(ii) Other material. None.

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300748; FRL–6039–4]

RIN 2070–AB78

Picloram; Time-Limited Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes time-limited tolerances for the indirect or inadvertent residues of the herbicide, picloram, 4-amino-3,5,6-trichloropicolinic acid and its potassium salt in or on certain raw agricultural commodities. Dow AgroSciences requested this tolerance under the Federal Food, Drug and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (Pub. L. 104–170).

DATES: The effective date of this rule is December 31, 1998. Objections and requests for hearings must be received by EPA on or before March 8, 1999.

ADDRESSES: Written objections and hearing requests, identified by the docket control number, [OPP–300748], 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–300748], 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. 119, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA.

A copy of objections and hearing requests filed with the Hearing Clerk may also be submitted electronically by sending electronic mail (e-mail) to: opp-docket@epamail.epa.gov. Copies of objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Copies of objections and hearing requests will also be accepted on disks in WordPerfect 5.1/6.1 file format or ASCII file format. All copies of objections and hearing requests in electronic form must be identified by the docket control number [OPP–300748]. 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: James A. Tompkins, Registration Division 7505C, Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail address: Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, (703) 305–5697, e-mail: tompkins.jim@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of May 13, 1997 (62 FR 26305), EPA issued a notice pursuant to section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(e) announcing the filing of a pesticide petition (PP 4F4412) for tolerances by DowElanco, 9330 Zionsville Road, Indianapolis, IN 46254. This notice included a summary of the petition prepared by DowElanco, the registrant. The petition requested that 40 CFR 180 be amended by establishing tolerances for inadvertent residues of the herbicide, picloram, 4-amino-3,5,6-trichloropicolinic acid, in or on sorghum grain at 0.3 parts per million (ppm), sorghum grain forage at 0.2 ppm, and sorghum stover at 0.5 ppm.

In the **Federal Register** of November 20,1998 (63 FR 64494), EPA issued a notice announcing that Dow AgroSciences amended the petition by also proposing to established a tolerance for residues of the herbicide picloram in or on the raw agricultural commodity aspirated grain fractions at 4 ppm. There were no comments received in response to the notices of filing. The tolerances will expire and will be revoked on December 31, 2000.

I. Risk Assessment and Statutory Findings

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***.''

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. For further discussion of the regulatory requirements of section 408 and a complete description of the risk assessment process, see the Final Rule on Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997) (FRL–5754–7).

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 adverse effect level'' or ''NOAEL'').

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

exposure into the NOAEL 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 NOAEL) 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/NOAEL is selected to be adequate for at least 7 days of exposure. (Toxicity results at lower levels when the dosing duration is increased.)

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

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

B. Aggregate Exposure

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

Percent of crop treated estimates are derived from Federal and private market survey data. Typically, a range of estimates are supplied and the upper end of this range is assumed for the exposure assessment. By using this upper end estimate of percent of crop treated, the Agency is reasonably certain that exposure is not understated for any significant subpopulation group. Further, regional consumption information is taken into account through EPA's computer-based model for evaluating the exposure of significant subpopulations including several regional groups, to pesticide residues. For this pesticide, the most highly exposed population subgroup non-nursing infants was not regionally based.

II. 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 picloram and to make a determination on aggregate exposure, consistent with section 408(b)(2), for a time-limited tolerance for indirect or inadvertent residues of picloram and its potassium salt in certain raw agricultural commodities when present therein as a result of the application of picloram as a herbicide. EPA's assessment of the dietary exposures and risks associated with establishing the tolerances follows:

A. Toxicological Profile

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

and its salts and esters are discussed below:

1. Rat acute oral studies with LD_{50s} greater than 5,000 milligrams (mg)/kilogram (kg) (males) and 4,012 mg/kg (females) with picloram acid and greater than 5,000 mg/kg (males) and 3,536 mg/kg (females) with the potassium salt of picloram

2. A 13–week rat feeding study with picloram acid with a No Observed Adverse Effect Level (NOAEL) 50 mg/kg/day and with a Lowest Observed Adverse Effect Level (LOAEL) of 150 mg/kg/day based on liver weight increases and minimal microscopic changes in the liver.

3. A 13–week rat feeding study with the isooctyl ester of picloram with a NOAEL 73 mg/kg/day and with a LOAEL of 220 mg/kg/day based on increased liver weights accompanied by slight/very slight hepatocellular hypertrophy and increased kidney weights in males only.

4. A 13–week rat feeding study with the triisopropanolamine salt of picloram with a NOAEL 90 mg/kg/day and with a LOAEL of 550 mg/kg/day based on hepatocellular hypertrophy; decreased body weight gain and increased liver and kidney weights (females only) at 1,800 mg/kg/day.

5. A 6 month dog feeding study with picloram acid with a NOAEL of 35 mg/kg/day and a LOAEL of 175 mg/kg/day based on decreased mean body weight gain and food consumption.

6. A 21–day dermal study with potassium salt of picloram in rabbits with a NOAEL for systemic effects greater than 753 mg/kg/day, the maximum amount of test material that could be practically maintained at the test site - limit of test.

7. A 21–day dermal study with triisopropanolamine salt of picloram in rabbits with a NOAEL for systemic effects greater than 1,320 mg/kg/day - limit of test.

8. A dog chronic feeding study with picloram acid with a NOAEL of 35 mg/kg/day and a LOAEL of 175 mg/kg/day based on increased absolute and relative liver weights.

9. A rat chronic feeding/carcinogenicity study with picloram acid with a systemic NOAEL of 20 mg/kg/day and a systemic LOAEL of 60 mg/kg/day based on increased size and altered staining properties of centrilobular hepatocytes and increased absolute and/or relative liver weights in both sexes. Negative for carcinogenicity.

10. A second rat chronic feeding/carcinogenicity study with picloram acid with a systemic NOAEL less than 250 mg/kg/day and a systemic LOAEL of 250 mg/kg/day based on increases in the incidence and severity of glomerulonephritis, blood in the urine, decreased specific gravity of the urine, increased size of hepatocytes that often had altered staining properties, increase in the incidence of unilateral or bilateral renal papillary necrosis and increases in absolute and relative kidney weights. There was no evidence of increased tumor incidence.

11. A mouse carcinogenicity study with picloram acid with a NOAEL was 500 mg/kg/day and the LOAEL was 1,000 mg/kg/day based on increased absolute and relative kidney weights in males. There was no evidence of carcinogenicity.

12. A two-generation rat reproduction study with picloram acid with a parental systemic NOAEL of 200 mg/kg/day and a reproductive NOAEL of 1,000 mg/kg/day [Highest Dose Tested (HDT)] and a Parental Systemic LOAEL of 1,000 mg/kg/day based on microscopic lesions in male (and some female) kidneys, blood in urine, decreased urine specific gravity, increased absolute and relative kidney weights.

13. A rat developmental study (picloram acid) with a maternal NOAEL of 500 mg/kg/day and a developmental LOAEL of 500 mg/kg/day [Lowest Dose Tested] based on transient delayed ossification of 5th sternebrae (fetuses but not litters) and with a maternal LOAEL of 750 mg/kg/day based on hyperactivity and mild diarrhea and deaths.

14. A rat developmental study with the potassium salt of picloram with a maternal NOAEL of 174 mg/kg/day and a developmental NOAEL of 347 mg/kg/day [HDT] and with a maternal LOAEL of 347 mg/kg/day based on excessive salivation.

15. A rabbit developmental study with the potassium salt of picloram with a maternal NOAEL of 40 mg/kg/day and a developmental NOAEL of 400 mg/kg/day [HDT] and with a maternal LOAEL of 200 mg/kg/day based on reduced maternal weight gain during gestation.

16. A rat developmental study with the isooctyl ester of picloram with a maternal NOAEL of 100 mg/kg/day and a developmental NOAEL of 1,000 mg/kg/day [HDT] and with a maternal LOAEL of 500 mg/kg/day based on decreased body weight gain during early gestation.

17. A rabbit developmental study with the isooctyl ester of picloram with a maternal NOAEL of 20 mg/kg/day and a developmental NOAEL of 500 mg/kg/day [HDT] and with a maternal LOAEL of 100 mg/kg/day based on an increase in incidence of clinical signs (decreased feces at 500 and decreased body weight gain at 100 mg/kg/day and above).

18. A rat developmental study with the triisopropanolamine salt of picloram with a maternal NOAEL of 500 mg/kg/day and a developmental NOAEL of 1,000 mg/kg/day [HDT] and with a maternal LOAEL of 1,000 mg/kg/day based on excessive salivation, decreased body weight gain and food consumption.

19. A rabbit developmental study with the triisopropanolamine salt of picloram with a maternal NOAEL of 54 mg/kg/day and a developmental NOAEL of 1,000 mg/kg/day [HDT] and with a maternal LOAEL of 180 mg/kg/day based on increased rate of abortions at 1,000 mg/kg/day, increased clinical signs at 538 mg/kg/day and above and decreased food consumption and body weight gain at 180 mg/kg/day and above.

20. In a gene mutation assay (Ames assay) picloram acid did not produce a mutagenic response either in the presence or absence of activation. In a gene mutation assay in Chinese hamster ovary (CHO) cells picloram acid was found to be negative for inducing forward mutation with and without metabolic activation. In gene mutation assay with CHO/HGPRT+ cells picloram acid did not induce a mutagenic response at doses up to and including those generally associated with severe cytotoxicity. In a cytogenetics *in vivo* study picloram acid did not produce cytogenetic effects. In an other genotoxic effects study picloram acid was negative for unscheduled DNA synthesis treated up to cytotoxic levels. In a gene mutation assay (Ames test) the isooctyl ester of picloram did not induce a mutagenic response in the presence or absence of metabolic activation. In a gene mutation assay (mammalian CHO cells) isooctyl ester of picloram there was no evidence of a mutagenic response at any dosage level in either the S9 activated trials or the non-activated trials. In a structural chromosomal aberration assay isooctyl ester of picloram demonstrated no potential for inducing chromosomal aberrations. In a micronucleus test in mice the isooctyl ester was found not to be clastogenic. In a gene mutation assay (Ames test) the triisopropanolamine salt of picloram did not produce a mutagenic response either in the presence or absence of activation. In a cytogenetics assay the triisopropanolamine salt of picloram was non-clastogenic in mice, as determined by lack of mutagenic effect at doses up to lethality. In another genotoxic effects assay the triisopropanolamine salt of picloram was negative for inducing unscheduled

DNA synthesis at doses up to toxic levels.

21. A rat metabolism study showed that radio-labeled ^{14}C-picloram acid is rapidly absorbed, distributed and excreted following oral and intra-venous (i.v.) administration. A rat metabolism study demonstrated that isooctyl ester of picloram is hydrolyzed rapidly to picloram (free acid) and 2-ethyl hexanol, and that picloram isooctyl ester does not influence the excretion of picloram in the rat. For the triisopropanolamine salt of picloram, the metabolism study showed that the conversion of the salt to picloram was not affected by the presence of triisopropanolamine.

B. Toxicological Endpoints

1. *Acute toxicity*. EPA could not identify any toxicological effects that could be attributable to a single oral exposure (dose) in any of the available toxicological studies.

2. *Short- and intermediate-term toxicity*. EPA could not identify any toxicological effects that could be attributable to short- or intermediate-term dermal or inhalation exposure. No systemic effects were observed in available dermal studies. In addition, no endpoints for short- or intermediate-term exposure could be identified from available oral studies.

3. *Chronic toxicity*. EPA has established the RfD for picloram at 0.2 mg/kg/day. This RfD is based on NOAEL of 20 mg/kg/day in the combined chronic toxicity/carcinogenicity study in rats with a 100–fold safety factor to account for inter-species extrapolation (10x) and intra-species variability (10x).

4. *Carcinogenicity*. The Health Effects Division Carcinogenicity Peer Review Committee has classified picloram acid and its potassium salt as Group E ''no evidence of carcinogenicity'' to humans based on the lack of carcinogenicity in rats and mice. A carcinogenicity risk assessment is required for hexachlorobenzene (HCB) a process impurity in picloram.

C. Exposures and Risks

1. *From food and feed uses*. Tolerances have been established (40 CFR 180.292) previously for the residues of picloram, and its salts in or on raw agricultural commodities from use on barley, grasses, oats and wheat. Appropriate tolerances are established for secondary residues of picloram and its salts occurring in meat, milk, poultry, or eggs. Risk assessments were conducted by EPA to assess dietary exposures and risks from picloram from the proposed and registered uses as follows:

i. *Acute exposure and risk*. Acute dietary risk assessments are performed for a food-use pesticide if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1 day or single exposure. No toxicological effect that could be attributable to a single oral exposure was identified, and therefore picloram is not expected to present an acute dietary risk.

ii. *Picloram chronic exposure and risk*. The Reference Dose (RfD) for picloram is 0.02 mg/kg/day. This value is based on the systemic LOAEL of 200 mg/kg/day in the rat chronic feeding/carcinogenicity study with a 100–fold safety factor to account for interspecies extrapolation (10x) and intraspecies variability (10x). start

A Dietary Risk Evaluation System (DRES) chronic exposure analysis was conducted using established tolerance levels for proposed tolerances, meat, milk and eggs, and percent crop treated information for cereal grains to estimate dietary for the general population and 22 subgroups. The chronic analysis showed that dietary exposure for non-nursing infants (the subgroup with the highest exposure) would be 2% of the Reference Dose (RfD). The exposure for the general U.S. population would be less than 1% of the RfD.

Section 408(b)(2)(F) states that the Agency may use data on the actual percent of food treated for assessing chronic dietary risk only if the Agency can make the following findings: (1) That the data used are reliable and provide a valid basis to show what percentage of the food derived from such crop is likely to contain such pesticide residue; (2) that the exposure estimate does not underestimate exposure for any significant subpopulation group; and (3) if data are available on pesticide use and food consumption in a particular area, the exposure estimate does not understate exposure for the population in such area. In addition, the Agency must provide for periodic evaluation of any estimates used.

The Agency used percent crop treated (PCT) information as follows. A routine chronic dietary exposure analysis for picloram was based on 2% of cereal grain crop treated. The Agency believes that the three conditions listed above have been met. With respect to (1), EPA finds that the (PCT) information described above for picloram used on cereal grains is reliable and has a valid basis based on past pesticide use surveys. Approval of crop rotation of the minor use corp sorghum after treatment with picloram is not likely to significant increase the percentage of the total U.S. cereal grains treated with picloram. As to (2) and (3), regional consumption information and consumption information for significant subpopulations is taken into account through EPA's computer-based model for evaluating the exposure of significant subpopulations including several regional groups. Use of this consumption information in EPA's risk assessment process ensures that EPA's exposure estimate does not understate exposure for any significant subpopulation group and allows the Agency to be reasonably certain that no regional population is exposed to residue levels higher than those estimated by the Agency. Other than the data available through national food consumption surveys, EPA does not have available information on the regional consumption of food to which picloram may be applied in a particular area.

iii. *HCB (hexachlorobenzene) chronic exposure and risk*. EPA calculated the chronic dietary carcinogenic risk from all known pesticidal sources of HCB, including picloram. Eight pesticides were included in the calculations, three of which were major contributors to HCB levels in the diet: chlorothalonil, pentachloronitrobenzene and picloram. The estimated dietary carcinogenic risk for HCB from all known pesticidal sources is 6.3×10^{-7} which is less than the 1×10^{-6} point which is generally considered to be negligible.

2. *From drinking water*- i. *Acute risk*. Because no acute dietary endpoint was determined, no acute risk is expected.

ii. *Chronic risk*. Based on the chronic dietary (food) exposure and using default body weights and water consumption figures [70 kg weight/2L water consumed (adult male), 60 kg/2L (adult female), and 10 kg/1L (child)], the chronic drinking water levels of concern (DWLOC) for drinking water were calculated. To calculate the DWLOC, the chronic dietary food exposure was subtracted from the RfD.

$DWLOC_{chronic}$ = [chronic water exposure (mg/kg/day) x (body weight)]/[consumption (L) x 10^{-3} mg/μg]

where chronic water exposure (mg/kg/day) = [RfD - (chronic food + residential exposure) (mg/kg/day)]

The results are summarized in the following Table:

Population Subgroup[1]	Chronic Scenario					
	RfD mg/kg/day	Food Exposure mg/kg/day	Maximum Water Exposure mg/kg/day[2]	DWLOC (µg/L)	SCI-GROW2 EEC (µg/L)[3]	GENEEC EEC (µg/L)[3]
U.S. Population	0.20	0.0011	0.20	7000	379	103.1
Females (13–19 years old, not pregnant or nursing)	0.20	0.00090	0.20	6000	379	103.1
Non-Nursing Infants (< 1yr old)	0.20	0.0043	0.20	2,000	379	103.1

[1] Population subgroups chosen were U.S. population (70 kg. body weight assumed), the adult female subgroup with the highest food exposure (60 kg. body weight assumed) and the infant/child subgroup with the highest food exposure (10 kg. body weight assumed).
[2] Maximum Water Exposure (mg/kg/day) = RfD (mg/kg/day) - ARC from DRES (mg/kg/day).
[3] The crop producing the highest level was used.

For the most highly exposed populations subgroup, non-nursing infants (< 1 year old), chronic dietary (food only) exposure occupies 2% of the RfD. The chronic drinking water level of concern (DWLOC) for non-nursing infants (< 1 yr old) is 2,000 µg/L (ppb). The GENEEC model predicted that with the present use pattern, the 56–day average picloram surface water concentration for the highest application rate (2 lbs/A) would be 103.1 µg/L (ppb). The SCI-GROW2 model estimated that the ground water concentration from the current uses of picloram for the highest application rate would be 379 µg/L (ppb). Therefore, exposure from water is below DWLOC for chronic dietary exposure for any of the populations examined.

iii. *Dietary cancer risk for hexachlorobenzene (HCB) - (combined food and water).* HCB is persistent and relatively immobile in the environment. Based on the high binding potentials of HCB, contamination of ground water resources is relatively unlikely. The dietary cancer risk for HCB from all pesticidal uses is 6.3×10^{-7}. In order to calculate a DWLOC for HCB, the Anticipated Residue Contribution (ARC's) for each of the pesticides included in the risk calculation are needed. Although a few significant figures are lost with this calculation, an estimate of the overall dietary exposure can be made by dividing the risk value by the Q*. The calculation is as follows: $(6.3 \times 10^{-7}/1.02 = 6.2 \times 10^{-7})$. Based on summaries of monitoring data and fate properties, long term concentrations of HCB in filtered surface water are not likely to exceed 10 ppt or 0.01 ppb. The amount of HCB in water is also estimated from uses of other chemicals with HCB as an impurity, not just picloram. The chronic water exposure is calculated by dividing the negligible risk (1.0×10^{-6}) by the Q* and subtracting from that the chronic food plus residential exposure. $1.0 \times 10^{-6}/1.02$ mg/kg/day^{-1} = 9.8×10^{-7} mg/kg/day. Using the equation for calculating the DWLOC (ppb), the DWLOC for the general population for dietary cancer risk for HCB from all pesticidal uses is calculated as follows:

9.8×10^{-7} mg/kg/day x 70kg/2L x 10^{-3} mg/µg = 0.034 µg/L (ppb)

The DWLOC of 0.034 ppb is greater than 0.01 ppb, the maximum concentration of HCB estimated in surface water.

3. *From non-dietary exposure.* Picloram is a Restricted Use Pesticide that has no residential uses. For uses currently registered under the Federal Insecticide, Fungicide and Rodenticide Act, rights-of-way, forestry, pastures, range lands, and small grains; entry into a treated area soon after the application of picloram is limited by the re-entry restrictions on the picloram labels. Non-dietary exposure to picloram will be minimal for the general population.

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.'' Picloram is a pyridine carboxylic acid herbicide. Other herbicides in this class include clopyralid, quinclorac and thiazopyr.

EPA does not have, at this time, available data to determine whether picloram 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, picloram 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 picloram has a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the Final Rule for Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997).

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

1. *Acute risk.* Picloram is not expected to pose an acute risk.

2. *Chronic risk.* The Reference Dose (RfD) for picloram is 0.02 mg/kg/day. This value is based on the systemic LOAEL of 200 mg/kg/day in the rat chronic feeding/carcinogenicity study with a 100–fold safety factor to account for interspecies extrapolation (10x) and intraspecies variability (10x). The dietary exposure for non-nursing infants (the subgroup with the highest exposure) is 2% of the Reference Dose (RfD). The exposure for the general U.S. population would be less than 1% of the RfD.

The drinking water level of concerns (DWLOCs) for chronic exposure to picloram in drinking water calculated for U.S. population was 7,000 parts per billion (ppb) assuming that an adult weighs 70 kg and consumes a maximum of 2 liters of water per day, for females 13–19 years old (not pregnant or nursing) the DWLOC was 6,000 assuming that an adult female weighs 60 kg and consumes a maximum of 2 liters of water per day, and for children (1 – 6 years old) the DWLOC was 2,000 ppb assuming that a child weighs 10 kg and consumes a maximum of 1 liter of water per day.

The drinking water estimated concentration (DWECs) for groundwater (picloram acid) calculated from the highest application rate for the 56 day average is 379 ppb which does not exceed DWLOC of 2,000 ppb for children (1–6 years old). The DWEC for surface water based on the computer model Generic Expected Environmental Concentration (GENEEC) was calculated to be 103.1 ppb for chronic concentration (parent picloram and degradate thiadone) which does not exceed the DWLOC of 2,000 ppb for children (1–6 years old). From

groundwater monitoring the maximum concentration reported was 4.6 ppb. Picloram is regulated under the Safe Drinking Water Act (SDWA). Water supply systems are required to sample for it. A Maximum Contaminate Level (MCL) of 500 ppb and a 1–10 day health advisory of 20,000 ppb have been established.

EPA concludes that there is a reasonable certainty that no harm will result from aggregate exposure to picloram residues.

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

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

FFDCA section 408 provides that EPA shall apply an additional tenfold margin of safety for infants and children in the case of threshold effects to account for pre- and post-natal toxicity and the completeness of the database unless EPA determines that a different margin of safety will be safe for infants and children. There is no indication of increased sensitivity to young rats or rabbits following pre- and/or post-natal exposure to picloram in the standard developmental and reproductive toxicity studies, there was no indication that picloram is a neurotoxic herbicide. Therefore, a 10–fold safety factor for children and infants is not required to be used in the aggregate dietary acute and chronic risk assessments.

III. Other Considerations

A. Metabolism In Plants and Animals

The nature of the residue in rotated sorghum is adequately understood. The residues of concern for the tolerance expression are picloram and its salts. Appropriate tolerances are established to cover any secondary residues which would occur in animal commodities from the proposed and registered uses.

B. Analytical Enforcement Methodology

An adequate analytical method, gas chromatography/mass spectrometry with selected ion monitoring, is available for enforcement purposes. Because of the long lead time from establishing these tolerances to publication of the enforcement methodology in the Pesticide Analytical Manual, Vol. II, the analytical methodology is being made available in the interim to anyone interested in pesticide enforcement when requested from: Calvin Furlow, Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: Room 101FF, CM #2, 1921 Jefferson Davis Highway, Arlington, VA 22202, (703–305–5229).

C. Endocrine Effects

EPA is required to develop a screening program to determine whether certain substances (including all pesticides and inerts) ''may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or such other effect***.'' The Agency is currently working with interested stakeholders, including other government agencies, public interest groups, industry and research scientists in developing a screening and testing program and a priority setting scheme to implement this program. Congress has allowed 3 years from the passage of FQPA (August 3, 1999) to implement this program. At that time, EPA may require further testing of this active ingredient and end use products for endocrine disrupter effects.

D. Magnitude of Residues

Due to the data gap, an aspirated grain fraction study; EPA believes it is inappropriate to establish permanent tolerances for the proposed use of picloram at this time. EPA believes that the existing data support tolerances to December 31, 2000. The nature of the residue in plants is adequately understood for the purposes of these tolerances.

E. International Residue Limits

There are no Codex Alimentarius Commission (Codex) Maximum Residue Levels (MRLs) for picloram.

F. Rotational Crop Restrictions

Tolerances for indirect or inadvertent residues of picloram and its potassium salt established by this regulation will cover any residues in sorghum planted in treated fields in accordance with the restrictions that appear on the labeling proposed for registration under the Federal Insecticide Fungicide and Rodenticide Act (FIFRA), as amended.

IV. Conclusion

The analysis for picloram and its salts using crop tolerances, percentage of crop estimates, and estimated drinking water concentrations for all population subgroups examined by EPA shows the proposed rotation to sorghum from the registered uses of picloram will not cause exposure at which the Agency believes there is an appreciable risk during the period of time for the tolerance. Therefore EPA concludes there is a reasonable certainty of no harm from aggregate exposure to picloram. Based on the information cited above, EPA has determined that establishing tolerances for the residues of the herbicide, picloram in or on aspirated grain fractions at 4.0 ppm, sorghum grain at 0.3 ppm, sorghum grain forage at 0.2 ppm and sorghum grain stover at 0.5 ppm will be safe. These tolerances will expire and be revoked on December 31, 2000. Therefore, the tolerances are established as set forth below.

V. 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 March 8, 1999, 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) or a request for a fee waiver. If a hearing is requested, the objections must include a statement of the factual issues on which a hearing is requested, the requestor's contentions on such issues, and a summary of any

evidence relied upon by the requestor (40 CFR 178.27). A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established, resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issues in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

VI. Public Record and Electronic Submissions

EPA has established a record for this rulemaking under docket control number [OPP–300748]. 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 119 of the Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA.

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.

VII. Regulatory Assessment Requirements

A. Certain Acts and Executive Orders

This final rule establishes tolerances under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 et seq., or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Pub. L. 104–4). Nor does it require any prior 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 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.

B. Executive Order 12875

Under Executive Order 12875, entitled *Enhancing the Intergovernmental Partnership* (58 FR 58093, October 28, 1993), EPA may not issue a regulation that is not required by statute and that creates a mandate upon a State, local, or tribal government, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by those governments. If the mandate is unfunded, EPA must provide to OMB a description of the extent of EPA's prior consultation with representatives of affected State, local, and tribal governments, the nature of their concerns, copies of any written communications from the governments, and a statement supporting the need to issue the regulation. In addition, Executive Order 12875 requires EPA to develop an effective process permitting elected officials and other representatives of State, local, and tribal governments ''to provide meaningful and timely input in the development of regulatory proposals containing significant unfunded mandates.''

Today's rule does not create an unfunded Federal mandate on State, local, or tribal governments. The rule does not impose any enforceable duties on these entities. Accordingly, the requirements of section 1(a) of Executive Order 12875 do not apply to this rule.

C. Executive Order 13084

Under Executive Order 13084, entitled *Consultation and Coordination with Indian Tribal Governments* (63 FR 27655, May 19, 1998), EPA may not issue a regulation that is not required by statute, that significantly or uniquely affects the communities of Indian tribal governments, and that imposes substantial direct compliance costs on those communities, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by the tribal governments. If the mandate is unfunded, EPA must provide OMB, in a separately identified section of the preamble to the rule, a description of the extent of EPA's prior consultation with representatives of affected tribal governments, a summary of the nature of their concerns, and a statement supporting the need to issue the regulation. In addition, Executive Order 13084 requires EPA to develop an effective process permitting elected officials and other representatives of Indian tribal governments ''to provide meaningful and timely input in the development of regulatory policies on matters that significantly or uniquely affect their communities.''

Today's rule does not significantly or uniquely affect the communities of Indian tribal governments. This action does not involve or impose any requirements that affect Indian tribes. Accordingly, the requirements of section 3(b) of Executive Order 13084 do not apply to this rule.

VIII. Submission to Congress and the Comptroller General

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small

Business Regulatory Enforcement Fairness Act of 1996, generally provides that

before a rule may take effect, the Agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and the Comptroller General of the United States. EPA will submit 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 United States prior to publication of the rule in the **Federal Register**. This rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

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

Dated: December 22, 1998.

James Jones,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180–[AMENDED]

1. In Part 180:

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

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

b. Section 180.292 is amended by designating the existing text as paragraph (a), adding a paragraph heading and designating the text following the paragraph heading as paragraph (a)(1); by adding and reserving with headings paragraphs (b) and (c); and by adding paragraph (d) to read as follows:

§ 180.292 Picloram; tolerances for residues.

(a) *General.* (1) * * *

(b) *Section 18 emergency exemptions.* [Reserved]

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

(d) *Indirect or inadvertent residues.* Tolerances are established for indirect or indadvertent residues of the herbicide picloram, 4-amino-3,5,6-trichloropicolinic acid, from application of its potassium form on barley, fallow cropland, oats, and wheat in or on the following raw agricultural commodities:

Commodity	Parts per million	Expiration/ Revocation Date
Aspirated grain fractions	4.0	12/31/00
Sorghum grain	0.3	12/31/00
Sorghum grain, forage	0.2	12/31/00
Sorghum grain, stover	0.5	12/31/00

PART 185–[AMENDED]

2. In Part 185:

a. The authority citation continues to read as follows:

Authority: 21 U.S.C. 346a and 348.

§ 185.4850—[Partially Redesignated and Removed]

b. The text of § 185.4850, including the table, is redesignated as paragraph (a)(2) of § 180.292. The remainder of § 185.4850 is removed.

PART 186–[AMENDED]

3. In Part 186:

a. The authority citation continues to read as follows:

Authority: 21 U.S.C. 342, 348, and 371.

§ 186.4850 [Partially Redesignated and Removed]

b. The text of § 186.4850, including the table, is redesignated as paragraph (a)(3) of § 180.292. The remainder of § 186.4850 is removed.

[FR Doc. 98–34830 Filed 12–31–98; 8:45 am]

BILLING CODE 6560–50–F

DEPARTMENT OF TRANSPORTATION

Federal Transit Administration

49 CFR Parts 653 and 654

[Docket No. FTA–98–3474]

RIN 2132–AA61

''Maintenance'' Under Definition of Safety-Sensitive Functions in Drug and Alcohol Rules

AGENCY: Federal Transit Administration, DOT.

ACTION: Final rule.

SUMMARY: The Federal Transit Administration (FTA) is amending its regulations to require drug and alcohol testing of all maintenance workers, including those engaged in engine, revenue service vehicle, and parts rebuilding and overhaul. This change will eliminate the distinction between maintenance workers involved in on-going, daily maintenance and repair work and those who, on a routine basis, perform rebuilding and overhauling work.

EFFECTIVE DATE: February 4, 1999.

FOR FURTHER INFORMATION CONTACT: For program issues: Judy Meade, Director of the Office of Safety and Security (202) 366–2896 (telephone) or (202) 366–7951 (fax). For legal issues: Michael Connelly, Office of the Chief Counsel (202) 366–4011 (telephone) or (202) 366–3809 (fax). Electronic access to this and other rules may be obtained through FTA's Transit Safety Bulletin Board at 1–800–231–2061, or through the FTA World Wide Web home page at http://www.fta.dot.gov; both services are available seven days a week.

SUPPLEMENTARY INFORMATION: On March 2, 1998, FTA published a Notice of Proposed Rulemaking (NPRM) proposing to amend its drug and alcohol rules to require testing all maintenance workers, including those engaged in engine, revenue service, and parts rebuilding and overhaul. The NPRM came in response to concern that FTA was permitting a segment of workers who routinely performed safety-sensitive functions to evade otherwise applicable drug and alcohol testing. FTA received 11 comments over a three-month period.

I. ''Maintenance''

Comments

Of the 11 comments received, seven favored adoption of the proposed amendment; four commenters opposed. Those in favor of the amendment noted that employees performing routine repair and those performing overhaul and rebuilding should be treated similarly. The workers performing those tasks are drawn, generally, from the same pool of applicants, and perform equally important tasks. Those opposed to the amendment generally focused on a perceived increased cost in securing contractors able to perform overhaul and rebuilding functions. Comments on the NPRM, as well as suggestions from those generally in favor of the amendment, include:

—Three commenters (Bloomington-Normal (Illinois) Public Transit System (B–NPTS)), the Bay Area (California) Transit Drug Testing Task Force, and the Los Angeles County Metropolitan Transportation Authority (LACMTA) expressed concern that ''extending'' testing to contract maintenance workers would increase the cost to both the grantee and the contractor. The Task Force and LACMTA both suggest that some of their overhaul and rebuilding