GLOBAL PACKAGE LINK SERVICE TO HONG KONG—Continued

Weight not over (pounds)	Annual volume first 100,000 packages—no discount, premium service (dollars)
2	18.75
3	22.00
4	25.20
5	28.45
6	31.65
7	34.90
8	38.10
9	41.35
10	44.55
11	47.80
12	51.00
13	54.25
14	57.45
15	60.70
16	63.90
17	67.15
18	70.35
19	73.60
20	76.80
21	80.05
22	83.25
23	86.50
24	89.70
25	92.90
26	96.15
27	99.35
28	102.60
29	105.80
30	109.05
31	112.25
32	115.50
33	118.70
34	121.95
35	125.15
36	128.40
37	131.60
38	134.85
39	138.05
40	141.30
41	144.50
42	147.75
43	150.95
44	154.20

Number of pieces in contract year	Discount
1–100,000	None
100,001+	3 percent of base rate.

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Stanley F. Mires,

Chief Counsel Legislative.

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300545; FRL–5741–2]

RIN 2070–AB78

Maneb; Pesticide Tolerances for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes time-limited tolerances for residues of maneb (manganous ethylenebisdithiocarbamate), calculated as zinc ethylenebisdithiocarbamate, and its metabolite ethylenethiourea in or on walnuts. This action is in connection with a crisis exemption declared by the state of California under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act authorizing use of the pesticides on walnuts in California. This regulation establishes a maximum permissible level for residues of maneb 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 June 15, 1998.

DATES: This regulation is effective September 24, 1997. Objections and requests for hearings must be received by EPA on or before November 24, 1997.

ADDRESSES: Written objections and hearing requests, identified by the docket control number, [OPP–300545], 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–300545], must also be submitted to: Public Information and Records Integrity Branch, Information Resources and Services Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring a copy of objections and hearing requests to Rm. 1132, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA.

A copy of objections and hearing requests filed with the Hearing Clerk may also be submitted electronically by sending electronic mail (e-mail) to: opp-docket@epamail.epa.gov. Copies of objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Copies of objections and hearing requests will also be accepted on disks in WordPerfect 5.1 file format or ASCII file format. All copies of objections and hearing requests in electronic form must be identified by the docket control number [OPP–300545]. No Confidential Business Information (CBI) should be submitted through e-mail. Electronic copies of objections and hearing requests on this rule may be filed online at many Federal Depository Libraries.

FOR FURTHER INFORMATION CONTACT: By mail: Libby Pemberton, Registration Division 7505C, Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail address: Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, (703) 308-9364, e-mail: pemberton.libby@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: EPA, on its own initiative, pursuant to section 408(e) and (l)(6) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(e) and (l)(6), is establishing tolerances for residues of the fungicide 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 June 15, 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) of the FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is ''safe.'' Section 408(b)(2)(A)(ii) defines ''safe'' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue. . . .''

Section 18 of FIFRA authorizes EPA to exempt any Federal or State agency from any provision of FIFRA, if EPA determines that ''emergency conditions exist which require such exemption.'' This provision was not amended by FQPA. EPA has established regulations governing such emergency exemptions in 40 CFR part 166.

Section 408(l)(6) of the FFDCA requires EPA to establish a time-limited tolerance or exemption from the requirement for a tolerance for pesticide chemical residues in food that will result from the use of a pesticide under an emergency exemption granted by EPA under section 18 of FIFRA. Such tolerances can be established without providing notice or period for public comment.

Because decisions on section 18-related tolerances must proceed before EPA reaches closure on several policy issues relating to interpretation and implementation of the FQPA, EPA does not intend for its actions on such tolerance to set binding precedents for the application of section 408 and the new safety standard to other tolerances and exemptions.

II. Emergency Exemption for Maneb on Walnuts and FFDCA Tolerances

On February 24, 1997, the California Department of Pesticide Regulation availed itself of the authority to declare the existence of a crisis situation within the state, thereby authorizing use under FIFRA section 18 of maneb on walnuts for control of 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 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 (calculations based on its metabolite ethylenethiourea) and its metabolite in or on walnuts. In doing so, EPA considered the new 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 new safety standard and with FIFRA section 18. Consistent with the need to move quickly on the emergency exemption in order to address an urgent non-routine situation and to ensure that the resulting food is safe and lawful, EPA is issuing 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 June 15, 1998, 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. 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 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 a basis for registration of maneb 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 section 18 as identified in 40 CFR part 166. For additional information regarding the emergency exemption for maneb, contact the Agency's Registration Division at the address provided above.

III. Risk Assessment and Statutory Findings

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. First, EPA determines the toxicity of pesticides based primarily on toxicological studies using laboratory animals. These studies address many adverse health effects, including (but not limited to) reproductive effects, developmental toxicity, toxicity to the nervous system, and carcinogenicity. Second, EPA examines exposure to the pesticide through the diet (e.g., food and drinking water) and through exposures that occur as a result of pesticide use in residential settings.

A. Toxicity

1. *Threshold and non-threshold effects.* For many animal studies, a dose response relationship can be determined, which provides a dose that causes adverse effects (threshold effects) and doses causing no observed effects (the ''no-observed effect level'' or ''NOEL'').

Once a study has been evaluated and the observed effects have been determined to be threshold effects, EPA generally divides the NOEL from the study with the lowest NOEL by an uncertainty factor (usually 100 or more) to determine the Reference Dose (RfD). The RfD is a level at or below which daily aggregate exposure over a lifetime will not pose appreciable risks to human health. An uncertainty factor (sometimes called a ''safety factor'') of 100 is commonly used since it is assumed that people may be up to 10 times more sensitive to pesticides than the test animals, and that one person or subgroup of the population (such as infants and children) could be up to 10 times more sensitive to a pesticide than another. In addition, EPA assesses the potential risks to infants and children based on the weight of the evidence of the toxicology studies and determines whether an additional uncertainty factor is warranted. Thus, an aggregate daily exposure to a pesticide residue at or below the RfD (expressed as 100% or less of the RfD) is generally considered acceptable by EPA. EPA generally uses the RfD to evaluate the chronic risks posed by pesticide exposure. For shorter term risks, EPA calculates a margin of exposure (MOE) by dividing the estimated human exposure into the NOEL from the appropriate animal study. Commonly, EPA finds MOEs lower than 100 to be unacceptable. This 100-fold MOE is based on the same rationale as the 100-fold uncertainty factor.

Lifetime feeding studies in two species of laboratory animals are conducted to screen pesticides for cancer effects. When evidence of increased cancer is noted in these studies, the Agency conducts a weight of the evidence review of all relevant toxicological data including short-term and mutagenicity studies and structure activity relationship. Once a pesticide has been classified as a potential human carcinogen, different types of risk assessments (e.g., linear low dose extrapolations or MOE calculation based on the appropriate NOEL) will be carried out based on the nature of the carcinogenic response and the Agency's knowledge of its mode of action.

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

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

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

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

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

B. Aggregate Exposure

In examining aggregate exposure, FFDCA section 408 requires that EPA take into account available and reliable information concerning exposure from the pesticide residue in the food in question, residues in other foods for which there are tolerances, residues in groundwater or surface water that is consumed as drinking water, and other non-occupational exposures through pesticide use in gardens, lawns, or buildings (residential and other indoor uses). Dietary exposure to residues of a pesticide in a food commodity are estimated by multiplying the average daily consumption of the food forms of that commodity by the tolerance level or the anticipated pesticide residue level. The Theoretical Maximum Residue Contribution (TMRC) is an estimate of the level of residues consumed daily if each food item contained pesticide residues equal to the tolerance. In evaluating food exposures, EPA takes into account varying consumption patterns of major identifiable subgroups of consumers, including infants and children. The TMRC is a ''worst case'' estimate since it is based on the assumptions that food contains pesticide residues at the tolerance level and that 100% of the crop is treated by pesticides that have established tolerances. If the TMRC exceeds the RfD or poses a lifetime cancer risk that is greater than approximately one in a million, EPA attempts to derive a more accurate exposure estimate for the pesticide by evaluating additional types of information (anticipated residue data and/or percent of crop treated data) which show, generally, that pesticide residues in most foods when they are eaten are well below established tolerances.

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

IV. Aggregate Risk Assessment and Determination of Safety

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

1. *Acute toxicity.* The acute dietary risk assessment is being conducted for ethylenethiourea (ETU) rather than maneb, since the NOEL for acute dietary risk for ETU is 4 times lower (5 mg/kg/

day) than the NOEL for acute dietary risk for maneb (20 mg/kg/day). Therefore, an acceptable MOE for ETU will also be protective of exposure to maneb. The oral developmental NOAEL (No-observed-adverse-effect-level) 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 NOEL is more correctly identified as a slightly lower dose level which is close to a threshold NOAEL in the developmental study. The EDBC PD-4 stated that MOEs could be calculated from the 5 mg/kg/day NOAEL, which was close to the NOEL, and was the lowest dose tested.

2. *Short - and intermediate - term non-dietary toxicity.* OPP recommends use of the systemic NOEL of 100 mg/kg/day from the 3-week dermal toxicity study in rabbits. At the LOEL 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 RfD for ETU at 0.00008 milligrams/kilogram/day (mg/kg/day). This RfD is based on the LOEL 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 NOEL for ETU, a factor of 10 for data gaps for ETU, and a factor of 100 to take into accoutn 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.

B. 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, 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 and maneb as follows:

i. *Acute exposure and risk.* Acute dietary risk assessments are performed for a food-use pesticide if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a one day or single exposure. The 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 data 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 apercentage of the RfD is 24.4%.

2. *From drinking water.* There is no established Maximum Concentration Level (MCL) for residues of maneb in drinking water. No drinking water health advisory levels have been established for maneb. Environmental fate studies suggest that maneb is moderately persistent and has moderate potential to leach into ground water. Maneb could potentially leach to groundwater and run off to surface water under certain environmental conditions.

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 NOEL's) and assumptions about body weight and consumption, to calculate, for each pesticide, the increment of aggregate risk contributed by consumption of contaminated water. While EPA has not yet pinpointed the appropriate bounding figure for exposure from contaminated water, the ranges the Agency is continuing to examine are all below the level that would cause maneb 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 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 is currently registered for use on the following residential non-food sites: turf, lawn, trees, and shrubs.

i. *Acute exposure and risk.* EPA generally will not include residential or other non-dietary exposure as a component of the acute exposure assessment. Theoretically, it is also possible that a residential, or other non-dietary, exposure could be combined with the acute total dietary exposure from food and water. However, the Agency does not believe that aggregating multiple exposure to large amounts of pesticide residues in the residential environment via multiple products and routes for a one day exposure is a reasonably probable event. It is highly unlikely that, in one day, an individual would have multiple high-end exposures to the same pesticide by treating their lawn and garden, treating their house via crack and crevice application, swimming in a pool, and be maximally exposed in the food and water consumed. Additionally, the concept of an acute exposure as a single exposure does not allow for including post-application exposures, in which residues decline over a period of days after application. Therefore, the Agency believes that residential exposures are more appropriately included in the short-term exposure scenario discussed below.

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

iii. *Short- and intermediate-term exposure and risk.* There are residential uses of maneb and EPA acknowledges that there may be short and intermediate-term non-occupational exposure scenarios. The EPA has identified a toxicity endpoint for short and intermediate term non-occupational risks. However, no acceptable reliable exposure data to assess the potential risks are available at this time. Based on the level of the short and intermediate-term endpoints, the Agency does not expect the short and intermediate-term aggregate risk to exceed the level of concern.

4. *Cumulative exposure to substances with common mechanism of toxicity.* Section 408(b)(2)(D)(v) requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider ''available information'' concerning the cumulative effects of a particular pesticide's residues and ''other substances that have a common mechanism of toxicity.'' The Agency believes that ''available information'' in this context might include not only toxicity, chemistry, and exposure data, but also scientific policies and methodologies for understanding common mechanisms of toxicity and conducting cumulative risk assessments. For most pesticides, although the Agency has some information in its files that may turn out to be helpful in eventually determining whether a pesticide shares a common

mechanism of toxicity with any other substances, EPA does not at this time have the methodologies to resolve the complex scientific issues concerning common mechanism of toxicity in a meaningful way. EPA has begun a pilot process to study this issue further through the examination of particular classes of pesticides. The Agency hopes that the results of this pilot process will increase the Agency's scientific understanding of this question such that EPA will be able to develop and apply scientific principles for better determining which chemicals have a common mechanism of toxicity and evaluating the cumulative effects of such chemicals. The Agency anticipates, however, that even as its understanding of the science of common mechanisms increases, decisions on specific classes of chemicals will be heavily dependent on chemical specific data, much of which may not be presently available.

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

EPA does not have, at this time, available data to determine whether maneb 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 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 maneb has a common mechanism of toxicity with other substances.

C. 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 above, EPA has concluded that aggregate exposure to maneb 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 in drinking water, EPA does not expect the aggregate exposure to exceed 100% of the RfD. EPA concludes that there is a reasonable certainty that no harm will result from aggregate exposure to maneb residues.

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

The MOE for the U.S. population exceeds the desired MOE, therefore, EPA has no short- and intermediate-term aggregate risk concerns.

D. Aggregate Cancer Risk for U.S. Population

The aggregate dietary cancer risk for ETU was calculated to be 1.2×10^{-6} for all the published and pending uses for maneb including this section 18 use and for all commodities which contain ETU as a result of the use of EDBC compounds. In EPA's best scientific judgement, additional potential exposure from residues in water would not increase cancer risk estimates above the Agency's level of concern.

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, EPA considered data from developmental toxicity studies in the rat and a two-generation reproduction study in the rat. The developmental toxicity studies are designed to evaluate adverse effects on the developing organism resulting from maternal pesticide exposure during gestation. Reproduction studies provide information relating to effects from exposure to the pesticide on the reproductive capability of mating animals and data on systemic toxicity.

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

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

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

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 conservative exposure assumptions described above, EPA has concluded that aggregate exposure to maneb from food will utilize 78.4% of the RfD for non-nursing infants (<1 year old). EPA generally has no concern for exposures below 100% of the RfD because the RfD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health. Despite the potential for exposure to maneb in drinking water, EPA does not expect the aggregate exposure to exceed 100% of the RfD. EPA concludes that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to maneb residues.

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.

V. 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 ethylenethiourea. 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. Prior to publication in PAM II, additional enforcement methodology is available in the interim to anyone who is interested in pesticide enforcement when requested from: Calvin Furlow, Public Response and Program Resource Branch, Field Operations Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: Rm 1128, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA 22202, 703-305-5805.

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.

VI. 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.

VII. Objections and Hearing Requests

The new FFDCA section 408(g) provides essentially the same process for persons to ''object'' to a tolerance regulation issued by EPA under new section 408(e) and (l)(6) as was provided in the old section 408 and in section 409. However, the period for filing objections is 60 days, rather than 30 days. EPA currently has procedural regulations which govern the submission of objections and hearing requests. These regulations will require some modification to reflect the new law. However, until those modifications can be made, EPA will continue to use those procedural regulations with appropriate adjustments to reflect the new law.

Any person may, by November 24, 1997, file written objections to any aspect of this regulation and may also request a hearing on those objections. Objections and hearing requests must be filed with the Hearing Clerk, at the address given above (40 CFR 178.20). A copy of the objections and/or hearing requests filed with the Hearing Clerk should be submitted to the OPP docket for this rulemaking. The objections submitted must specify the provisions of the regulation deemed objectionable and the grounds for the objections (40 CFR 178.25). Each objection must be accompanied by the fee prescribed by 40 CFR 180.33(i). If a hearing is requested, the objections must include a statement of the factual issues on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the requestor (40 CFR 178.27). A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established, resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issues in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as Confidential Business Information (CBI). Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

VIII. Public Docket

EPA has established a record for this rulemaking under docket control number [OPP–300545] (including any comments and data submitted electronically). A public version of this record, including printed, paper versions of electronic comments, which does not include any information claimed as CBI, is available for inspection from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The public record is located in Room 1132 of the Public Information and Records Integrity Branch, Information Resources and Services Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA.

Electronic comments may be sent directly to EPA at:
opp-docket@epamail.epa.gov.

Electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of encryption.

The official record for this rulemaking, as well as the public version, as described above will be kept in paper form. Accordingly, EPA will transfer any copies of objections and hearing requests received electronically into printed, paper form as they are received and will place the paper copies in the official rulemaking record which will also include all comments submitted directly in writing. The official rulemaking record is the paper record maintained at the Virginia address in ''ADDRESSES'' at the beginning of this document.

IX. Regulatory Assessment Requirements

This final rule establishes a time-limited tolerance under FFDCA section

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

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

X. Submission to Congress and the General Accounting Office

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

List of Subjects in 40 CFR Part 180

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

Dated: August 29, 1997.

James Jones,

Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

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

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

2. Section 180.110 is revised to read as follows:

§ 180.110 Maneb; tolerances for residues.

(a) *General* . Tolerances for residues of the fungicide maneb (manganous ethylenebisdithiocarbamate), calculated as zinc ethylenebisdithiocarbamate, are established in or on raw agricultural commodities in the following table:

Commodity	Parts per million	Expiration/Revocation Date
Almonds	0.1	None
Apples	2	None
Apricots	10	None
Bananas (not more than 0.5 part per million) shall be in the pulp after peel is removed and discarded (preharvest application only).	4	None
Beans (dry form)	7	None
Beans (succulent form)	10	None
Broccoli	10	None
Brussels sprouts	10	None
Cabbage	10	None
Carrots	7	None
Cauliflower	10	None
Celery	5	None
Chinese cabbage	10	None
Collards	10	None
Cranberries	7	None
Cucumbers	4	None
Eggplants	7	None
Endive (escarole)	10	None
Figs	7	None
Grapes	7	None
Kale	10	None
Kohlrabi	10	None
Lettuce	10	None
Melons	4	None
Mustard greens	10	None
Nectarines	10	None
Onions	7	None
Papayas	10	None
Peaches	10	None
Peppers	7	None
Potatoes	0.1	None
Pumpkins	7	None
Rhubarb	10	None
Spinach	10	None
Sugar beet tops	45	None

Commodity	Parts per million	Expiration/Revocation Date
Summer squash	4	None
Sweet corn (kernels plus cob with husk removed)	5	None
Tomatoes	4	None
Turnip roots	7	None
Turnip tops	10	None
Winter squash	4	None

(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	6/15/98

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

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

[FR Doc. 97–25097 Filed 9-23-97; 8:45 am]

BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 180 and 185

[OPP–300544; FRL–5740–8]

RIN 2070–AB78

Endothall; Pesticide Tolerances for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a time-limited tolerance for residues of endothall in or on canola seed. 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 canola in Minnesota. This regulation establishes a maximum permissible level for residues of endothall 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 August 31, 1998.

DATES: This regulation is effective September 24, 1997. Objections and requests for hearings must be received by EPA on or before November 24, 1997.

ADDRESSES: Written objections and hearing requests, identified by the docket control number, [OPP–300544], 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–300544], must also be submitted to: Public Information and Records Integrity Branch, Information Resources and Services Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring a copy of objections and hearing requests to Rm. 1132, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA.

A copy of objections and hearing requests filed with the Hearing Clerk may also be submitted electronically by sending electronic mail (e-mail) to: opp-docket@epamail.epa.gov. Copies of objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Copies of objections and hearing requests will also be accepted on disks in WordPerfect 5.1 file format or ASCII file format. All copies of objections and hearing requests in electronic form must be identified by the docket control number [OPP–300544]. 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: Andrea Beard, Registration Division 7505C, Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail address: Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, (703) 308-9356, e-mail: beard.andrea@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 endothall, in or on canola seed at 0.3 part per million (ppm). This tolerance will expire and is revoked on August 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