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

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

X. Submission to Congress and the General Accounting Office

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

List of Subjects in 40 CFR Part 180

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

Dated: August 26, 1997.

Peter Caulkins,

Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

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

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

2. In § 180.442, by alphabetically inserting the following item into the table in paragraph (b) to read as follows:

§ 180.442 Bifenthrin; tolerances for residues.

* * * * *

(b) * * *

Commodity	Parts per million	Expiration/Revocation Date
Canola, Seed	0.5	9/30/98
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[FR Doc. 97–23720 Filed 9–4–97; 8:45 am]

BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 180 and 186

[OPP–300536; FRL–5738–9]

RIN 2070–AB78

2,4–D; Pesticide Tolerances for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a time-limited tolerance for 2,4-dichlorophenoxyacetic acid (2,4-D) in or on wild rice. 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 wild rice. This regulation establishes a maximum permissible level for residues of 2,4-D in this food

commodity pursuant to section 408(l)(6) of the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996. The tolerance will expire and is revoked on August 31, 1998.

DATES: This regulation is effective September 5, 1997. Objections and requests for hearings must be received by EPA on or before November 4, 1997.

ADDRESSES: Written objections and hearing requests, identified by the docket control number, [OPP–300536], 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–300536], 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–300536]. No Confidential Business Information (CBI) should be submitted through e-mail. Electronic copies of objections and hearing requests on this rule may be filed online at many Federal Depository Libraries.

FOR FURTHER INFORMATION CONTACT: By mail: Daniel Rosenblatt, Registration Division 7505C, Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail address: Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, (703) 308–9375, e-mail: rosenblatt.dan@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: EPA, on its own initiative, pursuant to section 408(e) and (l)(6) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(e) and (l)(6), is establishing a tolerance for residues of the herbicide 2,4-dichlorophenoxyacetic acid, in or on wild rice at 0.1 parts per million (ppm). This tolerance will expire and is revoked on August 31, 1998. EPA will publish a document in the **Federal Register** to remove the revoked tolerance from the Code of Federal Regulations.

I. Background and Statutory Authority

The Food Quality Protection Act of 1996 (FQPA) (Pub. L. 104–170) was signed into law August 3, 1996. FQPA amends both the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 301 *et seq*., and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. 136 *et seq* . The FQPA amendments went into effect immediately. Among other things, FQPA amends FFDCA to bring all EPA pesticide tolerance-setting activities under a new section 408 with a new safety standard and new procedures. These activities are described below and discussed in greater detail in the final rule establishing the time-limited tolerance associated with the emergency 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 2,4-D on Wild Rice and FFDCA Tolerances

The cultivation of wild rice involves flooding fields. Common waterplantain (*Alisma plantage-aquatica*) is an aquatic plant pest that has established itself in areas where wild rice is produced. There are no herbicides registered for use on wild rice. An analysis submitted in support of the FIFRA section 18 exemption for this use suggests that common waterplantain will reduce yields in Minnesota by approximately 50% in certain areas. EPA considers that this loss lies outside the range of normal profitability fluctuation. Such loss would, therefore, represent a significant economic loss for growers. Therefore, EPA has authorized under FIFRA section 18 the use of 2,4-D on wild rice for control of common waterplantain in Minnesota. 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 2,4-D in or on wild rice. 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 31,

1998, under FFDCA section 408(l)(5), residues of the pesticide not in excess of the amounts specified in the tolerance remaining in or on wild rice 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 2,4-D meets EPA's registration requirements for use on wild rice or whether a permanent tolerance for this use would be appropriate. Under these circumstances, EPA does not believe that this tolerance serves as a basis for registration of 2,4-D by a State for special local needs under FIFRA section 24(c). Nor does this tolerance serve as the basis for any State other than Minnesota 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 2,4-D, contact the Agency's Registration Division at the address provided above.

III. Risk Assessment and Statutory Findings

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

A. Toxicity

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

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

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

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

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

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

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

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

B. Aggregate Exposure

In examining aggregate exposure, FFDCA section 408 requires that EPA take into account available and reliable

information concerning exposure from the pesticide residue in the food in question, residues in other foods for which there are tolerances, residues in 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 (infants less than a year old) was not regionally based.

IV. Aggregate Risk Assessment and Determination of Safety

Consistent with section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action, EPA has sufficient data to assess the hazards of 2,4-D and to make a determination on aggregate exposure, consistent with section 408(b)(2), for a time-limited tolerance for residues of 2,4-dichlorophenoxyacetic acid on wild rice at 0.1 ppm. EPA's assessment of the dietary exposures and risks associated with establishing the tolerance follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. The nature of the toxic effects caused by 2,4-D are discussed below.

1. *Acute toxicity*. For the purpose of the acute dietary risk assessment, EPA recommends use of a NOEL of 67 mg/kg/day from the rat acute neurotoxicity study. The effects observed at the LOEL of 227 mg/kg/day were increased incidence of incoordination, slight gait abnormalities, and decreased motor activity. As neurotoxicity is the effect of concern, this risk assessment will evaluate acute dietary risk to all population subgroups.

2. *Short - and intermediate - term toxicity.* For short-term MOE calculations, EPA supports use of the maternal NOEL of 30 mg/kg/day from the oral developmental toxicity study in rabbits. The Lowest Effect Level (LEL) was 90 mg/kg/day, based on abortions, ataxia, decreased motor activity, cold extremities during gestation, and decreased weight gain. For intermediate-term dermal MOE calculations, EPA recommended use of the NOEL of 1.0 mg/kg/day from the 90–day oral toxicity study in dogs. The LEL of 3 mg/kg/day was based on clinical chemistry changes and lesions in the kidneys. For short- and intermediate-term inhalation risk, EPA concludes that exposure by the inhalation route was of no concern and that this risk assessment was not required for any exposure duration.

3. *Chronic toxicity*. EPA has established the RfD for 2,4-D at 0.01 milligrams/kilogram/day (mg/kg/day). This RfD is based on a 1–year oral toxicity study in dogs with a NOEL of 1 mg/kg/day and an uncertainty factor of 100. The LEL of 5 mg/kg/day was based on alterations in serum chemistry with corroborative histopathological lesions in the liver and kidneys.

4. *Carcinogenicity*. EPA's Cancer Peer Review Committee has classified 2,4-D as a Group D chemical (''not classifiable as to human carcinogenicity'') on the basis that, ''the evidence is inadequate and cannot be interpreted as showing either the presence or absence of a carcinogenic effect.''

B. Exposures and Risks

1. *From food and feed uses.* Tolerances have been established (40 CFR 180.142) for residues of 2,4-D as the acid or various of its salts and esters, in or on a variety of raw agricultural commodities, including rice. In addition, there are also tolerances for 2,4-D for meat, milk, and eggs. Risk assessments were conducted by EPA to assess dietary exposures and risks from 2,4-D 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. Wild rice is not uniquely identified in the system which the Agency uses to calculate acute and chronic dietary risk. Therefore, the Agency must estimate the additional exposure to 2,4-D associated with this use. Based on the proposed tolerance level and the probable low average consumption of this commodity, the Agency believes it is likely that any incremental increase in acute dietary risk would be negligible. In addressing this area, the Agency assessed the potential acute dietary exposure from 2,4-D based on all of the chemical's existing tolerances and uses. For this analysis, EPA assumed tolerance level residues and 100% crop-treated. MOEs were calculated for all population subgroups. MOEs ranged from 112 for infants (less than 1 year old) to 558 for males and females 13 years and older. Although these MOEs do not represent a level of concern to EPA, if the analysis were to incorporate anticipated residue levels and actual percent crop-treated, the MOEs would be even larger. Therefore, this assessment should be viewed as conservative.

ii. *Chronic exposure and risk.* As mentioned above, wild rice is not a commodity that is uniquely identified in the Agency's current food consumption data system. However, EPA has estimated that the incremental chronic dietary risk from this Section 18 use of 2,4-D on wild rice adds less than 1 percent to the RfD values for this chemical. For the purpose of assessing potential chronic dietary exposure from 2,4-D, EPA assumed Anticipated Residue Contributions (ARCs) for major identifiable subgroups of consumers, including infants and children, from the

existing uses of 2,4-D. The RfD values range from 58% for non-nursing infants less than 1 year old to 31% for the U.S. population (48 states).

2. *From drinking water.* In examining aggregate exposure, FQPA directs EPA to consider available information concerning exposures from the pesticide residues in food and all other non-occupational exposures. The primary non-food sources of exposure the Agency looks at include drinking water (whether from ground or surface water), and exposure through pesticide use in gardens, lawns, or buildings (residential and other indoor uses). Based on data available to EPA, 2,4-D is soluble in water. The average field half-life is 10 days. The chemical is potentially mobile, but rapid degradation in soil and removal by plant uptake minimizes leaching. A Maximum Contaminant Level (MCL) of 0.07 mg/L has been established. In addition, the following Health Advisories (HAs) have been established: for a 10-kg child, a range of 1 mg/L from 1–day exposure to 0.1 mg/L for longer-term exposure up to 7 years; for a 70 kg adult, a range of 0.4 mg/L for longer-term exposure to 0.07 mg/L for lifetime exposure.

i. *Acute exposure and risk.* EPA developed acute exposure levels for adults and children assuming the high end residue value of 57.1 micrograms/L in drinking water. Adult exposure was calculated to be 1.6×10^{-3} mg/kg/day. Child exposure was calculated to be 5.7×10^{-3} mg/kg/day. The child exposure calculations assumed a body weight of 10 kg and all the drinking water consumed in the United States was assumed to contain the high end level of residues (57 micrograms/L). The assessment is quite conservative since only just over 2% of all wells monitored from 1979-1991 contained detectable residues of 2,4-D. The adult calculations assumed a body weight of 70 kg and the high end of residue (57 micrograms/L). The acute NOEL for 2,4-D is 67 mg/kg/day. The acute MOE is thus calculated to be 42,000 for adults and 12,000 for children.

ii. *Chronic exposure and risk.* The RfD for 2,4-D is 0.01 mg/kg/day. Thus, the levels of adult and child exposure correspond to a chronic dietary (water only) exposure of 16% of the RfD for adults and 57% of the RfD for children.

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 2,4-D 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 2,4-D 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.* 2,4-D is currently registered for use on the following residential non-food sites: ornamental turf, lawns, and grasses, golf course turf, recreational areas, and several other indoor and outdoor uses. This herbicide is widely used. By volume, 2,4-D is among the top pesticides used in non-agricultural settings. EPA does not have data on hand upon which to base calculation of non-dietary exposure of 2,4-D for purposes of inclusion in an aggregate risk assessment. However, there are several characteristics of 2,4-D which suggest the chemical presents a low risk from non-dietary, non-occupational exposure, particularly the chemical's high acute toxicity NOEL, the short half life in soil, low dermal penetration and high acute dietary MOE. Further, EPA has concluded that for the purposes of short- and intermediate-term risk, the inhalation route was of no health concern.

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

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

EPA does not have, at this time, available data to determine whether 2,4-D 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, 2,4-D 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 2,4-D has a common mechanism of toxicity with other substances.

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

1. *Acute risk.* EPA calculates acute aggregate risks by taking into account MOEs from food and MOEs from water. As described above in this document,

for the subgroup U.S. population the MOE for food is 223, the MOE for water is 42,000. Taken together, the aggregate MOE is 222. This figure does not exceed the Agency's level of concern for acute dietary exposure.

2. *Chronic risk.* Using the ARC exposure assumptions described above, EPA has concluded that aggregate exposure to 2,4-D from food and water will utilize 47% of the RfD for the U.S. population. The major identifiable subgroup with the highest aggregate exposure is infants and children. See below for a discussion of the analysis of the risks for that subgroup. 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 2,4-D 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 2,4-D residues.

D. Aggregate Risks and Determination of Safety for Infants and Children

1. *Safety factor for infants and children.* i. In assessing the potential for additional sensitivity of infants and children to residues of 2,4-D, 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 maternal pesticide exposure during gestation. Reproduction studies provide information relating to effects from exposure to the pesticide on the reproductive capability of mating animals and data on systemic toxicity.

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

ii. *Developmental toxicity studies.* In the rat developmental toxicity analysis, the maternal NOEL was greater than 75 mg/kg/day at the highest dose tested (HDT). The developmental (fetal) NOEL was 25 mg/kg/day, based on delayed ossification at the developmental LOEL of 75 mg/kg/day. In the rabbit developmental toxicity study, the maternal NOEL was 30 mg/kg/day, based on ataxia, decreased motor activity, cold extremities, and decreased body weight gain at the LOEL of 90 mg/kg/day. The developmental (fetal) NOEL was 90 mg/kg/day.

iii. *Reproductive toxicity study.* In the 2-generation reproductive toxicity study in rats, the parental (systemic) NOEL of 5 mg/kg/day was based on degenerative effects in the kidneys of males and decreased body weight gain in females at the LOEL of 20 mg/kg/day. The reproductive (pup) NOEL was 5 mg/kg/day, based on decreased pup weight at the LEL of 20 mg/kg/day. The reproductive effects occurred in the presence of parental toxicity.

iv. *Pre- and post-natal sensitivity.* The pre and post-natal toxicology data base for 2,4-D is complete with respect to current data requirements. In the developmental toxicity study in rats, evidence of toxicity occurred in developing fetuses (NOEL of 25 mg/kg/day) in the absence of maternal toxicity. This finding suggests that extra pre-natal sensitivity may be present in rat fetuses exposed to 2,4-D in the absence of maternal toxicity. However, the results from the developmental toxicity study in rabbits demonstrate that maternal toxicity occurred (NOEL of 30 mg/kg/day) in the absence of developmental toxicity (NOEL of 90 mg/kg/day), thus suggesting no extra pre-natal sensitivity. Since the developmental NOELs for rats (25-fold) and rabbits (90-fold) are greater than the RfD NOEL of 1 mg/kg/day from the 1–year oral toxicity study in dogs, an additional uncertainty factor to protect infants and children is not warranted.

v. *Conclusion.* Based on the reproductive toxicity study in rats discussed above, there does not appear to be an increased sensitivity for pre- and post-natal effects. Based on these findings, EPA concludes that reliable data support use of the standard 100-fold margin of exposure/uncertainty factor and that an additional margin/ factor is not needed for 2,4-D to protect the safety of infants and children.

2. *Acute risk.* EPA has determined aggregate MOE calculations which incorporate exposure to 2,4-D from food and water. The aggregate MOEs for 2,4-D are: 111 for infants less than a year old, 147 for children 1-6 years old, and 556 for females 13 and older. These MOEs do not exceed EPA's level of concern. Further, they were prepared using conservative risk estimates; data refinement would result in lower acute aggregate exposure estimates. Therefore, EPA concludes that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to 2,4-D residues.

3. *Chronic risk.* Using the conservative exposure assumptions described above, EPA has concluded that aggregate exposure to 2,4-D from food and water will utilize 87% of the RfD for nursing infants, 115% for non-nursing infants, 114% for children 1-6 years old, and 100% for children 7-12 years old. EPA notes that the food exposure estimate is partially refined while the water estimate is quite conservative. Further refinement using additional anticipated residue values in crops and percent crop-treated information, and well water monitoring data would result in lower chronic dietary (food) and chronic dietary (water) exposure estimates, thus reducing the aggregate risk estimate. Given these factors, along with the completeness and reliability of the toxicity data, EPA concludes that there is a reasonable certainty that no harm will result to infants and children from aggregate chronic exposure to 2,4-D residues.

V. Other Considerations

A. Metabolism in Plants and Animals

The nature of the residue of 2,4-D is adequately understood. The regulable residue is 2,4-D per se, as established in 40 CFR 180.142. No livestock feed issues are raised by this action.

B. Analytical Enforcement Methodology

EN-CAS Method ENC-2/93 is available to enforce this time-limited tolerance on wild rice.

C. Magnitude of Residues

Adequate residue data are available to support a time-limited tolerance for residues of 2,4-D in/on wild rice at 0.1 ppm. Wild rice hulls, obtained from processing, have no recognized food or feed use. Secondary residues are not expected in meat, milk, poultry, or eggs from this use since no feed items are associated with wild rice. Further, the

label restricts against use of treated water to irrigate other crops or to water livestock.

D. International Residue Limits

There are no Codex, Canadian, or Mexican maximum residue limits (MRLs) for use of 2,4-D on wild rice. Therefore, international harmonization is not an issue for this commodity. There is a Codex MRL of 0.05 ppm for 2,4-D on rice, a Mexican MRL of 0.1 ppm for 2,4-D on rice; and a Canadian MRL of 0.1 ppm for 2,4-D on cereal grains.

VI. Conclusion

Therefore, the time limited tolerance is established for residues of 2,4-dichlorophenoxyacetic acid in wild rice at 0.1 ppm. Since the FQPA has eliminated the distinctions between processed food, feed, and raw agricultural commodities, the tolerance in § 186.1450 is being renumbered and transfered to § 180.142(a)(12). Therefore, § 186.1450 is being removed.

VII. Objections and Hearing Requests

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

Any person may, by November 4, 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 Record

EPA has established a record for this rulemaking under docket control number [OPP–300536] (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 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 final rule establishes a time-limited tolerance under FFDCA section 408(d). The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled Regulatory Planning and Review (58 FR 51735, October 4, 1993). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Pub. L. 104–4). Nor does it require any prior consultation as specified by Executive Order 12875, entitled Enhancing the Intergovernmental Partnership (58 FR 58093, October 28, 1993), or special considerations as required by Executive Order 12898, entitled Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations (59 FR 7629, February 16, 1994), or require OMB review in accordance with Executive Order 13045, entitled Protection of Children from Environmental Health Risks and Safety Risks (62 FR 19885, April 23, 1997).

In addition, since these tolerances and exemptions that are established on the basis of a petition under FFDCA section 408 (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 Parts 180 and 186

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

Dated: August 25, 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 180.142 is amended as follows:

i. By adding a heading to paragraph (a), by redesignating paragraphs (a)(1) and (a)(2) as paragraphs (a)(1)(i) and (a)(1)(ii), respectively, by designating the introductory text of paragraph (a) as paragraph (a)(1), and by adding new paragraph (a)(12).

ii. By redesignating the introductory text of paragraph (b) as the introductory text of paragraph (a)(2), and paragraphs (b)(1), (b)(1)(i), (b)(1)(ii), and (b)(2) as paragraphs (a)(2)(i), (a)(2)(i)(A), (a)(2)(i)(B), and (a)(2)(ii), respectively.

iii. By redesignating paragraphs (c) through (k) as paragraphs (a)(3) through (a)(11), respectively.

iv. By adding a new paragraph (b).

v. By adding and reserving paragraphs (c) and (d) with headings.

§ 180.142 2,4-D; tolerances for residues.

(a) *General.* * * *

(12) The following tolerances are established for residues of 2,4-D (2,4-dichloro-phenoxyacetic acid) in the following processed feeds. Such residues may be present therein only as a result of application to the growing crop of the herbicides identified in this section:

(i) 5 parts per million in sugarcane bagasse and sugarcane molasses.

(ii) 2 parts per million in the milled fractions derived from barley, oats, rye, and wheat to be ingested as animal feed or converted into animal feed.

(b) *Section 18 emergency exemptions.* A time-limited tolerance is established for 2,4-dichlorophenoxyacetic acid (2,4-D) in or on wild rice in connection with use of the pesticide under a section 18 emergency exemption granted by EPA. The tolerance will expire on the dates specified in the following table.

Commodity	Parts per million	Expiration/Revocation Date
Wild rice	0.1 ppm	August 31, 1998

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

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

2. In part 186:

a. The authority citation for part 186 continues to read as follows:

Authority: 21 U.S.C. 342, 348, and 701.

§ 186.1450 [Removed]

b. Section 186.1450 is removed.

[FR Doc. 97–23684 Filed 9–4–97; 8:45 am]
BILLING CODE 6560–50–F

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

49 CFR Part 571

[Docket No. 85–6; Notice 12]

RIN 2127–AG05

Federal Motor Vehicle Safety Standards; Hydraulic Brake Systems; Passenger Car Brake Systems

AGENCY: National Highway Traffic Safety Administration (NHTSA), Department of Transportation.

ACTION: Final rule.

SUMMARY: This document amends Federal Motor Vehicle Safety Standards Nos. 105 *Hydraulic Brake Systems* and 135 *Passenger Car Brake Systems* to accommodate the brake systems on electric vehicles. The amendments address unique characteristics of brake systems on electric vehicles, such as regenerative braking, and are intended to assure safe performance for those brake systems. The amendments of Standard No. 105 apply to electric trucks, buses, and multipurpose passenger vehicles. They also apply to electric passenger cars that have not availed themselves of the option of conforming to Standard No. 135, which is mandatory for all passenger cars manufactured on and after September 1, 2000. The amendments to Standard No. 135 complement those made to Standard No. 105.

DATES: The amendments to both standards are effective October 20, 1997. Compliance with Standard No. 105 is mandatory as of September 1, 1998.

Compliance with Standard No. 135 is mandatory as of September 1, 2000, the effective date of Standard No. 135. Petitions for reconsideration of the final rule must be submitted not later than October 20, 1997.

ADDRESS: Petitions for reconsideration should be addressed to Docket 85–6; Notice 12, and submitted to Docket Room, NHTSA, Room 5108, 400 Seventh St. SW, Washington, DC 20590.

FOR FURTHER INFORMATION CONTACT: Samuel Daniel, Vehicle Dynamics Division, Office of Vehicle Safety Standards, NHTSA (Phone: 202–366–4921).

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