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Metam Sodium

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

NOV 24 1992

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: **Section 18: 93DA0001 - 15.** Quarantine Exemption Renewal Request by APHIS for the Use of Various Pesticides on Multiple Nonfood/Nonfeed Commodities.

Tox.Chem. Nos.: see below
PC Nos.: see below
Barcode/Submission Nos.: D183930/S427779, D183936/S427784, D183942/S427785, D183945/S427786, D1183946/S427788, D183947/S427791, D183948/S427792, D183949/S427793, D183950/S427794, D183953/S427795, D183954/S427796, D183955/S427797, D183956/S427798, D183957/S427801, D183958/S427802

FROM: Linnea J. Hansen, Ph.D. Linnea J. Hansen 11-23-92 PM 11/23/92
Section IV, Tox. Branch I
Health Effects Division (H7509C)

TO: Rebecca Cool, Manager, PM Team 41
Libby Pemberton, Reviewer, PM Team 41
Registration Division (H7505C)

THRU: Marion P. Copley, D.V.M., D.A.B.T., Section Head
Section IV, Tox. Branch I Marion Copley 11/23/92
Health Effects Division (H7509C)

Karl Baetcke, Ph.D., Branch Chief M Copley 11/24/92 for KB
Tox. Branch I
Health Effects Division (H7509C)

I. CONCLUSIONS

The toxicology database supports reissuance of a Section 18 emergency quarantine exemption requested by the Animal and Plant Health Inspection Service (APHIS) Plant Protection and Quarantine (PPQ) for use of methyl bromide, d-phenothrin, malathion, malathion/carbaryl, sodium hypochlorite, captan, trifluran, sodium carbonate, sodium carbonate with sodium silicate and sodium hydroxide to treat various nonfood and nonfeed items to prevent establishment of foreign pests (see "Action Requested" section for details). However, the toxicology data base does not support use of metam sodium or ferbam due to lack of studies.

The uses supported by the toxicology database are standard

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and are performed on a limited basis by APHIS applicators who are trained or certified in application of these pesticides. Use of appropriate worker protection according to label, Federal, State, local and APHIS Treatment Manual requirements during application should provide adequate MOEs for these use patterns. Captan and trifluran both have Q_1^* values of 3.6×10^{-3} and 7.7×10^{-3} $(mg/kg/day)^{-1}$, respectively but are not anticipated to pose unreasonable risk to applicators for the reasons cited above.

There are no dietary concerns for these uses since all are nonfood/nonfeed.

II. ACTION REQUESTED

On October 16, 1992 APHIS, PPQ (USDA) requested a quarantine exemption renewal for use of several chemicals to prevent establishment of foreign plant pests in this country (letter from Peter L. Joseph, APHIS). The current exemption expires on January 10, 1993. This request was comprised of 15 separate use patterns for the chemicals listed below on non-food and non-feed commodities at various ports of entry.

Treatment is to be conducted at Ports of Entry throughout the United States only at preapproved treatment sites and following all appropriate label, Federal, State, local and APHIS Treatment Manual requirements. The following applications were described:

1) **Methyl Bromide** (100%). PC no. 053201; Tox. Chem no. 555: fumigant on imported nonfood/nonfeed cargo for control of khapra beetles and other plant pests; in ship holds, chambers, under tarpaulins or other temporary enclosures at 4 - 15 lb/1000 cu.ft. for 4 - 72 hrs at 40°F and above (rate varies inversely with temperature).

2) **Methyl bromide** (100%): Fumigant for use on machinery, plant and nonplant materials to control golden nematode, gypsy moths, witchweed and cotton insects; under tarpaulins, in fields, within a quarantine area or at ports of entry, 4 - 23 lbs/1000 cu.ft. for 8 - 24 hrs at 40° and above (rate varies inversely with temperature)

3) **d-Phenothrin** (2%). PC no. 069005; Tox. Chem no. 652B: aerosol applied in aircraft and cargo containers for fruit flies and other soft-bodied insects; 10 g a.i./1000 cu.ft. in the presence of people and 40 g a.i./1000 cu.ft. (or 8 g @ 10%) in the absence of people.

4) **Malathion** (3%). PC no. 057701; Tox. Chem no. 535:

sprayed on surfaces associated with infestation of a quarantine insect on ship decks, bulkheads, pier areas or other storage facilities near infestation.

5) **Malathion/carbaryl** (25%/50%). Carbaryl PC no. 056801; Tox. Chem no. 160: 30 second dip for orchids and other plants not tolerant of methyl bromide fumigation at inspection stations around the country; dip prepared from 3 level tablespoons wettable powder of each ingredient (final concentration not specified).

6) **Sodium hypochlorite** (max. 12.5%). PC no. 014703; Tox. chem no. 776: application to propagative plant parts at inspection stations.

7) **Captan.** PC no. 081301; Tox. chem no. 159: for treatment of seeds and other propagative plant parts to control plant diseases; 0.3 - 9.0 oz. a.i. per 100 lbs seed, at inspection stations.

8) **Ferbam.** PC no. 034801; Tox. chem no. 458: sprayed on propagative plant parts to control plant diseases, 1 - 1.5 lbs. a.i./100 gallons water.

9) **Treflan (trifluran).** PC no. 036101; Tox. chem no. 889: 3.0 lb. a.i. per acre on established lawns and turf for control of witchweed (preemergence to witchweed; postemergence to lawn grasses).

10) **Methyl bromide** (98% and 2% **chlorpicrin**): 450 lb. per acre to kill witchweed seed in soil, in fallow fields and small land plots to be released from quarantine.

11) **Sodium carbonate** (4%). PC no. 073506; Tox. chem no. 752: to surfaces potentially exposed to animal diseases in semen containers.

12) **Sodium carbonate** (4%) with 0.1% **sodium silicate** (PC no. 072603; Tox. chem. no. 792) to aircraft surfaces potentially exposed to animal diseases.

13) **Sodium hypochlorite** (percent not specified): applied to surfaces potentially exposed to animal diseases.

14) **Sodium hydroxide** (concentration not specified). PC no. 075603; Tox. chem no. 773: applied to exposed surfaces, animal product containers, hay and straw.

15) **Metam sodium (vapam)** (32.7% a.i.). PC no. 039003; Tox. Chem no. 780: diluted 1 gal to 60 gal water and sprayed (low pressure equipment) to metal surfaces contaminated with soil (soil residue must be wet to

saturation) between 50 - 90° F.

Applications are by or under direction of certified pesticide applicators of PPQ Officers and/or State Cooperators and self-contained breathing apparatus or combination air supplied/SCBA respirator are available during fumigations.

III. TOX. BRANCH COMMENTS

Toxicology of chemicals handled by TB-II (carbaryl, trifluran and metam sodium) was briefly assessed in the attached memo from J. Rowland to L. Hansen, dated 11-17-92. An abbreviated toxicity profile of chemicals handled by TB-I is presented below.

The primary toxicological concern for chemicals to be used in this quarantine exemption request is for acute exposure to high levels of methyl bromide, which can be fatal. Applicator exposures are estimated to be similar to those calculated for previous Section 18 quarantine exemption requests by APHIS (see Risk/Exposure Assessment, below).

Of the remaining chemicals, captan and trifluran have potential carcinogenicity to humans (respective Q_1^*s = 3.6×10^{-3} and 7.7×10^{-3} $(mg/kg/day)^{-1}$. Assessments were based on feeding studies in rodents (see abbreviated toxicity profiles below). The proposed uses are not anticipated to pose an unreasonable risk to applicators due to limited use and to use of proper worker protection during application.

However, two of these chemicals, metam sodium and ferbam, have inadequate toxicology databases which do not support the proposed uses: metam sodium only has acceptable acute toxicity and genotoxicity studies available at this time and there is no data available on ferbam.

There are no dietary concerns since all proposed uses are nonfood/nonfeed.

IV. RISK/EXPOSURE ASSESSMENT

Exposure estimates were conducted by OREB for methyl bromide (attached memo from R. Lozada to L. Hansen dated 11-23-92). Exposures are unchanged from previous APHIS quarantine exemption use patterns (detailed discussion in memo from L. Hansen to L. Pemberton and R. Cool dated 11-13-92) and are not expected to pose an unreasonable risk to applicators, who are trained and/or certified in use of methyl bromide and have self-contained breathing apparatus available during application/aeration.

Uses proposed for d-phenothrin, malathion, malathion/carbaryl, captan, trifluran are likewise not

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anticipated to pose unreasonable risks to applicators. Applicator exposures were not determined for these uses because the treatments are done on a limited basis using standard application methods and are performed by trained APHIS personnel according to label directions. Appropriate protective clothing must be worn during applications. Cancer risk from exposure to captan or trifluralin is expected to be insignificant.

Sodium carbonate, sodium hydroxide and sodium hypochlorite are all widely used chemicals with known toxicity. Use of these chemicals as described is not anticipated to produce unacceptable risk to applicators when appropriate protection (impermeable rubber gloves, goggles, etc.) are used.

V. ABBREVIATED TOXICOLOGY PROFILE

A. **Methyl bromide**

Toxicology Database: not complete (chronic feeding, mouse inhalation oncogenicity, mutagenicity, neurotoxicity, metabolism).

Risk Assessment: RfD = 0.0014 mg/kg/day (subchronic rat gavage). RfC = 0.005 mg/m^3 (29-mo. rat inhalation; uncertainty factor = 100). Carcinogenicity: Class D (insufficient information).

Issues: Extremely acutely toxic (fatalities have occurred). Developmental toxicity - in rabbits, agenesis of gall bladder and fusion of sternebrae in fetuses (not referred to Developmental Toxicity Peer Review). Neurotoxicity - symptoms (eg. tremors, lateral recumbency) frequently seen; additional neurotoxicity studies required to better characterize effects.

B. **D-Phenothrin**

Toxicology Database: Not complete (rat chronic, mouse onco, rat developmental toxicity, structural chromosomal aberration, acutes except for inhalation, 90-day inhalation).

Risk Assessment: RfD = 0.071 (1 yr feeding, dog; uncertainty factor = 100). Carcinogenicity: not determined.

Issues: Previously submitted mouse oncogenicity and rat chronic/oncogenicity studies were not tested at a sufficiently high dose level. Testing at higher doses should help resolve the issue of biological significance of liver tumors in the mouse study.

C. **Malathion**

Toxicology Database: Not complete (acute delayed neurotoxicity, ocular toxicity, chronic/carcinogenicity studies with malathion and malaoxon in rats and carcinogenicity study in mice).

Risk Assessment: RfD = 0.02 (cholinesterase inhibition, 8 week feeding, humans; uncertainty factor = 10). Carcinogenicity: D (insufficient information).

Issues: Neurotoxicity - organophosphate. Ocular effects (Saku disease) and other symptoms reported following aerial application of malathion. Carcinogenicity - evidence of carcinogenicity includes genotoxicity and similar tumor types in several studies; however, available studies were not considered adequate for assessment of oncogenic potential.

D. **Captan**

Toxicology Database: Complete.

Risk Assessment: RfD = 0.13 mg/kg/day (3-generation reproduction, rat; uncertainty factor = 100). Carcinogenicity: B2 (probable human oncogen), Q_1^* = 3.6×10^{-3} $(mg/kg/day)^{-1}$ based on duodenal adenomas and adenocarcinomas in mice. Renal tumors in rats not used in quantitation of cancer risk due to possible α2u-globulin mechanism. Genotoxic in several assays.

Issues: Oncogenicity (see above). Captan is a Tox. category I eye irritant.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

MEMORANDUM

OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

SUBJECT: Section 18 Quarantine Exemption for the Use of Carbaryl, Metam Sodium and Trifluralin from Animal and Plant Health Inspection Service, Plant Protection and Quarantine of the USDA.

FROM: Jess Rowland, Toxicologist
Section II, Toxicology Branch II
Health Effects Division (H7509C)

TO: Linnea Hansen, Toxicologist
Toxicology Branch I
Health Effects Division (H7509C)

THRU: K.Clark Swentzel, Section Head
Section II, Toxicology Branch II
Health Effects Division (H7509C)
and
Marcia van Gemert, Ph.D., Chief
Toxicology Branch II
Health Effects Division (H7509C)

Submissions: **S427802; S427794; S427788**

DP Barcodes: **D183958; D183950; D183946**

ACTION REQUESTED: Determine if the toxicological data base will support a Section 18 quarantine exemption involving application of carbaryl, metam sodium and trifluralin to treat nonfood and nonfeed commodities.

CONCLUSION: The Toxicology Branch-II, based on toxicological considerations, recommends approval of the request for quarantine exemption of carbaryl and trifluralin and does not recommend approval of metam sodium due to existing data gaps with the technical product.

CARBARYL

I. Toxicology Data Base: The toxicology data base is complete for the formulation, *Sevin 80 WDG [80%]* but not for the technical product. Data gaps for the technical product include:

83-1a: Chronic toxicity study in rats.
83-2a: Carcinogenicity study in mice.
83-2b: Carcinogenicity study in rats.

Studies to fulfill these guideline requirements are currently underway. The registrant has submitted to the Agency, reports on the findings from an interim sacrifice [52 weeks].

II. Risk Assessment

a. Reference Dose [RfD]; An RfD of 0.1 mg/kg/day was derived using a NOEL of 10.0 mg/kg/day and an uncertainty factor of 100; the NOEL was established from a 2-year feeding study in rats. However, evaluation of the replacement studies in mice and rats to fulfill data gaps may necessitate re-evaluation of the RfD for carbaryl.

b. Classification of Carcinogenicity: None

c. DRES Analysis: Not required since the proposed use is to treat nonfood and nonfeed commodities.

III. Recommendation: Although the toxicology data base in not complete for the technical product, since this request is for a nonfood use [treat orchids and other plants], the Toxicology Branch II, based on toxicological considerations, has no objection to approval of the request for quarantine exemption of Carbaryl.

METAM SODIUM

I. Toxicology Data Base: The toxicology data base is complete for the formulation *Vaspam [32.7%]*. Data base is not complete for the technical product. Except for the acute and mutagenicity batteries which are complete for the technical product, significant data gaps exists for all the other toxicological end points.

II. Risk Assessment: Neither an RfD nor a classification for carcinogenicity exists for metam sodium.

III. Recommendation: The Toxicology Branch II, based on toxicological considerations, does not recommend approval of the request for quarantine exemption of metam sodium.

TRIFLURALIN

I. Toxicology Data Base: The toxicology data base is complete for the technical product and the formulation [*Treflan E.C 44.5%*].

II. Risk Assessment

a. Reference Dose [RfD]; An RfD of 0.0075 mg/kg/day was derived using a NOEL of 0.75 mg/kg/day and an uncertainty factor of 100; the NOEL was established from a 1-year feeding study in dogs.

b. Classification of Carcinogenicity: Trifluralin is classified as Group C carcinogen [possible human carcinogen] with a Q_1^* of 7.7×10^{-3}. The classification is based on an increase in incidence of malignant or combined malignant-and-benign tumors of the renal pelvis and benign tumors of the urinary bladder and in thyroid tumors.

c. DRES Analysis: Not required since the proposed use is to treat nonfood and nonfeed commodities.

III. Recommendation: The Toxicology Branch II, based on toxicological considerations, has no objection to approval of the request for quarantine exemption of trifluralin.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

NOV 24 1992

OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

MEMORANDUM

SUBJECT: REVIEW OF FIFRA SECTION 18 QUARANTINE EXEMPTION REQUESTS AND THE ESTIMATION OF WORKER EXPOSURE DURING FUMIGATIONS TO NONFOOD & NONFEED ITEMS WITH METHYL BROMIDE.

FROM: Radamés Lozada, Chemist 11/20/92

TO: Linnea Hansen, Toxicologist
Toxicology Branch I
Health Effects Division (H7509C)

THRU: Mark I. Dow, Ph.D., Section Head
Special Review and Registration Section II

Larry C. Dorsey, Acting Chief
Occupational and Residential Exposure Branch
Health Effects Division (H7509C)

Please find below, the OREB review of:

DP Barcode: D183928, D183933, D183951

Pesticide Chemical Code: 053201

Emergency Exeption No.:

93DA0001	FIFRA Section 18 - MeBr on imported nonfood/nonfeed cargo
93DA0002	FIFRA Section 18 - MeBr on machinery, plant & nonplant materials
93DA0010	FIFRA Section 18 - MeBr on soil and small plots of land to be released from quarantine

EPA MRID No.: none

Review Time: 2 days

PHED: NO

I. INTRODUCTION:

A. Background:

The United States Department of Agriculture, Animal and Plant Health Inspection Service (USDA, APHIS) has submitted to the Agency, FIFRA Section 18 Quarantine Exemption requests for the use of Methyl Bromide (MeBr) on several nonfood & nonfeed commodities. The fumigations are conducted on imported products to control any foreign plant pest not currently established in the U.S. These treatments are also conducted as a condition of trade. It appears that, in most cases, the only alternative to MeBr fumigation is to deny import or export. OREB, in May 1992, provided an exposure assessment for a similar Section 18 Quarantine Exemption request to use Methyl Bromide on several commodities.

B. Purpose:

OREB has been requested to review the submitted data and provide an exposure assessment for the use of Methyl Bromide to treat various nonfood and nonfeed items under the FIFRA Section 18 Quarantine Exemption.

II. DETAILED CONSIDERATIONS:

According to the APHIS Section 18 request, treatments will be conducted at Ports of Entry through the U.S. All treatment sites will be approved prior to treatment. Sites of application include ship holds, temporary or permanent locations which may be sealed. A fumigation enclosure may be constructed of tarpaulins or metals for this purpose. The methyl bromide label, Federal, State, local regulations, and APHIS Treatment requirements will be observed.

The following table summarizes the various uses and application rates specified in the Section 18 request.

Uses	Application Rate
Imported nonfood/nonfeed cargo	4 to 15 pound per 1000 cubic feet
Machinery, plant & nonplant materials	4 to 23 pound per 1000 cubic feet
Soil and small plots of land to be released from quarantine	450 pound per acre

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In a memorandum (attached) from Steven Knott (EPA/OPP/HED/OREB: May 6, 1992) a similar action was addressed. The application rates for the first two uses (93DA0001 and 93DA0002) do not vary from that of the MeBr used on Oak Logs addressed in the afore mentioned memorandum. Therefore, OREB will assume the exposure scenarios to remain unchanged and hence, will reissue the estimates for both the application and aeration scenarios. Please see the attached memorandum regarding clarification of any exposure assumptions and/or calculations.

The following table summarizes the daily and annual exposure estimates for the unprotected worker, and worker wearing SCBA for MeBr Used on Oak Logs.

Exposure Category	Air Conc. (ppm)	Unprot. Daily Exp. mg/kg/day	SCBA Daily Exp. mg/kg/day	Unprot. Annual Exp. mg/kg/yr	SCBA Annual Exp. mg/kg/yr
Application					
Range	0.02-14.3	0.0023-1.6	0.000046-0.033	0.025-18	0.00051-0.36
Mean	1.6	0.18	0.0037	2.0	0.040
Median	0.31	0.036	0.00071	0.39	0.0078
Aeration					
Range	0.10-502	0.012-58	0.00023-1.2	0.13-635	0.0025-13
Mean	135	16	0.31	171	3.4
Median	58.0	6.7	0.13	73	1.5

The following table summarizes the daily and annual exposures for workers applying MeBr on imported nonfood/nonfeed cargo and on machinery, plant & nonplant materials. They were obtained by adding the daily and annual exposures for application with those for aeration.

	Daily Exposure (mg/kg/day)	Annual Exposure (mg/kg/yr)
Range	0.014 - 1.2	0.15 - 13
Mean	0.49	5.4
Median	0.17	1.9

A different approach is needed for the exposure assessment of the use of MeBr on soil and small plots of land to be released from quarantine (93DA0010). In a memorandum (attached) from Ameesha Mehta (OREB) to Rebecca Cool (RSB/RD), dated May 26, 1992 a similar action was addressed. According to the applicant, MeBr (98 percent and 2 percent Chloropicrin) will be applied at a rate of 450 pounds per acre. According to the Memorandum from Peter L. Joseph (APHIS) to Steven Knott (OREB), dated April 1992, five treatments per year are executed. See attached memorandum for a detailed consideration of the assumptions and calculations.

The following table summarizes the daily and annual exposure estimates for workers when applying MeBr on soil and small plots of land to be released from quarantine.

Worker	No. of Replicates	Range ($\mu g/m^3$)	Mean ($\mu g/m^3$)	Daily Exposure ($\mu g/kg/day$)	Annual Exposure ($\mu g/kg/yr$)
Tractor Driver	27	0.07-9.75	1.22	0.24	1.2
Copilot	14	0.15-12.13	0.70	0.14	0.7
Shoveler	11	0.05-0.58	0.17	0.033	.17

III. CONCLUSIONS:

The following table summarizes the daily and annual exposures for workers applying MeBr on imported nonfood/nonfeed cargo and on machinery, plant & nonplant materials (93DA0001 and 93DA0002). They were obtained by adding the daily and annual exposures for application with those for aeration.

	Daily Exposure (mg/kg/day)	Annual Exposure (mg/kg/yr)
Range	0.014 - 1.2	0.15 - 13
Mean	0.49	5.4
Median	0.17	1.9

The following table summarizes the daily and annual exposure estimates for workers when applying MeBr on soil and small plots of land to be released from quarantine (93DA0010).

Worker	No. of Replicates	Range ($\mu g/m^3$)	Mean ($\mu g/m^3$)	Daily Exposure ($\mu g/kg/day$)	Annual Exposure ($\mu g/kg/yr$)
Tractor Driver	27	0.07-9.75	1.22	0.24	1.2
Copilot	14	0.15-12.13	0.70	0.14	0.7
Shoveler	11	0.05-0.58	0.17	0.033	.17

The above estimates are reissued from OREB's previous memoranda issued in May 1992, which calculated MeBr exposure estimates on various scenarios. OREB reiterates, again, that the application rates used in the previous memoranda do not differ from the rates requested in the current exemption.

IV. REFERENCES:

1. Memorandum from Steven Knott (OREB) to Rebecca Cool (RSB/RD) titled "Review of FIFRA Section 18 Quarantine Exemption Requests and the Estimation of Workers Exposure During Commodity Fumigations with Methyl Bromide", dated May 6, 1992.

2. Memorandum from Peter L. Joseph (APHIS) to Steven Knott (OREB) titled "Methyl Bromide Treatment Procedures", dated April 30, 1992.

3. Memorandum from Ameesha Mehta (OREB) to L. Hansen (TB-I) titled "Review of FIFRA Section 18 Quarantine Exemption Requests and the Estimation of Workers Exposure During Commodity Fumigations with Methyl Bromide, dated October 30, 1992.

4. Memorandum from Ameesha Mehta (OREB) to Rebecca Cool (RSB/RD) titled "Worker Exposure Review of a reissuance Request from the State of California, for a Section 18 Specific Exemption Using Methyl Bromide 99.5% on Carrots, dated May 26, 1992.

cc: R. Lozada, OREB (with attachments)
Correspondence File
Chemical File (053201 Methyl bromide)
Libby Pemberton, RSB/RD (H7505C) (with attachments)

Attachment 1

Memorandum from Steven Knott (OREB) to Rebecca Cool (RSB/RD) titled "Review of FIFRA Section 18 Quarantine Exemption Requests and the Estimation of Workers Exposure During Commodity Fumigations with Methyl Bromide", dated May 6, 1992.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

MAY 6 1992

OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

MEMORANDUM

SUBJECT: Review of FIFRA Section 18 Quarantine Exemption Requests and the Estimation of Worker Exposure During Commodity Fumigations with Methyl Bromide.

FROM: Steven M. Knott, Chemist

TO: Rebecca Cool, Section Chief
Emergency Response and Minor Use Section
Registration Division (H7505C)

THRU: Mark Dow, Ph.D., Section Head
Special Review and Registration Section II

Larry Dorsey, Acting Chief
Occupational and Residential Exposure Branch
Health Effects Division (H7509C)

Please find below, the OREB review of:

DP Barcode: No Bean Provided

Pesticide Chemical Code: 053201 Methyl Bromide

EPA Reg. No.:
91DA0029 FIFRA Section 18 - MeBr on Cane Berries
91DA0030 FIFRA Section 18 - MeBr on Asparagus
91DA0031 FIFRA Section 18 - MeBr on Bananas
92DA0005 FIFRA Section 18 - MeBr on Grapes
92DA0007 FIFRA Section 18 - MeBr on Pineapples
92DA0009 FIFRA Section 18 - MeBr on Melons
92DA0010 FIFRA Section 18 - MeBr on Oak Logs

EPA MRID No.: Not Provided

Review Time: 4 hours review + 40 hours exposure assessment

PHED: NO

Printed on Recycled Paper

I. INTRODUCTION:

A. Background:

The United States Department of Agriculture, Animal and Plant Health Inspection Service (USDA, APHIS) has submitted to the Agency FIFRA Section 18 Quarantine Exemption requests for the use of Methyl Bromide (MeBr) on several commodities. The fumigations are conducted on some imported products to control any foreign plant pest not currently established in the United States. The treatments are conducted on some exported products as a condition of trade. It appears that, in most cases, the only alternative to MeBr fumigation is to deny import or export.

B. Purpose:

Due to a recent fatality related to the use of MeBr for the fumigation of an apartment building, the Health Effects Division (HED) has been reevaluating toxicity and exposure information related to the various uses of this fumigant. As a part of this process, the Occupational and Residential Exposure Branch (OREB) has reviewed existing FIFRA Section 18 Quarantine Exemption requests and has attempted to provide an estimate of exposure for these uses. The following is OREB's evaluation.

II. DETAILED CONSIDERATIONS:

The Occupational and Residential Exposure Branch (OREB) has previously reviewed several studies of exposure to methyl bromide in which the application methods are similar to those that will be used for the APHIS quarantined commodity fumigations.[1,2] One of these studies was conducted by a MeBr registrant while the remainder were conducted by the California Department of Food and Agriculture (CDFA). These studies are listed in Table 1 with an identifying number and a brief description of the use scenario.

Table 1: MeBr Exposure Studies

ID Number	Study Sponsor	Scenario Description
EPA-264075	Registrant	Various scenarios for grain fumigation.
HS-902	CDFA	Fumigation of Almond Warehouse.
HS-1078	CDFA	Commodity fumigation, chambers.
HS-1084	CDFA	Fumigation of Tarpaulined Bins.
HS-1092	CDFA	Fumigation of Tarpaulined Bins.
HS-1168	CDFA	Commodity fumigation, chambers.
HS-1238	CDFA	Squirrel burrow fumigation.

All of the studies consist of MeBr air concentrations measured either during fumigation, during aeration of treated areas, or both. In addition, some of the studies contain data collected during the handling and transport of treated commodities.

Samples were collected by drawing air through charcoal sampling tubes. Some samples were collected from the breathing zone of the worker while others represent the general area where the fumigation or aeration occurs.

The main deficiency in these studies is the small number of replicate measurements that were collected (a problem that is common to many industrial hygiene investigations). Noting the similarities among the different fumigation scenarios in the studies, OREB pooled all the data together by assigning each data point to one of three categories. Pooling the data in this manner assumes that exposure is independent of the application rate. The data do not suggest that this is an unreasonable assumption. OREB believes that using this larger pool of data, that encompasses a range of application rates, may provide a more reliable estimate of the exposure. The three categories used for pooling the data are described below.

Application - Consisting of MeBr air concentrations measured during the opening of MeBr cylinders, the puncturing of cans of MeBr, and the subsequent fumigation. These activities, as monitored in EPA-264075, lasted from 9 to 134 minutes. The average time was 47 minutes (n=31).

Aeration - Consisting of MeBr air concentrations measured during the removal of materials used for sealing treatment areas, during the opening of windows and doors, during the removal of treated commodities from treatment chambers, and the subsequent aeration. These activities, as monitored in EPA-264075, lasted from 8 to 120 minutes. The average time was 49 minutes (n=24).

Other - Consisting of MeBr air concentrations measured during the handling of treated commodities (i.e., transporting...). These activities, as monitored in EPA-264075, lasted from 75 to 80 minutes. The average time was 78 minutes (n=2).

The detection limits within the studies ranged from 0.006 ppm to 0.06 ppm. To facilitate pooling data sets with different detection limits together and to estimate exposure in a manner that is consistent with previous OREB assessments for MeBr, a value of 0.02 ppm has been given to all air concentrations that were below the limit of detection or that were detectable and

less than 0.02 ppm. The result of pooling the data in this manner follows.

Application:

The total number of air samples derived from all studies that meet the above definition of "application" is 69. These samples were collected during the fumigation of various commodities held in flat storage buildings, silos, barges, fumigation chambers, tarpaulin covered bins, and trailers/freight cars. In addition, data collected during the fumigation of a flour mill, processing equipment, and ground squirrel burrows were included in this set.

Inspection of the data indicated that during the fumigation of flour mills and processing equipment air concentrations of MeBr were significantly higher than in other scenarios. The difference between this subset and the rest of the data was demonstrated to be statistically significant (α=0.05) and, therefore, these values were removed from this analysis. The resulting data set contains 53 replicate measurements ranging from **0.02** ppm to **14.3** ppm. The arithmetic mean air concentration is **1.6** ppm while the median and mode are **0.31** ppm and **0.02** ppm respectively.

Aeration:

The total number of air samples derived from all studies that meet the above definition of "aeration" is 70. In addition to the scenarios described under application, air samples were also collected during the aeration of an almond warehouse.

Once again, inspection of the data indicated that during the aeration (probably during the initial removal of seals) of barges, flour mills, and trailers/freight cars, air concentrations of MeBr were higher than in other scenarios. The difference between this subset and the rest of the data was demonstrated to be statistically significant (α=0.05) and, therefore, these values were removed and analyzed separately. The remaining 55 replicates range from **0.02** ppm to **71.0** ppm and yield an arithmetic mean, median, and mode of **3.54** ppm, **0.30** ppm, and **0.02** ppm respectively.

The 15 replicates that may represent the initial aeration of barge holds, flour mills, and freight cars range from **0.10** ppm to **502** ppm and yield an arithmetic mean and median of **135** ppm and **58.0** ppm respectively. There was no discernible mode for these data.

Other:

The total number of air samples derived from all studies that meet the above definition of "other" is 4. This number of replicates is unacceptable for exposure assessment purposes. The 4 samples consist of 2 measurements taken during the driving of a forklift to move treated almonds and 2 measurements taken during the loading and driving of a truck to transport grain. The samples range from **0.02** ppm to **0.90** ppm. There appears to be a difference between the samples taken from the forklift driver (moving almonds inside a warehouse) and those taken from the truck driver (transporting grain, outside); however, too few replicates are available to verify this difference. The arithmetic mean of these 4 samples is **0.44** ppm. No further exposure analysis for this scenario will be conducted.

To estimate exposure from these air concentrations of MeBr, OREB first converted the air concentrations from units of ppm to mg/m^3 using the following relationship:

Air concentration (mg/m^3) = Air concentration (ppm) x 3.88

The air concentrations, in units of mg/m^3, were then used with the following assumptions to calculate an hourly exposure.

1. An average worker weighs 70 kg.

2. The inhalation rate for the average worker engaged in moderate work is 2.5 m^3/hour.[4]

3. A protection factor of 50 is associated with the use of a Self Contained Breathing Apparatus (SCBA).[2] This factor assumes that SCBA will be used properly and is functioning properly.

The formula used for these calculations is as follows:

Hourly Exposure (mg/kg/hr) = Air Conc. (mg/m^3) x 2.5 m^3/hour x 1/70 kg x (1/50) (for SCBA)

The results of this analysis for the range, mean, and median of the air concentrations are presented in Table 2.

Table 2: MeBr Hourly Exposure Estimates

Exposure Category	Air Concentration (ppm)	Exposure Unprotected (mg/kg/hr)	Exposure with SCBA (mg/kg/hr)
Applic.			
Range	0.02 - 14.3	0.0028 - 2.0	0.000055 - 0.040
Mean	1.6	0.22	0.0044
Median	0.31	0.043	0.00086
Aeration			
Range	0.02 - 71	0.0028 - 9.8	0.000055 - 0.20
Mean	3.54	0.49	0.0098
Median	0.30	0.041	0.00083
Aeration (Initial)			
Range	0.10 - 502	0.014 - 70	0.00028 - 1.4
Mean	135	19	0.37
Median	58.0	8.0	0.16

To estimate single day and annual exposures to MeBr, usage information was derived from the registrant study (EPA-264075), the CDFA studies, FIFRA Section 18 quarantine exemption requests, and personal communications with USDA, APHIS contacts. The resulting assumptions follow:

1. One treatment (fumigation) will result in 50 minutes (0.83 hrs) of exposure to application air concentrations followed by 50 minutes of aeration air concentrations. This assumption may be very conservative in nature. The USDA, APHIS contact estimated that both application and aeration may result in a total of 50 minutes of exposure.[5] The Self Contained Breathing Apparatuses (SCBAs) are required during these time periods if air testing indicates that MeBr air concentrations are above the TLV (5 ppm).[3]

2. A maximum of 3 to 5 treatments (excluding Oak Logs) may be made in one day.[5]

3. An average of 11 treatments per year may be conducted by one applicator. This figure was derived during a telephone conversation with the USDA, APHIS contact.[5] A follow up letter from APHIS provided a refined estimate of 5 treatments per year per applicator.[3] Given the uncertainty of this assumption (the number of treatments at each port varies), OREB has decided to use the 11 treatments per year per applicator in the assessment.

Using these assumptions, daily and annual exposures were calculated in the following manner.

Daily Exposure (mg/kg/day) = Hourly Exposure (mg/kg/hr) x 0.83 hrs/treat. x 5 treat./day

Ann. Exposure (mg/kg/yr) = Hourly Exposure (mg/kg/hr) x 0.83 hrs/treat. x 11 treat./yr

The results of this analysis are presented in Tables 3 and 4. A separate daily exposure estimate is provided for log fumigation because it is only possible to conduct one of these per day. Also, the aeration concentration that is used for the log fumigation is the initial aeration value. This value was used because application rates for log fumigations are high (15 lbs MeBr per 1000 ft^3) and log fumigations may lead to higher exposures during aeration.

Table 3: MeBr Daily Exposure Estimates

Exposure Category	Air Concentration (ppm)	Exposure Unprotected (mg/kg/day)	Exposure with SCBA (mg/kg/day)
Applic.			
Range	0.02 - 14.3	0.012 - 8.2	0.00023 - 0.16
Mean	1.6	0.92	0.018
Median	0.31	0.18	0.0036
Aeration			
Range	0.02 - 71	0.012 - 41	0.00023 - 0.82
Mean	3.54	2.0	0.041
Median	0.30	0.17	0.0034
Aeration (Initial)			
Range	0.10 - 502	0.057 - 289	0.0012 - 5.8
Mean	135	78	1.6
Median	58.0	33	0.67
Applic. (Logs)			
Range	0.02 - 14.3	0.0023 - 1.6	0.000046 - 0.033
Mean	1.6	0.18	0.0037
Median	0.31	0.036	0.00071
Aeration (Logs)			
Range	0.10 - 502	0.012 - 58	0.00023 - 1.2
Mean	135	16	0.31
Median	58.0	6.7	0.13

Table 4: MeBr Annual Exposure Estimates

Exposure Category	Air Concentration (ppm)	Exposure Unprotected (mg/kg/yr)	Exposure with SCBA (mg/kg/yr)
Applic.			
Range	0.02 - 14.3	0.025 - 18	0.00051 - 0.36
Mean	1.6	2.0	0.040
Median	0.31	0.39	0.0078
Aeration			
Range	0.02 - 71	0.025 - 90	0.00051 - 1.8
Mean	3.54	4.5	0.090
Median	0.30	0.38	0.0076
Aeration (Initial)			
Range	0.10 - 502	0.13 - 635	0.0025 - 13
Mean	135	171	3.4
Median	58.0	73	1.5

III. CONCLUSIONS:

It cannot be overemphasized that these exposure estimates are only rough approximations (ball park estimates). The air concentration data used in this assessment were collected under a wide variety of conditions.

1. The application rates in the studies vary from 1.5 lbs MeBr per 1000 ft^3 to 15 lbs MeBr per 1000 ft^3. In some of the studies the application rates are unknown. However, OREB believes that the application rates used in all the studies encompass those proposed in the FIFRA Section 18 Quarantine Exemption requests.

2. Different types of application equipment are used in the studies. Some applications were made by passing MeBr liquid from cylinders to heat exchangers with the resulting vapors passing through hoses to the fumigation area. Others were made by puncturing 1.5 lb cans of MeBr placed under tarpaulins. According to the USDA, APHIS contact, the Section 18 applications will be made, almost exclusively, by the first method.[5]

3. The applications in the studies were made under varying conditions of ventilation and temperature. Some applications were conducted using chambers located indoors. Others were conducted outdoors. However, OREB believes that this is representative of the range of fumigation conditions that will occur during the Section 18 uses.

4. The air samplers used in the studies were positioned in a variety of locations. Some samplers were positioned on the worker while others were located near the floor, close to the fumigation area.

In addition, the MeBr usage information available for this assessment needs to be reviewed. OREB has initiated discussions with the Biological and Economic Analysis division to obtain a more accurate description of commodity fumigation processes.

Despite the above considerations, OREB believes that the following exposure estimates are reasonable for the evaluation of the FIFRA Section 18 Quarantine Exemption requests from the USDA.

Table 5: MeBr Daily and Annual Exposure Estimates for APHIS Quarantine Fumigations

Section 18 Number		Exposure (mg/kg/day)	Exposure (mg/kg/year)
91DA0029-30,	Range	0.023 - 5.8	0.051 - 13
92DA0005,7,9	Mean	3.0	6.5
(Food Commodities)	Median	0.35	0.77
92DA0010	Range	0.014 - 1.2	0.15 - 13
(Oak Logs)	Mean	0.49	5.4
	Median	0.17	1.9

These estimates were calculated by summing the daily (Table 3) and Annual (Table 4) exposures for application with those for aeration. Due to the requirement for the use of SCBA if MeBr air concentrations exceed the TLV, if the air concentration values (ppm) in Tables 3 or 4 were less than the TLV for MeBr (5 ppm), the "unprotected" exposure estimates were used. If the air concentration values exceeded the TLV, the "SCBA" exposure estimates were used (SCBA exposure estimates assume the SCBA will be used properly and is functioning properly). For the maximum in each range, "unprotected" exposure at the TLV (5 ppm) was assumed. As stated previously, a separate estimate was provided for oak logs due to a maximum of one application per day (as opposed to 5 for food commodities) and due to potentially higher exposures during aeration.

IV. REFERENCES:

1. David Jaquith, Review of Methyl Bromide Exposure Studies Conducted by CDFA, September 4, 1986.

2. David Jaquith, Exposure Assessment for Methyl Bromide, September 20, 1988.

3. Peter Joseph, Methyl Bromide Treatment Procedures: Memorandum to Steven Knott with copies of selected sections of the PPQ training manual, April 30, 1992.

4. USEPA, Exposure Factors Handbook, p. 3-4, March, 1990.

5. Scott Wood, Personal Communication with Steve Knott, April 29, 1992.

cc: Steven Knott, OREB
Correspondence File
Chemical File
Circulation
Linda Kutney, SACB, H7509C

Attachment 2

Memorandum from Ameesha Mehta (OREB) to Rebecca Cool (RSB/RD) titled "Worker Exposure Review of a reissuance Request from the State of California, for a Section 18 Specific Exemption Using Methyl Bromide 99.5% on Carrots, dated May 26, 1992.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

MAY 26 1992

OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

MEMORANDUM

SUBJECT: Worker Exposure Review of a Reissuance Request from the State of California, for a Section 18 Specific Exemption Using Methyl Bromide 99.5% on Carrots.

FROM: Ameesha Mehta, Chemist Ameesha Mehta 5/11/92

TO: Rebecca Cool, PM 41
Registration Support and Emergency Response Branch
Registration Division (H7505C)

THRU: John Tice, Acting Section Head
Special Review and Registration 5/26/92

Larry Dorsey, Acting Branch Chief
Occupational and Residential Exposure Branch
Health Effects Division H7509C 5/26/92

Please find below, the OREB review of:

D.P. Barcode: D174113

Pesticide Chemical Code: 053201 Methyl Bromide

EPA Reg. No.: 92CA0017

EPA MRID No.:

Review Time: 1 Day

PHED: No

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I. INTRODUCTION

A. Background:

Methyl Bromide, a preplant fumigant, is used to control soil nematodes. The current formulation (EPA Reg. No. 83536-12) is 99.5% methyl bromide, and 0.5% chloropicrin.

B. Purpose:

OREB has been requested to review and comment on the reissuance request from the State of California for a Section 18 Specific Exemption on carrots. Since the California suspension of 1,3 Dichloropropene permits in April 1990, growers were left with Metam-Sodium as the alternative. However, the product performance with Metam-sodium have shown to be erratic using soil injection methods; hence, the Section 18 request for Methyl Bromide. The total carrot acreage in California represents over 70% of the nationwide acres planted with carrots. Since the crop is planted throughout the year, depending upon the region, the exemption is requested for 1 year. Note, that this is a second year request from the State of California for this chemical.

II. DETAILED CONSIDERATIONS

A. Proposed Program:

The material is to be applied using chisels mounted on shanks fixed on a tool bar pulled by a tractor. The tractor is also equipped with a roller or cultipacker which is used to seal the soil immediately after the application. In most instances, the beds are tarped after fumigation. Methyl bromide is to be applied statewide for a maximum of 30,000 carrot acreages, at a rate of 300 lbs per treated acre. The preplant treatment is either by band or broadcast application method, once per growing season, and at least 3 days prior to planting of the crop.

From the attached label, it is illustrated that tarpless fumigation will be acceptable in California. The Re-entry Interval is set for a period of 48 hrs after fumigation, and seeds may be planted 3 days after the treatment. The Section 18 request is from February 15, 1992 to November 30, 1992.

B. Data Used:

Three worker exposure monitoring studies conducted by Maddy et. al, from 1980 to 1983 provide the only available data on potential exposure during methyl bromide soil fumigation.

However, the above three monitoring studies were completed before the FIFRA reregistration standards; hence, are missing representative exposure values due to lack of field and lab recoveries, adequate number of replicates, and /or sites sampled. These studies monitored respiratory exposures of workers to methyl bromide during application of the chemical to fallow fields by shallow injection. Methyl bromide was injected into the soil to a depth of approximately 8 inches with a tractor drawn injection rig. A plastic tarp is automatically laid behind the tractor after injection of the fumigation to retard dissipation into the atmosphere. A typical work crew of this type of application consisted of 3 workers; the tractor driver, a copilot who takes care of the minor problems with the equipment, and a shovelor whose task is the sealing of the edges of the tarp with soil.

After review of the studies, OREB compiled the number of replicates sampled for each type of worker, and calculated the average concentration. Since no information was available, on the label, regarding the number of days a Certified Pesticide Applicator will spend applying this chemical on carrot acreages; use information available from the Telone Data-Call-In (use, usage, July 1991) was used.

TABLE: Exposure Estimates For The Three Types of Workers to Methyl Bromide

WORKER	repl.	Range ug/m^3	Mean ug/m^3	ADE ug/kg/day	AADE ug/kg/day
Tractor Driver	27	0.07 - 9.75	1.22	0.20	0.018
Copilot	14	0.15 - 12.13	0.70	0.12	0.011
Shoveler	11	0.05 - 0.58	0.17	0.028	0.0026

C. Assumptions:

The route of exposure is primarily inhalation; hence, OREB assumes 100% absorption. OREB assumes 3 individuals are needed in the process of applying this chemical, and that a 70 kg body weight to represent average body weight. The ventilation rate for workers, according to Pesticide Assessment Guidelines Subdivision U, is 1.7 m^3 / hr.

The number of hours per day (6.75 hrs/day) workers are exposed, and days of maximum exposure (34 days/year) are based on

Telone's Use, Usage, Product Performance DCI, since no other information is currently available. Note, also that Telone use is similar to that of Methyl bromide. (See attachment)

D. Sample Calculation:

ADE (Tractor Driver) ug/kg/day:

$$\frac{\text{Mean Conc. ug/m}^3 * \text{Vent. Rate m}^3\text{/hr} * 6.75 \text{ hrs/day}}{\text{BW (70 kg)}}$$

$$\frac{1.22 \text{ ug/m}^3 * 1.7 \text{ m}^3\text{/hr} * 6.75 \text{ hrs/day}}{70 \text{ kg}} = 0.20 \text{ ug/kg/day}$$

AADE (Tractor driver) ug/kg/day:

$$\frac{\text{Mean Conc.ug/m}^3 * \text{Vent.Rate m}^3\text{/hr} * 6.75 \text{ hrs/d} * 34 \text{ d/yr} * \text{yr/365 d}}{\text{BW (70 kg)}}$$

= 0.018 ug/kg/day

IV CONCLUSION

OREB has provided the exposure estimates for methyl bromide fumigation using best available data. However, as noted previously, the studies used have serious limitations to them. They include: lack of lab and field recoveries, etc. OREB emphasizes that the data used from the three Maddy, et. al studies monitored application **with tarps**, no monitoring data is available for **tarpless** soil fumigation.

ATTACHMENT

cc: A. Mehta/OREB H7509C w/ attach.
L. Kutney/SACB H7509C w/ attach.
Correspondence file
Chemical file
Circulation