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**REPORT FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT, THE  
COUNCIL, THE EUROPEAN ECONOMIC AND SOCIAL COMMITTEE AND THE  
COMMITTEE OF THE REGIONS**

**Summary of the Synthesis Report on the operation of Regulation (EU) No 649/2012  
concerning the export and import of hazardous chemicals**

{SWD(2022) 218 final}

## **ABBREVIATIONS USED**

|       |   |
|-------|---|
| BPR   | Biocidal Products Regulation  |
| CLP   | Classification, Labelling and Packaging Regulation                              |
| DNA   | Designated National Authority   |
| ECHA  | European Chemicals Agency   |
| ePIC  | Software application for implementation of Regulation (EU) No 649/2012          |
| EU    | European Union  |
| FRA   | Final Regulatory Action   |
| NEA   | National Enforcement Authority  |
| OECD  | Organisation for Economic Cooperation and Development                           |
| PIC   | Prior Informed Consent  |
| PPPR  | Plant Protection Products Regulation  |
| REACH | Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation |
| RIN   | Reference Identification Number   |
| SDS   | Safety Data Sheet   |

# 1. INTRODUCTION

## 1.1. The PIC Regulation

Regulation (EU) No 649/2012<sup>1</sup> ('PIC Regulation') implements the Rotterdam Convention on the Prior Informed Consent (PIC) Procedure for Certain Hazardous Chemicals and Pesticides in International Trade. The Regulation aims to promote shared responsibility and cooperation in the international movement of hazardous chemicals, and to protect human health and the environment from potential harm by facilitating the exchange of information on the characteristics of hazardous chemicals, by providing for a decision-making process within the Union on their import and export and by disseminating decisions to Parties and other countries.

The PIC Regulation applies to chemicals listed in Annex III to the Rotterdam Convention and to industrial chemicals (used by professionals and consumers) and pesticides (including biocides) that are banned or severely restricted by Union legislation for health or environmental reasons. It goes beyond the requirements of the Convention since it applies to exports to all countries and requires the consent of the importing country for many more chemicals than those listed under the Convention. In addition, the requirements for export also apply to certain mixtures containing listed chemicals.

Under the PIC Regulation, exports are subject to different requirements depending on their listing in Annex I: chemicals listed in Part 1 of Annex I are subject to export notification to the importing country; chemicals listed in Parts 2 and 3 of Annex I are subject to export notification and explicit consent of the importing country, unless they are subject to the PIC procedure under the Convention and exported to a Party that has provided a positive import response. These obligations also apply to mixtures containing substances listed in Annex I to the Regulation in concentrations that trigger labelling obligations under the Classification, Labelling and Packaging (CLP) Regulation (EC) No 1272/2008<sup>2</sup>, and to certain articles.

The PIC Regulation also places obligations on the Commission to notify the Secretariat of the Convention of Final Regulatory Action (FRA) on chemicals that are banned or severely restricted in the Union in one use category of the Convention (industrial chemicals or pesticides) and which are listed in Part 2 of Annex I of the PIC Regulation. This process is known as the FRA notification and is the basis for the listing of chemicals in Annex III to the Convention.

For chemicals that are listed in Part 3 of Annex I (which reflects Annex III to the Convention), the Commission, on behalf of the Union and based on the empowerment in the PIC Regulation, establishes an import decision that outlines whether and under which conditions the chemical can be imported in the Union. This is sent to the Secretariat of the Convention.

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<sup>1</sup> 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, OJ L 201, 27.7.2012, pp. 60–106.

<sup>2</sup> 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, pp. 1–1355.

## **1.2. The reporting exercise**

Article 22 of the PIC Regulation requires the Commission to report on its activities under the Regulation every three years, and to compile a synthesis report on the performance of the PIC Regulation, integrating:

- The information submitted by Member States as per Article 22(1), concerning the operation of the procedures provided for in this Regulation, including customs controls, infringements, penalties and remedial action.
- The information submitted by the European Chemicals Agency (ECHA) as per Article 22(1), concerning the operation of the PIC Regulation's procedures.

This reporting exercise is the second under the PIC Regulation and covers the period 2017-2019. The online reporting questionnaire was made available to the Member States on 9 June 2021, with a deadline for completion set to 27 August 2021. All reports were submitted by mid-November 2021. The Agency published its report on the operation of the PIC Regulation<sup>3</sup> for the period 2017-2019 in August 2020. The present report is the summary of the synthesis report, which provides an overview of the implementation of the PIC Regulation in the period 2017-2019.

## **2. GOVERNANCE OF THE PIC REGULATION**

### **2.1. The Commission, the Agency and DNAs consider that the coordination of their activities in the implementation of the PIC Regulation is effective**

At national level, each Member State designates a national authority (DNA) to carry out the administrative functions foreseen by the PIC Regulation. As in the previous reporting period, Member States considered the coordination between DNAs and the Commission, and between DNAs and the Agency is satisfactory. Several DNAs valued the support provided by the Commission and the Agency for its swiftness and quality. The Agency rates collaboration with DNAs as similarly effective, including when handling disagreements. The Commission also considered the cooperation with DNAs to be effective, in particular through discussions at the twice-yearly PIC DNA meetings.

The Agency considered the collaboration with the Commission satisfactory, pointing however to a number of areas for improvement. The Commission also considered the cooperation with the Agency to be satisfactory, highlighting the regular exchanges on scientific, technical and legal questions arising in the context of implementation and their practical implementation.

### **2.2. The continuous increase in PIC activities creates challenges for maintaining an appropriate level of resources**

Resources dedicated to implementation of the PIC Regulation by the European Commission and ECHA remained quite stable compared to the previous reporting period, although both institutions reported a slight increase. The Agency's workload during the reporting period was in line with the predicted workload. The number of export notifications processed has continued to increase in line with the predicted 10% yearly increase.

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<sup>3</sup> ECHA (2020) Report on the operation of the Prior Informed Consent (PIC) Regulation. ECHA-20-R-10-EN.

The increase in export notifications has led to an increase in processing tasks to be performed by the Agency and in stakeholder support. Support provided by the Agency to the Commission, EU- and non-EU DNAs has taken approximately 30-40% of staff time during the reporting period. As the amount of resources is not increasing proportionally to the workload, ECHA stresses in its report the necessity to secure sufficient human and financial resources to implement the PIC Regulation and to further improve implementation practices, processes and tools.

PIC DNAs reported levels of resources dedicated to the implementation of the PIC Regulation ranging from 0.1 to 2 FTEs. To the extent that comparison is possible, resources have remained quite stable in many DNAs, with around eight reporting a decrease. In parallel, the workload linked to export notification processing has increased in many Member States (see section 4.2). Less Member States than in the previous reporting period stated that they have sufficient resources for enforcement (15 instead of 18).

### 3. UPDATES OF ANNEX I TO THE PIC REGULATION

According to Article 23, the list of chemicals in Annex I should be reviewed at least once a year by the Commission, on the basis of the developments in EU law – mainly in the REACH Regulation<sup>4</sup>, the BPR<sup>5</sup> and the PPPR<sup>6</sup> – and under the Convention. Annexes to the PIC Regulation are amended through delegated acts adopted by the Commission.

During the reporting period, 31 substances were included in Part 1 and seven in Part 2 of Annex I. Twenty-three of these substances were included due to the non-approval as plant protection products under the PPPR, and five after inclusion in Annex XVII to REACH (Table 1). Six were included in Part 3 of Annex I following their inclusion in Annex III to the Convention. With the exception of short chain chlorinated paraffins, these had already been included in Parts 1 and 2 of Annex I to the PIC Regulation.

**Table 1: Substances added to Annex 1 during the reporting period**

| Delegated Act   | Chemical                             | CAS number | Amendment of Annex I | Basis for inclusion |
|---|--------------------------------------|------------|----------------------|---------------------|
| Commission  | 3-decen-2-one                        | 10519-33-2 | Parts 1 and 2        | PPPR                |
| Delegated Regulation (EU) 2018/172 of 28 November 2017 amending Annexes I and V to Regulation | 5-tert-butyl-2,4,6-trinitro-m-xylene | 81-15-2    | Parts 1 and 2        | REACH               |
|   | Benzyl butyl phthalate               | 85-68-7    | Parts 1 and 2        | REACH               |
|   | Carbendazim                          | 10605-21-7 | Part 1               | PPPR                |
|   | Cybutryne                            | 28159-98-0 | Parts 1 and 2        | BPR                 |

<sup>4</sup> Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 on 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, pp. 1–854.

<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, pp. 1–123.

<sup>6</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, pp. 1–50.

| Delegated Act   | Chemical                           | CAS number                 | Amendment of Annex I | Basis for inclusion                  |
|---|------------------------------------|----------------------------|----------------------|--------------------------------------|
| (EU) No 649/2012  | Diisobutyl phthalate               | 84-69-5                    | Parts 1 and 2        | REACH                                |
|   | Diarsenic pentaoxide               | 1303-28-2                  | Parts 1 and 2        | REACH                                |
|   | Tepraloxydim                       | 149979-41-9                | Parts 1 and 2        | PPPR                                 |
|   | Triclosan                          | 3380-34-5                  | Parts 1 and 2        | BPR                                  |
|   | Triflumuron                        | 64628-44-0                 | Part 1               | BPR                                  |
|   | Tris (2-chloroethyl) phosphate     | 115-96-8                   | Parts 1 and 2        | REACH                                |
|   | Methamidophos                      | 10265-92-6                 | Parts 1 and 3        | Annex III<br>Rotterdam<br>Convention |
| Commission Delegated Regulation (EU) 2019/330 of 11 December 2018 amending Annexes I and V to Regulation (EU) No 649/2012 | Amitrole                           | 61-82-5                    | Parts 1 and 2        | PPPR                                 |
|   | Beta-cypermethrin                  | 65731-84-2                 | Parts 1 and 2        | PPPR                                 |
|   | Carbofuran                         | 1563-66-2                  | Parts 1 and 3        | Annex III<br>Rotterdam<br>Convention |
|   | DPX KE 459 (flupyrsulfuron-methyl) | 150315-10-9<br>144740-54-5 | Parts 1 and 2        | PPPR                                 |
|   | Fipronil                           | 120068-37-3                | Parts 1 and 2        | PPPR                                 |
|   | Iprodione                          | 36734-19-7                 | Parts 1 and 2        | PPPR                                 |
|   | Isoproturon                        | 34123-59-6                 | Parts 1 and 2        | PPPR                                 |
|   | Linuron                            | 330-55-2                   | Parts 1 and 2        | PPPR                                 |
|   | Maneb                              | 12427-38-2                 | Parts 1 and 2        | PPPR                                 |
|   | Orthosulfamuron                    | 213464-77-8                | Parts 1 and 2        | PPPR                                 |
|   | Picoxystrobin                      | 117428-22-5                | Parts 1 and 2        | PPPR                                 |
|   | Short-chain chlorinated paraffins  | 85535-84-8                 | Part 3               | Annex III<br>Rotterdam<br>Convention |
|   | Triasulfuron                       | 82097-50-5                 | Parts 1 and 2        | PPPR                                 |
|   | Trichlorfon                        | 52-68-6                    | Parts 1 and 3        | Annex III<br>Rotterdam<br>Convention |
| Commission Delegated Regulation (EU) 2019/1701 of 23 July 2019 amending Annexes I and V to Regulation (EU) No 649/2012    | 2-naphthyloxyacetic acid           | 120-23-0                   | Part 2               | PPPR                                 |
|   | Acetochlor                         | 34256-82-1                 | Parts 1 and 2        | PPPR                                 |
|   | Asulam                             | 3337-71-1<br>2302-17-2     | Parts 1 and 2        | PPPR                                 |
|   | Chloropicrin                       | 76-06-2                    | Parts 1 and 2        | PPPR                                 |
|   | Diphenylamine                      | 122-39-4                   | Part 2               | PPPR                                 |
|   | Flufenoxuron                       | 101463-69-8                | Parts 1 and 2        | PPPR                                 |
|   | Naled                              | 300-76-5                   | Parts 1 and 2        | PPPR                                 |
|   | Propanil                           | 709-98-8                   | Part 2               | PPPR                                 |
|   | Propargite                         | 2312-35-8                  | Parts 1 and 2        | PPPR                                 |
|   | Alachlor                           | 15972-60-8                 | Part 3               | Annex III<br>Rotterdam<br>Convention |
|   | Aldicarb                           | 116-06-3                   | Part 3               | Annex III<br>Rotterdam<br>Convention |
|   | Endosulfan                         | 115-29-7                   | Part 3               | Annex III<br>Rotterdam<br>Convention |

As per Article 11 of the PIC Regulation, the Commission must notify the Secretariat of the Convention, in writing, of the chemicals listed in Part 2 of Annex I, which qualify for PIC notification. Ten FRA notifications were submitted to the Secretariat during the reporting period:

- Acetochlor (2017)
- Amitrole (2019)
- Beta-cypermethrin (2019)
- Cybutryne (2019)
- Flupyr-sulfuron-methyl (2019)
- Iprodione (2019)
- Isoproturon (2019)
- Orthosulfamuron (2019)
- Picoxystrobin (2019)
- Triasulfuron (2019)

## 4. OPERATION OF THE PIC REGULATION

### 4.1. Awareness-raising activities and support provided by DNAs and the Agency to exporters have improved compliance

Twenty-seven Member States carried out awareness-raising and information activities targeting exporters and importers. The most common activity was the provision of online information (specific webpage or references to the Agency's webpages on PIC). Eleven Member States also provide helpdesk services via an existing helpdesk (e.g. REACH, CLP, BPR) and six operate a PIC national helpdesk; ten Member States indicated having a specific email address for information requirements. Almost all Member States stated that these activities improved compliance among exporters and importers with the PIC Regulation. Some DNAs noted an increase in the number of export notifications and improvements in their quality, an increase in the number of companies registered in ePIC or using it, and improved compliance with Article 10 reporting obligations.

The Agency is required to provide assistance, as well as technical and scientific guidance and tools to exporters and importers (Article 6(1)). The Agency provided information and support to exporters and importers through its website, weekly e-News, the ECHA Newsletter, social media, internal messaging in e-PIC, and the ECHA Helpdesk. The Agency published four guidelines ("In brief" documents) to assist companies with special RIN (Reference Identification Number) requests, waivers, reporting and filling section 6 of export notifications (prohibited and allowed uses). The Agency also prepared for post-Brexit export notifications by publishing a guideline on "[How to notify PIC exports to the UK after the UK's withdrawal from the EU](#)" and establishing a manual notification procedure (until those can be made in ePIC).

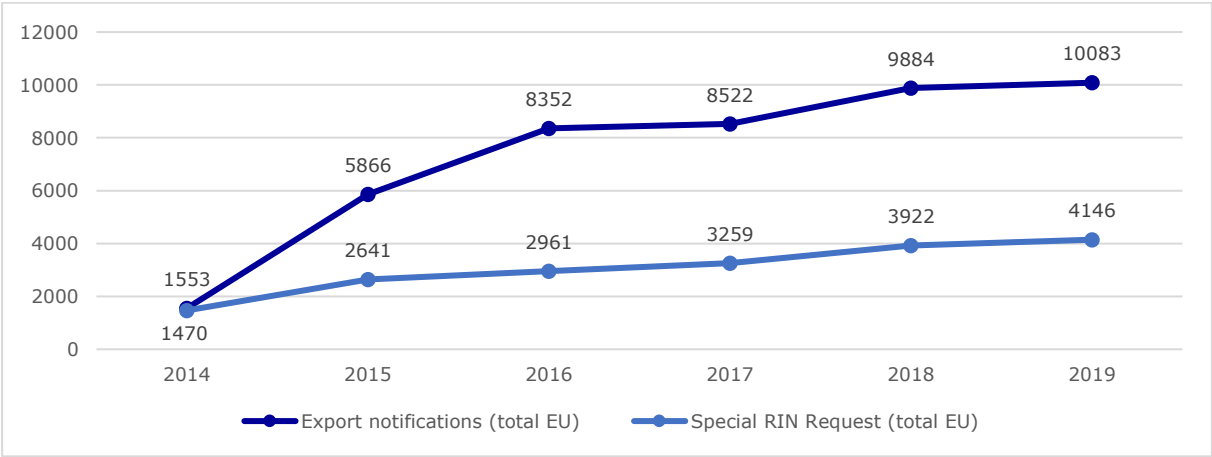
### 4.2. The number of export notifications handled by DNAs and ECHA has continuously increased since 2014 and their processing is unevenly distributed between Member States

The export notification is the instrument by which countries exchange information on banned or severely restricted chemicals. All EU based exporters must submit an export notification to their DNAs if they intend to export chemicals listed in Part 1 of Annex I to the PIC Regulation. Once the DNA has checked and accepted the notification, it is forwarded to the Agency, which also checks the compliance of the notification and transmits it to the DNA of the importing

country. If no acknowledgement of receipt is received, the Agency sends the notification again. The whole procedure is carried out through ePIC, and exporters must use the notification template provided by the system. For certain exports that are exempt from the PIC Regulation or from the export notification requirement, exporters are required to request a Special RIN from their DNA and to use it in the customs declaration to facilitate customs clearance.

The number of export notifications and Special RIN requests have continuously increased since 2014 (Figure 1). The Agency reported an increase in the number of export notifications from 8 455 in 2017 to 10 009 in 2019<sup>7</sup>. According to the Agency, this increase reflects increased compliance and the addition of new substances to Annex I.

**Figure 1 : Total number of export notifications accepted and forwarded to the Agency by DNAs and of Special RIN requests accepted by DNAs per year since 2014<sup>8</sup>**

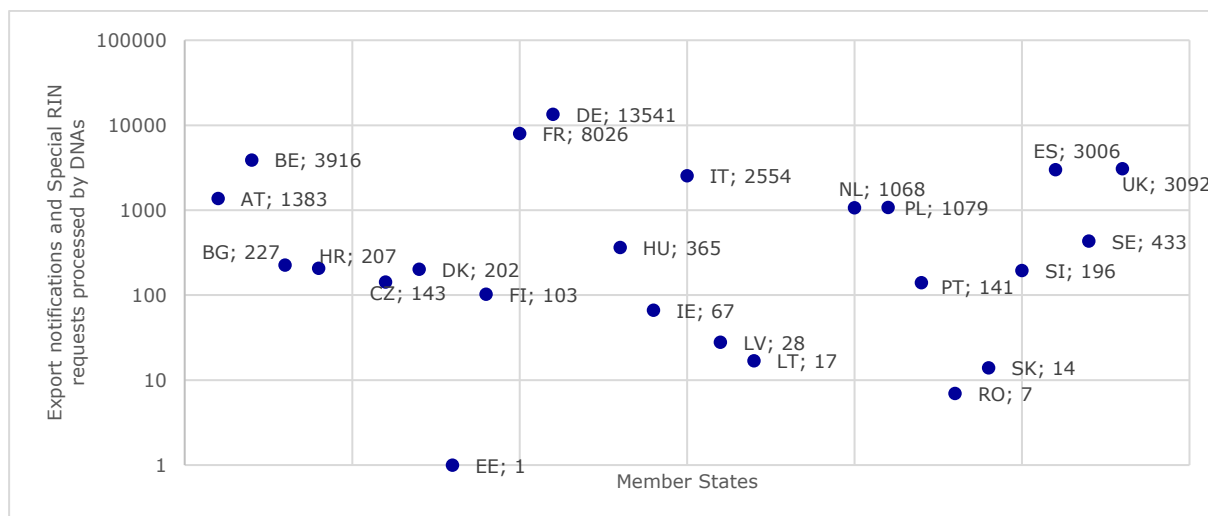


As in the previous reporting period, the number of export notifications and special RIN requests processed varied significantly between Member States (Figure 2). The highest numbers of export notifications were in Germany (8 645 notifications) and France (6 855), followed by Italy (2 453), Spain (2 383) and the UK (2 207). Twenty Member States processed more export notifications during this reporting period compared to the previous one and in nine Member States, this number more than doubled between the two reporting periods. The situation is similar for special RIN requests, where 11 Member States did not receive any, whilst Germany, Belgium and France were the Member States that accepted the highest number of them. Thirteen Member States processed more Special RIN requests during this reporting period compared to the previous one. Four Member States did not process any export notification (Cyprus, Greece, Luxembourg and Malta).

<sup>7</sup> Figures provided for the Agency includes initial submissions, re-submissions and rejections.  
<sup>8</sup> For 2014 the period covered is 1 March – 31 December (as the PIC Regulation became applicable on 1 March 2014).



**Figure 2 : Total number of export notifications and Special RIN requests accepted by DNAs during the reporting period**



#### **4.3. Incorrect filling of the export notification form still leads to a high number of requests for resubmission**

Member States and ECHA requested the resubmission by the exporter of 5 889 and 2 758 export notifications respectively during the reporting period. Main issues were the unclear or incorrect filling of section 6.2 of the export notification on prohibited and allowed uses, and of section 3.3 on intended uses. Another reason for requesting resubmission was the provision of incorrect or insufficient contact details for the importer. The provision of the SDS in an inappropriate language is also mentioned as an issue by DNAs and ECHA.

#### **4.4. Reporting under Article 10 generally worked effectively, although the quality of DNAs' reporting could still be improved**

Article 10 places obligations on exporters and importers to inform the DNA, during the first quarter of each year, of the quantity of chemicals listed in Annex I of the PIC Regulation exported to, or imported from, third countries during the preceding year. Exporters must also provide the DNA with the names and addresses of each importer. DNAs must, in turn, provide this information to the Agency annually, which then aggregates the data at EU level and makes it publicly available on its database<sup>9</sup>.

Information provided by the Agency and DNAs suggested that the reporting process under Article 10 worked effectively. Less Member States than in the previous reporting period (seven) stated that they experienced delays from exporters in submitting information on the quantity of the chemicals exported, and these delays did not affect the completion of DNA's reporting exercise. According to ECHA, reporting from DNAs has improved as less DNAs reported data that are out of scope. However, some of the data submitted by DNAs contained errors derived

<sup>9</sup> ECHA, Annual reporting on PIC exports and imports: <https://echa.europa.eu/regulations/prior-informed-consent/annual-reporting-on-pic-exports-and-imports>

from industry reporting and required correction, re-aggregation and resubmission of the reports by the DNAs. This has led to inefficiencies in the preparation of the overall report and ECHA therefore recommends that DNAs increase verification of aggregated data before submission.

#### **4.5. EU import decisions have been adopted for four substances listed in Annex III to the Rotterdam Convention**

As per Article 10 of the Convention, Parties are requested to adopt an import decision for each new chemical listed in Annex III and to submit it to the Secretariat. Pursuant to Article 13 of the PIC Regulation, the Union import decision is adopted by means of an implementing act of the Commission, which is drafted by the Commission services and submitted to the REACH Committee for an opinion, in accordance with the advisory procedure. During the reporting period, the Commission adopted one Implementing Decision in 2018, which provided new import decisions for four substances and amended one import decision (Table 2).

**Table 2: Union import decisions adopted during the reporting period**

| Implementing Act                                    | Chemicals                         | Nature / status of decision   |              | Import decision | Grounds for decision                                   |
|---|-----------------------------------|---|--------------|-----------------|--|
| Commission Implementing Decision of 10 October 2018 | Carbofuran                        | 1563-66-2   | New decision | Final           | No consent to import                                   |
|   | Trichlorfon                       | 52-68-6   | New decision | Final           | No consent to import                                   |
|   | Short-chain chlorinated paraffins | 85535-84-8  | New decision | Final           | Consent to import only subject to specified conditions |
|   | Tributyltin compounds             | 56-35-9; 1983-10-4; 2155-70-6; 4342-36-3; 1461-22-9; 24124-25-2; 85409-17-2 | New decision | Final           | Consent to import only subject to specified conditions |
|   | Ethylene Oxide                    | 75-21-8   | Modification | Final           | Consent to import only subject to specified conditions |

#### **4.6. The low response rate of non-EU countries to explicit consent requests remains a problem but many issues are effectively solved through good coordination between ECHA and DNAs**

Article 14 requires the consent of the importing country before an export of chemicals listed in parts 2 or 3 of Annex I can proceed. However, the DNA of the exporter can decide, on a case-by-case basis and in consultation with the Commission, to waive the requirement for explicit consent when a chemical qualifying for PIC notification is exported to an OECD country (Article 14(6)) or when no reply from the importing country has been received after 60 days and provided that certain conditions are met (Article 14(7)).

Nineteen Member States processed exports where the explicit consent procedure pursuant to Article 14 was involved. A total of 5 058 requests for explicit consent were processed by DNAs between 2017 and 2019, compared with 3 362 in the previous reporting period. In 15 Member States (out of 19), the number of requests was higher than in the previous reporting period.

As previously, the main challenge reported by DNAs was late responses from importing countries to consent requests (i.e. after the 60-day waiting period) or no response at all. The response rate remained rather low during this reporting period. Of the 5 058 requests for explicit consent, 54% received responses following either the initial request, the first or the second reminder, which is a roughly similar response rate as in the past. DNAs also stated that the response provided was not always clear or was difficult to interpret and that certain countries were particularly difficult to reach.

The Agency considered that this process is working smoothly and that collaboration with DNAs is effective. Despite a low response rate, the process has contributed, according to the Agency, to harmonised data and the reduction of clerical errors during the procedure.

Few Member States had to decide whether or not the requirement for explicit consent should be waived (eight for an export to an OECD country and 13 in the absence of a response from the competent authority of the importing country), and information provided by DNAs suggested that few implementation problems occurred. Fifteen Member States experienced cases where the export was allowed to proceed pending a reply to a new request for explicit consent (Article 14(8)). According to the Agency, Article 14(8) remained challenging to implement. However, the number of problematic cases (i.e. in which the Agency and the DNAs disagree on the interpretation) has been substantially reduced after it was discussed in a DNA meeting and the related ePIC functionality was enhanced accordingly.

#### **4.7. Few Member States reported non-compliance with requirements on information to accompany exported chemicals**

Article 17 states that exported chemicals must be packaged and labelled in accordance with the respective Union provisions, unless the importing country requires otherwise. An Safety Data Sheet compliant with Annex II of the REACH Regulation must be sent to each importer together with the chemical. Only six Member States reported compliance issues concerning the information accompanying exported chemicals, related to packaging requirements under the CLP Regulation and the SDS.

#### **4.8. All Member States have control and enforcement systems but a third of them do not have an enforcement strategy**

According to Article 18 of the PIC Regulation, Member States must designate authorities, such as customs authorities, to control imports and exports of chemicals listed in Annex I. All Member States have nominated these authorities. Customs are involved in the implementation of the PIC Regulation in all Member States, except Malta (and the United Kingdom for the reporting period before 1<sup>st</sup> January 2020). In six countries, the customs administration is the only NEA.

Fifteen Member States (compared to 18 in the previous reporting period) indicated that NEAs have sufficient resources to carry out their obligations under the PIC Regulation. Member States that highlighted resource issues within National Enforcement Authorities typically referred to the lack of human resources. Seventeen Member States reported having a strategy for the enforcement of the PIC Regulation and 16 Member States have established regular training for inspectors.

#### 4.9. Few infringements have been identified during the reporting period

The number of Member States that reported official control activities is quite comparable to the previous reporting period, and still rather low considering that 24 Member States reported trade activities. Unless Member States specified it in their report, it cannot be concluded whether this results from a lack of data collection or a lack of enforcement activities. Ten Member States reported customs controls on exports in which the PIC Regulation was covered, compared to 13 in the previous reporting period. Eleven Member States reported controls carried out by inspectors. Regarding imports, four Member States reported customs controls and ten reported controls carried out by inspectors.

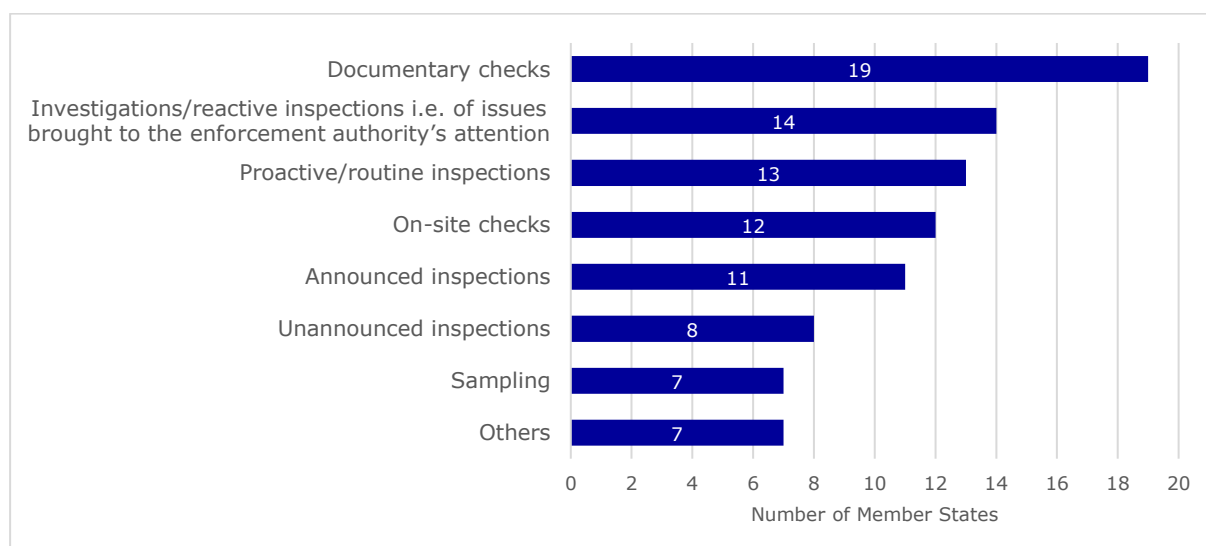
A total of 9 132 controls of exports were performed during the reporting period, compared to 6 474 controls in the period 2014-2016 (Table 3). On imports, 1463 controls have been carried out, compared to 1941 in 2014-2016, mostly due a decrease in customs controls on imports. As in the past, customs controls represent the majority of controls. The number of controls performed varied greatly between Member States, which could be due to the number of exports and imports of PIC chemicals in the country, the inspection strategy, or the types of controls performed (e.g. reactive controls versus regular monitoring).

Regarding the types of enforcement activities carried out, documentary checks are carried out in around two thirds of the Member States (19), while less than half reported carrying out proactive inspections or on-site checks (Figure 3).

**Table 3 : Total number of official controls on exports and imports in which the PIC Regulation was covered or enforced during the reporting period**

|                              | Controls performed by customs | Controls performed by inspectors | Controls performed by other entities |
|------------------------------|-------------------------------|----------------------------------|--------------------------------------|
| Official controls on exports | 8599                          | 526                              | 7                                    |
| Official controls on imports | 237                           | 1193                             | 33                                   |

**Figure 3: Enforcement activities carried out in Member States**



The number of infringements found (138) is rather low compared to the number of controls carried out. Five Member States reported infringements identified through customs controls and six through controls carried out by inspectors. The main category of infringement found by customs related to the absence of the RIN (13 infringements) and Box 44 of the single administrative document not being properly filled (12 infringements). Penalties were imposed in three Member States in 29 cases of infringements.

#### **4.10. The first pilot project on the enforcement of the PIC Regulation was implemented by the Forum during the reporting period**

The Forum for Exchange of Information on Enforcement (Forum) is a network of authorities responsible for the enforcement of the REACH, CLP, PIC and POP regulations. During 2017-2018, the Forum conducted a pilot project on the control of compliance with the PIC Regulation focusing on export notifications (Articles 8, 14, and 15) and information to accompany exported chemicals (Article 17), to which thirteen Member states participated. Member States completed 296 inspections, consisting of both on-site and desktop inspections<sup>10</sup>. In 2019, the Forum prepared a ‘Practical enforcement guide for the control of PIC obligations’ describing good practices in the enforcement of Articles 8, 14, 15 and 17 of the PIC Regulation, as developed during the pilot project.

Member States are generally satisfied with the activities carried out by the Forum. A number of DNAs underlined the benefits of the pilot project and suggested that other pilot projects should be implemented in the future.

#### **4.11. Several DNAs and the Agency have participated in technical assistance activities**

According to Article 21, the Commission, DNAs and the Agency must cooperate in promoting technical assistance, in particular to help developing countries and countries with economies in transition to implement the Convention and develop the infrastructure, capacity and expertise needed to manage chemicals properly throughout their lifecycles.

Five Member States participated in cooperation activities and four in projects or international activities related to capacity-building in chemicals management. DNA activities consisted of the provision of technical information through workshops, training, visits of experts’ delegations from third countries, etc., cooperation projects and support for the establishment or maintenance of DNAs. ECHA participated in several training events organised by the Rotterdam Convention, the Commission or DNAs. The Agency also provided support to pre- and candidate countries to increase their capacity in the area of chemical management via the EU Instrument for Pre-accession assistance (IPA).

#### **4.12. ePIC users generally found the IT tool user-friendly and adequate to support their work**

As requested by the PIC Regulation, the Agency developed and maintains the IT tool (ePIC) to support the implementation. A number of new features were added to the ePIC system during

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<sup>10</sup> ECHA (2018) Final report of the Forum pilot project on the control of PIC.

the reporting period in order to improve the functioning and usefulness of the tool. The tool is used by all relevant authorities, including enforcement authorities and customs, and by exporters and importers. The number of users from industry, DNAs and NEAs has increased since the previous reporting period.

Overall, DNAs found ePIC to be user-friendly and did not experience major issues using it. DNAs' opinion on ePIC has improved since the previous reporting period and more DNAs have experience with it. Feedback from industry users to the Agency and DNAs was also generally positive, as was the feedback from customs and enforcement authorities.

#### **4.13. Information and data on the implementation of the PIC Regulation are publicly available**

According to the PIC Regulation, the Agency should make the following data publicly available:

- The list of chemicals included in Annex I (Article 7);
- The updated list of chemicals subject to export notification, and the importing Parties and other countries for each calendar year (Article 8);
- Reports on actual quantities of chemicals subject to the PIC Regulation exported and imported (Article 10);
- Import decisions (Article 13);
- Non-confidential data on explicit consents received from non-EU countries (Article 14).

This information is available on the Agency's [webpage dedicated to the PIC Regulation](#) and the webpage dedicated to [chemicals subject to PIC](#), which provides a searchable database of chemicals subject to PIC, non-confidential data on EU export notifications, export notifications and explicit consents received from non-EU countries, and DNAs' contact details. Reports on actual quantities of PIC chemicals exported and imported (pursuant to Article 10) are provided on the page '[Annual reporting on PIC exports and imports](#)'. During the reporting period, the Agency published the first [Report on the operation of the PIC Regulation](#) (pursuant to Article 22) in 2017 and the [second Report on information exchange](#) (pursuant to Article 20) in 2018.

## **5. CONCLUSIONS**

The PIC Regulation implements the Rotterdam Convention in the Union and has the same objectives. However, the PIC Regulation goes beyond the requirements of the Convention in order to offer a higher level of protection, in particular to developing countries and countries with economies in transition.

This report demonstrates that the procedures established by the PIC Regulation operated well and that their implementation worked well, in particular due to effective coordination and cooperation between DNAs, ECHA and the Commission, both for EU internal and international work, which was the basis for achieving its objectives.

The export notification procedure provided the importing countries with important information on many chemicals and their export. With 10 000 export notifications in 2019 and its continuing upward trend, the scale of the information exchange and its potential to increase further is clearly visible. The increasing workload can only be handled with appropriate staff resources,

given the need to maintain the capacity for processing and support while ensuring the performance of the IT application 'ePIC', developed and maintained by the Agency.

The application of explicit consent procedure as a standard procedure for the export of certain chemicals, which goes beyond the Convention, has led to the high number of 5 058 requests for explicit consent sent to importing countries in the reporting period. Those requests presented a challenge for many importing countries, which is shown by the share of 46% that remained unanswered.

The exporters of chemicals subject to the PIC Regulation were generally aware of their obligations and able to meet them. If needed, the DNAs and the Agency provided the necessary assistance, which has contributed to the low number of infringements. During this reporting period, 9 132 controls on exports and 1 463 controls on imports were reported and 138 infringements were detected, out of which 29 led to penalties.

In general, the Member States met their obligations, although the high workload at the end of each year - caused by the large number of export notifications – presented a challenge for some Member States and sometimes led to problems with timeframes. The contribution of the Agency to implementation was fully in line with the requirements of the PIC Regulation and the basis for effective functioning of the procedures. The Commission completed its obligations under the PIC Regulation. Three Commission Delegated Regulations amending Annex I, as well as one Commission Implementing Decision adopting Union import decisions, were adopted in the reporting period. In addition, the Commission coordinated the contribution of the Union to the international work and represented the Union at the Convention.