US Environmental Protection Agency
Office of Pesticide Programs

Petition for Acetamiprid

June 2, 2009

Nisso

NISSO AMERICA INC.

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June 2, 2009

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Ms. Pat Cimino
Specialty Crops Advisor
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Mr. Robert Perlis
EPA – Office of General Council [2333A]
Ariel Rios Building
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Washington, DC 20460

Dear Ms. Angulo, Ms. Cimino, and Mr. Perlis:

PURPOSE

The purpose of this letter is to follow-up on the Nippon Soda Co., Ltd. (c/o Nisso America Inc.) (Nisso) August 11, 2008 request for an extension of the acetamiprid exclusive use period (Enclosure 1). We wish to ensure that the US Environmental Protection Agency (EPA or the Agency) has all the information it needs to make a prompt and affirmative decision on the requested extension and therefore are providing additional supportive information to serve this end.

We recognize that the Agency resources required to review this extension are substantial, and as the exclusive use data submitter, we wish to do all we can to facilitate an efficient EPA review. In that spirit, we are providing in this letter additional information available from U.S. Department of Agriculture (USDA) websites. This additional information supports the extension of the acetamiprid exclusive use period based on acetamiprid's role as an important product for use in integrated pest management (IPM) programs. The IPM justification is in addition to the strong rationale for granting the extension based on acetamiprid's reduced risk profile that is discussed in our August 11, 2008 submission and further amplified in this submission. It is our understanding that if each of the minor crop uses that form the basis for the extension request meets one of these criteria, then we have met the statutory requirements for an extension. To qualify for the maximum extension of three years, there must be nine minor uses that meet at least one of the extension criteria. We have identified 21 uses that meet at least one of the criteria and were registered by EPA within seven years of the first acetamiprid registration.

The extension of the exclusive use period for acetamiprid is critically important to Nisso. Given the practicalities of business planning, we would be very appreciative if EPA could complete its review soon.

DISCUSSION

Extending the Exclusive Use Period for Minor Uses

The 1996 Food Quality Protection Act (FQPA) amended the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) to provide for the extension of the period during which only the data submitter for the original registration of a new active ingredient may use data entitled to exclusive use protection to support additional registrations. FIFRA section 3(c)(1)(F)(ii) states that the exclusive use period can be extended one additional year for each three minor uses registered within seven years of the beginning of the exclusive use period. One of four specified criteria must be met in order for the Agency to extend the exclusive use period.

Acetamiprid meets at least two of these four criteria as follows:

1. "the alternatives to the minor use pesticide pose greater risks to the environment or human health" (EPA designated acetamiprid as a reduced risk and organophosphate (OP) replacement compound) .

2. "the minor use pesticide plays or will play a significant part in an integrated pest management program."

As stated earlier, our August 11, 2008, submission focused on the strong reduced risk record of acetamiprid. This submission addresses both extension period criteria.

Enclosure 2 is a table that provides information concerning acetamiprid uses registered by EPA. The table identifies the uses registered, the dates of registration, whether the use is a minor use, and whether the use meets the reduced risk extension period criterion, the IPM extension period criterion, or both.

EPA's Reduced Risk Program

The EPA website provides a detailed discussion of the Agency's reduced risk pesticide program. While FQPA formalized the reduced risk program, EPA had a program in place even prior to the passage of the FQPA in 1996. EPA's reduced risk program is clearly one of the Agency's success stories. Registrants were encouraged to develop reduced risk products. In return, the Agency agreed to expedite the review of the registration submissions. The public good of this program consisted of the introduction of reduced risk pesticides that competed with and took market share from riskier alternative products. It is important to note that the public health benefits begin to accrue as soon as EPA registers and allows marketing to begin for the reduced risk pesticides. Over the years, EPA has applauded the growing impact of reduced risk pesticides that took market share and reduced use of riskier alternatives including organophosphate, carbamate, and pyrethroid pesticides.

Reduced Risk and Minor Uses

There is less financial incentive for registrants to pursue the registration of pesticides for minor uses compared to major crops The FQPA amendments concerning the extension of the exclusive use period provided additional incentive for the pesticide industry to spend resources to support minor uses. Linking the extension to the reduced risk criterion created the potential not only to stimulate the development of minor use pesticides but also to

extend the reduced risk safety net beyond major crops to the minor uses. Nisso embraced this incentive by continuing to generate data supporting minor uses for acetamiprid even after the initial registration.

Justification and Support for Meeting Reduced Risk Criterion

EPA approved two reduced risk and OP replacement submissions for acetamiprid. Enclosure 3 provides the cover page, the executive overview and the executive summary for the initial submission, dated October 29, 1999. This submission covered a variety of uses including a number of minor uses. Enclosure 4 provides the same material for the submission dated March 15, 2003. This submission covered a requested use on potatoes, which is not considered a minor use crop, but is provided as part of the background of EPA's assessment of acetamiprid as a reduced risk pesticide.

Both Enclosures 3 and 4 summarize the human health, ecological effects and environmental fate characteristics of acetamiprid, and also summarize the reduced risk rationale. In each case, the enclosures also explain that acetamiprid presented reduced dietary and drinking risk, reduced worker exposure and risk, reduced ecological risk, and reduced environmental burden and replacement of OP compounds. The MRID numbers for these documents are 44988401 and 45900501. It is also noteworthy that both documents discuss the compatibility of acetamiprid in resistance management and IPM programs (acetamiprid's IPM use is addressed in further detail below).

Nisso will provide the complete reduced risk and OP replacement submissions if that will be helpful to EPA.

Enclosure 5 is a current data matrix that identifies the studies (including MRID Numbers) that support the continued registration and reduced risk and OP replacement status of acetamiprid.

On March 15, 2002, EPA registered the first acetamiprid uses. The initial registration included five crop groupings containing minor use crops. Nisso submitted residue data for twelve (12) individual minor use crops to support the reduced-risk registration for these crop groupings. Since the initial registration, Nisso submitted additional residue data to expand the label and increase the number of crop groupings that contain crops meeting the definition of minor use (Enclosure 2). Note that Nisso chose not pursue subsequent reduced risk designations after it submitted its reduced risk justification for potatoes on March 15, 2003 because the introduction of PRIA fees removed much of the expedited review incentive for devoting the time and resources needed to justify a reduced risk rationale.

On May 25, 2005, the Agency registered acetamiprid for use on potatoes. While not a minor use, the registration demonstrates the continued reduced risk status of acetamiprid.

On November 28, 2007, EPA published a final rule (72 FR 67256; Enclosure 6) establishing additional minor use tolerances for acetamiprid. This Federal Register publication contained a summary of the Agency's updated view of the toxicology and dietary risk presented by acetamiprid, and referenced an EPA docket that includes a detailed human health risk assessment (Enclosure 7; dated October 25, 2007) and a dietary exposure assessment (Enclosure 8; dated October 12, 2007).

On January 16, 2008, EPA published another final rule (73 FR 2809; Enclosure 9) establishing yet additional minor use tolerances for acetamiprid. In this rule, EPA referenced the risk discussion provided in the November 28, 2007 FR notice.

Enclosures 6, 7, 8 and 9 document the Agency has continued to actively review and reconsider the data base supporting acetamiprid. There are numerous food crop, ornamental crop, and residential uses for the compound. EPA has continued to carefully evaluate the toxicity of acetamiprid, and as recently as January 16, 2008,

concluded that no additional FQPA safety factor is required, and all risks (dietary, water, residential, and aggregate) are more than acceptable.

Most recently, on March, 12, 2009, the IR-4 Project submitted a request to EPA to designate additional minor uses of acetamiprid as reduced risk (Enclosure 10) and establish new or revised tolerances.

Finally, to this day, EPA's website continues to identify acetamiprid as a reduced risk and OP replacement compound.

While reduced risk pesticides have clearly had a positive impact in the reduced use of riskier alternatives, acetamiprid continues to compete with organophosphate, carbamate, and pyrethroid pesticides as it has since 2002. The reduced risk benefits of acetamiprid began to accrue in 2002, and these benefits continue to this day. Acetamiprid applications to registered minor crops reduces the quantity of OP and carbamate compounds released to the environment.

Justification and Support for Meeting IPM Criterion

In addition to fulfilling a criterion for the exclusivity extension under FIFRA § 3(c)(1)(F)(ii)(II) by being categorized as a reduced risk pesticide, several acetamiprid minor uses meet a second criterion for the exclusivity extension under FIFRA § 3(c)(1)(F)(ii) (IV);that is "...the minor use pesticide plays or will play a significant part in an integrated pest management program."

Information on Pest Management Strategic Plans (PMSP) derived from the USDA's National Information System for the Regional IPM Centers website [http://www.ipmcenters.org/pmsp] shows that there are currently 25 PMSPs representing 13 states and/or regions of the US where acetamiprid is listed as an alternative (or possible alternative) insecticide product for 16 minor use (i.e., <300,000 A) crops or crop groups. The list of minor use crop/state PMSPs and their respective websites are included in Enclosure 11.

Likewise the USDA's National Information System for the Regional IPM Centers website [http://www.ipmcenters.org/CropProfiles/] lists 19 Minor Crop/State profiles in which acetamiprid is referenced as an alternative insecticide product. The list of minor crop profiles and the associated websites are included in Enclosure 12. Nine of these are among the 21 uses listed on Enclosure 2 as supporting the extension of exclusive use protection for acetamiprid data.

CONCLUSION

Nisso made a timely request to extend the exclusive use period for acetamiprid and demonstrates that there are 21 minor crop uses meeting the statutory criteria for the extension thus there are more than the required 9 minor uses to achieve the maximum extension period. These 21 minor uses were registered within the first seven years of the acetamiprid exclusive use period and each of these minor uses meets either the reduced risk criterion or the IPM criterion of the statute, or both. Therefore, the Agency has sufficient grounds to extend the exclusivity period for acetamiprid for an additional three years as provided by FIFRA.

Again, because of the importance of this matter from a business perspective, Nisso would very much appreciate a timely response from EPA.

Thank you for your consideration of our request. Please contact Mr. John Wrubel of my staff should you wish further details.

Sincerely,

Toshifumi Kuwagata
President
Nisso America Inc.

cc: D. Edwards, EPA
L. Rossi, EPA

Nisso

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August 11, 2008

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ATTENTION: Minor Use – Exclusive Use Request

Re: Request for Extension of Exclusive Use Data Protection for Acetamiprid

Dear Ms. Cimino, Ms. Eagle, Ms. Laws, and Mr. Perlis,

Nippon Soda Co., Ltd. (Nisso), the sole registrant of the proprietary insecticide, acetamiprid, is hereby petitioning the Environmental Protection Agency for an extension of the exclusive use data protection under FIFRA § 3(c)(1)(F)(ii) for agricultural products containing acetamiprid.

Based on both the residue data generated by Nisso on 28 minor use food crops (twelve of which were categorized as "reduced-risk" uses) as well as the use on non-food greenhouse/nursery ornamentals that are currently on the acetamiprid product labels and registered on or after March 15, 2002, Nisso is formally petitioning to extend the data exclusivity period for acetamiprid for an additional three (3) years.

The current registrations held by Nisso for acetamiprid products used in the agriculture sector that are subject to extended exclusive use data protection are as follows:

Product Name	EPA Reg. No.
Acetamiprid Technical	8033-20
Acetamiprid RTU Insecticide	8033-21
TriStar 70 WSP Insecticide	8033-22
Assail 70 WP Insecticide	8033-23
Assail 30 SG Insecticide	8033-36
TriStar 30 SG Insecticide	8033-94
Acetamiprid 50 FS Insecticide Seed Treatment	8033-95

As mentioned previously, the active ingredient acetamiprid was originally approved by US EPA on March 15, 2002. It was registered as a reduced-risk, organophosphate replacement product under the Agency's "Safer Pesticide Policy" that was in place at the time. The original registration included use on the following crop groups containing minor use crops: citrus, fruiting vegetables (except cucurbits), leafy vegetables, pome fruit (excluding apples), and cole crops. Additionally the compound was initially approved for insect control on greenhouse and outdoor ornamentals that are considered another minor use area.

Since the original registration, Nisso has expanded the label to include uses in the stone fruit, cucurbit, tree nut, bulb vegetable, berries, and succulent legume crop groups, all of which contain crops fitting the definition of minor use. Minor crop growers find the acetamiprid labels very useful due to the flexibility offered by the range of approved crop groupings.

Because the current acetamprid labels allows use on nine (9) crop groups containing minor use crops and is based on residue data generated by Nisso on 28 individual representative minor use food crops, Nisso petitions the Agency to extend the exclusive use data protection for the acetamiprid registrations listed above for an additional three (3) years beyond the standard 10 year exclusive use period.

Attached Table 1 provides a summary list of the following: 1) the currently registered food crop or crop group on the acetamiprid labels, 2) the representative commodity on which residue data were generated, 3) the minor use determination (i.e., < 300,000 acres), 4) the registration date, 5) the "reduced-risk" status, and 6) the MRID number of the study that contains the residue data on the minor use crops. This concise tabular format allows for an expeditious review of this petition as it summarizes all pertinent information for the Agency.

Alternative products used on the minor use crops approved on the acetamiprid labels include various compounds in the organophosphate, carbamate, and pyrethroid classes of chemistry. In general, these chemistry classes are considered to pose greater risk to man and the environment than acetamiprid. Also acetamiprid is considered to be an "azinphos-methyl replacement product" and exhibits broad spectrum of activity against various insect pests.

Likewise, being a neonicotinoid, acetamiprid products are used in spray rotation programs with other mode of action chemistry and thereby reduce the possibility of insect resistance development.

Lastly, aside from providing an alternative mode of action, acetamiprid is known to be "soft" on beneficial insects and therefore plays an important role in integrated pest management programs.

For reasons addressed above, Nisso believes that acetamiprid has fully met and exceeded the statutory minimum number of required minor use registrations. We look forward to receiving the additional three years of exclusive use data protection under FIFRA § 3(c)(1)(F)(ii) for acetamiprid products.

Please contact me directly at 212-490-0351 should you have any questions or wish further detail regarding our request. Thank you in advance for your review of this petition.

Sincerely,

John J. Wrubel

John J. Wrubel
Regulatory Affairs Director

NISSO AMERICA INC.

Table 1.

Acetamiprid Crop Registrations and Minor Use Determination For Extension of the Exclusive Use Data Protection Period

Crop or Crop Group	Commodity	<300K Acres[1]	Registration Date[2]	Reduced Risk	MRID
Brassicas	Broccoli	✓	3/15/02	✓	44988607
	Cabbage	✓	"	✓	44988608
	Mustard greens	✓	"	✓	44988609
Citrus	Grapefruit	✓	3/15/02	✓	44988611
	Lemon	✓	"	✓	44988611
	Orange		"	✓	44988611
Pome Fruit	Apples		3/15/02	✓	44988612
	Pears	✓	"	✓	44988613
Fruiting Vegetables	Eggplant	✓	3/15/02	✓	44988615
	Peppers	✓	"	✓	44988616
	Tomatoes			✓	44988614
Leafy Vegetables	Celery	✓	3/15/02	✓	44988606
	Head lettuce	✓		✓	44988605
	Leaf lettuce	✓		✓	44988603
	Spinach	✓		✓	44988604
Grapes	Grapes		3/15/02	✓	44988620
Canola	Canola	✓	9/29/03		44988624
Tuberous vegetables	Potato		5/25/05	✓	45900508
Cucurbits[4]	Cantaloupe	✓	11/15/07		46265701
	Cucumber	✓	"		46265701
	Squash	✓	"		46265701
Legumes[4]	Green beans	✓	11/15/07		46785504
	Green peas		"		46785504
	Lima beans	✓	"		46785504
	Peas in pod	✓	"		46785504
Stone fruit[4]	Peach	✓	11/15/07		46265702
	Plum	✓	"		46265702
	Sweet cherry	✓	"		46265702
	Tart cherry	✓	"		46265702
Tree nuts[4]	Almond		11/15/07		46265703
	Pecan		"		46265703
Berries[4]	Blackberry	✓	1/21/08		46785502
	Blueberry	✓	"		46785502
	Raspberry	✓	"		46785502
	Strawberry[5]	✓	"		47013601
Bulb vegetables[4]	Bulb onion	✓	1/21/08		46785503
	Green onion	✓	"		46785503

1) Based on Residue Chemistry Test Guideline OPPTS 860.1500 Crop Field Trials.
2) Initial registration date March 15, 2002 for the new active ingredient, acetamiprid.
3) ✓ = yes
4) Nisso opted to not apply for reduced risk status for this use.
5) Strawberry residue data generated by IR-4

Enclosure 2.

Crop Registrations, Minor Use Determination, and Reduced Risk / IPM Status for Extension of the Exclusivity Period for Acetamiprid

Crop or Crop Group	Specific Commodity	Registration Date[2]	Residue Study MRID	<300K Acres[3]	Reduced Risk[4]	USDA's Regional IPM Center	
						PMSP[5]	Crop Profile[6]
Brassicas	Broccoli[1]	3/15/02	44988607	✓	✓		
	Cabbage	"	44988608	✓	✓		✓
	Mustard greens	"	44988609	✓	✓		
Citrus	Grapefruit	3/15/02	44988611	✓	✓	✓	✓
	Lemon	"	44988611	✓	✓	✓	✓
	Orange	"	44988611		✓	✓	✓
Pome Fruit	Apples	3/15/02	44988612		✓		
	Pears	"	44988613	✓	✓	✓	
Fruiting Vegetables	Eggplant	3/15/02	44988615	✓	✓	✓	✓
	Peppers	"	44988616	✓	✓	✓	✓
	Tomatoes	"	44988614		✓		
Leafy Vegetables	Celery	3/15/02	44988606	✓	✓	✓	✓
	Head lettuce	"	44988605	✓	✓		✓
	Leaf lettuce	"	44988603	✓	✓		✓
	Spinach	"	44988604	✓	✓	✓	✓
Grapes	Grapes	3/15/02	44988620		✓		
Canola	Canola	9/29/03	44988624	✓			
Tuberous vegetables	Potato	5/25/05	45900508		✓		
Cucurbits	Cantaloupe	11/15/07	46265701	✓		✓	
	Cucumber	"	46265701	✓		✓	
	Squash	"	46265701	✓		✓	
Legumes	Green beans	11/15/07	46785504	✓		✓	
	Green peas	"	46785504				
	Lima beans	"	46785504	✓			
	Peas in pod	"	46785504	✓			
Stone fruit	Peach	11/15/07	46265702	✓		✓	
	Plum	"	46265702	✓		✓	
	Sweet cherry	"	46265702	✓			
	Tart cherry	"	46265702	✓		✓	
Tree nuts	Almond	11/15/07	46265703				
	Pecan	"	46265703				
Berries	Blackberry	1/21/08	46785502	✓			
	Blueberry	"	46785502	✓		✓	
	Raspberry	"	46785502	✓			
	Strawberry[6]	"	47013601	✓		✓	
Bulb vegetables	Bulb onion	1/21/08	46785503	✓			
	Green onion	"	46785503	✓			

1) Green highlights indicate minor uses that qualify for one or more of the exclusivity extension criteria
2) Initial registration date March 15, 2002 for the new active ingredient, acetamiprid.
3) Based on Residue Chemistry Test Guideline OPPTS 860.1500 Crop Field Trials
4) ✓ = yes (Reduced Risk status granted); No check mark (✓) means the registrant chose to not apply for reduced risk status due to no expedited review advantage vis-a-vis PRIA (except canola).
5) ✓ = yes (Acetamiprid is mentioned in the USDA Regional IPM Center's Pest Management Strategic Plan for this crop.)
6) ✓ = yes (Acetamiprid is mentioned in the USDA Regional IPM Center's Crop Profile for this crop.)
7) Strawberry residue data generated by IR-4

MRID
44988401

REPORT TITLE

Reduced Risk and Organophosphate Replacement Rationale for Acetamiprid – Agricultural Uses

DATA REQUIREMENT

None

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COMPLETION DATE

October 29, 1999

SUBMITTED BY

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EXECUTIVE OVERVIEW

Rhône-Poulenc Ag Company (Rhône-Poulenc) is submitting two related reduced risk and organophosphate (OP) replacement documents for the active ingredient acetamiprid to the US Environmental Protection Agency (EPA or Agency). This document covers two acetamiprid-containing products, ASSAIL™ brand 70WP Insecticide for use on cotton, pome fruits, citrus, grapes, cole crops, leafy vegetables, and fruiting vegetables, and ADJUST™ brand 70WP Insecticide Seed Treatment for use on canola and mustard seed. The second reduced risk document covers non-agricultural uses of acetamiprid. Again, two products are involved; namely, PRISTINE™ brand RTU Insecticide, a ready-to-use product for homeowner use on outdoor ornamentals and in gardens, and CHIPCO® brand TriStar™ 70WSP Insecticide for professional use in greenhouses and nurseries and on established, outdoor ornamentals in commercial and residential landscapes. Rhône-Poulenc prepared two separate documents to facilitate Agency review of the multiple products and uses. In each case, the company believes there is a very strong reduced risk rationale.

Rhône-Poulenc requests an accelerated review of this acetamiprid submission for the following reasons:

- Acetamiprid is a strong reduced risk candidate.
- Acetamiprid is a strong OP replacement candidate. Over 4,000,000 pounds of OP active ingredients will be replaced during the first five years of acetamiprid use.
- Acetamiprid is a strong candidate for joint EPA-Canadian PMRA review. It clearly meets the criteria identified by EPA and the Pest Management Regulatory Agency (PMRA), the Canadian pesticide regulatory agency for joint review. Acetamiprid is a new chemical with major uses in common in both countries, applications for registration are being submitted simultaneously, and the labeling, packaging, and residue profiles are substantially similar in both countries. Acetamiprid will reduce risk in the United States; it will do the same in Canada where it can eliminate the use of lindane to treat canola and mustard seed.
- Based on PR Notice 97-2, acetamiprid will be used on crops falling under the minor use definition for EPA priority purposes (e.g., cole crops, leafy vegetables, fruiting vegetables).
- Acetamiprid meets the criteria for EPA priority attention related to vulnerable crop/pest combinations (e.g., cole crops/aphids, leafy vegetables/aphids).

Acetamiprid is very effective against a number of key pests for the crops mentioned above including whiteflies, aphids, codling moths, flea beetles, bud worms, Colorado potato beetles, leaf miners, citrus thrips, red scale, leaf hoppers, Japanese beetles, pyslla, and mealybugs. The compound offers equal to superior efficacy at lower application rates than most of the alternative compounds. In addition, unlike competitive products, acetamiprid has ovicidal activity.

Acetamiprid is not oncogenic. It is not a developmental or reproductive toxicant. It has very low neurotoxic potential. Based on the weight of the evidence, acetamiprid is not mutagenic or genotoxic. It degrades rapidly in the environment, is unlikely to drift, run-off or leach, and presents a very positive ecological risk profile compared to all alternatives including imidacloprid. Conservative risk assessments demonstrate little cause for concern. Acetamiprid meets the Food Quality Protection Act (FQPA) "reasonable certainty of no harm" standard, and the Federal Fungicide, Insecticide, and Rodenticide Act (FIFRA) no unreasonable risk standard. This stands in sharp contrast to many of the alternative insecticides.

The major alternatives are OPs (such as azinphos-methyl, methyl parathion, and chlorpyrifos), pyrethroids, carbaryl, and imidacloprid. Imidacloprid is in the same chemical family as acetamiprid; it has achieved important market shares in a number of areas. Acetamiprid will primarily replace OPs, pyrethroids and carbaryl. From a human risk perspective, the alternatives tend to have lower No Observed Effect Levels (NOELs) than acetamiprid. The alternatives tend to exhibit cholinesterase (ChE) inhibiting and neurotoxic properties. The OPs present significant dietary, aggregate, worker, and risk concerns. OPs are known to accumulate in mammalian systems following repeated exposure. Finally, the OPs and other alternatives, particularly the pyrethroids, raise significant ecological risk concerns. (While acetamiprid is very toxic to mysid shrimp, its overall ecological risk profile is far better than the alternatives).

In regards to the Canadian situation, canola and mustard seed are major crops representing significant economic value to Canadian agriculture. Lindane is currently the only insecticide used to treat canola and mustard seed for use in Canada. Imidacloprid is registered only for use on canola and mustard seed to be exported to the US. Lindane, an organochlorine compound, raises significant risk concerns. The product is undergoing a "special review" process in Canada; a final decision is expected in December, 2000. In addition to risk issues, the use of lindane in Canada creates a trade issue. Most canola and mustard seed used in the US comes from Canada; yet, there are no tolerances for the use of lindane on canola or mustard seed. The reduced risk characteristics of acetamiprid and problems with lindane use in Canada make acetamiprid an ideal candidate for joint US-Canada review. Such a review will address the need to facilitate the cross-border movement of treated seeds in parallel with the commitments of EPA and PMRA to facilitate making replacement products available for the 2001 season.

In conclusion, this document demonstrates fully the reduced risk and OP replacement potential presented by acetamiprid. In addition, acetamiprid can replace lindane use in Canada, and meets minor use and vulnerable crop/pest criteria. Moving forward on this compound makes sense for EPA, Canadian authorities, and growers and consumers on both sides of the border. Rhône-Poulenc trusts that the Agency will reach these same conclusions.

REDUCED RISK AND OP REPLACEMENT
RATIONALE FOR ACETAMIPRID

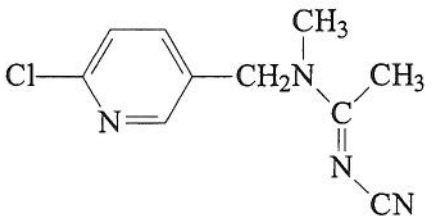
A. EXECUTIVE SUMMARY

1. Chemical Name: IUPAC: (E)-N^1-[(6-chloro-3-pyridyl)methyl]-N^2-cyano-N^1-methylacetamidine

2. Common Name: Acetamiprid

3. Chemical Abstract Service Registry Number: 135410-20-7

4. Chemical Structure:



5. Chemical Family: Chloronicotinyl

6. Mode of Action of the Active Ingredient

Acetamiprid acts as an agonist of the nicotinic acetylcholine receptor (nACHR) of the postsynaptic membrane of nerve cells. The active ingredient interrupts the function of the insect nervous system. Biochemical radioligand binding studies show that acetamiprid interacts with high affinity at the insect nACHR binding site and with low affinity at the vertebrate nACHR. The differences in the affinities of acetamiprid at the insect and vertebrate nACHR may indicate that there are structural differences between insect and vertebrate nACHRs, and may account for acetamiprid's selective toxicity to insects.

7. Proposed Use Pattern

There are two acetamiprid products covered by this reduced risk document. The first, ASSAIL™ brand 70WP Insecticide, is a wettable powder formulation for use on cotton, pome fruit, citrus, grapes, leafy vegetables, fruiting vegetables, cole crops, and canola and mustard seeds. The second product, ADJUST™ brand 70WP Insecticide Seed Treatment, is an identical formulation for use in treating canola and mustard seed. Draft labels for both products are provided in Appendix 1.

The ASSAIL™ product is effective against whiteflies, aphids, coddling moths and a number of other very harmful pests. It can be applied by ground or air. The canola and mustard seed treatment product will be used against flea beetles. Seed treatment is usually done by seed

companies, which then sell the treated seed to growers. Most of the canola and mustard treated seed used by growers in the United States is imported from Canada. Rhône-Poulenc is not only requesting that EPA determine that acetamiprid is a reduced risk pesticide that will reduce the use of OP products, but is also requesting EPA and PMRA to conduct a joint review of acetamiprid so that it can be registered rapidly in both countries. In Canada, acetamiprid will become a major alternative to lindane, which is the only currently registered insecticide in Canada for treating canola and mustard seed.

8. Competitive Products

Insects can be highly destructive causing significant reductions in yield and quality that lead to substantial economic losses. This is true for each of the crops addressed in this reduced risk document.

Conventional pesticides, BT products, and BT cotton are all used, generally as part of an IPM program, to control the various insect pests that are problematic in the crops in question. Older chemistry (the OPs, carbamates, pyrethroids) tend to dominate the market. Imidacloprid, a newer compound related to acetamiprid, has achieved important market shares.

Tables 1 and 2 provide information concerning acetamiprid and its major alternatives. Table 1 provides common and trade names for the alternatives; Table 2 identifies the major alternatives by crop, and also gives maximum application rate and maximum number of application information.

Table 1. Acetamiprid and Alternative Pesticides: Common Names and Representative Trade Names

Common Name	Trade Name
Acetamiprid	ASSAIL™ and ADJUST™ brand 70WP Insecticide
OP Alternatives	
Acephate	Orthene 90S, Orthene 75S
Azinphos-methyl	Guthion Solupak
Chlorpyrifos	Lorsban 4E, Lorsban 50W
Diazinon	D-Z-N Diazinon 50W
Dicrotophos	Bidrin 8
Dimethoate	Dimethoate 4EC, Dimethoate 400
Ethion	Ethion 4 Miscible
Malathion	Malathion 5
Methamidophos	Monitor 4
Methyl Parathion	Penncap-M
Oxydemeton-methyl	Metasystox-R
Phosmet	Imidan 70W
Profenofos	Curacron 8E
Non-OP Alternatives	
Abamectin	Agri-mek 0.15 EC
Carbaryl	Sevin Brand XLR PLUS
Carbofuran	Furadan 4F
Cyfluthrin	Baythroid 2
Endosulfan	Phaser 50WSB
Esfenvalerate	Asana XL
Formetanate Hydrochloride	Carzol SP
Imidacloprid	Provado 1.6F, Admire 2F, Gaucho
Methomyl	Lannate SP
Permethrin	Ambush 25W

Table 2. Acetamiprid and Alternative Pesticides:
Maximum Application Rates by Crop (lbs ai/acre) and (Maximum Number of Applications per Season)

Active Ingredient	Cotton	Pome	Citrus	Grapes	Cole	Leafy Veg.	Fruit Veg.	Canola and Mustard Seed
Acetamiprid	0.1 (4)	0.15 (4)	0.075 (4), 0.25 (1)	0.05 (2)	0.075 (5)	0.075 (5)	0.075 (4)	0.027[1]
OP Alternatives								
Acephate	1.0 (6)					1.0 (5)		
Azinphos-methyl		1.5 (4)						
Chlorpyrifos	1.0 (6)	1.5 (8)	3.5 (2)		0.5 (10 est)			
Diazinon				2.0 (5)	0.5 (5)	0.5 (5)		
Dicrotophos	0.5 (3)							
Dimethoate	0.25 (6)		2.0 (2)	2.0 (6)	0.5 (6)	0.25 (6 est)	0.25 (6 est)	
Ethion			3.0 (3)					
Malathion	2.5 (6)							
Methamidophos							1.0 (5)	
Methyl Parathion	1.0 (6)							
Oxydemeton-methyl					0.75 (3)			
Phosmet		3.5 (6)						
Profenofos	0.5 (10 est.)							

Table 2. Acetamiprid and Alternative Pesticides:
Maximum Application Rates by Crop (lbs ai/acre) and (Maximum Number of Applications per Season) (cont.)

Active Ingredient	Cotton	Pome	Citrus	Grapes	Cole	Leafy Veg.	Fruit Veg.	Canola and Mustard Seed
Non-OP Alternatives								
Abamectin		0.023 (2)	0.023 (2)					
Carbaryl				2.0 (5)				
Carbofuran	0.25 (2)							
Cyfluthrin			0.025 (1)					
Endosulfan		1.0 (3)				1.5 (2)	1.0 (6)	
Esfenvalerate							0.05 (10)	
Formetanate Hydrochloride			1.4 (3)					
Imidacloprid	0.05 (6)	0.1 (5)		0.008 (2)	0.05 (5)	0.05 (10)	0.05 (5)	0.027[1]
Methomyl		0.9 (5)		0.9 (5)				
Permethrin					0.2 (5)	0.2 (10)		

[1] 5.0 g ai/kg seed which is equivalent to 0.027 lbs ai/acre based upon a seeding rate of 6 lbs seed/acre.

9. Summary of Human Health, Ecological Effects, and Environmental Fate Characteristics

Acetamiprid presents a low toxicity, low exposure, low risk profile. The uses covered by this reduced risk document meet all FQPA and FIFRA safety standards as will be demonstrated by the following discussion. The potential risks resulting from the use of acetamiprid are far less than the possible risks presented by alternative compounds.

a. Human Health

Acetamiprid has low mammalian toxicity. It is not oncogenic, and based on the weight of the evidence it is not mutagenic or genotoxic. It does not cause developmental or reproductive toxicity. It presents low neurotoxic potential, and does not have any cumulative effects such as ChE inhibition associated with the OP compounds. There is no indication of any effects on the endocrine system. There is no indication of any increased sensitivity of infants or children.

The two end-use products are Toxicity Category III requiring the use of the signal word "Caution".

Conservative risk assessments show that dietary exposure utilizes only a small portion of the RfD; 6% of the acute RfD and 0.5% of the chronic RfD for the most exposed subpopulations. Drinking water exposure to acetamiprid and its metabolites is projected to be extremely low, and therefore, is not of concern; especially when acetamiprid's toxicity profile is considered.

MOEs for applying the ASSAIL ™ acetamiprid product range from over 14,000 to over 526,000. Day 0 MOEs for re-entry workers range from over 1,500 to over 20,000; the REI for all uses will be 12 hours. For the ADJUST™ seed treatment product, worker MOEs range from 370 to 476.

b. Environmental Fate

A complete battery of environmental fate studies show that acetamiprid has a low environmental risk profile. The primary route of degradation is through microbial degradation. Acetamiprid degrades rapidly in the environment; the major soil metabolites degrade more slowly. Field soil dissipation studies show little potential for acetamiprid or its metabolites to leach into ground water.

c. Ecological Effects

The proposed uses of acetamiprid present minimal risk to non-target organisms including endangered species, and certainly present less risk than the alternatives.

Avian and mammalian risk assessments were performed using worst-case models. No Levels of Concern (LOC) are exceeded for the foliar or seed treatment uses of acetamiprid.

No LOCs are exceeded for freshwater organisms or marine fish. LOCs are exceeded for mysid shrimp; more refined modeling may reduce the Risk Quotients (RQs) below the LOC.

Acetamiprid is non- toxic to aquatic plants. For a few terrestrial plants, LOCs are exceeded for worst-case, channelized runoff scenarios.

Finally, acetamiprid is moderately toxic to honey bees when contacted by a foliar spray; however, there is no residual toxicity once sprays have dried. Acetamiprid is much less toxic to bees than imidacloprid and many of the other alternative pesticides.

10. Tier I Statement - Meeting FQPA Reduced Risk Criteria

As will be demonstrated by this reduced risk submission, the proposed uses of acetamiprid meet each of the four FQPA reduced risk criteria. Namely, acetamiprid:

- Reduces the risk of pesticides to human health;
- Reduces the risk of pesticides to non-target organisms;
- Reduces the potential for contamination of ground water, surface water, or other valued environmental resources; and
- Broadens the adoption of integrated pest management strategies, or makes such strategies more available or more effective.

11. Reduced Risk Statement

The market introduction of the two acetamiprid products, ASSAIL™ brand 70WP Insecticide, and ADJUST™ brand 70WP Insecticide Seed Treatment, will reduce exposure, will reduce risk, and will reduce pounds of pesticides used. The reduction in pesticide use will be accomplished, to a large extent, at the expense of the OP alternatives. Workers, consumers, non-target organisms, and the environment will benefit. In addition to the reduced risk benefits that will result from the use of acetamiprid in the United States, Rhône-Poulenc is also hopeful that a timely registration of acetamiprid in Canada will contribute to the reduction in the use of lindane as a canola and mustard seed treatment. Thus, a prompt joint review by US and Canadian regulatory authorities can achieve reduced risk in both countries. (Note that, in addition to

canola, Rhône-Poulenc is seeking a joint review for grapes, pome fruit, cole crops, and leafy and fruiting vegetables. Harmonization of tolerances will be a benefit for both countries). The reduced risk benefits that will be achieved in the US are discussed in more detail below.

a. Reduced Dietary and Drinking Water Risk

The acetamiprid products will compete against a variety of alternatives including OP and pyrethroid compounds. Acetamiprid has an excellent toxicity profile compared to the alternatives. Lower exposure (acetamiprid is efficacious at very low application rates) and fewer toxicity concerns translates to reduced dietary risk. Acetamiprid presents no drinking water risk. Acetamiprid will be used on foods that are typical risk drivers for children (e.g., apples, pears, grapes, and oranges). These foods and the current OP insecticides are of particular concern to the Agency. When methyl parathion use on apples, pears and grapes was voluntarily cancelled in August, growers were left with the basic option of switching to another OP compound. With acetamiprid, real reduced use of OPs on children's foods and real reduced risk can be achieved.

In some cases, dietary risk from individual OP compounds may be acceptable. However, the Agency appears to be moving toward a decision that most or all of the OPs share a common mechanism of toxicity. Thus, risk from cumulative use and exposure would be added together; almost guaranteeing that OP dietary exposure is excessive. Acetamiprid provides EPA and growers a different class of chemistry whose "risk cup" is dramatically less full compared to the current OP pesticides. For example, a conservative dietary risk assessment shows that only 6% of the acute Reference Dose (RfD) will be utilized by children from one to six years of age, the most exposed subpopulation.

b. Reduced Worker Exposure

Rhône-Poulenc has performed risk assessments for mixer-loaders, applicators, re-entry workers and seed company workers (who will treat canola and mustard seed with acetamiprid). MOEs for acetamiprid are well in excess of acceptable standards – in the hundreds for workers treating seed, in the thousands for re-entry workers based on estimated day 0 dislodgeable residues, and in the hundreds of thousands for other workers. This risk picture is quite different from the worker risk information being released by EPA as it conducts worker risk assessments in conjunction with the FQPA reassessment of the OPs – often the Agency concludes that MOEs for OP use are less than acceptable even when maximum worker protection measures are considered. Consider the alternatives. With acetamiprid, workers can re-enter apple orchards and perform hand labor in 12 hours, the minimum time period under current regulations. On the other hand, in the case of azinphos-methyl, for example, EPA has reported that risk estimates for reentry workers pose "serious risk concerns based on current application rates and REIs" (reentry intervals). The Agency has stated that the registrant is significantly increasing the REIs for a number of crops, but EPA still has serious risk concerns.

c. Reduced Ecological Risk

The low application rates for acetamiprid and relatively rapid environmental degradation combined with a favorable ecological toxicity profile means that non-target organisms will be faced with less exposure and less risk when growers use acetamiprid. A detailed ecological risk assessment was performed on a crop-by-crop basis to evaluate the potential ecological impact of acetamiprid compared to its alternatives. In summary, acetamiprid has substantially lower risk quotients (RQs) than the vast majority of competitor active ingredients for all crops. Acetamiprid has RQs approximately equal to imidacloprid except for bee toxicity; acetamiprid is much less toxic to honey bees than imidacloprid. RQ values for both compounds are well below EPA's levels of concern (LOCs) for all animal groups for all crops except for mysid shrimp. In contrast, the other active ingredients exceed LOCs for a variety of animal groups and uses by a large margin.

d. Reduced Environmental Burden and OP Replacement

The introduction of acetamiprid will result in a substantial reduction in the pounds of active ingredients placed in the environment each year. Acetamiprid's application rates are lower than most of the alternatives, particularly the OPs. Acetamiprid degrades rapidly, and fate data indicate that the compound is not likely to drift, run-off or leach. In the first year of use, Rhône-Poulenc estimates that slightly more than 76,000 pounds of acetamiprid will replace over 360,000 pounds of alternative active ingredients; almost 300,000 pounds of this total represents a reduction in OP use. In the fifth year of sales, slightly more than 226,000 pounds of acetamiprid will replace over 1,270,000 pounds of alternative pesticide active ingredients; over 1,000,000 pounds of this total consists of OP active ingredients. Cumulatively, a reduction of over 4,800,000 pounds of competitive active ingredients, including over 4,000,000 pounds of OP active ingredients will be achieved during the first five years of use. That total will be offset by the use of about 890,000 pounds of acetamiprid.

e. Compatible with Resistance Management and IPM Programs

Rhône-Poulenc has established a global resistance monitoring program for acetamiprid. The company has an ongoing, product stewardship program to work with growers in order to reduce the potential for resistance to develop. Acetamiprid offers growers the ability to use a low application rate of a low toxicity insecticide to achieve fast control of a wide spectrum of difficult to control pests. Acetamiprid is generally not a problem for beneficials. Acetamiprid also has been shown to have ovicidal activity allowing for more complete control and decreasing the potential for the development of resistant pest populations. In addition, acetamiprid has been shown to have ovicidal activity allowing for more complete control and thus, a decreased potential for the development of resistant insect populations. In short, it will work well in resistance management and integrated pest management (IPM) programs.

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Title

Reduced Risk and Organophosphate Replacement Rationale for Acetamiprid – Potato Use

Company Product Code

Ni-25

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Guideline Reference

EPA Pesticide Regulation Notice 97-3
Guidelines for Expedited Review of Conventional Pesticides Under the Reduced-Risk Initiative and for Biological Pesticides

Report No.

Acet-RR-01

Completed On

15 March 2003

Submitted By

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A. EXECUTIVE OVERVIEW

Nippon Soda Co. Ltd. (Nisso) is requesting expedited review under the Reduced-Risk Initiative for the use of Assail™ brand 70WP Insecticide on potatoes. Assail contains 70% acetamiprid as the single active ingredient.

Acetamiprid active ingredient and the formulated product, Assail Insecticide are currently registered on cotton, pome fruit, citrus, grape, leafy vegetables and cole crops and fruiting vegetables. Registration is pending as a seed treatment for canola and mustard seed. The petition for tolerances on potatoes has been submitted to the EPA.

Nisso requests an accelerated review of this acetamiprid submission for the following reasons:

- Acetamiprid was previously registered as a reduced risk product and is a strong reduced risk candidate for this use.

- Acetamiprid is a strong OP and carbamate replacement candidate. Over 580,000 pounds of cholinesterase inhibitor products (OP and carbamate active ingredients) will be replaced during the first five years of acetamiprid use in potatoes. In addition, thousands of pounds of potential carcinogenic compounds will be replaced by acetamiprid.

Acetamiprid is very effective against a number of key pests in potatoes, (e.g., aphids, Colorado potato beetles) and sweet potato (silverleaf whiteflies). The compound offers equal to superior efficacy at lower application rates than most of the alternative compounds. In addition, unlike competitive products, acetamiprid has ovicidal activity and has shown a broader spectrum of control, for example, lepidopteran, than other compounds in this class.

Acetamiprid is not oncogenic or a teratogenic. It has very low neurotoxic potential. Based on the weight of the evidence, acetamiprid is not mutagenic or genotoxic. It degrades rapidly in the environment, is unlikely to drift, run-off or leach, and presents a very positive ecological risk profile compared to all alternatives. Conservative risk assessments demonstrate little cause for concern. Risk assessments conducted by EPA show that acetamiprid meets the Food Quality Protection Act (FQPA) "reasonable certainty of no harm" standard, and the Federal Insecticide Fungicide and Rodenticide Act (FIFRA) no unreasonable risk standard. This stands in sharp contrast to many of the alternative insecticides.

The major alternative insecticides are OP (methamidophos and dimethoate) and carbamate (oxamyl and carbofuran) insecticides, as well as pyrethroids, other chloronicotinoids and pymetrozine. Imidacloprid is in the same chemical family as acetamiprid and has achieved important market shares in a number of areas. This indicates that there is a significant market for chloronicotinoids in potatoes in addition to other crops. Acetamiprid will primarily replace OPs and carbamates with lesser amounts of pyrethroids, other chloronicotinoids and pymetrozine.

From a human risk perspective, many of the alternatives tend to have lower No Observed Effect Levels (NOELs) than acetamiprid. The primary alternatives being replaced exhibit cholinesterase (ChE) inhibiting properties. The OPs present significant dietary and aggregate risk concerns. OPs are known to cause cumulative ChE inhibition in mammalian systems. Finally, the OPs and other alternatives, particularly the pyrethroids, raise significant ecological risk concerns. (While acetamiprid is very toxic to mysid shrimp, its overall ecological risk profile is far better than most of the alternatives).

In conclusion, this document demonstrates fully the reduced risk and OP replacement potential presented by acetamiprid. It will replace significant amounts of compounds with both human health and ecological risk concerns.

B. EXECUTIVE SUMMARY

1. Chemical Name

IUPAC: (E)-N^1-[(6-chloro-3-pyridyl)methyl]-N^2-cyano-N^1-methylacetamidine

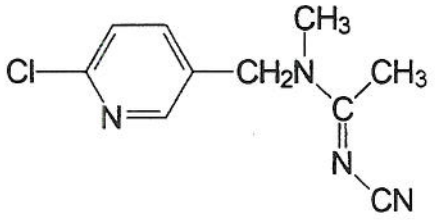
2. Common Name:

Acetamiprid

3. Chemical Abstract Service Registry Number:

135410-20-7

4. Chemical Structure:



5. Chemical Family:

Chloronicotinyl

6. Mode of Action of the Active Ingredient

Acetamiprid acts as an agonist of the nicotinic acetylcholine receptor (nACHR) of the postsynaptic membrane of nerve cells. The active ingredient interrupts the function of the insect nervous system. Biochemical radioligand binding studies show that acetamiprid interacts with high affinity at the insect nACHR binding site and with low affinity at the vertebrate nACHR. The differences in the affinities of acetamiprid at the insect and vertebrate nACHR may indicate that there are structural differences between insect and vertebrate nACHRs, and may account for acetamiprid's selective toxicity to insects.

7. Proposed Use Pattern

Assail™ brand 70WP Insecticide is a wettable powder formulation containing 70% acetamiprid as the single active ingredient. It will be labeled for the control of Colorado potato beetles and aphids in potatoes. The draft label for Assail is provided in Appendix 1.

8. Competitive Products

Insects can be highly destructive causing significant reductions in yield and quality that lead to substantial economic losses. Conventional pesticides are used, generally as part of an IPM program, to control the various insect pests that are problematic in potatoes. Older chemistry (the OPs, carbamates, pyrethroids) tend to dominate the market. Imidacloprid, a compound related to acetamiprid, has achieved important market shares.

Table 1 provides information concerning acetamiprid and its major alternatives. Active ingredients, trade names, producers and the major application parameters are shown.

Table 1: **Summary of Acetamiprid and the Major Competitive Insecticides Presently Registered for Insect Control in Potatoes in the U.S.**

Active Ingredient	Trade Name	Company	Maximum Single Application Rate (Lbs. A.I./A)	Maximum Number of Applications/ Season*	Maximum Seasonal Application Rate (Lbs. A.I./A)	Application Method(s)
Acetamiprid	**Assail™ 70WP**	Nisso	**0.075**	**4**	**0.30**	**Ground & aerial**
Carbofuran	Furadan® 4F	FMC	1.000	2	2.00	Ground & aerial
Cyfluthrin	Baythroid® 2	Bayer	0.044	6	0.263	Ground & aerial
Cyfluthrin and Imidacloprid	Leverage™ 2.7	Bayer	0.032	4	0.128	Ground & aerial
			0.047	4	0.188	Ground & aerial
Esfenvalerate	Asana® XL	DuPont	0.050	7	0.35	Ground & aerial
Imidacloprid	Provado® 1.6F	Bayer	0.047	4	0.188 (foliar)	Ground & aerial
Methamidophos	Monitor® 4	Bayer	1.000	4	4.00	Ground & aerial
Oxamyl	Vydate®	Dupont	1.000	6	6.00	Ground & aerial
Pymetrozine	Fulfill®	Syngenta	0.086	2	0.172	Ground & aerial
Permethrin	Ambush® 25WP	Amvac (formerly Syngenta)	0.200	8	1.60	Ground & aerial
Thiamethoxam	Actara™	Syngenta	0.047	1	0.047	Ground & aerial

* NS = Not specified

9. Summary of Human Health, Ecological Effects, and Environmental Fate Characteristics

Acetamiprid presents a low toxicity, low exposure, low risk profile. The use on potatoes covered by this reduced risk document meets all FQPA and FIFRA safety standards as will be demonstrated by the following discussion. The potential risks resulting from the use of acetamiprid are far less than the possible risks presented by alternative compounds.

9.1 Human Health

Acetamiprid has low mammalian toxicity. It is not oncogenic, and based on the weight of the evidence it is not mutagenic or genotoxic. It is not teratogenic. It presents low neurotoxic potential, and does not have any cumulative effects such as ChE inhibition associated with the OP and carbamates compounds.

The end-use product is Toxicity Category III requiring the use of the signal word "Caution".

A Tier 3 dietary risk assessment shows that dietary exposure utilizes only a small portion of the RfD/PAD; 15.4% of the acute RfD and 1.3% of the chronic PAD for the most exposed subpopulation. Drinking water exposure to acetamiprid is projected to be extremely low, consuming less than 2% of the aRfD and significantly less than 1% of the cPAD for the worst case scenario.

The MOEs for applying Assail acetamiprid product on potatoes are 1,162 for open-cab groundboom mix/load/application, 433 for enclosed-cab groundboom mix/load/application and for aerial mix/load, and 26,700 for pilots. The Day 0 MOE for re-entry workers is 1,050; the REI for the use on potatoes will be 12 hours.

9.2 Environmental Fate

A complete battery of environmental fate studies show that acetamiprid has a low environmental risk profile. The primary route of degradation is through microbial degradation. Field soil dissipation studies show little potential for acetamiprid or its metabolites to leach into ground water.

9.3 Ecological Effects

The proposed use of acetamiprid on potatoes presents low risk to non-target organisms including endangered species, and certainly presents less risk than most of the alternatives.

Avian and mammalian risk assessments were performed using worst-case models. No Levels of Concern (LOCs) are exceeded for the foliar use of acetamiprid on potatoes.

No LOCs are exceeded for freshwater organisms or marine fish. LOCs are slightly exceeded for mysid shrimp (RQ = 1.97) based in tier I modeling; more refined modeling is expected to reduce the Risk Quotients (RQs) below the LOC.

Acetamiprid use in potatoes poses negligible risk to aquatic plants. Most terrestrial plants are at minimal risk from acetamiprid. For a few terrestrial plants, LOCs are slightly exceeded for worst-case, channelized runoff scenarios.

Finally, acetamiprid is moderately toxic to honey bees when contacted by a foliar spray; however, there is no residual toxicity once sprays have dried. The duration of residual toxicity is less than 3 hours at rates above the rate proposed for potatoes. Acetamiprid is much less toxic to bees than all of the major alternative pesticides with the exception of pymetrozine.

10. Tier I Statement - Meeting FQPA Reduced Risk Criteria

As will be demonstrated by this reduced risk submission, the proposed use of acetamiprid on potatoes meets each of the four FQPA reduced risk criteria. Namely, acetamiprid:

- Reduces the risk of pesticides to human health;
- Reduces the risk of pesticides to non-target organisms;
- Reduces the potential for contamination of ground water, surface water, or other valued environmental resources; and
- Broadens the adoption of integrated pest management strategies, or makes such strategies more available or more effective.

11. Reduced Risk Statement

The market introduction of the acetamiprid product, Assail 70WP Insecticide, for use on potatoes will reduce exposure, will reduce risk, and will reduce pounds of pesticides used. The reduction in pesticide use will be accomplished, to a large extent, at the expense of the OP and carbamate alternatives. Workers, consumers, non-target organisms, and the environment will benefit. The reduced risk benefits that will be achieved in the US are discussed in more detail below.

11.1 Reduced Dietary and Drinking Water Risk

The acetamiprid product will compete against a variety of alternatives including OP and carbamates insecticides, other chloronicitinoids and pyrethroid compounds. Acetamiprid has an excellent toxicity profile compared to the alternatives. Low exposure (acetamiprid is efficacious at very low application rates) and fewer toxicity concerns translates to reduced dietary risk. Acetamiprid presents no significant drinking water risk.

The Agency has determined that the OPs share a common mechanism of toxicity. Thus, risk from cumulative use of OPs on potatoes and other crops (and resulting exposure) would be added together; resulting in a risk significantly higher than that for acetamiprid. Acetamiprid can provide potato growers with an alternative to OPs and carbamates and is

a compound whose "risk cup" is less full compared to the current OP and carbamate pesticides. For example, a conservative dietary risk assessment shows that only 15.4% of the aRfD and 1.3% of the cPAD will be utilized by the most exposed subpopulation. Drinking water exposure to acetamiprid is projected to be extremely low, consuming less than 2% of the aRfD and significantly less than 1% of the cPAD for the worst case scenario.

11.2 Reduced Worker Exposure

Risk assessments for mixer-loaders, applicators and re-entry workers have been preformed. MOEs for acetamiprid are well in excess of acceptable standards with the lowest MOEs well over 400. This risk picture is quite different from the worker risk information for OPs and carbamates which are cholinesterase inhibitors (CEIs). The Day 0 MOE for re-entry workers is 1,050; the REI for the use on potatoes will be 12 hours. The Agency has often concluded that MOEs for OP use are less than acceptable even when maximum worker protection measures are considered.

11.3 Reduced Ecological Risk

The low application rate for acetamiprid and relatively rapid environmental degradation to less toxic or practically non-toxic metabolites combined with a favorable ecotoxicity profile means that non-target organisms are much less likely to be impacted when potato growers use acetamiprid. A detailed ecological risk assessment was performed for the potato use to evaluate the potential ecological impact of acetamiprid compared to its alternatives. Only one chemical (pymetrozine) has a similar favourable profile. All the other competitors present a clearly higher risk than acetamiprid for at least one group of non-target organisms.

The RQs of acetamiprid for birds and wild mammals are below the LOCs, but are exceeded for a number of the competitors (carbofuran, methamidophos, oxamyl and permethrin). Acetamiprid is significantly less toxic to aquatic invertebrates than several competitors, particularly pyrethroids, making acetamiprid a desirable alternative to pyrethroids.

The moderate toxicity of acetamiprid to honeybees and the low risk posed by the proposed use in potatoes makes this product one of the safest among competitors in the market. Eight of the nine insecticides included in the analysis are highly toxic to bees and their use in potatoes presents a potential risk of mortality based in a theoretical hazard quotient. In comparison with imidacloprid and thiomethoxam, the other two chemicals of the family class of chloronicotinoids, acetamiprid clearly has safer bee profile.

11.4 Reduced Environmental Burden and OP Replacement

The introduction of acetamiprid will result in a substantial reduction in the pounds of active ingredients placed in the environment each year. Acetamiprid's application rates are lower than many of the alternatives, including the OP and carbamate as well as one of the

pyrethroids. Acetamiprid degrades rapidly, and fate data indicate that the compound is not likely to drift, run-off or leach. In the first five years of use, Nisso estimates that over 500,000 pounds of alternative active ingredients will be reduced; 376,000 pounds of this total represents a reduction in OP use and over 130,000 lbs of this total represents carbamate use.

11.5 Compatible with Resistance Management and IPM Programs

Nisso supports resistance management concepts as a means to preserve the chloronicotinyl class of chemistry for long-term insecticidal use. Label information and product stewardship education efforts will strive to ensure that growers follow the guidance given them.

Because resistance to imidacloprid by both Colorado potato beetle and green peach aphid has developed in some populations, the introduction of another chloronicotinyl, acetamiprid, may result in some cross resistance unless adequate safeguards are instituted. An alternate strategy of making foliar applications to discrete generations and rotating chemistry can reduce the ability of a population to adapt and therefore extend the usefulness of pesticides such as chloronicotinyls.

12. Data Matrix

A data matrix identifying the data submitted in support of the applications to register acetamiprid and establish tolerances is provided in a separate addendum (Appendix 2).

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
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DATA MATRIX

Date 4-14-09	EPA Reg No./File Symbol 8033-20	Page 1 of 19
Applicant's/Registrant's Name & Address Nippon Soda Co., Ltd. c/o Nisso America Inc., 45 Broadway, Suite 2120, New York, NY 10006	Product Acetamiprid Technical	

Ingredient acetamiprid

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
N/A	Crop Reduced Risk Package/OP Replacement	44988401	Aventis transferred to Nippon Soda	OWN	
N/A	Ornamental Reduced Risk Package/OP Replacement	44988402	Aventis transferred to Nippon Soda	OWN	
N/A	Tuberous and Corm Vegetable Reduced Risk Package / OP Replacement	45900501	Nippon Soda	OWN	
N/A	Potato Market Analysis Data	45900502	Nippon Soda	OWN	
N/A	Potato Efficacy and Comparative Performance Data	45900503	Nippon Soda	OWN	
N/A	Tier II and Tier III OECD Summary Documents	44988403	Aventis transferred to Nippon Soda	OWN	
N/A	Novigen Dietary Exposure and Risk Assessment for Acetamiprid Project Identification: Acetamiprid 99-01	44988404	Aventis transferred to Nippon Soda	OWN	
N/A	Exponent Dietary Exposure and Risk Assessment including Potato Use	45900504	Nippon Soda	OWN	
N/A	Assessment of the Non-Dietary Exposure to Acetamiprid From Use on Agricultural Crops and Outdoor Residential Sites. August 27, 1999.	45039701	Aventis transferred to Nippon Soda	OWN	
N/A	Dietary and Aggregate Exposure and Risk Assessments for Acetamiprid; ACETAMIPRID 04-01	46255601	Nippon Soda	OWN	
N/A	Exposure Estimates and Risk Assessment for Acetamiprid. August 30, 1999	44988405	Aventis transferred to Nippon Soda	OWN	
N/A	Assessment of Handler Exposure Resulting from the commercial Application of Acetamiprid to Canola and Mustard Seed, May 8, 2002	45673401	Aventis transferred to Nippon Soda	OWN	
N/A	Assessment of the Non-Dietary Exposure to Acetamiprid From Use on Potatoes and Tobacco	45900505	Nippon Soda	OWN	
N/A	Dietary and Aggregate Exposure and Risk Assessments for Acetamiprid ; Acetamiprid 06-01	46785501	Nippon Soda	OWN	
N/A	Petition for Tolerance Establishment	Admin.	Aventis transferred to Nippon Soda	OWN	
N/A	Petition for Potato Tolerance Establishment	Admin.	Nippon Soda	OWN	

Signature John J Wunderl

Date 4-14-09

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

DATA MATRIX

Date 4-14-09	EPA Reg No./File Symbol 8033-20	Page 2 of 19
Applicant's/Registrant's Name & Address Nippon Soda Co., Ltd. c/o Nisso America Inc., 45 Broadway, Suite 2120, New York, NY 10006	Product Acetamiprid Technical	

Ingredient acetamiprid

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
N/A	Petition for Stone Fruit / Cucurbit / Tree Nut Tolerances	Admin.	Nippon Soda	OWN	
N/A	Petition for Berry / Bulb Vegetable / Succulent Legume Tolerances	Admin.	Nippon Soda	OWN	
N/A	Petition for Food Handling Establishment Tolerance	Admin.	Nippon Soda	OWN	
N/A	Petition for Clover Tolerance and Higher Grape Tolerance	Admin.	IR-4		
61	Product Identity and Composition NPTL 3-9801	44651803	Aventis transferred to Nippon Soda	OWN	
	10/20/00 Responses to 9/20/00 Letter of Deficiency Review from US EPA and Canadian PMRA	45245300	Aventis transferred to Nippon Soda	OWN	
62-1 (830.1700) 62-2 (830.1750) 62-3 (830.1800	Preliminary analysis, Certified Limits, Analytical methods Lab No. 2-9404	44651804	Aventis transferred to Nippon Soda	OWN	
62-3 (830.1800)	Validation of Analytical Methods for Active ingredient Project No. 29608	44651805	Aventis transferred to Nippon Soda	OWN	
62-3 (830.1800)	Analytical Methods for Impurities by HPLC Project No. 2-9503	44651806	Aventis transferred to Nippon Soda	OWN	
63-2 (830.6302) 63-3 (830.6303) 63-4 (830.6304)	Color, Physical State and Odor of Technical Grade Active Ingredient and Analytical Standard Project No. 2-9619	44651807	Aventis transferred to Nippon Soda	OWN	
63-5 (830.7200)	Melting Point Project No. 2-9406	44651808	Aventis transferred to Nippon Soda	OWN	
63- 7 (830.7300)	Specific Gravity for Acetamiprid Project No. 2-9407	44651809	Aventis transferred to Nippon Soda	OWN	
63-8 (unassigned)	Solubility in Organic Solvents Study No. 2-83	44651810	Aventis transferred to Nippon Soda	OWN	
63-8 (830.7840)	NI-25 Solubility in Water Study No. 2-81	44651811	Aventis transferred to Nippon Soda	OWN	
63-9 (830.7950	Vapor Pressure Study No. 2-79	44651812	Aventis transferred to Nippon Soda	OWN	
63-10 (830.7370)	NI-25 Dissociation Constant in Water (pKa) Study No. 2-88	44651813	Aventis transferred to Nippon Soda	OWN	
63-10 (830.7370)	Dissociation Constant of IM-1-5; NCAS 02-132	46255602	Nippon Soda	OWN	
63-11 (830.7550)	Octanol/Water Partition Coefficient Study No. 2-84	44651814	Aventis transferred to Nippon Soda	OWN	

Signature John J Wimbel

Date 4-14-09

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

DATA MATRIX

Date 4-14-09	EPA Reg No./File Symbol 8033-20	Page 3 of 19
Applicant's/Registrant's Name & Address Nippon Soda Co., Ltd. c/o Nisso America Inc., 45 Broadway, Suite 2120, New York, NY 10006	Product Acetamiprid Technical	

Ingredient acetamiprid

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
63-12 (830.7000)	pH of Aqueous Suspension of acetamiprid Lab No. 2-9621	44651815	Aventis transferred to Nippon Soda	OWN	
63-13 830.6313)	Stability of Acetamiprid Project No. 2-9618	44651816	Aventis transferred to Nippon Soda	OWN	
63-15 (830.6315) 63-16 (830.6316)	Acetamiprid Physio-Chemical Properties Surface Tension, Flammability Explosive Properties and Relative Self-Ignition Project No. NOD-005	44651817	Aventis transferred to Nippon Soda	OWN	
None (830.7050)	Spectra (UVNIS, IR, NMR, MS) ofNI-25 Project No. 2-9713	44651818	Aventis transferred to Nippon Soda	OWN	
71-1 (850.2100)	NI-25 Acute Oral Toxicity (LD50) to the Mallard Duck (technical) Nisso No. 62932516	44651859	Aventis transferred to Nippon Soda	OWN	
71-2 (850.2200)	NI-25 Subacute Dietary Toxicity (LC50) to Bobwhite Quail (technical) Nisso No. RD 9436N	44651860	Aventis transferred to Nippon Soda	OWN	
71-2 (850.2200)	NI-25 Subacute Dietary Toxicity (LC 50) to Mallard Ducks HRC NPS60942075	44651861	Aventis transferred to Nippon Soda	OWN	
71-2 (850.2200)	5-Day Dietary Toxicity Test with IM-I-4 Metabolite in the Mallard Duck EBA No. 019803	44651862	Aventis transferred to Nippon Soda	OWN	
71-4 (850.2300)	Reproduction study in Bobwhite Quail EBA No. 029604	44988407	Aventis transferred to Nippon Soda	OWN	
71-4 (850.2300)	Reproduction Study with Acetamiprid in Mallard Ducks Study No. 029708	44988408	Aventis transferred to Nippon Soda	OWN	
71-4 (850.2300)	Reply to EPA Data Evaluation Record (DER) for a Northern Bobwhite Reproduction Study with Acetamiprid (MRID 44988407)	46014801	Nippon Soda	OWN	
71-4 (850.2300)	Acetamiprid (NI-25) – Reproductive Toxicity Test with Mallard Duck (Anas platyrhynchos); Lab ID 13798.4105	46369201	Nippon Soda	OWN	
71-4 (850.2300)	Acetamiprid: A Reproduction Study with the Northern Bobwhite, Report No. 437-104	46555601	Nippon Soda	OWN	
71-4 (850.2300)	Response to EPA DER for Acetamiprid (NI-25) Reproductive Toxicity Test with Mallard Duck (Anas platyrhynchos); MRID 46369201, Report No. NAI 05-001	46717701	Nippon Soda	OWN	
72-1 (850.1075)	Acetamiprid Acute Toxicity (96 hour) to Bluegill (Lepomis macrochirus) Under Flow-Through conditions SA. 96120	44651863	Aventis transferred to Nippon Soda	OWN	

Signature John J Wunbel

Date 4-14-09

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

DATA MATRIX

Date 4-14-09	EPA Reg No./File Symbol 8033-20	Page 4 of 19
Applicant's/Registrant's Name & Address Nippon Soda Co., Ltd. c/o Nisso America Inc., 45 Broadway, Suite 2120, New York, NY 10006	Product Acetamiprid Technical	

Ingredient acetamiprid

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
72-1 (850.1075)	Acute Toxicity Study in Rainbow Trout Under Semi-Static Conditions Project No. HO88	44651864	Aventis transferred to Nippon Soda	OWN	
72-1 (850.1075)	IM-I-4 Acute Toxicity to Rainbow Trout Under Semi-Static Conditions SANo.97231	44651865	Aventis transferred to Nippon Soda	OWN	
72-2 (850.1010	Acute Toxicity Study in Daphnids Nisso No. H-I00	44651866	Aventis transferred to Nippon Soda	OWN	
72-2 (850.1010)	IM-1-2 Metabolite Acute Toxicity (48 hour) to Daphnids SA No.97046	44651867	Aventis transferred to Nippon Soda	OWN	
72-2 (850.1010)	IM-1-4 Acute Toxicity (48 hour) to Daphnids SA 97047	44651868	Aventis transferred to Nippon Soda	OWN	
72-2 (850.1010)	IC-O Metabolite Acute Toxicity to Daphnids under Semi-Static Conditions SA No. 97045	44988409	Aventis transferred to Nippon Soda	OWN	
72-2 (850.1010)	IM-1-5 (N^1-[(6-chloro-3-pyridyl)methyl]-N^1-methylacetamidine): Acute toxicity to Daphnia magna; NCAS 02-197	46255608	Nippon Soda	OWN	
(850.1020)	Acetamiprid Technical: Acute Toxicity to Gammarids (Gammarus faciatus) Under Static Conditions	45932501	Nippon Soda	OWN	
72-2	Acetamiprid Technical: Acute Toxicity to Midge (Chironomus riparius) Under Static Conditions	45916201	Nippon Soda	OWN	
72-2	IM-1-5 Acute Toxicity to Midge (Chironomus riparius) Under Static Conditions; 13798.6111	46255610	Nippon Soda	OWN	
72-3 (850.1035)	Acetamiprid Technical Acute Toxicity to Mysids Under Flow-Through Conditions SLI 97-9-7100	44651869	Aventis transferred to Nippon Soda	OWN	
72-3 (850.1035)	IM 1-4 Acute Toxicity to Mysids Under Static Conditions SLI No. 98-3-7276	44651870	Aventis transferred to Nippon Soda	OWN	
72-3 (850.1025)	Acetamiprid Acute Toxicity to Eastern Oyster under Flow through Conditions SLI No. 97-10-7105	44988410	Aventis transferred to Nippon Soda	OWN	
72-3 (850.1075)	Acetamiprid Acute Toxicity to Sheepshead Minnows Under Flow-Through Conditions SLI No. 97-10-7104	44988411	Aventis transferred to Nippon Soda	OWN	

Signature John J. Wimbel

Date 4-14-09

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

DATA MATRIX

Date 4-14-09	EPA Reg No./File Symbol 8033-20	Page 5 of 19
Applicant's/Registrant's Name & Address Nippon Soda Co., Ltd. c/o Nisso America Inc., 45 Broadway, Suite 2120, New York, NY 10006	Product Acetamiprid Technical	

Ingredient acetamiprid

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
72-4 (850.1300)	Acetamiprid Daphnia magna Life Cycle (21 day) Static Chronic Toxicity Study SA No.96122	44651871	Aventis transferred to Nippon Soda	OWN	
72-4 (850.1300)	IM-1-5 Full Life-Cycle Toxicity Test with Water Fleas, Daphnia magna, Under Static Renewal Conditions; 13798.6112	46255609	Nippon Soda	OWN	
72-4 (850.1400)	Acetamiprid Early life Stage Toxicity Test to Fathead Minnow SA No.96123	44651872	Aventis transferred to Nippon Soda	OWN	
72-4 (850.1400)	Response to Data Evaluation Report on the Toxicity of Acetamiprid (NI-25) to Fathead Minnow (Pimephales promelas), Fish Early Life Cycle (MRID 44651872); NAI 06-002	46729101	Nippon Soda	OWN	
72-4 (850.1350)	Acetamiprid Technical Chronic Toxicity to Mysids Under Flow-Through Conditions SLI No.98-2- 7230	44651873	Aventis transferred to Nippon Soda	OWN	
Canadian Data Requirement	Earth Worm Evaluation NPS No. 63	44988412	Aventis transferred to Nippon Soda	OWN	
No Guideline Number	Acetamiprid: Comments on the Results of PMRA Review for the Acute Earthworm Study (MRID 44988412); NAI 06-001	46729103	Nippon Soda	OWN	
No Guideline Number	IM-1-5 Acute Toxicity to the Earthworm; NOD 217	46255613	Nippon Soda	OWN	
No Guideline Number	Effects of IM-1-5 on Reproduction and Growth of Earthworms Eisenia fetida in Artificial Soil; 15723022	46255614	Nippon Soda	OWN	
122-1 (850.4100)(850.4150) and 123-1 (850.4250) (850.4225)	Determination of Effects on Seedling Emergence and Vegetative Vigor of Ten Plant Species SLI No. 97-12-7184	44988413	Aventis transferred to Nippon Soda	OWN	
122-1 (850-4150) and 123-1 (850-4250)	Acetamiprid – Determination of Effects on Vegetative Vigor of Lettuce (*Lactuca sativa*)	45921401	Nippon Soda	OWN	
122-2 (850.5400)	Acetamiprid Toxicity To Fresh Water Green Algae SLI No. 97-5-6987	44988414	Aventis transferred to Nippon Soda	OWN	
122-2 (850.4440)	Acetamiprid Toxicity To Duckweed SLI No. 97-7-7029	44918415	Aventis transferred to Nippon Soda	OWN	
122-2 (850.5400)	Acetamiprid Toxicity To Freshwater Blue-Green Alga SLI 97-6-7008	44988416	Aventis transferred to Nippon Soda	OWN	

Signature John J Wimbel		Date 4-14-09

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

DATA MATRIX

Date 4-14-09	EPA Reg No./File Symbol 8033-20	Page 6 of 19
Applicant's/Registrant's Name & Address Nippon Soda Co., Ltd. c/o Nisso America Inc., 45 Broadway, Suite 2120, New York, NY 10006	Product Acetamiprid Technical	

Ingredient acetamiprid

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
122-2 (850.5400)	Acetamiprid Toxicity To Fresh Water Diatom SLI No. 97-6-7005	44988417	Aventis transferred to Nippon Soda	OWN	
122-2 (850.5400)	Acetamiprid Toxicity To Marine Diatom SLI No.97-6-7028	44988418	Aventis transferred to Nippon Soda	OWN	
Special Study	Acetamiprid: Pharmacological Studies in Experimental Animals No.G-0832	44988419	Aventis transferred to Nippon Soda	OWN	
81-1 (870.1100)	Acetamiprid Acute Oral Toxicity Study in Rats. (technical) No.G0820	44651833	Aventis transferred to Nippon Soda	OWN	
81-1 (870.1100)	Acetamiprid Suspended in Corn Oil: Acute Oral Toxicity Study in Rats; H221	46255620	Nippon Soda	OWN	
81-1 (870.1100)	IC-O Metabolite Acute Oral Toxicity Study in Rats No.G-0941	44988420	Aventis transferred to Nippon Soda	OWN	
81-1 (870.1100)	IM-O Metabolite Acute Oral Toxicity Study In Rats No. G-0887	44988421	Aventis transferred to Nippon Soda	OWN	
81-1 (870.1100)	IM 1-2 Metabolite Acute Oral Toxicity Study in Rats Nisso No. G963	44651835	Aventis transferred to Nippon Soda	OWN	
81-1 (870.1100)	IM 2-1 Metabolite Acute Oral Toxicity Study in Rats Nisso No. G0931	44988422	Aventis transferred to Nippon Soda	OWN	
81-1 (870.1100)	IM-1-4 Metabolite Acute Oral Toxicity Study in Rats Covance No. 6840-103	44651834	Aventis transferred to Nippon Soda	OWN	
81-1 (870.1100)	IM-1-5: Acute Oral Toxicity Study in Rats; H220	46255621	Nippon Soda	OWN	
81-2 (870.1200)	Acetamiprid Acute Dermal Toxicity Study in Rats (technical) Nisso No. G0882	44651836	Aventis transferred to Nippon Soda	OWN	
81-2 (870.1200)	IM- 1-4 Metabolite Acute Dermal Study in Rats Covance No.6840-104	44988423	Aventis transferred to Nippon Soda	OWN	
81-3 (870.1300)	Acetamiprid Acute (four hour) Inhalation Study in Rats (technical) Nisso NODNo.4970598	44651837	Aventis transferred to Nippon Soda	OWN	
81-4 (870.2400)	Acetamiprid Primary eye irritation study in Rabbits (technical) Nisso No. G-0826	44651838	Aventis transferred to Nippon Soda	OWN	
81-5 (870.2500)	Acetamiprid-Primary Dermal Irritation Study in Rabbits (technical) Nisso No. G-0827	44651839	Aventis transferred to Nippon Soda	OWN	

Signature John J Wrubel		Date 4-14-09

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

DATA MATRIX

Date 4-14-09	EPA Reg No./File Symbol 8033-20	Page 7 of 19
Applicant's/Registrant's Name & Address Nippon Soda Co., Ltd. c/o Nisso America Inc., 45 Broadway, Suite 2120, New York, NY 10006	Product Acetamiprid Technical	

Ingredient acetamiprid

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
81-6 (870.2600)	Skin Sensitization in the Guinea-Pig (technical) Nisso NODNo.008973169SS	44651840	Aventis transferred to Nippon Soda	OWN	
81-8 (870.6200)	Dose Range Finding Neurotoxicity to Rats by Acute Oral Administration RPN No.510970145	44651841	Aventis transferred to Nippon Soda	OWN	
81-8 (870.6200)	Neurotoxicity to Rats by Acute Oral Administration RPN 509970851	44651842	Aventis transferred to Nippon Soda	OWN	
82-1 (870.3150)	A Subchronic (3-month) Oral Toxicity Study of NI-25 in the Dog Via Dietary Administration. Study Number 91-3727	44988424	Aventis transferred to Nippon Soda	OWN	
	"NI-25 - 4 Week Oral Toxicity related to MRID # 44988424 and 44651846 Study in the Dog Dietary Administration"	45245306	Aventis transferred to Nippon Soda	OWN	
82-1 (870.3100)	Acetamiprid 13 Week Dietary Sub chronic Toxicity Study in Mice Project No. G-0769	44988425	Aventis transferred to Nippon Soda	OWN	
82-1 (870.3100)	Acetamiprid Thirteen Week Dietary Subchronic Toxicity to Rats Nisso No. G-0768	44651843	Aventis transferred to Nippon Soda	OWN	
82-1 (870.3100)	IM-1-4 Metabolite Sub chronic Toxicity Study in Rats Covance No. 6840-102	44988426	Aventis transferred to Nippon Soda	OWN	
82-1 (870.3100)	IM-O Metabolite Thirteen Week Dietary Subchronic toxicity Study in Rats Nisso No. G-0889	44988427	Aventis transferred to Nippon Soda	OWN	
82-2 (870.3200)	21 Day Dermal Toxicity Study in Rabbits with Acetamiprid (technical) Covance No. 6224-236	44651844	Aventis transferred to Nippon Soda	OWN	
82-5 (870.6200)	Acetamiprid Neurotoxicity to Rats by Dietary Administration for 13 weeks RPN511971179	44651845	Aventis transferred to Nippon Soda	OWN	
870.6300	An Oral Developmental Neurotoxicity Study of Acetamiprid in Rats; WIL-21193	46255619	Nippon Soda	OWN	
Supplement to 82-5 (870.6200)	Supplemental Statistical Analysis and Historical Background Data for the Report Titled" Acetamiprid - Neurotoxicity to Rats by Dietary Administration for 13 Weeks (MRID # 44651845)"	45130801	Aventis transferred to Nippon Soda	OWN	

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Date 4-14-09

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

DATA MATRIX

Date 4-14-09	EPA Reg No./File Symbol 8033-20	Page 8 of 19
Applicant's/Registrant's Name & Address Nippon Soda Co., Ltd. c/o Nisso America Inc., 45 Broadway, Suite 2120, New York, NY 10006	Product Acetamiprid Technical	

Ingredient acetamiprid

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
870.6300	Rebuttal of Data Evaluation Record for Acetamiprid (WIL No. 21193, EPA Acetamiprid 099050, MRID 46255619); Report No. NAI 06-004	46779201	Nippon Soda	OWN	
870.6300	A Dose Range-Finding Study for a Developmental Neurotoxicity Study of Acetamiprid in Rats; Report No. WIL-21192	46779202	Nippon Soda	OWN	
Supplement to 870.6300	Validation of Developmental Neurotoxicity Endpints in Rats Administered Methimazole in Drinking Water; Report No. WIL-99199	46779203	Nippon Soda		
Supplement to 870.6300	A Validation Study for Developmental Neurotoxicity Endpoints at WIL Research Laboratories, Inc.: Effect of Propylthiouracil (PTU) on Developmentat Neurotoxicity Enpoints in Crl:CD(SD)IGS BR Rats (WIL-99126); Report No. WIL-99126	46779204	Nippon Soda		
870.6300	Acetamiprid DNT study: Response to EPA CEB statistical analysis, Report No. WD0771.000 E0T0	47237401	Nippon Soda	OWN	
83-1 (870.4100)	A Chronic (12-Month) Oral Toxicity Study ofNI-25 in the Dog Via Dietary Administration Pharmaco No. 92-3-117	44651846	Aventis transferred to Nippon Soda	OWN	
	"NI-25 - 4 Week Oral Toxicity Study in the Dog Dietary Administration" related to MRID # 44988424 and 44651846	45245306	Aventis transferred to Nippon Soda	OWN	
83-2 (870.4200)	18-Month Dietary Oncogenicity Study in Mice. Laboratory Project Identification 449-016	44988428	Aventis transferred to Nippon Soda	OWN	
	"Supplemental Historical Background Data" *10/16/00* as Supplemental Report to MRID # 44988428	45245305	Aventis transferred to Nippon Soda	OWN	
83-3 (870.3700)	Acetamiprid Teratogenicity Study in Rats Nisso No. G0829	44651847	Aventis transferred to Nippon Soda	OWN	
	"Litter-based Incidence *10/16/00* as Supplemental Report to MRID # 44651847of Fetal Observations and Historical Control Data"	45245302	Aventis transferred to Nippon Soda	OWN	

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Date 4-14-09

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

DATA MATRIX

Date 4-14-09	EPA Reg No./File Symbol 8033-20	Page 9 of 19
Applicant's/Registrant's Name & Address Nippon Soda Co., Ltd. c/o Nisso America Inc., 45 Broadway, Suite 2120, New York, NY 10006	Product Acetamiprid Technical	

Ingredient acetamiprid

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
83-3 (870.3700)	Acetamiprid Teratogenicity Study in Rabbits Nisso No. G0830	44651848	Aventis transferred to Nippon Soda	OWN	
	"Litter-based Incidence of Fetal Observations and Historical Control Data"*10/16/00* as Supplemental Report to MRID # 44651848	45245303	Aventis transferred to Nippon Soda	OWN	
83-4 (870.3800)	Two-Generation Reproduction Study with NI-25 in Rats.(Reproduction and Fertility Effects) Covance Report Number 6840-108	44988430	Aventis transferred to Nippon Soda	OWN	
83-4 (870.3800)	"Mean Pup Weights Per Litter (Male and Female Combined)" 10/16/00 as Supplemental Report to MRID # 44988430	45245301	Aventis transferred to Nippon Soda	OWN	
83-5 (870.4300)	Two Year Dietary Toxicity and Oncogenicity Study in Rats. Study Number449-015	44988429	Aventis transferred to Nippon Soda	OWN	
	"Supplemental Historical Background Data" 10/20/00 as Supplemental Report to MRID # 44988429	45245304	Aventis transferred to Nippon Soda	OWN	
	Supplemental Information: Biological and Statistical Analysis of Mammary Gland Findings in the Chronic Rat Study on Acetamiprid (MRID # 44988429)	45532301	Aventis transferred to Nippon Soda	OWN	
	Supplemental Information: Supplemental Historical Control Data for the Chronic Rat Study on Acetamiprid (MRID # 44988429)	45532302	Aventis transferred to Nippon Soda	OWN	
84-2 (870.5100)	Acetamiprid Reverse Mutation Study on Bacteria (Technical) Nisso No. G0831	44651849	Aventis transferred to Nippon Soda	OWN	
84-2 (870.5100)	IM-1-2 Metabolite Reverse Mutation Study on Bacteria Nisso No. G-964	44651850	Aventis transferred to Nippon Soda	OWN	
84-2 (870.5100)	IM 1-4 Metabolite Reverse Mutation Study on Bacteria No. G-940	44651851	Aventis transferred to Nippon Soda	OWN	

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Form Approved OMB No. 2070-0060

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DATA MATRIX

Date 4-14-09	EPA Reg No./File Symbol 8033-20	Page 10 of 19
Applicant's/Registrant's Name & Address Nippon Soda Co., Ltd. c/o Nisso America Inc., 45 Broadway, Suite 2120, New York, NY 10006	Product : Acetamiprid Technical	

Ingredient acetamiprid

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
84-2 (870.5385	Mutagenicity Test on NI-25 in an In Vivo Mouse Micronucleus Assay Covance No.159010455	44651852	Aventis transferred to Nippon Soda	OWN	
84-2 (870.5550)	Unscheduled DNA Synthesis (UDS) Test with Mammalian Liver Cell in Vivo with technical acetamiprid G97 AG26.381	44651853	Aventis transferred to Nippon Soda	OWN	
84-2 (870.5385)	Metaphase Analysis in the Rat Bone Marrow In Vivo with technical Acetamiprid Nisso No. 235017R2	44651854	Aventis transferred to Nippon Soda	OWN	
84-2 (870.5375)	Acetamiprid Chromosomal Aberration Study in Chinese Hampster Ovary(CHO) Cell Nisso No. G0800	44651855	Aventis transferred to Nippon Soda	OWN	
84-2 (870.5550)	Genotoxicity Test on NI-25 in the Assay of Unscheduled DNA Synthesis in Rat Liver Primary Cell Cultures with a Confirmatory Assay Covance No. 5901044R	44651856	Aventis transferred to Nippon Soda	OWN	
84-2 (870.5300)	Acetamiprid Mammalian Cell Mutagenicity Assav NOD No.006971139	44561857	Aventis transferred to Nippon Soda	OWN	
84-2 (870.5300)	IM 1-4 Metabolite CHO/HGPRT Forward Mutation AssavyNo.6840-106	44988431	Aventis transferred to Nippon Soda	OWN	
84-2 (870.5100)	IM -0 Metabolite Reverse Mutation Study in Bacteria Nisso No. G949	44988432	Aventis transferred to Nippon Soda	OWN	
84-2 (870.5100)	IM-2-1 Metabolite Reverse Mutation Study in Bacteria Nisso No. G-932	44988433	Aventis transferred to Nippon Soda	OWN	
84-2 (870.5385)	IM 1-4 Metabolite In Vivo Mouse Micronucleus Assay Covance No. 18981-0-455	44988501	Aventis transferred to Nippon Soda	OWN	
84-2 870.5100)	IC-O Metabolite Reverse Mutation Study in Bacteria Nisso No. G942	44988502	Aventis transferred to Nippon Soda	OWN	
85-1 (870.7485)	C-14 Acetamiprid Metabolism Study in Rats (Summary Report) NCASNo.EC-912	44988503	Aventis transferred to Nippon Soda	OWN	
85-1 (870.7485)	C-14 Acetamiprid Study in Rats (Qualitative and Quantitative Analysis of Metabolites in Group C NCAS EC No.95-108	44988504	Aventis transferred to Nippon Soda	OWN	
85-1 (870.7485)	C-14 Acetamiprid Metabolism Study in Rats NCAS 2-94 EC-724	44988505	Aventis transferred to Nippon Soda	OWN	
85-1 (870.7485)	Adsorption, Distribution, Metabolism Elimination and Pharmacokinetics After Chronic Dosing of 14-C Acetamiprid in Rats Study No.42207	44988506	Aventis transferred to Nippon Soda	OWN	

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DATA MATRIX

Date 4-14-09	EPA Reg No./File Symbol 8033-20	Page 11 of 19
Applicant's/Registrant's Name & Address Nippon Soda Co., Ltd. c/o Nisso America Inc., 45 Broadway, Suite 2120, New York, NY 10006	Product Acetamiprid Technical	

Ingredient acetamiprid

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
85-1 (870.7485)	C-14 Acetamiprid Biliarv Excretion in Rats Study No. 42206	44988507	Aventis transferred to Nippon Soda	OWN	
No Guideline Number	Metabolism Study of Acetamiprid in Rat (Determination of IM-1-5); NSM02-024	46255622	Nippon Soda	OWN	
85-3 (870.7600)	Dermal Adsorption of 14-C NI-25 in Male Rats (Primary and Definitive Phases) Covance No.6224234	44651858	Aventis transferred to Nippon Soda	OWN	
141-1 (850.3020)	Laboratory Oral and Contact Toxicity Test with Honeybees Springborn No.96-045-1013	44651874	Aventis transferred to Nippon Soda	OWN	
141-2 (850.3030)	Evaluation of Toxicity of Residues of Acetamiprid (NI-25) on Alfalfa to Honey Bees SLINo.98-1-7214	44651875	Aventis transferred to Nippon Soda	OWN	
141-2 (850.3030)	Evaluation of Toxicity of Residues of Acetamiprid (NI-25) and Procure 50WS on Alfalfa to Honev Bees (Apis mellifera)	45346901	Aventis transferred to Nippon Soda	OWN	
No Guideline Number	Acetamiprid: Toxicity of Foliar Residue to Honey Bees – Response to US EPA Regarding the Review of MRID 44651875	45932502	Nippon Soda	OWN	
No Guideline Number	Acute Contact and Oral Toxicity of EXP 60707A to the Bumble-bee [Bombus terrestris L.] Under Laboratory Conditions	45932503	Nippon Soda	OWN	
No Guideline Number	A Semi-Field Study on the Effects on Honey Bees (Apis mellifera L.) of ASSAIL 70 WP (EXP 61842A, Acetamiprid 70%) Straight and in Combination with the Fungicide PROCURE 50WS (Triflumizole 50%)	45932504	Nippon Soda	OWN	
No Guideline Number	A Semi-Field Study on the Effects of a Foliar Application of EXP 60707A (Acetamiprid 20% SP) on the Brood Development of the Honey Bee (Apis mellifera L.)	45932505	Nippon Soda	OWN	
No Guideline Number	Insecticidal Activity of Acetamiprid Metabolites: IM-1-5 and IM-1-5 HCl; NAI04-004	46255615	Nippon Soda	OWN	
No Guideline Number	Effects of IM-1-5 on Reproduction of the Collembola Folsomia candida in Artificial Soil; 15721016	46255612	Nippon Soda	OWN	
No Guideline Number	Effects of IM-1-5 on the Reproduction of Rove Beetles Aleochara bilineata in the Laboratory; 15722070	46255611	Nippon Soda	OWN	

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DATA MATRIX

Date 4-14-09	EPA Reg No./File Symbol 8033-20	Page 12 of 19
Applicant's/Registrant's Name & Address Nippon Soda Co., Ltd. c/o Nisso America Inc., 45 Broadway, Suite 2120, New York, NY 10006	Product Acetamiprid Technical	

Ingredient acetamiprid

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
161-1	NI-25 (Acetamiprid) Hydrolysis Nisso No. 2-89	44651876	Aventis transferred to Nippon Soda	OWN	
161-1	Hydrolysis of IM 1-4 and IC-O Metabolites PTRLNo.225G	44651877	Aventis transferred to Nippon Soda	OWN	
Supplement to161-1	Stability of IM 1-5 Metabolite in Water NCAS No.012NG	44651878	Aventis transferred to Nippon Soda	OWN	
161-2	Acetamiprid Aqueous Photodegradation of 14-C Acetamiprid at pH7 and Determination of Quantum Yield, Study No 96-82	44988509	Aventis transferred to Nippon Soda	OWN	
Supplement to161-2	Acetamiprid-Verification of the Identity of the Photolyte Obtained at pH7. (Supplement to Study No 96-82)	44988510	Aventis transferred to Nippon Soda	OWN	
161-2	Aqueous Photolysis of C-14 IM 1-4 Under Laboratory Conditions RPA No.97-166	44988511	Aventis transferred to Nippon Soda	OWN	
No Guideline Number	Position Statement on IB-1-1; RD-03200	46255606	Nippon Soda	OWN	
161-3	Acetamiprid Soil Photolysis EC-97-359	44988508	Aventis transferred to Nippon Soda	OWN	
162-1	Acetamiprid (NI-25) Aerobic Soil Metabolism EC No. 96-351	44651879	Aventis transferred to Nippon Soda	OWN	
Supplement to162-1	14-C NI-25 Metabolism in One Soil Incubated Under Aerobic Conditions RCC No.373994	44699101	Aventis transferred to Nippon Soda	OWN	
Supplement to162-1	Acetamiprid (NI-25) Metabolism in Collombey Soil EC No. 97-406	44651880	Aventis transferred to Nippon Soda	OWN	
Supplement to162-1	14-C NI-25 Rate of Aerobic Degradation in Three soil Types RPAC No.11256	44651881	Aventis transferred to Nippon Soda	OWN	
Supplement to162-1	NI-25 Rate of Degradation of the Acid Metabolite (14-C) IC-O In Three Soils RPAC No. 11257	44651882	Aventis transferred to Nippon Soda	OWN	

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DATA MATRIX

Date 4-14-09	EPA Reg No./File Symbol 8033-20	Page 13 of 19
Applicant's/Registrant's Name & Address Nippon Soda Co., Ltd. c/o Nisso America Inc., 45 Broadway, Suite 2120, New York, NY 10006	Product Acetamiprid Technical	

Ingredient acetamiprid

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
162-1	[14C]-Acetamiprid: Rate of Degradation in Three Calcareous Soils at 20°C; CX/01/013	46255603	Nippon Soda	OWN	
162-3	Anaerobic Aquatic Metabolism Study for Technical Acetamiprid EC No. 97-404	44988512	Aventis transferred to Nippon Soda	OWN	
162-4	Aerobic-Aquatic Metabolism Study for Technical Acetamiprid EC No.96-352	44988513	Aventis transferred to Nippon Soda	OWN	
No Guideline Number	IM-1-4, Persistence in Sediment	46255607	Nippon Soda	OWN	
163-1	Acetamiprid (NI-25) Soil Adsorption/Desorption Study RPAC No. EC 97-381	44651883	Aventis transferred to Nippon Soda	OWN	
163-1	6-Chloronicotinic Acid Metabolite, soil adsorption/Desorption RPAC EC No. 97-370	44651884	Aventis transferred to Nippon Soda	OWN	
163-1	14-C N Methyl-(6-chloro-3-pyridyl)Methylamine IM-1-4 Metabolite Soil Adsorption/Desorption Study RPAC No. EC 97-382	44651885	Aventis transferred to Nippon Soda	OWN	
163-1	C-14 NI-25: Leaching characteristics of Aged Residues in One Soil RCC No. 374005	44651886	Aventis transferred to Nippon Soda	OWN	
163-1	[^{14}C]-Acetamiprid: Aged Residue Column Leaching Study in Two Calcareous Soils; CX/02/018	46255604	Nippon Soda	OWN	
164-1	Terrestrial Soil Dissipation of Acetamiprid Following Applications of EXP80667A 70WP to Ornamental Crops SLN 97512637	44988514	Aventis transferred to Nippon Soda	OWN	
164-1	Terrestrial Soil Dissipation of Acetamiprid (EXP 80667 A) Under Agricultural Field Conditions. Study Number 97512643	44988515	Aventis transferred to Nippon Soda	OWN	
None (850.7100)	No. 97512637) Field Soil Dissipation Studies. Method Validation Report for Acetamiprid Performance Summary of Methods of Analysis for NI-25 and Its Metabolites, IC-O, IM-1-4 and 1M 1-2 in US Soils Using LC/MS/MS. RPAC Report Number 45841	44988516	Aventis transferred to Nippon Soda	OWN	

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DATA MATRIX

Date 4-14-09	EPA Reg No./File Symbol 8033-20	Page 14 of 19
Applicant's/Registrant's Name & Address Nippon Soda Co., Ltd. c/o Nisso America Inc., 45 Broadway, Suite 2120, New York, NY 10006	Product Acetamiprid Technical	

Ingredient acetamiprid

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
None (850.7100)	Independent Laboratory Validation of Analytical Methods for NI-25 acetamiprid) and its Metabolites IC-O, IM-1-2 and IM-1-4 in Soil Using LC/MS/MSEC No.98-447	44988517	Aventis transferred to Nippon Soda	OWN	
No Guideline Number	Position Statement on Persistence and Mobility of IM-1-5 in Soil; NAI04-003	46255605	Nippon Soda	OWN	
(860.1000(f)(3))	Identification of Pyrolysis Products of [^{14}C] Acetamiprid in Cigarette Smoke	45900506	Nippon Soda	OWN	
171-4 (860.1300)	Foliar Applied 14-C Acetamiprid: Metabolic Fate and Distribution in Cotton EC No.97-367	44988518	Aventis transferred to Nippon Soda	OWN	
171-4 (860.1300)	C-14 Metabolism in Carrots Lab No. 11253	44988519	Aventis transferred to Nippon Soda	OWN	
171-4 (860.1300)	C-14 Acetamiprid Nature of Residue in Apple Plants Report No. 742-1	44988520	Aventis transferred to Nippon Soda	OWN	
171-4 (860.1300)	C-14 Nature of Residue in Egg Plants EC No.391-3	44988521	Aventis transferred to Nippon Soda	OWN	
171-4 (860.1300)	C-14 Nature of Residue in Cabbage Plants EC No. 743-1	44988522	Aventis transferred to Nippon Soda	OWN	
171-4 (860.1300)	C-14 NI-25 Acetamiprid Adsorption, Distribution, Metabolism and Excretion After Repeated Oral Administration to Laying Hens RCC 628143	44988523	Aventis transferred to Nippon Soda	OWN	
171-4 (860.1300)	C-14 NI-25 Acetamiprid Adsorption, Distribution, Metabolism and Excretion After Repeated Oral Administration to Lactating Goats RCC No. 628132	44988524	Aventis transferred to Nippon Soda	OWN	

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DATA MATRIX

Date 4-14-09	EPA Reg No./File Symbol 8033-20	Page 15 of 19
Applicant's/Registrant's Name & Address Nippon Soda Co., Ltd. c/o Nisso America Inc., 45 Broadway, Suite 2120, New York, NY 10006	Product Acetamiprid Technical	

Ingredient acetamiprid

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
171-4 (860.1340)	Independent Laboratory Validation for the Analysis of Acetamiprid in Plants and Plant Processed Fractions Version 2 Citrus EC No. 98-438 7309-001	44988525	Aventis transferred to Nippon Soda	OWN	
171-4 (860.1340)	Methods for the Analysis of Acetamiprid (NI-25) in Plants and Plant Processed Fractions (Version 3: Citrus) EC No. 98-438 10230	44988526	Aventis transferred to Nippon Soda	OWN	
171-4 (860.1340)	Validation of Residue Analytical Methods of Acetamiprid in Crops-Parent Method EC No.97-388 No. 10200	44988527	Aventis transferred to Nippon Soda	OWN	
171-4 (860.1340)	ILV of Methods for the Analysis of Acetamiprid in Plant and Plant Processed Fractions Version I: Fruit (Non-Citrus) and Vegetable Crops EC No. 98-414 No.980017	44988528	Aventis transferred to Nippon Soda	OWN	
171-4 (860.1340)	Methods for the Analysis of Acetamiprid in Plants and Plant Processed Fractions Version 2 Fruit (Non-Citrus) and Vegetable Crops EC No. 98-414- No.10229 Supportive	44988529	Aventis transferred to Nippon Soda	OWN	
171-4 (860.1340)	ILV of Acetamiprid and its Metabolite IM-1-2: Analytical Method for the Determination of Residues in Foodstuffs of Ruminant Origin (Milk, Muscle, Fat, Liver and Kidney) EC 98-442	44988530	Aventis transferred to Nippon Soda	OWN	
171-4 (860.1340)	Acetamiprid and its Metabolite IM 2-1: Radiovalidation of an Analytical Method for the Determination of Residues in Foodstuff or Ruminant Origin(Liver and Milk) RPA 97-170	44988531	Aventis transferred to Nippon Soda	OWN	
171-4 (860.1340)	Acetamiprid and its Metabolite IM 2-1: Analytical Method for the Determination of Residues in Foodstuffs of Ruminant Origin (Milk, Muscle, Fat, Liver and Kidney) RPA 97-96 No.660216	44988532	Aventis transferred to Nippon Soda	OWN	
171-4 (860.1340)	Acetamiprid and its Metabolite IM 2-1: Analytical Method for the Determination of Residues in Foodstuffs of Hen Origin (Egg, Muscle, Fat, Liver) RPA No.97-113 No.660-227	44988533	Aventis transferred to Nippon Soda	OWN	
171-4 (860.1340)	Independent Lab Validation; ML06-1306-NIP	47185401	Nippon Soda	OWN	
171-4(m) (860-1360)	PAM I Multi-residue Testing for Acetamiprid EC No. 97-376	44988534	Aventis transferred to Nippon Soda	OWN	
171-4(e) (860-1380)	Acetamiprid and Its Metabolites in Soil During Prolonged Freezer Storage Lab No. 97512642	45039702	Aventis transferred to Nippon Soda	OWN	

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DATA MATRIX

Date 4-14-09	EPA Reg No./File Symbol 8033-20	Page 16 of 19
Applicant's/Registrant's Name & Address Nippon Soda Co., Ltd. c/o Nisso America Inc., 45 Broadway, Suite 2120, New York, NY 10006	Product Acetamiprid Technical	

Ingredient acetamiprid

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
171-4(e) (860.1380)	Crop Storage Stability Evaluation	44988535	Aventis transferred to Nippon Soda	OWN	
171-4 (860-1400)	Methods for Determination of Acetamiprid in Water (Validation Study) Lab No. 97-007	44988536	Aventis transferred to Nippon Soda	OWN	
171-4 (860.1460)	Magnitude of the Residue of Acetamiprid in/on Stored Food Following an Application of F5025 70 WP; Lab ID 502MIX04R1	47462801	Nippon Soda	OWN	
171-4(j) (860-1480)	Acetamiprid: Magnitude of Residue in Dairy Cow Milk and tissues RPAC No. 98514428	44988601	Aventis transferred to Nippon Soda	OWN	
171-4(j) (860-1480)	Acetamiprid: Magnitude of Residues in Poultry Tissues and Eggs RPAC No. 98514429	44988602	Aventis transferred to Nippon Soda	OWN	
171-4(k) (860-1500)	Acetamiprid Magnitude of residues in Leaf Lettuce as representative of Leafy Vegetable Crop Group RPAC No. 97512110	44988603	Aventis transferred to Nippon Soda	OWN	
171-4(k) (860-1500)	Acetamiprid Magnitude of Residues in Spinach as representative of Leafy Vegetable Crop Group RPAC No. 97512111	44988604	Aventis transferred to Nippon Soda	OWN	
171-4(k) (860-1500)	Acetamiprid Magnitude of Residues in Head Lettuce as representative of Leafy Vegetable Crop Group RAPC No. 97512109	44988605	Aventis transferred to Nippon Soda	OWN	
171-4(k) (860-1500)	Acetamiprid Magnitude of Residues in Celery as representative of Leafy Vegetable Crop Group RPAC No. 97512112	44988606	Aventis transferred to Nippon Soda	OWN	
171-4(k) (860-1500)	Acetamiprid Magnitude of Residues in Broccoli as Representative of Cole Crop Group RPAC No. 97512645	44988607	Aventis transferred to Nippon Soda	OWN	
171-4(k) (860-1500)	Acetamiprid: Magnitude of Residues in/on Cabbage Resulting from Foliar Application of EXP 80667A (1997) RPAC Study No: 97512646	44988608	Aventis transferred to Nippon Soda	OWN	
171-4(k) (860-1500)	Acetamiprid: Magnitude of Residues in/on Mustard Greens Resulting from Foliar Application of EXP 80667A (1997 RPAC Study No. 97512647	44988609	Aventis transferred to Nippon Soda	OWN	

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
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DATA MATRIX

Date 4-14-09	EPA Reg No./File Symbol 8033-20	Page 17 of 19
Applicant's/Registrant's Name & Address Nippon Soda Co., Ltd. c/o Nisso America Inc., 45 Broadway, Suite 2120, New York, NY 10006	Product Acetamiprid Technical	

Ingredient acetamiprid

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
171-4(k) (860-1500)	Magnitude of Acetamiprid Residues in/on Cottonseed and Gin Trash Study Number 97512104	44988610	Aventis transferred to Nippon Soda	OWN	
171-4(k) (860-1500)	Grapefruit, Lemon Treated with Five Applications of EXP-8067A Insecticide with a 7 day PHI. Study Number 97512102	44988611	Aventis transferred to Nippon Soda	OWN	
171-4(k) (860-1500)	Magnitude of Residues in or on Apple RAC Resulting from Foliar Applications of EXP 80667A Insecticide (Pome Fruit Representative crop group) RPAC No. 97512648	44988612	Aventis transferred to Nippon Soda	OWN	
171-4(k) (860-1500)	Magnitude of the Residues in or on Pear RAC Resulting from Foliar Applications of EXP 80667A Insecticide (Pome Fruit Representative crop group) RPAC No. 96512649	44988613	Aventis transferred to Nippon Soda	OWN	
171-4(k) (860-1500)	Magnitude of Residues in/on Tomato RPAC Study number 97512107 as member of Fruiting Vegetable Crop Group	44988614	Aventis transferred to Nippon Soda	OWN	
171-4(k) (860-1500)	Magnitude of Residues in/on Eggplant RAC Study number 97512114 as member of Fruiting Vegetable Crop Group	44988615	Aventis transferred to Nippon Soda	OWN	
171-4(k) (860-1500)	Acetamiprid Magnitude of Residues in/on Peppers as Representative Fruiting Vegetable Crop group RPAC No. 97512106	44988616	Aventis transferred to Nippon Soda	OWN	
171-4(k) (860-1500)	Acetamiprid: Magnitude of Residues in/on Grapes Resulting from Foliar Applications of EXP 80667 A RPAC, Study No 97512653	44988620	Aventis transferred to Nippon Soda	OWN	
171-4(k) (860.1500)	Acetamiprid: Magnitude of residues in canola from treated seeds. Study No. 99517981	44988624	Aventis transferred to Nippon Soda	OWN	
171-4(k) (860.1500)	Amended Final Study Report of Acetamiprid (NI-25): Magnitude of Residues in Canola from Treated Seed	45336901	Aventis transferred to Nippon Soda	OWN	
171-4(k) (860.1500)	Magnitude of Acetamiprid Residues In or On Green and Cured Tobacco Leaves Resulting From Four Applications of ASSAIL, USA 2001	45900507	Nippon Soda	OWN	

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DATA MATRIX

Date 4-14-09	EPA Reg No./File Symbol 8033-20	Page 18 of 19
Applicant's/Registrant's Name & Address Nippon Soda Co., Ltd. c/o Nisso America Inc., 45 Broadway, Suite 2120, New York, NY 10006	Product Acetamiprid Technical	

Ingredient acetamiprid

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
171-4(k) (860.1500)	Assail 70WP: Magnitude of Acetamiprid Residues In/On Potatoes Treated with Four Applications of EXP -61842A Insecticide with a 7 Day PHI (2001)	45900508	Nippon Soda	OWN	
171-4(k) (860.1500)	Assail 70 WP Insecticide Field Residue Study in Cucurbit Crop Group, Study No. KP-2003-23	46265701	Nippon Soda	OWN	
171-4(k) (860.1500)	Assail 70 WP Insecticide Field Residue Study in Stone Fruit Crop Group, Study No. KP-2003-19	46265702	Nippon Soda	OWN	
171-4(k) (860.1500)	Assail 70 WP Insecticide Field Residue Study in Tree Nut Crop Group; Study No. KP-2003-20	46265703	Nippon Soda	OWN	
171-4(k) (860.1500)	Assail 70 WP Insecticide Field Residue Study in Berry Crop Group, Study No. KP-2004-14	46785502	Nippon Soda	OWN	
171-4(k) (860.1500)	Assail 70 WP Insecticide Field Residue Study in Legume Crop Group, Study No. KP-2004-13	46785504	Nippon Soda	OWN	
171-4(k) (860.1500)	Assail 70 WP Insecticide Field Residue Study in Onion Crop Group, Study No. KP-2004-15	46785503	Nippon Soda	OWN	
171-4(k) (860.1500)	Acetamiprid: Magnitude of the Residue on Strawberry PR# 09058	47013601	IR-4		
171-4(k) (860.1500)	Acetamiprid: Magnitude of the Residue on Grape PR# 09057	47716902	IR-4		
171-4(k) (860.1500)	Acetamiprid: Magnitude of the Residue on Tomato (Greenhouse), PR# 08354	47716903	IR-4		
171-4(k) (860.1500)	Acetamiprid: Magnitude of the Residue on Red Clover (Grown for Seed Only), PR# 09600	47716901	IR-4		

Signature John J Wumbel

Date 4-14-09

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

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DATA MATRIX

Date 4-14-09	EPA Reg No./File Symbol 8033-20	Page 19 of 19
Applicant's/Registrant's Name & Address Nippon Soda Co., Ltd. c/o Nisso America Inc., 45 Broadway, Suite 2120, New York, NY 10006	Product Acetamiprid Technical	

Ingredient acetamiprid

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
171-4(1) (860-1520)	Acetamiprid: Magnitude of Residues in Grape Processed Fractions Resulting from Foliar Applications of EXP80667A RPAC 97512651	44988617	Aventis transferred to Nippon Soda	OWN	
171-4(1) (860-1520)	Cotton Processing Study for acetamiprid Report Number 97 512105	44988618	Aventis transferred to Nippon Soda	OWN	
171-4(1) (860-1520)	Fruit and Citrus Processed Fractions (dry pulp, oil, and juice) Derived from Oranges from Orchards Treated with EXP-80667 A Insecticide RP AC No. 97512103	44988619	Aventis transferred to Nippon Soda	OWN	
171-4(1) (860-1520)	Acetamiprid: Magnitude of Residues in/on Tomato Processed Fractions RPAC No. 7512108	44988621	Aventis transferred to Nippon Soda	OWN	
171-4(1) (860-1520)	Magnitude of Residues in Apple Processed Commodities Resulting From Foliar Applications of EXP 80667A Insecticide RPAC No. 97512650	44988622	Aventis transferred to Nippon Soda	OWN	
171-4(k) (860.1520)	Assail 70WP: Magnitude of Acetamiprid Residues In/On Potatoes and Potato Processed Fractions (Flakes, Chips, Wet Peel) Derived from Potatoes Treated with EXP-618942A Insecticide (2001)	45900509	Nippon Soda	OWN	
165-1 (860-1850)	C-14 Acetamiprid Foliar Treatment: Accumulation Study in Confined Rotational Crops EC-97-368	44988623	Aventis transferred to Nippon Soda	OWN	
165-1 (860.1850)	NI-25 (Acetamiprid): Consideration of the Storage Stability in the Confined Rotational Crop Study of Acetamiprid; NAI 06-003	46729102	Nippon Soda	OWN	
(875.2100)	ACETAMIPRID: Dissipation of Dislodgeable Residues on cotton.	45323001	Aventis transferred to Nippon Soda	OWN	

Signature John J Wumbel

Date 4-14-09

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.

EPA File Copy

his or her designated representatives, no person or vessel is allowed within 100 yards of the Hawaii Superferry when it is underway, moored, position-keeping, or at anchor, unless authorized by the Captain of the Port or his or her designated representatives.

(4) Persons desiring to transit the security zone in this section may contact the Captain of the Port at telephone number (808) 927–0865 or on VHF channel 12 to seek permission to transit the area. If permission is granted, all persons and vessels must comply with the instructions of the Captain of the Port or his or her designated representatives. When conditions permit, the Captain of the Port, or his or her designated representatives, may permit vessels that are at anchor, restricted in their ability to maneuver, or constrained by draft to remain within the security zone in order to ensure navigational safety.

(e) *Enforcement.* Any Coast Guard commissioned, warrant, or petty officer, and any other Captain of the Port representative permitted by law, may enforce this temporary security zone.

Dated: November 21, 2007.

Sally Brice-O'Hara,

Rear Admiral, U.S. Coast Guard, Commander, Fourteenth Coast Guard District.

[FR Doc. 07–5872 Filed 11–26–07; 1:53 pm]

BILLING CODE 4910–15–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2007–0105; FRL–8340–6]

Acetamiprid; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of acetamiprid in or on almond, hulls; fruit, stone, group 12, except plum, prune; nut, tree, group 14; pea and bean, succulent shelled, subgroup 6B; pistachio; plum, prune, dried; plum, prune, fresh; vegetable, cucurbit, group 9; and vegetable, legume, edible podded, subgroup 6A. Nippon Soda Co., Ltd. requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective November 28, 2007. Objections and requests for hearings must be received on or before January 28, 2008, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPP–2007–0105. To access the electronic docket, go to *http://www.regulations.gov*, select "Advanced Search," then "Docket Search." Insert the docket ID number where indicated and select the "Submit" button. Follow the instructions on the regulations.gov website to view the docket index or access available documents. All documents in the docket are listed in the docket index available in regulations.gov. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available in the electronic docket at *http://www.regulations.gov*, or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: Susan Stanton, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–5218; e-mail address: *stanton.susan@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected entities may include, but are not limited to those engaged in the following activities:

- Crop production (NAICS code 111), e.g., agricultural workers; greenhouse, nursery, and floriculture workers; farmers.
- Animal production (NAICS code 112), e.g., cattle ranchers and farmers, dairy cattle farmers, livestock farmers.
- Food manufacturing (NAICS code 311), e.g., agricultural workers; farmers; greenhouse, nursery, and floriculture workers; ranchers; pesticide applicators.
- Pesticide manufacturing (NAICS code 32532), e.g., agricultural workers; commercial applicators; farmers; greenhouse, nursery, and floriculture workers; residential users.

This listing is not intended to be exhaustive, but rather to provide a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Access Electronic Copies of this Document?

In addition to accessing an electronic copy of this **Federal Register** document through the electronic docket at *http://www.regulations.gov*, you may access this **Federal Register** document electronically through the EPA Internet under the "**Federal Register**" listings at *http://www.epa.gov/fedrgstr*. You may also access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's pilot e-CFR site at *http://www.gpoaccess.gov/ecfr*.

C. Can I File an Objection or Hearing Request?

Under section 408(g) of FFDCA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2007–0105 in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk as required by 40 CFR part 178 on or before January 28, 2008.

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing that does not contain any CBI for inclusion in the public docket that is described in **ADDRESSES**. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit this copy, identified by docket ID number EPA–HQ–OPP–2007–0105, by one of the following methods:

• *Federal eRulemaking Portal*: *http://www.regulations.gov*. Follow the on-line instructions for submitting comments.

• *Mail*: Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.

• *Delivery*: OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. Deliveries are only accepted during the Docket's normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket Facility telephone number is (703) 305–5805.

II. Petition for Tolerance

In the **Federal Register** of September 15, 2004 (69 FR 55625) (FRL–7674–9), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 4F6833) by Nippon Soda Co., Ltd., c/o Nisso America Inc., 220 East 42nd Street, Suite 3002, New York, NY, 10017. The petition requested that 40 CFR 180.578 be amended by establishing tolerances for residues of the insecticide acetamiprid, N1-[(6-chloro-3-pyridyl)methyl]-N2-cyano-N1-methylacetamidine, in or on the cucurbit crop group at 0.5 parts per million (ppm); the stone fruit crop group, except plum, prune, fresh and dried at 1.2 ppm; plum, prune, fresh and dried at 0.3 ppm; the tree nut crop group, except almond hulls at 0.1 ppm; and almond hulls at 5.0 ppm. That notice included a summary of the petition prepared by Nippon Soda Co., Ltd., the registrant, which is available to the public in the docket ID Number EPA–HQ–OPP–2004–0223, *http://www.regulations.gov*. Comments were received on the notice of filing from a private citizen. EPA's response to these comments is discussed in Unit IV.C below.

In the **Federal Register** of September 22, 2006 (71 FR 55468) (FRL–8091–9), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 6F7051) by Nippon Soda Co., Ltd., c/o Nisso America Inc., 45 Broadway, Suite 2120, New York, NY, 10006. The petition requested that 40 CFR 180.578 be amended by establishing tolerances for residues of the insecticide acetamiprid, N1-[(6-chloro-3-pyridyl)methyl]-N2-cyano-N1-methylacetamidine, in or on bulb vegetables crop group 3 at 3 ppm; edible podded legume vegetables, crop subgroup 6a at 0.5 ppm; succulent shelled pea and beans, crop subgroup 6b, at 0.5 ppm; and berries, crop group 13 at 1 ppm. The notice also announced the filing of amended pesticide petition 4F6833, requesting a tolerance for residues of acetamiprid in or on pistachio at 0.1 ppm in addition to the tolerances described in the preceding paragraph. That notice referenced a summary of the petition prepared by Nippon Soda Co., Ltd., the registrant, which is available to the public in the docket ID Number EPA–HQ–OPP–2006–0733, *http://www.regulations.gov*. There were no comments received in response to the notice of filing.

EPA is deferring to a later date the decision regarding the proposed tolerances for residues of acetamiprid on bulb vegetables crop group 3 and berry crop group 13. Based upon review of the data supporting the petitions, EPA has modified the tolerance levels and/or commodity terms for several of the other proposed tolerances. The reasons for these changes are explained in Unit V.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is "safe." Section 408(b)(2)(A)(ii) of FFDCA defines "safe" to mean that "there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information." This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to "ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue...." These provisions were added to FFDCA by the Food Quality Protection Act (FQPA) of 1996.

Consistent with section 408(b)(2)(D) of FFDCA, and the factors specified in section 408(b)(2)(D) of FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for the petitioned-for tolerance for residues of acetamiprid on Almond, hulls at 5.0 ppm; Fruit, stone, group 12, except plum, prune at 1.20 ppm; Nut, tree, group 14 at 0.10 ppm; Pea and bean, succulent shelled, subgroup 6B at 0.40 ppm; Pistachio at 0.10 ppm; Plum, prune, dried at 0.40 ppm; Plum, prune, fresh at 0.20 ppm; Vegetable, cucurbit, group 9 at 0.50 ppm; and Vegetable, legume, edible podded, subgroup 6A at 0.60 ppm. EPA's assessment of exposures and risks associated with establishing the tolerance follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. Specific information on the studies received and the nature of the adverse effects caused by acetamiprid as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at *http://www.regulations.gov* in the document *Acetamiprid: Human Health Risk Assessment for Proposed Food Uses on Stone Fruits, Cucurbit Vegetables, Tree Nuts, Berries, Strawberries, Bulb Vegetables, Legumes (Peas and Beans) and for Residential/Commercial Insecticide/Termiticide Uses*. The referenced document is available in the docket established by this action, which is described under **ADDRESSES**, and is identified as document ID number EPA–HQ–OPP–2007–0105–0003 in that docket.

The toxicity database for acetamiprid is complete. The acute toxicity data indicate that acetamiprid is moderately toxic via the oral route and is minimally toxic via the dermal and inhalation routes. Acetamiprid is not an eye or skin irritant, and it is not a dermal sensitizer. Based on subchronic, chronic, developmental and reproductive studies in rats, rabbits, and dogs, acetamiprid does not appear to have specific target organ toxicity. Generalized nonspecific toxicity was observed as decreases in body weight, body weight gain, food consumption and food efficiency when determined. Generalized effects were also observed in the liver in the form of hepatocellular hypertrophy in both mice and rats and hepatocellular vacuolation in the rat. The hepatocellular hypertrophy in mice is considered to be adaptive; it is likely that the

vacuolization in rats is more related to liver activity in response to the presence of the chemical rather than frank toxicity. Neurotoxicity was observed in the form of decreased locomotor activity in the acute neurotoxicity study in rats and as decreased auditory startle response in the developmental neurotoxicity study in rats.

Developmental studies showed no evidence of either quantitative or qualitative susceptibility of the rat or rabbit fetuses from *in utero* exposure. However, both the developmental neurotoxicity (DNT) study and the multi-generation reproduction studies showed an increase in qualitative susceptibility of pups. Effects in pups in the reproduction study included delays in preputial separation, vaginal opening and pinna unfolding as well as reduced litter size, decreased early pup viability and weaning indices; offspring effects observed in the DNT study included decreased body weight and body weight gains, decreased early pup viability and decreased maximum auditory startle response in males. These effects were seen in the presence of less severe effects (decreased body weight and body weight gain) in the maternal animals.

Based on acceptable carcinogenicity studies in rats and mice, EPA has determined that acetamiprid is not likely to be carcinogenic to humans. This determination is based on the absence of a dose-response or statistical significance for the increased incidence in mammary adenocarcinomas observed in the rat carcinogenicity study, as well as the lack of evidence of carcinogenic effects in the mouse cancer study.

B. Toxicological Endpoints

For hazards that have a threshold below which there is no appreciable risk, the toxicological level of concern (LOC) is derived from the highest dose at which the NOAEL in the toxicology study identified as appropriate for use in risk assessment. However, if a NOAEL cannot be determined, the LOAEL is sometimes used for risk assessment. Uncertainty/safety factors (UFs) are used in conjunction with the LOC to take into account uncertainties inherent in the extrapolation from laboratory animal data to humans and in the variations in sensitivity among members of the human population as well as other unknowns. Safety is assessed for acute and chronic risks by comparing aggregate exposure to the pesticide to the acute population adjusted dose (aPAD) and chronic population adjusted dose (cPAD). The aPAD and cPAD are calculated by dividing the LOC by all applicable UFs. Short-term, intermediate-term, and long-term risks are evaluated by comparing aggregate exposure to the LOC to ensure that the margin of exposure (MOE) called for by the product of all applicable UFs is not exceeded.

For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk and estimates risk in terms of the probability of occurrence of additional adverse cases. Generally, cancer risks are considered non-threshold. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see *http://www.epa.gov/pesticides/factsheets/riskassess.htm.*

A summary of the toxicological endpoints for acetamiprid used for human risk assessment can be found at *http://www.regulations.gov* at pages 21–22 in the document *Acetamiprid: Human Health Risk Assessment for Proposed Food Uses on Stone Fruits, Cucurbit Vegetables, Tree Nuts, Berries, Strawberries, Bulb Vegetables, Legumes (Peas and Beans) and for Residential/Commercial Insecticide/Termiticide Uses* in docket ID number EPA–HQ–OPP–2007–0105.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to acetamiprid, EPA considered exposure under the petitioned-for tolerances as well as all existing acetamiprid tolerances in (40 CFR 180.578). EPA assessed dietary exposures from acetamiprid in food as follows:

i. *Acute exposure.* Quantitative acute dietary exposure and risk assessments are performed for a food-use pesticide if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1–day or single exposure. In estimating acute dietary exposure to acetamiprid, EPA used food consumption information from the U.S. Department of Agriculture (USDA) 1994–1996 and 1998 Nationwide Continuing Surveys of Food Intake by Individuals (CSFII). As to residue levels in food, EPA relied upon anticipated residues derived from field trial data for certain commodities (apples; broccoli; cabbage, celery; grapefruit; grapes; lettuce; oranges; pears; peppers; spinach; tomatoes; stone fruits; and cucurbits) and assumed residues were present at tolerance levels in all other commodities. EPA also relied on percent crop treated (PCT) information for some of the currently registered commodities (apples, broccoli , celery, lettuce, pears, grapefruit, grapes, oranges, peppers, spinach and tomatoes) but assumed 100 PCT for all of the new commodities.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the food consumption data from the USDA 1994–1996 and 1998 CSFII. As to residue levels in food, EPA assumed all foods for which there are tolerances or for which tolerances are being established contain tolerance-level residues. EPA relied on PCT information for two currently registered crops (apples and oranges) but assumed 100 PCT for all other commodities.

iii. *Cancer.* As noted above, EPA has determined that acetamiprid is not likely to be carcinogenic to humans. Therefore, an exposure assessment for use in a quantitative cancer risk assessment is unnecessary.

iv. *Anticipated residue and PCT information.* Section 408(b)(2)(E) of FFDCA authorizes EPA to use available data and information on the anticipated residue levels of pesticide residues in food and the actual levels of pesticide residues that have been measured in food. If EPA relies on such information, EPA must pursuant to section 408(f)(1) of FFDCA require that data be provided 5 years after the tolerance is established, modified, or left in effect, demonstrating that the levels in food are not above the levels anticipated. For the present action, EPA will issue such data call-ins as are required by section 408(b)(2)(E) of FFDCA and authorized under section 408(f)(1) of FFDCA. Data will be required to be submitted no later than 5 years from the date of issuance of this tolerance.

Section 408(b)(2)(F) of FFDCA states that the Agency may use data on the actual percent of food treated for assessing chronic dietary risk only if:

a. The data used are reliable and provide a valid basis to show what percentage of the food derived from such crop is likely to contain such pesticide residue.

b. The exposure estimate does not underestimate exposure for any significant subpopulation group.

c. Data are available on pesticide use and food consumption in a particular area, the exposure estimate does not understate exposure for the population in such area. In addition, the Agency must provide for periodic evaluation of any estimates used. To provide for the periodic evaluation of the estimate of PCT as required by section 408(b)(2)(F) of FFDCA, EPA may require registrants to submit data on PCT.

The Agency used PCT information as follows:

For the acute assessment, maximum PCT estimates were used for the following commodities: Apples (15%),

broccoli (5%), celery (15%), lettuce (10%), pears (25%), and grapefruit, grapes, oranges, peppers, spinach and tomatoes, each at 2.5%.

For the chronic assessment, average PCT estimates were used for the following commodities: Apples (10%) and oranges (1%).

EPA uses an average PCT for chronic dietary risk analysis. The average PCT figure for each existing use is derived by combining available Federal, state, and private market survey data for that use, averaging by year, averaging across all years, and rounding up to the nearest multiple of 5% except for those situations in which the average PCT is less than one. In those cases <1% is used as the average and <2.5% is used as the maximum. EPA uses a maximum PCT for acute dietary risk analysis. The maximum PCT figure is the single maximum value reported overall from available Federal, state, and private market survey data on the existing use, across all years, and rounded up to the nearest multiple of 5%. In most cases, EPA uses available data from USDA/National Agricultural Statistics Service (USDA/NASS), Proprietary Market Surveys, and the National Center for Food and Agriculture Policy (NCFAP) for the most recent six years.

The Agency believes that the three conditions listed in this unit have been met. With respect to Condition A, PCT estimates are derived from Federal and private market survey data, which are reliable and have a valid basis. The Agency is reasonably certain that the percentage of the food treated is not likely to be an underestimation. As to Conditions B and C, regional consumption information and consumption information for significant subpopulations is taken into account through EPA's computer-based model for evaluating the exposure of significant subpopulations including several regional groups. Use of this consumption information in EPA's risk assessment process ensures that EPA's exposure estimate does not understate exposure for any significant subpopulation group and allows the Agency to be reasonably certain that no regional population is exposed to residue levels higher than those estimated by the Agency. Other than the data available through national food consumption surveys, EPA does not have available information on the regional consumption of food to which acetamiprid may be applied in a particular area.

2. *Dietary exposure from drinking water.* The Agency lacks sufficient monitoring data to complete a comprehensive dietary exposure analysis and risk assessment for acetamiprid in drinking water. Because the Agency does not have comprehensive monitoring data, drinking water concentration estimates are made by reliance on simulation or modeling taking into account data on the environmental fate characteristics of acetamiprid. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at *http://www.epa.gov/oppefed1/models/water/index.htm.*

Based on the First Index Reservoir Screening Tool (FIRST) and Screening Concentration in Ground Water (SCI-GROW) models, the estimated environmental concentrations (EECs) of acetamiprid for acute exposures are estimated to be 20.1 parts per billion (ppb) for surface water and 1.6 ppb for ground water. The EECs for chronic exposures are estimated to be 4.9 ppb for surface water and 1.6 ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For acute dietary risk assessment, the water concentration value of 20.1 ppb was used to assess the contribution to drinking water. For chronic dietary risk assessment, the water concentration of value 4.9 ppb was used to assess the contribution to drinking water.

3. *From non-dietary exposure.* The term "residential exposure" is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets).

Acetamiprid is currently registered for the following residential non-dietary sites: As a pre- and post-construction termiticide/insecticide for use in subterranean or hard-to-reach structure components and building perimeters; and as a crack, crevice or spot application using gel bait formulations for control of ants and cockroaches in residential settings. EPA assessed residential exposure using the following assumptions: The pre- and post-construction termiticide/insecticide uses of acetamiprid are limited to licensed Pest Control Operators (PCOs); therefore, homeowner handler exposures are not expected to occur. Nor are post-application exposures of adults or children expected as a result of these uses, since applications are limited to subterranean or hard-to-reach structure components and building perimeters. EPA has determined that short-term and intermediate-term dermal exposure of residential handlers may occur from use of the gel bait formulations in residential settings; however, due to the low vapor pressure of acetamiprid and its formulation as a gel, inhalation exposure of handlers is not expected. Post-application exposures of adults and children from this use are expected to be negligible for the following reasons: (i) Homeowners are unlikely to revisit the crack, crevice or spot where the gel bait has been applied, thereby minimizing potential exposure; (ii) inhalation exposure is expected to be minimal due to acetamiprid's low vapor pressure and its formulation as a gel; and (iii) the gel bait products contain a bittering agent which is used to prevent ingestion by children and animals, thereby further reducing potential for incidental oral exposures of children. For these reasons, EPA assessed only residential handler dermal exposures from the gel bait uses of acetamiprid.

4. *Cumulative effects from substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity."

Acetamiprid is a member of the neonicotinoid class of pesticides which also includes thiamethoxam, clothianidin, imidacloprid and several other active ingredients. Structural similarities or common effects do not constitute a common mechanism of toxicity. Evidence is needed to establish that the chemicals operate by the same, or essentially the same sequence of major biochemical events. Although the neonicotinoids bind selectively to insect nicotinic acetylcholine receptors (nAChR), the specific binding site(s)/receptor(s) are unknown at this time. Additionally, the commonality of the binding activity itself is uncertain, as preliminary evidence suggests that clothianidin operates by direct competitive inhibition, while thiamethoxam is a non-competitive inhibitor. Furthermore, even if future research shows that neonicotinoids share a common binding activity to a specific site on insect nicotinic acetylcholine receptors, there is not necessarily a relationship between this pesticidal action and a mechanism of toxicity in mammals. Structural variations between the insect and mammalian nAChRs produce quantitative differences in the binding affinity of the neonicotinoids towards these receptors, which, in turn, confers the notably greater selective toxicity of this class towards insects, including

aphids and leafhoppers, compared to mammals. Additionally, the most sensitive toxicological effect in mammals differs across the neonicotinoids (e.g., testicular tubular atrophy with thiamethoxam; mineralized particles in thyroid colloid with imidaclopid). Thus, there is currently no evidence to indicate that neonicotinoids share common mechanisms of toxicity, and EPA is not following a cumulative risk approach based on a common mechanism of toxicity for the neonicotinoids. In addition, acetamiprid does not appear to produce a toxic metabolite produced by other substances. Therefore, for the purposes of this tolerance action, EPA has not assumed that acetamiprid has a common mechanism of toxicity with other substances. For more information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's website at *http://www.epa.gov/pesticides/cumulative.*

D. Safety Factor for Infants and Children

1. *In general.* Section 408 of FFDCA provides that EPA shall apply an additional ("10X") tenfold margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the FQPA safety factor. In applying this provision, EPA either retains the default value of 10X when reliable data do not support the choice of a different factor, or, if reliable data are available, EPA uses a different additional FQPA safety factor value based on the use of traditional UFs and/or special FQPA safety factors, as appropriate.

2. *Prenatal and postnatal sensitivity.* The pre- and postnatal toxicology database for acetamiprid includes rat and rabbit developmental toxicity studies, a 2–generation reproduction toxicity study in rats and a DNT study in rats. There was no evidence of quantitative or qualitative susceptibility of rat or rabbit fetuses following *in utero* exposure to acetamiprid in the developmental toxicity studies. However, both the DNT and multi-generation reproduction studies showed an increase in qualitative susceptibility of pups. Effects in pups in the reproduction study included delays in preputial separation, vaginal opening and pinna unfolding, as well as reduced litter size, decreased early pup viability and weaning indices; offspring effects observed in the DNT study included decreased body weight and body weight gains, decreased early pup viability and decreased maximum auditory startle response in males. These effects were seen in the presence of decreased body weight and body weight gain in the maternal animals, indicating increased qualitative susceptibility of fetuses and offspring to acetamiprid. Quantitative evidence of increased susceptibility was not observed in any study.

In considering the overall toxicity profile and the endpoints and doses selected for the acetamiprid risk assessment, EPA characterized the degree of concern for the effects observed in the acetamiprid DNT and the 2–generation reproduction study as low, noting that there is a clear NOAEL for the offspring effects in both studies, the toxicology database is complete, and regulatory doses were selected to be protective of potential offspring effects in both the DNT and the 2–generation study. No other residual uncertainties were identified. Based on the available data, EPA determined that changes in motor activity, auditory startle reflex, learning and memory assessments, and even changes in the brain morphometrics can occur as the result of a single exposure at a critical junction during pregnancy or from multiple exposures throughout pregnancy and lactation. Therefore, the NOAEL for offspring effects observed in the DNT was selected as the dose for acute dietary exposures (co-critical with the acute neurotoxicity study), as well as short-term and intermediate-term non-dietary risk assessment. Use of the DNT NOAEL is protective of effects seen in the 2-generation study (the NOAEL from the DNT is 10.0 mg/kg/day and the NOAEL from the 2–generation study is 17.9 mg/kg/day). The chronic dietary study in rats yielded a lower long-term NOAEL (7.1 mg/kg/day) and was, therefore, used for assessing chronic dietary risk. EPA believes that the endpoints and doses selected for acetamiprid are protective of adverse effects in both offspring and adults.

3. *Conclusion.* EPA has determined that reliable data show that it would be safe for infants and children to reduce the FQPA safety factor to 1X. That decision is based on the following findings:

i. The toxicity database for acetamiprid is complete.

ii. There is no evidence that acetamiprid results in increased susceptibility in *in utero* rats or rabbits in the prenatal developmental studies. Although there is qualitative evidence of increased susceptibility in the multi-generation reproduction study and in the DNT study, the risk assessment team did not identify any residual uncertainties after establishing toxicity endpoints and traditional UFs to be used in the risk assessment of acetamiprid. The degree of concern for pre- and/or postnatal toxicity is low.

iii. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments were performed based on tolerance-level residues or anticipated residues derived from reliable field trial data. The PCT estimates used in the dietary assessment were derived from valid, reliable Federal and private market survey data and are unlikely to be exceeded. Conservative ground and surface water modeling estimates were used to assess exposures to acetamiprid from drinking water; and residential, non-dietary exposure of infants and children to acetamiprid is not expected to occur. EPA believes these assessments will not underestimate the exposure and risks posed by acetamiprid.

E. Aggregate Risks and Determination of Safety

Safety is assessed for acute and chronic risks by comparing aggregate exposure to the pesticide to the aPAD and cPAD. The aPAD and cPAD are calculated by dividing the LOC by all applicable UFs. For linear cancer risks, EPA calculates the probability of additional cancer cases given aggregate exposure. Short-term, intermediate-term, and long-term risks are evaluated by comparing aggregate exposure to the LOC to ensure that the MOE called for by the product of all applicable UFs is not exceeded.

1. *Acute risk.* Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food and water to acetamiprid will occupy 35% of the aPAD for children 1 to 2 years old, the population group receiving the greatest exposure.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to acetamiprid from food and water will utilize 35% of the cPAD for children 1 to 2 years old, the population group with greatest exposure. Based on the use pattern, chronic residential exposure to residues of acetamiprid is not expected.

3. *Short-term risk.* Short-term aggregate exposure takes into account residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

Acetamiprid is currently registered for use that could result in short-term residential exposure and the Agency has determined that it is appropriate to aggregate chronic food and water and short-term exposures for acetamiprid. Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded that food, water, and residential exposures aggregated result in aggregate MOEs of 900 for adults 20 to 49 years old and 930 for adults 50 years and older who apply gel bait acetamiprid products for ant and cockroach control.

4. *Intermediate-term risk.* Intermediate-term aggregate exposure takes into account residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Acetamiprid is currently registered for use that could result in intermediate-term residential exposure and the Agency has determined that it is appropriate to aggregate chronic food and water and intermediate-term exposures for acetamiprid. Since the short-term and intermediate-term dermal exposures and endpoints for acetamiprid are the same, intermediate-term aggregate MOEs for adult residential handlers are the same as the short-term aggregate MOEs reported above (900 to 930).

5. *Aggregate cancer risk for U.S. population.* EPA has classified acetamiprid as "Not likely to be carcinogenic to humans. Acetamiprid is not expected to pose a cancer risk.

6. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children from aggregate exposure to acetamiprid residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate residue analytical methods are available for the enforcement of established and new tolerances for plant commodities (gas chromotography /electron capture detector and high performance liquid chromotography/ ultra violet detection (GC/ECD and HPLC/UV) and animal commodities (HPLC/UV)). These methods may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755–5350; telephone number: (410) 305–2905; e-mail address: *residuemethods@epa.gov.*

B. International Residue Limits

There are no Codex, Canadian or Mexican maximum residue levels (MRLs) established on the commodities associated with these petitions.

C. Response to Comments

Comments were received from a private citizen objecting to establishing these tolerances or any exemptions for acetamiprid or approval of its sale. The commenter objected to acetamiprid residues in food as well as EPA's reliance on animal testing on the basis that animal tests are inhumane and not relevant to human toxicity. The Agency has received these same or similar comments from this commenter on numerous previous occasions. Refer to **Federal Register** 70 FR 37686 (June 30, 2005), 70 FR 1354 (January 7, 2005), and 69 FR 63096 (October 29, 2004) for the Agency's response to these objections.

V. Conclusion

Based upon review of the data supporting the petitions, EPA has modified the proposed tolerances as follows: (1) PP 4F6833: Modified the commodity terms for stone fruit, tree nuts and cucurbit vegetables to agree with recommended commodity terms in the Office of Pesticide Program's Food and Feed Commodity Vocabulary (Fruit, stone, group 12, except plum, prune; Nut, tree, group 14; and Vegetable, cucurbit, group 9); and modified the commodity terms and established separate tolerances for Plum, prune, dried at 0.40 ppm and Plum, prune, fresh at 0.20 ppm (fresh) based on the field trial results showing different residues in the dried and fresh forms. (2) PP 6F7051: Revised the commodity terms and tolerance levels for edible podded legumes and succulent shelled peas and beans to read "Vegetable, legume, edible podded, subgroup 6A" at 0.60 ppm and "Pea and bean, succulent shelled, subgroup 6B" at 0.40 ppm. EPA revised these tolerance levels based on analyses of the residue field trial data using the Agency's Tolerance Spreadsheet in accordance with the Agency's Guidance for Setting Pesticide Tolerances Based on Field Trial Data Standard Operating Procedure (SOP).

EPA is deferring to a later date the decision regarding the proposed tolerances for residues of acetamiprid on bulb vegetables crop group 3 and berry crop group 13.

Therefore, tolerances are established for residues of acetamiprid, N1-[(6-chloro-3-pyridyl)methyl]-N2-cyano-N1-methylacetamidine, in or on Almond, hulls at 5.0 ppm; Fruit, stone, group 12, except plum, prune at 1.20 ppm; Nut, tree, group 14 at 0.10 ppm; Pea and bean, succulent shelled, subgroup 6B at 0.40 ppm; Pistachio at 0.10 ppm; Plum, prune, dried at 0.40 ppm; Plum, prune, fresh at 0.20 ppm; Vegetable, cucurbit, group 9 at 0.50 ppm; and Vegetable, legume, edible podded, subgroup 6A at 0.60 ppm.

VI. Statutory and Executive Order Reviews

This final rule establishes a tolerance under section 408(d) of FFDCA in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Because this rule has been exempted from review under Executive Order 12866, this rule is not subject to Executive Order 13211, *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under section 408(d) of FFDCA, such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply.

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of FFDCA. As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000) do not apply

to this rule. In addition, This rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104–4).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note).

VII. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the **Federal Register**. This final rule is not a "major rule" as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: November 14, 2007.

Donald R. Stubbs,

Acting Director, Registration Division, Office of Pesticide Programs.

■ Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

■ 1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

■ 2. Section 180.578 is amended by alphabetically adding the following commodities to the table in paragraph (a)(1) to read as follows:

§ 180.578 Acetamiprid; tolerances for residues.

(a) *General.* * * *

(1) * * *

Commodity	Parts per million
Almond, hulls	5.0
* * *	* *
Fruit, stone, group 12, except plum, prune	1.20
* * *	* *
Nut, tree, group 14	0.10
Pea and bean, succulent shelled, subgroup 6B	0.40
Pistachio	0.10
Plum, prune, dried	0.40
Plum, prune, fresh	0.20
* * *	* *
Vegetable, cucurbit, group 9	0.50
* * *	* *
Vegetable, legume, edible podded, subgroup 6A	0.60
* * *	* *

[FR Doc. E7–23055 Filed 11–27–07; 8:45 am]

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

DATE: 10/25/07

OFFICE OF PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Acetamiprid: Human Health Risk Assessment for Proposed Food Uses on Stone Fruits, Cucurbit Vegetables, Tree Nuts, Berries, Strawberries, Bulb Vegetables, Legumes (Peas and Beans) and for Residential/Commercial Insecticide/Termiticide Uses.
Regulatory Action: Section 3 Registration
Risk Assessment Type: Single Chemical Aggregate
PC Code: 099050
Petition Nos: 4F6833, 6F7051, 6E7163
DP Barcode: D303171

FROM: Kimberly D. Harper, Toxicology
William Drew, Chemistry
Margarita Collantes and Zaida Figueroa, Occupational and Residential Exposure
Tom Moriarty, Risk Assessment
Registration Action Branch 2
Health Effects Division (7509P)

THROUGH: Christina Swartz, Branch Chief
Richard Loranger, Branch Senior Scientist
Registration Action Branch 2
Health Effects Division (7509P)

TO: Akiva Abramovitch/John Hebert, PM Team 07
Insecticide/Rodenticide Branch
Registration Division (7505P)

Summary: HED has completed a risk assessment for the three petitions (4F6833, 6F7051, and, 6E7163) submitted by Nisso America, and the IR-4 for proposed uses of acetamiprid on stone fruits, tree nuts, cucurbits, legumes (pea and beans), and berry and bulb vegetables. The dietary assessment incorporates exposure from currently registered uses along with those being proposed. The aggregate assessment incorporates estimated dietary (food + water) exposure with residential exposure estimates from currently registered uses. Occupational and residential risk assessments have also been performed for the proposed uses.

Table of Contents

1.0 Executive Summary

Acetamiprid {N1-[(6-chloro-3-pyridyl)methyl]-N2-cyano-N1-methylacetamidine} is a chloronicotinyl insecticide registered to control sucking type insects (e.g., aphids, whitefly, etc.) on a wide variety of crops including cotton, leafy vegetables, fruiting vegetables, and citrus fruits. Tolerances are established for acetamiprid residues in assorted crops and livestock commodities under 40 CFR 180.578. The majority of the agricultural uses are for broadcast foliar spray (via ground or aerial equipment), but there are also registered seed treatment uses on mustard and canola. Ready-to-use, and bait formulations are registered for residential uses. The petitioner, Nisso America Incorporated, is seeking Section 3 registrations for use of acetamiprid on several agricultural crops under the two product labels ASSAIL® 70WP, and Assail® 30SG. HED has also included an assessment of the termiticide/insecticide (product F4688 50WP) for use by commercial operators at residential sites.

The acute toxicity data indicate that acetamiprid is moderately toxic via the oral route and is minimally toxic via the dermal and inhalation routes. Acetamiprid is not an eye or skin irritant, and it is not a dermal senstitizer. The toxicity data base for acetamiprid is complete. Based on subchronic, chronic, developmental and reproductive studies in rats, rabbits, and dogs, acetamiprid does not appear to have specific target organ toxicity. Since the last review of acetamiprid hazard data in 2003, an acceptable developmental neurotoxicity (DNT) study has been submitted and reviewed.

Developmental studies showed no evidence of either quantitative or qualitative susceptibility of the rat or rabbit fetuses from *in utero* exposure. However, both the DNT study and the multi-generation reproduction studies showed an increase in qualitative susceptibility of pups; effects in pups consisted of decreased pup viability, and maternal toxicity consisted of decreased body weight and body weight gain. HED has reduced the FQPA Safety Factor to 1X, because: (i) the endpoints selected for risk assessment are based upon the effects of concern in offspring; (ii) there is a clear NOAEL for the offspring effects; (iii) the toxicology database is complete; and, (iv) HED has no residual uncertainties with regards to pre- and postnatal toxicity. HED has determined that acetamiprid is not likely to be carcinogenic to humans.

With the exception of chronic dietary, HED has chosen the NOAEL (10 mg/kg/day) from the DNT study (LOAEL = 45 mg/kg/day) as the endpoint and dose for dietary, non-occupational and occupational risk assessments for all durations and routes of exposure. For the chronic dietary assessment, HED has chosen the NOAEL (7.1 mg/kg/day) from the chronic toxicity/oncogenicity study (LOAEL = 17.5 mg/kg/day).

HED has refined the dermal penetration value to 10% (from 30% in the previous assessment) based upon a closer examination of structural/chemical characteristics of related compounds. The default 100% absorption factor was used for all inhalation exposure scenarios.

The nature of the residue is adequately understood for both plants and animals, and acceptable method validation has been submitted for all proposed uses. Acceptable residue data have been submitted to support the proposed uses as well as the tolerances recommended at the conclusion of this section. The proposed use on strawberry was part of a joint review with PMRA Canada.

The dietary assessment is partially refined, using field trial data, percent crop-treated values, and

various empirical processing factors. Estimated drinking water concentrations (EDWCs), which are based upon the highest application values of all registered and proposed uses, have been incorporated directly into the dietary exposure model. Both acute and chronic dietary risk estimates for all population subgroups did not indicate a risk of concern. Children 1-2 years old are the highest exposed population subgroup for both acute and chronic exposure scenarios. Acute exposure constituted 35% of the acute population adjusted dose (aPAD), and the chronic exposure constituted 35% of the chronic population adjusted dose (cPAD).

Petition 4F6833 initially included a proposed insecticide/termiticide for use (label F4688 50WSP) in residential sites. Based upon a draft HED assessment, this product was approved in May, 2007. However, since that time new toxicity endpoints have been chosen and, therefore, HED has included these uses in the current assessment. The proposed uses of F4688 Insecticide/Termiticide are to subterranean structural components during construction; subterranean, and hard-to-reach structural components post construction and outdoor perimeter use. Based upon the uses of F4688, HED believes no residential/non-occupational exposures will occur; however, the anticipated occupational exposures were assessed.

Aggregate risk assessments for acute, short-term, and chronic durations were conducted. Residential exposures incorporated into the aggregate assessments were based on currently registered residential uses (ant and cockroach gel bait products). All aggregate assessments indicated no risks of concern (aggregate MOEs $\geq$ 900).

Occupational handler (mixer/loaders, applicators, and flaggers) assessments were conducted for the proposed agricultural uses of acetamiprid. HED's assessment indicated that exposures to occupational handlers were not a risk concern when the personal protective equipment (PPE) specified on the proposed labels was assumed to be worn by the handler. HED identified no post-application risk concerns for the proposed uses on the day of application, and set the restricted entry interval (REI) at 12 hours based upon the acute toxicity categories of acetamiprid.

For the termiticide/insecticide use, HED determined that exposures to licenced certified operators (LCOs) were not of concern when the PPE specified on the label was assumed to be worn by the handler.

Environmental Justice Considerations

Potential areas of environmental justice concerns, to the extent possible, were considered for this human health risk assessment, in accordance with US Executive Order 12898, Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations, http://www.eh.doe.gov/oepa/guidance/justice/eo12898.pdf.

As a part of every pesticide risk assessment, OPP considers a large variety of consumer subgroups according to well-established procedures. In line with OPP policy, HED estimates risks to population subgroups from pesticide exposures that are based on patterns of that subgroup's food and water consumption, and activities in and around the home that involve pesticide use in a residential setting. Extensive data on food consumption patterns are compiled by USDA under the CSFII, and are used in pesticide risk assessments for all registered food uses

of a pesticide. These data are analyzed and categorized by subgroups based on age, season of the year, ethnic group, and region of the country. Whenever appropriate, non-dietary exposures based on home use of pesticide products, associated risks for adult applicators, and for toddlers, youths, and adults entering or playing on treated areas post-application are evaluated. Further considerations are currently in development as OPP has committed resources and expertise to the development of specialized software and models that consider exposure to bystanders and farm workers as well as lifestyle and traditional dietary patterns among specific subgroups.

Review of Human Research

This risk assessment relies in part on data from studies in which adult human subjects were intentionally exposed to a pesticide or other chemical. These studies, which comprise the Pesticide Handlers Exposure Database (PHED), have been determined to require a review of their ethical conduct, and have received that review. The studies in PHED were considered appropriate (or ethically conducted) for use in risk assessments

1.1 Summary of Recommendations (see also Section 10.0)

- Current labels for use on berries, bulb vegetables, edible podded legume vegetables, succulent shelled beans, and peas, or strawberries and other low-growing berries should be amended to remove directions regarding the use of surfactants.

- The tolerance expression proposed in Section F of PP#6E7163 by IR-4 with respect to strawberry, bearberry, bilberry, blueberry (lowbush), cloudberry, cranberry, lingonberry, muntries, and partridgeberry should be revised to exclude the word "combined."

- HED recommends the establishment of acetamiprid tolerances listed in Appendix D, Table 1.

- HED recommends the establishment of Section 3 registrations for the proposed uses of the subject petitions.

- Dermal absorption data from other neonicitinoids (thiamethoxam, and clothianidin) was used to refine the dermal absorption factor for acetamiprid. HED recommends that RD consider whether any data compensation issues are associated with this refinement.

1.2 Summary of Proposed Uses

Table 1 below summarizes the uses associated with the subject petitions.

Table 1. Summary of Subject Petitions and Proposed Uses for Acetamiprid					
PP #	**Petition Description**	**Product Description**	**Use Sites**	**Single Max App. Rate (lb a.i./A)**	**Application Characteristics**
4F6833	New Uses on: cucurbit vegetables (crop group 9) stone fruit (crop group 12) tree nuts (crop group 14)	ASSAIL® 70WP 70% ai EPA Reg. No: 8033-23 ASSAIL® 30 SG 30% a.i. EPA Reg No. 8033-36	Stone fruit	0.050 - 0.15	4 apps/season; 10 day treatment interval; 7 day PHI[1]; Max seasonal rate = 0.6 lb ai/A aerial and ground spray
			Cucurbits	0.050 – 0.10	5 apps/season; 5 day treatment interval; 0 day PHI; Max seasonal rate = 0.5 lb ai/A aerial and ground spray
			Tree nuts	0.050 – 0.18	4 apps/season; 7 day treatment interval; 14 day PHI; Max seasonal rate = 0.72 lb ai/A aerial and airblast spray
	New Uses for Residential Pest Control (These new uses were not officially part of PP# 4F6833 but were assessed at the time PP# 4F6833 was originally submitted for review.)	F4688 50 WSP Insecticide/Termiticide 22.73 % ai EPA Reg. No.:8033-96 For Commercial Use in Residential/ Commercial Settings (also includes Bifenthrin as an active ingredient.)	outdoor pest	0.0043 lbs ai/gal	Apply to a band of soil and vegetation 3 feet wide and 2-3 feet height around and adjacent to the structure. Do not apply to lawn or turf. Apply no more than 1 bag (0.3 oz) per 1,000 ft^2 handgun sprayer; low pressure spray or paint brush; sprinkling can; hose-end sprayer
			ant control	0.0043 lbs ai/gal	sprinkling can; handgun sprayer; low pressure spray or paint brush; hose-end sprayer or injection Do not apply outside 3 feet perimeter around structures, do not apply to lawn or turf For ant mound treatment. Apply no more than 1 bag (0.3 oz) per 1,000 ft^2
			termiticide	0.0043 lbs ai/gal	Control of subterranean termite infestations. For pre-construction termite control applications shall be made by low pressure sprayer. For post-construction termite control applications made by injection.
6F7051	New Uses on: berries (crop group 13) bulb vegetables (crop group 3) edible podded legumes (crop group 6A) succulent shelled peas and beans (crop group 6B)	ASSAIL® 70WP 70% ai EPA Reg. No: 8033-23 ASSAIL® 30 SG 30% a.i. EPA Reg No. 8033-36	berries	0.044 – 0.10	5 apps/season; 7-day treatment interval; Max seasonal rate = 0.5 lb ai/acre aerial and ground spray
			bulb vegetables	0.094 – 0.15	4 apps/season; 7-day treatment interval; Max seasonal rate = 0.6 lb ai/acre aerial and ground spray
			legumes, peas and beans	0.044 – 0.1	3apps/season; 7-day treatment interval; Max seasonal rate = 0.3 lb ai/acre aerial and ground spray
6E7163	Strawberry and other low growing berries	ASSAIL® 70WP 70% ai EPA Reg. No: 8033-23 ASSAIL® 30 SG 30% a.i. EPA Reg No. 8033-36	Strawberries and other low growing berries	0.044 – 0.10	5 apps/season; 7-day treatment interval; Max seasonal rate = 0.5 lb ai/acre aerial and ground spray

1: PHI = pre-harvest interval

2.0 Ingredient Profile

Acetamiprid {N1-[(6-chloro-3-pyridyl)methyl]-N2-cyano-N1-methylacetamidine} is an insecticide that falls into the chloronicotinyl class of compounds. It has a molecular weight of 222.68 Daltons and is not volatile (vapor pressure = 7.5×10^{-9} Torr at 25°C; Henry's Law Constant = $5.17\ x10^{-11}$ atm M^3/mole at 25°C). Acetamiprid is quite soluble in water (4.25 g/L) as well as organic solvents (>200 g/L in ethanol, acetone, and dichloromethane). The log K_{OW} of acetamiprid is 0.8. Based on these data, acetamiprid vapors should not present a significant inhalation risk and this compound is not expected to concentrate in fatty tissues. Technical-grade acetamiprid does not contain impurities of known or potential toxicological concern. The nomenclature and physiochemical properties of acetamiprid are presented below in Tables 2 and 3.

Table 2. Test Compound Nomenclature

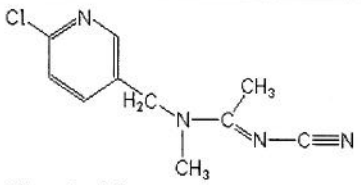
Compound	 **Chemical Structure**
Common Name	**Acetamiprid**
Company Experimental Name	**EXP-61842A, AEF124370, NI-25**
IUPAC Name	**(*E*)-N^1-[(6-chloro-3-pyridyl)methyl]-N^2-cyano-N^1-methylacetamidine**
CAS Name	**(1*E*)-*N*-[(6-chloro-3-pyridinyl)methyl]-*N'*-cyano-*N*-methylethanimidamide**
CAS #	**135410-20-7**
End-Use Product	**Assail® 70WP, Assail® 30SG, F4688 50WSP**
Chemical Name of Acetamiprid Metabolite IM-2-1	**N^1-[(6-chloro-3-pyridyl)methyl]-N^2-cyano-acetamidine**
Chemical Name of Acetamiprid Metabolite IM-2-1-amide (also referred to as IM-2-2)	**N^2-aminocarbonyl-N^1-[(6-chloro-3-pyridyl)methyl]acetamidine**

Table 3. Physicochemical Properties of Acetamiprid	
Parameter	**Value**
Melting Point/Range (°C)	98.9
pH (20°C)	6.08 (Aqueous Solution)
Density (20°C)	1.33 g/cm^3
Water Solubility (25°C)	4.25 g/L
Solvent Solubility (25°C) in: Acetone Ethanol Dichloromethane n-Hexane	 >20 g/100 g >20 g/100 g >20 g/100 g 6.54 ppm
Vapor Pressure (mm Hg)	7.5×10^{-9}
Dissociation Constant (pK_a)	0.7
Octanol/Water Partition Coefficient, Log K_{OW} (20°C)	0.8
UV/Visible Absorption Spectrum	(Not Available)

3.0 Hazard Characterization/Assessment

Since HED's last hazard assessment of acetamiprid in 2003, a DNT study has been received and reviewed. The toxicity data base is complete for the purpose of human health risk assessment.

3.1 Hazard Characterization

The scientific quality of the toxicology database is high and the toxicity profile can be characterized for all effects, including potential developmental, reproductive, carcinogenic, and neurotoxic effects. The acute toxicity data indicate that acetamiprid is moderately toxic via the oral route (Toxicity Category II) and is minimally toxic via the dermal and inhalation routes (Toxicity Category III). Acetamiprid is not an eye or skin irritant, nor is it a dermal sensitizer.

Acetamiprid does not appear to have specific target organ toxicity. In all species tested, generalized nonspecific toxicity was observed as decreases in body weight, body weight gain, food consumption and food efficiency when determined. Generalized effects were also observed in the liver in the form of hepatocellular hypertrophy in both mice and rats and hepatocellular vacuolation in the rat. Hepatocellular hypertrophy was observed in the rat subchronic feeding study at doses of 50 mg/kg/day and above, and in the rat chronic feeding study at doses of 17.5 mg/kg/day and above at both the 12-month sacrifice as well as at study termination. In mouse studies, hepatocellular hypertrophy was observed at 430 mg/kg/day at 90 days and at 186 mg/kg/day at 12 and 18 months. These effects are considered to be adaptive. Hepatocellular

vacuolation was observed at 17.5 mg/kg/day in the rat chronic study. In light of the lack of major liver effects in the rat studies, it is likely that the vacuolization is more related to liver activity in response to the presence of the chemical rather than frank toxicity. Other effects observed in the oral studies include amyloidosis of multiple organs in the mouse oncogenicity study, tremors in high dose females in the mouse subchronic study, and microconcretions in the kidney papilla and mammary hyperplasia in the rat chronic feeding/oncogenicity study.

No effects were observed in the 21-day dermal study in the rabbit and no inhalation studies were conducted.

A dermal absorption study with acetamiprid was conducted using male rats with exposure durations of 0.5, 1, 2, 4, 10 and 24 hours. Measured absorption was small and increased with duration of exposure. The quantity absorbed also generally increased with dose. In the previous acetamiprid risk assessment, the highest dermal absorption value (6.34% at 24 hours) was added to the residue remaining on the skin at 24 hours (25%) to estimate a 30% dermal absorption value. However, HED has refined the dermal absorption value (to 10%) based upon comparison to clothianidin, which is structurally related. HED believes that a refined dermal penetration value for acetamiprid of 10% is reasonable and protective. See Section 3.4.3 for more details.

There is no quantitative or qualitative evidence of increased susceptibility of rat or rabbit fetuses to *in utero* exposure in the developmental studies. In the rat, an increase in the incidence of shortening of the 13th rib was observed in fetuses at the same LOAEL as the dams. Maternal effects included reduced mean body weight, body weight gain and food consumption and increased liver weights. No developmental toxicity was observed in the rabbit fetuses at dose levels that induced maternal effects including body weight loss and decreased food consumption.

In the multi-generation reproduction study, qualitative evidence of increased susceptibility of rat pups was observed. The parental and offspring systemic NOAELs were 17.9/21.7 (M/F) mg/kg/day and the offspring/parental systemic LOAELs were 51.0/60.1 mg/kg/day based on a decrease in mean body weight, body weight gain, and food consumption in the parents and significant reductions in pup weights in both generations. Also observed was reduction in litter size, and viability and weaning indices among F_2 offspring as well as significant delays in the age to attain vaginal opening and preputial separation in the offspring. These offspring effects were considered to be more severe than the parental effects.

In the DNT study there was evidence of increased qualitative susceptibility. The purpose of the DNT study is to evaluate the potential functional and morphological effects to the nervous system which may arise in the offspring from exposure of the mother during pregnancy and lactation. It provides data on sensorimotor function and on habituation which is considered to be a simple form of learning. In the acetamiprid DNT, the offspring NOAEL was 10 mg/kg/day based on decreased body weights and body weight gains in males and females, decreased pre-weaning survival (PND 0-1), and decreased maximum auditory startle response in males on PND 20 and PND 60, at the LOAEL of 45 mg/kg/day. Although there were reductions in the maximum auditory startle response in the 10 mg/kg/day in males on PND 20 and PND 60, the mean response was within the range of historical control means and standard deviations among other DNT studies conducted (by the same laboratory) within a 5-year span of the Acetamiprid

DNT study. HED noted that statistical significance could only be achieved by combining data for both sexes at both time points (PND 20, and PND 60). Agency scientists agreed that it was appropriate to combine the data for the sexes, but there was no definitive consensus regarding combining the data from the different time points. The discussion regarding the combining the data from the two time points centred around the equipment used to measure the auditory startle reflex, and how it is calibrated differently to account for increases in body weight as the animals grow. Based upon the analysis of the DNT, technical arguments submitted by the registrant, and consideration of all other data in the acetamiprid toxicity profile, HED believes that the decrease in maximum startle response in males is only treatment related only at the high-dose level of 45 mg/kg/day.

In the acute neurotoxicity study, decreased locomotor activity was seen in both sexes post dosing at 30 mg/kg/day. HED has low confidence in the locomotor activity data presented in the DNT study due to problems with the controls. The decreased auditory startle response in males in conjunction with the decreases in pup body weight and body weight gains and decreased pup viability lead the Agency to a weight-of-evidence LOAEL determination of 45 mg/kg/day. For a more detailed discussion of the DNT study refer to the DNT DER (MRID 46255619) and cover memo entitled Acetamiprid: Data Evaluation Record for Acetamiprid Developmental Neurotoxicity Study and EPA Response to Rebuttals Submitted by Nisso America, (TXR 0054508). The decrease in auditory startle response observed in pups occurred in the presence of maternal toxicity. However, the maternal toxicity observed in this study was restricted to decreased body weight and body weight gains during gestation only. The decreased pup viability at 45 mg/kg/day is considered to be more severe than the maternal effects. Other maternal effects observed in the DNT included a dose-related increased incidence of clinical signs including hair loss, dried red material and scabbing on the forelimbs as well as animals wiping their mouths/burying their heads in the bedding post- dosing. These clinical signs began during gestation but were of unknown toxicological significance and were not used to determine the study NOAEL/LOAEL.

In an acute rat neurotoxicity study, a decrease in locomotor activity was observed in both sexes on the day of dosing. A slight decrease in the duration of movements persisted in some males on days 7 and 14. Functional observational battery evaluations revealed several treatment-related observations on the day of dosing. High-dose males exhibited tremors, difficulty in handling, walking on toes, dilated pupils and coldness to the touch. High-dose males also had decreased forelimb grip strength and hind limb foot splay. High-dose females displayed tremors, chewing, coldness to the touch, and dilated pupils. High-dose females had decreased hind limb foot splay and were seen to have abnormal gaits and/or posture, including walking on toes and hunched posture. However, in a subchronic rat neurotoxicity study, the only effects observed were related to decreases in body weight/body weight gain, food consumption and food efficiency. No neuropathology was observed in any of the three neurotoxicity studies. Tremors in high dose female mice in the subchronic feeding study were the only other potentially neurotoxic effects observed in any other studies.

Acetamiprid tested negative in a *Salmonella typhimurium* (Ames) assay, a forward mutation assay in Chinese hamster ovary cells, an *in vivo* chromosome aberration assay in Sprague-Dawley (CD) rats, a mouse micronucleus assay, and in repeat assays for unscheduled DNA

synthesis (UDS) in rat liver primary cell cultures. Acetamiprid tested positive as a clastogen in an *in vitro* mammalian chromosome aberration assay in Chinese hamster ovary (CHO) cells. However, the *in vivo* chromosomal aberration study does not support the results of the *in vitro* study. All acetamiprid metabolites tested were negative for mutagenicity.

As stated previously, acetamiprid does not appear to have specific target organ toxicity. Generalized non-specific toxicity was observed in subchronic and chronic studies as decreases in body weight, body weight gain, food consumption and food efficiency when estimated, and hepatocellular hypertrophy as well as hepatocellular vacuolation, which are likely to be related to pharmacological activity rather than frank toxicity. Two studies in which the toxicological effects are more significant are the multigeneration reproduction study and the developmental neurotoxicity study. In the two-generation reproduction study, delays in preputial separation, vaginal opening and pinna unfolding and reduced litter size, viability and weaning indices were observed at dose levels where only reduced body weight and food consumption were observed in the parents, indicating increased qualitative susceptibility in the pups exposed *in utero*. Similar offspring effects were observed in the DNT where offspring exposed *in utero* and/or post-natally showed signs of decreased body weight and body weight gains in males and females, decreased pup viability and decreased maximum auditory startle response in males on PND 20 and PND 60. These effects were seen in the presence of decreased body weight and body weight gains in the maternal animals. The decrease in pup viability is considered more severe than the maternal effects; therefore, there is evidence of increased qualitative susceptibility in the DNT study.

3.2 FQPA Hazard Considerations

3.2.1 Adequacy of the Toxicity Database

The acetamiprid data base is adequate to characterize potential pre- and/or postnatal risk for infants and children. Acceptable guideline studies for developmental and reproductive toxicity are available for FQPA assessment. The registrant has also submitted an acceptable DNT study (MRID 46255619) to the Agency in 2004.

3.2.2 Determination of Susceptibility

HED determined that neither quantitative nor qualitative evidence of increased susceptibility of fetuses to *in utero* exposure to acetamiprid was observed in either the developmental toxicity study in rat, or in rabbit. However, in the multigeneration reproduction study, qualitative evidence of increased susceptibility of rat pups was observed. While parental and offspring NOAELs and LOAELs are set at the same doses (17.9 and 51.0 mg/kg/day, respectively), the effects in the offspring are considered to be more severe than the parental effects. Likewise, in the DNT study maternal and offspring effects were observed at the same dose (45 mg/kg/day). However, the offspring effects included decreased pup viability which is considered to be more severe than the maternal body weight effects. Therefore, HED concluded that there was evidence of increased qualitative susceptibility to fetuses exposed *in utero* and/or during lactation in the DNT study. Quantitative evidence of increased susceptibility was not observed in any study.

3.2.3 Degree of Concern Analysis and Residual Uncertainties

Since there is evidence of increased qualitative susceptibility of the young following *in utero* exposure to acetamiprid in the rat reproduction study, and increased qualitative susceptibility to pups in the DNT study, HED performed a degree of concern analysis to: 1) determine the level of concern for the effects observed when considered in the context of all available toxicity data; and, 2) identify any residual uncertainties after establishing toxicity endpoints and traditional uncertainty factors to be used in the acetamiprid risk assessment. If residual uncertainties are identified, HED examines whether the residual uncertainties can be addressed by a FQPA safety factor, and if so, what factors should be retained.

Considering the overall toxicity profile and the endpoints and doses selected for the acetamiprid risk assessment, HED characterized the degree of concern for the effects observed in the acetamiprid DNT study as *low*, noting that there is a clear NOAEL for the offspring effect, the toxicology database is complete, and regulatory doses were selected to be protective of potential offspring effects. No other residual uncertainties were identified. Based on the available data, HED determined that changes in motor activity, auditory startle reflex, learning and memory assessments, and even changes in the brain morphometrics can occur as the result of a single exposure at a critical junction during pregnancy or from multiple exposures throughout pregnancy and lactation. Therefore, the NOAEL for offspring effects observed in the DNT was selected as the dose for acute dietary exposures (co-critical with the acute neurotoxicity study), as well as, short-term and long-term non-dietary risk assessment. The chronic dietary study in rats yielded a lower long-term NOAEL (7.1 mg/kg/day) and will be used for assessing chronic dietary risk. HED believes that the endpoints and doses selected for acetamiprid are protective of adverse effects in both offspring and adults.

3.3 FQPA Safety Factor(s) For Infants and Children

HED has determined that no additional FQPA safety factor is needed for acetamiprid (i.e. the Safety Factor has been reduced to 1X) for the following reasons: (1) the toxicology database is complete; (2) HED is regulating based upon the effects of concern, i.e., developmental effects in pups following pre-and/or post-natal exposure; (3) the rat appears to be the most sensitive species tested, and the NOAEL and LOAEL selected from the DNT study in rats are protective of effects observed in other species throughout the toxicology database; and, (4) there are no residual uncertainties for pre- and/or post-natal toxicity. The recommended FQPA safety factor also reflects HED's conclusion that the exposure databases (dietary food, drinking water, and residential) are complete and that the risk assessment for each potential exposure scenario includes all metabolites and/or degradates of concern and does not underestimate the potential risk to infants or children.

3.4 Hazard Identification and Toxicity Endpoint Selection

3.4.1 Acute Dietary Endpoint

Study Selected: Developmental Neurotoxicity Study in Rats
MRID No.: 46255619

Executive Summary: In a developmental neurotoxicity study (MRID 46255619), Acetamiprid (>99% a.i., lot # NNI-03) was administered to 25 mated female Crl:CD®(SD)IGS BR rats/dose by gavage at doses of 0, 2.5, 10 and 45 mg/kg/day from gestation day (GD) 6 through lactation day (LD) 21 in a volume of 5 mL/kg body weight. A Functional Operational Battery (FOB) was performed on 10 dams/dose on GDs 6 and 12, and on LDs 4 and 7. On postnatal day (PND) 4, litters were culled to yield four males and four females (as closely as possible). Offspring were allocated for FOB and assessment of motor activity, auditory startle reflex habituation, learning and memory, and neuropathology at study termination (day 72 of age). On postnatal day 11, the whole brain was collected from 10 pups/sex/dose group for micropathologic examination and morphometric analysis. Pup physical development was assessed by body weight. The age of sexual maturation (vaginal opening in females and preputial separation in males) was assessed.

In the dams, no systemic toxicity was seen at the doses tested. The maternal toxicity observed was restricted to decreased body weight and body weight gains during gestation at the LOAEL of 45 mg/kg/day (NOAEL 10 mg/kg/day).

Treatment-related effects in the offspring at the high dose (45 mg/kg/day) include decreased body weights, and body weight gains in males and females post-weaning, decreased pup viability and decreased maximum auditory startle response in males on PND 20 and PND 60. Treatment had no adverse effects on clinical signs, developmental landmarks, FOB, brain weight or brain morphology. There is low confidence in the motor activity data because of problems with the control data (i.e. the normal developmental pattern was not seen in control animals). Therefore, no conclusions could be made on motor activity evaluation. The maximum auditory startle response amplitude was decreased 27% (PND 20) and 40% (PND 60) at 10 mg/kg/day, and it was decreased 42% (PND 20) and 53% (PND 60) at 45 mg/kg/day; only the decreased maximum auditory startle response in the 45 mg/kg/day males (PND 20 and PND 60) was considered treatment related. No conclusions can be made on the effects of acetamiprid on learning and memory because of the high variability in the data.

The offspring LOAEL is 45 mg/kg/day based on decreased body weights and body weight gains in males and females, decreased pre-weaning survival (PND 0-1), and decreased maximum auditory startle response in males on PND 20 and PND 60. The offspring NOAEL is 10 mg/kg/day.

ACN Executive Summary: In an acute neurotoxicity study (MRID 44651842), groups of fasted male and female Crl:CD-BR rats (10/sex/dose), were given a single oral dose of acetamiprid (99.9%) by gavage, in 0.5% sodium carboxymethylcellulose at doses of 0, 10, 30, or 100 mg/kg bw and observed for 14 days. There were no mortalities during the study. Body weight gain, food consumption, and food efficiency were unaffected in females. Treatment with acetamiprid had no effect on brain size or weight and there was no evidence of neuropathology. Clinical

signs of toxicity were limited to the high-dose animals, and included tremors, hunched posture, unsteady gait and coldness to touch. In addition, one high-dose female had slight brown nasal staining from study day 2 until termination.

High-dose males and females had significantly reduced body temperature on the day of dosing. Significantly decreased motor activity was observed in the mid- and high-dose males and in high-dose females on the day of dosing. A slight decrease in the duration of movements persisted in mid- and high-dose males on days 7 and 14. Functional observational battery evaluations revealed several treatment-related observations on the day of dosing. High-dose males exhibited tremors, difficulty in handling, walking on toes, dilated pupils and coldness to touch. High-dose males also had decreased forelimb grip strength and hind limb foot splay. High-dose females displayed tremors, chewing, coldness to touch, and dilated pupils. High-dose females had decreased hind limb foot splay. High-dose females were seen to have abnormal gaits and/or posture, including walking on toes and hunched posture.

The LOAEL for neurotoxicity was 30 mg/kg bw, based on the observed reduction in locomotor activity in males. The NOAEL for neurotoxicity was 10 mg/kg bw.

Dose and Endpoint for Risk Assessment: NOAEL = 10 mg/kg/day based on decreased body weights and body weight gains in males and females, decreased pre-weaning survival (PND 0-1), and decreased maximum auditory startle response in males on PND 20 and PND 60 of the DNT study at 45 mg/kg/day, as well as, decreased locomotor activity in males in the ACN study at 30 mg/kg bw.

Comments about Study/Endpoint/Uncertainty Factors: These endpoints and dose were selected because 1) the oral route of exposure is relevant to dietary risk assessment, 2) the duration of exposure is relevant to acute dietary risk (both endpoints can be considered the result of a single dose), and 3) they are protective of potential offspring effects. Based on the available data, HED determined that changes in motor activity, auditory startle reflex, learning and memory assessments, and changes in the brain morphometrics can occur as the result of a single exposure at a critical junction during pregnancy or from multiple exposures throughout pregnancy and lactation. The standard uncertainty factors (100x) were applied to all dietary exposure scenarios (10x for intraspecies variability and 10x for interspecies extrapolation).

3.4.2 Chronic Dietary Endpoint

Studies Selected: Chronic/Oncogenicity Study in the Rat
MRID Nos.: 44988429, 45245304

Executive Summary: In a chronic toxicity/oncogenicity study (MRID 44988429 & 45245304), acetamiprid, [NI-25 (>99% a.i.; Lot No. NNI-01)] was administered to groups of 60 male and 60 female Crl-CD®BR rats in the diet at concentrations of 0, 160, 400, and 1000 ppm (0, 7.1, 17.5, and 46.4 mg/kg/day for males and 0, 8.8, 22.6, and 60 mg/kg/day for females). Ten rats per sex per dose were sacrificed at 12 months for interim evaluations; the remaining animals were maintained on their respective diets for up to 24 months.

There were no treatment-related effects on mortality; eyes; hematology, clinical chemistry or

urinalysis parameters; or gross findings in either sex administered any dose of the test material. Clinical signs that were observed at significantly increased incidences in treated animals included rales in high dose males (7/48 vs 0/46 for controls) during weeks 66-78 and at all doses in males during weeks 79-91 (0/44, 8/49, 19/45, and 17/48 at 0, 160, 400, and 1000 ppm, respectively). Also in high-dose male rats, the incidences of labored breathing (15/48 vs 5/46 for controls, $p<0.05$) was increased during weeks 66-78, red material around the nose during weeks 1-13 (7/60 vs 0/60 for controls) and weeks 92-104 (5/46 vs 0/37), and hunched posture (5/46 vs 0/37) during weeks 92-104. The lack of pathologic correlates indicates that the clinical signs are not biologically significant.

Treatment-related effects on body weight, body weight gain, and food consumption were observed in both sexes. High-dose male rats, weight 10-13% ($p<0.01$) less than controls throughout the study, gained 44%less weight during week 1, 14% less during the first year and 18% less over the entire study. High-dose group males also consumed 19% ($p<0.01$) less food (g/animal/day) during week 1 and 4-9% ($p<0.01$ or <0.05) less at different time points during the remaining weeks of the study. Food efficiency measured during the first 14 weeks was reduced for males in all dose groups during the first week of the study and showed an inconsistent pattern for the remaining 13 weeks. Mid-dose female rats weighed 4-17% ($p<0.01$) less than controls throughout the study and high-dose females weighed 6-27% ($p<0.01$) less. Mid- and high-dose group females, respectively, gained 27 and 42% less weight than controls during week 1, 15% and 32% less during the first year, and 16% and 23% less over the entire study. Food consumption was 6-10% and 9-19% less for mid- and high-dose group females, respectively, for most of the study. Food efficiency was reduced for mid- and high-dose group females during week 1 and showed inconsistent patterns for the remaining 13 weeks.

The postmortem examination showed statistically significant changes in absolute and/or relative weights of several organs in high-dose group male and female rats, and these changes are attributed to the decreased terminal body weight. Treatment-related microscopic changes were observed in the liver, kidney, and mammary glands. Trace to mild hepatocyte hypertrophy in the liver of mid- and high-dose male rats and high-dose female rats at interim sacrifice and in the main study groups is considered an adaptive response rather than an adverse effect. Hepatocyte vacuolation also was observed in mid- and high-dose group male rats; the incidence was 10/12 and 10/11, respectively, compared with 2/12 for controls at interim sacrifice and 22/48 and 29/48, respectively, compared with 10/48 for the controls in the main study. An increased incidence of microconcretions in the kidney papilla was noted for high-dose male rats (37/49 vs 17/48 for controls, $p<0.01$) in the main study. The incidence of 24/49 ($p<0.05$) for mammary hyperplasia in high-dose group females compared with 14/49 for controls appeared to be treatment related, but the toxicologic significance of this finding is uncertain.

The lowest-obeserved-adverse-effect-level (LOAEL) for acetamiprid is 400 ppm (17.5 mg/kg/day for males and 22.6 mg/kg/day for females) for male and female rats based on reduced body weight and body weight gains for females and hepatocellular vacuolation for males. The no-observed-adverse-effect-level (NOAEL) is 160 ppm (7.1 mg/kg/day for males and 8.8 mg/kg/day for females)

Dose and Endpoint for Risk Assessment: NOAEL = 7.1 mg/kg/day based on decreased body weights and body weight gains in females and hepatocellular vacuolation in males observed at the LOAEL of 17.5 mg/kg/day.

Comments about Study/Endpoint/Uncertainty Factors: This endpoint and dose was selected because: 1) the oral route of exposure is relevant to dietary risk assessment, 2) the duration of exposure is relevant to chronic risk scenarios, and 3) it is the lowest endpoint in the toxicology database and is therefore protective of both chronic and potential offspring effects. The standard uncertainty factors were applied to all dietary exposure scenarios (10x for intraspecies variability and 10x for interspecies extrapolation).

3.4.3 Dermal Absorption

In the previous risk assessment (3/11/2002; D263648), HED used a 30% dermal penetration value derived from an acetamiprid dermal penetration study in rats (MRID 44651858), in which multiple doses were tested for durations ranging from 0.5 to 24 hours. To arrive at the 30% value, HED added the highest dermal absorption value (6.34%) to the amount sequestered in the skin at 24 hours (approximately 25%). To validate this estimate and determine whether further refinement was needed, HED reexamined the dermal penetration study with acetamiprid, and reviewed the dermal penetration information of several other neonicitinoid insecticides.

To refine its assumption regarding treatment of sequestered acetamiprid on the skin, HED looked at the amount of radioactivity remaining at the application site. The amount of radiolabeled material remaining at the application site at various intervals varied between 0–5% percent between time points. If the radioactivity remaining at the application site is added to that which is absorbed, a maximum penetration value for acetamiprid would be 11%. However, since the duration of the acetamiprid study was only 24 hours, HED examined the thiamethoxam dermal penetration study, another neonicitinoid, which was terminated after 336 hours (14 days). Results from that study indicate little additional absorption (1 – 3%) occurred between 24 hours post dosing and 14 days post dosing.

HED also considered the K_{ow} and octanol/water coefficient data of other neonicitinoid compounds, and found acetamiprid is most closely related to clothianidin with respect to its log K_{ow} and octanol/water coefficient, and therefore would likely act most similarly to clothianidin when applied to the skin. The dermal penetration value for clothianidin (1%) is based upon dermal penetration study with monkeys. See Table 4 below.

Table 4. Absorption Parameters for Selected Neonicitinoids.

Compound	Log K_{ow}	Octanol/Water Coefficient	Dermal Penetration Value
Acetamiprid	0.8	6.3	30% (dermal penetration study with rat)
Clothianidin	0.9	8	1% (dermal penetration study in monkeys)

Adjustment of the monkey dermal penetration value for clothianidin to account for the 2-10 fold increased dermal sensitivity of rats compared to humans (dermal penetration of monkey is considered equivalent to human) would yield a comparative rat dermal penetration value for acetamiprid of 2% – 10%. Likewise, if the current dermal penetration value for acetamiprid is adjusted downward to account for the increased sensitivity of rats to humans, then a value of 10% - 15% results. Since the acetamiprid study shows 6% dermal penetration at 24 hours, a refined dermal penetration value reflecting a longer dermal exposure, would likely be greater than 6%, and may lie between 10 -15 %.

Based upon its reconsideration of the acetamiprid dermal penetration study, and on comparison of acetamiprid to the structurally related clothianidin, HED determined that a refined dermal penetration value for acetamiprid of 10% is reasonable and protective. Based upon this, HED would not require any additional dermal penetration data for acetamiprid.

3.4.4 Short- and Intermediate-Term Dermal Endpoints

Study Selected: Developmental Neurotoxicity Study in Rats
MRID No.: 46255619

Executive Summary: see Section 4.3.1

Dose and Endpoint for Risk Assessment: NOAEL = 10 mg/kg/day based on decreased body weights and body weight gains in males and females, decreased pre-weaning survival (PND 0-1), and decreased maximum auditory startle response in males on PND 20 and PND 60 of the DNT study at 45 mg/kg/day, as well as decreased locomotor activity in males in the ACN study at 30 mg/kg bw.

Comments about Study/Endpoint/Uncertainty Factors: The NOAEL and LOAEL from the DNT study were selected for dermal risk assessment because they are protective of developmental effects present in rat pups seen in the presence of less severe maternal effects at similar doses. Although a dermal (route specific) toxicity study in rabbits was submitted, no effects were seen at the highest dose tested of 1000 mg/kg/day. Use of the route-specific study for dermal risk assessment would not be protective of the offspring effects observed in both the DNT, and the multigeneration reproduction studies because the effects seen could occur as a result of a single exposure at a critical junction during pregnancy or from multiple exposures throughout pregnancy lactation. Therefore, the NOAEL for offspring effects observed in the DNT was selected as the dose for both short-term, and intermediate-term dermal exposure scenarios. The standard uncertainty factors were applied to all exposure scenarios (10x for intraspecies variability and 10x for interspecies extrapolation).

3.4.5 Short- and Intermediate-Term Inhalation Endpoints

Study Selected: Developmental Neurotoxicity Study in Rats
MRID No.: 46255619

Executive Summary: see Section 4.3.1

Dose and Endpoint for Risk Assessment: NOAEL = 10 mg/kg/day based on decreased body weights and body weight gains in males and females, decreased pre-weaning survival (PND 0-1), and decreased maximum auditory startle response in males on PND 20 and PND 60 of the DNT study at 45 mg/kg/day, as well as, decreased locomotor activity in males of the ACN study at 30 mg/kg bw.

Comments about Study/Endpoint/Uncertainty Factors: No route-specific information is available for the inhalation toxicity of acetamiprid. In the absence of a route-specific study, the NOAEL and LOAEL from an oral study, along with an inhalation absorption factor (100%), are used to estimate inhalation exposure and the associated risk. In this case, the NOAEL and LOAEL from the DNT study were selected because the duration is appropriate for short- and intermediate-term exposures and it is protective of potential effects in offspring. Because effects seen in the DNT can occur as the result of a single exposure at a critical junction during pregnancy or from multiple exposures throughout pregnancy and lactation, the NOAEL for offspring effects observed in the DNT was selected as the dose for both short- and intermediate-term inhalation exposure scenarios. The standard uncertainty factors were applied to all exposure scenarios (10x for intraspecies variability and 10x for interspecies extrapolation).

Based upon the proposed use patterns, HED dose not anticipate any long-term dermal or inhalation exposure scenarios. Therefore, no long-term dose/endpoints were selected.

3.4.6 Level of Concern for Margin of Exposure (MOE)

Table 5. Level of Concern for Margin of Exposure*

Route	Short-Term (1-30 Days)	Intermediate-Term (1-6 Months)	Long-Term (> 6 Months)
Occupational (Worker) Exposure			
Dermal	100	100	N/A
Inhalation	100	100	N/A
Residential Exposure			
Dermal	100	100	N/A
Inhalation	100	100	N/A
Incidental Oral	100	100	N/A

* The level of concern is based upon a 10X intra-species variability factor, and a 10X inter-species extrapolation factor.

3.4.7 Recommendation for Aggregate Exposure Risk Assessment

The FQPA requires that HED aggregate pesticide exposures from the three major exposure routes (oral, dermal, and inhalation) when there is potential residential exposure to a pesticide. HED has chosen a single endpoint and dose from the DNT study as the appropriate endpoint for

all exposure scenarios and all durations for acetamiprid, with the exception of chronic dietary exposure. Therefore, short-, and intermediate-term dermal, oral and inhalation exposures can be combined and aggregated with the dietary (food + water) exposures.

3.4.8 Classification of Carcinogenic Potential

HED has determined that acetamiprid is not likely to be carcinogenic to humans (EPA Draft Guidelines for Carcinogen Risk Assessment; July, 1999). The classification is based on the absence of a dose-response and the lack of a statistically significant increase in the mammary adenocarcinoma incidence by pair-wise comparison of the mid- and high- dose groups with the controls; although the incidence exceeded the historical control data from the same laboratory, it was within the range of values from the supplier.

Table 6. Summary of Toxicological Doses and Endpoints of Acetamiprid for Use in Dietary and Non-Occupational Human Health Risk Assessment				
Exposure Scenario	**Dose Used in Risk Assessment**	**Uncertainty Factors/FQPA Safety Factors**	**RfD, PAD Level of Concern for Risk Assessment**	**Study and Toxicological Effect**
Acute Dietary general population including infants and children	NOAEL[1] = 10 mg/kg/day	UF_A [1]= 10x UF_H [1]= 10x FQPA SF[2] = 1x	aPAD = 0.10 mg/kg/day	Developmental Neurotoxicity in rat LOAEL[5] = 45 mg/kg/day based on decreased body weight and body weight gains in offspring, decreased early pup survival on PND 0-1, and decreased startle response on PND 20/60 in males. Acute Neurotoxicity Study in rat LOAEL = 30 mg/kg/day based on decreased locomotor activity
Chronic Dietary all populations	NOAEL = 7.1 mg/kg/day	UF_A = 10x UF_H = 10x FQPA SF = 1x	cPAD = 0.071 mg/kg/day	Chronic Toxicity/Oncogenicity Study in rats LOAEL = 17.5 mg/kg/day based on decreased body weight and body weight gains in females and hepatocellular vacualation in males.
Short- and Intermediate-Term Incidental Oral (1-30 days and 1 - 6 mo.) Residential setting	NOAEL = 10 mg/kg/day	UF_A = 10x UF_H = 10x FQPA SF[2] = 1x	LOC[3] for MOE[4] = 100 (Residential)	Developmental Neurotoxicity in rat LOAEL[5] = 45 mg/kg/day based on decreased body weight and body weight gains in offspring, decreased early pup survival on PND 0-1, and decreased startle response on PND 20/60 in males.
Short- and Intermediate-term Dermal (1-30 days, 1 – 6 mo.) Residential setting	NOAEL = 10 mg/kg/day	UF_A = 10x UF_H = 10x FQPA SF[2] = 1x dermal absorption rate = 10%	LOC for MOE = 100 (Residential)	Developmental Neurotoxicity in rat LOAEL[5] = 45 mg/kg/day based on decreased body weight and body weight gains in offspring, decreased early pup survival on PND 0-1, and decreased startle response on PND 20/60 in males.
Short- and Intermediate-term Inhalation (1-30 days, 1 – 6 mo.) Residential setting	NOAEL = 10 mg/kg/day	UF_A = 10x UF_H = 10x FQPA SF[2] = 1x inhalation absorption rate = 100%	LOC for MOE = 100 (Residential)	Developmental Neurotoxicity in rat LOAEL[5] = 45 mg/kg/day based on decreased body weight and body weight gains in offspring, decreased early pup survival on PND 0-1, and decreased startle response on PND 20/60 in males.
Cancer (oral, dermal, inhalation) - not likely to be carcinogenic to humans.				

1: NOAEL = No Observed Adverse Effect Level.
UF_A: uncertainty factor applied for extrapolation from animal to human (interspecies)
UF_H: uncertainty factor applied for extrapolation from human to human due to potential variation in sensitivity among members of the human population (intra-species)
2: FQPA SF= Food Quality Protection Act Safety Factor
3: LOC = Level of Concern
4: MOE = Margin of Exposure
5: LOAEL = Lowest Observed Adverse Effect Level

Table 7. Summary of Toxicological Doses and Endpoints of Acetamiprid for Use in Occupational Human Health Risk Assessment				
Exposure Scenario	**Dose Used in Risk Assessment**	**Uncertainty Factors**	**Level of Concern for Risk Assessment**	**Study and Toxicological Effect**
Short-, Intermediate-term Dermal (1 - 30 days, 1 - 6 mo.)	oral study NOAEL[1]= 10 mg/kg/day dermal absorption rate = 10%	UF_A [1]= 10x UF_H [1]= 10x	LOC[2] for MOE[3] = 100 (Occupational)	Developmental Neurotoxicity in rat LOAEL[4] = 45 mg/kg/day based on decreased body weight and body weight gains in offspring, decreased early pup survival on PND 0-1, and decreased startle response on PND 20/60 in males.
Short- and Intermediate-term Inhalation (1 - 30 days, 1 - 6 mo.)	Oral study NOAEL= 10 mg/kg/day inhalation absorption rate = 100%	UF_A = 10x UF_H = 10x	LOC for MOE = 100 (Occupational)	
Cancer (oral, dermal, inhalation) - not likely to be carcinogenic to humans.				

1: NOAEL = No Observed Adverse Effect Level.
UF_A: uncertainty factor applied for extrapolation from animal to human (interspecies)
UF_H: uncertainty factor applied for extrapolation form human to human due to potential variation in sensitivity among members of the human population (intra-species)
2: LOC = Level of Concern
3: MOE = Margin of Exposure
4: LOAEL = Lowest Observed Adverse Effect Level

3.5 Endocrine Disruption

EPA is required under the FFDCA, as amended by FQPA, to develop a screening program to determine whether certain substances (including all pesticide active and other ingredients) "may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or other such endocrine effects as the Administrator may designate." Following recommendations of its Endocrine Disruptor Screening and Testing Advisory Committee (EDSTAC), EPA determined that there was a scientific basis for including, as part of the program, the androgen and thyroid hormone systems, in addition to the estrogen hormone system. EPA also adopted EDSTAC's recommendation that the Program include evaluations of potential effects in wildlife. For pesticide chemicals, EPA will use FIFRA and, to the extent that effects in wildlife may help determine whether a substance may have an effect in humans, FFDCA authority to require the wildlife evaluations. As the science develops, and resources allow, screening of additional hormone systems may be added to the Endocrine Disruptor Screening Program (EDSP).

When the appropriate screening and/or testing protocols being considered under the Agency's EDSP have been developed, acetamiprid may be subjected to additional screening and/or testing to better characterize effects related to endocrine disruption.

4.0 Public Health Data

No public health data were considered at this time.

5.0 Dietary Exposure/Risk Characterization

5.1 Metabolism in Crops and Livestock

The nature of acetamiprid residue in plants has been adequately delineated and is based on radiolabeled studies with carrot, cabbage, cotton, apple, and eggplant. In plants, there appears to be little translocation of acetamiprid following foliar application. In cabbage, there was significant uptake and translocation of acetamiprid to the above ground portions of the plant following a soil application. However, due to the rapid dissipation of acetamiprid in the field, root uptake is not a likely source of residues in plants.

The qualitative nature of acetamiprid residue in livestock is also adequately understood based upon metabolism studies in ruminants (lactating goat) and laying hens. HED has determined that for risk assessment purposes, the residues of concern in livestock tissue (except ruminant muscle) are acetamiprid *per se*, plus its IM-2-1 metabolite. In ruminant muscle, the residues of concern for risk assessment are acetamiprid plus IM-2-1 plus IM-2-1-amide. Residues of IM-2-1-amide in ruminant muscle tissue can be estimated by applying a 10-fold factor to residues of IM-2-1 in muscle.

HED has concluded that the tolerance expression should include acetamiprid *per se* for plant commodities and combined residues of acetamiprid and IM-2-1 [N1-[(6-chloro-3-pyridyl)methyl]-N2-cyano-acetamidine] for livestock commodities. Based upon available rotational crop data, HED has determined that the residue of concern in rotational crops would be acetamiprid, *per se*, but tolerances for acetamiprid are not needed in rotational crops. Discussion of the nature of the acetamiprid residue and analytical methodology associated with the subject petitions can be found in the following HED memoranda: for cucurbit vegetables, stone fruits, and tree nuts, see HED memorandum, W.Drew, 11/5/2004, D303623; and, for berries, bulb vegetables, succulent shelled pea and beans, and strawberry and other low growing berries, see HED memorandum, W.Drew, 10/23/2007, D328216.

5.1.1 Analytical Methodology

The method used to analyze samples for acetamiprid residues in/on raw agricultural commodities (RACs) was Method Number 45800, entitled *Methods for the Analysis of Acetamiprid (NI-25) In Plants and Plant Processed Fractions* (MRID # 44988529). This method is adequate for data collection based on acceptable concurrent method recovery data. Acetamiprid is not recovered through the FDA Multiresidue Protocols.

Adequate residue analytical methods are available for the enforcement of established and proposed tolerances for plant commodities (GC/ECD and HPLC/UV) and animal commodities (HPLC/UV). These methods were submitted to ACB/BEAD for petition method validation (PMV) and were successfully validated. The registrant has also requested that the HPLC/MS/MS method utilized for data collection (in PP#3F6575 and PP#4F6833) replace the current tolerance enforcement method (GC/ECD) for the proposed uses on stone fruits, tree nuts, and cucurbit vegetables. An independent laboratory validation (ILV) for this method was previously required by HED. These data have been submitted (MRID 47185401), and are currently under review. Table 8 summarizes the analytical methodologies for acetamiprid.

Table 8. Summary of Analytical Methods for Acetamiprid.					
Target Matrices	**Method/ Method Description**	**Validated for Enforcement**	**LOQ (ppm)**	**Method Validation**	
				Fortification levels (ppm)	**Recovery Range (%)**
Vegetables and Non-Citrus Fruits	GC/ECD Method Methanol extraction, residues partitioned into dichloromethane, Florisil/silica gel column cleanup, and GC/ECD determination	Yes	0.010	0.010, 0.050	68-112
	Proposed HPLC/MS/MS Method	The submitted ILV for this method is currently under review			
Citrus Fruits	HPLC/UV Method Acetonitrile extraction, coextractives partitioned into hexane, residues partitioned into dichloromethane, Florisil/C18 column cleanup, and HPLC/UV determination.	Yes	0.050	0.050, 0.250	77-100
Eggs, Milk, and Ruminant and Poultry Tissues	HPLC/UV Method Acetonitrile extraction, residues partitioned into dichloromethane, Florisil/C18 column cleanup, and HPLC/UV determination. The method determines both acetamiprid and IM-2-1.	Yes	0.010 ppm (muscle, fat, milk, and eggs)	0.010, 0.100	78-103 (acetamiprid) 81-109 (IM-2-1)
			0.050 (liver and kidney)	0.050, 0.500	

5.1.2 Metabolism and Degradates of Concern

The residue chemistry database for acetamiprid has been previously examined and can be found in earlier HED memorandum (H.Bietlot, 11/16/2001, D278652; and, M.Doherty, 12/31/2001, D264154).

A comparison of the available acute toxicity data for the parent versus the metabolites indicates that the metabolites IC-0, IM-0, IM-2-1, IM-1-4, IM-1-2, are either similar, or less acutely toxic than the parent. In subchronic feeding and mutagenicity studies the tested metabolites were shown to be either equivalent to, or less toxic than the parent. The acute toxicity and mutagenicity data indicate that the metabolite of concern in livestock, IM-2-1, is less toxic than the parent and is of similar mutagenic potential to the parent. Subchronic studies were not submitted to address the long-term toxicity of the IM-2-1 metabolite. Table 9 summarizes the residues of concern (parent and metabolites) that will be considered for regulation.

Table 9. Summary of Metabolism Findings for Acetamiprid		
Matrix	**Residues of Concern**	
	Risk Assessment	**Tolerance Expression**
Target Crops	Acetamiprid	Acetamiprid
Livestock	Acetamiprid and IM-2-1 (and IM-2-1-amide in ruminant muscle only)	Acetamiprid and IM-2-1
Rotational Crops	Acetamiprid	None at this time
Drinking Water	Acetamiprid	Not applicable

5.1.3 Drinking Water Residue Profile

The drinking water residues used in the dietary risk assessment were provided by EFED (G.Orrick, 6/21/2005, D303582, and G.Orrick, 6/24/2007, D331596 and D336256), and were incorporated directly into the dietary assessment. Acute and chronic estimates of drinking water concentrations (EDWCs) in surface water were generated using the screening mechanistic model, FIRST v1.0 (Aug. 1, 2001). Ground water concentration estimates were generated using the screening regression model SCI-GROW v2.3 (Jul 29, 2003). For the surface water assessment, the application rate for citrus was used (0.25 lb ai/acre, at 2 applications), which represents the highest label rate for a single application of any currently registered or proposed use of acetamiprid. For the groundwater assessment, the maximum application rate for tree nut, was used which represents the highest label rate on a seasonal basis (0.72 lb ai/acre/season, applied in four applications at 0.18 lb ai/acre). Concentrations of acetamiprid degradates were not estimated since HED has determined that they are not of concern in drinking water. Because the EDWCs are based on the highest application rates, the estimated concentrations can be considered conservative. EDWCs are summarized in Table 10.

Table 10. Estimated Drinking Water Concentrations for Acetamiprid			
Drinking Water Source	**Maximum Use Pattern**	**Exposure Duration**	**EDWC**
Surface water	Citrus fruit	Acute	20.1 ppb
		Chronic	4.9 ppb
Ground water	Tree nut	Acute and Chronic	1.6 ppt

5.1.4 Food Residue Profile

5.1.4.1 Crop Field Trials

Crop Field Trials

HED has reviewed the field trial data submitted to support the three subject petitions, 4F6833, 6F7051, and, 6E7163. The MRID's for the submitted studies are listed in Table 11 below. In an earlier review, completed in connection with PP# 0F6082 (M.Doherty, 12/2004, D264154) HED noted a data gap associated with rotational crop storage stability. Since that time, these data have been submitted (MRID 46729102) and reviewed and, therefore, are no longer considered a data gap.

Table 11.
Summary of Field Trial Data Submitted in Connection with Petitions 4F6833, 6F7051, and 6E7163.

Petition	Crop(s)	Field Trial Data
4F6833	Cucurbit Vegetables (Crop Group 9)	MRID 46265701
	Stone Fruits (Crop Group 12)	MRID 46265702
	Tree Nuts (Crop Group 14)	MRID 46265703
6F7051	Bulb vegetables (Crop Group 3)	MRID 46785503
	Berries (crop group 13)	MRID 46785502
	Edible Podded Legum Vegetables (Crop Subgroup 6A)	MRID 46785504
	Succulent Shelled Peas and Beans (Crop Subgroup 6B)	MRID 46785504
6E7163	Strawberry	MRID 47013601

Cucurbit Vegetables, Stone Fruits, Tree Nuts
The data submitted to support the uses on the cucurbit vegetables crop group, the stone fruits crop group, and the tree nuts crop group are adequate. Based upon submitted residue data, HED has determined that a group tolerance in the stone fruits group can be established at 1.20 ppm, (where the petitioner requested 1.2 ppm); and, a separate tolerance (0.20 ppm) in prune plum is recommended, (where the petitioner requested 0.30 ppm). In addition, although the submitted almond and pecan field trial data may be used to support use on pistachios, a separate tolerance must be established in pistachios until the Code of Federal Regulations No. 40 is modified to include pistachio in the crop group definition for tree nuts.

Processing data indicate that residues of acetamiprid may concentrate in dried prunes. Based upon the average processing factor (2.9X) reported in the data, and the residue data for plum (HAFT residue of 0.112), HED recommends a separate tolerance of 0.40 ppm in dried prune plum.

Based upon the data submitted in connection with PP# 4F6833, HED recommends establishing the tolerances for acetamiprid, *per se,* in/on the commodities listed below in Table 12.

Bulb Vegetables
Field trial data have been submitted on the representative commodities (bulb and green onions) for Crop Group 3. While no residue decline data were submitted with the field trial data, previously submitted residue decline data indicate that residues of acetamiprid do not increase with increasing harvest intervals. Because the residues in the green onions exceeded those of the bulb onions by more than 5x, HED does not recommend a single group tolerance, as requested by the petitioner. Rather, HED recommends that tolerances be set on the individual crops in the two pending bulb vegetable subgroups (i) a 0.02 ppm tolerance in bulb onion subgroup 3A; and (ii) a 4.5 ppm tolerance in the green onion subgroup 3B.

Eddible Podded Legume Vegetables (Crop Subgroup 6A) and Succulent Shelled Pea and Beans (Crop Subgroup 6B)
Adequate field trial data have been submitted on the representative commodities of the two crop subgroups, 6A and 6B. Even though reported residues from representative commodities within the 6B crop subgroup differed greater than the usual 5x limit, (i.e., 5.9x), HED can recommend a single crop subgroup tolerance be set because the residues were all relatively low. Therefore, HED recommends a 0.60 ppm acetamiprid tolerance in edible podded legume vegetables (Crop Subgroup 6A) and a 0.40 ppm acetamiprid tolerance in succulent shelled pea and beans (Crop Subgroup 6B).

Berries (Crop Group 13)
At the time of the review, HED determined that inadequate field trial data were submitted in connection with the petition for a Berries group tolerance (Crop Group 13). The data submitted for one of the two representative crops (a bushberry crop for crop subgroup 13A) were sufficient. However, the data submitted for the other representative crop (a caneberry crop for crop subgroup 13B) were inadequate. These data have already been submitted and currently are under review (MRID 47224701). Based upon the adequate bushberry crop field trial data and HED's preliminary review of the caneberry data, HED recommends that a 1.6 ppm tolerance for berries (Crop Group 13) be established.

HED also recommends a separate 1.6 ppm acetamiprid tolerance be set in lingonberry, which is pending to become a member of Crop Subgroup 13B.

Strawberry
Field trial data submitted for strawberries are adequate. Residue decline data submitted with the strawberries indicate that acetamiprid residues decline with lengthened sampling intervals. The submitted data on strawberries are also adequate to support acetamiprid tolerances on the following crops: bearberries, bilberries, cloudberries, cranberries, muntries, and partridgeberries. Since the establishment of a crop subgroup is pending for these crops (Crop Subgroup 13G), HED currently recommends a 0.60 ppm tolerance be set in each commodity.

In its submission, the petitioner requested a tolerance for acetamiprid on lowbush blueberries, and included this request in conjunction with its strawberry petition. HED notes that an acetamiprid tolerance for lowbush blueberry would be covered by the recommended tolerance

for Berries (Crop Group 13). A summary of recommended tolerances for the commodities associated with the three subject petitions is listed below in Table 12.

Based upon the submitted data, HED recommends establishing unconditional registrations and tolerances for acetamiprid, *per se,* in connection with the three subject petitions. The acetamiprid tolerances should be revised not only to reflect the HED recommended tolerance levels, including individual and crop group tolerances while the establishment of various crop groups is pending, but also to reflect the correct commodity definitions. A summary table of proposed and recommended tolerances for acetamiprid associated with all three subject petitions can be found in Appendix D, Table 1.

5.1.4.2 International Residue Limits

There are no Codex, Canadian or Mexican MRL's established on the commodities associated with these petitions.

5.1.4.3 Livestock Commodities

Adequate cattle feeding study data are also available to support the proposed uses of acetamiprid. No poultry feed items are associated with this petition. The existing tolerances for residues in livestock commodities are adequate to cover all uses associated with the present petitions.

Table 12. Summary of Crop and Crop Groups Recommended for Tolerances in Connection with Subject Petitions			
Petition No.	**Crop Group or Commodity Recommended for Tolerance**	**Recommended Tolerance (ppm)**	**List of Commodities Included**
PP# 4F6833	Tree Nuts (Crop Group 14)	0.1	almonds; beechnut; butternut; cashew; chestnut; chinquapin; filbert; brazil nut; hickory nut; macadamia nut; processed nutmeat (except peanut); nuts; pecan; walnut
	Pistachio	0.10	Pistachio
	Almond, hulls	5.0	Almond, hulls
	Fruit, stone, except plum, prune fresh and dried (Crop Group 12)	1.2	apricot; cherry (sweet and tart); nectarine; peach; plum; plum, chickasaw; plum, damson; plum, Japanese
	Plum, prune, fresh	0.2	plum, prune; plum, prune, fresh
	Plum, prune, dried	0.4	plum, prune, dried
	Vegetable, cucurbit group (Crop Group 9)	0.5	balsam apple; balsam pear; cantaloupe; chayote fruit; cucumber; cucumber, Chinese; gherkin, West Indian; gourd, edible; melon; melon, citron; muskmelon; pumpkin; squash; squash, summer; squash, winter; watermelon; waxgourd, chinese
PP# 6F7051	Vegetable, legume, edible podded, (Subgroup 6A)	0.6	Bean, moth; bean, runner; bean, snap; bean, wax; bean, yardlong; jackbean; longbean, Chinese; pea, dwarf; pea, edible podded; pea, pigeon; pea, snow; pea, sugar snap; soybean, immature seed; swordbean.
	Pea and bean, succulent, shelled (Subgroup 6B)	0.4	Bean, broad; bean, lima succulent; cowpea; cowpea seed; pea, blackeyed; pea, English; pea, garden; pea, green; pea, pigeon; pea, southern
	Bushberry Subgroup 13B	1.6	Blueberry; currant; elderberry; gooseberry; huckleberry; Aronia berry; Buffalo currant; Chilean guava; European barberry; Highbush cranberry; Honeysuckle; Jostaberry; Juneberry; Lingonberry; Native currant; Salal; Sea buckthorn
	Bulb Onion (Subgroup 3A)	0.02	Onion, bulb; Fritillaria, bulb; Daylily, bulb; Garlic, bulb; Garlic, great headed, bulb; Garlic, Serpent, bulb; Lily, bulb; Onion, Chinese, bulb; Onion, Pearl; Onion, potato, bulb; Shallot, bulb
	Green Onion (Subgroup 3B)	4.5	Onion, green; Chive, fresh leaves; Chive, Chinese, fresh leaves; Elegans hosta; Fritillaria, leaves; Kurrat; Lady's leek; Leek; Leek, wild; Onion, Beltsville bunching; Onion, fresh; Onion, macrostem; Onion, tree, tops; Onion, Welsh, tops; Shallot, fresh leaves
PP# 6E7163	Berry, group 13	1.6	Blackberry; blueberry; caneberry; currant; elderberry; gooseberry; huckleberry; loganberry; raspberry
	Berries, low-growing, subgroup 13G	0.6	bearberry, bilberry, cloudberry, cranberry, muntries, partridgeberry, strawberry

5.2 Dietary Exposure/Risk Pathway

Dietary risk assessment incorporates both exposure and toxicity of a given pesticide. For acute and chronic dietary risk assessments, the risk is expressed as a percentage of the population adjusted dose (PAD). The acute PAD (aPAD) is derived by dividing the selected acute dietary dose (NOAEL) by the appropriate uncertainty and FQPA safety factors. The chronic PAD (cPAD) is derived by dividing the selected chronic dietary dose (NOAEL) by the appropriate uncertainty and FQPA safety factors. Typically, HED has dietary risk concerns when the estimated exposure exceeds 100% of the aPAD and/or cPAD.

5.2.1 Dietary Exposure and Risk

Acute and chronic dietary risk assessments were conducted for acetamiprid using the Dietary Exposure Evaluation Model (DEEM-FCID™, Version 2.03) which uses food consumption data from the USDA's Continuing Surveys of Food Intakes by Individuals (CSFII, 1994-1996 and 1998). The acute and chronic dietary analyses are considered partially refined by the inclusion of percent crop treated values and processing data. The full dietary analysis for the subject peitions can be found in the HED memorandum *Acetamiprid: Acute and Chronic Dietary Exposure Assessments*, 10/12/07, D335205.

The current acute and chronic dietary exposure assessments include existing uses and the tolerances proposed by Nisso America Incorporated (representing Nippon Soda Company Limited), and IR-4 associated with PP# 4F6833, 6F7051, and 6E7163. The recommended tolerances incorporated into the dietary analysis are shown above in Table 12. These crops are supported by adequate field trial data.

For the acute dietary assessment, field trial residues were refined when possible. If field trial residues were reported below the limit of quantification (LOQ), HED assumed ½ LOQ (i.e., 0.005 ppm). In certain cases where it was appropriate, HED translated field trial data from one commodity to another (e.g., peaches to nectarines, or plum to apricots). Percent crop treated estimates, which exist for only several of the subject crops (apples, broccoli, celery, lettuce, pears, grapefruit, grapes, oranges, peppers, spinach, and tomatoes), were incorporated into the acute dietary assessment as a refinement. Average percent crop treated values for apples and oranges were applied to the chronic dietary assessment, and maximum percent crop treated values were applied to the acute dietary assessment. Processing data is applied to the dietary analysis in order to further characterize the effect (reduction or concentration) on pesticide residues on a commodity as a result of various processing or preparation procedures (such as washing, juicing, trimming, etc). Processing factors based on submitted studies were incorporated into the acute dietary analyses for the following commodities: apple juice, orange juice, grape juice, raisins, dried prunes, tomato paste, and tomato puree. For all other commodities included in the acute assessment, the DEEM™ Version 7.87 default processing factors were used. Those default factors were used for all processed commodities in the chronic

assessment except for dried prunes. Finally, tolerance level residues were also used for livestock commodities.

As mentioned above, under Section 5.1.3, HED incorporated EDWCs directly into the DEEM™ FCID model for "water, direct, all sources" and "water, indirect, all sources." For the acute assessment, an EDWC of 20.1 ppb was entered into the model, and for the chronic assessment, the value of 4.9 ppb was used.

5.2.2 Exposure and Risk Characterization

The dietary analyses reflect all currently registered and proposed acetamiprid uses and indicate that both the acute and chronic dietary exposure do not present a risk concern for HED for the general U.S. population or any of population subgroup.

The most highly exposed population subgroup for both acute and chronic dietary exposure durations is children 1-2 years old. Children 1-2 years old are exposed to approximately 35% of both the aPAD and the cPAD. The general population is exposed to approximately 18% of the aPAD and 9% of the cPAD. Dietary exposure and risk estimates are summarized below in Table 13.

Table 13. Summary of Dietary (Food + Water) Exposure and Risk for Acetamiprid

Population Subgroup	Acute Dietary (99.9th Percentile)		Chronic Dietary	
	Dietary Exposure (mg/kg/day)	% aPAD	Dietary Exposure (mg/kg/day)	% cPAD
General U.S. Population	0.018258	18	0.006186	8.7
All Infants (< 1 year old)	0.026198	26	0.014224	20
Children 1-2 years old	0.034993	35	0.024647	35
Children 3-5 years old	0.024443	24	0.016879	24
Children 6-12 years old	0.016024	16	0.008748	12
Youth 13-19 years old	0.011152	11	0.004819	6.8
Adults 20-49 years old	0.011895	12	0.004189	5.9
Adults 50+ years old	0.009593	9.6	0.004486	6.3
Females 13-49 years old	0.009539	9.5	0.004414	6.2

5.2.3 Cancer Dietary Risk

HED has classified acetamiprid as "not likely to be carcinogenic to humans." Based upon this classification, HED has determined there is no cancer risk associated with the proposed uses.

6.0 Residential (Non-Occupational) Exposure/Risk Pathway

Residential Handler Exposure

Product F4688 50WSP, which was assessed at the time PP# 4F6833 was originally submitted for review, is currently registered for use in commercial and residential settings (EPA stamped approved 5/2007). The registration approval was based upon a *draft* occupational/residential risk assessment. The draft assessment indicated that, based on the then proposed uses of F4688 50WSP, residential handler (and residential post-application) exposures were negligible. Intended uses of F4688 50WSP included subterranean structure components during construction, subterranean, and hard-to-reach structure components associated with post construction and outdoor perimeter uses. In addition, the label specified that application was permitted by licensed individuals only (also known as Pest Control Operators – PCO's), not homeowners. The *draft* assessment also indicated that the occupational exposures were not of risk concern to HED.

Even though this product is now registered, HED has included it in this assessment in order to formalize its risk conclusions. HED continues to believe that no residential exposures result from its use, and therefore, it does not present any residential risks concerns for HED.

HED previously conducted a residential assessment on acetamiprid products, such as the "*Bait Gel*" products for ant and cockroach control, used in a residential setting (2/17/2005; DP 304214). In this previous assessment, HED determined that the *Bait* products could result in potential handler exposure. Since completion of the previous assessment, HED has selected a new toxicological endpoint (10 mg/kg/day from the DNT study). Based upon the updated toxicological endpoint, the recalculated residential handler risks from the bait products remain below HED's level of concern (for both short-, and intermediate-term durations). A summary of updated residential handler risks from the acetamiprid bait products is presented below in Table 14.

As discussed in its previous assessment cited above, HED believes that potential post-application exposures from the "bait" products are negligible for the following reasons. First, HED does not anticipate homeowners are likely to revisit the crack crevice or spot where the Gel Bait has been applied, thereby minimalizing potential dermal or incidental oral exposure. Secondly, inhalation exposure is expected to be minimal due to acetamiprid's low vapor pressure, and gel formulation which further reduces the potential of acetamiprid to become airborne. Finally, gel bait products contain a bittering agent, (Bitrex®), which is used to prevent ingestion by children and animals, further reducing potential incidental ingestion. Based on these reasons, HED determined that a

quantitative post-application exposure assessment was not required.

Table 14.
Short- and Intermediate-term Dermal Handler (Mixer/Loader/Applicator) Exposure and Risk for Acetamiprid Bait and Gel Products

Product	Weight Fraction (ai)[a]	Dermal Daily Dose[b]	Absorbed Dermal Daily Dose[c] (mg/kg/day)	MOE [d]
Acetamiprid (F5025) 15% products (EPA Reg. Nos.: 8033-28;8033-29; 8033-30; and 8033-31)	0.0015	0.0283	0.00283	3500
Acetamiprid (F5025) 35% products (EPA Reg. Nos.: 8033-32; and 8033-35	0.0035	0.0659	0.00659	1500

a. Weight Fraction (ai) - Fraction of active ingredient on product (0.0015 or 0.0035)
b. Daily Dermal Dose (DDD) = [weight fraction (0.15% ai or 0.35% ai) x formulation density (1.0 g/cm^3) x conversion factor (1.0 x 10^3 mg/g) x gel thickness (2.0 x 10^{-3} cm) x skin surface area (565 cm^2)] / BW (60 kg)
c. Absorbed Daily Dermal Dose (mg/kg/day) = DDD x DA (0.10)
d. MOE= NOAEL (10 mg/kg/day) / Absorbed Daily Dermal Dose (mg/kg/day)

6.1 Spray Drift

Spray drift is a potential source of exposure for residents living in close proximity to spraying operations. This situation is particularly the case with aerial application. However, to a lesser extent, spray drift resulting from the ground application of acetamiprid could also be a potential source of exposure. The Agency has been working with the Spray Drift Task Force (a membership of US pesticide registrants), EPA Regional Offices, State lead Agencies for pesticide regulation, and other parties to develop the best spray drift management practices. The Agency is now requiring interim mitigation measures for aerial applications that must be placed on product labels/labeling. The Agency has completed its evaluation of the new database submitted by the Spray Drift Task Force, and is developing a policy on how to appropriately apply the data and the AgDRIFT computer model to its risk assessments for pesticides applied by air, orchard airblast, and ground hydraulic methods. After the policy is in place, the Agency may impose further refinements in spray drift management practices to reduce off-target drift and risks associated with pesticide application.

7.0 Aggregate Risk Assessment and Risk Characterizations

Consistent with FQPA, HED considers aggregate risk to a pesticide from the three major routes (dermal, oral, and inhalation) when potential residential exposures exist. In its acetamiprid aggregate assessment, HED combined dietary (food + water) and non-dietary (residential handler) exposure sources to obtain an estimated aggregate exposure. When aggregating exposures and risks from various sources, HED considers both the route and duration of exposure. Based upon the residential use pattern of acetamiprid products, HED has determined that acute, short-term, intermediate-term and chronic aggregate risk assessments are appropriate.

7.1 Acute Aggregate Risk

The acute aggregate risk is equal to the acute dietary exposure via food and drinking water, and therefore is identical to the exposure and risk characterization found in Section 5.2.2. The acute aggregate risks for acetamiprid are less than 100% of the aPAD for all population subgroups and, therefore, do not pose a risk concern for HED.

7.2 Short-Term and Intermediate-Term Aggregate Risk

Short-term aggregate risk is based on the chronic (average) dietary exposure (food + water) combined with short-term residential exposure. Intermediate-term aggregate risk is based on the chronic (average) dietary exposure combined with intermediate-term residential exposure.

As noted above, HED does not believe that the uses of F4688 50WSP result in either handler or post-application residential exposures. However, other currently registered acetamiprid products, such as "bait" products have residential (handler) exposures. HED incorporated the (high-end) residential handler exposure estimates from the "bait" products into the short-term and intermediate-term aggregate assessment (see Table 14, above).

Because the short-term and intermediate-term dermal exposures and endpoints are the same, the short-term and intermediate term residential risks are also the same. Consequently, short-term and intermediate-term aggregate risks are identical.

HED assessed short-term and intermediate-term aggregate risk to the population subgroups it believes are most likely to be exposed to acetamiprid from residential uses, i.e., "adults 20 – 49 years" and "adults 50+ years." Estimated short-term and intermediate-term aggregate risks do not pose a risk concern to HED (MOE $\geq$ 100), and are summarized below in Table 15.

Table 15. Acetamiprid Short- and Intermediate–term Aggregate Risk Calculations					
Population Subgroup[1]	**Dietary Exposure[2] (mg/kg/day)**	**Dietary MOE[3]**	**Residential Dermal Exposure[4]**	**Residential Dermal MOE[5]**	**Aggregate MOE[6]**
Adults 20 – 49 years old	0.004189	2400	0.00659	1500	930
Adults 50+ years old	0.004486	2200	0.00659	1500	900

1. Population subgroup chosen was adults 20 – 49 yrs old and 50+ years since these individuals would likely handle *Bait* products.
2. Dietary exposure = [food exposure + drinking water exposure] taken from Table 13.
3. Dietary MOE = short-term, and intermediate-term incidental oral NOAEL (10 mg/kg/day) ÷ average dietary exposure (mg/kg/day) from DEEM
4. Residential dermal exposure estimated for adults who handle *Bait* products, Table 14.
5. Residential dermal MOE = short-, and intermediate-term NOAEL (10 mg/kg/day) ÷ residential dermal exposure (mg/kg/day).
6. Aggregate MOE : since short-, and intermediate term incidental oral endpoint and short-,and intermediate dermal endpoints are the same, the exposures from these two routes can be added. Therefore, aggregate MOE= NOAEL [10 mg/kg/day]) ÷ dietary exposure + residential dermal exposure.

7.3 Chronic Aggregate Risk

The dietary exposure pathway (food and drinking water) is the only source of chronic exposure to acetamiprid (i.e., 180 consecutive days or more). Therefore, the chronic aggregate exposure and risk estimates are equivalent to the chronic dietary exposure and risk estimates discussed in Section 5.2.2 above. The chronic aggregate risks for acetamiprid are less than 100% of the cPAD for all population subgroups and, do not pose a risk concern for HED.

8.0 Cumulative Risk Characterization/Assessment

FQPA (1996) stipulates that when determining the safety of a pesticide chemical, EPA shall base its assessment of the risk posed by the chemical on, among other things, available information concerning the cumulative effects to human health that may result from dietary, residential, or other non-occupational exposure to other substances that have a common mechanism of toxicity. The reason for consideration of other substances is due to the possibility that low-level exposures to multiple chemical substances that cause a common toxic effect by a common mechanism could lead to the same adverse health effect as would a higher level of exposure to any of the other substances individually. A person exposed to a pesticide at a level that is considered safe may in fact experience harm if that person is also exposed to other substances that cause a common toxic effect by a mechanism common with that of the subject pesticide, even if the individual exposure levels to the other substances are also considered safe.

Acetamiprid is a member of the neonicotinoid class of pesticides which also includes thiamethoxam, clothianidin, imidacloprid and several other active ingredients. Structural

similarities or common effects do not constitute a common mechanism of toxicity. Evidence is needed to establish that the chemicals operate by the same, or essentially the same sequence of major biochemical events (EPA, 2002). Although the neonicotinoids bind selectively to insect nicotinic acetylcholine receptors (nAChR), the specific binding site(s)/receptor(s) are unknown at this time. Additionally, the commonality of the binding activity itself is uncertain, as preliminary evidence suggests that clothianidin operates by direct competitive inhibition, while thiamethoxam is a non-competitive inhibitor. Furthermore, even if future research shows that neonicotinoids share a common binding activity to a specific site on insect nicotinic acetylcholine receptors, there is not necessarily a relationship between this pesticidal action and a mechanism of toxicity in mammals. Structural variations between the insect and mammalian nAChRs produce quantitative differences in the binding affinity of the neonicotinoids towards these receptors, which, in turn, confers the notably greater selective toxicity of this class towards insects, including aphids and leafhoppers, compared to mammals. Additionally, the most sensitive toxicological effect in mammals differs across the neonicotinoids (*e.g.*, testicular tubular atrophy with thiamethoxam; mineralized particles in thyroid colloid with imidaclopid). Thus, there is currently no evidence to indicate that neonicotinoids share common mechanisms of toxicity, and EPA is not following a cumulative risk approach based on a common mechanism of toxicity for the neonicotinoids. In addition, acetamiprid does not appear to produce a toxic metabolite produced by other substances. Therefore, for the purposes of this tolerance action, EPA has not assumed that acetamiprid has a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the policy statements concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism released by EPA's Office of Pesticide Programs on EPA's website at http://www.epa.gov/pesticides/cumulative/.

9.0 Occupational Exposure/Risk Pathway

9.1 Agricultural Handlers and Pesticide Control Operators

No chemical-specific data for assessing handler exposures were submitted to the Agency in support of the proposed uses associated with the three subject petitions. Therefore, when estimating occupational exposures, HED used surrogate data from the Pesticide Handlers Exposure Data Base (PHED) v1.1, Outdoor Residential Exposure Task Force (ORETF) data, and standard assessment variables established by the Health Effects Division Science Advisory Council for Exposure (e.g. maximum application rates, standard acres treated per day, 70 kg body weight for workers, and standard protection factors assumed with specified personal protective equipment). The estimated exposures are believed to be reasonable high-end estimates.

Based on the anticipated application practices for the Assail® 70WP and Assail® 30 SG products, and the currently registered F4688 50WSP product label, as well as information provided by the registrant, HED anticipates that handler exposures are of short- and

intermediate-term duration. Table 16 below summarizes the proposed personal protective equipment for each label and associated occupational exposure scenario conducted for each label/formulation/use.

Table 16. Summary of Exposure Scenarios Assessed and PPE as Stated on the Proposed Labels

Exposure Scenario Assessed	Product/ Formulation	App. Methods Assessed	Use Sites	PPE Specified on Proposed Label
Mixer/Loader	Wettable Powder Assail® 70 WP	groundboom airblast aerial	Cucurbits, stone fruits, legumes, peas and beans, berry, including strawberry and bulb vegetables	- long pants, long-sleeved shirt, shoes plus socks; - waterproof gloves. - chemical resistant headgear for overhead exposures - 12 hour Restricted Entry Interval (REI)
	soluble granule Assail®30 SG	groundboom air blast aerial		
Applicator	Formulation is not relevant to applicator exposure Assail® 70 WP Assail®30 SG	groundboom, airblast, aerial	Cucurbits, stone fruits, legumes, peas and beans, berry, including strawberry and bulb vegetables	
Flagger	Formulation is not relevant to applicator exposure Assail® 70 WP Assail®30 SG	groundboom, airblast, aerial	Cucurbits, stone fruits, legumes, peas and beans, berry, including strawberry and bulb vegetables	
Mixer/Loader/ Applicator	Liquid, and Water Soluble Packets, F4688 50 WSP Insecticide Termiticide	low pressure hand wand; handgun sprayer; injector; foam application; sprinkling can hose-end sprayer	Outdoor pests, ants, termite control	- long pants, long-sleeved shirt, shoes plus socks; - chemical resistant gloves (for mixing). - after the product is diluted, or when using closed system, or in-line system, handlers must wear shirt, pants, shoes plus socks, and water proof gloves. - respitory protection and protective eyewear when working in a non-ventilated space or applying by rodding or sub-slab injection. - No Restricted Entry Interval (REI) is specified

9.2 Handler and Pesticide Control Operator Risk Characterization

Since both dermal and inhalation endpoints for occupational exposures were the same, the route specific exposure values were combined to calculate a total exposure which was compared to the NOAEL (10 mg/kg/day from the DNT) to determine the MOEs. Estimated exposures for all scenarios of the three product labels do not present a risk concern to HED when the PPE stated on the proposed label is assumed. That is, exposures to agricultural handlers associated with the

proposed uses on Assail® 70WP, and Assail® 30SG are not a risk concern to HED provided handlers obey the personal protection directions specified on the proposed labels. Likewise, exposures to PCO's from the labeled uses of F4688 50WSP are not a risk concern to HED provided PCO's obey the personal protection directions specified on the label. An expanded table of handler MOEs is attached as Appendix B.

9.3 Post-application Exposure and Risk

No chemical specific post-application data were submitted in support of the subject petitions. Therefore, exposures during post-application agricultural activities were estimated using dermal transfer coefficients from the Science Advisory Council for Exposure SOP Number 3.1., and standard assumptions with respect to dislodgeable residues. Both short-term, and intermediate-term post-application MOEs were greater than 100 on day zero after application and, do not present a risk concern to HED. However, as per the Worker Protection Standard, (WPS), a restricted entry interval (REI) of 12 hours is required based on the acute toxicity of acetamiprid technical material which is classified as Category III and IV for acute dermal, dermal irritation, and eye irritation. Therefore, the 12-hour REI which appears on the proposed labels Assail® 70WP, and Assail® 30SG is adequate. A summary of post-application MOEs is provided below in Table 17.

Table 17. Post-application Risks for Acetamiprid

Crop	App. Rate	Contact Potential	Activity	Transfer Coefficient Value	MOE[2] At Day Zero
Stone Fruits	0.15 lb ai/A	low	Propping, scouting, irrigation, and hand harvesting	1,500	1500
		high	Thinning	3,000	750
Cucurbit Vegetables	0.10 lb ai/A	low	Scouting, thinning, irrigation and hand weeding	1,500	2,200
		high	Leaf pulling, turning, thinning, hand harvesting and pruning	2,500	1,300
Bulb Vegetables	0.15 lb ai/A	low	Irrigation, scouting, thinning, and hand weeding	300	7,700
		high	Hand harvesting	2,500	910
Tree nuts	0.18 lb ai/A	low	Scouting, thinning, and irrigation	500	3,700
		high	Thinning, hand harvesting and pruning	2,500	740
Legumes	0.1 lb ai/a	low	Scouting, irrigation, hand weeding , and thinning	100	33,000
		high	Hand harvest	2,500	1,300
Low Berry		low	Pruning, thinning, and scouting	400	8,300
		high	Hand pruning and harvesting	1,500	2,200
High Berry		low	Hedging, irrigation, hand weeding	500	6,700
		high	Hand harvest, pruning, training, tying	5,000	670

The information in the table is based on proprietary and non-proprietary data.
1: daily dose = [DFR (ug/cm^2) x Tc (cm^2/hr) x 0.001 mg/ug x dermal absorption (0.1) x 8 hrs/day] ÷ body weight (60 kg)
2: NOAEL/Daily Dose (Short- and Intermediate-term NOAEL = 10 mg/kg/day)

10.0 Data Needs, Deficiencies, and Label Recommendations

Directions for Use:
Current labels for use on berries, bulb vegetables, edible podded legume vegetables, succulent shelled beans, and peas, or strawberries and other low-growing berries should be amended to remove directions regarding the use of surfactants. The field trials submitted to support these crops were not conducted with surfactants, and the labels should be amended to be consistent with the field trial data.

Petition for Tolerances for "Combined" Residues:
The tolerance expression proposed by IR-4 with respect to strawberry, bearberry, bilberry, blueberry (lowbush), cloudberry, cranberry, lingonbery, muntries, and, partridgeberry should be revised to exclude the word "combined." HED has determined that combined residues of acetamiprid and its IM-2-1 metabolite are only valid with respect to residues in livestock commodities.

Unconditional Registrations:
HED recommends unconditional registrations for the following proposed uses:
Tree nuts,
Cucurbit vegetables,
Stone fruit,
Edible podded legume vegetables (crop subgroup 6A)
Succulent shelled peas and beans (crop subgroup 6B)
Bulb vegetables (crop subgroups 3A, and 3B)
Berries (crop subgroup 13B and 13G)

Tolerances:
HED recommends tolerances for acetamiprid be established as specified in Appendix D, Table 1.

Appendix A. References

Acetamiprid. Acute and Chronic Dietary Exposure Assessments to Support Section 3 Registration of Uses on Tree Nuts; Cucurbits; Stone Fruit; Legumes (Subgroup 6A); Pea and bean (Subgroup 6B); Berry (Subgroups 13B and 13G); and Bulb vegetables (Subgroups 3A and 3B). October 12, 2007; D335205.

Acetamprid: Occupational/Residential Exposure and Risk Assessment for Proposed Food Use on Stone Fruits, Cucurbit Vegetables, Tree Nuts, Berries, Bulb Vegetables, Edible Podded Legumes and Succulent Shelled Peas and Beans and Insecticide/Termiticide Uses. October 23, 2007; Z.Figueroa, M.Collantes; D345240.

Acetamiprid: Occupational and Residential Exposure Assessment for Proposed Section 3 Registration for General Pest Control Uses. 02/17/05; D304214.

Acetamiprid. Tolerance Petition Requesting Section 3 Registration for Food Use of the Insecticide on Cucurbit Vegetables (Crop Group 9), Stone Fruits (Crop Group 12), and Tree Nuts (Crop Group 14). Summary of Analytical Chemistry and Residue Data. Petition Number 4F6833. 11/5/2004; W.T.Drew; D303623.

Acetamiprid. Petitions Requesting the Establishment of Permanent Tolerances (Associated with Section 3 Registration) for New Food/Feed Uses of the Insecticide on Berries (Crop Group 13), Bulb Vegetables (Crop Group 3), Edible Podded Legume Vegetables (Crop Subgroup 6A), Succulent Shelled Pea and Bean (Crop Subgroup 6B), and Strawberry and Other Low-growing Berries. Summary of Analytical Chemistry and Residue Data. Petition Numbers 6F7051 (Various Crops) and 6E7163 (Strawberry). 10/23/2007; W.T.Drew; D328216.

Tier I Drinking Water Exposure Assessment for Acetamiprid on Cucutbit, Stone Fruit, and Tree Nut Crop Groups. June 21, 2005; G.Orrick; D303582.

Acetamiprid New Uses (Bulb Vegetables, Succulent Legumes, Strawberries, and Other Berries): Transmittal of Tier I Drinking Water Exposure Assessment. July 24, 2007; D331596, and D336256.

Appendix B. Occupational Exposure and Risk Table

Appendix B, Table 1 Occupational Handler Exposure and Risk for Proposed Uses of Acetamiprid										
Exposure Scenario	**Crop**	**Mtigation Level**	**Dermal Unit Exposure (mg/lb a.i.)**	**Inhalation Unit Exposure (mg/lb a.i.)**	**Maximum Application Rate (lb a.i./A)**	**Area Treated (A/Day)**	**Dermal Dose (mg/kg/day)**	**Inhalation Dose (mg/kg/day)**	**Total Dose (mg/kg/day)**	**Total MOE**
MIXER/LOADER										
Groundboom Wettable Powder	Curcurbits, berries, legumes	Baseline	3.7	.043	0.1	80	0.04933	0.005733	0.055	180
	Bulb vegetables				0.15		0.074	0.0086	0.0826	120
Groundboom Soluble Granule	Curcurbits, berries, legumes	Single layer & Gloves	0.066	0.00077	0.1		0.00088	0.0001	0.00098	10,000
	Bulb vegetables				0.15		0.00132	0.000154	0.00147	6,800
Airblast Wettable Powder	Stone fruit	Baseline	3.7	0.043	0.15	40	0.037	0.0043	0.0413	240
	Tree nuts				0.18		0.0444	0.00516	0.04956	200
Airblast Soluble Granule	Stone Fruit	Single layer & Gloves	0.066	0.00077	0.15		0.00066	0.000077	0.000737	14,000
	Tree nuts				0.18		0.000792	0.00000924	0.00084	11,000
Aerial Wettable Powder	Curcurbit, berry, legume	Single layer & Gloves	0.17	0.043	0.1	350	0.009917	0.025	0.035	290
	Stone fruit, bulb vegetables				0.15		0.0148	0.0376	0.0525	190
	Tree nut				0.18		0.01785	0.04515	0.063	160
Aerial Soluble Granule	Curcurbit, berry, legume		0.066	0.00077	0.1	350	0.00385	0.000449	0.004299	2,300
	Stone fruit, bulb vegetables				0.15		0.005775	0.000674	0.006445	1600
	Tree nut				0.18		0.00693	0.0008	0.007739	1,300

Appendix B, Table 1 Occupational Handler Exposure and Risk for Proposed Uses of Acetamiprid										
Exposure Scenario	**Crop**	**Mtigation Level**	**Dermal Unit Exposure (mg/lb a.i.)**	**Inhalation Unit Exposure (mg/lb a.i.)**	**Maximum Application Rate (lb a.i./A)**	**Area Treated (A/Day)**	**Dermal Dose (mg/kg/day)**	**Inhalation Dose (mg/kg/day)**	**Total Dose (mg/kg/day)**	**Total MOE**
APPLICATOR										
Groundboom	Curcurbit, berry, legume	Single layer & Gloves	0.014	0.00074	0.1	80	0.000187	0.000098	0.000285	35,000
	Bulb vegetables				0.15		0.00028	0.000148	0.000430	23,000
Airblast	Stonefruit	Baseline	0.36	0.0045	0.15	40	0.0036	0.00045	0.00405	2500
	Tree Nut				0.18		0.00432	0.00054	0.00486	2100
Aerial	Curcurbit, berry, legume	Engineering Controls	0.005	0.000068	0.1	350	0.00029	3.9E-5	0.00033	30,000
	Bulb Veg. Stone Fruit				0.15		0.00044	5.9E-5	0.000497	20,000
	Tree Nut				0.18		0.000525	7.1E-5	0.00059	17,000
Flagger	Curcurbit, berry, legume	Baseline	0.011	0.00035	0.1	350	0.000642	0.0002	0.000846	12,000
	Bulb Veg., Stone Fruit				0.15		0.00096	0.0003	0.00127	7900
	Tree Nut				0.18		0.001155	0.000368	0.001523	6600
MIXER/LOADER/APPLICATOR										
Liquids for Low Pressure Handwand (ORETF data surrogate for WSP)	Outdoor pest, ant, termite control	Baseline	15	0.0027	0.0043 (lb ai/gal)	40 gals/day	0.0043	0.0000077	0.0043	2300
Water Soluble Packets for Handgun Sprayer (LCO ORETF)	Outdoor pest, ant, termite control	Single Layer, Gloves	0.64	0.0072		100 gals./day	0.00046	0.0000516	0.00051	20,000
Liquids w/ Injector	Termiticide		0.36	0.0022		1000 gal/day	0.00258	0.000158	0.00274	3700

Appendix B, Table 1 Occupational Handler Exposure and Risk for Proposed Uses of Acetamiprid										
Exposure Scenario	**Crop**	**Mtigation Level**	**Dermal Unit Exposure (mg/lb a.i.)**	**Inhalation Unit Exposure (mg/lb a.i.)**	**Maximum Application Rate (lb a.i./A)**	**Area Treated (A/Day)**	**Dermal Dose (mg/kg/day)**	**Inhalation Dose (mg/kg/day)**	**Total Dose (mg/kg/day)**	**Total MOE**
MIXER/LOADER/APPLICATOR (continued)										
Water Soluble Packets for Foam Application (using PHED data for low pressure handwand)	Ant control, Termiticide	Single Layer, Gloves	8.6	1.1	0.0043 (lb ai/gal)	40 gals/day	0.00247	0.0032	0.0056	1800
Liquids with a Paint Brush	Outdoor pest, ant control	Baseline	180	0.280		2 gals/day	0.00258	0.00004	0.00262	3800
Liquids with Sprinkling Can (ORETF hose-end data as surrogate for WSP)			5	0.017		10 gals/day	0.00036	0.000012	0.000371	27,000
Liquids with Hose-end Sprayer (ORETF data as surrogate for WSP)						100 gals/day	0.00358	0.000122	0.0037	2700

1: Dermal Dose (mg/kg/day) = $\frac{\text{Rate (lb ai/A) x UE (mg /lb ai) x DA (0.1) x Acres Treated (A/day) or (gal/day)}}{\text{BW (60 kg)}}$

2: Inhalation Dose (mg/kg/day) = $\frac{\text{Rate (lb ai/A) x UE (mg /lb ai) x Acres Treated (A/day) or (gal/day)}}{\text{BW (60 kg)}}$

5: Total Dose (mg/kg/day) = Dermal Dose (mg/kg/day) + Inhalation Dose (mg/kg/day)

6: Total MOE = NOAEL (10 mg/kg/day)/Total Dose (mg/kg/day)

Appendix C. Acetamiprid Toxicology Assessment

Toxicity Profile for Acetamiprid

Appendix C, Table 1.
Acute Toxicity of Technical Acetamiprid

GDLN	Study Type	MRID	Results	Tox Category
870.1100	Acute Oral - rat	44651833	LD_{50}: 217 mg/kg (M) LD_{50}: 146 mg/kg (F)	II
870.12	Acute Dermal - rat	44651836	LD_{50} > 2000 mg/kg	III
870.13	Acute Inhalation - rat	44651837	LC_{50}: > 1.15 mg/L (~) > 1.15 mg/L (~)	III
870.24	Primary Eye Irritation - rabbit	44651838	Not irritating to the eye	IV
870.25	Primary Skin Irritation - rabbit	44651839	Not irritating to the skin	IV
870	Dermal Sensitization - Guinea pig	44651840	Is not a sensitizer under conditions of study.	N/A

Subchronic, Chronic and Other Toxicity Profile for Acetamiprid

Appendix C, Table 2. Toxicity Profile of Technical Acetamiprid	
Guideline No./Study Type	**Results**
870.3100 13-Week feeding - rat	**NOAEL**: 12.4/14.6 mg/kg/day (M/F) **LOAEL**: 50.8/56.0 mg/kg/day (M/F: decreased BW, BW gain and food consumption).
870.3100 13-Week feeding - mouse	**NOAEL**: 106.1/129.4 mg/kg/day (M/F) **LOAEL**: 211.1/249.1 mg/kg/day (reduced BW and BW gain, decreased glucose and cholesterol levels, reduced absolute organ weights).
870.3150 3-Month feeding - dog	**NOAEL**: 13/14 mg/kg/day (M/F) **LOAEL**: 32 mg/kg/day (reduced BW gain in both sexes).
870.3200 21-Day dermal toxicity - rabbit	**NOAEL**: 1000 mg/kg/day (HDT) **LOAEL**: >1000 mg/kg/day
870.3700 Developmental toxicity - rat	**Maternal NOAEL**: 16 mg/kg/day **Maternal LOAEL**: 50 mg/kg/day (reduced BW & BW gain and food consumption, increased liver weights). **Developmental NOAEL**: 16 mg/kg/day **Developmental LOAEL**: 50 mg/kg/day (increased incidence of shortening of the 13th rib)
870.3700 Developmental toxicity - rabbit	**Maternal NOAEL**: 15 mg/kg/day **Maternal LOAEL**: 30 mg/kg/day (BW loss and decreased food consumption). **Developmental NOAEL**: 30 mg/kg/day (HDT) **Developmental LOAEL**: > 30 mg/kg/day
870.3800 2-Generation reproduction - rat	**Parental systemic NOAEL**: 17.9/21.7 mg/kg/day (M/F) **Parental systemic LOAEL**: 51.0/60.1 mg/kg/day (M/F) (decreased body weight, body weight gain and food consumption). **Offspring systemic NOAEL**: 17.9/21.7 mg/kg/day (M/F) **Offspring systemic LOAEL**: 51.0/60.1 mg/kg/day (M/F: reductions in pup weight, litter size, viability and weaning indices; delay in age to attain preputial separation and vaginal opening). **Reproductive NOAEL**: 17.9/21.7 mg/kg/day (M/F) **Reproductive LOAEL**: 51.0/60.1 mg/kg/day (M/F: reductions in litter weights and individual pup weights on day of delivery).
870.4100 1-Year oral - dog	**NOAEL**: 20/21 mg/kg/day (M/F) **LOAEL**: 55/61 mg/kg/day (M/F: initial BW loss and overall reduction in BW gain).
870.4200 Carcinogenicity - mouse	**NOAEL**: 20.3/75.9 mg/kg/day (M/F) **LOAEL**: 65.6/214.6 mg/kg/day (M/F: decreased BW & BW gain and amyloidosis in numerous organs (M) and decreased BW and BW gain (F)). Not oncogenic under conditions of study.
870.4300 Chronic/carcinogenicity - rat	**NOAEL**: 7.1/8.8 mg/kg/day (M/F) **LOAEL**: 17.5/22.6 mg/kg/day (M/F, decreases in mean BW & BW gain (F) and hepatocellular vacuolation (M)) Evidence of treatment-related increase in mammary tumors.
870.5100 *Salmonella typhimurium/E. coli* Reverse gene mutation assay	Not mutagenic under the conditions of the study.

Appendix C, Table 2. Toxicity Profile of Technical Acetamiprid	
Guideline No./Study Type	**Results**
870.5300 Mammalian cells in culture Forward gene mutation assay - CHO cells	Not mutagenic under the conditions of the study.
870.5375 *In vitro* mammalian chromosomal aberrations - CHO cells	Acetamiprid is a clastogen under the conditions of the study.
870.5385 *In vivo* mammalian chromosome aberrations - rat bone marrow	Acetamiprid did not induce a significant increase in chromosome aberrations in bone marrow cells when compared to the vehicle control group.
970.5395 *In vivo* mammalian cytogenetics - micronucleus assay in mice	Acetamiprid is not a clastogen in the mouse bone marrow micronucleus test.
870.5550 UDS assay in primary rat hepatocytes/mammalian cell culture	Acetamiprid tested negatively for UDS in mammalian hepatocytes *in vivo.*
870.6200 Acute neurotoxicity - rat	**NOAEL**: 10 mg/kg **LOAEL**: 30 mg/kg (reduction in locomotor activity).
870.6200 Subchronic neurotoxicity - rat	**NOAEL**: 14.8/16.3 mg/kg/day (M/F) **LOAEL**: 59.7/67.6 mg/kg/day (M/F: reductions in BW, BW gain, food consumption and food efficiency).
870.6300 Developmental neurotoxicity study - rat	**Maternal NOAEL:** 10 mg/kg/day **Maternal LOAEL:** 45 mg/kg/day, (decreased body weight and body weight gains during gestation only) **Developmental NOAEL:** 10 mg/kg/day **Developmental LOAEL:** 45 mg/kg/day (decreased maximum auditory startle response in males on PND 20 and PND 60, and decreased body weight and body weight gain, and pup viability.
N/A 28-Day feeding - dog	**NOAEL**: 16.7/19.1 mg/kg/day (M/F) **LOAEL**: 28.0/35.8 mg/kg/day (reduced BW gain).
870.7485 Metabolism - rat	Extensively and rapidly metabolized. Metabolites 79-86% of administered dose. Profiles similar for males and females for both oral and intravenous dosing. Thirty-seven percent of dose recovered in urine and feces as unchanged test article. Urinary and fecal metabolites from 15-day repeat dose experiment only showed minor differences from single-dose test. Initial Phase I biotransformation: demethylation of parent. 6-chloronicotinic acid was the most prevalent metabolite. Phase II metabolism shown by the increase in glycine conjugate.
870.7485 Metabolism - mice, rats, rabbits Special study	Male mice, rats or rabbits were administered single doses of acetamiprid by gavage, intraperitoneal injection (i.p.) or intravenous injection (i.v.) up to 60 mg/kg. The animals were assessed for a variety of neurobehavioral parameters. *In vitro* experiments were also done using isolated ileum sections from guinea pigs to assess contractile responses in the absence and presence of agonists (acetylcholine, histamine diphosphate, barium chloride and nicotine tartrate). Acetamiprid was also assessed via i.v. in rabbits for effects on respiratory rate, heart rate and blood pressure; via gavage in mice for effects on gastrointestinal motility; and via i.p. in rats for effects on water and electrolyte balance in urine, and blood coagulation, hemolytic potential and plasma cholinesterase activity. **Based on a number of neuromuscular, behavioral and physiological effects of acetamiprid in**

Appendix C, Table 2. Toxicity Profile of Technical Acetamiprid	
Guideline No./Study Type	**Results**
	male mice, under the conditions of this study, a overall NOAEL of 10 mg/kg (threshold) and LOAEL of 20 mg/kg could be estimated for a single dose by various exposure routes.
§ 870.7600 Dermal absorption	Revised dermal absorption rate of 10% (from 30%) is based upon the dermal absorption study with acetamiprid (MRID 44651858) and consideration of dermal penetration values from other neonicitinoid insecticides (thiamethoxam), and consideration of K_{ow} and octanol/water coefficient data of other neonicitinoid compounds (clothianidin).

Appendix D. Tolerance Summary Table for Petitions

Appendix D, Table 1. Tolerance Summary for Acetamiprid PP# 4F6833, PP#6F7051, and PP#6E7163			
Commodity	**Proposed Tolerance (ppm)**	**Recommended Tolerance (ppm)**	**Comments; *Correct Commodity Definition****
Proposed Tolerances			
Almond hulls	5.0	5.0	*Almond, hulls*
Bulb vegetables crop group (Group 3)	3.0	Remove	Separate tolerances should be proposed for the individual crops in the pending green onion and bulb onion subgroups.
Edible podded legume vegetables (Subgroup 6A)	0.5	0.60	*Vegetable, legume, edible podded, subgroup 6A*
Succulent shelled peas and beans (Subgroup 6B)	0.5	0.40	*Pea and bean, succulent shelled, subgroup 6B*
Berries crop group (Group 13)	1.0	1.6	*Berry, group 13*
Bearberry	0.60	0.60	Tolerances on commodities included in the pending low-growing berries subgroup 13G.
Bilberry	0.60	0.60	
Blueberry, lowbush	0.60	Remove (not needed).	Lowbush blueberry is already a member of the berries group 13.
Cloudberry	0.60	0.60	Tolerances on commodities included in the pending low-growing berries subgroup 13G.
Cranberry	0.60	0.60	
Lingonberry	0.60	1.6	Lingonberry is a member of the pending bushberries subgroup 13B, for which a higher tolerance is recommended.
Muntries	0.60	0.60	Tolerances on commodities included in the pending low-growing berries subgroup 13G.
Partridgeberry	0.60	0.60	
Strawberry	0.60	0.60	

Appendix D, Table 1. Tolerance Summary for Acetamiprid PP# 4F6833, PP#6F7051, and PP#6E7163			
Commodity	**Proposed Tolerance (ppm)**	**Recommended Tolerance (ppm)**	**Comments; *Correct Commodity Definition****
Tolerances That Need to be Proposed			
Aronia berry	--	1.6	Tolerances on commodities included in the pending bushberries subgroup 13B, along with lingonberry.
Buffalo currant	--	1.6	
Chilean guava	--	1.6	
European barberry	--	1.6	
Highbush cranberry	--	1.6	
Honeysuckle, edible	--	1.6	
Jostaberry	--	1.6	
Juneberry	--	1.6	
Native currant	--	1.6	
Salal	--	1.6	
Sea buckthorn	--	1.6	
Onion, bulb	--	0.02	Tolerances on commodities included in the pending bulb onion subgroup 3A.
Fritillaria, bulb	--	0.02	
Daylily, bulb	--	0.02	
Garlic, bulb	--	0.02	
Garlic, great headed, bulb	--	0.02	
Garlic, Serpent, bulb	--	0.02	
Lily, bulb	--	0.02	
Onion, Chinese, bulb	--	0.02	
Onion, Pearl	--	0.02	
Onion, potato, bulb	--	0.02	
Shallot, bulb	--	0.02	

Appendix D, Table 1.
Tolerance Summary for Acetamiprid PP# 4F6833, PP#6F7051, and PP#6E7163

Commodity	Proposed Tolerance (ppm)	Recommended Tolerance (ppm)	Comments; *Correct Commodity Definition**
Onion, green	--	4.5	Tolerances on commodities included in the pending green onion subgroup 3B.
Chive, fresh leaves	--	4.5	
Chive, Chinese, fresh leaves	--	4.5	
Elegans hosta	--	4.5	
Fritillaria, leaves	--	4.5	
Kurrat	--	4.5	
Lady's leek	--	4.5	
Leek	--	4.5	
Leek, wild	--	4.5	
Onion, Beltsville bunching	--	4.5	
Onion, fresh	--	4.5	
Onion, macrostem	--	4.5	
Onion, tree, tops	--	4.5	
Onion, Welsh, tops	--	4.5	
Shallot, fresh leaves	--	4.5	
Stone Fruit group, except prune plum	1.2	1.20	*Fruit, stone, group 12 (except plum, prune)*
Fresh prune plum	0.30	0.20	Proposed tolerance was too high. *Plum, prune, fresh*
Dried prune plum	0.30	0.40	Proposed tolerance was too low. *Plum, prune, dried*
Tree nut group	0.10	0.10	*Nut, tree, group 14*
Pistachio	None proposed	0.10	Although tree nut field trial data may be used to support use on pistachio, a separate tolerance is needed for pistachio. *Pistachio*
Cucurbit vegetable group	0.50	0.50	*Vegetable, cucurbit, group 9*

* Refer to HED Memorandum dated 6/14/2006 by Bernard Schneider for pending changes to crop groups, and commodity definitions.

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

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

MEMORANDUM

DATE: October 12, 2007

SUBJECT: **Acetamiprid**. Acute and Chronic Dietary Exposure Assessments to Support Section 3 Registration of Uses on Tree Nuts; Cucurbits; Stone Fruit; Legumes (Subgroup 6A); Pea and bean (Subgroup 6B); Berry (Subgroups 13B and 13G); and bulb vegetables (Subgroups 3A and 3B).

PC Code: 099050
Data Package No.: D335205
Petition Nos.: 4F6833; 6F7051; and 6E7163

REVIEWER: Christina Swartz, Chemist
Registration Action Branch 2
Health Effects Division (7509P)

THROUGH: Thurston Morton, Chemist
Mohsen Sahafeyan, Chemist
Dietary Exposure Science Advisory Council (DESAC)
Health Effects Division (7509P)

and

Richard Loranger, Ph.D., Branch Senior Scientist
Registration Action Branch 2
Health Effects Division (7509P)

TO: Thomas Moriarty, Env. Prot. Specialist
Registration Action Branch 2
Health Effects Division (7509P)

Executive Summary

Acute and chronic dietary (food + water) risk assessments were conducted using the Dietary Exposure Evaluation Model (DEEM-FCID™, Version 2.03) which uses food consumption data

from the USDA's Continuing Surveys of Food Intakes by Individuals (CSFII, 1994-1996 and 1998). The analyses were performed to support the requested Section 3 registration of acetamiprid on stone fruit, tree nut and cucurbit vegetables; a previous assessment (C. Swartz, DP Barcode No. D309740, 10/28/2004) has been revised to reflect updated dose and endpoint selection for acute and chronic dietary exposure and risk, as well as the incorporation of percent crop treated (%CT) information. In addition, the current assessment includes additional proposed uses on legumes, berries, and bulb vegetables; petitions for tolerances associated with these uses were received before the previous assessment was completed, so the 2 actions have been combined.

Acute Dietary (Food and Drinking Water) Exposure Results and Characterization

The probabilistic acute dietary exposure assessment included anticipated residues from field residue trials, processing factors, maximum %CT estimates (for existing uses only) generated by the Biological and Economic Analysis Division (BEAD), and the modeled peak concentration of acetamiprid residues in surface water sources of drinking water. Although the acute assessment has been refined, the resulting exposure estimates are still somewhat conservative because field trial data were the basis for the anticipated residues, and because a lower tier drinking water model (FIRST) was used to estimate residues in drinking water. No food or water monitoring data were available to further refine the exposure estimates.

Acute dietary exposure estimates, based on the existing and proposed uses for acetamiprid, are below HED's level of concern for the general US population and all other population subgroups. The estimated exposure of 0.018 mg/kg/day for the general US population corresponds to 18% of the acute population adjusted dose (aPAD); children 1-2 years old were the highest exposed subpopulation, with an acute dietary exposure estimate of 0.035 mg/kg/day, or 35 %aPAD.

Chronic Dietary (Food and Drinking Water) Exposure Results and Characterization

For the chronic analysis, tolerance-level residues were assumed for all food commodities with current and proposed acetamiprid tolerances; in addition, an assumption of 100 %CT was used for all commodities except apples and oranges, for which the average %CT was used. The chronic analysis also included the modeled surface water annual average residue in drinking water. Even though %CT information was used in the chronic analysis, the exposure and risk estimates are still conservative since tolerance level residues were used, because 100 %CT was assumed for all crops other than apples and oranges, and because a lower tier drinking water model (FIRST) was used.

Chronic dietary exposure to acetamiprid, including existing and proposed uses, is below HED's level of concern for the US population and all other population subgroups. For the general US population, and estimated exposure of 0.006 mg/kg/day corresponds to 9% of the chronic population adjusted dose (cPAD); children 1-2 years old were the highest exposed population subgroup, with an estimate of 0.025 mg/kg/day, or 35 %cPAD. Risks for all population subgroups are less than 100 %cPAD, and are not of concern.

I. Introduction

Dietary risk assessment incorporates both exposure and toxicity of a given pesticide. For acute and chronic assessments, the risk is expressed as a percentage of a maximum acceptable dose (i.e., the dose which HED has concluded will result in no unreasonable adverse health effects). This dose is referred to as the population adjusted dose (PAD). The PAD is equivalent to a point of departure (POD, NOAEL, LOAEL, e.g.) divided by the required uncertainty or safety factors.

For acute and non-cancer chronic exposures, HED is concerned when estimated dietary risk exceeds 100% of the PAD. References which discuss the acute and chronic risk assessments in more detail are available on the EPA/pesticides web site: "Available Information on Assessing Exposure from Pesticides, A User's Guide," 6/21/2000, web link: http://www.epa.gov/fedrgstr/EPA-PEST/2000/July/Day-12/6061.pdf ; or see SOP 99.6 (8/20/99).

The most recent dietary risk assessment for acetamiprid was conducted by C. Swartz (DP Barcode No. D309740, 10/28/04) which included proposed uses on tuberous and corm vegetables as well as additional proposed uses on cucurbits, tree nuts and stone fruit. Tolerances for residues in or on tuberous and corm vegetables were subsequently established under 40 CFR §180.578(a).

II. Residue Information

Tolerances are established for residues of the insecticide acetamiprid [40 CFR §180.578(a)], N1-[(6-chloro-3-pyridyl)methyl]-N2-cyano-N1- methylacetamidine, in or on canola, seed, 0.01 ppm; mustard, seed, 0.01 ppm; citrus, dried pulp, 1.20 ppm; cotton, gin byproducts, 20 ppm; cotton, undelinted seed, 0.60 ppm, fruit, citrus group, 0.50 ppm; fruit, pome group, 1.0 ppm; grape, 0.20 ppm; tomato, paste, 0.40 ppm; vegetable, Brassica, leafy, (group 5), 1.20 ppm; vegetable, fruiting (group 8), 0.20 ppm; vegetable, leafy, except Brassica, (group 4), 3.00 ppm; tuberous and corm vegetables (Group 1C), 0.01 ppm. Tolerances are established for the combined residues of the insecticide acetamiprid, N1-[(6-chloro-3-pyridyl)methyl]-N2-cyano-N1-methylacetamidine, and its metabolite N1-[(6-chloro-3-pyridyl)methyl]-N2-cyano- acetamidine [40 CFR §180.578(b)] in or on fat and meat of cattle, goat, hog, horse and sheep, 0.1 ppm; meat by-products of cattle, goat, hog horse and sheep, 0.2 ppm; milk, 0.1 ppm; poultry meat and fat, 0.01 ppm; poultry liver, 0.05 ppm; and egg, 0.01 ppm.

The current acute and chronic dietary exposure assessments include existing uses and the Section 3 tolerances proposed by Nisso America Incorporated (representing Nippon Soda Company Limited) associated with the proposed uses on tree nuts (Crop Group 14), Stone Fruit (Crop Group 12), Cucurbits (Crop Group 9), Legumes (Subgroup 6A); Pea and Bean (Subgroup 6B); Berry (Subgroups 13B and 13G); and Bulb Vegetables (Subgroups 3A and 3B). The recommended tolerances shown below are supported by adequate residue data.

Crop Group or Commodity	List of Commodities Included	Recommended Tol. (ppm)
Tree Nuts (Crop Group 14)	almonds; beechnut; butternut; cashew; chestnut; chinquapin; filbert; brazil nut; hickory nut; macadamia nut; processed nutmeat (except peanut); nuts; pecan; walnut	0.1
Pistachio	Pistachio	0.1
Almond, hulls	Almond, hulls	5.0
Fruit, stone, except plum, prune fresh and dried (Crop Group 12)	apricot; cherry (sweet and tart); nectarine; peach; plum; plum, chickasaw; plum, damson; plum, Japanese	1.2
Plum, prune, fresh	plum, prune; plum, prune, fresh	0.2
Plum, prune, dried	plum, prune, dried	0.4
Vegetable, cucurbit group (Crop Group 9)	balsam apple; balsam pear; cantaloupe; chayote fruit; cucumber; cucumber, Chinese; gherkin, West Indian; gourd, edible; melon; melon, citron; muskmelon; pumpkin; squash; squash, summer; squash, winter; watermelon; waxgourd, chinese	0.5
Vegetable, legume, edible podded, (Subgroup 6A)	Bean, moth; bean, runner; bean, snap; bean, wax; bean, yardlong; jackbean; longbean, Chinese; pea, dwarf; pea, edible podded; pea, pigeon; pea, snow; pea, sugar snap; soybean, immature seed; swordbean.	0.6
Pea and bean, succulent, shelled (Subgroup 6B)	Bean, broad; bean, lima succulent; cowpea; cowpea seed; pea, blackeyed; pea, English; pea, garden; pea, green; pea, pigeon; pea, southern	0.4
Berry, group 13	Blackberry; blueberry; caneberry; currant; elderberry; gooseberry; huckleberry; loganberry; raspberry	1.6
Berries, low-growing, subgroup 13G	bearberry, bilberry, cloudberry cranberry, muntries, partridgeberry, strawberry	0.6

Crop Group or Commodity	List of Commodities Included	Recommended Tol. (ppm)
Bushberry Subgroup 13B	Blueberry; currant; elderberry; gooseberry; huckleberry; Aronia berry; Buffalo currant; Chilean guava; European barberry; Highbush cranberry; Honeysuckle; Jostaberry; Juneberry; Lingonberry; Native currant; Salal; Sea buckthorn	1.6
Bulb Onion (Subgroup 3A)	Onion, bulb; Fritillaria, bulb; Daylily, bulb; Garlic, bulb; Garlic, great headed, bulb; Garlic, Serpent, bulb; Lily, bulb; Onion, Chinese, bulb; Onion, Pearl; Onion, potato, bulb; Shallot, bulb	0.02
Green Onion (Subgroup 3B)	Onion, green; Chive, fresh leaves; Chive, Chinese, fresh leaves; Elegans hosta; Fritillaria, leaves; Kurrat; Lady's leek; Leek; Leek, wild; Onion, Beltsville bunching; Onion, fresh; Onion, macrostem; Onion, tree, tops; Onion, Welsh, tops; Shallot, fresh leaves	4.5

Acute Dietary Exposure Assessment

The acute dietary assessment was conducted using anticipated residues from field trials [apples; broccoli; cabbage, celery; grapefruit; grapes; lettuce; oranges; pears; peppers; spinach; tomatoes; stone fruit (crop group 12); and cucurbits (crop group 9)]. For each of the above-listed commodities, the individual field trial residue values (from trials reflecting the 1X application rate and label PHI) were incorporated into a residue distribution file (RDF) for the probabilistic acute dietary exposure assessment. For field trial residues below the limit of quantification (LOQ) of 0.01 ppm, a residue value of ½ LOQ, or 0.005 ppm was assumed. For cabbage and head lettuce, residues in the RDF were for the raw agricultural commodity (RAC) without wrapper leaves. For commodities with %CT data available, the RDF includes an indication of the number of zeroes assumed for the percent of the commodity not treated. For the proposed uses on legumes, berries and bulb vegetables, proposed tolerance level residues were used in the dietary assessment. Tolerance level residues were also used for livestock commodities.

A summary of the rdfs is included in Attachment 1. The peach RDF was translated to nectarines, the orange RDF was translated to grapefruit, and the plum RDF was translated to apricots. These translations are appropriate since the field trials were conducted on the representative crops, and cover potential residues in the related crops, and since no adjustment for %CT was made in these RDFs.

Chronic Dietary Exposure Assessment

For the chronic dietary exposure assessment, current and recommended tolerance-level residues were used, for all RACs and livestock commodities.

Processing Factors

The acute dietary exposure assessment was refined with processing factors for apple juice, orange juice, grape juice, raisins, dried prunes, tomato paste and tomato puree. The processing factors were reviewed in conjunction with residue data used to determine if separate tolerances were needed for processed commodities. For all other commodities, the DEEM™ Version 7.81 default processing factors were used. Processing factors from study data were incorporated into the acute dietary assessment as follows (Table 1):

Table 1. Summary of Processing Studies Conducted with Acetamiprid.

RAC	Processed Commodity	Processing Factor	Comments
Apple	Juice	0.88	Also used for pear juice
Citrus	Juice	<0.16	0.16X used for both orange and grapefruit juice
Grape	Juice	1	Study data showed RAC tolerance would cover residues in juice. 1X factor used in acute assessment.
	Raisins	0.9	0.9X used in assessment
Tomato	Puree	1.4	1.4X used for puree in assessment
	Paste	3.0	1X used for paste in acute assessment, since there is a separate tolerance for residues in paste.
Plum	Prune, dried	2.9X	1X used for dried prunes used in acute assessment, since there is a separate tolerance for residues in dried prunes. The drying factor was translated to dried apricots and dried peaches in the acute dietary assessment.

For the chronic dietary exposure assessment, the DEEM™ Version 7.81 default processing factors were used, with the exception of dried prunes, for which a separate tolerance is recommended.

Usage Data

In order to refine the dietary exposure estimates for acetamiprid, HED requested a Screening Level Usage Analysis (SLUA), which was conducted by the Biological and Economic Analysis Division (BEAD), 7/7/05. The SLUA includes estimates of maximum %CT for the acute assessment and average %CT for determining chronic exposure. Commodities with the most significant acetamiprid usage in terms of maximum %CT include pears (25%), apples (15%), celery (15%), and lettuce (10%). Commodities with the most significant usage in terms of lbs ai applied include apples (9,000), cotton (8,000), and pears (3,000). The SLUA is included as

Attachment 3.

For the acute analysis, %CT was incorporated into RDFs for the following commodities:

- apples (15%), broccoli (5%), celery (15%), lettuce (10%), pears (25%)
- grapefruit, grapes, oranges, peppers, spinach and tomatoes, all at 2.5%.

For the chronic analysis, average %CT was included (as adjustment factor 2) for apples (10%) and oranges (1%).

Incorporation of Potential Residues in Drinking Water

In conjunction with the proposed uses, the Environmental Fate and Effects Division (EFED) of OPP prepared an estimate of potential residues in drinking water [G. Orrick, Tier I Drinking Water Exposure Assessment for Acetamiprid on Cucurbit, Stone Fruit and Tree Nut Crop Groups, 6/21/05, D303582]. Estimated drinking water concentrations for acetamiprid in surface water were generated using the FIRST (*F*QPA *I*ndex *R*eservoir *S*creening *T*ool, v. 1.0) model. The results of the model reflect potential residues in a small drinking water reservoir surrounded by a runoff-prone watershed, assuming maximum pesticide application rates and no buffer between the reservoir and treated fields. Acetamiprid residues in ground water sources of drinking water were estimated using the screening regression model SCI-GROW (*S*creening *C*oncentration *I*n *Gro*und *W*ater, v. 2.3). The SCI-GROW residue estimate is based on environmental fate properties of the pesticide, maximum application rates, and existing data from small-scale prospective ground-water monitoring studies in vulnerable sites.

For surface water, the maximum application rate for the existing use of acetamiprid on citrus was used to provide model estimates of drinking water concentrations; for ground water, the proposed use on tree nut crops was used. However, since modeled surface water residues were considerably higher than ground water residues, only the surface water residues were used quantitatively in the dietary (food + water) assessment. In a memo dated 7/24/07 [G. Orrick, D331596 and D336256], EFED notified HED that new drinking water estimates would not be provided for the proposed use on bulb vegetables, legumes, strawberries and other berries because the drinking water estimates derived from the uses on citrus and tree nuts reflect the maximum use patterns for acetamiprid.

For the acute assessment, an estimated drinking water concentration of 20.1 ppb was entered into the DEEM™-FCID model for "water, direct, all sources" and "water, indirect, all sources." For the chronic assessment, the value of 4.9 ppb was used. The ground water estimate of 1.6 ppt was much lower than surface water residues; therefore, dietary exposure and risk calculated using surface water residues are considered protective of potential exposure through ground water.

III. Exposure Model and Consumption Information

Acetamiprid acute and chronic dietary exposure assessments were conducted using the Dietary

Exposure Evaluation Model software with the Food Commodity Intake Database DEEM-FCID™,Version 2.03 which incorporates consumption data from USDA's Continuing Surveys of Food Intakes by Individuals (CSFII), 1994-1996 and 1998. The 1994-96, 98 data are based on the reported consumption of more than 20,000 individuals over two non-consecutive survey days. Foods "as consumed" (e.g., apple pie) are linked to EPA-defined food commodities (e.g. apples, peeled fruit - cooked; fresh or N/S; baked; or wheat flour - cooked; fresh or N/S, baked) using publicly available recipe translation files developed jointly by USDA/ARS and EPA. For chronic exposure assessment, consumption data are averaged for the entire U.S. population and within population subgroups, but for acute exposure assessment are retained as individual consumption events. Based on analysis of the 1994-96, 98 CSFII consumption data, which took into account dietary patterns and survey respondents, HED concluded that it is most appropriate to report risk for the following population subgroups: the general U.S. population, all infants (<1 year old), children 1-2, children 3-5, children 6-12, youth 13-19, adults 20-49, females 13-49, and adults 50+ years old.

For chronic dietary exposure assessment, an estimate of the residue level in each food or food-form (e.g., orange or orange juice) on the food commodity residue list is multiplied by the average daily consumption estimate for that food/food form to produce a residue intake estimate. The resulting residue intake estimate for each food/food form is summed with the residue intake estimates for all other food/food forms on the commodity residue list to arrive at the total average estimated exposure. Exposure is expressed in mg/kg body weight/day and as a percent of the cPAD. This procedure is performed for each population subgroup.

For acute exposure assessments, individual one-day food consumption data are used on an individual-by-individual basis. The reported consumption amounts of each food item can be multiplied by a residue point estimate and summed to obtain a total daily pesticide exposure for a deterministic exposure assessment, or "matched" in multiple random pairings with residue values and then summed in a probabilistic assessment. The resulting distribution of exposures is expressed as a percentage of the aPAD on both a user (i.e., only those who reported eating relevant commodities/food forms) and a per-capita (i.e., those who reported eating the relevant commodities as well as those who did not) basis. In accordance with HED policy, per capita exposure and risk are reported for all tiers of analysis. However, for tiers 1 and 2, any significant differences in user vs. per capita exposure and risk are specifically identified and noted in the risk assessment.

IV. Toxicological Information

Doses and endpoints selected for acute and chronic dietary exposure and risk assessments are summarized as shown in Table 2, below. Details regarding hazard characterization and endpoint selection can be found in the risk assessment associated with the proposed uses [ref. here].

Table 2. Acetamiprid Toxicological Doses/Endpoints for Dietary Risk Assessment.

Exposure Scenario	Point of Departure	Uncertainty/FQPA Safety Factors	RfD, PAD, Level of Concern	Study and Toxicological Effects
Acute Dietary [All Populations]	NOAEL=10.0 mg/kg/day	UF_A= 10x UF_H= 10x FQPA SF= 1x Total UF=100X	Acute RfD = 0.10 mg/kg/day aPAD = 0.10 mg/kg/day	Developmental Neurotox., Rat LOAEL = 45.0 mg/kg/day based on decreased startle response on PND20/60 in males Co Critical study - Acute Neurotox., Rat LOAEL = 30 mg/kg/day based on reduced locomotor activity in males.
Chronic Dietary [all populations]	NOAEL = 7.1 mg/kg/day	UF_A= 10x UF_H= 10x FQPA SF= 1x Total UF =100X	Chronic RfD = 0.071 mg/kg/day cPAD = 0.071 mg/kg/day	Chronic/oncogenicity, Rat LOAEL= 17.5 mg/kg/day based on reduced body weight and body weight gain (♀) and hepatocellular vacuolation (♂).
Cancer (All routes)	Not likely to be a human carcinogen.			

V. Results/Discussion

As stated above, for acute and chronic assessments, HED is concerned when dietary risk exceeds 100% of the PAD. For both the acute and chronic analyses, the estimated dietary exposures are below HED's level of concern for all population subgroups; the most highly exposed population subgroup for both acute and chronic durations is children 1-2 years old.

Acute dietary exposure estimates at the 99.9^{th} percentile are below HED's level of concern for the general US population and all other population subgroups. For the US population, the estimated exposure of 0.018 mg/kg/day corresponds to 18 %aPAD; for children 1-2 years old, the estimated exposure of 0.035 mg/kg/day corresponds to an acute dietary risk of 35 % aPAD.

Chronic dietary exposure and risk are below HED's level of concern for the general US population and all other population subgroups. For the general US population, an estimated exposure of 0.006 mg/kg/day corresponds to 9 %cPAD. The most highly exposed population subgroup, children 1-2 years old had an estimated exposure of 0.025 mg/kg/day, or 35 %cPAD.

The results of the acute and chronic analyses are shown in Tables 3 and 4.

Table 3. Results of Acetamiprid Acute Dietary (Food + Water) Exposure Analysis.							
Population Subgroup	**aPAD (mg/kg/day)**	**95th Percentile**		**99th Percentile**		**99.9th Percentile**	
		Exposure (mg/kg/day)	**% aPAD**	**Exposure (mg/kg/day)**	**% aPAD**	**Exposure (mg/kg/day)**	**% aPAD**
General U.S. Population	0.10	0.005347	5.4	0.009821	9.8	0.018211	18
All Infants (< 1 year old)	0.10	0.010857	11	0.018487	18	0.026037	26
Children 1-2 years old	**0.10**	**0.013764**	**14**	**0.019750**	**20**	**0.034611**	**35**
Children 3-5 years old	0.10	0.009699	9.7	0.014955	15	0.024339	24
Children 6-12 years old	0.10	0.006088	6.1	0.009418	9.4	0.016020	16
Youth 13-19 years old	0.10	0.003534	3.5	0.005841	5.8	0.011135	11
Adults 20-49 years old	0.10	0.003202	3.2	0.005199	5.2	0.011900	12
Adults 50+ years old	0.10	0.003168	3.2	0.005413	5.4	0.009595	9.6
Females 13-49 years old	0.10	0.003215	3.2	0.005205	5.2	0.009543	9.5

Table 4. Summary of Dietary (Food + Water) Exposure and Risk for Acetamiprid				
Population Subgroup	Acute Dietary (99.9th Percentile)		Chronic Dietary	
	Dietary Exposure (mg/kg/day)	% aPAD	Dietary Exposure (mg/kg/day)	% cPAD
General U.S. Population	0.018211	18	0.006184	8.7
All Infants (< 1 year old)	0.026037	26	0.014228	20
Children 1-2 years old	**0.034611**	**35**	**0.024648**	**35**
Children 3-5 years old	0.024339	24	0.016880	24
Children 6-12 years old	0.016020	16	0.008745	12
Youth 13-19 years old	0.011135	11	0.004820	6.8
Adults 20-49 years old	0.011900	12	0.004189	5.9
Adults 50+ years old	0.009595	9.6	0.004481	6.3
Females 13-49 years old	0.009543	9.5	0.004414	6.2

VI. Characterization of Inputs/Outputs

The acute dietary exposure assessment for acetamiprid is somewhat refined, since field trial residue distributions were used in the probabilistic assessment, and percent crop treated information was incorporated for some commodities. In addition, empirical processing factors for various processed commodities, especially juices, provided an additional measure of refinement.

However, the assessment is still somewhat conservative because tolerance-level residues were used for proposed uses and some of the existing uses, as well as livestock commodities. Additional refinements could be made to the assessment with the use of additional field trial residue data. Even though the acute probabilistic assessment has not been completely refined, acute dietary exposure and risk estimates for acetamiprid are below HED's level of concern of 100 %aPAD.

The chronic dietary exposure assessment is largely unrefined, with the exception of the use of %CT data for apples and oranges. For all commodities, tolerance level residues were used, and DEEM 7.81 default processing factors were applies. Further refinements are possible in the future, including the use of average field trial residues, empirical processing factors and additional %CT refinements.

VII. Conclusions

Acute and chronic dietary (food + water) risks for acetamiprid are below HED's level of concern for dietary exposure and risk. Children 1-2 years old are the most highly exposed population subgroup, with risks of 35 %aPAD and 35 %cPAD. Risks were lower for all other population subgroups, including the general US population. The acute and chronic dietary exposure assessments support the new uses proposed for acetamiprid.

VIII. List of Attachments

Attachment 1. Acetamiprid Residue Distribution Files
Attachment 2. Acetamiprid Screening Level Usage Analysis (SLUA)
Attachment 4. Acute Residue Input Files
Attachment 5 Summary of Acute Results
Attachment 6. Chronic Residue Input File
Attachment 7. Summary of Chronic Results

Attachment 1. Acetamiprid Residue Distribution Files

Acetamiprid/Apple TOTALZ=363 Est. Max. %CT = 16 MRID No. 44988626 0.15, 0.16, 0.59, 0.59 0.25 0.29, 0.11, 0.16, 0.12, 0.12 0.24, 0.32, 0.17, 0.18, 0.20 0.23, 0.13, 0.14, 0.21, 0.28 0.09, 0.15, 0.24, 0.28, 0.22 0.39, 0.17, 0.20, 0.45, 0.64 0.22, 0.28, 0.23, 0.23, 0.21 0.25, 0.30, 0.30, 0.25, 0.26 0.26, 0.36, 0.14, 0.16, 0.23 0.27, 0.08, 0.10, 0.30, 0.34 0.25, 0.29, 0.08 0.10, 0.10 0.23, 0.18, 0.21, 0.61, 0.71 0.34, 0.35, 0.21, 0.24	Acetamiprid/Broccoli Estimated max %CT = 5 TOTALZ=437 MRID No. 44988631 0.02, 0.04, 0.04, 0.05, 0.01 0.01, 0.005, 0.02, 0.01, 0.02 0.005, 0.01, 0.07, 0.11, 0.18 0.25, 0.02, 0.097, 0.10, 0.080 0.092, 0.081, 0.10	Acetamiprid/Cabbage w/out wrapper leaves, 5 %CT TOTALZ=380 MRID No. 44988631 0.005, 0.02, 0.005, 0.01, 0.005 0.005, 0.005, 0.005, 0.03, 0.03 0.005, 0.005, 0.01, 0.02, 0.02 0.02, 0.05, 0.05, 0.03, 0.03	Acetamiprid/Celery Estimated Max. %CT = 15 TOTALZ=91 MRID No. 44988603 0.775, 0.780, 0.167, 0.182 0.396, 0.426, 0.287, 0.352 0.250, 0.290, 0.255, 0.281 0.499, 0.517, 0.068, 0.084
Acetamiprid/Cucurbit Assume 100%CT MRID No. 46265701 0.024, 0.038, 0.015, 0.026 0.024, 0.030, 0.038, 0.045 0.082, 0.091, 0.017, 0.019 0.070, 0.090, 0.035, 0.076 0.011, 0.026, 0.011, 0.021 0.035, 0.037, 0.065, 0.142, 0.091, 0.094, 0.075, 0.136 0.053, 0.068, 0.166, 0.221 0.004, 0.075	Acetamiprid/Grape Estimated Max. %CT=2.5 TOTALZ=1092 MRID No. 44988634 0.12, 0.14, 0.08, 0.08, 0.04 0.05, 0.07, 0.07, 0.05, 0.06 0.02, 0.03, 0.03, 0.04, 0.02 0.03, 0.06, 0.07, 0.04, 0.07 0.06, 0.06, 0.05, 0.07, 0.04 0.08, 0.071, 0.084	Acetamiprid/Head Lettuce MRID No. 44988603 Estimated Max. %CT = 10% TOTALZ=162 0.155, 0.184, 0.253, 0.294, 0.017, 0.018, 0.047, 0.057 0.005, 0.005, 0.060, 0.061 0.014, 0.014, 0.010, 0.010 0.074, 0.14	Acetamiprid/Leaf Lettuce Estimated Maximum %CT=10 TOTALZ=180 MRID No. 44988603 0.716, 1.02, 0.108, 0.123 0.565, 0.646, 0.265, 0.330 0.374, 0.449, 0.848, 1.07 0.098, 0.114, 0.435, 0.479 0.12, 0.18, 0.074, 0.14
Acetamiprid/Orange TOTALZ=2535 Est. max %CT=2.5 MRID No. 4498611 0.14, 0.15, 0.11, 0.12, 0.09 0.13, 0.19, 0.29, 0.18, 0.21 0.29, 0.097, 0.11, 0.15, 0.21 0.20, 0.20, 0.058, 0.084, 0.088 0.15, 0.11, 0.15, 0.094, 0.12 0.19, 0.20, 0.19, 0.21, 0.26 0.29, 0.21, 0.23, 0.025, 0.025 0.13, 0.14, 0.081, 0.12, 0.14 0.14, 0.083, 0.12, 0.025, 0.025, 0.025, 0.025, 0.025, 0.098 0.23, 0.27, 0.12, 0.14, 0.079 0.096, 0.087, 0.12, 0.12, 0.16 0.31, 0.37, 0.16, 0.31, 0.26 0.39	Acetamiprid/Peach Assume 100%CT TOTALZ=0 MRID No. 46265702 0.294, 0.344, 0.311, 0.565 0.184, 0.225, 0.163, 0.188 0.182, 0.223, 0.117, 0.138 0.153, 0.166, 0.283, 0.387 0.205, 0.233, 0.192, 0.240 0.211, 0.242, 0.0927, 0.133 0.186, 0.199	Acetamiprid/Pear TOTALZ=192 Est. Max. %CT = 25 MRID No. 44988626 0.15, 0.16, 0.59, 0.59 0.25 0.29, 0.11, 0.16, 0.12, 0.12 0.24, 0.32, 0.17, 0.18, 0.20 0.23, 0.13, 0.14, 0.21, 0.28 0.09, 0.15, 0.24, 0.28, 0.22 0.39, 0.17, 0.20, 0.45, 0.64 0.22, 0.28, 0.23, 0.23, 0.21 0.25, 0.30, 0.30, 0.25, 0.26 0.26, 0.36, 0.14, 0.16, 0.23 0.27, 0.08, 0.10, 0.30, 0.34 0.25, 0.29, 0.08 0.10, 0.10 0.23, 0.18, 0.21, 0.61, 0.71 0.34, 0.35, 0.21, 0.24	Acetamiprid/Peppers Estimated Max. %CT = 2.5 TOTALZ=1170 MRID No. 44988616 0.005, 0.005, 0.01, 0.02, 0.01 0.01, 0.03, 0.05, 0.03, 0.04 0.01, 0.01, 0.02, 0.03, 0.02 0.02, 0.08, 0.09, 0.03, 0.03 0.06, 0.07, 0.04, 0.07, 0.05 0.06, 0.12, 0.16, 0.08, 0.08
Acetamiprid/Plum Assume 100%CT TOTALZ=0 MRID No. 46265702 0.108, 0.116, 0.0648, 0.119 0.0139, 0.0238, 0.0103, 0.0154 0.0515, 0.0624, 0.0401, 0.0429 0.0305, 0.0458, 0.0258, 0.0392	Acetamiprid/Spinach Assume 100%CT TOTALZ=858 MRID No. 44988603 0.034, 0.037, 0.184, 0.238 0.026, 0.036, 1.06, 1.20, 2.46 2.58, 0.516, 0.588, 1.95, 2.22 0.463, 0.466, 0.15, 0.23, 0.18 0.18, 0.19, 0.22	Acetamiprid/Tomatoes Estimated Max. %CT=2.5 TOTALZ=1404 MRID No. 44988616 0.01, 0.01, 0.005, 0.005, 0.005, 0.005, 0.01, 0.04, 0.08, 0.11 0.005, 0.01, 0.07, 0.08, 0.06 0.11, 0.02, 0.03, 0.02, 0.04 0.02, 0.02, 0.03, 0.03, 0.05 0.07, 0.03, 0.05, 0.06, 0.06 0.03, 0.05, 0.02, 0.02, 0.005 0.005	

Attachment 2. Acetamiprid Screening Level Usage Analysis (SLUA)

Acetamiprid (099050)
Screening Level Usage Analysis (SLUA)
Date: July 7, 2005

What is a Screening Level Usage Analysis (SLUA)?

- Available estimates of pesticide usage data for a particular active ingredient that is used on **agricultural** crops in the United States.

What does it contain?

- Pesticide usage data for a **single** active ingredient only.
- Agricultural use sites (crops) that the pesticide is *reported* to be used on.
- Available pesticide usage information (i.e., does not include all of the United States).
- Annual percent of crop treated **(average & maximum)** for each agricultural crop.
- Average annual pounds of the pesticide applied for each agricultural crop (i.e., for the states surveyed, not for the entire United States).

What assumptions can I make about the reported data?

- **Average pounds of active ingredient applied** - Values are calculated by merging pesticide usage data sources together; averaging by year, averaging across all years, & then rounding. ***Note:*** *If the estimated value is less than 500, then that value is labeled <500. Estimated values between 500 & <1,000,000 are rounded to 1 significant digit. Estimated values of 1,000,000 or greater are rounded to 2 significant digits.)*
- **Average percent of crop treated** - Values are calculated by merging data sources together; averaging by year, averaging across all years, & rounding to the nearest multiple of 5. ***Note:*** *If the estimated value is less than 1, then the value is labeled <1.*
- **Maximum percent of crop treated** - Value is the single maximum value reported across all data sources, across all years, & rounded up to the nearest multiple of 5. ***Note:*** *If the estimated value is less than 2.5, then the value is labeled <2.5.*

What are the data sources used?

- **USDA-NASS** (United States Department of Agriculture's National Agricultural Statistics Service) – pesticide usage data from 1998 to 2003.
- **NCFAP** (National Center for Food and Agricultural Policy) – pesticide usage data from 1997 & is ***only*** used if data is not available from the other sources.
- **Private pesticide market research** – pesticide usage data from 1998 to 2003.
- California DPR data can be requested separately.

What are the limitations to the data?

- Additional registered uses may exist but are not included because the available surveys do not report usage (e.g., small acreage crops).

- Lack of reported usage data for the pesticide on a crop **does not imply** zero usage.
- Usage data on a particular site may be noted in data sources, but **not quantified.** In these instances, the site would not be reported in the SLUA.
- Non-agricultural use sites (e.g., turf, post-harvest, mosquito control, etc.) are not reported in the SLUA. A separate request must be made to receive these estimates.

Who do I contact for further information and/or questions on this SLUA?

- Cynthia Doucoure
- 703-308-8133 or doucoure.cynthia@epa.gov

Thursday, July 7, 2005

Screening Level Estimates of Agricultural Uses of Acetamiprid
Sorted Alphabetically

	Crop	Pounds of Active Ingredient	Percent of Crop Treated	Maximum Percent of Crop Treated
1	Apples	9,000	10	15
2	Broccoli	<500	<1	5
3	Celery	<500	5	15
4	Cotton	8,000	<1	<2.5
5	Grapefruit	<500	<1	<2.5
6	Grapes	<500	<1	<2.5
7	Lemons	<500	5	5
8	Lettuce	1,000	5	10
9	Oranges	2,000	<1	<2.5
10	Pears	3,000	20	25
11	Peppers	<500	<1	<2.5
12	Spinach	<500	<1	<2.5
13	Tomatoes	<500	<1	<2.5

All numbers rounded.
'<500' indicates less than 500 pounds of active ingredient.
'<2.5' indicates less than 2.5 percent of crop is treated.

Attachment 3. DEEM-FCID™ Acute Residue Input File

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U.S. Environmental Protection Agency                                    Ver. 2.02
DEEM-FCID Acute analysis for ACETAMIPRID
Residue file name: C:\Documents and Settings\cswart02\My
Documents\RAB2chemicals\Acetamiprid\DEEM_Lifeline inputs\PRIAacetamiprid_acuteAR_berrybulb.R98
Analysis Date 10-12-2007            Residue file dated: 10-12-2007/18:33:43/8
Reference dose: aRfD = 0.1 mg/kg bw/day  NOEL = 10 mg/kg bw/day
Comment: Acute/Chronic - UFs = 100
--------------------------------------------------------------------------------
RDL indices and parameters for Monte Carlo Analysis:
Index Dist Parameter #1           Param #2    Param #3    Comment
  #   Code
----- ---- ------------           ----------- ----------- ----------
  1     6   orange.RDF
  2     6   Apple.RDF
  3     6   spinach.rdf
  4     6   cabbage.RDF
  5     6   peach.RDF
  6     6   Plum.RDF
  7     6   Pear.RDF
  8     6   Broccoli.RDF
  9     6   Celery.RDF
  10    6   HeadLettuce.RDF
  11    6   LeafLettuce.RDF
  12    6   cucurbit.RDF
  13    6   Grapes.RDF
  14    6   Peppers.RDF
  15    6   Tomatoes.RDF

  EPA     Crop Food Name                          Def Res     Adj.Factors  RDL  Comment
  Code     Grp                                    (ppm)        #1     #2   Pntr
-------- ---- --------------------------------  ----------  ------ ------ ---  -------
14000030 14   Almond                             0.100000   1.000  1.000
14000031 14   Almond-babyfood                    0.100000   1.000  1.000
14000040 14   Almond, oil                        0.100000   1.000  1.000
14000041 14   Almond, oil-babyfood               0.100000   1.000  1.000
04010050 4A   Amaranth, leafy                    3.000000   1.000  1.000
11000070 11   Apple, fruit with peel             1.000000   1.000  1.000   2
11000080 11   Apple, peeled fruit                1.000000   1.000  1.000   2
11000081 11   Apple, peeled fruit-babyfood       1.000000   1.000  1.000   2
11000090 11   Apple, dried                       1.000000   8.000  1.000   2
11000091 11   Apple, dried-babyfood              1.000000   8.000  1.000   2
11000100 11   Apple, juice                       1.000000   0.880  1.000   2
11000101 11   Apple, juice-babyfood              1.000000   0.880  1.000   2
11000110 11   Apple, sauce                       1.000000   1.000  1.000   2
11000111 11   Apple, sauce-babyfood              1.000000   1.000  1.000   2
12000120 12   Apricot                            1.200000   1.000  1.000   6
12000121 12   Apricot-babyfood                   1.200000   1.000  1.000   6
12000130 12   Apricot, dried                     1.200000   2.900  1.000   6
12000140 12   Apricot, juice                     1.200000   1.000  1.000   6
12000141 12   Apricot, juice-babyfood            1.200000   1.000  1.000   6
01030150 1CD  Arrowroot, flour                   0.010000   1.000  1.000
01030151 1CD  Arrowroot, flour-babyfood          0.010000   1.000  1.000
01030170 1CD  Artichoke, Jerusalem               0.010000   1.000  1.000
04010180 4A   Arugula                            3.000000   1.000  1.000
09020210 9B   Balsam pear                        0.500000   1.000  1.000  12
06020310 6B   Bean, broad, succulent             0.400000   1.000  1.000
06020330 6B   Bean, cowpea, succulent            0.400000   1.000  1.000
06020370 6B   Bean, lima, succulent              0.400000   1.000  1.000
06010430 6A   Bean, snap, succulent              0.600000   1.000  1.000
06010431 6A   Bean, snap, succulent-babyfood     0.600000   1.000  1.000
21000440 M    Beef, meat                         0.100000   1.000  1.000
21000441 M    Beef, meat-babyfood                0.100000   1.000  1.000
21000450 M    Beef, meat, dried                  0.100000   1.920  1.000
21000460 M    Beef, meat byproducts              0.200000   1.000  1.000
21000461 M    Beef, meat byproducts-babyfood     0.200000   1.000  1.000
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21000470	M	Beef, fat	0.100000	1.000	1.000	
21000471	M	Beef,fat-babyfood	0.100000	1.000	1.000	
21000480	M	Beef, kidney	0.200000	1.000	1.000	
21000490	M	Beef, liver	0.200000	1.000	1.000	
21000491	M	Beef, liver-babyfood	0.200000	1.000	1.000	
13010550	13A	Blackberry	1.600000	1.000	1.000	
13010560	13A	Blackberry, juice	1.600000	1.000	1.000	
13010561	13A	Blackberry, juice-babyfood	1.600000	1.000	1.000	
13020570	13B	Blueberry	1.600000	1.000	1.000	
13020571	13B	Blueberry-babyfood	1.600000	1.000	1.000	
13010580	13A	Boysenberry	1.600000	1.000	1.000	
14000590	14	Brazil nut	0.100000	1.000	1.000	
05010610	5A	Broccoli	1.200000	1.000	1.000	8
05010611	5A	Broccoli-babyfood	1.200000	1.000	1.000	8
05010620	5A	Broccoli, Chinese	1.200000	1.000	1.000	8
05020630	5B	Broccoli raab	1.200000	1.000	1.000	
05010640	5A	Brussels sprouts	1.200000	1.000	1.000	
14000680	14	Butternut	0.100000	1.000	1.000	
05010690	5A	Cabbage	1.200000	1.000	1.000	4
05020700	5B	Cabbage, Chinese, bok choy	1.200000	1.000	1.000	
05010710	5A	Cabbage, Chinese, napa	1.200000	1.000	1.000	
05010720	5A	Cabbage, Chinese, mustard	1.200000	1.000	1.000	
09010750	9A	Cantaloupe	0.500000	1.000	1.000	12
04020760	4B	Cardoon	3.000000	1.000	1.000	
09010800	9A	Casaba	0.500000	1.000	1.000	12
14000810	14	Cashew	0.100000	1.000	1.000	
01030820	1CD	Cassava	0.010000	1.000	1.000	
01030821	1CD	Cassava-babyfood	0.010000	1.000	1.000	
05010830	5A	Cauliflower	1.200000	1.000	1.000	8
04020850	4B	Celery	3.000000	1.000	1.000	9
04020851	4B	Celery-babyfood	3.000000	1.000	1.000	9
04020860	4B	Celery, juice	3.000000	1.000	1.000	9
04020870	4B	Celtuce	3.000000	1.000	1.000	
09020880	9B	Chayote, fruit	0.500000	1.000	1.000	12
12000900	12	Cherry	1.200000	1.000	1.000	
12000901	12	Cherry-babyfood	1.200000	1.000	1.000	
12000910	12	Cherry, juice	1.200000	1.500	1.000	
12000911	12	Cherry, juice-babyfood	1.200000	1.500	1.000	
14000920	14	Chestnut	0.100000	1.000	1.000	
40000930	P	Chicken, meat	0.010000	1.000	1.000	
40000931	P	Chicken, meat-babyfood	0.010000	1.000	1.000	
40000940	P	Chicken, liver	0.050000	1.000	1.000	
40000950	P	Chicken, meat byproducts	0.050000	1.000	1.000	
40000951	P	Chicken, meat byproducts-babyfoo	0.050000	1.000	1.000	
40000960	P	Chicken, fat	0.010000	1.000	1.000	
40000961	P	Chicken, fat-babyfood	0.010000	1.000	1.000	
40000970	P	Chicken, skin	0.010000	1.000	1.000	
40000971	P	Chicken, skin-babyfood	0.010000	1.000	1.000	
09021020	9B	Chinese waxgourd	0.500000	1.000	1.000	12
19011030	19A	Chive	4.500000	1.000	1.000	
04011040	4A	Chrysanthemum, garland	3.000000	1.000	1.000	
10001060	10	Citrus citron	0.500000	1.000	1.000	
10001070	10	Citrus hybrids	0.500000	1.000	1.000	
10001080	10	Citrus, oil	0.500000	1.000	1.000	
05021170	5B	Collards	1.200000	1.000	1.000	4
95001280	O	Cottonseed, oil	0.600000	1.000	1.000	
95001281	O	Cottonseed, oil-babyfood	0.600000	1.000	1.000	
11001290	11	Crabapple	1.000000	1.000	1.000	
95001300	O	Cranberry	0.600000	1.000	1.000	
95001301	O	Cranberry-babyfood	0.600000	1.000	1.000	
95001310	O	Cranberry, dried	0.600000	1.000	1.000	
95001320	O	Cranberry, juice	0.600000	1.100	1.000	
95001321	O	Cranberry, juice-babyfood	0.600000	1.100	1.000	
04011330	4A	Cress, garden	3.000000	1.000	1.000	
04011340	4A	Cress, upland	3.000000	1.000	1.000	
09021350	9B	Cucumber	0.500000	1.000	1.000	12
13021360	13B	Currant	1.600000	1.000	1.000	
13021370	13B	Currant, dried	1.600000	1.000	1.000	

04011380	4A	Dandelion, leaves	3.000000	1.000	1.000	
01031390	1CD	Dasheen, corm	0.010000	1.000	1.000	
13011420	13A	Dewberry	1.600000	1.000	1.000	
70001450	P	Egg, whole	0.010000	1.000	1.000	
70001451	P	Egg, whole-babyfood	0.010000	1.000	1.000	
70001460	P	Egg, white	0.010000	1.000	1.000	
70001461	P	Egg, white (solids)-babyfood	0.010000	1.000	1.000	
70001470	P	Egg, yolk	0.010000	1.000	1.000	
70001471	P	Egg, yolk-babyfood	0.010000	1.000	1.000	
08001480	8	Eggplant	0.200000	1.000	1.000	
13021490	13B	Elderberry	1.600000	1.000	1.000	
04011500	4A	Endive	3.000000	1.000	1.000	
04021520	4B	Fennel, Florence	3.000000	1.000	1.000	
14001550	14	Filbert	0.100000	1.000	1.000	
14001560	14	Filbert, oil	0.100000	1.000	1.000	
03001640	3	Garlic	0.020000	1.000	1.000	
03001650	3	Garlic, dried	0.020000	1.000	1.000	
03001651	3	Garlic, dried-babyfood	0.020000	1.000	1.000	
01031660	1CD	Ginger	0.010000	1.000	1.000	
01031661	1CD	Ginger-babyfood	0.010000	1.000	1.000	
01031670	1CD	Ginger, dried	0.010000	1.000	1.000	
23001690	M	Goat, meat	0.100000	1.000	1.000	
23001700	M	Goat, meat byproducts	0.200000	1.000	1.000	
23001710	M	Goat, fat	0.100000	1.000	1.000	
23001720	M	Goat, kidney	0.200000	1.000	1.000	
23001730	M	Goat, liver	0.200000	1.000	1.000	
13021740	13B	Gooseberry	1.600000	1.000	1.000	
95001750	O	Grape	0.200000	1.000	1.000	13
95001760	O	Grape, juice	0.200000	1.000	1.000	13
95001761	O	Grape, juice-babyfood	0.200000	1.000	1.000	13
95001770	O	Grape, leaves	0.200000	1.000	1.000	13
95001780	O	Grape, raisin	0.200000	0.900	1.000	13
95001790	O	Grape, wine and sherry	0.200000	1.000	1.000	13
10001800	10	Grapefruit	0.500000	1.000	1.000	1
10001810	10	Grapefruit, juice	0.500000	0.160	1.000	1
14001850	14	Hickory nut	0.100000	1.000	1.000	
09011870	9A	Honeydew melon	0.500000	1.000	1.000	12
24001890	M	Horse, meat	0.100000	1.000	1.000	
13021910	13B	Huckleberry	1.600000	1.000	1.000	
05021940	5B	Kale	1.200000	1.000	1.000	
05011960	5A	Kohlrabi	1.200000	1.000	1.000	
10001970	10	Kumquat	0.500000	1.000	1.000	
03001980	3	Leek	4.500000	1.000	1.000	
10001990	10	Lemon	0.500000	1.000	1.000	
10002000	10	Lemon, juice	0.500000	2.000	1.000	
10002001	10	Lemon, juice-babyfood	0.500000	2.000	1.000	
10002010	10	Lemon, peel	0.500000	1.000	1.000	
04012040	4A	Lettuce, head	3.000000	1.000	1.000	10
04012050	4A	Lettuce, leaf	3.000000	1.000	1.000	11
10002060	10	Lime	0.500000	1.000	1.000	
10002070	10	Lime, juice	0.500000	2.000	1.000	
10002071	10	Lime, juice-babyfood	0.500000	2.000	1.000	
13012080	13A	Loganberry	1.600000	1.000	1.000	
11002100	11	Loquat	1.000000	1.000	1.000	
14002130	14	Macadamia nut	0.100000	1.000	1.000	
28002210	M	Meat, game	0.100000	1.000	1.000	
27002220	D	Milk, fat	0.100000	1.000	1.000	
27002221	D	Milk, fat - baby food/infant for	0.100000	1.000	1.000	
27012230	D	Milk, nonfat solids	0.100000	1.000	1.000	
27012231	D	Milk, nonfat solids-baby food/in	0.100000	1.000	1.000	
27022240	D	Milk, water	0.100000	1.000	1.000	
27022241	D	Milk, water-babyfood/infant form	0.100000	1.000	1.000	
27032251	D	Milk, sugar (lactose)-baby food/	0.100000	1.000	1.000	
05022290	5B	Mustard greens	1.200000	1.000	1.000	
12002300	12	Nectarine	1.200000	1.000	1.000	5
08002340	8	Okra	0.200000	1.000	1.000	
03002370	3	Onion, dry bulb	0.020000	1.000	1.000	
03002371	3	Onion, dry bulb-babyfood	0.020000	1.000	1.000	

03002380	3	Onion, dry bulb, dried	0.020000	9.000	1.000	
03002381	3	Onion, dry bulb, dried-babyfood	0.020000	9.000	1.000	
03002390	3	Onion, green	4.500000	1.000	1.000	
10002400	10	Orange	0.500000	1.000	1.000	1
10002410	10	Orange, juice	0.500000	0.160	1.000	1
10002411	10	Orange, juice-babyfood	0.500000	0.160	1.000	1
10002420	10	Orange, peel	0.500000	1.000	1.000	1
04012480	4A	Parsley, leaves	3.000000	1.000	1.000	
06022550	6B	Pea, succulent	0.400000	1.000	1.000	
06022551	6B	Pea, succulent-babyfood	0.400000	1.000	1.000	
06012570	6A	Pea, edible podded, succulent	0.600000	1.000	1.000	
06022590	6B	Pea, pigeon, succulent	0.400000	1.000	1.000	
12002600	12	Peach	1.200000	1.000	1.000	5
12002601	12	Peach-babyfood	1.200000	1.000	1.000	5
12002610	12	Peach, dried	1.200000	2.900	1.000	5
12002611	12	Peach, dried-babyfood	1.200000	2.900	1.000	5
12002620	12	Peach, juice	1.200000	1.000	1.000	5
12002621	12	Peach, juice-babyfood	1.200000	1.000	1.000	5
11002660	11	Pear	1.000000	1.000	1.000	7
11002661	11	Pear-babyfood	1.000000	1.000	1.000	7
11002670	11	Pear, dried	1.000000	6.250	1.000	7
11002680	11	Pear, juice	1.000000	0.880	1.000	7
11002681	11	Pear, juice-babyfood	1.000000	0.880	1.000	7
14002690	14	Pecan	0.100000	1.000	1.000	
08002700	8	Pepper, bell	0.200000	1.000	1.000	14
08002701	8	Pepper, bell-babyfood	0.200000	1.000	1.000	14
08002710	8	Pepper, bell, dried	0.200000	1.000	1.000	14
08002711	8	Pepper, bell, dried-babyfood	0.200000	1.000	1.000	14
08002720	8	Pepper, nonbell	0.200000	1.000	1.000	14
08002721	8	Pepper, nonbell-babyfood	0.200000	1.000	1.000	14
08002730	8	Pepper, nonbell, dried	0.200000	1.000	1.000	14
14002820	14	Pistachio	0.100000	1.000	1.000	
12002850	12	Plum	1.200000	1.000	1.000	6
12002851	12	Plum-babyfood	1.200000	1.000	1.000	6
12002860	12	Plum, prune, fresh	0.200000	1.000	1.000	6
12002861	12	Plum, prune, fresh-babyfood	0.200000	1.000	1.000	6
12002870	12	Plum, prune, dried	0.400000	1.000	1.000	6
12002871	12	Plum, prune, dried-babyfood	0.400000	1.000	1.000	6
12002880	12	Plum, prune, juice	0.200000	1.400	1.000	6
12002881	12	Plum, prune, juice-babyfood	0.200000	1.400	1.000	6
25002900	M	Pork, meat	0.100000	1.000	1.000	
25002901	M	Pork, meat-babyfood	0.100000	1.000	1.000	
25002910	M	Pork, skin	0.100000	1.000	1.000	
25002920	M	Pork, meat byproducts	0.200000	1.000	1.000	
25002921	M	Pork, meat byproducts-babyfood	0.200000	1.000	1.000	
25002930	M	Pork, fat	0.100000	1.000	1.000	
25002931	M	Pork, fat-babyfood	0.100000	1.000	1.000	
25002940	M	Pork, kidney	0.200000	1.000	1.000	
25002950	M	Pork, liver	0.200000	1.000	1.000	
01032960	1C	Potato, chips	0.010000	1.000	1.000	
01032970	1C	Potato, dry (granules/ flakes)	0.010000	6.500	1.000	
01032971	1C	Potato, dry (granules/ flakes)-b	0.010000	6.500	1.000	
01032980	1C	Potato, flour	0.010000	1.000	1.000	
01032981	1C	Potato, flour-babyfood	0.010000	1.000	1.000	
01032990	1C	Potato, tuber, w/peel	0.010000	1.000	1.000	
01032991	1C	Potato, tuber, w/peel-babyfood	0.010000	1.000	1.000	
01033000	1C	Potato, tuber, w/o peel	0.010000	1.000	1.000	
01033001	1C	Potato, tuber, w/o peel-babyfood	0.010000	1.000	1.000	
60003010	P	Poultry, other, meat	0.010000	1.000	1.000	
60003020	P	Poultry, other, liver	0.050000	1.000	1.000	
60003030	P	Poultry, other, meat byproducts	0.050000	1.000	1.000	
60003040	P	Poultry, other, fat	0.010000	1.000	1.000	
60003050	P	Poultry, other, skin	0.010000	1.000	1.000	
10003070	10	Pummelo	0.500000	1.000	1.000	
09023080	9B	Pumpkin	0.500000	1.000	1.000	12
09023090	9B	Pumpkin, seed	0.500000	1.000	1.000	12
11003100	11	Quince	1.000000	1.000	1.000	
29003120	M	Rabbit, meat	0.100000	1.000	1.000	

04013130	4A	Radicchio	3.000000	1.000	1.000	
05023180	5B	Rape greens	1.200000	1.000	1.000	
20003190	20	Rapeseed, oil	0.010000	1.000	1.000	
20003191	20	Rapeseed, oil-babyfood	0.010000	1.000	1.000	
13013200	13A	Raspberry	1.600000	1.000	1.000	
13013201	13A	Raspberry-babyfood	1.600000	1.000	1.000	
13013210	13A	Raspberry, juice	1.600000	1.000	1.000	
13013211	13A	Raspberry, juice-babyfood	1.600000	1.000	1.000	
04023220	4B	Rhubarb	3.000000	1.000	1.000	
03003380	3	Shallot	0.020000	1.000	1.000	
26003390	M	Sheep, meat	0.100000	1.000	1.000	
26003391	M	Sheep, meat-babyfood	0.100000	1.000	1.000	
26003400	M	Sheep, meat byproducts	0.200000	1.000	1.000	
26003410	M	Sheep, fat	0.100000	1.000	1.000	
26003411	M	Sheep, fat-babyfood	0.100000	1.000	1.000	
26003420	M	Sheep, kidney	0.200000	1.000	1.000	
26003430	M	Sheep, liver	0.200000	1.000	1.000	
19023540	19B	Spices, other	0.010000	1.000	1.000	
19023541	19B	Spices, other-babyfood	0.010000	1.000	1.000	
04013550	4A	Spinach	3.000000	1.000	1.000	3
04013551	4A	Spinach-babyfood	3.000000	1.000	1.000	3
09023560	9B	Squash, summer	0.500000	1.000	1.000	12
09023561	9B	Squash, summer-babyfood	0.500000	1.000	1.000	12
09023570	9B	Squash, winter	0.500000	1.000	1.000	12
09023571	9B	Squash, winter-babyfood	0.500000	1.000	1.000	12
95003590	O	Strawberry	0.600000	1.000	1.000	
95003591	O	Strawberry-babyfood	0.600000	1.000	1.000	
95003600	O	Strawberry, juice	0.600000	1.000	1.000	
95003601	O	Strawberry, juice-babyfood	0.600000	1.000	1.000	
01033660	1CD	Sweet potato	0.010000	1.000	1.000	
01033661	1CD	Sweet potato-babyfood	0.010000	1.000	1.000	
04023670	4B	Swiss chard	3.000000	1.000	1.000	
10003690	10	Tangerine	0.500000	1.000	1.000	
10003700	10	Tangerine, juice	0.500000	2.300	1.000	
01033710	1CD	Tanier, corm	0.010000	1.000	1.000	
08003740	8	Tomatillo	0.200000	1.000	1.000	15
08003750	8	Tomato	0.200000	1.000	1.000	15
08003751	8	Tomato-babyfood	0.200000	1.000	1.000	15
08003760	8	Tomato, paste	0.400000	1.000	1.000	15
08003761	8	Tomato, paste-babyfood	0.400000	1.000	1.000	15
08003770	8	Tomato, puree	0.200000	1.400	1.000	15
08003771	8	Tomato, puree-babyfood	0.200000	1.400	1.000	15
08003780	8	Tomato, dried	0.200000	14.300	1.000	15
08003781	8	Tomato, dried-babyfood	0.200000	14.300	1.000	15
08003790	8	Tomato, juice	0.200000	1.500	1.000	15
50003820	P	Turkey, meat	0.010000	1.000	1.000	
50003821	P	Turkey, meat-babyfood	0.010000	1.000	1.000	
50003830	P	Turkey, liver	0.050000	1.000	1.000	
50003831	P	Turkey, liver-babyfood	0.050000	1.000	1.000	
50003840	P	Turkey, meat byproducts	0.050000	1.000	1.000	
50003841	P	Turkey, meat byproducts-babyfood	0.050000	1.000	1.000	
50003850	P	Turkey, fat	0.010000	1.000	1.000	
50003851	P	Turkey, fat-babyfood	0.010000	1.000	1.000	
50003860	P	Turkey, skin	0.010000	1.000	1.000	
50003861	P	Turkey, skin-babyfood	0.010000	1.000	1.000	
01033870	1CD	Turmeric	0.010000	1.000	1.000	
05023890	5B	Turnip, greens	1.200000	1.000	1.000	
14003910	14	Walnut	0.100000	1.000	1.000	
86010000	O	Water, direct, all sources	0.020000	1.000	1.000	
86020000	O	Water, indirect, all sources	0.020000	1.000	1.000	
09013990	9A	Watermelon	0.500000	1.000	1.000	12
09014000	9A	Watermelon, juice	0.500000	1.000	1.000	12
01034060	1CD	Yam, true	0.010000	1.000	1.000	
01034070	1CD	Yam bean	0.010000	1.000	1.000	

Summary of Residue Distribution Files (RDF) listed in C:\Documents and Settings\cswart02\My Documents\RAB2chemicals\Acetamiprid\DEEM_Lifeline inputs\PRIAacetamiprid_acuteAR_berrybulb.R98

RDF #	File Name	N residues w freq's	N residues w/o freq's	N LODs	LOD Value	N Zeros
1	orange.RDF	0	65	0	0	2535
2	Apple.RDF	0	64	0	0	363
3	spinach.rdf	0	22	0	0	858
4	cabbage.RDF	0	20	0	0	380
5	peach.RDF	0	26	0	0	0
6	Plum.RDF	0	16	0	0	0
7	Pear.RDF	0	64	0	0	192
8	Broccoli.RDF	0	23	0	0	437
9	Celery.RDF	0	16	0	0	91
10	HeadLettuce.RDF	0	18	0	0	162
11	LeafLettuce.RDF	0	20	0	0	180
12	cucurbit.RDF	0	34	0	0	0
13	Grapes.RDF	0	28	0	0	1092
14	Peppers.RDF	0	30	0	0	1170
15	Tomatoes.RDF	0	36	0	0	1404

Attachment 4. Summary of DEEM-FCID™ Acute Results

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U.S. Environmental Protection Agency                                    Ver. 2.02
DEEM-FCID ACUTE Analysis for ACETAMIPRID                              (1994-98 data)
Residue file: PRIAacetamiprid_acuteAR_berrybulb.R98
Adjustment factor #2 NOT used.
Analysis Date: 10-12-2007/18:46:11    Residue file dated: 10-12-2007/18:33:43/8
NOEL (Acute) =  10.000000 mg/kg body-wt/day
Daily totals for food and foodform consumption used.
MC iterations = 1000      MC list in residue file     MC seed = 1026
Run Comment: "Acute/Chronic - UFs = 100"
================================================================================

Summary calculations (per capita):
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95th Percentile			99th Percentile			99.9th Percentile		
Exposure	% aRfD	MOE	Exposure	% aRfD	MOE	Exposure	% aRfD	MOE
U.S. Population:								
0.005347	5.35	1870	0.009821	9.82	1018	0.018211	18.21	549
All infants:								
0.010857	10.86	921	0.018487	18.49	540	0.026037	26.04	384
Children 1-2 yrs:								
0.013764	13.76	726	0.019750	19.75	506	0.034611	34.61	288
Children 3-5 yrs:								
0.009669	9.67	1034	0.014955	14.96	668	0.024339	24.34	410
Children 6-12 yrs:								
0.006088	6.09	1642	0.009418	9.42	1061	0.016020	16.02	624
Youth 13-19 yrs:								
0.003534	3.53	2829	0.005841	5.84	1712	0.011135	11.14	898
Adults 20-49 yrs:								
0.003202	3.20	3123	0.005199	5.20	1923	0.011900	11.90	840
Adults 50+ yrs:								
0.003168	3.17	3156	0.005413	5.41	1847	0.009595	9.59	1042
Females 13-49 yrs:								
0.003215	3.22	3110	0.005205	5.20	1921	0.009543	9.54	1047

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U.S. Environmental Protection Agency                                    Ver. 2.02
DEEM-FCID ACUTE Analysis for ACETAMIPRID                            (1994-98 data)
Residue file: PRIAacetamiprid_acuteAR_berrybulb.R98
Adjustment factor #2 NOT used.
Analysis Date: 10-12-2007/18:46:11    Residue file dated: 10-12-2007/18:33:43/8
NOEL (Acute) =  10.000000 mg/kg body-wt/day
Acute Reference Dose (aRfD) =   0.100000 mg/kg body-wt/day
Daily totals for food and foodform consumption used.
MC iterations = 1000      MC list in residue file     MC seed = 1026
Run Comment: "Acute/Chronic - UFs = 100"
================================================================================
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U.S. Population — Daily Exposure Analysis /a (mg/kg body-weight/day)

	per Capita	per User
Mean	0.001841	0.001845
Standard Deviation	0.001961	0.001962
Margin of Exposure 2/	5,430	5,421
Percent of aRfD	1.84	1.84

Percent of Person-Days that are User-Days = 99.83%

Estimated percentile of user-days falling below calculated exposure in mg/kg body-wt/day with Margin of Exposure (MOE) and Percent of aRfD

Perc.	Exposure	% aRfD	MOE	Perc.	Exposure	% aRfD	MOE
10.00	0.000471	0.47	21,235	90.00	0.003774	3.77	2,649
20.00	0.000672	0.67	14,870	95.00	0.005352	5.35	1,868
30.00	0.000854	0.85	11,706	97.50	0.007170	7.17	1,394
40.00	0.001046	1.05	9,557	99.00	0.009827	9.83	1,017
50.00	0.001262	1.26	7,927	99.50	0.012234	12.23	817
60.00	0.001530	1.53	6,535	99.75	0.014613	14.61	684
70.00	0.001907	1.91	5,242	99.90	0.018217	18.22	548
80.00	0.002522	2.52	3,965				

Estimated percentile of per-capita days falling below calculated exposure in mg/kg body-wt/day with Margin of Exposure (MOE) and Percent of aRfD

Perc.	Exposure	% aRfD	MOE	Perc.	Exposure	% aRfD	MOE
10.00	0.000467	0.47	21,405	90.00	0.003770	3.77	2,652
20.00	0.000670	0.67	14,927	95.00	0.005347	5.35	1,870
30.00	0.000852	0.85	11,739	97.50	0.007165	7.17	1,395
40.00	0.001044	1.04	9,576	99.00	0.009821	9.82	1,018
50.00	0.001259	1.26	7,940	99.50	0.012227	12.23	817
60.00	0.001528	1.53	6,545	99.75	0.014605	14.60	684
70.00	0.001905	1.91	5,248	99.90	0.018211	18.21	549
80.00	0.002519	2.52	3,969				

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a/ Analysis based on all two-day participant records in CSFII 1994-98
   with 2 days of valid drinking water records.
2/ Margin of Exposure = NOEL/ Dietary Exposure.
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Attachment 5. DEEM-FCID™ Chronic Inputs

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U.S. Environmental Protection Agency                                    Ver. 2.00
DEEM-FCID Chronic analysis for ACETAMIPRID                            1994-98 data
Residue file: C:\Documents and Settings\cswart02\My
Documents\RAB2chemicals\Acetamiprid\DEEM_Lifeline
inputs\PRIADNTacetamipridCT_berrybulb_chronic.R98
                                                          Adjust. #2 NOT used
Analysis Date 10-12-2007            Residue file dated: 10-12-2007/18:35:20/8
Reference dose (RfD) = 0.071 mg/kg bw/day
Comment:Acute/Chronic - UFs = 100
```

Food Crop EPA Code	Grp	Food Name	Residue (ppm)	Adj.Factors #1	#2	Comment
14000030	14	Almond	0.100000	1.000	1.000	
14000031	14	Almond-babyfood	0.100000	1.000	1.000	
14000040	14	Almond, oil	0.100000	1.000	1.000	
14000041	14	Almond, oil-babyfood	0.100000	1.000	1.000	
04010050	4A	Amaranth, leafy	3.000000	1.000	1.000	
11000070	11	Apple, fruit with peel	1.000000	1.000	0.100	
11000080	11	Apple, peeled fruit	1.000000	1.000	0.100	
11000081	11	Apple, peeled fruit-babyfood	1.000000	1.000	0.100	
11000090	11	Apple, dried	1.000000	8.000	0.100	
11000091	11	Apple, dried-babyfood	1.000000	8.000	0.100	
11000100	11	Apple, juice	1.000000	1.300	0.100	
11000101	11	Apple, juice-babyfood	1.000000	1.300	0.100	
11000110	11	Apple, sauce	1.000000	1.000	0.100	
11000111	11	Apple, sauce-babyfood	1.000000	1.000	0.100	
12000120	12	Apricot	1.200000	1.000	1.000	
12000121	12	Apricot-babyfood	1.200000	1.000	1.000	
12000130	12	Apricot, dried	1.200000	6.000	1.000	
12000140	12	Apricot, juice	1.200000	1.000	1.000	
12000141	12	Apricot, juice-babyfood	1.200000	1.000	1.000	
01030150	1CD	Arrowroot, flour	0.010000	1.000	1.000	
01030151	1CD	Arrowroot, flour-babyfood	0.010000	1.000	1.000	
01030170	1CD	Artichoke, Jerusalem	0.010000	1.000	1.000	
04010180	4A	Arugula	3.000000	1.000	1.000	
09020210	9B	Balsam pear	0.500000	1.000	1.000	
06020310	6B	Bean, broad, succulent	0.400000	1.000	1.000	
06020330	6B	Bean, cowpea, succulent	0.400000	1.000	1.000	
06020370	6B	Bean, lima, succulent	0.400000	1.000	1.000	
06010430	6A	Bean, snap, succulent	0.600000	1.000	1.000	
06010431	6A	Bean, snap, succulent-babyfood	0.600000	1.000	1.000	
21000440	M	Beef, meat	0.100000	1.000	1.000	
21000441	M	Beef, meat-babyfood	0.100000	1.000	1.000	
21000450	M	Beef, meat, dried	0.100000	1.920	1.000	
21000460	M	Beef, meat byproducts	0.200000	1.000	1.000	
21000461	M	Beef, meat byproducts-babyfood	0.200000	1.000	1.000	
21000470	M	Beef, fat	0.100000	1.000	1.000	
21000471	M	Beef,fat-babyfood	0.100000	1.000	1.000	
21000480	M	Beef, kidney	0.200000	1.000	1.000	
21000490	M	Beef, liver	0.200000	1.000	1.000	
21000491	M	Beef, liver-babyfood	0.200000	1.000	1.000	
13010550	13A	Blackberry	1.600000	1.000	1.000	
13010560	13A	Blackberry, juice	1.600000	1.000	1.000	
13010561	13A	Blackberry, juice-babyfood	1.600000	1.000	1.000	
13020570	13B	Blueberry	1.600000	1.000	1.000	
13020571	13B	Blueberry-babyfood	1.600000	1.000	1.000	
13010580	13A	Boysenberry	1.600000	1.000	1.000	
14000590	14	Brazil nut	0.100000	1.000	1.000	
05010610	5A	Broccoli	1.200000	1.000	1.000	
05010611	5A	Broccoli-babyfood	1.200000	1.000	1.000	
05010620	5A	Broccoli, Chinese	1.200000	1.000	1.000	
05020630	5B	Broccoli raab	1.200000	1.000	1.000	
05010640	5A	Brussels sprouts	1.200000	1.000	1.000	

14000680	14	Butternut	0.100000	1.000	1.000
05010690	5A	Cabbage	1.200000	1.000	1.000
05020700	5B	Cabbage, Chinese, bok choy	1.200000	1.000	1.000
05010710	5A	Cabbage, Chinese, napa	1.200000	1.000	1.000
05010720	5A	Cabbage, Chinese, mustard	1.200000	1.000	1.000
09010750	9A	Cantaloupe	0.500000	1.000	1.000
04020760	4B	Cardoon	3.000000	1.000	1.000
09010800	9A	Casaba	0.500000	1.000	1.000
14000810	14	Cashew	0.100000	1.000	1.000
01030820	1CD	Cassava	0.010000	1.000	1.000
01030821	1CD	Cassava-babyfood	0.010000	1.000	1.000
05010830	5A	Cauliflower	1.200000	1.000	1.000
04020850	4B	Celery	3.000000	1.000	1.000
04020851	4B	Celery-babyfood	3.000000	1.000	1.000
04020860	4B	Celery, juice	3.000000	1.000	1.000
04020870	4B	Celtuce	3.000000	1.000	1.000
09020880	9B	Chayote, fruit	0.500000	1.000	1.000
12000900	12	Cherry	1.200000	1.000	1.000
12000901	12	Cherry-babyfood	1.200000	1.000	1.000
12000910	12	Cherry, juice	1.200000	1.500	1.000
12000911	12	Cherry, juice-babyfood	1.200000	1.500	1.000
14000920	14	Chestnut	0.100000	1.000	1.000
40000930	P	Chicken, meat	0.010000	1.000	1.000
40000931	P	Chicken, meat-babyfood	0.010000	1.000	1.000
40000940	P	Chicken, liver	0.050000	1.000	1.000
40000950	P	Chicken, meat byproducts	0.050000	1.000	1.000
40000951	P	Chicken, meat byproducts-babyfoo	0.050000	1.000	1.000
40000960	P	Chicken, fat	0.010000	1.000	1.000
40000961	P	Chicken, fat-babyfood	0.010000	1.000	1.000
40000970	P	Chicken, skin	0.010000	1.000	1.000
40000971	P	Chicken, skin-babyfood	0.010000	1.000	1.000
09021020	9B	Chinese waxgourd	0.500000	1.000	1.000
19011030	19A	Chive	4.500000	1.000	1.000
04011040	4A	Chrysanthemum, garland	3.000000	1.000	1.000
10001060	10	Citrus citron	0.500000	1.000	1.000
10001070	10	Citrus hybrids	0.500000	1.000	1.000
10001080	10	Citrus, oil	0.500000	1.000	1.000
05021170	5B	Collards	1.200000	1.000	1.000
95001280	O	Cottonseed, oil	0.600000	1.000	1.000
95001281	O	Cottonseed, oil-babyfood	0.600000	1.000	1.000
11001290	11	Crabapple	1.000000	1.000	1.000
95001300	O	Cranberry	0.600000	1.000	1.000
95001301	O	Cranberry-babyfood	0.600000	1.000	1.000
95001310	O	Cranberry, dried	0.600000	1.000	1.000
95001320	O	Cranberry, juice	0.600000	1.100	1.000
95001321	O	Cranberry, juice-babyfood	0.600000	1.100	1.000
04011330	4A	Cress, garden	3.000000	1.000	1.000
04011340	4A	Cress, upland	3.000000	1.000	1.000
09021350	9B	Cucumber	0.500000	1.000	1.000
13021360	13B	Currant	1.600000	1.000	1.000
13021370	13B	Currant, dried	1.600000	1.000	1.000
04011380	4A	Dandelion, leaves	3.000000	1.000	1.000
01031390	1CD	Dasheen, corm	0.010000	1.000	1.000
13011420	13A	Dewberry	1.600000	1.000	1.000
70001450	P	Egg, whole	0.010000	1.000	1.000
70001451	P	Egg, whole-babyfood	0.010000	1.000	1.000
70001460	P	Egg, white	0.010000	1.000	1.000
70001461	P	Egg, white (solids)-babyfood	0.010000	1.000	1.000
70001470	P	Egg, yolk	0.010000	1.000	1.000
70001471	P	Egg, yolk-babyfood	0.010000	1.000	1.000
08001480	8	Eggplant	0.200000	1.000	1.000
13021490	13B	Elderberry	1.600000	1.000	1.000
04011500	4A	Endive	3.000000	1.000	1.000
04021520	4B	Fennel, Florence	3.000000	1.000	1.000
14001550	14	Filbert	0.100000	1.000	1.000
14001560	14	Filbert, oil	0.100000	1.000	1.000
03001640	3	Garlic	0.020000	1.000	1.000
03001650	3	Garlic, dried	0.020000	1.000	1.000

03001651	3	Garlic, dried-babyfood	0.020000	1.000	1.000
01031660	1CD	Ginger	0.010000	1.000	1.000
01031661	1CD	Ginger-babyfood	0.010000	1.000	1.000
01031670	1CD	Ginger, dried	0.010000	1.000	1.000
23001690	M	Goat, meat	0.100000	1.000	1.000
23001700	M	Goat, meat byproducts	0.200000	1.000	1.000
23001710	M	Goat, fat	0.100000	1.000	1.000
23001720	M	Goat, kidney	0.200000	1.000	1.000
23001730	M	Goat, liver	0.200000	1.000	1.000
13021740	13B	Gooseberry	1.600000	1.000	1.000
95001750	O	Grape	0.200000	1.000	1.000
95001760	O	Grape, juice	0.200000	1.200	1.000
95001761	O	Grape, juice-babyfood	0.200000	1.200	1.000
95001770	O	Grape, leaves	0.200000	1.000	1.000
95001780	O	Grape, raisin	0.200000	4.300	1.000
95001790	O	Grape, wine and sherry	0.200000	1.000	1.000
10001800	10	Grapefruit	0.500000	1.000	1.000
10001810	10	Grapefruit, juice	0.500000	2.100	1.000
14001850	14	Hickory nut	0.100000	1.000	1.000
09011870	9A	Honeydew melon	0.500000	1.000	1.000
24001890	M	Horse, meat	0.100000	1.000	1.000
13021910	13B	Huckleberry	1.600000	1.000	1.000
05021940	5B	Kale	1.200000	1.000	1.000
05011960	5A	Kohlrabi	1.200000	1.000	1.000
10001970	10	Kumquat	0.500000	1.000	1.000
10001990	10	Lemon	0.500000	1.000	1.000
10002000	10	Lemon, juice	0.500000	2.000	1.000
10002001	10	Lemon, juice-babyfood	0.500000	2.000	1.000
10002010	10	Lemon, peel	0.500000	1.000	1.000
04012040	4A	Lettuce, head	3.000000	1.000	1.000
04012050	4A	Lettuce, leaf	3.000000	1.000	1.000
10002060	10	Lime	0.500000	1.000	1.000
10002070	10	Lime, juice	0.500000	2.000	1.000
10002071	10	Lime, juice-babyfood	0.500000	2.000	1.000
13012080	13A	Loganberry	1.600000	1.000	1.000
11002100	11	Loquat	1.000000	1.000	1.000
14002130	14	Macadamia nut	0.100000	1.000	1.000
28002210	M	Meat, game	0.100000	1.000	1.000
27002220	D	Milk, fat	0.100000	1.000	1.000
27002221	D	Milk, fat - baby food/infant for	0.100000	1.000	1.000
27012230	D	Milk, nonfat solids	0.100000	1.000	1.000
27012231	D	Milk, nonfat solids-baby food/in	0.100000	1.000	1.000
27022240	D	Milk, water	0.100000	1.000	1.000
27022241	D	Milk, water-babyfood/infant form	0.100000	1.000	1.000
27032251	D	Milk, sugar (lactose)-baby food/	0.100000	1.000	1.000
05022290	5B	Mustard greens	1.200000	1.000	1.000
12002300	12	Nectarine	1.200000	1.000	1.000
08002340	8	Okra	0.200000	1.000	1.000
03002370	3	Onion, dry bulb	0.020000	1.000	1.000
03002371	3	Onion, dry bulb-babyfood	0.020000	1.000	1.000
03002380	3	Onion, dry bulb, dried	0.020000	9.000	1.000
03002381	3	Onion, dry bulb, dried-babyfood	0.020000	9.000	1.000
03002390	3	Onion, green	4.500000	1.000	1.000
10002400	10	Orange	0.500000	1.000	0.010
10002410	10	Orange, juice	0.500000	1.800	0.010
10002411	10	Orange, juice-babyfood	0.500000	1.800	0.010
10002420	10	Orange, peel	0.500000	1.000	0.010
04012480	4A	Parsley, leaves	3.000000	1.000	1.000
06022550	6B	Pea, succulent	0.400000	1.000	1.000
06022551	6B	Pea, succulent-babyfood	0.400000	1.000	1.000
06012570	6A	Pea, edible podded, succulent	0.600000	1.000	1.000
06022590	6B	Pea, pigeon, succulent	0.400000	1.000	1.000
12002600	12	Peach	1.200000	1.000	1.000
12002601	12	Peach-babyfood	1.200000	1.000	1.000
12002610	12	Peach, dried	1.200000	7.000	1.000
12002611	12	Peach, dried-babyfood	1.200000	7.000	1.000
12002620	12	Peach, juice	1.200000	1.000	1.000
12002621	12	Peach, juice-babyfood	1.200000	1.000	1.000

11002660	11	Pear	1.000000	1.000	1.000
11002661	11	Pear-babyfood	1.000000	1.000	1.000
11002670	11	Pear, dried	1.000000	6.250	1.000
11002680	11	Pear, juice	1.000000	1.000	1.000
11002681	11	Pear, juice-babyfood	1.000000	1.000	1.000
14002690	14	Pecan	0.100000	1.000	1.000
08002700	8	Pepper, bell	0.200000	1.000	1.000
08002701	8	Pepper, bell-babyfood	0.200000	1.000	1.000
08002710	8	Pepper, bell, dried	0.200000	1.000	1.000
08002711	8	Pepper, bell, dried-babyfood	0.200000	1.000	1.000
08002720	8	Pepper, nonbell	0.200000	1.000	1.000
08002721	8	Pepper, nonbell-babyfood	0.200000	1.000	1.000
08002730	8	Pepper, nonbell, dried	0.200000	1.000	1.000
14002820	14	Pistachio	0.100000	1.000	1.000
12002850	12	Plum	1.200000	1.000	1.000
12002851	12	Plum-babyfood	1.200000	1.000	1.000
12002860	12	Plum, prune, fresh	0.200000	1.000	1.000
12002861	12	Plum, prune, fresh-babyfood	0.200000	1.000	1.000
12002870	12	Plum, prune, dried	0.400000	1.000	1.000
12002871	12	Plum, prune, dried-babyfood	0.400000	1.000	1.000
12002880	12	Plum, prune, juice	0.200000	1.400	1.000
12002881	12	Plum, prune, juice-babyfood	0.200000	1.400	1.000
25002900	M	Pork, meat	0.100000	1.000	1.000
25002901	M	Pork, meat-babyfood	0.100000	1.000	1.000
25002910	M	Pork, skin	0.100000	1.000	1.000
25002920	M	Pork, meat byproducts	0.200000	1.000	1.000
25002921	M	Pork, meat byproducts-babyfood	0.200000	1.000	1.000
25002930	M	Pork, fat	0.100000	1.000	1.000
25002931	M	Pork, fat-babyfood	0.100000	1.000	1.000
25002940	M	Pork, kidney	0.200000	1.000	1.000
25002950	M	Pork, liver	0.200000	1.000	1.000
01032960	1C	Potato, chips	0.010000	1.000	1.000
01032970	1C	Potato, dry (granules/ flakes)	0.010000	6.500	1.000
01032971	1C	Potato, dry (granules/ flakes)-b	0.010000	6.500	1.000
01032980	1C	Potato, flour	0.010000	1.000	1.000
01032981	1C	Potato, flour-babyfood	0.010000	1.000	1.000
01032990	1C	Potato, tuber, w/peel	0.010000	1.000	1.000
01032991	1C	Potato, tuber, w/peel-babyfood	0.010000	1.000	1.000
01033000	1C	Potato, tuber, w/o peel	0.010000	1.000	1.000
01033001	1C	Potato, tuber, w/o peel-babyfood	0.010000	1.000	1.000
60003010	P	Poultry, other, meat	0.010000	1.000	1.000
60003020	P	Poultry, other, liver	0.050000	1.000	1.000
60003030	P	Poultry, other, meat byproducts	0.050000	1.000	1.000
60003040	P	Poultry, other, fat	0.010000	1.000	1.000
60003050	P	Poultry, other, skin	0.010000	1.000	1.000
10003070	10	Pummelo	0.500000	1.000	1.000
09023080	9B	Pumpkin	0.500000	1.000	1.000
09023090	9B	Pumpkin, seed	0.500000	1.000	1.000
11003100	11	Quince	1.000000	1.000	1.000
29003120	M	Rabbit, meat	0.100000	1.000	1.000
04013130	4A	Radicchio	3.000000	1.000	1.000
05023180	5B	Rape greens	1.200000	1.000	1.000
20003190	20	Rapeseed, oil	0.010000	1.000	1.000
20003191	20	Rapeseed, oil-babyfood	0.010000	1.000	1.000
13013200	13A	Raspberry	1.600000	1.000	1.000
13013201	13A	Raspberry-babyfood	1.600000	1.000	1.000
13013210	13A	Raspberry, juice	1.600000	1.000	1.000
13013211	13A	Raspberry, juice-babyfood	1.600000	1.000	1.000
04023220	4B	Rhubarb	3.000000	1.000	1.000
03003380	3	Shallot	0.020000	1.000	1.000
26003390	M	Sheep, meat	0.100000	1.000	1.000
26003391	M	Sheep, meat-babyfood	0.100000	1.000	1.000
26003400	M	Sheep, meat byproducts	0.200000	1.000	1.000
26003410	M	Sheep, fat	0.100000	1.000	1.000
26003411	M	Sheep, fat-babyfood	0.100000	1.000	1.000
26003420	M	Sheep, kidney	0.200000	1.000	1.000
26003430	M	Sheep, liver	0.200000	1.000	1.000
19023540	19B	Spices, other	0.010000	1.000	1.000

19023541	19B	Spices, other-babyfood	0.010000	1.000	1.000
04013550	4A	Spinach	3.000000	1.000	1.000
04013551	4A	Spinach-babyfood	3.000000	1.000	1.000
09023560	9B	Squash, summer	0.500000	1.000	1.000
09023561	9B	Squash, summer-babyfood	0.500000	1.000	1.000
09023570	9B	Squash, winter	0.500000	1.000	1.000
09023571	9B	Squash, winter-babyfood	0.500000	1.000	1.000
95003590	O	Strawberry	0.600000	1.000	1.000
95003591	O	Strawberry-babyfood	0.600000	1.000	1.000
95003600	O	Strawberry, juice	0.600000	1.000	1.000
95003601	O	Strawberry, juice-babyfood	0.600000	1.000	1.000
01033660	1CD	Sweet potato	0.010000	1.000	1.000
01033661	1CD	Sweet potato-babyfood	0.010000	1.000	1.000
04023670	4B	Swiss chard	3.000000	1.000	1.000
10003690	10	Tangerine	0.500000	1.000	1.000
10003700	10	Tangerine, juice	0.500000	2.300	1.000
01033710	1CD	Tanier, corm	0.010000	1.000	1.000
08003740	8	Tomatillo	0.200000	1.000	1.000
08003750	8	Tomato	0.200000	1.000	1.000
08003751	8	Tomato-babyfood	0.200000	1.000	1.000
08003760	8	Tomato, paste	0.400000	1.000	1.000
08003761	8	Tomato, paste-babyfood	0.400000	1.000	1.000
08003770	8	Tomato, puree	0.200000	3.300	1.000
08003771	8	Tomato, puree-babyfood	0.200000	3.300	1.000
08003780	8	Tomato, dried	0.200000	14.300	1.000
08003781	8	Tomato, dried-babyfood	0.200000	14.300	1.000
08003790	8	Tomato, juice	0.200000	1.500	1.000
50003820	P	Turkey, meat	0.010000	1.000	1.000
50003821	P	Turkey, meat-babyfood	0.010000	1.000	1.000
50003830	P	Turkey, liver	0.050000	1.000	1.000
50003831	P	Turkey, liver-babyfood	0.050000	1.000	1.000
50003840	P	Turkey, meat byproducts	0.050000	1.000	1.000
50003841	P	Turkey, meat byproducts-babyfood	0.050000	1.000	1.000
50003850	P	Turkey, fat	0.010000	1.000	1.000
50003851	P	Turkey, fat-babyfood	0.010000	1.000	1.000
50003860	P	Turkey, skin	0.010000	1.000	1.000
50003861	P	Turkey, skin-babyfood	0.010000	1.000	1.000
01033870	1CD	Turmeric	0.010000	1.000	1.000
05023890	5B	Turnip, greens	1.200000	1.000	1.000
14003910	14	Walnut	0.100000	1.000	1.000
86010000	O	Water, direct, all sources	0.005000	1.000	1.000
86020000	O	Water, indirect, all sources	0.005000	1.000	1.000
09013990	9A	Watermelon	0.500000	1.000	1.000
09014000	9A	Watermelon, juice	0.500000	1.000	1.000
01034060	1CD	Yam, true	0.010000	1.000	1.000
01034070	1CD	Yam bean	0.010000	1.000	1.000

Attachment 6. Summary of DEEM-FCID™ Chronic Results.

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U.S. Environmental Protection Agency                                    Ver. 2.00
DEEM-FCID Chronic analysis for ACETAMIPRID                          (1994-98 data)
Residue file name: C:\Documents and Settings\cswart02\My
Documents\RAB2chemicals\Acetamiprid\DEEM_Lifeline
inputs\PRIADNTacetamipridCT_berrybulb_chronic.R98
                                                  Adjustment factor #2 NOT used.
Analysis Date 10-12-2007/18:35:42     Residue file dated: 10-12-2007/18:35:20/8
Reference dose (RfD, Chronic) = .071 mg/kg bw/day
COMMENT 1: Acute/Chronic - UFs = 100
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Total exposure by population subgroup

Population Subgroup	Total Exposure mg/kg body wt/day	Total Exposure Percent of Rfd
U.S. Population (total)	0.006184	8.7%
U.S. Population (spring season)	0.006213	8.8%
U.S. Population (summer season)	0.006202	8.7%
U.S. Population (autumn season)	0.006146	8.7%
U.S. Population (winter season)	0.006176	8.7%
Northeast region	0.006988	9.8%
Midwest region	0.006102	8.6%
Southern region	0.005475	7.7%
Western region	0.006676	9.4%
Hispanics	0.006955	9.8%
Non-hispanic whites	0.005984	8.4%
Non-hispanic blacks	0.006050	8.5%
Non-hisp/non-white/non-black	0.007994	11.3%
All infants (< 1 year)	0.014228	20.0%
Nursing infants	0.007533	10.6%
Non-nursing infants	0.016769	23.6%
Children 1-6 yrs	0.018720	26.4%
Children 7-12 yrs	0.008087	11.4%
Females 13-19 (not preg or nursing)	0.004703	6.6%
Females 20+ (not preg or nursing)	0.004427	6.2%
Females 13-50 yrs	0.004803	6.8%
Females 13+ (preg/not nursing)	0.005414	7.6%
Females 13+ (nursing)	0.005804	8.2%
Males 13-19 yrs	0.004890	6.9%
Males 20+ yrs	0.004119	5.8%
Seniors 55+	0.004512	6.4%
Children 1-2 yrs	0.024648	34.7%
Children 3-5 yrs	0.016880	23.8%
Children 6-12 yrs	0.008745	12.3%
Youth 13-19 yrs	0.004820	6.8%
Adults 20-49 yrs	0.004189	5.9%
Adults 50+ yrs	0.004481	6.3%
Females 13-49 yrs	0.004414	6.2%

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

■ 1. The authority citation for 21 CFR part 522 continues to read as follows:

Authority: 21 U.S.C. 360b.

■ 2. In § 522.970, revise paragraph (b)(2) and add paragraph (b)(4) to read as follows:

§ 522.970 Flunixin.

* * * * *

(b) * * *

(2) See Nos. 057561, 059130, and 061623 for use as in paragraphs (e)(1), (e)(2)(i)(A), (e)(2)(ii)(A), and (e)(2)(iii), of this section.

* * * * *

(4) See No. 055529 for use as in paragraphs (e)(1) and (e)(2) of this section.

* * * * *

Dated: January 4, 2008.

Bernadette Dunham,

Deputy Director, Center for Veterinary Medicine.

[FR Doc. E8–699 Filed 1–15–08; 8:45 am]

BILLING CODE 4160–01–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2006–0733; FRL–8348–1]

Acetamiprid; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of acetamiprid in or on bushberry subgroup 13–07B; caneberry subgroup 13–07A; low growing berry subgroup 13–07G; onion, bulb, subgroup 3–07A; and onion, green, subgroup 3–07B. Nippon Soda Co., Ltd. requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective January 16, 2008. Objections and requests for hearings must be received on or before March 17, 2008, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION.**

ADDRESSES: EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPP–2006–0733. To access the electronic docket, go to *http://www.regulations.gov*, select "Advanced Search," then "Docket Search." Insert the docket ID number where indicated and select the "Submit" button. Follow the instructions on the regulations.gov website to view the docket index or access available documents. All documents in the docket are listed in the docket index available in regulations.gov. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available in the electronic docket at *http://www.regulations.gov*, or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: Susan Stanton, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–5218; e-mail address: *stanton.susan@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected entities may include, but are not limited to those engaged in the following activities:

- Crop production (NAICS code 111), e.g., agricultural workers; greenhouse, nursery, and floriculture workers; farmers.
- Animal production (NAICS code 112), e.g., cattle ranchers and farmers, dairy cattle farmers, livestock farmers.
- Food manufacturing (NAICS code 311), e.g., agricultural workers; farmers; greenhouse, nursery, and floriculture workers; ranchers; pesticide applicators.
- Pesticide manufacturing (NAICS code 32532), e.g., agricultural workers; commercial applicators; farmers; greenhouse, nursery, and floriculture workers; residential users.

This listing is not intended to be exhaustive, but rather to provide a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT.**

B. How Can I Access Electronic Copies of this Document?

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C. Can I File an Objection or Hearing Request?

Under section 408(g) of FFDCA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2006–0733 in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk as required by 40 CFR part 178 on or before March 17, 2008.

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing that does not contain any CBI for inclusion in the public docket that is described in **ADDRESSES.** Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit this copy, identified by docket ID number EPA–HQ–OPP–2006–0733, by one of the following methods:

- *Federal eRulemaking Portal*: *http://www.regulations.gov.* Follow the on-line instructions for submitting comments.
- *Mail*: Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.

• *Delivery*: OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. Deliveries are only accepted during the Docket's normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket Facility telephone number is (703) 305–5805.

II. Petition for Tolerance

In the **Federal Register** of September 22, 2006 (71 FR 55468) (FRL–8091–9), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 6F7051) by Nippon Soda Co., Ltd., c/o Nisso America Inc., 45 Broadway, Suite 2120, New York, NY, 10006. The petition requested that 40 CFR 180.578 be amended by establishing tolerances for residues of the insecticide acetamiprid, *N*1-[(6-chloro-3-pyridyl)methyl]-*N*2-cyano-*N*1-methylacetamidine, in or on bulb vegetables crop group 3 at 3 ppm; edible podded legume vegetables, crop subgroup 6a at 0.5 ppm; succulent shelled peas and beans, crop subgroup 6b, at 0.5 ppm; and berries, crop group 13 at 1 ppm. That notice referenced a summary of the petition prepared by Nippon Soda Co., Ltd., the registrant, which is available to the public in the docket ID Number EPA–HQ–OPP–2006–0733, *http://www.regulations.gov*. There were no comments received in response to the notice of filing.

In the **Federal Register** of April 2, 2007 (72 FR 16352) (FRL–8119–2), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 6E7163) by Interregional Research Project Number 4 (IR-4), 500 College Road East, Suite 201 W, Princeton, NJ 08540. The petition requested that 40 CFR 180.578 be amended by establishing tolerances for residues of the insecticide acetamiprid, *N*1-[(6-chloro-3-pyridyl)methyl]-*N*2-cyano-*N*1-methylacetamidine, in or on strawberry, bearberry, bilberry, lowbush blueberry, cloudberry, cranberry, lingonberry, muntries and partridgeberry at 0.60 parts per million (ppm). That notice referenced a summary of the petition prepared by Nippon Soda Co., Ltd., the registrant, which is available to the public in the docket ID Number EPA–HQ–OPP–2007–0105, *http://www.regulations.gov*. There were no comments received in response to the notice of filing.

In the **Federal Register** of November 28, 2007 (72 FR 67256) (FRL–8340–6), EPA issued a final rule establishing tolerances for residues of acetamiprid in/on edible-podded legume vegetables and succulent shelled peas and beans but deferred to a later date the decision on the petitioned-for tolerances on the bulb vegetable and berry commodities requested in these petitions. EPA is establishing the bulb vegetable and berry tolerances at this time but has modified the commodity terms and most of the proposed tolerance levels. The reasons for these changes are explained in Unit V.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is "safe." Section 408(b)(2)(A)(ii) of FFDCA defines "safe" to mean that "there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information." This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to "ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue. . . ." These provisions were added to FFDCA by the Food Quality Protection Act (FQPA) of 1996.

Consistent with FFDCA section 408(b)(2)(D), and the factors specified in FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for the petitioned-for tolerance for residues of acetamiprid on bushberry subgroup 13–07B at 1.6 ppm; caneberry subgroup 13–07A at 1.6 ppm; low growing berry subgroup 13–07G at 0.60 ppm; onion, bulb, subgroup 3–07A at 0.02 ppm; and onion, green, subgroup 3–07B at 4.5 ppm. EPA's assessment of exposures and risks associated with establishing the tolerance follows.

As noted above, on November 28, 2007, EPA issued a final rule in the **Federal Register** establishing tolerances for residues of acetamiprid in/on edible-podded legume vegetables and succulent shelled peas and beans. When the Agency conducted the risk assessments in support of this tolerance action it assumed that acetamiprid residues would be present on bulb vegetables and commodities in the aforementioned berry subgroups as well as on all foods covered by the proposed and established tolerances. Therefore, establishing the bulb vegetable and berry tolerances will not change the most recent estimated aggregate risks resulting from use of acetamiprid, as discussed in the November 28, 2007 **Federal Register**. Refer to the November 28, 2007 **Federal Register** document (72 FR 67256) (FRL–8340–6), available at *http://www.regulations.gov*, for a detailed discussion of the aggregate risk assessments and determination of safety. EPA relies upon those risk assessments and the findings made in the **Federal Register** document in support of this action.

Based on the risk assessments discussed in the final rule published in the **Federal Register** of November 28, 2007 (72 FR 67256) (FRL–8340–6), EPA concludes that there is a reasonable certainty that no harm will result to the general population, and to infants and children from aggregate exposure to acetamiprid residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate residue analytical methods gas chromatography/electron-capture detection (GC/ECD) and high-performance liquid chromatography/ultraviolet detector (HPLC/UV)) are available for the enforcement of established and new tolerances for plant and animal commodities. These methods may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755–5350; telephone number: (410) 305–2905; e-mail address: *residuemethods@epa.gov*.

B. International Residue Limits

There are no Codex, Canadian or Mexican MRLs established for acetamiprid on the commodities associated with these petitions.

V. Conclusion

The registrant, Nippon Soda Co., Ltd., petitioned for tolerances on bulb vegetables group 3 and berries group 13 as those crop groups were defined at the time of the petition. IR-4 also petitioned for individual tolerances on strawberry, bearberry, bilberry, lowbush blueberry, cloudberry, cranberry, lingonberry, muntries and partridgeberry (PP 6E7163). In the **Federal Register** of

December 7, 2007 (72 FR 69150) (FRL–8340–6), EPA issued a final rule that revised the crop grouping regulations. As part of this action, EPA expanded and revised bulb vegetables group 3 and berries group 13. Changes to crop group 3 (bulb vegetables) included adding new commodities, creating subgroups for bulb and green onions, and changing the name of one of the representative commodities from "onion, dry bulb" to "onion, bulb". Changes to crop group 13 (berries) included adding new commodities, revising existing subgroups and creating new subgroups (including a low growing berry subgroup consisting of the commodities requested in PP 6E7163 and cultivars, varieties, and/or hybrids of these).

EPA indicated in the December 7, 2007 final rule as well as the earlier May 23, 2007 proposed rule (72 FR 28920) (FRL–8126–1) that, for existing petitions for which a notice of filing had been published, the Agency would attempt to conform these petitions to the rule. Therefore, consistent with this rule, EPA is establishing tolerances on bushberry subgroup 13–07B; caneberry subgroup 13–07A; low growing berry subgroup 13–07G; onion, bulb, subgroup 3–07A; and onion, green, subgroup 3–07B. The low growing berry subgroup 13–07G consists of the berries for which tolerances were requested in PP 6E7163. The other subgroups include the remaining berries and bulb vegetables for which tolerances were requested in PP 6F7051.

EPA concludes it is reasonable to revise the petitioned-for tolerances so that they agree with the recent crop grouping revisions because (1) although the new crop groups/subgroups include several new commodities, the added commodities are closely related minor crops which contribute little to overall dietary or aggregate exposure and risk; and acetamiprid exposure from these added commodities was considered when EPA conducted the dietary and aggregate risk assessments supporting this action; and (2) the representative commodities for the revised crop groups/subgroups have not changed.

Based upon review of the data supporting PP 6F7051, EPA has also revised the tolerance levels for bushberry subgroup 13–07B and caneberry subgroup 13–07A to 1.6 ppm; onion, bulb, subgroup 3–07A to 0.02 ppm; and onion, green, subgroup 3–07B to 4.5 ppm. EPA revised these tolerance levels based on analyses of the residue field trial data using the Agency's Tolerance Spreadsheet in accordance with the Agency's Guidance for Setting Pesticide Tolerances Based on Field Trial Data Standard Operating Procedure (SOP).

Therefore, tolerances are established for residues of acetamiprid, *N*1-[(6-chloro-3-pyridyl)methyl]-*N*2-cyano-*N*1-methylacetamidine, in or on bushberry subgroup 13–07B at 1.6 ppm; caneberry subgroup 13–07A at 1.6 ppm; low growing berry subgroup 13–07G at 0.60 ppm; onion, bulb, subgroup 3–07A at 0.02 ppm; and onion, green, subgroup 3–07B at 4.5 ppm.

VI. Statutory and Executive Order Reviews

This final rule establishes a tolerance under section 408(d) of FFDCA in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Because this rule has been exempted from review under Executive Order 12866, this rule is not subject to Executive Order 13211, *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under section 408(d) of FFDCA, such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply.

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of FFDCA. As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000) do not apply to this rule. In addition, This rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104–4).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note).

VII. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the **Federal Register**. This final rule is not a "major rule" as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: January 8, 2008.

Donald R. Stubbs,

Acting Director, Registration Division, Office of Pesticide Programs.

■ Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

■ 1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

■ 2. Section 180.578 is amended by alphabetically adding the following commodities to the table in paragraph (a)(1) to read as follows:

180.578 Acetamiprid; tolerances for residues.

(a) * * * (1) * * *

Commodity	Parts per million
* * * * *	
Berry, low growing subgroups 13–07G	0.60
Bushberry subgroup 13–07B	1.6
Caneberry subgroup 13–07A	1.6
* * * * *	
Onion, bulb, subgroup 3–07A	0.02
Onion, green, subgroup 3–07B	4.5
* * * * *	

* * * * *

[FR Doc. E8–683 Filed 1–15–08; 8:45 am]
BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2007–0461; FRL–8346–6]

Mandipropamid; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for residues of mandipropamid, 4-chloro-N-[2-[3-methoxy-4-(2-propynyloxy)phenyl]ethyl]-alpha-(2-propynyloxy)-benzeneacetamide in or on Brassica, head and stem, subgroup 5A; Brassica, leafy greens, subgroup 5B; vegetable, cucurbit, group 9; vegetable, fruiting, group 8; okra; vegetable, leafy except brassica, group 4; vegetable, tuberous and corm, subgroup 1C; grape; grape, raisin; onion, dry bulb; onion, green; and potato, wet peel. Syngenta Crop Protection Inc. requested this tolerance under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective January 16, 2008. Objections and requests for hearings must be received on or before March 17, 2008, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPP–2007–0461. To access the electronic docket, go to *http://www.regulations.gov*, select "Advanced Search," then "Docket Search." Insert the docket ID number where indicated and select the "Submit" button. Follow the instructions on the regulations.gov website to view the docket index or access available documents. All documents in the docket are listed in the docket index available in regulations.gov. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available in the electronic docket at *http://www.regulations.gov*, or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: Rose Mary Kearns, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305-5611; e-mail address: *kearns.rosemary@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected entities may include, but are not limited to those engaged in the following activities:

- Crop production (NAICS code 111), e.g., agricultural workers; greenhouse, nursery, and floriculture workers; farmers.
- Animal production (NAICS code 112), e.g., cattle ranchers and farmers, dairy cattle farmers, livestock farmers.
- Food manufacturing (NAICS code 311), e.g., agricultural workers; farmers; greenhouse, nursery, and floriculture workers; ranchers; pesticide applicators.
- Pesticide manufacturing (NAICS code 32532), e.g., agricultural workers; commercial applicators; farmers; greenhouse, nursery, and floriculture workers; residential users.

This listing is not intended to be exhaustive, but rather to provide a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

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C. Can I File an Objection or Hearing Request?

Under section 408(g) of FFDCA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2007–0461 in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk as required by 40 CFR part 178 on or before March 17, 2008.

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing that does not contain any CBI for inclusion in the public docket that is described in

The IR-4 Project
Providing Safe and Effective Pest Management Solutions for Specialty Crop Growers

IR-4 Project Headquarters
Rutgers, The State University of New Jersey
500 College Road East, Suite 201W
Princeton, NJ 08540
732.932.9575 fax: 609-514-2612
www.ir4.rutgers.edu

March 12, 2009

Mr. Stephen Schaible
c/o Document Processing Desk
Registration Division (7505C)
U.S. Environmental Protection Agency
1 Potomac Yard
2777 Crystal Drive
Arlington, VA 22202

Dear Mr. Schaible,

RE: Reduced Risk Status for IR-4 Acetamiprid Petitions
Fruit, small, vine climbing, except fuzzy kiwifruit, subgroup 13-07F
Berry, low growing, subgroup 13-07G
Clover (grown for seed)
Tomato (greenhouse)

On behalf of the IR-4 Project I request that the subject IR-4 acetamiprid uses be designated as reduced risk. IR-4 feels it would be beneficial to officially classify these uses as reduced risk. EPA has previously granted reduced risk status to other proposed uses of this insecticide, including grape and field-grown fruiting vegetables on March 15, 2002.

Acetamiprid (the active ingredient in Assail® insecticide from Nisso America, Inc.) is an insecticide in the pyridylmethylamine class that controls aphids, Japanese beetles, lygus bugs, plant bugs, thrips, grape berry moths, and whiteflies. The attached table contains labeled insecticide options capable of controlling these insects in some of the target crops.

Strawberry growers currently use pyrethroids, carbamates, and organophosphates for control of aphids, Japanese beetle, lygus bugs, plant bugs, thrips, and whiteflies. Lowbush blueberry growers currently use organophosphates, carbaryl, pyrethroids, other neonicotinoids, and pyriproxyfen for control of blueberry maggot, blueberry spanworm, cranberry fruitworm, Japanese beetle, oblique-banded leafroller, aphids, and leafhoppers. Cranberry growers currently use tebufenozide, along with organophosphates, carbaryl, and indoxacarb for control of cranberry fruitworm, fireworms, and flea beetles. Clover growers currently rely on chlorpyrifos for control of aphids and need an alternative that is safe to bees. Acetamiprid is currently registered on grape, but a 3-day PHI is needed in order for this Reduced Risk product to be useful at harvest time. Growers of other vine climbing small fruit have few or no insecticide options. Greenhouse tomato growers are limited to a small subset of insecticides registered on tomato (field) for control of aphids, thrips, whiteflies, and lepidopterous pests, including bifenthrin and malathion. Acetamiprid will increase the margin of safety compared to these and should qualify as a reduced risk insecticide. Thank you very much for your consideration.

Sincerely,

Kenneth S. Samoil
Technical Coordinator
IR-4 Project

KSS
Enclosure

Major funding for IR-4 is provided by Special Research Grants and Hatch Act Funds from USDA-CSREES, in cooperation with the State Agricultural Experimental Stations and USDA-ARS.

Crop	PP No.	Pests	Proposed Use Pattern for Acetamiprid	Labeled Insecticides
Strawberry	6E7163	Japanese beetle Plant bugs Sap beetles Thrips Whiteflies Aphids Spittlebug	2.0-6.9 oz. Assail 30 SG/acre Total 13.8 oz. Assail 30 SG/acre/year 7 day interval between applications PHI=1 day	Abamectin Bifenthrin Fenpropathrin Diazinon Methomyl Malathion Dibrom Spinetoram Carbaryl Tebufenozide
Blueberry, lowbush	6E7163	Blueberry maggot Blueberry spanworm Cranberry fruitworm Japanese beetle Oblique-banded leafroller Aphids Leafhoppers	2.0-6.9 oz. Assail 30 SG/acre Total 13.8 oz. Assail 30 SG/acre/year 7 day interval between applications PHI=1 day	Thiamethoxam Tebufenozide Fenpropathrin Pyriproxyfen Methoxyfenozide Malathion Imidacloprid Carbaryl Spinosad
Cranberry	6E7163	Cranberry fruitworm Fireworms Flea beetles	4.0-6.9 oz. Assail 30 SG/acre Total 13.8 oz. Assail 30 SG/acre/year 7 day interval between applications PHI=1 day	Thiamethoxam Indoxacarb Methoxyfenozide Diazinon Phosmet Acephate Carbaryl Spinosad
Clover		Clover aphid Pea aphid	2.5-4.0 oz. Assail 30 SG/acre or 1.1-1.7 oz. Assail 70 WP/acre Maximum 1 application/year PHI=28 days	Azadirachtin Bifenthrin Malathion Chlorpyrifos Oxydemeton-methyl Zeta-cypermethrin
Grape and Crop subgroup 13-07F		Grape berry moth Japanese beetle Grape leafhopper Grape cane girdler Vine mealybug Thrips	2.5-5.3 oz. Assail 30 SG/acre or 1.1-2.3 oz. Assail 70 WP/acre Maximum 10.6 oz. Assail 30 SG or 4.6 oz. Assail 70 WP/acre per year 14 day interval between applications PHI= 3 days	Abamectin Acephate Thiamethoxam Chlorantraniliprole Azadirachtin Bifenthrin Carbaryl Clothianidin Fenpropathrin Diazinon Spinosad Pyriproxyfen Malathion Zeta-cypermethrin Dinotefuran
Tomato (greenhouse)		Aphids Lepidopterous pests Thrips Whiteflies	0.4 oz. Tristar 30 SG per 1000 plants (0.075 lb ai/acre @ 10,000 plants/acre) Maximum two applications via chemigation PHI=1 day	Thiodan Malathion Lambda-cyhalothrin Azadirachtin Pyriproxyfen Bifenthrin

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In addition to fulfilling a criterion for the data exclusivity extension under FIFRA § 3(c)(1)(F)(ii)(II) by being categorized as a reduced-risk pesticide, a second criterion for the data exclusivity extension is fulfilled under FIFRA § 3(c)(1)(F)(ii) (IV). That is "...the minor use pesticide plays or will play a significant part in an integrated pest management program."

Information on Pest Management Strategic Plans (PMSP) derived from the USDA's National Information System for the Regional IPM Centers website [http://www.ipmcenters.org/pmsp] shows that there are currently 25 PMSPs representing 13 states and/or regions of the US where acetamiprid is listed as an alternative (or possible alternative) insecticide product for 17 minor use (i.e., <300,000 A) crops or crop groups. The list of minor use crop/state PMSPs and their respective websites are as follows:

1) Peach / Eastern US
http://www.ipmcenters.org/pmsp/pdf/EastPeach.pdf

2) Peach / New Jersey
http://www.ipmcenters.org/pmsp/pdf/njpeach.pdf

3) Peach / California
http://www.ipmcenters.org/pmsp/pdf/CAPEACHPMSP.pdf

4) Cherry, tart / General
http://www.ipmcenters.org/pmsp/pdf/MITartCherry2.pdf

5) Plum / California
http://www.ipmcenters.org/pmsp/pdf/CAPLUMPMSP.pdf

6) Nectarine / California
http://www.ipmcenters.org/pmsp/pdf/CANECTARINEPMSP.pdf

7) Pear / California
http://www.ipmcenters.org/pmsp/pdf/CAPear.pdf

8) Citrus (except orange) / California
http://www.ipmcenters.org/pmsp/pdf/CACitrusPMSP%20.pdf

9) Leeks / New Jersey
http://www.ipmcenters.org/pmsp/pdf/NJleekPMSP.pdf

10) Snap Beans / Virginia, North Carolina, Delaware
http://www.ipmcenters.org/pmsp/pdf/VA-NC-DEsnapbeanPMSP.pdf

11) Snap Beans / Oregon and Washington
http://www.ipmcenters.org/pmsp/pdf/ORWA%20SnapBean.pdf

12) Spinach / Texas
http://www.ipmcenters.org/pmsp/pdf/TXspinachPMSP.pdf

13) Spinach / Delaware, Maryland, New Jersey
http://www.ipmcenters.org/pmsp/pdf/DESpinach.pdf

14) Celery / California
http://www.ipmcenters.org/pmsp/pdf/CAcelery.pdf

15) Parsley / Ohio
http://www.ipmcenters.org/pmsp/pdf/OHparsleyPMSP.pdf

16) Pepper / Delaware, Maryland, New Jersey
http://www.ipmcenters.org/pmsp/pdf/DE-MD-NJpepperPMSP.pdf

17) Pepper / California
http://www.ipmcenters.org/pmsp/pdf/CAPepper.pdf

18) Pepper / Ohio
http://www.ipmcenters.org/pmsp/pdf/OHPepper.pdf

19) Eggplant / General
http://www.ipmcenters.org/pmsp/pdf/Eggplant.pdf

20) Cucumbers / Delaware, Maryland
http://www.ipmcenters.org/pmsp/pdf/DEpickle.pdf

21) Cucurbits / Tennessee
http://www.ipmcenters.org/pmsp/pdf/TNcucurbit.pdf

22) Watermelon / Delaware, Maryland, New Jersey, North Carolina
http://www.ipmcenters.org/pmsp/pdf/DE-MD-NJ-NCWatermelonPMSP.pdf

23) Blueberry / Oregon and Washington
http://www.ipmcenters.org/pmsp/pdf/ORWABlueberry.pdf

24) Blueberry / North Central US
http://www.ipmcenters.org/pmsp/pdf/MI-INblueberryPMSP.pdf

25) Strawberry/ Tennessee
http://www.ipmcenters.org/pmsp/pdf/TNstrawberry.pdf

The USDA's National Information System for the Regional IPM Centers website also lists 19 Minor Crop / State profiles in which acetamiprid is listed as an alternative insecticide product. The list of minor crop profiles and the associated websites can be found below:

1) Citrus (excluding oranges) / California
http://www.ipmcenters.org/cropprofiles/docs/CAcitrus2.pdf

2) Citrus (minor) / Florida
http://www.ipmcenters.org/cropprofiles/docs/FLCitrus(minor).pdf

3) Arugula / New Jersey
http://www.ipmcenters.org/cropprofiles/docs/NJarugula.pdf

4) Peppers / Delaware
http://www.ipmcenters.org/cropprofiles/docs/DEgreenpeppers.pdf

5) Peppers / New Jersey
http://www.ipmcenters.org/cropprofiles/docs/NJpeppersbell.pdf

6) Peppers / Ohio
http://www.ipmcenters.org/cropprofiles/docs/OHpeppers-sweet.pdf

7) Eggplant / New Jersey
http://www.ipmcenters.org/cropprofiles/docs/NJeggplants.pdf

8) Eggplant / Florida
http://www.ipmcenters.org/cropprofiles/docs/FLeggplant_.pdf

9) Greens, leafy / Tennessee
http://www.ipmcenters.org/cropprofiles/docs/TNleafygreens.pdf

10) Spinach / Delaware
http://www.ipmcenters.org/cropprofiles/docs/DEspinach.pdf

11) Spinach / Oklahoma
http://www.ipmcenters.org/cropprofiles/docs/OKspinach.pdf

12) Spinach / New Jersey
http://www.ipmcenters.org/cropprofiles/docs/NJspinach.pdf

13) Lettuce/ Florida
http://www.ipmcenters.org/cropprofiles/docs/FLlettuce.pdf

14) Parsley (in Rosemary profile) / Florida
http://www.ipmcenters.org/cropprofiles/docs/FLherbs.pdf

15) Celery / Florida
http://www.ipmcenters.org/cropprofiles/docs/FLcelery.pdf

16) Cabbage / Virginia
http://www.ipmcenters.org/cropprofiles/docs/VAcabbage.pdf

17) Kale / New Jersey
http://www.ipmcenters.org/cropprofiles/docs/NJkale.pdf

18) Onions, green / Ohio
http://www.ipmcenters.org/cropprofiles/docs/OHonions-green.pdf

19) Watermelons / Delaware
http://www.ipmcenters.org/cropprofiles/docs/DEwatermelons.pdf