

III. What Action is the Agency Taking?

Under contract number GS-10F-0127J, MRI of 425 Volker Boulevard, Kansas City, MO, will assist the Office of Pollution Prevention and Toxics (OPPT) in providing technical support for chemical management activities authorized under TSCA on halogenated dibenzodioxins and dibenzofurans (HDDs/HDFs) in commercial products. They will also provide support in the review of analytical protocols; sampling; and quality assurance projects plans, submitted by industries involved in the production, processing, distribution, use, and disposal of chemicals listed in 40 CFR 766.27.

In accordance with 40 CFR 2.306(j), EPA has determined that under EPA contract number GS-10F-0127J, MRI will require access to CBI submitted to EPA under sections 4 and 5 of TSCA, to perform successfully the duties specified under the contract.

MRI personnel was given access to information submitted to EPA under sections 4 and 5 of TSCA. Some of the information may be claimed or determined to be CBI. Access to the confidential data submitted to EPA under sections 4 and 5 of TSCA occurred as a result of an approved waiver dated June 24, 2002. This waiver was necessary to allow MRI to assist OPPT in providing technical support for chemical management activities authorized under TSCA on HDDs/HDFs in commercial products.

EPA is issuing this notice to inform all submitters of information under sections 4 and 5 of TSCA, that the Agency may provide MRI access to these CBI materials on a need-to-know basis only. All access to TSCA CBI under this contract will take place at EPA's Region VII site in Kansas City, MO and MRI's site located at 425 Volker Boulevard, Kansas City, MO. However, access will not occur at MRI's Kansas City, MO facility until after it has been inspected and approved for the storage of TSCA CBI.

MRI will be required to adhere to all provisions of EPA's *TSCA Confidential Business Information Security Manual*.

Clearance for access to TSCA CBI under this contract may continue until January 14, 2003.

MRI personnel will be required to sign nondisclosure agreements and will be briefed on appropriate security procedures before they are permitted access to TSCA CBI.

List of Subjects

Environmental protection,
Confidential business information.

Dated: July 25, 2002.

Allan S. Abramson,

Director, Information Management Division,
Office of Pollution Prevention and Toxics.

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ENVIRONMENTAL PROTECTION AGENCY

[OPP-2002-1531; FRL-7192-4]

Organophosphate Pesticides; Reassessment of Meat Commodity Tolerances for Tetrachlorvinphos

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: As part of its ongoing review of existing organophosphate (OP) tolerances under the Food Quality Protection Act (FQPA), EPA has determined that 11 meat commodity tolerances for tetrachlorvinphos can be reassessed at this time. These "non-contributor" tolerances meet the FQPA safety standard in section 408(b)(2) of the Federal Food, Drug and Cosmetic Act (FFDCA) and can be reassessed for the purposes of FFDCA section 408 (q). EPA has concluded that these tolerances make, at most, a negligible contribution to the cumulative risk from OP pesticides. This notice closely relates to a previous **Federal Register** notice of May 22, 2002 (67 FR 35991, FRL-7178-9) in which EPA announced the reassessment of non-contributing tolerances for certain meats, animal feeds, and refined sugars. EPA expects that additional tolerances will be appropriate for reassessment based on the kind of approach described in this notice.

DATES: The reassessment of these tolerances is effective as of July 23, 2002.

FOR FURTHER INFORMATION CONTACT: Karen Angulo, Special Review and Reregistration Division (7805C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 308-8004; e-mail address: angulo.karen@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

This action is directed to the public in general who are interested in the use of pesticides on food. As such, the Agency has not attempted to specifically describe all the entities potentially affected by this action. 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 and Other Related Documents?

1. *Electronically.* You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet 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 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/>. In addition, copies of this notice may also be accessed at <http://www.epa.gov/oppsrrd1/op>.

2. *In person.* The Agency has established an official record for this action under docket ID number OPP-2002-1531. 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 #2, 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

The Food Quality Protection Act of 1996 significantly amended the FFDCA, creating a new safety standard for judging the acceptability of tolerances for pesticide residues in food. The new statutory standard allows EPA to approve a new tolerance or leave an existing tolerance in place only if the tolerance is "safe." The statute defines "safe" to mean "that there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable data" [FFDCA section

408(b)(2)(A)(ii)]. In making the safety determination, EPA “shall consider, among other relevant factors . . . available information concerning the cumulative effects of such residues and other substances that have a common mechanism of toxicity” [FFDCA section 408(b)(2)(D)(v)]. The FQPA amendments not only made the new safety standard applicable to new tolerances, but also to tolerances in existence when FQPA became law. FQPA set a ten year schedule for EPA to reassess all existing tolerances, with interim deadlines for completion of 33 percent and 66 percent of tolerance reassessments three and six years, respectively, after the date of enactment. Pesticide tolerances subject to reassessment under the FQPA section 408(q) may only remain in effect without modification if they meet the section 408(b)(2) safety standard. Finally, FQPA instructed EPA to give priority to the review of tolerances which appear to pose the greatest risk to public health.

Consistent with the FQPA mandate, EPA identified organophosphate pesticides as high priority for tolerance reassessment. EPA has determined that the OPs share a “common mechanism of toxicity,” and therefore that the Agency will consider the cumulative risks of OPs in making the safety determination for any tolerance for a pesticide in this group. The Agency has reviewed individual OP pesticides to determine whether they meet the current health and safety standards of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the FFDCA safety standard, and has presented its determinations in documents called “Interim Reregistration Eligibility Decisions” (IREDs). When the pesticide covered by an IRED shares a common mechanism of toxicity with other pesticides, the IRED addresses the aggregate risk of the chemical but does not take a position on the FFDCA standard until the Agency has also considered the potential cumulative risks of the group of pesticides.

In addition to its consideration of individual OP pesticides, EPA has also conducted a preliminary CRA for all of the OPs and sought public comment on the assessment. The Agency recently released the revised OP CRA for public comment. The preliminary and revised OP cumulative risk assessment documents are available at www.epa.gov/pesticides/cumulative. In addition, EPA presented the assessments to its FIFRA Scientific Advisory Panel (SAP) for expert, independent scientific peer review. The SAP provided a generally favorable review of the preliminary assessment.

See www.epa.gov/scipoly/sap/index.htm. EPA has raised with stakeholders during a number of public meetings the concept of reassessing selected OP tolerances because, based on available data and assessments, EPA could determine that they make, at most, no more than a negligible contribution to risk. Most recently, the concept of reassessing such “non-contributors” was an agenda topic for the February, 2002, meeting of the Committee to Advise on Reassessment And Transition (CARAT). In a **Federal Register** notice of May 22, 2002 (67 FR 35991, FRL-7178-9), EPA announced the reassessment of non-contributing tolerances for certain meats, animal feeds, and refined sugars, and requested suggestions on other approaches for identifying tolerances that do not contribute risk to the OP cumulative risk assessment.

III. What Action is the Agency Taking?

A. Reassessment of Non-Contributor Tolerances

In this notice, EPA identifies non-contributor meat commodity tolerances for the OP pesticide tetrachlorvinphos and considers these tolerances reassessed for the purposes of FQPA section 408 (q) as of July 23, 2002. A pesticide tolerance subject to reassessment under the FQPA section 408(q) may only remain in effect without modification if it meets the section 408(b) safety standard. This standard is met if EPA finds that “there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue.” In evaluating tolerances under the standard, the FQPA also instructs the Agency to consider the cumulative effects of the pesticide and other substances that have a common mechanism of toxicity. The Agency has now completed the Interim Reregistration Eligibility Decision (IRED) for tetrachlorvinphos, which found that, apart from consideration of the potential cumulative risks from all of the OPs, each of the tolerances would meet the FFDCA safety standard. EPA has now considered the impact of these cumulative risks in the reassessment of these tolerance and has determined that these tolerances make, at most, only a negligible contribution to the overall risks from OPs. Therefore, these tolerances can be maintained regardless of the outcome of the OP cumulative assessment and any potential regulatory action taken as a result of that assessment. Accordingly, EPA believes it is appropriate to consider these

tolerances reassessed for the purposes of FQPA section 408(q) as of July 23, 2002.

In making the determination that these tolerances contribute negligible (if any) residues and/or risk, EPA considered, among other things, the nature of the use of the pesticide, the data used in conducting aggregate risk assessments for each individual OP, the potential for drinking water contamination, and other data and analyses available to the Agency (such as food residue monitoring and other information that the Agency is using for the CRA). The Agency concludes that these pesticide uses result in minimal or no detectable residues in food, and have no or negligible effects through drinking water. Because a tolerance may apply to more than one raw agricultural commodity, no tolerance is herein reassessed as a non-contributor unless all of the raw agricultural commodities (food forms) that are part of that tolerance are also considered to be non-contributors. EPA also considered the potential impacts of future OP risk management decisions and determined that such decisions would be very unlikely to increase the use of the pesticide on these use sites in a manner or to a degree that the potential exposure under the tolerance would no longer be negligible. As part of its preliminary cumulative risk assessment, the Agency developed an estimate of the potential contribution that OP pesticides used in different parts of the country could make to overall risk as a result of the presence of residues of such pesticides in drinking water. Because of the nature of the available data, EPA’s estimate employs assumptions that are designed not to understate potential drinking water exposure. The OP preliminary and revised CRA concluded that drinking water was not a significant source of potential exposure. In reaching the determination to reassess these tolerances, EPA has considered this analysis, the public comment and the SAP’s advice, as well as the information developed to assess the aggregate exposure from drinking water for each of the individual pesticides being reassessed.

The Agency’s assessment of these tolerances is effectively complete and the tolerances are considered reassessed. Nothing in this notice is intended to modify in any way any determination or requirement set forth in individual pesticide IREDs, or affect existing or future regulatory agreements or use cancellation actions required for some other purpose (e.g., due to worker or ecological risk concerns). For any of the uses that may be cancelled pursuant

to any such decision, EPA expects that the associated tolerance would be revoked at the appropriate time unless it is properly supported for an import tolerance. In addition, all of these pesticide/use pattern combinations are included in the preliminary CRA and will remain in the CRA even though they involve exposures that pose negligible/minimal risk.

No conclusions about reassessment should be drawn about tolerances that are not identified as non-contributors in this notice. EPA expects that additional tolerances will be appropriate for reassessment based on the kind of approach described here and in a previous the **Federal Register** notice of May 22, 2002 (67 FR 35991, FRL-7178-9) in which EPA announced the reassessment of non-contributing tolerances for certain meats, animal feeds, and refined sugars. Additional tolerances may be reassessed without the need for regulation upon completion of the CRA. In other words, the failure of a tolerance to be identified as a non-contributor in this or any other announcement does not imply that the pesticide/use combination will ultimately be subject to regulatory action. For tolerances reassessed as announced in this notice or using the approach described herein, EPA has concluded that the decision to reassess these tolerances will have no impact on any subsequent determination or decisions that may be necessary if the CRA were to conclude that cumulative exposure to the OPs poses risks of concern.

B. Meat Commodity Tolerances for Tetrachlorvinphos

EPA has determined that 11 meat commodity tolerances for tetrachlorvinphos, listed later in the notice, are reassessed at this time. EPA reassessed other OP non-contributing meat tolerances in an earlier **Federal Register** notice (May 22, 2002, 67 FR 35991, FRL-7178-9). The assessment approach applied to those meat tolerances is now being applied to the tetrachlorvinphos non-contributor meat commodity tolerances listed in this notice, and is described below.

Currently, there are OP tolerances for many animal commodities: Milk, eggs, poultry, and other meats (cattle, goats, hogs, horses, and sheep). Human exposure to pesticide residues can occur as a consequence of the use of a pesticide on animals or their feed if the residues transfer to the animal commodities that humans consume. EPA examined the potential for the transfer to such human foods of OP residues from animal feeds, and from

the direct application of the OP to an animal (e.g., to control nuisance pests such as biting flies), and concludes that residue transfer generally does not occur, or if it does, the transfer is minimal. The following summarizes the factors that the Agency considered in making the decision to reassess these tolerances.

The Agency examined the available study data for the OPs, which includes extensive livestock feeding/metabolism studies. These study results are confirmed by extensive monitoring data on animal commodities reflecting all registered uses. There are very few detectable residues in the OP monitoring data for animal commodities. The extensive monitoring data are from the U.S. Department of Agriculture's (USDA) Pesticide Data Program (PDP) and U.S. Food and Drug Administration's (FDA) Total Diet Study (TDS) covering residues of multiple OPs in meats and poultry. The residue monitoring data showed infrequent detections, and those residues were detected at low levels. Out of approximately 400 meat samples analyzed by the TDS for multiple OPs from 1991-1999, only 9 samples detected any OP residues (the residues ranged between 0.002 ppm and 0.009 ppm). Out of the approximately 500 poultry samples analyzed by PDP for multiple OPs for 1997-2000, only 1 sample detected an OP residue (0.01 ppm) for a pesticide that currently has a tolerance.

For milk and eggs, extensive monitoring data are available from USDA's PDP and FDA's Surveillance Program. The residue monitoring data show no detectable OP residues in milk (there was only one trace sample detected out of approximately 1,800 samples analyzed by PDP for multiple OPs from 1996-1998). The residue monitoring for eggs also showed no detectable OP residues (only one trace sample was detected out of approximately 1,300 samples analyzed by the FDA's Surveillance Program for multiple OPs from 1992-1998).

In addition to an examination of the meat, poultry, milk, and egg monitoring data, as described above, the potential risk associated with the detected residues was addressed in the Agency's preliminary CRA of the OP pesticides. Although EPA concluded that OP residues would not be expected to occur in significant amounts in meat or milk, EPA nonetheless made the conservative assumption that all meat food forms contained OP residues equal to a level that was the highest found in the FDA monitoring program (TDS). Despite the fact that this assumption would

overestimate potential exposure, the analysis in the OP CRA indicated that animal commodities do not significantly contribute to OP dietary exposure and total OP dietary risk.

EPA expects to announce other meat/poultry/egg/milk and animal feed tolerances as reassessed in future notices as appropriate in light of their individual OP assessments. In addition, some of these tolerances may be revoked in future notices in the **Federal Register** if EPA determines that the tolerances are no longer needed. The Agency plans to issue a notice announcing the Agency's intention to revoke several animal meat tolerances because they are no longer necessary.

The following 11 tetrachlorvinphos meat commodity tolerances (40 CFR 180.252) are considered reassessed:

Cattle, beef
Cattle, dairy
Cattle, fat
Egg
Goat, fat
Hog
Hog, fat
Horse
Horse, fat
Milk, fat
Poultry, fat

List of Subjects

Environmental protection, Chemicals, Pesticides and pests.

Dated: July 31, 2002.

Lois A. Rossi,

Director, Special Review and Reregistration Division, Office of Pesticide Programs.

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ENVIRONMENTAL PROTECTION AGENCY

[OPP-2002-0152; FRL-7192-6]

Organophosphate Pesticides; Reassessment of Additional Non-Contributing Commodity Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: As part of its ongoing review of existing organophosphate (OP) tolerances under the Food Quality Protection Act (FQPA), EPA has determined that 37 OP tolerances can be reassessed at this time. EPA has concluded that these tolerances make, at most, a negligible contribution to the cumulative risk from OP pesticides. These tolerances are considered to be "non-contributors" based on the especially small number (less than 1 percent) of reported pesticide residue