

**COMMISSION IMPLEMENTING DECISION****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**

(2016/C 61/06)

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 <sup>(1)</sup>, 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 (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 <sup>(2)</sup>,

Whereas:

- (1) In accordance with Regulation (EU) No 649/2012 the Commission is to decide on behalf of the Union whether or not to permit the import into the Union of each chemical subject to the Prior Informed Consent (PIC) procedure.
- (2) The United Nations Environment Programme (UNEP) and the Food and Agriculture Organization (FAO) have been appointed to provide secretariat services for the operation of the PIC procedure established by the Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade ('the Rotterdam Convention'), approved by Council Decision 2006/730/EC <sup>(3)</sup>.
- (3) The Commission, acting as common designated authority, is required to forward import decisions on chemicals subject to the PIC procedure to the Secretariat of the Rotterdam Convention ('the Secretariat'), on behalf of the Union and its Member States.
- (4) The chemical methamidophos has been added to Annex III to the Rotterdam Convention, as a pesticide, by Decision RC 7/4 of the seventh meeting of the Conference of the Parties. This requires each Party to submit an import response to the Secretariat for the listing of methamidophos as a pesticide. The existing listing of severely hazardous pesticide formulations (soluble liquid formulations that exceed 600 g active ingredient/l) containing methamidophos in Annex III will be deleted, including the import responses submitted for that entry. The Commission has received information thereof in the form of a decision guidance document from the Secretariat. The placing on the market and use of methamidophos as a component of mixtures acting as plant protection products is banned by Regulation (EC) No 1107/2009 of the European Parliament and of the Council <sup>(4)</sup>.
- (5) It is necessary to amend previous import decisions in relation to the chemicals DDT and ethylene oxide in order to reflect the enlargement of the Union on 1 July 2013 as well as to take account of regulatory developments in the Union since those decisions were adopted.
- (6) The making available on the market and use of ethylene oxide under Regulation (EU) No 528/2012 of the European Parliament and of the Council <sup>(5)</sup> is restricted to one specific area pursuant to Commission Delegated Regulation (EU) No 1062/2014 <sup>(6)</sup>. Consequently, imports are only allowed for that specific use. Member States can decide whether they authorise that use allowed under Regulation (EU) No 528/2012 in their territory.

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

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

<sup>(3)</sup> Council Decision 2006/730/EC of 25 September 2006 on the conclusion, on behalf of the European Community, of the Rotterdam Convention on the Prior Informed Consent Procedure for certain hazardous chemicals and pesticides in international trade (OJ L 299, 28.10.2006, p. 23).

<sup>(4)</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>(5)</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>(6)</sup> 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).

- (7) The production, placing on the market and use of DDT, whether on its own, in preparations or as a constituent of articles, is prohibited in the European Union pursuant to Regulation (EC) No 850/2004 of the European Parliament and of the Council <sup>(1)</sup>.
- (8) The import decision concerning methamidophos should be adopted and Commission Decisions 2005/416/EC <sup>(2)</sup> and 2009/966/EC <sup>(3)</sup> should be amended accordingly,

HAS DECIDED AS FOLLOWS:

*Article 1*

The decision on the import of methamidophos set out in the form for import response in Annex I is adopted.

*Article 2*

The decision on the import of ethylene oxide set out in Annex II to Decision 2009/966/EC is replaced by the import decision for ethylene oxide set out in the form for import response in Annex II to this Decision.

*Article 3*

The decision on the import of DDT set out in Annex I to Decision 2005/416/EC is replaced by the import decision for DDT set out in the form for import response in Annex III to this Decision.

Done at Brussels, 11 February 2016.

*For the Commission*

Karmenu VELLA

*Member of the Commission*

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<sup>(1)</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).

<sup>(2)</sup> Commission Decision 2005/416/EC of 19 May 2005 adopting Community import decisions for certain chemicals pursuant to Regulation (EC) No 304/2003 of the European Parliament and of the Council and amending Decisions 2000/657/EC, 2001/852/EC and 2003/508/EC (OJ L 147, 10.6.2005, p. 1).

<sup>(3)</sup> Commission Decision 2009/966/EC of 30 November 2009 adopting Community import decisions for certain chemicals pursuant to Regulation (EC) No 689/2008 of the European Parliament and of the Council and amending Commission Decisions 2000/657/EC, 2001/852/EC, 2003/508/EC, 2004/382/EC and 2005/416/EC (OJ L 341, 22.12.2009, p. 14).

## ANNEX I

## Import decision for methamidophos



## ROTTERDAM CONVENTION

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



## FORM FOR IMPORT RESPONSE

Country:

**European Union**

(Member States: Austria, Belgium, Bulgaria, Croatia, 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

- 1.1 Common name
- 1.2 CAS number
- 1.3 Category  Pesticide  
 Industrial  
 Severely hazardous pesticide formulation

## SECTION 2 INDICATION REGARDING PREVIOUS RESPONSE, IF ANY

- 2.1  This is a first time import response for this chemical in the country.
- 2.2  This is a modification of a previous response.  
Date of issue of the previous response: .....

## SECTION 3 RESPONSE REGARDING FUTURE IMPORT

- Final decision (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 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

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**

Description of the national legislative or administrative measure:

It is prohibited to place on the market or use plant protection products containing methamidophos, since this active substance is not approved under 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).

Furthermore, it is prohibited to make available on the market or use biocidal products containing methamidophos, since no biocidal products containing that active substance are authorised pursuant to 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).

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**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 final regulatory action:

The following assistance is requested from the Secretariat in evaluating the chemical:

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**SECTION 6 RELEVANT ADDITIONAL INFORMATION, WHICH MAY INCLUDE:**

Is this chemical currently registered in the country?  Yes  No

Is this chemical manufactured in the country?  Yes  No

**If yes to either one of these questions:**

Is this intended for domestic use?  Yes  No

Is this intended for export?  Yes  No

**Other remarks**

In accordance with Regulation (EC) No 1272/2008, which implements the UN Globally Harmonised System of Classification and Labelling of Chemicals in the EU, methamidophos is classified as:

Acute Tox. 2\* – H 300 — Fatal if swallowed.

Acute Tox. 2\* – H 330 — Fatal if inhaled.

Acute Tox. 3\* – H 311 – Toxic in contact with skin.

Aquatic Acute 1 – H 400 — Very toxic to aquatic life.

(\* = This classification shall be considered as a minimum classification)

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**SECTION 7 DESIGNATED NATIONAL AUTHORITY**

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Position of person in charge	Principal Policy Officer
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Date, signature of DNA and official seal: .....

**PLEASE RETURN THE COMPLETED FORM TO:**

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## ANNEX II

## Revised import decision for ethylene oxide



## ROTTERDAM CONVENTION

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



## FORM FOR IMPORT RESPONSE

Country:

**European Union**

(Member States: Austria, Belgium, Bulgaria, Croatia, 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

- 1.1 Common name
- 1.2 CAS number
- 1.3 Category  Pesticide  
 Industrial  
 Severely hazardous pesticide formulation

## SECTION 2 INDICATION REGARDING PREVIOUS RESPONSE, IF ANY

- 2.1  This is a first time import response for this chemical in the country.
- 2.2  This is a modification of a previous response.  
Date of issue of the previous response: 01/2010 .....

## SECTION 3 RESPONSE REGARDING FUTURE IMPORT

- Final decision (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 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

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**

Description of the national legislative or administrative measure:

## 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:

*For plant protection products*

It is prohibited to place on the market or use plant protection products containing ethylene oxide, since this active substance is not approved under 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).

*For biocidal products*

In accordance with 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 of 22 May 2012 concerning the making available on the market and use of biocidal products (OJ L 167, 27.6.2012, p. 1), this substance is listed in Annex II only allowing placing on the market for uses in PT2 (disinfectants and algacides not intended for direct application to humans or animals).

Responses of individual Member States of the European Union for the only allowed uses of ethylene oxide in biocidal products in PT2 (disinfectants and algacides not intended for direct application to humans or animals) are as follows:

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

Member States that consent to import (for import prior written authorisation is required): Austria, Belgium, Croatia, Finland, Hungary, Italy, Lithuania, Netherlands, Poland, Portugal, Slovenia.

Member States that consent to import only for sterilisation of surgical tools in accordance with Directive 93/42/EC (for import prior written authorisation is required): Bulgaria, 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 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 final regulatory action:

The following assistance is requested from the Secretariat in evaluating the chemical:

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**SECTION 6 RELEVANT ADDITIONAL INFORMATION, WHICH MAY INCLUDE:**

Is this chemical currently registered in the country?  Yes  No

Is this chemical manufactured in the country?  Yes  No

**If yes to either one of these questions:**

Is this intended for domestic use?  Yes  No

Is this intended for export?  Yes  No

**Other remarks**

In accordance with Regulation (EC) No 1272/2008, which implements the UN Globally Harmonised System of Classification and Labelling of Chemicals in the EU, ethylene oxide is classified as:

Press. Gas

Flam. Gas 1 – H 220 – Extremely flammable gas.

Skin Irrit. 2 – H 315 – Causes skin irritation.

Eye Irrit. 2 – H 319 – Causes serious eye irritation.

Acute Tox. 3\* – H 331 – Toxic if inhaled.

STOT SE 3 – H 335 – May cause respiratory irritation.

Muta. 1B – H 340 – May cause genetic defects.

Carc. 1B – H 350 – May cause cancer.

(\* = This classification shall be considered as a minimum classification)

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**SECTION 7 DESIGNATED NATIONAL AUTHORITY**

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## ANNEX III

## Revised import decision for DDT



## ROTTERDAM CONVENTION

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



## FORM FOR IMPORT RESPONSE

Country:

**European Union**

(Member States: Austria, Belgium, Bulgaria, Croatia, 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

1.1 Common name

1.2 CAS number

1.3 Category  Pesticide  
 Industrial  
 Severely hazardous pesticide formulation

## SECTION 2 INDICATION REGARDING PREVIOUS RESPONSE, IF ANY

2.1  This is a first time import response for this chemical in the country.

2.2  This is a modification of a previous response.  
Date of issue of the previous response: 06/2005 .....

## SECTION 3 RESPONSE REGARDING FUTURE IMPORT

Final decision (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 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

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**

Description of the national legislative or administrative measure:

The production, placing on the market and use of DDT, whether on its own, in preparations or as a constituent of articles, is prohibited in the European Union pursuant to 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).

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**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 final regulatory action:

The following assistance is requested from the Secretariat in evaluating the chemical:

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**SECTION 6 RELEVANT ADDITIONAL INFORMATION, WHICH MAY INCLUDE:**

Is this chemical currently registered in the country?  Yes  No

Is this chemical manufactured in the country?  Yes  No

**If yes to either one of these questions:**

Is this intended for domestic use?  Yes  No

Is this intended for export?  Yes  No

**Other remarks**

In accordance with Regulation (EC) No 1272/2008, which implements the UN Globally Harmonised System of Classification and Labelling of Chemicals in the EU, DDT is classified as:

Acute Tox. 3\* – H 301 — Toxic if swallowed.

Carc. 2 – H 351 – Suspected of causing cancer.

Stot. RE 1 – H 372 – Causes damage to organs through prolonged or repeated exposure.

Aquatic Acute 1 – H 400 — Very toxic to aquatic life.

Aquatic Chronic 1 – H 410 — Very toxic to aquatic life with long lasting effects.

(\* = This classification shall be considered as a minimum classification)

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**SECTION 7 DESIGNATED NATIONAL AUTHORITY**

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

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