DEPARTMENT OF LABOR

Occupational Safety and Health Administration

29 CFR Part 1904

Recording and Reporting Occupational Injuries and Illnesses; Office of Management and Budget Control Numbers Under the Paperwork Reduction Act

AGENCY: Occupational Safety and Health Administration, Department of Labor.

ACTION: Final rule.

SUMMARY: The Occupational Safety and Health Administration (OSHA) is adding a new section to its regulation for recording and reporting of occupational injuries and illnesses (29 CFR part 1904). The new section will be used to consolidate and display all of the control numbers assigned by the Office of Management and Budget (OMB) for ''approved'' information collection requirements in Part 1904. None of the requirements are new; they have been promulgated by OSHA at various times over the past 25 years. The display of OMB control numbers is required under the implementing rules and regulations of OMB and under the Paperwork Reduction Act of 1995

DATE: Effective August 22, 1997.

FOR FURTHER INFORMATION CONTACT: Mr. Stephen A. Newell, Office of Statistics, U.S. Department of Labor, Occupational Safety and Health Administration, Room N3507; 200 Constitution Avenue, NW, Washington, DC 20210 (202–219–6463, FAX 202–219–5161).

SUPPLEMENTARY INFORMATION:

I. Background

OSHA has a number of provisions within its regulation for recording and reporting occupational injuries, illnesses and deaths that require employers to collect or prepare information. These types of provisions are broadly classified as ''information collection requirements.'' All information collection requirements are subject to review and approval by OMB on not more than a three-year cycle. It should be noted that OHSA cannot impose a penalty on employers for violating collection of information (recordkeeping, reporting, etc.) requirements if the agency has failed to obtain OMB approval of the requirement. When OMB approves collection of information requirements, it issues a ''control number'' for the collection of information provision. All agencies are required to display [show to the public] the OMB control numbers so the public will know that OMB has given the agency approval to require the information [report, record, documentation, form, etc.] to be collected. In the past, OSHA has displayed the relevant OMB control numbers of the injury and illness recordkeeping requirements by printing them at the end of each section in part 1904 to which they were pertained. However, to enable the public to easily and readily identify all of the collection of information requirements, OSHA is dedicating one section in part 1904 (1904.30) to list the sections with information collection requirements and show the appropriate OMB control numbers. As a result of this new format, the parenthetical notes and approval/control numbers now printed at the end of the individual sections of Part 1904 can be removed.

None of the specific requirements to collect and provide information is new. The control numbers listed in this document were assigned previously by OMB; but not necessarily published in the regulations. This document makes no substantive change to the current OMB information collection budget or to any regulatory provision.

II. Exemption From Notice and Comment Procedures

This action is a rule of agency procedure and practice and is not subject to the rulemaking requirements of the Administrative Procedures Act. 5 U.S.C. § 553(b)(A). It does not affect the substantive requirements or coverage of the regulations themselves. Furthermore, this document does not modify or revoke existing rights or obligations, nor does it establish new ones. With this action, the Agency is only providing information. OSHA, therefore, finds that notice and public procedure are impracticable and unnecessary within the meaning of 5 U.S.C. 553(b)(3)(B).

III. Exemption From Delayed Effective Date Requirement

Under 5 U.S.C. 553, OSHA finds that there is good cause for making this Document effective upon publication in the **Federal Register.** This display of control numbers simply provides additional information on the existing regulatory burden without increasing that burden.

List of Subjects in 29 CFR Part 1904

Reporting and recordkeeping requirements.

Accordingly, pursuant to sections 8 and 24 of the Occupational Safety and Health Act of 1970 (29 U.S.C. 657, 673), Secretary of Labor's Order No. 1–90 (55 FR 9033), and 5 U.S.C. 553, 29 CFR Part 1904 is hereby amended as set forth below.

Signed in Washington, D.C., this 5th day of August, 1997.

Gregory R. Watchman,

Acting Assistant Secretary of Labor.

PART 1904—[AMENDED]

1. The authority citation for Part 1904 continues to read as follows:

Authority: Secs. 8, 24, Occupational Safety and Health Act of 1970 (29 U.S.C. 657, 673), Secretary of Labor's Order No. 12–71 (36 FR 8754), 8–76 (41 FR 25059), 9–83 (48 FR 35736), 1–90 (55 FR 9033) or 6–96 (62 FR 111), as applicable.

Section 1904.7, 1904.8 and 1904.17 are also issued under 5 U.S.C. 553.

2. Section 1904.30 is added to read as follows:

§ 1904.30 OMB control numbers under the Paperwork Reduction Act

The following sections each contain a collection of information requirement which has been approved by the Office of Management and Budget under the control number listed.

29 CFR citation	OMB control No.
1904.2	1218–0176
1904.4–7	1218–0176
1904.8	1218–0007
1904.17	1218–0214
1904.21	1220–0045

3. Remove the parenthetical note relating to the OMB control number that appears at the end of each of the following sections: 1904.2; 1904.4; 1904.5; 1904.6; 1904.15; 1904.21.

[FR Doc. 97–22380 Filed 8–21–97; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300527; FRL–5736–9]

RIN 2070–AB78

Pyridate; Pesticide Tolerances for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a time-limited tolerance for combined residues of pyridate in or on chickpeas . 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 chickpeas. This regulation establishes a maximum permissible level for residues of pyridate in this food commodity pursuant to section 408(l)(6) of the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996. The tolerance will expire and is revoked on December 31, 1998.

DATES: This regulation is effective August 22, 1997. Objections and requests for hearings must be received by EPA on or before October 21, 1997.

ADDRESSES: Written objections and hearing requests, identified by the docket control number, [OPP–300527], 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–300527], 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–300527]. No Confidential Business Information (CBI) should be submitted through e-mail. Electronic copies of objections and hearing requests on this rule may be filed online at many Federal Depository Libraries.

FOR FURTHER INFORMATION CONTACT: By mail: Andrew Ertman, Registration Division 7505C, Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail address: Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, (703) 308-9367, e-mail: ertman.andrew@epamail.epa.gov.

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 combined residues of the herbicide pyridate (*O*- (6-chloro-3-phenyl-4-pyridazinyl)-*S*-octyl-carbonothioate), the metabolite 6-chloro-3-phenyl-pyridazine-4-ol and conjugates of 6-chloro-3-phenyl-pyridazine-ol, expressed as pyridate, in or on chickpeas at 0.1 part per million (ppm). This tolerance will expire and is revoked on December 31, 1998. EPA will publish a document in the **Federal Register** to remove the revoked tolerance from the Code of Federal Regulations.

I. Background and Statutory Authority

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

New section 408(b)(2)(A)(i) of the FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is ''safe.'' Section 408(b)(2)(A)(ii) defines ''safe'' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue. . . .''

Section 18 of FIFRA authorizes EPA to exempt any Federal or State agency from any provision of FIFRA, if EPA determines that ''emergency conditions exist which require such exemption.'' This provision was not amended by FQPA. EPA has established regulations governing such emergency exemptions in 40 CFR part 166.

Section 408(l)(6) of the FFDCA requires EPA to establish a time-limited tolerance or exemption from the requirement for a tolerance for pesticide chemical residues in food that will result from the use of a pesticide under an emergency exemption granted by EPA under section 18 of FIFRA. Such tolerances can be established without providing notice or period for public comment.

Because decisions on section 18-related tolerances must proceed before EPA reaches closure on several policy issues relating to interpretation and implementation of the FQPA, EPA does not intend for its actions on such tolerance to set binding precedents for the application of section 408 and the new safety standard to other tolerances and exemptions.

II. Emergency Exemption for Pyridate on Chickpeas and FFDCA Tolerances

The applicants state that chickpea growers in the irrigated region of central Washington and north-central Oregon face an immediate crisis with broadleaf weeds infesting their chickpea crop. The problem occurred when there was a period of unusually cool, wet weather after planting in late March to mid-April, causing a delay in both crop and weed emergence. This delay, coupled with the breakdown in the pre-emergence herbicide used, created a condition where broadleaf weeds were competing on an equal basis with the chickpea crop. Chickpeas are poor competitors with broadleaf weeds. The applicants state that the pre-emergence herbicides that were used (Sonalan and Prowl) have a shorter period of soil activity than the most effective pre-emergence herbicide available (Pursuit). However, because crop rotation includes potatoes, Pursuit could not be used.

Because there are no post-emergence herbicides that are currently registered for use on chickpeas to control broadleaf weeds, the applicants assert that left uncontrolled, the broadleaf weed infestation could reduce crop yields by 50 to 60%. EPA has authorized under FIFRA section 18 the use of pyridate on

chickpeas for control of broadleaf weeds in Washington and Oregon. After having reviewed the submission, EPA concurs that emergency conditions exist for these states.

As part of its assessment of this emergency exemption, EPA assessed the potential risks presented by residues of pyridate in or on chickpeas. In doing so, EPA considered the new safety standard in FFDCA section 408(b)(2), and EPA decided that the necessary tolerance under FFDCA section 408(l)(6) would be consistent with the new safety standard and with FIFRA section 18. Consistent with the need to move quickly on the emergency exemption in order to address an urgent non-routine situation and to ensure that the resulting food is safe and lawful, EPA is issuing this tolerance without notice and opportunity for public comment under section 408(e), as provided in section 408(l)(6). Although this tolerance will expire and is revoked on December 31, 1998, under FFDCA section 408(l)(5), residues of the pesticide not in excess of the amounts specified in the tolerance remaining in or on chickpeas 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 pyridate meets EPA's registration requirements for use on chickpeas 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 pyridate by a State for special local needs under FIFRA section 24(c). Nor does this tolerance serve as the basis for any States other than Washington and Oregon 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 pyridate, 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 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 (children 1-6 years old) was not regionally based.

IV. Aggregate Risk Assessment and Determination of Safety

Consistent with section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action, EPA has sufficient data to assess the hazards of pyridate and to make a determination on aggregate exposure, consistent with section 408(b)(2), for a time-limited tolerance for combined residues of pyridate on chickpeas 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 pyridate are discussed below.

1. *Chronic toxicity*. EPA has established the RfD for pyridate at 0.11 milligrams/kilogram/day (mg/kg/day). This RfD is based on a two year chronic feeding study in rats with a NOEL of 10.8 mg/kg/day and an uncertainty factor of 100 based on body weight depression in the males at the lowest effect level (LEL) of 67.5 mg/kg/day. The 3-generation reproduction study was considered co-critical with a NOEL of 10.8 mg/kg/day and an lowest observed effect level (LOEL) of 67.5 mg/kg/day. Depressed maternal and pup body weight gains were observed at the LOEL.

2. *Carcinogenicity*. Pyridate has not been to the Office of Pesticide Program's Cancer Peer Review Committee. However, mouse and rat oncogenicity studies indicate that pyridate was negative in both species for carcinogenic effects.

B. Exposures and Risks

1. *From food and feed uses.* Tolerances have been established (40 CFR 180.462) for the combined residues of pyridate (*O*- (6-chloro-3-phenyl-4-pyridazinyl)-*S*-octyl-carbonothioate), the metabolite 6-chloro-3-phenyl-pyridazine-4-ol and conjugates of 6-chloro-3-phenyl-pyridazine-ol, expressed as pyridate, in or on a variety of raw agricultural commodities including cabbage, corn (grain, fodder, forage, silage) and peanuts (nutmeats, hulls), all at 0.03 ppm. Risk assessments were conducted by EPA to assess dietary exposures and risks from pyridate as follows:

Chronic exposure and risk. In conducting this chronic dietary risk assessment, EPA has made very conservative assumptions -- 100% of chickpeas and all other commodities having pyridate tolerances will contain residues and those residues would be at the level of the tolerance -- which result in an overestimate of human dietary exposure. Thus, in making a safety determination for this tolerance, EPA is taking into account this conservative exposure assessment.

The existing pyridate tolerances (published, pending, and including the necessary Section 18 tolerance(s)) result in a Theoretical Maximum Residue Contribution (TMRC) that is equivalent to the following percentages of the RfD:

U.S. population at <1.0%; nursing infants at <1.0%; non-nursing infants (<1 year old) at <1.0%; children (1-6 years old) at <1.0%; and, children (7-12 years old) at <1.0%

The subgroups listed above are: (1) the U.S. population (48 states); (2) those for infants and children; and, (3) the other subgroups for which the percentage of the RfD occupied is greater than that occupied by the subgroup U.S. population (48 states).

2. *From drinking water.* Based on information available to the Agency, pyridate is not persistent and not mobile. There is no established Maximum Contaminant Level for residues of (pyridate) in drinking water. No health advisory levels for pyridate in drinking water have been established.

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 pyridate 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 pyridate 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.* Pyridate is not registered for any residential uses at this time. Therefore, no non-dietary, non-occupational exposure is anticipated.

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 pyridate 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, pyridate 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 pyridate has a common mechanism of toxicity with other substances.

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

1. *Acute risk.* An acute aggregate risk is not required for pyridate as no acute toxicity endpoint has been identified. There are also no non-dietary non-occupational exposures. The Agency acknowledges the potential for exposure to pyridate in drinking water, but does not expect that exposure would result in an aggregate (margin of exposure) MOE (food plus water) that would exceed the Agency's level of concern for acute dietary exposure.

2. *Chronic risk.* Using the conservative TMRC exposure assumptions, and taking into account the completeness and reliability of the toxicity data, EPA has concluded that aggregate exposure to pyridate from food will utilize <1.0% of the RfD for the U.S. population. 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 pyridate in drinking water, 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 chronic aggregate exposure to pyridate residues.

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

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

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

b. *Developmental toxicity studies.* In the developmental study in rats, the maternal (systemic) NOEL was 165 mg/kg/day, based on mortality and decreased body weight at the LOEL of 400 mg/kg/day. The developmental (fetal) NOEL was 165 mg/kg/day, based on increased incidence of missing and/or unossified sternabrae and decreased

fetal body weight at the LOEL of 400 mg/kg/day.

In the developmental toxicity study in rabbits, the maternal (systemic) NOEL was 300 mg/kg/day, based on body weight depression at the LOEL of 600 mg/kg/day. The developmental (pup) NOEL was 600 mg/kg/day, the highest dose tested.

c. *Reproductive toxicity study*. In the 3-generation reproductive toxicity study in rats, the maternal (systemic) NOEL was 10.8 mg/kg/day, based on body weight depression at the LOEL of 67.5 mg/kg/day. The developmental/reproductive (pup) NOEL was 10.8 mg/kg/day, based on body weight loss at the LOEL of 67.5 mg/kg/day.

d. *Pre- and post-natal sensitivity*. The toxicological data base for evaluating pre- and post-natal toxicity for pyridate 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 3-generation rat reproductive toxicity study. Based on the developmental and reproductive toxicity studies discussed above, there does not appear to be an extra sensitivity for pre- or post-natal effects.

e. *Conclusion*. 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 to protect infants and children.

2. *Chronic risk*. Using the conservative exposure assumptions described above, EPA has concluded that aggregate exposure to pyridate from food will utilize less than 1% 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 pyridate 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 pyridate residues.

V. Other Considerations

A. Metabolism In Plants and Animals

The nature of the pyridate residue in plants and ruminants is adequately understood. The total toxic residue consists of pyridate (*O*- (-chloro-3-phenyl-4-pyridazinyl) -*S*-octyl-carbonothioate), its metabolite 6-chloro-3-phenyl-pyridazine-4-ol (aka CL9673), and conjugates of that metabolite, all expressed as pyridate. .

B. Analytical Enforcement Methodology

A total residue method using UV—HPLC is available for residue data gathering and enforcement purposes. The method has been adequately validated by recovery data, has passed a successful method trial, and has been forwarded to FDA for publication in PAM-II. The limit of quantitation is 0.03 ppm..

C. Magnitude of Residues

Residues of pyridate, its metabolite 6-chloro-3-phenyl-pyridazine-4-ol and conjugates of that metabolite all expressed as pyridate are not expected to exceed 0.1 ppm in/on chickpeas. Secondary residues are not expected in animal commodities as no feed items are associated with this Section 18 use.

D. International Residue Limits

There are no CODEX, Mexican, or Canadian MRLs established for pyridate in/on chickpeas.

VI. Conclusion

Therefore, the tolerance is established for combined residues of pyridate (*O*-(6-chloro-3-phenyl-4-pyridazinyl)-*S*-octyl-carbonothioate), the metabolite 6-chloro-3-phenyl-pyridazine-4-ol and conjugates of 6-chloro-3-phenyl-pyridazine-ol, expressed as pyridate in/on chickpeas at 0.1 ppm.

VII. Objections and Hearing Requests

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

Any person may, by October 21, 1997, file written objections to any aspect of this regulation and may also request a hearing on those objections. Objections and hearing requests must be filed with the Hearing Clerk, at the address given above (40 CFR 178.20). A copy of the objections and/or hearing requests filed with the Hearing Clerk should be submitted to the OPP docket for this rulemaking. The objections submitted must specify the provisions of the regulation deemed objectionable and the grounds for the objections (40 CFR 178.25). Each objection must be accompanied by the fee prescribed by 40 CFR 180.33(i). If a hearing is requested, the objections must include a statement of the factual issues on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the requestor (40 CFR 178.27). A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established, resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issues in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as Confidential Business Information (CBI). Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

VIII. Public Docket

EPA has established a record for this rulemaking under docket control number [OPP–300527] (including any comments and data submitted electronically). A public version of this record, including printed, paper versions of electronic comments, which does not include any information claimed as CBI, is available for inspection from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The public record is located in Room 1132 of the Public Information and Records Integrity Branch, Information Resources and Services Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA.

Electronic comments may be sent directly to EPA at:

opp-docket@epamail.epa.gov.

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

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

IX. Regulatory Assessment Requirements

This final rule establishes a tolerance under FFDCA section 408(d). 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 12, 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 180.462 is amended to read as follows:

a. By designating the existing text as paragraph (a) and adding a heading.

b. By adding paragraph (b).

c. By adding the headings and reserving paragraphs (c) and (d).

Section 180.462, as amended, reads as follows:

§ 180.462 Pyridate; tolerances for residues.

(a) *General* . * * *

(b) *Section 18 emergency exemptions.* A time-limited tolerance is established for the residue of the herbicide pyridate in connection with use of the pesticide under section 18 emergency exemptions granted by EPA. This tolerance will expire and is revoked on the date specified in the following table:

Commodity	Parts per million	Expiration/ revocation date
Chickpeas	0.1	12/31/98

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

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

[FR Doc. 97–22373 Filed 8–21–97; 8:45 am]
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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300533; FRL–5738–6]

RIN 2070–AB78

Sethoxydim; Pesticide Tolerances for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a time-limited tolerance for residues of sethoxydim and its metabolites containing the 2-cyclohexen-1-one moiety in or on horseradish. 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 horseradish in Illinois. This regulation establishes a maximum permissible level for residues of sethoxydim 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 September 30, 1998.

DATES: This regulation is effective August 22, 1997. Objections and requests for hearings must be received by EPA on or before October 21, 1997.

ADDRESSES: Written objections and hearing requests, identified by the docket control number, [OPP–300533], 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–300533], 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