

contact, or inhalation, AgriVir, LLC concludes that there is a reasonable certainty that no harm to infants and children will result from dietary exposure to residues which could occur as a result of approval of this petition.

3. *Sensitive individuals.* Since the available information reliably supports that IMMGV will not produce adverse effects in humans of any age as a result of exposure by ingestion, dermal contact, or inhalation, and indeed that IMMGV appears to be biologically inactive in other than its natural host, AgriVir, LLC concludes that there is a reasonable certainty that no harm to sensitive persons will result from dietary exposure to residues which could occur as a result of approval of this petition.

G. International Tolerances

There are no Codex maximum residue levels established for residues of IMMGV. IMMGV containing products are presently not registered for pest control outside of the U.S.

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ENVIRONMENTAL PROTECTION AGENCY

[FRL-7537-7]

Framework for Application of the Toxicity Equivalence Methodology for Polychlorinated Dioxins, Furans, and Biphenyls in Ecological Risk Assessment (External Review Draft); Notice of Availability

AGENCY: Environmental Protection Agency.

ACTION: Notice of availability and opportunity for public comment.

SUMMARY: The U.S. Environmental Protection Agency (EPA) is announcing a 60-day public comment period for the draft document titled Framework for Application of the Toxicity Equivalence Methodology for Polychlorinated Dioxins, Furans, and Biphenyls in Ecological Risk Assessment. The document is intended to describe a methodology for assessing ecological risks associated with complex mixtures of dioxins, furans, and dioxin-like PCBs in the environment. EPA will consider the public comments in revising the document.

DATES: Comments must be received by September 29, 2003.

ADDRESSES: The draft is available via the Internet at <http://cfpub.epa.gov/ncea/raf/recordisplay.cfm?deid=55669>. Comments may be submitted

electronically, by mail, or in person, as described in the instructions under Supplementary Information. Comments may be viewed at EPA Dockets at <http://www.epa.gov/edocket> (under Docket ID No. ORD-2003-0002).

FOR FURTHER INFORMATION CONTACT: Marilyn Brower, U.S. EPA, ORD National Center for Environmental Assessment, Risk Assessment Forum Staff (8601D), 1200 Pennsylvania Ave. NW., Washington, DC 20460; telephone: 202-564-3363; fax: 202-565-0062; e-mail: brower.marilyn@epa.gov.

SUPPLEMENTARY INFORMATION:

I. Submission of Comments

You may submit comments electronically, by mail, or through hand delivery/courier. To ensure proper receipt by EPA, identify the appropriate docket identification number (ORD-2003-0002) in the subject line on the first page of your comment. Please note that all comments received in response to this notice will be placed in a public record. For that reason, comments should not contain personal information (such as medical data or home address), Confidential Business Information, or information protected by copyright.

A. Electronically to EPA Dockets

Your use of EPA's electronic public docket (EPA Dockets) to submit comments is EPA's preferred method for receiving comments. Go directly to EPA Dockets at <http://www.epa.gov/edocket> and follow the online instructions for submitting comments. Once in the system, select "search," and then key in Docket ID No. ORD-2003-0002. The system is an "anonymous access" system, which means EPA will not know your identity, e-mail address, or other contact information unless you provide it. EPA recommends that you include your name and contact information in the body of your comment to ensure that you can be identified as the submitter of the comment and to allow EPA to contact you in case EPA cannot read your comment due to technical difficulties or needs further information on the substance of your comment.

B. By Mail

Comments may be sent to: Office of Environmental Information Docket, Environmental Protection Agency, Mailcode: 28220T, 1200 Pennsylvania Ave. NW, Washington, DC 20460, Attention Docket ID No. ORD-2003-0002.

C. By Hand Delivery or Courier

Deliver your comments to: Office of Environmental Information Docket, EPA

West, Room B102, 1301 Constitution Ave. NW, Washington, DC, Attention Docket ID No. ORD-2003-0002. Such deliveries are only accepted during the Docket's normal hours of operation from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the docket is 202-566-1752.

II. Background

Polychlorinated dioxins (PCDDs), furans (PCDFs), and biphenyls (PCBs) commonly occur as complex mixtures in the environment. For more than a decade, EPA and other organizations have estimated the combined risks that such mixtures pose to human health using a method known as the toxicity equivalence methodology. The methodology is based on findings that certain PCDDs, PCDFs, and PCBs share a common mechanism of action for their effects but differ in potency. The methodology uses potency factors (such as Toxicity Equivalence Factors, or TEFs) assigned to each chemical in the mixture as a way of integrating the risks from the entire mixture. Application in ecological risk assessments has proceeded more slowly than in human health risk assessment, in part because of the variety of species from different taxonomic classes (e.g., fish, birds, and mammals) to be considered.

As both data and experience with the methodology have accumulated, however, experts have concluded that the toxicity equivalence methodology can strengthen assessments of ecological risks. At a World Health Organization consultation in 1997, international consensus TEFs for PCDDs, PCDFs, and PCBs were reviewed and the toxicity equivalence methodology expanded to include class-specific TEFs for mammals, birds and fish. In 1998, EPA and the U.S. Department of Interior sponsored a workshop that recommended the development of further guidance on application of the toxicity equivalence methodology. This draft framework has been developed in direct response to that workshop recommendation by a technical panel under EPA's Risk Assessment Forum.

Organized in accordance with EPA's *Guidelines for Ecological Risk Assessment* (63 FR 26846), this framework is intended to assist EPA scientists in using the methodology, as well as to inform EPA decision makers, other agencies, and the public about this methodology. It provides ecological risk assessors with an understanding of the uncertainties associated with the application of the methodology in general and with situation-specific decisions made in applying the