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

### IX. Regulatory Assessment Requirements

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

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

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

### List of Subjects in 40 CFR Part 180

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

Dated: July 16, 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. By adding § 180.510 to read as follows:

### § 180.510 Pyriproxyfen; tolerances for residues.

(a) *General* . [Reserved]

(b) *Section 18 emergency exemptions.* Time-limited tolerances are established for the residues of the insect growth regulator pyriproxyfen, in connection with the use of the pesticide under section 18 emergency exemptions granted by EPA. The tolerances will expire on the dates specified in the following table.

| Commodity | Parts per million | Expiration/Revocation Date |
|---|---|---|
| Cotton seed | 0.05 | 7/31/98 |
| Cotton, gin byproducts | 2.0 | 7/31/98 |

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

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

[FR Doc. 97–19671 Filed 7–24–97; 8:45 am]

BILLING CODE 6560–50–F

## ENVIRONMENTAL PROTECTION AGENCY

## 40 CFR Part 180

**[OPP–300516; FRL–5732–3]**

**RIN 2070–AB78**

## Sodium Salt of Acifluorfen; Pesticide Tolerances for Emergency Exemptions

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

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes time-limited tolerances for the combined residues of the sodium salt of acifluorfen and its metabolites in or on lima beans, cowpeas, and southern peas . 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 lima beans, cowpeas, and southern peas. This regulation establishes a maximum permissible level for residues of the sodium salt of acifluorfen in these food commodities pursuant to section 408(l)(6) of the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996. The tolerances will expire and are revoked on December 31, 1998.

**DATES:** This regulation is effective July 25, 1997. Objections and requests for hearings must be received by EPA on or before September 23, 1997.

**ADDRESSES:** Written objections and hearing requests, identified by the docket control number, [OPP–300516], 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–300516], 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–300516]. 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: Olga Odiott, 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) 308-9363, e-mail: odiott.olga@epamail.epa.gov.

**SUPPLEMENTARY INFORMATION:** EPA, on its own initiative, pursuant to section 408(e) and (l)(6) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(e) and (l)(6), is establishing tolerances for the combined residues of the herbicide sodium salt of acifluorfen and its metabolites (the corresponding acid, methyl ester and amino analogues), in or on lima beans, cowpeas, and southern peas at 0.1 part per million (ppm). These tolerances will expire and are revoked on December 31, 1998. EPA will publish a document in the **Federal Register** to remove the revoked tolerances from the Code of Federal Regulations.

## I. Background and Statutory Authority

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

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

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

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

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

## II. Emergency Exemption for the Sodium Salt of Acifluorfen on Lima Beans, Cowpeas, and Southern Peas and FFDCA Tolerances

According to the Tennessee Extension Service the Hophornbeam copperleaf (*Acalypha ostryaefolia*) has become such an overwhelming pest that entire fields were abandoned in 1995. The fields in question constitute some of the most fertile agricultural land in West Tennessee, an area where farming and agriculturally related businesses are the primary sources of income. The Applicant stated that registered herbicides and/ or cultivation practices do not provide effective control of this weed. The State is concerned that uncontrolled Hophornbeam copperleaf could have a devastating effect for growers and the local economy. EPA has authorized under FIFRA section 18 the use of acifluorfen on lima beans, cowpeas, and southern peas for control of Hophornbeam copperleaf in Tennessee. After having reviewed the submission, EPA concurs that emergency conditions exist for this state.

As part of its assessment of this emergency exemption, EPA assessed the potential risks presented by residues of the acifluorfen in or on lima beans, cowpeas, and southern peas. 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 lima beans, cowpeas, and southern peas 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 acifluorfen meets EPA's registration requirements for use on

lima beans, cowpeas, and southern peas 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 acifluorfen by a State for special local needs under FIFRA section 24(c). Nor does this tolerance serve as the basis for any State other than Tennessee 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 acifluorfen, 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 acifluorfen and to make a determination on aggregate exposure, consistent with section 408(b)(2), for a time-limited tolerance for the combined residues of the sodium salt of acifluorfen and its metabolites ( the corresponding acid, methyl ester, and amino analogues) in or on lima beans, cowpeas, and southern peas 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 acifluorfen are discussed below.

1. *Acute toxicity.* An acute dietary endpoint was not identified from the toxicity studies available to the Agency; therefore, this risk assessment was not conducted.

2. *Short - and intermediate - term toxicity.* Based on the available data, the Office of Pesticide Programs (OPP) has determined that the NOEL of 300 mg/kg/day from a 21-day dermal toxicity study in rabbits should be used to assess risks from short- and intermediate-term dermal exposures. The Lowest Effect Level (LEL) of 1,000 mg/kg/day was based on increased mortality (95%) by Day 8. For short- and intermediate-term inhalation toxicity, the OPP has determined that the NOEL of 20 mg/kg/day from a developmental toxicity study in rabbits should be used to assess risks for residential exposure scenarios. The LEL of 90 mg/kg/day was based on reduced mean fetal weights.

3. *Chronic toxicity.* EPA has established the RfD for acifluorfen at 0.013 milligrams/kilogram/day (mg/kg/day). This RfD is based on a 2-generation reproductive toxicity study in rats. The NOEL (parental and reproductive) of 1.25 mg/kg/day was based on decreased survival and an increased incidence of kidney lesions at the LEL of 25.0 mg/kg/day. A 100-fold uncertainty factor (UF) was added to account for inter-species extrapolation and intra-species variability .

4. *Carcinogenicity.* Acifluorfen has been classified as a Group B2 (probable human carcinogen) chemical by the OPP Cancer Peer Review Committee (CPRC), based on an increased number of liver tumors in both sexes of mice and a high incidence of uncommonly occurring stomach papillomas in male mice. The Committee recommended using the $Q_1$* approach for quantification of human risk. The $Q_1$* is 0.11 $(mg/kg/day)^{-1}$.

### *B. Exposures and Risks*

1. *From food and feed uses.* Tolerances have been established (40 CFR 180.383) for the combined residues of the sodium salt of acifluorfen and its metabolites (the acid, methyl ester, and amino analogues), in or on peanuts, rice, and soybeans at 0.1 ppm; strawberries at 0.05 ppm; and, animal commodities at 0.02 ppm. Risk assessments were conducted by EPA to assess dietary exposures and risks from acifluorfen as follows:

*Chronic exposure and risk.* This chronic dietary risk assessment was partially refined using percent crop-treated estimates and anticipated residue values for selected commodities. Expansion of these refinements to the remaining commodities would result in a lower chronic dietary exposure estimate. The risk assessment took into account the published tolerances (none are currently pending) for the regulable residues of the sodium salt of acifluorfen, plus this Section 18 tolerance. The population subgroup with the largest percentage of the RfD occupied is children 1 to 6 year old, at 0.4% of the RfD.

2. *From drinking water.* Based on available data used in EPA's assessment of environmental risk, acifluorfen (acid) is persistent, readily leaches, and is highly mobile. No Maximum Contaminant Level is established for acifluorfen residues in drinking water. Health Advisory Levels for acifluorfen residues in drinking water are established as follows: for a 10-kg child, a range of 2 mg/L from 1-day exposure to 0.1 mg/L for longer-term exposure up to 7 years; for a 70-kg adult, 0.4 mg/L for longer-term exposure.

Information in the EPA Pesticides in Groundwater Database indicates that a total of 1,185 discrete wells in 8 states (AR, CA, GA, IA, LA, MS, VA, WA) were sampled for residues of acifluorfen during the period 1984-1991. Detectable residues were reported (0.003-0.025 µg/L) in only 0.3% of the sampled wells.

*Chronic exposure and risk.* The EPA has calculated chronic exposure levels to acifluorfen residues in drinking water for the U.S. population and children. The Agency estimated adult exposure to be $0.7 \times 10^{-6}$ mg/kg/day and child exposure to be $2.5 \times 10^{-6}$ mg/kg/day. The Agency used very conservative assumptions for the exposure assessments. EPA used the highest acifluorfen residue level (0.025 ug/L) found from the monitoring of 1,185 wells over an 8-year period in the 8 states mentioned above to estimate exposure. In addition, all the drinking water consumed in the US was assumed to contain this high end level of acifluorfen residues (even though only 0.3% of all the wells monitored from 1984-91 contained detectable residues of acifluorfen). The Agency estimated that the chronic dietary risks from drinking water will utilize <0.01% of

the RfD for adults and <0.02% of the RfD for children.

3. *From non-dietary exposure.* Acifluorfen is currently registered for use on the following outdoor residential sites: ornamentals (flowering plants, plants, lawns, woody shrubs); mulch; and, walkways, paths, trails, lanes, and private roads. Based on the nature of the outdoor uses, the EPA concludes that acute and chronic exposure scenarios do not exist for acifluorfen. A short- and/or intermediate-term exposure scenario may exist.

*Short- and intermediate-term exposure and risk.* The outdoor residential uses of acifluorfen may constitute a short- and/or intermediate-term exposure scenario, but the Agency currently lacks residential-related exposure data to complete a comprehensive residential risk assessment of acifluorfen.

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).

Acifluorfen is a member of the diphenyl ether group of herbicides. Other members include bifenox, diclofop methyl, fomesafen, lactofen, nitrofen, and oxyfluorfen. Acifluorfen is a major metabolite of lactofen in plants, and is assumed to share a common mechanism of toxicity with lactofen. At present, there is not sufficient information to determine if any other pesticides may also share this common mechanism of toxicity. For purposes of this Section 18 time-limited tolerance action, the Agency has not assumed that acifluorfen and lactofen have a common mechanism of toxicity with any other substances.

To estimate the cumulative (acifluorfen + lactofen) aggregate (food + water) dietary and cancer exposures, estimates for lactofen on its regulated commodities (snap beans, soybeans, and cottonseed) were added to estimates for acifluorfen (encompassing all its established plant and animal commodity tolerances and the tolerance proposed for this Section 18 use).

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

1. *Chronic risk.* Using the ARC exposure assumptions described above, and taking into account the completeness and reliabilty of the toxicity data, EPA has concluded that aggregate exposure to acifluorfen from food and water will utilize ≈0.2% (≈0.2% from food + ≈0.01% from water) of the RfD for the U.S. population.

The chronic dietary (food only) risk assessment for lactofen was based on percent crop-treated values for soybeans and anticipated residue estimates for soybeans, snap beans, and cottonseed. Using these partially refined exposure assumptions, the Agency determined that chronic dietary (food only) exposure will utilize <1% of the RfD for lactofen (established at 0.02 mg/kg/day) for the U.S. population. The Agency determined that exposure to lactofen from drinking water will utilize <1% of the RfD. This assessment was based on acifluorfen monitoring data. The aggregate chronic (food + water) dietary exposure contributed by lactofen residues will utilize <2% (<0.0004 mg/kg/day) of the lactofen RfD (and corresponds to 3% of the acifluorfen RfD). The cumulative (acifluorfen + lactofen) aggregate chronic dietary (food + water) exposure was estimated to be on the order of 3 - 4% of the RfD for acifluorfen. 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.

There are no registered indoor residential uses of acifluorfen and the Agency has determined that chronic exposure scenarios do not exist for the the outdoor residential uses of acifluorfen. Lactofen is not registered for residential uses.Therefore, residential exposure is not considered to be a contributing factor to cumulative aggregate chronic exposure.

The Agency concludes that there is a reasonable certainty that no harm will result from cumulative chronic aggregate exposure to lactofen and the sodium salt of acifluorfen residues.

2. *Short- and intermediate-term risk.* Short- and intermediate-term aggregate exposure takes into account chronic dietary food and water (considered to be a background exposure level) plus indoor and outdoor residential exposure.

There are no registered residential uses of lactofen. There are no registered indoor uses of acifluorfen. Although the outdoor residential uses of acifluorfen may constitute a short- and/or intermediate-term exposure scenario, the Agency currently lacks sufficient residential-related exposure data to complete a comprehensive residential risk assessment for many pesticides, including acifluorfen.

Based on the low percentage (≈3 - 4%) of the RfD occupied by the cumulative (lactofen + acifluorfen) aggregate dietary exposure, and in the best scientific judgment of the EPA, the short- and intermediate-term aggregate exposure to residues of lactofen and the sodium salt of acifluorfen will not exceed the Agency's level of concern.

### *D. Aggregate Cancer Risk for U.S. Population*

Based on published tolerances (none are currently pending), and this proposed Section 18 use, the dietary (food only) cancer risk from /acifluorfen residues was calculated as $0.65 \times 10^{-6}$ (upper bound estimate). The calculation used the partially refined exposure

assumptions described above for generating ARCs, and amortized the cancer risk over a 70-year lifetime. The drinking water cancer risk from acifluorfen residues was estimated as $0.08 \times 10^{-6}$. The aggregate dietary (food + water) cancer risk from exposure to acifluorfen residues is thus $0.73 \times 10^{-6}$.

Based on the tolerances for lactofen (a B2 carcinogen with a $Q_1$* of 0.17 (mg/kg/day)$^{-1}$) in/on snap beans, soybeans, and cottonseed, the dietary (food only) cancer risk from residues of lactofen was estimated as $0.45 \times 10^{-6}$ (upper bound) for the U.S. population. For this analysis the Agency used percent crop-treated values for soybeans only and anticipated residue estimates for all 3 crops. The drinking water cancer risk estimate for lactofen was based on the acifluorfen monitoring data discussed above. As previously indicated, the drinking water cancer risk from acifluorfen residues was estimated as $0.08 \times 10^{-6}$. The cumulative (lactofen + acifluorfen) aggregate (food + water) upper bound lifetime dietary cancer risk for the U.S. population from exposure to acifluorfen and lactofen residues is thus the sum of:

Acifluorfen (food)—$0.65 \times 10^{-6}$
Lactofen (food)—$0.45 \times 10^{-6}$
Acifluorfen/Lactofen (water)—$0.08 \times 10^{-6}$
*Cumulative Aggregate Total*:—$1.2 \times 10^{-6}$

This cumulative aggregate dietary cancer risk of $1.2 \times 10^{-6}$ for the U.S. population from exposure to acifluorfen and lactofen is considered by EPA to be a very conservative estimate because:

(1) The chronic/cancer analyses for acifluorfen and lactofen were only partially refined by use of anticipated residue estimates and percent crop-treated (%CT) values on selected commodities, and are thus over-estimates of exposure.

(2) Lactofen use on snap beans is currently limited to Oregon and Tennesse, which comprises only approximately 20% of the U.S. production (for processing, in tons; approximately 12% based on acres planted; Ag. Stat. 1992), so use of actual %CT values would be expected to significantly reduce the estimate of exposure; snap beans represents 88% of the lactofen dietary (food) cancer risk contributions.

(3) Exposure estimates for lactofen/soybeans and acifluorfen/soybeans were treated as additive for purposes of assessing cumulative risk, and thus are likely an over-estimate of exposure,

(4) Tolerance levels for acifluorfen and lactofen are based on a summing of the method sensitivity levels for each component of their respective regulable residues, and do not reflect the presence of detectable residues.

In fact, there is a consistent absence of quantifiable residues in crops treated with either acifluorfen or lactofen.

For these reasons, the EPA considers that the cumulative (lactofen + acifluorfen) aggregate (food + water) upper bound dietary cancer risk estimate of $1.2 \times 10^{-6}$ for the U.S. population from exposure to acifluorfen and lactofen represents a worst case scenario. Further refinement would result in a lower risk estimate. In the best scientific judgment of the Agency, this cumulative aggregate dietary cancer risk estimate does not exceed the Agency's level of concern, and EPA concludes that there is a reasonable certainty that no harm in the form of cancer will result from cumulative aggregate exposure to acifluorfen and lactofen residues.

The EPA notes that there are no registered indoor or outdoor residential uses of lactofen, no registered indoor uses of acifluorfen, and that the registered outdoor residential uses of acifluorfen are not considered by the Agency to constitute a chronic exposure scenario. Thus, no non-dietary, non-occupational chronic exposure to acifluorfen or lactofen is expected, or is a factor in cumulative aggregate cancer risk.

*E. 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 acifluorfen, EPA considered data from developmental toxicity studies in the rat and rabbit and a two-generation reproduction study in the rat. The developmental toxicity studies are designed to evaluate adverse effects on the developing organism resulting from maternal pesticide exposure during gestation. Reproduction studies provide information relating to effects from exposure to the pesticide on the reproductive capability of mating animals and data on systemic toxicity.

FFDCA section 408 provides that EPA shall apply an additional tenfold margin of safety for infants and children in the case of threshold effects to account for pre-and post-natal toxicity and the completeness of the database unless EPA determines that a different margin of safety will be safe for infants and children. Margins of safety are incorporated into EPA risk assessments either directly through use of a MOE analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans. EPA believes that reliable data support using the standard 100-fold safety factor (usually for combined inter- and intra-species variability) and not the additional 10-fold safety factor when EPA has a complete data base under existing guidelines and when the severity of the effect in infants or children or the potency or unusual toxic properties of a compound do not raise concerns regarding the adequacy of the standard safety factor.

b. *Developmental toxicity studies—Rats*. The maternal (systemic) NOEL was 90 mg/kg/day, based on decreased body weight at the Lowest Observed Effect Level (LOEL) of 180 mg/kg/day, the highest dose tested (HDT). The developmental (fetal) NOEL was 20 mg/kg/day, based on decreased fetal weight at the LOEL of 90 mg/kg/day.

*Rabbits*. Both the maternal (systemic) and developmental NOEL were 36 mg/kg/day at the HDT.

c. *Reproductive toxicity study*. In a 2-generation reproductive toxicity study in rats, both the parental (systemic) and reproductive (pup) NOEL were 1.25 mg/kg/day, based on decreased survival and an increased incidence of kidney lesions at the LOEL of 25.0 mg/kg/day.

d. *Pre- and post-natal sensitivity*. The toxicological data base for evaluating pre- and post-natal toxicity for acifluorfen is complete with respect to current data requirements. The available data indicate that no developmental or maternal toxicity was observed in rabbits at the highest dose tested (36 mg/kg/day).

In the developmental toxicity study in rats, an increased sensitivity to acifluorfen was seen in developing fetuses as evidenced by decreased fetal weights at the NOEL of 20 mg/kg/day (LOEL = 90 mg/kg/day). Maternal toxicity was observed at the highest dose tested (LOEL = 180 mg/kg/day) and was based on decreased body weight. Based on these findings, an additional UF (3X or 10X) would be justified in order to be protective of infants and children. However, a 100-fold UF has already been applied to the RfD NOEL of 1.25 mg/kg/day, and the developmental NOEL is more than 16-fold greater than the RfD NOEL. Therefore, an additional UF does not appear to be necessary.

There was no parental or reproductive toxicity observed in a 2-generation reproductive toxicity study in rats at doses up to 150 mg/kg/day (HDT).

e. *Conclusion*. The cumulative data discussed above indicates minimal concern for developmental or reproductive toxicity. Thus, these data

support use of the standard uncertainty factor of 100 and an additional safety factor is not needed to protect infants and children.

2. *Chronic risk.* Using the conservative exposure assumptions described above, EPA has concluded that aggregate dietary (food + water) exposure to acifluorfen will utilize ≤0.4% (up to ≈0.4% from food + ≈0.02% from water) of the RfD for any of the infant and children subgroups of the U.S. population.

The Agency estimated that the dietary (food) exposure to lactofen residues willl utilize <1% of the RfD (the RfD for lactofen is 0.02 mg/kg/day) for any of the infant and children subgroups of the U.S. population (based on percent crop-treated values for soybeans and anticipated residue estimates for soybeans, snap beans, and cottonseed). The dietary (water) exposure of children to lactofen was based on acifluorfen monitoring data, and estimated as <1% of the RfD. The chronic aggregate (food + water) dietary exposure contributed by lactofen tolerances is thus <2% (<0.0004 mg/kg/day) of the lactofen RfD (and corresponds to 3% of the acifluorfen RfD).

Cumulative (acifluorfen + lactofen) chronic aggregate (food + water) dietary exposure for infants and children is thus on the order of 3-4% of the RfD of acifluorfen.

There are no registered indoor residential uses of acifluorfen. EPA believes that the outdoor residential uses of acifluorfen do not constitute a chronic exposure scenario. Lactofen is not registered for residential uses. Therefore, residential exposure will not be a contributing factor to cumulative chronic aggregate exposure to infants and children.

EPA concludes that there is a reasonable certainty that no harm will result to infants and children from cumulative chronic aggregate exposure to lactofen and acifluorfen residues.

3. *Short- or intermediate-term risk.* There are outdoor residential uses of acifluorfen, and these may constitute a short- and/or intermediate-term exposure scenario, but the Agency currently lacks residential-related exposure data to complete a comprehensive residential risk assessment of acifluorfen. Based on the lack of an identified acute toxicological endpoint for acifluorfen, and the low (≈3-4%) percentage of the acifluorfen RfD occupied by cumulative (lactofen + acifluorfen) aggregate (food + water) dietary exposure for any of the infant and children subgroups of the U.S. population, in the best scientific judgment of EPA, short- and/or intermediate-term cumulative aggregate exposure of acifluorfen and lactofen to infants and children will not exceed the Agency's level of concern.

## V. Other Considerations

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

The nature of the residue in rice and goats is adequately understood. Additional metabolism studies have been requested. At present, the residue of concern in plants and animals is considered to be as specified in 40 CFR 180.383 .

### *B. Analytical Enforcement Methodology*

Adequate enforcement methodology (GLC/ECD and GLC/MS) is available in the Pesticide Analytical Manual, Volume II, Methods 180.383 I and A, to enforce the tolerance expression of 40 CFR 180.383.

### *C. Magnitude of Residues*

Combined residues of the sodium salt of acifluorfen and its regulated metabolites are not expected to exceed 0.1 ppm in/on lima beans, southern peas, or cowpeas as a result of use under this Section 18 program. According to Table 1 of the OPPTS Test Guidelines, Series 860, Residue Chemistry, 8/96, there are no processed commodities associated with lima beans, southern peas, or cowpeas. Cowpea seed, forage, and hay are the only livestock feedstuffs associated with this Section 18 action and, in the absence of residue data, their use for feed or forage is being restricted under this Section 18 program. For the purpose of this Section 18 program and its limited acreage, the EPA will prohibit the use of treated plants for feed or forage. Thus, secondary residues in animal commodities are not expected to exceed existing tolerances as a result of this Section 18 use.

### *D. International Residue Limits*

There are no Codex, Canadian, or Mexican maximum residue limits established for acifluorfen.

### *E. Rotational Crop Restrictions*

Under this Section 18 use, in case of crop failure, only peanuts, soybeans, rice, lima beans, southern peas, or cowpeas may be immediately replanted. Further plantback restrictions, applying to crops without acifluorfen tolerances, are listed on the federal label, and are also to be followed under this Section 18 program.

## VI. Conclusion

Therefore, the tolerance is established for the combined residues of the sodium salt of acifluorfen and its metabolites (the acid, methyl ester, and amino analogues) in or on lima beans, cowpeas, and southern peas 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 September 23, 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–300516] (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 time-limited tolerances under FFDCA section 408(l)(6) response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled Regulatory Planning and Review (58 FR 51735, October 4, 1993). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Pub. L. 104-4). Nor does it require any prior consultation as specified by Executive Order 12875, entitled Enhancing the Intergovernmental Partnership (58 FR 58093, October 28, 1993), or special considerations as required by Executive Order 12898, entitled Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations (59 FR 7629, February 16, 1994), or require OMB review in accordance with Executive Order 13045, entitled Protection of Children from Environmental Health Risks and Safety Risks (62 FR 19885, April 23, 1997).

In addition, since these tolerances and exemptions that are established under FFDCA section 408 (l)(6), such as the tolerances 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 acations published on May 4, 1981 (46 FR 24950), and was provided to the Chief Counsel for Advocacy of the Small Business Administration.

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

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

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

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

Dated: July 10, 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 180.383 is amended as follows:

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

ii. By adding paragraph (b).

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

Section 180.383, as amended, reads as follows:

**§ 180.383 Sodium salt of acifluorfen; tolerances for residues.**

(a) *General.* * * *

(b) *Section 18 emergency exemptions.* Time-limited tolerances are established for the combined residues of the herbicide sodium salt of acifluorfen and its metabolites (the corresponding acid, methyl ester, and amino analogues) in connection with use of the pesticide under section 18 emergency exemptions granted by EPA. The tolerances will expire and are revoked on the dates specified in the following table:

| Commodity | Parts per million | Expiration/Revocation Date |
|---|---|---|
| Cowpeas | 0.1 | December 31, 1998 |
| Lima beans | 0.1 | December 31, 1998 |
| Southern peas | 0.1 | December 31, 1998 |

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

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

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