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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 136

Guidelines Establishing Test Procedures for the Analysis of Pollutants

CFR Correction

In Title 40 of the Code of Federal Regulations, parts 136 to 149, revised as of July 1, 1997, page 17, § 136.3, Table 1C, entry 53, ''2,3'' is corrected to read ''2,4''.

BILLING CODE 1505–01–D

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300700; FRL 6023–8]

RIN 2070–AB78

Triasulfuron; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for residues of triasulfuron [3-(6-methoxy-4-methyl-1,3,5-triazin-2-yl)-1-(2-(2-chloroethoxy)phenylsulfonyl)urea] in or on cattle, kidney; goat, kidney; grass, forage; grass, hay; horse, kidney; and sheep, kidney. Novartis Crop Protection, Inc., 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 August 18, 1998. Objections and requests for hearings must be received by EPA on or before October 19, 1998.

ADDRESSES: Written objections and hearing requests, identified by the docket control number, [OPP–300700], 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–300700], must also be submitted to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring a copy of objections and hearing requests to Rm. 119, CM#2, 1921 Jefferson Davis Hwy., Arlington, VA.

A copy of objections and hearing requests filed with the Hearing Clerk may also be submitted electronically by sending electronic mail (e-mail) to: opp-docket@epamail.epa.gov. Copies of objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Copies of objections and hearing requests will also be accepted on disks in WordPerfect 5.1/6.1 or ASCII file format. All copies of objections and hearing requests in electronic form must be identified by the docket control number [OPP–300700]. 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: Jim Tompkins, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail address: Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, 703–305–5697; e-mail: tompkins.jim@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of May 29, 1998 (63 FR 29401), (FRL 5791–2) 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 3F4225) for tolerance by Novartis Crop Protection Inc., P.O. Box 18300, Greensboro, North Carolina 27419–8300. This notice included a summary of the petition prepared by Novartis Crop Protection Inc., the registrant. There were no comments received in response to the notice of filing.

The petition requested that 40 CFR 180.459 be amended by establishing a permanent tolerance for residues of the herbicide triasulfuron in or on cattle, kidney at 0.5 parts per million (ppm); goat, kidney at 0.5 ppm; grass, forage at 7.0 ppm; grass, hay at 2.0 ppm; horse, kidney at 0.5 ppm, and sheep, kidney at 0.5 ppm.

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% 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 three sources are not typically added because of the very low probability of this occurring in most cases, and because the other conservative assumptions built into the assessment assure adequate protection of public health. However, for cases in which high-end exposure can reasonably be expected from multiple sources (e.g. frequent and widespread homeowner use in a specific geographical area), multiple high-end risks will be aggregated and presented as part of the comprehensive risk assessment/characterization. Since the toxicological endpoint considered in this assessment reflects exposure over a period of at least 7 days, an additional degree of conservatism is built into the assessment; i.e., the risk assessment nominally covers 1–7 days exposure, and the toxicological endpoint/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.

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 triasulfuron and to make a determination on aggregate exposure, consistent with section 408(b)(2), for a tolerance for residues of triasulfuron on cattle, kidney at 0.5 ppm; goat, kidney at 0.5 ppm; grass, forage at 7.0 ppm; grass, hay at 2.0 ppm; horse, kidney at 0.5 ppm, and sheep, kidney at 0.5 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 triasulfuron are discussed below.

1. *Acute Toxicity*. A battery of acute studies were conducted. The acute oral estimated lethal dose (LD_{50}) which is acutely lethal to 50% of the animals tested in rats is greater than (>) 5 grams/kilogram (g/kg) which is toxicity Category IV. The acute dermal LD_{50} in rats is > 2 g/kg which is toxicity Category III. The acute inhalation lethal concentation LC_{50} in the rat is > 5.19 mg/liter/4 hours of exposure for technical grade triasulfuron, which is Toxicity Category IV. Triasulfon is classified in toxicity Category III for eye irritation (rabbit), toxicity Category IV for skin irritation, and did not cause dermal sensitization.

2. *Subchronic Toxicity (technical)*. A 13–week subchronic feeding study in rats produced a NOEL (no observable effect level) of 10/mg/kg/day and a LOEL (lowest observable effect level) of 500 mg/kg/day based on decreased weight gain and food intake in both sexes.

A 21–day dermal toxicity study in rabbits produced no NOEL for systemic effects, a NOEL for irritation of 1,000 mg/kg/day, and a LOEL for systemic effects of 10 mg/kg/day based on dyspnea, and ruffled fur that were not considered appropriate endpoints for human risk assessment.

3. *Chronic toxicity (technical)*. A chronic feeding study in dogs produced a NOEL of 2.5 mg/kg/day and a LOEL of 25 mg/kg/day based on increased prostrate cystic hyperplasia.

An carcinogenicity study in mice produced a NOEL of 1.2 mg/kg/day and a LOEL of 129 mg/kg/day based on centrilobular hepatocytomegaly in male mice. There was no evidence of oncogenicity.

A chronic feeding/carcinogenicity study in rats produced a NOEL of 32.1 mg/kg/day and a LOEL of 220.8 mg/kg/day based on decreased mean body weight and decreased body weight gain. There was no evidence of carcinogenicity.

B. Toxicological Endpoints

1. *Acute toxicity*. A toxicological effect attributable to a single exposure (dose) was not identified in the studies available in the data base including the developmental toxicity studies in rats and rabbits. Additionally, there were no data requirements for acute or subchronic rat neurotoxicity studies since there was no evidence of neurotoxicity in any of the toxicology studies at very high doses.

2. *Short - and intermediate - term toxicity*. The short- and intermediate-term dermal and inhalation endpoints are based on oral developmental and subchronic studies, respectively and route-to-route extrapolation. The short-term dermal and inhalation No Observable Effect Level (NOEL) dose of 100 mg/kg/day is based on decreased body weight and decreased body weight gain in pregnant rats, while the intermediate-term dermal and inhalation NOEL dose of 10 mg/kg/day is based on decreased body weight and food intake in rats of both sexes.

3. *Chronic toxicity*. EPA has established the RfD for triasulfuron at 0.01 milligrams/kilogram/day (mg/kg/day). This RfD is based on the NOEL of 1.2 mg/kg/day established from the chronic feeding/carcinogenicity study in mice.

4. *Carcinogenicity*. Classified as category E: not likely to be a human carcinogen.

C. Exposures and Risks

1. *From food and feed uses*. Tolerances have been established (40 CFR 180.459) for the residues of triasulfuron, in or on a variety of raw agricultural commodities. Permanent tolerances are already established on barley, wheat, and various livestock commodities fat, meat and meat by product of cattle, hogs, sheep, goats and horses other than kidney, and milk. Risk assessments were conducted by EPA to assess dietary exposures and risks from triasulfuron 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. An acute dietary risk assessment is not required because no acute toxicological endpoints were identified for triasulfuron.

ii. *Chronic exposure and risk*. The Dietary Risk Exposure System (DRES) was used for conducting a chronic dietary (food only) exposure analysis . The analysis evaluates individual food consumption, as reported by respondents in the USDA 1977–78 Nationwide Food Consumption Survey, and accumulates exposure to the chemical for each commodity.

In conducting this chronic dietary (food) risk assessment, the Agency has made very conservative assumptions: that all commodities having triasulfuron tolerances will contain residues of triasulfuron and those residues will be at the level of the tolerance. This results in an over estimate of human dietary exposure.

Using the assumptions and data parameters described above, the DRES exposure analysis results in an exposure that is equivalent to the following percentages of the RfD:

Population Subgroup	Exposure (mg/kg/day)	%RfD
U.S. Population (48 states)	0.00046	4.6%
Nursing Infants (<1 year old)	0.00040	4.0%
Non-Nursing Infants (<1 year old)	0.0015	15%
Children (1–6 years old)	0.0011	11%
Children (7–12 years old)	0.00073	7.3%
Females (13–19 years old, not preg. or nursing)	0.00040	4.0%
Hispanics	0.00056	5.6%
Non-Hispanic others	0.00050	5.0%
Males (13–19 years old)	0.00052	5.2%

2. *From drinking water*. No monitoring data are available to perform a quantitative drinking water risk assessment for triasulfuron at this time. The Agency used a Tier I drinking water assessment. This assessment utilized the SCI-GROW and GENEEC screening models to provide estimates of ground and surface water contamination respectively from triasulfuron, but did not consider the behavior of degradates.

i. *Acute exposure and risk.* An acute drinking water risk assessment is not required because no acute toxicological endpoints were identified for triasulfuron.

ii. *Chronic exposure and risk.* Based on the chronic dietary (food) exposure and using default body weights and water consumption figures, chronic drinking water levels of concern (DWLOC) for drinking water were calculated. To calculate the DWLOC, the chronic dietary food exposure was subtracted from the RfD.

Chronic water exposure (mg/kg/day) x (body weight) $DWLOC_{chronic}$ = consumption (L) x 10^{-3} mg/µg where chronic water exposure (mg/kg/day) = RfD - (chronic food + residential exposure (mg/kg/day)

The Agency's default body weights and water consumption values used to calculate DWLOCs are as follows: 70 kg/2L (adult male), 60 kg/2L (adult female), and 10 kg/1L (child).

For the most highly exposed populations subgroup, non-nursing infants (< 1 year old), chronic dietary (food only) exposure occupies 15% of the RfD. This is a conservative risk estimate for reasons described above. The chronic DWLOC for the non-nursing infants (< 1 year old) subgroup is 85 ppb. The predicted 56–day average surface water concentration by the GENEEC model is 1.68 g/L (ppb) and the estimated ground water concentration by the SCI-GROW model is 0.19 g/L (ppb). Therefore, exposure from water is below EPA's DWLOC for chronic dietary exposure for all of the populations examined.

3. *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 triasulfuron 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, triasulfuron 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 triasulfuron has a common mechanism of toxicity with other substances.

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

1. *Acute risk.* The Agency has concluded that the acute aggregate risk from the proposed use is acceptable. A toxicological effect attributable to a single exposure dose was not identified in any of the studies available in the data base .

2. *Chronic risk.* Using the TMRC exposure assumptions described above, EPA has concluded that aggregate exposure to triasulfuron from food will utilize 4.6% of the RfD for the U.S. population. The major identifiable subgroup with the highest aggregate exposure is discussed below. EPA generally has no concern for exposures below 100% of the RfD because the RfD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health. Despite the potential for exposure to triasulfuron in drinking water and the diet, EPA does not expect the aggregate exposure to exceed 100% of the RfD. There are no registered residential uses of triasulfuron.

3. *Aggregate cancer risk for U.S. population.* In 1991, the Agency classified triasulfuron as a ''Group E - Evidence of non-carcinogenicity for humans.'' Therefore, the proposed use is not expected to pose an unacceptable carcinogenic risk.

4. *Conclusion.* Aggregate exposure to residues of triasulfuron in the diet and drinking water is not expected to exceed 100% of the reference dose. EPA concludes that there is a reasonable certainty that no harm will result from aggregate exposure to triasulfuron residues in food and drinking water.

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 triasulfuron, 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 uncertainty factor usually 100 for combined inter- and intra-species variability and not the additional tenfold MOE/uncertainty is not necessary because 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 do not raise concerns regarding the adequacy of the standard MOE/safety factor.

ii. *Developmental toxicity studies.* Triasulfuron was evaluated in a developmental study in Tif: RAIF (SPF) rats. The following dose levels were administered by gavage on days 6–15 of gestation: 0, 100, 300 or 900 mg/kg/day. The maternal NOEL was 100 mg/kg/day and the maternal LOEL was 300 mg/kg/day based on decreased body weight and decreased body weight gain during gestation. The developmental NOEL and LOEL were 300 and 900 mg/kg/day (HDT), respectively based on reduced ossification of vertebrae, metatarsals and phalanges.

Triasulfuron was administered to pregnant female chinchilla rabbits by gavage at dose levels of 0, 40, 120, or 240 mg/kg from days 6 through 18 of gestation. Triasulfuron did not elicit evidence of developmental toxicity at doses up to and including the high dose of 240 mg/kg/day. The developmental toxicity NOEL is > 240 mg/kg/day. Maternal toxicity was observed at 240 mg/kg/day manifested as decreased body weight gain during gestation. The maternal toxicity LOEL is 240 mg/kg/day and the NOEL is 120 mg/kg/day.

iii. *Reproductive toxicity study.* Triasulfuron was evaluated in a 2–generation reproduction study in the Sprague-Dawley rat. Dosage levels employed were 0, 0.5, 50, or 250 mg/kg/day. The parental LOEL is 250 mg/kg/day based on significant decreases in premating and total body weight gain for the F0 and F1 parental animals. The parental NOEL is 50 mg/kg/day. The reproductive NOEL and LOELs are 50 and 250 mg/kg/day, respectively based on reduced F1a pup weights at birth and during lactation .

iv. *Pre- and post-natal sensitivity.* The data provided noindication of increased susceptibility of rats or rabbits to *in utero* and/or postnatal exposure to triasulfuron. In the prenatal developmental toxicity study in rats, developmental toxicity was seen only in the presence of maternal toxicity. In the developmental toxicity study in rabbits, no evidence of developmental toxicity was seen, even in the presence of maternal toxicity at the highest dose tested. In the two–generation reproduction study in rats, effects in the offspring were observed only at or above treatment levels that resulted in evidence of parental toxicity. In addition, there is no indication that triasulfuron is a neurotoxic herbicide. No additional safety factor is needed.

v. *Conclusion.* The database is complete and the data provided no indication of increased susceptibility of rats or rabbits to *in utero* and/or postnatal exposure to triasulfuron. Therefore, EPA concluded that no additional safety factor is needed to protect the safety of infants and children.

2. *Chronic risk.* Using the conservative exposure assumptions described above, EPA has concluded that aggregate exposure to triasulfuron from food will utilize 15% of the RfD for infants and children. EPA generally has no concern for exposures below 100% of the RfD because the RfD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health. Despite the potential for exposure to triasulfuron in drinking water and the diet, EPA does not expect the aggregate exposure to exceed 100% of the RfD. There are no registered residential uses of triasulfuron. EPA concludes that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to triasulfuron residues in food and drinking water.

III. Other Considerations

A. Metabolism In Plants and Animals

In the rat, triasulfuron is excreted primarily in the urine (70–99%) with lesser amounts excreted in the feces. The majority of excretion occurs in the first 24 hours following exposure. Residue levels in the tissues are < 0.1% of the administered dose. The major excretion product is unchanged triasulfuron in both urine and feces.

In plants, residues of triasulfuron are systemic, and the residue of regulating conern is exclusively the parent compound. In wheat, the nature of triasulfuron residues and metabolism are adequately understood, where metabolism proceeds by hydroxylation of the pheny ring and hydrolytic cleavage of the urea dridge. EPA has concluded that triasulfuron metabolism in wheat can be translated to grasses, and that only the parent compound is of regulatory concern in grasses. The nature of the residue in ruminants and poultry is adequately understood. The nature of regulatory concern is the parent compound.

B. Analytical Enforcement Methodology

1. *Plants.* Suitable analytical methodology exists to enforce the extension of the tolerances on grasses. Method AG-500B column switching HPLC with UV detection has undergone successful petition method validations on wheat grain and straw and has been accepted by the Agency as the enforcement analytical method for wheat and barley. The registrant has validated this method in grass forage and hay at the limit of quantitation (LOQ), 0.05 ppm. The Agency has previously concluded that Method AG-500B is acceptable to enforce tolerances on grass hay and forage.

2. *Animals.* Suitable analytical methodology exists to enforce the tolerances on animal commodities, including the tolerances on kidneys. Method AG-508B revised column switching HPLC with UV detection has undergone successful petition method validation on milk, beef muscle and kidney and has been accepted by the Agency as the enforcement analytical method for animal commodities. The validated LOQ is 0.01 ppm for milk; 0.05 ppm for beef muscle, fat, liver, and kidney; 0.05 ppm for eggs; and 0.05 ppm for poultry meat, fat, and liver.

3. *Multiresidue methods.* Triasulfuron and four of its metabolites were tested through the FDA multiresidue protocols. The submission was forwarded to FDA for evaluation. Triasulfuron was not determinable by any of the protocols .

C. Magnitude of Residues

The field trial data on grasses support tolerance levels of 7 ppm in grass forage and 2 ppm in grass hay for residues of triasulfuron in conjunction with the proposed use pattern. Also see Meat, Milk, Poultry, and Eggs. No additional field trial data are required for this petition.

1. *Meat, milk, poultry, and eggs.* Grasses are feedstuffs for beef and dairy cattle. An acceptable feeding study in dairy cattle conducted at 15, 75, and 150 ppm has previously been reviewed and various animal commodity tolerances were subsequently established (milk, 0.02 ppm; meat, fat, and meat by-products of cattle, goats, hogs, horses, and sheep at 0.1 ppm). The existing tolerances for triasulfuron in animal commodities are adequate to cover the use of triasulfuron on grasses with the exception of the tolerances on kidneys. Accordingly, higher triasulfuron tolerances of 0.5 ppm for the kidneys of cattle, goats, horses, and sheep are required to support the tolerances on grasses.

2. *Processed Food/Feed.* There are no processed commodities associated with grasses.

D. International Residue Limits

There are no CODEX, Canadian, or Mexican maximum residue limits for residues of triasulfuron.

E. Rotational Crop Restrictions

There are extensive, very specific rotational crop restrictions on the product label for the crops: barley, rye, oats, Bermudagrass, proso millet, field corn, grain sorghum, soybeans, sugar beets, sunflowers, and onions. There are no rotational or reseeding restrictions for the planting of wheat.

IV. Conclusion

Therefore, the tolerances are established for residues of triasulfuron in cattle, goat, horse, and sheep kidney at 0.5 ppm, grass forage at 7 ppm, grass hay at 2 ppm.

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 October 19, 1998 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 Record and Electronic Submissions

EPA has established a record for this rulemaking under docket control number [OPP–300700] (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 Rm. 119 of the Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA.

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.

VII. Regulatory Assessment Requirements

This final rule establishes a tolerance under FFDCA section 408(d) inresponse 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 tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. Nevertheless, the Agency haspreviously 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 Comptroller General

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fariness Act of 1996, generally provides that before a rule may take effect, the Agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in

the **Federal Register**. This rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

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

Dated: August 11, 1998.

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 180.459, is amended as follows:

i. By adding a heading to paragraph (a).

ii. In paragraph (b), by alphabetically adding the commodities to the table in paragraph (a), removing the remaining text, and by reserving and adding a heading.

iii. By adding heading and reserving paragraphs (c) and (d) to read as follows.

§180.459 Triasulfuron; tolerances for residues

(a) *General.* * * *

Commodity	Parts per million
Cattle, kidney	00.5
Goat, kidney	00.5
Grass, forage	07.0
Grass, hay	02.0
Horses, kidney	00.5
Sheep, kidney	00.5

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

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

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

[FR Doc. 98–22192 Filed 8–17–98; 8:45 am]

BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 271

[FRL–6145–2]

Delaware: Final Authorization of State Hazardous Waste Management Program Revisions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Immediate final rule.

SUMMARY: The State of Delaware has applied for final authorization of revisions to its hazardous waste program under the Resource Conservation and Recovery Act (RCRA). The Environmental Protection Agency (EPA) has reviewed Delaware's application and has determined that Delaware's hazardous waste program revision satisfies all of the requirements necessary to qualify for final authorization. Unless adverse written comments are received on this action during the review and comment period provided in a companion document in the ''Proposed Rules'' section of today's **Federal Register**, EPA's decision to approve Delaware's hazardous waste program revision will take effect as provided below. Delaware's application for program revision is available for public review and comment.

DATES: Final authorization for the State of Delaware shall be effective October 19, 1998 unless EPA publishes a prior **Federal Register** action withdrawing this immediate final rule. Any comments on Delaware's program revision application must be filed as provided in the companion document on this action, appearing in the Proposed Rules section of today's **Federal Register**.

ADDRESSES: Copies of Delaware's program revision application are available from 8 a.m. to 4:30 p.m., Monday through Friday, at the following addresses for inspection and copying: Delaware Department of Natural Resources and Environmental Control, 89 Kings Highway, P.O. Box 1401, Dover, DE 19903; and U.S. EPA Region III, Waste & Chemicals Management Division, 10th Floor, 1650 Arch Street, Philadelphia, PA 19103 phone (215) 814–3384. Written comments should be sent to Marie Owens, Mailcode 3WC21, RCRA State Programs Branch, 1650 Arch Street, Philadelphia, PA 19103, phone (215) 814–3384.

FOR FURTHER INFORMATION CONTACT: Marie Owens, Mailcode 3WC21, RCRA State Programs Branch, 1650 Arch Street, Philadelphia, PA 19103, phone (215) 814–3384.

SUPPLEMENTARY INFORMATION:

A. Background

States with final authorization under section 3006(b) of the Resource Conservation and Recovery Act (''RCRA or ''the Act''), 42 U.S.C. 6929(b), have a continuing obligation to maintain a hazardous waste program that is equivalent to, consistent with, and no less stringent than the Federal hazardous waste program. In addition, as an interim measure, the Hazardous and Solid Waste Amendments of 1984 (Public Law 98–616, November 8, 1984, hereinafter ''HSWA'') allows States to revise their programs to become substantially equivalent instead of equivalent to RCRA requirements promulgated under HSWA authority. States exercising the latter option receive ''interim authorization'' for the HSWA requirements under section 3006(g) of RCRA, 42 U.S.C. 6926(g), and later apply for final authorization for the HSWA requirements.

Revisions to State hazardous waste programs are necessary when Federal or State statutory or regulatory authority is modified or when certain other changes occur. Most commonly, State program revisions are necessitated by changes to EPA's regulations in 40 CFR parts 124, 260 through 266, 268, 270, 273 and 279.

B. Delaware

Delaware received final authorization effective June 22, 1984 (see 53 FR 23837, June 8, 1984) to implement its hazardous waste management program in lieu of the Federal program. On January 31, 1986 (see 51 FR 3954), the authorized Delaware program was incorporated by reference into the Code of Federal Regulations (CFR). On April 9, 1996, Delaware submitted a program revision application for additional approval in accordance with the requirements of 40 CFR 271.21(b)(3) (Procedures for Revisions of State Programs). Delaware received final authorization on this program revision application on October 7, 1996 (see 61 FR 41345). On June 15, 1998, Delaware submitted a second program revision application for additional approval in accordance with the requirements of 40 CFR 271.21(b)(3) (Procedures for Revisions of State Programs).

EPA has reviewed Delaware's application, and has made an immediate final decision, subject to review and comment, that Delaware's hazardous waste program revision satisfies all of the requirements necessary to qualify for final authorization. Consequently, EPA intends to grant final authorization