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COVER NOTE

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COMMISSION STAFF WORKING DOCUMENT

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

Accompanying the document

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

{COM(2018) 697 final}

Contents

Abbreviations used

BPR	Biocidal Products Regulation
CLP	Classification, Labelling and Packaging Regulation
CN	Combined Nomenclature
CoP	Conference of the Parties to the Rotterdam Convention
CRC	Chemical Review Committee of the Rotterdam Convention
CUS	Customs Union and Statistics
DNA	Designated National Authority
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
POPs	Persistent Organic Pollutants
PPPR	Plant Protection Products Regulation
RC	Rotterdam Convention
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation
RIN	Reference Identification Number
SAICM	Strategic Approach to International Chemicals Management
SDS	Safety Data Sheet

1 INTRODUCTION

1.1 The PIC Regulation

Regulation (EU) No 649/2012[1] ('the PIC Regulation') implements the Rotterdam Convention on the Prior Informed Consent (PIC) Procedure for Certain Hazardous Chemicals and Pesticides in International Trade, adopted in 1998 and ratified by the EU in 2002. 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 concerning the characteristics of hazardous chemicals, providing for a decision-making process within the EU on the import and export of such chemicals, and disseminating decisions to Parties to the Convention and other countries (Article 1).

The PIC Regulation applies to chemicals subject to the PIC procedure under the Rotterdam Convention, as well as to industrial chemicals (used by professionals and consumers) and pesticides (including biocides) that are banned or severely restricted by EU legislation for health or environmental reasons. The Regulation places obligations on companies intending to export such chemicals to third countries, whether or not they are Parties to the Rotterdam Convention. Exports are subject to different requirements depending on their listing in Annex I to the Regulation: chemicals listed in Part 1 of Annex I are subject to export notification to the authority of the importing country; chemicals listed in Parts 2 and 3 of Annex I are subject to export notification and explicit consent of the authority 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, or to a country that has waived its right to be notified. 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 Regulation (EC) No 1272/2008[2] (CLP Regulation), and to articles containing substances listed in Parts 2 or 3 of Annex I in unreacted form, or mixtures containing substances listed in Parts 2 or 3 of Annex I in concentrations that trigger labelling obligations under the CLP Regulation.

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 through FRA in the EU 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, as well as to inform other Parties about their potential risks and allow them to consider whether or not risk management measures are needed in their own territories. 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, in close cooperation with the Member States, decides if the chemical can be imported in the EU and under which conditions. This is done through an import decision, which is then sent to the Secretariat of the Convention.

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[1] 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.

[2] 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 following:

- 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 first under the new PIC Regulation. It covers the three years of implementation since the Regulation became applicable (2014[3]-2016). A common reporting format for Designated National Authorities (DNAs) was established by Commission Implementing Decision (EU) 2016/770 of 14 April 2016[4], in order to collect consistent information across Member States. Similarly, a reporting format for the Agency's report was adopted through Commission Implementing Decision (EU) 2016/1115 of 7 July 2016[5].

Although the Member States and the Agency were required to report by 31 May 2017, the reporting process encountered some delays. The report from the Agency was received on 18 July 2017, while the Member States' reporting was completed on 5 October 2017, when the final reporting questionnaire was submitted.

The present report is the synthesis report (as per Article 22 of the PIC Regulation), bringing together the findings from the reports of the Commission, the Agency's, and Member States. It provides an overview of the implementation of the PIC Regulation in the period 2014-2016.

1.3 Methodology

1.3.1 Preparation of the Commission's report

The report is divided into two sections, the first addressing the work of the Commission with respect to implementation within the EU, and the second addressing the international work of the Commission as the EU DNA to the Rotterdam Convention.

Additional relevant information was compiled from EUR-lex, the website of the Rotterdam Convention, and documents published on CIRCABC, including minutes of meetings, and other documents discussed at DNA meetings (see Table 1). Other information was obtained first-hand from Commission officials. Sources used for this report are listed in Table 1 below. The report was then used as a source for the synthesis report.

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[3] Regulation (EU) No 649/2012 applied from 1 March 2014.

[4] Commission Implementing Decision (EU) 2016/770 of 14 April 2016 establishing a common format for the submission of information concerning the operation of the procedures pursuant to Regulation (EU) No 649/2012 of the European Parliament and of the Council concerning the export and import of hazardous chemicals, C/2016/2068, OJ L 127, 18.5.2016, pp. 32–51.

[5] Commission Implementing Decision (EU) 2016/1115 of 7 July 2016 establishing a format for the submission by the European Chemicals Agency of information concerning the operation of the procedures pursuant to Regulation (EU) No 649/2012 of the European Parliament and of the Council concerning the export and import of hazardous chemicals, C/2016/4141, OJ L 186, 9.7.2016, pp. 13–23.

Table 1: List of relevant documents consulted for the Commission report

List of relevant documents consulted
Implementing and delegated acts • Commission Delegated Regulation (EU) No 1078/2014 amending Annex I to the PIC Regulation. • Commission Delegated Regulation (EU) 2015/2229 amending Annex I to the PIC Regulation. • Commission Implementing Decision of 11 February 2016 adopting Union import decisions (2016/C 61/06). • Commission Implementing Decision of 15 May 2014 adopting Union import decisions (2014/C 152/02). • Commission Implementing Decision of 14 April 2016 establishing a common format for the submission of information concerning the operation of the procedures pursuant to Regulation (EU) No 649/2012 of the European Parliament and of the Council concerning the export and import of hazardous chemicals. • Commission Implementing Decision of 7 July 2016 establishing a format for the submission by the European Chemicals Agency of information concerning the operation of the procedures pursuant to Regulation (EU) No 649/2012 of the European Parliament and of the Council concerning the export and import of hazardous chemicals. **DNA meeting documents** • Minutes of 23rd, 24th, 25th, 26th, 27th and 28th DNA meetings. • Amendments to Annex I to Regulation (EU) No 649/2012 presented at 23rd, 24th, 25th, 26th, 27th and 28th DNA meetings. • Import decisions presented at 23rd, 24th, and 26th DNA meetings. • Submission of notifications to the PIC secretariat presented at 23rd, 24th, 25th, 26th, 27th and 28th DNA meetings. • Implementation issues presented at 23rd, 24th, 25th, 26th, 27th and 28th DNA meetings. • Documents on the preparation of COP 7 and 8 presented at 25th, 26th and 28th DNA meetings. **Rotterdam Convention documents** • PIC circulars published by the Rotterdam Convention.

1.3.2 Implementation of the common format for reporting for Member States in the form of a web-based questionnaire

The common reporting format was made available online to Member States on 2 February 2017, through EU Survey. A guidance document for Member States accompanied the invitation email. The project team was also available to answer DNA questions on EU Survey and/or the reporting format, as well as supporting the DNAs in submitting their questionnaires.

To facilitate Member State reporting, the Agency has made data from ePIC available to DNAs for the following questions:

- Section 2 - Question 10: number of export notifications and Special RIN requests accepted by DNA and forwarded to the Agency.
- Section 5 - Question 20: number of export notifications sent back to the exporter either to request resubmission or because the notification was rejected.
- Section 7 - Question 40: number of requests for explicit consent and number of responses received per year.
- Section 7 - Question 43: number of cases where DNA had to decide if no explicit consent was required in case of chemicals listed in Part 2 of Annex I to be exported to OECD countries.
- Section 7 - Question 45: number of waiver requests received by DNAs.
- Section 7 - Question 47: number of cases where the export was allowed to proceed pending a reply to a new request for explicit consent.

For consistency, the data provided by the Agency were used for these questions, even where the data provided by the Member States differed from that data sent by the Agency.

1.3.3 Synthesis of Member States' reporting

Once all Member States had returned their reporting questionnaires, the full dataset and statistics were downloaded in excel format from EU Survey. The information provided by the DNAs was compiled and summarised for each question and presented visually, where relevant. The full set of DNA responses is available in Annex II.

1.3.4 Drafting the synthesis report and summary

The synthesis report combines the information from the Commission report, the Member States' reporting questionnaires and the Agency's questionnaire. It follows the structure of the common Member States' reporting questionnaire and the questionnaire for the Agency's reporting, integrating the information from the Commission report, where relevant. The summary follows the same structure as that of the synthesis report, presenting the key facts and conclusions from each section.

2 GOVERNANCE OF THE PIC REGULATION

2.1 Organisation of the implementation of the PIC Regulation

2.1.1 European Commission

The Commission, in cooperation with the Member States, is responsible for policy work under the PIC Regulation, in particular the adoption of amendments to Annexes I and V to the Regulation. In addition, the Commission is responsible for the legal interpretation of the Regulation, and representation of the Union in the Convention and towards non-EU Parties, which includes acting as a common designated authority for the administrative functions of the Convention with respect to the PIC procedure (see Section 2.3). The Commission also chairs the DNA meetings that occur twice a year, normally in April and October.

DG Environment takes charge of the PIC Regulation. Unit B.2 – sustainable chemicals has one policy coordinator responsible for implementation of the PIC Regulation, including policy and legal matters and international cooperation and representation. The policy coordinator is supported by a lawyer for legal questions, and by a secretary for all organisational work. For international work, Unit B.2 has one expert (the policy coordinator) who was nominated to the Convention bodies, i.e. the Chemical Review Committee (CRC) and the intersessional working group on the process of listing chemicals in Annex III to the Convention. In addition, colleagues of Unit F.3, which is responsible for multilateral environmental cooperation, contribute to the international work, particularly in the context of the CoP, by dealing with horizontal and cross-cutting matters such as financial resources, budget, technical assistance and some legal matters. The staff resources occupied by this work amount to 0.4 FTE for the policy coordinator and 0.4 FTE for the supporting work, including international matters.

2.1.2 European Chemicals Agency (Agency)

The Agency plays a central role in ensuring that the export notification procedure functions properly, as well as developing and operating the application to process export notifications and the explicit consent given by the importing countries (ePIC). More specifically, the tasks of the Agency include:

- Registering the export notifications established by the exporters and sent by EU DNAs, assigning them a Reference Identification Number (RIN), checking their completeness and forwarding them to the DNA of the importing country (Article 8(2).
- Sending a second export notification if the Agency does not receive an acknowledgement of receipt from the authority in the non-EU country within 30 days of the first notice (Article 8(3)).
- Making available to all EU DNAs export notifications received from third country DNAs (Article 9(1)).
- Acknowledging receipt of export notifications received from non-EU countries (Article 9(1)).
- Sending a reminder for an explicit consent request if no response is received from the authorities in the non-EU country within 30 days of the initial request; sending a second reminder after a further 30 days if a response is still outstanding (Article 14(6)).
- Managing ePIC and keeping all relevant document available on the platform;
- Supporting the EU DNAs and the European Commission in assessing waivers pursuant to Article 14(6) and 14(7).
- Aggregating and summarising the data received each year from DNAs on the quantities of exported and imported chemicals, and making non-confidential information publicly available (Article 10(3)).

- Every two years, compiling and publishing the information transmitted by the Commission, the Member States and the Agency to the authorities in third countries on the chemicals subject to the Regulation.
- The Agency's Secretariat of the Forum for Exchange of Information on Enforcement established by the REACH Regulation also provides coordination and support to discussions related to PIC (Article 18(2)).
- Participate in the twice-yearly DNA meetings organised by the Commission and provide updates on the operations and opinions of relevant documents discussed at these meetings.

In addition, the Agency provides assistance and technical and scientific guidance to industry, the DNAs from Member States and third countries, and the European Commission (Article 6).

Resources dedicated by the Agency to the operation of the PIC Regulation have remained stable over the reporting period (see Table 2).

Table 2: Agency's staff working on the PIC Regulation

	Number of staff working on PIC (FTE)
2014	7
2015	7
2016	7

The Agency's staff working on PIC also collaborate with the staff working on other EU regulations for which the Agency is responsible, i.e. REACH, CLP and the Biocidal Products Regulation (BPR), where there are synergies with processes that run across the various pieces of legislation. For example, the Agency's staff collaborate on:

- Development and maintenance of ePIC in order to benefit from synergies between all the Agency's IT tools concerning login and account management;
- Support to (Article 8(2) stakeholders;
- Substance identity check of substances added to the PIC Regulation;
- Publication of data on the Agency's website;
- Safety Data Sheet (SDS) checks (e.g. inaccuracies in defining the concentration of a substance, a mixture composition, doubts about classification, etc.);
- Support to the Commission in drafting FRA notifications submitted to the Rotterdam Convention Secretariat;
- Support to the Commission and the Member States by the presence of a nominee on the CRC;
- Drafting guidance for the implementation of the PIC Regulation;
- Legal advice;
- Communications;
- Human resources.

The Agency's workload during the reporting period was higher than predicted before the entry into force of the Regulation. As highlighted in its report, the number of export notifications increased beyond the predicted 10% yearly increase (see Table 3), which led to an increase in processing tasks to be performed by the Agency and thus the time spent on supporting DNAs (from EU and non-EU countries), which takes 30-40% of staff time. The increase in export notifications also made additional improvements of ePIC necessary (e.g. increasing the automation of certain processes to reduce the workload for industry users and authorities and enable them to meet legal deadlines), and caused more requests for support from the Agency (see Table 4).

Table 3: No. of export notifications predicted vs. processed by the Agency

	2014	2015	2016
No. of estimated notifications	4,000	4,300	6,300
Actual no. of notifications	4,575	5,460	7,967

Table 4: No. of requests for technical/regulatory support from the Agency

	2014	2015	2016
No. of requests for technical/ regulatory support	1,000	1,500	1,800

As the distribution of work is uneven during the calendar year, peaking during the winter months, the Agency reported regularly hiring interim staff for several months every year to meet the increased need.

2.1.3 DNAs

Member States play a major role in the application, implementation, and enforcement of the PIC Regulation. As per Article 4 of the PIC Regulation, Member States must designate one or several authorities to carry out the administrative functions required by the Regulation. A total of 35 authorities have been designated by Member States. Article 18 of the PIC Regulation also requires Member States to designate enforcement authorities, such as customs authorities (see Section 4.10).

The responsibilities of the Member States are largely discharged by DNAs and can be divided in four categories: administrative tasks, enforcement, monitoring and reporting, and exchange of information[6].

Administrative tasks

- Check compliance of export notifications with Annex II and forward these to the Agency (Article 8(2)).
- Request explicit consent from the DNA/appropriate authority of the importing country for the export of the chemicals listed in Parts 2 and 3 of Annex I. In the case of export of Annex I Part 2 chemicals to OECD countries, decide (in consultation with the Commission) if the requirement for explicit consent may be waived on the basis of the chemical being licensed, registered or authorised in the OECD country concerned (Article 14(6)).
- Consult the Commission and take decisions on the granting of a waiver for the export of chemicals listed in Parts 2 and 3 of Annex I in cases where no response is received within 60 days of a request for explicit consent (Article 14(7)).
- Assist the Commission in its periodic review of explicit consents and waivers (Article 14(8)).
- Forward export notifications received from third countries to the Agency (Article 9 (2)).
- Provide the Commission with sufficient information on FRA to ban or severely restrict a chemical at national level and consider any comments received from other Member States (Article 11(8)).
- Inform the Commission of national regulatory actions related to PIC chemicals so that this information can be taken into account in EU import decisions (Article 13(2)) and make EU import decisions available to those concerned within their competence (Article 13(5)).

[6] Adapted from: ECHA, *Guidance for implementation of Regulation (EU) No 649/2012 concerning the export and import of hazardous chemicals*, version 1.1, 2015.

- Forward information on chemicals subject to the PIC procedure and on decisions of importing parties regarding import conditions applicable to those chemicals to those concerned within its jurisdiction (Article 14(3) in conjunction with Article 14(1)).
- Handle Special RIN requests.
- Participate in twice-yearly DNA meetings organised by the Commission, and provide opinions on relevant documents discussed at these meetings.

Enforcement

- Ensure that exporters meet their obligations, in particular those relating to Articles 8, 10, 14, 15 and 17.
- Take measures to ensure compliance, including the establishment of penalties for infringements (Article 28).
- Participate in the activities of the Forum for Exchange of Information on Enforcement related to the PIC Regulation (Article 18(2)).

Monitoring and reporting

- Provide the Agency with annual aggregated reports on trade in chemicals listed in Annex I (Article 10(3)).
- Every three years, provide the Commission with information on the operation of the PIC Regulation (Article 22).

Provision and exchange of information

- Provide importing countries with additional information relating to exported chemicals, on request (Article 8(7)).
- Assist the Commission in compiling additional information with respect to FRA notifications, on request (Article 11(6)).
- Where requested, advise and assist importing countries to obtain additional information to help them with an import response for PIC chemicals (Article 14(5)).
- Forward to the Commission (with a copy to the Agency) any information required by an importing Party to the Convention that has been provided by the exporter concerned prior to each transit movement of a chemical listed in Part 3 of Annex I (Article 16(3)).
- Facilitate the exchange of information (Article 20) and cooperate in the promotion of technical assistance (Article 21).

Most Member States (22) have only one DNA, while six have two or three (Table 5). DNAs are mostly Ministries or agencies responsible for environment, chemicals, and health or health and safety. In a few cases, the Ministries responsible for economy, competition, labour or agriculture have been designated as competent authorities. In the Netherlands, the customs authority is the only DNA.

Table 5: Distribution of responsibilities across DNAs in Member States with more than one DNA

Member States	Distribution of responsibilities
Greece	Directorate of Energy, Industrial and Chemical Products, General Chemical State Laboratory: responsible for industrial chemicals Department of Plant Protection Products and Biocides, Ministry of Rural Development and Food: responsible for pesticides
Hungary	Ministry of Human Capacities: responsible for industrial chemicals National Food Chain Safety Office: responsible for pesticides
Ireland	The Health and Safety Authority: DNA for industrial chemicals The Revenue Commissioners: solely for the purposes of Article 18 of the PIC Regulation The Minister for Agriculture, Food and the Marine: responsible for pesticides (other than for the purposes of Article 18 of the Rotterdam Regulation)

Member States	Distribution of responsibilities
Latvia	Latvian Environment, Geology and Meteorology Centre: responsible for industrial chemicals State Plant Protection Service: responsible for pesticides
Slovakia	Ministry of Economy: responsible for industrial chemicals Ministry of Agriculture and Rural Development: responsible for pesticides
UK	Health and Safety Executive: DNA for Great Britain Health and Safety Executive Northern Ireland: DNA for Northern Ireland

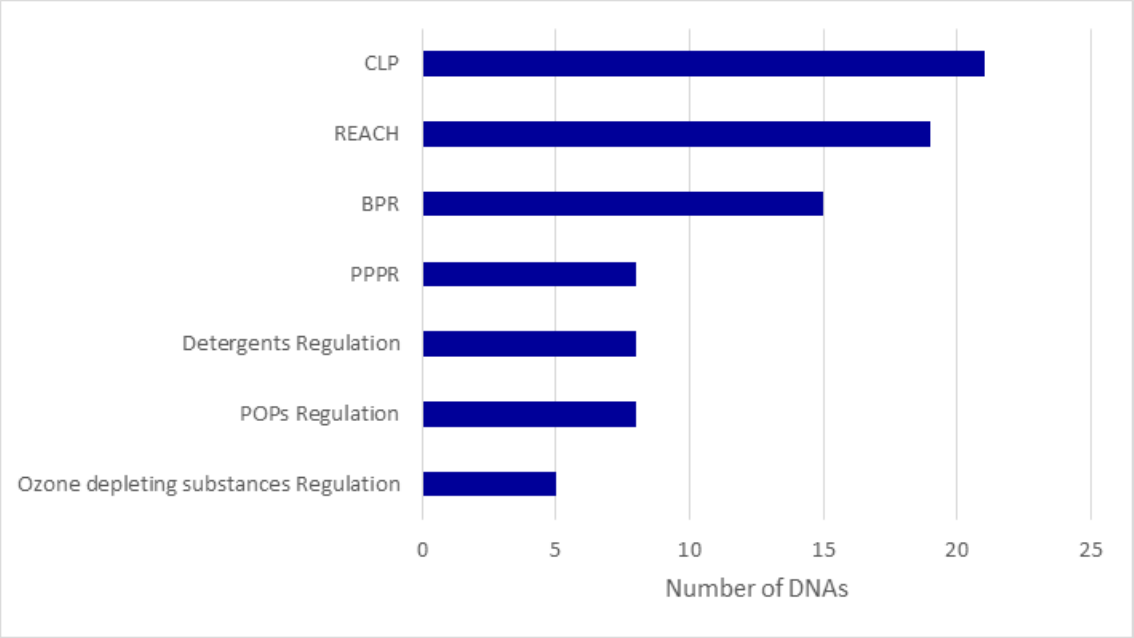
Although the UK officially has two DNAs, through an agreement between Great Britain and Northern Ireland, all of the UK DNA work is carried out by the Health and Safety Executive.

In Member States with more than one DNA, responsibilities are generally divided, with one DNA responsible for industrial chemicals while another is responsible for pesticides. Table 5 provides information on the distribution of responsibilities among those Member States with several DNAs.

With the exception of the Netherlands, DNAs in all other Member States are involved in the implementation of other EU or international chemicals management instruments, such as legislation, conventions or programmes (see Figure 1). Twenty DNAs (in 19 Member States) are also responsible for the implementation of the REACH Regulation, 21 DNAs (in 20 Member States) for CLP, 15 for the BPR and 8 for the PPPR. In eight Member States, the DNAs are also involved in the implementation of the Stockholm Convention.

The resources needed to implement the PIC Regulation in Member States, in particular the human resources, largely depend on the number of export notifications and requests for explicit consent that are processed. The figures provided by Member States for human resources working on PIC in the DNAs vary between 0.1 FTE for those Member States with few or no export notifications to process, and 2 FTE for those Member States with the highest numbers of export notifications.

Figure 1: Other EU legislation for which PIC DNAs are also responsible



2.2 Coordination between the Commission, the Agency and Designated National Authorities

2.2.1 Coordination between DNAs and the Commission

All Member States considered the coordination between the DNAs and the Commission to be satisfactory. Three Member States mentioned that the regular DNA meetings are an important coordination mechanism, and seven indicated that the support provided by the Commission to DNAs (especially answers to DNA questions) is quick and of good quality.

According to the DNAs, the update of annexes (Article 23) and the obligation to monitor exporters' compliance (Article 18(1)) are areas that could still be improved. Several DNAs also mentioned that relevant documents should be made available in due time before DNA meetings.
For its part, the Commission also considered the cooperation with DNAs to be satisfactory. There have been regular exchanges during the reporting period on scientific, technical and legal questions arising in the context of implementation, in particular through discussions at the twice-yearly PIC DNA meetings. The Commission also coordinates and consults with DNAs on any submissions to the Secretariat of the Rotterdam Convention.

2.2.2 Coordination between DNAs and the Agency

All Member States considered the coordination between the DNAs and the Agency to be satisfactory. Eight Member States specified that the assistance provided by the Agency to DNAs is valued for its swiftness and quality.

The main areas of improvement, according to the DNAs, are the updating of annexes (Article 23), followed by technical assistance (Article 21), and the provision of additional information on exported chemicals, on request (Article 8(7)).

According to the Agency, the collaboration with DNAs is also satisfactory. It indicated that collaboration with DNAs is efficient and friendly, including when handling disagreements. Cooperation could be improved, however, regarding the implementation of Article 8(2) on the timelines for processing export notifications, Article 8(5) on export in case of an emergency situation, Article 14(6) on substances that cannot be exported unless certain conditions are fulfilled, and Article 14(6) and (7) on decisions that the export can proceed in the absence of an explicit consent.

2.2.3 Coordination between the Agency and the Commission

The Commission considered cooperation with the Agency to be satisfactory, as there were regular exchanges on scientific, technical and legal questions arising in the context of implementation, in particular on the legal interpretation of provisions and their practical implementation. The Agency participated in all DNA meetings to report on the work done in the area of implementation. The Commission contributed to the development of the guidance produced by the Agency, as well as to the work of the Forum on Exchange of Information on Enforcement.

Regarding the cooperation with third countries and the Secretariat of the Rotterdam Convention, the Commission and the Agency have closely coordinated their activities to ensure that the most appropriate and effective assistance is provided and that resources are used efficiently.

According to the Agency, coordination with the Commission is generally satisfactory. It did, however, point to the following areas which could be improved:

- **Preparation of FRA notifications to the Rotterdam Convention Secretariat**: In some cases, tasks have been assigned with a short deadline and without advance warning. Increased predictability and common planning would help the Agency to ensure timely development of good quality notifications.
- **Technical preparation of meetings:** the Agency mentioned that documents are often sent by the Commission for checking/drafting with very short deadlines, making it difficult for the Agency to produce high-quality documents. Preparation for the meetings could be improved by greater collaboration between the Agency and the Commission/ Member State experts.
- **Article 14(6) and (7) on decisions that the export can proceed in the absence of an explicit consent**: The Agency mentioned that there is a relatively high number of cases in which they need to ask the Commission to verify and subsequently amend/reject the decision (when relevant) due to clerical errors (e.g. incorrect validity dates, missing translations of documents, questionable supporting documentation). This slows down the process and, in many cases, triggers requests for clarification from exporters. An enhanced role for the Agency in this process could improve its efficiency and effectiveness.
- **Article 23 on updating annexes**: The Agency believes it would be beneficial for it to be involved at an early stage in the adoption of amendments to the Regulation. For example, it suggested checking the substance identity of chemicals proposed for amendments to ensure consistency with processes under the other legislations it manages. It also proposed that, based on Article 6(1)(f), the Commission could consider asking for its support in identifying and proposing further candidate substances for inclusion in the PIC Regulation. Finally, the Agency would like to contribute to the planning of the entry into application of amendments to the Regulation, in order to avoid co-occurrence with the annual export notification peak in the winter.
- **Day-to-day exchanges between the Agency and the Commission**: According to the Agency, there is room for improvement in the timing of replies, as delays create problems for the performance of its operational tasks.

2.3 The EU as a Party to the Rotterdam Convention

The Commission, as the EU DNA, is the main interface with the Secretariat of the Convention. In particular, the Commission is responsible for:

- Representation of the EU to the Rotterdam Convention.
- Coordination of EU input on all technical issues related to the Convention, the preparation of the CoP, the CRC and other subsidiary bodies of the CoP.
- Submission to the Secretariat of relevant FRA notifications concerning chemicals qualifying for PIC notification.
- Transmission of information on other FRA involving chemicals not qualifying for PIC notification.
- Submission to the Secretariat of EU import responses for chemicals subject to the PIC procedure.
- Exchange of information with the Secretariat in general.

The Member States, as Parties to the Convention, also participate in the CoP, the CRC and activities under the Convention, such as the intersessional working group on the process of listing chemicals in Annex III to the Convention. The Member States and their DNAs provide input to the EU position on matters discussed at the CoP. Some DNAs also participate in technical assistance activities under the Convention, to which the Agency also contributes.

2.3.1 Coordination of Union input to the Conference of the Parties (CoP)

The 7th Conference of the Parties to the Rotterdam Convention took place from 4 to 15 May 2015 (thus during the reporting period), back-to-back with the 12th CoP to the Basel Convention and the 7th CoP to the Stockholm Convention.

Before CoP 7, the Commission prepared the draft position of the EU on matters discussed at the meeting:

- A proposal for a Council Decision establishing the EU position on amendments to Annex III to the Convention, seeking a mandate for decision-making at the CoP. This document was then discussed by the Council Working Party on International Environmental Issues and by the Council Working Party on Environment, and adopted by the Council on 6 March 2015.
- A position paper, discussed with the Member States at the Council Working Party on International Environmental Issues' meetings, outlining the position to be taken on the various items that would be discussed at the CoP. The final version of this position paper was adopted in April 2015.
- A position paper on budget and management issues covering the Rotterdam, Basel and Stockholm Conventions, as the Programmes of Work and budgets of the three Conventions were addressed in a joint session.
- A position paper on technical assistance and financial issues, also covering each of the Rotterdam, Basel and Stockholm Conventions.

After CoP 7, the Commission presented the outcomes of the CoP to DNAs at the 26th DNA meeting on 21 October 2015. The Commission also submitted, together with the Presidency, an information note on the outcomes of the CoPs of the Rotterdam, Basel and Stockholm Convention, transmitted by the General Secretariat of the Council to the delegations on 10 June 2015. In addition, all of the statements made during the CoP on behalf of the EU by the Commission and on behalf of the EU and its Member States by the Presidency were published, together with the statements made at the 12th CoP to the Basel Convention and the 7th CoP to the Stockholm Convention, through an information note of the General Secretariat of the Council to delegations on 6 July 2015.

2.3.2 Participation in committees and expert groups

During the reporting period, the EU had five or six members nominated as experts in the CRC, including two representatives in the bureau: Mr Jürgen Helbig from the Commission, nominated by Spain, who acted as Chair for three meetings of the CRC during the reporting period (October 2014, October 2015 and September 2016), and Ms Magdalena Frydrych, nominated by Poland, acting as Vice-chair (see Table 6).

Table 6: EU Members of the CRC during the reporting period

CRC meetings	EU Members of the CRC
CRC-10, October 2014	Ms Anja Bartels (Austria) Ms Parvoleta Angelova Luleva (Bulgaria) Ms Mirijam Seng (Germany) Ms Leonarda Christina van Leeuwen (Netherlands) Ms Magdalena Frydrych (Poland) Mr Jürgen Helbig (Spain)
CRC-11, October 2015	Ms Anja Bartels (Austria) Ms Parvoleta Angelova Luleva (Bulgaria) Ms Mirijam Seng (Germany) Ms Leonarda Christina van Leeuwen (Netherlands) Ms Magdalena Frydrych (Poland) Mr Jürgen Helbig (Spain)

CRC meetings	EU Members of the CRC
CRC-12, September 2016	Ms Parvoleta Angelova Luleva (Germany) Ms Leonarda Christina van Leeuwen (Netherlands) Ms Magdalena Frydrych (Poland) Mr Jürgen Helbig (Spain) Ms Johanna Peltola-Thies (UK)

Eight EU experts were also nominated to the intersessional working group on the process of listing chemicals in Annex III to the Convention:

- Mr Björn Hansen (European Commission)
- Mr Jürgen Helbig (European Commission)
- Ms Anja Bartels (Austria)
- Ms Mara Curaba (Belgium)
- Ms Jutta Emig (Germany)
- Ms Silvija Nora Kalnins (Latvia)
- Ms Magdalena Frydrych (Poland)
- Mr Richard Vincent (UK)

2.3.3 Financial contributions to the Rotterdam Convention

As a Party to the Rotterdam Convention, the EU paid the mandatory contribution to the Convention's Trust Fund and also contributed to the Special Voluntary Trust Fund for the implementation of the programme of work for technical assistance (see Table 7).

Table 7: Financial contributions from the EU to the Rotterdam Convention's Trust Fund and Special Voluntary Trust Fund (EUR)[7]

Year	EU contribution to Trust Fund	EU contribution to Special Voluntary Trust Fund
2014	51,195	277,331
2015	55,474	302,815
2016	54,582	513,603

As all Member States are Parties to the Convention, they also contribute to the Convention's Trust Fund through their mandatory contributions to the budget of the Convention adopted by the CoP. In addition, some Member States contribute to the Special Voluntary Trust Fund (see Table 8).

Table 8: Member States' contributions to the Special Voluntary Trust Fund (EUR)

Member State	2014	2015	2016
Finland	0	79,900	0
France	0	5,000	0
Germany	0	20,000	14,950
Netherlands	84,325	70,000	61,000
Sweden	0	23,000	0

[7] From the Rotterdam Convention website, amounts converted from USD to EUR at November 2017 rates.

3 UPDATES OF ANNEX I AND ANNEX V 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, the BPR and the PPPR) and under the Convention. Annexes to the PIC Regulation are amended through delegated acts adopted by the Commission. Since the procedure for adoption of delegated acts is rather new, the Commission explained at the 23rd and subsequent DNA meetings that it does not require the opinion of a comitology committee but, rather, the consultation of an expert group. That consultation is undertaken by presenting the draft amendment at the PIC DNA meeting and inviting comments from all of the Member State experts present, together with other stakeholders. In addition, the delegated act adopted by the Commission is submitted to the European Parliament and the Council, and only enters into force if neither objects.

3.1 Update of Annex I

Amendments to Parts 1 and 2 of Annex I are triggered by regulatory actions changing the legal status of a substance under other relevant EU legislation, in particular:

- Decision not to approve or to withdraw an active substance under the PPPR;
- Decision not to approve or to withdraw an active substance under the BPR;
- Decision to subject a chemical to authorisation by adding it to the Authorisation List (Annex XIV) of the REACH Regulation;
- Decision to restrict the use of a chemical (Annex XVII) under the REACH Regulation.

During the reporting period, two Delegated Regulations amending Annex I were adopted, in 2014 and 2015 (see Table 9). Of the substances added to Annex I, many were proposed for inclusion in Parts 1 and 2 of Annex I of the PIC Regulation having been already banned for use as pesticides under Regulation (EC) No 1107/2009. This is the case for bitertanol, cyhexatin, azocyclotin, cinidon-ethyl, cyclanilide, ethoxysulfuron, oxadiargyl, didecyldimethylammonium chloride, and warfarin in 2014, and fenbutatin oxide in 2015. In addition, substances severely restricted as pesticides, such as rotenone and cyfluthrin, were added to Annex I in 2014.

Lead compounds, dibutyltin compounds, dioctyltin compounds, trichlorobenzene, pentachloroethane, 1,1,2,2-tetrachloroethane, 1,1,1,2-tetrachloroethane, 1,1,2-trichloroethane and 1,1-dichloroethene were added to Annex I in 2015, as these are severely restricted as industrial chemicals for public use, in accordance with REACH.

Amendments to Part 3 of Annex I reflect the decision of the CoP to include certain chemicals in Annex III of the Convention, making them subject to the PIC procedure. Azinphos-methyl, perfluorooctane sulfonic acid, perfluorooctane sulfonates, perfluorooctane sulfonamides and perfluorooctane sulfonyls, commercial pentabromodiphenyl ether, including tetra- and pentabromodiphenyl ether, as well as commercial octabromodiphenyl ether, including hexa- and heptabromodiphenyl ether were included in Part 3 of Annex I during the reporting period, following their inclusion in Annex III to the Rotterdam Convention.

Table 9: Substances added to Annex 1 during the reporting period

Delegated Act	Chemical	Amendment of Annex I	Basis for inclusion
Commission Delegated Regulation (EU) No 1078/2014 of 7 August 2014 amending Annex I to Regulation (EU) No 649/2012	Azocyclotin	Part 1 and 2	PPPR
	Bitertanol	Part 1 and 2	PPPR
	Cinidon-ethyl	Part 1 and 2	PPPR
	Cyclanilide	Part 1 and 2	PPPR
	Cyfluthrin	Part 1and 2	PPPR
	Cyhexatin	Part 1 and 2	PPPR
	Ethoxysulfuron	Part 1 and 2	PPPR
	Didecyldimethylammonium Chloride	Part 1	PPPR
	Oxadiargyl	Part 1 and 2	PPPR
	Rotenone	Part 1 and 2	PPPR
	Warfarin	Part 1	PPPR
	Azinphos-methyl	Part 3	Annex III to RC
	Perfluorooctane sulfonic acid	Part 3	Annex III to RC
	Perfluorooctane sulfonates	Part 3	Annex III to RC
	Perfluorooctane sulfonamides	Part 3	Annex III to RC
	Perfluorooctane sulfonyls	Part 3	Annex III to RC
Commission Delegated Regulation (EU) 2015/2229 of 29 September 2015 amending Annex I to Regulation (EU) No 649/2012	1,1-Dichloroethene	Part 1	REACH
	1,1,2-Trichloroethane	Part 1	REACH
	1,1,1,2-Tetrachloroethane	Part 1	REACH
	1,1,2,2-Tetrachloroethane	Part 1	REACH
	Dibutyltin compounds	Part 1	REACH
	Dioctyltin compounds	Part 1	REACH
	Fenbutatin oxide	Part 1 and 2	PPPR
	Lead compounds	Part 1	REACH
	Pentachloroethane	Part 1	REACH
	Trichlorobenzene	Part 1	REACH
	Commercial pentabromodiphenyl ether, including: tetrabromodiphenyl ether, and pentabromodiphenyl ether	Part 3	Annex III to RC
	Commercial octabromodiphenyl ether, including hexabromodiphenyl ether and heptabromodiphenyl ether	Part 3	Annex III to RC

The inclusion of other substances in Annex I was discussed in 2016, but has not yet been formally adopted through a Delegated Regulation (see Table 10).

Table 10: Chemicals proposed for inclusion in Annex I

Chemical	Amendment of Annex I	Basis for inclusion
Tepraloxydim	Part 1 and 2	PPPR
Carbendazim	Part 1 and 2	PPPR
Triflumuron	Part 1	BPR
Triclosan	Part 1 and 2	BPR
cybutryne	Part 1 and 2	BPR
2,4-dinitrotoluene	Part 1 and 2	REACH
4,4'-diaminodiphenylmethane (MDA)	Part 1 and 2	REACH
5-tert-butyl-2,4,6-trinitro-m-xylene	Part 1 and 2	REACH
benzyl butyl phthalate	Part 1 and 2	REACH
Diisobutyl phthalate	Part 1 and 2	REACH
Diarsenic pentaoxide and tris(2-chloroethyl) phosphate	Part 1 and 2	REACH
Methamidophos	Part 1 and 3	Annex III to RC

3.2 Updates of Annex V

At the 27th meeting of the DNAs in April 2016, an amendment to Annex V was discussed – the inclusion of hexabromocyclododecane in Part 1 of Annex V of the PIC Regulation. Hexabromocyclododecane has been included in Part A of Annex I to Regulation (EC) No 850/2004 (Persistent Organic Pollutants (POPs) Regulation), since the decision was taken under the Stockholm Convention to list this chemical in Part 1 of Annex A to the Stockholm Convention. It should therefore be listed in Annex V of the PIC Regulation.

4 OPERATION OF THE PIC REGULATION

4.1 Support to exporters and importers

The Agency is required to provide assistance, as well as technical and scientific guidance and tools, to exporters and importers (Article 6(1)). Although it is not a legal obligation under the PIC Regulation, most DNAs have provided support and carried out awareness-raising activities for national exporters and importers during the reporting period.

Both the Agency and Member States were asked to provide information (in their respective reporting questionnaires) on the awareness-raising and communication activities carried out during the reporting period and requests received from exporters and importers (Section 3 of Member State and the Agency's questionnaires).

Both DNAs and the Agency stated that the support provided to companies, as well as the awareness-raising activities carried out during the reporting period, had improved exporter and importer compliance with the PIC Regulation.

4.1.1 Support provided by DNAs

Awareness-raising activities

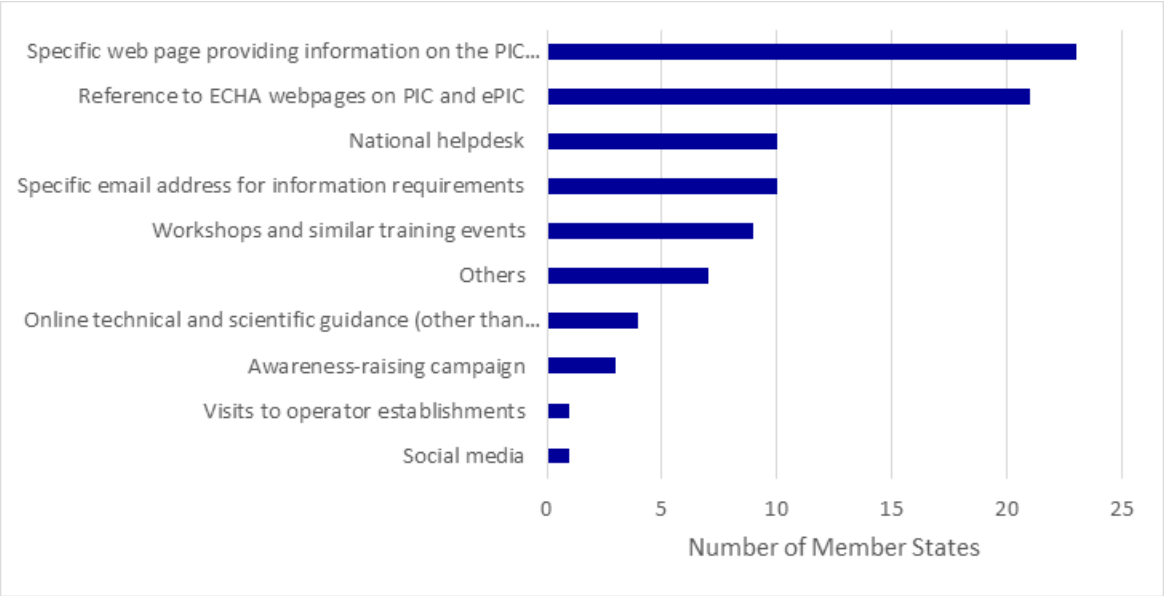
Twenty-five Member States stated that they had carried out awareness-raising and information activities for exporters and importers during the reporting period (see Figure 2). Member States that did not carry out any such activities were either small Member States with little or no exports and imports falling within the scope of the Regulation, or Member States providing information to exporters and importers on request.

The most common activities carried out by Member States were the provision of online information, such as a specific webpage providing information on the PIC Regulation, and references to the Agency's webpages on PIC and ePIC. Ten Member States also provide a national helpdesk.

Other awareness-raising activities carried out by Member States included mail or telephone correspondence between the DNA and importers or exporters, guidelines for importers and exporters, and information spread through the Strategic Approach to International Chemicals Management (SAICM) Platform.

Almost all of the Member States carrying out awareness-raising and information provision activities considered such activities to have improved exporter and importer compliance with the PIC Regulation. For example, some DNAs noted an increase in the number of export notifications received by the DNA during the reporting period, an increase in the number of companies registered in ePIC, or improved compliance with the Article 10 reporting obligations.

Figure 2: Question 11. Have any awareness-raising and information activities been put in place by the DNA(s) to support exporters and importers to comply with the PIC Regulation?



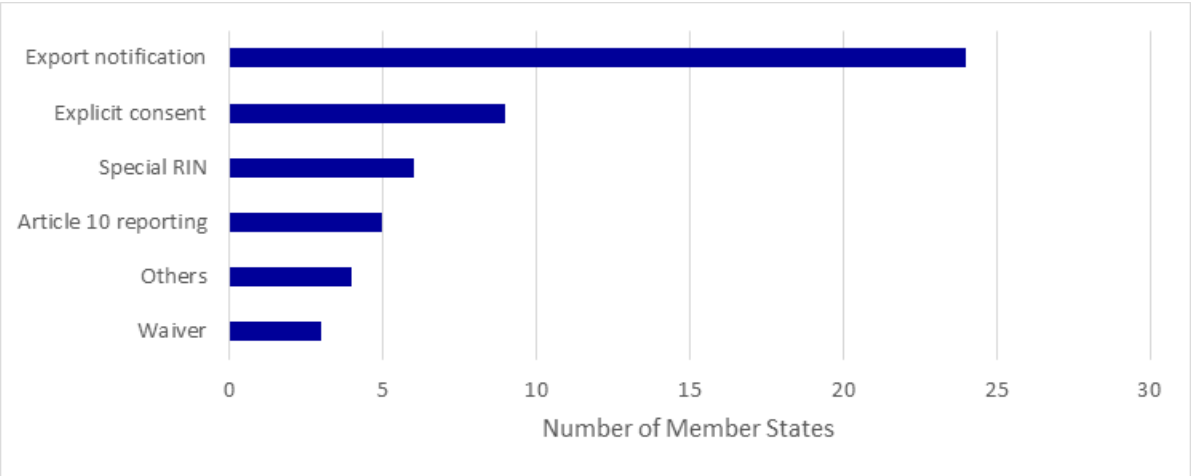
Requests from exporters and importers

The most frequent requests from exporters and importers to DNAs relate to export notifications and explicit consents (see Figure 3).

Estimated amount of time spent on support

In the majority of Member States, providing support to exporters and importers takes less than 10% of the DNA's working time. This rises to 40% in three Member States.

Figure 3: Question 13. On which matters do(es) the DNA(s) get the two most frequent requests for support coming from exporters and importers?



4.1.2 Support provided by the Agency

Awareness-raising activities

The Agency has fulfilled its obligations under Article 6 of the PIC Regulation through the following activities:

<u>*Technical and scientific guidance*</u>

The Agency published version 1.0 of the *Guidance for implementation of Regulation (EU) No 649/2012 concerning the export and import of hazardous* chemicals ('Guidance on

PIC') in December 2014 (in English only) and a corrigendum to it (version 1.1) in July 2015 (to take into account the end of certain CLP transition periods). Translations of version 1.1 into 14 languages (Bulgarian, Croatian, Czech, Danish, Dutch, German, Finnish, French, Spanish, Italian, Polish, Portuguese, Slovenian and Swedish) were published in March 2016, with translations into the remaining eight official EU languages (Estonian, Greek, Hungarian, Latvian, Lithuanian, Maltese, Romanian and Slovak) published in October 2016.

Webpages on the PIC Regulation and ePIC
The Agency has created a specific webpage on the PIC Regulation (https://echa.europa.eu/regulations/prior-informed-consent-regulation) and a webpage dedicated to ePIC (https://echa.europa.eu/support/dossier-submission-tools/epic). These pages are in all official EU languages.

Internal messaging in ePIC
The communication via messages sent in ePIC is typically used in the following cases:

- To remind exporters/importers of upcoming legal deadlines;
- To advertise publication of updated user manuals, new factsheets, etc.;
- To inform of policy changes;
- To alert users in advance of maintenance breaks.

Awareness-raising campaign
The Agency reminds exporters and importers of PIC-related news, such as upcoming legal deadlines or workload peaks, using different communication means, including the weekly e-News and the Agency Newsletter. These channels are also used to highlight new substances added to Annex I or included in group entries.

Support to individual companies
This is done through replies to Helpdesk incidents and/or telephone support.

Workshops, webinars and similar training events
The Agency has organised a number of workshops on PIC, mainly related to the initial development of ePIC:

- Three workshops for Member States and industry representatives organised at the Agency's premises during the development of ePIC (June 2013, November 2013 and May 2014) in order to gather their feedback and invite their contributions to the application specifications.
- WebEx discussions during the development of the ePIC system.
- Training workshop organised at the Agency's premises in September 2014, just after the launch of the ePIC system, to instruct users on the use of ePIC application.

In addition, the Agency takes part in conferences and training, seeing them as an opportunity to reach out to industry directly, to provide updates on ePIC and policy issues, and to address specific concerns.

IT user manuals, factsheets and Q&A (FAQs)
After the launch of ePIC, the Agency published a user manual, which was subsequently translated into all official EU languages and is updated every time there is a new release of the application. The Agency has also prepared factsheets dedicated to specific topics and has a Q&A document on ePIC, which is updated in parallel with new releases of the application.

According to the Agency, these activities have improved exporter and importer compliance with the PIC Regulation. Similarly, it partially attributes the increase in the number of companies registered in ePIC (390 in March 2014 compared to 1177 at the end of the reporting period) to the awareness-raising activities and the visibility given to ePIC.

Requests from exporters and importers
Through its helpdesk, the Agency received 123 requests for information or support from exporters and importers in 2014, 245 in 2015 and 227 in 2016.

The largest number of requests from exporters and importers' concerned:

- Scope-related issues: which chemicals are subject to the PIC Regulation;
- Reasons why an export has not been allowed to proceed;
- Exporters' obligations under the PIC Regulation, as determined by the listing of a chemical in Annex I;
- Clarification on which Member State shall receive the export notification (e.g. where the legal entity holding the contract for an export is in one Member State but the shipment is leaving from a different Member State);
- Article 10 on the reporting required of exporters and importers during the first quarter of each calendar year.

In addition, the Agency received a low number of more complex questions, e.g. the link between the PIC Regulation and other legislation, the triggering of labelling obligations for mixtures under CLP, or the responsibility for the export notification when the manufacturer is based outside the EU but chemicals are shipped from the EU to third countries.

Estimated amount of time spent on such support
Four FTEs working in the Dossier Submission & PIC Unit provide replies to the requests received from companies. This task takes approximately 10% of their time, on average.

4.2 Export notifications forwarded to Parties and other countries (Article 8)

The export notification is the instrument under the PIC Regulation by which countries exchange information on banned or severely restricted chemicals. All EU based exporters must submit an export notification to their DNA if they intend to export chemicals listed in Part 1 of Annex I to the PIC Regulation to a third country (Party or non-Party to the Rotterdam Convention), irrespective of the use of the chemical in the country of destination. Once the DNA has checked and accepted the notification (after resubmission if necessary), it is forwarded to the Agency, which also verifies the compliance of the notification and transmits it to the DNA of the importing country. If no acknowledgement of receipt is received, the Agency re-sends the notification. The whole procedure is carried out by means of ePIC, and exporters must use the notification template provided by the system.

DNAs and the Agency were asked to provide data on the number of export notifications and Special RIN requests processed during the reporting period, information on difficulties encountered by exporters and authorities in carrying out the procedures, emergency situations, and the provision of additional information on exported chemicals.

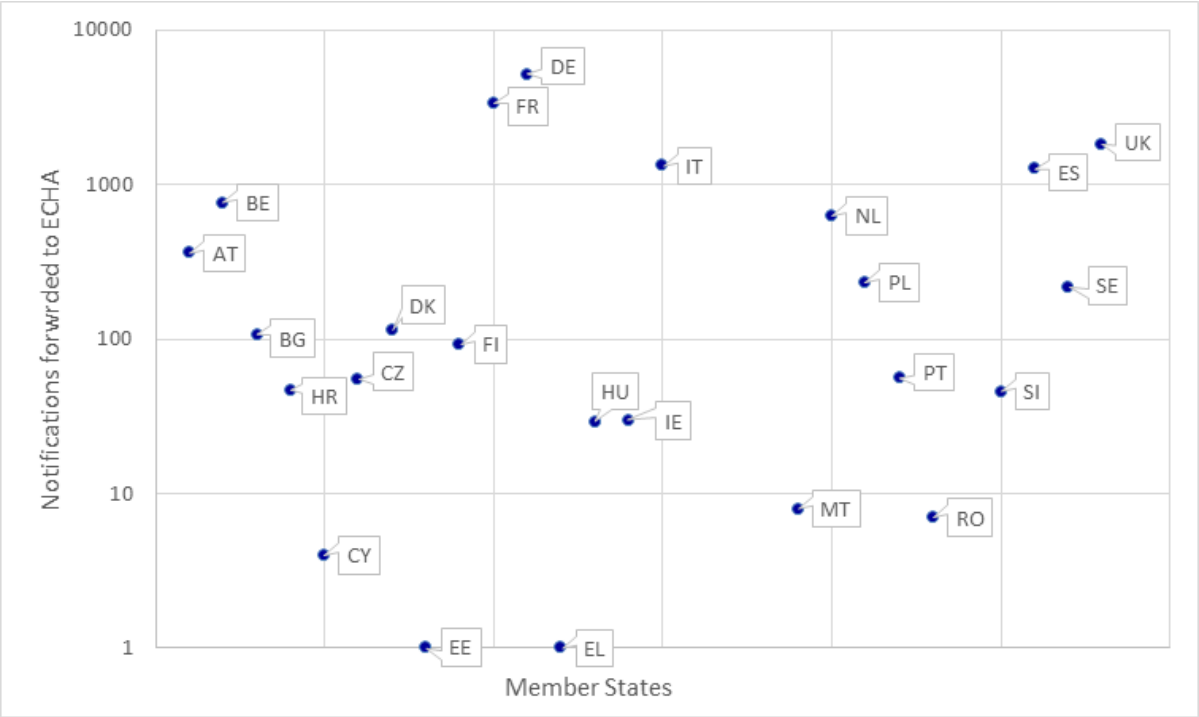
The number of export notifications and Special RIN requests increased between 2014 and 2016, and their number varied significantly between Member States. According to the Agency, this shows that compliance has increased during the reporting period. In a relatively high number of cases, the DNAs or the Agency requested resubmission of a notification, usually relating to issues with section 6 of the notification form (summary of, and reasons for, the FRA and date of entry into force) and to the SDS (inappropriate language or SDS not matching the notification). Although some DNAs and the Agency reported problems in complying with the timeframes of the notification procedure, the number of notifications processed late remained low.

4.2.1 Export notifications processed during the reporting period[8]

During the reporting period, DNAs accepted and forwarded to the Agency 15,771 notifications, and rejected 1,214 notifications[9].

The number of export notifications processed varies significantly between Member States (see Figure 4). Four Member States did not process any export notification during the reporting period (Latvia, Lithuania, Luxembourg and Slovakia) and five Member States processed fewer than 10 notifications. The highest numbers of export notifications during the reporting period were in Germany (5,196 notifications), France (3,358), the UK (1,829), Italy (1,321) and Spain (1,265). The importing countries that received the highest numbers of export notifications from the EU were Switzerland (1,044 notifications), Turkey (984), Russia (890), the USA (754) and China (601).

Figure 4: Total number of export notifications accepted and forwarded to the Agency by DNAs during the reporting period



The number of export notifications accepted and forwarded to the Agency by DNAs increased significantly during the reporting period, from 1,553 in 2014, to 5,866 in 2015, to 8,352 in 2016[10] (see Table 11).

[8] This section and those that follow are based on data extracted from ePIC by the Agency and provided to the Commission, the DNAs and the consultant.

[9] Figures provided by DNAs include rejected/re-submitted notifications, in addition to 'validated' notifications (i.e. accepted and processed).

[10] For 2014 the period covered is 1 March – 31 December (as the PIC Regulation became applicable on 1 March 2014).

The Agency also reported an increase in the number of export notifications accepted and processed during the reporting period, from 4,575 in 2014, to 5,460 in 2015, to 7,967 in 2016[11], thus beyond the 10% increase originally envisaged (see Table 11). The number of companies involved in PIC activities has also increased substantially, from 390 in 2014 to 1,177 in 2016[12]. The Agency concluded from this increase that awareness and compliance with the Regulation has significantly improved during the reporting period. The main factor that contributes to this increase is the inclusion of new chemicals in Annex I. Table 11**Error! Reference source not found.** summarises the activities carried out by the Agency in relation to export notifications during the reporting period.

Table 11: Export notifications and related tasks handled by the Agency during the reporting period

	2014	2015	2016
Export notifications handled (including initial submissions, resubmissions and rejections)	1,550[13]	5,845	8,335
Export notifications forwarded	460	4,642	7,229
Acknowledgments of receipt received	190	3,077	4,575
Export notifications forwarded a second time	270	1,565	2,654

An acknowledgement of receipt is requested by the Agency for all export notifications sent (not just the first one after Annex I inclusion, as stated in Article 8(3)), as this is an important means of ensuring that the information has been received, especially as contact details in non-EU countries change frequently.

4.2.2 Special RIN requests processed during the reporting period

Exporters of chemicals exported for research or analysis purposes in quantities that do not exceed 10kg from each exporter to each importing country per calendar year use the Special RIN request procedure, in which the exporter requests a Special RIN from the DNA. If the request is accepted, this activates a Special RIN that the exporter can use on the customs declaration. The Special RIN request procedure is also used in cases where the exporter is exempt from export notifications, such as emergency situations, when a positive import response has been given by the importing party and when a country has waived its right to be notified.

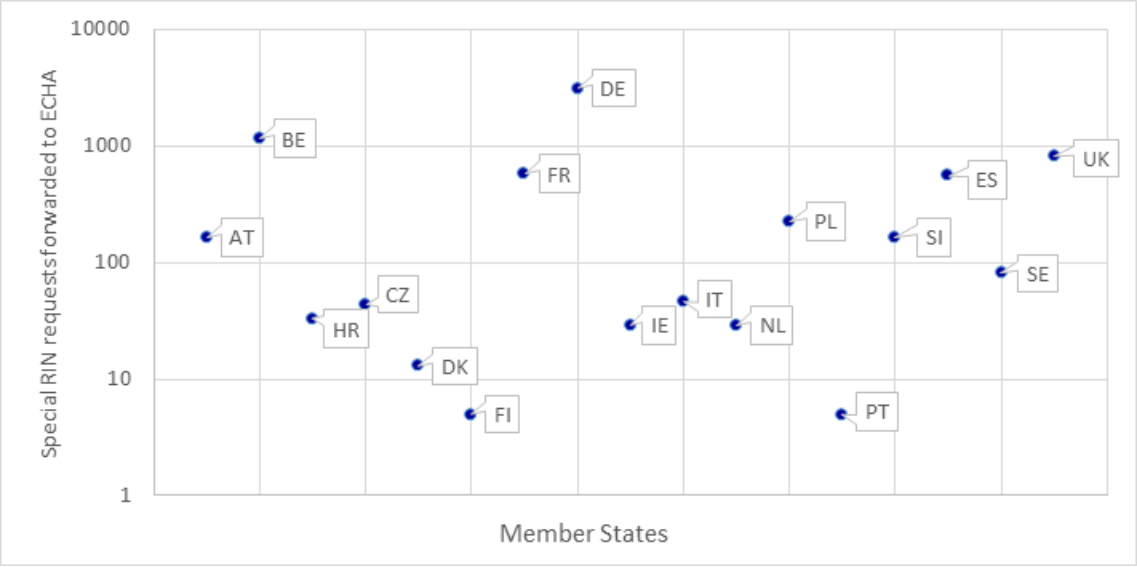
During the reporting period, 17 Member States accepted 7,072 Special RIN requests. Eleven Member States did not have to deal with any such request in the past three years (Bulgaria, Cyprus, Estonia, Greece, Hungary, Latvia, Lithuania, Luxembourg, Malta, Romania, and Slovakia). Germany, the UK and Belgium were the Member States that accepted the highest number of Special RIN requests (see Figure 5).

[11] Figures provided for the Agency only include 'validated' notifications (i.e. accepted and processed) and exclude rejected/re-submitted notifications, which explains the discrepancy with the figures provided for DNAs.

[12] ECHA, Increase in notifications providing information on the export of hazardous chemicals, press release ECHA/PR/17/15, 6 September 2017: https://echa.europa.eu/-/increase-in-notifications-providing-information-on-the-export-of-hazardous-chemicals

[13] Data available from 1 March 2014 (all other data in this column were available after go-live of the PIC submission system, i.e. 2 September 2014).

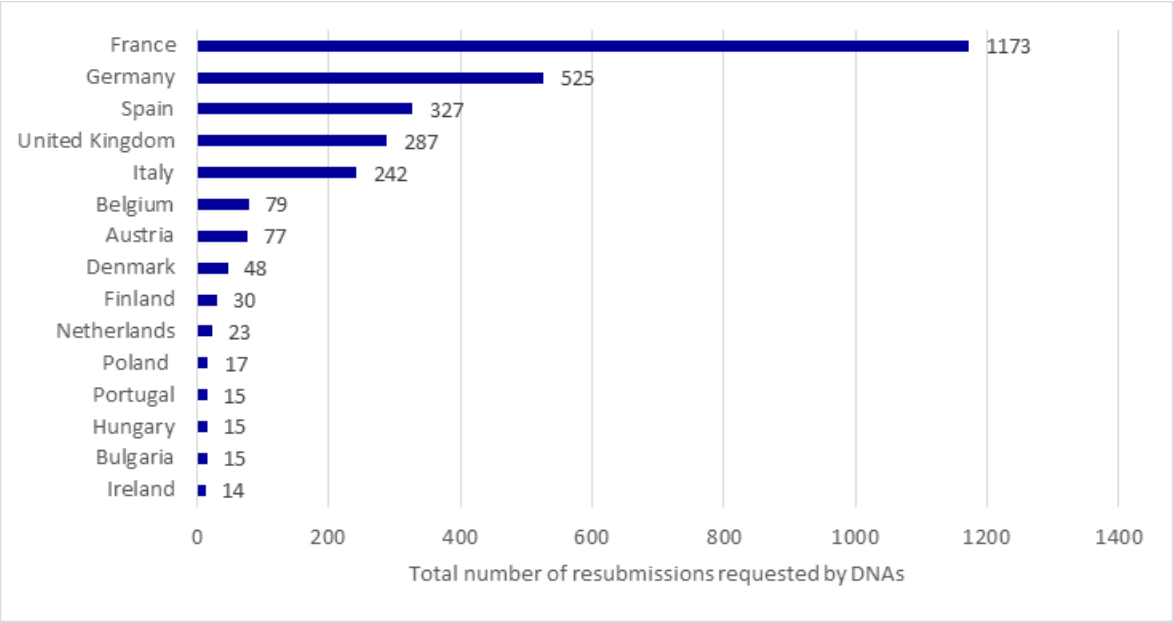
Figure 5: Total number of Special RIN requests accepted by DNAs during the reporting period



4.2.3 Requests for resubmission and rejection of export notifications

Member States requested the resubmission of 2,904 export notifications during the reporting period. Figure 6 shows the significant variations between Member States.

Figure 6: Total number of resubmissions of export notifications requested by DNAs[14] in the reporting period



[14] Only Member States that requested the resubmission of more than 10 notifications are represented on the graph.

DNAs explained that resubmission of notifications were necessary where information requirements were not met. Several DNAs further specified the missing or incorrect information typically triggering the request for resubmission:

- Information requirements not met in section 6 of the export notification form – summary of, and reasons for, the FRA and date of entry into force (five DNAs).
- Information requirements not met in section 1 of the export notification form – identity of the chemical subject to the export notification: CAS number, concentrations, name of product (one DNA).
- Information requirements not met in section 3 of the export notification form – information concerning the export, e.g. phone number, importer address (one DNA). One DNA also reported that in some cases exporters incorrectly ticked the emergency situation box in order to avoid the 35-day waiting period.
- Information requirements not met in section 4 of the export notification form – information on hazards and/or risks of the chemical and precautionary measures, e.g. wrong classification (one DNA).

Several Member States also highlighted problems with the SDS attached to export notifications:

- The SDS was not submitted in the correct language (five DNAs).
- The SDS did not match the export notification (four DNAs). Two DNAs specifically mentioned inconsistencies in the composition of mixtures. Italy also pointed to cases where the type of product (substance / mixture) was different on the SDS and notification form.
- Two DNAs mentioned errors on the SDS, in particular relating to codes.

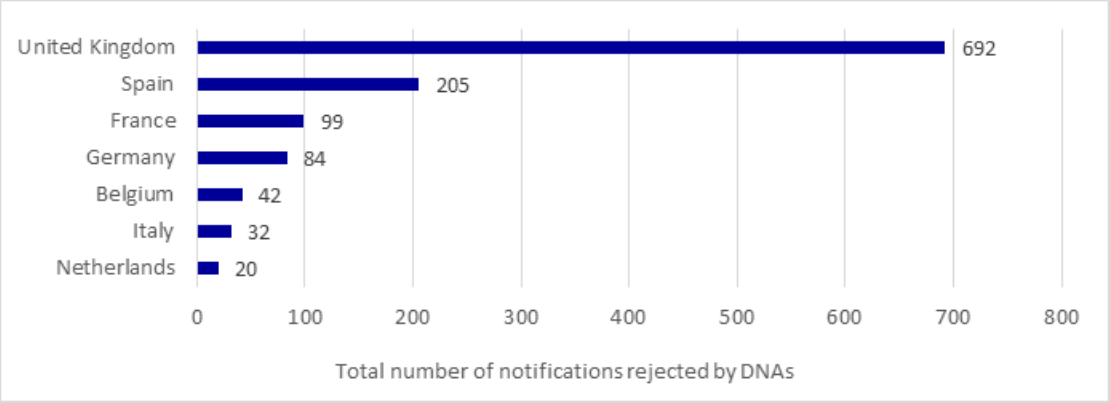
The Agency requested the resubmission of 609 export notifications during the reporting period (43 in 2014[15], 334 in 2015, and 232 in 2016). The main reasons for requesting resubmission of a notification were:

- Issues with the data provided in Section 6.1 'Summary of and reasons for the final regulatory action and date of entry into force' (incorrect text/language).
- Problems with the SDS: incorrect SDS attached to the notification; SDS unavailable because attached in the incorrect place in ePIC; SDS language incorrect.
- Discrepancy between the data on the substance/mixture composition on ePIC and on the SDS.

Member States rejected 1,214 export notifications during the reporting period. Figure 7 shows the numbers of rejected notifications for those Member States in which rejections occurred most frequently.

[15] Data only available after go-live of the PIC submission system (2 September 2014)

Figure 7: Total number of export notifications rejected by DNAs during the reporting period[16]



12 Member States stated that export notifications were rejected because they were not applicable for the following reasons:

- Duplication of notifications (10 DNAs).
- The resubmission occurred too late (one DNA).
- The emergency situation was not justified (one DNA).
- Conditions for granting a special RIN were met (two DNAs).
- Rejection requested by exporting company (two DNAs).
- PIC chemical missing in mixture (one DNA).

Other Member States indicated that rejection was based on flaws in the export notification:

- Information requirements not met or incorrect information provided (three DNAs).
- Wrong identification, e.g. substance notified as mixture and vice versa (one DNA).
- Missing SDS in appropriate language (two DNAs).

Finally, one DNA pointed to cases where a notification was rejected because of the negative consent received from the importing country.

The Agency rejected 175 notifications during the reporting period (51 in 2015 and 124 in 2016). In 2015, a large number of export notifications for didecyldimethylammonium chloride were rejected because the substance was notified in a mixture at a concentration level which did not trigger labelling of the mixture, irrespective of the presence of any other substance (in accordance with Article 8(1)). In 2016, 124 notifications were rejected because the importing country had waived the requirement to receive export notifications for exports of certain chemicals from the EU, or because the mixture was not classified as hazardous, based on the information provided in the SDS.

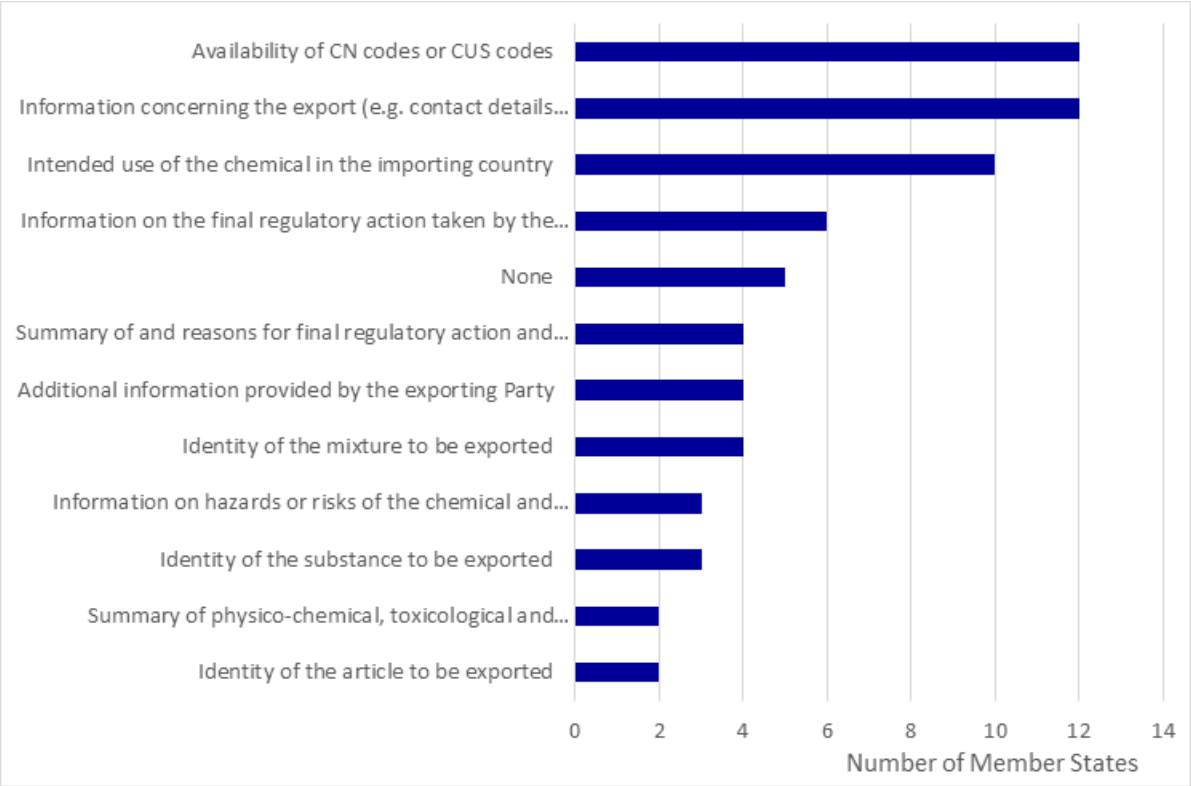
4.2.4 Difficulties encountered in the export notification procedure

Difficulties encountered by exporters in completing the export notification form

According to the Agency and DNAs, exporters have experienced difficulties in providing information on the export (e.g. contact details of importers) and the intended use of the chemical in the importing country (see Figure 8).

[16] Only Member States that rejected more than 10 notifications are represented on the graph.

Figure 8: Question 19. What are the information requirements requested in the export notification form where exporters have difficulties in providing the information?



In addition, the Agency indicated that the identity of the substance to be exported and the summary of, and reasons for, the FRA and date of entry into force had also proved problematic for exporters. Twelve DNAs also stated that the availability of Combined Nomenclature (CN) or Customs Union and Statistics (CUS) codes were a particular problem for exporters.

In addition to these issues, several DNAs highlighted other problem areas:

- Two DNAs mentioned that providing the SDS in the correct language was an issue for some exporters.
- One DNA stated that the grouping of chemicals was a particular problem, and that biocides were sometimes considered industrial chemicals and other times pesticides.
- One DNA indicated problems with the identification of research or analysis use and applications for Special RIN requests.
- One DNA mentioned problems with the identification of mixtures falling within the scope of the Regulation.

The Agency also noted the following problems or mistakes:

- If their chemical is not in ePIC, companies are not sure whether or not its export is subject to the PIC Regulation (this issue relates specifically to group entries, e.g. cadmium and its compounds, for which the list of cadmium compounds in ePIC is not comprehensive).
- Some exporters confuse export notifications for substances and mixtures.
- Section 3.1 of the export notification (foreseen category and foreseen use in importing country) is often confused with section 6.2 (category for which the FRA was taken).
- The intended use and use category for exports of biocides can be problematic due to the fact that the EU considers 'biocides' to be a sub-category of the pesticides category, whereas many non-EU countries consider biocides industrial chemicals.

- Some companies insert controversial, non-factual messages in section 6.1 on the FRA (e.g. they disagree with the fact that the substance was banned or severely restricted in the EU) that are not acceptable, and the Agency has to ask for such statements to be removed.
- Not all companies provide the SDS (or equivalent information) in the official language of the importing country or in an appropriate language.
- The definition of an exporter (Article 3(18)) was not always easily applicable to certain cases in which, for example, the holder of the contract was in a non-EU country (Switzerland) but the export was physically shipped from the EU.
- The obligation to notify the export of an article is set out in Article 15, in conjunction with Article 3(4). It was often unclear to exporters, DNAs and the Agency whether or not a given article is subject to the PIC Regulation.

Complying with timeframes

According to the Agency, some DNAs experienced difficulties in coping with the timeframe to forward the export notifications. However, the number of export notifications it received less than 25 days before the export remains relatively low compared to the total number of notifications processed (725, or 4.9% of the total number of notifications).

Seven Member States stated that they experienced such difficulties during the reporting period. In particular, four Member States indicated that they have difficulties in complying with the timeframes during the 'peak season' in winter. Two Member States mentioned that companies did not respect deadlines for resubmission, thereby delaying the whole procedure. The Agency explained that where the exporter had submitted the export notification on time and the delay was in fact due to late processing by the DNA, they processed the late export notification in order not to further penalise the exporter and to allow the export process to continue. The Agency added that the authority in the importing country is always alerted by a separate communication where an export notification was delivered less than 15 days before the expected date of export (as foreseen by Article 8(2) of the PIC Regulation).

The Agency indicated that it, too, experienced difficulties in coping with the timeframe to process and forward export notifications to the importing country. However, the number of late notifications remains very low. 171 notifications were sent late to the importing countries, around 1.2% of the total number of export notifications forwarded to importing countries during the reporting period. This is mostly due to delays in receiving the notifications from the DNAs. In 30 cases, however, the delay was caused by the Agency itself, mainly because of IT issues. According to the Agency, the authority in the importing country is always informed accordingly.

4.2.5 Emergency situations (Article 8(5))

According to Article 8(5), when the export relates to an emergency situation in which any delay may endanger public health or the environment in the importing country, the DNA, in consultation with the Commission, may exempt the exporter from the notification requirements or the waiting period. According to the Agency and the DNAs, only a small number of export notifications referred to an emergency situation, most of which did not meet Article 8(5) criteria and were rejected. Only two DNAs (Belgium and Greece) stated that they had to deal with an emergency situation during the reporting period. In Belgium, the export notification was rejected as it did not meet Article 8(5) criteria. In Greece, the emergency situation concerned 1,3-dichloropropene imported by Turkey, requesting a 120-day authorisation to use the chemical as a soil fumigant.

4.2.6 Provision of available additional information on exported chemicals

According to Article 8(7), the Commission, DNAs, the Agency and exporters should provide additional information on the exported chemicals, at the request of the importing party. The Agency received many requests to provide additional information or clarifications on exported chemicals to importing parties and other countries. These typically related to additional information on the importing company, clarification on the intended use of the chemical in the importing country or on the quantities exported, clarification on the reasons for notifying the export of the chemical or for requesting the explicit consent for chemicals which are not listed in Annex III to the Rotterdam Convention, and cases where the export notification was sent to the wrong authority.

Eight DNAs received similar requests. Information requested by the importing countries related primarily to importer contact details. Other requested information related to the chemical itself, e.g. name of the chemical, or information on the reasons for its ban or restriction in the EU.

4.2.7 Administrative fee for export notifications

Member States are allowed to establish administrative fees for exporters for each export notification and for each request for explicit consent made, corresponding to the cost they incur in carrying out the procedures. Eight Member States request an administrative fee for export notifications, and these fees vary greatly between Member States (from EUR 25 to EUR 250). Three Member States request a fee for requests for explicit consent. Member States received no complaints from exporters, nor did they note any significant impact of the fee on the number of export notifications.

4.3 Export notifications from Parties and other countries (Article 9)

As per Article 9, the Agency must make available on its database the export notifications it receives from third countries, acknowledge receipt of the notification to the DNA of the exporting country and provide a copy to the DNA of the Member State(s) receiving the import. The Agency was asked to provide information on the export notifications received and acknowledgements sent.

The Agency received 1,105 export notifications from non-EU countries in the reporting period (see Table 12). The number of notifications almost doubled between 2014 and 2016.

Table 12: Export notifications received from non-EU countries and acknowledgements sent during the reporting period

	2014	2015	2016	Total
Export notifications received	209	486	410	1,105
Acknowledgements sent	3[17]	122	92	217

The difference between the number of notifications received and the number of acknowledgements sent is due to the fact that the Agency does not send acknowledgements of receipt to the US, based on a bilateral agreement between the two parties, while the US is the country sending the greatest number of notifications to the EU.

[17] Data only available after go-live of the PIC submission system (2 September 2014).

4.4 Information on export and import of chemicals (Article 10)

Article 10 places obligations on exporters and importers to inform the DNA of the quantity of chemicals listed in Annex I of the PIC Regulation exported to or imported from third countries during the preceding year. This must be done during the first quarter of each 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.

DNAs and the Agency were asked (in their respective questionnaires) about any delays and difficulties encountered in fulfilling their obligations under Article 10. Their responses suggest that the reporting under Article 10 works well.

Delays in collecting information
Ten DNAs stated that several exporters had delayed the submission of information on the quantity of the chemicals exported, but said that exporters generally submitted the information after a reminder. Eight DNAs stated that they had experienced delays from importers in submitting their information. These delays did not affect the completion of the reporting exercise under Article 10, as the Agency did not encounter similar delays from DNAs in receiving the aggregated national reports on the quantity of exported and imported chemicals.

Reporting through ePIC
Very few DNAs reported problems with reporting through ePIC, with only two indicating that they had experienced difficulties in their Article 10 reporting. Two DNAs indicated that they experienced delays in submitting aggregated information through ePIC.

Aggregating information at EU level
According to the Agency, the aggregation of information was complicated by incorrect reporting by some DNAs, which had included data on exports of PIC chemicals exported for research and analysis purposes (below 10kg per year and per importing country). These exports are out of the scope of Article 10 and should not be reported by DNAs.

Use of Article 10 data
Data gathered for the purposes of Article 10 reporting are used by the DNAs, customs or other enforcement authorities in 16 Member States. Eight DNAs indicated that the data are used for enforcement activities, with six specifying that it is used for REACH enforcement activities (e.g. cross-checking compliance with registration requirements, or checking compliance with restrictions).

4.5 Notification of banned or severely restricted chemicals under the Convention (Article 11-12)

As per Article 11 of the PIC Regulation, the Commission must notify the Secretariat of the Rotterdam Convention, in writing, of the chemicals listed in Part 2 of Annex I, which qualify for PIC notification. The Commission, assisted by the Agency, drafted the notifications and submitted these to the DNAs for comments before submitting them to the Secretariat. Three notifications were submitted to the Secretariat during the reporting period (see Table 13).

Table 13: PIC notifications sent to the Secretariat during the reporting period

Basis for notification	Chemicals notified	Date of notification
Commission Regulation (EC) No 73/2013 (2014)	Naled	2014
Commission Delegated Regulation (EU) No 1078/2014	Bitertanol	October 2016
Chemicals notified after inclusion in Annex Commission Delegated Regulation (EU) No 2015/2229	Fenbutatin oxide	October 2016

4.6 Obligations in relation to importing chemicals (Article 13)

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 within nine months of receipt of the notification of the listing and the decision guidance document. Pursuant to Article 13 of the PIC Regulation, the import decision is adopted by means of an implementing act. The Commission drafts the implementing act containing relevant import decisions, which is then submitted to the REACH Committee for an opinion, in accordance with the advisory procedure.

During the reporting period, the Commission adopted two Implementing Decisions (see Table 14). In 2014, the Commission drafted import decisions for azinphos-methyl, commercial pentabromodiphenyl ether, commercial octabromodiphenyl ether, perfluorooctane sulfonic acid, perfluorooctane sulfonates, perfluorooctane sulfonamides and perfluorooctane sulfonyls, which were submitted to the REACH Committee on 7 April, with the Commission Implementing Decision adopted on 15 May 2014. In 2015, the Commission drafted a new import decision for methamidophos and revised the import decisions on DDT and ethylene oxide, which were submitted to the REACH Committee in late 2015. The Implementing Decision was adopted on 11 February 2016.

Table 14: EU import responses adopted during the reporting period

Implementing Act	Chemicals	Nature / status of decision		Import decision	Grounds for decision
Commission Implementing Decision of 15 May 2014	Azinphos-methyl	New decision	Final	No consent to import	Banned for use under PPPR
	Commercial pentabromodiphenyl ether	New decision	Final	Consent to import only subject to specified conditions	Banned for use, subject to specific exemptions under POPs Regulation
	Commercial octabromodiphenyl ether	New decision	Final	Consent to import only subject to specified conditions	Banned for use, subject to specific exemptions under POPs Regulation
	Perfluorooctane sulfonic acid, perfluorooctane sulfonates, perfluorooctane sulfonamides and perfluoro-octane sulfonyls	New decision	Final	No consent to import	Banned for use, subject to specific exemptions under POPs Regulation

Implementing Act	Chemicals	Nature / status of decision		Import decision	Grounds for decision
Commission Implementing Decision of 11 February 2016	Methamidophos	New decision	Final	No consent to import	Banned for use under PPPR
	Ethylene oxide	Amending previous decision	Interim	Consent to import only subject to specified conditions	Banned for use under PPPR and restricted under BPR
	DDT	Amending previous decision	Final	No consent to import	Banned for use under POPs Regulation

Article 13(5) requires the DNAs to make EU import decisions available to those concerned within their competence. DNAs fulfil this requirement by email and by publishing those decisions on their website.

4.7 Obligations in relation to exports of chemicals, other than export notifications (Article 14)

Article 14 requires the explicit consent of the importing country before an export of chemicals listed in Parts 2 or 3 of Annex I can proceed, unless a positive import response is available in the latest PIC Circular for chemicals listed in Part 3 of Annex I.

DNAs and the Agency were asked to provide data on explicit consent procedures carried out during the reporting period, as well as any difficulties they encountered in doing so. Nineteen Member States implemented the explicit consent procedure during the last three years, highlighting some importing countries' difficulties in handling requests sent by Member States as the main challenge. Fewer Member States dealt with Article 14(6) and (7) provisions, and the information provided by DNAs suggests that few implementation problems occurred. Although, according to the Agency, it was initially challenging to interpret the cases to which Article 14(8) provisions applied, the number of problem cases has nonetheless been reduced to a very low level.

4.7.1 Communication of information and decisions to those concerned within the jurisdiction of a Member State (Article 14(3))

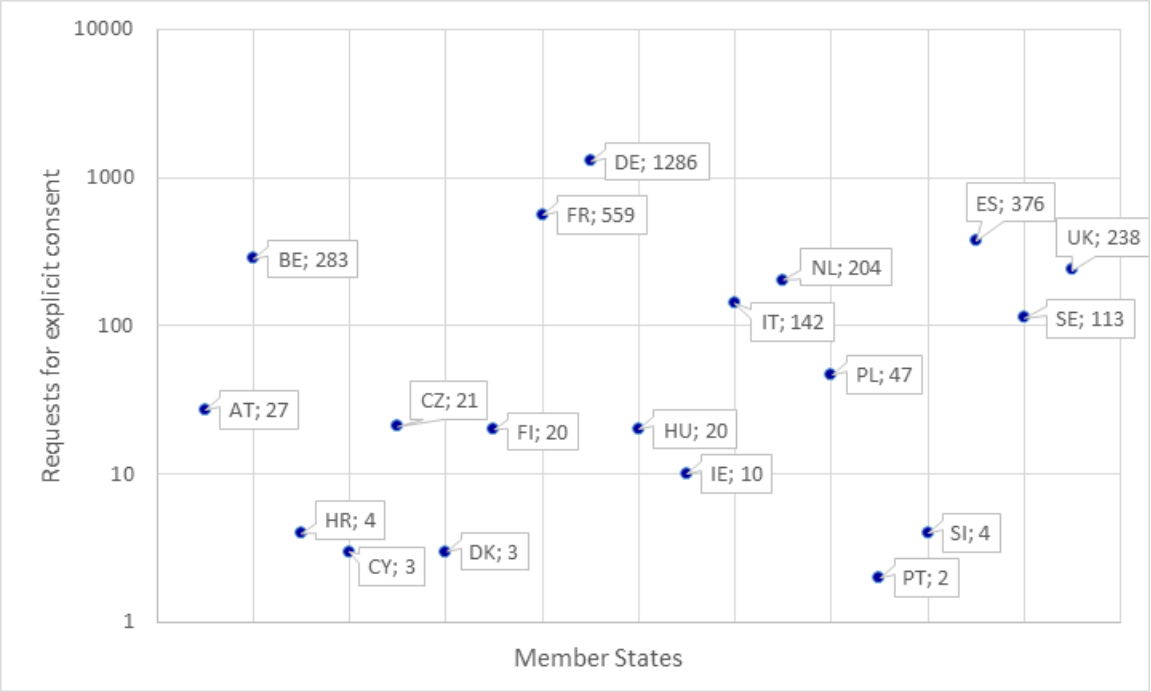
Article 14(1) requires the Commission to forward PIC circulars and other relevant information received from the Secretariat of the Convention to Member States, the Agency, and industry associations. The Member States then communicate this information to those concerned in their jurisdiction. All DNAs fulfil this requirement, mainly through emails and the provision of information on their website (Article 14(3)).

4.7.2 Explicit consent (Article 14(6))[18]

During the reporting period, 19 Member States sought explicit consent from the DNA of the importing country, under Article 14(6)(a). A total of 3,362 requests for explicit consent were handled by DNAs (see Figure 9).

[18] This section and those that follow are based on data extracted from ePIC by the Agency and provided to the Commission, the DNAs and the consultant.

Figure 9: Number of requests for explicit consent received by DNAs during the reporting period[19]



Of the 3,362 requests for explicit consent, 56% were answered. The share decreased over the reporting period (61% in 2014, 58% in 2015, and 51% in 2016). This explained why the Agency had to send a significant number of reminders. A first reminder was sent for 65% of the requests, and a second reminder for 42% of the requests (see Table 15).

Table 15: Reminders for explicit consent requests sent by the Agency during the reporting period

	First reminder	Second reminder
2014	469	235
2015	826	627
2016	899	563
Total	2,194	1,425

During the reporting period, there were four instances in France and Germany where for chemicals listed in Part 3 of Annex I, explicit consent from the DNA of the importing country was provided by the latest circular issued by the Secretariat of the Rotterdam Convention, according to Article 14(6)(b) (see Table 16).

Table 16: Number of requests for explicit consent pursuant to Article 14(6)(b)

Member State	2014	2015	2016	Total
France	0	0	1	1
Germany	0	0	1	1

[19] For 2014, the period covered is 1 March-31 December (as the PIC Regulation became applicable on 1 March 2014).

Difficulties encountered in the implementation of the explicit consent procedure

Eight Member States reported having experienced difficulties in implementing the explicit consent procedure. According to most DNAs, the main challenge was late responses from importing countries to consent requests (i.e. after the 60-day waiting period) or no response at all. The DNAs also stated that the response provided was not always clear or was difficult to interpret, that certain countries were particularly difficult to reach (e.g. where the request had to be sent by regular mail), and that certain countries imposed additional national rules that caused further delays.

The Agency's involvement in the explicit consent procedure consists of verifying the metadata associated with explicit consent requests after it is uploaded to ePIC by the DNA (and before it can be used for processing purposes). According to the Agency, this process has worked smoothly in recent years and has contributed to harmonised data and the reduction of clerical errors during the procedure.

The Agency also mentioned that it had agreed a procedure with the Commission and the EU DNAs for the handling of requests for explicit consent received from a non-EU country, as the PIC Regulation does not provide any such procedure. This procedure, it stated, could be reflected in the legal text.

4.7.3 Waivers (Article 14(6) and (7))

Explicit consent in case of exports of chemicals listed in Part 2 of Annex I to OECD countries

According to Article 14(6), when a chemical qualifying for PIC notification is exported to an OECD country, the DNA can waive the requirement for explicit consent on a case-by-case basis, at the request of the exporter and after consulting the Commission. Six Member States were requested to decide whether or not explicit consent was required in the case of export of chemicals listed in Part 2 of Annex I to OECD countries (see Table 17). None of the Member States experienced difficulties in taking such a decision.

Table 17: Number of cases where DNAs were required to decide whether or not explicit consent was required in case of export of chemicals listed in Part 2 of Annex I to OECD countries

Member State	2014	2015	2016	Total
France	0	8	1	9
Germany	0	2	0	2
Italy	15	19	15	49
Netherlands	0	1	3	4
Sweden	0	2	1	3
United Kingdom	0	1	0	1

DNA decisions that export may proceed 60 days after an explicit consent request was made

According to Article 14(7), the DNA of the exporting country can take the decision, on a case-by-case basis and in consultation with the Commission, assisted by the Agency, to waive the explicit consent requirement when no reply from the importing country has been received after 60 days. Such waivers can only be granted if certain conditions are met and for a maximum period of 12 months, after which time the exporter will need to seek explicit consent again. Eleven Member States received waiver requests in accordance with Article 14(7) during the reporting period (see Table 18).

Table 18: Number of waiver requests received per Member State during the reporting period

Member State	2014	2015	2016	Total
Belgium	11	16	11	38
Finland	0	0	1	1
France	5	19	9	33
Germany	14	50	34	98
Hungary	0	2	1	3
Italy	1	26	10	37
Netherlands	2	1	8	11
Poland	0	3	0	3
Spain	1	8	16	25
Sweden	0	17	14	31
United Kingdom	1	14	12	27

Two Member States stated that they experienced difficulties in implementing the waiver procedure. One DNA had difficulties with the languages in which the documents were submitted and had to request translations, while the second found it difficult to identify whether or not the documents provided were valid.

4.7.4 Validity of explicit consent (Article 14(8))

According to the procedure described in Article 14(6), explicit consent, once obtained, is valid for three calendar years, after which it must be requested again, unless the terms of the consent require otherwise. Export may continue for an additional 12 months after the three-year period, however, pending a response to a new request for explicit consent.

Fourteen Member States experienced cases where the export was allowed to proceed pending a reply to a new request for explicit consent (see Table 19). The highest number was reported by Germany, with 138 cases in total.

Table 19: Number of cases where the export was allowed to proceed pending a reply to a new request for explicit consent, by Member State, during the reporting period

Member State	2014	2015	2016	Total
Austria	0	1	1	2
Belgium	0	10	1	11
Cyprus	0	1	0	1
Finland	0	4	6	10
France	0	13	5	18
Germany	1	103	34	138
Hungary	0	1	2	3
Italy	0	2	2	4
Netherlands	0	3	11	14
Poland	0	2	0	2
Slovenia	0	0	1	1
Spain	0	9	17	26
Sweden	0	5	7	12
United Kingdom	0	14	18	32

According to the Agency, Article 14(8) was initially difficult to implement due to misunderstandings in its interpretation and a lack of understanding of the cases to which it applied. The issue was then discussed at the 25th DNA meeting (on 21 April 2015) and a common approach was identified. Once the way forward had been agreed, the related functionality in ePIC was also modified in order to better support the implementation of

this provision. Since then, although the provision remains challenging to implement, the number of problem cases (i.e. in which the Agency and the DNAs disagree on the interpretation) has been reduced to a very low level.

4.8 Information on transit movement (Article 16)

None of the Member States implemented Article 16 during the reporting period.

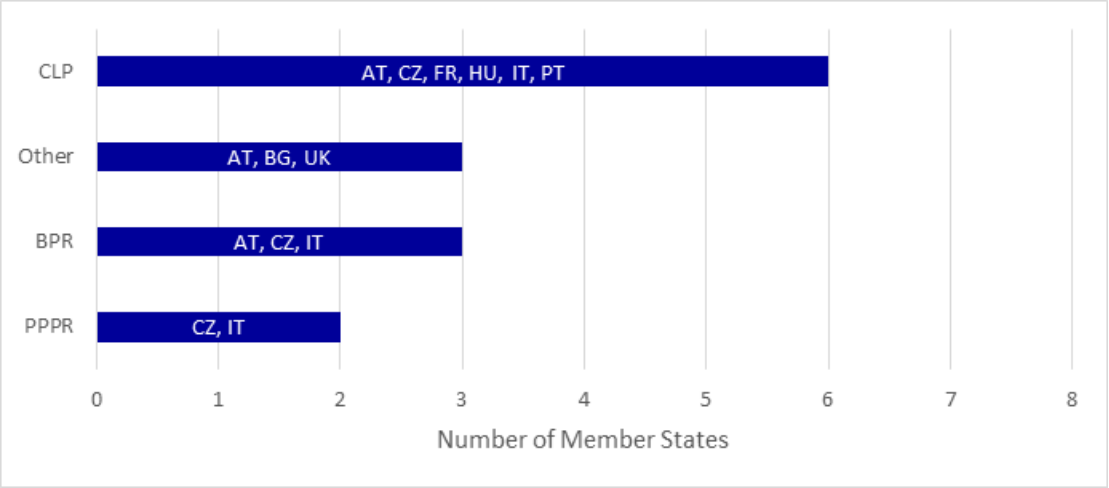
4.9 Requirements linked to exported chemicals and accompanying information (Article 17)

Article 17 states that exported chemicals must be packaged and labelled in accordance with the provisions on packaging and labelling in the CLP Regulation, the PPPR and the BPR. The information on the label must also include the expiry date (for different climate zones if necessary) and the production date. An SDS compliant with Annex II of the REACH Regulation must be sent to each importer, together with the chemical. The information on the label and the SDS should be given in the official languages, or in one or more of the principal languages, of the country of destination or of the area of intended use, insofar as possible.

The DNAs were asked to provide information on compliance issues observed during the reporting period. Any such issues chiefly related to packaging requirements under the CLP Regulation and the SDS.

Compliance issues relating to packaging and labelling requirements
The national enforcement authorities in eight Member States experienced compliance issues concerning the information accompanying exported chemicals. Six Member States indicated that they had identified compliance issues relating to the packaging requirements of the CLP Regulation (see Figure 10).

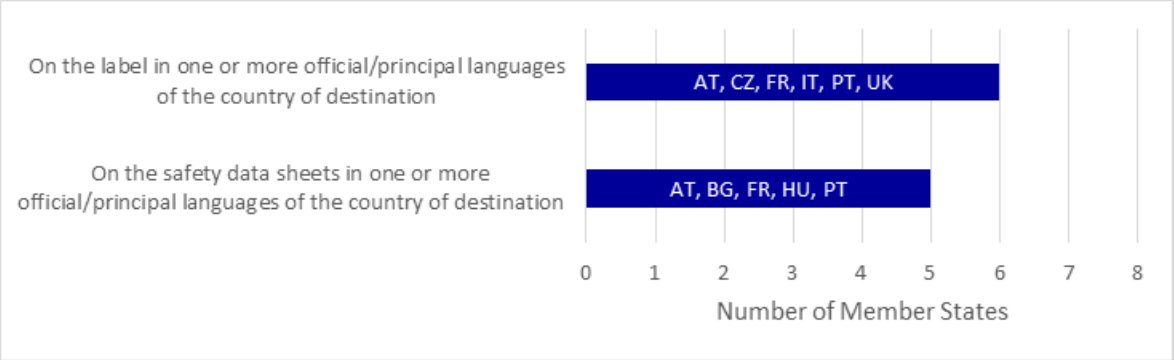
Figure 10: Question 52. Were these compliance issues related to the application of packaging and labelling requirements under PPPR, BPR, CLP or other regulations?



Compliance issues with the SDS and the language(s) of the label or SDS
Six Member States reported finding compliance issues relating to the application of SDS requirements under the REACH Regulation.

Other compliance issues concerned the obligation to give information in one or more official/principal languages of the country of destination, both on the label and on the SDS (see Figure 11).

Figure 11: Question 54. Were these compliance issues related to the obligation to give information: on the label in one or more official/principal languages of the country of destination or on the SDS in one or more official/principal languages of the country of destination?



Finally, two Member States reported experiencing compliance issues regarding the information and packaging requirements linked to the exported products. Both indicated that these compliance issues were related to the expiry date and the storage conditions on the label.

4.10 Enforcement of Regulation (EU) No 649/2012 (Article 18)

According to Article 18 of the PIC Regulation, Member States must designate authorities (such as customs authorities) to control the import and export of chemicals listed in Annex I. The Commission, supported by the Agency, and the Member States must coordinate their enforcement activities in respect of the PIC Regulation. The Forum for Exchange of Information on Enforcement, established by the REACH Regulation, should also be used to coordinate the network of authorities responsible for enforcement of the PIC Regulation.

Article 18 states that Member States must provide information on the activities of their enforcement authorities in their Article 22 reports. The questionnaire asked Member States to report on: the organisation of enforcement activities at national level and their enforcement strategy; training of inspectors; enforcement actions and their penalty system; collaboration between National Enforcement Authorities (NEA) and DNAs and Forum activities; and asked them to provide data on the enforcement activities and infringements observed during the reporting period.

Information provided by the DNAs shows that all Member States have put in place a system to ensure compliance with the PIC Regulation. All Member States have nominated authorities responsible for the enforcement of the PIC Regulation (in most Member States, this is the customs authority and the environmental/health inspectorate). Many Member States have put in place some kind of enforcement strategy (including rules of procedures, written instructions, etc.), and around half have established regular training of inspectors. Most Member States have also described their applicable penalty system. Twenty Member States reported having carried out controls on exports or imports during the reporting period, 11 of which provided data on the results of the controls, showing that few infringements were detected. Finally, DNA feedback on the Forum activities was positive, with some welcoming the launch of a pilot project dedicated to the PIC Regulation.

4.10.1 National enforcement authorities (NEAs)

Most Member States have several authorities in charge of enforcing the PIC Regulation. Customs are involved in the implementation of the PIC Regulation in all Member States

except Malta and the United Kingdom. In four countries, the customs administration is the sole NEA (Spain, Croatia, Italy and Slovakia). Other enforcement authorities are typically environmental, chemical and/or health inspection services. In nine Member States, the NEA is part of the same institution as the DNA.

In almost all of the Member States in which NEAs are involved in the enforcement of the PIC Regulation, they are also typically involved in the enforcement of the CLP Regulation (27 Member States), the REACH Regulation (25 Member States), and the BPR (22 Member States).

The majority of Member States (18) indicated that NEAs have sufficient resources to carry out their obligations under the PIC Regulation. Where Member States pointed to insufficient resources in NEAs, they referred specifically to the lack of human resources.

4.10.2 Training inspectors

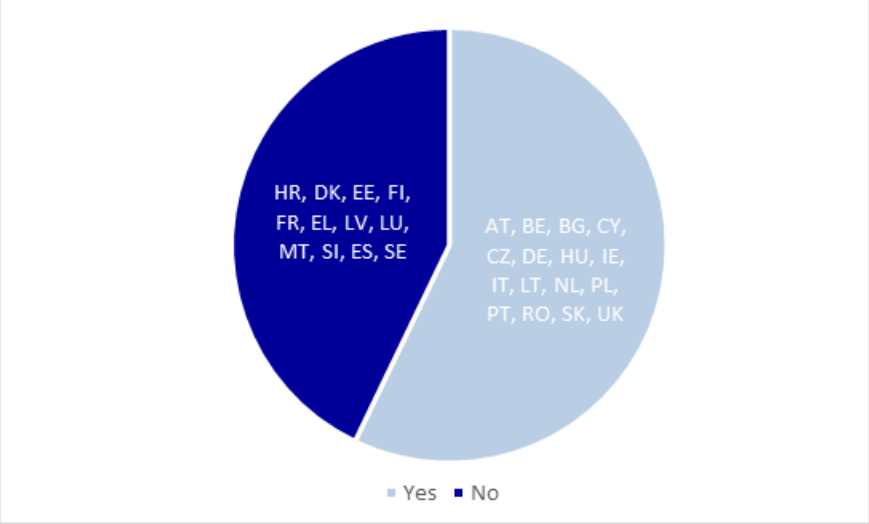
Fifteen Member States indicated that inspectors are regularly trained on the PIC Regulation. Among the Member States that have organised regular training, eight stated that such training is included as part of general training on chemicals legislation, while four mentioned training specific to the PIC Regulation. Nine reported training specifically targeting inspectors, while four mentioned training for customs officers.

Most Member States with no regular training on PIC explained that specific/regular training was not needed during the reporting period, often because of training provided by the Agency, national guidelines, and regular exchanges of information between the DNAs and the NEAs. Only one Member State reported that training had not taken place because of the lack of specialised trainers.

4.10.3 Enforcement strategy

Sixteen Member States reported having a strategy for the enforcement of the PIC Regulation, of which 14 have already implemented that strategy (see Figure 12).

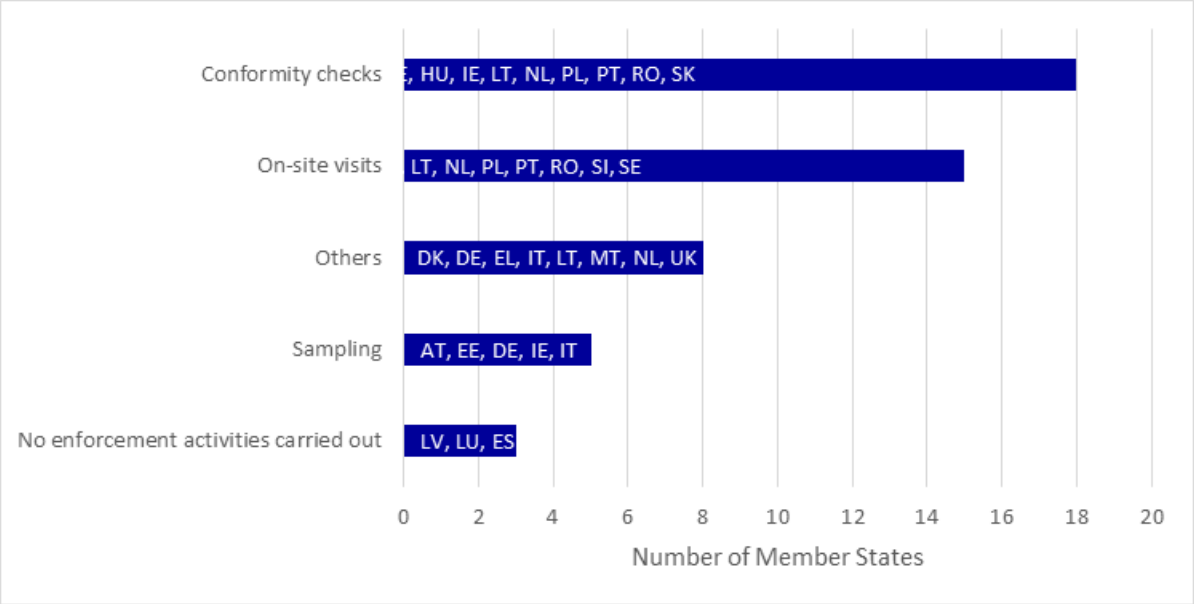
Figure 12: Question 62. Does your authority (or any other relevant authority) have an enforcement strategy for Regulation (EU) No 649/2012?



4.10.4Enforcement activities

During the reporting period, 18 Member States carried out conformity checks and 15 carried out on-site visits in which the PIC Regulation was covered (see Figure 13).

Figure 13: Enforcement activities carried out in Member States[20]



Eight Member States mentioned other enforcement activities (see Table 20):

- Reactive operations/investigation of issues brought to the DNA's attention;
- Controls carried out as part of integral controls on compliance with REACH/CLP;
- Cooperation with customs;
- Risk-oriented random checks during custom clearance;
- Conformity checks to assess whether or not a substance falls within the scope of the PIC Regulation;
- Document checks;
- Checking reports submitted to the national database.

In 13 Member States, customs performed controls related to the PIC Regulation during the reporting period, representing the largest number of controls in most countries. NEAs performed controls on exports in 11 Member States. DNAs reported the following data:

Table 20: Total number of official controls on exports in which the PIC Regulation was covered or enforced during the reporting period, by Member State

Member State	Customs	Inspectors	Others
Austria[21]	561	16	N/A
Belgium[22]	N/A	29	N/A

[20] Luxembourg and Latvia ticked 'other', indicating that no enforcement activities were carried out (as no exports took place during the reporting period).

[21] Available data from the inspectors cover only parts of the inspection activities, as export control is not separated from general controls; consistent statistics on export-related enforcement activities of NEAs will be available from 2017 onwards (implementation of a new Reporting scheme).

[22] Information missing (N/A) as the cooperation agreement between the DNA and the customs is not yet in force.

Member State	Customs	Inspectors	Others
Bulgaria	463	0	N/A
Croatia	N/A	0	N/A
Cyprus	3	1	0
Czech Republic	N/A	N/A	N/A
Denmark	N/A	0	N/A
Estonia	1	0	0
Finland[23]	3633	1	N/A
France	123	N/A	N/A
Germany[24]	1	29	0
Greece	N/A	N/A	17[25]
Hungary	35	30	N/A
Ireland	43	N/A	N/A
Italy	401	N/A	N/A
Latvia	0	0	0
Lithuania	0	1	0
Luxembourg	0	0	0
Malta	0	0	4
Netherlands	275	661	0
Poland	N/A	0	N/A
Portugal	135	1	N/A
Romania	0	0	0
Slovakia	0	0	0
Slovenia	0	9	0
Spain	0	0	0
Sweden	N/A	0	N/A
United Kingdom	0	1	0

In four Member States, customs carried out controls on imports during the reporting period. NEAs reported performing controls on imports in nine Member States. DNAs reported the data contained in Table 21.

Table 21: Total number of official controls on imports in which the PIC Regulation was covered or enforced during the reporting period, by Member State[26]

Member State	Customs	Inspectors
Austria	0	0
Belgium	N/A	N/A
Bulgaria	0	40
Croatia	N/A	0
Cyprus[27]	N/A	0
Czech Republic	N/A	N/A
Denmark	N/A	0
Estonia	6	8
Finland	N/A	0

[23] For Year 1, figures from the customs authority cover the whole year 2014 – including the period before the entry into force of the new PIC Regulation.

[24] No statistics or records are kept by the customs authorities in Germany.

[25] The category 'other' includes conformity checks to assess whether a substance falls within the scope of PIC regulation or not.

[26] Member States could report other types of controls in the column 'other', although none did.

[27] The DNA indicated that data for customs were not available.

Member State	Customs	Inspectors
France	N/A	N/A
Germany	0	20
Greece	N/A	N/A
Hungary	N/A	63
Ireland	43	N/A
Italy	804	N/A
Latvia	0	0
Lithuania	0	1
Luxembourg	0	0
Malta	0	0
Netherlands	0	661
Poland	N/A	7
Portugal	248	24
Romania	0	16
Slovakia	0	0
Slovenia	0	0
Spain	0	0
Sweden	N/A	0
United Kingdom	0	0

4.10.5 Enforcement actions and penalty systems

Member States were asked to describe the measures that enforcement authorities can take to ensure compliance with the PIC Regulation, and their penalty system in case of infringement. DNAs typically described a mix of enforcement measures, such as seizure and detention of goods, withdrawal from the market, suspension of activities etc. Ten Member States stated that NEAs could issue letters of formal notice to request compliance within a certain timeframe. On penalties for infringements, 23 Member States indicated that they impose fines for specific infringements, often with a scale of fines depending of the gravity of the infringement. In seven Member States, a penalty of imprisonment can be imposed on the most serious infringements.

4.10.6 Infringements during the reporting period

Infringements found through customs controls

Three Member States reported identifying infringements through customs controls (Germany, France and Italy) (see Table 22). The number of infringements is very low compared to the number of customs controls performed[28]. Germany indicated that the infringement found by customs concerned a chemical that did not conform to the export notification.

Table 22: Number of customs controls and infringements observed during the reporting period

Member State	Controls on exports	Controls on imports	Infringements found
France	123	N/A	3
Germany	1	0	1
Italy	401	804	9

[28] Germany reported one infringement for one control but specified that records of customs controls were not kept.

Infringements found through inspectors' controls

Nine Member States found infringements through controls carried out by inspectors (Table 23). As there might be overlaps between the numbers of controls performed on exports and imports, it was deemed better not to calculate shares of infringements. However, it should be noted that the number of infringements compared to the number of controls varies greatly across the nine Member States. One reason for this variation might be that different types of controls were performed. For example, the UK DNA explained that reactive controls were performed, which might explain the low number of controls and the high probability of detection of an infringement.

Table 23: Numbers of controls carried out by inspectors and infringements observed during the reporting period

Member State	Controls on exports	Controls on imports	Infringements found
Austria	16	0	8
Belgium	29	N/A	10
Bulgaria	0	40	7
Finland	1	0	1
Germany	29	20	21
Hungary	30	63	2
Lithuania	1[29]	1	1
Netherlands	661[30]	661	2
United Kingdom	1	0	1

The main category of infringement found through inspections was non-conformity of the chemical with the export notification. Infringements relating to SDS and labelling requirements were also found (see Table 24).

Table 24: Types of infringements of the PIC Regulation observed by inspectors during the reporting period

Member State	Labelling requirements	Safety data sheets	Expiry date of the chemical	Chemical not in conformity with export notification	Other
Austria	4	3	0	1	0
Belgium	0	0	0	10	N/A
Bulgaria	0	0	0	0	0
Finland	0	0	0	0	1
Germany	0	0	0	18	0
Hungary	1	1	0	2	2
Lithuania	0	0	0	1	1
Netherlands	0	0	0	2	0
United Kingdom	0	0	0	1	0

The four infringements reported as 'other' concerned: omitting to report imports (Finland); missing the reporting obligations under Article 10 (Hungary) and exporting without export notification (Lithuania).

Of the infringements reported in 'other', none were through the controls reported in the category 'other' (i.e. made by neither customs nor inspectors).

[29] Lithuania reported that one exporter was identified as exporting without notification and controlled. Although one control is reported for exports and one for imports, it is the same control.

[30] As the Netherlands reported the exact same number of controls by inspectors for exports and imports in 2014, 2015, and 2016, it can be assumed that both exports and imports were checked during the same controls.

Penalties

Thirteen infringements led to penalties in four Member States. In Lithuania, the Netherlands and Austria, all infringements led to penalties, while only a small percentage of infringements (10%) resulted in a penalty in Germany (see Table 25).

Table 25: Number of infringements that led to penalties during the reporting period

Member State	Number of infringements
Austria	8
Germany	2
Lithuania	1
Netherlands	2

4.10.7 Collaboration between DNAs and NEAs

Collaboration between DNAs and NEAs

Twenty-three Member States reported regular exchanges of information between the DNA(s) and enforcement authorities. Six Member States stated that, as the DNA and the NEA are in the same institution, the exchange of information occurs on a daily basis, as necessary. Six other Member States indicated that regular meetings were held between DNAs and NEAs to exchange information, while a further eight mentioned regular exchange of information by email through contact points, or following procedures provided for in laws, agreements or guidelines, or through annual inspection reports sent to the DNA.

Few Member States described the types of information exchanged: cases of exports and imports and exporting/importing companies (four Member States), interpretation and scope of the PIC Regulation (two Member States), updates and changes in the PIC Regulation (one Member State).

Eleven Member States made suggestions to improve collaboration between the DNAs and enforcement authorities. Some also mentioned the following exchanges of information between authorities at national level:

- Enhance information exchange / updates between the DNA and enforcement authorities, including customs;
- Organise face-to-face meeting at least once a month;
- Organise training courses on PIC issues for all enforcement authorities;
- Keep information available on DNA and NEA websites up to date with legal changes.

Other comments related to actions to be taken at EU level:

- Exchange of best practices between Member States with a lot of experience in PIC controls and those with quite limited numbers of exports subject to PIC Regulation provisions;
- Make the PIC procedure more visible in the Forum;
- Improve cooperation and coordination by DG ENV with DG TAXUD;
- Fully implement the Single Window System, to control all customs declarations that have indicated a RIN code, not only the customs declaration physically or controlled by documentation;
- Ensure specific CN codes are used, as these are easier to control than products with generic CN codes.

Collaboration between DNAs and national members of the Forum for Exchange of Information on Enforcement

Twenty-three Member States reported regular exchange of information between the DNAs and the national member(s) of the Forum.

Of those Member States reporting close collaboration, seven explained that regular exchanges of information occur without formal communication or coordination mechanisms, as the Forum member is also a member of the DNA or is part of the same institution[31]. Other Member States indicated regular exchange of information, either through written/electronic communication channels or through regular meetings between institutions on outcomes of DNA and Forum meetings and activities of the Forum related to PIC (e.g. pilot projects, guidance development).
Nearly all Member States (26) indicated their satisfaction with the collaboration with the national Forum members.

Five Member States provided suggestions for improving collaboration between DNAs and Forum members:

- Inform DNAs about any Forum activities concerning the PIC Regulation, provide DNAs with direct access to Forum documents, or give DNAs the option to participate in Forum meetings;
- The Forum Secretariat at the Agency, which also reports to the DNA meetings, should inform Forum members in advance, so that they can contact their DNA(s) about issues in enforcement;
- Invite Forum members involved in PIC activities to attend PIC DNA meetings;
- Increase communication between DNAs and Forum members.

One DNA added that the planned PIC pilot enforcement project presents a good opportunity to enhance collaboration between DNAs, Forum members, NEAs and customs.

4.10.8 Forum activities

The Forum did not engage in any regular exchange of information on the PIC Regulation during the reporting period, but such exchange is part of the Forum's Multiannual Work Programme. In 2016, the Forum decided to run a pilot project on PIC enforcement, focusing on export notifications. The preparation and execution of this project will take place in the next reporting period. The Forum has also defined the specifications for the PIC form in the ICSMS tool (Commission-owned IT platform for exchange of information in a secure way between NEAs).

Although Forum activities on PIC are just beginning, 19 Member States indicated their satisfaction with the activities carried out by the Forum.

Eight Member States suggested improvements to the activities of the Forum in respect of the PIC Regulation:

- Five Member States pointed to the need to carry out enforcement projects or pilot projects related to the PIC Regulation;
- One Member State suggested adding the PIC Regulation to the general controls on REACH, CLP, POPs, mercury;
- One Member State underlined the importance of keeping the PIC best practice document up-to-date;
- One DNA suggested increasing the possibilities for sharing experiences between Member States;
- One Member State suggested that DNA experts should be invited to Forum meetings for discussions on activities relating to PIC Regulation.

According to the Agency, careful prioritisation of PIC activities is essential, given the limited resources of the Forum, and the many priority areas for coordinated

[31] One Member State provided the same justification for replying 'no'.

enforcement. One potential improvement would be to increase the number of PIC-related activities, including integration into enforcement projects relating to other legislation.

4.11 Exchange of information (Article 20)

According to Article 20, the Commission, assisted by the Agency, and the Member States must facilitate the provision of scientific, technical, economic and legal information to other countries on chemicals subject to the PIC Regulation, including toxicological, ecotoxicological and safety information. Every two years, the Agency must compile all of the relevant information that has been transmitted.

Information provided following ad-hoc requests

The Commission provided an answer to two requests from third countries in 2014-2015[32]:

- One from Peru, asking whether or not three particular mixtures were subject to an export notification under the EU PIC Regulation.
- One from Serbia, requesting clarifications of the provisions on mercury with respect to Regulation (EU) No 649/2012 and Regulation (EC) No 1102/2008.

The Commission replied to four requests in 2016 from four countries (Canada, Indonesia, Lebanon and Syrian Arab Republic) concerning four chemicals. In addition, information was sent to Ecuador in response to a request.

The Agency did not receive any requests within the scope of Article 20 in either 2014 or 2015. It received two requests in 2016, from the authorities in the Syrian Arab Republic and China, respectively.

EU Member States did not receive any ad-hoc requests for information during the reporting period.

Reporting on the information transmitted

The Agency published its first compilation of transmitted information in November 2016[33], covering the first two years of implementation of the PIC Regulation (2014-2015). The report addresses information submitted by means of export notifications, FRA notifications, and following ad-hoc requests. The next Article 20 report will cover the 2016-2017 period.

The Agency did not experience difficulties in collecting the information from the Commission and the Member States on the data transmitted. The only challenge it reported was in clarifying the scope of the report with the Commission and Member States, as it was the first of its kind. The scope of the report was clarified between the Commission and the Agency and discussed with the DNAs at the 27th DNA Meeting (held on 26 April 2016). The Agency shared the lessons learned from this reporting exercise at the 28th DNA meeting (14 December 2016) in order to achieve more clarity for the next reporting period.

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[32] ECHA, *Overview on the exchange of information under Article 20 of the PIC Regulation - Compilation of the information collected by the European Commission, assisted by the Member States and the European Chemicals Agency (ECHA*), 2016, available at: https://echa.europa.eu/documents/10162/21728206/pic_article_20_report_2014-2015_en.pdf/ad0e2b0d-4f12-486f-b1da-9fd2ddbbb187

[33] Idem.

4.12 Technical assistance (Article 21)

Under 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 to develop the infrastructure, capacity and expertise necessary to manage chemicals properly throughout their lifecycles. In addition, the Commission and DNAs must actively participate in international activities in capacity-building in chemicals management, and consider giving support to NGOs.
The Agency and DNAs were asked to describe the activities in which they participated. The Agency mainly participated in activities intended to explain the specific provisions of the PIC Regulation and the differences with the provisions of the Convention. DNA activities, by contrast, consisted of the provision of technical expertise or technical information through training workshops, visits, twinning projects, etc.

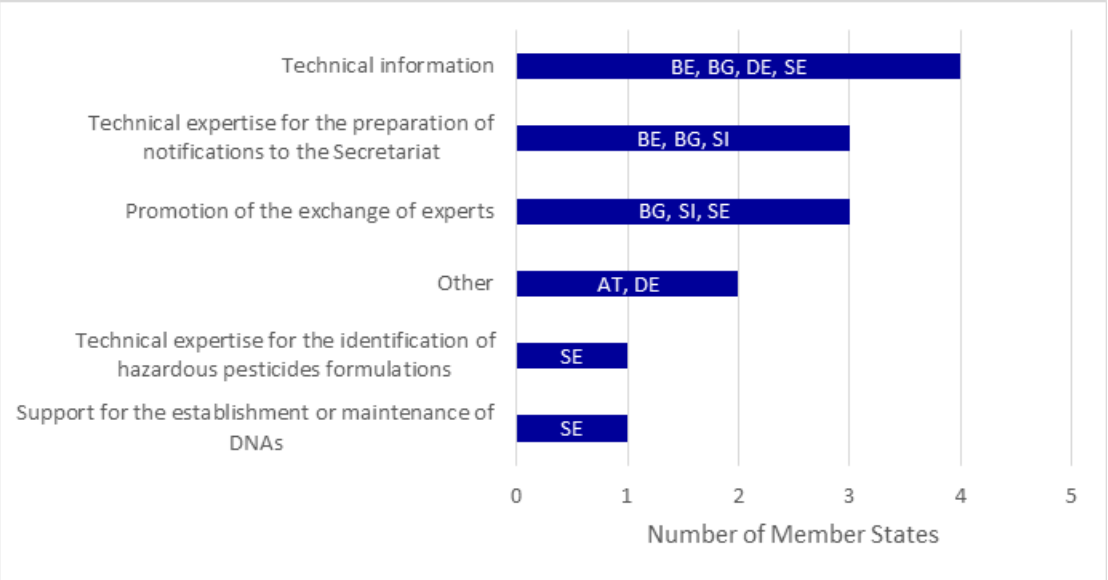
Cooperation with developing countries, countries with economies in transition and NGOs

During the reporting period, the Agency was involved in the following cooperation activities:

- 2015 workshop organised by the Rotterdam Convention Secretariat to strengthen cooperation on the implementation of the Convention between the DNAs of Burundi, Cameroon, Congo, Djibouti, Gabon and Rwanda. The aim was to clarify the provisions of the Rotterdam Convention and highlight the differences with the EU PIC Regulation.
- 2016 workshop organised by the Rotterdam Convention Secretariat to strengthen cooperation on the implementation of the Convention between the DNAs of Benin, Burkina Faso, Cabo Verde, Ivory Coast, Gambia, Guinea, Guinea – Bissau, Mali, Mauritania, Niger, Senegal, Chad and Togo. Although the Agency cancelled its participation, it had already contributed to preparing the training materials, presentations, etc.

Five Member States participated in cooperation activities, mostly relating to the provision of technical information and technical expertise in the preparation of FRA notifications to the Secretariat (see Figure 14).

Figure 14: Question 56. What types of cooperation have you been involved in?



Three DNAs mentioned other types of cooperation:

- Participation in sub-regional workshops organised by the Secretariat of the Convention (Yaoundé, 16-19 November 2015 and Dakar, 28 November-1 December 2016), mentioned above by the Agency (Belgium);
- Expert assistance in setting up the international dimension of the Georgian Ministry of Environment's Waste and Chemicals Management Department and Legal Department, in particular on the development of national legislation and training staff on the implementation and enforcement of the Rotterdam Convention and the EU PIC Regulation within a twinning project on Waste Management in Georgia GE/10/ENP-PCA/EN06, 2012-2014 (Bulgaria);
- Visits of an expert delegation to the Member States' institutions (visit of the Federal Institute for Operational Safety and Health in Dortmund) (Germany).

Capacity-building activities

The Agency organised or participated in capacity-building activities on the sound management of chemicals. These targeted EU candidate countries and potential candidates for EU accession, with a view to supporting them at a technical level to align with the REACH, CLP, BRP and PIC Regulations. These activities took place under the EU Instrument for Pre-accession assistance (IPA), the European Neighbourhood and Partnership Instrument (ENPI), the Technical Assistance and Information Exchange instrument (TAIEX) and twinning projects. PIC-related issues were also put on the agenda of third country visits to the Agency's premises.
The Agency provided some examples of capacity-building activities:

- 2014 workshop on PIC and ePIC for EU candidate countries and potential candidates;
- 3-day visit of a delegation from Turkey to the Agency's premises, to provide an overview of the Rotterdam Convention and the EU PIC Regulation;
- Participation in PIC and ePIC training organised by a technical assistance project for Turkey;
- Bilateral discussions with 47 non-EU countries at the margins of the 7th Conference of the Parties to the Rotterdam Convention to clarify the specific provisions of the PIC Regulation, discuss problem cases and gather feedback from the authorities in the non-EU countries.

Six Member States participated in projects or international activities relating to capacity-building in chemicals management during the reporting period:

- Twinning project on Waste Management in Georgia (Bulgaria, see above);
- Activities related to the Minamata Convention and SAICM (France);
- Visit of the Federal Institute for Operational Safety and Health in Dortmund (Germany, see above);
- A TAIEX project in Turkey (Italy);
- Twinning Project (2015–2017) on the Further Development of Chemicals and Biocides Products Management in the Republic of Serbia (Slovenia);
- International training courses financed by the Swedish International Development Cooperation Agency, regional meetings and working sessions focussing on capacity-building and other aspects of the sound management of chemicals in Southeast Asian countries, Southern African Development Community countries, Brazil, Indonesia, China and Serbia (Sweden).

4.13 IT-related aspects

Under Regulation (EU) No 649/2012, the Agency developed and continues to maintain the IT tool ePIC to support the implementation of the PIC Regulation, in particular the exchange of information between industry users, i.e. exporters, and authorities. ePIC was launched in September 2014, shortly after the entry into force of Regulation (EU)

No 649/2012 and replaced the previous EDEXIM database. It consists of three interfaces, one for industry users, one for authority users (DNAs, the Commission, the Agency and enforcement authorities) and one for customs officers.

For the purposes of this reporting exercise, the Agency was asked to provide information on the operation and use of ePIC and the data made publicly available on its website. Member States were asked to provide information on the use of ePIC data at national level and their experiences in using ePIC.

Overall, the DNAs assessed ePIC as user-friendly and reported no major issues in using it. Feedback from industry users to the Agency and DNAs was also generally positive, as was the feedback from customs and enforcement authorities received by DNAs. The Agency identified some improvement needs for ePIC that will be implemented in the next reporting period, some of which are based on user feedback. All of the data that should have been made publicly available by the Agency according to the Regulation, were indeed made available online during the reporting period.

4.13.1 The ePIC system

During the reporting period, a total of 2,352 authority and industry users used ePIC (see Table 26).

Table 26: Number of ePIC users during the reporting period[34]

	Number of users
Industry	1,836
DNAs	127
Commission	1
NEAs	388

As there is no user management for the customs application, the Agency could only provide estimates for the use of the customs interface:

- 26 Member States consulted the application;
- One Member State checked over 2,500 individual notifications;
- One Member State checked approximately 600 individual notifications;
- Five Member States checked between 100-350 individual notifications;
- Seven Member States checked between 40-100 individual notifications;
- 12 Member States checked fewer than 20 individual notifications.

The following new features were added to the ePIC system during the reporting period:

- Management of Article 10 report through ePIC: submission of Article 10 report by exporters and importers; checking of reports by DNAs; aggregation of national reports by DNAs and submission to the Agency; compilation of Member State data by the Agency.
- Enhanced explicit consent metadata, with the new 'RIN match algorithm' functionality.
- Waiver management.
- Bulk special RIN submissions available to industry.
- Automated sending of all email communication for export notifications, including cover notes, second sending of export notifications after 30 days (in the absence of an acknowledgement of receipt) and explicit consent reminders.
- Pre-filled explicit consent request forms for DNAs.
- Possibility for the Agency users to add/edit PIC chemicals.

[34] Regarding DNA and NEA accounts: the numbers provided in the table refer to the existing number of accounts created and tokens issued for ePIC. They do not necessarily refer to 'active users' of ePIC.

- Implementation of fully-fledged workflows with associated task items and deadlines.
- Event history, submission history and message history available, allowing traceability for audit purposes and for everyday follow-up of tasks/actions.
- Message box embedded in task items.
- Enhanced security of the application.

According to the Agency, these new features reduced processing time, increased efficiency, enabled traceability and contributed to ensuring consistency and reliability of the data in the system. They also enabled all stakeholders (industry, DNAs, the Commission and the Agency itself) to manage an increasing number of tasks and meet legal deadlines without significantly increasing their staff numbers.

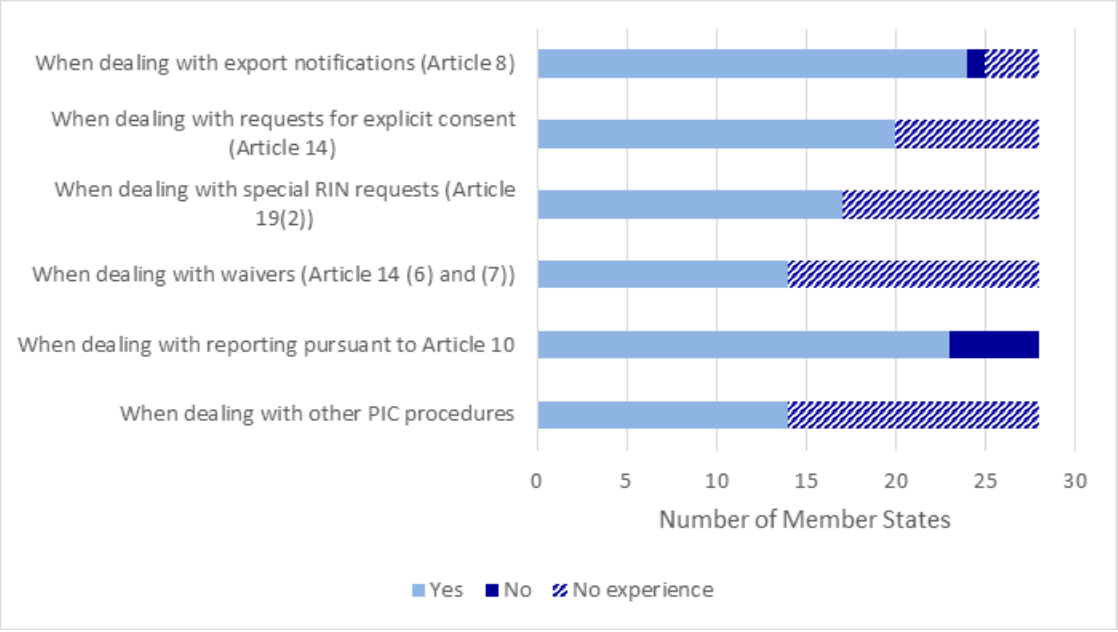
4.13.2 User-friendliness of the ePIC system

DNAs

According to the Agency, the feedback received from the DNAs was generally positive. Many of their suggestions for improvement were implemented during the reporting period.

In their reporting questionnaires, the DNAs were also generally positive about the user-friendliness of ePIC in carrying out their main obligations under the PIC Regulation. The only area where several Member States reported difficulties was the Article 10 reporting (see Figure 15).

Figure 15: Question 79. Is the ePIC system easy to use for DNAs?



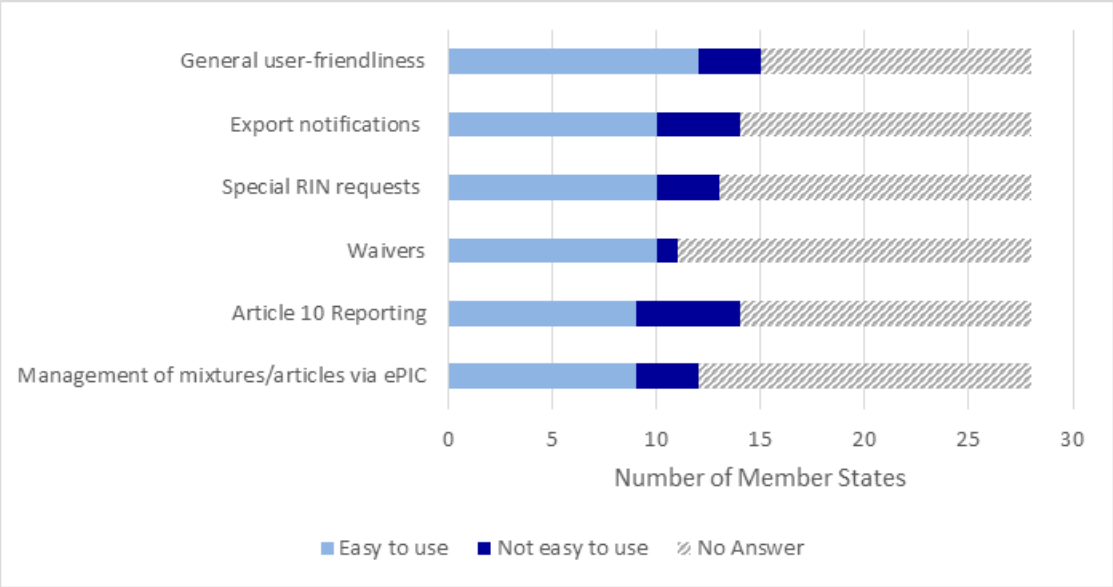
Exporters and importers

Similarly, the Agency received generally positive feedback from industry users, with stakeholder surveys indicating that 87% of industry users in 2015 and 96.7% in 2016 were satisfied with ePIC. The simplicity of the application and the pre-filled data were reported as being particularly valuable.

The feedback received by DNAs from industry users was also generally positive, although it should be noted that only around half of the Member States replied to this

question (see Figure 16). Levels of satisfaction with ePIC are slightly lower for export notifications and Article 10 reporting.

Figure 16: Question 80. Where possible, please provide feedback from exporters on the user-friendliness of the ePIC system.



One DNA mentioned that companies judged the ePIC User Manual too lengthy and detailed, and suggested that it would be useful to create user-friendly factsheets, or short guidance, such as those that exist for REACH. Another DNA recommended that guidance and tools should be provided in national languages.

One DNA stated that exporters would find the export notification process more user-friendly if they could communicate directly with the Agency to understand, for instance, why a notification is rejected or pending resubmission. It pointed out that the exporter does not receive the importing country's answer in cases where it does not give explicit consent or rejects the export notification, creating problems for companies who do not know why consent has not been given, or how they might amend their notification or assist their clients in the importing country with their approach to their own authorities. The same DNA also mentioned that exporters would find it helpful to have the Active RIN Period in the overview.

On Article 10 reporting, one DNA stated that exporters would find it easier to submit a single report containing all of the information rather than having to enter different information (amount, country, etc.) separately.

For enforcement authorities

19 Member States reported that their customs authorities used ePIC, the majority of whom (12) stated their belief that customs found ePIC easy to use and adequate to support their work.

As national enforcement authorities other than customs have only had access to ePIC since the second quarter of 2016, the Agency has not yet received any relevant feedback. Six Member States, however, indicated that their enforcement authorities used ePIC and considered it easy to use and adequate to support their work.

4.13.3 Areas of improvement

The Agency identified the following improvement needs for ePIC with a view to reducing processing times, reducing the occurrence of clerical errors, increasing compliance with legal obligations, and providing for a better user experience overall:

- Include the generation of non-confidential Article 10 reports in ePIC;
- Improve the RIN match algorithms;
- Improve the management of the chemicals database to make the chemicals easier to search and edit, simplify the insertion of new amendments, make the breakdown of group entries more transparent to companies, and facilitate data dissemination;
- Improve usability for exporters by improving data validation checks, standardising alerts and error messages, improving the document upload functionality and related options;
- Further refine search options to facilitate navigation through the increased volume of data in the system;
- Improve internal messaging to ensure that as much communication as possible can happen within the system, for traceability and audit purposes;
- Enhance the Agency's back-office functionality to reduce the number of manual tasks or tasks which require database changes.

4.13.4 Data dissemination

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).

The Agency has a specific webpage dedicated to the PIC Regulation, where the content of the legislation and the different procedures are explained. The webpage also contains:

- A link to the legal text and its amendments[35];
- Article 10 reports on actual quantities of chemicals exported and imported[36];
- Article 20 reports on information exchange, published for the first time in November 2016[37].

According to the Agency, the approach to Article 10 reporting, in particular the calculation and presentation of data, has been significantly revised compared to previous years. The new approach enables the disclosure of more data while respecting the Eurostat recommendations on data confidentiality. The data are presented in two levels of aggregation, one focused on the exported chemical(s) and the other on the countries of export and destination.

As required by the PIC Regulation, the Agency has also set up a database containing:

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[35] PIC legislation: https://echa.europa.eu/regulations/prior-informed-consent/legislation

[36] Annual reporting on PIC exports and imports: https://echa.europa.eu/regulations/prior-informed-consent/annual-reporting-on-pic-exports-and-imports

[37] Reporting on information exchange: https://echa.europa.eu/regulations/prior-informed-consent-regulation/reporting-on-information-exchange

- The list of chemicals subject to the PIC Regulation[38];
- High-level information and statistics on export notifications[39];
- High-level information and statistics on import notifications[40];
- Non-confidential data on explicit consents received from non-EU countries[41];
- EU and non-EU DNA contact details[42].

In addition, information on substances subject to the PIC Regulation is also made available through the Agency''s webpages 'Information on chemicals', which provide an infocard for each substance, and, for others, a more detailed profile.

Feedback received by the Agency on the publicly available data from authorities in non-EU countries was positive. In particular, those authorities found it useful to have summaries of export notifications and explicit consents for their countries. Feedback from companies and trade associations was more mixed. A small number of companies, together with one of the main industry trade associations, highlighted that the chemicals subject to the PIC Regulation (especially the breakdown of group entries) is not always clear on the website and could be improved. The Agency has noted this request for improvement and will consider it at a later stage.

[38] Chemicals subject to PIC: https://echa.europa.eu/information-on-chemicals/pic/chemicals

[39] Export notifications: https://echa.europa.eu/information-on-chemicals/pic/export-notifications

[40] Import notifications: https://echa.europa.eu/information-on-chemicals/pic/import-notifications

[41] Explicit consents: https://echa.europa.eu/information-on-chemicals/pic/explicit-consents

[42] DNAs: https://echa.europa.eu/information-on-chemicals/pic/designated-national-authority

Annex

Report of the European Commission on the Operation of the PIC Regulation (EU) No 649/2012

Contents

Abbreviations used

BPR	Biocidal Products Regulation
CAS	Chemical Abstracts Service
CoP	Conference of the Parties to the Rotterdam Convention
DDT	Dichlorodiphenyltrichloroethane
DNA	Designated National Authority
ECHA	European Chemicals Agency
PIC	Prior Informed Consent
POPs	Persistent Organic Pollutants
PPPR	Plant Protection Products Regulation
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation

1. Introduction

Article 22 of Regulation (EU) No 649/201243 ('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 actions.
- 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 first under the new PIC Regulation. It covers the three years of implementation since the Regulation entered into force in 2014 (2014-2016). A common reporting format for Designated National Authorities (DNAs) was established by Commission Implementing Decision (EU) 2016/770 of 14 April 2016[44], in order to collect consistent information across Member States. A reporting format for the Agency's report was adopted through Commission Implementing Decision (EU) 2016/1115 of 7 July 2016[45].

The present report is the Commission report on the performance of the functions for which it is responsible under the PIC Regulation, for the period 2014-2016. As per Article 22(2), it is incorporated in the synthesis report on the operation of the procedures during the period 2014-2016 provided for in Regulation (EU) No 649/2012, together with the information submitted by the Member States and the Agency.

In drafting this report, relevant information was compiled from EUR-lex, the website of the Rotterdam Convention, and documents published on CIRCABC, including minutes of meetings, and other documents discussed at DNA meetings. The sources used for this report are listed in Table 1.

This report is divided into two sections, the first addressing the internal work of the Commission, and the second addressing the international work of the Commission, as the EU DNA, coordinator of input provided by the EU and its Member States, and representative of the EU under the Rotterdam Convention.

Table 1 : List of relevant documents consulted

List of relevant documents consulted
Implementing and delegated acts • Commission Delegated Regulation (EU) No 1078/2014 amending Annex I to the PIC Regulation. • Commission Delegated Regulation (EU) 2015/2229 amending Annex I to the PIC

[43] 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.

[44] Commission Implementing Decision (EU) 2016/770 of 14 April 2016 establishing a common format for the submission of information concerning the operation of the procedures pursuant to Regulation (EU) No 649/2012 of the European Parliament and of the Council concerning the export and import of hazardous chemicals, C/2016/2068, OJ L 127, 18.5.2016, pp. 32–51.

[45] Commission Implementing Decision (EU) 2016/1115 of 7 July 2016 establishing a format for the submission by the European Chemicals Agency of information concerning the operation of the procedures pursuant to Regulation (EU) No 649/2012 of the European Parliament and of the Council concerning the export and import of hazardous chemicals, C/2016/4141, OJ L 186, 9.7.2016, pp. 13–23.

List of relevant documents consulted

Regulation.

- Commission Implementing Decision of 11 February 2016 adopting Union import decisions (2016/C 61/06).
- Commission Implementing Decision of 15 May 2014 adopting Union import decisions (2014/C 152/02).
- Commission Implementing Decision of 14 April 2016 establishing a common format for the submission of information concerning the operation of the procedures pursuant to Regulation (EU) No 649/2012 of the European Parliament and of the Council concerning the export and import of hazardous chemicals.
- Commission Implementing Decision of 7 July 2016 establishing a format for the submission by the European Chemicals Agency of information concerning the operation of the procedures pursuant to Regulation (EU) No 649/2012 of the European Parliament and of the Council concerning the export and import of hazardous chemicals.

DNA meeting documents

- Minutes of 23rd, 24th, 25th, 26th, 27th and 28thDNA meetings.
- Amendments to Annex I to Regulation (EU) No 649/2012, presented at 23rd, 24th, 25th, 26th, 27th and 28th DNA meetings.
- Import decisions presented at 23rd, 24th, and 26th DNA meetings.
- Submission of notifications to the PIC Secretariat, presented at 23rd, 24th, 25th, 26th, 27th and 28th DNA meetings.
- Implementation issues presented at 23rd, 24th, 25th, 26th, 27th and 28th DNA meetings.
- Documents on the preparation of COP 7 and 8, presented at 25th, 26th and 28th DNA meetings.

Rotterdam Convention's documents

- PIC circulars published by the Rotterdam Convention.

2. Internal work of the Commission

2.1. Internal organisation and resources

2.1.1. Resources

DG Environment is in charge of the PIC Regulation. Unit B.2 – sustainable chemicals has one policy coordinator responsible for carrying out the Commission's administrative functions under PIC. The policy coordinator is supported by a lawyer for legal questions and by a secretary for all organisational work. For international work, Unit B.2 has one expert (the policy coordinator) nominated to the Convention bodies, i.e. the CRC and the intersessional working group on the process of listing chemicals in Annex III to the Convention. In addition, colleagues of Unit F.3, responsible for multilateral environmental cooperation, contribute to the international work, in particular in the context of the Conference of the Parties (CoP), by dealing with horizontal and cross-cutting matters, such as financial resources, budget, technical assistance and some legal matters. The staff resources occupied by this work amount to 0.4 FTE for the policy coordinator and 0.4 FTE for the supporting work, including international matters.

2.1.2. The Agency's budget

According to Article 24, the budget of the Agency for the operation of the PIC Regulation consists of a subsidy granted by the EU for the purposes of this Regulation. The subsidy for the period 2014-2016 was set by the Commission as part of its Multiannual Financial Framework 2014-2020.

2.1.3. Coordination between the Commission and the Agency

The Commission and the Agency cooperate closely in the implementation of Regulation (EU) No 649/2012. There are regular exchanges on scientific, technical and legal questions arising in the context of implementation, in particular the legal interpretation of provisions and their practical implementation. The Agency participates in all PIC DNA meetings and reports on the work done in the area of implementation, including the operation of the IT application (ePIC) and the work of the Forum on the Exchange of Information on Enforcement. The Commission contributed to the development of the guidance produced by the Agency and also to the work of the Forum on Exchange of Information on Enforcement.

For cooperation with third countries and the Secretariat of the Rotterdam Convention, the Commission and the Agency closely coordinate their activities to ensure that the most appropriate and effective assistance is provided, and that resources are used efficiently.

2.1.4. Coordination between the Commission and DNAs

The Commission and the DNAs of the Member States closely cooperate in the implementation of Regulation (EU) No 649/2012. There are regular exchanges on scientific, technical and legal questions arising in the context of implementation, in particular through discussions at the twice-yearly PIC DNA meetings. If necessary, and where appropriate, the Commission consults DNAs in writing on specific questions. At the same time, individual DNAs consult the Commission on specific questions of interpretation and implementation of the Regulation.

The Commission coordinates and consults with DNAs on any submissions to the Secretariat of the Rotterdam Convention. On cooperation with third countries, the Commission and DNAs coordinate some of their activities to ensure coherence of the assistance provided and efficient use of resources.

2.2. Policy work

2.2.1. Amendments of Annexes I and V to the PIC Regulation

Annexes to the PIC Regulation are amended through delegated acts, adopted by the Commission, in accordance with Articles 23 and 26 of Regulation (EU) No 649/2012. The procedure for adoption of delegated acts requires the Commission to consult experts on draft amendments. As the Commission explained in the 23rd and subsequent DNA meetings, this consultation is carried out by presenting the drafts at the DNA meetings in order to ensure that all Member State experts, as well as observers, have the opportunity to comment. Delegated acts are also scrutinised by the European Parliament and the Council to ensure that the Commission does not exceed its powers.

Amendments to Annex I

Proposed amendments to Parts 1 and 2 of Annex I are triggered by regulatory actions changing the legal status of a substance under other relevant EU legislation, in particular:

- Decision not to approve or to withdraw an active substance under the PPPR.
- Decision not to approve or to withdraw an active substance under the BPR.
- Decision to subject a chemical to authorisation by adding it to the Authorisation List (Annex XIV) of the REACH Regulation.
- Decision to restrict the use of a chemical (Annex XVII) under the REACH Regulation.

During the reporting period, two Delegated Regulations amending Annex I were adopted, in 2014 and 2015 (see Table 2). Of the substances added to Annex I, many were proposed for inclusion in Parts 1 and 2 of Annex I to the PIC Regulation because they had been banned for use as plant protection products under Regulation (EC) No 1107/2009, which represented a ban or severe restriction in the use category 'pesticide'. This was the case for bitertanol, cyhexatin, azocyclotin, cinidon-ethyl, cyclanilide, ethoxysulfuron, oxadiargyl, didecyldimethylammonium chloride, and warfarin in 2014, and fenbutatin oxide in 2015. In addition, substances severely restricted as pesticides, such as rotenone and cyfluthrin in 2014, were added to Annex I.

Table 2 : Substances added to Annex 1 during the reporting period

Delegated Act	Chemical	Amendment of Annex I	Basis for inclusion
Commission Delegated Regulation (EU) No 1078/2014 of 7 August 2014 amending Annex I to Regulation (EU) No 649/2012	Azocyclotin	Part 1 and 2	PPPR
	Bitertanol	Part 1 and 2	PPPR
	Cinidon-ethyl	Part 1 and 2	PPPR
	Cyclanilide	Part 1 and 2	PPPR
	Cyfluthrin	Part 1and 2	PPPR
	Cyhexatin	Part 1 and 2	PPPR
	Ethoxysulfuron	Part 1 and 2	PPPR
	Didecyldimethylammonium Chloride	Part 1	PPPR
	Oxadiargyl	Part 1 and 2	PPPR
	Rotenone	Part 1 and 2	PPPR
	Warfarin	Part 1	PPPR
	Azinphos-methyl	Part 3	Annex III to RC
	Perfluorooctane sulfonic acid	Part 3	Annex III to RC
	Perfluorooctane sulfonates	Part 3	Annex III to RC
	Perfluorooctane sulfonamides	Part 3	Annex III to RC
	Perfluorooctane sulfonyls	Part 3	Annex III to RC
Commission Delegated Regulation (EU) 2015/2229 of 29 September 2015 amending Annex I to Regulation (EU) No 649/2012	1,1-Dichloroethene	Part 1	REACH
	1,1,2-Trichloroethane	Part 1	REACH
	1,1,1,2-Tetrachloroethane	Part 1	REACH
	1,1,2,2-Tetrachloroethane	Part 1	REACH
	Dibutyltin compounds	Part 1	REACH
	Dioctyltin compounds	Part 1	REACH
	Fenbutatin oxide	Part 1 and 2	PPPR
	Lead compounds	Part 1	REACH
	Pentachloroethane	Part 1	REACH
	Trichlorobenzene	Part 1	REACH
	Commercial pentabromodiphenyl ether, including: tetrabromodiphenyl ether, and pentabromodiphenyl ether	Part 3	Annex III to RC
	Commercial octabromodiphenyl ether, including hexabromodiphenyl ether and heptabromodiphenyl ether	Part 3	Annex III to RC

Lead compounds, dibutyltin compounds, dioctyltin compounds, trichlorobenzene, pentachloroethane, 1,1,2,2-tetrachloroethane, 1,1,1,2-tetrachloroethane, 1,1,2-trichloroethane and 1,1-dichloroethene were added to Annex I in 2015, as they were severely restricted as industrial chemicals for public use under the REACH Regulation.

Amendments to Part 3 of Annex I reflect the decisions of the CoP to include certain chemicals in Annex III to the Convention, bringing them under the PIC procedure. Azinphos-methyl, perfluorooctane sulfonic acid, perfluorooctane sulfonates, perfluorooctane sulfonamides and perfluorooctane sulfonyls, commercial pentabromodiphenyl ether including tetra- and pentabromodiphenyl ether, as well as commercial octabromodiphenyl ether including hexa- and heptabromodiphfaenyl ether, were included in Part 3 of Annex I during the reporting period, following their inclusion in Annex III to the Rotterdam Convention.

The inclusion of other substances in Annex I was under discussion in 2016, but has not yet been formally adopted through a Delegated Regulation. These substances are listed in Table 3.

Table 3 : Chemicals proposed for inclusion in Annex I

Chemical	Amendment of Annex I	Basis for inclusion
Tepraloxydim	Part 1 and 2	PPPR
Carbendazim	Part 1 and 2	PPPR
Triflumuron	Part 1	BPR
Triclosan	Part 1 and 2	BPR
cybutryne	Part 1 and 2	BPR
2,4-dinitrotoluene	Part 1 and 2	REACH
4,4'-diaminodiphenylmethane (MDA)	Part 1 and 2	REACH
5-tert-butyl-2,4,6-trinitro-m-xylene	Part 1 and 2	REACH
benzyl butyl phthalate	Part 1 and 2	REACH
Diisobutyl phthalate	Part 1 and 2	REACH
Diarsenic pentaoxide and tris(2-chloroethyl) phosphate	Part 1 and 2	REACH
Methamidophos	Part 1 and 3	Annex III Rotterdam Convention

Amendments to Annex V

At the 27th meeting of the DNAs in April 2016, an amendment to Annex V was discussed, notably the inclusion of hexabromocyclododecane to Part 1 of Annex V to the PIC Regulation. Hexabromocyclododecane was included in Part A of Annex I to Regulation (EC) No 850/2004 (POPs Regulation), following the decision taken under the Stockholm Convention to list this chemical in Part 1 of Annex A to the Stockholm Convention, and should thus be listed in Annex V to the PIC Regulation.

2.2.2. Union import decisions

As per Article 10 of the Convention, Parties are required to adopt an import decision for each new chemical listed in Annex III and to submit it to the Secretariat within nine months of receipt of the notification of the listing and the decision guidance document. Pursuant to Article 13 of the PIC Regulation, the import decision is adopted by means of an implementing act, following the advisory procedure. The Commission drafts the import decision, which is then submitted to the REACH Committee for an opinion, in accordance with the advisory procedure.

During the reporting period, the Commission adopted two Implementing Decisions (see Table 4). In 2014, the Commission drafted import decisions for azinphos-methyl,

commercial pentabromodiphenyl ether, commercial octabromodiphenyl ether, perfluorooctane sulfonic acid, perfluorooctane sulfonates, perfluorooctane sulfonamides and perfluorooctane sulfonyls, which were submitted to the REACH Committee on 7 April and the Commission Implementing Decision was adopted on 15 May. In 2015, the Commission drafted a new import decision for methamidophos and revised the import decisions on DDT and ethylene oxide, which were submitted to the REACH Committee in late 2015. The Implementing Decision was then adopted on 11 February 2016.

Table 4 : Union import responses adopted during the reporting period

Implementing Act	Chemicals	Nature / status of decision		Import decision	Grounds for decision
Commission Implementing Decision of 15 May 2014	Azinphos-methyl	New decision	Final	No consent to import	Banned for use under PPPR
	Commercial pentabromodiphenyl ether	New decision	Final	Consent to import only subject to specified conditions	Banned for use, subject to specific exemptions under POPs Regulation
	Commercial octabromodiphenyl ether	New decision	Final	Consent to import only subject to specified conditions	Banned for use, subject to specific exemptions under POPs Regulation
	Perfluorooctane sulfonic acid, perfluorooctane sulfonates, perfluorooctane sulfonamides and perfluorooctane sulfonyls	New decision	Final	No consent to import	Banned for use, subject to specific exemptions under POPs Regulation
Commission Implementing Decision of 11 February 2016	Methamidophos	New decision	Final	No consent to import	Banned for use under PPPR
	Ethylene oxide	Amending previous decision	Interim	Consent to import only subject to specified conditions	Banned for use under PPPR and restricted under BPR
	DDT	Amending previous decision	Final	No consent to import	Banned for use under POPs Regulation

2.2.3. Guidance to Member States on the legal interpretation of the PIC Regulation

During the reporting period, the Commission, together with the Agency, clarified a number of implementation issues concerning the PIC Regulation, either based on implementation experience or requests from Member States. These were discussed in DNA meetings under implementation issues (see Table 5).

Table 5 : Implementation issues discussed at DNA meetings

DNA meeting	Implementation issues discussed
23rd DNA meeting (April 2014)	Period for application of the waiver for export to OECD countries
	Exports of mercury containing measuring devices
	Revision of explicit consent form to adapt it to the new PIC terminology
24th DNA meeting (December 2014)	Explicit consents for nonylphenol and nonylphenol ethoxylates
	Interpretation and implementation of replies to requests for explicit consent
	Interpretation of acknowledgement of receipt of an export notification as an explicit consent
25th DNA meeting (April 2015)	Use category applied in importing countries
	Interpretation of the second paragraph of Article 14(8)
	Management of requests for explicit consent by India
26th DNA meeting (December 2015)	Waiver on certain chemicals exported to Brazil
	Explicit consent requests received from Serbia
27th DNA meeting (April 2016)	Interpretation of consent covering only the CAS number of paraquat
	Interpretation and implementation of replies to requests for explicit consent
28th DNA meeting (December 2016)	Classification of DDAC when exported
	EU position on language of submitted SDS
	Content of section 6.1 of export notifications

In 2015, the Commission also provided guidance on the implementation of the Regulation by drafting a PIC customs factsheet providing information on the PIC Regulation to customs. Member States were asked to distribute the factsheet to the relevant authorities.

2.2.4. Adoption of a format for reporting on the implementation of PIC

Every three years, Member States and the Agency are required to submit information on the operation of the PIC Regulation's procedures (Article 22(1)). According to Article 22, the Commission was to adopt a common format for reporting through an implementing act. Two implementing acts, one laying down the common format for reporting for Member States (Decision 2016/770) and the other for the Agency (Decision 2016/1115) were adopted, in April and July 2016, respectively, after a long consultation process with Member States and the Agency (see Table 6).

Table 6 : Implementing acts adopted during the reporting period

Decision	Title	Date
Commission Implementing Decision (EU) 2016/770	Common format for the submission of information concerning the operation of the procedures pursuant to Regulation (EU) No 649/2012	April 2016
Commission Implementing Decision (EU) 2016/1115	Format for the submission by the European Chemicals Agency of information concerning the operation of the procedures pursuant to Regulation (EU) No 649/2012	July 2016

2.3. Implementation and enforcement of the PIC Regulation

2.3.1. Emergency situations (Article 8(5)) and waivers (Article 14(7))

According to Article 8(5), when the export of a chemical relates to an emergency situation in which any delay may endanger public health or the environment in the importing Party or another country, the DNA can waive in whole or in part the obligations of the notification procedure (waiting period and/or notification requirements). The DNA's decision must be taken in consultation with the Commission, assisted by the Agency. Few export notifications referred to an emergency situation during the reporting period.

According to Article 14(7), a DNA can decide that an export of chemicals listed in Part 2 or 3 of Annex I can proceed if no response to a request for explicit consent has been received within 60 days, or if no evidence from official sources of final regulatory action (FRA) to ban or severely restrict the use of the chemical has been taken by the importing Party or another country. The DNA must consult the Commission in making this decision.

In both cases, the procedures worked smoothly during the reporting period, and the Commission was positive about its coordination with the DNAs.

2.3.2. Enforcement of the PIC Regulation

The Commission cooperates with the Forum for Exchange of Information on Enforcement with respect to enforcing the PIC Regulation. During the reporting period, the Forum gave a mandate to the Working Group Electronic Information Exchange System (EIES) to analyse the requirements for a system for exchange of information on PIC enforcement. The Working Group recommended using ICSMS, the Commission-owned IT platform for exchange of information between National Enforcement Authorities (NEAs), once it has been adapted to the needs of PIC enforcement authorities. The Commission informed the Member States at the 28th DNA meeting in December 2016 that these changes would be implemented into ICSMS in the first half of 2017.

In 2015, the Commission also drafted a PIC customs factsheet, providing customs authorities in the Member States with appropriate information on the PIC Regulation, in particular the obligations of relevant stakeholders and their enforcement.

3. International work of the Commission

The international work of the Commission covers its participation in Rotterdam Convention activities and all exchanges with the Secretariat of the Convention. The Commission acts as the common designated authority of the EU for the administrative functions of the Convention with reference to the PIC procedure (Article 5(2)). As the EU DNA, the Commission is responsible for:

- Representation of the EU to the Rotterdam Convention.
- Coordination of EU input on all technical issues related to the Convention, the preparation of the CoP, the Chemical Review Committee (CRC), and other subsidiary bodies of the CoP.
- Submission to the Secretariat of relevant FRA notifications concerning chemicals qualifying for PIC notification.
- Transmission of information concerning other FRA involving chemicals not qualifying for PIC notification.
- Submission to the Secretariat of Union import responses for chemicals subject to the PIC procedure.
- Exchange of information with the Secretariat in general.

3.1. Preparation, coordination and submission of EU input to the Secretariat, the COP, the CRC and other subsidiary bodies

Representation of the Union to the Rotterdam Convention and coordination of EU input

- ***7th Conference of the Parties to the Rotterdam Convention***

During the reporting period, the Commission represented the EU at the 7th Conference of the Parties to the Rotterdam Convention, which took place from 4-15 May 2015, back-to-back with the 12th CoP to the Basel Convention and the 7th CoP to the Stockholm Convention.
Before CoP 7, the Commission prepared and consulted with the Member States (as it did for previous CoPs) on the position of the EU on matters discussed at the meeting, which consisted of:

- A proposal for a Council Decision establishing the EU position on amendments to Annex III to the Convention, to get the mandate for decision-making at the CoP. This document was then discussed at the Council Working Party on International Environmental Issues and at the Council Working Party on Environment, and adopted by the Council on 6 March 2015.
- A position paper, discussed with the Member States at the Council Working Party on International Environmental Issues' meetings, presenting the position to be taken on the various items that would be discussed at the CoP. The final version of this position paper was agreed in April 2015.
- A position paper on budget and management issues, covering the Rotterdam, Basel and Stockholm Conventions, as the Programmes of Work and budgets of the three Conventions were addressed in a joint session.
- A position paper on technical assistance and financial issues, also covering the Rotterdam, Basel and Stockholm Conventions.

All position papers were accompanied by a document outlining the statements to be delivered on behalf of the EU or the EU and its Member States in plenary sessions of the COP. Those documents were also drafted by the Commission, in consultation with the Member States.

After CoP 7, the Commission presented the outcomes of the CoP to DNAs at the 26th DNA meeting on 21 October 2015. The Commission also submitted, together with the Presidency, an information note on the outcomes of the CoP to the Rotterdam, Basel and Stockholm Convention, transmitted by the General Secretariat of the Council to the delegations on 10 June 2015. In addition, all of the statements made on behalf of the EU or on behalf of the EU and its Member States during the CoP were published, together with the statements made at the 12th CoP to the Basel Convention and the 7th CoP to the Stockholm Convention, through an information note of the General Secretariat of the Council to delegations on 6 July 2015.

- ***8th Conference of Parties to the Rotterdam Convention***

During the reporting period, the Commission started preparing the proposal for a Council Decision on the amendments of Annex III to the Convention and the position of the EU and its Member States on matters that would be discussed at the next CoP, scheduled to take place from 24 April- 5 May 2017.

Participation in committees and expert groups

Members of the Commission participated as experts in the various Convention bodies, along with experts from Member States:

- The CRC, where a Commission official was nominated by Spain and acted as Chair of the three meetings of the CRC that occurred during the reporting period: the 10th Meeting of the CRC in October 2014, the 11th meeting in October 2015 and the 12th meeting in September 2016.

- The intersessional working group on the process of listing chemicals in Annex III to the Convention, where one official represented the Commission.

The Commission on the CRC meetings and the work of the intersessional working group of the Convention at the subsequent DNA meetings.

3.2. Communication of information to the Secretariat of the Rotterdam Convention

Notification of FRA

As per Article 11 of the PIC Regulation, the Commission must notify the Secretariat of the Rotterdam Convention, in writing, of the chemicals listed in Part 2 of Annex I which qualify for PIC notification. The Commission drafts the notifications, which are submitted to DNAs and observers for comments before being submitted to the Secretariat.

Three notifications were submitted to the Secretariat during the reporting period:

- **Chemicals notified after inclusion in Annex I by Commission Regulation (EC) No 73/2013 (2014)**
  - Naled
- **Chemicals notified after inclusion in Annex I by Commission Delegated Regulation (EU) No 1078/2014 (October 2016)**
  - Bitertanol
- **Chemicals notified after inclusion in Annex I by Commission Delegated Regulation (EU) No 2015/2229 (October 2016)**
  - Fenbutatin oxide

Communication of Union import responses

In line with Article 10 of the Rotterdam Convention and Article 13 of the PIC Regulation, the Commission communicated the formally adopted import decisions to the Secretariat of the Rotterdam Convention. The import decisions were published on the Convention website in December 2014 and June 2017.

Ad-hoc Secretariat requests

The Commission replied to a number of information requests from the Rotterdam Convention Secretariat, e.g. on the definition of pesticides, or information on exports, export notifications and information exchange.

Following the 6th CoP, the Secretariat of the Convention asked that Parties complete questionnaires on the exchange of information on exports between Parties, and whether export notifications are being submitted by exporting Parties and acknowledged by importing Parties. The Commission, as the EU DNA, prepared the answer to the questionnaire on behalf of the EU and its Member States.

3.3. Financial contribution to the Rotterdam Convention

As a Party to the Rotterdam Convention, the EU contributes to the Convention's Trust Fund and Special Voluntary Trust Fund for the implementation of the programme of work for technical assistance (see Table 7).

On its contribution to the Special Voluntary Trust Fund, the Commission works with the Secretariat of the Convention to specify the content of the projects to be carried out in cooperation with the beneficiary Parties. Those projects aim to assist Parties that are developing countries or countries with economies in transition, in order to improve the implementation of the Convention.

Table 7 : Financial contributions from the EU to the Rotterdam Convention's Trust Fund and Special Voluntary Trust Fund (EUR)[46]

Year	EU Contribution to Trust Fund	EU Contribution to Special Voluntary Trust Fund
2014	51,195	277,331
2015	55,474	302,815
2016	54,582	513,603

3.4. Exchange of information (Article 20)

According to Article 20, the Commission, assisted by the Agency and the Member States, must facilitate the provision of scientific, technical, economic and legal information to other countries about chemicals subject to the PIC Regulation, including toxicological, ecotoxicological and safety information.
The Commission provided an answer to two requests in the period 2014-2015[47]:

- One from Peru, asking whether three mixtures were subject to an export notification under the EU PIC Regulation.
- One from Serbia, requesting clarification of provisions on mercury with respect to Regulation 649/2012 and Regulation 1102/2008.

The Commission replied to four requests in 2016 from four countries (Canada, Indonesia, Lebanon and Syrian Arab Republic) concerning four chemicals. In addition, information was sent to Ecuador in response to a request.

[46] From Rotterdam Convention website, amounts converted from USD to EUR at November 2017 rates.

[47] ECHA, *Overview on the exchange of information under Article 20 of the PIC Regulation - Compilation of the information collected by the European Commission, assisted by the Member States and the European Chemicals Agency (ECHA),* 2016, available at: https://echa.europa.eu/documents/10162/21728206/pic_article_20_report_2014-2015_en.pdf/ad0e2b0d-4f12-486f-b1da-9fd2ddbbb187