#### COMMISSION IMPLEMENTING DECISION

#### of 10 October 2018

laying down the final import response on behalf of the Union concerning the future import of certain chemicals pursuant to Regulation (EU) No 649/2012 of the European Parliament and of the Council and amending Commission Implementing Decision C(2016) 747

(2018/C 376/06)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) No 649/2012 of the European Parliament and of the Council of 4 July 2012 concerning the export and import of hazardous chemicals (¹), and in particular the second subparagraph of Article 13(1) thereof,

After consulting the Committee established by Article 133 of Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (²),

#### Whereas:

- (1) The Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade ('the Convention') is implemented by Regulation (EU) No 649/2012. In accordance with that Regulation, the Commission is to provide the Secretariat of the Convention with final or interim import responses on behalf of the Union concerning the future import of all chemicals that are subject to the Prior Informed Consent procedure (the 'PIC procedure').
- (2) At its eighth meeting, held in Geneva from 24 April to 5 May 2017, the Conference of the Parties to the Convention agreed to list certain chemicals in Annex III to the Convention with the effect that they became subject to the PIC procedure. A decision guidance document for each chemical was sent to the Commission on 15 September 2017 with a request for a decision regarding future import of the chemical.
- (3) Carbofuran has been added to Annex III to the Convention as a pesticide. The placing on the market and use of carbofuran as a component of plant protection products are prohibited under Regulation (EC) No 1107/2009 of the European Parliament and of the Council (3). Furthermore, the placing on the market and use of carbofuran as a component of biocidal products are prohibited under Regulation (EU) No 528/2012 of the European Parliament and of the Council (4). Therefore, consent under the Rotterdam Convention should not be given to the future import of carbofuran to the Union.
- (4) Trichlorfon has been added to Annex III to the Convention as a pesticide. The placing on the market and use of trichlorfon as a component of plant protection products are prohibited under Regulation (EC) No 1107/2009. Furthermore, the placing on the market and use of trichlorfon as a component of biocidal products are prohibited under Regulation (EU) No 528/2012. Therefore, consent under the Convention should not be given to the future import of trichlorfon to the Union.
- (5) Short-chain chlorinated paraffins (SCCPs) have been added to Annex III to the Convention as industrial chemicals. The production, placing on the market and use of SCCPs are prohibited, subject to specific derogations, under Regulation (EC) No 850/2004 of the European Parliament and of the Council (5). Therefore, consent under the Convention should be given subject to specified conditions.

<sup>(1)</sup> OJ L 201, 27.7.2012, p. 60.

<sup>(2)</sup> OJ L 396, 30.12.2006, p. 1.

<sup>(\*)</sup> Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC (OJ L 309, 24.11.2009, p. 1).

<sup>(4)</sup> Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products (OJ L 167, 27.6.2012, p. 1).

<sup>(5)</sup> Regulation (EC) No 850/2004 of the European Parliament and of the Council of 29 April 2004 on persistent organic pollutants and amending Directive 79/117/EEC (OJ L 158, 30.4.2004, p. 7).

- (6) Tributyltin compounds have been added to Annex III to the Convention as industrial chemicals. The placing on the market and use of tributyltin compounds as industrial chemicals are allowed, subject to compliance with the conditions set out in Regulation (EC) No 1907/2006, in particular the restriction set out in Annex XVII to that Regulation on the manufacture, placing on the market and use of organostannic compounds. Therefore, consent under the Convention should be given subject to those conditions.
- (7) The placing on the market and use of ethylene oxide as a component in plant protection products are prohibited under Regulation (EC) No 1107/2009. The making available on the market and use of ethylene oxide as a component in biocidal products in accordance with Regulation (EU) No 528/2012 are only allowed with regard to certain products pursuant to Commission Delegated Regulation (EU) No 1062/2014 (¹). According to Article 89(2) of Regulation (EU) No 528/2012 Member States can still decide whether and under which conditions such products are to be authorised in their territory.
- (8) After the adoption of the import response for ethylene oxide laid down in Annex II to Commission Implementing Decision C(2016) 747 (²) there have been some regulatory developments in the Member States with regard to the making available on the market and use of ethylene oxide. Therefore, Implementing Decision C(2016) 747 should be amended accordingly,

HAS DECIDED AS FOLLOWS:

#### Article 1

The import responses for carbofuran, trichlorfon, short-chain chlorinated paraffins and tributyltin compounds are set out in Annex I.

### Article 2

Annex II to Implementing Decision C(2016) 747 is replaced by Annex II to this Decision.

Done at Brussels, 10 October 2018.

For the Commission

Karmenu VELLA

Member of the Commission

<sup>(</sup>¹) Commission Delegated Regulation (EU) No 1062/2014 of 4 August 2014 on the work programme for the systematic examination of all existing active substances contained in biocidal products referred to in Regulation (EU) No 528/2012 of the European Parliament and of the Council (OJ L 294, 10.10.2014, p. 1).

<sup>(2)</sup> Commission Implementing Decision C(2016) 747 of 11 February 2016 adopting Union import decisions for certain chemicals pursuant to Regulation (EU) No 649/2012 of the European Parliament and of the Council and amending Commission Decisions 2005/416/EC and 2009/966/EC (OJ C 61, 17.2.2016, p. 5).

# ANNEX I

### Import response for carbofuran

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Co	и	nı	r١	•

### **European Union**

SECTION 1	IDENTITY OF CHE	MICAL
1.1	Common name	Carbofuran
1.2	CAS number	1563-66-2
1.3	Category	☑ Pesticide
		☐ Industrial
		☐ Severely hazardous pesticide formulation
SECTION 2	INDICATION REG	ARDING PREVIOUS RESPONSE, IF ANY
2.1		me import response for this chemical in the country.
2.2		cation of a previous response.  f the previous response:
SECTION 3	RESPONSE REGA	RDING FUTURE IMPORT
⊠ Final decis	sion (Fill in section 4	below) OR
SECTION 4	FINAL DECISION,	PURSUANT TO NATIONAL LEGISLATIVE OR ADMINISTRATIVE MEASURES
4.1	No consent to	import
	Is the import of	the chemical from all sources simultaneously prohibited? $\ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \$
	Is domestic pro	duction of the chemical for domestic use simultaneously prohibited? ☒ Yes ☐ No

4.2		Consent to import		
4.3		Consent to import only subject to specified conditions		
		The specified conditions are:		
		Are the conditions for import of the chemical the same for all sources of import?	☐ Yes	□No
		Are the conditions for domestic production of the chemical for domestic use the same as for all imports?	☐ Yes	□No
4.4		National legislative or administrative measure upon which the final decision	is based	t
		Description of the national legislative or administrative measure:		
		In the Union, it is prohibited to place on the market or use plant protection carbofuran, since that active substance has not been approved under Regulation of the European Parliament and of the Council of 21 October 2009 concerning protection products on the market and repealing Council Directives 79/117/EE (OJ L 309, 24.11.2009, p. 1).	(EC) No the placir C and 9	1107/2009 ng of plant 1/414/EEC
		Furthermore, it is prohibited to make available on the market or use biocidal carbofuran, since that active substance has not been approved pursuant. No 528/2012 of the European Parliament and of the Council of 22 May 2012 con available on the market and use of biocidal products (OJ L 167, 27.6.2012, p. 1).	to Regula	ation (EU)
SECTION 5	IN	TERIM RESPONSE		
5.1		No consent to import		
		Is the import of the chemical from all sources simultaneously prohibited?	☐ Yes	□No
		Is domestic production of the chemical for domestic use simultaneously prohibited?	☐ Yes	□No
5.2		Consent to import		
5.3		Consent to import only subject to specified conditions		
		The specified conditions are:		
		Are the conditions for import of the chemical the same for all sources of import?	☐ Yes	□No
		Are the conditions for domestic production of the chemical for domestic use the same as for all imports?	☐ Yes	□No
5.4		Indication of active consideration in order to reach a final decision		
		Is a final decision under active consideration?	☐ Yes	□No
5.5		Information or assistance requested in order to reach a final decision		
		The following additional information is requested from the Secretariat:		

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The folio action:	wing additional informati	on is requested from the country that not	ified the final regul	latory
The follo	owing assistance is reque	ested from the Secretariat in evaluating th	ie chemical:	
SECTION 6 RELEVANT	ADDITIONAL INFORMA	ATION, WHICH MAY INCLUDE:		
Is this chemical currently regist	ered in the country?		☐ Yes	⊠ No
Is this chemical manufactured i	in the country?		☐ Yes	⊠ No
If yes to either one of these	questions:			
Is this intended for domestic us	se?		☐ Yes	□No
Is this intended for export?			☐ Yes	□No
Other remarks				
Acute Toxicity 2* - H 330 — F Aquatic Acute 1 - H 400 — V Aquatic Chronic 1 - H410 — V (* = This classification shall be	ery toxic to aquatic life. Very toxic to aquatic life			
SECTION 7 DESIGNATE	ED NATIONAL AUTHOR	ITY		
Institution	European Commi	ssion, DG Environment		
Address	Rue de la Loi 200	), 1049 Brussels, Belgium		
Name of person in charge	Dr Juergen Helbiç	3		
Position of person in charge	International Cher	nicals Policy Coordinator		
Telephone	+32 22988521			
Telefax	+32 22967616			
Email address	Juergen.Helbig@e	ec.europa.eu		
Date, signature of DNA and off	ficial seal:			
PLEASE RETURN THE COMP	PLETED FORM TO:			
Secretariat for the Rotterdam C Food and Agriculture Organizat		Secretariat for the Rotterdam Con United Nations Environment	vention	

Secretariat for the Hotterdam Convention Food and Agriculture Organization of the United Nations (FAO) Viale delle Terme di Caracalla 00100 Rome ITALIA

Tel. +39 0657053441 Fax +39 0657056347 Email: pic@pic.int Secretariat for the Rotterdam Convention United Nations Environment Programme (UNEP) 11-13, Chemin des Anémones CH-1219 Châtelaine, Geneva SWITZERLAND

Tel. +41 229178177 Fax +41 229178082 Email: pic@pic.int

OR

# Import response for trichlorfon

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### **European Union**

SECTION 1	IDENTITY OF CHE	MICAL		
1.1	Common name	Trichlorfon		
1.2	CAS number	52-68-6		
1.3	Category	<ul> <li>✓ Pesticide</li> <li>☐ Industrial</li> <li>☐ Severely hazardous pesticide formulation</li> </ul>		
SECTION 2	INDICATION REGA	ARDING PREVIOUS RESPONSE, IF ANY		
2.1 2.2	☐ This is a modifi	me import response for this chemical in the country. cation of a previous response. f the previous response:		
SECTION 3	RESPONSE REGA	RDING FUTURE IMPORT		
⊠ Final decis	sion (Fill in section 4	below) OR	below)	
SECTION 4	FINAL DECISION,	PURSUANT TO NATIONAL LEGISLATIVE OR ADMINISTRATIVE	: MEASUR	RES
4.1		import the chemical from all sources simultaneously prohibited? duction of the chemical for domestic use simultaneously prohibited?	⊠ Yes ⊠ Yes	□ No

4.2		Consent to import		
4.3		Consent to import only subject to specified conditions		
		The specified conditions are:		
		Are the conditions for import of the chemical the same for all sources of import?	☐ Yes	□ No
		Are the conditions for domestic production of the chemical for domestic use the same as for all imports?	☐ Yes	□No
4.4		National legislative or administrative measure upon which the final decision	is based	t
		Description of the national legislative or administrative measure:		
		In the European Union, it is prohibited to place on the market or use plant prote taining trichlorfon, since that active substance has not been approved und No 1107/2009 of the European Parliament and of the Council of 21 October 2 placing of plant protection products on the market and repealing Council Directiv 91/414/EEC (OJ L 309, 24.11.2009, p. 1).	er Regula 009 conc	ation (EC) erning the
		Furthermore, it is prohibited to make available on the market or use biocidal trichlorfon, since that active substance has not been approved pursuant t No 528/2012 of the European Parliament and of the Council of 22 May 2012 cor available on the market and use of biocidal products (OJ L 167, 27.6.2012, p. 1).	to Regula	ation (EU)
SECTION 5	IN	TERIM RESPONSE		
5.1		No consent to import	_	_
		Is the import of the chemical from all sources simultaneously prohibited?  Is domestic production of the chemical for domestic use simultaneously prohibited?	☐ Yes	□ No
		is domestic production of the chemical for domestic use simultaneously prohibited?	∐ Yes	∐No
5.2		Consent to import		
5.3		Consent to import only subject to specified conditions		
		The specified conditions are:		
		Are the conditions for import of the chemical the same for all sources of import?	☐ Yes	 □ No
		Are the conditions for domestic production of the chemical for domestic use the same as for all imports?	☐ Yes	□No
5.4		Indication of active consideration in order to reach a final decision		
		Is a final decision under active consideration?	☐ Yes	□No
5.5		Information or assistance requested in order to reach a final decision		
		The following additional information is requested from the Secretariat:		

	The following additional information is requested from the colaction:	untry that notified the final regu	latory
	The following assistance is requested from the Secretariat in	evaluating the chemical:	
SECTION 6	RELEVANT ADDITIONAL INFORMATION, WHICH MAY INCLU	DE:	
ls this chemical cur	rently registered in the country?	☐ Yes	⊠ No
Is this chemical ma	nufactured in the country?	☐ Yes	⊠ No
If yes to either on	e of these questions:		
Is this intended for	domestic use?	☐ Yes	□No
ls this intended for	export?	☐ Yes	□No
Other remarks			
and Labelling of C	n Regulation (EC) No 1272/2008, which implements the UN Glothemicals in the EU, trichlorfon is classified as:	oally Harmonised System of Cla	assification
1 '	· H 302 — Harmful if swallowed. 1 – H 317 — May cause an allergic skin reaction.		
	H 400 — Very toxic to aquatic life.		
l '	- H 410 — Very toxic to aquatic life with long lasting effects.		
(* = This classifica	tion shall be considered as a minimum classification)		
SECTION 7	DESIGNATED NATIONAL AUTHORITY		

Institution European Commission, DG Environment
Address Rue de la Loi 200, 1049 Brussels, Belgium

Name of person in charge Dr Juergen Helbig

Position of person in charge International Chemicals Policy Coordinator

Telephone +32 22988521
Telefax +32 22967616

Email address Juergen.Helbig@ec.europa.eu

Date, signature of DNA and official seal: .....

# PLEASE RETURN THE COMPLETED FORM TO:

Secretariat for the Rotterdam Convention Food and Agriculture Organization of the United Nations (FAO) Viale delle Terme di Caracalla 00100 Rome ITALIA

Tel. +39 0657053441 Fax +39 0657056347 Email: pic@pic.int Secretariat for the Rotterdam Convention United Nations Environment Programme (UNEP) 11-13, Chemin des Anémones CH-1219 Châtelaine, Geneva SWITZERLAND

Tel. +41 229178177 Fax +41 229178082 Email: pic@pic.int

OR

# Import response for short-chain chlorinated paraffins

С				

### **European Union**

SECTION 1	IDENTITY OF CH	EMICAL
1.1	Common name	Short-chain chlorinated paraffins
1.2	CAS number	85535-84-8
1.3	Category	☐ Pesticide
		☑ Industrial
		☐ Severely hazardous pesticide formulation
SECTION 2	INDICATION REG	ARDING PREVIOUS RESPONSE, IF ANY
2.1		ime import response for this chemical in the country.
2.2		fication of a previous response.  of the previous response:
SECTION 3	RESPONSE REG	ARDING FUTURE IMPORT
☑ Final deci	sion (Fill in section 4	below) OR Interim response (Fill in section 5 below)
SECTION 4	FINAL DECISION	, PURSUANT TO NATIONAL LEGISLATIVE OR ADMINISTRATIVE MEASURES
4.1	☐ No consent to	
		of the chemical from all sources simultaneously prohibited?  Yes No eduction of the chemical for domestic use simultaneously prohibited?  Yes No
	is domestic pro	oduction of the chemical for domestic use simultaneously prohibited? $\Box$ Yes $\Box$ No

4.2		Consent to import		
4.3	$\boxtimes$	Consent to import only subject to specified conditions		
		The specified conditions are:		
		In the European Union, the production, placing on the market and use of sho paraffins (SCCPs), whether on their own, in preparations or as constituents of art pursuant to Regulation (EC) No 850/2004. This prohibition also includes the in chlorinated paraffins (SCCPs).	ticles, are nport of s	prohibited short-chain
		By way of derogation, the placing on the market and use (including the imporpreparations containing SCCPs in concentrations lower than 1 % by weight is allo		stances or
		Are the conditions for import of the chemical the same for all sources of import?	⊠ Yes	□No
		Are the conditions for domestic production of the chemical for domestic use the same as for all imports?	⊠ Yes	□No
4.4		National legislative or administrative measure upon which the final decision	ı is based	d
		Description of the national legislative or administrative measure:		
		Regulation (EC) No 850/2004 of the European Parliament and of the Council of persistent organic pollutants and amending Directive 79/117/EEC (OJ L 158, 30 lates that the production, placing on the market and use of short-chain of (SCCPs), whether on their own, in preparations or as constituents of articles, are By way of derogation, the production, placing on the market and use of substar containing SCCPs in concentrations lower than 1 % by weight or articles contain centrations lower than 0,15 % by weight are allowed.	.4.2004, p chlorinated prohibited nces or pr	o. 7) stipu- I paraffins I. reparations
SECTION 5	IN <sup>.</sup>	TERIM RESPONSE		
SECTION 5	IN'	TERIM RESPONSE  No consent to import		
	_		☐ Yes	□No
	_	No consent to import	☐ Yes	□ No
	_	No consent to import  Is the import of the chemical from all sources simultaneously prohibited?	_	
5.1	_	No consent to import  Is the import of the chemical from all sources simultaneously prohibited?  Is domestic production of the chemical for domestic use simultaneously prohibited?	_	
5.1	_	No consent to import  Is the import of the chemical from all sources simultaneously prohibited?  Is domestic production of the chemical for domestic use simultaneously prohibited?  Consent to import	_	
5.1	_	No consent to import  Is the import of the chemical from all sources simultaneously prohibited?  Is domestic production of the chemical for domestic use simultaneously prohibited?  Consent to import  Consent to import only subject to specified conditions	_	
5.1	_	No consent to import  Is the import of the chemical from all sources simultaneously prohibited?  Is domestic production of the chemical for domestic use simultaneously prohibited?  Consent to import  Consent to import only subject to specified conditions	_	
5.1	_	No consent to import  Is the import of the chemical from all sources simultaneously prohibited?  Is domestic production of the chemical for domestic use simultaneously prohibited?  Consent to import  Consent to import only subject to specified conditions  The specified conditions are:	☐ Yes	□ No
5.1	_	No consent to import  Is the import of the chemical from all sources simultaneously prohibited?  Is domestic production of the chemical for domestic use simultaneously prohibited?  Consent to import  Consent to import only subject to specified conditions  The specified conditions are:  Are the conditions for import of the chemical the same for all sources of import?  Are the conditions for domestic production of the chemical for domestic use the	☐ Yes	□ No
5.1 5.2 5.3	_	No consent to import  Is the import of the chemical from all sources simultaneously prohibited?  Is domestic production of the chemical for domestic use simultaneously prohibited?  Consent to import  Consent to import only subject to specified conditions  The specified conditions are:  Are the conditions for import of the chemical the same for all sources of import?  Are the conditions for domestic production of the chemical for domestic use the same as for all imports?	☐ Yes	□ No
5.1 5.2 5.3	_	No consent to import  Is the import of the chemical from all sources simultaneously prohibited?  Is domestic production of the chemical for domestic use simultaneously prohibited?  Consent to import  Consent to import only subject to specified conditions  The specified conditions are:  Are the conditions for import of the chemical the same for all sources of import?  Are the conditions for domestic production of the chemical for domestic use the same as for all imports?  Indication of active consideration in order to reach a final decision	☐ Yes☐ Yes☐ Yes☐ Yes☐ Yes☐ Yes☐ Yes☐ Yes	□ No □ No

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The follo action:	wing additional informatio	n is requested from the country that n	otified the final regul	latory
The follo	owing assistance is reques	sted from the Secretariat in evaluating	the chemical:	
SECTION 6 RELEVANT	ADDITIONAL INFORMAT	TION, WHICH MAY INCLUDE:		
Is this chemical currently regist	ered in the country?		☐ Yes	⊠ No
Is this chemical manufactured i	n the country?		☐ Yes	⊠ No
If yes to either one of these	·		_ :••	
Is this intended for domestic us	-		☐ Yes	□No
Is this intended for export?			□ Yes	□No
'			00	
Other remarks				
Carc. 2 – H 351 — Suspected Aquatic Acute 1 – H 400 — V Aquatic Chronic 1 – H 410 —	d of causing cancer. ery toxic to aquatic life.	inated paraffins are classified as: with long lasting effects.		
SECTION 7 DESIGNATE	ED NATIONAL AUTHORI	тү		
Institution	European Commis	sion, DG Environment		
Address	Rue de la Loi 200,	1049 Brussels, Belgium		
Name of person in charge	Dr Juergen Helbig			
Position of person in charge	International Chem	icals Policy Coordinator		
Telephone	+32 22988521			
Telefax	+32 22967616			
Email address	Juergen.Helbig@ed	c.europa.eu		
Date, signature of DNA and off	icial seal:			
PLEASE RETURN THE COMP	LETED FORM TO:			
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OR

# Import response for tributyltin compounds

### Country:

### **European Union**

SECTION 1				
1.1	Common name	Tributyltin compounds, i.e. all tributyltin compounds including  — Tributyltin oxide  — Tributyltin fluoride  — Tributyltin methacrylate  — Tributyltin benzoate  — Tributyltin chloride  — Tributyltin linoleate  — Tributyltin naphthenate	1	
1.2	CAS number	56-35-9 — Tributyltin oxide 1983-10-4 — Tributyltin fluoride 2155-70-6 — Tributyltin methacrylate 4342-36-3 — Tributyltin benzoate 1461-22-9 — Tributyltin chloride 24124-25-2 — Tributyltin linoleate 85409-17-2 — Tributyltin naphthenate		
1.3	Category	<ul> <li>□ Pesticide</li> <li>☑ Industrial</li> <li>□ Severely hazardous pesticide formulation</li> </ul>		
SECTION 2	INDICATION REGA	RDING PREVIOUS RESPONSE, IF ANY		
2.1	<ul> <li>☑ This is a first time import response for this chemical in the country.</li> <li>☐ This is a modification of a previous response.</li> <li>Date of issue of the previous response:</li> </ul>			
SECTION 3	RESPONSE REGARDING FUTURE IMPORT			
⊠ Final decis	sion (Fill in section 4	below) OR	below)	
SECTION 4	FINAL DECISION, PURSUANT TO NATIONAL LEGISLATIVE OR ADMINISTRATIVE MEASURES			RES
4.1	·	import the chemical from all sources simultaneously prohibited? uction of the chemical for domestic use simultaneously prohibited?	☐ Yes	□ No

4.2	☐ Consent to import
4.3	□ Consent to import only subject to specified conditions
4.0	
	The specified conditions are:
	In the European Union, the placing on the market and use (including import) of tributyltin compounds as industrial chemicals are allowed, subject to compliance with the conditions set out in Regulation (EC) No 1907/2006, in particular the restriction with regard to organostannic compounds laid down in Annex XVII to that Regulation, which stipulates that organostannic compounds:
	<ol> <li>Shall not be placed on the market, or used, as substances or in mixtures where the substance or mixture is acting as biocide in free association paint.</li> </ol>
	2. Shall not be placed on the market, or used, as substances or in mixtures where the substance or mixture acts as biocide to prevent the fouling by micro-organisms, plants or animals of:
	(a) all craft irrespective of their length intended for use in marine, coastal, estuarine and inland
	waterways and lakes; (b) cages, floats, nets and any other appliances or equipment used for fish or shellfish farming;
	(c) any totally or partly submerged appliance or equipment.
	3. Shall not be placed on the market, or used, as substances or in mixtures where the substance or mixture is intended for use in the treatment of industrial waters.
	Are the conditions for import of the chemical the same for all sources of import? 🛛 Yes 🔲 No
	Are the conditions for domestic production of the chemical for domestic use the $\  \  \  \  \  \  \  \  \  \  \  \  \ $
4.4	National legislative or administrative measure upon which the final decision is based  Description of the national legislative or administrative measure:
	Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ L 396, 30.12.2006, p. 1), in particular the restriction with regard to organostannic compounds laid down in Annex XVII to that Regulation stipulates that the placing on the market and use (including import) of tributyltin compounds as industrial chemicals are allowed, subject to compliance with certain conditions.
SECTION 5	INTERIM RESPONSE
5.1	☐ No consent to import
	Is the import of the chemical from all sources simultaneously prohibited?
	Is domestic production of the chemical for domestic use simultaneously prohibited?
5.2	☐ Consent to import
	·
5.3	☐ Consent to import only subject to specified conditions

Are the conditions for import of the chemical the same for all sources of import?

Are the conditions for domestic production of the chemical for domestic use the

☐ Yes ☐ No

☐ Yes ☐ No

The specified conditions are:

same as for all imports?

	Indication of active consideration in order to reach a final decision		
	Is a final decision under active consideration?	☐ Yes	□No
5.5	Information or assistance requested in order to reach a final decision		
	The following additional information is requested from the Secretariat:		
	The following additional information is requested from the country that notified action:	the final regu	latory
	The following assistance is requested from the Secretariat in evaluating the ch	nemical:	
SECTION 6	RELEVANT ADDITIONAL INFORMATION, WHICH MAY INCLUDE:		
Is this chemical c	urrently registered in the country?	⊠ Yes	□No
Is this chemical manufactured in the country?			□No
is this chemical m	andiactured in the country:	🛛 Yes	
	one of these questions:	<b>△</b> 163	
	one of these questions:	⊠ Yes	□No
If yes to either o	one of these questions: or domestic use?		_
If yes to either o	one of these questions: or domestic use?	⊠ Yes	□ No
If yes to either of Is this intended for Is this intended for Other remarks  In accordance wand Labelling of	one of these questions: or domestic use?		□ No □ No assification the below
If yes to either of ls this intended for ls this intended for Other remarks  In accordance wand Labelling of classification apple classification):	one of these questions: or domestic use? or export?  ith Regulation (EC) No 1272/2008, which implements the UN Globally Harmonised Chemicals in the EU, tributyltin compounds are classified as follows (It should I		□ No □ No assification the below
If yes to either of Is this intended for Is this intended for Other remarks  In accordance wand Labelling of classification appropriate (Cassification):  Acute Tox. 3 – Hacute Tox. 4* – Heroscience (Cassification)	one of these questions:  or domestic use?  or export?  ith Regulation (EC) No 1272/2008, which implements the UN Globally Harmonised Chemicals in the EU, tributyltin compounds are classified as follows (It should lolies to all tributyltin compounds with the exception of those individual compound 301 (Toxic if swallowed.)  H 312 (Harmful in contact with skin.)		□ No □ No assification the below
If yes to either of Is this intended for Is this intended for Other remarks  In accordance w and Labelling of classification appropriate (assification):  Acute Tox. 3 – H. Acute Tox. 4* – H. Skin Irrit. 2 – H. Skin Irrit. 3 – H. Skin Irrit. 4 – H. Skin Irrit.	ith Regulation (EC) No 1272/2008, which implements the UN Globally Harmonised Chemicals in the EU, tributyltin compounds are classified as follows (It should I olies to all tributyltin compounds with the exception of those individual compounds (Toxic if swallowed.)  1 312 (Harmful in contact with skin.)		□ No □ No assification the below
If yes to either of Is this intended for Is this intended for Other remarks  In accordance w and Labelling of classification appropriately classification):  Acute Tox. 3 – H Acute Tox. 4* – H Skin Irrit. 2 – H Eye Irrit. 2 – H Stye Irrit. 2 – H S	ith Regulation (EC) No 1272/2008, which implements the UN Globally Harmonised Chemicals in the EU, tributyltin compounds are classified as follows (It should I olies to all tributyltin compounds with the exception of those individual compounds (Toxic if swallowed.)  1312 (Harmful in contact with skin.)  1515 (Causes skin irritation.)		□ No □ No assification the below
If yes to either of Is this intended for Is this intended for Other remarks  In accordance we and Labelling of classification applicassification):  Acute Tox. 3 – H. Acute Tox. 4* – H. Skin Irrit. 2 – H. Skin Irrit. 2 – H. Stype Irrit. 2 – H. Sty	ith Regulation (EC) No 1272/2008, which implements the UN Globally Harmonised Chemicals in the EU, tributyltin compounds are classified as follows (It should I blies to all tributyltin compounds with the exception of those individual compounds (Toxic if swallowed.)  H 312 (Harmful in contact with skin.)  It (Causes skin irritation.)  19 (Causes serious eye irritation.)  372 ** (Causes damage to organs through prolonged or repeated exposure.)		□ No □ No assification the below
If yes to either of Is this intended for Is this intended for Other remarks  In accordance w and Labelling of classification appropriate (assification):  Acute Tox. 3 – H. Acute Tox. 4* – I. Skin Irrit. 2 – H. 3. STOT RE 1 – H. Aquatic Acute 1	ith Regulation (EC) No 1272/2008, which implements the UN Globally Harmonised Chemicals in the EU, tributyltin compounds are classified as follows (It should I blies to all tributyltin compounds with the exception of those individual compound 301 (Toxic if swallowed.)  1 312 (Harmful in contact with skin.)  315 (Causes skin irritation.)  19 (Causes serious eye irritation.)  372 ** (Causes damage to organs through prolonged or repeated exposure.)  1 400 (Very toxic to aquatic life.)		□ No □ No assification the below
If yes to either of Is this intended for Is this intended for Other remarks  In accordance w and Labelling of classification applicassification): Acute Tox. 3 – H. Acute Tox. 4* – H. Skin Irrit. 2 – H. 3 STOT RE 1 – H. Aquatic Acute 1. Aquatic Chronic	ith Regulation (EC) No 1272/2008, which implements the UN Globally Harmonised Chemicals in the EU, tributyltin compounds are classified as follows (It should I blies to all tributyltin compounds with the exception of those individual compound 301 (Toxic if swallowed.) H 312 (Harmful in contact with skin.) B15 (Causes skin irritation.) 19 (Causes serious eye irritation.) 372 ** (Causes damage to organs through prolonged or repeated exposure.) H 400 (Very toxic to aquatic life.) 1 - H 410 (Very toxic to aquatic life with long lasting effect.)		□ No □ No assification
If yes to either of Is this intended for Is this intended for Is this intended for Other remarks  In accordance we and Labelling of classification appropriate (Cassification):  Acute Tox. 3 – How Acute Tox. 4* – How Skin Irrit. 2 – How Stin Irrit. 2 – How Stort RE 1 – How Aquatic Acute 1  Aquatic Acute 1  Aquatic Chronic Repr. 1B – H360	ith Regulation (EC) No 1272/2008, which implements the UN Globally Harmonised Chemicals in the EU, tributyltin compounds are classified as follows (It should I blies to all tributyltin compounds with the exception of those individual compound 301 (Toxic if swallowed.)  1 312 (Harmful in contact with skin.)  315 (Causes skin irritation.)  19 (Causes serious eye irritation.)  372 ** (Causes damage to organs through prolonged or repeated exposure.)  1 400 (Very toxic to aquatic life.)		□ No □ No assification the below

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Date, signature of DNA and official seal: .....

OR

# PLEASE RETURN THE COMPLETED FORM TO:

Secretariat for the Rotterdam Convention Food and Agriculture Organization of the United Nations (FAO) Viale delle Terme di Caracalla 00100 Rome ITALIA

Tel. +39 0657053441 Fax +39 0657056347 Email: pic@pic.int Secretariat for the Rotterdam Convention United Nations Environment Programme (UNEP) 11-13, Chemin des Anémones CH-1219 Châtelaine, Geneva SWITZERLAND

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### ANNEX II

### Import response for ethylene oxide

# Country:

### **European Union**

SECTION 1	IDENTITY OF CHE	DENTITY OF CHEMICAL			
1.1	Common name	Ethylene oxide			
1.2	CAS number	75-21-8			
1.3	Category	☑ Pesticide			
		☐ Industrial			
		☐ Severely hazardous pesticide formulation			
SECTION 2	INDICATION REGA	ARDING PREVIOUS RESPONSE, IF ANY			
2.1	☐ This is a first tin	ne import response for this chemical in the country.			
2.2	<ul> <li>☐ This is a modification of a previous response.</li> <li>☐ Date of issue of the previous response: 03/2017</li></ul>				
SECTION 3	RESPONSE REGA	RDING FUTURE IMPORT			
⊠ Final decis	sion (Fill in section 4	below) OR			
SECTION 4	FINAL DECISION,	PURSUANT TO NATIONAL LEGISLATIVE OR ADMINISTRATIVE MEASURES			
4.1	☐ No consent to	import			
	·	the chemical from all sources simultaneously prohibited?			
	Is domestic prod	luction of the chemical for domestic use simultaneously prohibited?			

Consent	to	import
	☐ Consent	☐ Consent to

#### 4.3 Consent to import only subject to specified conditions

The specified conditions are:

#### For plant protection products

In the European Union, it is prohibited to place on the market (including import) or use plant protection products containing ethylene oxide, since that active substance has not been approved under Regulation (EC) No 1107/2009.

#### For biocidal products

Ethylene oxide is under review in accordance with Regulation (EU) No 528/2012 for uses covered by product type 2 and therefore the making available on the market and use of biocidal products containing ethylene oxide is only allowed for uses covered by product-type 2, which are disinfectants and algaecides not intended for direct application to humans or animals as defined in Annex V to that Regulation.

Responses of individual Member States of the European Union for ethylene oxide in biocidal products falling within product-type 2 are as follows:

Member States that consent to import, subject to any national restrictions that may apply: Belgium, Denmark, France, Germany, Estonia, Ireland, Latvia, Luxembourg, Sweden, UK.

Member States that consent to import, subject to prior written authorisation: Austria, Bulgaria, Croatia, Finland, Hungary, Italy, Lithuania, Netherlands, Poland, Portugal, Slovenia.

Member States that consent to import only for sterilisation of surgical tools in accordance with Council Directive 93/42/EC concerning medical devices (OJ L 169, 12.7.1993, p. 1), subject to prior written authorisation: Cyprus, Greece, Slovakia, Spain, Romania.

Member States that do not consent to import: Czech Republic, Malta.

Are the conditions for import of the chemical the same for all sources of import?	☑ Yes	∐ No
Are the conditions for domestic production of the chemical for domestic use the	⊠ Yes	□No
same as for all imports?		

### 4.4 National legislative or administrative measure upon which the final decision is based

Description of the national legislative or administrative measure:

### Plant protection products

Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC (OJ L 309, 24.11.2009, p. 1) prohibits to place on the market or use plant protection products containing ethylene oxide.

#### **Biocidal products**

Ethylene oxide has not been approved as an active substance under Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products (OJ L 167, 27.6.2012, p. 1). It is, however, under review and listed in Annex II to Commission Delegated Regulation (EU) No 1062/2014 of 4 August 2014 on the work programme for the systematic examination of all existing active substances contained in biocidal products referred to in Regulation (EU) No 528/2012 of the European Parliament and of the Council (OJ L 294, 10.10.2014, p. 1). Consequently, in the European Union, the making available on the market and use of biocidal products containing ethylene oxide is only allowed for uses covered by product-type 2 (disinfectants and algaecides not intended for direct application to humans or animals) as defined in Annex V to Regulation (EU) No 528/2012.

SECTION 5	INTERIM RESPONSE		
5.1	☐ No consent to import		
	Is the import of the chemical from all sources simultaneously prohibited?	☐ Yes	□No
	Is domestic production of the chemical for domestic use simultaneously prohibited?	☐ Yes	□No

5.2		Consent to import		
5.3		Consent to import only subject to specified conditions		
		The specified conditions are:		
		Are the conditions for import of the chemical the same for all sources of import?	⊠ Yes	□No
		Are the conditions for domestic production of the chemical for domestic use the same as for all imports?	⊠ Yes	□No
5.4		Indication of active consideration in order to reach a final decision		
		Is a final decision under active consideration?	⊠ Yes	□No
5.5		Information or assistance requested in order to reach a final decision		
		The following additional information is requested from the Secretariat:		
		The following additional information is requested from the country that notified the faction:	inal regul	atory
		The following assistance is requested from the Secretariat in evaluating the chemic	al:	
SECTION 6	DE	ELEVANT ADDITIONAL INFORMATION, WHICH MAY INCLUDE:		
SECTION 0	nE	LEVANT ADDITIONAL INFORMATION, WHICH MAT INCLUDE.		
Is this chemical c	urrer	ntly registered in the country?	⊠ Yes	□No
		factured in the country?	✓ Yes	☐ No
•		of these questions:	_	_
Is this intended for			⊠ Yes	□No
Is this intended fo	r ex	port?	⊠ Yes	□No
Other remarks				
		Regulation (EC) No 1272/2008, which implements the UN Globally Harmonised Systemicals in the EU, ethylene oxide is classified as:	em of Cla	ssification
Flam. Gas 1 - H	220	) – Extremely flammable gas.		
		- Causes skin irritation.		
		- Causes serious eye irritation. 11 – Toxic if inhaled.		
1		May cause respiratory irritation.		
		May cause genetic defects.		
		May cause cancer. n shall be considered as a minimum classification)		

#### SECTION 7 DESIGNATED NATIONAL AUTHORITY

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Name of person in charge Dr Juergen Helbig

Position of person in charge International Chemicals Policy Coordinator

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