



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

OFFICE OF  
PREVENTION, PESTICIDES  
AND TOXIC SUBSTANCES

**MEMORANDUM**

Date: 09-MAR-2007

Subject: PP#s: 5E6911, 5E6926 and 5E6991. **Indoxacarb**. Petitions for Tolerances on Vegetable, Leafy, Except *Brassica* (Group 4), Pome Fruits (Group 11, except pear), Tuberous and Corm Vegetables (Subgroup 1C), Cucurbit Vegetables (Group 9), Stone Fruits (Group 12), Cranberry, Mint, Okra, and Southern Pea. **Summary of Analytical Chemistry and Residue Data.**

DP#s: 325479, 326516, 326544, 333333	Decision #s: 355154, 360904, 356203, 355154
PC Code: 067710	MRID#s: 46520901, 46520902, 46487001, 46487002, 46651501, 46651502, 46651503, 46651504, 46651505, 46651506, 46651507
40 CFR 180.564	Chemical Class: Oxadiazine Insecticide

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## Executive Summary

Indoxacarb is an oxadiazine insecticide (Group 22) used for control of lepidopteran pests on a variety of fruit, vegetable and field crops. Permanent tolerances are established for the combined residues of indoxacarb, (*S*)-methyl 7-chloro-2,5-dihydro-2-[[[(methoxycarbonyl)[4-(trifluoromethoxy)phenyl]amino]carbonyl]indeno[1,2-*e*][1,3,4]oxadiazine-4a(3*H*)-carboxylate, and its inactive *R*-enantiomer in/on various plant commodities at levels ranging from 0.01 ppm in/on peanuts and potatoes to 50 ppm in/on alfalfa hay [40 CFR §180.564(a)]. Tolerances are also established for combined residues of indoxacarb + its *R*-enantiomer in livestock commodities at levels ranging from 0.03 ppm in livestock meat byproducts to 4.0 ppm in milk fat.

The Interregional Research Project No. 4 (IR-4) has submitted three petitions proposing new uses of indoxacarb, formulated as a 30% water-dispersible granule (WDG; DuPont Avaunt<sup>®</sup> Insecticide; EPA Reg. No. 352-597) on following crops or crop groups: cranberry, cucurbit vegetables (group 9), mint, southern pea and stone fruits (group 12). Under these petitions, IR-4 has also proposed expanding existing uses and tolerances on apples, lettuce, peppers and potatoes to cover pome fruits (except pear, group 11), leafy vegetables except *Brassica* (group 4), okra, and tuberous and corm vegetables (subgroup 1C). The proposed uses on leaf petiole vegetables, mint, okra, and southern pea are for up to four broadcast foliar applications at 0.065 lb ai/A, at minimum retreatment intervals (RTIs) of 3-5 days, for a total application rate of 0.26 lb ai/A/crop. The proposed uses on cranberry, leafy green vegetables (except spinach), pome fruits, stone fruits, and tuberous and corm vegetables are for up to four broadcast foliar applications at 0.11 lb ai/A, at minimum RTIs of 3-7 days, for a total application rate of 0.44 lb ai/A/crop. All uses allow applications using either ground or aerial equipment, and the proposed preharvest intervals (PHIs) range from 3 days (for cucurbits, okra, and leafy vegetables, except *Brassica*, group 4) to 30 days (for cranberries). In conjunction with these uses, IR-4 is proposing permanent tolerances for combined indoxacarb residues at levels ranging from 0.01 ppm in/on for tuberous and corm vegetables to 14 ppm in/on leafy vegetables, except *Brassica*, group 4.

Adequate studies are available depicting the uptake and metabolism of [<sup>14</sup>C]indoxacarb following applications to cotton, lettuce and tomatoes. Based on these studies, HED has determined that indoxacarb +its *R*-enantiomer are the residues of concern to be used in risk assessment and the tolerance expression for plants. Adequate studies are also available depicting the metabolism of indoxacarb in ruminants and poultry. Based on the livestock metabolism and feeding studies, HED has determined that the tolerance expression should include indoxacarb + its *R*-enantiomer for milk and ruminant commodities and the combined residues of indoxacarb, its *R*-enantiomer and metabolites IN-JT333, IN-KT319, IN-JU873, IN-KG433, and IN-KB687 for poultry commodities. For purposes of risk assessment, metabolite IN-MP819 will also be considered for milk and 5-OH-IN-JT333 and Metabolite F will also be considered for poultry commodities.

Issues pertaining to livestock tolerances are not addressed under these petitions as the proposed uses will not affect the current livestock tolerances. The only livestock feed items associated with the proposed uses are wet apple pomace and potato culls and processed waste. The impact of indoxacarb residues from these commodities on livestock diets were previously addressed under earlier petitions for uses on apples and potatoes.

Two high-performance liquid chromatography (HPLC)/column switching/ultraviolet (UV) methods (AMR 2712-93 and DuPont-11978) are available for enforcing indoxacarb tolerances on plant commodities, and a third gas chromatography (GC)/mass-selective detector (MSD) method (AMR 3493-95, Supplement No. 4) is available for confirmation of residues in plants. The limits of quantitation (LOQs) for the HPLC methods are 0.01-0.05 ppm for a variety of plant commodities, and the limits of detection (LODs) are 0.0025-0.006 ppm. For the GC/MSD method, the LOQs range from 0.2 to 1.0 ppm depending on the matrix, and the LODs are 0.0008-0.21 ppm. Each of these methods determines both indoxacarb + its R-enantiomer as a single component.

Another HPLC/column switching/UV Method (AMR 3337-95) is also available for enforcing the current tolerances on livestock commodities. The LOQ for this method is 0.01 ppm and the LOD is 0.002-0.003 ppm.

In the field trials and processing studies submitted with the current petitions, combined indoxacarb residues were determined using either the GC/MSD method (AMR 3493-95), the HPLC/UV Method (AMR 2712-93), or a modified version of the HPLC method. Each method was adequately validated in conjunction with sample analyses. The validated LOQs for indoxacarb residues were 0.01 ppm for cantaloupes, cucumbers, southern peas, peaches, plums and prunes, 0.02 ppm for cherries, spinach and celery, 0.05 ppm for cranberries and mint tops, and 0.10 ppm for mint oil.

Adequate storage stability data have been previously reviewed indicating that indoxacarb residues are stable in frozen storage for up to 6-23 months in a wide variety of plant commodities. In addition, adequate storage stability data were provided with the new field trials and processing studies. These data also indicate that indoxacarb is stable in frozen storage for at least 1.5 months in cranberries, 5-8 months in peaches, plums, prunes, and mint tops and oil, 10-12 months in peas, celery, spinach, cantaloupes, and squash, 15 months in cherries, and 24 months in cucumbers. These data support the sample storage intervals and conditions used in the submitted field trails and processing studies.

The submitted field trials on spinach, cucurbit vegetables, stone fruits, cranberries and mint are adequate and support the proposed use patterns for indoxacarb (30% WDG) on these crops or crop groups. The number and geographic distribution of the field trials are adequate, and the appropriate samples were collected at the proposed PHIs. The available field trial data on celery are adequate to support a crop group tolerance for the crop group vegetable, leafy, except *Brassica* (group 4). The southern pea field trials are also adequate; however, the petitioner did not specify if they wanted succulent or dry. The field trial data the submitted were for dry peas. The proposed label directions for southern peas should be amended to allow for applications only to varieties used to produce dry seed. If the petitioner intends to support a generalized use on southern peas, then field trials will be required for succulent varieties as well. Acceptable field trial data are also available from earlier petitions supporting uses of indoxacarb (30% WDG) on potatoes, leaf and head lettuce, apples and peppers. Data on the representative crops of potatoes, lettuce, and apples will support expanding the use of indoxacarb to cover similar uses on tuberous and corm vegetables (subgroup 1C), vegetable, leafy, except *Brassica* (group 4), and pome fruits (group 11, except pear). The available field trials on tomatoes and peppers will be translated to support the same use pattern for indoxacarb (WDG) on okra, as okra is now considered part of the “vegetable, fruiting, group 8” crop group.

Adequate processing studies are available for mint and plums. A separate tolerance is not required for mint oil as residues were reduced on average by 0.028x in mint oil. Although residues were shown to concentrate by 4x in prunes, a separate tolerance is not required for prunes. Based on the highest-average field trial (HAFT) residues for plums (0.185 ppm) and the above processing factor, the maximum expected residues in prunes would be 0.74 ppm, which is below the recommended tolerance for stone fruits (0.90 ppm). Processing studies on apples and potatoes were previously considered under earlier petitions. Based on these petitions, no tolerances were required for potato processed products and a 3.0 ppm tolerance was established for wet apple pomace.

With regards to rotational crops, an adequate confined rotational crop study is available, and HED has concluded the residues of concern in rotational crops are indoxacarb + its R-enantiomer. HED has also concluded that the 30-day rotational crop restriction, currently on the label, is acceptable for all crops without registered indoxacarb uses.

### Residue Chemistry Deficiencies

Pending submission of a revised Section B (see requirements under Directions for Use), and a revised Section F (see requirements under Proposed Tolerances), there are no residue chemistry issues that would preclude granting an unconditional registration for the requested uses of indoxacarb. The proposed uses and the submitted data support the following permanent tolerances for the combined residues of indoxacarb + its R-enantiomer in/on the following raw agricultural commodities (RACs):

Cranberry .....	0.90 ppm
Fruit, pome, except pear, group 11 .....	1.0 ppm
Fruit, stone, group 12 .....	0.90 ppm
Vegetable, leafy, except Brassica, group 4.....	14 ppm
Peppermint.....	11 ppm
Spearmint.....	11 ppm
Okra.....	0.50 ppm
Pea, southern, seed.....	0.10 ppm
Vegetable, cucurbit, group 9 .....	0.60 ppm
Vegetable, tuberous and corm, subgroup 1C .....	0.01 ppm

A human-health risk assessment will be prepared as a separate document.

## Background

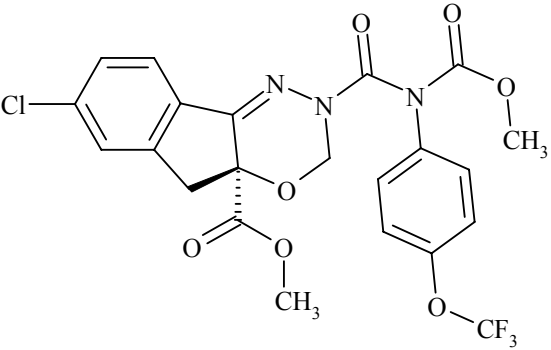
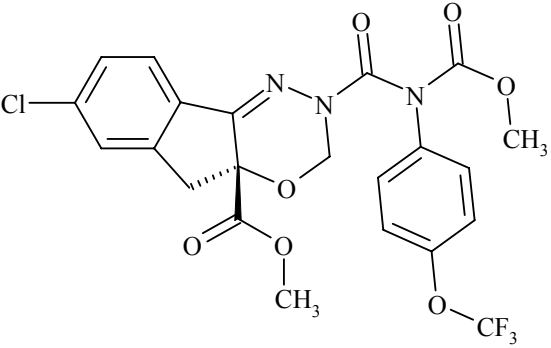
Indoxacarb is an oxadiazine insecticide (mode of action group 22) used primarily to control larval stages of lepidopteran pests on a variety of fruit, vegetable and field crops. It is a reduced-risk insecticide registered for use on various food and feed crops to E.I. du Pont de Nemours Company as a 30% WDG (DuPont Avaunt<sup>®</sup> Insecticide; EPA Reg. No. 352-597) and a 1.25 lb/gal FIC (DuPont Steward<sup>®</sup> Insecticide; EPA Reg. No. 352-598). These end-use formulations contain an isometric mixture of indoxacarb (insecticidally active S-enantiomer; DPX-KN128) + its R-enantiomer (insecticidally inactive; IN-KN127); however, the percentage of ai listed on the labels and the labeled use rates for each crop are based only on the amount of indoxacarb.

Permanent tolerances are currently established for the combined residues of indoxacarb + its inactive R-enantiomer in/on various plant commodities at levels ranging from 0.01 ppm in/on peanuts and potatoes to 50 ppm in/on alfalfa hay [40 CFR §180.564(a)]. Tolerances are also established in livestock commodities at levels ranging from 0.03 ppm in meat byproducts to 4.0 ppm in milk fat.

IR-4 has submitted petitions (PP# 5E6911, 5E6926, and 5E6991) proposing to amend the label for DuPont's 30% WDG to include new uses on cranberry, cucurbit vegetables (group 9), leafy vegetables except *Brassica*, mint, okra, pome fruits (group 11, except pear), southern peas, stone fruits (group 12), and tuberous and corm vegetables (subgroup 1C). In conjunction with these uses, the petitioner is proposing the following tolerances:

Cranberry .....	1 ppm
Fruit, pome, except pear, group 11 .....	1.0 ppm
Fruit, stone group 12 .....	1 ppm
Leafy vegetables except <i>Brassica</i> .....	14 ppm
Mint.....	10 ppm
Okra.....	0.5 ppm
Pea (southern) .....	0.1 ppm
Vegetable, cucurbit, group 9 .....	0.5 ppm
Vegetable, tuberous and corm, subgroup 1C .....	0.01 ppm

The nomenclature and physicochemical properties of indoxacarb are presented below in Tables 1 and 2.

<b>Table 1. Indoxacarb Nomenclature.</b>	
Compound	
Common name	Indoxacarb
Company experimental name	DPX-KN128
IUPAC name	(S)-methyl 7-chloro-2,5-dihydro-2-[[[(methoxycarbonyl)[4-(trifluoromethoxy)phenyl]amino]carbonyl]indeno[1,2-e][1,3,4]oxadiazine-4a(3H)-carboxylate
CAS name	methyl (4aS)-7-chloro-2,5-dihydro-2-[[[(methoxycarbonyl)[4-(trifluoromethoxy)phenyl]amino]carbonyl]indeno[1,2-e][1,3,4]oxadiazine-4a(3H)-carboxylate
CAS registry number	173584-44-6
End-use product (EP)	30% WDG (DuPont Avaunt® Insecticide; EPA Reg. No. 352-597)
Regulated Enantiomer	
Company experimental name	IN-KN127 (inactive R-enantiomer)

<b>TABLE A.2. Physicochemical Properties of Technical Grade Indoxacarb.</b>		
Parameter	Value	Reference
Melting point/range	140-141°C	Memo, S. Levy, 19-JAN-2000; DP#: 244253
pH	5.32 at 25°C	
Relative Density	1.34 at 20°C	
Water solubility (25°C)	15.4 ± 2.3 ppb in pH 5 buffer	
Solvent solubility(25°C)	1.72 g/L in n-heptane; 14.5 g/L in 1-octanol; 103 g/L in methanol; 117 g/L in o-xylene; 139 g/L in acetonitrile; 160 g/L in ethyl acetate; and >250 g/kg in methylene chloride, acetone, and dimethyl-formamide	
Vapor pressure (25°C) <sup>1</sup>	2.5 x 10 <sup>-8</sup> Pa	
Dissociation constant, pK <sub>a</sub> <sup>1</sup>	Does not dissociate at pHs of 2.42-11.36	
Octanol/water partition coefficient, Log(K <sub>OW</sub> )	4.65 at pH 5	
UV/visible absorption spectrum (λ <sub>max</sub> , nm) <sup>1</sup>	Molar absorptivities at 3 maxima were affected by pH, but not over wavelengths of environmental significance.	

<sup>1</sup> Properties are for pure active ingredient. These properties were not reported for technical grade indoxacarb.

**860.1200 Directions for use**

IR-4 has proposed amending the label for DuPont™ Avaunt® Insecticide (EPA Reg. No. 352-597) to include new uses on cranberry, cucurbit vegetables (group 9), mint, southern peas, and stone fruits (group 12). The petitioner has submitted new field trial data to support these uses. IR-4 has also proposed using existing field trial data, as well as some new field trial data (for some crops), on apples, lettuce, peppers, and potatoes to support expanding the uses on the 30% WDG to cover pome fruits (except pear), leafy vegetables except *Brassica*, okra, and tuberous and corm vegetables. The petitioner provided both a summary of the proposed uses and an example label from DuPont containing the use directions. The proposed use directions are summarized below in Table 3.

<b>Table 3. Summary of Proposed Use Directions for Indoxacarb.</b>						
Applic. Timing, Type, and Equip. <sup>1</sup>	Formulation [EPA Reg. No.]	Applic. Rate (lb ai/A)	Max. No. Applic. per Season	Max. Seasonal Applic. Rate (lb ai/A)	PHI (days)	Use Directions and Limitations <sup>2</sup>
<b>Cranberry</b>						
Broadcast foliar applications using ground or aerial equipment	30% WDG [352-597]	0.11	4	0.44	30	Minimum RTI is 7 days. Do not apply to flow through bogs or allow release of irrigation water from bogs for at least 1 day following application.
<b>Cucurbit Vegetables</b>						
Broadcast foliar applications using ground or aerial equipment	30% WDG [352-597]	0.045-0.11	4	0.44	3	Minimum RTI is 5 days. Make uniform application of insecticide in 10-50 GPA of water. For ground application, apply using a minimum of 10 GPA of water.
<b>Leafy Green Vegetables, except spinach</b>						
Broadcast foliar applications using ground or aerial equipment	30% WDG [352-597]	0.045-0.11	4	0.44	3	Minimum RTI is 3 days.
<b>Leaf Petiole Vegetables</b>						
Broadcast foliar applications using ground or aerial equipment	30% WDG [352-597]	0.065	4	0.26	3	Minimum RTI is 3 days.
<b>Mint</b>						
Broadcast foliar applications using ground or aerial equipment	30% WDG [352-597]	0.065	4	0.26	7	Minimum RTI is 3 days. Use a minimum of 20 GPA of water for ground applications.
<b>Okra</b>						
Broadcast foliar applications using ground or aerial equipment	30% WDG [352-597]	0.065	4	0.26	3	Minimum RTI is 5 days.
<b>Pome Fruits, except pears</b>						
Foliar applications using ground or aerial equipment	30% WDG [352-597]	0.056-0.11	4	0.44	14	Minimum RTI is 7 days. For best results, apply a uniform application of insecticide in 50-150 GPA of water. Do not apply in a dilute application of more than 200 GPA of water.
<b>Southern Pea</b>						
Broadcast foliar applications using ground or aerial equipment	30% WDG [352-597]	0.065	4	0.26	7	Minimum RTI is 3 days. Make a uniform application in approximately 20-100 GPA of water.

<b>Table 3. Summary of Proposed Use Directions for Indoxacarb.</b>						
Applic. Timing, Type, and Equip. <sup>1</sup>	Formulation [EPA Reg. No.]	Applic. Rate (lb ai/A)	Max. No. Applic. per Season	Max. Seasonal Applic. Rate (lb ai/A)	PHI (days)	Use Directions and Limitations <sup>2</sup>
<b>Spinach</b>						
Broadcast foliar applications using ground or aerial equipment	30% WDG [352-597]	0.065	4	0.26	3	Minimum RTI is 3 days.
<b>Stone Fruits</b>						
Foliar applications using ground or aerial equipment	30% WDG [352-597]	0.09-0.11	4	0.44	14	Minimum RTI is 7 days. For best results, apply a uniform application of insecticide in 50-150 GPA of water. Do not apply in a dilute application of more than 200 GPA of water.
<b>Tuberous and Corm Vegetables</b>						
Broadcast foliar applications using ground or aerial equipment	30% WDG [352-597]	0.045-0.11	4	0.44	7	Minimum RTI is 5 days. For aerial application, use a minimum of 5 GPA of water.

<sup>1</sup> Do not apply through any type of irrigation equipment, except as allowed by supplemental labels.

<sup>2</sup> The label currently specifies a minimum re-entry interval (REI) of 12 hours and a rotation crop restriction of 30 days for food/feed crops not registered for use with indoxacarb. Unless otherwise specified, apply aerial applications in a minimum of 5 gallons per acre (GPA) or 10 GPA for tree and orchard crops.

RTI = retreatment interval.

**Conclusions.** The proposed use directions adequately reflect the use patterns used in the new or previously reviewed field trials, with the exception of southern peas. Based on the available southern pea field trials, it is unclear whether the petitioner is pursuing a use on succulent or dry southern peas. The proposed label directions for southern peas should be amended to allow applications only to varieties used to produce dry seed. If the petitioner intends to support a generalized use on southern peas, field trials will be required for the succulent variety as well. In addition, the use directions for southern peas should prohibit applications to varieties grown for livestock feed. **A revised Section B should be submitted.**

### 860.1300 Nature of the Residue – Plants

Adequate metabolism studies on cotton, lettuce, and tomatoes were reviewed in conjunction with an earlier petition (Memo, S. Levy, 19-JAN-2000; DP#: 244253). Based on these studies, the HED Metabolism Assessment Review Committee (MARC) determined that the residue of concern in plants is indoxacarb + its R-enantiomer (Memo, S. Levy, 10-JUL-2000; DP#: 263986).

### 860.1300 Nature of the Residue – Livestock

Adequate ruminant and poultry metabolism studies were reviewed in conjunction with an earlier petition (Memo, S. Levy, 19-JAN-2000; DP#: 244253). Based on these studies, the MARC has determined that the tolerance expression for milk and ruminant commodities will include indoxacarb + its R-enantiomer (Memo, S. Levy, 10-JUL-2000; DP#: 263986). However, for purposes of risk assessment, the metabolite IN-MP819 will also be considered in milk. For poultry commodities, HED has recommended that tolerances be established for the combined residues of the indoxacarb + its R-enantiomer, IN-JT333, IN-KT319, IN-JU873, IN-KG433, and IN-KB687 (Memo, S. Levy, 22-SEP-2004; DP#: 297936). For purposes of risk assessment,

residues of concern in poultry commodities also includes 5-OH-IN-JT333 and Metabolite F (Memo, S. Levy, 04-OCT-2001; DP#: 277922).

### 860.1340 Residue Analytical Methods

A number of adequate methods are available for enforcing indoxacarb + its R-enantiomer tolerances on plant and livestock commodities, and each of these methods determines both indoxacarb + its R-enantiomer as a single component.

The primary method for plant commodities is an HPLC/column switching/UV method (Method AMR 2712-93), which was validated by HED and forwarded to the United States Food and Drug Administration (U. S. FDA) for inclusion in Pesticide Analytical Manual (PAM) Vol. II (Memo, S. Levy, 12-OCT-2000; DP#: 267339). For this method, residues are extracted with hexane-saturated acetonitrile (ACN):ACN-saturated hexane and centrifuged. Residues in the ACN phase are purified by solid-phase extraction (SPE) using silica-gel and strong-anion exchange (SAX) cartridges. Residues are then determined by column switching HPLC/UV (310 nm) using C<sub>18</sub> and cyano columns, with an external standard. The method LOQs range from 0.01-0.05 ppm for a variety of plant commodities, and the LOD is 0.0025 ppm.

For confirmation of residues in plant commodities, a GC/MSD method (Method AMR 3493-95, Supplement No. 4) is available, which was also validated by HED and forwarded to the FDA (Memo, S. Levy, 09-MAY-2002; DP#: 282821). For this method, residues are extracted with ethyl acetate:water and filtered, and residues in the ethyl acetate fraction are concentrated and purified using silica gel and carbon SPE cartridges. Residues are then determined by GC/MSD using an external standard. Residues are quantified using the m/z 527 ion, and confirmatory analyses utilize the 218, 321 and 527 ions. The method LOQs range from 0.2-1.0 ppm depending on the matrix, and the LODs are 0.0008-0.21 ppm.

An additional HPLC/column switching/UV method (Method DuPont-11978; Memo, S. Levy, 18-FEB-2005; DP#: 313518) is also available, which combines the extraction procedures of Method AMR-3493-95 with the cleanup and determination procedures of Method AMR 2712-93. For this method, residues are extracted with ethyl acetate:water, and residues in the ethyl acetate fraction are purified by SAX SPE and determined by column switching HPLC/UV (310 nm) using cyano and C<sub>18</sub> columns, with an external standard. For grape matrices, the method LOQ is 0.01 ppm and the LOD is 0.006 ppm.

For enforcing the current tolerances in livestock commodities, another HPLC/column switching/UV Method (Method AMR 3337-95) is available, which is capable of determining residues of parent and the metabolite IN-JT333 in livestock matrices. This method has also been forwarded to the FDA for inclusion in PAM, Vol. II (Memo, S. Levy, 12-OCT-2000; DP#: 267339). Depending on the matrix, residues extracted with either ACN, ACN:hexane or ethyl acetate. Residues are then purified by solvent partitioning between ACN and hexane, followed by cleanup by SPE using either C<sub>18</sub> or silica gel cartridges. Residues are determined by column switching HPLC/UV (310 nm) using cyano and C<sub>18</sub> columns, with an external standard. The method LOQ is 0.01 ppm and the LOD is 0.002-0.003 ppm. Residues can be confirmed by GC/MSD using the m/z 527 and 469 ions.

In the field trials and processing studies submitted with the current petitions, combined indoxacarb residues were determined using one of the plant enforcement methods or a modification of an enforcement method. Each data collection method was adequately validated in conjunction with the samples analyses, using control samples fortified at an appropriate range of concentrations. Acceptable recoveries were obtained for all commodities.

The GC/MSD method AMR 3493-95 was used for determining residues in spinach, celery, cranberries and mint tops and oil. The validated method LOQs were 0.02 ppm for spinach and celery, 0.05 ppm for cranberries and mint tops, and 0.10 ppm for mint oil.

The HPLC/column switching/UV method AMR 2712-93 was used for determining residues in squash, and a modified version of this method, using only a single cyano column for analysis, was used for determining residues in southern peas and stone fruits. The validated method LOQs were 0.01 ppm for southern peas, peaches, plums and prunes, and 0.02 ppm for cherries.

Another modified version of Method AMR 2712-93 was used for determining residues in cantaloupes and cucumbers. The method was modified by eliminating the SPE cleanup step and using LC/MS/MS for determination of residues. The validated method LOQ was 0.01 ppm for both cantaloupes and cucumbers.

*Conclusions.* Adequate methods are available for enforcing the proposed tolerances on plant commodities, and residues in the available field trials and processing studies were determined using either an enforcement methods or an adequate method derived from an enforcement method.

### **860.1360 Multiresidue Methods**

Acceptable data are available depicting the recovery of indoxacarb + its R-enantiomer using FDA multiresidue method protocols (PAM, Vol. I) C, D, and E. Indoxacarb + its R-enantiomer were not evaluated through Protocol A because it does not possess an N-methylcarbamate structure. It was not tested through Protocol B because it does not possess a carboxylic acid or phenolic moiety. It was not tested through Protocol F because indoxacarb + its R-enantiomer are not recoverable from Florisil at a level  $\geq 30\%$ . Indoxacarb + its R-enantiomer are completely recovered through Protocol D; however, matrix enhancement effects were seen in certain matrices. The results of multiresidue testing were forwarded to FDA for review (Memo, S. Levy, 03-NOV-1999; DP#: 260955).

### **860.1380 Storage Stability**

Storage stability data have been reviewed in conjunction with earlier petitions (Memos, S. Levy, 19-JAN-2000; DP#: 244253; 07-SEP-2000; DP#: 267325; and 14-APR-2004; DP#: 290172) indicating that residues of indoxacarb + its R-enantiomer are relatively stable in frozen storage on a wide variety of plant commodities. These studies indicate that indoxacarb + its R-enantiomer are stable in frozen storage for up to 6 months in apple juice; 10-12 months in broccoli, wet apple pomace, wet grape pomace, wine, tomatoes, peppers, and cotton hulls, meal and refined oil; 13-15 months in pears, cabbage, lettuce, cottonseed, and cotton gin byproducts; 18 months in apples and grapes; and 19-23 months in corn forage, stover and ears.

In addition to the above data, storage stability studies were conducted in conjunction with each of the new field trials and processing studies. In each study, control samples were fortified with indoxacarb at 0.1-1.0 ppm and placed in frozen storage with the field trial or processing study samples. At intervals reflecting the maximum storage interval for treated crops, duplicate or triplicate stored samples were analyzed along with a control sample and freshly fortified samples. Average corrected recoveries of indoxacarb following frozen storage were 85-109% for each commodity, with the exception of spinach, which had a recovery of 73%. These data indicate that indoxacarb is stable in frozen storage for at least 1.5 months in cranberries; 5-8 months in mint tops and oil, peaches, plums and prunes; 10-12 months in peas, celery, spinach, cantaloupes, and squash; 15 months in cherries; and 24 months in cucumbers.

*Conclusions.* The available storage stability data are adequate and support the sample storage intervals and conditions used in the field trails and processing studies.

### **860.1400 Water, Fish, and Irrigated Crops**

There are no aquatic uses are being proposed in the current petitions. Although cranberry fields can be flooded for irrigation and are flooded for harvest of fruit, the proposed PHI for cranberries is 30 days and the label directions also prohibit releasing irrigation water from bogs for at least 1 day following application. Therefore, no data are required under this guideline.

### **860.1460 Food Handling**

This guideline requirement is not relevant to the current petition as no food handling uses are being proposed.

### **860.1480 Meat, Milk, Poultry, and Eggs**

The only livestock feed items associated with the proposed uses are wet apple pomace and potato culls and processed waste, which are covered under the proposed uses for pome fruits and tuberous and corm vegetables. The effects of indoxacarb residues in these commodities on livestock diets were previously addressed under earlier petitions supporting uses on apples and potatoes (Memos, S. Levy, 19-JAN-2000; DP#: 244253 and 30-MAY-2002; DP#: 276516). As the proposed uses will not alter the dietary exposure of livestock, data requirements pertaining to meat, milk, poultry, and eggs will not be further addressed under the current petitions.

### **860.1500 Crop Field Trials**

46520901.der (southern pea)  
46487002.der (celery)  
46651503.der (summer squash)  
46651506.der1 (plum)

46520902.der1 (mint)  
46651501.der (cantaloupe)  
46651504.der (cherry)  
46651507.der (cranberry)

46487001.der (spinach)  
46651502.der (cucumber)  
46651505.der (peach)

To support the proposed new uses of indoxacarb (30% WDG), IR-4 has submitted crop field trials on cherries, plums, peaches, cucumbers, summer squash, cantaloupes, mint, cranberry, and southern peas. The results from these studies are discussed below and summarized in Table 4.

To support the proposed uses on pome fruits (group 11, except pear), leafy vegetables except *Brassica* (group 4), and tuberous and corm vegetables (subgroup 1C), IR-4 cited the existing tolerances and field trial data on apples, leaf and head lettuce, and potatoes. IR-4 also submitted new field trial data on spinach and celery to support the crop group tolerance on leafy vegetables except *Brassica* (group 4). Furthermore, IR-4 requested that the existing tolerance and residue data on peppers be translated to support the proposed use on okra.

<b>Table 4. Summary of Residue Data from Field Trials on Spinach, Celery, Cucurbit Vegetables, Southern Pea, Stone Fruits, Cranberry, and Mint Following Application of Indoxacarb (30% WDG).</b>									
Commodity	Total Applic. Rate (lb ai/A)	PHI (days)	Residue Levels (ppm) <sup>1</sup>						
			n	Min.	Max.	HAFT <sup>2</sup>	Median	Mean	Std. Dev.
<b>Leafy Vegetables except <i>Brassica</i>, group 4</b> (proposed maximum application rate: 0.26 lb ai/A; PHI: 3 days)									
Spinach	0.268	3	16	2.2	13.0	10.5	4.45	5.27	2.59
		7	16	0.49	6.1	5.20	2.90	3.16	1.44
		14	14	0.29	2.5	2.35	1.90	1.69	0.70
Celery Untrimmed Stalks (RAC)	0.268	7	12	0.32	1.80	1.70	1.20	1.07	0.62
		14	12	0.12	1.00	0.99	0.37	0.51	0.36
		21	12	0.11	0.77	0.50	0.21	0.27	0.18
Celery Trimmed Stalks	0.268	3	12	0.31	1.90	1.75	0.54	0.82	0.55
		7	12	0.21	0.65	0.62	0.37	0.38	0.13
		14	12	0.12	0.53	0.38	0.19	0.24	0.13
<b>Southern Peas</b> (proposed maximum application rate: 0.26 lb ai/A; PHI: 7 days)									
Mature Seed <sup>3</sup>	0.255-0.266	6-7	14	<0.01	0.067	0.065	0.014	0.021	0.021
<b>Cucurbit Vegetables</b> (proposed maximum application rate: 0.44 lb ai/A; PHI: 3 days)									
Cantaloupe	0.437-0.475	3-4	22	0.018	0.393	0.312	0.064	0.102	0.095
Cucumber	0.414-0.463	3	20	<0.01	0.069	0.055	0.020	0.022	0.014
Summer Squash	0.423-0.459	2-4	22	<0.01	0.120	0.102	0.024	0.032	0.033
<b>Stone Fruits</b> (proposed maximum application rate: 0.44 lb ai/A; PHI: 14 days)									
Cherry	0.437-0.468	12-14 <sup>4</sup>	32	0.07	0.64	0.63	0.20	0.25	0.16
Peach	0.420-0.449	13-14 <sup>4</sup>	30	0.03	0.59	0.59	0.10	0.16	0.14
Plum	0.431-0.448	13-15	22	<0.01	0.19	0.185	0.020	0.045	0.050
<b>Cranberry</b> (proposed maximum application rate: 0.44 lb ai/A; PHI: 30 days)									
Cranberry	0.438-0.451	13-15	12	0.11	0.39	0.32	0.22	0.23	0.09
		28-30	12	0.086	0.69	0.63	0.15	0.22	0.20
<b>Mint</b> (proposed maximum application rate: 0.26 lb ai/A; PHI: 7 days)									
Mint Tops	0.260-0.270	7-8	12	2.10	6.84	6.37	3.06	3.87	1.83

<sup>1</sup> The validated LOQ is 0.01 ppm for cantaloupes, cucumbers, squash, southern peas, peaches and plums; 0.02 ppm for spinach, celery and cherries; and 0.05 ppm for cranberries and mint. For samples having residues <LOQ, ½ LOQ was used for calculating of the median, mean and standard deviation.

<sup>2</sup> HAFT = Highest-Average Field Trial.

<sup>3</sup> Samples were only identified as "mature seed" and did not specify whether samples were dry seed or succulent seed.

<sup>4</sup> Includes samples from one cherry trial collected at 5 days after the last application (DALA) and one peach trial at 7 DALA. Residues in/on samples from these earlier intervals were similar to residues in/on samples collected at ~14 DALA.

**Tuberous and Corm Vegetables (subgroup 1C).** Acceptable field trial data are available supporting the use of indoxacarb (30% WDG) on potatoes (Memo, S. Levy, 30-MAY-2002; DP#: 276516). As potatoes are the representative crop for subgroup 1C and the proposed use is identical to the existing use on potatoes, the potato field trial data will support the expanded use of indoxacarb (30% WDG) on tuberous and corm vegetables.

**Vegetable, Leafy, except *Brassica*, (group 4)**

The representative commodities for the vegetable, leafy, except *Brassica*, (group 4) are celery, head lettuce, leaf lettuce, and spinach. Acceptable field trial data are available supporting the use of indoxacarb (30% WDG) on leaf and head lettuce (Memo, S. Levy, 19-JAN-2000; DP#: 244253). Additional spinach and celery data have been submitted in support of the current petition.

**Spinach.** In eight field trials conducted in the growing zones 1, 2, 6, 9 and 10 during 1996-1997, indoxacarb (30% WDG) was applied to spinach as four broadcast foliar applications during crop development at 0.0669 lb ai/A/application, at RTIs of 2-4 days, for totals of 0.268 lb ai/A (1x rate). All applications were made using ground equipment at 15-35 GPA, without the use of any adjuvants. Duplicate control and treated samples of mature spinach were harvested from each trial at 3, 7 and 14 DALA, and additional samples were collected at 0 and 20 DALA from one site to examine residue decline. Samples were stored frozen up to 11 months prior to extraction for analysis, an interval supported by the available concurrent storage stability data. Samples were analyzed for combined indoxacarb residues using an adequate GC/MSD method (AMR-3493-95), which has a validated LOQ was 0.02 ppm. The LOD was not reported.

Following four applications totaling 0.268 lb ai/A (1x rate), combined indoxacarb residues in/on spinach were 2.2-13 ppm at 3 DALA (proposed PHI), 0.49-6.1 ppm at 7 DALA, and 0.29-2.5 ppm at 14 DALA. Average residues at 3, 7 and 14 DALA were 5.27, 3.16, and 1.69 ppm, respectively, and the HAFT residues at the same intervals were 10.5, 5.20, and 2.35 ppm.

**Celery.** In seven field trials conducted during 1996 in the U.S., indoxacarb was applied to celery as four broadcast foliar applications during crop development at 0.0669 lb ai/A/application, at RTIs of 3-5 days, for a total rate of 0.268 lb ai/A (1x rate). Six field trials used the 30% WDG formulation, and one field trial used the 15% suspension concentrate (1.25 lb/gal FIC). All applications were made using ground equipment at 20-50 GPA, without the use of any adjuvants. Duplicate control and treated samples of untrimmed celery (RAC) were collected from each trial at 7, 14, and 21 DALA, and duplicate samples of trimmed celery were collected from each trial at 3, 7, and 14 DALA. In two decline studies, untrimmed celery samples were collected at 0, 7, 14, 21 and 28 DALA, and trimmed celery samples were collected at 0, 3, 7, 14, and 21 DALA. Samples were stored frozen up to 10.5 months prior to extraction for analysis, an interval supported by the available concurrent storage stability data. Samples were analyzed for combined indoxacarb residues using an adequate GC/MSD method (AMR-3493-95), which has a validated LOQ was 0.02 ppm and a reported LOD of 0.007 ppm.

Following four broadcast foliar applications of the 30% WDG at a 1x rate, combined residues in/on untrimmed celery (RAC) were 0.32-1.8 ppm at 7 DALA, 0.12-1.0 ppm at 14 DALA, and 0.11-0.77 ppm at 21 DALA. Average residues in/on untrimmed celery were 1.07, 0.51, and 0.24 ppm at 7, 14, and 21 DALA, respectively; and HAFT residues were 1.70, 0.99, and 0.50 ppm at the same intervals. Combined residues in/on trimmed celery samples were 0.31-1.90 ppm at 3 DALA, 0.21-0.65 ppm at 7 DALA, and 0.12-0.53 ppm at 14 DALA. Average residues in/on trimmed celery were 0.82, 0.38, and 0.24 ppm at 3, 7, and 14 DALA, respectively; and HAFT residues were 1.75, 0.62, and 0.38 ppm at the same intervals. Residue data from the field trial using the 1.25 lb/gal FIC were not included in calculating residue ranges and averages.

Note that data are not available for untrimmed celery at the proposed PHI of 3 days. However, HED used the trimmed celery residue data to estimate untrimmed celery residues as follows: Indoxacarb residue concentrations in trimmed and untrimmed celery were compared for 0-day, 7-day, and 14-day PHI samples. Based on this comparison, trimmed to untrimmed ratios were determined to be 2.32 for the 0-day PHI samples, 3.0 for the 7-day PHI samples and 2.3 for the 14-day PHI samples. The average residue ratio for these three sampling intervals was calculated to be 2.5. The 3-day trimmed celery residue data were entered into the U.S. EPA tolerance calculator, resulting in a trimmed celery tolerance of 3.5 ppm. To determine an untrimmed tolerance value, the 3.5 ppm value was multiplied by the average trimmed to untrimmed residue ratio of 2.5, resulting in a value of ~9.0 ppm.

### **Cucurbit Vegetables (group 9)**

**Cantaloupes.** In 11 field trials conducted in the U.S. and Canada during 2003, indoxacarb (30% WDG) was applied to cantaloupes as four broadcast foliar applications during fruit development at 0.101-0.129 lb ai/A/application, at RTIs of 4-6 days, for a total of 0.436-0.475 lb ai/A/season (1x rate). All applications were made using ground equipment at 21-45 GPA, without the use of any adjuvants. Duplicate control and treated samples of mature cantaloupes were harvested from 10 sites at 3-4 DALA, and at one site, samples were harvested at 1, 3, 5 and 12 DALA to assess residue decline. Samples were stored frozen for up to 360 days prior to extraction for analysis, an interval supported by available concurrent storage stability data. Samples were analyzed for combined indoxacarb residues using an adequate LC/MS/MS method, which is a modified version of a tolerance enforcement (HPLC/UV Method AMR 2712-93). The lowest limit of method validation (LLMV) was 0.01 ppm, and the calculated LOQ and LOD were 0.008 and 0.003 ppm, respectively.

Following four applications at a total rate of 0.436-0.475 lb ai/A (1x rate), combined residues were 0.018-0.393 ppm in/on 22 samples of cantaloupes harvested at 3-4 DALA. The HAFT residues were 0.312 ppm, and average residues were 0.102 ppm. In the residue decline trial, average residues declined steadily from 0.126 ppm at 1 DALA to 0.044 ppm at 12 DALA.

**Cucumbers.** In ten field trials conducted in the U.S. during 2002, indoxacarb (30% WDG) was applied to cucumbers as four broadcast foliar applications during flowering and fruit development at 0.077-0.121 lb ai/A/application, at RTIs of 3-6 days, for totals of 0.414-0.463 lb ai/A/season (~1x rate). All applications were made using ground equipment at 20-45 GPA, without the use of any adjuvants. Duplicate control and treated samples of mature cucumbers were harvested from each site at 3 DALA (proposed PHI), and additional samples were collected at 1, 6 and 12 DALA at two sites to assess residue decline. Samples were stored frozen up to 697 days prior to extraction for analysis, an interval supported by available concurrent storage stability data. Samples were analyzed for combined indoxacarb residues using an adequate LC/MS/MS method, which is a modified version of a tolerance enforcement (HPLC/UV Method AMR 2712-93). The LLMV is 0.01 ppm, and the calculated LOQ and LOD are 0.011 and 0.004 ppm, respectively.

Following four applications at a total rate of 0.414-0.463 lb ai/A (1x rate), combined residues were <0.01-0.069 ppm in/on 20 samples of cucumbers harvested at 3 DALA. Average residues

were 0.022 ppm, and HAFT residues were 0.055 ppm. In the two residue decline trials, average residues declined steadily from 0.028 ppm at 1 DALA to <0.01 ppm by 12 DALA.

**Summer Squash.** In 12 field trials conducted in the U.S. and Canada during 2003, indoxacarb (30% WDG) was applied to summer squash as either four (11 trials) or five (1 trial) broadcast foliar applications during flowering and fruit development at 0.103-0.119 lb ai/A/application, at RTIs of 4-7 days, for total application rates of 0.423-0.459 lb ai/A (1x rate) or 0.541 lb ai/A (1.2x rate). All applications were made using ground equipment at 20-41 GPA, without the use of any adjuvants. Single control and duplicate treated samples of mature squash were harvested from each site at 2-4 DALA; the proposed PHI is 3 days. Samples were stored frozen up to 301 days prior to extraction for analysis, an interval supported by available concurrent storage stability data. Samples were analyzed for the combined indoxacarb residues using an HPLC/UV method, which is a modified version of a tolerance enforcement method (Method AMR 2712-93). The LLMV was 0.01 ppm, and the calculated LOQ and LOD were 0.014 and 0.005 ppm, respectively.

Following four applications at a total rate of 0.423-0.459 lb ai/A the 1x rate, residues were <0.01-0.120 ppm in/on 22 samples of squash harvested at 2-4 DALA. The HAFT residues were 0.102 ppm and average residues were 0.032 ppm. For the one trial at the 1.2x rate, residues were <0.01 ppm in/on both samples harvested at 3 DALA.

**Pome fruits (group 11, except pear).** Acceptable field trial data are available supporting the use of indoxacarb (30% WDG) on apples (Memo, S. Levy, 19-JAN-2000; DP#: 244253). As apple is the representative crop for group 11 (except pear) and the proposed use is identical to the existing use on apples, the apple field trial data will support the expanded use of indoxacarb (30% WDG) on pome fruits, except pear.

### **Stone Fruits (group 12)**

**Cherry.** In 16 field trials conducted in the U.S. and Canada during 2002-2004, indoxacarb (30% WDG) was applied to sweet (4 trials) and tart (12 trials) cherries as four foliar applications during fruit development at 0.106-0.118 lb ai/A/application, at RTIs of 6-10 days, for total application rates of 0.437-0.468 lb ai/A (1x rate). All applications were made using ground equipment at 80-129 GPA, without the use of any adjuvants. Duplicate control and treated samples of cherries were harvested at 12-14 DALA, except in one trial where samples were harvested at 5 DALA. Samples were stored frozen up to 315 days prior to extraction for analysis, an interval supported by the available concurrent storage stability data. Samples were analyzed for the combined indoxacarb residues using a modified version of an HPLC/UV method (Method AMR 2712-93). The LLMV was 0.02 ppm, and the calculated LOQ and LOD were 0.007 and 0.002 ppm, respectively.

Following four foliar applications at a total rate of 0.437-0.468 lb ai/A (1x rate), combined residues were 0.07-0.64 ppm in/on sweet and tart cherries harvested at 12-14 DALA, and the two samples harvested at 5-DALA had similar residues (0.45 ppm). The HAFT residues were 0.63 ppm and average residues were 0.25 ppm.

**Peach.** In 16 field trials conducted in the U.S. and Canada during 2003, indoxacarb (30% WDG) was applied to peaches as four or five (1 trial) foliar applications during fruit development at

0.105-0.113 lb ai/A/application, at RTIs of typically 6-7 days. Total application rates were 0.420-0.449 lb ai/A in 15 trials (1x rate) and 0.55 lb ai/A (1.3x rate) in one trial. All applications were made using ground equipment at 48-141 GPA, without the use of any adjuvants. Duplicate control and treated samples of peaches were harvested at 13-15 DALA, except in one trial where samples were harvested at 7 DALA. Samples were stored frozen up to 119 days prior to extraction for analysis, an interval supported by the available concurrent storage stability data. Samples were analyzed for the combined residues of indoxacarb + its R-enantiomer using a modified version of an HPLC/UV method (Method AMR 2712-93). The LLMV was 0.01 ppm, and the calculated LOQ and LOD were 0.003 and 0.001 ppm, respectively.

Following four foliar applications at a total rate of 0.420-0.449 lb ai/A (1x rate), combined residues were 0.03-0.59 ppm in/on 28 samples of peaches harvested at 13-14 DALA, and the two samples harvested at 7-DALA had similar residues (0.07 ppm). The HAFT residues were 0.59 ppm and average residues were 0.16 ppm. For the field trial conducted at 0.55 lb ai/A/season (1.3x rate), residues at 15 DALA were similar (0.48 and 0.58 ppm) to the other trials.

**Plum.** In 11 field trials conducted in the U.S. and Canada during 2003, indoxacarb (30% WDG) was applied to plums as four foliar applications during fruit development at 0.106-0.114 lb ai/A/application, at RTIs of typically 6-9 days, for totals of 0.431-0.448 lb ai/A (1x rate). All applications were made using ground equipment at 59-141 GPA, without the use of any adjuvants. Duplicate control and treated samples of plums were harvested from each trial at 13-15 DALA, and samples were stored frozen up to 155 days prior to extraction for analysis, an interval supported by the available concurrent storage stability data. Samples were analyzed for the combined indoxacarb residues using a modified version of an HPLC/UV method (Method AMR 2712-93). The LLMV was 0.01 ppm, and the calculated LOQ and LOD were 0.008 and 0.003 ppm, respectively.

Following four foliar applications at a total rate of 0.431-0.448 lb ai/A (1x rate), combined residues were <0.01-0.19 ppm in/on 22 samples of plums harvested at 13-15 DALA. The HAFT residues were 0.185 ppm and average residues were 0.045 ppm.

### Miscellaneous Crops

**Cranberry.** In six field trials conducted in the U.S. during 2002-2003, indoxacarb (30% WDG) was applied to cranberries as four broadcast foliar applications during fruit development at 0.108-0.115 lb ai/A/application, at RTIs of 6-8 days, for a total application rate of 0.436-0.451 lb ai/A (1x rate). All applications were made using ground equipment at 28-46 GPA, without the use of any adjuvants. Duplicate control and treated samples of cranberries were harvested twice from each trial, at 13-15 and 28-30 DALA; the proposed PHI is 30 days. Samples were stored frozen up to 45 days prior to extraction for analysis, an interval supported by the available concurrent storage stability data. Samples were analyzed for combined indoxacarb residues using an adequate GC/MSD method (AMR-3493-95). The LLMV was 0.05 ppm, and the calculated LOQ and LOD were 0.019 and 0.003 ppm, respectively.

Following four foliar applications at a total rate of 0.436-0.451 lb ai/A (1x rate), combined indoxacarb residues in/on cranberries were 0.11-0.39 ppm at 13-15 DALA and 0.086-0.69 at 28-30 DALA. Average residues were 0.23 and 0.22 ppm at the first and second harvest intervals,

respectively; and the HAFT residues were 0.32 and 0.63 ppm. Residue levels declined at the later harvest interval in four trials, remained relatively unchanged in one trial, and increased in one trial.

**Mint.** In six field trials conducted in the growing Zones 5 and 11 during 2002, indoxacarb (30% WDG) was applied to mint as four broadcast foliar applications during crop development at 0.062-0.070 lb ai/A/application, at RTIs of 2-4 days, for a total application rate of 0.260-0.270 lb ai/A (1x rate). All applications were made using ground equipment at 20-46 GPA, without the use of any adjuvants. Duplicate control and treated samples of commercially mature mint tops were harvested from each trial at 7 or 8 DALA, and samples were stored frozen up to 4.6 months prior to extraction for analysis, an interval supported by the available concurrent storage stability data. Mint samples were analyzed for combined indoxacarb residues using an adequate GC/MSD method (AMR-3493-95). The LLMV was 0.05 ppm, and the calculated LOQ and LOD were 0.053 and 0.018 ppm, respectively.

Following four applications at a total rate of 0.260-0.270 (1x rate), residues were 2.10-6.84 ppm in/on 12 samples of mint harvested at 7-8 DALA. The HAFT residues were 6.37 ppm, and average residues were 3.87 ppm. No residue decline trial was conducted.

**Southern Pea.** In seven field trials conducted in growing Zones 2, 5 and 10 during 2002, indoxacarb (30% WDG) was applied to southern peas as four broadcast foliar applications during pod development and maturation at 0.063-0.067 lb ai/A/application, at RTIs of 2-4 days, for a total rates of 0.255-0.266 lb ai/A (1x rate). All applications were made using ground equipment at 29-79 GPA, without the use of any adjuvants. Duplicate control and treated samples of "mature seed" were harvested from each trial at 6-7 DALA. However, the study did not indicate whether "mature seed" samples were dry seed or succulent seed. Samples were stored frozen up to 8.5 months prior to extraction for analysis, an interval supported by available concurrent storage stability data. Samples were analyzed using a modified version of a HPLC/UV tolerance enforcement method (Method AMR 2712-93). The lowest limit of method validation (LLMV) was 0.01 ppm, and the calculated LOQ and LOD were 0.009 and 0.003 ppm, respectively.

Following four applications at total rates of 0.255-0.266 lb ai/A (1x rate), combined indoxacarb residues were <0.01-0.067 ppm in/on 14 samples of southern pea seeds harvested at 6-7 DALA. The HAFT residues were 0.065 ppm and average residues were 0.021 ppm.

**Okra.** Field trial data are not available for indoxacarb on okra. However, IR-4 has requested that previously-reviewed bell and non-bell pepper field trial data (Memo, S. Levy, 19-JAN-2000; DP#: 244253) with the same use pattern be used to support the proposed use on okra for the following reasons: i) the growth habit and stage of maturity at commercial harvest is similar for okra and non-bell type peppers, ii) the major growing zones for peppers including the major growing zones for okra, and iii) the proposed use pattern on okra is identical to the existing use on peppers.

**Conclusions.** The submitted field trial data on spinach, cantaloupes, cucumbers, summer squash, cherries, peaches, plums, cranberries, and mint are adequate and support the proposed use patterns for indoxacarb (30% WDG) on these crops or crop groups. The number and geographic distribution of the field trials are adequate, and the appropriate samples were

collected at the proposed PHIs. The samples were analyzed using adequate analytical methods and the sample storage intervals are supported by the available storage stability data.

The southern pea field trial data are also adequate; however, the petitioner did not specify if they wanted succulent or dry. The field trial data submitted were for dry peas. The proposed label directions for southern peas should be amended to allow for applications only to varieties used to produce dry seed. If the petitioner intends to support a generalized use on southern peas, then field trials will be required for succulent varieties as well.

Acceptable field trial data are also available to support existing uses of indoxacarb (30% WDG) on potatoes, leaf and head lettuce, apples and peppers (Memos, S. Levy, 19-JAN-2000; DP#: 244253; and 30-MAY-2002; DP#: 276516). These data on the representative crops of potatoes, lettuce, and apples will support expanding the use of indoxacarb (WDG) to cover similar uses on tuberous and corm vegetables (subgroup 1C), vegetable, leafy, except *Brassica*, group 4, and pome fruit (group 11, except pear).

The residue data on tomatoes and peppers can be translated to support the same use pattern for indoxacarb (WDG) on okra, as there is already a crop group tolerance established on "vegetable, fruiting, group 8" and okra is now considered part of the "vegetable, fruiting, group 8" crop group.

The available field trial data on celery (the representative crop for subgroup 4B) would not be adequate to support a subgroup tolerance, as only six field trials were conducted using the WDG formulation, rather than the required eight field trials, but are adequate to support a crop group tolerance for the crop group vegetable, leafy, except *Brassica* (group 4).

## 860.1520 Processed Food and Feed

46520902.der2 (mint)

46651506.der2 (plum/prune)

**Apple and Potato.** The proposed uses on pome fruits and tuberous and corm vegetables include apples and potatoes. Processing studies on apples and potatoes were previously evaluated under earlier petitions (Memos, S. Levy, 19-JAN-2000; DP# 244253 and 30-MAY-2002; DP#: 276516). Based on these petitions, no tolerances were required for potato processed products and a 3.0 ppm tolerance was established for wet apple pomace.

**Mint.** In two field trials conducted in 2002, indoxacarb (30% WDG) was applied to mint as four broadcast foliar applications during crop development at 0.062-0.067 lb ai/A/application, at RTIs of 2-4 days, for a total of 0.260 lb ai/A (1x rate). Applications were made using ground equipment at 24-46 GPA, without the use of any adjuvants. Duplicate control and treated samples of commercially mature mint tops were harvested from each trial at 7 or 8 DALA, along with single bulk control and treated samples used for processing. The bulk samples of tops were distilled using simulated commercial procedures to yield mint oil. Samples of mint tops and oil were stored frozen up to 5.4 months prior to extraction for analysis, an interval supported by the available concurrent storage stability data. Samples of mint tops and oil were analyzed for the combined indoxacarb residues using a GC/MSD method (AMR-3493-95), which is an approved tolerance enforcement method. The LLMV was 0.05 ppm for tops and 0.1 ppm for oil. The

calculated LOQ and LOD were respectively 0.053 and 0.018 ppm for tops, and 0.11 and 0.037 ppm for oil.

Residues averaged 2.49 and 6.06 ppm in/on fresh mint hay harvested at 7-8 DALA from the two field trials, and residues in mint oil were <0.1 ppm for both trials. The processing factor for mint oil was 0.017x and 0.04x for the two trials and averaged 0.028x.

**Plums/prunes.** In a field trial conducted during 2003 in CA, indoxacarb (30% WDG) was applied to plum trees as four foliar applications during fruit development at 0.109-0.111 lb ai/A/application, at RTIs of 7 days, for a total of 0.440 lb ai/A/season (1x rate). Single bulk samples of control and treated plums were harvested at commercial maturity, at 14 DALA. Following harvest, plums were dried to prunes using simulated commercial procedures. Prior to analysis, plums and prunes were stored frozen up to 155 and 189 days, respectively, an interval supported by the available concurrent storage stability data. Samples were analyzed for the combined indoxacarb residues using a modified version of an HPLC/UV method (Method AMR 2712-93). The LLMV was 0.01 ppm for both plum and prunes. For plums and prunes, respectively, the calculated LOQs were 0.008 and 0.003 ppm, and the LODs were 0.003 and 0.001 ppm.

Residues were 0.01 ppm in/on plums harvested at 14 DALA, and 0.04 ppm in/on prunes processed from fresh plums. Residues concentrated in prunes by 4x, which is slightly higher than the 3.5x theoretical concentration factors based on water loss.

*Conclusions.* The available mint and plum processing studies are adequate. As indoxacarb residues were reduced on average by 0.028x in mint oil, a separate tolerance is not required for mint oil. Residues concentrated by 4x in prunes, which is higher than the theoretical concentration factor of 3.5x. However, based on HAFT residues of 0.185 ppm for plums, the maximum expected residues in prunes would be 0.74 ppm, which is below the recommended tolerance for stone fruits (0.90 ppm). Therefore a separate tolerance is not required for prunes.

#### **860.1650 Submittal of Analytical Reference Standards**

As of AUG-2006, an analytical reference standard for indoxacarb is available at the EPA National Pesticide Standards Repository.

#### **860.1850/860.1900 Confined and Field Accumulation in Rotational Crops**

An adequate confined rotational crop study was reviewed in conjunction with an earlier petition (PP#8F04948, S. Levy, 19-JAN-2000; DP#: 244253), and the MARC concluded that the residues of concern in rotated crops include parent only (Memo, S. Levy, 10-JUL-2000; DP#: 263986). Based on the confined study, HED has also concluded that the available data support a 30-day plant-back interval (PBI) for all non-labeled crops (Memo, S. Levy, 07-SEP-2000; DP#: 256351).

## 860.1550 Proposed Tolerances

The MARC has determined that the tolerance expression for plants should include parent only, which includes indoxacarb + its R-enantiomer. Permanent tolerances are currently established for the combined residues of indoxacarb + its inactive R-enantiomer in/on various plant commodities at levels ranging from 0.01 ppm in/on peanuts and potatoes to 50 ppm in/on alfalfa hay [40 CFR §180.564(a)]. Tolerances are also established for livestock commodities; however, livestock tolerances are not addressed in this petition as the proposed uses do not include any new uses on crops having livestock feed items.

The tolerances proposed by the petitioner are listed below in Table 5, along with the HED's recommended tolerance levels. The recommended tolerance levels for each RAC or crop group in the current petitions were determined using recent Agency Guidance (*Guidance for Setting Pesticide Tolerances Based on Field Trial Data SOP*). For southern peas, the recommended tolerance was based on the observed maximum residue value. For those commodities for which the tolerance spreadsheet was used to calculate the appropriate tolerance level, the residue data used for the tolerance calculations and the supporting spreadsheet outputs are presented in Appendix II.

For purposes of determining tolerances, adequate field trial data are available to set individual tolerances on southern peas, cranberries, and mint. In addition, the available data on cantaloupes, cucumbers, and squash will support a crop group tolerance on cucurbit vegetables, and the available data on cherries, peaches and plums will support a crop group tolerance on stone fruits. As residues were highest in cantaloupes and cherries, these data were used to set tolerances for their respective crop groups.

Based on previously reviewed field trial data supporting the existing tolerances on leaf and head lettuce (10 and 5.0 ppm, respectively) and the currently-submitted spinach and celery data, a new crop group tolerance can be established at 14 ppm for "vegetable, leafy, except *Brassica*, group 4." As residues were highest in spinach, these data were used to set the crop group tolerance.

Based on previously reviewed field trial data supporting the existing tolerances on potatoes and apples, new tolerances can be established at the same levels on tuberous and corm vegetables (subgroup 1C) and pome fruit (group 11, except pear). The existing pear tolerance (0.20 ppm) can be translated to pear, oriental. In addition, the residue data on peppers can be translated to support the same use pattern for indoxacarb (WDG) on okra, as okra is now considered part of the "vegetable, fruiting, group 8" crop group.

Based on the mint and plum processing studies, separate tolerances are not required for either mint oil or prunes. Residues were reduced in mint oil by 0.028x. Although residues concentrated in prunes by 4x, the maximum expected residues in prunes would be 0.74 ppm, which is below the recommended tolerance for stone fruits (0.90 ppm).

There are no established or proposed Codex or Canadian maximum residue limits (MRLs) for indoxacarb. However, Mexico has established MRLs for indoxacarb on several crops at levels ranging from 0.5 mg/kg on tomatoes and pepper to 10 mg/kg on corn (Appendix I). None of the proposed tolerances currently have equivalent Mexican MRLs, therefore, there are no international harmonization issues associated with these petitions.

Crop Commodity	Proposed or Existing Tolerance (ppm)	Recommended Tolerance (ppm)	Comments (Corrected commodity definition)
Cranberry	1	0.90 <sup>1</sup>	Adequate residue data are available.
Fruit, pome, except pear, group 11	1.0	1.0 <sup>2</sup>	The existing residue data on apples are adequate and will support an expanded use and a tolerance on <i>Fruit, pome, group 11, except pear</i> .
Pear, oriental	--	0.20 <sup>2</sup>	The existing pear tolerance can be translated to set a separate <i>Pear, oriental</i> tolerance.
Apple	1.0	Delete	Once the tolerance is established on group 11, the separate tolerance on apple should be deleted.
Fruit, stone group 12	1	0.90 <sup>1</sup>	Adequate residue data are available on cherries, plums and peaches. The group tolerance is based on residue data from cherries. <i>Fruit, stone, group 12</i>
Leafy vegetables except <i>Brassica</i>	14	14 <sup>1</sup>	The existing residue data on leaf and head lettuce are adequate, as well as the currently-submitted spinach and celery data will support a crop group tolerance for <i>Vegetable, Leafy, Except Brassica, Group 4</i> .
Lettuce, head	5.0	Delete	Once the tolerance is established on <i>Vegetable, Leafy, except Brassica, Group 4</i> , the separate tolerances on leaf and head lettuce should be deleted.
Lettuce, Leaf	10.0		
Mint	10	11 <sup>1</sup>	Adequate residue data are available. Separate tolerances should be established for <i>Peppermint</i> and <i>Spearmint</i> .
Okra	0.5	0.50 <sup>2</sup>	The existing residue data on tomatoes and peppers will be translated to support the same use pattern and tolerance on okra, as okra is now considered part of the "vegetable, fruiting, group 8" crop group.
Pea (southern)	0.1	0.10 <sup>1</sup>	Adequate residue data are available for dried pea only. <i>Pea, southern, seed</i>
Vegetable, cucurbit, group 9	0.5	0.60 <sup>1</sup>	Adequate residue data are available on cucumbers, squash, and cantaloupes. The tolerance is based on residue data from cantaloupes.
Vegetable, tuberous and corm, subgroup 1C	0.01	0.01 <sup>2</sup>	The existing residue data on potatoes are adequate and will support an expanded use and a tolerance on <i>Vegetable, tuberous and corm, subgroup 1C</i> .
Potato	0.01	Delete	Once the tolerance is established on subgroup 1C, the separate tolerance on potato should be deleted.

<sup>1</sup> Tolerance was determined using tolerance calculating spread sheet (see Appendix II).

<sup>2</sup> Tolerance is based on translation of existing residue data.

**Attachments**

Appendix I - International Residue Limits Status

Appendix II -Tolerance Assessment Calculations

cc: S. Levy (RAB1)

RDI: RAB1 Chemists (21-FEB-2007), G.F. Kramer (09-MAR-2007)

S. Levy: S10953:PY-S:(703)-305-0783:7509P:RAB1

Template Version September 2005

**References**

DP#: 260953  
Subject: PP# 8F04948. Multiresidue Method Testing of DPX-JW062.  
From: S. Levy  
To: F. Griffith  
Dated: 03-NOV-1999  
MRID#: 44477340

DP#s: 244253, 244460, 245424, 248057  
Subject: PP#8F04948. New Chemical - Indoxacarb (DPX-MP062) in/on *Brassica*, Sweet Corn, Cotton, Fruiting Vegetables, Lettuce (Head and Leaf) and Pome Fruits. Evaluation of Residue Data and Analytical Methods.  
From: S. Levy/S. Chun  
To: D.Peacock/A. Layne  
Dated: 19-JAN-2000  
MRID#s: 44477101-44477112, 44477317, 44477318, 44477321-44477344, 44477401-44477417, 44583301, 44815204 44815801-44815803, 44815805-44815808, 44491704.

DP#: 263986  
Subject: Results of HED Metabolism Assessment Review Committee (MARC) Meeting of 6/12/00. Indoxacarb (DPX-MP062). PP#8F04948.  
From: S. Levy/M. Copley  
To: G. Kramer  
Dated: 10-JUL-2000  
MRID#: None

DP#s: 256351 and 256354  
Subject: Indoxacarb (DPX-MP062). Additional Data to Amend HED's Residue Data and Analytical Methods in/on *Brassica*, Sweet Corn, Cotton, Fruiting Vegetables, Lettuce (Head and Leaf) and Pome Fruits Memorandum (D267325, S. Levy, 1-Jan-2000) and Response to Petitioner's Proposal to Lower Plant-back Intervals for Non-Labeled Crops.  
From: S. Levy  
To: D.Peacock/A. Layne  
Dated: 07-SEP-2000  
MRID: 44815801-44815808

DP#: 267339  
Subject: Memo to Mark Wirtz of FDA regarding Enforcement Methods for Plant and Animal Commodities.  
From: S. Levy  
To: M. Wirtz  
Dated: 12-OCT-2000  
MRID#s: 44477330-4477332, 44491704, 44477327, and 44477338

DP#: 277922  
Subject: Indoxacarb: Results of Health Effects Division (HED) Metabolism Assessment Review Committee (MARC) Meeting of 9/18/01. PP#: 000352-00594.  
From: S. Levy/J. Kidwell  
To: Y. Donovan  
Dated: 04-OCT-2001  
MRID#: None

DP#: 282821  
Subject: Memo to Mark Wirtz of FDA regarding Enforcement Method for Indoxacarb.  
From: S. Levy  
To: M. Wirtz  
Dated: 09-MAY-2002  
MRID#: 45384306

DP#s: 276516, 276518, 276541 and 278090  
Subject: PP# 1F06301. Indoxacarb in/on Alfalfa, Lettuce, Peanut, Potato, and Soybean. Evaluation of Residue Data and Analytical Methods.  
From: S. Levy  
To: G. McCann and M. Laws  
Dated: 30-MAY-2002  
MRID#s: 45384301-45384310

DP#s: 290172  
Subject: Indoxacarb. Review of Amendment Submitted in Response to HED's Memorandums of 19-JAN-2000 and 07  
From: S. Levy  
To: R. Kumar/D. Kenny  
Dated: 14-APR-2004  
MRID#s: 45795818 and 45795819

DP#s: 276516, 276518, 276541 and 278090  
Subject: Indoxacarb. Review of Amendment Submitted in Response to HED's Memorandum of 19-JAN-2000.  
From: S. Levy  
To: R. Kumar/D. Kenny  
Dated: 22-SEP-2004  
MRID#: 46114302

DP#s: 290126 and 293792  
Subject: Indoxacarb in/on Grapes, *Brassica* Leafy Vegetables, and Turnip Greens. Summary of Analytical Chemistry and Residue Data. Petition#s: 3F6576 and 2E6482.  
From: S. Levy  
To: A. Hanger  
Dated: 18-FEB-2005  
MRID#s: 45718701, 45718702, 45900301, and 45900303

DP#: 313518  
Subject: Memo to Mark Wirtz of FDA regarding Enforcement Methods for Plant  
Commodities.  
From: S. Levy  
To: M. Wirtz  
Dated: 18-FEB-2005  
MRID#: 45900303

**Appendix I. International Residue Limit Status Sheet**

INTERNATIONAL RESIDUE LIMIT STATUS			
Chemical Name: (S)-methyl 7-chloro-2,5-dihydro-2- [[[(methoxycarbonyl)[4-(trifluoro methoxy)phenyl]amino]carbonyl] indeno[1,2-e][1,3,4]oxadiazine- 4a(3H)-carboxylate	Common Name: Indoxacarb	<input checked="" type="checkbox"/> Proposed tolerances <input type="checkbox"/> Reevaluated tolerance <input type="checkbox"/> Other	Date: 08-SEP-2006
Codex Status (Maximum Residue Limits)		U. S. Tolerances	
<input checked="" type="checkbox"/> No Codex proposal step 6 or above <input type="checkbox"/> No Codex proposal step 6 or above for the crops requested		Petition#: 5E6911, 5E6926, 5E6991 DP#: 325479, 326516, 326544 Other Identifier: DPX-MP062; DPX-JW062; DPX-KN128	
Residue definition (step 8/CXL): N/A		Reviewer/Branch: S. Levy, RAB1	
		Residue definition: Combined residues of indoxacarb + its R-enantiomer	
Crop (s)	MRL (mg/kg)	Crop(s)	Tolerance (ppm)
		Cranberry	0.9
		Fruit, pome, except pear, group 11	1.0
		Fruit, stone, group 12	0.9
		Leafy greens, except spinach, subgroup 4A	10
		Leaf petioles subgroup 4B	4.5
		Mint	10
		Okra	0.5
		Pea, southern, seed	0.1
		Spinach	14
		Vegetable, cucurbit, group 9	0.6
		Vegetable, tuberous and corm, subgroup 1C	0.01
Limits for Canada		Limits for Mexico	
<input checked="" type="checkbox"/> No Limits <input type="checkbox"/> No Limits for the crops requested		<input type="checkbox"/> No Limits <input checked="" type="checkbox"/> No Limits for the crops requested	
Residue definition: N/A		Residue definition: Indoxacarb	
Crop(s)	MRL (mg/kg)	Crop(s)	MRL (mg/kg)
		Broccoli	5
		Brussels sprouts	5
		Cabbage	5
		Cauliflower	5
		Corn	10
		Cotton	2
		Pepper	0.5
		Tomato	0.5
Notes/Special Instructions:			

## Appendix II -Tolerance Assessment Calculations

The Agency's *Guidance for Setting Pesticide Tolerances Based on Field Trial Data* was utilized for determining appropriate tolerance levels on southern peas, cucurbit vegetables, stone fruits, cranberries and mint. Residue levels in these commodities were readily quantifiable, and with the exception of peas, <10% of the residue values were below the LOQ.

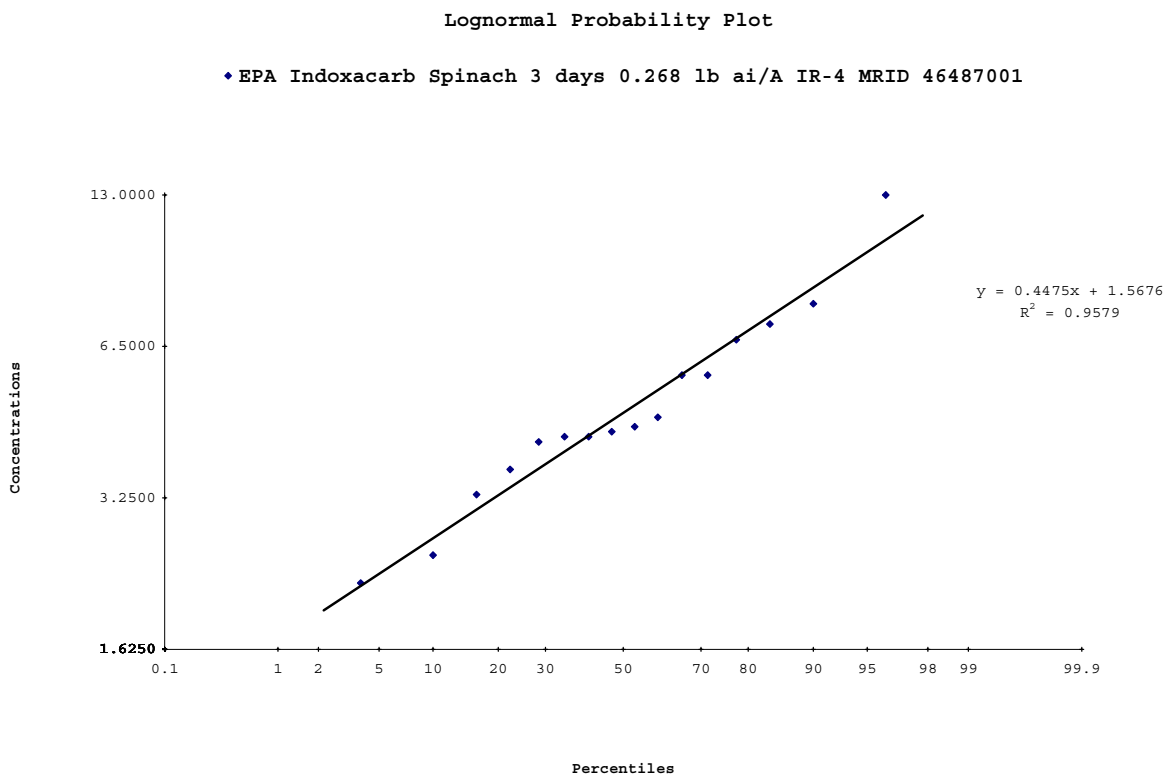
The datasets used to establish tolerances consisted of field trial data representing applications of the appropriate formulation (WDG) at ~1x maximum proposed maximum use rates. As specified by the *Guidance for Setting Pesticide Tolerances Based on Field Trial Data* SOP, the field trial application rates were within 25% of the maximum label application rate, and the PHIs were consistent with the appropriate stage of maturity and the proposed PHI for each commodity. The residues values used to calculate the tolerances are provided in Tables II-1 through II-7. As residues were highest in cantaloupes, cherries, and spinach, the data on these crops were used to set tolerances for their respective crop groups.

The datasets were entered into the tolerance spreadsheet and visual inspection of the lognormal probability plots indicates that the datasets are reasonably lognormal, and with the exceptions of the data sets for southern pea and plums. For the remaining commodities, the results from the approximate Shapiro-Francia test statistic confirmed that the assumption of lognormality should not be rejected.

The calculated tolerance levels are 0.60 ppm for vegetable, cucurbit, group 9, 0.90 ppm for fruit, stone, group 12 and cranberry, 14 ppm for vegetable, leafy, except *Brassica*, group 4, and 11 ppm for mint.

<b>Table II-1. Combined Indoxacarb Residue Data on Spinach.</b>			
<b>Regulator:</b>	<b>EPA</b>		
<b>Chemical:</b>	<b>Indoxacarb</b>		
<b>Crop:</b>	<b>Spinach</b>		
<b>PHI:</b>	<b>3 days</b>	<b>7 days</b>	<b>14 days</b>
<b>App. Rate:</b>	<b>0.268 lb ai/A</b>		
<b>Submitter:</b>	<b>IR-4</b>		
<b>MRID Citation:</b>	<b>MRID 46487001</b>		
	<b>Combined Indoxacarb Residues</b>		
	7.9	4.3	2.2
	13	4.8	1.8
	2.5	2.2	1.1
	4.5	2.3	2.4
	3.7	3.0	2.2
	3.3	3.1	1.6
	5.7	4.7	0.3
	5.7	3.8	0.4
	4.7	1.2	2.2
	4.3	2.1	2.5
	4.3	2.8	2.0
	4.2	2.7	2.1
	7.2	4.3	1.3
	6.7	6.1	1.5
	2.2	0.5	
	4.4	2.6	

**Figure II-1. Lognormal probability plot of indoxacarb (WDG) field trial data for spinach at proposed 3-day PHI following four broadcast foliar applications at 1x rate.**

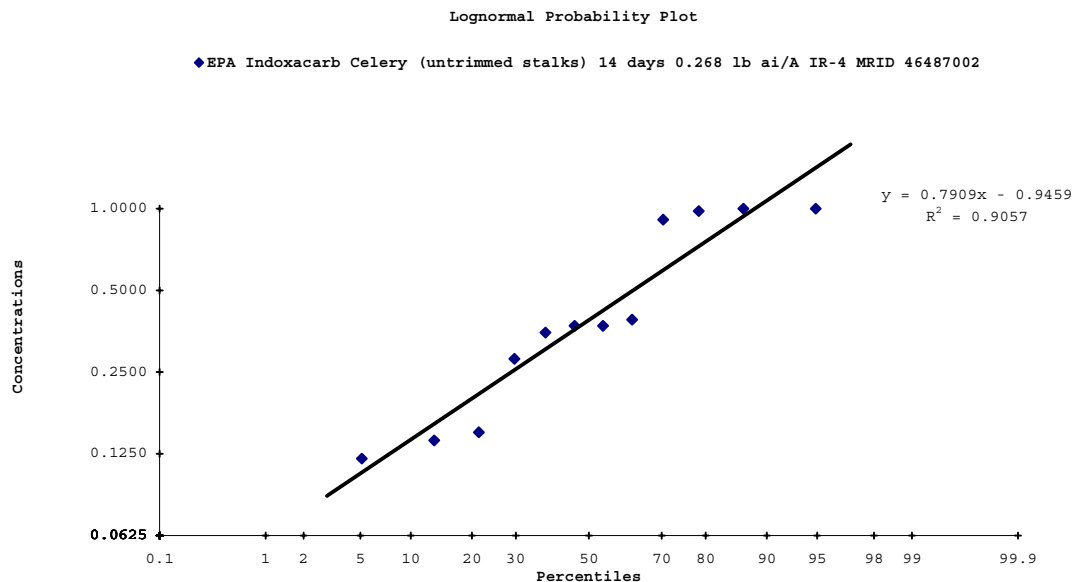


**Figure II-2. Tolerance spreadsheet summary of field trial data for spinach at proposed 3-day PHI following four broadcast foliar applications of indoxacarb (WDG).**

Regulator: EPA Chemical: Indoxacarb Crop: Spinach PHI: 3 days App. Rate: 0.268 lb ai/A Submitter: IR-4 MRID Citation: MRID 46487001  n: 16 min: 2.20 max: 13.00 median: 4.45 average: 5.27			
	95th Percentile	99th Percentile	99.9th Percentile
EU Method I Normal	10 (12)	12 (15)	14 (--)
EU Method I Log Normal	10 (15)	14 (25)	19 (--)
EU Method II Distribution-Free	13		
California Method $\mu + 3\sigma$	14		
UPLMedian95th	30		
Approximate Shapiro-Francia Normality Test	0.9579 p-value > 0.05 : Do not reject lognormality assumption		

<b>Table II-2. Combined Indoxacarb Residue Data on Celery.</b>			
<b>Regulator:</b>	<b>EPA</b>		
<b>Chemical:</b>	<b>Indoxacarb</b>		
<b>Crop:</b>	<b>Celery (untrimmed stalks)</b>		
<b>PHI:</b>	<b>7 days</b>	<b>14 days</b>	<b>21 days</b>
<b>App. Rate:</b>	<b>0.268 lb ai/A</b>		
<b>Submitter:</b>	<b>IR-4</b>		
<b>MRID Citation:</b>	<b>MRID 46487002</b>		
	<b>Combined Indoxacarb Residues</b>		
	0.39	0.28	0.089
	0.38	0.14	0.055
	1.60	0.91	0.220
	1.80	1.00	0.770
	0.67	0.39	0.430
	1.60	0.37	0.340
	1.10	1.00	0.210
	1.30	0.98	0.240
	0.33	0.12	0.110
	0.32	0.15	0.190
	1.80	0.35	0.210
	1.60	0.37	0.210

**Figure II-3. Lognormal probability plot of indoxacarb (WDG) field trial data for celery at proposed 14-day PHI following four broadcast foliar applications at 1x rate.**

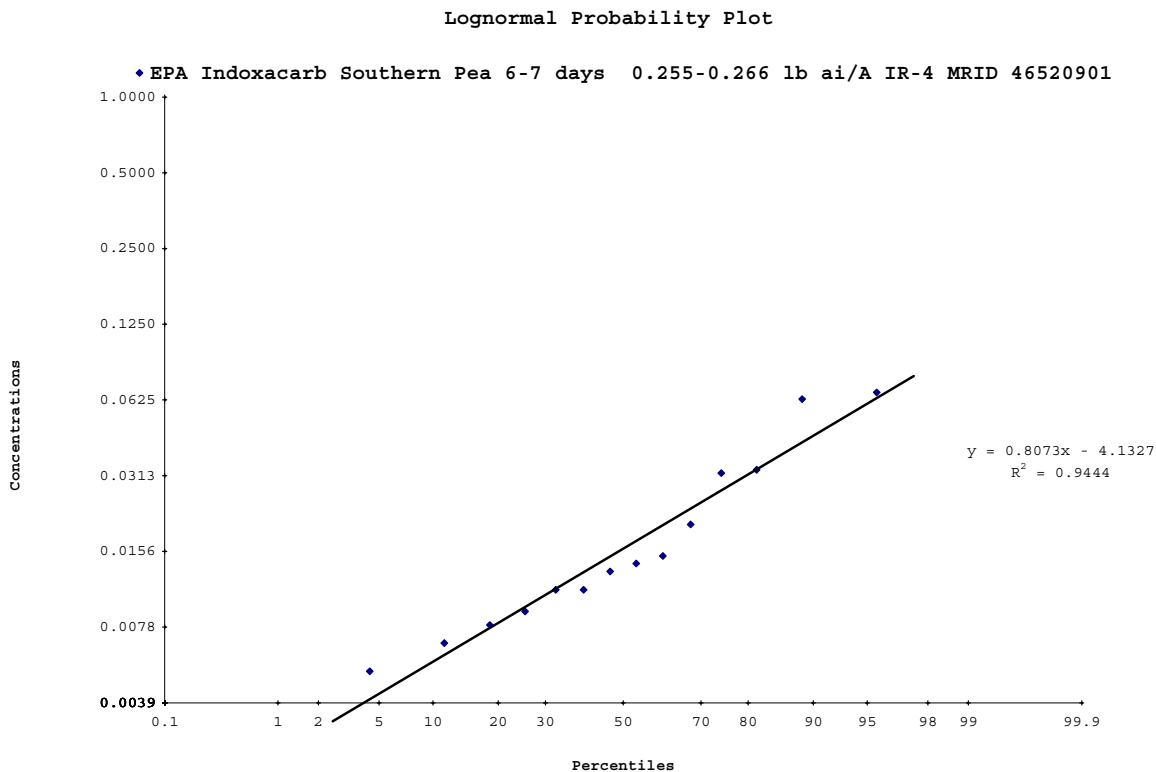


**Figure II-4. Tolerance spreadsheet summary of field trial data for celery at proposed 14-day PHI following four broadcast foliar applications of indoxacarb (WDG).**

Regulator: EPA Chemical: Indoxacarb Crop: ery (untrimmed stalks) PHI: 14 days App. Rate: 0.268 lb ai/A Submitter: IR-4 MRID Citation: MRID 46487002			
n: 12 min: 0.12 max: 1.00 median: 0.37 average: 0.51			
	95th Percentile	99th Percentile	99.9th Percentile
EU Method I Normal	1.1 (1.5)	1.4 (1.9)	1.7 (--)
EU Method I Log Normal	1.5 (3.5)	2.5 (8.0)	4.5 (--)
EU Method II Distribution-Free California Method $\mu + 3\sigma$	2.0		
UPLMedian95th	1.6		
UPLMedian95th	3.0		
Approximate Shapiro-Francia Normality Test	0.9057		
	p-value > 0.05 : Do not reject lognormality assumption		

<b>Table II-3. Combined Indoxacarb Residue Data on Southern Pea.</b>	
<b>Regulator:</b>	<b>EPA</b>
<b>Chemical:</b>	<b>Indoxacarb</b>
<b>Crop:</b>	<b>Southern Pea</b>
<b>PHI:</b>	<b>6-7 days</b>
<b>App. Rate:</b>	<b>0.255-0.266 lb ai/A</b>
<b>Submitter:</b>	<b>IR-4</b>
<b>MRID Citation:</b>	<b>MRID 46520901</b>
	<b>Combined Indoxacarb Residues</b>
	0.0052*
	0.0068*
	0.0080*
	0.0090*
	0.0670
	0.0630
	0.0130
	0.0140
	0.0110
	0.0110
	0.0330
	0.0200
	0.0150
	0.0320
* Fill-in Residues from MLE for Values = LOQ.	

**Figure II-5. Lognormal probability plot of indoxacarb (WDG) field trial data for southern peas following four broadcast foliar applications at 1x rate.**

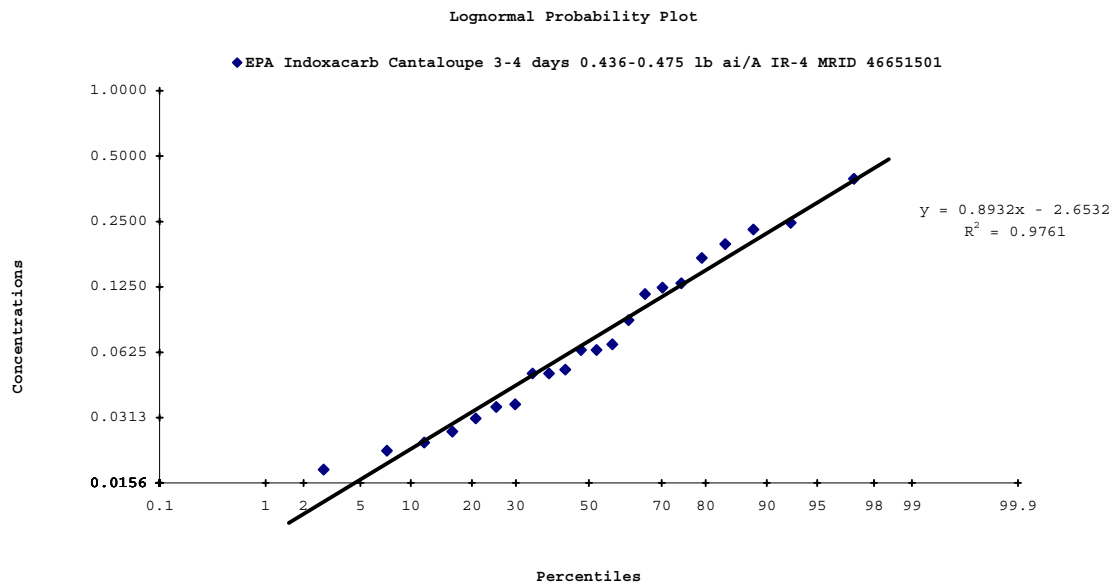


**Figure II-6. Tolerance spreadsheet summary of field trial data for southern peas following four broadcast foliar applications of indoxacarb (WDG).**

	<b>Regulator:</b>	EPA	
	<b>Chemical:</b>	Indoxacarb	
	<b>Crop:</b>	Southern Pea	
	<b>PHI:</b>	6-7 days	
	<b>App. Rate:</b>	0.255-0.266 lb ai/A	
	<b>Submitter:</b>	IR-4	
	<b>MRID Citation:</b>	MRID 46520901	
	<b>n:</b>	14	
	<b>min:</b>	0.01	
	<b>max:</b>	0.07	
	<b>median:</b>	0.01	
	<b>average:</b>	0.02	
	<b>95th Percentile</b>	<b>99th Percentile</b>	<b>99.9th Percentile</b>
<b>EU Method I Normal</b>	0.06 (0.08)	0.07 (0.10)	0.09 (--)
<b>EU Method I Log Normal</b>	0.06 (0.15)	0.15 (0.30)	0.20 (--)
<b>EU Method II Distribution-Free</b>		0.07	
<b>California Method <math>\mu + 3\sigma</math></b>		0.09	
<b>UPLMedian95th</b>		0.10	
<b>Approximate Shapiro-Francia Normality Test</b>		0.9444	
	p-value > 0.05 : Do not reject lognormality assumption		
Would you like the above values rounded? (Y or N)==>		Y	

<b>Table II-4. Combined Indoxacarb Residue Data on Cucurbit Vegetables.</b>			
<b>Regulator:</b>	<b>EPA</b>		
<b>Chemical:</b>	<b>Indoxacarb</b>		
<b>Crop:</b>	<b>Cantaloupe</b>	<b>Cucumber</b>	<b>Squash</b>
<b>PHI:</b>	<b>3-4 days</b>	<b>3 days</b>	<b>2-4 days</b>
<b>App. Rate:</b>	<b>0.436-0.475 lb ai/A</b>	<b>0.414-0.463 lb ai/A</b>	<b>0.423-0.466 lb ai/A</b>
<b>Submitter:</b>	<b>IR-4</b>	<b>IR-4</b>	<b>IR-4</b>
<b>MRID Citation:</b>	<b>MRID 46651501</b>	<b>MRID 46651502</b>	<b>MRID 46651503</b>
	<b>Combined Indoxacarb Residues</b>		
	0.027	0.018	0.120
	0.247	0.015	0.014
	0.130	0.025	0.110
	0.393	0.025	0.040
	0.088	0.01	0.01
	0.031	0.023	0.022
	0.050	0.040	0.035
	0.036	0.031	0.012
	0.050	0.013	0.026
	0.116	0.019	0.01
	0.018	0.016	0.01
	0.064	0.020	0.084
	0.197	0.028	0.013
	0.170	0.014	0.048
	0.230	0.01	0.032
	0.068	0.022	0.01
	0.022	0.069	0.034
	0.064	0.031	0.026
	0.035	0.012	0.013
	0.052	0.018	0.028
	0.124		0.01
	0.024		0.022

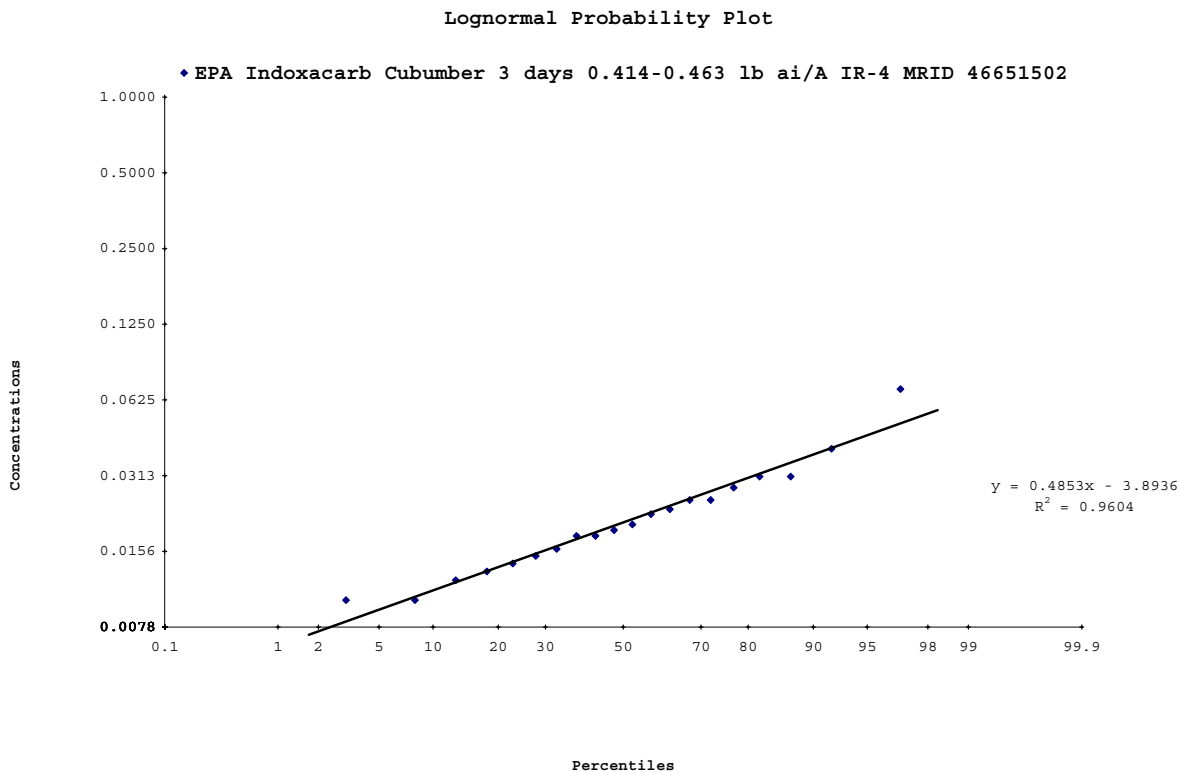
**Figure II-7. Lognormal probability plot of indoxacarb (WDG) field trial data for cantaloupes following four broadcast foliar applications at 1x rate.**



**Figure II-8. Tolerance spreadsheet summary of field trial data for cantaloupes following four broadcast foliar applications of indoxacarb (WDG).**

	Regulator: EPA Chemical: Indoxacarb Crop: Cantaloupe PHI: 3-4 days App. Rate: 0.436-0.475 lb ai/A Submitter: IR-4 MRID Citation: MRID 46651501		
	n: 22 min: 0.02 max: 0.39 median: 0.06 average: 0.10		
	95th Percentile	99th Percentile	99.9th Percentile
EU Method I Normal	0.30 (0.35)	0.35 (0.45)	0.40 (--)
EU Method I Log Normal	0.30 (0.60)	0.60 (1.2)	1.1 (--)
EU Method II	0.30		
Distribution-Free California Method $\mu + 3\sigma$	0.40		
UPLMedian95th	0.40		
Approximate Shapiro-Francia Normality Test	0.9761		
	p-value > 0.05 : Do not reject lognormality assumption		

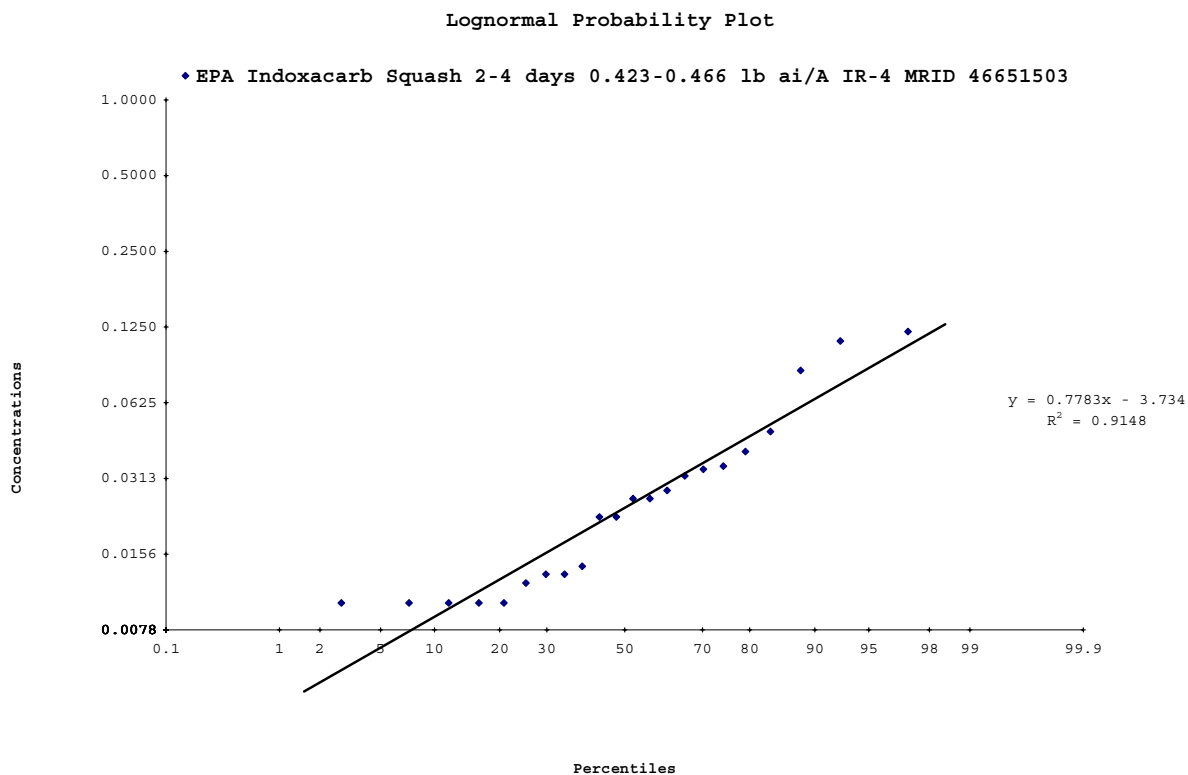
**Figure II-9. Lognormal probability plot of indoxacarb (WDG) field trial data for cucumbers following four broadcast foliar applications at 1x rate.**



**Figure II-10. Tolerance spreadsheet summary of field trial data for cucumbers following four broadcast foliar applications of indoxacarb (WDG).**

	<b>Regulator:</b>	EPA	
	<b>Chemical:</b>	Indoxacarb	
	<b>Crop:</b>	Cubumber	
	<b>PHI:</b>	3 days	
	<b>App. Rate:</b>	0.414-0.463 lb ai/A	
	<b>Submitter:</b>	IR-4	
	<b>MRID Citation:</b>	MRID 46651502	
	<b>n:</b>	20	
	<b>min:</b>	0.01	
	<b>max:</b>	0.07	
	<b>median:</b>	0.02	
	<b>average:</b>	0.02	
		<b>95th Percentile</b>	<b>99th Percentile</b>
<b>EU Method I</b>		0.05	0.06
<b>Normal</b>		(0.06)	(0.07)
<b>EU Method I</b>		0.05	<b>0.07</b>
<b>Log Normal</b>		<b>(0.07)</b>	(0.10)
<b>EU Method II</b>			0.06
<b>Distribution-Free</b>			
<b>California Method</b>			<b>0.07</b>
<b><math>\mu + 3\sigma</math></b>			
<b>UPLMedian95th</b>			<b>0.15</b>
<b>Approximate</b>		0.9604	
<b>Shapiro-Francia</b>		p-value > 0.05 : Do not reject lognormality assumption	
<b>Normality Test</b>			
Would you like the above values rounded? (Y or N)==>			
		Y	

**Figure II-11. Lognormal probability plot of indoxacarb (WDG) field trial data for summer squash following four broadcast foliar applications at 1x rate.**



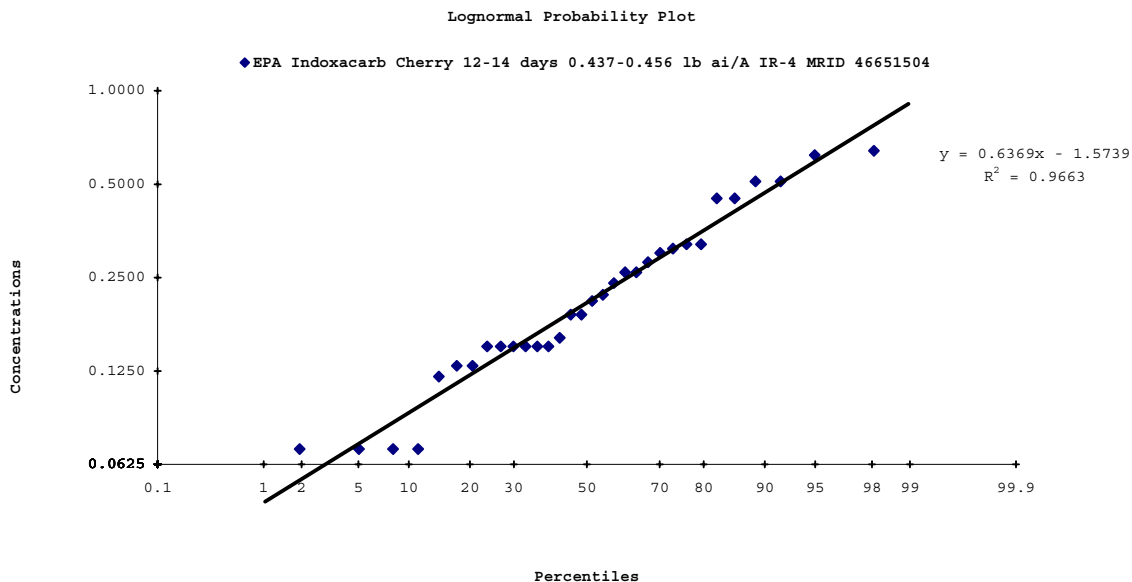
**Figure II-12. Tolerance spreadsheet summary of field trial data for summer squash following four broadcast foliar applications of indoxacarb (WDG).**

Regulator:	EPA		
Chemical:	Indoxacarb		
Crop:	Squash		
PHI:	2-4 days		
App. Rate:	0.423-0.466 lb ai/A		
Submitter:	IR-4		
MRID Citation:	MRID 46651503		
n:	22		
min:	0.01		
max:	0.12		
median:	0.02		
average:	0.03		
	<b>95th Percentile</b>	<b>99th Percentile</b>	<b>99.9th Percentile</b>
EU Method I Normal	0.09 (0.15)	0.15 (0.15)	0.15 (--)
EU Method I Log Normal	0.09 (0.20)	<b>0.15</b> (0.35)	0.30 (--)
EU Method II Distribution-Free		0.08	
California Method $\mu + 3\sigma$		<b>0.15</b>	
UPLMedian95th		<b>0.15</b>	
Approximate Shapiro-Francia Normality Test		0.9148	
	p-value > 0.05 : Do not reject lognormality assumption		
Would you like the above values rounded? (Y or N)==>		Y	

<b>Table II-5. Combined Indoxacarb Residue Data on Stone Fruits.</b>			
<b>Regulator:</b>	<b>EPA</b>		
<b>Chemical:</b>	<b>Indoxacarb</b>		
<b>Crop:</b>	<b>Cherry</b>	<b>Peach</b>	<b>Plum</b>
<b>PHI:</b>	<b>12-14 days</b>	<b>13-14 days</b>	<b>13-15 days</b>
<b>App. Rate:</b>	<b>0.437-0.456 lb ai/A</b>	<b>0.400-0.449 lb ai/A</b>	<b>0.431-0.448 lb ai/A</b>
<b>Submitter:</b>	<b>IR-4</b>	<b>IR-4</b>	<b>IR-4</b>
<b>MRID Citation:</b>	<b>MRID 46651504</b>	<b>MRID 46651505</b>	<b>MRID 46651506</b>
	<b>Combined Indoxacarb Residues</b>		
	0.07	0.07	0.0052*
	0.07	0.26	0.0068*
	0.15	0.13	0.02
	0.45	0.03	0.02
	0.22	0.04	0.02
	0.19	0.1	0.03
	0.15	0.09	0.07
	0.16	0.09	0.04
	0.3	0.1	0.07
	0.51	0.09	0.19
	0.24	0.3	0.02
	0.12	0.16	0.02
	0.26	0.19	0.01
	0.31	0.58	0.02
	0.13	0.07	0.02
	0.62	0.06	0.02
	0.07	0.29	0.03
	0.07	0.13	0.07
	0.15	0.04	0.04
	0.45	0.04	0.07
	0.21	0.1	0.18
	0.19	0.09	0.01
	0.15	0.1	
	0.15	0.1	
	0.32	0.09	
	0.51	0.3	
	0.28	0.16	
	0.15	0.2	
	0.26	0.59	
	0.32	0.07	
	0.13		
	0.64		

\* Fill-in Residues from MLE for Values = LOQ.

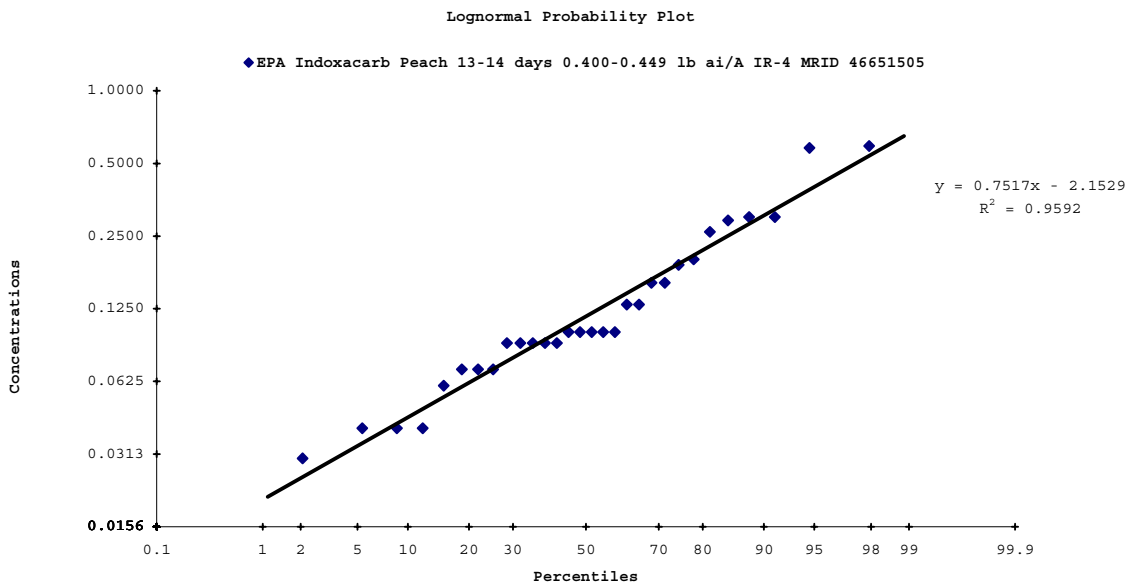
**Figure II-13. Lognormal probability plot of indoxacarb (WDG) field trial data for cherries following four foliar applications at 1x rate.**



**Figure II-14. Tolerance spreadsheet summary of field trial data for cherries following four foliar applications of indoxacarb (WDG).**

Regulator: EPA Chemical: Indoxacarb Crop: Cherry PHI: 12-14 days App. Rate: 0.437-0.456 lb ai/A Submitter: IR-4 MRID Citation: MRID 46651504			
n: 32 min: 0.07 max: 0.64 median: 0.20 average: 0.25			
	95th Percentile	99th Percentile	99.9th Percentile
EU Method I Normal	0.60 (0.60)	0.70 (0.80)	0.80 (--)
EU Method I Log Normal	0.60 (0.90)	0.90 (1.5)	1.5 (--)
EU Method II Distribution-Free California Method $\mu + 3\sigma$	0.70  0.80		
UPLMedian95th	1.2		
Approximate Shapiro-Francia Normality Test	0.9663 p-value > 0.05 : Do not reject lognormality assumption		

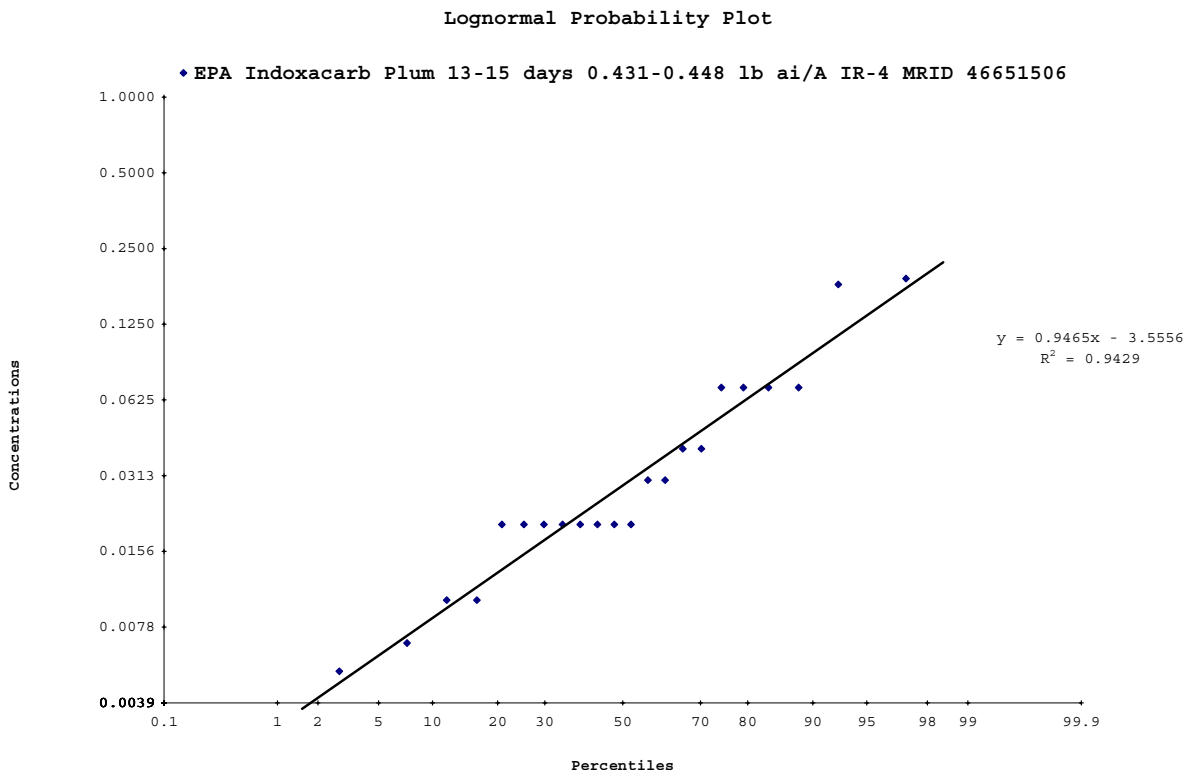
**Figure II-15. Lognormal probability plot of indoxacarb (WDG) field trial data for peaches following four foliar applications at 1x rate.**



**Figure II-16. Tolerance spreadsheet summary of field trial data for peaches following four foliar applications of indoxacarb (WDG).**

Regulator: EPA Chemical: Indoxacarb Crop: Peach PHI: 13-14 days App. Rate: 0.400-0.449 lb ai/A Submitter: IR-4 MRID Citation: MRID 46651505			
n: 30 min: 0.03 max: 0.59 median: 0.10 average: 0.16			
	95th Percentile	99th Percentile	99.9th Percentile
EU Method I Normal	0.40 (0.50)	0.50 (0.60)	0.60 (--)
EU Method I Log Normal	0.40 (0.70)	0.70 (1.2)	1.2 (--)
EU Method II	0.40		
Distribution-Free California Method $\mu + 3\sigma$	0.60		
UPLMedian95th	0.60		
Approximate Shapiro-Francia Normality Test	0.9592		
	p-value > 0.05 : Do not reject lognormality assumption		

**Figure II-17. Lognormal probability plot of indoxacarb (WDG) field trial data for plums following four foliar applications at 1x rate.**

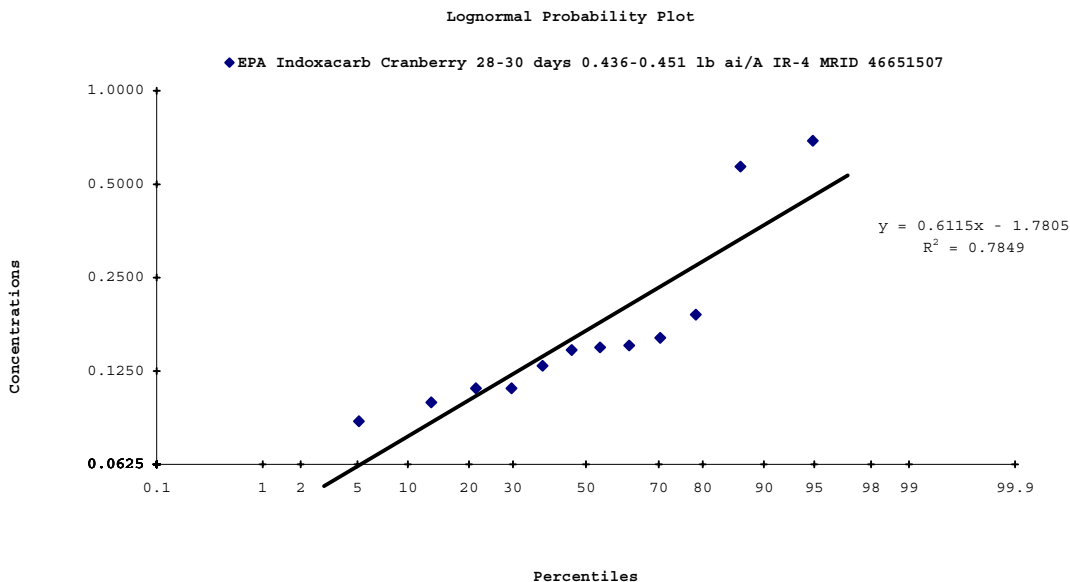


**Figure II-18. Tolerance spreadsheet summary of field trial data for plums following four foliar applications of indoxacarb (WDG).**

	<b>Regulator:</b>	EPA	
	<b>Chemical:</b>	Indoxacarb	
	<b>Crop:</b>	Plum	
	<b>PHI:</b>	13-15 days	
	<b>App. Rate:</b>	0.431-0.448 lb ai/A	
	<b>Submitter:</b>	IR-4	
	<b>MRID Citation:</b>	MRID 46651506	
	<b>n:</b>	22	
	<b>min:</b>	0.01	
	<b>max:</b>	0.19	
	<b>median:</b>	0.02	
	<b>average:</b>	0.04	
		<b>95th Percentile</b>	<b>99th Percentile</b>
<b>EU Method I Normal</b>	0.15 (0.20)	0.20 (0.25)	0.20 (--)
<b>EU Method I Log Normal</b>	0.15 <b>(0.30)</b>	<b>0.30</b> (0.60)	0.60 (--)
<b>EU Method II Distribution-Free</b>		0.15	
<b>California Method <math>\mu + 3\sigma</math></b>		0.20	
<b>UPLMedian95th</b>		0.15	
<b>Approximate Shapiro-Francia Normality Test</b>		0.9429	
	p-value > 0.05 : Do not reject lognormality assumption		
Would you like the above values rounded? (Y or N)==>			
		Y	

<b>Table II-6. Combined Indoxacarb Residue Data on Cranberries.</b>		
<b>Regulator:</b>	<b>EPA</b>	
<b>Chemical:</b>	<b>Indoxacarb</b>	
<b>Crop:</b>	<b>Cranberry</b>	
<b>PHI:</b>	<b>13-15 days</b>	<b>28-30 days</b>
<b>App. Rate:</b>	<b>0.436-0.451 lb ai/A</b>	
<b>Submitter:</b>	<b>IR-4</b>	
<b>MRID Citation:</b>	<b>MRID 46651507</b>	
	<b>Combined Indoxacarb Residues</b>	
	0.157	0.086
	0.170	0.151
	0.110	0.099
	0.360	0.190
	0.300	0.130
	0.390	0.570
	0.219	0.146
	0.213	0.149
	0.110	0.110
	0.280	0.160
	0.170	0.110
	0.230	0.690

**Figure II-19. Lognormal probability plot of indoxacarb (WDG) field trial data for cranberries 28-30 days (proposed PHI) following four foliar applications at 1x rate.**

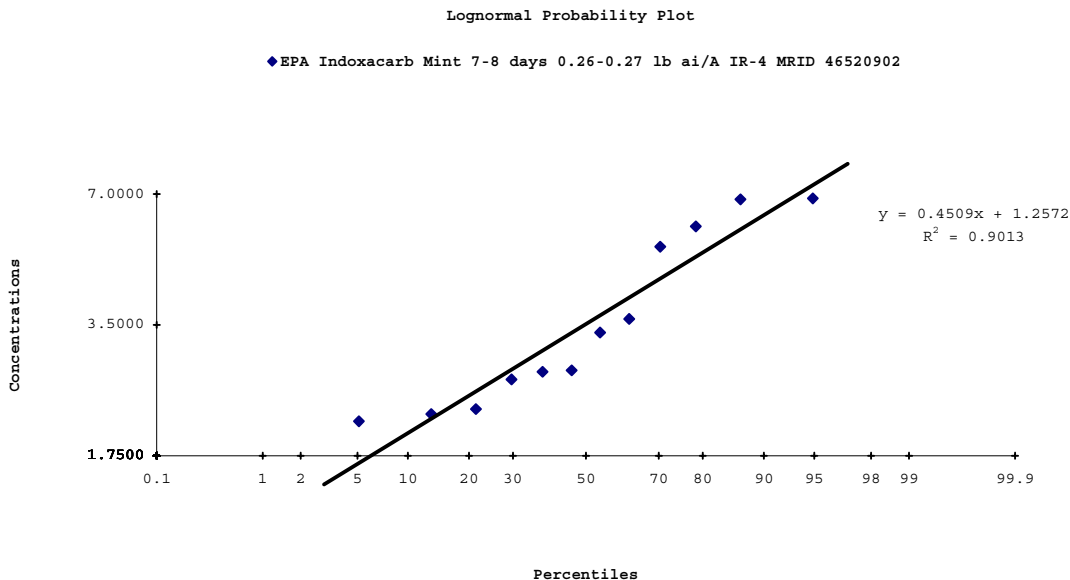


**Figure II-20. Tolerance spreadsheet summary of field trial data for cranberries following four foliar applications of indoxacarb (WDG).**

Regulator: EPA Chemical: Indoxacarb Crop: Cranberry PHI: 28-30 days App. Rate: 0.436-0.451 lb ai/A Submitter: IR-4 MRID Citation: MRID 46651507			
n: 12 min: 0.09 max: 0.69 median: 0.15 average: 0.22			
	95th Percentile	99th Percentile	99.9th Percentile
EU Method I Normal	0.60 (0.80)	0.70 (1.0)	0.90 (--)
EU Method I Log Normal	0.50 (1.1)	<b>0.80</b> (2.0)	1.3 (--)
EU Method II Distribution-Free California Method $\mu + 3\sigma$	0.40		
UPLMedian95th	<b>0.90</b>		
UPLMedian95th	1.1		
Approximate Shapiro-Francia Normality Test	0.7849 p-value <= 0.01: Reject lognormality assumption		

<b>Table II-7. Combined Indoxacarb Residue Data on Mint.</b>	
<b>Regulator:</b>	<b>EPA</b>
<b>Chemical:</b>	<b>Indoxacarb</b>
<b>Crop:</b>	<b>Mint</b>
<b>PHI:</b>	<b>7-8 days</b>
<b>App. Rate:</b>	<b>0.26-0.27 lb ai/A</b>
<b>Submitter:</b>	<b>IR-4</b>
<b>MRID Citation:</b>	<b>MRID 46520902</b>
	<b>Combined Indoxacarb Residues</b>
	6.84
	5.90
	5.30
	6.81
	3.61
	2.62
	2.24
	2.73
	2.18
	2.10
	2.75
	3.36

**Figure II-21. Lognormal probability plot of indoxacarb (WDG) field trial data for mint following four broadcast foliar applications at 1x rate.**



**Figure II-22. Tolerance spreadsheet summary of field trial data for mint following four broadcast foliar applications of indoxacarb (WDG).**

Regulator: EPA Chemical: Indoxacarb Crop: Mint PHI: 7-8 days App. Rate: 0.26-0.27 lb ai/A Submitter: IR-4 MRID Citation: MRID 46520902			
n: 12 min: 2.10 max: 6.84 median: 3.06 average: 3.87			
	95th Percentile	99th Percentile	99.9th Percentile
EU Method I Normal	7.0 (9.0)	9.0 (11)	10 (--)
EU Method I Log Normal	8.0 (13)	<b>11</b> (19)	15 (--)
EU Method II Distribution-Free	12		
California Method $\mu + 3\sigma$	10		
UPLMedian95th	25		
Approximate Shapiro-Francia Normality Test	0.9013 p-value > 0.05 : Do not reject lognormality assumption		