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Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade
Chemical Review Committee
Fifth meeting
Rome, 23–27 March 2009
Item 4 (c) (ii) of the provisional agenda*

Listing of chemicals in Annex III to the Rotterdam Convention: consideration of the draft decision guidance document for aldicarb

Draft decision guidance document for aldicarb

Note by the Secretariat

1. At its fourth meeting, the Chemical Review Committee reviewed the notifications of final regulatory actions for aldicarb from the European Community and Jamaica, including the supporting documentation referenced therein, and, taking into account each of the specific requirements set out in Annex II of the Rotterdam Convention, concluded that the requirements of that Annex had been met.

2. Accordingly, the Committee agreed to recommend to the Conference of the Parties that aldicarb should be listed in Annex III of the Rotterdam Convention. In addition, the Committee adopted a rationale for that recommendation and agreed to establish an intersessional drafting group to produce a draft decision guidance document for aldicarb.[1] A detailed workplan for the development of the decision guidance document was prepared by the Committee, in line with the process adopted by the Conference of the Parties in decision RC-2/2. The rationale, decision and workplan were attached to the report of the Committee on the work of its fourth meeting (UNEP/FAO/RC/CRC.4/11, annex I). The workplan was subsequently modified and an updated version posted on the Convention website.

* UNEP/FAO/RC/CRC.5/1.

1 The members of the drafting group on alachlor, established by the Chemical Review Committee at its fourth meeting, were Mr. Klaus Berend (Netherlands) and Ms. Norma Nudelman (Argentina) (co-chairs), Mr. Kamatari Aloys (Rwanda), Ms. Kyunghee Choi (Republic of Korea), Mr. Hubert Binga (Gabon), Ms. Anja Bartels (Austria), Ms. Marit Randall (Norway), Ms. Darina Liptokova (Czech Republic), Ms. Karmen Krajnc (Slovenia), Mr. Shan Zhengjun (China), Mr. Mohamed Khalifa (Libyan Arab Jamahiriya), Mr. Jasbir Singh (India), Mr. Idris Goji (Nigeria) and Mr. Ernest Mashimba (United Republic of Tanzania).

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3. The material available to the drafting group included a summary of the outcome of the fourth meeting of the Committee, a copy of a working paper on the preparation of internal proposals and decision guidance documents for banned or severely restricted chemicals, the notifications of final regulatory actions and the associated supporting documentation available to the Chemical Review Committee at its fourth meeting.

4. In accordance with the agreed workplan, the co-chairs of the drafting group, in consultation with the Secretariat, prepared an internal proposal document based on the notifications and the supporting documentation. That proposal was circulated to members of the drafting group for comment on 5 May 2008. The document was amended in the light of the comments received and was circulated, on 11 July 2008, to all members of the Committee and the observers who had attended the fourth meeting of the Committee.[2] Responses were received from members of the Committee and observers and taken into consideration in revising the draft decision guidance document on aldicarb.

5. A status report on the work of the drafting group, including a compilation of the comments and the draft decision guidance document, was circulated to drafting group members on 25 September 2008. As a result of this last round of comments, several minor editorial changes were incorporated into the draft decision guidance document.

6. A tabular summary of all of the comments received and how they were addressed is available in document UNEP/FAO/RC/CRC.5/INF/6.

7. The text of the draft decision guidance document on aldicarb, as submitted to the Secretariat by the drafting group, is set out in the annex to the present note. The annex has not been formally edited by the Secretariat.

2 The observers comprised 26 countries, 10 non-governmental organizations and one intergovernmental organization.

Annex

Rotterdam Convention
Operation of the Prior Informed Consent procedure
for banned or severely restricted chemicals

Draft Decision Guidance Document

ALDICARB

Secretariat for 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 [3] 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[4] 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/reduce such risks. However, inclusion does not imply that all Parties to the Convention have banned or severely restricted this 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 XXXX meeting, held in XXXX on XXXX the Conference of the Parties agreed to list aldicarb 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 the Designated National Authorities on [xxxx] 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 provide a decision regarding future import of the chemical.

The decision guidance document is prepared by the Chemical Review Committee (CRC). The CRC is a group of government designated experts established in line with Article 18 of the Convention, that evaluates candidate chemicals for possible inclusion in the Convention. The decision guidance document reflects the information provided by two or more Parties in support of the national regulatory actions to ban or severely restrict the chemical. It is not intended as the only source of information on a chemical nor is it updated or revised following its adoption by the Conference of the Parties.

There may be additional Parties that have taken regulatory actions to ban or severely restrict the chemical as well as others that have not banned or severely restricted it. Such risk evaluations or information on alternative risk mitigation measures submitted by Parties may be found on the Rotterdam Convention web-site (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.

Disclaimer

The use of trade names in this 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

[3] "'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."

[4] "'Party' means a State or regional economic integration organisation that has consented to be bound by this Convention and for which the Convention is in force."

include all trade names presently in use, only a number of commonly used and published trade names have been included in this document.

While the information provided is believed to be accurate according to data available at the time of preparation of this Decision Guidance Document, the Food and Agriculture Organization of the United Nations (FAO) and the United Nations Environment Programme (UNEP) disclaim any responsibility for omissions or any consequences that may flow 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.

ABBREVIATIONS	
<	less than
≤	less than or equal to
<<	much less than
>	greater than
≥	greater than or equal to
>>	much greater than
µg	microgram
µm	micrometer
AChE	acetylcholinesterase
ADI	acceptable daily intake
ADP	adenosine diphosphate
AOEL	acceptable operator exposure level
ARfD	acute reference dose
a.s.	active substance
ATP	adenosine triphosphate
b.p.	boiling point
bw	body weight
^{o}C	degree Celsius (centigrade)
CA	chemical association
CAS	chemical abstract service
cc	cubic centimetre
ChE	cholinesterase
CHO	Chinese hamster ovary
CIPAC	Collaborative International Pesticides Analytical Council
cm	centimetre
CS	capsule suspension
d	day(s)
DNA	Deoxyribose nucleic acid
DT_{50}	time 50% of a chemical to degrade
E.C.	European Community
EC	Emulsifiable Concentrate
EC_{50}	effect concentration, 50% (median effective concentration)
ED_{50}	effect dose, 50% (median effective dose)
EEC	European Economic Community
EHC	Environmental Health Criteria
EINECS	European inventory of existing commercial substances
FAO	Food and Agriculture Organisation of the United Nations
g	gram
GEMS/Food	Global Environment Monitoring System - Food contamination monitoring and assessment programme
h	hour
ha	hectare
IARC	International Agency for Research on Cancer

ABBREVIATIONS

IC_{50}	inhibition concentration, 50%;
IESTI	international estimate of short-term dietary intake
ILO	International Labour Organisation
i.m.	intramuscular
i.p.	intraperitoneal
IPCS	International Programme on Chemical Safety
IPM	Integrated Pest Management
ISO	International Organisation for Standardisation
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)
k	kilo- (x 1000)
kg	kilogram
Koc	organic carbon-water partition coefficient
l	litre
LC_{50}	lethal concentration, 50%
LD_{LO}	lowest lethal dose
LD_{50}	lethal dose, 50%
LOAEL	lowest observed adverse effect level
LOEL	lowest observed effect level
Log P	logarithm of the octanol/water partition coefficient
m	metre
mg	milligram
m.p.	melting point
ml	millilitre
MOE	margin of exposure
mPa	milliPascal
MRL	maximum residue level (or limit)
MTD	maximum tolerated dose
ng	nanogram
NOAEL	no-observed-adverse-effect level
NOEC	no-observed-effect-concentration
NOEL	no-observed-effect level
NRA	National Registration Authority for Agricultural and Veterinary Chemicals (Australia)
NTP	National Toxicology Program
OECD	Organisation for Economic Co-operation and Development
OHS	Occupational Health and Safety
PCM	phase contrast microscopy
PEC	predicted environmental concentration
PNEC	predicted no-effect concentration
Pow	octanol-water partition coefficient
PPE	personal protective equipment
RfD	reference dose for chronic oral exposure (comparable to ADI)
RTECS	Registry of Toxic Effects of Chemical Substances

ABBREVIATIONS	
SMR	standardized mortality ratio
STEL	short term exposure limit
STMR	supervised trials median residues
TER(s)	toxicity/exposure ratio(s)
TLV	threshold limit value
TWA	time weighted average
UL	ultra low volume liquid
UNEP	United Nations Environment Programme
US EPA	United States Environmental Protection Agency
UV	ultraviolet
WHO	World Health Organization
wt	weight

Decision guidance document for a banned or severely restricted chemical

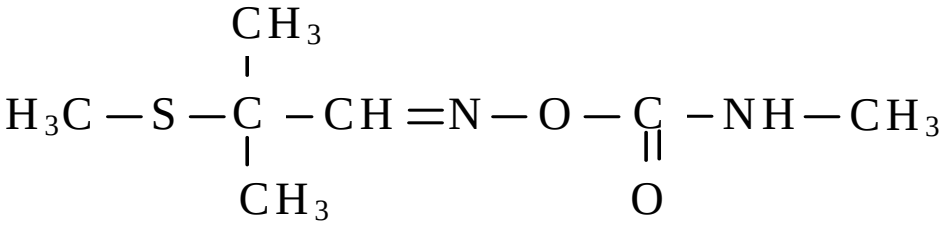
Aldicarb **Published:**

1. Identification and uses (see Annex 1)

Common name **Aldicarb**

Chemical name IUPAC: 2-methyl-2-(methylthio)propionaldehyde-O-methylcarbamoyl-oxime

Other names/ synonyms CA: 2-methyl-2-(methylthio)propanal –O- [(methylamino)carbonyl]-oxime



Molecular formula $C_7H_{14}N_2O_2S$

Structural formula

CAS-No. 116-06-3

Harmonised System Customs Code HS code for aldicarb: 2930 90
HS code for preparations containing aldicarb: 3808 91

Other numbers: CN code: 2930 90 85 (European Communities' Combined Nomenclature)
CIPAC: 215
EINECS: 204-123-2
RTECS: UE2275000

Category Pesticide

Regulated Category Pesticide

Use(s) in regulated category Aldicarb is an oxime carbamate insecticide, nematicide and acaricide. Aldicarb and its main biologically active metabolites (aldicarb sulfoxide and aldicarb sulfone) are systemic pesticides.

European Community: All intended uses were related to the soil application of granular formulations. Harmful organisms to be controlled covered a large range of insects, nematodes and aphids over a wide range of crops, including fruits (citrus, grape, strawberries, bananas), tomatoes, carrots, parsnips, brassica roots, leafy and headed brassica onions (bulb and seeds), potatoes, cereals, carnations, chrysanthemums, cotton, fodder beet, fodder peas, gladiolus, maize, ornamentals and perennial plants, roses, nurseries.

Jamaica: Temik 10 and 15 granular formulations of aldicarb were known to be used as insecticides to control sucking aphids, mites, leaf miner and nematodes particularly in citrus fruit and ornamentals. They were available to all farmers and could be applied to vegetables. They were applied to soil by hand.

Trade names	Selected trade names: Temik; Sanacarb, Sentry; Tranid Mixtures: Cardinal (+ fipronil); Regent Plus (+ fipronil) ; Trident (+ fipronil) *This is an indicative list. It is not intended to be exhaustive.*
Formulation types	Granules (GR)
Uses in other categories	No reported use as an industrial chemical.
Basic manufacturers	Bayer CropSciences, Agrochem, Dow AgriSciences (Pesticide Manual, 2006) *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

Aldicarb is included in the PIC procedure as a pesticide. It is listed on the basis of the final regulatory actions taken by the European Community and by Jamaica to ban aldicarb as a pesticide.

No final regulatory actions relating to industrial chemical uses have been notified.

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

European Community: It is prohibited to place on the market or use plant protection products containing aldicarb. Aldicarb is not included in the list of authorised active ingredients in Annex I to Directive 91/414/EEC.
The authorisations for plant protection products containing aldicarb had to be withdrawn by 18 September 2003. From the date of adoption of Council Decision 2003/199/EC (18 March 2003), no authorisations for plant protection products containing aldicarb could be granted or renewed.

Certain essential uses listed in the Annex to Council Decision 2003/199/EC remained authorised until 30 June 2007 under specific conditions.

Reason: It was concluded that it had not been demonstrated that aldicarb fulfilled the safety requirements laid down in Article 5 (1) (a) and (b) of Directive 91/414/EEC, in particular with regard to its possible impact on non-target organisms. Of particular concern were the risks to small birds and to earthworms.

Jamaica: Aldicarb was on the Second Schedule (prohibited list) of the Pesticides Act 1975, however, a registration was subsequently found on the Jamaican register of pesticides. In December1994, re-registration was refused and it was decided that no further registrations would be considered.

Reason: Use of the product represents an unacceptable risk to the health of small farmers, to human health through contaminated food and water, and to the environment due to possible contamination of groundwater and the risk to avian species.

2.2 Risk evaluation (see Annex 1 for details)

European Community: Directive 91/414/EEC provides for the European Commission to carry out a programme of work for the examination of existing active substances used in plant protection products which were on the market on 25 July 1993, with a view to their possible inclusion in the list of active ingredients in Annex I to the Directive. Within this context, a company notified its wish to secure the inclusion of aldicarb in the list of active ingredients in Annex I to the Directive, which can then be used in plant protection products to be authorised by the Member States. A Member State was designated to undertake a hazard and risk assessment based on the dossier submitted by the notifier.

The assessment report was subject to peer review during which the Commission undertook extensive consultations with experts of the Member States as well as with the notifier. The results were then reviewed by the Member States and the Commission within the Standing Committee on the Food Chain and Animal Health (SCFCAH). The dossier and the information from the review were also submitted to the Scientific Committee for Plants.

The evaluation was based on a review of scientific data generated for aldicarb and two representative formulations (Temik 10G and Temik 5G) in the context of the conditions prevailing in the European Community (intended uses, recommended application rates, good agricultural practices). Only data that have been generated according to scientifically recognized methods were validated and used for the evaluation. Moreover data reviews were performed and documented according to generally recognized scientific principles and procedures.

Human Health
The risk evaluation included assessments of exposure of both operators and consumers and potential effects on human health under conditions of use in the European Union. This evaluation concluded that use of aldicarb by operators protected in accordance with label requirements via hand held injectors and tractor mounted granule applicators with direct in-soil placement was not of risk to human health. The use of hand held application equipment in greenhouses and of tractor-mounted granule applicators with surface application and subsequent incorporation in soil was not fully assessed. Based on the available information it was concluded that there was no appreciable health risk for adults, young children and infants arising from possible residues in food.

Environmental impact
Final regulatory action was taken to protect non-target organisms, in particular birds and earthworms. Concerns were identified with regard to:

- **Terrestrial vertebrates**: The toxicity/estimated exposure ratios were very low on the basis of laboratory studies. The assessment of uses leads to an unacceptable risk to small birds. A probabilistic risk assessment for birds was submitted by the notifier. This refinement indicated that effects on national populations would not be expected, although some local impact might occur. Broadcast administration of aldicarb was not acceptable due to risks for birds and mammals. Incorporation in soil was considered as part of the evaluation, but the actual quantities of granules remaining on the soil, and thus available for small birds, depended strongly on the quality of the application conditions. Thus the risk to small birds through exposure to the granules cannot be reduced to an acceptable level. The risk to birds and small mammals via ingestion of earthworms as a food source was considered acceptable.
- **Aquatic species**: Aldicarb is very toxic to aquatic organisms. The toxicity/estimated exposure ratios were very low. Risks from broadcast applications at rates above 2.5 kg aldicarb/ha were unacceptable.
- **Bees and other arthropods species**: there was no risk to bees for an application rate up to 3.7 kg a.s./ha, but higher application rates were not addressed. A high risk for other non-target arthropod species was identified.
- **Earthworms:** acute risk was acceptable at application rates of up to 1 kg a.s./ha. For higher application rates, more field data concerning the acute risk of aldicarb on earthworms were requested: a study under agricultural field conditions revealed no significant effects at application rates of up to 3.36 kg a.s./ha. However, at the time of the regulatory action, the available information from field studies about the effects of aldicarb or its metabolites on earthworms was considered as still insufficient to conclude that the risks were acceptable.

Jamaica: The Pesticides Control Authority produced a Report on the Prohibition of Aldicarb in December 1994, which carried out a benefit/risk analysis which arrived at a decision to prohibit aldicarb from importation and use in Jamaica.

Human Health
Aldicarb represents a major risk to humans due to its high toxicity (WHO Class Ia). Aldicarb is the most acutely toxic agricultural chemical currently being used in both Jamaica and the USA. It is twice as acutely toxic as parathion which is banned in Jamaica. Epidemiological studies suggested that toxic effects were observed at exposure levels lower than the US National Academy of Sciences estimated safe level of 0.01 mg/kg. It was noted that aldicarb has a very steep dose-response curve, there is a broad variation in sensitivity of individuals to its toxic effects and it is toxic by all exposure routes; oral, dermal and by inhalation.

It is quite soluble in water and readily leaches through soil into groundwater and poses a serious risk of surface water contamination. The product is only available in granular form due to the extreme toxicity of the parent compound and its use is highly restricted in other countries due to the possible risk to handlers of the compound.

Residue risks: Adults and especially, infants and children may be exposed to dangerous levels of aldicarb due to its pollution of groundwater combined with aldicarb residues in popular foods. Aldicarb is mostly used on citrus fruit. In the USA, where positive displacement equipment is used to ensure consistent deposition in the ground and operators are highly trained, aldicarb has still been detected at level up to 0.2 ppm in fruit.

Risk to workers: Aldicarb was used primarily on citrus and ornamentals on small and medium farms in Jamaica. In

the years before 1994, specific products were made available to a limited number of farms under a stewardship program implemented by the manufacturer. However, it was reported that products containing aldicarb were in the hands of persons that were not capable of handling them and were being used on a wide range of crops including tomatoes. Pesticide operators on such small farms do not have access to protective gear. Also hot tropical climatic conditions make protective clothing uncomfortable. Use of the product was considered to represent an unacceptable risk to the health of these small farmers.

Environmental impact

In the USA, aldicarb is registered for use under very restricted conditions. This entails strong enforcement measures under environmental conditions that are less susceptible to contamination than found in an island ecology such as Jamaica. Due to the small size of an island such as Jamaica overall water resources are more limited than in larger continental countries and it is impractical to apply large buffer zones to protect water from pesticide contamination. However, aldicarb has been found in groundwater in Florida and other states where aldicarb is still used. In New York where the pesticide was used on potatoes, over ten times the Health Advisory level (100 ppb as against 10 ppb) has been detected in the groundwater. Aldicarb is now banned in the State of New York.

In Florida where aldicarb is still used on citrus, levels in excess of 30 ppb have been detected in groundwater. Aldicarb has contaminated groundwater in at least 14 states including California and has been detected on Long Island 15 years after its use was banned.

Jamaica has several areas of limestone and underground rivers where much of the farming is done. The water from these catchments become the source of drinking and irrigation water. Water contamination is therefore a real concern when determining which pesticides to register. Consequently, as evidenced by the incidents of pollution in the US, there is a risk of contamination of groundwater and surface water.

The risk evaluation took into consideration the island's ecology, compared it to the conditions in the US where the contamination occurred and also the measures that the US had put in place to prevent the contamination. The decision was taken on the basis that the pesticide presented an unacceptable risk of contamination of ground and surface water.

Ingestion of aldicarb granules poses a great threat to avian species; aldicarb is very toxic to birds and poses a danger to endangered species as well as the indigenous species of Jamaica.

3. Protective measures that have been applied concerning the chemical

3.1 Regulatory measures to reduce exposure

European Community: All applications as plant protection products were banned, except the essential uses listed below. Authorisations for essential uses were maintained until 30 June 2007 by the EC Member States indicated, provided that they:

(a) ensured that such plant protection products remaining on the market are relabelled in order to match the restricted use conditions;

(b) imposed all appropriate risk mitigation measures to reduce any possible risks in order to ensure the protection of human and animal health and the environment;

(c) ensured that alternative products or methods for such uses are being seriously sought, in particular, by means of action plans.

For all non-essential uses, for which existing authorisations had to be withdrawn by 18 September 2003, the EC Member States may have granted a period of grace for disposal, storage, placing on the market and use of existing stocks that expired no later than 18 September 2004. For essential uses that continued to be authorised until 30 June 2007, the grace period for disposal etc of existing stocks was 6 months (*i.e.* up until 31 December 2007).

List of essential uses that may have continued to be authorised (until 31 December 2007)

Member State	Use
Belgium	beet
Greece	potatoes and tobacco
Spain	cotton, citrus (young plantation) and woody nurseries
France	sugar beet and vineyards
Italy	sugar beet, tobacco and nurseries
Netherlands	ornamentals, sugar beet and potatoes (seed and starch)
Portugal	ctrus, floriculture and vineyards
United Kingdom	ptatoes, carrots (including parsnips), onions and ornamentals

Jamaica: All forms of aldicarb including Temik 10G and 15G which were registered at the time of the decision were banned and no formulation or use remained. Hence there was no longer any exposure of farmers and consumers to aldicarb.

3.2 Other measures to reduce exposure

European Community

As the regulatory action was a complete ban of all uses of aldicarb no further measures were taken.

Jamaica

As the regulatory action was a complete ban of all uses of aldicarb no further measures were taken.

3.3 Alternatives

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. Countries should consider promoting, as appropriate, integrated pest management (IPM) strategies as a means of reducing or eliminating the use of hazardous pesticides.

Advice may be available through National IPM focal points, the FAO, and agricultural research or development agencies. Where it has been made available by governments, additional information on alternatives to aldicarb may be found on the Rotterdam Convention website www.pic.int.

European Community: No information provided.

Jamaica: There are other products registered that will allow chemical control of the pests in question. Furadan granular which is of the same carbamate family of chemicals, may be used as a systemic acaricide/insecticide and as an effective nematicide. Neoron, Agri-Mek and Vendex all represent acaricides that are effective against red spider mites. Shell white oil along with Diazinon is effective against scales.

The use of Integrated Pest Management programmes will reduce the necessity of toxic pesticides for control of pests and represent the way forward for efficient cultivation. Improved management regarding the monitoring of the infestation of pests, the level of the population and the early and proper timing of contact and systemic sprays will provide effective control of insect pests and reduce the requirement for highly toxic chemicals.

3.4 Socio-economic effects

No detailed assessments of socio-economic effects were undertaken by the notifying parties.

4. Hazards and Risks to human health and the environment

4.1 Hazard Classification

WHO / IPCS	Ia Extremely Hazardous
IARC	3 (IARC, 1991) Not classifiable as to carcinogenicity in humans
US EPA	Category E, evidence of non-carcinogenicity for humans, based on the lack of evidence of carcinogenicity in studies in rats and mice and the absence of a mutagenicity concern.
European Community	Classification in the EC in accordance with Council Directive 67/548/EEC T+ (Very toxic); R26/28 (Very toxic by inhalation and if swallowed) T (Toxic); R24 (Toxic in contact with skin). N (Dangerous for the environment); R50/53 (Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment).

4.2 Exposure limits

Food: Acceptable Daily Intake (ADI) of 0-0.0025 mg/kg bw (ECCO, 1997).

Acute reference dose (ARfD) of 0.0025 mg/kg bw based on cholinesterase depression in a single oral dose study in human volunteers with a safety factor of 10 (ECCO. 1997).

The FAO/WHO Joint Meeting on Pesticide Residues (JMPR) have set an ADI of 0.003 mg/kg bw (JMPR, 1992) and an ARfD of 0.003 mg/kg bw/day (JMPR, 1995) based on the same human volunteer study.

Drinking water: WHO Drinking Water Guideline value of 0.01 mg/l: (WHO 2004a) based on an ADI of 0.003 mg/kg body weight/day, cholinesterase depression in a single oral dose study in human volunteers. Allocation to water of 10% of the ADI and a 60 kg adult consuming 2 litres of water per day.

4.3 Packaging and labelling

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

Hazard Class:	UN: 6.1 Toxic substances
Packing Group:	UN: I
International Maritime Dangerous Goods (IMDG) Code	Marine pollutant Do not transport with food and feedstuff.
Transport Emergency Card	61GT7-II

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.

Exposure: AVOID ALL CONTACT! AVOID EXPOSURE OF ADOLESCENTS AND CHILDREN! IN ALL CASES CONSULT A DOCTOR!

Inhalation:

Acute hazards/symptoms: sweating, papillary constriction, muscle cramp, excessive salivation. Dizziness. Laboured breathing. Nausea. Vomiting. Convulsions. Unconsciousness.

First aid: Fresh air, rest. Artificial respiration may be needed. Refer for medical attention as specific treatment is necessary.

Skin:

Acute hazards/symptoms: MAY BE ABSORBED! (for further see Inhalation).

First aid: Remove contaminated clothes. Rinse then wash skin with water and soap. Refer for medical attention as specific treatment is necessary.

Eyes:

First aid: First rinse with plenty of water for several minutes (remove contact lenses if easily possible), then take to a doctor.

Ingestion:

Acute hazards/symptoms: Abdominal cramps. Diarrhoea. Nausea (for further see Inhalation)

First aid: Give a slurry of activated charcoal in water to drink. Refer for medical attention as specific treatment is necessary.

(IPCS, 1994) Further information may be found on the website of the IPCS/WHO at ***www.inchem.org*** (see also HSG, 1991)

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 pesticide stocks the following guidelines are available: *FAO Guidelines on Prevention of Accumulation of Obsolete Pesticide Stocks* (1995), *The Pesticide Storage and Stock Control Manual* (1996) and *Guidelines for the management of small quantities of unwanted and obsolete pesticides* (1999).

In all cases waste should be disposed in accordance with the provisions of the Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and Their Disposal (1996), any guidelines there under (SBC, 1994), and any other relevant regional agreements.

For example in the European Community all non-essential uses, for which existing authorisations had to be withdrawn by 18 September 2003, Member States may have granted a period of grace for disposal, storage, placing on the market and use of existing stocks that expired no later than 18 September 2004. For essential uses that continued to be authorised until 30 June 2007, the grace period for disposal etc of existing stocks was 6 months (*i.e*. up until 31 December 2007).

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* (1996).

Specific information on aldicarb

Sweep spilled aldicarb into containers. If appropriate, moisten first to prevent dusting. Carefully collect remainder, and then remove to a safe place. A personal chemical protection suit, including a self-contained breathing apparatus, should be worn. Do not let this chemical enter the environment (IPCS, 1994).

Storage requires provision to contain effluent from fire extinguishing. Separated from food and feedstuffs (IPCS, 1994)

Store aldicarb indoors in an isolated, well-ventilated, clean, dry, cool area (not above 46°C). Store away from incompatible substances, such as highly alkaline materials. Aldicarb should be stored in a manner that will preclude mixing with water, because the resultant solution may be seriously hazardous. Do not store near food, animal feed, or other items intended for human or animal consumption. Make certain that the storage area is inaccessible to children (IPCS, 1994, see also HSG, 1991).

Annexes

Annex 1 Further information on Aldicarb

Introductory text to Annex I

The information presented in this Annex reflects the conclusions of the two notifying parties: European Community and Jamaica. In a general way, information provided by these two parties on the hazards are synthesised and presented together, while the risk evaluation, specific to the conditions prevailing in European Community and Jamaica, are presented separately. This information is contained in the documents referenced in the notifications in support of their final regulatory actions, severely restricting (European Community) and banning (Jamaica) aldicarb. The notification from European Community was first reported in PIC Circular XIX of June 2004 and the notification from Jamaica in PIC Circular XXVI of December 2007. Both notifications were considered in the fourth Meeting of the Chemical Review Committee in March 2008.

The notification of the European Community is based on its own risk evaluation of aldicarb. The full report, Monograph on the Review of aldicarb was produced by the European Community in 1997 (ECCO, 1997). This report was subsequently updated by various addenda.

The notification of Jamaica includes consideration of the Environmental Health Criteria document published by the International Programme on Chemical Safety (IPCS, 1991) and a Special Review Technical Support Document on aldicarb produced by the US Environmental Protection Agency (US EPA, 1988), comparing the worker exposure and leaching conditions with the conditions of use in Jamaica. Some further data have been taken from these documents to complete the information in this document.

The FAO/WHO Joint Meeting on Pesticide Residues (JMPR) have carried out a number of evaluations on aldicarb in 1979, 1982, 1992 and 1995 and an acceptable daily intake (ADI) was set in 1992 and confirmed in 1995 when an Acute Reference Dose (RfD) was also derived (JMPR, 1992, 1995).

Annex 1 – Further information on aldicarb

1. Physico-Chemical properties

1.1	**Identity**	ISO: aldicarb IUPAC: 2-methyl-2-(methylthio)propionaldehyde-O-methylcarbamoyl-oxime CA: 2-methyl-2-(methylthio)propanal –O- [(methylamino)carbonyl]-oxime
1.2	**Formula**	$C_7H_{14}N_2O_2S$
1.3	**Molecular Mass**	190.3
1.4	**Melting point**	102-103°C
1.5	**Colour and Texture**	White crystalline solid
1.6	**Relative Density**	1.195 (specific gravity at 25°C)
1.7	**Vapour pressure**	3.4×10^{-3} Pa at 25°C
1.8	**Henry's Law Constant**	1.23×10^{-4} kPa m^3 g mol^{-1} at 25°C (calculated)
1.9	**Solubility**	In water: pH 5 : 5.29 g/l at 20°C pH 7 : 4.93 g/1 at 20°C pH 9 : 4.95 g/l at 20°C (significant decomposition) In hexane: 1 g/l In acetone: 373 g/l In dichloromethane: 578 g/l
1.10	**Partition coefficient (log P_{ow})**	1.15 at 25°C
1.11	**Hydrolytic stability (DT_{50})**	pH 4: -- pH 7:-- pH 8.5: 170 d
1.12	**Photo stability**	4.1 d (pH 5 at 25°C) in water

2 Toxicological properties

2.1	**General**	
2.1.1	**Mode of Action**	Aldicarb is an inhibitor of 'true' brain acetyl cholinesterase. It has been designed to resemble *O*-acetylcholine.
2.1.2	**Symptoms of poisoning**	Acute hazards/symptoms for inhalation and dermal exposure: sweating, papillary constriction, muscle cramp, excessive salivation. Dizziness. Laboured breathing. Nausea. Vomiting. Convulsions. Unconsciousness. For exposure by ingestion, the above symptoms and abdominal cramps, diarrhoea and nausea.
2.1.3	**Absorption, distribution, excretion and metabolism in mammals**	When aldicarb is given orally to rats, it is absorbed readily (93% within 2 days), distributed widely in the body, and excreted rapidly (95% excreted within 4 days). The potential for accumulation is negligible. The main animal metabolites identified are: aldicarb sulfoxide, aldicarb sulfone.
2.2	**Toxicological studies**	
2.2.1	**Acute toxicity**	

Acute toxicity	
LD_{50} (oral, rat)	0.5 mg/kg, (T+), R 28
LD_{50} (dermal, rat)	218 mg/kg, (T), R 24
LC_{50} (inhalation, rat)	0.0039 mg/l, (T+), R 26
Skin and eye irritation	no data on a.s., 36% aldicarb in dichloromethane, not classifiable

		High acute oral, dermal and inhalation toxicity. Signs of toxicity are those commonly associated with cholinesterase inhibition by a carbamate insecticide. Human studies have revealed a pattern of rapid cholinesterase inhibition and rapid recovery. Transient erythrocyte cholinesterase depression was seen at single doses of 0.05 mg/kg bw and the NOEL for erythrocyte cholinesterase depression was 0.025 mg/kg bw (ECCO, 1997).
2.2.2	**Short term toxicity**	Signs of toxicity of repeated administration are those commonly associated with cholinesterase inhibition by a carbamate insecticide. The most sensitive indicator of exposure is cholinesterase depression. Target / critical effect brain, erythrocyte / cholinesterase inhibition Lowest relevant NOAEL 0.065 mg/kg bw/d, 1 year dog study
2.2.3	**Genotoxicity (including mutagenicity)**	From weight of evidence, aldicarb and its major toxic metabolites, aldicarb sulfoxide and aldicarb sulfone do not exhibit genotoxic potential of relevance to man. Aldicarb and its metabolites are not mutagenic in bacterial or mammalian gene mutation tests. Aldicarb is negative in *in vitro* DNA damage tests or *in vivo* micronucleus or dominant lethal tests. It is weakly positive in *in vitro* sister chromatid exchange (SCE) assays and positive in a DNA damage assay in *S typhimurium*.
2.2.4	**Long term toxicity and carcinogenicity**	The most sensitive indicator of exposure in rats and dogs is cholinesterase depression. Target / critical effect brain, erythrocyte / cholinesterase inhibition Lowest relevant NOAEL 0.5 mg/kg, 2 year rat study There is no carcinogenic potential in rat and mouse in lifetime studies.
2.2.5	**Effects on reproduction and teratogenicity**	Reproduction negative Developmental toxicity negative Aldicarb did not produce a teratogenic response with orally administered aldicarb (by gavage) at levels up to 0.5 mg/kg bw/day. There was no increased incidence of malformations in the absence of maternal toxicity. The NOEL was 0.125 mg/kg bw/day for maternal toxicity and 0.25 mg/kg bw/day for embryo-fetal toxicity and teratogenicity. In a two-generation reproduction study, the NOEL for reproductive and developmental endpoints was 10 ppm and the NOEL for cholinesterase depression was 5 ppm (ECCO, 1997).
2.2.6	**Special studies on neurotoxicity**	**Delayed neurotoxicity** Did not induce a delayed neurotoxic syndrome (as induced by other organophosphate esters).
2.2.7	**Summary of mammalian toxicity and overall evaluation**	WHO has classified aldicarb as Ia extremely hazardous (WHO 2004b). The LD_{50} values for aldicarb include 0.5 mg/kg, (oral, rat), and 218 mg/kg, (dermal, rat) and LC_{50} (inhalation, rat) is 0.0039 mg/l. There was no information on skin or eye irritation or sensitization with the active substance. Signs of toxicity were those commonly associated with cholinesterase inhibition by a carbamate insecticide: Acute hazards/symptoms for inhalation and dermal exposure: sweating, papillary constriction, muscle cramp, excessive salivation. Dizziness. Laboured breathing. Nausea. Vomiting. Convulsions. Unconsciousness. For exposure by ingestion, the above symptoms and abdominal cramps, diarrhoea and nausea. Aldicarb had no genotoxic potential of relevance to man, was not carcinogenic and had no reproductive or developmental toxicity. There were no concerns identified from immunological and neurobehavioural studies and it was negative for delayed neurotoxicity. The most relevant toxicological endpoint is the depression of cholinesterase activity

in brain or erythrocyte.

Acceptable Daily Intake (ADI) of 0-0.0025 mg/kg bw

Acute reference dose (ARfD) of 0.0025 mg/kg bw
Acceptable Operator Exposure (AOEL) of 0.0025 mg/kg bw/day

These values were based on cholinesterase depression in a single oral dose study in human volunteers with a safety factor of 10 (ECCO, 1997).

JMPR have set a ADI of 0.003 mg/kg bw (JMPR, 1992) and ARfD of 0.003 mg/kg bw/day (JMPR, 1995) based on the same human volunteer study.

3 Human exposure/Risk evaluation

3.1 Food

European Community

The final regulatory action was taken to protect the environment. However an evaluation of the risks to human health was also undertaken as part of the complete evaluation. Aldicarb is very toxic by inhalation if swallowed, and in contact with skin.

This evaluation focused on the risk presented by aldicarb to operator and consumer health only for formulations and uses which were intended in the European Community, i.e. soil application/incorporation of granular formulation at application rates ranging from 0.25 to 20 kg aldicarb/ha and use of appropriate personal protective equipment

The initial European Community risk assessment based on a theoretical maximum daily intake of aldicarb sulfoxide and aldicarb sulfone in the total diet suggested that they exceeded the proposed Acceptable Daily Intake (ADI). However, a later comparison of the toxicological data and the potential dietary exposure to aldicarb residues in potatoes, carrots, oranges and bananas for adults, young children and infants, as derived by the probabilistic approach at selected high percentiles of the exposure distribution, showed that the estimated exposures were below the Acceptable Daily Intake (ADI). Based on the available information it was concluded that there was no appreciable health risk for adults, young children and infants arising from possible residues in food (ECCO, 1997).

Jamaica

Residues have been detected in the USA in a variety of crops on which aldicarb has been applied. In the USA there has been aldicarb intoxication from eating contaminated water melons (in California and Oregon) and cucumbers (in Nebraska). Aldicarb was not approved for use on these crops. In a survey of potatoes in New York State, over 50% of samples contained aldicarb sulfoxide or sulfone (not aldicarb itself) (IPCS, 1991).

In USA, up to 0.2 ppm of aldicarb has been detected in citrus fruit. Considering that aldicarb is used under very restricted conditions by highly trained workers, including the use of positive displacement equipment to ensure consistent deposition of the pesticide in the ground, aldicarb was still detected in citrus fruit. The evaluation of Jamaica considered this to be of concern.

The evaluation by Jamaica stated that it had been reported that the aldicarb product, Temik, was in the hands of persons that were not capable of handling the product and were not wearing PPE, and it was being used on vegetable and other products where there were potential health concerns for both consumer and user (PCA, 1994).

It was concluded that there was an unacceptable risk of contamination of food products in Jamaica based on known incidents in the USA and the normal pattern of use under the prevailing conditions in Jamaica.

3.2 Air

European Community

Concentrations of aldicarb in air are expected to be low due to the low volatility of aldicarb, the relatively low Henry's Law constant and its incorporation into soil (ECCO, 1997).

3.3 Water

Jamaica

Aldicarb is registered for use in the USA under very restricted conditions. This entails strong enforcement measures under environmental conditions that are less susceptible to contamination than island ecology like Jamaica (PCA, 1994). Even so, aldicarb has been found in the groundwater of at least 14 states including California and Florida (US EPA, 1988). In New York State where aldicarb is used on potatoes, aldicarb has been detected in groundwater at 100 µg/l, over ten times the Health Advisory level for drinking water (10 µg/l). Aldicarb has still been detected in Long Island groundwater, 15 years after it was banned. Due to the small size of an island such as Jamaica overall water resources are more limited than in larger continental countries and it is impractical to apply large buffer zones to protect water from pesticide contamination (PCA, 1994).

The US EPA has estimated that when drinking water contains 10 µg/l aldicarb, as many as 13% of consuming infants could be exposed to a dose of 0.001 mg/kg body weight or greater of aldicarb (US EPA, 1988). The corresponding margin of safety for cholinesterase inhibition would then be 10 or less, based on the No Observed Adverse Effect Level estimated by the National Academy of Sciences (NAS; US EPA, 1988). The evaluation in Jamaica noted that epidemiological studies of actual human poisoning incidents had found ill effects caused by aldicarb at exposure levels lower than the NAS estimated safe level of 10 µg/l (PCA, 1994).

As Jamaica has several areas of limestone and underground rivers where much of the farming is done it was concluded that there was a risk of contaminating ground water and hence, drinking water, based on known incidences in the USA.

3.4 Occupational exposure

European Community

The first risk assessment performed concluded that the overall application by *downward placement* and *band application* might be acceptable but further exposure data were required. Usage of *hand held equipment* and overall application by *broadcast* was considered unacceptable.

While the available toxicological information supported the setting of an AOEL value of 0.0025 mg/kg bw (based on a NOEL from human volunteer study with an assessment factor of 10), exposure predictions for the various scenarios of use were uncertain, pending the submission of specific field studies conducted under relevant conditions.

During the course of the evaluation process, a new study was provided which enabled it to be concluded that for tractor-mounted equipment, the measured exposure is well below the AOEL with either a 10 % or 100 % dermal absorption factor.

Due to the particular modes of application of this plant protection product, specific information was needed on exposure for the various techniques of application used. Additional information was submitted to the Rapporteur Member State on hand held application in citrus with a study conducted in the field using hand held injectors. The study data combined with a dermal penetration factor of 10% as recommended by the Rapporteur Member State showed an acceptable margin of safety for operators protected in accordance with label recommendations.

The use of hand held applications in greenhouse was not fully assessed. A further study examined the use of tractor-mounted granule applicators with surface application and subsequent incorporation. Although not regarded as fully meeting the required standard for a registration study, these data indicated an estimated systemic exposure of 0.007 mg/kg/bw, corresponding to 40% of the AOEL.

Therefore it was concluded that further data would be required to support this method of application.

Jamaica
In their evaluation, Jamaica considered that aldicarb was the most acutely toxic agricultural chemical being used in the country. It was twice as acutely toxic as the organophosphate pesticide parathion (LD_{50} 2 mg/kg body weight) which is banned in Jamaica and 1500 times more toxic than malathion. It is extremely toxic to the human nervous system at low doses. The evaluation in Jamaica noted that epidemiological studies of actual human poisoning incidents had found ill effects caused by aldicarb exposure at levels lower than the NAS estimated safe levels (PCA, 1994).

A particularly hazardous characteristic of aldicarb was its very steep dose-response curve with a small difference between a dose with no or mild clinical signs and one causing severe clinical signs or even death. Additionally the history of aldicarb poisonings indicates a broad range of sensitivities to its toxic effects.

Pesticide operators, mainly small farmers, in Jamaica do not have access to protective gear (PIC, 2008). A further reason why they fail to wear protective clothing is that it is uncomfortable in the hot tropical climatic conditions. Therefore, use of the product was considered to represent an unacceptable risk to the health of small farmers (PCA, 1994).

3.5 Medical data

The symptoms reported for accidental or occupational poisoning or controlled human exposure are cholinergic and usually subside spontaneously usually within 6 hours, unless fatal. Clinical signs and symptoms include dizziness, salivation, excessive sweating, nausea, epigastric cramps, vomiting, diarrhoea, bronchial secretion, blurred vision, non-reactive contracting pupils, dyspnoea and muscular fasciculations. The intensity of these varies with the extent of exposure (IPCS, 1991).

There have been a number of reported aldicarb poisonings due to the consumption of fruit including water melons and cucumbers. The poisoning of about 1000 people from contaminated watermelons occurred in 1985 in California with the most serious signs and symptoms being unconsciousness and cardiac arrhythmias. Six deaths and two stillbirths were reported (IPCS, 1991).

Human volunteer studies were conducted on 12 men given 0.025, 0.05 or 0.10 mg/kg body weight. Mild signs and symptoms were observed at the highest dose and blood cholinesterase levels were depressed in a dose-dependent fashion after 1 hour but then became elevated after 4 hours, returning to near normal by 6 hours (IPCS, 1991).

3.6 Summary – overall risk evaluation

European Community: The risk evaluation included assessments of exposure of both operators and consumers and potential effects on human health under conditions of use in the European Union. This evaluation concluded that there were no unacceptable risks to consumers and that the use of aldicarb by operators protected in accordance with label requirements via hand held injectors and tractor mounted granule applicators with direct in-soil placement represented an acceptable risk to human health. The use of hand held applications in greenhouse application and of tractor-mounted granule applicators with surface application and subsequent incorporation in soil was not fully assessed.

Jamaica: The risk evaluation was based on concerns about the health effects of aldicarb to small-scale farmers as a result of occupational exposure and to consumers through the potential contamination of water and residues in food.

4 Environmental fate and effects

4.1 Fate

4.1.1 Soil and sediment

Aldicarb is not persistent in soil. Aldicarb degraded with half-lives of 2-12 days in laboratory studies. Aldicarb is oxidised to aldicarb sulfoxide and then to aldicarb sulfone. In field studies the dissipation of total carbamate residues (aldicarb, aldicarb sulfoxide and aldicarb sulfone) occurred with $DT_{50\ field}$ 0.5 to 2 months and $DT_{90field}$ 2.5 to 4.7 months (ECCO, 1997).

Aldicarb is mobile in most types of soil. Incidents of groundwater contamination with aldicarb have been primarily associated with sandy soils as it binds poorly to this soil type (sands, loamy sands and sandy loams, primarily) and any water input to sandy soil (rain and irrigation) tends to recharge rapidly though the profile, carrying aldicarb with it (US EPA, 1988).

4.1.2 Water

Ground water: Laboratory sorption studies for aldicarb (Koc 21 to 68), aldicarb sulfoxide (Koc 13 to 48) and aldicarb sulfone (Koc 11 to 32) suggest that all three could leach to groundwater under vulnerable conditions (ECCO, 1997).

Surface water: chemical hydrolysis of aldicarb is unlikely to be significant under environmental conditions since the shortest half life of 170 days did not occur until pH 8.5 (15°C). At 25°C, aldicarb photolysed with a half-life of 4.1 days (ECCO, 1997).

Water sediment system: DT_{50} (aldicarb, total system) = 5.5 days. Main pathway is loss of the carbamate moiety, aldicarb sulfoxide and aldicarb sulfone were minor metabolites < 3%. Aldicarb sulfone is rapidly degraded in the water sediment systems with a DT_{50} of 4.0 days. Aldicarb sulfoxide is rapidly degraded in water sediment systems with a DT_{50} of 5 days (ECCO, 1997).

4.1.3 Air

Due to the low vapour pressure of aldicarb and soil incorporation, air is not a likely route of environmental contamination for aldicarb (ECCO, 1997).

4.1.4 Bioconcentration /bioaccumulation

The log P_{ow} values of 1.15 indicates that there is unlikely to be significant bioaccumulation or sorption to sediment/suspended matter and/or accumulation in biota (ECCO, 1997).

4.1.5 Persistence

In soil, aldicarb degrades with $t_{1/2}$ of 2-12 days breaking down to sulfoxide and sulfone. The dissipation of these residues occurs with $DT_{50field}$ of 0.5-2 months and $DT_{90field}$ 2.5-4.7 months suggested that the residues are moderately persistent in soil. Chemical hydrolysis of aldicarb is unlikely to be significant under environmental conditions. However, aldicarb photolysed with a $t_{1/2}$ of 4.1 days and aldicarb sulfoxide and sulfone with $t_{1/2}$ of 131 and 47 days (at pH 8) and 11 and 4.5 (at pH 9) respectively (ECCO, 1997).

4.2 Effects on non-target organisms

4.2.1 Terrestrial vertebrates

Birds:

Acute toxicity	Mallard duck	LD_{50} = 1.0 mg/kg bw
Short term dietary	Mallard duck	LC_{50} = 71 mg/kg (ppm)

Mammals

Acute toxicity	Rabbit	LD_{50} = 1.3 mg a.s./kg bw
Acute toxicity	Mouse	LD_{50} = 0.382 mg a.s./kg bw
Dietary toxicity	Rat	NOEL = 1.6 mg a.s./kg bw/day
Dietary toxicity	Mouse	NOEL = 0.6 mg a.s./kg bw/day

(ECCO, 1997)

4.2.2	**Aquatic species**	Fish (96 hours)	Bluegill sunfish	LC_{50} = 0.063 mg a.s./l
		Invertebrate(48 hours)	Daphnia	EC_{50} = 0.41 mg a.s./l
		Algae(96 hours)	*Scenedesmus subspicatus*	EC_{50} = 1.4 mg a.s./l (growth)
		(ECCO, 1997)		
4.2.3	**Honeybees and other arthropods**	LD_{50} (contact) = 0.029 µg/bee. Extremely dangerous to bees. *Poecilus cupreus:* application rate 5 kg a.s./ha: 100 % mortality (laboratory test) *Pterostichus melanarius*: application rate 5 kg a.s./ha: no effect on survival (semi-field) (ECCO, 1997)		
4.2.4	**Earthworms**	*Eisenia foetida*: LC_{50} (48 hr) = 8 mg as./kg bw (moderately toxic) (ECCO, 1997)		
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

European Community

In the risk evaluation of the European Community, the Predicted environmental concentration (PEC) was estimated for soil. In the calculation, an application rate of 20 kg/ha was used together with a soil depth of 20 cm (due to the incorporation of aldicarb granules into soil) and soil density of 1.5 g/cm^3. The short-term values were from 6.67 mg/kg at 0 hours to 6.37 at 4 days. The long-term values were from 6.15 mg/kg at 7 days to 2.10 at 100 days (ECCO, 1997).

The Toxicity Exposure Ratio (TER) is a measure of the risk: it is calculated by dividing the no effect values of sensitive organisms, the predicted exposure to the substance. The Trigger value represents a value of the TER above which the risk should be acceptable. The Trigger value may include a margin of precaution.

The toxicity/estimated exposure ratios for terrestrial vertebrates are given in Table 1 below.

Table 1 Critical TER (Toxicity Exposure Ratio) values for terrestrial vertebrates (ECCO, 1997)

Application rate	Endpoint (consumption)	
Trigger value	**Species**	**TER value**
-	Acute toxicity (granules)	
10	Sparrow	**0.046**
-	Acute toxicity (granules)	
10	Mouse	**0.002**
22.4 kg a.s./ha	Short term dietary toxicity (vegetation)	
10	Bobwhite quail	**0.71**
22.4 kg a.s./ha	Short term dietary toxicity (vegetation)	
10	Bobwhite quail	**14.2**
20 kg a.s./ha	Acute toxicity (vegetation)	
10	Rabbit	**0.03**
20 kg a.s./ha	Acute toxicity (earthworms)	
10	Song thrush	**2.0**
20 kg a.s./ha	Acute toxicity (earthworms)	
10	Shrew	**0.19**

- The TER values for nearly all species are very low.
- Although direct consumption of granules is not considered probable, there is unacceptable risk to small birds and mammals with broadcast application.
- There is no use for which exposure of small birds to aldicarb was acceptable.

Jamaica

The threat to avian species that ingest aldicarb granules was considered unacceptable. Aldicarb is very toxic to birds and was considered to pose a danger to endangered species as well as to those species that are indigenous to Jamaica (PCA, 1994).

5.2 Aquatic species

European Community

PECs were also derived for surface and groundwater. Data were taken from a Dutch field leaching study. Concentrations found in soil water of 115 µg/l (at 1.6 and 3.2 m depth) can drain into surface water. If an application rate of 20 kg a.s./ha was assumed (rather than 3 kg a.s./ha in the Dutch study), it was predicted that residues entering surface water could be in the range, 100-1000 µg/l (no aldicarb was detected and 50% of the residues was sulfoxide and 50% sulfone) (ECCO, 1997).

The groundwater PEC was based directly on the observed environmental concentrations in the Dutch study. The maximum concentrations for sulfoxide and sulfone were 177 and 285 µg/l and the averaged annual concentration for carbamate residues was 115 µg/l (mainly sulfoxide and sulfone, aldicarb not detected). For an application rate of 20 kg a.s./ha, this corresponds to a concentration of 766 µg/l (ECCO, 1997).

Acute risk

The toxicity/estimated exposure ratios for aquatic species are given in Table 2 below.

Table 2 Critical TER values for aquatic species (ECCO, 1997)

Application rate	Endpoint (consumption)		Species	TER value
	Trigger value			
1 kg a.s./ha	Acute toxicity	Bluegill sunfish	**0.63**	100
2.5 kg a.s./ha (Dilution by 10)	Acute toxicity	*Daphnia magna*	**128 (sulfoxide) 88 (sulfone)**	100

- TER value for fish is very low
- Aldicarb is highly toxic to aquatic species. Broadcast application was found to be unacceptable.
- TER values for Daphnia were found to be acceptable.
- Concentrations above 2.5 kg a.s./ha were found to be unacceptable.

Chronic risk

- Broadcast application was found to be unacceptable.

There is a lack of data on chronic effects.

Jamaica

Aldicarb is registered for use in USA under very restricted conditions. This entails strong enforcement measures under environmental conditions that are less susceptible to contamination than an island ecology like Jamaica. Even so, aldicarb has been found in the groundwater of at least 14 states including California and Florida. Although said to degrade rapidly, aldicarb has still been detected in Long Island groundwater, 15 years after it was banned. Jamaica has several areas of limestone and underground rivers, where much of the farming is done. Due to the small size of an island such as Jamaica overall water resources are more limited than in larger continental countries and it is impractical to apply large buffer zones to protect water from pesticide contamination (PCA, 1994).

5.3 Honey bees and other arthropod species

European Community

No risk to bees for an application rate up to 3.7 kg a.s./ha due to the granular application form. Although dangerous to bees on direct contact, the nature of the formulated products and their method of application make it unlikely that bees will come into direct contact with aldicarb.

There is, however, a high risk for other non-target arthropods (ECCO, 1997).

5.4 Earthworms

European Community

TER of 24.4 for acute risk is greater than 10 (trigger value) at 1 kg a.s./ha and thus

acceptable (ECCO, 1997). Further studies revealed no significant effects up to 3.36 kg a.s./ha. However, at time of regulatory action, the available information from field studies about the effects of aldicarb or its metabolites on earthworms was considered as still insufficient to conclude that the risk was acceptable.

5.5 Soil microorganisms

European Community

No conclusion due to a lack of data.

5.6 Summary – overall risk evaluation

European Community

- **Terrestrial vertebrates**: The toxicity/estimated exposure ratios were very low on the basis of laboratory studies. The assessment of uses leads to an unacceptable risk to small birds. The risk to birds was further described by means of a probabilistic risk assessment submitted by the notifier. This refinement indicated that effects on national populations would not be expected, although some local impact might occur. Broadcast administration was not acceptable regarding birds and mammals. Incorporation in soil was considered as part of the evaluation, but the actual quantities of granules remaining on the soil, and thus available for small birds, depended strongly on the quality of the application conditions. Thus the risk to small birds through exposure to the granules cannot be totally minimised to an acceptable level. The risk to birds and small mammals via ingestion of earthworms as a food source was considered as acceptable.
- **Aquatic species**: The toxicity/estimated exposure ratios were very low. Aldicarb is very toxic to aquatic organisms. A broadcast application was unacceptable. Application rates above 2.5 kg aldicarb/ha were unacceptable.
- **Bees and other arthropods species**: There was no risk to bees for an application rate up to 3.7 kg a.s./ha, but higher application rates were not addressed. A high risk for other non-target arthropod species was identified.
- **Earthworms:** The acute risk was acceptable at 1 kg a.s./ha. For higher application rates, more field data concerning the acute risk of aldicarb on earthworms were requested: A study under agricultural field conditions revealed no significant effects up to 3.36 kg a.s./ha. However, at the time of the regulatory action, the available information from field studies about the effects of aldicarb or its metabolites on earthworms was considered as still insufficient to conclude that the risks were acceptable.

Jamaica

In the USA, aldicarb is registered for use under very restricted conditions. This entails strong enforcement measures under environmental conditions that are less susceptible to contamination than found in island ecology such as Jamaica. However, aldicarb has been found in groundwater in Florida and other states where aldicarb is still used. Aldicarb has contaminated groundwater in at least 14 states including California. Due to the small size of an island such as Jamaica overall water resources are more limited than in larger continental countries and it is impractical to apply large buffer zones to protect water from pesticide contamination.

Jamaica has several areas of limestone and underground rivers where much of the farming is done. Consequently, as evidenced by the incidents of pollution in the US, there is a risk of contamination of groundwater and surface water.

Ingestion of aldicarb granules poses a great threat to avian species, aldicarb is very toxic to birds and poses a danger to endangered species as well as the indigenous species of Jamaica.

Annex 2 – Details on final regulatory actions reported

Country Name: European Community

1	**Effective date(s) of entry into force of actions**	18/09/2003 (Authorisations for plant protection products containing aldicarb had to be withdrawn by then with the exception of certain essential uses as described in Section 3.1).
	Reference to the regulatory document	Council Decision 2003/199/EC of 18/03/2003 concerning the non-inclusion of aldicarb in Annex I to Council Directive 91/414/EEC and the withdrawal of authorisations for plant protection products containing this active substance (Official Journal of the European Union L76 of 22/03/2003, pp. 21-24).
2	**Succinct details of the final regulatory action(s)**	It is prohibited to place on the market or use plant protection products containing aldicarb. Aldicarb is not included in the list of authorised active ingredients in Annex I to Directive 91/414/EEC. The authorisations for plant protection products containing aldicarb had to be withdrawn by 18 September 2003. From the date of adoption of Council Decision 2003/199/EC (18 March 2003), no authorisations for plant protection products containing aldicarb could be granted or renewed. Certain essential uses listed in the Annex to Council Decision 2003/199/EC were allowed to remain authorised until 30 June 2007 under specific conditions.
3	**Reasons for action**	An unacceptable risk to the environment.
4	**Basis for inclusion into Annex III**	Final regulatory action to ban aldicarb as a pesticide based on a risk evaluation taking into account the normal pattern of use in the European Community and the effects caused by the application of the substance.
4.1	**Risk evaluation**	Although the regulatory action mentions small birds and earthworms in particular as being at risk, the risk evaluation in addition, concluded that aldicarb also posed an unacceptable environmental risk for some aquatic species and some arthropods (other than bees).
4.2	**Criteria used**	Risk to the environment when applying patterns of use relevant to the European Community.
	Relevance to other States and Regions	Similar problems likely to occur in other countries where the substance is used, particularly in developing countries.
5	**Alternatives**	No information
6	**Waste management**	No specific measures outlined
7	**Other**	

Country Name: Jamaica.

1	**Effective date(s) of entry into force of actions**	December 1994
	Reference to the regulatory document	Pesticides Act 1975 Second Schedule. Specific Decision in December 1994
2	**Succinct details of the final regulatory action(s)**	Aldicarb was on the Second Schedule (prohibited list) of the Pesticide Act 1975, however, a registration was found on the register of pesticides. In 1994, re-registration refused and no further registration will be considered
3	**Reasons for action**	Unacceptable health risk to small farmers, and contamination of food and the water table.
4	**Basis for inclusion into Annex III**	Final regulatory action to ban aldicarb was based on a risk evaluation taking into consideration local conditions.
4.1	**Risk evaluation**	It was concluded that the use of aldicarb would pose an unacceptable risk to human health: small farmers and workers using aldicarb and adults, infants and children through the possible contamination of food and water, and risk to the environment through the toxic effects on avian species.
4.2	**Criteria used**	Comparison of conditions in agricultural areas in Jamaica with similar conditions in the USA where contamination of groundwater and drinking water has been described despite use under very restricted conditions. The island ecology of Jamaica is more vulnerable than conditions in the USA. Contamination of citrus fruit has also been observed in the USA. The lack of access to and proper use of protective equipment in Jamaica by small-scale farmers were also considered.
	Relevance to other States and Region	The decision was discussed at the regional level at the Coordinating Group of Pesticides Control Board and was found to be relevant to other countries in the region. Belize had banned aldicarb.
5	**Alternatives**	There are other products registered that will allow chemical control of the pests in question. Furadan (carbofuran) granular which is of the same carbamate family of chemicals, may be used as a systemic acaricide/insecticide and as an effective nematicide. Neoron (bromopropylate), Agri-Mek (abamectin) and Vendex (fenbutatin oxide) all represent acaricides that are effective against red spider mites. Shell white oil along with Diazinon are effective against scales. The use of Integrated Pest Management programmes will reduce the necessity of toxic pesticides for control of pests and represent the way forward for efficient cultivation. Improved management regarding the monitoring of the infestation of pests, the level of the population and the early and proper timing of contact and systemic sprays will provide effective control of insect pests and reduce the requirement for highly toxic chemicals.
6	**Waste management**	No specific measures outlined
7	**Other**	

Annex 3 – Addresses of designated national authorities

EUROPEAN COMMISSION

DG Environment European Commission Rue de la Loi, 200 B-149 Brussels Belgium *Paul Speight* Administrator	***Phone*** ***Fax*** ***e-mail***	+ 322 296 41 35 + 322 296 69 95 Paul.Speight@ec.europa.eu

JAMAICA

Ministry of Health and the Environment Pesticides Control Authority 2-4 King Street Kingston Jamaica *Mr. Michael Ramsay* Registrar	***Phone*** ***Fax*** ***e-mail***	+876 967 1281 +876 967 1285 ramsay@caribpesticides.net

Annex 4 – References

Final Regulatory Actions

European Community

Council Decision 2003/199/EC of 18/03/2003 concerning the non-inclusion of aldicarb in Annex I to Council Directive 91/414/EEC and the withdrawal of authorisations for plant protection products containing this active substance (Official Journal of the European Union L76 of 22/03/2003, pp. 21-24).

Jamaica

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