COMMISSION IMPLEMENTING DECISION (EU) 2020/2182
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 the Commission Implementing Decision of 15 May 2014 adopting Union
import decisions for certain chemicals pursuant to that Regulation
(notified under document C(2020) 8977)

THE EUROPEAN COMMISSION,

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

the export and import of hazardous chemicals (1), and in particular the second and third subparagraphs 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

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 ninth meeting, held in Geneva from 29 April to 10 May 2019, 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 16 September 2019
with a request for a decision regarding future import of the chemical.

(3) Phorate has been added to Annex III to the Convention as a pesticide. The placing on the market and use of phorate
as a component of plant protection products is 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 phorate as a component of
biocidal products is 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
phorate to the Union.

(4) Hexabromocyclododecane has been added to Annex III to the Convention as an industrial chemical. The
manufacturing, placing on the market and use of hexabromocyclododecane are prohibited under Regulation (EU)
2019/1021 of the European Parliament and of the Council (5). Therefore, consent under the Rotterdam Convention
should not be given to the future import of hexabromocyclododecane to the Union.

(1) OJ L 201, 27.7.2012, p. 60.
(4) Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the
Commercial pentabromodiphenyl ether (including tetra- and pentabromodiphenyl ether), commercial octabromodiphenyl ether (including hexa- and heptabromodiphenyl ether) and perfluorooctane sulfonic acid, perfluorooctane sulfonates, perfluorooctane sulfonamides and perfluorooctane sulfonyls were added to the PIC procedure as industrial chemicals at the sixth meeting of the Conference of the Parties to the Convention. Import responses for those chemicals have been adopted in the Commission Implementing Decision of 15 May 2014 adopting Union import decisions for certain chemicals pursuant to Regulation (EU) No 649/2012 of the European Parliament and of the Council (6).

The manufacturing, placing on the market and use of commercial pentabromodiphenyl ether (including tetra- and pentabromodiphenyl ether) and commercial octabromodiphenyl ether (including hexa- and heptabromodiphenyl ether) are, subject to certain exemptions, prohibited under Regulation (EU) 2019/1021. Therefore, consent under the Rotterdam Convention should only be given to the future import of pentabromodiphenyl ether and commercial octabromodiphenyl ether to the Union, if certain conditions are met.

The manufacturing, placing on the market and use of perfluorooctane sulfonic acid, perfluorooctane sulfonates, perfluorooctane sulfonamides and perfluorooctane sulfonyls (PFOS) are, subject to certain exemptions, prohibited under Regulation (EU) 2019/1021. Therefore, consent under the Rotterdam Convention should only be given to the future import of PFOS to the Union, if certain conditions are met.

Since the regulatory developments in the Union brought about by Regulation (EU) 2019/1021 have taken place after the adoption of the Implementing Decision of 15 May 2014, that Decision should be amended accordingly.

HAS DECIDED AS FOLLOWS:

Article 1

The import responses for phorate and hexabromocyclododecane are set out in Annex I.

Article 2

Annex II to the Implementing Decision of 15 May 2014 adopting Union import decisions for certain chemicals pursuant to Regulation (EU) No 649/2012 is replaced by Annex II to this Decision.

Done at Brussels, 18 December 2020.

For the Commission
Virginijus SIKENIUS
Member of the Commission

ANNEX I

Import response for phorate

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 - The United Kingdom withdrew from the European Union as of 1 February 2020. During the transition period, which ends on 31 December 2020, unless extended, Union law, with a few limited exceptions, continues to be applicable to and in the United Kingdom and any reference to Member States in Union law shall be understood as including the United Kingdom.

SECTION 1 IDENTITY OF CHEMICAL

1.1 Common name Phorate
1.2 CAS number 298-02-2

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:


Furthermore, it is prohibited to make available on the market or use biocidal products containing phorate, since that active substance has not been approved 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).

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:

[Blank]

The following additional information is requested from the country that notified the final regulatory action:

[Blank]

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

[Blank]

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


- Acute Toxicity 2* - H300 – Fatal if swallowed.
- Acute Toxicity 1 – H310 – Fatal in contact with skin.
- Aquatic Acute 1 – H400 - Very toxic to aquatic life.
- Aquatic Chronic 1 - H410 - Very toxic to aquatic life with long lasting effects.

(* = This classification is to be considered as a minimum classification)
SECTION 7 DESIGNATED NATIONAL AUTHORITY

Institution: European Commission, DG Environment
Address: Rue de la Loi 200, B-1049 Brussels, Belgium
Name of person in charge: Dr. Juergen Helbig
Position of person in charge: International Chemicals Policy Coordinator
Telephone: 32 2 298 85 21
Telefax: 32 2 296 76 16
E-mail 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
I - 00100 Rome, Italy
Tel: (+39 06) 5705 3441
Fax: (+39 06) 5705 6347
E-mail: pic@pic.int

OR

Secretariat for the Rotterdam Convention
United Nations Environment Programme (UNEP)
11-13, Chemin des Anémones
CH - 1219 Châtelaine, Geneva, Switzerland
Tel: (+41 22) 917 8177
Fax: (+41 22) 917 8082
E-mail: pic@pic.int

Import response for hexabromocyclododecane

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 - The United Kingdom withdrew from the European Union as of 1 February 2020. During the transition period, which ends on 31 December 2020, unless extended, Union law, with a few limited exceptions, continues to be applicable to and in the United Kingdom and any reference to Member States in Union law shall be understood as including the United Kingdom.
SECTION 1  I DENTITY OF CHEMICAL

1.1  Common name  Hexabromocyclododecane
1.2  CAS number  134237-50-6, 134237-51-7, 134237-52-8, 25637-99-4, 3194-55-6
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:

**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:

**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


Repro. 2 – H361 - Suspected of damaging fertility or the unborn child.
Lact. – H362 - May cause harm to breast-fed children.

SECTION 7 DESIGNATED NATIONAL AUTHORITY

Institution
European Commission, DG Environment
Address
Rue de la Loi 200, B-1049 Brussels, Belgium
Name of person in charge
Dr. Juergen Helbig
Position of person in charge
International Chemicals Policy Coordinator
Telephone
32 2 298 85 21
Telefax
32 2 296 76 16
E-mail address
Juergen.Helbig@ec.europa.eu

Date, signature of DNA and official seal: ___________________________________

PLEASE RETURN THE COMPLETED FORM TO:

Secretariat for the Rotterdam Convention
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E-mail: pic@pic.int
ANNEX II

Import response for commercial pentabromodiphenyl ether

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 - The United Kingdom withdrew from the European Union as of 1 February 2020. During the transition period, which ends on 31 December 2020, unless extended, Union law, with a few limited exceptions, continues to be applicable to and in the United Kingdom and any reference to Member States in Union law shall be understood as including the United Kingdom.

SECTION 1 IDENTIFY OF CHEMICAL

1.1 Common name
Commercial pentabromodiphenyl ether including:
— Tetrabromodiphenyl ether
- Pentabromodiphenyl ether

1.2 CAS number
40088-47-9 - Tetrabromodiphenyl ether
32534-81-9 - Pentabromodiphenyl ether

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: 18 June 2014 .................................................................

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:

Pursuant to Regulation (EU) 2019/1021, the placing on the market and use of commercial pentabromodiphenyl ether is only allowed in accordance with Directive 2011/65/EU, where the following provisions apply:
The import of commercial pentabromodiphenyl ether is only allowed for placing on the market and use in cables or spare parts for the repair, the reuse, the updating of functionalities or upgrading of capacity of the following:
(a) electrical and electronic equipment (EEE) placed on the market before 1 July 2006;
(b) medical devices placed on the market before 22 July 2014;
(c) in vitro diagnostic medical devices placed on the market before 22 July 2016;
(d) monitoring and control instruments placed on the market before 22 July 2014;
(e) industrial monitoring and control instruments placed on the market before 22 July 2017;
(f) all other EEE that was outside the scope of Directive 2002/95/EC and which is placed on the market before 22 July 2019;
(g) EEE which benefited from an exemption and which was placed on the market before that exemption expired as far as that specific exemption is concerned.
Spare parts are defined as a separate part of an EEE that can replace a part of an EEE. The EEE cannot function as intended without that part of the EEE. The functionality of EEE is restored or is upgraded when the part is replaced by a spare part.

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:

In the Union, the manufacturing, placing on the market and use of tetrabromodiphenyl ether and pentabromodiphenyl ether are, subject to certain exemptions, prohibited pursuant to Regulation (EU) 2019/1021 of the European Parliament and of the Council of 20 June 2019 on persistent organic pollutants (OJ L 169, 25.06.2019, p. 45).
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:

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


Lact. – H 362 – May cause harm to breast-fed children.

STOT RE 2 * – H 373 - May cause 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 is to be considered as a minimum classification)

SECTION 7 DESIGNATED NATIONAL AUTHORITY

Institution European Commission, DG Environment
Address Rue de la Loi 200, B-1049 Brussels, Belgium
Name of person in charge Dr. Juergen Helbig
Position of person in charge International Chemicals Policy Coordinator
Telephone 32 2 298 85 21
Telefax 32 2 296 76 16
E-mail address Juergen.Helbig@ec.europa.eu

Date, signature of DNA and official seal: ___________________________

PLEASE RETURN THE COMPLETED FORM TO:

Secretariat for the Rotterdam Convention
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OR

Secretariat for the Rotterdam Convention
United Nations Environment Programme (UNEP)
11-13, Chemin des Anémones
CH - 1219 Châtelaine, Geneva, Switzerland
Tel: (+41 22) 917 8177
Fax: (+41 22) 917 8082
E-mail: pic@pic.int
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 - The United Kingdom withdrew from the European Union as of 1 February 2020. During the transition period, which ends on 31 December 2020, unless extended, Union law, with a few limited exceptions, continues to be applicable to and in the United Kingdom and any reference to Member States in Union law shall be understood as including the United Kingdom.

SECTION 1  IDENTITY OF CHEMICAL

1.1 Common name
Commercial octabromodiphenyl ether including:
— Hexabromodiphenyl ether
— Heptabromodiphenyl ether

1.2 CAS number
36483-60-0 - Hexabromodiphenyl ether
68928-80-3 - Heptabromodiphenyl ether

1.3 Category
☒ Industrial
☐ Severely hazardous pesticide formulation
☐ Pesticide

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: …18 June 2014…………………………………………………………

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:

Pursuant to Regulation (EU) 2019/1021, the placing on the market and use of commercial octabromodiphenyl ether is only allowed in accordance with Directive 2011/65/EU, where the following provisions apply:

- The import of commercial octabromodiphenyl ether is only allowed for placing on the market and use in cables or spare parts for the repair, the reuse, the updating of functionalities or upgrading of capacity of the following:
  - (a) electrical and electronic equipment (EEE) placed on the market before 1 July 2006;
  - (b) medical devices placed on the market before 22 July 2014;
  - (c) in vitro diagnostic medical devices placed on the market before 22 July 2016;
  - (d) monitoring and control instruments placed on the market before 22 July 2014;
  - (e) industrial monitoring and control instruments placed on the market before 22 July 2017;
  - (f) all other EEE that was outside the scope of Directive 2002/95/EC and which is placed on the market before 22 July 2019;
  - (g) EEE which benefited from an exemption and which was placed on the market before that exemption expired as far as that specific exemption is concerned.

Spare parts are defined as a separate part of an EEE that can replace a part of an EEE. The EEE cannot function as intended without that part of the EEE. The functionality of EEE is restored or is upgraded when the part is replaced by a spare part.

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
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:

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

SECTION 7 DESIGNATED NATIONAL AUTHORITY

Institution European Commission, DG Environment
Address Rue de la Loi 200, B-1049 Brussels, Belgium
Import response for perfluorooctane sulfonic acid, perfluorooctane sulfonates, perfluorooctane sulfonamides and perfluorooctane sulfonyls

**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 - The United Kingdom withdrew from the European Union as of 1 February 2020. During the transition period, which ends on 31 December 2020, unless extended, Union law, with a few limited exceptions, continues to be applicable to and in the United Kingdom and any reference to Member States in Union law shall be understood as including the United Kingdom.
SECTION 1  IDENTITY OF CHEMICAL

1.1  Common name
Perfluorooctane sulfonic acid, perfluorooctane sulfonates, perfluorooctane sulfonamides and perfluorooctane sulfonyls

1.2  CAS number
Relevant CAS numbers are:
- 1763-23-1 - Perfluorooctane sulfonic acid
- 2795-39-3 - Potassium perfluorooctane sulfonate
- 29457-72-5 - Lithium perfluorooctane sulfonate
- 29081-56-9 - Ammonium perfluorooctane sulfonate
- 70225-14-8 - Diethanolamine perfluorooctane sulfonate
- 56773-42-3 - Tetraethylammonium perfluorooctane sulfonate
- 251099-16-8 - Didecyldimethylammonium perfluorooctane sulfonate
- 4151-50-2 - N-Ethylperfluorooctane sulfonamide
- 31506-32-8 - N-Methylperfluorooctane sulfonamide
- 1691-99-2 - N-Ethyl-N-(2-hydroxyethyl) perfluorooctane sulfonamide
- 24448-09-7 - N-(2-hydroxyethyl)-N-methylperfluorooctane sulfonamide
- 307-35-7 - Perfluorooctane sulfonyl fluoride

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: …18 June 2014 ………………………………………………

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:
Imports of perfluorooctane sulfonic acid and its derivatives (PFOS) must be in compliance with Regulation (EU) 2019/1021 of the European Parliament and of the Council of 20 June 2019 on persistent organic pollutants (OJ L 169, 25.06.2019, p. 45), which sets out the following:

1. The production, placing on the market and use of PFOS, whether on their own, in mixtures or as constituents of articles, shall be prohibited.

2. The prohibition shall not apply to PFOS occurring as an unintentional trace contaminant in substances, mixtures or articles, provided that
   (a) concentrations of PFOS are equal to or below 10 mg/kg (0.001 % by weight) when it occurs in substances or in mixtures or
   (b) concentrations of PFOS in semi-finished products or articles, or parts thereof, are lower than 0.1 % by weight calculated with reference to the mass of structurally or micro-structurally distinct parts that contain PFOS or, for textiles or other coated materials, if the amount of PFOS is lower than 1 μg/m² of the coated material.

3. If the quantity of PFOS released into the environment is minimised, production and placing on the market is allowed for the following specific uses provided that Member States report to the Commission every four years on progress made to eliminate PFOS:
   — mist suppressants for non-decorative hard chromium (VI) plating in closed loop systems.

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? ☒ ☐

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

Description of the national legislative or administrative measure:

In the Union, the manufacturing, placing on the market and use of perfluorooctane sulfonic acid and its derivatives (PFOS) are prohibited pursuant to Regulation (EU) 2019/1021 of the European Parliament and of the Council of 20 June 2019 on persistent organic pollutants (OJ L 169, 25.06.2019, p. 45). However, that Regulation allows for specific exemptions, which are outlined in section 4.3.

SECTION 5 NTERIM 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
   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? ☐ ☐
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:

**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**


Acute Tox. 4 * - H302 - Harmful if swallowed.

Acute Tox. 4 * - H332 – Harmful if inhaled.

Carc. 2 - H351 – Suspected of causing cancer.

Lact. - H362 – May cause harm to breast-fed children.

STOT RE 1 - H372 - Causes damage to organs through prolonged or repeated exposure.

Aquatic Chronic 2 - H411 - Toxic to aquatic life with long lasting effects.

Repr. 1B - H360D - May damage the unborn child.

(* = This classification is to be considered as a minimum classification)
SECTION 7  DESIGNATED NATIONAL AUTHORITY

Institution European Commission, DG Environment
Address Rue de la Loi 200, B-1049 Brussels, Belgium
Name of person in charge Dr. Juergen Helbig
Position of person in charge International Chemicals Policy Coordinator
Telephone 32 2 298 85 21
Telefax 32 2 296 76 16
E-mail address Juergen.Helbig@ec.europa.eu

Date, signature of DNA and official seal: _____________________________

PLEASE RETURN THE COMPLETED FORM TO:

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Viale delle Terme di Caracalla
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OR

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