at 30, 90, and 271 days after soil application.

Lettuce did not germinate at 30- or 90-day PBIs, and was replaced with mustard at the 271-day PBI, from which both immature and mature mustard were harvested. The 30-day plant-back radishes germinated, but did not survive to maturity. Radish tops and roots were harvested from the 90- and 271-day PBI. Wheat forage, hay, mature grain, and straw were harvested at each of the PBIs.

The TRR levels were determined by extraction and/or combustion. The TRRs were <0.01 ppm in all matrices from each label at all PBIs, except wheat hay and straw. For wheat hay and straw, residues in crops at all plant-back intervals ranged from 0.001 to 0.046 ppm eq./kg (parent equivalents) The BE-label wheat samples residue levels were consistently lower than the PH- and PY-labels, which were below 0.01 ppm. These data demonstrate that neither parent nor soil degradates are significantly taken up by plants grown in soil treated with florpyrauxifen-benzyl. Most of the metabolites found in the crop rotation study correspond to metabolites found in the plant metabolism studies.

Table 4.1.3-1: Total Radioactive Residues in Confined Rotational Crops Grown in Aged Soil Treated with Florpyrauxifen-benzyl.

Matrix ^a	Plant-back interval (days)	TRR		
		¹⁴ C-PH ppm	¹⁴ C-PY ppm	¹⁴ C-BE Ppm
Immature Lettuce	30	NS	NS	NS
Mature Lettuce	30	NS	NS	NS
Immature Lettuce	90	NS	NS	NS
Mature Lettuce	90	NS	NS	NS
Immature Mustard	271	<LOQ ^c	<LOQ ^c	<LOQ ^c
Mature Mustard	271	<LOQ ^c	<LOQ ^c	<LOQ ^c
Radish Tops	30	NS	NS	NS
Radish Roots	30	NS	NS	NS
Radish Tops	90	0.004	0.005	<LOQ ^c
Radish Roots	90	0.003	0.006	0.004
Radish Tops	271	<LOQ ^c	<LOQ ^c	<LOQ ^c
Radish Roots	271	<LOQ ^c	<LOQ ^c	<LOQ ^c
Wheat Forage	30	0.004	0.006	0.003
Wheat Forage	90	0.003	0.004	0.002
Wheat Forage	271	<LOQ ^c	0.008 ^a	<LOQ ^c
Wheat Hay	30	0.017	0.013	0.007
Wheat Hay	90	0.013	0.028	0.005
Wheat Hay	271	0.005	0.026 ^{a,b}	<LOQ ^c
Wheat Straw	30	0.025	0.033	0.006
Wheat Straw	90	0.034	0.046	0.005
Wheat Straw	271	0.006	0.033 ^a	<LOQ ^c
Wheat Grain	30	0.002	0.002	0.005
Wheat Grain	90	0.003	<LOQ ^c	0.002
Wheat Grain	271	<LOQ ^c	<LOQ ^c	<LOQ ^c

Control samples (not shown) contained from 11 to 163 dpm/g and represented <LOQ to 0.002mg /kg.

NS = no sample; crop did not grow to the desired growth stage

^a The PY-labeled wheat planted 271 days after application to soil did not grow well; the pH was abnormally low.

^b TRR calculated as 0.022 mg eq/kg was adjusted to a target moisture content of 15% (from 29.4%, see Section.

^c where LOQ = 0.0028 ppm.

Table 4.1.3-2: Distribution of the Parent and the Metabolites in 30 DAT Wheat Hay Rotational Crop Matrices when Dosed with ¹⁴C-Labeled Florpyrauxifen-benzyl.

	¹⁴ C-PH		¹⁴ C-PY		¹⁴ C-BE	
	%TRR	ppm ^a	%TRR	ppm ^a	%TRR	ppm ^a
Total Radioactive Residue (TRR) ^b	100.0%	0.017	100.0%	0.013	100.0%	0.006
Total extractable ^c	82.7%	0.014	83.4%	0.011	24.8%	0.002
Total extractable analysed by HPLC ^d	62.5%	0.010	65.1%	0.008	Not Applicable, TRR less than 0.01 ppm	
XDE-848-benzyl ester X11959130 (34 min) ^e	Not Detected		Not Detected			
X11438848 (28 min) ^e	Not Detected		Not Detected			
X12427971 (26 min) ^e	Not Detected		Not Detected			
X11966341 (22 min) ^e	11.8	0.002	10.4	0.001		
X12431475 (20 min) ^e	6.5	0.001	4.2	0.001		
X12431091 (17 min) ^e	44.3	0.007	50.5	0.006		
Total Identified ^f	62.5	0.010	65.1	0.008		
Total unextractable	16.5%	0.003	14.7%	0.002	70.6%	0.005
Accountability ^g	99.2%	0.016	98.1%	0.013	95.5%	0.007

^a mg XDE-848-benzyl ester eq/kg

^b TRR in mg XDE-848-benzyl ester mg/kg values from TRR table.

^c The sum of all six extractions.

^d This is the amount remaining after combining the first four extracts and purification procedures by SPE.

^e These metabolites were tentatively identified by co-chromatography with reference standards.

^f Total identified = sum of metabolites that were tentatively identified.

^g Accountability = total extractable + unextractable.

Table 4.1.3-3: Distribution of the Parent and the Metabolites in 30 DAT Wheat Straw Rotational Crop Matrices when Dosed with ¹⁴C-Labeled Florpyrauxifen-benzyl.

	¹⁴ C-PH		¹⁴ C-PY		¹⁴ C-BE	
	%TRR	ppm ^a	%TRR	ppm ^a	%TRR	ppm ^a
Total Radioactive Residue (TRR) ^b	100.0%	0.025	100.0%	0.033	100.0%	0.005
Total extractable ^c	80.2%	0.020	82.5%	0.027	44.5%	0.002
Total extractable analysed by HPLC ^d	64.0%	0.016	65.6%	0.022	Not Applicable, TRR less than 0.01 ppm	
XDE-848-benzyl ester X11959130 (34 min) ^e	Not Detected		Not Detected			
X11438848 (28 min) ^e	Not Detected		4.1	0.001		
X11966341 (22 min) ^e	22.6	0.006	17.7	0.006		
X12431475 (20 min) ^e	3.5	0.001	2.9	0.001		
X12431091 (17 min) ^e	19.6	0.005	15.8	0.005		
Analyzed by HPLC but unidentified ^f	18.3	0.005	25.2	0.008		
Largest unidentified peak ^g	6.9	0.002	7.1	0.002		
Total Identified ^h	45.7	0.012	40.4	0.013	55.5%	
Total unextractable	18.3%	0.005	18.9%	0.006		
Accountability ⁱ	98.5%	0.025	101.4%	0.034	112.8%	0.005

^a mg XDE-848-benzyl ester eq/kg

^b TRR in mg XDE-848-benzyl ester eq/kg values from **Error! Reference source not found.**

^c The sum of all six extractions.

^d This is the amount remaining after combining the first four extracts and purification procedures by SPE.

^e These metabolites were tentatively identified by co-chromatography with reference standards.

^f These were peaks of extractable radioactivity that did not co-chromatograph with parent XDE-848-benzyl ester compound, X11438848, X12427971, X11966341, X12431475 or X12431091.

^g This was the largest unidentified peak.

^h Total identified = sum of metabolites that were tentatively identified.

ⁱ Accountability = total extractable + unextractable.

	¹⁴ C-PH		¹⁴ C-PY		¹⁴ C-BE	
	%TRR	ppm ^a	%TRR	ppm ^a	%TRR	ppm ^a
Total Radioactive Residue (TRR) ^b	100.0%	0.013	100.0%	0.028	100.0%	0.005
Total extractable ^c	72.7%	0.010	71.2%	0.020	23.2%	0.001
Total extractable analysed by HPLC ^d	56.9%	0.008	49.8%	0.014	Not Applicable, TRR less than 0.01 ppm	
XDE-848-benzyl ester X11959130 (34 min) ^e	Not Detected		Not Detected			
X11438848 (28 min) ^e	2.7	<0.001	3.0	0.001		
X11966341 (22 min) ^e	12.5	0.002	10.9	0.003		
X12431475 (20 min) ^e	4.8	0.001	4.2	0.001		
X12431091 (17 min) ^e	18.6	0.002	14.2	0.004		
Analyzed by HPLC but unidentified ^f	18.3	0.002	17.4	0.005		
Largest unidentified peak ^g	5.0	0.001	4.4	0.001		
Total Identified ^h	38.7	0.005	32.4	0.009		
Total unextractable	21.2%	0.003	15.5%	0.004		
Accountability ⁱ	93.9%	0.013	86.7%	0.024	96.8%	0.005

^a mgXDE-848-benzyl ester eq/kg

^b TRR in mg XDE-848-benzyl ester eq/kg values from TRR table.

^c The sum of all six extractions.

^d This is the amount remaining after combining the first four extracts and purification procedures by SPE.

^e These metabolites were tentatively identified by co-chromatography with reference standards.

^f These were peaks of extractable radioactivity that did not co-chromatograph with parent XDE-848-benzyl ester compound, X11438848, X12427971, X11966341, X12431475 or X12431091.

^g This was the largest unidentified peak.

^h Total identified = sum of metabolites that were tentatively identified.

ⁱ Accountability = total extractable + unextractable.

	¹⁴ C-PH		¹⁴ C-PY		¹⁴ C-BE	
	%TRR	ppm ^a	%TRR	ppm ^a	%TRR	ppm ^a
Total Radioactive Residue (TRR) ^b	100.0%	0.034	100.0%	0.046	100.0%	0.005
Total extractable ^c	75.6%	0.026	73.2%	0.034	36.4%	0.002
Total extractable analysed by HPLC ^d	84.4%	0.029	46.4%	0.021	Not Applicable, TRR less than 0.01 ppm	
XDE-848-benzyl ester X11959130 (34 min) ^e	Not Detected		Not Detected			
X11438848 (28 min) ^e	4.6	0.002	Not Detected			
X11966341 (22 min) ^f	24.6	0.008	14.2	0.007		
X12431475 (20 min) ^e	3.8	0.001	3.1	0.001		
X12431091 (17 min) ^f	17.3	0.006	13.3	0.006		
Analyzed by HPLC but unidentified ^g	34.1	0.012	15.8	0.007		

Table 4.1.3-5: Distribution of the Parent and the Metabolites in 90 DAT Wheat Starw Rotational Crop Matrices when Dosed with ¹⁴C-Labeled Florpyrauxifen-benzyl.

	¹⁴ C-PH		¹⁴ C-PY		¹⁴ C-BE	
	%TRR	ppm ^a	%TRR	ppm ^a	%TRR	ppm ^a
Largest unidentified peak ^h	6.0	0.002	3.0	0.001		
Total Identified ^d	50.3	0.017	30.6	0.014		
Total unextractable	29.8%	0.010	30.7%	0.014	91.0%	0.005
Accountability ^j	105.4%	0.036	104.0%	0.048	127.3%	0.006

^a mg XDE-848-benzyl ester mg/kg.

^b TRR in mg XDE-848-benzyl ester eq/kg values from TRR table.

^c The sum of all six extractions.

^d This is the amount remaining after combining the first four extracts and purification procedures by SPE.

^e These metabolites were tentatively identified by co-chromatography with reference standards.

^f These metabolites were positively identified by both mass spectrometry analysis and co-chromatography with reference standards.

^g These were peaks of extractable radioactivity that did not co-chromatograph with parent XDE-848-benzyl ester compound, X11438848, X12427971, X11966341, X12431475 or X12431091.

^h This was the largest unidentified peak.

ⁱ Total identified = sum of metabolites that were tentatively identified.

^j Accountability = total extractable + unextractable.

Table 4.1.3-6: Distribution of the Parent and the Metabolites in 271 DAT Wheat Hay and Straw Rotational Crop Matrices when Dosed with ¹⁴C-Labeled Florpyrauxifen-benzyl.

	¹⁴ C-PY Wheat Hay		¹⁴ C-PY Wheat Straw	
	%TRR	ppm ^a	%TRR	ppm ^a
Total Radioactive Residue (TRR) ^b	100.0%	0.026	100.0%	0.033
Total extractable ^c	86.3%	0.023	76.7%	0.025
Total extractable analysed by HPLC ^d	50.4%	0.013	38.6%	0.013
XDE-848-benzyl ester X11959130 (34 min) ^e	3.5 ^j	0.001 ^j	Not Detected	
X11438848 (28 min) ^e	17.0 ⁱ	0.004 ^j	4.5 ^j	0.001 ^j
X11966341 (22 min) ^e	25.4	0.007	11.2	0.004
X12431475 (20 min) ^e	Not Detected		2.3	0.001
X12431091 (17 min) ^e	4.5	0.001	9.9	0.003
Analyzed by HPLC but unidentified ^f	Not Detected		10.7	0.003
Largest unidentified peak ^g	Not Detected		4.5	0.001
Total Identified ^h	50.4	0.013	27.9	0.009
Total unextractable	20.1%	0.005	31.5%	0.010
Accountability ^j	106.3%	0.028	108.2%	0.035

^a mg XDE-848-benzyl ester /kg

^b TRR in mg XDE-848-benzyl ester /kg values from TRR table.

^c The sum of all six extractions.

^d This is the amount remaining after combining the first four extracts and purification procedures by SPE.

^e These metabolites were tentatively identified by co-chromatography with reference standards.

^f These were peaks of extractable radioactivity that did not co-chromatograph with parent XDE-848-benzyl ester compound, X11438848, X12427971, X11966341, X12431475 or X12431091.

^g This was the largest unidentified peak.

^h Total identified = sum of metabolites that were tentatively identified.

ⁱ Accountability = total extractable + unextractable.

^j Note that these plants (PY-label, 271 day plant-back) did not grow well, presumably due to low soil pH, which may have also slowed XDE-848 benzyl ester.

Conclusions:

The confined rotational crop studies provided for phenyl-, pyridine-, and benzyl-labeled ¹⁴C-florpyrauxifen-benzyl adequately defines the nature of the residue in three crop types planted in treated soil at intervals of 30, 90, and 271 days. Lettuce didn't germinate at 30 and 90-day including radish at the 30-day PBI. The TRRs were <0.01 ppm in all matrices from each label at all PBIs, except wheat hay and straw. Parent and metabolites were not detected on most of the crops or were only detected at low levels (≤ 0.01 ppm). The metabolism in confined rotational crops was similar to primary plants.

4.1.4 Summary of Metabolites and Degradates

Appendix A summarizes the metabolites found in the plant, livestock, and bluegill sunfish metabolism studies. Appendix B provides proposed metabolic pathway diagrams.

4.2 Comparison of Metabolic Pathways

The metabolic pathways in rice is well understood based on characterization and identification of the residues. The metabolism in confined rotational crops was similar to that in primary plants, with similar metabolites. Parent, florpyrauxifen-benzyl, X11438848, X11966341 are the major residues. The majority of the metabolites in plants are also rat metabolites.

The nature of the residue in ruminants, poultry, and fish is adequately understood based on acceptable studies conducted on lactating goats, laying hens, and bluegill sunfish metabolism studies. The metabolism studies indicate degradation pathways similar to the plant and rat metabolism pathways.

On basis of the metabolites identified, the major metabolic pathways in plants, rotational crops, and livestock include: cleavage of the benzyl ester to give X11438848 metabolite and benzyl alcohol (theoretical hydrolysis product). The X11438848 undergoes demethylation to give X11966341.

4.3 Residues of Concern Summary and Rationale

ROCKS Decision Memo Reference: Ideliz Encarnacion, D436519, 11/29/2016

Residues of Concern for Tolerance Enforcement: Parent florpyrauxifen-benzyl and X11438848 were the predominant residues observed in primary crops, rotational crops, fish and livestock. Based on this, HED recommends parent florpyrauxifen-benzyl and X11438848 as the residues of concern for tolerance enforcement. It is important to note that tolerance on rice grain is being established for trade purposes only.

The hydroxy acid (X11966341) is a hydrolysis product of X11438848 and was not a major residue (<0.01 ppm) in the edible tissues, kidney and liver. Therefore, it is not included in the residue of concern.

Residues of Concern for Risk Assessment: Residues of concern in plants, livestock, fish, and water were not selected for risk assessment purposes based on the absence of adverse effects at the highest doses tested in all of the required toxicity studies for florpyrauxifen-benzyl, and the structural similarity of most degradates/metabolites with the parent compound. Those that retain

all the rings of the parent compound are expected to have the same or lesser toxicity and similar hazard. Based on this, no quantitative assessment is necessary for parent or degradates/metabolites at this time.

The ROCKS recommends the following language for the tolerance expression for primary crops, rotational crops, fish (including shellfish), and livestock commodities:

Tolerances are established for residues of florpyrauxifen-benzyl, including its metabolites and degradates, in or on the commodities in the table below. Compliance with the tolerance levels for florpyrauxifen-benzyl is to be determined by measuring only the sum of florpyrauxifen-benzyl (Benzyl 4-amino-3-chloro-6-(4-chloro-2-fluoro-3-methoxy-phenyl)-5-fluoro-pyridine-2-carboxylate) and its acid metabolite X11438848 (4-Amino-3-chloro-6-(4-chloro-2-fluoro-3-methoxy-phenyl)-5-fluoro-pyridine-2-carboxylic acid), calculated as the stoichiometric equivalent of florpyrauxifen-benzyl, in or on the commodity.

Table 4.3. Summary of Metabolites and Degradates to be included in the Risk Assessment and Tolerance Expression			
Matrix		Residues included in Risk Assessment	Residues included in Tolerance Expression
Plants	Primary Crop	Not applicable ¹	florpyrauxifen-benzyl + X11438848 (4-Amino-3-chloro-6-(4-chloro-2-fluoro-3-methoxy-phenyl)-5-fluoro-pyridine-2-carboxylic acid), expressed as florpyrauxifen-benzyl
	Rotational Crop	Not applicable ¹	florpyrauxifen-benzyl + X11438848 (4-Amino-3-chloro-6-(4-chloro-2-fluoro-3-methoxy-phenyl)-5-fluoro-pyridine-2-carboxylic acid), expressed as florpyrauxifen-benzyl
Livestock	Ruminant	Not applicable ¹	florpyrauxifen-benzyl + X11438848 (4-Amino-3-chloro-6-(4-chloro-2-fluoro-3-methoxy-phenyl)-5-fluoro-pyridine-2-carboxylic acid), expressed as florpyrauxifen-benzyl
	Poultry	Not applicable ¹	florpyrauxifen-benzyl + X11438848 (4-Amino-3-chloro-6-(4-chloro-2-fluoro-3-methoxy-phenyl)-5-fluoro-pyridine-2-carboxylic acid), expressed as florpyrauxifen-benzyl
Fish (including shellfish)		Not applicable ¹	florpyrauxifen-benzyl + X11438848 (4-Amino-3-chloro-6-(4-chloro-2-fluoro-3-methoxy-phenyl)-5-fluoro-pyridine-2-carboxylic acid), expressed as florpyrauxifen-benzyl
Drinking Water		Not applicable	

¹ No hazard has been identified in the toxicological studies conducted on florpyrauxifen-benzyl, therefore no risk assessment is required.

5.0 Residue Profile

5.1 Residue Analytical Methods (860.1340)

Tier II Summaries 49677881 Ref: IIA 4.3/3-7

5.1.1 Data-Collection Methods

Tier II Summaries 49677883

The method was used for analysis of florpyrauxifen-benzyl, X11438848 and X11966341 in the MOR (magnitude of the residue) studies for rice field trials, freezer storage, and processing. Residues are extracted using acetonitrile:0.1 M HCl, 90:10 (v/v) and cleaned up using Oasis HLB SPE. Extracted residue levels are determined by LC-MS/MS. The method limit of quantitation (LOQ) is 0.01 ppm (ppm) for each analyte. The method is considered suitable for pre-registration purposes.

The ion transitions monitored for florpyrauxifen-benzyl are m/z 439→91 (quantitation) and m/z 441→65 (confirmation) and for X11438848 are m/z 349→268 (quantitation) and m/z 349→270 (confirmation).

Adequate concurrent method recovery data were submitted with each of the crop field trials and processing studies, from crop samples fortified at the LOQ and at least one additional fortification level. The fortification levels adequately reflected the observed residues in/on all tested raw agricultural and processed crop commodities.

Livestock Commodities

Data-collection method: An analytical method was developed and validated for the detection, quantification and confirmation of florpyrauxifen-benzyl, its acid metabolite (X11438848) and its hydroxy acid metabolite (X11966341) in livestock matrices including chicken egg, bovine milk, cream, muscle, liver, kidney, and fat. The method was validated over the concentration range of 0.01-0.10 ppm with a validated limit of quantitation of 0.01 ppm. The ion transitions monitored for florpyrauxifen-benzyl are m/z 441→91 (quantitation) and m/z 439→91 (confirmation) and for X11438848 are m/z 351→270 (quantitation) and m/z 349→268 (confirmation) and for X1196634 are m/z 335→254 (quantitation) and m/z 337→256 (confirmation).

Briefly, residues of florpyrauxifen-benzyl, X11438848 and X11966341 are extracted with homogenization (excluding milk and cream) and shaking into ACN:0.1 M HCl, 90:10 (v/v). The extract is purified using Oasis HLB SPE, then analysed and quantified with HPLC-MS/MS.

Recoveries at all spiking levels in all matrices were generally within the acceptable range of 70-120% with the coefficient of variation at <20%.

The method was successfully validated in bovine milk and poultry liver by an independent laboratory.

Extraction efficiency was assessed in cream and fat for florpyrauxifen-benzyl; in liver, kidney and fat for X11438848; and in liver, kidney and fat for X11966341. Residue results obtained with the extraction procedure described in MRID 49677824 were compared to those obtained with the extraction procedure used in a nature of residue study. The residue results differed by between 0% and 21%.

5.1.2 Multiresidue Methods (860.1360)

FDA multiresidue methods (MRMs) analysis was not submitted. The QuEChERS (EN 15662) method is suitable for the enforcement of florpyrauxifen-benzyl and X11438848.

5.1.3 Tolerance Enforcement Methods

Tier II Summaries 49677881 Ref: IIA 4.3/1 and IIA 4.3/2

Plants/Livestock: An adequate analytical method QuEChERS (EN 15662) which uses HPLC/MS-MS to quantitate residues of florpyrauxifen-benzyl in various crops is available for enforcement. The ion transitions monitored for florpyrauxifen-benzyl are m/z 439→91 (quantitation) and m/z 441→65 (confirmation) and for X11438848 are m/z 349→268 (quantitation) and m/z 349→270 (confirmation). The method is considered suitable for enforcement purposes.

Briefly, residues of florpyrauxifen-benzyl and X11438848 are extracted from samples with acetonitrile. After addition of $MgSO_4$, NaCl, and buffering citrate salts, the samples are shaken and centrifuged. For fatty samples only, extracts are stored for ≥ 4 hours in a freezer in order to precipitate the majority of fat from the sample. For oilseed rape (seeds) samples only, an additional clean-up step is carried out by transferring an aliquot into a tube containing C18 material and intensively shaking. For all matrices, an aliquot of the acetonitrile phase is evaporated to dryness before reconstitution in methanol/water (1:1) containing 0.1% formic acid.

The method was validated over the concentration range of 0.01-0.10 ppm (primary and confirmatory analysis) for diverse crops (high water (lettuce), high starch (wheat), high oil (rapeseed), and high acid (lemon)). Recoveries were within acceptable limits (70-120%) and RSDs were $<20\%$. The method was subjected to independent laboratory validation (ILV) using samples of diverse crops (high water (lettuce), high starch (barley), high oil (rapeseed), and high acid (lemon) fortified with florpyrauxifen-benzyl at 0.01 and 1.0 ppm. Recoveries were within acceptable limits (70-120%), and RSDs were $<20\%$.

The method was validated over the concentration range of 0.01-1.0 ppm (primary and confirmatory analysis) in livestock matrices (poultry eggs and bovine fat, liver, meat, and whole milk). Recoveries were within acceptable limits (70-120%) and RSDs were $<20\%$. The method was subjected to independent laboratory validation (ILV) using samples of diverse crops (high water (lettuce), high starch (barley), high oil (rapeseed), and high acid (lemon) fortified with florpyrauxifen-benzyl at 0.01 and 0.1 ppm. Recoveries were within acceptable limits (70-120%), and RSDs were $<20\%$.

The method was subjected to ILV using samples of milk and poultry liver fortified with florpyrauxifen-benzyl at 0.01 and 0.1 ppm. The recoveries were within acceptable limits (70-120%), and RSDs were $<20\%$. The method was successfully validated for milk and poultry liver only.

Conclusions: The residue analytical method for plants and livestock is adequate. An acceptable method is available for tolerance enforcement purposes for the residue of concern in/on plant and livestock commodities. The method LOD and LOQ are 0.003 ppm and 0.01 ppm (ppm),

respectively for each analyte. The method underwent successful independent laboratory validation for use as an enforcement analytical method. Extraction efficiency data were included for the plant and livestock enforcement method (LC/MS/MS Method).

5.1.4 Submittal of Analytical Reference Standards (860.1650)

Analytical reference standards for florpyrauxifen-benzyl and florpyrauxifen acid are currently available at the EPA National Pesticide Standards Repository (personal communication with Theresa Cole, ACB, 10/05/2016) with expiration date of 10/22/2017 and 10/3/2017, respectively.

To re-supply the analytical reference standards, a (5 g) and the Certificate of Analysis and the MSDS must be supplied. The reference standard should be sent to the Analytical Chemistry Lab, which is located at Fort Meade, Maryland, to the attention of either Theresa Cole or Thuy Nguyen at the following address:

USEPA
National Pesticide Standards Repository/Analytical Chemistry Branch/OPP
701 Mapes Road
Fort George G. Meade, MD 20755-5350

(Note that the mail will be returned if the extended zip code is not used.)

5.2 Storage Stability (860.1380)

Tier II Summaries 49677883 Ref: IIA 6.1.1

Homogenized rice (grain and straw) and rice processed fractions (bran, hulls, and flour) were separately fortified with florpyrauxifen-benzyl, its acid metabolite (X11438848) and its hydroxyl acid metabolite (X11966341) at 0.1 ppm, and deep frozen at $\leq -18^{\circ}\text{C}$. The samples were stored in amber glass bottles at -18°C or below and were analysed at the storage intervals of 0, 29, 92, 189 days, and 12 months. Concurrent fresh recovery experiments were conducted at all storage intervals by spiking control samples. Samples were analysed for florpyrauxifen-benzyl, its acid metabolite and its hydroxyl acid metabolite in duplicate on the day of storage initiation and in duplicate 29, 92, 189, and 365 days after storage at -18°C .

Acceptable concurrent recoveries were reported for all sample types at spiking level of 0.1 ppm for each analyte separately. At all sampling dates (0-12 months) and in all sample materials, the relevant components of the residue of florpyrauxifen-benzyl were above 70%. The mean recovery of stored samples spiked at 0.1 ppm for each analyte and matrices were in the range of 70-120% for florpyrauxifen-benzyl, X11438848 and X11966341. Thus, all analytes can be considered stable in all relevant plant matrix types for a period of at least 12 months

Actual maximum storage intervals for the crop matrices were 288 days for rice grain and 251 days for rice straw (US 2014 data); 153 days for rice forage and 161 days for processed commodities (hulls and bran).

For the confined rotational crop studies, the maximum storage period of frozen samples for

florpyrauxifen-benzyl and metabolites was 4 months.

Homogenized (except milk) animal matrices (milk, muscle, liver, egg) were separately fortified with florpyrauxifen-benzyl, its acid metabolite (X11438848) and its hydroxyl acid metabolite (X11966341) at 0.1 ppm, and deep frozen at $\leq -18^{\circ}\text{C}$ (milk $2-8^{\circ}\text{C}$). The samples were stored in amber glass bottles at -18°C or below and were analysed at the storage intervals of 0, 27 and 65-71 days. Concurrent fresh recovery experiments were conducted at all storage intervals by spiking control samples. Samples were analysed for florpyrauxifen-benzyl, its acid metabolite and its hydroxyl acid metabolite in duplicate on the day of storage initiation and in duplicate 0, 27 and 65-71 days after storage at -18°C .

Acceptable concurrent recoveries were reported for all sample types at spiking level of 0.01 ppm for each analyte separately. At all sampling dates (0-71 days) and in all sample materials, the relevant components of the residue of florpyrauxifen-benzyl were above 70% (except liver). Residues of florpyrauxifen-benzyl begin to hydrolyse to X11438848 in liver when stored frozen for 65 days. The mean recovery of stored samples spiked at 0.1 ppm for each analyte and matrices were in the range of 70-120% (except liver) for florpyrauxifen-benzyl, X11438848 and X11966341. Thus, all analytes can be considered stable in all relevant livestock matrix types (except liver) for a period of at least 65 days.

Table 5.2-1. Storage Stability of Florpyrauxifen-benzyl, its Acid Metabolite (X11438848) and its Hydroxyl Acid Metabolite (X11966341) on Rice and Rice Processed Commodities.					
Commodity	Spike Level (ppm)	Maximum Storage Interval (days)	Mean Concurrent Recovery (%)	Uncorrected Mean Recovery (%)	Corrected % Mean Recovery*
Florpyrauxifen-benzyl					
Rice Grain	0.1	365	103	86	84
Rice Straw	0.1	365	94	87	92
Rice Hulls	0.1	365	126	117	93
Rice Bran	0.1	365	108	122	113
Rice Flour	0.1	365	100	94	94
X11438848					
Rice Grain	0.1	365	96	88	92
Rice Straw	0.1	365	92	86	93
Rice Hulls	0.1	365	98	90	92
Rice Bran	0.1	365	95	89	93
Rice Flour	0.1	365	98	94	96
X11966341					
Rice Grain	0.1	365	94	87	93
Rice Straw	0.1	365	94	75	79
Rice Hulls	0.1	365	108	104	96
Rice Bran	0.1	365	86	82	95
Rice Flour	0.1	365	96	98	103

* Corrected for mean concurrent recovery

Table 5.2-2. Summary of Procedural Recoveries for Florpyrauxifen-benzyl, its Acid Metabolite (X11438848) and its Hydroxyl Acid Metabolite (X11966341) on Livestock Commodities.					
Commodity	Spike Level (ppm)	Maximum Storage Interval (days)	Mean Concurrent Recovery (%)	Uncorrected Mean Recovery (%)	Corrected % Mean Recovery*
Florpyrauxifen-benzyl					
Milk	0.1	71	93	96	103
Muscle	0.1	66	88	89	102
Liver	0.1	27	--	46	48
Liver	0.1	65	79	43	54
Liver (hydrolysis)	0.1	70	N/A	72	91
Egg	0.1	70	90	93	103
X11438848					
Milk	0.1	71	99	86	87
Muscle	0.1	66	88	71	80
Liver	0.1	65	78	73	93
Egg	0.1	70	89	80	89
X11966341					
Milk	0.1	71	95	75	78
Muscle	0.1	66	74	60	80
Liver	0.1	65	70	69	98
Egg	0.1	70	92	81	89

Table 5.2-2. Summary of Storage Conditions and Intervals of Samples from Crop Field Trial and Processing Studies.			
Matrix*	Storage Temperature (C)	Maximum Storage Duration Days (months)	Interval of Demonstrated Storage Stability
Crop Field Trials/Processing			
Rice Grain	Frozen	288	Concurrent storage stability study indicated that florpyrauxifen-benzyl, its acid metabolite (X11438848) and its hydroxyl acid metabolite (X11966341) were stable for 365 days.
Rice Straw	Frozen	251	
Rice Forage	Frozen	153	
Rice Bran	Frozen	161	
Rice Hulls	Frozen	161	
Rice Flour	Frozen	146	

¹ The storage duration is the time from field sampling to analysis.

Conclusions: The available storage stability data are adequate to support the storage durations of samples for the rice field trials for 12 months. The freezer storage stability data indicate that residues of florpyrauxifen-benzyl and metabolites are stable in livestock commodities for up to 65 days when stored under frozen conditions. Storage stability data for livestock commodities is not needed since samples were stored for less than 6 months. Reanalysis of liver and kidney samples demonstrated stability for about a year; %TRRs were similar.

5.3 Residue Data

5.3.1 Crop Field Trials (860.1500)

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The number and distribution of trials (U.S.) fulfilled the requirements of OCSPP 860.1500 for rice studies.

The residues of florpyrauxifen-benzyl, its acid metabolite (X11438848) and its hydroxyl acid metabolite (X11966341) were quantitated using LC-MS/MS method. The LOQ was 0.010 ppm and the LOD was 0.003 ppm for each analyte.

Concurrent recoveries were measured for all compounds with each set of samples for each crop commodity including processed commodities to verify method performance. Acceptable concurrent recoveries were reported. Residues of florpyrauxifen-benzyl, have been shown to be stable in rice for up to 12 months (365 days) under frozen conditions. The available storage stability data are adequate to support the storage durations of samples in the current rice field trials and processing studies.

Rice (2013)

Table B.5.3.1-1. Summary of Residue Data from Crop Field Trials with Florpyrauxifen-benzyl.									
Commodity	Total Applic. Rate, g ai/ha (lb ai/A)	PHI (days)	Residue Levels (ppm) (XDE-848 BE + XDE-848 acid (reported as XDE-848 BE equivalents))						
			N	Min.	Max.	HAFT*	Median (STMdR)	Mean (STMR)	Std. Dev.
Rice (proposed use = 0.053 lb ai/A total application rate, 60-day PHI)									
Whole grain	100 (0.090) (GF-3162)	60	24	ND	ND	ND	ND	ND	NA
Whole grain	400 (0.357) (GF-3187) ^a	60	24	ND	0.0257	0.0195	ND	0.0032	0.0062
Straw	100 (0.090) (GF-3162)	60	24	ND	0.574	0.538	0.0173	0.0713	0.148
Straw	400 (0.357) (GF-3187) ^a	60	24	ND	1.139	0.864	0.0604	0.2179	0.333

N = Number of Field Trials.

* HAFT = Highest Average Field Trial.

^a This use pattern is not intended for the US label.

Magnitude of the residue studies were conducted during 2013 growing season on rice with either GF-3162 (19 g ai/L) or GF-3187 (1.2 ai (w/w)). Twelve (12) trials were conducted encompassing Regions 4 (3 trials in AK, 3 trials in LO, and 1 trial in MI), 5 (1 trial in MI), 6 (2 trials in TX), and 10 (2 trials in CA) during the 2013 growing season.

At each test location, one treated plot received two foliar applications of GF-3162 at a target

formulated product (fp) rate of 1017 mL/A (2513 mL/ha), equivalent to 50 g ai/ha (0.045 lb ai/A) with a total seasonal rate of 100 g ai/ha (0.09 lb ai/A), ~2X U.S. label rate). Spray volumes ranged from 15.9 to 51.2 gal/A (149 to 479 L/ha), with no adjuvant added. The second treated plot received two applications of GF-3187 at a target rate of 200 g ai/ha (0.178 lb ai/A) for a total rate of 400 g ai/ha (0.357 lb ai/A), ~7X U.S. label rate). For all treatments, intervals between applications were approximately 7 days, with exceptions up to 13 days. Test substance applications were timed such that the last application would occur approximately 60 days before harvest at peak maturity. Raw Agricultural Commodity (RAC) samples were stored frozen a maximum of 93 days prior to analysis.

In grain collected following treatment with GF-3187, residues of florpyrauxifen-benzyl were found in samples from five trials, but exceeded LOQ only at one trial (0.0195 ppm mean at 60 days after the last test substance application (DALA). Metabolite residues were non-detectable in grain samples collected after treatment with GF-3187, with one exception (X11438848) which was slightly above LOD but below LOQ. In rice straw, residues of one or more analytes were detectable (>0.003 ppm) in most treated samples. In individual samples harvested at 59-63 DALA, residues of florpyrauxifen-benzyl ranged from ND to 0.4503 ppm following treatment with GF-3162, and from ND to 0.9964 ppm following treatment with GF-3187. Maximum X11438848 residues were 0.0987 ppm and 0.1571 ppm, following GF-3162 and GF-3187 treatments, respectively. In straw samples from one decline trial, a decline of >50% was observed for all analytes from 51 to 72 DALA, but no clear trend was observed at the second decline trial due to low residues.

Rice US (2014)

Table B.5.3.1-2. Summary of Residue Data from Crop Field Trials with Florpyrauxifen-benzyl.									
Commodity	Total Applic. Rate, g a.i./ha (lb ai/A)	PHI (days)	Residue Levels (ppm) (XDE-848 BE + XDE-848 acid (reported as XDE-848 BE equivalents))						
			N	Min.	Max.	HAFT*	Median (STMdR)	Mean (STMR)	Std. Dev.
Rice (proposed use = 0.053 lb ai/A total application rate, 60-day PHI)									
Whole grain	80 (0.07) (GF-3206)	58-64	24	ND	0.0926	0.0764	0.0764	0.0102	0.0246
Whole grain	150 (0.134) (GF-3187) ^a	58-64	24	ND	0.0178	(0.0089)	(0.0089)	ND	0.0036
Whole grain	80 (0.07) (GF-3301)	58-64	24	ND	0.2470	0.2146	0.2146	0.0330	0.0765
Straw	80 (0.07) (GF-3206)	58-64	24	ND	0.9776	0.9013	0.0443	0.1444	0.2534
Straw	150 (0.134) (GF-3187) ^a	58-64	24	ND	0.2150	0.1619	0.0325	0.0468	0.0503
Straw	80 (0.07) (GF-3301)	58-64	24	ND	1.9524	1.7989	0.2691	0.4784	0.6249

N = Number of Field Trials

* HAFT = Highest Average Field Trial.

^a This use pattern is not intended for the US label.

Magnitude of the residue studies were conducted during 2014 growing season on rice with either GF-3206 (19 g ai/L) or GF-3187 (1.2 ai (w/w) or GF-3301 (300 g ai/L). Twelve (12) trials were conducted encompassing Regions 4 (3 trials in Arkansas, 2 trials in Louisiana, 1 trial in Missouri,

and 1 trial in Mississippi), 5 (1 trial in Missouri), 6 (2 trials in Texas), and 10 (2 trials in California).

At each test location, an untreated control plot and three treated plots were included: One treated plot received two foliar applications of GF-3206 at a target interval of 10 days, at a target rate of 648 mL/A (40 g ai/ha) (0.036 lb ai/A) for a total rate of 80 g ai/ha (0.070 lb ai/A), 1.4X U.S. label rate). Spray volumes ranged from 15.3 to 28.6 GPA (143 to 268 L/ha) with no adjuvant; the second treated plot received two granular broadcast applications of GF-3187 at a target interval of 10 days, at a target rate of 2529 g fp/A (75 g ai/ha) (0.07 lb ai/A) for a total rate of 150 g ai/ha (0.134 lb ai/A), 2.5X U.S. label rate); the third treated plot received two foliar applications of GF-3301 at RTI of 10-days at a target rate of 54 mL/A (40 g ai/ha) (0.036 lb ai/A) for a total rate of 80 g ai/ha (0.070 lb ai/A), 1.4X U.S. label rate). Spray volumes ranged from 15.2 to 28.9 gal/A (142 to 270 L/ha), with methylated seed oil (MSO).

Residues of florpyrauxifen-benzyl and X11438848 in untreated RAC and processed samples were non-detectable. Residues of the parent florpyrauxifen-benzyl and the metabolite in treated rice grain samples were also non-detectable, except in samples from two Region 10 trials following treatment with liquid formulations, and in one sample collected after granular treatment at one of those trials. For the two California trials, residues of florpyrauxifen-benzyl and X11438848 on grain samples treated with GF-3206 ranged from 0.0372 to 0.0805 ppm and <0.01 (LOQ) to 0.0123 ppm, respectively. Residues of florpyrauxifen-benzyl on grain samples treated with GF-3187 ranged from ND to 0.0178 ppm. Residues were non-detectable for X11438848. Residues of florpyrauxifen-benzyl and X11438848 on grain samples treated with GF-3301 ranged from 0.156 to 0.299 ppm, 0.0113 to 0.0331 ppm, respectively.

In rice straw, residues of parent florpyrauxifen-benzyl were quantifiable. In individual samples harvested at approximately 60 DALA, residues of florpyrauxifen-benzyl ranged from ND to 0.750 ppm following treatment with GF-3206, from ND to 0.342 ppm following treatment with GF-3187, and from ND to 1.81 ppm following treatment with GF-3301.

In rice straw, residues of X11438848 were quantifiable. In individual samples harvested at approximately 60 DALA, residues of X11438848 ranged from ND to 0.181 ppm following treatment with GF-3206, from ND to 0.0280 ppm following treatment with GF-3187, and from ND to 0.158 ppm following treatment with GF-3301.

Results of florpyrauxifen-benzyl and X11438848 within the three treatments at the two decline trials showed generally slight and irregular trends in residue detections over the 21 days of decline sampling. Residues detected in straw increased marginally and irregularly in many cases, but showed unclear results in others. Residues in grain were not detected at the decline trial in Region 4 while residues in grain from the Region 10 decline increased slightly following GF-3301 treatment but showed no trend following GF-3206 treatment.

Rice (Australia)

Table B.5.3.1-3. Summary of Residue Data from Crop Field Trials with Florpyrauxifen-benzyl.									
Commodity	Total Applic. Rate, g a.i./ha (lb ai/A)	PHI (days)	Residue Levels (ppm) (XDE-848 BE + XDE-848 acid (reported as XDE-848 BE equivalents))						
			N	Min.	Max.	HAFT*	Median (STMdR)	Mean (STMR)	Std. Dev.
Rice (proposed use = 0.053 lb ai/A total application rate, 60-day PHI)									
Whole grain	60 (0.054) (GF-3206)	111-112	3	ND	ND	NA	ND	ND	NA
Whole grain	120 (0.107) (GF-3206)	111-112	3	ND	ND	NA	ND	ND	NA
Whole grain	60 (0.054) (GF-3262)	111-112	3	ND	ND	NA	ND	ND	NA
Straw	60 (0.054) (GF-3206)	111-112	3	ND	0.035	NA	0.035	0.023	0.020
Straw	120 (0.107) (GF-3206)	111-112	3	ND	0.102	NA	0.068	0.057	0.052
Straw	60 (0.054) (GF-3262)	111-112	3	0.075	0.189	NA	0.135	0.133	0.057

N = Number of Field Trials.

* HAFT = Highest Average Field Trial.

Magnitude of the residue studies were conducted on rice in Australia. Three (3) trials were conducted during the 2013/2014 growing season.

At each test location, one treated plot received two foliar applications of GF-3206 (25 g ai/L) at a target rate of 30 g ai/ha (0.0268 lb ai/A) for a total rate of 60 g ai/ha (0.054 lb ai/A), 1X U.S. label rate). The second treated plot received two foliar applications of GF-3206 at a target rate of 60 g ai/ha (0.054 lb ai/A) for a total rate of 120 g ai/ha (0.107 lb ai/A), 2X U.S. label rate). The third treated plot received two foliar applications of GF-3262 (300 g ai/L with methylated soybean oil at a target rate of 2 L/ha, equivalent to 30 g ai/ha (0.0268 lb ai/A) for a total rate of 60 g ai/ha (0.054 lb ai/A), 1X U.S. label rate). Spray volumes were targeted at 100 L/ha, with no adjuvant added to the first and second treated plots. For all treatments, intervals between applications were approximately 42-45 days. Test substance applications were timed such that the last application would occur approximately 111-112 days before harvest at peak maturity. RAC samples were stored frozen a maximum of 153 days prior to analysis.

Untreated samples of forage, grain, and straw did not show any detectable residues of florpyrauxifen-benzyl and X11438848. In the first treated plot (two foliar applications of GF-3206 at a target rate of 30 g ai/ha), residues on whole grain samples were non-detectable for florpyrauxifen-benzyl and X11438848. In straw samples, residues ranged from ND – (0.01) ppm for florpyrauxifen-benzyl and ND – 0.02 ppm for X11438848. In the second treated plot (two foliar applications of GF-3206 at a target rate of 60 g ai/ha) residues on whole grain samples were non-detectable for florpyrauxifen-benzyl and X11438848. In straw samples, residues ranged from ND – 0.044 ppm for florpyrauxifen-benzyl and ND – 0.046 ppm for X11438848. In the third treated plot (two foliar applications of GF-3262 at a target rate of 30 g ai/ha) residues on whole grain samples were non-detectable for florpyrauxifen-benzyl and X11438848. In straw samples, residues ranged from 0.062 – 0.14 ppm for florpyrauxifen-benzyl and (0.01) – 0.039 ppm for X11438848.

Rice (Southern Europe)

Table B.5.3.1-4. Summary of Residue Data from Crop Field Trials with Florpyrauxifen-benzyl.									
Commodity	Total Applic. Rate, g a.i./ha (lb ai/A)	PHI (days)	Residue Levels (ppm) (XDE-848 BE + XDE-848 acid (reported as XDE-848 BE equivalents))						
			N	Min.	Max.	HAFT*	Median (STMdR)	Mean (STMR)	Std. Dev.
Rice (proposed use = 0.053 lb ai/A total application rate, 60-day PHI)									
Whole grain	60 (0.054) (GF-3206)	54-62	4	ND	0.021	0.021	0.0045	0.0075	0.010
Whole grain	25 (0.022) (GF-3206)	54-62	4	ND	0.024	0.024	0.0050	0.0086	0.011
Dehulled grain	60 (0.054) (GF-3206)	54-62	4	ND	ND	ND	ND	ND	NA
Dehulled grain	25 (0.022) (GF-3206)	54-62	4	ND	ND	ND	ND	ND	NA
Straw	60 (0.054) (GF-3206)	54-62	4	0.015	0.126	0.126	0.069	0.070	0.059
Straw	25 (0.022) (GF-3206)	54-62	4	0.0040	0.059	0.059	0.033	0.032	0.028

N = Number of Field Trials.

* HAFT = Highest Average Field Trial.

Magnitude of the residue studies were conducted on rice in southern Europe. Four (4) trials were conducted encompassing Southern Europe (2 trials in Italy, 1 trial in Greece and 1 trial in Spain) during the 2014 growing season.

At each test location, one treated plot received two foliar applications of GF-3206 (25 g ai/L at a target rate of 1.2 L/ha, equivalent to 30 g ai/ha (0.027 lb ai/A) for a total rate of 60 g ai/ha (0.054 lb ai/A), 1X U.S. label rate). Spray volumes ranged from 286 to 427 L/ha, with no adjuvant added. The second treated plot received one application of GF-3206 at a target rate of 1.0 L/ha equivalent to 25 g ai/ha (0.0223 lb ai/A). For all treatments, intervals between applications were approximately 7 days, with exceptions up to 9 days. Test substance applications were timed such that the last application would occur approximately 60 days before harvest at peak maturity. RAC samples were stored frozen a maximum of 154 days prior to analysis.

Residues of florpyrauxifen-benzyl ranged from ND to 0.065 ppm in grain and from 0.004 to 0.139 ppm in straw. Residues of X11438848 ranged from ND to 0.005 ppm in grain and from ND to 0.054 in straw. Residues in treated samples of grain without hull were not detectable for all analytes.

Rice (Argentina)

Table B.5.3.1-5. Summary of Residue Data from Crop Field Trials with Florpyrauxifen-benzyl.									
Commodity	Total Applic. Rate, g a.i./ha (lb ai/A)	PHI (days)	Residue Levels (ppm) (XDE-848 BE + XDE-848 acid (reported as XDE-848 BE equivalents))						
			N	Min.	Max.	HAFT*	Median (STMdR)	Mean (STMR)	Std. Dev.
Rice (proposed use = 0.053 lb ai/A total application rate, 60-day PHI)									
Whole grain	120 (0.107)	58-60	2	ND	ND	NA	ND	ND	NA
Dehulled grain	120 (0.107)	58-60	2	ND	ND	NA	ND	ND	NA
Straw	120 (0.107)	58-60	2	(0.005)	0.017	NA	0.01	0.012	0.01

N = Number of Field Trials.

* HAFT = Highest Average Field Trial.

Magnitude of the residue studies were conducted during 2014 growing season on rice. Two (2) trials were conducted in rice growing regions, (1 trial in Entre Rios, 1 trial in Corrientes province). In addition, in compliance of local requirements, two (2) more trials are done in the subsequent season of 2015.

At each test location, one treated plot received two foliar applications of GF-3206 (25 g/L) at a target rate of 2.4 L/ha, equivalent to 60 g ai/ha (0.054 lb ai/A) for a total rate of 120 g ai/ha (0.107 lb ai/A), 2X U.S. label rate). Spray volumes ranged from 120 to 170 L/ha, with no adjuvant added. Intervals between applications were approximately 15 days. Test substance applications were timed such that the last application would occur approximately 60 days before harvest at peak maturity. RAC samples were stored frozen a maximum of 108 days prior to analysis.

Residues of florpyrauxifen-benzyl and X11438848 in grain with hulls and without hulls were not detectable. Residues in treated samples of straw ranged from ND to 0.005 ppm for florpyrauxifen-benzyl and 0.003 to 0.0074 ppm for X11438848.

Rice (Brazil)

Table B.5.3.1-6. Summary of Residue Data from Crop Field Trials with Florpyrauxifen-benzyl.									
Commodity	Total Applic. Rate, (g a.i./ha)	PHI (days)	Residue Levels (ppm) (XDE-848 BE + XDE-848 acid (reported as XDE-848 BE equivalents))						
			N	Min.	Max.	HAFT*	Median (STMdR)	Mean (STMR)	Std. Dev.
Rice (proposed use = 0.053 lb ai/A total application rate, 60-day PHI)									
Whole grain	120 (GF-3206)	60	4	ND	0.0066	NA	ND	ND	0.0033
Dehulled grain	120 (GF-3206)	60	4	ND	ND	NA	ND	ND	NA
Straw	120 (GF-3206)	60	4	ND	0.062	NA	0.0037	0.017	0.030

N = Number of Field Trials.

* HAFT = Highest Average Field Trial.

Magnitude of the residue studies were conducted on rice in Brazil. Four (4) trials were conducted during the 2014/2015 growing season in Restinga Seca (RS) (1 Trial), Santa Cruz do Sul (RS) (1 Trial), Santa Maria (RS) (1 Trial), and Rolândia (PR) (1 Trial).

At each test location, one treated plot received two foliar applications of GF-3206 (25 g/L) at a target rate of 2.4 L/ha, equivalent to 60 g ai/ha (0.054 lb ai/A) for a total rate of 120 g ai/ha (0.107 lb ai/A), 1X U.S. label rate). Spray volumes ranged from 152 to 158 L/ha, with no adjuvant added. For all treatments, intervals between applications were approximately 15 days, with exceptions up to 18 days. Test substance applications were timed such that the last application would occur approximately 60 days before harvest at peak maturity. RAC samples were stored frozen a maximum of 79 days prior to analysis, with storage stability data supporting this timeframe.

Untreated samples of whole grain, straw and dehulled grain did not show any detectable residues of florpyrauxifen-benzyl and X11438848. In whole grain samples, residues ranged from ND –

0.0132 ppm for florpyrauxifen-benzyl, and were non-detectable in X11438848. In dehulled grain samples, residues ranged from ND – (0.0056) ppm for florpyrauxifen-benzyl, and were non-detectable in X11438848. In straw samples, residues ranged from ND – (0.0089) ppm for florpyrauxifen-benzyl and ND – 0.0554 ppm for X11438848.

Rice Japan

Table B.5.3.1-7. Summary of Residue Data from Crop Field Trials with Florpyrauxifen-benzyl.									
Commodity	Total Applic. Rate, g a.i./ha (lb ai/A)	PHI (days)	Residue Levels (ppm) (XDE-848 BE + XDE-848 acid (reported as XDE-848 BE equivalents))						
			N	Min.	Max.	HAFT*	Median (STMR)	Mean (STMR)	Std. Dev.
Rice (proposed use = 0.053 lb ai/A total application rate, 60-day PHI)									
Whole grain	250 (0.223)	60	2	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ
Dehulled grain	250 (0.223)	60	2	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ
Straw	250 (0.223)	60	2	0.7	1.58	NA	1.14	1.14	NA

N = Number of Field Trials.

* HAFT = Highest Average Field Trial.

Magnitude of the residue studies were conducted on rice in Japan. Two (2) trials were conducted encompassing Japanese rice growing regions (1 trial in Furukawa, 1 trial in Okayama province) during the 2014 growing season.

At each test location, one treated plot received 30 days after transplanting one application of DAH-1401, a granular formulation containing 1.5% ai (w/w), at a target rate of 10 kg/ha (150 g ai/ha) (0.134 lb ai/A). Later, two foliar applications of GF-2978 (12.6% ai (v/v)) at a target rate of 0.4 L/ha, equivalent to 50 g ai/ha (0.045 lb ai/A) for a total rate of 100 g ai/ha (0.09 lb ai/A), totaling 250 g ai/ha (0.223 lb ai/A), 4X U.S. label rate), at the target PHI of 60 days. Decline data was also taken from samples at 75 and 45 days relative to harvest time. Spray volumes were 1000 L/ha, with no adjuvant added. Intervals between applications were approximately 15 days. RAC samples were stored frozen a maximum of 122 days prior to analysis.

In grain with hulls samples, residues of florpyrauxifen-benzyl and X11438848 were not detectable at the target PHI of 60 days. Only one sample from Furukawa at 45 days before harvest showed residues of 0.22 ppm for florpyrauxifen-benzyl and 0.01 ppm for X11438848. Residues in treated samples of grain without hull were not detectable for florpyrauxifen-benzyl and X11438848. Residues in treated samples of straw at PHI of 60 days were 0.66 and 1.46 ppm for florpyrauxifen-benzyl and 0.04 and 0.12 ppm for X11438848.

Rice China

Table B.5.3.1-8. Summary of Residue Data from Crop Field Trials with Florpyrauxifen-benzyl.									
Commodity	Total Applic. Rate, g a.i./ha (lb ai/A)	PHI (days)	Residue Levels (ppm) (XDE-848 BE + XDE-848 acid (reported as XDE-848 BE equivalents))						
			N	Min.	Max.	HAFT*	Median (STMdR)	Mean (STMR)	Std. Dev.
Rice (proposed use = 0.053 lb ai/A total application rate, 60-day PHI)									
Whole grain	80 (0.07) (GF-3206)	59-60	10	0.087	0.0032	0.085	0.0032	0.028	0.036

Table B.5.3.1-8. Summary of Residue Data from Crop Field Trials with Florpyrauxifen-benzyl.									
Commodity	Total Applic. Rate, g a.i./ha (lb ai/A)	PHI (days)	Residue Levels (ppm) (XDE-848 BE + XDE-848 acid (reported as XDE-848 BE equivalents))						
			N	Min.	Max.	HAFT*	Median (STMdR)	Mean (STMR)	Std. Dev.
Whole grain	120 (0.107) (GF-3206)	59-60	10	0.105	0.0059	0.099	0.0059	0.039	0.048
Dehulled grain	80 (0.07) (GF-3206)	59-60	10	ND	ND	ND	ND	ND	NA
Dehulled grain	120 (0.107) (GF-3206)	59-60	10	ND	ND	ND	ND	ND	NA
Straw	80 (0.07) (GF-3206)	59-60	10	0.228	0.067	0.212	0.067	0.101	0.090
Straw	120 (0.107) (GF-3206)	59-60	10	0.324	0.092	0.317	0.092	0.132	0.119

N = Number of Field Trials.

* HAFT = Highest Average Field Trial.

Magnitude of the residue studies were conducted on rice in China. Five trials and one decline trial were conducted encompassing the Hainan province during the 2014 growing season.

At each test location, one treated plot received two foliar applications of GF-3206 (25 g/L) at a target rate of 1.6 L/ha, equivalent of 40 g ai/ha (0.036 lb ai/A) for a total rate of 80 g ai/ha (0.070 lb ai/A), 1.4X U.S. label rate). A separate plot was treated with two foliar applications of GF-3206 at a target rate of 2.0 L/ha, equivalent to 60 g ai/ha (0.054 lb ai/A) for a total rate of 120 g ai/ha (0.107 lb ai/A), 2X U.S. label rate). Spray volumes were targeted at 100 to 500 L/ha, with no adjuvant added. For all treatments, intervals between applications were approximately 15 days. Test substance applications were timed such that the last application would occur approximately 60 days before harvest at peak maturity. RAC samples were stored frozen a maximum of 223 days prior to analysis.

Florpyrauxifen-benzyl residues in samples from (two applications at 40 g ai/ha each) ranged from not-detected (ND) to 0.078 ppm in grain and ND to 0.168 ppm in straw. Florpyrauxifen-benzyl residues in samples from (two applications at 60 g ai/ha each) ranged from ND to 0.094 ppm in grain and ND to 0.226 ppm in straw. X11438848 residues in samples from (two applications at 40 g ai/ha each) ranged from ND to 0.007 ppm in grain and ND to 0.049 ppm in straw. X11438848 residues in samples from (two applications at 60 g ai/ha each) ranged from ND to 0.009 ppm in grain and ND to 0.078 ppm in straw. There were no detectable residues in any of the dehulled grain samples. In the decline trials, residues in the straw samples generally show a trend to decline. Residues in the grain samples are too low to determine a decline.

Conclusions: Twenty-four crop field trial studies were conducted in the US during the 2013 and 2014 growing seasons. The number and geographic representation of these trials were adequate following 860.1500 guidelines. The field trials were carried out at an exaggerated rate but are sufficient for determining the magnitude of the residue since they were within 25% of the labeled seasonal rate. In addition, a number of crop field trial studies were also provided which were undertaken in Australia, Southern Europe, Argentina, Brazil, Japan, and China. These trials were carried out at higher rates than those conducted in the US; however, residues were lower than the US trials.

5.3.2 Field Rotational Crops (860.1900)

Tier II Summaries 49677883 Ref: IIA 6.6.3

The waiver request submitted is acceptable due to low level of residues observed in the confined rotational crop study. The confined rotational crop studies adequately define the nature of the residue in three crop types planted in treated soil at intervals of 30, 90, and 271 days. The TRRs were <0.01 ppm in all matrices from each label at all PBIs, except wheat hay and straw. Parent and metabolites were not detected on most of the crops or were only detected at low levels (<0.01 ppm). The proposed 3-month PBI interval is sufficient.

5.3.3 Processed Food and Feed (860.1520)

Tier II Summaries 49677883 Ref: IIA 6.3.1-6.3.6

Magnitude of the residue studies were conducted during 2014 growing season on rice. A processing study was conducted (Arkansas) with florpyrauxifen-benzyl using GF-3206 formulation (19 g ai/L) and was applied at an exaggerated 5X rate of 3238 mL fp/A (400 g ai/ha) (0.357 lb ai/A), with spray volume of 18.2 gal/A (170 to 171 L/ha). Processed fractions were generated from bulk grain samples by standard milling as well as by milling of parboiled rice.

Samples of rice grain and processed commodities (hulls, bran and flour) were analysed for florpyrauxifen-benzyl (BE), X11438848, and X11966341 using LC-MS/MS Dow method 2. Acceptable concurrent recoveries were reported for rice grain and processed commodities with concurrent recoveries at 0.01 – 0.1 ppm ranging from 70-120% with relative standard deviations <20%, thus validating the method. The LOQ was 0.01 ppm per analyte.

Samples of rice grain and processed commodities were stored frozen for up to 161 days (5.4 months) prior to analysis. The available storage stability data are adequate to support the rice processing study.

Residues of florpyrauxifen-benzyl and metabolites were non-detectable (<0.003 ppm) in 5X-treated grain samples from which processed fractions were generated, and in samples of the processed fractions.

Conclusions: The processing study is considered scientifically acceptable. The results of the studies (exaggerated 5x) showed that florpyrauxifen-benzyl and metabolites are non-quantifiable and residues did not concentrate upon processing.

5.3.4 Meat, Milk, Poultry and Eggs (860.1480)

Based on the low transfer of residues of florpyrauxifen-benzyl in the hen metabolism study, a poultry feeding study was not conducted. The submitted waiver request for the poultry feeding study is acceptable.

5.3.4.1 Dietary Burden

The livestock feedstuffs associated with the proposed crop uses in this action are rice grain and rice bran.

The livestock dietary burdens of florpyrauxifen-benzyl are presented below (using the Pesticide Management Regulatory Agency (PMRA) Dietary Burden Calculator), and reflect the most recent "OECD Guidance Document on Residues in Livestock.", Sept 2013. The calculated dietary burdens of florpyrauxifen-benzyl are 0.004 ppm for beef cattle and for dairy cattle; and 0.003 ppm for poultry and for swine.

More Balanced Diet (MBD)							
Crop	Commodity	Type	Residue ppm	input	%DM	%Diet	Dietary Contribution ppm
Beef Cattle							
Rice	Grain	CC	0.01	Median	88	20	0.002
Rice	Bran	CC	0.01	Median	90	15	0.002
Untreated feed	NA	NA	NA	NA	NA	65	0
Total	NA	NA	NA	NA	NA	100	0.004
Dairy Cattle							
Rice	Grain	CC	0.01	Median	88	20	0.002
Rice	Bran	CC	0.01	Median	90	15	0.002
Untreated feed	NA	NA	NA	NA	NA	65	0
Total	NA	NA	NA	NA	NA	100	0.004
Poultry							
Rice	Bran	CC	0.01	Median	90	10	0.001
Rice	Grain	CC	0.01	Median	88	20	0.002
Untreated feed	NA	NA	NA	NA	NA	70	0
Total	NA	NA	NA	NA	NA	100	0.003
Swine							
Rice	Bran	CC	0.01	Median	90	10	0.001
Rice	Grain	CC	0.01	Median	88	20	0.002
Untreated feed	NA	NA	NA	NA	NA	70	0
Total	NA	NA	NA	NA	NA	100	0.003

R: Roughage; CC: Carbohydrate concentrate; PC: Protein concentrate.

Contribution = ([residue (Median/HAFT /% DM] X % diet) for beef and dairy cattle; contribution = (Median/HAFT residue] X % diet) for poultry and swine.

Cattle

Tier II Summaries 49677883

Four treatment groups of four dairy cows each were dosed orally for 28 consecutive days with florpyrauxifen-benzyl. The average dose levels of florpyrauxifen-benzyl based on concentration in the diet (DM feed basis) were 2.58 ppm (1x), 13.11 ppm (5x), 23.87 ppm (10x) and 110.77 ppm (45x). Three cows were not dosed to serve as controls. Sixteen of the cows in the 45x treatment group were used to generate depuration data. The dosing levels of the groups represent 600x (for the 2.5x), the dietary burden to beef cattle and dairy cattle.

Samples of whole milk were taken from each cow at each milking (PM and AM). For each cow, a combined proportional sample was constructed from the PM and AM samples, on the basis of milk yields recorded at the corresponding milkings. A portion of the Day 22 and 26 milk sample from the combined evening and morning milk yield was processed into cream and skim milk for analysis. Representative samples of liver (different areas of the organ)), kidney (each), fat

(approximately equal composite of omental, renal, and subcutaneous), and muscle (hind leg or flank, loin and diaphragm muscle) were collected. On some occasions, the amount of subcutaneous, mesenteric and perirenal fat were limited. On each of these occasions, only one replicate sample was collected.

Samples of cattle matrices were analysed for residues of florpyrauxifen-benzyl, X11438848, and X11966341 using HPLC/MS/MS. Residues were expressed in terms of each analyte. The method was adequate for based on acceptable method recoveries 70-120% for parent, X11438848, and X11966341. The validated LOQs in each matrix were 0.01 ppm for florpyrauxifen-benzyl and metabolites.

Results showed that residues of florpyrauxifen-benzyl above the LOQ do not transfer into whole milk, skimmed milk, muscle, liver, or kidney at any dosing level. Residues of florpyrauxifen-benzyl above the LOQ transfer into cream, subcutaneous fat, mesenteric fat, and perirenal fat at the 45x dosing level. Residues of X11438848 above the LOQ do not transfer into whole milk, skimmed milk, cream or muscle at any dosing level. Residues of X11438848 transfer into liver, subcutaneous fat, mesenteric fat, and perirenal fat at the 45x dosing level and into kidney at the 5x, 10x, and 45x dosing levels.

Table 5.3.4.1-1 Maximum Residues of XDE-Benzyl Ester in Cattle Commodities by Feeding Level.				
Cattle Matrix	2.5 ppm	12.5 ppm	25 ppm	112.5 ppm
XDE-Benzyl Ester				
Milk	ND	ND	ND	ND
Cream	ND	0.004	0.008	0.046
Muscle	ND	ND	ND	0.006
Liver	ND	ND	ND	ND
Kidney	ND	ND	ND	0.003
Fat ¹	ND	0.01	0.024	0.155
XDE-Benzyl Ester Acid				
Milk	ND	ND	ND	0.004
Cream	ND	ND	ND	ND
Muscle	ND	ND	ND	0.004
Liver	ND	ND	0.003	0.068
Kidney	ND	ND	ND	0.003
Fat ¹	ND	0.004	0.011	0.1
XDE-Benzyl Ester Hydroxy Acid				
Milk	ND	ND	ND	ND
Cream	ND	ND	ND	ND
Muscle	ND	ND	ND	ND
Liver	0.005	0.032	0.068	0.294
Kidney	0.009	0.025	0.055	0.183
Fat ¹	ND	0.013	0.016	0.071

¹ Includes subcutaneous, perirenal, and mesentric fat.

The data indicate that residues of florpyrauxifen-benzyl and X11438848 were non-quantifiable in all matrices. The data indicate that quantifiable residues of florpyrauxifen-benzyl and X11438848 occur in fat (except the lower dose), and cream and liver (at the highest dose level). Transfer factors for florpyrauxifen-benzyl and metabolites were calculated for each matrix at each feeding level, using the maximum observed residue level for tissues. The calculated transfer factors are presented in Table 5.3.4.1-2.

Table 5.3.4.1-2 Calculated transfer factors in cattle.^{1,2}				
Commodity	2.5 ppm	12.5 ppm	25 ppm	112.5 ppm
XDE-Benzyl Ester				
Milk	ND	ND	ND	ND
Cream	ND	0.00032	0.00032	0.00041
Muscle	ND	ND	ND	0.000053
Liver	ND	ND	ND	ND
Kidney	ND	ND	ND	0.000027
Fat	ND	0.0008	0.00096	0.0014
XDE-Benzyl Ester (Acid)				
Milk	ND	ND	ND	0.000036
Cream	ND	ND	ND	ND
Muscle	ND	ND	ND	0.000036
Liver	ND	ND	0.00012	0.00060
Kidney	ND	ND	ND	0.000027
Fat	ND	0.00032	0.00044	0.00089
XDE-Benzyl Ester Hydroxy Acid				
Milk	ND	ND	ND	ND
Cream	ND	ND	ND	ND
Muscle	ND	ND	ND	ND
Liver	0.002	0.0026	0.00272	0.0026
Kidney	0.0036	0.0002	0.0022	0.00163
Fat ¹	ND	0.00104	0.00064	0.00063

¹ Transfer factor calculated by dividing residue value by feeding level. nd = not determined; residues were below the LOQ.

² For all tissues, the transfer factor was calculated using the maximum residue value observed at the specified feeding level.

Based on the current MRBD for beef cattle and dairy cattle, the dosing levels represent 31x, 164x, 298x, and 1385x, respectively, the dietary burden to beef cattle and dairy cattle. Based on no transfer of residues in fat ($0.014 \times 0.004 = <0.001$, LOQ/10) at 1x maximum dietary burden, tolerances are not needed in livestock and hog commodities (a §180.6(a) (3) situation).

Based on the current MRBD for poultry, the dosing levels of 12 ppm used in the poultry metabolism study correspond to 4000x the current dietary burden. If the maximum residues of florpyrauxifen-benzyl found in poultry commodities are converted to a 1x feeding level, expected residues at a 10x dosing level would be <0.01 ppm.

Conclusions: For the purpose of this petition, there is no reasonable expectation of finite florpyrauxifen-benzyl residues of concern in livestock commodities [40 CFR §180.6(a)(3)] as a result of the proposed uses. Therefore, livestock tolerances on livestock commodities are not required. The submitted waiver request for the poultry feeding study is acceptable.

5.3.4.2 Estimated Secondary Residues in Livestock

5.3.5. Food Handling (860.1460)

This guideline is not applicable. There are no requests for food and/or feed handling uses for florpyrauxifen-benzyl.

5.3.6 Water, Fish, and Irrigated Crops (860.1400)

Ref: 49677836

The purpose of the study was to determine the extent that florpyrauxifen-benzyl (aquatic herbicide), and its major degradates accumulate in the edible tissues of two representative freshwater fish species (crustacean and a freshwater mollusk) under field conditions as well as monitor magnitude of residues in water through time. The species tested were the bottom-feeding channel catfish (*Ictalurus punctatus*), the predatory bluegill sunfish (*Lepomis macrochirus*), the northern crayfish (*Orconectes virilis*), and the freshwater clam (*Anodonta grandis*).

Channel catfish, bluegill sunfish and northern crayfish were exposed to 150 µg/L in static aquatic systems with a sediment substrate for a duration of 7 days, followed by a 3-day depuration. Freshwater clams were exposed to 150 µg/L in a static aquatic system without sediment substrate for a duration of 7 days, followed by a 3-day depuration.

Samples were analyzed for florpyrauxifen-benzyl, and its metabolites X11438848 and X12482999 (XDE-848 taurine conjugate) using a HPLC/MS/MS procedure based on methodology validated at Smithers Viscient. The method was validated for crayfish tissue, channel catfish, bluegill sunfish and clam for florpyrauxifen-benzyl, X11438848 and X12482999 (crayfish only) over the concentration range of 10-1000 µg/kg with a validated LOQ of 1.00 µg/kg. Recoveries were within acceptable limits (70-120%) and RSDs were <20%. The samples were stored frozen a maximum of 30 days from sample collection to analysis.

Measured concentrations of florpyrauxifen-benzyl in channel catfish ranged from approximately 280 to 1780 µg/kg during the exposure phase, and decreased to approximately 29.4 µg/kg during the depuration phase. Measured concentrations of X11438848 ranged from approximately 16.9 to 108 µg/kg during the exposure phase, and decreased to approximately 1.75 µg/kg during the depuration phase. Measured concentrations of X12482999 ranged from approximately 12.6 to 43.6 µg/kg during the exposure phase, and decreased to < LOQ during the depuration phase. All channel catfish controls monitored during the test were free of florpyrauxifen-benzyl and its metabolites.

Residues of florpyrauxifen-benzyl in bluegill sunfish ranged from 183 to 991 µg/kg during the exposure phase, and decreased to < LOQ during the depuration phase. Residues of X11438848 ranged from 16.3 to 156 µg/kg during the exposure phase, and decreased to < LOQ during the

deuration phase. Residues of X12482999 ranged from 2.47 to 8.59 µg/kg during the exposure phase, and decreased to < LOQ during the deuration phase. All bluegill sunfish controls monitored during the test were free of florpyrauxifen-benzyl and its metabolites.

Residues of florpyrauxifen-benzyl in crayfish ranged from 62.2 to 291 µg/kg during the exposure phase, and decreased to 8.84 µg/kg during the deuration phase. Residues of X11438848 ranged from approximately 19.0 to 170 µg/kg during the exposure phase, and decreased to < LOQ during the deuration phase. Residues of X12482999 ranged from < LOQ to 1.85 µg/kg during the exposure phase, and decreased to < LOQ during the deuration phase. All crayfish controls monitored during the test were free of florpyrauxifen-benzyl and its metabolites.

Residues of florpyrauxifen-benzyl in clam ranged from 1350 to 18,400 µg/kg during the exposure phase, and decreased to approximately 326 µg/kg during the deuration phase. These concentrations are likely elevated relative to a true field condition given the absence of a sediment phase for the florpyrauxifen-benzyl to temporarily associate with during the test. Residues of X11438848 ranged from 40.4 to 86.1 µg/kg during the exposure phase, and decreased to 10.1 µg/kg during the deuration

Florpyrauxifen-benzyl's major metabolite, X11438848, was present at <0.50 µg/L at 1-hour, and increased to approximately 7.5 to 8.6 µg/L by day 7. All remaining metabolites produced residues ranging from < LOQ to approximately 1.0 µg/L, with the exception of X11966341 (XDE-848 acid phenol or hydroxy acid) which yielded residues in the pond exposure ranging from approximately 3.2 to 7.8 µg/L at day 7. X11438848 and X11966341 had measureable concentrations <0.10 µg/L during the deuration phase while the remaining metabolites were below LOQ in the deuration phase for the pond exposure. During the aquaria exposure, X11438848 had recoveries ≤1.7 µg/L in the deuration phase, with the remaining metabolites recovering <0.10 µg/L.

All aqueous, sediment and tissue controls monitored during both the pond and aquaria tests were free of florpyrauxifen-benzyl and its metabolites.

B.7.6.2-1. Analytical Results for the Concentration of Florpyrauxifen-benzyl and its Metabolites in the Aqueous Fraction of the Pond Exposure during the Magnitude of Residue Study with GF-3301.								
Matrix	Interval	Replicate ID	Residues (µg/L)					
			XDE-848 benzyl ester	XDE-848 acid	XDE-848 phenol	XDE-848 acid phenol	XDE-848 DCA	XDE-848 deschloro
Water	1-Hour	A	121.64	0.181	0.0153	< 0.0106	< 0.00974	0.201
		B	144.23	0.282	0.0161	< 0.0106	< 0.00974	0.314
		C	172.03	0.335	0.0138	< 0.0106	< 0.00974	0.418
		D	170.19	0.194	0.013	< 0.0106	< 0.00974	0.256
		E	176.34	0.368	<0.0108	< 0.0106	< 0.00974	0.524
		F	164.01	0.325	0.0118	< 0.0106	< 0.00974	0.562
		G	166.27	0.352	0.016	< 0.0106	< 0.00974	0.561
	6-Hour	A	159.13	0.475	0.0116	< 0.0106	0.0106	1.08
		B	156.02	0.545	0.0185	< 0.0106	< 0.00974	0.86
		C	178.99	0.519	0.022	< 0.0106	0.0154	0.891
		D	176.04	0.474	0.0233	< 0.0106	< 0.00974	0.775
		E	185.56	0.608	0.0256	< 0.0106	0.0205	0.742
		F	187.24	0.715	0.0237	< 0.0106	< 0.00974	0.74
		G	186.07	0.623	0.0225	< 0.0106	< 0.00974	0.745
	B	125.05	1.8	0.029	0.022	0.0267	0.217	

B.7.6.2-1. Analytical Results for the Concentration of Florpyrauxifen-benzyl and its Metabolites in the Aqueous Fraction of the Pond Exposure during the Magnitude of Residue Study with GF-3301.

Matrix	Interval	Replicate ID	Residues (µg/L)					
			XDE-848 benzyl ester	XDE-848 acid	XDE-848 phenol	XDE-848 acid phenol	XDE-848 DCA	XDE-848 deschloro
	Day 1	C	132.88	2.39	0.0532	0.027	0.0536	0.23
		D	131.76	1.54	0.045	0.0264	0.0479	0.2
		E	147.51	2.28	0.0605	0.0373	0.0699	0.195
		F	105.95	2.2	0.0528	0.0363	0.0544	0.19
		G	128.27	3.03	0.0625	0.0378	0.0441	0.182
	Day 2	C	27.07	4.82	0.0709	0.126	0.0488	0.0447
		D	32.19	2.8	0.0813	0.135	0.0319	0.0711
		E	36.82	3.47	0.107	0.211	0.0426	0.0868
		F	28.56	4.72	0.102	0.189	0.0391	0.0863
	Day 3	G	52.11	5.29	0.115	0.19	0.0359	0.0874
		C	22.56	7.25	0.0432	0.0312	0.0475	0.0146
		E	20.79	5.98	0.088	0.63	0.0372	0.0246
Day 7	F	15.26	6.83	0.108	0.637	0.0446	0.0351	
	G	17.12	6.79	0.1	0.638	0.0365	0.0394	
	C	5.24	8.36	0.0623	4.67	0.0334	0.0156	
Day 8	E	4.05	7.47	0.155	3.24	0.0328	0.0194	
	G	7.07	8.59	0.126	7.76	0.0224	0.0191	
Day 10	C	0.0368	0.0756	< 0.00930	0.0136	< 0.0108	< 0.00884	
	E	0.0354	0.0514	< 0.00930	0.012	< 0.0108	< 0.00884	
		C	0.152	0.0843	< 0.00939	0.0135	< 0.00974	< 0.0103

B.7.6.2-2. Analytical Results for the Concentration of Florpyrauxifen-benzyl and its Metabolites in the Sediment Fraction of the Pond Exposure during the Magnitude of Residue Study with GF-3301.

Matrix	Interval	Replicate ID	Residues (µg/kg)					
			XDE-848 benzyl ester	XDE-848 acid	Florpyrauxifen-benzyl phenol	XDE-848 acid phenol	XDE-848 DCA	XDE-848 deschloro
Sediment	1-Hour	A	13.3	< 0.877	< 0.921	< 1.09	< 1.13	2.19
	6-Hour	A	116	< 0.877	< 0.921	< 1.09	< 1.13	1.89
	Day 1	B	240	1.83	< 0.921	< 1.09	< 1.13	1.95
	Day 2	D	760	8.24	5.63	2.3	< 1.13	1.59
	Day 3	E	666	6.43	4.96	2.57	< 1.13	1.61
	Day 7	C	667	17.3	15.9	13.5	< 0.910	1.15
		F	1171	63	46.6	65.9	< 0.910	1.61
		G	575	11	22.4	23.6	< 0.910	1.29
	Day 8	F	192	< 0.877	7.71	< 1.09	< 0.910	< 0.988
	Day 10	C	80.8	< 0.877	3.97	< 1.09	< 0.910	< 0.988

B.7.6.2-3. Analytical Results for the Concentration of Florpyrauxifen-benzyl and its Metabolites in the Fish and Crayfish Fractions of the Pond Exposure during the Magnitude of Residue Study with GF-3301.

Matrix	Interval	Replicate ID	Residues (µg/kg)		
			XDE-848	XDE-848 acid	XDE-848 taurine conjugate
Bluegill	6-Hour	A	991	73	4.69
	Day 1	B	873	156	8.59
	Day 2	D	683	62.9	2.47
	Day 3	E	659	76	2.9
	Day 7	G	183	16.3	< 0.975
	Day 8	F	76.1	< 1.08	< 0.975
	Day 10	C	< 1.08	< 1.08	< 0.975
Catfish	6-Hour	A	1050	88.7	12.6
	Day 1	B	1590	108	43.6
	Day 2	D	1430	81	25.1
	Day 3	E	1780	72	37.7

B.7.6.2-3. Analytical Results for the Concentration of Florpyrauxifen-benzyl and its Metabolites in the Fish and Crayfish Fractions of the Pond Exposure during the Magnitude of Residue Study with GF-3301.

Matrix	Interval	Replicate ID	Residues (µg/kg)		
			XDE-848	XDE-848 acid	XDE-848 taurine conjugate
	Day 7	G	280	16.9	< 1.08
	Day 8	F	128	3.32	< 1.08
	Day 10	C	29.4	1.75	< 1.08
Crayfish	6-Hour	A	291	19	< 0.903
	Day 1	B	214	58.1	< 0.903
	Day 2	D	179	158	1.85
	Day 3	E	219	170	1.55
	Day 7	G	62.2	22.2	< 0.903
	Day 8	F	13.1	4.69	< 0.903
	Day 10	C	8.84	< 1.08	< 0.903

B.7.6.2-4. Summary of Analytical Results for the Concentration of Florpyrauxifen-benzyl and its Metabolites in the Fish and Crayfish Fractions of the Pond Exposure during the Magnitude of Residue Study with GF-3301.

Matrix	Sampling Interval	Replicate ID	XDE-848 BE (ppm)	XDE-848 Acid (ppm)	XDE-848 Hydroxy Acid (ppm)	Total XDE-848 BE+Acid (ppm)
Bluegill	6-Hour	A	0.991	0.073	0.00469	1.083
Bluegill	Day 1	B	0.873	0.156	0.00859	1.069
Bluegill	Day 2	D	0.683	0.0629	0.00247	0.762
Bluegill	Day 3	E	0.659	0.076	0.0029	0.755
Bluegill	Day 7	G	0.183	0.0163	<0.000975	0.204
Bluegill	Day 8	F	0.0761	<0.00108	<0.000975	0.077
Bluegill	Day 10	C	<0.00108	<0.00108	<0.000975	<LOQ
Bluegill	Day 10	C	<0.00108	<0.00108	<0.000975	<LOQ
Catfish	6-Hour	A	1.05	0.0887	0.0126	1.162
Catfish	Day 1	B	1.59	0.108	0.0436	1.726
Catfish	Day 2	D	1.43	0.081	0.0251	1.532
Catfish	Day 3	E	1.78	0.072	0.0377	1.871
Catfish	Day 7	G	0.28	0.0169	<0.00108	0.301
Catfish	Day 8	F	0.128	0.00332	<0.00108	0.132
Catfish	Day 10	C	<0.00108	<0.00108	<0.00108	<LOQ
Catfish	Day 10	C	0.0294	0.00175	<0.00108	0.032
Crayfish	6-Hour	A	0.291	0.019	<0.000903	0.315
Crayfish	Day 1	B	0.214	0.0581	<0.000903	0.287
Crayfish	Day 2	D	0.179	0.158	0.00185	0.378
Crayfish	Day 3	E	0.219	0.17	0.00155	0.433
Crayfish	Day 7	G	0.0622	0.0222	<0.000903	0.090
Crayfish	Day 8	F	0.0131	0.00469	<0.000903	0.019
Crayfish	Day 10	C	<0.00108	<0.00108	<0.000903	<LOQ

B.7.6.2-4. Summary of Analytical Results for the Concentration of Florpyrauxifen-benzyl and its Metabolites in the Fish and Crayfish Fractions of the Pond Exposure during the Magnitude of Residue Study with GF-3301.

Matrix	Sampling Interval	Replicate ID	XDE-848 BE (ppm)	XDE-848 Acid (ppm)	XDE-848 Hydroxy Acid (ppm)	Total XDE-848 BE+Acid (ppm)
Crawfish	Day 10	C	0.00884	<0.00108	<0.000903	0.010

B.7.6.2-5. Analytical Results for the Concentration of Florpyrauxifen-benzyl and its Metabolites in the Clam Tissues in the Aquaria Exposure during the Magnitude of Residue Study with GF-3301.

Matrix	Interval	Replicate ID	Residues (µg/kg)		
			XDE-848 BE	XDE-848 acid	XDE-848 taurine conjugate
Clam	6-Hour	A	18400	86.1	< 1.03
	Day 1	B	7960	79.3	< 1.03
	Day 2	D	4480	69	< 1.03
	Day 3	E	2760	44.7	< 1.03
	Day 7	G	1350	40.4	< 1.03
	Day 8	F	329	16.2	< 1.03
	Day 10	C	326	10.1	< 1.03

B.7.6.2-6. Summary of Analytical Results for the Concentration of Florpyrauxifen-benzyl and its Metabolites in the Clam Tissues in the Aquaria Exposure during the Magnitude of Residue Study with GF-3301.

Matrix	Sampling Interval	Replicate ID	XDE-848 BE (ppm)	XDE-848 Acid (ppm)	XDE-848 Acid Taurine Conjugate (ppm)	Total XDE-848 BE+Acid (ppm)
Clam	6-Hour	A	18.4	0.0861	<0.00103 ^b	18.5
Clam	Day 1	B	7.96	0.0793	<0.00103	8.06
Clam	Day 2	D	4.48	0.069	<0.00103	4.57
Clam	Day 3	E	2.76	0.0447	<0.00103	2.82
Clam	Day 7	G	1.35	0.0404	<0.00103	1.40
Clam	Day 8	F	0.329	0.0162	<0.00103	0.349
Clam	Day 10	C	0.326	0.0101	<0.00103	0.339

Conclusions: Provided the Section F is amended as specified in Section 2.2.2, the submitted aquatic study is adequate to fulfill data requirements. The aquatic study was conducted at the proposed maximum rate (annual). The recommended tolerances for residues of florpyrauxifen-benzyl and its metabolites are as follows: 2.0 ppm for freshwater fish, 0.50 ppm for crustacean shellfish, and 20 ppm for mollusc shellfish.

5.4 Food Residue Profile

Adequate residue data are available to support the proposed tolerances for the herbicide florpyrauxifen-benzyl in/on rice commodities and fish. Residues are quantifiable in fish treated in accordance with the proposed aquatic use label. Residues are quantifiable in rice treated in accordance with the proposed label (foliar uses). Rice straw is no longer considered to be a significant livestock feedstuff; therefore, no tolerance is required for rice straw. Processing

studies were conducted on rice; residues of florpyrauxifen-benzyl were non-quantifiable. The data indicate that residues of florpyrauxifen-benzyl do not concentrate in processed commodities (hulls, bran and flour). Therefore, tolerances are not needed for the processed commodities. Based on no transfer of residues (<0.001), tolerances are not needed in livestock commodities (i.e., no finite residues of florpyrauxifen-benzyl and/or its metabolites are expected (the proposed uses fall under 40 CFR §180.6(a)(3)).

6.0 Tolerance Derivation

The recommended tolerance levels for rice commodities were obtained by use of the Organization of Economic Cooperation and Development calculation procedure. Combined average residues of parent and its acid metabolite converted to parent equivalent from field trials conducted according to the proposed label were used in the calculations.

Only the results from the 12 U.S. field trials made in 2014 at the rate of 80 g ai/ha (0.070 lb ai/A) were input for MRL calculation since residues were higher. The detected residues were adjusted to reflect the proposed use pattern. The OECD calculation procedures recommend that a tolerance of 0.30 ppm be established for rice grain. The OECD calculation procedures are globally recognized for calculating MRLs to facilitate the harmonization of regulatory limits.

The recommended tolerances for freshwater fish (2.0 ppm), crustacean shellfish (0.50 ppm) and mollusc shellfish (20 ppm) were based on one trial. The recommended tolerance for shellfish mollusc was revised based on the residue data provided which included the 0-day data. It appears that the registrant did not consider the 0-day data. The OECD calculation procedures were not used to estimate these tolerances since only decline data were available.

7.0 ChemSAC Reference

This memorandum was reviewed by the Chemistry Science Advisory Council (ChemSAC) on 11/09/2016 and has been revised to reflect the recommendations of that group.

Appendix A. Tabular Summary of Metabolites

TableA1. Tabular Summary of Metabolites and Degradates.

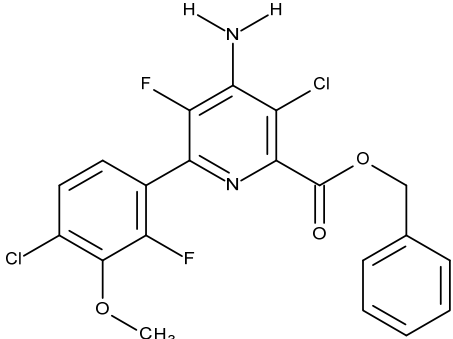
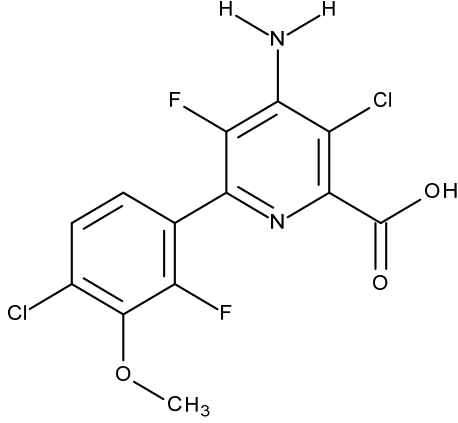
Table A1. Tabular Summary of Metabolites and Degradates from Metabolism Studies.				
Chemical Name (other names in parentheses) and Structure	Matrix	Percent TRR (PPM)		
		Matrices - Major Residue ($\geq 10\%$ TRR)	Matrices - Minor Residue ($< 10\%$ TRR)	
 <p>IUPAC: benzyl 4-amino-3-chloro-6-(4-chloro-2-fluoro-3-methoxy-phenyl)-5-fluoro-pyridine-2-carboxylate</p> <p>Florpyrauxifen-benzyl, XDE-benzyl ester, XDE-BE, X11959130</p>	Mature Rice Straw (W)	10.1 (0.011)-PH 13.0 (0.014)-BE	8.3 (0.006)-PY	
	Mature Rice Hulls (W)		7.0 (0.002)	
	Mature Rice Straw (F)	17.4 (0.175)-PH 19.1 (0.199)-PY 38.8 (0.781)-BE		
	Mature Rice Hulls (F)	14.2 (0.056)-PH 15.7 (0.049)-PY 19.2 (0.016)-BE		
	Mature Rice Grain (F)		6.0 (0.002)-PH 3.9 (0.001)-PY	
	Mature Rice Straw (D)	20.3 (0.223)-PH 23.0 (0.390)-PY 20.5 (0.098)-BE		
	Wheat Hay (271-PBI)		3.5 (0.001)-PY	
	Fillet (bluegill fish)	27.8 (0.331)		
	 <p>IUPAC: 4-amino-3-chloro-6-(4-chloro-2-fluoro-3-methoxy-phenyl)-5-fluoro-pyridine-2-carboxylic acid</p> <p>Florpyrauxifen (XDE-848 acid, X11438848)</p>	Mature Rice Straw (W)	47.8 (0.054)-PH 41.9 (0.029)-PY	
		Mature Rice Hulls (W)	38.6 (0.014)	
Mature Rice Straw (F)		38.8 (0.781)-BE	4.3 (0.043)-PH 5.4 (0.056)-PY	
Mature Rice Hulls (F)			3.4 (0.013)-PH 3.8 (0.012)-PY	
Mature Rice Grain (F)			4.0 (0.001)-PH	
Mature Rice Straw (D)			4.5 (0.050)-PH 6.0 (0.101)-PY	
Liver (Goat)			6.9 (0.001)-PH 6.0 (0.001)-PY	
Kidney		27.9 (0.004)-PH 44.7 (0.01)-PY		
Wheat Straw (30-PBI)			4.1 (0.001)-PY	
Wheat Hay (90-PBI)			2.7 (0.001)-PH 3.0 (0.001)-PY	
Wheat Hay (271-PBI)		17 (0.004)-PY		
Wheat Straw (271-PBI)			4.5 (0.001)-PY	

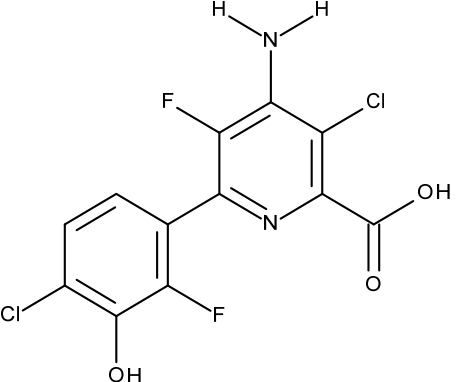
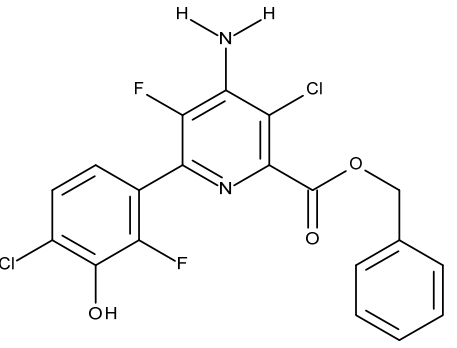
Table A1. Tabular Summary of Metabolites and Degradates from Metabolism Studies.				
Chemical Name (other names in parentheses) and Structure	Matrix	Percent TRR (PPM)		
		Matrices - Major Residue ($\geq 10\%$ TRR)	Matrices - Minor Residue ($< 10\%$ TRR)	
	Fillet (bluegill fish)	52.6 (0.626)		
 <p>IUPAC: 4-amino-3-chloro-6-(4-chloro-2-fluoro-3-hydroxy-phenyl)-5-fluoro-pyridine-2-carboxylic acid</p> <p>XDE-848 hydroxy acid (XR-848 hydroxy acid, X11966341)</p>	Mature Rice Straw (W)		2.4 (0.003)-PH	
	Mature Rice Hulls (F)		1.6 (0.006)-PH 1.7 (0.005)-PY	
	Mature Rice Grain (F)		3.2 (0.001)-PH 2.1 (0.001)-PY	
	Mature Rice Straw (D)	11.1 (0.123)-PH 14.0 (0.238)-PY		
	Liver (Goat)	20.8 (0.002)-PH 20.8 (0.003)-PY		
	Kidney	24.9 (0.003)-PH 24 (0.005)-PY		
	Wheat Hay (30-PBI)	11.8 (0.002)-PH 10.4 (0.001)-PY		
	Wheat Straw (30-PBI)	22.6 (0.006)-PH 17.7 (0.006)-PY		
	Wheat Hay (90-PBI)	12.5 (0.002)-PH 10.9 (0.003)-PY		
	Wheat Straw (90-PBI)	24.6 (0.008)-PH 14.2 (0.007)-PY		
	Wheat Hay (271-PBI)	25.4 (0.007)-PH		
	Wheat Straw (271-PBI)	11.2 (0.004)-PY		
 <p>IUPAC: benzyl 4-amino-3-chloro-6-(4-chloro-2-fluoro-3-hydroxy-phenyl)-5-fluoro-pyridine-2-carboxylate</p> <p>XDE-848 Benzyl Hydroxy (XDE-848 Hydroxy BE, X12300837)</p>	Mature Rice Straw (F)		2.6 (0.026)-PH 1.4 (0.028)-BE	
	Mature Rice Hulls (F)		1.3 (0.005)-PH	

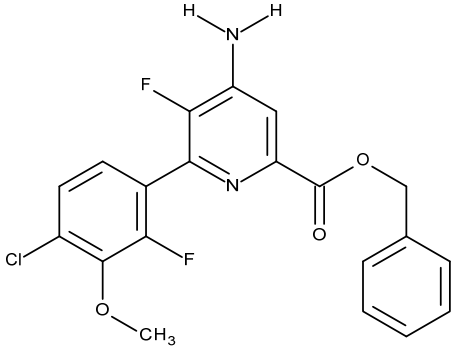
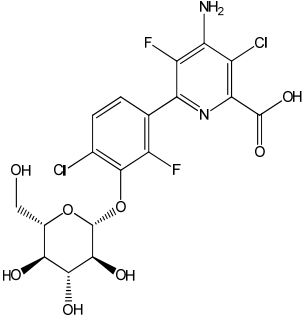
Table A1. Tabular Summary of Metabolites and Degradates from Metabolism Studies.			
Chemical Name (other names in parentheses) and Structure	Matrix	Percent TRR (PPM)	
		Matrices - Major Residue ($\geq 10\%$ TRR)	Matrices - Minor Residue ($< 10\%$ TRR)
 <p>IUPAC: benzyl 4-amino-6-(4-chloro-2-fluoro-3-methoxy-phenyl)-5-fluoro-pyridine-2-carboxylate</p> <p>De-chlorinated XDE-848 Benzyl Ester (De-chlorinated XDE-848 BE, X12131932)</p>	Mature Rice Straw (F)		4.0 (0.04)-PH 3.8 (0.04)-PY 2.8 (0.055)-BE
	Mature Rice Hulls (F)		5.8 (0.023)-PH 4.2 (0.013)-PY
	Mature Rice Grain (F)		2.6 (0.001)-PH
	Mature Rice Straw (D)		5.5 (0.061)-PH 4.4 (0.074)-PY 4.4 (0.021)-BE
 <p>4-amino-3-chloro-6-(4-chloro-2-fluoro-3-((2S,3R,4S,5S,6R)-3,4,5-</p>	Mature Rice Straw (F)		2.6 (0.027)-PH 2.2 (0.023)-PY
	Mature Rice Straw (D)		2.9 (0.032)-PH 9.2 (0.157)-PY
	Wheat Hay (30-PBI)	44.3 (0.007)-PH 50.5 (0.006)-PY	
	Wheat Straw (30-PBI)	19.6 (0.005)-PH 15.8 (0.005)-PY	
	Wheat Hay (90-PBI)	18.6 (0.002)-PH 14.2 (0.004)-PY	
	Wheat Straw (90-PBI)	17.3 (0.006)-PH 13.3 (0.006)-PY	
	Wheat Hay (271-PBI)		4.5 (0.001)-PY

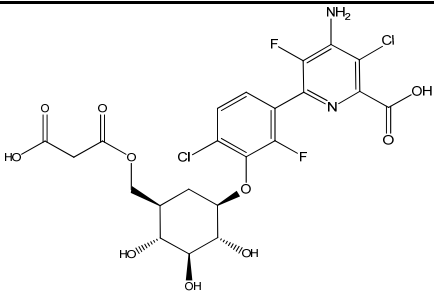
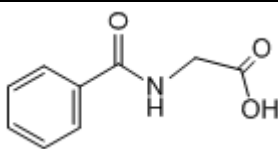
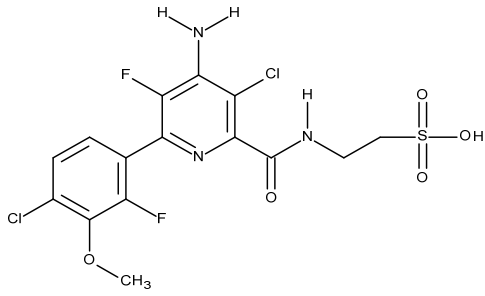
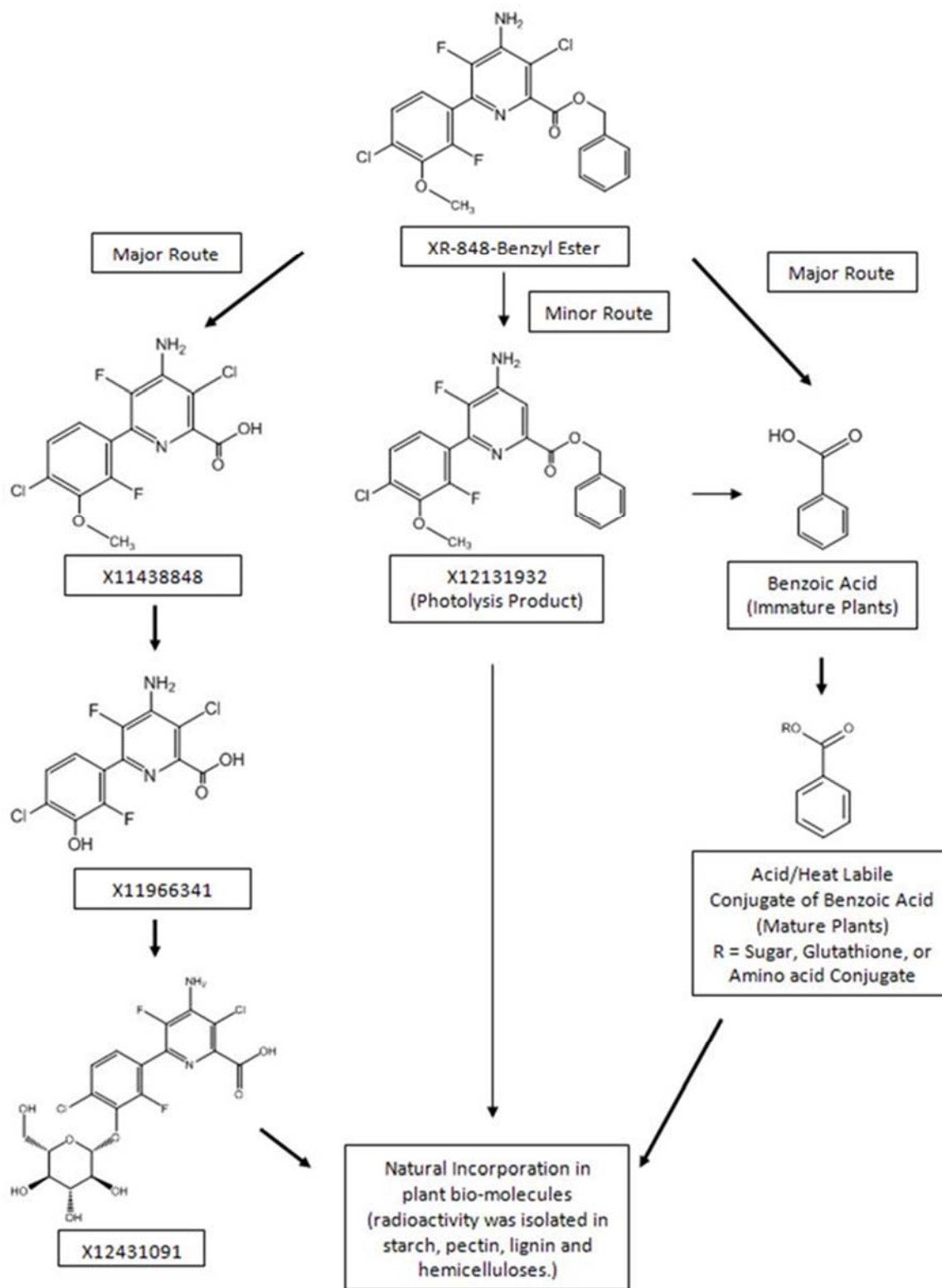
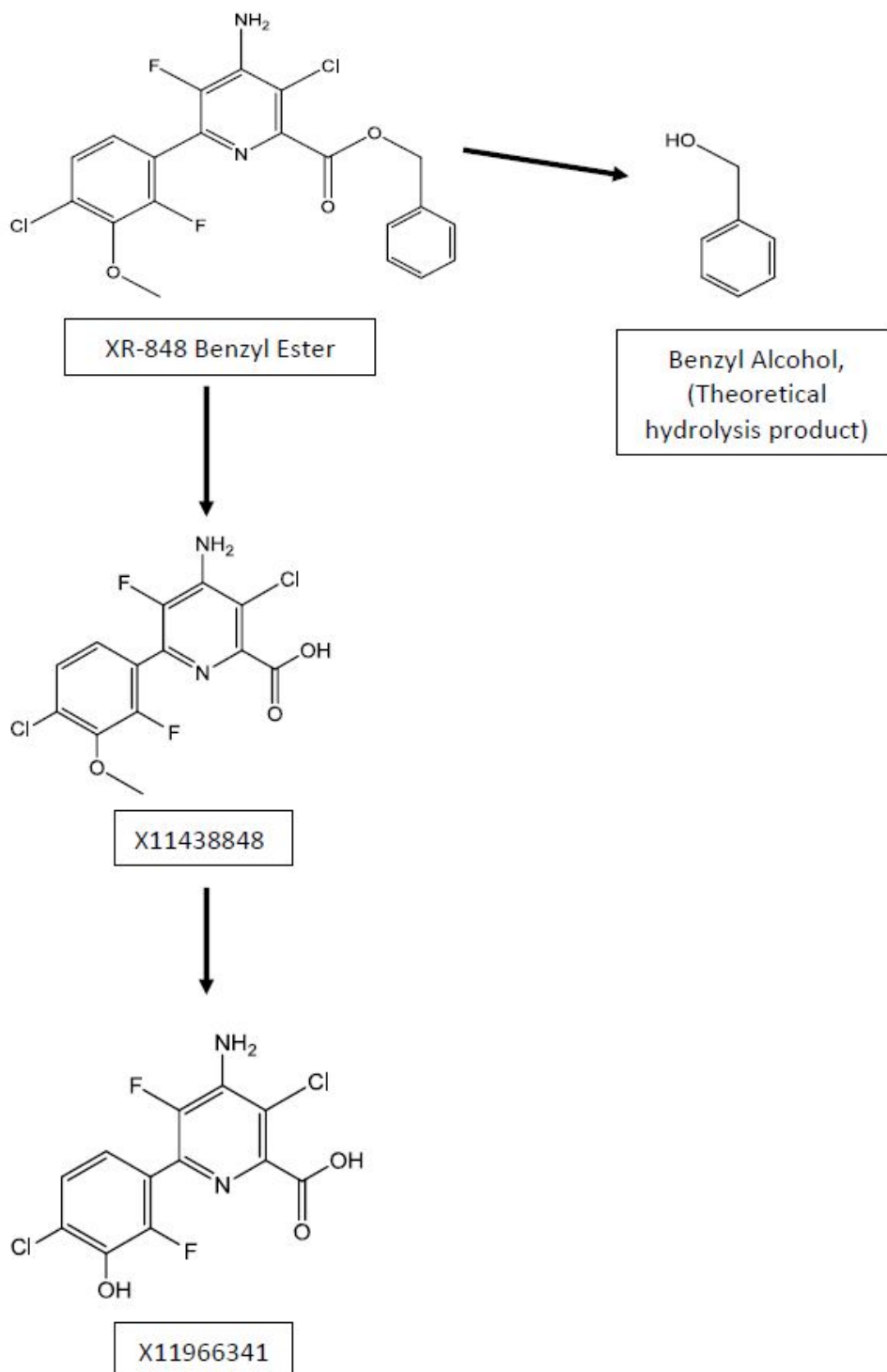
Table A1. Tabular Summary of Metabolites and Degradates from Metabolism Studies.			
Chemical Name (other names in parentheses) and Structure	Matrix	Percent TRR (PPM)	
		Matrices - Major Residue ($\geq 10\%$ TRR)	Matrices - Minor Residue ($< 10\%$ TRR)
trihydroxy-6-(hydroxymethyl)- tetrahydro-2H- pyran-2- yoxyl)phenyl)-5-fluoropicolinic acid X12431091 Glucose conjugate of XR-848 Hydroxy Acid (X11966341)	Wheat Straw (271- PBI)		9.9 (0.003)-PY
 <p>4-amino-6-(3-[[6-O-(carboxyacetyl)hexopyranosyl]oxy]- 4-chloro- 2-fluorophenyl)-3-chloro-5- fluoropyridine-2- carboxylic acid</p> <p>X12431475 (glucose-malonic acid conjugate of X11966341)</p>	Mature Rice Straw (D)		0.5 (0.005)-PH 0.8 (0.013)-PY
	Wheat Hay (30-PBI)		6.5 (0.001)-PH 4.2 (0.001)-PY
	Wheat Straw (30-PBI)		3.5 (0.001)-PH 2.9 (0.001)-PY
	Wheat Hay (90-PBI)		4.8 (0.001)-PH 4.2 (0.001)-PY
	Wheat Straw (90-PBI)		3.8 (0.001)-PH 3.1 (0.001)-PY
	Wheat Straw (271- PBI)		2.3 (0.001)-PY
(2 <i>S</i> ,3 <i>S</i> ,4 <i>S</i> ,5 <i>S</i>)-3,4,5-trihydroxy-6- (hydroxymethyl)-tetrahydro-2 <i>H</i> -pyran-2- yl-4- amino-3-chloro-6-(4-chloro-2-fluoro- 3- methoxyphenyl)-5-fluoropicolinate X12427971	Mature Rice Straw (D)		2.3 (0.026)-PH 2.5 (0.042)-PY
 <p>(2-oxo-2-phenylethyl)carbamic acid</p> <p>X194907 (conjugate of benzoic acid)</p>	Liver (Goat)	13.8 (0.003)-BE	
	Kidney	99.7 (0.02)-BE	

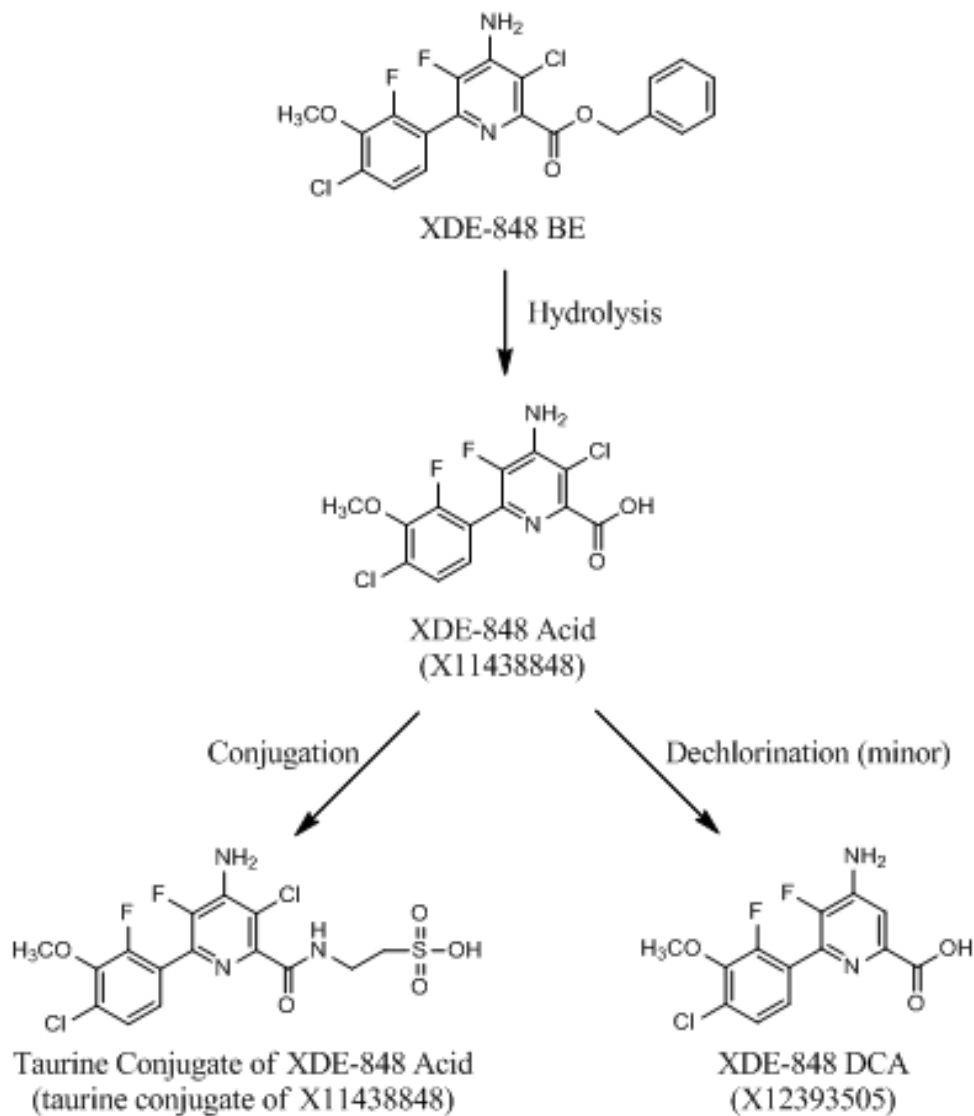
Table A1. Tabular Summary of Metabolites and Degradates from Metabolism Studies.			
Chemical Name (other names in parentheses) and Structure	Matrix	Percent TRR (PPM)	
		Matrices - Major Residue ($\geq 10\%$ TRR)	Matrices - Minor Residue ($< 10\%$ TRR)
 <p>IUPAC: 2-[[4-amino-3-chloro-6-(4-chloro-2-fluoro-3-methoxy-phenyl)-5-fluoro-pyridine-2-carbonyl]amino]ethanesulfonic acid</p> <p>X12482999 Taurine conjugate of XDE-848 acid (Taurine conjugate of X11433848)</p>	Fillet (bluegill fish)		6.2 (0.074)

Appendix B. Metabolic Pathways

Proposed Metabolic Pathway of Florpyrauxifen-benzyl in Rice



Proposed Metabolic Pathway of Florpyrauxifen-benzyl in Lactating Goats and Laying Hens

Proposed Metabolic Pathway of Florpyrauxifen-benzyl in Bluegill Sunfish

Appendix C. OECD MRL Calculation Procedure Inputs/Outputs

Tolerance estimates for rice were derived using the field trial data and the OEC) calculation procedure. The procedure is designed to estimate the 95th percentile of the distribution.

Rice (U.S.)

Combined average residues of parent and its acid metabolite converted to parent equivalent from field trials conducted according to the proposed label were used in the calculations. Only the results from the 12 U.S. field trials made in 2014 at the rate of 80 g ai/ha (0.070 lb ai/A) were input for MRL calculation since residues were higher. The detected residues were adjusted to reflect the proposed use pattern. The recommended tolerance is 0.30 ppm.

Florpyrauxifen-benzyl	
Rice	
US EPA (2014)	
60 g ai/ha (0.054 lb ai/A); PHI-60-days	
Total number of data (n)	12
Percentage of censored data	83%
Number of non-censored data	2
Lowest residue	0.010
Highest residue	0.165
Median residue	0.010
Mean	0.034
Standard deviation (SD)	0.055
Correction factor for censoring (CF)	0.444
 <u>Proposed MRL estimate</u>	
- Highest residue	0.165
- Mean + 4 SD	0.255
- CF x 3 Mean	0.045
Unrounded MRL	<u>0.255</u>
 Rounded MRL	 <u>0.3</u>

High uncertainty of MRL estimate.
[High level of censoring]

Appendix D. Field Trial Geographic Distribution

The number and distribution of the field trials (US) are adequate for US registration.

Table C-1. Trial Numbers and Geographical Locations.							
Zone	4	5	6	10			Total
US Required*							
Submitted	7	1	2	2			12
*As per EPA Residue Chemistry Test Guidelines (crop group reduction).							

Table C-2. Trial Numbers and Geographical Locations.							
Zone	4	5	6	10			Total
US Required*							
Submitted	7	1	2	2			12
*As per EPA Residue Chemistry Test Guidelines (crop group reduction).							

Appendix E: International Residue Limits Table

Florpyrauxifen-benzyl (PC Code 030093)

Summary of US and International Tolerances and Maximum Residue Limits				
<i>Residue Definition:</i>				
US	Canada	Mexico ²	Codex	
40 CFR 180.XXX:	None		None	
<i>Commodity¹</i>	<i>Tolerance (ppm) /Maximum Residue Limit (ppm)</i>			
	US	Canada	Mexico ²	Codex
Rice, grain	0.30			
Fish - freshwater finfish	2.0			
Fish - shellfish, crustacean	0.50			
Fish - shellfish, mollusc	20			
Completed: M. Negussie; 10/10/16				

¹ Includes only commodities of interest for this action. Tolerance values 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.