promoters, terminators, and enhancers, that control the expression of the genetic material encoding the Cry1F protein.

[FR Doc. 04–21877 Filed 9–29–04; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2004–0318; FRL–7680–8]

Dichlormid; Time-Limited Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes time-limited tolerances for residues of the inert ingredient (herbicide safener) dichlormid (Acetamide, 2,2-dichloro-*N,N*-di-2-propenyl-) in or on sweet corn commodities at 0.05 parts per million (ppm). Dow AgroSciences requested this tolerance under the Federal Food, Drug, and Cosmetic Act, (FFDCA) as amended by the Food Quality Protection Act of 1996 (FQPA). The tolerances will expire on December 31, 2005.

DATES: This regulation is effective September 30, 2004. Objections and requests for hearings must be received on or before November 29, 2004.

ADDRESSES: To submit a written objection or hearing request follow the detailed instructions as provided in Unit VI. of the **SUPPLEMENTARY INFORMATION**. After submitting your original written objection or hearing request as instructed in Unit VI., you can use EDOCKET or regulations.gov to submit the requested copy (see also Unit VI.A.2.). EPA has established a docket for this action under Docket identification (ID) number OPP–2004–0318. All documents in the docket are listed in the EDOCKET index at *http://www.epa.gov/edocket*. Although listed in the index, some information is not publicly available, i.e., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically in EDOCKET or in hard copy at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1801 S. Bell St., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: Kathryn Boyle, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: 703–305– 6304; e-mail *address:boyle.kathryn@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

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

- Industry (NAICS 111), e.g., Crop Production, e.g., agricultural workers; greenhouse, nursery, and floriculture workers; farmers.
- Industry (NAICS 112), e.g., Animal Production, e.g., cattle ranchers and farmers, dairy cattle farmers, livestock farmers.
- Industry (NAICS 311), e.g., Food Manufacturing, e.g., agricultural workers; farmers; greenhouse, nursery, and floriculture workers; ranchers; pesticide applicators.
- Industry (NAICS 32532), e.g., Pesticide Manufacturing, e.g., agricultural workers; commercial applicators; farmers; greenhouse, nursery, and floriculture workers; residential users.

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 person listed under **FOR FURTHER INFORMATION CONTACT**.

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

In addition to using EDOCKET (*http://www.epa.gov/edocket/*), 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 E-CFR Beta Site Two at *http://www.gpoaccess.gov/ecfr/*. To access the OPPTS Harmonized Guidelines referenced in this document, go directly to the guidelines at*http://www.epa.gpo/opptsfrs/home/guidelin.htm/*.

II. Background and Statutory Findings

In the **Federal Register** of November 21, 2003 (68 FR 65708) (FRL–7333–7), EPA issued a notice pursuant to section 408(d)(3) of the FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 3E6676) by Dow AgroSciences LLC, 9330 Zionsville Rd., Indianapolis, IN 46268. This notice included a summary of the petition prepared by Dow AgroSciences, the petitioner.

The petition requested that 40 CFR 180.469 be amended by establishing time-limited tolerances for residues of the herbicide safener dichlormid, (*N,N*-diallyl-2,2-dichloroacetamide or Acetamide, 2,2-dichloro-*N,N*-di-2-propenyl-) (CAS Reg. No. 37764 –25–3), in or on sweet corn commodities at 0.05 parts per million (ppm). There were no comments received in response to the notice of filing.

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 ''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. 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 time-limited tolerances for residues of dichlormid on sweet corn commodities at 0.05 ppm. EPA's assessment of exposures and risks associated with establishing the time-limited tolerances follows.

A. Toxicological Profile and Endpoints

In 1999, the Agency prepared a risk assessment which was used as the basis for establishing time-limited tolerances for residues of dichlormid in or on field and pop corn commodities. A final rule for these time-limited tolerances published in the **Federal Register** of March 27, 2000 (65 FR 16143) (FRL–6498–7). Based on that risk assessment, EPA concluded at that time that all of the risks were below the Agency's level of concern and there was a reasonable certainty that no harm would result to the general population, and to infants and children from aggregate exposure to residues of dichlormid on corn commodities.

No additional toxicity data has been reviewed and evaluated by the Agency since that time. For a complete description of the toxicological profile and endpoints, the uncertainty factors, the exposure assessment which included dietary exposure for both food and drinking water, the safety factor for infants and children, and aggregate risk for dichlormid, see the final rule of March 27, 2000.

In response to the new petition, to establish time-limited tolerances for sweet corn commodities, the Agency has prepared a new assessment that evaluates the acute and chronic dietary and drinking water risks from exposure to dichlormid in or on field, pop and sweet corn commodities. The drinking water exposure estimates are the same as those in the March 27, 2000 Final Rule. Since, no other assessments or evaluations are needed for assessing the risk of dichlormid, only the acute and chronic scenarios are discussed in Unit III. below.

B. Exposure Assessment

1. *Dietary exposure from food and feed uses.* Time-limited tolerances (expiring December 31, 2005) are established in 40 CFR 180.469 for residues of dichlormid, in or on field and pop corn commodities. Risk assessments were conducted by EPA to assess dietary exposures from dichlormid in or on field, pop and sweet corn commodities 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.

In conducting the acute dietary risk assessment EPA used the Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM-FCID™), which incorporates food consumption data as reported by respondents in the USDA 1994–1996 and 1998 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 risk analyses incorporated tolerance level residues and assumed 100% of the corn commodities were treated with dichlormid.

ii. *Chronic exposure.* In conducting the chronic dietary risk assessment EPA used the DEEM-FCID™, which incorporates food consumption data as reported by respondents in the USDA 1994–1996 and 1998 Nationwide CSFII, and accumulated exposure to the chemical for each commodity. The following assumptions were made for the chronic exposure assessments: The chronic dietary risk analyses incorporated tolerance level residues and assumed 100% of the corn commodities had been treated with dichlormid.

2. *Dietary exposure from drinking water.* The Agency lacks sufficient monitoring exposure data to complete a comprehensive dietary exposure analysis and risk assessment for dichlormid in drinking water. Because the Agency does not have comprehensive monitoring data, drinking water concentration estimates are made by reliance on simulation or modeling taking into account data on the physical characteristics of dichlormid.

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.

The Agency used the Generic Estimated Environmental Concentration (GENEEC) to estimate pesticide concentrations 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.

Using GENEEC 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

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.

None of these models include consideration of the impact processing (mixing, dilution, or treatment) of raw water for distribution as drinking water would likely have on the removal of pesticides from the source water. The primary use of these models by the Agency at this stage is to provide a coarse screen for sorting out pesticides for which it is highly unlikely that drinking water concentrations would ever exceed human health levels of concern.

Since the models used are considered to be screening tools in the risk assessment process, the Agency does not use EECs from these models to quantify drinking water exposure and risk as a percent of reference dose (%RfD) or percent of population adjusted dose (%PAD). Instead drinking water levels of comparison (DWLOCs) are calculated and used as a point of comparison against the model estimates of a pesticide's concentration in water. DWLOCs are theoretical upper limits on a pesticide's concentration in drinking water in light of total aggregate exposure to a pesticide in food, and from residential uses. Since DWLOCs address total aggregate exposure to dichlormid they are further discussed in Unit III.D.

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). Dichlormid is not approved for use on

any sites that would result in residential exposure.

4. *Cumulative Effects.* 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 the cumulative effects of a particular pesticide's residues and ''other substances that have a common mechanism of toxicity.''

Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to dichlormid. Dichlormid does not appear to produce a toxic metabolite produced by other substances. For the purposes of this 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 policy statements released by EPA's Office of Pesticide Programs concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA's website at *http://www.epa.gov/pesticides/cumulative/*.

C. 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 database 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. In applying this provision, EPA either retains the default value of 10X when reliable data do not support the choice of a different factor, or, if reliable data are available, EPA uses a different additional safety factor value based on the use of traditional uncertainty factors and/or special FQPA safety factors, as appropriate.

2. *Conclusion.* The additional FQPA safety factor of 10X is retained for acute risks 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. The additional FQPA safety factor of 30X is applied for chronic risks for the reasons discussed above for acute risks and for the data gap for the chronic toxicity study in dogs.

D. Aggregate Risks and Determination of Safety

To estimate total aggregate exposure to a pesticide from food, drinking water, and residential uses, the Agency calculates DWLOCs which are used as a point of comparison against the model estimates of a pesticide's concentration in water. DWLOC values are not regulatory standards for drinking water. DWLOCs are theoretical upper limits on a pesticide's concentration in drinking water in light of total aggregate exposure to a pesticide in food and residential uses. In calculating a DWLOC, the Agency determines how much of the acceptable exposure (i.e., the PAD) is available for exposure through drinking water (e.g., allowable chronic water exposure (mg/kg/day) = cPAD - (average food + residential exposure)). This allowable exposure through drinking water is used to calculate a DWLOC.

A DWLOC will vary depending on the toxic endpoint, drinking water consumption, and body weights. Default body weights and consumption values as used by the USEPA Office of Water are used to calculate DWLOCs: 2 liter (L)/70 kg (adult male), 2L/60 kg (adult female), and 1L/10 kg (child). Default body weights and drinking water consumption values vary on an individual basis. This variation will be taken into account in more refined screening-level and quantitative drinking water exposure assessments. Different populations will have different DWLOCs. For dichlormid, a DWLOC was calculated for the acute and chronic scenarios for the U.S. population and for the most highly exposed population subgroup.

When EECs for surface water and groundwater are less than the calculated DWLOCs, the Office of Pesticide Programs (OPP) concludes with reasonable certainty that exposures to the pesticide in drinking water (when considered along with other sources of exposure for which OPP has reliable data) would not result in unacceptable levels of aggregate human health risk at this time. Because OPP considers the aggregate risk resulting from multiple exposure pathways associated with a pesticide's uses, levels of comparison in drinking water may vary as those uses change. If new uses are added in the future, OPP will reassess the potential impacts of residues of the pesticide in drinking water as a part of the aggregate risk assessment process.

1. *Acute risk.* Using the exposure assumptions previously discussed for acute exposure, the acute dietary exposure from food to dichlormid will occupy 3% of the aPAD for the U.S. population, and 9% of the aPAD for non-nursing infants <1 year old. In addition, there is potential for acute dietary exposure to dichlormid in drinking water. Since the modeled groundwater and surface water concentrations are less than the DWLOCs, EPA does not expect the aggregate exposure to exceed 100% of the aPAD, as shown in the following Table 1:

TABLE 1.—AGGREGATE RISK ASSESSMENT FOR ACUTE EXPOSURE TO DICHLORMID

Population Subgroup	aPAD /(mg/kg/day)	%aPAD/(Food)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Acute DWLOC (ppb)
U.S. Population	0.01	3	27.29	<1	338
Non-nursing infants (<1 year old)	0.01	9	27.29	<1	91

2. *Chronic risk.* Using the exposure assumptions previously described for chronic exposure, EPA has concluded that exposure to dichlormid from food will utilize 5% of the cPAD for the U.S. population, and 11% of the cPAD for children 1–6 years old. In addition, there is potential for chronic dietary exposure to dichlormid drinking water. Since the modeled groundwater and surface water concentrations are less than the DWLOCs, EPA does not expect

the aggregate exposure to exceed 100% of the cPAD, as shown in the following Table 2:

TABLE 2.—AGGREGATE RISK ASSESSMENT FOR CHRONIC (NON-CANCER) EXPOSURE TO DICHLORMID

Population Subgroup	cPAD /(mg/kg/day)	%cPAD/(Food)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Chronic DWLOC (ppb)
U.S. Population	0.0022	5	8.98	<1	73
Children (1-6 years old)	0.0022	11	8.98	<1	20

3. *Conclusion.* 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 residues of the herbicide safener dichlormid, (*N,N*-diallyl-2,2-dichloroacetamide or Acetamide, 2,2-dichloro-*N,N*-di-2-propenyl-) (CAS Reg. No. 37764 –25–3).

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 inerts 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. Analytical Enforcement Methodology

Adequate enforcement methodology (gas chromatography with a nitrogen selective detector) is available to enforce the tolerance expression. The method may be requested from: Calvin Furlow, Public Information and Record Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 305–5229; e-mail address: *furlow.calvin@epa.gov*.

C. International Residue Limits

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

D. Conditions

There are several data gaps which needed to be addressed before permanent tolerances can be established. The following studies have been submitted for Agency review and evaluation (1) 2-Generation Reproduction Study-Rat, (2) General Metabolism (3) Acute Neurotoxicity (4) Subchronic Neurotoxicity, (5) Crop Field Trials, and (6) Rotational Crop (Confined). The Agency will review and evaluate these studies, and then prepare a new risk assessment.

The data gaps are not as extensive as it would seem. For the crop field trials, both pre-and post-emergent data using dichlormid have been provided. The additional field trials are to fulfill the guideline requirements. To account for the incomplete toxicological database, the Agency retained an additional 10X safety factor for infants and children as to acute risk and an additional 30X safety factor as to chronic risk.

V. Conclusion

Therefore, time-limited tolerances expiring December 31, 2005, are established for residues of the herbicide safener dichlormid, (*N,N*-diallyl-2,2-dichloroacetamide or Acetamide, 2,2-dichloro-*N,N*-di-2-propenyl-) (CAS Reg. No. 37764–25–3) in or on sweet corn commodities at 0.05 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), 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–2004–0318 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 November 29, 2004.

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 (1900L), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001. You may also deliver your request to the Office of the Hearing Clerk in Suite 350, 1099 14th St., NW., Washington, DC 20005. 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) 564–6255.

2. *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 **ADDRESSES**. Send us your copies, identified by docket ID number OPP-2004–0318, using one of the following methods:

• *Federal eRulemaking Portal*: *http://www.regulations.gov/*. Follow the on-line instructions for submitting comments.

• *Agency Website*: *http://www.epa.gov/edocket/*. EDOCKET, EPA's electronic public docket and comment system, is EPA's preferred method for receiving electronic copies. Follow the on-line instructions for submitting materials to the docket.

• *E-mail*: *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.

• *Mail*: 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.

• *Hand Delivery*: In person or by courier, bring a copy to the location of the PIRIB described in *ADDRESSES*.

Do not include any CBI in the copy you submit for the public docket.

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. Congressional Review Act

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: September 23, 2004.

Lois Rossi,

Director, Registration Division, Office of Pesticide Programs.

■ Therefore, 40 CFR chapter I is amended as follows:

PART180-[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 amended by revising the section heading, and the introductory text of paragraph (a), and by adding alphabetically new commodities to the table in paragraph (a) to read as follows:

§ 180.469 Dichlormid; tolerances for residues.

(a) *General.* Tolerances are established for residues of dichormid; (Acetamide, 2,2-dichloro-*N,N*-di-2-propenyl-)(CAS Reg. No. 37764–25–3) when used as an inert ingredient (herbicide safener) in pesticide formulations in or on the following food commodities:

Commodity	Parts per million	Expiration/ revocation date
* *	* *	*
Corn, sweet, forage	0.05	12/31/05
Corn, sweet, kernel plus cob with husks removed	0.05	12/31/05
Corn, sweet, stover	0.05	12/31/05

* * * * *

[FR Doc. 04–21930 Filed 9–29–04; 8:45 am]
BILLING CODE6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2004–0211; FRL–7367–4]

Cyazofamid; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for the combined residues of cyazofamid and its metabolite CCIM in or on potatoes, tomatoes, cucurbits, and imported wine. ISK Biosciences Corporation requested this tolerance under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA).

DATES: This regulation is effective September 30, 2004. Objections and requests for hearings must be received on or before November 29, 2004.

ADDRESSES: To submit a written objection or hearing request follow the detailed instructions as provided in Unit VI. of the **SUPPLEMENTARY INFORMATION.** EPA has established a docket for this action under Docket ID number OPP–2004–0211. All documents in the docket are listed in the EDOCKET index at*http://www.epa.gov/edocket.* Although listed in the index, some information is not publicly available, *i.e.*, CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically in EDOCKET or in hard copy at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1801 S. Bell St., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: Janet Whitehurst, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW.,Washington, DC 20460–0001; telephone number: (703) 305–6129; e-mail address:*whitehurst.janet@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

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

- Crop production (NAICS 111), e.g., agricultural workers; greenhouse, nursery, and floriculture workers; farmers.
- Animal production (NAICS 112), e.g., cattle ranchers and farmers, dairy cattle farmers, livestock farmers.
- Food manufacturing (NAICS 311), e.g., agricultural workers; farmers; greenhouse, nursery, and floriculture workers; ranchers; pesticide applicators.
- Pesticide manufacturing (NAICS 32532), e.g., agricultural workers; commercial applicators; farmers; greenhouse, nursery, and floriculture workers; residential users.

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 person listed under **FOR FURTHER INFORMATION CONTACT**.

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

In addition to using EDOCKET *(http://www.epa.gov/edocket/)*, 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 E-CFR Beta Site Two at *http://www.gpoaccess.gov/ecfr/.* To access the OPPTS Harmonized Guidelines referenced in this document, go directly to the guidelines at*http://www.epa.gpo/opptsfrs/home/guidelin.htm/.*

II. Background and Statutory Findings

In the **Federal Register** of May 7, 2003 (68 FR 24463) (FRL–7305–7), EPA issued a notice pursuant to section 408(d)(3) of the FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 1F06305) by ISK Biosciences Corporation, Concord, OH. That notice included a summary of the petition prepared by ISK Biosciences Corporation, the registrant. There were no comments received in response to the notice of filing.

The petition requested that 40 CFR part 180 be amended by establishing tolerances for combined residues of the fungicide cyazofamid, 4-chloro-2-cyano-*N,N*-dimethyl-5-(4-methylphenyl)-1H-imidazole-1-sulfonamide and its metabolite CCIM, 4-chloro-5-(4-methylphenyl)-1H-imidazole-2-carbonitrile, expressed as cyazofamid, in or on cucurbit vegetables (Group 9) at 0.10 parts per million (ppm), potato at 0.01 ppm, tomato at 0.20 ppm, and grape wine at 1.0 ppm.

Following review of the residue and metabolism data, EPA has made several minor changes to the proposed tolerances. For cucurbits and potatoes, EPA expanded the tolerance expression to cover both cyazofamid and its metabolite CCIM, which is also a residue of concern. This expansion of the toleranceexpression necessitated a raising of the tolerance level for potatoes from 0.01 ppm to 0.02 ppm. No change in the tolerance values was needed for tomatoes. Finally, residue and processing data for grape wine showed that residues might slightly exceed 1.0