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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 for the period 2020-2022

{SWD(2025) 278 final}

Abbreviations used

Agency	European Chemicals Agency (ECHA)
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 implementing Regulation (EU) No 649/2012
EU	European Union
FRA	Final Regulatory Action
IT	Information technology
NEA	National Enforcement Authority
OECD	Organisation for Economic Cooperation and Development
OJ	Official Journal of the European Union
PIC	Prior Informed Consent
POP	Persistent Organic Pollutant
PPPR	Plant Protection Products Regulation
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation
RIN	Reference Identification Number
SDS	Safety Data Sheet

1 INTRODUCTION

1.1 The PIC Regulation

Regulation (EU) No 649/2012 [1] ('the PIC Regulation') implements the Rotterdam Convention on the Prior Informed Consent (PIC) Procedure for Certain Hazardous Chemicals and Pesticides in International Trade. The Regulation aims to promote shared responsibility and cooperation in the international movement of hazardous chemicals, and to protect human health and the environment from potential harm by facilitating the exchange of information on the characteristics of hazardous chemicals, 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.

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

Under the PIC Regulation, exports are subject to different requirements depending on their listing in Annex I: chemicals listed in Part 1 of Annex I are subject to export notification to the importing country, whereas chemicals listed in Parts 2 and 3 of Annex I are subject to export notification and explicit consent of the importing country unless they are subject to the PIC procedure under the Convention and exported to a Party that has provided a positive import response. These obligations also apply to mixtures containing substances listed in Annex I to the Regulation in concentrations that trigger labelling obligations under the Classification, Labelling and Packaging (CLP) Regulation (EC) No 1272/2008 [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 of chemicals that are banned or severely restricted in one use category of the Convention (industrial chemicals or pesticides) and are listed in Part 2 of Annex I to the PIC Regulation. This process is known as 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 corresponds to Annex III to the Convention), the Commission, on behalf of the EU and based on the empowerment in the PIC Regulation, draws up an import decision outlining whether and under which conditions the chemical can be imported to the EU. This is sent to the Secretariat of the Convention.

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 that includes the following:

- information submitted by Member States under Article 22(1) on the operation of the procedures provided for in the Regulation, including for customs controls, infringements, penalties and remedial action;

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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. https://eur-lex.europa.eu/eli/reg/2012/649/oj.

[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. https://eur-lex.europa.eu/eli/reg/2008/1272/oj.

- information submitted by the Agency under Article 22(1) on the operation of the Regulation's procedures.

This third reporting exercise covers the period 2020-2022. The online reporting questionnaire was made available to Member States on 28 March 2024 with a deadline for completion of 10 May 2024. All reports were submitted by 28 June 2024. The Agency published its 2020-2022 report on the operation of the procedures of the PIC Regulation [3] in October 2023.

The present report is the summary of the synthesis report that provides an overview of the implementation of the PIC Regulation in the period 2020-2022.

2 GOVERNANCE OF THE PIC REGULATION

2.1 The Commission, the Agency and DNAs consider that the coordination of their activities to implement the PIC Regulation continues to be effective.

At national level, each Member State designates a DNA to carry out the administrative functions provided for by the PIC Regulation. As in the previous reporting period, Member States considered that coordination between DNAs and the Commission, and between DNAs and the Agency, had been satisfactory.

The Commission considered that cooperation with DNAs and the Agency had been satisfactory, as concerns both regular exchanges during the reporting period and discussions at the twice-yearly PIC DNA meetings.

The Agency reported that they had continued to work well with the DNAs, that coordination with the Commission had generally been satisfactory, and that the predictability and planning of work had improved.

2.2 A scarcity of resources jeopardises effective implementation and impedes improvement and enforcement activities.

Resources dedicated to the Commission's and ECHA's implementation of the PIC Regulation remained at a similar level as in the previous reporting period.

The number of export notifications processed by the Agency decreased over the period. However, the overall processing-related workload of the Agency's PIC team remained high due to an increase in other processing and related tasks, including a notable increase in the number of requests for technical / regulatory support.

Due to the high and growing number of submissions, the Agency continued to invest human and financial resources in maintaining and improving the ePIC application, as often requested by DNAs, and in the Agency's processes and ways of working to implement the Regulation.

PIC DNAs reported resource levels dedicated to implementing the PIC Regulation ranging from 0.05 to 3.25 FTEs. The number of Member States reporting that their national enforcement authorities have sufficient resources to fulfil their obligations under the Regulation fell to 12, from 15 in the previous and 18 in the first reporting period. Similarly, 10 Member States, compared to 8 in the previous and 7 in the first reporting period, stated that they do not have sufficient resources.

[3] ECHA (2023) Report on the operation of the Prior Informed Consent (PIC) Regulation. ECHA-23-R-11-EN, https://echa.europa.eu/documents/10162/18272234/report_pic_art_22_2023_en.pdf.

3 UPDATING ANNEXES I AND V TO THE PIC REGULATION

3.1 Updates to Annex I

Article 23 requires the Commission to review the list of chemicals in Annex I at least once a year on the basis of the developments in EU law – mainly the REACH Regulation [4], the BPR [5] and the PPPR [6] – and under the Convention. Annexes to the PIC Regulation are amended through delegated acts adopted by the Commission.

During the reporting period, 48 substances were added to Annex I, 44 of which were included in Parts 1 and 2 of Annex I. Of these, 35 substances were included because they had been banned under the PPPR, 1 due to its non-approval for use in biocidal products under the BPR, 6 due to restriction under REACH (3 for public use, 3 for professional use), and 2 due to restriction under the POPs Regulation. 4 substances were added to Part 3 of Annex I following their inclusion in Annex III to the Convention. In addition, the EU's Combined Nomenclature codes, listed in Annex I to the PIC Regulation, have been updated.

Under Article 11 of the Regulation, the Commission must notify the Secretariat of the Convention in writing of chemicals listed in Part 2 of Annex I that qualify for PIC notification. During the reporting period, 31 FRA notifications were submitted to the Secretariat.

3.2 Updates to Annex V

Amendments to Part 1 of Annex V to the PIC Regulation (chemicals subject to an export ban) are triggered by the inclusion of a substance in Annex I to the POPs Regulation [7]. During the reporting period, five substances were added to Part 1 of Annex V.

Part 2 of Annex V to the PIC Regulation lists chemicals other than POPs subject to an export ban. During the reporting period, certain mixtures containing mercury or mercury compounds and certain mercury-added products were added to Part 2.

4 APPLICATION OF THE PIC REGULATION

4.1 Awareness-raising and support to exporters and importers by DNAs and the Agency have continued to improve, boosting compliance.

24 Member States reported having carried out awareness-raising and information measures, in particular providing information online. Almost all the Member States that carried out such measures considered that this had led to better compliance by exporters and importers.

The Agency continued to provide information and support to exporters and importers through its website, weekly e-News, newsletter, social media, internal messaging in ePIC and the helpdesk. It also improved the usability of the ePIC pages [8].

Other Agency activities included awareness-raising campaigns for exporters, running various outreach events and publishing guidance on the UK's withdrawal from the EU and on the

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[4] Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), http://data.europa.eu/eli/reg/2006/1907/oj.

[5] Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products, http://data.europa.eu/eli/reg/2012/528/oj.

[6] Regulation (EC) No 1107/2009 concerning the placing of plant protection products on the market, http://data.europa.eu/eli/reg/2009/1107/oj.

[7] Regulation (EU) 2019/1021 on persistent organic pollutants, OJ L 169, 25.6.2019, p. 45-77, http://data.europa.eu/eli/reg/2019/1021/oj.

[8] https://echa.europa.eu/support/dossier-submission-tools/epic.

Northern Ireland Protocol to inform companies of their obligations under the PIC Regulation after Brexit [9].

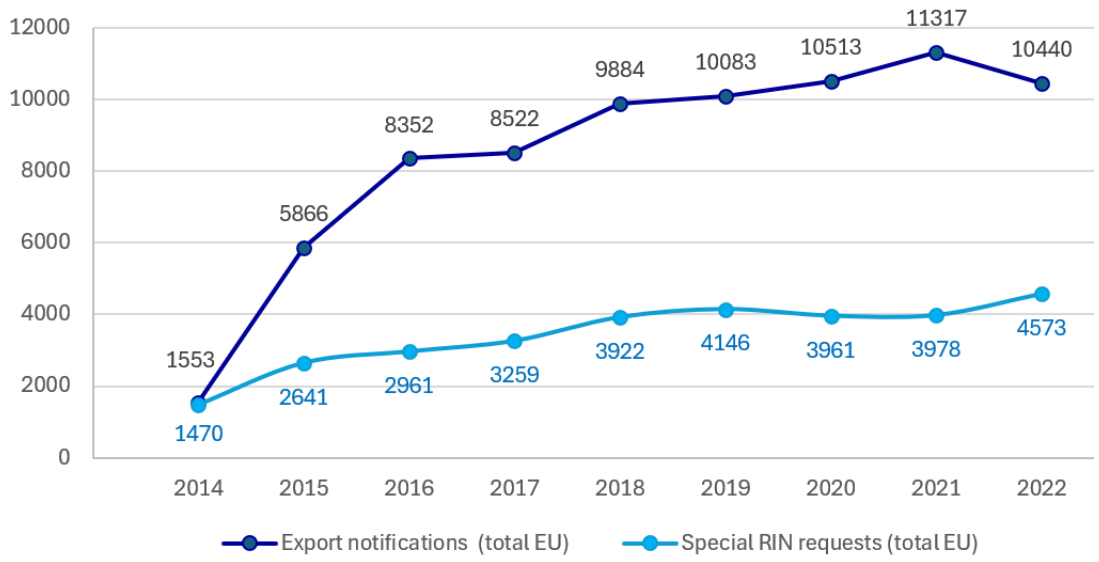
4.2 The increase in the number of export notifications handled by DNAs and ECHA has levelled off, and the number of notifications processed by Member States continues to vary significantly.

Export notifications are the tool by which countries exchange information on banned or severely restricted chemicals. EU-based exporters intending to export a chemical listed in Part 1 of Annex I to the Regulation must submit an export notification to their DNA. Once the DNA has checked and accepted the notification, it is forwarded to the Agency, which verifies it and sends 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 through ePIC, and exporters must use the notification template provided. For certain exports that are exempt from the Regulation or from the export notification requirement, exporters must request a special RIN from their DNA and use it in the customs declaration to facilitate customs clearance.

The number of export notifications and special RIN requests increased steadily from 2014 to 2019 but showed signs of levelling off during the current reporting period (Figure 1).

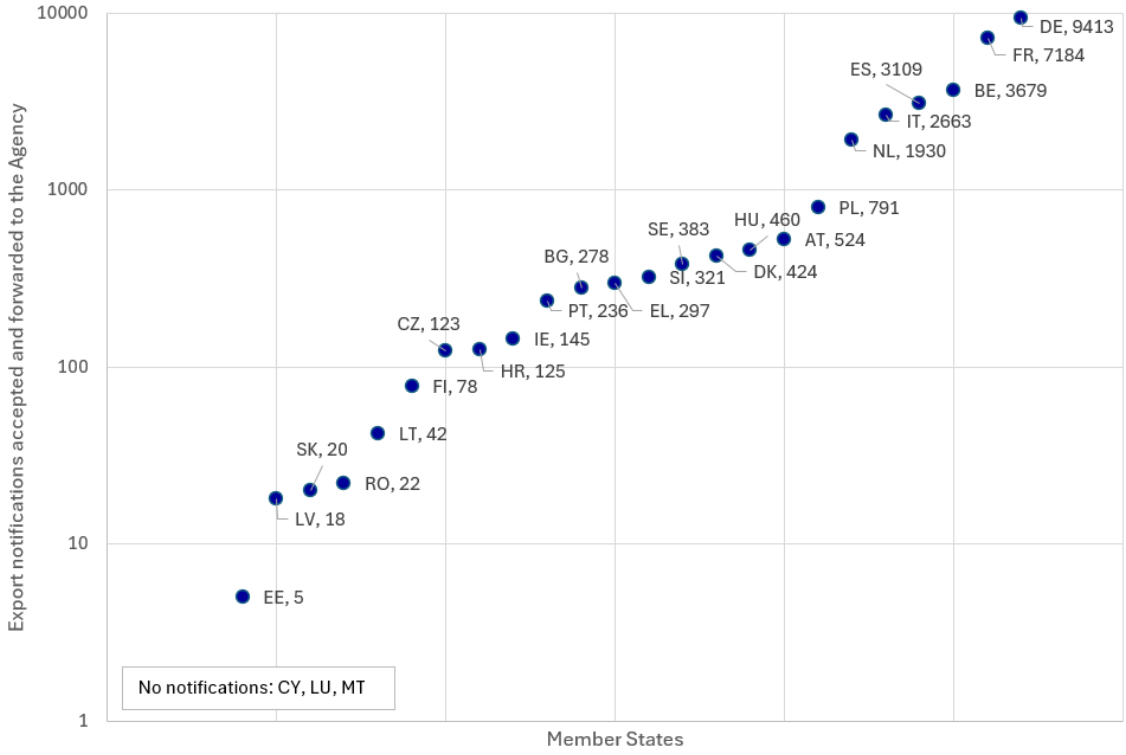
Figure 1. Total number of a) export notifications accepted and forwarded to the Agency by DNAs, and b) special RIN requests accepted by DNAs per year



As in the past, the number of export notifications processed varied significantly between Member States (Figure 2).

[9] https://echa.europa.eu/advice-to-companies-q-as/pic (Brexit), and https://echa.europa.eu/advice-to-companies-q-as/northern-ireland.

Figure 2. Total number of export notifications accepted and forwarded to the Agency by DNAs during the reporting period



21 Member States processed more export notifications during this reporting period than in the previous one. The number of notifications processed increased the most in Belgium (+ 1 660), followed by the Netherlands (+ 901), Germany (+ 768) and Spain (+ 726).

The number of special RIN requests processed by Member States varied widely. Germany, Belgium and France continued to accept the highest number of requests.

4.3 The number of export notification forms that need to be resubmitted due to incorrect filling has fallen but remains high.

During the reporting period, Member States requested the resubmission of 3 010 export notifications, compared to 5 889 in the previous period and 2 904 in the period before that. The main reasons were failure to meet information requirements and issues with the SDS attached to the export notification.

The Agency requested the resubmission of 1 760 export notifications over the reporting period, down from 2 758 in the previous one. The trend is similar for resubmissions requested by DNAs.

Member States rejected 738 export notifications during the reporting period, up from 544 in the previous one. DNAs report that the main difficulties encountered by exporters were the availability of CN or CUS codes and information directly linked to the exports (such as the contact details of the importer), where there had been little or no improvement, and the intended use of the chemical in the importing country, where there had been significant improvement.

There had also been considerable improvement in reported difficulties linked to the summary of and reasons for the final regulatory action, the date of entry into force and information on the final regulatory action taken by the EU.

4.4 The number of export notifications from non-EU countries has increased.

Article 9 requires the Agency to enter export notifications it receives from non-EU countries in 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 1 863 notifications from non-EU countries in the current reporting period, up from 1 371 in the previous period. After a drop in 2020, the number of notifications more than doubled by 2022.

4.5 Reporting by DNAs on the export and import of chemicals has become more effective but could still be improved.

Article 10 requires exporters and importers of chemicals listed in Annex I to the Regulation to inform the DNA of the quantities they exported to or imported from non-EU 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 annually to the Agency, which aggregates the data at EU level and makes it publicly available [10].

Information provided by the Agency and DNAs suggests the reporting process under Article 10 worked smoothly. 7 Member States reported late submission of information by exporters and 9 (compared to 5 in the previous reporting period) by importers. There were more mistakes in reported quantities, also because the Agency has improved the reporting functionality in ePIC by including warnings of potentially erroneous quantities. It has also prepared a checklist for DNAs to help them verify industry reports and draw up aggregated national reports on the quantity of exported and imported chemicals. However, unlike in the previous two reporting periods, the Agency noted a delay in the submission of reports from some DNAs.

4.6 The EU has adopted import decisions for five substances listed in Annex III to the Rotterdam Convention.

Under Article 10 of the Convention, the Parties are required to adopt an import decision for each new chemical listed in Annex III and to submit it to the Secretariat. Under Article 13 of the PIC Regulation, EU import decisions are adopted by means of a Commission implementing act submitted to the REACH Committee for an opinion in accordance with the advisory procedure.

During the reporting period the Commission adopted one implementing decision, which provided new import decisions for two substances, and amended decisions on three other substances.

4.7 Non-EU countries' response rate to explicit consent requests remains low but is rising, and improved systems and good coordination between the Agency and DNAs has had a positive effect.

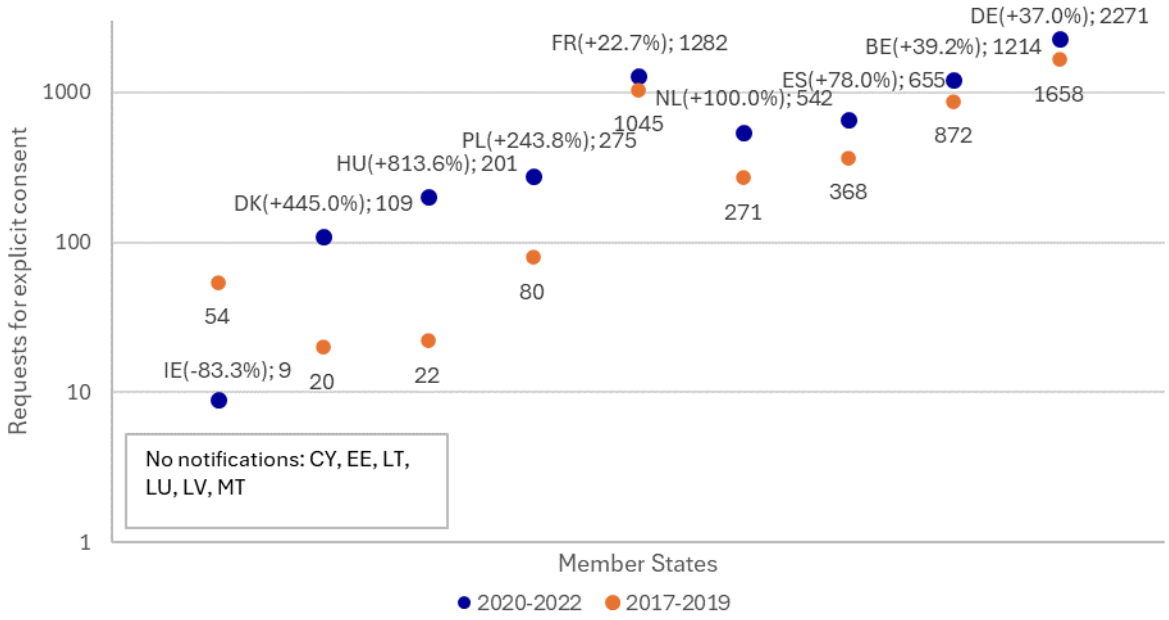
Article 14 requires the explicit consent of the importing country before chemicals listed in Parts 2 or 3 of Annex I can be exported. However, the DNA of the exporter can decide, on a case-by-case basis and in consultation with the Commission, to waive this requirement when a chemical listed in Part 2 is exported to an OECD country or when the importing country has not replied within 60 days, provided that certain conditions are met.

During the current reporting period, 19 Member States handled explicit consent requests, processing a total of 7 233 requests, up from 5 058 in the previous period and 3 362 in the

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

period before that. The number of requests processed was higher than in the previous period in 13 Member States (Figure 3).

Figure 3. Number of requests for explicit consent processed by Member States during the current period compared to the previous period for those experiencing the greatest change (% change shown in brackets).



10 Member States reported difficulties in implementing the explicit consent procedure, 3 more than in the previous reporting period. Communication with the importing countries' DNAs continued to be the main challenge. Of the 7 233 requests for explicit consent, 58% received a response, slightly more than the 54% of the previous period.

As in the past, the Agency considered this process to be working smoothly and collaboration to be effective. According to feedback from DNAs, determining the validity period and some specific restrictions (i.e. RIN specificity, exporter specificity) are the most difficult issues faced when interpreting responses.

11 Member States, compared to 8 in the previous period and 6 in the period before that, had to decide whether explicit consent was required for exporting chemicals listed in Part 2 of Annex I to OECD countries. No Member States reported difficulties in taking this decision.

15 Member States, up from 13 in the previous period and 11 in the period before that, received waiver requests under Article 14(7). The number of waiver requests increased from 571 in the previous period to 1 328 in the current period. Only 1 Member State reported difficulties in implementing the waiver procedure.

The Commission considered the waiver procedure to work smoothly in general and assessed collaboration with the DNAs as positive. The Agency also considered the process to be working smoothly overall and certain inefficiencies reported in previous periods to have been addressed.

10 Member States reported cases where exports were allowed to go ahead pending the reply to a request for explicit consent under Article 14(8). The total number of cases was 181 compared with 569 in the previous reporting period. The Agency reported no difficulties, a marked improvement from the previous period. This was mainly due to improvements in the ePIC functionality.

4.8 There were fewer instances of non-compliance with information requirements for exported chemicals.

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

Only 3 Member States reported compliance issues, compared to 6 in the previous period, concerning the information that must accompany exported chemicals.

4.9 All Member States have control and enforcement systems, but fewer Member States report having an enforcement strategy.

All Member States have designated authorities with responsibility for enforcing the Regulation with respect to controlling the import and export of chemicals listed in Annex I in accordance with Article 18. In all Member States except one this involves customs, and in most Member States the environmental/health inspectorate is also involved.

12 Member States have an enforcement strategy, down from 16 in the previous period. In some Member States this was because enforcement was already in place and no further development was needed. 12 Member States provide regular training for inspectors and some include the PIC Regulation as an occasional topic in general training on chemicals legislation. Overall, regular training has declined and for the first time, a few Member States indicated that no training was carried out due to lack of resources or financial constraints.

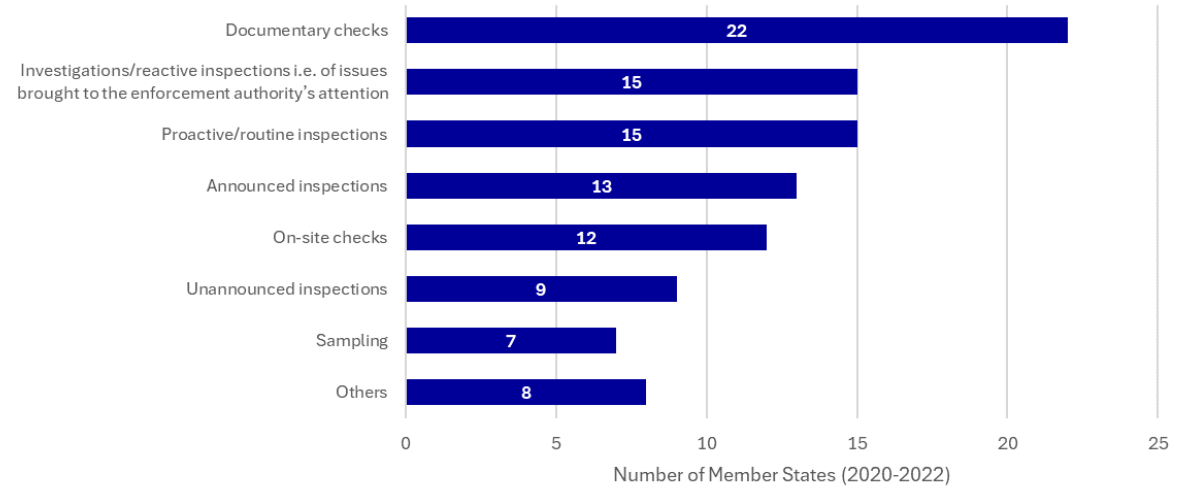
17 Member States reported having carried out controls on exports and 12 on imports during the period. As in the past, few infringements were detected. DNA feedback on the Forum activities was mostly positive.

The number of Member States indicating that enforcement authorities have sufficient resources to fulfil their obligations under the Regulation fell from 15 in the previous period to 12 in the current period. 10 Member States, compared to 8 in the previous period, stated they did not have sufficient financial and/or human resources.

4.10 While enforcement activities have increased in some Member States, fewer infringements lead to penalties.

The types of enforcement activity carried out were largely the same as in the previous period (Figure 4). However, documentary checks were performed by 4 more Member States (80%) and proactive/routine inspections by 3 more Member States. More than half conducted investigations or reactive or proactive inspections, and just under half reported carrying out inspections or on-site checks.

Figure 4. Enforcement activities carried out in the Member States



During the reporting period, a total of 93 691 controls were performed on exports, up from 9 132 in the previous period and 6 474 in the period before that. This significant increase is mostly due to desktop inspections conducted by Bulgaria (40 425) and unspecified controls by Spain (42 168) (Table 1). With respect to imports, 60 421 controls were carried out, up from 1 463 in the previous period and 1 941 in the period before that. This large increase is mostly due to controls by Spain (58 177). Customs controls continue to account for the majority of controls.

Table 1. Total number of official controls on exports and imports involving checks under the PIC Regulation during the reporting period (previous period in brackets)

	Controls performed by customs	Controls performed by inspectors	Controls performed by other entities
Official controls on exports	93 308 (8 599)	383 (526)	0 (7)
Official controls on imports	59 299 (237)	1 082 (1 193)	40 (33)

7 Member States, compared to 5 in the previous and 3 in the first reporting period, reported that they had identified infringements through customs controls, but the ratio of infringements was very low (around 0.3%) [11]. As in the previous reporting period, 6 Member States (compared to 9 in the first reporting period) found infringements through controls carried out by inspectors. The ratio of infringements is higher than for customs controls (around 5.4% [12]).

The main category of infringement found by customs related to Box 44 of the single administrative document not being properly filled in (60 infringements) and absence of a RIN (46 infringements). The main category of infringements found by inspectors concerned Safety Data Sheet provisions (35 infringements) and absence of an export notification for the chemical (20 infringements).

13 infringements in 3 Member States led to penalties during this reporting period, compared to 29 infringements in 3 Member States in the previous period and 13 infringements in 4 Member States in the first period.

[11] Due to possible overlaps between controls performed on exports and on imports, this is only an indicative figure for comparison.

4.11 Technical assistance by the Agency continued to be welcomed.

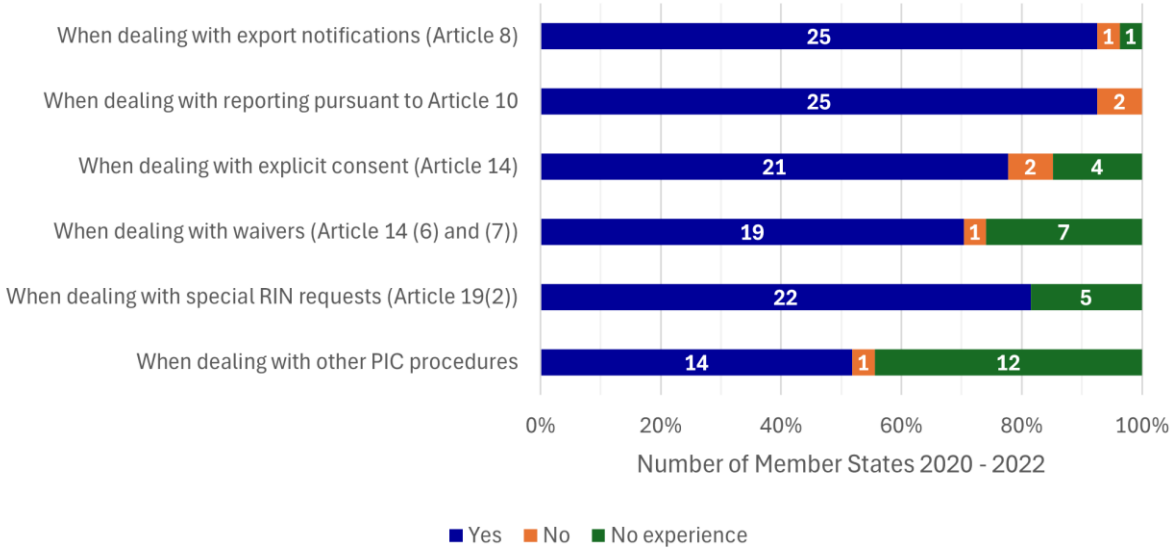
The Agency was involved in cooperation activities, including three regional workshops to improve the capacity of parties to the Rotterdam Convention, two webinars and a workshop organised by the Convention to support different regions. The Agency also provided support to candidate countries, aimed at increasing their chemical management capacity, via the EU Instrument for Pre-accession Assistance. No Member States participated in cooperation activities during this reporting period.

4.12 ePIC users generally found the IT tool more user-friendly and useful to their work.

The Agency developed and maintains ePIC, the IT tool used by all relevant authorities, including enforcement authorities and customs, as well as by exporters and importers. The number of ePIC users from industry has doubled since the previous period, accounting for 91% of users.

New features added to ePIC during the period led to reduced processing times, more efficient processes and improved case traceability and consistency and reliability of data. DNAs generally rated ePIC as user-friendly and helpful in carrying out their main tasks and saw improvement since the previous period (Figure 5).

Figure 5. Is the ePIC system easy to use for DNAs?



Both DNAs and the Agency reported mainly positive feedback on ePIC from industry. The usability study launched by the Agency at the end of 2022 had produced a number of proposals for improvement, some of which had been prioritised for implementation, with more planned for a later stage.

4.13 Information and data on the implementation of the PIC Regulation has become more accessible.

An improved PIC dissemination platform went live in November 2022 to ensure efficient dissemination of PIC data and better integration with the Agency's cross-regulation

dissemination platform. In December 2022 information was added on EU import responses under the Rotterdam Convention [12].

The Agency has published three reports on trade for 2019, 2020 and 2021 under Article 10, two reports on the exchange of information covering 2018-2019 and 2020-2021 under Article 20 [13], and a report on the operation of the Regulation covering 2020-2022 pursuant to Article 22 [14].

5 CONCLUSIONS

The PIC Regulation transposes the Rotterdam Convention in EU law. It has the same objectives but goes beyond the provisions of the Convention to offer a higher level of protection, in particular to developing countries and countries with economies in transition.

This report shows that the procedures laid down by the PIC Regulation and their implementation work smoothly, in particular thanks to effective coordination and cooperation between DNAs, ECHA and the Commission on both internal EU tasks and international work. This has been fundamental to achieving the objectives of the Regulation.

The export notification procedure ensures the importing countries receive important information on the chemicals and their exports. There are more than 10 000 export notifications per year, which clearly shows the scale of this information exchange. This creates a high workload for the Agency and DNAs that can only be handled with appropriate staff resources. The performance of the IT application 'ePIC', developed and maintained by the Agency, plays an important role in this regard.

The use of the explicit consent procedure as a standard procedure for exporting a number of chemicals, which goes beyond the Convention, meant that 7 233 requests for explicit consent were sent to importing countries in the reporting period. This high number of requests created difficulties for many importing countries, with 42% of requests remaining unanswered.

Exporters of chemicals subject to the PIC Regulation were generally aware of their obligations and able to meet them. The DNAs and the Agency provided the necessary assistance, helping to keep the number of infringements low. Although customs authorities carried out a high number of controls on exports (93 308) and imports (59 299), the rate of infringements was very low at around 0.3%. The rate was somewhat higher, at around 5.4%, for controls performed by inspectors.

In general, while the Member States were able to meet their obligations they sometimes struggled to cope with the high number of export notifications at the end of each year and to meet deadlines. The Agency's work was fully in line with the requirements of the PIC Regulation and essential to the smooth functioning of the procedures. The Commission fulfilled its obligations under the PIC Regulation, adopting two delegated regulations that added 48 chemicals to Annex I and one implementing decision on EU import decisions during the reporting period. In addition, the Commission coordinated the EU's contribution to international work and represented the EU at the Convention.

[12] https://echa.europa.eu/eu-import-responses-under-the-rotterdam-convention.

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

[14] https://echa.europa.eu/reports-on-the-operation-of-pic-regulation.