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

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

CERTIFIED MAIL

Dear Registrant:

This is to inform you that the Environmental Protection Agency (hereafter referred to as EPA or the Agency) has completed its tolerance reassessment decision for norflurazon. This letter, signed on May 31, 2002, and the attached "Overview" document serve as EPA's "Report of the Food Quality Protection Act (FQPA) Tolerance Reassessment Progress and Risk Management Decision (TRED)" for norflurazon. A Notice of Availability, soliciting public comment for a 30 day comment period, will be published in the *Federal Register* (FR) Notice shortly.

FFDCA, as amended, requires EPA to reassess all the tolerances for registered chemicals in effect on or before the date of the enactment of the Food Quality Protection Act (FQPA) in August of 1996 against the new safety standard adopted in the FQPA. In reassessing these tolerances, the Agency must consider, among other things, aggregate risks from non-occupational sources of pesticide exposure, whether there is increased susceptibility to infants and children, and the cumulative effects of pesticides with a common mechanism of toxicity. The tolerances are considered reassessed once the safety finding has been made or a modification or revocation occurs. A reregistration eligibility decision (RED) for norflurazon was completed in June 1996, prior to FQPA enactment; therefore, it needed to be updated to reassess the tolerances under the FQPA standard.

The Agency has evaluated the dietary risk associated with norflurazon and has determined that there is a reasonable certainty that no harm to any population subgroup will result from aggregate exposure to norflurazon when considering dietary exposure and all other non-occupational sources of pesticide exposure for which there is reliable information. Therefore, no mitigation measures are needed, and the tolerances established for residues of norflurazon on raw agricultural commodities are now considered reassessed as safe under section 408(q) of the FFDCA.

FQPA requires that EPA consider "available information" concerning the cumulative effects of a particular pesticide's residues and "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. EPA did not perform a cumulative risk assessment as part of this reregistration review of norflurazon, because the Agency has not determined if there are any other chemical substances that have a mechanism of toxicity common with that of norflurazon. If EPA identifies other substances that share a common mechanism of toxicity with norflurazon, then a cumulative risk assessment will be conducted that includes norflurazon once the final framework EPA will use for conducting cumulative risk assessments is available. Further, EPA is in the process of developing criteria for characterizing and testing endocrine disrupting chemicals and plans to implement an Endocrine Disruptor Screening Program. Norflurazon will be reevaluated at that time and additional studies may be required.

The Agency's human health findings for the pesticide norflurazon, were discussed in a closure conference call on May 30, 2002, and are summarized in the attached "Overview of Norflurazon Risk Assessment." The risk assessments and other documents pertaining to the norflurazon tolerance reassessment decision are listed at the end of this document and are available on the Internet at http://www.epa.gov/pesticides/reregistration/status.htm and in the public docket for viewing.

Tolerances are established for residues of norflurazon and desmethyl norflurazon in/on raw agricultural commodities as defined in 40 CFR 180.356. The norflurazon TRED pertains to the reassessment of 58 tolerances and accounts for 63 tolerances in the tolerance reassessment count from August 1996 based on double counting of meat by-product tolerances. Four tolerances for cattle, hogs, horse and sheep liver are proposed for increase from 0.25 ppm to 0.50 ppm. All other tolerances are reassessed at the current level. The Codex Commission has established several maximum residue limits (MRLs) for residues of norflurazon on various raw agricultural and processed commodities. The Codex MRLs are expressed in terms of norflurazon *per se*. The Codex MRLs and the U.S. tolerances will be incompatible when the U.S. tolerance expression for plant commodities is revised to include both residues of norflurazon and the desmethyl metabolite. The following table summarizes EPA's tolerance reassessment decision:

Norflurazon Tolerances

Commodity	Current Tolerance (ppm)	Reassessed Tolerance (ppm)	Comment
Alfalfa, Forage	3.0	3.0	
Alfalfa, Hay	5.0	5.0	
Alfalfa, Seed	0.1	0.1	
Almonds, Hulls	1.0	1.0	
Almonds, Meat	0.1	0.1	

Commodity	Current Tolerance (ppm)	Reassessed Tolerance (ppm)	Comment
Apricots	0.1	0.1	
Apples	0.1	0.1	
Asparagus	0.05	0.05	
Avocados	0.20	0.20	
Blackberries	0.1	0.1	
Blueberries	0.2	0.2	
Cattle, Fat	0.1	0.1	
Cattle, Liver	0.25	0.50	Increase based on feed item tolerance petition which has been withdrawn
Cattle, Meat	0.1	0.1	
Cattle, MBYP (Exc Liver)	0.1	0.1	
Cherries	0.1	0.1	
Citrus Fruits	0.2	0.2	
Citrus, Molasses	1.0	1.0	
Citrus, Pulp, Dried	0.4	0.4	
Cotton, Seed	0.1	0.1	
Cranberries	0.1	0.1	
Filberts	0.1	0.1	
Goats, Fat	0.1	0.1	
Goats, Liver	0.25	0.50	Increase based on feed item tolerance petition which has been withdrawn
Goats, Meat	0.1	0.1	
Goats, MBYP (Exc. Liver)	0.1	0.1	
Grapes	0.1	0.1	
Hogs, Fat	0.1	0.1	
Hogs, Liver	0.25	0.50	Increase based on feed item tolerance petition which has been withdrawn
Hogs, MBYP (Exc Liver)	0.1	0.1	
Hogs, Meat	0.1	0.1	
Hops, Dried	3.0	3.0	
Hops, Green	1.0	1.0	

Commodity	Current Tolerance (ppm)	Reassessed Tolerance (ppm)	Comment
Horses, Fat	0.1	0.1	
Horses, Liver	0.25	0.50	Increase based on feed item tolerance petition which has been withdrawn
Horses, MBYP (Exc. Liver)	0.1	0.1	
Horses, Meat	0.1	0.1	
Milk	0.1	0.1	
Nectarines	0.1	0.1	
Peaches	0.1	0.1	
Peanuts	0.05	0.05	
Peanuts, Hay	5.50	5.50	
Peanuts, Vines	1.5	1.5	
Pears	0.1	0.1	
Pecans	0.1	0.1	
Plums (Fresh Prunes)	0.1	0.1	
Poultry, Fat	0.1	0.1	
Poultry, MBYP	0.1	0.1	
Poultry, Meat	0.1	0.1	
Raspberries	0.2	0.2	
Sheep, Fat	0.1	0.1	
Sheep, Liver	0.25	0.50	Increase based on feed item tolerance petition which has been withdrawn
Sheep, MBYP (Exc. Liver)	0.1	0.1	
Sheep, Meat	0.1	0.1	
Soybeans	0.1	0.1	
Soybeans, Forage	1.0	1.0	
Soybeans, Hay	1.0	1.0	
Walnuts	0.1	0.1	

No additional generic or product specific data are required for norflurazon based on this tolerance reassessment.

If you have questions on this document, please contact the Chemical Review Manager, Beth Edwards at 703-305-5400. For questions regarding the product reregistration, please contact Karen Jones, at 703-308-5047.

Lois A. Rossi, Director
Special Review and
Reregistration

Attachments:

Norflurazon Tolerance Reassessment Eligibility Decision (TRED); Update of TRED Considering New Drinking Water Assessment. Chemical Number 105801. DP Barcode: D282851. (Memorandum from Michael S. Metzger to Susan T. Lewis dated 5/6/02.)

Refined Estimated Environmental Concentrations (EECs) for Norflurazon and Its Degradate Desmethylnorflurazon in Surface Water and Groundwater. (Memorandum from Elizabeth Behl and E. Laurence Libelo to Michael Metzger and Susan Lewis dated 5/1/02.)

Review of: Study MRID # 44364308 Wllgehausen, H. 1997. Adsorption/desorption of desmethyl norflurazon in various soils. Unpublished study performed and sponsored by Novartis Crop Protection AG, Basel, Switzerland. Study Number 97EH03. (Memorandum from E. Laurence Libelo to Susan Lewis dated 4/11/02.)

Norflurazon. HED Risk Assessment for Tolerance Reassessment Eligibility Decision (TRED). PC Code 105801. Case 0229. DP Barcode D279777. (Memorandum from William J. Hazel to Tracy Lindley dated 12/20/01.)

Norflurazon - Report of the FQPA Safety Factor Committee (Memorandum from Brenda Tarplee to Virginia Dobozy dated 10/26/00.)

PP# - 4E04383 and 6F04621: Norflurazon Acute and Chronic Dietary Exposure Analyses. DP Barcode D267639 and D267640. Chemical 105801. Case 285863 and 287141. Submission S528863 and S527472. (Memorandum from Tom Bloem dated 8/18/00.)

PP# 6F04621 - Norflurazon in/on Bermudagrass Forage and Hay. Petitioner's Response Dated 25-July-1997 to Deficiencies Identified in HED's Residue Chemistry Review: D230704, M. Rodriguez, 14-May-1997. DP Barcode D267067. Chemical 105801. Case 287141. Submission S527472. (Memorandum from Tom Bloem to Joanne Miller and Eugene Wilson dated 7/20/00.)

Overview of Norflurazon Risk Assessment

May 30, 2002

Introduction

The Agency has completed its review of public comments and announces the tolerance reassessment decision (TRED) for Norflurazon. This decision also releases the human health assessment and related documents supporting this decision to the public. The Agency's reassessment of dietary risk, including public exposure through food and drinking water is required by the Federal Food, Drug, and Cosmetic Act (FFDCA). This decision has been developed as part of the public participation process that EPA and U. S Department of Agriculture (USDA) are using to involve the public in the reassessment of pesticide tolerances under FFDCA. The Agency must review tolerance and tolerance exemptions that were in effect when the Food Quality and Protection Act (FQPA) was enacted in August 1996 to ensure that these existing pesticide residue limits for food and feed commodities meet safety standard of the new law. Accordingly, a norflurazon reregistration eligibility decision (RED) that required review, was completed in June 1996, prior to FQPA.

FFDCA requires the Agency to review all the tolerances for registered chemicals in effect on or before the date of the enactment. In reviewing these tolerances, the Agency must consider, among other things, aggregate risks from non-occupational sources of pesticide exposure, whether there is increased susceptibility to infants and children, and the cumulative effects of pesticides with a common mechanism of toxicity. The tolerances are considered reassessed once the safety finding has been made or a revocation occurs. A RED for norflurazon was completed June 1996, prior to FQPA enactment, therefore it needed to be updated to consider the provisions of the Act.

FQPA requires that the Agency, when considering whether to establish, modify, or revoke a tolerance, consider "available information" concerning the cumulative effects of the particular pesticide's residues and "other substances that have a common mechanism of toxicity." The Agency does not, at this time, have available data to determine whether norflurazon has a common mechanism of toxicity with other substances or how to include this pesticide in a cumulative risk assessment. Therefore, for the purposes of this risk assessment, the Agency has not assumed that norflurazon has a common mechanism of toxicity with other substances. If EPA identifies other substances that share a common mechanism of toxicity with norflurazon, a cumulative risk assessment for those substances will be performed.

The risk assessments and other documents pertaining to the norflurazon tolerance reassessment decision are listed at the end of this document and are available on the Internet at

http://www.epa.gov/pesticides/reregistration/status.htm and in the public docket for viewing. Because the risks posed by the use of norflurazon are low and not of concern to the Agency, the

normal process of meeting stakeholders (i.e. growers, extension offices, environmental and commodity groups, and other government offices) to discuss the risks of concern and solicit input on risk mitigation strategies was not necessary for this chemical. Rather, the Agency's report on FQPA tolerance reassessment progress will be announced in the Federal Register. Since there are no risk concerns for norflurazon alone, no further actions are warranted at this time pending a determination of whether a cumulative risk assessment for norflurazon may be needed.

Use Profile

- **Herbicide:** Norflurazon is used to control or suppress germinating grass and broadleaf weeds in fruits, vegetables, nuts, cotton, peanuts, soybeans, and various nonagricultural and industrial areas and is effective through the disruption of carotenoid synthesis (pyridazinone herbicide.) There are no products containing norflurazon registered for homeowner use. Norflurazon can be used on field-grown nursery stock and the nursery stock can be sold to homeowners, but this is not expected to result in residential exposures.

- **Formulation:** Norflurazon formulations include granular, flowable concentrate, and water dispersible granules.

- **Methods of Application:** Norflurazon is applied using aerial application, chemigation (drip and/or sprinkler), and soil treatment (broadcast and incorporation).

- **Use Rates:** Single application rate ranges from 0.56 lbs ai/acre to 2.84 lbs ai/acre. For citrus, soil drench applications are allowed at a maximum application rate of 8 lb ai/acre.

- **Annual Poundage:** Based on available pesticide survey use data in 1998 and 1999, an annual estimate of norflurazon's total domestic usage averaged approximately 2.08 million pounds active ingredient for 2.41 million acres treated. In terms of the total pounds active ingredient used, norflurazon has its largest markets in cotton, oranges, and almonds. Most of norflurazon is used in Alabama, Arkansas, California, Florida, Louisiana, Mississippi, Oregon, Texas, and Washington. Tolerances are established for the combined residues of norflurazon and its desmethyl metabolite in/on numerous commodities ranging from 0.05 (asparagus and peanuts) to 5.50 ppm (peanut hay).

- **Classification:** General Use Pesticide

- **Technical Registrant:** Syngenta Crop Protection, Inc.

Hazard

This risk assessment summarizes the Agency's current database on norflurazon and describes the aggregate dietary (food and drinking water) risks associated with its use as a preemergent herbicide. The toxicity data indicate that norflurazon has low acute oral, dermal, and inhalation toxicity. Norflurazon is neither a skin sensitizer nor an eye or skin irritant. Both the subchronic feeding studies showed that norflurazon induced liver and kidney toxicity. Norflurazon produced developmental toxicity in rabbits but not in rats, and it did not affect reproductive parameters in rats. Norflurazon has been classified as a Group C carcinogen (possible human carcinogen) based upon hepatic adenoma and combined adenoma/carcinoma in the mouse and rat carcinogenicity studies and does not require a quantitative risk assessment; therefore, only acute and chronic aggregate exposure assessments are necessary and these will only be concerned with exposure from food and water.

Human Health Risk Assessment

Acute dietary risk is calculated considering what is eaten in one day (i.e., the full range of consumption values as well as the range of residue in food.) Chronic dietary risk is calculated by using the average consumption values for food and average residue values for those foods over a 70-year lifetime. A risk estimate that is less than 100% of the acute Population Adjusted Dose (aPAD) and or the chronic Population Adjusted Dose (cPAD), at which an individual could be exposed on any given day and no adverse health effects would be expects, is not of concern to the Agency.

Table 1. Norflurazon Technical: Summary of Toxicological Endpoints and Factors for Use in Human Risk Assessment

Exposure Scenario	Dose Used in Risk Assessment, UF	FQPA Safety Factor and LOC for Risk Assessment	Study and Toxicological Endpoints
Acute Dietary (Females 13 - 50)	NOAEL = 10 mg/kg/day UF = 100	FQPA SF = 3x **aPAD = 0.03 mg/kg/day**	Developmental Toxicity Study in Rabbits LOAEL = 30 mg/kg/day, based on increased incidence in skeletal variations observed.
Acute Dietary (General population)	n/a	n/a	No endpoint established.
Chronic Dietary (all populations)	NOAEL = 1.5 mg/kg/day UF = 100	FQPA SF = 1x **cPAD = 0.015 mg/kg/day**	6-Month Feeding Study in Dogs LOAEL = 4.77 mg/kg/day, based on increased absolute and relative liver weight and increased cholesterol in both sexes.

[a]legend: UF = uncertainty factor, FQPA SF = FQPA safety factor, NOAEL = no observed adverse effect level, LOAEL = lowest observed adverse effect level, PAD = population adjusted dose (a = acute, c = chronic) RfD = reference dose;

For females (13-50 years) population subgroup, the acute No Observed Adverse Effects Level (NOAEL) of 10 mg/kg/day was established based on increased incidence in skeletal variations observed in the developmental toxicity study in rabbits at the Lowest Observed Adverse Effect Level (LOAEL) of 30 mg/kg/day. For the acute dietary general population subgroup, no endpoint was established. The chronic NOAEL of 1.5 mg/kg/day was established based on increased absolute and relative liver weight and increased cholesterol in both sexes in a 6-month feeding study in dogs at the LOAEL of 4.77 mg/kg/day.

The FQPA safety factor to account for the enhanced sensitivity of infants and children be reduced to 3X based on increased incidence in skeletal variations observed in the developmental toxicity study in rabbits. This determination is based on the following: the toxicity database is adequate; the development toxicity studies in the rat and rabbit are acceptable as an multi-generation study; a developmental neurotoxic study is not required because there is no indication of increased susceptibility in young rats to norflurazon exposure; and there are currently no residential uses for norflurazon. The FQPA safety factor is applicable to only females 13-50 population subgroup for acute dietary risk assessment.

The acute and chronic dietary exposure analyses are based on the Dietary Exposure Evaluation Model (DEEM^{TM}.) The acute dietary exposure estimates used the entire distribution of single day food consumption. The chronic dietary exposure estimates the three day average consumption for each population subgroup. The DEEM^{TM} analysis was conducted using consumption data from the USDA 1989-92 Continuing Surveys for Food Intake by Individuals (CSFII).

The acute dietary (food) assessment for norflurazon is a Tier 1 analysis at the 95th percentile, and the tolerance levels residues were assumed (default processing factors) and 100% crop treated for all registered and proposed commodities. The acute dietary exposure estimates for females 13-50 years old accounted for 10% of the aPAD. The chronic dietary (food) exposure assumed tolerance level residues for all registered and proposed commodities. Percent crop treated was maintained at 100% for all proposed commodities. The chronic dietary food exposure estimates for the most highly exposed subpopulation were children 1-6 years old at 11% of the cPAD.

Dietary (Food) Risk Assessments for Norflurazon

The acute dietary (food) assessment for norflurazon is a Tier 1 analysis at the 95th percentile, and the tolerance level residues were assumed (default processing factors) and 100% crop treated for all registered and proposed commodities. The acute dietary exposure estimates for females 13-50 years old accounted for 10% of the aPAD. The chronic dietary (food) exposure assumed tolerance level residues for all registered and proposed commodities. Percent crop treated was maintained at 100% for all proposed commodities. The chronic dietary food exposure estimates for the most highly exposed subpopulation were children 1-6 years old at 11% of the cPAD.

Table 2: Summary of Norflurazon Acute DEEM™ Analysis

subgroups	exposure[1] (mg/kg/day)	% aPAD[2]
Females (13-50 years old)	0.003424	10

[1] 95th percentile
[2] aPAD = 0.03 mg/kg/day

Table 3: Summary of Norflurazon Chronic DEEM™ Analysis

subgroups	exposure (mg/kg/day)	% cPAD[1]
U.S. pop - all seasons	0.000623	4
All Infants (<1 year old)	0.000851	6
Children (1-6 years old)	0.001635	11
Children (7-12 years old)	0.000981	6
Females (13-50 years old)	0.000450	3
Males (13-19 years old)	0.000612	4
Males (20+ years old)	0.000450	3
Seniors (55+ years old)	0.000448	3

[1] cPAD = 0.015 mg/kg/day

Drinking Water Dietary Risk

Drinking water exposure to pesticides can occur through surface and/or ground water contamination. The Agency considers acute (one day) and chronic (lifetime) drinking water risks and uses either modeling or actual monitoring data, if available, to estimate these risks. Modeling is carried out in tiers of further refinement, and is designed to provide a high end estimate of exposure.

Norflurazon is resistant to abiotic hydrolysis and has a relatively low volatilization potential. Norflurazon is relatively resistant to microbial degradation with aerobic and anaerobic half lives of 130 day (aerobic soil metabolism study), 6-8 months (aerobic aquatic metabolism study), and an 8 month (anaerobic aquatic metabolism study). The primary microbial degradate is desmethyl norflurazon. The relatively low soil/water partitioning of norflurazon indicates that norflurazon can leach to ground water and runoff will generally be via dissolution rather than absorption to eroding soil. The drinking water residues of concern are norflurazon and desmethyl norflurazon.

Norflurazon has been detected in ground water in Florida and North Carolina. According to the 1995 EFGWB Science Chapter, parent norflurazon was detected in groundwater Polk County, Florida at concentrations up to 64 ppb for both acute and chronic. In a monitoring study in North Carolina, norflurazon was detected in groundwater in concentrations ranging from 1.5 -

5.3 ppb. There have been reports of norflurazon detected in groundwater in non-target studies in several states. Although these non-target monitoring studies do not link pesticide application to the monitoring data, it is difficult to determine the accuracy of the results. Two new prospective groundwater (PGW) studies were conducted in Georgia and Florida to estimate environmental concentration (EEC) in groundwater for parent norflurazon and desmethyl norflurazon. PGW studies are targeted monitoring studies that link to known use areas and application rates in evaluating the potential for leaching to groundwater. The groundwater EEC for norflurazon is based on concentrations from the PGW studies of 29.9 ppb for norflurazon and 23.8 ppb for desmethyl norflurazon. The groundwater EECs are 53.7 ppb for acute exposure and 15 ppb for chronic exposure. These groundwater EECs are less than the Agency's Drinking Water Levels of Concern (DWLOC) for both acute and chronic dietary risk.

There is limited surface water monitoring information available from USGS studies, but the monitoring was not from targeted use areas and parent compound only was measured in some of the studies. Therefore, the available monitoring data is not sufficient for a drinking water assessment. EECs were calculated using Tier II modeling tools (PRZM-EXAMS/IR) for norflurazon and the Tier I modeling tool (FIRST) for desmethyl norflurazon. Total estimated residues were summed from the two models giving a peak value of 633 ppb for acute exposures and a one in ten year annual average concentration of 185 ppb for chronic exposures. The surface water EEC is less than the DWLOC for acute dietary risk. However, the surface water EEC for chronic dietary risk slightly exceeds the DWLOC for infants and children 1-12.

Even though the estimated concentrations slightly exceed the chronic DWLOC for some populations, the EPA concludes that these concentrations are an overestimate of the residues based on the combination of following four factors:

(1) The degradate was modeled using a Tier 1 tool because there was not enough data to refine the estimates with a higher tier assessment.

(2) The Tier 1 modeling was conducted with conservative degradation assumptions for desmethyl norflurazon. Data from studies conducted on parent norflurazon indicate that the degradate does not degrade rapidly, however, additional data on the degradate might lower the concentration estimates.

(3) The rate of 8 lb ai/A was considered. This is the maximum norflurazon rate and it is used in Florida citrus, so the modeling scenario is appropriate; however, the next lowest rate is significantly lower at 2.5 lb ai/A.

(4) The default PCA of 87% was used since norflurazon can be applied to a number of crops. While it is possible to use the 8 lb rate and it is also possible for 87% of a watershed to be treated with a herbicide, it is unlikely that 87% of the watershed would be treated at this rate.

Since these four conservative factors have a decisive effect on the estimated residues and changing any one of these factors would probably reduce the estimates to below the DWLOC, the EPA concludes that there is not a chronic drinking water concern from surface water.

Table 4: Acute and Chronic DWLOCs

Population Subgroup	PAD mg/kg/day	Dietary Exposure Estimate (mg/kg/day)	Allowable Drinking Water Exposure mg/kg/day	DWLOC[1](ppb)	EEC (ppb)	
					Surface Water	Ground Water
acute						
Females (13-50 years old)	0.03	0.003424	0.026576	797	633	53.7
chronic						
U.S. pop - all seasons	0.015	0.000623	0.014377	503	185	15
All Infants (<1 year old)	0.015	0.000851	0.014149	141	185	15
Children (1-6 years old)	0.015	0.001635	0.013365	134	185	15
Children (7-12 years old)	0.015	0.000981	0.014019	140	185	15
Females (13-50 years old)	0.015	0.000450	0.014550	436	185	15
Males (13-19 years old)	0.015	0.000612	0.014388	504	185	15
Males (20+ years old)	0.015	0.000450	0.014550	509	185	15
Seniors (55+ years old)	0.015	0.000448	0.014552	509	185	15

[1] $$\text{DWLOC} = \frac{(\text{PAD (mg / kg / day)} - \text{ dietary exposure (mg / kg / day)})(\text{body weight (kg)})}{\text{water consumption (liter / day)}} * 1000\mu\text{g / mg}$$

Non-dietary (Residential/Public) Risks

Norflurazon is not registered for home use. Thus, there is no residential exposure to assess nor aggregate with dietary exposure.

Occupational and Ecological Risk

Because norflurazon is under review for tolerance reassessment only, no occupational or ecological risk assessment was conducted for this TRED. Occupational and ecological risk management decisions were evaluated and risk management decisions were made as part of the 1996 Norflurazon RED. There are no changes to the 1996 RED decision based on submitted data.

Aggregate Risk

Aggregate risk looks at the combined risk from exposure through food, drinking water, and residential uses. Generally, all risks from these exposures must be less than 100% of the acute and chronic PADs. For norflurazon, the aggregate risks are limited to food and water exposure, because there are no residential uses.

To determine the maximum allowable contribution from water allowed in the diet, the Agency first looks at how much of the overall allowable risks is contributed by food and then determines a DWLOC to ascertain whether modeled or monitored concentration in drinking water exceed this level. Drinking water concentrations that are above the corresponding DWLOC are of concern to the Agency. To assess aggregate risk, the acute and chronic dietary (food) risk estimates are combined with the corresponding surface and ground water (drinking water) estimated concentrations. When the acute and chronic DWLOCs were compared with the estimated concentration of norflurazon in drinking water, the groundwater concentration for both acute and chronic were less than the DWLOCs. The surface water DWLOC for acute is not of concern. While the surface water EEC apparently slightly exceeds the chronic DWLOC for infant and children sub-populations, this apparent exceedance is not considered to be a concern based on conservative assumptions used in modeling the chronic EECs.

Tolerance Reassessment Summary

Tolerances for residues of norflurazon in or on food/feed commodities are established for the combined residues of norflurazon and its desmethyl metabolite in/on numerous commodities ranging from 0.05 ppm (asparagus and peanuts) to 5.50 ppm (peanut hay). This reassessment pertains to 58 tolerances and accounts for 63 tolerances in the tolerance reassessment count from August 1996 based on double counting of meat by-product tolerances. Acute and chronic dietary exposure analyses were conducted using DEEM™ and consumption data from the USDA 1989-92 CSFII. The acute dietary exposure estimates used the entire distribution of single food consumption. The acute analysis assumed tolerance level residues, default processing factors, and 100% crop treated for all registered and proposed commodities. The chronic dietary exposure estimates used the three day average consumption for each population subgroup. The chronic dietary exposure analysis assumed tolerance level residues for all registered and proposed commodities.

The following table summarizes EPA's tolerance reassessment decision:

Norflurazon Tolerances

Commodity	Current Tolerance (ppm)	Reassessed Tolerance (ppm)	Comment
Alfalfa, Forage	3.0	3.0	
Alfalfa, Hay	5.0	5.0	
Alfalfa, Seed	0.1	0.1	
Almonds, Hulls	1.0	1.0	
Almonds, Meat	0.1	0.1	
Apricots	0.1	0.1	
Apples	0.1	0.1	

Commodity	Current Tolerance (ppm)	Reassessed Tolerance (ppm)	Comment
Asparagus	0.05	0.05	
Avocados	0.20	0.20	
Blackberries	0.1	0.1	
Blueberries	0.2	0.2	
Cattle, Fat	0.1	0.1	
Cattle, Liver	0.25	0.50	Increase based on feed item tolerance petition which has been withdrawn
Cattle, Meat	0.1	0.1	
Cattle, MBYP (Exc Liver)	0.1	0.1	
Cherries	0.1	0.1	
Citrus Fruits	0.2	0.2	
Citrus, Molasses	1.0	1.0	
Citrus, Pulp, Dried	0.4	0.4	
Cotton, Seed	0.1	0.1	
Cranberries	0.1	0.1	
Filberts	0.1	0.1	
Goats, Fat	0.1	0.1	
Goats, Liver	0.25	0.50	Increase based on feed item tolerance petition which has been withdrawn
Goats, Meat	0.1	0.1	
Goats, MBYP (Exc. Liver)	0.1	0.1	
Grapes	0.1	0.1	
Hogs, Fat	0.1	0.1	
Hogs, Liver	0.25	0.50	Increase based on feed item tolerance petition which has been withdrawn
Hogs, MBYP (Exc Liver)	0.1	0.1	
Hogs, Meat	0.1	0.1	
Hops, Dried	3.0	3.0	
Hops, Green	1.0	1.0	
Horses, Fat	0.1	0.1	
Horses, Liver	0.25	0.50	Increase based on feed item tolerance petition which has been withdrawn

Commodity	Current Tolerance (ppm)	Reassessed Tolerance (ppm)	Comment
Horses, MBYP (Exc. Liver)	0.1	0.1	
Horses, Meat	0.1	0.1	
Milk	0.1	0.1	
Nectarines	0.1	0.1	
Peaches	0.1	0.1	
Peanuts	0.05	0.05	
Peanuts, Hay	5.50	5.50	
Peanuts, Vines	1.5	1.5	
Pears	0.1	0.1	
Pecans	0.1	0.1	
Plums (Fresh Prunes)	0.1	0.1	
Poultry, Fat	0.1	0.1	
Poultry, MBYP	0.1	0.1	
Poultry, Meat	0.1	0.1	
Raspberries	0.2	0.2	
Sheep, Fat	0.1	0.1	
Sheep, Liver	0.25	0.50	Increase based on feed item tolerance petition which has been withdrawn
Sheep, MBYP (Exc. Liver)	0.1	0.1	
Sheep, Meat	0.1	0.1	
Soybeans	0.1	0.1	
Soybeans, Forage	1.0	1.0	
Soybeans, Hay	1.0	1.0	
Walnuts	0.1	0.1	

Summary of Pending Data

No additional data are being called in based on this tolerance reassessment.