Dated: November 25, 1997.

Peter Caulkins,

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.

§ 180.443 [Amended]

2. In § 180.443, by amending paragraph (b) in the table, for the commodity ''cucurbit vegetables'' by removing ''November 30, 1997''and adding in its place ''November 30, 1998''.

[FR Doc. 97–32549 Filed 12–11–97; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300590; FRL–5759–5]

RIN 2070–AB78

Chlorothalonil; Pesticide Tolerances for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a time-limited tolerance for residues of chlorothalonil 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 chlorothalonil and its metabolite 4-hydroxy-2,5,6-trichloroisophthalonitrile, expressed as chlorothalonil, 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, 1998.

DATES: This regulation is effective December 12, 1997. Objections and requests for hearings must be received by EPA on or before February 10, 1998.

ADDRESSES: Written objections and hearing requests, identified by the docket control number, [OPP–300590], 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–300590], 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. 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 5.1/6.1 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–300590]. No Confidential Business Information (CBI) should be submitted through e-mail. Electronic copies of objections and hearing requests on this rule may be filed online at many Federal Depository Libraries.

FOR FURTHER INFORMATION CONTACT: By mail: Olga Odiott, Registration Division 7505C, Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail address: Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, (703) 308-9363, e-mail: odiott.olga@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: EPA, on its own initiative, pursuant to section 408(e) and (l)(6) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(e) and (l)(6), is establishing a tolerance for residues of the fungicide chlorothalonil and its 4-hydroxy-2,5,6-trichloroisophthalonitrile metabolite, expressed as chlorothalonil, in or on ginseng at 0.10 parts per million (ppm). This tolerance will expire and is revoked on December 31, 1998. EPA will publish a document in the **Federal Register** to remove the revoked tolerance from the Code of Federal Regulations.

I. Background and Statutory Authority

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

New section 408(b)(2)(A)(i) 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 Chlorothalonil on Ginseng and FFDCA Tolerances

The state of Wisconsin availed itself of the authority to declare a crisis exemption to use chlorothalonil to control the ginseng leaf and stem blight caused by *Alternaria panax*. *A. panax* may cause substantial losses of ginseng yield if not controlled. Specific emergency exemptions have been granted for the use of mancozeb for several years based on loss of efficacy of iprodione due to development of resistance in the pathogen to the latter fungicide. The state argues that while mancozeb affords good protection during typical years, during years of very heavy precipitation, as in 1996 and 1997, mancozeb is inadequate because it is easily washed off plants by rain. In this respect, the state claims, chlorothalonil provides superior control during very rainy summers. EPA has authorized under FIFRA section 18 the use of chlorothalonil on ginseng for control of leaf and stem blight in Wisconsin.

As part of its assessment of this emergency exemption, EPA assessed the potential risks presented by residues of chlorothalonil 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 section 408(e), as provided in section 408(l)(6). Although this tolerance will expire and is revoked on December 31, 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 ginseng 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 chlorothalonil 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 chlorothalonil 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 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 chlorothalonil, 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 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/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 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 (children 1 to 6 years 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 chlorothalonil and to make a determination on aggregate exposure, consistent with section 408(b)(2), for a time-limited tolerance for residues of chlorothalonil and its metabolite 4-hydroxy-2,5,6-trichloroisophthalonitrile, expressed as chlorothalonil, in or on ginseng at 0.10 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 chlorothalonil are discussed below. The nature of the toxic effects caused by hexachlorobenzene (HCB), a contaminant of chlorothalonil, are also discussed.

1. *Acute toxicity*. The lowest observed effect level (LOEL) of 175 milligrams/kilogram/day (mg/kg/day) (only dose tested) from a 3-month rat study was used for evaluating acute dietary risk from chlorothalonil to all subgroups. The LOEL was based on renal and gastric lesions observed within 4 days of testing. An uncertainty factor of 300 was recommended since a LOEL instead of a NOEL was used for the assessment.

No acute dietary endpoints have been identified for HCB.

2. *Short - and intermediate - term toxicity*. The NOEL of 600 mg/kg/day highest dose tested (HDT) from a 21-day dermal toxicity study in male Fischer 344 rats was recommended to assess risks from short and intermediate-term exposures to residues of chlorothalonil.

There is no toxicological endpoint identified for short and intermediate-term exposure to HCB.

3. *Chronic toxicity*. EPA has established the RfD for chlorothalonil at 0.018 mg/kg/day. This RfD is based on a 2-year dog feeding study with a NOEL of 1.8 mg/kg/day and an uncertainty factor of 100 (based on increased urinary bilirubin levels and kidney vacuolated epithelium at 3.5 mg/kg/day).

The EPA has established the RfD for HCB at 0.0008 mg/kg/day. This RfD is based on the NOEL of 0.08 mg/kg/day from a 130-week feeding study in rats. At the LEL of 0.29 mg/kg/day, there was hepatic centrilobular basophilic chromogenesis. An uncertainty factor of 100 was used to account for inter-species extrapolation and intra-species variability.

4. *Carcinogenicity*. The OPP Cancer Peer Review Committee (CPRC) classified chlorothalonil as a Group B2 (probable human carcinogen) chemical with a $Q_1^* = 7.66 \times 10^{-3}$ $(mg/kg/day)^{-1}$. The classification was based on

forestomach tumors in mice and renal tumors in rats. The Q_{1*} was based upon female rat renal (adenoma and/or carcinoma) tumor rates. A 3/4 scaling factor was used to determine the Q_1* from the rat data. HCB, an impurity in chlorothalonil, is also classified as a Group B2 chemical (probable human carcinogen) with a Q_1* = 1.02 (mg/kg/day)$^{-1}$. The classification was based on positive results in hamsters and rats.

B. Exposures and Risks

1. *From food and feed uses.* Tolerances have been established (40 CFR 180.275) for residues of chlorothalonil and its metabolite 4-hydroxy-2,5,6-trichloroisophthalonitrile, expressed as chlorothalonil, in or on a variety of raw agricultural commodities at levels ranging from 0.05 ppm in cocoa beans and bananas, edible pulp to 15 ppm in celery and papayas. There are no established tolerances on meat, milk, poultry and eggs. Risk assessments were conducted by EPA to assess dietary exposures and risks from chlorothalonil as presented below. Ginseng is not presently represented in the Dietary Risk Evaluation System (DRES) data files because of very low consumption in the U.S. Thus, the dietary exposure analysis does not include a contribution for ginseng. The consumption of ginseng is not expected to significantly alter exposure.

i. *Acute exposure and risk.* Acute dietary risk assessments are performed for a food-use pesticide if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1 day or single exposure. The acute dietary (food only) risk assessment used tolerance level residues (published and pending tolerances included). The resulting high-end exposure estimate of 0.2 mg/kg/day results in a dietary (food only) MOE of 1,500 for infants < 1 year old and children 1-6 years old. This should be viewed as a conservative risk estimate.

ii. *Chronic exposure and risk.* For the chronic dietary risk assessment, the Agency used anticipated residue data. The anticipated residues based on existing chlorothalonil tolerances (published and pending) result in an anticipated residue contribution (ARC) that is equivalent to percentages of the RfD that range from 19.8% for non-nursing infants to 85.8% for children 1 to 6 years old.

Estimates for HCB result in an ARC that is equivalent to percentages of the RfD that range from 0.01% for non-nursing infants to 0.05% for children 1 to 6 years old. Residues of HCB were estimated to be present at a level not exceeding 0.05% (the maximum, allowed in chlorothalonil formulations) of the residues of chlorothalonil.

2. *From drinking water.* Based on available data used in EPA's assessment of environmental risk, chlorothalonil is not persistent and is moderately mobile. Health advisory levels for chlorothalonil in drinking water have been established as follows: for a 10 kg child, the one day finalized level and the long term level is 0.2 mg/L; for a 70 kg adult, the long term is 0.5 kg/L. No lifetime health advisory level has been established for chlorothalonil, but the Office of Drinking Water estimates that a long term average chlorothalonil concentration of 150 µg/L would correspond to an additional lifetime carcinogenic risk of 10-4. Consequently, a concentration of 1.5 µg/L would correspond to a lifetime carcinogenic risk of 10^{-6}. Chlorothalonil is not currently regulated under the Safe Drinking Water Act (SDWA), therefore water supply systems are not required to sample and analyze for it. The intermediate soil/water partitioning of chlorothalonil should make the primary treatment processes employed by most surface water source supply systems at least partially effective in removing it.

Ground water. Degradates (metabolites) of chlorothalonil, not chlorothalonil itself, have been found in ground water in the states of New York, Massachusetts, Florida, Maine, and California (U.S. HED, 1993). The reported metabolites (SDS-46851, SDS-47525, SDS-3701, and SDS-19221) were measured at the highest combined concentration of approximately 16 ppb in New York's Suffolk County (Long Island) in 1981. It is not clear how the use of chlorothalonil in New York compares to use in other areas, but it is expected that the levels of chlorothalonil metabolites detected in the ground water in New York are unrepresentatively high compared to the country as a whole. A small-scale ground water monitoring study is underway, and will give the Agency a more quantitative measure of the ground water contamination potential.

Surface water. Chlorothalonil can contaminate surface water at application via spray drift. The intermediate soil/water partitioning of chlorothalonil indicates that its concentration in suspended and bottom sediment will be substantially greater than its concentration in water.

The following surface water label advisory is required for chlorothalonil:

Chlorothalonil can contaminate surface water through spray drift. Under some conditions, chlorothalonil may also have a high potential for runoff into surface water (via both dissolution in runoff water and adsorption to eroding soil), for several weeks to months post-application. These include poorly draining or wet soils with readily visible slopes toward adjacent surface waters, frequently flooded areas, areas over-laying extremely shallow ground water, areas with in-field canals or ditches that drain to surface water, areas not separated from adjacent surface waters with vegetated filter strips, and highly erodible soils.

The South Florida Water Management District (SFWMD; Miles and Pfeuffer 1994) summarized chlorothalonil detections in samples collected every 2 to 3 months from 27 surface water sites within the SFWMD from November 1988 through November 1993. Approximately 810 samples were collected. Chlorothalonil was detected in 25 samples at concentrations ranging from 0.003 to 0.035 µg/L (0.003 ppb to 0.035 ppb).

Exposures and risks. The Agency does not have sufficient data to complete a comprehensive drinking water risk assessment for the potential of chlorothalonil and its degradates to contaminate ground water. For this drinking water risk assessment the Agency assumed that the metabolites of chlorothalonil have the same toxicity as the parent chlorothalonil and used the highest measured concentration levels to calculate acute and chronic risks from drinking water exposures to residues of chlorothalonil. The Agency also assumed that adults weighing 70 kg consume 2 liters of drinking water per day while children weighing 10 kg drink 1 liter. The acute drinking water risk was calculated by dividing the LOEL identified for acute dietary risk assessment by the exposure from drinking water sources. The chronic risk for drinking water was calculated by comparing exposure from drinking water sources to the appropriate RfD.

The following risk assessments should be considered as worst case scenarios. As the necessary data are received, the risk assessments will be reviewed and evaluated based on the new data.

i. *Acute exposure and risk— Ground water.* In order to calculate acute drinking water risk, the highest concentration detected in ground water (16 ppb) was compared to the acute dietary exposure LOEL of 175 mg/kg/day. Acute exposures were estimated to be 0.0016 mg/kg/day for children and 0.00046 mg/kg/day for adults. The corresponding MOEs were estimated as 109,375 for children and 380,435 for adults.

Surface water. The available surface water monitoring information was used to perform an exposure assessment of

surface water as a drinking water source. The highest measured concentration (0.035 µg/L) and the acute dietary LOEL were used to estimate exposures and risks. Exposures were estimated to be 0.000035 mg/kg/day for children and 0.00001 mg/kg/day for adults. The corresponding MOEs were estimated as 5,000,000 for children and 17,500,000 for adults.

The large MOEs provide a reasonable certainty of no harm from the potential exposures associated with chlorothalonil in water.

Acute drinking water risk to HCB was not calculated since no acute dietary endpoint has been identified for HCB.

ii. *Chronic exposure and risk—Ground water.* The highest concentration detected in ground water (16 ppb) and the RfD for chlorothalonil were used to estimate exposures and risks. The Agency estimated that chronic dietary risks from drinking water will utilize 8% of the RfD for children and 2% of the RfD for adults.

Surface water. The highest measured concentration (0.035 µg/L) from the available surface water monitoring data and the RfD for chlorothalonil were used to estimate exposures and risks. The Agency estimated that chronic dietary risks from surface water exposures to residues of chlorothalonil will utilize < 1% of the RfD for both children and adults.

To estimate the chronic dietary risk from exposures to HCB, concentrations for chlorothalonil were assumed to be contaminated with 0.05% HCB. The resulting concentration was compared to the RfD for HCB (0.0008 mg/kg/day). The Agency estimated that chronic dietary risks from surface water exposures to residues of HCB will utilize < 1% of the RfD for both children and adults.

3. *From non-dietary exposure.* Chlorothalonil is currently registered for use on the following residential non-food sites: turf, lawn, trees, grasses, bulbs, plants, and shrubs. Indoor uses include: paints, coatings, adhesives, wood treatments, and resin emulsions.

The Agency currently lacks residential-related exposure data to complete a comprehensive residential risk assessment for many pesticides, including chlorothalonil.

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).

Chlorothalonil (tetrachloroisophthalonitrile) is a member of the substituted aromatics class of pesticides (George W. Ware, *The Pesticide Book*, 4th edition, page 144, Thomson Publications, 1994). Other members of this class include pentachloronitrobenzene (PCNB) and 2,6-dichloro-4-nitroaniline (dicloran, DCNA).

EPA does not have, at this time, available data to determine whether chlorothalonil has a common mechanism of toxicity with other substances or how to include this pesticide in a cumulative risk assessment. For the purposes of this tolerance action, therefore, EPA has not assumed that chlorothalonil has a common mechanism of toxicity with other substances.

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

1. *Acute risk.* For the overall U.S. population the calculated MOE value (food) is 2,000 for chlorothalonil. For acute drinking water risk, the calculated MOE for adults, based on ground water monitoring data, is 380,435. The acute aggregate risk for general U.S. population is 1,163 (175 mg/kg/day ÷ 0.15046 mg/kg/day). The acute aggregate risk for chlorothalonil for all population subgroups is below HED's level of concern.

2. *Chronic risk.* Using the ARC exposure assumptions described above, EPA has concluded that aggregate exposure to chlorothalonil from food and water will utilize ≈46.5% (44.5% from food + ≈ 2% from water) of the RfD for the U.S. population. The aggregate exposure to HCB from food and water will utilize ≈1.03% (0.03% from food + ≈1% from water) of the RfD for the U.S. population. The major identifiable subgroup with the highest aggregate exposure is children 1 to 6 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. EPA concludes that there is a reasonable certainty that no harm will result from aggregate exposure to chlorothalonil and HCB residues.

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

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

D. Aggregate Cancer Risk for U.S. Population

The cancer risk from food uses of chlorothalonil (a B2 carcinogen with a Q_1^* of 7.66×10^{-3} $(mg/kg/day)^{-1}$) for the general U.S. population was estimated as 1.1×10^{-6} (upper bound). The calculation was based on ARC estimates. EPA used all the published, pending and new uses for chlorothalonil

and substracted the risk figures from consumption of meat and milk products. Residues of chlorothalonil per se are not expected to transfer from feed items to meat and milk, but residues of the 4-hydroxy metabolite (which is not of carcinogenic concern) could occur in these commodities. Thus, there is no carcinogenic risk attributable to chlorothalonil from its use on livestock feed items.

The dietary (food) cancer risk from HCB (a B2 carcinogen with a Q_1* of 1.02 $(mg/kg/day)^{-1}$) for the general U.S. population was estimated as 3.6×10^{-7} (upper bound). The concentrations for chlorothalonil were assumed to be contaminated with 0.05% HCB. The calculation was based on ARC estimates and all the published, pending and new uses for chlorothalonil.

The drinking water cancer risk from exposure to chlorothalonil residues was estimated as 2×10^{-7} for children and 7×10^{-8} for adults. These estimates are based on the highest measured concentration from the available surface water monitoring data. Only metabolites of chlorothalonil have been found in ground water. These metabolites are not of carcinogenic concern, therefore an assessment of the cancer risks associated with dietary exposures to chlorothalonil from ground water sources was not conducted. The drinking water cancer risk from exposure to HCB residues was estimated as 1×10^{-7} for children and 5×10^{-9} for adults. The concentrations for chlorothalonil were assumed to be contaminated with 0.05% HCB.

For the drinking water risk assessment the Agency assumed that water comes from the same source containing the same contaminant level and is consumed throughout a 36-year period. This is extremely conservative, since it is likely that frequency and amounts of chlorothalonil used vary widely over this time, and most of the U.S. population moves at some time and does not live in the same area, drinking from the same water source for a 36-year period. Therefore, the risk to both adults and children from drinking water is likely an over-estimate.

The Agency concludes that the aggregate (food + water) cancer risks from exposures to chlorothalonil and HCB do not exceed the levels 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 chlorothalonil, 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 data base unless EPA determines that a different margin of safety will be safe for infants and children. Margins of safety are incorporated into EPA risk assessments either directly through use of a MOE analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans. EPA believes that reliable data support using the standard 100-fold safety factor (for combined inter- and intra-species variability) and not the additional tenfold safety factor when EPA has a complete data base under existing guidelines and when the severity of the effect in infants or children or the potency or unusual toxic properties of a compound do not raise concerns regarding the adequacy of the standard safety factor.

ii. *Developmental toxicity studies—Rats.* The maternal (systemic) NOEL was 100 mg/kg/day, based on increased mortality and reduced weight gain at the LOEL of 400 mg/kg/day. The developmental (fetal) NOEL was 100 mg/kg/day, based on increase in total resorptions and resorptions per dam with related increase in postimplantation loss at the LOEL of 400 mg/kg/day.

Rabbits. The maternal (systemic) NOEL was 10 mg/kg/day, based on reductions in weight gain and food consumption during dosing at the LOEL of 20 mg/kg/day. The developmental (fetal) NOEL was 20 mg/kg/day (HDT).

iii. *Reproductive toxicity study—Rats.* In the 2-generation reproductive toxicity study in rats, the maternal (systemic) NOEL was less than 38 mg/kg/day lowest dose tested (LDT), based on hyperplasia of renal and forestomach tissues at the LOEL of 38 mg/kg/day. The reproductive/developmental (pup) NOEL was 115 mg/kg/day, based on decreased pup weight on day 21 of lactation and a suggestive increase in the incidence of neonatal renal pelvis dilation in the F_{1a} generation at the LOEL of 234 mg/kg/day.

iv. *Pre- and post-natal sensitivity.* The toxicological data base for evaluating pre- and post-natal toxicity for chlorothalonil is complete with respect to current data requirements. There are no pre- or post-natal toxicity concerns for infants and children, based on the results of the rat and rabbit developmental toxicity studies and the 2-generation rat reproductive toxicity study. In these studies, the fetal or pup NOELs occur at or above the maternal NOELs indicating that there is no extra-sensitivity for infants and children.

v. *Conclusion.* Based on the above, HED concludes that reliable data support use of the standard uncertainty factor of 100 and that an additional safety factor is not needed to protect infants and children.

2. *Acute risk.* The acute dietary MOE (food) was calculated to be 1,500 for infants (<1 year), 1,500 for children (1-6 years), and 3,000 for females 13+ years (accounts for both maternal and fetal exposure). The acute aggregate MOE (food and water) for the most highly exposed subpopulation (children 1 - 6 years old) was calculated to be 868. These MOE calculations were based on the systemic LOEL in rats of 175 mg/kg/day. This risk assessment assumed 100% crop-treated with tolerance level residues on all treated crops consumed, resulting in a significant over-estimate of dietary exposure. The large acute dietary MOE calculated for females 13+ years provides assurance that there is a reasonable certainty of no harm for both females 13+ years and the pre and post-natal development of infants.

3. *Chronic risk.* Using the conservative exposure assumptions described above, EPA has concluded that aggregate dietary (food + water) exposure to chlorothalonil will utilize percentages of the RfD that range from 27.8% (19.8% for food + 8% for water) for nursing infants, up to 93.8% (85.8% for food + 8% for water) for children 1-6 years old.

The percentage of the RfD that will be utilized by aggregate exposure food + water to residues of HCB ranges from ≈1.01% for nursing infants, up to ≈1.05% for children 1-6 years 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. EPA concludes that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to chlorothalonil residues.

V. Other Considerations

A. Metabolism In Plants and Animals

The nature of the residue in plants and animals is adequately understood. The residues of concern are chlorothalonil and its metabolite 4-hydroxy-2,5,6-trichloroisophthalonitrile is an impurity in chlorothalonil products.

B. Analytical Enforcement Methodology

Adequate enforcement methodology (gas chromatography-electron capture detection) is available in PAM II (Method I) to enforce the tolerance expression.

C. Magnitude of Residues

Residues of chlorothalonil and its metabolite 4-hydroxy-2,5,6-trichloroisophthalonitrile are not expected to exceed 0.10 ppm in/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 section 18 use.

D. International Residue Limits

There are no Codex proposals, Canadian limits, or Mexican limits for chlorothalonil on ginseng.

E. Rotational Crop Restrictions

EPA has determined that rotational crop studies will not be required for uses of pesticides on ginseng.

VI. Conclusion

Therefore, the tolerance is established for chlorothalonil and its metabolite 4-hydroxy-2,5,6-trichloroisophthalonitrile (expresed as chlorothalonil) in ginseng at 0.10 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 February 10, 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

EPA has established a record for this rulemaking under docket control number [OPP–300590] (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 (7502C), 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)(d). 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 on the basis of a petition under FFDCA section 408 (l)(6), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. Nevertheless, the Agency has previously assessed whether establishing tolerances, exemptions from tolerances, raising tolerance levels or expanding exemptions might adversely impact small entities and concluded, as a generic matter, that there is no adverse economic impact. The factual basis for

the Agency's generic certification for tolerance acations published on May 4, 1981 (46 FR 24950), and was provided to the Chief Counsel for Advocacy of the Small Business Administration.

X. Submission to Congress and the General Accounting Office

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

List of Subjects in 40 CFR Part 180

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

Dated: December 1, 1997.

Peter Caulkins,

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. In § 180.275, by adding a heading to paragraph (a); by redesignating paragraph (b) as paragraph (c) and adding a heading; by adding new paragraph (b); and by adding and reserving paragraph (d) with a heading to read as follows:

§ 180.275 Chlorothalonil; tolerances for residues.

(a) *General* . * * *

(b) *Section 18 emergency exemptions.* Time-limited tolerances are established for chlorothalonil and its metabolite 4-hydroxy-2,5,6-trichloroisophthalonitrile (expresed as chlorothalonil) in connection with use of the pesticide under the section 18 emergency exemptions granted by EPA. The tolerances will expire and are revoked on the dates specified in the following table:

Commodity	Parts per million	Expiration/revocation date
Ginseng	0.10	12/31/98

(c) *Tolerances with regional registrations.* * * *

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

[FR Doc. 97–32548 Filed 12–11–97; 8:45 am]

BILLING CODE 6560–50–F

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

43 CFR Parts 3740, 3810, and 3820

[WO–340–1220–00–24 1A]

RIN 1004–AD05

Multiple Use, Mining; Mining Claims Under the General Mining Laws

AGENCY: Bureau of Land Management, Interior.

ACTION: Final rule.

SUMMARY: The Bureau of Land Management (BLM) is removing several obsolete or unnecessary regulations, and revising regulations concerning mining on Papago Indian Reservation lands. The regulations BLM is removing concern certain programs under the Multiple Minerals Development Act: claimant's rights; opening of Helium reserves to mining location and mineral leasing; and regulations under the statute entitled ''Mining Rights in Prescott National Forest'' concerning mining in the watershed of the city of Prescott, Arizona. Each of the regulations being removed is unnecessary or obsolete, either because it describes programs which no longer exist or because it contains requirements already achieved by statutes or other applicable regulations. Removing these items will have no impact on BLM customers or the public at large.

EFFECTIVE DATE: January 12, 1998.

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

FOR FURTHER INFORMATION CONTACT: Roger Haskins, Bureau of Land Management, Solid Minerals Group, 1849 C Street, N.W., Washington, DC 20240; Telephone: 202–452–0355.

SUPPLEMENTARY INFORMATION:

I. Background and Discussion of Final Rule as Adopted

The regulations that are being removed are obsolete and unnecessary, and therefore can be eliminated without negative consequences.

Subpart 3744 concerns the rights of leasable minerals mining claimants. These rights are derived from the Multiple Mineral Development Act, 30 U.S.C. 521 *et seq.* (the Leasing Act). However, rather than implementing or interpreting the Act, subpart 3744 merely quotes Sections 7(d) and 8 of the Act, 30 U.S.C. 527(d), 528. The regulation consists entirely of duplicated statutory language and adds nothing to the protections of mining claimants' rights already contained in the statute. Because those rights are preserved by the statute and not the regulation, this regulation serves no substantive purpose, and can be deleted without any impact on the regulated community or the United States.

Subpart 3745, concerning the conditions for opening Helium Reserves to mining location and mineral leasing, also consists of unnecessary recitation of the Leasing Act. 43 CFR 3745.1(a) is merely a direct quote of section 9 of the Act, 30 U.S.C. 529. In addition, 43 CFR 3745.1(b) contains language not derived from the Act, asserting that applications filed prior to published notice to open the helium reserves will confer no rights. However, this provision is completely obsolete and without any substantive importance. Merely filing an application cannot confer any rights until the application is approved. Furthermore, Helium Reserves Numbers 1 and 2 were opened in 1955, have since been withdrawn, and BLM has determined that no pre-existing applications under this subpart currently exist. Therefore, because this regulation contains only duplicated statutory language and obsolete provisions, it can be deleted without