

teleconference, may contact Dr. Thomas Armitage, Designated Federal Officer (DFO), U.S. EPA Science Advisory Board by telephone/voice mail at (202) 564-4539, fax at (202) 501-0582, or via e-mail at [armitage.thomas@epa.gov](mailto:armitage.thomas@epa.gov). General information about the SAB can be found in the SAB Web site at <http://www.epa.gov/sab>.

#### SUPPLEMENTARY INFORMATION:

##### Background

Pursuant to the Federal Advisory Committee Act, Public Law 92-463, notice is hereby given that the Panel will hold a public teleconference and a public meeting to provide advice to the EPA on the Agency's Report on the Environment. Background on the Panel and the focus of the public teleconference and meeting described in this notice was provided in a **Federal Register** notice published on June 17, 2003 (68 FR 35883-35884).

The purpose of the public teleconference is to discuss the review charge and provide an opportunity for questions or clarifications from the Panel on the ROE prior to the March public meeting. The purpose of the March public meeting is for the Panel to review the ROE. The agendas and charge questions will be posted on the SAB Web site, <http://www.epa.gov/sab/agendas.htm>, prior to the teleconference and meeting. The ROE documents may be found at: <http://www.epa.gov/indicators/roe/html/roePDF.htm>.

##### Procedures for Providing Public Comments

It is the policy of the EPA SAB to accept written public comments of any length, and to accommodate oral public comments whenever possible. The SAB Staff Office expects that public statements presented at the ROE panel meetings will not be repetitive of previously submitted oral or written statements. *Oral Comments:* In general each individual or group requesting an oral presentation at a face-to-face meeting will be limited to a total time of 10 minutes (unless otherwise indicated). In general, for teleconference meetings, opportunities for oral comment will be limited to no more than three minutes per speaker and no more than 15 minutes total. Requests to provide oral comments must be in writing (e-mail, fax or mail) and received by the DFO no later than noon eastern time five business days prior to the teleconference in order to reserve time on the teleconference agenda. *Written Comments:* Although the SAB Staff Office accepts written comments until the date of the meeting (unless otherwise stated), written comments

should be received in the SAB Staff Office at least seven business days prior to the teleconference date so that the comments may be made available to the committee or panel for their consideration. Comments should be supplied to the DFO at the address/contact information noted above in the following formats: one hard copy with original signature, and one electronic copy via e-mail (acceptable file format: Adobe Acrobat, WordPerfect, Word, or Rich Text files (in IBM-PC/Windows 95/98 format)). Those providing written comments and who attend the meeting are also asked to bring 35 copies of their comments for public distribution.

##### Meeting Accommodations

Individuals requiring special accommodation to access the public meetings listed above should contact the DFO at least five business days prior to the meeting so that appropriate arrangements can be made.

Dated: January 23, 2004.

**Vanessa Vu,**

*Director, EPA Science Advisory Board Staff Office.*

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BILLING CODE 6560-50-P

#### ENVIRONMENTAL PROTECTION AGENCY

[OPP-2003-0360; FRL-7334-4]

##### Carbamate Cumulative Assessment Group; Availability

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

**ACTION:** Notice.

**SUMMARY:** Section 408(b)(2)(D)(v) and (vi) of the Federal Food Drug and Cosmetic Act (FFDCA), as amended by Food Quality Protection Act of 1996 (FQPA), specifies that when determining the safety of a pesticide chemical, EPA shall base its risk assessment on aggregate exposure and available information concerning the cumulative effects to human health that may result from exposure to pesticides and other substances that have a common mechanism of toxicity. EPA has determined that certain substances in the carbamate class of pesticides share a common mechanism of toxicity. This notice announces EPA's determination regarding the specific substances which will be included within this cumulative assessment group (CAG) for the N-methyl carbamate pesticide cumulative risk assessment.

**DATES:** EPA expects a preliminary cumulative assessment will be available

for public comment by the Spring of 2005. EPA will announce its availability and request public comments in a future **Federal Register** Notice.

##### FOR FURTHER INFORMATION CONTACT:

*Technical issues:* David Miller, Health Effects Division (7509C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 305-5352; e-mail address: [miller.davidj@epa.gov](mailto:miller.davidj@epa.gov).

*General issues:* John Leahy, Special Review and Reregistration Division (7508C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 305-6703; e-mail address: [leahy.john@epa.gov](mailto:leahy.john@epa.gov).

#### SUPPLEMENTARY INFORMATION:

##### I. General Information

###### A. Does this Action Apply to Me?

This notice is directed to the public in general; however, persons may be interested who work in agricultural settings or persons who are concerned about implementation of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA); the Federal Food, Drug, and Cosmetic Act (FFDCA); and the amendments to both of these major pesticide laws by the Food Quality Protection Act (FQPA) of 1996. 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 applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**. Potentially affected entities may include but are not limited to: Agricultural workers and farmers; pesticide industry and trade associations; environmental, consumer and farmworker groups; pesticide users and growers; pest consultants; State, local and Tribal governments; academia; public health organizations; food processors; and the public.

###### B. How Can I Get Copies of this Document and Other Related Information?

1. *Docket.* EPA has established an official public docket for this action under docket identification (ID) number OPP-2003-0360. The official public docket consists of the documents specifically referenced in this action, any public comments received, and other information related to this action. Although a part of the official docket, the public docket does not include Confidential Business Information (CBI)

or other information whose disclosure is restricted by statute. The official public docket is the collection of materials that is available for public viewing at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305-5805.

2. *Electronic access.* You may access this **Federal Register** document electronically through the EPA Internet under the "**Federal Register**" listings at <http://www.epa.gov/fedrgrstr/>.

An electronic version of the public docket is available through EPA's electronic public docket and comment system, EPA Dockets. You may use EPA Dockets at <http://www.epa.gov/edocket/> to submit or view public comments, access the index listing of the contents of the official public docket, and to access those documents in the public docket that are available electronically. Once in the system, select search, then key in the appropriate docket ID number.

Certain types of information will not be placed in the EPA Dockets. Information claimed as CBI and other information whose disclosure is restricted by statute, which is not included in the official public docket, will not be available for public viewing in EPA's electronic public docket. EPA's policy is that copyrighted material will not be placed in EPA's electronic public docket but will be available only in printed, paper form in the official public docket. To the extent feasible, publicly available docket materials will be made available in EPA's electronic public docket. When a document is selected from the index list in EPA Dockets, the system will identify whether the document is available for viewing in EPA's electronic public docket. Although not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility identified in Unit I.B. EPA intends to work towards providing electronic access to all of the publicly available docket materials through EPA's electronic public docket.

## II. Background

The Food Quality Protection Act (FQPA) of 1996 amended the laws under which EPA evaluates the safety of pesticide residues in food. Section 408(b)(2)(D)(v) and (vi) of the Federal Food Drug and Cosmetic Act, as amended by FQPA, specifies that when determining the safety of a pesticide

chemical, EPA shall base its risk assessment on aggregate exposure (i.e., total dietary including water, residential, and other non-occupational) and available information concerning the cumulative effects to human health that may result from dietary, residential, or other non-occupational exposure to pesticides and other substances that have a common mechanism of toxicity. Further, in carrying out the FQPA tolerance reassessment provisions, EPA is instructed to give priority to review of the tolerances or exemptions that appear to pose the greatest risk to public health. (Section 408(q)(2))

Both the organophosphorus and carbamate classes of pesticides have been given high priority by the Office of Pesticide Programs for the reassessment of their tolerances and the completion of cumulative risk assessments in accordance with the mandates of FQPA. A revised cumulative risk assessment for the organophosphorus pesticides has been completed and is available on the EPA website at <http://www.epa.gov/pesticides/cumulative/> (Ref. 7). The carbamate class of pesticides have been given the next highest priority by OPP for the reassessment of tolerances in accordance with the mandates of FQPA, and OPP expects a preliminary cumulative risk assessment for the relevant acetylcholinesterase-inhibiting members of this class to be available to the public by spring of 2005.

### A. Determining the Common Mechanism Group

In order to assess the carbamate class for cumulative toxic effects, the Agency needed to first identify as a Common Mechanism Group (CMG) those carbamate pesticides that cause a common toxic effect by a common mechanism. The purpose of this notice is to:

1. Describe the approach, process, and reasoning used by the Agency in identifying, categorizing, and selecting the N-methyl carbamate pesticides which have been designated as a common mechanism group; and
2. Identify the N-methyl carbamate pesticides which OPP expects to be assessed and evaluated in the N-methyl carbamate cumulative risk assessment document.

As the cumulative assessment proceeds, the public and other interested parties will be provided the opportunity to comment and provide input concerning all aspects of the assessment.

As had been done for the organophosphorus pesticides, OPP began its review of the carbamates by commissioning a report by the Risk Sciences Institute (RSI), part of the

International Life Sciences Institute (ILSI), which considered whether the carbamate pesticides shared a common mechanism of toxicity. The RSI panel evaluated the potential for two or more carbamate pesticides to act by the same mechanism by applying three principles. The principles were:

- They cause the same critical effect(s)
- They act on the same molecular target at the same target tissue
- They act by the same biochemical mechanism of action perhaps because they share a common toxic intermediate (Ref. 2)

The RSI panel focused on cholinesterase (ChE) inhibition as a scientifically accepted mechanism of action for the carbamates and found that the three principles were met for the ChE-inhibiting carbamates. The panel issued its report, "Common Mechanism of Toxicity: Evaluation of Carbamate Pesticides," to OPP in March 1999 and concluded that the ChE-inhibiting carbamates should be considered to act by a common mechanism of toxicity. RSI also pointed out that some carbamates also produce effects that may not be related to ChE inhibition (Ref. 1).

Subsequent to this ILSI report, OPP prepared its own report on this grouping and presented its analysis in a draft document entitled "A Science Policy on a Common Mechanism of Toxicity: The Carbamate Pesticides And the Grouping of Carbamate with the Organophosphorus Pesticides" to the FIFRA Scientific Advisory Panel (SAP) for review in September 1999 (Ref. 3). This draft document generally concluded that while all of the carbamate pesticides appeared to share a similar chemical structure, they differed in the types of toxic effects they caused and therefore it was appropriate to divide the group into three distinct subgroups: Carbamates, thiocarbamates, and dithiocarbamates. Subcategories of carbamates based on structural characteristics of the carbamate moiety and ChE inhibiting potential are described in this draft document. The report resulting from this September 22, 1999 SAP meeting endorsed OPP's position in that "the Panel agreed unanimously with the Agency's conclusion that acetylcholinesterase provides a sufficient basis for determining a common mechanism of toxicity for grouping carbamate pesticides" (Ref. 4). The SAP, however, also pointed out that other toxic effects (e.g., developmental, thyroid, neurotoxic) should be evaluated as endpoints for grouping the thiocarbamates and dithiocarbamates.

Upon consideration of the ILSI report, the SAP comments, and reviews by OPP, it has been concluded by OPP that the pesticides that comprise the subgroup of N-methyl carbamates, based on their structural characteristics and similarity and their shared ability to inhibit acetylcholinesterase by carbamylation of the serine hydroxyl group located in the active site of the enzyme, should be designated as a Common Mechanism Group. (Ref. 5).

The thiocarbamates and dithiocarbamates are not included in the CMG for cholinesterase-inhibiting carbamates. The thio- and dithiocarbamate subgroups were the subject of a separate FIFRA SAP meeting, September 7, 2001 - Common Mechanism of Action of Thiocarbamates and Dithiocarbamates, in which it was determined that acetylcholinesterase inhibition was not their principal mechanism of toxicity<sup>1</sup> (Ref. 6). As pointed out in the Cumulative Guidance, "refined quantitative estimates should generally focus on common effects that represent the principal toxicities for the CMG" ...so that cumulative risk assessments are efficient and protect public health (Ref. 8). Thus, neither the thiocarbamates nor the dithiocarbamates are included in the cumulative assessment of N-methyl carbamates since they do not share ChE inhibition as a common principal mechanism of toxicity.

#### B. Determining the Cumulative Assessment Group

Once the constituents of a CMG are identified, a necessary follow-on step in assessing the cumulative risk of a common mechanism group (here, the N-methyl carbamates) involves selecting a

subset of these CMG chemicals as a Cumulative Assessment Group (CAG) (see Ref. 8). As described in the Cumulative Guidance (Ref. 8), this subset of CMG chemicals is selected because not all chemicals grouped by common mechanism of toxicity should necessarily be included in a quantitative cumulative risk assessment. For example, initial cumulative assessments should not attempt to quantify risk resulting from chemicals with low hazard potential or from minor exposure scenarios, but should instead focus on those chemicals that are likely to be risk contributors. Specifically (and again as detailed in the cumulative guidance document), the CAG—and consequently the cumulative risk assessment—should exclude those chemicals, those chemical uses, and those exposure scenarios/routes/pathways for which risk and exposure does not contribute in any meaningful or substantive ways to the total cumulative risk picture<sup>2</sup>.

OPP began the process of determining the members of the CAG by identifying those carbamates which contained the N-methyl structural moiety. These are listed in the upper rows of Table 1 and identified as such by an X in the second column. Next, OPP further narrowed the list of the potential CAG-candidates by reviewing OPP databases to determine those CMG members that have active food or residential registrations. This information is summarized in columns 3 and 4 of Table 1 which lists those carbamates which have one or more active food/feed or residential registrations, respectively. Those carbamates which have neither food nor residential (non-food) current registrations were eliminated from

further consideration for inclusion in the CAG.

Next, OPP investigated the presence, pattern, and magnitudes of residues in the USDA's Pesticide Data Program (PDP) database through 2002. Those carbamates for which PDP has collected data and those for which detectable residues were found in the PDP database through 2002 are listed via an X in the 5<sup>th</sup> and 6<sup>th</sup> columns of Table 1. Those chemicals for which PDP did collect residue data but did not detect any residues were eliminated from consideration from the CAG if there were no residential uses. Thus, those chemicals without residential registrations were eliminated for further consideration if an X is present in Column 5 and absent from Column 6. No chemicals were excluded from the CAG as a result of this analysis.

Finally, the 7<sup>th</sup> column of Table 1 lists those that are currently undergoing phase-out or cancellation. As was done with the OP assessment, chemicals currently undergoing phase-out or cancellation are not included in the CAG since exposures are expected to be zero at some point in the near future.

Based on the above information, N-methyl carbamates which OPP expects to include in the cumulative risk assessment for the carbamate pesticides is as follows: Aldicarb, aldoxycarb, carbaryl, carbofuran, formetanate HCl, methiocarb, methomyl, oxamyl, pirimicarb, propoxur, and thiodicarb.

These carbamates all display ChE-inhibiting activity, have current active registrations, and are expected to contribute to the carbamate cumulative risk assessment through quantitatively meaningful exposure scenarios.

TABLE 1.—SUMMARY OF SELECTION CRITERIA FOR CARBAMATE CAG GROUPING

	N-methyl?	Registration		PDP Data		Phase Out or Cancellation?
		Food Use Registration <sup>a</sup> ?	Non-Food Use Registration (e.g., Residential Uses)?	Any PDP Data Available?	Any PDP Detects?	
Aldicarb	X	X		X	X	
Aldoxycarb	X	X		X	X	
Carbaryl	X	X	X	X	X	
Carbofuran	X	X		X	X	

<sup>1</sup>For example, the thiocarbamates and dithiocarbamate pesticides are the sulfur analogs of carbamates, and are not used as insecticides but rather as herbicides or fungicides because these carbamates generally do not appear to be effective

cholinesterase inhibitors. Neuropathology is the primary effect of concern for these chemicals.

<sup>2</sup>As stated in the Cumulative Guidance (USEPA 2002), "This focus on likely risk contributors is important ... since a large number of chemicals may increase the complexity and uncertainty with no

substantial change in total exposure. Additionally, including a large number of chemicals in the refined quantitation of risk also may confound the interpretation and utility of the assessment results for risk management decisions" (Ref. 8).

TABLE 1.—SUMMARY OF SELECTION CRITERIA FOR CARBAMATE CAG GROUPING—Continued

	N-methyl?	Registration		PDP Data		Phase Out or Cancellation?
		Food Use Registration <sup>a</sup> ?	Non-Food Use Registration (e.g., Residential Uses)?	Any PDP Data Available?	Any PDP Detects?	
Formetanate HCl	X	X		X	X	
Methiocarb	X		X	X	X	
Methomyl	X	X		X	X	
Oxamyl	X	X		X	X	
Pirimicarb	X	X		X	X	
Propoxur	X	X	X	X		
Thiodicarb <sup>d</sup>	X	X		X	X	
Aminocarb (Matacil)	X					X
Bendiocarb	X			X		X
Bufencarb (bux)	X					X
Carbosulfan	X					X
Cloethocarb (Lance)	X					X
Dimetilan (Elecron, Famid)	X					X
Ethiofencarb	X			X		X
Isolan (Primin)	X					X
Isoproc carb (Etrofolan, MIPC)	X					X
Mexacarbate (Zectran)	X					X
Promecarb (Carbamult)	X					X
Trimethacarb (Broot, Landrin)	X					X
Asulam		X				
Barban				X		X
Chlorpropham		X		X	X	
Desmidapham		X		X	X	
2-EEEEBC <sup>b</sup>						X
Fenoxycarb (torus)		X				
IPBC <sup>c</sup>			X			
Karbutilate		X				
Phenmediphan		X		X	X	
Propamocarb		X				
Propham						X
Thiophanate (methyl)		X	X			
Butylate		X		X		
Cycloate				X		
EPTC				X		

TABLE 1.—SUMMARY OF SELECTION CRITERIA FOR CARBAMATE CAG GROUPING—Continued

	N-methyl?	Registration		PDP Data		Phase Out or Cancellation?
		Food Use Registration <sup>a</sup> ?	Non-Food Use Registration (e.g., Residential Uses)?	Any PDP Data Available?	Any PDP Detects?	
Molinate				X		X
Pebulate				X		
Vernolate				X		
Diallate						X
Triallate		X		X		
Thiobencarb		X		X		
Mancozeb		X	X			
Maneb		X	X			
Metiram		X	X			
Zineb						X
Metam Na, K		X	X			
Thiram		X	X			
Ferbam		X	X			
Ziram		X	X			

<sup>a</sup> This includes Food Handling Establishment use for carbaryl and propoxur

<sup>b</sup> 2-2(ethoxyethoxy)ethyl 2-benzimidazole carbamate

<sup>c</sup> 3-iodo-2-propynyl butylcarbamate (aka Trotsan polyphase)

<sup>d</sup> Thiodicarb is a dimer of methomyl and is analyzed as methomyl by the PDP program

Note: The following carbamate pesticides were excluded from the above table since they are not N-methyl carbamates, they do not possess current U.S. registrations for food or non-food uses, there exist no detections in the USDA PDP program, and there is no indication that these have been actively phased out or cancelled: Alanycarb, allyxycarb, benfuracarb, butacarb, butocarboxim, butoxycarboxim, carbanolate, carboxazole, chlorprocarb, decarbofuran, dichlormate, dicresyl, dimetan, dioxacarb, EMPC, fenasulam, fenethacarb fenobucarb furathiocarb, hyquinicarb, nitrilacarb, promacyl tazimcarb, terbucarb thiocarboxime, thiofanox, XMC, xylycarb, and NaDMDTC.

#### D. References

1. International Life Sciences Institute (ILSI). 1999 Common Mechanism of Toxicity: Evaluation of Carbamate Pesticides, International Life Science Institute Report, Washington DC.

2. Mileson, B., JE Chambers, WL Chen, W Dettbarn, M Ehrich, AT Eldefrawi, DW Gaylor, K Hammernik, E Hodgson, AG Karczmar, S Padilla, CN Pope, RJ Richardson, DR Saunders, LP Sheets, LG Sultatos and KB Wallace. Common Mechanism of Toxicity: a case study of organophosphorus pesticides. Toxicological Sciences 41, pp.8–20.

3. USEPA, 1999a. A Science Policy on a Common Mechanism of Toxicity: The Carbamate Pesticides And the Grouping of Carbamate with the Organophosphorus Pesticides; draft document. August 30, 1999. <http://www.epa.gov/scipoly/sap/1999/september/carbam.pdf>.

4. USEPA, 1999b. SAP Report No. 99-05. November 18, 1999. <http://www.epa.gov/scipoly/sap/1999/september/finalrpt.pdf>.

[www.epa.gov/scipoly/sap/1999/september/finalrpt.pdf](http://www.epa.gov/scipoly/sap/1999/september/finalrpt.pdf).

5. USEPA, 2001a. Memorandum from Marcia Mulkey to Lois Rossi. Implementation of the Determinations of a Common Mechanism of Toxicity for N-Methyl Carbamate Pesticides and for Certain Chloroacetanilide Pesticides. July 12, 2001. [http://www.epa.gov/oppfead1/cb/csb\\_page/updates/carbamate.pdf](http://www.epa.gov/oppfead1/cb/csb_page/updates/carbamate.pdf).

6. USEPA, 2001b. Memorandum from Paul Lewis to Marcia Mulkey. SAP Report 2001–11. November 1, 2001. <http://www.epa.gov/scipoly/sap/2001/september7/september2001finalsapreport.pdf>.

7. USEPA, 2002a. Organophosphate Pesticides; Availability of the Revised Organophosphate Cumulative Risk Assessment. (67 FR 41993; June 20, 2002)

8. USEPA, 2002b. Guidance on Cumulative Risk Assessment of Pesticide Chemicals That Have a Common Mechanism of Toxicity.

January 14, 2002. (67 FR 2210; January 16, 2002) [http://www.epa.gov/pesticides/trac/science/cumulative\\_guidance.pdf](http://www.epa.gov/pesticides/trac/science/cumulative_guidance.pdf).

#### List of Subjects

Environmental protection.

Dated: January 20, 2004.

**James Jones,**

Director, Office of Pesticides Program.

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**BILLING CODE 6560–50–S**

#### ENVIRONMENTAL PROTECTION AGENCY

[OPP–2004–0008; FRL–7341–9]

#### Experimental Use Permit; Receipt of Application

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

**ACTION:** Notice.