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

February 21, 1995

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Linuron. (035506) Addendum to RED Residue Chemistry Chapter.
Reregistration Case No. 0047
DP Barcode: D212230; CBRS No. 15113; No MRID No.

FROM: Susan V. Hummel, Acting Section Head
Special Review Section II
Chemistry Branch II--Reregistration Support
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Susan V. Hummel

THRU: Francis Suhre, Acting Branch Chief
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Francis B. Suhre

TO: Karen Jones, PM Team 73
Reregistration Branch
Special Review and Reregistration Division (7508W)

In the final proofreading of the Agency Linuron RED, it came to our attention that there were several corrections which needed to be made in the text regarding residue chemistry data and tolerance reassessment, and the table on tolerance reassessment, because numerous reviews have been completed since the completion of the RED Residue Chemistry Chapter. These changes have been made in both the text and the corresponding section of the tables. The MRID Numbers of the additional data have been added to table C, along with references to the completed reviews. The corrected text and tables B and C are included in this document, and you will receive an electronic copy of this document.

Tolerance levels for corn, field, grain and wheat, grain have been reassessed at 0.1 ppm. The tolerance level for wheat, straw has been reassessed at 2 ppm, consistent with the proposal in PP#4F4293. However, no data were submitted for wheat, forage. These data are still needed, as a feeding restriction for wheat forage is not practical. The tolerance level for carrots has been reassessed at 1 ppm, with a requirement to add a 14 day PHI. The tolerance for cottonseed should be revoked if no registrant is supporting the use.

We note that the reassessed tolerances for livestock commodities have been changed since our last proofreading of the RED. Current linuron tolerances for all livestock commodities are 1 ppm. A petition (PP#0F3832) was submitted to lower tolerances in potatoes to 0.2 ppm, and livestock commodities except liver and kidney to 0.1 ppm. Tolerances for liver and kidney would remain at 1 ppm. We recommended against the proposed tolerances, due to inadequate data on livestock feed



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items and poultry metabolism (PP#OF3832, F. Griffith, 6/11/90, DEB Nos. 6210, 6211, 6212, 6213, 6214, 6215). Although additional data are still required for some livestock commodities (sorghum forage and fodder, sweet corn fodder, and wheat forage, we can reassess the livestock tolerances based on the available data.

The Residue Chemistry Chapter for the Linuron RED indicates that the livestock dietary burden for linuron is about 3.1 ppm. In a linuron cattle feeding study (MRID 00018210, 1954?), two Guernsey cows were fed linuron at 50.0 ppm for 30 days. Linuron residues of concern were up to 13 ppm in kidney, 13 ppm in liver, 0.48 ppm in muscle, 1.10 ppm in subcutaneous fat, and 0.37 ppm in milk. Based on this study, maximum linuron residues in livestock commodities of cattle, goats, horses, hogs, and sheep would be expected to be 0.81 ppm in liver and kidney, 0.03 ppm in muscle, 0.07 ppm in fat, and 0.02 ppm in milk. Thus, the proposed linuron tolerances of 0.1 ppm in meat, fat, and meat byproducts (except liver and kidney) are supported. Linuron tolerances for liver and kidney should remain at 1.0 ppm.

Recent linuron reviews have not made any conclusions regarding the need for linuron tolerances in poultry commodities. The Linuron Registration Standard Residue Chemistry Chapter includes a poultry feeding study, where poultry fed 1 ppm for 28 days had no detectable residues in liver, skin, muscle, or fat; and poultry fed 0.7 ppm linuron for 21 days showed no detectable residues in tissues or eggs (MRID 00018383, 1963). More recently, a linuron poultry metabolism study conducted at the 10 ppm (20 x) feeding level for 5 days resulted in detectable residues in poultry tissues; however, when the rate is adjusted to the 1x feeding level, non-detectable residues would result. No linuron tolerances for poultry commodities are needed.

Attachment: Corrected Exerpt from the Linuron RED Residue Chemistry Chapter

cc:RF, Circu, S. Hummel, Linuron RSF, SF
RDI:FBS:02/21/95
7509C:CBRS:SVH:svh:CM#2:Rm804:02/21/95

Corrected Excerpt from the Linuron RED Residue Chemistry Chapter

A tabular summary of the residue chemistry science assessments for reregistration of linuron is presented in Table C. The conclusions regarding the reregistration eligibility of linuron on the crops listed in Table C are based on the use patterns registered by the basic producers, E.I. du Pont de Nemours and Company, Griffin Corporation, and Drexel Chemical Company. When end-use product DCIs are developed (e.g., at the issuance of the RED), RD should require that all end-use product labels (e.g., MAI labels, SLNs, and products subject to the generic data exemption) be amended such that they are consistent with the basic producer labels. An Agency memorandum (CBRS Nos. 6663 and 6994, 3/26/91, R. Perfetti) required label amendments for products with uses on carrots, celery, cotton, and potatoes; we note that all registrants have modified applicable labels appropriately.

GLN 171-4 (a): Plant Metabolism: The qualitative nature of the residue in plants is adequately understood (D. McNeilly, 11/17/93). Metabolism studies with corn, soybeans, and potatoes indicate that linuron is absorbed from the soil and translocated (i.e., systemic). The metabolic pathway involves demethylation to 3-(3,4-dichlorophenyl)-1-methoxyurea which is further metabolized to 3,4-dichloroaniline; metabolism may also occur through demethoxylation of linuron. The terminal residues of concern are the parent and its metabolites which are convertible to 3,4-dichloroaniline. (MRIDs 00018173, 00018176, 00027624, 00164195, 00164196, 40084801, 41716101, 41716102, 41938101, 42542101, and 42548401).

GLN 171-4 (b): Animal Metabolism: The qualitative nature of the residue in ruminants and poultry is adequately understood (D. McNeilly, 11/17/93). An acceptable metabolism study with goats indicates that linuron is rapidly metabolized by demethylation, demethoxylation, and hydroxylation and is primarily eliminated by excretion. The metabolism of linuron in poultry has been found to be consistent with the goat study. The terminal residues of concern are the parent and its metabolites which are convertible to 3,4-dichloroaniline. (MRIDs 00029932 and 42635401, and 43245101).

GLN 171-4 (c/d): Residue Analytical Methods - Plants/Animals: Adequate enforcement methods are available for the determination of linuron in plant and animal commodities. The Pesticide Analytical Manual (PAM) Vol. II lists a colorimetric method (Method I, Bleidner et. al.) and a paper chromatographic method (Method II). Residues of diuron may interfere in Method I. A modified version of Method I (H. L. Pease, *Journal of Agric. and Food Chem.*, 1962, Vol. 10, p. 279), which includes a cellulose column step to separate linuron from diuron, is currently the preferred method for the enforcement of tolerances. Both these methods determine linuron and all metabolites hydrolyzable to 3,4-dichloroaniline and have limits of detection of 0.05 ppm. A GLC/ECD method for linuron residues in/on asparagus from the CA Department of Food and Agriculture has been validated by the Agency and sent to FDA to be published in PAM Vol. II as Method III. This method determines residues of linuron *per se* and the limit of detection is 0.05 ppm. We note however that this method is inadequate for tolerance enforcement since it does not determine all the residues of concern. In addition, this method uses benzene as the extraction solvent. (MRIDs 00018087, 00018089, 00018127, and 00018176).

The FDA Pestrak Database (PAM Vol. I) contains data concerning the applicability of multiresidue methods D and E (fatty and nonfatty foods) for recovery of linuron and its metabolites 3-(3,4-dichlorophenyl)-1-methoxyurea, 3-(3,4-dichlorophenyl)-1-methylurea, 3,4-dichlorophenyl urea and 3,4-dichloroaniline. Linuron is partially recovered using Multiresidue Method E (fatty and nonfatty foods); recovery using Method D is variable. Linuron metabolites 3-(3,4-dichlorophenyl)-1-

methoxyurea, 3-(3,4-dichlorophenyl)-1-methylurea, and 3,4-dichlorophenyl urea are not recovered using Method E (fatty and nonfatty foods); 3-(3,4-dichlorophenyl)-1-methylurea is recovered using Method D but 3-(3,4-dichlorophenyl)-1-methoxyurea is not likely to be recovered using this method. Linuron metabolite 3,4-dichloroaniline is not recovered using Method E (nonfatty foods) and has variable recovery using Method D.

GLN 171-4 (e): Storage Stability: Residues of linuron in potatoes have been shown to be stable for a period of at least 12 months. Residues of linuron in/on soybeans, sugar beet tops, wheat, carrots, and asparagus have been shown to be stable for up to approximately two years of storage at -20 C. CBRS will translate this data in accordance with the Storage Stability Guidance Document (1/93) concerning translation of crop stability data to crop groupings. CBRS concludes that linuron is stable in oilseeds/nuts, leafy vegetables, and root vegetables for a period of at least two years. The conclusion regarding this latter crop grouping assumes that the registrant submits acceptable 18 month storage interval data for the potato and processed potato commodity storage stability study currently in progress.

~~Storage stability data for the following commodities remain outstanding: carrots (raw and cooked; 19 months); field corn processed commodities (12 months); potatoes, and cooked and processed potato commodities (20 months); sorghum and sorghum processed commodities (12 months); and soybean processed commodities (6 months). Additional storage stability data are required to support outstanding field residue and processing studies.~~

Linuron has been shown to be stable in corn grain, corn oil, sorghum grain, and sorghum starch for a period of at least 3 months (D. McNeilly, CBRS No. 13160; 3/30/94). The registrant has indicated that additional storage data for a 12-month interval for these commodities will be submitted as supplemental information. If acceptable 12-month storage stability data are provided to CBRS, CBRS will conclude that linuron is stable on non-oily grain crops for a period of at least one year.

CBRS concludes that additional storage stability data (beyond those already promised to CBRS) will not be necessary provided that storage intervals do not exceed one year for non-oily grains and two years for oilseeds/nuts, leafy vegetables, and root crops: the registrant has provided (or will provide) sufficient data to indicate that significant linuron residue declines are not expected to occur in oilseeds/nuts, leafy vegetables, root vegetables, and non-oily grains over short to intermediate storage intervals. Since residues have been shown to be stable in several matrices, the additional required storage stability data are considered confirmatory of several different crop groupings, no additional storage data other than studies currently in progress discussed above will be required, provided that linuron is not registered for use on fruits, fruiting vegetables, or citrus.

(MRIDs 00159802, 41716103, 42836701, and 42836702, 42913301, 42974401, 43040001, 43215901, 43215902, 43256202, 43256203, 43288301, 43288302).

GLN 171-4 (k): Magnitude of the Residue in Plants: All data for magnitude of the residue in carrots; corn, field, grain; corn, field, forage and fodder; parsley; parsnips; potatoes; and sorghum grain; soybeans; and wheat, grain and straw have been evaluated and deemed adequate to reassess tolerances for these commodities. (MRIDs 00018067, 00018076, 00018087, 00018089, 00018148, 00018171, 00018172, 00018175, 00018206, 00018375, 00018382, 00018443, 00018450, 00027635,

00163267, 40210901, 40537601, 41189801, 41377601, 41452601, 41452701, 41501501, 41503401, 41569901, 42605901, 42948501, 43104401)

Field residue data remain outstanding for the following crops: asparagus; ~~carrots; corn, field, grain; corn, field, forage and fodder; corn, sweet (K + CWHR); corn, sweet, forage; sorghum forage and fodder; soybeans, forage and hay; wheat, grain; and wheat, forage and straw.~~ Data are also needed for corn, field, aspirated grain fractions

Sufficient data to reassess tolerances for these commodities are not available at this time. Although sufficient field trial data are not available to reassess tolerances for all crops, sufficient data are available to do a reliable exposure assessment.

Two additional field residue studies on corn (1990; MRID 41510501) and soybeans (1990; MRID 41591801) have been submitted. However, data from these submissions were not evaluated because they were generated by Craven Laboratories. Adequate replacement data are currently being prepared for submission. ~~have been submitted for corn, field, grain, forage, and fodder, and for soybeans. However, no data were submitted for soybeans, forage and hay.~~

GLN 171-4 (i): Processed Food/Feed: All data for magnitude of the residue in processed food/feed have been evaluated and deemed adequate except that a full processing study is required for cottonseed (R. Perfetti, 3/26/91) and additional data are required to upgrade an existing potato processing study (S. Knizner, 9/2/92). DuPont in a letter to the Agency (Marie Chubb, 7/23/91) stated that they are canceling linuron use on cotton. Apparently no other registrants have come forward to support this use, therefore, CBRS recommends that the registered use on cotton be canceled, and the tolerance revoked. In this case, the cottonseed processing study will no longer be required.

Outstanding potato processing data are considered confirmatory; sufficient data are available to reassess tolerances and estimate dietary exposure for potato processed products. Food additive tolerances must be proposed for potato chips and granules, and feed additive tolerances must be proposed for wet and dry peel waste.

NOTE: Linuron is assessed as a c-nonquantifiable oncogen, therefore Delaney issues are involved. (MRIDs 00018206, 40049201, 41241202, 42397201, 42462901, 42542102, and 42560001).

GLN 171-4 (j): Magnitude of the Residue in Meat, Milk, Poultry and Eggs: All data for magnitude of the residues in meat, milk, poultry, and eggs have been evaluated and deemed adequate. No tolerances are required for poultry and eggs. (MRIDs 00018209, 00018210, 00018375, 00018383, 00018450, 00018775, and 00029932).

Recently the Agency received interim data from DuPont indicating that residues levels of linuron in or on corn fodder exceeded the 1 ppm tolerance. Preliminary data from field trials on corn indicate a tolerance of 6 ppm will be required to cover residues resulting from current registered uses. These data were submitted to the Agency under 6(A) (2) of FIFRA.

Since corn fodder is a major feed item for ruminants throughout the U.S. a revision to the previously estimated dietary burden to ruminants is required. The Residue Chemistry Chapter (6/29/82) to the

Linuron Registration Standard previously estimated a "maximum plausible dietary load of 1.4 ppm." This estimate utilized the established tolerance of 1.0 ppm in or on corn fodder. However, assuming residues are present at levels ca 6 ppm, the level at which tolerances may be required considering the currently available 6 (a)(2) data, a hypothetical diet based on feeding 50% corn grain and 50% corn fodder would result in a dietary burden of ca. 3.1 ppm.

Based on available ruminant feeding studies CBRS concludes that established tolerances for meat and milk are adequate to cover the increased dietary burden of 3.1 ppm. It should be noted however that the estimated residue level in ruminant liver (0.81 ppm) and kidney (0.81 ppm) are approaching the established tolerances of 1.0 ppm. Should the currently estimated ruminant dietary burden of 3.1 ppm be increased, established linuron tolerances for ruminant liver and kidney will need to be reassessed.

A final determination concerning the adequacy of meat and milk tolerances cannot be made until all the replacement corn data are submitted.

GLNs 165-1 and 165-2: Confined/Field Rotational Crops: All data for nature of the residue in confined rotational crops have been evaluated and deemed adequate. The requirement for field rotational crop studies has been waived. (MRIDs 40104101 and 40730101). The following are rotational crop restrictions:

If initial seeding fails to produce a stand, crops registered for the rate of "Lorox" that has been applied may be planted into the treated area.

Unless otherwise directed, any crop may be planted after 4 months except for cereals where only barley, oats, rye, and wheat may be planted.

GLN 171-5: Reduction of Residues: All data for reduction of residues have been evaluated and deemed adequate except that additional information is required to upgrade existing potato and carrot cooking studies. (MRIDs 41241201, 42379901, 42397201, 42462901, and 42462902).

The asparagus cooking study shows washing with water reduces residues by 40%. Boiling removes an additional 25% of the residues, while steaming had little or no effect on reducing residue levels in or on asparagus (Ref: D. McNeilly, 3/18/93).

A carrot cooking study was reviewed (C. Olinger, 10/31/89) and found to be unacceptable due to residues below the limit of quantitation. However, the study does indicate that cooking in boiling water does reduce overall residues.

The potato cooking study shows that linuron residues concentrate in or on oven baked potatoes (1.5X) and microwave baked potatoes (1.6X), but are reduced in or on boiled potatoes (0.48X) (S. Knizner, 9/2/92).

Table C. Residue chemistry science assessments for reregistration of linuron.

GLN: Data Requirements	Tolerance, ppm [40 CFR]	Must Additional Data Be Submitted?	References ¹
171-4 (a): Plant Metabolism		No	00018173, 00027624, 00018176, 00164195 00164196, 40084801 ² 41716101 ³ , 41716102 ³ 41938101 ⁴ , 42542101 ⁵ 42548401 ⁶
171-4 (b): Animal Metabolism		No	00029932, 42635401 ⁷ 43245101 ⁸
171-4 (c/d): Residue Analytical Methods		No	00018087, 00018089, 00018127, 00018176
171-4 (e): Storage Stability		Yes ⁹	00159802, ¹⁰ 41716103, ³ 42836701 ¹¹ , 42836702 ¹¹ 42913301 ¹² , 42974401 ¹² 43040001 ¹² , 43215901 ¹³ 43215902 ¹³ , 43256202 ¹³ 43256203 ¹³ , 43288301 ¹⁴ 43288302 ¹⁴
171-4 (k): Magnitude of the Residue in Plants			
<u>Root and Tuber Vegetable Group</u>			
- Carrots	1 [180.184(a)]	Yes ¹⁵	00018172, 00027635, 00163267, ¹⁶ 40210901, ¹⁷ 40537601, 41503401 ¹⁸
- Parsnips	0.5 [180.184(a)]	No ¹⁹	00018171
- Parsnips, tops	0.5 [180.184(a)]	No ²⁰	
- Potatoes	1 [180.184(a)]	No	00027635, 00163267, ¹⁶ 40210901, ¹⁷ 41452701 ¹⁸
<u>Leafy Vegetables Group</u>			
- Celery	0.5 [180.184(a)]	No ²¹	00018443, 40537601, 41501501 ¹⁸
- Parsley	0.25 [180.184(b)]	No	41189801 ²²
<u>Legume Vegetables Group</u>			
- Soybeans	1 [180.184(a)]	No ²³	00018076, 00018206, 00027635, 00163267, ¹⁶ 40210901 ¹⁷ , 43110401 ²⁴
<u>Foliage of Legume Vegetables Group</u>			
- Soybean forage and hay	1 [180.184(a)]	Yes ²⁵	00018076, 00018206, 00027635

Table C (continued).

GLN: Data Requirements	Tolerance, ppm [40 CFR]	Must Additional Data Be Submitted?	References ¹
<u>Cereal Grains Group</u>			
- Barley, grain	0.25 [180.184(a)]	No ²⁶	
- Corn, field, grain	0.25 [180.184(a)]	Yes ²⁷	00018171, 00018206, 00018375, 00018382, 00018450, 00163267, ¹⁶ 40210901, ¹⁷ 40537601, 42648501²⁸, 43044101²⁸
- Corn, pop, grain	0.25 [180.184(a)]	No ²⁹	
- Corn, sweet (K + CWHR)	0.25 [180.184(a)]	Yes ³⁰	00018171, 00018206, 00018375, 00018382, 00018450
- Sorghum, grain	0.25 [180.184(a)]	No	00018171, 00018148, 40537601, 41377601
- Wheat, grain	0.25 [180.184(a)]	No ³¹	00018171, 00018175, 40537601, 42605901 ³⁴
- Oats, grain	0.25 [180.184(a)]	No ³²	
- Rye, grain	0.25 [180.184(a)]	No ³³	
<u>Forage, Fodder, and Straw of Cereal Grains Group</u>			
- Barley, forage, hay and straw	1 [180.184(a)]	No ³⁵	
- Corn, field, forage and fodder	1 [180.184(a)]	Yes ³⁶	00018171, 00018206, 00018375, 00018382, 00018450, 00163267, ¹⁶ 40210901, ¹⁷ 40537601
- Corn, pop, forage and fodder	1 [180.184(a)]	No ²⁰	
- Corn, sweet, fodder	1 [180.184(a)]	No ³⁷	
- Corn, sweet, forage	1 [180.184(a)]	Yes ³⁸	00018171, 00018206, 00018375, 00018382, 00018450
- Oats, forage, hay and straw	1 [180.184(a)]	No ³⁹	
- Rye, forage, hay and straw	1 [180.184(a)]	No ⁴⁰	
- Sorghum forage and fodder	1 [180.184(a)]	Yes ⁴¹	00018171, 00018148, 40537601
- Wheat forage and straw	0.5 [180.184(a)]	Yes ⁴²	00018171, 40537601, 42605901 ³⁴
- Wheat, hay	0.5 [180.184(a)]	No ⁴³	
<u>Miscellaneous Commodities</u>			
- Asparagus	3 [180.184(a)]	Yes ⁴⁴	00018087, 00018089, 00163267, ¹⁶ 40210901, ¹⁷ 41452601 ¹⁸

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Table C (continued).

GLN: Data Requirements	Tolerance, ppm [40 CFR]	Must Additional Data Be Submitted?	References ¹
- Cotton, seed	0.25 [180.184(a)]	No ⁴⁵	00018067, 41569901 ¹⁸
171-4 (l): Magnitude of the Residue in Processed Food/Feed			
- Corn, field	--	No	42560001 ⁴⁶
- Cotton, seed	--	Yes ⁴⁷	
- Potatoes	--	Yes ⁴⁸	40049201, ⁴⁹ 42397201 ⁵⁰
- Sorghum, grain	--	No	42542102 ⁵
- Soybeans	--	No	00018206, 41241202, ⁵¹ 42462901 ⁵²
- Wheat, grain	--	No ⁵³	
171-4 (j): Magnitude of the Residue in Meat, Milk, Poultry, and Eggs			
- Cattle	1 (fat, meat, and meat byproducts) [180.184(a)]	No	00018209, 00018210, 00018375, 00018450, 00018775
- Goats	1 (fat, meat, and meat byproducts) [180.184(a)]		00029932
- Hogs	1 (fat, meat, and meat byproducts) [180.184(a)]		
- Horses	1 (fat, meat, and meat byproducts) [180.184(a)]		
- Sheep	1 (fat, meat, and meat byproducts) [180.184(a)]		
- Poultry and Eggs	--		00018383
171-4 (f): Magnitude of the Residue in Potable Water		N/A	
171-4 (g): Magnitude of the Residue in Fish		N/A	
171-4 (h): Magnitude of the Residue in Irrigated Crops		N/A	
171-4 (i): Magnitude of the Residue in Food Handling Establishments		N/A	
171-5: Reduction of Residues		Yes ⁵⁴	41241201, ^{51, 51} 42397201, ⁵⁰ 42379901, ⁵⁵ 42462901, ⁵² 42462902 ⁵²
165-1: Rotational Crops (Confined)		No	40104101, 40730101
165-2: Rotational Crops (Field)		No ⁵⁶	

Table C (continued).

1. Bolded reference(s) were reviewed in the Update of 6/20/90. Unbolded references were reviewed in the Residue Chemistry Science Chapter of the Registration Standard dated 6/30/82. All other references were reviewed as noted.
2. CBRS No. 2838, 12/24/87, L. Propst; review of corn metabolism data.
3. CBRS No. 7523, DP Barcode D160079, 4/25/91, R. Perfetti.
4. CBRS No. 8391, DP Barcode D167107, 5/21/92, P. Deschamp.
5. CBRS No. 11358, DP Barcode D187993, 11/18/93, D. McNeilly; review of potato metabolism data.
6. CBRS No. 11359, DP Barcode D187998, 11/18/93, D. McNeilly; review of soybean metabolism data.
7. CBRS No. 11361, DP Barcode D188002, 11/18/93, D. McNeilly; review of poultry metabolism data.
8. CB 13915, 7/27/94, D. Miller
9. **Additional storage stability data are required to support outstanding field residue and processing studies (see page 4). CBRS tentatively concludes that the registrant has submitted adequate storage stability data for the following crop groupings (i) oilseeds/nuts, leafy vegetables, and root vegetables to support a storage interval of two years; and (ii) non-oily grain crops to support a storage interval of at least one year, pending submission of an acceptable data from the ongoing 18 month potato study and 12 month corn grain/corn oil/sorghum grain/sorghum starch storage stability studies.**
CBRS recommends that any future crop field trial (magnitude of the residue) studies include the collection of concurrent storage stability data.
10. CBRS No. 1244, 8/12/85, J. Garbus.
11. CBRS No. 12553, DP Barcode D195090, 10/5/93, D. McNeilly.
12. CB 13160, 3/29/94, D. McNeilly.
13. CB 13789, 14366, 1/11/95, S. Hummel
14. CB 14229, 9/23/94, D. Miller.
15. **Griffin and Drexel must submit data reflecting application of the 4 lb/gal FIC formulation at the maximum registered rate (Reference 18). E.I. du Pont de Nemours Inc. must submit revised product labels, establishing a 14-day PHI is required for carrots.**
16. CBRS No. 1317, 10/29/86, J. Garbus.
17. CBRS No. 2333, 6/2/87, J. Garbus.
18. CBRS Nos. 6663 and 6994, 3/26/91, R. Perfetti. **Labels must prohibit use on potatoes west of the Rockies. All labels must specify a 14 day PHI for carrots.**

Table C (continued).

19. Data requirements pertaining to the use of a DF or FIC formulation on parsnips have been waived (4/25/90, E. Zager). Residue data for field trials conducted from 1986 to 1988 on asparagus, carrots, celery, corn, cotton, potatoes, sorghum, soybeans, and wheat indicate similar residue patterns regardless of formulation.
20. Parsnip tops are no longer considered as a separate raw agricultural commodity.
21. Registered use is only for East of the Rocky Mountains. End-Use labels should prohibit use of linuron West of the Rockies (R. Perfetti, 3/26/91).
22. CB No. 5658, 10/5/89, F. Griffith. Regional registration for all states east of the Mississippi river.
23. Craven data were submitted to support reregistration of linuron on soybeans. This data is being replaced (see R. Lascola, 9/9/91). Data reflecting postemergence application of the 50% DF or 4 lb/gal FIC formulation at the maximum registered rate have been submitted and are acceptable (see D. McNeilly, 3/16/94).
24. CB 13213, 3/16/94, D. McNeilly.
25. Restrictions against the feeding of treated soybean forage and hay exist on all pertinent product labels, however, these restrictions are no longer considered practical. Tolerances and supporting residue data are required. ~~data are required and the established tolerances for soybean forage and hay should be revoked.~~
26. There are no registered uses of linuron on barley. Applicable tolerances should be revoked.
27. Craven data were generated to support the reregistration of linuron on corn. These data are being replaced. Data reflecting a single postemergence application of the 50% DF formulation at the maximum registered rate remain outstanding. In addition, data pertaining to linuron residues of concern in grain dust must be submitted (Reference 46).
28. CB 12835, 12/15/93, D. McNeilly.
29. There are no registered uses of linuron on pop corn. Applicable tolerances for commodities of popcorn should be revoked.
30. No data have been submitted in response to the Update. Data reflecting a single postemergence application of the 50% DF formulation at the maximum registered rate remain outstanding.
31. CB 11362, D. McNeilly, 5/10/93.
32. There are no registered uses of linuron on oats. Applicable tolerances should be revoked.
33. There are no registered uses of linuron on rye. Applicable tolerances should be revoked.
34. CBRS No. 11362, DP Barcode D188028, 5/10/93, D. McNeilly.
35. There are no registered uses of linuron on barley. Applicable tolerances should be revoked.

Table C (continued).

36. ~~Craven data were generated to support the reregistration of linuron on corn. These data are being replaced. DuPont has recently submitted 6(a)(2) data (D. McNeilly, 12/15/93) from these replacement studies indicating residues will exceed the established tolerance. Data pertaining to residues in/on field corn forage and fodder following a single postemergence application of the 50% DF formulation at the maximum registered rate remain outstanding. CB 13161, D. McNeilly, 3/31/94.~~
37. No longer considered a raw agricultural commodity.
38. No data have been submitted in response to the Update. Data pertaining to residues in/on sweet corn forage following a single postemergence application of the 50% DF formulation at the maximum registered rate remain outstanding.
39. There are no registered uses on oats. Applicable tolerances should be revoked.
40. There are no registered uses on rye. Applicable tolerances should be revoked.
41. No data have been submitted in response to the Update. Data pertaining to residues in/on sorghum forage and fodder following a single postemergence application of the 50% DF formulation at the maximum registered rate remain outstanding.
42. At the request of the Agency DuPont, has submitted a petition (PP#4F4293) to amend the use on wheat and increase linuron tolerances on wheat straw. CB 13020, 13021, D. McNeilly, 3/9/94. ~~No data were submitted for wheat forage. These data are required. Restrictions against the feeding of wheat forage are not considered practical.~~
43. No longer considered a raw agricultural commodity.
44. Data reflecting application of the 4 lb/gal FIC formulation at the maximum registered rate remain outstanding. In addition, a higher tolerance for asparagus must be proposed (Reference 18).
45. A Federal Register Notice (3/4/92) was issued canceling use of products 352-270, 352-391, and 352-394 on cotton (DuPont products).
46. CBRS No. 11360, DP Barcode D188001, 7/13/93, D. McNeilly.
47. No data have been submitted in response to the Update. Data depicting residues in cotton meal, hulls, soapstock, and crude and refined oil remain outstanding. DuPont in a letter to the Agency stated that they are canceling linuron use on cotton (M. Chubb, 7/23/91). If these uses are canceled (i.e., other registrant also cancel use on cotton), additional data for cottonseed commodities will not be required.
48. Additional information pertaining to sample storage, the processing protocol, and limit of quantitation determination, as well as an explanation for low method recoveries from potato chips, are required to upgrade the submitted potato processing study (CBRS No. 10368, DP Barcode D181454, 9/2/92, S. Knizner).
49. CBRS No. 2279, 6/2/87, J. Garbus.
50. CBRS No. 10368, DP Barcode D181454, 9/2/92, S. Knizner.

Table C (continued).

51. CBRS No. 5858, 10/31/89, C. Olinger.
52. CBRS No. 10586, DP Barcode D182595, 3/18/93, D. McNeilly.
53. The requirement for a wheat processing study has been waived (CBRS No. 11063, DP Barcode D185892, 1/15/93, R. Perfetti).
54. Additional information on sample storage, the cooking protocol, and the determination of limits of quantitation is required to upgrade the potato cooking study (Reference 50).
Additional information on the determination of limits of quantitation and an adequate description of the cooking procedure are required to upgrade the carrot cooking study (Reference 55).
55. CBRS No. 10370, DP Barcode D181455, 9/8/92, S. Knizner.
56. The requirements for field rotational crop studies have been waived based on the results of the Confined Rotational Crop (GLDN 165-1) study.

TOLERANCE REASSESSMENT SUMMARY

Tolerances Listed Under 40 CFR §180.184(a)

The tolerances listed under 40 CFR §180.184(a) for residues of linuron in/on plant and animal commodities are expressed in terms of residues of linuron *per se*. The tolerance expression under 40 CFR §180.184(a) should be revised as follows: "Tolerances are established for the combined residues of the herbicide linuron (3-(3,4-dichlorophenyl)-1-methoxy-1-methylurea) and its metabolites convertible to 3,4-dichloroaniline, calculated as linuron, in or on the following raw agricultural commodities:". A summary of the reassessment of tolerances listed in 40 CFR §180.184(a) is presented in Table D.

Sufficient data are available to support the established tolerances for the following crops: ~~carrots;~~ celery; cottonseed; parsnips; potatoes; ~~and sorghum, grain, soybeans, and wheat, grain and straw.~~

Additional residue data are required if all registered uses of linuron are to be covered under established tolerances for: asparagus; ~~carrots;~~ corn, field, grain; corn, field, forage and fodder; corn, sweet (K + CWHR); corn, sweet, forage; sorghum forage and fodder; soybeans; ~~wheat, grain;~~ and wheat forage and ~~straw~~. In addition, ~~grain dust aspirated grain fraction~~ data remain outstanding for field corn.

A processing study remains outstanding for cottonseed, if registrants other than DuPont decide to support ~~this use on cotton.~~

Food additive tolerance proposals are required for "potatoes, granules" at 0.8 ppm and "potatoes, chips" at 0.6 ppm, and a feed additive tolerance proposal is required for "potatoes, waste from processing" at 10 ppm. However, Delaney issues may prevent the establishment of these tolerances.

The established tolerances for barley, oats, and rye, forage, grain, hay, and ~~straw, and corn, popcorn, forage and fodder~~ should be revoked since there are no registered uses of linuron on these commodities. In addition, the established tolerances for ~~sweet corn, sweet, fodder, parsnips tops, and wheat hay~~ should be revoked since these commodities are not listed in Table II as raw agricultural commodities of sweet corn, parsnips, and wheat, respectively. ~~The established tolerances for soybean forage and hay should be revoked since restrictions against the feeding of these commodities exist on all pertinent linuron product labels.~~

Tolerances have been proposed for lettuce at 0.1 ppm (PP#1E02486), and ginger and taro at 1 ppm (PP#3E2920). Tolerance revisions have been proposed for potatoes at 0.2 ppm; the meat, fat, and mby (except kidney and liver) of cattle, goats, hogs, horses, and sheep at 0.1 ppm; and the liver and kidney of cattle, goats, hogs, horses, and sheep at 1.0 ppm (PP#0F3832).

~~A~~ 6(a)(2) data submission indicates linuron residues in or on corn fodder will need to be raised to cover residues up to 5.5 ppm in corn fodder. The current tolerance is 1 ppm.

Tolerances Listed Under 40 CFR §180.184(b)

The tolerance listed under 40 CFR §180.184(b) is with regional restriction and is expressed in terms of residues of linuron *per se*. The tolerance expression under 40 CFR §180.184(b) should be revised as follows: "Tolerances are established for the combined residues of the herbicide linuron (3-(3,4-dichlorophenyl)-1-methoxy-1-methylurea) and its metabolites convertible to 3,4-dichloroaniline, calculated as linuron, in or on the following raw agricultural commodities:". A summary of the reassessment of tolerances listed in 40 CFR §180.184(b) is presented in Table D.

Sufficient data are available to support the established tolerance for parsley.

Dietary Exposure Estimate (Risk Assessment)

CBRS recommends that anticipated residue estimates provided to DRES in 1987 in connection with the Linuron Special Review be used to estimate dietary risk. Revised anticipated residues estimates are not being provided at this time because linuron is now classified as a nonquantifiable C carcinogen and less than 17% of the RfD is accounted for by current uses.

UNCERTAINTY

Because the metabolism of linuron in plant and animal is adequately understood the uncertainty in estimating residues is lessened. Additionally, available field trials, processing studies, reduction of the residue studies, and animal feeding studies provide sufficient information to estimate exposure and in some cases to evaluate appropriate tolerance levels. This also reduces the uncertainty in estimating exposure.

~~Field trial data are outstanding for soybeans and corn. Treatment of soybeans is a major linuron use. However, previous dietary exposure estimates conducted in connection with the Special Review indicate that linuron residues in these commodities will be low. Therefore, this source of uncertainty should not significantly affect the linuron risk estimate one way or the other.~~

Linuron storage stability data are considered confirmatory. Data currently available indicate that linuron residue are stable in frozen storage. Thus these data should not impact the exposure estimate/risk estimate.

Dietary exposure estimates based on residue data from field trial generally reflect a conservative estimate.

Table D. Tolerance Reassessment Summary.

Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	Comment/Correct Commodity Definition
Tolerances listed under 40 CFR 180.184(a):			
Asparagus	3	Reserved	Data are still needed for the FIC. The current tolerance is inadequate. Based on available data, the tolerance will need to be raised to 7 ppm.
Barley, forage	0.5	Revoke	No registered uses.
Barley, grain	0.25	Revoke	No registered uses.
Barley, hay	0.5	Revoke	No registered uses; not a RAC in Table II.
Barley, straw	0.5	Revoke	No registered uses.
Carrots	1	1	A 14-day PHI is required.
Cattle, fat	1	0.1	Proposed tolerance revision 0.1 ppm. PP#OF3832
Cattle, mbyp	1	1	Cattle, kidney Cattle, liver
		0.1	Cattle, mbyp (exc. liver and kidney)/Proposed tolerance revision 0.1 ppm. PP#OF3832
Cattle, meat	1	0.1	Proposed tolerance revision 0.1 ppm. PP#OF3832
Celery	0.5	0.5	The available data support use west of the Rocky Mountains, all labels must reflect this restriction.
Corn, field, fodder	1	6	6(a)(2) data have been submitted by DuPont indicating a higher tolerance 6 ppm in/on fodder is required. This conclusion is tentative pending submission of the final data submission.
Corn, field, forage	1	1	
Corn, fresh (inc. sweet K + CWHR)	0.25	Reserved	Corn, sweet (K + CWHR) Additional data required.
Corn, grain (inc. pop)	0.25	0.1	Corn, field, grain Pop corn grain tolerance should be deleted since there are no registered uses.

Table D (continued).

Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	Comment/Correct Commodity Definition
Tolerances listed under 40 CFR 180.184(a):			
Corn, pop, fodder	1	Revoke	No registered uses.
Corn, pop, forage	1	Revoke	
Corn, sweet, fodder	1	Revoke	Not a RAC in Table II.
Corn, sweet, forage	1	Reserved	Additional data required
Cottonseed	0.25	Revoke	<i>Cotton, seed</i> Use is not supported Processing study needed
Goats, fat	1	0.1	Proposed tolerance revision to 0.1 ppm. PP#OF3832
Goats, mbyop	1	1	<i>Goats, kidney</i> <i>Goats, liver</i>
		0.1	<i>Goats, mbyop (exc. liver and kidney)/Proposed tolerance revision to 0.1 ppm.</i> PP#OF3832
Goats, meat	1	0.1	Proposed tolerance revision to 0.1 ppm. PP#OF3832
Hogs, fat	1	0.1	Proposed tolerance revision to 0.1 ppm. PP#OF3832
Hogs, mbyop	1	1	<i>Hogs, kidney</i> <i>Hogs, liver</i>
		0.1	<i>Hogs, mbyop (exc. liver and kidney)/Proposed tolerance revision to 0.1 ppm.</i> PP#OF3832
Hogs, meat	1	0.1	Proposed tolerance revision to 0.1 ppm. PP#OF3832
Horses, fat	1	0.1	Proposed tolerance revision to 0.1 ppm. PP#OF3832
Horses, mbyop	1	1	<i>Horses, kidney</i> <i>Horses, liver</i>
		0.1	<i>Horses, mbyop (exc. liver and kidney)/Proposed tolerance revision to 0.1 ppm.</i> PP#OF3832
Horses, meat	1	0.1	Proposed tolerance revision to 0.1 ppm. PP#OF3832
Oats, forage	0.5	Revoke	No registered uses.

Table D (continued).

Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	Comment/Correct Commodity Definition
Tolerances listed under 40 CFR 180.184(a):			
Oats, grain	0.25	Revoke	No registered uses.
Oats, hay	0.5	Revoke	No registered uses; not a RAC in Table II.
Oats, straw	0.5	Revoke	No registered uses.
Parsnips (with or without tops)	0.5	0.5	<i>Parsnips, roots</i>
Parsnips, tops	0.5	Revoke	Not a RAC in Table II.
Potatoes	1	0.2* ¹	Proposed revision to the established tolerance. * - All registrants must submit revised labels prohibiting use west of the Rocky Mountains.
Rye, forage	0.5	Revoke	No registered uses.
Rye, grain	0.25	Revoke	No registered uses.
Rye, hay	0.5	Revoke	No registered uses; not a RAC in Table II.
Rye, straw	0.5	Revoke	No registered uses.
Sheep, fat	1	0.1	Proposed tolerance revision to 0.1 ppm. PP#0F3832
Sheep, mbyop	1	1	<i>Sheep, kidney</i> <i>Sheep, liver</i>
		0.1	<i>Sheep, mbyop (exc. liver and kidney)/Proposed tolerance revision to 0.1 ppm.</i> PP#0F3832
Sheep, meat	1	0.1	Proposed tolerance revision to 0.1 ppm. PP#0F3832
Sorghum, fodder	1	Reserved	
Sorghum, forage	1	Reserved	
Sorghum, grain (milo)	0.25	0.2-0.25	<i>Sorghum, grain</i>
Soybeans, (dry or succulent)	1	1	<i>Soybeans</i>
Soybeans, forage	1	Reserved	Feeding restrictions impractical
Soybeans, hay	1	Reserved	Feeding restrictions impractical
Wheat, forage	0.5	Reserved	Additional data required
Wheat, grain	0.25	0.1	
Wheat, hay	0.5	Revoke	Not a RAC in Table II.

Table D (continued).

Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	Comment/Correct Commodity Definition
Tolerances listed under 40 CFR 180.184(a):			
Wheat, straw	0.5	10	Registrant is petitioning for amended use and increased tolerance (PP#4F4293).
Tolerances listed under 40 CFR 180.184(b):			
Parsley	0.25	0.25	
Tolerances to be proposed under 40 CFR 185 and 186			
Potatoes, chips	--	0.6	
Potatoes, granules	--	0.8	
Potatoes, waste from processing	--	10	

¹ Delaney issues may prevent the establishment of these tolerances.

CODEX HARMONIZATION

No Codex MRLs have been established for linuron; therefore, issues of compatibility between Codex MRLs and U.S. tolerances do not exist.