Summary of Submissions Received During the 30-day Public Comment Period on the NC DEQ Division of Air Quality Report: *Risk Analysis and Acceptable Ambient Level Recommendation for Methyl Bromide, dated February 22, 2019.*

On February 22, 2019 the DAQ presented to the Secretaries' Science Advisory Board (SSAB) the document, *Risk Analysis and Acceptable Ambient Level Recommendation for Methyl Bromide*. This revision of the October 22, 2018 document presenting DAQ's recommendation for the methyl bromide acceptable ambient level (AAL) for log fumigation operations reflected the SSAB's suggestion from the discussions taking place during the February 4, 2019 SSAB meeting to provide a range-of-risk values for methyl bromide. During those discussions, DAQ's toxicologist stated that her recommendation for a range-of-risk values would apply the IRIS chronic RfC as the upper-bound AAL value and the lower-bound value would consider the increased sensitivity to neurotoxic effects in the sub-population with the GSH Phase II metabolism isoenzyme polymorphism. The lower-bound AAL value reflects an estimate of the increased sensitivity to neurotoxic effects in this sub-population. The lower-bound range-of-risk value addition and discussion is the only technical revision to prior methyl bromide AAL text provided to the SSAB. Subsequent to the February 22, 2019 document release to the SSAB and the public, a 30-day comment period was identified. What follows is a summary of those comments, received from both private citizens/residents, non-profit organizations representing the interest of residents and environmental justice concerns. This document also includes submissions from the log fumigation industry, the forestry industry and methyl bromide and pesticide trade groups. All comments submitted to DEQ during the 30-day comment period are included in their entirety, arranged by source (as bookmarked sections) in chronological order of receipt. The following table summarizes those comments by recommendation categories. Attachments submitted by the Southern Environmental Law Center (SELC) with the recommendations cover letter are included as a separate file due to their length.

Submit comments to:

Dr. Sandra L. Mort, MS, PhD
Environmental Toxicologist
Secretary's Office
N.C. Department of Environmental Quality
sandy.mort@ncdenr.gov
(919) 707-8217

Summary Table of All Comments Received During the 30-day Public Comment Period for the N.C. Division of Air Quality Proposed Methyl Bromide Acceptable Ambient Level (AAL)

Comment classification	Number of comments, (%)[a]	Notes
No use of methyl bromide for log fumigation	18 (45%)	Residents [b]
Most stringent regulation or support proposed AAL	13 (32%)	Residents, Brunswick County Health and Human Services, NC Conservation Network, NAACP-Brunswick Branch, Southern Environmental Law Center (SELC)
Capture/degrade, reuse or debark	2 (5%)	Private citizens, residents
Oppose MALEC permit	2 (5%)	Resident, NC WARN 501(c)(3) non-profit
Opposed to proposed AAL and/or 24-hour averaging time	5 (12%)	National Pest Management Assoc. (NPMA), NC Forestry Assoc., Methyl Bromide Industry Panel, Ecolab, Western Fumigation
Total number of submissions supporting the proposed AAL or opposed to use of methyl bromide	**35 (88%)[c]**	
Total Number of Comment Submissions	**40**	

a. Percentage of the total number of comments received from all groups, including industry and trade groups

b. "Residents" represents submissions by individual private citizens

c. Percentage of comments submitted by combined citizens/residents and groups representing residents or environmental justice concerns

Mort, Sandra L

From: Leigh Lane <lmcmanus5@gmail.com>
Sent: Tuesday, March 26, 2019 7:57 PM
To: Comments.SABReport
Subject: [External] Methyl Bromide Response

This is a response to the Methyl Bromide report.

Columbus County already suffers a public health crisis of poverty, of health issues surrounding pulmonary and pulmonary related diseases such as asthma from natural causing substances including radon, and of high unemployment. Poverty and high unemployment are not reasons offer employment opportunities when the trade off is further contamination of areas in the county.

DAQ noted that in ATSDR's 1992 review (ATSDR 1992) they derived an acute exposure guideline, but the acute value was removed in the updated review (ATSDR 2018a, ATSDR 2018b). ATSDR noted (ATSDR 2018b) that the acute exposure database was inadequate to develop an acute MRL and noted a concern that acute values may not be protective due to the well-documented delayed effect recognition associated with methyl bromide exposures, as well as the implications of the steep dose-response curve. "A steep dose-response curve suggests that there is a substantial increase in the severity of effects over a relatively small range of increasing exposure concentrations". Since the ATSDR cannot determine an adequate exposure database and there is a "well-documented" delay of effects due to methyl bromide exposure then zero should be the acute value for inhalation. Until the "draft" ATSDR Chronic MRL is finalized and then supported by a five year and 10 year follow up study of adverse health effects, the operation should not be considered because there are not current established acceptable values.

Are there no studies within the past 10 years to show more relevant data? Yes, there are so it would be ideal to show current trends. The studies actually show negative health effects, even related to air that is ingested. Barry et al (2012) showed in a study that stomach cancer increase due to oral exposure as well as prostate cancer increases. North Carolina was a state in this study. Gemmill et al (2013) showed in a study that there were negative fetal effects, specifically fetal growth, when living within 3 miles of methyl bromide operations. In these cases, NIMBY is certainly an appropriate response because there is data showing this chemical is harmful to humans even in small quantities.

"The SSAB recommends a range of Acceptable Ambient Level (AAL) values to be considered by the EMC for methyl bromide as 0.002 mg/m3 to 0.005 mg/m3 and a 24-hour averaging time for the protection of public health." Where is the acceptable range for onsite workers and truck drivers making frequent trips for the spraying? What is the safety equipment used to ensure their protection? Since methyl bromide is odorless, unless DEQ has an acceptable way to contain this harmful inhaled chemical then zero is the acceptable value. The NIOSH IDLH value from the 1970's is not an acceptable value in ppm now some 40 to 50 years later. Therefore, onsite workers and truck drivers are not nor should be considered safe from air exposure. Even residual methyl bromide has negative effects. Budnik et al (2012) showed in a study that while limited, container studies revealed toxic effects exists as well.

Based on current EPA recommendations to eliminate the use of methyl bromide, current research on negative health effects on ingested/breathed due to methyl bromide exposure, current research on other negative health effects including cancer, respiratory distress, reproductive issues, and abnormal fetal development as a few examples, and unsafe working conditions due to methyl bromide exposure, I adamantly oppose any use of this neurotoxin not only locally, in Columbus County, but throughout the stated. There are safe alternatives available that should be used as a replacement.

Current Study References:

Barry, K. H., Koutros, S., Lubin, J. H., Coble, J. B., Barone-Adesi, F., Beane Freeman, L. E., Sandler, D. P., Hoppin, J. A., Ma, X., Zheng, T., … Alavanja, M. C. (2012). Methyl bromide exposure and cancer risk in the Agricultural Health Study. *Cancer causes & control: CCC*, *23*(6), 807-18.

Budnik, L. T., Kloth, S., Velasco-Garrido, M & Baur, X. (2012). Prostate cancer and toxicity from critical use exemptions of methyl bromide: Environmental protection helps protect against human health risks. Environmental Health, 11(5). https://doi.org/10.1186/1476-069X-11-5

Gemmill, A., Gunier, R. B., Bradman, A., Eskenazi, B., & Harley, K. G. (2013). Residential proximity to methyl bromide use and birth outcomes in an agricultural population in California. *Environmental health perspectives*, *121*(6), 737-43.

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Regards,

Dr Leigh Lane
DHA MBA MCHES
252-717-4145

Mort, Sandra L

From: BWilliams <bwilliams@ec.rr.com>
Sent: Monday, March 25, 2019 2:05 PM
To: Comments.SABReport
Subject: [External] Methyl Bromide

I believe there should be no acceptable level for Methyl Bromide in the air I need to breathe to sustain life. I own property in the Columbus County area of the proposed log treatment facility. My 94 year old breathing impaired mother lives in close proximity to the facility. I live on property in New Hanover County near the Port. The alarming lack of meaningful regulation has resulted in some existing facilities being within a few hundred feet of residential communities. Please protect public health. Please do not allow approval/renewal of permits for Methyl Bromide use. There are other less harmful methods.

Rosie Williams
1918 Glen Meade Road
Wilmington, NC 28403

Mort, Sandra L

From: Merla Jackson <mjackson1944@att.net>
Sent: Friday, March 22, 2019 10:51 PM
To: Comments.SABReport
Subject: [External] methyl Bromide

I support the NC Daq in their recommendation for an acceptable Amblent level for Methyl Bromide of 1 ppb at a 24 hour averaging time.

These actions by DAQ will help to address community concerns and protect public health.

Sincerely,
Merla Jackson
Riegelwood, NC. 28456.

Sent from my iPad by Merla Jackson

Mort, Sandra L

From: Kathy Boettinger <kabncbound@gmail.com>
Sent: Tuesday, March 12, 2019 4:02 PM
To: Comments.SABReport
Subject: [External] Methyl Bromide

To Whom it may concern,
I am not a scientist, just a resident of Brunswick County, who is alarmed after reading through this report on Methyl Bromide with growing alarm about all the potential health problems that can occur with even small amounts of this chemical being emitted into the air. People from other states will learn of this issues in our area and not want to move here. This affects home values and growth.

I ask that the most stringent regulations be developed and enforced to protect the human and animal population of this county and state from this chemical and any others including byproducts known to be harmful to any degree.

Thank you for the opportunity to comment,

Kathy Boettinger

Mort, Sandra L

From: Martin, Sharon L.
Sent: Monday, March 11, 2019 2:28 PM
To: Comments.SABReport
Subject: FW: [External] Re: Methyl Bromide Report open for public comment

Forwarding a comment received in my inbox

Sharon Martin
Public Information Officer, Division of Air Quality
North Carolina Department of Environmental Quality
919.707.8446 (Office)
919.675.4912 (Mobile)
Sharon.Martin@ncdenr.gov

From: SteveB [mailto:parrothead_21228@yahoo.com]
Sent: Sunday, March 10, 2019 5:13 PM
To: Martin, Sharon L. <sharon.martin@ncdenr.gov>
Subject: [External] Re: Methyl Bromide Report open for public comment

The chemical Methyl Bromide is toxic.

To whom this may concern,
With all of the current issues that we have with water and air quality posing potential health issues. I have a concern with the use of this chemical and even small amounts being emitted in the air. I know that depending on certain air conditions IE fog, clouds can

produce stronger amounts in the air due to the chemicals being pushed lower to the ground. That company from what I understand was investigated due to them violating their permit. With the population in the five counties, there is the potential of more illnesses possibly deaths from exposure to all these toxic chemicals.

People from other states will learn of all of these issues in our area and not want to move here. This affects home values and growth.

Please do what is right for all health and well being.

Thank you,

Steve Boettinger

On Friday, March 1, 2019, 8:29:44 AM EST, Martin, Sharon L. <sharon.martin@ncdenr.gov> wrote:

As interested parties on the issue of methyl bromide use in log fumigation, wanted to pass this along:

The N.C. DEQ Division of Air Quality has posted the following report for a 30-day public comment period, Risk Analysis and Acceptable Ambient Level Recommendation for Methyl Bromide.

The 30-day comment period will end on **March 27, 2019.**

Please submit comments on this report to: Comments.sabreport@ncdenr.gov, or by mail to Ms. Louise Hughes, Dept. of Environmental Quality, 1601 Mail Service Center, Raleigh, NC 27699-1601. Please direct any questions to Ms. Louise Hughes at (919) 707-8655.

The Secretaries' Science Advisory Board (SAB) will be considering any comments received at their upcoming April 1, 2019 meeting. For more information on the SAB's work, please see: https://deq.nc.gov/news/hot-topics/genx-investigation/secretaries-science-advisory-board

Thank you,

Sharon

Sharon Martin
Public Information Officer, Division of Air Quality
North Carolina Department of Environmental Quality
919.707.8446 (Office)
919.675.4912 (Mobile)
Sharon.Martin@ncdenr.gov

Mort, Sandra L

From: Ann Debono <adebono5@icloud.com>
Sent: Wednesday, March 6, 2019 5:04 PM
To: Comments.SABReport
Subject: [External] Methyl Bromide

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I have never understood how anyone could justify polluting the air, water and food that humans depend upon to live a healthy life. I'm thrilled that Malec Brothers was denied a permit to fumigate and thankful that the DEQ protected our environment. Please continue to do so!

With gratitude,

Ann Debono

Sent from my iPad

Mort, Sandra L

From: Elizabeth Elder <lizelder61@gmail.com>
Sent: Tuesday, March 5, 2019 3:23 PM
To: Comments.SABReport
Subject: [External]

To Whom It May Concern:

Please do not issue permits for the unnecessary use of methyl bromide. The log industry has two options to treat their logs: debarking or treatment with methyl bromide. Why not use debarking? Poisoning the local population, the wildlife, and the environment should not be permitted when there is a simple solution that does not require hazardous chemicals. We need you to protect the environment from companies trying to use toxic chemicals to increase their bottom line. Our area has already been exposed to a disproportionate amount of industrial waste from Chemours, factory farming, coal ash, etc. There are well documented health effects associated with methyl bromide inhalation exposure, it is imperative that the protection of public health always
overrides any industrial pollution going forward.

Thank you,

Elizabeth Elder

Mort, Sandra L

From: Mark Lemley <lemleys1@gmail.com>
Sent: Tuesday, March 5, 2019 3:06 PM
To: Comments.SABReport
Subject: [External] METHYL BROMIDE

The following are my comments regarding the proposed methyl bromide standard:

Methyl Bromide can harm health including neurological, reproductive, respiratory, kidney, liver and esophageal damage as well as nasal lesions. Because of those effects and its damage to the ozone layer, methyl bromide has been largely banned internationally in over 150 countries. The present exempted annual (QPS) use of methyl bromide is around 11,000 metric tons which is the largest unregulated emissive use of any halogenated gas affecting the ozone layer. There are a few "critical exemptions" to kill pests, including the fumigation of some fruits and logs for export. In log fumigation, the wood is placed inside shipping containers, which are then pumped with methyl bromide gas. After 16-72 hours, the containers are opened and the gas escapes into the air. An estimated 88% of the methyl bromide applied during standard commercial practice is emitted to the atmosphere from log fumigations or approximately 9680 metric tons that destroy the ozone layer. However, it has limited penetration in logs, particularly across the grain and into wet timber. Green logs are problematic to treat due to the high moisture content (80%) and presence of bark (very absorbent). Facilities in North Carolina do not use pollution controls on the containers although that technology is available. More than 4000 people live within a mile and a half of North Carolina's four log fumigation facilities and some are just 220 – 630 feet away.

DAQ staff used computer modeling to estimate ambient air levels at the fenceline of four existing log fumigation facilities. Based on the amount of methyl bromide used and the type of logs fumigated (hardwoods require more gas than softwoods, like pine) none of the current facilities would comply with the proposed 0.005 ppm level, even if they aerated just one container per day. There is no way to require adequate monitoring of methyl bromide concentrations outside the downwind boundary line of the facilities.

There are alternatives to methyl bromide and Malec Brothers is importing scrubbers and thermal destruction equipment from a company called Mebrom in Australia. Value Recovery and Nordiko, also an Australian company, use carbon based technology. Recapture systems also offer the ability to reuse 30% of the methyl bromide.

Heat treatment has been accepted as a quarantine treatment for logs and timber to be shipped to the USA and many other countries for many years. Kiln drying of timber to a moisture content of less than 20% using temperatures over 70 degrees C is often a commercial requirement but has also been accepted as a quarantine requirement by most importing countries. Hot water and steam treatment has long been used for risk mitigation for hardwood veneer logs imported into New Zealand. Moist heat treatment is an integral part of log conditioning prior to peeling but has the additional benefit of eliminating quarantine risk.

Water soaking or immersion provides a process for control of pests on imported logs.

Debarking has long been a key strategy in reducing contamination of logs and reducing the risk that logs and sawn timber carry insects and fungi of quarantine concern, particularly for high value logs.

F.A.S.T (Fumigation Abatement & Scrubbing Treatment) System scrubber can capture and destroy fumigant gases such as methyl bromide. The F.A.S.T. system contains a depository holding scrubbing material that causes a substantially complete chemical breakdown of te fumigant introduced. The solution is non-carbon based and is mostly aqueous containing chemical degradation properties. Any alkyl halide such as methyl bromide agitated through the depository can be broken down through scrubbing by a SN2 chemical reaction. By-products of the reaction are retained in the scrubber depository leaving only ambient air to be released into the atmosphere. This system has the ability to destroy the harmful fumigants on site using a durable and easily operated design that allows an accelerated and convenient process for removing harmful and potential safety hazards from fumigants. The F.A.S.T. system can be used with pallets, ISPM-15 shipping containers, export quarantine logs, fumigation chambers, trailers, flour mills and grain bins.

In summary, methyl bromide is a hazardous chemical to humans and the ozone layer. There are alternative technologies for remediating methyl bromide which should be evaluated and implemented rather than just applying an emission standard that cannot be measured or enforced. Methyl bromide should not just be allowed to be exhausted into the atmosphere with its huge detrimental effects to people and the environment.

Sincerely,

Mark Lemley

2494 Meridian Rd NE

Leland, NC 28451

617-894-3165

Mort, Sandra L

From: Mary Lee McKell <mckellmarylee@gmail.com>
Sent: Tuesday, March 5, 2019 1:06 PM
To: Comments.SABReport
Subject: [External] Methyl bromide use in NC

NC has a big stake in the lumber industry. We don't want to lose that.

What is concerning is the use of the highly toxic methyl bromide to fumigate logs, pallets and other "commodities."

Controlling pests is a necessity to avoid invasive species from populating other states and other countries.

There are alternatives for using methyl bromide for fumigation.

It's unacceptable to allow the log workers and surrounding communities to continue to be at risk.

If there is NOT a total ban on companies using methyl bromide, there must be a safe way to capture the fumes and have tighter oversight when it's being used.

NC is experiencing a migration of populations from northern states across the country.

Please ban the use of this toxic poison!!

Mary Lee McKell

https://www3.epa.gov/pesticides/chem_search/ppls/008536-00029-20150930.pdf

Mort, Sandra L

From: cheyn@verizon.net
Sent: Tuesday, March 5, 2019 10:25 AM
To: Comments.SABReport
Subject: [External] Use of Methyl Bromide

To Whom It May Concern:

Please do not issue permits for the unnecessary use of methyl bromide. The log industry has two options to treat their logs: debarking or treatment with methyl bromide. Why not use debarking? Poisoning the local population, the wildlife, and the environment should not be permitted when there is a simple solution that does not require hazardous chemicals. We need you to protect the environment from companies trying to use toxic chemicals to increase their bottom line. Our area has already been exposed to a disproportionate amount of industrial waste from Chemours, factory farming, coal ash, etc. There are well documented health effects associated with methyl bromide inhalation exposure, it is imperative that the protection of public health always overrides any industrial pollution going forward.

Thank you,
Christen Heyn

Mort, Sandra L

From: Jessica DeGolyer <j.s.degolyer@gmail.com>
Sent: Tuesday, March 5, 2019 9:15 AM
To: Comments.SABReport
Subject: [External] Choose people over profit

Do not issue permits for the unnecessary use of methyl bromide. The log industry has two options to treat their logs: debarking or treatment with methyl bromide. Why not use debarking? Poisoning the local population, the wildlife, and the environment should not be permitted when there is a simple solution that does not require hazardous chemicals. We need you to protect the environment from companies trying to use toxic chemicals to increase their bottom line. Our area has already been exposed to a disproportionate amount of industrial waste from Chemours, factory farming, coal ash, etc. Protection of public health should always override any industrial pollution from this point forward.

Thank you,
Jessica DeGolyer

Mort, Sandra L

From: Marsha Freedman <renee55150@aol.com>
Sent: Tuesday, March 5, 2019 7:35 AM
To: Comments.SABReport
Cc: paulfree17@earthlink.net; renee55150@aol.com
Subject: [External] Compass Pointe Resident

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I am a resident of Brunswick County, NC, who is concerned with any process that adds toxins to our air, water, soil, food supply or other component of our environment. We love this county and continue to realize there are numerous health and safety concerns impacting our lives

I have had reactions to the noxious odor in the community which include nausea, dizziness, headaches and constant coughing. I've had family visiting that noticed and questioned what was the bad smell in the air.

We moved here as our plan to retire and have family visit us often and possibly move here when they're ready to retire. That won't happen because now not only is our water supply not safe neither is our air. No one wants live in this kind of environment.

We added a reverse osmosis unit to our sink water for drinking and washing our fruits and vegetables but there's nothing we can do to make our air safe.

This is NOT part of my idea of living safely in North Carolina.

I read through this report with growing alarm about neurological problems resulting from exposure for workers. I read about the absence of an enzyme in some portion of the population that exacerbates the negative effects of exposure. Testing on rats and other animals also resulted in very negative consequences.

I ask that the most stringent regulations be developed and enforced to protect the human and animal population of this county and state from this and any other industrial chemical or process byproduct known to be harmful to any degree. That the residents are made aware of the timetables for businesses to comply. That there is transparency in tests run for air quality for residents to read.

Thank you for the opportunity to comment.

Marsha Freedman
Paul Freedman
2236 Compass Pointe North Wynd
Leland, NC 28451
973-970-4180

Mort, Sandra L

From: Larry Ingram <lingram3@nc.rr.com>
Sent: Monday, March 4, 2019 3:59 PM
To: Comments.SABReport
Subject: [External] Methyl Bromide report

What Industries in the Leland, NC area are emitting these gases into the atmosphere? Why are Industries allowed to pump these chemicals into the air unregulated? Have any complaints been filed against these Industries? I moved to Leland in December, 2014. Since then I have experience Prostate problems and Breathing problems requiring me to use oxygen. Could this chemical cause these medical concerns? Since moving here in 2014 I have had respiratory problems requiring medical treatment every year including now.

Larry Creed Ingram

101 Potomac Ct.

Winnabow, NC

910-769-0065

Mort, Sandra L

From: MIchael Weber <webobx4@gmail.com>
Sent: Monday, March 4, 2019 3:53 PM
To: Comments.SABReport
Subject: [External] Toxins

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I am a Brunswick County resident and am highly concerned with any process that adds toxins to air, water, soil, food or any component of the environment. I find your report absolutely alarming!
I ask that the most stringent regulations be developed AND enforced to protect all life from this and other industrial chemical or process byproduct known to be harmful to any degree.
Thank You
Michael Weber
Sent from my iPad

Mort, Sandra L

From: Elizabeth Weber <delmar1259@gmail.com>
Sent: Monday, March 4, 2019 3:19 PM
To: Comments.SABReport
Subject: [External] Comment period - Chemical Guidelines

I am a Brunswick County resident and am highly concerned with any process that adds toxins to air, water, soil, food or any component of the environment. I find your report absolutely alarming!
I ask that the most stringent regulations be developed AND enforced to protect all life from this and other industrial chemical or process byproduct known to be harmful to any degree.
Thank You
Elizabeth Weber

Mort, Sandra L

From: Donna Lichti <donna.lichti@gmail.com>
Sent: Monday, March 4, 2019 8:57 AM
To: Comments.SABReport
Subject: [External] Compass pointe resident

CAUTION: External email. Do not click links or open attachments unless you verify. Send all suspicious email as an attachment to report.spam@nc.gov<mailto:report.spam@nc.gov>

I am a resident of Brunswick County, NC, who is concerned with any process that adds toxins to our air, water, soil, food supply or other component of our environment. We love this county and continue to realize there are numerous health and safety concerns impacting our lives

I have had reactions to the noxious odor in the community which include nausea, dizziness and headache. My grandchildren were visiting just last week and commented on the “stinky air”. This is NOT part of my idea of living safely in North Carolina.

I read through this report with growing alarm about neurological problems resulting from exposure for workers. I read about the absence of an enzyme in some portion of the population that exacerbates the negative effects of exposure. Testing on rats and other animals also resulted in very negative consequences.

I ask that the most stringent regulations be developed and enforced to protect the human and animal population of this county and state from this and any other industrial chemical or process byproduct known to be harmful to any degree. That the residents are made aware of the timetables for businesses to comply. That there is transparency in tests run for air quality for residents to read.

Thank you for the opportunity to comment.

Donna Lichti
Charles Lichti
2345 Kingbird Bend NE
Leland, NC

Sent from my iPhone

Mort, Sandra L

From: Kathy Kuehn <BullyTed@aol.com>
Sent: Monday, March 4, 2019 6:09 AM
To: Comments.SABReport
Subject: [External] Methyl Bromide Report

CAUTION: External email. Do not click links or open attachments unless you verify. Send all suspicious email as an attachment to report.spam@nc.gov<mailto:report.spam@nc.gov>

We MUST keep the harmful chemical out of our air. Between the GenX in our water and possibly permitting Methyl Bromide in the air, is North Carolina purposely trying to kill its residents for the sake of dollars in kickbacks from these polluting companies. Do the right thing.
Kathryn Kuehn
Compass Pointe

Sent from my iPad

Mort, Sandra L

From: Sharon Rogers <sarogersnc1@gmail.com>
Sent: Saturday, March 2, 2019 5:00 PM
To: Comments.SABReport
Subject: [External] Methyl Bromide

To whom this may concern,
With all of the current issues that we have with water and air quality posing potential health issues. I have a concern with the use of this chemical and even small amounts being emitted in the air. I know that depending on certain air conditions IE fog, clouds can produce stronger amounts in the air due to the chemicals being pushed lower to the ground. I myself had worked with the Department of Air Quality for several years for concerns with a company emitting very strong odors off of highway 74/76. That company from what I understand was investigated due to them violating their permit. With the population in the five counties, there is the potential of more illnesses possibly deaths from exposure to all these toxic chemicals. People from other states will learn of all of these issues in our area and not want to move here. This affects home values and growth.
Please do what is right for all health and well being.
Thank you
Sharon Rogers

Mort, Sandra L

From: Sharon Rogers <sarogersnc1@gmail.com>
Sent: Saturday, March 2, 2019 4:58 PM
To: Comments.SABReport
Subject: [External] Methyl Bromide

I am not a scientist, just a resident of Brunswick County, NC, who is concerned with any process that adds toxins to our air, water, soil, food supply or other component of our environment. I read through this report with growing alarm about neurological problems resulting from exposure for workers accidentally exposed. I read about the absence of an enzyme in some portion of the population that exacerbates the negative effects of exposure. Testing on rats and other animals also resulted in very negative consequences.

I ask that the most stringent regulations be developed and enforced to protect the human and animal population of this county and state from this and any other industrial chemical or process byproduct known to be harmful to any degree.

Thank you for the opportunity to comment.

Sharon Rogers

Mort, Sandra L

From: pamela darrah <pam_darrah@outlook.com>
Sent: Saturday, March 2, 2019 10:37 AM
To: Comments.SABReport
Subject: [External]

I am a resident of Brunswick County, NC, and am alarmed by the findings in the Risk Analysis report on Methyl Bromide. I have concerns with any process that adds pollutants to our air, water, soil, food supply, etc, but the health risks caused by these chemicals identified in the limited studies available are disturbing.

I ask that the most stringent regulations be developed and enforced to protect the human and animal population of this county and state from this and any other industrial chemical or process byproduct known to be harmful to any degree.

Pam Darrah
Sent from Mail for Windows 10

Mort, Sandra L

From: Mary Denz <denzmary@gmail.com>
Sent: Saturday, March 2, 2019 10:14 AM
To: Comments.SABReport
Subject: [External] North Carolina log fumigation plants need new procedures and regulations for the use of methyl bromide

I feel it is time to put the shipping containers used for the fumigation of logs with methyl bromide inside a controlled environment— a metal/concrete building with the proper decomposition process for the methyl bromide chemical prior to its release to the open air that human's breathe.

One can not regulate the wind, which can carry this chemical quickly across the state of North Carolina. In addition, a controlled fumigation environment with a chemical decomposition procedure for the methyl bromide that releases no hazards to humans in the open air, or a way to capture this chemical for another commercial use or for reuse of the chemical in the fumigation plant itself, provides a safe working environment to protect the employees from the adverse effects of being exposed to this chemical. Let's keep the North Carolina people safe from this dangerous chemical. It is time to address the current process used for log fumigation in North Carolina and put a process with regulations in place that is safe for everyone.

Regards,
Mary Denz
Leland, NC

Mort, Sandra L

From: Steve Rogness <rogslash@gmail.com>
Sent: Saturday, March 2, 2019 7:05 AM
To: Comments.SABReport
Subject: [External] Risk Analysis and Acceptable Ambient Level Recommendation for Methyl Bromide.

Good Morning,
I am a new resident of Leland, North Carolina and have been following the attempts by Malec Brothers to operate a plant using this chemical only a few miles upwind from my residence. I have attempted to read and understand this report and frankly do not have the technical ability to evaluate or understand the recommended levels. My position would be to avoid all potential impact by banning the use of the chemical completely. Using Malec Brothers as a frame of reference, they responded to community concerns by abandoning the effort and apparently still have a model to conduct there business. There needs to be a point where we collectively decide to stop the assault on our environment simply for economic benefit for a few, that can not demonstrably be proven to outweigh long term impactgs to life.
Thank you.
Steven Rogness
Leland, NC

Mort, Sandra L

From: Terri Gans <terri.gans@gmail.com>
Sent: Saturday, March 2, 2019 6:21 AM
To: Comments.SABReport
Subject: [External] methyl bromide

I am not a scientist, just a resident of Brunswick County, NC, who is concerned with any process that adds toxins to our air, water, soil, food supply or other component of our environment. I read through this report with growing alarm about neurological problems resulting from exposure for workers accidentally exposed. I read about the absence of an enzyme in some portion of the population that exacerbates the negative effects of exposure. Testing on rats and other animals also resulted in very negative consequences.

I ask that the most stringent regulations be developed and enforced to protect the human and animal population of this county and state from this and any other industrial chemical or process byproduct known to be harmful to any degree.

Terri Gans

Mort, Sandra L

From: Mary Lee McKell <mckellmarylee@gmail.com>
Sent: Friday, March 1, 2019 11:02 PM
To: Comments.SABReport
Subject: [External] Methyl bromide

Recapture, debark. No more release of methyl bromide in our air!

Mort, Sandra L

From: MarieT D'Angelo <skipnros@gmail.com>
Sent: Friday, March 1, 2019 3:08 PM
To: Comments.SABReport
Subject: [External] Methyl Bromide

My comment is "get this stuff out of our air"! This report is too long and complex for the average citizen that is not a scientist. If this methyl bromide causes diseases or death it should not be allowed in our air. Not to mention it stinks!

--

Marie ***D'Angelo***

Mort, Sandra L

From: Jeff Bresler <jbresler1999@yahoo.com>
Sent: Friday, March 1, 2019 1:52 PM
To: Comments.SABReport
Subject: [External] Methyl Bromide

There are no levels of methyl bromide that are acceptable in my air. Let's think about the environment for once and the future. And let's not think about who's contributing to what campaign or what company is willing to offer of money for a favorable vote. Responsible government officials and politicians will realize at some point the error of their ways by voting for contaminants in our water and air.
Jeff Bresler
Leland, NC
Sent from my iPhone

Mort, Sandra L

From: Paula Dudley <pdud1026@yahoo.com>
Sent: Friday, March 1, 2019 1:08 PM
To: Comments.SABReport
Subject: [External] Methyl Bromide comments

CAUTION: External email. Do not click links or open attachments unless you verify. Send all suspicious email as an attachment to report.spam@nc.gov<mailto:report.spam@nc.gov>

Ms. Louise Hughes, hello,
My name is Paula Dudley and I live at 104 Green Rd in Riegelwood NC 28456. Recently our community was in the middle of controversy with Malec Brothers over their proposed use of 140 tons of Methyl Bromide.
Thanks to the DEQ and concerned citizens, Malec Brothers did not use Methyl Bromide and has since, revoked their permit for use. They are using a debarking system and that has worked out fine with the community.
Please I implore you to impose the most strict allowances you are able to regarding the amount of Methyl Bromide a company can use. My number one request would be that NC totally bans the use of Methyl Bromide. Debarking works just as well and it is so much less hazardous to communities.
If you can't ban it totally, then my next request would be to please make it less than 10 tons per year with a recapture system.
My fear is, that Malec Brothers is waiting to see what you decide and then they will reapply for a permit. I don't want to go through a second controversy on this issue with Malec Brothers. It put a big strain on our community. It was a very stressful time. We worry about our kids and our elderly. Please remove the use of Methyl Bromide of any amount from North Carolina.
Thank you,
Paula Dudley
910-655-9822
Sent from my iPhone

Mort, Sandra L

From: MARY CARROLL <marycarroll9@icloud.com>
Sent: Friday, March 1, 2019 11:46 AM
To: Comments.SABReport
Subject: [External] Methyl Bromide Report Comments

I am not a scientist, just a resident of Brunswick County, NC, who is concerned with any process that adds toxins to our air, water, soil, food supply or other component of our environment. I read through this report with growing alarm about neurological problems resulting from exposure for workers accidentally exposed. I read about the absence of an enzyme in some portion of the population that exacerbates the negative effects of exposure. Testing on rats and other animals also resulted in very negative consequences.

I ask that the most stringent regulations be developed and enforced to protect the human and animal population of this county and state from this and any other industrial chemical or process byproduct known to be harmful to any degree.

Thank you for the opportunity to comment.

Mary Carroll
2549 Sugargrove Trail NE
Leland, NC 28451

Sent from my iPad

Mort, Sandra L

From: deni <denisindel@gmail.com>
Sent: Friday, March 1, 2019 10:06 AM
To: Comments.SABReport
Subject: [External] Report on Methyl Bromide

CAUTION: External email. Do not click links or open attachments unless you verify. Send all suspicious email as an attachment to report.spam@nc.gov<mailto:report.spam@nc.gov>

I read the report, digested a lot of it and got glassy eyed with some of it but here is my synopsis:
* This is a poison for humans and animals,
* It stays in the air for at least a year,
* 2 different studies were performed showing poor outcomes for rats and ultimately humans who are exposed to it,
* Debarking the logs is the alternative to chemicals that can, and will, kill us all,
* That there are currently no State air quality regulations ("since methyl bromide is not listed as a North Carolina Toxic Air Pollutant (TAP), there are no state air quality regulations.") as stated in page 1

When will we stop killing ourselves and our planet? We need better protection from greed in corporate America, ignorant lawmakers and short sighted politicians. It is beyond my comprehension why we do not have state air quality regulations in place. It is time to stop the continuing destruction of our state and our health.

If debarking the logs will also work for controlling insects rather than fumigation then why not do that. I'm guessing the cost is a factor. They would rather poison us and our beautiful state than spend money to use a method that perhaps costs money.

Fumigation and it's affect on us should be outweighed by the common good and common sense. Alternatives should be used that do not contain chemicals and/or chemical processes that are toxic.

Let's start by putting air quality controls in place and steep fines for abusers of them. We are already being poisoned with GenX and other chemicals in our water supply which is ongoing and loosely fined, but we can and do drink bottled water. Is bottled air next?

Wake up people! Corporate greed will, and is already, harming us all

Deni Sindel
Leland, NC

Mort, Sandra L

From: Kari Feuer <karifeuer@yahoo.com>
Sent: Friday, March 1, 2019 9:53 AM
To: Comments.SABReport
Subject: [External] Stop fumigation!

The amount, frequency and nearness to densely-settled neighborhoods, combined with the lax provisions of use means we should oppose further acceptance of this practice.
Kari Feuer
2321 Kingbird Bend
Leland NC

Mort, Sandra L

From: V. Carey <gardenia3@ec.rr.com>
Sent: Friday, March 1, 2019 9:52 AM
To: Comments.SABReport
Subject: [External] Methyl Bromide

To whom this may concern,

With all of the current issues that we have with water and air quality posing potential health issues. I have a concern with the use of this chemical and even small amounts being emitted in the air. I know that depending on certain air conditions IE fog, clouds can produce stronger amounts in the air due to the chemicals being pushed lower to the ground. I myself had worked with the Department of Air Quality for several years for concerns with a company emitting very strong odors off of highway 74/76. That company from what I understand was investigated due to them violating their permit. With the population in the five counties, there is the potential of more illnesses possibly deaths from exposure to all these toxic chemicals. People from other states will learn of all of these issues in our area and not want to move here. This affects home values and growth.
Please do what is right for all health and well being.
Thank you
The Carey's

Sent from my T-Mobile REVVL 2 PLUS

Brunswick County Health and Human Services

David Stanley, Director
PO Box 9
Bolivia, NC 28422
David.Stanley@brunswickcountync.gov
910-253-2250
Fax: 910-253-2387 Toll Free: 888-428-4429

RECEIVED 3/27/19

March 14, 2019

Ms. Louise Hughes
Dept. of Environmental Quality
1601 Mail Service Center
Raleigh, NC 27699-1601

Subject: Comments to Department of Environmental Quality Division of Air Quality's Methyl Bromide Acceptable Ambient Level (AAL) Recommendation for Log Fumigation Operations

Brunswick County would like to thank the Department of Health and Human Services (DHHS), Department of Environmental Quality (DEQ), as well as the Secretaries' Science Advisory Board (SSAB) for their efforts to protect our community's public health and the opportunity to comment. We support their efforts to add methyl bromide to the list of state air toxics and establishing an acceptable ambient level (AAL) to guide regulation to protect the public health. We encourage DEQ to continue to work on a permanent rule with the guidance of the SSAB and through the Environmental Management Commission.

Specific to the AAL, we have reviewed and generally support the materials submitted by the DEQ concerning their report to the SSAB to assist in protecting all persons that may live, work, and go to school in areas subject to repeated airborne releases of methyl bromide from log fumigation operations. The information reviewed concerning the current methyl bromide toxicological and risk science, the current IRIS chronic inhalation reference concentration, and the chronic exposure characteristics associated with log fumigation operations, seems to support the recommended range of Acceptable Ambient Level (AAL) values to be considered by the EMC for methyl bromide. However, I would advocate for the most protective value of the suggested range, 0.002 mg/m3 and a 24-hour averaging time for the best protection of public health.

The AAL model presented lacks specific explanation for how an actionable acute exposure threshold would be addressed by regulators should it occur. We would encourage DEQ to specifically address in their rulemaking proposal acute actionable threshold levels in proposed rulemaking to the EMC. Furthermore, we encourage DEQ to work on rules which also address the specific operation, monitoring, and waste capture standards of methyl bromide facilities and to that end, advocate for rulemaking which have the most protective impact to public health. Thank you for the opportunity to comment.

Sincerely,

David M. Stanley III

David Stanley, Executive Director
Health and Human Services
Brunswick County Health Department

North Carolina Public Health
Working for a healthier and safer North Carolina
Everywhere. Everyday. Everybody.

Mort, Sandra L

From: Jamie Cole <jamie@ncconservationnetwork.org>
Sent: Thursday, March 28, 2019 8:30 AM
To: Comments.SABReport
Subject: [External] SAB AAL Report Comment Letter
Attachments: Methyl Bromide Report Comment Letter _ March 27 2019.pdf

Good evening,

Attached is a letter from the NC Conservation Network in support of the proposed Acceptable Ambient Level for Methyl Bromide.

Thank you,

Jamie Cole, J.D.
EJ, Air, & Materials Policy Manager
NC Conservation Network
234 Fayetteville Street, 5th Floor
Raleigh, NC 27601
919.857.4699 x 113
http://www.ncconservationnetwork.org/


North Carolina Conservation Network

234 Fayetteville Street

5th Floor Raleigh, NC 27601

ncconservationnetwork.org

919.857.4699

March 27, 2019

Ms. Louise Hughes
Department of Environmental Quality
1601 Mail Service Center
Raleigh, NC 27699-1601
Comments.sabreport@ncdenr.gov

Re: Risk Analysis and Acceptable Ambient Level Recommendation for Methyl Bromide Report

Dear Ms. Hughes:

The NC Conservation Network (NCCN) appreciates the opportunity to submit this comment on the Risk Analysis and Acceptable Ambient Level (AAL) Recommendation for Methyl Bromide Report. NCCN works to protect North Carolina's environment and promote solutions for a safe state. We collaborate with nearly 100 environmental groups and mobilize tens of thousands of people to support strong policies at all levels of government. NCCN submits this comment to furtherer express our support for the efforts DAQ has undertaken to protect

public health through the rulemaking process.[1] Specifically, we call on the Science Advisory Board (SAB) to recommend the proposed AAL of .005 mg/m^3 at a 24-hour averaging time for the use of methyl bromide in log fumigation in North Carolina.

Meaningful involvement and response

We are especially impressed with the urgent manner by which DAQ and the SAB have acted in the development of this AAL and in response to community voices. The voices of the thousands of residents who spoke out at public meetings and submitted comments opposing the permit application of Tima Capital in Wilmington, NC and the application to emit 140 tons per year of Methyl Bromide in Delco, NC by Malec Brothers. Both applications, since withdrawn, triggered unprecedented public response from the immediate community and residents of the surrounding counties that pushed DAQ to take these affirmative steps forward. These actions are a testament of the power of an informed community and the result of what can happen when a regulatory agency prioritizes the meaningful engagement of impacted communities.

Commitment to needed actions

We applaud the proposed AAL as well as the other proactive efforts of the Division of Air Quality. These actions include:

1) Placing a hold on any pending air permit applications for methyl bromide fumigation in North Carolina,

2) Formally requesting that the Environmental Protection Agency list methyl bromide fumigation as a source category under 112(c) of the Clean Air Act,

3) Designating methyl bromide as a state toxic air pollutant, and

4) Drafting rules to regulate the use of methyl bromide.

These plans toward providing regulations and oversight for an expanding industry in North Carolina is imperative. Setting an AAL for methyl bromide is not only necessary to protect public health – it will also provide regulatory certainty for an industry that currently has several existing permits from DAQ and three pending.

[1] NCCN is also a signatory on a comment letter submitted by the Southern Environmental Law Center - expressing support for the proposed AAL Recommendation for Methyl Bromide by the Division of Air Quality (DAQ).

Conclusion

We encourage the Science Advisory Board and DAQ to continue to move forward with this necessary and timely action to develop an AAL of .005 mg/m^3 at a 24-hour averaging time for methyl bromide. We appreciate the opportunity to comment on this very important and urgent issue. Please feel free to contact us if we can be of further assistance in this process.

Sincerely,

Jamie Cole

Jamie Cole

Policy Manager

NC Conservation Network

jamie@ncconservationnetwork.org

Mort, Sandra L

From: Heather Hillaker <hhillaker@selcnc.org>
Sent: Wednesday, March 27, 2019 3:25 PM
To: Comments.SABReport
Cc: Hughes, Louise G
Subject: [External] Comments - DAQ's Proposed Methyl Bromide AAL
Attachments: 2019-03-27 Comments on DAQ_s MeBr AAL Recommendation.PDF

Ms. Hughes,

The Southern Environmental Law Center, on behalf of itself and Clean Air Carolina, Medical Advocates for Healthy Air, and the North Carolina Conservation Network ("Conservation Groups"), respectfully submit the attached comments on the report issued by DAQ entitled, *Risk Analysis and Acceptable Ambient Level Recommendations for Methyl Bromide*. Attachments will be sent in a separate email.

Please let me know if you have any issues with the comments or attachments.

Best,

Heather Hillaker
Associate Attorney | Southern Environmental Law Center
601 West Rosemary Street, Suite 220 | Chapel Hill, NC 27516-2356
T: 919-967-1450 Ext. 132
F: 919-929-9421
E: hhillaker@selcnc.org
http://www.southernenvironment.org

The complete SELC submission includes more than 1400 additional pages in 4 attachments. Due to the size of these documents, they are included in a separate file.
NC DAQ

SOUTHERN ENVIRONMENTAL LAW CENTER

Telephone 919-967-1450 601 WEST ROSEMARY STREET, SUITE 220 CHAPEL HILL, NC 27516-2356 Facsimile 919-929-9421

March 27, 2019

Via Electronic Mail (Comments.sabreport@ncdenr.gov)

Louise Hughes
N.C. Department of Environmental Quality
1601 Mail Service Center
Raleigh, NC 27699-1601

Re: Comments on DAQ Report: *Risk Analysis and Acceptable Ambient Level Recommendation for Methyl Bromide*

Dear Ms. Hughes:

The Southern Environmental Law Center, on behalf of itself and Clean Air Carolina, Medical Advocates for Healthy Air, and the North Carolina Conservation Network, (hereinafter, "Conservation Groups") respectfully submit the following comments on the report issued by the North Carolina Department of Environmental Quality, Division of Air Quality ("DAQ") entitled, *Risk Analysis and Acceptable Ambient Level Recommendation for Methyl Bromide*. Conservation Groups applaud DAQ's recognition that its previous approach to methyl bromide log fumigation in the state is insufficient, and support DAQ's recent efforts to move forward quickly, but thoroughly with its efforts to regulate this highly toxic chemical. In particular, Conservation Groups support the proposed Acceptable Ambient Level ("AAL") recommended by DAQ and urges the Science Advisory Board to adopt and recommend the AAL for the use of methyl bromide in log fumigation.

DAQ's proposed AAL of .005 mg/m^3 (1 ppbv) at a 24-hour averaging time is supported by the most recent and scientifically defensible research into the human health impacts of methyl bromide exposure. DAQ's efforts to ensure that a methyl bromide AAL is protective of the public health is not only commendable, but such a bench mark is provided for in North Carolina's toxic air pollutant regulations. Moreover, the Department's stated mission to "[p]rovide science-based environmental stewardship for the *health and prosperity of ALL North Carolinians*"[1] also supports setting the AAL at levels to protect the public health, which includes particular sensitive subpopulations.

[1] N.C. DEQ, *Our Mission*, https://deq.nc.gov/about/history-of-deq (last visited Mar. 26, 2019) (emphasis added).

I. Health & Environmental Effects of Methyl Bromide

Methyl bromide is a "highly toxic" chemical[2] and organic compound that readily diffuses in the air. It is dangerous to people even in small doses and for short durations, causing central nervous system and respiratory system failures. Methyl bromide is also a controlled stratospheric ozone-depleting substance under the Montreal Protocol. Because of the dangers it poses to people and the environment, methyl bromide is regulated under the Clean Air Act ("CAA") as a hazardous air pollutant. Although DAQ's proposal is limited to methyl bromide's impact on human health, it is also important that DAQ and the Science Advisory Board understand the environmental consequences of using this chemical.

a. Methyl bromide exposure causes serious health problems, including respiratory and neurological issues.

Methyl bromide, also called Bromomethane, is a known "developmental, neurological, and respiratory toxin," with both "acute and chronic toxicity."[3] Exposure to methyl bromide occurs primarily through inhalation or dermal absorption (i.e., contact with skin).[4] Acute inhalation of methyl bromide can cause severe injury to the lungs, impairment of respiratory functions, and neurological symptoms, including headaches, dizziness, fainting, weakness, confusion, speech impairment, visual effects, numbness, twitching, seizures, and tremors.[5] Methyl bromide exposure can also irritate the eyes and skin, causing itching, redness, and blisters.[6] In cases of severe exposure, methyl bromide can cause paralysis, convulsions, kidney damage, and death from respiratory or cardiovascular failure.[7] More recent data has also demonstrated a link between methyl bromide exposure, both on- and off-site of the fumigation activity, and developmental and reproductive issues and risk of prostate cancer.[8]

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[2] EPA, *Methyl Bromide (Bromomethane*) 1 (Apr. 1992, updated Jan. 2000) (Attachment 1).

[3] Lygia T. Budnik, et al., *Prostate Cancer and Toxicity from Critical Use Exemptions of Methyl Bromide: Environmental Protection Helps Protect Against Human Health Risks*, 3 Envtl. Health (2012) (Attachment 2).

[4] *Id*. at 2. There is also a potential for "off gassing" exposure because methyl bromide persists on clothing and other items. This type of "transient exposure" can cause "nervous system symptoms, including headache, nausea, vomiting, dizziness, blurred vision, impairment of coordination and twitching." *Id.*

[5] *See* EPA, *Methyl Bromide (Bromomethane*), *supra* note 2, at 1-2; Robert B. Gunier, et al., *Residential Proximitiy to Agricultural Fumigant Used and IQ, Attention and Hyperactivity in 7-Year Old Children*, 158 Envtl. Res. 358, 358 (2017) (Attachment 3); Nat'l Res. Council, *Methyl Bromide Risk Characterization in California* 2, 8, 12-32 (2000) ("Methyl bromide also appears to be a developmental and possibly a reproductive toxicant.") (Attachment 4); Budnik, *supra* note 3, at 4 (Table 1: Toxic effects of methyl bromide (data 1990-2011)).

[6] EPA, *Methyl Bromide (Bromomethane*), *supra* note 2, at 2; Budnik, *supra* note 3, at 3.

[7] EPA, *Methyl Bromide (Bromomethane*), *supra* note 2, at 2; Budnik, *supra* note 3, at 3 ("Throat irritation, chest pain and shortness of breath are the most likely first respiratory symptoms with inflammation of the bronchi or lung edema after severe acute exposure. Death may result from respiratory or cardiovascular failure."); U.S. GAO, *Pesticides: The Phaseout of Methyl Bromide in the United States* 5 (Dec. 1995) ("In severe cases [exposure to methyl bromide] can cause central nervous system and respiratory systems to fail. Gross permanent disabilities or death may result.") (Attachment 5).

[8] Nat'l Res. Council, *supra* note 5, at 1 ("Methyl bromide also appears to be a developmental and possibly a reproductive toxicant."); Budnik, *supra* note 3, at 1 ("Both the epidemiological evidence and toxicology data suggest a possible link between methyl bromide exposure and serious health problems, including prostate cancer risk from occupational and community exposure."); *see* Julia R. Barrett, *Getting the Drift: Methyl Bromide Application and Adverse Birth Outcomes in an Agricultural Area*, 121 Envtl. Health Perspectives A198 (2013) (Attachment 6).

Numerous studies indicate public health concerns from chronic, low-level exposure to methyl bromide that has drifted from the fumigation site.[9] "Since [methyl bromide] is three times heavier than air, it diffuses outward and downward readily,"[10] causing potential exposure problems for the surrounding community. Specifically, Gunier (2017) found a "direct relationship between nearby agricultural use [of methyl bromide] and potential community exposure" within a five-mile radius of the fumigation site.[11]

Children are considered particularly sensitive to methyl bromide exposure. Methyl bromide use has been known to impact prenatal, postnatal, and childhood development for pregnant women and children living within five miles of fumigation sites.[12] In particular, prenatal exposure has been associated with decreased birth weight and postnatal and childhood exposure has been linked to decreased IQ.[13]

b. Methyl bromide has known environmental impacts, including its ozone-depleting potential.

Methyl bromide is a Class I ozone-depleting substance regulated by the Montreal Protocol and the CAA. The Montreal Protocol provided for the complete phase-out of methyl bromide by 2005 except in certain circumstances, including what is referred to as "quarantine and pre-shipment uses" ("QPS").[14] Accordingly, EPA only allows methyl bromide use in limited circumstances, including QPS uses such as the fumigation of logs for export.[15] Although methyl bromide is permitted for QPS uses, that does not change the fumigant's "remarkable potency as a depletor of atmospheric ozone."[16] Moreover, some countries have indicated a concern with pollution of surface and ground water and effects on soil biodiversity from methyl

[9] Budnik, *supra* note 3, at 9 ("The exposure assessment data and epidemiological analysis indicate a health risk concern for both workers and the general public."); Nat'l Res. Council, *supra* note 5, at 8 (noting that "inhalation exposure to agricultural workers and the general public" of methyl bromide "is of considerable concern"); Gunier, *supra* note 5, at 1 ("Fumigants are more likely than other pesticides to drift from application sites due to their high vapor pressure.").

[10] USDA APHIS, *Treatment Manual* 2-3-2 (2013) (Attachment 7).

[11] Gunier, *supra* note 5, at 1-2. Although this report focused on the use of methyl bromide in agricultural fumigation, the results are also applicable to methyl bromide use for log fumigation as both processes involve the eventual release of methyl bromide emissions into the air.

[12] *See generally id.* (examining the relationship between residential proximity to agricultural fumigation, including methyl bromide, and neurodevelopment in 7-year old children); Alison Gemmill, et al., *Residential Proximity to Methyl Bromide Use and Birth Outcomes in an Agricultural Population in California*, 121 Envtl. Health Perspectives 737 (2013) (concluding that "[r]esidential proximity to methyl bromide use during the second trimester was associated with markers of restricted fetal growth") (Attachment 8).

[13] Gunier, *supra* note 5, at 2 ("We previously found that living within 5 km of methyl bromide use in the second trimester of pregnancy was associated with decreased birth weight, length, and head circumference."), 364 ("We observed decreases in Full-Scale intelligence quotient with increased methyl bromide . . . use within 8 km of residences during the child's lifetime.").

[14] EPA, *Methyl Bromide*, https://www.epa.gov/ods-phaseout/methyl-bromide (last visited Mar. 20, 2019).

[15] *Id.*

[16] Budnik, *supra* note 3, at 2.

bromide uses.[17] Potential water contamination is of particular concern for some of the methyl bromide log fumigation operations in North Carolina that are located nearby to surface waters.

II. Proposed Acceptable Ambient Level

Despite the potential public health and environmental impacts of methyl bromide, this highly toxic and harmful chemical is not currently regulated by the state of North Carolina. As a result, some methyl bromide log fumigation operations in the state are located within a few hundred feet of residential communities. Additionally, interest in the use of methyl bromide for log fumigation has increased over the past few years, with permit applications and inquiries for additional and much larger facilities.[18]

In 2018, after several large-scale proposed methyl bromide log fumigation companies withdrew their air permit applications in response to significant public outcry,[19] DAQ took its first steps towards providing meaningful regulation and oversight to the operation of this expanding industry in North Carolina. In particular, DAQ announced its plan to designate methyl bromide as a state toxic air pollutant and draft accompanying regulations to govern the use of methyl bromide in log fumigation.[20] All pending air permits for methyl bromide log fumigation were put on hold until such regulations are finalized. As part of this process, DAQ decided that the best way to address the risks to the public health from methyl bromide exposure was to set an Acceptable Ambient Level ("AAL") that all operators will have to meet.

a. The proposed AAL is supported by the most updated and scientifically defensible studies.

After months of research and consideration, DAQ has proposed a methyl bromide AAL of .005 mg/m^3 (which equates to 1 ppbv) at a 24-hour averaging period. The recommended AAL reflects the EPA's Integrated Risk Information System ("IRIS") program's chronic inhalation

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[17] UN Environmental Programme, *Report of the Methyl Bromide Technical Options Committee* 15 (2014) (Attachment 9).

[18] *See* DAQ, *Risk Analysis and Acceptable Ambient Level Recommendation for Methyl Bromide* 1 (Feb. 22, 2019) [hereinafter, Methyl Bromide AAL Report] (stating that DAQ has seen an "increase in the number of permit applications and inquiries from entities interested in using methyl bromide for log fumigation.").

[19] In 2013, a permit for a proposed methyl bromide log fumigation operation in Morehead City was withdrawn in response to public opposition. Mark Hibbs, *Company Drops Fumigation Plan*, Coastal Review Online (Sept. 18, 2013), https://www.coastalreview.org/2013/09/company-drops-fumigation-plan/ (Attachment 10). This past year, Tima Capital applied for a permit to increase its use of methyl bromide for log fumigation from less than 10 tons per year to 60 tons per year at a facility in Wilmington. After overwhelming opposition from the public (over 2,000 comments receive), Tima withdrew their permit application and announced that it would completely end its use of methyl bromide at the Wilmington facility. *Companies to Halt Fumigation Operations*, Coastal Review Online (Mar. 29, 2018), https://www.coastalreview.org/2018/03/companies-to-halt-fumigation-operations/ (Attachment 11). Finally, Malec Brothers applied for a permit to emit up to 140 tons per year of methyl bromide at a new log fumigation operation in Delco. Malec also withdrew its permit application in response to public outcry—over 600 people attended two public hearings on the permit and DAQ received over 1,000 public comments. Lisa Sorg, *Malec Brothers Withdraws Air Permit Application to Use Methyl Bromide*, NC Policy Watch (Jan. 30, 2019), http://pulse.ncpolicywatch.org/2019/01/30/breaking-malec-brothers-withdraws-air-permit-application-to-use-methyl-bromide/ (Attachment 12).

[20] N.C. DEQ, *Division of Air Quality to Take Action on Methyl Bromide Log Fumigation* (Jul. 26, 2018), https://deq.nc.gov/news/press-releases/2018/07/26/division-air-quality-take-action-methyl-bromide-log-fumigation.

reference concentration ("RfC") for methyl bromide. According to DAQ, "the IRIS chronic RfC is the most appropriate and scientifically valid human health value to provide protection for the long-term health of persons in North Carolina[.]"[21]

Conservation Groups agree with DAQ's assessment that the AAL for methyl bromide should be based on the IRIS chronic RfC, which represents the most up to date and scientifically defensible research on the subject. IRIS reference concentrations are the preferred source of toxicity information for EPA, and are important resources relied on by state and local agencies, including DAQ. The process for deriving an IRIS RfC is extensive and involves a comprehensive review of all available research, as well as an internal EPA review and external peer review. For purposes of methyl bromide, EPA has indicated a "high confidence" level in the IRIS chronic RfC of .005 mg/m^3.

Although the IRIS chronic RfC for methyl bromide was set in the late 80s, recent studies have confirmed the .005 mg/m^3 reference concentration and supported its continued used for purposes of protecting the public health from methyl bromide exposure. For example, in 2018 the Agency for Toxic Substances and Disease Registry ("ATSDR") conducted a comprehensive review of the most up to date research and concluded that the IRIS chronic RfC was still the most representative and appropriate number to use for methyl bromide exposure. This ATSDR study reinforced DAQ's reliance on the IRIS chronic RfC and supports its conclusion that the less stringent methyl bromide AALs (or AAL equivalencies) in place in some other states are not appropriate for purposes of North Carolina's AAL. Specifically, DAQ uncovered that numbers used in other states were often unsupported, based off of occupational studies (which, as discussed below, are not protective to the general public), or were based on outdated research and methodologies. DAQ rightfully concluded that using the IRIS chronic RfC, as verified by the 2018 ATSDR study, was the most scientifically valid approach.

Conservation Groups also support DAQ's proposal that the methyl bromide AAL be measured at a 24-hour averaging time. Several characteristics of methyl bromide make the chemical particularly harmful to human health and therefore support the use of a longer averaging time. Specifically, it is often difficult to recognize potentially harmful and even severely harmful levels of methyl bromide exposure because the chemical is colorless, odorless, and symptoms are known to have a delayed onset. A 24-hour averaging time is also warranted because methyl bromide is rapidly absorbed and distributed throughout the body, has a steep exposure-effect curve, and may be particularly harmful to a large portion of the population that are genetically predisposed for increased effects of methyl bromide exposure.

b. The proposed "range of risk" is appropriate to account for particularly sensitive subpopulations.

DAQ has proposed a methyl bromide AAL of .005 mg/m^3, with a possible "range of risk" beginning at .002 mg/m^3 to account for particularly sensitive subpopulations that are genetically predisposed to have increased susceptibility to the neurotoxic effects of methyl bromide exposure. Although Conservation Groups agree that a range of risk is not necessary in cases

[21] Methyl Bromide AAL Report, *supra* note 18, at 1.

such as this where the AAL is based on an IRIS chronic RfC, Conservation Groups support DAQ's proposed range, which is aimed at protecting the general public.

The "general public," as it relates to public health, "encompasses subpopulations, such as infants, children, the elderly and persons with pre-existing conditions or a genetic predisposition that may manifest as increased susceptibility to the adverse effects associated with inhalation of methyl bromide and other toxicants."[22] To protect the "general public" from methyl bromide exposure, several important facts need to be taken into consideration.

First, methyl bromide has a steep exposure-response curve, meaning that the severity in effects of methyl bromide exposure increases substantially with only a relatively small change in the exposure concentration. As stated by DAQ, "the dost-response curve for methyl bromide lethality is steep and the margin of safety between no-effect and lethal values is small."[23] Given that even a slight increase in the amount of methyl bromide a person is exposed to can cause drastic and severe effects, including death, DAQ is right to err on the side of caution and provide a range of risk that is adjusted downwards from the IRIS RfC.

Second, research shows that a significant portion of the population—60 to 70 percent—has a genetic variation that makes them particularly sensitive to the effects of methyl bromide exposure. In particular, "large segments of the human population have *enhanced susceptibility to methyl bromide induced neurotoxic effects*[.]"[24] This particular genetic variation is not present in rodent populations and is therefore not accounted for in rodent-based methyl bromide exposure studies. Because the general public encompasses such genetically predisposed populations, DAQ appropriately considered this fact in setting its range of risk at a level that would protect the public health.

c. The proposed AAL accurately relies on data necessary to protect the public health, rather than data relevant to set occupational levels.

DAQ selected a methyl bromide AAL that is protective of the public health, taking into account particularly sensitive subpopulations. According to DAQ's report, studies based on occupational exposure levels are not appropriate and should not be relied on when considering the public health impacts of methyl bromide exposure. Conservation Groups agree with this approach.

As acknowledged by DAQ, AALs should be set at levels protective of the public health: "An Acceptable Ambient Level (AAL) is an airborne chemical concentration level *established to protect human health*." [25] This is reaffirmed by North Carolina regulations relating to toxic air pollutants, the purpose of which is to "set forth the rules for the control of toxic air pollutants to *protect human health*. [26] Moreover, "[a] facility shall not emit [a] toxic air pollutants[] in such

[22] *Id.* at 12.
[23] *Id.* at 17.
[24] *Id.* at 5 (emphasis added).
[25] N.C. DEQ, *Acceptable Ambient Level*, https://files.nc.gov/ncdeq/Air%20Quality/toxics/risk/sab/aaldisc.pdf (last visited Mar. 24, 2019) (emphasis added).
[26] 15A N.C. Admin. Code 02D .1101 (emphasis added).

quantities that may cause or contribute beyond the premises . . . to any significant ambient air concentrations that may *adversely affect human health*."[27]

Occupational exposure levels, however, are not representative of effects on the general population, including sensitive subpopulations. Whereas the "[g]eneral public exposure must consider the possibility that persons will be exposed daily over their lifetime," occupational levels instead "assume 8-hr per day, 5-day per week exposures to healthy adults over less than a lifetime."[28] Moreover, the available methyl bromide occupational levels are outdated. For example, the Occupational Safety and Health Administration's ("OSHA") occupation level of 5 ppm was set in 1969 and is based on research conducted in the 50s and 60s.

Finally, occupational levels should not be used in setting the methyl bromide AAL due to the proximity of some existing facilities to residential communities. According to DAQ, "[s]ome of the facilities are within *a few hundred feet* of residential communities."[29] It is estimated that "[m]ore than 4,000 people live within a mile and a half of North Carolina's four log fumigation facilities, and some are just 220 to 630 feet away[.]"[30] For example, Royal Pest Solutions' operation in Chadbourn, North Carolina, has two residential homes in close proximity (at 463 feet and 610 feet away), and the Flowers Timber operation in Seven Springs, North Carolina, is only 220 feet from a residential community.[31] Occupational exposure levels will not protect these communities from the harmful effects of methyl bromide exposure. Instead, an AAL must be based on levels sufficient to protect all members of the general population, including children, the elderly, and the 60 to 70 percent of the population that are predisposed to increased susceptibility from methyl bromide exposure.

III. Conclusion

Conservation Groups are glad to see DAQ taking affirmative action to regulate the use of methyl bromide, a highly toxic chemical that is often used in close proximity to residential communities. For the reasons discussed above, we urge the Science Advisory Board to adopt and recommend DAQ's proposed AAL of .005 mg/m^3 at a 24-hour averaging time.

Conservation Groups also urge DAQ and the Science Advisory Board to continue its efforts to draft a methyl bromide log fumigation regulation as quickly as possible in order to provide regulatory certainty to the industry and ensure that the public is protected from current and future operations. In the meantime, we encourage DAQ to continue its current hold on any pending air permit applications for methyl bromide log fumigation in the state. Finally, Conservation Groups strongly urge DAQ to formally request that EPA list methyl bromide log fumigation as a source category under Section 112(c) of the CAA in order to ensure some

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[27] 15A N.C. Admin. Code 02D .1104 (emphasis added).
[28] Methyl Bromide AAL Report, *supra* note18, at 19-20.
[29] *Id*. at 1.
[30] Lisa Sorg, *Thousands of People Live Near Log Fumigation Operations; Royal Pest Solutions Fined for Methyl Bromide Emissions Violations*, NC Policy Watch (Nov. 8, 2018) (Attachment 13).
[31] N.C. DEQ, *Temporary and Permanent Rulemaking for Control of Hazardous Air Pollutants from Log Fumigation Operations* at Slide 27-30 (Nov. 2018) (PowerPoint presentation), https://files.nc.gov/ncdeq/Air%20Quality/Calendar/Planning/november2018aqc/Abraczinskas_fumigation_EMC_Nov_2018_FINAL.pdf.

consistency among different states and guidance on the appropriate standards and technologies appropriate for methyl bromide log fumigation.[32]

Respectfully submitted,

Heather Hillaker
Associate Attorney
hhillaker@selcnc.org
Southern Environmental Law Center
601 West Rosemary Street, Suite 220
Chapel Hill, North Carolina 27516

On behalf of Clean Air Carolina, Medical Advocates for Health Air, and the North Carolina Conservation Network

[32] *See generally* Letter from Robert H. Colby & William O'Sullivan, Co-Chairs, Air Toxics Comm., Nat'l Assoc. of Clean Air Agencies, to Janet McCabe, Acting Assistant Adm'r, Office of Air & Radiation, U.S. EPA (Mar. 21, 2016), http://www.4cleanair.org/sites/default/files/Documents/NACAA_Source_Category_List_Letter_3-21-16.pdf (Attachment 14).

Mort, Sandra L

From: Shoesand <shoesand@ec.rr.com>
Sent: Tuesday, March 19, 2019 11:48 AM
To: Comments.SABReport
Cc: 'carl parker'; 'Charles Warren'; 'Marilyn Priddy'; 'Charlene Irvin'
Subject: [External] Methyl Bromide Comments from the Brunswick Branch, NAACP
Attachments: NCDEQ Methyl Bromide Comments.pdf

Dear Ms. Hughes,

On behalf of the Brunswick Branch of the NAACP please accept our attached comments for your consideration and review for the Risk Analysis and Acceptable Ambient Level (AAL) Recommendation for Methyl Bromide.

Please know that the original letter will be forwarded to you by mail.

Sincerely,

Brayton Willis
Member, Environmental and Climate Justice Committee
NAACP - Brunswick Branch #5452
P.O. Box 364
Supply, NC 28462

Carl L. Parker, President

1st Vice Bernest Hewett

Anne S. Parker, Secretary

Assistant Jerlyn McMillan

March 19, 2019

Ms. Louise Hughes
NC Department of Environmental Quality
1601 Mail Service Center
Raleigh, NC 27699-1601

RE: Risk Analysis and Acceptable Ambient Level (AAL) Recommendation for Methyl Bromide

Dear Ms. Hughes:

As President of the Brunswick Branch of the NAACP, I would like to thank you for the opportunity to comment on NC DEQ Division of Air Quality's (DAQ) Risk Analysis and Acceptable Ambient Level (AAL) Recommendation for Methyl Bromide dated February 22, 2019. Please be advised that we are very concerned that the use of methyl bromide to fumigate logs for export can become an environmental justice issue when higher risks of exposure are borne by residents in impoverished, rural areas. Further, we believe that no groups of people should bear a disproportionate share of negative environmental consequences resulting from industrial, governmental and commercial operations or policies. As a result, our Environmental and Climate Justice Committee has taken the time to develop a list of comments for your review and consideration.

Because there is still much we do not know about this hazardous chemical, our committee commends the DAQ on its extensive review of the literature and incorporating uncertainty factors in recommending a very low AAL. However, because methyl bromide has no warning properties, protecting the safety and health of workers and neighbors will depend on obtaining accurate air monitoring data, we offer the following comments:

Comment 1: We recommend that as part of the permitting process for these toxic facilities, a mandatory community survey be performed prior to the issuance of any permit to insure that the siting of such facility does not adversely impact residents in impoverished, rural areas.

Comment 2: We recommend that the permittee enforce and maintain a 500-foot public exclusion zone.

Comment 3: We recommend signage posted in conspicuous places around the site notifying the public in English and Spanish of fumigation operations prior to the startup of operations. The signs shall remain in place until completion of the process and shall conform to the format for placards mandated by the federally approved fumigant label.

Comment 4: We recommend limits on the annual tonnage of the VOC calculated monthly as the sum of each consecutive 12-month period.

Comment 5: We recommend that DAQ specify the type of air monitors to be used and that they be able to withstand harsh outdoor conditions and be able to detect methyl bromide at concentrations below the AAL.

Comment 6: We recommend that DAQ review each fumigation site and specify the number and location of air monitors.

Comment 7: We recommend that DAQ require calibration, maintenance procedures and compliance records for air monitoring instrumentation at the permittee's site and that a copy of those records be maintained at the site. Calibration and maintenance should be based upon the manufacturer's recommendations.

Comment 8: Operation records should also include scheduled and unscheduled maintenance and operator training.

Comment 9: DAQ should specify how often they will review a permittee's monitoring data and records.

Comment 10: DAQ should coordinate with Department of Agriculture to ensure compliance with the extensive pesticide label and MSDS requirements.

Comment 11: DAQ should only permit the use of those methyl bromide products that have an added olfactory warning agent.

Comment 12: DAQ should require that the permittee satisfactorily demonstrate correct air monitoring procedures before allowing fumigation to begin and that the permittee designate who on their staff will be the responsible employee for the operation, maintenance and record keeping of all monitoring equipment on that site.

Comment 13: If the proposed AAL is adopted, what would be the DAQ budget requirements for enforcement?

Comment 14: Fumigating logs in shipping containers is a risky process unto itself. To our knowledge there is no standard for serviceability of these containers for the intended use of log fumigation with methyl bromide. The operation of moving logs in and out of the storage containers itself will induce significant wear and tear on these vessels. We see the great risk of leakage of this toxic chemical through excessive structural degradation of these containers. We recommend that DAQ establish a minimum safe standard for facility operations and all equipment and plant ancillary to that safe operation.

Comment 15: We understand that a "no observable adverse effect level" has not yet been established, and the DAQ notes an "unquantified influence" on neurotoxic effects associated with certain segments of our population due to genetic differences. We believe that this unknown could represent significant risk to that population segment and begs for further research.

Comment 16: We recommend an acceptable capture and control system for the fumigant.

Comment 17: We recommend that all shipping containers be appropriately marked with placards designating that these vessels contain logs treated with methyl bromide fumigate gas or other suitable signage that meets federal standards for "restricted use pesticides."

Comment 18: We recommend that, as part of the permitting process, an evacuation buffer zone be clearly defined on a site plan. That plan should show all buildings, residences, schools, hospitals as well as places where the public may gather. This plan should also contain a wind rose depicting the relative frequency of wind directions at that location. This plan should be submitted to the local governmental jurisdiction for comment and approval and that all those falling within the evacuation buffer zone can be notified as to the pending operation.

Comment 19: We recommend an emergency spill/leak alarm system be installed at each site that will sound when the AAL is exceeded at the site's perimeter and that the alarm be tested periodically.

Comment 20: From our research, it would appear that it becomes increasingly difficult to kill insects with methyl bromide when the temperature is 10 °C (50 °F) or less. In general, the effectiveness of methyl bromide becomes unreliable below 10 °C. With that, we

effectiveness of methyl bromide becomes unreliable below 10 °C. With that, we recommend fumigation not be permitted where the temperature is expected to fall below 10 °C at any stage during the exposure period.

Comment 21: We believe that it is imperative that the chemicals and chemical containers stored on site should be sufficiently secured from perils of vandalism, wind, hail, flooding and other adverse acts of nature. DAQ should also establish the size of chemical containers and the amounts of chemicals allowed to be stored on site at any one time.

Comment 22: We recommend that before any permittee sets foot on the proposed fumigation site, the permittee performs an environmental site assessment to establish the current and past history and uses of the proposed property, what was previously on the site and did any such usage contaminate the soil or groundwater underlying the site.

Comment 23: We recommend that after all fumigation operations have ceased and prior to the abandonment of the site by the permittee, that the permittee be required to remove all pollution or contaminants from environmental media such as soil, groundwater, sediment, or surface water caused by that operation which could negatively impact human health and the environment.

Comment 24: We agree with the DAQ's position that occupational exposure limits are not adequate to protect the general public. With that, there are a couple of errors on page 19 worth of pointing out. The American Conference of Governmental Industrial Hygienists (ACGIH) Threshold Limit Value (TLV) value is currently 1 part per million (ppm), not 5 ppm as reported. The AGGIH also assigned a Skin notation, which is not mentioned or defined in this section. The skin notation is an alert that overexposure may occur following contact with liquid and aerosols even when airborne concentrations are below the TLV. The report also references the NC occupational exposure limit as higher than the federal Occupational Safety and Health Administration (OSHA) Permissible Exposure Limit, which is not allowed.

Comment 25: There can be actual methyl bromide exposure risks from fumigated shipping containers for groups such as dockworkers, warehouse workers, and customs officers. As this chemical is classified by the Department of Transportation as a toxic gas, we recommend a prohibition on opening such containers until a proper risk assessment by qualified safety/health personnel concludes that it is safe to do so. We also recommend providing mandatory safety and personal protective equipment training for employees who will be charged with performing this work.

Please know that the sisters and brothers of our Branch along with all those who live in our area support your efforts in this critical matter.

Thank you.

Carl Parker, President
NAACP - Brunswick County Branch #5452
P.O. Box 364
Supply, NC 28462
910-619-4974

Charles Warren, Chairman
Environmental and Climate Justice Committee
NAACP - Brunswick County Branch #5452

Copy to:

The Honorable Roy Cooper, Governor of North Carolina
Mr. Michael Regan, NC DEQ Secretary
Rev. Dr. T. Anthony Spearman, President, North Carolina NAACP
Mr. Derrick Johnson, President, NAACP
Mr. Courtney Patterson, 4th Vice President, NAACP
Ms. Deborah Maxwell, New Hanover Branch NAACP
Senator Bill Rabon, North Carolina, District 8
Honorable State Representative Deb Butler, District 18, State of North Carolina
Honorable State Representative Frank Iler, District 17, State of North Carolina
Mr. Michael Regan, Secretary, North Carolina Department of Environmental Quality
Mr. Frank Williams, Chairman, Brunswick County Board of Commissioners
Mr. Randy Thompson, Vice Chair, Brunswick County Board of Commissioners
Mr. J. Martin (Marty) Cooke, Commissioner, Brunswick County Board of Commissioners
Ms. Pat Sykes, Commissioner, Brunswick County Board of Commissioners
Mr. Mike Forte, Commissioner, Brunswick County Board of Commissioners
Ms. Ann Hardy, Brunswick County Manager
Honorable Mayor Garry Keaton, Town of Sandyfield, NC
Honorable Mayor James A. Knox, Town of Northwest. NC
Honorable Mayor Eulis Willis, Town of Navassa
Mr. Geoff Gisler, Senior Attorney, Southern Environmental Law Center
Ms. Janet Hoy, Co-President, League of Women Voters of North Carolina
Ms. Naeema Muhammad, Co-Director, North Carolina Environmental Justice Network
Ms. Veronica Carter, Member, NC DEQ Environmental Justice and Equity Advisory Board
Mr. Harold J. Daggett, President, ILA, AFL-CIO
Mr. Greg Washington, President, ILA Local 1426
Mr. Charles Seaton, President, ILA Local 1766
Mr. Michael Clemmons, President, ILA Local 1838

Mort, Sandra L

From: John Runkle <jrunkle@pricecreek.com>
Sent: Thursday, March 14, 2019 9:01 AM
To: Comments.SABReport
Subject: [External] Risk Analysis and Acceptable Ambient Level Recommendation for Methyl Bromide
Attachments: malec brothers methyl bromide.pdf

Comments on Methyl Bromide report:

1. Attached is a copy of the comments I submitted on behalf of NC WARN on the proposal by the Malec Brothers to use methyl bromide. It addresses the international condemnation of the use of methyl bromide under nearly all circumstances, and nearly all levels. There does not appear to be an ambient level that would be acceptable in terms of public health and environmental impact.

2. The risk analysis and AAL recommendation for methyl bromide lacks weight, and to some extent credibility, in that it does not contain any information about the preparers of the report, including their names and qualifications.

John D. Runkle
Attorney at Law
2121 Damascus Church Rd.
Chapel Hill, NC 27516
919-942-0600
jrunkle@pricecreek.com

JOHN D. RUNKLE
ATTORNEY AT LAW
2121 DAMASCUS CHURCH ROAD
CHAPEL HILL, N.C. 27516

919-942-0600
jrunkle@pricecreek.com

VIA MAIL & EMAIL

May 8, 2018

Ms. Urva Patel
Division of Air Quality
1641 Mail Service Center
Raleigh, North Carolina 27699-1641
publiccomments@ncdenr.gov

Re: Malec Brothers Fumigation
Draft Air Quality Permit

Dear Ms. Patel:

My client, NC WARN Inc., opposes the issuance of the proposed air quality permit for the Malec Brothers Transport in Columbus County. In addition to the serious health issues presented by commenters at the public hearing and in written testimony, NC WARN adds the following:

1. Methyl bromide was banned by the 1987 Montreal Protocol on Substances that Deplete the Ozone Layer, the international treaty designed to protect the ozone layer by phasing out the production of numerous substances that are responsible for ozone depletion. The protocol has been signed by all of the members of the United Nations, including the United States. All of the countries have banned methyl bromide because of its serious contributors to the global climate crisis. Elemental bromine is even more devastating to atmospheric ozone than chlorine.

2. In the United States, almost the entire use of methyl bromide is as a fumigant and then only under a "critical-use exemption" pursuant to US EPA criteria. Regardless of the exemption, methyl bromide was on track to be completely phased out by 2005, although the US EPA has continued its use for certain activities. www.epa.gov/ods-phaseout/methyl-bromide As a result, the US appears to be in non-compliance with the Montreal Protocol by continuing the use of methyl bromide.

3. In its application, Malec Brothers have not shown its use of methyl bromide fits under the critical-use exemption as there are cost-effective and economically

alternatives to the proposed use of methyl bromide, such as heat treatment. See other alternatives from Methyl Bromide Alternative Outreach, an annual conference of regulators, scientists, and industry representatives. https://mbao.org/

4. North Carolina industries currently use only small quantities of methyl bromide for specific prescribed purposes. Malec Brothers' emissions will be at least 30 times greater than all of the other emission combined. This excessive emission of an internationally-banned substance is unacceptable.

Please notify me of any actions you take on the proposed permit.

FOR NC WARN

/s/ John D. Runkle

_____
John D. Runkle

Mort, Sandra L

From: Jim Fredericks <jfredericks@pestworld.org>
Sent: Wednesday, March 27, 2019 4:24 PM
To: Comments.SABReport; Hughes, Louise G
Cc: Jim Fredericks
Subject: [External] NPMA Comments re: Risk Analysis and Acceptable Ambient Level Recommendation for Methyl Bromide
Attachments: FINAL NPMA NC Methyl Bromide Comments 2018.03.27.pdf

Attached, please find comments from the National Pest Management Association in response to the North Carolina Department of Environmental Quality, Division of Air Quality Risk Analysis and Acceptable Ambient Level Recommendation for Methyl Bromide.

Please feel free to contact me with questions or concerns.

Regards,

Jim Fredericks, Ph.D.
Vice President, Technical and Regulatory Affairs, National Pest Management Association
Executive Director, Pest Management Foundation
10460 North Street Fairfax, VA 22030
(703) 352-6762 Main Office
(800) 678-6722 Toll Free

National Pest Management Association

Our Mission is Your Protection

March 27, 2019

Louise Hughes
North Carolina Department of Environmental Quality
Division of Air Quality
217 West Jones Street
Raleigh, North Carolina 27699

Submitted electronically via email to comments.sabreport@ncdenr.gov and Louise.Hughes@ncdenr.gov

Re: National Pest Management Association Comments on North Carolina Department of Environmental Quality, Division of Air Quality Risk Analysis and Acceptable Ambient Level Recommendation for Methyl Bromide

Dear Ms. Hughes:

The National Pest Management Association ("NPMA"), appreciates the opportunity to submit comments on the North Carolina Department of Environmental Quality, Division of Air Quality (DAQ) Risk Analysis and Acceptable Ambient Level Recommendation for Methyl Bromide ("the Report").

NPMA is a non-profit trade association, established in 1933 to support the pest management industry, that represents hundreds of member companies in North Carolina alone and more than 5,000 member companies across the United States. The U.S. pest management industry is comprised of approximately 20,000 companies with annual revenues estimated at $8.5 billion. NPMA's member companies manage pests including rats, mice, ants, cockroaches, bed bugs, mosquitoes, spiders, stinging insects, termites and other pests in countless commercial, residential, institutional, and industrial settings. NPMA members are committed to providing high-quality,

professional pest management service, including methyl bromide fumigation, that protects public health, food, and property.

NPMA supports by reference the comments submitted by Western Industries, Ecolab, and the Methyl Bromide Industry Panel (MIBP) regarding the Report. As detailed in the Ecolab and MIBP comments, a large amount of rigorous scientific data is available that has not been considered in the current Report. Additionally, methyl bromide applications are already highly regulated at both the state and federal levels and the unnecessary restrictions proposed in the Report would essentially eliminate the use of methyl bromide in North Carolina due to the lack of existing real-time detection technologies sensitive enough to detect methyl bromide levels at the proposed Ambient Air Level (AAL) to demonstrate compliance. This de-facto ban would negatively impact a multitude of industries while realizing no additional human or environmental health benefit.

DAQ RECOMMENDATIONS ARE INCONSISTENT WITH CURRENT SCIENCE – BASED REGULATORY MEASURES REQUIRED BY THE U.S. ENVIRONMENTAL PROTECTION AGENCY AND THE NORTH CAROLINA DEPARTMENT OF AGRICULTURE AND CONSUMER SERVICES

Based on a review of the Report, NPMA believes that the underlying assumptions and data used in the Report are inconsistent with current U.S. EPA requirements detailed in the 2006 Report of FQPA Tolerance Reassessment and Risk Management Decision for Methyl Bromide, and Reregistration Eligibility Decision for Methyl Bromide's Commodity Uses (RED). DAQ's Report disregards the U.S. EPA's guidance for safeguarding workers and bystanders from methyl bromide exposures.

The use of methyl bromide is already subject to comprehensive regulatory scrutiny by the U.S. Environmental Protection Agency (EPA), United States Department of Agriculture, Animal Plant Health Inspection Service (APHIS), and the North Carolina Department of Agriculture and Consumer Services (NCDA&CS). Under the Federal Insecticide Rodenticide and Fungicide Act (FIFRA), applicators are bound by law to strictly adhere to pesticide label language, as evidenced by the statement found on all methyl bromide labels: "it is a violation of Federal law to use this product in a manner inconsistent with its labeling". EPA requires methyl bromide product labels

to bear instructions regarding Fumigation Management Plans (FMP) and science-based requirements for "buffer zones" intended to protect workers, bystanders and the public from exposures above 1 ppm.

In the 2006 RED, EPA explicitly stated that its approach, requiring FMPs and buffer zones was intended to mitigate negative exposures, both acute and chronic, to workers and bystanders, including surrounding communities.

DAQ RECOMMENDATIONS WOULD EFFECTIVELY PROHIBIT THE USE OF METHYL BROMIDE IN NORTH CAROLINA RESULTING IN ADVERSE IMPACTS TO MANY INDUSTRIES AND JOBS

Methyl bromide is a necessary step in the importation and exportation of many commodities in ports across the country. In North Carolina, the exportation of logs is dependent on the use of methyl bromide to comply with the requirements of importing countries to eliminate the risk of spreading invasive pests including insects, nematodes and disease organisms. With no alternative measures available, fumigators are required to adhere to strict requirements outlined in the APHIS Plant Protection and Quarantine Treatment Manual or the official requirements of the importing country before export can occur.

Fumigators are incapable of demonstrating compliance with the artificially low AAL recommended by DAQ in the Report, as portable methyl bromide monitoring instruments able to detect methyl bromide concentrations at the proposed levels do not exist. As a result, compliance by licensed fumigators would be virtually impossible and methyl bromide fumigation would cease in North Carolina. The inability to utilize this important tool in North Carolina would result in significant negative economic impacts as industries dependent on methyl bromide fumigation would need to relocate to other states. For instance, log exports from North Carolina ports represent an important and growing industry. According to data from the United States International Trade Commission, the value of logs exported from North Carolina ports has grown from approximately $19,000,000 in 2016 to $34,000,000 in 2017. In 2018, the value of log exports is estimated to be in excess of $42,000,000. Because fumigation would no longer be a viable treatment option under the proposed AAL, log exports from North Carolina would need to move to other states. In

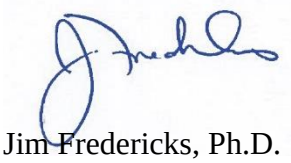
addition to the actual value of logs lost, ports could potentially see even greater losses due to shippers relocating operations to other states.

DAQ SHOULD WITHDRAW THE RECOMMENDATIONS IN THE CURRENT REPORT AND RECONSIDER THEIR FINDINGS BASED ON CURRENT DATA AND REGULATORY REQUIREMENTS

In conclusion, NPMA strongly recommends that DAQ withdraw their current recommendation and reconsider the approach to methyl bromide fumigations, incorporating more recent EPA findings as well as current and accurate toxicological data available which is missing from the current Report.

Thank you for the opportunity to comment on this matter. Please feel free to contact NPMA with any additional questions or clarifications needed regarding these comments.

Respectfully Submitted,



Jim Fredericks, Ph.D.
Vice President, Technical & Regulatory Affairs
National Pest Management Association

Mort, Sandra L

From: John Hatcher <jhatcher@ncforestry.org>
Sent: Monday, March 25, 2019 4:14 PM
To: Comments.SABReport
Subject: [External] Risk Analysis and Acceptable Ambient Level Recomendation for Methyl Bromide
Attachments: Comments to SAB_Methyl Bromide.pdf

To Whom It May Concern,

Please find attached the North Carolina Forestry Association's comments on the proposed AAL recommendation for methyl bromide.

Best Regards,

John E. Hatcher, Jr., Ph.D., CF
Executive Vice President
North Carolina Forestry Association
1600 Glenwood Avenue, Suite 1
Raleigh,NC 27608

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Fax: (919)832-6188
Mobile: (803)640-9125

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NORTH CAROLINA Forestry Association

NC Department of Health & Human Services
Secretaries' Science Advisory Board (SAB)
217 West Jones Street
Raleigh, NC 27603

NC Department of Environmental Quality
217 West Jones Street
Raleigh, NC 27603

RE: The North Carolina Department of Environmental Quality and The Department of Health & Human Services Secretaries' Science Advisory Board Notice of Proposed Risk Analysis and Acceptable Ambient Level Recommendation for Methyl Bromide (February 22, 2019)

Dear SAB members:

Over 100 years ago, North Carolina became the birthplace of science-based forest management thanks to George and Edith Vanderbilt's investment in the Biltmore Estate and subsequent founding of the Biltmore Forest School. North Carolinians continue to embrace sound science and technology and grow more timber volume per acre per year than ever before. In fact, our state's forestland is growing 50% more softwood and 100% more hardwood than is being harvested annually. Our state's overall timber inventory has increased 45% since 1974. North Carolina's forests are healthy, robust and produce a wide variety of species used in numerous ways. Sustainability is critical for our landowners and millions of our forested acres are certified by sustainability systems like the Sustainable Forestry Initiative (SFI), American Tree Farm (ATF) and Forest Stewardship Council (FSC).

Our forest sector, which includes forestry, logging, and forest products industries, ranks third among manufacturing sector employers in the state behind food products and fabricated metal product industries. According to a recent study by North Carolina State Extension, the total economic contribution of the forest sector was $32.7 billion, supporting approximately 150,000 full- and part-time jobs with a payroll of $7.8 billion. Collectively, forest product firms export receipts total $1.44 billion annually.

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NORTH CAROLINA
Forestry Association

Currently, North Carolina landowners are exporting North Carolina-grown Southern Yellow Pine logs to Asian customers, primarily in China and India. While most of our logs continue to be consumed domestically, there is an international demand for this product requiring fumigation currently performed at a few, existing facilities near the Port of Wilmington.

NCDAQ is proposing a 24-hour AAL for methyl bromide, the fumigant used at these sites, at a range of 2 micrograms per cubic meter to 5 micrograms per cubic meter. The 5 microgram per cubic meter threshold is consistent with the U.S. EPA's reference concentration (RfC) for chronic risk effects. The RfC is defined by U.S. EPA as:

"An estimate (with uncertainty spanning perhaps an order of magnitude) of a continuous inhalation exposure to the human population (including sensitive subgroups) that is likely to be without an appreciable risk of deleterious effects during a lifetime."

Dispersion modeling analyses, when conducted for chronic risk evaluations, compare average **annual** impacts (based on a 1 year or multi-year data period) to the RfC to determine if predicted risks pose any unacceptable risk to public health. The annual averaging period in the model is selected as a representative of the lifetime exposure included in the RfC definition. Since the chronic health impacts are of primary concern for methyl bromide, the annual average is the most appropriate averaging period to be used for setting an AAL. Acute health effects are based on shorter averaging periods (typically 1-hour or 24-hour) but those reference concentrations are much higher than the range of 2 to 5 microgram per cubic meter level proposed by NCDAQ. Table 1 below summarizes standards from a number of other states in the U.S.

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NORTH CAROLINA Forestry Association

Table 1. Summary of Various Methyl Bromide Standards

State	Averaging Period	Standard (µg/m3)
South Carolina	24-Hour	100
Virginia	1-Hour	950
	Annual	38
Georgia	15-Minute	8,000
	Annual	5
Alabama	8-Hour	97[a]
	Annual	9
Texas	1-Hour	120
	Annual	5
Michigan	Annual	5
Minnesota	1-Hour	2,000
	Month	100
	Annual	5
Idaho	24-Hour	950
Washington	24-Hour	5[b,c]
Florida Louisiana Mississippi	No standards	

[a] Screening threshold triggering refined annual analysis
[b] Screening threshold triggering facility-wide risk analysis
[c] Standards under review by Washington Dept. of Ecology

As shown, several states utilize a threshold of 5 micrograms per cubic meter, however each of those states apply that level to the annual averaging period. Washington state does have a 24-hour threshold of 5 micrograms per cubic meter, however that value is applied as a de minimis level for new projects to determine if a more refined risk analysis is warranted. That risk analysis would then be conducted for sites to demonstrate that their chronic risk impacts are acceptable, again using the 5 micrograms per cubic meter threshold applied on an annual basis. South Carolina and Idaho set 24-hour standards in their toxics regulations, however at much less stringent levels of 100 and 950 micrograms per cubic meter, respectively.

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NORTH CAROLINA
Forestry Association

For these reasons, I respectfully request that you **oppose** the Division of Air Quality's proposed AAL of 2 micrograms per cubic meter to 5 micrograms per cubic meter and establish a higher AAL, based on more appropriate and well-documented acute risk factors for methyl bromide. NC Forestry Association's 4000 members and other landowners in the state strive to be competitive with our neighboring states. We ask that you not adopt standards that make us less competitive. Thank you, in advance, for your consideration and for the opportunity to provide these written comments. Should you have any questions or need additional information, please do not hesitate to contact us.

Sincerely,

John E. Hatcher, Jr.

John E. Hatcher, Jr., Ph.D.
Executive Vice President
North Carolina Forestry Association
(919)834-3943

Mort, Sandra L

From: Reichert, Kurt <kreichert@westernpest.com>
Sent: Wednesday, March 27, 2019 1:13 PM
To: Comments.SABReport; Hughes, Louise G
Cc: Gsheehan@kilpatricktownsend.com; jmarshall@scsengineers.com; Borja, Miriam
Subject: [External] Western Fumigation Comments on the Risk Analysis and Acceptable Ambient Level Recommendation for Methyl Bromide
Attachments: Western Fumigation Comments on the Risk Analysis and Acceptable Ambient Level Recommendation for Methyl Bromide.pdf

Good afternoon,

Please see the attached comments for Western.

Please let me know if you have any questions.

Sincerely,

Kurt S Reichert
Fumigation Director

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Lester, PA 19029

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March 27, 2019
OUR 91st YEAR

Via Electronic Mail

Comments.sabreport@ncdenr.gov
North Carolina Department of Environmental Quality

Louise.Hughes@ncdenr.gov
Louise Hughes
North Carolina Department of Environmental Quality
Division of Air Quality

RE: Western Fumigation Comments on the Risk Analysis and Acceptable Ambient Level Recommendation for Methyl Bromide

Dear Ms. Hughes:

Western Industries – North, LLC (Western Fumigation) appreciates the opportunity to submit the following comments on the Department of Environmental Quality's (DEQ) Risk Analysis and Acceptable Ambient Level Recommendation for Methyl Bromide report, dated February 22, 2019 (the Report).

Western Fumigation is a commercial fumigation applicator that provides services to customers throughout the United States. Commodity and structural fumigations are the treatment of a product or building with a gas to eliminate pest infestations that can contaminate the product or introduce foreign pests into the US. Fumigation necessarily supports businesses such as transportation, shipping, manufacturing, warehousing, milling, and agriculture, and it protects US agriculture and forestry from invasive species.

Western Fumigation hereby supports by reference the comments submitted by both Ecolab, Inc. and by the Methyl Bromide Industry Panel (MBIP) on the Report. We also encourage the Science Advisory Board to closely review the information submitted by Ecolab and the MBIP, as well as the information to be presented by these entities and Western Fumigation at the Board meeting on April 1, 2019.

Without repeating the Ecolab and MBIP comments in their entirety, Western Fumigation has focused its comments on just three important issues at this time:

First, the Report is highly inaccurate in its statement that there are no existing federal or state regulations designed "to protect the public from log fumigation related to methyl bromide releases." Report, at 1. To the contrary, there are numerous federal and state programs that both

regulate and provide guidance regarding many aspects of methyl bromide fumigation, including the discharge of the used fumigant. These programs include, among others:

- US Environmental Protection Agency (US EPA) Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) requirements
- United States Department of Agriculture (USDA) Animal and Plant Health Inspection Service (APHIS) Plant Protection Quarantine (PPD) Treatment Manual requirements
- Occupational Safety and Health Act (OSHA) regulations
- USDA pesticide control program, and
- North Carolina Department of Agriculture Consumer Services pesticide applicator licensing and certification program.

The rules and requirements implemented through these programs are explicitly designed to ensure the protection of human health and the environment while also ensuring that the fumigation is effective in preventing the spread of invasive species within the US and internationally. These regulations are founded on sound science and are the result of decades of scientific studies performed by state and federal government agencies. In summary, the methyl bromide fumigation industry is, in fact, heavily regulated by multiple existing programs that are designed to ensure the health and safety of the public.

Second, the Report is based on a fundamentally flawed misapplication of the toxicological methodology for developing ambient air quality standards. In short, the Report recommends the adoption of an *acute/short-term* reference concentration (RfC) that was actually developed and intended for use as a *chronic/long-term* standard. The proposed application of a *chronic* RfC for an *acute* exposure scenario does not follow the scientific method, is inconsistent with guidance provided by EPA and other federal government agencies, does not adhere to environmental risk assessment practices, and conflicts with RfCs developed by other states.

The Report recommends the adoption of the lifetime inhalation RfC developed by EPA's Integrated Risk Information System (IRIS) to serve as a 24-hour Acceptable Ambient Air Limit (AAL). The US EPA and the Agency for Toxic Substances and Disease Registry (ATSDR) have developed definitions of "acute" and "chronic" for human exposure to certain chemicals. These definitions are based on scientific studies and acknowledge the difference between a short-term exposure (acute) as opposed to a long-term exposure (chronic) when setting forth exposure limits. The Report's proposed adoption of the EPA IRIS chronic RfC for acute exposures is inconsistent with the basic definitions of "acute" and "chronic" as commonly used in the environmental risk assessment community, and as required by the methodologies provided by federal government agencies.

Furthermore, in the Report, North Carolina specifically references EPA's IRIS data in developing its own standards, and yet despite this acknowledgement, the Report then uses the "chronic" standard while ignoring the IRIS' "acute" standard instead. This misapplication of the data results in a standard that is inconsistent with the basic definitions of "acute" and "chronic." Sound scientific data exists upon which these numbers should be based, and that science should be the foundation of any future air emission regulations developed by the State that will govern methyl bromide.

Third, unless the toxicological errors noted above are corrected, Western Fumigation believes that the Report's recommended RfC would effectively prohibit the use of methyl bromide for any and all fumigation activities in the State. The proposed acute RfC is so low that compliance would be virtually impossible, and Western Fumigation would be unable to complete any fumigations in compliance with the standard. As such, all business related to the methyl bromide fumigation industry would be forced to relocate to other states. The economic impact on the State would be significant and many jobs and industries would be adversely impacted.

Again, we thank you for the opportunity to submit comments on the Report, and we look forward to working with the Department on this important issue. Please do not hesitate to contact me if you have any questions or need any additional information.

Sincerely,

Kurt S Reichert
Fumigation Director
Western Fumigation

cc: Gary R. Sheehan Jr., Esq., Kilpatrick Townsend & Stockton LLP

Mort, Sandra L

From: Hughes, Louise G
Sent: Friday, March 15, 2019 1:45 PM
To: Mort, Sandra L
Subject: FW: [External] Request for 30-Day Extension for Public Comments on the Risk Analysis and Acceptable Ambient Level Recommendation for Methyl Bromide
Attachments: Western Fumigation Comment Letter_March 15 2019.pdf

FYI. –L.

From: Reichert, Kurt [mailto:kreichert@westernpest.com]
Sent: Friday, March 15, 2019 12:22 PM
To: 'Tom.Auspurger@ncdenr.gov' <Tom.Auspurger@ncdenr.gov>; Hughes, Louise G <louise.hughes@ncdenr.gov>
Cc: Gsheehan@kilpatricktownsend.com; Borja, Miriam <MBorja@westernpest.com>
Subject: [External] Request for 30-Day Extension for Public Comments on the Risk Analysis and Acceptable Ambient Level Recommendation for Methyl Bromide

Good afternoon Tom and Louise,

Please see the attached letter and let me know if you have any questions.

Sincerely,

Kurt S Reichert
Fumigation Director

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March 15, 2019
OUR 90th YEAR

Via Electronic Mail

Tom.Auspurger@ncdenr.gov
Tom Auspurger, Ph.D.
Chairman – Secretaries' Science Advisory Board
North Carolina Department of Environmental Quality

Louise.Hughes@ncdenr.gov
Louise Hughes
North Carolina Department of Environmental Quality
Division of Air Quality

RE: Request for 30-Day Extension for Public Comments on the Risk Analysis and Acceptable Ambient Level Recommendation for Methyl Bromide

Dear Mr. Auspurger and Ms. Hughes:

Western Industries – North, LLC ("Western Fumigation") hereby requests a 30-day extension to file comments on the Department of Environmental Quality's ("DEQ") Risk Analysis and Acceptable Ambient Level Recommendation for Methyl Bromide report, dated February 22, 2019 (the "Report").

Western Fumigation is a commercial fumigation applicator that provides services to customers throughout the United States, including North Carolina. Commodity and structural fumigations are the treatment of a product or building with a gas to eliminate pest infestations that can contaminate the product or introduce foreign pests into the US. Fumigation necessarily supports businesses such as transportation, shipping, manufacturing, warehousing, milling, and agriculture, and it protects US agriculture and forestry from invasive species.

Western Fumigation believes that it is critical for all persons with an interest in the Report to be provided meaningful time to review and respond to the Report. To do so, interested parties must be afforded time to *both* attend the scheduled Science Advisory Board meeting on April 1, 2019 and submit comments in response to information presented at the meeting.

Our initial review of the materials released by DEQ has revealed that the documents present significant questions regarding the Department's approach to risk assessment. Due to the complexity of the scientific issues involved and the significant impact that the Report would have on the methyl bromide industry, logging industry, fumigation applicators, and international trade constitute, Western Fumigation believes that it is necessary and appropriate for the DEQ to extend the comment period and provide an additional 30 days until April 26, 2019.

We look forward to working with the Department on this important issue. Please do not hesitate to contact me if you have any questions or need any additional information. Please also reply to me at your earliest convenience to confirm the 30-day extension of the comment period.

Sincerely,

Kurt Reichert
Fumigation Director

cc: Gary R. Sheehan Jr., Esq., Kilpatrick Townsend & Stockton LLP

Mort, Sandra L

From: Marwitz, Alison <alison.marwitz@ecolab.com>
Sent: Thursday, March 14, 2019 4:45 PM
To: Comments.SABReport
Cc: Johnston, Staci; Achzet, John; Mueller, John
Subject: [External] Ecolab Requests for Time to Present and Extension for Public Comments
Attachments: 2019.03.14 - Ecolab.MethylBromide.AAL.Extension.Request.pdf

Dear Mr. Augspurger and Ms. Hughes:
As you are likely aware, Ecolab, Inc. (Ecolab) acquired Royal Pest Solutions, a pest elimination company that has a long history of providing fumigation services to businesses in the State of North Carolina. Fumigation services are critical to North Carolina's agriculture and trade industry and are also a vital tool for preventing the spread of invasive species. Ecolab is continuing to provide these services in accordance with air permits granted by the State of North Carolina. We are submitting the attached document to request for an extension on the comment period regarding the Methyl Bromide Risk Analysis and Acceptable Ambient Level Recommendation for Methyl Bromide (Risk Analysis). In addition, Ecolab is requesting time to present during the April 1, 2019, Science Advisor Board meeting to further expand on our concerns and provide an opportunity to directly address concerns the SAB may have as it relates to fumigation. Our requests are further detailed in the attached document for your review.

Ecolab looks forward to continuing to provide these important services in North Carolina and working cooperatively with the DEQ to ensure that fumigation air regulations protect human health and the environment while allowing the industry to continue its vital role in the agriculture and trade industry. Please contact me if you have any questions or concerns. Thank you.

Alison Marwitz, J.D.
SENIOR REGULATORY SPECIALIST II, PEST ELIMINATION DIVISION

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March 14, 2019

Tom Augspurger, Ph.D.
Chairman – Secretaries' Science Advisory Board
North Carolina Department of Environmental Quality

Louise Hughes
North Carolina Department of Environmental Quality
Division of Air Quality
217 West Jones Street
Raleigh, NC 27699

RE: Request for Time to Present to the SAB on April 1; and
Request for 30-Day Extension for Public Comments on the Risk Analysis and Acceptable Ambient Level Recommendation for Methyl Bromide

Dear Mr. Augspurger and Ms. Houghes:

Ecolab Inc. (Ecolab) provides fumigation services in North Carolina and is deeply committed to ensuring that our fumigation operations are protective of human health and the environment. We support the North Carolina Department of Environmental Quality's (DEQ) efforts to ensure such protection across the fumigation industry. We do, however, note the importance of ensuring the continued viability of these fumigation services which play a critical role in protecting our agricultural industry and preventing the spread of invasive species. It is within this context that we hereby request time to present from perspective of a fumigation company that holds or operates under six DEQ-issued air permits at the Science Advisory Board's (SAB) April 1 meeting and request a 30-day extension to file comments on the Risk Analysis and Acceptable Ambient Level Recommendation for Methyl Bromide (Risk Analysis).

On February 25, 2019, the DEQ published the Risk Analysis providing a 30-day comment period, which given the complexity and importance of this Risk Analysis to future rule-making in North Carolina, is insufficient to allow industry and opportunity to fully review, analyze, and respond. The DEQ is requesting comments on the 63-page technical report, research documents, as well as associated presentations and audio recordings of previous board meeting discussions. A 30-day window does not allow enough time to review this volume of material or to provide a fully-informed response.

Initially, our review of the materials raises concerns regarding the application of the scientific-method, characterization of the current regulatory oversight, as well as the lack of engagement from the fumigation, import-export, and agriculture business sectors, specifically including the logging industry. Ecolab intends to perform a fulsome review of the materials and to provide well-informed feedback to the agency to ensure that DEQ and SAB have a comprehensive view of the implications that this proposed standard will have on North Carolina's agriculture industry.

As indicated, Ecolab currently holds or operates six DEQ-issued air permits to perform fumigation activities in the State of North Carolina. In addition to the controls set-forth by the DEQ in these permits, Ecolab must comply with numerous federal and state regulatory requirements, including the US Environmental Protection Agency (US EPA) Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) requirements, United States Department of Agriculture (USDA) Animal and Plant Health Inspection Service (APHIS) Plant Protection Quarantine (PPD) Treatment Manual requirements, Occupational Safety and Health Act (OSHA) regulations, USDA pesticide control program, and North Carolina

Department of Agriculture Consumer Services pesticide applicator licensing and certification program, among others. The opening paragraph of the Risk Analysis states as follows:

> "Although listed as a HAP, there is no specific regulation to protect the public from log fumigation related to methyl bromide releases. Similarly, since methyl bromide is not listed as a North Carolina Toxic Air Pollutant (TAP), there are no state air quality regulations."

As outlined above, contrary to this statement there are numerous regulations governing methyl bromide, including regulations designed to protect the public from release. Ecolab finds this statement to be inaccurate and misleading.

In addition, Ecolab is concerned about the scientific basis for DEQ's recommended adoption of the lifetime inhalation reference concentration developed by EPA ISIS to serve as the 24-hour Acceptable Ambient Air Limit (AAL). It is Ecolab's position that DEQ's proposition is inconsistent with the actual definitions of 'acute' and 'chronic,' as well as those provided in the EPA ISIS glossary. It is Ecolab's position that this inconsistency results in a misapplication of the standard such that the resulting proposed threshold no longer has its basis in EPA's ISIS data.

Finally, Ecolab is apprehensive about the proposed AAL as it relates presently available technology used to detect ambient air levels of methyl bromide. Methyl bromide is a volatile organic compound (VOCs). While there are several makes of photo-ionization detectors (PIDs) on the market, these PIDs are non-specific (i.e. do not distinguish which VOC is present) and cannot reliably measure to the proposed AAL. In fact, typical PIDs can only measure to approximately 0.1 part per million (ppm), which is approximately 80 times higher than DEQ's proposed AAL. Infrared devices, which are able to detect individual chemicals, are also available. However, as with PIDs, they can only measure to approximately 0.1 ppm. Finally, there are air canisters which can be used to collect and sample ambient air for analysis. While this method can measure to the proposed AAL, the samples cannot be tested in real time and the results can take up to two weeks. This delay would not identify releases in the amount of time necessary to accomplish the DEQ's stated goal of protecting the public. Further, this type of sampling is very extensive and is not something that would typically be undertaken in association with on-going fumigation activities.

Because of Ecolab's experience as a permitted fumigation company, we believe it is appropriate and necessary for SAB to be presented with a summary of the current safety measures, monitoring challenges, and further discussion around the use of terms 'acute' and 'chronic' in the proposed AAL. As such, we request 10 minutes during the April 1 SAB meeting to present prepared remarks and respond to any questions that SAB may have. The extension of the comment period would also enable Ecolab to fully respond in writing to any questions that SAB members may raise at that meeting.

In summary, the complexity of the scientific issues involved and the significant impact that the Report would have on the methyl bromide industry, logging industry, fumigation applicators, and international trade constitute good cause for the SAB to provide the MBIP time to present at the April 1, 2019 meeting, and for DEQ to extend the comment period an additional 30 days until April 26, 2019.

Best Regards.

Alison Marwitz, JD
Sr. Regulatory Specialist, II
Ecolab

Cc: Staci Johnston, Ecolab
John Achzet, Ecolab
John Mueller, Ecolab

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Submitted electronically via email to comments.sabreport@ncdenr.gov & Louise.Hughes@ncdenr.gov

March 27, 2019

Tom Augspurger, Ph.D.
Chairman, Secretaries' Science Advisory Board
North Carolina Department of Environmental Quality

Louise Hughes
North Carolina Department of Environmental Quality
Division of Air Quality
217 West Jones Street
Raleigh, NC 27699

RE: Comments of Ecolab Inc. on the North Carolina Department of Environmental Quality Risk Analysis and Acceptable Ambient Level Recommendation for Methyl Bromide

Dear Mr. Augspurger and Ms. Hughes:

Ecolab Inc. (Ecolab) provides fumigation services in North Carolina and is deeply committed to ensuring that our fumigation operations are protective of human health and the environment. We support the North Carolina Department of Environmental Quality's (NC DEQ) and Science Advisory Board's (SAB) efforts to ensure such protection across the fumigation industry.

We do, however, note the importance of ensuring the continued viability of these fumigation services that play a critical role in supporting North Carolina's logging industry and protecting our natural resources by preventing the spread of invasive species. It is within this context that we hereby submit our comments, developed with the assistance of SCS Engineers, on the Risk Analysis and Acceptable Ambient Level Recommendation for Methyl Bromide (Risk Analysis). Ecolab further expressly supports by reference comments submitted by the Methyl Bromide Industry Panel, Western Fumigation, and the National Pest Management Association.

For the reasons set forth in our comments, Ecolab urges the DEQ to reconsider adoption of the proposed standards set forth in the Risk Analysis. Ecolab stands ready to work cooperatively with DEQ toward reasonable regulations that are scientifically sound and further DEQ's goal of protecting human health and the environment.

Best regards,

Alison Marwitz, JD
Sr. Regulatory Specialist, II

CC: Jeff Marshall, SCS Engineers
Sara Peterson, Parkway Law
Anne Bookout, AEB Consulting
Staci Johnston, Ecolab Inc.
John Achzet, Ecolab Inc.
John Mueller, Ecolab Inc.

Ecolab Inc. Comments on Proposed Risk Analysis and Acceptable Ambient Level Recommendation for Methyl Bromide

ABSTRACT

I. CURRENT METHYL BROMIDE REGULATIONS

In its Risk Analysis and Acceptable Ambient Level Recommendation for Methyl Bromide (Risk Analysis), the North Carolina Department of Environmental Quality (NC DEQ) failed to identify, acknowledge, and account for most of the existing federal and state regulatory programs and guidance tools applicable to the fumigation of logs using methyl bromide when making the conclusory statement that there are no existing regulations governing methyl bromide emissions.

II. PROPOSED APPLICATION OF CHRONIC TOXICITY STANDARD FOR AN ACUTE EXPOSURE SCENARIO

NC DEQ is proposing the adoption of the lifetime inhalation reference concentration (RfC) developed by EPA Integrated Risk Information System (IRIS) for use as a 24-hour Acceptable Ambient Air Limit (AAL). In summary, the proposed application of a chronic RfC for an acute exposure scenario does not follow the scientific method, is inconsistent with guidance provided by EPA and other federal government agencies, does not adhere to environmental risk assessment practices, and conflicts with RfCs developed by other states such as New Jersey and California. In accordance with the scientific methodology set forth in EPA's IRIS study, the RfC (5 $\mu g/m^3$) is an appropriate value for application as a chronic (e.g., one year or more) standard, but not for application as a 24-hour standard. A 24-hour standard should reflect more acute exposure conditions such as the 3,900 $\mu g/ m^3$ ($\approx$ 1 ppm) standard used by California and New Jersey.

III. COMPLIANCE WITH THE PROPOSED AAL CANNOT BE DEMONSTRATED USING REAL-TIME, PORTABLE METHYL BROMIDE MONITORING EQUIPMENT

Methyl bromide is a volatile organic compound (VOC) the monitoring of which is typically performed at various locations and various stages of the fumigation process pursuant to current regulatory requirements. Common monitoring devices employed for methyl bromide fumigation include photo-ionization detectors (PIDs), thermal conductivity cells (T/C), and infrared (IR) meters, as required or recommended by the PPQ Treatment Manual. While there are several makes of photo-ionization detectors (PIDs) on the market, these PIDs are non-specific (i.e. do not distinguish which VOC is present) and cannot reliably measure to the proposed AAL. In fact, typical PIDs can only measure to approximately 0.1 part per million (ppm), which is approximately 80 times higher than DEQ's proposed AAL. Infrared devices, which are able to detect individual chemicals, are also available. However, as with PIDs, they can only measure to approximately 0.1 ppm. Finally, there are air canisters which can be used to collect and sample ambient air for laboratory analysis. While this method can measure to the proposed AAL, the samples cannot be tested in real time and the results can take up to two weeks. This delay would not identify releases in the amount of time necessary to accomplish the DEQ's stated goal of protecting the public.

IV. BUSINESS IMPACTS: THE PROPOSED AAL WOULD HAVE SIGNIFICANT IMPACT ON THE LOG FUMIGATION INDUSTRY AND THE AND ASSOCIATED EXPORT BUSINESS IN NORTH CAROLINA

Ecolab has provided fumigation services at ports and other locations along the US East Coast (including North Carolina) for more than 30 years. Based on our experience and knowledge of the fumigation industry, we expect that existing fumigation facilities would not be able meet the AAL standard proposed by the NC DEQ when trying to demonstrate compliance. To the contrary, our experience in North Carolina demonstrates that even the current permit requirements are resulting in a reduction in our log fumigation business. Furthermore, during recent years Ecolab has engaged in on-going discussions with the NC DEQ regarding the permits Ecolab owns or operates under. Over the course of these meetings, Ecolab and the NC DEQ have discussed various business models and monitoring options in an attempt to find a feasible option to meet the proposed AAL or further reduce emissions. To date, none have been identified. Additionally, the options discussed either require significant and wide-reaching changes to business practices (that would still not meet the proposed AAL) or would require the use of technology that, to our knowledge, does not currently exist.

While Ecolab is interested in continuing on-going conversations with the NC DEQ, should the proposed AAL become effective, Ecolab does not see a realistic option under which it could continue its log fumigation operations in North Carolina. Further, Ecolab anticipates that other fumigation companies would be similarly restricted.

I. CURRENT METHYL BROMIDE REGULATIONS

The opening paragraph of the document (page 1) provides the following statement: "Although listed as a HAP, there is no specific regulation to protect the public from log fumigation related to methyl bromide releases. Similarly, since methyl bromide is not listed as a North Carolina Toxic Air Pollutant (TAP), there are no state air quality regulations."

This is inaccurate and misleading. There are numerous federal and state programs that both regulate and provide guidance regarding many aspects of methyl bromide fumigation, including the discharge of the used fumigant. These include US Environmental Protection Agency (US EPA) Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) requirements, United States Department of Agriculture (USDA) Animal and Plant Health Inspection Service (APHIS) Plant Protection Quarantine (PPD) Treatment Manual requirements, Occupational Safety and Health Act (OSHA) regulations, USDA pesticide control program, and North Carolina Department of Agriculture Consumer Services pesticide applicator licensing and certification program, among others. The focus of this section will be on the following:

- The U.S. Environmental Protection Agency (EPA) Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) program;
- The United States Department of Agriculture's (USDA) invasive species control program; and
- The North Carolina Department of Agriculture and Consumer Services' pesticide applicator licensing and certification program.

A. USEPA PESTICIDE REGULATION UNDER FIFRA

The USEPA, Office of Pesticide Programs (OPP) plays a role in managing quarantine and pre-shipment (QPS) fumigation through its pesticide labeling program established under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA). FIFRA requires that before anyone can sell or distribute a pesticide in the United States, they must obtain a registration, or license, from EPA. "Pesticide registration is the process through which EPA examines the ingredients of a pesticide; the site or crop on which it is to be used; the amount, frequency and timing of its use; and storage and disposal practices. EPA evaluates the pesticide to ensure that it will not have unreasonable adverse effects on humans, the environment and non-target species. Pesticides must be registered or exempted by EPA's Office of Pesticide Programs before they may be sold or distributed in the U.S. Once registered, a pesticide may not legally be used unless the use is consistent with the approved directions for use on the pesticide's label or labeling." (Reference: http://www.epa.gov/opp00001/regulating/registering/, April 11, 2013).

Methyl bromide was introduced as a pesticide in 1932 and was first registered in the US in 1961. Because of advances in science, public policy, and pesticide use practices, USEPA requires that pesticides first registered before November 1, 1984 must be reregistered to ensure that they meet today's more stringent standards (Reference: RED Fact Sheet for Methyl Bromide. US Environmental Protection Agency, Office of Pesticide Programs. July 10, 2008).

> Reregistration involves a thorough review of the scientific database underlying a pesticide's registration. The purpose of the Agency's review is to reassess the potential risks arising from the currently registered uses of the pesticide; to determine the need for additional data on health and environmental effects; and to determine whether or

not the pesticide meets the "no unreasonable adverse effects" criteria of FIFRA. (Reference: Amended Reregistration Eligibility Decision for Methyl Bromide (soil and non-food structural uses), EPA 738-R-09-311, USEPA Office of Prevention, Pesticides and Toxic Substances, May 2009, page 12).

The reregistration process for methyl bromide was completed in late 2016. Thus, the requirements imposed by the updated FIFRA label represent current state-of-the-art fumigation science and protocols. The recent reregistration process resulted in two separate registrations for methyl bromide – one for use as a soil fumigant, and another for use as a structural and commodity (e.g., logs) fumigant. Methyl bromide will continue to be subject to routine FIFRA registration reviews at least every 15 years to determine whether it continues to meet the FIFRA standard for registration.

In conjunction with the recent FIFRA reregistration process and the development of an updated and revised FIFRA label, EPA has established a buffer zone program for commodity fumigations such as the log fumigations performed in North Carolina. The Methyl Bromide Commodity Fumigation Buffer Zone Lookup program provides minimum buffer zone distances that must be maintained during fumigation and aeration (the discharge of fumigant after the active fumigation period). The buffer zones were developed by EPA using the Probabilistic Exposure and Risk Model for Fumigants (PERFUM) – a customized air modeling and risk assessment process designed specifically to address the unique aspects of fumigation using methyl bromide. The risk assessment process considers facility workers and bystanders.

"Bystander" is a term used in the FIFRA risk assessment program for personnel who do not participate in fumigant application – i.e., "... any other person who lives or works in the vicinity of a fumigation site."[1]. Bystanders may include onsite facility personnel who are not participants in the fumigation event, e.g., security guards, and offsite personnel.

The buffer zone provides a distance between the application site and bystanders, allowing airborne residues to disperse before reaching the bystanders. This FIFRA buffer zone approach was established to reduce the chances that air concentrations where bystanders are located will cause acute adverse health effects.

EPA's Methyl Bromide Commodity Fumigation Buffer Zone Lookup Tables include hundreds of buffer zone lookup tables (totaling hundreds of pages) for various fumigation scenarios. Determination of the buffer zone for a specific fumigation event is based upon site-specific factors employed by the facility, including the enclosure size (ft^3); application rate, or methyl bromide dose (lbs per 1,000 ft^3, as specified by the USDA APHIS treatment schedule or the product label); retention rate (as affected by fugitive emissions, breakdown, and adsorption into the commodity); treatment duration (e.g., two options: 8 hours or less, and longer than 8 hours); aeration method (e.g., passive aeration; active aeration with attached vertical stacks; active aeration with open-area vertical stacks; active aeration with no stacks; active aeration with horizontal stacks); stack height; and air exchange rate (per hour), a function of aeration fan rate and enclosure size.

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[1] "Report of Food Quality Protection Act (FQPA) Tolerance Reassessment and Risk Management Decision (TRED) for Methyl Bromide, and Reregistration Eligibility Decision (RED) for Methyl Bromide's Commodity Uses," EPA 738-R-06-026, US Environmental Protection Agency, Office of Prevention, Pesticides and Toxic Substances, August 2006.

In summary, the buffer zone approach allows the determination of an acceptable buffer distance for each fumigation event based upon no fewer than seven distinct treatment and aeration parameters.

Additional details concerning the FIFRA buffer zones for methyl bromide commodity fumigation activities are provided at: https://www.epa.gov/pesticide-registration/mbcommoditybuffer.

In addition to the buffer zone tables, the revised FIFRA label for methyl bromide requires that fumigant applicators develop and implement facility-specific Fumigation Management Plans (FMPs). The purpose of the FMP is to ensure the safety of the fumigators, other on-site employees, the surrounding community, and the environment. It is also designed to ensure an effective fumigation that complies with FIFRA label requirements.

Under the revised FIFRA label, the following elements must be addressed in FMPs:

- General site information (site address, site operator/owner, phone number)
- Type of fumigation (e.g., quarantine, structural, mill, ship)
- Description of enclosure/chamber/structure (map or sketch of the facility, volume of treatment area, enclosure materials, commodities fumigated, maximum rates and dosage times, local exhaust ventilation systems, methyl bromide destruction/capture systems, proximity to other structures and common walls)
- Estimate of loss/retention rate (methods for evaluating and documenting)
- Descriptions and locations of control rooms, storage areas, restricted areas, other work areas, and sensitive surrounding sites (such as homes, schools, hospitals, employee housing centers)
- Fumigator/applicator information (license #, address, phone, contact information for person supervising the fumigation, i.e., the responsible party)
- Treatment and aeration procedures
- Maximum rates and dosage for each commodity
- Location of gas introduction site (including map and description)
- Leak testing procedures
- Interior and perimeter air monitoring of treated areas (methods, procedures, and equipment)
- Buffer zones (per FIFRA label method to calculate treatment and aeration buffer zones based on Agency look-up tables)
- Authorized on-site personnel
- Fumigators (fumigation workers must be certified applicators, or be working under the direct supervision of a certified applicator)
- Other on-site workers
- Personal protective equipment (selection, fit-testing, maintenance, storage procedures)
- Posting and notification (plans, procedures, record of notifications)
- Record keeping
- Emergency procedures (evacuation routes, emergency utility shut-offs, locations of telephones, emergency company, local/state/federal contacts, key personnel and emergency responsibilities in case of an incident, equipment failure, or other emergency)
- Site security
- Hazard communication (product labels, Safety Data Sheets, etc.)
- Name, address, contact information, credentials, and signature of certifying party

Each fumigation worker must sign a statement acknowledging review of the FMP before the treatment begins, and the site supervisor must attest to "clearing;" that is, the process required by the product label of verifying that the fumigant concentration has decreased to the point where members of the public may return to the site and control of the site is relinquished by the fumigator.

B. US DEPARTMENT OF AGRICULTURE (USDA), ANIMAL AND PLANT HEALTH INSPECTION SERVICE (APHIS)

NC DEQ is proposing the development of an AAL for methyl bromide, which is used to fumigate commodities, including logs, destined for export and various items imported into the US from overseas that may bring in invasive species. Together these are known as "quarantine and pre-shipment treatments," or QPS. Pre-shipment fumigation is typically conducted in accordance with USDA APHIS requirements and protocols, and QPS fumigations can take place only at sites approved by APHIS. Pre-shipment applications take place within 21 days prior to export and must meet the official requirements of the importing country or existing official requirements of the exporting country. Official requirements are those that are performed by, or authorized by, a national plant, animal, environmental, health or stored product authority.

APHIS has developed a series of detailed fumigation protocols for commodities through its Plant Protection and Quarantine (PPQ) division. The protocols and treatment schedules are published in the PPQ Treatment Manual. The treatment protocols published in the Treatment Manual are highly prescriptive and dictate detailed requirements for many aspects of the fumigation process, including but not limited to the following issues:

- Fumigation chemical (e.g., methyl bromide);
- Dosage - pounds of fumigant per 1,000 cubic feet of fumigated space;
- Maintenance of dosage by monitoring fumigant concentrations within the treatment enclosure throughout the treatment period and periodic addition of fumigant as necessary to maintain the required concentration;
- Treatment duration;
- Limitations on the volume of commodity in relation to the total enclosure volume;
- Forced recirculation within the enclosure to maintain the correct mixture of the fumigant in air throughout the prescribed treatment period;
- Monitoring the temperature of the environment and the commodity at multiple locations within the treatment enclosure throughout the treatment period;
- Weatherization of the treatment enclosure;
- Impervious flooring (applicable to bulk fumigations, as opposed to container fumigations);
- Availability of utilities;
- Arrangement of commodities within the treatment enclosure;
- Aeration of the commodity and treatment enclosure at the conclusion of the treatment period; and
- Safety requirements for release of the commodity and reentry of facility personnel into the area at the end of the treatment.

The PPQ Treatment Manual (940 pages as of February 2019) is frequently updated, and available online:

https://www.aphis.usda.gov/aphis/ourfocus/planthealth/complete-list-of-electronic-manuals and https://www.aphis.usda.gov/import_export/plants/manuals/ports/downloads/treatment.pdf

C. NORTH CAROLINA DEPARTMENT OF AGRICULTURE AND CONSUMER SERVICES, PESTICIDE APPLICATOR LICENSING AND CERTIFICATION PROGRAM

As required by the North Carolina Pesticide Law of 1971, both firms and personnel that perform pesticide application (including fumigation) in North Carolina are required to obtain the applicable license and certification (e.g., Registered Technicians and Certified Applicators) through the North Carolina Department of Agriculture and Consumer Services (NCDA&CS), Structural Pest Control and Pesticide Division. NCDACS licensing and certification requirements include training and examinations. Continuing education requirements must be met for renewals.

D. SUMMARY

There exist numerous state and federal regulations governing the release of methyl bromide into the atmosphere that are written with the intention of protecting human health and the environment while also ensuring that its use if efficacious as it relates to preventing the spread of invasive species within the US and internationally. These regulations are founded on sound science and are the result of decades of scientific studies performed by state and federal government agencies. It is insincere to promote the idea that regulations were not designed with the protection of workers, members of the public, and the environment at the forefront of their requirements. Furthermore, it is inaccurate to claim that "there is no specific regulation to protect the public from log fumigation relates to methyl bromide releases" or that "there are no state air quality regulations" governing methyl bromide. As the above discussion clearly demonstrates, methyl bromide is a heavily regulated chemical and there exist numerous measures to ensure that the public is protected.

II. PROPOSED APPLICATION OF CHRONIC INHALATION TOXICITY STANDARD FOR AN ACUTE EXPOSURE SCENARIO

The NC DEQ document recommends the adoption of the lifetime inhalation reference concentration (RfC) developed by EPA IRIS to serve as a 24-hour Acceptable Ambient Air Limit (AAL). In summary, the proposed application of a chronic RfC for an acute exposure scenario does not follow the scientific method, is inconsistent with guidance provided by EPA and other federal government agencies, does not adhere to environmental risk assessment practices, and conflicts with RfCs developed by other states such as New Jersey and California.

NC DEQ's proposed adoption of the EPA IRIS chronic RfC for acute exposures is inconsistent with the basic definitions of "acute" and "chronic" as commonly used in the environmental risk assessment community, and as required by the methodologies provided by federal government agencies.

A. EPA IRIS DEFINITIONS

The EPA IRIS glossary provides several pertinent definitions regarding the terms acute and chronic. These definitions are available in the below link and are also included below for your reference.
Reference:
https://iaspub.epa.gov/sor_internet/registry/termreg/searchandretrieve/glossariesandkeywordlists/search.do?details=&vocabName=IRIS%20Glossary

EPA IRIS Acute Terminology

- Acute Toxicity – Any poisonous effect produced within a short period of time following an exposure, usually 24 to 96 hours.
- Acute Exposure – Exposure by the oral, dermal, or inhalation route for 24 hours or less.
- Acute Reference Concentration – An estimate (with uncertainty spanning perhaps an order of magnitude) of a continuous inhalation exposure for an acute duration (24 hours or less) to the human population (including sensitive subgroups) that is likely to be without an appreciable risk of deleterious effects during a lifetime. It can be derived from a NOAEL, LOAEL, or benchmark concentration, with uncertainty factors generally applied to reflect limitations of the data used. General used in EPA's noncancer health assessment.
- Acute Reference Dose – An estimate (with uncertainty spanning perhaps an order of magnitude) of a daily oral exposure for an acute duration (24 hours or less) to the human population (including sensitive subgroups) that is likely to be without an appreciable risk of deleterious effects during a lifetime. It can be derived from a NOAEL, LOAEL, or benchmark dose, with uncertainty factors generally applied to reflect limitations of the data used. Generally used in EPA's noncancer health assessments.

EPA IRIS Chronic Terminology

- Chronic Effect – An effect that occurs as a result of repeated or longer term (chronic) exposures.
- Chronic Exposure – Repeated exposure by the oral, dermal, or inhalation route for more than approximately 10% of the life span in humans (more than approximately 90 days to 2 years in typically used laboratory animal species).
- Chronic Reference Concentration – An estimate (with uncertainty spanning perhaps an order of magnitude) of a continuous inhalation exposure for a chronic duration (up to a lifetime) to the human population (including sensitive subgroups) that is likely to be without an appreciable risk of deleterious effect during a lifetime. It can be derived from NOAEL, LOAEL, or benchmark concentration, with uncertainty factors generally applied to reflect limitations of the data used. Generally used in EPA's noncancer health assessments.
- Chronic Reference Dose – An estimate (with uncertainty spanning perhaps an order of magnitude) of a continuous inhalation exposure for a chronic duration (up to a lifetime) to the human population (including sensitive subgroups) that is likely to be without an appreciable risk of deleterious effects during a lifetime. It can be derived from a NOAEL, LOAEL, or benchmark concentration, with uncertainty factors generally applied to reflect limitations of the data used. Generally used in EPA's noncancer health assessments.

B. AGENCY FOR TOXIC SUBSTANCES AND DISEASE REGISTRY (ATSDR) DEFINITIONS

The current Toxicological Profile for bromomethane (aka methyl bromide) is dated September 1992. ATSDR issued an updated *Draft Toxicological Profile for Bromomethane for Public Comment in April 2018. The public comment period for the 233-page draft closed October 31, 2018. The draft is available at* https://www.atsdr.cdc.gov/ToxProfiles/tp.asp?id=822&tid=160.

Table 8-1 of the recent draft Toxicological Profile provides Regulations, Advisories, and Guidelines Applicable to Bromomethane. The table includes one inhalation Reference Concentration (RfC): $5x10^{-3}$ mg/m^3 (= 5 ug/m^3). The source of this RfC is identified as IRIS (i.e., EPA's Integrated Risk Information System).

Section 10 provides a Glossary of key terms, including the following definitions:

ATSDR Definitions

- Reference Concentration (RfC) – An estimate (with uncertainty spanning perhaps an order of magnitude) of continuous inhalation exposure to the human population (including sensitive subgroups) that is like to be without an appreciate risk of deleterious noncancer health effects during a lifetime. The inhalation reference concentration is for continuous inhalation exposures and is appropriately expressed in units of mg/m3 or ppm.
- Acute Exposure – Exposure to a chemical for a duration of 14 days or less, as specified in the Toxicological Profiles.
- Chronic Exposure – Exposure to a chemical for 365 days or more, as specified in the Toxicological Profiles.

Considering the EPA and ATSDR definitions provided above, the EPA IRIS RfC is based on lifetime exposure, which clearly falls within the definition of chronic exposure. NC DEQ's proposed adoption of the RfC as a 24-hour limit is consistent with the definition for acute exposures – not chronic. NC DEQ's application of "acute" and "chronic" with respect to the proposed AAL is inconsistent with EPA IRIS and ATSDR.

C. OTHER STATES

Several states have developed both acute and chronic ambient air guidelines and/or standards for methyl bromide. As with North Carolina, California and New Jersey also have considerable experience with methyl bromide. In recent years, California and New Jersey have devoted significant resources to examining the compound, making them valid resources for scientific studies of this compound.

California Office of Environmental Health Hazard Assessment

The California Office of Environmental Health Hazard Assessment (OEHHA) is one of five state departments within the California Environmental Protection Agency (CalEPA) and is the lead state agency for the assessment of health risks posed by environmental contaminants. OEHHA has established the following acute and chronic reference exposure levels for methyl bromide:

- Acute Inhalation Reference Exposure Level: 3,900 µg/ m^3 (=1 ppm), with an averaging time of one hour.
- Chronic Inhalation Reference Exposure Level: 5 µg/ m^3 (=0.00129 ppm = 1.29 ppb)

Reference: https://oehha.ca.gov/chemicals/methyl-bromide

New Jersey Department of Environmental Protection (NJDEP) Reference Concentrations (used for Risk Assessment)

NJDEP has developed both chronic and acute inhalation RfCs for use in risk assessments and air emissions regulation:

- Short-term/acute reference concentration: 3,900 µg/ m^3 (≈ 1 ppm), based on an averaging time of one hour.
- Long-term/chronic (e.g., annual) reference concentration: 5 µg/ m^3 (= 0.00129 ppm = 1.29 ppb).

Reference: Toxicity Values for Inhalation Exposure. NJDEP Division of Air Quality, Bureau of Evaluation and Planning - Air Quality Evaluation Section. August 2018:

https://www.state.nj.us/dep/aqpp/risk.html and
https://www.state.nj.us/dep/aqpp/downloads/risk/ToxAll2018.pdf

D. SUMMARY

The US EPA and ATSDR have developed definitions of "acute" and "chronic" for human exposure to certain chemicals. These definitions are based on scientific studies and acknowledge the difference between a short-term exposure (acute) as opposed to a long-term exposure (chronic) when setting forth exposure limits. Furthermore, the reference concentrations (RfC) expressly account for sensitive subgroups, thereby not limiting the applicability of their results to the healthiest in the population. Furthermore, in the AAL, North Carolina specifically references EPA's IRIS data in developing its own standards. In doing so, the AAL uses the "chronic" standard while ignoring the IRIS' "acute" standard instead choosing to develop a new number. This mis-application of the data results in a standard that is inconsistent with the basic definitions of "acute" and "chronic." Sound scientific data exists upon which these numbers should be based, and that science should be the foundation of any future air emission regulations developed by the NC DEQ that will govern methyl bromide.

III. COMPLIANCE WITH THE PROPOSED AAL CANNOT BE DEMONSTRATED USING REAL-TIME, PORTABLE METHYL BROMIDE MONITORING EQUIPMENT

Monitoring of the methyl bromide concentrations (if any) in air is commonly performed at various locations and various stages of the fumigation process. Common monitoring devices employed for methyl bromide fumigation include photo-ionization detectors (PIDs), thermal conductivity cells (T/C), and infrared (IR) meters, as required or recommended by the PPQ Treatment Manual. For example, ECOLAB uses Tiger® and Cub® PIDs manufactured by Ion Science; Fumiscope® T/Cs by Key Chemical; and MBContainIR® and MB400® IR meters from Spectros Instruments. Multiple devices are necessary, as the devices accurately measure concentrations only within specified ranges, and fumigators need to know that they have reached the concentration necessary to control the pest as well as the low concentration at which a site is "cleared."

A. PHOTO-IONIZATION DETECTORS (PID)

A PID is a non-specific vapor detector, capable of detecting many organic and some inorganic chemicals. The unit includes a lamp that ionizes volatile organic compounds (VOCs), followed by a detector that measures the ionization energy and converts this to a concentration value. Any constituent that has an ionization potential (IP) less than the PID lamp value can be detected and will provide a positive reading.

Detection limits for portable, real-time PIDs are typically in the range of about 0.1 ppm to 1.0 ppm (= 390 µg/m^3 to 3,900 µg/m^3 for methyl bromide). A few recent models reportedly have lower detection

limits (e.g, about 0.01 ppm = 39 µg/m^3 for methyl bromide). These detection limits are higher than the NC DEQ proposed AAL of 5 µg/m^3 (~ 0.0013 ppm), and therefore cannot be used to monitor at such a low concentration.

The use of a PID for ambient air monitoring also has the disadvantage of potentially reporting false positives (with respect to the absence or presence of methyl bromide), as the PID will provide a positive reading for any VOC that the meter detects. As mentioned above, PIDs are non-specific. For example, many Cub PIDs (provided by Ion Science) employ a 10.6 eV lamp. Any chemical with an ionization potential of less than 10.6 eV can be detected; there are approximately 300 chemicals known to be in this IP range. Included among the chemicals that has a detectible IP is methyl bromide, which has an ionization potential of 10.54 eV. Therefore, in an environment where any of these other chemicals are present, they will be detected in addition to methyl bromide. This scientific reality results in the detection of methyl bromide as well as other chemicals thus overinflating the actual detection data and misidentifying the presence of methyl bromide.

The potential for false positives due to background VOCs becomes greater when using PIDs with lower detection limits as ambient air can contain a variety of invisible chemicals at background concentrations in the ppb range. The use of PIDs can also be problematic when monitoring ambient air in situations where nearby operations may be emitting detected chemicals, and in situations where other VOCs (that will provide positive readings) such as combustion exhaust are or may be present. PIDs can also experience problems when operating in extreme environments such as high humidity or freezing temperatures.

B. INFRARED DETECTORS (IRs)

The MBContainIR® manufactured by Spectros Instruments, is another portable methyl bromide monitor employed by the fumigation industry and discussed in the PPQ Treatment Manual. The unit employs a non-dispersive infrared detector, and has a reported detection range of 50 ppm to 60,000 ppm (reference: MBContainIR™ Data Sheet, Version 1.0, February 2018, prepared by Spectros Instruments, http://assets.spectrosinstruments.com/docs/Spectros%20Instruments%20MBContainIR%20Data%20Sheet.pdf). This device is aimed more at monitoring the methyl bromide concentrations inside a fumigation enclosure during the active phase of the process. The lower detection range of the MBContainIR instrument is 50 ppm (~ 195,000 µg/ m^3), which is many orders of magnitude above the proposed AAL (5 µg/ m^3). As such, the MBContainIR is not capable of demonstrating compliance with the proposed AAL.

C. THERMOCOUPLE DETECTORS (T/Cs)

Similarly, the Fumiscope® by Key Chemical measures high concentrations of methyl bromide and is not considered accurate below approximately 200 ppm. Due to these limitations, the Fumiscope is an ineffective tool to verify compliance with the proposed AAL.

D. SUMMARY

In summary, real-time, portable methyl bromide monitoring instrumentation is not capable of demonstrating compliance with the proposed AAL. To achieve this exceptionally low methyl bromide concentration, the industry would be required to collect ambient air samples (e.g., using Summa canisters) for analysis at an off-site, fixed laboratory using advanced methods such as gas

chromatography/mass spectroscopy operated in selected ion mode (GS/MS SIM). GC/MS SIM is a modified version of EPA Method TO-15, with a typical turnaround time of about two weeks. As such, this approach does not provide real-time data that could be used to provide field adjustments to the fumigation procedures.

IV. BUSINESS IMPACTS: THE PROPOSED AAL WOULD LIKELY RESULT IN CLOSURE OF THE LOG FUMIGATION AND ASSOCIATED EXPORT BUSINESS IN NORTH CAROLINA

Ecolab has provided fumigation services at ports and other locations along the US East Coast for more than 30 years. Its expertise in quarantine and pre-shipment treatments is nationally and internationally recognized, it holds a patent on innovative fumigation equipment, and it has worked with USDA and other agencies in the design of fumigation facilities. As DEQ has expressed its concerns over log fumigations, Ecolab has offered its experience and expertise, participating in lengthy meetings and teleconferences with DEQ personnel. Ecolab has provided information on the fumigation industry and sought additional information from its industry colleagues, and it has evaluated proposed changes in operation in consultation with its most experienced fumigators. Should the proposed exposure standards outlined in the AAL be promulgated into North Carolina DEQ's air regulations, we expect that existing fumigation facilities would not be able to meet the new regulations and would consequently discontinue operations in North Carolina.

Ecolab currently owns or operates under six air permits issued by the NC DEQ. The NC DEQ has discontinued issuing new air permits in recent months unless an applicant (e.g. fumigation company) can demonstrate compliance with the proposed AAL. Based on our customer demand, this lack of ability to provide fumigation services to the logging industry has resulted in a reduction in the amount of logs being fumigated by Ecolab in the state of North Carolina. If the proposed AAL were to become the new standard, fumigation of these types of logs could not meet the compliance requirements and therefore would not be performed in North Carolina.

As mentioned, Ecolab has engaged in on-going discussions with the NC DEQ. During these discussion, alternative business practices, use of monitoring equipment, as well as questions regarding use of control technology have been broached. While the dialogue between Ecolab and the NC DEQ continues, the alternatives that have been discussed to date have not resulted in a feasible means of meeting the proposed AAL. As it relates to business practices, the measures proposed were of a wide-reaching nature that would impact the logging, trucking, import/export, and fumigation companies in a significant manner. Due to the magnitude of the proposed changes, Ecolab anticipates that many companies would choose to do businesses in other states rather than attempt such major shifts in their operations. As it relates to monitoring (e.g., sampling and laboratory analysis), there is no real-time practicable, proven and cost-effective technology for treating methyl bromide emissions from log fumigation (as discussed in Section III). Finally, Ecolab and the NC DEQ have briefly discussed control technology, otherwise known as scrubbing. SCS Engineers, environmental consulting firm used by Ecolab and Western Fumigation, has been actively evaluating potential technologies for the capture and control of methyl bromide emissions for about a decade. The results of their evaluations demonstrate a lack of cost-effective means to demonstrate real-time compliance.

It is anticipated that the proposed AAL would result in the significant decline of, if not complete closure of, the North Carolina log fumigation facilities, with major implications on the associated log agriculture and export industries.

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Mort, Sandra L

From: Hughes, Louise G
Sent: Tuesday, March 19, 2019 8:57 AM
To: Mort, Sandra L
Subject: FW: [External] Methyl Bromide Industry Panel Requests for Time to Present and Extension for Public Comments
Attachments: MBIP Request for Time to Present and 30-Day Extension.pdf

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From: Mahan, Grace [mailto:GMahan@wileyrein.com]
Sent: Wednesday, March 13, 2019 5:21 PM
To: Augspurger, Tom <Tom.Augspurger@ncdenr.gov>; Hughes, Louise G <louise.hughes@ncdenr.gov>
Cc: Heinzman, Tracy <THeinzman@wileyrein.com>; Miksad, Roger H. <RMiksad@wileyrein.com>
Subject: [External] Methyl Bromide Industry Panel Requests for Time to Present and Extension for Public Comments

Dr. Augspurger and Ms. Hughes,

As discussed during my telephone conversation with Ms. Hughes yesterday, attached you will find the Methyl Bromide Industry Panel's combined requests for time to present to the Secretaries' Scientific Advisory Board on April 1 and for a 30-day extension for public comments on the Risk Analysis and Acceptable Ambient Air Level Recommendation for Methyl Bromide.

Please direct any questions regarding our requests to Tracy Heinzman (theinzman@wileyrein.com) and Roger Miksad (rmiksad@wileyrein.com). We look forward to hearing from you.

Thank you.

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mbip
Methyl Bromide Industry Panel

March 13, 2018

Tom Augspurger, Ph.D.
Chairman – Secretaries' Science Advisory Board
North Carolina Department of Environmental Quality

Louise Hughes
North Carolina Department of Environmental Quality
Division of Air Quality
217 West Jones Street
Raleigh, NC 27699

RE: Request for Time to Present to the SAB on April 1; and
Request for 30-Day Extension for Public Comments on the Risk Analysis and Acceptable Ambient Level Recommendation for Methyl Bromide

Dear Mr. Augspurger and Ms. Hughes:

The Methyl Bromide Industry Panel ("MBIP") hereby requests time to present toxicological information on methyl bromide at the Science Advisory Board's April 1 meeting, and requests a 30-day extension to file comments on the above listed Risk Analysis and Acceptable Ambient Level Recommendation for Methyl Bromide ("the Report").

The MBIP represents companies which manufacture, distribute, and hold technical and end-use registrations for methyl bromide fumigation products under the Federal Insecticide Fungicide and Rodenticide Act ("FIFRA"). Our members would be greatly impacted by the state's implementation of the Report and wish to genuinely participate in the comment process. As the registrants of methyl bromide products, the members of the MBIP have generated a significant toxicology database for use by EPA's pesticide program over the past 50+ years which would be relevant to DEQ's analysis.

The North Carolina Department of Environmental Quality ("DEQ") published the Report on February 25, 2019 and provided only a 30-day comment period. In its February 25th posting, DEQ requests comments on an extensive set of materials concerning methyl bromide including the 63-page Report, research documents, presentations, and audio recordings of past board meeting discussions.

Our initial review of the materials released by DEQ has revealed that the documents present significant questions regarding the author's approach to risk assessment, especially as related to the

application of uncertainty factors. Further, the Report does not adequately consider acute acceptable ambient air levels ("AALs") as they relate to acute (one day) and short term (a few weeks) exposure. For example, the Report appears to claim that there is no data available with which to set an acute AAL. However, the methyl bromide toxicologic database is extensive, and the MBIP response will include acute and short-term endpoints relative to those exposure durations.

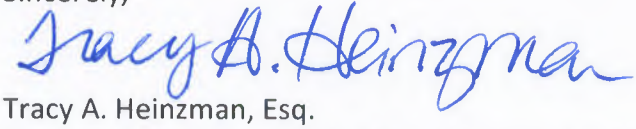
The Report's authors appear to have primarily relied on an EPA document from 1992, which in turn relied on an EPA analysis from 1989. This is a glaring deficiency because significant new data has been developed by EPA and the methyl bromide industry in the intervening 29 years—including significant toxicological reviews by EPA between 2002 and 2012—none of which is reflected in the Report.

The MBIP intends to fully review and provide meaningful feedback to the agency to ensure DEQ and the SAB have the most up-to-date and best available science to use in this extremely important discussion. The potential ramifications of the Report and its implementation require us to conduct a thorough scientific investigation executed in consultation with relevant toxicological experts. It is imperative that DEQ provide stakeholders with a meaningful and sufficient time period in which to comment on the Report—the 30-day comment period currently allotted by DEQ is insufficient.

The MBIP also believes it is appropriate, and necessary, for the SAB to be presented with a summary of the current state of the toxicological science at the April 1 SAB meeting. The MBIP requests 15 minutes during that meeting to present prepared remarks and to respond to any questions the SAB may have. The extension of the comment period would also enable the MBIP to fully respond in writing to any questions the SAB members may raise at that meeting.

In summary, the complexity of the scientific issues involved and the significant impact that the Report would have on the methyl bromide industry, logging industry, fumigation applicators, and international trade constitute good cause for the SAB to provide the MBIP with time to present at the April 1, 2019 meeting, and for DEQ to extend the comment period an additional 30 days until April 26, 2019.

Sincerely,



Tracy A. Heinzman, Esq.
Executive Director – Methyl Bromide Industry Panel

March 27, 2019

Tom Augspurger, Ph.D.
Chairman – Secretaries' Science Advisory Board
North Carolina Department of Environmental Quality

Louise Hughes
North Carolina Department of Environmental Quality
Division of Air Quality
217 West Jones Street
Raleigh, NC 27699

RE: Comments of the Methyl Bromide Industry Panel on the North Carolina Department of Environmental Quality Risk Analysis and Acceptable Ambient Level Recommendation for Methyl Bromide

Dear Chairman Augspurger and Ms. Hughes:

The Methyl Bromide Industry Panel ("MBIP") submits these comments on the North Carolina Department of Environmental Quality ("DEQ"), Division of Air Quality's ("DAQ") Risk Analysis and Acceptable Ambient Level Recommendation for Methyl Bromide ("the Report").[1]

The MBIP represents companies which manufacture, distribute, and hold technical and end-use registrations for methyl bromide fumigation products under the Federal Insecticide Fungicide and Rodenticide Act ("FIFRA"). The MBIP has been the primary data generator of federally required toxicological data on methyl bromide for the last 30+ years and is uniquely situated to shed light and offer guidance on the science underlying the use of that data. Accordingly, the MBIP looks forward to helping DAQ conduct a rational, science-based review of the methyl bromide toxicological literature as it works to establish recommendations that are both effective and appropriate.[2]

The MBIP appreciates the opportunity to comment on the Report. As more fully explained in the attached Technical Assessment, the analyses and recommendations set forth therein are

[1] The Report was made available for public comment on February 25, 2019 at https://deq.nc.gov/news/press-releases/2019/02/25/state-requests-public-comment-methyl-bromide-report.
[2] The MBIP supports by reference the comments submitted by Ecolab, Inc., Western Fumigation, and the National Pest Management Association.

inconsistent with the best and most up-to-date information and are out of alignment with existing regulatory regimes at both the state and federal level. The comments below, and the attached Technical Assessment, detail several of the most critical errors that permeate the Report and remind DEQ of its statutory mandate. In short, the MBIP has significant concerns that DAQ failed to use the best available science in the creation and development of the recommended AAL as required by North Carolina law.

As it stands, unless the deficiencies and methodological errors identified by the MBIP are corrected, it would be arbitrary and capricious under the North Carolina Administrative Procedure Act for DEQ to act on the recommendations currently presented in the Report. The MBIP recommends that DAQ reconsider the current recommendations in light of the new information presented and revise its work in alignment with the best available science.

I. THE RISKS DAQ IS ATTEMPTING TO REGULATE ARE ALREADY WELL REGULATED

DAQ seems to fundamentally misunderstand the regulatory framework that governs log fumigation operations. DAQ's Report states that the Department's intent is to protect "all persons that may live or work in areas subject to airborne releases of methyl bromide from log fumigation operations" and that "there is no specific federal regulation to protect the public from log fumigation related methyl bromide releases." However, these statements ignore the existence and primacy of EPA's regulation of fumigation under FIFRA.

Because all methyl bromide fumigation products are federally registered pesticides, EPA has chosen to use its FIFRA program as the primary regulatory tool to protect the public from methyl bromide exposures. The residential bystander exposures for which DAQ has conveyed concern have expressly been addressed and mitigated by EPA as part of label amendments within the last ten years. Those label amendments imposed mandatory application procedures and risk mitigation measures to protect bystanders, including residential bystanders. And, labels are binding and legally enforceable regulatory documents that ensure that the actual use of a product is consistent with its approved use. FIFRA § 12(a)(2)(G). Each methyl bromide product clearly bears the warning, "[i]t is a violation of Federal law to use this product in a manner inconsistent with its labeling."

As part of its regulation of fumigation through labeling, EPA required methyl bromide registrants to implement mandatory label requirements for applicators to establish "buffer zones"

around each fumigation site into which bystanders may not enter or be present.[3] In seeking to mitigate fumigation exposures, EPA chose to rely on bystander exclusions zones, or "buffer zones" because they protect both bystanders and workers from methyl bromide exposures that could exceed EPA's level of concern. TRED at p. 25. "[Buffer zones] represent the distances within which all bystanders must be excluded to ensure that their acute exposure to methyl bromide does not exceed the Agency's level of concern. EPA believes that requiring buffers at these distances combined with other mitigation measures described in this document will ensure that exposures will not exceed the Agency's level of concern." TRED at 30.

EPA also required applicators to follow "a comprehensive approach that requires mitigation measures such as fumigation management plans (FMPs), buffer zones, air monitoring, posting and notification, and record keeping, [that] will ensure that acute risks from inhalation exposure to both workers involved in the fumigation process and bystanders in areas around enclosures do not exceed EPA's level of concern." TRED at 25. This "comprehensive approach" was explicitly intended to protect residential bystanders from the very chronic risks which DAQ asserts are unregulated: "The Agency has concluded that measures to ensure that acute risks are below EPA's level of concern will also mitigate risks for other exposure durations (i.e. short-term, intermediate-term, **and chronic**) to levels below EPA's level of concern." TRED at p. 24-25 (emphasis added).[4]

The chronic exposure scenarios which the Report claims are unregulated and which DAQ seeks to protect bystanders from are thus already well regulated, and DAQ's assertion that additional bystander protections are needed is incorrect. DAQ should work with the permit holders to better understand how these label requirements are implemented and how those measures already protect residential bystanders to a very high degree.

II. DAQ'S RECOMMENDED ACUTE EXPOSURE MONITORING LIMIT IS IMPROPERLY DERIVED FROM CHRONIC TOXICOLOGY DATA

As described in more detail in the Technical Assessment attached to this document, DAQ's Report contains significant toxicological errors. Namely, DAQ is recommending that DEQ use an *annual* chronic exposure value as a *24-hour* averaging limit. This choice conflates a chronic exposure

[3] EPA Report of Food Quality Protection Act (FQPA) Tolerance Reassessment and Risk Management Decision for Methyl Bromide, and Reregistration Eligibility Decision (RED) for Methyl Bromide's Commodity Uses (TRED), at p. 24 (August 2006).

[4] A more detailed summary of the various mitigation measures required by the labels has been provided by EcoLab.

end-point with an acute exposure window and therefore would apply a significantly over-restrictive regulatory requirement without providing any public safety benefit.

As more fully explained in the attached Technical Assessment, DAQ's chosen approach is in conflict with established sound science and practice for choosing ambient air monitoring limits. Where, as here, an agency wishes to implement a 24-hour average monitoring window, the appropriate toxicological endpoint for consideration is an acute toxicological endpoint. DAQ's approach contradicts the methods and guidelines for conducting a risk assessment from the authorities on which DAQ relies, as well as commonly accepted practice for risk assessments. All of the guidelines and analyses presented above confirm that a risk analysis must generate any recommendations and/or limits based on data relevant to the same duration of exposure (i.e., acute data for acute exposures; chronic data for chronic exposures).

DAQ's recommendation also ignores factual reality. In effect, by using the chronic year-long RfC as a 24-hour acute limit, DAQ assumes that the permitted fumigation activities emit methyl bromide at a constant rate, 24-hours per day, 365 days per year. This ignores reality and sound practice. As the permit approving body for these facilities, DAQ is well aware that methyl bromide emissions are infrequent and periodic, with some days having higher emissions than others, and many days having no emissions. This means that the chronic (e.g., annual) average ambient air level will be far lower than any particular acute (e.g., one day) ambient air level. This is why the sound regulatory approach used by EPA and other regulatory authorities is to utilize an acute exposure limit for short-term monitoring limits, and to use the chronic RfC for long-term, annual, exposure limits.

As further explained in the Technical Assessment, DAQ should retract and reconsider its current recommendation and develop recommendations that are in accord with accepted scientific practices.

III. ACCEPTANCE OF THE DAQ'S FLAWED AAL RECOMMENDATION WOULD VIOLATE THE NC APA

Under North Carolina law and in alignment with principals of good rulemaking, DAQ must rely on accurate and up-to-date information regarding the characteristics and use of methyl bromide in establishing an Acceptable Ambient Level ("AAL"). DAQ must also apply that data using valid scientific methods. Failing to do so is at odds with DAQ's goal of "providing *science-based* environmental stewardship for the health and prosperity of all North Carolinians

(https://deq.nc.gov/about/history-of-deq) and is contrary to the regulations that govern DAQ's creation of AALs. N.C. Gen. Stat. § 150B-19.1; N.C. Gen. Stat. § 150B-51.

Per the North Carolina Administrative Procedure Act ("APA"), DAQ is required to ensure that rulemakings, including the establishment of an AAL, are "based on sound, reasonably available scientific, technical, economic, and other relevant information." § 150B-19.1(a)(5). If DAQ fails to support its determinations and documents with substantial evidence, its actions will be deemed arbitrary, capricious, and an abuse of discretion. § 150B-51(b)(5)(6).

As set out above, DAQ's Report is based on a fundamental misunderstanding of the existing federal regulations applicable to log fumigations. Further, the state's chosen approach to selecting a 24-hour averaging threshold is in direct contravention to the best available scientific, technical, and other available information. A continuation of this misguided approach to rulemaking on the part of DAQ would violate the requirements of the NC APA.

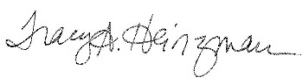
Additionally, although they do not address an un-regulated hazard, the AALs proposed for methyl bromide in the Report are much more restrictive than those involved in EPA's FIFRA processes. The very risks which DAQ claims to be addressing have already been addressed by the U.S. EPA through the enforceable label restrictions. Therefore, there is no actual un-regulated threat to public health, safety, or welfare. DAQ may not impose a more restrictive standard, limitation, or requirement than those imposed by federal law or rule. N.C. Gen. Stat. § 150B-19.3(a).

Finally, North Carolina law mandates that DAQ "reduce the burden upon those persons or entities who must comply with its promulgated rules." N.C. Gen. Stat. § 150B-19.1(a)(2). The Report's substantial decrease in the ambient air levels for methyl bromide would greatly burden the operations of MBIP's members and other methyl bromide stakeholders in North Carolina. However, as laid out above, the decrease serves no real value. Similar statutory regimes in other states do not require such strict ambient air levels for methyl bromide and yet, no great harms have befallen the public or the environment in those jurisdictions. Additionally, the Report's proposed methyl bromide levels are not supported by the large body of science that has developed over the past several decades. Therefore, the levels set out in the Report are disproportionately burdensome in comparison to the to the benefit they confer.

IV. CONCLUSION

Because of the foundational errors in the Report, DAQ must set aside the current recommendations and reconsider the state's approach to these issues. At a minimum, DAQ must recognize the large body of toxicological data not included in the Report and should restart the process of investigating appropriate ambient air levels for methyl bromide. As the registrants of methyl bromide products, the members of the MBIP have generated a significant toxicology database for use by EPA's pesticide program over the past 30+ years and are particularly equipped to help DAQ in this process. The MBIP understands both the science underlying methyl bromide and the day-to-day realities associated with its use. The MBIP looks forward to helping DAQ develop and implement an ambient air level for methyl bromide that is effective and in alignment with accurate and up-to-date science.

Respectfully Submitted,



Tracy A. Heinzman
Executive Director, Methyl Bromide Industry Panel

Attachments

March 27, 2019

Methyl Bromide Industry Panel
Technical Assessment of DAQ Report:
Risk Analysis and Acceptable Ambient Level Recommendation for Methyl Bromide

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Rick Reiss, M.S., ScD[2]

I. Introduction

The North Carolina Department of Environmental Quality, Division of Air Quality (DAQ) issued a report entitled "Risk Analysis and Acceptable Ambient Level Recommendation for Methyl Bromide" on February 22, 2019. In that document DAQ recommends 5 μg/m^3 methyl bromide (0.005 mg/m^3 or 1 ppbv) in air as the 24-hour N.C. Acceptable Ambient Level (AAL). While 24-hour maximum ambient exposure limits are normally established using acute toxicity data, DAQ has chosen to recommend an AAL set at the chronic reference concentration (RfC) established by the U.S. Environmental Protection Agency's (EPA) Integrated Risk Information System (IRIS) program. This approach is flawed and without precedent from any regulatory authority.

The DAQ risk assessment further posits, without substantiation and in contravention to the fumigation practices required by the products' labeling under Federal pesticide law, that persons living adjacent to log fumigation operations may be exposed to fumigants released to the ambient air under exposure frequency and duration conditions that reflect the EPA chronic exposure definition. DAQ is therefore proposing to set the 24-hour averaging time for acute methyl bromide exposure using the same level as that for potential chronic systemic (non-cancer) effects associated with the chronic RfC endpoint; a proposal without precedent from any other federal or state regulatory body.

It appears that DAQ had considered using acute exposure data to set its limit, but the DAQ document inaccurately states that neither the EPA, the EPA's IRIS program, or the ATSDR provide acute health values protective of the general public for methyl bromide inhalation exposures. This statement suggests that DAQ may have been unaware of the EPA reregistration risks assessments and other documents related to methyl bromide's registration review. In these documents EPA clearly recognizes that exposure durations to pesticides can be acute, short/intermediate term, or chronic; and EPA selected toxicological endpoints specifically relevant to each of these exposure durations. To the extent DAQ was not aware of this acute toxicological data, summarized below, DAQ should revisit its approach to establishing its AAL in light of this new data.

In particular for methyl bromide commodity fumigations, it is important to conduct risk assessments and establish acceptable limits of exposure for scenarios that reflect actual use and exposure patterns, and that use the best available science. Establishing limits based on inaccurate assumptions, that do not reflect actual use patterns, and that do not use the best and

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most applicable science and data would represent a significant departure from best risk assessment practices.

The purpose of this document is to address the key areas in the DAQ document that need modification or changes, and to provide certain data of which DAQ may not have been aware:

1. The use of a chronic exposure endpoint for the establishment of 24-hour acute exposure monitoring limits contradicts established and accepted scientific practice
2. A summary of available acute and short/intermediate term toxicological endpoints
3. The apparently overly conservative uncertainty factors used in the risk assessment
4. A summary of available data on the carcinogenic potential of methyl bromide

II. Definitions of Acute and Chronic Exposures

As an initial matter, a fundamental issue presented by the DAQ report is the staff's use of a chronic exposure RfC to inform their choice of a recommended acute exposure limit. This paper will use the below standard and accepted definitions when referring to acute and chronic exposures.

An "acute" exposure is one that one that occurs over one day (24 hours) or less. USEPA (1998).

A "chronic" exposure is one that occurs over a much longer period, for example over lifetime. USEPA (1998). A chronic exposure level is intended to represent and measure the long-term health impacts a particular chemical may have on the human body and is intentionally measured over a long period of time to account for periodic elevated exposures which are likely to be below the short-term acute exposure limit, and also to account for periods of low or no exposure.

III. DAQ's Use of a Chronic Exposure Endpoint to Set an Acute Monitoring Threshold Contradicts Established and Accepted Scientific Practice

DAQ bases its proposal to adopt the IRIS RfC on the assertion that "[p]ersons living adjacent to log fumigation operations may be exposed to fumigants released to the ambient air under exposure frequency and duration conditions that reflect the EPA chronic exposure definition" (p. 1) concluding, "The DAQ identifies the IRIS chronic RfC as the most appropriate and scientifically valid human health value to provide protection for the long-term health of persons in North Carolina, including sensitive subpopulations that may live adjacent to a log fumigation facility that repeatedly releases methyl bromide to the ambient air during operations." (p.1).

While DAQ asserts that their recommendations are based off potential chronic exposures and that recommendations are for "long-term health," the DAQ chooses to apply an AAL exposure duration that corresponds to acute exposures (i.e., 24-hour AAL). This is directly contrary to recommendations and guidelines for risk assessment analysis, as well as precedents set by the EPA and ATSDR – which the DAQ purports to have based its risk assessment and subsequent recommendations upon.

As an initial matter, the exposure at any given location is affected by a number of different factors, such that a 24-hour average ambient air level on any particular day is likely to be significantly different than other days, and the chronic exposure level for the same location.

1. Meteorology: Meteorological conditions greatly influence downwind concentrations. For example, wind direction typically varies from hour to hour and from day to day. Thus, winds will carry a gas emission to different downwind locations at different times. For this reason, the peak exposure at a given location may be much less than the longer-term exposure. Also, atmospheric stability varies with general climatic conditions, time of day, and season. In more stable atmospheres, a given unit of emission will result in relatively higher concentrations than in less stable conditions. Thus, variations in meteorological conditions will result in variability in downwind concentrations.

2. Operation hours: Log fumigations do not occur continuously. On some days, there may be no fumigations, and there are peak periods of fumigation throughout the year.

3. Emissions: The log fumigations include a treatment and aeration phase. Duration treatment emissions are smaller but occur over a longer period. Aeration removes the remaining gas quickly. The downwind concentration peak will likely occur at different locations for emissions during treatment and aeration.

For all of these reasons, the emissions at a given downwind location can vary significantly. Thus, while a peak 24-hour acute concentration might be higher than the target chronic average concentration at the same location, the changes in concentration caused by varying meteorology, operational hours, and emissions which vary from day to day will typically lead to much lower average exposures across the one-year or longer timeframes applicable to chronic exposures.

Indeed, the inappropriateness of conflating a chronic exposure level and an acute exposure level is recognized in the document which provides the instructions for use of the very RfC on which DAQ has chosen to rely. EPA's guidance for the "IRIS methodology for calculation of RfC" instructs:

> Extrapolation from one exposure regimen to another has uncertainties, most of which are not quantified . . . The exposure-health relationship may be dependent on factors, including (1) the number of exposure hours per day; (2) the exposure scenario, that is, continuous versus interrupted (e.g., 1 week of exposure, 1 week of air, 1 week of exposure, etc.), versus intermittent (X hours per day, Y days per week) regimens; (3) the time of endpoint assessment (e.g., acute versus subchronic versus chronic studies or studies with recovery time before observation); (4) the endpoint(s); and (5) the mechanism of toxicity. (USEPA 1994, p. 2-28).

Additionally, discussion of various study methods indicates that acute and short-term exposure durations are not relevant to the calculation of an RfC: "Clinical studies are typically of acute or short duration and therefore, as such, are less useful as the basis of an RfC. . ." (USEPA 1994, p. 2-3)." "Although such [nonepidemiologic] studies for ethical reasons are typically for acute

durations and therefore, by definition, do not meet the criteria for development of a chronic RfC estimate. . .” (USEPA 1994, p. 2-19).

Further, numerous other guidance and instructional documents from EPA and other authoritative sources reiterate and emphasize this admonition.

In the “General Principles for Performing Aggregate Exposure and Risk Assessments” released by EPA in 2001, EPA states:

> In addition to the selection of an appropriate hazard endpoint for each route of exposure (e.g., oral, dermal, inhalation), an aggregate risk assessment should attempt to match the anticipated frequency and duration of exposure with toxicity studies that reflect comparable timing of exposure. For example, if an effect occurs only after several days of chemical dosing (of animals), it would be inappropriate to compare the estimated exposure over a single day with the exposure associated with an effect which requires multiple days to develop. (USEPA, 2001; p. 17).

In the “Framework for Human Health Risk Assessment to Inform Decision Making” released by the EPA in 2014, the document states:

> The exposure assessment component of the analysis plan is developed by drawing on the information, considerations and decisions represented by the conceptual model for human health. Accordingly, the analysis plan describes the exposure assessment elements specified in the conceptual model, including the relevant routes and pathways, frequency and duration of exposures, populations and life stages, and assessment metrics. (USEPA 2014, p. 31).

In the Human Health Risk Assessment for methyl bromide released by EPA in 2006, the risk assessment is stratified by exposure duration with categorizations broken down into acute, short- and intermediate-term inhalation (defined as 1 day to 6 months), and long-term inhalation (>6 months).

Health endpoints are examined for each of the three exposure durations independently (USEPA 2006, Table 4 pp. 15-16). From this analysis, we see that the duration of exposure used to set Human Equivalent Concentration (HEC) values, is equal to the duration of the toxicological studies analyzed.

EPA explained that “[r]isks from acute exposures were calculated using the maximum 24-hour TWA values measured at each station and comparing them to the acute 24-hour (“agricultural”) HEC and not the 8-hour (“commodity”) HEC because these ambient air results are all 24-hour time-weighted averages. Risks for short- and intermediate-term exposures (i.e., same HEC and uncertainty factors apply to both durations) were calculated using the mean of 8 weekly means calculated by DPR for samples taken over the course of the use season and comparing them to the short- and intermediate-term HEC. This approach was taken in order to statistically weigh equally each week’s contribution to the overall seasonal mean because of differing numbers of

samples in some weeks. Concentrations over the course of a season monitored in these studies did not vary extensively so calculation of average concentrations for shorter durations (e.g., 4 weeks) or even the use of an overall mean of all samples would not expected [sic] to be dramatically different than estimates used in this assessment" (USEPA 2006, pp. 46-47).

In a training package developed by Children's Health and the Environment (CHEST), materials indicate:

> "The method used to calculate HAs [Health Advisories] is similar to that for the RfD's using uncertainty factors. Data from toxicity studies with durations of length appropriate to the HA are being developed." (CHEST 2003, p. 19).

In the "Guidelines for Exposure Assessment" published by the EPA in 1992, the following is stated:

> "The frequency and duration of sample collection will depend on whether the risk assessor is concerned with acute or chronic exposures, how rapidly contamination patterns are changing, ways in which chemicals are released into the environment, and whether and to what degree physical conditions are expected to vary in the future." (USEPA 1992, p. 41).

In "Guidance for Applying Quantitative Data to Develop Data-Derived Extrapolation Factors for Interspecies and Intraspecies Extrapolation" published by EPA in 2014 states:

> "For a given chemical, the appropriate dose metric will also be determined by, and can vary with, the MOA, duration of exposure, and the adverse effect of concern." (USEPA 2014, p. 22).

In conclusion, there is no precedent for the recommendations provided by DAQ (i.e., using a RfC to establish a 24-hour AAL), and DAQ's approach contradicts the methods and guidelines for conducting a risk assessment from the authorities on which DAQ relies, as well as commonly accepted practice for risk assessments. All of the guidelines and analyses presented above confirm that a risk analysis must generate any recommendations and/or limits based on data relevant to the same duration of exposure (i.e., acute data for acute exposures; chronic data for chronic exposures). Further, no other source identified by DAQ (e.g., National Research Council, California Office of Environmental Health Hazards Assessment [OEHHA], National Toxicology Program, etc.) uses toxicological studies from chronic exposures to make recommendations for acute exposure levels. Additionally, none of these sources equate or indicate comparability between acute and chronic exposure limits.

IV. Critical Data on Acute and Short/Intermediate Term Toxicological Endpoints Are Available and Should be Considered

DAQ attempts to justify its use of RfC for an acute monitoring timeframe by alleging that there is insufficient or no acute toxicological information available for Methyl Bromide. This statement is incorrect and ignores a significant and robust body of data available on that very topic. During the pesticide reregistration for methyl bromide products under Federal Insecticide,

Fungicide, and Rodenticide Act (FIFRA), EPA conducted numerous and extensive reviews of acute toxicological data and published numerous publicly available reviews of that data.

A. Acute endpoint for risk assessment

EPA published an initial guidance document entitled Hazard Identification - Toxicology Endpoint Selection (August 11, 1998[3]). This guidance document discusses studies that are relevant acute hazard identification as given below. Although the guidance was specific to oral exposures at the time, the criteria are also relevant to other exposure regimens such as inhalation.

1. The Acute Neurotoxicity Study in Rats which is pertinent because animals receive a single oral dose to which all toxicological effects can be attributed to the single dose received and as multiple dose levels are tested, a NOAEL [No Observable Adverse Effect Level] can be derived for the acute effects. (At the time of publication of the EPA document, acute neurotoxicity studies had not been conducted for most pesticide chemicals and for this reason, other default studies were considered.)

2. Prenatal Developmental Toxicity Studies can be used for acute oral assessments as a presumption can be made that developmental effects could result from a single dose exposure. Developmental toxicity studies were considered relevant as the treatment route is oral, a single dose may be administered at a possible critical point in fetal development and a possible relationship between maternal toxicity and developmental effects may be determined.

3. Other studies such as subchronic, chronic, reproductive or carcinogenicity studies conducted via the oral route are considered if any toxicological effects are seen within the first few days of dosing and can be extrapolated to an acute event. This may include human data as the first priority with supportive findings from animal studies.

Although an acute neurotoxicity (ANT) study by the inhalation route (Driscoll and Hurley, 1993) was conducted with methyl bromide, EPA selected an inhalation developmental toxicity study in rabbits as having the most conservative NOAEL for acute inhalation risk assessment. In the ANT study, rats were exposed to methyl bromide concentrations of 0, 30, 100 or 350 ppm for 6 hours. The NOAEL for neurobehavioral effects was 100 ppm.

The developmental toxicity study (Breslin et. al., 1990) was conducted with pregnant New Zealand white rabbits. The rabbits were exposed for six hours/day on gestation days 7 through 19 to methyl bromide concentrations of 0, 20, 40 or 80 ppm. At 80 ppm, maternal toxicity was seen that included decreased body weight gain and clinical signs of neurotoxicity characterized by right-sided head tilt, ataxia, lateral recumbency and lethargy. Developmental effects were only noted in maternally toxic 80 ppm group and consisted of low incidences of omphalocele, hemorrhaging with or without edema, retroesophageal right subclavian artery, gall bladder

[3] http://nepis.epa.gov/Exe/ZyPDF.cgi/901A0000.PDF?Dockey=901A0000.PDF

agenesis and fused sternebrae. The NOAEL for both maternal neurotoxicity and developmental toxicity was 40 ppm.

EPA evaluated 3 acute exposure scenarios in reregistration which included agricultural bystander (ambient 24-hour exposure), greenhouse/structural and commodity bystander and occupational. Methyl bromide log fumigation fits the commodity bystander scenario. As noted previously, EPA conservatively selected the 40 ppm NOAEL from the Breslin study as the endpoint for acute inhalation exposure. The Agency calculated an HEC for the commodity bystander scenario of 40 ppm using methodology similar to that of DAQ and assigned a 30X uncertainty factor (UF) (3X UF for animal to human extrapolation with dosimetric adjustment, and UF 10 for human variability) to this value. Using the approach of DAQ, this results in an Acceptable Ambient Level (AAL) of 1.3 ppm.

B. Short/intermediate term endpoint for risk assessment.

Similarly, EPA evaluated short/intermediate term exposure which is defined as a few days to several weeks of exposure. Two short/intermediate exposure scenarios were evaluated; agricultural bystander and commodity bystander or occupational exposure.

The toxicologic endpoint for this study was selected from 2 subchronic inhalation neurotoxicity study in beagle dogs. In a subchronic (5- to 7-week) inhalation toxicity study (Newton, 1994), methyl bromide (tech., 100% a.i.) was administered 7 hours/day, 5 days/week to 4 beagle dogs/sex/dose by whole body exposure at target concentrations of 0, 5, 10/150, 25, 50 or 100 ppm (actual mean concentrations 0, 5.3, 11.0/158.0, 26.0, 53.1 or 102.7 ppm). The systemic toxicity NOAEL was 26 ppm. The lowest-observed-adverse-effect level (LOAEL) was 53.1 ppm based on decreased activity.

In a six-week nonguideline inhalation toxicity study (Schaeffer et. al, 2002) specifically designed to evaluate neurotoxicity, four groups of beagle dogs consisting of 4 males and 4 females/group were exposed to methyl bromide by whole body exposure at concentrations of 0, 5.3, 10, and 20 ppm. The exposures were for seven hours/day, five days/week for six weeks(total of 30 exposures). The NOAEL was 5.3 ppm and the LOAEL was 10 ppm based on the absence of proprioceptive placing and the increased incidence of feces-findings (soft, mucoid feces, and/or diarrhea).

EPA selected the 5.3 ppm NOAEL from the Schaeffer study as the endpoint for short/intermediate inhalation exposure. The Agency calculated an HEC for the ambient air bystander scenario of 1 ppm and assigned a 30X uncertainty factor (UF) to this value. Using the approach of DAQ, the resultant AAL is 33 ppb for short to intermediate term exposure. The California Department of Pesticide Regulation (CDPR) also conducted risk assessments for short/intermediate scenarios.

V. Critical Data on Carcinogenicity is Available and Should be Considered

The DAQ document indicated that methyl bromide was "not classifiable as to human carcinogenicity." This judgment was based on the results from an inadequate oral gavage study with methyl bromide and ignores more recent and accurate science.

EPA reviewed the chronic toxicity/carcinogenicity studies for methyl bromide via the inhalation route in rats (Reuzel et. al, 1987) and in mice (NTP, 1992). Based on the results of these studies, EPA has classified methyl bromide as a not likely human carcinogen. (USEPA, 2007; USEPA, 2013).

VI. DAQ Applied Unnecessary Uncertainty Factors in Its Risk Assessment

Further, DAQ's derivation of chronic toxicological endpoints used an additional, and unnecessary, 3X uncertainty factor adjustment, not required by the existing data. This error further exacerbates the problems caused by the issues described above. If DAQ attempts to move forward with an appropriate chronic exposure limit (e.g., a one-year average), the uncertainty factor issue described here must also be corrected.

It appears from the Report that DAQ attempted to use a traditional approach to conducting human health risk assessments as used by international regulatory bodies by the application of UFs to the NOAEL derived from appropriately selected toxicity studies in animals. The primary UFs are the **interspecies** uncertainty factor and the **intraspecies** uncertainty factor. The interspecies UF is intended to account for the uncertainty involved in extrapolating from animal data to humans. The intraspecies UF is intended to account for the potential variation in sensitivity among human populations and subpopulations including infants and children. The standard default value for each of these factors is 10x with the standard application of a total 100x applied to acute and chronic dietary risk assessments or an acceptable Margin of Exposure (MOE) of 100 for occupational exposures. But DAQ appears to have chosen to add an additional, and unnecessary, 3x uncertainty factor.

When conducting inhalation risk assessments, however, the magnitude of the UFs applied is dependent on the methodology used to determine the appropriate point of departure. DAQ's assessment used the LOAEL from the chronic/carcinogenicity inhalation study in rats as the point of departure and calculated an inhalation RfC or HEC. Since the RfC methodology takes into consideration many pharmacokinetic (PK) differences but not pharmacodynamic (PD) differences between species, the UF for interspecies extrapolation may be reduced to 3x (to account for the PD differences) while the UF for intraspecies variation is retained at 10x. Thus, the UF when using the RfC methodology is customarily 30x.

Based on the strength, quality and completeness of the data under evaluation, the application of additional UFs may be required. Specific criteria that may necessitate application of additional UFs include:

- Extrapolation from the LOAEL to a surrogate NOAEL, if an appropriate NOAEL is not identified in the toxicology database.

- Extrapolation from subchronic toxicity study results to chronic exposure to derive a chronic reference dose when appropriate chronic studies are not available.

- An uncertainty factor to account for deficiencies or the absence of key studies or data in the database for the chemical under evaluation.

As no NOAEL was identified for the portal of entry effects observed in the chronic/carcinogenicity inhalation study in rats that was used for the long-term inhalation risk assessment, DAQ assigned an additional 3X uncertainty factor consistent with the extrapolation from a LOAEL to a NOAEL. EPA in its chronic inhalation assessment for methyl bromide similarly applied the 3X uncertainty factor as the effects noted at this dose level (3 ppm) were not severe, an uncertainty factor of 3x was applied for the LOAEL to NOAEL extrapolation. It should be noted that the nasal lesions were related to both concentration and duration of exposure. The NOAEL for the nasal lesions was >90 ppm after one year of exposure, 3 ppm after 24 months of exposure and >3 ppm after 29 months of exposure.

At a February 4, 2019 meeting, DAQ requested from the Scientific Advisory Board thoughts and recommendations on the topic of the range of risk as it is referenced in the *NCSAB Risk Assessment Guidelines* document on the prior SAB's webpage (NCSAB 1997a). As a result, the DAQ document states:

> In response to the EMC's desire for a range of risk values, DAQ further recommends a factor of 3 (3 = the square root of an UF = 10) placed on the IRIS chronic RfC as an appropriate adjustment factor to reduce the potential for adverse health effects to the subpopulation that possess the Phase II GSTT1 enzyme variant that predisposes them to increased neurotoxic effects. This could represent a lower bound in range of AAL values that could be considered by the EMC.

The overall DAQ risk assessment strongly concludes that the IRIS chronic RfC represents the most sensitive endpoint of the range of adverse health effects observed in the current methyl bromide inhalation toxicity database. The finding, damage to the olfactory epithelial tissues leading to degenerative and proliferative lesions, is an effect deemed of concern to public health. DAQ recommended that an additional 3X uncertainty factor as related to subpopulation sensitivity related to Phase II GSTT1 enzyme variant and increased potential for neurotoxicity be included in the assessment. The additional 3X UF is unwarranted for the following reasons:

1. A 10X interspecies UF for human variability has been applied to the nasal olfactory effects. This "interspecies" uncertainty factor is specifically applied for the protection of sensitive populations which would include those with the Phase II GSTT1 enzyme variant

2. The concentration inducing nasal effects is protective of neurotoxicity.

The LOAEL for nasal toxicity from the Reuzel study was 3 ppm and an additional 3X uncertainty factor was applied to the LOAEL resulting in an "estimated" NOAEL of 1 ppm. Neurotoxicity is the most common toxic effect for inhalation exposure for methyl bromide with neurotoxic effects seen throughout the database in all tested species. The NOAEL and LOAEL for studies in which neurotoxicity was assessed by validated Functional Observational Battery (FOB) and motor activity procedures or noted by study clinical signs or histopathological findings are summarized in the following table. It is noteworthy that no clinical signs related to neurotoxicity were noted at methyl bromide concentrations up to 90 ppm (highest tested concentration) in the Reuzel study in which the nasal effects were seen and serves as the basis for the chronic risk assessment.

Study (Reference)[4]	**NOAEL (ppm)**	**LOAEL (ppm)**	**Neurotoxic Effects**
Acute neurotoxicity (Driscoll and Hurley, 1993)	100	350	Decreased activity and alertness as measured in a functional observation battery examination, decreased motor activity and decreased body temperature in males and females were observed. A slight decrease in hind-limb grip strength in males may have been treatment-related.
Subchronic neurotoxicity (Norris et al., 1993)	30	70	Increased mortality (2 animals), convulsions (2 animals affected), effects on several FOB parameters and brain histopathology in males.
Developmental toxicity-rabbit (Breslin, 1990)	40	80	Lethargy, right side head tilt, ataxia and lateral recumbency.
Subchronic dog 1 (Schaefer et al., 2002)	5.3	10	Absence of proprioceptive placing in males.
Subchronic dog 2 (Newton, 1994)	26	53.1	Decreased activity.
Mouse oncogenicity (NTP, 1992)	33	100	Mortality (males), neurological signs (abnormal posture, tremors, ataxia, limb paralysis and emaciation.), decreased body weight/weight gain and microscopic lesions in the brain, heart, sternum and olfactory epithelium.
Developmental neurotoxicity-rat(Beck, 2005)	25	50	Decreased motor activity.

As compared to the "estimated" NOAEL for nasal effects (1ppm), the NOAELS for neurotoxicity findings from these studies clearly demonstrate that the 1ppm values is protective

[4] The MBIP can make copies of studies subject to MBIP's copyright protections available to DAQ and the SAB subject to appropriate protections from public release. The MBIP can also provide copies of EPA's Data Evaluation Records for these studies.

of humans, including sensitive humans, from neurotoxicity. Therefore, the recommended addition of a 3X UF to protect subpopulation sensitivity related to Phase II GSTT1 enzyme variant is not necessary.

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