

*Populations and Low-Income Populations* (59 FR 7629, February 16, 1994). In addition, since this type of action does not require any proposal, no action is needed under the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*).

## II. 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 rule in the **Federal Register**. This is a technical correction to the **Federal Register** and 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: November 4, 1998.

**James Jones,**

*Director, Registration Division, Office of Pesticide Programs.*

Therefore, 40 CFR chapter I is amended as follows:

### PART 180—[CORRECTED]

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

**Authority:** 21 U.S.C. 346a and 371.

#### § 180.472 [Amended]

In § 180.472, in the issue of October 7, 1998, on page 53829, in FR Doc. 98-26903, the amendatory language item number 2, for § 180.472, is corrected to read as follows:

2. In § 180.472, in the table to paragraph (a), in the third column, for the commodities "beet roots," "beet tops," "turnip roots," and "turnip tops" the date "11/29/98" is revised to read "6/30/00", and in the table to paragraph (b), in the third column, for the commodities "citrus fruits crop group" and "dried citrus pulp" the date "12/31/98" is revised to read "6/30/00".

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## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 180

[OPP-300747; FRL-6038-5]

RIN 2070-AB78

### Cymoxanil; Pesticide Tolerances for Emergency Exemptions

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes a time-limited tolerance for residues of cymoxanil (2-cyano-N-[(ethylamino)carbonyl]-2-(methoxyimino) acetamide) in or on dried hops. This action is in connection with a crisis exemption declared under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act authorizing use of the pesticide on dried hops. This regulation establishes a maximum permissible level for residues of cymoxanil in this food commodity pursuant to section 408(l)(6) of the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996. The tolerance will expire and is revoked on April 15, 2000.

**DATES:** This regulation is effective December 2, 1998. Objections and requests for hearings must be received by EPA on or before February 1, 1999.

**ADDRESSES:** Written objections and hearing requests, identified by the docket control number, [OPP-300747], 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-300747], must also be submitted to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), 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. 119, Crystal Mall #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 5.1/6.1 file format or ASCII file format. All copies of objections and hearing requests in electronic form must be identified by the docket control number [OPP-300747]. 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 (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail address: Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, (703) 308-9364, e-mail: pemberton.libby@epamail.epa.gov.

**SUPPLEMENTARY INFORMATION:** EPA, on its own initiative, pursuant to sections 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 (2-cyano-N-[(ethylamino)carbonyl]-2-(methoxyimino) acetamide), in or on dried hops at 1 part per million (ppm). This tolerance will expire and is revoked on April 15, 2000. 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.* The FQPA amendments went into effect immediately. 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 (November 13, 1996, 61 FR 58135)(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. Such tolerances can be established without providing notice or 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 tolerances to set binding precedents for the application of section 408 and the new safety standard to other tolerances and exemptions.

## II. Emergency Exemption for Cymoxanil on Hops and FFDCA Tolerances

On July 16, 1998, the Idaho Department of Agriculture availed itself of the authority to declare the existence of a crisis situation within the state, thereby authorizing use under FIFRA section 18 of cymoxanil on hops for control of downy mildew.

As part of its assessment of this emergency exemption, EPA assessed the potential risks presented by residues of cymoxanil in or on dried hops. In doing so, EPA considered the safety standard in FFDCA section 408(b)(2), and EPA

decided that the necessary tolerance under FFDCA section 408(l)(6) would be consistent with the safety standard and with FIFRA section 18. Consistent with the need to move quickly on the emergency exemption 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 April 15, 2000, under FFDCA section 408(l)(5), residues of the pesticide not in excess of the amounts specified in the tolerance remaining in or on dried hops after that date will not be unlawful, provided the pesticide is applied in a manner that was lawful under FIFRA, and the residues do not exceed a level that was authorized by this tolerance at the time of that application. 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.

Because this tolerance is being approved under emergency conditions EPA has not made any decisions about whether cymoxanil meets EPA's registration requirements for use on hops or whether a permanent tolerance for this use would be appropriate. Under these circumstances, EPA does not believe that this tolerance serves as a basis for registration of cymoxanil by a State for special local needs under FIFRA section 24(c). Nor does this tolerance serve as the basis for any State other than Idaho to use this pesticide on this crop under section 18 of FIFRA without following all provisions of EPA's regulations implementing section 18 as identified in 40 CFR part 166. For additional information regarding the emergency exemption for cymoxanil, contact the Agency's Registration Division at the address provided above.

## III. Aggregate Risk Assessment and Determination of Safety

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 and a complete description of the risk assessment process, see the Final Rule on Bifenthrin Pesticide Tolerances (November 26, 1997, 62 FR 62961)(FRL-5754-7).

Consistent with section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the

hazards of cymoxanil and to make a determination on aggregate exposure, consistent with section 408(b)(2), for a time-limited tolerance for residues of 2-cyano-N-[(ethylamino)carbonyl]-2-(methoxyimino) acetamide on dried hops at 1 ppm. EPA's assessment of the dietary 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 cymoxanil are discussed below.

1. *Acute toxicity.* For females 13+, the developmental no observed adverse effect level (NOAEL) = 4 mg/kg/day based on an increase in skeletal malformations of the cervical and thoracic vertebrae and ribs at 8 milligrams/kilogram/day (mg/kg/day). EPA has determined that the 10x factor to account for enhanced sensitivity of infants and children should be reduced to 3x. For acute dietary risk assessment, a margin of exposure (MOE) of 300 is required for protection of females 13+ from acute dietary exposure to cymoxanil. A dose and endpoint were not selected for the general U.S. population and infants and children because there were no effects observed in oral toxicological studies including maternal toxicity in the developmental toxicity studies in rats and rabbits that could be attributable to a single exposure (dose).

2. *Chronic toxicity.* EPA has established the Reference dose (RfD) for cymoxanil at 0.013 mg/kg/day. This RfD is based on a NOAEL of 4.08 mg/kg/day and an uncertainty factor of 300. NOAEL established from a combined chronic toxicity/carcinogenicity study in rats, based on decreases in body weight and body weight gain, reduced food efficiency and histopathological lesions in the eyes and testes of males at 30.3 mg/kg/day lowest observed effect level (LOEL). EPA has determined that the 10x factor to account for enhanced sensitivity of infants and children should be reduced to 3x.

3. *Carcinogenicity.* Based on the lack of evidence of carcinogenicity in mice and rats at doses that were judged to be adequate to assess the carcinogenic potential, cymoxanil was classified as a "not likely" human carcinogen.

## B. Exposures and Risks

### 1. From food and feed uses.

Tolerances have been established (40 CFR 180.503) for the residues of 2-cyano-N-[(ethylamino)carbonyl]-2-(methoxyimino) acetamide, in or on potatoes. In addition, a time-limited tolerance in or tomatoes has also been established. Risk assessments were conducted by EPA to assess dietary exposures and risks from cymoxanil as follows:

i. *Acute exposure and risk.* Acute dietary risk assessments are performed for a food-use pesticide if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a one day or single exposure. The acute exposure analysis for female (13+) subgroup was performed using tolerance level residues and 100 percent crop treated and resulted in an acceptable MOE of 300.

ii. *Chronic exposure and risk.* EPA has concluded that the percent of the RfD that will be utilized by chronic dietary exposure to residues of cymoxanil is less than 5% for all population subgroups. EPA does not consider the chronic dietary risk to exceed the level of concern.

2. *From drinking water.* EPA has calculated drinking water levels of concern for acute exposure to cymoxanil in drinking water for females (13+ years old) to be 280 parts per billion (ppb). For chronic (non-cancer), the drinking water levels of concern are 440 and 120 ppb for U.S. population, children (1-6 years old), respectively. EPA has determined that cymoxanil and its degradates should not pose a threat to ground water. The estimated maximum concentration of cymoxanil in surface water is 4.13 ppb.

i. *Acute exposure and risk.* The maximum estimated concentrations of cymoxanil in surface water are less than EPA's levels of concern for cymoxanil in drinking water as a contribution to acute aggregate exposure. Taking into account the present uses and this proposed use, EPA concludes with reasonable certainty that residues of cymoxanil in drinking water would not result in unacceptable levels of aggregate human health risk at this time.

ii. *Chronic exposure and risk.* The maximum estimated concentrations of cymoxanil in surface water are less than EPA's levels of concern for cymoxanil in drinking water as a contribution to chronic aggregate exposure. Taking into account the present uses and this proposed use, EPA concludes with reasonable certainty that residues of cymoxanil in drinking water would not

result in unacceptable levels of aggregate human health risk at this time.

### 3. From non-dietary exposure.

Cymoxanil is not currently registered for use on residential non-food sites.

4. *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."

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. For more 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 (November 26, 1997, 62 FR 62961).

## C. Aggregate Risks and Determination of Safety for U.S. Population

1. *Acute risk.* From the acute dietary (food only) risk assessment, a high-end exposure estimate was calculated for the subgroup, females 13+ years. The maximum estimated concentrations of cymoxanil in surface and ground water are less than EPA's levels of concern for cymoxanil in drinking water as a contribution to acute aggregate exposure. Therefore, EPA concludes with reasonable certainty that residues of cymoxanil in drinking water do not contribute significantly to the aggregate acute human health risk at the present time.

2. *Chronic risk.* Using the Dietary Exposure Evaluation Model, EPA has concluded that aggregate exposure to cymoxanil from food will utilize 2% of the RfD for the U.S. population. The major identifiable subgroup with the highest aggregate exposure is children (1-6 years old) "discussed below." EPA generally has no concern for exposures below 100% of the RfD because the RfD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks

to human health. The estimated average concentrations of cymoxanil in surface and ground water are less than EPA's levels of concern for cymoxanil in drinking water as a contribution to chronic aggregate exposure. Therefore, EPA does not expect the aggregate exposure to exceed 100% of the RfD.

Short- and intermediate-term aggregate exposure takes into account chronic dietary food and water (considered to be a background exposure level) plus indoor and outdoor residential exposure.

3. *Aggregate cancer risk for U.S. population.* A cancer risk assessment is not needed since cymoxanil was classified as a "not likely" human carcinogen.

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

## D. Aggregate Risks and Determination of Safety for Infants and Children

1. *Safety factor for infants and children—i. In general.* In assessing the potential for additional sensitivity of infants and children to residues of cymoxanil, EPA considered data from developmental toxicity studies in the rat and rabbit and a 2-generation reproduction study in the rat. This is the case. The developmental toxicity studies are designed to evaluate adverse effects on the developing organism resulting from maternal pesticide exposure during gestation. Reproduction studies provide information relating to effects from exposure to the pesticide on the reproductive capability of mating animals and data on systemic toxicity.

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 margin of exposure (MOE) analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans. EPA believes that reliable data support using the standard MOE and uncertainty factor (usually 100 for combined inter- and intra-species variability) and not the additional tenfold MOE/uncertainty 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 MOE/safety factor.

EPA determined that for cymoxanil, the 10x factor for the enhanced sensitivity of infants and children will be reduced to 3x for the following reasons:

a. There was no sensitivity to perinatal animals following pre- and/or postnatal exposure with cymoxanil. In one prenatal developmental toxicity study in rabbits, where sensitivity was suggested by observations of developmental toxicity at a dose which was not maternally toxic, the lower developmental NOEL was attributed to inadequacies in study design and conduct.

b. There were no data gaps for the assessment of potential effects on offspring following in utero and/or postnatal exposure to cymoxanil via the standard screening studies required by 40 CFR Part 158. However, following a weight-of-the-evidence review of the database, which suggested that neuropathological lesions could result from long-term exposure to cymoxanil, a developmental neurotoxicity study in rats was recommended.

ii. *Developmental toxicity studies.* The NOAEL was 4 mg/kg/day and the LOEL was 8 mg/kg/day based on an increase in skeletal malformations of the cervical and thoracic vertebrae and ribs; at 32 mg/kg/day, cleft palate was also observed.

iii. *Reproductive toxicity study.* For parental systemic toxicity, the NOAEL was 100 ppm (6.5 mg/kg/day for males, 7.9 mg/kg/day for females) and LOEL was 500 ppm based on reduced prenatally body weight, body weight gain, and food consumption for P males; and decreased gestation and lactation body weight for F1 females. For offspring systemic toxicity, the NOAEL was 100 ppm (6.5 mg/kg/day for males, 7.9 mg/kg/day for females) and the LOEL was 500 ppm (32.1 mg/kg/day for males, 40.6 mg/kg/day for females) based on decreased F1 pup viability on postnatal days 0-4 and on a significant reduction in F2b pup weight.

iv. *Pre- and post-natal sensitivity.* The developmental toxicity and multigeneration reproduction study data demonstrated no indication of increased susceptibility of rats or rabbits to in utero and/or postnatal exposure to cymoxanil. Overall, in the developmental toxicity studies in rats and rabbits, and in the 2-generation reproductive toxicity study with cymoxanil in rats, offspring toxicity was observed only at treatment levels which were toxic to parental adults.

v. *Conclusion.* There were no data gaps for the assessment of potential effects on offspring following in utero and/or postnatal exposure to cymoxanil via the standard screening studies required by 40 CFR Part 158. However, following a weight-of-the-evidence review of the database, which suggested that neuropathological lesions could result from long-term exposure to cymoxanil, a developmental neurotoxicity study in rats is required. There is a complete toxicity database for cymoxanil and exposure data is complete or is estimated based on data that reasonably accounts for potential exposures.

2. *Acute risk.* The large acute dietary MOEs calculated for females 13+ years old provides assurance that there is a reasonable certainty of no harm for both females 13+ years and the pre-natal development of infants.

3. *Chronic risk.* Using the exposure assumptions described above, EPA has concluded that aggregate exposure to cymoxanil from food will range from 1% for nursing infants less than one year old, up to 5% for children (1-6 years old). EPA generally has no concern for exposures below 100% of the RfD because the RfD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health. Despite the potential for exposure to cymoxanil in drinking water and from non-dietary, non-occupational exposure, EPA does not expect the aggregate exposure to exceed 100% of the RfD.

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

#### **IV. Other Considerations**

##### *A. Metabolism In Plants and Animals*

The nature of the residue in tomatoes and potatoes is adequately understood. For purposes of this action, EPA was willing to translate these data to hops. The residues of concern in hops are cymoxanil per se, as specified in 40 CFR 180.503.

##### *B. Analytical Enforcement Methodology*

An adequate enforcement method (DuPont Method AMR 2358-92, unpublished) is available to enforce the proposed tolerance on hops. Quantitation is by GLC using a nitrogen/phosphorus detector.

Adequate enforcement methodology (example - gas chromatography) 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, 401 M St., SW., Washington, DC 20460. Office location and telephone number: Rm 101FF, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA 22202, (703-305-5229).

##### *C. Magnitude of Residues*

Residues of cymoxanil are not expected to exceed 1.0 ppm in/on hops, dried. Secondary residues are not expected in animal commodities as no feed items are associated with this section 18 use.

##### *D. International Residue Limits*

There are no Codex, Canadian or Mexican residue limits established for cymoxanil on hops. Therefore, no compatibility problems exist for the proposed tolerance on hops.

##### *E. Rotational Crop Restrictions*

Residues in rotational crops are not expected as hops fields are not rotated.

#### **V. Conclusion**

Therefore, the tolerance is established for residues of 2-cyano-*N*-[(ethylamino)carbonyl]-2-(methoxyimino) acetamide in dried hops at 1 ppm.

#### **VI. 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 February 1, 1999, 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.

## VII. Public Record and Electronic Submissions

EPA has established a record for this rulemaking under docket control number [OPP-300747] (including any comments and data submitted electronically). 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 public record is located in Room 119 of the Public Information and Records Integrity Branch, Information Resources and Services Division (7502C) Office of Pesticide Programs, Environmental Protection Agency, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA.

Electronic comments may 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.

The official record for this rulemaking, as well as the public version, as described above will be kept in paper form. Accordingly, EPA will transfer any copies of objections and

hearing requests received electronically into printed, paper form as they are received and will place the paper copies in the official rulemaking record which will also include all comments submitted directly in writing. The official rulemaking record is the paper record maintained at the Virginia address in ADDRESSES at the beginning of this document.

## VIII. Regulatory Assessment Requirements

### A. Certain Acts and Executive Orders

This final rule establishes a tolerance under FFDCA section 408 (l)(6). The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Pub. L. 104-4). Nor does it require any prior consultation as specified by Executive Order 12875, entitled *Enhancing the Intergovernmental Partnership* (58 FR 58093, October 28, 1993), or special considerations as required by Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994), or require OMB review in accordance with Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997).

In addition, since tolerances and exemptions that are established under FFDCA section 408 (l)(6), 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. Nevertheless, the Agency has previously assessed whether establishing tolerances, exemptions from tolerances, raising tolerance levels or expanding exemptions might adversely impact small entities and concluded, as a generic matter, that there is no adverse economic impact. The factual basis for the Agency's generic certification for tolerance actions published on May 4, 1981 (46 FR 24950), and was provided to the Chief Counsel for Advocacy of the Small Business Administration.

### B. Executive Order 12875

Under Executive Order 12875, entitled *Enhancing the Intergovernmental Partnership* (58 FR 58093, October 28, 1993), EPA may not issue a regulation that is not required by statute and that creates a mandate upon a State, local, or tribal government, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by those governments. If the mandate is unfunded, EPA must provide to OMB a description of the extent of EPA's prior consultation with representatives of affected State, local, and tribal governments, the nature of their concerns, copies of any written communications from the governments, and a statement supporting the need to issue the regulation. In addition, Executive Order 12875 requires EPA to develop an effective process permitting elected officials and other representatives of State, local, and tribal governments "to provide meaningful and timely input in the development of regulatory proposals containing significant unfunded mandates."

Today's rule does not create an unfunded Federal mandate on State, local, or tribal governments. The rule does not impose any enforceable duties on these entities. Accordingly, the requirements of section 1(a) of Executive Order 12875 do not apply to this rule.

### C. Executive Order 13084

Under Executive Order 13084, entitled *Consultation and Coordination with Indian Tribal Governments* (63 FR 27655, May 19, 1998), EPA may not issue a regulation that is not required by statute, that significantly or uniquely affects the communities of Indian tribal governments, and that imposes substantial direct compliance costs on those communities, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by the tribal governments. If the mandate is unfunded, EPA must provide to OMB, in a separately identified section of the preamble to the rule, a description of the extent of EPA's prior consultation with representatives of affected tribal governments, a summary of the nature of their concerns, and a statement supporting the need to issue the regulation. In addition, Executive Order 13084 requires EPA to develop an effective process permitting elected officials and other representatives of Indian tribal governments "to provide meaningful and timely input in the development of regulatory policies on

matters that significantly or uniquely affect their communities.”

Today's rule does not significantly or uniquely affect the communities of Indian tribal governments. This action does not involve or impose any requirements that affect Indian tribes. Accordingly, the requirements of section 3(b) of Executive Order 13084 do not apply to this rule.

#### **IX. 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 the rule in the **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: October 15, 1998.

**James Jones,**

*Director, Registration Division, Office of Pesticide Programs.*

Therefore, 40 CFR chapter I is amended as follows:

#### **PART 180—[AMENDED]**

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

**Authority:** 21 U.S.C. 346a and 371.

2. Section 180.503 is amended, by alphabetically adding to the table in paragraph (b), the commodity to read as follows:

#### **§ 180.503 Cymoxanil; tolerance for residues.**

- (a) \* \* \*
- (b) \* \* \*

Commodity	Parts per million	Expiration/Revocation Date
Hops, dried .....	1	4/15/00

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#### **DEPARTMENT OF COMMERCE**

#### **National Oceanic and Atmospheric Administration**

#### **50 CFR Part 229**

[Docket No. 970129015-8287-08; I.D. 042597B]

RIN 0648-A184

#### **Taking of Marine Mammals Incidental to Commercial Fishing Operations; Harbor Porpoise Take Reduction Plan Regulations**

**AGENCY:** National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

**ACTION:** Final rule; notice of availability of take reduction plan.

**SUMMARY:** Pursuant to the Marine Mammal Protection Act (MMPA), NMFS issues a final rule to implement a harbor porpoise take reduction plan (HPTRP) in the Gulf of Maine and Mid-Atlantic waters. The HPTRP is contained in the HPTRP/ Environmental Assessment/ Final Regulatory Flexibility Analysis (HPTRP/EA/FRFA), available upon request (see addresses below). In the Gulf of Maine, these final regulations put into place a series of time and area closures where pingers are required: in the Mid-Coast Closure Area (September 15 through May 31), the Massachusetts Bay and Cape Cod South Closure Areas (December 1 through February 28/29 and April 1 through May 31) and establish a new closure area, the Offshore Closure Area, where pingers are required November 1 through May 31. A complete closure has been added in the Cashes Ledge Closure Area, February 1-28/29. These regulations require any fishermen using pingers in the closed areas where pingers are allowed, to receive training and be certified in pinger use. A certificate must be carried onboard the vessel. In the Mid-Atlantic, this plan closes New Jersey waters from January 1 through April 30 to large and small mesh gear unless gear meets the specified gear modifications. This plan closes southern Mid-Atlantic waters from February 1 through April 30 to large and small mesh gear unless gear meets the specified gear modifications. This plan closes New Jersey waters from April 1-April 20 and southern Mid-Atlantic waters from February 15-March 15 for large mesh gear. The region known as

the New Jersey Mudhole is closed to small and large mesh gear from February 15-March 15. All small and large mesh gear in the Mid-Atlantic must be tagged by January 1, 2000.

**DATES:** Effective January 1, 1999, except for § 229.33 (a)(2) which becomes effective December 2, 1998, § 229.33(a)(5) which becomes effective December 8, 1998, and § 229.33(a)(3) and (a)(4) which become effective December 16, 1998.

**ADDRESSES:** Copies of the draft plan prepared by the Gulf of Maine Take Reduction Team (GOMTRT), the final report from the Mid-Atlantic Take Reduction Team (MATRT) and the HPTRP/EA/FRFA may be obtained from Donna Wieting, Office of Protected Resources, National Marine Fisheries Service, 1315 East-West Highway, Silver Spring, MD 20910-3226.

**FOR FURTHER INFORMATION CONTACT:** Donna Wieting, NMFS, 301-713-2322, or Laurie Allen, NMFS, Northeast Region, 978-281-9291.

**SUPPLEMENTARY INFORMATION:** This final rule implements a take reduction plan (TRP) for the Gulf of Maine (GOM) stock of harbor porpoise, a strategic marine mammal stock that interacts with the Northeast (NE) multispecies gillnet fishery and with the Mid-Atlantic coastal gillnet fishery. A strategic stock is a stock: (1) for which the level of direct human-caused mortality exceeds the potential biological removal (PBR) level (the maximum number of animals, not including natural mortalities, that may be annually removed from a marine mammal stock without compromising the ability of that stock to reach or maintain its optimum population level); (2) that is declining and is likely to be listed under the Endangered Species Act (ESA) in the foreseeable future; or (3) that is listed as a threatened or endangered species under the ESA. NMFS proposed listing the GOM harbor porpoise as threatened under the ESA (58 FR 3108, January 7, 1993), but no final action has been taken on that proposal.

The NE multispecies sink gillnet fishery is a Category I fishery, and the Mid-Atlantic coastal gillnet fishery is a Category II fishery, as classified under Section 118 of the MMPA. A Category I fishery is a fishery that has frequent incidental mortality and serious injury