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Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade
Chemical Review Committee
Fourth meeting
Geneva, 10–13 March 2008
Item 5 (b) (ii) of the provisional agenda*

Inclusion of chemicals in Annex III of the Rotterdam Convention: review of notifications of final regulatory action to ban or severely restricted a chemical: aldicarb

Aldicarb: supporting documentation provided by the European Community

Note by the Secretariat

The Secretariat has the honour to provide, in the annex to the present note, the supporting documentation provided by the European Community in support of its notification of final regulatory action on aldicarb.

* UNEP/FAO/RC/CRC.4/1

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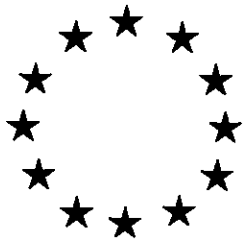
Annex

ECCO: Full Report on Aldicarb

Documentation to support the notification of final regulatory action to severely restrict aldicarb in the framework of the Rotterdam Convention

European Commission

Peer Review Programme



ECCO Meetings

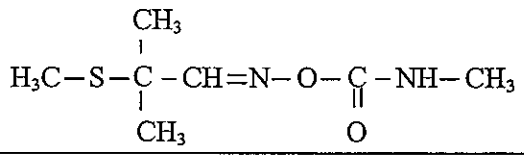
Full Report on Aldicarb

- Reports of ECCO-meetings
- Comments on the monograph from Member States and notifiers
- Other documents tabled at ECCO-meetings

ECCO-Team, in: Biologische Bundesanstalt für Land- und Forstwirtschaft

10.01.1997

IDENTITY, PHYSICAL AND CHEMICAL PROPERTIES

Common Name (ISO)	aldicarb
Chemical Name (IUPAC)	2-methyl-2-(methylthio)propionaldehyde *o*-methylcarbamoyl-oxime
Chemical Name (CA)	2-methyl-2-(methylthio)propanal *o*-[(methylamino)carbonyl]-oxime (9Cl)
CIPAC No	215
CAS No	116-06-3
EEC No	204-123-2
Minimum purity	920 g/kg (FAO specification 1988)
Molecular Formula	$C_7H_{14}N_2O_2S$
Molecular Mass	190.3
Structural Formula	

PHYSICAL-CHEMICAL PROPERTIES

Melting point	102-103°C
Boiling point	
Appearance	white crystalline solid
Relative density	1.195 (specific gravity at 25°C)
Vapor pressure	3.4 x 10^{-3} Pa at 25°C
Henry's law constant	1.23 x 10^{-9} atm m^3 g mol^{-1} at 25°C (calculated)
Solubility in water	pH 5 : 5.29 g/l at 20°C
	pH 7 : 4.93 g/l at 20°C
	pH 9 : 4.95 g/l at 20°C (significant decomposition)
Solubility in organic solvents (at 25°C)	hexane : 1 g/l
	acetone: 373 g/l
	dichloromethane: 578 g/l
Partition coefficient (log P_{ow})	1.5 at 25°C
Hydrolytic stability (DT_{50})	pH 4: -- ; pH 7: --
	pH 8.5: 170 d
Dissociation constant	--
UV/VIS absorption (max.)	not submitted
photostability (DT_{50})	4.1 d (pH 5 at 25°C) in water

Analytical methods

Technical a.s.	IR method, determin. at 1740 cm^{-1}. CIPAC Handbook 1A
Residues	**Plant products**: GC-FPD, LOQ :0.002 - 0.05 (determ. as aldicarb sulfone); **soil**: HPLC; **water**: HPLC, LOQ: 0.5 µg/1 each component (aldicarb, sulfoxide, sulfone)

17.12.1996

MAMMALIAN TOXICOLOGY

CRITICAL END POINTS	ALDICARB
Absorption, distribution, excretion and metabolism in mammals (Annex II 5.1)	
Rate and extent of absorption	oral, 93% within 2 days, rat
Distribution	widely
Potential for accumulation	negligible
Rate and extent of excretion	rapid, 95% excreted within 4 days
Main animal metabolites	aldicarb sulfoxide, - sulfone
Acute toxicity (Annex II 5.2)	
Rat LD50 oral	0.5 mg/kg, (T+), R 28
Rat LD50 dermal	218 mg/kg, (T), R 24
Rat LC50 inhalation	0.0039 mg/l, (T+), R 26
Skin irritation	no data on a.i. but exposure to pure substance not expected, 36% aldicarb in dichloromethane not classifiable
Eye irritation	no data on a.i. but exposure to pure substance not expected, 36% aldicarb in dichloromethane not classifiable
Sensitization	Notifier to justify adequacy of sensitization study including dose level
Short term toxicity (Annex 11 5.3)	
Target 1 critical effect	cholinesterase inhibition (brain, erythrocyte)
Lowest relevant NOAEL	0.05 mg/kg, 2 year dog
Genotoxicity (Annex 11 5.4)	no genotoxic potential of relevance to man
Long term toxicity and carcinogenicity	(Annex II 5.5)
Target / critical effect	cholinesterase inhibition (brain, erythrocyte)
Lowest relevant NOAEL	0.5 mg/kg, 2 year rat
Carcinogenicity	negative
Reproductive toxicity (Annex II 5.6)	
Reproduction	negative
Developmental toxicity	negative
Delayed neurotoxicity (Annex II 5.7)	negative

Other toxicological studies (Annex II 5.8)
no further concerns identified by immunological and neurobehavioural studies
Medical data (Annex 11 5.9)
NOAEL for depression of erythrocyte cholinesterase 0.025 mg/kg
Summary (Annex 11 5.10)

ADI	0.0025 mg/kg (human volunteer study, safety factor 1 0)
AOEL	0.0025 mg/kg (human volunteer study, safety factor 1 0)

Dermal absorption (Annex Ill 7.3)
100%
Acceptable exposure scenario

Operator	First risk evaluation: Overall application by downward placement and band application might be acceptable but further exposure data are required usage of hand held equipment and overall application by broadcast is considered unacceptable → *Updated information*: 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 RMS 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.
Workers	exposure of glasshouse workers needs to be addressed
Bystanders	acceptability subject to satisfactory operator exposure data

CRITICAL END POINTS ALDICARB

FATE AND BEHAVIOUR IN SOIL

Route of degradation	
Aerobic:	
Mineralisation after 100 days	<2% (60d, 25°C)
Non-extractable residues after 100 days	8.8% (60d, 25°C)
Relevant metabolites:	Aldicarb sulfoxide 86% (14d) sulfone 80.1% (21 d)
Name and/or code	
% of applied (range and maximum)	
Supplemental studies	
Anaerobic	Aerobic (30d)/anaerobic (60d): Aldicarb 1.7% (aerobic 30d) 0.2% (anaerobic 30d) Aldicarb sulfoxide 37% (aerobic 30d) 2.2% (anaerobic 60d) Non-extractable 6.7-11.8%, Mineralisation rate not determined
Soil Photolysis	DT50 0.7 d
Remarks	
Laboratory studies:	
Aerobic:	
DT50lab (20°C)	Aldicarb 2d (20 °C)
DT90lab (20°C)	
DT50lab (10°C)	Aldicarb 2d (20 °C)
Anaerobic	
DT50lab (20°C)	Aerobic 5d, anaerobic no significant decrease
Field studies:	
DT90f from soil dissipation studies:	2.5-4.7 months (total carbamate residues: aldicarb, sulfoxide and sulfone)
Soil accumulation studies	
Soil residue studies	
Remarks :	Aldicarb 2-9 d (15°C), 7-12d (25°C),
e.g. effect of soil pH on degradation rate	Sulfoxide 20-53d (15°C), 77d (6°C),
	Sulfone 18-154d (15°C)
Adsorption/desorption:	
K_{OC} / K_{OM}	K_{OC}: aldicarb: 21-68, sulfoxide: 13-48, sulfone: 11-32.
soil type, pH, oc/om content	Aldicarb: sand, sandy loam, silt loam, clay Metabolites: silty clay loam (pH 6.7), sandy loam (pH 5.3), silt loam (pH 6.7), loamy sand (pH 5. 1), sediment (pH 8. 1)
Mobility:	
Laboratory studies:	
- Column leaching	94 - 100% of applied carbamate in the leachate
- Aged residue leaching	

Field studies:

Lysimeter/Field leaching studies	Lysimeter study (interim report first year) (Germany). Only metabolites found in leachate of one lysimeter: Sulfoxide 0.235µg/l (average) and sulfone 1.012 µg/l. Field leaching study (Netherlands): total aldicarb carbamate residues 96 and 136 µg/l (average one year). No aldicarb found
Remarks:	→ *Updated information*: It was concluded that the aldicarb could leach under vulnerable conditions, but that in other situations, the risk for groundwater could be acceptable, depending on the specific uses. This conclusion is supported by the opinion of the Scientific Committee for Plants, who stated that based on expert judgements and the evidence from existing data it believed that use scenarios exist where there will be an acceptable risk to groundwater.

FATE AND BEHAVIOUR IN WATER

Abiotic degradation:

Hydrolytic degradation:	Aldicarb, DT50 170 days (pH 8.5, 15°C),
DT50 at pH 4/5	
7	
9	
relevant metabolites	Sulfoxide, DT50 10 days, Sulfoxone, DT50 5 days.
Photolytic degradation:	DT50: 4.1 d at pH 5

Biological degradation:

Ready biological degradability: yes/no	No study submitted.
Water/sediment study:	
DT50 water	→ *Updated information:*
DT50 whole system	DT_{50} (aldicarb, total system) = 5.5 days.
relevant metabolites	Main pathway is loss of the carbamate moiety, aldicarb
- residues in the water phase (% of applied)	sulfoxide and aldicarb sulfone were minor metabolites <
maximum at day	3%. Aldicarb sulfone is rapidly degraded in the water
at the end of the study at day....	sediment systems with a DT_{50} of 4.0 days. Aldicarb
- residues in the sediment (% of applied)	sulfoxide is rapidly degraded in water sediment systems
maximum at day....	with a DT_{50} of 5 days.
at the end of the study at day....	

Accumulation in water and/or sediment

Degradation in the saturated zone
Remarks:

PEC (SOIL)

Method of calculation	DT50 2 months (max. field). Application rate 20 kg/ha. Total carbamate. Soil depth of 20 cm due to incorporation of aldicarb granules into soil, soil density 1.5 g/cm3

PEC(S)		single application	single application	multiple application	multiple application
		actual	time weighted average	actual	time weighted average
initial	0 h	6.67 mg/kg			
short term					
	24h	6.59 mg/kg			
	2d	6.59 mg/kg			
	4d	6.37 mg/kg			
long term					
	7d	6.15 mg/kg			
	28d	4.82 mg/kg			
	50d	3.74 mg/kg			
	100d	2.10 mg/kg			

Remarks:

PEC (SURFACE WATER)

Method of calculation

Concentrations found in soil water of 115 µg/1 (at 1.6 and 3.2 m depth from Dutch field leaching study) can drain into surface water. Aldicarb itself was not detected above the limit of detection (1 µg/1). If an application rate of 20 kg as/ha is assumed (rather than 3 kg as/ha for the Dutch study) it is predicted that the order of magnitude of residues entering surface water could be 100-1000 µg/1 (half of the residues are sulfoxide and half are sulfone)

PEC(sw)		single application	single application	multiple application	multiple application
		actual	time weighted average	actual	time weighted average
initial	0 h				
short term					
	24h				
	2d				
	4d				
long term					
	7d				
	14d				
	21d				
	28d				
	42d				

Remarks:

PEC (SEDIMENT)

Method of calculation

PEC(sw)	single application	single application	multiple application	multiple application

	actual	time weighted average	actual	time weighted average
initial				
short term				
long term				

Remarks:

PEC (GROUNDWATER)

Method of calculation

Bearing in mind the problems associated with simulations of low concentrations of plant protection products in groundwater, it was decided to base PEC gw on the observed environmental concentrations from the Dutch field leaching study.
Field leaching studies. Application rate 3 kg/ha. Limit of detection: 1 µg/1

PEC(gw)

maximum concentrations: Aldicarb not detected
combined sulfoxide and sulfone: 177 and 285 µg/1.

averaged annual concentrations: Aldicarb carbamate residues 115 µg/1 (mainly sulfoxide and sulfone, aldicarb not detected) For an application rate of 20 kg as/ha correspondingly 766 µg/1.

Remarks:

FATE AND BEHAVIOUR IN WATER

Volatility

Vapour pressure 3.86 mPa/24°C
Henry's law constant 1.25 10-4 kPa m^3 mol^{-1}

Photolytic degradation

Direct photolysis in air
Photochemical oxidative degradation in air
DT50

Remarks:

PEC (AIR)

Method of calculation

Quantitative concentrations in air have not been predicted but are expected to be very low due to the low volatility of aldicarb, the relatively small Henry's law constant and its incorporation in the soil.

PEC (A)
Maximum concentration at day...
Remarks:

ECOTOXICOLOGY

Specific comments on the active substances in the section **ecotoxicology** are listed below. The conclusions of the meeting were as follows:

ALDICARB

Rapporteur Member State: UK

1. Effects on **terrestrial vertebrates**

Table 1: Critical TER (Toxicity exposure ratio) values for terrestrial vertebrates

application rate	end point	species assessed	**TER value**	Annex VI trigger value	reference
	acute toxicity (consumption of granules)	sparrow	**0.046**	10	p. 234, Vol. 3
	acute toxicity (consumption of granules)	mouse	**0.002**	10	p. 251, Vol. 3
22.4 kg as/ha	short term dietary toxicity (consumption of vegetation)	bobwhite quail	**0.71**	10	p. 235, Vol. 3
22.4 kg as/ha	short term dietary toxicity (consumption of vegetation)	bobwhite quail	**14.2**	10	p. 235, Vol. 3
20 kg as/ha	acute toxicity (consumption of vegetation)	rabbit	**0.03**	10	p. 252, Vol. 3
20 kg as/ha	acute toxicity (consumption of earthworms)	song thrush	**2.0**		p. 237, Vol. 3
20 kg as/ha	acute toxicity (consumption of earthworms)	shrew	**0.19**	10	p. 253, Vol. 3

- TER values are very low.
- There is a non-acceptable risk to small birds. At the moment there is no evidence that the use is safe. GAPs where there is no exposure to birds are acceptable.
- Direct consumption of granules was not considered to be probable for small mammals.
- The monitoring studies were discussed. The experts were not convinced. The notifier has failed to demonstrate that the risk is acceptable.
- Broadcast application is not acceptable regarding birds and mammals. Furrow application (incorporation in soil) is unacceptable the way it is used today.
- The notifier should address the unacceptable risk

a) arising from the ingestion by small birds of granules from the soil incorporation field uses - and

b) arising for the ingestion by vegetation and worm feeding birds arising from field treatments - and

c) arising from the ingestion of worms and vegetation by small mammals.

Demand for further information (Level 4): the data requirements proposed by the rapporteur concerning birds were agreed, except for 4.1 ii (p. 39, Vol. 1) which was deleted.

→ *Updated information*:
During the first step of the risk evaluation, the toxicity/estimated exposure ratios were very low on the basis of laboratory studies. Uses lead to an unacceptable risk to small birds. The risk to birds was investigated by means of a probabilistic risk assessment. The 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.

(ALDICARB continued)

2. Effects on **aquatic species**

2.1 Acute risk

Table 2: Critical TER values for aquatic species

application rate	end point	species tested	**TER value**	Annex VI trigger value	reference
1 kg as/ha	acute toxicity	Bluegill sunfish	**0.63**	100	p. 28, Vol. 1
2.5 kg as/ha (dilution by 10)	acute toxicity	*Daphnia magna*	**128** (sulfoxide) **88** (sulfone)	100	p. 28, Vol. 1

- TER values are very low.
- Aldicarb is highly toxic to aquatic species. A broadcast application is unacceptable.
- The experts realized that there is a risk but could not quantitate it due to the lacking quantitative data: how much dilution will occur from leaching of aldicarb from the ground water to the surface water. The notifier needs to address more information (= cases) concerning the level of dilution (leaching of aldicarb).
- The notifier needs to address toxicity of the metabolites to fish.
- TER values for Daphnia are acceptable (baring in mind that it is only 2.5 kg as/ha and a dilution by 10).
- Concentrations above 2.5 kg as/ha are unacceptable (with the data available).

2.2 Chronic risk

- Broadcast application in unacceptable.
- Chronic risk data for both fish and Daphnia are needed. Chronic risk data for metabolites must be addressed.
- Demand for further information (Level 4): the data requirements proposed by the rapporteur concerning aquatic life were agreed, except for 4.1 ii (p. 39, Vol. 1) which was deleted and 4.1 iii (p. 39, Vol. 1) which was changed: "...free swimming organisms..." was detailed by the addendum 'fish and Daphnia'.

3. Effects on **bees** and **other arthropods species**

- The experts agreed that there is no risk to bees for an application rate up to 3.7 kg as/ha.
- Higher application rates must be addressed.

- The experts concluded that on the basis of the data available there is a high risk for other non-target arthropod species.
- Appropriate risk management measures are needed in each Member State.

Demand for further information (Level 4): the specific data requirements proposed by the rapporteur concerning other arthropods were deleted (p. 40, Vol. 1). However the notifier should address the problem of the risk for non-target arthropod species.

(ALDICARB continued)

4. Effects on **earthworms** and **other soil macro-organisms**

- TER of 24.4 for acute risk is greater than 10 (trigger value) at 1 kg as/ha and thus acceptable.
- For higher application rates more field data concerning the acute risk of aldicarb on earthworms are needed.

Demand for further information (Level 4): the data requirements proposed by the rapporteur concerning earthworms were agreed, only the wording using *Eisenia foetida"* on page 40 ii (Vol. 1) was deleted.

→ *Updated information:*
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. The risk to birds and small mammals via ingestion of earthworms as a food source was considered as acceptable.

5. Effects on **soil micro-organisms**

- Due to the lack of data no conclusion could be drawn at first. A better translation of the study was needed. H. EHLE (BBA) gave an oral presentation of the study.
- The notifier has addressed the effects for an application rate up to 10 kg as/ha.
- The experts regarded the effects on soil microorganisms as acceptable.
- The notifier has to address for applications above 10 kg as/ha.

6. Effects on **other non-target organisms (flora and fauna)**

- The experts took notice that no data were submitted. No risk is expected.

7. Effects on **biological methods of sewage treatment**

- The experts agreed that contamination of sewage treatment plants from the normal use of aldicarb is unlikely. No risk is expected.

8. The proposals of the rapporteur concerning ecotoxicological **classification** and **labelling** were agreed (hazard symbol N, risk phrases R 50, R 53, safety phrases S 60, S 61).

9. Studies indicated by the notifier as **protected** (Volume 3) were also agreed by the experts as essential, except the following study:

   Handley, J.W., Sewell, LG., Balett, A.J. 1991: An assessment of the effect of aldicarb on the reproduction of *Daphnia magna.* (report no. 2821112)

10. All **comments** received were discussed:

- Greece, 16 October 1996 (doc 0386/ECC018BN96)
- Sweden, 15 October 1998 (doc 0292/ECCOIBBA/96)
- The Netherlands, 10 October 1996 (doc 0309/ECCOIBBA/96)

Overall conclusions for aldicarb:

- A listing in Annex 1 was recommended only for glasshouse use.

Postponement regarding inclusion in Annex 1 was recommended for all field uses (soil incorporation).

No listing in Annex 1 was recommended for intended broadcast uses.

EUROPEAN COMMISSION
DIRECTORATE-GENERAL
ENVIRONMENT
Directorate C - Air quality, Climate change, Chemicals & Biotechnology
ENV.C4 - Biotechnology & Pesticides

Documentation provided by
the European Community in support of the notification of a final regulatory action to severely restrict

ALDICARB

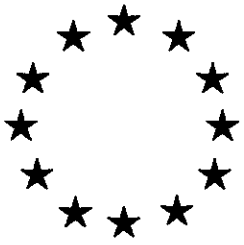
in the framework of the

Convention of Rotterdam
on the Prior Informed Consent procedure for certain hazardous chemicals and pesticides in international trade

The following excerpts of the documentation, which were drafted at an early stage of the review process, have where appropriate been updated in order to reflect subsequent discussions and conclusions.

UK RAPPORTEUR MONOGRAPH
(excerpt)

Council Directive 91/414/EEC
Regulation 3600/92



Aldicarb

Report and Proposed Decision of the United Kingdom made to the European Commission under Article 7(1) of Regulation 3600/92

March 1996

CONTENTS

LEVEL 2

Aldicarb

OVERALL CONCLUSIONS

2.1 Identity

All points of Annex IIA and IIIA Section 1 have been addressed and the information supplied is acceptable.

2.2 Physical, chemical properties

Aldicarb is an oxime carbarmate insecticide, nematicide and acaricide which is formulated as granular products. Data submitted indicate that the active substance shows no evidence of adverse physical and chemical properties. Limited information submitted on the formulations indicate that they are stable under ambient conditions although accelerated storage studies were either of poor quality or have not been supplied. Further data are required to complete the data packages for both the active substance and the products.

2.3 Details of uses and further information

Information supplied adequately addresses methods for handling the active substance and plant protection products for inclusion in Annex 1. Further information is required for individual plant protection product authorisations.

2.4 Impact on human and animal health

2.4.1 Effects having relevance to human and animal health arising from exposure to the active substance or to impurities contained in the active substance or to their transformation products

When aldicarb is given orally to rats, it is absorbed readily, distributed widely in the body, and excreted rapidly. When male rats were administered single oral doses of radiolabelled aldicarb, most of the aldicarb metabolites were excreted within 24 hours; after four days, more than 95% of the administered dose had been excreted and no residues were detected in body tissues. In another study, although radioactive metabolites were found at low levels in a variety of tissues during the first days after treatment, there was no indication that residues accumulated in the body. By the fifth day, residues were no longer detected. Within the first 24 hours of this study, 80% of the administered dose of aldicarb was eliminated in the urine and 5% in the faeces. Aldicarb given orally to rats as a single acute dose was excreted primarily as aldicarb sulfoxide (40%) and the sulfoxide oxime (30%); only trace amounts of aldicarb were found in the urine. In rats, aldicarb is rapidly oxidized to the relatively stable aldicarb sulfoxide; then more slowly, a small portion of aldicarb sulfoxide is oxidized to aldicarb sulfone. Both products are converted to the corresponding oximes, which are, in turn, slowly degraded to the corresponding nitriles, aldehydes, acids, and alcohols.

Aldicarb has high acute oral, dermal, and inhalation toxicity. Signs of toxicity are those commonly associated with acetylcholinesterase inhibition by a carbamate insecticide: cholinergic signs of poisoning, which are alleviated rapidly on cessation of exposure. A toxic metabolite, aldicarb sulfoxide is of the same order of potency for inhibition of acetylcholinesterase as aldicarb itself, while aldicarb sulfone is considerably less toxic than either aldicarb or aldicarb sulfoxide. Aldicarb is not irritating to the eyes or skin and has been demonstrated to have no dermal sensitization properties.

As in the case of acute administration, signs of toxicity of repeated administration are those commonly associated with acetylcholinesterase inhibition by a carbamate insecticide: cholinergic signs of poisoning, which are alleviated rapidly on cessation of exposure. In assessing the subchronic toxicity of aldicarb, the most sensitive indicator of exposure is cholinesterase depression. In some of the earlier studies the techniques used for estimation of cholinesterase inhibition (including the long time period between dosing and sample collection), render the studies of little toxicological significance. Although the most recent dog studies are of good quality and contain reliable cholinesterase investigations, the subchronic studies in rats and mice are less reliable and in many cases it is not possible to derive NOAELS. However, it is evident that when rodents are dosed via the diet they are able to tolerate doses equivalent to greater than the LD_{50}, without mortality. The NOAELs in dogs in studies up to 52 weeks in duration (based on acetyl cholinesterase depression) are around 0.06 mg/kg bw/ day.

From the weight of the evidence it can be concluded that aldicarb and its major toxic metabolites , aldicarb sulfoxide and aldicarb sulfone do not exhibit genotoxic potential. Aldicarb and its metabolites are not mutagenic in bacterial or mammalian gene mutation tests. Aldicarb is negative in *in vitro* unscheduled DNA damage tests as well as *in vivo* micronucleus and dominant lethal tests. It was shown to be weakly positive in *in vitro* sister chromatid exchange (SCE) studies and positive in a DNA damage assay in *S. typhimurium.*

Aldicarb has been shown to have no oncogenic potential when administered to rat's or mice in lifetime experiments. Cholinesterase depression is the most sensitive indicator of exposure in the chronic studies in rats and dogs. No other clear indicators of toxicity have been demonstrated. A chronic NOEL of 0.05 mg/kg/day and 0.59 mg/kg/day have been determined for aldicarb in male and female rats, respectively.

Aldicarb did not produce a teratogenic response when administered orally by gavage in rabbits at dosage levels up to 0.5 mg/kg bw/day. In the rat, a significantly increased incidence of dilated lateral ventricles with tissue depression was observed only at 0.5 mg/kg bw/day. This dose level also caused severe maternal toxicity, including death in 3 out of 25 animals. No increased incidence of malformation was observed 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 2-generation reproduction study, the NOEL for reproductive and developmental endpoints was 10 ppm; and the NOEL for cholinesterase depression was 5 ppm.

Aldicarb did not induce a delayed neurotoxic syndrome similar to that induced by certain organophosphate esters. Studies were performed to assess aldicarb's potential acute neurotoxicity using a functional observational battery (FOB), a motor activity test, and a neuropathological evaluation. The NOEL for the FOB and motor activity evaluations was 0.1 mg/kg bw for both sexes. The NOEL for peripheral cholinesterase measurements was 0.05 mg/kg bw. The NOEL for brain cholinesterase was 0.1 mg/kg bw. The observed NOEL for neuropathology findings was 0.5 mg/kg bw, the highest dose tested in the study. There was, no evidence of immunotoxicity in mice in a number of functional assays of cell-mediated immunity and in host resistance to respiratory infection.

human data

The anticholinesterase potential of aldicarb has been extensively investigated in humans. These studies revealed the same pattern of rapid cholinesterase inhibition and rapid recovery seen in experimental animals. 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.

Poisoning incidents have been reported from the agricultural use of aldicarb, but there has been no indication that the workers overexposed continued to experience adverse effects once removed from the exposure source. Although deaths have been reported, all of these cases have been attributed to suicide or gross neglect. Incidents of food-borne aldicarb intoxications have been reported in the literature. These have all been associated with misuse and reliable quantification of the dose of aldicarb involved has not been possible.

2.4.2 Proposal for an acceptable daily intake

The NOAEL for clinical signs in the recently conducted human volunteer study was 0.05 mg/kg bw, while the NOAEL for depression of erythrocyte cholinesterase activity was 0.025 mg/kg bw. An acceptable daily intake (ADI) for dietary exposure of 0.003 mg/kg bw can thus be established using a 10-fold safety factor applied to the NOEL of 0.025 mg/kg bw.

Although this volunteer study was a single dose study it is considered appropriate to use this study in setting the ADI since the toxicity of aldicarb is rapidly reversible and chronic toxicity of aldicarb is effectively a series of repeated acute exposures. It follows that the acute dietary reference dose for aldicarb (relevant for risk assessment for single mealtime exposures to aldicarb residues) should also be 0.003 mg/kg bw.

2.4.3 Proposal for a maximum allowable concentration in drinking water

It is considered appropriate to base a maximum allowable concentration (MAC) in drinking water on the ADI derived from the human volunteer study (0.003 mg/kg bw). To calculate the MAC an additional safety factor of 10 is applied to the ADI and a daily intake of 0.0003 mg/kg bw is thus derived. The International Programme on Chemical Safety (WHO, 1994) suggests that for risk assessment purposes a reference human is considered to weigh 64 kg and have a daily intake of drinking water of 1.4 litres. Hence a daily intake of 0.0003 mg aldicarb/kg bw would be achieved by a 64 kg human consuming 1.4 1 drinking water/day containing 0.014 mg/l aldicarb. Thus a MAC for aldicarb in drinking water of 0.014 mg/l can be derived. Historically the WHO Task Group on Guidelines for Drinking Water Quality has used slightly different body weight and water intake figures (60 kg and 2 litres) in calculating MACs. Using these figures the MAC derived from the ADI of 0.003 mg/kg bw would be 0.009 mg/l.
In the toxicology data supplied for aldicarb there is a 29 day rat study investigating the toxicity of a 1:1 mixture of aldicarb and aldicarb sulfoxide when administered via the drinking water. The NOAEL in this study is 3.8 mg/l. The results of this study are not inconsistent with the proposed MACs.

2.4.4 Proposal for an acceptable operator exposure level

During the application of TEMIK® granules operators are liable to be exposed to aldicarb by the dermal (dust) and inhalation (dust and vapour) routes. There are no dermal or inhalation studies which are suitable for use in setting an AOEL. The NOAEL which is of most relevance to operators is identical to that used for derivation of the ADI, i.e. that for depression of erythrocyte cholinesterase activity in the recently conducted human volunteer study which was 0.025 mg/kg bw. An acceptable operator exposure level (AOEL) of 0.003 mg/kg bw can thus be established using a 10-fold safety factor applied to the NOEL of 0.025 mg/kg bw. Since this AOEL relates to a systemic dose, account should be taken of the extent of oral absorption. Aldicarb is rapidly and extensively absorbed from the gastro-intestinal tract, and it is proposed that no correction value is necessary to account for the extent of oral absorption.

2.4.5 Impact on human and animal health arising from exposure to the active substance or to impurities contained in it.

2.4.5.1 Operators, bystanders and workers

Band and overall (by broadcast or downward placement via fishtails) application of Temik 10G by tractor driven equipment have been taken as being representative of EU use.

There are no models to allow an estimate of exposure for granular products but limited published data on exposure from band and broadcast application were available. An exposure of 3 to over 300 times the AOEL (0.003 mg/kg bw/day) was estimated for an unprotected worker a plying Temik 10G.

For band application the data allowed an estimate of exposure for a worker wearing a coverall; predicted exposure ranged from 0.3 to nearly 7 times the AOEL. The level of protection provided by the coverall, suggests that additional protective clothing (gloves, hood, eye protection and RPE) will reduce exposure to within the AOEL. Maximum inhalation exposure represented nearly 70% of the AOEL and RPE when filling the hopper is therefore appropriate since this operation has the highest potential for exposure.

Band application with incorporation is therefore considered acceptable with the following PPE:

i) coverall, hood, gauntlet gloves, eye protection and RPE (e.g. filtering face piece respirator) when filling the hopper.
ii) coverall, hood and gauntlet gloves when handling contaminated surfaces during application
iii) coverall and hood during application

Compared with band application, overall application by downward placement via fishtails results in a very wide band of granules. However, the two techniques are very similar in other respects. It is therefore assumed that operator exposure from downward placement via fishtails will be similar to that from band application although there are no data to directly support this assumption.

Overall application by downward placement is therefore acceptable but data are required to confirm this conclusion. The PPE specified for band application is also appropriate for overall application by downward placement.

For overall application by broadcast (via spinning disc, oscillating spout or full width boom spreader), the data did not allow an estimate of exposure for a worker wearing PPE. However, for an unprotected operator, predicted exposure was over 300 times the AOEL. Therefore, PPE would have to provide 99.7% protection to reduce this to the AOEL. In the study on band application a coverall provided 90% protection; if a coverall provided the same degree of protection during broadcast application then exposure would still exceed the AOEL by about 30 times.
Additional PPE may offer further protection but it is not clear that this would be sufficient. Overall application by broadcast is therefore not acceptable given the uncertainties in the risk assessment.

The published data used to estimate exposure were unsatisfactory for a number of reasons (see Annex B, Section B 5.14.1) and further data, to modern standards, are therefore required to confirm the above conclusions for all application techniques when individual plant protection products are authorised.

Application equipment is only cleaned in the event of a blockage and cleaning is by means of a soft brush to clear the hopper and teed mechanism. Appropriate protective clothing to protect against the hazard from the dust is coverall, gauntlet gloves, eye protection, RPE (disposable filtering facepiece respirator) and rubber boots. Water should not be used to clean equipment since this leads to rapid breakdown of the granules and formation of a slurry which increases the potential for exposure and dermal absorption of the active.

It is possible that a wide range of hand held equipment may be used in horticulture, viticulture and arboriculture. However, there is a high potential for exposure from use of such equipment. Therefore, information on usage of hand held equipment and operator exposure from such use are required to allow the risk assessment to be completed.

→ *Updated information:*
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 RMS 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.

For tractor mounted positive displacement granule applicators with direct in soil placement, two studies were conducted: the first study, taking the maximum exposures from this study expressed as µg/kg a.s. indicates that for an EU scenario of 10 ha treated at 3 kg/ha that systemic exposure would be <50% of the AOEL [assuming 10% dermal absorption and 100% inhalation exposure]. In the second study, monitoring exposures during application of Temik 10G Gypsum (treatment doses: 0.64 to 0.86 kg a.s./ha; application areas: 3.3-9.4 ha), indicated that:
- During loading hand exposure was detected in only one case, equivalent to 8.7 µg/kg a.s.. Potential inhalation exposure was detected in two cases and ranged from <0.01 to 3.9 µg (not per kg a.s. handled).
- During application potential dermal exposures were all below LOD (<110 µg) as was actual exposupe (<41 µg). Inhalation exposure also was not detected (<1.6 µg).

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.

The published data indicate exposure for an unprotected worker of about 300 times the AOEL. These exposures relate to use of the product over a full working day and include exposure from filling the hopper. It was estimated that hopper filling accounted for up to 40% of the total exposure even though it accounted for only 1 0% of the operators time. Bystanders will not be exposed during hopper filling, will be outside the immediate treatment area and will not be exposed for a full working day. Therefore exposure of bystanders is unlikely to exceed the AOEL.

Aldicarb products are incorporated into the soil and residues are transmitted systemically within the plant. Therefore, foliar residues pose negligible risk to workers re-entering treated fields or to those handling treated plants.

2.4.5.2 Consumers

Intakes of residues by domestic animals are expected to be low; in poultry, these will be <0.0009 mg/animal/day and no further data on residues in products of this origin are required.

Theoretical maximum daily intakes based on aldicarb sulfoxide and aldicarb sulfone in the total diet using the UK and WHO models exceeded the proposed ADI of 0.003 mg/kg bw/day. Approvals should be rationalised and amended to reduce consumer exposure to an acceptable level. Acute intakes were also calculated based on residues in potatoes and bananas. The ADI would be exceeded by infant consumers of potatoes or bananas and child and infant consumers of a meal made up of bananas and potatoes. These calculations take into account the applicants proposal to amend the PHI for bananas to 180 days and MRL proposed by the notifier of 0.1 mg/kg. Further data are required to assess the distribution of residues in individual edible crop parts (i.e. one orange, one carrot etc.) where residues occur in bulk samples above the limit of determination. Approvals should be

rationalised and amended to reduce consumer exposure to an acceptable level based on acute intakes.

2.5 Methods of analysis

The methods of analysis submitted for the active substance and plant protection products (GC/FPD or HPLC/fluorescence (post column reaction)) were generally acceptable. Further data are required in a number of areas, particularly validation.

2.6 Definition of the residues

2.6.1 Definition of the residues relevant to MRLs

Based on the metabolism data submitted for certain plants, residues should be defined as the sum of aldicarb, aldicarb sulfoxide and aldicarb sulfone, expressed as aldicarb equivalents. Aldicarb sulfoxide and aldicarb sulfone were not considered to be major metabolites in any of the tissue and other samples from domestic animals, the major metabolites were aldicarb nitrile sulfone (detected in all samples) and aldicarb nitrile sulfoxide. Since the predicted intakes by domestic animals are not expected to lead to measurable levels of any of the metabolites detected, it is proposed that the residue is defined as the sum of aldicarb, aldicarb sulfoxide and aldicarb sulfone, expressed as aldicarb equivalents since these two metabolites are considered to be of toxicological significance. This definition may need to be reconsidered once the toxicological significance of other metabolites detected in domestic animal metabolism studies has been assessed.

2.6.2 Definition of the residues relevant to the environment

Based on the laboratory degradation studies and the field dissipation studies, residues in soil should be defined as aldicarb, aldicarb sulfoxide and aldicarb sulfone.

Although aldicarb degrades rapidly in soil, its movement below the root zone can not be entirely ruled out because of its potential mobility. Therefore, it is proposed that the residue in surface and ground water is defined as aldicarb, aldicarb sulfoxide and aldicarb sulfone.

2.7 Residues

The metabolism of aldicarb has been studied in 7 crops covering 3 different crop groups (leafy, root and oilseeds). Generally [14C]-aldicarb was translocated from roots to the foliage of plants. Aldicarb was extensively metabolised with only low amounts of parent being detected in plant parts. The main metabolites were aldicarb sulfoxide and aldicarb sulfone although up to 12 different metabolites were detected in plants. Generally the pattern of metabolites detected was comparable between crops. Significant amounts of radioactivity were found to be water soluble. Further work was carried out on these fractions to release the associated radioactivity with ß-glucosidase; this yielded various sulfone and sulfoxides which had been also been identified as free metabolites. It was noted that residues in potato tubers reached a maxima at 60 days after application. Up to 8 of the metabolites identified in plants were not identified in mammalian (rat) metabolism studies although ca. 30% of radioactivity in this study was attributed to water soluble compounds; further work was not carried out to release and identify this radioactivity.

In cattle, 90% of the applied dose was excreted in urine. Very low levels of radioactivity were detected in tissues. The major metabolite in milk was identified as aldicarb nitrile sulfone although small amounts of aldicarb sulfoxide and aldicarb sulfone were detected. In goats and hens, again, a large amount of applied radioactivity was excreted via urine/excreta (ca. 60-65%) and levels in tissues were very low. The highest levels of residues were detected in liver samples; detectable residues were also found in kidney samples. In poultry samples, the major metabolite was aldicarb nitrile sulfone; no residues of aldicarb sulfoxide or aldicarb sulfone were detected. Up to 8 of the metabolites identified in products of animal origin were not identified in mammalian (rat) metabolism studies.

The non mammalian (rat) metabolites which had been identified in plants or products of animal origin were aldehyde sulfone, amide sulfoxide, amide sulfoxide, amide sulfone, alcohol sulfoxide, alcohol sulfone, acid sulfoxide, acid sulfone and methane sulphonic acid.

Based on the metabolism data submitted for certain plants, residues should be defined as the sum of aldicarb, aldicarb sulfoxide and aldicarb sulfone, expressed as aldicarb equivalents. Aldicarb sulfoxide and aldicarb sulfone were not considered to be major metabolites in any of the tissue and other samples from domestic animals, the major metabolites were aldicarb nitrile sulfone (detected in all samples) and aldicarb nitrile sulfoxide. Since the predicted intakes by domestic animals are not expected to lead to measurable levels of any of the metabolites detected, it is proposed that the residue is defined as the sum of aldicarb, aldicarb sulfoxide and aldicarb sulfone, expressed as aldicarb equivalents since these two metabolites are considered to be of toxicological significance. This definition may need to be reconsidered once the toxicological significance of other metabolites detected in domestic animal metabolism studies has been assessed.

Although a large amount of residues data were submitted, many of the studies had not been carried out at rates and timings that reflected GAP or the reports were not of sufficient quality oft en lacking vital field or analytical data. MRLs have been proposed for a number of crops/products of animal origin. For a number of crops (carrots and sugar beet tops), residues at unusually high levels were detected in a number of samples; further data are required to assess the validity of these studies.

Data to assess the stability of residues in potatoes was submitted but more data are required to support studies where samples have been stored for a significant length of time prior to analysis.

The losses of aldicarb residues fmllowing processing of potatoes was studied in a number of different fractions. Losses varied between 16 and 63% depending on the preparation method. No data were submitted on microwave 'boiling' of early potatoes. No data were submitted assessing any qualitative changes to residues on processing.

A feeding study was carried out on cattle using increasing and exaggerated doses. Residues in milk were low not exceeding 0.008 mg/kg. Due to the dosing regime used, it is not possible to use this study to propose MRLs in some products of animal origin.

Residues in rotational crops were investigated using an extensive study carried out in the USA. The highest detectable residues were found in cereal forage (immature) crops but residues in mature straw samples did not exceed 0.05 mg/kg.

Intakes of residues by domestic animals are expected to be low; in poultry, these will be <0.0009 mg/animal/days and no further data on residues in products of this origin are required.

Theoretical maximum daily intakes based on aldicarb sulfoxide and aldicarb sulfone in the total diet using the UK and WHO models exceeded the proposed ADI of 0.003 mg/kg bw/day. Approvals should be rationalised and amended to reduce consumer exposure to an acceptable level. Acute intakes were also calculated based on residues in potatoes and bananas. The ADI would be exceeded by infant consumers of potatoes or bananas and child and infant consumers of a meal made up of bananas and potatoes. These calculations take into account the applicants proposal to amend the PHI for bananas to 180 days and MRL proposed by the notifier of 0.1 mg/kg. Further data are required to assess the distribution of residues in individual edible crop parts (i.e. one orange, one carrot etc.) where residues occur in bulk samples above the limit of determination. Approvals should be rationalised and amended to reduce consumer exposure to an acceptable level based on acute intakes.

2.8 Fate and behaviour in the environment

Aldicarb is a carbamate insecticide which is soil incorporated. It is formulated either as a 5%w/w granule (Temik 5G) or a 10%w/w granule (Temik 10G). It is used on a range of crops and at application rates up to 20 kg as/ha (non bearing vines, France). The majority of application rates, however, are below 5 kg as/ha.

2.8.1 Fate and behaviour in soil

Aldicarb degraded with half lifes of 2-12 days in laboratory studies. Aldicarb is oxidised to aldicarb sulfoxide and then to aldicarb sulfone. All three carbamates can be degraded to oximes and nitriles. In six field studies (four in Germany, two in the Netherlands) the dissipation of total carbamate residues (aldicarb, aldicarb sulfoxide and aldicarb sulfone) occurred with $DT_{50field}$ 0.5 to 2 months and $DT_{90field}$ 2.5 to 4.7 months. Photolysis of aldicarb was shown to occur but not considered to be relevant since aldicarb is incorporated in to the soil.

The highest application rate of aldicarb could be 20 kg as/ha which would give an initial PEC of 6.67 mg/kg soil. A depth of 20 cm is assumed since the granules are incorporated. Assuming a $DT_{50field}$ of 2 months, predicted concentrations of aldicarb carbamate residues after 7, 28 and 50 days would be 6.15, 4.82, and 3.74 mg/kg soil. At lower application rates the PEC will be correspondingly lower.

2.8.2 Fate and behaviour in water

2.8.2.1 Groundwater

The 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. However, in a Dutch field trial only aldicarb sulfoxide and aldicarb sulfone were detected in groundwater, indicating that in practice, aldicarb degrades before large scale leaching occurs.

PELMO predicted average and maximum concentrations of total carbamate residues of 0.788-0.835 µg/l and 4-5 µg/l using an application rate of 1 kg as/ha and DT50 of 44 days. Bearing in mind the problems associated with simulations of low concentrations of pesticides in groundwater, it was decided to base PECgw on the observed environmental concentrations from the Dutch field study. Aldicarb sulfoxide and aldicarb sulfone were detected in groundwater (1.6 m and 3.2 m from the soil surface) over a prolonged period of time (1 year) at a combined average concentration of 115 µg/l. For an application rate of 20 kg as/ha, this gives a PECgw of 766 µg/l for combined aldicarb sulfoxide and aldicarb sulfone residues. Aldicarb was not detected above the sensitivity limit, giving a PECgw of 0 to <1 µg/l for aldicarb following application at 3 kg as/ha.

Since drinking water is usually abstracted from depths lower than 3.2 m and degradation has been demonstrated in reducing anaerobic subsoils, concentrations of carbamate residues reaching drinking water are likely to be lower than those predicted. However, the body of evidence supplied does not adequately demonstrate that contamination of potable supplies above 0.1 µg/l will not occur and the details of the monitoring programs in Europe are insufficient to contradict this.

→ *Updated information*:
It was concluded that the aldicarb could leach under vulnerable conditions, but that in other situations, the risk for groundwater could be acceptable, depending on the specific uses. This conclusion is supported by the opinion of the Scientific Committee for Plants, who stated that based on expert judgements and the evidence from existing data it believed that use scenarios exist where there will be an acceptable risk to groundwater.

2.8.2.2 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).

However, at 25°C, aldicarb photolysed with a half life of 4.1 days. The hydrolysis of aldicarb sulfoxide and aldicarb sulfone in water were dependant on pH and temperature. At 14°C aldicarb sulfoxide degraded with a half life of 131 days (pH 8), 11 days (pH 9) and aldicarb sulfone degraded with half lives of 47 (pH 8) and 4.5 (pH 9). The possible contribution of microbial degradation of aldicarb carbamate residues in water, or partitioning between sediment and water was not addressed.

PECsw have not been proposed by the applicant because spray drift and run-off are minimised due to the incorporation of aldicarb granules in soil. Whilst this is true, surface water may also be contaminated with aldicarb carbamate residues by leaching through soil. A worst case estimate of the order of magnitude of residues entering surface water can be obtained by assuming that the concentrations of 115 µg/l found in soil water (1.6 and 3.2m depth, from Dutch study) can drain into surface water. If an application rate of 20kg as/ha is assumed (rather than 3kg as/ha in Dutch study) it is predicted that the order of magnitude of residues entering

surface waters could be 100-1000 µg/1. Lower application rates would correspondingly lower estimates of contamination. In the absence of data indicating microbial degradation or partitioning, dilution may be the only factor significantly reducing concentrations of aldicarb sulfoxide and aldicarb sulfone entering surface waters of low pH.

→ *Updated information*:
Additional studies on degradation in water/sediment system were provided in the course of the review process: DT_{50} of aldicarb in the total system was evaluated to be 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.

2.8.3 Fate and behaviour in air

Due to the low vapour pressure of aldicarb, this is not a likely route of environmental contamination.

2.9. Effects on non-target species

2.9.1. Effects on terrestrial vertebrates

Birds and mammals are thought to be exposed to aldicarb mainly from feeding directly on the young foliage of treated crops such as sugar beet, consuming contaminated insects or earthworms or eating the actual granules of product either directly or adhering to food items. The acute toxicity of aldicarb to birds is high (LC 50 1.0 mg/kg bw for the Mallard duck). The short term dietary toxicity for the Mallard is 71 ppm (71 mg/kg). No data were provided on the toxicity of the two major metabolites of aldicarb, aldicarb sulfoxide and aldicarb sulfone to birds.

Birds which take grit might consume granules of aldicarb products as grit. A small bird such as a sparrow weighing 28.2 g can consume 20 granules of grit a day. Based on the acute toxicity of aldicarb to the mallard duck of 1.0 mg/kg bw, a sparrow would have to consume less than one granule of 'Temik 10G', containing 0.0306 mg aldicarb, to acquire a lethal dose of 0.028 mg aldicarb.

In order to reduce risk from this route of exposure application must be restricted to methods of application which ensure incorporation of granules into soil in the same operation as application.

Studies must also be submitted to confirm the applicant's assertion that the formulated product is repellent to birds which would reduce the risk from consumption of granules. These requirements must be satisfactorily fulfilled before inclusion of aldicarb on Annex 1.

The TERs for birds from a consumption of vegetation treated at recommended rates, based on acute toxicity of aldicarb and assuming that all the aldicarb is present as parent compound, are below the Annex VI trigger value of 10 and therefore unacceptable. If dietary toxicity figures are used, only application at the lowest recommended dose, one kg a.s./ha, gives an acceptable TER, 14.2.

However, it is necessary to have appropriate residue data from field grown plants of the type and at the growth stage which would be foraged. Aldicarb is rapidly metabolized in the plant, the major metabolites being aldicarb sulfoxide and aldicarb sulfone. Information is needed on the proportions of these present.
The toxicity of the major metabolites to birds has not been reported. Data on these are needed. Both these areas must be satisfactorily addressed before inclusion of aldicarb in Annex 1.

The TER for a bird based on consumption of earthworms contaminated with 2 mg aldicarb/kg bw from consumption of soil treated at 20 kg aldicarb/ha and an acute oral LD 50 of 1 mg/kg bw would be 2.0 which is below the trigger of 10 in Annex VI and unacceptable. At an application rate of 3.36 kg/ha the TER would be 11.9 indicating that application at this and lower rates would be acceptable.

Basing the calculation of TER on the short term dietary toxicity of 71 ppm (71 mg/kg) for the bobwhite quail and consumption of earthworms exposed to applications at the maximum dose of 20 kg a.s./ha a figure of 36 is produced i.e. greater than the trigger value of 10, indicating that risk from application at this and any other of the rates recommended would be acceptable.

If it is considered that a bird might eat worms which had consumed granules, a bird such as a song thrush could consume considerably more than a lethal dose of aldicarb in a day, 7564 mg/kg bw giving a TER of 0.00013. If the dietary toxicity of 71 ppm (71 mg/kg) is used, the TER is 0.0009. Both these TERs are below the threshold of acceptability of 10 set in Annex VI of 911414 EC. However, consumption of earthworms which have fed solely on granules is considered to be an extreme worst case and unlikely to occur.

The acute toxicity of aldicarb to mammals, 1.3 mg a s/kg bw for the rabbit and 0.382 mg a s/kg bw for the mouse, is high. The acute toxicity of aldicarb sulfoxide and aldicarb sulfone respectively to the rabbit were 0.4 mg/kg bw and 75 mg/kg bw and to the mouse 0.49 mg/kg bw and 25 mg/kg bw. The acute toxicity to the rabbit of formulated product 'Temik 10G' is 7.94 mg product/kg bw and of 'Temik 5G' 31.9 mg product/kg bw. The dietary toxicity of aldicarb to the mouse and the rat were 0.6 and 1.6 mg/kg bw/day respectively.

The lethal dose of aldicarb for a 28.2 g mouse is 0.0068 mg a.s/mouse. If a mouse were to consume granules of product either directly or sticking to a food item, it would need to eat less than one granule to acquire a lethal dose. As for birds, data must be produced to confirm the notifier's assertion that the formulated product is repellent to mammals to an extent which would reduce the risk of exposure via this route to an acceptable level. In addition, methods of application must be restricted to those which ensure incorporation of the granules into the soil in the same operation as application.

If a rabbit were to consume all its food as vegetation treated with 22.4 kg aldicarb/ha, which is slightly higher than the highest recommended dose of 20 kg as/ha, the TER is 0.03, based on an acute toxicity of 1.3 mg a.s./kg bw and assuming that all the aldicarb remained as parent compound. If the application rate were 1.0 kg a.s./ha, the lowest recommended dose, the TER is 0.672. Both these TERs are below the trigger value of 10 set in Annex VI of 91/414 EC, indicating unacceptability.

However, allowing for metabolism in the plant, the amount of aldicarb would be less than used in the above, calculation. Using the figure of 1.5% of total aldicarb present as parent compound the TER from consumption of vegetation treated at an application rate of 3.36 kg a.s./ha is 13.3 i.e. above the trigger of 10 set in Annex VI of 91/414 EC and indicates that the risk posed by aldicarb parent compound via this route from applications at this and lower rates would be acceptable.

The TER for the metabolite aldicarb sulfone, based on the percentage of this metabolite quoted as present in the study used, for an application rate of 22.4 kg a.s./ha would be 12 which is above the Annex VI trigger of 10 indicating that the risk from this and all lower doses would be acceptable.

The TER for the metabolite aldicarb sulfoxide from application at the lowest rate of 1 kg a.s./ha is 0.3 which is below the trigger of 10 set in Annex VI of 91/414 EC and indicates that an unacceptable risk from aldicarb sulfoxide is posed by use at all recommended application rates.

However, as discussed with respect to risk to birds, the reliability of the data on residues in plants is crude and data are needed on residues of aldicarb, aldicarb sulfoxide and aldicarb sulfone from field grown plants of the type and at the growth stage which would be grazed for further consideration of aldicarb for Annex 1 listing.

A small mammal such as a shrew feeding entirely on earthworms contaminated by direct consumption of granules would take in the equivalent of 3061 mg a.s./kg bw Based on the acute LC50 of 0.382 mg/kg bw for the mouse, the TER would be 0.00012 which is far below the trigger of 10 set in Annex VI of 91/414 EC and indicates that the risk is unacceptable. A small mammal feeding entirely on earthworms which had consumed soil contaminated with aldicarb at the lowest application rate of 1.0 kg a.s./ha would take in 0.1 mg as/kg bw and the TER would be 3.8, which is below the threshold of 10 set in Annex VI of 911414 EC and indicates an unacceptable risk. If the no effect level of 0.6 mg/kg bw for dietary toxicity to the mouse is used, the TER for the lowest application rate is raised to 5.9, but remains below the threshold for acceptability.

Such low TERs indicate that the risk to mammals from this route of exposure is high. This does not take into account the metabolism of aldicarb in the earthworm or the potential to bioaccumulate. The risk to mammals from consumption of contaminated earthworms should be further investigated. Data are required on the residues of aldicarb and its metabolites in earthworms at application rates up to 20 kg aldicarb/ha.

→ *Updated information:*

During the first step of the risk evaluation, the toxicity/estimated exposure ratios were very low on the basis of laboratory studies. Uses lead to an unacceptable risk to small birds. The risk to birds was investigated by means of a probabilistic risk assessment. The 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.

A study under agricultural field conditions revealed no significant effects on earthworms up to 3.36 kg a.s./ha. The risk to birds and small mammals via ingestion of earthworms as a food source was considered as acceptable.

2.9.2 Effects on aquatic species

Acute risk

Aldicarb is highly toxic to aquatic life with a 96 hr LC 50 of 0.063 mg aldicarb/l to the most sensitive fish species, the Bluegill sunfish, 48 hr EC 50 of 0.41 mg aldicarb/l to *Daphnia magna* and 96 hr EC50 (growth inhibition) of 1.4 mg aldicarb/1 to the alga *Scenedesmus subspicatus*. Data provided on the acute toxic of the metabolites to *D magna* gave 48 hr EC 50s of 0.8 mg/1 and 0.55 mg/l for the sulfoxide and the sulfone, respectively. For the alga *Scenedesmus subspicatus* 96 hr EC 50 (biomass) was 7.6 mg/1 for aldicarb sulfoxide and the EC 50 (growth) was 1.0 mg/l for aldicarb sulfone. Data provided on acute toxicity of the metabolites to fish were from studies not done to modern standards and their reliability is questionable. Further studies will, therefore, be required for consideration of Annex 1 listing of aldicarb.

It is currently recommended for some applications of aldicarb products that they be broadcast and subsequently incorporated into the soil. There exists, therefore, the risk that some of the granules may fall onto surface waters. If the assumption is made that all the product applied were to fall into water, at the lowest application rate of 1.0 kg aldicarb/ha, the TER, calculated using the LC 50 for the most sensitive aquatic species of 0.063 mg/l for the bluegill sunfish, is 0.63 which is below the Annex VI trigger of 100 and indicates an unacceptable risk. The most effective way of managing this risk will be by not permitting broadcast application i.e. restricting methods of application to those which ensure incorporation of granules into soil in the same operation as application.

Aldicarb and its metabolites may reach surface waters by leaching. Following an application of 20 kg a s/ha a worst case estimate of the order of magnitude of total carbamate residues entering surface water is 0.1 - 1 mg/1 (B. 7.S.). It is likely that these will consist of aldicarb sulfoxide and aldicarb sulfone in approximately equal concentrations i.e. 0.5 mg/l, with negligible amounts of parent compound.

The aquatic organism most sensitive to both aldicarb sulfoxide and aldicarb sulfone is *Daphnia magna* with 48 hour EC 50s of 0.8 and 0.55 mg/l for aldicarb sulfoxide and aldicarb sulfone, respectively. Assuming worst case PECs for both metabolites of 0.5 mg/1 following application of aldicarb at 20 kg/ha, the TERs would be 1.6 and 1.1 for the sulfoxide and sulfone, respectively. Following application at the lowest dose, 1 kg a s/ha, the TER for aldicarb sulfone is 22 and for aldicarb sulfoxide is 32. All these TERs are below the trigger value of 100 set in Annex VI of 91/414 EC.

This assessment is based on the concentration in the actual leachate and takes no account of dilution in surface waters. A conservative estimate of this would be dilution by a factor of 1 0 which would increase all the TERs 10 times. Hence, the TERs for aldicarb sulfone and aldicarb sulfoxide at 1 kg as/ha are above the threshold of 100 in Annex VI 91/414/EEC. At 2.5 kg as/ha, the TER for the sulfoxide is 128, however, the TER for the sulfone is 88, i.e. below the trigger of 100. At 3.2 kg as/ha the TER for the sulfoxide is 100, however, the TER for the sulfone is 69 and is below the 100 trigger value. All TERs for the sulfoxide and sulfone for higher application rates are below the 100 trigger values.

The figures for concentration in the leachate are a very worst estimate. Total amounts reaching water and rate of degradation on which proportions of metabolites present depend will vary depending on soil type and climatic conditions. A more specific assessment of acute exposure under specific climatic and geographic conditions will be needed at Member State level for re-registration.

In view of the unreliability of the study on the toxicity of the metabolites aldicarb sulfoxide and aldicarb sulfone to fish, an acute toxicity study for each of these metabolites, done to modern standards must be submitted for consideration of Annex I listing for aldicarb.

Chronic risk

From section B.7.5, leaching contamination of the sulfoxide and sulfone metabolites may occur. The likelihood of leaching contamination of parent aldicarb is low. No data on degradation of aldicarb and its metabolites in sediment/water systems have been submitted. From section B.7.4 degradation of the sulfoxide and sulfone in water is slow in the absence of biodegradation, with half lives of 797 and 328 days, respectively (at pH 7 and 14°C).

No chronic or prolonged aquatic toxicity data are available for the sulfoxide or sulfone. In the absence of these data and a sediment water degradation study, a chronic risk assessment for organisms in the water column cannot be carried out.

Depending on the results of the sediment water degradation study, appropriate chronic/prolonged toxicity data on the aldicarb metabolites for free swimming organisms will be required.

No data have been provided on toxicity to sediment dwelling organisms. No sediment/water study has been provided, so there is no detailed information on the partitioning or persistence of aldicarb and/ or its metabolites in sediment.

Depending on the results of the sediment water degradation study, data will also be required on toxicity to a sediment dwelling organism e.g. *Chironomus riparius.* Which of aldicarb and its major metabolites aldicarb sulfoxide and aldicarb sulfone are studied will depend on whether the study on fate and behaviour indicates their presence in significant amounts.

→ *Updated information*

Additional studies on degradation in water/sediment system were provided during the course of the review process: DT_{50} of aldicarb in the total system was evaluated to be 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.

2.9.3. Effects on bees and other arthropod species

Aldicarb is extremely dangerous to bees based on its contact toxicity. However, due to the nature of the formulated products and their method of application it is unlikely that bees will come into direct contact with aldicarb and risk from this route of exposure can be considered negligible.

No data on acute oral toxicity have been provided. Aldicarb is systemic and it is likely that the parent compound or, more likely its major metabolites will be present in some degree in pollen and nectar. However, a field test in a flowering crop in which bees were foraging showed no significant effect of treatment with aldicarb and risk from this route of exposure can also be considered negligible.

Aldicarb is not an insect growth regulator and it is not considered that it will have an effect on the developmental stages of bees.

The tests carried out on other non-target arthropods were not entirely in line with the requirements of Annexes II and III. Test insects were not at the most susceptible stage and application rates were lower than the maximum recommended for the commercial products. The species tested in the laboratory and in the fields are considered similar enough to he regarded as one. In view of the nature of the use of the. product, tests on a predatory mite and a parasitoid which are required by the Annexes, may be waived, since these are not appropriate species. However further tests on ground dwelling predatory species to include species appropriate to all crops treated are still required before a complete assessment of risk to non-target arthropods can be made and a decision taken on inclusion of aldicarb in Annex 1.

2.9.4. Effects on earthworms and other soil macro-organisms

Aldicarb was moderately toxic to earthworms with an acute LC 50 of 8 mg aldicarb/kg bw. Aldicarb is not persistent in soil and is not applied frequently. The TERs for acute effects, indicate that risk from use at an application rate of 1 kg a.s./ha, 24.24 is acceptable as this is above the trigger of 10 in Annex VI. The TERs from use at the higher application rates all fall in the range of 1-10 indicating that there is a need to know more about long term effects. No NOEC or precise information on sub lethal effects have been provided, although there was some indication of the possibility of the latter in some of the studies provided.

No information were provided on the metabolism of aldicarb or its potential or that of its metabolites to accumulate in earthworms. In view of the fact that earthworms are a food source for some birds and mammals this is of significance and more data are required on residues in earthworms.

→ *Updated information*

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. The risk to birds and small mammals via ingestion of earthworms as a food source was considered as acceptable.

2.9.5 Effects on soil micro-organisms

A study was submitted but it was inadequate to demonstrate the presence or absence of any effect on soil microbial processes. Data are needed on the effect of aldicarb, aldicarb sulfoxide and aldicarb sulfone on soil microbial processes in terms of nitrogen metabolism and carbon mineralization before aldicarb can be considered for inclusion in Annex 1.

2.9.6. Effects on other non-target organisms (flora and fauna)

No data were submitted on the effects of aldicarb on other non-target organisms (flora and fauna) than those reported on above.

2.9.7. Effects on biological methods of sewage treatment

No data were submitted on this. It is not considered likely that the normal use of aldicarb will result in contamination of sewage treatment plants and no data are required.

2.10 Classification and labelling

2.10.1 Aldicarb

2.10.1.1 Human health effects

a) Current classification and labelling

Aldicarb is included in Annex 1 of Council Directive 67/548/EEC, as shown below:

Hazard symbol. T+ [1]

Indication of danger: Very Toxic [1]

Risk phrases:

R27	Very toxic in contact with skin
R28	Very toxic if swallowed

Safety phrases:

S1/2	Keep locked up and out of reach of children
S22	Do not breathe dust
S36/37	Wear suitable protective clothing and gloves
S45	In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible)

b) Proposals of the rapporteur

The rapporteur agrees with the current classification and labelling. On the basis of the available data aldicarb requires classification only on the basis of acute toxicity. There is no requirement for classification on the basis of any repeat dose toxicity test, or on the basis of irritation or sensitization. Based on the acute oral and dermal LD50 aldicarb would require to be classified as 'very toxic' by the oral and dermal routes (R27 and R 28).

[1] Updated information

2.10.1.2 Ecotoxicological effects

a) Current classification and labelling

None.

b) Proposals of the rapporteur

Hazard symbol: N Dangerous for the environment

Risk phrases:
R50-R53 Very toxic to aquatic organisms
May cause long-term adverse effects in the aquatic environment.

Safety phrases
S60 This material and its container must be disposed of as hazardous waste.
S61 Avoid release to the environment. Refer to special instructions/Safety data sheet.

Justification
According to Directive 67/548/EEC, as the acute LC/EC50s for fish and *Daphnia* are < 1 mg/l, being 0.063 and 0.4 mg/l respectively, the log K_{ow} is >3 and aldicarb is not readily degradable, the active substance should be classified as above. On the basis of the R50-R53 classification, aldicarb should also carry the 'N' symbol on the active substance label.

2.10.2 Temik 5G and Temik 10G

2.10.2.1 Human health effects

Proposals of the rapporteur

The proposals of the rapporteur are given below. For information on the basis of the proposals see Annex B, section B. 5.11.

Temik 5G

Risk phrases:
R25 Toxic if swallowed

Safety phrases:
S1/2 Keep locked up and out of reach of children.
S13 Keep away from food, drink and animal feeding stuffs
S20/21 When using do not eat, drink or smoke.
S22 Do not breathe dust
S36/37 Wear suitable protective clothing and suitable gloves.
S45/46 Medical advice. (in the UK linked to anticholinesterase properties)

Temik 10G

Risk phrases:

R25	Toxic if swallowed
R21	Harmful in contact with skin

Safety phrases:

S1/2	Keep locked up and out of reach of children.
S13	Keep away from food, drink and animal feeding stuffs.
S20/21	When using do not cat, drink or smoke.
S22	Do not breathe dust
S36/37	Wear suitable protective clothing and suitable gloves
S45/46	Medical advice. (in the UK linked to anticholinesterase properties)

2.10.2.2 Ecotoxicological effects

Proposals of the rapporteur

Aquatic life

In the absence of guidance in the EC as to classification of pesticides in terms of acute hazard to aquatic life a hazard classification based on current UK hazard level guidelines is proposed. Temik 5 G and Temik 10 G are simple formulations which can be classified on the basis of active substance toxicity data. The acute LC 50 to the most sensitive aquatic species is 63 µg as/l, or 0.063 mg as/1. Both products should, therefore, be classified under UK rules as 'DANGEROUS TO FISH AND OTHER AQUATIC LIFE.'

Bees

The 48 hr contact LD 50 for Temik 10G is 0.285 µg/bee. There are no data on the a.s.. In the absence of guidance in the EC as to classification of pesticides in terms of acute hazard to bees a hazard classification based on current UK hazard level guidelines is proposed. Making the assumption that the toxicity is proportional to the amount of a.s. in the formulation i.e. 102 g/kg, the LD 50 for the a.s. would be 0.029 µg/bee and the a.s. would be classified as EXTREMELY DANGEROUS TO BEES.