ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300809; FRL–6067–9]

RIN 2070–AB78

Maneb (manganous ethylenebisdithiocarbamate); Pesticide Tolerances for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a time-limited tolerance for residues of maneb (manganous ethylenebisdithiocarbamate), calculated as zinc ethylenebisdithiocarbamate and its metabolite ethylenethiourea in or on walnuts . 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 walnuts.This regulation establishes a maximum permissible level for residues of maneb (manganous ethylenebisdithiocarbamate) in this food commodity pursuant to section 408(l)(6) of the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996. The tolerance will expire and is revoked on December 31, 2000.

DATES: This regulation is effective March 17, 1999. Objections and requests for hearings must be received by EPA on or before May 17, 1999.

ADDRESSES: Written objections and hearing requests, identified by the docket control number [OPP–300809], 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–300809], must also be submitted to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring a copy of objections and hearing requests to Rm. 119, Crystal Mall 2 (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@epa.gov. Copies of electronic objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Copies of objections and hearing requests will also be accepted on disks in WordPerfect 5.1/6.1 or ASCII file format. All copies of electronic objections and hearing requests must be identified by the docket control number [OPP–300809]. No Confidential Business Information (CBI) should be submitted through e-mail. Copies of electronic objections and hearing requests on this rule may be filed online at many Federal Depository Libraries.

FOR FURTHER INFORMATION CONTACT: By mail: Meredith Laws, 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: Rm. 282, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA, (703) 308–9366, laws.meredith@epa.gov.

SUPPLEMENTARY INFORMATION: EPA, on its own initiative, pursuant to sections 408 and (l)(6) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a and (l)(6), is establishing a tolerance for residues of the fungicide maneb (manganous ethylenebisdithiocarbamate), calculated as zinc ethylenebisdithiocarbamate and its metabolite ethylenethiourea, in or on walnuts at 0.05 part per million (ppm). This tolerance will expire and is revoked on December 31, 2000. EPA will publish a document in the **Federal Register** to remove the revoked tolerance from the Code of Federal Regulations.

I. Background and Statutory Findings

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 in this preamble 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 tolerances to set binding precedents for the application of section 408 and the new safety standard to other tolerances and exemptions.

II. Emergency Exemption for Maneb (manganous ethylenebisdithiocarbamate) on Walnuts and FFDCA Tolerances

The California Department of Pesticide Regulation has requested an emergency exemption under FIFRA section 18 to use maneb on walnuts to control bacterial blight. Currently,

copper based bactericides are the only registered products for control of this disease. The increase of walnut blight since 1992 is attributed to the development of a tolerance to copper based bactericides. The state has demonstrated that copper resistant bacteria have become economically important, with a potential 55,000 acres affected. EPA has authorized under FIFRA section 18 the use of maneb (manganous ethylenebisdithiocarbamate) on walnuts for control of bacterial blight in California. After having reviewed the submission, EPA concurs that emergency conditions exist for this state.

As part of its assessment of this emergency exemption, EPA assessed the potential risks presented by residues of maneb (manganous ethylenebisdithiocarbamate) in or on walnuts. In doing so, EPA considered the safety standard in FFDCA section 408(b)(2), and EPA decided that the necessary tolerance under FFDCA section 408(l)(6) would be consistent with the safety standard and with FIFRA section 18. Consistent with the need to move quickly on the emergency exemption in order to address an urgent non-routine situation and to ensure that the resulting food is safe and lawful, EPA is issuing this tolerance without notice and opportunity for public comment under section 408(e), as provided in section 408(l)(6). Although this tolerance will expire and is revoked on December 31, 2000, under FFDCA section 408(l)(5), residues of the pesticide not in excess of the amounts specified in the tolerance remaining in or on walnuts after that date will not be unlawful, provided the pesticide is applied in a manner that was lawful under FIFRA, and the residues do not exceed a level that was authorized by this tolerance at the time of that application. EPA will take action to revoke this tolerance earlier if any experience with, scientific data on, or other relevant information on this pesticide indicate that the residues are not safe.

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

III. Aggregate Risk Assessment and Determination of Safety

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. For further discussion of the regulatory requirements of section 408 and a complete description of the risk assessment process, see the final rule on Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997) (FRL–5754–7) .

Consistent with section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of maneb (manganous ethylenebisdithiocarbamate) and to make a determination on aggregate exposure, consistent with section 408(b)(2), for a time-limited tolerance for residues of maneb (manganous ethylenebisdithiocarbamate), calculated as zinc ethylenebisdithiocarbamate and its metabolite ethylenethiourea on walnuts at 0.05 ppm. EPA's assessment of the dietary exposures and risks associated with establishing the tolerance follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. The nature of the toxic effects caused by maneb (based on calculations on its metabolite, ethylenethiourea) are discussed in this unit.

B. Toxicological Endpoint

1. *Acute toxicity*. The acute dietary risk assessment is being conducted for ethylenethiourea (ETU) rather than maneb, since the no observed adverse effect level (NOAEL) for acute dietary risk for ETU is 4 times lower (5 milligrams/kilogram/day (mg/kg/day)) than the NOAEL for acute dietary risk for maneb (20 mg/kg/day). Therefore, an acceptable margin of exposure (MOE) for ETU will also be protective of exposure to maneb. The oral developmental NOAEL in rats for ETU is 5 mg/kg/day, based on a threshold finding of delayed ossification in the fetal skeletal structures at the NOAEL. The NOAEL is more correctly identified as a slightly lower dose level which is close to a threshold NOAEL in the developmental study. The EBDC PD-4 stated that MOEs could be calculated from the 5 mg/kg/day NOAEL, which was close to the NOAEL, and was the lowest dose tested.

2. *Short - and intermediate - term toxicity*. EPA recommends use of the systemic NOAEL of 100 mg/kg/day from the 3-week dermal toxicity study in rabbits. At the lowest observed adverse effect level (LOAEL) of 300 mg/kg/day, there were slightly increased thyroid weights and follicular cell hypertrophy of the thyroid.

3. *Chronic toxicity*. EPA has established the Reference Dose (RfD) for ETU at 0.00008 mg/kg/day. This RfD is based on the LOAEL of 0.25 mg/kg/day due to thyroid hyperplasia in a 2-year rat feeding study, with an uncertainty factor of 3,000. The uncertainty factor of 3,000 was based on a factor of 3 for absence of a NOAEL for ETU, a factor of 10 for data gaps for ETU, and a factor of 100 to take into account inter- and intra-species variability.

4. *Carcinogenicity*. Maneb has been classified as a Group B2, probable human carcinogen, based on evidence of thyroid tumors in rats and liver tumors. The Q1* for quantitation of human oral risk is 0.0601 $(mg/kg/day)^{-1}$ for the carcinogenic metabolite, ETU.

C. Exposures and Risks

1. *From food and feed uses*. Tolerances have been established (40 CFR 180.110) for the residues of maneb (manganous ethylenebisdithiocarbamate), calculated as zinc ethylenebisdithiocarbamate and its metabolite ethylenethiourea, in or on a variety of raw agricultural commodities including almonds at 0.1 ppm. Risk assessments were conducted by EPA to assess dietary exposures and risks from maneb (manganous ethylenebisdithiocarbamate) 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 high end dietary exposure for the population subgroup of concern, females 13+ years

old, is 0.000036 mg/kg/day, which results in an MOE of 5,000. Maximum field trial residue values were used to calculate the MOE. This is considered a partially refined risk estimate.

ii. *Chronic exposure and risk*. The chronic exposure estimate for the general population is 0.000020 mg/kg/day and the anticipated residue contribution (ARC) as percentage of the RfD is 24.4%.

Section 408(b)(2)(E) authorizes EPA to use available data and information on the anticipated residue levels of pesticide residues in food and the actual levels of pesticide chemicals that have been measured in food. If EPA relies on such information, EPA must require that data be provided 5 years after the tolerance is established, modified, or left in effect, demonstrating that the levels in food are not above the levels anticipated. Following the initial data submission, EPA is authorized to require similar data on a time frame it deems appropriate. As required by section 408(b)(2)(E), EPA will issue a data call-in for information relating to anticipated residues to be submitted no later than 5 years from the date of issuance of this tolerance.

Section 408(b)(2)(F) states that the Agency may use data on the actual percent of food treated (PCT) for assessing chronic dietary risk only if the Agency can make the following findings: That the data used are reliable and provide a valid basis to show what percentage of the food derived from such crop is likely to contain such pesticide residue; that the exposure estimate does not underestimate exposure for any significant subpopulation group; and if data are available on pesticide use and food consumption in a particular area, the exposure estimate does not understate exposure for the population in such area. In addition, the Agency must provide for periodic evaluation of any estimates used. To provide for the periodic evaluation of the estimate of percent crop treated as required by the section 408(b)(2)(F), EPA may require registrants to submit data on PCT.

The Agency used PCT information as follows:

In the Dietary Risk Evaluation Model (DEEM), it was assumed that 100% of the walnut crop would be treated under this emergency exemption. Refined percent crop treated values were used for some commodities such as 10% for cranberries, 50% for apples, 15% for pears, and 10% for almonds. The DEEM run did not use refined percent crop treated values for all registered uses, however, 100% crop treated was used for a number of commodities such as tomatoes, cucurbits, peppers, broccoli, onions, potatoes, and corn.

The Agency believes that the three conditions, discussed in section 408 (b)(2)(F) in this unit concerning the Agency's responsibilities in assessing chronic dietary risk findings, have been met. The PCT estimates are derived from Federal and private market survey data, which are reliable and have a valid basis. 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 the PCT, the Agency is reasonably certain that that the percentage of the food treated is not likely to be underestimated. The regional consumption information and consumption information for significant subpopulations is taken into account through EPA's computer-based model for evaluating the exposure of significant subpopulations including several regional groups. Use of this consumption information in EPA's risk assessment process ensures that EPA's exposure estimate does not understate exposure for any significant subpopulation group and allows the Agency to be reasonably certain that no regional population is exposed to residue levels higher than those estimated by the Agency. Other than the data available through national food consumption surveys, EPA does not have available information on the regional consumption of food to which maneb may be applied in a particular area.

2. *From drinking water.* Submitted environmental fate studies suggest that maneb has moderate potential to leach into ground water; thus maneb could potentially leach to ground water and runoff to surface water under certain environmental conditions. There are no established Maximum Contaminant Levels (MCLs) for residues of maneb in drinking water. No Health Advisories (HA) for maneb in drinking water have been established. However, EPA has considered the carcinogenic risk resulting from a maximum theoretical drinking water residue of 1.0 parts per billion (ppb) for ETU. ETU, which is highly soluble in water, is assumed to be persistent and highly mobile.

Chronic exposure and risk. 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 no observed adverse effect levels (NOAEL'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 maneb (manganous ethylenebisdithiocarbamate) to exceed the RfD if the tolerance being considered in this document were granted. The Agency has therefore concluded that the potential exposures associated with maneb (manganous ethylenebisdithiocarbamate) 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 tolerance is granted.

3. *From non-dietary exposure.* Maneb (manganous ethylenebisdithiocarbamate) is currently registered for use on the following residential non-food sites: turf, lawn, trees, and shrubs. Maneb is not registered for indoor uses. While EPA does not consider that these types of outdoor residential uses constitute a chronic residential exposure scenario, EPA acknowledges that there may be short- and intermediate-term non-occupational exposure scenarios. The Agency has identified toxicity endpoints for short- and intermediate-term residential risk assessments. For this action, the risk to public health from the use of maneb is calculated based on it's metabolite/degradate ETU. However, no acceptable reliable exposure data to assess these potential risks are available at this time. Given the time-limited nature of this request, the need to make emergency exemption decisions quickly, the significant scientific uncertainty at this time about how to aggregate non-occupational exposure with dietary exposure, the Agency will make it's safety determination for these tolerances based on those factors which it can reasonably integrate into a risk assessment.

i. *Chronic exposure and risk.* The Agency has concluded that a chronic residential exposure scenario does not exist for non-occupational uses of maneb.

ii. *Short- and intermediate-term exposure and risk*. The amortized ETU cancer risk for the U.S. population for short- and intermediate-term exposure to the turf use of maneb has been calculated to be 2.2 x 10^{-7}.

4. *Cumulative exposure to substances with common mechanism of toxicity*. Section 408(b)(2)(D)(v) requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider ''available information'' concerning the cumulative effects of a particular pesticide's residues and ''other substances that have a common mechanism of toxicity.''

EPA does not have, at this time, available data to determine whether maneb (manganous ethylenebisdithiocarbamate) 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, maneb (manganous ethylenebisdithiocarbamate) does not appear to produce a toxic metabolite produced by other substances, other than ETU, a metabolite common to the EBDC pesticides. For more information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the final rule for Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997).

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

1. *Acute risk*. The MOE for females 13+ years was calculated to be 5,000. Therefore, aggregate acute risk estimates do not exceed the Agency's level of concern.

2. *Chronic risk*. Using the ARC exposure assumptions described in this unit, EPA has concluded that aggregate exposure to maneb (manganous ethylenebisdithiocarbamate) from food will utilize 24.4% of the RfD for the U.S. population. The major identifiable subgroup with the highest aggregate exposure is non-nursing infants (<1 year old) discussed below. EPA generally has no concern for exposures below 100% of the RfD because the RfD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health. Despite the potential for exposure to maneb (manganous ethylenebisdithiocarbamate) in drinking water and from non-dietary, non-occupational exposure, EPA does not expect the aggregate exposure to exceed 100% of the RfD.

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.

Although surface and ground water monitoring data are limited, maneb does have the potential to leach into groundwater and run off to surface water. California monitoring programs have picked up one detect of .725 ppb, in three years of sampling (1986–89). Subsequent sampling 4 - 5 months later showed no residues. California has not found ETU when surveying high EBDC use areas. There were two detections in the U.S. EPA's National Pesticide Survey. The MOE for the U.S. population exceeds the desired MOE, therefore, EPA has no short- or intermediate-term aggregate risk concerns.

4. *Aggregate cancer risk for U.S. population*. The aggregate dietary cancer risk for maneb is based on ETU. The dietary cancer risk is calculated using the Q* for ETU, 0.601 mg/kg/day^{-1}. EPA calculated that the dietary cancer risk for the EBDC pesticides, including this use on walnuts is 1.2 x 10^{-6}. This risk assessment is partially refined; incorporation of percent crop treated information for all commodities would result in a lower dietary exposure estimate. The cancer risk from the residential uses of EBDC pesticides is approximately 10^{-7}. The aggregate cancer risk estimate would not exceed EPA's acceptable level unless the drinking water concentration exceeds 1 ppb. The availability of surface-water and ground-water monitoring data for maneb and ETU is limited. EPA is not aware of any surface-water monitoring data for either maneb or ETU, and it does not have any ground-water monitoring data for maneb. However, EPA has ground-water monitoring data which indicates that ETU has leached into the ground water; some of which are direct drinking water sources.

In California from 1986 to 1989, 65 wells were monitored for ETU. One well in San Joaquin County during March 1988 had an ETU concentration of 0.725 ppb. The remainder of the samples had no ETU detections (limit of detection (LOD) of 0.5 ppb). The California Department of Food and Agriculture concluded that this ETU concentration in the ground water did not represent a legal agriculture use based upon another sampling event where this well and five nearby wells in a predominantly walnut orchard use area were sampled 125 days or more subsequent to the March sampling event. ETU was not detected in any of these ground-water samples at that later date.

There were two ETU detections in the ground water in the U.S. EPA's statistically designed National Pesticide Survey (NPS). The NPS analyzed a statistically representative sample of wells to provide a national assessment of the presence of pesticides in drinking water wells. On the basis of this study, EPA estimated that nationally, 8,470 rural domestic wells could contain ETU over the NPS reporting limit of 4.5 ppb. The 95% confidence interval ranged from 1 to 111,000 wells. One quantified ETU detection of 16.0 ppb was obtained from a rural well in Warren County, Illinois. A second detection, described as a ''trace'' detection, was reported in Iowa. For this compound in the NPS, samples containing ETU at concentrations greater than 9.0 ppb were quantified; samples containing concentrations between 4.5 and 9.0 ppb were reported as ''trace''; and no detections were reported if concentrations were below 4.5 ppb. The source of the ETU was not determined; however, both agricultural and industrial practices may contribute to ETU contamination of the ground water.

These limited sampling results indicate some potential for ETU to be found in ground water. However, there are significant uncertainties associated with using these data in quantitative carcinogenic risk assessment for purposes of national tolerance-setting. EPA is uncertain as to whether a significant subpopulation would be exposed to high enough concentrations of ETU (greater than 1 ppb) for a long enough period of time to pose a significant carcinogenic risk. For example, in the ground-water sampling conducted in San Joaquin County between 1986–1989, the single contaminated well (out of 65 tested) subsequently was found 4 months later to have no detectable levels of ETU. Additionally, although the NPS results show two detections of ETU in ground water, it is not clear whether agricultural or industrial practices were the source of the ETU. If the source of the ETU was industrial and not agricultural use, it is likely that contamination of ground water with ETU would be less widespread than is suggested by the statistical analysis of the NPS results. EPA does not believe that the available data demonstrate that a significant subpopulation would be exposed to residues of ETU in drinking water greater than 1 ppb; therefore, EPA does not believe that the aggregate cancer risk associated with the granting

of this tolerance would exceed acceptable levels.

5. *Determination of safety*. Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result from aggregate exposure to maneb (manganous ethylenebisdithiocarbamate) residues.

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 maneb (manganous ethylenebisdithiocarbamate), EPA considered data from developmental toxicity studies in the rat 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 maternal pesticide exposure during gestation. Reproduction studies provide information relating to effects from exposure to the pesticide on the reproductive capability of mating animals and data on systemic toxicity.

FFDCA section 408 provides that EPA shall apply an additional tenfold margin of safety for infants and children in the case of threshold effects to account for pre-and post-natal toxicity and the completeness of the database unless EPA determines that a different margin of safety will be safe for infants and children. Margins of safety are incorporated into EPA risk assessments either directly through use of a margin of exposure (MOE) analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans. EPA believes that reliable data support using the standard MOE and uncertainty factor (usually 100 for combined inter- and intra-species variability) and not the additional tenfold MOE/uncertainty factor when EPA has a complete data base under existing guidelines and when the severity of the effect in infants or children or the potency or unusual toxic properties of a compound do not raise concerns regarding the adequacy of the standard MOE/safety factor.

ii. *Developmental toxicity studies*. From the rat developmental study for ETU, the oral developmental NOAEL is 5 mg/kg/day, based on a threshold finding of delayed ossification in the fetal skeletal structures at the NOAEL.

iii. *Reproductive toxicity study*. There is no reproduction study with ETU available. In the rat reproduction study for maneb, the parental (systemic) NOAEL was 6.0 mg/kg/day, based on decreased body weight and food consumption at the LOAEL of 25 mg/kg/day. The developmental (pup) NOAEL was 6.0 mg/kg/day, based on increased startle response at the LOAEL of 25 mg/kg/day.

iv. *Pre- and post-natal sensitivity*. The rat developmental study with ETU demonstrated a special prenatal sensitivity for infants and children. The results of the rat reproduction study with maneb do not demonstrate any additional special post-natal sensitivity for infants and children, since the NOAEL and LOAEL for parental toxicity and pup toxicity occur at the same doses and the pup effects are not of unusual concern.

v. *Conclusion*. In the absence of a complete data base for ETU, EPA is assuming an additional tenfold safety factor to account for the possibility of special prenatal sensitivity for infants and children.

2. *Acute risk*. The acute dietary risk assessment for ETU residues demonstrated an MOE of 5,000 based on the NOAEL of 5 mg/kg/day in the rat developmental study. Therefore, this calculated MOE for ETU for females 13+ years of age shows that the MOEs for this population subgroup are far in excess of the required dietary MOE of 1,000 due to ETU data gaps. Therefore, the acute dietary risks for ETU to females 13+ years of age are below EPA's level of concern. The RfD for ETU incorporates an uncertainty factor of 3,000. The uncertainty factor was based on a factor of 3 for absence of a NOAEL for ETU, a factor of 10 for data gaps needed to assess extra sensitivity to infants and children for ETU, and the normal factor of 100 for converting between and within species (EBDC PD/4, 3/2/92).

3. *Chronic risk*. Using the exposure assumptions described in this unit, EPA has concluded that aggregate exposure to maneb (manganous ethylenebisdithiocarbamate) from food will utilize 78.4% of the RfD for nonnursing 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 maneb (manganous ethylenebisdithiocarbamate) in drinking water and from non-dietary, non-occupational exposure, EPA does not expect the aggregate exposure to exceed 100% of the RfD.

4. *Short- or intermediate-term risk*. The MOEs for infants and children exceed the desired MOE, therefore, EPA has no short- and intermediate-term aggregate risk concerns.

5. *Determination of safety*. Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to maneb (manganous ethylenebisdithiocarbamate) residues.

IV. Other Considerations

A. Metabolism In Plants and Animals

The nature of the residue in plants is adequately understood. The residues of concern are the fungicide maneb, calculated as zinc ethylenebisdithiocarbamate, and its metabolite ethylenthiourea. Secondary residues are not expected in animal commodities as no feed items are associated with this use.

B. Analytical Enforcement Methodology

Adequate enforcement methodology is available for maneb in the Pesticide Analytical Manual (PAM) II Method III.

C. Magnitude of Residues

Residues of maneb (manganous ethylenebisdithiocarbamate) calculated as zinc ethylenebisdithiocarbamate and its metabolite ethylenethiourea are not expected to exceed 0.05 ppm in or on walnuts as a result of this proposed use. Secondary residues are not expected in animal commodities as no feed items are associated with this use.

D. International Residue Limits

No Codex, Canadian, or Mexican maximum residue levels have been established for residues of maneb in/on walnuts.

V. Conclusion

Therefore, the tolerance is established for residues of maneb (manganous ethylenebisdithiocarbamate), calculated as zinc ethylenebisdithiocarbamate and its metabolite ethylenethiourea in walnuts at 0.05 ppm.

VI. Objections and Hearing Requests

The new FFDCA section 408(g) provides essentially the same process for persons to ''object'' to a tolerance regulation issued by EPA under new section 408 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 May 17, 1999, file written objections to any aspect of this regulation and may also request a hearing on those objections. Objections and hearing requests must be filed with the Hearing Clerk, at the address given under the ''ADDRESSES'' section (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). EPA is authorized to waive any fee requirement ''when in the judgement of the Administrator such a waiver or refund is equitable and not contrary to the purpose of this subsection.'' For additional information regarding tolerance objection fee waivers, contact James Tompkins, 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: Rm. 239, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA, (703) 305–5697, tompkins.jim@epa.gov. Requests for waiver of tolerance objection fees should be sent to James Hollins, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460.

If a hearing is requested, the objections must include a statement of the factual issues on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the requestor (40 CFR 178.27). A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established, resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issues in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

VII. Public Record and Electronic Submissions

EPA has established a record for this regulation under docket control number [OPP–300809] (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 Rm. 119 of the Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA.

Objections and hearing requests may be sent by e-mail directly to EPA at:
opp-docket@epa.gov.

E-mailed objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption.

The official record for this regulation, as well as the public version, as described in this unit 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 record which will also include all comments submitted directly in writing. The official record is the paper record maintained at the Virginia address in ''ADDRESSES'' at the beginning of this document.

VIII. Regulatory Assessment Requirements

A. Certain Acts and Executive Orders

This final rule establishes a tolerance under section 408 of the FFDCA. 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 special considerations as required by Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994), or require OMB review in accordance with Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997).

In addition, since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(l)(6), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. Nevertheless, the Agency previously assessed whether establishing tolerances, exemptions from tolerances, raising tolerance levels or expanding exemptions might adversely impact small entities and concluded, as a generic matter, that there is no adverse economic impact. The factual basis for the Agency's generic certification for tolerance actions published on May 4, 1981 (46 FR 24950), and was provided to the Chief Counsel for Advocacy of the Small Business Administration.

B. Executive Order 12875

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

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

Executive Order 12875 do not apply to this rule.

C. Executive Order 13084

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

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

IX. Submission to Congress and the Comptroller General

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the Agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

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

Dated: March 5, 1999.

James Jones,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

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

Authority: 21 U.S.C. 321(q), 346a and 371.

2. In § 180.110, by revising paragraph (b) to read as follows:

§ 180.110 Maneb; tolerances for residues.

* * * * *

(b) *Section 18 emergency exemptions.* A time-limited tolerance is established for residues of the fungicide maneb (manganous ethylenebisdithiocarbamate), calculated as zinc ethylenebisdithiocarbamate, and its metabolite ethylenethiourea in connection with use of the pesticide under a section 18 emergency exemption granted by EPA. The tolerance will expire and is revoked on the date specified in the following table:

Commodity	Parts per million	Expiration/revocation date
Walnuts	0.05	12/31/00

* * * * *

[FR Doc. 99–6383 Filed 3–16–99; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300797; FRL–6064–2]

RIN 2070–AB78

Propiconazole; Extension of Tolerances for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation extends time-limited tolerances for combined residues of the fungicide propiconazole and its metabolites in or on almond nutmeats at 0.1 parts per million (ppm), and in or on almond hulls at 2.5 ppm, for an additional 1–year period. These tolerances will expire and are revoked on July 31, 2000. This action is in response to EPA's granting of an emergency exemption under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) authorizing use of the pesticide on almonds. Section 408(l)(6) of the Federal Food, Drug, and Cosmetic Act 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 FIFRA section 18.

DATES: This regulation becomes effective March 17, 1999. Objections and requests for hearings must be received by EPA, on or before May 17, 1999.

ADDRESSES: Written objections and hearing requests, identified by the docket control number [OPP–300797], 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–300797], must also be submitted to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring a copy of objections and hearing requests to Rm. 119, Crystal Mall 2 (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@epa.gov. Copies of electronic objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Copies of objections and hearing requests will also be accepted on disks in WordPerfect 5.1/6.1 or ASCII file format. All copies of electronic objections and hearing requests must be identified by the docket control number [OPP–300797]. No Confidential Business Information (CBI) should be submitted through e-mail. Copies of electronic objections and hearing requests on this rule may be