c. In paragraph (a), remove the phrase ''on-site records of the maximum design capacity'' and add, in its place ''on-site records of the design capacity report which triggered § 60.752(b)'';

d. Add paragraph (f) to read as follows:

§ 60.758 Recordkeeping Requirements.

* * * * *

(f) Landfill owners or operators who convert design capacity from volume to mass or mass to volume to demonstrate that landfill design capacity is less than 2.5 million megagrams or 2.5 million cubic meters, as provided in the definition of ''design capacity'', shall keep readily accessible, on-site records of the annual recalculation of site-specific density, design capacity, and the supporting documentation. Off-site records may be maintained if they are retrievable within 4 hours. Either paper copy or electronic formats are acceptable.

14. Amend § 60.759 as follows:

a. In paragraph (a)(3)(iii), remove the sentence ''The values for k, L_O, and $C_{NM}OC$ determined in field testing shall be used, if field testing has been performed in determining the NMOC emission rate or the radii of influence.'' and add, in its place, the sentence ''The values for k and $C_{NM}OC$ determined in field testing shall be used, if field testing has been performed in determining the NMOC emission rate or the radii of influence (the distance from the well center to a point in the landfill where the pressure gradient applied by the blower or compressor approaches zero).''

b. In paragraph (a)(3)(iii), remove the sentence ''If field testing has not been performed, the default values for k, L_O, and $C_{NM}OC$ provided in § 60.754(a)(1) shall be used'' and add, in its place, the sentence ''If field testing has not been performed, the default values for k, L_O and $C_{NM}OC$ provided in § 60.754(a)(1) or the alternative values from § 60.754(a)(5) shall be used.

[FR Doc. 98–15007 Filed 6–15–98; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 180, 185 and 186

[OPP–300663; FRL–5793–5]

RIN 2070–AB78

Quizalofop-p ethyl ester; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for combined residues of quizalofop-p ethyl ester [ethyl (*R*)-(2-[4-((6-chloroquinoxalin-2-yl)oxy)phenoxyl] propanoate), and its acid metabolite quizalofop-p [(*R*)-(2-[4-((6-chloroquinoxalin-2-yl)oxy)phenoxyl]propionate) and the *S* enantiomers of the ester and the acid, all expressed as quizalofop-p ethyl ester in or on canola seed, canola meal, peppermint tops and spearmint tops. DuPont Agricultural Products requested the tolerances for canola and the Interregional Research Project Number 4 (IR-4) requested the tolerances for peppermint and spearmint. These tolerances were requested under the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996 (Pub. L. 104-170).

DATES: This regulation is effective June 16, 1998. Objections and requests for hearings must be received by EPA on or before August 17, 1998.

ADDRESSES: Written objections and hearing requests, identified by the docket control number, [OPP–300663], 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–300663], 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 file format or ASCII file format. All copies of objections and hearing requests in electronic form must be identified by the docket control number [OPP–300663]. 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: Sidney Jackson, 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) 305-7610; e-mail: jackson.sidney@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: In the **Federal Register** published on October 29, 1997 (62 FR 56176 (mint)) (FRL–5749–7) and December 17, 1997, 62 FR 66080 (canola)) (FRL–5758–3), EPA, issued notices pursuant to section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(e) announcing the filing of pesticide petitions (PP) 6E4652 and 5F4545 for tolerances by the IR-4 and DuPont Agricultural Products, Wilmington, Delaware. These notices included a summary of the petitions prepared by DuPont Agricultural Products, Wilmington, Delaware, the registrant. There were no comments received in response to these notices of filing.

The petitions requested that 40 CFR 180.441 be amended by establishing tolerances for combined residues of the herbicide quizalofop-p ethyl ester [ethyl (*R*)-(2-[4-((6-chloroquinoxalin-2-yl)oxy)phenoxyl] propanoate), and its acid metabolite quizalofop-p [(*R*)-(2-[4-((6-chloroquinoxalin-2-yl)oxy)phenoxyl] propionate) and the *S* enantiomers of the ester and the acid, all expressed as quizalofop-p ethyl ester, in or on canola seed at 1.0 part per million (ppm), canola meal at 1.5 ppm, and peppermint tops and spearmint tops at 2.0 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.

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

II. Aggregate Risk Assessment and Determination of Safety

Consistent with section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action, EPA has sufficient data to assess the hazards of quizalofop-p ethyl ester and to make a determination on aggregate exposure, consistent with section 408(b)(2), for a tolerance for combined residues of quizalofop-p-ethyl ester on canola seed at 1.0 ppm, canola meal at 1.5 ppm, and peppermint tops and spearmint tops at 2.0 ppm. EPA's assessment of the dietary exposures and risks associated with establishing the tolerances follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. The nature of the toxic effects caused by quizalofop-p ethyl ester are discussed below.

1. *Acute toxicity*. Acute toxicology studies include: acute oral toxicity (lethal dose) (LD_{50}s) at 1,480 and 1,670 milligrams (mg)/kilogram (kg) for female and male rats, respectively); eye irritation (not an eye irritant); dermal toxicity (LD_{50} > 5,000 mg/kg in rats); inhalation toxicity (lethal concentration) (LC_{50} = 5.8 mg/liter(L)in rats); and dermal irritation (not a dermal sensitizer).

2. *Genotoxicity*. Quizalofop ethyl was negative in the following genotoxicity tests: bacterial gene mutation assays (Ames assay); chromosomal aberration assays in Chinese hamster ovary (CHO) cells; unscheduled DNA synthesis; and combinant assays and reversion assay in *Salmonella*.

3. *Reproductive and developmental toxicity*. A developmental toxicity study in rats administered dosage levels of 0, 30, 100, and 300 mg/kg/day. The maternal toxicity NOEL was 30 mg/kg/day and a developmental toxicity NOEL was greater than 300 mg/kg/day, highest dose tested (HDT). The maternal NOEL was based on reduced food consumption and body weight, and increased liver weights. There were no developmental effects observed.

A developmental toxicity study in rabbits administered dosage levels of 0, 7, 20, and 60 mg/kg/day with no developmental effects noted at 60 mg/kg/day (HDT). The maternal toxicity NOEL was established at 20 mg/kg/day based on decreased food consumption and body weight at 60/mg/kg/day (HDT).

In a two-generation reproductive toxicity study, Sprague-Dawley rats were fed diets containing quizalofop-p-ethyl at 0, 25, 100, or 400 ppm (0, 1.25, 5.0, or 20 mg/kg/day respectively). The parental NOEL was 100 ppm (5.0 mg/kg/day) and the lowest-observed effect level (LOEL) was 400 ppm (20 mg/kg/day), based on decreased body weights in males of both generations. The developmental NOEL for effects on the offspring was 25 ppm (1.25 mg/kg/day) and the offspring developmental LOEL was 100 ppm (5.0 mg/kg/day), based on increased incidence of eosinophilic changes in the livers of F2 weanling. In addition, at 400 ppm (20 mg/kg/day), reductions in litter size, survival, body weights, and spleen weight were seen in offspring.

4. *Subchronic toxicity*. A 90-day study was conducted in rats fed diets containing 0, 40, 128, 1,280 ppm (or approximately 0, 2, 6.4 and 64 mg/kg/day, respectively). The NOEL was 2 mg/kg/day. This was based on increased liver weights at 6.4 mg/kg.

A 90-day feeding study in mice was conducted with diets that contained 0, 100, 316 or 1,000 ppm (or approximately 0, 15, 47.4, and 150 mg/kg/day, respectively). The NOEL was < 15 mg/kg/day (lowest dose tested) based on increased liver weights and reversible histopathological effects in the liver at the lowest dose tested.

5. *Chronic toxicity*. An 18-month carcinogenicity study was conducted in CD-1 mice fed diets containing 0, 2, 10, 80 or 320 ppm (or approximately 0, 0.3, 1.5, 12, and 48 mg/kg/day, respectively). There were no carcinogenic effects observed under the conditions of the study at levels up to and including 12 mg/kg/day. A marginal increase in the incidence of hepatocellular tumors was observed at 48 mg/kg/day, the highest dose tested (HDT) which exceeded the maximum tolerated dose (MTD).

A 2-year chronic toxicity/carcinogenicity study was conducted in rats fed diets containing 0, 25, 100 or 400 ppm (or 0, 0.9, 3.7, and 15.5 mg/kg/day for males and 0, 1.1, 4.6, and 18.6 mg/kg/day for females, respectively). There were no carcinogenic effects observed under the conditions of the study at levels up to and including 18.6 g/kg/day (HDT). The systemic NOEL was 0.9 mg/kg/day based on altered red cell parameters and slight/minimal centrilobuler enlargement of the liver at 3.7 mg/kg/day.

A 1-year feeding study was conducted in dogs fed diets containing 0, 25, 100 or 400 ppm (or approximately 0, 0.625, 2.5, or 10 mg/kg/day, respectively). The NOEL was greater than 10 mg/kg/day, the lowest dose tested (LDT).

B. Toxicological Endpoints

1. *Acute toxicity*. There were no effects observed in oral toxicity studies that could be attributable to a single dose (exposure). Therefore, a dose and an endpoint have not been identified for this risk assessment. This risk assessment is not required. .

2. *Short - and intermediate - term toxicity*. In a 21-day dermal toxicity study, New Zealand White rabbits (5/sex/dose) received 15 repeated dermal applications (aqueous paste) of quizalofop-p-ethyl ester at doses of 0, 125, 600 or 2,000 mg/kg/day, 6 hours/day, 5 days/week over a 21-day period. There was no dermal or systemic toxicity. The NOEL was 2,000 mg/kg/day. In addition, no maternal or developmental toxicity was observed following in utero exposures in rats and rabbits. These risk assessments are not required.

3. *Chronic toxicity*. EPA has established the RfD for quizalofop-p ethyl ester at 0.009 mg/kg/day. This RfD is based on the 2-year feeding study in rats. Groups of male and female Sprague-Dawley rats (50/sex/dose) were fed diets containing quizalofop-p-ethyl ester at 0, 25, 100 or 400 ppm for 104 weeks. For chronic toxicity, the NOEL

was 25 ppm (0.9 mg/kg/day) and the LOEL was 100 ppm based on the occurrence of generalized hepatocyte enlargement in female rats and red blood cell destruction in males. In addition, there was generalized hepatocyte enlargement and red blood cell destruction in both sexes at 400 ppm.

RfD = 0.9 mg/kg/day (NOEL) = 0.009 mg/kg/day 100 (UF).

4. *Carcinogenicity*. OPP's Health Effects Division, Carcinogenicity Peer Review Committee (CPRC) has evaluated the rat and mouse cancer studies for quizalofop-p ethyl ester along with other relevant short-term toxicity, mutagenicity studies, and structure-activity relationships. The CPRC has classified quizalofop-p ethyl as a Group D carcinogen (not classifiable as to human cancer potential). The Group D classification is based on an approximate doubling in the incidence of mice liver tumors between controls and the high dose. This finding was not considered strong enough to warrant the classification of a Category C (possible human carcinogen): the increase was of marginal statistical significance, occurred at high dose which exceeded the MTD, and occurred in a study in which the concurrent control for liver tumors was somewhat low as compared to the historical controls, while the high dose control group was at the upper end of previous historical control groups. No new cancer studies are required for quizalofop-p ethyl ester at this time.

C. Exposures and Risks

1. *From food and feed uses.* Tolerances have been established (40 CFR 180.441) for the combined residues of quizalofop-p ethyl ester and its acid metabolite quizalofop-p and the *S* enantiomers of the ester and the acid, all expressed as quizalofop-p ethyl ester in or on a variety of raw agricultural commodities. Tolerances are established for cottonseed at 0.1 ppm, lentils at 0.05 ppm. Time-limited tolerances are established for sugarbeet roots at 0.1 ppm, sugarbeet tops at 0.5 ppm, legume vegetables crop group at 0.25 ppm, and foliage of legume vegetables (except soybeans) at 3.0 ppm. Risk assessments were conducted by EPA to assess dietary exposures and risks from quizalofop-p ethyl ester 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. There are no acute toxicological concerns for quizalofop-p ethyl ester.

ii. *Chronic exposure and risk.* In conducting this chronic dietary risk assessment, EPA has made very conservative assumptions -- 100% of mint, canola, and all other commodities having quizalofop-p-ethyl ester tolerances will contain the regulable residues and those residues will be at the level of the tolerance. Thus, in making a safety determination for these tolerances, EPA is taking into account this conservative exposure assessment. The Dietary Risk Evaluation System (DRES) was used for the chronic dietary exposure analysis. The analysis evaluates individual food consumption as reported by respondents in the USDA 1977-78 Nationwide Food Consumption Survey (NFCS) and accumulates exposure to the chemical for each commodity. Regional consumption information is taken into account through EPA's computer-based model for evaluating the exposure of significant subpopulations including several regional groups. Review of these regional data allows the Agency to be reasonably certain that no regional population is exposed to residue levels higher than those estimated by the Agency.

Existing tolerances and this rule for canola and mint result in a TMRC of 5.40×10^{-4} mg/kg/day for the U.S. general population (48 States), which represents 6.0% of the RfD. The use on canola will add a TMRC of 7.7×10^{-5} mg/kg/day, which represents 0.9% of the RfD for the U.S. population. The use on mint will add a TMRC of 2×10^{-6} mg/kg/day, which represents 0.016% of the RfD. Existing tolerances and this rule result in a TMRC of 1.7×10^{-3} mg/kg/day for the highest exposed population subgroup (non-nursing infants <1 year old), which represents 19%. These tolerances for canola and mint will not contribute to the dietary burden of this population subgroup. Based on the risk estimates calculated, chronic dietary exposure does not exceed EPA's level of concern.

2. *From drinking water*— i. *Acute exposure and risk*. There are no acute toxicological concerns for quizalofop-p ethyl ester.

ii. *Chronic exposure and risk*. Drinking water levels of concern (DWLOC) were calculated for chronic dietary exposure. To calculate the DWLOC, chronic dietary food exposure (from DRES analysis) was subtracted from the RfD. DWLOC were then calculated using default bodyweights and drinking water consumption figures. For adults, the estimate was based on a body weight of 60 kg (female)/70 kg(female) and consumption of 2 liters of water per day. For children, a body weight of 10 kg and a consumption of 1 liter of water per day were used. The DWLOC are calculated at 296 parts per billion (ppb) for the U.S. population, 256 ppb for females (13+ years old, not pregnant or nursing) and 73 ppb for infants and children. Agency estimates for quizalofop-p ethyl ester contamination is 8 ppb for surface water and 0.15 ppb for groundwater. These levels are significantly less than levels of concern to EPA.

3. *From non-dietary exposure.* Quizalofop-p ethyl ester is not registered for residential use sites.

4. *Cumulative exposure to substances with common mechanism of toxicity*. Quizalofop-p ethyl is a member of the oxyphenoxy acid ester class of pesticides. Other members of this class include fluazifop-butyl, diclofop-methyl, fenoxaprop-ethyl, and haloxyfop-methyl.

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 quizalofop-p ethyl ester 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, quizalofop-p ethyl ester 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 quizalofop-p ethyl ester has a common mechanism of toxicity with other substances.

5. *Endocrine disruption*. EPA is required to develop a screening program to determine whether certain substances (including all pesticides and inerts) ''may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or such other endocrine effect....''

The Agency is currently working with interested stakeholders, including other government agencies, public interest groups, industry and research scientists in developing a screening and testing program and a priority setting scheme to implement this program. Congress has allowed 3 years from the passage of FQPA (August 3, 1999) to implement this program. EPA may require further testing of this active ingredient and end use products for endocrine disrupter effects.

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

1. *Acute risk*. There are no acute toxicological concerns for quizalofop-p ethyl ester.

2. *Chronic risk*. Using the TMRC exposure assumptions described above, EPA has concluded that aggregate exposure to quizalofop-p ethyl ester from food will utilize 6.0% of the RfD for the U.S. population. The major identifiable subgroup with the highest aggregate exposure is non-nursing infants <1 year old at 19% of the RfD. EPA generally has no concern for exposures below 100% of the RfD because the RfD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health. Despite the potential for exposure to quizalofop-p ethyl ester in drinking water and from non-dietary, non-occupational exposure, EPA does not expect the aggregate exposure to exceed 100% of the RfD. EPA concludes that there is a reasonable certainty that no harm will result from aggregate exposure to quizalofop-p ethyl ester residues.

E. Aggregate Cancer Risk for U.S. Population

The Agency has classified quizlopfop-p ethyl as a Category D chemical (not classifiable as to human cancer potential) based on results of rat and mouse cancer studies along with other relevant short-term toxicity, mutagenicity studies, and structure-activity relationships. The Group D classification is based on an approximate doubling in the incidence of mice liver tumors between controls and the high dose. This finding was not considered strong enough to warrant the classification of a Category C (possible human carcinogen): the increase was of marginal statistical significance, occurred at high dose which exceeded the MTD, and occurred in a study in which the concurrent control for liver tumors was somewhat low as compared to the historical controls, while the high dose control group was at the upper end of previous historical control groups. Based on results of the above adequate studies and the Category D classification, the Agency believes that any cancer risk posed by quizalofop-p ethyl is negligible and there is reasonable certainty that no harm will result from exposure to residue of quizalofop-p ethyl.

F. 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 quizalofop-p ethyl ester, 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 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 factor when EPA has a complete data base under existing guidelines and when the severity of the effect in infants or children or the potency or unusual toxic properties of a compound do not raise concerns regarding the adequacy of the standard MOE/safety factor.

ii. *Developmental toxicity studies*. Developmental toxicity studies showed no increased sensitivity in fetuses as compared to maternal animals following in utero exposures in rats and rabbits.

iii. *Reproductive toxicity study*. In a two generation reproductive toxicity study, rats were fed diets of 0, 1.25, 5.0 or 20 mg/kg/day of quizalofop-p ethyl. The parental NOEL was 5.0 mg/kg/day and the LOEL was 20 mg/kg/day, based on decreased body weights in males of both generations. The developmental NOEL for effects on the offspring was 1.25 mg/kg/day and the offspring developmental LOEL was 5.0 mg/kg/day, based on increased incidence of eosinophilic changes in the livers of F2 weanling. In addition, at 20 mg/kg/day, reductions in litter size, survival, body weights, and spleen weight were seen in the offspring.

iv. *Pre- and post-natal sensitivity*. The histopathology data for F2 weanlings in the two-generation reproductive toxicity study suggested an increased sensitivity to the offspring. In that study, an increase in the incidence of eosinophilic changes in the liver were noted in the F2 weanlings, and the offspring NOEL was less than the parental systemic NOEL. However, the significance of these observations in the two-generation reproductive toxicity study is rendered questionable due to: (a) The changes in the weanling livers were not well characterized; (b) the biological significance of this endpoint was not known; (c) the precise dose of test substance to 21-day old weanlings cannot be determined with any accuracy, but it is likely to exceed that of the adults; (d) this endpoint

(eosinophilic changes), in adults, would not be considered appropriate for use in regulation of a chemical because of the questionable biological significance of this effect; and, (e) previous toxicological studies show the liver as the target organ in rats. No particular significance to the offspring is attributed to the liver effects.

v. *Conclusion*. The database is complete and the weight of the evidence reveals no special susceptibility to developmental toxicity. Therefore, EPA has determined that reliable data support use of the standard 100-fold safety factor. An additional ten-fold safety factor is not necessary to protect the safety of infants and children.

2. *Acute aggregate risk*. There are no acute toxicological concerns for quizalofop-p ethyl ester.

3. *Chronic aggregate risk*. Using the conservative exposure assumptions described above, EPA has concluded that aggregate exposure to quizalofop-p ethyl ester from food will utilize 19% of the RfD for the highest exposed population subgroup (non-nursing infants <1 year old). 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. Because there are no indoor or outdoor residential uses for quizalofop-p ethyl, and the estimates of quizalofop-p ethyl chronic residues in drinking water are much less (estimated at 8.08 ppb) than the 73 ppb concern level, aggregate (food, water, and residential) chronic exposure for infants, children, and adults will not exceed the Agency's level of concern. EPA concludes that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to quizalofop-p ethyl ester residues.

4. *Short- or intermediate-term risk*. Because no toxicological endpoints have been identified for short-, intermediate-, and/or chronic-term dermal or inhalation exposures, the Agency believes there is reasonable certainty that no harm will result from exposure to quizalofop-p ethyl due to approved tolerances.

III. Other Considerations

A. Metabolism In Plants and Animals

The Agency has previously concluded that the nature of the quizalofop-p ethyl residue in plants is adequately understood. The residues of concern are quizalofop-p ethyl ester and its acid metabolite, quizalofop-p, and the *S* enantiomers of both the ester and the acid, all expressed as quizalofop-p (40 CFR 180.441(c)). In animals, the residues of concern are slightly different and include quizalofop ethyl, quizalofop methyl, and quizalofop acid, all expressed as quizalofop-ethyl (40 CFR 180.441(b)).

B. Analytical Enforcement Methodology

An adequate enforcement method for determination of quizalofop-p-ethyl and related regulated residues is available in PAM II.

C. Magnitude of Residues

The maximum residues detected on fresh mint foliage at the proposed labeled level of DuPont's product, Assure, of 0.2 pounds(lbs) active ingredient(ai) per acre (1x) applied 30 days before harvest were 0.22, 0.46, and 1.0 ppm for Indiana, Oregon and Washington, respectively. The largest residue found on fresh mint foliage, 2.6 ppm, was detected in a Washington sample treated with 0.4 lbs. per acre (2x) 29 days before harvest, twice the maximum yearly rate allowed. At the Level of Quantitation (LOQ) of 0.05 ppm, there were no detectable residues in the mint oil, either at the proposed label rate of 0.2 lbs. ai/acre(A), or at the exaggerated rate of 0.4 lbs. ai/A, indicating that quizalofop-p ethyl and its acid metabolite are not concentrated during the oil distillation process. Adequate residue data were provided to support a tolerance of 2.0 ppm for mint. There are no livestock feedstuffs associated with mint.

Adequate residue data were provided to support proposed tolerances canola seed and canola meal. Processing data provided for canola seed indicated concentration in canola meal. Based on the concentration factor of 2.3x and the highest average field trial (HAFT) residue level of 0.65 ppm for canola seed, a tolerance at 1.5 ppm for canola meal is considered adequate.

Results of a ruminant feeding study lead to the conclusion that the established quizalofop and quizalofop-p ethyl tolerance in milk, and in fat, meat, and meat by-products of cattle, goats, hogs, horse, and sheep are adequate and need not be increased from the additional use on canola. Additionally, the established tolerances of quizalofop and quizalofop-p ethyl in eggs, and in fat, meat, and meat by-products of poultry are adequate and need not be changed from the additional use on canola.

D. International Residue Limits

There are no Codex, Canadian, or Mexican Maximum Residue Limits (MRLs) for quizalofop-p ethyl residues in/on mint. Since there are no Mexican or Codex MRLs/tolerances for quizalofop-p-ethyl in/on canola seed, compatibility is not a problem at this time. Compatibility cannot be achieved with the Canadian negligible residue types limit at 0.1 ppm as the U.S. use pattern had findings of real residues above 0.1 ppm. Additionally, the Canadian MRL is in terms of parent only, thus the tolerance expressions are not compatible.

E. Rotational Crop Restrictions

Available data support a 120 day plant back interval.

IV. Conclusion

Therefore, tolerances are established for combined residues of quizalofop-p ethyl ester [ethyl (*R*)-(2[4-((6-chloroquinoxalin-2-yl)oxy)phenoxyl]-propanoate), and its acid metabolite quizalofop-p [*R*-(2-[4-((6-chloroquinoxalin-2-yl)oxy)phenoxyl)propionate and the *S* enantiomers of the ester and the acid, all expressed as quizalofop-p ethyl ester in or on canola seed at 1.0 ppm, canola meal at 1.5 ppm, and peppermint tops and spearmint tops at 2.0 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 August 17, 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 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–300663] (including any comments and data submitted electronically). A public version of this record, including printed, paper versions of electronic comments, which does not include any information claimed as CBI, is available for inspection from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The public record is located in Room 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 Hwy., Arlington, VA.

Electronic comments may be sent directly to EPA at:

opp-docket@epamail.epa.gov.

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

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

VII. Regulatory Assessment Requirements

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

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

VIII. Submission to Congress and the 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 rule in the **Federal Register**. This rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects

40 CFR Part 180

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

40 CFR Part 185

Environmental protection, Food additives, Pesticides and pests.

40 CFR Part 186

Environmental protection, Animal feeds, Pesticides and pests.

Dated: May 28, 1998.

Peter Caulkins,

Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180— [AMENDED]

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

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

2. Section 180.441 is revised to read as follows:

§ 180.441 Quizalofop ethyl; tolerances for residues.

(a) *General.* (1) Tolerances are established for the combined residues of the herbicide quizalofop (2-[4-(6-chloroquinoxalin-2-yl oxy)phenoxy]propanoic acid) and quizalofop ethyl (ethyl-2-[4-(6-chloroquinoxalin-2-yl oxy)phenoxy]propanoate), all expressed as quizalofop ethyl, in or on the following agricultural commodities:

Commodity	Parts per million
Soybean flour	0.5
Soybean hulls	0.02
Soybean meal	0.5
Soybean soapstock	1.0
Soybeans	0.05

(2) Tolerances are established for the combined residues of the herbicide quizalofop (2-[4-(6-chloroquinoxalin-2-yl oxy)phenoxy]propanoic acid), quizalop-ethyl (ethyl-2-[4-(6-chloroquinoxalin-2-yl oxy)phenoxy]propanoate), and quizalofop-methyl (methyl 2-[4-(6-chloroquinoxalin-2-yl-oxy)phenoxy]propanoate, all expressed as quizalofop ethyl, as follows:

Commodity	Parts per million
Cattle, fat	0.05
Cattle, meat	0.02
Cattle, mbyp	0.05
Eggs	0.02
Goats, fat	0.05
Goats, meat	0.02
Goats, mbyp	0.05
Hogs, fat	0.05
Hogs, meat	0.02
Hogs, mbyp	0.05
Horses, fat	0.05
Horses, meat	0.02
Horses, mbyp	0.05
Milk	0.01
Milk, fat	0.05
Poultry, fat	0.05
Poultry, meat	0.02
Poultry, mbyp	0.05
Sheep, fat	0.05
Sheep, meat	0.02
Sheep, mbyp	0.05

(3) Tolerances are established for the combined residues of the herbicide quizalofop-p ethyl ester [ethyl (*R*)-(2-[4-((6-chloroquinoxalin-2-yl)oxy)phenoxy)propanoate], and its acid metabolite quizalofop-p [*R*-(2-(4-((6-quinoxalin-2-yl)oxy)phenoxy)propanoic acid], and the *S* enantiomers of both the ester and the acid, all expressed as quizalofop-p-ethyl ester, in or on the following raw agricultural commodities;

Commodity	Parts per million
Canola, meal	1.5
Canola, seed	1.0
Cottonseed	0.1
Lentils	0.05
Peppermint, tops	2.0
Spearmint, tops	2.0

(4) Time limited tolerances to expire on June 14, 1999 are established for the combined residues of the herbicide quizalofop-p ethyl ester (ethyl (*R*)-(2-(4-((6-chloroquinoxalin-2-yl)oxy)phenoxy)propanoate) and it acid metabolite quizalofop-p [*R*-(2-(4-((6-chloroquinoxalin-2-yl)oxy)phenoxy)propanoic acid), and the *S* enantiomers of both the ester and the acid, all expressed as quizalofop-p-ethyl ester in or on the following raw agricultural commodities:

Commodities	Parts per million
Foliage of legume vegetables (except soybeans)	3.0
Legume vegetables (succulent or dried) group	0.25
Sugarbeet molasses	0.2
Sugarbeet, root	0.1
Sugarbeet, top	0.5

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

(c) *Tolerances with regional registrations.* Tolerances with regional registration, as defined in § 180.1(n), are established for the combined residues of the herbicide quizalofop-*p* ethyl ester [ethyl (*R*)-2-[4-((6-chloroquinoxalin-2-yl)oxy)phenoxy] propionate], its acid metabolite quizalofop-*p* [*R*-(2-[4-((6-chloroquinoxalin-2-yl)oxy)phenoxy]) propanoic acid], and the *S* enantiomers of both the ester and the acid, all expressed as quizalofop-*p* ethyl ester, in or the raw agricultural commodities, as follows:

Commodity	Parts per million
Pineapple	0.1

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

PART 185— [AMENDED]

3. In part 185:

a. The authority citation for part 185 continues to read as follows:

Authority: 21 U.S.C. 346a and 348.

§ 185.5250 [Removed]

b. Section § 185.5250 is removed.

PART 186— [AMENDED]

4. In part 186:

a. The authority citation for part 186 continues to read as follows:

Authority: 21 U.S.C. 342, 348, and 701.

§ 186.5250 [Removed]

b. Section § 186.5250 is removed.

[FR Doc. 98–15746 Filed 6–15–98; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 300

[FRL–6111–2]

National Oil and Hazardous Substances Pollution Contingency Plan; National Priorities List Update

AGENCY: Environmental Protection Agency.

ACTION: Notice of deletion of the Southern Shipbuilding Corporation Superfund site from the National Priorities List.

SUMMARY: The Environmental Protection Agency (EPA) Region 6 announces the deletion of the Southern Shipbuilding Corporation Superfund Site (the ''Site'') from the National Priorities List (NPL). The NPL, promulgated pursuant to section 105 of the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) of 1980, as amended, is codified at Appendix B to the National Oil and Hazardous Substances Pollution Contingency Plan (NCP), 40 CFR Part 300. EPA in consultation with the State of Louisiana, through the Louisiana Department of Environmental Quality (LDEQ), has determined that no further response is appropriate since all federally funded actions specified in the Record of Decision for Operable Units One (1) and Two (2) have been implemented. Consequently, the Site is hereby deleted from the NPL.

EFFECTIVE DATE: June 16, 1998.

ADDRESSES: Comprehensive information on the Site has been compiled in a public deletion docket which may be reviewed and copied during normal business hours at the following Southern Shipbuilding Corporation Superfund Site information repositories:

U.S. EPA Region 6 Library (12th Floor), 1445 Ross Avenue, Dallas, Texas 75202–2733, 1–800–533–3508.

St. Tammany Parish Public Library, Slidell Branch, 555 Robert Blvd., Slidell, Louisiana 70450, (504) 643–4120.

FOR FURTHER INFORMATION CONTACT:

Mr. Mark A. Hansen, Remedial Project Manager (6SF–LT), U.S. Environmental Protection Agency, Region 6 1445 Ross Avenue, Dallas, Texas 75202–2733, (214) 665–7548

or

Mr. Duane Wilson, Louisiana Department of Environmental Quality, 7290 Bluebonnet Road, Baton Rouge, Louisiana 70809, (504) 765–0487.

SUPPLEMENTARY INFORMATION: The site to be deleted from the NPL is the Southern Shipbuilding Corporation Superfund Site, Slidell, St. Tammany Parish, Louisiana (EPA Site Spill No. 066Z; CERCLIS No. LAD008149015). A Notice of Intent to Delete (NOID) was published on March 31, 1998 (63 FR 15346). The closing date for public comment on the NOID was April 30, 1998. EPA received no public comments and therefore, no Responsiveness Summary was prepared.

The EPA identifies sites which appear to present a significant risk to public health, welfare, or the environment and