POPRC-9/9: Effective participation in the work of the Persistent Organic Pollutants Review Committee

The Persistent Organic Pollutants Review Committee,

Recalling that at its sixth meeting the Conference of the Parties to the Stockholm Convention requested the Secretariat to continue the activities listed in decision POPRC-8/12, including the organization of webinars and face-to-face activities, among other things, to assist developing countries and countries with economies in transition to participate effectively in the work of the Committee,

Taking note of the activities undertaken to date to assist developing-country parties and parties with economies in transition to participate effectively in the work of the Committee, in particular the series of successful webinars held on topics related to the Committee's work,

Recognizing the need to make use of the experience gained by the members of the Committee and their potential to support and serve as resource persons that can assist parties in participating effectively in the work of the Committee,

Recognizing also that parties face difficulties in responding to requests for information from the Committee,

1. *Invites* the Secretariat to continue its activities related to supporting effective participation in the Committee's work, subject to the availability of resources, including:

(a) Organization of webinars, training and online meetings on topics related to the Committee's work[1] with support from current and former members who can share their expertise and lessons learned;

(b) Use of web-based platforms to facilitate the intersessional work of the Committee, to which relevant stakeholders, including parties, observers, members of the academic community, research institutions and companies could be invited to contribute their knowledge and experience;

(c) Organization, with the support of current and former Committee members, the regional centres of the Stockholm Convention and the Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and Their Disposal, regional networks and the regional offices of the United Nations Environment Programme and the Food and Agriculture Organization of the United Nations, of workshops and other face-to-face activities aimed at building the capacities of parties, training incoming Committee members and training trainers;

(d) Organization, with the support of current and former Committee members and drawing on the practices of the Chemical Review Committee of the Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade, of orientation workshops to train incoming members in matters relating to the work of the Committee;

(e) Facilitation, in cooperation with members of the Committee, the Basel Convention and Stockholm Convention regional centres and experts of the Rotterdam Convention, of the development of pilot projects that can stimulate the active involvement in the work of the Committee of various stakeholders such as the academic community and research institutes;

(f) Development of tools to facilitate the sharing of information and resources to support the effective participation of parties and others in the Committee's work, including, for example, the development of training modules and videos;

(g) Revision and updating of the handbook for effective participation in the Persistent Organic Pollutants Review Committee under the Stockholm Convention[2] to include terminology regularly used during the meetings of the Committee and other relevant information to facilitate incoming members' rapid understanding of the Committee's processes;

[1] Webinars could address, among other topics, candidate chemicals being evaluated, persistent organic pollutants in products, endocrine disruptors, persistent organic pollutants and climate change, alternatives to persistent organic pollutants, experience in phasing out persistent organic pollutants, how to respond to information requests and topics of relevance to the Committee's work upon request by members and parties.

[2] UNEP/POPS/COP.4/INF/9.

2. *Invites* current and former members, on a voluntary basis, to be actively involved in activities to promote the effective participation of parties in the Committee's work, to support the Basel Convention and Stockholm Convention regional centres and experts of the Rotterdam Convention and to disseminate the work being undertaken by the Committee within their countries and regions;

3. *Encourages* the Basel Convention and Stockholm Convention regional centres and experts of the Rotterdam Convention, subject to the availability of resources, to play an active role in providing assistance to facilitate effective participation in the Committee's work, including through the exchange of information and expert knowledge in their areas of expertise and with support from current and former Committee members;

4. *Invites* parties and observers in a position to do so to contribute to the Committee's work and to provide financial support for the implementation of activities in support of effective participation by parties in that work.

Annex II

Composition of intersessional working groups (2013–2014)[3]

Working group on pentachlorophenol and its salts and esters

Committee members

Ms. Estefania Moreira (Brazil) **(Chair until 4 May 2014)**
Mr. Joswa Aoudou (Cameroon)
Mr. Robert Chénier (Canada)*
Mr. José Álvaro Rodríguez (Colombia)*
Ms. Floria Roa-Gutierrez (Costa Rica)*
Mr. Jorge Álvarez (Cuba)
Mr. Timo Seppälä (Finland)*
Mr. Sylvain Bintein (France) **(Drafter)**
Mr. Reiner Arndt (Germany)*
Mr. Ram Niwas Jindal (India)
Mr. Agus Haryono (Indonesia)
Ms. Caroline Wamai (Kenya)
Mr. Martien Janssen (Netherlands)
Mr. Peter Dawson (New Zealand)*
Ms. Kyunghee Choi (Republic of Korea) **(Chair from 5 May 2014)**
Mr. Azhari Abdelbagi (Sudan)
Ms. Francisca Katagira (United Republic of Tanzania)*
Ms. Svitlana Sukhorebra (Ukraine)*

Observers

Mr. Jack Holland (Australia)**
Mr. Gary Fan (Australia)
Ms. Ingrid Hauzenberger (Austria)**
Ms. Tamara Kukharchyk (Belarus)**
Ms. Michelle Kivi (Canada)**
Mr. Pavel Čupr (Czech Republic)**
Ms. Rikke Donchil Homberg (Denmark)
Ms. Consuelo Meneses (Ecuador)**
Ms. Katinka Van der Jagt (European Union)
Ms. Sandrine Andres (France)
Mr. Hubert Binga (Gabon)**
Mr. Tirthankar Basu (India)
Mr. Seyed Jamaleddin Shahtaheri (Islamic Republic of Iran)**
Mr. Shuji Tamura (Japan)
Mr. Yusuke Kusakawa (Japan)
Mr. Nobutada Kimura (Japan)
Mr. Noriyasu Nagai (Japan)
Mr. Hirotaka Yamamoto (Japan)
Mr. Naoki Hashizume (Japan)
Mr. Kiyohiro Kubota (Japan)
Ms. Mantoa Sekota (Lesotho)**
Mr. Christophe Rosiers (New Zealand)
Ms. Christina Tolfsen (Norway)
Mr. Said Ali Alzadjali (Oman)**
Mr. Marcus Richard (Saint Vincent and Grenadines)**
Mr. Ousmane Sow (Senegal)**
Mr. Jayakody Sumith (Sri Lanka)**
Ms. T.K.I.G. Kumari (Sri Lanka)
Ms. Maria Delvin (Sweden)**
Mr. Armando Diaz (Bolivarian Republic of Venezuela)**

[3] Committee members whose names are marked with one asterisk in the present annex will end their terms as members on 4 May 2014. Similarly, observers whose names are marked with two asterisks will begin terms as members of the Committee on 5 May 2014; until such time, they will participate in the intersessional working groups as observers.

Ms. Vivian Cardenas (United Nations Development Programme, Honduras)
Ms. Pamela Miller (Alaska Community Action on Toxics)
Mr. Philippe Chatton (CropLife International)
Mr. Shunmugam Ganesan (Indian Chemical Council)
Ms. Mariann Lloyd-Smith (International POPs Elimination Network)
Mr. Joseph DiGangi (International POPs Elimination Network)
Ms. Eva Kruemmel (Inuit Circumpolar Council)
Ms. Emily Marquez (Pesticide Action Network, USA)
Ms. Meriel Watts (Pesticide Action Network, Asia Pacific)
Mr. Herbert Estreicher (Wood Preservation Canada)

Working group on decabromodiphenyl ether

Committee members

Mr. Robert Chénier (Canada)*
Mr. Jianxin Hu (China)*
Ms. Floria Roa-Gutierrez (Costa Rica)*
Mr. Jorge Álvarez (Cuba)
Mr. Raouf Okasha (Egypt)*
Mr. Timo Seppälä (Finland)*
Mr. Sylvain Bintein (France)
Mr. Reiner Arndt (Germany)*
Mr. Ram Niwas Jindal (India)
Mr. Agus Haryono (Indonesia)
Mr. Mohammed Khashashneh (Jordan)*
Ms. Caroline Wamai (Kenya)
Ms. Lulwa Ali (Kuwait)
Ms. Haritiana Rakotoarisetra (Madagascar)
Mr. Martien Janssen (Netherlands)
Mr. Peter Dawson (New Zealand)* **(Chair until 4 May 2014)**
Ms. Liselott Säll (Norway) **(Drafter)**
Ms. Kyunghee Choi (Republic of Korea)
Mr. Azhari Abdelbagi (Sudan)
Ms. Svitlana Sukhorebra (Ukraine)*

Observers

Mr. Jack Holland (Australia)** **(Chair from 5 May 2014)**
Mr. Gary Fan (Australia)
Ms. Ingrid Hauzenberger (Austria)**
Ms. Tamara Kukharchyk (Belarus)**
Ms. Michelle Kivi (Canada)**
Mr. Jean-François Ferry (Canada)
Mr. Pavel Čupr (Czech Republic)**
Ms. Rikke Donchil Homberg (Denmark)
Ms. Consuelo Meneses (Ecuador)**
Ms. Katinka Van der Jagt (European Union)
Ms. Sandrine Andres (France)
Mr. Hubert Binga (Gabon)**
Mr. Seyed Jamaleddin Shahtaheri (Islamic Republic of Iran)**
Mr. Shuji Tamura (Japan)
Mr. Yusuke Kusakawa (Japan)
Mr. Nobutada Kimura (Japan)
Mr. Noriyasu Nagai (Japan)
Mr. Hirotaka Yamamoto (Japan)
Mr. Naoki Hashizume (Japan)
Mr. Kiyohiro Kubota (Japan)
Ms. Mantoa Sekota (Lesotho)**
Mr. Sidi Ould Aloueimine (Mauritania)**
Mr. Christophe Rosiers (New Zealand)
Ms. Christina Tolfsen (Norway)
Ms. Trine Celius (Norway)
Mr. Said Ali Alzadjali (Oman)**

Ms. Anna Graczyk (Poland)
Ms. Magdalena Pyjor (Poland)
Mr. Marcus Richard (Saint Vincent and the Grenadines)**
Mr. Ousmane Sow (Senegal)**
Ms. Maria Delvin (Sweden)**
Mr. Armando Diaz (Bolivarian Republic of Venezuela)**
Ms. Vivian Cardenas (United Nations Development Programme, Honduras)
Ms. Pamela Miller (Alaska Community Action on Toxics)
Ms. Caroline Ciuciu (Bromine Science and Environmental Forum)
Mr. Olivier de Matos (Bromine Science and Environmental Forum)
Ms. Venetia Spencer (Bromine Science and Environmental Forum)
Ms. Sylvia Jacobi (Bromine Science and Environmental Forum)
Mr. Philippe Chatton (CropLife International)
Ms. Mariann Lloyd-Smith (International POPs Elimination Network)
Mr. Joseph DiGangi (International POPs Elimination Network)
Ms. Eva Kruemmel (Inuit Circumpolar Council)

Working group on perfluorooctane sulfonic acid, its salts and perfluorooctane sulfonyl fluoride

Committee members

Mr. José Álvaro Rodríguez (Colombia)*
Mr. Raouf Okasha (Egypt)*
Mr. Sylvain Bintein (France)
Mr. Reiner Arndt (Germany)*
Mr. Ram Niwas Jindal (India)
Mr. Agus Haryono (Indonesia) **(Co-Chair)**
Ms. Caroline Wamai (Kenya)
Ms. Lulwa Ali (Kuwait)
Ms. Haritiana Rakotoarisetra (Madagascar)
Mr. Martien Janssen (Netherlands) **(Co-Chair)**
Mr. Peter Dawson (New Zealand)*
Ms. Kyunghee Choi (Republic of Korea)
Mr. Azhari Abdelbagi (Sudan)
Ms. Svitlana Sukhorebra (Ukraine)*
Mr. Samuel Banda (Zambia)*

Observers

Mr. Jack Holland (Australia)**
Mr. Gary Fan (Australia)
Ms. Ingrid Hauzenberger (Austria)**
Ms. Tamara Kukharchyk (Belarus)**
Ms. Michelle Kivi (Canada)**
Mr. Jean-François Ferry (Canada)
Mr. Pavel Čupr (Czech Republic)**
Ms. Rikke Donchil Homberg (Denmark)
Ms. Katinka Van der Jagt (European Union)

Ms. Sandrine Andres (France)
Mr. Hubert Binga (Gabon)**
Mr. Tirthankar Basu (India)
Mr. Seyed Jamaleddin Shahtaheri (Islamic Republic of Iran)**
Mr. Shuji Tamura (Japan)
Mr. Yusuke Kusakawa (Japan)
Mr. Nobutada Kimura (Japan)
Mr. Noriyasu Nagai (Japan)
Mr. Hirotaka Yamamoto (Japan)
Mr. Naoki Hashizume (Japan)
Mr. Kiyohiro Kubota (Japan)
Ms. Trine Celius (Norway)
Mr. Said Ali Alzadjali (Oman)**
Mr. Ousmane Sow (Senegal)**

Mr. Jayakody Sumith (Sri Lanka)**
Ms. T.K.I.G Kumari (Sri Lanka)
Ms. Maria Delvin (Sweden)**
Ms. Pamela Miller (Alaska Community Action on Toxics)
Mr. Philippe Chatton (CropLife International)
Mr. Richard Holt (FluoroCouncil)
Mr. Ronald Bock (FluoroCouncil)
Ms. Mariann Lloyd-Smith (International POPs Elimination Network)
Mr. Joseph DiGangi (International POPs Elimination Network)
Ms. Eva Kruemmel (Inuit Circumpolar Council)
Mr. Edson Dias da Silva (Leaf-Cutting Ant Baits Industries Association)
Ms. Juliana Berti (Leaf-Cutting Ant Baits Industries Association)
Mr. Luiz Carlos Forti (Leaf-Cutting Ant Baits Industries Association)

Annex III

Workplan for the preparation of a draft risk profile and draft risk management evaluation during the period between the ninth and tenth meetings of the Persistent Organic Pollutant Review Committee

Scheduled date	*Interval between activities (weeks)*	*Activity (for each chemical under review)*
18 October 2013	-	The Committee establishes an ad hoc working group.
25 October 2013	1	The Secretariat requests parties and observers to provide the information specified in Annex E for risk profiles and Annex F for risk management evaluations.
10 January 2014	11	Parties and observers submit the information specified in annex E for risk profiles and Annex F for risk management evaluations to the Secretariat. • The Secretariat sends a reminder to parties and observers regarding the request for information by 13 December 2013.
28 February 2014	7	The working group chair and the drafter complete the first draft. • The drafter prepares the first draft and sends it to the chair by 24 February 2014. • The chair sends the first draft to the working group by 28 February 2014.
14 March 2014	2	The members of the working group submit comments on the first draft to the chair and the drafter.
28 March 2014	2	The working group chair and the drafter finish their review of the initial comments from the working group and complete the second draft and a compilation of responses to those comments.
4 April 2014	1	The Secretariat distributes the second draft to parties and observers for comments.
23 May 2014	7	Parties and observers submit their comments to the Secretariat.
6 June 2014	2	The working group chair and the drafter review the comments from parties and observers and complete the revised (third) draft and a compilation of responses to those comments. • The drafter prepares the third draft and sends it to the chair by 2 June 2014. • The chair sends the third draft to the working group by 6 June 2014.
20 June 2014	2	The members of the working group submit their final comments on the third draft to the chair and the drafter.
11 July 2014	3	• The working group chair and the drafter review the final comments and complete the final draft and a compilation of responses to those comments. • The drafter prepares the final draft and sends it to the chair by 30 June 2014. • The chair sends the final draft to the Secretariat by 4 July 2014.
18 July 2014	1	The Secretariat sends the final draft to the Division of Conference Services for editing and translation.
12 September 2014	8	The Division of Conference Services completes the editing and translation of the final draft.
15 September 2014	<1	The Secretariat distributes the final draft in the six official languages of the United Nations.
27–31 October 2014	6	Tenth meeting of the Committee.

Annex IV

Dicofol

1. The text below is the outcome of the work of the drafting group on dicofol established during the Committee's ninth meeting under agenda item 7 (b). It consists of a draft decision on dicofol and, as an annex to the draft decision, a draft evaluation of the proposal to list dicofol in the annexes to the Convention, as they stood at the end of the meeting.

2. As the drafting group was unable to reach agreement and the Committee did not take any decision on dicofol at its ninth meeting, the Committee decided to annex the draft decision and evaluation to the report of the meeting for possible further consideration at its tenth meeting. The entire text is enclosed in square brackets to indicate that it is not the subject of agreement.

3. The draft decision includes two sets of alternative paragraphs, each of which is enclosed in square brackets. In addition, alternative conclusions regarding each criterion in Annex D are presented in square brackets in the draft evaluation, and the argument supporting each such conclusion is presented in a text box immediately following the conclusion itself.

[Draft decision POPRC-[/]: Dicofol

Submission by the drafting group on dicofol

The Persistent Organic Pollutants Review Committee,

Having examined the proposal by the European Union to list dicofol in Annexes A, B and/or C to the Stockholm Convention on Persistent Organic Pollutants and having applied the screening criteria specified in Annex D to the Convention,

[1. *Decides,* in accordance with paragraph 4 (a) of Article 8 of the Convention, that it is satisfied that the screening criteria have been fulfilled for dicofol as described in the evaluation contained in the annex to the present decision;

2. *Also decides,* in accordance with paragraph 6 of Article 8 of the Convention and paragraph 29 of decision SC-1/7, to establish an ad hoc working group to review the proposal further and to prepare a draft risk profile in accordance with Annex E to the Convention;

3. *Invites,* in accordance with paragraph 4 (a) of Article 8 of the Convention, parties and observers to submit to the Secretariat the information specified in Annex E before 10 January 2014.]

[1. *Decides*, in accordance with paragraph 4 (b) of Article 8 of the Convention, that it is not satisfied that the screening criteria have been fulfilled for dicofol, as set out in the evaluation contained in the annex to the present decision;

2. *Requests* the Secretariat to make the proposal and the evaluation of the Committee available to all Parties and observers;

3. *Decides* that the proposal shall be set aside.]

Annex to decision POPRC-[/]

Evaluation of dicofol against the criteria of Annex D

A. Background

1. The primary source of information for the preparation of this evaluation was the proposal submitted by the European Union that is Party to the Convention, contained in document UNEP/POPS/POPRC.9/3.

2. Additional sources of scientific information included critical reviews prepared by recognized authorities, the Risk Profile and Summary Report for dicofol from April 2002, prepared for UNECE and, prepared by Rasenberg et al. 2003 as well as its Addenda from December 2005 and February 2009 respectively Track A Summary of Dicofol Reviews from April 2009 performed by the UNECE Task Force on POPs, reports by EFSA, AMAP and OSPAR, USEPA, Pesticide Programs Washington

D.C and the Pesticide Manual (14th edition), as well as recent scientific publications, investigated on a screening basis for relevant information on dicofol.

B. Evaluation

3. The proposal was evaluated in the light of the requirements of Annex D, regarding the identification of the chemical (paragraph 1 (a)) and the screening criteria (paragraphs 1 (b)–(e)):

(a) Chemical identity:

(i) Adequate information was provided in the proposal, which relates to dicofol, Chemical Abstracts Services no. 115-32-2. and its isomers (*p,p'*-dicofol, CAS RN: 115-32-2 and *o,p'*-dicofol, CAS RN: 10606-46-9)

(ii) The chemical structures were provided;

The chemical identity of dicofol and its isomers is adequately established;

(b) Persistence:

(i) Degradation in water is primarily by hydrolysis. At pH5, the half-life of dicofol's main *p,p'*-isomer was 85 days, fulfilling the cut-off value of 60 days for persistence in water. Approximately 10 per cent of northern EU nation surface waters have a pH of around 5. (Belfroid A et al. 2005 (Ref. 1) and Belfroid A et al. 2009 (Ref. 2); Also, blackwater rivers found in several areas around the world (Australia, Amazonia, Europe, Indonesia, Orinoco basin, Northern and Southern United States) typically have a pH of around 5. Conservative estimates for half-life in aerobic soil of dicofol (considering the parent compound and its major degradates) are as high as 313 days fulfilling the cut-off value of 6 months for persistence in water. Isomers of dicofol hydrolize relatively quickly at neutral and alkaline pH. Both isomers hydrolize within 8 hours at pH 7 with half-lives of 64 hours. Dicofol hydrolizes very rapidly under neutral and alkaline conditions (USEPA RED 1998) (Ref.3). Half-life is less than sixty days in soil and less than one day in sediment [(Canadian Technical Comments on Dicofol Dossier 2009) (Ref 4)].

(ii) According to the Japanese NITE database dicofol is characterized as non-biodegradable.

[There is sufficient evidence that dicofol meets the persistence criterion;]

There is sufficient evidence that dicofol meets the persistence criterion because:

- *The half-life of the chemical in water at pH 5 is of 85 days.*
- *The half-life of the chemical in aerobic soil is of 313 days.*

[There is no sufficient evidence that dicofol meets the persistence criterion;]

There is no sufficient evidence that dicofol meets the persistence criterion because:

- *The pH in the global ocean surface waters ranges from 7.9-8.2. The vast areas of subtropical oceans have seasonally varied pH values from 8.05 during warmer months to 8.15 during colder months.*
- *Dicofol is not persistent in natural waters near or above neutral pH and not expected to be persistent in water above pH 5.5.*
- *Half-life is less than sixty days in soil and less than one day in sediment*

(c) Bioaccumulation:

(i) A study with *p,p'*-dicofol in bluegill sunfish resulted in BCF of 10000. A study with fathead minnows after 296 days of exposure to dicofol reported BCF values as high as 43000. p,p'-dicofol residues accumulated in bluegill sunfish with bioconcentration factors of 6,600, 17,000 and 10,000 in fillet, viscera, and whole fish, respectively during 28 days of exposure No information is available on bioaccumulation in fish for o,p'-dicofol since o,p'-dicofol hydrolizes quickly. (USEPA RED 1998) (Ref 3). BCF values are available in the Japanese METI-NITE database of 8200 and 6100 obtained for common carp which were in the same range as the BCF values found in their own study with zebra fish. Comparison with BCF values obtained from QSAR

models showed good agreement with those obtained in their study. Therefore, there is strong evidence from several fish studies indicating that BCFs are above the threshold of 5000.

Metabolism testing on rat elimination half-lives were estimated to be 1.5-4 days for o, p'- dicofol and 4-7 days for p,p'-dicofol (OECD 1995) (Ref.5).

Measured log Kow value of dicofol is 4.30 as per the Pesticide Manual 14th edition 2012. Measured log Kow values vary from 4.08 to 5.02. A high log Kow of 6.06 has been reported in USEPA RED 1998 (Ref 3). A high log Koa of 8.9 is reported indicating in air breathing organisms (Kelly 2007) (Ref 6).

[There is sufficient evidence that dicofol meets the bioaccumulation criterion;]

There is sufficient evidence that dicofol meets the bioaccumulation criterion because:

- *BCF is greater than 5000: A study with p,p'-dicofol in bluegill sunfish resulted in BCF of 10000. A study with fathead minnows after 296 days of exposure to dicofol reported BCF values as high as 43000. p,p'-dicofol residues accumulated in bluegill sunfish with bioconcentration factors of 6,600, 17,000 and 10,000 in fillet, viscera, and whole fish, respectively during 28 days of exposure.*
- *BCF values are available in the Japanese METI NITE database of 8200 and 6100 obtained for common carp which were in the same range as the BCF values found in their own study with zebra fish.*
- *A high log Koa of 8.9 is reported indicating in air breathing organisms.*

[There is no sufficient evidence that dicofol meets the bioaccumulation criterion;]

There is no sufficient evidence that dicofol meets the bioaccumulation criterion because:

- *Log Koa is a parameter that is not in the scope of the Convention.*
- *Measured log Kow value of dicofol is 4,30 as per the Pesticide Manual 14th edition 2012*
- *The references quoted in the proposal by the EU are from 1982, 1986, the later being not published.*
- *Metabolism testing on rat elimination half-lives were estimated to be 1.5-4 days for o, p'- dicofol and 4-7 days for p,p'-dicofol.*
- *Dicofol residues depurated relatively quickly with an estimated elimination of half-life 33 days.*
- *- There is uncertainty on bioaccumulation.*

(d) Potential for long-range environmental transport:

(i) and (ii) There are little data on presence of dicofol in remote areas. Dicofol has been detected in the Arctic environment (Zhong et al. 2012) (Ref.7). [In 2009, no evidence of long range transport for dicofol was found by UNECE (2009).]

(iii) The estimated atmospheric half-lives exceed the screening criteria of 2 days (3to 10.5 days). The calculated transport distance in Europe is 1650 km for dicofol.

[There is sufficient evidence that dicofol meets the criterion on potential for long-range environmental transport;]

There is sufficient evidence that dicofol meets the criterion on potential for long-range environmental transport because:

- *Dicofol has been detected in the Arctic environment.*
- *The estimated atmospheric half-lives exceed the screening criteria of 2 days (3to 10.5 days).*
- *The modeled transport distance in Europe is 1650 km for dicofol.*

[There is no sufficient evidence that dicofol meets the criterion on potential for long-range environmental transport;]

There is no sufficient evidence that dicofol meets the criterion on potential for long-range environmental transport because:

- *Dicofol does not degrade to DDT or DDE. Presence of dicofol may be related to presence of dicofol and its metabolites.*
- *No information is available on dicofol in remote areas.*
- *References quoted in the proposal by the EU are based on evidence of DDT or DDE signature.*
- *There is no actual field evidence of LRT of dicofol.*

(e) Adverse effects:

(i) There are no specific data available;

(ii) There are animal data showing a potential of dicofol to have adverse effects on human health, including effects on the liver, kidney, adrenal gland and urinary bladder. The no observed adverse effect level (NOAEL) for induction in mice is 2.1 mg/kg bw/day. UNEP/POPS/POPRC.8/INF13 concluded that based on available data there is no evidence for carcinogenicity of dicofol, however a recent study (Liu et al.2012) (Ref.8) indicates that dicofol might raise the risk of cancer incidence through effects on frame conformation of proteins, disturbing the physiological function.

A 2-year study with rats, liver, growth, enzyme induction and other changes in the liver, adrenal gland and urinary bladder were observed at doses of 2.5 mg/kg/day, resulting in a limit dose value (ADI) of 0.0022 mg/kg bw day (JMPR 2011) (Ref.9).

In another two-year study on hormonal effects in dogs a NOAEL of 0.22 mg/kg/day has been determined leading to a RfD of 0.0004 mg/kg/day (USEPA RED 1998) (Ref. 3).

A dietary concentration of 7 mg/kg dicofol fed to mice for 3 generations produced defects in 12 days old offspring of the third generation. Effects however, where not identified in another study with rabbits at similar exposure and at higher exposure levels.

Dicofol is highly toxic to aquatic animals as defined in Global Harmonised System (GHS). It is classified as aquatic acute and chronic category 1 in EU-CLP Regulation.

The lowest LC50 for fish is 0.053 mg/l, the lowest value for crustaceans is 0.06 mg/l (OSPAR 2002) (Ref.11).

The NOEC in a 60 d-fish early life stage test was 4.4 µg/L as well as NOEC for chronic exposure of 4.5 – 9 µg/L. The USEPA RED (1998) (Ref.3) cites effects on the reproductive physiology of the fathead minnow as low as 5 µg/L.

A two generation study by MacLellan et al. (1996) (Ref. 12) showed significantly thinner egg shells at 20 mg/kg of dicofol. Male embryos from females dosed with 5 and 20 mg/kg of dicofol had gonads that were significantly different from the control chicks.

Wiemeyer et al 2001 reported the lowest observed dietary effect concentration for eggshell thinning was 3 mg/kg and the no/observed adverse effect concentration was 1 µg/g. This is slightly lower than the NOEC of 2.5 ppm (2.5 mg/kg) for eggshell thinning in ducks as reported in the original report.

According to the OSPAR document on dicofol (OSPAR, 2002) (Ref.11), the pattern and magnitude of dicofol on eggshell thinning was similar as observed with p,p'-DDE. Schwarzbach et al (1988), cited in OSPAR2002 (Ref.11) showed that dicofol was not metabolised to DDE in birds and therefore concluded that the adverse effect is based on dicofol itself.

In a study with earthworms by Shi et al. (2006) (Ref.13), dicofol significantly inhibited the reproduction ability of earthworms

Lavado et al (2004) (Ref.14) and Thibaut and Porte (2004) (Ref.15) showed that dicofol can interfere with the synthesis of sexhormones in fish microsomes

Haeba et al. (2008) (Ref.16) demonstrated in daphnia that 0.1 mg/L of dicofol resulted in a significant shift of the sex ration in favour of males at 0.1 mg/L. Kojima et al. (2004) (Ref.17) showed estrogenic activity of dicofol in in vitro test.

Endocrine effects were also observed by e.g. Vinggaard et al., 2000 (Ref.18); Okubo et al., 2004 (Ref.19), Hoekstra et al. (2006) (Ref.20), and Thiel et al. (2011) (Ref.21).

[There is sufficient evidence that dicofol meets the criterion on adverse effects.]

There is sufficient evidence that dicofol meets the criterion on adverse effects because:

- *There are animal data showing a potential of dicofol to have adverse effects on human health, including effects on the liver, kidney, adrenal gland and urinary bladder. The no observed adverse effect level (NOAEL) for induction in mice is 2.1 mg/kg bw/day. UNEP/POPS/POPRC.8/INF/13 concluded that based on available data there is no evidence for cardinogenicity of Dicofol, however a recent study (Liu et al.2012) (Ref.8) indicates that dicofol might raise the risk of cancer incidence through effects on frame conformation of proteins, disturbing the physiological function.*
- *A 2-year study with rats, liver, growth, enzyme induction and other changes in the liver, adrenal gland and urinary bladder were observed at doses of 2.5 mg/kg/day, resulting in a limit dose value (ADI) of 0.0022 mg/kg bw day (JMPR 2011) (Ref.9).*
- *In another two-year study on hormonal effects in dogs a NOAEL of 0.22 mg/kg/day has been determined leading to a RfD of 0.0004 mg/kg/day (USEPA RED 1998) (Ref. 3).*
- *A dietary concentration of 7 mg/kg dicofol fed to mice for 3 generations produced defects in 12 days old offspring of the third generation, Effects however, where not identified in another study with rabbits at similar exposure and at higher exposure levels.*
- *Dicofol is highly toxic to aquatic animals as defined in Global Harmonised System (GHS). It is classified as aquatic acute and chronic category 1 in EU CLP Regulation.*
- *The lowest LC50 for fish is 0.053 mg/l, the lowest value for crustaceans is 0.06 mg/l (OSPAR 2002) (Ref.11).*
- *The NOEC in a 60 d-fish early life stage test was 4.4 µg/L as well as NOEC for chronic exposure of 4.5 – 9 µg/L. The USEPA RED (1998) (Ref.3) cites effects on the reproductive physiology of the fathead minnow as low as 5 µg/L.*
- *A two generation study by MacLellan et al. (1996) (Ref. 12) showed significantly thinner egg shells at 20 mg/kg of dicofol. Male embryos from females dosed with 5 and 20 mg/kg of dicofol had gonads that were significantly different from the control chicks.*
- *Wiemeyer et al 2001 reported the lowest observed dietary effect concentration for eggshell thinning was 3 mg/kg and the no/observed adverse effect concentration was 1 µg/g. This is slightly lower than the NOEC of 2.5 ppm (2.5 mg/kg) for eggshell thinning in ducks as reported in the original report.*
- *According to the OSPAR document on dicofol (OSPAR, 2002) (Ref.11), the pattern and magnitude of dicofol on eggshell thinning was similar as observed with p,p'-DDE. Schwarzbach et al (1988), cited in OSPAR2002 (Ref.11) showed that dicofol was not metabolised to DDE in birds and therefore concluded that the adverse effect is based on dicofol itself.*
- *In a study with earthworms by Shi et al. (2006) (Ref.13), dicofol significantly inhibited the reproduction ability of earthworms*
- *Lavado et al. (2004) (Ref.14) and Thibaut and Porte (2004) (Ref.15) showed that dicofol can interfere with the synthesis of sexhormones in fish microsomes*
- *Haeba et al. (2008) (Ref.16) demonstrated in daphnia that 0.1 mg/L of dicofol resulted in a significant shift of the sex ration in favour of males at 0.1 mg/L. Kojima et al. (2004) (Ref.17) showed estrogenic activity of dicofol in in vitro test.*
- *Endocrine effects were also observed by e.g. Vinggaard et al., 2000 (Ref.18); Okubo et al., 2004 (Ref.19), Hoekstra et al. (2006) (Ref.20), and Thiel et al. (2011) (Ref.21).*

[There is no sufficient evidence that dicofol meets the criterion on adverse effects.]

There is no sufficient evidence that dicofol meets the criterion on adverse effects because:

- *UNEP/POPS/POPRC.8/INF/13 concludes that available data there is no evidence for carcinogenicity of dicofol.*
- *Available field data suggest that dicofol does not cause significant adverse effects on avian reproduction and does not present an unreasonable risk to ecosystem.*
- *Metabolism testing effects on adrenal cortical synthesis on dogs, dicofol has a negative effect.*
- *As per the International Agency for Research on Cancer (IARC) classification, dicofol has been classified under group 3.*
- *Carcinogenic bioassays of dicofol were carried out by the National Cancer Institute in rats and mice. No compound-related tumours were observed at either dose.*
- *Dicofol is not classified for any carcinogenic, mutagenic or reprotoxic effects according to regulation (EC) 1272/2008.*
- *Examination of selected liver sections from long term study in mice showed no evidence for carcinogenic effect of dicofol in male mice at doses of 264 and 558 ppm/day.*
- *Various experiments were conducted on test animal on reproductive toxicity of dicofol. No treatment related effects were observed on the number of stillborns, mean litter sizes at birth, sex ratio, viability, clinical signs, or body weight of offspring. No treatment related effects were observed on parameters of reproductive function of performance: length of estrous cycle.*
- *For dicofol, evidence for endocrine disruption is suggested but not definite.*
- *Available field data suggest that dicofol does not pose significant adverse effects on avian reproduction and does not present an unreasonable risk to ecosystem.*
- *- Dicofol is a weak hER agonist due to activity of the achiral p,p' isomer and (-)-o,p' substituted enantiomer and emphasizes the influence of the chemical structure and configuration on biological responses from chiral compounds.*

C. Conclusion

4. [The Committee concluded that dicofol meets the screening criteria specified in Annex D.] [The Committee concluded that dicofol does not meet the screening criteria specified in Annex D.]

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