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 to 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.

IV. 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 to 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: October 1, 1998.

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. 346a and 371.

§ 180.414 [AMENDED]

2. In § 180.414, by amending paragraph (b) by changing the date ''10/1/98'' to read ''4/1/00.''

[FR Doc. 98–27270 Filed 10–8–98; 8:45 am]

BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300714; FRL–6029–5]

RIN 2070–AB78

Mancozeb; Pesticide Tolerances for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a time-limited tolerance for the combined residues of mancozeb, calculated as zinc ethylenebisdithiocarbamate, and it's metabolite ethylenethiourea (ETU) in or on ginseng. 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 ginseng. This regulation establishes a maximum permissible level for residues of mancozeb and ETU 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, 1999.

DATES: This regulation is effective October 9, 1998. Objections and requests for hearings must be received by EPA on or before December 8, 1998.

ADDRESSES: Written objections and hearing requests, identified by the docket control number, [OPP–300714], 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–300714], 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 (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 5.1/6.1 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–300714]. 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: Daniel Rosenblatt, 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: CM #2, 1921 Jefferson Davis Hwy., Arlington, VA, (703) 308–9375, e-mail: rosenblatt.dan@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: EPA, on its own initiative, pursuant to section 408(e) and (l)(6) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(e) and (l)(6), is establishing a tolerance for residues of the fungicide mancozeb, calculated as zinc ethylenebisdithiocarbamate, and it's metabolite (ETU), in or on ginseng at 2.0 parts per million (ppm). This tolerance will expire and is revoked on December 31, 1999. EPA will publish a document in the **Federal Register** to remove the revoked tolerance from the Code of Federal Regulations.

I. Background and Statutory Authority

The Food Quality Protection Act of 1996 (FQPA) (Pub. L. 104–170) was signed into law August 3, 1996. FQPA amends both the FFDCA, 21 U.S.C. 301 *et seq*., and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. 136 *et seq*. 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 published in the **Federal Register** of November 13, 1996, (61 FR 58135)(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 Mancozeb on Ginseng and FFDCA Tolerances

On January 29, 1998, the Wisconsin Department of Agriculture, Trade, and Consumer Protection requested that EPA consider issuing a specific emergency exemption under section 18 for the use of mancozeb on Ginseng (*Panax quinquefolium L.*) to control leaf and stem blight. In past years, these problems have resulted in severe yield loss. In addition, growers have not had satisfactory experience with the alternative pesticides registered for this use. Analysis suggests that reliance on the registered alternatives would result in a yield loss of nearly 40%. Following EPA's assessment that growers in Wisconsin may experience a severe economic loss without the availability of mancozeb, the Agency granted an emergency exemption for ginseng growers which permitted the application of mancozeb in the state this past growing season.

As part of its assessment of this emergency exemption, EPA assessed the potential risks presented by residues of mancozeb and ETU in or on ginseng. 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 FFDCA section 408(e), as provided in FFDCA section 408(l)(6). Although this tolerance will expire and is revoked on October 31, 1999, under FFDCA section 408(l)(5), residues of the pesticide not in excess of the amounts specified in the tolerance remaining in or on ginseng 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 mancozeb meets EPA's registration requirements for use on ginseng 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 mancozeb 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 Wisconsin to use this pesticide on this crop under FIFRA section 18 of without following all provisions of FIFRA section 18 as identified in 40 CFR part 166. For additional information regarding the emergency exemption for mancozeb, 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 Adverse Effect Level'' or ''NOAEL'').

Once a study has been evaluated and the observed effects have been determined to be threshold effects, EPA generally divides the NOAEL from the study with the lowest NOAEL 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 NOAEL from the appropriate animal study. Commonly, EPA finds MOEs lower than 100 to be unacceptable. This one hundredfold MOE is based on the same rationale as the one hundredfold 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 NOAEL) 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 three 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/NOAEL 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 ground water 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 less than a year old) was not regionally based.

IV. Aggregate Risk Assessment and Determination of Safety

Consistent with FFDCA 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 mancozeb and to make a determination on aggregate exposure, consistent with FFDCA section 408(b)(2), for a time-limited tolerance for residues of mancozeb and ETU on ginseng at 2.0 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 mancozeb and ETU are discussed below.

1. *Acute toxicity.* For acute dietary risk assessment, the Agency recommends use of the oral developmental NOAEL for ETU of 5 milligrams/kilogram/day (mg/kg/day) from the rat developmental study. The effect observed at the NOAEL is a threshold finding of delayed ossification in the fetal skeletal structures.

2. *Short- and intermediate-term toxicity.* For short and intermediate term MOE calculations, EPA recommends the use of the maternal NOAEL of 30 mg/kg/day for mancozeb from the rabbit developmental toxicity study. At the maternal Lowest Effect Level (LEL) of 80 mg/kg/day, there were deaths, ataxia, and abortions.

3. *Chronic toxicity.* EPA has established the RfD for ETU at 0.003 mg/kg/day. This RfD is based on a 90-day oral dog toxicity study with a NOAEL of 3 mg/kg/day and an uncertainty factor of 1,000 based on decreased weight gain and hypogenesis of the prostate at the LEL of 30 mg/kg/day.

4. *Carcinogenicity.* Mancozeb has been classified as a Group B2, probable human carcinogen, by the Cancer Peer Review Committee (Committee) and Science Advisory Panel based on evidence of thyroid tumors in mice. The Committee recommended using the Q* approach. The Q* is 0.0601 $(mg/kg/day)^{-1}$ and is based on ETU.

B. Exposures and Risks

1. *From food and feed uses.* Tolerances have been established (40 CFR 180.176) for the residues of mancozeb, in or on a variety of raw agricultural commodities at levels ranging from 0.1 ppm in corn to 65.0 ppm in sugar beet tops. There are no livestock feed items associated with this section 18 use, so no additional livestock dietary burden is expected. Risk assessments were conducted by EPA to assess dietary exposures and risks from mancozeb and ETU 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. Because it is a minor crop, ginseng is not uniquely identified in the data system which the Agency uses to calculate acute and chronic dietary risk. However, in conjunction with the EPA's assessment of a separate registration action involving an ethylenebisdithiocarbamate (EBDC)-pesticide, the chemical family to which mancozeb belongs, the Agency has recently conducted a comprehensive analysis for EBDCs and ETU. That risk assessment evaluated the chronic, acute, and cancer risks associated with the EBDCs and ETU. For that review, EPA used the dietary endpoint for ETU of 5 mg/kg/day. The resulting estimate of high-end dietary exposure for the population subgroup of concern, females 13-plus years old, results in an MOE of 5,000. Maximum field trial data values were used to calculate the MOE. This is considered a partially refined risk estimate; further refinement using anticipated residue values and percent crop-treated data in conjunction with Monte Carlo analysis would result in a lower acute dietary exposure estimate. Thus, in EPA's judgement, the additional dietary burden associated with consumption of ginseng would not lower the MOE to a level that poses a concern.

ii. *Chronic exposure and risk.* In conjunction with the comprehensive EBDC evaluation mentioned above, EPA calculated exposures for the U.S. population and various subgroups including infants and children. For the subgroup U.S. population (48 states), EPA concluded that the anticipated residue contribution (ARC) from food for ETU would be 0.000020 mg/kg/day. This results in an exposure equal to 24% of the RfD. The highest exposure level was calculated for non-nursing infants (<1 year old) exposed at 78% of the RfD.

This assessment used anticipated residue refinement and percent crop treated data for selected commodities. Thus, this assessment should be viewed as partially refined. Further refinement would lower dietary exposure estimates. As mentioned above, although ginseng consumption data was not included in the referenced assessment, the increased exposures associated with this tolerance would not be expected to trigger a level of concern through chronic consumption of treated foods.

2. *From drinking water.* Submitted environmental fate studies suggest that mancozeb has moderate potential to leach into ground water; thus, mancozeb could potentially leach to ground water and runoff to surface water under certain environmental conditions. There are no established Maximum Contaminant Levels (MCL) for residues of mancozeb in drinking water. No Health Advisories (HA) for mancozeb 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.

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 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 mancozeb or ETU 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 mancozeb or ETU 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* —i. Mancozeb is currently registered for use on the following residential non-food sites: turf, lawn, trees and shrubs. Mancozeb 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 assessment. For this action, the risk to public health from the use of mancozeb 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.

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 mancozeb has been calculated to be 2.2×10^{-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.'' 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 toxicity will be assumed).

Mancozeb is a member of the EBDC class of pesticides. Other members of this class include among others: maneb, metiram, and nabam. EPA does not have, at this time, available data to determine whether mancozeb has a common mechanism of toxicity with other non-EBDC 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, mancozeb does not appear to produce a toxic metabolite produced by other substances.

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

1. *Acute risk.* EPA concludes that the MOE for ETU for the population subgroup of concern (females 13-plus years and older) is 5,000. This MOE is well above the Agency's level of concern for acute dietary exposure.

2. *Chronic risk.* Using the ARC exposure assumptions described above, EPA has concluded that aggregate exposure to ETU from food will utilize 24% of the RfD for the U.S. population. The major identifiable subgroup with the highest aggregate exposure is non-nursing infants less than a year old at 78% of the RfD. A complete discussion of the risks posed by mancozeb and ETU to children is presented 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 mancozeb in drinking water and from non-dietary, non-occupational exposure, EPA does not expect the aggregate exposure to exceed 100% of the RfD. EPA concludes that there is a reasonable certainty that no harm will result from aggregate exposure to mancozeb or ETU 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. Although residential exposure data are not available for ornamental lawn uses of mancozeb, EPA notes that large MOEs were calculated for occupational exposure, greater than 19,000 for the most highly exposed group. EPA concludes that there is a reasonable certainty that no harm will result from aggregate exposure to mancozeb residues.

D. Aggregate Cancer Risk for U.S. Population

The cancer risk for mancozeb is based on ETU. The dietary cancer risk is calculated using the Q1* for ETU, $0.0601\ mg/kg/day^{-1}$. EPA calculated that the dietary cancer risk for the EBDC pesticides, including this use on ginseng, is approximately 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. Although surface and ground water monitoring data are limited, California has analyzed 65 wells for ETU from 1986–89, some of which were in maneb (an EBDC) use areas. Only one detection of .725 ppb was reported; however, residues were not present at a subsequent sampling 4 or 5 months later. A single detect of 16 ppb from an area in Illinois of no known EBDC use is believed to be an anomaly and may be derived from a point source. Regardless of this detection above 1 ppb, there is little evidence that any significant subpopulation is exposed at levels above 1 ppb for a significant period of time. Thus, a very conservative estimate of the aggregate (dietary + residential + drinking water) cancer risk from the EBDCs would be 10^{-6}. In EPA's best scientific judgement, the potential exposure from residues on ginseng and in water would not increase cancer risk estimates above EPA'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 mancozeb, EPA considered data from developmental toxicity studies in the rat and rabbit and a 2–generation reproduction study in the rat. The developmental toxicity studies are designed to evaluate adverse effects on the developing organism resulting from 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 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.* For mancozeb, developmental toxicity information indicated that the maternal NOAEL was 32 mg/kg/day, based on decreased food consumption at the lowest observed effect level (LOEL) of 128 mg/kg/day. The developmental (fetal) NOAEL was 128 mg/kg/day, based on dilated ventricles, spinal cord hemorrhage, delayed and incomplete ossification of skull, and ribs at the LOEL of 512 mg/kg/day. In the rabbit developmental toxicity study for mancozeb, the maternal (systemic) NOAEL was 30 mg/kg/day, based on death, ataxia, and abortion at the LOEL of 80 mg/kg/day. The developmental (fetal) NOAEL was greater than 80 mg/kg/day Highest Dose Tested (HDT).

For ETU, there is no adequate rabbit developmental toxicity study available. In the rat, 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.* From the rat reproductive study, the maternal (systemic) NOAEL for mancozeb was 1.5 mg/kg/day, based on increased liver weight in males and renal pigment in both sexes at the LOEL of 6.0 mg/kg/day. The reproductive (pup) NOAEL was 60 mg/kg/day at the HDT. There is no adequate rat reproduction study for ETU.

iv. *Pre- and post-natal sensitivity.* For this assessment, EPA used the developmental NOAEL of 5 mg/kg/day from the oral developmental study on ETU in the rat to evaluate pre- and post-natal sensitivity. The effect observed involved delayed ossification in the fetal skeletal structures at the NOAEL. However, there is no adequate rabbit developmental toxicity study available. For this reason, EPA is applying an additional tenfold safety factor and requiring a minimum MOE of 1,000. The calculated MOE is 5,000 based on the NOAEL of 5 mg/kg/day. In EPA's judgement, this MOE does not suggest a level of concern.

v. *Conclusion.* As mentioned above, due to the fact that a data gap exists for ETU, EPA has concluded that the risk assessment for developmental and reproductive toxicity should use an additional safety factor in order to protect the population subgroup of concern, females 13+ years old. For this assessment, EPA has determined that a minimum MOE of 1,000 is necessary. Based on the NOAEL of 5 mg/kg/day described above, EPA calculates that the MOE is 5,000. Therefore, in EPA's judgement, the calculated exposure does not suggest a level of concern.

2. *Acute risk.* The acute risk assessment for infants and children used the dietary endpoint for ETU of 5 mg/kg/day. The MOE for the population subgroup of concern, females 13+ years old, is 5,000. Maximum field trial data values were used to calculate the MOE. This is considered a partially refined risk estimate.

3. *Chronic risk.* Using the conservative exposure assumptions described above, EPA has concluded that aggregate exposure to ETU from food will utilize 78% of the RfD for infants and children. 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 mancozeb and ETU in drinking water and from non-dietary, non-occupational exposure, EPA does not expect the aggregate exposure to exceed 100% of the RfD. EPA concludes that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to mancozeb or ETU residues.

V. Other Considerations

A. Metabolism In Plants and Animals

The nature of the residues of mancozeb and ETU are adequately understood. The regulable residue listed at 40 CFR 180.176 lists the parent compound only, calculated as zinc ethylenebisdithiocarbamate. EPA concludes the residues of concern to be the fungicide mancozeb, calculated as zinc ethylenebisdithiocarbamate, and it's metabolite ETU. There are no animal feed items associated with ginseng, therefore a discussion of animal metabolism is not germane to this action.

B. Analytical Enforcement Methodology

Adequate enforcement methodology is available in the Pesticide Analytical Manual (PAM II, Method III) to enforce the current tolerance expression for EBDCs. An enforcement method is also available for ETU. The residues of mancozeb or ETU are not expected to exceed 2.0 ppm in/on ginseng as a result of this FIFRA section 18 use.

C. Magnitude of Residues

EPA concludes that the combined regulable residues of mancozeb and ETU are not expected to exceed 2.0 ppm in or on ginseng as a result of this section 18 use. Secondary residues are not expected in animal commodities as no feed items are associated with this FIFRA section 18 use.

D. International Residue Limits

There are no Codex, Canadian, or Mexican international residue limits, established for residues of mancozeb on ginseng.

E. Rotational Crop Restrictions

Ginseng is not rotated to other crops, therefore, there is no concern for inadvertent residues in rotated crops.

VI. Conclusion

Therefore, a time-limited tolerance is established for the combined residues of mancozeb, calculated as zinc ethylenebisdithiocarbamate, and it's metabolite (ETU) in ginseng at 2.0 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 December 7, 1998, 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 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 and Electronic Submissions

EPA has established a record for this rulemaking under docket control number [OPP–300714] (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 Highway, Arlington, VA.

Electronic comments may be sent directly to EPA at:

opp-docket@epamail.epa.gov.

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

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

IX. Regulatory Assessment Requirements

A. Certain Acts and Executive Orders

This final rule establishes a time-limited tolerance under FFDCA section 408(d) in response to a petition submitted to the Agency. 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 acations 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 to 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.

X. 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 to 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.

September 30, 1998.

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. 346a and 371.

2. Section 180.176 is amended by revising the section heading, designating the existing text as paragraph (a) and adding a paragraph heading, adding new paragraph (b), and adding and reserving paragraphs (c) and (d) with headings to read as follows:

§ 180.176 Mancozeb; tolerances for residues.

(a) *General.* * * *

(b) *Section 18 emergency exemptions.* A time-limited tolerance is established for combined residues of the fungicide mancozeb, calculated as zinc ethylenebisdithiocarbamate and it's metabolite ETU 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 dates specified in the following table.

Commodity	Parts per million	Expiration/Revocation Date
Ginseng	2.0	12/31/99

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

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

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FEDERAL EMERGENCY MANAGEMENT AGENCY

44 CFR Part 64

[Docket No. FEMA–7697]

List of Communities Eligible for the Sale of Flood Insurance

AGENCY: Federal Emergency Management Agency (FEMA).

ACTION: Final rule.

SUMMARY: This rule identifies communities participating in the National Flood Insurance Program (NFIP). These communities have applied to the program and have agreed to enact certain floodplain management measures. The communities' participation in the program authorizes the sale of flood insurance to owners of property located in the communities listed.

EFFECTIVE DATES: The dates listed in the third column of the table.

ADDRESSES: Flood insurance policies for property located in the communities listed can be obtained from any licensed