

Hydrocarbons, Incorporation by reference, Intergovernmental relations, Lead, Nitrogen dioxide, Ozone, Particulate matter, Reporting and recordkeeping requirements, Sulfur oxides, Volatile organic compounds.

40 CFR Part 70

Environmental protection, Administrative practice and procedure, Air pollution control, Intergovernmental relations, Operating permits, Reporting and recordkeeping requirements.

Dated: April 2, 1997.

Dennis Grams,

Regional Administrator.

Chapter I, title 40 of the Code of Federal Regulations is amended as follows:

PART 52—[AMENDED]

1. The authority citation for part 52 continues to read as follows:

Authority: 42 U.S.C. 7401–7671q.

Subpart AA—Missouri

2. Section 52.1320 is amended by adding paragraph (c)(96) to read as follows:

§ 52.1320 Identification of plan.

* * * * *

(c) * * *

(96) A revision to the Missouri SIP submitted by the Missouri Department of Natural Resources on August 6, 1996, pertaining to its intermediate operating permit program. The EPA is not approving provisions of the rules which pertain to the basic operating permit program.

(i) Incorporation by reference.

(A) Regulations 10 CSR 10–6.020, Definitions and Common Reference Tables, effective June 30, 1996; and 10 CSR 10–6.065, Operating Permits, effective June 30, 1996, except sections (4)(A), (4)(B), and (4)(H).

PART 70—[AMENDED]

1. The authority citation for part 70 continues to read as follows:

Authority: 42 U.S.C. 741, et seq.

2. Appendix A to part 70 is amended by adding paragraph (b) to the entry for Missouri to read as follows:

Appendix A to Part 70—Approval Status of State and Local Operating Permits Programs

* * * * *

Missouri

(a) * * *

(b) The Missouri Department of Natural Resources program submitted on January 13, 1995; August 14, 1995; September 19, 1995; October 16, 1995; and August 6, 1996.

Full approval effective June 13, 1997.

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[FR Doc. 97–12631 Filed 5–13–97; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300485; FRL–5716–1]

RIN 2070–AB78]

Cymoxanil; Pesticide Tolerance for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a time-limited tolerance for residues of the fungicide cymoxanil in or on the raw agricultural commodity potatoes in connection with EPA's granting of emergency exemptions under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act authorizing use of cymoxanil on potatoes in the states of Alabama, California, Colorado, Delaware, Florida, Idaho, Indiana, Maine, Massachusetts, Michigan, Minnesota, Montana, Nebraska, Nevada, New Jersey, New York, North Carolina, North Dakota, Oregon, Pennsylvania, Virginia, Washington and Wisconsin. This tolerance will expire and is revoked on March 15, 1999.

DATES: This regulation becomes effective May 14, 1997. Objections and requests for hearings must be received by EPA on or before July 14, 1997.

ADDRESSES: Written objections and hearing requests, identified by the docket control number, [OPP–300485], must be submitted to: Hearing Clerk (1900), Environmental Protection Agency, Rm. M3708, 401 M St., SW., Washington, DC 20460. Fees accompanying objections and hearing requests shall be labeled "Tolerance Petition Fees" and forwarded to: EPA Headquarters Accounting Operations Branch, OPP (Tolerance Fees), P.O. Box 360277M, Pittsburgh, PA 15251. A copy of any objections and hearing requests filed with the Hearing Clerk identified by the docket control number, [OPP–300485], must also be submitted to: Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring a copy of objections and hearing requests to Rm. 1132, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA.

A copy of objections and hearing requests filed with the Hearing Clerk may also be submitted electronically by sending electronic mail (e-mail) to: opp-docket@epamail.epa.gov. Copies of objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Copies of objections and hearing requests will also be accepted on disks in WordPerfect 5.1 file format or ASCII file format. All copies of objections and hearing requests in electronic form must be identified by the docket number [OPP–300485]. No Confidential Business Information (CBI) should be submitted through e-mail. Electronic copies of objections and hearing requests on this rule may be filed online at many Federal Depository Libraries.

FOR FURTHER INFORMATION CONTACT: By mail: Libby Pemberton, Registration Division (7505W), Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail address: Sixth Floor, Crystal Station #1, 2800 Jefferson Davis Hwy., Arlington, VA, (703) 308–8326, e-mail: pemberton.libby@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: EPA, on its own initiative, pursuant to section 408(e) and (l)(6) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(e) and (l)(6), is establishing a tolerance for residues of the fungicide cymoxanil on potatoes at 0.05 parts per million (ppm). This tolerance will expire and be revoked by EPA on March 15, 1999. After March 15, 1999, EPA will publish a document in the **Federal Register** to remove the revoked tolerance from the Code of Federal Regulations.

I. Background and Statutory Authority

The Food Quality Protection Act of 1996 (FQPA) (Pub. L. 104–170) was signed into law August 3, 1996. FQPA amends both the FFDCA, 21 U.S.C. 301 et seq., and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. 136 et seq. Among other things, FQPA amends FFDCA to bring all EPA pesticide tolerance-setting activities under a new section 408 with a new safety standard and new procedures. These activities are described below and discussed in greater detail in the final rule establishing the time-limited tolerance associated with the emergency exemption for use of propiconazole on sorghum (61 CFR 58135, November 13, 1996)(FRL–5572–9).

New 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...."

Section 18 of FIFRA authorizes EPA to exempt any Federal or State agency from any provision of FIFRA, if EPA determines that "emergency conditions exist which require such exemption." This provision was not amended by FQPA. EPA has established regulations governing such emergency exemptions in 40 CFR part 166. Section 408(l)(6) of the FFDCA requires EPA to establish a time-limited tolerance or exemption from the requirement for a tolerance for pesticide chemical residues in food that will result from the use of a pesticide under an emergency exemption granted by EPA under section 18 of FIFRA.

Because decisions on section 18-related tolerances must proceed before EPA reaches closure on several policy issues relating to interpretation and implementation of the FQPA, EPA does not intend for its actions on such tolerance to set binding precedents for the application of section 408 and the new safety standard to other tolerances and exemptions.

II. Emergency Exemptions for Cymoxanil on Potatoes and FFDCA Tolerances

EPA has authorized under FIFRA section 18 the use of cymoxanil on potatoes for control of late blight, as requested by the states previously listed. Recent failures to control late blight in potatoes as well as tomatoes with the registered fungicides, have been caused almost exclusively by immigrant strains of late blight (*Phytophthora infestans*), which are resistant to the control of choice, metalaxyl. Before the immigrant strains of late blight arrived, all of the strains in the United States were previously controlled by treatment with metalaxyl. Presently, there are no fungicides registered in the United States that will provide adequate control

of the immigrant strains of late blight. After having reviewed their submissions, EPA concurs that emergency conditions exist.

As part of its assessment of these specific exemptions, EPA assessed the potential risks presented by residues of cymoxanil on potatoes. In doing so, EPA considered the new safety standard in FFDCA section 408(b)(2), and EPA decided that the necessary tolerance under FFDCA section 408(l)(6) would clearly be consistent with the new safety standard and with FIFRA section 18. This tolerance for residues of cymoxanil will permit the marketing of potatoes treated in accordance with the provisions of the section 18 emergency exemptions. Consistent with the need to move quickly on these emergency exemptions in order to address an urgent non-routine situation and to ensure that the resulting food is safe and lawful, EPA is issuing this tolerance without notice and opportunity for public comment under section 408(e) as provided in section 408(l)(6). Although this tolerance will expire and is revoked on March 15, 1999, under FFDCA section 408(l)(5), residues of cymoxanil not in excess of the amount specified in these tolerances remaining in or on potatoes after that date will not be unlawful, provided the pesticide is applied during the term of, and in accordance with all the conditions of, section 18 of FIFRA. EPA will take action to revoke this tolerance earlier if any experience with, scientific data on, or other relevant information on this pesticide indicate that the residues are not safe.

EPA has not made any decisions about whether cymoxanil meets EPA's registration requirements for use on potatoes or whether a permanent tolerance for this use would be appropriate. This tolerance does not serve as a basis for registration of cymoxanil by a State for special local needs under FIFRA section 24(c). Nor does this action serve as the basis for any States other than previously listed and states which are subsequently granted specific exemptions for this use to use this pesticide on this crop under section 18 of FIFRA without following all provisions of section 18 as identified in 40 CFR part 166. For additional information regarding the emergency exemptions for cymoxanil, contact the Agency's Registration Division at the address provided above.

III. Risk Assessment and Statutory Findings

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. For many of these studies, a dose response relationship can be determined, which provides a dose that causes adverse effects (threshold effects) and doses causing no observed effects (the "no-observed effect level" or "NOEL").

Once a study has been evaluated and the observed effects have been determined to be threshold effects, EPA generally divides the NOEL from the study with the lowest NOEL by an uncertainty factor (usually 100 or more) to determine the Reference Dose (RfD). The RfD is a level at or below which daily aggregate exposure over a lifetime will not pose appreciable risks to human health. An uncertainty factor (sometimes called a "safety factor") of 100 is commonly used since it is assumed that people may be up to 10 times more sensitive to pesticides than the test animals, and that one person or subgroup of the population (such as infants and children) could be up to 10 times more sensitive to a pesticide than another. In addition, EPA assesses the potential risks to infants and children based on the weight of the evidence of the toxicology studies and determines whether an additional uncertainty factor is warranted. Thus, an aggregate daily exposure to a pesticide residue at or below the RfD (expressed as 100 percent or less of the RfD) is generally considered acceptable by EPA.

Lifetime feeding studies in two species of laboratory animals are conducted to screen pesticides for cancer effects. When evidence of increased cancer is noted in these studies, the Agency conducts a weight of the evidence review of all relevant toxicological data including short term and mutagenicity studies and structure activity relationship. Once a pesticide has been classified as a potential human carcinogen, different types of risk assessments (e.g., linear low dose extrapolations or margin of exposure (MOE) calculation based on the appropriate NOEL) will be carried out based on the nature of the carcinogenic response and the Agency's knowledge of its mode of action.

In examining aggregate exposure, FFDCA section 408 requires that EPA take into account available and reliable information concerning exposure from the pesticide residue in the food in question, residues in other foods for

which there are tolerances, and other non-occupational exposures, such as where residues leach into groundwater or surface water that is consumed as drinking water. Dietary exposure to residues of a pesticide in a food commodity are estimated by multiplying the average daily consumption of the food forms of that commodity by the tolerance level or the anticipated pesticide residue level. The Theoretical Maximum Residue Contribution (TMRC) is an estimate of the level of residues consumed daily if each food item contained pesticide residues equal to the tolerance. The TMRC is a "worst case" estimate since it is based on the assumptions that food contains pesticide residues at the tolerance level and that 100 percent of the crop is treated by pesticides that have established tolerances. If the TMRC exceeds the RfD or poses a lifetime cancer risk that is greater than approximately one in a million, EPA attempts to derive a more accurate exposure estimate for the pesticide by evaluating additional types of information (anticipated residue data and/or percent of crop treated data) which show, generally, that pesticide residues in most foods when they are eaten are well below established tolerances.

IV. 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. Cymoxanil is not registered by EPA for use in the United States. Nevertheless, EPA believes it has sufficient data to assess the hazards of cymoxanil and to make a determination on aggregate exposure, consistent with section 408(b)(2), for the time-limited tolerances for residues of cymoxanil on potatoes at 0.05 ppm. EPA's assessment of the dietary exposures and risks associated with establishing these tolerances follows.

A. Toxicological Profile

1. *Chronic toxicity.* Based on the available chronic toxicity data, the Office of Pesticide Programs (OPP) has selected an RfD for cymoxanil of 0.02 milligrams/kilogram/day (mg/kg/day). This RfD is based on a NOEL of 1.6 mg/kg/day in a 1-year dog feeding study, using an uncertainty factor of 100. The lowest observed effect level (LOEL) of 3.1 mg/kg/day was based on decreased food consumption, decreased body weight, and decreased feed efficiency.

2. *Acute toxicity.* Agency toxicologists have recommended that the acute

endpoint of 10 mg/kg/day from the rat developmental toxicity study be used for acute dietary risk calculations. The developmental LOEL of 25 mg/kg/day is based on increased skeletal effects in fetuses. The population of concern for this risk assessment is females 13+ years old.

3. *Short-term non-dietary inhalation and dermal toxicity.* The OPP recommends use of the developmental toxicity study in rabbits for short-term non-dietary risk calculations. The maternal NOEL was 8.0 mg/kg/day. At the LOEL of 16 mg/kg/day there was an increased incidence of animals with cold ears, reduced food consumption, decreased defecation, and decreased weight gain.

4. *Carcinogenicity.* Cymoxanil has not been classified as to carcinogenic potential. No cancer risks have been identified in the available cymoxanil data evaluation records.

B. Aggregate Exposure

There are no established U.S. tolerances for cymoxanil, and there are no registered uses for cymoxanil in the United States.

For the purpose of assessing chronic dietary exposure from cymoxanil, EPA assumed tolerance level residues and 100% of crop treated for the proposed use of cymoxanil. These conservative assumptions result in overestimation of human dietary exposures. Secondary residues of cymoxanil are not expected to transfer to animal commodities as a result of the proposed use.

In examining aggregate exposure, FQPA directs EPA to consider available information concerning exposures from the pesticide residue in food and all other non-occupational exposures. The primary non-food sources of exposure the Agency looks at include drinking water (whether from groundwater or surface water), and exposure through pesticide use in gardens, lawns, or buildings (residential and other indoor uses).

Because the Agency lacks sufficient water-related exposure data to complete a comprehensive drinking water risk assessment for many pesticides, EPA has commenced and nearly completed a process to identify a reasonable yet conservative bounding figure for the potential contribution of water related exposure to the aggregate risk posed by a pesticide. In developing the bounding figure, EPA estimated residue levels in water for a number of specific pesticides using various data sources. The Agency then applied the estimated residue levels, in conjunction with appropriate toxicological endpoints (RfD's or acute dietary NOEL's) and assumptions about

body weight and consumption, to calculate, for each pesticide, the increment of aggregate risk contributed by consumption of contaminated water. While EPA has not yet pinpointed the appropriate bounding figure for consumption of contaminated water, the ranges the Agency is continuing to examine are all below the level that would cause cymoxanil to exceed the RfD if the tolerances being considered in this document were granted. The Agency has therefore concluded that the potential exposures associated with cymoxanil in water, even at the higher levels the Agency is considering as a conservative upper bound, would not prevent the Agency from determining that there is a reasonable certainty of no harm if the tolerances are granted.

There is no entry for cymoxanil in the "Pesticides in Groundwater Data Base" (EPA 734-12-92-001, September 1992). There is no established Maximum Concentration Level (MCL) for residues of cymoxanil in drinking water. No drinking water health advisory levels have been established for cymoxanil. Cymoxanil is not registered for any residential uses so no exposure from this route is expected. Because there are no short- or intermediate-term non-dietary, non-occupational exposure scenarios associated with cymoxanil, a short- or intermediate-term aggregate risk assessment is not required.

C. Cumulative Exposure to Substances with 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." The Agency believes that "available information" in this context might include not only toxicity, chemistry, and exposure data, but also scientific policies and methodologies for understanding common mechanisms of toxicity and conducting cumulative risk assessments. For most pesticides, although the Agency has some information in its files that may turn out to be helpful in eventually determining whether a pesticide shares a common mechanism of toxicity with any other substances, EPA does not at this time have the methodologies to resolve the complex scientific issues concerning common mechanism of toxicity in a meaningful way. EPA has begun a pilot process to study this issue further through the examination of particular classes of pesticides. The Agency hopes that the results of this pilot process will

increase the Agency's scientific understanding of this question such that EPA will be able to develop and apply scientific principles for better determining which chemicals have a common mechanism of toxicity and evaluating the cumulative effects of such chemicals. The Agency anticipates, however, that even as its understanding of the science of common mechanisms increases, decisions on specific classes of chemicals will be heavily dependent on chemical specific data, much of which may not be presently available.

Although at present the Agency does not know how to apply the information in its files concerning common mechanism issues to most risk assessments, there are pesticides as to which the common mechanism issues can be resolved. These pesticides include pesticides that are toxicologically dissimilar to existing chemical substances (in which case the Agency can conclude that it is unlikely that a pesticide shares a common mechanism of activity with other substances) and pesticides that produce a common toxic metabolite (in which case common mechanism of activity will be assumed).

EPA does not have, at this time, available data to determine whether cymoxanil 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, cymoxanil 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 cymoxanil has a common mechanism of toxicity with other substances.

D. Safety Determinations For U.S. Population

Based on the completeness and reliability of the toxicity data, EPA has concluded that dietary exposure to cymoxanil in food from published tolerances will utilize less than 1 percent of the RfD for the U.S. population. A dietary (food only) MOE of 25,000 was calculated. This MOE value does not exceed the Agency's level of concern for acute dietary exposure. Whatever reasonable bounding figure the Agency eventually decides upon for the contribution from water, exposure to cymoxanil is not expected to exceed the RfD or to pose acute dietary concerns. EPA concludes that there is a reasonable certainty that no harm will result from aggregate exposure to cymoxanil residues.

E. Determination of Safety for Infants and Children.

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 pre- and post-natal toxicity and the completeness of the database 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 either case, EPA generally defines the level of appreciable risk as exposure that is greater than 1/100 of the NOEL in the animal study appropriate to the particular risk assessment. This hundredfold uncertainty (safety) factor/MOE (safety) is designed to account for combined inter- and intra-species variability. EPA believes that reliable data support using the standard hundredfold margin/factor not the additional tenfold margin/factor 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 margin/factor. Based on current toxicological data requirements, the data base for cymoxanil relative to pre- and post-natal toxicity is not complete.

Cymoxanil demonstrates extra pre-natal sensitivity for infants and children based on the results of the developmental study in rats. The developmental NOEL and LOEL were 10 and 25 mg/kg/day respectively. In comparison, the maternal NOEL and LOEL were 25 and 75 mg/kg/day respectively. This difference means that developmental effects (skeletal findings) occurred in the absence of maternal effects at 25 mg/kg/day. Therefore, OPP recommended that an acute dietary risk assessment be performed for females 13+ years. Given that the database is incomplete, and available data suggest extra pre-natal sensitivity, an extra uncertainty factor (3X) is appropriate for MOE calculations. That is, provided the MOE for females 13+ is greater than 300 the Agency would have no concerns for pre-natal exposure. The calculated MOE of 25,000 clearly demonstrates that the acute pre-natal risk to unborn children from exposure to aggregate residues of cymoxanil does not exceed the Agency's level of concern.

The results of the rabbit developmental study did not suggest

any pre-natal toxicity concerns. The developmental NOEL was 32 mg/kg/day (highest dose tested) and the maternal NOEL was 8 mg/kg/day.

The results of the rat reproduction study did not demonstrate any special post-natal toxicity. The parental NOEL and LOEL and the pup NOEL and LOEL occurred at the same dose levels (5 and 25 mg/kg/day, respectively). EPA has concluded that the percent of the RfD that will be utilized by chronic dietary (food) exposure to residues of cymoxanil is less than 1% for all population subgroups which includes nursing and non-nursing infants (<1 year old), and children (1 to 6 years old) and (7 to 12 years old). This calculation assumes tolerance level residues and is therefore an over-estimate of dietary risk. Refinement of the dietary risk assessment by using anticipated residue data would reduce dietary exposure. The addition of potential exposure from cymoxanil residues in drinking water is not expected to result in an exposure which would exceed the RfD. Therefore, EPA concludes that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to cymoxanil residues.

V. Other Considerations

The metabolism of cymoxanil in potatoes is adequately understood for the purposes of this tolerance. There are no Codex maximum residue levels established for residues of cymoxanil. The residue of concern, for the purposes of this tolerance, is cymoxanil. The proposed enforcement methods include Multi-Residue Protocol D, a method (adequate for generation of field trial residue data) submitted by Du Pont and a gas chromatography (GC) method published in the open literature. The methods are available to anyone who is interested in pesticide residue enforcement from: By mail, Calvin Furlow, Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: Crystal Mall #2, Rm. 1128, 1921 Jefferson Davis Hwy., Arlington, VA 703-305-5805.

VI. Conclusion

Therefore, a tolerance in connection with the FIFRA section 18 emergency exemptions is established for residues of cymoxanil in or on potatoes at 0.05 ppm.

VII. Objections and Hearing Requests

The new FFDCA section 408(g) provides essentially the same process

for persons to "object" to a tolerance regulation issued by EPA under new section 408(e) and (l)(6) as was provided in the old section 408 and in section 409. However, the period for filing objections is 60 days, rather than 30 days. EPA currently has procedural regulations which govern the submission of objections and hearing requests. These regulations will require some modification to reflect the new law. However, until those modifications can be made, EPA will continue to use those procedural regulations with appropriate adjustments to reflect the new law.

Any person may, by July 14, 1997, file written objections to any aspect of this regulation and may also request a hearing on those objections. Objections and hearing requests must be filed with the Hearing Clerk, at the address given above (40 CFR 178.20). A copy of the objections and/or hearing requests filed with the Hearing Clerk should be submitted to the OPP docket for this rulemaking. The objections submitted must specify the provisions of the regulation deemed objectionable and the grounds for the objections (40 CFR 178.25). Each objection must be accompanied by the fee prescribed by 40 CFR 180.33(i). If a hearing is requested, the objections must include a statement of the factual issues on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the requestor (40 CFR 178.27). A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is 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 in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32). 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.

VIII. Public Docket

The official record for this rulemaking, as well as the public version, has been established for this rulemaking under docket control number [OPP-300485] (including comments and data submitted electronically as described below). A public version of this record, including printed, paper versions of electronic comments, which does not include any information claimed as CBI, is available for inspection from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The official rulemaking record is located at the Virginia address in "ADDRESSES".

Electronic comments can be sent directly to EPA at: opp-docket@epamail.epa.gov

Electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Comment and data will also be accepted on disks in Wordperfect 5.1 file format or ASCII file format. All comments and data in electronic form must be identified by the docket number [OPP-300485]. Electronic comments on this proposed rule may be filed online at many Federal Depository Libraries.

IX. Regulatory Assessment Requirements

Under Executive Order 12866 (58 FR 51735, October 4, 1993), this action is not "a significant regulatory action" and, since this action does not impose any information collection requirements as defined by the Paperwork Reduction Act, 44 U.S.C. 3501 et seq., it is not subject to review by the Office of Management and Budget. In addition, this action does not impose any enforceable duty, or contain any "unfunded mandates" as described in Title II of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4), or require prior consultation as specified by Executive Order 12875 (58 FR 58093, October 28, 1993), or special considerations as required by Executive Order 12898 (59 FR 7629, February 16, 1994).

Because FFDCA section 408(l)(6) permits establishment of this regulation

without a notice of proposed rulemaking, the regulatory flexibility analysis requirements of the Regulatory Flexibility Act, 5 U.S.C. 604(a), do not apply. Nonetheless, the Agency has previously assessed whether establishing tolerances or exemptions from tolerance, raising tolerance levels, or expanding exemptions adversely impact small entities and concluded, as a generic matter, that there is no adverse impact. (46 FR 24950) (May 4, 1981).

Under 5 U.S.C. 801(a)(1)(A) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Title II of Pub. L. 104-121, 110 Stat. 847), EPA submitted 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 General Accounting Office prior to publication of the rule in today's **Federal Register**. This 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: May 1, 1997.

James Jones,

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. 346a and 371.

2. By adding § 180.503 to read as follows:

§ 180.503 Cymoxanil, tolerance for residues.

(a) *General.* [Reserved]

(b) *Section 18 emergency exemptions.* A time-limited tolerance is established for residues of the fungicide cymoxanil in connection with use of the pesticide under section 18 emergency exemptions granted by EPA. The tolerance is specified in the following table. The tolerances will expire and are revoked on the dates specified in the following table:

Commodity	Parts per million	Expiration/Revocation Date
Potatoes	0.05	3/15/99

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

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

[FR Doc. 97-12475 Filed 5-13-97; 8:45 am]

BILLING CODE 6560-50-F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP-300483; FRL-5715-5]

RIN 2070-AB78

Dimethomorph; Pesticide Tolerances for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a time-limited tolerance for residues of the fungicide dimethomorph in or on the food commodity potatoes in connection with EPA's granting of emergency exemptions under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act authorizing use of dimethomorph on potatoes in the states of Alabama, California, Colorado, Delaware, Florida, Idaho, Indiana, Maine, Maryland, Massachusetts, Michigan, Minnesota, Montana, Nebraska, Nevada, New Jersey, New York, North Carolina, North Dakota, Ohio, Oregon, Pennsylvania, Virginia, Washington, and Wisconsin. The tolerance will expire and is revoked on March 15, 1999.

DATES: This regulation is effective May 14, 1997. Objections and requests for hearings must be received by EPA on or before July 14, 1997.

ADDRESSES: Written objections and hearing requests, identified by the document control number, [OPP-300483], must be submitted to: Hearing Clerk (1900), Environmental Protection Agency, Rm. M3708, 401 M St., SW., Washington, DC 20460. Fees accompanying objections and hearing requests shall be labeled "Tolerance Petition Fees" and forwarded to: EPA Headquarters Accounting Operations Branch, OPP (Tolerance Fees), P.O. Box 360277M, Pittsburgh, PA 15251.

A copy of any objections and hearing requests filed with the Hearing Clerk identified by the document control number, [OPP-300483], must also be submitted to: Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring

a copy of objections and hearing requests to Rm. 1132, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA.

A copy of objections and hearing requests filed with the Hearing Clerk may also be submitted electronically by sending electronic mail (e-mail) to: oppdocket@epamail.epa.gov. Copies of objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Copies of objections and hearing requests will also be accepted on disks in WordPerfect 5.1 file format or ASCII file format. All copies of objections and hearing requests in electronic form must be identified by the document control number [OPP-300483]. No Confidential Business Information (CBI) should be submitted through e-mail. Electronic copies of objections and hearing requests on this rule may be filed online at many Federal Depository Libraries.

FOR FURTHER INFORMATION CONTACT: By mail: Libby Pemberton, Registration Division (7505W), Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail: Sixth Floor, Crystal Station #1, 2800 Jefferson Davis Highway, Arlington, VA, 703-308-8326, e-mail: pemberton.libby@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: EPA, on its own initiative, pursuant to section 408(e) and (l)(6) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(e) and (l)(6), is establishing a tolerance for residues of the fungicide dimethomorph on potatoes at 0.05 parts per million (ppm). This tolerance will expire and is revoked by EPA on March 15, 1999. After March 15, 1999, EPA will publish a document in the **Federal Register** to remove the revoked tolerance from the Code of Federal Regulations.

I. Background and Statutory Authority

The Food Quality Protection Act of 1996 (FQPA) (Pub. L. 104-170) was signed into law August 3, 1996. FQPA amends both the FFDCA, 21 U.S.C. 301 *et seq.*, and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. 136 *et seq.* Among other things, FQPA amends FFDCA to bring all EPA pesticide tolerance-setting activities under a new FFDCA section 408 with a new safety standard and new procedures. These activities are described below and discussed in greater detail in the final rule establishing the time-limited tolerance associated with the emergency exemption for use of propiconazole on

sorghum (61 CFR 58135, November 13, 1996)(FRL-5572-9).

New 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 commodity) 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...."

Section 18 of FIFRA authorizes EPA to exempt any Federal or State agency from any provision of FIFRA, if EPA determines that "emergency conditions exist which require such exemption." This provision was not amended by FQPA. EPA has established regulations governing such emergency exemptions in 40 CFR part 166. Section 408(l)(6) of the FFDCA requires EPA to establish a time-limited tolerance or exemption from the requirement for a tolerance for pesticide chemical residues in food commodities that will result from the use of a pesticide under an emergency exemption granted by EPA under section 18 of FIFRA. Such tolerances can be established without providing notice or a period for public comment.

Because decisions on section 18-related tolerances must proceed before EPA reaches closure on several policy issues relating to interpretation and implementation of the FQPA, EPA does not intend for its actions on such tolerance to set binding precedents for the application of FFDCA section 408 and the new safety standard to other tolerances and exemptions.

II. Emergency Exemptions for Dimethomorph on Potatoes and FFDCA Tolerances

EPA has authorized under FIFRA section 18 the use of dimethomorph on potatoes for control of late blight, as requested by the states previously listed. Recent failures to control late blight in potatoes as well as tomatoes with the registered fungicides, have been caused almost exclusively by immigrant strains