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

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

{SWD(2018) 438 final}

ABBREVIATIONS USED

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

1. INTRODUCTION

1.1. The PIC Regulation

Regulation (EU) No 649/2012[1] ('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 Union 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 on the characteristics of hazardous chemicals, by providing for a decision-making process within the Union on their import and export and by disseminating decisions to Parties and other countries (Article 1).

The PIC Regulation applies to chemicals subject to the PIC procedure under the Rotterdam Convention and to industrial chemicals (used by professionals and consumers) and pesticides (including biocides) that are banned or severely restricted by Union legislation for health or environmental reasons. 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 (CLP) Regulation (EC) No 1272/2008[2], and to certain articles.

The PIC Regulation also places obligations on the Commission to notify the Secretariat of the Convention of Final Regulatory Action (FRA) that bans or severely restricts the use of a chemical in the Union in a use category of the Convention (industrial chemicals or pesticides). Chemicals for which such notification is required are listed in Part 2 of Annex I of the PIC Regulation. The FRA notification aims at informing other Parties about the potential risks from the use of those chemicals 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 and based on Union law, establishes an import decision that outlines whether and under which conditions the chemical can be imported in the Union. This, too, is 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 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 this PIC Regulation and 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. A reporting format for the Agency's report was similarly adopted through Commission Implementing Decision (EU) 2016/1115 of 7 July 2016 [5].

Member States and the Agency were required to report by 31 May 2017, but 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, upon submission of the final reporting questionnaire.

The present report is the summary of 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.

2. GOVERNANCE OF THE PIC REGULATION

2.1. All Member States have designated their national competent authority

As per Article 4 of the PIC Regulation, Member States must designate one or several authorities (Designated National Authorities, or DNAs) to carry out the administrative functions required by the PIC Regulation. DNAs play an important part in the export notification procedure: checking compliance of export notifications and forwarding them to the Agency); handling requests for explicit consent and deciding on waivers; handling Special Reference Identification Number (RIN) requests; and informing the Commission

[3] Regulation 649/2012 applies 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.

on decisions to ban or severely restrict a chemical at national level. Under Article 10, DNAs also have reporting obligations, such as providing the Agency with information on trade in chemicals listed in Annex I. They are also responsible for providing information to importing countries on request, facilitating the exchange of information on chemicals, and cooperating in the promotion of technical assistance.

Thirty-five such authorities have been designated by Member States. Most Member States (22) have only one DNA, while six have two or three. DNAs are mostly Ministries or agencies responsible for environment, chemicals, and health or health and safety. Member States with more than one DNA generally divide their responsibilities, with one DNA overseeing industrial chemicals, while the other deals with pesticides.

The resources needed to implement the PIC Regulation in Member States, in particular the human resources, 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 export notifications to process and 2 FTE for those Member States with the highest numbers of export notifications.

2.2. The Agency's workload has been higher than expected before the entry into force of the Regulation

The Agency plays a central role in ensuring that the export notification procedure functions properly by:

- Registering the export notifications, checking their completeness and forwarding them to the DNA of the importing country (Article 8(2);
- Sending a second export notification if it does not receive an acknowledgement of receipt from the authority in the non-EU country within 30 days of the first sending (Article 8(3));
- Making export notifications received from third country DNAs available to all EU 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));
- Supporting the EU DNAs and the Commission in assessing waivers pursuant to Article 14(6) and 14(7);
- Collecting, summarising and publishing the data received each year from DNAs on the quantities of chemicals exported and imported (Article 10(3)).

The Agency is responsible for developing and operating the application for processing export notifications and explicit consents given by the importing countries (ePIC). In addition, it provides assistance and technical and scientific guidance to industry, the DNAs from EU Member States and third countries, and the European Commission (Article 6).

As highlighted in the Agency's report, the number of export notifications has increased beyond the predicted 10% yearly uplift, generating additional workload beyond what was expected, as well as increasing the time spent on supporting DNAs (from EU and non-EU countries). Efforts to support EU and non-EU DNAs takes between 30% and 40% of staff time. The increase in export notifications also necessitated improvements to the PIC

application, e.g. increasing the automation of certain processes to reduce the workload for industry users and authorities and thus assist them to meet legal deadlines.

Table 1: No. of notifications predicted vs. processed by the Agency

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

The Agency indicated that the current workload confirms this trend and that undertaking this additional work will require additional human and financial resources.

2.3. The Commission, the Agency and DNAs consider the coordination between EU and national institutions effective

Member States generally considered the coordination between DNAs and the Commission, and between DNAs and the Agency to be satisfactory. Several DNAs valued the support provided by the Commission and the Agency for its swiftness and quality. The Agency rates collaboration with DNAs as similarly effective, including when handling disagreements. The Commission also considered the cooperation with DNAs to be effective, in particular through discussions at the twice-yearly PIC DNA meetings.

The Agency considered the collaboration with the Commission satisfactory, pointing to a number of areas for improvement, such as the preparation of notifications of FRA, the preparation of meetings, the implementation of Article 14(6) and 14(7) and the procedure for updating Annexes. The Commission also considered the cooperation with the Agency to be satisfactory, highlighting the regular exchanges on scientific, technical and legal questions arising in the context of implementation, in particular the legal interpretation of provisions and their practical implementation.

3. UPDATES OF ANNEX I TO THE PIC REGULATION

According to Article 23, the list of chemicals in Annex I should be reviewed at least once a year by the Commission, on the basis of the developments in EU law – mainly in the REACH Regulation[6], the BPR[7] and the PPPR[8] – and under the Convention. Annexes to the PIC Regulation are amended through delegated acts adopted by the Commission.

During the reporting period, 21 substances were included in Part 1 and 10 in Part 2 of Annex I. Twelve of these substances were included following a ban on their use as pesticides under the PPPR, and nine after inclusion in Annex XVII to REACH. Seven were

[6] Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC, OJ L 396, 30.12.2006, pp. 1–854.

[7] Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products, OJ L 167, 27.6.2012, pp. 1–123.

[8] Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC, OJ L 309, 24.11.2009, pp. 1–50.

included in Part 3 Annex I following their inclusion in Annex III to the Rotterdam Convention.

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 1 and 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

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

Table 3: 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	April 2014
Commission Delegated Regulation (EU) No 1078/2014	Bitertanol	October 2016
Commission Delegated Regulation (EU) No 2015/2229	Fenbutatin oxide	October 2016

4. OPERATION OF THE PIC REGULATION

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

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, most DNAs provided support and carried out awareness-raising activities targeting national exporters and importers during the reporting period.

Twenty-five Member States carried out awareness-raising and information activities targeting exporters and importers during the reporting period. Most created specific webpages providing information on the PIC Regulation and references to the Agency webpages on the PIC Regulation and ePIC. Ten Member States also set up a national helpdesk. Almost all Member States stated that these activities improved compliance among exporters and importers with the PIC Regulation. For example, some DNAs noted an increase in the number of export notifications received by the DNA, an increase in the number of companies registered in ePIC, and improved compliance with Article 10 reporting obligations.

During the reporting period, the Agency published its *Guidance for implementation of Regulation (EU) No 649/2012 concerning the export and import of hazardous chemicals*, as well as several user manuals on ePIC (for the different user groups). It provided information to exporters and importers through its website, weekly e-News or the Newsletter, and organised a number of workshops on the PIC Regulation, mainly relating to the initial development of ePIC. According to the Agency, the increase in the number of export notifications sent by EU exporters and the number of companies implementing the PIC Regulation indicates that awareness of, and compliance with, the Regulation has significantly improved during the reporting period, in part due to its own awareness-raising activities and those of the DNAs.

4.2. The workload relating to the implementation of the PIC Regulation is unevenly distributed between Member States

The export notification is the PIC Regulation instrument by which countries exchange information on banned or severely restricted chemicals. All EU based exporters must submit an export notification to their DNAs if they intend to export chemicals listed in Part 1 of Annex I to the PIC Regulation to a third country. Once the DNA has checked and accepted the notification (after resubmission if necessary), it is forwarded to the Agency, which also checks the compliance of the notification and transmits it to the DNA of the importing country. If no acknowledgement of receipt is received, the Agency sends

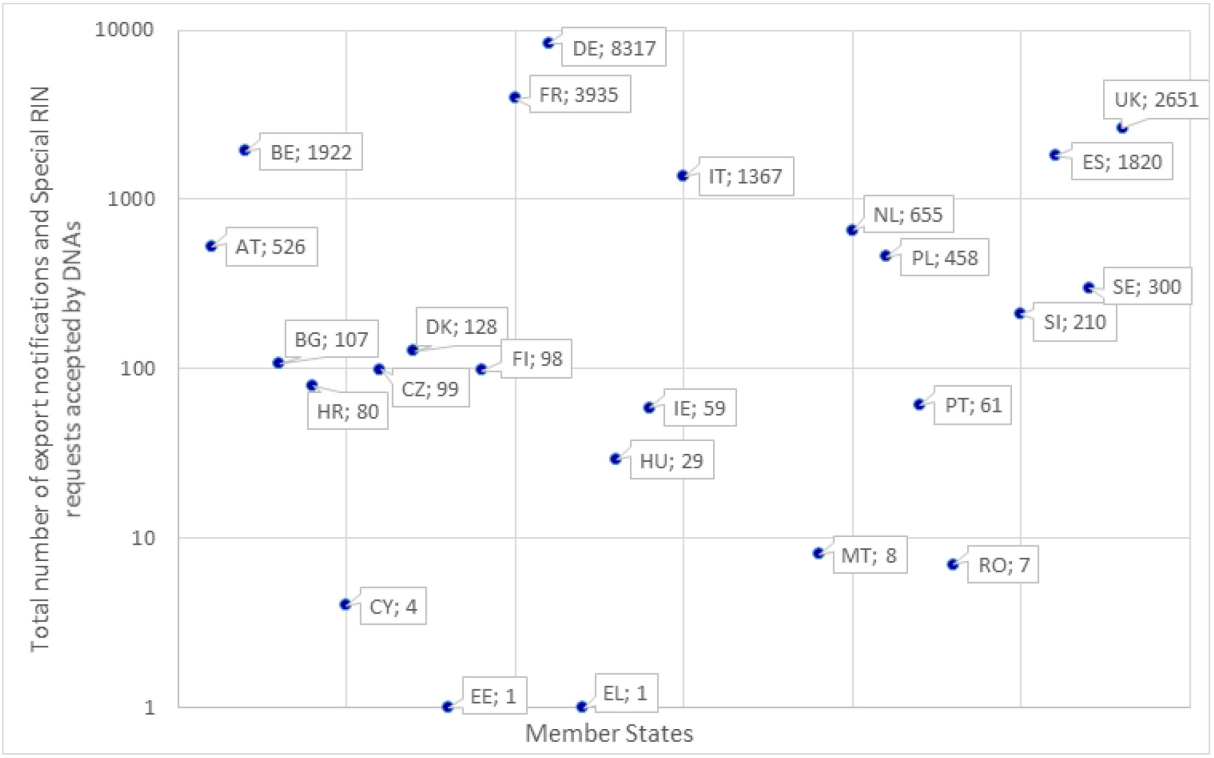
the notification again. The whole procedure is carried out through ePIC, and exporters must use the notification template provided by the system.

During the reporting period, Member States accepted and forwarded 15,771 export notifications to the Agency and rejected 1,214. The number of export notifications processed varied significantly between Member States. Three Member States did not process any export notification during the reporting period and five Member States had fewer than 10 notifications. The highest numbers of export notifications were processed by Germany (5,196 notifications), France (3,358), the United Kingdom (1,829), Italy (1,321) and Spain (1,265). The importing countries that received the highest numbers of export notifications from the Union were Switzerland (1,044 notifications), Turkey (984), Russia (890), the USA (754) and China (601).

For certain exports that are exempt from the PIC Regulation or from the export notification requirement, exporters are required to request a Special RIN from their DNA and to use it in the customs declaration to facilitate customs clearance.

During the reporting period, 17 Member States accepted 7,072 Special RIN requests, which are mainly used for exports that are exempted from the Regulation since they are for research or analysis purposes. Eleven Member States did not deal with any such request in the past three years. Germany, the United Kingdom and Belgium accepted the highest numbers of these Special RIN requests (see Figure 1).

Figure 1 : Total number of export notifications and Special RIN requests accepted by DNAs during the reporting period



4.3. Exporters encountered difficulties in completing the export notification form

According to the Agency and the DNAs, exporters 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. In particular, the intended use and use category for exports of biocides was an issue for exporters. Twelve DNAs also stated that exporters had problems with the availability of the Combined Nomenclature (CN) or Customs Union and Statistics (CUS) codes. The Agency also reported problems with section 6.1 of the form, on the summary of and reasons for the FRA and date of entry into force, as some exporters introduced inappropriate statements. In addition, several DNAs and the Agency all highlighted issues with the provision of the Safety Data Sheet (SDS) in the correct language, exports of mixtures, and entries of chemical groups in ePIC, which are not necessarily comprehensive, and which created confusion among exporters as to whether or not a chemical was subject to the PIC Regulation.

4.4. The number of requests for resubmission was relatively high in the three-year period

In a relatively high number of cases, the DNAs or the Agency requested resubmission of a notification. In 2015-2016, they requested the resubmission of 2,503 export notifications altogether, of which 566 export notification resubmissions were requested by the Agency (334 in 2015 and 232 in 2016). The main reasons for resubmission related to section 6 of the notification form (summary of, and reasons for, the FRA and date of entry into force) and SDS (e.g. language, or SDS not matching the notification).

4.5. No major delays were encountered in the export notification procedure

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. The number of notifications received by the Agency less than 25 days before the export (which is the deadline specified in the Regulation) accounted for 4.9% of the total number of export notifications. In addition, 171 notifications were sent late to the importing countries by the Agency, or 1.2% of the total number of notifications forwarded to importing countries during the reporting period. Reasons for delays typically related to difficulties in processing export notifications during the winter peak season, companies failing to respect deadlines for resubmissions, and, on the Agency's side, delays in receiving notifications from the DNAs.

4.6. The number of export notifications received from non-EU countries almost doubled between 2014 and 2016

As per Article 9, the Agency must make export notifications received from third countries available on its database, 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 received 1,105 export notifications from non-EU countries in the reporting period, mainly from the USA and Switzerland. The number of notifications almost doubled between 2014 and 2016.

Table 4: Export notifications received from non-EU countries and acknowledgements of receipt sent by the Agency during the reporting period

	2014	2015	2016	Total
Export notifications received	209	486	410	1,105

4.7. Reporting under Article 10 worked effectively

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

Information provided by the Agency and DNAs suggested that few problems were encountered in the reporting process under Article 10. Around one-third of the DNAs stated that they experienced delays from exporters or importers in the submission of information, although these delays did not affect the completion of the reporting exercise under Article 10. Similarly, the Agency encountered few complications in the compilation of Member State information, where DNAs included data on exports of chemicals listed in Annex I that were exported for research or analysis purposes and were therefore outside the scope of the PIC Regulation and the resulting reporting obligation.

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, six further specified that it is used for REACH enforcement activities (e.g. cross-checking compliance with registration requirements, or checking compliance with restrictions).

4.8. EU import decisions have been adopted for seven substances listed in Annex III to the Rotterdam Convention

As per Article 10 of the Convention, Parties are requested to adopt an import decision for each new chemical listed in Annex III and to submit it to the Secretariat. Pursuant to Article 13 of the PIC Regulation, the Union import decision is adopted by means of an implementing act, which is drafted by the Commission and submitted to the REACH Committee for an opinion, in accordance with the advisory procedure.

Import decisions were established through two implementing decisions adopted by the Commission in the course of the reporting period.

Table 5: Union import decisions 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 pentabromo-diphenyl ether	New decision	Final	Consent to import only subject to specified conditions	Banned for use, subject to specific exemptions under POPs Regulation
	Commercial	New	Final	Consent to	Banned for use,

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

Implementing Act	Chemicals	Nature / status of decision		Import decision	Grounds for decision
	octabromo-diphenyl ether	decision		import only subject to specified conditions	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

4.9. Several third country DNAs experienced difficulties in handling explicit consent requests

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

During the reporting period, 19 Member States implemented the explicit consent procedure pursuant to Article 14. They stated that the main challenge was the difficulty experienced by several importing countries in handling explicit consent requests, either because the DNAs responded after the 60-day waiting period or did not respond at all. Of the 3,362 requests for explicit consent processed by DNAs, 56% received an answer. The share decreased over the reporting period (61% in 2014, 58% in 2015 and 51% in 2016), while the number increased. This explains 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.

Few Member States had to decide whether or not the requirement for explicit consent should be waived (e.g. six for an export to an OECD country and 11 in the absence of a response from the competent authority of the importing country), and information provided by DNAs suggested that few implementation problems occurred. Although the Agency stated that it was initially challenging to interpret the cases to which the Article 14(8) provisions applied, the number of problem cases has been reduced to a very low level.

4.10. Non-compliance with requirements on information to accompany exported chemicals was primarily linked to packaging and SDS

Article 17 states that exported chemicals must be packaged and labelled in accordance with the respective Union provisions, unless the importing country requires otherwise. An SDS compliant with Annex II of the REACH Regulation must be sent to each importer together with the chemical.

National Enforcement Authorities (NEAs) in eight Member States experienced compliance issues in respect of the information accompanying exported chemicals. Six Member States indicated that those compliance issues related to packaging requirements under the CLP Regulation, while a further six indicated that they had found compliance issues with the application of SDS requirements under the REACH Regulation.

4.11. All Member States have put in place a system for controlling the export and import of chemicals subject to the PIC Regulation

According to Article 18 of the PIC Regulation, Member States must designate authorities, such as customs authorities, to control imports and exports of chemicals listed in Annex I. All Member States have nominated these authorities. Customs are involved in the implementation of the PIC Regulation in all Member States, except Malta and the United Kingdom. In four countries, the only national enforcement authority (NEA) is the customs administration (Spain, Croatia, Italy and Slovakia). Other enforcement authorities are typically environmental, chemicals and/or health inspection services. In nine Member States, the NEA is part of the same institution as the DNA.

In almost all Member States, NEAs involved in the enforcement of the PIC Regulation are also involved in the enforcement of other chemicals legislation, such as the CLP Regulation (27 Member States), the REACH Regulation (25 Member States), and the BPR (22 Member States).

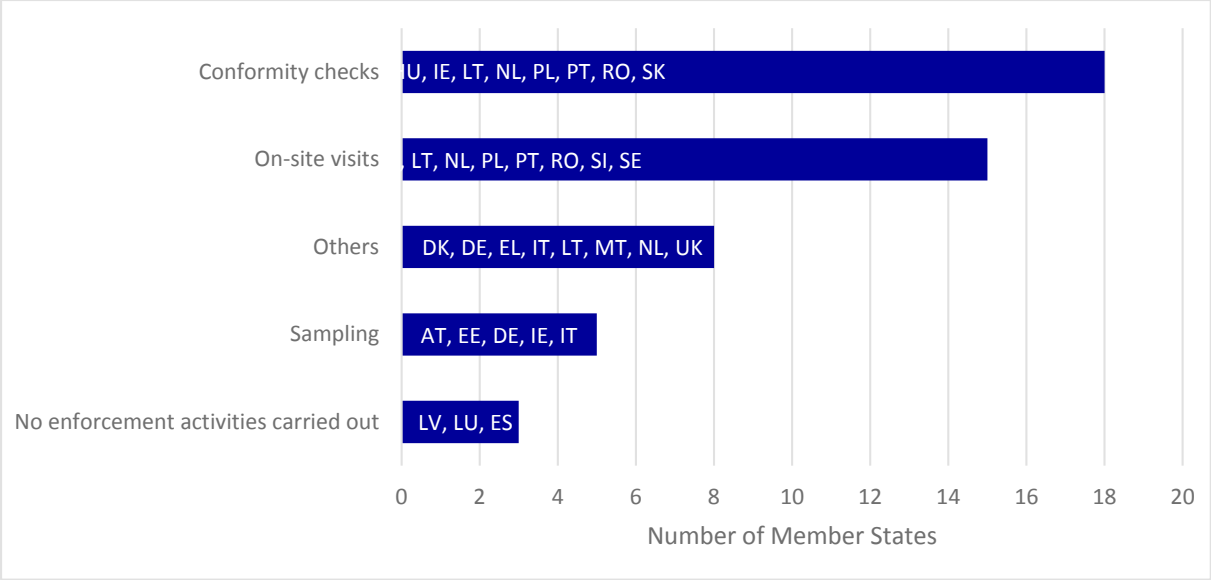
The majority of Member States (18) indicated that NEAs have sufficient resources to carry out their obligations under the PIC Regulation. Member States who highlighted resource issues within NEAs typically referred to the lack of human resources.

16 Member States have put in place some kind of enforcement strategy (including rules of procedures, written instructions, etc.) and 15 Member States have established regular training for inspectors. Most Member States have also described their applicable penalty system for infringements of the PIC Regulation. 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 mentioned 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 on the gravity of the infringement. In seven Member States, a penalty of imprisonment can be imposed for the most serious infringements.

4.12. Almost all Member States have carried out enforcement activities and identified a high level of conformity

During the reporting period, 18 Member States carried out conformity checks, while 15 carried out on-site visits in which the PIC Regulation was covered.

Figure 2 : Enforcement activities carried out by Member States



According to the data provided by DNAs, customs and other NEAs have carried out controls on exports of chemicals in 17 Member States, and on imports of chemicals subject to the PIC Regulation in 11 Member States[10]. The number of controls performed varied greatly between Member States, which could be due to the number of exports and imports of PIC chemicals in the country, the inspection strategy, or the types of controls performed (e.g. reactive controls versus regular monitoring). Three Member States reported infringements found through customs controls, with a very low number of infringement cases. Nine Member States reported cases found through controls carried out by inspectors, and the level of infringement varied considerably across these Member States. In some cases, this might be linked to the type of controls performed (e.g. reactive controls are more likely to find infringements). Thirteen infringement cases led to penalties in four Member States.

Table 6: Number of controls performed and infringements observed by customs and inspectors during the reporting period[11]

Member State	Controls on exports and	Infringements found by customs	Controls on exports and imports by	Infringements found by inspectors

[10] One DNA did not provide any information on exports, six DNAs did not provide information on customs controls on exports. Five DNAs did not provide any information on imports; eight DNAs did not provide information on customs controls on imports. Caution should be exercised in comparing data between Member States as there might be discrepancies in their recording parameters for enforcement activities.

[11] The table only includes those Member States where infringements were found.

	imports by customs		inspectors	
Austria	561	0	16	8
Belgium	N/A	N/A	29	10
Bulgaria	463	0	40	7
Finland	3633	N/A	1	1
France	123	3	N/A	N/A
Germany	1[12]	1	49	21
Hungary	35	0	93	2
Italy	1205	9	N/A	N/A
Lithuania	0	0	2	1
Netherlands	275	0	661	2
United Kingdom	0	0	1	1

The main category of infringement found through inspections was non-conformity of the chemical with the export notification. Infringements related to SDS and labelling requirements were also found.

Coordination of enforcement activities happens through the Forum for Exchange of Information, with both the Agency and the DNAs reporting positive feedback on Forum activities. Some DNAs welcomed the launch of a pilot project dedicated to enforcement of the PIC Regulation.

4.13. The first report pursuant to Article 20 was published

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. The Agency must therefore compile a report on all transmitted information every two years.

The Agency published the first compilation of information transmitted to third countries in November 2016[13], covering the first two years of implementation of the PIC Regulation (2014-2015). The Agency did not experience difficulties in collecting the transmitted information from the Commission and the Member States. The only challenge was to define the scope of the report with the Commission and Member States, as it was the first of its kind. The Commission received and responded to two requests for information in 2014-2015 and four requests in 2016.

4.14. Several DNAs and the Agency have participated in technical assistance activities

According to Article 21, the Commission, DNAs and the Agency must cooperate in

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

[13] 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/regulations/prior-informed-consent-regulation/reporting-on-information-exchange

promoting technical assistance, in particular to help developing countries and countries with economies in transition to implement the Convention and develop the infrastructure, capacity and expertise needed to manage chemicals properly throughout their lifecycles.

Five Member States participated in cooperation activities and six in projects or international activities related to capacity-building in chemicals management. DNA activities consisted of the provision of technical expertise or technical information through training workshops, visits, twinning projects, etc. The Agency organised or participated in several capacity-building activities, either assisting EU candidate countries or explaining the specific provisions of the PIC Regulation and the differences with the provisions of the Convention to authorities in non-EU countries.

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

As requested by Regulation (EU) No 649/2012, the Agency developed and continues to maintain the IT tool (ePIC) to support the implementation of the PIC Regulation. ePIC was launched in September 2014, shortly after the entry into force of the Regulation, and replaced the previous EDEXIM database. The Commission, DNAs, enforcement authorities, the Agency, exporters and importers, and customs officers all have access to ePIC.

Overall, DNAs found ePIC to be user-friendly and did not experience major issues in its use. Feedback from industry users to the Agency and DNAs was also generally positive, as was the feedback from customs and enforcement authorities.

4.16. Relevant information and data have been made publicly available

The PIC Regulation contains a number of requests to make information and data available to the public, and these have been duly implemented by the Agency.

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[14];
- Article 10 reports on actual quantities of PIC chemicals exported and imported[15];
- Article 20 reports on information exchange[16].

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

- The list of chemicals subject to PIC[17];
- High-level information and statistics on export notifications[18];

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

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

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

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

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

- High-level information and statistics on import notifications[19];
- Non-confidential data on explicit consents received from non-EU countries[20];
- EU and non-EU DNA contact details[21].

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

5. CONCLUSIONS

Regulation (EU) No 649/2012 implements the Rotterdam Convention in the EU and has the same objectives, i.e. to promote shared responsibility and cooperation in the international movement of hazardous chemicals, and to protect human health and the environment from potential harm by facilitating the exchange of information on hazardous chemicals and their trade. Regulation (EU) No 649/2012 goes beyond the requirements of the Convention in order to offer a higher level of protection, in particular to developing countries and countries with economies in transition.

This report demonstrates that the procedures established by Regulation (EU) No 649/2012 operated well and contributed to achieving its objectives. Good cooperation between all stakeholders formed the basis for successful implementation. The export notification procedure functioned well and provided the importing countries with important information on many chemicals and their export. With almost 8,000 export notifications in 2016 and its continuing upward trend, the scale of the information exchange and its potential to increase further is clearly visible. The related workload can only be handled with reasonable staff resources, given the need to maintain the capacity for processing and support while ensuring the performance of the IT application 'ePIC', developed and maintained by the Agency.

The explicit consent procedure, which goes beyond the Convention as a standard procedure for the export of certain chemicals, has led to the high number of 3,362 requests for explicit consent sent to importing countries in the reporting period. Experience suggested that those requests presented a challenge for many importing countries, largely because the procedure is rarely used under the Convention and many Parties may not be aware of its existence. This may have resulted in a high number of exports not being allowed to proceed due to unanswered requests for consent. The possibility to apply for a waiver under certain conditions ensured that the number of exports blocked for this reason was kept to a minimum.

The exporters of chemicals subject to the Regulation were generally aware of their obligations and able to meet them. Where problems arose, the DNAs and the Agency provided the necessary assistance, and this may have contributed to the low number of infringements. The main category of infringement found through inspections was non-conformity of the chemical with the export notification. Infringements related to SDS and labelling requirements were also identified.

In general, the Member States met their obligations, although the high workload at the end of each year - caused by the large number of export notifications – presented a

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

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

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

challenge for some Member States and sometimes led to problems with timeframes. The contribution of the Agency to implementation was fully in line with the requirements of the Regulation, and its solid performance was the basis for effective functioning of the relevant procedures. The Commission completed its obligations under the Regulation. Two Commission Delegated Regulations amending Annex I, as well as two Commission Implementing Decisions adopting Union import decisions, were adopted in the reporting period. In addition, the Commission coordinated the contribution of the Union to the international work and represented the Union to the Convention.