Petitions for Judicial Review

Under section 307(b)(1) of the CAA, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by November 18, 1997. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this rule for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Carbon monoxide, Hydrocarbons, Incorporation by reference, Intergovernmental relations, Nitrogen dioxide, Ozone, Reporting and recordkeeping requirements.

List of Subjects in 40 CFR Part 81

Environmental protection, Air pollution control, National parks, Wilderness areas.

Dated: September 5, 1997.

A. Stan Meiburg,

Acting Regional Administrator.

Chapter I, title 40, *Code of Federal Regulations*, is amended as follows:

PART 52—[AMENDED]

1. The authority citation for part 52 continues to read as follows:

Authority: 42 U.S.C. 7401–7671q.

Subpart B—Alabama

2. Section 52.66 is added to read as follows:

§ 52.66 Control Strategy: Ozone.

The redesignation request submitted by the State of Alabama, on March 16, 1995 for the Birmingham marginal ozone nonattainment area from nonattainment to attainment was disapproved on September 19, 1997.

[FR Doc. 97–24942 Filed 9–18–97; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300550; FRL–5744–2]

RIN 2070–AB78

Cloransulam-methyl; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of cloransulam-methyl in or on soybeans, soybean forage and soybean hay. DowElanco requested this tolerance under the Federal Food, Drug and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (Pub. L. 104–170).

DATES: This regulation is effective September 19, 1997. Objections and requests for hearings must be received by EPA on or before November 18, 1997.

ADDRESSES: Written objections and hearing requests, identified by the docket control number, [OPP–300550], 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–300550], 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–300550]. No Confidential Business Information (CBI) should be submitted through e-mail. Electronic copies of objections and hearing requests on this rule may be filed online at many Federal Depository Libraries.

FOR FURTHER INFORMATION CONTACT: By mail: James A. Tompkins, Registration Division 7505C, Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail address: Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, (703) 305-5697, e-mail: tompkins.jim@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of March 26, 1997 (52 FR 14421)(FRL–5592–8), EPA, issued a notice pursuant to section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(e) announcing the filing of a pesticide petition (PP) 5F4560 for tolerance by DowElanco, 9330 Zionville Road, Indianapolis, IN 46268-1054. This notice included a summary of the petition prepared by DowElanco. There were no comments received in response to the notice of filing.

The petition requested that 40 CFR 180 be amended by establishing tolerances for residues of the herbicide cloransulam-methyl, *N*-(2-carboxymethyl-6-chlorophenyl)-5-ethoxy-7-fluoro-(1,2,4)-triazolo[1,5c]-pyrimidine-2-sulfonamide, in or on soybean seed at 0.02 parts per million (ppm), soybean forage at 0.1 ppm, and soybean hay at 0.2 ppm. The tolerance expression is being editorially amended to read cloransulam-methyl plus its acid, cloransulam, calculated as parent ester.

I. Risk Assessment and Statutory Findings

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 * * *''

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 percent or less of the RfD) is generally considered acceptable by EPA. EPA generally uses the RfD to evaluate the chronic risks posed by pesticide exposure. For shorter term risks, EPA calculates a margin of exposure (MOE) by dividing the estimated human exposure into the 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 (non-nursing infants <1 year old) was not regionally based.

II. Aggregate Risk Assessment and Determination of Safety

Consistent with section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action, EPA has sufficient data to assess the hazards of cloransulam-methyl, *N*-(2-carboxymethyl-6-chlorophenyl)-5-ethoxy-7-fluoro-(1,2,4)-triazolo[1,5c]-pyrimidine-2-sulfonamide, and to make a determination on aggregate exposure, consistent with section 408(b)(2), tolerances for residues of cloransulam-methyl plus its acid, cloransulam, calculated as parent ester on soybean seed at 0.02 ppm, soybean forage at 0.1 ppm, and soybean hay at 0.2 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 cloransulam-methyl are discussed below.

1. A rat acute oral study with a LD_{50} greater than 5,000 milligrams (mg)/kilogram (kg) for males and for females.

2. A 90–day mouse feeding study with a No Observed Effect Level (NOEL) of 50 mg/kg/day for males and a Lowest Observed Effect Level (LOEL) of 100 mg/kg/day for males based on increased levels of alkaline phosphatase and increased liver weights and an increase in the size of hepatocytes.

3. A 21–day rabbit dermal study with a Dermal Irritation NOEL greater than 1,000 mg/kg/day for males and females and with a Systemic NOEL of 500 mg/kg/day (males and females) and a Systemic LOEL of 1,000 mg/kg/day based on decreased red cell count, hemoglobin and hematocrit, anisocytosis and macrocytosis of red cells for females.

4. A carcinogenicity study in mice with a NOEL of 10 mg/kg/day for both sexes and a LOEL of 100 mg/kg/day (males and females) based on a decrease in renal tubule vacuolation in male mice, increased size of centrilobular and midzonal hepatocytes accompanied by altered tinctorial properties in females and centrilobular hepatocyte hypertrophy in males. Total tumor incidence (adenoma + carcinoma) was not increased by dosing with cloransulam-methyl.

5. A rat chronic feeding/carcinogenicity study with a NOEL of 75 mg/kg/day and LOEL of 325 mg/kg/day for both sexes based on significant increase in hemoglobin, hematocrit, and red cell count in males, activities of the liver enzymes aspartate and alanine aminotransferase as well as alkaline phosphatase were decreased in males, cholesterol was decreased in females, specific gravity of urine was decreased in females, increased relative wight in liver and relative weight of testes in males, males exhibited an increased incidence of collecting duct hypertrophy and females exhibited increased incidence of vacuolation in the kidney. There was no evidence of carcinogenicity for cloransulam-methyl in this study.

6. A dog chronic feeding study with a NOEL of 10 mg/kg/day and a LOEL of 50 mg/kg/day based on hepatocellular hypertrophy and accumulation of pigment, and increased activity of alkaline phosphatase and alanine aminotransferase liver enzymes and decrease in albumin and total bilirubin.

7. A two-generation reproduction study in rats with a Parental Systemic Toxicity NOEL of 10 mg/kg/day and a Parental Systemic Toxicity LOEL of 100 mg/kg/day ppm based on hypertrophy of the collecting ducts and vacuolation consistent with fatty changes. The Reproductive and Developmental NOEL is 100 mg/kg/day and the Reproductive and Developmental LOEL is 500 mg/kg/day based on decreased live pups and increased pup deaths.

8. A developmental toxicity study in rabbits with a Maternal NOEL of 100 mg/kg/day and Developmental NOEL of 300 mg/kg/day (Highest Dose Tested [HDT]) and a Maternal LOEL of 300 mg/kg/day based on reduced weight gain, food efficiency, increased abortions, and cesarean section observations.

9. A developmental toxicity study in rats with a Maternal NOEL and Developmental NOEL of 1,000 mg/kg/day (HDT).

10. In a mouse micronucleus assay no lethality or evidence of target tissue cytotoxicity and no significant increase in frequency of micro nucleated polychromatic erythrocytes were observed. In two cytogenetic assays, cloransulam-methyl did not induce either cytotoxic or clastogenic effects in rat lymphocytes. In a cultured chinese hamster ovary cell study, cloransulam-methyl was neither cytotoxic nor mutagenic.

11. A rat metabolism study showed that radio labeled cloransulam-methyl was excreted mainly via urine in females and urine and feces in males. Less than 0.1% of administered dose was found in any tissue at 72 hours post-dose.

B. Toxicological Endpoints

1. *Acute toxicity*. EPA has concluded that a risk estimate is not required since no endpoint exists to suggest any evidence of significant toxicity from one-day or single-event exposure.

2. *Short - term and intermediate - term toxicity*. EPA has concluded that available evidence does not indicate any evidence of significant toxicity from short and intermediate term exposure.

3. *Chronic toxicity*. EPA has established the RfD for cloransulam-methyl at 0.1 milligrams/kilogram/day (mg/kg/day). This RfD is based on the systemic NOEL of 10 mg/kg/day in the dog chronic feeding study with a 100-fold safety factor to account for interspecies extrapolation and intraspecies variability.

4. *Carcinogenicity*. The Health Effects Division Carcinogenicity Peer Review Committee has classified cloransulam-methyl as ''not likely'' to be carcinogenic to humans based on the lack of carcinogenicity in rats and mice.

C. Exposures and Risks

1. *From food and feed uses.* The proposed tolerances would be the first tolerances established in 40 CFR part 180 for the residues of cloransulam-

methyl plus its acid, cloransulam, calculated as parent ester in or on raw agricultural commodities. Risk assessments were conducted by EPA to assess dietary exposures and risks from cloransulam-methyl as follows:

The dietary risk assessment uses very conservative assumptions that 100% of the soybeans will contain cloransulam-methyl residues and that these residues would be at the tolerance level. The theoretical maximum residue contribution (TMRC) from the proposed tolerances is 0.000007 mg/kg/day and utilizes 0.007 percent of the RfD for the overall U. S. population. For exposure of the most highly exposed subgroup in the population, non-nursing infants, the TMRC is 0.000033 mg/kg/day which utilizes 0.033 percent of the RfD.

2. *From drinking water.* Cloransulam-methyl concentration in surface water has been estimated by using the Generic Expected Environmental Concentrations (GENEEC) model. The worst case exposure estimate for surface water is 1.83 parts per billion (ppb). Based on the estimated exposures to Cloransulam-methyl from drinking water, the percentage of the RfD utilized for a child would be 0.183% of the Reference Dose (RfD). The exposure for a female would be 0.061% of the RfD.

3. *From non-dietary exposure.* There are no non-food uses of cloransulam-methyl currently registered under the Federal Insecticide, Fungicide and Rodenticide Act, as amended. No non-dietary exposures are expected for the general population.

4. *Cumulative exposure to substances with common mechanism of toxicity.* Cloransulam-methyl is a triazolopyrimidine sulfonamide herbicide. Another member of this class is Flumetsulam. 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 cloransulam-methyl 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, cloransulam-methyl 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 cloransulam-methyl has a common mechanism of toxicity with other substances.

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

1. *Acute, short-term, and intermediate-term risk.* EPA has concluded that no endpoint exists to suggest any evidence of significant toxicity from acute, short-term or intermediate-term exposures from the use of cloransulam-methyl on soybeans.

2. *Chronic risk.* Using the conservative exposure assumptions described above, EPA has concluded that aggregate exposure to cloransulam-methyl from food and drinking water will utilize less than 0.061% of the RfD for females 20 years old (not pregnant - not nursing). For the major identifiable subgroup with the highest aggregate exposure, non-nursing infants, the aggregate exposure to cloransulam-methyl from food and drinking water will utilize less than 0.216% of the RfD. 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.

E. Aggregate Cancer Risk for U.S. Population

EPA has classified cloransulam-methyl as ''not likely'' to be carcinogenic to humans based on the lack of carcinogenicity in rats and mice.

F. 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 cloransulam-methyl, EPA considered data from developmental toxicity studies in the rat and rabbit and a two-generation reproduction study in the rat. The developmental toxicity studies are designed to evaluate adverse effects on the developing organism resulting from pesticide exposure during prenatal development to one or both parents. Reproduction studies provide information relating to effects from exposure to the pesticide on the reproductive capability of mating animals and data on systemic toxicity.

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

concerns regarding the adequacy of the standard MOE/safety factor.

b. *Developmental and Reproductive toxicity studies.* The pre- and post-natal toxicology data base for cloransulam-methyl is complete with respect to current toxicological data requirements. The results of these studies indicate that infants and children are not more sensitive to exposure, based on the results of the oral rat and rabbit developmental toxicity studies and the 2-generation reproductive toxicity study in rats. Therefore, EPA concludes that an additional ten-fold safety factor is not necessary.

2. *Chronic risk.* Using the conservative exposure assumptions described above, EPA has concluded that aggregate exposure to cloransulam-methyl from food and drinking water will utilize less than 0.216% of the RfD for infants and children. EPA generally has no concern for exposures below 100% of the RfD because the RfD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health. EPA concludes that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to cloransulam-methyl residues.

III. Other Considerations

A. Metabolism In Plants and Animals

The metabolism of cloransulam-methyl in plants and animals is adequately understood for purposes of this tolerance.

B. Analytical Enforcement Methodology

An adequate analytical method, Capillary Gas Chromatography with Mass Spectrometry is available for enforcement purposes. Because of the long lead time from establishing these tolerances to publication of the enforcement methodology in the Pesticide Analytical Manual, Vol. II, the analytical methodology is being made available in the interim to anyone interested in pesticide enforcement when requested from: Calvin Furlow, Public Information and Records Integrity Branch, Information Resources and Services Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: Room 1130A, CM #2, 1921 Jefferson Davis Highway, Arlington, VA 22202, (703–305–5937).

C. Magnitude of Residues

The nature of the residue in plants is adequately understood for the purposes of this tolerance. Based on the results of animal metabolism studies it is unlikely that significant residues would occur in secondary animal commodities from this use.

D. Rotational Crop Restrictions

No tolerances for inadvertent residues of cloransulam-methyl are required in rotational crops. The restrictions that appear on the labeling proposed for registration under the Federal Insecticide Fungicide and Rodenticide Act (FIFRA), as amended, are due to potential of phytotoxicity to susceptible plants.

E. International Residue Limits

There are no Codex Alimentarius Commission (Codex) Maximum Residue Levels (MRLs) for cloransulam-methyl.

IV. Conclusion

The analysis for cloransulam-methyl using tolerance level residues for all population subgroups examined by EPA shows the use on soybeans will not cause exposure at which the Agency believes there is an appreciable risk. Based on the information cited above, EPA has determined that establishing tolerances for residues of cloransulam-methyl plus its acid, cloransulam, calculated as parent ester in or on soybean seed at 0.02 parts per million (ppm), soybean forage at 0.1 ppm, and soybean hay at 0.2 ppm will be safe; therefore, the tolerances are established as set forth below.

V. Objections and Hearing Requests

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

Any person may, by November 18, 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.

VI. Public Docket

EPA has established a record for this rulemaking under docket control number [OPP–300550] (including any comments and data submitted electronically). A public version of this record, including printed, paper versions of electronic comments, which does not include any information claimed as CBI, is available for inspection from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The public record is located in Room 1132 of the Public Information and Records Integrity Branch, Information Resources and Services Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA.

Electronic comments may be sent directly to EPA at:

opp-docket@epamail.epa.gov.

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

VII. Regulatory Assessment Requirements

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

In addition, since these tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the 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.

VIII. 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 29, 1997.

Daniel M. Barolo,

Director, 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 § 180.514 to read as follows:

§ 180.514 Cloransulam-methyl; tolerances for residues.

(a) *General.* Tolerances are established for residues of the herbicide, cloransulam-methyl, *N*-(2-carboxymethyl-6-chlorophenyl)-5-ethoxy-7-fluoro-(1,2,4)-triazolo[1,5c]-pyrimidine-2-sulfonamide, plus its acid, cloransulam, calculated as parent ester in or on the following raw agricultural commodities:

Commodity	Parts per million
Soybean, forage	0.1
Soybean, hay	0.2
Soybean seed	0.02

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

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

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

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 271 and 272

[FRL–5871–3]

Texas:Final Authorization and Incorporation by Reference of State Hazardous Waste Management Program

AGENCY: Environmental Protection Agency (EPA)

ACTION: Immediate final rule.

SUMMARY: Texas has revised its hazardous waste program under the Resource Conservation and Recovery Act (RCRA). The EPA has reviewed Texas' changes to its program and has made a decision, subject to public review and comment, that Texas' hazardous waste program revisions satisfy all of the requirements necessary to qualify for final authorization. Unless adverse written comments are received during the review and comment period provided for public participation in this process, EPA intends to approve Texas' hazardous waste program revisions. Texas' program revisions are available for public review and comment. In addition, today's document corrects technical errors made in the table of authorities published in the May 24, 1990, April 11, 1994 and April 12, 1994 authorization notices for Texas.

The EPA uses part 272 of Title 40 Code of Federal Regulations (CFR) to provide notice of the authorization status of State programs, and to incorporate by reference those provisions of the State statutes and regulations that EPA will enforce under RCRA Sections 3008, 3013 and 7003. Thus, EPA intends to codify the Texas authorized State program in 40 CFR part 272. The purpose of this action is to incorporate by reference EPA's approval of Texas' base hazardous waste program and its revisions to that program.

DATES: Final authorization for Texas' program revisions shall be effective December 3, 1997 unless EPA publishes a prior **Federal Register** action withdrawing this immediate final rule. All comments on Texas' program revisions must be received by the close of business November 3, 1997. The corrections to the May 24, 1990, April 11, 1994, and April 12, 1994 authorization notices go into effect immediately. The incorporation by reference of certain Texas statutes and regulations was approved by the Director of the Federal Register as of December 3, 1997 in accordance with 5 U.S.C. 552(a) and 1 CFR part 51.