#### COMMISSION IMPLEMENTING DECISION

#### of 2 Jun 2023

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

(2023/C 198/07)

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 Article 13(1), second and third subparagraphs, 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 (<sup>2</sup>),

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 the face-to-face segment of its tenth meeting, held in Geneva from 6 to 17 June 2022, 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 21 October 2022 with a request for a decision regarding future import of the chemical.
- (3) Decabromodiphenyl ether ('decaBDE') has been added to Annex III to the Convention as an industrial chemical. The manufacturing, placing on the market and use of decaBDE are, subject to certain exemptions, prohibited under Regulation (EU) 2019/1021 of the European Parliament and of the Council (<sup>3</sup>). Therefore, consent under the Rotterdam Convention should only be given to the future import of decaBDE to the Union, if certain conditions are met.
- (4) Perfluorooctanoic acid (PFOA), its salts and PFOA-related compounds has been added to Annex III to the Convention as an industrial chemical. The manufacturing, placing on the market and use of PFOA, its salts and PFOA-related compounds 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 PFOA, its salts and PFOA-related compounds to the Union, if certain conditions are met,

HAS DECIDED AS FOLLOWS:

#### Sole Article

The import responses for decabromodiphenyl ether ('decaBDE') and perfluorooctanoic acid (PFOA), its salts and PFOArelated compounds are set out in the Annex to this Decision.

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

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

<sup>&</sup>lt;sup>(3)</sup> Regulation (EU) 2019/1021 of the European Parliament and of the Council of 20 June 2019 on persistent organic pollutants (OJ L 169, 25.6.2019, p. 45).

Done at Brussels, 2 Jun 2023.

For the Commission Virginijus SINKEVIČIUS Member of the Commission

ANNEX

#### Import response for decabromodiphenyl ether

### **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: | <b>European Union</b><br>Member States: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czechia, Denmark,<br>Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania,<br>Luxembourg, Malta, Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia,<br>Spain, Sweden. |
|----------|--|
|----------|--|

#### SECTION 1 IDENTITY OF CHEMICAL

| 1.1 | Common name | Dec | cabromodiphenyl ether                    |
|-----|-------------|-----|--|
| 1.2 | CAS number  | 116 | 3-19-5                                   |
| 1.3 | Category    |     | Pesticide                                |
|     |             | X   | Industrial                               |
|     |             |     | Severely hazardous pesticide formulation |

#### SECTION 2 INDICATION REGARDING PREVIOUS RESPONSE, IF ANY

| 2.1 | X | 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

# 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 Z Consent to import only subject to specified conditions

The specified conditions are:

(1) Under Part A of Annex I 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), the placing on the market and use of decabromodiphenyl ether ('decaBDE') is only allowed, by way of derogation:

(a) in the manufacturing of an aircraft, for which type approval has been applied for before 2 March 2019 and has been received before December 2022, until 18 December 2023, or, in cases where the continuing need is justified, until 2 March 2027;

(b) in the manufacturing of spare parts for either of the following:

 (i) an aircraft, for which type approval has been applied for before 2 March 2019 and has been received before December 2022, produced before 18 December 2023, or, in cases where the continuing need is justified, produced before 2 March 2027, until the end of service life of that aircraft;

(ii) motor vehicles within the scope of Directive 2007/46/ EC of the European Parliament and of the Council of 5 September 2007 establishing a framework for the approval of motor vehicles and their trailers, and of systems, components and separate technical units intended for such vehicles (Framework Directive) (OJ L 263 9.10.2007, p. 1) (OJ L 169, 25.6.2019, p. 45), produced before 15 July 2019, either until 2036 or the end of service life of those motor vehicles, whichever date comes earlier;

(c) in electric and electronic equipment within the scope of Directive 2011/65/EU.

(2) The specific exemptions for spare parts for use in motor vehicles referred to in point (1) (b)(ii) shall apply for the manufacturing and use of commercial decaBDE falling into one or more of the following categories:

(a) powertrain and under-hood applications such as battery mass wires, battery interconnection wires, mobile air condition (MAC) pipes, powertrains, exhaust manifold bushings, under- hood insulation, wiring and harness under-hood (engine wiring, etc.), speed sensors, hoses, fan modules and knock sensors;

(b) fuel system applications such as fuel hoses, fuel tanks and fuel tanks under body;

(c) pyrotechnical devices and applications affected by pyrotechnical devices, such as airbag ignition cables, seat covers/fabrics (only if airbag relevant) and airbags (front and side).

(3) The exemption granted under point (1)(c) is subject to the following conditions, as regards the use of commercial decaBDE in electric and electronic equipment that falls within the scope of Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment (OJ L 174 1.7.2011, p. 88):

(a) The import of decabromodiphenyl 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:

(i) electrical and electronic equipment (EEE) placed on the market before 1 July 2006;

(ii) medical devices placed on the market before 22 July 2014;

- (iii) in vitro diagnostic medical devices placed on the market before 22 July 2016;
- (iv) monitoring and control instruments placed on the market before 22 July 2014;
- (v) industrial monitoring and control instruments placed on the market before 22 July 2017;

(vi) all other EEE that did not fall under the scope of Directive 2002/95/EC of the European Parliament and of the Council of 27 January 2003 on the restriction of the use of certain hazardous substances in electrical and electronic equipment (OJ L 037, 13.2.2003, p.19) and that was placed on the market before 22 July 2019;

(vii) EEE which benefited from a specific exemption and which was placed on the market before that exemption expired, as far as that specific exemption is concerned.

(b) For the purposes of point (a), 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  $\square$  Yes  $\square$  No import?

Are the conditions for domestic production of the chemical for domestic  $\square$  Yes  $\square$  No 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 decabromodiphenyl ether are, subject to certain exemptions, prohibited pursuant to Regulation (EU) 2019/1021 of the European Parliament and of the Council 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                                   | ion |     |    |
|     | 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? | X        | 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   | <u> </u> |     | - |    |

#### 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 00100 Roma, ITALIA Tel. +39 0657053441 Fax +39 0657056347 Email: 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 229178177 Fax +41 229178082 Email: pic@pic.int

#### Import response for perfluorooctanoic acid (PFOA), its salts and PFOA-related compounds

**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, Czechia, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden.

#### SECTION 1 IDENTITY OF CHEMICAL

| 1.1   | Common name | Perfluorooctanoic acid (PFOA), its salts and PFOA-related compounds |
|---|-------------|---|
| 1.2     CAS number     335-67-1       1.3     Category     □       Pesticide       Industrial | 335-67-1    |   |
| 1.3   | Category    |   |
|   |             | Industrial  |
|   |             | Severely hazardous pesticide formulation                            |

#### SECTION 2 INDICATION REGARDING PREVIOUS RESPONSE, IF ANY

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

#### SECTION 3 RESPONSE REGARDING FUTURE IMPORT

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# 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?          |   | Ye-<br>s | No |
|     | Is domestic production of the chemical for domestic use simultaneously prohibited? |   | Ye-<br>s | No |

#### 

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

The specified conditions are:

Under Part A of Annex I 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), the placing on the market and use of perfluorooctanoic acid (PFOA), its salts and PFOA-related compounds is only allowed, by way of derogation, for the following purposes:

- (a) photolithography or etch processes in semiconductor manufacturing, until 4 July 2025;
- (b) photographic coatings applied to films, until 4 July 2025;
- (c) textiles for oil- and water-repellency for the protection of workers from dangerous liquids that comprise risks to their health and safety, until 4 July 2023;
- (d) invasive and implantable medical devices, until 4 July 2025;
- (e) in fire-fighting foam for liquid fuel vapour suppression and liquid fuel fire (Class B fires) already installed in systems, including both mobile and fixed systems, until 4 July 2025, subject to the following conditions:
  - (i) fire-fighting foam that contains or may contain PFOA, its salts and/or PFOA-related compounds shall not be used for training;
  - (ii) fire-fighting foam that contains or may contain PFOA, its salts and/or PFOA-related compounds shall not be used for testing unless all releases are contained;
  - (iii) as from 1 January 2023, uses of fire-fighting foam that contains or may contain PFOA, its salts and/or PFOA-related compounds shall only be allowed in sites where all releases can be contained;
  - (iv) fire-fighting foam stockpiles that contain or may contain PFOA, its salts and/or PFOArelated compounds shall be managed in accordance with Article 5 of Regulation (EU) 2019/1021.
- (f) the use of perfluooroctyl bromide containing perfluoroctyl iodide for the purpose of producing pharmaceutical products.

Are the conditions for import of the chemical the same for all sources of  $\blacksquare$  Ye-  $\Box$  No import? S

Are the conditions for domestic production of the chemical for domestic  $\blacksquare$  Ye-  $\Box$  No use the same as for all imports? S

#### 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 perfluorooctanoic acid (PFOA), its salts and PFOA-related compounds 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 |

5.4

5.5

#### 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 |  |
|--|------|-----|--|
| Are the conditions for domestic production of the chemical for domestic use the same as for all imports? |      | Yes |  |
| Indication of active consideration in order to reach a final decisio                                     | n    |     |  |
| Is a final decision under active consideration?  |      | Yes |  |
| Information or assistance requested in order to reach a final decision                                   | sion |     |  |
| 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? | X | 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 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p.1), which implements the UN Globally Harmonised System of Classification and Labelling of Chemicals in the Union, perfluorooctanoic acid (PFOA) (CAS number 335-67-1) is classified as:

Acute Tox. 4 – H302 – Harmful if swallowed. Eye Dam. 1 – H318 – Causes serious eye damage. 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 (liver) – Causes damage to organs through prolonged or repeated exposure. Repr. 1B – H360D – May damage the unborn child.

#### 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 Roma, ITALIA Tel. +39 0657053441 Fax +39 0657056347 Email: pic@pic.int

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