U.S.C. 3501 *et seq.*, or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Pub. L. 104-4). Nor does it require any prior consultation as specified by Executive Order 12875, entitled Enhancing the Intergovernmental Partnership (58 FR 58093, October 28, 1993), or special considerations as required by Executive Order 12898, entitled Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations (59 FR 7629, February 16, 1994), or require OMB review in accordance with Executive Order 13045, entitled Protection of Children from Environmental Health Risks and Safety Risks (62 FR 19885, April 23, 1997).

In addition, since these tolerances and exemptions that are established under FFDCA section 408 (l)(6), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. Nevertheless, the Agency has previously assessed whether establishing tolerances, exemptions from tolerances, raising tolerance levels or expanding exemptions might adversely impact small entities and concluded, as a generic matter, that there is no adverse economic impact. The factual basis for the Agency's generic certification for tolerance 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: August 15, 1997.

Peter Caulkins,

Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

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

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

2. In § 180.412, by adding text to paragraph (b) to read as follows:

§ 180.412 Sethoxydim: tolerance for residues.

* * * * *

(b) *Section 18 emergency exemptions.* A time-limited tolerance is established for combined residues of the herbicide sethoxydim and its metabolites containing the 2-cyclohexen-1-one moiety, calculated as the herbicide in connection with use of the pesticide under section 18 emergency exemptions granted by EPA. This tolerance will expire and is revoked on the date specified in the following table:

Commodity	Parts per million	Expiration/revocation date
Horseradish	4	September 30, 1998

* * * * *

[FR Doc. 97–22377 Filed 8–21–97; 8:45 am]

BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300529; FRL–5737–7]

RIN 2070–AB78

Chlorfenapyr; Pesticide Tolerances for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes time-limited tolerances for chlorfenapyr in or on cottonseed; cotton gin byproducts; milk; milk fat; meat of cattle, goats, hogs, horses, and sheep; fat of cattle, goats, hogs, horses, and sheep; and meat byproducts of cattle, goats, hogs, horses and sheep. This action is in response to EPA's granting of emergency exemptions under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act authorizing use of the pesticide on cotton. This regulation establishes maximum permissible level for residues of chlorfenapyr in/on 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. These tolerances will expire and are revoked on July 31, 1999.

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

ADDRESSES: Written objections and hearing requests, identified by the docket control number, [OPP–300529], 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–300529], 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–300529]. No Confidential Business

Information (CBI) should be submitted through e-mail. Electronic copies of objections and hearing requests on this rule may be filed online at many Federal Depository Libraries.

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

SUPPLEMENTARY INFORMATION: EPA, on its own initiative, pursuant to section 408(e) and (l)(6) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(e) and (l)(6), is establishing tolerances for the insecticide chlorfenapyr in or on cottonseed at 0.5 parts per million (ppm); cotton gin byproducts at 2.0 ppm; milk at 0.01 ppm; milk fat at 0.15 ppm; meat of cattle, goats, hogs, horses, and sheep at 0.01 ppm; fat of cattle, goats, hogs, horses, and sheep at 0.10 ppm; and meat byproducts of cattle, goats, hogs, horses, and sheep at 0.3 ppm. These tolerances will expire and are revoked on July 31, 1999. EPA will publish a document in the **Federal Register** to remove the revoked tolerances from the Code of Federal Regulations.

I. Background and Statutory Authority

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

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

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

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

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

II. Emergency Exemption for Chlorfenapyr on Cotton and FFDCA Tolerances

Beet armyworm has infested cotton fields to a high degree in recent growing seasons. EPA received submissions from Texas, Mississippi, Alabama, Arkansas, Florida, Georgia, Louisiana, South Carolina, and California for a section 18 exemption for the use of the unregistered pesticide chlorfenapyr to address the problem. The resistant tobacco budworm is also negatively affecting yields in these states. EPA has reviewed the submissions and has concluded that these pest situations represent urgent and non-routine problems. Therefore, EPA has authorized under FIFRA section 18 the use of the new pesticide chlorfenapyr on cotton for control of beet armyworm and resistant tobacco budworm in the listed states.

As part of its assessment of these emergency exemptions, EPA assessed the potential risks presented by residues of chlorfenapyr in or on cottonseed; cotton gin byproducts; milk; milk fat; meat of cattle, goats, hogs, horses, and sheep; fat of cattle, goats, hogs, horses, and sheep; and meat byproducts of cattle, goats, hogs, horses, and sheep. In doing so, EPA considered the new safety standard in FFDCA section 408(b)(2), and EPA decided that the necessary tolerances under FFDCA section 408(l)(6) would be consistent with the new safety standard and with FIFRA section 18. Consistent with the need to move quickly on the emergency exemption in order to address an urgent non-routine situation and to ensure that the resulting food is safe and lawful, EPA is issuing these tolerances without notice and opportunity for public comment under section 408(e), as provided in section 408(l)(6). Although these tolerances will expire and are revoked on July 31, 1999, under FFDCA section 408(l)(5), residues of the pesticide not in excess of the amounts specified in the tolerance remaining in or on cottonseed; cotton gin byproducts; milk; milk fat; meat of cattle, goats, hogs, horses, and sheep; fat of cattle, goats, hogs, horses, and sheep; and meat byproducts of cattle, goats, hogs, horses, and sheep after that date will not be unlawful, provided the pesticide is applied in a manner that was lawful under FIFRA. EPA will take action to revoke these tolerances earlier if any experience with, scientific data on, or other relevant information on this pesticide indicate that the residues are not safe.

Because these tolerances are being approved under emergency conditions EPA has not made any decisions about whether chlorfenapyr meets EPA's registration requirements for use on cotton or whether permanent tolerances for these uses would be appropriate. Under these circumstances, EPA does not believe that these tolerances serve as a basis for registration of chlorfenapyr by a State for special local needs under FIFRA section 24(c). Nor do these tolerances serve as the basis for any States other than previously listed 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 chlorfenapyr, 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 only are applicable since there are no residential uses of chlorfenapyr. For cases in which high-end exposure can reasonably be expected from multiple sources (e.g. frequent and widespread homeowner use in a specific geographical area), multiple high-end risks will be aggregated and presented as part of the comprehensive risk assessment/characterization. Since the toxicological endpoint considered in this assessment reflects exposure over a period of at least 7 days, an additional degree of conservatism is built into the assessment; i.e., the risk assessment nominally covers 1-7 days exposure, and the toxicological endpoint/NOEL is selected to be adequate for at least 7 days of exposure. (Toxicity results at lower levels when the dosing duration is increased.)

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

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

B. Aggregate Exposure

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

residues in most foods when they are eaten are well below established tolerances.

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

IV. Aggregate Risk Assessment and Determination of Safety

Consistent with section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action, EPA has sufficient data to assess the hazards of chlorfenapyr and to make a determination on aggregate exposure, consistent with section 408(b)(2), for a time-limited tolerance for residues of chlorfenapyr in or on cottonseed at 0.5 ppm; cotton gin byproducts at 2.0 ppm; milk at 0.01 ppm; milk fat at 0.15 ppm; meat of cattle, goats, hogs, horses, and sheep at 0.01 ppm; fat of cattle, goats, hogs, horses, and sheep at 0.10 ppm; and meat byproducts of cattle, goats, hogs, horses, and sheep at 0.3 ppm. EPA's assessment of the dietary exposures and risks associated with establishing these 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 chlorfenapyr are discussed below.

1. *Acute toxicity*. For acute dietary risk assessment, EPA recommends use of a NOEL for chlorfenapyr of 45 mg/kg/day from the rat acute neurotoxicity study. The Lowest Exposure Level (LEL) of 90 mg/kg/day was based on lethargy of the rats on the day of treatment. An MOE of 1,000 is required for all subgroups. An additional modifying factor of 10 was applied because the neurotoxicity study was classified as supplemental.

2. *Short - and intermediate - term toxicity*. For short- and intermediate-term MOE calculations, EPA recommends the use of a NOEL of 100 mg/kg/day from the 28-day dermal toxicity study in rabbits. The LEL of 400 mg/kg/day was based on increased serum cholesterol, increased relative liver weights, and unspecified histological lesions. EPA concludes that an MOE of 1,000 is required.

3. *Chronic toxicity*. EPA has established the RfD for chlorfenapyr at 0.003 milligrams/kilogram/day (mg/kg/day). This RfD is based on an 80-week feeding study in mice with a NOEL of 2.8 mg/kg/day and an LEL of 16.0 mg/kg/day based on brain lesions (both sexes) and scabbing of skin (males) An uncertainty factor of 1,000 was used with an additional modifying factor of 10 due to uncertainties regarding neurological risks in infants and children.

4. *Carcinogenicity*. EPA has classified chlorfenapyr as a Group D (not classifiable as to human carcinogenicity) chemical.

B. Exposures and Risks

1. *From food and feed uses.* Chlorfenapyr is an unregistered pesticide. The manufacturer has submitted registration applications for approval for chlorfenapyr products, however, none have been approved to date. This is the first tolerance-related action associated with this chemical. Risk assessments were conducted by EPA to assess dietary exposures and risks from chlorfenapyr as follows:

i. *Acute exposure and risk.* Acute dietary risk assessments are performed for a food-use pesticide if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a one day or single exposure. The acute dietary exposure endpoint of concern for chlorfenapyr is lethargy the day of dosing, which would affect all population subgroups. The acute analysis assumed tolerance level residues for all commodities. For all the population subgroups, the calculated MOE values are greater than 1,125. These MOEs do not represent a level of concern to EPA. Further, it should be noted that if the analysis were to incorporate anticipated residue levels and percent crop-treated, the MOEs would be even larger.

ii. *Chronic exposure and risk.* For the purposes of chronic dietary risk analysis, EPA assumed tolerance level residues and 100% crop treated for all commodities. The Theoretical Residue Contributions (TMRC) attributable to the use of this pesticide in accordance with the section 18 authorizations referenced in this notice are equivalent to RfD contributions that range from 23% for the U.S. population (48 states) to 76% for non-nursing infants less than a year old.

2. *From drinking water.* In examining aggregate exposure, FQPA directs EPA to consider available information concerning exposures from the pesticide residues in food and all other non-occupational exposures. The primary non-food sources of exposure the Agency looks at include drinking water (whether from ground or surface water), and exposure through pesticide use in gardens, lawns, or buildings (residential and other indoor uses). Based on data available to EPA, chlorfenapyr is considered immobile and has a relatively high affinity for soil. The mobility characteristics exhibited by this compound are not those generally associated with compounds found in groundwater. However, the chemical behavior of chlorfenapyr does present surface water concerns. Special models were used by EPA to calculate Tier II Estimated Environmental Concentrations (EECs) to estimate the exposure of chlorfenapyr from surface water. The values represent an upper bound estimate of the concentration in an edge-of-the-field pond with no outlet. The recommended values for drinking water exposure for use in human health risk assessment for surface water are 11 micrograms/L for acute drinking water exposure and 9 micrograms/L for chronic drinking water exposure .

i. *Acute exposure and risk.* EPA developed acute exposure levels for adults and children. For children, the acute exposure from drinking water is calculated to be 0.0011 mg/kg/day (11 micrograms/L x 10^{-3} mg/ug x L/day divided by 10 kg). For adults, the acute exposure is calculated to be 0.0003 mg/kg/day.

ii. *Chronic exposure and risk.* The chronic exposure form drinking water to children is calculated to be 30% of the RfD (9 micrograms/L x 10^{-3} mg/ug x 1 L/day divided by 10 kg divided by 0.003 mg/kg/day x 100 = 30%). The exposure for the general U.S. population would be 10% of the RfD.

iii. *Short- and intermediate-term exposure and 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. However, since there is no potential residential indoor/outdoor non-dietary non-occupational exposure scenarios for

chlorfenapyr, an aggregate short- and intermediate-term risk assessment is not necessary.

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

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

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

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

1. *Acute risk.* In order to assess aggregate risks, EPA combines the acute MOE calculations for food and water. EPA's processes for determining acute dietary (food only) and surface water exposures are described elsewhere in this notice. The most highly exposed subgroup for chlorfenapyr is infants less than a year old, with a combined dietary and drinking water exposure at 0.0153 mg/kg/day. Using the NOEL of 45 mg/kg/day, produces an aggregate acute risk assessment MOE of 2,900. Therefore, in EPA's judgement, aggregate acute risk to chlorfenapyr does not exceed levels of concern.

2. *Chronic risk.* Using the TMRC exposure assumptions described above, EPA has concluded that aggregate exposure to chlorfenapyr from food and water will utilize 33% of the RfD for the U.S. population. The major identifiable subgroup with the highest aggregate exposure is infants and children. See below for a discussion of the analysis of the risks for that subgroup. EPA generally has no concern for exposures below 100% of the RfD because the RfD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health.

3. *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. However, since there is no potential residential indoor/outdoor non-dietary non-occupational exposure scenarios for chlorfenapyr, an aggregate short- and intermediate-term risk assessment is not necessary.

D. Aggregate Cancer Risk for U.S. Population

Chlorfenapyr has been classified as a Group D chemical signifying that it is ''not classifiable as to human carcinogenicity.

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

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

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

ii. *Developmental toxicity studies.* In the rat developmental toxicity study, the maternal (systemic) NOEL was 25 mg/kg/day. The LEL of 75 mg/kg/day was based on decreased body weight gain, decreased relative feed intake, and decreased water consumption. The developmental (pup) NOEL was greater than 225 mg/kg/day (HDT). In the rabbit developmental toxicity study, the maternal (systemic) NOEL was 5 mg/kg/day. The LEL of 15 mg/kg/day was based on decreased body weight gain. The reproductive developmental NOEL was greater than 30 mg/kg/day (HDT).

iii. *Reproductive toxicity study.* From the multigeneration reproductive toxicity study in the rat, the maternal (systemic) NOEL was 5 mg/kg/day. The LEL of 22 mg/kg/day was based on decreased body weight gain (pre-mating). The reproductive developmental NOEL was 5 mg/kg/day.

The LEL of 22 mg/kg/day was based on decreased weight gain during lactation.

iv. *Pre- and post-natal sensitivity.* The pre- and post-natal toxicity data base for chlorfenapyr is complete. EPA notes that the developmental toxicity NOELs of greater than 225 mg/kg/day (HDT in rats) and greater than 30 mg/kg/day (HDT in rabbits) demonstrate that there is no developmental (prenatal) toxicity present at levels which produce maternal effects. Additionally, these developmental NOELs are 75- and 10-fold higher in the rats and rabbits, respectively, than the NOEL of 1.8 mg/kg/day from the 1-year feeding study in dogs (the basis of the RfD).

In the reproductive toxicity study in the rat, the reproductive developmental NOEL (5 mg/kg/day) is equal to the parental NOEL (5 mg/kg/day). Both the pup LEL and the parental LEL of 22 mg/kg/day were based on decreased body weight. This finding suggests that there is no special post-natal sensitivity present in the reproductive study and that young rats have the same sensitivity to chlorfenapyr as adult animals.

v. *Conclusion.* The developmental and reproductive toxicity studies indicate that infants and children have no special sensitivity to chlorfenapyr relative to other population subgroups. An additional safety factor for infants and children is not necessary for the use authorized in association with this tolerance.

2. *Acute risk.* To determine acute dietary and drinking water risks to children, an MOE approach is used where the total acute exposure from the diet and drinking water is compared to the acute dietary endpoint of concern, the NOEL of 45 mg/kg/day. Infants less than a year old are the most highly exposed subgroup and have a combined dietary and drinking water exposure at 0.0153 mg/kg/day which yields an MOE of 2,900. Therefore, in EPA's judgement, the aggregate acute risks to children and infants to chlorfenapyr does not exceed levels of concern.

3. *Chronic risk.* Using the conservative exposure assumptions described above, EPA has concluded that aggregate exposure to chlorfenapyr from food will utilize 45% of the RfD for nursing infants, 106% for non-nursing infants, 91% for children 1-6 years old, and 69% for children 7-12 years old. These figures are quite conservative since TMRC's and 100% crop treated assumptions were used in the assessment. If anticipated residue and refined percent crop-treated data were used, the calculated risk would be much lower. In addition, the RfD of 0.003 mg/kg/day was established using an uncertainty factor (UF) of 1,000. The UF contains an additional modifying factor of 10 due to uncertainties regarding neurological risks in infants and children. It is EPA's best scientific judgment that the aggregate chronic risks posed by chlorfenapyr do not exceed our level of concern.

4. *Short- or intermediate-term risk.* Since there is no potential residential indoor/outdoor non-dietary non-occupational exposure scenarios for chlorfenapyr, an aggregate short- and intermediate-term risk assessment is not necessary.

V. Other Considerations

A. Metabolism In Plants and Animals

The nature of the residue of chlorfenapyr in plants and ruminants is adequately understood. The residue of concern is the parent compound. For chlorfenapyr dietary risk assessments on ruminant commodities (excluding meat byproducts), residues of parent only will be used. However, chlorfenapyr dietary risk assessments on ruminant meat byproducts should include the two metabolites CL 303,268, and CL 325,195 as well as the parent (CL 303,630). The ruminant meat byproduct risk assessment will use a factor (i.e. ratio parent plus metabolites/parent) multiplied by the parent-based tolerance determined from the residue levels of the three moieties in the ruminant metabolism studies.

B. Analytical Enforcement Methodology

Adequate enforcement methodology is available to enforce the tolerance expression. American Cyanamid has prepared a method for cottonseed, meat, and milk.

C. Magnitude of Residues

Residues of chlorfenapyr are not expected to exceed 0.5 ppm in/on cottonseed as a result of this use. No concentration of parent residues (average level of 0.30 ppm in ginned cottonseed) occurred in crude/refined cottonseed oil or hulls. Therefore, separate tolerances for cottonseed processed commodities are not required. Cotton gin byproduct field trial data have not been submitted. In the absence of these required data, EPA recommends a tolerance of 2.0 ppm of chlorfenapyr residues in/on cotton gin byproducts.

Residues of chlorfenapyr in animal commodities are not expected to exceed: 0.01 ppm in milk; 0.15 ppm in milk fat; 0.01 ppm in meat of cattle, goats, hogs, horses, and sheep; 0.10 ppm in fat of cattle, goats, hogs, horses, and sheep; and 0.3 ppm in meat byproducts of cattle, goats, hogs, horses, and sheep.

D. International Residue Limits

No Codex, Canadian, or Mexican Maximum Residue Limits (MRLs) exist. Therefore, there are no compatibility issues with respect to this action.

VI. Conclusion

Therefore, tolerances are established for chlorfenapyr in or on cottonseed at 0.5 ppm; cotton gin byproducts at 2.0 ppm; milk at 0.01 ppm; milk fat at 0.15 ppm; meat of cattle, goats, hogs, horses, and sheep at 0.01 ppm; fat of cattle, goats, hogs, horses, and sheep at 0.10 ppm; and meat byproducts of cattle, goats, hogs, horses, and sheep at 0.3 ppm.

VII. Objections and Hearing Requests

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

Any person may, by October 21, 1997, file written objections to any aspect of this regulation and may also request a hearing on those objections. Objections and hearing requests must be filed with the Hearing Clerk, at the address given above (40 CFR 178.20). A copy of the objections and/or hearing requests filed with the Hearing Clerk should be submitted to the OPP docket for this rulemaking. The objections submitted must specify the provisions of the regulation deemed objectionable and the grounds for the objections (40 CFR 178.25). Each objection must be accompanied by the fee prescribed by 40 CFR 180.33(i). If a hearing is requested, the objections must include a statement of the factual issues on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the requestor (40 CFR 178.27). A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established, resolve one or more of such issues in favor of

the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issues in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as Confidential Business Information (CBI). Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

VIII. Public Docket

EPA has established a record for this rulemaking under docket control number [OPP–300529] (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 tolerances under FFDCA section 408(1)(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(1)(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: August 12, 1997.

James Jones,

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 180.513 is added to read as follows:

§ 180.513 Chlorfenapyr; tolerances for residues.

(a) *General.* [Reserved]

(b) *Section 18 emergency exemptions.* Time-limited tolerances are established for the insecticide chlorfenapyr in connection with use of the pesticide under section 18 emergency exemption granted by EPA. These tolerances will expire and are revoked on the date specified in the following table:

Commodity	Parts per million	Expiration/revocation date
Cattle, fat	0.10	7/31/99
Cattle, mbyp	0.3	7/31/99
Cattle, meat	0.01	7/31/99
Cottonseed	0.5	7/31/99
Cotton gin byproducts	2.0	7/31/99
Goats, fat	0.10	7/31/99
Goats, mbyp	0.3	7/31/99
Goats, meat	0.01	7/31/99

Commodity	Parts per million	Expiration/revocation date
Hogs, fat	0.10	7/31/99
Hogs, mbyp	0.3	7/31/99
Hogs, meat	0.01	7/31/99
Horses, fat	0.10	7/31/99
Horses, mbyp	0.3	7/31/99
Horses, meat	0.01	7/31/99
Milk	0.01	7/31/99
Milk fat	0.15	7/31/99
Sheep, fat	0.10	7/31/99
Sheep, mbyp	0.3	7/31/99
Sheep, meat	0.01	7/31/99

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

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

[FR Doc. 97–22396 Filed 8-21-97; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300538; FRL–5739–4]

RIN 2070–AB78

Coat Protein of Papaya Ringspot Virus and the Genetic Material Necessary for its Production; Exemption From the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final Rule.

SUMMARY: This rule establishes an exemption from the requirement of a tolerance for residues of the biological pesticide Coat Proteins of Papaya Ringspot Virus and the genetic material necessary for its production in or on all raw agricultural commodities. Cornell University submitted a petition to EPA under the Federal Food, Drug and Cosmetic Act as amended by the Food Quality Protection Act of 1996 requesting the tolerance exemption. This regulation eliminates the need to establish a maximum permissible level for residues of Coat Proteins of Papaya Ringspot Virus and the genetic material necessary for its production.

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

ADDRESSES: Written objections and hearing requests, identified by the docket control number [OPP–300538], 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–300538], 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 be submitted electronically by sending electronic mail (e-mail) to: opp-docket@epamail.epa.gov. Copies of electronic objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Copies of electronic objections and hearing requests will also be accepted on disks in WordPerfect 5.1 file format or ASCII file format. All copies of electronic objections and hearing requests must be identified by the docket control number [OPP–300538]. No Confidential Business Information (CBI) should be submitted through e-mail. Copies of electronic objections and hearing requests on this rule may be filed online at many Federal Depository Libraries.

FOR FURTHER INFORMATION CONTACT: By mail: Linda Hollis, c/o Product Manager (PM) 90, Biopesticides and Pollution Prevention Division (7501W), Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number and e-mail: Rm. 5th fl., CS#1 2800 Crystal Drive, Arlington, VA 22202, (703) 308–8733, e-mail: hollis.linda@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of April 2, 1997 (62 FR 15689–15690) EPA issued a notice pursuant to section 408(d), of the Federal Food Drug & Cosmetic Act (FFDCA), 21 U.S.C. 346a(d), announcing the filing of a pesticide tolerance petition by Cornell University, Geneva, NY. The notice contained a summary of the petition prepared by the petitioner and this summary contained conclusions and arguments to support its conclusion that the petition complied with the Food Quality Protection Act (FQPA) of 1996. The petition requested that 40 CFR part 180 be amended by establishing an exemption from the requirement of a tolerance for residues of the biological pest control agent Coat Protein of Papaya Ringspot Virus and the genetic material necessary for its production in or on all raw agricultural commodities.

There were no comments or requests for referral to an advisory committee received in response to the notice of filing.

The data submitted in the petition and other material have been evaluated. The toxicology data requirements in support of this exemption from the requirement of a tolerance were satisfied via data waivers from the open scientific literature.

I. Risk Assessment and Statutory Findings

New section 408(c)(2)(A)(i) of the FFDCA allows EPA to establish an exemption from the requirement for 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(c)(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