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

Chemical Review Committee
Twelfth meeting
Rome, 14–16 September 2016
Item 4 (a) (i) of the provisional agenda*

Technical work: consideration of draft decision guidance documents: carbofuran

Draft decision guidance document for carbofuran

Note by the Secretariat

I. Introduction

1. At its eleventh meeting, the Chemical Review Committee reviewed notifications of final regulatory action for carbofuran submitted by the European Union, Canada and seven African parties – Cabo Verde, Chad, the Gambia, Mauritania, the Niger, Senegal and Togo – together with the supporting documentation referenced therein, and concluded that the requirements set out in Annex II to the Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade had been met.

2. In its decision CRC-11/3, the Committee recommended that the Conference of the Parties list carbofuran in Annex III to the Convention as a pesticide. By the same decision, the Committee adopted a rationale for its conclusion and agreed to establish an intersessional drafting group to produce a draft decision guidance document.[1] A detailed workplan for the preparation of the draft decision guidance document was prepared by the Committee in line with the process adopted by the Conference of the Parties by decision RC-2/2 and amended by decisions RC-6/3 and RC-7/3. The recommendation, rationale and workplan were annexed to the report of the Committee on the work of its eleventh meeting (UNEP/FAO/RC/CRC.11/9, annexes I and III).

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

* UNEP/FAO/RC/CRC.12/1.

[1] The members of the drafting group were: Mr. Malverne Spencer (Antigua and Barbuda), Mr. Jack Holland (Australia), Mr. Gilberto Fillman (Brazil), Ms. Parvoleta Angelova Luleva (Bulgaria), Mr. Peter Ayuk Enoh (Cameroon), Mr. Jeffery R. Goodman (Canada), Ms. Jinye Sun (China), Mr. Omar S. Bah (the Gambia), Ms. Mirijam Seng (Germany), Mr. Ram Niwas Jindal (India), Mr. Mohd Fauzan Yunus (Malaysia), Ms. Leonarda Christina van Leeuwen (Netherlands), Ms. Magdalena Frydrych (Poland), Mr. Jung-Kwan Seo (Republic of Korea), Mr. Jürgen Helbig (Spain), Ms. Sarah Maillefer (Switzerland), Ms. Nuansri Tayaputch (Thailand) and Mr. N'Ladon Nadjo (Togo).

4. In accordance with the agreed workplan, the co-chairs of the intersessional drafting group, Mr. Jack Holland (Australia) and Ms. Leonarda Christina van Leeuwen (Netherlands), in consultation with the Secretariat, prepared an internal proposal based on the notifications and the supporting documentation. That internal proposal was circulated to the members of the drafting group for comments on 15 December 2015. It was amended in the light of the comments received and was circulated on 23 February 2016 to all Committee members and to the observers who had attended the eleventh meeting. Responses were received from Committee members and observers and taken into consideration in the preparation of the draft decision guidance document.

5. The outcomes of the work of the intersessional drafting group, including a compilation of the comments received and the draft decision guidance document, were circulated to the members of the drafting group on 28 April 2016.

6. The text of the draft decision guidance document, taking into account comments received and as submitted by the drafting group, is set out in the annex to the present note. It has not been formally edited. A tabular summary of the comments received, including information on how they were addressed, is set out in document UNEP/FAO/RC/CRC.12/INF/6.

II. Proposed action

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

Annex

Rotterdam Convention

Operation of the Prior Informed Consent Procedure
for Banned or Severely Restricted Chemicals

Draft Decision Guidance Document

Carbofuran

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

Food and Agriculture Organization of the United Nations

UNEP

Introduction

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

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

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

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

Purpose of the decision guidance document

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

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

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

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

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

Disclaimer

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

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

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

Standard core set of abbreviations

STANDARD CORE SET OF ABBREVIATIONS	
<	less than
≤	less than or equal to
>	greater than
≥	greater than or equal to
µg	microgram
µm	micrometre
AR	applied radioactivity
ARfD	acute reference dose
a.i.	active ingredient
ADI	acceptable daily intake
AOEL	acceptable operator exposure level
b.p.	boiling point
bw	body weight
^{o}C	degree Celsius (centigrade)
CAS	Chemical Abstracts Service
cc	cubic centimetre
CILSS	Permanent Interstate Committee for Drought Control in the Sahel
cm	centimetre
DNA	deoxyribose nucleic acid
DT_{50}	dissipation time 50%
EC	European Community
EC_{50}	median effective concentration
ED_{50}	median effective dose
EEC	European Economic Community
EFSA	European Food Safety Authority
EHC	Environmental Health Criteria
EU	European Union
FAO	Food and Agriculture Organization of the United Nations
g	gram
GAP	Good Agricultural Practices
h	hour
ha	hectare
i.m.	intramuscular
i.p.	intraperitoneal
IARC	International Agency for Research on Cancer
IC_{50}	median inhibitory concentration
IFOAM	International Federation of Organic Movements
ILO	International Labour Organization
IPCS	International Programme on Chemical Safety
IPM	Integrated Pest Management
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	soil organic partition coefficient.
Kow	octanol–water partition coefficient
kPa	kilopascal
L	litre
LC_{50}	median lethal concentration
LD_{50}	median lethal dose
LOAEL	lowest-observed-adverse-effect level
LOD	Limit of detection

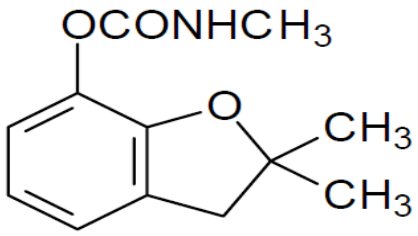
STANDARD CORE SET OF ABBREVIATIONS

LOEL	lowest-observed-effect level
LOQ	Limit of quantification
m	metre
m.p.	melting point
mg	milligram
ml	millilitre
mPa	millipascal
MRL	maximum residue limit
MTD	maximum tolerated dose
ng	nanogram
NOAEC	no-observed-adverse-effect concentration
NOAEL	no-observed-adverse-effect level
NOEC	no-observed-effect concentration
NOEL	no-observed-effect level
OECD	Organisation for Economic Co-operation and Development
PCPA	Pest Control Products Act
PEC	predicted environmental concentration
PHED	pesticide handler's exposure database
PNEC	predicted no-effect concentration
Pow	octanol-water partition coefficient, also referred to as Kow
PMRA	Pest Management Regulatory Agency (Canada)
PPE	personal protective equipment
ppm	parts per million (used only with reference to the concentration of a pesticide in an experimental diet. In all other contexts the terms mg/kg or mg/L are used).
RfD	reference dose (for chronic oral exposure; comparable to ADI)
RMS	Rapporteur Member State
SMR	standard(ized) mortality ratio
SPC	Sahelian Pesticide Committee
STEL	short-term exposure limit
TER	toxicity exposure ratio
TLV	threshold limit value
TWA	time-weighted average
UNEP	United Nations Environment Programme
US EPA	United States Environmental Protection Agency
UV	ultraviolet
VOC	volatile organic compound
w/w	weight for weight
WHO	World Health Organization
wt	weight

Decision guidance document for a banned or severely restricted chemical

Carbofuran	**Published:**

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

Common name	Carbofuran (ISO common name, UNEP/FAO/RC/CRC.11-INF-11.En, EFSA (2006), p8 & 50)
Chemical name and other names or synonyms	IUPAC: 2,3-dihydro-2,2-dimethylbenzofuran-7-yl methylcarbamate CA: 2,3-dihydro-2,2-dimethyl-7-benzofuranyl methylcarbamate PIN: 2,2-dimethyl-2,3-dihydro-1-benzofuran-7-yl methylcarbamate .
Molecular formula	$C_{12}H_{15}NO_3$
Chemical structure	
CAS-No.(s)	1563-66-2.
Harmonized System Customs Code	2932 99
Other numbers	EINECS: 216-353-0 CIPAC: 276 Combined nomenclature (CN) code for the European Union 2932 99 00.
Category	Pesticide
Regulated category	Pesticide
Use(s) in regulated category	According to the European Union (EU) notification, carbofuran was used as insecticide through incorporation into soil (at drilling) to control soil insects where maize, sugar beet or sunflowers are grown. Both references note that carbofuran can be used as acaricide, insecticide and nematicide, but during the peer review process only the insecticide use was evaluated. According to the Canadian notification carbofuran was applied using conventional ground equipment to canola, mustard, sunflower, corn (sweet, field and silage), sugar beet, green pepper, potato, raspberry, strawberry, turnip and rutabaga and could also be applied by aerial equipment to corn (field, silage and sweet), canola and mustard. According to the notifications from Cabo Verde, Chad, the Gambia, Mauritania, the Niger, Senegal and Togo[3] (hereafter referred to as the CILSS countries carbofuran is used in agriculture to control a great variety of defoliators and wood boring insects which attack many fruit and vegetable crops, potatoes, corn and soybean, banana, coffee, sugar beet and rice. It is also stated to be used in forests.
Trade names	Trade names from the EU notification (UNEP/FAO/RC/CRC.11-INF-11.En, EFSA (2006), p8): The representative formulated products for the EU evaluation were Furadan 5G, a granule (GR) and Diafuran 5G, a microgranule (MG). Trade names from the Canadian notification (UNEP/FAO/RC/CRC.11-INF-12.En, Health Canada (2009), p43): The registered carbofuran products at the time of the risk assessment were Furadan 480 Flowable Systemic Insecticide and

[3] These seven parties share a common pesticide registration body, the Sahelian Pesticides Committee set up by the Permanent Interstate Committee for Drought Control in the Sahel (CILSS). As the CILSS member states take together decisions on the registration of pesticides at a regional level, the notifications submitted by the seven African parties refer to the same final regulatory action.

	Furadan 480 F Systemic Liquid Insecticide. Trade names from the notifications from the CILSS countries (UNEP/FAO/RC/CRC.11-INF-13.En, SPC (2012), p1): carbofuran is sold under the trade name of Furadan by Food Machinery Corporation (FMC Corporation), the main producer in the USA. Carbofuran is also sold under other trade names such as Carbodan, Carbosip, Chinofur, Curaterr, Furacarb, Kenafuran, Pillarfuron, Rampart, Nex, and Yaltox, Crisfuran, and by Crystal Chemical Inter America.
Formulation types	The formulations in the EU notification are Furadan 5G, a granule (GR) and Diafuran 5G, a microgranule (MG, UNEP/FAO/RC/CRC.11-INF-11.En, EFSA (2006), p8). The content of carbofuran in the representative formulations is 50.5 g/kg (pure) and 50.27 g/kg (pure), respectively (EFSA (2006), p9). The formulations in the Canadian notification (UNEP/FAO/RC/CRC.11-INF-12.En, Health Canada (2009), p43), Furadan 480 Flowable Systemic Insecticide and Furadan 480 F Systemic Liquid Insecticide, are both suspensions with a carbofuran content of 480 g/L. The types of formulations mentioned in the CILSS notification (UNEP/FAO/RC/CRC.11-INF-13.En, SPC (2012), p1) and their content of carbofuran is not clear.
Uses in other categories	There is no reported use as an industrial chemical.
Basic manufacturers	There are two applicants mentioned in the EU notification, FMC and Dianica (EFSA (2006), p11), as well as two registrants in the Canadian notification, FMC Corporation and Bayer CropScience Inc. (UNEP/FAO/RC/CRC.11-INF-12.En, Health Canada (2009), p43). Two manufacturers are also mentioned in the CILSS notification (UNEP/FAO/RC/CRC.11-INF-13.En, SPC (2012), p1), the Food Machinery Corporation (FMC Corporation), the main producer in the USA, and Crystal Chemical Inter America.

2. Reasons for inclusion in the PIC procedure

Carbofuran is included in the PIC procedure as a pesticide. It is listed on the basis of the final regulatory actions taken by the European Union, Canada and the CILSS countries (for details see 2.1 below) to ban carbofuran as a pesticide.
It should be noted that the severely hazardous pesticide formulation, "Dustable powder formulations containing a combination of benomyl at or above 7 percent, carbofuran at or above 10 per cent and thiram at or above 15 percent", is already listed in Annex III of the Convention.
No final regulatory actions relating to industrial chemical uses have been notified.

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

European Union

The final regulatory action taken in the EU is Commission Decision 2007/416/EC of 13 June 2007 concerning the non-inclusion of carbofuran in Annex I to Council Directive 91/414/EEC and the withdrawal of authorizations for plant protection products containing this active substance (Official Journal of the European Union L 156 of 16.06.2007, p. 30-31). It is prohibited to place on the market or use plant protection products containing carbofuran. Carbofuran is not included in the list of approved active ingredients under Regulation (EC) No 1107/2009, which replaces Directive 91/414/EEC. The authorizations for plant protection products containing carbofuran had to be withdrawn by 13 December 2007. As of 16 June 2007, no authorisations for plant protection products containing carbofuran were allowed to be granted or renewed (UNEP/FAO/RC/CRC.11/6).

Reason: Human Health and the Environment

Canada

As a result of the Pest Management Regulatory Agency, Health Canada (2010): Carbofuran – RVD2010-16 Re-evaluation Decision of 8 December 2010, sale of pesticides containing carbofuran was prohibited in Canada effective December 31, 2010. The use of products containing carbofuran was prohibited after December 31, 2012. Pesticide products containing carbofuran can no longer be used in Canada **(**UNEP/FAO/RC/CRC.11/6**)**.

Reason: Human Health and the Environment

CILSS countries.
The CILSS countries involved are Cabo Verde, Chad, the Gambia, Mauritania, the Niger, Senegal and Togo. These seven parties share a common pesticide registration body, the Sahelian Pesticides Committee (SPC) set up by the Permanent Interstate Committee for Drought Control in the Sahel (CILSS). As the CILSS member states take together decisions on the registration of pesticides at a regional level, the notifications submitted by the seven African parties refer to the same final regulatory action.
On the recommendation of the SPC, carbofuran has been banned by the decision of CILSS Coordinating Minister N 008/MAE-MC/2015 of 08 April 2015. The decision was based on the reasons stated in Sahelian Pesticide Committee: Annex to the decision to ban Carbofuran; June 2012/reviewed in November 2014 (UNEP/FAO/RC/CRC.11/6, and UNEP/FAO/RC/CRC.11-INF-13.En, Sahelian Pesticide Committee: SPC (2012)).
Reason: Human Health and the Environment

2.2 Risk evaluation (see Annex 1 and 2 for further details)

European Union

Human Health

A risk assessment was carried out on the basis of Directive 91/414/EEC (replaced by Regulation (EC) 1107/2009*)* It concluded that carbofuran was not demonstrated to fulfil the safety requirements laid down in Article 5 (1) (a) and (b) of Directive 91/414/EEC (replaced by Regulation (EC) 1107/2009). The consumer risk assessment, which raised a concern about the acute exposure of vulnerable groups of consumers, in particular children, could not be finalised due to the lack of information as regards certain relevant residues (notification forms, section 2.4.2.1, p. 8) **(**UNEP/FAO/RC/CRC.11/6**)**.

Environment

It was concluded that carbofuran was not demonstrated to fulfil the safety requirements laid down in Article 5 (1) (a) and (b) of Directive 91/414/EEC (replaced by Regulation (EC) 1107/2009). The environmental risk assessment identified a number of concerns with regard to ecotoxicology. The risk for ground water contamination was assessed to be high, but could not be concluded, in particular because the data did not provide sufficient information about a number of metabolites which have a hazardous profile. Furthermore, concerns remain as regards the risk assessment for birds and mammals, aquatic organisms, bees, non-target arthropods, earthworms, and soil non-target organisms (UNEP/FAO/RC/CRC.11/6).

Canada

Human Health

A risk assessment was carried out and published in two documents; Pest Management Regulatory Agency (PMRA) Health Canada (2010): Carbofuran – RVD2010-16 Re-evaluation Decision, 8 December 2010; Pest Management Regulatory Agency (PMRA) Health Canada (2009): Carbofuran – PRVD2009-11 Proposed Re-evaluation Decision, 31 July 2009. Based on the label directions of pesticide products containing carbofuran that were registered at the time of the review, use of the pesticide carbofuran posed an unacceptable risk to workers conducting certain mixing, loading, applying or post-application activities. An aggregate dietary risk assessment demonstrated that exposure to carbofuran from food and drinking water was unacceptable. Therefore it was concluded that carbofuran did not meet Health Canada's current standards for human health protection (UNEP/FAO/RC/CRC.11/6).

Environment

In the above risk assessments, based on the label directions of pesticide products containing carbofuran that were registered at the time of the review, use of the pesticide carbofuran posed an unacceptable risk to terrestrial and aquatic organisms, and therefore did not meet Health Canada's standards for environmental protection.

Additionally, thirty three environmental incident reports from the United States and Canada were considered during the review of carbofuran, and indicated that exposure to carbofuran under the registered use pattern resulted in avian, small wild mammal and bee mortality (UNEP/FAO/RC/CRC.11/6).

CILSS countries

Human health and the environment

Carbofuran presents risks to human health and especially to non-target organisms in the environment, making it very difficult to handle it without risks for users in Sahelian countries. These risks have justified its ban in many countries of the world among which include the European Union member states.
A consultation mission conducted on behalf of the Sahelian Pesticide Committee (SPC) concluded that the SPC should stop the registration of the pesticides of toxicity class Ib since they are used by poorly trained small farmers who don't respect the safety measures (CILSS countries supporting documentation p. 32 paragraph 4.2.4).
The Sahelian Pesticide Committee stopped the registration of carbofuran-based pesticides in CILSS countries in 2006 taking into account:

- The fragile ecology of CILSS countries already characterized by an imbalance of ecosystems and the disappearance of organisms useful to the environment;
- Non-compliance with recommended measures for a safe use of carbofuran by users in the context of CILSS countries;
- The presence of pesticide residues in harvested crops and the behaviour of local people make the risk unacceptable.

Further to the pollution of Sahel ground water which constitutes the main drinking water resource with open wells, several sources agree that carbofuran is highly toxic to birds. One single grain may kill a bird (oral LD_{50} of 0.4 mg/kg body weight). Carbofuran is highly toxic to fresh water invertebrates and moderately to highly toxic to fresh water fish (UNEP/FAO/RC/CRC.11/6).

3. Protective measures that have been applied concerning the chemical

3.1 Regulatory measures to reduce exposure

European Union	The complete entry into force of all provisions of Commission Decision 2007/416/EC of 13 June 2007 was 13 December 2008 since all uses of plant protection products containing carbofuran were prohibited as from that date at the latest (notification form).
Canada	Sale of pesticides products containing carbofuran was prohibited in Canada effective December 31, 2010. The use of pesticide products containing carbofuran was prohibited after December 31, 2012. Pesticide products containing carbofuran can no longer be used in Canada (notification form).
CILSS countries	On the recommendation of the Sahelian Pesticides Committee (SPC), carbofuran was banned by the decision of CILSS Coordinating Minister N 008/MAE-MC/2015 of 08 April 2015. Carbofuran products can no longer be used in the CILSS countries (notification form).

3.2 Other measures to reduce exposure

European Union
None reported – none required since all uses of plant protection products containing carbofuran were prohibited in the EU.

Canada
None reported – none required since pesticide products containing carbofuran can no longer be used in Canada.

CILSS countries
None reported – none required since carbofuran products can no longer be used in the CILSS countries.

3.3 Alternatives

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

European Union

No information on alternatives was provided in the EU notification or in the supporting documentation.

Canada

At the time of the regulatory action, registered alternative products were available for some uses of carbofuran, however, for canola, mustard, raspberry, strawberry and sugar beet, there were no registered (or viable) alternative active ingredients to carbofuran for the control of certain pests (UNEP/FAO/RC/CRC.11-INF-12.En, Health Canada 2008 and 2010).

CILSS countries

Chemical alternatives: Several alternative pesticides to carbofuran were identified by CILSS countries. The Indian Committee of pesticide experts recommended the following pesticides on paddy rice and other crops: chlorantraniliprole, flubendiamide and quinalphos.

According to Jon Tollefson and Erin Hodgson, from the Department of Entomology of IOWA State University in the USA, the alternative for the protection of corn against root worms is to add seeds treated with a neonicotinoid pesticide like Poncho™ in the applicator. In case of post-emergence liquid treatment Lorsban™ 4E, an ethylchlorpyriphos-based formulation is an option. Currently five formulations authorized by the Sahelian Pesticide Committee under the name of Dursban are ethylchlorpyriphos-based.

Capture™ 2EC of the new generation of pyrethroids is an effective alternative to carbofuran (UNEP/FAO/RC/CRC.11-INF-13.En, Sahelian Pesticide Committee: SPC 2012, p4).

Integrated Pest and production management (IPPM): The experience in IPPM launched by FAO in collaboration with the Ministries of Agriculture in several countries of the Sahel yielded important results in agricultural production and pest management. This initiative of Good Agricultural Practices (GAP) will improve the agricultural productivity and train several growers who are potential facilitators. According to the CILSS IPPM is based on the following principles:
- A sound and judicious use of pesticides ;
- The acquisition of knowledge and practical skills critical to pest control;
- The reinforcement of decision-making capacity of growers at a field level;
- The development of a better low-cost productivity which protects the environment
(UNEP/FAO/RC/CRC.11-INF-12.En, SPC (2012), p1).

General

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), agroecology and organic agriculture as a means of reducing or eliminating the use of hazardous pesticides.

Advice may be available through National IPM focal points, the FAO, International Federation of Organic Movements (IFOAM), and agricultural research or development agencies. Where it has been made available by governments, additional information on alternatives to carbofuran may be found on the Rotterdam Convention website www.pic.int.

3.4 Socio-economic effects

European Union

No information on socio-economic effects was reported.

Canada

No information on socio-economic effects was reported.

CILSS countries

No information on socio-economic effects was reported.

4. Hazards and Risks to human health and the environment	
4.1 Hazard Classification	
WHO / IPCS	Highly hazardous (Class 1b) (UN classification)
IARC	Group 1 Acetylcholinesterase (AChE) inhibitors, 1A Carbamates (Canadian notification).
European Union	Classification of the EU in accordance with Council Directive 67/548/EEC **T+** - Very toxic. **R26** - Very toxic by inhalation. **R28** - Very toxic if swallowed. **N** - Dangerous for the environment. **R5O/53** - Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment. Classification of the EU according to Regulation (EC) No 1272/2008, which implements the UN GHS in the European Union **Acute Tox. 2** * - H330 - Fatal if inhaled. **Acute Tox. 2** * - H300 - Fatal if swallowed. **Aquatic Acute 1** - H400 - Very toxic to aquatic life. **Aquatic Chronic 1** - H410 - Very toxic to aquatic life with long lasting effects. (* = This classification shall be considered as a minimum classification.)
US EPA	Classification of the USEPA according to the USEPA's 2007 Reregistration Eligibility Decision for Carbofuran Acute oral toxicity category I: Highly acutely toxic Acute dermal toxicity category III: Slightly acutely toxic Acute inhalation toxicity category I: Highly acutely toxic Acute eye irritation category III: Minimal irritation Primary dermal irritation category IV: Mild or slight irritation Skin sensitization: Non sensitizer

4.2 Exposure limits

The following have been obtained from the **CODEX Pesticide Residues in Food Online database** available at (http://www.fao.org/fao-who-codexalimentarius/standards/pestres/pesticide-detail/en/?p_id=96) in relation to carbofuran.

Commodity	MRL (mg/kg)	Year of adoption	
Banana	0.1 mg/Kg	2013	(*)
Meat of cattle, goats, horses, pigs and sheep	0.05 mg/Kg	1999	(*)
Horse fat	0.05 mg/Kg	1999	(*)
Cattle fat	0.05 mg/Kg	1999	(*)
Goat fat	0.05 mg/Kg	1999	(*)
Maize	0.05 mg/Kg	2005	(*) (#)
Rape seed	0.05 mg/Kg	2004	(*)
Sheep fat	0.05 mg/Kg	1999	(*)
Pig fat	0.05 mg/Kg	1999	(*)
Edible offal of cattle, goats, horses, pigs & sheep	0.05 mg/Kg	1999	(*)
Sorghum	0.1 mg/Kg	1999	(*)
Sunflower seed	0.1 mg/Kg	1999	(*)
Sugar cane	0.1 mg/Kg	1999	(*)
Spices, roots and rhizomes	0.1 mg/Kg	2011	
Cotton seed	0.1 mg/Kg	2004	
Rice, Husked	0.1 mg/Kg	2004	
Sugar beet	0.2 mg/Kg	2005	(#)
Mandarin	0.5 mg/Kg	2010	(#)
Oranges, Sweet, Sour (including Orange-like hybrids): several cultivars	0.5 mg/Kg	2010	
Sorghum straw and fodder, Dry	0.5 mg/Kg	2001	
Rice straw and fodder, Dry	1 mg/Kg	2004	
Coffee beans	1 mg/Kg	1999	
Citrus pulp, Dry	2 mg/Kg	2001	(#)

(*) At or about the limit of determination
(#) Based on the use of carbosulfan

Other information

The CODEX Pesticide Residues in Food Online database reference above also contains the following information:

Acceptable Daily Intake (ADI)/PTDI	0-0.001 mg/kg body weight (2008)
Residue definition	Definition of the residue (for compliance with the MRL and for estimation of dietary intake) for plant and animal commodities: carbofuran and 3-hydroxycarbofuran expressed as carbofuran. The residue is not fat-soluble

An earlier reference identified as the carbofuran chapter from Pesticide residues in food 2008 – Joint FAO/WHO meeting on pesticide residues; Report 2008; FAO Plant Production and Protection Paper 196 (JMPR, 2009).
(http://www.fao.org/fileadmin/templates/agphome/documents/Pests_Pesticides/JMPR/Report09/Carbofuran.pdf) contains the following information on **Acceptable Daily Intake (ADI)/Acute Reference Dose (ARfD).**

A periodic review of the toxicology of carbofuran was carried out by the 1996 JMPR. An ADI of 0–0.002 mg/kg bw was established. In 2002, an ARfD of 0.009 mg/kg bw was established. The 2008 JMPR evaluated newly submitted studies on acute toxicity and re-examined relevant data which had been considered by previous Meetings. The 2008 Meeting established an **ARfD of 0.001 mg/kg bw**. The Meeting noted that this ARfD was lower than the current ADI of 0– 0.002 mg/kg bw. The Meeting concluded that the ADI and ARfD for carbofuran should be based on the same NOAEL and **revised the ADI to 0–0.001 mg/kg bw**.

A periodic review of the residue and analytical aspects of both carbofuran and carbosulfan was carried out by the 1997 JMPR. The carbofuran residue is defined as carbofuran + 3-hydroxycarbofuran for compliance with MRLs. For the purposes of dietary intake, the residue definition for carbofuran arising from use of carbosulfan and carbofuran is carbofuran + free and

conjugated 3-hydroxycarbofuran, expressed as carbofuran. The analytical methods include an acid hydrolysis step to release the conjugate.

European Union

MRLs The EU notification (UNEP/FAO/RC/CRC.11-INF-11.En, EFSA 2006), p25, as well as EFSA(2009), p40) reports that MRLs for carbofuran residues, defined as sum of carbofuran and 3-hydroxycarbofuran expressed as carbofuran equivalents, have been proposed by the Rapporteur Member State (RMS) at the LOQ level. This results in different MRLs proposed by the RMS for the same crop, since the proposal is based on the respective LOQ reached in the residue trials submitted by the two different applicants.

Sugar beet	0.02* mg/kg (based on Dianica studies);	0.1* mg/kg (based on FMC studies)
Maize	0.02* mg/kg (based on Dianica studies);	0.1* mg/kg (based on FMC studies)
Sunflower seed	0.02* mg/kg (based on Dianica studies)	

It was noted that the data base (per applicant) from which the MRL proposals are derived was not complete according to current requirements and consequently the MRL proposals should be considered as provisional.

European Union Safety Values (taken from UNEP/FAO/RC/CRC.11-INF-11.En, EFSA (2009), pp23-24):

EU Risk Assessment Acceptable Daily Intake (ADI) = 0.00015 mg/kg bw/day. This is based on the LOAEL of 0.03 mg/kg bw/day in pups on post-natal day 11 from the acute neurotoxicity study in rats for brain Acetylcholinesterase (AChE) inhibition. An uncertainty factor of 200 to account for inter- and intra-species variation, and to extrapolate to a NOAEL was applied.

EU Risk Assessment Provisional Acceptable Operator Exposure Level (AOEL) = 0.0003 mg/kg bw/day. This is based on the NOAEL of 0.03 mg/kg bw/day in adults from the acute neurotoxicity study in rats for brain AChE inhibition. The adult NOAEL was considered to be the most representative value for exposure to carbofuran for operators. An uncertainty factor of 100, to account for inter- and intra-species variation, was applied.

EU Risk Assessment Provisional Acute Reference Dose (ARfD) = 0.00015 mg/kg bw/day. This is based on the LOAEL of 0.03 mg/kg bw/day in pups on post-natal day 11 from the acute neurotoxicity study in rats for brain AChE inhibition. An uncertainty factor of 200 to account for inter- and intra-species variation, and to extrapolate to a NOAEL was applied.

Canada (the following has been taken from UNEP/FAO/RC/CRC.11-INF-12.En, Health Canada (2009), p17-19)

Determination of Acceptable Daily Intake to estimate dietary risk from repeat exposure to carbofuran, the two acute oral cholinesterase activity studies in the rat (as discussed under 3.3.1 Determination of Acute Reference Dose) were selected for risk assessment. The quick-acting and reversible nature of carbamate inhibition is considered as justification to default to the acute LOAEL which is lower than the subchronic or chronic NOAELs. In the case of carbofuran, long-term daily exposures are considered as multiple daily exposures with each causing transient inhibition of cholinesterase with potential resulting toxicity. Standard uncertainty factors of 10-fold for inter-species extrapolation and 10-fold for intra-species variability were applied along with an additional 3-fold uncertainty factor because a NOAEL was not achieved in these studies. With respect to the Pest Control Products Act (PCPA) factor, all of the required studies relevant to assessing risks to infants and children were available for this assessment. Accordingly, the PCPA factor was reduced to 1-fold and the composite assessment factor was 300. **ADI = 0.05 mg/kg bw/day/300 = 0.0002 mg/kg bw/day.**

This ADI provides a margin of safety of >2,500 to the developmental NOAEL (decreased viability), >500 to the lowest NOAEL for testicular effects and >1,000 to the lowest LOAEL for maternal toxicity. It is thus considered protective of all populations including men, pregnant women, infants and children.

Determination of Acute Reference Dose To estimate acute dietary risk (1 day), the LOAEL of 0.05 mg/kg bw was selected from the two acute oral cholinesterase activity studies in the rat based on cholinesterase inhibition. Standard uncertainty factors of 10-fold for interspecies extrapolation and 10-fold for intraspecies variability were applied along with an additional 3-fold uncertainty factor because a NOAEL was not achieved in these studies. With respect to the PCPA factor, all of the required studies relevant to assessing risks to infants and children were available for this assessment. Accordingly, the PCPA factor was reduced to 1-fold and the composite assessment factor was 300. **ARfD = 0.05 mg/kg bw / 300 = 0.0002 mg/kg bw.**

WHO drinking water guideline

On the basis of the JMPR ADI (2.2 µg/kg of body weight, if not rounded) and assuming a 60-kg body weight, drinking-water consumption of 2 litres/day and an allocation of 10% of the ADI to

drinking-water, a guideline value of 7 µg/litre (rounded figure) can be calculated for carbofuran (WHO 2004, 2011).

4.3 Packaging and labelling

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

Hazard Class and Packing Group:	- Hazard Class: 6.1 - Packing Group: I, II and III- IMDG Code: UN No.2757 For further information on the classification of mixtures, special provisions and packing instructions see United Nations (2015). It is recommended to follow the FAO Guidelines on good labelling practice for pesticides (FAO 2015)
International Maritime Dangerous Goods (IMDG) Code	For carbofuran (pure substance): UN No. 2757 Carbamate pesticide, solid, toxic (carbofuran) Class 6.1 Marine pollutant, taken from the TEC (http://www.inchem.org/documents/icsc/icsc/eics0122.htm)
Transport Emergency Card	TEC (R)-61GT7-I (http://www.inchem.org/documents/icsc/icsc/eics0122.htm).

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.

The following has been taken from the FAO/WHO Data Sheets on Pesticides No 56 Carbofuran, published in an Annex to the DGD for the severely hazardous pesticide formulation, i.e. dustable powder formulations containing a combination of benomyl at or above 7 percent, carbofuran at or above 10 per cent and thiram at or above 15 percent (FAO/UNEP (2004/2005), also available at http://www.pic.int/Portals/5/DGDs/DGD_Dustable%20powder%20formulations_EN.pdf)

EMERGENCY AID

General - Carbofuran is a carbamate pesticide of very high toxicity. It is an acute poison, absorbed by inhalation of dust and spray mist; from the gastrointestinal tract; and, to a lesser extent, through the intact skin. Most formulations should be handled by trained personnel wearing suitable protective clothing.

Early symptoms of poisoning - Early symptoms of poisoning may include headache, weakness, giddiness and nausea. Later there may be perspiration, stomach pains, blurred vision, excessive salivation, slurred speech, and muscle twitching, tremor, diarrhoea and vomiting.

Treatment before person is seen by a physician, if these symptoms appear following exposure - The person should stop work immediately, remove contaminated clothing and wash the affected skin with soap and water, if available, and flush the area with large quantities of water. If swallowed, vomiting should be induced immediately if the person is conscious. In the event of collapse, artificial respiration should be given, preferably by mechanical means. If mouth-to-mouth resuscitation is used vomit may contain toxic amounts of carbofuran. If the eyes are contaminated, flush them with water for at least 15 minutes. If carbofuran is inhaled, remove victim to fresh air immediately (FAO/UNEP 2004/2005).

MEDICAL DIAGNOSIS AND TREATMENT IN CASES OF POISONING

General information - Carbofuran is a carbamate insecticide of very high toxicity. It is absorbed from the gastrointestinal tract and by inhalation, and only to a limited extent through the intact skin. Its mode of action is by reversible inhibition of acetyl cholinesterase. Erythrocyte cholinesterase is more inhibited than plasma cholinesterase. Symptoms of mild poisoning are short lasting and in case of occupational over-exposure occur without delay and at doses well below the fatal dose. Because of its rapid metabolism and excretion it does not accumulate in the tissues.

Symptoms and signs - Symptoms of poisoning include excessive sweating, headache, chest tightness, weakness, giddiness, nausea, vomiting, stomach pains, salivation, blurred vision, slurred speech and muscle twitching. Paraesthesia and mild skin reactions have also been reported. Diagnosis can be based on a recent history of activities and non-reactive pupils of the eyes.

Laboratory - Because carbofuran is a reversible inhibitor of cholinesterase, measurements of cholinesterase activity should be made by a method which minimizes the reactivation of inhibited enzyme. Erythrocyte cholinesterase determination is more informative than either plasma or whole blood cholinesterase, but the enzyme will only be inhibited for a short time (few hours) after exposure. The presence of metabolites of carbofuran in urine is also indicative of exposure.

Treatment - If the pesticide has been ingested, unless the patient is vomiting, rapid gastric lavage should be performed using 5% sodium bicarbonate, if available. For skin contact, the skin should be washed with soap and water. If the compound has entered the eyes, they should be washed with isotonic saline or water. Since the symptoms of poisoning with carbofuran are of short duration, atropine treatment is usually not necessary by the time the patient reaches a place where this antidote is available. Where there are manifest symptoms 1-2 mg of atropine sulfate (adult dose) may be given intramuscularly or even intravenously and repeated as necessary. Care should be taken to avoid overdosage of atropine, especially when treating children. In extreme cases, if the patient is unconscious or is in respiratory distress, oxygen may be required. Provide patient support as required, including; suction of secretions, maintenance of airways, intravenous fluids *pro re nata* and bladder catheterization. Morphine, aminophylline, phenothiazines, reserpine, furosemide and ethacryoic acid are contraindicated. Pralidoxime chloride is of doubtful value but if muscle weakness is severe a dilute solution may be given cautiously intravenously. If convulsions occur diazepam may be given, the patient must be monitored for respiratory depression and hypotensive reactions.

Prognosis - If the acute toxic effect is survived, the chances of complete recovery are very good. (FAO/UNEP (2004/2005)

The transport emergency card (http://www.inchem.org/documents/icsc/icsc/eics0122.htm) offers the following advice following exposure.

IN ALL CASES CONSULT A DOCTOR!
For inhalation - Fresh air, rest. Artificial respiration may be needed. Refer for medical attention. See Notes.
For spills on the skin - Remove contaminated clothes. Rinse and then wash skin with water and soap.
For splashing into the eye - First rinse with plenty of water for several minutes (remove contact lenses if easily possible), then refer for medical attention.
For ingestion - Give a slurry of activated charcoal in water to drink. Refer for medical attention. See Notes.
Notes - Specific treatment is necessary in case of poisoning with this substance; the appropriate means with instructions must be available.
Do NOT take working clothes home.
Carrier solvents used in commercial formulations may change physical and toxicological properties. If the substance is formulated with solvents also consult the ICSCs of these materials.

4.5 Waste management

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

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

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

Annexes

Annex 1 Further information on the substance

Introduction

The information presented in this Annex reflects the conclusions of the notifying parties in three prior informed consent (PIC) regions: Europe (European Union), North America (Canada) and Africa (Cabo Verde, Chad, the Gambia, Mauritania, the Niger, Senegal and Togo[4]). Summaries of the notifications were included in PIC Circular XXXV of June 2012, PIC Circular XL of December 2014 and PIC Circular XLI of June 2015, respectively.

Where possible, information on hazards provided by the notifying parties has been presented together, while the evaluation of the risks, specific to the conditions prevailing in the notifying Parties are presented separately. This information has been taken from the documents referenced in the notifications in support of their final regulatory actions to ban carbofuran from the European Union (UNEP/FAO/RC/CRC.11-INF-11.En, EFSA Scientific Report 2006), Canada (UNEP/FAO/RC/CRC.11-INF-12.En, Health Canada 2009, 2010) and CILSS countries (UNEP/FAO/RC/CRC.11-INF-13.En, the Sahelian Pesticide Committee 2012).

[4] These seven parties share a common pesticide registration body, the Sahelian Pesticides Committee set up by the Permanent Interstate Committee for Drought Control in the Sahel (CILSS). As the CILSS member states take together decisions on the registration of pesticides at a regional level, the notifications submitted by the seven African parties refer to the same final regulatory action.

Annex 1 – Further information on carbofuran

1.	**Physico-Chemical properties (most of the information has been sourced from the EU notification UNEP/FAO/RC/CRC.11-INF-11.En and EFSA (2006), pp 51-53, except where indicated some additional is from the Canadian notification UNEP/FAO/RC/CRC.11-INF-12.En and Health Canada (2009) p10 – the former indicates these have been sourced from the Pesticides Manual , thirteenth edition, 2004)**	
1.1	**Identity**	ISO: Carbofuran (UNEP/FAO/RC/CRC.11-INF-11.En, EFSA (2006), p8) IUPAC: 2,3-dihydro-2,2-dimethylbenzofuran-7-yl methylcarbamate (UNEP/FAO/RC/CRC.11-INF-11.En, EFSA (2006), p8 & 50; UNEP/FAO/RC/CRC.11-INF-12.En, Health Canada (2009), p9) CAS: 2,3-dihydro-2,2-dimethyl-7-benzofuranyl methylcarbamate (EFSA (2006), p50, Health Canada (2009), p9)
1.2	**Formula**	$C_{12}H_{15}NO_3$ (UNEP/FAO/RC/CRC.11-INF-11.En EFSA (2006), p50; Health Canada (2009) p9; UNEP/FAO/RC/CRC.11-INF-13.En, Sahelian Pesticide Committee (2012), p1).
1.3	**Colour and Texture**	Arysta: white crystalline solid, odourless (purified active substance) FMC: off-white powder, aromatic acid-like odour (99.3%)
1.4	**Melting point**	Dianica: melting point 153.1°C (98.2%) FMC: melting range 151.2 – 153.7°C (99.3%) 153-154°C
1.5	**Boiling Point**	Dianica: boiling with partial decomposition at 276°C (98.2%) FMC: boiling at 254.1°C (no decomposition) (99.6%)
1.6	**Relative Density (g/cm^3)**	Dianica: D_4^{20} = 1.228 (98.2%) FMC: D_4^{22} = 1.290 (99.3%) 1.18 at 20°C
1.7	**Vapour Pressure**	Dianica: 2.25 X 10^{-4} Pa at 20°C FMC: 8 X 10^{-5} Pa at 25°C 0.031 mPa at 20°C, 0.072 mPa at 25°C (UNEP/FAO/RC/CRC.11-INF-12.En, Health Canada (2009) p10)
1.8	**Henry's Law Constant**	Dianica: 1.58 X 10^{-4} Pa.m^3.mol^{-1} at 20°C FMC: 5 X 10^{-5} Pa.m^3.mol^{-1} at 25°C 2.50 X10^{-10} atm.m^3.mol^{-1}
1.9	**Solubility in Water)**	Dianica: 315 mg/L at 19.5 ± 2.0°C, no effect of pH FMC: 322 mg/L at 20.0 ± 0.5°C, no effect of pH 320 mg/L at 20°C, 351 mg/L at 25°C (UNEP/FAO/RC/CRC.11-INF-12.En, Health Canada (2009), p10)
1.10	**Solubility in Organic Solvents**	Dianica: solubility at 20°C (g/L) n-heptane 0.1, xylene 7.8, 1,2-dichloroethane 106.5, methanol 71.0, acetone 107.0, ethyl acetate 66.9. FMC: solubility at 20°C (g/L) n-heptane 0.13, xylene 8.0, 1,2-dichloroethane 91.0, methanol 72.8, acetone 103.4, ethyl acetate 56.1. In dichloromethane >200, isopropanol 20-50, toluene 1-20 (all in g/L, 20°C) (Canadian notification form).
1.11	**Partition co-efficient (log K_{OW})**	Dianica: 1.8 at 20°C, no effect of pH FMC: 1.62 at 22°C, no effect of pH Log Kow = 1.52 at 20°C (UNEP/FAO/RC/CRC.11-INF-12.En, Health Canada (2009) p10)
1.12	**Dissociation Constant**	Dianica: no pKa in environmentally relevant pH range FMC: no pKa in environmentally relevant pH range None (UNEP/FAO/RC/CRC.11-INF-12.En, Health Canada (2009) p10)
1.13	**Surface tension**	Dianica: 48.9 mN/m at 20.3°C (90% saturated solution) FMC: 54.7 mN/m at 20°C (90% saturated solution)
1.14	**Hydrolytic stability (DT50)**	*Dianica*: pH 4: hydrolytically stable; pH 7, 25°C: DT_{50} = 45.7 d; pH 9, 25°C: DT_{50} = 0.1 d *FMC:* pH 7, 25°C: DT_{50} = 28 d; pH 7.5, 25°C: DT_{50} = 9.1 d; pH 8, 25°C: DT_{50} = 2.7 d

2 Toxicological properties

2.1 General

2.1.1 Mode of Action

Carbofuran is a broad spectrum, non-cumulative carbamate insecticide of very high toxicity. It is absorbed from the gastrointestinal tract and by inhalation, and only to a limited extent through the intact skin. Its mode of action is by reversible inhibition of acetyl cholinesterase. Erythrocyte cholinesterase is more inhibited than plasma cholinesterase. Symptoms of mild poisoning are short lasting and in case of occupational over-exposure occur without delay and at doses well below the fatal dose. Because of its rapid metabolism and excretion it does not accumulate in the tissues (FAO/UNEP (2004/2005), available at http://www.pic.int/Portals/5/DGDs/DGD_Dustable%20powder%20formulations_EN.pdf).

2.1.2 Symptoms of poisoning

Early symptoms of poisoning may include headache, weakness, giddiness and nausea. Later there may be perspiration, stomach pains, blurred vision, excessive salivation, slurred speech, and muscle twitching, tremor, diarrhoea and vomiting. Symptoms of poisoning also include excessive sweating, chest tightness, weakness, giddiness and nausea. Paraesthesia and mild skin reactions have also been reported. Diagnosis can be based on a recent history of activities and non-reactive pupils of the eyes (FAO/UNEP (2004/2005), available at http://www.pic.int/Portals/5/DGDs/ DGD_Dustable%20powder%20formulations_EN.pdf).

2.1.3 Absorption, distribution, excretion and metabolism in mammals

European Union

Carbofuran is rapidly and completely absorbed and excreted in the rat (32 hours after dosing, 83% of the administered dose was excreted, and 96 hours after a dose, 92% and <4% were excreted in urine and faeces, respectively). In man, the two formulations have a dermal absorption value of 10%. Distribution is rapid, with the liver having the maximum concentration after 1 hour, and accumulation does not occur. Carbofuran is metabolized to form 3-hydroxycarbofuran and then glucuronic acid, of which the latter is excreted in the bile. Enterohepatic recirculation may occur. Hydrolysis and hydroxylation of 3-hydroxycarbofuran also yield 3-hydroxycarbofuran-7-phenol and 3-ketocarbofuran, respectively, the latter is subsequently hydrolysed to 3-ketocarbofuran-7-phenol. These three metabolites are conjugated and excreted primarily in the urine. Oxidation of carbofuran to N-OH-methylcarbofuran also occurs, which is then hydroxylated to 3-OH-N-OH-methylcarbofuran and then carbon dioxide, which is excreted in expired air (UNEP/FAO/RC/CRC.11/6).

The EU notification adds that 92% of phenyl part is excreted within 48 h mainly via urine (89%) and faeces (2.5%); carbamate moiety excreted within 32 h in air as CO_2. Carbofuran and metabolites with the carbamate moiety are the toxicologically significant compounds (animals, plants and environment) (UNEP/FAO/RC/CRC.11-INF-11.En, EFSA (2006), p60).

Canada

Carbofuran was rapidly absorbed, metabolized and eliminated mainly in the urine after oral administration to mice and rats. The first step in the metabolic pathway is hydroxylation of carbofuran to 3-hydroxycarbofuran then oxidation resulting in the formation of 3-ketocarbofuran. Breakage of the carbamate ester linkage results in liberation of the phenolic derivatives and their corresponding conjugates, principally glycosides. These degradation products are then excreted mainly as conjugates of glucuronic acid and sulfate. The most common carbamate metabolites are 3-hydroxycarbofuran and 3-ketocarbofuran. There were no sex differences noted in the absorption, distribution, metabolism or excretion of carbofuran. Most metabolites were found to be significantly less toxic than the parent compound in

acute oral lethality tests. One metabolite 3-hydroxycarbofuran showed similar acute oral toxicity as carbofuran (UNEP/FAO/RC/CRC.11-INF-12.En, Health Canada, 2009, p11).

2.2 Toxicology studies

2.2.1 Acute toxicity

European Union

Carbofuran:

- is very toxic by ingestion (LD_{50} 7 mg/kg bw);
- and by inhalation (LC_{50} 0.05 mg/L);
- whereas toxicity during dermal exposure is moderate (LD_{50} 1000-2000 mg/kg bw);
- Carbofuran is not a skin irritant, eye irritant, or skin sensitizer, but mortality was reported after exposure to eyes (UNEP/FAO/RC/CRC.11-INF-11.En, EFSA, 2009, pp16-17).

Canada

In acute toxicity studies, carbofuran was highly toxic via the oral route of exposure in rats but showed low dermal toxicity. Acute inhalation studies were not available. Carbofuran was a minimal eye irritant and was not a dermal sensitizer. The acute effects observed in oral studies were typical for cholinesterase inhibition: ataxia, salivation, lacrimation, exophthalmos, hyperpnea, cyanosis and generalized tremors. As with other carbamate compounds, carbofuran's cholinesterase-inhibiting effect is short-term and reversible (UNEP/FAO/RC/CRC.11-INF-12.En, Health Canada, 2009, p11).

CILSS countries

Carbofuran belongs to WHO class Ib (highly hazardous). Some formulations belong to class I (highly hazardous or extremely hazardous) or to class II (moderately hazardous). It is extremely toxic via oral route and by inhalation (LD_{50} is 5 to 13 mg/kg in rats, 2 mg/kg in mice). Dermal toxicity is low. It is minimally irritating to the eyes and to the skin. It is not a skin sensitizer. Thermal degradation may release toxic vapours. Among all pesticides used in crops carbofuran presents the most acute toxicity to human health, apart from aldicarb and parathion. It is neurotoxic being a cholinesterase inhibitor. This is of short duration and reversible. A person exposed to doses higher than 0.25 mg/kg of body weight may present such symptoms as: salivation, abdominal pains, sleepiness, dizziness, anxiety, vomiting, loss of control, even coma and cardiac arrest. It is a strong endocrine disruptor which may affect the concentration of several human and animal hormones even at very low doses UNEP/FAO/RC/CRC.11-INF-13.En,SPC (2012).

2.2.2 Short term toxicity

European Union

The overall oral short term no-observed-adverse-effect-level (NOAEL) is 0.1 mg/kg bw/day from the 1-year dog studies with the NOAELs of 0.1 and 0.25 mg/kg bw/day, based on red blood cell (RBC) AChE inhibition and clinical signs of neurotoxicity and testicular degeneration (UNEP/FAO/RC/CRC.11-INF-11.En, EFSA, 2009, p17).

Canada

In repeat-dose dietary studies in various species (mouse, rat and dog), the dog appeared to be the most sensitive species with respect to cholinergic symptoms. Cholinesterase inhibition was seen in all species with the mouse being the least sensitive. Inhibition of cholinesterase activity is also seen via the dermal route of entry in the rabbit. Repeat-dose inhalation studies were not available. No gender sensitivities were seen in repeat-dose dietary studies. Additional effects noted in the repeat-dose dietary studies include: a decrease in weight gain in mice and rats and testicular effects in dogs. The rodent studies highlight the differences between gavage and dietary dosing as animals tolerated chronic dietary dose-levels that were equivalent to or even exceeded

the LD_{50} values in acute gavage studies. Repeat-dose dietary studies in the rat and dog did not indicate that an increase in the duration of dosing resulted in increased toxicity with respect to cholinesterase activity and/or effects (UNEP/FAO/RC/CRC.11-INF-12.En, Health Canada, 2009).

2.2.3 Genotoxicity (including mutagenicity)

European Union

Carbofuran is positive in *in vitro* studies, but negative in *in vivo* studies.

In vitro results were negative for the Ames test and V79 cell line assay using carbofuran from Arysta, but were positive for the Ames test and mouse lymphoma assays, with and without S9 metabolic activation, for carbofuran from FMC.

In vivo results were negative for the micronuclei assay using mouse bone marrow cells for carbofuran from Arysta and in chromosomal aberration for carbofuran from FMC (UNEP/FAO/RC/CRC.11/6).

Canada

Assessments of mutagenic potential in a variety of bacterial and mammalian *in vitro* and *in vivo* studies were performed for carbofuran.

Positive results in studies with bacteria have been recorded in *S. typhimurium* (TA 1535 and occasionally TA 98 & TA 1538), while negative results have been reported in other strains of *S. typhimurium*, *S. cerevisiae*, *E. coli* and *B. subtillis*.

In the mouse lymphoma mutagenesis assay, carbofuran displayed weak positive results. Positive evidence from other tests includes the in vivo chromosomal aberration assay and micronucleus assay; however, these positive results occurred at levels noted to induce lethality in the acute LD_{50} studies. Negative results were achieved with the Drosophila sex-linked recessive lethal mutation, mitotic recombination in yeast, in vitro chromosome aberration, sister chromatid exchange and unscheduled DNA synthesis assays.

There is sufficient evidence to support weak mutagenic properties for carbofuran in bacteria and mammalian cells (UNEP/FAO/RC/CRC.11-INF-12.En, Health Canada, 2009, p12).

2.2.4 Long term toxicity and carcinogenicity

European Union

No carcinogenic potential was observed in four chronic studies (two in rat and two in mice). Tumours observed in the studies were considered to be spontaneous and unrelated to carbofuran treatment.
Rats (strain and sex unspecified, dietary, 2 years): NOAEL = 0.462 mg/kg bw/day (reduced bodyweight, reduced food efficiency and reduced red blood cell and brain AChE). Lowest relevant long-term NOAEL (UNEP/FAO/RC/CRC.11/6).

Canada

Studies for chronic toxicity/carcinogenicity were conducted on mice and rats. In all studies reviewed, there was no evidence of carcinogenicity (UNEP/FAO/RC/CRC.11-INF-12.En, Health Canada, 2009, p12).

CILSS countries

Carbofuran is not known to have carcinogenic effects. It has not been demonstrated that carbofuran is teratogenic or mutagenic, either (UNEP/FAO/RC/CRC.11-INF-13.En, SPC, 2012).

2.2.5	**Effects on reproduction**	**European Union** Carbofuran induced decreased body weight in pups as well as pup survival at parental toxic doses. Results from the open literature demonstrated that in utero or lactational exposure to carbofuran during whole gestation or lactation period caused testicular effects and spermatotoxicity in pups at dose levels of 0.4 mg/kg bw not associated with inducing general toxic effects, these effects were reproduced in a more recent study with dietary administration, however, the effects were far less pronounced and occurred only at systemically toxic doses (18 mg/kg bw/day); they were not reproduced upon gavage administration. Therefore, no classification regarding reproduction toxicity was proposed (UNEP/FAO/RC/CRC.11-INF-11.En, EFSA, 2009, pp3-4). **Canada** The developmental toxicity studies in mice, rats and rabbits showed no evidence of teratogenicity and no additional sensitivity of the fetus following in utero exposure to carbofuran. Developmental effects in the fetuses included mortality, decreased weight and increased variations alongside maternal observations of mortality, clinical signs and reduced weight gain. At higher dose levels, carbofuran caused sperm and reproductive system damage when fed to either adult male rats or rats exposed in utero or during lactation. Degeneration was seen in the Sertoli cells along with atrophied seminiferous tubules. Disturbed spermatogenesis (decreased sperm count, abnormal sperm morphology and altered testicular enzymes) was noted in the rats. Effects on sperm quantity and quality were observed in carbofuran-treated rabbits. In the one-year dog study, testicular effects were manifested as decreased weight, degeneration of the seminiferous tubules and aspermia. Despite these effects, no reproductive effects were noted in the multigeneration reproductive study. Parental effects were limited to reduced weight gain and food intake whereas offspring effects included reduced weight gain and viability. In view of the findings in the rat, rabbit and dog, carbofuran should be viewed as having some potential for reproductive toxicity (UNEP/FAO/RC/CRC.11-INF-12.En, Health Canada, 2009, pp12-13). **CILSS countries** Sub-chronic administration of carbofuran to rats may be toxic to sperm and testicles. Prolonged or repeated exposure to carbofuran may cause the same effects as an acute exposure. It has not been demonstrated that carbofuran can cause reproductive effects to humans and animals at expected exposure levels. However, chronic ingestion of high doses damages testicles in dogs. Doses of 5 mg/kg/day to rats and mice during two years showed loss of weight; carbofuran is known to affect reproduction and development. A daily diet of 100 ppm of carbofuran in pregnant rats considerably reduces newborn survival. However, in a three-generation reproductive toxicity study, Charles River rats were given carbofuran (95.6 % purity) at concentrations of 0, 20 or 100 mg/kg food, the NOAEL was 20 mg/kg food, equal to 1.2 mg/kg body weight per day, based on the reduction of body weight gain in parental generation and the reduction of growth and survival of offspring generation to 100 mg/kg food (UNEP/FAO/RC/CRC.11-INF-13.En, SPC, 2012).
2.2.6	**Neurotoxicity/ delayed neurotoxicity, Special studies where available**	**European Union** At the occasion of the resubmission of carbofuran, new sets of acute neurotoxicity studies were assessed. No NOAEL could be established in pups at post-natal day 11 (PND11) based on a significant inhibition of the brain acetylcholinesterase, the low-observed-adverse-effect-level (LOAEL) was 0.03 mg/kg bw. In young adult rats, the NOAEL was 0.03 mg/kg bw; overall, clinical signs were observed from 0.3 mg/kg bw onwards (UNEP/FAO/RC/CRC.11-INF-11.En, EFSA, 2009, p4).

Canada

Although no guideline acute neurotoxicity study was available, two published studies highlighted the short-acting effects typically associated with carbamate inhibitors of cholinesterase.
Subchronic neurotoxicity studies (dietary) showed clinical signs, decreased motor activity and altered neurological functioning but lacked cholinesterase measurements. Results from the chronic rat study suggest that cholinesterase inhibition was occurring at the levels causing the neurological impairment. In a developmental neurotoxicity study (dietary), doses high enough to cause neonatal death, marked growth retardation and developmental delays did not cause persistent neurological effects. No evidence of neuropathology was noted in any of the available studies (UNEP/FAO/RC/CRC.11-INF-12.En, Health Canada, 2009, p12).

2.2.7 Summary of mammalian toxicity and overall evaluation

European Union

Carbofuran is rapidly and completely absorbed and excreted in the rat. It is very toxic by ingestion (LD_{50} 7 mg/kg bw) and by inhalation (LC_{50} 0.05 mg/L) whereas toxicity during dermal exposure is moderate (LD_{50} 1000-2000 mg/kg bw). Carbofuran is not a skin irritant, eye irritant, or skin sensitizer, but mortality was reported after exposure to eyes.

It is genotoxic *in vitro* but negative in *in vivo* studies. The relevant long term NOAEL is 0.462 mg/kg bw/day from the rat study.
At the occasion of the resubmission of carbofuran, new sets of acute neurotoxicity studies were assessed. No NOAEL could be established in pups at post-natal day 11 (PND11) based on a significant inhibition of the brain acetylcholinesterase, the low-observed-adverse-effect-level (LOAEL) was 0.03 mg/kg bw. In young adult rats, the NOAEL was 0.03 mg/kg bw; overall, clinical signs were observed from 0.3 mg/kg bw onwards (UNEP/FAO/RC/CRC.11-INF-11.En, EFSA, 2009).

Canada

A detailed review of the toxicological database for carbofuran was conducted. The toxicology database for carbofuran is primarily based on studies from the registrant. Carbofuran was rapidly absorbed, metabolized and eliminated mainly in the urine after oral administration to mice and rats. Most metabolites were found to be significantly less toxic than the parent compound in acute oral lethality tests. One metabolite, 3-hydroxycarbofuran, showed similar acute oral toxicity as carbofuran.

In acute toxicity studies, carbofuran was highly toxic via the oral route of exposure in rats but showed low dermal toxicity. Acute inhalation studies were not available. Carbofuran was a minimal eye irritant and was not a dermal sensitizer.

In repeat-dose dietary studies in various species (mouse, rat and dog), the dog appeared to be the most sensitive species with respect to cholinergic symptoms. Repeat-dose dietary studies in the rat and dog did not indicate that an increase in the duration of dosing resulted in increased toxicity with respect to cholinesterase activity and/or effects.

Although no guideline acute neurotoxicity study was available, two published studies highlighted the short-acting effects typically associated with carbamate inhibitors of cholinesterase.

Subchronic neurotoxicity studies (dietary) showed clinical signs, decreased motor activity and altered neurological functioning but lacked cholinesterase measurements. Results from the chronic rat study suggest that cholinesterase inhibition was occurring at the levels causing the neurological impairment. In a developmental neurotoxicity study (dietary), doses high enough to cause neonatal death, marked growth retardation and developmental delays did not cause persistent neurological effects. No evidence of neuropathology was noted in any

of the available studies.

There is sufficient evidence to support weak mutagenic properties for carbofuran in bacteria and mammalian cells.

Studies for chronic toxicity/carcinogenicity were conducted on mice and rats. In all studies reviewed, there was no evidence of carcinogenicity.

In view of the findings in the rat, rabbit and dog, carbofuran should be viewed as having some potential for reproductive toxicity (UNEP/FAO/RC/CRC.11-INF-12.En, Health Canada (2009), pp11-13).

CILSS countries

Toxicological data

Acute toxicity - Carbofuran belongs to WHO class Ib (highly hazardous). Some formulations belong to class I (highly hazardous or extremely hazardous) or to class II (moderately hazardous). It is extremely toxic via oral route and by inhalation (LD_{50} is 5 to 13 mg/kg in rats, 2 mg/kg in mice). Dermal toxicity is low. It is minimally irritating to the eyes and to the skin. It is not a skin sensitizer. It is neurotoxic being a cholinesterase inhibitor. This is of short duration and reversible. It is a strong endocrine disruptor which may affect the concentration of several human and animal hormones even at very low doses. The exposure to carbofuran is presents a risk for the population, children and infants even if used normally. The antidote to carbofuran is atropine.

Chronic toxicity - Carcinogenic, teratogenic and mutagenic effects - Carbofuran is not known to have carcinogenic effects. It has not been demonstrated that carbofuran is teratogenic or mutagenic, either.

Reproductive and development effects - Sub-chronic administration of carbofuran to rats may be toxic to sperm and testicles. Prolonged or repeated exposure to carbofuran may cause the same effects as an acute exposure. It has not been demonstrated that carbofuran can cause reproductive effects to humans and animals at expected exposure levels.

The Decision Guidance Document for dustable powder formulations containing a combination of benomyl at or above 7%, carbofuran at or above 10% and thiram at or above 15%, FAO/UNEP (2004/2005) contains the FAO/WHO Data Sheets on Pesticides No 56 Carbofuran as an Annex which also contains a more extensive summary on human and mammalian toxicology (UNEP/FAO/RC/CRC.11-INF-13.En, SPC (2012).

Residues

From the available data it can be concluded that the degradation and metabolism of carbofuran in plants following a soil application proceeds primarily via hydroxylation on the furan ring to yield the major metabolite 3-hydroxycarbofuran, which forms due to successive oxidation and hydrolysis steps 3- ketocarbofuran, 2-hydroxymethyl-3-ketocarbofuran and the phenol metabolites 3-OH-7-phenol and 3-keto-7-phenol. The first two metabolites were considered as toxicologically relevant but the others are of lower toxicity than carbofuran and 3-hydroxycarbofuran. It is proposed to define the residue for risk assessment purposes as the sum of carbofuran and 3-hydroxycarbofuran, expressed as carbofuran (soil applied uses). Residue trial data with carbofuran under field conditions from both European regions were submitted by both applicants on sugar beet and maize, and on sunflowers. The data indicate residues being below the respective LOQ for both analytes in maize grain. In maize silage positive residues (0.03 mg/kg) were found in Northern and Southern European trials. Taking all the available results on sugar beets from both applicants together (complete data set), it was considered a

'low residue' situation as opposed to a 'no residue' situation in sugar beet (UNEP/FAO/RC/CRC.11-INF-11.En, EFSA, 2006).

3 Human exposure/Risk evaluation

3.1 Food

European Union

Due to the data gaps identified the consumer risk assessment could not be finalized. Though the RMS had provided a comprehensive dietary exposure and risk assessment for consumers using both the EFSA PRIMo and the UK model. The sum of intakes of carbofuran and 3-hydroxycarbofuran from the primary crop, rotational crops and food of animal origin was considered and compared to the toxicological reference values for carbofuran (ADI and ARfD, both 0.00015 mg/kg bw /day). This approach was deemed to be appropriate as the metabolite 3-hydroxycarbofuran is assumed to be of comparable toxicity as carbofuran based on acute toxicity studies.

An exceedance of the ADI was noted for UK toddlers in both models (EFSA PRIMo 173% ADI; UK model 101% ADI). The risk assessment could be further refined when residues in sugar are not considered at the level of the LOQ of the analytical method for sugar beet, but at a level of 0 mg/kg.

However, the acute consumer risk assessment indicates the ARfD is significantly exceeded for a number of crops consumed by children and by adults/the general population. A great exceedance of the ARfD was observed for leafy (up to 1800% ARfD) and root/tuber crops (up to 615% ARfD). These results highlight the importance of residue data on succeeding crops to enable further refinement of the dietary risk assessment for consumers (UNEP/FAO/RC/CRC.11-INF-11.En, EFSA (2009), pp37-38).

Canada

Acute dietary risk from food-only exposure to carbofuran is of concern for all subpopulations. Chronic dietary risk from food-only exposure to carbofuran is not of concern for all subpopulations (UNEP/FAO/RC/CRC.11-INF-12.En, Health Canada, 2009).

Acute dietary exposure to carbofuran as a percentage of the acute reference dose ranges from 141% for adults aged 50+ years old to 733% for children aged 1 to 2 years old, and is 339% for the general population. The acute dietary exposure to carbofuran is higher than the acute reference dose for all population subgroups; therefore, it is of concern. Chronic dietary exposure to carbofuran as a percentage of the acceptable daily intake ranges from 19% for adults aged 50+ years old to 76% for children aged 1 to 2 years old, and is 30% for the general population. The chronic dietary exposure to carbofuran is less than the acceptable daily intake for all population subgroups; therefore, it is not of concern (UNEP/FAO/RC/CRC.11-INF-12.En, Health Canada, 2010).

3.2 Air

The general population is not expected to be exposed to carbofuran via air as carbofuran is not very stable in air.

3.3 Water

European Union

In the consumer risk assessment performed by the rapporteur Member State the possible intake of carbofuran through drinking water derived from groundwater had not been considered. EFSA noted that significant contribution to the acute and chronic exposure might be expected if any restrictions that might be considered were not effective. To assess this situation EFSA estimated consumer exposure (not peer reviewed) with regard to carbofuran residues in ground water used as drinking water on the basis of the predicted PEC groundwater levels (annual average, based on the model FOCUS PEARL) in order to reflect the worst case. The estimates were based on the default assumptions laid down in the WHO Guidelines for drinking water quality for the consumer groups of adults (weighing 60 kg), toddlers

(10 kg) and bottle-fed infants (5 kg) with a daily per capita consumption of 2 L, 1 L and 0.75 L, respectively.

It is further noted that the toxicological reference values of carbofuran are also applicable to the metabolites 3-hydroxycarbofuran and 3-ketocarbofuran. Therefore the sum of all 3 compounds leaching into groundwater was expressed as carbofuran equivalents and considered in the consumer risk assessment.

The predicted concentrations of carbofuran toxicological equivalents in the most vulnerable scenarios may lead to the exceedance of the toxicological reference values ADI and ARfD for toddlers and infants. In terms of the acute assessment it is noted that the daily consumption figures used might rather reflect a mean consumption than a high consumption that is normally considered for acute intake estimates, and thus the actual acute consumer exposure (single day event) might be even higher than estimated (UNEP/FAO/RC/CRC.11-INF-11.En, EFSA (2009), pp38-39).

Canada

The following was concluded in relation to dietary risk from drinking water. Since acute dietary exposure exceeds the ARfD for food alone, there is concern about any additional exposure through drinking water.

Health Canada (2010), p4 notes that an aggregate risk assessment combining exposure from food and drinking water was conducted using either estimated environmental concentrations (EECs) from the modelling assessment or EECs from monitoring data. The dietary risks from food and drinking water are of concern whether EECs from modelling or monitoring data are used (UNEP/FAO/RC/CRC.11-INF-11.En, Health Canada (2009), p37).

3.4 Occupational exposure

European Union

The acceptable operator exposure level (AOEL) is 0.0003 mg/kg bw/day, based on the NOAEL of 0.03 mg/kg bw in young adults from the acute neurotoxicity studies and a safety factor of 100 applied. For granular formulations the estimated operator exposure according to the US Pesticide Handler's Exposure Database (PHED) is below the AOEL i.e. 95 % if personal protective equipment (PPE) as gloves, normal work wear and respiratory protective equipment (RPE) are worn during loading and spreading of the product and assuming an application rate of 0.6 kg carbofuran/ha and a maximum work rate of 10 ha/day. Worker exposure is unlikely to occur, as the formulation is incorporated by mechanical means into the soil when sowing (UNEP/FAO/RC/CRC.11-INF-11.En, EFSA (2009), p4).

Canada

The following was concluded in relation to Occupational Risk. Risk estimates associated with applying, mixing and loading activities for certain proposed agricultural label uses are of concern even when engineering controls or personal protective equipment are used. Post-application risks for workers were of concern for certain scenarios; mitigation measures that would diminish the risk were considered, however, the mitigation measures calculated to reduce post-application risk may be agronomically unfeasible (UNEP/FAO/RC/CRC.11-INF-11.En, Health Canada (2009), p37).

Risk estimates associated with certain mixing, loading and applying activities are of concern to the PMRA. Based on the precautions and directions for use on the existing carbofuran product labels, post-application risks to workers performing activities, such as thinning, pruning and harvesting of most crops, did not meet current standards and are also of concern (UNEP/FAO/RC/CRC.11-INF-11.En, Health Canada (2009), p5).

3.5	**Medical data contributing to regulatory decision**	**European Union** A low number of carbofuran intoxications have been reported. The majority of the incidents resulted from maintenance or equipment cleaning work. Under normal work conditions, employees wear rubber gloves, long sleeve shirts, eye protection and head covering (UNEP/FAO/RC/CRC.11-INF-11.En, EFSA (2009), p4). **Canada** Starting April 26, 2007, registrants are required by law to report incidents, including adverse effects to health and the environment, to the PMRA within a set time frame. There was one incident report related to human health that was submitted to the PMRA for carbofuran. The report indicates that the protective clothing required by carbofuran labels for the use was not worn during spraying. The individual was treated and released from hospital. No other incidents involving human health have been reported to the PMRA as of 29 September 2008 (UNEP/FAO/RC/CRC.11-INF-12.En, Health Canada (2009), p20). However, in the United States, in 2007 the USEPA published that more than 700 possible carbofuran poisoning incidents were reported. In most cases, symptoms for carbofuran incidents were specific to cholinergic poisoning and most resulted from dermal and inhalation exposure, rather than oral exposure, and the majority of illnesses were of a systemic type. Eye problems were also widely reported, accounting for approximately one quarter of all recorded incidents. Causes of these incidents included: failure to wear appropriate personal protective equipment, exposure during cleaning or repair of spray equipment, spray drift or early entry into treated fields. The majority of incidents occurred among handlers who mix, load, and apply carbofuran in agricultural fields. The USEPA concluded that the number and rate of poisoning cases due to carbofuran exposure is sufficient to warrant priority attention to risk reduction measures for this pesticide (UNEP/FAO/RC/CRC.11-INF-12.En, Health Canada (2009), p20-21). **CILSS countries** 2342 cases of carbofuran poisoning have been reported in farmers in Thailand in 2003. Carbofuran caused farmers' skin and eye burns strongly affecting their health. The long term effects may cause permanent damage to the nervous system (UNEP/FAO/RC/CRC.11/6 under Acute toxicity).
3.6	**Public exposure**	**European Union** The granular formulation is applied by ground-directed equipment that is nearly dust free; therefore, the level of bystander exposure to vapour or airborne particles at the time of application is likely to be negligible (UNEP/FAO/RC/CRC.11-INF-11.En, EFSA (2009). **Canada** The following was concluded in relation to Non-Occupational Risk. Given that there are no residential uses of carbofuran, a risk assessment for this scenario was not conducted. UNEP/FAO/RC/CRC.11-INF-11.En, Health Canada (2009), p37
3.7	**Summary-overall risk evaluation**	**European Union** It was concluded that carbofuran was not demonstrated to fulfil the safety requirements laid down in Article 5 (1) (a) and (b) of Directive 91/414/EEC (replaced by Regulation (EC) 1107/2009). The consumer risk assessment, which raised a concern about the acute exposure of vulnerable groups of consumers, in particular children, could not be finalised due to the lack of information as regards certain relevant residues.

Canada

Health Canada concluded that an evaluation of available scientific information found that, under the then-current conditions of use, carbofuran products posed an unacceptable risk to human health and the environment and therefore did not meet Health Canada's standards for human health and environmental protection. As a result, all uses of carbofuran were proposed for phase-out. This included registered uses on canola, mustard, sunflower, corn (sweet, field and silage), sugar beet, green pepper, potato, raspberry and strawberry as well as temporary emergency uses on turnip and rutabaga. The proposal affected all end-use products registered in Canada that contained carbofuran (UNEP/FAO/RC/CRC.11-INF-12.En, Health Canada 2009 and 2010).

CILSS countries

Carbofuran presents risks to human health and especially to non-target organisms in the environment, making it very difficult to handle it without risks for users in Sahel countries. These risks have justified its ban in many countries of the world among which all the European Union countries. The Sahelian Pesticides Committee has stopped the registration of carbofuran based pesticides in CILSS countries since 2006 taking into account:

- The fragile ecology of CILSS countries already characterized by an imbalance of ecosystems and the disappearance of organisms useful to the environment;
- Non-compliance with recommended measures for a safe use of carbofuran by users in the context of CILSS countries;
- Non-compliance with the pre-harvest intervals (PHI) in particular, entailing the presence of pesticide residues in harvested foodstuff;
- The low utilization rate of protective equipment by growers :
- The existence of alternatives to the use of carbofuran.

The Coordinating Ministry of CILSS Countries issued this ban to make public the decision to ban carbofuran based pesticides, and this in a transparent way, in order to improve human health and to preserve the environment in these countries (UNEP/FAO/RC/CRC.11-INF-13.En, Sahelian notification SPC 2012).

4 Environmental fate and effects

4.1 Fate

4.1.1 Soil

European Union

Variable results have been obtained from different laboratory degradation experiments, which indicate that carbofuran may be of low to high persistency in soil (lab DT_{50} = 5.7 - 387 days, field DT_{50} = 1.3 - 27 days).

Field studies have indicated that 3-hydroxycarbofuran, 3-keto-carbofuran and carbofuran-7-phenol are formed, with some levels being reported as 3% of the total residue (TR), 20% TR and <LOD, respectively. EU field trials have indicated that the half-life of carbofuran (as a metabolite of carbosulfan) is 1.3 - 27 days. However, US field studies (at a similar climate compared to the EU) indicate that the half-life for carbofuran as the parent compound is 5-121 days. Only the EU studies were considered applicable.

A 56 day laboratory study under dark aerobic conditions at 20°C and 10°C examined the metabolism of carbofuran in four soils. No metabolites over 10% AR were detected in the study performed at 20°C, however, at 10°C 3-ketocarbofuran reached a 7.7% AR. Minor

uncharacterised metabolites were detected at <2.5% AR, unextractable residue was up to 57.7% and mineralisation was 66% AR after 120 days. A second study under dark aerobic conditions at 25°C used a sandy loam soil. 3-ketocarbofuran peaked at 12.41 % AR after 181 days, with minor metabolites being 3-hydroxycarbofuran (maximum 1.32% after 122 days), 3-keto-7 -phenol and carbofuran-7 -phenol. Another aerobic metabolism study reported that 3-hydroxycarbofuran and carbofuran-7-phenol reached maximums of 0.9% AR and 9% AR, respectively, after 184 days.

The same metabolites were also detected in an aerobic/anaerobic study; after the aerobic phase, 3-ketocarbofuran reached a maximum of 6.2% AR. An anaerobic soil study under dark conditions at 20°C found that after 28 days, carbofuran-7-phenol was the major metabolite at a maximum of 62.9% AR and other minor unspecified metabolites were reported. After 120 days, mineralisation was low (CO_2 6.2% AR) and bound residues reached a maximum of 62.7% AR.

Although conflicting results regarding photolysis have been reported, it is concluded that photolysis in soil does not occur (as study limitations are reported for the results of the conflicting study).

Based on a Koc of 17-28 mL/g, carbofuran is classified as being of very high mobility in soil. Additionally, an aged column leaching study reports that carbofuran, 3-ketocarbofuran and carbofuran-7-phenol are mobile and may leach (UNEP/FAO/RC/CRC.11-INF-11.En, EFSA, 2006, pp3-4 and pp26-28).

Canada

Carbofuran is classified as relatively non-volatile under field conditions. Phototransformation is not an important route of transformation for carbofuran in soil.

Transformation of carbofuran in aerobic soil appears to have resulted from a combination of hydrolysis and biotransformation. In an acidic soil (pH 5.7), carbofuran degraded with a half-life of 321 days, but in soil of pH 7.7, the half-life dropped to 149 days. The major identified transformation product was 3- ketocarbofuran. The persistence of carbofuran may decrease in soils that have been previously treated with carbofuran because of microbial adaptations.

No information was available addressing the soil biotransformation of carbofuran under anaerobic conditions.

Soil adsorption studies indicate that carbofuran has a high to very high mobility in soils. Koc values ranged from 10 to 63 in a variety of soils. Carbofuran was shown to be mobile in soil column leaching studies with 33 to 78% of the radioactivity in the aged soils collected in the leachate. Carbofuran was the major extractable residue in both the aged soils and the leachate.

Carbofuran would be considered non-persistent to moderately persistent from field soil dissipation studies conducted in the U.S. according to the classification of Goring et al. (1975) (UNEP/FAO/RC/CRC.11-INF-12.En, Health Canada, 2009, p. 21-22).

Table 1 of Appendix IX, in Health Canada (2009, p. 71-72) contains a detailed table of environmental fate and toxicity data.

CILSS countries

The GUS (groundwater ubiquity score) of carbofuran is 3.02, which represents a high risk of ground water pollution through leaching.

Carbofuran is soluble in water and has a high to very high mobility in sandy and loamy soil and a moderate mobility in clay soil.

Photolysis half-life in soil is 78 days. It is very persistent in soil in aerobic conditions. Its half-life varies according to soil pH

(half-life=149 d at pH 7.7, and half-life = 321 d at pH 5.7).

Carbofuran degrades fairly slowly in non-sterile, neutral or acid aerobic soils, with half-lives ranging from 1 to 8 weeks. It is more stable in sterile soils and instable in alkaline conditions. Under anaerobic conditions, carbofuran may take twice as long to degrade (UNEP/FAO/RC/CRC.11-INF-13.En, SPC 2012).

4.1.2 Water

European Union

In water, hydrolysis of carbofuran is extremely dependent on pH; half-lives of none, 28-45.7 days and 0.1 days were observed under acidic (pH 4), neutral (pH 7) and alkaline (pH 9) conditions, respectively, at 25°C. In all cases, the major metabolite was carbofuran-7-phenol.

Photolysis does not significantly occur and no indication of ready biodegradation is apparent.

A 102 day water sediment dissipation study showed that under acidic conditions, degradation of carbofuran occurred with a half-life of 70 days, 32.8% AR occurred as bound residues and mineralisation was low. Half-lives of 6.9 - 8.5 days in the water phase were reported from dark aerobic systems under neutral or alkaline conditions, with half-lives of 9.0 - 11.6 days being reported for degradation in the whole system. Carbofuran-7-phenol (maximum 12% AR after 4 days) was the only major metabolite in the water phase and in the sediment, only carbofuran exceeded levels of 10% AR. Minor unspecified metabolites were identified (max. 5.9% AR). The maximum amount of bound residues at the end of the study (after 120 days) was 74-78% AR (UNEP/FAO/RC/CRC.11-INF-11.En, EFSA (2006), p. 4-5 and 28-29).

Canada

The reported solubility of carbofuran in water (700 mg/L at 25°C), would classify it as very soluble.

Carbofuran is stable to hydrolysis at pHs < 6, but becomes increasingly susceptible to hydrolysis as the pH increases, hydrolyzing rapidly at alkaline pHs (half-lives of less than a day).

Phototransformation is an important route of transformation for carbofuran in shallow clear water. Biotransformation was an important route of transformation in aquatic habitats under aerobic conditions. The major transformation product formed in aquatic systems was carbofuran phenol. Biotransformation was also a route of transformation in aquatic systems under anaerobic conditions, however degradation may not have been due strictly to anaerobic metabolic processes, hydrolysis may have also contributed. The major transformation product was carbofuran phenol and was predominantly associated with the sediment fraction.

In alkaline environments, carbofuran appears to have a low potential to accumulate in fish (UNEP/FAO/RC/CRC.11-INF-12.En, Health Canada, 2009, p. 22).

Table 1 of Appendix IX, in Health Canada (2009, p. 71-72) contains a detailed table of environmental fate and toxicity data.

CILSS countries

Carbofuran is also very persistent in water in anaerobic conditions where its half-life is 189 days. Because of its high mobility, carbofuran presents a risk of surface water pollution in sandy areas. This pesticide has been detected in surface waters in a few rivers in Quebec at maximum concentrations ranging from 0.14 to 2.7 ppb. Following its percolation into the soil, carbofuran leaches into soil and has been detected in ground waters after it had been used in agriculture (UNEP/FAO/RC/CRC.11-INF-13.En, SPC 2012).

4.1.3 Air

European Union

In air, long range transport of carbofuran is not expected. At environmental temperatures (20-25°C), carbofuran has a vapour pressure of 1 $x10^{-5}$ - 2.25 $x10^{-4}$Pa, a Henry's Law constant of 5 $x10^{-5}$ - 1.58 $x10^{-4}$ $Pa.m^3$/mol and a photochemical degradation half-life of <5 hours (UNEP/FAO/RC/CRC.11-INF-11.En, EFSA, 2006, p30).

CILSS countries

Carbofuran exists in the air both in the form of vapour and absorbed to suspended particulates (UNEP/FAO/RC/CRC.11-INF-13.En, SPC 2012).

4.1.4 Bioconcentration

European Union

Bioaccumulation: Maximum BCFs for carbofuran have been reported to be 3.8 (fillet), 22 (viscera) and 12 (whole fish), which indicate it is unlikely to bioaccumulate. This is supported by the rapid clearance time CT_{50} (1.4 days). Indeed, the level of residues in organisms after the 14 day depuration phase is <5% (whole fish) (UNEP/FAO/RC/CRC.11/6).

4.1.5 Persistence

Based on the above summaries carbofuran may range from low to high persistence in soil and in water with the latter depending on the pH, with much slower degradation at acidic pH.

4.2 Effects on non-target organisms

4.2.1 Terrestrial vertebrates

Birds

European Union

Acute toxicity: LD_{50} Mallard (*Anas platyrhynchos*, male) = 0.71 mg a.i./kg b.w.

Dietary toxicity: LC_{50} Mallard (*Anas platyrhynchos*) = 1.6 mg a.i./kg b.w./day

Reproductive toxicity: No agreed endpoint

(UNEP/FAO/RC/CRC.11-INF-11.En, EFSA (2006), Appendix 1.6, p82)

Canada

Acute oral toxicity (Carbofuran technical):
Fulvous Whistling-Duck (*Dendrocygna bicolor*) LD_{50} = 0.24 mg a.i./kg bw
Mallard (*Anas platyrhynchos*) LD_{50} = 0.37 - 0.63 mg a.i./kg bw
Red-winged Blackbird (*Agelaius phoeniceus*) LD_{50} = 0.42 mg a.i./kg bw
Red-billed Quelea (*Quelea quelea*) LD_{50} = 0.422-0.562 mg a.i./kg bw
Americal Kestrel (*Falco sparverius*) LD_{50} = 0.6 mg a.i./kg bw
House Finch (*Carpodacus mexicanus*) LD_{50} = 0.75 mg a.i./kg bw
House Sparrow (*Passer domesticus*) LD_{50} = 1.33 mg a.i./kg bw
Rock Dove (*Columba livia*) LD_{50} = 1.33 mg a.i./kg bw
Brown-headed Cowbird (*Molothrus ater*) LD_{50} = 1.33 mg a.i./kg bw
Common Grackle (*Quiscalus quiscula*) LD_{50} = 1.33 - 3.16 mg a.i./kg bw
Japanese Quail (*Cotumix coturnix*) LD_{50} = 1.7- 1.9 mg a.i./kg bw
Eastern Screech-Owl (*Otus asio*) LD_{50}= 1.9 mg a.i./kg bw
Ring-necked Pheasant (*Phasianus colchicus*) LD_{50} = 4.2 mg a.i./kg bw
Northern Bobwhite (*Colinus virginianus*) LD_{50} = 5.0 - 12 mg a.i./kg bw
European Starling (*Sturnus vulgaris*) LD_{50} = 5.6 mg a.i./kg bw
Dietary: Mallard duck (*Anas platyrhynchos*) LD_{50} = 79 mg a.i./kg diet
Chronic: Mallard duck (*Anas platyrhynchos*) LOAEC < 2.0 mg a.i./kg diet
(UNEP/FAO/RC/CRC.11-INF-12.En, Health Canada (2009), Appendix IX, Table 2, pp73-76).

CILSS countries

Several sources agree that carbofuran is highly toxic to birds. One single grain may kill a bird (LD_{50} oral of 0.4 mg/kg body weight) (UNEP/FAO/RC/CRC.11-INF-13.En, SPC 2012).

4.2.2 Aquatic species

European Union

The data below are for the most sensitive species from each group:

Fish

Bluegill sunfish *(Lepomis macrochirus)* 96 hours semi-static LC_{50} = 0.18 mg/L Sheepshead minnow *(Cyprinodon variegatus)* 35 day fish early life stage NOEL = 0.006 mg/L

Invertebrates

Water flea *(Daphnia magna)* 48 hours static EC_{50} (mortality) = 0.0094 mg/L

Water flea *(Daphnia magna)* 21 days semi-static NOEC (reproduction) = 0.008 mg/L

Water flea *(Ceriodaphnia dubia)* 7 days semi-static NOEC (reproduction) = 0.00016 mg/L

Scud *(Gammarus fasciatus)* 96 hours static LC_{50} = 0.0028 mg/L

Algae (note *Selenastrum capricornutum* is now called *Pseudokirchneriella subcapitata*).

Green algae *(Pseudokirchneriella subcapitata)* 72 hours static EbC_{50} (biomass) = 6.5 mg/L

Green algae *(Pseudokirchneriella subcapitata)* 72 hours static ErC_{50} (growth) = 19 mg/L

(UNEP/FAO/RC/CRC.11-INF-11.En, EFSA (2006), Appendix 1.6, p83)

Canada

Fish (freshwater, carbofuran technical)

Acute: Bluegill sunfish (*Lepomis macrochirus*) 96 h LC_{50} = 88 µg a.i./L

Yellow perch (*Perca flavescens*) 96 h LC_{50} = 120 µg a.i./L

Lake trout (*Salvelinus namaycush*) 96 h LC_{50} = 164 µg a.i./L

Channel catfish (*Ictalurus punctatus*) 96 h LC_{50} = 248 µg a.i./L

Brown trout (*Salmo trutta*) 96 h LC_{50} = 280 µg a.i./L

Rainbow trout (*Oncorhynchus mykiss*) 96 h LC_{50} = 362 µg a.i./L

Coho salmon (*Oncorhynchus kisutch*) 96 h LC_{50} = 530 µg a.i./L

Fathead minnow (*Pimephales promelas*) 96-h LC_{50} = 872 µg a.i./L

Chronic (Early Life Stage): Rainbow trout (*Oncorhynchus mykiss* 101-d NOEC = 24.8 µg a.i./L

Fish (salt water, carbofuran technical**)**

Acute: Atlantic silverside (*Menidia menidia*) juvenile) 96 h LC_{50} = 33 µg a.i./L

Longnose killifish (*Fundulus similis*) 96 h LC_{50} > 100 µg a.i./L

Sheepshead minnow (*Cyprinodon variegatus*)) 96 h LC_{50} = 386 µg a.i./L

Chronic: Sheepshead minnow (*Cyprinodon variegatus*) 35 d NOEC = 2.6 µg a.i./L

Amphibians (Acute formulation)

Bog Frog (*Rana limnocharis*) 48 h LC_{50} = 11,226 µg a.i./L

Aquatic invertebrates (freshwater, carbofuran technical)

Acute: Water flea (*Daphnia magna*) 48 h LC_{50} = 29 µg a.i./L

Water flea (*Ceriodaphnia dubia*) 48 h LC_{50} = 2.6 µg a.i./L

Crayfish (*Procambarus clarkii*) 48 h LC_{50} = 2700 µg a.i./L

Chronic water flea (*Daphnia magna*) 21 d NOEC 9.8 µg a.i./L

Aquatic Invertebrates (saltwater , carbofuran technical)

Acute: Eastern oyster (*Crassostrea virginica*) 96 h LC_{50} > 1000 µg a.i./L

Pink shrimp *(Penaeus duorarum)* 96 h LC_{50} = 7.3 µg a.i./L

Opossum shrimp (*Neonysis mercedis*) 96 h LC_{50} = 2.7 µg a.i./L

Copepod (*Tigriopus brevicornis*) 96 h LC_{50} = 17.7 µg a.i./L

Chronic: Mysid shrimp (*Mysidopsis bahia*) 28-d NOEC = 0.4 µg a.i./L

Algae (Chronic)

Green algae (*Chlorella pyrenoidosa*) 75% a.i. 8-10 week NOEC = 750 µg a.i./L
Vascular Plants (Acute, 40.6% a.i.)
Duckweed (*Lemna minor*) 48 h NOEC > 10,000 µg a.i./L
Sago pondweed (*Potamogeton pectinatus*) 48 h NOEC > 10,000 µg a.i./L
(UNEP/FAO/RC/CRC.11-INF-12.En, Health Canada (2009), Appendix IX, Table 2, pp73-76).

CILSS countries
Carbofuran is moderately to high toxic to freshwater fish (LC_{50} 96 h = 88 at 1 990 ppb). It is extremely toxic to *Daphnia magna*, LC_{50} is 0.015 mg/L, on algae LC_{50} is 19.9 mg/L
(UNEP/FAO/RC/CRC.11-INF-13.En, SPC 2012).

4.2.3 Honeybees and other arthropods

European Union
Honeybees
Acute oral toxicity: No data.
Honeybees, acute contact toxicity: LD_{50} (48 h) = 0.0357 µg a.i./bee
Arthropod species
Ground beetle *(Poecilus cupreus)*, adults Diafuran 5G 12 kg/ha = 20% mortality
Beetle *(Aleochara bilineata)*, adult females Diafuran 5G 12 kg/ha = 100% mortality
Beetle *(Aleochara bilineata)*, adults Diafuran 5G 12 kg/ha = 4.5% mortality & 60.4% reduction in parasitism rate
Beetle *(Aleochara bilineata)*, adults Furadan 5G 1-10 kg/ha (extended test) LD_{50} = 3.58 g/ha
Thin legged wolf spiders *(Pardosa* sp.), adults and sub-adults Diafuran 5G 12 kg/ha = 100% mortality.
Thin legged wolf spiders *(Pardosa* sp.), adults and sub-adults Diafuran 5G 12 kg/ha = 13.3% mortality & 5.2% increase in food consumption
Thin legged wolf spiders *(Pardosa* sp.), adults and sub-adults Furadan 5G 3.2-32 kg/ha (extended test) LD_{50} = 2.7 kg/ha
Predatory mite *(Typhlodromus pyri)*, protonymphs carbofuran 1.8-18 g/ha (extended test) LD_{50} = 3.65 g/ha
Cereal aphid parasite *(Aphidius rhopalosiphi)*, adults carbofuran 1-32 g/ha (extended test) LD_{50} = 2.68 g/ha.
(UNEP/FAO/RC/CRC.11-INF-11.En, EFSA (2006), Appendix 1.6, p83-84).

Canada
Acute contact Honey bee (*Apis mellifera*) Carbofuran Technical 48 h LD_{50} = 0.16 µg a.i./bee
(UNEP/FAO/RC/CRC.11-INF-12.En, Health Canada (2009), Appendix IX, Table 2, pp73-76).

CILSS countries
Carbofuran is extremely toxic to bees, with LD_{50} acute by contact of 0.16 µg/bee.
(UNEP/FAO/RC/CRC.11-INF-13.En, SPC 2012).

4.2.4 Earthworms

European Union
Earthworm:
Acute toxicity LC_{50} = 4487 mg Diafuran 5G/kg dry soil
LC_{50} > 1000 mg Furadan 5G/kg dry soil
Reproductive toxicity NOEC <16.8 mg Diafuran 5G/kg dry soil
(UNEP/FAO/RC/CRC.11-INF-11.En, EFSA (2006), Appendix 1.6, p84-85).

Canada
Earthworm (*Allolobophora caliginosa*) 14 d LC_{50} = 0.28 mg a.i./kg soil
Earthworm (*Eisenia foetida*) 14 d LC_{50} = 3.09 - 28.3 mg a.i./kg soil
Earthworm (*Lumbricus terrestris*) 14 d LC_{50} = 4.7 mg a.i./kg soil

(UNEP/FAO/RC/CRC.11-INF-12.En, Health Canada (2009), Appendix IX, Table 2, pp73-76).

4.2.5	**Soil microorganisms**	**<u>European Union</u>** **Nitrogen mineralisation:** No adverse effects of Furadan 5G at 0.8 and 4 mg carbofuran/kg soil after 28 days **Carbon mineralisation**: No adverse effects of Furadan 5G at 0.8 and 4 mg carbofuran/kg soil after 28 days (UNEP/FAO/RC/CRC.11-INF-11.En, EFSA (2006), Appendix 1.6, p86).
4.2.6	**Terrestrial plants**	No non-target plant toxicity data was provided in the EU, Canadian and Sahelian notifications.

5 Environmental Exposure/Risk Evaluation

5.1	**Terrestrial vertebrates**	**<u>European Union</u>** A risk assessment for birds and mammals was conducted based on a granule size of 0.4-0.85 mm and an average weight of 0.87 mg. The loading of one granule was assumed to be 0.0437 mg a.i./granule. The number of granules to reach the acute and dietary LD_{50} was calculated to be 0.2 and 0.5 granules for a 15 g bird, indicating a potential high risk to birds. A high risk to birds was identified in the first-tier risk assessment for the uptake of contaminated food items (sugar beet seedlings, earthworms and arthropods). Reduced fraction of food type in diet and fraction of diet obtained in treated area value were suggested in the refined risk assessment together with measured residues in food items. However, a higher tier risk assessment could not be completed due to data deficiencies in the residue trials conducted on these food items. No long-term reproductive NOEL could be derived from the reproduction study because parental mortality was observed even at the lowest tested dose. It was not clear if the effects of carbofuran are only acute effects The number of granules to reach the acute LD_{50} and the long-term NOAEL was calculated to be 1.82 for a small mammal of 15 g indicating a potential high acute risk to mammals. A risk assessment for unintentional uptake of granules conducted according to the European and Mediterranean Plant Protection Organization (EPPO) scheme resulted in an acceptable risk to mammals. The refined risk assessment was based on measured residues in sugar beet seedlings, earthworms and arthropods, but the residue values were not accepted to be used in the risk assessment (see discussion above for birds). Further refinements were also judged to be not acceptable. A risk assessment for birds and mammals for the uptake of contaminated drinking water was also available. The resulting acute TER for small granivorous mammals was 20 but the acute TER for birds was significantly below the trigger of 10, suggesting a potential risk only for the latter. However, it was noted that a high risk could prevail for situations where puddles are formed at locations where high numbers of granules are left on the soil surface (e.g. end of row) (UNEP/FAO/RC/CRC.11-INF-11.En, edited version of the summary of the environmental risk assessment contained in EFSA (2009), Section 5.1 Effects on Terrestrial Vertebrates, pp 50-53). **<u>Canada</u>** A risk assessment of carbofuran to terrestrial organisms was based upon an evaluation of toxicity data for fifteen bird and one mammal species representing vertebrates (acute, dietary, reproduction exposure). For the assessment of risk, toxicity endpoints chosen from the most sensitive species were used as surrogates for the wide range of species that can be potentially exposed following treatment with

carbofuran. The risk assessment for birds did not include a screening level risk assessment but instead used the conclusions of a special review conducted in Canada and the results of a refined probabilistic risk assessment conducted by the USEPA, since the label rates used for the USEPA risk assessment were similar to Canadian label rates.

The conclusions of the USEPA risk assessment and Canadian special review for flowable carbofuran were that evidence from field studies and incident reports support the modelled estimations, showing that approved or registered agricultural use of liquid carbofuran sprays results in mortality to birds. In addition to direct avian mortality, these field studies and bird kill incident reports indicate that flowable carbofuran has the potential to cause secondary avian mortality in cases where raptors ingest prey species, such as small birds and mammals that have previously succumbed to carbofuran intoxication.

The acute oral risk to small wild mammals feeding on the site of carbofuran applications from standard exposure scenarios on vegetation and other food sources showed the level of concern from acute exposure is exceeded for most generic body weights and feeding guilds of small wild mammals feeding on the site of carbofuran applications. Small wild mammals feeding on the site of carbofuran applications are therefore at risk from acute exposure to contaminated vegetation.

The chronic risk to small wild mammals feeding on the site of carbofuran applications showed the level of concern from chronic exposure is exceeded for all the generic weights and feeding guilds following one or two applications at 528 g a.i./ha and single applications at 1132 g a.i./ha and 2500 g a.i./ha. The chronic level of concern is exceeded for all 15 and 35 g insectivores and 35 g herbivores for all of the application rates, and for 1000 g herbivores at all the application rates. Small wild mammals feeding on the site of carbofuran applications are therefore at risk from chronic exposure to contaminated vegetation.

Some small wild mammals were also estimated to be at risk from acute and chronic exposure from the consumption of food items contaminated from spray drift off the site of application following both ground boom and aerial applications of carbofuran (UNEP/FAO/RC/CRC.11-INF-12.En, edited version of the summary of the environmental risk assessment contained in Health Canada (2009), Section 4.2.1 Effects on Terrestrial Organisms, pp 23-27).

5.2 Aquatic species

European Union

Aquatic invertebrates were the most sensitive group of aquatic organisms tested. The acute and long term TERs did not indicate a high risk for fish, algae and sediment dwellers with the model FOCUS step3 PECsw. The TERs indicated a high risk for crustaceans (*Daphnia magna*, *Ceriodaphnia dubia*) in the FOCUS model scenarios which are based on drainage (D3, D4). The exposure via run-off was negligible in the FOCUS model run-off scenarios R1 and R3.

No further refinement of the aquatic risk assessment was provided and a high risk to the aquatic environment cannot be excluded for the representative use of carbofuran at an application rate of 600 g a.i./ha for environmental conditions represented by the FOCUS model drainage scenarios.

The risk from the metabolites 3-ketocarbofuran, 3-hydroxycarbofuran and carbofuran-phenol was assessed as low (UNEP/FAO/RC/CRC.11-INF-11.En, EFSA (2009), p54).

Canada

A risk assessment of carbofuran to freshwater aquatic organisms was based upon an evaluation of toxicity data for the following four

freshwater invertebrate species (acute and chronic exposure); eight freshwater fish species (acute and chronic exposure); one freshwater algae; two freshwater vascular plant species; one amphibian species; five estuarine/marine invertebrate species (acute and chronic exposure) and three estuarine/marine fish species (acute and chronic exposure).

The initial conservative screening level EEC calculations for aquatic systems were based on a direct application to water depths of 15 and 80 cm. The 15 cm depth was chosen to represent a temporary body of water that could be inhabited by amphibians. The 80 cm depth was chosen to represent a typical permanent water body for applications of pest control products in agriculture. The screening level risk assessment indicated that carbofuran poses both an acute and chronic risk to freshwater and estuarine/marine aquatic invertebrates and fish for most of the application rates. The level of concern was not exceeded for freshwater algae and vascular plants. The level of concern was only exceeded for amphibians at the highest application rate of 2500 g a.i./ha.

A refined risk assessment to aquatic organisms from carbofuran spray drift and runoff was conducted for those taxa that exceeded the level of concern in the screening level risk assessment. This showed the acute and chronic levels of concern for freshwater aquatic invertebrates were exceeded for all use-patterns following ground boom applications with the exception of one application at 72 g a.i./ha. The acute and chronic levels of concern for freshwater aquatic invertebrates were also exceeded for all use-patterns following aerial applications. The risk assessment also concluded the level of concern for benthic invertebrates, and the acute and chronic levels of concern for freshwater fish as well as estuarine/marine fish and invertebrates were also exceeded following ground boom and aerial applications, but generally at higher rates.

The refined risk assessment to aquatic organisms from carbofuran runoff showed that the acute and chronic level of concern for freshwater aquatic invertebrates, estuarine/marine invertebrates and for estuarine/marine fish is exceeded for all of the use-pattern scenarios, and for benthic aquatic invertebrates and for freshwater fish for all of the use-pattern scenarios with the exception of the New Brunswick potato scenario (UNEP/FAO/RC/CRC.11-INF-12.En, edited version of the summary of the environmental risk assessment contained in Health Canada (2009), Section 4.2.2 Effects on Aquatic Organisms, pp 27-30).

5.3 Honey bees and above ground arthropods

European Union

Carbofuran is very toxic to bees with acute oral and contact LC_{50} values ranging from 0.0357 µg a.i./bee to 0.05 µg a.i./bee. No exposure of bees is expected from the use in sugar beet since sugar beets are wind pollinated and the production crop is harvested before flowering. Therefore the risk to bees from the representative use in sugar beets is considered to be low.

Effects of >50% were observed in extended laboratory studies and semi-field tests with the ground dwelling beetles *Aleochara bilineata* and *Poecilus cupreus* and the formulation Curaterr GR5. A field study was conducted at an application rate of 375 g a.i./ha where recovery was observed within 2 months of all invertebrate taxa investigated. The application rate in the field study does not cover the supported use of 600 g a.i./ha in sugar beet. Therefore a data gap remains to address the risk to non-target arthropods for an application rate of 600 g a.i./ha (UNEP/FAO/RC/CRC.11-INF-11.En, EFSA (2009), p54).

Canada

The screening level risk assessment indicated that the level of concern for bees was exceeded at application rates of 528 g a.i./ha and higher. However, a higher level risk assessment could not be located in the

		reference and appears not to have been carried out (UNEP/FAO/RC/CRC.11-INF-12.En, Health Canada (2009), Section 4.2.1 Effects on Terrestrial Organisms, pp 23-26).
5.4	**Earthworms and other soil macro-organisms**	**European Union** The acute risk to earthworms was assessed as low but the long-term TER values were below the trigger of 5 indicating a high long-term risk to earthworms. However, it was concluded that the information provided by the applicants is not sufficient to address the potential high long-term risk to earthworms. In laboratory studies with the formulation Furadan 5G and *Folsomia candida* and *Hypoaspis aculeifer* the NOECs (reproduction) were 0.21 mg a.i./kg dry soil and 10.4 mg a.i./kg dry soil. The resulting TERs based on the initial PECsoil of 0.8 mg a.i./kg dry soil were 0.26 and 13, indicating a potential high risk to collembola. Collembola were also investigated in the field study with non-target arthropods (see above). Recovery was observed in this study but the application rate of 375 g a.i./ha did not cover the supported use of 600 g a.i./ha in sugar beet. Therefore the risk to other soil non-target macro organisms needs to be addressed further (data gap) (UNEP/FAO/RC/CRC.11-INF-11.En, EFSA (2009), p55). **Canada** The screening level risk assessment indicated that the level of concern for earthworms was exceeded at application rates of 528 g a.i./ha and higher. However, a higher level risk assessment could not be located in the reference and appears not to have been carried out (UNEP/FAO/RC/CRC.11-INF-12.En, Health Canada (2009), Section 4.2.1 Effects on Terrestrial Organisms, pp 23-26).
5.5	**Soil microorganisms**	**European Union** No effects on soil respiration and nitrification were observed after 28 days of exposure to a concentration of 0.8 and 4 mg carbofuran/kg soil equivalent to an application rate of 12 kg Furadan 5G/ha and 60 kg Furadan 5G/ha. A strong impact on nitrogen turnover was observed at days 7 and 14. However, the risk to soil micro-organisms is considered to be low for the representative uses since the nitrogen level in the treated samples was similar to controls after 28 days (UNEP/FAO/RC/CRC.11-INF-11.En, EFSA (2009), p56).
5.6	**Terrestrial plants**	**European Union** While no data on the risk to non-target organisms (flora and fauna) was provided, due to the mode of application (in furrow) exposure of non-target plants was assumed to be negligible suggesting a low risk to non-target plants. (UNEP/FAO/RC/CRC.11-INF-11.En, EFSA 2009, p56).
5.7	**Summary – overall risk evaluation**	**European Union** Overall it was concluded that a high risk to birds and mammals was indicated for the representative use evaluated. The EPCO experts for ecotoxicology expressed their doubts that a safe use could be demonstrated even with further refinement of the risk assessment. Overall it can be concluded that a high risk to aquatic organisms cannot be excluded for the application rate of 600 g a.i./ha and environmental conditions represented by the FOCUS model drainage scenarios (D3, D4). Further refinement of the risk assessment is needed. The risk was considered to be low for environmental conditions represented by the run-off scenarios (R1 and R3). The risk to bees from the representative use in sugar beets is considered to be low, but data gaps remain to address the risk to non-target arthropods and other soil non-target macro organisms for an application rate of 600 g a.i./ha, as well as the potential high long-term risk to earthworms (UNEP/FAO/RC/CRC.11-INF-11.En, EFSA 2009,

p54-55).

Canada

The risk assessment of carbofuran indicates adverse effects on non-target terrestrial invertebrates and vertebrates and aquatic organisms some of which cannot be mitigated. There is potential that carbofuran may appear in surface water through runoff and in groundwater through leaching (UNEP/FAO/RC/CRC.11-INF-12.En, Health Canada 2009, Section 7.2 Environmental Risk, p 38).

The CILSS countries

The Sahelian Pesticide Committee has stopped the registration of carbofuran-based pesticides in CILSS countries in 2006 taking into account the fragile ecology of CILSS countries already characterized by an imbalance of ecosystems and the disappearance of organisms useful to the environment.

Further to the pollution of Sahel ground water which constitutes the main drinking water resource with open wells, several sources agree that Carbofuran is highly toxic to birds. One single grain may kill a bird (oral LD_{50} of 0.4 mg/kg body weight.

Carbofuran is highly toxic to fresh water invertebrates and extremely toxic to birds.

Carbofuran is moderately to highly toxic to fresh water fish (UNEP/FAO/RC/CRC.11/6).

Annex 2 – Details on final regulatory actions reported

Country Name: European Union

1	**Effective date(s) of entry into force of actions**	The complete entry into force of all provisions of Commission Decision 2007/416/EC of 13 June 2007 was 13 December 2008 since all uses of plant protection products containing carbofuran were prohibited as from that date at the latest.
	Reference to the regulatory document	Commission Decision 2007/416/EC of 13 June 2007 concerning the non-inclusion of carbofuran in Annex I to Council Directive 91/414/EEC and the withdrawal of authorizations for plant protection products containing this active substance (Official Journal of the European Union L 156 of 16.06.2007, p. 30-31). Commission Decision 2007/416/EC states that the authorizations for plant protection products containing carbofuran had to be withdrawn by 13 December 2007. As of 16 June 2007, no authorisations for plant protection products containing carbofuran could be granted or renewed.
2	**Succinct details of the final regulatory action(s)**	It is prohibited to place on the market or use plant protection products containing carbofuran. Carbofuran is not included in the list of approved active ingredients under Regulation (EC) No 1107/2009, which replaces Directive 91/414/EEC.
3	**Reasons for action**	Human health: it has not been demonstrated that risks are acceptable for consumers, in particular children. Environment: it has not been demonstrated that risks are acceptable for ground water contamination and for birds and mammals, aquatic organisms, bees, non-target arthropods, earthworms, and soil non-target organisms.
4	**Basis for inclusion into Annex III**	The final regulatory action to ban carbofuran was based on a risk evaluation taking into consideration local conditions in the EU Member States.
4.1	**Risk evaluation**	**Human Health** A risk assessment was carried out on the basis of Directive 91/414/EEC (replaced by Regulation (EC) 1107/2009*)*, which provides for the European Commission to issue a work programme for the examination of existing active substances used in plant protection products with a view to their possible inclusion in Annex I to the Directive, and in accordance with the provisions of Article 8(7) of Regulation (EC) No 451/2000. A Member State (Belgium) was designated to undertake the risk assessment based on the information submitted by the notifiers and to establish a draft assessment report, which was subject to peer review organised by the European Food Safety Authority (EFSA). The conclusions provided by EFSA were reviewed by the Member States and the Commission and submitted to the Standing Committee on the Food Chain and Animal Health (SCFCAH). The evaluation was based on a review of scientific data, taking into account the conditions prevailing in the European Union (intended uses, recommended application rates, good agricultural practices). Only data that had been generated according to scientifically-recognised methods were validated and used for the evaluation. Moreover, data reviews were performed and documented according to generally recognised scientific principles and procedures. The risk assessment resulted in several documents, including: Review Report for the active substance carbofuran finalised in the Standing Committee on the Food Chain and Animal Health at its meeting on 24 November 2006 (SANC0/10054/2006 final) http://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/public/?event=activesubstance.detail&language=EN&selecte

		dID=1082 and (EFSA (2006): Conclusion regarding the peer review of the pesticide risk assessment of the active substance carbofuran. (EFSA Scientific Report (2006) 90, p. 1-88.) The risk assessment concluded that carbofuran was not demonstrated to fulfil the safety requirements laid down in Article 5 (1) (a) and (b) of Directive 91/414/EEC (replaced by Regulation (EC) 1107/2009). The consumer risk assessment, which raised a concern about the acute exposure of vulnerable groups of consumers, in particular children, could not be finalised due to the lack of information as regards certain relevant residues (UNEP/FAO/RC/CRC.11/6, section 2.4.2.1, p. 8). **Environment** It was concluded that carbofuran was not demonstrated to fulfil the safety requirements laid down in Article 5 (1) (a) and (b) of Directive 91/414/EEC (replaced by Regulation (EC) 1107/2009). The environmental risk assessment identified a number of concerns with regard to ecotoxicology. The risk for ground water contamination was assessed to be high, but could not be concluded, in particular because the data did not provide sufficient information about a number of metabolites which have a hazardous profile. Furthermore, concerns remain as regards the risk assessment for birds and mammals, aquatic organisms, bees, non-target arthropods, earthworms, and soil non-target organisms.
4.2	**Criteria used**	Human Health and the Environment
	Relevance to other States and Region	Similar health and environmental problems are likely to be encountered in other countries where the substance is used particularly those with similar climatic conditions as well as in developing countries.
5	**Alternatives**	None reported
6	**Waste management**	None reported
7	**Other**	None reported

Country Name: Canada

1	**Effective date(s) of entry into force of actions**	Sale of pesticides containing carbofuran was prohibited in Canada effective December 31, 2010. The use of products containing carbofuran was prohibited after December 31, 2012.
	Reference to the regulatory document	Pest Management Regulatory Agency, Health Canada (2010): Carbofuran – RVD2010-16 Re-evaluation Decision, 8 December 2010.
2	**Succinct details of the final regulatory action(s)**	Sale of pesticides containing carbofuran was prohibited in Canada effective December 31, 2010. The use of products containing carbofuran was prohibited after December 31, 2012. Pesticide products containing carbofuran can no longer be used in Canada.
3	**Reasons for action**	Human health: unacceptable risk to workers and to consumers due to dietary exposure from food and drinking water. Environment: unacceptable risk to terrestrial and aquatic organisms.
4	**Basis for inclusion into Annex III**	The final regulatory action to ban carbofuran was based on a risk evaluation taking into consideration local conditions in both Canada and the United States.
4.1	**Risk evaluation**	A risk assessment was carried out and published in two documents; Pest Management Regulatory Agency (PMRA) Health Canada (2010): Carbofuran – RVD2010-16 Re-evaluation Decision, 8 December 2010; Pest Management Regulatory Agency (PMRA) Health Canada (2009): Carbofuran – PRVD2009-11 Proposed Re-evaluation Decision, 31 July 2009. **Human Health** Based on the label directions of carbofuran products that were registered at the time of the review, use of the pesticide carbofuran posed an unacceptable risk to workers conducting certain mixing, loading, applying or post-application activities. An aggregate dietary risk assessment demonstrated that exposure to carbofuran from food and drinking water was unacceptable. Therefore it was concluded that carbofuran did not meet Health Canada's standards for human health protection. **Environment** In risk assessments based on the label directions of carbofuran products that were registered at the time of the review, use of the pesticide carbofuran posed an unacceptable risk to terrestrial and aquatic organisms, and therefore does not meet Health Canada's current standards for environmental protection. Additionally, thirty three environmental incident reports from the United States and Canada were considered during the review of carbofuran, and indicated that exposure to carbofuran under the registered use pattern resulted in avian, small wild animal and bee mortality.
4.2	**Criteria used**	Human Health and the Environment
	Relevance to other States and Region	Similar health and environmental problems are likely to be encountered in other countries where the substance is used particularly those with similar climatic conditions as well as in developing countries.
5	**Alternatives**	Registered alternatives are available for some uses of carbofuran, however, for canola, mustard, raspberry, strawberry and sugar beet, there are no registered (or viable) alternative active ingredients to carbofuran for the control of certain pests
6	**Waste management**	None reported
7	**Other**	None reported

Country Name: CILSS countries (Cabo Verde, Chad, the Gambia, Mauritania, the Niger, Senegal and Togo)[5]

1	**Effective date(s) of entry into force of actions**	Carbofuran was banned by the decision of CILSS Coordinating Minister N 008/MAE-MC/2015 of 08 April 2015.
	Reference to the regulatory document	Carbofuran was banned by the decision of CILSS Coordinating Minister N 008/MAE-MC/2015 of 08 April 2015. The decision was based on the reasons stated in Sahelian Pesticide Committee: Annex to the decision to ban Carbofuran; June 2012/reviewed in November 2014.
2	**Succinct details of the final regulatory action(s)**	Carbofuran was banned in these CILSS countries as of 08 April 2015.
3	**Reasons for action**	Human health: unacceptable risk to users and to consumers due to exposure from food and drinking water. Environment: high risk to birds and fresh water invertebrates.
4	**Basis for inclusion into Annex III**	The final regulatory action to ban carbofuran was based on a risk evaluation taking into consideration local conditions in the Sahel.
4.1	**Risk evaluation**	Carbofuran presents risks to human health and especially to non-target organisms in the environment, making it very difficult to handle it without risks for users in Sahel countries. These risks have justified its ban in many countries of the world among which (are) all the European Union member states. A consultation mission conducted on behalf of the Sahelian Pesticide Committee (SPC) concluded that the SPC should stop the registration of the pesticides of toxicity class Ib since they are used by poorly trained small farmers who don't respect the safety measures (CILSS countries supporting documentation p. 32 paragraph 4.2.4). The Sahelian Pesticide Committee stopped the registration of carbofuran based pesticides in CILSS countries in 2006 taking into account: • The fragile ecology of CILSS countries already characterized by an imbalance of ecosystems and the disappearance of organisms useful to the environment; • Non-compliance with recommended measures for a safe use of carbofuran by users in the context of CILSS countries; • The presence of pesticide residues in harvested crops and the behaviour of local people make the risk unacceptable Further to the pollution of Sahel ground water which constitutes the main drinking water resource with open wells, several sources agree that carbofuran is highly toxic to birds. One single grain may kill a bird (oral LD_{50} of 0.4 mg/kg body weight). Carbofuran is highly toxic to fresh water invertebrates and extremely toxic to birds. Carbofuran is moderately to highly toxic to fresh water fish.
4.2	**Criteria used**	Human Health and the Environment
	Relevance to other States and Region	Similar health and environmental problems are likely to be encountered in other countries where the substance is used particularly those with similar climatic conditions.

[5] These seven parties share a common pesticide registration body, the Sahelian Pesticides Committee set up by the Permanent Interstate Committee for Drought Control in the Sahel (CILSS). As the CILSS member states take together decisions on the registration of pesticides at a regional level, the notifications submitted by the seven African parties referred to the same final regulatory action.

5	**Alternatives**	**Chemical alternatives:** Several alternative molecules to carbofuran exist. The India Committee of pesticide experts recommended the following pesticides on paddy rice and other crops: chlorantraniliprole, flubendiamide and quinalphos. According to Jon Tollefson and Erin Hodgson, from the Department of Entomology of IOWA State University in the USA, the alternative for the protection of corn against root worms is to add seeds treated with a neonicotinoid pesticide like Poncho™ in the applicator. In case of post-emergence liquid treatment Lorsban™ 4E, an ethylchlorpyriphos-based formulation is an option. Currently five formulations authorized by the Sahelian Pesticide Committee under the name of Dursban are ethylchlorpyriphos based. Capture™ 2EC of the new generation of pyrethroids is an alternative to carbofuran thanks to its effectiveness. **Integrated Pest and production management (IPPM)**: The experience in IPPM launched by FAO in collaboration with the Ministries of Agriculture in several countries of the Sahel yielded important results in agricultural production and pest management. This initiative of Good Agricultural Practices (GAP) will improve the agricultural productivity and train several growers who are potential facilitators. IPPM is based on the following principles: - A sound and judicious use of pesticides; - The acquisition of knowledge and practical skills critical to pest control; - The reinforcement of decision-making capacity of growers at a field level; - The development of a better low-cost productivity which protects the environment.
6	**Waste management**	None reported
7	**Other**	None reported

Previous notifications A severely hazardous pesticide formulation, i.e. dustable powder formulations containing a combination of benomyl at or above 7 percent, carbofuran at or above 10 per cent and thiram at or above 15 percent is already listed in Annex III of the Convention.

Annex 3 – Addresses of designated national authorities

European Union

Directorate-General for the Environment European Commission Unit A.3 - Chemicals Office BU 9, 05/041 Brussels 1049 European Union Mr. Juergen Helbig International Chemicals Policy Coordinator	**Phone** +32 2 298 8521 **Fax** +32 2 296 7617 **E-mail** Juergen.Helbig@ec.europa.eu

Canada

Pest Management Regulatory Agency 2720 Riverside Drive Ottawa ON K1A 0K9 Canada Trish MacQuarrie Director General of the Policy, Communications and Regulatory Affairs Directorate	**Phone** 1-613-736-3660 **Fax** 1-613-736-3659 **E-mail** Trish.Macquarrie@hc-sc.gc.ca

CILSS countries

Ministere du Developpement Rural – Direction Generale du Developpement Rural – Direction des Services de l'Agriculture B.P. 278 – Praia ilha de Santiago – Cabo Verde Celestino Gomes Mendes Tavares Cabo Verde	**Phone** 00238 66 52 52 **Fax** - **E-mail** Celestino.Tavares@mdr.gov.cv
Ministère de l'Agriculture et de l'Environnement BP 1551 Ndjamena Tchad Moussa Abderaman Abdoulaye Directeur de la Protection des Végétaux et du Conditionnement Chad	**Phone** 00235 516 00 89 **Fax** - **E-mail** charafara2009@gmail.com
National Environment Agency Jimpex Road, Kanifing PMB 48, Banjul, The Gambia Omar S Bah Designated National Authority, Rotterdam Convention The Gambia	**Phone** 220 9953796, 220 4399423 **Fax** 220 4399430 **E-mail** Omar16bah@yahoo.ca
Ministere de l'Agriculture Bp 180, Tel 45211466 Mohamed Abdallahi Mohamed Moloud Conseiller du Ministere de l'Agriculture Mauritania	**Phone** 0022222351042 **Fax** - **E-mail** ouldmaouloudm@yahoo.fr
General Direction of Plant Protection B.P. 323 Niamey Niger Mme Abdou Alimatou Douki Director of Plant Regulation and Environmental Monitoring Niger	**Phone** 00227 20 74 25 56 **Fax** 00227 20 74 19 83 **E-mail** dpv@intnet.ne, douki_a@yahoo.fr

Direction de l'Envirronnement et de Etablissements Classes Parc Forestier et Zoologique de Hann-Route des Peres Tel: 221 33 859 13 43 Aita sarr SECK Chef de la Division Prevention et Controle des Pollutions et Nuisances Senegal	**Phone** 221 77 511 47 59 **Fax** 221 33 822 62 12 **E-mail** aitasec@yahoo.fr
Direction de la Protection des Végétaux, Ministère de l'Agriculture, de l'Elevage et de la Pêche BP: 1347, Lomé-Togo DJATOITE Minto Ing. Agrochimiste, Chef Section Phytopharmacie Togo	**Phone** 00228 90 86 71 72 / 22 47 49 58 / 22 51 44 04 **Fax** 00228 22 51 08 88 **E-mail** djatminto07@gmail.com

C Industrial chemicals

CP Pesticides and industrial chemicals

P Pesticides

Annex 4 – References

Regulatory actions

European Union:

2007/416/EC: Commission Decision of 13 June 2007 concerning the non-inclusion of carbofuran in Annex I to Council Directive 91/414/EEC and the withdrawal of authorisations for plant protection products containing that substance (Official Journal of the European Union L 156 of 16.06.2007, p. 30-31). Available at: http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:32007D0416

Canada:

Health Canada (2010): Carbofuran –Re-evaluation Decision RVD2010-16: Carbofuran, 8 December 2010, Document UNEP/FAO/RC/CRC.11/INF-12.

CILSS countries:

Decision of CILSS Coordinating Minister N 008/MAE-MC/2015 of 08 April 2015 – Portant interdiction du carbofuran. Document UNEP/FAO/RC/CRC.11/INF-13, p.3-4

Supporting documentation provided by the European Union:

EFSA (2006): Conclusion regarding the peer review of the pesticide risk assessment of the active substance carbofuran, EFSA Scientific Report 90, p. 1-88, Document UNEP/FAO/RC/CRC.11/ INF-11.

EFSA (2009): Conclusion regarding the peer review of the pesticide risk assessment of the active substance carbofuran. EFSA Scientific Report 310, p. 1-132, Document UNEP/FAO/RC/CRC.11/ INF-11.

EU (2007): Review report for the active substance carbofuran – SANCO/10054/2006 final 7 September 2007.

Supporting documentation provided by Canada:

Health Canada (2009):– Proposed Re-evaluation Decision PRVD2009-11: Carbofuran, 31 July 2009, Document UNEP/FAO/RC/CRC.11/INF-12.

Supporting documentation provided by CILLS countries:

Sahelian Pesticide Committee (SPC, 2012): Annex to the decision to ban Carbofuran; June 2012/reviewed in November 2014, Document UNEP/FAO/RC/CRC.11/INF-13.

Other Documents

FAO/UNEP (2004/2005) Decision Guidance Document dustable powder formulations containing a combination of benomyl at or above 7%, carbofuran at or above 10% and thiram at or above 15%. Available at: http://www.pic.int/Portals/5/DGDs/DGD_Dustable%20powder%20formulations_EN.pdf

Pesticide Manual 11th Edition – Carbofuran; p186.

Relevant guidelines and reference documents

Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and their Disposal 1996. Available at: www.basel.int

FAO/WHO Food Standards (accessed 21 April 2016): Codex Alimentarius, MRLs for Carbofuran. Available at: http://www.codexalimentarius.org/standards/pestres/pesticide-detail/en/?p_id=96

FAO (2015): Guidelines on good labelling practice for pesticides FAO, Rome. Available at: http://www.fao.org/3/a-i4854e.pdf

FAO (1996a): The Pesticide Storage and Stock Control Manual, Rome. Available at: http://www.fao.org/agriculture/crops/obsolete-pesticides/resources0/en/

FAO (1996b): Technical guidelines on disposal of bulk quantities of obsolete pesticides in developing countries. Available at: http://www.fao.org/agriculture/crops/thematic-sitemap/theme/pests/code/list-guide-new/en/

FAO (1999): Guidelines for the management of small quantities of unwanted and obsolete pesticides, Rome. Available at: http://www.fao.org/agriculture/crops/thematic-sitemap/theme/pests/code/list-guide-new/en/

JMPR (2009). Pesticide residues in food 2008 – Joint FAO/WHO meeting on pesticide residues; Report 2008; FAO Plant Production and Protection Paper 196.

United Nations (2015): UN Recommendations on the Transport of Dangerous Goods - Model Regulations, Nineteenth revised edition. Available at: http://www.unece.org/fileadmin/DAM/trans/danger/publi/unrec/rev19/Rev19e_Vol_I.pdf

WHO (2004): Carbofuran in Drinking-water. Background document for development of WHO Guidelines for Drinking-water Quality. Available at: http://www.who.int/water_sanitation_health/dwq/chemicals/carbofuran.pdf

WHO (2010): The WHO recommended classification of pesticides by hazard and guidelines to classification: 2009. Available at: www.who.int/ipcs/publications/pesticides_hazard/en/

WHO (2011): WHO Guidelines for drinking-water quality, fourth edition. Available at: http://www.who.int/water_sanitation_health/publications/2011/dwq_guidelines/en/index.html