

list submittal, contact Mr. Charles Martin, Virginia Department of Environmental Quality, at (804) 698-4462.

SUPPLEMENTARY INFORMATION:

What is required of the Section 303(d) list?

Federal regulations include two requirements that are most pertinent to EPA's partial disapproval of Virginia's 1998 Section 303(d) list. First, the regulations require that states consider all existing and readily available water quality-related data and information in identifying waters for the 303(d) list. See 40 CFR 130.7(b)(5). Second, if EPA disapproves a list, the Agency must identify the waters to which the disapproval applies. See 40 CFR 130.7(d)(2).

What did Virginia's Section 303(d) list include?

EPA received Virginia's final 1998 Section 303(d) report on October 16, 1998. The report included five parts plus appendices. Parts I and II of the report are the impaired waters that the Commonwealth determined require TMDLs. EPA considers Parts I and II to be the Commonwealth's Section 303(d) list. Parts III, IV and V are waters of concern that the Commonwealth determined do not require TMDLs. EPA considers these three parts to be for informational purposes only, outside the Section 303(d) list. Among the appendices to the submission is Appendix D, which lists the waters which the Commonwealth included on its 1996 Section 303(d) list but did not include on its 1998 list. Virginia explained that it did not include these waters because point sources on these waters had reportedly been issued water quality-based effluent limits that would eliminate the impairment within the next two-year reporting cycle.

Why did EPA partially disapprove Virginia's 1998 Section 303(d) list?

In reviewing the list, EPA determined that Virginia had omitted certain waters from the list even though existing and readily available water quality-related data and information show that these waters do not meet water quality standards even after required technology-based and other controls are applied. On November 16, 1998 EPA disapproved the omission of these waters from the list and on December 16, 1998 identified the waters to be added to the list.

Which waters did EPA identify to be added to Virginia's 1998 Section 303(d) list?

On December 16, 1998 EPA identified the following five groups of waters to be added to Virginia's 1998 303(d) list:

1. Portions of the mainstem Chesapeake Bay and three tidal tributaries because existing and readily available water quality-related data and information show that the water quality standards for dissolved oxygen are not being met. EPA identified those portions of the mainstem Chesapeake Bay and three tidal tributaries as high priority for TMDL development. In addition, EPA identified excessive nutrients as the pollutants of concern causing violations of the applicable water quality standard for dissolved oxygen.

2. 77 waters presented in Appendix D of Virginia's report (waters that were listed in 1996 as needing TMDLs but were not included on the 1998 list). The only data the Commonwealth provided to EPA (i.e., that submitted with the 1996 Section 303(d) list) indicated that these segments are impaired. EPA designated these waters as low priority for TMDL development.

3. 47 waters presented in Part V of Virginia's report (waters reportedly impaired by natural conditions and not identified as requiring TMDL development) because they fail to meet water quality standards. EPA designated these waters as low priority for TMDL development.

4. 10 waters that were identified as impaired (not meeting water quality standards or designated uses) in the Commonwealth's 1998 Section 305(b) report but were not included by Virginia on the Section 303(d) list.

5. 6 waters that are already listed for one or more pollutants but, based on information from the Commonwealth's 1998 Section 305(b) report, should be listed for an additional pollutant.

In addition to identifying the five groups of waters above, EPA recommends that the Commonwealth modify the priority rankings, from medium to high, for four waters identified by the U.S. Fish and Wildlife Service as adversely impacting endangered species.

Dated: December 16, 1998.

Thomas J. Maslany,

Director, Water Protection Division, EPA Region III.

[FR Doc. 98-34548 Filed 12-29-98; 8:45 am]

BILLING CODE 6560-50-U

ENVIRONMENTAL PROTECTION AGENCY

[PF-850; FRL-6050-1]

Notice of Filing of Pesticide Petitions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces the initial filing of pesticide petitions proposing the establishment of regulations for residues of certain pesticide chemicals in or on various food commodities.

DATES: Comments, identified by the docket control number PF-850, must be received on or before January 29, 1999.

ADDRESSES: By mail submit written comments to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticides Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person bring comments to: Rm. 119, CM #2, 1921 Jefferson Davis Highway, Arlington, VA.

Comments and data may also be submitted electronically by following the instructions under "SUPPLEMENTARY INFORMATION." No confidential business information should be submitted through e-mail.

Information submitted as a comment concerning this document may be claimed confidential by marking any part or all of that information as "Confidential Business Information" (CBI). CBI should not be submitted through e-mail. Information marked as CBI will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the comment 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. All written comments will be available for public inspection in Rm. 119 at the address given above, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays.

FOR FURTHER INFORMATION CONTACT: The product manager listed in the table below:

Product Manager	Office location/telephone number	Address
Treva C. Alston	Rm. 707B, CM #2, 703-308-8373, e-mail:alston.treva@epamail.epa.gov.	1921 Jefferson Davis Hwy, Arlington, VA
Hoyt Jamerson	Rm. 268, CM #2, 703-308-9368, e-mail: jamerson.hoyt@epamail.epa.gov.	Do.

SUPPLEMENTARY INFORMATION: EPA has received pesticide petitions as follows proposing the establishment and/or amendment of regulations for residues of certain pesticide chemicals in or on various food commodities under section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a. EPA has determined that these petitions contain data or information regarding the elements set forth in section 408(d)(2); however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data supports granting of the petition. Additional data may be needed before EPA rules on the petition.

The official record for this notice of filing, as well as the public version, has been established for this notice of filing under docket control number [PF-850] (including comments and data submitted electronically as described below). 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 official record is located at the address in "ADDRESSES" at the beginning of this document.

Electronic comments can 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. Comment and data will also be accepted on disks in Wordperfect 5.1 file format or ASCII file format. All comments and data in electronic form must be identified by the docket number [PF-850] and appropriate petition number. Electronic comments on this notice may be filed online at many Federal Depository Libraries.

List of Subjects

Environmental protection, Agricultural commodities, Food additives, Feed additives, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: December 17, 1998.

James Jones,

Director, Registration Division, Office of Pesticide Programs.

Summaries of Petitions

Petitioner summaries of the pesticide petitions are printed below as required by section 408(d)(3) of the FFDCA. The summaries of the petitions were prepared by the petitioners and represent the views of the petitioners. EPA is publishing the petition summaries verbatim without editing them in any way. The petition summary announces the availability of a description of the analytical methods available to EPA for the detection and measurement of the pesticide chemical residues or an explanation of why no such method is needed.

1. Huntsman Corporation of Houston, Texas

PP 8E4992

EPA has received a pesticide petition (PP 8E4992) from Huntsman Corporation of Houston, Texas, proposing pursuant to section 408(d) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 346a(d), to amend 40 CFR part 180 to establish an exemption from the requirement of a tolerance for propylene carbonate and butylene carbonate (4-(methyl and ethyl)-(1,3-dioxolan-2-one)) when used in accordance with good agricultural practice as an inert ingredient in pesticide formulations applied to growing crops or to raw agricultural commodities after harvest. EPA has determined that the petition contains data or information regarding the elements set forth in section 408(d)(2) of the FFDCA; however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data supports granting of the petition. Additional data may be needed before EPA rules on the petition.

A. Residue Chemistry

Analytical method. An analytical residue method utilizing chromatography with a flame-ionization detector is available for enforcement purposes.

B. Toxicological Profile

1. *Acute toxicity.* Acute toxicity studies include an acute oral rat study

on propylene carbonate with an LD₅₀ of 29,100 milligrams/kilogram of body weight (mg/kg/bwt), an acute oral mouse study on propylene carbonate with an LD₅₀ of 20,700 mg/kg/bwt, an acute dermal toxicity study in the rat with an LD₅₀ >5,000 mg/kg, acute inhalation studies in the rat, dog, and guinea pig with an LD₅₀ values >3,000 mg/L (airborne concentration), a primary eye irritation study with rabbits indicating that propylene carbonate is a slight eye irritant, a primary dermal irritation study in the rabbit showing propylene carbonate to be a non-irritant and dermal sensitization studies in humans showing propylene carbonate is not a skin sensitizer.

2. *Genotoxicity.* The mutagenic potential of propylene carbonate has been evaluated in several studies covering a variety of endpoints. It is concluded that propylene carbonate is not mutagenic. Mutagenic studies with propylene carbonate include gene mutation assays in bacterial and mammalian cells; *in vitro*, and *in vivo* chromosomal aberration assays; and an *in vivo* DNA repairs assay in mammalian cells. All studies were negative for genotoxicity.

3. *Reproductive and developmental toxicity.* A developmental toxicity study with rats given oral gavage doses of up to 5,000 mg/kg/day from days 6 through 15 of gestation resulted in a no observed adverse effect level (NOAEL) for maternal toxicity of 3,000 mg/kg/day based upon bwt reduction at the highest doses. There was no evidence of developmental toxicity or any malformations in fetuses at any of the dose levels, including the highest dose of 5,000 mg/kg/day.

4. *Subchronic toxicity.* A 28 day oral subchronic toxicity study was conducted with propylene carbonate in rats at rates up to 5,000 mg/kg/day. Treatment related increased ovary weights, and testes weights were observed at the highest dose and increased ovary weights were observed at the two highest dose levels of 3,000 and 5,000 mg/kg/day. The NOAEL was 1,000 mg/kg/day.

i. A 90 day oral subchronic toxicity study was conducted with propylene carbonate in rats at rates up to 5,000 mg/kg/day. There was reduced body weight and food consumption at the high dose level. Male kidneys also had reduced weight at the high dose group and there

were some minor blood chemistry changes. The authors concluded that there were no apparent toxicological effects from the consumption of propylene carbonate at rates up to 5,000 mg/kg/day over 90 days.

ii. A 14 week whole-body exposure inhalation toxicity study was conducted with propylene carbonate in rats at rates up to 1,000 mg/m³. In this study, neurotoxic motor responses were also monitored. The authors concluded that there were no toxicological effects from the consumption of propylene carbonate at rates up to 1,000 mg/m³ except minimal eye irritation.

5. *Chronic toxicity.* A 24 month chronic oral toxicity study in mice was conducted with propylene carbonate by application twice per week to clipped areas of the back. There were no tumors and no skin irritation as a result of treatment propylene carbonate in this study.

C. Aggregate Exposure

The following is a description of the likelihood of exposure to propylene and butylene carbonate from various routes.

1. *Dietary exposure.* Propylene and butylene carbonate are cleared as an indirect food additive under 21 CFR 175.105 for use as an indirect food additive in packaging. This clearance obtains from the use of propylene, and butylene carbonate in packaging glue and other indirect food additive uses. Little or no migration into the food substance is expected from these uses according to the information included in 21 CFR.

Propylene and butylene carbonate are not cleared for any applications to growing crops or to crops after harvest at this time, but following granting of this exemption, this will be the primary source of dietary exposure.

2. *Non-dietary exposure.* Propylene and butylene carbonate are solvents used in surface cleaners, degreasers, dyes, fibers, plastics, batteries, and as a gelling agent for clays. There would be additional exposure from these routes.

D. Cumulative Effects

Propylene and butylene carbonate are members of a class of compounds with structures containing the carbonate moiety. The closest related compound, ethylene carbonate, is used in similar, non-agricultural applications, but does not have any uses which would result in agricultural exposure or dietary exposure.

E. Safety Determination

1. *U.S. population.* Owing to the very high reference dose, it is not reasonable to assume any acute or chronic health

effects to the U. S. population.

Propylene and butylene carbonate are reduced-risk inert solvents which will reduce exposure to more toxic inert solvents.

2. *Infants and children.* There is a complete data base for propylene, and butylene carbonate which includes pre- and post-natal developmental toxicity data. The toxicological effects of propylene and butylene carbonate on rodents are well understood.

In a developmental toxicity study in rats, all reproductive parameters investigated showed no treatment-related effects except slightly retarded growth rate. Maternal effects were seen at 5,000 mg/kg/day without developmental effects. The NOAEL for reproductive effects in offspring is 5,000 mg/kg/day.

F. International Tolerances

A maximum residue level has not been set for propylene and butylene carbonate by the Codex Alimentarius Commission.

2. Interregional Research Project Number 4 (IR-4)

PP 0E3909, 2E4052, 2E4092, 3E4162, and 9E5049

EPA has received a request regarding pesticide petitions (PP 0E3909, 2E4052, 2E4092, 3E4162) from IR-4, New Jersey Agricultural Experiment Station, Rutgers University, New Brunswick, New Jersey 08903 to remove the time limitations on the established tolerances in 40 CFR part 180.412 for the herbicide sethoxydim (2-1-(ethoxymino)butyl-5-2-(ethylthio)propyl-3-hydroxy-2-cyclohexen-1-one) and its metabolites containing the 2-cyclohexen-1-one moiety (calculated as the herbicide) in or on asparagus at 4.0 parts per million (ppm), carrot at 1.0 ppm, cranberry at 2.0 ppm, peppermint, and spearmint tops at 30 ppm. EPA has also received a petition (PP 9E5049) from IR-4 proposing pursuant to section 408(d) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 346a(d), to amend 40 CFR part 180 by establishing a tolerance for residues of sethoxydim and its metabolites containing the 2-cyclohexen-1-one moiety (calculated as the herbicide) in or on the raw agricultural commodity horseradish at 4 ppm. EPA has determined that the petitions contain data or information regarding the elements set forth in section 408(d)(2) of the FFDC; however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data supports granting of the permanent tolerances. Additional data may be needed before

EPA rules on the petitions. This notice includes a summary of the petitions prepared by BASF Corporation, Agricultural Products, P.O. Box 13528, Research Triangle Park, NC 27709.

A. Residue Chemistry

1. *Plant metabolism.* The qualitative nature of the residues in plants and animals is adequately understood for the purposes of registration.

2. *Analytical method.* Analytical methods for detecting levels of sethoxydim and its metabolites in or on food with a limit of detection that allows monitoring of food with residues at or above the levels set in these tolerances were submitted to EPA. The proposed analytical method involves extraction, partition, and clean-up. Samples are then analyzed by gas chromatography with sulfur-specific flame photometric detection. The limit of quantitation (LOQ) is 0.05 ppm.

B. Toxicological Profile

1. *Acute toxicity.* Based on the available acute toxicity data, sethoxydim does not pose any acute dietary risks. A summary of the acute toxicity studies follows.

i. *Acute oral toxicity—Rat.* Toxicity Category III; LD₅₀=3125 milligrams/kilogram(mg/kg) (male), 2676 mg/kg (female).

ii. *Acute dermal toxicity—Rat.* Toxicity Category III; LD₅₀ >5,000 mg/kg (male and female).

iii. *Acute inhalation toxicity—Rat.* Toxicity Category III; LC₅₀ (4-hour)=6.03 mg/L (male), 6.28 mg/L (female).

iv. *Primary eye irritation—Rabbit.* Toxicity Category IV; no irritation.

v. *Primary dermal irritation—Rabbit.* Toxicity Category IV; no irritation.

vi. *Dermal sensitization—Guinea pig.* Waived because no sensitization was seen in guinea pigs dosed with the end-use product Poast (18% a.i.).

2. *Genotoxicity.* Ames assays were negative for gene mutation in *Salmonella typhimurium* strains TA98, TA100, TA1535, and TA 1537, with and without metabolic activity.

A Chinese hamster bone marrow cytogenetic assay was negative for structural chromosomal aberrations at doses up to 5,000 mg/kg in Chinese hamster bone marrow cells *in vivo*.

Recombinant assays and forward mutations tests in *Bacillus subtilis*, *Escherichia coli*, and *S. typhimurium* were all negative for genotoxic effects at concentrations of greater than or equal to 100%.

3. *Reproductive and developmental toxicity.* A developmental toxicity study in rats fed dosages of 0, 50, 180, 650, and 1,000 mg/kg/day with a maternal

no-observed adverse effect level (NOAEL) of 180 mg/kg/day and a maternal lowest observed adverse effect level (LOAEL) of 650 mg/kg/day (irregular gait, decreased activity, excessive salivation, and anogenital staining); and a developmental NOAEL of 180 mg/kg/day, and a developmental LOAEL of 650 mg/kg/day (21 to 22% decrease in fetal weights, filamentous tail, and lack of tail due to the absence of sacral and/or caudal vertebrae, and delayed ossification in the hyoids, vertebral centrum and/or transverse processes, sternebrae and/or metatarsals, and pubes).

A developmental toxicity study in rabbits fed doses of 0, 80, 160, 320, and 400 mg/kg/day with a maternal NOAEL of 320 mg/kg/day and a maternal LOAEL of 400 mg/kg/day (37% reduction in body weight gain without significant differences in group mean body weights and decreased food consumption during dosing); and a developmental NOAEL greater than 400 mg/kg/day highest dose tested (HDT).

A 2-generation reproduction study with rats fed diets containing 0, 150, 600, and 3,000 ppm (approximately 0, 7.5, 30, and 150 mg/kg/day) with no reproductive effects observed under the conditions of the study.

4. *Subchronic toxicity* A 21 day dermal study in rabbits with a NOAEL of >1,000 mg/kg/day (limit dose). The only dose-related finding was slight epidermal hyperplasia at the dosing site in nearly all males and females dosed at 1,000 mg/kg/day. According to BASF this was probably an adaptive response.

5. *Chronic toxicity.* A summary of the chronic toxicity studies follows.

A 1-year feeding study with dogs fed diets containing 0, 8.86/9.41, 17.5/19.9, and 110/129 mg/kg/day (males/females) with a NOAEL of 8.86/9.41 mg/kg/day (males/females) based on equivocal anemia in male dogs at the 17.5-mg/kg/day dose level.

A 2-year chronic feeding/carcinogenicity study with mice fed diets containing 0, 40, 120, 360, and 1,080 ppm (equivalent to 0, 6, 18, 54, and 162 mg/kg/day) with a systemic NOAEL of 120 ppm (18 mg/kg/day) based on non-neoplastic liver lesions in male mice at the 360-ppm (54 mg/kg/day) dose level. There were no carcinogenic effects observed under the conditions of the study. The maximum tolerated dose (MTD) was not achieved in female mice.

A 2-year chronic feeding/carcinogenic study with rats fed diets containing 0, 2, 6, and 18 mg/kg/day with a systemic NOAEL greater than or equal to 18 mg/kg/day HDT. There were no carcinogenic effects observed under the

conditions of the study. This study was reviewed under current guidelines and was found to be unacceptable because the doses used were insufficient to induce a toxic response and an MTD was not achieved.

A second chronic feeding/carcinogenic study with rats fed diets containing 0, 360, and 1,080 ppm (equivalent to 18.2/23.0, and 55.9/71.8 mg/kg/day (males/females)). The dose levels were too low to elicit a toxic response in the test animals and failed to achieve an MTD or define a LOAEL. Slight decreases in body weight in rats at the 1,080 ppm dose level, although not biologically significant, support a free-standing NOAEL of 1,080 ppm (55.9/71.8 mg/kg/day (males/females)). There were no carcinogenic effects observed under the conditions of the study.

6. *Animal metabolism.* In a rat metabolism study, excretion was extremely rapid and tissue accumulation was negligible.

7. *Metabolite toxicology.* As a condition to registration, BASF had been asked to submit additional toxicology studies for the hydroxy metabolites of sethoxydim. EPA agreed with BASF's recommendation to use the most abundant metabolite, 5-OH-MSO₂, as surrogate for all metabolites. Based on these data, it was concluded that the toxicological potency of the plant hydroxymetabolites is likely to be equal to or less than that of the parent compound. The tolerance expression for sethoxydim measures sethoxydim and its metabolites containing the 2-cyclohexen-1-one moiety, measured as parent. Hence, the hydroxymetabolites are figured into all tolerance calculations.

8. *Endocrine disruption.* No specific tests have been performed with sethoxydim to determine whether the chemical may have an effect in humans that is similar to an effect produced by naturally-occurring estrogen or other endocrine effects.

C. Aggregate Exposure

1. *Dietary exposure.* For purposes of assessing the potential dietary exposure, BASF has estimated aggregate exposure based on the Theoretical Maximum Residue Contribution (TMRC) from existing and pending tolerances for sethoxydim. (The TMRC is a "worst case" estimate of dietary exposure since it is assumed that 100% of all crops for which tolerances are established are treated and that pesticide residues are at the tolerance levels.) The TMRC from existing tolerances for the overall U.S. population is estimated at approximately 44% of the RfD. BASF

estimates indicate that dietary exposure will not exceed the RfD for any population subgroup for which EPA has data. This exposure assessment relies on very conservative assumptions 100% of crops will contain sethoxydim residues and those residues would be at the level of the tolerance which results in an over estimate of human exposure.

2. *Other exposure.* Other potential sources of exposure of the general population to residues of pesticides are residues in drinking water and exposure from non-occupational sources. Based on the available studies submitted to EPA for assessment of environmental risk, BASF does not anticipate exposure to residues of sethoxydim in drinking water. There is no established Maximum Concentration Level (MCL) for residues of sethoxydim in drinking water under the Safe Drinking Water Act (SDWA).

BASF has not estimated non-occupational exposure for sethoxydim. Sethoxydim is labeled for use by homeowners on and around the following use sites: flowers, evergreens, shrubs, trees, fruits, vegetables, ornamental groundcovers, and bedding plants. Hence, the potential for non-occupational exposure to the general population exists. However, these use sites do not appreciably increase exposure. Protective clothing requirements, including the use of gloves, adequately protect homeowners when applying the product. The product may only be applied through hose-end sprayers or tank sprayers as a 0.14% solution. Sethoxydim is not a volatile compound so inhalation exposure during and after application would be negligible. Dermal exposure would be minimal in light of the protective clothing and the low application rate. According to BASF post-treatment (re-entry) exposure would be negligible for these use sites as contact with treated surfaces would be low. BASF concludes that the potential for non-occupational exposure to the general population is insignificant.

D. Cumulative Effects

BASF also considered the potential for cumulative effects of sethoxydim and other substances that have a common mechanism of toxicity. BASF is aware of one other active ingredient which is structurally similar, clethodim. However, BASF believes that consideration of a common mechanism of toxicity is not appropriate at this time. BASF does not have any reliable information to indicate that toxic effects produced by sethoxydim would be cumulative with clethodim or any other

chemical; thus BASF is considering only the potential risks of sethoxydim in its exposure assessment.

E. Safety Determination

1. *U.S. population—Reference dose (RfD).* Using the conservative exposure assumptions described above, BASF has estimated that aggregate exposure to sethoxydim will utilize 44% of the RfD for the U.S. population. EPA generally has no concern for exposures below 100% of the RfD. Therefore, based on the completeness and reliability of the toxicity data, and the conservative exposure assessment, BASF concludes that there is a reasonable certainty that no harm will result from aggregate exposure to residues of sethoxydim, including all anticipated dietary exposure and all other non-occupational exposures.

2. *Infants and children—i. Developmental toxicity.* Developmental toxicity was observed in a developmental toxicity study using rats but was not seen in a developmental toxicity study using rabbits. In the developmental toxicity study in rats a maternal NOAEL of 180 mg/kg/day and a maternal LOAEL of 650 mg/kg/day (irregular gait, decreased activity, excessive salivation, and anogenital staining) was determined. A developmental NOAEL of 180 mg/kg/day and a developmental LOAEL of 650 mg/kg/day (21 to 22% decrease in fetal weights, filamentous tail and lack of tail due to the absence of sacral and/or caudal vertebrae, and delayed ossification in the hyoids, vertebral centrum and/or transverse processes, sternbrae and/or metatarsals, and pubes). Since developmental effects were observed only at doses where maternal toxicity was noted, BASF concludes that the developmental effects observed are believed to be secondary effects resulting from maternal stress.

ii. *Reproductive toxicity.* A 2-generation reproduction study with rats fed diets containing 0, 150, 600, and 3,000 ppm (approximately 0, 7.5, 30, and 150 mg/kg/day) produced no reproductive effects during the course of the study. Although the dose levels were insufficient to elicit a toxic response, the Agency has considered this study usable for regulatory purposes and has established a free-standing NOAEL of 3,000 ppm (approximately 150 mg/kg/day) Proposed Rule at 60 FR 13941.

iii. *Reference dose.* Based on the demonstrated lack of significant developmental or reproductive toxicity BASF believes that the RfD used to assess safety to children should be the

same as that for the general population, 0.09 mg/kg/day. Using the conservative exposure assumptions described above, BASF has concluded that the most sensitive child population is that of children ages 1-6. BASF calculates the exposure to this group to be approximately 95% of the RfD for all uses (including those proposed in this document). Based on the completeness and reliability of the toxicity data and the conservative exposure assessment, BASF concludes that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the residues of sethoxydim, including all anticipated dietary exposure and all other non-occupational exposures.

F. International Tolerances

A maximum residue level has not been established for sethoxydim on asparagus, carrot, cranberry, peppermint, spearmint or horseradish by the Codex Alimentarius Commission.

[FR Doc. 98-34291 Filed 12-29-98; 8:45 am]

BILLING CODE 6560-50-F

ENVIRONMENTAL PROTECTION AGENCY

[OPP-00538A; FRL-6051-4]

Announcement of the Availability and Request for Comments on Protocols for Testing the Efficacy of Disinfectants Used to Inactivate Hepatitis B Virus and Corresponding Label Claims

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of availability.

SUMMARY: EPA is announcing the availability and requesting comments on two protocols for testing the efficacy of disinfectants against Hepatitis B Virus (HBV). The protocols use Duck Hepatitis B Virus (DHBV) in an *in-vitro* or an *in-vivo* assay system. These protocols were presented at an HBV workshop which was held on July 23 and 24, 1998 at the Double Tree Hotel, Crystal City, VA. As a result of the workshop EPA agreed to publish the testing protocols and proposed labeling claims in the **Federal Register** with a 45-day comment period before the Agency makes a final decision about the use of protocols.

DATES: Comments, identified by the docket control number (OPP-00538A) should be received on or before February 16, 1999, to be given full consideration.

ADDRESSES: Submit comments and other information identified by the docket

control number OPP-00538A by mail 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 comments directly to the OPP Docket Office which is located in Rm. 119 of Crystal Mall 2 (CM #2), 1921 Jefferson Davis Highway, Arlington, VA.

Comments and data may also be submitted electronically to: opp-docket@epamail.epa.gov. Follow the instructions under Unit III of this document. No Confidential Business Information (CBI) should be submitted through e-mail.

Information submitted as a comment concerning this document 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 comment that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential will be included in the public docket by EPA without prior notice. The public docket is available for public inspection in Rm. 119 at the Virginia address given above, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays.

FOR FURTHER INFORMATION CONTACT: By mail: Ibrahim Barsoum, Antimicrobials Division (7510C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: 308W7, CM #2, 1921 Jefferson Davis Highway, Arlington, VA 22202. Tel. (703) 308-6417, Fax (703) 308-6466, e-mail: barsoum.ibrahim@epamail.epa.gov.

SUPPLEMENTARY INFORMATION:

I. Electronic Availability

Electronic copies of this document and various support documents are available from the EPA home page at the Federal Register-Environmental Documents entry for this document under "Laws and Regulations" (<http://www.epa.gov/fedrgstr/>).

II. Background

EPA held a workshop in July, 1998 to discuss alternative models for testing disinfectants against human HBV. The workshop was attended by representatives from academia, research centers, testing laboratories, and industry. Presentations were given by experts in hepatitis on various animal models of HBV infection followed by