



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

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Technical work: consideration of draft decision
guidance documents: terbufos

Draft decision guidance document for terbufos

Note by the Secretariat

1. At its seventeenth meeting, the Chemical Review Committee reviewed notifications of final regulatory action for terbufos submitted by Canada and Mozambique, 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 its decision CRC-17/2, the Committee adopted a rationale for its conclusion and recommended, in accordance with paragraph 6 of Article 5 of the Convention, that the Conference of the Parties list terbufos 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 terbufos.
3. Pursuant to decision CRC-17/2 and the workplan for the preparation of draft decision guidance documents adopted by the Committee (UNEP/FAO/RC/CRC.17/10, annex III), the intersessional drafting group established at the seventeenth meeting prepared a draft decision guidance document for terbufos.
4. At its eighteenth meeting, the Committee further revised and, by its decision CRC-18/2, adopted the draft decision guidance document for terbufos as set out in the annex to the present note, and decided to forward it, together with the related tabular summary of comments (UNEP/FAO/RC/CRC.18/INF/5/Rev.1), to the Conference of the Parties for its consideration. The draft decision guidance document has not been formally edited.

Annex

Rotterdam Convention

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

Draft Decision Guidance Document

Terbufos



**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 chemicals¹ 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 Parties² 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 terbufos 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 of 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 listed in the relevant category(ies) in Annex III to the Convention. Further information on import response can be found on the website of the Rotterdam Convention³.

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.

³ <http://www.pic.int/Procedures/ImportResponses/tabid/1162/language/en-US/Default.aspx>.

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

<	less than
≤	less than or equal to
>	greater than
≥	greater than or equal to
μg	microgram
ARfD	acute reference dose
a.i.	active ingredient
ADI	acceptable daily intake
bw	body weight
°C	degree Celsius (centigrade)
CAS	Chemical Abstracts Service
DNA	deoxyribose nucleic acid
EC	European Community
EC ₅₀	median effective concentration
EU	European Union
FAO	Food and Agriculture Organization of the United Nations
g	gram
h	hour
ha	hectare
HHP	Highly Hazardous Pesticide
IARC	International Agency for Research on Cancer
IPCS	International Programme on Chemical Safety
IPM	Integrated Pest Management
IUPAC	International Union of Pure and Applied Chemistry
JMPM	Joint FAO/WHO Meeting on Pesticide Management
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)
k	kilo- (x 1000)
kg	kilogram
Kow	octanol–water partition coefficient
kPa	kilopascal
L	litre
LC ₅₀	median lethal concentration
n	
LD ₅₀	median lethal dose
LOAEL	lowest-observed-adverse-effect level
m	metre
mg	milligram
ml	millilitre
mPa	millipascal
MRL	maximum residue limit
MOE	margin of exposure
ng	nanogram
NOAEC	no-observed-adverse-effect concentration
NOAEL	no-observed-adverse-effect level

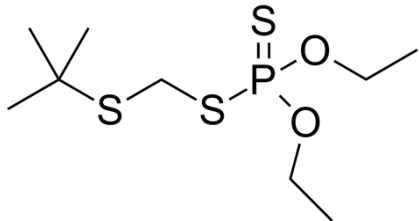
STANDARD CORE SET OF ABBREVIATIONS	
NOEC	no-observed-effect concentration
NOEL	no-observed-effect level
OECD	Organisation for Economic Co-operation and Development
PEC	predicted environmental concentration
PMRA	Health Canada's Pest Management Regulatory Agency
Pow	octanol-water partition coefficient, also referred to as Kow
PPE	personal protective equipment
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).
RfD	reference dose (for chronic oral exposure; comparable to ADI)
SAICM	Strategic Approach to International Chemicals Management
UNEP	United Nations Environment Programme
USEPA	United States Environmental Protection Agency
UV	ultraviolet
w/w	weight for weight
WHO	World Health Organization
wt	weight

Decision guidance document for a banned or severely restricted chemical

Terbufos

Published:

1. Identification and uses (see Annex 1 for further details)

Common name	Terbufos
Chemical name and other names or synonyms	<u>IUPAC</u> : S-[(<i>tert</i> -Butylsulfanyl)methyl] <i>O,O</i> -diethyl phosphorodithioate <u>CAS</u> : S-[[[1,1-Dimethylethyl)thio]methyl] <i>O,O</i> -diethyl phosphorodithioate <i>Other IUPAC</i> : <i>tert</i> -butylsulfanylmethylsulfanyl-diethoxy-sulfanylidene- λ^5 -phosphane
Molecular formula	C ₉ H ₂₁ O ₂ PS ₃
Chemical structure	
CAS-No.(s)	13071-79-9
Harmonized System Customs Code	293090 (active ingredient) 380891 (formulation)
Other numbers	EC number 235-963-8
Category	Pesticide
Regulated category	Pesticide
Use(s) in regulated category	Terbufos was registered in Mozambique as an insecticide to be used on maize, sorghum, potato and beans. Terbufos was registered in Canada as an insecticide and nematicide for use on canola, corn, mustard, rutabaga and sugar beet.
Trade names	Trade names listed by Mozambique: Moz Terbufos 15% GR, Rotam Terbufos 15% GR and Bongo. Trade names listed by Canada: Counter 5-G Soil Insecticide and Counter 15-G Lock'n Load Soil Insecticide Granular. Contraven, Aragan, Cyanater. <i>This is an indicative list. It is not intended to be exhaustive.</i>
Formulation types	Moz Terbufos 15% GR, Rotam Terbufos 15% GR, Counter 5-G Soil Insecticide and Counter 15-G Lock'n Load Soil Insecticide Granular are granular formulations. Both notifications indicate "G" or "GR" for granules.
Uses in other categories	There is no reported use as an industrial chemical
Basic manufacturers	AMVAC Chemical Corporation, BASF, American Cyanamid <i>This is an indicative list of current and former manufacturers. It is not intended to be exhaustive.</i>

2. Reasons for inclusion in the PIC procedure

Terbufos is included in the PIC procedure as a pesticide. It has been listed on the basis of the final regulatory actions to ban its use notified by Canada and Mozambique.

2.1 Final regulatory action (see Annex 2 for further details)

Canada

According to the Pest Management Regulatory Agency, Health Canada. 2004. Re-evaluation Decision RRD2004-04: Re-evaluation of terbufos, and Pest Management Regulatory Agency, Health Canada. 2008. Re-evaluation Note REV2008-06: Update on the use of terbufos on sugar beets, the sale of pesticides containing terbufos was prohibited in Canada effective May 1, 2012. The use of products containing terbufos was prohibited after August 1, 2012.

The final regulatory action has been taken for the pesticide category to protect the environment.

Reason: Environment

Mozambique

Based on the decision Nr 001/DNSA/2014, terbufos was banned by the National Directorate of Agrarian Services (The Pesticide Register Authority) from further import and use in Mozambique. The ban of all uses and the cancellation of the products containing terbufos in the country was decided due to the toxic nature and hazardous properties of this active substance which, combined with the improper use in the country due to the local specific conditions of use, can damage human and animal health. The decision to cancel the registration of terbufos was taken as the last step of the project for Risk Reduction of Highly Hazardous Pesticides (HHPs), which identified HHPs that are registered in Mozambique. After consultations with different actors (public sector, private sector, civil society and others), cancellation of registrations and consequent non-approval for their use in Mozambique was approved. The regulatory action entered into force on 15 July 2014.

The final regulatory action has been taken for the pesticide category to protect human health.

Reason: Human Health

2.2 Risk evaluation (see Annex 1 for further details)

Canada

A re-evaluation of the active ingredient terbufos and its end-use products for use on canola, corn, mustard, rutabaga was conducted under the authority of Section 16 of the Pest Control Products Act.

Health Canada's Pest Management Regulatory Agency (PMRA) identified extremely high hazards to terrestrial organisms resulting from all currently registered uses of terbufos. The assessment is supported by reports of incidents in Canada and the USA.

The PMRA identified extremely high hazard to aquatic organisms resulting from all currently registered uses of terbufos. The assessment is supported by reports of incidents of adverse effects in the USA. Similar effects may have occurred in Canada, but there is no equivalent reporting system.

Risk quotients determined for applications of the end-use terbufos formulations Counter 5-G and Counter 15-G indicate risks for all groups of organisms (i.e., birds, mammals, fish and aquatic invertebrates) for all application scenarios. Based on the available toxicity data, risk is classified as high to extremely high for aquatic organisms and in most cases high to extremely high for birds. Similarly, risk to mammals is classified as low for large mammals to high for small mammals.

Mozambique

The notification states that the ban of all uses and the cancellation of the products containing terbufos in Mozambique was decided based on the toxic nature and hazardous properties which combined with the improper use in the country due to the local specific conditions of use can damage human and animal health.

Terbufos and the products containing terbufos were considered as harmful for human health taking into consideration the local conditions of use in Mozambique and the requirements for risk mitigation measures. The notification refers to a consultancy report *Reducing Risks of Highly Hazardous Pesticides in Mozambique: Step 1 – Shortlisting highly hazardous pesticides* (Come & van der Valk, 2014), which identified terbufos formulations as Extremely hazardous Class Ia according to the JMPM criteria for HHPs based on the WHO International Classification of Pesticides by Hazards, and therefore considered and shortlisted as HHP (Come & van der Valk, 2014).

A field survey of 325 subsistence farmers was carried out in selected regions and cropping systems in Mozambique. The main goal of the survey was to identify the conditions under which pesticides are being used in the country and their contribution to potential risks for human health and the environment.

Although specific information related to actual or measured terbufos exposure of agricultural workers in Mozambique was not included as part of the risk evaluation, the notification and supporting documentation provide an assessment of the prevailing conditions of use of pesticides in Mozambique. While no imports of terbufos formulations were recorded in the four years (2010–2013) prior to and including the period when the survey of users was carried out, registrations of those formulations remained in place and therefore future use could not be precluded. The registered uses for terbufos formulations were for maize, sorghum, potato and beans. These cropping systems were included in the survey of users conducted, and were the predominant crops in three of the regions of Mozambique surveyed. In addition, vegetable crops were reported as being the crops most frequently oversprayed by HHPs, which poses a risk to human health given the local conditions of use (application as many as 14 times per growing season). The notification and supporting documentation indicate that the use of pesticides in general, and of HHPs (such as terbufos) in particular, was likely to result in excessive exposure of farmers given the low availability and knowledge in the use of PPE among farmers, and was evidenced by a high level of reports of adverse health effects. The final regulatory action was taken as a result of the national objective of Mozambique of reducing the greatest risks associated with pesticide use.

Thus, terbufos and the products containing terbufos were considered harmful for human health under the local conditions of use in Mozambique requiring risk mitigation measures. Therefore, the authorities decided to ban terbufos from future use in the country and to cancel the registration of all the products containing terbufos.

3. Protective measures that have been applied concerning the chemical

3.1 Regulatory measures to reduce exposure

Canada The Pest Management Regulatory Agency, Health Canada. 2004. Re-evaluation Decision RRD2004-04: Re-evaluation of terbufos, and Pest Management Regulatory Agency, Health Canada. 2008. Re-evaluation Note REV2008-06: Update on the use of terbufos on sugar beets, prohibited the sale of pesticides containing terbufos in Canada effective May 1, 2012. The use of products containing terbufos was prohibited after August 1, 2012.

Mozambique Terbufos was banned by the National Directorate of Agrarian Services from further import and use in Mozambique by the decision Nr 001/DNSA/2014. The regulatory action entered into force on 15 July 2014.

3.2 Other measures to reduce exposure

Canada

None reported

Mozambique

None reported

3.3 Alternatives

Canada

At the time of the regulatory action, there were effective alternatives for management of flea beetle on canola and mustard. These included one other organophosphate, two carbamates, three pyrethroids and two neonicotinoids. Products containing imidacloprid, thiamethoxam, cypermethrin, deltamethrin, *lambda*-cyhalothrin, carbaryl and carbofuran were registered for controlling flea beetle in canola.

Alternative soil insecticides that were registered for control of corn rootworm, seedcorn maggot and wireworm in corn included carbaryl, chlorpyrifos, diazinon, tefluthrin and phorate.

Azinphos-methyl, chlorpyrifos, diazinon and phorate were registered as a prophylactic treatment at planting to control cabbage maggot on rutabaga. Carbaryl, endosulfan, methoxychlor, diazinon and cypermethrin were registered for controlling flea beetle on rutabaga.

Mozambique

Mozambique's Ministry of Agriculture and Food Security engaged with the producer association to assess alternative insecticide options and to facilitate registration of lower-risk products. In parallel, the Ministry is also promoting the use of biological pest control measures.

General

It is essential that before a country considers substituting a substance with alternatives, it ensures that the use is relevant to its national needs, and the anticipated local conditions of use. The hazards of the substitute materials and the controls needed for safe use should also be evaluated.

There are a number of alternative methods involving chemical and non-chemical strategies, including alternative technologies available, depending on the individual crop-pest complex under consideration. Where necessary, priority should be given to the introduction of integrated pest management or integrated vector management, agroecology and organics that make optimal use of agro-ecological approaches and reduces reliance on pesticides. This approach is explicitly supported by a broad range of international policy documents, including those of FAO, UNEP, WHO, World Bank and the OECD Development Assistance Committee.

SAICM's Fourth International Conference on Chemicals Management recommended that awareness should be raised to identify and share information about viable alternatives to HHPs, including cultural and environmental management measures, biological controls, biopesticides or less hazardous pesticides.

Information on such agroecologically-based practices can be found at the following websites:

FAO Agroecology hub: <http://www.fao.org/agroecology/en/>

IPAM (International Peoples Agroecology Multiversity): <http://ipam-global.org/>

OISAT (Online Information Service for Non-Chemical Pest Management in the Tropics):

<http://www.oisat.org/>

Replacing Chemicals with Biology: Phasing out Highly Hazardous Pesticides with Agroecology:

<https://saicmknowledge.org/library/replacing-chemicals-biology-phasing-out-highly-hazardous-pesticides-agroecology>

3.4 Socio-economic effects**Canada**

A significant challenge for Health Canada's PMRA was a regulatory decision that moved towards the goal of eliminating terbufos in a manner that was least disruptive to the need to protect agricultural crops from pests. To meet its challenge, the PMRA has considered the availability of alternatives and the need for a transition period for those uses for which no or limited alternatives were available.

A significant challenge for industry was to develop alternatives in the relatively short timeframe of the phase-out. A significant challenge for the agricultural sector was in adopting alternatives during the transition period.

Mozambique

None reported

4. Hazards and Risks to human health and the environment	
4.1 Hazard Classification	
WHO / IPCS	I a — Extremely Hazardous (WHO, 2019)
IARC	Not evaluated
European Union	Classification according to Regulation (EC) No 1272/2008 of the European Parliament and of the Council (CLP-Regulation) Acute Toxicity 2* - H300 (Fatal if swallowed) Acute Toxicity 1 - H310 (Fatal in contact with skin) Aquatic Acute 1 - H400 (Very toxic to aquatic life) Aquatic Chronic 1 - H410 (Very toxic to aquatic life with long lasting effects)
US EPA	1 (highly toxic) (US EPA, 1988)

4.2 Exposure limits**JMPR (2004)**

Acute reference dose (ARfD): 0.002 mg/kg bw

The Meeting established an acute RfD of 0.002 mg/kg bw based on a NOAEL of 0.15 mg/kg bw per day for miosis in the study of neurotoxicity in rats given a single dose of terbufos, and a 100-fold safety

factor. Since only in this study miosis was observed in the absence of inhibition of cholinesterase activity, it may be possible to refine the acute RfD after better characterization of this effect.

Acceptable Daily Intake (ADI): 0-0.0006 mg/kg bw

The Meeting established an ADI of 0-0.0006 mg/kg bw based on an overall NOAEL of 0.06 mg/kg bw per day and a safety factor of 100 for inhibition of brain cholinesterase activity in a 1-year toxicity study in rats, 13-week study of neurotoxicity and two-generation study of reproduction in rats, and 1-year study in dogs.

Canadian risk evaluation:

Acute reference dose (ARfD): 0.00015 mg/kg bw

In animal studies, the adverse effects noticeable at the lowest dose (i.e., the toxicity end point) were clinical signs observed in an acute rat neurotoxicity study (NOAEL = 0.15 mg/kg bw). The uncertainty factor was 100 (10x for interspecies extrapolation x 10x intraspecies variability). An additional safety factor of 10x was applied to account for the steepness of the dose response and the high degree of potency (based on lethality at very low doses). The acute reference dose (ARfD) was calculated to be 0.00015 mg/kg bw (0.15 mg/kg bw ÷ 1000). This value was considered to be protective of infants and children.

Acceptable Daily Intake (ADI): 0.00015 mg/kg bw/d

As the ARfD value was lower than any acceptable daily intake (ADI) derived from any of the repeat-dose toxicity studies (reflecting the high acute toxicity and use of the additional safety factor), the ADI was established at the same value as the ARfD. Thus, the ADI is 0.00015 mg/kg bw/d.

Environmental Risk Quotients:

Estimated environmental concentrations exceed acute and chronic effects levels in both fish and aquatic invertebrates. The risk quotients for acute effects on the majority of aquatic invertebrates tested were greater than 1, the threshold of concern. Values ranged from 10 to 409 following use on canola and from 28 to 2795 following use on corn, sugar beets or rutabaga. These risk quotients are classified as high risk to extremely high risk. The risk quotients for acute effects on fish were greater than 1, the threshold of concern. Values ranged from 4 to 106 following canola application rates and from 11 to 726 following use on corn, sugar beets or rutabaga. These risk quotients are classified as moderate risk to very high risk.

Maximum Residue Limits

JMPR (2005)

Commodity	MRL	Symbol
http://www.fao.org/fao-who-codexalimentarius/codex-texts/dbs/pestres/commodities/en/?cm=131 - CM131 Banana	0.05 mg/kg	
http://www.fao.org/fao-who-codexalimentarius/codex-texts/dbs/pestres/commodities/en/?cm=240 - CM240 Coffee beans	0.05 mg/kg	(*)
http://www.fao.org/fao-who-codexalimentarius/codex-texts/dbs/pestres/commodities/en/?cm=198 - CM198 Edible offal (mammalian)	0.05 mg/kg	(*)
http://www.fao.org/fao-who-codexalimentarius/codex-texts/dbs/pestres/commodities/en/?cm=229 - CM229 Eggs	0.01 mg/kg	(*)
http://www.fao.org/fao-who-codexalimentarius/codex-texts/dbs/pestres/commodities/en/?cm=156 - CM156 Maize	0.01 mg/kg	(*)

http://www.fao.org/fao-who-codexalimentarius/codex-texts/dbs/pestres/commodities/en/?cm=51 - CM51 Maize fodder (dry)	0.2 mg/kg	
http://www.fao.org/fao-who-codexalimentarius/codex-texts/dbs/pestres/commodities/en/?cm=195 - CM195 Meat (from mammals other than marine mammals)	0.05 mg/kg	(*)
http://www.fao.org/fao-who-codexalimentarius/codex-texts/dbs/pestres/commodities/en/?cm=187 - CM187 Milks	0.01 mg/kg	(*)
http://www.fao.org/fao-who-codexalimentarius/codex-texts/dbs/pestres/commodities/en/?cm=233 - CM233 Poultry meat	0.05 mg/kg	(*)
http://www.fao.org/fao-who-codexalimentarius/codex-texts/dbs/pestres/commodities/en/?cm=236 - CM236 Poultry, edible offal of	0.05 mg/kg	(*)
http://www.fao.org/fao-who-codexalimentarius/codex-texts/dbs/pestres/commodities/en/?cm=160 - CM160 Sorghum	0.01 mg/kg	(*)
http://www.fao.org/fao-who-codexalimentarius/codex-texts/dbs/pestres/commodities/en/?cm=55 - CM55 Sorghum straw and fodder, dry	0.3 mg/kg	dry wt
http://www.fao.org/fao-who-codexalimentarius/codex-texts/dbs/pestres/commodities/en/?cm=349 - CM349 Sugar beet	0.02 mg/kg	
http://www.fao.org/fao-who-codexalimentarius/codex-texts/dbs/pestres/commodities/en/?cm=319 - CM319 Sweet corn (corn-on-the-cob)	0.01 mg/kg	

(*): At or about the limit of determination.

Residue definition: For compliance with MRLs and for estimation of dietary intake in plant and animal commodities: Sum of terbufos, its oxygen analogue and their sulphoxides and sulphones, expressed as terbufos.

European Union

Pursuant to Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin (Official Journal of the European Union L 70, 16.3.2005, p. 1), the maximum residue limit is 0.01 mg/kg, except 0.05 mg/kg for bananas. The limit values are specified in Commission Regulation (EC) No 149/2008 (OJ L 58, 1.3.2008, p. 1–398).

https://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/mrls/?event=details&pest_res_ids=384&product_ids=&v=1&e=search.pr

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 2783 UN Hazard Class: 6.1 UN Pack Group: I Source: https://incchem.org/documents/icsc/icsc/eics1768.htm

International Maritime Dangerous Goods (IMDG) Code	Severe Marine Pollutant Source: https://pubchem.ncbi.nlm.nih.gov/compound/Terbufos#section=Shipment-Methods-and-Regulations
Transport Emergency Card	Not available

Further specific guidance on appropriate symbols and label statements for terbufos products may be available in the FAO 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.*

Safety and first aid recommendations extracted from the IPCS/WHO chemical safety card

(see complete chemical safety card at <https://inchem.org/documents/icsc/icsc/eics1768.htm>)

Avoid exposure of adolescents and children! Strict hygiene! First aid: use personal protection. In all cases consult a doctor!

Fire and explosion

Acute hazards: Combustible. Prevention: no open flames. Fire fighting: In case of fire in the surroundings: all extinguishing agents allowed.

Inhalation

Symptoms: Blurred vision. Headache. Dizziness. Muscle spasms. Weakness. Vomiting. Diarrhoea. Abdominal pain.

Prevention: Avoid inhalation of aerosol.

First aid: Fresh air, rest. Refer immediately for medical attention.

Skin

Symptoms: EASILY ABSORBED! Blurred vision. Headache. Dizziness. Muscle spasms. Weakness. Vomiting. Diarrhoea. Abdominal pain.

Prevention: Protective gloves. Protective clothing.

First aid: Remove contaminated clothes. Rinse and then wash skin with water and soap. Refer immediately for medical attention.

Eyes

Symptoms: No information

Prevention: Wear face shield

First aid: Rinse with plenty of water (remove contact lenses if easily possible). Refer for medical attention.

Ingestion

Symptoms: Blurred vision. Headache. Dizziness. Muscle spasms. Weakness. Vomiting. Diarrhoea. Abdominal pain.

Prevention: Do not eat, drink, or smoke during work. Wash hands before eating.

First aid: Rinse mouth. Refer immediately for medical attention. Give a slurry of activated charcoal in water to drink.

Spillage Disposal

Personal protection: chemical protection suit including self-contained breathing apparatus. Do NOT let this chemical enter the environment. Collect leaking liquid in covered containers. Then store and dispose of according to local regulations.

PubChem [internet]

Note: Terbufos is a cholinesterase inhibitor.

Signs and Symptoms of Acute Terbufos Exposure: Acute exposure to terbufos may produce the following signs and symptoms: pinpoint pupils, blurred vision, headache, dizziness, muscle spasms, and profound weakness. Vomiting, diarrhea, abdominal pain, seizures, and coma may also occur. The heart rate may decrease following oral exposure or increase following dermal exposure. Chest pain may be noted. Hypotension (low blood pressure) may be noted,

although hypertension (high blood pressure) is not uncommon. Respiratory symptoms include dyspnea (shortness of breath), respiratory depression, and respiratory paralysis. Psychosis may occur.

Emergency Life-Support Procedures: Acute exposure to terbufos may require decontamination and life support for the victims. Emergency personnel should wear protective clothing appropriate to the type and degree of contamination. Air-purifying or supplied-air respiratory equipment should also be worn, as necessary. Rescue vehicles should carry supplies such as plastic sheeting and disposable plastic bags to assist in preventing spread of contamination.

Inhalation Exposure: 1. Move victims to fresh air. Emergency personnel should avoid self-exposure to terbufos. 2. Evaluate vital signs including pulse and respiratory rate, and note any trauma. If no pulse is detected, provide CPR. If not breathing, provide artificial respiration. If breathing is labored, administer oxygen or other respiratory support. 3. Obtain authorization and/or further instructions from the local hospital for administration of an antidote or performance of other invasive procedures. 4. Transport to a health care facility.

Dermal/Eye Exposure: 1. Remove victims from exposure. Emergency personnel should avoid self-exposure to terbufos. 2. Evaluate vital signs including pulse and respiratory rate, and note any trauma. If no pulse is detected, provide CPR. If not breathing, provide artificial respiration. If breathing is labored, administer oxygen or other respiratory support. 3. Remove contaminated clothing as soon as possible. 4. If eye exposure has occurred, eyes must be flushed with lukewarm water for at least 15 minutes. 5. Wash exposed skin areas three times with soap and water. 6. Obtain authorization and/or further instructions from the local hospital for administration of an antidote or performance of other invasive procedures. 7. Transport to a health care facility.

Ingestion Exposure: 1. Evaluate vital signs including pulse and respiratory rate, and note any trauma. If no pulse is detected, provide CPR. If not breathing, provide artificial respiration. If breathing is labored, administer oxygen or other respiratory support. 2. Obtain authorization and/or further instructions from the local hospital for administration of an antidote or performance of other invasive procedures. 3. Vomiting may be induced with syrup of Ipecac. If elapsed time since ingestion of terbufos is unknown or suspected to be greater than 30 minutes, do not induce vomiting and proceed to Step 4. Ipecac should not be administered to children under 6 months of age. Warning: Ingestion of terbufos may result in sudden onset of seizures or loss of consciousness. Syrup of Ipecac should be administered only if victims are alert, have an active gag-reflex, and show no signs of impending seizure or coma. If ANY uncertainty exists, proceed to Step 4. The following dosages of Ipecac are recommended: children up to 1 year old, 10 mL (1/3 oz); children 1 to 12 years old, 15 mL (1/2 oz); adults, 30 mL (1 oz). Ambulate (walk) the victims and give large quantities of water. If vomiting has not occurred after 15 minutes, Ipecac may be readministered. Continue to ambulate and give water to the victims. If vomiting has not occurred within 15 minutes after second administration of Ipecac, administer activated charcoal. 4. Activated charcoal may be administered if victims are conscious and alert. Use 15 to 30 g (1/2 to 1 oz) for children, 50 to 100 g (1-3/4 to 3-1/2 oz) for adults, with 125 to 250 mL (1/2 to 1 cup) of water. 5. Promote excretion by administering a saline cathartic or sorbitol to conscious and alert victims. Children require 15 to 30 g (1/2 to 1 oz) of cathartic; 50 to 100 g (1-3/4 to 3-1/2 oz) is recommended for adults. 6. Transport to a health care facility.

Drugs and Antidotes: Specific treatment includes the antimuscarinic agent atropine and the enzyme reactivator pralidoxime.

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.

It should be noted that the disposal/destruction methods recommended in the literature are often not available in, or suitable for, all countries; e.g., high temperature incinerators may not be available. Consideration should be given to the use of alternative destruction technologies. Further information on possible approaches may be found in *Technical Guidelines for the Disposal of Bulk Quantities of Obsolete Pesticides in Developing Countries* (FAO, 1996b).

The most recent FAO tools and resources on pesticide related waste management are available from the Pesticide Related Waste Management section of the International Code of Conduct on Pesticide Management website (<https://www.fao.org/pest-and-pesticide-management/pesticide-risk-reduction/code-conduct/waste->

[management/en/](#)) and via the FAO's Pesticide disposal series webpage at <https://www.fao.org/publications/search/en/?serialtitle=RkFPIFB1c3RpY2lkZSBEaXNwb3NhbCBTZlJpZlZlM>

Disposal Methods for this chemical

PubChem [internet]

Recycle any unused portion of the material for its approved use or return it to the manufacturer or supplier. Ultimate disposal of the chemical must consider: the material's impact on air quality; potential migration in soil or water; effects on animal, aquatic, and plant life; and conformance with environmental and public health regulations.

Safety data sheets (SDS) for typical terbufos pest control products such as Counter® 20G or Terbufos 150 recommend disposal of waste product as hazardous waste via a licensed disposal contractor to an approved landfill or incinerator. The recommended disposal method for Terbufos 150 is incineration. Waste management and disposal indications specify not to discharge into drains or sewers and not to contaminate crops, grazing, rivers or dams with the chemical or used containers. Empty containers may retain some product residues. It is advised not to re-use containers, to triple rinse, render container unusable by crushing and/or puncturing and dispose in a safe manner via a licensed disposal contractor to an approved landfill or incinerator. Compliance with any local legislation applying to waste disposal is reiterated.

Counter® 20G SDS: https://s3-us-west-1.amazonaws.com/agrian-cg-fs1-production/pdfs/Counter_20G_Lock_n_Load_MSDS1n.pdf

Terbufos 150 SDS: http://envirobiochem.co.za/Resources/productPDFs/Terbufos%20150_MSDS.pdf

Annexes

- | | |
|---------|---|
| Annex 1 | Further information on the substance |
| Annex 2 | Details on Final regulatory action |
| Annex 3 | Address of designated national authorities |
| Annex 4 | References |

Annex 1	Further information on the substance
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The information presented in this Annex reflects the conclusions of the notifying parties: Canada and Mozambique. The notification from Canada was published in PIC Circular XXVII of June 2008⁴. The notification from Mozambique was published in PIC Circular LI of June 2020.

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 documents referenced in the notifications in support of the final regulatory actions to ban terbufos.

Furthermore, information from the FAO/WHO JMPR 2004 monograph of the toxicological evaluation of terbufos, as well as other sources such as PubChem, has been taken into account.

Annex 1 – Further information on notified chemical

1.	Physico-Chemical properties	
1.1	Identity	<u>ISO</u> : Terbufos <u>IUPAC</u> : S-[(tert-Butylsulfanyl)methyl] O,O-diethyl phosphorodithioate <u>CAS</u> : S-[[[(1,1-Dimethylethyl)thio]methyl] O,O-diethyl phosphorodithioate
1.2	Molecular Formula	C ₉ H ₂₁ O ₂ PS ₃
1.3	Molecular weight	288.43 g/mol
1.4	Colour and Texture	Colourless to pale yellow with a mercaptan-like odour
1.5	Melting point	Product is liquid at room temperature
1.6	Boiling Point	55°C at 0.02 mm Hg
1.7	Vapour Pressure	3.16 x 10 ⁻⁴ mm Hg at 25°C 6.98 x 10 ⁻⁴ mm Hg at 35°C 12.4 x 10 ⁻⁴ mm Hg at 45°C
1.8	Henry's Law Constant	0.000024 atm m ³ /mole, derived from its vapor pressure, 0.00032 mm Hg
1.9	Relative density	1.11 at 20°C
1.10	Solubility in water	4.5 mg/l (27°C)
1.11	Solubility in organic solvents	Solubility was >100 g/100mL solvent for each of the following solvents at 20°C: Acetone, acetonitrile, benzene, chloroform, dichloroethane, ethanol, n-heptane, dichloromethane, and toluene
1.12	Partition coefficient	Log Kow = 4.71
1.13	Dissociation constant	Not applicable; compound does not dissociate
1.14	Hydrolysis	At pH 5 and 20-25°C, half-life 4.5 days At pH 7 and 25°C, half-life 5.5 days At pH 9 and 25°C, half-life 8.5 days

⁴ The revised notification of final regulatory action from Canada submitted on 29 January 2021 replaces the notification for the same chemical submitted on 3 February 2008 and published in the PIC Circular XXVII, June 2008. The synopsis of the revised notification was published in the PIC Circular LIII in June 2021.

		At the conclusion of a four-week study, 75.1, 72.4, and 68.3% of the radioactivity at pH 5, 7, and 9, respectively, was hydrophilic, with formaldehyde constituting the principal degradation product. Organophilic products consisted of the phosphorylated series of oxidative metabolites.
1.15	Photolysis	Less than 1% of the applied dose (4 ppm) of terbufos remained after 1-day exposure to natural sunlight in pond water, with the sulfoxide CL 94301 accounting for 45.2%. Formaldehyde appeared to be the principal water-soluble reaction product. Organophilic radioactivity was due mainly to the phosphorylated oxidative metabolites and a minor amount of the methylated mercaptan series.
1.16	Decomposition temperature	Decomposes on prolonged heating above 120°C
1.17	Resistance to acids	Hydrolysed by strong acids (pH < 2)
	Resistance to alkalis	Hydrolysed by strong alkalis (pH > 9)
1.18	Storage stability	Stable for more than two years at room temperature.
2	Toxicological properties	
2.1	General	
2.1.1	Mode of Action	<p><u>Canada</u></p> <p>Acetylcholinesterase (AChE) inhibition</p> <p>Inhibition of acetylcholinesterase, an enzyme necessary for the proper functioning of the nervous system, or clinical signs of cholinergic toxicity. Phosphorylated terbufos metabolites (terbufos sulfoxide and terbufos sulfone) are of comparable toxicity to terbufos.</p>
2.1.2	Symptoms of poisoning	<p><u>PubChem [internet]</u></p> <p>Acute exposure to terbufos may produce the following signs and symptoms: pinpoint pupils, blurred vision, headache, dizziness, muscle spasms, and profound weakness. Vomiting, diarrhea, abdominal pain, seizures, and coma may also occur. The heart rate may decrease following oral exposure or increase following dermal exposure. Chest pain may be noted. Hypotension (low blood pressure) may be noted, although hypertension (high blood pressure) is not uncommon. Respiratory symptoms include dyspnea (shortness of breath), respiratory depression, and respiratory paralysis. Psychosis may occur.</p> <p>Signs and symptoms of acute intoxication by organophosphorus insecticides include muscarinic, nicotinic, and central nervous system (CNS) manifestations. Symptoms may develop rapidly, or there may be a delay of several hours after exposure before they become evident. The delay tends to be longer in the case of more lipophilic compounds, which also require metabolic activation. Symptoms may increase in severity for more than one day and may last for several days. In severe cases, respiratory failure is a dominant effect.</p>
2.1.3	Absorption, distribution, excretion and metabolism in mammals	<p><u>Canada</u></p> <p>Terbufos has a high dermal absorption potential. Phosphorylated terbufos metabolites (terbufos sulfoxide and terbufos sulfone) are of comparable toxicity to terbufos</p> <p><u>JMPR (2004)</u></p> <p>Rate and extent of oral absorption: rapid and fairly complete. Dermal absorption: rapidly penetrating following dermal or ocular application. Distribution: relatively rapid and fairly complete. Potential for accumulation: little. Rate and extent of excretion: relatively rapid and complete; most eliminated in 24–48 h; elimination in urine predominates. Metabolism in animals: sulfoxidation and desulfuration of</p>

terbufos is followed by hydrolysis of the thiophosphorus bond (S-P), enzymatic S-methylation and then additional S-oxidation.

2.2 Toxicology studies

2.2.1 Acute toxicity

Canada

In laboratory animals, terbufos was found to be extremely acutely toxic following acute oral, dermal and inhalation exposures. Following both single and repeated dosing, one of the most sensitive indicators of toxicity was the inhibition of acetylcholinesterase, an enzyme necessary for the proper functioning of the nervous system, or clinical signs of cholinergic toxicity. Phosphorylated terbufos metabolites (terbufos sulfoxide and terbufos sulfone) are of comparable toxicity to terbufos.

One of the most remarkable features of terbufos was the steepness and potency of the dose—response with acute and short-term dosing via the oral and inhalation routes. NOAELs were very close to dose levels that elicited mortality in the test animals. Terbufos has a high dermal absorption potential; however, the steepness and potency of the dose—response observed in oral studies was lacking with repeated dermal dosing.

Mozambique

Terbufos formulations registered in Mozambique were identified as Extremely Hazardous Class Ia according to the JMPM criteria for HHPs based on the WHO International Classification of Pesticides by Hazards.

JMPR (2004)

Terbufos is of very high acute toxicity when administered by the oral, dermal, or inhalation routes. LD₅₀ values for acute oral toxicity in rodents and dogs were similar, ranging from 1.4 to 9.2 mg/kg bw. The acute dermal LD₅₀ was about 1 mg/kg bw in rabbits, and the acute inhalation LC₅₀ in rats ranged from 0.0012 to 0.0061 mg/L. Clinical signs observed were those typical of cholinergic toxicity and, depending on the study, route and species, included tremors, salivation, exophthalmos, prostration, decreased activity, chromodacryorrhoea, diuresis, piloerection, ataxia, urogenital staining, nasal discharge, anorexia, and laboured breathing. Deaths following acute exposures occurred within minutes to hours or up to a week after administration.

Pesticide Manual. 16th Edition

Acute oral LD₅₀ for male and female albino rats 1.6 mg/kg and 5.4 mg/kg, respectively. Skin and eye acute percutaneous LD₅₀ for rats 9.8 mg/kg, rabbits 1.0 mg/kg. Skin and eye irritant. Inhalation LC₅₀ (4 h) for male rats 0.0061 mg/L air; for females 0.0012 mg/L air.

2.2.2 Short term toxicity

Canada

In animal studies, the adverse effects noticeable at the lowest dose (i.e., the toxicity end point) were clinical signs observed in an acute rat neurotoxicity study (NOAEL of 0.15 mg/kg bw). Other relevant NOAELs used for occupational end points include a NOAEL of 0.1 mg/kg bw/d from a developmental study for short-term dermal risk assessment in which there were increased resorptions and post-implantation losses at the next dose level, a NOAEL of 0.072 mg/kg bw/d from a multigeneration reproduction study for intermediate-term dermal risk assessment in which there were reproductive and offspring toxicity at the next dose level, and a NOAEL of 0.016 mg/kg bw/d from a 21-d inhalation study for short- and intermediate-term inhalation risk assessment, in which there was inhibition of cholinesterase activity and mortality at the next dose level.

JMPR (2004)

Target/critical effect: Inhibition of brain cholinesterase activity. Lowest relevant oral NOAEL 0.059 mg/kg bw per day (13-week study of neurotoxicity in rats).

Lowest relevant dermal NOAEL: Data not available. Lowest relevant inhalation NOAEC: No appropriate data available.

2.2.3 Genotoxicity
(including mutagenicity)

Canada

Terbufos was not found to be genotoxic to either rats or mice.

JMPR (2004)

Unlikely to be genotoxic. Most of the tests for mutagenicity with terbufos *in vitro* and *in vivo* gave negative results. However, in one acceptably performed study of dominant lethal mutation *in vivo*, results were inconclusive. In a paper from the open scientific literature, positive results were reported in an acceptably performed assay for mitotic gene conversion in yeast cells (*ade* locus) with technical-grade terbufos in the presence or absence of a metabolic activation system, and also with a commercial grade of terbufos, without metabolic activation. However, insufficient purity and analytical data were provided in the paper for the materials tested.

Although the results of an assay for unscheduled DNA repair synthesis in cells in primary culture were negative, only male Fischer 344 rat hepatocytes were used; an optimal protocol would also have included assessment of hepatocytes from female rats.

End-point	Test object	Concentration/dose	Results
<i>In vitro</i>			
Reverse mutation	<i>S. typhimurium</i> TA98, TA100, TA1535, TA1537, TA1538; <i>E. coli</i> WP2 <i>uvrA</i> ⁻	50–5000 µg/plate, 1000 µg/disc in DMSO, ±S9	Negative
Point mutation	Chinese hamster ovary cells (CHO-K ₁ -BH ₄), <i>Hprt</i> locus	10–100 µg/ml & in DMSO, ±S9	Negative
Chromosomal aberration	Chinese hamster ovary cells	2.5–100 nl/ml in DMSO, ±S9	Negative
Unscheduled DNA synthesis	Primary rat (male, Fischer 344) hepatocytes	0.33–33.33 µg/well in DMSO	Negative
Mitotic gene conversion	<i>S. cerevisiae</i> strain D4 (<i>ade</i> and <i>trp</i> loci)	Apparently 0.33–33 µg/tube in DMSO, ±S9	Technical-grade: positive at the <i>ade</i> locus (±S9); Commercial-grade: weakly positive at the <i>ade</i> locus (-S9)
<i>In vivo</i>			
Dominant lethal mutation (10 mating cycles)	Cr1 : CD(SD)BR rats (10 male rats per group)	0, 0.1, 0.2, or 0.4 mg/kg bw per day in corn oil by gavage daily for 5 days at the start of the first mating cycle	Inconclusive

Chromosomal aberration	Sprague-Dawley rats (20 males, 20 females per group), bone-marrow cells	Single intraperitoneal doses of 0, 0.2, 0.6, 1.5 (females only) or 1.8 mg/kg bw in corn oil	Negative
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2.2.4 Long term toxicity and carcinogenicity

Canada

Terbufos was not found to be carcinogenic to either rats or mice.

JMPR (2004)

Target/critical effect: inhibition of brain cholinesterase activity. Lowest relevant NOAEL: 0.055 mg/kg bw per day (1-year study in rats).

Carcinogenicity: no evidence of carcinogenicity; unlikely to pose a risk to humans.

2.2.5 Effects on reproduction

Canada

Terbufos did not cause fetal malformations in either rats or rabbits, but minimally increased resorptions and post-implantation losses were noted in the rat developmental study at a dose anticipated to cause cholinesterase inhibition in the maternal animals. In a reproductive toxicity study in rats, adverse effects following prolonged exposure to terbufos included reduced pregnancy rate, male fertility, litter size and viability of the young. The developmental and reproductive toxicity studies did not demonstrate any sensitivity of young animals relative to adult animals, although lack of cholinesterase measurements in these studies precluded a definitive assessment of this issue.

JMPR (2004)

Reproduction target/critical effect: decreases in male fertility and female pregnancy rate. Lowest relevant reproductive NOAEL: 0.086 mg/kg bw per day (rats). Developmental target/critical effect: not teratogenic; reduced fetal body weight. Lowest relevant developmental NOAEL: 0.25 mg/kg bw per day (rabbits).

2.2.6 Neurotoxicity/delayed neurotoxicity, Special studies where available

Canada

Terbufos did not cause any apparent delayed neurotoxicity and there was no evidence of histopathological effects on the central nervous system in any of the available studies.

JMPR (2004)

Acute neurotoxicity: Target/critical effect: miosis. Relevant NOAEL: 0.15 mg/kg bw (rats). 13-week study of neurotoxicity: Target/critical effect: inhibition of brain cholinesterase activity. Relevant NOAEL: 0.059 mg/kg bw per day (rats). Delayed neuropathy: No evidence to suggest toxicity at dietary exposures.

2.2.7 Summary of mammalian toxicity and overall evaluation

Canada

In laboratory animals, terbufos was found to be extremely acutely toxic following acute oral, dermal and inhalation exposures. Following both single and repeated dosing, one of the most sensitive indicators of toxicity was the inhibition of acetylcholinesterase, an enzyme necessary for the proper functioning of the nervous system, or clinical signs of cholinergic toxicity. Phosphorylated terbufos metabolites (terbufos sulfoxide and terbufos sulfone) are of comparable toxicity to terbufos. Terbufos did not cause any apparent delayed neurotoxicity and there was no evidence of histopathological effects on the central nervous system in any of the available studies. Terbufos was not found to be genotoxic nor was it carcinogenic to either rats or mice. Terbufos did not cause fetal malformations in either rats or rabbits, but minimally increased resorptions and post-implantation losses were noted in the rat developmental study at a dose anticipated to cause cholinesterase inhibition in the maternal animals. In a reproductive toxicity study in rats, adverse effects following prolonged exposure to terbufos included reduced pregnancy rate, male

fertility, litter size and viability of the young. The developmental and reproductive toxicity studies did not demonstrate any sensitivity of young animals relative to adult animals, although lack of cholinesterase measurements in these studies precluded a definitive assessment of this issue. Despite the lack of demonstrated sensitivity, these studies were considered during the risk assessment due to the serious nature of end points affected. One of the most remarkable features of terbufos was the steepness and potency of the dose—response with acute and short-term dosing via the oral and inhalation routes. NOAELs were very close to dose levels that elicited mortality in the test animals. Terbufos has a high dermal absorption potential; however, the steepness and potency of the dose—response observed in oral studies was not observed with repeated dermal dosing.

3 Human exposure/Risk evaluation

3.1 Food

Canada

Acute dietary risk from foods treated with terbufos was not a concern for the general Canadian population and all population subgroups (i.e., less than 100% of the ARfD is consumed). At the 99.9th percentile of exposure, the most highly exposed population subgroups, infants (<1 year old) and children (1-6 years old), consume 67% and 52% of the ARfD, respectively, in their food. The assessment has been conducted using market basket and residue data, as well as U.S. tolerances for imported crops. Percent crop treated data were used for domestic and imported crops, and processing factors were used for relevant matrices.

Bananas are the principal contributor to the acute dietary risk for terbufos. An import MRL is recommended at 0.005 ppm based on the dietary risk assessment. This proposed MRL is supported by field residue data.

Chronic dietary risk from foods treated with terbufos is not a concern for the general Canadian population and all population subgroups (i.e., less than 100% of the ADI is consumed). The most highly exposed population subgroups, infants (<1 year old) and children (1-6 years old), both consume 4% of the ADI in their food. The risk assessment was conducted using average residues, percent crop treated data and processing factors.

3.2 Air

JMPR (2004)

Terbufos is of very high acute toxicity when administered by the inhalation route. The acute inhalation LC₅₀ in rats ranged from 0.0012 to 0.0061 mg/L.

3.3 Water

JMPR (2004)

The important metabolites terbufos sulfoxide and terbufos sulfone are more mobile and persistent than parent terbufos. The sulfoxide and sulfone half-lives are 116 and 96 days, respectively. These metabolites are also mobile in all tested soils and may reach ground water when terbufos is used in a location where irrigation or rain water moves through the soil profile to groundwater. In addition, terbufos and its metabolites may enter surface water as a result of run-off events.

3.4 Occupational exposure

Canada

Workers can be exposed to a pesticide through mixing, loading, or applying the pesticide, and re-entering a treated site. Worker risk is estimated by a MOE that determines how close the occupational exposure comes to the NOAEL taken from animal studies. For workers entering a treated site, re-entry intervals (REIs) may be calculated to determine the minimum length of time required before workers or others are allowed to enter.

The risks associated with loading and applying the clay-based granular Counter 15-G (15% active ingredient) are below the PMRA's level of concern when a Lock'n Load closed handling system and other mitigation measures are used. The clay-based granular is sold exclusively in Lock'n Load packaging, according to the registrant.

The risk associated with exposure to Counter 5-G (corn-cob-based granular containing 5% active ingredient) during blending with seed commercially or on-farm and subsequent planting is expected to exceed the PMRA's level of concern.

Chemical-specific exposure data was used to assess the closed handling system scenario (i.e., representative of Counter 15-G). The Pesticide Handlers' Exposure Database (PHED) was used to assess the open mixing and loading scenario (i.e., representative of Counter 5-G).

For Counter 15-G, adequate worker protection would be afforded under the following conditions: for loading activities: Lock'n Load packaging and PPE including a long-sleeved shirt, long pants, chemical resistant apron and gloves. For application activities: closed cab, long-sleeved shirt and pants. As an interim measure pending implementation of closed cabs, coveralls over long pants and long-sleeved shirts, chemical registrant footwear and a respirator are recommended for application activities. These mitigation measures are the same as those in the recent US EPA re-evaluation of occupational risk to Counter 15-G.

MOEs for on-farm uses of Counter 5-G (open mixing and loading scenario) exceed the PMRA's level of concern based on available exposure information (PHED). No exposure study is available for commercial seed blending; however, due in part to the larger quantity of terbufos handled, longer duration of exposure and the open-bag loading scenario, commercial blending of Counter 5-G is also expected to exceed the PMRA's level of concern. Although the PMRA used toxicity end points and safety factors that differed from the EPA terbufos re-evaluation, use of the EPA toxicity end points and safety factors still resulted in inadequate MOEs for Counter 5-G. Furthermore, the EPA also expressed concerns over open-bag loading of terbufos on-farm. Commercial blending of terbufos is not a registered use in the USA.

Exposure to persons entering treated sites after application or exposure from drift to residential areas is considered minimal due to the application method (i.e., soil incorporation at planting with ground equipment). An REI of 48 h based on acute toxicity is sufficient to protect workers who may re-enter treated areas.

Mozambique

Field surveys on general pesticide use and exposure in Mozambique (325 subsistence farmers interviewed) revealed that almost none of the farmers (93%) owned or wore adequate PPE having only one or no protective items at all. Only 2% of those applying HHPs wore adequate full body protection PPE. About half of the farmers (50.2%) had not received any training on the use of pesticides. The majority of pesticide applicators used manual sprayers (36%), followed by electric sprayers with batteries (33%), and followed by inappropriate equipment such as watering cans (13.5%) or other (unknown) means (12.5%). Approximately about half of the farmers surveyed reported that they noticed to receive pesticide on their clothes, bare skin or eyes when using pesticides. The main health symptoms associated with pesticide use by farmers noticing symptoms were headaches, skin rashes, burning eyes, vomiting, burning nose, blurred vision, dizziness and excessive sweating. Almost half of the farmers declared they did not read pesticide labels, including use instructions such as proper dosage and protective measures, the main reason being illiteracy. One out of four farmers poorly understood the hazard colour band on pesticide labels that indicates acute toxicity.

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| 3.5 | Medical data contributing to regulatory decision | None reported |
| 3.6 | Public exposure | <u>JMPR (2004)</u>
There have been a number of reports of occupational and non-occupational poisoning incidents associated with exposure to terbufos. With regard to possible effects from terbufos manufacturing facilities, no "reportable incidents" have been noted and no other information was available. |
| 3.7 | Summary-overall risk evaluation | As part of Mozambique's national objective of reducing risks of the most dangerous pesticides including HHPs, Mozambique has conducted a risk evaluation of the human health effects of terbufos. Taking into consideration the results of the survey of pesticide use practices in selected cropping systems in Mozambique, (some of |

which are representative of potential terbufos use), which included the identification of inadequate availability and use of PPE and terbufos' high acute toxicity (WHO hazard classification Ia – extremely hazardous), Mozambique concluded that the use of terbufos was likely to result in excessive exposure of farmers in Mozambique and that enforcing risk mitigation measures depending solely on wearing the appropriate PPE under the local conditions of use would be difficult and unlikely to protect the human health.

4 Environmental fate and effects

4.1 Fate

4.1.1 Soil

Canada

Terbufos is susceptible to transformation by both abiotic and biotic processes. Hydrolysis appears to be a major abiotic transformation route for parent terbufos. Hydrolysis of terbufos sulfoxide and terbufos sulfone is pH dependent and is slower than for the parent compound. The major route for biotic transformation is aerobic biotransformation with terbufos sulfoxide, terbufos sulfone and CO₂ as the major transformation products. Based on available data, terbufos will be slightly to moderately persistent in terrestrial soil systems depending on temperature and soil conditions.

4.1.2 Water

Canada

Terbufos has low solubility in water and has moderate volatility potential from moist soil or water surfaces. The physical and chemical properties of terbufos indicate that in aquatic systems it will partition into sediments. Data on transformation rates for water—sediment systems indicate half-lives of 27-41 d, with relative rapid transformation in the water phase, primarily through hydrolysis, and slower transformation in sediment-sorbed terbufos. Both major terrestrial transformation products, terbufos sulfoxide and terbufos sulfone, were significantly more persistent than parent terbufos. Based on incident reports from the USA, it is evident that terbufos enters aquatic systems primarily via runoff from treated fields.

4.1.3 Air

PubChem (Internet)

If released to air, a vapor pressure of 0.00032 mm Hg at 20-25 °C indicates terbufos will exist solely as a vapor in the ambient atmosphere. Vapor-phase terbufos will be degraded in the atmosphere by reaction with photochemically-produced hydroxyl radicals; the half-life for this reaction in air is estimated to be 1.6 hours. Terbufos does not contain functional groups that are expected to absorb light at wavelengths >290 nm, and would not be expected to be susceptible to direct photolysis by sunlight in air. Volatilization from moist soil surfaces is expected based upon a Henry's Law constant of 0.000024 atm m³/mole. However, adsorption to soil is expected to attenuate volatilization. Volatilization from dry soil surfaces is not expected based upon its vapor pressure. Volatilization from water surfaces is expected based upon this compound's Henry's Law constant. Estimated volatilization half-lives for a model river and model lake are 2.8 and 26 days, respectively. However, volatilization from water surfaces is expected to be attenuated by adsorption to suspended solids and sediment in the water column.

4.1.4 Bioconcentration

Canada

n-Octanol-water partition coefficients indicate potential for a bioaccumulation of the parent compound and limited bioaccumulation potential for terbufos sulfone or terbufos sulfoxide. Bioconcentration studies with fish indicate a potential for bioconcentration.

4.1.5 Persistence

Canada

The PMRA has concluded that terbufos does not meet persistence criteria according to Canada's Toxic Substances Management Policy. Based on available data, terbufos is slightly to moderately persistent in terrestrial soil systems depending on temperature and soil conditions. In water-sediment systems, the half-lives of terbufos ranged from 27 to 41 d, with relatively rapid transformation in the water phase, and slower transformation in sediment sorbed terbufos.

4.2	Effects on non-target organisms	
4.2.1	Terrestrial vertebrates	<u>PPDB (Internet)</u> Mammals - Acute Oral LD ₅₀ = 1.3 mg/kg Rat Mammals - Short term dietary NOEL = 1 ppm Rat (2 year study) Birds - Acute LD ₅₀ > 185 mg/kg <i>Anas platyrhynchos</i>
4.2.2	Aquatic species	<u>PPDB (Internet)</u> Fish - Acute 96 hour LC ₅₀ > 0.004 mg/L <i>Lepomis macrochirus</i> Fish - Chronic 21 day NOEC = 0.0006 mg/L <i>Oncorhynchus mykiss</i> growth Aquatic invertebrates - Acute 48 hour EC ₅₀ = 0.0031 mg/L <i>Daphnia magna</i> . Aquatic crustaceans - Acute 96 hour LC ₅₀ = 0.00022 mg/L <i>Americamysis bahia</i> . Algae - Acute 72 hour EC ₅₀ , growth = 1.4 mg/L. Unknown species.
4.2.3	Honeybees and other arthropods	<u>PPDB (Internet)</u> Contact acute LD ₅₀ for honeybees (worst case from 24, 48 and 72 hour values - µg bee ⁻¹) = 4.1 µg/bee <i>Apis</i> spp.
4.2.4	Earthworms	<u>PPDB (Internet)</u> Acute 96 hour LC ₅₀ = 4 mg/kg
4.2.5	Soil microorganisms	No data available
4.2.6	Terrestrial plants	No data available
5	Environmental Exposure/Risk Evaluation	
5.1	Terrestrial vertebrates	<u>Canada</u> The PMRA has identified extremely high hazards to terrestrial organisms resulting from all currently registered uses of terbufos. This assessment is supported by reports of incidents in Canada and the USA. The estimated exposure concentrations for terrestrial organisms exceed acute effects levels for both birds and mammals. The acute risk from the direct consumption of granules is greatest for smaller species. The number of lethal doses (LD ₅₀ s) that are available within one square meter immediately after application (LD ₅₀ s/m ²) is used as the risk quotient for granular products. Risk quotients for acute effects in mammals were greater than 1 LD ₅₀ /m ² , the threshold of concern for tested species, following use of Counter 15-G in corn, rutabaga and sugar beets. Risk quotients ranged from 5 to 5910 LD ₅₀ /m ² depending on the size of the animal and the incorporation efficiency. Risk quotients for acute effects in mammals following use of Counter 5-G on canola ranged from 0.1 to 88 LD ₅₀ /m ² , depending on the size of the animal and the incorporation efficiency. For birds, risk quotients ranged from 7 to 11 250 LD ₅₀ /m ² depending on the size of the bird and the incorporation efficiency following use of Counter 15-G on corn, rutabaga or sugar beets. Risk quotients for acute effects on birds following use of Counter 5-G on canola ranged from 0.2 to 170 LD ₅₀ /m ² , depending on the size of the animal and the incorporation efficiency.

5.2	Aquatic species	<p>Canada</p> <p>The PMRA has identified extremely high hazard to aquatic organisms resulting from all currently registered uses of terbufos. This assessment is supported by reports of incidents of adverse effects in the USA. Similar effects may have occurred in Canada, but there is no equivalent reporting system.</p> <p>Estimated environmental concentrations exceed acute and chronic effects levels in both fish and aquatic invertebrates. The risk quotients for acute effects on the majority of aquatic invertebrates tested were greater than 1, the threshold of concern. Values ranged from 10 to 409 following use on canola and from 28 to 2795 following use on corn, sugar beets or rutabaga. These risk quotients are classified as high risk to extremely high risk. The risk quotients for acute effects on fish were greater than 1, the threshold of concern. Values ranged from 4 to 106 following canola application rates and from 11 to 726 following use on corn, sugar beets or rutabaga. These risk quotients are classified as moderate risk to very high risk.</p>
5.3	Honey bees	No information reported
5.4	Earthworms	No information reported
5.5	Soil microorganisms	No information reported
5.6	Summary – overall risk evaluation	<p>Health Canada’s PMRA identified extremely high hazards to terrestrial organisms resulting from all currently registered uses of terbufos. The assessment is supported by reports of incidents in Canada and the USA.</p> <p>The PMRA identified extremely high hazard to aquatic organisms resulting from all currently registered uses of terbufos. The assessment is supported by reports of incidents of adverse effects in the USA. Similar effects may have occurred in Canada, but there is no equivalent reporting system.</p> <p>Risk quotients determined for applications of the end-use terbufos formulations Counter 5-G and Counter 15-G indicate risks for all groups of organisms (i.e., birds, mammals, fish and aquatic invertebrates) for all application scenarios. Based on the available toxicity data, risk is classified as high to extremely high for aquatic organisms and in most cases high to extremely high for birds. Similarly, risk to mammals is classified as low for large mammals to high for small mammals.</p>

Annex 2 – Details on final regulatory actions reported

Country Name: Canada

1	Effective date(s) of entry into force of actions	1 August 2012
	Reference to the regulatory document	Pest Management Regulatory Agency, Health Canada. 2004. Re-evaluation Decision RRD2004-04: Re-evaluation of Terbufos. Pest Management Regulatory Agency, Health Canada. 2008. Re-evaluation Note REV2008-06: Update on the use of Terbufos on sugar beets.
2	Succinct details of the final regulatory action(s)	The sale of pesticides containing terbufos was prohibited in Canada effective May 1, 2012. The use of products containing terbufos was prohibited after August 1, 2012.
3	Reasons for action	Terbufos can cause harm to the environment. Preventing use of this chemical protects the environment and non-target organisms from the risk of exposure.
4	Basis for inclusion into Annex III	The final regulatory action was based on a risk evaluation taking into account the prevailing conditions in Canada.
4.1	Risk evaluation	<p>A re-evaluation of the active ingredient terbufos and its end-use products for use on canola, corn, mustard, rutabaga and sugar beet was conducted under the authority of Section 16 of the Pest Control Products Act.</p> <p>With regards to human health, occupational, dietary and aggregate (exposures from food and drinking water) risk assessments were conducted. A deterministic assessment of the environmental risks of pest control products was also conducted. Environmental risk was characterized by the quotient method, which uses the ratio of the estimated environmental concentrations to the end point of concern for effects on non-target organisms. Quotient values less than one are considered indicative of a low hazard to non-target organisms, whereas values greater than one are considered to indicate that some degree of hazard exists for effects on non-target organisms. The risk assessments were also subject to a 60-day public consultation period to allow interested parties an opportunity to provide input into the re-evaluation decision.</p> <p>Terbufos has low solubility in water and has moderate volatility potential from moist soil or water surfaces. n-Octanol-water partition coefficients indicate potential for a bioaccumulation of the parent compound and limited bioaccumulation potential for terbufos sulfone or terbufos sulfoxide. Bioconcentration studies with fish indicate a potential for bioconcentration.</p> <p>Terbufos is susceptible to transformation by both abiotic and biotic processes. Hydrolysis appears to be a major abiotic transformation route for parent terbufos. Hydrolysis of terbufos sulfoxide and terbufos sulfone is pH dependent and is slower than for the parent compound. The major route for biotic transformation is aerobic biotransformation with terbufos sulfoxide, terbufos sulfone and CO₂ as the major transformation products. Based on available data, terbufos will be slightly to moderately persistent in terrestrial soil systems depending on temperature and soil conditions.</p> <p>The physical and chemical properties of terbufos indicate that in aquatic systems it will partition into sediments. Data on transformation rates for water—sediment systems indicate half-lives of 27-41 d, with relative rapid transformation in the water phase, primarily through hydrolysis, and slower transformation in sediment-sorbed terbufos. Both major terrestrial transformation products, terbufos sulfoxide and terbufos sulfone, were significantly more persistent than parent terbufos.</p>

Based on incident reports from the USA, it is evident that terbufos enters aquatic systems primarily via runoff from treated fields.

The PMRA has identified extremely high hazards to terrestrial organisms resulting from all currently registered uses of terbufos. This assessment is supported by reports of incidents in Canada and the USA.

The PMRA has identified extremely high hazard to aquatic organisms resulting from all currently registered uses of terbufos. This assessment is supported by reports of incidents of adverse effects in the USA. Similar effects may have occurred in Canada, but there is no equivalent reporting system.

Risk quotients determined for applications of the end-use terbufos formulations Counter 5-G and Counter 15-G indicate risks for all groups of organisms (i.e., birds, mammals, fish and aquatic invertebrates) for all application scenarios. Based on the available toxicity data, risk is classified as high to extremely high for aquatic organisms and in most cases high to extremely high for birds. Similarly, risk to mammals is classified as low for large mammals to high for small mammals.

4.2	Criteria used Relevance to other States and Region	Risks to the environment Environmental risks are likely to be relevant in other countries with similar terbufos use pattern.
5	Alternatives	See section 3.3.
6	Waste management	None reported
7	Other	None reported

Country Name: Mozambique

1	Effective date(s) of entry into force of actions	July 15 th , 2014
	Reference to the regulatory document	Deliberação Nr. 001/DNSA/2014 by the National Directorate of Agriculture and Agrarian Services (The pesticide register Authority).
2	Succinct details of the final regulatory action(s)	Based on the decision Nr 001/DNSA/2014 terbufos was banned by the National Directorate of Agrarian Services from further import and use in Mozambique. The ban of all uses and the cancellation of the products containing terbufos in the country was decided due to the toxic nature and hazardous properties of this active substance which combined with the improper use in the country due to the local specific conditions of use can damage human and animal health. The decision to cancel the registration of terbufos was taken as the last step of the project for Risk Reduction of HHPs, which identified HHPs that are registered in Mozambique. After consultations with different actors (public sector, private sector, civil society and others), cancellation of registrations and consequent non-approval for their use in Mozambique was approved.
3	Reasons for action	Reducing the risk posed by the use of HHPs in Mozambique especially terbufos in the context of human health.
4	Basis for inclusion into Annex III	The final regulatory action was based on a risk evaluation taking into account the prevailing conditions in Mozambique.
4.1	Risk evaluation	<p>The notification states that the final regulatory action was based on a risk or hazard evaluation involving prevailing conditions within the Party in order to protect human health (UNEP/FAO/RC/CRC.17/8/Rev.1, section 2.4 of the Mozambique notification). With the goal of reducing the greatest risks associated with pesticide use in Mozambique, the Reducing Risks of Highly Hazardous Pesticides in Mozambique project was initiated by the Government of Mozambique, with the technical support of FAO's Pesticides Management Unit, and funded by SAICM Quick Start Programme Trust Fund. Its ultimate goal was to develop and implement an "HHP Risk Reduction Action Plan" in Mozambique for the most dangerous pesticides and use situations, resulting over time in the implementation of a variety of risk reduction measures based on a review of use conditions. These could include the cancellation of specific registrations of HHPs, implementation of risk mitigation measures, appropriate use restrictions, development of alternative pest management strategies, promotion of good agricultural practices, and possible phase-out of specific pesticides (UNEP/FAO/RC/CRC.17/INF/18).</p> <p>In the first step of the project, a review of all the pesticides registered in Mozambique was carried out and a shortlist of HHPs was established. This shortlist was based on an assessment of the hazards of the pesticides, based on criteria established by the FAO/WHO JMPM (FAO/WHO, 2008).</p> <p>During the second step of the project, a use survey was carried out in selected regions and cropping systems in Mozambique. The main goal of the survey was to identify the conditions under which pesticides are being used in the country and their contribution to potential risks for human health and the environment.</p> <p>The third step of the project consisted of a stakeholder consultation to further discuss the use and risks of HHPs in Mozambique and fine-tune the shortlist based on the survey results and the expertise and experience of stakeholders.</p> <p>As result, a short list of HHPs, including "coming close" to HHPs, which were used in the country, was established. Terbufos was shortlisted as a HHP based on the following FAO/WHO JMPM criterion for identification of HHPs:</p> <ul style="list-style-type: none"> - pesticide formulations that meet the criteria of classes Ia or Ib of the WHO Recommended Classification of Pesticides by Hazard.

To evaluate this criterion, all pesticide formulations registered in Mozambique were classified using the above mentioned hazard classification. The oral and dermal LD₅₀ value of the formulation, as provided in the registration dossier, was used as the basis for the classification.

LD₅₀ values for the formulation were available or could be estimated for all registered pesticide products except for three microbial pesticides and one citronella oil based product (i.e. > 99% of the total).

Terbufos formulations were identified as Extremely hazardous Class Ia according to the JMPM criteria for HHPs based on the WHO International Classification of Pesticides by Hazards, and therefore considered and shortlisted as a HHP (Come & van der Valk, 2014).

During the second phase of the project, field surveys on the pesticide use and exposure were carried out. The surveys (325 subsistence farmers interviewed) revealed that most of the farmers applied pesticides (95%), and that the conditions of use were likely to result in undue (excessive) exposure. Half of the farmers interviewed never received any training on pesticides use, and even the other half that did, often lacked understanding of the risks involved. Farmers were spraying vegetable crops at least 14 times per growing season. One out of three applications was involving one of the HHP containing formulation (Farmers using HHPs includes almost 30% of the interviewed farmers).

Also, almost none of the farmers (93%) owned or wore adequate PPE having only one or no protective items at all. Only 2% of those applying HHPs wore adequate full body protection PPE. About half of the farmers (50.2%) had not received any training on the use of pesticides. The majority of pesticide applicators used manual sprayers (36%), followed by electric sprayers (with batteries) (33%), and followed by inappropriate equipment such as watering cans (13.5%) or other (unknown) means (12.5%). Approximately about half of the farmers surveyed reported that they noticed to receive pesticide on their clothes, bare skin or eyes when using pesticides. The main health symptoms associated with pesticide use by farmers noticing symptoms were headaches, skin rashes, burning eyes, vomiting, burning nose, blurred vision, dizziness and excessive sweating. Almost half of the farmers declared they did not read pesticide labels, including use instructions such as proper dosage and protective measures, the main reason being illiteracy. One out of four farmers poorly understood the hazard colour band on pesticide labels that indicates acute toxicity.

The survey results showed that the use of pesticides in general, and of HHPs in particular, was likely to result in excessive exposure of farmers in Mozambique. Therefore, enforcing risk mitigation measures depending solely on wearing the appropriate PPE under the local conditions of use was considered difficult and unlikely to give results.

The third step of the project consisted of a stakeholder consultation to further discuss the use and risks of highly hazardous pesticides in Mozambique and fine-tune the shortlist based on the survey results and the expertise and experience of stakeholders.

Terbufos and the products containing terbufos were considered harmful for the human health under the local conditions of use in Mozambique requiring risk mitigation measures. Therefore, the authorities decided to ban terbufos from future use in the country and to cancel the registration of all the products containing terbufos.

4.2	Criteria used	Risks to human health
	Relevance to other States and Region	Countries with similar conditions as well as where the farmers use pesticides without protective equipment could make similar decision in order to protect the human health.
5	Alternatives	See section 3.3.
6	Waste management	None reported
7	Other	None reported

Annex 3 – Addresses of designated national authorities***CANADA***

(From PIC website: 13 October 2021)

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(From PIC website: 13 October 2021)

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