§ 180.493 [Corrected]

1. On page 39961, amendatory instruction 2 is corrected to read as follows:

''2. Section 180.493 is amended in paragraph (b) by revising the introductory text and alphabetically adding the following tolerances to the table to read as follows:.''

2. Correct the table by adding in paragraph (b) five stars at the beginning of the table.

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 180, 185 and 186

[OPP–300549; FRL–5743–6]

RIN 2070–AB78

Triadimefon; Pesticide Tolerances for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes time-limited tolerances for residues of triadimefon in or on asparagus and in or on artichokes. This action is in response to EPA's granting of an emergency exemption under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act authorizing use of the pesticide on asparagus and artichokes. This regulation establishes maximum permissible levels for residues of triadimefon in these food commodities pursuant to section 408(l)(6) of the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996. These tolerances will expire and are revoked on September 1, 1999.

DATES: This regulation is effective September 10, 1997. Objections and requests for hearings must be received by EPA on or before November 10, 1997.

ADDRESSES: Written objections and hearing requests, identified by the docket control number, [OPP–300549], 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–300549], must also be submitted to: Public Information and Records Integrity Branch, Information Resources and Services 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 control number [OPP–300549]. 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: Olga Odiott, 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) 308–9363, e-mail: odiott.olga@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 tolerances for residues of the fungicide triadimefon, in or on asparagus at 0.15 part per million (ppm), and in or on artichokes at 0.6 ppm. These tolerances will expire and are revoked on September 1, 1999. EPA will publish a document in the **Federal Register** to remove the revoked tolerances 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 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)(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 tolerance to set binding precedents for the application of section 408 and the new safety standard to other tolerances and exemptions.

II. Emergency Exemption for Triadimefon on Asparagus and Artichokes and FFDCA Tolerances

The state of Michigan availed itself of the authority to declare a crisis exemption to use triadimefon to control the asparagus rust (*Puccinia asparagi*). EBDC fungicides are available and are effective against the asparagus rust but processors in Michigan will not accept asparagus treated with EBDCs, leaving the Michigan growers with no alternative for control of the disease. Yield declines of 20 to 50% are possible without the use of triadimefon.

The state of California stated that powdery mildew, caused by the fungus *Leveillula taurica* Lev., is a relatively new disease of artichokes that was first detected by growers in California during the summer of 1985. It is now endemic in most artichoke growing districts, affecting more than 65% of the artichoke acreage. Currently, there are no registered fungicides or alternative practices available that will control powdery mildew on artichokes. If triadimefon is not available for use, yield losses of 30 to 50% are expected. EPA has authorized under FIFRA section 18 the use of triadimefon on asparagus and artichokes for control of rust in Michigan and powdery mildew in California. After having reviewed their submissions, EPA concurs that emergency conditions exist for these states.

As part of its assessment of this emergency exemption, EPA assessed the potential risks presented by residues of triadimefon in or on asparagus and in or on artichokes. In doing so, EPA considered the new safety standard in FFDCA section 408(b)(2), and EPA decided that the necessary tolerances under FFDCA section 408(l)(6) would be consistent with the new 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 these tolerances without notice and opportunity for public comment under section 408(e), as provided in section 408(l)(6). Although these tolerances will expire and are revoked on September 1, 1999, under FFDCA section 408(l)(5), residues of the pesticide not in excess of the amounts specified in the tolerance remaining in or on asparagus and in or on artichokes after that date will not be unlawful, provided the pesticide is applied in a manner that was lawful under FIFRA. EPA will take action to revoke these tolerances earlier if any experience with, scientific data on, or other relevant information on this pesticide indicate that the residues are not safe.

Because these tolerances are being approved under emergency conditions EPA has not made any decisions about whether triadimefon meets EPA's registration requirements for use on asparagus and artichokes or whether permanent tolerances for these uses would be appropriate. Under these circumstances, EPA does not believe that these tolerances serves as a basis for registration of triadimefon by a State for special local needs under FIFRA section 24(c). Nor do these tolerances serve as the basis for any State other than Michigan and California to use this pesticide on these crops 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. Second, EPA examines exposure to the pesticide through the diet (e.g., food and drinking water) and through exposures that occur as a result of pesticide use in residential settings.

A. Toxicity

1. *Threshold and non-threshold effects.* For many animal 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. EPA generally uses the RfD to evaluate the chronic risks posed by pesticide exposure. For shorter term risks, EPA calculates a margin of exposure (MOE) by dividing the estimated human exposure into the NOEL from the appropriate animal study. Commonly, EPA finds MOEs lower than 100 to be unacceptable. This 100-fold MOE is based on the same rationale as the 100-fold uncertainty factor.

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 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.

2. *Differences in toxic effect due to exposure duration.* The toxicological effects of a pesticide can vary with different exposure durations. EPA considers the entire toxicity data base, and based on the effects seen for different durations and routes of exposure, determines which risk assessments should be done to assure that the public is adequately protected from any pesticide exposure scenario. Both short and long durations of exposure are always considered. Typically, risk assessments include ''acute'', ''short-term'', ''intermediate term'', and ''chronic'' risks. These assessments are defined by the Agency as follows.

Acute risk, by the Agency's definition, results from 1–day consumption of food and water, and reflects toxicity which could be expressed following a single oral exposure to the pesticide residues. High end exposure to food and water residues are typically assumed.

Short-term risk results from exposure to the pesticide for a period of 1–7 days, and therefore overlaps with the acute risk assessment. Historically, this risk assessment was intended to address primarily dermal and inhalation exposure which could result, for example, from residential pesticide applications. However, since enaction of FQPA, this assessment has been expanded to include both dietary and non-dietary sources of exposure, and will typically consider exposure from food, water, and residential uses when reliable data are available. In this assessment, risks from average food and water exposure, and high-end residential exposure, are aggregated. High-end exposures from all 3 sources are not typically added because of the very low probability of this occurring in most cases, and because the other conservative assumptions built into the assessment assure adequate protection of public health. However, for cases in which high-end exposure can reasonably be expected from multiple sources (e.g. frequent and widespread homeowner use in a specific geographical area), multiple high-end risks will be aggregated and presented as part of the comprehensive risk assessment/characterization. Since the toxicological endpoint considered in this assessment reflects exposure over a period of at least 7 days, an additional degree of conservatism is built into the assessment; i.e., the risk assessment nominally covers 1–7 days exposure, and the toxicological endpoint/NOEL is selected to be adequate for at least 7 days of exposure. (Toxicity results at lower levels when the dosing duration is increased.)

Intermediate-term risk results from exposure for 7 days to several months. This assessment is handled in a manner similar to the short-term risk assessment.

Chronic risk assessment describes risk which could result from several months to a lifetime of exposure. For this assessment, risks are aggregated considering average exposure from all sources for representative population subgroups including infants and children.

B. Aggregate Exposure

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, residues in groundwater or surface water that is consumed as drinking water, and other non-occupational exposures through pesticide use in gardens, lawns, or buildings (residential and other indoor uses). 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. In evaluating food exposures, EPA takes into account varying consumption patterns of major identifiable subgroups of consumers, including infants and children.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% 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.

Percent of crop treated estimates are derived from federal and private market survey data. Typically, a range of estimates are supplied and the upper end of this range is assumed for the exposure assessment. By using this upper end estimate of percent of crop treated, the Agency is reasonably certain that exposure is not understated for any significant subpopulation group. Further, regional consumption information is taken into account through EPA's computer-based model for evaluating the exposure of significant subpopulations including several regional groups, to pesticide residues. For this pesticide, the most highly exposed population subgroup (non-nursing infants < 1 year old) was not regionally based.

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, 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 tolerances for residues of triadimefon in or on asparagus at 0.15 ppm and in or on artichokes at 0.6 ppm. EPA's assessment of the dietary exposures and risks associated with establishing these tolerances 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 triadimefon are discussed below. Triadimenol is a metabolite of triadimefon and is also an active ingredient in pesticide products (ex. Baytan). Toxicological endpoints for triadimefon and triadimenol are presented below.

1. *Acute toxicity*. The NOEL of 20 mg/kg/day from a rabbit developmental study was selected for assessing acute dietary risk from residues of triadimefon. The risk assessment will evaluate acute dietary risks for females 13+ years old.

The Agency has determined that an acute dietary risk assessment is not required for triadimenol. This decision was based on the lack of developmental effects at a maternally toxic dose of triadimenol in a rabbit developmental study.

2. *Short - and intermediate - term toxicity*. The Agency determined that the NOEL of 20 mg/kg/day from the developmental toxicity study in rabbits should be used to assess risks from short and intermediate-term exposures to residues of triadimefon.

The Agency determined that the NOEL of 250 mg/kg/day (highest dose tested) from a 21–day dermal toxicity study in rabbits should be used to assess risks from short- and intermediate-term exposures to residues of triadimenol.

3. *Chronic toxicity*. EPA has established the RfD for triadimefon at 0.04 milligrams/kilogram/day (mg/kg/day). This RfD is based on a 2–year dog feeding study. The NOEL for systemic toxicity in dogs of either sex was 11.4 mg/kg/day and the LOEL was 33.7 mg/kg/day based on decreased food intake, depression in weight gain, and significantly ($p < 0.05$) increased alkaline phosphatase activity in both sexes. An uncertainty factor (UF) of 300 was applied to account for inter-species extrapolation (10), intra-species variability (10) and the lack of an adequate reproductive toxicity study in rats (3).

The RfD for triadimenol was established at 0.038 mg/kg/day. This RfD is based on 2–year and 6–month

feeding studies in dogs with a NOEL of 3.75 mg/kg/day and an uncertainty factor of 100 based on changes in enzyme levels at the LOEL of 15.0 mg/kg/day.

4. *Carcinogenicity*. The Agency's Carcinogenicity Peer Review Committee (CPRC) has classified triadimefon as a Group C (possible human carcinogen) chemical without a Q_1* and recommended using the RfD approach to assess dietary cancer risk. The classification was based on an increase in thyroid adenomas in male rats and an increase in hepatocellular adenomas, with a positive dose-related trend, in both male and female mice.

The CPRC classified triadimenol as a Group C (possible human carcinogen) chemical based on liver tumors in female mice. The Committee recommended using the RfD approach to assess dietary cancer risk.

B. Exposures and Risks

1. *From food and feed uses.* Tolerances have been established (40 CFR 180.410) for the combined residues of triadimefon and its metabolites containing chlorophenoxy and triazole moieties (expressed as triadimefon), in or on a variety of raw agricultural commodities ranging from 0.04 ppm in poultry meat to 145 ppm in grass seed cleanings.

Tolerances have been established (40 CFR 180.450(a)) for the combined residues of the fungicide triadimenol (KWG-0519,β-(4-chlorophenoxy)-α-(1,1-dimethylethyl)-1*H*-1,2,4-triazol-1-ethanol) and its butanediol metabolite (KWG-1342; 4-(4-chlorophenoxy)-2,2-dimethyl-4-(1*H*-1,2,4-triazol-1-yl)-1,3-butanediol), calculated as triadimenol, in or on various commodities including barley, oats and wheat grain at 0.05 ppm; barley, oats and wheat forage at 2.5 ppm; and barley, oats and wheat straw at 0.1 ppm. Tolerances have been established (40 CFR 180.450(b)) for the combined residues of triadimenol and its metabolites containing the chlorophenoxy moiety (calculated as triadimenol) in or on the fat, meat, and meat by-products of cattle, goats, hogs, horses and sheep at 0.1 ppm; milk at 0.01 ppm; the fat, meat, and meat by-products of poultry at 0.01 ppm; and eggs at 0.01 ppm. Risk assessments were conducted by EPA to assess dietary exposures and risks from triadimefon and triadimenol 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 1–day or single exposure. The acute dietary (food only) risk assessment for triadimefon used tolerance level residues and assumed 100% crop treated. For the population subgroup of concern, females 13+ years old, the resulting high-end exposure estimate of 0.05 mg/kg/day results in a dietary (food only) MOE of 400. This MOE should be viewed as a conservative risk estimate. Refinement of the risk assessment using anticipated residue values and percent crop-treated data would result in a lower acute dietary exposure estimate.

Acute dietary endpoints were not identified for triadimenol, so this risk assessment was not conducted.

ii. *Chronic exposure and risk.* The chronic dietary risk assessment for triadimefon assumed that 100% of asparagus and artichokes and all other commodities having established and pending triadimefon tolerances will contain triadimefon residues and those residues will be at tolerance level, which result in an overestimate of human dietary exposure. The existing triadimefon tolerances (published, pending, and including the necessary Section 18 tolerances) result in a TMRC that is equivalent to percentages of the RfD that range from 18% for the U.S. population to 75% for non-nursing infants < 1 year old.

The chronic dietary risk assessment for triadimenol assumed that all commodities having established and pending triadimenol tolerances will contain triadimenol residues and those residues will be at the level of the tolerance, which result in an overestimate of human dietary exposure. Thus, in making a safety determination for triadimenol, EPA is taking into account this conservative exposure assessment. The existing triadimenol tolerances (published and pending) result in a TMRC that is equivalent to percentages of the RfD that range from 1% for the U.S. population to 3% for non-nursing infants < 1 year old.

2. *From drinking water.* Based on available data used in EPA's assessment of environmental risk, triadimefon and triadimenol are mobile and have the potential to leach into ground water. There are no established Maximum Contaminant Levels for residues of triadimefon or triadimenol in drinking water, and no Health Advisory levels for triadimefon or triadimenol in drinking water have been established. According to the ''Pesticides in Groundwater Database'', EPA 734–12–92–001, Sept 1992, 14 wells in California were sampled for triadimefon from 1984–1989. No wells had detectable residues. There was no entry for triadimenol.

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 exposure from contaminated water, the ranges the Agency is continuing to examine are all below the level that would cause triadimefon and triadimenol 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 triadimefon and triadimenol 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.

3. *From non-dietary exposure.* Triadimefon is currently registered for use on non-food sites such as ornamentals and turfgrass. Triadimenol is currently registered for use on turfgrass. Based on the nature of the outdoor residential uses, the EPA concludes that chronic residential exposure scenarios do not exist for triadimefon. Short and/or intermediate term exposure scenarios may exist. However, the Agency currently lacks sufficient residential-related exposure data to complete a comprehensive residential risk assessment for many pesticides, including triadimefon.

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.'' 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).

Triadimefon and triadimenol are members of the triazole class of pesticides. Other members of this class include tebuconazole, propiconazole, cyproconazole, penconazole, myclobutanil, and difenoconazole. 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, with the exception of triadimenol. A regulated metabolite of triadimefon, triadimenol is itself a fungicide active ingredient registered for use on several crops. In plants, the residue of concern for triadimenol is triadimenol and its butanediol metabolite. In animal commodities, the residue of concern for triadimenol is triadimenol and its metabolites containing the chlorophenoxy moiety.

To estimate the cumulative (triadimefon + triadimenol) aggregate dietary exposures, estimates for triadimenol on its regulated commodities were added to estimates for triadimefon.

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

1. *Acute risk*. For the population subgroup of concern, females 13+ years, the calculated MOE value for triadimefon dietary (food) exposure is 400. Although there is potential for exposure to triadimefon in drinking water, the Agency does not expect the aggregate exposure (food plus water) to exceed the Agency's level of concern.

No acute toxicity endpoints were identified for triadimenol, therefore an acute aggregate risk assessment was not conducted.

2. *Chronic risk*. Using the TMRC exposure assumptions described above, EPA has concluded that aggregate exposure to triadimefon and triadimenol from food will utilize 19% of the RfD for the U.S. population. The major identifiable subgroup with the highest aggregate exposure is non-nursing infants < 1 year 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 triadimefon and triadimenol in drinking water and from non-dietary, non-occupational exposure, EPA does not expect the aggregate exposure to exceed 100% of the RfD. EPA concludes that there is a reasonable certainty that no harm will result from aggregate exposure to triadimefon and triadimenol residues.

3. *Short- and intermediate-term risk*. 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.

Based on the registered uses of fenarimol short and/or intermediate term exposure scenarios may exist. However, the Agency currently lacks sufficient residential-related exposure data to complete a comprehensive residential risk assessment for many pesticides, including triadimefon.

D. Aggregate Cancer Risk for U.S. Population

The Agency's CPRC recommended the RfD approach for assessment of dietary cancer risk. Dietary risk concerns due to long-term exposures to triadimefon and triadimenol residues are adequately addressed by the aggregate chronic dietary risk assessment.

E. 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 triadimefon and triadimenol, EPA considered data from developmental toxicity studies in the rat and rabbit and a two-generation reproduction study in the rat. 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 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 100-fold safety factor (for combined inter- and intra-species variability) and not the additional tenfold safety 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 safety factor.

ii. *Developmental toxicity studies*— a. *Rats*. For triadimefon, the maternal systemic NOEL was 30 mg/kg/day and the LOEL was 90 mg/kg/day. Effects seen at the LOEL include statistically significant body weight gain decrement during gestational days 6–15. The developmental NOEL was 30 mg/kg/day and the developmental LOEL was 90 mg/kg/day, based on the increased incidence of skeletal variations, unossified and incompletely ossified hyoid, and full and rudimentary ribs.

For triadimenol, the maternal (systemic) NOEL was 25 mg/kg/day, based on decreased body weight and food consumption at the LOEL of 125 mg/kg/day. The developmental (fetal) NOEL was 125 mg/kg/day (highest dose tested (HDT)).

b. *Rabbits.* For triadimefon, the maternal (systemic) NOEL was 50 mg/kg/day and the LOEL was 120 mg/kg/day. The maternal LOEL was based on increased clinical signs such as increased hyperactivity, reddish discharge, and decreased body weight gain during gestational days 6–10. The developmental NOEL was 20 mg/kg/day and the LOEL was 50 mg/kg/day, based on irregular spinous process and incomplete ossification of various bones.

For triadimenol, the maternal (systemic) NOEL was 8 mg/kg/day, based on decreased body weight and food consumption at the LOEL of 40 mg/kg/day. The developmental (fetal) NOEL was 40 mg/kg/day, based on post-implantation loss, decreased fetal body weight, and skeletal anomalies at the LOEL of 200 mg/kg/day.

iii. *Reproductive toxicity study.* An acceptable reproductive toxicity study is not available for triadimefon.

For triadimenol, the maternal (systemic) NOEL from a 2-generation reproductive toxicity study in rats was 5.0 mg/kg/day. The NOEL was based on decreased body weight at the LOEL of 25 mg/kg/day. The developmental (pup) NOEL was 5.0 mg/kg/day, based on decreased body weight at the LOEL of 25 mg/kg/day. The reproductive NOEL was 25 mg/kg/day (HDT).

iv. *Pre- and post-natal sensitivity.* The toxicological data base for evaluating pre- and post-natal toxicity for triadimefon is not complete with respect to current data requirements. However, in calculating the RfD, an uncertainty factor (UF) of 300 was applied to account for inter-species extrapolation (10), intra-species variability (10), and the lack of an adequate reproductive toxicity study in rats (3). 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 (on which the MOE calculations for acute dietary risks are based) is lower than the maternal systemic NOEL of 50 mg/kg/day from the same rabbit developmental study. The Agency believes that the additional 3X uncertainty factor, together with the very conservative assumptions made for the exposure assessment, provide adequate protection to infants and children from the risks associated with exposures to triadimefon residues.

The toxicological data base for evaluating pre- and post-natal toxicity for triadimenol is complete with respect to current data requirements. There are no pre- or post-natal toxicity concerns for infants and children, based on the results of the rat and rabbit developmental toxicity studies and the 2-generation rat reproductive toxicity study. The rat developmental study had no developmental effects up to the highest dose tested, which produced maternal toxicity. The rabbit developmental toxicity study demonstrated maternal toxicity at a dose at which no developmental toxicity was apparent. In the rat reproductive toxicity study, the parental and pup effects occur at the NOELs and LOELs and the same effect (decreased body weight) occurred in both pups and parental animals.

v. *Conclusion.* Based on the above considerations and in EPA's best scientific judgment, the application of a margin of exposure/uncertainty factor of 300 provides adequate protection for infants and children from the risks associated with exposures to triadimefon residues.

The EPA also concludes that, for triadimenol, reliable data support use of the standard 100-fold margin of exposure/ uncertainty factor and that an additional margin/factor is not needed to protect infants and children.

2. *Acute risk.* For triadimefon, the acute dietary (food only) MOE was calculated to be 400 for females 13+ years old (accounts for both maternal and fetal exposure), the population subgroup of concern. This risk assessment for triadimefon used tolerance level residues and assumed 100% crop treated. This MOE should be viewed as a conservative risk estimate; further refinement using anticipated residue values and percent crop-treated data would result in a lower acute dietary exposure estimate. The large acute dietary MOE calculated for females 13+ years provides assurance that there is a reasonable certainty of no harm for both females 13+ years and the pre-natal development of infants. Despite the potential for exposure to triadimefon in drinking water, the Agency does not expect the aggregate exposure (food + water) to exceed the Agency's level of concern for acute dietary exposure.

No acute toxicity endpoints were identified for triadimenol, so an acute aggregate risk assesment was not conducted.

3. *Chronic risk.* Using the conservative exposure assumptions described above, EPA has concluded that aggregate exposure to triadimefon and triadimenol from food will utilize percentages of the RfD that range from 28% for children 7–12 years old, up to 78% for non-nursing infants less than 1 year 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 triadimefon and triadimenol in drinking water and from non-dietary, non-occupational exposure, EPA does not expect the aggregate exposure to exceed 100% of the RfD. EPA concludes that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to triadimefon and triadimenol residues.

4. *Short- or intermediate-term risk.* Based on the registered uses of fenarimol short and/or intermediate term exposure scenarios may exist. However, the Agency currently lacks sufficient residential-related exposure data to complete a comprehensive residential risk assessment for many pesticides.

V. Other Considerations

A. Metabolism In Plants and Animals

The nature of triadimefon residues in plants is adequately understood. The Agency's Metabolism Committee determined that the residues of concern are triadimefon and its metabolites containing chlorophenoxy and triazole moieties, expressed as triadimefon. The nature of triadimefon residues in animals is not germane to these tolerances as no livestock feed items are involved.

B. Analytical Enforcement Methodology

Adequate enforcement methods (GC/MS) are published in the Pesticide Analytical Manual, Volume II, Pesticide Reg. Sec. 180.410, as Methods I and II. In addition, Mobay Method No. 80488 has undergone a successful method trial and has been validated for determination of triadimefon and its metabolites relevant to 40 CFR 180.410 on plant commodities.

C. Magnitude of Residues

Regulable residues of triadimefon are not expected to exceed 0.15 ppm in/on asparagus and 0.6 ppm in/on globe artichokes as a result of these section 18 uses. Secondary residues are not expected in animal commodities as no feed items are associated with these section 18 uses.

D. International Residue Limits

There are no CODEX, Canadian, or Mexican maximum residue limits (MRLs) established for residues of

triadimefon in/on asparagus or in/on artichokes.

VI. Conclusion

Therefore, time-limited tolerances are established for the regulable residues of triadimefon in asparagus at 0.15 ppm and in artichokes at 0.6 ppm. In addition, because the FQPA eliminated the distinctions between processed food, feed and raw agricultural commodities, OPP is transferring the tolerances for residues of triadimefon in §§ 185.800 and 186.800 to the table in paragraph (a) of § 180.410 and removing the remainder of §§ 185.800 and 186.800.

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 November 10, 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 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

EPA has established a record for this rulemaking under docket control number [OPP–300549] (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 1132 of the Public Information and Records Integrity Branch, Information Resources and Services Division (7506C), 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.

IX. Regulatory Assessment Requirements

This final rule establishes time-limited tolerances under FFDCA section 408(d 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 these tolerances and exemptions that are established under FFDCA section 408(l)(6), such as the tolerances 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 acations published on May 4, 1981 (46 FR 24950), and was provided to the Chief Counsel for Advocacy of the Small Business Administration.

X. Submission to Congress and the General Accounting Office

Under 5 U.S.C. 801(a)(1)(A), as added by the Small Business Regulatory Enforcement Fairness Act of 1996, the Agency has 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 this rule in today's **Federal Register**. This is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects

40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

40 CFR Part 185

Environmental protection, Food additives, Pesticides and pests.

40 CFR Part 186

Environmental protection, Animal feeds, Pesticides and pests.

Dated: August 29, 1997.

James Jones,

Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

1. In part 180:

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

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

b. By amending § 180.410 as follows:

i. By revising the section heading.

ii. By adding a subject heading to paragraph (a).

iii. By revising paragraphs (b) and (c).

iv. By adding and reserving paragraph (d) with a subject heading.

§ 180.410 Triadimefon; tolerances for residues.

(a) *General .* * * *

(b) *Section 18 emergency exemptions.* Time-limited tolerances are established for the combined residues of the fungicide triadimefon, 1-(4-chlorophenoxy)-3,3-dimethyl-1(1*H*-1,2,4-triazol-1-yl)-2-butanone and its metabolites containing chlorophenoxy and triazole moieties (expressed as the fungicide) in connection with use of the pesticide under the section 18 emergency exemptions granted by EPA. The tolerances will expire and are revoked on the dates specified in the following table:

Commodity	Parts per million	Expiration/revocation date
Artichokes	0.6	September 1, 1999
Asparagus	0.15	September 1, 1999
Chili peppers	0.5	November 8, 1997

(c) *Tolerances with regional registrations.* Tolerances with regional registration are established for the combined residues of the fungicide 1-(4-chlorophenoxy)-3,3-dimethyl-1(1*H*-1,2,4-triazol-l-yl)-2-butanone and its metabolites containing chlorophenoxy and triazole moieties (expressed as the fungicide) in or on the following raw agricultural commodities:

Commodity	Parts per million
Raspberries	2.0

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

PART 185—[AMENDED]

2. In part 185:

a. The authority citation for part 185 continues to read as follows:

Authority: 21 U.S.C. 346a and 348.

§ 185.800 [Removed]

b. In § 185.800 by transferring the entries in the table and alphabetically adding them to the table in paragraph (a) of § 180.410, and by removing the remainder of § 185.800.

PART 186—[AMENDED]

3. In part 186:

a. The authority citation for part 185 continues to read as follows:

Authority: 21 U.S.C. 342, 348, and 701.

§ 186.800 [Removed]

b. In § 186.800 by transferring the entries in the table and alphabetically adding them to the table in paragraph (a) of § 180.410, and by removing the remainder of § 186.800.

[FR Doc. 97–23975 Filed 9-9-97; 8:45 am]

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DEPARTMENT OF THE INTERIOR

Bureau of Land Management

43 CFR Part 1810

[WO–420–1050–00–24–1A]

RIN 1004–AC 81

Public Land Records

AGENCY: Bureau of Land Management, Interior.

ACTION: Final rulemaking.

SUMMARY: This final rule amends Part 1810 of Title 43 of the Code of Federal Regulations (CFR) by completely removing Subpart 1813. That subpart contains general information about public land records and explains Bureau of Land Management (BLM) practices. Instead, we will place these internal procedures in information brochures and BLM's manual system, which is appropriate given the administrative nature of Subpart 1813.

EFFECTIVE DATE: October 10, 1997.

ADDRESSES: You may send inquiries or suggestions to: Director (630), Bureau of Land Management, 1849 C Street, NW, Washington, D.C. 20240.

FOR FURTHER INFORMATION CONTACT: Frances Watson, Telephone: 202–452–5006 (Commercial or FTS).

SUPPLEMENTARY INFORMATION:

I. Background

One of the objectives of President Clinton's regulatory reform initiative is to eliminate unnecessary regulations from the CFR. To meet that objective, BLM is removing from the CFR material that provides general information about public land records and explains BLM practices. Instead, BLM will provide this information in public information releases and the BLM Manual, both of which are available to the public, are more detailed, and can be more easily updated. Removing this material from the CFR will not deprive the public of any notice, right, administrative process or information required by law.

The final rule published today is a stage of the rulemaking process that will culminate in the removal of the regulations in 43 CFR Subpart 1813. This rule was preceded by a proposed rule that was published in the **Federal Register** on December 23, 1996 (61 FR 67517). The BLM invited public comments for 60 days, and received three comments—one from a petroleum association, one from a county government agency, and one from a law firm.

II. Final Rule as Adopted

The final rule completely removes 43 CFR subpart 1813, which contains BLM procedures on maintaining the public land records. Removing this material is appropriate since it will continue to be available to the public through other means—informational brochures and the BLM manual system. The final rule is being published without change from the December 23, 1996, proposed rule.

III. Responses to Comments

The three comments that we received on the proposed rule expressed concern about removing 43 CFR subpart 1813. The commenters interpreted the regulation to mean that BLM will no