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Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade

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Item 5 (a) (i) of the provisional agenda*

Technical work: consideration of draft decision guidance documents: methyl bromide

Draft decision guidance document for methyl bromide

Note by the Secretariat

I. Introduction

1. At its first and eighteenth meetings, the Chemical Review Committee reviewed notifications of final regulatory action for methyl bromide submitted, respectively, by the Kingdom of the Netherlands and Colombia, together with the supporting documentation referred to therein, and concluded that the notifications met all the criteria of Annex II to the Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade.

2. In decision CRC-18/3, the Committee adopted a rationale for its conclusion related to the notification from Colombia and recommended, in accordance with paragraph 6 of Article 5 of the Convention, that the Conference of the Parties list methyl bromide in Annex III to the Convention as a pesticide. By paragraph 4 of that decision, the Committee decided, in accordance with paragraph 1 of Article 7 of the Convention, to prepare a draft decision guidance document for methyl bromide. The rationale for its conclusion that the notification of final regulatory action submitted by the Kingdom of the Netherlands in respect of methyl bromide met the criteria of Annex II to the Rotterdam Convention is set out in part A of annex V to the report of the Chemical Review Committee on the work of its first meeting (UNEP/FAO/RC/CRC.1/28).

3. Pursuant to decision CRC-18/3 and the workplan for the preparation of draft decision guidance documents adopted by the Committee (UNEP/FAO/RC/CRC.18/15, annex III), the intersessional drafting group established at the eighteenth meeting has prepared a draft decision guidance document for methyl bromide, which is set out in the annex to the present note, without formal editing. A compilation of comments relating to the draft decision guidance document received from Committee members and observers, including information on how those comments were addressed, is set out in document UNEP/FAO/RC/CRC.18/INF/4.

II. Proposed action

4. The Committee may wish to finalize the draft decision guidance document and to forward it, together with its recommendation to list methyl bromide in Annex III to the Convention as a pesticide, for consideration by the Conference of the Parties at its twelfth meeting.

* UNEP/FAO/RC/CRC.19/1/Rev.1.

Annex

Draft Decision Guidance Document

Methyl bromide

Rotterdam Convention

Operation of the prior informed consent procedure
for banned or severely restricted chemicals

Secretariat of the Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade

Introduction

The objective of the Rotterdam Convention is to promote shared responsibility and cooperative efforts among Parties in the international trade of certain hazardous chemicals in order to protect human health and the environment from potential harm and to contribute to their environmentally sound use, by facilitating information exchange about their characteristics, by providing for a national decision-making process on their import and export and by disseminating these decisions to Parties. The Secretariat of the Convention is provided jointly by the United Nations Environment Programme (UNEP) and the Food and Agriculture Organization of the United Nations (FAO).

Candidate chemicals[1] for inclusion in the prior informed consent (PIC) procedure under the Rotterdam Convention include those that have been banned or severely restricted by national regulatory actions in two or more Parties[2] in two different regions. Inclusion of a chemical in the PIC procedure is based on regulatory actions taken by Parties that have addressed the risks associated with the chemical by banning or severely restricting it. Other ways might be available to control or reduce such risks. Inclusion does not, however, imply that all Parties to the Convention have banned or severely restricted the chemical. For each chemical included in Annex III of the Rotterdam Convention and subject to the PIC procedure, Parties are requested to make an informed decision whether they consent or not to the future import of the chemical.

At its […] meeting, held in […] on […], the Conference of the Parties agreed to list methyl bromide in Annex III of the Convention and adopted the decision-guidance document with the effect that this chemical became subject to the PIC procedure.

The present decision-guidance document was communicated to designated national authorities on […], in accordance with Articles 7 and 10 of the Rotterdam Convention.

Purpose of the decision guidance document

For each chemical included in Annex III to the Rotterdam Convention, a decision-guidance document has been approved by the Conference of the Parties. Decision-guidance documents are sent to all Parties with a request that they make a decision regarding future import of the chemical.

Decision-guidance documents are prepared by the Chemical Review Committee. The Committee is a group of government-designated experts established in line with Article 18 of the Convention, which evaluates candidate chemicals for possible inclusion in Annex III of the Convention. Decision-guidance documents reflect the information provided by two or more Parties in support of their national regulatory actions to ban or severely restrict the chemical. They are not intended as the only source of information on a chemical nor are they updated or revised following their adoption by the Conference of the Parties.

There may be additional Parties that have taken regulatory actions to ban or severely restrict the chemical and others that have not banned or severely restricted it. Risk evaluations or information on alternative risk mitigation measures submitted by such Parties may be found on the Rotterdam Convention website (www.pic.int).

Under Article 14 of the Convention, Parties can exchange scientific, technical, economic and legal information concerning the chemicals under the scope of the Convention including toxicological, ecotoxicological and safety information. This information may be provided directly to other Parties or through the Secretariat. Information provided to the Secretariat will be posted on the Rotterdam Convention website.

Information on the chemical may also be available from other sources.

[1] According to the Convention, the term “chemical” means a substance, whether by itself or in a mixture or preparation and whether manufactured or obtained from nature, but does not include any living organism. It consists of the following categories: pesticide (including severely hazardous pesticide formulations) and industrial.

[2] According to the Convention, the term “Party” means a State or regional economic integration organization that has consented to be bound by the Convention and for which the Convention is in force.

Disclaimer

The use of trade names in the present document is primarily intended to facilitate the correct identification of the chemical. It is not intended to imply any approval or disapproval of any particular company. As it is not possible to include all trade names presently in use, only a number of commonly used and published trade names have been included in the document.

While the information provided is believed to be accurate according to data available at the time of preparation of the present decision-guidance document, FAO and UNEP disclaim any responsibility for omissions or any consequences that may arise there from. Neither FAO nor UNEP shall be liable for any injury, loss, damage or prejudice of any kind that may be suffered as a result of importing or prohibiting the import of this chemical.

The designations employed and the presentation of material in this publication do not imply the expression of any opinion whatsoever on the part of FAO or UNEP concerning the legal status of any country, territory, city or area or of its authorities or concerning the delimitation of its frontiers or boundaries.

Standard core set of abbreviations

STANDARD CORE SET OF ABBREVIATIONS	
<	less than
≤	less than or equal to
>	greater than
≥	greater than or equal to
µg	microgram
AAC	Acceptable Air Concentration
ADR	transport of dangerous goods by road
ArfD	acute reference dose
ADI	acceptable daily intake
bw	body weight
°C	degree Celsius (centigrade)
CAS	Chemical Abstracts Service
CAC	Codex Alimentarius Commission
CCPR	Codex Committee on Pesticide Residues
cm	centimetre
cP	centipoise
Ctgb	Dutch Board for the Authorisation of plant protection products and biocides (in Dutch: College voor de toelating van gewasbeschermingsmiddelen en biociden)
CXLs	codex maximum residue levels
DT_{50}	dissipation time 50%
EC	European Community
ECNC	Estimated Concentration of No Concern
EC_{50}	median effective concentration
EU	European Union
FAO	Food and Agriculture Organization of the United Nations
g	gram
GLs	guideline levels
h	hour
ha	hectare
IARC	International Agency for Research on Cancer
IATA	International Air Transport Association
ILO	International Labour Organization
IMDG	International Maritime Dangerous Goods
IPCS	International Programme on Chemical Safety
IPPC	International Plant Protection Convention
IUPAC	International Union of Pure and Applied Chemistry
JMPR	Joint FAO/WHO Meeting on Pesticide Residues (Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and a WHO Expert Group on Pesticide Residues)

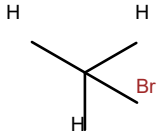
STANDARD CORE SET OF ABBREVIATIONS

kg	kilogram
Koc	soil organic carbon-water partition coefficient.
Kow	octanol–water partition coefficient
kPa	kilopascal
L	litre
LC_{50}	median lethal concentration
LD_{50}	median lethal dose
LOAEL	lowest-observed-adverse-effect level
LOEL	lowest-observed-effect level
MB	methyl bromide
MBTOC	Methyl Bromide Technical Options Committee
mg	milligram
ml	millilitre
mmHg	millimeter mercury
MRL	maximum residue limit
ng	nanogram
NOAEL	no-observed-adverse-effect level
NOEC	no-observed-effect concentration
NOEL	no-observed-effect level
OECD	Organisation for Economic Co-operation and Development
PEC	predicted environmental concentration
Pow	octanol-water partition coefficient, also referred to as Kow
PPDB	Pesticides Properties DataBase
ppm	parts per million (used only with reference to the concentration of a pesticide in an experimental diet. In all other contexts the terms mg/kg or mg/L are used).
QPS	Quarantine and Pre-shipment
QPSTF	Quarantine and Pre-shipment Task Force
RfD	reference dose (for chronic oral exposure; comparable to ADI)
RID	regulation concerning the international carriage of dangerous goods by rail
TEAP	Technology and Economic Assessment Panel
TWA	time-weighed average
UNEP	United Nations Environment Programme
USEPA	United States Environmental Protection Agency
UV	ultraviolet
WHO	World Health Organization
wt	weight

Decision guidance document for a banned or severely restricted chemical

Methyl bromide **Published:**

1. Identification and uses (see annex 1 to the decision guidance document for further details)

Common name	Methyl bromide
Chemical name and other names or synonyms	IUPAC: Bromomethane Synonym: Monobromomethane
Molecular formula	CH_3Br
Chemical structure	
CAS-No.(s)	74-83-9
Harmonized System Customs Code	2903.61 (Methyl bromide, Bromomethane) 3827.40 (Formulations containing methyl bromide)
Other numbers	EC number 200-813-2 InChIKey: GZUXJHMPEANEGY-UHFFFAOYSA-N InChI: InChI=1S/CH3Br/c1-2/h1H3 (Source: http://www.bcpcpesticidecompendium.org)
Category	Pesticide
Regulated category	Pesticide
Use(s) in regulated category	In Colombia methyl bromide was used as a soil fumigant. The use of gaseous formulations of methyl bromide is still allowed for quarantine treatment in the control of quarantine pests in agricultural products and packaging at ports and border crossings. Use of authorized and airtight fumigation chambers is required. In the Netherlands methyl bromide was used as a fungicide and as a soil disinfectant (fungicide/nematicide). Space fumigation in gasproof rooms is still allowed[3].
Trade names	Dowfume; Halon 1001; M-B-R98; AB-01916; Bercema; Tri-Brom-Methyl-Bromide-Rodent-Fumigant; Brom-O-Sol; Caswell-No-555; Curafume; Detia Gas Ex-M; Dowfume MC-2; Dowfume MC-33 Dowfume MC-2 Soil Fumigant; Edco; Embafume; EPA-Pesticide-Cbemical-Code-053201; M-B-C Fumigant; Brom-O-Gas; Brom-O-Gas Methyl Bromide Soil Fumigant; Haltox; Iscobrome; Kayafume; MB; MBC-Soil-Fumigant; MBC-33 Soil Fumigant; MBX; Dowfume MC-2R; Dowfume MC-2 Fumigant; MEBR; Metabrom; Meth-O-Gas; Methogas; Superior Methyl Bromide-2; Metbyl-fume; Pestmaster; Pestmaster Soil Fumigant; Drexel-Plant-Bed-Gas; Rotox; Terabol; Terr-O-Gas; Zytox(HSDB); Celfume; Dawson 100; Metafume; Profume; R 40B l; RCRA wast number U029; Terr-O-Cide; Terr-0-Gas 67; Terr-O-Gas 100 (RTECS); Brozone; Isobrome, Mebrom 100, Desbrom, MBR-2, Methybrom, Methyl-o-gas, Sobrom 9B. This is an indicative list of trade names. It is not intended to be exhaustive.
Formulation types	Formulations include mixtures with other fumigants, most frequently with chloropicrin or hydrocarbons, as inert diluents. Chloropicrin (2%) or amyl acetate (0.3%) are added to methyl bromide to serve as a warning agent. Example of formulations with chloropicrin: Bromopic, Sobrom 67, Terr-o-gas (80-30%, with decreasing methyl bromide and increasing chloropicrin content) (IPCS, 1995).

[3] According to the supporting documentation provided by the Netherlands in 2005 (UNEP/FAO/RC/CRC.1/18/Add.2) the use of methyl bromide as space fumigant was still authorized in 2005. In 2009 the last authorization in the Netherlands for the use of methyl bromide in space fumigations was withdrawn by the Dutch Board for the Authorisation of plant protection products and biocides (Ctgb, 2023).

Uses in other categories	Use as a chemical intermediate in the manufacture of various industrial chemicals, including pesticides (UNEP, 1994).
Basic manufacturers	Dow, Intech Organics Ltd., Sarthi Chem Pvt. Ltd., Mebrom. This is an indicative list of current and former manufacturers. It is not intended to be exhaustive.

2. Reasons for inclusion in the PIC procedure

Methyl bromide is included in the PIC procedure as a pesticide. It has been listed on the basis of the final regulatory actions to severely restrict its use, notified by Colombia and the Netherlands. Contact details of the designated national authorities of these two Parties are set out in annex 3 to the decision guidance document.

2.1 Final regulatory action (see annex 2 to the decision guidance document for further details)

Colombia

Resolution 2152 of 1996 of the Ministry of Health and Social Protection of Colombia severely restricted methyl bromide and authorizes the import, commercialization and use of methyl bromide, only for quarantine treatment for control of exotic pests in fresh plant tissues at the port and border crossing level, until a viable substitute is found that allows its replacement. Its application must be airtight and with a closed pesticide recovery system.

Amendments were made to Article 1 of resolution 2152 in order to make a more controlled and restrictive use of methyl bromide by Resolutions 00643 of 2004, 01800 of 2006, 03587 of 2008 and the Resolution 5049 of 2008. The notification indicates that Resolution 2152 of 1996 and Resolution 5049 of 2008 are currently in force.

Resolution 5049 of 2008 further severely restricts the import, commercialization and use of methyl bromide. Due to the further restriction methyl bromide can only be used in quarantine treatment for the control of quarantine pests in agricultural products and wood packaging at the level of influence zones established within a maximum radius of ten (10) kilometres from the port and/or border crossing. The fumigation has to be carried out in authorized airtight chambers.

(UNEP/FAO/RC/CRC.18/10, Section 2.2.1)

Reason: Human Health and Environment

Netherlands

In 1981, the use of methyl bromide as a soil disinfectant was prohibited. Based on Article 16a of the Dutch Pesticide Law of 1962, an exemption could be granted based on individual requests. In 1992 methyl bromide was completely banned for use as a soil disinfectant.

Only the uses as space fumigant in gas proof rooms is still allowed[4].

(UNEP/FAO/RC/CRC.1/18/Add.2, Section 2.2.1 and 1.7.1)

Reason: Human Health and Environment

2.2 Risk evaluation (see annex 1 to the decision guidance document for further details)

Colombia

According to the evaluation related to human health the following information was identified:

(a) Methyl bromide is an irritating and vesicant gas, extremely toxic to humans that affects different organs and systems, with high potential risks of producing acute poisoning by inhalation and absorption through the skin and mucous membranes.

(b) Methyl bromide was included in the Montreal Protocol as an ozone depleting substance under the Copenhagen Amendment (1992).

(c) Reducing the use of methyl bromide in Colombia, will contribute to the reduction of emissions of an ozone layer depletory agent and, indirectly, to reducing the risk of skin cancer by increased solar radiation. This was supported by the 1989 report of the Montreal Protocol Environmental Effect Assessment Panel, which defines that "skin cancer will increase with any increase in UV-B radiation, the relationship between skin cancer and ozone decrease is not one to one. For every 1% decrease of the total ozone will result in a 3% increase in the incidence of melanoma or skin cancer". It has also

[4] According to the supporting documentation provided by the Netherlands in 2005 (UNEP/FAO/RC/CRC.1/18/Add.2) the use of methyl bromide as space fumigant was still authorized in 2005. In 2009 the last authorization in the Netherlands for the use of methyl bromide in space fumigations was withdrawn by the Dutch Board for the Authorisation of plant protection products and biocides (Ctgb, 2023).

been identified that the incidence of cataracts and the severity of different infections has been increased since the immune system is suppressed from radiation.

(d) The quantities of methyl bromide used in Colombia in 1994 as soil fumigant for certain crops were reported (at least 32 000 kg). This use was identified as an important source of emission into the environment because a predictive theoretical analysis explained in the UNEP 1992 Report (Albritton and Watson, 1992) and the UNEP 1994 report on Scientific Assessments of Ozone Depletion identified that between 45 and 53% of the amount used in agricultural activities could be released into the atmosphere.

Consequently, the elimination of the use of methyl bromide as soil fumigant will contribute to the reduction of incidence of skin cancer and other diseases related to ozone depletion.

According to the evaluation related to the environment the following information was identified:

(a) Methyl bromide was included in the Montreal Protocol as an ozone depleting substance under the Copenhagen Amendment.

(b) The quantities of methyl bromide used in Colombia in 1994 as soil fumigant for certain crops were reported. This use was identified as an important source of emission into the environment because a predictive theoretical analysis explained in the 1992 and 1994 UNEP reports identified that between 45 and 53% of the amount used in agricultural activities could be released to the atmosphere.

Consequently, the elimination of the use of methyl bromide as soil fumigant will contribute to the reduction of the destruction of the ozone layer.

Netherlands

According to the evaluation related to human health the following information was identified:

(a) The risk evaluation by the Netherlands focussed on the behaviour and effects of methyl bromide in air, groundwater and surface water. It took into account all relevant data on the substance concerning the physico-chemical data, among others the ozone depletion potential, and data on the leaching potential, i.e. sorption and soil degradation.

(b) Concerns that methyl bromide could leach to groundwater and surface water. Both types of water resources are used for the abstraction of water intended for the production of drinking water.

(c) Estimated concentration in groundwater amounted to 100 µg/L. Groundwater should be free of pesticides based on the precautionary principle.

(d) Concerns about the ozone depletion potential of methyl bromide.

(e) Concerns about safety aspects related to storage, transport and use (for general population and workers).

According to the evaluation related to the environment the following information was identified:

(a) The risk evaluation by the Netherlands focussed on the behaviour and effects of methyl bromide in air, groundwater and surface water. It took into account all relevant data on the substance concerning the physico-chemical data, among others the ozone depletion potential, data on the leaching potential, i.e. sorption and soil degradation, and data on the ecotoxicological effects of methyl bromide, e.g. the toxicity to fish.

(b) The measured concentrations in surface water amounted to approximately 9 mg/L, therefore a very high risk for fish was expected.

3. Protective measures that have been applied concerning the chemical

3.1 Regulatory measures to reduce exposure

Colombia

Methyl bromide was severely restricted by Resolution 2152 of 1996 which was further restricted by Resolution 5049 of 2008 indicating that methyl bromide can only be imported, commercialized and used for the purpose of quarantine treatment for the control of quarantine pests in agricultural products and wood packaging at the level of influence zones established within a maximum radius of ten (10) kilometres from the port and/or border crossing. The fumigation has to be carried out in authorized airtight chambers.

Netherlands

In 1981, the use of methyl bromide as a soil disinfectant was prohibited. Based on Article 16a of the Dutch Pesticide Law of 1962, an exemption could be granted based on individual requests. In 1992 methyl bromide was completely banned for use as a soil disinfectant.

Only the uses as space fumigant in gas proof rooms is still allowed[5].

3.2 Other measures to reduce exposure

Colombia

None reported.

Netherlands
None reported.

3.3 Alternatives

Colombia

The following information on alternatives was made available:

For quarantine treatments, the following alternatives are currently used:

- Hot steam treatment (T106-e) for yellow pitahaya fruit and tommy atkins mango infested with eggs and larvae of the Mediterranean fruit fly (*Ceratitis capitata* Wiedeman).
- Cold quarantine treatment (T107-a-1) as a mitigation measure of *Anastrepha fraterculus* in feijoa fruits.

For quarantine treatments, the following alternatives are currently tested:

- Evaluation and quality testing of phosphine have been performed on basil and feijoa.

(UNEP/FAO/RC/CRC.18/10, Section 2.5.3.2)

Netherlands

No information on alternatives was made available.

General

The assessment of alternatives to methyl bromide is an important topic under the Montreal Protocol and is dealt with by the Methyl Bromide Technical Options Committee (MBTOC). MBTOC is a committee of experts of the Technology and Economic Assessment Panel (TEAP) and was established by the Parties to the Montreal Protocol. MBTOC identifies existing and potential alternatives to methyl bromide (MB). It addresses the technical feasibility of chemical and non-chemical alternatives for the uses as a soil fumigant; as a fumigant of durable commodities and structures; and as a fumigant for Quarantine and Pre-shipment (QPS). The MBTOC published reports in 2002 and 2018 (UNEP, 2002 and UNEP, 2018).

TEAP set up a Quarantine and Pre-shipment Task Force (QPSTF). TEAP, in consultation with the International Plant Protection Convention (IPPC) secretariat, reviewed all relevant, currently available information on the use of methyl bromide for Quarantine and Pre-shipment (QPS) applications and related emissions, to assess trends in the major uses, available alternatives, other mitigation options and barriers to the adoption of alternatives, and determine what additional information or action may be required to meet those objectives to further protect the stratospheric ozone layer. QPSTF published the final report in 2009 (UNEP, 2009).

The International Plant Protection Convention (IPPC) published recommendations on the replacement or reduction of the use of methyl bromide as a phytosanitary measure (IPPC, 2017).

FAO published a manual on alternatives to replace methyl bromide for soil-borne pest control in East and Central Europe (FAO, 2008).

The Australian Pesticides and Veterinary Medicines Authority (APVMA) has registered in 2022 a new soil fumigant containing iodomethane, which is intended to replace soil fumigation using methyl bromide (APVMA, 2022).

[5] According to the supporting documentation provided by the Netherlands in 2005 (UNEP/FAO/RC/CRC.1/18/Add.2) the use of methyl bromide as space fumigant was still authorized in 2005. In 2009 the last authorization in the Netherlands for the use of methyl bromide in space fumigations was withdrawn by the Dutch Board for the Authorisation of plant protection products and biocides (Ctgb, 2023).

3.4 Socio-economic effects

Colombia

No assessment of socio-economic effects was reported.

Netherlands

No assessment of socio-economic effects was reported.

4. Hazards and Risks to human health and the environment

4.1 Hazard Classification

WHO	Fumigant, not classified
IARC	Group 3 carcinogen (not classifiable)
European Union	According to the harmonised classification and labelling (ATP02) approved by the European Union, this substance is classified as follows (ECHA, Substance Infocard). Press. Gas Acute Tox. 3, H301 – Toxic if swallowed. Skin Irrit. 2, H315 – Causes skin irritation Eye Irrit. 2, H319 – Causes serious eye irritation Acute Tox. 3, H331 – Toxic if inhaled STOT SE 3, H335 – May cause respiratory irritation Muta. 2, H341 – Suspected of causing genetic defects STOT RE 2, H373 – May cause damage to organs through prolonged or repeated exposure Aquatic acute 1, H400 – Very toxic to aquatic life (Acute M = 100). Ozone 1, H420 – Harms public health and the environment by destroying ozone in the upper atmosphere.
US EPA	Highly toxic (EPA, 2000)

4.2 Exposure limits

US EPA

Chronic ADI 0.0014 mg/kg bw/day

Subchronic RfD 0.014 mg/kg bw/day

Chronic RfD 0.0014 mg/kg bw/day

Subchronic inhalation RfD 0.076 mg/kg bw/day

Chronic inhalation RfD 0.0076 mg/kg bw/day

(EPA, 2007)

EFSA

ADI 0.001 mg/kg bw/day

ARfD 0.003 mg/kg bw

Acceptable Air Concentration (AAC) – single 2.7 ppm

Acceptable Air Concentration (AAC) – repeat 0.08 ppm

Acceptable Air Concentration (AAC) – continuous 0.025 ppm

(EFSA, 2011)

Drinking water values

USA: New York State: 5 µg/L (EPA, 1998)

4.3 Packaging and labelling

The United Nations Committee of Experts on the Transportation of Dangerous Goods classifies the chemical in:

Hazard Class and Packing Group:	UN Number 1062 UN Hazard Class: 2.3 Source: https://www.inchem.org/documents/icsc/icsc/eics0109.htm
UN shipping names	ADR/RID/IMDG: METHYL BROMIDE IATA: Methyl bromide (SDS, 2021)

International Maritime Dangerous Goods (IMDG) labelling	The marine pollutant mark is required when transported in sizes of >5 L or >5 kg  (IMO, 2012)
Transport Emergency Card	Methyl-Bromide-Safety-Handbook.pdf (iclgroupv2.s3.amazonaws.com)

Further specific guidance on appropriate symbols and label statements applicable for methyl bromide products may be available in the FAO/WHO *Guidelines on Good Labelling Practice for Pesticides* (FAO, 2015).

4.4 First aid

NOTE: The following advice is based on information available from the World Health Organisation and the notifying countries and was correct at the time of publication. This advice is provided for information only and is not intended to supersede any national first aid protocols.

International Chemical Safety Cards (ICSCs): ICSC 0109 - METHYL BROMIDE (ilo.org).

Description of first aid measures

Strict hygiene! In all cases consult a doctor! First aid: use personal protection			
	Symptoms	**Prevention**	**First Aid**
Inhalation	Cough. Sore throat. Dizziness. Headache. Abdominal pain. Vomiting. Weakness. Shortness of breath. Confusion. Hallucinations. Loss of speech. Incoordination. Convulsions. Symptoms may be delayed. See Notes.	Use ventilation, local exhaust or breathing protection	Fresh air, rest. Half-upright position. Artificial respiration may be needed. Refer immediately for medical attention.
Skin	MAY BE ABSORBED! Tingling sensation. Itching. Burning sensation. Redness. Blisters. Pain. ON CONTACT WITH LIQUID: FROSTBITE. Further see Inhalation.	Cold-insulating gloves. Protective clothing.	Rinse skin with plenty of water or shower. ON FROSTBITE: rinse with plenty of water, do NOT remove clothes. Refer immediately for medical attention.
Eyes	Redness. Pain. Blurred vision. Temporary loss of vision.	Wear safety goggles, face shield or eye protection in combination with breathing protection	Rinse with plenty of water (remove contact lenses if easily possible). Refer immediately for medical attention
Ingestion			

Fire-Fighting Measures

	Acute Hazards	**Prevention**	**Fire Fighting**
Fire & Explosion	Combustible under specific conditions. Gives off irritating or toxic fumes (or gases) in a fire. Risk of fire and explosion on contact with aluminium, zinc, magnesium or oxygen.	NO open flames. NO contact with aluminium, zinc, magnesium or pure oxygen	Shut off supply; if not possible and no risk to surroundings, let the fire burn itself out. In other cases extinguish with appropriate extinguishing agent. In case of fire: keep cylinder cool by spraying with water

Spillage disposal:

Evacuate danger area! Consult an expert! Personal protection: complete protective clothing including self-contained breathing apparatus. Ventilation. NEVER direct water jet on liquid.

Storage:

Fireproof if in building. Separated from strong oxidants, aluminium and cylinders containing oxygen. Cool. Ventilation along the floor.

Routes of exposure

The substance can be absorbed into the body by inhalation and through the skin also as a vapour.

Effects of short-term exposure

The substance, as a liquid, is severely irritating to the skin. The substance, as a liquid, is irritating to the eyes and respiratory tract. Inhalation may cause lung oedema. See Notes. Rapid evaporation of the liquid may cause frostbite. The substance may cause effects on the central nervous system and kidneys. The effects may be delayed up to 48 hours. Exposure at high levels could cause death. Medical observation is indicated.

Inhalation risk

A harmful concentration of this gas in the air will be reached very quickly on loss of containment.

Effects of long-term or repeated exposure

The substance may have effects on the nervous system, kidneys and liver. This may result in impaired functions. Animal tests show that this substance possibly causes toxicity to human reproduction or development.

Occupational exposure limits

TLV: 1 ppm as TWA; (skin); A4 (not classifiable as a human carcinogen).
MAK: peak limitation category: I(2); carcinogen category: 3; pregnancy risk group: C.

Environment

The substance is toxic to aquatic organisms. Avoid release to the environment because of its impact on the ozone layer. This substance does enter the environment under normal use. Great care, however, should be taken to avoid any additional release, for example through inappropriate disposal.

Notes

Depending on the degree of exposure, periodic medical examination is suggested.
The symptoms of lung oedema often do not become manifest until a few hours have passed and they are aggravated by physical effort. Rest and medical observation are therefore essential.
Toxic effects on the nervous system may be delayed for several hours.
Immediate administration of an appropriate inhalation therapy by a doctor, or by an authorized person, should be considered.
Turn leaking cylinder with the leak up to prevent escape of gas in liquid state.

4.5 Waste management

Regulatory actions to ban a chemical should not result in creation of a stockpile requiring waste disposal. For guidance on how to avoid creating stockpiles of obsolete pesticides the following guidelines are available: FAO *Guidelines on Prevention of Accumulation of Obsolete Pesticide Stocks (FAO, 1995), The Pesticide Storage and Stock Control Manual (FAO, 1996a) and Guidelines for the management of small quantities of unwanted and obsolete pesticides (FAO, 1999)*.

In all cases waste should be disposed of in accordance with the provisions of the Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and Their Disposal (1996), any guidelines thereunder, and any other relevant regional agreements.

The waste code for methyl bromide according to the European Waste Catalogue is 160504*: Gases in pressure containers (including halons) containing dangerous substances.

Methyl bromide is a gas that is provided in cylinder. Unused product in cylinder should be returned to supplier. Supplier should be contacted if guidance is required.

Must not be discharged to the atmosphere.

Large quantities must be incinerated through safe and efficient methods such as appropriate combustion chambers.

Disposal of fumigant products containing bromomethane, equipment washwaters, or rinsate must not contaminate or be released to water as this pesticide is toxic to mammals and birds. (Toxicological Profile for Bromomethane (cdc.gov).

Spills may accumulate in lowered spaces as this gas is heavier than air; disposal of spills by trained experts includes personal protection requiring complete protective clothing and self-contained breathing apparatus;

ventilation is critical, and a direct water jet should never be used on spills containing bromomethane (Toxicological Profile for Bromomethane (cdc.gov).

5. References

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Annexes to the decision guidance document

Annex 1 to the decision guidance document - Further information on methyl bromide

The information presented in this annex reflects the conclusions of the notifying Parties: Colombia and the Netherlands. The notification from Colombia was published in PIC Circular LII of December 2020. The notification from the Netherlands was published for the first time in PIC Circular XV of June 2002. A second notification replacing the first one was made available at CRC1 in the following document: UNEP/FAO/RC/CRC.1/18/Add.2.

The presented physico-chemical properties are taken from both notifications. Where possible, information on hazards provided by the notifying parties has been presented together, while the evaluation of the risks, specific to the conditions prevailing in the notifying Parties are presented separately. This information has been taken from the notifications of the final regulatory actions to ban methyl bromide and the supporting documents.

Furthermore, information from the IARC Monographs on the identification of carcinogenic hazards to human volume 71 and the OECD Screening Information Dataset of 2001 has been taken into account.

1. Physico-Chemical properties

1.1	**Identity**	IUPAC: Bromomethane
1.2	**Formula**	CH_3Br
1.3	**Colour and Texture**	Colourless gas
1.4	**Molecular weight**	94.94 g/mol
1.5	**Freezing point**	-94.1°C -93°C
1.6	**Boiling point**	3.56°C (1013 hPa)
1.7	**Vapour pressure**	1400 mm Hg (20°C) 2600 mm Hg (40°C) 190 kPa (20°C, PPDB)
1.8	**Henry's law constant**	0.533 kPa m^3 mol^{-1} (Calculated using atmospheric pressure)
1.9	**Relative density**	1.732 (0°C)
1.10	**Density of vapor**	~3.27 (760 mmHg, 0°C, air = 1)
1.11	**Viscosity**	0.397 cP (0°C)
1.12	**Solubility in water**	1.75 g/100 g (20°C) 1.34 g/100 g (25°C) 16-18.5 g/L (20°C)
1.13	**Solubility in organic solvents**	Freely soluble in alcohol, chloroform, ether, carbon disulfide and benzene
1.14	**Partition co-efficient n-octanol/water (log Pow)**	1.19
1.15	**logKoc**	1.155

2 Toxicological properties

2.1	**General**	
2.1.1	**Mode of Action**	Respiratory action (PPDB)
2.1.2	**Symptoms of poisoning**	Signs of methyl bromide toxicity after acute exposure include irritation of the eyes and respiratory tract, tremor, lack of coordination, depression of the central nervous system and seizures. Long-term exposure induces pulmonary congestion, effects on the central nervous system, kidney and liver lesions. After oral administration to rats, hyperplasia and hyperkeratosis (and squamous cell carcinomas) were observed in the stomach of the rats (IARC, 1986).

Inhalation Cough. Sore throat. Dizziness. Headache. Abdominal pain. Vomiting. Weakness. Shortness of breath. Confusion. Hallucinations. Loss of speech. Incoordination. Convulsions. Symptoms may be delayed. See Notes. (ICSC, 2009)

Skin MAY BE ABSORBED! Tingling sensation. Itching. Burning sensation. Redness. Blisters. Pain. ON CONTACT WITH LIQUID: FROSTBITE. Further see Inhalation (ICSC, 2009)

Eyes Redness. Pain. Blurred vision. Temporary loss of vision. (ICSC, 2009)

2.1.3 Absorption, distribution, excretion and metabolism in mammals

IARC, 1999

Humans

No study describing toxicokinetics of methyl bromide in humans in vivo was available for evaluation. In human erythrocytes in vitro, methyl bromide is consumed, probably with formation of a glutathione conjugate. The reaction involves a glutathione S-transferase enzyme that metabolizes methyl halides. This enzyme has not been found in erythrocytes of mouse, rat, cattle, sheep, pig or rhesus monkey. The enzyme is present only in part of the human population: among 45 people investigated, only 27 conjugated glutathione with methyl bromide. The enzyme in erythrocytes of conjugators is different from other glutathione S-transferases with respect to substrate specificity, affinity chromatography, and inhibition characteristics; it has been designated as glutathione S-transferase θ (Hallier et al., 1990; Schröder et al., 1992; Hallier et al., 1993; Pemble et al., 1994; Schröder et al., 1996). The interindividual differences in the ability of humans to conjugate methyl bromide suggest that the polymorphic human glutathione S-transferase enzyme present in erythrocytes is relevant for the disposition of methyl bromide in humans. Iwasaki et al. (1989) described a field study of methyl bromide workers in Japan, whose levels of the methyl bromide-derived haemoglobin adduct (S-methylcysteine in haemoglobin) were measured. In a subgroup of seven workers with the highest exposure levels (filling of spray cans and gas cylinders), three had high adduct levels (the highest levels in the whole study), whereas the four other workers of the same exposure subgroup had levels that were close to the background in nonexposed persons (Iwasaki, 1988a,b; Iwasaki et al., 1989)

Experimental animals

Studies on rats and dogs have shown that inhaled methyl bromide is rapidly absorbed through the lungs. In rats, it is also rapidly absorbed following oral exposure. After absorption, methyl bromide or metabolites are rapidly distributed to many tissues including the lung, adrenal gland, kidney, liver, nasal turbinates, brain, testis and adipose tissue. In an inhalation study in rats, the methyl bromide concentrations in tissues reached a maximum after 1 h of exposure but decreased rapidly. Methyl bromide is probably metabolized by glutathione conjugation, the formed S-methylglutathione being sequentially catabolized to S-methyl-L-cysteine and then to carbon dioxide. Methylation of proteins and lipids has been observed in the tissues of several species, including humans, after exposure via inhalation. Methylated DNA bases have also been detected following exposure of rodents in vivo or rodent cells in vitro to methyl bromide. In inhalation studies using ^{14}C-labelled methyl bromide, exhalation of $^{14}CO_2$ was the major route of elimination of ^{14}C. A smaller amount of ^{14}C was excreted in the urine. Following oral administration, urinary excretion was the major route of elimination of ^{14}C (IARC, 1986). After exposure of male CD rats (nose only) to 55 ppm [213 mg/m^3] [^{14}C] methyl bromide for 3 min, 43% of the radioactivity was exhaled during an observation period of 32 h (Jaskot et al., 1988).

2.2 Toxicology studies

2.2.1 Acute toxicity

- In rats a concentration of 51400 mg/m^3 is lethal in 6 minutes, whereas a concentration of 884 mg/m^3 produces death in 26 hours. At 432 mg/m^3 no rats died after 22 hours (RIVM/CSR, 1992).
- Signs of toxicity after a single 8-h exposure included decreases in body temperature, body weight and locomotor activity at 500 mg/m^3 and above; no effects were seen at 250 mg/m^3 (RIVM/CSR, 1992).
- Acute toxic effects of 1 h inhalatory exposure of mice to methyl bromide at 870 to 5930 mg/m^3 included kidney lesions at 3500 mg/m^3 and above, decreased lung and liver weight at 2200 and 2700 mg/m^3 and decreased motor co-ordination at 5770 mg/m^3 (HSDB).

- Methyl bromide (bromomethane) exhibits moderate acute toxicity by the oral and inhalation routes. The oral LD_{50} in rats ranged from 104 to 214 mg/kg. Toxicity by the inhalation route is both time and concentration dependent. In mice, LC_{50} values ranged from 1700 ppm (6,630 mg/m^3) for a 30 minutes exposure to 405 ppm (1,575 mg/m^3) for a 4-hour exposure. Similarly in rats, the LC_{50} for a 30-minute exposure was reported as 2833 ppm (11,049 mg/m^3) while that for an 8-hour exposure was 302 ppm (1,178 mg/m^3) (OECD, 2001).

2.2.2 Short term toxicity

Target organ/critical effect:

Oral

- Cats fed fumigated peanuts containing methyl bromide at 0.5 to 1.25 mg/day for 4 months showed no changes in motor responses (HSDB).
- Dogs fed methyl bromide fumigated pelleted food in doses equal to 35, 75 and 150 mg/kg/day for 6 to 8 weeks were observed for 1 year and showed no or minimal evidence of toxicity at 35 and 75 mg/kg/day. At 150 mg/kg/day the animals showed lethargy, occasional salivation and diarrhea, but no changes in blood chemistry, haematology, urinalysis of histology (HSDB).
- Cattle fed pelleted food containing methyl bromide at 170, 511, 1062, 2633 and 4650 mg/kg for 49 days showed uncoordinated movement and gait and recumbency (HSDB).

Inhalation

- In a subacute study with male rats exposed by inhalation to methyl bromide at 582, 776, 1164, or 1552 mg/m^3 paralysis of extremities and ataxia were noted at 1164 and 1552 mg/m^3. Necrosis of the heart occurred at all concentrations (HSDB).
- Biochemical examination of male rats exposed continuously by inhalation to methyl bromide at 4, 19.4 or 39 mg/m^3 during 3 weeks revealed changes in blood glucose, creatinine phosphokinase, Hb, glutathione, SGPT, SGOT, LDH, serum total protein at 19.4 and 39 mg/m^3 (HSDB). Neurological effects were seen only at 39 mg/m^3.
- Exposure of 10 weeks old male rat by inhalation to methyl bromide at 776 or 1164 mg/m^3, 4 h/day, 5 day/week for 3 weeks resulted in relatively prolonged dysfunction of the peripheral nerves and disturbance in spontaneous circadian rhythm activity at 1164 mg/m^3. No macroscopic or microscopic abnormalities were found in CNS or in peripheral nerves (HSDB).
- Rats and rabbits exposed by inhalation to methyl bromide at 252 mg/m^3 for 5 hours/day, 5 days/week during 4 weeks showed significantly reduced eye blink responses and nerve conduction velocity in rabbits, but had no effects on rats (HSDB).
- In a standard subacute inhalation study with mice trembling, jumpiness and paralysis were observed at all tested concentrations. The effects were slight at 48 and 100 mg/m^3 but obvious at concentrations >=200 mg/m^3. These effects were not reflected in histopathological abnormalities (RIVM/CSR, 1992).
- In a subacute inhalation study in rats and methyl bromide at 0, 70, 200 or 600 mg/m^3 administered for 6 h/day, 5 or 7 days/week during 4 weeks staggered gait was observed in all animals at 200 mg/m^3 and above and in 3/12 animals at 70 mg/m^3. In addition at 600 mg/m^3 mortality and morphological blood abnormalities were noted, serum enzyme levels were elevated and histopathological changes occurred in heart and lungs (RIVM/CSR, 1992).
- Male rats exposed by inhalation to methyl bromide at 0, 350, 680, 970 or 1260 mg/m^3 for 6 h/day during 5 days showed diarrhea, haemoglubinuria and in some cases, gait disturbances at 970 and 1260 mg/m^3. Vacuolar degeneration of the zona fasciculata of the adrenal glands, cerebellar granule cell degeneration, and nasal olfactory sensory cell degeneration were seen at 680 mg/m^3 and above. Cerebral cortical degeneration and minor alterations in testicular histology were seen only at 1260 mg/m^3. At 970 and 1260 mg/m^3 hepatocellular degeneration was seen. No changes in kidney and epididymis (HSDB).

2.2.3 Genotoxicity (including mutagenicity)

In-vitro

- Positive results were found in *Salmonella typhimurium* TA100 in concentrations of 0.02-0.2% in desiccators without metabolic activation (IARC).
- Positive results were obtained in *Salmonella typhimurium* strain T100 in a liquid assay (10-100 mg/1) and in a plate assay (closed containers with 500-50000 mg/m^3) with metabolic activation (IARC).
- Methyl bromide tested in a closed container at 500-5000 mg/m^3 was mutagenic to *Salmonella typhimurium* TA1535 and TA100 (not to TA1537, TA1538 or TA98) and *Escherichia coli* WP2 *hcr* in the absence of metabolic activation (IARC).
- Methyl bromide (aqueous solution 0.5-6 mM) induced mutations to streptomycine independence in *E. coli* (IARC).
- In a fluctuation test, methyl bromide (950-19000 mg/m^3) induced mutations to streptomycin resistance in *Klebsiella pneumoniae* (IARC).
- Treatment of barley kernels with 1.4 mM methyl bromide for 24 h in closed vessels induced a few chlorophyll mutations (IARC).
- In primary cultures of rat hepatocytes, treated in air-tight bottles, methyl bromide did not induce unscheduled DNA synthesis (IARC).
- Treatment of L5178Y mouse lymphoma cells with 0.030-30 mg/L methyl bromide in air-tight bottles resulted in a dose-related increase in 6-thioguanine- and bromodeoxyuridine-resistant mutants (IARC).
- Exposure of human lymphocyte cultures to 4.3% methyl bromide for 100 sec. Increased frequency of sister chromatid exchanges from 10.0 to 16.8 per cell (IARC).

In-vivo

- In a sex-linked recessive lethal test with *Drosophila melanogaster* (strain Berlin K) exposed to methyl bromide at 70-750 mg/m^3 for increasing periods, mutation frequencies were significantly increased at the highest nontoxic concentrations (IARC).
- After exposure of *Drosophila melanogaster* larvae to methyl bromide at 0-20 mg/L, incidences of wing twin spots and wing single spots were increased (IARC).
- Mice exposed to ^{14}C-methyl bromide by inhalation or i.p. injection showed alkylation of guanine-N-7 in DNA of liver and spleen (IARC).
- In bone-marrow cells of rats exposed by inhalation for 6 hours/day, 5 days/week for 2 weeks, the incidence of polychromatic erythrocytes with micronuclei increased by ten fold in males and three fold in females at 1311 mg/m^3 (IARC).
- Increases in SCEs and micronuclei were observed in bone marrow cells of mice exposed by inhalation to methyl bromide at 778 mg/m^3 6 hours/day, 5 days/week during 14 days. The increases were more pronounced in females (IPCS, 1995).
- No increases in SCEs and micronuclei were observed in bone marrow cells of mice exposed by inhalation to methyl bromide at 467 mg/m^3 during 13 weeks.
- In bone-marrow cells and in peripheral blood cells of mice exposed by inhalation for 6 hours/day, 5 days/week for 2 weeks, the incidence of polychromatic erythrocytes with micronuclei in bone marrow cells increased by ten fold in males at 776 mg/m^3 and by six fold in females at 600 mg/m^3 and those in peripheral blood cells increased by 32 fold in males at 776 mg/m^3 and by three fold in females at 600 mg/m^3 (IARC).

2.2.4 Long term toxicity and carcinogenicity

IARC, 1999

Methyl bromide, administered by tube (50 mg/kg five days per week) for 13 weeks to Wistar rats induced inflammation, acanthosis, fibrosis and a high incidence of stomach pseudoepitheliomatous hyperplasia; these changes were aggravated with continuous administration for a total of 25 weeks, at which time all 11 rats examined showed hyperplastic changes. In the groups in which treatment was discontinued after 13 weeks, the changes receded, but adhesions, fibrosis and mild acanthosis persisted for 12 weeks (week 25 of the experiment).

After inhalation exposure of male Sprague-Dawley rats for 4 h per day, five days per week, at 150 ppm [580 mg/m^3] for 11 weeks or 200, 300 or 400 ppm [780,1160 or

1550 mg/m^3] for six weeks, mortality occurred at exposure levels ≥ 300 ppm. The observed effects included necrotic areas in the brain and heart, degeneration of fat in the liver, acinar cell necrosis isolated in the pancreas and, at the highest concentration, atrophic changes in the testicles. After short-term inhalation exposure to 160 ppm [620 mg/m^3] of methyl bromide (6 h per day, five days per week, up to six weeks), it was discovered that B6C3F1 mice were more sensitive than Fischer 344/N rats: 50% of male mice died after eight exposures and 50% of female mice after six exposures, while similar mortality was observed in male rats only after 14 exposures. Neural necrosis and testicular degeneration were observed in both species; nephrosis was observed in almost all mice, while necrosis of the olfactory epithelium was more marked in rats. Myocardial degeneration occurred in rats and, to a lesser extent, in male mice. In the adrenal cortex, there was cytoplasm vacuolation in rats and atrophy of the inner zone in female mice.

In an inhalation study in which Wistar rats were exposed to 3, 30 or 90 ppm [12, 120 or 350 mg/m^3] for 6 h per day, five days per week, for 29 months, a dose-dependent increase in basal cell hyperplasia of the olfactory epithelium was observed in both sexes; this could be observed after 12 months and did not increase significantly in frequency or severity at 24 or 29 months. In the higher dose group, there was an increase in the incidence of cardiac thrombi in females and males; myocardial degeneration was observed in females and cartilaginous metaplasia in both sexes. The incidence of suffocation hyperkeratosis was high in treated males and females but reached significance only in men in the highest dose group. Stomach hyperkeratosis was more frequent in the higher dose group, but it was not a significant excess. Extensive destruction of the olfactory epithelium was observed in the male Fischer 344 rats exposed to 200 ppm [780 mg/m^3] of methyl bromide, 6 h per day for five days. On day 3, despite continued exposure, there was replacement of the olfactory epithelium by a layer of squamous cells, followed by a progressive reorganization towards normal architecture, and at week 10, 75-80% of the epithelium seemed histologically normal. Olfactory epithelial cell replication was maximal on day 3 of exposure, with a labelling rate of 14.7% compared to 0.7% in controls. Degeneration and subsequent regeneration were also observed in an inhalation experiment with Fischer 344 rats exposed to 175 ppm [680 mg/m^3] 6 hours twice, separated by an interval of 28 days. Nasal olfactory cell degeneration was observed at exposure levels ≥ 175 ppm [680 mg/m^3], when Fischer 344 rats were exposed to methyl bromide, 6 h per day for five days. (IARC monographs on the evaluation of carcinogenic risks to human, volume 71 reevaluation of some organic chemicals, hydrazine and hydrogen peroxide.

Oral

Because methyl bromide tends to volatize and exists mainly as a gas at room temperature, only a few (sub)chronic oral studies have been performed (ATSDR, 1992).

- In two oral gavage sub-chronic studies in rats irritation of the stomach was the chief effect. Tue 13-week study of Danse et al. (1984) reported a NOAEL of 0.4 mg/kg bw/day and a LOAEL of 2 mg/kg bw/day (ATSDR, 1992). Similar findings were reported by Boorman et al. (1986) and Hubbs and Harrington et al. (1986). In subsequent studies, these effects were shown to regress after termination of treatment (IPCS, 1995).
- Rats were fed diets fumigated with methyl bromide (80, 200, or 500 mg total Br/kg food) for two years. A slight decrease in body weight was seen in males from week 60 onwards. A NOAEL of 200 mg/kg food could be established (IPCS, 1995).

Inhalation

- Mouse were exposed by inhalation to 0, 39, 128, and 389 mg/m^3 methyl bromide 6 hours/day, 5 days/week during 2 years. Increased incidence of nonneoplastic lesions in brain, bone, heart and nose was seen at all doses. At 389 mg/m^3: high mortality, decrease in body weight and thymus weight, tremors, abnormal posture, and limb paralysis (NTP, 1992; cited in IPCS, 1995).
- Mice were exposed to methyl bromide at 0, 16, 62, or 250 mg/m^3 6 hours/day, 5 days/week for 2 years. Depression of body weight gain, changes in blood

biochemistry (increase in CPK, inorganic P, and chloride and decrease in albumin) and atrophy of the granular layer of the cerebellum at 250 mg/m^3. The NOAEL was found to be 62 mg/m^3 (IPCS, 1995).

- In a chronic toxicity/carcinogenicity study, rats were exposed by inhalation to methyl bromide at 0, 12, 116 or 349 mg/m^3, 6 hours/day, 5 days/week for 29 months. Increased incidences of degenerative and hyperplastic changes of the nasal olfactory epithelium were observed in all groups. Exposure to 349 mg/m^3 resulted in lesions in the heart and hyperkeratosis in the oesophagus and forestomach. See also 'carcinogenicity' (IPCS, 1995).
- Rats and guinea-pigs were exposed to 130-850 mg/m^3 methyl bromide for 7.5-8. hours/day, 5 days/week during 6 months. All animals died after a few exposures to 850 mg/m^3; clinical signs of toxicity in rats at 420 mg/m^3 included poor general appearance, weight loss, pulmonary congestion and renal and hepatic lesions. No effects were observed at 130 and 250 mg/m^3 in rats and guineapigs (IARC). The NOAEL is 250 mg/m^3.
- Rats were exposed to methyl bromide at 16, 78, or 389 mg/m^3, 6 hours/day, 5 days/week for 2 years. Inflammation of the nasal cavity was seen in males at all doses. At 78 mg/m^3 and above protein in urine decreased in males. At 389 mg/m^3 changes in haematology and blood biochemistry parameters and necrosis and respiratory metaplasia of the olfactory epithelium (IPCS, 1995).
- No effects on nerve conduction velocity, open field activity or co-ordination were seen in rats exposed to methyl bromide at 214 mg/m^3, 6 hours/day, 5 days/week, 36 weeks over 12 months (IPCS, 1995).
- Rabbits were exposed by inhalation to 65-850 mg/m^3 methyl bromide for 7.5-8 hours/day, 5 days/week during 6 months. Rabbits exposed to 130 and 250 mg/m^3 developed characteristic paralysis of the legs and died after several exposures; animals tolerated repeated exposures to 65 mg/m^3 (IARC). NOAEL is 65 mg/m^3.
- Rats and mice were exposed by inhalation to methyl bromide for 12 or 13 weeks. Observed effects included mortality, growth retardation, crossing and curling of hindlimbs, increased testes weight and reduced sperm motility. For mice a LOEL and NOEL of 160 and 80 mg/m^3 were established, respectively. For rats the LOEL and NOEL were 240 and 120 mg/m^3, respectively (RIVM/CSR, 1992).
- Rats exposed by inhalation to methyl bromide for 13 weeks showed increased WBC and decreases in plasma albumin, alkaline phosphatase, liver weight and small hepatocytes with eosinophilic cytoplasm at 170 mg/m^3; no effects were seen at 26 mg/m^3 (RIVM/CSR, 1992).
- Monkeys were exposed by inhalation to 130-420 mg/m^3 methyl bromide for 7.5-8 hours/day, 5 days/week during 6 months. Exposure to 250 mg/m^3 led to hyperactivity, Joss of equilibrium, inability to stand, convulsions and paralysis. No such effects were observed at 130 mg/m^3 (IARC).
- Rabbits were exposed by inhalation to methyl bromide at 105 and 252 mg/m^3; the animals received a total exposure duration of 900 hr over a period of 8 months. No signs of toxicity at 105 mg/m^3.
- At 252 mg/m^3 severe neuromuscular losses, impaired blink reflexes and decreased body weights were observed (HSDB).

Carcinogenicity

- In a 13-weeks gavage study in rats and <loses of 0, 0.4, 2, 10 or 50 mg/kg bw methyl bromide in arachis oil, a dose-related increase in hyperplasia and hyperkeratosis of the forestomach epithelium was observed in both sexes. At 50 mg/kg bw papillomas of the forestomach were seen in 2/10 males and squamous-cell carcinomas (accompanied by marked hyperplasia, hyperkeratosis, inflammation and ulceration) were noted in 7/10 males and 6/10 females. At 10 mg/kg bw hyperplasia was observed and at the lowest dose group (2 mg/kg bw) slight hyperplasia occurred. At 0.4 mg/kg bw no effects occurred (RIVM/CSR, 1987).
- In rats exposed by inhalation to methyl bromide at 0, 12, 120 or 360 mg/m^3 for 6 h/day, 5 days/week during 28 months, signs of toxicity at 360 mg/m^3 included mortality, decreased growth, increased incidence of haemothorax, and increased incidence of myocardial degeneration and thrombi in the heart. In addition, the

incidence of hyperkeratosis in the oesophagus and stomach was elevated a 120 mg/ m^3. The incidence of degenerative and hyperplastic changes in the nasal cavity was dose-related increased a t all dose levels. No increase in tumour incidence was noted. In this study 12 mg/m^3 was a marginal effect level (RIVM/CSR, 1987).

- Mice were exposed by inhalation to methyl bromide at 0, 39, 128 or 390 mg/ m^3 for 6 h/day, 5 days/week during 103 weeks. Mortality occurred at 390 mg/m^3 and surviving mice of this group showed signs of neurotoxicity (tremors, abnormal posture, tachypnea, and hind leg paralysis), neurobehaviour changes (less active and higher sensitivity in the startle response), nonneoplastic lesions in brain, heart, sternum and nose, degenerative changes in cerebellum and cerebrum, myocardial degeneration and cardiomyopathy, increased incidence of olfactory epithelial necrosis and metaplasia within the nasal cavity. No signs of carcinogenicity were found (NTP, 1992).

2.2.5 Effects on reproduction

Oral

- Oral exposure of female rats to methyl bromide at 0, 3, 10, or 30 mg/kg bw/day during day 6-15 of gestation and female rabbits to 0, 1, 3, or 10 mg/kg bw/day during day 6-18 of gestation, resulted in maternal toxicity in the high-dose females of both species (decreased body weight and food consumption and erosive lesions in the stomach and surrounding organs) foetuses remained unaffected (DOSE).
- Pregnant rats were administered methyl bromide in peanut oil at 0, 0.5, 5, 25, or 50 mg/kg bw during day 5-20 of gestation. Signs of mater al toxicity were observed at 25 and 50 mg/kg bw (NOAEL is 5 mg/kg bw). Total resorption of embryos was seen at 50 mg/kg bw, probably due to the poor health of the pregnant animals. No effects on skeleton or internal organs at 25 mg/kg bw.

Inhalation

- In a sperm abnormality assay male mice were exposed by inhalation to methyl bromide at 0, 78, or 272 mg/m^3, 7 hours/day, for 5 days. No sperm abnormalities were found (IPCS, 1995).
- Male rats exposed to methyl bromide at 778 or 1167 mg/m^3, 4 hours/day, 5 days/week, for 6 weeks showed atrophy of seminal epithelium, incomplete spermatogenesis, and giant cells in seminal tubules at 778 and 1167 mg/m^3 (IPCS, 1995).
- Rats were exposed by inhalation to 0, 78 or 272 mg/m methyl bromide during pre- and/or gestational periods for 7 h/day, 5 days/week, for 21 and 19 days, respectively. Maternal body weights were reduced during gestation in the groups receiving pre- and gestational exposure to 272 mg/m^3. No toxic effects or anomalies were observed in fetuses (IARC).
- Rabbits were exposed by inhalation to methyl bromide in concentrations of 0, 78 or 272 mg/m^3 for 7 h/day during gestation. Because of high maternal mortality in the high dose group exposure was stopped after 15 days. Fetuses of this dose group could not be examined. No maternal or fetal toxicity was observed at 78 mg/m^3 (IARC).
- Male rats (11-13 wk) were exposed by inhalation to methyl bromide at O or 776 mg/m3 for 6 h/day during 5 days; animals were sacrificed on day 1, 3, 5, and additional groups on day 6, 10, 17, 24, 38, 52, and 73. Plasma testosterone concentration and nonprotein sulfhydryl content of the liver and testis were reduced during exposure but returned to normal levels by day 8. Reproductive indices were not affected at any time point of examination (HSDB).
- Male rats and mice were exposed to methyl bromide at 622 mg/m^3, 6 hours/day, 5 days/week for up to 6 weeks. Testicular degeneration with separation and sloughing of spermatocytes, late-stage spermatids and intratubular giant cells and testicular atrophy with variable lass of all components of spermatogenic epithelium was seen in rats and less severe in mice (IPCS, 1995).
- Male mice exposed by inhalation to methyl bromide at 39, 156, or 467 mg/m^3 for 13 weeks showed a decrease in body weight and an increase of epididymis and testis weight. A decrease in sperm density and an increase in the percentage abnormal sperm was also noted (IPCS, 1995).

- Male rats exposed by inhalation to methyl bromide at 117, 233, or 467 mg/m^3 for 13 weeks showed a decrease in body weight and cauda epididymis weight, and an increase in testis weight. A decrease in sperm motility was also observed. (IPCS, 1995).
- In a multi-generation experiment rats were exposed by inhalation to methyl bromide at 0, 12, 117, or 350 mg/m^3 6 hours/day, 5 days/week, for around 8 months. Body weight of males was depressed at pre-mating observation periods and at final sacrifice at 350 mg/m^3. No effects on body weight in the F1 generation. In the F2a litter a slight body weight depression was seen in gestating and lactating dams at 350 mg/m^3 and the female fertility index was marginally reduced at 117 and 350 mg/m^3. In the F1a generation survival of pups in late lactation was reduced at 350 mg/m^3. Body weight of pups were reduced at 117 and 350 mg/ m^3 in the F1a, F2a and F2b generations. A decreased brain weight was seen in F0 males and in F1 males and females at 350 mg/m^3. Final body weights were reduced in F2b males at 350 mg/m^3 and F2b females at 117 and 350 mg/m^3. Analysis of F2b progeny organs revealed decreases in female brain, heart and kidney at 350 mg/m^3 and liver at 117 and 350 mg/m^3 (IPCS, 1995). The NOAEL is 12 mg/m^3.

2.2.6 Neurotoxicity/ delayed neurotoxicity, Special studies where available

- Chronic methyl bromide toxicity usually is limited to central nervous system, although mild elevation of serum hepatic aminotransferase levels has been reported in industrial workers (HSDB).
- A fumigator chronically exposed to methyl bromide developed paresthesia of the extremities, dysesthesias and visual impairment secondary to optic atrophy (HSDB).
- Mild neurologic dysfunction (decreased finger sensitivity, reduced cognitive performance and behavioural abnormalities) was detected in soil fumigators (HSDB),
- Inhalation of methyl bromide showed after 3-12 hours the following signs of toxicity:1) dizziness and headache, 2) anorexia, nausea, vomiting and abdominal pain, 3) lassitude, profound weakness, slurring of speech and staggering gait, 4) transient blurring of vision, diplopia, strabismus and temporary blindness, 5) mental confusion, mania, tremors and epileptic convulsions; 6) rapid respiration associated with signs of severe pulmonary edema, cyanosis, pallor and collaps; 7) coma, areflexia and death :from respiratory or circulatory collapse (HSDB).
- A case of brief skin exposure to quickly decontaminated methyl bromide spray did not produce burn, but resulted in severe, delayed neuromuscular disturbances (twitching, fits, convulsions) and permanent brain damage (cerebellum and pyranedal tract) (HSDB).

2.2.7 Summary of mammalian toxicity and overall evaluation

Major clinical signs of toxicity after inhalation of methyl bromide included neurological manifestations (twitching and paralysis), irritation of mucosal membranes, histopathological changes in brain, heart, liver and testis. The overall NOAEL for exposure by inhalation is 26 mg/m^3.
According to FAO/WHO (1988), the level causing no effect in experimental animals was 12 mg bromide/kg bw/day (IPCS, 1995).

Methyl bromide has been found to be mutagenic in several in-vitro and in-vivo test systems. It induces sex-linked recessive lethal mutations in Drosophila melanogaster and mutation in cultured mammalian cells. It does not induce unscheduled DNA synthesis or cell transformation in cultured mammalian cells. DNA methylation of the liver and spleen was observed in mice administered methyl bromide by various routes. Micronuclei were induced in bone-marrow and peripheral blood cells of rats and mice (IPCS, 1995).

Long-term inhalation studies on rats and mice did not reveal any evidence of carcinogenicity. Lesions originally interpreted as carcinomas of the forestomach in rats following gavage administration, were shown in a subsequent study to regress after termination of treatment, and were considered not relevant for human risk assessment (IPCS, 1995).

No teratogenic effects have been observed in rats or rabbits. Embryotoxicity occurred in rats and rabbits only at doses that were also maternally toxic. In a rat

multi-generation study a reduction infertility index was observed in the second generation (IPCS, 1995).

The major health concern is from acute exposure. Delayed onset of symptoms may occur. Fatal poisoning has resulted from exposures to relatively high concentrations (from 33000 mg/m^3 or 8600 ppm onwards) of methyl bromide vapours. Non-fatal poisoning has resulted from exposure to concentrations as low as 390-1950 mg/m^3 Organs affected by exposure include the nervous system, lung, nasal mucosa, kidney, eye, and skin. There are no epidemiological data on reproductive toxicity and carcinogenicity in humans. There are no data on any human health effects of methyl bromide residues in food or drinking-water (IPCS, 1995),

3 Human exposure/Risk evaluation

3.1 Food

There are no data on any human health effects of methyl bromide residues in food or drinking-water (IPCS, 1995)

In 1966, the FAO/WHO established and acceptable daily intake (ADI) of 1 mg/kg bw as bromide ion. In 1988 this ADI was confirmed (FAO/WHO, 1988; cited in IPCS, 1995).

In 2021, at its 44th session the Codex Alimentarius Commission (CAC) endorsed the recommendation of the Codex Committee on Pesticide Residues (CCPR) to revoke the MRLs (CXLs) of bromide ion (CCPR, 2021).

Methyl bromide residue data from an extensive set of supervised trials from a number of locations in the USA from 1987 to 1990 were made available to the Meeting. Crops were grown to first maturity in soils which had been treated with methyl bromide usually at 335-380 kg ai/ha. Crops included in the trials were blueberry, raspberry, strawberry, carrot, potato, radish, sugar beet, taro, onion, asparagus, celery, head lettuce, leaf lettuce, spinach, broccoli, cabbage, cauliflower, bush beans, green beans, peas, soya beans, okra, sweet corn, sweet peppers, tomatoes, cucumber, watermelons, cantaloupe, summer squash, peanut, pineapple, ginger, alfalfa, clover, and peanut hay. Methyl bromide residues were not detected in any sample from this soil treatment programme. The limit of determination was 0.005 or 0.01 mg/kg (JMPR, 1992).

3.2 Air

Estimated concentration of no concern (ECNC) of polluting agents in air for humans: the ECNC is derived from the NOAEL of 12 mg/m^3 in the 128-d reproduction study and corrected for continuous exposure to 2.1 mg/m^3. By applying an UF (uncertainty factor) of 100 an ECNC of 20 µg/m^3 is established for air. (Rademaker & Linders, 1996).

On the basis of the sub-chronic NOAEL of 0.4 mg/kg bw in rats, the ATSDR established an intermediate duration MRL of 0.003 by adjusting the NOAEL for intermittent exposure and using an uncertainty factor of 100 (ATSDR).

In 1987, RIVM derived a guideline of 0.7 mg/m^3 for short-term exposures on the basis of a marginal effect level of 70 mg/m^3 from a sub-chronic study in rats and using an uncertainty factor of 100.

A guideline of 0.1 mg/m^3 was derived for long-term exposures, based on a marginal effect level of 12 mg/m^3 from a chronic rat study using an uncertainty factor of 100 (RIVM/CSR, 1987).

3.3 Water

Estimated concentration of no concern of polluting agents in drinking water for humans: the ECNC is derived from the NOAEL of 12 mg/m^3 in the 128-d reproduction study and corrected for continuous exposure to 2.1 mg/m^3. The ECNC for drinking water (assuming a human body weight of 70 kg, a drinking water volume of 2 liters per day, and an allocation of 10 percent) is 3.5 mg/L. (Rademaker & Linders, 1996).

Netherlands

Prior to the final regulatory action estimated concentration in groundwater amounted to 100 µg/L and the measured concentrations in surface water amounted to approximately 9 mg/L.

3.4	**Occupational exposure**	**IARC, 1999** According to the 1981–83 National Occupational Exposure Survey (NOES, 1997), approximately 5000 workers in the United States were potentially exposed to methyl bromide (see General Remarks). Occupational exposures may occur in its production, in pest control for vegetables and fruits and in fumigation of soil.
3.5	**Medical data contributing to regulatory decision**	**Netherlands/Colombia** No reported adverse effects in workers or poisoning incidents.
3.6	**Public exposure**	**Netherlands** In the Netherlands groundwater is used for the production of drinking water and therefore groundwater must remain free from pesticides (precautionary principle). Prior to the final regulatory action estimated concentration in groundwater amounted to 100 µg/L. **IARC, 1999** More than 950 methyl bromide poisonings have been reported, involving fatalities, systemic poisoning, irritation to skin, eyes and respiratory tract, and damage to the central nervous system, liver and kidney (IARC, 1986). Several reports on poisonings after short- and long-term exposure to methyl bromide, some of them fatal, have also been published.
3.7	**Summary-overall risk evaluation**	**Colombia** Reducing the use of methyl bromide in Colombia, will contribute to the reduction of emissions of an ozone layer depletory agent and, indirectly, to reducing the risk of skin cancer by increased solar radiation. This is based on the evidence that "skin cancer increases with any increase in UV-B radiation, the relationship between skin cancer and ozone decrease is for every 1% decrease of the total ozone results in a 3% increase in the incidence of melanoma or skin cancer. It has also been identified that the incidence of cataracts and the severity of different infections has been increased since the immune system is suppressed from radiation. The quantities of methyl bromide used in Colombia in 1994 as soil fumigant for certain crops were reported (at least 32000 kg). This use was identified as an important source of emission to the environment because a predictive theoretical analysis mentioned in the 1992 and 1994 UNEP reports that between 45 and 53% of the amount of methyl bromide used in agricultural activities could be released to the atmosphere. Consequently, the elimination of the use of methyl bromide as soil fumigant will contribute to the reduction of incidence of skin cancer and other diseases related to ozone depletion. **Netherlands** The risk evaluation of the Netherlands focussed on the behaviour and effects of methyl bromide in air, groundwater and surface water. It took into account all relevant data on the substance concerning the physico-chemical data, among others the ozone depletion potential, data on the leaching potential, i.e. sorption and soil degradation, and data on the ecotoxicological effects of methyl bromide, e.g. the toxicity to fish It was estimated that methyl bromide could leach to groundwater and surface water. Both types of water resources are used for the abstraction of water intended for the production of drinking water. Prior to the final regulatory action estimated concentration in groundwater amounted to 100 µg/L. Groundwater should be free of pesticides based on the precautionary principle. The measured concentrations in surface water amounted to approximately 9 mg/L, therefore a very high risk for fish was expected.

The elimination of the use of methyl bromide as soil fumigant will significantly reduce emissions to air and ground- and/or surface water. Consequently, the risk for human health and the environment will be significantly reduced.

4 Environmental fate and effects

4.1 Fate

4.1.1 Soil

Methyl bromide released to soil is expected to be primarily lost by volatilization. Methyl bromide may also leach due to its weak adsorption to soil. A (low) sorption constant of about 2.5 L/kg was used in the Dutch environmental exposure scenarios (RIVM/CSR, 1992). Hydrolysis of methyl bromide to methanol and bromide ions and biodegradation may also occur in soil. (HSDB).

4.1.2 Water

Release of methyl bromide to water is expected to result primarily in volatilization. Hydrolysis to methanol and bromide ions will occur with a half-life of 20-26.7 days. (HSDB).

4.1.3 Air

A predictive theoretical analysis identified that between 45 and 53% of the amount of methyl bromide used in agricultural activities could be released to the atmosphere (Albritton and Watson, 1992).

4.1.4 Bioconcentration

Bioconcentration is not expected to be significant (HSDB).

4.1.5 Persistence

Hydrolysis to methanol and bromide ions will occur with a half-life of 20-26.7 days. (HSDB). A soil degradation half-life time of about 15 days was used in the Dutch environmental exposure scenarios (RIVM/CSR, 1992).

4.2 Effects on non-target organisms

Methyl bromide applied under plastic to soil organisms at concentrations of 300 000 mg/m^3 killed all insects; some nematodes and mites survived in small numbers (HSDB).

Methyl bromide did not cause any permanent changes in soil enzyme activity or affect the mycorrhizal root development of pine seedlings (IPCS, 1995).

Methyl bromide applied at 22000 mg/m^2 showed no long-term effects on aerobic soil bacteria and actinomycetes (IPCS, 1995).

4.2.1 Terrestrial vertebrates

Hens fed on diets fumigated with methyl bromide showed delayed sexual maturity, adversely affected egg flavour and taste of meat (IPCS, 1995).

4.2.2 Aquatic species

Algae
48-h EC_{50} for 2 species 3.2-5.0 mg/L (RIVM/CSR, 1992)

Crustacea
48-h EC_{50} *Daphnia magna* 1.7 mg/L (RIVM/CSR, 1992)
12-d NOEC (mort., reprod.) *Daphnia magna* 0.06 mg/L (RIVM/CSR, 1992)

Fish
96-h LC_{50} *Menidia beryllina* 4.68 mg/1 (BUA)-11 mg/L (DOSE)
96-h LC_{50} *Lepomis macrochirus* 4.18 mg/1 (BUA)-12 mg/L (DOSE)
48-h LC_{50} *Poecilia reticulata* 1.2 mg/L (BUA)
96-h LC_{50} *Poecilia reticulata* and *Oryzias Latipes* 0.8 mg/L (RIVM/CSR, 1992)
96-h NOEC (mortality) *Poecilia reticulata* 0.56 mg/L (IPCS, 1995)
96-h NOEC (mortality) *Oryzias latipes* 1.0 mg/L (IPCS, 1995)
1-month NOEC (mortality) *Poecilia reticulata* 0.06 mg/L (RIVM/CSR, 1992)
1-month NOEC (mortality) *Oryzias latipes* 0.40 mg/L (RIVM/CSR, 1992)
3-month NOEC (mortality) *Poecilia reticulata* and *Oryzias latipes* 0.32 mg/L (IPCS, 1995)

The potential impact of the main degradation product of methyl bromide, inorganic bromide, was also evaluated:

Algae
24-96 h EC_{50} (growth) *Scenedesmus pannonicus* 5800-10000 mg Br^-/L
24-96 h NOEC (growth) *Scenedesmus pannonicus* 2500 mg Br^-/L

Crustacea
48-h EC_{50} *Daphnia magna* 5800 mg Br^-/L
48-h NOEC *Daphnia magna* 4300 mg Br^-/L

Fish
96-h LC_{50}-values ranges from 16000 to 24000 mg Br^-/L
96-h NOEC (mortality) 7800 mg Br^-/L

96-h NOEC (abn. behaviour) ranges from 25 to 250 mg Br^-/L

The NOEC-values from medium-term toxicity tests using sodium bromide and 11 different freshwater species ranges from 10 mg/L for effect on reproduction of *Daphnia magna* and *Lymnea stagnalis* to 10000 mg/L for the effect on hatching growth in *Oryzias latipes* (IPCS, 1995).

4.2.3 Honeybees and other arthropods

Methyl bromide is considered non-toxic to bees (DOSE).

The 24-h LC_{50} for beetles Coleoptera amounts to 4.51 mg/L (DOSE).

LD_{50}-values for 32 different insects range from 9 to 32000 mg/m^3 (IPCS, 1995).

4.2.4 Earthworms

Methyl bromide is very toxic to earthworms (concentration not given) (IPCS, 1995).

4.2.5 Soil microorganisms

24-h LD_{50} *Phialophora cinerescens*

Verticilium alboartum

Fusarium oxysporium 6 mg/1 (BUA)

Methyl bromide was tested on several morphologically and functionally different groups of soil microbes. In isolated soil samples, treated and maintained under constant temperature (22-23 °C) and humidity (16-18%), microorganisms were counted at 2, 21, 54, and 87 days following fumigation with 300 g methyl bromide/m^3. After 2 days, most bacteria were dead; after 87 days, there were very low counts of fungi, aerobic nitrogen-fixing, nitrifying, and cellulolytic bacteria, whereas denitrifying, proteolytic, amylolytic, and ammonifying bacteria showed a marked resurgence in recolonization. The selective-action effects of methyl bromide fumigation on a given microbe population in soil appear to be more significant than the effects on microbe number (IPCS, 1995).

In a study on bacterial flora involved in the nitrogen cycle, hot fumigation with methyl bromide at concentrations of 80 g/m^3 was carried out in greenhouses at 6 different sites. Seven months after treatment, the total aerobic mesophile bacteria count, aerobic nitrogen-fixing, ammonifying, ammonia-oxidizing, and nitrite-oxidizing bacteria, always showed higher values in fumigated than in unfumigated control soils. Recolonization was more marked in the upper 0-30 cm soil samples in which the development of ammonifying and nitrifying bacteria was highly significant (IPCS, 1995).

In a study the recolonization of soils sterilized in the laboratory and returned to their original pasture and forest sites, under four different types of field conditions was described. Sampling took place over 166 days (midsummer to midwinter) with two of the sites having a moderate, and two a high, rainfall. Both microbial biomass and dehydrogenase activity recovered rapidly but remained consistently lower in the fumigated than in the untreated samples in all four sites. Bacterial numbers also recovered rapidly. Fungal hyphal lengths were 25% lower in the fumigated soil. Fumigation showed no detectable effects on the subsequent rates of nitrogen mineralization and little effect on nitrification rates. Protozoa were almost completely eliminated by fumigation, numbers recovering most rapidly in moist forest soil and slowly in dry pasture soil. Nematodes were eliminated by fumigation; recolonization was first detected on day 26. Numbers (10 and 62/g, respectively) and species (10 and 31, respectively) remained much lower in fumigated, compared with untreated, soil (IPCS, 1995).

After sterilization of greenhouse soil with methyl bromide (75 g/m^2), there were profound qualitative and quantitative disturbances up to a soil depth of 30 cm; 7-9 species of soil mycoflora were isolated from the fumigated soil compared with 107 from control soils. The 31-40 cm soil layer was not affected by disinfestation. After two months, recolonization had taken place of only 35-40% in species and 60-63% in density of the primary microflora (IPCS, 1995).

4.2.6	**Terrestrial plants**	Methyl bromide can have adverse as well as positive effects on plants. The phytotoxic effects of methyl bromide as a soil sterilant can be caused by: (1) the action on plants of methyl bromide itself; (2) the action of inorganic bromide formed by the breakdown of methyl bromide in the soil; (3) indirect action through effects of either methyl bromide or inorganic bromide on soil microflora, soil structure, or composition (IPCS, 1995).

5 Environmental Exposure/Risk Evaluation

5.1	**Terrestrial vertebrates**	**Colombia/Netherlands** There was no information on risks or exposure regarding terrestrial vertebrates.
5.2	**Aquatic species**	**Netherlands** According to the evaluation undertaken by the Netherlands related to the environment, a very high risk of methyl bromide to fish is expected.
5.3	**Honeybees**	**Colombia/Netherlands** There was no information on risks or exposure regarding honeybees.
5.4	**Earthworms**	**Colombia/Netherlands** There was no information on risks or exposure regarding earthworms.
5.5	**Soil microorganisms**	**Colombia/Netherlands** There was no information on risks or exposure regarding soil microorganisms.
5.6	**Summary – overall risk evaluation**	**Colombia** The quantities of methyl bromide used in Colombia in 1994 as soil fumigant for certain crops were reported. This use was identified as an important source of emission to the environment because a predictive theoretical analysis mentioned in the 1992 and 1994 UNEP reports identified that between 45 and 53% of the amount used in agricultural activities could be released to the atmosphere. Consequently, the elimination of the use of methyl bromide as soil fumigant will contribute to the reduction of the destruction of the ozone layer. **Netherlands** The risk evaluation of the Netherlands focussed on the behaviour and effects of methyl bromide in air, groundwater and surface water. It took into account all relevant data on the substance concerning the physico-chemical data, among others the ozone depletion potential, data on the leaching potential, i.e. sorption and soil degradation, and data on the ecotoxicological effects of methyl bromide, e.g. the toxicity to fish. Based on a measured surface water concentration of approximately 9 mg/L a very high risk for fish was expected.

Annex 2 to the decision guidance document – Details on final regulatory actions reported

Country Name: Columbia

1	**Effective date(s) of entry into force of actions**	12 December 2008
	Reference to the regulatory document	Resolution 5049 of 2008 of the Ministry of Social Protection, Bogotá D. C., 12 December 2008.
2	**Succinct details of the final regulatory action(s)**	Resolution 2152 of 1996 of the Ministry of Health and Social Protection of Colombia severely restricted methyl bromide and authorizes the import, commercialization and use of methyl bromide, only for quarantine treatment for control of exotic pests in fresh plant tissues at the port and border crossing level, until a viable substitute is found that allows its replacement. Its application must be airtight and with a closed pesticide recovery system. Amendments were made to Article 1 of resolution 2152 in order to make a more controlled and restrictive use of methyl bromide by Resolutions 00643 of 2004, 01800 of 2006, 03587 of 2008 and the Resolution 5049 of 2008. The notification indicates that Resolution 2152 of 1996 and Resolution 5049 of 2008 are currently in force. Resolution 5049 of 2008 further severely restricts the import, commercialization and use of methyl bromide. Due to the further restriction methyl bromide can only be used in quarantine treatment for the control of quarantine pests in agricultural products and wood packaging at the level of influence zones established within a maximum radius of ten (10) kilometres from the port and/or border crossing. The fumigation has to be carried out in authorized airtight chambers.
3	**Reasons for action**	Resolution 2152 of 1996: Since methyl bromide is an ozone depletor the regulation aimed at a significant decrease of environmental release via the ban of soil fumigations and allowing only quarantine treatment for the control of quarantine pests in agricultural products and wood packaging at the level of ports and/or border crossings. Significant reduction of the emission to the atmosphere of ozone depletory agent methyl bromide will reduce ozone depletion and consequently it can be expected that the risk of negative health impacts from solar radiation will be reduced. Resolution 5049 of 2008: Colombia identified in 1996 that, for sanitary actions in plant quarantines, methyl bromide was the only fumigant authorized for the treatment of fresh plant tissues at the ports of entry and exit. Taking into account what was identified by the panel of experts of the Montreal Protocol, hermetic use with a closed pesticide recovery system was required. Subsequently, some aspects to improve the fumigation process were identified to reduce the risk to the environment and health. Specifically, fumigations with methyl bromide were carried out in tents. This kind of fumigation generated concern of possible emissions to the environment and exposure of workers to the pesticide. As a result, Resolution 5049 of 2008 further restricting resolution 2152 of 1996 was generated.
4	**Basis for inclusion into Annex III**	The final regulatory action was taken to protect human health and the environment. The regulatory action was based on a risk evaluation taking into account the prevailing conditions in Colombia.
4.1	**Risk evaluation**	According to the evaluation related to human health the following information was identified (UNEP/FAO/RC/CRC.18/10, Section 2.4.2.1): a) Methyl bromide is an irritating and vesicant gas, extremely toxic to humans that affects different organs and systems, with high potential risks of producing acute poisoning by inhalation and absorption through the skin and mucous membranes. b) Methyl bromide was included in the Montreal Protocol as an ozone depleting substance under the Copenhagen Amendment. c) Reducing the use of methyl bromide in Colombia, will contribute to the reduction of emissions of an ozone layer depletory agent and, indirectly, to reducing the risk of skin cancer by increased solar radiation. This was

supported by the 1989 report of the Montreal Protocol Environmental Effect Assessment Panel, which defines that "skin cancer will increase with any increase in UV-B radiation, the relationship between skin cancer and ozone decrease is not one to one. For every 1% decrease of the total ozone will result in a 3% increase in the incidence of melanoma or skin cancer". It has also been identified that the incidence of cataracts and the severity of different infections has been increased since the immune system is suppressed from radiation.

d) The quantities of methyl bromide used in Colombia in 1994 as soil fumigant for certain crops were reported (at least 32000 kg). This use was identified as an important source of emission into the environment because a predictive theoretical analysis explained in the UNEP 1992 Report (Albritton and Watson, 1992) and the UNEP 1994 report on Scientific Assessments of Ozone Depletion identified that between 45 and 53% of the amount used in agricultural activities could be released into the atmosphere.

Consequently, the elimination of the use of methyl bromide as soil fumigant will contribute to the reduction of incidence of skin cancer and other diseases related to ozone depletion.

According to the evaluation related to the environment the following information was identified (UNEP/FAO/RC/CRC.18/10, Section 2.4.2.2):

a) Methyl bromide was included in the Montreal Protocol as an ozone depleting substance under the Copenhagen Amendment.

b) The quantities of methyl bromide used in Colombia in 1994 as soil fumigant for certain crops were reported (UNEP/FAO/RC/CRC.18/10, Section 2.4.2.1, Table 3). This use was identified as an important source of emission into the environment because a predictive theoretical analysis explained in the 1992 and 1994 UNEP reports identified that between 45 and 53% of the amount used in agricultural activities could be released to the atmosphere (UNEP/FAO/RC/CRC.18/INF/19, p. 179).

Consequently, the elimination of the use of methyl bromide as soil fumigant will contribute to the reduction of the destruction of the ozone layer.

4.2 Criteria used

Risks to human health and the environment

Relevance to other States and Region

According to the notification: Some countries mainly developing countries or countries with economies in transition can still use methyl bromide. If it is used as it was used in Colombia it might generate health and environment impacts. According to published information on the Montreal Protocol Website: the UNEP 2018 report of the Methyl Bromide Technical Option Committee of the Montreal Protocol mentions that 50 countries are still regularly using methyl bromide for QPS. Additionally, the report mentions that almost all structural and commodity treatments with methyl bromide are carried out for QPS purposes. Consequently, the use of methyl bromide for QPS is not limited to a geographical area and it is a major use for this pesticide in many countries. Further, the report mentions that worldwide many fumigations continue to be conducted in poorly sealed enclosures, leading to high rates of leakage and gas loss.

It can be expected that for similar reasons as mentioned in the Colombian notification (minimization of emission of a highly toxic and ozone depleting gas) other countries still using methyl bromide for QPS purposes in poorly sealed enclosures, consider introducing regulations to replace methyl bromide and/or adopt technologies to capture the fumigant and minimize its emission.

5 Alternatives

The following information on alternatives was made available:

For quarantine treatments, the following alternatives are currently used:

- Hot steam treatment (T106-e) for yellow pitahaya fruit and tommy atkins mango infested with eggs and larvae of the Mediterranean fruit fly (*Ceratitis capitata* Wiedeman).
- Cold quarantine treatment (T107-a-1) as a mitigation measure of *Anastrepha fraterculus* in feijoa fruits.

		For quarantine treatments, the following alternatives are currently tested: • Evaluation and quality testing of phosphine have been performed on basil and feijoa. See also Section 3.3.
6	**Waste management**	None reported. See Section 4.5.
7	**Other**	None reported.

Country Name: Netherlands

1	**Effective date(s) of entry into force of actions**	1992, last amended 24th December 2004
	Reference to the regulatory document	Decree of Ministry of Agriculture and Fisheries, Ministerial Order of 31 December 1980/5 January 1981
2	**Succinct details of the final regulatory action(s)**	In 1981, the use of methyl bromide as a soil disinfectant was prohibited. Based on Article 16a of the Dutch Pesticide Law of 1962, an exemption could be granted based on individual requests. In 1992 methyl bromide was completely banned for use as a soil disinfectant. Only the use as space fumigant in gas proof rooms is still allowed[6].
3	**Reasons for action**	By the end of 1980 the occurrence of methyl bromide in a number of private drinking waterpipes, in combination with new toxicological data (a number of positive mutagenicity tests) was reason to start regulatory actions. In addition, there was concern about safety aspects related to storage, transport and use of methyl bromide (possibility of emission to air) and the leaching potential (leaching to surface water or groundwater). In the Netherlands groundwater and surface water can be used for the production of drinking water and therefore groundwater must remain free from pesticides (precautionary principle). The effect on the ozone layer was also a subject of concern. Methyl bromide and bromide (active bromine species) are partly responsible for the destruction of the ozone layer. Methyl bromide is included in the Montreal Protocol.
4	**Basis for inclusion into Annex III**	The final regulatory action was taken to protect human health and the environment.
4.1	**Risk evaluation**	According to the evaluation related to human health the following information was identified (UNEP/FAO/RC/CRC.1/18/Add.2, Section: 2.4.1) a) The risk evaluation by the Netherlands focussed on the behaviour and effects of methyl bromide in air, groundwater and surface water. It took into account all relevant data on the substance concerning the physico-chemical data, among others the ozone depletion potential, and data on the leaching potential, i.e. sorption and soil degradation. b) Concerns that methyl bromide could leach to groundwater and surface water. Both types of water resources are used for the abstraction of water intended for the production of drinking water. c) Estimated concentration in groundwater amounted to 100 µg/L. Groundwater should be free of pesticides based on the precautionary principle. d) Concerns about the ozone depletion potential of methyl bromide. e) Concerns about safety aspects related to storage, transport and use (for general population and workers). According to the evaluation related to the environment the following information was identified (UNEP/FAO/RC/CRC.1/18/Add.2): a) The risk evaluation by the Netherlands focussed on the behaviour and effects of methyl bromide in air, groundwater and surface water. It took into account all relevant data on the substance concerning the physico-chemical data, among others the ozone depletion potential, data on the leaching potential, i.e. sorption and soil degradation, and data on the ecotoxicological effects of methyl bromide, e.g. the toxicity to fish.

[6] According to the supporting documentation provided by the Netherlands in 2005 (UNEP/FAO/RC/CRC.1/18/Add.2) the use of methyl bromide as space fumigant was still authorized in 2005. In 2009 the last authorization in the Netherlands for the use of methyl bromide in space fumigations was withdrawn by the Dutch Board for the Authorisation of plant protection products and biocides (Ctgb, 2023).

		b) The measured concentrations in surface water amounted to approximately 9 mg/L, therefore a very high risk for fish was expected.
4.2	**Criteria used**	Risks to human health and the environment
	Relevance to other States and Region	The notification indicates that surrounding states had also severely restricted the use of methyl bromide.
5	**Alternatives**	None reported. See Section 3.3.
6	**Waste management**	None reported. See Section 4.5.
7	**Other**	None reported.

Annex 3 to the decision guidance document – Addresses of designated national authorities

Colombia	
Rotterdam Convention Designated national authority for pesticides (DNA P) Name: Ms. Gilma Sandra Molina Galindo Job title: Directora Técnica de Inocuidad e Insumos Agrícolas Department: Dirección Técnica de Inocuidad e Insumos Agrícolas Institution: Instituto Colombiano Agropecuario - ICA	Postal address: Calle 68 A #24 B-10, Bogota DC, Colombia Phone: + 57 1 332 3700 ext. 1339 Email: gilma.molina@ica.gov.co, direccion.insumosagr@ica.gov.co

Netherlands	
Rotterdam Convention Designated national authority for industrial chemicals and pesticides (DNA CP), Stockholm Convention National focal point (NFP) Name: Ms. Nicolette Bouman Job title: Chemicals Coordinator Institution: Ministry of Infrastructure and Water Management	Postal address: P.O. Box 20901 2500 EX The Hague Netherlands Phone: +31 6 2116 0206 Email: nicolette.bouman@minienw.nl, postbus.chemwaste@minienw.nl

C Industrial chemicals

CP Pesticides and industrial chemicals

P Pesticides