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

Chemical Review Committee
Eighth meeting
Geneva, 19–23 March 2012
Item 5 (b) (i) of the provisional agenda*

Technical work: review of notifications of final regulatory actions: dicofol

Dicofol

Note by the Secretariat

1. Under Article 5 of the Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade, when the Secretariat has received at least one notification of final regulatory action to ban or severely restrict a chemical from each of two prior informed consent (PIC) regions containing the information required in Annex I to the Convention, it shall forward the notifications and accompanying documentation to the members of the Chemical Review Committee. The Committee shall review the information provided in such notifications and, in accordance with the criteria set out in Annex II to the Convention, recommend to the Conference of the Parties whether the chemical in question should be included in Annex III to the Convention and whether a decision guidance document should be drafted.

2. The Secretariat has received two notifications of final regulatory action for dicofol (CAS No. 115-32-2) that meet the information requirements of Annex I from two PIC regions: Asia (Japan) and Europe (European Union). Summaries of these notifications were included in PIC Circular XXXII of December 2010 and PIC Circular XXXIII of June 2011. The notifications, as received from the notifying countries, are set out in the annex to the present note.

3. The supporting documentation provided by the European Union and Japan is set out in documents UNEP/FAO/RC/CRC.8/4/Add.1 and Add.2, respectively.

* UNEP/FAO/RC/CRC.8/1.

Annex

Notification of final regulatory action for dicofol by the European Union

Notification of final regulatory action for dicofol by Japan

ROTTERDAM CONVENTION

SECRETARIAT FOR THE ROTTERDAM CONVENTION
ON THE PRIOR INFORMED CONSENT PROCEDURE
FOR CERTAIN HAZARDOUS CHEMICALS AND PESTICIDES
IN INTERNATIONAL TRADE

FORM FOR NOTIFICATION
OF FINAL REGULATORY ACTION TO BAN OR SEVERELY RESTRICT A CHEMICAL

Country:

European Union Member States are: Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, United Kingdom

SECTION 1 IDENTITY OF CHEMICAL SUBJECT TO THE FINAL REGULATORY ACTION

1.1	**Common name**	**Dicofol**
1.2	**Chemical name according to an internationally recognized nomenclature (e.g. IUPAC), where such nomenclature exists**	**IUPAC: 2,2,2-trichloro-1,1-bis(4-chlorophenyl)ethanol** **CA: 4-chloro-α-(4-chlorophenyl)-α-(trichloromethyl)benzenemethanol**
1.3	**Trade names and names of preparations**	**Kelthane MF** **Kelthane MF-B**

1.4 Code numbers

1.4.1	CAS number	115-32-2
1.4.2	Harmonized System customs code	2906 29

1.4.3	Other numbers (specify the numbering system)	EINECS: 204-082-0 CIPAC: 123 Combined Nomenclature (CN) code of the European Union: 2906 29 00

1.5 Indication regarding previous notification on this chemical, if any

1.5.1 ☒ This is a first time notification of final regulatory action on this chemical.

1.5.2 ☐ This notification replaces all previously submitted notifications on this chemical.
Date of issue of the previous notification: _____

SECTION 2 FINAL REGULATORY ACTION

2.1 The chemical is: ☒ **banned** **OR** ☐ **severely restricted**

2.2 Information specific to the final regulatory action

2.2.1 Summary of the final regulatory action

It is prohibited to place on the market or use plant protection products containing dicofol. Dicofol is not included in the list of authorised active substances in Annex I to Directive 91/414/EC. Authorisations for plant protection products containing dicofol had to be withdrawn by 30 March 2009.

From 1 October 2008, no authorisations for plant protection products containing dicofol were allowed to be granted or renewed by the Member States and all uses of plant protection products containing dicofol were prohibited as from 30 March 2010.

2.2.2 Reference to the regulatory document, e.g. where decision is recorded or published

Commission Decision 2008/764/EC of 30 September 2008 concerning the non-inclusion of dicofol 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 262, 1.10.2008, p.40-41)

http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:262:0040:0041:EN:PDF

2.2.3 Date of entry into force of the final regulatory action

Complete entry into force of all provisions of Commission Decision 2008/764/EC of 30 September 2008 was 30 March 2010 since all uses of plant protection products containing dicofol were prohibited as from that date at the latest.

2.3 Category or categories where the final regulatory action has been taken

2.3.1 All use or uses of the chemical in your country prior to the final regulatory action

Dicofol is a plant protection product acting as a non-systemic organochlorine acaricide used to control several phytophagous mite pests in tomatoes and cucurbits grown outdoors. It is effective against all stages of mites.

2.3.2 Final regulatory action has been taken for the category ☐ Industrial

Use or uses prohibited by the final regulatory action

Not relevant

Use or uses that remain allowed (only in case of a severe restriction)

Not relevant

2.3.3 Final regulatory action has been taken for the category ☒ Pesticide

Formulation(s) and use or uses prohibited by the final regulatory action

All applications as a plant protection product

Formulation(s) and use or uses that remain allowed
(only in case of a severe restriction)

Not relevant

2.4 Was the final regulatory action based on a risk or hazard evaluation?

☒ **Yes**

☐ **No** (If no, you may also complete section 2.5.3.3)

2.4.1 If yes, reference to the relevant documentation, which describes the hazard or risk evaluation

A risk assessment was carried out on the basis of Directive 91/414/EEC, 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.

This resulted in several documents, including:

European Commission (2008): Review report for the active substance dicofol finalised in the Standing Committee on the Food Chain and Animal Health at its meeting on 20 May 2008 (SANCO/1356/08- rev.0, 25 April 2008).

http://ec.europa.eu/food/plant/protection/evaluation/existactive/dicofol.pdf

Spain (2006): Monograph prepared in the context of the inclusion of the following active Substance in Annex I of the Council Directive 91/414/EEC – Dicofol. Volume 1 – Report and proposed decision.

2.4.2 Summary description of the risk or hazard evaluation upon which the ban or severe restriction was based.

2.4.2.1 Is the reason for the final regulatory action relevant to human health? ☒ Yes ☐ No

If yes, give summary of the hazard or risk evaluation related to human health, including the health of consumers and workers

Based on the available data, health concerns were raised about the operator, worker and consumer exposure to dicofol. There are clear indications that it may be expected that the substance has harmful effects on human health and in particular on both operators and workers, because the exposure is greater than 100% of the AOEL. The Draft Assessment Report underlined that there was a considerable risk for operators using and applying dicofol and for workers re-entering a field treated with dicofol.

The review report also stressed that there was substantial lack of data to assess consumer exposure to dicofol.

Expected effect of the final regulatory action

Reduction of risk from the use of plant protection products.

2.4.2.2 Is the reason for the final regulatory action relevant to the environment? ☒ Yes ☐ No

If yes, give summary of the hazard or risk evaluation related to the environment

Based on the available data, environmental concerns were raised about the potential of dicofol for bioaccumulation in aquatic species and the long-term risk to birds and mammals. The Draft Assessment Report identified unacceptable long term risk for herbivorous, insectivorous and vermivorous birds. It also

mentioned that vermivorous mammals could be exposed to unacceptable risk due to secondary poisoning. The review report also underlined that there was a substantial lack of data to assess the risk to birds, aquatic organisms, mammals and arthropods exposed to dicofol.

Expected effect of the final regulatory action

Reduction of risk from the use of plant protection products.

2.5 Other relevant information regarding the final regulatory action

2.5.1 Estimated quantity of the chemical produced, imported, exported and used

	Quantity per year (MT)	Year
produced	No information	
imported	No information	
exported	No information	
used	No information	

2.5.2 Indication, to the extent possible, of the likely relevance of the final regulatory action to other states and regions

Similar health and environmental problems are likely to be encountered in other countries where the substance is used, particularly in developing countries.

2.5.3 Other relevant information that may cover:

2.5.3.1 Assessment of socio-economic effects of the final regulatory action

2.5.3.2 Information on alternatives and their relative risks, e.g. IPM, chemical and non-chemical alternatives

2.5.3.3 Basis for the final regulatory action if other than hazard or risk evaluation

2.5.3.4 Additional information related to the chemical or the final regulatory action, if any

Dicofol has been identified as active substance used in biocidal products pursuant to Directive 98/8/EC, but no notification has been submitted for that active substance. Therefore, all uses of biocidal products containing dicofol have been prohibited as from 1 September 2006 pursuant to Commission Regulation (EC) No 2032/2003 (Official Journal of the European Union L 307, 24.11.2003, p. 1) as amended by Commission Regulation (EC) No 1048/2005 (Official Journal of the European Union L 178, 9.7.2005, p. 1).

SECTION 3 PROPERTIES

3.1 Information on hazard classification where the chemical is subject to classification requirements

International classification systems **e.g. WHO, IARC, etc.**	**Hazard class**
IARC	Group 3

Other classification systems **e.g. EU, USEPA**	**Hazard class**
Classification of the EU in accordance with Council Directive 67/548/EEC	Xn: Harmful R21/22: Harmful in contact with skin and if swallowed Xi: Irritant R38: Irritating to skin R43: May cause sensitization by skin contact N: Dangerous for the environment R50/53: 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 of the European Parliament and of the Council	Acute Tox. 4* - H312: Harmful in contact with skin Acute Tox. 4* - H302: Harmful if swallowed Skin Irrit. 2 – H315: Causes skin irritation Skin Sens. 1 – H317: May cause an allergic skin reaction

	Aquatic Acute 1 – H400: Very toxic to aquatic life Aquatic Chronic 1 – H410: Very toxic to aquatic life with long lasting effects

3.2 Further information on the properties of the chemical

3.2.1 Description of physico-chemical properties of the chemical

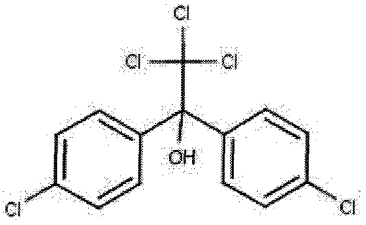
Minimum Purity: 950 g/kg

FAO Specification: Active ingredient: isomer content (p,p'+o,p') 950 g/kg minimum

Molecular Formula: $C_{14}H_9Cl_5O$

Molecular Mass: 370.5

Structural formula (p,p'-dicofol) :



Appearance: White powder (p,p'-dicofol/o,p'-dicofol)
Viscous red-brown liquid (technical kelthane)

Melting Point: 73.5-123.5°C (p,p'-dicofol/o,p'-dicofol)
Not applicable (technical dicofol)

Boiling Point: Decomposition was observed before boiling occurred

Vapour pressure: 5.33 $x10^{-5}$ (p,p'-dicofol)
2.83 $x10^{-5}$ (o,p'-dicofol)

Volatility:

Henry's Law Constant: 0.024 Pa.m³/mol at 25°C (p,p'-dicofol)
0.038 Pa.m³/mol at 25°C (o,p'-dicofol)

Solubility in Water: 0.45 mg/l at 25°C (p,p'-dicofol)
0.14 mg/l at 20°C (o,p'-dicofol)

Solubility in Organic Solvents: at 20°C
n-Heptane: >333 g/l
Xylene: >1200 g/l

	1,2-dichloroethane: >1400 g/l
	Methanol: 700 g/l
	Acetone:1100 g/l
	Ethyl acetate: 550 g/l
Partition co-efficient:	log K_{ow} = 4.08 (p,p'-dicofol)
	log K_{ow} = 4.32 (o,p'-dicofol)

Reference

Spain (2006): Monograph prepared in the context of the inclusion of the following active substance in Annex 1 of Council Directive 91/414/EEC - Dicofol. Volume I: Report and Proposed Decision.

3.2.2 Description of toxicological properties of the chemical

Absorption, Distribution, Excretion and Metabolism in Mammals:

Dicofol is almost completely and rapidly absorbed, with 85-123% of radiolabel detected in excreta 48 hours after dosing. Once absorbed, dicofol is rapidly and widely distributed, with the fat, adrenals and gonads having the highest content. 10 days post dosing, 22% of radiolabelled dose was still present in fat. Dicofol is metabolised to a more polar metabolite. Excretion of dicofol is mainly via the faeces (60-65%), with amounts also excreted via urine (18-19%).

Acute Toxicity:

LD50 (rat, oral, male and female)	595-578 mg/kg bw
LD50 (rat, dermal)	>5000 mg/kg bw
LC50 (rat, inhalation)	>5.0 mg/l

Irritation and Sensitisation:

Dicofol was irritating to the skin but not the eyes of New Zealand white rabbits.

Dicofol induced delayed hypersensitivity in guinea pigs in a modified Buehler skin sensitisation test.

Subchronic Toxicity:

Rat (oral, 90 days): NOAEL = 0.64 mg/kg bw/day for males and 0.78 mg/kg bw/day for females (increased liver weights, hepatocellular hypertrophy).

Mice (oral, 90 days) NOAEL = 1.6 mg/kg bw/day (decreased bodyweights, increased liver weights)

Dog (oral, 90 days): NOAEL = 0.3 mg/kg bw/day (Increases in liver weights, hepatocellular hypertrophy, decreases in cortisol response to ACTH and hypertrophy of adrenal cortex with cortical vacuolation).

Genotoxicity:

In vitro

Dicofol was not genotoxic in a bacterial gene mutation assay with *Salmonella typhimurium* with added S9 metabolic activity, however, inconclusive results were obtained without S9.

Negative results were obtained in a mammalian gene mutation study in Chinese Hamster Ovary HPRT cells, both with and without S9.

Dicofol was also negative in a mammalian chromosome aberration test in CHO cells, both with and without S9.

It was also negative in a mammalian DNA damage unscheduled DNA synthesis assay in rat hepatocytes.

In vivo

Dicofol was negative in a chromosome aberration study in rat bone marrow cells.

Carcinogenicity:

Rat:

Rats were administered dicofol for 24 months. Changes in the liver and adrenal glands were noted. No increase in tumour formation occurred. A NOAEL of 0.22 mg/kg bw/day has been identified from this study.

Reproductive Toxicity:

Rat (diet, 2-generation study): Parental NOAEL = 0.4 mg/kg bw/day (decrease in bodyweight and bodyweight gain, changes in liver weight and hepatocytes hypertrophy).

Offspring NOAEL = 1.7 mg/kg bw/day (changes in liver weight and hepatocytes hypertrophy).

Rat (diet, developmental study): Parental NOAEL = 2.5 mg/kg bw/day (decreased bodyweight and hepatocytes hypertrophy).

Offspring NOAEL = 25 mg/kg bw/day (no effects).

Rabbit (diet, developmental toxicity):	Parental NOAEL: 0.4 mg/kg bw/day (decreased bodyweight and histopathological findings). Offspring NOAEL: 4 mg/kg bw/day (reduction in neonatal bodyweight).

Neurotoxicity:

Rats (oral, acute): NOAEL = 15 mg/kg bw/day (reduced bodyweights, increase in incidence of ataxia, other signs of sensorimotor dysfunction and decreased motor activity).

Rats (chronic, oral): NOAEL = 0.3 mg/kg bw/day (parameters of Functional Observational Battery (FOB) affected, altered organ weights and reduced bodyweights, feed consumption values and motor activity).

Safety Values:

Acceptable Daily Intake (ADI):	0.0022 mg/kg bw/day
Acceptable Operator Exposure Level (AOEL):	0.003 mg/kg bw/day
Acute Reference Dose (ARfD):	0.15 mg/kg bw/day

Reference

Spain (2006): Monograph prepared in the context of the inclusion of the following active substance in Annex 1 of Council Directive 91/414/EEC - Dicofol. Volume I: Report and Proposed Decision.

3.2.3 Description of ecotoxicological properties of the chemical

Air

Limited data are available on the rate and route of degradation of dicofol in air. However a vapour pressure of 5.33 $x10^{-5}$ at 25°C indicates that dicofol will not significantly partition into air. Based on the Atkinson estimation, the degradation half life of dicofol in air is estimated to be 3.1 days.

Water

Both isomers of dicofol are hydrolysed. The hydrolysis half life for p,p'-dicofol is 85 days at pH 5, 64-99 hours at pH 7 and 0.14 hours at pH 9. the hydrolysis half life for o,p'-dicofol is 47 days at pH5, 8 hours at pH 7 and 0.15 hours at pH 9. The aqueous photolysis half lives for p,p'-dicofol and o,p'-dicofol are 243 and 28 days, respectively.

In water/sediment systems both isomers of dicofol are rapidly degraded with first-order DT50 values in the water phase of 6 to 9 hours for p,p'-dicofol and 1 hour for o,p'-dicofol.

Soil

o,p'-Dicofol degraded more rapidly than p,p'-dicofol in laboratory conditions. In a US silt loam soil at 25°C, the DT50 was 31.5 days for p,p'-dicofol and 8.5 days for o,p'-dicofol. Degradation under aerobic conditions was also investigated in three European soils at 20°C; a DT50 of 204 days was determined for p,p'-dicofol and 18 and 468 days for o,p'-dicofol. No degradation was observed in two soils for p,p'-dicofol and in one soil for o,p'-dicofol. Photolysis is a significant pathway for p,p'-dicofol, which is more slowly degraded by other processes.

Adsorption Koc values ranged from 5000 to 6983 ml/g for p,p'-dicofol and from 14780 to 25701 ml/g for o,p'-dicofol, both in four soil types. Therefore, both isomers were considered immobile in soil.

Ecotoxicology

- Bacteria

The effect of dicofol on soil micro-organisms has not been appropriately investigated. The effect of dicofol in activated sludge was tested at 0.5 mg/l (due to its low solubility in water). The respiration inhibition was lower than 5%, therefore, no adverse effects on sewage treatment are expected.

- Terrestrial Plants

Crop species, grass leaf species, broad leaf species and broad leaf weed species were tested in pre and post emergence tests. Plants were exposed at two application rates of 16.8 and 600 g dicofol/ha. No adverse effects higher than 34% (seedling emergence) and 22% (post emergence) at the maximum rate were observed in any of the tested plants. The risk to non-crop plants outside the treatment area caused by spray drift is considered acceptable for an application rate of 600 g dicofol/ha.

- Terrestrial birds

Bobwhite quail (*Colinus virginianus*): NOAEC not provided (one generation reproductive study).

Mallard duck (*Anas platyrhynchos*): NOEC = 0.26 mg/kg bw/day (one generation reproductive study.

- Honey Bee

Honey bee (*Apis mellifera*): 48 hour LD50 (contact) = 36.3 µg/bee

Honey bee (*Apis mellifera*): 48 hour LD50 (oral) = 57.1 µg/bee

- Earthworm

Earthworm (*Eisenia foetida*): 14 day LC50 = >354 mg/kg soil

Earthworm (*Eisenia foetida*): 14 day LC50 = >227 mg/kg soil

Earthworm (*Eisenia foetida*): 56 day NOEC = 2.4 mg/kg soil

- Arthropod Species

Cereal aphid parasitoid (*Aphidius rhopalosiphi*): Mortality = 46.6 g/ha

Predatory mite (*Typhlodromus pyri*): Mortality = 6.78 g/ha

- Freshwater Species

Fish: Acute

Rainbow trout (*Oncorhynchus mykiss*): 96 hour EC50 (mortality) = 0.11 mg/l

Rainbow trout (*Oncorhynchus mykiss*): 96 hour EC50 (mortality) = 2.29 mg/l (metabolite p,p'-DCBP)

Rainbow trout (*Oncorhynchus mykiss*): 96 hour EC50 (mortality) = 0.243 mg/l (metabolite p,p'-DFW-152)

Fish: Chronic

Fathead minnow (*Pimephales promelas*): 290 day NOEC (growth) = 0.0045 mg/l

Rainbow trout (*Oncorhynchus mykiss*): 99 day NOEC (growth) = 0.009 mg/l

- Marine Species

No data

- Bioconcentration

A BCF of 25000 indicates that dicofol is expected to bioaccumulate in fish. The depuration rate (CT90) is 110 days, indicating slow clearance.

Reference

Spain (2006): Monograph prepared in the context of the inclusion of the following active substance in Annex 1 of Council Directive 91/414/EEC - Dicofol. Volume I: Report and Proposed Decision.

SECTION 4 DESIGNATED NATIONAL AUTHORITY

Institution	European Commission
Address	B-1049 Brussels Belgium
Name of person in charge	Juergen Helbig
Position of person in charge	Policy Officer
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Telefax	+322 296 7617
E-mail address	Juergen.Helbig@ec.europa.eu

Date, signature of DNA and official seal: 11.4.11

Commission Européenne
D.G. ENV

ROTTERDAM CONVENTION

SECRETARIAT FOR THE ROTTERDAM CONVENTION
ON THE PRIOR INFORMED CONSENT PROCEDURE
FOR CERTAIN HAZARDOUS CHEMICALS AND PESTICIDES
IN INTERNATIONAL TRADE

UNEP

FORM FOR NOTIFICATION
OF FINAL REGULATORY ACTION TO BAN OR SEVERELY RESTRICT A CHEMICAL

Country: JAPAN

SECTION 1 IDENTITY OF CHEMICAL SUBJECT TO THE FINAL REGULATORY ACTION

1.1	**Common name**	Dicofol, also known as Kelthane
1.2	**Chemical name according to an internationally recognized nomenclature (e.g. IUPAC), where such nomenclature exists**	2,2,2-Trichloro-1,1-bis(4-chlorophenyl)ethanol
1.3	**Trade names and names of preparations**	Dicofol, Kelthane

1.4 Code numbers

1.4.1	CAS number	115-32-2
1.4.2	Harmonized System customs code	2906.29
1.4.3	Other numbers (specify the numbering system)	

1.5 Indication regarding previous notification on this chemical, if any

1.5.1 ☐ This is a first time notification of final regulatory action on this chemical.

1.5.2 ☒ This notification replaces all previously submitted notifications on this chemical.
Date of issue of the previous notification: _December 12, 2005

SECTION 2 FINAL REGULATORY ACTION

2.1 The chemical is: ☒ **banned** **OR** ☐ **severely restricted**

2.2 Information specific to the final regulatory action

2.2.1 Summary of the final regulatory action

This chemical is prohibited to sale and use as agricultural chemical.

This chemical is designated as Class I Specified Chemical Substances. It is prohibited to manufacture, import or use this chemical substance.

2.2.2 Reference to the regulatory document, e.g. where decision is recorded or published

Agricultural Chemicals Regulation Law and Ministerial ordinance of Agriculture, Forestry, and Fisheries,Ministerial Order of March 5, 2003

The Chemical Substances Control Law (CSCL) and its Enforcement Order

2.2.3 Date of entry into force of the final regulatory action

Ministerial ordinance of Agriculture, Forestry, and Fishries: 1st April, 2010
The Chemical Substances Control Law (CSCL) and its Enforcement Order: 1st, April, 2005

2.3 Category or categories where the final regulatory action has been taken

2.3.1 All use or uses of the chemical in your country prior to the final regulatory action

As agricultural chemical, there is no utilization over the last 5 years

2.3.2 Final regulatory action has been taken for the category ☒ Industrial

Use or uses prohibited by the final regulatory action

All uses

Use or uses that remain allowed (only in case of a severe restriction)

2.3.3 Final regulatory action has been taken for the category ☒ Pesticide

Formulation(s) and use or uses prohibited by the final regulatory action

Agricultural uses

Formulation(s) and use or uses that remain allowed
(only in case of a severe restriction)

2.4 **Was the final regulatory action based on a risk or hazard evaluation?**

☒ **Yes**

☐ **No** (If no, you may also complete section 2.5.3.3)

2.4.1 If yes, reference to the relevant documentation, which describes the hazard or risk evaluation

2.4.2 Summary description of the risk or hazard evaluation upon which the ban or severe restriction was based.

2.4.2.1 Is the reason for the final regulatory action relevant to human health?

☒ Yes

☐ No

If yes, give summary of the hazard or risk evaluation related to human health, including the health of consumers and workers

It is based on the result that existing toxic data were evaluated synthetically.

Expected effect of the final regulatory action

Reduction of human exposure to this substance as its use is phased out.

2.4.2.2 Is the reason for the final regulatory action relevant to the environment?

☐ Yes

☐ No

If yes, give summary of the hazard or risk evaluation related to the environment

Expected effect of the final regulatory action

2.5 Other relevant information regarding the final regulatory action

2.5.1 Estimated quantity of the chemical produced, imported, exported and used

	Quantity per year (MT)	Year
produced		
imported		
exported		
used		

2.5.2 Indication, to the extent possible, of the likely relevance of the final regulatory action to other states and regions

2.5.3 Other relevant information that may cover:

2.5.3.1 Assessment of socio-economic effects of the final regulatory action

2.5.3.2 Information on alternatives and their relative risks, e.g. IPM, chemical and non-chemical alternatives

2.5.3.3 Basis for the final regulatory action if other than hazard or risk evaluation

2.5.3.4 Additional information related to the chemical or the final regulatory action, if any

SECTION 3 PROPERTIES

3.1 Information on hazard classification where the chemical is subject to classification requirements

International classification systems **e.g. WHO, IARC, etc.**	**Hazard class**

Other classification systems **e.g. EU, USEPA**	**Hazard class**

3.2 Further information on the properties of the chemical

3.2.1 Description of physico-chemical properties of the chemical

Reference

3.2.2 Description of toxicological properties of the chemical

Reference

3.2.3 Description of ecotoxicological properties of the chemical

Reference

SECTION 4 DESIGNATED NATIONAL AUTHORITY

Institution	Global Environment Division, International Cooperation Bureau, Ministry of Foreign Affairs of Japan
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Position of person in charge	Senior Coordinator
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Telefax	+81-3-5501-8244
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Date, signature of DNA and official seal: 25 June 2010

PLEASE RETURN THE COMPLETED FORM TO:

Secretariat for the Rotterdam Convention
Plant Protection Service,
Plant Production and Protection Division, FAO
Viale delle Terme di Caracalla
00100 Rome, Italy

Tel: (+39 06) 5705 2188
Fax: (+39 06) 5705 6347
E-mail: pic@pic.int

OR

Secretariat for the Rotterdam Convention
UNEP Chemicals

11-13, Chemin des Anémones
CH – 1219 Châtelaine, Geneva, Switzerland

Tel: (+41 22) 917 8296
Fax: (+41 22) 917 8082
E-mail: pic@pic.int

Definitions for the purposes of the Rotterdam Convention according to Article 2:

(a) '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;

(b) 'Banned chemical' means a chemical all uses of which within one or more categories have been prohibited by final regulatory action, in order to protect human health or the environment. It includes a chemical that has been refused approval for first-time use or has been withdrawn by industry either from the domestic market or from further consideration in the domestic approval process and where there is clear evidence that such action has been taken in order to protect human health or the environment;

(c) 'Severely restricted chemical' means a chemical virtually all use of which within one or more categories has been prohibited by final regulatory action in order to protect human health or the environment, but for which certain specific uses remain allowed. It includes a chemical that has, for virtually all use, been refused for approval or been withdrawn by industry either from the domestic market or from further consideration in

Information submitted to Secretariat of the Rotterdam Convention From Japan

Information on alpha-HCH, beta-HCH, chlordecone, dicofol, lindane and pentachlorobenzene

January 18, 2011

Information of Final Regulatory Measures from Japan requested by the E-mail on 09, Dec, 2010	Information submitted from Japan
(1) Section 3: information of Final Regulatory Measures from Japan on alpha-HCH, beta-HCH, chlordecone, dicofol, lindane and pentachlorobenzene	- Item 3.1: Other classification systems alpha-HCH Japan CSCL : Class I Specified Chemical Substance Japan Agricultural Chemicals Regulation Law : The substance prohibited to sale and use as agricultural chemical beta-HCH Japan CSCL : Class I Specified Chemical Substance Japan Agricultural Chemicals Regulation Law : The substance prohibited to sale and use as agricultural chemical chlordecone Japan CSCL : Class I Specified Chemical Substance Japan Agricultural Chemicals Regulation Law : The substance prohibited to sale and use as agricultural chemical dicofol Japan CSCL : Class I Specified Chemical Substance Japan Agricultural Chemicals Regulation Law : The substance prohibited to sale and use as agricultural chemical lindane Japan CSCL : Class I Specified Chemical Substance Japan Agricultural Chemicals Regulation Law : The substance prohibited to sale and use as agricultural chemical pentachlorobenzene Japan CSCL : Class I Specified Chemical Substance Japan Agricultural Chemicals Regulation Law : The substance prohibited to sale and use as agricultural chemical - For other items in section3.1 not filled in Japan's FRM notifications, Japan does not have information for these columns.
(2) Section 3.2.3: Description of ecotoxicological properties of the chemical	alpha-HCH : No information available beta-HCH : No information available chlordecone : No information available dicofol : No information available lindane : No information available pentachlorobenzene : No information available

Information submitted to Secretariat of the Rotterdam Convention From Japan

Information on Dicofol

May 27, 2011

Information requested by the E-mail on 15, April, 2011	Information submitted from Japan
(1) Section 3.2.1 ・ Description of physico-chemical properties of the chemical ・ Reference Source: Syracuse Research Corporation (SRC) http://www.syrres.com/what-we-do/databaseforms.aspx?id=386	CAS Number : 000115-32-2 Chem Name : DICOFOL Mol Formula: C14H9Cl5O Mol Weight : 370.49 Melting Pt : 77.5 deg C Boiling Pt : 193 deg C at 3.60E+02 mm Hg Water Solubility: Value : 0.8 mg/L Temp : 25 deg C Type : EXP Ref : TOMLIN,C (1997) Log P (octanol-water): Value : 5.02 Type : EXP Ref : SAITO,H ET AL. (1993) Vapor Pressure: Value : 3.98E-007 mm Hg Temp : 25 deg C Type : EXP Ref : TOMLIN,C (1997) pKa Dissociation Constant: Value : Temp : Type : Ref : Henry's Law Constant: Value : 2.42E-007 atm-m3/mole Temp : 25 deg C Type : EST Ref : VP/WSOLAtmospheric OH Rate Constant: Value : 3.43E-012 cm3/molecule-sec Temp : 25 deg C Type : EST Ref : MEYLAN,WM & HOWARD,PH (1993)

(2) Section 3.2.2 · Description of toxicological properties of the chemical · Reference Foss,J.(1992) Acute neurotoxicity study of dicofol administered orally via gavage to Crl:CDBR VAF/Plus Rats: Final report :Lab project NO: 018-018:92RC-005.Unpblished report from Argus Research Labs.,Inc Hazelton, G.A.&Harris, J.C.(1989) Dicofol (Kelthane technical miticide):24- Month dietary chronic/oncogenic study in rats Unpublished report No.8R-1990 from Rohm and hass Company, Spring House, PA, USA Solomon,H.M.&Kulwich, B.A. (1991)Dicofol: Two-generation study in rats. Unpublished report No.89R-028 from Rohm and Haas Company, Spring House, PA , USA. DiDonato,J.J., Steigerwalt,P.B.,&Longavre, S.L.(1987)o,p'-Dicofol and p,P'-dicofol:Kinetic study in female rats. Unpublished report No86R-173 from Rohm and Haas Company, Spring House, PA , USA. Krzwickiet al.(1985),Onisi(1989),R&H(1987),deGroot(1974)	(ADI) 2 μ g/kg/day (Rat, 24-month oral repeated dose toxicity) hypertrophy of liver cell, adrenal cortex cell vacuolation at 2.2 mg/kg/day (Rat, Two-Generation Reproduction Toxicity Study) ovary stromal cell vacuolation at 250 ppm(P1), 25 ppm(P2), decreased body weights at birth and decreased viability index at 250 ppm(F1) and 125 ppm(F2) (Rat, half life time) male: 1.5-4 days, female: 4-7 days (Rat, Mouse, Rabbit, Acute Oral Toxicity) Bad nervous condition including decrease in spontaneous activity, staggering gait, drowsiness, trembling
(3) Section 3.2.3 · Description of ecotoxicological properties of the chemical · Reference IUCLID	(IUCLID) NOEC Oral: 160 mg/kg/day (Coturnix coturnix japonica) NOEC Oral: 120 ppm (Colinnus virginianus) NOEC Oral: 0.5 ppm (Anas platyrhynchas)