## ENVIRONMENTAL PROTECTION AGENCY

**[FRL–7151–4]**

### EPA Draft Human Health and Ecological Risk Assessment of Perchlorate

**AGENCY:** Environmental Protection Agency.

**ACTION:** Notice of second extension of public comment period.

**SUMMARY:** The U.S. Environmental Protection Agency (EPA) is extending the public comment period on the revised draft report, ''Perchlorate Environmental Contamination: Toxicological Review and Risk Characterization'' (NCEA–1–0503), by 45 days to April 5, 2002. On January 2, 2002, EPA published a **Federal Register** notice (67 FR 75) announcing: (1) The public availability, expected on January 9, 2002, of the revised draft document; (2) the beginning of a 30-day public comment period; and (3) an external peer review workshop in Sacramento, California, on March 5 and 6, 2002. In addition, a notice correcting the address for electronic registration and electronic submission of public comments was published on January 14, 2002 (67 FR 1759). Because of an approximately one-week delay in public release and availability of the perchlorate external review draft, EPA extended the public comment period to February 19, 2002 (67 FR 3493, January 24, 2002). EPA has decided to extend the comment period to April 5, 2002, in response to the high level of interest in this draft document and because of several requests for extension of the comment period.

Therefore, comments postmarked by February 19, 2002, will be made available to the peer review panel prior to the peer review. Comments received between February 19 and March 5, 2002, will be made available to the peer reviewers at the peer review meeting. Comments received after the peer review meeting and up until April 5, 2002, will also be made available to the peer reviewers. It should be noted that, as with all peer review meetings, the panelists are not charged directly with reading or considering all observer comments. Rather, it is up to the professional judgment of the reviewers to consider observer comments as they deem appropriate. In addition, the review of and response to public comments is the responsibility of the EPA, as the Agency moves forward with the development of the assessment.

In order to be most effective, external comments need to be provided to the Agency contractor, Eastern Research Group, Inc. (ERG), by April 5, 2002. As is the EPA's normal procedure, the Agency will summarize and indicate the disposition of all major comments provided by April 5, 2002, in preparation for its release of the assessment in final form.

**DATES:** Comments should be in writing and must be received (not postmarked) by April 5, 2002.

**ADDRESSES:** Written comments on the draft document should be submitted to Eastern Research Group (ERG), Attn: Meetings, 110 Hartwell Avenue, Lexington, MA 02421. Comments under 50 pages may be sent via e-mail attachment (in Word, WordPerfect, or pdf) to meetings@erg.com. The external review draft of the perchlorate document is available on EPA's National Center for Environmental Assessment (NCEA) Web site at *http://www.epa.gov/ncea*.

**FOR FURTHER INFORMATION CONTACT:** Questions regarding observer registration for the workshop and submission of written comments should be directed to EPA's contractor, ERG, at 781–674–7374. For technical inquiries, please contact: Annie M. Jarabek, U.S. Environmental Protection Agency (MD 52), U.S. EPA Mailroom, Research Triangle Park, NC 27711; telephone 919–541–4847; facsimile 919–541–1818; e-mail *jarabek.annie@epa.gov*.

Dated: February 22, 2002.

**George W. Alapas,**

*Acting Director, National Center for Environmental Assessment.*

[FR Doc. 02–4789 Filed 2–27–02; 8:45 am]

**BILLING CODE 6560–50–M**

## ENVIRONMENTAL PROTECTION AGENCY

**[OPP–00757; FRL–6820–6]**

### Pesticides; Determination of the Appropriate FQPA Safety Factor(s) in Tolerance Assessment

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

**ACTION:** Notice of availability.

**SUMMARY:** EPA announces the availability of the revised version of the pesticide science policy document entitled ''Determination of the Appropriate FQPA Safety Factor(s) in Tolerance Assessment.'' This notice is one in a series concerning science policy documents related to the implementation of the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA).

**FOR FURTHER INFORMATION CONTACT:** Vicki Dellarco, Environmental Protection Agency (7503C), 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 305–1803; fax number: (703) 305–5147–; e-mail address: dellarco.vicki@epa.gov.

**SUPPLEMENTARY INFORMATION:**

#### I. General Information

*A. Does this Action Apply to Me?*

You may be potentially affected by this action if you 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 |

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether or not this notice affects certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

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

1. *Electronically*. You may obtain electronic copies of this document, the science policy documents, and certain other related documents that might be available from the Office of Pesticide Programs' Home Page at http://www.epa.gov/pesticides. On the Office of Pesticide Programs' Home Page select ''FQPA'' and then look up the entry for this document under ''Science Policies.'' You can also go directly to the listings at the EPA Home page at http://www.epa.gov. On the Home Page select ''Laws and Regulations,''' Regulations and Proposed Rules,'' and then look up the entry to this document under ''**Federal Register**—-Environmental Documents.'' You can go directly to the **Federal Register** listings at http://www.epa.gov/fedrgstr.

2. *In person*. The Agency has established an official record for this action under docket control number OPP–00757. In addition, the documents

referenced in the framework notice, which published in the **Federal Register** on October 29, 1998 (63 FR 58038) (FRL–6041–5) under docket control number OPP–00557, are considered as part of the official record for this action under docket control number OPP–00757 even though not placed in the official record. The official record consists of the documents specifically referenced in this action, 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# 12, 1921 Jefferson Davis Hwy., 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 Information

On August 3, 1996, FQPA was signed into law. The FQPA significantly amended the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and FFDCA. Among other changes, FQPA established a stringent health-based standard (a reasonable certainty of no harm) for pesticide residues in foods to assure protection from unacceptable pesticide exposure and strengthened health protections for infants and children from pesticide risks.

Thereafter, the Agency established the Food Safety Advisory Committee (FSAC) as a subcommittee of the National Advisory Council for Environmental Policy and Technology (NACEPT) to assist in soliciting input from stakeholders and to provide input to EPA on the broad policy choices facing the Agency and on strategic direction for the Office of Pesticide Programs (OPP). The Agency has used the interim approaches developed through discussions with FSAC to make regulatory decisions that meet the new FFDCA standard, but that could be revisited if additional information became available or as the science evolved. In addition, the Agency seeks independent review and public participation, generally through presentation of the science policy issues to the FIFRA Scientific Advisory Panel, a group of independent, outside experts who provide peer review and scientific advice to OPP.

During 1998 and 1999, EPA and the U.S. Department of Agriculture (USDA) established a second subcommittee of NACEPT, the Tolerance Reassessment Advisory Committee (TRAC) to address FFDCA issues and implementation. TRAC comprised more than 50 representatives of affected user, producer, consumer, public health, environmental, states, and other interested groups. The TRAC met from May 27, 1998, through April 29, 1999.

In order to continue the constructive discussions about FFDCA, EPA and USDA have established, under the auspices of NACEPT, the Committee to Advise on Reassessment and Transition (CARAT). The CARAT provides a forum for a broad spectrum of stakeholders to consult with and advise the Agency and the Secretary of Agriculture on pest and pesticide management transition issues related to the tolerance reassessment process. The CARAT is intended to further the valuable work initiated by the FSAC and TRAC toward the use of sound science and greater transparency in regulatory decisionmaking, increased stakeholder participation, and reasonable transition strategies that reduce risks without jeopardizing American agriculture and farm communities.

As a result of the 1998 and 1999 TRAC process, EPA decided that the implementation process and related policies would benefit from providing notice and comment on major science policy issues. The TRAC identified nine science policy areas it believed were key to implementation of tolerance reassessment. EPA agreed to provide one or more documents for comment on each of the nine issues by announcing their availability in the **Federal Register**. In a notice published in the **Federal Register** of October 29, 1998 (63 FR 58038), EPA described its intended approach. Since then, EPA has been issuing a series of draft documents concerning the nine science policy issues. This notice announces the availability of the revised science policy document concerning the FPQA safety factor.

## III. Summary of ''Determination of the Appropriate FQPA Safety Factor(s) in Tolerance Assessment''

On August 3, 1996, the Food Quality Protection Act of 1996 was signed into law, significantly amending the Federal Insecticide, Fungicide, and Rodenticide Act and the Federal Food, Drug, and Cosmetic Act. Among other changes, the new law provides heightened protections for infants and children, directing EPA, in setting pesticide tolerances, to use an additional tenfold margin of safety to protect infants and children, taking into account the potential for pre- and postnatal toxicity and the completeness of the toxicology and exposure databases. The statute authorizes EPA to replace this tenfold FQPA safety factor with a different FQPA factor only if reliable data demonstrate that the resulting level of exposure would be safe for infants and children.

EPA established a Task Force of senior scientists, knowledgeable in the fields of hazard and exposure assessment, to help it identify the types of information that would be appropriate for evaluating the safety of pesticides for infants and children. The Task Force included representatives from the Agency's Office of Prevention, Pesticides and Toxic Substances, Office of Research and Development, Office of Children's Health Protection, Office of Water, and Office of Solid Waste and Emergency Response. The Task Force made many useful recommendations considered by the Office of Pesticide Programs during the development of this guidance. Comments from the public and from the FIFRA Scientific Advisory Panel also contributed to this document.

This document describes how the Office of Pesticide Programs (OPP) determines the appropriate FQPA safety factor(s) when developing aggregate risk assessments and regulatory decisions for single active and ''other'' (i.e., inert) ingredients of pesticide products. The guidance is specifically addressed to OPP risk assessors but also serves as an important source of information for the public and the regulated community. This guidance explains the legal framework for the FQPA safety factor and key interpretations of statutory terms (See Appendix 1) and describes how the FQPA safety factor provision both formalizes and expands OPP's past practice of applying uncertainty factors to account for deficiencies in the toxicological database. Because this guidance only addresses the statutory provisions of FQPA, it does not apply to any of the Agency's other regulatory programs or risk assessment processes which are carried out under different statutory authorities. As explained below, this guidance explains how OPP intends to ''take into account...potential pre- and post-natal toxicity and completeness of the data with respect to exposure and toxicity to infants and children'' as directed by FFDCA Section 408(b)(2)(C)(i).

A primary consideration in implementation of the FQPA safety factor provision is assessing the degree of concern regarding the potential for pre- and postnatal effects. In many cases, concerns regarding pre- and postnatal toxicity can be addressed by calculating a Reference Dose (RfD) or Margin of Exposure (MOE) from the pre- or postnatal endpoints in the offspring and traditional uncertainty factors (i.e., use of a factor to account for estimating a No-Observed-Adverse-Effect-Level from a Lowest-Observed Adverse-Effect-Level, estimating chronic effects from a subchronic study, and an incomplete toxicology data base) are fully considered. In some instances, however, data may raise uncertainties or a high concern for infants or children which cannot be addressed in the derivation of an RfD or MOE. OPP intends to analyze the degree of concern and to assess the weight of all relevant evidence for each case. This involves examining the level of concern for sensitivity/susceptibility and assessing whether traditional uncertainty factors already incorporated into the risk assessment are adequate to protect the safety of infants and children, as well as the adequacy of the exposure assessment.

The guidance also explains how data deficiency uncertainty factors will be used to address the FQPA safety factor provision's expressed concern as to the ''completeness of the data with respect to ... toxicity to infants and children...'' The FQPA safety factor provision regarding the completeness of the toxicity database is similar to the traditional data deficiency uncertainty factors used by the Agency to address inadequate or incomplete data. Thus, when deriving RfDs and evaluating the protection provided by FQPA safety factors, OPP intends to consider current Agency practice regarding data deficiency uncertainty factors.

Another important consideration for the FQPA safety factor is the completeness of the exposure database. Whenever appropriate data are available, OPP estimates exposure using reliable empirical data on specific pesticides. In other cases, exposure estimates may be based on models and assumptions (which in themselves are based on other reliable empirical data). This document explains how, in the absence of case specific exposure data, OPP will evaluate the safety of the exposure estimate as to infants and children and correspondingly, the appropriate FQPA safety factor.

Finally, the decision to retain the default 10X FQPA safety factor or to assign a different FQPA safety factor is informed by the conclusions presented in the risk characterization, and is not determined as part of the RfD process. This guidance document describes the integrated approach used when making FQPA safety factor decisions. This is a ''weight-of-the-evidence'' approach in which all of the data, concerning both hazard and exposure, are considered together for the pesticide under evaluation. The FQPA safety factor determination includes an evaluation of the level of confidence in the hazard and exposure assessments and an explicit judgement of whether there are any residual uncertainties identified in the risk characterization. It is at this integration stage that OPP determines how the completeness of the toxicology and exposure databases and the potential for pre and postnatal toxicity were handled in the risk assessment.

### IV. Policies Not Rules

The policy document discussed in this notice is intended to provide guidance to EPA personnel and decision-makers, and to the public. As a guidance document and not a rule, the policy in this guidance is not binding on either EPA or any outside parties. Although this guidance provides a starting point for EPA risk assessments, EPA will depart from its policy where the facts or circumstances warrant. In such cases, EPA will explain why a different course was taken. Similarly, outside parties remain free to assert that a policy is not appropriate for a specific pesticide or that the circumstances surrounding a specific risk assessment demonstrate that a policy should not be applied.

### List of Subjects

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

Dated: February 20, 2002.

**Stephen L. Johnson,**

*Assistant Administrator for Prevention, Pesticides and Toxic Substances.*

[FR Doc. 02–4793 Filed 2–27–02; 8:45 a.m.]

BILLING CODE 6560–50–S

## ENVIRONMENTAL PROTECTION AGENCY

**[OPP–00759; FRL–6822–3]**

## Pesticides; Consideration of the FQPA and Other Safety Factors in Cumulative Risk Assessment

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

**ACTION:** Notice of availability.

**SUMMARY:** To assure that EPA's policies related to implementing the Food Quality Protection Act of 1996 (FQPA) are transparent and open to public participation, EPA is soliciting comments on the pesticide draft science policy document titled, ''Consideration of the FQPA Safety Factor and Other Uncertainty Factors in Cumulative Risk Assessment of Chemicals Sharing a Common Mechanism of Toxicity.'' This notice is one in a series concerning science policy documents related to the implementation of the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by FQPA.

**DATES:** Comments for the draft science policy document, identified by docket control number OPP–00759, must be received on or before April 29, 2002.

**ADDRESSES:** Comments may be submitted by mail, electronically, or in person. Please follow the detailed instructions for each method as provided in Unit I. of the **SUPPLEMENTARY INFORMATION**. To ensure proper receipt by EPA, it is imperative that you identify docket control number OPP–00759 in the subject line on the first page of your response.

**FOR FURTHER INFORMATION CONTACT:** Randy Perfetti, Health Effects Division (7509C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 305–5381; e-mail address: perfetti.randolph@epa.gov.

**SUPPLEMENTARY INFORMATION:**

### I. General Information

*A. Does this Action Apply to Me?*

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