documents can be directed to Tim Torma at (202) 260–5180 or Steve Marquardt at (312) 353–3214. To be included on the Chicago Project XL mailing list about future public meetings, XL progress reports and other mailings from CDOE on the XL project, contact Alexandra Holt at (312) 744–3172, CDOE, 30 N. LaSalle Suite 2500, Chicago, IL 60602. For information on all other aspects of the XL Program contact Christopher Knopes at the following address: Office of Policy Economics and Innovation, United States Environmental Protection Agency, 1200 Pennsylvania Avenue NW, Washington, DC 20460, Room M3802 (1802), Washington, DC 20460. Additional information on Project XL, including documents referenced in this notice, other EPA policy documents related to Project XL, regional XL contacts, application information, and descriptions of existing XL projects and proposals, are available via the Internet at http://www.epa.gov/ProjectXL.

Dated: August 21, 2000.

Elizabeth A. Shaw,

Director, Office of Environmental Policy Innovation.

[FR Doc. 00–21781 Filed 8–24–00; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[OPP–00673; FRL–6736–5]

Pesticides; Protocols for Testing the Efficacy of Disinfectants Against Hepatitis B Virus (HBV); Notice of Availability

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of availability.

SUMMARY: The Agency is announcing the availability of guidance titled ''Protocol for Testing the Efficacy of Disinfectants Used to Inactivate Hepatitis B Virus and Corresponding Label Claims.'' Through this guidance, EPA expresses its view that the appropriate and preferred test relies on *in vitro* duck assays which use duck hepatitis B virus as a surrogate for human hepatitis B virus (HHBV) to evaluate the efficacy of disinfectants used to inactivate HHBV. Use of such assays will greatly minimize the use of animals for testing. The Agency is also making available its responses to comments on the draft protocols that were made available for public comment.

FOR FURTHER INFORMATION CONTACT: Ibrahim Barsoum, Antimicrobials Division (7510C), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 308–6417; fax number: (703) 308–8481; e-mail address: barsoum.ibrahim@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

This action is directed to the public in general. This action may be of particular interest to those persons who manufacture or formulate pesticides. Potentially affected categories and entities may include, but are not limited to:

Categories	NAICS	Examples of potentially affected entities
Pesticide Producers	32532	Pesticide manufacturers Pesticide formulators

Since other entities may also be interested, the Agency has not attempted to describe all the specific entities that may be affected by this action. If you have any questions regarding the information in this notice, consult the person listed under **FOR FURTHER INFORMATION CONTACT.**

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

1. *Electronically.* You may obtain electronic copies of this document from the Office of Pesticide Programs' Home Page at http://www.epa.gov/pesticides/. You can also go directly to the listings from the EPA Internet Home Page at http://www.epa.gov/. To access this document, on the Home Page select ''Laws and Regulations,'' ''Regulations and Proposed Rules,'' and then look up the entry for this document under the '' **Federal Register**—Environmental Documents. '' You can also go directly to the **Federal Register** listings at http://www.epa.gov/fedrgstr/.

2. *Fax–on –demand.* You may request a faxed copy of the guidance, as well as supporting information, by using a faxphone to call (202) 401–0527. Select item 6067 for the document titled ''Protocol for Testing the Efficacy of Disinfectants Used to Inactivate Hepatitis B Virus and Corresponding Label Claims.'' Select item 6068 for the document titled ''Responses to Public Comments on Protocols for Testing the Efficacy of Disinfectants Used to Inactivate Hepatitis B Virus.'' You may also follow the automated menu.

3. *In person.* The Agency has established an official record for this action under docket control number OPP–00673. The official record consists of the documents specifically referenced in this action, any public comments received during an applicable comment period, and other information related to this action, including any information claimed as confidential business information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period, is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305–5805.

II. Background

A. What Guidance Does this Notice Provide?

EPA has authority through the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) to register pesticide products, including antimicrobial pesticide products, for sale and distribution in the United States. FIFRA section 3(c)(5) requires that the composition of a pesticide product is such as to warrant the claims made for it, i.e., that a product work as claimed. Although registrants must maintain data demonstrating efficacy in their files and must submit these data to the Agency upon request, EPA does not routinely review efficacy data prior to registration of most insecticides, fungicides, herbicides, and non-public health antimicrobial pesticides. However, for public health pesticide products (i.e., those that work against pests in situations where they pose public health threats) the Agency reviews efficacy data prior to registration. The Agency believes that the potential consequences of performance failure for public health products warrant this extra precautionary step in the review process. Moreover, for public health products intended to control bacteria, fungi and viruses, the user is typically unable to determine whether the product is working, due simply to the microscopic size of these organisms.

Subdivision G of the Pesticide Assessment Guidelines describes the efficacy tests routinely used to validate the claims made by antimicrobial public health pesticide products. These guidelines are available from the National Technical Information Service, 5285 Port Royal Road, Springfield, VA 22161 (1–800–553–6847).

For the past several years, EPA has been engaged in a process to identify scientifically and statistically adequate test protocols for evaluating the efficacy of disinfectants used to inactivate human hepatitis B virus (HHBV). In May 28, 1986 (51 FR 19174), the Agency published a Notice of Amendment to Policy regarding certain virucidal claims. Specifically, the Notice stated that virucidal claims for HBV would be permissible only for sterilizer products until such time that acceptable protocols to demonstrate virus isolation and disinfectant product efficacy could be developed.

In 1990, the Agency received and approved a chimpanzee testing protocol to support HBV efficacy claims for hard, environmental surface disinfection products. While the data were being generated using the approved protocol, a General Accounting Office (GAO) Report was issued (August 1990) that criticized the Agency for accepting test methods without criteria or a systematic review process. In response to this criticism, the Agency initiated a process whereby new protocols would undergo external review by scientific experts. In 1995, as a result of this change in process, the chimpanzee protocol was subjected to external review by experts working in various scientific institutions, including the Food and Drug Administration (FDA), Center for Disease Control (CDC), National Institutes of Health (NIH), and two university medical schools. The experts were asked to review the data generated using the EPA-approved protocol as well as similar data developed by Bond *et al.* 1983, at CDC. After careful review of all comments received, the Agency concluded that the chimpanzee data submitted by the applicant, when considered together with the data developed by Bond *et al.* 1983, were sufficient to support a label claim of disinfection against HBV.

During the 1995 external review process for the chimpanzee protocol, several experts urged the Agency to accept data developed using a surrogate virus, thus making available an alternative to chimpanzee testing. One expert stated that it would be unjustified to permit the use of any type of animal for germicidal testing and that such testing could be avoided though the use of properly designed *in vitro* methods. As a result of these concerns, the Agency began to seek alternative means of testing the product performance of disinfectant products intended for inactivation of HBV. One of the steps in this process was consultation with the FIFRA Scientific Advisory Panel (SAP) in September 1997. At that meeting the questions posed to the Panel were as follows:

1. If the Agency decides to replace the chimpanzee test used in testing the efficacy of disinfectants against human hepatitis B-type virus, what test methodologies could be used as a replacement? Two possibilities that have been proposed to the Agency are the duck hepatitis B Virus Test (DHVT) and the Morphological Alteration and Disintegration Test (MADT). Could one or both of these tests be used to test for efficacy against HHVB?

2. If a surrogate test system (i.e., the DHVT) is found to be acceptable for efficacy testing using HVB, would the results be sufficient to allow the registrant to make a label claim that the product was efficacious against HHBV, even though it was tested against a surrogate virus (i.e., duck hepatitis B virus) and not the human virus?

Briefly, the SAP's responses to these questions were as follows. The Panel concurred with the notion that it is unethical to continue to require testing using a species of primates, chimpanzees, where alternative methods are available, and observed that there is a long history of using surrogate microbes to assess the efficacy of disinfection/sterilization technologies against various classes of microorganisms. The Panel stated that the duck hepatitis B virus (DHBV) constitutes an appropriate HHBV surrogate and added that an advantage to this surrogate is that the DHBV can be utilized in both *in vivo* and *in vitro* settings. In particular, the Panel stated that the DHBV approach would allow for sufficient numbers of test samples to be used for each set of experimental conditions so that statistically significant results can be obtained. The Panel discussed the possibility that DHBV may be more resistant to germicidal chemical activity but, in essence, felt that even if this were true it was not a serious issue, given that hepatitis B-type viruses have been demonstrated to be sensitive to the activity of a wide spectrum of liquid chemical germicides including low level disinfectants. While the panel did not discuss the MADT alternative at great length or exclude the possibility of its use, it did observe that the test is only subjective. The Panel stated its belief that registrants who use DHBV could make a label claim of product efficacy to either the specific virus or in the alternative to perhaps the whole virus family as a group. The example of claims against *Mycobacterium tuberculosis* by testing against *Mycobacterium bovis* was cited as precedent for the use of a surrogate in disinfectant efficacy testing. If tests validate that a surrogate virus is less or equally susceptible to inactivation by disinfectants, then logically any product which demonstrates efficacy against the surrogate virus should be allowed a label claim against HHBV.

The responses of the SAP to these questions provided invaluable guidance to the Agency in its pursuit of scientifically adequate test protocols for evaluating the efficacy of disinfectants used to inactivate HHBV. The Antimicrobials Division of the Office of Pesticide Programs sponsored a workshop in July 1998 to discuss alternative models for testing disinfectants against HHBV. 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 for use against HHBV. 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. Many participants in the workshop proposed that EPA leave the label claim broad, such as ''effective against HBV'' or ''hepadnavirucidal'' and not 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 HHBV label claims using surrogate animal models. Subsequently, the Agency published an FR Notice on December 30, 1998 (63 FR 71924) (FRL–6051–4) announcing the availability of and requesting comments on two protocols for testing the efficacy of disinfectants against HHBV. These protocols were for an *in vitro* assay using duck hepatocytes and DHBV and an *in vivo* assay using ducklings and DHBV.

The Agency received 12 sets of comments in response to that Notice. Comments were received from consultants, an animal rights organization, university scientists, the regulated industry, the California

Department of Pesticide Regulation, and private organizations. These comments in their entirety are available in the public docket (OPP–00673). Many of the comments were similar in content, and pertained to general issues concerning Agency policy or specific sections within the protocols themselves. To facilitate review and consideration of the comments, the Agency has grouped comments addressing similar issues together.

After the Agency reviewed the comments, it reached three conclusions:

1. It is the Agency's position that duck HBV serves as an adequate surrogate for human HBV and that the *in vitro* assay is sufficiently sensitive to preclude the need for any *in vivo* testing. The Agency is adopting, where possible, policies and data requirements that minimize animal testing, and when animal testing must be conducted, EPA is committed to reducing the number of animals needed for testing, reducing the pain and suffering of the test animals, and whenever scientifically-defensible, replacing animals with validated non-animal test systems. Therefore, relying heavily on the recommendations of the SAP, the Agency expects to rely on the use of the *in vitro* duck protocol as the method for evaluating the efficacy of disinfectants used to inactivate HHBV. Notwithstanding its commitment to maximize the reduction or elimination ofanimal testing where feasible, the Agency recognizes that some testing may already have been initiated or completed using the duck *in vivo* methodology as of the date of this Notice. On a case-by-case basis, the Agency will generally accept these data, if deemed valid, to support a registration.

2. Label claims against either the Hepadnavirus family or, more specifically, HHBV will be permitted when supported by adequate efficacy claims as described below. In addition, the following label claim language will be deemed acceptable: ''effective against HBV.'' The Agency believes that these label claims can be supported by appropriate DHBV efficacy tests, since the surrogate DHBV has been shown to be a reliable predictor of resistence to chemical disinfection for the Hepadnavirus family as a whole.

3. To ensure that the *in vitro* duck method has been adequately validated, data should be provided from at least two independent laboratories for each product tested (two batches per product per laboratory). The validation of a protocol requires the use of a common positive control disinfectant to be tested concurrently with all new products. The recommended control is alkyldimethylammonium chloride (BTC-835, Onyx Chemical Co.) (AOAC Official Methods of Analysis, Chapter 6, p. 136, 15th Edition, 1990). This agent should serve as both an intra-laboratory and an inter-laboratory control and will be used for analyzing the reproducibility of the efficacy data results for that particular protocol. In order to obtain the necessary inter-laboratory data, all submissions must additionally be subjected to confirmatory testing, with the common positive control, at a second laboratory test facility. It is critical for the Agency to know that a test method is repeatable; i.e., that there is an appropriately small standard deviation of log reduction (LR) values found when the test is repeated on different occasions in the same laboratory as well as when the test is conducted in different laboratories. The use of the common positive control and the generation of confirmatory data in a second testing facility will achieve these goals. A more detailed document outlining the criteria for validation is available electronically under the section titled ''Related Documents'' section of the electronic version of this Notice (''Protocol for Testing the Efficacy of Disinfectants Used to Inactivate Hepatitis B Virus''). This document may also be requested by mail directly from the Agency (refer to **FOR FURTHER INFORMATION CONTACT** section of this Notice).

B. Guidance Documents

The guidance discussed in this notice is intended to provide guidance to EPA personnel and to pesticide applicants and registrants. This notice is not binding on EPA, applicants and registrants, and EPA may depart from the guidance where circumstances warrant and without prior notice. Registrants and applicants may propose altenatives to the protocols described in this notice and the Agency will assess them on a case-by-case basis.

List of Subjects

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

Dated: August 17, 2000.

Marcia E. Mulkey,

Director, Office of Pesticide Programs.

[FR Doc. 00–21784 Filed 8–24–00]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[FRL–6857–6]

Notice of Proposed Settlement Under Section 122(h) of the Comprehensive Environmental Response, Compensation and Liability Act; St. Louis River Site, Duluth, MN

AGENCY: U.S. Environmental Protection Agency.

ACTION: Notice; request for public comment.

SUMMARY: Notice of Settlement for recovery of past costs. In accordance with section 122(i)(1) of the Comprehensive Environmental Response, Compensation and Liability Act of 1980, as amended (CERCLA), notice is hereby given of a proposed administrative settlement under section 122(h) of CERCLA concerning the St. Louis River Superfund Site, Duluth, Minnesota. The Agreement was signed by the Director, Superfund Division, U.S. Environmental Protection Agency, Region 5, (U.S. EPA) on August 3, 2000. Subject to review by the public pursuant to this Notice, the agreement was approved by the United States Department of Justice on July 31, 2000. Below are listed the parties who have executed binding certifications of their consent to participate in the settlement: Domtar, Inc.; Honeywell International, Inc.; and The Interlake Corporation. These parties will pay a total of $833,000 in a settlement payment for past response costs under the agreement subject to the contingency that U.S. EPA may elect not to complete the settlement based on matters brought to its attention during the public comment period established by this Notice. This amount represents approximately ninety percent of past response costs U.S. EPA and the Agency for Toxic Substances and Disease Registry have expended at the St. Louis River Superfund Site as of January 31, 2000.

U.S. EPA is authorized to enter into this agreement under the authority of section 122(h) and 107 of CERCLA. Section 122(h) authorizes settlements with potentially responsible parties for the recovery of past costs expended by the Agency where these claims have not been referred to the U.S. Department of Justice for further action.

U.S. EPA will receive written comments relating to this agreement for thirty days from the date of publication of this notice. The Agency will consider all comments received and may withdraw its consent to the settlement if comments received disclose facts or considerations which indicate that the