(1) *Designated representative* means any Coast Guard commissioned, warrant, or petty officer that has been authorized to act on behalf of the COTP.

(2) *Escorted Vessel* means any vessel operating in the RNA deemed by the COTP to be in need of escort protection for security reasons or under other circumstances. A designated representative aboard a Coast Guard cutter or patrol boat will accompany vessels deemed in need of escort protection into the RNA.

(3) *Navigation rules* mean international and inland navigation rules in 33 CFR chapter I, subchapters D and E.

(4) *Vessel* means every description of watercraft or other artificial contrivance used, or capable of being used, as a means of transportation on water, except U.S. Coast Guard or U.S. naval vessels.

(d) *Regulations.* (1) No person or vessel may enter into the security zones under this section unless authorized by the COTP Guam or a designated representative.

(2) A vessel in the RNA established under paragraph (a) of this section operating within 500 yards of an escorted vessel must proceed at a minimum speed necessary to maintain a safe course, unless required to maintain speed by the navigation rules.

(3) When an escorted vessel in the RNA approaches within 100 yards of a vessel that is moored, or anchored in a designated anchorage area, the stationary vessel must stay moored or anchored while it remains within the escorted vessel's security zone unless it is either ordered by, or given permission from the COTP Guam or a designated representative to do otherwise.

(4) The COTP will inform the public of the existence or status of the security zones around escorted vessels in the RNA periodically by Broadcast Notice to Mariners.

(5) Persons or vessels that must enter a security zone or exceed speed limits established in this section may contact the COTP at command center telephone number (671) 339–6100 or on VHF channel 16 (156.8 Mhz) to request permission.

(6) All persons and vessels within 500 yards of an escorted vessel in the RNA must comply with the orders of the COTP Guam or his designated representatives.

(e) *Authority.* In addition to 33 U.S.C. 1231 and 50 U.S.C. 191, the authority for this section includes 33 U.S.C. 1226.

Dated: January 17, 2003.

G.A. Wiltshire,

Captain, Coast Guard, Commander, Fourteenth Coast Guard District (Acting).

[FR Doc. 03–2061 Filed 1–28–03; 8:45 am]

BILLING CODE 4910–15–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 82

Protection of Stratospheric Ozone

CFR Correction

In Title 40 of the Code of Federal Regulations, Parts 81 to 85, revised as of July 1, 2002, on page 346, part 82 is corrected by removing the second § 82.7.

[FR Doc. 03–55502 Filed 1–28–03; 8:45 am]

BILLING CODE 1505–01–D

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 112

Oil Pollution Prevention

CFR Correction

In Title 40 of the Code of Federal Regulations, Parts 100 to 135, revised as of July 1, 2002, Appendix F to part 112 is corrected as follows:

1. In section 1.0 paragraph B, by adding the words ''required by'' before 40 CFR 112.3;

2. In section 1.8.3 by revising '' 267–4085–4065'' to read ''(202) 267–4085''; and

3. In Attachment F–1, add footnote 1 to read:

Attachment F–1–Response Plan Cover Sheet

* * * * *

Dun & Bradstreet number: [1]

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[1]These numbers may be obtained from public library resources.

[FR Doc. 03–55500 Filed 1–28–03; 8:45 am]

BILLING CODE 1505–01–D

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2002–0245; FRL–7199–4]

4-(Dichloroacetyl)-1-Oxa-4-Azaspiro[4.5]Decane; Pesticide Import Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes import tolerances for residues of 4-(dichloroacetyl)-1-oxa-4-azaspiro[4.5]decane (CAS No. 71526–07–3) in or on corn commodities. Monsanto Company requested this tolerance under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act (FQPA) of 1996.

DATES: This regulation is effective January 29, 2003. Objections and requests for hearings, identified by docket ID number OPP–2002–0245, must be received on or before March 31, 2003.

ADDRESSES: Written objections and hearing requests may be submitted electronically by mail, or through hand delivery/courier. Follow the detailed instructions as provided in Unit VI. of the **SUPPLEMENTARY INFORMATION**.

FOR FURTHER INFORMATION CONTACT: By mail: Bipin Gandhi, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW.,Washington, DC 20460–0001; telephone number: (703) 308–8380; e-mail address: gandhi.bipin@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:

• Industry, (NAICS 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 this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the technical person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Get Copies of this Document and Other Related Information?

1. *Docket.* EPA has established an official public docket for this action under docket identification (ID) number OPPT–2002–0245. The official public docket consists of the documents

specifically referenced in this action, any public comments received, and other information related to this action. Although a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The official public docket is the collection of materials that is available for public viewing at the EPA Docket Center, Rm. B102-Reading Room, EPA West, 1301 Constitution Ave., NW., Washington, DC. The EPA Docket Center is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The EPA Docket Center Reading Room telephone number is (202) 566–1744 and the telephone number for the OPPT Docket, which is located in EPA Docket Center, is (202) 566–0280.

2. *Electronic access.* You may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at http://www.epa.gov/fedrgstr/. A frequently updated electronic version of 40 CFR part 180 is available at http://www.access.gpo.gov/nara/cfr/cfrhtml_00/Title_40/40cfr180_00.html, a beta site currently under development. To access the OPPTS Harmonized Guidelines referenced in this document, go directly to the guidelines at http://www.epa.gov/opptsfrs/home/guidelin.htm.

An electronic version of the public docket is available through EPA's electronic public docket and comment system, EPA Dockets. You may use EPA Dockets at http://www.epa.gov/edocket/ to submit or view public comments, access the index listing of the contents of the official public docket, and to access those documents in the public docket that are available electronically. Although not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility identified in Unit I.B.1. Once in the system, select ''search,'' then key in the appropriate docket ID number.

II. Background and Statutory Findings

In the **Federal Register** of January 28, 1998 (63 FR 4252) (FRL–5763–6), EPA issued a notice pursuant to section 408 of the FFDCA, 21 U.S.C. 346a, as amended by the FQPA (Public Law 104–170), announcing the filing of a pesticide petition (PP 5E4503) by Monsanto Company, 800 North Lindbergh Blvd., St. Louis, MO 63167. This notice included a summary of the petition prepared by Monsanto Company, the petitioner. There were no comments received in response to the notice of filing.

Previously, time-limited tolerances had been established (40 CFR 180.465) for the residues of 4-(dichloroacetyl)-1-oxa-4-azaspiro[4.5]decane, in or on corn commodities (April 14, 1993) (58 FR 19387). These tolerances expired on January 31, 1998.

In the above mentioned pesticide petition (5E4503) Monsanto Corporation requested permanent tolerances for 4-(dichloroacetyl)-1-oxa-4-azaspiro[4.5]decane in or on corn commodities at 0.005 ppm.

The petitioner asked in a letter dated January 15, 2002, that 40 CFR 180.465 be amended by establishing an import tolerance for residues of the herbicide safener 4-(dichloroacetyl)-1-oxa-4-azaspiro[4.5]decane, in or on corn commodities at 0.005 parts per million (ppm) with no U.S. registrations.

In the United States a tolerance is the maximum residue level of a pesticide permitted in or on food or feed grown in the United States and food or feed imported into the United States from other countries. Typically, EPA would establish tolerance(s) or exemption(s) from the requirement of a tolerance at the same time that it registered the use of a pesticide for that commodity in the United States. Where no U.S. registration exists, interested persons may submit a petition requesting that EPA establish an import tolerance for a pesticide residue that would allow treated food to be legally imported into the United States. The term ''import tolerance'' is used as a convenience to refer to a tolerance that exists where there is no accompanying registration under the Federal Insecticide, Fungicide, Rhodenticide Act (FIFRA). There is no statutory or regulatory distinction between an ''import tolerance'' and any other tolerance issued by EPA. The same food safety standards apply to both domestically produced and imported food.

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) of the FFDCA defines ''safe'' to mean that'' there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of the FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensurethat 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 topesticide residues. For further discussion of the regulatory requirements of section 408 of the FFDCA 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) of the FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure, consistent with section 408(b)(2) of the FFDCA, for a tolerance for residues of 4-(dichloroacetyl)-1-oxa-4-azaspiro[4.5]decane on corn commodities at 0.005 ppm. EPA's assessment of exposures and risks associated with establishing the tolerance follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. The nature of the toxic effects caused by 4-(dichloroacetyl)-1-oxa-4-azaspiro[4.5]decane are discussed in the following Table 1 as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies reviewed.

TABLE 1.—SUBCHRONIC, CHRONIC, AND OTHER TOXICITY

Guideline No.	Study Type	Results
870.3100	90–Day oral toxicity rodents	NOAEL = 48 mg/kg/day LOAEL = 192 mg/kg/day based on decreased mean body weights, increased platelets , changes in clinical parameters and histopathological findings.
870.3150	90–Day oral toxicity in nonrodents	NOAEL = would be equal to or greater than 30 mg/kg/day LOAEL = not determined; but would be greater than 30 mg/kg/day.
870.3700	Prenatal developmental in rodents-rats (1989 study)	Maternal NOAEL = 10 mg/kg/day mg/kg/day based on decreased body weight gain, decreased food consumption, increased preimplantation loss. Developmental NOAEL = 75 mg/kg/day LOAEL = 150 mg/kg/day based on increased incidences of skeletal malfunctions and variations.
	Prenatal developmental in rodents-rat (1985 study)	Maternal NOAEL = 80 mg/kg/day LOAEL = 200 mg/kg/day based on clinical signs (alopecia, wet fur with urinary staining, piloerection. Developmental NOAEL = 80 mg/kg/day LOAEL = 200 mg/kg/day based on increased fetal malfunctions.
870.3700	Prenatal developmental in rabbits-nonrodents	Maternal NOAEL = 10 mg/kg/day LOAEL = 30 mg/kg/day based on decreased body weight gain. Developmental NOAEL = would be equal to or greater than 30 mg/kg/day LOAEL = would be greater than 30 mg/kg/day .
870.3800	Reproduction and fertility effects	Parental/Systemic NOAEL = 6.34/7.32 male/female mg/kg/day LOAEL = 61.48/72.30 male/female mg/kg/day based on reduced body weight and body weight gain in P & F1a. Reproductive NOAEL = 6.34/7.32 male/female mg/kg/day LOAEL = 61.48/72.30 male/female mg/kg/day based on decreased pup body weights.
870.4200	Carcinogenicity mice	NOAEL = 10.71/16.82 male/female mg/kg/day LOAEL = 107.50/166.57 male/female mg/kg/day based on increased absolute and relative liver weights as well as histopathological lesions in the liver, and stomach mucosa.
870.4300	Chronic/Carcinogenicity rats	NOAEL = 2.21/2.78 male/female mg/kg/day LOAEL = 22.09/29.18 male/female mg/kg/day based upon histopathological changes in the liver and stomach including cystic liver degeneration, periportal hepatocellular vacuolation, and pyloric intestinal metaplasia of the stomach.
870.5300	Gene Mutation	*In vitro* gene mutation in CHO cells. Negative for mutagenicity.
870.5300	Cytogenetics	*In vitro* bone marrow assay did not induce a clastogenic response.
870.5550	Gene Mutation	*In vitro* UDS assay did not induce a genotoxic effect.
870.5100	Gene Mutation	*S.typhimurium*/mammalian microsome assay did not induce a genotoxic effect.
870.7600	Dermal penetration	There were no dermal absorption studies and no appropriate toxicity studies available to allow an estimation of the dermal absorption by a route-to-route comparison of toxicity. However, two structurally related chemicals, acetochlor and alachlor, have experimentally derived dermal data indicating that absorption is 20 to 25 percent, respectively. Therefore, the estimated dermal absorption is 25%

B. Toxicological Endpoints

The dose at which the NOAEL from the toxicology study identified as appropriate for use in risk assessment is used to estimate the toxicological level of concern (LOC). However, the LOAEL is sometimes used for risk assessment if no NOAEL was achieved in the toxicology study selected. An uncertainty factor (UF) is applied to reflect uncertainties inherent in the extrapolation from laboratory animal data to humans and in the variations in sensitivity among members of the human population as well as other unknowns. An UF of 100 is routinely used, 10X to account for interspecies differences and 10X for intra species differences. An additional 3x uncertainty factor was applied due to the data gap for a chronic toxicity study in dogs.

For dietary risk assessment (other than cancer) the Agency uses the UF to calculate an acute or chronic reference dose (acute RfD or chronic RfD) where the RfD is equal to the NOAEL divided by the appropriate UF (RfD = NOAEL/UF). Where an additional safety factor is retained due to concerns unique to the FQPA, this additional factor is applied to the RfD by dividing the RfD by such additional factor. The acute or chronic Population Adjusted Dose (aPAD or cPAD) is a modification of the RfD to accommodate this type of FQPA Safety Factor.

For non-dietary risk assessments (other than cancer) the UF is used to determine the LOC. For example, when 100 is the appropriate UF (10X to

account for interspecies differences and 10X for intraspecies differences) the LOC is 100. To estimate risk, a ratio of the NOAEL to exposures (margin of exposure (MOE) = NOAEL/exposure) is calculated and compared to the LOC.

The linear default risk methodology (Q*) is the primary method currently used by the Agency to quantify carcinogenic risk. The Q* approach assumes that any amount of exposure will lead to some degree of cancer risk. A Q* is calculated and used to estimate risk which represents a probability of occurrence of additional cancer cases (e.g., risk is expressed as 1 x 10^{-6} or one in a million). Under certain specific circumstances, MOE calculations will be used for the carcinogenic risk assessment. In this non-linear approach, a ''point of departure'' is identified below which carcinogenic effects are not expected. The point of departure is typically a NOAEL based on an endpoint related to cancer effects though it may be a different value derived from the dose response curve. To estimate risk, a ratio of the point of departure to exposure (MOE_{cancer}= point of departure/exposures) is calculated. A summary of the toxicological endpoints for 4-(dichloroacetyl)-1-oxa-4-azaspiro[4.5]decane used for human risk assessment is shown in the following Table 2:

TABLE 2.—SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR 4-(DICHLOROACETYL)-1-OXA-4-AZASPIRO[4.5]DECANE FOR USE IN HUMAN RISK ASSESSMENT

Exposure Scenario	Dose Used in Risk Assessment, UF	FQPA SF* and Level of Concern for Risk Assessment	Study and Toxicological Effects
Acute Dietary (Females 13–50 years of age)	NOAEL = 10 mg/kg/day UF = 100 Acute RfD = 0.1 mg/kg/day	FQPA SF = 3 aPAD = acute RfD/FQPA SF = 0.033 mg/kg/day	Development toxicity in rabbits LOAEL = 75 mg/kg/day based on decreased body weight gain on day 3 of dosing.
Acute Dietary (General population, including infants and children)	NOAEL = 10 mg/kg/day UF = 100 Acute RfD = 0.1 mg/kg/day	FQPA SF = 1 aPAD = acute RfD/FQPA SF = 0.1 mg/kg/day	Development toxicity in rabbits Material LOAEL = 75 mg/kg/day based on decreased body weight gain on day 3 of dosing.
Chronic Dietary (All populations)	NOAEL = 2.21 mg/kg/day UF = 300 Chronic RfD = 0.007 mg/kg/day	FQPA SF = 1 cPAD = chronic RfD/FQPA SF = 0.007 mg/kg/day	Chronic/Carcinogenicity in rats LOAEL = 22.09 mg/kg/day based on histopathological changes in liver and stomach including cystic liver degeneration, periportal hepatocellular vacuolation, and pyloric intestinal metaplasia of the stomach
Short-, intermediate Term Dermal	Dermal (or oral) study NOAEL = 10 mg/kg/day (dermal absorption rate = 25 %)	LOC for MOE = 100 (Residential)	Development toxicity in rabbit LOAEL = 75 mg/kg/day based on decreased body weight gain on day 3 of dosing.
Long-Term Dermal	Oral study NOAEL= 2.21 mg/kg/day (dermal absorption rate = 25 %when appropriate)	LOC for MOE = 100 (Residential)	Chronic/Carcinogenicity in rats LOAEL = 22.09 mg/kg/day was used for deriving the chronic RfD.
Inhalation any time period	Oral study NOAEL = 10 mg/kg/day (inhalation absorption rate = 100%)	LOC for MOE = 100 (Residential)	Development toxicity in rabbit LOAEL = 75 mg/kg/day based on decreased body weight gain on day 3 of dosing
Cancer (Oral, dermal, inhalation)	Q_1* =4.85x10^{-2} (mg/kg/day)$^{-1}$		Likely to be carcinogenic to humans (combined hepatocellular adenoma and /or carcinoma in male mice).

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* The tolerances to be established are import tolerances. Thus, the only dietary exposure would be residues of 4-(dichloroacetyl)-1-oxa-4-azaspiro[4.5]decane, in imported corn commodities. Therefore, risk assessments were conducted by EPA to assess dietary exposures from 4-(dichloroacetyl)-1-oxa-4-azaspiro[4.5]decane in food as follows:

i. *Acute exposure.* 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 one day or single exposure. The Dietary Exposure Evaluation Model (DEEM™) analysis evaluated the individual food consumption as reported by respondents in the USDA 1989–1992 nationwide Continuing Surveys of Food Intake by Individuals (CSFII) and accumulated exposure to the chemical for each commodity. The following assumptions were made for the acute exposure assessments:

The acute dietary (food only) assessment is based on Tier 1 assumptions (tolerance level residues, 100% crop treated). For all population subgroups the estimated dietary (food only) risks are less than 1% of the acute population-adjusted dose (PAD). This is well below the Agency's level of concern for the dietary exposure (100% of the PAD).

ii. *Chronic exposure.* In conducting this chronic dietary risk assessment the Dietary Exposure Evaluation Model (DEEM™) analysis evaluated the individual food consumption as reported by respondents in the USDA 1989–1992 nationwide Continuing

Surveys of Food Intake by Individuals (CSFII) and accumulated exposure to the chemical for each commodity. The following assumptions were made for the chronic exposure assessments:

The chronic dietary (food only) assessment is based on Tier 2 assumptions (tolerance-level residues and 25% crop treated estimates). For all population subgroups, the estimated dietary (food only) risks are less than 1% of the chronic PAD.

iii. *Cancer*. The cancer dietary (food only) assessment is based on Tier 2 assumptions (tolerance-level residues and 25% crop treated estimates). Based on these assumptions, the estimated dietary exposure for the U.S. Population is 0.000013 mg/kg/day. Applying a Q^{1*} of $4.85x10^{-2}$ $(mg/kg/day)^{-1}$ results in a cancer risk estimate of $6.5x10^{-7}$. Generally the Agency is not concerned with cancer risk less than the range of $1x10^{-6}$.

iv. *Anticipated residue and percent crop treated (PCT) information*.Section 408(b)(2)(F) of the FFDCA states that the Agency may use data on the actual percent of food reated for assessing chronic dietary risk only if the Agency can make the following findings: Condition 1, that the data used are reliable and provide a valid basis to show what percentage of the food derived from such crop is likely to contain such pesticide residue; Condition 2, that the exposure estimate does not underestimate exposure for any significant subpopulation group; and Condition 3, if data are available on pesticide use and food consumption in a particular area, the exposure estimate does not understate exposure for the population in such area. In addition, the Agency must provide for periodic evaluation of any estimates used. To provide for the periodic evaluation of the estimate of PCT as required by section 408(b)(2)(F) of the FFDCA, EPA may require registrants to submit data on PCT.

The Agency used PCT information as follows:

For the acute dietary risk assessment, the Agency assumed 100% crop treated i.e., that the entire crop was treated. For chronic (non-cancer and cancer) dietary analyses it was assumed that 25% of the corn was treated.

For assessing chronic dietary risk, the Agency believes that the three conditions listed above have been met. With respect to condition 1, it was assumed that 25% of the corn was treated. The information was based on the percent crop treated data for acetochlor since 4-(dichloroacetyl)-1-oxa-4-azaspiro[4.5]decane can be used as a safener with acetochlor to treat corn. This 25% crop treated estimate is likely to significantly overestimate the percentage of corn treated with 4-(dichloroacetyl)-1-oxa-4-azaspiro[4.5]decane. According to information supplied by the USDA, Economic Research Service, the total production of corn in the United States. was 239.55 and 251.85 million metric tons for the growing seasons of 1999–2000 and 2000–2001 respectively. United States corn imports were 328.393 and 195.603 metric tons for the years 1999 and 2000 respectively. Thus, treated amount of imported corn is less than 1% of domestic U.S. corn production.

As to conditions 2 and 3, regional consumption information and the consumption information for significant subgroups is taken into account through EPA's computer-based model for evaluating the exposure of significant subpopulations including several regional groups. Use of this consumption information in EPA's risk assessment procedure ensures that EPA's exposure estimate does not understate exposure for any significant subpopulation group and allows the Agency to be reasonably certain that no regional population is exposed to residue evels higher than those estimated by the agency. Other than the data available through national food consumption surveys, EPA does not have available information on the regional consumption of food.

2. *Dietary exposure from drinking water*. Residues in drinking water (either ground water or surface water) are not expected to result as a consequence of establishing an import tolerance for 4-(dichloroacetyl)-1-oxa-4-azaspiro[4.5]decane residues in or on corn commodities. There are currently no registered products containing 4-(dichloroacetyl)-1-oxa-4-azaspiro[4.5]decane being distributed or sold in the United States. The one registered product containing 4-(dichloroacetyl)-1-oxa-4-azaspiro[4.5]decane is pending request for cancellation (October 16, 2002, 67 FR 63909; FRL–7276–6). Therefore, exposure through drinking water is unlikely.

3. *From non-dietary exposure*. The term ''residential exposure'' is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets). 4-(dichloroacetyl)-1-oxa-4-azaspiro[4.5]decane is not registered in the United States and the petition is for import tolerances only, therefore, there would be no residential exposure.

4. *Cumulative exposure to substances with a common mechanism of toxicity*. Section 408(b)(2)(D)(v) of the FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider ''available information'' concerning 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 4-(dichloroacetyl)-1-oxa-4-azaspiro[4.5]decane 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, 4-(dichloroacetyl)-1-oxa-4-azaspiro[4.5]decane 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 4-(dichloroacetyl)-1-oxa-4-azaspiro[4.5]decane 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. Safety Factor for Infants and Children

1. *In general*. Section 408 of the FFDCA 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 on toxicity and exposure 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 MOE analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans.

2. *Prenatal and postnatal sensitivity*. There are two developmental toxicity studies in the rat. In a 1995 study, fetal malfunctions were observed at 200 mg/kg/day in the presence of minimal maternal toxicity (clinical signs), Both maternal and developmental OAEL's are 80 mg/kg/day. In a 1989 study, resorption and malfunctions were observed in the presence of a maternal clinical signs including decreased body

weight gain and food consumption at 150 mg/kg/day. Maternal toxicity at 75 my/kg/day is a conservative call based on decreased food consumption. The susceptibility assumption is based on effects at the high dose.

In a development toxicity study with rabbits there is no evidence of increased susceptibility since there was no evidence of developmental toxicity at the highest dose tested in the presence of maternal toxicity. In the two generation reproductive toxicity study in rats, there is no evidence of increased susceptibility of offspring.

3. *Conclusion*. The Agency determined that the FQPA safety factor of 10x for protection of infants and children be reduced to 3x since:

i. The toxicity data base is complete for an FQPA assessment;

ii. No increase in susceptibility was seen in the rabbit developmental study or in the 2–generation reproduction in rats;

iii. A developmental neurotoxicity study is not required for 4-(dichloroacetyl)-1-oxa-4-azaspiro[4.5]decane; and

iv. The exposure data are understood and the food exposure assessment will not underestimate the residues resulting from the use of 4-(dichloroacetyl)-1-oxa-4-azaspiro[4.5]decane.

E. Aggregate Risks and Determination of Safety

1. *Aggregate risks*. The Agency has concluded that exposure to 4-(dichloroacetyl)-1-oxa-4-azaspiro[4.5]decane from food imported corn commodities will utilize less than 1% of the aPAD and cPAD for all population groups.

The cancer risk estimates from aggregate exposure to 4-(dichloroacetyl)-1-oxa-4-azaspiro[4.5]decane in food has also been assessed. For the U.S. population, the cancer dietary risk from food is 6.5×10^{-7} which is below the Agency's concern for excess lifetime cancer risk.

There are no uses for 4-(dichloroacetyl)-1-oxa-4-azaspiro[4.5]decane that will result in drinking water or residential exposure.

2. *Determination of safety*. Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, and to infants and children from aggregate exposure to 4-(dichloroacetyl)-1-oxa-4-azaspiro[4.5]decane residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

An adequate enforcement method (gas chromatography method using electron capture detection) 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, 1200 Pennsylvania Ave., NW., Washington DC 20460–0001; telephone number; (703) 305–5229; e-mail address: furlow.calvin@epa.gov.

B. International Residue Limits

There are no CODEX, Canadian or Mexican limits for residues of 4-(dichloroacetyl)-1-oxa-4-azaspiro[4.5] decane in corn.

V. Conclusion

Therefore, import tolerances are established for residues of 4-(dichloroacetyl)-1-oxa-4-azaspiro[4.5]decane, in or on corn commodities at 0.005 ppm.

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, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) of the FFDCA 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) of the FFDCA, as was provided in the old sections 408 and 409 of the FFDCA. 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 ID number OPP–2002–0245 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 March 31, 2003.

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 (1900C), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460. You may also deliver your request to the Office of the Hearing Clerk in Rm. 104, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. 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 (703) 603–0061.

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, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.

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, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.

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 ID number OPP–2002–0245, to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001. 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: opp-docket@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 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. Statutory and Executive Order Reviews

This final rule establishes a tolerance under section 408(d) of the FFDCA in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Because this rule has been exempted from review under Executive Order 12866 due to its lack of significance, this rule is not subject to Executive Order 13211, *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001). 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 special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994); or 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 section 408(d) of the FFDCA, such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. 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 section 408(n)(4) of the FFDCA. For these same reasons, the Agency has determined that this rule does not have any ''tribal implications'' as described in Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000). Executive Order 13175, requires EPA to develop an accountable process to ensure ''meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.'' ''Policies that have tribal implications'' is defined in the Executive order to include regulations that have ''substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.'' This rule will not have substantial direct effects on tribal governments, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

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: January 10, 2003.

Peter Caulkins,

Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

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

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

2. Section 180.465 is revised to read as follows:

§ 180.465 4-(Dichloroacetyl)-1-oxa-4-azaspiro[4.5]decane.

(a) *General.* Tolerances are established for the residues of 4-(dichloroacetyl)-1-oxa-4-azaspiro[4.5]decane, (CAS No. 71526–07–3) when used as an inert ingredient (safener) in or on the following raw agricultural commodities:

Commodity[1]	Parts per million
Corn, field, forage	0.005
Corn, field, grain	0.005
Corn, field, stover	0.005
Corn, pop, grain	0.005
Corn, pop, stover	0.005

[1]There are no U.S. registered products containing 4-(dichloroacetyl)-1-oxa-4-azaspiro[4.5]decane as of June 17, 2002.

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

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

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

[FR Doc. 03–1768 Filed 1–28–03; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 268

Land Disposal Restrictions

CFR Correction

In Title 40 of the Code of Federal Regulations, Parts 266 to 299, revised as of July 1, 2002, § 268.44 is corrected in the table by adding footnote 8 to read as follows:

§ 268.44 Variance from a treatment standard.

Table–Wastes Excluded From the Treatment Standards Under § 268.40

* * * * *[8]

[8]Dupont Environmental Treatment–Chambers Works must dispose of this waste in their on–site Subtitle C hazardous waste landfill.

[FR Doc. 03–55501 Filed 1–28–03; 8:45 am]

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CHEMICAL SAFETY AND HAZARD INVESTIGATION BOARD

40 CFR Part 1610

Transcripts of Witness Testimony in Investigations

AGENCY: Chemical Safety and Hazard Investigation Board.

ACTION: Final rule.

SUMMARY: The Chemical Safety and Hazard Investigation Board (''CSB'' or ''Board'') implements a new rule concerning transcripts of the testimony of witnesses appearing at Board depositions. The rule provides that witnesses have the right to petition to procure a copy of a transcript of their testimony, except that due to the nonpublic nature of Board depositions, witnesses (and their counsel) may for good cause be limited to inspection of the official transcript of their testimony.

DATES: Effective February 28, 2003.

FOR FURTHER INFORMATION CONTACT: Raymond C. Porfiri, 202–261–7600.

SUPPLEMENTARY INFORMATION: The Chemical Safety and Hazard Investigation Board is mandated by law to ''investigate (or cause to be investigated), determine and report to the public in writing the facts, conditions, and circumstances and the cause or probable cause of any accidental release [within its jurisdiction] resulting in a fatality, serious injury or substantial property damages.'' 42 U.S.C. 7412(r)(6)(C)(i). The Board has developed practices and procedures for conducting investigations under this provision in 40 CFR 1610 and has spelled out the rights of witnesses to be represented in such proceedings (section 1610.1) and rules concerning attorney misconduct, (section 1610.2) and sequestration of witnesses and exclusion of counsel (section 1610.3). The Board has determined that it would be useful to add a provision concerning the taking, handling, and inspection of transcripts of Board depositions.

In the **Federal Register** of December 9, 2002 (67 FR 72890), the CSB published a proposed rule setting forth new practices and procedures for the taking, handling, and inspection of transcripts of Board depositions. The proposed rule provided for a 30-day comment period. No comments were received in response to the proposed rule and invitation for comments. This final rule is unchanged from the proposed rule.

In promulgating this regulation, the Board is following section 555(c) of the Administrative Procedure Act, which provides:

> A person compelled to submit data or evidence is entitled to retain or, on payment of lawfully prescribed costs, procure a copy or transcript thereof, except that in a nonpublic investigatory proceeding the witness may for good cause be limited to inspection of the official transcript of his testimony.

On its face, section 555(c) recognizes that it is sometimes necessary to balance a compelled witness' right to have access to his or her testimony, and an agency's need to limit the dissemination of sensitive matters revealed in such testimony.

Board depositions are nonpublic investigatory proceedings. Attendance at depositions is limited to the minimum number of necessary CSB staff, the witness, and one attorney representing the witness. Depositions are not open to multiple attorneys representing the witness, non-attorney representative of the witness, or representatives of other parties (40 CFR part 1610). The Board's regulations on Freedom of Information Act requests (40 CFR part 1601) and on Production of Records in Legal Proceedings (40 CFR part 1612) further demonstrate that the Board recognizes that some of the information obtained in its investigation may not be appropriate for public dissemination.

Several considerations have led the Board to conclude that it is necessary to establish a mechanism to ensure appropriate control over the dissemination of deposition transcripts while also respecting witness' rights under the Administrative Procedure Act. Because of the nature of Board investigations, deposition testimony may contain sensitive information. For example, testimony may reveal trade secrets and confidential business information, which are protected by the Trade Secrets Act, 18 U.S.C. 1905.

Protection of the integrity of Board investigations also necessitates control over the dissemination of deposition transcripts. First-hand witness accounts are an invaluable source of information about the events leading to, and causes of, chemical incidents. Witnesses can be reluctant to cooperate, though, out of fear of whistleblower retaliation. The CSB would likely have greater difficulty obtaining vital testimony if witnesses believed that their testimony could easily become known to their employers and to other witnesses. Reasonable limits, such as those included in this regulation, on the dissemination of transcripts also helps to prevent the coaching of future witnesses based on testimony already given. Such preparation is undesirable in health and safety investigations, where it is important to gather unvarnished facts and untainted recollections.

Ultimately, the Board's duty is to obtain the facts about chemical incidents and to report objectively based on those facts. The Administrative Procedure Act provision limiting the release of transcripts in non-public proceedings is intended to facilitate missions such as the Board's. It protects