1-BROMOPROPANE PUBLIC MEETING MARCH 30, 2016

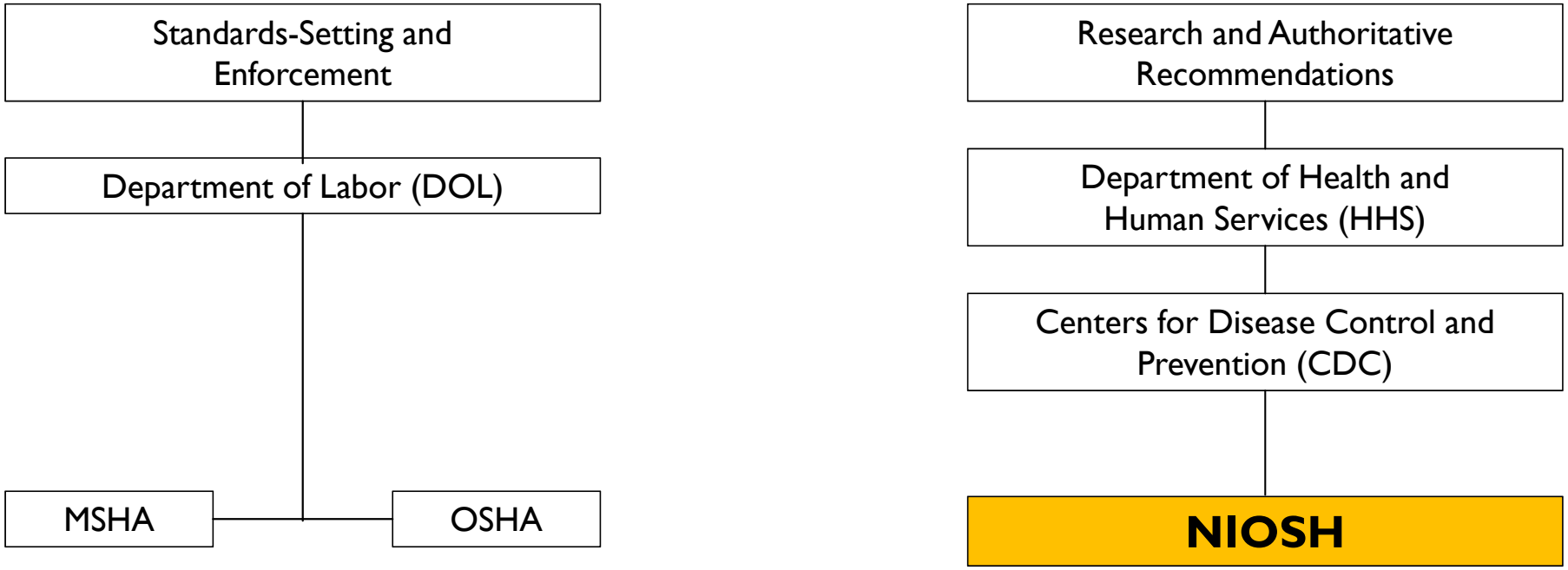
NATIONAL INSTITUTE FOR OCCUPATIONAL SAFETY AND HEALTH

CINCINNATI, OHIO 45226

BACKGROUND OF THE DRAFT CRITERIA DOCUMENT

PAUL SCHULTE, PhD
DIRECTOR
NIOSH/EDUCATION AND INFORMATION DIVISION

OCCUPATIONAL SAFETY AND HEALTH ACT OF 1970



1-BROMOPROPANE (1-BP)

- Increased global attention as a potential alternative for (1) ozone-depleting substances and (2) other regulated chemicals
- Primarily used as an organic solvent
- Increased number of products containing 1-BP in commerce
- The health hazards of 1-BP have been assessed by multiple federal agencies

CONCERNS ABOUT OCCUPATIONAL EXPOSURES TO 1-BP

- Workers produce, use and handle 1-BP and 1-BP-containing materials
- Reports of neurological effects in workers exposed to 1-BP
- On September 16, 2009, NIOSH published in the Federal Register* a request for information and an announcement of its intention to evaluate the scientific data on 1-BP

*Reference: [74 (178) FR 47593]

OSHA – NIOSH HAZARD ALERT (2013)*

- Joint publication between OSHA and NIOSH
- Released to address the growing health concerns of occupational exposures to 1-BP

OSHA • NIOSH

HAZARD ALERT

1-Bromopropane

1-Bromopropane (1-BP) is a solvent that is used in degreasing, dry cleaning, spray adhesives, and aerosol solvents. Occupational exposure to 1-BP has been linked to neurological illnesses. Animal studies show that 1-BP may also cause cancer and reproductive disorders. Controls and personal protective equipment are available to protect workers from 1-BP exposure.

What is 1-Bromopropane?

1-Bromopropane, also known as n-propyl bromide (nPB), is a solvent (CAS 106-94-5) with several commercial applications. Use of 1-BP has increased in workplaces over the past 20 years. 1-BP is often found in products used in:

- Vapor and immersion degreasing operations for cleaning metals, plastics and electronic and optical components;
- Adhesive spray applications;
- Dry cleaning; and
- Solvent sprays used in operations like asphalt production, aircraft maintenance, and synthetic fiber manufacturing.

Photo: CDC/NIOSH

Dry cleaning operation

Health Effects of 1-BP and How Workers Are Exposed

Exposure to 1-BP can cause irritation (for example, of the eyes, mucous membranes, upper airways and skin) and can damage the nervous system. Neurologic effects can appear as headaches, dizziness, loss of consciousness, slurred speech, confusion, difficulty walking, muscle twitching, and/or loss of feeling in arms and legs [Ichihara et al. 2012]. These effects may continue among affected persons even after exposure to 1-BP has ended [Majersik et al. 2007].

As with many other solvents, workers can be exposed to 1-BP by breathing in vapor or mists of spray. Workers might also be exposed if the chemical touches their skin because it can be absorbed [Hanley et al. 2006; Frasch et al. 2011]. Additionally, the risk of health effects to workers increases the longer they work with or near 1-BP. Impacts on health have been seen in workers after exposures for as little as two days, although symptoms are more commonly associated with longer exposure [Ichihara et al. 2012].

Federal OSHA does not currently have a specific exposure standard for 1-BP; however, employers are required by law to keep their workers safe from this recognized hazard. Degreasing, spray adhesive, aerosol solvent and dry cleaning operations expose workers to air concentrations of 1-BP greater than the limits set by the California Occupational Safety and Health Administration (Cal-OSHA) and the American Conference of Governmental Industrial

1-800-321-OSHA (6742) • www.osha.gov 1 1-800-CDC-INFO (1-800-232-4636) • www.cdc.gov/niosh

*Available at: http://www.cdc.gov/niosh/docs/2013-150/pdfs/2013-150.pdf

PURPOSE OF THE DRAFT CRITERIA DOCUMENT

- Summarize the data on occupational exposures and toxicity of 1-BP
- Provide the rationale and justification for a proposed NIOSH recommended exposure limit (REL) for 1-BP
- Provide recommendations for eliminating or reducing occupational exposures to 1-BP

NIOSH DRAFT POLICY DOCUMENT REVIEW PROCESS

Kathleen MacMahon, DVM, MS
Associate Director for Science
NIOSH Education and Information Division

DRAFT POLICY DOCUMENT REVIEW PROCESS

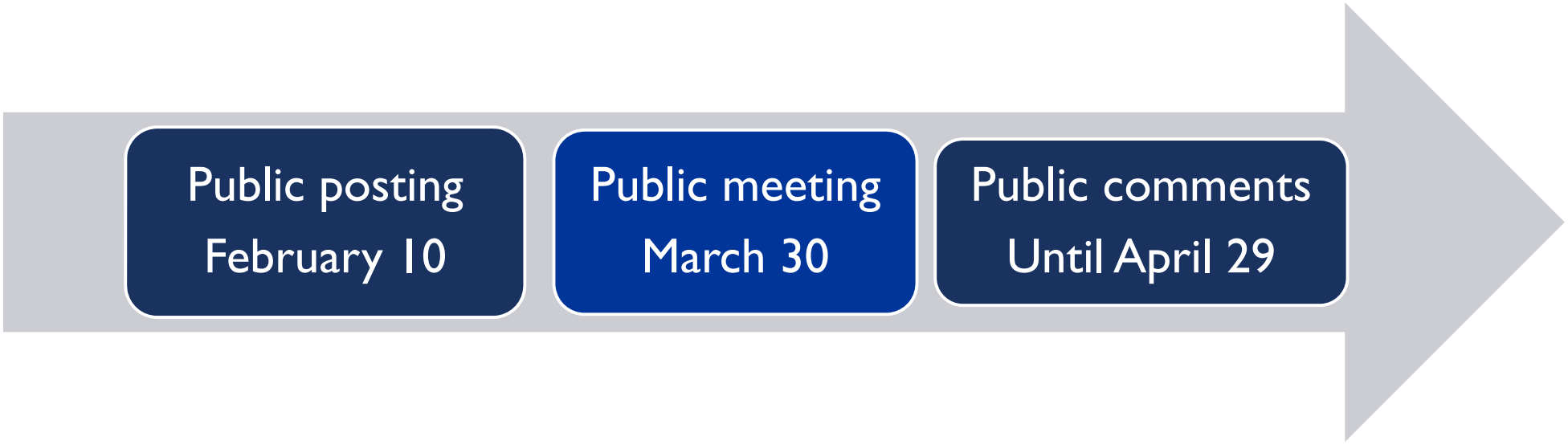
- Transparency
- Documentation
- Consistency

- Obtain variety and balance of viewpoints
  - Labor, industry, other agencies, public

→ Strengthens the assessment

Draft Policy Document Review Process

OPPORTUNITIES FOR PUBLIC INPUT



Public comment period: February 10, 2016 – April 29, 2016

PUBLIC MEETING – MARCH 30, 2016

- NIOSH Presentations
  - Summarize key information
  - Scientific basis for recommendations
- Public Presentations
  - Opportunity for public input

NIOSH DOCKET WEB PAGE

- NIOSH Draft Documents for Public Review
  - http://www.cdc.gov/niosh/review/public/
- NIOSH Docket 057-A
  - **Draft document**
  - **Federal Register notice**
  - **Instructions for submitting public comments**
  - **http://www.cdc.gov/niosh/docket/review/docket057a/default.html**

REGULATIONS.GOV

- To submit public comments
- https://www.regulations.gov/
- Search for CDC-2016-0003
- Comment Now!

PEER REVIEW PROCESS

- Ensure scientific quality, integrity, and credibility
  - Expertise – disciplines related to the draft
  - Balance – balanced range of scientific opinions
  - Independence – not involved with draft development
  - Consider conflicts of interest – real and perceived

PEER REVIEW PROCESS

- NIOSH Peer Review Agenda Web Page
  - http://www.cdc.gov/niosh/review/peer/
- Highly Influential Scientific Assessments
  - http://www.cdc.gov/niosh/review/peer/hisa/propbrom-pr.html
- Charge to peer reviewers – questions for reviewers

Next Steps

External review of draft document

Consider all external review comments

- Respond to comments

Revise draft NIOSH document

- In response to peer and public comments

Final NIOSH review and publication

- Also publish response to external comments

NIOSH CONTACT

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SUBMIT PUBLIC COMMENTS AT REGULATIONS.GOV

- https://www.regulations.gov/
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- Public comments accepted until April 29, 2016

EXECUTIVE SUMMARY OF THE CRITERIA DOCUMENT

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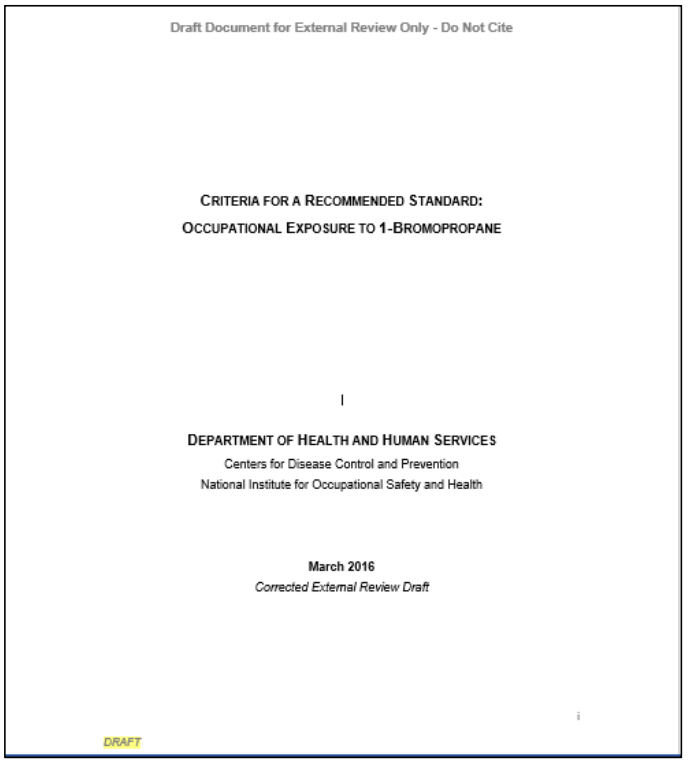
NIOSH/EDUCATION AND INFORMATION DIVISION

DRAFT CRITERIA DOCUMENT CONTENT

- **Background Information**
- **Human Studies and Exposure Assessments**
- **Toxicity**
- Disposition and Toxicokinetics
- Mode of Action
- Quantitative Risk Assessments
- NIOSH Recommendations
- Medical Monitoring
- Exposure Monitoring
- Research Needs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CRITERIA FOR A RECOMMENDED STANDARD:
OCCUPATIONAL EXPOSURE TO 1-BROMOPROPANE

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Centers for Disease Control and Prevention
National Institute for Occupational Safety and Health

March 2016
Corrected External Review Draft

DRAFT

Available at http://www.cdc.gov/niosh/docket/review/docket057a/default.html

BACKGROUND

- Increased usage of 1-BP in the late 20th century as a replacement for ozone-depleting substances and regulated chemicals
- Used as an organic solvent in multiple industrial and commercial applications
- 12-15 millions pounds used produced/imported annually in the United States
- Available data indicate:
  - 2,540 to 9,280 businesses use 1-BP
  - 3,320 to 69,100 potentially exposed workers
  - Largest use is as a vapor degreaser within 500 to 2,500 businesses and 8,300 to 40,300 potentially exposed workers
  - Second largest use is as an adhesive in the manufacturing of foam cushions and laminates estimated to impact 100 to 280 businesses and 400 to 9,800 potentially exposed workers

OCCUPATIONAL EXPOSURE LIMITS

Exposure recommendation	Airborne concentration	Adverse effects (species)
AEL [EPA 2003a]*	25 ppm 8-hour TWA	Decreased sperm motility (rats)
AEL [EPA 2007b]	17–30 ppm 8-hour TWA	Decreased sperm motility (rats)
PEL [CA DIR 2009]	5 ppm 8-hour TWA; skin notation	Reproductive effects in both sexes (rats)
TLV [ACGIH 2005]	10 ppm 8-hour TWA	CNS toxicity; reproductive toxicity (male, female); developmental toxicity
TLV [ACGIH 2014]	0.1 ppm 8-hour TWA	CNS toxicity; male and female reproductive toxicity; developmental toxicity

Abbreviations: AEL = acceptable exposure limit; CNS = central nervous system; ppm = parts per million; PEL = permissible exposure limit; TLV® = threshold limit value; TWA = time-weighted average.
*** = rescinded**

HUMAN STUDIES AND EXPOSURE ASSESSMENTS

- Limited human (epidemiological) and exposure data available
- Criteria Document summarizes available literature including:
  - Six (6) case studies
  - Seven (7) peer reviewed journal articles (epidemiological investigations or exposure assessments)
  - Five (5) NIOSH Health Hazard Evaluations (HHEs)
- Investigations focused on multiple operations including:
  - Foam cushion manufacturing
  - Dry cleaning
  - Vapor degreasing
  - General purpose solvent cleaning

HUMAN STUDIES AND EXPOSURE ASSESSMENTS

- Conclusions of human studies and exposure assessments
  - Limited exposure data in case studies
  - Cross-sectional studies
  - NIOSH HHEs provide exposure data, but limited response data
  - Occupational exposures to 1-BP associated with neurological, reproductive and hematological effects in male and female workers
  - Occupational exposures occur via the inhalation and dermal routes
  - Neurological effects associated with exposures at < 3 ppm (Ichihara et al. 2004)
  - Identification of potential biomarkers of exposure (Hanley et al. 2006, 2009, 2010)

TOXICITY OF 1-BP

- Inhalation, repeat-dose studies (n = >40)

- Noncancer health endpoints
  - Reproductive* and development effects in both sexes
  - Neurological effects (central nervous system [CNS] and peripheral nervous system [PNS])*
  - Hepatological effects
  - Hematological effects*

- Cancer health endpoints
  - Tumors of the lungs
  - Tumors of the skin
  - Tumors of the bowel

*Denotes effects also reported in human studies

CANCER ENDPOINTS

- NTP conducted a 2-year bioassay using multiple rodent species (mice and rats)
  - Inhalation study
- Conclusion of the study:
  - Significant increase in tumors in multiple organ systems
  - Tumors sites:
    - Lung
    - Skin
    - Large bowel

Tumors observed in mice and rats exposed to 1-BP by inhalation.

Tumor endpoints	**Conc.**	**Sample size**	**Results**
Pulmonary adenomas + carcinomas	ppm	No. mice	No. tumors
female B6C3F_1 mice	0	50	1
	62.5	50	9
	125	50	8
	250	50	14
Large intestine adenomas	ppm	No. rats	No. tumors
female F344 rats	0	50	0
	125	50	1
	250	50	2
	500	50	5
Dermal keratoacanthoma	ppm	No. rats	No. tumors
+ squamous cell carcinoma	0	50	1
male F344 rats	125	50	4
	250	50	6
	500	50	8

SUMMARY

- Increased usage of 1-BP in multiple industrial and commercial operations
- Occupational exposures associated with neurological, reproductive and hematological effects in male and female workers
- Experimental in vivo studies reported numerous noncancer health endpoints and increased tumors in multiple organ systems
- Sufficient evidence exists to identify 1-BP as an occupational carcinogen

NIOSH QUANTITATIVE RISK ASSESSMENT FOR 1-BP

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TOXICOLOGIST, RISK EVALUATION BRANCH

NIOSH/EDUCATION AND INFORMATION DIVISION

STUDY

NTP [2011] chronic bioassay

- Two-year inhalation study
  - $B6C3F_1$ mice
  - F344 rats
- Exposure concentrations
  - 0, 62.5, 125, 250 ppm for mice
  - 0, 125, 250, 500 ppm for rats

Tumors observed in mice and rats exposed to 1-BP by inhalation.

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Dermal keratoacanthoma	ppm	No. rats	No. tumors
+ squamous cell carcinoma	0	50	1
male F344 rats	125	50	4
	250	50	6
	500	50	8

METHODS

Dose-response Modeling

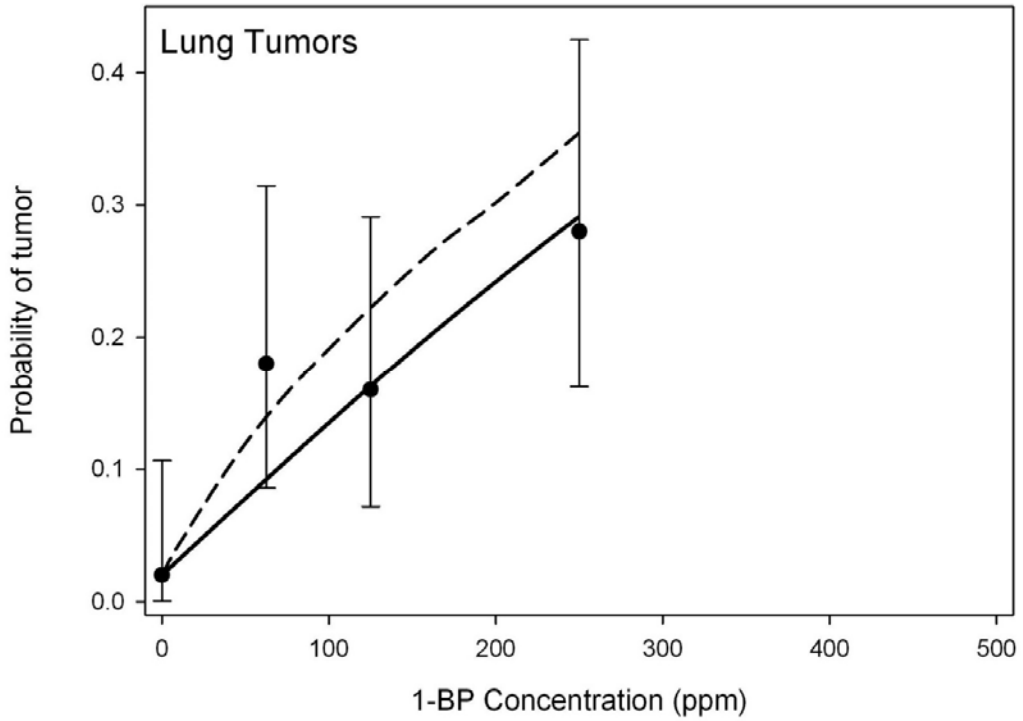
- Benchmark dose modeling
- Model averaging per Wheeler and Bailer [2007]
  - Multistage, log-probit, and Weibull models
  - Models restricted to avoid supralinear behavior
- Benchmark response level 0.1%, or 1 in a 1000 lifetime added risk
- 95% lower bound on BMC (BMCL) via bootstrapping
  - 5000 iterations

METHODS

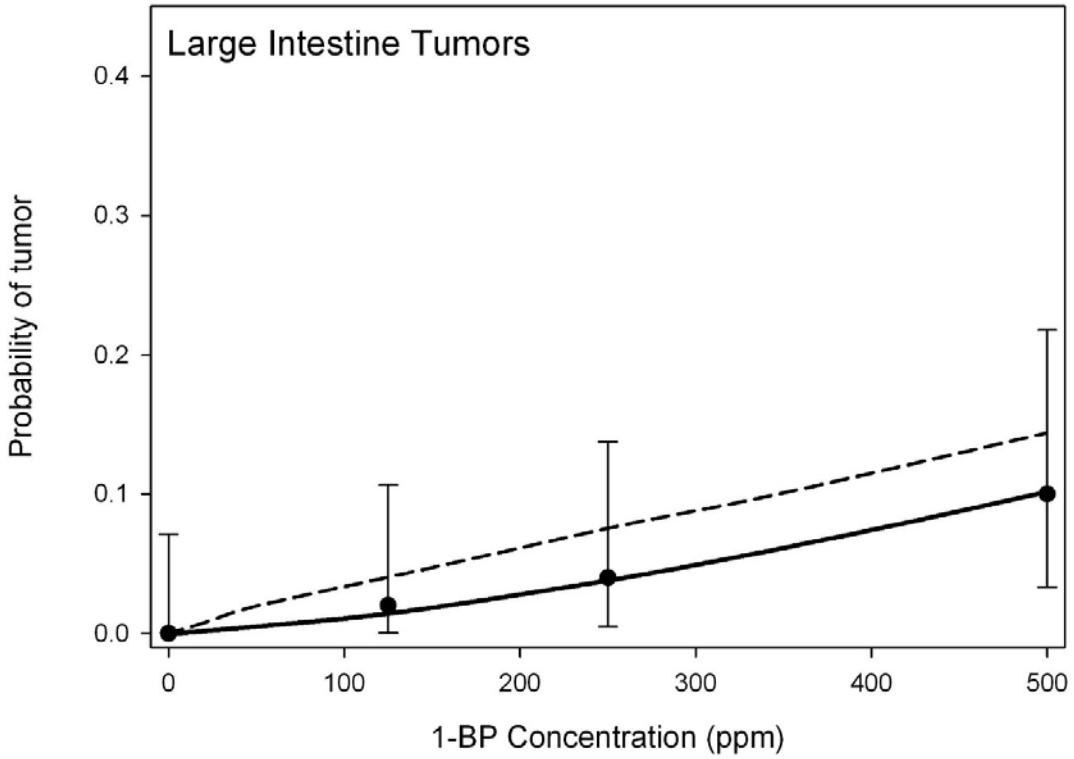
Extrapolation to Human-Equivalent Concentrations

- BMCs/BMCLs converted to mg/kg/day inhaled
  - Assumed body weights and inhalation rates for chronic studies [EPA 1988]
- Extrapolate to humans based on $(\text{body weight})^{0.75}$
  - Human body weight assumed to be 70 kg
- Convert to human-equivalent concentration for occupational exposures
  - Occupational inhalation rate assumed to be 9.6 m^3 per day
  - Lifetime (45-year) occupational exposure is assumed

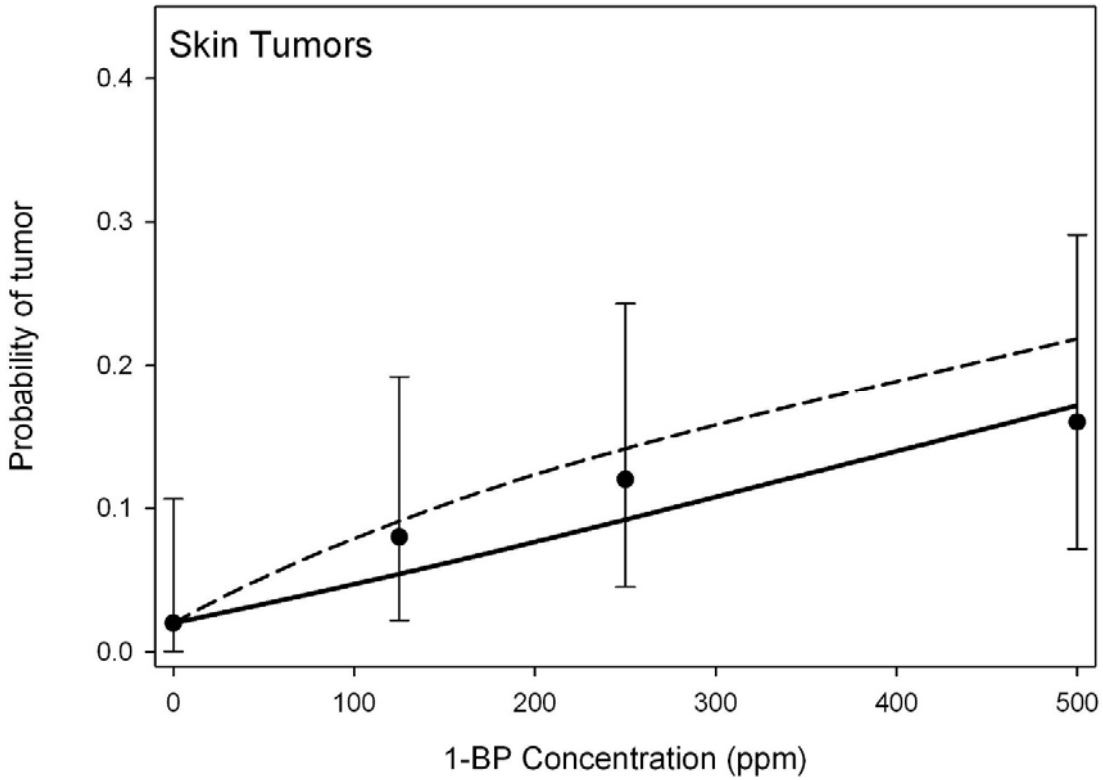
DOSE-RESPONSE MODELING



DOSE-RESPONSE MODELING



DOSE-RESPONSE MODELING



BENCHMARK CONCENTRATIONS

Model average BMC and BMCL estimates for 1-BP tumor endpoints in the NTP [2011] study.
Benchmark response rate = 0.1% added risk

Endpoint	Rodent Strain, Sex	Rodent BMC (ppm)	Rodent BMCL (ppm)
Alveolar/bronchiolar adenoma + carcinoma	B6C3F$_1$, Female	0.85	0.64
Large intestine adenoma	F344, Female	13.5	4.85
Keratoacanthoma +squamous cell carcinoma of skin	F344, Male	3.73	2.25

HUMAN EQUIVALENT CONCENTRATIONS

Human-equivalent BMC and BMCL estimates for 1-BP tumor endpoints in the NTP [2011] study.
Benchmark response rate = 0.1% added risk

Endpoint	Extrapolated Human BMC (ppm)	Extrapolated Human BMCL (ppm)
Alveolar/bronchiolar adenoma + carcinoma	0.39	0.30
Large intestine Adenoma	6.17	2.22
Keratoacanthoma +squamous cell carcinoma of skin	1.75	1.05

CONCLUSIONS

Chronic exposure to 1-BP via inhalation:

- Causes tumors in both mice and rats
- Extrapolated 1 in 1000 risks for occupational exposures = 0.39 ppm (BMC) or 0.30 ppm (BMCL) based on mouse lung tumors
  - Based on an assumed 45-year exposure

NIOSH RECOMMENDATIONS

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- Background Information
- Human Studies and Exposure Assessments
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- Quantitative Risk Assessments
- **Recommended Exposure Limit (REL)**
- Medical Monitoring
- **Exposure Monitoring**
- Research Needs


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PROPOSED NIOSH REL

- 0.3 ppm
  - 8-hour time-weighted average concentration
  - 40-hour workweek
  - Excess risk of 1 in 1,000 associated with a 45-year working lifetime of exposure to 1-BP at the proposed REL
  - Based on results of NIOSH quantitative risk assessment
  - Most sensitive health endpoint – lung cancer in female mice
  - Quantifiable by NIOSH analytical method 1025

PROPOSED NIOSH REL

- Maximum 8-hour TWA concentration of 1-BP to which a worker may be exposed
- Corresponds to the 95% lower confidence limit of 1 in 1,000 excess risk estimate
- The risk limit of 1 in 1,000 is the minimum practical level of protection
- Residual risk of lung cancer and other health effects at the proposed REL
- Exposures should always be kept below 0.3 ppm

NIOSH RECOMMENDATIONS

- All reasonable efforts should be made to reduce worker exposures below the proposed REL through:
  - The use of the hierarchy of controls
  - A comprehensive safety and health program includes:
    - Worker education and training
    - Hazard communication
    - Exposure monitoring
    - Medical monitoring and surveillance

CONTROLLING WORKPLACE EXPOSURES

- Hierarchy of Controls
  - Elimination or substitution
  - Engineering controls
  - Administrative and work practice controls
  - Personal protective equipment (PPE)

- Specific recommendations focus on:
  - Dry cleaning
  - Vapor degreasing

REVISED HAZARD COMMUNICATION STANDARD (2012)*

- OSHA has aligned the Hazard Communication Standard (29 CFR 1910.1200)* with the Globally Harmonized System of Classification and Labeling of Chemicals (GHS)
- Allows for the incorporation of a common and coherent approach to classifying chemicals and communicating hazard information on labels and safety data sheets
- NIOSH has developed GHS designations for 1-BP based on the OSHA HCS
  - Based on data contained in the Criteria Document, seven (7) designations assigned to 1-BP

*29 CFR 1910.1200 available at https://www.osha.gov/dsg/hazcom/standards.html

GHS endpoint	Hazard category [Criteria]	Rationale (Species)	References	Pictogram	Hazard phrase	Signal word
Acute toxicity	Category 4, inhalation [LC_{50} value range: >2,500 and ≤ 20,000]	4-hour LC_{50} value -- 6,957 ppm (rats)	Elf Atochem [1997] Kim et al. [1999b]		Harmful if inhaled	Warning
Eye irritation	Category 2B [Human data demonstrating eye irritation]	Irritation of the eyes and mucous linings (humans)	Ichihara et al. [2004a]		Causes serious eye damage	Warning
Skin irritation	Category 2 [Pronounced variability of response among animals, with very definite positive effects related to chemical exposure]	Erythema and edema (rabbits)	Jacobs et al. [1987] Pálovics [2004]		Causes skin irritation	Warning

GHS endpoint	Hazard category [Criteria]	Rationale (Species)	References	Pictogram	Hazard phrase	Signal word
Carcinogen	Category 1B [Presumed to have carcinogenic potential for humans]	Evidence of multisite tumors occurring following inhalation of 1-BP (rats; mice)	NTP [2011, 2014] Morgan et al. [2011]		May cause cancer via inhalation exposures	Danger
Reproductive	Category 1B [Suspected human reproductive toxicant]	Morphological abnormalities in the reproductive systems of male and female animals Sperm morphological and motility abnormalities; (*Continued*) Irregularities in menstrual cycles (rats; mice; humans)	WIL Research Laboratories [2001] Yamada et al. [2003] Ichihara et al. [2000a, 2004a] Liu et al. [2009] NTP [2001]		May damage fertility or the unborn children via inhalation exposure	Danger

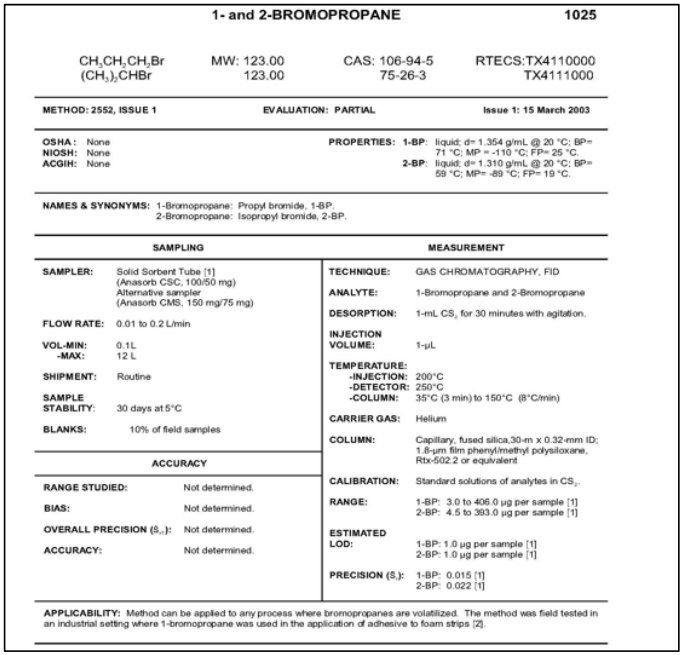
GHS endpoint	Hazard category [Criteria]	Rationale (Species)	References	Pictogram	Hazard phrase	Signal word†
Specific target organ toxicity-repeated exposure	Category 1	Neurotoxicity (rats; mice; humans) Hepatotoxicity (liver) (rats; mice; humans)	Ichihara et al. [2000a, 2004a,b] WIL Research Laboratories [2001] Majersik et al. [2007] Li et al. [2010] ClinTrials BioReasech [1997b] Ichihara et al. [2004b] Li et al. [2010] NTP [2011]		Causes damage to nervous system, liver and blood through prolonged or repeated exposure if inhaled	Danger
Germ cell mutagens	Category 2	Direct acting mutagen in bacteria DNA damage in in vitro assay (human leukocytes)	Barber et al. [1981] Toraason et al. [2006]		Suspected of causing genetic defects	Warning

EXPOSURE MONITORING PROGRAM

- Characterize exposure of all potentially exposed workers
- Identify specific work areas or job tasks where exposures may exceed the proposed REL
- Evaluate the effectiveness of engineering controls, work practices, use of PPE including respirators, and training

SAMPLING FOR 1-BP

- Proposed NIOSH REL is 0.3 ppm as an 8-hour TWA
- Use of NIOSH Manual of Analytical Methods (NMAM) 1025*
  - Solid sorbent tube (Anasorb CSC, 100/50 mg)
  - Flowrate: 0.01 to 0.2 liter/minute
  - Sample personal breathing zone of workers
  - Full shift and task based samples
  - GC-FID



1- and 2-BROMOPROPANE **1025**

$CH_3CH_2CH_2Br$ / $(CH_3)_2CHBr$ — MW: 123.00 / 123.00 — CAS: 106-94-5 / 75-26-3 — RTECS: TX4110000 / TX4111000

METHOD: 2552, ISSUE 1 — **EVALUATION:** PARTIAL — **Issue 1:** 15 March 2003

OSHA: None
NIOSH: None
ACGIH: None

PROPERTIES: **1-BP:** liquid; d= 1.354 g/mL @ 20 °C; BP= 71 °C; MP = -110 °C; FP= 25 °C.
2-BP: liquid; d= 1.310 g/mL @ 20 °C; BP= 59 °C; MP= -89 °C; FP= 19 °C.

NAMES & SYNONYMS: 1-Bromopropane: Propyl bromide, 1-BP.
2-Bromopropane: Isopropyl bromide, 2-BP.

SAMPLING

SAMPLER: Solid Sorbent Tube [1] (Anasorb CSC, 100/50 mg) Alternative sampler (Anasorb CMS, 150 mg/75 mg)
FLOW RATE: 0.01 to 0.2 L/min
VOL-MIN: 0.1L
-MAX: 12 L
SHIPMENT: Routine
SAMPLE STABILITY: 30 days at 5°C
BLANKS: 10% of field samples

ACCURACY

RANGE STUDIED: Not determined.
BIAS: Not determined.
OVERALL PRECISION ($\hat{S}_{rT}$): Not determined.
ACCURACY: Not determined.

MEASUREMENT

TECHNIQUE: GAS CHROMATOGRAPHY, FID
ANALYTE: 1-Bromopropane and 2-Bromopropane
DESORPTION: 1-mL CS_2 for 30 minutes with agitation.
INJECTION VOLUME: 1-µL
TEMPERATURE:
-INJECTION: 200°C
-DETECTOR: 250°C
-COLUMN: 35°C (3 min) to 150°C (8°C/min)
CARRIER GAS: Helium
COLUMN: Capillary, fused silica,30-m x 0.32-mm ID; 1.8-µm film phenylmethyl polysiloxane, Rtx-502.2 or equivalent
CALIBRATION: Standard solutions of analytes in CS_2.
RANGE: 1-BP: 3.0 to 406.0 µg per sample [1]
2-BP: 4.5 to 393.0 µg per sample [1]
ESTIMATED LOD: 1-BP: 1.0 µg per sample [1]
2-BP: 1.0 µg per sample [1]
PRECISION ($\hat{S}_r$): 1-BP: 0.015 [1]
2-BP: 0.022 [1]

APPLICABILITY: Method can be applied to any process where bromopropanes are volatilized. The method was field tested in an industrial setting where 1-bromopropane was used in the application of adhesive to foam strips [2].

*Reference: http://www.cdc.gov/niosh/docs/2003-154/pdfs/1025.pdf

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