ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180
[OPP–300444; FRL–5574–8]

RIN 2070-AB78

Triadimefon; Pesticide Tolerances for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a time-limited tolerance for combined residues of the fungicide triadimefon in or on the raw agricultural commodity chili peppers in connection with EPA's granting of an emergency exemption under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act authorizing use of triadimefon on chili peppers in New Mexico. This regulation establishes a maximum permissible level for residues of triadimefon in this food pursuant to section 408(l)(6) of the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996. This tolerance will expire and be revoked automatically without further action by EPA on November 8, 1998.

DATES: This regulation becomes effective December 2, 1996. This regulation expires and is revoked automatically without further action by EPA on November 8, 1998. Objections and requests for hearings must be received by EPA on or before January 31, 1997.

ADDRESSES: Written objections and hearing requests, identified by the docket control number, [OPP–300444], 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–300444], 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–300444]. 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: David Deegan, 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 22202. (703) 308-8327, e-mail: deegan.dave@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 triadimefon, 1-(4-chlorophenoxy)-3,3-dimethyl-1-(1-H-1,2,4-triazol-1-yl)-2-butanone, in or on chili peppers at 0.5 part per million (ppm). This tolerance will expire and be revoked automatically without further action by EPA on November 8, 1998.

I. Background and Statutory Authority

The Food Quality Protection Act of 1996 (FQPA) (Pub. L. 104170) was signed into law August 3, 1996. FQPA amends both the Federal Food, Drug, and Cosmetic Act (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 (61 FR 58135, November 13, 1996).

New section 408(b)(2)(A)(i) 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, 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) 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. Section 408(l)(6) also requires EPA to promulgate regulations by August 3, 1997, governing the establishment of tolerances and exemptions under section 408(l)(6) and requires that the regulations be consistent with section 408(b)(2) and (c)(2) and FIFRA section 18.

Section 408(l)(6) allows EPA to establish tolerances or exemptions from the requirement for a tolerance, in connection with EPA's granting of FIFRA section 18 emergency exemptions, without providing notice or a period for public comment. Thus, consistent with the need to act expeditiously on requests for emergency exemptions under FIFRA, EPA can establish such tolerances or exemptions under the authority of section 408(e) and (l)(6) without notice and comment rulemaking.

In establishing section 18-related tolerances and exemptions during this interim period before EPA issues the section 408(l)(6) procedural regulation and before EPA makes its broad policy decisions concerning the interpretation and implementation of the new section 408, EPA does not intend to set precedents for the application of section

408 and the new safety standard to other tolerances and exemptions. Rather, these early section 18 tolerance and exemption decisions will be made on a case-by-case basis and will not bind EPA as it proceeds with further rulemaking and policy development. EPA intends to act on section 18-related tolerances and exemptions that clearly qualify under the new law.

II. Emergency Exemption for Triadimefon on Chili Peppers and FFDCA Tolerances

On September 10, 1996, the New Mexico Department of Agriculture availed of itself the authority to declare the existence of a crisis situation within the state, thereby authorizing use under FIFRA section 18 of triadimefon on chili peppers to control powdery mildew (*Oidiopsis taurica*). New Mexico stated that emergency conditions developed due to unusually wet conditions in the chili pepper growing regions of the state, which resulted in an outbreak of powdery mildew. This pest, New Mexico asserts, can have devastating effects on growers' production and revenue.

As part of its assessment of this crisis declaration, EPA assessed the potential risks presented by residues of triadimefon in or on chili peppers. In doing so, EPA considered the new safety standard in FFDCA section 408(b)(2), and EPA decided to grant the section 18 exemptions only after concluding 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 triadimefon will permit the marketing of chili peppers treated in accordance with the provisions of the section 18 emergency exemption. Consistent with the need to move quickly on the emergency exemption 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 be revoked automatically without further action by EPA on November 8, 1998, under FFDCA section 408(l)(5), residues of triadimefon not in excess of the amount specified in the tolerance remaining in or on chili peppers after that date will not be unlawful, provided the pesticide is applied during the term of, and in accordance with all the conditions of, the emergency exemptions. 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 triadimefon meets the requirements for registration under FIFRA section 3 for use on chili peppers, or whether a permanent tolerance for triadimefon for chili peppers would be appropriate. This action by EPA does not serve as a basis for registration of triadimefon by a State for special local needs under FIFRA section 24(c). Nor does this action serve as the basis for any State other than New Mexico to use this product 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 exemption for triadimefon, 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 by EPA to pose a reasonable certainty of no harm.

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 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. Triadimefon is already registered by EPA for use on almonds, apples, apricots, barley, chick pea seed, cucurbits, grapes, grass, nectarines, peaches, pears, pineapples, plums, raspberries, sugar beets, and wheat (see 40 CFR 180.410 for specific tolerances). At this time, EPA is not in possession of a registration application for triadimefon on chili peppers. However, based on information submitted to the Agency, EPA has sufficient data to assess the hazards of triadimefon and to make a determination on aggregate exposure, consistent with section 408(b)(2), for a time-limited tolerance for residues of triadimefon on chili peppers at 0.5 ppm. EPA's assessment of the dietary exposures and risks associated with establishing the tolerance follows.

A. Toxicological Profile

1. *Chronic toxicity*. Based on the available chronic toxicity data, EPA has established the RfD for triadimefon at 0.04 milligrams(mg)/kilogram(kg)/day. This RfD is based on a 2-year dog feeding study with a NOEL of 11.4 mg/kg/day and an uncertainty factor of 300. An uncertainty factor of 300 was applied to account for inter-species extrapolation (10), intra-species variability (10), and the lack of an adequate reproduction study (3). Decreased food intake, depression in weight gain, and significantly ($p < 0.05$) increased alkaline phosphatase activity in both sexes were the effects observed at the lowest effect level (LEL).

2. *Acute toxicity*. Agency toxicologists recommended that the developmental NOEL from the rabbit developmental toxicity study (20 mg/kg/day) be used for acute dietary risk calculations. The rabbit developmental study is discussed below under Unit IV.D. of this preamble. The population of concern for this risk assessment is females 13+ years old.

3. *Carcinogenicity*. Using its Guidelines for Carcinogen Risk Assessment published September 24, 1986 (51 FR 33992), EPA has classified triadimefon as Group ''C'' for carcinogenicity (possible human carcinogen) based on the results of carcinogenicity studies in two species. The classification as Group C was based on borderline statistically significant increases in thyroid adenomas in male rats, and increases in liver adenomas in both sexes of mice. Because the tumors were benign, and there were no apparent genotoxicity concerns, the Cancer Peer Review Committee recommended the RfD approach for quantitation of human risk.

B. Aggregate Exposure

Tolerances have been established (40 CFR 180.410) for the combined residues of triadimefon and its metabolites containing chlorophenoxy and triazole moieties (expressed as the fungicide) in or on various raw agricultural commodities ranging from 0.04 ppm in milk, eggs, and fat, meat and meat by-products in hogs and poultry to 145.0 ppm in grass seed cleanings (including hulls). There are no animal feed items associated with chili peppers, therefore the livestock dietary burden will not be increased by this section 18 exemption.

In conducting this exposure assessment, EPA has made very conservative assumptions--that 100% of chili peppers and all other commodities having triadimefon tolerances will contain triadimefon residues and those residues would be at the level of the tolerance--which result in an overestimate of human dietary exposure. Thus, in making a safety determination for this tolerance, EPA is taking into account this conservative exposure assessment.

1. *Chronic exposure*. Given the emergency nature of this request for the use of triadimefon and the resulting need for a timely analysis and risk assessment, EPA has utilized the TMRC to estimate chronic dietary exposure from the tolerance for triadimefon on chili peppers at 0.5 ppm. The TMRC is obtained by multiplying the tolerance level residue for chili peppers by average consumption data, which estimate the amount of chili peppers and chili peppers products eaten by various population subgroups. This calculation is performed as well for every food having existing triadimefon tolerances. The risk assessment is therefore considered to be overestimated. The Agency has extensive experience refining chronic dietary risk assessments for a broad range of pesticide chemicals. It is the Agency's experience that when the chronic dietary risk assessment is refined using ARC (anticipated residue contribution) estimates derived from anticipated residue levels and percent of crop treated data, the percent of the RfD occupied by the ARC is generally in the range of an order of magnitude lower than the percent of the RfD occupied by the unrefined TMRC.

Other potential sources of exposure of the general population to residues of pesticides are residues in drinking water and exposure from non-occupational sources.

Based on the available studies used in EPA's assessment of environmental risk, triadimefon and its metabolites are mobile and persistent and have the potential to leach into groundwater. There is no established Maximum Concentration Level for residues of triadimefon in drinking water. No drinking water health advisory levels have been issued for triadimefon or its metabolite triadimenol. The ''Pesticides in Groundwater Database (EPA 734-12-92-001, September 1992) indicated that triadimefon was monitored for in 14 wells in California from 1984 to 1989. There were no detectable residues (limit of detection was not stated). The Agency does not have available data to perform a quantitative drinking water risk assessment for triadimefon at this time.

Previous experience with more persistent and mobile pesticides for which there have been available data to perform quantitative risk assessments have demonstrated that drinking water exposure is typically a small percentage of the total exposure when compared to the total dietary exposure. This observation holds even for pesticides detected in wells and drinking water at levels nearing or exceeding established MCLs. Based on this experience and the Agency's best scientific judgement, EPA concludes that it is not likely that the potential exposure from residues of triadimefon in drinking water added to the current dietary exposure will result in an exposure which exceeds the RfD.

Triadimefon is currently registered for residential use as a preservative treatment for wood and for lawn and ornamental uses. At this time, the Agency does not have reliable data which would allow quantitative incorporation of risk from these uses into a human health risk assessment.

Given the time-limited nature of this request, the need to make emergency exemption decisions quickly, and the significant scientific uncertainty at this time about how to aggregate non-dietary, non-occupational exposure with dietary exposure, the Agency will make its safety determination for this tolerance based on those factors which it can reasonably integrate into a risk assessment.

2. *Acute exposure*. EPA has not estimated non-occupational exposures other than dietary for triadimefon. Acceptable, reliable data are not currently available with which to assess acute risk. Triadimefon is registered for outdoor residential use (lawn use). While dietary and residential scenarios could possibly occur in a single day, triadimefon would rarely be present on both the food eaten and the lawn on that single day. Even assuming this were the case, it is yet more unlikely that residues would be present at tolerance level on all food eaten that day for

which triadimefon tolerances exist, as is assumed in the acute dietary risk analysis, and on the lawn that same day.

Because the acute dietary exposure estimate assumes tolerance level residues and 100% crop treated for all crops evaluated it is a large over-estimate of exposure and it is considered to be protective of any acute exposure scenario.

At this time, the Agency has not made a determination that triadimefon and other substances that may have a common mode of toxicity would have cumulative effects. For purposes of this tolerance only, the Agency is considering only the potential risks of triadimefon in its aggregate exposure.

C. Determination of Safety for U.S. Population

1. *Chronic risk.* Using the conservative exposure assumptions described above and taking into account the completeness and reliability of the toxicity data, EPA has concluded that dietary exposure to triadimefon will utilize 7.8 percent of the RfD for the U.S. population. EPA generally has no concern for exposures below 100 percent 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. Acceptable, reliable data are not available to quantitatively assess risk from drinking water or from residential uses. However, EPA concludes that there is a reasonable certainty that no harm will result from aggregate exposure to triadimefon residues.

2. *Acute risk.* For the population subgroup of concern, females 13+ years old, the calculated Margin Of Exposure (MOE) value is 555. This MOE does not exceed the Agency's level of concern for acute dietary exposure.

D. Determination of Safety for Infants and Children

In assessing the potential for additional sensitivity of infants and children to residues of triadimefon, EPA considered data from developmental toxicity studies in the rat and rabbit. The developmental toxicity studies are designed to evaluate adverse effects on the developing organism resulting from pesticide exposure during prenatal development.

In the developmental toxicity study in rats, the maternal systemic NOEL was 30 mg/kg/day and the LOEL 90 mg/kg/day. The NOEL for developmental toxicity was 30 mg/kg/day and the LOEL was 90 mg/kg/day. In the developmental toxicity study in rabbits, the maternal systemic NOEL was 50 mg/kg/day and the LOEL 120 mg/kg/day. The NOEL for developmental toxicity was 20 mg/kg/day and the LOEL was 50 mg/kg/day. Effects seen at the developmental LEL in the rabbit study were irregular spinous process and ossification of various bones.

An acceptable 2-generation reproduction study in rats is not available.

1. *Chronic risk.* Using the conservative exposure assumptions described above, EPA has concluded that the percentage of the RfD that will be utilized by aggregate exposure to residues of triadimefon ranges from 25.6 percent for children 7-12 years old, up to 74.8 percent for non-nursing infants.

FFDCA section 408 provides that EPA shall apply an additional safety factor for infants and children in the case of threshold effects to account for pre- and post-natal toxicity and the completeness of the data base unless EPA concludes that a different margin of safety is appropriate. Based on current toxicological data requirements, the data base for triadimefon relative to pre- and post-natal toxicity is not complete. An additional 3-fold uncertainty factor has already been incorporated into the calculation of the RfD because of the absence of an acceptable reproduction study. The reproduction study would provide additional information regarding post-natal toxicity to infants and children.

The Agency notes that there is approximately a two-fold difference between the developmental NOEL of 20 mg/kg/day from the rabbit developmental toxicity study and the NOEL of 11.4 mg/kg/day from the 2-year dog feeding study which was the basis of the RfD. It is further noted that in the rabbit developmental toxicity study, the developmental NOEL of 20 mg/kg/day is lower than the maternal systemic NOEL of 50 mg/kg/day, suggesting the possibility of increased sensitivity for the pre-natal child.

The TMRC value for the most highly exposed infant and children subgroup (non-nursing infants <1 year old) occupies 74.8% of the RfD. However, this calculation also assumes 100% crop treated and uses tolerance level residues for all commodities. As mentioned previously, refinement of the dietary risk assessment by using percent of crop treated and anticipated residue data would likely greatly reduce the dietary exposure estimate and result in an anticipated residue contribution (ARC) which would occupy a percent of the RfD that is substantially lower than the currently calculated TMRC value.

Should an additional uncertainty factor be deemed appropriate, when considered in conjunction with a refined exposure estimate, it is unlikely that the dietary risk will exceed 100 percent of the RfD. Therefore, taking into account the completeness and reliability of the toxicity data and the conservative exposure assessment, EPA concludes that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to triadimefon residues.

2. *Acute risk.* At present, the acute dietary MOE for females 13+ years old is 555. This MOE calculation was based on the developmental NOEL of 20 mg/kg/day, compared to the less sensitive maternal NOEL of 50 mg/kg day from the same rabbit developmental study. This risk assessment also assumed 100% crop treated with tolerance level residues on all treated crops consumed, resulting in a significant over estimate of dietary exposure. The large acute dietary MOE 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.

V. Other Considerations

The metabolism of triadimefon in plants and animals is adequately understood for the purposes of this tolerance. There are no Codex maximum residue levels established for residues of triadimefon on chili peppers. There is a practical analytical method for detecting and measuring levels of triadimefon in or on food with a limit of detection that allows monitoring of food with residues at or above the levels set in this tolerance. Enforcement methods are published in PAM Vol. II Pesticide Reg. Sec. 180.410 as Methods I and II.

VI. Conclusion

Therefore, a tolerance in connection with the FIFRA section 18 emergency exemptions is established for residues of triadimefon in chili peppers at 0.5 ppm. This tolerance will expire and be automatically revoked without further action by EPA on November 8, 1998.

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 January 31, 1996, file written objections to any aspect of this regulation (including the automatic revocation provision) 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 Confidential Business Information (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

A record has been established for this rulemaking under docket number [OPP–300444]. A public version of this record, which does not include any information claimed as CBI, is available for inspection from 8 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The public record is located in Room 1132 of the Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA.

The official record for this rulemaking, as well as the public version, as described above, is kept in paper form. Accordingly, in the event there are objections and hearing requests, 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. The official rulemaking record is the paper record maintained at the address in ''ADDRESSES'' at the beginning of this document.

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 mandate as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4), or require prior consultation with State officials 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.

Under 5 U.S.C. 801(a)(1)(A) of the Administrative Procedure Act (APA) as amended by 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) of the APA as amended.

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 20, 1996.

Daniel M. Barolo,

Director, 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. In 180.410, by adding a new paragraph (c) to read as follows:

§ 180.410 1-(4-chlorophenoxy)-3,3-dimethyl-1-(1-H-1,2,4-triazol-1-yl)-2-butanone; tolerances for residues.

* * * * *

(c) A time-limited tolerance is established for residues of the fungicide triadimefon 1-(4-chlorophenoxy)-3,3-dimethyl-1-(1-H-1,2,4-triazol-1-yl)-2-butanone in connection with use of the pesticide under the section 18 emergency exemption granted by EPA. The tolerance is specified in the following table. The tolerance expires and is automatically revoked on the date specified in the table without further action by EPA.

Commodity	Parts per million	Expiration/Revocation Date
Chili peppers	0.5	November 8, 1997

[FR Doc. 96–30552 Filed 11–29–96; 8:45 am]
BILLING CODE 6560–50–F

40 CFR Part 721

[OPPTS–50623; FRL–4964–3]

RIN 2070–AB27

Significant New Uses of Certain Chemical Substances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: EPA is promulgating significant new use rules (SNURs) under section 5(a)(2) of the Toxic Substances Control Act (TSCA) for certain chemical substances which were the subject of premanufacture notices (PMNs) and subject to TSCA section 5(e) consent orders issued by EPA. Today's action requires persons who intend to manufacture, import, or process these substances for a significant new use to notify EPA at least 90 days before commencing the manufacturing or processing of the substance for a use designated by this SNUR as a significant new use. The required notice will provide EPA with the opportunity to evaluate the intended use, and if necessary, to prohibit or limit that activity before it occurs. EPA is promulgating this SNUR using direct final procedures.

DATES: The effective date of this rule is January 31, 1997. This rule shall be promulgated for purposes of judicial review at 1 p.m. (e.s.t.) on December 16, 1996.

If EPA receives notice before January 2, 1997 that someone wishes to submit adverse or critical comments on EPA's action in establishing a SNUR for one or more of the chemical substances subject to this rule, EPA will withdraw the SNUR for the substance for which the notice of intent to comment is received and will issue a proposed SNUR providing a 30-day period for public comment.

ADDRESSES: Each comment or notice of intent to submit adverse or critical comment must bear the docket control number OPPTS–50623 and the name(s) of the chemical substance(s) subject to the comment. All comments should be sent in triplicate to: OPPT Document Control Officer (7407), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 401 M Street, SW., Room G–099, East Tower, Washington, DC 20460.

All comments which are claimed confidential must be clearly marked as such. Three additional sanitized copies of any comments containing confidential business information (CBI) must also be submitted. Nonconfidential versions of comments on this rule will be placed in the rulemaking record and will be available for public inspection. Comments and data may also be submitted electronically by sending electronic mail (e-mail) to: oppt.ncic@epamail.epa.gov. Electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of encryption.

Comments and data will also be accepted on disks in WordPerfect in 5.1 file format or ASCII file format. All comments and data in electronic form must be identified by the docket number 50623. No CBI should be submitted through e-mail. Electronic comments on this final rule may be filed online at many Federal Depository Libraries. Additional information on electronic submissions can be found in Unit X of this document.

FOR FURTHER INFORMATION CONTACT: Susan Hazen, Director, Environmental Assistance Division (7408), Office of Toxic Substances, Environmental Protection Agency, Rm. E–543B, 401 M St., SW., Washington, DC 20460, telephone: (202) 554–1404, TDD: (202) 554–0551; e-mail: TSCA-Hotline@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: This SNUR will require persons to notify EPA at least 90 days before commencing manufacturing or processing a substance for any activity designated by this SNUR as a significant new use. The supporting rationale and background to this rule are more fully set out in the preamble to EPA's first direct final SNURs published in the Federal Register of April 24, 1990 (55 FR 17376). Consult that preamble for further information on the objectives, rationale, and procedures for the rules and on the basis for significant new use designations including provisions for developing test data.

I. Authority

Section 5(a)(2) of TSCA (15 U.S.C. 2604(a)(2)) authorizes EPA to determine that a use of a chemical substance is a ''significant new use.'' EPA must make this determination by rule after considering all relevant factors, including those listed in section 5(a)(2). Once EPA determines that a use of a chemical substance is a significant new use, section 5(a)(1)(B) of TSCA requires persons to submit a notice to EPA at least 90 days before they manufacture, import, or process the substance for that use. The mechanism for reporting under this requirement is established under 40 CFR 721.10.

II. Applicability of General Provisions

General provisions for SNURs appear under subpart A of 40 CFR part 721. These provisions describe persons subject to the rule, recordkeeping requirements, exemptions to reporting requirements, and applicability of the rule to uses occurring before the effective date of the final rule. Provisions relating to user fees appear at 40 CFR part 700. Persons subject to this SNUR must comply with the same notice requirements and EPA regulatory procedures as submitters of PMNs under section 5(a)(1)(A) of TSCA. In particular, these requirements include the information submission requirements of section 5(b) and 5(d)(1), the exemptions authorized by section 5 (h)(1), (h)(2), (h)(3), and (h)(5), and the regulations at 40 CFR part 720. Once EPA receives a SNUR notice, EPA may take regulatory action under section 5(e), 5(f), 6, or 7 to control the activities on which it has received the SNUR notice. If EPA does not take action, EPA is required under section 5(g) to explain in the Federal Register its reasons for not taking action.

Persons who intend to export a substance identified in a proposed or final SNUR are subject to the export notification provisions of TSCA section 12(b). The regulations that interpret section 12(b) appear at 40 CFR part 707. Persons who intend to import a chemical substance identified in a final SNUR are subject to the TSCA section 13 import certification requirements, which are codified at 19 CFR 12.118 through 12.127 and 127.28. Such persons must certify that they are in compliance with SNUR requirements. The EPA policy in support of the import certification appears at 40 CFR part 707.

III. Substances Subject to This Rule

EPA is establishing significant new use and recordkeeping requirements for the following chemical substances under 40 CFR part 721, subpart E. In this unit, EPA provides a brief description for each substance, including its PMN number, chemical name (generic name if the specific name is claimed as CBI), CAS number (if assigned), basis for the action taken by EPA in the section 5(e) consent order or as a non-section 5(e) SNUR for the substance (including the statutory citation and specific finding), toxicity concern, and the CFR citation assigned in the regulatory text section of this rule. The specific uses which are designated as significant new uses are cited in the regulatory text section of this document by reference to 40 CFR part 721, subpart B where the significant