

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[TD 8874]

RIN 1545-AW10

Travel and Tour Activities of Tax-Exempt Organizations; Correction

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Correction to final regulations.

SUMMARY: This document contains corrections to final regulations which were published in the *Federal Register* on Monday, February 7, 2000 (65 FR 5771), clarifying when the travel and tour activities of tax-exempt organizations are substantially related to the purposes of which exemptions was granted.

DATES: This correction is effective February 7, 2000.

FOR FURTHER INFORMATION CONTACT: Robin Ehrenberg at (202) 622-6080 (not a toll-free number).

SUPPLEMENTARY INFORMATION:**Background**

The final regulations that are the subject of these corrections are under section 513 of the Internal Revenue Code.

Need for Correction

As published, the final regulations (TD 8874) contain errors that may prove to be misleading and are in need of clarification.

Correction of Publication

Accordingly, the publication of the final regulations (TD 8874), which were the subject of FR Doc. 00-2154, is corrected as follows:

1. On page 5772, in the first column, under the caption "Background", in the last line of the first paragraph, the language, "circumstances test in four situations" is corrected to read "circumstances test".

§ 1.513-7 [Corrected]

2. On page 5774, third column, in § 1.513-7(b) *Example 7*, line 10, the language, "contribution to W of q dollars. Each year, W" is corrected to read "contribution to W of \$q. Each year, W".

Dale D. Goode,

Federal Register Liaison, Assistant Chief Counsel (Corporate).

[FR Doc. 00-5248 Filed 3-24-00; 8:45 am]

BILLING CODE 4830-01-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP-300988; FRL-6498-7]

RIN 2070-AB78

Dichlormid; Time-Limited Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes time-limited tolerances for residues of the inert ingredient (herbicide safener) dichlormid (*N,N*-diallyl dichloroacetamide) in or on corn commodities (forage, grain, stover) at 0.05 ppm. Zeneca Ag Products requested these tolerances under the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996. The tolerances will expire and be revoked on March 27, 2002.

DATES: This regulation is effective March 27, 2000. Objections and requests for hearings, identified by docket control number OPP-300988, must be received by EPA on or before May 26, 2000.

ADDRESSES: Written objections and hearing requests may be submitted by mail, in person, or by courier. Please follow the detailed instructions for each method as provided in Unit VI. of the **SUPPLEMENTARY INFORMATION**. To ensure proper receipt by EPA, your objections and hearing requests must identify docket control number OPP-300988 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Treva Alston, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, Ariel Rios Bldg., 1200 Pennsylvania Avenue, NW., Washington, DC 20460; telephone number: (703-308-8373; and e-mail address: alston.treva@epa.gov.

SUPPLEMENTARY INFORMATION:**I. General Information***A. Does This Action Apply to Me?*

You may be affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected categories and entities may include, but are not limited to:

Cat-egories	NAICS	Examples of potentially affected entities
Industry	111 112 311 32532	Crop production. Animal production. Food manufacturing. Pesticide manufacturing.

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

B. How Can I Get Additional Information, Including Copies of this Document and Other Related Documents?

1. *Electronically.* You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet Home Page at <http://www.epa.gov/>. To access this document, on the Home Page select "Laws and Regulations" and then look up the entry for this document under the "Federal Register—Environmental Documents." You can also go directly to the **Federal Register** listings at <http://www.epa.gov/fedrgstr/>.

2. *In person.* The Agency has established an official record for this action under docket control number OPP-300988. The official record consists of the documents specifically referenced in this action, and other information related to this action, including any information claimed as Confidential Business Information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305-5805.

II. Background and Statutory Findings

The Agency previously established under the Federal Food, Drug, and Cosmetic Act in a **Federal Register** Notice dated March 18, 1994 (59 FR 12857), a time-limited tolerances for dichlormid which expired on December 31, 1998. These tolerances were for corn, forage (field), at 0.05 ppm; corn, fodder (field) at 0.05 ppm; and corn, grain (field) at 0.05 ppm. In the **Federal Register** of September 16, 1998 (63 FR 49568–49574) (FRL–6025–8), EPA issued a notice pursuant to section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a as amended by the Food Quality Protection Act of 1996 (FQPA) (Public Law 104–170) announcing the filing of pesticide petition (PP) 6F03344 for tolerance by Zeneca Ag Products, 1800 Concord Pike, Wilmington, DE. This notice included a summary of the petition prepared by Zeneca Ag Products, the petitioner. There were no comments received in response to the notice of filing.

The petition requested that 40 CFR 180.469 be amended to establish again tolerances for residues of the safener dichlormid, in or on field corn grain, field corn forage, and field corn fodder at 0.05 ppm. The tolerances will expire and be revoked on March 27, 2002.

Section 408(b)(2)(A)(i) of the 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) 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) 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....”

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. First, EPA determines the toxicity of pesticides based primarily on toxicological studies using laboratory animals. These studies address many adverse health effects, including (but not limited to) reproductive effects, developmental toxicity, toxicity to the

nervous system, and carcinogenicity. Second, EPA examines exposure to the pesticide through the diet (e.g., food and drinking water) and through exposures that occur as a result of pesticide use in residential settings. For further discussion of the regulatory requirements of section 408 and a complete description of the risk assessment process, see the final rule on Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997) (FRL–5754–7).

III. Aggregate Risk Assessment and Determination of Safety

Consistent with 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, consistent with section 408(b)(2), for time limited tolerances for residues of dichlormid on corn, field, forage at 0.05 ppm; corn, field, grain, at 0.05 ppm; corn, field, stover at 0.05 ppm; corn, pop, grain at 0.05 ppm; corn, pop, stover at 0.05 ppm. EPA's assessment of the dietary exposures and risks associated with establishing the tolerances 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. The nature of the toxic effects caused by dichlormid are discussed in this unit.

1. *Acute oral toxicity to the rat.* Lethal Dose, LD₅₀, is 2,146 mg/kg. Clinical signs of neurotoxicity included upward curvature of the spine, piloerection, salivation, tip toe gait (Toxicity Category III).

2. *Acute dermal toxicity.* LD₅₀ < 2,000 mg/kg (limit dose) (Toxicity Category III).

3. *Acute inhalation.* Lethal Concentration (LC₅₀) is greater than 5.5 mg/L limit dose. Clinical signs of neurotoxicity included head flicking, paw flicking, and salivation.

4. *Primary eye irritation.* Mild Ocular Irritant (Toxicity Category IV).

5. *Primary dermal irritation.* Severe Dermal Irritant (Toxicity Category II).

6. Skin sensitization. Mild dermal sensitizer.

7. *90-day feeding study/rat.* The no-observed-adverse-effect level (NOAEL) is 20 ppm (intake of approximately 1.4

mg/kg/day for males and 1.6 mg/kg/day for females). Based on minor decreases in body weight gains and food efficiency in females and on increased liver weight and a slightly increased incidence of liver lipidosis in males, the lowest-observe-adverse-effect level (LOAEL) is 200 ppm under the conditions of this study (intake of approximately 14 mg/kg/day for males and 16 mg/kg/day for females).

8. *90-day feeding (capsule) study.* The NOAEL is 5 mg/kg/day for both sexes in the 90-day dog study. Based on decreased body weight gains, hematological and clinical chemistry alterations, liver toxicity, and voluntary muscle pathological changes, the LOAEL is 25 mg/kg/day for both males or females under the conditions of this study.

9. *90-day inhalation study.* The NOAEL is 2 mg/m³ (2 µg/L) in the 90-day rat inhalation study. The LOAEL is 19.9 mg/m³ (19.9 µg/L) based on clinical signs, gross pathology, ophthalmology, liver and kidney weights, and non-neoplastic histology.

10. *Carcinogenicity in the mouse.* Under the conditions of the study, there was no evidence of carcinogenic potential. The NOAEL for chronic toxicity is 50 ppm (equivalent to 7.0 mg/kg/day for male mice and 9.2 mg/kg/day for females). The LOAEL for chronic toxicity is 500 ppm (equivalent to 70.7 mg/kg/day for male mice and 92.4 mg/kg/day for females) based on changes in reproductive organs and kidney changes in males.

11. *Combined chronic toxicity/carcinogenicity in the rat.* Under the conditions of this study, there was no evidence of carcinogenic potential. The NOAEL for chronic toxicity is 100 ppm (6.5 mg/kg/day and 7.5 mg/kg/day for males and females respectively). The LOAEL is 500 ppm (32.8 mg/kg/day and 37.1 mg/kg/day in males and females respectively) based on liver clinical pathology, liver histopathology, and increased liver weight.

12. *Developmental toxicity in the rat.* The developmental toxicity NOAEL is 40 mg/kg/day. The maternal toxicity NOAEL is 10 mg/kg/day. The maternal toxicity LOAEL is 40 mg/kg/day based on decreased mean absolute body weights, body weight gains, and food consumption. The developmental toxicity LOAEL is 160 mg/kg/day based on a marginal increase in skeletal anomalies.

13. *The developmental toxicity in the rabbit.* The developmental toxicity and the maternal toxicity NOAEL are 30 mg/kg/day. The maternal toxicity LOAEL is 180 mg/kg/day based on an increased incidence of alopecia and decreased

mean maternal body weight gains and food consumption. The developmental toxicity LOAEL is 180 mg/kg/day based on increases in post-implantation loss accompanied by an increased number of resorptions per doe (both early and late resorptions), a decreased number of fetuses per litter, and slightly decreased mean fetal body weights.

14. *Mutagenicity/gene mutation.* Dichlormid was negative for mutagenic activity in *Salmonella typhimurium* strains TA 1535, TA 1537, TA 98, & TA 100 in both the absence and presence of metabolic activation up to cytotoxic doses. Dichlormid was positive for mutagenic activity both in the absence and presence of metabolic activation *in vitro* L5178Y Mouse Lymphoma Cells at doses that extend to the cytotoxic range.

15. *Mutagenicity/structural chromosomal aberration.* Dichlormid was negative for mutagenicity in an *in vitro* cytogenetic assay in human lymphocytes in the presence and absence of S-9 up to cytotoxic doses. Dichlormid was not clastogenic or aneugenic mutagenicity in an *in vivo* mouse micronucleus assay up to 2,000 mg/kg.

16. *Mutagenicity/other.* Dichlormid was negative for induced unscheduled DNA synthesis in rat primary hepatocytes.

B. Toxicological Endpoints

1. *Acute dietary toxicity.* For an acute dietary risk assessment, the Agency selected a maternal toxicity NOAEL of 10 mg/kg/day from the developmental toxicity study in the rat. The LOAEL is 40 mg/kg/day based on decreased body weight gain and food consumption (most significant on days 7–10 of dosing).

2. *Short-term dermal toxicity.* For a short-term dermal risk assessment the Agency selected the maternal toxicity NOAEL of 10 mg/kg/day. The LOAEL of 40 mg/kg/day was based on decreased body weight gain and food consumption. This dose was also selected for the acute toxicity. The duration of the short term dermal scenarios for dichlormid are comparable to the duration of exposure in the rat developmental toxicity study.

3. *Intermediate and long term dermal toxicity.* For intermediate and long-term dermal risk assessment, the Agency selected a NOAEL of 6.5 mg/kg/day (100 ppm) from a 2-year chronic toxicity/carcinogenicity rat feeding study. The LOAEL of 32.8 mg/kg/day (500 ppm) was based on an increased incidence of liver clinical pathology/histopathology and increased liver weight in the 2-year study in rats.

4. *Inhalation (all durations).* For an inhalation risk assessment, the Agency selected an inhalation NOAEL of 2 µg/L based on clinical signs, increased liver and kidney weight, gross pathology findings and non-neoplastic histopathology at the LOAEL of 19.9 µg/L (14-week inhalation study).

5. *Chronic dietary toxicity.* For a chronic dietary risk assessment the Agency selected a NOAEL of 6.5 mg/kg/day (100 ppm) from a 2-year chronic toxicity/carcinogenicity rat feeding study. The LOAEL of 32.8 mg/kg/day (500 ppm) was based on an increased incidence of liver clinical pathology/histopathology and increased liver weight in the 2-year study in rats.

6. *Carcinogenicity.* There is no evidence of carcinogenic potential in the rat and mouse carcinogenicity studies based on evaluation of the above described studies.

7. *Dermal penetration.* Dermal penetration could not be determined due to the absence of appropriate dermal studies and therefore a value of 100% dermal penetration was used.

8. *Safety factors.* The Agency will use the above NOAELs and LOAELs levels to assess the risks of using dichlormid to the general population and certain subgroups of the general population. However, the Agency first modifies these values numerically downward by dividing the NOAEL by two or more safety factors. The safety (uncertainty) factors used are: a 10-fold factor to account for intraspecies variability (the differences in how the test animals reacted to the test substance) and a 10-fold factor to account for interspecies variation (the use of animal studies to predict human risk).

FDCA Section 408 provides that the Agency shall apply an additional 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 data base unless the Agency determines that a different margin of safety will be safe for infants and children. As noted, the Agency has added an additional ten fold factor to both the acute and chronic dietary risk assessment due to the qualitative evidence of increased susceptibility demonstrated following *in utero* exposure in the prenatal developmental toxicity study in rabbits; and the incompleteness of the toxicity database. There are data gaps for the 2-generation reproduction study in rats, and acute and subchronic neurotoxicity studies.

i. *Acute dietary toxicity.* The Agency divided the NOAEL by 1,000 (10x interspecies extrapolation, 10x intraspecies variation and 10x safety

factor) to address additional susceptibility in the fetus and data gaps. The acute Population Adjusted Dose (aPAD) is equal to 0.010 mg/kg/day.

ii. *Chronic dietary toxicity.* The Agency divided the NOAEL of 6.5 mg/kg/day by 3,000 (10x interspecies extrapolation, 10x intraspecies variation, 10x for additional susceptibility and the data gap for the 2 generation reproductive study, and 3x for the data gap for the chronic toxicity study in dogs). The chronic Population Adjusted Dose (cPAD) is equal to 0.0022 mg/kg/day.

C. Exposures and Risks

1. *From food and feed uses.* Time-limited tolerances were previously established in 40 CFR 180.469 for residues of dichlormid at 0.05 ppm, in or on corn. Risk assessments were conducted by EPA to assess dietary exposures from dichlormid as follows:

i. *Acute exposure and risk.* Acute dietary 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 performing the acute dietary risk assessment, the Agency's level of concern is for exposures greater than 100% aPAD. For all population groups, including U.S. Population, infants and children, the acute dietary exposures are less than the Agency's level of concern at the 95th percentile using tolerance level residues and assuming 100%CT. The population groups with the highest dietary exposures are all infants (> 1 year) (5%), non nursing infants (> 1 year) (5%), and children (1–6 years of age) (4%), children (7–12 years of age) (3%).

ii. *Chronic exposure and risk.* In performing the chronic dietary risk assessment, the Agency's level of concern is for exposures greater than 100% cPAD. Using tolerance level residues and assuming 100%CT, the population groups with the highest percentages are all infants (> 1 year) (7%), non-nursing infants (> 1 year) (9%), Children (1–6 years old) (7%), children (7–12 years old) (5%), and males (13–19 years)(4%).

2. *From drinking water.* A Drinking Water Level of Comparison (DWLOC) is a theoretical exposure to a pesticide in food, drinking water, and through residential uses. A DWLOC will vary depending on the toxic endpoint, with drinking water consumption, and body weights. Different populations will have different DWLOCs. The Agency uses DWLOCs internally in the risk assessment process as a surrogate measure of potential exposure

associated with exposure through drinking water. In the absence of monitoring data for pesticides, it is used as a point of comparison against conservative model estimates of a pesticide's concentration in water. DWLOC values are not regulatory standards for drinking water. They do have an indirect regulatory impact through aggregate exposure and risk assessments.

Dichlormid is relatively short-lived in aerobic soil. Carbon dioxide was the only major identified aerobic soil metabolite. Significant amounts of other soil degradates were resistant to harsher extraction and presumably remain as bound residues. Dichlormid was stable against hydrolysis and photolysis in soil and water. Dichlormid's low sorptivity to soil indicates high mobility. Based on its low sorptivity to soil, high solubility in water (4.4 g/L), and low octanol to water partitioning ratio, bioconcentration is not anticipated.

Drinking water exposure estimates are based on degradation and transport factors for dichlormid coupled with the Agency's current GENEEC (surface water) and SCI-GROW (groundwater) screening models for surface and ground water, respectively. Model results are for an application rate of dichlormid of 0.5 lbs/acre.

For ground water, the Agency used its SCI-GROW (Screening Concentration in Ground Water) screening model and environmental fate data to determine the Estimated Environmental Concentration (EEC) of dichlormid in ground water. SCI-GROW is an empirical model based upon actual ground water monitoring data collected for the registration of a number of pesticides that serve as benchmarks for the model. The current version of SCI-GROW appears to provide realistic estimates of pesticide concentrations in shallow, highly vulnerable ground water sites (i.e., sites with sandy soils and depth to ground water of 10 to 20 feet). The SCI-GROW ground water screening concentration is 0.046 ppb.

For surface water, the Agency used its GEENE (Generic Estimated Environmental Concentration) screening model and environmental fate data to determine the EECs of dichlormid in surface water. GENEEC simulates a 1 hectare by 2 meter deep edge-of-the-field farm pond which receives pesticide runoff from a treated 10 hectare field. GENEEC can substantially overestimate true pesticide concentrations in drinking water. It has certain limitations and is not the ideal tool for use in drinking water risk assessments. However, it can be used in screening calculations and does provide

an upper bound on the concentration of true drinking water concentrations. It will be necessary to refine the GENEEC estimate when the level of concern is exceeded. In those situations where the level of concern is exceeded and the GENEEC value is a substantial part of the total exposure, the Agency can use a variety of methods to refine the exposure estimates.

Using the GENEEC model and available environmental fate data, EPA calculated the following Tier 1 EECs for dichlormid:

Peak (Acute) EEC: 27.29 ppb
Average (Chronic) EEC 26.93 ppb

However, the interim Agency policy allows the average (chronic) GENEEC value to be divided by 3 to obtain a value of 8.98 ppb for use in chronic risk assessment calculations. It is current Agency policy that the following subpopulations be addressed when calculating drinking water levels of concern: U.S. Population (48 States), any other adult populations whose %PAD is greater than that of the U.S. population, and the Female and Infant/Children subgroups (1 each) with the highest food exposure. The subgroups which are listed below are those which fall into these categories.

i. *Acute exposure and risk.* Based on the acute dietary exposure estimates, an acute drinking water level of comparison (DWLOC) for dichlormid was calculated to be 340 ppb and 95 ppb for the U.S. population and non-nursing infants (> 1 year old) respectively.

ii. *Chronic exposure and risk.* Based on the chronic dietary exposure estimates, chronic drinking water levels of comparison (DWLOC) for dichlormid was calculated to be 75 ppb and 20 ppb for the U.S. population and non-nursing infants (> 1 year old), respectively.

iii. *Drinking water risks.* The modeled groundwater and surface water concentrations are less than the DWLOCs for dichlormid in drinking water for acute and chronic aggregate exposures. Thus, the Agency is able to screen out dichlormid drinking water risks.

3. *From non-dietary exposure.* There are no existing residential uses for dichlormid; therefore, no assessment was performed for residential exposure.

4. *Cumulative exposure to substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) 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."

EPA does not have, at this time, available data to determine whether dichlormid has a common mechanism of toxicity with other substances or how to include this pesticide in a cumulative risk assessment. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, dichlormid does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has not assumed that dichlormid 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 final rule for Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997).

D. Aggregate Risks and Determination of Safety for U.S. Population

1. *Acute risk.* High-end dietary exposure estimates through food were calculated for the U.S. Population and other subgroups. The % aPADs for the U.S. population and all other subgroups were > 5% which is below the Agency's level of concern of 100% at the 95th percentile. The acute estimated concentrations of dichlormid in surface and ground water are less than the Agency's DWLOCs for dichlormid. Therefore, EPA does not expect the aggregate risk to exceed 100% of the aPAD.

2. *Chronic risk.* There are no registered residential uses for dichlormid. Chronic aggregate exposure will include food and water only. Using tolerance level residues and 100% crop treated assumptions, the percent cPADS for the U.S. population and all other subgroups were > 9%. The estimated chronic dietary risk from food is below the Agency's level of concern (100%). The estimated average concentrations of dichlormid in surface and ground water are less than the Agency's DWLOCs for dichlormid in drinking water. Therefore, EPA does not expect the aggregate risk to exceed 100% of the cPAD.

3. *Short- and intermediate-term risk.* Short- and intermediate-term aggregate exposure takes into account chronic dietary food and water (considered to be a background exposure level) plus indoor and outdoor residential exposure. There are no existing residential uses for dichlormid; therefore, no short-term or intermediate-term risk assessment was performed.

4. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result from aggregate exposure to dichlormid residues.

E. Aggregate Risks and Determination of Safety for Infants and Children

1. *Safety factor for infants and children—i. In general.* In assessing the potential for additional sensitivity of infants and children to residues of dichlormid, EPA considered data from developmental toxicity studies in the rat and rabbit. The developmental toxicity studies are designed to evaluate adverse effects on the developing organism resulting from maternal pesticide exposure gestation.

FFDCA section 408 provides that EPA shall apply an additional 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 data base unless EPA determines that a different margin of safety will be safe for infants and children. Margins of safety are incorporated into EPA risk assessments either directly through use of a margin of exposure (MOE) analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans. EPA believes that reliable data support using the standard uncertainty factor (usually 100 for combined interspecies and intraspecies variability) when EPA has a complete data base under existing guidelines and when the severity of the effect in infants or children or the potency or unusual toxic properties of a compound do not raise concerns regarding the adequacy of the standard MOE/safety factor.

ii. *Conclusion.* An additional safety factor is to be retained at 10x since: (1) There is qualitative evidence of increased susceptibility in the rabbit developmental study; and (2) the toxicity database is incomplete. There are data gaps for the 2-generation reproduction study in rats, and acute and subchronic neurotoxicity studies.

2. *Acute risk.* From the acute dietary risk assessments, high-end exposure estimates were calculated for the U.S. Population and other subgroups. At the 95th percentile the highest dietary exposure for infants < 1 year and non-nursing infants (< 1 year old) is 5% aPAD. The estimated acute dietary risk associated with the use of dichlormid on corn is below the Agency's level of concern. The maximum estimated concentrations of dichlormid in surface and ground water are less than the Agency's DWLOCs for dichlormid.

Therefore, EPA does not expect the acute risk to exceed 100% of the aPAD.

3. *Chronic (non cancer) risk.* There are no registered residential uses for dichlormid. Therefore, chronic aggregate exposure will include food and water only. Using tolerance level residues and 100% crop treated assumptions, the highest exposure is from an infants and children subgroup, non-nursing infants (< 1 year old), with an estimated dietary exposure of 9% cPAD. The estimated chronic dietary risk associated with the use of dichlormid on corn is below the Agency's level of concern. The estimated average concentrations of dichlormid in surface and groundwater are less than the Agency's DWLOCs for dichlormid in drinking water. Therefore, EPA does not expect the chronic risk to exceed 100% of the cPAD.

4. *Short- or intermediate-term risk.* Short- and intermediate-term aggregate exposure takes into account chronic dietary food and water (considered to be a background exposure level) plus indoor and outdoor residential exposure. There are no existing residential uses for dichlormid, therefore, no short and intermediate term risk assessment was performed.

5. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to dichlormid residues.

IV. Other Considerations

A. Endocrine Disruptor Effects

FQPA requires the Agency to develop a screening program to determine whether certain substances (including all pesticides and inert or active ingredients) "may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or such other endocrine effect..." The Agency has been working with interested stakeholders to develop a screening and testing program as well as a priority setting scheme. As the Agency proceeds with implementation of this program, further testing of products containing the inert ingredient dichlormid for endocrine effects may be required.

B. Metabolism in Plants and Animals

No data pertaining to the metabolism of dichlormid have been submitted. The nature of the residue in corn was previously found to be understood based on the published metabolism studies of *N,N*-diallyl-2-chloroacetamide. It was concluded that

the metabolism of dichlormid would follow the pathway of *N,N*-diallyl-2-chloroacetamide.

C. Analytical Enforcement Methodology

Adequate enforcement methodology is available to enforce the tolerance expression. The method may be requested from: Calvin Furlow, PRRIB, IRSD (7502C), Office of Pesticide Programs, Environmental Protection Agency, Ariel Rios Bldg., 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 305-5229; e-mail address: furlow.calvin@epa.gov.

D. Magnitude of Residues

Crop field trial data for dichlormid were submitted and reviewed. The submitted data support the time-limited tolerance level of 0.05 ppm for all corn commodities.

E. International Residue Limits

There is neither a Codex proposal, nor Canadian or Mexican limits for residues of dichlormid in corn commodities.

V. Conclusion

Therefore, the time limited tolerances are established for residues of the inert ingredient herbicide safener, *N,N*-diallyldichloroacetamide in corn, field, forage at tolerance level of 0.05 ppm; corn, field, grain at a tolerance level of 0.05 ppm; corn, field, stover at a tolerance level of 0.05 ppm; corn, pop, grain at a tolerance level of 0.05 ppm; and corn, pop, stover at a tolerance level of 0.05 ppm. The tolerances will expire and be revoked 2 years from the date of this publication. These tolerances are being established on a time-limited basis due to an incomplete data base. The following toxicological data gaps (OPPTS Harmonized Test Guideline) have been identified (1) Chronic Feeding Study in Dogs, Test Guidelines 870.4100; (2) 2-Generation Reproductive Study in Rats, Test Guideline 870.3800; (3) General Metabolism Study, Test Guideline 870.7485; (4) Acute Neurotoxicity Study, Test Guideline 870.6200; and (5) Subchronic Neurotoxicity Study, Test Guideline 870.6200.

The following product and residue chemistry data were also identified: (1) Product Chemistry Data-color, Test Guideline 830.6302; physical state, Test Guideline 830.6303; odor, 830.6304; melting point, Test Guideline 830.7200; boiling point, Test Guideline 830.7220; water solubility, Test Guideline 830.7840; and stability, Test Guideline 830.6313; (2) Plant Metabolism Study, Test Guideline 860.1300; (3) Animal Metabolism Studies, Test Guideline

860.1300; (4) Crop Field Trials, 860.1500; (5) Rotational Crop Study, Test Guideline 860.1850 (Confined Study). The toxicological, product chemistry and residue chemistry data gaps as identified must be addressed before a permanent tolerance can be established.

VI. Objections and Hearing Requests

Under section 408(g) of the FFDCA, as amended by the FQPA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. The EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. Although the procedures in those regulations require some modification to reflect the amendments made to the FFDCA by the FQPA of 1996, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) provides essentially the same process for persons to "object" to a regulation for an exemption from the requirement of a tolerance issued by EPA under new section 408(d), as was provided in the old FFDCA sections 408 and 409. However, the period for filing objections is now 60 days, rather than 30 days.

A. What Do I Need to Do to File an Objection or Request a Hearing?

You must file your objection or request a hearing on this regulation in accordance with the instructions provided in this unit and in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket control number OPP-300988 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 on or before May 26, 2000.

1. *Filing the request.* Your objection must specify the specific provisions in the regulation that you object to, and the grounds for the objections (40 CFR 178.25). If a hearing is requested, the objections must include a statement of the factual issues(s) on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the objector (40 CFR 178.27). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked

confidential may be disclosed publicly by EPA without prior notice.

Mail your written request to: Office of the Hearing Clerk (1900), Environmental Protection Agency, Ariel Rios Bldg., 1200 Pennsylvania Ave., NW., Washington, DC 20460. You may also deliver your request to the Office of the Hearing Clerk in Rm. M3708, Waterside Mall, 401 M St., SW., Washington, DC 20460. The Office of the Hearing Clerk is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Office of the Hearing Clerk is (202) 260-4865.

2. *Tolerance fee payment.* If you file an objection or request a hearing, you must also pay the fee prescribed by 40 CFR 180.33(i) or request a waiver of that fee pursuant to 40 CFR 180.33(m). You must mail the fee to: EPA Headquarters Accounting Operations Branch, Office of Pesticide Programs, P.O. Box 360277M, Pittsburgh, PA 15251. Please identify the fee submission by labeling it "Tolerance Petition Fees."

EPA is authorized to waive any fee requirement "when in the judgement of the Administrator such a waiver or refund is equitable and not contrary to the purpose of this subsection." For additional information regarding the waiver of these fees, you may contact James Tompkins by phone at (703) 305-5697, by e-mail at tompkins.jim@epa.gov, or by mailing a request for information to Mr. Tompkins at Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, Ariel Rios Bldg., 1200 Pennsylvania Ave., NW., Washington, DC 20460.

If you would like to request a waiver of the tolerance objection fees, you must mail your request for such a waiver to: James Hollins, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, Ariel Rios Bldg., 1200 Pennsylvania Ave., NW., Washington, DC 20460.

3. *Copies for the Docket.* In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit VI.A., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in Unit I.B.2. Mail your copies, identified by docket control number OPP-300988, to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, Ariel Rios Bldg., 1200 Pennsylvania Ave., NW., Washington, DC 20460. In person or by courier, bring a copy to the location of

the PIRIB described in Unit I.B.2. You may also send an electronic copy of your request via e-mail to: oppdocket@epa.gov. Please use an ASCII file format and avoid the use of special characters and any form of encryption. Copies of electronic objections and hearing requests will also be accepted on disks in WordPerfect 6.1/8.0 file format or ASCII file format. Do not include any CBI in your electronic copy. You may also submit an electronic copy of your request at many Federal Depository Libraries.

B. When Will the Agency Grant a Request for a Hearing?

A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is a genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issues(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

VII. Regulatory Assessment Requirements

This final rule establishes a time-tolerance under FFDCA section 408(d) 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). 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.*, or 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). Nor does it require any prior consultation as specified by Executive Order 13084, entitled *Consultation and Coordination with Indian Tribal Governments* (63 FR 27655, May 19, 1998); special considerations as required by Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994); or require OMB review or any Agency action under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). 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). Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), 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. In addition, the Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure "meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications." "Policies that have federalism implications" is defined in the Executive Order to include regulations that have "substantial direct effects on the States,

on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government." This final rule directly regulates growers, food processors, food handlers and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4).

VIII. Submission to Congress and the Comptroller General

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, 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: March 16, 2000

James Jones,

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 180.469 is revised to read as follows:

§ 180.469 N,N-diallyl dichloroacetamide; tolerances for residues.

(a) *General.* Tolerances are established for residues of dichlormid; N,N-diallyl dichloroacetamide (CAS Reg. No. 37764-25-3) when used as an inert ingredient (safener) in pesticide formulations in or on the following food commodities:

Commodity	Parts per million	Expiration/Revocation Date
Corn, field, forage	0.05	March 27, 2002
Corn, field, grain	0.05	March 27, 2002
Corn, field, stover	0.05	March 27, 2002
Corn, pop, grain	0.05	March 27, 2002
Corn, pop, stover	0.05	March 27, 2002

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[FR Doc. 00-7416 Filed 3-24-00; 8:45 am]

BILLING CODE 6560-50-F

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[DA 00-552; MM Docket No. 97-251; RM-9199]

Radio Broadcasting Services; Breckenridge and Graford, Texas

AGENCY: Federal Communications Commission.

ACTION: Final rule; dismissal.

SUMMARY: The Commission, at the request of Big Country Radio, Inc., licensee of Station KLXK(FM), Channel 228C2, Breckenridge, Texas, dismisses the petition for rule making requesting the substitution of Channel 228C3 for Channel 228C2 at Brackenridge and the reallocation of Channel 228C3 to Graford, Texas. See 63 FR 02355 (January 15, 1998).

FOR FURTHER INFORMATION CONTACT: Victoria M. McCauley, Mass Media Bureau, (202) 418-2180.

SUPPLEMENTARY INFORMATION: This is a synopsis of the Commission's Report and Order, MM Docket No.97-251, adopted March 1, 2000, and released March 10, 2000. The full text of this Commission decision is available for inspection and copying during normal business hours in the FCC Reference Center (Room 239), 445 12th Street, SW, Washington, DC. The complete text of this decision may also be purchased

from the Commission's copy contractor, International Transcription Services, Inc., (202) 857-3800, 1231 20th Street, NW, Washington, DC 20036.

List of Subjects in 47 CFR Part 73

Radio broadcasting.

Federal Communications Commission.

John A. Karousos,

Chief, Allocations Branch, Policy and Rules Division, Mass Media Bureau.

[FR Doc. 00-7389 Filed 3-24-00; 8:45 am]

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