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

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

May 31, 2002

CERTIFIED MAIL

Ronald Landis, Ph.D.
Landis International
3185 Madison Highway
PO Box 5126
Valdosta, GA 31603-5126

Dear Mr. Landis:

This is the Environmental Protection Agency's (hereafter referred to as EPA or the Agency) "Report of the Food Quality Protection Act (FQPA) Tolerance Reassessment Progress and Risk Management Decision (TRED) for Linuron", which was approved on May 31, 2002. A Notice of Availability of this tolerance reassessment decision will be published in the *Federal Register* (FR) shortly.

The Federal Food, Drug and Cosmetic Act (FFDCA), as amended by FQPA, requires EPA to reassess all the tolerances for registered chemicals in effect on or before the date of the enactment of the FQPA, which was in August of 1996. 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. Once a safety finding has been made that aggregate risks are not of concern, the tolerances are considered reassessed. A Reregistration Eligibility Decision (RED) for linuron was completed in March, 1995, prior to FQPA enactment. Therefore, the tolerances need to be reassessed to meet the FQPA standard.

The Agency has evaluated the dietary risk associated with linuron and has determined that there is a reasonable certainty that no harm to any population subgroup will result from aggregate exposure to linuron when considering dietary exposure and all other non-occupational sources of pesticide exposure for which there is reliable information. However, for chronic drinking water risk from surface water, potential (average) Estimated Environmental Concentrations (EECs) of linuron (18 ppb) exceeds the chronic Drinking Water Level of Comparison (DWLOC) (6 ppb) for infants and children, the most sensitive population subgroups. The chronic EECs were estimated using modeling and exceed the DWLOC slightly. The EEC estimate is based on upper-end input parameters such as an assumption that 87% of a watershed would be treated with linuron. EECs predicted from this model are likely higher than would be found in drinking water from surface reservoirs because it is unlikely that 87% of a watershed would be treated with linuron. Nonetheless, additional data are being required that will further refine the chronic drinking water risk assessment. A *leaching/adsorption/desorption study* will provide data on the mobility of linuron and a *terrestrial field dissipation study* will provide information on what happens

to linuron under field conditions.

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 considering other substances is because of 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 review of linuron, because the Agency has not determined that there are any other chemical substances that have a mechanism of toxicity common with that of linuron. If EPA identifies other substances that share a common mechanism of toxicity with linuron, then a cumulative risk assessment will be conducted that includes linuron 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. Linuron will be reevaluated at that time and additional studies may be requested.

The Agency's human health findings for the pesticide linuron, were discussed in a closure conference call, and are summarized in the enclosed *Linuron Overview* and *Linuron Summary* of the risk assessments. The risk assessments and other documents pertaining to the linuron tolerance reassessment decision are available on the Internet at http://www.epa.gov/pesticides/reregistration/status.htm and are in the public docket for viewing.

The Agency has reassessed all 40 tolerances for linuron and can make a FQPA safety determination. In addition, three new tolerances are proposed for use on cotton gin by-products (9.0 ppm), celeriac (1.0 ppm), and rhubarb (0.5 ppm). The Agency has sufficient residue data for reassessing the tolerances for linuron and is requiring additional confirmatory data for celery, corn, sorghum, and wheat. Anticipated residues for all commodities were calculated from field trial data and subsequently utilized to estimate the dietary exposure to linuron. For commodities that require additional residue data, the *Current Tolerance* value was used in the acute and chronic dietary risk assessments and this is the value that will continue to be used for enforcement purposes until the additional confirmatory data are reviewed. Acute and chronic dietary risks from exposure do not exceed the Agency's level of concern. Final tolerances are being proposed as part of this Tolerance Reassessment Decision. Tolerances may be revised once the confirmatory field trial data have been submitted to and reviewed by the Agency.

Table 1. Tolerance Reassessment Summary for Linuron.

Commodity	Current Tolerance (ppm)[1]	Reassessed Tolerance Level (ppm)	Comment/*Correct Commodity Definition*
Tolerances listed under 40 CFR §180.184(a):			
Asparagus	7.0	7.0	
Carrots	1.0	1.0	*[Carrot]*
Cattle, fat	1.0	0.2	

Commodity	Current Tolerance (ppm)[1]	Reassessed Tolerance Level (ppm)	Comment/*Correct Commodity Definition*
Cattle, mbyp	1.0	0.1	*[Cattle, meat byproducts, except kidney and liver]*
Cattle, meat	1.0	0.1	
Celery	0.5	0.5 / (TBD[4)]	The available data support use east of the Rocky Mountains; additional data are required to support use on celery west of the Rocky Mountains.
Corn, field, fodder	1.0	6.0	*[Corn, field, stover]*
Corn, field, forage	1.0	1.0	
Corn, fresh (inc. sweet K+CWHR)	0.25	0.25 / (TBD[4)]	Additional crop field trial data are required. *[Corn, sweet (K+CWHR)]*
Corn, grain (inc. popcorn)	0.25	0.1	Popcorn grain tolerance should be deleted since there are no registered uses. [*Corn, field, grain*]
Corn, sweet, fodder	1.0	1.0 / (TBD[4)]	Additional crop field trial data are required. *[Corn, sweet, stover]*
Corn, sweet, forage	1.0	1.0 / (TBD[4])	Additional crop field trial data are required.
Cottonseed	0.25	Reassign	This tolerance should be reclassified under 180.184(c) because use of linuron on cotton is restricted to east of the Rocky Mountains.
Goats, fat	1.0	0.2	*[Goat, fat]*
Goats, mbyp	1.0	0.1	*[Goat, meat byproducts, except kidney and liver]*
Goats, meat	1.0	0.1	*[Goat, meat]*
Hogs, fat	1.0	0.05	*[Hog, fat]*
Hogs, mbyp	1.0	0.1	*[Hog, meat byproducts]*
Hogs, meat	1.0	0.05	*[Hog, meat]*
Horses, fat	1.0	0.2	*[Horse, fat]*

Commodity	Current Tolerance (ppm)[1]	Reassessed Tolerance Level (ppm)	Comment/*Correct Commodity Definition*
Horses, mbyp	1.0	0.1	*[Horse, meat byproducts, except kidney and liver]*
Horses, meat	1.0	0.1	*[Horse, meat]*
Parsnips (with tops)	0.5	0.05	*[Parsnip, root]*
Parsnips (without tops)	0.5	0.05	*[Parsnip, root]*
Potatoes	1.0	Reassign	This tolerance should be reclassified under 180.184(c) as use of linuron on potatoes is restricted to east of the Rocky Mountains.
Sheep, fat	1.0	0.2	
Sheep, mbyp	1.0	0.1	*[Sheep, meat byproducts, except kidney and liver]*
Sheep, meat	1.0	0.1	
Sorghum, fodder	1.0	1.0 / (TBD[4)]	Additional crop field trial data are required. *[Sorghum, stover]*
Sorghum, forage	1.0	1.0 / (TBD[4)]	Additional crop field trial data are required.
Sorghum, grain (milo)	0.25	0.25	*[Sorghum, grain]*
Soybeans (dry)	1.0	1.0	*[Soybean, seed]*
Soybeans (succulent)	1.0	1.0	*[Soybean, seed]*
Soybean, forage	1.0	Revoke	These tolerances should be revoked, provided all pertinent labels are amended to include the following feeding restriction on the product labels: "The feeding of treated forage or hay to livestock is prohibited.
Soybean, hay	1.0	Revoke	

Commodity	Current Tolerance (ppm)[1]	Reassessed Tolerance Level (ppm)	Comment/*Correct Commodity Definition*
Wheat, forage	0.5	Reassign	These tolerances should be reclassified under 180.184(c), as use of linuron on wheat is restricted to ID, OR, and WA.
Wheat, grain	0.25	Reassign	
Wheat, hay	0.5	Reassign	
Wheat, straw	0.5	Reassign	
Tolerances listed under 40 CFR §180.184(c):			
Parsley	0.25	0.25	
Tolerances established under 40 CFR §180.184(a):			
Cattle, kidney	Not applicable	2.0	
Cattle, liver	Not applicable	2.0	
Celeraic	Not applicable	1.0	
Goat, kidney	Not applicable	2.0	
Goat, liver	Not applicable	2.0	
Horse, kidney	Not applicable	2.0	
Horse, liver	Not applicable	2.0	
Milk	Not applicable	0.05	
Rhubarb	Not applicable	0.5	
Sheep, kidney	Not applicable	2.0	
Sheep, liver	Not applicable	2.0	
Tolerances established under 40 CFR §180.184(c):			
Cotton, gin byproducts	Not applicable	9.0	Additional field trial data and/or information is required.
Cottonseed	0.25	0.05	This tolerance should be reclassified under 180.184(c) because use of linuron on cotton is restricted to east of the Rocky Mountains. *[Cotton, undelinted seed]*
Potatoes	1.0	0.2	This tolerance should be reclassified under 180.184(c) because use of linuron on potatoes is restricted to east of the Rocky Mountains. *[Potato]*

Commodity	Current Tolerance (ppm)[1]	Reassessed Tolerance Level (ppm)	Comment/*Correct Commodity Definition*
Wheat, forage	0.5	0.5 / (TBD[4)]	Crop field trial data are required. This tolerance should be reclassified under 180.184(c), because use of linuron on wheat is restricted to ID, OR, and WA.
Wheat, grain	0.25	0.05	This tolerance should be reclassified under 180.184(c), because use of linuron on wheat is restricted to ID, OR, and WA.
Wheat, hay	0.5	0.5 / (TBD[4)]	Crop field trial data are required. This tolerance should be reclassified under 180.184(c), because use of linuron on wheat is restricted to ID, OR, and WA.
Wheat, straw	0.5	2.0	The registrants may wish to generate additional crop field trial data at 1x instead of proposing an increased tolerance. This tolerance should be reclassified under 180.184(c), because use of linuron on wheat is restricted to ID, OR, and WA.

1 Expressed in terms of linuron *per se*.

2 Refer to sections on *Magnitude of the Residue in Crop Plants, Magnitude of the Residue in Processed Food/Feed*, and *Magnitude of the Residue in Meat, Milk, Poultry, and Eggs* for detailed discussion of residues in plant and animal commodities.

3 Expected residues at a 1x feeding level.

4 These commodities were included in the dietary risk assessment using the *Current Tolerance* level. Additional confirmatory field trial residue data are required; therefore, the final tolerance may be revised.

No maximum residue limits (MRLs) for linuron have been established by Codex for any agricultural commodity. In addition, no Canadian nor Mexican MRLs have been established for linuron. Therefore, no compatibility questions exist with respect to U.S. tolerances.

Note that you will be sent a Section 3(c)(2)(B) Data-Call-In (DCI) letter under the Federal Insecticide, Fungicide, Rodenticide Act (FIFRA) in a separate mailing. If you have questions on this document, please contact the Chemical Review Manager, Dirk V. Helder, at (703) 305-4610.

Sincerely,

Lois A. Rossi, Director
Special Review and
Reregistration Division

Enclosures: "*Linuron Overview*" and "*Linuron Summary*"