

DELEGATION STATUS FOR PART 63 STANDARDS—ARIZONA—Continued

Subpart	Description	ADEQ ¹	MCESD ²	PDEQ ³	PCAQCD ⁴
XXX	Ferroalloys Production	X

¹ Arizona Department of Environmental Quality.
² Maricopa County Environmental Services Department.
³ Pima County Department of Environmental Quality.
⁴ Pinal County Air Quality Control District.

[FR Doc. 01-28342 Filed 11-15-01; 8:45 am]
 BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP-301191; FRL-6810-2]

RIN 2070-AB78

Linear alkyl C₁₂₋₁₆ propoxyamine ethoxylate; Exemption from the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes an exemption from the requirement of a tolerance for residues of poly[oxy(methyl-1,2-ethanediyl)], α-[2-bis(2-hydroxyethyl)amino]propyl]-ω-hydroxy,-ether with α-hydro-ω-hydroxypoly(oxy-1,2-ethanediyl) (1:2), mono-C₁₂₋₁₆ alkyl ethers (hereinafter “linear alkyl C₁₂₋₁₆ propoxyamine ethoxylate”) when used as an inert ingredient (surfactant) when applied to growing crops, or to raw agricultural commodities after harvest. Huntsman Corporation submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA) requesting an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of linear alkyl C₁₂₋₁₆ propoxyamine ethoxylate.

DATES: This regulation is effective November 16, 2001. Objections and requests for hearings, identified by docket control number OPP-301191, must be received by EPA on or before January 15, 2002.

ADDRESSES: Written objections and hearing requests may be submitted by mail, in person, or by courier. Please follow the detailed instructions for each method as provided in Unit VIII. of the **SUPPLEMENTARY INFORMATION.** To ensure proper receipt by EPA, your objections and hearing requests must identify docket control number OPP-301191 in

the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Treva Alston, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 308-8373; and e-mail address: alston.treva@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected categories and entities may include, but are not limited to:

Categories	NAICS Codes	Examples of Potentially Affected Entities
Industry	111 112 311 32532	Crop production Animal production Food manufacturing Pesticide manufacturing

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in the table could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether or not this action might apply to certain entities. If you have questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT.**

B. How Can I Get Additional Information, Including Copies of this Document and Other Related Documents?

1. *Electronically.* You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet Home Page at <http://www.epa.gov/>. To access this document, on the Home Page select

“Laws and Regulations,” “Regulations and Proposed Rules,” and then look up the entry for this document under the “**Federal Register—Environmental Documents.**” You can also go directly to the **Federal Register** listings at <http://www.epa.gov/fedrgstr/>. A frequently updated electronic version of 40 CFR part 180 is available at http://www.access.gpo.gov/nara/cfr/cfrhtml/180/Title_40/40cfr180_00.html, a beta site currently under development.

2. *In person.* The Agency has established an official record for this action under docket control number OPP-301191. The official record consists of the documents specifically referenced in this action, and other information related to this action, including any information claimed as Confidential Business Information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305-5805.

II. Background and Statutory Findings

In the **Federal Register** of August 14, 1998 (63 FR 43708) (FRL-6019-8), EPA issued a notice pursuant to section 408 of the FFDCA, 21 U.S.C. 346a, as amended by the FQPA (Public Law 104-170) announcing the filing of a pesticide petition (PP 5E4487) by Huntsman Petrochemical Corporation, 3040 Post Oak Blvd., Houston, TX 77056. This notice included a summary of the petition prepared by the petitioner. There were no comments received in response to the notice of filing.

The petition requested that 40 CFR 180.1001(c) be amended by establishing an exemption from the requirement of a tolerance for residues of

[poly[oxy(methyl-1,2-ethanediyl)], α -[2-bis(2-hydroxyethyl)amino]propyl]- ω -hydroxy-ether with α -hydro- ω -hydroxypoly(oxy-1,2-ethanediyl) (1:2), mono- C_{12-16} alkyl ethers (CAS Reg. No. 176022-82-5).

Section 408(b)(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(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. Second, EPA examines exposure to the pesticide through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings.

III. Inert Ingredient Definition

Inert ingredients are all ingredients that are not active ingredients as defined in 40 CFR 153.125 and include, but are not limited to, the following types of ingredients (except when they have a pesticidal efficacy of their own): Solvents such as alcohols and hydrocarbons; surfactants such as polyoxyethylene polymers and fatty acids; carriers such as clay and diatomaceous earth; thickeners such as carrageenan and modified cellulose; wetting, spreading, and dispersing agents; propellants in aerosol dispensers; microencapsulating agents; and emulsifiers. The term "inert" is not intended to imply nontoxicity; the ingredient may or may not be chemically active. Generally, EPA has exempted inert ingredients from the requirement of a tolerance based on the low toxicity of the individual inert ingredients.

IV. Toxicological Profile

Consistent with section 408(b)(2)(D) of FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action and considered its validity, completeness and reliability and the relationship of this information 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 linear alkyl C_{12-16} propoxyamine ethoxylate were evaluated by two methods: A process known as structure activity relationship (SAR) assessment and review and evaluation of submitted data.

A. SAR Assessment

Linear alkyl C_{12-16} propoxyamine ethoxylate is an inert ingredient. To the best of the Agency's knowledge, linear alkyl C_{12-16} propoxyamine ethoxylate has no active ingredient properties; therefore, the complete 40 CFR part 158 data base has not been required. For linear alkyl C_{12-16} propoxyamine ethoxylate, toxicity was assessed, in part, by the SAR process. In this process, the chemical's structural similarity to other chemicals (for which data are available) is used to determine toxicity. For human health, this process, can be used to assess absorption and metabolism, mutagenicity, carcinogenicity, developmental and reproductive effects, neurotoxicity, systemic effects, immunotoxicity, and sensitization and irritation. This is a qualitative assessment using terms such as good, not likely, poor, moderate, or high.

For linear alkyl C_{12-16} propoxyamine ethoxylate the SAR assessment determined that the chemical was not structurally related to any known carcinogens or developmental/reproductive toxicants. The following human exposures were examined as part of the analysis: inhalation, dermal, exposures to the eyes, and drinking water. There were concerns for irritation to eyes, skin, lungs, and mucous membranes. Overall, the level of concern for human health was characterized as low to moderate. Absorption was rated as poor through the skin, good through the lungs, and moderate through the gastrointestinal tract.

B. Review of Submitted Data

1. *Acute oral toxicity - rat.* Lethal Dose (LD₅₀) for combined sexes is from 1,154 to 1,993 milligrams/kilograms

(mg/kg). Clinical effects observed in both sexes included decreased activity, poor grooming, abnormal stance and gait, diarrhea, dyspnea, chromodacryorrhea, decreased muscle tone, lacrimation, and prostration. (Toxicity Category III).

2. *Acute dermal toxicity - rabbit.* The observed lethal dose for males and females is greater than 2,000 mg/kg. Clinical signs of toxicity included abnormal gait, abnormal stance, unspecified alopecia, decreased muscle tone, salivation, decreased activity, and poor grooming. (Toxicity Category III).

3. *Primary eye irritation - rabbit.* It was determined that the test substance was a severe but reversible ocular irritant. (Toxicity Category II).

4. *Primary dermal irritation - rabbit.* Several dermal irritations characterized by severe erythema and edema, necrosis, fissuring, and sloughing of the epidermis was observed. (Toxicity Category II).

5. *Dermal sensitization - guinea pig.* It was observed that the test substance was a dermal sensitizer.

6. *Subchronic oral toxicity feeding - rats.* The no observable adverse effect level (NOAEL) is 1,000 ppm in males (equivalent to 58.9 mg/kg/day) and 500 ppm (equivalent to 35.4 mg/kg/day) in females. The lowest observable adverse effect level (LOAEL) is 3,000 ppm (equivalent to 173.6 mg/kg/day) in males and 1,000 ppm (equivalent to 68.9 mg/kg/day) in females based on decreased body weight gain.

7. *90-Day feeding capsule - dog.* The NOAEL is 10 mg/kg/day. The LOAEL is 30 mg/kg/day based on clinical signs of toxicity in females and decreased body weight gain in males.

8. *Oral developmental toxicity - rats.* The test material was administered by gavage to pregnant rats on gestation days 6 through 15. The maternal NOAEL is 25 mg/kg/day. The maternal LOAEL is 75 mg/kg/day, based on clinical signs of toxicity and reductions in body weight, body weight gains, and food consumption. The developmental NOAEL is 75 mg/kg/day. The developmental LOAEL is 150 mg/kg/day, based on decreased fetal weights and increases in incidences of skeletal variation related to decreased ossification.

9. *In vitro mammalian cytogenetics - chromosome aberrations in human lymphocytes.* There were no statistically significant increases in chromosome aberrations at any dose level with or without metabolic activation. No mutagenic concerns were demonstrated.

10. *Salmonella typhimurium and Escherichia coli mammalian activation reverse gene mutation assay.* There were

no statistically significant differences in the number of revertant colonies in any tester strain at any dose level or condition. No mutagenic concerns were demonstrated.

C. Toxicological Endpoints

1. *Acute dietary toxicity.* For an acute dietary risk assessment, the Agency selected a developmental NOAEL of 75 mg/kg/day from the developmental toxicity study in the rat. The LOAEL is 150 mg/kg/day.

2. *Short-term dermal toxicity.* For a short-term dermal risk assessment, the Agency selected a developmental NOAEL of 75 mg/kg/day from the developmental toxicity study in the rat. The LOAEL is 150 mg/kg/day.

3. *Intermediate- and long-term dermal toxicity.* For intermediate- and long-term dermal risk assessment, the Agency selected a NOAEL of 10 mg/kg/day from a 90-day toxicity study in dogs (capsules). The LOAEL is 30 mg/kg/day.

4. *Short-term inhalation.* For a short-term inhalation risk assessment, the Agency selected a NOAEL of 75 mg/kg/day from the developmental study in the rat. The LOAEL is 150 mg/kg/day.

5. *Intermediate- and long-term inhalation.* For an intermediate- and long-term inhalation risk assessment, the Agency selected a NOAEL of 10 mg/kg/day from a 90-day toxicity study in the dog (capsules). The LOAEL is 30 mg/kg/day.

6. *Chronic dietary toxicity.* For a chronic dietary risk assessment, the Agency selected a NOAEL of 10 mg/kg/day from the 90-day dog (capsule) study. The LOAEL is 30 mg/kg/day.

7. *No dermal studies or dermal absorption data were submitted.* However, the SAR analysis rated absorption through the skin as poor. Therefore, a dermal absorption factor of 10% will be used.

8. *No inhalation studies were submitted.* However, the SAR assessment rated absorption through the lungs as good. Therefore, an inhalation absorption factor of 100% will be used.

D. Conclusions

The SAR assessment rated linear alkyl C₁₂₋₁₆ propoxyamine ethoxylate as a low to moderate toxicity chemical. Linear alkyl C₁₂₋₁₆ propoxyamine ethoxylate is a surfactant, that is, a chemical used to modify the nature of a surface, such as reducing the surface tension of water. Surfactants can be used as wetting agents, detergents, penetrants, and emulsifiers. However, it is believed that the low to moderate rating is indicative of the known properties of a surfactant, not necessarily of the toxicological

effects unique to linear alkyl C₁₂₋₁₆ propoxyamine ethoxylate. By their very nature, surfactants are often corrosive and irritating. The effects displayed in the reviewed studies (decreased body weight gain, and possibly even the salivation) were probably due to the corrosion/irritation factor and not to other mechanisms of toxicity. The findings of the SAR assessment did not conflict with the data reviews.

Based on the SAR assessment, and review and evaluation of the submitted data, the Agency concludes that linear alkyl C₁₂₋₁₆ propoxyamine ethoxylate is a low/moderate toxicity chemical with the demonstrated effects consistent with the characteristics of a surfactant. No other effects of concern were noted. No additional toxicity data are required.

E. Population Adjusted Doses

1. *Safety factors.* The Agency will use the NOAELs and LOAELs in Unit IV.C. to assess the risks of using linear alkyl C₁₂₋₁₆ propoxyamine ethoxylate to the general population and certain subgroups of the general population. However, the Agency first modifies these values numerically downward by dividing the NOAEL by two or more safety factors. The safety (uncertainty) factors used are: A 10-fold factor to account for intraspecies variability (the differences in how the test animals reacted to the test substance) and a 10-fold factor to account for interspecies variation (the use of animal studies to predict human risk).

2. *Acute dietary toxicity.* The Agency divided the NOAEL by 100 (10X interspecies extrapolation, 10X intraspecies variation) to calculate the acute Population Adjusted Dose (aPAD). The aPAD is the quantity of a substance which if consumed in a single day is not expected to pose significant risk of adverse health effects. For linear alkyl C₁₂₋₁₆ propoxyamine ethoxylate the aPAD is equal to 0.75 mg/kg/day.

3. *Chronic dietary toxicity.* The Agency divided the NOAEL of 10 mg/kg/day by 300 (10X interspecies extrapolation, 10X intraspecies variation, and 3X for extrapolating a NOAEL from a subchronic study for a chronic scenario) to calculate the chronic Population Adjusted Dose (cPAD). The cPAD is the quantity of a substance which if absorbed on a daily basis over a lifetime is not expected to pose significant risk of adverse health effects. For linear alkyl C₁₂₋₁₆ propoxyamine ethoxylate the cPAD is equal to 0.03 mg/kg/day.

V. Aggregate Exposures

In examining aggregate exposure, FFDCA section 408 directs EPA to

consider available information concerning exposures from the pesticide residue in food and all other non-occupational exposures, including drinking water from groundwater or surface water and exposure through pesticide use in gardens, lawns, or buildings (residential and other indoor uses).

EPA establishes exemptions from the requirement of a tolerance only in those cases where it can be clearly demonstrated that the risks from aggregate exposure to pesticide chemical residues under reasonably foreseeable circumstances will pose no appreciable risks to human health. In order to determine the risks from aggregate exposure to pesticide inert ingredients, the Agency considers the toxicity of the inert in conjunction with possible exposure to residues of the inert ingredient through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings. If EPA is able to determine that a finite tolerance is not necessary to ensure that there is a reasonable certainty that no harm will result from aggregate exposure to the inert ingredient, an exemption from the requirement of a tolerance may be established.

A. Dietary Exposure

1. *Food.* No tolerances have been established for linear alkyl C₁₂₋₁₆ propoxyamine ethoxylate. Huntsman Corporation has requested a tolerance exemption for the use of linear alkyl C₁₂₋₁₆ propoxyamine ethoxylate as a surfactant only in glyphosate formulations. Glyphosate is one of the most widely used pesticide chemicals; it is used on a multitude of food crops. There are over 140 glyphosate tolerances which include major food crops, such as wheat, soybeans, and corn, as well as other widely-consumed foods such as potatoes, peanuts, and all bulb, cucurbit, fruiting, and leafy vegetables. Thus, a pesticide formulation containing glyphosate as the active ingredient and linear alkyl C₁₂₋₁₆ propoxyamine ethoxylate as an inert ingredient, a surfactant, has the potential for being used on this multitude of food crops.

There are no field trial data or monitoring data available for residues of linear alkyl C₁₂₋₁₆ propoxyamine ethoxylate, which is the Agency's traditional source of exposure data for conducting a quantitative dietary risk assessment. The Agency has estimated residue levels for linear alkyl C₁₂₋₁₆ propoxyamine ethoxylate using a ratio of linear alkyl C₁₂₋₁₆ propoxyamine ethoxylate to glyphosate in the

formulated product. Thus, the glyphosate tolerance level residues were adjusted using this ratio to estimate linear alkyl C₁₂₋₁₆ propoxyamine ethoxylate residues. It should be noted that the glyphosate tolerance level residues are considered to be conservative exposure estimates which assume that 100% of the crops having glyphosate tolerances receive an application of glyphosate and that all residue levels are at the maximum legally permissible level. It is unlikely that either or both of these assumptions would actually occur, thus leading to the conservative nature of the exposure estimates. Using a ratio to adjust the glyphosate tolerance level residues to linear alkyl C₁₂₋₁₆ propoxyamine ethoxylate residue levels is a reasonable approach for this assessment for the following reasons:

Many of the uses of glyphosate are pre-emergent (i.e., take place prior to planting or emergence of the crop) and typically result in non-detectable residues of glyphosate in the harvested commodities. Although data indicate that linear alkyl C₁₂₋₁₆ propoxyamine ethoxylate is longer-lived in the environment than glyphosate, residues of linear alkyl C₁₂₋₁₆ propoxyamine ethoxylate resulting from pre-emergent uses are also expected to be non-detectable since unlike glyphosate, linear alkyl C₁₂₋₁₆ propoxyamine ethoxylate is not expected to be systemic (i.e., not able to translocate through the plant to the crop commodity). The non-systemic nature of the surfactant, that is, its inability to translocate in and of itself offers a wide margin of protection.

Some uses of glyphosate are post-emergent (i.e., made after the crops emerge). Most of these applications are for the purpose of desiccation of the crops to aid harvest. These have fairly short preharvest intervals (PHIs), which is the mandated wait period, usually given in number of days, from application of the pesticide to harvest. A short PHI means that there may be insufficient time for the applied chemicals to metabolize/degrade and therefore can still be present in significant quantities at the time of harvest. The glyphosate tolerances that result from these short PHIs, once adjusted by the ratio methodology to be linear alkyl C₁₂₋₁₆ propoxyamine ethoxylate residue levels are not likely to significantly underestimate dietary (food) exposure to linear alkyl C₁₂₋₁₆ propoxyamine ethoxylate.

The methodology by which these residue levels were estimated (ratio in formulation, conservative assumptions of 100% crop treated and maximum

legally permissible residue levels) should not underestimate residue levels of linear alkyl C₁₂₋₁₆ propoxyamine ethoxylate since: (a) For pre-emergent applications linear alkyl C₁₂₋₁₆ propoxyamine ethoxylate is not expected to translocate through the plant to the crop commodity, and thus, as explained, should result in non-detectable residues; and (b) for post-emergent uses given the lack of time for metabolism/degradation to occur for either glyphosate or linear alkyl C₁₂₋₁₆ propoxyamine ethoxylate, the persistence of linear alkyl C₁₂₋₁₆ propoxyamine ethoxylate is not a significant factor and the estimated residue levels should not underestimate food exposure to linear alkyl C₁₂₋₁₆ propoxyamine ethoxylate.

i. *Acute exposure.* Acute dietary risk assessments are performed for a food-use pesticide if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single event exposure. The Agency has conducted Tier 1 acute food exposure assessments for linear alkyl C₁₂₋₁₆ propoxyamine ethoxylate using the Dietary Exposure Evaluation Model (DEEM®). This model incorporates consumption data generated in USDA's Continuing Surveys of Food Intakes by Individuals (CSFII), 1989-1992. For this acute food risk assessment, the entire distribution of single day food consumption events is combined with a single residue level (deterministic analysis) to obtain a distribution of exposure in mg/kg/day. For a Tier 1 analysis, the Agency generally considers exposure at the 95th percentile to be representative of high end exposure. The Agency's level of concern is for exposures greater than 100% of the aPAD. For the population subgroup of concern, females 13-50 years, at the 95th percentile, the dietary exposure is 2% of the aPAD.

ii. *Chronic exposure.* In conducting this chronic dietary risk assessment the DEEM® analysis evaluated the individual food consumption as reported by respondents in the USDA 1989-1992 nationwide CSFII and accumulated exposure to the chemical for each commodity. For chronic food risk assessments, the 3-day average consumption for each subpopulation is combined with residues in commodities to determine average exposure in mg/kg/day. In performing the chronic dietary risk assessment, the Agency's level of concern is for exposures greater than 100% cPAD. The population groups with the highest percentages are children (1-6 years old) (54%), all infants (< 1 year) (51%), children (7-12

years old) (36%), total U.S. population (25%), and females (13-50 years) (19%).

2. *Drinking water exposure.* Given the limited environmental fate information, qualitatively linear alkyl C₁₂₋₁₆ propoxyamine ethoxylate can be described as a chemical that is moderately persistent to persistent based on complete mineralization (metabolism to carbon dioxide, water and basic minerals), has intermediate mobility (estimated K_{oc} ranging from 630 to 6,300) with respect to runoff in water and eroding soil/sediment, and is possibly a compound which has significant potential to bioconcentrate based on an estimated partition coefficient between water and octanol (K_{ow}).

The Agency lacks sufficient monitoring exposure data to complete comprehensive dietary exposure analysis and risk assessment for linear alkyl C₁₂₋₁₆ propoxyamine ethoxylate. Because the Agency does not have comprehensive monitoring data, drinking water concentration estimates are made by reliance on simulation or modeling taking into account data on the characteristics of linear alkyl C₁₂₋₁₆ propoxyamine ethoxylate.

None of these models include consideration of the impact processing (mixing, dilution, or treatment) of raw water for distribution as drinking water would likely have on the removal of pesticides from the source water. The primary use of these models by the Agency at this stage is to provide a coarse screen for sorting out pesticides for which it is highly unlikely that drinking water concentrations would ever exceed human health levels of concern.

Since the models used are considered to be screening tools in the risk assessment process, the Agency does not use estimated environmental concentrations (EECs) from these models to quantify drinking water exposure and risk as a % PAD. Instead drinking water levels of comparison (DWLOCs) are calculated and used as a point of comparison against the model estimates of a pesticide's concentration in water. DWLOCs are theoretical upper limits on a pesticide's concentration in drinking water in light of total aggregate exposure to a pesticide in food, and from residential uses.

In lieu of submitted environmental fate studies on linear alkyl C₁₂₋₁₆ propoxyamine ethoxylate, the water modeling inputs were estimated based on available fate and transformation data. The assumption ranged from no sorption to soil and no degradation to some sorption and some degradation. Considering the number of crops on

which glyphosate is used, a percent crop area adjustment was not used. To model Tier 1 surface water concentrations, the Agency uses the FQPA Index Reservoir Screening Tool (FIRST) to calculate the concentrations used in the drinking water assessment. It represents a small drinking water reservoir surrounded by a run-off prone watershed. FIRST estimates expected concentrations from a few basic chemical parameters and pesticide label application information. It is a Tier 1 model which uses a chemical's soil/water partition coefficient and degradation half-life values to estimate runoff from an agricultural field into a drinking water reservoir. FIRST considers reductions in dissolved pesticide concentration due to adsorption of pesticide to soil or sediment, incorporation, degradation in soil before wash off to a water body, direct deposition of spray drift into the water body, and degradation of the pesticide within the water body.

Using FIRST, the estimated acute concentrations for surface water ranged from 43 to 185 µg/L. The estimated chronic concentrations from surface water ranged from 6 to 133 µg/L. Both ranges include an estimate with the assumption that the chemical is stable to biotic and abiotic processes and infinitely mobile. Reasonable high-end estimates of exposure based on a metabolism half-life in soil and water of 110 days and a partition coefficient of 630 mL/g O.C. (organic carbon) are 13 µg/L for a yearly average concentration and 92 µg/L for a peak concentration.

SCI-GROW (Screening Concentration in Ground Water) estimates "worst case" groundwater concentrations of pesticides considering the maximum allowable use rate in an area where the groundwater is exceptionally vulnerable to contamination. The model uses existing environmental fate properties of the chemical being examined, the application rate from the label, and the existing body of data from Agency-required small-scale prospective and two large-scale prospective groundwater monitoring studies for all pesticides. It should be noted that SCI-GROW is biased in the sense that negative data were ignored, i.e., studies where the pesticide was not detected in groundwater were not included in the data set. Thus, it is not expected that SCI-GROW estimates would be exceeded.

With most groundwater sources there are no known predictable seasonal or longer term trends in concentration of pesticide contaminants. Therefore, only one concentration is estimated which should be used for both acute and

chronic scenarios. Using SCI-GROW, for groundwater for both acute and chronic effects, the estimated concentration of 0.3 µg/L is based on a metabolism half-life in soil and water of 110 days and a partition coefficient of 630 mL/g O.C.

3. *From non-occupational exposure.* The term "residential exposure" is used in this document to refer to non-occupational, non-dietary exposure. Linear alkyl C₁₂₋₁₆ propoxyamine ethoxylate will be used in glyphosate formulations, which can be used in and around the home (e.g., lawn, garden, and ornamental uses). Since this is a residential assessment, and given the nature and non-repetitiveness of the exposure only a short-term (1-7 days) assessment was performed. The level of concern for residential exposures is a margin of exposure (MOE) of less than 100. A dermal absorption factor of 10% (based on the SAR assessment which rated absorption as poor through the skin) was used. Exposure estimates were generated using the Standard Operating Procedures (SOPs) for Residential Exposure Assessments, which are standardized methodologies for estimating exposures using information such as percent in the formulation. All MOEs for residential uses are greater than 100.

4. *Safety factor for infants and children.* In assessing the potential for additional sensitivity of infants and children to residues of linear alkyl C₁₂₋₁₆ propoxyamine ethoxylate, EPA considered data from a developmental toxicity study in the rat and the SAR assessment. The SAR assessment did not indicate a concern for developmental or reproductive effects. This assessment which was made on surrogate data, is supported by a rat developmental toxicity study conducted with linear alkyl C₁₂₋₁₆ propoxyamine ethoxylate. A developmental toxicity study is designed to evaluate adverse effects on the developing organism resulting from maternal pesticide exposure gestation. The Agency's review and evaluation of the submitted developmental toxicity study indicated that there was no increase in susceptibility. The maternal NOAEL is 25 mg/kg/day. The developmental NOAEL is 75 mg/kg/day. Thus, the mother would be impacted before the developing fetus.

FFDCA section 408 provides that EPA shall apply an additional 10-fold margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the data base 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. When a quantitative risk assessment is performed for inert ingredients which have no active ingredient uses, the Agency reviews all of the available and reliable data. For linear alkyl C₁₂₋₁₆ propoxyamine ethoxylate, a surfactant that is characterized as having low to moderate toxicity, the Agency believes that the following support the use of the standard uncertainty factor: The SAR assessment does not indicate any concerns for developmental or reproductive effects; and EPA's review and evaluation of the rat developmental toxicity study indicates that there is no increase in susceptibility.

For assessing exposure, estimates were estimated based on data that reasonably accounts for potential exposures. Thus, based on the above rationales, EPA concludes that the 10X safety factor should be removed.

5. *Aggregate risks and determination of safety—i. In general.* To estimate total aggregate exposure to a pesticide from food, drinking water, and residential uses, the Agency calculates DWLOCs which are used as a point of comparison against the model estimates of a chemical's concentration in water (EECs). DWLOC values are not regulatory standards for drinking water. DWLOCs are theoretical upper limits on a chemical's concentration in drinking water in light of total aggregate exposure to a pesticide chemical in food and residential uses. In calculating a DWLOC, the Agency determines how much of the acceptable exposure (i.e., the PAD) is available for exposure through drinking water (e.g., allowable chronic water exposure (mg/kg/day) = cPAD - (average food + residential exposure)). This allowable exposure through drinking water is used to calculate a DWLOC.

A DWLOC will vary depending on the toxic endpoint, drinking water consumption, and body weights. Default body weights and consumption values as used by the USEPA Office of Water are used to calculate DWLOCs: 2L/70 kg (adult male), 2L/60 kg (adult female), and 1L/10 kg (child). Default body weights and drinking water consumption values vary on an individual basis. This variation will be taken into account in more refined screening-level and quantitative drinking water exposure assessments. Different populations will have different DWLOCs. Generally, a DWLOC is calculated for each type of risk

assessment performed. For linear alkyl C₁₂₋₁₆ propoxyamine ethoxylate, these are acute, short-term, and chronic.

When EECs for surface water and groundwater are less than the calculated DWLOCs, the Agency concludes with reasonable certainty that exposures to the pesticide in drinking water (when considered along with other sources of exposure for which reliable data are available) would not result in unacceptable levels of aggregate human health risk at this time.

ii. *Acute risk.* As previously discussed in the unit for acute dietary exposure, the acute dietary exposure from food to linear alkyl C₁₂₋₁₆ propoxyamine ethoxylate will occupy 2% of the aPAD for the populations subgroup females 13–50 years. In addition, there is potential for acute dietary exposure to linear alkyl C₁₂₋₁₆ propoxyamine ethoxylate in drinking water. The Agency calculated a DWLOC of 22,000 µg/L which is significantly greater than the 0.3 µg/L estimated for groundwater and 92 µg/L estimated for surface water. Thus, EPA does not expect the acute aggregate exposure to exceed 100% of the aPAD.

iii. *Chronic risk.* As previously discussed in the unit for chronic dietary exposure, the chronic dietary exposure from food to linear alkyl C₁₂₋₁₆ propoxyamine ethoxylate will occupy 54% of the cPAD for children (1–6 years old), 51% of the cPAD for all infants (< 1 year), 36% of the cPAD for children (7–12 years old), 25% of the cPAD for the total U.S. population, and 19% of the cPAD for females (13–50 years) (19%). There are no residential uses for linear alkyl C₁₂₋₁₆ propoxyamine ethoxylate that result in chronic residential exposure to linear alkyl C₁₂₋₁₆ propoxyamine ethoxylate. There is a potential for chronic dietary exposure to linear alkyl C₁₂₋₁₆ propoxyamine ethoxylate in drinking water. The Agency calculated DWLOCs of 790 µg/L for adults and 140 µg/L for children. Both are greater than the 0.3 µg/L estimated ground water and the 13 µg/L estimated for surface water. Thus, EPA does not expect the chronic aggregate exposure to exceed 100% of the aPAD.

iv. *Short-term risk.* Short-term aggregate exposure takes into account residential exposure plus chronic exposure to food and water (considered to be a background exposure level). As previously discussed, in the non-occupational exposure unit, there is the potential for residential exposure to linear alkyl C₁₂₋₁₆ propoxyamine ethoxylate. The Agency calculated a DWLOC of 24,000 µg/L for homeowner adult applicators. An adult post-

application exposure estimate would be less, thus resulting in a larger DWLOC. The Agency calculated a DWLOC of 7,300 µg/L for post-application exposure for a child. Both are greater than the estimates for surface and groundwater concentrations. Thus, EPA does not expect the short-term aggregate exposure to exceed its level of concern.

VI. Cumulative Effects

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.”

EPA does not have, at this time, available data to determine whether linear alkyl C₁₂₋₁₆ propoxyamine ethoxylate 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, linear alkyl C₁₂₋₁₆ propoxyamine ethoxylate 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 linear alkyl C₁₂₋₁₆ propoxyamine ethoxylate has a common mechanism of toxicity with other substances. For information regarding EPA’s efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the final rule for Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1999).

VII. Determination of Safety for U.S. Population, Infants and Children

Based on the SAR assessment as well as the quantitative and qualitative risk assessments conducted using the available data, EPA concluded that there is a reasonable certainty that no harm will result to the general population, and to infants and children from aggregate exposure to [poly[oxy(methyl-1,2-ethanediyl)], α-[2-bis(2-hydroxyethyl)amino]propyl]-ω-hydroxy,-ether with α-hydro-ω-hydroxypoly(oxy-1,2-ethanediyl) (1:2), mono-C₁₂₋₁₆ alkyl ethers residues. Critical factors supporting this finding include: Linear alkyl C₁₂₋₁₆ propoxyamine ethoxylate is of low/moderate toxicity. Moreover, the effects displayed in the reviewed studies (decreased body weight gain, and possibly even the salivation) were probably due to the corrosion/irritation

factor common to surfactants such as linear alkyl C₁₂₋₁₆ propoxyamine ethoxylate and not to other mechanisms of toxicity generally considered to be of greater concern. The Agency is requiring a limitation on the use of linear alkyl C₁₂₋₁₆ propoxyamine ethoxylate, “not to exceed 15% in the formulated product.” This limitation should be sufficiently protective for the corrosive effects common to surfactants. Further, in performing the dietary assessment the Agency took into account that linear alkyl C₁₂₋₁₆ propoxyamine ethoxylate is to be used in glyphosate products, a pesticide product registered for use on most commonly-consumed foods. Accordingly, the risk assessment assumes that linear alkyl C₁₂₋₁₆ propoxyamine ethoxylate will be present in most commonly-consumed foods. Finally, the residue levels used in performing the food assessment were very conservative (health protective). The conservative assumptions (ratio in formulation, 100% of crop treated and maximum legally permissible residue levels) especially when considered with the non-systemic nature of linear alkyl C₁₂₋₁₆ propoxyamine ethoxylate, and the short PHIs for glyphosate products are considered to produce estimates that do not underestimate food exposure and are likely to substantially overestimate exposure.

Because linear alkyl C₁₂₋₁₆ propoxyamine ethoxylate is unlikely to pose a dietary risk under reasonably foreseeable circumstances, EPA finds that exempting poly[oxy(methyl-1,2-ethanediyl)], α-[2-bis(2-hydroxyethyl)amino]propyl]-ω-hydroxy,-ether with α-hydro-ω-hydroxypoly(oxy-1,2-ethanediyl) (1:2), mono-C₁₂₋₁₆ alkyl ethers from the requirement of a tolerance will be safe.

VIII. Other Considerations

A. Endocrine Disruptors

FQPA requires EPA to develop a screening program to determine whether certain substances, including all pesticide chemicals (both inert and active ingredients), “may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or such other endocrine effect....” EPA has been working with interested stakeholders to develop a screening and testing program as well as a priority setting scheme. As the Agency proceeds with implementation of this program, further testing of products containing linear alkyl C₁₂₋₁₆ propoxyamine ethoxylate for endocrine effects may be required.

B. Analytical Method

An analytical method is not required for enforcement purposes since the Agency is establishing an exemption from the requirement of a tolerance without any numerical limitation.

C. Existing Exemptions

There are no existing exemptions for linear alkyl C₁₂₋₁₆ propoxyamine ethoxylate.

D. International Tolerances

The Agency is not aware of any country requiring a tolerance for linear alkyl C₁₂₋₁₆ propoxyamine ethoxylate nor have any CODEX Maximum Residue Levels (MRLs) been established for any food crops at this time.

IX. Conclusions

Based on the information in this preamble, EPA concludes that there is a reasonable certainty of no harm from aggregate exposure to residues of linear alkyl C₁₂₋₁₆ propoxyamine ethoxylate. Accordingly, EPA finds that exempting [poly[oxy(methyl-1,2-ethanediyl)], α -[2-bis(2-hydroxyethyl)amino]propyl]- ω -hydroxy,-ether with α -hydro- ω -hydroxypoly(oxy-1,2-ethanediyl) (1:2), mono-C₁₂₋₁₆ alkyl ethers from the requirement of a tolerance will be safe.

X. Objections and Hearing Requests

Under section 408(g) of the FFDCA, as amended by the FQPA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. The EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. Although the procedures in those regulations require some modification to reflect the amendments made to the FFDCA by the FQPA of 1996, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) provides essentially the same process for persons to "object" to a regulation for an exemption from the requirement of a tolerance issued by EPA under new section 408(d), as was provided in the old FFDCA sections 408 and 409. However, the period for filing objections is now 60 days, rather than 30 days.

A. What Do I Need to Do to File an Objection or Request a Hearing?

You must file your objection or request a hearing on this regulation in accordance with the instructions provided in this unit and in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket control number OPP-301191 in the subject line

on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk on or before January 15, 2002.

1. *Filing the request.* Your objection must specify the specific provisions in the regulation that you object to, and the grounds for the objections (40 CFR 178.25). If a hearing is requested, the objections must include a statement of the factual issues(s) on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the objector (40 CFR 178.27). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

Mail your written request to: Office of the Hearing Clerk (1900), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460. You may also deliver your request to the Office of the Hearing Clerk in Rm. C400, Waterside Mall, 401 M St., SW., Washington, DC 20460. The Office of the Hearing Clerk is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Office of the Hearing Clerk is (202) 260-4865.

2. *Tolerance fee payment.* If you file an objection or request a hearing, you must also pay the fee prescribed by 40 CFR 180.33(i) or request a waiver of that fee pursuant to 40 CFR 180.33(m). You must mail the fee to: EPA Headquarters Accounting Operations Branch, Office of Pesticide Programs, P.O. Box 360277M, Pittsburgh, PA 15251. Please identify the fee submission by labeling it "Tolerance Petition Fees."

EPA is authorized to waive any fee requirement "when in the judgement of the Administrator such a waiver or refund is equitable and not contrary to the purpose of this subsection." For additional information regarding the waiver of these fees, you may contact James Tompkins by phone at (703) 305-5697, by e-mail at tompkins.jim@epa.gov, or by mailing a request for information to Mr. Tompkins at Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

If you would like to request a waiver of the tolerance objection fees, you must mail your request for such a waiver to:

James Hollins, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

3. *Copies for the Docket.* In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit VIII.A., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in Unit I.B.2. Mail your copies, identified by docket control number OPP-301191, to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460. In person or by courier, bring a copy to the location of the PIRIB described in Unit I.B.2. You may also send an electronic copy of your request via e-mail to: opp-docket@epa.gov. Please use an ASCII file format and avoid 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 6.1/8.0 or ASCII file format. Do not include any CBI in your electronic copy. You may also submit an electronic copy of your request at many Federal Depository Libraries.

B. When Will the Agency Grant a Request for a Hearing?

A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is a 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(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

XI. Regulatory Assessment Requirements

This final rule establishes an exemption from the tolerance requirement 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). Because this rule has been exempted from review under Executive Order 12866 due to its lack of significance, this rule is not subject to Executive

Order 13211, *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001). 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) (Public Law 104-4). Nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994); or OMB review or any Agency action under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104-113, section 12(d) (15 U.S.C. 272 note). Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the exemption 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. In addition, the Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure “meaningful and timely input

by State and local officials in the development of regulatory policies that have federalism implications.” “Policies that have federalism implications” is defined in the Executive Order to include regulations that have “substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.” This final rule directly regulates growers, food processors, food handlers and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). For these same reasons, the Agency has determined that this rule does not have any “tribal implications” as described in Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000). Executive Order 13175, requires EPA to develop an accountable process to ensure “meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.” “Policies that have tribal implications” is defined in the Executive Order to include regulations that have “substantial direct effects on one or more Indian tribes, on the relationship between the Federal government and the Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes.” This rule will not have substantial direct effects on tribal governments, on the relationship between the Federal government and Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

XII. Submission to Congress and the Comptroller General

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and 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 this final rule in the **Federal Register**. This final 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: November 5, 2001.

James Jones,
Acting 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. 321(q), 346(a) and 371.

2. In § 180.1001, the table in paragraph (c) is amended by adding alphabetically the following inert ingredient to read as follows:

§ 180.1001 Exemptions from the requirement of a tolerance.

* * * * *
(c) * * *

Inert ingredients	Limits	Uses
[Poly[oxy(methyl-1,2-ethanediyl), ethylamino]propyl]- ω -hydroxy,-ether hydroxypoly[oxy-1,2-ethanediyl] (1:2), ethers, (CAS Reg. No. 176022-82-5)	α -[2-bis(2-hydroxy-with α -hydro- ω -mono-C ₁₂₋₁₆ alkyl	Surfactant
* * *	* * *	
* * *	* * *	
* * *	* * *	

Not to exceed 15% in the formulated product; only for use with glyphosate

* * * * *

[FR Doc. 01-28734 Filed 11-15-01; 8:45 am]

BILLING CODE 6560-50-S

**ENVIRONMENTAL PROTECTION
AGENCY****40 CFR Part 271**

[FRL-7101-9]

**New York: Final Authorization of State
Hazardous Waste Management
Program Revision****AGENCY:** Environmental Protection Agency (EPA).**ACTION:** Immediate final rule.

SUMMARY: New York has applied to EPA for Final authorization of changes to its hazardous waste program under the Solid Waste Disposal Act, as amended, commonly referred to as the Resource Conservation and Recovery Act (RCRA). EPA has determined that these changes satisfy all requirements needed to qualify for Final authorization, and is authorizing the State's changes through this immediate final action. EPA is publishing this rule to authorize the changes without a prior proposal because we believe this action is not controversial and do not expect comments that oppose it. Unless we get written comments which oppose this authorization during the comment period, the decision to authorize New York's changes to its hazardous waste program will take effect as provided below. If we get comments that oppose this action, we will publish a document in the **Federal Register** withdrawing this rule before it takes effect and a separate document in the proposed rules section of this **Federal Register** will serve as a proposal to authorize the changes.

DATES: This Final authorization will become effective on January 15, 2002 unless EPA receives adverse written comment by December 17, 2001. If EPA receives such comment, it will publish a timely withdrawal of this immediate final rule or those paragraphs or sections of this rule which are the subject of the comments opposing this authorization in the **Federal Register**, and inform the public that this authorization will not take effect (See Section E of this rule for further details).

ADDRESSES: Send written comments to Michael Infurna, Division of Environmental Planning and Protection, EPA, Region II, 290 Broadway, 22nd Floor, New York, NY 10007, Phone number: (212) 637-4177. You can view and copy New York's application during business hours at the following

addresses: EPA Region 2 Library, 290 Broadway, 16th Floor, New York, NY 10007, Phone number: (212) 637-3185; or New York State Department of Environmental Conservation, Division of Solid and Hazardous Materials, 625 Broadway, Albany, NY 12233-7250, Phone number: (518) 402-8730. The public is advised to call in advance to verify the business hours of the above locations.

FOR FURTHER INFORMATION CONTACT:

Michael Infurna, Division of Environmental Planning and Protection, EPA, Region II, 290 Broadway, 22nd Floor, New York, NY 10007, Phone number: (212) 637-4177.

SUPPLEMENTARY INFORMATION:**A. Why Are Revisions to State Programs Necessary?**

States which have received final authorization from EPA under RCRA section 3006(b), 42 U.S.C. 6926(b), must maintain a hazardous waste program that is equivalent to, consistent with, and no less stringent than the Federal program. As the Federal program changes, States must change their programs and ask EPA to authorize the changes. Changes to State programs may be necessary when Federal or State statutory or regulatory authority is modified or when certain other changes occur. Most commonly, States must change their programs because of changes to EPA's regulations in 40 Code of Federal Regulations (CFR) parts 124, 260 through 266, 268, 270, 273 and 279.

B. What Decisions Have We Made in This Rule?

We conclude that New York's application to revise its authorized program meets all of the statutory and regulatory requirements established by RCRA. Therefore, we grant New York Final authorization to operate its hazardous waste program with the changes described in the authorization application. New York has responsibility for permitting Treatment, Storage, and Disposal Facilities (TSDFs) within its borders (except in Indian Country) and for carrying out the aspects of the RCRA program described in its revised program application, subject to the limitations of the Hazardous and Solid Waste Amendments of 1984 (HSWA). New Federal requirements and prohibitions imposed by Federal regulations that EPA promulgates under the authority of HSWA take effect in authorized States before they are authorized for the requirements. Thus, EPA will implement those requirements and prohibitions in New York, including

issuing permits if necessary, until the State is granted authorization to do so.

C. What Is the Effect of Today's Authorization Decision?

The effect of this decision is that a facility in New York subject to RCRA will now have to comply with the authorized State requirements instead of the equivalent Federal requirements in order to comply with RCRA. New York has enforcement responsibilities under its State hazardous waste program for violations of such program, but EPA retains its authority under statutory provisions, including but not limited to, RCRA sections 3007, 3008, 3013, and 7003. These sections include, but may not be limited to, the authority to:

- Do inspections, and require monitoring, tests, analyses or reports
- Enforce RCRA requirements and suspend or revoke permits
- Take enforcement actions regardless of whether the State has taken its own actions.

This action does not impose additional requirements on the regulated community because the regulations for which New York is being authorized by today's action are already effective, and are not changed by today's action.

D. Why Wasn't There a Proposed Rule Before Today's Rule?

EPA did not publish a proposal before today's rule because we view this as a routine program change and do not expect comments that oppose this approval. We are providing an opportunity for public comment now. In addition to this rule, in the proposed rules section of today's **Federal Register**, we are publishing a separate document that proposes to authorize the State program changes.

E. What Happens if EPA Receives Comments That Oppose This Action?

If EPA receives comments that oppose this authorization, we will withdraw this rule by publishing a document in the **Federal Register** before the rule becomes effective. EPA will base any further decision on the authorization of the State program changes on the proposal mentioned in the previous paragraph. We will then address all public comments in a later final rule. You may not have another opportunity to comment. If you want to comment on this authorization, you must do so at this time.

If we receive comments that oppose only the authorization of a particular change to the State hazardous waste program, we will withdraw that part of this rule but the authorization of the