

interpreted and managed in the studies that support the model.

6. Refinements of the model related to absorption, tissue distribution, and metabolism were accomplished, or

suitably explained, including the role of extrahepatic metabolism as it impacts the model dose metrics and route-to-route extrapolation; appreciably improving prior PBPK models of EDC.

It is EPA's decision that the HAP Task Force can proceed with the Tier II Testing under the schedule set forth in Table 1. of this **Federal Register** document.

TABLE 1.—REQUIRED TESTING, TEST STANDARDS, AND REPORTING REQUIREMENTS FOR EDC

Testing segment	Required testing	Test standard	Deadline for final report <sup>1</sup> (months)
Tier II testing and/or extrapolation reporting	Subchronic toxicity route-to-route extrapolation of dose-response (oral Tier II testing to inhalation) of a study reported by Daniel, et al., (1994)	ECA appendix C.2 and C.6	12
	Subchronic neurotoxicity (oral)	40 CFR 799.9620 (as annotated in ECA appendix D.2)	18
	Subchronic neurotoxicity route-to-route extrapolation of dose-response (oral Tier II testing to inhalation)	ECA appendix C.3 and C.6	21
	Reproductive toxicity (oral)	40 CFR 799.9380 (as annotated in ECA appendix D.3)	25
	Reproductive toxicity route-to-route extrapolation of dose-response (oral data to inhalation, including Tier II testing and extant studies reported by Alumot, et al., (1976), Rao, et al., (1980), and Lane, et al., (1982))	ECA appendix C.4 and C.6	28

<sup>1</sup>Number of months after the date of publication of this **Federal Register** document, which announces that EPA has concluded the EPA Program Review, when the final report is due. In addition, every 6 months from the effective date of the Order until the end of the ECA testing program, interim reports describing the status of all testing to be performed under this ECA must be submitted by the Companies to EPA.

### III. References

1. D'Souza, R.W., Francis, W.R., Bruce R.D., and Andersen, M.E. Physiologically based pharmacokinetic model for ethylene dichloride and its application in risk assessment. P. 286–301, In: *Pharmacokinetics in Risk Assessment*. National Academy Press. Washington, D.C. (1987).

2. D'Souza, R.W., Francis, W.R., and Andersen, M.E. Physiological model for tissue glutathione depletion and increased resynthesis after ethylene dichloride exposure. *Journal of Pharmacology and Experimental Therapeutics*. 245(2):563–568. (1988).

3. EPA, Office of Prevention, Pesticides and Toxic Substances, Chemical Control Division. Letter from Jim Willis, Director, CCD to Dr. Peter Voytek, HAP Task Force. RE: EPA Tier I Program Review for EDC. January 10, 2007.

4. EPA and HAP Task Force. Technical Consultation Meeting on 1, 2-Ethylene Dichloride Program Review. February 12, 2007.

5. HAP Task Force. Letter from Peter E. Voytek, Manager, HAP Task Force to Jim Willis, Director, Chemical Control

Division, Office of Pollution Prevention and Toxics, with Enclosure: Response to Issues Raised in EPA's Tier 1 Data Evaluation Meeting. May 23, 2007.

6. Sweeny, L. M. and Gargas, M.I. Physiologically based pharmacokinetic model development and simulations for ethylene dichloride (1,2-dichloroethane) in rats. Prepared by the Sapphire Group, Dayton Ohio for the HAP Task Force, Millwood, Virginia. Revised Draft Report. March 11, 2009.

7. Sweeny, L. M., Saghir, S. A., and Gargas, M.I. Physiologically based pharmacokinetic model development and simulations for ethylene dichloride (1,2-dichloroethane) in rats. *Regulatory Toxicology and Pharmacology*. 51:311–323. (2008).

8. EPA. Email from Rob Dewoskin, PhD, DABT, US EPA/NCEA (National Center for Environmental Assessment) to John Schaeffer. Review of Final report - EDC ECA Program Review Completion. April 22, 2009.

#### List of Subjects

Environmental protection, 1,2-Ethylene Dichloride, EDC, Hazardous chemicals.

Dated: July 10, 2009.

**Jim Willis,**

*Director, Chemical Control Division, Office of Pollution Prevention and Toxics.*

[FR Doc. E9–17170 Filed 7–21–09; 8:45 am]

**BILLING CODE 6560–50–S**

### ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–ORD; FRL–8930–3]

#### Flexible Approaches to Environmental Measurement—The Evolution of the Performance Approach

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Notice.

**SUMMARY:** Assuring the quality of environmental measurements is essential to the implementation of the Environmental Protection Agency's (EPA's or the Agency's) environmental programs, both regulatory and voluntary. In an October 6, 1997, Notice of Intent (FRL–5903–2), the Agency outlined a “Performance Based Measurement System (PBMS)” concept

which was expected to “\* \* \* have the overall effect of improving data quality and encouraging advancement of analytical technologies.” EPA has recently revisited the 1997 concept, gauged the Agency’s progress towards achieving its goals, and redefined steps needed to ensure continued progress.

The Agency has determined that while specifying performance criteria in a manner that is independent of methods, techniques, or instruments may be possible, developing a single protocol for the validation of these measurements that could be applied to all measurements, including measurements made with techniques yet to be invented, may not be possible. Accordingly, EPA is introducing principles that reflect flexible approaches to environmental measurement. These principles capture the Agency’s experience of the past ten years, set the stage for future progress in improving data quality, and encourage the advancement of environmental measurement technologies.

Key goals for this flexible approach are as follows: Increased emphasis on flexibility when choosing sampling and analytical approaches to meet regulatory requirements for measurements; development of processes for validation to confirm measurements meet quality requirements; increased collaboration with stakeholders to develop validation processes for new measurement technology; and timely assessment of new or modified technologies, methods, and procedures.

The purpose of this notice is to provide the public with an up-to-date communication on the Agency’s progress to Flexible Measurement—The Evolution of the Performance Approach.

**FOR FURTHER INFORMATION CONTACT:** For specific information regarding this notice, contact Lara Autry, Environmental Protection Agency, Office of the Science Advisor, E243-05, 109 TW Alexander Drive, Research Triangle Park, NC 27709; telephone number: 919-541-5544; fax number: 919-541-4261; e-mail address: [autry.lara@epa.gov](mailto:autry.lara@epa.gov).

**SUPPLEMENTARY INFORMATION:** The Forum on Environmental Measurements (FEM) is a standing committee of senior EPA managers established to develop policies to guide the EPA measurement community in validating and disseminating methods for environmental monitoring; for ensuring that monitoring studies are scientifically rigorous, statistically sound, and yield representative data; and for employing a quality systems approach that ensures that the data gathered and used by the

Agency is of known and documented quality. The Forum was established to promote consistency and consensus within the EPA on measurement issues.

Historically, most EPA programs have specified required analytical methods to be used by the regulated community in the analysis of environmental samples for regulatory compliance purposes. EPA has published its methods in regulations and a number of compendia, such as “Manual of Methods for Chemical Analysis of Water and Wastes” and “Methods for the Determination of Organic Compounds in Drinking Water.” The requirement to use specific analytical methods for compliance purposes is one of several means for assuring appropriate consistency and reliability in environmental monitoring.

In certain instances, in order to provide regulated parties with the flexibility to use alternative methods, EPA programs have established administrative processes by which the public could submit a proposed method for Agency review and approval. Before alternative methods are used in regulatory compliance applications, EPA’s regulations require that such methods be approved by the Agency through formal rulemaking.

In past instances, the approval processes have been lengthy. For example, in some cases, the approval process took several years to receive consent for a proposed method or method modification after the Agency completed its evaluation. The approach of specifying required methods and approving new methods was identified as a major barrier to using innovative monitoring technology. In order to address these concerns, EPA’s former Environmental Monitoring Management Council (EMMC) established a work group of scientists representing EPA’s Headquarters and Regional offices to consider the advisability for establishing a performance-based approach to specifying analytical testing requirements. Based on the work group’s recommendations in 1997, the Agency announced its intent to incorporate the PBMS approach, to the extent feasible, into its programs.

At the same time, the Agency intended that PBMS would provide the regulated community with flexibility in conducting required environmental monitoring, expedite the use of new and innovative techniques, and result in less costly approaches to conducting required monitoring and measurements. Under PBMS, the Agency envisioned that this approach would continue to allow use of its current required methods as well.

EPA has revisited the 1997 concept, gauged the Agency’s progress towards achieving its goals, and redefined steps needed to ensure continued progress. EPA has determined that while it may sometimes be possible to specify performance criteria in a manner that is independent of methods, techniques, or instruments, the development of a single protocol for validating these measurements that could be applied to all measurements, including measurement made with techniques yet to be invented, is simply not possible. Accordingly, EPA is introducing flexible approaches in environmental measurement. These flexible approaches capture the Agency’s experience of the past ten years, set the stage for future progress in improving data quality, and encourage the advancement of environmental measurement technologies.

The key goals for the flexible approaches are as follows.

#### **(1) Increase Emphasis on the Flexibility of Choosing Sampling and Analytical Approaches To Meet Regulatory Requirements for Measurements**

Setting measurement requirements begins with identifying goals and considering such factors as action levels, technology performance, mandates, and/or limitations of the program or project. These goals may be applied broadly across a program and established by a program office, or may be specific to a project or permit. Goals are translated into measurement requirements, which may take a variety of forms. In some applications, a general requirement on accuracy may be present; while in others, measurement requirements may be coupled to a technology, method, or procedure (e.g., criteria for evaluating modifications to published reference methods).

The Agency recognizes that some of its measurement quality requirements that appear throughout its regulations may be more specific than necessary, and it will strive to make these requirements more flexible as time and resources permit.

#### **(2) Develop Processes for Validations That Confirm That Measurements Meet Quality Requirements**

A validation process should provide evidence that measurement quality requirements are achieved. According to ISO 17025,<sup>1</sup> “validation is the confirmation by examination and the provision of objective evidence that the particular requirements for specific

<sup>1</sup> ISO/IEC 17025 General requirements for the competence of testing and calibration laboratories.

intended use are fulfilled.” Validation is typically performed in two phases. The first phase provides evidence on general performance of a measurement system for a range of materials that define a matrix class; the second phase (often called “verification”), demonstrates that the requirements for a specific use are met. Both phases are important for scientific and legal defensibility.

More general measurement requirements call for more specific validation processes. A general requirement on accuracy that is specified in a manner independent of technique, method, or instrument should be accompanied by detailed validation for each method of measurement. Conversely, a measurement quality requirement to use a particular procedure can require essentially no validation, as a detailed procedure often includes a complete specification of required quality control activities.

EPA intends to develop processes for validation that allow for an appropriate choice of specificity. For some applications, validation processes may continue to use defined procedures with ongoing quality control. For other applications, validation processes may place emphasis on greater flexibility and include verification that the requirements for a specific use are achieved.

### (3) Increase Collaboration With Stakeholders To Develop Validation Processes for New Measurement Technology

Validation required for new technology may be difficult to specify in advance due to the wide variety of performance issues which may be encountered. The Agency anticipates that developing validation processes for applications of new technology will require collaborating with stakeholders to ensure timely development of these processes. During this process, the Agency expects to continue to play a key role in the validation development.

### (4) Timely Assessment of New or Modified Technologies, Methods, and Procedures

In the event that the measurement requirements in a program are specific to a technology, method, or procedure, the Agency is committed to the assessment of proposed alternatives to these requirements and to rendering timely decisions of these alternatives when approval is sought.

Today's notice is not a formal agency action, but a statement of the Agency's approach to environmental measurement flexibility. It creates no

rights enforceable by any party in litigation with the United States.

Dated: June 30, 2009.

**Kevin Teichman,**

*Acting EPA Science Advisor.*

[FR Doc. E9-17402 Filed 7-21-09; 8:45 am]

**BILLING CODE 6560-50-P**

## ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPP-2009-0481; FRL-8429-8]

### Proposed Stipulated Injunction Involving Pesticides and Eleven Species Listed as Threatened or Endangered Under the Endangered Species Act; Notice of Availability; Reopening of Comment Period

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Notice; reopening of comment period.

**SUMMARY:** EPA issued a notice in the **Federal Register** of July 1, 2009, announcing the availability of a proposed Stipulated Injunction that would establish a series of deadlines for the Agency to make “effects determinations” and initiate consultation, as appropriate, with the U.S. Fish and Wildlife Service for certain pesticides in regard to one or more of 11 species found in the greater San Francisco Bay area that are listed as endangered or threatened under the Endangered Species Act. The proposed Stipulated Injunction, if entered by the Court, would resolve a lawsuit brought against EPA by the Center for Biological Diversity in the United States District Court for the Northern District of California. The July 1, 2009 notice provided a 15-day comment period which closed on July 16, 2009. This document reopens the comment period for 30 days.

**DATES:** Comments, identified by docket identification (ID) number EPA-HQ-OPP-2009-0481, must be received on or before August 17, 2009.

**ADDRESSES:** Follow the detailed instructions as provided under **ADDRESSES** in the **Federal Register** document of July 1, 2009.

**FOR FURTHER INFORMATION CONTACT:** Arty Williams, Environmental Fate and Effects Division (7507P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 305-7695; e-mail address: [williams.arty@epa.gov](mailto:williams.arty@epa.gov).

**SUPPLEMENTARY INFORMATION:** On July 1, 2009 (74 FR 31427) (FRL-8425-1), EPA

issued a notice in the **Federal Register** opening a 15-day comment period on a proposed Stipulated Injunction. The proposed Stipulated Injunction if entered by the United States District Court for the Northern District of California, would resolve a lawsuit brought against EPA by the Center for Biological Diversity (*Center for Biological Diversity v. EPA*, No. C 07-02794 JCS (N.D.Cal.)).

The original comment period closed on July 16, 2009. However, based on comments received, EPA is reopening the comment period for 30 days to allow the public additional time to develop meaningful comments on the proposed Stipulated Injunction. Comments must be received on or before August 17, 2009.

To submit comments, or access the docket, please follow the detailed instructions as provided under **ADDRESSES** in the July 1, 2009 **Federal Register** document. If you have questions, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

### List of Subjects

Environmental protection,  
Endangered species.

Dated: July 15, 2009.

**Debra Edwards,**

*Director, Office of Pesticide Programs.*

[FR Doc. E9-17396 Filed 7-17-09; 4:15 pm]

**BILLING CODE 6560-50-S**

## ENVIRONMENTAL PROTECTION AGENCY

EPA-HQ-OPP-2009-0484; FRL-8425-8]

### Notice of Receipt of Several Pesticide Petitions Filed for Residues of Pesticide Chemicals in or on Various Commodities

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Notice.

**SUMMARY:** This notice announces the Agency's receipt of several initial filings of pesticide petitions proposing the establishment or modification of regulations for residues of pesticide chemicals in or on various commodities.

**DATES:** Comments must be received on or before August 21, 2009.

**ADDRESSES:** Submit your comments, identified by the docket identification (ID) number and the pesticide petition number (PP) for the petition of interest as shown in the body of this document, by one of the following methods: