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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 for the period 2020 - 2022

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 for the period 2020-2022

{COM(2025) 557 final}

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Abbreviations used

Agency	European Chemicals Agency (ECHA)
ATD	Access To Document
BPR	Biocidal Products Regulation
CAS	Chemical Abstract Service
CFL	Compact Fluorescent Lamps
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
ECHA	European Chemicals Agency
ePIC	Software application for implementing Regulation (EU) No 649/2012
EU	European Union
FRA	Final Regulatory Action
ICSMS	Information and communication system for the pan-European market surveillance
IPA	EU Instrument for Pre-accession Assistance
IT	Information technology
NEA	National Enforcement Authority
NGO	Non-Governmental Organisation
OECD	Organisation for Economic Cooperation and Development
OJ	Official Journal of the European Union
PIC	Prior Informed Consent
PFOA	Perfluorooctanoic acid
PFOS	Perfluorooctanate sulfonate
POPs	Persistent Organic Pollutants
PPPR	Plant Protection Products Regulation
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation
RoHS	Restriction of Hazardous Substances Directive
RIN	Reference Identification Number
SCIP	Substance of Concern in Products (database)
SDS	Safety Data Sheet
WPIEI	Council Working Party on International Environmental Issues (Chemicals/Synergies)

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. It goes beyond the requirements of the Convention since it applies to exports to all countries and requires the consent of the importing country for many more chemicals than those listed under the Convention. In addition, the requirements for export also apply to certain mixtures containing listed chemicals.

Under the PIC Regulation, exports are subject to different requirements depending on their listing in Annex I: chemicals listed in Part 1 of Annex I are subject to export notification to the importing country; chemicals listed in Parts 2 and 3 of Annex I are subject to export notification and explicit consent of the importing country, unless they are subject to the PIC procedure under the Convention and exported to a Party that has provided a positive import response. These obligations also apply to mixtures containing substances listed in Annex I to the Regulation in concentrations that trigger labelling obligations under the Classification, Labelling and Packaging 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) that bans or severely restricts a chemical in the EU in one use category of the Convention (industrial chemicals or pesticides) and which are listed in Part 2 of Annex I to 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, on behalf of the EU and based on the empowerment in the PIC Regulation, establishes an import decision that outlines whether and under which conditions the chemical can be imported in the EU. This import decision is sent to the Secretariat of the Convention.

[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

1.2 Exclusion of Great Britain (GB) and Northern Ireland (NI)

The United Kingdom left the European Union at the end of 2020. Therefore, the European Commission decided not to consider the United Kingdom (GB and NI) for this report. The requirement to report applies to Member States.

1.3 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 under 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, or the Agency) as per Article 22(1), concerning the operation of the PIC Regulation's procedures.

This reporting exercise is the third under the PIC Regulation and covers the period 2020-2022. As in the previous two reporting exercises, the questionnaire follows the common reporting format for Designated National Authorities (DNAs), which was established by Commission Implementing Decision (EU) 2016/770 of 14 April 2016[3]. The reporting questionnaire was re-created and updated to improve the user-friendliness of the questionnaire and the clarity of some of the questions. The online reporting questionnaire was made available to Member State 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 report on the operation of the PIC Regulation[4] for the period 2020-2022 in October 2023.

The present report is the Synthesis Report (Article 22 of the PIC Regulation), bringing together the findings from the reports of the Commission, the Agency and Member States. It provides an overview of the implementation of the PIC Regulation in the period 2020-2022.

1.4 Methodology

1.4.1 Preparation of the Commission's report

The Commission's report, provided as an **Annex** to this report, is divided into two sections, the first section presenting the work of the Commission with respect to the implementation of the Regulation within the EU, and the second section presenting the international work of the Commission as the EU DNA to the Rotterdam Convention, during the period 2020-2022.

To prepare this report, relevant information was compiled from EUR-Lex, the websites of the Rotterdam Convention and the Agency, and documents published on CIRCABC, including minutes of meetings, and other documents discussed at DNA meetings (Table 1). Other information was obtained first-hand from Commission officials. This report was then used as a source for the Synthesis Report.

[3] 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. https://eur-lex.europa.eu/eli/dec_impl/2016/770/oj

[4] 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

Table 1. List of relevant documents consulted for the Commission Report

List of relevant documents consulted
Implementing and delegated acts:
• Commission Delegated Regulation (EU) 2019/1701
• Commission Delegated Regulation (EU) 2020/1068
• Commission Implementing Decision (EU) 2020/2182 and its August 2021 correction
• Commission Delegated Regulation (EU) 2022/643
• Commission Delegated Regulation (EU) 2023/1656
Associated report:
• Report from the Commission to the European Parliament and to the Council on the exercise of the delegation conferred on the Commission pursuant to Regulation (EU) No 649/2012 of the European Parliament and of the Council of 4 July 2012 concerning the export and import of hazardous chemicals. COM(2023) 448 final
DNA meeting documents:
• Minutes of the DNA meetings that were held in 2020, 2021 and 2022 (respectively, the 35th, 36th, 37th, 38th, 39th, and 40th meeting of the DNAs).
• Any and all amendments to Annex I of the PIC Regulation as presented at the above meetings.
• Any import decisions presented at DNA meetings.
• Submission of notifications to the PIC Secretariat, as presented at the 35th, 36th, 37th, 38th, 39th, and 40th DNA meeting.[5]
Rotterdam Convention documents:
• Documentation relating to EU preparations for/actions arising from relevant Rotterdam Convention Conference of the Parties (COP) meetings, specifically CoP10 of 26-30 July 2021 and 6-17 June 2022, CoP11 of 1-12 May 2023.
• PIC Circulars published by the Rotterdam Convention Secretariat (six were published during 2020-2022, Circulars LI to LVI).[6]
The Agency's reports on Article 20 and the Operation of the PIC Regulation:
• Report on the exchange of information under the PIC Regulation in 2020-2021[7]
• Report on the exchange of information under the PIC Regulation in 2022-2023[8]
• Report on the operation of the Prior Informed Consent (PIC) Regulation 2023[9]
CoP documents
• Council Decision (EU) 2022/1024 of 7 April 2022 on the position to be taken on behalf of the EU at CoP10[10]

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

Before the launch of the questionnaire, the questionnaire was reviewed with a view to increase its clarity and usability for DNAs. As the reporting format had been adopted through a Commission Implementing Decision, most changes were limited to improving the format or

[5] As but one example, how to implement the (then new) listing of "benzene as a constituent of other substances" in Annex I Part 1 of the PIC Regulation was discussed in some of these meetings.

[6] https://www.pic.int/Implementation/PICCircular/tabid/1168/language/en-US/Default.aspx

[7] https://echa.europa.eu/documents/10162/1244645/pic_article_20_report_2020-2021_en.pdf

[8] Selected data supplied as a draft prior to publication.

[9] https://echa.europa.eu/documents/10162/18272234/report_pic_art_22_2023_en.pdf

[10] http://data.europa.eu/eli/dec/2022/1024/oj

wording of the questions, add clarifications, definitions and guidance where needed etc. Increased opportunity was provided for respondents to provide positive and negative feedback in response to the same question if necessary. Some changes encouraged consistent wording for common responses, whilst allowing new responses to be added. There was also more opportunity to provide focussed additional comments if desired.

The common reporting format was made available online to Member States on 28 February 2024, through EU Survey. A guidance document for Member States accompanied the invitation email together with contact details of the consultants running the survey available to assist with completion if needed. To facilitate Member State reporting, the Agency 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 Organisation for Economic Cooperation and Development (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.

1.4.3 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 data received was checked for completeness, adequacy and consistency of logic between answers, and clarification was sought from Member States where necessary.

1.4.4 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, available in the **Annex** to this report, 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 the representation of the EU at 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 is in charge of the PIC Regulation. Unit B.2 has one team leader for international chemicals policy responsible for carrying out the Commission's administrative functions under PIC. The team leader is supported by a policy officer, a lawyer for legal questions and a secretary for all organisational work. For international work, Unit B.2 had two experts (the team leader and a policy officer) nominated to the Chemical Review Committee of the Rotterdam Convention (CRC). The Head of Unit is also involved, in particular regarding the Conference of the Parties (CoP) where they normally lead the EU delegation and represent the EU. In addition, a policy officer from Unit B.2 is involved in the international work and colleagues from Unit F.3 (Global Environmental Cooperation & Multilateralism) who are responsible for multilateral environmental cooperation, contributed to its 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, certain legal matters and the technical assistance contracts on implementation of the Rotterdam Convention. The staff resources occupied by this work amount to 0.4 FTE[11] for the team leader, 0.3 FTE for policy officers/legal officers, and 0.1 FTE for the supporting work, including international matters

2.1.2 European Chemicals Agency (ECHA or the 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 importing country within 30 days of the first notice (Article 8(3)).
- Making available to all EU DNAs export notifications received from non-EU 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 importing 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)).

[11] Full time equivalent.

- Managing ePIC and keeping all relevant documents 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 non-EU countries on the chemicals subject to the Regulation.
- The Agency's Secretariat of the Forum for Exchange of Information on Enforcement established by the Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (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 contribute to the discussions at these meetings.

In addition, the Agency provides assistance and technical and scientific guidance to industry, the DNAs from Member States and non-EU 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 (Table 2). The Agency has maintained staffing at the same level as compared to the previous period.[12]

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

Year	Number of staff working on PIC (FTE)*
2020	8
2021	8
2022	8

* The number covers staff in the PIC operations team in Unit A3 (7 FTEs) plus 1 FTE in horizontal activities (e.g. HR, finance, IT).

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, Persistent Organic Pollutants (POPs) Regulation, the Biocidal Products Regulation (BPR), Chemical Agents Directive, Carcinogens and Mutagens Directive, and the Waste Framework Directive Substance of Concern in Products (SCIP) database, where there are synergies with processes that run across the various pieces of legislation. For example, the Agency's staff collaborate on:

- Scientific, technical and regulatory support including:
    - Substance identity check of chemicals added to the PIC Regulation by means of an amendment or in cases of substances belonging to groups (following ad-hoc requests from companies and Member States),
    - Checking the identification of substances to be added to the PIC Regulation,
    - Checking compliance of Safety Data Sheets (SDS),
    - Checking the application of CLP rules,

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

- Checking the regulatory status and background of substances under BPR or REACH,
- Drafting Final Regulatory Action (FRA) notifications for the Rotterdam Convention Secretariat, in support to the Commission,
- Drafting decision guidance documents (DGD) for the Chemical Review Committee, in support to the Commission (since 2022),
- Providing support to stakeholders (including through the Helpdesk, the publication/update of various manuals, guidelines and factsheets, and communication actions, the Agency Newsletter, social media, etc.).

- Development and maintenance of ePIC in order to benefit from synergies between all the Agency's IT tools concerning login and account management;
- Making available of PIC data (dissemination);
- Planning, data mining and reporting (i.e. optimise the planning and reporting of the Agency's activities across the various legislations and activities);
- Legal advice; and
- Human resources and finance.

The number of export notifications processed by the Agency decreased over the whole reporting period. The continuous rising trend in the number of export notifications received and processed annually that was observed during the previous reporting periods, was reversed during the period 2020-2022; therefore, the previous estimate of a ~10% yearly increase was not followed.

The figures in Table 3 below for 2020 include export notifications submitted from the United Kingdom (733 validated for 2020), whereas 2021 and 2022 refer to submissions after BREXIT - i.e. not including export notifications from the United Kingdom (specifically Great Britain) to other non-EU countries. However, the overall processing-related workload of the Agency's PIC Team remained high, since other processing and related tasks have increased in balance over the same period.

Table 3. Number of export notifications predicted versus processed by the Agency[13]

	2020	2021	2022
Estimated No. of notifications (based on 10% year on year rise)	12 000	13 200	14 500
Actual no. of notifications processed	11 971	10 699	10 072

The number of export notifications received from other countries increased over the period as shown in Table 4 due to the notifications received from the United Kingdom (Great Britain) for 2021 and 2022. Over 400 notifications were received and processed annually from the UK(GB) for imports of PIC chemicals into the EU during both of these years.[14]

Table 4. Number of export notifications received from other countries processed by the Agency[13]

	2020	2021	2022
Number of export notifications processed	381	674	811

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

[14] More details can be found here: https://echa.europa.eu/information-on-chemicals/pic/import-notifications

There has been a notable increase in the number of requests for technical / regulatory support from the agency as shown in Table 5.

Table 5. Number of requests for technical/regulatory support from the Agency[13]

	2020	2021	2022
Number of requests for technical / regulatory support	3 450	3 550	3 800

Most chemicals that were added to the list of chemicals subject to the PIC procedures (Annex I) during the reporting period (through amending regulations (EU) 2020/1068 and (EU) 2022/643) require an explicit consent from the authorities in the country of destination before the export can take place. This leads to the need for additional stakeholder support towards both the EU Member States' DNAs, and authorities in non-EU importing countries. Follow-up enquiries from companies on the status of their notifications also naturally increase since such exports are often not allowed at the time when notifications are validated. Furthermore, queries increased because new types of entries were introduced in the reporting period that are more complex to implement. These entries were:

- "Benzene as a constituent of other substances in concentrations equal to, or greater than 0,1% by weight". This is the first "substance in substances" type entry subject to the PIC Regulation requirements,
- Substances previously in part 1 (only) of Annex I and added to part 2, and
- Entries for chemicals (e.g. thiram, thiamethoxam) that are exported in treated seeds.

To cope with the uneven distribution of work during the calendar year (with a peak of export notification submissions during the winter months – October to January – which can make up for up to 70 - 80% of the total yearly submissions), the Agency reported hiring interim staff for several months every year during the peak period. This situation was similar in the previous reporting period. Due to the timing of entry into application of annual amendments to Annex I in the course of the export year (e.g. July), an additional (mini) peak in the workload was always expected immediately after the publication of the amendment and triggers challenges in terms of availability of resources and planning.

The high and increasing number of submissions led the Agency to continue investing human and financial resources in the enhancement and maintenance of the ePIC application, further improving the existing features and more generally the Agency's processes and ways of working in implementing the PIC Regulation.

The Agency recommended that further enhancements to the application should be considered to support all actors to cope with a high workload and to meet their legal obligations[15]. IT development is nevertheless resource-demanding as the Agency's PIC Team has to be involved in specifying the requirements for improvements, supporting the developers in the analysis phase, as well as in the testing and roll-out activities. More generally, it should be noted that since its initial certification under the ISO 9001 Standard in 2015, the Agency's implementation of the PIC Regulation has regularly been audited successfully, which confirms that the PIC processes and the use of resources are under control, optimised and subject to continuous improvement.

An increased interest of media and non-government organisations (NGOs) on PIC data in general, and the topic of the export of EU banned substances in particular led to a substantial number of Access To Document (ATD) requests on PIC data during the reporting period (21 in

[15] Concrete suggestions provided under question 43 reported by ECHA, Report on the operation of the Prior Informed Consent (PIC) Regulation 2023, October 2023 ECHA-23-R-11-EN

total), some of them being very large and complex in scope. The listing of neonicotinoids to Annex I in 2020 intensified the already high public interest in exports of PIC substances (in particular pesticides) leading to an increase in the number and complexity of ATD requests. Should the Agency continue to receive large numbers of PIC ATD requests, additional resources would be needed, or alternatively, effective solutions should be identified to reduce the number of such ATD requests

The introduction of a ban on the production for export of hazardous chemicals that are banned in the EU could however lead to a decrease in the current pressure on the Agency's PIC resources, hence clarity in the scope and timelines for this initiative under the Chemical Strategy for Sustainability may confirm this resource need or not.

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. According to Article 24(3), the Commission must examine whether it is appropriate for the Agency to charge a fee for the services provided to exporters and, if so, submit a proposal. The Commission tendered a study in 2019 to fulfil this obligation. The study analysed the implementation of fee systems used by DNAs, analysed the costs of the different services provided by the Agency under the PIC Regulation and developed several options for a fee system. The options included an assessment of the financial and technical feasibility and appropriateness of the options for the different stakeholder groups impacted (the Agency, exporters, and DNAs), as well as of potential impacts on the overall implementation of the PIC Regulation and on trade. The study was completed in June 2020. Taking into account the results of the study and the consultation of the Agency and Member States, the Commission decided not to submit a proposal.

2.1.3 DNAs

Member States play a major role in the application, implementation, and enforcement of the PIC Regulation. They must designate one or several authorities to carry out the administrative functions required by the PIC Regulation (Article 4). A total of 36 authorities have been designated by Member States. Article 18 also requires Member States to designate enforcement authorities, such as customs authorities (see Section 4.10).

The responsibilities of the Member States are largely performed by DNAs covering four areas of activity: administrative tasks, enforcement, monitoring and reporting, and exchange of information[16].

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)).

[16] Adapted from: ECHA, *Guidance for implementation of Regulation (EU) No 649/2012 concerning the export and import of hazardous chemicals*, version 1.1, 2015. https://echa.europa.eu/guidance-documents/guidance-on-pic

- Forward export notifications received from non-EU 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)).
- 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).

Table 6. Distribution of responsibilities across DNAs in Member States with more than one DNA

Member State	Distribution of responsibilities
Denmark	Danish Environmental Protection Agency (Danish EPA) carries out general PIC work; Danish Ministry of Environment is the connection between PIC and the Rotterdam Convention

Member State	Distribution of responsibilities
Germany[17]	Federal Institute for Occupational Safety and Health (BAuA) is responsible for the national administrative procedures in relation to Regulation (EU) No. 649/2012; Federal Office for Consumer Protection and Food Safety (BVL) is responsibilities relating to the Rotterdam Convention in relation to pesticides
Ireland	Health and Safety Authority (HSA) is responsible for industrial chemicals; Department of Agriculture, Food and the Marine (DAFM) is responsible for the Biocidal Products Regulation and the Plant Protection Products Regulation; Revenue Commissioners are responsible in respect of Article 18 of the PIC Regulation
Greece	Independent Authority for Public Revenue - DG of the General Chemical State Laboratory-Directorate of Energy, Industrial and Chemical Products-'Section B' is responsible for industrial chemicals; Hellenic Ministry of Rural Development and Food - General Directorate of Agriculture - Directorate of Plant Produce Protection - Department of Plant Protection Products and Biocides Department is responsible for Pesticides
Italy	Ministry of Health (ex DG Health prevention) manages the implementation of PIC, supports companies, manages notifications, manages explicit consent requests and cooperates with customs for enforcement activities. The Ministry of Health should coordinate with the other two DNAs but this task was not applied because during the period 2020-2022 because there was lack of dedicated human resources in these ministries; Ministry of the Environment and Energetic Safety does not perform any activities in order to implement the PIC regulation; Ministry of Enterprises and 'Made in Italy' does not perform any activities in order to implement the PIC Regulation
Latvia	State Limited Liability Company "Latvian Environment, Geology and Meteorology Centre" (LEGMC), for industrial chemicals; State Plant Protection Service (SPPS), for pesticides
Hungary	National Center for Public Health and Pharmacy (NCPHP) is responsible for industrial chemicals and other pesticides; National Food Chain Safety Office is responsible for pesticides used as plant protection products
Netherlands	Ministry of Infrastructure and Water Management: over all responsible for the policy area and politically responsible for the correct implementation/enforcement of the regulation. The Human Environment and Transport Inspectorate, which is the supervising authority of the Ministry, is tasked with supervision; Tax and Customs Administration: the administrative tasks related to ePIC have been delegated/ commissioned by the Ministry to the Central Import and Export Office, which is part of the tax and customs administration. Documentary checks are done by customs at the border (on the basis of export notifications)
Slovakia	Ministry of Economy is responsible for industrial chemicals and pesticides; Ministry of Agriculture and Rural Development is responsible for pesticides

Most Member States (18) had only 1 DNA, while 9 had 2 or 3. DNAs were mostly Ministries or agencies responsible for environment, chemicals, and health or health and safety. In a few cases, Ministries responsible for economy, competition, consumption, labour or agriculture were designated as competent authorities. Since the previous reporting exercise, one Member State had designated a new DNA (DK).

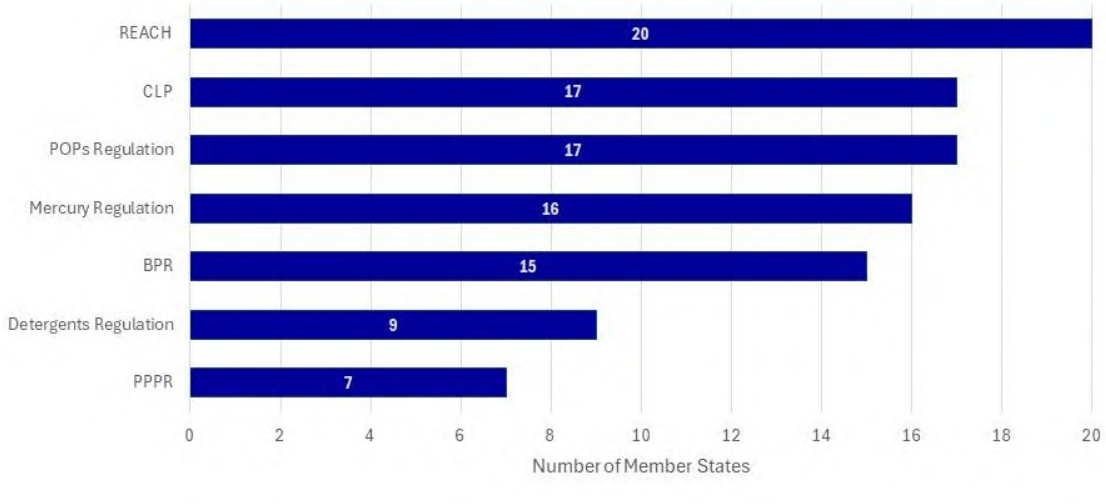
In 5 Member States (out of nine) that had more than one DNA, responsibilities were divided between 1 DNA responsible for industrial chemicals and one DNA responsible for pesticides. In other cases, there was one main DNA responsible for the implementation of the Regulation

[17] Germany indicated that they have one DNA for the implementation of the PIC Regulation, but that regarding the Rotterdam Convention there are two DNAs, one for pesticides and one for industrial chemicals.

(and in some cases delegated tasks to another authority). Table 6 above provides information on the distribution of responsibilities in Member States with several DNAs.

PIC DNAs in 25 Member States were involved in the implementation of other EU or international chemicals legislation, convention, or other instruments as illustrated in Figure 1. 19 DNAs were also involved in supporting 14 other legal requirements.[18]

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



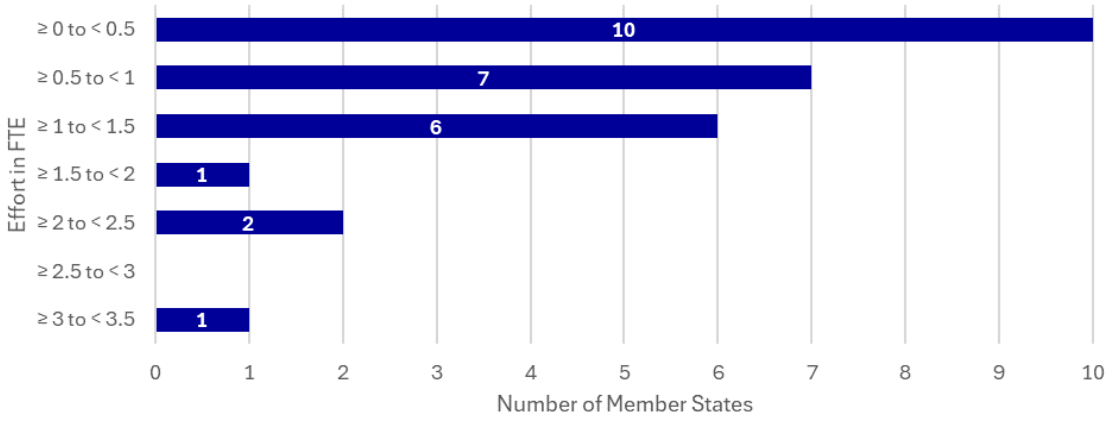
DNAs reported levels of resources dedicated to the implementation of the PIC Regulation ranging from 0.05 to 3.25 FTEs (see Figure 2). In the previous period the maximum resources dedicated to PIC were 2 FTE, whereas in this period 3 Member States indicated effort in excess of 2 FTE. Most Member States devoted much lower resources with 10 reporting less than 0.5 FTE, and a further 13 less than 1.5 FTE – however there were periodic fluctuations during the year.

[18] Support regarding Drug Precursors, F-gas, Global Framework on Chemicals (SAICM), Ozone Depleting substances (ODS), or Restriction of Hazardous Substances (RoHS) was reported by two Member States.

Support was provided regarding Chemical Weapons Convention (CWC), Emissions, Explosive Precursors, Genetically Modified Organisms (GMO), Good Laboratory Practice (GLP), Greenhouse Gases (GHG), Tobacco, Transboundary impact of industrial accidents (TEIA), or Volatile Organic Compounds (VOC) by one Member State.

Note that the Member States concerned in each case may not be the same.

Figure 2: Q8. Please specify the human resources (in full-time equivalent-FTE) in the DNA(s) working on the implementation of the PIC Regulation[19]



2.2 Coordination between the Commission, the Agency and DNAs

2.2.1 Coordination between the Commission and the DNAs

As in the previous reporting exercise, all Member States considered the coordination between the DNAs and the Commission to be satisfactory. Member States mentioned that the support provided by the Commission to DNAs (especially answers to DNA questions) is quick and of good quality.

The main areas of improvement according to DNAs regarded:

- Article 14(5): *Advice and assistance to importing parties upon request* - 4 Member States;
- Article 11(7): *Evaluation of the need to propose measures at EU level* - 3 Member States;
- Article 11(8): *Procedure in case a Member State takes national final regulatory action* - 3 Member States;
- Article 18(1): *Commission, Member State, ECHA obligation to monitor exporter compliance* - 3 Member States. This was one of the main areas of improvement cited in the previous period.

Either 1 or 2 Member States also gave the following as areas for improvement:

- Article 8(5): *Export in case of an emergency situation;*
- Article 8(7): *Additional information to be provided on request concerning the exported chemical;*
- Article 14(6): *Member State decision that no explicit consent is required;*
- Article 14(7): *Member State decision that export may proceed;*
- Article 14(7): *Member State consideration of possible impacts on human health or environment;*
- Article 14(8): *Periodic review of the validity of explicit consent.*
- Article 20: *Exchange of information;*
- Article 21: *Technical assistance;*
- Article 23: *Updating annexes.* This was the other main area of improvement mentioned by DNAs in the previous period.

[19] Not all Member States collect data on how effort expended on PIC is divided between multiple personnel some of whom work on other requirements (not just the PIC Regulation). As such the data was indicative in some cases.

Over half of the DNAs (14) replied that none of the proposed areas of coordination (listed in the question[20]) need to be improved.

Further ad hoc comments on improvements were provided by Member States as follows:

- Two Member States mentioned that it would be helpful if the documents needed for DNA meetings were provided earlier in order to enable them to prepare as currently this is challenging. One also mentioned that the minutes from the previous meeting arrive only a few days before the next meeting. The other asked that decisions taken during DNA meetings be communicated shortly afterwards.[21]
- Coordination could be improved when requesting access to information.
- Changes to the annexes of the PIC regulation should only enter into force on the 1st January of each year (and not earlier or later). While chapter 3 of each SDS ('Composition/information on ingredients') for mixtures is not stored in ePIC, it is completely uncertain which cases fall under the amendment and RINs therefore have to be made inactive at the date of entering into force This is an ongoing issue which has yet to be resolved satisfactorily.

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 and on replies to requests for explicit consent received from other Parties.

2.2.2 Coordination between the Agency and the DNAs

As in the previous reporting exercise all Member States considered the coordination between the DNAs and the Agency to be satisfactory. Member States mentioned that the assistance provided by the Agency to DNAs is appreciated for its swiftness, helpfulness and high quality – quick responses to questions, informal exchanges when needed, support on specific issues when raised, information about updated tools or guidance.

The main area of improvement according to DNAs regarded:

- Article 6(1)(c): *assistance and technical and scientific guidance and tools for the industry* – 5 Member States. This is an area of improvement which was not flagged in the previous reporting exercise. Two specific proposals were provided in this area 1) CN numbers for all chemicals subject to PIC to be added against each entry in the Agency's public online database[22], and 2) Multilingual ePIC user manuals for industry should be updated according to updates made in the English language version of the manual.

[20] Article 8(5) — export in case of an emergency situation; Article 8(7) — additional information to be provided on request concerning the exported chemical; Article 11(6) — Member State obligation to assist the Commission in compiling information; Article 11(7) — evaluation of the need to propose measures at EU level; Article 11(8) — procedure in case a Member State takes national final regulatory action; Article 13(6) — evaluation of the need to propose measures at EU level; Article 14(1) — obligation to forward information received from the Secretariat; Article 14(5) — advice and assistance to importing parties upon request; Article 14(6) — Member State decision that no explicit consent is required; Article 14(7) — Member State decision that export may proceed; Article 14(7) — Member State consideration of possible impacts on human health or environment; Article 14(8) — periodic review of the validity of explicit consent; Article 18(1) — Commission, Member State, ECHA obligation to monitor exporter compliance; Article 20 — exchange of information; Article 21 — technical assistance; Article 23 — updating annexes.

[21] This Member State gave as examples 1) that the Annex listing articles examples is still not available and they are awaiting feedback on their comments on this issue, and 2) they are awaiting the Commission's position on treated seeds notifications.

[22] https://echa.europa.eu/information-on-chemicals/pic/chemicals

Either 1 or 2 Member States also mentioned the following as areas for improvement as in the previous period:

- Article 8(7): *Additional information to be provided on request concerning the exported chemical*;
- Article 21: *Technical assistance*;
- Article 23: *Updating annexes*.

and four further areas not mentioned in the previous period:

- Article 11(6): *Member State obligation to assist the Commission in compiling information*;
- Article 11(7): *Evaluation of the need to propose measures at EU level*;
- Article 18(1): *Commission, Member State, ECHA obligation to monitor exporter compliance*. In particular, it could be useful to evaluate involvement of DG TAXUD to support the identification of the appropriate CN code for mixtures subject to the PIC regulation in order to facilitate custom activities.
- Article 20: *Exchange of information*.

Over half of the DNAs (17) replied that none of the proposed areas of coordination (listed in the question[23]) need to be improved.

The Agency reported that they and the DNAs continued to work together in a collaborative, efficient and friendly manner and this is often acknowledged by the DNAs at DNA meetings. In addition to day-to-day exchanges and to foster the collaboration, ad hoc supplementary support was provided to the DNAs over the reporting period. This included:

- Organising online training sessions on the new functionalities of the enhanced messaging module in ePIC (8 June 2021), and on explicit consent management (17 November 2021);
- Providing detailed practical guidelines on how to request consent responses for the export notifications referring to substances that starting with 1 July 2022 moved from part 1 to part 2 of Annex I. (The Commission delegated Regulation (EU) 2022/643 amending Annexes I and V to the PIC Regulation was published on 20 April 2022. The Agency emailed guidelines to the DNAs on 21 April 2022);
- To support the DNAs in the preparations and submission of the annual reports according to Article 10 of the PIC Regulation, the Agency prepared a checklist that included the main steps for verification of the industry reports, tips to identify errors, and actions for submitting the national reports. (This was provided to the DNAs in August 2022 and then as attachment to the periodic reminders for submitting their annual national reports);
- Organising a workshop with the Finnish DNA and Customs to share experiences with the PIC Regulation processes from different perspectives and identify potential actions (4 October 2022).

However, the Agency indicated that there are areas in which the collaboration could be smoother and more efficient. Those areas include the implementation of Article 8(2) on the timelines for processing export notifications, Article 8(5) on export in case of an emergency

[23] Article 6(1)(c) — assistance and technical and scientific guidance and tools for the industry; Article 8(7) — additional information to be provided on request concerning the exported chemical; Article 11(6) — Member State obligation to assist the Commission in compiling information; Article 11(7) — evaluation of the need to propose measures at EU level; Article 13(6) — evaluation of the need to propose measures at EU level; Article 20 — exchange of information; Article 21 — technical assistance; Article 23 — updating annexes.

situation. Both of these areas of improvements were mentioned in the previous Agency's reports for the periods 2014-2016, and 2017-2020.

2.2.3 Coordination between the Commission and the Agency

The Commission considered cooperation with the Agency to be satisfactory. The Commission and the Agency cooperated closely in the implementation of the PIC Regulation. There were 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 participated 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 information sheets produced by the Agency (for instance, the information sheet on waivers[24]). For cooperation with non-EU countries and the Secretariat of the Rotterdam Convention, the Commission and the Agency closely coordinated their activities to ensure that the most appropriate and effective assistance were provided, and that resources were used efficiently.

As in the previous reporting period, the Agency indicated that the coordination with the Commission is generally satisfactory. In addition to the day-to-day email exchanges between the Agency's PIC Operations Team and the Commission, the continuing regular teleconferences (every six weeks on average), established in the previous period, to discuss the Agency's PIC-related tasks/activities, and in particular when the involvement of other Agency expert colleagues is needed, had contributed to increasing the predictability and planning of work.

The overall efficiency of waiver management had improved. The number of cases leading to a revision of the initial decision (mentioned in the two past reports) decreased. Certain cases were still clarified through day-to-day exchange between the Agency and the Commission since the Agency often has a better visibility on the communications of ongoing clarifications regarding the consent responses.

The Agency indicated that coordination and cooperation with the Commission could be further improved in some areas:

- **Technical preparation of meetings** (e.g. DNA meetings, Chemical Review Committee, Conference of the Parties to the Rotterdam Convention). In particular regarding the biannual DNA meetings, the documents were often sent to the Agency for checking/drafting with short response deadlines. This made it challenging for the Agency to produce good quality documentation at the desired time. The Agency considered more advanced planning including a stronger collaboration in identification of agenda items, preparation of the discussions, and development of the related supporting meeting documents.
- **Article 23 of Regulation (EU) No 649/2012 on updating annexes.** Early involvement of the Agency in changes to Annexes I and V was invaluable. If amendments to annexes entered into application on 1st January only, it would minimise the administrative burden on all parties to the process.

  Such timing would improve the predictability and better planning not only for the Agency, but also for the duty holders to prepare for their exports and the related notification obligations. In addition, a small window between the publication and the

[24] Proposing waivers through ePIC: https://echa.europa.eu/proposing-waivers-through-epic

entry into application tended to create pressure to have the export notifications and explicit consents in place within a very short period of time, in cases where companies planned to continue the exports after the date of entry into application of the regulation. As an example, in 2020 there were only 42 calendar days between the publication and entry into application (published on 21 July 2020 and entry into application 1 September 2020).

Clarity as to the reasons and regulatory basis for the listing of entries to the PIC Regulation is of prime importance for all the actors involved. This information is the basis for the legal texts developed by the Agency and made available in ePIC for exporters to fill in the Section 6.1 of their export notifications. Such a clear and explicit mapping of the reasons and regulatory basis for the listing of a substance at the time of its inclusion into Annex I, would support the establishment of a more systematic monitoring of the regulatory status within EU of the substance after its listing.

Note that Article 23 was also mentioned as an area needing attention by 2 Member States (see Section 2.2.2). Further clarification of what is desired would need to be sought from DNA concerned.

- The timing of replies with regards to the **day-to-day exchanges** between the Agency and the Commission. Whereas some delays were understandable for certain policy issues (which are often complex in nature and may require an involvement of other Commission services), they could create challenges on operational issues which, for example, concern a specific export. In such cases, the Agency was often put under pressure by the exporter/exporter's DNA. This was noted as an area in need of improvement for the three previous periods.

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:

- Representing the EU to the Rotterdam Convention.
- Coordinating the EU input on all technical issues related to the Convention, the preparation of the CoP, the CRC and other subsidiary bodies of the CoP.
- Submitting to the Secretariat 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 and in the definition of the EU position on matters discussed. They nominate experts who serve in the CRC and the Compliance Committee and contribute to other activities under the Convention. Some DNAs also participate in technical assistance activities under the Convention, to which the Agency also contributes.

2.3.1 Coordination of EU input to the Conferences of the Parties (CoP)

During the reporting period, the Commission represented the EU at the 10th CoP, which took place from 26 to 30 July 2021 (online segment which dealt with operational matters only), and from 6 to 17 June 2022 (face-to-face segment which dealt with technical and financial matters).

Preparation for the 11th CoP which took place from 1 to 12 May 2023 also occurred so is reported here.

CoP-10[25]

Before the CoP, 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 position to be adopted on behalf of the European Union within the Conference of the Parties as regards amendments of Annex III to the Rotterdam Convention. This concerned the proposal to add decabromodiphenyl ether (decaBDE) and perfluorooctanoic acid (PFOA), its salts and PFOA related compounds to Annex III. This proposal was adopted and submitted to the Council on 20 April 2021.

As for the previous CoP, the Commission contributed to the drafting of the position paper of the EU and its Member States and to the corresponding statements for their participation in the CoP. The position paper and statements cover all agenda items of the meeting. During the CoP, the Commission represented the EU and the EU and its Member States in contact groups and in any bilateral meetings with Parties, the Secretariat of the Convention and other stakeholders, and contributed to the drafting of Conference Room Papers.

After CoP-10, the Commission presented the outcomes of the CoP to DNAs at the 40th DNA meeting on 20 October 2022. As regards listing of additional chemicals in Annex III, out of 7 chemicals only 2 had been listed; decabromodiphenyl ether (decaBDE) and perfluorooctanoic acid (PFOA), its salts and related compounds.

CoP-11[26]

In preparation for the CoP, which occurred after the present reporting period, the Commission prepared and consulted with the Member States on the position of the EU on matters discussed at the meeting concerning:

Two new candidates for listing in Annex III that would be on the agenda, based on the recommendation of the CRC - iprodione and terbufos. The position to be taken on behalf of the EU at the COP as regards their listing would be laid down in a Council Decision, which would be based on a Commission proposal. The EU and its Member States position on all other agenda items that will be addressed at the CoP would be discussed in WPIEI and laid down in an EU-MS position paper.

2.3.2 Participation in committees and expert groups

Chemical review committee (CRC)

During the reporting period, 5 or 6 EU Member States had nominated experts to participate in the 16th, 17th and 18th meetings of the CRC (Table 7).

Table 7. EU Members of the CRC during the reporting period[27]

CRC meetings	EU Members of the CRC

[25] https://www.pic.int/TheConvention/ConferenceoftheParties/Meetings/COP10/tabid/8398/language/en-US/Default.aspx

[26] https://www.pic.int/TheConvention/ConferenceoftheParties/Meetings/COP11/tabid/9312/language/en-US/Default.aspx

[27] UNEP/FAO/RC/CRC.18/INF/3 Information on the rotation of the membership of the Chemical Review Committee, https://www.pic.int/TheConvention/ChemicalReviewCommittee/Meetings/CRC18/Overview/tabid/9036/language/en-US/Default.aspx

CRC-16, September 2020[28]	Experts nominated by Belgium, Latvia, Malta, Austria, Poland, Finland
CRC-17, September 2021[29]	Experts nominated by Belgium, Latvia, Malta, Austria, Poland, Finland
CRC-18, September 2022[30]	Experts nominated by Belgium, Germany, Latvia, Netherlands, Austria

Due to the Covid-19 pandemic, the 16th meeting and 17th meeting of CRC were held online in 2020 and 2021 respectively.

At the 16th meeting, the CRC agreed to recommend that the CoP list PFOA, its salts and PFOA-related compounds in Annex III to the Convention. The CRC also clarified the decision guidance document (DGD) on decaBDE, which accompanies the recommendation that decaBDE be listed in Annex III.

CRC-17 took place 20-24 September 2021, in between the CoP-10 online meeting and the face-to-face part of CoP-10 which took place in 2022. As outcome of this meeting, the Committee recommended listing of iprodione and terbufos in Annex III to the Convention.

CRC-18 took place 19-23 September 2022 and adopted decisions to recommend the listing of paraquat and methyl bromide in Annex III.

Intersessional work between CRC meetings

1. CRC work between CRC-15 and CRC-16:

   A task group was formed on PFOA, its salts and PFOA-related compounds to undertake an initial review of the new notification and supporting documentation and prepare an analysis as to whether and how the notification met the criteria set out in Annex II to the Convention. All committee members participated.[31] A revised draft decision guidance document arose from discussions in the 16th CRC meeting ready for discussion at the tenth meeting of the Conference of the Parties.

2. CRC work between CRC-16 and CRC-17:

   Intersessional task groups worked on review of notifications of final regulatory action for the following chemicals, producing draft task group reports[32] [33]:

   - Carbaryl
   - Chlorfenvinphos
   - Decabromodiphenyl ether (BDE-209) present in commercial decabromodiphenyl ether
   - Iprodione
   - Methidathion
   - Methyl parathion
   - Terbufos
   - Thiodicarb.

3. CRC work between CRC-17 and CRC-18:[34]

[28] UNEP/FAO/RC/CRC.16/6 Report of the Chemical Review Committee on the work of its sixteenth meeting, https://www.pic.int/TheConvention/ChemicalReviewCommittee/Meetings/CRC16/Overview/tabid/8437/language/en-US/Default.aspx

[29] UNEP/FAO/RC/CRC.17/10 Report of the Chemical Review Committee on the work of its seventeenth meeting, https://www.pic.int/TheConvention/ChemicalReviewCommittee/Meetings/CRC17/Overview/tabid/8605/language/en-US/Default.aspx

[30] UNEP/FAO/RC/CRC.18/15 Report of the Chemical Review Committee on the work of its eighteenth meeting, https://www.pic.int/TheConvention/ChemicalReviewCommittee/Meetings/CRC18/Overview/tabid/9036/language/en-US/Default.aspx

[31] From part VI section A paragraph 55 of UNEP/FAO/RC/CRC.16/6 Report of the Chemical Review Committee on the work of its sixteenth meeting, https://www.pic.int/TheConvention/ChemicalReviewCommittee/Meetings/CRC16/Overview/tabid/8437/language/en-US/Default.aspx

[32] UNEP/FAO/RC/CRC.17/10 agenda https://www.pic.int/TheConvention/ChemicalReviewCommittee/Meetings/CRC17/Overview/tabid/8605/language/en-US/Default.aspx

[33] Part V Section B, paragraph 43 of UNEP/FAO/RC/CRC.18/15.

[34] Part II Section B paragraph 15 agenda item 5 of UNEP/FAO/RC/CRC.18/15: https://www.pic.int/Default.aspx?tabid=9197

Draft decision guidance documents were prepared for iprodione and terbufos. Notifications of final regulatory action were reviewed for carbaryl, chlorfenvinphos, methidathion, methyl parathion and thiodicarb ongoing from intersessional work from CRC-16 to 17. In addition, reviews of notifications of final regulatory action for substances were also carried out for the following, which were deferred for review until after CRC-17:

- Amitrole
- Carbon Tetrachloride
- Methyl Bromide
- Mirex
- Paraquat.

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 (Table 8).

Table 8. Financial contributions from the EU to the Rotterdam Convention's Trust Fund and Special Voluntary Trust Fund (USD)

Year	EU Contribution to Trust Fund[35]	EU contribution to special voluntary trust fund[36]
2020	79 417	617 131
2021	80 440	0
2022	78 738	0

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. No Member States contributed to the Special Voluntary Trust Fund during the present period (Table 9). Contributions for the years 2017 to 2019 were not reported in the previous report (2017-2019) so are included here for completeness.

Table 9. Member States' contributions to the Special Voluntary Trust Fund (USD)[37]

Member State	2017	2018	2019	2020	2021	2022
Germany	44 574	70 514	0	0	0	0
France	0	113 636	0	0	0	0
Netherlands	41 116	39 773	0	0	0	0

[35] The contributions published on the Convention website are calculated in US dollars - USD.

[36] Commitments in accordance with the agreement concluded with the Secretariat of the Convention in the respective year.

[37] From the Rotterdam Convention website, amounts converted from USD to EUR at January 2022 rates between 2014 - 2018. For 2022, the values are the actual Euro value paid as given in status of contributions website, 12/31/2022. https://www.pic.int/TheConvention/FinanceBudget/SpecialVoluntaryTrustFundRC/2022SpecialVoluntaryTrustFundRC/tabid/9169/language/en-US/Default.aspx

3 UPDATES OF ANNEX I AND ANNEX 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 the PIC Regulation. The procedure for adoption of delegated acts requires the Commission to consult experts on draft acts. This consultation is carried out by presenting the drafts at the DNA meetings in order to ensure that all Member State experts have the opportunity to comment. Draft delegated acts are also submitted via the public feedback mechanism to the general public to give them the opportunity to comment. After adoption, the delegated acts are scrutinised by the European Parliament and the Council to ensure that the Commission does not exceed its powers.

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 an active substance under the PPPR;
- Decision not to approve 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.

Amendments to Part 3 of Annex I reflect the decisions of the CoP to include certain chemicals in Annex III to the Convention, making them subject to the PIC procedure.

During the reporting period 2020 to 2022, two Delegated Regulations amending Annex I were adopted:

- Commission Delegated Regulation (EU) 2020/1068[38];
- Commission Delegated Regulation (EU) 2022/643[39].

In Commission Delegated Regulation (EU) 2022/643, there were sufficient alterations to existing entries that the whole of Annex I was substituted with a replacement annex. These alterations were mainly necessary to update the customs codes provided in Annex I.

Substances added to Annex 1

Of the 48 substances added to Annex I during the reporting period:

- 35 substances 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 (PPPR), which represented a ban or severe restriction in the use category ‘pesticide’, as shown in Table 2 (basis for inclusion is noted as ‘PPPR’).
- 1 substance was added to Parts 1 and 2 of Annex I following its non-approval for use in biocidal products in accordance with the BPR Regulation (EU) No. 528/2012.
- 6 were added to Parts 1 and 2 of Annex I on the basis of the REACH Regulation because they were severely restricted or banned as industrial chemicals – 3 for public use, 3 for professional use.

[38] Commission Delegated Regulation (EU) 2020/1068 of 15 May 2020 amending Annexes I and V to Regulation (EU) No 649/2012 of the European Parliament and of the Council concerning the export and import of hazardous chemicals, (OJ L 234, 21.7.2020, p. 1–7). http://data.europa.eu/eli/reg_del/2020/1068/oj

[39] Commission Delegated Regulation (EU) 2022/643 of 10 February 2022 amending Regulation (EU) No 649/2012 of the European Parliament and of the Council as regards the listing of pesticides, industrial chemicals, persistent organic pollutants and mercury and an update of customs codes, (OJ L 118, 20.4.2022, p. 14–54). https://eur-lex.europa.eu/eli/reg_del/2022/643/oj

- 2 were added to Parts 1 and 2 of Annex I because they were severely restricted as industrial chemicals under the POPs Regulation (EU) 2019/1021.
- Finally, 4 were included in Part 3 of Annex I following their inclusion in Annex III to the Rotterdam Convention (RC).

Table 10. Chemicals added to Annex 1 during the reporting period

Delegated Act	Chemical name	CAS number	Amendment of Annex I	Basis for inclusion
Commission Delegated Regulation (EU) 2020/1068 of 15 May 2020	Chlorothalonil	1897-45-6	Parts 1 and 2	PPPR
	Chlorpropham	101-21-3	Parts 1 and 2	PPPR
	Clothianidin	210880-92-5	Parts 1 and 2	PPPR
	Desmedipham	13684-56-5	Parts 1 and 2	PPPR
	Dimethoate	60-51-5	Parts 1 and 2	PPPR
	Diquat, including diquat dibromide	2764-72-9 85-00-7	Parts 1 and 2	PPPR
	Ethoprophos	13194-48-4	Parts 1 and 2	PPPR
	Fenamidone	161326-34-7	Parts 1 and 2	PPPR
	Flurtamone	96525-23-4	Parts 1 and 2	PPPR
	Glufosinate, including glufosinate-ammonium	51276-47-2 77182-82-2	Parts 1 and 2	PPPR
	Hexabromocyclododecane	25637-99-4, 3194-55-6, 134237-50-6, 134237-51-7, 134237-52-8 and others	Part 3	RC
	Imidacloprid	138261-41-3	Part 1	PPPR
	Oxasulfuron	144651-06-9	Parts 1 and 2	PPPR
	Phorate	298-02-2	Parts 1 and 3	RC
	Propiconazole	60207-90-1	Part 1	PPPR
	Propineb	12071-83-9 9016-72-2	Parts 1 and 2	PPPR
	Pymetrozine	123312-89-0	Parts 1 and 2	PPPR
	Quinoxyfen	124495-18-7	Parts 1 and 2	PPPR
	Thiamethoxam	153719-23-4	Parts 1 and 2	PPPR
	Thiram	137-26-8	Parts 1 and 2	PPPR
Commission Delegated Regulation (EU) 2022/643 of 10 February 2022	2,4-Dinitrotoluene (2,4-DNT)	121-14-2	Parts 1 and 2	REACH
	4,4'-Diaminodiphenylmethane (MDA)	101-77-9	Parts 1 and 2	REACH
	Azinphos-ethyl	2642-71-9	Part 2	PPPR
	Benalaxyl	71626-11-4	Parts 1 and 2	PPPR

Delegated Act	Chemical name	CAS number	Amendment of Annex I	Basis for inclusion
	Benzene as a constituent of other substances in concentrations equal to, or greater than 0.1% by weight. Except motor fuels subject to Directive 98/70/EC of the European Parliament and of the Council of 13 October 1998 relating to the quality of petrol and diesel fuels (OJ L 350, 28.12.1998, p. 58). Part of EU combined nomenclature (CN) code 2707 10 00	71-43-2	Part 1	REACH
	Beta-cyfluthrin	1820573-27-0	Parts 1 and 2	PPPR
	Bifenthrin	82657-04-3	Parts 1 and 2	PPPR
	Bis(pentabromophenyl) ether (decaBDE)	1163-19-5	Parts 1 and 2	POP
	Bromoxynil	1689-84-5 3861-41-4 56634-95-8 1689-99-2	Parts 1 and 2	PPPR
	Cadmium and its compounds	7440-43-9 and others	Part 2	REACH
	Chlorpyrifos	2921-88-2	Part 2	PPPR
	Chlorpyrifos-methyl	5598-13-0	Parts 1 and 2	PPPR
	Empenthrin	54406-48-3	Parts 1 and 2	BPR
	Epoxiconazole	135319-73-2	Parts 1 and 2	PPPR
	Ferbam	14484-64-1	Part 2	PPPR
	Fanamiphos	120068-37-3	Parts 1 and 2	PPPR
	Hexazinone	51235-04-2	Part 2	PPPR
	Lead (Pb) and its compounds	7439-92-1 598-63-0 1319-46-6 7446-14-2 7784-40-9 7758-97-6 1344-37-2 25808-74-6 13424-46-9 301-04-2 7446-27-7 15245-44-0 and others	Part 1	REACH
	Mancozeb	8018-01-7	Parts 1 and 2	PPPR
	Mecoprop	7085-19-0 93-65-2	Parts 1 and 2	PPPR
	Mercury	7439-97-6	Parts 1 and 2	REACH
	Methiocarb	2032-65-7	Parts 1 and 2	PPPR
	Methomyl	16752-77-5	Part 2	PPPR
	Commercial octabromodiphenyl ether, including hexa- and heptabromodiphenyl ether	36483-60-0 68928-80-3	Parts 1 and 3	RC

Delegated Act	Chemical name	CAS number	Amendment of Annex I	Basis for inclusion
	Commercial pentabromodiphenyl ether, including tetra- and pentabromodiphenyl ether	40088-47-9 32534-81-9	Parts 1 and 3	RC
	Pentachlorophenol and its salts and esters	87-86-5 and others	Parts 1 and 3	SC
	Perfluorooctanoic acid (PFOA), its salts and PFOA-related compounds	335-67-1 and others	Parts 1 and 2	POP
	Thiacoprid	111988-49-9	Parts 1 and 2	PPPR
	Thiophanate-methyl	23564-05-8	Parts 1 and 2	PPPR

Entries of Annex I modified during the reporting period

Commission Delegated Regulation (EU) 2022/643 of 10 February 2022 included a complete replacement of Annex I to Regulation (EU) No 649/2012 in order to update many entries to reflect changes to classifications of these chemicals in the European Union's Combined Nomenclature (CN).

Substances removed from Annex I

The following amendments are provided in Commission Delegated Regulation (EU) 2022/643 amending Regulation (EU) No. 649/2012.

By Implementing Regulation (EU) 2017/1506[40], the Commission decided to renew the approval of the active substance maleic hydrazide under Regulation (EC) No. 1107/2009, with the effect that maleic hydrazide and its choline, potassium and sodium salts are no longer banned for use in the subcategory 'pesticide in the group of plant protection products'. Therefore, those substances were removed from the list of chemicals in Part 1 of Annex I to Regulation (EU) No. 649/2012.

The new entry on commercial octabromodiphenyl ether in Part 3 of Annex I to Regulation (EU) No 649/2012 also covered the substance octabromodiphenyl ether listed in Parts 1 and 2 of Annex I to that Regulation. Therefore, octabromodiphenyl ether was removed from the lists of chemicals in Parts 1 and 2 of Annex I to Regulation (EU) No. 649/2012.

Dicofol was a new listing in Part 1 of Annex V. Since that listing prohibited the export of dicofol without any exemption, the listing of dicofol in Parts 1 and 2 of Annex I to that Regulation was no longer required and so was removed.

3.2 Updates of Annex V

Amendments to Part 1 of Annex V to the PIC Regulation (chemicals subject to export ban) are triggered by the inclusion of a substance in Annex I to the POPs Regulation (Regulation (EU) 2019/1021[41]). During the reporting period, the substances outlined in Table 11 were added to Part 1 of Annex V.

[40] Commission Implementing Regulation (EU) 2017/1506 of 28 August 2017 renewing the approval of the active substance maleic hydrazide in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011 (OJ L 222, 29.8.2017, p. 21).

[41] Regulation (EU) 2019/1021 of the European Parliament and of the Council of 20 June 2019 on persistent organic pollutants, OJ L 169, 25.6.2019, p. 45–77.

Table 11. Chemicals added to Part 1 of Annex V during the reporting period

Legal Act	Chemical name	CAS number
Commission Delegated Regulation (EU) 2022/643 of 10 February 2022	Dicofol is prohibited for export without any exemption	115-32-2
	Perfluorooctane sulfonic acid (PFOS), its salts and perfluorooctane sulfonyl fluoride. The export ban does not apply when PFOS, its salts and perfluorooctane sulfonyl fluoride is used as a mist suppressant for non-decorative hard chromium (VI) plating in closed loop systems.	1763-23-1, 2795-39-3, 70225-14-8, 56773-42-3 and others
	Pentachlorophenol and its salts and esters	87-86-5 and others
	Perfluorooctanoic acid (PFOA), its salts and PFOA-related compounds as regards its presence in fire-fighting foams. The export ban only applies to fire-fighting foam that contains or may contain PFOA, its salts and PFOA-related compounds.	335-67-1 and others
	Decabromodiphenyl ether	1163-19-5 and others

Changes to Part 1 of Annex V

The entry covering articles containing concentrations of tetra, penta-, hexa- and heptabromodiphenyl ether at or above 0.1% by weight when produced partially or fully from recycled materials or materials from waste prepared for re-use was been amended by Regulation (EU) 2019/1021, reducing the allowed concentrations in articles and adding decabromodiphenyl ether.

A number of classifications of chemicals in the European Union's Combined Nomenclature were changed since those chemicals were added to Annex I to Regulation (EU) No 649/2012. Those changes were reflected in the Annex.

Part 2 of Annex V

Part 2 of Annex V to the PIC Regulation lists chemicals subject to export ban other than POPs. Commission Delegated Regulation (EU) 2022/643 of 10 February 2022 added mercury, certain mixtures of metallic mercury with other substances, certain mercury compounds and certain mercury-added products to Part 2 of Annex V to Regulation (EU) No. 649/2012, in line with Regulation (EU) 2017/852.

Table 12. Chemicals added to Part 2 of Annex V during the reporting period

Legal Act	Chemical name	CAS number
Commission Delegated Regulation (EU) 2020/1068 of 15 May 2020	Additions to entry 3: The following mercury compounds except where they are exported for laboratory-scale research or laboratory analysis: Mercury (II) sulphate ($HgSO_4$); Mercury (II) nitrate ($Hg(NO_3)_2$).	7783-35-9, 10045-94-0
	New entry 5: Compact fluorescent lamps (CFLs) for general lighting purposes: (a) CFL.i ≤ 30 watts with a mercury content exceeding 2,5 mg per lamp burner; (b) CFL.ni ≤ 30 watts with a mercury content exceeding 3,5 mg per lamp burner.	n/a
	New entry 6: The following linear fluorescent lamps for general lighting purposes: (a) Triband phosphor < 60 watts with a mercury content exceeding 5 mg per lamp; (b) Halophosphate phosphor ≤ 40 watts with a mercury content exceeding 10 mg per lamp.	n/a
	New entry 7: High pressure mercury vapour lamps for general lighting purposes.	n/a

Legal Act	Chemical name	CAS number
	New entry 8: The following mercury-added cold cathode fluorescent lamps and external electrode fluorescent lamps for electronic displays: (a) short length (≤ 500 mm) with mercury content exceeding 3,5 mg per lamp; (b) medium length (> 500 mm and ≤ 1 500 mm) with mercury content exceeding 5 mg per lamp; (c) long length (> 1 500 mm) with mercury content exceeding 13 mg per lamp.'.	n/a
Commission Delegated Regulation (EU) 2022/643 of 10 February 2022	New entry 9: Batteries or accumulators that contain more than 0,0005% of mercury by weight.	n/a
	New entry 10: Switches and relays, except very high accuracy capacitance and loss measurement bridges and high frequency radio frequency switches and relays in monitoring and control instruments with a maximum mercury content of 20 mg per bridge, switch or relay.	n/a
	New entry 11: Cosmetics with mercury and mercury compounds, except those special cases included in entries 16 and 17 of Annex V to Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products (OJ L 342, 22.12.2009, p. 59).	n/a
	New entry 12: Pesticides, biocides and topical antiseptics that contain mercury or a mercury compound that was intentionally added.	n/a
	New entry 13: The following non-electronic measuring devices that contain mercury or a mercury compound that was intentionally added: (a) barometers; (b) hygrometers; (c) manometers; (d) thermometers and other non-electrical thermometric applications; (e) sphygmomanometers; (f) strain gauges to be used with plethysmographs; (g) mercury pycnometers; (h) mercury metering devices for determination of the softening point. This entry does not cover the following measuring devices: — non-electronic measuring devices installed in large-scale equipment or used for high precision measurement where no suitable mercury-free alternative is available; — measuring devices more than 50 years old on 3 October 2007; — measuring devices which are to be displayed in public exhibitions for cultural and historical purposes.	n/a

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.

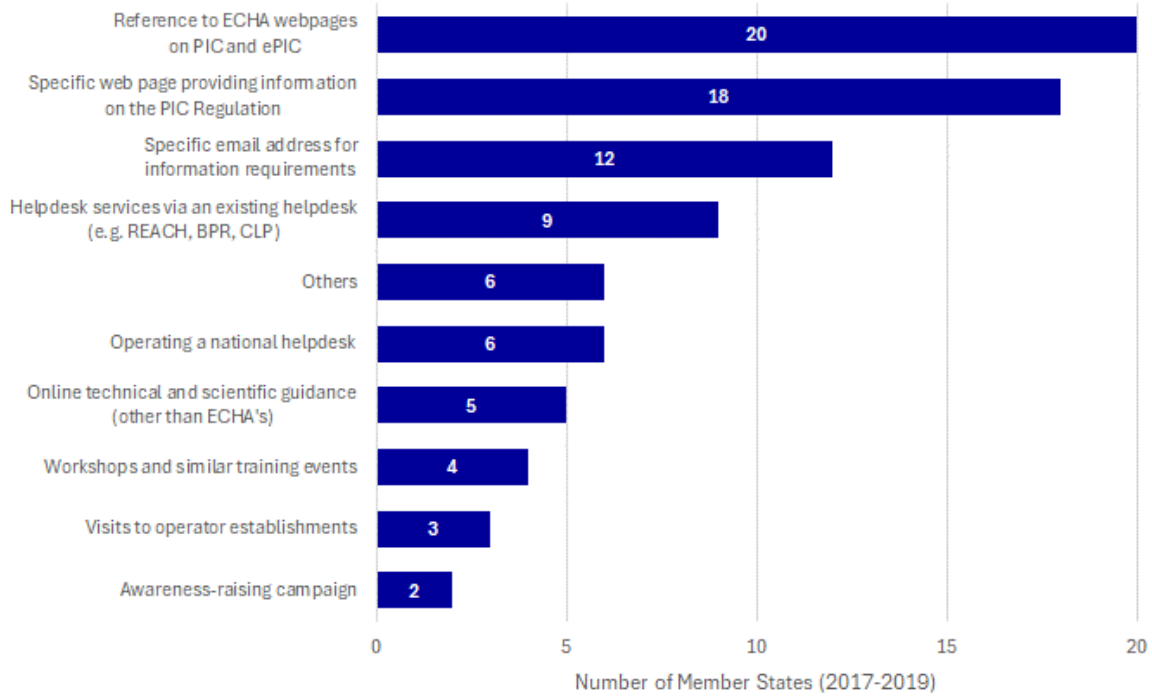
Both the Agency and Member States were asked to provide information (in their respective reporting questionnaires) on the awareness-raising and communication activities carried out during the reporting period and requests received from exporters and importers (Section 3 of Member State and the Agency's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

4.1.1 Support provided by DNAs

Awareness-raising activities

24 Member States stated that they had carried out awareness-raising and information activities for exporters and importers during the reporting period (Figure 3). Regarding the 3 Member States that did not carry out any such activities: 1 is a smaller Member State which explained that they do not have an industry exporting PIC substances but for the few imports they are giving support; a second larger state explained that, in general, companies are by now already well aware of the PIC Regulation, and questions by companies are answered on a case-by-case basis; the third, also a larger state, explained that information about PIC was on their website.

Figure 3. 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?



As in the previous reporting period, 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 (18 Member States – 2 fewer than in the previous period[42]), and references to the Agency's webpages on PIC and ePIC (20 Member States – same as previously[42]). 9 Member States also provided helpdesk services via an existing helpdesk (e.g. REACH, CLP, BPR) (same as before[42]) and 6 operate a national helpdesk (2 more than before[42]). 12 Member States indicated having a specific email address for information requirements (4 more than in the previous period[42]).

As in the previous two reporting exercises, almost all (24) of the Member States that carried out awareness-raising considered they have improved exporters' and importers' compliance with the PIC Regulation. Examples of how this improvement was manifested included:

- Feedback from industry that provision of clear information on national webpages is helpful. This improves cooperation between competent authorities, control authorities and industry, and helps implementation of hazardous chemical-related legislation. The issue of bulletin, guidance and consultations (e.g. by email) promotes awareness, understanding of legal duties, and engagement. Regular communication promotes compliance however some duty holders remain unaware of their obligations.
- Dedicated helpdesk, and/or e-mail and and/or telephone support/consultation are considered valuable to aid understanding and increase compliance and a reduction in incorrect submissions.
- Increases in export notifications received and processed – sometimes as a result of inspection campaigns, or an improvement in quality of notifications which reduces the need to revert to exporters.

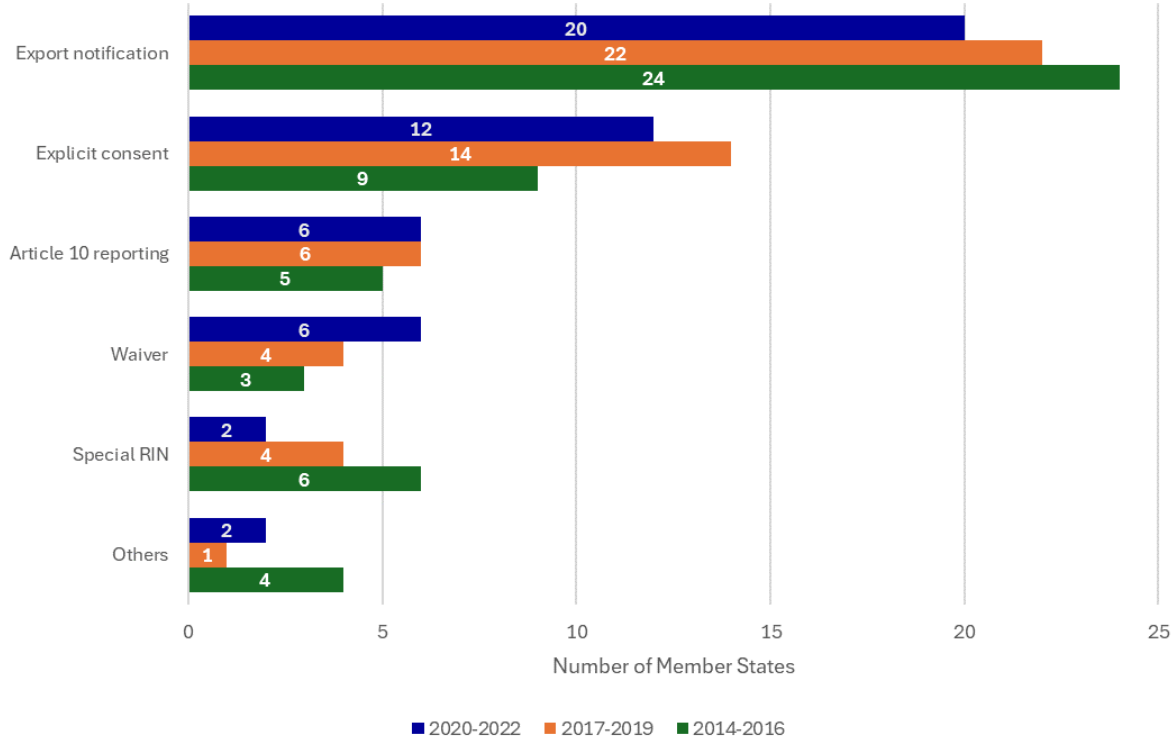
Regarding the other three Member States, one Member State reported new PIC activities for treated seeds had been required, and new categories of companies had therefore been needing to take action. These had been contacted through newsletters and industry associations. In the other two cases, one Member State provided no comments, and the other had not carried out any awareness-raising activities.

Requests from exporters and importers

As in the previous reporting period, the most frequent requests from exporters and importers to DNAs related to export notifications and explicit consents (Figure 4).

[42] For the EU 27. Data for the two UK DNAs included in the Synthesis Report for the previous period has been excluded to enable proper comparison in this report.

Figure 4. Question 13. On which matters do(es) the DNA(s) get the two most frequent requests for support coming from exporters and importers?

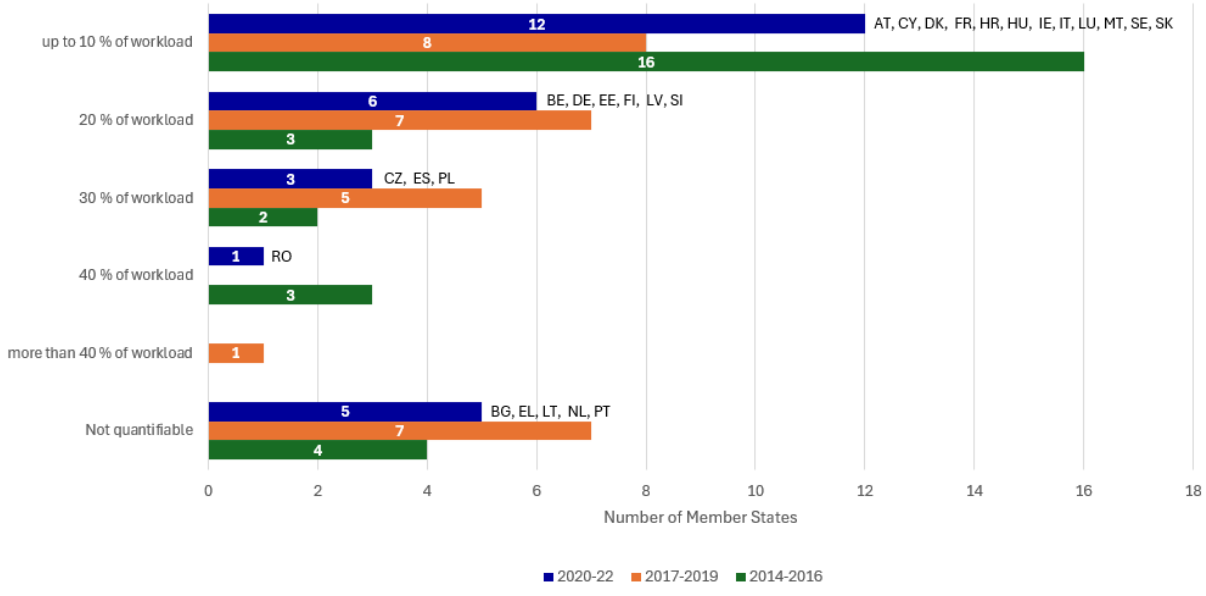


One of the 'other' matters concerned requests for support regarding pending activation of RINs due to consents being missing.

Estimated amount of time spent on support

In the majority of Member States (18), support to exporters and importers took up to 10% or 20% of the DNA's workload (Figure 5). This compared with 15 and 19 Member States in periods 2017-2019 and 2014-2016, respectively, which suggests there is no obvious trend change in workload. Similarly, between 6 and 8 Member States selected 30% of workload or more for the current and previous two periods indicating the level of effort overall remains similar.

Figure 5. Question 14: Can you estimate the amount of time spent by the DNA(s) on such support?



4.1.2 Support provided by the Agency

Awareness-raising activities

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

Webpages on the PIC Regulation and ePIC

The Agency improved or maintained the following dedicated landing web pages, and translated them in all official EU languages:

- Understanding PIC[43]

  The PIC Regulation web pages were revamped by introducing a new landing page (Understanding PIC) to facilitate the navigation between different sub-sections. The information was presented in a more structured way, together with new visual and information boxes to better illustrate the key points and processes. In the context of the revamp, the content of the following sub-sections was additionally updated:

  - Export notification procedure
  - Explicit consent requirement
  - Reporting on the operation of PIC Regulation
  - Waiver information sheet

- ePIC – Prior Informed Consent IT system[44]

  Similar revamp begun for ePIC pages to align the visualisation and structure with web pages for other Agency IT tools.

Direct links to the PIC Regulation legal texts (initial text, latest consolidated version, and non-consolidated latest amendments) were made available and kept up-to-date under the Legislation section of the Agency's public website.[45] The Agency also published on its website the 'PIC Circular' issued twice a year by the Secretariat of the Rotterdam Convention.[46]

Internal messaging in ePIC

This means of communication was typically used in the following cases:

- To remind exporters/importers of upcoming legal deadlines (e.g. Article 10 reporting deadline);
- To alert or remind exporters of typical shortcomings or elements they should pay particular attention to in their export notifications;
- To advertise the publication of updated user manuals, new Q&As, etc.;
- To inform on policy changes (e.g. following an agreement at a PIC DNA meeting);
- To alert users in advance of maintenance breaks of ePIC and Agency closures;
- To inform users on new functionalities in ePIC;
- To inform users on performance issues, bugs etc.

Awareness-raising campaign

The Agency regularly informed or reminded exporters/importers of various PIC-related issues such as: upcoming regular legal deadlines (e.g. regarding Article 10 reporting), new or clarified legal obligations (e.g. entry into application of a new amendment to Annex I and/or V), peaks

[43] https://echa.europa.eu/regulations/prior-informed-consent/understanding-pic

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

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

[46] https://echa.europa.eu/regulations/prior-informed-consent/pic-circular

in workload and related processing times and timelines to be expected. The Agency used different communication channels such as the *ECHA Weekly News* (by email) or the *ECHA Newsletter*.

Social media

The Agency published some posts on social media (LinkedIn, Twitter, Facebook) relating to the implementation of the PIC Regulation, either for general awareness-raising purposes or on specific topics such as the publication of the Agency's Article 10 reports and the Agency's participation in the meetings of the Parties to the Rotterdam Convention.

Support to individual companies

This support was mainly provided by means of replies to incoming Helpdesk incidents (cf. Question 8 for further details). When needed (e.g. communication/language issues), the Agency also provided ad hoc support over the phone, usually as a follow-up to initial exchanges via the Helpdesk. The Agency also contacted individual companies as regards their specific submissions by means of 'ad hoc' messages in ePIC to facilitate the processing of certain exceptional cases (e.g. in case of IT-related issues).

Workshops, webinars and similar training events

In September 2020 the Agency hosted a webinar "*Know your obligations when exporting hazardous chemicals outside the EU*". The webinar explained the scope and main requirements of the PIC Regulation and is regularly referred to as a useful piece of information in exchanges with stakeholders, e.g. in the context of helpdesk enquiries.[47]

Information on obligations under PIC were also presented at a virtual booth "*Do you know how the Prior Informed Consent Regulation works in the EU*?" as part of the Safer Chemicals Conference which was held on-line in October 2021.

IT user manuals, factsheets and Q&A (FAQs)

No changes were made to the ePIC Industry user manual since the improvements to existing features in the industry application were self-explanatory in their nature.

To support companies in identifying their obligations under the PIC Regulation after Brexit, Q&A guidance on the UK withdrawal from the EU and on the Northern Ireland Protocol (NIP) were developed and published[48].

No new topical factsheets were published during the reporting period however, the "*In Brief - Proposing Waivers through ePIC*" was updated to reflect the nature of the required supporting documents and related legal provisions. The Agency worked on a fact sheet for exports of articles and provided a first draft to the Commission however, the document has not been published yet due to a need for further clarifications on policy aspects.

At the end of this reporting period, ePIC had 1 475 registered companies of which 533 had actively used the submission system in 2022. The number of active companies decreased compared to the previous reporting period due to the revocation of accounts registered in the UK (specifically GB). The Agency was of the opinion that the support and communication activities it provided (via on-line events, information on it's website, news items, Q&As) had contributed to increasing awareness of and compliance with the PIC Regulation. A substantial number of export notifications to UK (GB) (2021: 620, 2022: 594) were submitted after the

[47] The webinar, presentations and Q&A are available at https://echa.europa.eu/-/know-your-obligations-when-exporting-hazardous-chemicals-outside-the-eu

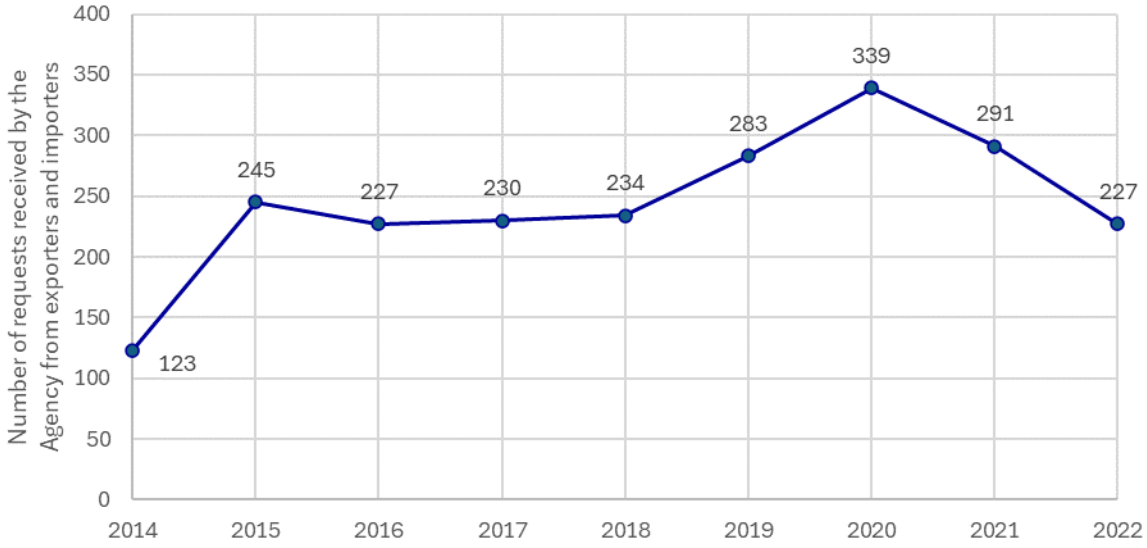
[48] https://echa.europa.eu/advice-to-companies-q-as/pic (Brexit), and https://echa.europa.eu/advice-to-companies-q-as/northern-ireland

Brexit transition period and trade (both export and import) was reported in accordance with Article 10.

Requests to the Agency helpdesk from exporters and importers

The number of requests received during the reporting period by the Agency helpdesk from exporters and importers showed an increase 2018 – 2020, after which it started to fall returning to the 2016 – 2018 levels in 2022 (see Figure 6). This may have been linked in part to the Brexit transition as many were related to chemicals subject to the regulation and other scope related issues, or activation of RINs and related issues.

Figure 6. Number of requests received by the Agency from exporters and importers



During the reporting period, the largest number of requests from exporters and importers' concerned:

- Follow-up questions on specific notifications, e.g.: companies do not always understand why no green light to export was given ("Why is my RIN not active/processed yet") or why the export notification is not activated until the end of the year; change requests to the information provided in export notifications (e.g. add/remove/change importers, estimated quantities, intended export date);
- Substance identification: whether a substance is subject to PIC or not;
- Article 10 on the reporting required of exporters and importers during the first quarter of each calendar year;
- General questions regarding obligations/procedures e.g. not always certain about applicable procedures;
- Definitions/concepts of 'exporter' and transit under PIC: which country should be notified when the exporter is located one Member State and the shipment leaves from another, how to deal with situations where when the manufacturer is based in a non- EU country, but the chemicals are shipped from the EU;
- Obligations on trade to/from the UK.

In addition, the Agency received a comparatively low number of more complex questions, which required reference to expert colleagues within the Agency or the European Commission:

- Questions related to exports of complex substances (UVCBs as defined under the REACH Regulation) containing benzene (e.g. "how to determine the destination country in case of complex supply chain?", exemptions covered by Directive 98/70/EC);

- Rules for classification and labelling of mixtures under CLP: e.g. "is the PIC substance present in their mixture in a high enough concentration to trigger labelling obligations under CLP?" or "is supplementary labelling a trigger for a notification?"
- Questions related to scope of the PIC Regulation e.g. exports of cosmetic/medicinal products, treated seeds or articles.

The questions related to the ePIC tool and its functionalities remained low in number (less than 10 per year) and not representative of any major issue. With the exception of Brexit, which was new, issues on which exporters and importers asked for support were generally the same as in the previous reporting period.

Estimated amount of time spent on such support

During this reporting period, an average of six members of the PIC Operations Team in the Submission and Processing Unit (A3) were directly involved in providing replies to the requests received from companies via the *ECHA Helpdesk*.[49] They spent on average, approximately 10% of their time on this specific activity (i.e. a total of 0.6 FTE). This represents the same level of loading and resource expended as the previous reporting period.

4.2 Export notifications sent 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 non-EU 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.

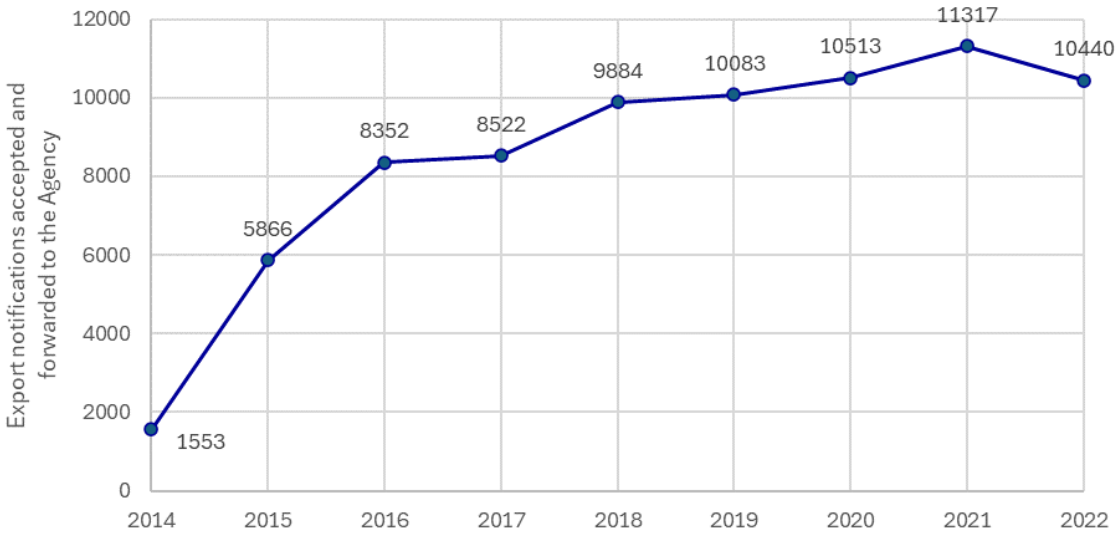
4.2.1 Export notifications processed during the reporting period[50]

During the reporting period, DNAs accepted and forwarded to the Agency 32 270 export notifications, compared with 28 489 in the period 2017-2019 and 15 771 in the period 2016-2014 (Figure 7). The number of notifications accepted and forwarded by DNAs grew rapidly from 2014-2016 since when it steadily increased until 2021. The 8% drop in 2022 may have been partly caused by the exit of the UK (GB). In the previous period the UK processed 2 207 notifications.

[49] https://echa.europa.eu/contact

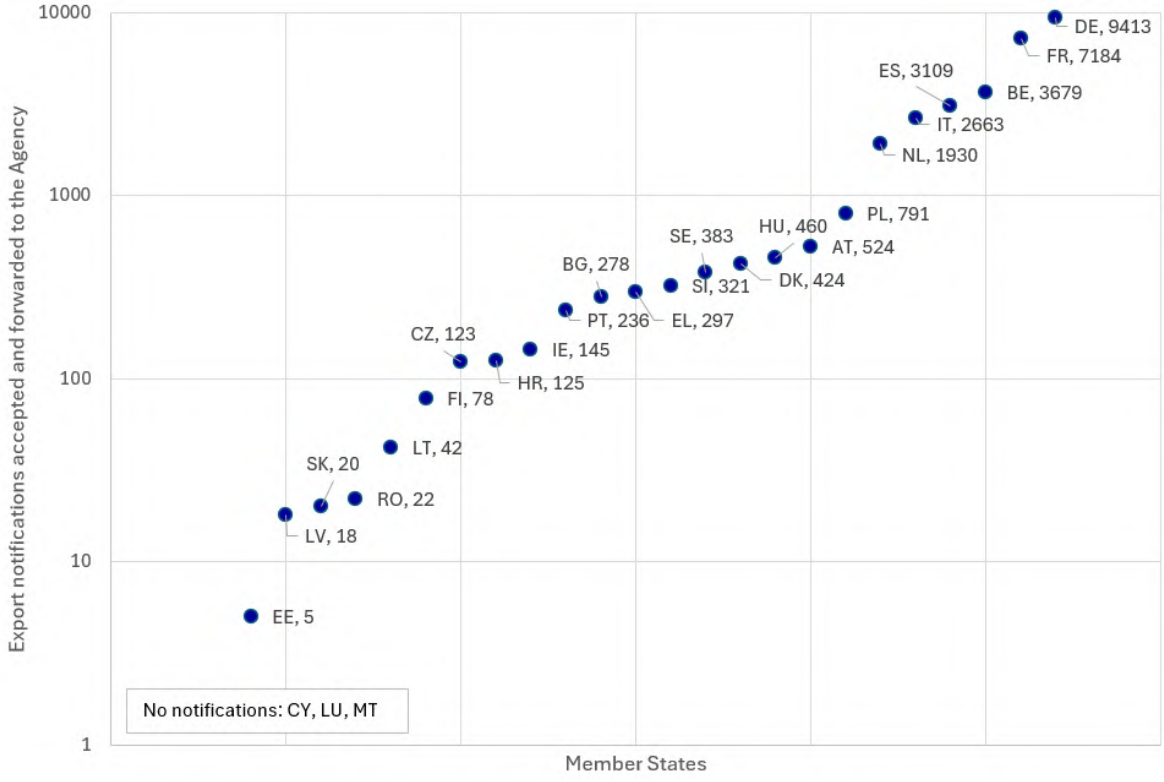
[50] This section and those that follow are based on data extracted from ePIC by the Agency and provided to the Commission, the DNAs and the consultant.

Figure 7. Number of export notifications accepted and forwarded to the Agency by DNAs per year



The number of export notifications processed varied significantly between Member States (Figure 8). Three Member States did not process any export notifications during the reporting period (Cyprus, Luxembourg and Malta - all of whom carried out no processing in the previous period), one Member State (Estonia) processed fewer than 10 notifications, and a further 5 Member States fewer than 100 notifications. The highest numbers of export notifications during the reporting period were, as in the previous period, in Germany (9 413 versus 8 645) and France (7 184 versus 6 855). This was followed by Belgium (3 679 versus 2 019), Italy (2 633 versus 2 453), Spain (3 109 versus 2 383) and the Netherlands (1 930 versus 1 029).

Figure 8. Number of export notifications accepted and forwarded to the Agency by DNAs during the reporting period[51]



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

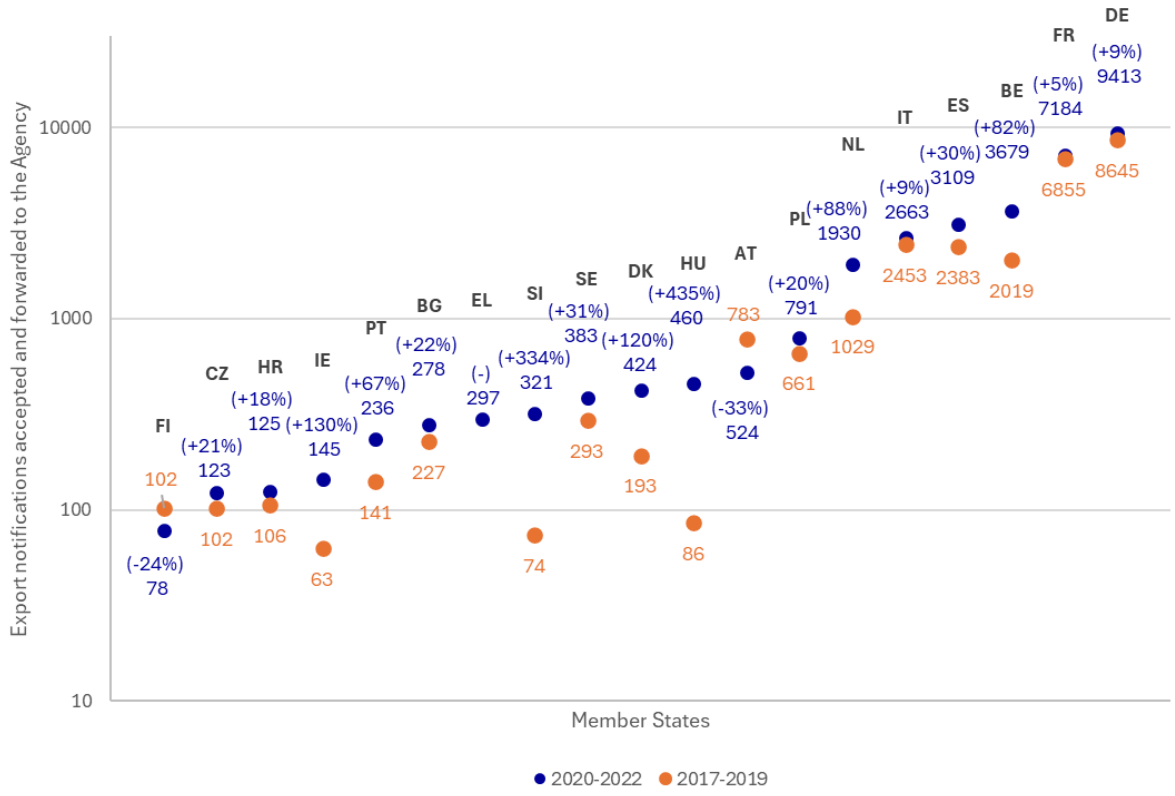
21 Member States processed more export notifications during this reporting period compared to the previous one (see Table 13).

Table 13. Number of export notifications accepted and forwarded to the Agency by DNAs in the reporting periods 2014-2016, 2017-2019, and 2020-2022

	Export notifications accepted and forwarded to the Agency		
Member State	**2014-2016**	**2017-2019**	**2020-2022**
Belgium	766	2 019	3 679
Bulgaria	107	227	278
Czechia	55	102	123
Denmark	115	193	424
Germany	5 196	8 645	9 413
Estonia	1	1	5
Ireland	30	63	145
Greece	1	0	297
Spain	1 265	2 383	3 109
France	3 358	6 855	7 184
Croatia	47	106	125
Italy	1 321	2 453	2 663
Cyprus	4	0	0
Latvia	0	28	18
Lithuania	38	17	42
Luxembourg	0	0	0
Hungary	29	86	460
Malta	8	0	0
Netherlands	588	1 029	1 930
Austria	361	783	524
Poland	232	661	791
Portugal	58	141	236
Romania	7	7	22
Slovenia	0	74	321
Slovakia	46	14	20
Finland	93	102	78
Sweden	216	293	383

In Member States who processed more than 50 notifications, 2 saw a fall in processed notifications (Austria 33% and Finland 24%) but 16 saw a rise. Of these Member States, 3 saw a rise of up to 10%, 6 between 10% and 50%, and 3 between 50 and 100%. 4 Member States saw the number of notifications processed more than doubled (Denmark 120%, Ireland 130%, Slovenia 334%, and Hungary 435%). In absolute terms, Belgium (1 660), followed by the Netherlands (901), Germany (768) and Spain (726) experienced the largest increase in notifications processed. This movement is illustrated in Figure 9 below.

Figure 9. Number of export notifications accepted and forwarded to the Agency by DNAs compared with the previous reporting period for those DNAs processing the most notifications



The Agency also reported an increase of export notifications accepted and processed during the reporting period (compared with 8 455 in 2017, 9 704 in 2018, and 10 009 in 2019[52] (Table 14)). 1 475 companies were registered (of which 533 active users) in ePIC at the end of the current reporting period (see section 4.1.2) compared with 2 343 (of which 578 active) at the end of the previous reporting period (2019). Thus, there is no correlation of the increase in notifications with the number of users registered or active. This would suggest that, in general, submissions per company increased.

Table 14. Export notifications and related tasks handled by the Agency during the reporting period

	2020	2021	2022
Export notifications handled (including initial submissions, resubmissions and rejections)	11 250	11 292	10 396
Export notifications forwarded	9 472	9 724	9 227
Acknowledgments of receipt received	6 367	6 698	6 568
Export notifications forwarded a second time	3 105	3 026	2 659

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. These reminders are managed by ePIC automatically so that there is no impact on the Agency's workload.

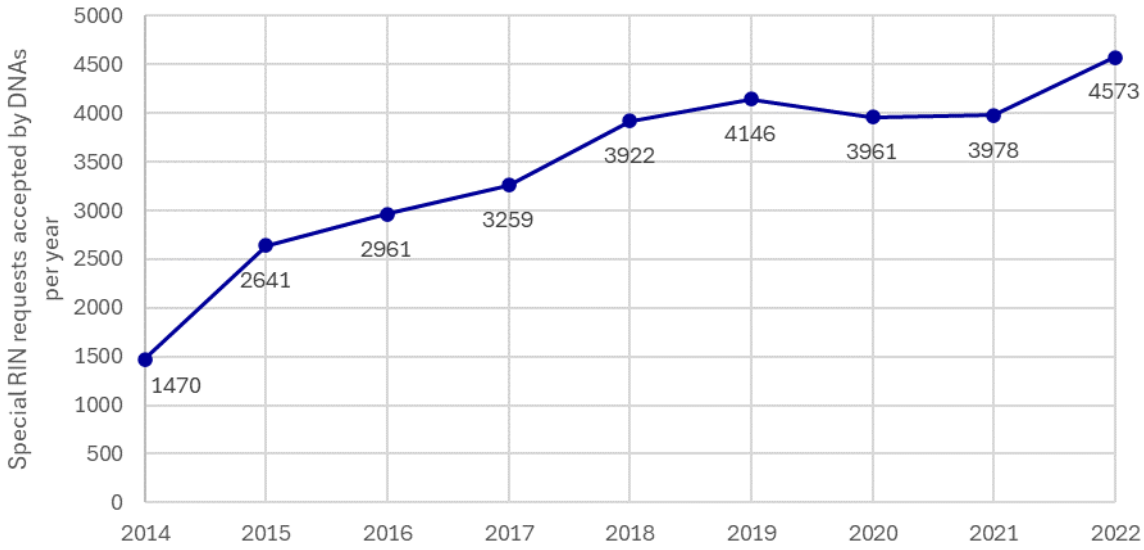
[52] Figures provided for the Agency include initial submissions, re-submissions and rejections.

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.

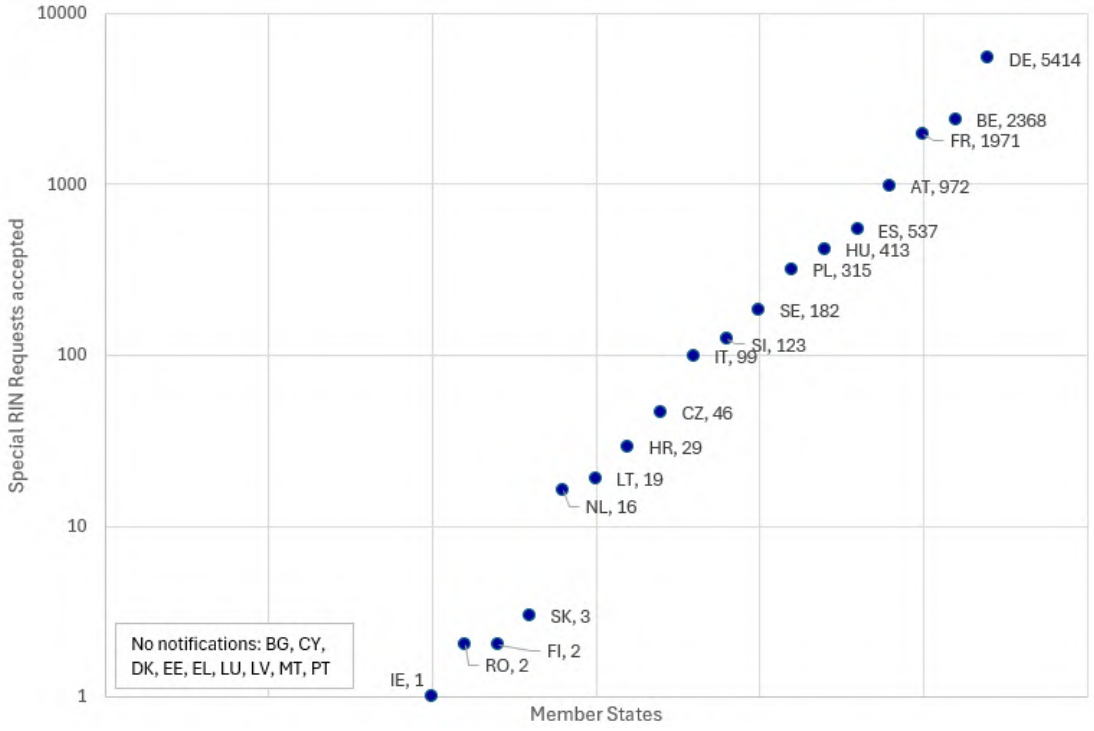
During the reporting period, DNAs accepted 12 512 Special RIN requests, a rise of 11% compared to 11 327 requests in the period 2017-2019. The number of requests in the period 2014-2016 were 7 072. Thus, while the number of Special RIN requests accepted and forwarded by DNAs continuously increased since 2014, the rate of increase slackened. This is illustrated in Figure 10.

Figure 10. Number of special RIN requests accepted by DNAs per year



The number of special RIN requests processed varies by four orders of magnitude between Member States (Figure 11). In the previous reporting period, 11 Member States did not have to deal with any Special RIN requests (Bulgaria, Cyprus, Estonia, Greece, Latvia, Lithuania, Luxembourg, Malta, Portugal, Romania, and Slovakia). This remained the case for all of these States except Greece, Lithuania, Romina and Slovakia. Germany, Belgium and France were the Member States that accepted the highest number of special RIN requests as in the previous period.

Figure 11. Number of special RIN requests accepted by DNAs during the reporting period



In the 10 Member States who processed more than 50 requests, 2 were almost at the same level as the previous period (Italy and Slovenia), 2 saw a fall (Poland 25% and Spain 14%), and 6 saw a rise (France 68%, Austria 62%, Hungary 48%, Sweden 30%, Belgium 25%, and Germany 11%). In absolute terms, France (800), Germany (518), Belgium (471) and Austria (372) experienced the largest increase of requests (Table 15).

Table 15. Number of Special RIN requests accepted by DNAs in the reporting periods 2014-2016, 2017-2019 and 2020-2022

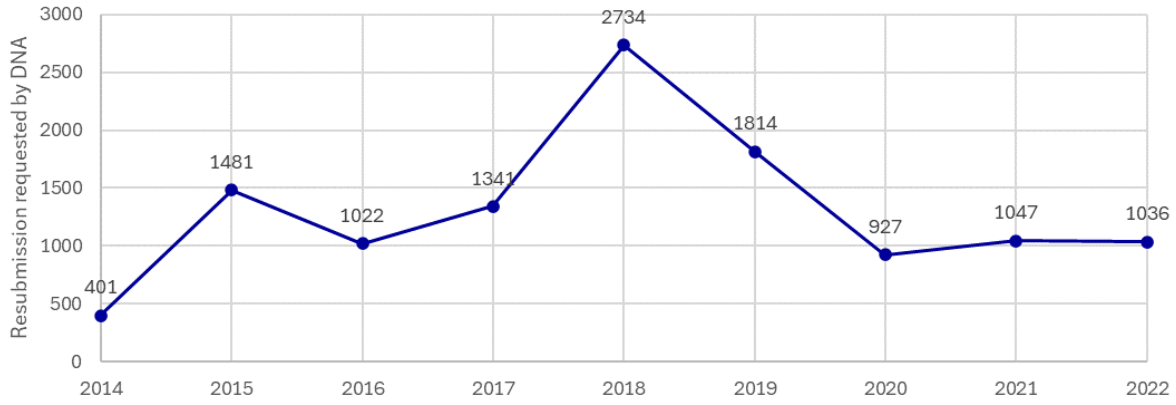
Member State	2014-2016	2017-2019	2020-2022
Belgium	1 156	1 897	2 368
Bulgaria	0	0	0
Czechia	44	41	46
Denmark	13	9	0
Germany	3 121	4 896	5 414
Estonia	0	0	0
Ireland	29	4	1
Greece	0	0	0
Spain	555	623	537
France	577	1 171	1 971
Croatia	33	101	29
Italy	46	101	99
Cyprus	0	0	0
Latvia	0	0	0
Lithuania	0	0	19

Member State	2014-2016	2017-2019	2020-2022
Luxembourg	0	0	0
Hungary	0	279	413
Malta	0	0	0
Netherlands	29	39	16
Austria	165	600	972
Poland	226	418	315
Portugal	5	0	0
Romania	0	0	2
Slovenia	210[53]	122	123
Slovakia	164	0	3
Finland	5	1	2
Sweden	82	140	182

4.2.3 Requests for resubmission and rejection of export notifications

Member States requested the resubmission of 3 010 export notifications during the reporting period, compared to 5 889 requests for resubmission during the period 2017-2019 and 2 904 during the period 2014-2016 (Figure 12). In the previous report (2017-2019) it was suggested that the increase in resubmission requests compared with the period before (2014-2016) was probably the consequence of the increase in the number of export notifications accepted by DNAs (see section 4.2.1). However, in the present period (2020-2022) the number of export notifications accepted by DNAs has risen while the number of resubmission requests has fallen markedly. One possible reason for this may be that companies, in particular those who make multiple separate notifications, have a better understanding of the requirements and so make fewer mistakes.

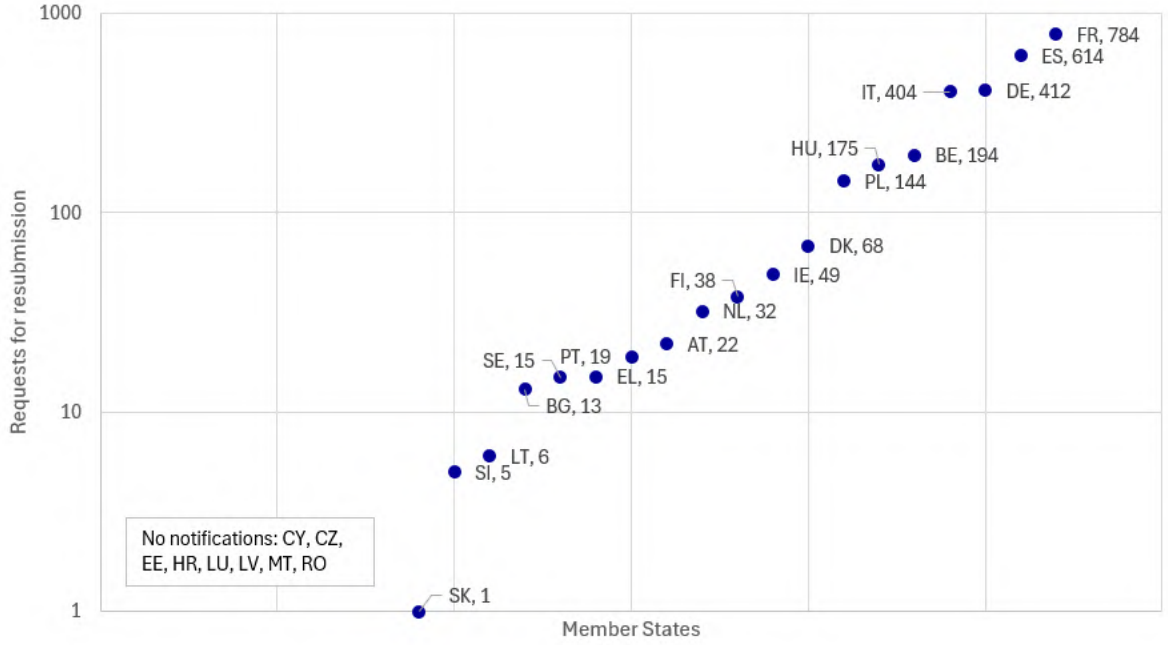
Figure 12. Number of resubmissions of export notifications requested by DNAs per year



As in the previous reporting period, variations between Member States in the number of resubmissions requested corresponded to variations in the number of notifications handled, i.e. Member States that handled a high number of notifications (e.g. FR, DE, BE, ES and IT) were also generally those that requested resubmissions more frequently (Figure 13).

[53] Corrected figure for this year provided by Slovenia. Previous report stated "0".

Figure 13. Number of resubmissions of export notifications requested by DNAs in the reporting period



As in the previous reporting period, the main reasons for requesting the resubmission of a notification were that information requirements were not met, or issues with the SDS attached to export notification. More specifically, Member States reported reasons for requesting resubmission as illustrated in Figure 14.

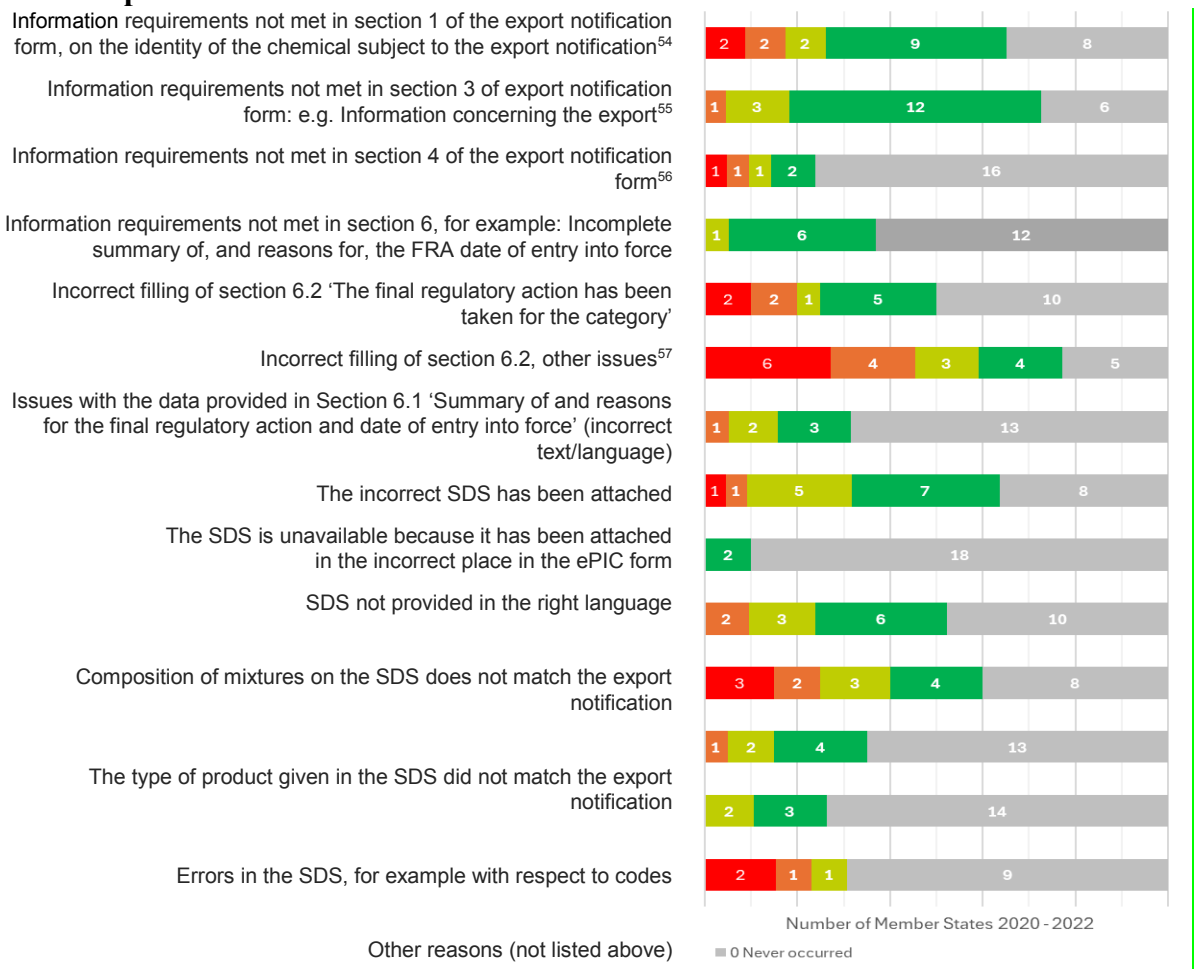
Note that not all Member States provided responses to every question where not judged to be relevant.

The other reasons comprised:

- Cases where the importing country explicitly stated that it does not wish to receive a particular chemical – cited as most frequent by 1 Member State;
- Discrepancy between inputs in Sections 3.3 (foreseen use) and 6.2 (allowed/prohibited uses). This was thought likely to be as a result of the exporter not consulting the user manual prior to filling out the form. Most of the times Section 6.2 contained product descriptions and not information on the prohibited/allowed uses in the EU of the PIC substance(s) triggering the notification obligation – cited as most frequent by one Member State;
- Delay in the payment of administrative fee – cited as next least frequent by one Member State;

Information requirements not met. Several export notifications for mixtures that contain only one and the same PIC substance in similar mixtures with different flavours when classification and labelling of the mixtures and the uses remain the same – cited as next least frequent by one Member State.

Figure 14: Question 20. Most frequent reasons for requesting resubmission of export notifications



The Agency requested the resubmission of 1 760 export notifications during the reporting period, compared to 2 758 in the period 2017-2019 and 609 in the period 2014-2016 (Figure 15). The trend is similar to that of resubmissions requested by DNAs (see Figure 12) – with a peak in 2018 and decreases in the last year of the reporting period, 2016 and 2019.

In 2020 and 2021, the main reason for resubmission requests was related to unclear or irrelevant information under Section 6.2 on prohibited and allowed uses. This was the reason for many cases in 2022. Other reasons for resubmission requests in 2020 were incomplete or incorrect importers' details, discrepancies between the information in the SDS and in the notification or incorrectly categorized intended uses.

In 2021, many notifications were sent back because of inconsistencies between the concentration of the PIC substance in the mixture as stated in the export notification (Section 2.5) and in the attached SDS, irrelevant information included in the section for the intended use in the importing countries, incomplete contact details for the importers, or unnecessary multiple submissions for the same mixture which only differed in the colour of the product. Similarly in

[54] For example, CAS number incorrect, concentrations incorrect, or incorrect name of product.

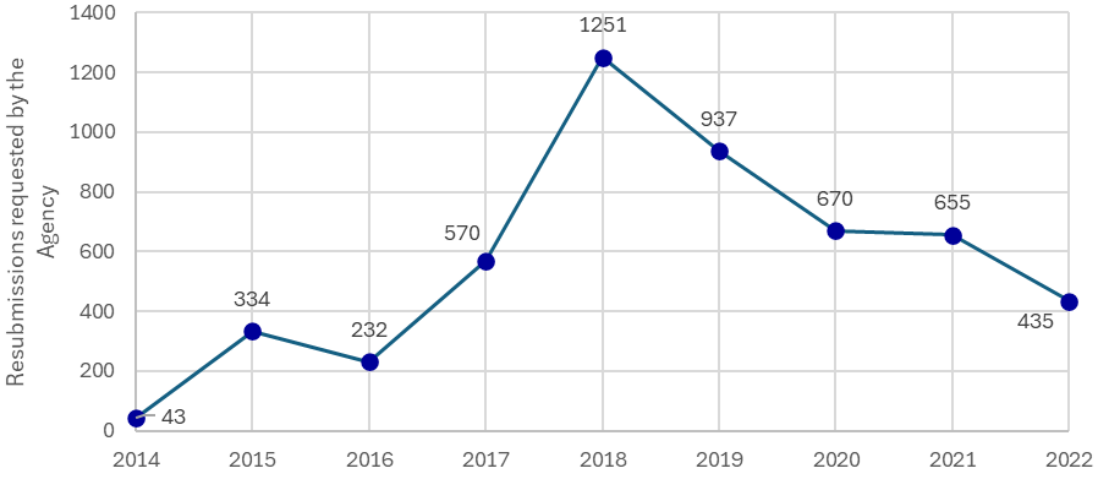
[55] For example, invalid phone nr., missing importer address; exporter incorrectly ticked emergency situation box to avoid 35-day waiting period.

[56] For example, information on hazards and/or risks of the chemical and precautionary measures, e.g. wrong classification.

[57] For example, Errors in allowed uses; Inadequate information provided on prohibited uses; Lack of clarity on the use of the exported chemical; Issues with section 6.2 'The final regulatory action has been taken for the category'.

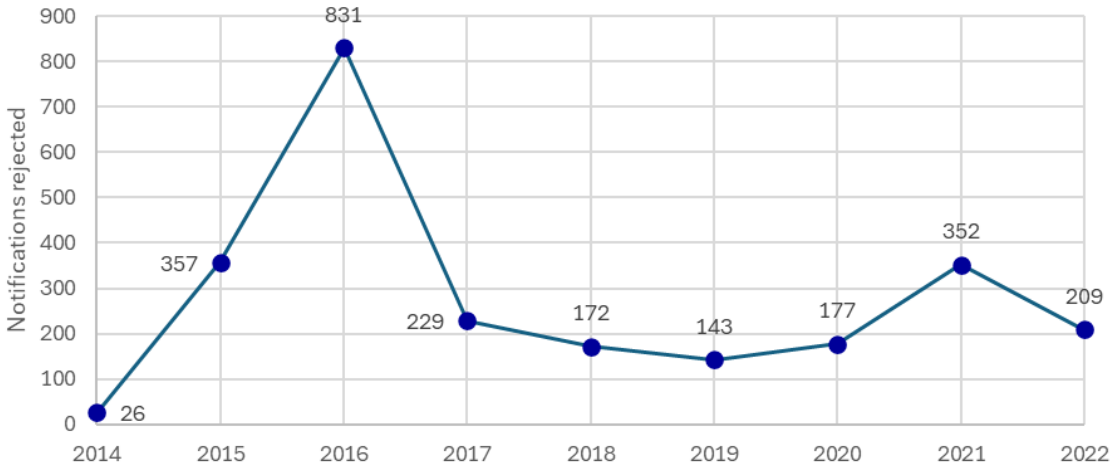
2022, many resubmission requests were due to inconsistencies between the concentration of the PIC substance in the mixture as stated in the export notification (Section 2.5) and in the attached SDS or because additional PIC chemicals were identified in the SDS that were not included in the notification.

Figure 15. Number of resubmissions requested by the Agency per year[58]



Member States rejected 738 export notifications during the reporting period, which is an increase from 544 in the period 2017-2019. Even so the overall level of rejections remains well below the peak experienced in 2016 (Figure 16).

Figure 16. Number of export notifications rejected by DNAs per year



As above, variations between Member States in the number of notifications rejected corresponded to variations in the number of notifications handled, i.e. Member States that handled a high number of notifications awee also generally those that rejected notifications more frequently (Figure 17).

As in the previous two reporting periods, the main reason reported by DNAs to reject a notification is the duplication of notifications (Figure 18). Other frequent reasons mentioned were that the notification was rejected at the request of the export company, or the information requirements were not met correctly.

[58] For 2014, data was only available after go-live of the PIC submission system (2 September 2014).

Figure 17. Number of export notifications rejected by DNAs in the reporting period

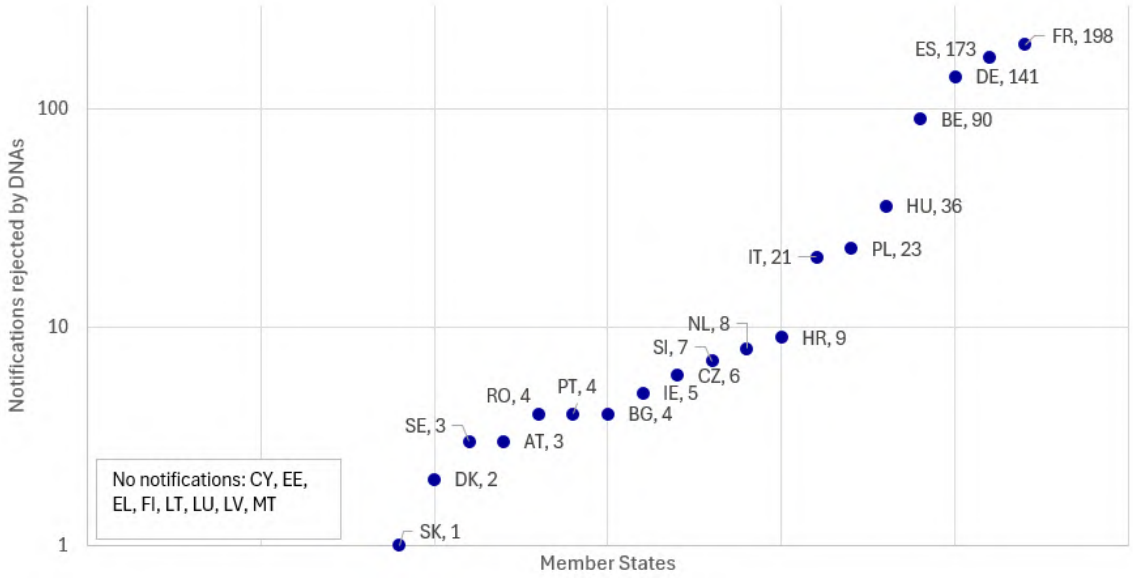
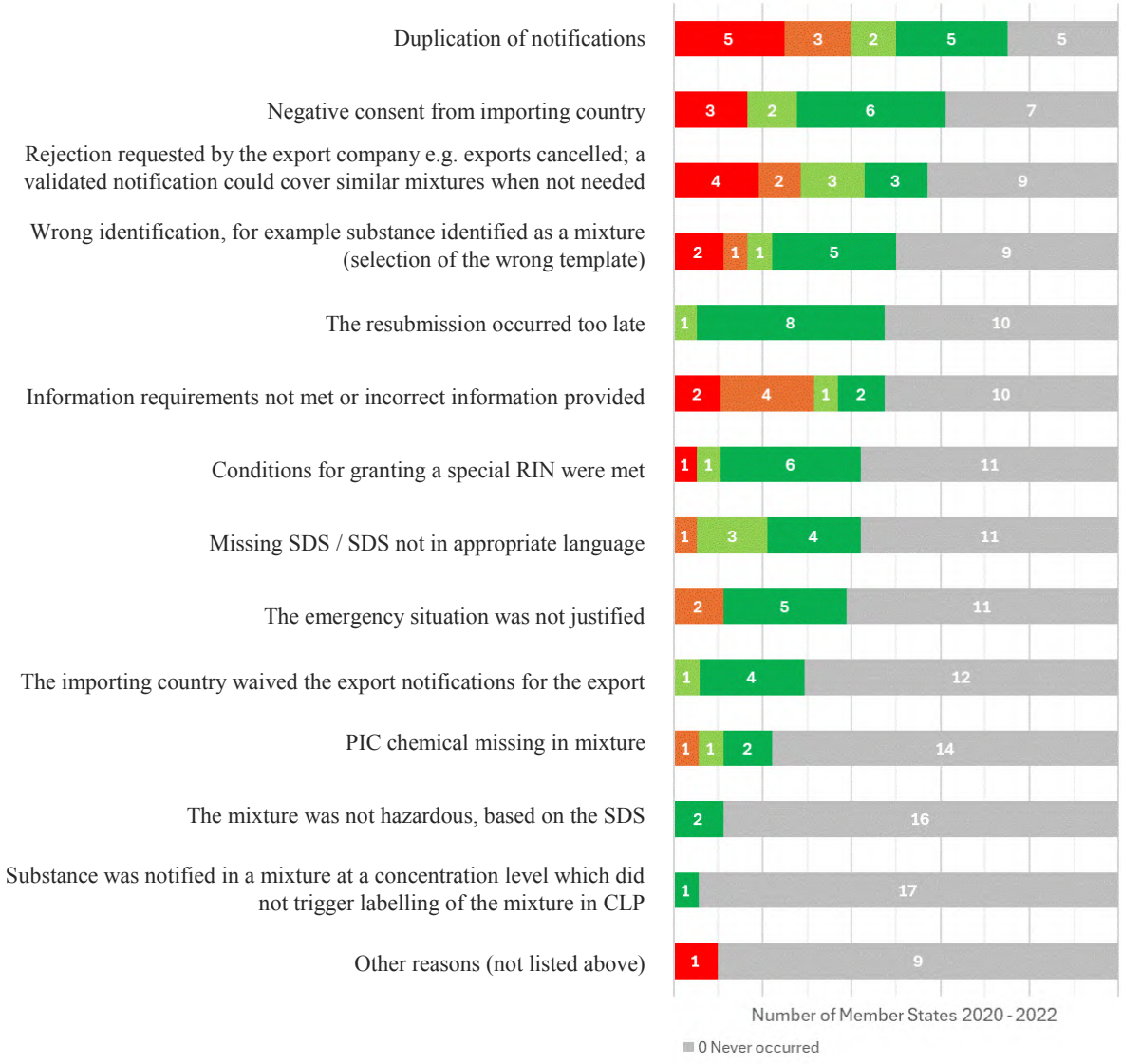


Figure 18: Question 20. Most frequent reasons for rejecting export notification

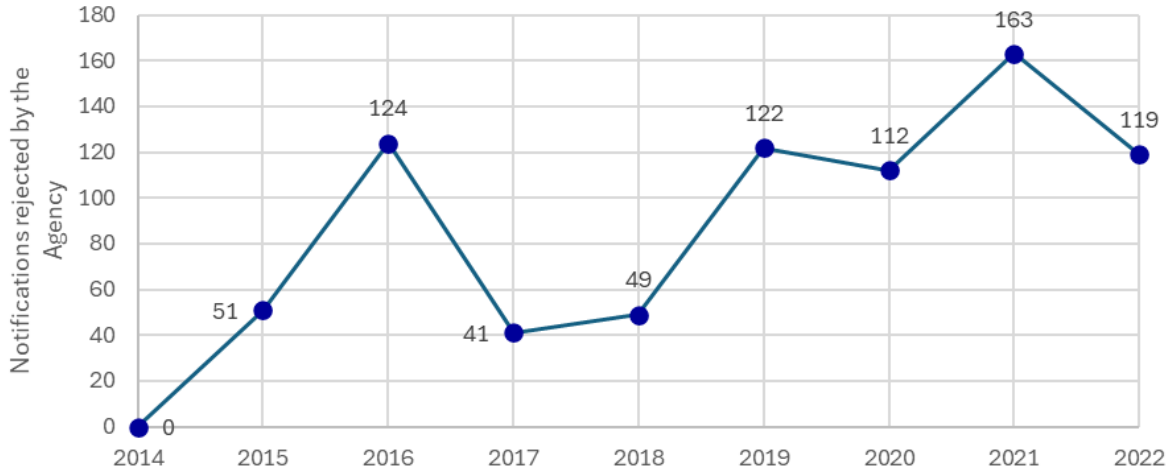


Note that not all Member States provided responses to every question where not judged to be relevant.

The only other, and most frequent reason for rejection regarded enforcement of Article 83 of the French law - EGALIM (Export ban of pesticides in mixtures for agriculture uses). A second reason for rejection was with regard to notification of treated seeds as articles.

The Agency rejected more notifications (394) during the reporting period than in the period 2017-2019 (212) (Figure 19) as did DNAs (Figure 16). The overall trend appears to be a gradual rise in rejections by the Agency.

Figure 19. Number of export notifications rejected by the Agency per year



Over the entire period, most rejections were due to unnecessary duplicate notifications. Other reasons which arose throughout the period were selection of the wrong template for the notification (e.g. mixture instead of pure substance or vice versa), and rejection owing to a mismatch between the stated importing country and the importer's address. In 2020 and 2022, rejections at the request of the exporting companies were mentioned. In 2020 and 2021, some notifications were rejected because they should have been submitted as special RIN requests.

4.2.4 Difficulties encountered in the export notification procedure

Difficulties encountered by exporters in completing the export notification form

According to the DNAs, exporters mainly experienced difficulties to provide information in the following areas:

- The availability of CN codes or CUS codes, and information on the export itself (such as the contact details of the importer) where there has been little or no improvement since the previous period, and
- The intended use of the chemical in the importing country where difficulties have fallen significantly.

There had been a particular reduction in reported difficulties concerning:

- Summary of and reasons for the final regulatory action and date of entry into force, and
- Information on the final regulatory action taken by the European Union.

Compared to the previous reporting, the number of Member States replying 'none' only increased by one (Figure 20) to 11. Of these, 7 Member States processed fewer than 100 notifications per annum, and the other 4 fewer than 300 notifications per annum.

Under 'other', the issue was improper completion of sections 6.2 and 6.3 of the form.

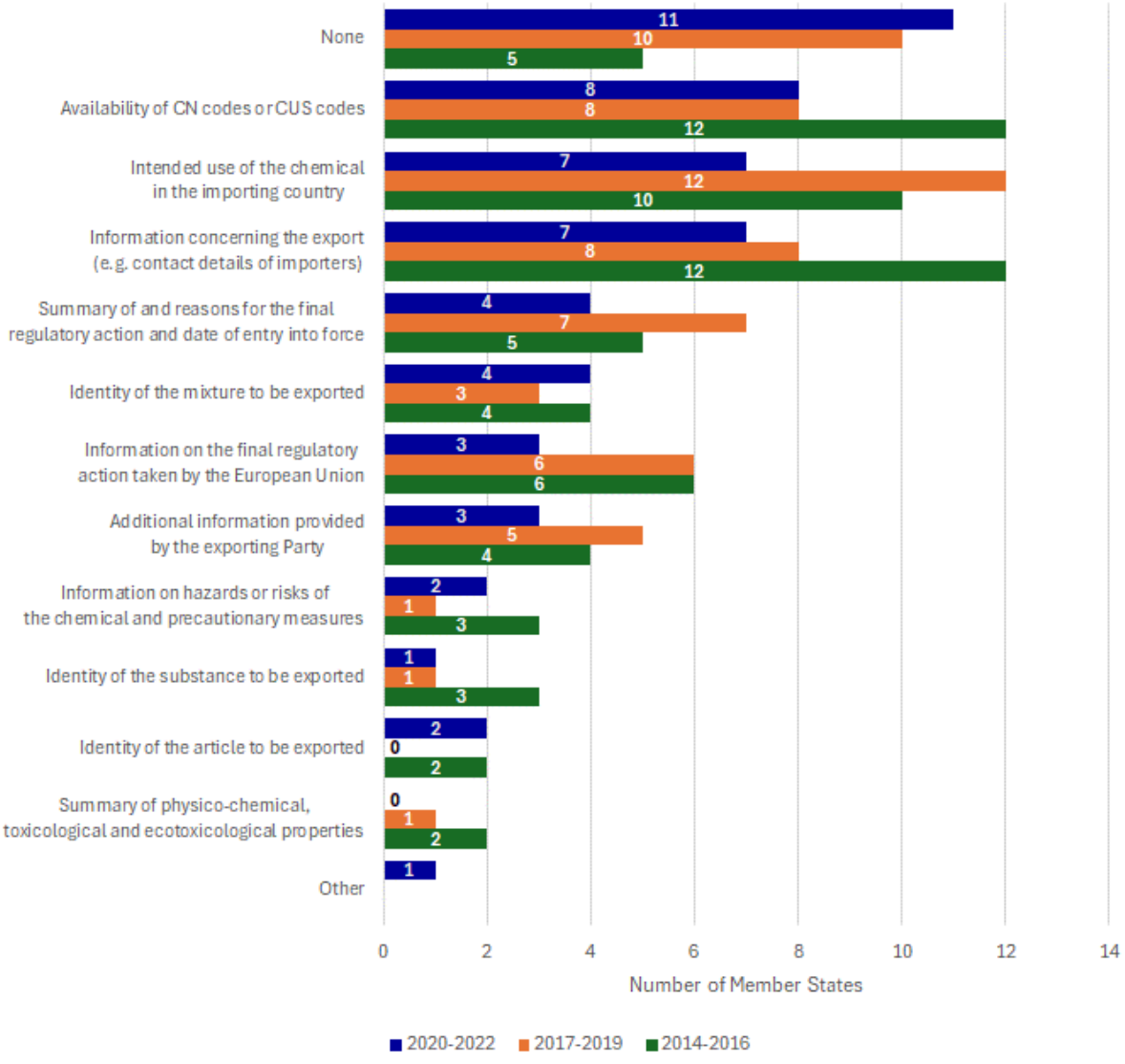
In addition to these issues, one or two DNAs highlighted difficulties with:

- Providing a current SDS and in the correct language;
- Clarity regarding section 6.2. Exporters were not clear that this section refers to Section 6.1;
- Export of plant protection products to Ukraine. In many cases the exporters do not provide the Ukrainian authorisation number.

When processing export notifications, the Agency noticed the following issues/ mistakes:

- "Prohibited and allowed uses" (Section 6.2): companies seemed unaware of the prohibited and/or allowed uses of the exported PIC chemical since the information provided was often incorrect or misleading, and sometimes reflected more the intended uses in the importing country rather than the regulatory status in the EU;
- Confusion on what was being exported and discrepancies of information between the notification and the associated SDS: The concentration of the PIC substance in the exported mixture (Section 2.5) did not correspond to the information provided in the SDS (Section 3); The selected export notification template (i.e. chemical, mixture, article) did not correspond the information provided in the SDS;

Figure 20. Question 19. What are the information requirements requested in the export notification form where exporters have difficulties in providing the information?



- Importer(s) details (Section 3.4): exporters often provided incomplete or incorrect contact details for the trade partners in the country of destination. They also often referred to importers who could not be identified/reached by the authorities of the importing country;
- The use category and foreseen use in the importing country: for exports of biocidal active substance/products there could be misunderstandings and complications in the processing, because the EU considers a biocidal use as a sub-category of the pesticides category, but many non-EU countries consider biocidal substances/products as industrial chemicals. Also, the foreseen uses in the importing country under Section 3.3 were often inadequately described, which might lead to misunderstandings and delays of the processing in the destination country.

As in the previous period, both the Agency and the DNAs highlighted Section 6.2 as a part of the notification where exporters experienced most difficulties in providing the requested information. It was also one of the main reasons for resubmission requests.

Complying with timeframes

According to the Agency, DNAs experienced difficulties in coping with the timeframe to forward the export notifications to the Agency. As shown in Table 16, the number of export notifications forwarded late remained relatively low compared to the total number of notifications processed (4.9% of the total). Whilst the number of notifications reduced steadily over the current reporting period (to 3.6%), there was no immediately obvious trend across the period 2014 to 2022.

Table 16. Number of export notifications received late by the Agency per year

Year	Number of late notifications	% of total yearly number of notifications
2014	6	1.2%
2015	348	6.4%
2016	371	4.7%
2017	312	3.7%
2018	880	9.1%
2019	594	5.9%
2020	640	5.7%
2021	619	5.5%
2022	378	3.6%
Total 2014-2016	725	4.9%
Total 2017-2019	1 786	6.3%
Total 2020-2022	1 637	4.9%

As mentioned in the previous period report, the Agency noticed that the difficulties of certain Member State DNAs to cope with the legal timeframe for the checking of export notifications usually appeared during and right after the peak submissions periods; i.e. in November/December/January months. This was especially the case when these coincided with holiday periods when very limited or no resources for processing were available. The situations in which the Agency received export notifications late, often related to re-submissions (the notification was sent back to the exporter for correction) without a request to change the export date, in which case the deadlines remained the same as for the initial submission. It was recommended that DNAs provide the companies with a clear deadline by when the re-

submission should be done at the latest, and possibly require a change of foreseen export date so as to allow sufficient processing time for both the Member State DNAs and the Agency. Alternatively, it could be considered that re-submissions are dealt with in the same timeframe as initial submissions (clock set back to 35 days) and ePIC adapted accordingly.

Three Member States (the same number as in the previous reporting period) reported difficulties in complying with a timeframe to forward the notifications to the Agency. In the previous period the three Member States were among those that process the largest number of export notifications (France, Germany and Italy). In the present period, Italy cited the same difficulty while Austria mentioned difficulties when companies notify very late and both DNA representatives were unavailable, and Portugal mentioned difficulty in ensuring payment of their administrative fee within the established deadline.

The Agency reported that the number of export notifications which were forwarded later than 15 days before the expected date of export specified in the notification had significantly decreased over the reporting period. The Agency had reminded Member State DNAs on several occasions (during DNA meetings, emails) about the importance to adhere to the legal deadlines so that enough time was provided to the authorities in the importing country to react to the notifications. Typically issues related to re-submissions and either a notification received from the DNA was already overdue (less than 15 days before the expected date of export) or very close to the due date or late. When the Agency noticed that the exporter had submitted the export notification on time and that the delay was due to late processing by the DNA, and provided that all the required information had been submitted, the Agency processed the late export notification immediately, in order not to further penalise the exporter and to allow the export process to continue.

Table 17. Number of export notifications processed late by the Agency per year

Year	Number of late notifications	% of total yearly number of notifications
2014	3	0.7%
2015	18	1.4%
2016	9	1.1%
2017	14	0.2%
2018	42	0.4%
2019	4	0.04%
2020	21	0.2%
2021	15	0.1%
2022	7	0.1%
Total 2014-2016	30	1.2%
Total 2017-2019	60	0.2%
Total 2020-2022	43	0.1%

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.

The Agency reported that more export notifications were submitted in accordance with Article 8(5) compared to previous reporting period (51 versus 15). Of these 22 were validated - these

cases mainly concerned disinfectants in relation to the Covid-19 pandemic. The other 29 were found not to meet the criteria described in Article 8(5) and were rejected by the Agency or by the Member State DNAs. The companies were asked to submit a new "standard" export notification instead. These rejected cases referred to situations where companies tried using the emergency notification to overcome the waiting period specified in Article 8(2), or the justification provided by the company was not found adequate.

During the reporting period, 4 Member States reported having to deal with an emergency situation:

- Germany's case concerned a component in a Covid-19 test. They noted that the *ECHA Guideline* states that a special RIN had to be generated, but pointed out that in reality an export notification plus additional proving papers must be generated in ePIC;
- Poland's case concerned the export of chloroform (CAS 67-66-3) used for the production of chemicals used various critical laboratory and industrial applications including those in hospitals, pharmaceuticals and environmental protection agencies;
- Slovenia's case concerned an urgent need for personal protective products in the destination country;
- Spain's case concerned disinfectant products containing didecyldimethylammonium chloride, (CAS 7173-51-5) required to combat the Covid-19 pandemic.

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.

As in the previous reporting period, the Agency received a high number of requests from authorities in importing countries to provide additional information or clarifications on exported chemicals. As in the previous reporting period, these requests 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.

Six DNAs (compared to five in the period 2017-2019 and eight in the period 2014-2016) received similar requests. Information requested by the importing countries related primarily to importer contact details but also substance concentrations. One DNA pointed out that in most cases, they have to correspond with the importing country until clarification is achieved and this requires time and resources. Responses for explicit consent and case studies were sometimes delayed by the DNA of importing countries or not provided making it extremely difficult for the exporters' DNA to work.

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.

Seven Member States requested an administrative fee for export notifications (Belgium, Bulgaria, Finland, Germany, Hungary (depending on the DNA), Portugal, and Slovenia) as in the previous reporting period. However, Greece no longer requested a fee. Fees vary greatly between Member States from EUR 35 to EUR 276, as compared to a range from EUR 25 to EUR 265 in the previous period.

As in the previous reporting period, four Member States required a fee for requests for explicit consent. Three of these (Finland, Germany and Portugal) were the same as in the previous period, however Bulgaria no longer required a fee. The new Member State requiring a fee was Greece (depending on the DNA concerned). Fees ranged from EUR 108 to EUR 276, as compared to EUR 25 to EUR 265 in the previous period.

As in the previous period, no complaints were reported regarding fees levied and these were generally not considered to have an impact on the number of notifications, although one Member State suggested the fee may deter precautionary notifications submitted (i.e. those which are not used).

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

The Agency must make available on its database the export notifications it receives from non-EU 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 (Article 9).

The Agency received 1 863 export notifications from non-EU countries in the reporting period, which is more than in the previous reporting period (1 371 notifications) (see Table 18). The number of notifications increased considerably across the reporting period from a low in 2020 to over twice that in 2022. The Covid-19 pandemic may have had an impact on the number of notifications in 2020, but the introduction during the period of the new entry "Benzene as a constituent of other substances in concentrations equal to, or greater than 0.1% by weight", is likely to have had a significant impact.[59]

Table 18. Export notifications received from non-EU countries and acknowledgements sent during the reporting period

	2020	2021	2022	Total
Export notifications received	381	671	811	1 863
Acknowledgements sent	82	506	470	1 058

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 United States of America (USA), based on a bilateral agreement, while the USA is the country sending the greatest number of export notifications to the EU, based on their national legislation and notwithstanding that the USA is not a Party to the Convention.

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 non-EU 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.

[59] Trade in products containing benzene increased EU imports of hazardous chemicals, ECHA/NR/23/34, 20 December 2024 https://echa.europa.eu/-/trade-in-products-containing-benzene-increased-eu-imports-of-hazardous-chemicals: "Substances containing benzene is the first "substance in substance" entry under the PIC Regulation, with 96% (18 845 530,34 tonnes) of imports reported in 2022 concerning these substances."

Delays in collecting information

Seven Member States (one more than in the previous reporting period[61]) stated that they experienced delays from exporters in the submission of information on the quantity of the chemical exported, requiring to send reminders.

Nine Member States (compared to five in the previous reporting period and eight in the period before that) indicated that they had experienced delays from importers in submitting their information. For both exports and imports issues that were reported by Member States, responses included:

- The sometimes needed to send out multiple reminders to report even after the reporting deadline (e.g. in April).
- Late submissions of reports from companies. An example was provided of having to take enforcement action to persuade one company to submit which they eventually did but only after the deadline.
- Orphan reports had to be addressed every year (statistics cannot be retrieved from ePIC).

Issues for reporting of exports included:

- Delays due to misunderstanding of obligation or sporadic use of ePIC. This included lack of awareness of the need to report actual quantities exported in the last year and that this also included the case where there were zero exports.
- One Member State noted that when an email address was updated by a company in the contact sheet it did not synchronise with the email address that appeared on a notification. Therefore, time was lost trying to use outdated emails addresses.

For reporting of imports, particular issues included:

- For one Member State, all companies importing from UK were not aware of the reporting requirement when it started (2021 imports).
- Importers were not always aware of their requirements and the need to provide the information via ePIC.
- Information on chemicals subject to the PIC regulation was received late at the national level. The ePIC system was closed at that time and it was technically impossible to submit this information.
- Delays owing to incomplete information from some of the companies mentioned in an import notification. There were delays as these companied were contacted to confirm the import and obtain the quantities imported in 2021.

Reporting through ePIC

No Member States reported difficulties in making their Article 10 submissions through ePIC. Only two Member States reported delays in doing so both citing missing information from exporters or importers – sometimes owing to holiday periods.

Based on the issues identified during the previous reporting period, the Agency improved the reporting functionality in ePIC by introducing warnings to potentially erroneous quantities to improve the quality of the data submitted by industry, and to assist the checking of the data by DNAs. It also prepared a checklist for DNAs to help them in verifying industry reports, and in submitting their national reports. The number of mistakes in quantities have decreased however, issues were still identified during the compilation of the EU-level report and corrections/clarifications were needed. The mistakes identified were typically related to very high quantities. A careful verification of industry data by DNAs before the aggregation and submission to the Agency was recommended.

Aggregating information at EU level

Unlike in the previous two reporting periods, the Agency did encounter delays from DNAs in receiving the aggregated national reports on the quantity of exported and imported chemicals by the agreed deadline (i.e. by the end of September) from some Member States. The Agency followed this up in each case by sending reminders and offering additional support (by phone, targeted emails with instructions on steps to take). Delays in receiving the national reports, and mistakes contained in them, continually led to inefficiencies, slowing down the Agency's preparations, compilation and publication of the EU-level reports, as well as requiring more support and hence resources from the Agency PIC Team.

The Agency recommended that DNAs monitor the progress of industry reports and follow-up the timely reporting and/or revisions by companies, as needed. It was apparent from the DNA's reports that in many cases diligent and timely efforts are made to effect this, but the required cooperation and response was not always forthcoming.

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 12 Member States. Five DNAs specifically mentioned the data is used by customs authorities. Eight DNAs indicated that the data are used for enforcement activities, with two specifying that it was used for checking compliance with REACH restrictions. This information was also shared with enforcement colleagues working on pesticides (PPPR and BPR) in two Member States.

4.5 Notification of banned or severely restricted chemicals under the Convention

Under 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, supported by the Agency, drafts the notifications, which are submitted to DNAs and observers for comments before being submitted to the Secretariat. Thirty-one notifications were submitted to the Secretariat during the reporting period: [60]

- 5-tert-butyl-2,4,6-trinitro-m-xylene (Musk xylene) (2022)
- Arsenic pentoxide (2022)
- Benzyl butyl phthalate (2022)
- Chlorothalonil (2021)
- Chlorpropham (2021)
- Chlorpyrifos (2022)
- Cybutryne (2020)
- Diisobutyl phthalate (2020)
- Dimethoate (2021)
- Diquat (2021)
- Ethoprophos (2021)
- Fenamidone (2022)
- Flupyrsulfuron (2020)
- Flurtamone (2022)
- Isoproturon (2020)
- Linuron (2020)
- Mancozeb (2022)
- Mercury (2022)
- Methiocarb (2022)
- Orthosulfamuron (2020)
- Oxasulfuron (2022)
- Propineb (2022)
- Pymetrozine (2022)
- Quinoxyfen (2022)
- Tepraloxydim (2022)
- Thiamethoxam (2022)
- Thiram (2022)
- Triasulfuron (2020)
- Triclosan (2020)
- Tricyclazole (2020)
- Tris(2-chloroethyl) phosphate (2020)

[60] https://www.pic.int/Countries/CountryProfiles/tabid/1087/language/en-US/Default.aspx, select region European Union, select tab 'Submissions' then 'Final Regulatory Actions' to see a list of "Notifications of Final Regulatory Action - Non-Annex III Chemicals"

4.6 Obligations in relation to importing chemicals (Article 13)

Under 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 EU import decision is adopted by means of an implementing act of the Commission. The Commission services draft 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 one implementing decision that provided new import decisions for phorate and hexabromocyclododecane, and amended existing decisions concerning two commercial brominated diphenyl ethers and PFOS (Table 19).

Table 19. EU import responses adopted during the reporting period

Implementing Act*	Chemical names	CAS number	Nature / status of decision	Import decision	Grounds for decision
(EU) 2020/2182 of 18 December 2020	Phorate	298-02-2	New decision / Final	No consent to import	Banned for use by PPPR
	Hexabromocyclo-dodecane	134237-50-6, 134237-51-7, 134237-52-8, 25637-99-4, 3194-55-6	New decision / Final	No consent to import	Banned for use by POPs Regulation
	Commercial pentabromodiphenyl ether including - tetrabromodiphenyl ether - Pentabromo-diphenyl ether	40088-47-9, 32534-81-9	Modified decision / Final	Consent to import only subject to specified conditions	Exemption for continued use for spare parts /upgrade in certain EEE provided by RoHS Directive
	Commercial octabromodiphenyl ether including: Hexabromodiphenyl ether Heptabromodiphenyl ether	36483-60-0, 68928-80-3	Modified decision / Final	Consent to import only subject to specified conditions	Exemption for continued use for spare parts /upgrade in certain EEE provided by RoHS Directive
	Perfluorooctane sulfonic acid, perfluorooctane sulfonates, perfluorooctane sulfonamides and perfluorooctane sulfonyls (PFOS)	1763-23-1, 2795-39-3, 29457-72-5, 29081-56-9, 70225-14-8, 56773-42-3, 251099-16-8, 4151-50-2, 31506-32-8, 1691-99-2, 24448-09-7, 307-35-7	Modified decision / Final	Consent to import only subject to specified conditions	Banned for use by POPs Regulation - specific derogation

* Commission Implementing Decision

Article 13(5) requires the DNAs to make EU import decisions available to those concerned within their competence. As in the previous reporting exercise, DNAs generally fulfilled this requirement by email, newsletters, or via their website. However, seven Member States indicated that they did make EU import decisions available.

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 late or no response from some importing countries as the continuing main difficulty. More Member States dealt with Article 14(6) and (7) provisions than in the previous period with a significantly increased volume of work which had proved challenging. Even so, the information provided by DNAs suggested that implementation problems were manageable.

The Agency reported no difficulties with the implementation of Article 14(8) and that the majority of the cases were processed following standard workflows within ePIC. No Member States had been requested by importing Parties to advise and/or assist them in obtaining further information needed to prepare a response to the Secretariat of the Rotterdam Convention concerning the import of a given chemical (Article 14(5)).

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. As in the previous reporting period, all DNAs fulfilled this requirement, mainly through emails and the provision of information on their website (Article 14(3)). One Member State also used the telephone, and another ran an annual workshop on chemicals management.

4.7.2 Explicit consent (Article 14(6))

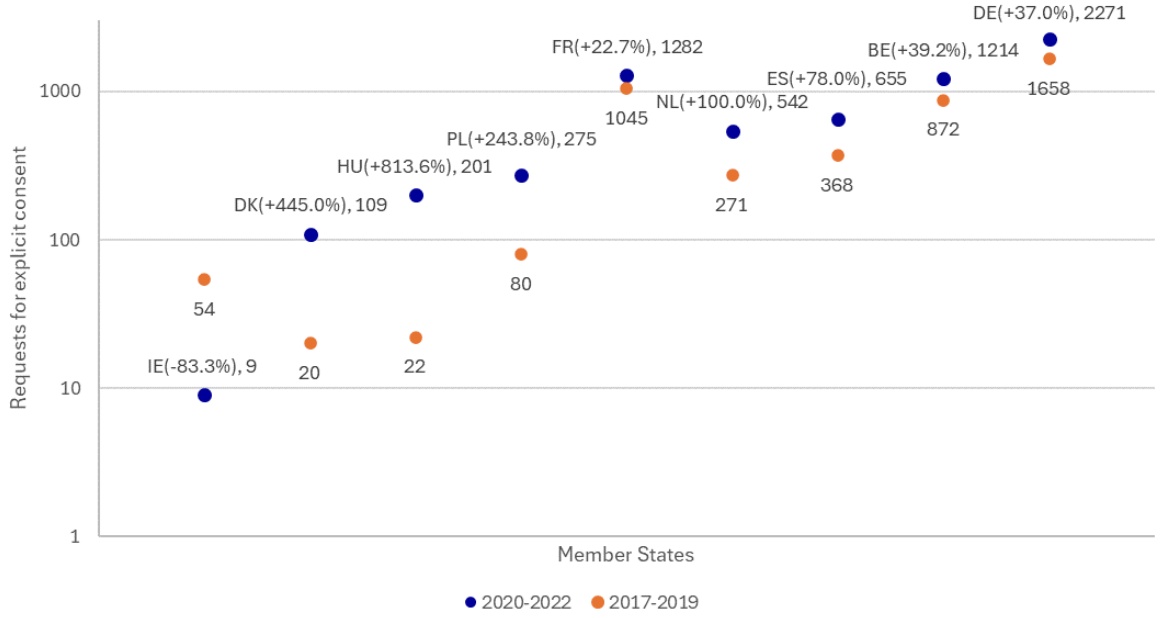
Nineteen Member States (one more than in the previous reporting period[61]) sought explicit consent from the DNA of the importing country, under Article 14(6)(a) of the PIC Regulation. A total of 7 233 requests for explicit consent were processed by DNAs in the present period compared with 5 058 in the period 2017-2019, and 3 362 in the period 2014-2016. As in the previous reporting period, the Member States that processed the highest number of requests were Germany, France, Belgium, Spain, and the Netherlands (Figure 21).

[61] Data for the UK has been excluded to enable proper comparison.

Figure 21. Number of requests for explicit consent processed by DNAs during the reporting period

In 13 Member States (out of 19), the number of requests processed by the DNA was higher than in the previous reporting period. In 8 Member States, the increase was quite significant as illustrated in Figure 22. 3 other Member States (Austria, Czechia and Slovenia) processed an additional 20 to 30 requests, and 2 (Italy and Slovakia) processed an additional 1 to 19 requests. Of the 5 Member States who processed fewer requests than in the previous, Ireland processed 45 fewer (a fall of 83%); the others 4 saw a fall of between 4 and 13 in requests processed.

Figure 22. Comparison of number of requests for explicit consent processed by DNAs during the present period versus the previous period for those DNAs experiencing the greatest change. (% change shown in parentheses)



As the Agency reported, of the 7 233 requests for explicit consent, 58% of the requests received responses, following either the initial request, the first or the second reminder - a slight rise from 54% in the previous period. In 17% of cases, the response was received after the first reminder (see Table 20) and did not require a second reminder to be sent. The overall response rate increased by 4% compared to the previous reporting period, and even though it still

remained rather low, the system of reminders – of which the vast majority were triggered and sent automatically - was considered effective and efficient.

Table 20. Reminders for explicit consent requests sent by the Agency during the reporting period

Year	First reminder	Second reminder
2020	1 679	1 201
2021	1 388	1 013
2022	1 718	1 196
Total	4 785	3 410

During the reporting period, there were 64 instances across five Member States 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 21). This compared with just 14 such instances during the previous period from two Member States (Germany and Spain).

Table 21. Number of requests for explicit consent pursuant to Article 14(6)(b)

Member State	2020	2021	2022	Total
Germany	1	8	10	19
Hungary	0	0	1	1
Ireland	1	0	0	1
Romania	1	0	1	2
Slovenia	10	18	13	41

Difficulties encountered in the implementation of the explicit consent procedure

10 Member States reported having experienced difficulties in implementing the explicit consent procedure, three more than in the previous period. As in the previous report the main challenges reported concerned communication with DNAs of importing countries. In general, these concerned difficulties in getting in contact with the relevant DNAs and lack of response - sometimes no response at all from certain countries even after multiple and explicit requests; responses which were inadequate either because they did not answer the question, were unclear, or provided irrelevant information; lack of understanding of the EU Regulation on the part of the contacts concerned. In addition, certain countries imposed additional national rules that caused further delays. One Member State commented that implementation of the explicit consent procedure remains the main challenge for both DNAs and industry too: “In many cases, the DNAs still did not receive answers from the importing country and the 60-day waiting period is a significant burden for the industry to be able to request a waiver."

Also mentioned were the difficulties of having to use websites indicated by the importing DNA to verify the possibility of export when this was available only in the domestic language. One Member State experienced some difficulties with the consents for biocidal products where the import authorities were confused with the pesticide use for biocidal products and for phytosanitary products. This arose mainly with Central American and Middle Eastern countries.

To improve the processing of requests for explicit consent, one DNA suggested (as in the previous period) that it would be useful for processing DNAs to receive an email alert from ePIC indicating when responses to explicit consent requests had not been received after 30 and 60 days. This would allow the DNA to advise companies in relation to waivers.

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). As in the previous reporting period, the Agency considered that this process was working smoothly and that collaboration with DNAs in cases where the interpretation of the explicit consent is difficult was effective. An on-line workshop with DNAs was organised on 17 November 2021 on the explicit consent management. According to the feedback received from DNAs, defining the validity period and some specific restrictions (i.e. RIN-specificity, exporter-specificity) were the most challenging elements in the interpretation of the responses. According to the Agency, the process contributed to harmonised data and the reduction of clerical errors during the procedure.

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

When an exporter submits a waiver request, their Member State DNA checks it and, if they approve, it is sent to the Commission for final verification/approval. Once approved, the Agency will then be tasked to activate the related RIN(s) should there be any pending exports which match the criteria for the waiver.

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.

11 Member States (compared to 8 in the period 2017-2019, and 6 in the period 2014-2016) 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 (5 other Member State DNAs stated that they were not required to make a decision, and the remaining eleven indicated that they did not receive any such export notifications. No Member States reported difficulties in taking this decision.

Table 22).

Five other Member State DNAs stated that they were not required to make a decision, and the remaining eleven indicated that they did not receive any such export notifications. No Member States reported difficulties in taking this decision.

The number of cases varies greatly between these Member States. 6 Member States (DK, FI, EL, HU, PL and ES) reported a handful of cases (between 2 and 6). The other 5 reported in excess of 20 cases (BE, FR, DE, IT and SI). In the previous two periods the largest number of cases were reported by Italy (30 in the period 2017-2019, 49 in the period 2014-2016) and this continued with 35 cases in the present period. Belgium at 32 and France at 28 experienced similar levels of cases.

5 other Member State DNAs stated that they were not required to make a decision, and the remaining eleven indicated that they did not receive any such export notifications. No Member States reported difficulties in taking this decision.

Table 22. 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	2020	2021	2022	Total
Belgium	18	8	6	**32**
Denmark	2	0	1	**3**

Member State	2020	2021	2022	Total
Germany	2	6	13	**21**
Greece	2	0	0	**2**
Spain	2	3	0	**5**
France	12	14	2	**28**
Italy	11	11	13	**35**
Hungary	2	0	0	**2**
Poland	0	3	3	**6**
Slovenia	0	10	11	**21**
Finland	2	4	0	**6**

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.

Fifteen Member States (compared to thirteen in the period 2017-2019, and eleven in the period 2014-2016) received waiver requests in accordance with Article 14(7) during the reporting period (see Table 23). The number of waiver requests received by DNAs varies greatly between Member States, from one request in Bulgaria to 333 in Belgium (compared with 148 in the previous period). Overall, the number of waiver requests has risen from 571 to 1 328.

Table 23. Number of waiver requests received per Member State during the reporting period

Member State	2020	2021	2022	Total
Belgium	167	114	52	333
Bulgaria	0	0	1	1
Denmark	8	17	16	41
Germany	62	34	185	281
Greece	13	23	0	36
Spain	29	36	42	107
France	111	60	23	194
Italy	10	13	25	48
Hungary	14	22	7	43
Netherlands	38	96	17	151
Austria	1	2	0	3
Poland	4	7	12	23
Slovenia	10	11	11	32
Finland	2	2	4	8
Sweden	13	3	11	27
Total	482	440	406	1 328

Only one Member State stated that they experienced difficulties in implementing the waiver procedure and this concerned lack of response from the importing country.

The Commission generally considered that the waiver procedure worked smoothly during the reporting period, and that collaboration with the DNAs was positive. However, the Commission mentioned that the quality of the evidence provided by exporters to demonstrate that the conditions of Article 14(7) are met could still be improved.

The Agency considered that, overall, the process was working smoothly and improvements were identified and implemented to address the inefficiencies reported during the two previous reporting periods. In particular, changes were introduced in ePIC to support a more efficient workflow. More specifically, the waiver submission wizard was updated to prompt companies to upload a mandatory cover letter explaining the nature/validity of the alternative evidence and a translation (when necessary) to improve the quality/completeness of the documentary evidence. Flags were also introduced to the DNA task to prevent clerical mistakes and acceptance of standard waivers in the absence of an explicit consent request. The whole workflow was made transparent so that the different stages of the approval process is now visible to companies. In addition, the waiver factsheet was updated to better describe the conditions and the required evidence/supporting documents, and a link to this factsheet was included within the waiver submission wizard/tasks in ePIC.

Although further clarifications/follow-up actions of individual cases had decreased, the efficiency of the process could still be further enhanced. Additional IT improvements could be considered in both industry and authority tasks in ePIC, to further improve the quality of the evidence provided by companies and the identification of waiver conditions.

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

According to the procedure described in Article 14(8), 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.

Ten Member States experienced cases where the export was allowed to proceed pending a reply to a new request for explicit consent (see Table 24). This compared with fourteen cases in the previous period.[61] The total number of cases was 181 compared with 569 in the previous period. The highest number was reported by Belgium with 56 compared with 42 in the previous period. Cases in France fell from 193 in the previous period to 21, and Germany from 163 to 49.

Table 24. 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	2020	2021	2022	Total
Belgium	4	15	37	56
Denmark	0	1	1	2
Germany	13	11	25	49
Greece	0	3	1	4
Spain	6	9	14	29
France	5	12	4	21
Italy	1	0	0	1
Hungary	0	1	0	1
Poland	4	4	7	15

Member State	2020	2021	2022	Total
Finland	0	1	2	3
Total	33	57	91	181

The Agency reported no difficulties and that the majority of the cases were processed following standard workflows within ePIC. However, certain cases still required specific assessments and exchanges with the concerned Member States. This is marked improvement from the previous period when implementation of Article 14(8) was seen as challenging. This would indicate that the closer agreement between the Agency and DNAs and the related enhancements in ePIC functionality, reported in the previous period, have borne fruit.

4.8 Information on transit movement (Article 16)

None of the Member States implemented Article 16 during the reporting period as in the previous two reporting periods.

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. Only three Member States reported compliance issues. Another 15 stated they had no issues, 5 said this not applicable, and 4 did not know.

Compliance issues relating to packaging and labelling requirements

The national enforcement authorities in three Member States (compared to six in the previous reporting exercise) experienced compliance issues concerning the information accompanying exported chemicals. In each case, the issues reported were different; CLP, BPR and in the other case it was an unspecified customs matter. By contrast, in the previous reporting exercise, five Member States reported issues linked to CLP.

Compliance issues with the SDS and the language(s) of the label or SDS

Only two 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, on the label (one Member State) and on the SDS (one Member State).

Compliance issues concerning the information and packaging requirements linked to the exported products

Finally, only one Member State reported experiencing compliance issues regarding the information and packaging requirements linked to the exported products. This concerned a product containing a POP substance (mercury containing lamps) under Annex V.

4.10 Enforcement of the PIC Regulation (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 showed that all Member States had put in place a system to ensure compliance with the PIC Regulation. All Member States had nominated authorities responsible for the enforcement of the PIC Regulation (in most Member States, this was the customs authority and the environmental/health inspectorate). Twelve Member States had put in place an enforcement strategy (including rules of procedures, written instructions, etc.), down from sixteen in the last reporting period.[61] Some Member States indicated this was because the enforcement was in place and did not require development. Twelve Member States had established regular training of inspectors and some others include PIC as an occasional topic in general chemicals regulatory training. For the first time, a couple of Member States indicated that training was not carried out due to lack of resource or financial constraints.

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

4.10.1 National enforcement authorities (NEAs)

Most Member States had several authorities in charge of enforcing the PIC Regulation. Customs were involved in the implementation of the PIC regulation in all Member States except Denmark, which was a change since the last reporting period. Malta did not involve customs in the past, whereas Denmark did. In 5 countries, the customs administration was the only NEA (Italy, Slovakia and Spain, Luxembourg, Sweden). In the previous reporting period, this was the case in 6 Member States[62]. Czechia, Poland, and Latvia previously had only the customs administration but had expanded enforcement to other authorities. Conversely, Luxembourg and Sweden had other enforcement authorities involved in the past and now no longer did.

Enforcement authorities were typically environmental, chemical and/or health inspection services. In 9 Member States, the NEA was part of the same institution as the DNA. In almost all the Member States, authorities involved in the enforcement of the PIC Regulation were also typically involved in the enforcement of the CLP Regulation (24 Member States), the REACH Regulation (24 Member States), and the BPR (20 Member States). 13 Member States were also involved in enforcing PPPR.

12 Member States (compared to 15 in the previous reporting period, and 18 in the first reporting period) indicated that NEAs had sufficient resources to carry out their obligations under the PIC Regulation, while 10 (compared to 8 in the previous reporting period and 7 in the first reporting period) stated they do not have appropriate resources. Where reasons were given, they related to the lack of financial resources and lack of people, in particular in enforcement.

[62] Czechia, Italy, Latvia, Poland, Slovakia and Spain.

4.10.2 Training inspectors

12 Member States (compared to 16 in the previous reporting period and 15 in the first reporting period) indicated that inspectors were regularly trained on the PIC Regulation.[61] Among the Member States that had organised regular training, seven mentioned training activities addressed to inspectors, and three mentioned training activities addressed to customs' officers. Seven stated that such training was included as part of general training on chemicals legislation. DNAs mentioned various types of activities, including meetings, workshops and specific training for new inspectors.

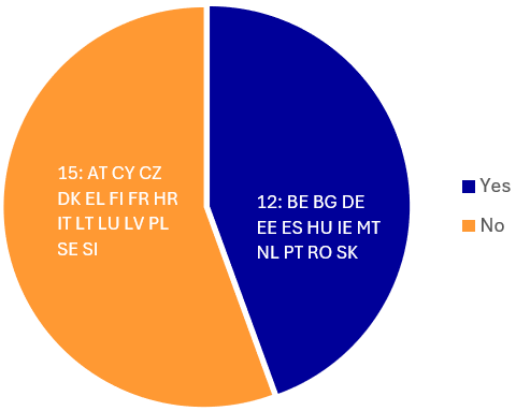
Most Member States that had not organised regular training on the PIC Regulation explained either that training was done on a more ad-hoc basis (such as meetings, internal exchanges). Some said training was not carried out due to lack of resources / financial burden. Others said training had not been requested / was not necessary. Some said that training covered chemicals related regulation more generally and PIC was only occasionally covered or had not been covered in this period. Some suggested EU level webinars and workshops, and mutual learning such as through an enforcement expert group, for example using the Forum for Information Exchange on Enforcement.

4.10.3 Enforcement strategy

12 Member States reported having a strategy for the enforcement of the PIC Regulation, down from 15 in the previous reporting period. [61] 8 Member States had fully implemented their strategies. 3 Member States had partially implemented their strategies and one was just beginning. 2 Member States with partially implemented strategies did not have strategies in the previous reporting period.

6 Member States had a strategy in the last reporting period and now no longer did. Of these 2 explained that their existing processes worked well. 2 cited lack of funds as the reason, 1 said they planned to have a future strategy, and 1 said the organisation responsible for enforcement was not the correct organisation to determine strategy.

Figure 23. Question 62. Does your authority (or any other relevant authority) have an enforcement strategy for Regulation (EU) No 649/2012?

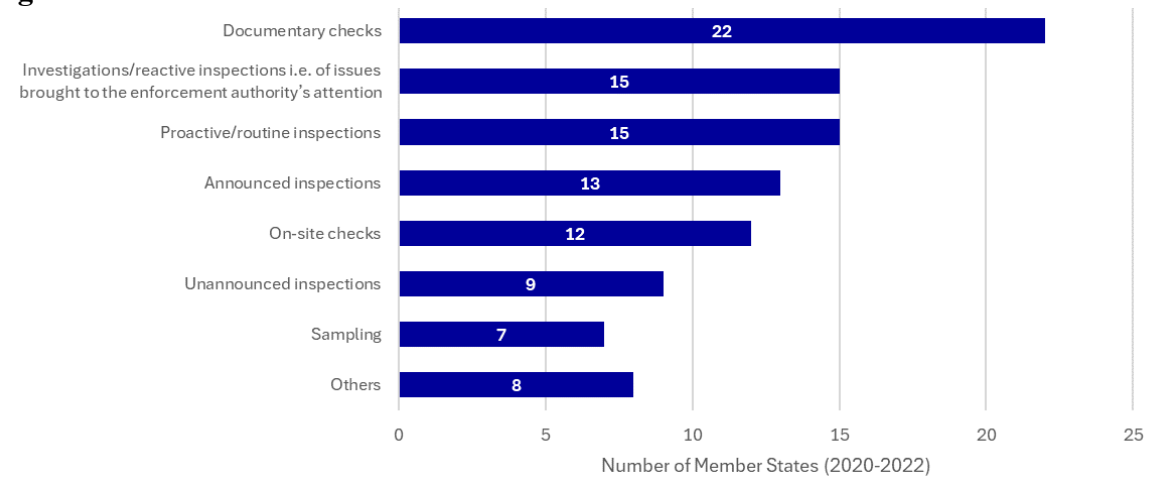


4.10.4 Enforcement activities

During the reporting period, documentary checks were carried out in around 80% of the Member States (22). More than half investigate or conduct reactive inspections (i.e. of issues

brought to the enforcement authority's attention) or conduct proactive inspections. Fewer than half reported carrying out announced or unannounced inspections or on site checks (Figure 24).

Figure 24. Enforcement activities carried out in Member States



8 Member States mentioned other enforcement activities, which were:

- Customs, Inspection and examination of documents, including:
  - Verifying in the ePIC database the status of the RIN or special RIN for the exported chemicals, which exporters are obliged to provide in the export declaration;
  - Controlling the compliance with packaging and labelling conditions,
  - Checking the required documents, e.g. attaching the safety data sheet,
  - Post-analysis of the previous year importations and contact/visits to companies if considered necessary;
- Answering questions of companies;
- Proactive ePIC search, such as analysis of previous year and conducting visits if considered necessary;
- Inspection of companies on other chemical regulation (CLP, BPR, PPPR) might give rise to a PIC concern, which is then also investigated;
- Interaction with the DNA to assess if substances are biocides/PIC chemicals or not.

One Member State said all possible methods could be used, but the method chosen depended on the situation. Another Member State referred to the powers provided to customs in Regulation No. 952/2013 to indicate the powers available.[63]

Table 25. 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
Belgium	1 820	30	N/A
Bulgaria	40 425	N/A	N/A
Czechia	N/A	N/A	N/A
Denmark	0	0	0
Germany	3	45	0
Estonia	0	0	0
Ireland	35	0	0

[63] Regulation (EU) No 952/2013 of the European Parliament and of the Council of 9 October 2013 laying down the Union Customs Code, https://eur-lex.europa.eu/eli/reg/2013/952/oj

Member State	Customs	Inspectors	Others
Greece	0	0	0
Spain	42 168	0	N/A
France	325	N/A	N/A
Croatia	1 320	0	0
Italy	220	N/A	N/A
Cyprus[64]	5	5	0
Latvia	65	0	N/A
Lithuania	0	0	0
Luxembourg	0	0	0
Hungary	18	82	N/A
Malta	N/A	0	N/A
Netherlands	282	42	0
Austria	N/A	87	N/A
Poland	N/A	N/A	N/A
Portugal	1 512	0	0
Romania	N/A	10	0
Slovenia	1 180	82	0
Slovakia	0	0	0
Finland	3 930	0	N/A
Sweden	N/A	N/A	N/A

In relation to the above table, various Member States provided explanations for their responses of N/A or zeroes:

- Austria indicated that chemical inspectors and customs authorities check compliance with Regulation (EU) 649/2012 in course of their routine inspections, but numerical data on official controls by the customs authorities are not available.
- Greece indicated that 400 inspections are carried out every year, but they are not focussed on PIC.

The following comments were provided against Table 25 above for exports, and Table 26 below for imports:

- Although Poland indicated inspections are not applicable, the Chief Sanitary Inspectorate carried out controls at the end of 2021 and the beginning of 2022. There was no available information on how many controls were in each year. 60 companies were controlled against classification and labelling, SDS, and reporting under Article 10 (import, export). It was not specified if the controlled companies were exporters or importers. There was no precise information from the National Revenue Administration about export controls covering PIC chemicals because it was impossible to filter the amount of the above-mentioned controls in customs declaration systems.
- Ireland noted extensive inspections were carried out under CLP, BPR and PPPR, but not specifically for PIC. However, any issues discovered regarding PIC would be investigated also.

[64] Cyprus indicated the numbers are on average.

- In Romania, the customs authority did not carry out official controls, it had the competence to carry out customs control according to national and EU legislation. According to the Agency project, REF-10 from 2022, the inspection plan was aimed at the integrated control of chemicals in products.

In Table 26 concerning imports, several Member States noted that there was no statistical data available on imports. One explained this was because there is no obligation for a notification for import, so there were no controls for import by Customs or Inspectors. Inspections on imports by Customs and/or REACH/CLP/POP/BPR inspectors were only required for the REACH/CLP/POP/BPR legislation. In addition:

- Bulgaria noted that during the reporting period, inspectors reported 178 inspections carried out in relation to imports. During the period, 12 non-conformities were identified according to the legislation.
- Portugal noted that in addition to the individual controls undertaken by each enforcement entity, joint controls have been made by The General Inspectorate (IGAMAOT) and Customs.

Table 26. Number of official controls on imports in which the PIC Regulation was covered or enforced during the reporting period, by Member State

Member State	Customs	Inspectors	Others
Belgium	N/A	N/A	N/A
Bulgaria	N/A	178	N/A
Czechia	N/A	N/A	N/A
Denmark	0	0	0
Germany	0	9	0
Estonia	0	0	0
Ireland	N/A	719	N/A
Greece	0	0	0
Spain	58 177	0	N/A
France	0	N/A	N/A
Croatia	0	0	0
Italy	46	N/A	N/A
Cyprus[65]	10	10	0
Latvia	0	81	N/A
Lithuania	0	0	0
Luxembourg	0	3	0
Hungary	0	31	N/A
Malta	N/A	N/A	N/A
Netherlands[66]	0	N/A	0
Austria	N/A	N/A	N/A

[65] Cyprus: Numbers are on average

[66] Netherlands: Inspectors from another NEA were responsible for enforcing the PPR. If an import notification of PPR was received by the ILT, these colleagues would be informed.

Member State	Customs	Inspectors	Others
Poland	N/A	N/A	N/A
Portugal	1 066	25	40
Romania	N/A	6	0
Slovenia	0	20	0
Slovakia	0	0	0
Finland	N/A	0	N/A
Sweden	N/A	N/A	N/A

As part of its report, the Agency provided estimates of the use of the ePIC customs interface by DNAs. They reported that users from 22 Member States consulted the application:

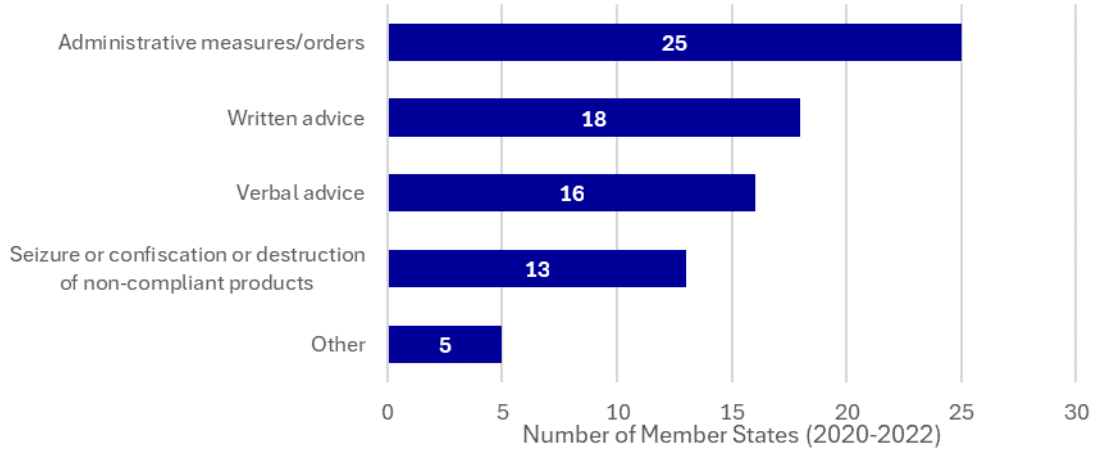
- 1 Member State checked more than 2 000 individual notifications
- 1 Member State checked ~1 000 individual notifications
- 2 Member States checked between 600 and 700 individual notifications
- 1 Member State checked ~275 individual notifications
- 5 Member States checked between 100 and 200 individual notifications
- 3 Member States checked between 50 and 100 individual notifications
- 4 Member States checked between 10 and 50 individual notifications
- 5 Member States checked less than 10 individual notifications

Overall, the trend is that fewer checks were carried out using ePIC during this period compared to the previous period.

4.10.5 Powers of enforcement authorities

Member States were asked to describe the measures that enforcement authorities can take to ensure compliance with the PIC Regulation (Figure 25). In nearly all Member States (25), administrative measures / orders could be used by enforcement authorities to ensure compliance with the PIC Regulation. Two thirds of Member States (18) provided written advice, and slightly over half of the Member States (16) indicated they can use verbal advice. Just under half (13) could seize, confiscate or destroy non-compliant products.

Figure 25. Measures that can be taken by enforcement authorities to ensure compliance with the PIC Regulation



Other measures mentioned by Member States (most common first) include:

- Notifying law enforcement, lawsuits and fines;

- Withdrawal of the goods from the market / sanctions;
- Does not clear customs / goods not released to the market;
- Discussions with the DNA and requirement to rectify deficiencies;
- Documentary controls; and
- Testing of goods.

4.10.6 Infringements during the reporting period

Infringements found through Customs' controls

Seven Member States (compared to five in the previous reporting period and three in the first reporting period) reported identifying infringements through customs controls (Belgium, Bulgaria, Croatia, Finland, France, Italy and Latvia) (see Table 27). The number of infringements was very low (0.3%, assuming no overlap between controls on exports and on imports[67]) compared to the number of customs controls performed.

Table 27. Number of customs controls and infringements observed during the reporting period

Member State	Controls on exports	Controls on imports	Infringements found
Belgium	1 820	N/A	97
Bulgaria	40 425	N/A	255
Germany	3	0	0
Ireland	35	N/A	0
Greece	0	0	0
Spain	42 168	58 177	N/A
France	325	0	14
Croatia	1 320	0	41
Italy	220	46	4
Cyprus	5	10	0
Latvia	65	0	1
Hungary	18	0	0
Netherlands	282	0	0
Austria	N/A	N/A	N/A
Poland	N/A	N/A	0
Portugal	1 512	1 066	0
Romania	N/A	N/A	0
Slovenia	1 180	0	0
Finland	3 930	N/A	2

Infringements found through Inspectors' controls

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 (Table 28). The number of infringements compared to the number of controls varied greatly across the 6 Member States,

[67] As there may be overlaps between the numbers of controls performed on exports and imports this is evidently only an indicative figure useful for comparison.

but was generally higher compared to the ratio shown above for customs controls: - 5.4%, assuming no overlap between controls on exports and on imports.[67]

Infringements found through other controls

Only Spain reported infringements found via controls performed by other authorities (24 in total for the reporting period).

Table 28. Numbers of controls carried out by inspectors and infringements observed during the reporting period

Member State	Controls on exports	Controls on imports	Infringements found
Belgium	30	N/A	5
Bulgaria	N/A	178	N/A
Germany	45	9	26
Ireland	0	719	0
Croatia	0	0	0
Cyprus	5	10	0
Latvia	0	81	21
Luxembourg	0	3	0
Hungary	82	31	11
Netherlands	42	N/A	0
Austria	87	N/A	16
Poland	N/A	N/A	N/A
Portugal	0	25	0
Romania	10	6	0
Slovenia	82	20	0
Finland	0	0	4
Sweden	N/A	N/A	N/A

Types and numbers of infringements

As shown in Table 29, the main category of infringement found by customs related to Box 44 of the single administrative document not being properly completed (60 infringements) and the absence of a RIN (46 infringements).

Table 29. Types and numbers of infringements of the PIC Regulation observed by customs during the reporting period

Type of infringement	BE	FI	FR	HR	LV	ES
No export notification provided for the chemical	0	0	0	0	0	0
Chemical not in conformity with export notification	0	0	0	0	0	0
No RIN provided (Article 8)	22	0	4	0	0	20
RIN not valid during export period (Article 8)	5	1	0	0	0	4
Box 44 of the single administrative document not properly filled in accordance with provisions (Article 19 (1))	16	0	3	41	0	0
Expiry date of the chemical	0	0	0	0	0	0
Packaging provisions (Article 17(1))	0	0	0	0	0	0
Labelling provisions (Article 17(1))	0	0	0	0	0	0
Safety Data Sheets provisions (Article 17(3))	0	0	0	0	0	0
Language provisions (Article 17(4))	0	0	0	0	0	0

Type of infringement	BE	FI	FR	HR	LV	ES
Other	53	1[68]	7[69]	0	1[70]	0

As shown in Table 30, the main category of infringements found by inspectors related to Safety Data Sheets provisions (35 infringements) and the absence of export notification for the chemical (20 infringements).

Table 30. Types and numbers of infringements of the PIC Regulation observed by inspectors during the reporting period

Type of infringement	AT	BE	BG	FI	DE	HU	LV	PL
No export notification provided for the chemical	1	3	0	0	16	0	0	0
Chemical not in conformity with export notification	0	1	0	0	2	0	0	0
No RIN provided (Article 8)	0	1	0	0	1	0	0	0
RIN not valid during export period (Article 8)	0	0	0	0	4	9	0	0
Box 44 of the single administrative document not properly filled in accordance with provisions (Article 19 (1))	0	0	0	0	1	0	0	0
Expiry date of the chemical	0	0	0	0	0	0	0	0
Packaging provisions (Article 17(1))	0	0	0	0	0	0	0	0
Labelling provisions (Article 17(1))	1	0	0	0	0	0	11	5
Safety Data Sheets provisions (Article 17(3))	13	0	12	0	0	0	10	0
Language provisions (Article 17(4))	1	0	0	0	0	0	0	0
Other	0	0	0	4[71]	1[72]	2[73]	0	0

4.10.7 Penalties

In all Member States, administrative or criminal fines were applied in case of infringement of the PIC Regulation, which is higher than in the previous reporting period where 26 Member States had indicated that they could impose fines for specific infringements, often with a scale of fines depending on the gravity of the infringement. Ten Member States indicated that a penalty of imprisonment could be imposed on the most serious infringements.

[68] Finland - Special-RIN requested after the export took place.

[69] France – Infringement to Customs Regulations.

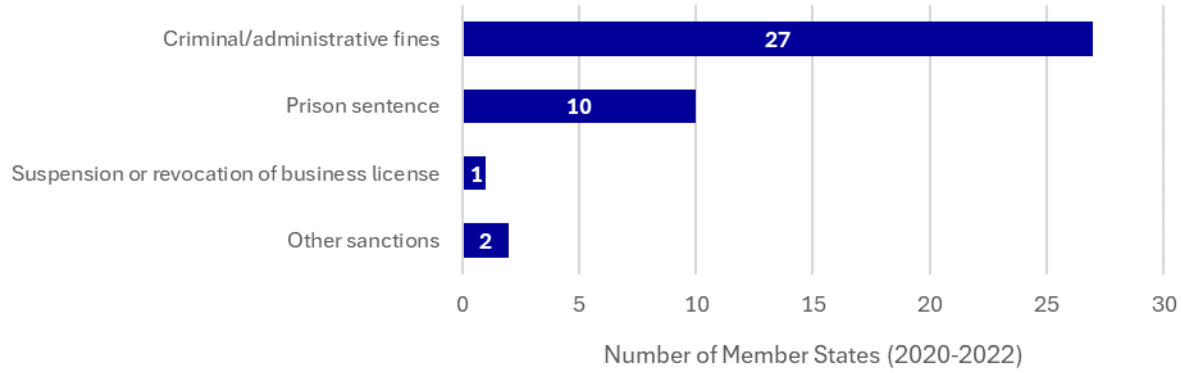
[70] Latvia - In 2022, export was prohibited due to the inability to provide all requested information: documents (invoice, payment order, proof of sale of the goods) proving the change of ownership of the goods (from a UK company to NL), the contract between the consignor and the consignee, and proof of payment for the goods (if prepaid).

[71] Finland - Article 10 report on import not submitted in time (all 4 cases).

[72] Germany - Infringement due to the fact that Article 10 Report has not been generated.

[73] Hungary – Infringement of annual reporting provisions according to Article 10.

Figure 26. Penalties applied in case of infringement of the PIC Regulation



13 infringements in 3 Member States led to penalties during this period, compared to 29 infringements in 3 Member States in the previous period, and compared to 13 infringements in 4 Member States in the first reporting period (see Table 31).

Table 31. Number of infringements that led to penalties during the reporting period

Member State	Number of infringements found	Number of infringements that led to penalties
Belgium	5	4
Germany	26	7
Latvia	22	2

4.10.8 Collaboration between DNAs and NEAs

Collaboration between DNAs and NEAs

22 Member States (compared to 24 in 2017-2019[61]) indicated that there is a regular exchange of information between the DNA(s) and enforcement authorities. 5 Member States stated that, as the DNA and the NEA are in the same institution or co-located, information sharing occurs easily, whenever necessary. 7 Member States indicated that regular information exchange and meetings were held between DNAs and NEAs, while 5 mentioned regular exchanges of information through email to contact points, or following procedures provided for in laws, agreements or guidelines. 8 mentioned regular exchange and/or meetings with customs authorities.

5 Member States made suggestions to improve collaboration between the DNAs and enforcement authorities at national level:

- Enhancing information exchange, organising seminars, workshops and/or training (3 Member States). 3 Member States raised the same request in the last period.
- Establishing communication strategy between DNA and Enforcement Authorities (1 Member State).
- Enhancing cooperation in the implementation of risk-based approach (1 Member State).
- Organising more regular meetings between DNA and Enforcement Authorities (1 Member State).

In addition, two comments related to actions to be taken at EU level:

- An Enforcement Forum Project involving focus on Integrated Chemical Control of Products between REACH, CLP, BPR, PPP and PIC (1 Member State).

- EU-level webinars and workshops (1 Member State).

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

The Agency's Forum for exchange of information on enforcement (the Forum) provides a platform for enforcement authorities to collaborate and share experiences on all of the chemical legislation covered by the Agency.

23 Member States (1 more than in the previous reporting period[61]) indicated that there was a regular exchange of information between the DNAs and the national member(s) of the Forum. As was the case in the previous reporting period, 11 Member States explained that since the Forum member was also a member of the DNA, or was part of the same institution, regular exchanges of information occurred without formal communication/coordination mechanisms. 5 Member States indicated that there were regular exchanges of information, either through written/electronic communication channels or through regular meetings between institutions on outcomes of DNA meetings, outcomes of Forum meetings, and Forum's activities related to PIC.

In Czechia, a National Forum for Enforcement facilitated exchange of information and coordination of joint enforcement projects in the field of chemical safety. Members of the National Forum included representatives from major supervisory authorities and other government bodies and organizations in the field of chemicals (Czech Environmental Inspection, State Labor Inspection Office, General Customs Directorate, Central Control and Testing Institute for Agriculture, State Health Institute, regional public health offices, Ministry of the Environment, Ministry of Health, Ministry of Industry and Trade). The National Forum was chaired by a member of the Forum for Exchange of Information on Enforcement at the European Chemicals Agency for the Czechia.

Nearly all DNAs stated (24) that they were satisfied with the collaboration with Forum members. Two Member States were not satisfied with the collaboration and made the following comments:

- Further improvement of the cooperation was needed.
- DNA was not aware of the discussions of the Forum, therefore they did not know if anything related with compliance of PIC was discussed there.

4 Member States provided suggestions for improving collaboration between DNAs and Forum members which included suggestions regarding the above points:

- Regular report from the Forum secretariat at the DNA meetings should continue (one Member State). The Forum Chairs and the Forum Secretariat (Harmonised Enforcement Team at the Agency) could take over such presentations, if indicated.
- Organisation of meetings between the Forum and the DNAs to discuss enforcement (suggested online).
- Strengthen communication between the DNAs and Forum members generally.
- DNAs could be invited as observers to the Forum meetings under the agenda points dedicated to the PIC Regulation.

These suggestions are identical to previous report, except for the final bullet.

4.10.9 Forum activities

Specific actions

No specific actions related to PIC enforcement were noted at the Forum during the reporting period, and none of the Forum projects during the reporting period mention PIC[74].

Regular exchange of information on coordination of enforcement

The Agency reported that in 2020 the Forum addressed the requirement under Article 17 of the PIC Regulation that the SDSs must accompany substances and mixtures that are exported, where it is required for them. This was in context of discussing the requirements for availability of SDS at the moment of importation under REACH.

In 2021 the Forum considered the proposal for an enforcement project on PIC duty for export notification under Articles 8 and 15.1 related to suspected export of articles containing substances listed in part 2 or 3 of Annex I to the PIC Regulation in unreacted form (i.e. lamp and batteries containing mercury, cadmium and potentially other substances). The project was ultimately not prioritised because the Forum considered there would not be sufficient number of duty holders in multiple Member States. In 2021 the Forum also asked the Commission for information on the status of PIC Article 22(2) report. Regular exchange of information on coordination of enforcement.

The DNAs in 23 Member States reported participating in regular exchange of information with their country's member(s) of the Forum, 4 did not.

Opportunities for improvement of enforcement

The Agency reported that the Forum considered in its work programme 2019-2023 that inspections of PIC duties should become part of the NEAs' enforcement routine. 17 Member States indicated that their DNAs were satisfied with the activities carried out by the Forum. Nine Member States said that their DNA had no experience of Forum activities. One Member State said that their DNA was not satisfied with activities carried out by the Forum, because there was no periodic slot in the Forum Agenda on enforcement PIC issues; they said a recurring slot devoted to this issue would be desirable.

6 other Member States also made suggestions for improving the activities of the Forum concerning the PIC Regulation:

- 3 Member States underlined the benefits of pilot projects, such as the one conducted in 2018, and suggested that the Forum could organise similar pilot projects in the future.
- 2 Member States suggested a project on harmonised enforcement, with one Member Stated indicating it could cover sharing of experience, training, producing a guideline, joint action and reporting.
- 1 Member State suggested that when the scope of articles covered by the PIC regulation is clarified, it might be worth conducting a campaign on compliance with Article 15.1.
- 1 Member State stated that they supported integration of PIC considerations into the REACH Enforcement projects (REF) carried out by the Forum in future.

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

[74] https://echa.europa.eu/about-us/who-we-are/enforcement-forum/forum-enforcement-projects

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

In 2020 and 2021, the Agency received 11 ad-hoc requests falling within the scope of Article 20, from 9 non-EU countries: Togo (2), Sri-Lanka (2), Philippines, Korea, Gabon, Kenya, Lebanon. Morocco and Burkina Faso. The details of the requests are described in the Article 20 report covering the period 2020 – 2021.[75] These requests related to the following topics:

- Questions related to the reason for listing didecyldimethylammonium chloride and sodium dimethylarsinate, their scientific and regulatory background, and how to handle and dispose of these chemicals safely (Togo);
- Request for clarification on the EU procedures for exports for the substances not listed in Annex III to the Rotterdam Convention (Togo);
- Question related to the biocidal regulation in EU (Sri Lanka);
- Question related to the labels for the products in the export notifications (Philippines);
- Request to receive a list with all the chemicals banned or restricted in the EU under the PIC Regulation and their regulatory background (Republic of Korea);
- Question related to the regulatory status of permethrin in the EU (Gabon);
- Question related to the import of diphenylamine from the EU, whether it falls under the EU PIC requirements or not (Kenya);
- Question related to the possibility of verifying the status of certain biocides in the EU and also in the EU Member State that appears as the place of manufacturing (Sri Lanka);
- Question related to the regulatory status of treated seeds with thiram within the EU (Lebanon);
- Request to receive a list with all the banned or restricted pesticides in the EU (Morocco);
- Request related to the procedures for exports of chemicals that are not listed in Annex III to Rotterdam Convention (Burkina Faso).

In 2022, the Agency received 7 enquiries, from Kenya (5), Jordan and South Africa. The nature and topic of these requests will be further elaborated in the next Article 20 report, covering the period 2022 – 2023, which is due by the end of 2024.[76] For ease of reference, links to the previous two reports 2016-2017[77], and 2018-2019[78] are provided in the relevant footnotes.

Reporting on the information transmitted

Every two years the Agency publishes summaries of information provided by the Commission, DNAs and the Agency to authorities in non-EU countries. The reports address information submitted by means of export notifications, FRA notifications, and following ad-hoc requests.

The Agency did not experience difficulties in collecting the information from the Commission and the Member States on the data transmitted, nor in compiling the report in accordance with Article 20(4) of the PIC Regulation. The report covering period 2020 – 2021 contained a new

[75] Report on the exchange of information under the PIC Regulation 2020-2021: Compilation of information transmitted by the European Commission, Member States and ECHA under Article 20 of the PIC Regulation, , Reference: ECHA-22-R-05-EN, https://echa.europa.eu/documents/10162/1244645/pic_article_20_report_2020-2021_en.pdf, Section 4.2, page 16.

[76] Report on the operation of the Prior Informed Consent (PIC) Regulation 2023, October 2023, https://echa.europa.eu/documents/10162/18272234/report_pic_art_22_2023_en.pdf, page 32.

[77] ECHA, Overview on the exchange of information under Article 20 of the PIC Regulation 2016-2017. Compilation of the information collected by the European Commission, assisted by the Member States and the European Chemicals Agency, ECHA-2018-R-20-EN, November 2018: https://echa.europa.eu/documents/10162/1244645/pic_article_20_report_2016-2017_en.pdf/

[78] ECHA, Report on the exchange of information under the PIC Regulation in years 2018-2019. Compilation of the information transmitted by the European Commission, the Member States and the European Chemicals Agency, under Article 20 of the PIC Regulation, ECHA-20-R-15-EN, 2020: https://echa.europa.eu/documents/10162/1244645/pic_article_20_report_2018-2019_en.pdf/

section (3) on information submitted through explicit consent responses to the Parties to the Rotterdam Convention or other countries.

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 and DNAs participated in activities intended to promote a better understanding and implementation of the provisions of the PIC Regulation and a better implementation of the Rotterdam Convention.

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

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

- In 2021, the Agency provided support to the Commission in the preparation and delivery of three regional workshops to strengthen the capacity of parties to the Rotterdam Convention. The online sessions were held in February, March and April in all three languages of the Convention.[79]
- In April 2021, the Agency also participated in a webinar session organised by the Rotterdam Convention for the Asian Region[80], where the Agency presented the implementation of the Convention in the EU and clarified specific parts in the follow-up Q&A session. The webinar also had the aim of strengthening collaboration between DNAs at national and regional level.
- In June 2021, the Agency provided support to another webinar organised by the Rotterdam Convention, in Arabic[81] where the Agency presented and answered the follow-up questions.
- In February 2022, the Agency provided support to the Commission in the preparations and delivery of a workshop organized jointly by the Russian Federation and the Secretariat of the Rotterdam Convention, where the Agency presented the implementation of the Rotterdam Convention in the EU and provided support to the follow-up Q&A session.
- In May 2022, the Agency attended the 10th meeting of the Conference of the Parties to the Rotterdam Convention and, in cooperation with the Commission and some Member State DNAs and the Secretariat of the Rotterdam Convention contributed to the preparations and delivery of five lunch hour regional group meeting[82], in which over 70 delegates from 37 non-EU countries participated. The aim was to clarify the specific provisions of the EU PIC Regulation, to discuss problematic cases and to gather feedback from the authorities in the non-EU countries. The COP is an excellent

[79] https://www.pic.int/Default.aspx?tabid=4215&meetId=124C5035-4565-EB11-8934-005056857856&lang=en

[80] https://www.pic.int/Default.aspx?tabid=4215&meetId=83549A86-3F86-EB11-8939-005056857856&lang=en

[81] https://www.pic.int/Default.aspx?tabid=4215&meetId=AF6C4951-81CE-EB11-927E-005056857856&lang=en

[82] One with the African group countries in English, and another with the African group (and other francophones) countries in French; one with the Asia-Pacific group countries in English; one with the Central and Eastern group countries in English and Russian; finally, one with the Latin American and Caribbean group countries in Spanish.

opportunity for approaching delegations from non-EU countries (typically the unresponsive ones) to refresh obsolete contact details, explain our procedures, clarify any specific misunderstandings and finally to identify ways and means to improve and further develop the information exchange and communication on hazardous substances that are exported from the EU to these countries.

Some specific issues were raised by some of the importing countries, such as the lack of accuracy of the contact details of importers in non-EU countries, the very high estimated quantities included in the notification form, the language of the SDSs provided with the export notifications. There have been concerns raised also regarding the imports of part 1 chemicals for which the importing country sent a negative response, also possibility of the exporting/importing country of providing information regarding the transit country within the export notification. It has been noted also, as in the previous attendance to this event, the limited capacity in non-EU countries to respond to EU's requests for explicit consent. The Agency also had one-to-one discussions with several non-EU countries authorities, in particular with the aim of understanding the reasons and find practical solutions to the issue of non-responsive authorities in the importing countries.

There was always good feedback from the importing countries regarding these events and it was mentioned that more support/training of this type would be appreciated.

No Member States participated in cooperation activities during this reporting period, down from five Member States in the previous reporting exercise. Regarding notifications to the Secretariat, Member States were always consulted on drafts and provided comments in preparation of such notifications.

Capacity-building activities

Through the EU Instrument for Pre-accession assistance (IPA), the Agency continuously provided training and support to pre- and candidate countries to increase capacity in the area of chemical management. This included supporting beneficiaries' efforts in aligning the provision of their national regulation regarding the implementation of the Rotterdam Convention with those in the EU.

In addition, the Agency was involved in non-PIC-specific activities but which may cover the PIC Regulation. During the reporting period, the Agency finalised two in-depth analyses, launched respectively in 2019 and 2020. These assessed the readiness and harmonisation with the EU acquis[83] for chemicals management in 1) Montenegro and Serbia and 2) Albania, Bosnia and Herzegovina, Kosovo, North Macedonia and Turkey. The aim of the studies was to:

- Identify needs for support,
- Map the actions required to fill existing gaps in capacity for these countries,
- Provide a better understanding of inter-dependencies between existing needs,
- Provide an understanding of cost and resources needed to fill those gaps.

The outcome of the studies and national action plans are available on the Agency's website.[84]

No Member States carried out capacity building activities of this kind, down from four in the last reporting period.

[83] The European Union (EU) acquis is the collection of common rights and obligations that constitute the body of EU law, and is incorporated into the legal systems of EU Member States.

[84] https://echa.europa.eu/about-us/partners-and-networks/international-cooperation/support-to-eu-external-relations-policies/activities-under-ipa/2020-2022

4.13 IT-related aspects

Under the PIC Regulation, 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 the PIC Regulation and replaced the previous EDEXIM database. It consists of 3 interfaces: for industry users, authority users (DNAs, the Commission, the Agency and enforcement authorities), and 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, DNAs find ePIC user-friendly and identified some improvements to aid understanding and administrative efficiency. Answers to the questionnaire show that DNAs' opinion on ePIC had improved since the previous reporting period and that more DNAs had experience with ePIC. 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 which were also identified by NEAs. All of the data that should have been made publicly available by the Agency according to the Regulation had been made available online.

4.13.1 The ePIC system

The number of ePIC users from industry, DNAs and NEAs increased since the previous reporting period (see Table 32).

Table 32. Number of ePIC users during the reporting period by type[85]

Users	2020-2022	2017-2019	2014-2016
Industry	4 924	2 398	1 836
DNAs	111	137	127
Commission	2	1	1
NEAs	401	445	388

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

- Integration of Article 10 non-confidential report generation within ePIC removing the need to use a separate tool outside of ePIC as was the case before. This reduced the Agency's work in generating this annual report.
- Enhanced messaging: ePIC was integrated with the common communication module (EDOMOD) together with new features:
  - A new type of message ("ad-hoc") was introduced to reduce the need to contact exporters outside the system;
  - New search options for messages (message box - inbox and outbox);
  - Alert and quick link to inbox in ePIC homepage for new messages.
- Improvements in waiver workflow to increase the efficiency of the process in response to various issues identified during the two previous reporting periods:

[85] 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.

    - A flag to DNA and Commission tasks was added to inform about the availability of an explicit consent response for the referenced export notification;
    - A cover letter and a translation (where relevant) were made mandatory supporting documents in addition to the original evidence in the industry wizard;
    - A link to the fact sheet describing the waiver requirements was added in the tasks;
    - the event history was updated to make the approval steps transparent to companies.
- Efficiency improvements in processing tasks:
    - Bulk upload for the Agency record acknowledgement of receipts received from non-EU countries;
    - Automated selection of designated national authorities in both DNA explicit consent and the Agency forwarding notification tasks;
    - Automated email alerts for DNAs to flag expiring RINs and to reduce 'manual' monitoring of candidates for explicit consent renewals.
- Changes in chemicals database to support data dissemination and to facilitate access to reference data (legal context):
    - Inclusion in Annex V was amended by introducing a display of parts 1 and 2;
    - links to legal texts (so called "CELEX codes") were added to each chemical in both Annex I and V.
- Adaptations following Brexit/Northern Ireland Protocol (NIP)
    - The majority of the changes in relation to BREXIT were already developed during the previous reporting period and made available in October 2020 to allow companies to comply with Article 8 of the PIC Regulation;
    - Further development was still required to adapt ePIC with Northern Ireland Protocol, those changes were also applied in October 2020.
    - revocation of UK companies' and authorities' access rights took place on 1 January 2021.
- Improved searches:
    - To increase the efficiency in the authority processing tasks, option to filter authority tasks by Annex/part of the associated chemical was added;
    - To identify submissions under Article 8(6) first sub-paragraph, search for special RIN requests was amended accordingly;
    - Search of chemicals by Annex/part and use category.
- Change of forwarding rules and the threshold alert (10 kg) for special RIN requests for group substances, to align the implementation with the approaches adopted in the 35th DNA meeting on 10 July 2020.
- Advance submission of Special RIN requests was enabled for chemicals introduced by a regulation amendment with entry into application date in the future.
- Article 10 improvements:
    - A flag was introduced to highlight very large quantities reported by companies to reduce clerical mistakes;
    - Insertion of manual entries by introducing a CAS/EC number.

Additional information:

The above-mentioned new/improved features contributed to a reduction of processing times and an increase in the overall efficiency of processes. They also enabled better traceability of cases and contributed to ensuring consistency and reliability of the data in the system. Continuous improvements to the ePIC submission system should ensure that some of the identified issues are solved, that process efficiency keeps improving as well as the capacity to process an increasing number of tasks. Lack of resources had however proven to be a limiting factor over the years.

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 prioritised and implemented during the reporting period.

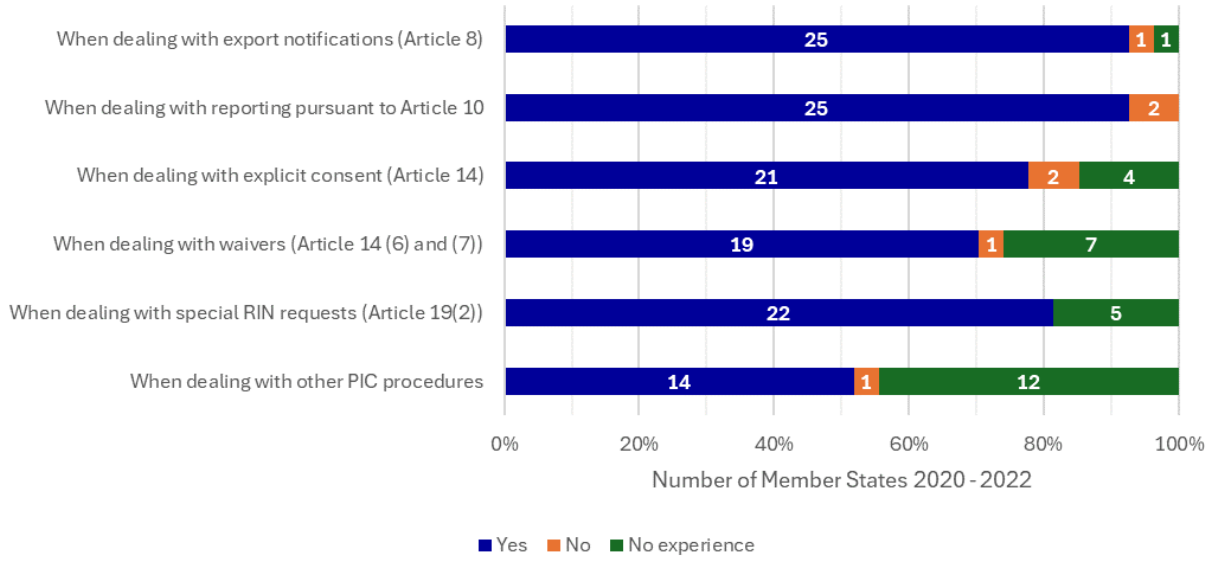
In their reporting questionnaires, the DNAs were also generally positive about the user-friendliness of ePIC in carrying out their main obligations under the PIC Regulation. Comparison with results from the previous reporting show that (accounting for the UK DNA removal) DNAs' opinion on ePIC has stayed the same and has dropped a little in relation to dealing with requests for explicit consent, and when dealing with other PIC procedures (Figure 27).

Exporters and importers

According to the Agency, the feedback received from industry (representatives), for example in the margins of the DNA meetings, was mainly positive and some improvement proposals were prioritised for implementation (e.g. advance special RIN requests for chemicals not yet in force, insertion of entries by CAS in Article 10 reports). Some comments and suggestions for further improvements were collected, such as:

- Providing the capability to communicate with DNAs and the Agency directly within ePIC;
- Making usability improvements (e.g. duplicate functionality for special RIN requests, easier Article 10 creation, data insertion for Section 6.2. "Prohibited/Allowed uses"); and
- Enabling advanced submissions for chemicals contained in draft amendments (due to the short submission window following publication).

Figure 27. Question 79. Is the ePIC system easy to use for DNAs?

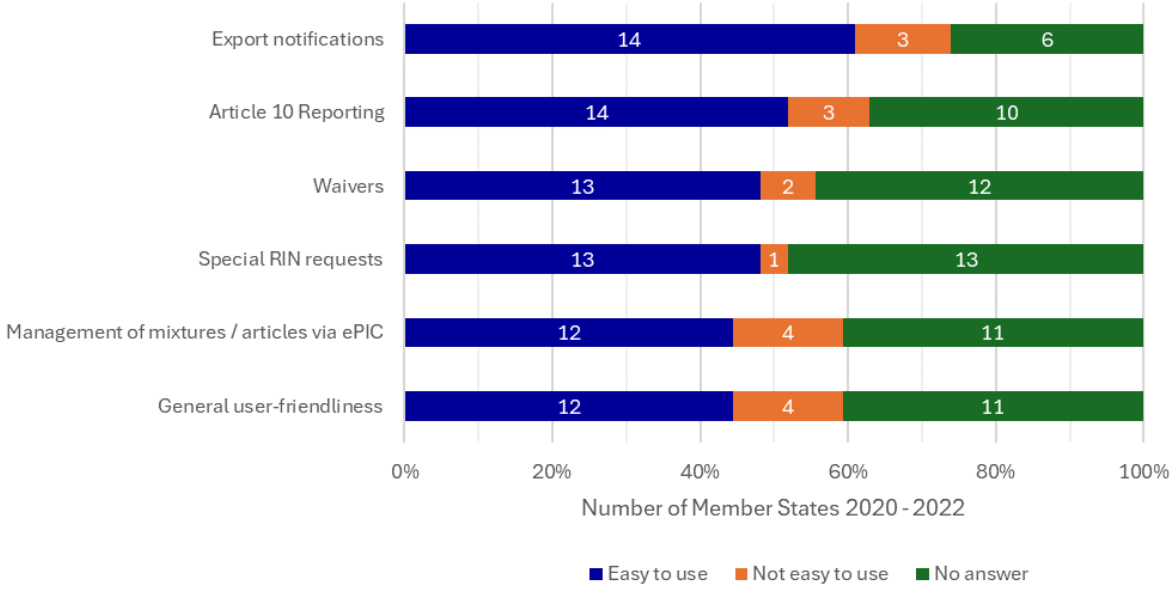


In addition, a usability study to capture user insights from the Agency's IT tools was launched at the end of 2022 and the results will be analysed and reflected in the future development of ePIC.

As in the previous reporting period, the feedback received by DNAs from industry users was also generally positive. Over half of the Member States replied to this question (Figure 28), which was higher than in previous reporting periods. Responses were relatively similar compared to the previous reporting period.

- 1 Member State mentioned language issues as sometimes information or guidance is only available in English. This was also identified in the previous reporting period.
- 2 Member States reported that the method of attaching or changing already attached documents is not intuitive and this creates problems. An example is when a change of mixture needs recording against information generated in ePIC under manage mixtures (new SDS). The process to update is not easy. Also, SDS can only be entered if ending in "pdf"; even "PDF" does not work. These issues were also identified in the previous reporting period.
- 1 Member State noted issues with account management: exporters have difficulties in changing/ updating account details. It is not clear where and how it can be done.

Figure 28. Question 80. Where possible, please provide feedback from exporters on the user- friendliness of the ePIC system.



- 1 Member State said that after having added benzene >= 0.1%, the amount of actual benzene imported/exported can only be guessed. It is the same issue with UVCBs containing benzene in varying amounts.
- 1 Member State mentioned Article 10 Reporting and said an interface/export to insert an Excel file is needed.
- A Member State asked if it could be possible to answer the replies from authority directly in ePIC. This would provide a message history in the tool, instead of having to step out of the system and send an email. They asked if e-mail exchange can be provided directly in ePIC in the case of RIN. It was also important to enable the export automatically if DNA and the Agency both approve it, instead of having to wait 35 days for the status change in the platform.
- A Member State also requested that changes of Annexes I and V not be implemented during the year, but instead enter into force only on "First of January". This is beneficial as reporting is required for the calendar year, which is problematic if the requirement starts part way through the calendar year.

Customs authorities

20 Member States reported that their customs authorities used ePIC, the majority of whom (14 Member States) believed that customs found ePIC easy to use and half stated that customs considered it was an adequate tool to support them in controlling the application of the PIC Regulation (10 Member States). Others stated they had no information.

According to the Agency, some Member States had expressed interest in automating the checks of export controls, and to integrate ePIC data to a centralised application ("Single Window"). This desire was also identified in the last reporting period. Feedback from the Commission to the Agency indicated that DG TAXUD also has an interest in integrating ePIC data to such a centralised Customs application.

Other enforcement authorities

10 Member States replied that, to their knowledge, other enforcement authorities were using ePIC (against 5 in the previous reporting) and 8 that they were not (against 6 in the previous reporting). 9 Member States did not have the information. Of the 10 Member States with other enforcement authorities using ePIC, eight replied that these enforcement authorities consider ePIC easy to use. 7 replied, to their knowledge, these other enforcement authorities considered ePIC adequate to support them in their enforcement work.

Other information or comments regarding data availability

The Agency received some improvement proposals from NEAs during the reporting period (through DNAs) related to data availability. Via the survey, 1 Member State indicated that a lack of open data created a significant administrative burden in responding to requests for information from NGOs. Another Member State said the ePIC system did not provide the ability to export and use detailed information from the notifications for the purpose of analysis for risk-based inspections. The export dataset lacked details of the exporters and importers (origin, destination, name and address); substance ID; an entry in the list of substances included in the Convention; product or tradename and intended use of the product (for example plant protection, chemical industry).

4.13.3 Areas of ePIC improvement

The main improvement needs/new functionalities for ePIC that the Agency were considering - pending availability of resources and budget - are listed below. In addition, there is a backlog which includes many small improvements which have been requested, mainly by DNAs and industry users:

- A reporting tool for DNAs, to enable Member States to prepare various reports concerning exports/imports independently and reducing ad hoc requests to the Agency (e.g. for ATD purposes);
- Further improvements to management of the chemicals database to increase efficiency, such as:
  - Improved back-office functionality for amendments to ensure prompt publication of new entries;
  - New back-office functionality to create chemical specific business rules/alerts/warnings
    (e.g. for dual use chemicals) to reduce manual verification;
  - Submissions for certain chemicals in articles (which are otherwise banned for export).
- Change in the way acknowledgements of receipt are requested if it is decided that the current way of the process needs to be aligned with the provisions of the legal text.
- More automation/simplification of processing steps/tasks to reduce manual verification/steps in the processing (e.g. partial/full (pre-)validation of export

notifications for Annex I, Part 1 substances, pre-filling/change of information in Section 6.2 depending on policy decisions.
- Further improvements in the waiver workflow (e.g. standardised cover letters, transparency of case details).
- Any potential changes/improvements following developments of the Commission's initiative to ban the production for export of certain hazardous chemicals and developments in the legal text.

As regards the further development and maintenance of submissions systems, the Agency had started transitioning from having monolithic end-to-end regulation-specific IT systems to solutions made of small reusable regulation-agnostic common modules. The messaging and access management modules in ePIC were already relying on such common modules and ePIC would likely follow this transition by gradually on-boarding to more of these modules. Overall, this should facilitate the maintainability, improve standardisation and bring synergies with other Agency applications. The transition to the new modules would bring opportunities to implement new features and re-design the existing functionalities to better accommodate the needs, including those highlighted above. This evolution might however, at some point in the future, require specific, additional resources; the Agency would keep the Commission informed about this project and discuss any resource needs if and when relevant.

4.13.4 Data dissemination via the Agency Website

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); and
- Non-confidential data on explicit consents received from non-EU countries (Article 14).

The Agency's website section dedicated to PIC[86] provided the following:

- Chemicals subject to PIC: the chemicals subject to PIC and listed in its Annex I (all Parts) or Annex V (all Parts), can be searched (full/sub-lists per chemical name, per EC or CAS number), with the possibility to apply specific filters (e.g. on use category, use limitation in the EU, EU regulatory reference).
- Export notifications: non-confidential data on exports notifications can be searched, and high-level statistics (summaries by importing EU Member State, by exporting non-EU country, by chemical/ mixture/ article and per month) found.
- Import notifications: non-confidential data on import notifications can be searched, and high-level statistics (summaries by exporting EU Member State, by importing non-EU country) are made available.
- Explicit consents: non-confidential data on explicit consents received from non-EU countries can be searched.
- EU and non-EU Designated National Authorities up-to-date contact details are provided.

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

- Information on EU import responses under the Rotterdam Convention is also available in the form of an Excel sheet.

In addition to the above, information on substances subject to the PIC Regulation was also made available through the Agency's cross-regulations dissemination platform (infocards, brief profiles, and detailed source data). Reports on actual quantities of PIC chemicals exported and imported (pursuant to Article 10) for each year of the reporting period can be found here: https://echa.europa.eu/regulations/prior-informed-consent/annual-reporting-on-pic-exports-and-imports. Reports on information exchange (pursuant to Article 20) can be found here: https://echa.europa.eu/regulations/prior-informed-consent-regulation/reporting-on-information-exchange .

4.13.5 Improvements to the Agency's PIC dissemination website

An enhanced PIC dissemination platform went live in November 2022 to ensure a robust and sustainable dissemination of the PIC data and a better integration with the Agency's cross-regulations dissemination platform.

Based on the results of a consultation with stakeholders and an analysis carried out by the Agency in 2020, the following information was made available, in addition to what was published already:

- Full regulatory context/history for Annex I and V chemicals, including links to legal acts;
- Chemicals not yet in force (added by amendment with entry into application date in the future);
- Information on Annex V chemicals by parts (part 1 and 2);
- Foreseen use category for export notifications and explicit consents;
- Indication if an alias was provided for a mixture/article in export notifications;
- Information on PIC chemicals present in mixtures/articles in export notifications (instead of displaying the mixture name only);
- Accepted waivers;
- Indication if a country is Party to the Rotterdam Convention and/or member of OECD in DNA contact details section;
- Change dates in DNA contacts;
- All chemicals present in import notifications.

In December 2022, information on EU import responses under the Rotterdam Convention were added and are available at https://echa.europa.eu/eu-import-responses-under-the-rotterdam-convention .

Three reports on actual trade in 2019, 2020 and 2021 pursuant to Article 10 and two reports on information exchange covering periods 2018 - 2019 and 2020 – 2021 pursuant to Article 20 were published during the reporting period. In addition, an update to the Article 20 report for 2018 – 2019 was also made available.

During the reporting period, the Agency published the second Report on the operation of the PIC Regulation (pursuant to Article 22) in 2022 and the third, which covers this reporting period: Reporting on the operation of PIC Regulation 2023.[87]

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

The report on information exchange for 2020 – 2021 (pursuant to Article 20) is available at Reporting on information exchange.[88] The report for 2022-2023 is also available at this website.

4.13.6 Agency PIC dissemination website feedback

The Agency reported that overall the improvements compared to the previous portal had been appreciated. Further suggestions for improvement had been received as regards some search options and the data display (e.g. PIC chemicals should be displayed on the result table and not only in the details view).

As regards the information made publicly available, in particular related to export notifications, some Member States had enquired whether more data on export notifications could be made available (e.g. company name, estimated quantity).

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

Annex

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

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LIST OF TABLES

Abbreviations used

Agency	European Chemicals Agency
BPR	Biocidal Products Regulation
CAS	Chemical Abstract Service
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
ECHA	European Chemicals Agency
ePIC	Software application for implementing Regulation (EU) No 649/2012
EU	European Union
FRA	Final Regulatory Action
ICSMS	Information and communication system for the pan-European market surveillance
NEA	National Enforcement Authority
NPs/NPEs	Nonylphenols and Nonylphenol Ethoxylates
OECD	Organisation for Economic Cooperation and Development
PIC	Prior Informed Consent
POPs	Persistent Organic Pollutants
PPPR	Plant Protection Products Regulation
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation
RoHS	Restriction of Hazardous Substances Directive
RIN	Reference Identification Number
SDS	Safety Data Sheet
WPIEI	Council Working Party on International Environmental Issues (Chemicals/Synergies)

1 INTRODUCTION

Article 22 of Regulation (EU) No 649/2012[1] ('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 pursuant to 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 Agency under Article 22(1) concerning the operation of the PIC Regulation's procedures.

This reporting exercise for the period 2020-2022 is the third under the PIC Regulation.

The present report is the Commission report on the performance of the functions for which it is responsible under the PIC Regulation. As per Article 22(2), the information provided in this report will be incorporated in the synthesis report on the operation of the PIC Regulation, 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, the Agency's website and reports, 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 2.

This report is divided into two sections, the first addressing the European Union 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.

Note on Brexit: With the departure of the UK from the EU it has been decided by the Commission to confine this exercise to the present 27 Member States.

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

List of relevant documents consulted
Implementing and delegated acts:
• Commission Delegated Regulation (EU) 2019/1701
• Commission Delegated Regulation (EU) 2020/1068
• Commission Implementing Decision (EU) 2020/2182 and its August 2021 correction
• Commission Delegated Regulation (EU) 2022/643
• Commission Delegated Regulation (EU) 2023/1656
Associated report:
• Report from the Commission to the European Parliament and to the Council on the exercise of the delegation conferred on the Commission pursuant to Regulation (EU) No 649/2012 of the European Parliament and of the Council of 4 July 2012 concerning the export and import of hazardous chemicals. COM(2023) 448 final
DNA meeting documents:
• Minutes of the DNA meetings that were held in 2020, 2021 and 2022 (respectively, the 35th, 36th, 37th, 38th, 39th, and 40th meeting of the DNAs).

[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

List of relevant documents consulted
• Any and all amendments to Annex I of the PIC Regulation as presented at the above meetings.
• Any import decisions presented at DNA meetings.
• Submission of notifications to the PIC Secretariat, as presented at the 35th, 36th, 37th, 38th, 39th, and 40th DNA meeting.[2]
Rotterdam Convention documents:
• Documentation relating to EU preparations for/actions arising from relevant Rotterdam Convention Conference of the Parties (COP) meetings, specifically CoP10 of 26-30 July 2021 and 6-17 June 2022, CoP11 of 1-12 May 2023.
• PIC Circulars published by the Rotterdam Convention Secretariat (six were published during 2020-2022, Circulars LI to LVI).[3]
The Agency's reports on Article 20 and the Operation of the PIC Regulation:
• Report on the exchange of information under the PIC Regulation in 2020-2021[4]
• Report on the exchange of information under the PIC Regulation in 2022-2023[5]
• Report on the operation of the Prior Informed Consent (PIC) Regulation 2023[6]
CoP documents
• Council Decision (EU) 2022/1024 of 7 April 2022 on the position to be taken on behalf of the EU at CoP10[7]

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 has one team leader for international chemicals responsible for carrying out the Commission's administrative functions under PIC. The team leader is supported by a policy officer, a lawyer for legal questions and a secretary for all organisational work.

For international work, Unit B.2 had two experts (the team leader and a policy officer) nominated to the Chemical Review Committee of the Rotterdam Convention (CRC). The Head of Unit is also involved, in particular regarding the Conference of the Parties (CoP) where they normally lead the EU delegation and represent the EU. In addition, a policy officer from Unit B.2 is involved in the international work and colleagues from Unit F.3 (Global Environmental Cooperation & Multilateralism) who are responsible for multilateral environmental cooperation, contribute to its 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, certain legal matters and the technical assistance contracts on implementation of the Rotterdam Convention. The staff resources occupied by this work amount to 0.4 FTE for the team leader, 0.3 FTE for policy officers/legal officers, and 0.1 FTE for the supporting work, including international matters.

[2] As but one example, how to implement the (then new) listing of "benzene as a constituent of other substances" in Annex I Part 1 of the PIC Regulation was discussed in some of these meetings.

[3] https://www.pic.int/Implementation/PICCircular/tabid/1168/language/en-US/Default.aspx

[4] https://echa.europa.eu/documents/10162/1244645/pic_article_20_report_2020-2021_en.pdf

[5] Selected data supplied as a draft prior to publication.

[6] https://echa.europa.eu/documents/10162/18272234/report_pic_art_22_2023_en.pdf

[7] http://data.europa.eu/eli/dec/2022/1024/oj

2.1.2 The Agency's budget

According to Article 24(1), 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 2020-2022 was set by the Commission as part of its the Multiannual Financial Frameworks for the periods 2014-2020 and 2021-2027.

According to Article 24(3), the Commission must examine whether it is appropriate for the Agency to charge a fee for the services provided to exporters and, if so, submit a proposal. The Commission tendered a study in 2019 to fulfil this obligation. The study analysed the implementation of fee systems used by DNAs, analysed the costs of the different services provided by the Agency under the PIC Regulation and developed several options for a fee system. The options included an assessment of the financial and technical feasibility and appropriateness of the options for the different stakeholder groups impacted (the Agency, exporters, and DNAs), as well as of potential impacts on the overall implementation of the PIC Regulation and on trade. The study was completed in June 2020. Taking into account the results of the study and the consultation of the Agency and Member States, the Commission decided not to submit a proposal.

2.1.3 Coordination between the Commission and the Agency

The Commission and the Agency cooperate closely in the implementation of the PIC Regulation. 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 information sheets produced by the Agency (for instance, the information sheet on waivers[8]). For cooperation with non-EU 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 the PIC Regulation. 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 PIC 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.

[8] Proposing waivers through ePIC: https://echa.europa.eu/proposing-waivers-through-epic

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 the PIC Regulation. The procedure for adoption of delegated acts requires the Commission to consult Member states' experts on draft amendments. Draft delegated acts are presented at the DNA meetings in order to ensure that all Member State experts, as well as observers, have the opportunity to comment. Draft delegated acts are also subject to a four-week public consultation, where any citizen or stakeholder can provide feedback on the act. Adopted delegated acts are also scrutinised by the European Parliament and the Council to ensure that the Commission does not exceed its powers. Once the act is adopted, the Parliament and Council have two months to formulate any objections. If no objections are raised, the act enters into force.

2.2.1.1 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.

Amendments to Part 3 of Annex I reflect the decisions of the CoP to include certain chemicals in Annex III to the Convention, making them subject to the PIC procedure.

During the reporting period 2020 to 2022, two Delegated Regulations amending Annex I were adopted:

- Commission Delegated Regulation (EU) 2020/1068[9]
- Commission Delegated Regulation (EU) 2022/643[10]

In Commission Delegated Regulation (EU) 2022/643, there were sufficient alterations to existing entries that the whole of Annex I was substituted with a replacement annex. These alterations were mainly necessary to update the customs codes provided in Annex I.

Subsequent to this reporting period, some of the changes being considered during the time period were implemented in the subsequent Commission Delegated Regulation (EU) 2023/1656 of 15 June 2023. As these substances were not added to Annex 1 or V during the 2020 – 2022 time period they are not included in the tables below.

Substances added to Annex 1

Of the 48 substance entries added to Annex I during the reporting period:

- 35 substances 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

[9] Commission Delegated Regulation (EU) 2020/1068 of 15 May 2020 amending Annexes I and V to Regulation (EU) No 649/2012 of the European Parliament and of the Council concerning the export and import of hazardous chemicals, (OJ L 234, 21.7.2020, p. 1–7). http://data.europa.eu/eli/reg_del/2020/1068/oj

[10] Commission Delegated Regulation (EU) 2022/643 of 10 February 2022 amending Regulation (EU) No 649/2012 of the European Parliament and of the Council as regards the listing of pesticides, industrial chemicals, persistent organic pollutants and mercury and an update of customs codes, (OJ L 118, 20.4.2022, p. 14–54). https://eur-lex.europa.eu/eli/reg_del/2022/643/oj

Regulation (EC) No 1107/2009 (PPPR), which represented a ban or severe restriction in the use category 'pesticide', as shown in Table 2 (basis for inclusion is noted as 'PPPR').

- 1 substance was added to Parts 1 and 2 of Annex I following its non-approval for use in biocidal products in accordance with the BPR Regulation (EU) No. 528/2012.
- 6 were added to Parts 1 and 2 of Annex I on the basis of the REACH Regulation because they were severely restricted or banned as industrial chemicals – 3 for public use, 3 for professional use.
- 2 were added to Parts 1 and 2 of Annex I because they were severely restricted as industrial chemicals under the POPs Regulation (EU) 2019/1021.
- Finally, 4 were included in Part 3 of Annex I following their inclusion in Annex III to the Rotterdam Convention (RC).

Table 2. Chemicals added to Annex I during the reporting period

Delegated Act	Chemical name	CAS number	Amendment of Annex I	Basis for inclusion
Commission Delegated Regulation (EU) 2020/1068 of 15 May 2020	Chlorothalonil	1897-45-6	Part 1 and 2	PPPR
	Chlorpropham	101-21-3	Part 1 and 2	PPPR
	Clothianidin	210880-92-5	Part 1 and 2	PPPR
	Desmedipham	13684-56-5	Part 1 and 2	PPPR
	Dimethoate	60-51-5	Part 1 and 2	PPPR
	Diquat, including diquat dibromide	2764-72-9 85-00-7	Part 1 and 2	PPPR
	Ethoprophos	13194-48-4	Part 1 and 2	PPPR
	Fenamidone	161326-34-7	Part 1 and 2	PPPR
	Flurtamone	96525-23-4	Part 1 and 2	PPPR
	Glufosinate, including glufosinate-ammonium	51276-47-2 77182-82-2	Part 1 and 2	PPPR
	Hexabromocyclododecane	25637-99-4, 3194-55-6, 134237-50-6, 134237-51-7, 134237-52-8 and others	Part 3	RC
	Imidacloprid	138261-41-3	Part 1	PPPR
	Oxasulfuron	144651-06-9	Part 1 and 2	PPPR
	Phorate	298-02-2	Part 1 and 3	RC
	Propiconazole	60207-90-1	Part 1	PPPR
	Propineb	12071-83-9 9016-72-2	Part 1 and 2	PPPR
	Pymetrozine	123312-89-0	Part 1 and 2	PPPR
	Quinoxyfen	124495-18-7	Part 1 and 2	PPPR
	Thiamethoxam	153719-23-4	Part 1 and 2	PPPR
	Thiram	137-26-8	Part 1 and 2	PPPR

Delegated Act	Chemical name	CAS number	Amendment of Annex I	Basis for inclusion
Commission Delegated Regulation (EU) 2022/643 of 10 February 2022	2,4-Dinitrotoluene (2,4-DNT)	121-14-2	Part 1 and 2	REACH
	4,4'-Diaminodiphenylmethane (MDA)	101-77-9	Part 1 and 2	REACH
	Azinphos-ethyl	2642-71-9	Part 2	PPPR
	Benalaxyl	71626-11-4	Part 1 and 2	PPPR
	Benzene as a constituent of other substances in concentrations equal to, or greater than 0.1% by weight. Except motor fuels subject to Directive 98/70/EC of the European Parliament and of the Council of 13 October 1998 relating to the quality of petrol and diesel fuels (OJ L 350, 28.12.1998, p. 58). Part of EU combined nomenclature (CN) code 2707 10 00	71-43-2	Part 1	REACH
	Beta-cyfluthrin	1820573-27-0	Part 1 and 2	PPPR
	Bifenthrin	82657-04-3	Part 1 and 2	PPPR
	Bis(pentabromophenyl) ether (decaBDE)	1163-19-5	Part 1 and 2	POP
	Bromoxynil	1689-84-5 3861-41-4 56634-95-8 1689-99-2	Part 1 and 2	PPPR
	Cadmium and its compounds	7440-43-9 and others	Part 2	REACH
	Chlorpyrifos	2921-88-2	Part 2	PPPR
	Chlorpyrifos-methyl	5598-13-0	Part 1 and 2	PPPR
	Empenthrin	54406-48-3	Part 1 and 2	BPR
	Epoxiconazole	135319-73-2	Part 1 and 2	PPPR
	Ferbam	14484-64-1	Part 2	PPPR
	Fanamiphos	120068-37-3	Part 1 and 2	PPPR
	Hexazinone	51235-04-2	Part 2	PPPR
	Lead (Pb) and its compounds	7439-92-1 598-63-0 1319-46-6 7446-14-2 7784-40-9 7758-97-6 1344-37-2 25808-74-6 13424-46-9 301-04-2 7446-27-7 15245-44-0 and others	Part 1	REACH
	Mancozeb	8018-01-7	Part 1 and 2	PPPR
	Mecoprop	7085-19-0 93-65-2	Part 1 and 2	PPPR
	Mercury	7439-97-6	Part 1 and 2	REACH

Delegated Act	Chemical name	CAS number	Amendment of Annex I	Basis for inclusion
	Methiocarb	2032-65-7	Part 1 and 2	PPPR
	Methomyl	16752-77-5	Part 2	PPPR
	Commercial octabromodiphenyl ether, including hexa- and heptabromodiphenyl ether	36483-60-0 68928-80-3	Part 1 and 3	RC
	Commercial pentabromodiphenyl ether, including tetra- and pentabromodiphenyl ether	40088-47-9 32534-81-9	Part 1 and 3	RC
	Pentachlorophenol and its salts and esters	87-86-5 and others	Part 1 and 3	SC
	Perfluorooctanoic acid (PFOA), its salts and PFOA-related compounds	335-67-1 and others	Part 1 and 2	POP
	Thiacoprid	111988-49-9	Part 1 and 2	PPPR
	Thiophanate-methyl	23564-05-8	Part 1 and 2	PPPR

Entries of Annex I modified during the reporting period

Commission Delegated Regulation (EU) 2022/643 of 10 February 2022 included a complete replacement of Annex I to Regulation (EU) No 649/2012 in order to update many entries to reflect changes to classifications of these chemicals in the European Union's Combined Nomenclature (CN).

Substances removed from Annex I

The following amendments are provided in Commission Delegated Regulation (EU) 2022/643 amending Regulation (EU) No 649/2012:

By Implementing Regulation (EU) 2017/1506[11], the Commission decided to renew the approval of the active substance maleic hydrazide under Regulation (EC) No 1107/2009, with the effect that maleic hydrazide and its choline, potassium and sodium salts are no longer banned for use in the subcategory 'pesticide in the group of plant protection products'. Therefore, those substances were removed from the list of chemicals in Part 1 of Annex I to Regulation (EU) No 649/2012.

The new entry on commercial octabromodiphenyl ether in Part 3 of Annex I to Regulation (EU) No 649/2012 also covers the substance octabromodiphenyl ether listed in Parts 1 and 2 of Annex I to that Regulation. Therefore, octabromodiphenyl ether was removed from the lists of chemicals in Parts 1 and 2 of Annex I to Regulation (EU) No 649/2012.

Dicofol is a new listing in Part 1 of Annex V. Since a listing in Part 1 of Annex V to Regulation (EU) No 649/2012 prohibits the export of a substance without any exemption, the listing of dicofol in Parts 1 and 2 of Annex I to that Regulation is no longer required and was removed.

[11] Commission Implementing Regulation (EU) 2017/1506 of 28 August 2017 renewing the approval of the active substance maleic hydrazide in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011 (OJ L 222, 29.8.2017, p. 21).

2.2.1.2 Amendments to Annex V

Amendments to Part 1 of Annex V to the PIC Regulation (chemicals subject to export ban) are triggered by the inclusion of a substance in Annex I to the POPs Regulation (Regulation (EC) 850/2004[12], replaced in 2019 by Regulation (EU) 2019/1021[13]).

During the reporting period, the following substances were added to Part 1 of Annex V.

Table 3. Chemicals added to Part I of Annex V during the reporting period

Legal Act	Chemical name	CAS number
Commission Delegated Regulation (EU) 2022/643 of 10 February 2022	Dicofol is prohibited for export without any exemption	115-32-2
	Perfluorooctane sulfonic acid (PFOS), its salts and perfluorooctane sulfonyl fluoride. The export ban does not apply when PFOS, its salts and perfluorooctane sulfonyl fluoride is used as a mist suppressant for non-decorative hard chromium (VI) plating in closed loop systems.	1763-23-1, 2795-39-3, 70225-14-8, 56773-42-3 and others
	Pentachlorophenol and its salts and esters	87-86-5 and others
	Perfluorooctanoic acid (PFOA), its salts and PFOA-related compounds as regards its presence in fire-fighting foams. The export ban only applies to fire-fighting foam that contains or may contain PFOA, its salts and PFOA-related compounds.	335-67-1 and others
	Decabromodiphenyl ether	1163-19-5 and others

Changes to Part 1 of Annex V

The entry covering articles containing concentrations of tetra, -penta-, hexa- and heptabromodiphenyl ether at or above 0.1% by weight when produced partially or fully from recycled materials or materials from waste prepared for re-use has been amended by Regulation (EU) 2019/1021, reducing the allowed concentrations in articles and adding decabromodiphenyl ether.

A number of classifications of chemicals in the European Union's Combined Nomenclature have been changed since those chemicals were added to Annex I to Regulation (EU) No 649/2012. Those changes have been reflected in the Annex.

Part 2 of Annex V

Part 2 of Annex V to the PIC Regulation lists chemicals subject to export ban other than POPs.

Commission Delegated Regulation (EU) 2022/643 of 10 February 2022 adds the export of mercury, certain mixtures of metallic mercury with other substances, certain mercury compounds and certain mercury-added products to Part 2 of Annex V to Regulation (EU) No 649/2012, in line with Regulation (EU) 2017/852.

[12] Regulation (EC) No 850/2004 of the European Parliament and of the Council of 29 April 2004 on persistent organic pollutants and amending Directive 79/117/EEC, OJ L 158, 30.4.2004, p. 7–49. This Regulation was in force for most of the reporting period before being replaced in 2019 by Regulation (EU) 2019/1021. Among other changes, the recast clarified certain definitions and aligned them with the definitions used in other chemical and waste regulations and updated the Annexes of the Regulation to comply with the Stockholm Convention.

[13] Regulation (EU) 2019/1021 of the European Parliament and of the Council of 20 June 2019 on persistent organic pollutants, OJ L 169, 25.6.2019, p. 45–77.

Table 4. Chemicals added to Part 2 of Annex V during the reporting period

Legal Act	Chemical name	CAS number
Commission Delegated Regulation (EU) 2020/1068 of 15 May 2020	Additions to entry 3: The following mercury compounds except where they are exported for laboratory-scale research or laboratory analysis: Mercury (II) sulphate ($HgSO_4$); Mercury (II) nitrate ($Hg(NO_3)_2$).	7783-35-9, 10045-94-0
	New entry 5: Compact fluorescent lamps (CFLs) for general lighting purposes: (a) CFL.i ≤ 30 watts with a mercury content exceeding 2,5 mg per lamp burner; (b) CFL.ni ≤ 30 watts with a mercury content exceeding 3,5 mg per lamp burner.	n/a
	New entry 6: The following linear fluorescent lamps for general lighting purposes: (a) Triband phosphor < 60 watts with a mercury content exceeding 5 mg per lamp; (b) Halophosphate phosphor ≤ 40 watts with a mercury content exceeding 10 mg per lamp.	n/a
	New entry 7: High pressure mercury vapour lamps for general lighting purposes.	n/a
	New entry 8: The following mercury-added cold cathode fluorescent lamps and external electrode fluorescent lamps for electronic displays: (a) short length (≤ 500 mm) with mercury content exceeding 3,5 mg per lamp; (b) medium length (> 500 mm and ≤ 1 500 mm) with mercury content exceeding 5 mg per lamp; (c) long length (> 1 500 mm) with mercury content exceeding 13 mg per lamp.'.	n/a
Commission Delegated Regulation (EU) 2022/643 of 10 February 2022	New entry 9: Batteries or accumulators that contain more than 0,0005% of mercury by weight.	n/a
	New entry 10: Switches and relays, except very high accuracy capacitance and loss measurement bridges and high frequency radio frequency switches and relays in monitoring and control instruments with a maximum mercury content of 20 mg per bridge, switch or relay.	n/a
	New entry 11: Cosmetics with mercury and mercury compounds, except those special cases included in entries 16 and 17 of Annex V to Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products (OJ L 342, 22.12.2009, p. 59).	n/a
	New entry 12: Pesticides, biocides and topical antiseptics that contain mercury or a mercury compound that was intentionally added.	n/a
	New entry 13: The following non-electronic measuring devices that contain mercury or a mercury compound that was intentionally added: (a) barometers; (b) hygrometers; (c) manometers; (d) thermometers and other non-electrical thermometric applications; (e) sphygmomanometers; (f) strain gauges to be used with plethysmographs; (g) mercury pycnometers; (h) mercury metering devices for determination of the softening point. This entry does not cover the following measuring devices: — non-electronic measuring devices installed in large-scale equipment or used for high precision measurement where no suitable mercury-free alternative is available; — measuring devices more than 50 years old on 3 October 2007; — measuring devices which are to be displayed in public exhibitions for cultural and historical purposes.	n/a

2.2.2 EU import decisions

Article 10 of the Convention requires Parties 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 EU import decision is adopted by means of an implementing act of the Commission. The Commission services draft 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 one Implementing Decision in 2020 and a correcting Implementing Decision in 2021.

The 2020 implementing decision provided new import decisions for phorate and hexabromocyclododecane (HBCDD). Modified decisions were provided for commercial pentabromodiphenyl ether, commercial octabromodiphenyl ether, and PFOS.

The 2021 correcting Decision confirmed that the import decision for azinphos-methyl continues to apply after mistakenly being omitted in Implementing Decision (EU) 2020/2182.

Table 5. EU import responses adopted during the reporting period

Implementing Act*	Chemical names	CAS number	Nature / status of decision	Import decision	Grounds for decision
(EU) 2020/2182 of 18 December 2020	Phorate	298-02-2	New decision / Final	No consent to import	Banned for use by PPPR
	Hexabromo-cyclododecane	134237-50-6, 134237-51-7, 134237-52-8, 25637-99-4, 3194-55-6	New decision / Final	No consent to import	Banned for use by POPs Regulation
	Commercial Pentabromo-diphenyl ether including - tetrabromo-diphenyl ether - Pentabromo-diphenyl ether	40088-47-9, 32534-81-9	Modified decision / Final	Consent to import only subject to specified conditions	Exemption for continued use for spare parts /upgrade in certain Electrical and Electronic Equipment (EEE) provided by RoHS Directive
	Commercial octabromo-diphenyl ether including: Hexabromo-diphenyl ether Heptabromo-diphenyl ether	36483-60-0, 68928-80-3	Modified decision / Final	Consent to import only subject to specified conditions	Exemption for continued use for spare parts /upgrade in certain EEE provided by RoHS Directive
	Perfluorooctane sulfonic acid, perfluorooctane sulfonates, perfluorooctane sulfonamides and perfluorooctane sulfonyls (PFOS)	1763-23-1, 2795-39-3, 29457-72-5, 29081-56-9, 70225-14-8, 56773-42-3, 251099-16-8, 4151-50-2, 31506-32-8, 1691-99-2, 24448-09-7, 307-35-7	Modified decision / Final	Consent to import only subject to specified conditions	Banned for use by POPs Regulation - specific derogation

* Commission Implementing Decision

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 various implementation issues (see Table 6).

Table 6. Implementation issues discussed at DNA meetings

DNA Meeting	Implementation issued discussed
35th – July 2020	Application of the provisions of the PIC Regulation to Annex I group entries. Export of PIC substances as impurities of non-PIC substances. Use of ePIC mixture template for the notification of exports of NPs/NPEs.
36th – November 2020	Metallic mercury under the PIC Regulation. Labelling trigger for non-hazardous mixtures. Approach for the recording of import notifications with several final destination countries.
37th – April 2021	Use category when notifying pesticides to be (primarily) used in industrial settings in the importing country. Definition of an article under PIC. Approach for the implementation of the new PIC Annex I entry for "Benzene as a constituent of other substances in concentrations equal to, or greater than 0,1% by weight".
38th – October 2021	Approach for notifying treated/coated seeds.
39th – April 2022	PIC Regulation and exports to Russia and Belarus with regard to sanctions and dual-use items. Shortage of containers and fulfilment of PIC obligations. Amendments to the PIC Regulation and existing export notifications.
40th – October 2022	Legal entity change, asset transfer and company name change.

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 a chemical listed in Parts 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 addition, when a chemical listed in Part 2 of Annex I is exported to an OECD country, according to Article 14(6), the DNA of the exporter's Member State '*may, at the request of the exporter, in consultation with the Commission and on a case-by-case basis, decide that no explicit consent is required if the chemical, at the time of importation into the OECD country concerned, is licensed, registered or authorised in that OECD country*' (procedure known as 'OECD waiver').

Two matters concerning Article 14(7) were addressed during the reporting period. One concerned the operation of ePIC regarding searching for PIC chemicals. The other concerned modification of the "In brief" fact sheet on waivers.

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. No specific actions related to enforcement have been noted during the reporting period.

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 of the Rotterdam Convention (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 EU 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

3.1.1 Representation of the EU to the Rotterdam Convention and coordination of EU input to the 10th and 11th Conferences of the Parties (CoP) to the Rotterdam Convention

During the reporting period, the Commission represented the EU at the 10th CoP, which took place from 26 to 30 July 2021 (online segment which dealt with operational matters only), and from 6 to 17 June 2022 (face-to-face segment which dealt with technical matters). Preparation for the 11th CoP which took place from 1 to 12 May 2023 also occurred so is reported here.

CoP-10

Before the CoP, 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:

- Proposal for a Council Decision establishing the position to be adopted on behalf of the European Union within the Conference of the Parties as regards amendments of Annex III to the Rotterdam Convention. This concerned the proposal to add decabromodiphenyl ether (decaBDE) and perfluorooctanoic acid (PFOA), its salts and PFOA related compounds to Annex III. This proposal was adopted and submitted to the Council on 20 April 2021.

As for the previous CoP, the Commission contributed to the drafting of the position paper of the EU and its Member States and to the corresponding statements for their participation in the CoP. The position paper and statements cover all agenda items of the meeting.

During the CoP, the Commission represented the EU and the EU and its Member States in contact groups and in any bilateral meetings with Parties, the Secretariat of the Convention and other stakeholders, and contributed to the drafting of Conference Room Papers.

After CoP-10, the Commission presented the outcomes of the CoP to DNAs at the 40th DNA meeting on 20 October 2022. As regards listing of additional chemicals in Annex III, out of 7 chemicals only 2 had been listed; decabromodiphenyl ether (decaBDE) and perfluorooctanoic acid (PFOA), its salts and related compounds.

CoP-11

In preparation for the CoP, which occurred after the present reporting period, the Commission prepared and consulted with the Member States on the position of the EU on matters discussed at the meeting concerning:

- Two new candidates for listing in Annex III that would be on the agenda, based on the recommendation of the CRC - iprodione and terbufos. The position to be taken on behalf of the EU at the COP as regards their listing would be laid down in a Council Decision, which would be based on a Commission proposal. The EU and its Member States position on all other agenda items that will be addressed at the CoP would be discussed in WPIEI and laid down in an EU-MS position paper.

3.1.2 Participation in committees and expert groups

Members of the Commission participated as experts in the CRC, along with experts from Member States as follows:

- 1 May 2018 until 30 April 2022 – a Commission official was nominated by Malta.
- Since 1 May 2020 – a Commission official was nominated by Austria. That official also acted as member of the bureau of the CRC.

3.2 Communication of information to the Secretariat of the Rotterdam Convention

3.2.1 Notification of FRA

Under 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, supported by the Agency, drafts the notifications, which are submitted to DNAs and observers for comments before being submitted to the Secretariat. Twenty-nine notifications were submitted to the Secretariat during the reporting period:[14]

- 5-tert-butyl-2,4,6-trinitro-m-xylene (Musk xylene) (2022)
- Arsenic pentoxide (2022)
- Benzyl butyl phthalate (2022)
- Chlorothalonil (2021)
- Chlorpropham (2021)
- Chlorpyrifos (2022)
- Cybutryne (2020)
- Diisobutyl phthalate (2020)
- Dimethoate (2021)
- Diquat (2021)
- Ethoprophos (2021)

[14] https://www.pic.int/Countries/CountryProfiles/tabid/1087/language/en-US/Default.aspx, select region European Union, select tab submissions to see a list of "Notifications of Final Regulatory Action - Non-Annex III Chemicals"

- Fenamidone (2022)
- Flupyrsulfuron (2020)
- Flurtamone (2022)
- Isoproturon (2020)
- Linuron (2020)
- Mancozeb (2022)
- Mercury (2022)
- Methiocarb (2022)
- Oxasulfuron (2022)
- Propineb (2022)
- Pymetrozine (2022)
- Tepraloxydim (2022)
- Thiamethoxam (2022)
- Thiram (2022)
- Triasulfuron (2020)
- Triclosan (2020)
- Tricyclazole (2020)
- Tris(2-chloroethyl) phosphate (2020)

3.2.2 Communication of EU import responses

In line with Article 10 of the Rotterdam Convention and Article 13 of the PIC Regulation, the Commission communicated the formally adopted EU import decisions to the Secretariat of the Rotterdam Convention. The following final import decisions were submitted and published on the Convention website:[15]

- Commercial pentabromodiphenyl ether (including tetra- and pentabromodiphenyl ether)
- Commercial octabromodiphenyl ether (including hexa- and heptabromodiphenyl ether)
- Hexabromocyclododecane
- Perfluorooctane sulfonic acid, perfluorooctane sulfonates, perfluorooctane sulfonamides and perfluorooctane sulfonyls (PFOS)
- Phorate.

3.2.3 Ad-hoc Secretariat requests

The Commission replied to a number of information requests from the Rotterdam Convention Secretariat by collecting, compiling and submitting the requested information as follows:

- Information on exports, export notifications and information exchange (i.e. implementation of paragraph 2 of Article 11 and Articles 12 and 14 of the Convention);
- Data on international trade in chemicals listed in Annex III or recommended for listing;
- Information on the measurable impact of listing in Annex III;
- Data on synergies in preventing and combating illegal traffic and trade in hazardous chemicals and wastes.
- Information on international trade in chemicals subject to review by the CRC.

[15] https://www.pic.int/Procedures/ImportResponses/Database/tabid/1370/language/en-US/Default.aspx, select tab submissions to see a list of "Import Responses by Party" and enter European Union. See also Commission Implementing Decision (EU) 2020/2182 of 18 December 2020 (C(2020) 8977), https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32020D2182

In addition, the Commission has submitted comments, agreed in WPIEI, on the recommendations from the CRC for amending Annex III to the Rotterdam Convention to be considered at CoP-10 on behalf of the EU. In that reply, the EU supported the listing of all chemicals that were recommended for listing by the CRC.

The Commission also provided ongoing technical assistance projects with the Secretariat throughout this reporting period.

3.3 Replies to requests for explicit consent received from other Parties

The PIC Regulation does not provide any specific rules for cases where an exporting non-EU country requests the explicit consent of the EU for the export of a chemical to the EU. Nevertheless, the Commission, acting as the designated authority of the EU, responds to such requests by establishing a reply on behalf of the EU to the non-EU country.

Therefore, when an exporting non-EU country submits an export notification with a request for explicit consent to the Commission, asking whether the EU consents to the export of a chemical to the EU, a reply is provided by the Commission after consultation of the Member States.

The export notification is, as usual, processed by the Agency, which includes sending an acknowledgement of receipt of the export notification to the notifying non-EU country (unless otherwise preferred by the importing country). If a Member State receives an export notification together with a request for explicit consent, it forwards the request and the corresponding export notification to the Commission and the Agency for processing.

During the reporting period, the EU submitted 41 explicit consent responses to parties to the Rotterdam Convention or other countries. In 40 of these cases the exporting country was the UK, in the other it was Burkina Faso.[16]

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.

During the period 2020-2022, the Commission did not receive any ad-hoc requests falling within the scope of Article 20 of the PIC Regulation.[16]

3.5 Financial contribution to the Rotterdam Convention

As a Party to the Rotterdam Convention, the EU contributes to the Convention's Trust Fund and the 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. The money paid into the Special Voluntary Trust Fund during this period was for projects that were based on the programme of work adopted by COP-9 in 2019.

[16] Report on the exchange of information under the PIC Regulation in 2020-2021, October 2022, https://echa.europa.eu/documents/10162/1244645/pic_article_20_report_2020-2021_en.pdf, page 16

Table 7. Financial contributions from the EU to the Rotterdam Convention's Trust Fund and Special Voluntary Trust Fund

Year	EU Contribution to Trust Fund	EU contribution to special voluntary trust fund[17]
2020	79,417 USD	617,131 USD
2021	80,440 USD	0 USD
2022	78,738 USD	0 USD

[17] Commitments in accordance with the agreement concluded with the Secretariat of the Convention in the respective year.