

Dated: August 1, 1997.

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## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 180

[OPP-300517; FRL-5731-7]

RIN 2070-AB78

### Herbicide Safener HOE-107892; Pesticide Tolerances for Emergency Exemptions

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes a time-limited tolerance for the inert ingredient, herbicide safener HOE-107892 (mefenpyr-diethyl) and its 2,4-dichlorophenyl-pyrazoline metabolites HOE-094270 and HOE-113225 in or on wheat grain and wheat straw. 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 herbicide safener on wheat grain and wheat straw in North Dakota and Montana. This regulation establishes a maximum permissible level for residues of the Herbicide safener HOE-107892 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 tolerances will expire and are revoked on August 1, 1998.

**DATES:** This regulation is effective August 8, 1997. Objections and requests for hearings must be received by EPA on or before October 7, 1997.

**ADDRESSES:** Written objections and hearing requests, identified by the docket control number, [OPP-300517], 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-300517], must also be submitted to: Public Information and Records

Integrity Branch, Information Resources and Services Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring a copy of objections and hearing requests to Rm. 1132, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA.

A copy of objections and hearing requests filed with the Hearing Clerk may also be submitted electronically by sending electronic mail (e-mail) to: opp-docket@epamail.epa.gov. Copies of objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Copies of objections and hearing requests will also be accepted on disks in WordPerfect 5.1 file format or ASCII file format. All copies of objections and hearing requests in electronic form must be identified by the docket control number [OPP-300517]. 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: Pat Cimino, 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) 308-9357, e-mail: cimino.pat@epamail.epa.gov.

**SUPPLEMENTARY INFORMATION:** EPA, on its own initiative, pursuant to section 408(e) and (l)(6) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(e) and (l)(6), is establishing tolerances for the inert ingredient herbicide safener HOE-107892 (mefenpyr-diethyl) and its 2,4-dichlorophenyl-pyrazoline metabolites HOE-094270 and HOE-113225 in or on wheat grain and wheat straw at 0.01 and 0.05 ppm respectively. These tolerances will expire and are revoked on August 1, 1998. EPA will publish a document in the **Federal Register** to remove the revoked tolerances 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 Herbicide Safener HOE-107892 (mefenpyr-diethyl) on Wheat Grain and Wheat Straw and FFDCA Tolerances

The North Dakota and Montana State Departments of Agriculture requested the use of PUMA 1EC Herbicide for control of green and yellow foxtail (pigeon grass) in durum wheat in North Dakota and Montana. The active ingredient in PUMA 1EC is fenoxaprop-ethyl which has tolerances established for uses on wheat. However, fenoxaprop-ethyl is phytotoxic to durum wheat without the addition of an inert ingredient safener. The herbicide safener HOE-107892 allows the active ingredient, fenoxaprop-ethyl, to control yellow and green foxtail without harming the durum wheat. Although HOE-107892 (mefenpyr-diethyl) is an inert ingredient, tolerances for residues from its use on foods/feeds are required by the FFDCA. EPA has authorized under FIFRA section 18 the use of the Herbicide safener HOE-107892 on wheat grain and wheat straw for control of green and yellow foxtail (pigeon grass) in North Dakota and Montana. After having reviewed the submissions, EPA concurs that emergency conditions exist for these States.

As part of its assessment of this emergency exemption, EPA assessed the potential risks presented by residues of the Herbicide safener HOE-107892 in or on wheat grain and wheat straw. 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 August 1, 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 wheat grain and wheat straw 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 Herbicide safener HOE-107892 meets EPA's registration requirements for use on wheat grain and wheat straw or whether permanent tolerances for this use would be appropriate. Under these circumstances, EPA does not believe that these tolerances serve as a basis for registration of Herbicide safener HOE-107892 by a State for special local needs under FIFRA section 24(c). Nor do these tolerances serve as the basis for any States other than North Dakota and Montana 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 Herbicide safener HOE-107892, 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 enactment of FQPA, this assessment has been expanded to include both dietary and non-dietary sources of exposure, and will typically consider exposure from food, water, and residential uses when reliable data are available. In this assessment, risks from average food and water exposure, and high-end residential exposure, are aggregated. High-end exposures from all 3 sources are not typically added because of the very low probability of this occurring in most cases, and because the other conservative assumptions built into the assessment assure adequate protection of public health. However, for cases in which high-end exposure can reasonably be expected from multiple sources (e.g. frequent and widespread homeowner use in a specific geographical area), multiple high-end risks will be aggregated and presented as part of the comprehensive risk assessment/characterization. Since the toxicological endpoint considered in this assessment reflects exposure over a period of at least 7 days, an additional degree of conservatism is built into the assessment; i.e., the risk assessment nominally covers 1-7 days exposure, and the toxicological endpoint/NOEL is selected to be adequate for at least 7 days of exposure. (Toxicity results at lower levels when the dosing duration is increased.)

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

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

#### B. Aggregate Exposure

In examining aggregate exposure, FFQCA section 408 requires that EPA take into account available and reliable information concerning exposure from the pesticide residue in the food in question, residues in other foods for which there are tolerances, residues in groundwater or surface water that is consumed as drinking water, and other non-occupational exposures through pesticide use in gardens, lawns, or buildings (residential and other indoor uses). Dietary exposure to residues of a

pesticide in a food commodity are estimated by multiplying the average daily consumption of the food forms of that commodity by the tolerance level or the anticipated pesticide residue level. The Theoretical Maximum Residue Contribution (TMRC) is an estimate of the level of residues consumed daily if each food item contained pesticide residues equal to the tolerance. In evaluating food exposures, EPA takes into account varying consumption patterns of major identifiable subgroups of consumers, including infants and children. The TMRC is a "worst case" estimate since it is based on the assumptions that food contains pesticide residues at the tolerance level and that 100% of the crop is treated by pesticides that have established tolerances. If the TMRC exceeds the RfD or poses a lifetime cancer risk that is greater than approximately one in a million, EPA attempts to derive a more accurate exposure estimate for the pesticide by evaluating additional types of information (anticipated residue data and/or percent of crop treated data) which show, generally, that pesticide residues in most foods when they are eaten are well below established tolerances.

Percent of crop treated estimates are derived from federal and private market survey data. Typically, a range of estimates are supplied and the upper end of this range is assumed for the exposure assessment. By using this upper end estimate of percent of crop treated, the Agency is reasonably certain that exposure is not understated for any significant subpopulation group. Further, regional consumption information is taken into account through EPA's computer-based model for evaluating the exposure of significant subpopulations including several regional groups, to pesticide residues. For this pesticide, the most highly exposed population subgroup children 1-6 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 the Herbicide safener HOE-107892 and to make a determination on aggregate exposure, consistent with section 408(b)(2), for a time-limited tolerance for HOE-107892 and its 2,4-dichlorophenyl-pyrazoline metabolites HOE-094270 and HOE-113225 on wheat grain and wheat straw at 0.01 and 0.05 ppm respectively. EPA's

assessment of the dietary exposures and risks associated with establishing the tolerances 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 Herbicide safener HOE-107892 are discussed below.

1. *Acute toxicity.* The Agency recommended using the NOEL of 100 milligrams per kilogram per day (mg/kg/day) based on abortions and fetal intrauterine deaths without morphological developmental effects, at the lowest effect level (LEL) of 250 mg/kg/day from the rabbit developmental study. This NOEL is used to evaluate the Margin of Exposure (MOE) from the acute dietary risk to pregnant women 13+ years or older.

2. *Short- and intermediate-term toxicity.* No short- or intermediate-term non-dietary, non-occupational exposure scenario exists for HOE-107892 because no uses currently exist for the safener and only agricultural uses are requested for these section 18s.

3. *Chronic toxicity.* For purposes of this section 18 request use only, EPA has established the RfD for Herbicide safener HOE-107892 at 0.01 mg/kg/day. The temporary RfD is based on the chronic toxicity/carcinogenicity study in mice with a NOEL of 3.0 mg/kg/day (20 ppm) and an uncertainty factor of 300 (due to the absence of full evaluation of the toxicology data base). At the LEL of 1.5 mg/kg/day (100 ppm), dose-related hepatocellular hypertrophy was present in male mice.

4. *Carcinogenicity.* The mouse and rat cancer studies with the safener have not been reviewed and classified by the Agency. Perusal of the cancer studies by the Agency indicates no identifiable cancer concern in the mouse study. However, a possible concern regarding the increased incidence of thyroid follicular cell adenomas and carcinomas combined at the highest dose tested of 5,000 ppm in the rat carcinogenicity study was identified. This study requires an in-depth review by the Agency. Until that time, it is not known if a cancer risk assessment is required or what method of quantification would be appropriate. Therefore, for purposes of these Section 18s, a cancer risk assessment will not be conducted.

## B. Exposures and Risks

1. *From food and feed uses.* No permanent tolerances have been established for the inert ingredient herbicide safener HOE-107892. There are no indoor or outdoor residential uses registered for the safener. Risk assessments were conducted by EPA to assess dietary exposures and risks from Herbicide safener HOE-107892 as follows:

i. *Acute exposure and risk.* Acute dietary risk assessments are performed for a food-use pesticide if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a one day or single exposure. The acute dietary exposure endpoints of concern for the herbicide safener HOE-107892 are abortions and fetal intrauterine deaths without morphological developmental effects, which were observed in the rabbit developmental study. The population subgroup of concern is pregnant females 13+ years old. Acute dietary exposure (food only) was calculated using the high end exposure value and TMRC (worst case) assumptions. Therefore, this risk assessment is considered conservative. Despite the potential for acute exposure to the herbicide safener HOE-107892 in drinking water, EPA does not expect the aggregate acute exposure to exceed the Agency's level of concern.

ii. *Chronic exposure and risk.* In conducting exposure assessments for these section 18 requests, EPA used tolerance level residues and assumed that 100% of the crop would be treated with the pesticide (TMRC worst-case analysis assumptions) as described above.

2. *From drinking water.* The Agency's Environmental Fate data base indicates that HOE-107892 is persistent in the environment and has little potential for soil mobility or leaching.

Because the Agency lacks sufficient water-related exposure data to complete a comprehensive drinking water risk assessment for many pesticides, EPA has commenced and nearly completed a process to identify a reasonable yet conservative bounding figure for the potential contribution of water-related exposure to the aggregate risk posed by a pesticide. In developing the bounding figure, EPA estimated residue levels in water for a number of specific pesticides using various data sources. The Agency then applied the estimated residue levels, in conjunction with appropriate toxicological endpoints (RfD's or acute dietary NOEL's) and assumptions about body weight and consumption, to calculate, for each pesticide, the increment of aggregate risk contributed

by consumption of contaminated water. While EPA has not yet pinpointed the appropriate bounding figure for exposure from contaminated water, the ranges the Agency is continuing to examine are all below the level that would cause Herbicide safener HOE-107892 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 Herbicide safener HOE-107892 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. *Cumulative exposure to substances with common mechanism of toxicity.* Section 408(b)(2)(D)(v) requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity." The Agency believes that "available information" in this context might include not only toxicity, chemistry, and exposure data, but also scientific policies and methodologies for understanding common mechanisms of toxicity and conducting cumulative risk assessments. For most pesticides, although the Agency has some information in its files that may turn out to be helpful in eventually determining whether a pesticide shares a common mechanism of toxicity with any other substances, EPA does not at this time have the methodologies to resolve the complex scientific issues concerning common mechanism of toxicity in a meaningful way. EPA has begun a pilot process to study this issue further through the examination of particular classes of pesticides. The Agency hopes that the results of this pilot process will increase the Agency's scientific understanding of this question such that EPA will be able to develop and apply scientific principles for better determining which chemicals have a common mechanism of toxicity and evaluating the cumulative effects of such chemicals. The Agency anticipates, however, that even as its understanding of the science of common mechanisms increases, decisions on specific classes of chemicals will be heavily dependent on chemical specific data, much of which may not be presently available.

Although at present the Agency does not know how to apply the information in its files concerning common mechanism issues to most risk

assessments, there are pesticides as to which the common mechanism issues can be resolved. These pesticides include pesticides that are toxicologically dissimilar to existing chemical substances (in which case the Agency can conclude that it is unlikely that a pesticide shares a common mechanism of activity with other substances) and pesticides that produce a common toxic metabolite (in which case common mechanism of activity will be assumed).

EPA does not have, at this time, available data to determine whether Herbicide safener HOE-107892 has a common mechanism of toxicity with other substances or how to include this pesticide in a cumulative risk assessment. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, Herbicide safener HOE-107892 does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has not assumed that Herbicide safener HOE-107892 has a common mechanism of toxicity with other substances.

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

1. *Acute risk.* As discussed above, the acute dietary exposure endpoint of concern for HOE-107892 is abortions and fetal intrauterine deaths which were observed in the rabbit developmental toxicology study. For the U.S. populations subgroup of concern, females of childbearing age (13+ years old), an MOE value of 10,000 was calculated using the high end human exposure value of 0.00006 mg/kg/day. The Agency generally considers MOEs over 100 acceptable. This acute dietary (food only) risk assessment used tolerance level residues and assumed 100% crop-treated (TMRC worst-case analysis, described above). Despite the potential for risk from acute exposure to HOE-107892 in drinking water, the Agency does not expect acute aggregate exposure to exceed its level of concern. EPA concludes that there is reasonable certainty that no harm will result from acute aggregate exposure to HOE-107892.

2. *Chronic risk.* Using the conservative TMRC exposure assumptions described above, EPA has concluded that aggregate exposure to Herbicide safener HOE-107892 from food will utilize less than 0.01% of the RfD for the U.S. population and all population subgroups, including 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 Herbicide safener HOE-107892 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 Herbicide safener HOE-107892 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.

Because no short- or intermediate-term non-dietary, non-occupational exposure scenario exists for HOE-107892, a short- or intermediate-term aggregate risk assessment is not required.

#### D. Aggregate Risks and Determination of Safeness for Infants and Children

1. *Safety factor for infants and children—a. In general.* In assessing the potential for additional sensitivity of infants and children to residues of Herbicide safener HOE-107892, EPA considered data from developmental toxicity studies in the rat and rabbit and a two-generation reproduction study in the rat. The developmental toxicity studies are designed to evaluate adverse effects on the developing organism resulting from pesticide exposure during prenatal development to one or both parents. Reproduction studies provide information relating to effects from exposure to the pesticide on the reproductive capability of mating animals and data on systemic toxicity.

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.

b. *Developmental toxicity studies.* In the rat developmental toxicity study, the maternal (systemic) NOEL was 1,000 mg/kg/day (highest dose tested). The developmental (pup) NOEL was 1,000 mg/kg/day (highest dose tested).

In the rabbit developmental toxicity study, the maternal (systemic) NOEL of 100 mg/kg/day, was based on decreased body weight gain and food consumption, and abortions in the does at the LOEL of 250 mg/kg/day. The developmental (pup) NOEL was 100 mg/kg/day, based on intrauterine deaths of fetuses without morphological developmental effects at 250 mg/kg/day.

c. *Reproductive toxicity study.* In the rat reproduction study, the parental (systemic) NOEL was 75 mg/kg/day, based on decreased food consumption, body weight, increased spleen weights and increased splenic hematopoiesis at the LOEL of 396 mg/kg/day. The reproductive/developmental (pup) NOEL was 75 mg/kg/day, based on decreased body weight at the LEL of 396 mg/kg/day.

d. *Pre- and post-natal sensitivity.* The rabbit developmental study indicates a concern for pre-natal sensitivity for infants and children and an acute dietary risk assessment was required (discussed below, under acute risk) for pregnant females 13+ years of age. The results of the rat developmental study do not indicate any concerns for pre-natal sensitivity for infants and children. Both the maternal and developmental NOELs were 1,000 mg/kg/day (highest dose tested).

The results of the rat reproduction study did not demonstrate any concerns for post-natal sensitivity for infants and children. The parental and pup NOELs were both 75 mg/kg/day and at the LOELs of 396 mg/kg/day, the decrease in body weight in the pups was also seen in the parental animals.

e. *Conclusion.* Based on current toxicological data requirements, the data base for developmental and reproductive studies for HOE-107892 is complete. The Agency concluded that the developmental and reproductive findings in rats did not demonstrate any pre-natal or post-natal acute risk concerns for infants and children. The Agency concluded that the observed developmental effects in the rabbit study present a pre-natal acute risk concern for infants and children and that an acute risk assessment was required to evaluate a margin of

exposure. The acute risk assessment is described in detail below.

2. *Acute risk.* The Agency concluded that the observed developmental effects in the rabbit study, abortions and fetal intrauterine death, present a pre-natal acute risk concern for infants and children. An acute dietary risk assessment evaluating margin of exposure (MOE) for women of childbearing age (13+ years old) is required when the Agency determines that there is a pre- or post-natal acute risk effect of concern. The acute dietary MOE for women of childbearing age is 10,000 based on the rabbit developmental NOEL of 100 mg/kg/day and the high end human exposure value of 0.00006 mg/kg/day. This MOE is much higher than the minimal acceptable MOE of 100 for acute exposure to food. Despite the potential for acute exposure to HOE-107892 in drinking water, the Agency does not expect acute aggregate exposure to exceed its level of concern. EPA concludes that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to HOE-107892.

3. *Chronic risk.* Using the conservative exposure assumptions described above, EPA has concluded that aggregate exposure to Herbicide safener HOE-107892 from food will utilize less than 0.01% 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 Herbicide safener HOE-107892 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 Herbicide safener HOE-107892 residues.

4. *Short- or intermediate-term risk.* Because no short- or intermediate-term non-dietary, non-occupational exposure scenario exists for HOE-107892, a short- or intermediate-term aggregate risk assessment is not required.

#### V. Other Considerations

##### A. Metabolism In Plants and Animals

For purposes of the Section 18 use only, the nature of the residue for HOE-107892 in wheat is adequately understood. HOE-094270 was the major residue identified in grain, and HOE-094270 and HOE-113225 were the

major residues identified in straw. The residues of concern are HOE-107892 and its metabolites HOE-094270 and HOE-113225.

Because of the lack of quantifiable residues in wheat grain and straw, even at exaggerated treatment rates (up to 6.4x), and considering that this use is only for durum wheat, for purposes of this section 18 use only, the Agency will assume that there will be no quantifiable residues of the safener HOE-107892 or its metabolites in milk, meat, poultry or eggs resulting from this use.

The maximum theoretical concentration factors for wheat bran and shorts are 7.7 and 8.4x respectively. Because residues in wheat grain treated at the 6.4x rate were nondetectable (less than 0.01 ppm), for purposes of this section 18 use only, the Agency will assume that residues in processed wheat commodities will also be nondetectable (less than 0.01 ppm).

#### *B. Analytical Enforcement Methodology*

For purposes of this Section 18 use only, adequate enforcement methodology is available to quantify HOE-107892 and major metabolites in wheat grain and straw.

#### *C. Magnitude of Residues*

Combined residues of HOE-107892, HOE-094270 and HOE-113225 are not expected to exceed 0.01 ppm in wheat grain and 0.05 ppm in wheat straw as a result of this Section 18 use. Secondary residues of HOE-107892 are not expected in animal commodities associated with this Section 18 use.

#### *D. International Residue Limits*

Italy has established a maximum residue limit (MRL) of 0.05 ppm in or on wheat grain for residues of HOE-109782.

### **VI. Conclusion**

Therefore, tolerances are established for HOE-107892 (mefenpyr-diethyl) and its 2,4-dichlorophenyl-pyrazoline metabolites HOE-094270 and HOE-113225 in wheat grain and wheat straw at 0.01 and 0.05 ppm respectively.

### **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 October 7, 1997, file written objections to any aspect of this regulation and may also request a hearing on those objections. Objections and hearing requests must be filed with the Hearing Clerk, at the address given above (40 CFR 178.20). A copy of the objections and/or hearing requests filed with the Hearing Clerk should be submitted to the OPP docket for this rulemaking. The objections submitted must specify the provisions of the regulation deemed objectionable and the grounds for the objections (40 CFR 178.25). Each objection must be accompanied by the fee prescribed by 40 CFR 180.33(i). If a hearing is requested, the objections must include a statement of the factual issues on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the requestor (40 CFR 178.27). A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established, resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issues in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as Confidential Business Information (CBI). Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

### **VIII. Public Docket**

EPA has established a record for this rulemaking under docket control number [OPP-300517] (including any comments and data submitted electronically). A public version of this record, including printed, paper versions of electronic comments, which does not include any information claimed as CBI, is available for

inspection from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The public record is located in Room 1132 of the Public Information and Records Integrity Branch, Information Resources and Services Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA.

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

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

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

### **IX. Regulatory Assessment Requirements**

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

**X. Submission to Congress and the General Accounting Office**

Under 5 U.S.C. 801(a)(1)(A), as added by the Small Business Regulatory

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

**List of Subjects in 40 CFR Part 180**

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

Dated: July 24, 1997.

**James Jones,**

*Acting Director, Registration Division, Office of Pesticide Programs.*

Therefore, 40 CFR chapter I is amended as follows:

**PART 180—[AMENDED]**

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

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

2. Section 180.509 is added to read as follows :

**§ 180.509 HOE-107892 (mefenpyr-diethyl); tolerance for residues.**

(a) *General.* [Reserved]

(b) *Section 18 emergency exemptions.* Time-limited tolerances are established for residues of the herbicide safener HOE-107892 (mefenpyr-diethyl) and its 2,4-dichlorophenyl-pyrazoline metabolites HOE-094270 and HOE-113225 in connection with use of the herbicide safener under Section 18 emergency exemptions granted by the EPA. The tolerances will expire and are revoked on the dates specified in the following table:

Commodity	Parts per million	Expiration/revocation date
Wheat grain .....	0.01	August 1, 1998
Wheat straw .....	0.05	August 1, 1998

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

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

[FR Doc. 97-20844 Filed 8-7-97; 8:45 am]

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**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Part 180**

[OPP-300522 FRL-5732-9]

RIN 2070-AB78

**Myclobutanil; Pesticide Tolerances for Emergency Exemptions**

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes time-limited tolerances for combined residues of myclobutanil in or on tomatoes. 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 tomatoes. This regulation establishes a maximum permissible level for residues of myclobutanil 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 July 28, 1998.

**DATES:** This regulation is effective August 8, 1997. Objections and requests for hearings must be received by EPA on or before October 7, 1997.

**ADDRESSES:** Written objections and hearing requests, identified by the docket control number, [OPP-300522], 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-300522], must also be submitted to: Public Information and Records Integrity Branch, Information Resources and Services Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring a copy of objections and hearing

requests to Rm. 1132, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA.

A copy of objections and hearing requests filed with the Hearing Clerk may also be submitted electronically by sending electronic mail (e-mail) to: oppdocket@epamail.epa.gov. Copies of objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Copies of objections and hearing requests will also be accepted on disks in WordPerfect 5.1 file format or ASCII file format. All copies of objections and hearing requests in electronic form must be identified by the docket control number [OPP-300522]. 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: Andrew Ertman, 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) 308-9367, e-mail: ertman.andrew@epamail.epa.gov.