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, sternebrae 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 aspargus, 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

technical presentations on *in-vitro* and *in-vivo* duck models of infection that might be used in testing disinfectants against HBV. Presentations were followed by a discussion on criteria to be used in decision making about surrogate model(s) and proposed labeling claims of registered products. It was proposed in the workshop to leave the label claim broad, such as ''Effective against HBV'' or ''Hepadnavirucidal'' and not to add information about the test organism. Submitted protocols were evaluated and discussed by all participants. At the end of the workshop an outline was presented, showing the agency's implementation plans for allowing products to be registered with HBV label claims using surrogate animal models.

III. Public Record and Electronic Submissions

A record has been established for this action under docket number ''OPP–00538A'' (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 public record is located in Rm. 119 of the Public Information and Records Integrity Branch, Information Resources and Services Division, Office of Pesticide Programs, Environmental Protection Agency, CM #2, 1921 Jefferson Davis Highway, Arlington, VA.

Comments and other information may also be submitted electronically by sending electronic mail (e-mail) to:
opp-docket@epamail.epa.gov.

Electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form or encryption. Comments will also be accepted on disks in WordPerfect in 5.1/6.1 or ASCII file format. All comments and data in electronic form must be identified by the docket number ''OPP–00538A.'' No CBI should be submitted through e-mail. Electronic comments on this document may be filed online at many Federal Depository Libraries.

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

List of Subjects

Environmental protection, Antimicrobials, Pesticides and pest, Efficacy testing, Hepatitis Virus B (HBV).

Dated: December 17, 1998.

Frank Sanders,

Director, Antimicrobials Division, Office of Pesticide Programs.

[FR Doc. 98–34292 Filed 12–29–98; 8:45 am]
BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

[OPP–00558A; FRL–6054–5]

Pesticides: Science Policy Issues Related to the Food Quality Protection Act; Extension of Comment Period

AGENCY: Environmental Protection Agency (EPA).

ACTION: Extension of comment period on notice of availability .

SUMMARY: On November 5, 1998, EPA issued a notice of availability for two draft science policy papers—''Guidance for Submission of Probabilistic Exposure Assessments to the Office of Pesticide Program'' and ''Office of Pesticide Program's Science Policy on the Use of Cholinesterase Inhibition for Risk Assessments of Organophosphate and Carbamate Pesticides.'' The comment period would have ended January 4, 1999. Due to the holidays, EPA has decided to extend the comment period two weeks.

DATES: Written comments must be submitted to EPA by January 19, 1999.

ADDRESSES: By mail, submit written comments 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, deliver comments to: Rm. 1132, CM#2, 1921 Jefferson Davis Hwy., Arlington, VA.

Comments and data may also be submitted electronically by sending electronic mail (e-mail) to: opp-docket@epa.gov. Follow the instructions under Unit II. 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 in this unit, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays.

FOR FURTHER INFORMATION CONTACT: Jeff Kempter (7505C), Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: Room 713D, CM#2, 1921 Jefferson Davis Highway, Arlington, VA, 703–305–5448, e-mail: kempter.carlton@epa.gov.

SUPPLEMENTARY INFORMATION:

I. Background

The Agency has issued the two draft documents listed in the SUMMARY at the beginning of this document and solicited comments on them. The background on these documents can be found in the previous **Federal Register** notice published on November 5, 1998 (63 FR 59780) (FRL–6042–3). A time extension of two weeks is being provided such that the comment period will now end on January 19, 1999.

II. Public Record and Electronic Submissions

The official record for this rulemaking, as well as the public version, has been established for this rulemaking under docket control number OPP–00559 for ''Guidance for Submission of Probabilistic Exposure Assessments to the Office of Pesticide Programs'' and OPP–00560 for ''Office of Pesticide Program's Science Policy on the Use of Cholinesterase Inhibition for Risk Assessments of Organophosphate and Carbamate Pesticides'' (including comments and data submitted electronically as described in this unit). 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, except legal holidays. The official rulemaking record is located at the Virginia address in ''ADDRESSES'' at the beginning of this document.

Electronic comments can be sent directly to EPA at:
opp-docket@epa.gov

Electronic comments must be submitted as an ASCII file avoiding the