LOUISIANA—OZONE—Continued

Designated area	Designation		Classification	
	Date [1]	Type	Date	Type
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[1] This date is November 15, 1990, unless otherwise noted.

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 180 and 185

[OPP–300587; FRL–5754–5]

RIN 2070–AB78

Maleic hydrazide; Pesticide Tolerances for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes time-limited tolerances for residues of maleic hydrazide (1,2-dihydro-3,6-pyridazinedione) in or on rice commodities as well as tolerances for secondary residues in animal commodities. 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 rice in Louisiana. This regulation establishes a maximum permissible level for residues of maleic hydrazide in these food commodities 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 September 30, 1998.

DATES: This regulation is effective December 5, 1997. Objections and requests for hearings must be received by EPA on or before February 3, 1998.

ADDRESSES: Written objections and hearing requests, identified by the docket control number, [OPP–300587], 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–300587], 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–300587]. 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: Stephen Schaible, 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) 308–9362, e-mail: schaible.stephen@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: EPA, on its own initiative, pursuant to section 408(e) and (l)(6) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(e) and (l)(6), is establishing tolerances for residues of the herbicide maleic hydrazide (1,2-dihydro-3,6-pyridazinedione), in or on rice, grain at 105 part per million (ppm); rice, straw at 75 ppm; rice, hulls at 240 ppm; and rice, bran at 180 ppm. Additionally, the Agency is establishing tolerances for secondary residues in milk at 1.0 ppm; at 2.5 ppm in meat, 7 ppm in liver, 32 ppm in kidney, and 3 ppm in fat of cattle, goats, hogs, horses, and sheep; at 0.5 ppm in meat, liver, and fat of poultry; 1.4 ppm in poultry meat byproducts; and 0.5 ppm in eggs. These tolerances will expire and are revoked on September 30, 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 Maleic Hydrazide on Rice and FFDCA Tolerances

On June 19, 1997, the Louisiana Department of Agriculture and Forestry availed of itself the authority to declare the existence of a crisis situation within the State, thereby authorizing use under FIFRA section 18 of maleic hydrazide on rice to control red rice. Red rice is normally controlled by flood water management and rotating the rice crop to soybeans, where soybean herbicides are used that control red rice but are also phytotoxic to commercial rice. Over the last 5 years, farm land to be rotated into rice in 1997 has experienced three consecutive soybean seasons with poor control of red rice. This has resulted in increasing red rice infestations in the two intervening rice crop seasons, and a buildup of red rice seed in the soil. This situation gives rise to the possibility of an unprecedentedly high red rice infestation in 1997. Economic loss due to red rice occurs both through reductions in the yield of the rice crop and through reductions in the quality of the harvested crop. Because red rice and cultivated rice are closely related, there are few selective herbicides available; those that are have limited efficacy against red rice. The use of maleic hydrazide would not only increase yield and quality of the harvested crop this year, but would reduce red rice seed in the soil and therefore reduce the level of red rice infestation in the next rice crop. EPA has authorized under FIFRA section 18 the use of maleic hydrazide on rice for control of red rice in Louisiana. After having reviewed the submission, EPA concurs that emergency conditions exist for this State.

As part of its assessment of this emergency exemption, EPA assessed the potential risks presented by residues of maleic hydrazide in or on rice. In doing so, EPA considered the new safety standard in FFDCA section 408(b)(2), and EPA decided that the necessary tolerances 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 these tolerances without notice and opportunity for public comment under section 408(e), as provided in section 408(l)(6). Although these tolerances will expire and are revoked on September 30, 1998, under FFDCA section 408(l)(5), residues of the pesticide not in excess of the amounts specified in the tolerances remaining in or on rice grain, bran, hulls and straw or in meat, milk, poultry or eggs 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 these tolerances earlier if any experience with, scientific data on, or other relevant information on this pesticide indicate that the residues are not safe.

Because these tolerances are being approved under emergency conditions EPA has not made any decisions about whether maleic hydrazide meets EPA's registration requirements for use on rice 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 maleic hydrazide by a State for special local needs under FIFRA section 24(c). Nor do these tolerances serve as the basis for any State other than Louisiana 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 maleic hydrazide, 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 percent 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 hundredfold MOE is based on the same rationale as the hundredfold uncertainty factor.

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

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

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

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

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

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

B. Aggregate Exposure

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

Percent of crop treated estimates are derived from Federal and private market survey data. Typically, a range of estimates are supplied and the upper end of this range is assumed for the exposure assessment. By using this upper end estimate of percent of crop treated, the Agency is reasonably certain that exposure is not understated for any significant subpopulation group. Further, regional consumption information is taken into account through EPA's computer-based model for evaluating the exposure of significant subpopulations including several regional groups, to pesticide residues. For this pesticide, the most highly exposed population subgroup non-nursing infants less than 1 year 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 maleic hydrazide and to make a determination on aggregate exposure, consistent with section 408(b)(2), for time-limited tolerances for residues of maleic hydrazide (1,2-dihydro-3,6-pyridazinedione) on rice, grain at 105 ppm; rice, straw at 75 ppm; rice, hulls at 240 ppm; rice, bran at 180 ppm; time-limited tolerances are set at 2.5 ppm in meat, 7.0 ppm in liver, 32.0 ppm in kidney, and 3.0 ppm in fat of cattle, goats, hogs, horses, and sheep; 1.0 ppm in milk; 0.5 ppm in meat, liver, and fat of poultry; 1.4 ppm in poultry meat byproducts (except liver), and 0.5 ppm in eggs. 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 maleic hydrazide are discussed below.

1. *Acute toxicity*. The Agency has determined that an acute dietary risk assessment is not required for this chemical.

2. *Short - and intermediate - term toxicity.* Based on the available data base, the Agency has concluded that determination of short-term Margin of Exposure (MOE) calculations is not required. For intermediate-term MOE calculations, the Agency recommends use of the NOEL of 29 milligrams/kilogram/day (mg/kg/day) from the 1–year feeding study in dogs. Decreased weight gain and reduced heart weight are the effects observed at the Lowest Effect Level (LEL) of 87 mg/kg/day.

3. *Chronic toxicity*. EPA has established the RfD for maleic hydrazide at 0.25 mg/kg/day. This RfD is based on a NOEL of 25 mg/kg/day taken from a 2–year feeding study in rats in which decreased weight gain in males was the effect observed at the LEL of 500 mg/kg/day. An uncertainty factor of 100 was assigned to allow for inter- and intra-species variability.

4. *Carcinogenicity*. Maleic hydrazide has been classified as a Group E--evidence of non-carcinogenicity for humans in two species--chemical by the Agency. A carcinogenic risk assessment is not required.

B. Exposures and Risks

1. *From food and feed uses.* Tolerances have been established (40 CFR 180.175) for the residues of maleic hydrazide (1,2-dihydro-3,6-pyridazinedione), in or on dry bulb onions, potatoes and cranberries. Risk assessments were conducted by EPA to assess dietary exposures and risks from maleic hydrazide as follows:

i. *Acute exposure and risk.* Acute dietary risk assessments are performed for a food-use pesticide if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1 day or single exposure. The Agency has determined that this risk assessment is not required.

ii. *Chronic exposure and risk*. Refined residue and percent of crop treated information were used in the chronic exposure analysis to calculate the Anticipated Residue Contribution (ARC) from published and proposed uses of maleic hydrazide. The use of tolerance level residues for potatoes and dry bulb onions as well as the use of high end anticipated residues for animal commodities results in overestimation of chronic dietary risk.

2. *From drinking water.* Review of available data indicate that maleic hydrazide is neither mobile nor persistent. There is no established Maximum Contaminant Level for residues of maleic hydrazide in drinking water. Health advisory levels for maleic hydrazide in drinking water have been established at the following levels: for a 10 kg child, 10 mg/liter (1–day and 10–day levels) and 5 mg/liter (long term level); for a 70 kg adult, 20 mg/liter (long term level).

Chronic exposure and risk. Because the Agency lacks sufficient water-related exposure data to complete a comprehensive drinking water risk assessment for many pesticides, EPA has commenced and nearly completed a process to identify a reasonable yet conservative bounding figure for the potential contribution of water-related exposure to the aggregate risk posed by a pesticide. In developing the bounding figure, EPA estimated residue levels in water for a number of specific pesticides using various data sources. The Agency then applied the estimated residue levels, in conjunction with appropriate toxicological endpoints (RfD's or acute dietary NOEL's) and assumptions about body weight and consumption, to calculate, for each pesticide, the increment of aggregate risk contributed by consumption of contaminated water. While EPA has not yet pinpointed the appropriate bounding figure for exposure from contaminated water, the ranges the Agency is continuing to examine are all below the level that would cause maleic hydrazide 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 maleic hydrazide in water, even at the higher levels the Agency is considering as a conservative upper bound, would not prevent the Agency from determining that there is a reasonable certainty of no harm if the tolerance is granted.

3. *From non-dietary exposure.* Maleic hydrazide is currently registered for use on the following residential non-food sites: outdoor non-food sites such as non-bearing citrus and ornamentals.

i. *Chronic exposure and risk*. Based on the uses registered, a chronic, non-dietary exposure scenario is not expected.

ii. *Short- and intermediate-term exposure and risk*. Maleic hydrazide is currently registered for use on outdoor non-food sites such as non-bearing citrus, ornamental shade trees and plants, turf, lawns, utility and highway rights of way, industrial areas and airports. There are no indoor uses.

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).

Maleic hydrazide is a member of the hydrazide class of pesticides; another member of this class is Alar (daminozide). EPA does not have, at this time, available data to determine whether maleic hydrazide 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, maleic hydrazide 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 maleic hydrazide has a common mechanism of toxicity with other substances.

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

1. *Chronic risk.* Using the ARC exposure assumptions described in Unit IV.B. of this preamble, EPA has concluded that aggregate exposure to maleic hydrazide from food will utilize 14% of the RfD for the U.S. population. The major identifiable subgroup with the highest aggregate exposure is non-nursing infants less than 1 year old (discussed in Unit IV.E. of this preamble). 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 maleic hydrazide 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 maleic hydrazide residues.

2. *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. Data to quantify intermediate-term exposure from non-occupational, non-dietary uses are not available at this time. In the absence of a quantitative estimate of exposure, the Agency believes that the large MOEs calculated for mixers, loaders and applicators of the product (1,000 to 1,800, where 100 is considered to be the level at which the Agency has reasonable certainty of no harm resulting from occupational exposure to the chemical) demonstrate that intermediate aggregate risk from non-occupational uses of maleic hydrazide is below the Agency's level of concern.

D. Aggregate Cancer Risk for U.S. Population

Maleic hydrazide has been classified as a Group E chemical. A carcinogenic risk assessment is not required for this chemical.

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 maleic hydrazide, 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.

ii. *Developmental toxicity studies.* In the developmental toxicity study in rats, the maternal (systemic) NOEL was 1,600 mg/kg/day, the highest dose tested (HDT). The developmental NOEL was 1,200 mg/kg/day, based on minor skeletal variations at the LOEL of 1,600 mg/kg/day. In a second developmental toxicity study in rats, the maternal and developmental NOELs were greater than 1,000 mg/kg/day, the HDT. The Agency concluded that skeletal variations observed in the first study occurred at doses above 1 mg/kg/day, the limit dose, and therefore were of minimal concern. In the developmental toxicity study in rabbits, the maternal and developmental NOELs were 1,000 mg/kg/day, the HDT.

iii. *Reproductive toxicity study.* In the 2-generation reproductive toxicity study in rats, the maternal NOEL was 500 mg/kg/day, based on decreased body weight at the LOEL of 1,500 mg/kg/day. The reproductive/developmental NOEL was 500 mg/kg/day, based on post-natal decrease in body weight of pups during lactation at the LOEL of 1,500 mg/kg/day.

iv. *Pre- and post-natal sensitivity.* The toxicity data base for evaluating pre- and post-natal toxicity for maleic hydrazide 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.

v. *Conclusion.* Based on review of the required studies, EPA concludes that reliable data support use of the standard hundredfold MOE/uncertainty factor and that an additional margin/factor is not needed to protect infants and children.

2. *Chronic risk.* Using the conservative exposure assumptions described above, EPA has concluded that aggregate exposure to maleic hydrazide from food will utilize between 14 and 54% 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 maleic hydrazide 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 maleic hydrazide residues.

V. Other Considerations

A. Metabolism In Plants and Animals

The nature of the residue in plants is adequately understood. The residue of concern is maleic hydrazide (as specified in 40 CFR 180.175). The nature of the residue in animals is adequately understood for this section 18. The residue of concern is maleic hydrazide .

B. Analytical Enforcement Methodology

Adequate enforcement methodology (with spectrophotometric detection) for plants is available in PAM II to enforce the tolerance expression. An enforcement method has not been validated for animal commodities. However, a method for animal commodities is available, see Wood,

P.R., ''Determination of Maleic Hydrazide Residues in Plant and Animal Tissue,'' *Analytical Chemistry*, 25, 1879 (1953).

C. Magnitude of Residues

Residues of maleic hydrazide at a 14–day PHI are not expected to exceed 105.0 ppm on rice grain, 75.0 ppm on rice straw, 240.0 ppm on rice hulls, 180.0 ppm on rice bran, and 75.0 on the processed commodity polished rice as a result of this section 18 use. Time-limited tolerances should be established for rice grain, straw, bran, and hulls at these levels.

No tolerances on animal commodities have been established for maleic hydrazide. Secondary residues in animal commodities resulting from this use on rice and the registered use on potatoes are not expected to exceed 2.5 ppm in meat, 7.0 ppm in liver, 32.0 ppm in kidney, and 3.0 ppm in fat of cattle, goats, hogs, horses, and sheep; 1.0 ppm in milk; 0.5 ppm in meat, liver, and fat of poultry; 1.4 ppm in poultry meat byproducts (except liver), and 0.5 ppm in eggs.

D. International Residue Limits

There are currently no Codex, Canadian, or Mexican limits for residues of maleic hydrazide in or on rice or animal commodities. Therefore, establishment of time-limited tolerances will not pose a concern for international harmonization.

E. Rotational Crop Restrictions.

There are no rotational crop restrictions in the section 18 or Federal label.

VI. Conclusion

Therefore, tolerances are established for residues of maleic hydrazide (1,2-dihydro-3,6-pyridazinedione) in rice, grain at 105 ppm, rice, straw at 75 ppm, rice, hulls at 240 ppm, and rice, bran at 180 ppm. Additionally, tolerances are established for secondary residues of maleic hydrazide at 2.5 ppm in meat, 7 ppm in liver, 32 ppm in kidney, and 3 ppm in fat of cattle, goats, hogs, horses, and sheep; 1 ppm in milk; 0.5 ppm in meat, liver and fat of poultry; 1.4 ppm in poultry meat byproducts; and 0.5 ppm in eggs.

In addition because FQPA has eliminated the distinctions between tolerances for raw and processed food, OPP is transferring the food additive tolerances now found in § 185.3900 to § 180.175, and is removing § 185.3900.Therefore, to accomplish the transfer, and for the convenience of the user, OPP is revising § 180.175 in its entirety, although only paragraph (b) of § 180.175 is new.

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 3, 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 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 and Electronic Submissions

EPA has established a record for this rulemaking under docket control number [OPP–300587] (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 Highway, Arlington, VA.

Electronic comments may be sent directly to EPA at:

opp-docket@epamail.epa.gov.

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

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

IX. Regulatory Assessment Requirements

This action finalizes a tolerance requirement under FFDCA section 408(e). 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). In addition, 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 special 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, under the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 et seq.), the Agency previously assessed whether establishing tolerances, exemptions from tolerances, raising tolerance levels or expanding exemptions might adversely impact small entities and concluded, as a generic matter, that there is no adverse economic impact. The factual basis for the Agency's generic certification for tolerance actions published on May 4, 1981 (46 FR 24950), and was provided to the Chief Counsel for Advocacy of the Small Business Administration.

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

40 CFR Part 180

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

40 CFR Part 185

Environmental protection, Food additives, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: November 21, 1997.

Linda A. Travers,

Acting Director, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

1. In part 180:

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

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

ii. Section 180.175 is revised to read as follows:

§ 180.175 Maleic hydrazide; tolerances for residues.

(a) *General.* (1) Tolerances for residues of the herbicide and plant regulator maleic hydrazide (1,2-dihydro-3,6-pyridazinedione) are established in or on the following raw agricultural commodities:

Commodity	Parts per million
Onions, dry bulb	15.0
Potatoes	50.0

(2) A food additive known as maleic hydrazide (1,2-dihydro-3,6-pyridazinedione) may be present in potato chips when used in accordance with the following conditions:

(i) The food additive is present as a result of the application of a pesticide formulation containing maleic hydrazide to the growing potato plant in accordance with directions registered by the U.S. Environmental Protection Agency.

(ii) The label of the pesticide formulation containing the food additive conforms to labeling registered by the U.S. Environmental Protection Agency.

(iii) The food additive is present in an amount not to exceed 160 parts per million by weight of the finished food.

(b) *Section 18 emergency exemptions.* Time-limited tolerances are established for residues of the herbicide maleic hydrazide (1,2-dihydro-3,6-pyridazinedione) in connection with use of the pesticide under 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
Cattle, fat	3	9/30/98
Cattle, liver	7	9/30/98
Cattle, kidney	32	9/30/98
Cattle, meat	2.5	9/30/98
Eggs	0.5	9/30/98
Goats, fat	3	9/30/98
Goats, liver	7	9/30/98
Goats, kidney	32	9/30/98
Goats, meat	2.5	9/30/98
Hogs, fat	3	9/30/98
Hogs, liver	7	9/30/98
Hogs, kidney	32	9/30/98
Hogs, meat	2.5	9/30/98
Horses, fat	3	9/30/98
Horses, liver	7	9/30/98
Horses, kidney	32	9/30/98
Horses, meat	2.5	9/30/98
Milk	1	9/30/98
Poultry, fat	0.5	9/30/98
Poultry, liver	0.5	9/30/98
Poultry, meat	0.5	9/30/98
Poultry, meat byproducts (except liver)	1.4	9/30/98
Rice, bran	180	9/30/98
Rice, grain	105	9/30/98
Rice, hulls	240	9/30/98
Rice, straw	75	9/30/98
Sheep, fat	3	9/30/98

Commodity	Parts per million	Expiration/Revocation Date
Sheep, liver	7	9/30/98
Sheep, kidney	32	9/30/98
Sheep, meat	2.5	9/30/98

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

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

PART 185—[Amended]

2. In part 185:

i. The authority citation for part 185 continues to read as follows:

Authority: 21 U.S.C. 348.

§ 185.3900 [Removed]

ii. Section 185.3900 is removed.

[FR Doc. 97–31553 Filed 12–4–97; 8:45 am]

BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300586; FRL–5756–5]

RIN 2070–AB78

Fluorine Compounds; Time-Limited Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a time-limited tolerance for residues of the insecticidal fluorine compounds cryolite and/or synthetic cryolite (sodium aluminum fluoride) in or on the raw agricultural commodity (RAC) potatoes and in the processed animal feed commodity, potato waste. A petition requesting these tolerances was submitted by The Cryolite Task Force under the Federal Food Drug and Cosmetic Act (FFDCA) as amended by the Food Quality Protection Act of 1996 (Pub. L. 104–170). The tolerance will expire on November 21, 2001.

DATES: This regulation is effective December 5, 1997. Objections and requests for hearings must be received by EPA on or before February 3, 1998.

ADDRESSES: Written objections and hearing requests, identified by the document control number, OPP–300586, 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 document control number, [OPP–300586], must 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, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA 22202.

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 number [OPP–300586]. 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: Jacqueline Mosby, Environmental Scientist, 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) 305-6792, e-mail: mosby-romney.jackie2epamail.epa.gov.

SUPPLEMENTARY INFORMATION: EPA issued notices as follows regarding petitions for pesticide tolerances for insecticidal fluorine compounds in or on potatoes and in the processed animal feed, potato waste.

1. March 23, 1989 (54 FR 12009); PP 9F3739; filing notice;

2. April 3, 1991 (56 FR 13643); PP 1F3959 and FAP 1H5604; filing notice.

3. May 5, 1993 (58 FR 26687); PP 9F3739 and FAP 1H5604; final rule for time-limited tolerances.

4. May 8, 1996 (61 FR 20781) (FRL–5362–6); PP 9F3739 and FAP 1H5604); proposed rule for permanent tolerances.

The Agency did not publish a final rule establishing permanent tolerances prior to the enactment of the Food Quality and Protection Act (FQPA) of 1996. Because of new procedures under FQPA, The Cryolite Task Force, c/o Gowan Company, P.O. Box 5569, Yuma, AZ 85336 was required to submit a notice of filing requesting issuance of these tolerances in compliance with FQPA.

In the **Federal Register** of March 12, 1997 (62 FR 11437) EPA issued a notice of filing pursuant to section 408 of the Federal Food, Drug and Cosmetic Act (FFDCA), 21 U.S.C. 346a(e) announcing the filing of a pesticide petition (PP) for tolerance by The Cryolite Task Force. This notice contained a summary of the petition prepared by The Cryolite Task Force.

The petition requested that 40 CFR 180.145 be amended by establishing tolerances for residues of the insecticidal fluorine compounds cryolite and synthetic cryolite in or on potatoes at 2.0 parts per million (ppm) and processed potato waste at 22.0 ppm. These tolerances will expire on November 21, 2001.

I. Risk Assessment and Statutory Findings

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