ii. The existing text is designated as paragraph (a) ''General''.

iii. Paragraphs (b), (c), and (d) are added as follows:

§ 180.474 Tebuconazole; tolerances for residues.

(a) *General.* * * *

* * * * *

(b) *Section 18 emergency exemptions*—(1) *Use on grains, hay and other plant products.* Time-limited tolerances are established for residues of the fungicide tebuconazole (*alpha*-[2-(4-chlorophenyl)-ethyl]-*alpha*-(1,1-dimethylethyl)-1*H*-1,2,4-triazole-1-ethanol) in connection with use of the pesticide under 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
Barley, grain	2.0	June 30, 1998
Barley, hay	20.0	Do.
Barley, straw	20.0	Do.
Pistachios	1.0	Do.
Wheat, hay	15.0	Do.
Wheat, straw	2.0	Do.

(2) *Use on meat and meat byproducts.* Time-limited tolerances are established for the combined residues of the fungicide tebuconazole and its 1-(4-chlorophenyl)-4,4-dimethyl-3-(1*H*-1,2,4-triazole-1-yl-methyl)-pentane-3,5-diol metabolite (HGW 2061) in connection with use of the pesticide under 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
Milk	0.1	June 30, 1998
Cattle, meat byproducts	0.2	Do.
Goats, meat byproducts	0.2	Do.
Hogs, meat byproducts	0.2	Do.
Horses, meat byproducts	0.2	Do.
Poultry, meat byproducts	0.2	Do.
Sheep, meat byproducts	0.2	Do.

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

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

[FR Doc. 97–16216 Filed 6–19–97; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300348; FRL–5718–7]

RIN 2070–AC78

Terbacil; Pesticide Tolerances for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes time-limited tolerances for residues of the herbicide, terbacil in or on the raw agricultural commodities watermelons in connection with EPA's granting of emergency exemptions under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act authorizing use of terbacil on watermelons in Delaware, Maryland, and Virginia. This regulation establishes maximum permissible levels for residues of terbacil on watermelons 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 is revoked on May 31, 1998.

DATES: This regulation becomes effective June 20, 1997. Objections and requests for hearings must be received by EPA on August 19, 1997.

ADDRESSES: Written objections and hearing requests, identified by the docket control number, ''OPP–300348,'' 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–300348,'' should 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 control number ''OPP–300348.'' 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: Virginia Dietrich, Registration Division (7505C), Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location,

telephone number, and e-mail address: Document Processing Desk, (7505C), Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA 22202, (703) 308–9359, e-mail: dietrich.virginia@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: EPA, 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 herbicide terbacil (3-tert-Butyl-5-chloro-6-methyluracil and its three metabolites 3-tert-butyl-5-chloro-6-hydroxymethyluracil, 6-chloro-2,3-dihydro-7-hydroxymethyl-3,3-dimethyl-5H-oxazolo (3,2-a) pyrimidin-5-one, and 6-chloro-2,3-dihydro-3,3,7-trimethyl-5H-oxazolo (3,2-a) pyrimidin-5-one) which are calculated as terbacil in or on watermelons at 0.4 parts per million (ppm). This tolerance will expire and is revoked on May 31, 1998. After May 31, 1998, EPA will publish a document in the **Federal Register** to remove the revoked tolerance from the Code of Federal Regulations.

I. Background and Statutory Authority

The Food Quality Protection Act of 1996 (FQPA) (Pub. L. 104-170) was signed into law August 3, 1996. FQPA amends both the 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) 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 Exemptions for Terbacil on Watermelons and FFDCA Tolerances

Between November 4 and December 3, 1996, Departments of Agriculture from three states, Delaware, Maryland, and Virginia, each requested a specific exemption under FIFRA section 18 for the use of terbacil to control weeds in watermelons. They asserted that no efficacious pesticide is registered under section 3 of FIFRA for control of weeds in watermelons. This situation was caused by the suspension of dinoseb in 1987. They also said that growers will experience significant economic loss if the weeds are not controlled. After having reviewed their submission, EPA concurs that an emergency condition exists.

As part of its assessment of these applications for emergency exemption, EPA assessed the potential risks presented by residues of terbacil on watermelons. 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 terbacil will permit the marketing of watermelons treated in accordance with the provisions of the section 18 emergency exemptions. Consistent with the need to move quickly on the emergency exemptions 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). 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 terbacil meets the requirements for registration under FIFRA section 3 for use on watermelons or whether permanent tolerances for terbacil for watermelons would be appropriate. This action by EPA does not serve as a basis for registration of terbacil 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 Delaware, Maryland, and Virginia to use this product on watermelons under section 18 of FIFRA without following all provisions of section 18 as identified in 40 CFR 180.166. For additional information regarding the emergency exemptions for terbacil, 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 watermelons 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 watermelons 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. Terbacil is not registered by EPA for indoor or outdoor residential use. Existing food and feed use tolerances for terbacil are listed in 40 CFR 180.209. EPA has sufficient data to assess the hazards of terbacil and to make a determination on aggregate exposure, consistent with section 408(b)(2), for the time-limited tolerances for residues of terbacil in or on watermelons at 0.4 ppm. EPA's assessment of the dietary exposures and risks associated with establishing these tolerances follows.

A. Toxicological Profile

1. *Dietary endpoint selection*—i. *Acute risk*. For acute dietary risk assessment, the Agency selected the NOEL of 12.5 milligrams/kilograms/day (mg/kg/day) from the developmental study in rats. This was based on a decrease in the number of implants and a decrease in the number of live fetuses at the LEL of 62.5 mg/kg/day. This risk assessment will evaluate acute dietary risk to females age 13+.

ii. *Chronic risk*. The RfD of 0.013 mg/kg/day was established based on a chronic dog study with a NOEL of 1.25 mg/kg/day and an uncertainty factor of 100 based on increased thyroid:body weight ratio, slight increase in liver weight and elevated alkaline phosphatase at the LEL of 6.25 mg/kg/day.

iii. *Cancer risk*. Terbacil has been classified as a Group E chemical (evidence of noncarcinogenicity for humans) by the RfD Committee.

iv. *Infants and children*—a. *Developmental studies*—(1) *Rat*. From the rat developmental study, the maternal (systemic) NOEL was 12.5 mg/kg/day, based on decreased body weight at the lowest observed effect level (LOEL) of 62.5 mg/kg/day. The developmental (pup) NOEL was 12.5 mg/kg/day, based on decreased number of implantations and live fetuses at the LOEL of 62.5 mg/kg/day.

(2) *Rabbit*. From the rabbit developmental study, the maternal (systemic) NOEL was 200 mg/kg/day, based on decreased weight gain at the LOEL of 600 mg/kg/day. The developmental (pup) NOEL was 600 mg/kg/day (highest dose tested).

b. *Reproduction studies*. Rat - From the rat reproduction study, the parental (systemic) LOEL was 2.5 mg/kg/day [lowest dose tested], based on decreased body weight. The reproductive/developmental (pup) NOEL was 12.5 mg/kg/day [highest dose tested].

B. Aggregate Exposure and Risk

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

The nature of the residue in plants is adequately understood for the purposes of this section 18 request. The residues of concern are terbacil and its three metabolites (all calculated as terbacil). Tolerances currently exist for residues on more than a dozen commodities (see 40 CFR 180.209). Residues of terbacil and its regulated metabolites are not

expected to exceed 0.4 ppm in watermelons as a result of this use.

For purposes of assessing the potential dietary exposure under this tolerance, EPA assumed tolerance level residues and 100 percent of crop treated to estimate the TMRC from all established food uses for terbacil (for more than a dozen commodities) and the proposed use on watermelons. There are no watermelon animal feed items so no residue levels in animal commodities potentially resulting from feeding of these commodities were considered.

Because terbacil is very persistent and very mobile, there is potential for terbacil to leach to ground water and to subsequently be ingested in drinking water. In fact, terbacil has been found in groundwater. The document ''Pesticides in Groundwater Database'' EPA 734-12-92-001, September 1992 cites data that 6 wells out of 288 tested positive for terbacil at levels up to 0.009 ppm. However detections were at levels well below the Health Advisory Levels (1–day, 0.3 ppm, 10–day, 0.3 ppm, and lifetime, 0.09 ppm).

Because the Agency lacks sufficient water-related exposure data to complete a comprehensive drinking water risk assessment for many pesticides, EPA has commenced and nearly completed a process to identify a reasonable yet conservative bounding figure for the potential contribution of water-related exposure to the aggregate risk posed by a pesticide. In developing the bounding figure, EPA estimated residue levels in water for a number of specific pesticides using various data sources. The Agency then applied the estimated residue levels, in conjunction with appropriate toxicological endpoints (RfD's or acute dietary NOEL's) and assumptions about body weight and consumption, to calculate, for each pesticide, the increment of aggregate risk contributed by consumption of contaminated water. While EPA has not yet pinpointed the appropriate bounding figure for consumption of contaminated water, the ranges the Agency is continuing to examine are all well below the level that would cause terbacil 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 terbacil 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.

The Agency identified both acute and chronic duration of exposure as appropriate for aggregate risk assessment. For acute exposure, this estimate does not exceed the Agency's level of concern (MOE <100). For females 13+ years (the population subgroup of concern), the resulting high-end exposure estimate is 0.005 mg/kg/day. This results in a dietary (food only) MOE of 2,500. This acute aggregate risk assessment takes into account exposure from dietary food and water only. The acute dietary (food only) risk assessment used tolerance level residues and assumed 100% crop treated. Therefore this estimate should be viewed as a conservative risk estimate.

For aggregate chronic risk (food plus drinking water), the Agency estimates do not exceed the RfD for terbacil. For example, for non-nursing infants (<1 year old), the population subgroup most highly exposed, the Agency estimated that up to 72% of the RfD may be occupied by exposure to terbacil with risk from residues potentially present in water assumed to account for 10% of the total allowable chronic and acute risk until further data are provided. Estimates for other population subgroups were much less. The Agency used the following formula to estimate risk. The aggregate chronic risk is equal to the sum of the chronic risk from exposure from food + water + residential (indoor and outdoor) uses. Since terbacil is not registered for any residential uses, no exposure from this route is expected and thus not considered this estimate.

C. Cumulative Exposure to Substances With Common Mechanism of Toxicity

Section 408(b)(2)(D)(v) requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider ''available information'' concerning the cumulative effects of a particular pesticide's residues and ''other substances that have a common mechanism of toxicity.'' The Agency believes that ''available information'' in this context might include not only toxicity, chemistry, and exposure data, but also scientific policies and methodologies for understanding common mechanisms of toxicity and conducting cumulative risk assessments. For most pesticides, although the Agency has some information in its files that may turn out to be helpful in eventually determining whether a pesticide shares a common mechanism of toxicity with any other substances, EPA does not at this time have the methodologies to resolve the complex scientific issues concerning common mechanism of toxicity in a meaningful way. EPA has begun a pilot process to study this issue further through the examination of particular classes of pesticides. The Agency hopes that the results of this pilot process will increase the Agency's scientific understanding of this question such that EPA will be able to develop and apply scientific principles for better determining which chemicals have a common mechanism of toxicity and evaluating the cumulative effects of such chemicals. The Agency anticipates, however, that even as its understanding of the science of common mechanisms increases, decisions on specific classes of chemicals will be heavily dependent on chemical specific data, much of which may not be presently available.

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

EPA does not have, at this time, available data to determine whether terbacil has a common mechanism of toxicity with other substances or how to include this pesticide in a cumulative risk assessment. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, terbacil does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has not assumed that terbacil has a common mechanism of toxicity with other subtances.

D. Safety Determinations for U.S. Population

Based on the completeness and reliability of the toxicity data and the conservative TMRC dietary exposure assumptions, EPA has concluded that dietary exposure from food to terbacil will utilize 23 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. Whatever reasonable bounding figure the Agency eventually decides upon for the contribution from water, that number is expected to be well below 99% of the RfD. EPA

concludes that there is a reasonable certainty that no harm will result from aggregate exposure to terbacil residues.

E. Determination of Safety for Infants and Children

FFDCA section 408 provides that EPA shall apply an additional tenfold margin of safety for infants and children in the case of threshold effects to account for pre-and post-natal toxicity and the completeness of the data base unless EPA determines that a different margin of safety will be safe for infants and children. Margins of safety are incorporated into EPA risk assessments either directly through use of a MOE analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans. In either case, EPA generally defines the level of appreciable risk as exposure that is greater than 1/100 of the NOEL in the animal study appropriate to the particular risk assessment. This 100-fold uncertainty (safety) factor/margin of exposure (safety) is designed to account for combined inter- and intra-species variability. EPA believes that reliable data support using the standard 100-fold margin/factor not the additional tenfold margin/factor when EPA has a complete data base under existing guidelines and when the severity of the effect in infants or children or the potency or unusual toxic properties of a compound do not raise concerns regarding the adequacy of the standard margin/factor. Based on current toxicological data requirements, the data base for terbacil relative to pre-(provided by rat and rabbit developmental studies) and post-natal (provided by the rat reproduction study) toxicity is complete.

In assessing the adequacy of the standard uncertainty factor for terbacil, EPA considered data from developmental toxicity studies in the rat and rabbit and a 2-generation reproduction study in the rat. The developmental toxicity studies are designed to evaluate adverse effects on the developing organism resulting from pesticide exposure during prenatal development to one or both parents. Reproduction studies provide information relating to effects from exposure to the pesticide on the reproductive capability of mating animals and data on systemic toxicity.

In the rat developmental study, the NOEL and LOEL for developmental and maternal effects occurred at the same levels (12.5 and 62.5 mg/kg/day, respectively). The Agency notes that the effects seen at the LOEL were more severe in the pups than the maternal effects. This indicates a potential special, pre-natal sensitivity. The results of the rabbit developmental study demonstrated that there were no developmental effects up to 600 mg/kg/day (highest dose tested). There was no evidence of post-natal toxicity to infants and children, since the pup NOEL was 12.5 mg/kg/day [highest dose tested] in the 2-generation rat reproduction study. The acute dietary MOE for females 13+ years was 2,500. This MOE is considered sufficient to protect infants and children against a pre- and post-natal toxicity from aggregate exposure to terbacil.

OPP believes that reliable data show that the standard uncertainty factor will be protective of the safety of infants and children and an additional uncertainty factor is not needed.

Based on TMRC exposure estimates for food, as described above, EPA has concluded that the percentage of the RfD that will be utilized by dietary exposure to residues of terbacil does not exceed 100% of the RfD for any of the population subgroups. Estimates range from 20 percent for nursing infants up to 62 percent for non-nursing infants (the most highly exposed population subgroup). 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 terbacil residues.

V. Other Considerations

The metabolism of terbacil in plants is adequately understood for the purposes of this tolerance. There is no Codex maximum residue level established for residues of terbacil on watermelons. There is a practical analytical method (GC/ELCD) for detecting and measuring levels of terbacil in or on food with a limit of detection that allows monitoring of food with residues at or above the level set by the terbacil tolerance (Method II of PAM Vol. II). EPA has provided information on this method to FDA. The method is available to anyone who is interested in pesticide residue enforcement from: By mail, Calvin Furlow, 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. Office location and telephone number: Crystal Mall #2, Rm. 1128, 1921 Jefferson Davis Hwy., Arlington, VA 22202, 703–305–5805.

VI. Conclusion

Therefore, tolerances in connection with the FIFRA section 18 emergency exemptions are established for residues of terbacil in or on watermelons at 0.4 ppm. These tolerances will expire and be revoked by EPA on May 30, 1998. No further action will be taken by EPA to revoke these tolerances after the expiration of their term other than publishing a notification that the revocation has occurred.

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 August 19, 1997, 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 control number OPP–300348. A public version of this record, 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.

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), the Agency must determine whether the regulatory action is ''significant'' and therefore subject to review by the Office of Management and Budget (OMB) and the requirements of the Executive Order. Under section 3(f), the order defines ''a significant regulatory action'' as an action that is likely to result in a rule: (1) Having an annual effect on the economy of $100 million or more, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local or tribal governments or communities (also referred to as ''economically significant''); (2) creating serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement, grants, user fees, or loan programs or the rights and obligations thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in this Executive Order. Pursuant to the terms of this Executive Order, EPA has determined that this rule is not ''significant'' and is therefore not subject to OMB review. This action does not impose any enforceable duty, or contain any ''unfunded mandates'' as described in Title II of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4), or require prior consultation as specified by Executive Order 12875 (58 FR 58093, October 28, 1993), entitled ''Enhancing the Intergovernmental Partnership,'' or special consideration as required by Executive Order 12898 (59 FR 7629, February 16, 1994).

Because FFDCA section 408(l)(6) permits establishment of this regulation without a notice of proposed rulemaking, the regulatory flexibility analysis requirements of the Regulatory Flexibility Act, 5 U.S.C. 604(a), do not apply. Nonetheless, the Agency has previously assessed whether establishing tolerances or exemptions from tolerance, raising tolerance levels, or expanding exemptions adversely impact small entities and concluded, as a generic matter, that there is no adverse impact. (46 FR 24950) (May 4, 1981).

Under 5 U.S.C. 801(a)(1)(A) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Title II of Pub. L. 104-121, 110 Stat. 847), EPA submitted a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives and the Comptroller General of the General Accounting Office prior to publication of the rule in today's **Federal Register**. This rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

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

Dated: June 9, 1997.

James Jones,

Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR Chapter I is amended as follows:

PART 180 [AMENDED]

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

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

2. By revising 180.209 to read as follows:

§ 180.209 Terbacil; tolerances for residues.

(a) *General.* (1) Tolerances are established for residues of the herbicide terbacil (3-*tert*-butyl-5-chloro-6-methyluracil) in or on the following raw agricultural commodities:

Commodity	Parts per million
Apples	0.1
Citrus fruits	0.1
Peaches	0.1
Pears	0.1
Sugarcane	0.1

(2) Tolerances are established for combined residues of the herbicide terbacil (3-tert-butyl-5-chloro-6-methyluracil) and its metabolites 3-*tert*-butyl-5-chloro-6-hydroxymethyluracil, 6-chloro-2, 3-dihydro-7-hydroxymethyl-3,3-dimethyl-5H-oxazolo (3,2-a) pyrimidin-5-one, and 6-chloro-2,3-dihydro-3,3, 7-trimethyl-5H-oxazolo (3,2-a) pyrimidin-5-one (calculated as terbacil) in or on raw agricultural commodities as follows:

Commodity	Parts per million
Alfalfa, forage	5.0
Alfalfa, hay	5.0
Asparagus	0.2
Blueberries	0.1
Caneberries (blackberries, boysenberries, dewberries, loganberries, raspberries, and youngberries)	0.1
Cattle, fat	0.1
Cattle, mbyp	0.1
Cattle, meat	0.1
Goats, fat	0.1
Goats, mbyp	0.1
Goats, meat	0.1
Hogs, fat	0.1
Hogs, mbyp	0.1
Hogs, meat	0.1
Horses, fat	0.1
Horses, mbyp	0.1
Horses, meat	0.1
Milk, fat (=0.1 in whole milk)	0.5
Mint hay (peppermint and spearmint)	2.0
Pecans	0.1
Sainfoin, forage	5.0
Sainfoin hay	5.0
Sheep, fat	0.1
Sheep, mbyp	0.1

Commodity	Parts per million
Sheep, meat	0.1
Strawberries	0.1

(b) *Section 18 emergency exemptions.* Time limited tolerances are established for residues of the herbicide terbacil (3-tert-Butyl-5-chloro -6-methyluracil and its three metabolites 3-tert-butyl-5-chloro-6-hydroxymethyluracil, 6-chloro-2, 3-dihydro-7-hydroxymethyl 3,3-dimethyl-5H-oxazolo (3,2-a) pyrimidin-5-one, and 6-chloro-2,3-dihydro-3,3,7-trimethyl-5H-oxazolo (3,2-a) pyrimidin-5-one), calculated as terbacil, in connection with use of the pesticide under section 18 emergency exemptions granted by EPA. The tolerance is specified in the following table. The tolerance expires and will be revoked by EPA on the date specified in the table.

Commodity	Parts per million	Expiration/ revocation date
Watermelon	0.4	5/30/98

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

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

[FR Doc. 97–16214 Filed 6–19–97; 8:45 am]
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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 180 and 186

[OPP–300496; FRL–5720–4]

RIN 2070–AB78

Bentazon; Pesticide Tolerance for Emergency Exemption

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a time-limited tolerance for residues of the herbicide bentazon and its metabolite(s) in or on the raw agricultural commodity succulent peas in connection with EPA's granting an emergency exemption under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act authorizing use of the pesticide on succulent peas in Minnesota and Wisconsin. The tolerance will expire and is revoked on June 30, 1998.

DATES: This regulation becomes effective June 20, 1997. Objections and requests for hearings must be received by EPA on or before August 19, 1997.

ADDRESSES: Written objections and hearing requests, identified by the docket control number, [OPP–300496], must be submitted to: Hearing Clerk (1900), Environmental Protection Agency, Rm. M3708, 401 M St., SW., Washington, DC 20460. Fees accompanying objections and hearing requests shall be labeled ''Tolerance Petition Fees'' and forwarded to: EPA Headquarters Accounting Operations Branch, OPP (Tolerance Fees), P.O. Box 360277M, Pittsburgh, PA 15251. A copy of any objections and hearing requests filed with the Hearing Clerk identified by the document control number, [OPP–300496], must 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 number [OPP–300496]. 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: Virginia Dietrich, Registration Division (7505W), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail address: Sixth Floor, Crystal Station #1, 2800 Jefferson Davis Hwy., Arlington, VA (703) 308-8347, e-mail: dietrich.virginia@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 herbicide bentazon and its 6- and 8-hydroxy metabolites in or on succulent peas at 3 part per million (ppm). This tolerance will expire and is revoked on June 30, 1998. After June 30, 1998, EPA will publish a document in the **Federal Register** to remove the revoked tolerance from the Code of Federal Regulations.

I. Background and Statutory Authority

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

New Section 408(b)(2)(A)(i) of the FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is ''safe.'' Section 408(b)(2)(A)(ii) defines ''safe'' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue....''

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