Report on the operation of the Prior Informed Consent (PIC) Regulation 2023

October 2023

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1. Foreword

The European Chemicals Agency (ECHA), over the past three years[1], has continued to seek the optimisation of the implementation of the Prior Informed Consent Regulation (PIC) processes, both by providing support to the European Commission (Commission) and the Designated National Authorities (DNAs). We have also continued identifying and addressing challenges in the implementation of the legal text, while ensuring regular adaptations to the ePIC IT tool. Despite our efforts, a number of implementation issues remain challenging.

Increased workload
The overall processing workload has remained high despite a slight decrease of export notifications processed during the last three years. This is because of the constant addition of new chemicals subject to the PIC and the increase in the number of substances subject to the additional requirement of explicit consent from non-EU importing countries prior to their export.

Some of the new substances added have been particularly challenging, and even triggered a need for enhanced support to the EU and non-EU DNAs in their own tasks.

Increased public interest

In response to increased interest from the media and NGOs on the topic of the export of EU banned substances in the last few years, we have worked on an enhanced dissemination of the PIC data. It went live in November 2022 and made available more information in a more user-friendly way.

However, the number and complexity of requests for Access To Documents (ATD) has continued to increase over the whole reporting period, leading to a substantial amount of ECHA's and Member States' resources being used to process them. These tasks compete with the regular and foreseen tasks under the PIC Regulation.

More transparency, predictability and clarity needed

The increase in ATD requests has confirmed the need to increase the transparency of the data concerning exports and imports of hazardous chemicals by the introduction of specific provisions in the Regulation to enable ECHA to make even more PIC data available to the public.

In addition, in recent years, the irregular publication of amendments to the Regulation, subjecting new substances to the PIC requirement, has caused challenges for ECHA, DNAs and duty holders in planning their resources. Furthermore, other new and ad-hoc activities in support of the Commission e.g. reporting for the purpose of the Rotterdam Convention, have emerged.

Should the frame for the implementation of the PIC Regulation remain as the current high rate, additional resources would be needed. The outcome of the evaluation of the PIC Regulation and its potential review, as well as the potential ban for export of hazardous chemicals that are banned in the EU could, however, lead to a decrease in the current pressure on our PIC resources. Clarity in the scope and timelines of these initiatives would allow ECHA to plan our resources and work programme for this area.

To ensure effective implementation of the PIC regulation in the future the proposed legal

[1] This is the European Chemicals Agency's third Report on the operation of the PIC Regulation, for the period from 1 January 2020 to 31 December 2022, under Article 22 of the regulation

changes identified in this report should be introduced if the regulation is reopened.

Sharon McGuinness
Executive Director

2. PIC Regulation - Introduction

The Prior Informed Consent (PIC) Regulation governs the export and import of certain hazardous chemicals between the EU and non-EU countries, placing obligations mainly on companies that want to export these chemicals to non-EU countries.

Within the EU, the PIC Regulation implements the *Rotterdam Convention on the prior informed procedure for certain hazardous chemicals and pesticides in international trade*.

It aims to promote shared responsibility and cooperation in the international trade of hazardous chemicals. It also protects human health and the environment by providing developing countries with information on how to safely store, transport, use and dispose of hazardous chemicals.

The PIC Regulation entered into force in July 2012 and became applicable in March 2014 when its operational responsibility was handed to ECHA by the European Commission.

Among other tasks, ECHA carries out administrative and technical tasks related to implementing the PIC Regulation as well as providing technical and scientific assistance to industry and to the Designated National Authorities (DNAs) both from the EU and non-EU countries. ECHA also manages the IT tool (ePIC) which has been established to ensure that the requirements under the PIC Regulation are supported by appropriate IT systems.

3. Questionnaire

3.1 General information

1. **Organisation**: European Chemicals Agency (ECHA)
2. **Period covered**: 01.01.2020 – 31.12.2022

3.2 Information on the Agency

3.2.1 Human resources in the Agency (in full-time equivalent) working on the implementation of Regulation (EU) No 649/2012:

	2020	2021	2022
Number of staff[2] working on PIC	8	8	8

3.2.2 Is the Agency staff also involved in the implementation of other EU/international chemical legislation/conventions/programme?

☒ Yes

☐ No

If yes, please specify which legislation and describe the issues/topics on which staff working on Regulation (EU) No 649/2012 collaborates with staff working on a different piece of legislation:

The European Chemicals Agency is also responsible for the implementation of:

- Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH);
- Regulation (EC) No 1272/2008 of the European Parliament and of the Council on the classification, labelling and packaging of substances and mixtures (CLP);
- Regulation (EU) No 528/2012 of the European Parliament and of the Council concerning the making available on the market and use of biocidal products (BPR).

Furthermore, ECHA is involved in the implementation of:

[2] Temporary agents (TA) and Contract agents (CA). The number reported covers staff in the operational team in the Submission and Processing unit (7 FTEs), plus staff supporting ECHA's PIC operations in Agency's horizontal activities such as human resources, finances (1 FTE in total).

- Regulation (EU) No 2019/1021 of the European Parliament and of the Council of 20 June 2019 on persistent organic pollutants (POPs Regulation);
- Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work (Chemical Agents Directive) and Directive 2004/37/EC of the European Parliament and of the Council of 29 April 2004 on the protection of workers from the risks related to exposure to carcinogens or mutagens at work (Carcinogens and Mutagens Directive (Directive 2004/37/EC), and in particular in the setting of occupational exposure limit (OEL) values;
- Directive (EU) 2018/851 of the European Parliament and of the Council amending Directive 2008/98/EC on waste (Waste Framework Directive), and in particular in the establishment of the database for information on Substances of Concern In articles as such or in complex objects (Products) (SCIP Database);
- Directive (EU) 2020/2184 of the European Parliament and of the Council of 16 December 2020 on the quality of water intended for human consumption (a,k,a. Drinking Water Directive).

ECHA operational staff working on the implementation of the PIC Regulation (hereafter referred as "ECHA PIC Team") collaborate with ECHA staff involved in the implementation of the above-mentioned pieces of legislation and other contributions everywhere there are synergies with activities that are run across the various pieces of legislation and which can benefit both the Agency and its stakeholders (EU companies, Commission, Member States, non-EU countries, general public). In particular, the following fields and topics of collaboration can be mentioned:

- Scientific, technical and regulatory support: in order to provide the most accurate and appropriate support/advice to its various stakeholders, the ECHA PIC Team collaborates with an internal network of expert colleagues on REACH, CLP and BPR, for:
    - 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 compliance of Safety Data Sheets (SDS) submitted as part of PIC export notifications;
    - Checking the proper application of Classification, Labelling and Packaging rules under CLP, and in particular for mixtures;
    - Checking the regulatory status and background of substances under BPR or REACH (Authorisation; Restrictions), in particular for the purpose of the development of legal texts to be used under section 6.1 of export notifications, or for the drafting of "background documents" provided to the Commission for making decisions on explicit consent requests from non-EU countries under the Rotterdam Convention;
    - 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 (industry and Member States), by means of the Helpdesk, the publication/update of various manuals, guidelines and factsheets, and communication actions (ECHA Weekly News - by email, ECHA Newsletter, social media, etc.).

- IT tools development and maintenance: in order to benefit from potential efficiency gains and synergies between all ECHA's IT tools (e.g. concerning login and account management, standard modules in submission and processing IT tools), the ECHA PIC Team is working in close cooperation with their expert colleagues of the ECHA IT Department as well as those in charge of the management of other IT tools in the various operational units of the Agency;
- Making available of PIC data (dissemination) – please see further details in responses to questions 45 and 46;
- Planning, data mining and reporting, in order to align and optimise the planning and reporting of ECHA's activities across the various legislations and activities that is responsible for;
- Legal advice, and in particular in the context of applications for access to document (ATD requests);
- Human resources and Finances, to ensure the most efficient use of those shared transversal support resources in the management of ECHA's human and financial PIC resources.

3.2.3 Is the Agency's workload in line with the predicted workload?

☒ Yes

☐ No

Additional information:

The number of export notifications processed by ECHA has decreased over the whole reporting period, as illustrated by the numbers below:

	2020	2021	2022
No. of estimated notifications	12 000	13 200	14 500
Actual No. of notifications processed[3]	11 971	10 699	10 072

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 reporting period 2020 -2022, also implying that the initial estimate of a ~10% yearly increase was not confirmed. The figures in the above table 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 (Great Britain) to other non-EU countries.

However, the ECHA PIC Team overall processing-related workload has remained high, since other processing and related tasks have increased in balance over the same period.

[3] This number includes export notifications validated, as well as resubmissions and rejections, as it better reflects the actual workload of the Agency related to export notifications.

Firstly, the number of **import notifications** increased (381 in 2020; 674 in 2021 and 811 in 2022) 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. More details can be found here: https://echa.europa.eu/information-on-chemicals/pic/import-notifications.

Moreover, most of the chemicals that were added to the list of chemicals subject to the PIC procedures (Annex I) during the reporting period (through amendments Regulation EU 2020/1068 and Regulation (EU) 2022/643) require an explicit consent from the authorities in the country of destination before the export can take place. Consequently, the number of **explicit consent**-related tasks (evaluation of responses, RIN reconciliations, reminders) increased significantly over the reporting period. The number of consent responses recorded in ePIC **increased by 58% in 2020-2022** (a total of 4 281 responses registered) compared to the previous reporting period of 2017-2019 (2 701 registered responses). Typically, the requirement for an explicit consent also leads to the need for additional stakeholder support towards both the EU Member States' Designated National Authorities (DNA), 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 (please see further details in question 8).

Furthermore, both amendments during the reporting period introduced **new types of entries**, such as an entry for "Benzene as a constituent of other substances in concentrations equal to, or greater than 0,1 % by weight" (i.e. first "substance in substances" subject to the PIC Regulation requirements), substances previously in part 1 (only) of Annex I and added to part 2, or entries for chemicals (e.g. thiram, thiamethoxam) that are exported in treated seeds and more complex to implement.

The interest and capacity of (certain) importing countries to better manage their imports and use of hazardous chemicals has also opened a potential for an enhanced support from the EU, and hence ECHA, in receiving and analysing the data they get from PIC. However, the often limited capacity of those importing countries require the EU to adapt its procedures/communications and/or support towards those countries; some policy development - such as the implementation of the new Annex VIII to the Rotterdam Convention – may also trigger more exchanges – and possibly *ad-hoc* communications or procedures – with importing countries in the future.

Overall, the approximate figures reflecting the amount of support provided to the Commission, EU- and non-EU DNAs are summarized in the table below and, depending on the time of year, the ECHA PIC Team members spend in average between 30-40 % of their time on this task.

	2020	2021	2022
No. of requests for technical/ regulatory support	3450	3550	3800

As already stressed in the past, the yearly export notification requirement also implies an uneven distribution of the workload throughout the year, with an annual peak of submissions during the period between October and January, which can count for 70 – 80 % of the total yearly processing of export notifications. In order to meet its legal deadlines, to face the workload described above and to still provide the necessary level of stakeholder support, ECHA had to regularly hire and train interim staff and trainees for several months every year, as the core staff is insufficient to cover winter peak

periods. 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 is always expected immediately after the publication of the amendment and triggers challenges in terms of resources' availability and planning.

The high and increasing number of submissions has led ECHA to continue investing human and financial resources in the enhancement and maintenance of the **ePIC application** and in further improvements to the existing features and more generally ECHA's processes and ways of working in implementing the PIC Regulation. Further enhancements to the application should be considered to support all actors to cope with a high workload and to meet their legal obligations (concrete suggestions provided under question 43). IT development is nevertheless resource-demanding as the ECHA 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, ECHA'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, optimized and subject to continuous improvement.

Last but not least, an increased interest of media and NGOs on PIC data in general, and the topic of the export of EU banned substances in particular, and despite an enhanced dissemination of the PIC data which went live in the autumn 2022 and made available, more information and in a more user-friendly way (please see further details in responses to questions 45 and 46), a substantial number of **Access To Document** (ATD) requests on PIC data was received and processed during the reporting period (21 in total), some of them being very large and complex in scope, and hence highly resources-intensive. 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, also towards Member States who often have requested ECHA's expertise and support to deal with them. The processing of ATD requests is mainly carried out by the ECHA PIC team - in support to and in close collaboration with ECHA's Legal Affairs Unit - which deviates several of its members from their primary tasks in PIC, namely the processing of PIC submissions and the support to stakeholders. Should ECHA 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 (see section 13 for suggestions in that respect).
The outcome of the possible revision of the PIC Regulation and/or 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 ECHA'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.

3.3 Support to exporters and importers

3.3.1 In which of the following activities has the Agency set support and communication activities in place in order to assist exporters and importers in complying with Regulation (EU) No 649/2012?

- ☐ Technical and scientific guidance
- ☒ Web pages on Regulation (EU) No 649/2012 and ePIC
- ☒ Internal messaging in ePIC
- ☒ Awareness-raising campaign
- ☒ Social media
- ☐ Visits to operator establishments
- ☒ Support to individual companies
- ☒ Workshops, webinars and similar training events
- ☒ IT user manuals, factsheets and Q&A (frequently asked questions)
- ☐ Others

Additional information, if relevant:

Technical and scientific guidance:
The available Guidance document was not updated during the reporting period.

Web pages on Regulation (EU) No 649/2012 and ePIC:

ECHA has improved or maintained the following dedicated landing web pages, and translated them in all official EU languages:
https://echa.europa.eu/regulations/prior-informed-consent/understanding-pic (PIC Regulation)
https://echa.europa.eu/support/dossier-submission-tools/epic (ePIC)

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 is 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

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

Direct links to the PIC Regulation legal texts (initial text, latest consolidated version, and non-consolidated latest amendments) are made available and kept up-to-date under the section "Legislation" of the ECHA public website, at: https://echa.europa.eu/regulations/prior-informed-consent/legislation.

The "PIC Circular" issued twice a year by the Secretariat of the Rotterdam Convention is also published on the ECHA website, at: https://echa.europa.eu/regulations/prior-informed-consent/pic-circular.

Internal messaging in ePIC:
This means of communication is typically used in the following cases:

- To remind exports/importers of upcoming legal deadlines (e.g. Article 10 reporting deadline);
- To alert or remind exports 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 ECHA closures;
- To inform users on new functionalities in ePIC;
- To inform users on performance issues, bugs etc.

Awareness-raising campaign:
ECHA regularly informs or reminds exporters/importers of various PIC-related issues such as:

- upcoming regular legal deadlines (e.g. Article 10 reporting deadlines);
- new or clarified legal obligations (e.g. entry into application of a new amendment to Annex I and/or V);
- peaks in workload and related processing times and timelines to be expected.

For that, the Agency has used different communication channels, such as the ECHA Weekly News (by email) or the ECHA Newsletter.

Social media:
ECHA has 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 ECHA's Article 10 reports and ECHA's participation in the meetings of the Parties to the Rotterdam Convention.

Support to individual companies:
This support is mainly provided by means of replies to incoming Helpdesk incidents (*cf. Question 8 for further details*). When needed (e.g. communication/language issues), ECHA also provided *ad hoc* support over the phone, usually as a follow-up to initial exchanges via the Helpdesk.

ECHA additionally contacts 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 ECHA 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 how to submit the intended exports and actual quantities exported and imported within the ePIC application. The webinar included a Q&A session allowing the participants to send specific questions. The YouTube video of the webinar, presentations and the Q&A section are available on the ECHA Website, at:
https://echa.europa.eu/-/know-your-obligations-when-exporting-hazardous-chemicals-outside-the-eu
The webinar is regularly referred to as a useful piece of information to our stakeholders, e.g. in the context of helpdesk enquiries.

Information on obligations under PIC were additionally 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 (frequently asked questions):
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 to identify their obligations under PIC Regulation after BREXIT, Q&A pairs on the UK withdrawal from the EU and Northern Ireland Protocol (NIP) were developed and published on ECHA Website:
- https://echa.europa.eu/advice-to-companies-q-as/pic (Brexit)
- https://echa.europa.eu/advice-to-companies-q-as/northern-ireland

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. ECHA 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.

3.3.2 Does the Agency consider that these support and communication activities have improved the compliance of exporters and importers with Regulation (EU) No 649/2012?

☒ Yes

☐ No

Additional information:

At the end of this reporting period (end of December 2022), ePIC had 1 475 registered companies of which 533[4] had actively used the submission system in 2022. The number of active companies decreased in contrast to the previous reporting period due to the revocation of accounts registered in the United Kingdom (Great Britain). ECHA is of the opinion that the support and communication activities given by ECHA (via on-line events, information on ECHA's website, news items, Q&As) have contributed to increasing awareness of and compliance with the PIC

[4] In 2019, 578 companies had actively used ePIC.

Regulation. A substantial number of export notifications to United Kingdom (Great Britain) (2021: 620, 2022: 594), were submitted after the Brexit transition period and trade (both export and import) were reported in accordance with Article 10.

3.3.3 What is the nature of the most frequent requests for support coming from exporters and importers?

- ☒ Chemicals subject to Regulation (EU) No 649/2012 and other scope-related issues
- ☒ Activation of reference identification numbers and related issues (e.g. export notification and explicit consent/waiver)
- ☒ Article 10 of Regulation (EU) No 649/2012 on reporting
- ☒ ePIC functionality
- ☒ Others

Additional information, including the number of requests received and an indication on the distribution of the questions across the topics.

This table specifically refers to requests received from industry (the requests from other stakeholders are listed in response to Question 5) and are specific to PIC/ePIC.

	2020	2021	2022
No. of requests[5]	339	291	227

The largest number of enquiries ECHA received were on the following topics:

- 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: e.g. exporters are not always clear on whether their substance is subject to PIC or not, and especially when those are potentially falling within the scope of an Annex I so called "group entry" (e.g. cadmium and its compounds, substances containing Benzene as a constituent of other substances in concentrations equal to, or greater than 0,1 % by weight).
- Article 10 reporting: during the first quarter of every year, ECHA usually receives requests from exporters/importers related to their obligations for reporting exact quantities of PIC chemicals exported/imported during the previous calendar year, and/or editing their trade partners in the importing countries.

[5] Questions related to ECHA/ePIC user accounts, access management, etc. are considered to be out of scope.

- General questions related to obligations/procedures under PIC e.g. exporters and importers are not always certain about the applicable procedures ("How to notify exports/imports?", when the submissions of export notifications for chemicals that are listed in a draft amendment can proceed).
- Definitions/concepts of "exporter", "importer" and "transit" under PIC: e.g. from which country should the export notifications be submitted, e.g. when the legal entity holding the contract is in one Member State but the shipment is leaving from a different Member State? What are and who has obligations under PIC when the manufacturer is based in a non-EU country, for example in Switzerland, however, the chemicals are being shipped from the EU?
- Obligations under PIC on trade to/from the UK (e.g. "Does UK companies need to notify/report quantities under PIC, UK company shipping from the EU, EU company shipping from the UK?").

In addition to the above, the following are examples of which the numbers of enquiries are comparatively lower but usually require asking for the support of expert colleagues, being it within the Agency or in 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 relating to the ePIC tool and its functionalities have remained low and not representative of any major issue, indicating a good level of quality and service.

3.3.4 Estimated amount of time spent on such support (expressed as a percentage of the total number of full-time equivalents):

There are in average six members (FTEs) of the PIC Operations Team in the Submission and Processing Unit (A3) who are involved in providing replies to the requests received from companies via the Helpdesk. On average, approximately 10 % of their time is spent on this specific activity (i.e. 0.6 FTE).

3.4 Coordination between the Agency and the Commission/Designated National Authorities (DNAs)

3.4.1 Is the Agency satisfied with the collaboration with the Commission?

☒ Yes

☐ No

Additional information:

ECHA and the Commission overall work well together. In addition to the day-to-day email exchanges between the ECHA PIC Team and the Commission, regular teleconferences (in every six weeks in average) take place to discuss ECHA's PIC-related tasks/activities, in particular when the involvement of other ECHA experts colleagues is needed (e.g. regarding the drafting of Final Regulatory Action notifications). In 2020-2022 ECHA prepared notifications of Final Regulatory Action for 36 chemicals. The above-mentioned regular teleconferences between ECHA and the Commission have helped to improve the predictability and planning of the work in this field.

The overall efficiency of waiver management has improved (please also see response to question 26). The number of cases leading to a revision of the initial decision (mentioned in the two past reports), has decreased. Certain cases are still clarified through day-to-day exchange between ECHA and the Commission since ECHA often has a better visibility than the Commission on the communications of ongoing clarifications regarding the consent responses.

However, there are still some areas in which collaboration could be further improved in order to be more beneficial to both parties and to result in an even higher level of stakeholder satisfaction; those have been further elaborated upon in the section below.

3.4.2 Areas in which collaboration could be improved, if any:

☐ Article 6(1)(e) of Regulation (EU) No 649/2012 on drafting of decision guidance documents and other technical documents related to the implementation of the Convention

☐ Preparation of notifications of final regulatory action to the Rotterdam Convention Secretariat

☒ Technical preparation of meetings (e.g. DNA meetings, Chemical Review Committee, Conference of the Parties to the Rotterdam Convention)

☐ Participation in meetings (e.g. DNA meetings, Chemical Review Committee, Conference of the Parties to the Rotterdam Convention)

☐ Article 6(1)(f) of Regulation (EU) No 649/2012 on providing technical and scientific input in order to ensure the effective implementation of the Regulation

☐ Providing technical and scientific input and assistance concerning the Commission's role as common DNA of the Union

☐ Article 8(5) of Regulation (EU) No 649/2012 on export in case of an emergency situation

☐ Article 14(6) and (7) of Regulation (EU) No 649/2012 on decisions that the export can

proceed in the absence of an explicit consent

☐ Article 20 of Regulation (EU) No 649/2012 on exchange of information

☐ Article 21 of Regulation (EU) No 649/2012 on technical assistance

☒ Article 23 of Regulation (EU) No 649/2012 on updating annexes

☒ Other

Additional information:

Technical preparation of meetings:

In the context of the preparation for the biannual meetings of the Designated National Authorities for the PIC Regulation (DNA meetings), the documents are often sent to ECHA for checking/drafting with short deadlines to react. Taking into consideration the overall workload, it becomes a challenge for ECHA to comply with last-minute requests and to still produce good quality documentation. ECHA is of the opinion that there is still a potential for a more advanced planning and a stronger collaboration in the identification of agenda items, the preparations of the discussions and the development of the related supporting meeting documents.

Article 23 of Regulation (EU) No 649/2012 on updating annexes:

As outlined in the previous report, ECHA is nowadays involved at an earlier stage than in the past in the process of amending the Annexes I and V to the PIC Regulation, which has proven valuable. This enables the Agency to check and, if needed, advise the Commission on the most appropriate identification of the chemicals proposed for inclusion, and by that to ensure consistency with other legislations managed by ECHA, to limit the risk of having to solve at a later stage any substance identity-related issues, to provide clarity to companies and therefore to reduce the number of enquiries that ECHA receives via its helpdesk. In the particular case of new Annex I entries covering more than one substance and/or an open group of substances, it enables agreeing on the most appropriate approach to name and identify the entry/group and its members, and to structure and align the entry in Annex I and in ePIC.

As already communicated by ECHA, the entry into application of amendments to the Regulation are not always optimal and creates additional administrative burden to all actors involved, especially when happening in the middle of a calendar year and not coinciding somehow with the recurrent "end-of-year" peak in submissions. ECHA believes that the entry into application of amendments should, whenever possible, be targeted to 1 January or in the first quarter of the year to avoid two very distinct and disconnected annual peaks of submissions of export notifications and their processing related tasks, as well as support to stakeholders. Such timing would improve the predictability and better planning not only for ECHA and Member States, 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 entry into application tends to create pressure to have the export notifications and explicit consents in place within a very short period of time, in case companies plan 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).

ECHA would like to stress once again that the 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.

Firstly, this information is the basis for the legal texts developed by ECHA and made available in ePIC for exporters to fill in the Section 6.1 of their export notifications. As indicated in responses to other questions in this questionnaire (e.g. question 15), the Section 6 of export notifications is one of the main sources of difficulties for exporters in filling their export notifications, and hence of questions to the ECHA Helpdesk and reasons for resubmission requests. The clearer and more exhaustive is the information provided – e.g. as part of the "Whereas" clauses of the Commission delegated act introducing the new substances – the easier it is for ECHA to translate this regulatory basis into clear and useful standard legal texts in ePIC for Section 6.1 of the export notifications, to respond to related helpdesk questions and to develop meaningful resubmission requests messages, and for exporters to understand them. This would also ensure that the knowledge about the inclusion of a new (group of) substance(s) is not dependent on the actors involved in the preparation of the amendments to Annex I.

Secondly, 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 (e.g. if no longer banned as pesticide, or the scope of authorised uses under BPR has changed) and, if necessary, the identification of the need for an update of the listing of the substance in Annex I (or at least of the standard text for Section 6.1 in ePIC), should such a monitoring be decided.

Other

With regards to the day-to-day exchanges between ECHA and the Commission, and as already suggested in the questionnaire for the two previous reporting periods, there is room for improvement concerning the timing for replies. Whereas some delays are understandable for certain policy issues (which are often complex in nature and may require an involvement of other Commission services), they can create challenges on operational issues which, for example, concern a specific export. In such cases, ECHA is often put under pressure by the exporter/exporter's DNA.

3.4.3 Is the Agency satisfied with the collaboration with the DNAs?

☒ Yes

☐ No

Additional information:

3.4.4 Areas in which collaboration could be improved, if any:

☒ Article 8(2) of Regulation (EU) No 649/2012 on the timelines for processing export notifications

☒ Article 8(5) of Regulation (EU) No 649/2012 on export in case of an emergency situation

☐ Article 8(7) of Regulation (EU) No 649/2012 on additional information to provide on request concerning the exported chemical

☐ Article 14(6) of Regulation (EU) No 649/2012 on substances that cannot be exported

unless certain conditions are fulfilled

Article 14(6) and (7) of Regulation (EU) No 649/2012 on decisions that the export can proceed in the absence of an explicit consent

☐ Other

Additional information:

ECHA 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. There are areas in which the collaboration could be more smooth and efficient and they have been further elaborated upon in responses to questions 19, 23 and 24.

In addition to day-to-day exchanges and to foster the collaboration, the following ad hoc supplementary support actions were provided to the DNAs over the reporting period:

- On 8 June 2021 ECHA organised a WebEx training session for the DNAs on the new functionalities of the enhanced messaging module in ePIC; the training included a presentation, a practical demo and a Questions & Answers session.

- On 17 November 2021 ECHA organised a WebEx training session for the DNAs on explicit consent management. The session covered the main elements included in the DNA's tasks in ePIC (e.g. how to make a request, how to record the terms and conditions, close functionality), as well as practical cases illustrating some specific restrictions (i.e. RIN-specificity, exporter-specificity, validity period) which were identified as most challenging for the DNAs to assess.

- After the Commission delegated Regulation (EU) 2022/643 amending Annexes I and V to the PIC Regulation was published on 20 April 2022, on 21 April 2022 ECHA sent via email to the DNAs 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.

- To support the DNAs in the preparations and submission of the annual reports according to Article 10 of the PIC Regulation, ECHA prepared a check-list that included the main steps for verifications of the industry reports, tips to identify errors, as well the actions for submitting the national reports. The document was provided to the DNAs in August 2022 and then as attachment to the periodical reminders for submitting their annual national reports.

- On 4 October 2022, ECHA organised a workshop with the Finnish DNA and Customs to share experiences with the PIC Regulation processes from different perspectives and identify potential actions in support to more efficient ways of working and improved collaboration.

3.5 Export notifications forwarded to Parties to the Rotterdam Convention and other countries

3.5.1 How many export notifications and related tasks have been handled by the Agency per year (i.e. the year in which the export took place)?

	2020	2021	2022
Export notifications handled[6]	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

3.5.2 What are the information requirements requested in the export notification form where exporters experience difficulties?

☐ Identity of the substance to be exported

☒ Identity of the mixture to be exported

☐ Identity of the article to be exported

Information concerning the export

☐ Information on hazards and/or risks of the chemical and precautionary measures

☐ Summary of physico-chemical, toxicological and ecotoxicological properties

☒ Information on final regulatory action taken by the exporting country

☐ Additional information provided by the exporting Party

☐ Availability of CN codes or CUS codes

☒ Intended use of the chemical in the importing country

☐ Summary of and reasons for the final regulatory action and date of entry into force

Others

☐ Not applicable

Additional information:

- "Prohibited and allowed uses" (Section 6.2): companies seem to be unaware on the prohibited and/or allowed uses of the exported PIC chemical since the information

[6] This number includes initial submissions, re-submissions and rejections. Unlike in other parts of this questionnaire, the count is here done for the tasks processed for notifications with export year in the analysed period (e.g. export notifications submitted for exports in 2020 but processed in late 2019, are counted in 2020).

provided is often incorrect or misleading, and sometimes reflecting more the intended uses in the importing country rather than the regulatory status in the EU;

- Confusion on what is 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) does not correspond to the information provided in the SDS (section 3);
  - The selected export notification template (i.e. chemical, mixture, article) does not correspond the information provided in the SDS;
- Importer(s) details (Section 3.4): exporters often provide incomplete or incorrect contact details for the trade partners in the country of destination (e.g. PO Box addresses instead of physical address, importer's address and contact details not located in the destination country). They additionally often refer to importers who cannot be identified/reached by the authorities of the importing country;
- The use category and foreseen use in the importing country:
  - the foreseen use category and foreseen use for exports of biocidal active substance/products can lead to misunderstandings and complications in the processing, due to the fact that the EU considers a biocidal uses as a sub-category of the pesticides category however, many non-EU countries consider biocidal substances/products as industrial chemicals;
  - the foreseen uses in the importing country under Section 3.3 are often inadequately described, which may lead to misunderstandings and delays of the processing in the destination country.

3.5.3 What is the number of export notifications sent back to the exporter for the reasons mentioned in the table below?

Reason/Number per year	2020	2021	2022
Re-submission requested	670	655	435
Rejected	112	163	119

If relevant, please specify the most frequent reasons for requesting re-submission and for rejecting export notifications:

The number of re-submission requests and rejections decreased compared to the previous reporting period (2017 -2019). The main reasons for those actions remained mostly the same, as outlined below:

Reasons for re-submission requests:

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

2021 - Most of the resubmissions were requested because of unclear or irrelevant information under Section 6.2 on prohibited and allowed uses; in addition,

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 with only different colors of the products.

2022 - The same as for export year 2021, it was noted 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. However, many resubmissions remained still for unclear allowed/prohibited uses in EU under section 6.2.

Reasons for rejections:

2020 - Most of the rejections were done similarly as in the previous years due to unnecessary duplicate notifications; there were other various reasons such as the selection of the wrong template for the notification (e.g. mixture instead of pure substance), mismatch between the stated importing country and the importer's address, notifications that should have been submitted as SRIN requests instead, or rejections at the request of the exporters.

2021 – Few of the rejections were done for notifications submitted by companies from United Kingdom (Great Britain) before the end of the transition period for the Brexit, for that export year. Nevertheless, most of the rejections were done still for unnecessary duplicate notifications, wrong template used, or city of the importing company located in different importing country, as well as notifications that should have been submitted as SRIN requests instead.

2022 – As in the previous years, many rejections were done for unnecessary duplicate notifications, wrong template used (template for mixture instead of template for pure substance and vice-versa), incorrect identified importing country, also due to existing negative responses for certain chemicals and importing countries, or rejections at the request of the exporting companies.

3.5.4 Has the Agency noticed that the DNAs have experienced difficulties in coping with the time frame to forward the notifications to the Agency?

☒ Yes

☐ No

If yes, how many notifications were received late during the reporting period and which percentage of the total number of notifications did this represent:

Year	No. of late notifications	% of total yearly No. of notifications
2020	640	5.7%
2021	619	5.5%
2022	378	3.6%
Total	**1 637**	**4.9%**

Additional information:

ECHA has noticed that the difficulties of certain Member States DNAs to cope with the legal timeframe for the checking export notifications usually appears during and right after peak in submissions periods, i.e. in November/December/January months, and especially when those coincide with holiday periods when very limited or no resources for processing are available. The situations in which ECHA receives late the export notifications, often relates 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 remain the same as for the initial submission. It is 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 ECHA. Alternatively, it could be considered that re-submissions are dealt with the same timeframe as initial submissions (clock set back to 35 days) and ePIC adapted accordingly.

3.5.5 Has the Agency experienced difficulties in coping with the time frame to process and forward the notifications to the importing (non-EU) country?

☒ Yes

☐ No

If yes, how many notifications were processed late during the reporting period and which percentage of the total number of notifications did this represent:

Year	No of late notifications	% of total yearly No. of notifications
2020	173 (21)	0.2%
2021	78 (15)	0.1%
2022	48 (7)	0.1%
Total	**299 (43)**	**0.1%**

Note: in the cells relating to the "No of late notifications", the first number refers to the notifications checked late by the DNAs, i.e. even after ECHA's due date to process (with less than 15 days until the intended date of first export); the number in brackets refers to the notifications processed late by ECHA but for most of which DNAs also missed the deadlines (less than 25 days until intended export date).

The number of export notifications which were forwarded later than 15 days before the expected date of export specified in the notification have significantly decreased over the reporting period.

ECHA has reminded the Member State DNAs on several occasions (during DNA meetings, emails) about the importance to adhere to the legal deadlines so that enough time is provided to the authorities in the importing country to react to the notifications.

As already mentioned in response to question 17 above, typically the cases are related to re-submissions and either a notification is received from the DNA already overdue (less than 15 days before the expected date of export) or very close to/late on the due date. When the Agency notices that the exporter has submitted the export notification on time and that the delay is due to a late processing by the DNA, and provided that all the required information has been submitted, ECHA processes the late export notification immediately, in order not to further penalise the exporter and to allow the export process to continue.

Article 8(5) of Regulation (EU) No 649/2012 on export of a chemical relating to an emergency situation

3.5.6 Has the Agency experienced difficulties when processing an export notification submitted under the emergency situation procedure?

☒ Yes

☐ No

☐ No such export notification has been received

Additional information:

Compared to previous reporting period (2017 – 2019)[7], more export notifications were submitted as referring to an emergency situation in which any delay of the export may endanger public health or the environment in the importing Party or other country (in accordance with Article 8(5)). The outcome of their processing was as follows:

- 22 export notifications under the "emergency situation" procedure were validated and the cases were mainly for exports of disinfectants in relation to COVID pandemic;
- 29 emergency notifications were found not to meet the criteria described in Article 8(5). These cases were rejected by ECHA or by the Member State DNAs and companies were asked to submit a "standard" export notification instead;
- The rejected cases referred to business 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.

Article 8(7) of Regulation (EU) No 649/2012 on available additional information concerning exported chemicals

3.5.7 Was the Agency requested to provide additional information concerning exported chemicals to importing parties and other countries?

☒ Yes

☐ No

If yes, which type of information was requested:

[7] 15 emergency notifications were submitted during 2017 -2019, out of which two were accepted.

ECHA received a relatively large number of requests for clarification/additional information from the authorities in non-EU countries. The most frequent were the following:

- Clarification on the information provided in export notifications on the importing company(ies) in the country of destination of the export and the estimated quantities reported;
- Clarification on why the export of the chemical is being notified and/or explicit consent is being requested, for chemicals which are not listed in Annex III to the Rotterdam Convention but are subject to the provisions of the PIC Regulation;
- ECHA may have transmitted the export notification to the incorrect authority either based on the legislation in the importing country (e.g. a biocide is considered a pesticide sub-category in the EU but may be considered an industrial chemical in other countries) or due to changes of DNA contacts/ministries involved, etc;
- Regulatory information on the exported chemical in the EU.

3.6 Export notifications from Parties and other countries

Article 9(1) of Regulation (EU) No 649/2012 on export notifications received by the Agency from the authorities in non-EU countries

3.6.1 How many export notifications did the Agency receive from non-EU countries in the reporting period?

Year	Notifications received
2020	381
2021	671
2022	811
Total	**1 863**

3.6.2 How many acknowledgements of receipt for export notifications from non-EU countries did the Agency send in the reporting period?

Year	Acknowledgements sent[8]
2020	82
2021	506
2022	470
Total	**1 058**

[8] ECHA does not send acknowledgements of receipt to the United States based on a bilateral agreement.

3.7 Information on export and import of chemicals

Reporting of Designated National Authorities to the Agency (Article 10 of Regulation (EU) No 649/2012)

3.7.1 Did the Agency experience delays from Designated National Authorities in receiving the aggregated national reports on the quantity of the chemicals (as a substance and as contained in mixtures or in articles) exported to/imported from each Party or other country during the preceding year?

☒ Yes

☐ No

Additional information:

Over the reporting period, ECHA experienced delays in receiving the aggregated national reports by the agreed deadline (i.e. by end of September) from some Member States. ECHA followed-up the progress with those Member States by sending them 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 (see further details in response to question 24 below), have continually led to inefficiencies, slowing down ECHA's preparations, compilation and publication of the EU-level reports, as well as requiring more support and hence resources from the ECHA PIC Team.

To ensure timely submissions of national reports, it is recommended that DNAs monitor the progress of industry reports and follow-up the timely reporting and/or revisions by companies, as needed.

3.7.2 Other than the above, did the Agency experience any issues with the Designated National Authorities in relation to the reporting exercise under Article 10 of Regulation (EU) No 649/2012?

☒ Yes

☐ No

Additional information:

Based on the issues identified during the previous reporting period, ECHA improved the reporting functionality in ePIC by introducing warnings to potentially erroneous quantities with the view to improve the quality of the data submitted by industry as well as to facilitate the checking of the data by DNAs. In addition, ECHA has prepared a checklist to facilitate the work of the DNAs for the verifications of the industry reports, as well as for 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 ECHA is recommended.

3.8 Obligations in relation to export of chemicals other than export notification

Substances that cannot be exported unless certain conditions are fulfilled (Article 14(6) of Regulation (EU) No 649/2012)

3.8.1 Has the Agency experienced difficulties in relation to its involvement in the explicit consent procedure (e.g. in validating the explicit consent metadata inserted by the Designated National Authorities)?

☐ Yes

☒ No

Additional information:

For each explicit consent response received, Member State DNAs provide certain metadata to define its applicability to export notifications. That metadata is cross-checked by ECHA to avoid clerical errors and inconsistencies across Member States, before the response can be used for processing.

Overall, this process is working well, and the above-mentioned goals are achieved. Due to the complexity of the interpretation for many explicit consents (which are diverse in format/language/approach based on the issuing non-EU country), in several cases ECHA asks the Member State DNA to amend the so-called "terms and conditions" of the explicit consent. This process is carried out by ECHA and the DNAs in a collaborative spirit and results in harmonised data.

An on-line workshop with DNAs was organised on 17 November 2021 (please see Question 13) 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) are the most challenging elements in the interpretation of the responses.

DNAs decision (in consultation with the Commission supported by the Agency) that export may proceed 60 days after an explicit consent request was made (Article 14(7) of Regulation (EU) No 649/2012)

3.8.2 Has the Agency experienced difficulties in processing export notifications subject to the procedure under Article 14(7) of Regulation (EU) No 649/2012 or in assisting the Commission in the implementation of this provision?

☐ Yes

☒ No

Additional information:

The waiver workflow is such that an exporter submits a waiver request, their DNA checks it and (if they approve) it is sent to the Commission for final verification. ECHA will then get a task, should there be any pending exports which match the criteria for the waiver.

Overall, the process is 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 the 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 additionally 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 have decreased, the efficiency of the process can 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.

Explicit consent reminders (Article 14(6) of Regulation (EU) No 649/2012)

3.8.3 How many reminders for explicit consent requests did the Agency send pursuant to the third subparagraph of Article 14(6) of Regulation (EU) No 649/2012?

	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 (2020-2022), 58 % of the requests for Explicit Consent received responses, following either the initial request, the first or the second reminder. The figures above show that in 17% of cases, the response is received after the first reminder and do not require a second reminder to be sent. The overall response rate increased by 4% compared to the previous reporting period (2017-2019), and even though it still remains rather low, the system of reminders – of which the vast majority is triggered and sent automatically - is considered effective and efficient.

Validity of explicit consent (Article 14(8) of Regulation (EU) no 649/2012)

3.8.4 Has the Agency experienced difficulties in handling cases where the export was allowed to proceed pursuant to the second subparagraph pending a reply to a new request for explicit consent pursuant to point (a) of the first sub-paragraph of Article 14(8) of Regulation (EU) No 649/2012?

☐ Yes

☒ No

Additional information:

The majority of the cases were processed following standard workflows within ePIC; however, certain cases still required case-by-case assessments and exchanges with the concerned Member States.

3.9 Exchange of information

Exchange of information

3.9.1 In the context of Article 20(1) of Regulation (EU) No 649/2012, has the Agency received any requests for providing information of scientific, technical, economic or legal nature concerning the chemicals subject to the regulation?

☒ Yes

☐ No

If yes, please provide more details:

In 2020 and 2021, ECHA received 11 requests falling within the scope of Article 20, from nine 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

In 2022, ECHA received seven enquiries from Kenya (5), Jordan and South Africa. The nature and topic of these requests will be further elaborated upon in the next Article 20 report, which will cover the period 2022 – 2023, which is due by the end of 2024.

Reporting on the information transmitted

3.9.2 Did the Agency experience difficulties in collecting the information from the Commission and the Member States on the data transmitted?

☐ Yes

☒ No

If yes, please provide more details: n/a

3.9.3 Did the Agency experience difficulties in compiling the report in accordance with Article 20(4) of Regulation (EU) No 649/2012?

☐ Yes

☒ No

If yes, please provide more details:

The report covering period 2020 – 2021 contained a new section on information submitted through explicit consent responses to the Parties to the Rotterdam Convention or other countries. An update of the Article 20 report covering period 2018-2019 was published in October 2022 to include six additional substances for which the EU had submitted FRAs to the Rotterdam Convention over the reporting period.

3.10 Technical assistance

Cooperation

3.10.1 Has the Agency been involved in cooperation with developing countries, countries with economies in transition and non-governmental organisations to improve the proper management of chemicals and in particular to implement the Rotterdam Convention?

☒ Yes

☐ No

If yes, what type of cooperation:

☒ Technical information

☐ Technical expertise for the identification of hazardous pesticides formulations

☐ Technical expertise for the preparation of notifications to the Secretariat

☐ Other

If other, please specify.

In 2021, ECHA provided support to the European Commission in the preparations 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. The information has been stored and presentations recorded for future use as well, at the following link: *Export notification under Rotterdam Convention & implementation of the EU export notification procedure and EU explicit consent procedure - 18/02/2021 (English), 24/03/2021 (Spanish) and 21/04/2021 (French) (pic.int)*

In April 2021, ECHA also participated in a webinar session organised by the Rotterdam Convention for the *Asian Regional Awareness Raising and Training on the Rotterdam Convention (pic.int)*, where ECHA presented the implementation of the Convention in the EU and clarified specific parts in the follow-up Q&A session. The webinar had the aim to also strengthen collaboration between DNAs at national and regional level.

In June 2021, ECHA provided support to another webinar organised by the Rotterdam Convention, in Arabic language, named *Export notification procedure under Rotterdam Convention and the European Union - 30/06/2021 (pic.int)* where ECHA presented and answered the follow-up questions.

In February 2022, ECHA provided support to the European Commission in the preparations and delivery of a workshop organized jointly by the Russian Federation and the Secretariat of the Rotterdam Convention, where ECHA presented the implementation of the Rotterdam Convention in the EU and provided support to the follow-up Q&A session.

In May 2022, ECHA attended the 10th meeting of the Conference of the Parties to the Rotterdam Convention and, in cooperation with the Secretariat of the Rotterdam Convention, the Commission and some Member States DNAs, actively contributed to

the preparations and delivery of each time five lunch hour regional group meetings[9], to 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 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 Safety Data Sheets 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 consents. ECHA also had one-to-one discussions with several non-EU countries authorities, in particular with the aim to understand the reasons and find practical solutions to the issue of non-responsive authorities in the importing countries. There is always good feedback from the importing countries regarding these events and it has been mentioned that more support/training of this type will be appreciated.

In the future, the Agency is interested in continuing the collaboration in this field with the Rotterdam Convention Secretariat, in support to Commission.

Capacity building

3.10.2 Has the Agency participated in projects/international activities related to capacity building in chemicals management or supported non-governmental organisations involved in such activities?

☒ Yes

☐ No

If yes, please describe these activities:

Through the EU Instrument for Pre-accession assistance (IPA), the Agency continuously provides training and support to pre- and candidate countries to increase capacity in the area of chemical management. This includes, but not exclusively, support in beneficiaries' efforts in aligning their national regulation, for the provisions to implement Rotterdam Convention, with those in the EU.

During the reporting period, ECHA finalised two in-depth analysis, launched respectively in 2019 and 2020, of the readiness and harmonisation with the EU acquis for chemicals management in 1) Montenegro and Serbia and 2) Albania, Bosnia and Herzegovina, Kosovo, North Macedonia and Turkey. The aim of the studies, carried out by consultancy - Risk & Policy Analysts (RPA) – Europe, and VVA, was, in close

[9] 1 with the African group countries in English, 1 with the African group (and other francophones) countries in French, 1 with the Asia-Pacific group countries in English, 1 with the Central and Eastern group countries in English and Russian, 1 with the Latin American and Caribbean group countries in Spanish.

collaboration with national authorities, 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 ECHA's website at the following link: https://echa.europa.eu/about-us/partners-and-networks/international-cooperation/support-to-eu-external-relations-policies/activities-under-ipa/2020-2022.

3.11 Enforcement of Regulation (EU) No 649/2012

Role of the Forum for Exchange of Information on Enforcement ('the Forum'; Article 18(2) of Regulation (EU) No 649/2012)

3.11.1 Is there a regular exchange of information within the Forum on coordination of enforcement of Regulation (EU) No 649/2012?

☒ Yes

☐ No

If yes, please specify the topics discussed:
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 (practical issue 36.4).

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 prioritized because the Forum considered there would not be sufficient number of duty holders in multiple Member States. In 2021 the Forum also requested the COM for information on the status of PIC Article 22(2) report.

3.11.2 Has the Forum coordinated enforcement of Regulation (EU) No 649/2012 in this reporting period?

☐ Yes

☒ No

If yes, please describe these activities: n/a

3.11.3 How could the activities of the Forum with regard to the enforcement of Regulation (EU) No 649/2012 be improved?

The Forum considered in its work programme 2019-2023 that inspections of PIC duties should become part of the NEAs' enforcement routine on the national level. However, in this reporting period the Forum has not prioritized coordination of enforcement of PIC Regulation for a dedicated coordinated enforcement project. One of the reasons for this is likely that the level of non-compliance detected in the Forum pilot project in PIC (2018) is relatively low (~10%) so other legislations and duties where non-compliance is known to be higher were prioritised for coordinated enforcement. Nonetheless, Forum could discuss if and how it can include coordination of enforcement of Regulation No 649/2012 more regularly in its activities. For example, this could be through exchanging information on national experiences or coordinated enforcement through projects, combined with other legislations.

3.11.4 Has the Agency been involved in any enforcement activities related to Regulation (EU) No 649/2012 other than those handled by the Forum?

☐ Yes

☒ No

If yes, please describe these activities: n/a

3.12 IT-related aspects

The electronic system for implementation of Regulation (EU) No 649/2012 (ePIC)

3.12.1 How many external organisations/users are using ePIC for each of the following categories?

- Industry: 4 924 users[10] who have access to ePIC
- Designated National Authorities: 111 users [11]
- European Commission: 2 users
- Customs authorities: there is no user management for the customs application however, we can provide the following estimates for use of the customs application during the reporting period. 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
- National enforcement authorities: 401 users

3.12.2 Which new/enhanced features have been included in ePIC compared to the previous reporting period:

The list below comprises the main features added or improvements made to ePIC during the reporting period:

- Integration of Article 10 non-confidential report generation within ePIC: to generate the non-confidential Article 10 report in ePIC directly (and not outside of it with a separate tool as it was done before), which reduced ECHA's work in generating the non-confidential report on a yearly basis;

- 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;

[10] Of which 1 273 users have performed at least 1 submission in ePIC during this reporting period.

[11] The number of DNA and NEA accounts refers to the existing number of accounts created and tokens issued (for ePIC) but does not necessarily refer to "active users" who then use 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:
  - a flag to DNA and COM 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 ECHA record acknowledgement of receipts received from third countries;
  - automated selection of designated national authorities in both DNA explicit consent and ECHA 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 have contributed to a reduction of processing times and an increase in the overall efficiency of the processes. They also enabled a better traceability of the 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; the lack of resources has however proven to be a limiting factor over the years.

3.12.3 How many releases of the system were delivered in the reporting period:

	2020	2021	2022
Number of main releases	2	2	2
Number of patch releases (to fix issues)	4	4	4

3.12.4 Please provide details on the availability of the system to external users:

	2020	2021	2022
ePIC Industry application	99.99%	99.99%	99.99%
ePIC Authority application	99.99%	99.99%	99.99%

The data provided in the table above includes downtime due to scheduled maintenance activities.

3.12.5 High-level summary of feedback received by the Agency on ePIC from the following user communities:

- Industry: the feedback received from Industry (representatives), e.g. in the margins of the DNA meetings, was mainly positive and some improvement proposals were prioritised for implementation (e.g. advance SRINs 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:
  - possibility to communicate with DNAs and ECHA directly within ePIC;
  - usability improvements (e.g. duplicate functionality for special RIN requests, easier article 10 creation, data insertion for Section 6.2. "Prohibited/Allowed uses");
  - advanced submissions for chemicals contained in draft amendments (due to short submission window following publication).

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

- Designated National Authorities: the overall feedback is positive and is regularly mentioned at DNA meetings. Many of their suggestions for improvement have been prioritised and implemented during the reporting period.

- European Commission: the overall feedback received from the Commission has been positive. DG TAXUD has expressed an interest to integrate ePIC data to a centralised Customs application ("Single Window").

- National Enforcement Authorities (NEAs): some improvement proposals were received from NEAs during the reporting period (through DNAs) related to data availability.

- Customs: some countries have expressed their interest to automate the checks of the export controls, and to integrate ePIC data to a centralised application ("Single Window").

3.12.6 Please specify identified improvement needs for the IT system, if any:

The main improvement needs/new functionalities for ePIC that ECHA is 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 ECHA (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 (please see the comment on Article 8(3) in section 13 below) if it is decided that the current way of the process needs to be aligned with the provisions of the legal text.

- Further increase 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 Commissions 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, ECHA has 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 are already relying on such common modules and ePIC will 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 ECHA applications. The transition to the new modules will bring opportunities to implement new features and re-design the existing functionalities to better accommodate the needs, including those highlighted above. This evolution may however, at some point in the future, require specific, additional resources; ECHA will keep the Commission informed about this project and discuss any resource needs if and when relevant.

3.12.7 Which data originating from implementation of Regulation (EU) No 649/2012 is made publicly available on the Agency's website:

The following datasets are available in ECHA's PIC Dissemination platform, and information can be searched based on specific searching parameters/filters:

- **Chemicals subject to PIC**: the chemicals subject to the PIC Regulation and listed in its Annex I (all Parts) or Annex V (all parts), can be searched (PIC Annex entries/substances in scope, 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 per importing EU Member State, per exporting non-EU country, or per chemical / mixture / article) are also made available.
- **Import notifications**: non-confidential data on import notifications can be searched, and high-level statistics (summaries per exporting EU Member State, per importing non-EU country) are also made available.
- **Explicit consents**: non-confidential data on explicit consent requests and responses received from non-EU countries can be searched.
- EU and non-EU **Designated National Authorities up-to-date contact details**.
- Information on **EU import responses under the Rotterdam Convention** (in a form of an Excel sheet – no on-line searches enabled).

In addition to the above, information on substances subject to the PIC Regulation is also made available through ECHA'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):
https://echa.europa.eu/regulations/prior-informed-consent/annual-reporting-on-pic-exports-and-imports.

Reports on information exchange (pursuant to Article 20):
https://echa.europa.eu/regulations/prior-informed-consent-regulation/reporting-on-information-exchange.

3.12.8 Which new data has been made available since the last reporting period:

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 ECHA cross-regulations dissemination platform.

Based on the results of a consultation with stakeholders and an analysis carried out by ECHA 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 nowadays 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.

3.12.9 Has the Agency received any feedback on the data relating to implementation of Regulation (EU) No 649/2012 made available on its website?

☒ Yes

☐ No

If yes, please provide a high-level summary of this feedback:

Overall, the feedback on the enhanced PIC dissemination portal has been positive and the improvements compared to the previous portal have been appreciated. Further suggestions for improvement have 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 have enquired whether more data on export notifications could be made available (e.g. company name, estimated quantity).

3.13 Additional comments

3.13.1 Please provide any other information or comments related to the operation of the procedures under Regulation (EU) No 649/2012 that you consider relevant within the framework of the reporting pursuant to Article 22 of that Regulation.

Based on ECHA's experience during this third reporting period, it can be confirmed that a number of issues that were already identified in the previous reporting exercises still remain to be addressed, while some others have emerged.

ECHA would welcome the opportunity to discuss these further, including whether they could be considered in the context of the ongoing review of the PIC Regulation and should be addressed either via a targeted or wider revision of the current legal text, or through other means (e.g. Q&As, factsheets, Guidance).

Firstly, a certain number of clarifications or improvements to the current legal text of the PIC Regulation should aim at **enhancing its overall functioning and efficiency**, and by that contributing to the best use of the limited resources e.g. in the Member State DNAs and ECHA, as well as improving the support and service to duty holders and reduce any unnecessary administrative burden and/or lack of predictability of the PIC procedures.

Clarification or introduction of definitions:

- Exporter: although discussed and already largely clarified between authorities at the 36th PIC DNA meeting, the definition of an exporter (Article 3(18)) could be improved to explicitly address directly in the legal text concrete export scenarios, such as for example cases when a chemical is first imported into the EU (exported by company A, e.g. from Switzerland, to company B, e.g. in France) and then exported from the EU (by company B) to another non-EU importing country (company C, e.g. in Venezuela), but the holder of the contract with the importing non-EU company (company C in Venezuela) is the original non-EU company (company A in Switzerland) and not the EU exporting company (company B in France).

- Articles: the definition of an article and the requirement to notify the export of an article containing certain PIC substances are set out in Articles 3(4) and 15 of the PIC regulation respectively. The various questions received - e.g. from Member States DNAs - prove that it is often unclear to exporters, DNAs and ECHA whether or not a given product fulfils the definition of an article under the PIC Regulation, and therefore whether or not it is subject to the PIC Regulation. A two-step approach was suggested by ECHA at the 37th PIC DNA meeting of 23 April 2021 in view to clarify the obligations, however, it was found not to provide sufficient level of details for Member States to eliminate the ambiguities and address all concerns. This situation increases the risk of inconsistencies in the way export notifications for articles have been submitted and processed. It appears that part of the ambiguity could come from the differences in the definitions of an article under the REACH and PIC Regulations, and in particular if the definition of an article under PIC could be wider (e.g. extending to complex objects or combinations of articles and mixtures under REACH) or on the contrary more restrictive (e.g. applying to products in which the PIC substance in question has been specifically restricted at EU level), and/or based on different categorisation criteria (e.g. potential for emissions/exposures).

- Legal entities: the PIC Regulation mentions exporters and importers but never defines them as "legal entities". Such a definition would be welcome, especially if together with an approach on how to deal with legal entity changes and associated export

notifications. As an example, in the current legal framework, an exporter whose legal entity changes in the middle of a calendar year and is planning to export the same chemical to the same importing country before and after its legal entity has changed, will have in practice to submit twice the same export notification (i.e. one for each legal entity); this brings additional administrative burden to both the companies and the authorities, and tends to artificially populate the ECHA Database with unnecessary "duplicate" notifications. ECHA's experience with the REACH Regulation is that such a definition would be beneficial.

Clarifications and improvements to existing legal requirements or procedures:

- Timing of updates to PIC Annexes: Article 23 describes the Commission procedure to update the list of chemicals subject to PIC. The timing of the entry into application of the amendments is however not mentioned, and until now, the Regulation date has varied every year (e.g., 1 September in 2020, 1 July in 2022). As also described in response to question 11 above, a more predictable approach would facilitate the planning of all operators involved (companies/Member States/ECHA). It would additionally simplify Article 10 reporting and the comparison of quantities exported over the years if the quantities reported would always refer to one full export year. It could be considered that the entry into application of amendments is specified in the legal text to always take place at the same time every year (e.g. 1 January).

- Mixtures: in accordance with Article 8(1), export notification requirement applies to mixtures if the concentration of the PIC chemical present in the mixture triggers labelling obligations under CLP, irrespective of the presence of any other substances. A new export notification is required whenever the composition of the mixture in question changes so that the labelling of such mixture is altered (Article 8(4)). Companies are often confused about the obligations as regards exports of mixtures and there seem not to be a common understanding of these provisions based on the discussions in several DNA meetings. The main source of confusion is linked to (changes of) non-PIC substances present in the mixture and whether a (new) notification is required when the overall labelling changes, or the trigger for a new notification is the change of labelling of the PIC substance on its own. The discussion relates to a fairly large number of submissions for mixtures with very similar compositions without changes (or minor changes) in the concentration of the PIC substance in the composition. The export notification requirements for mixtures containing PIC chemicals should be clarified to achieve consistent implementation of those provisions, and as a second step, a potential approach to combine notifications of very similar mixtures could be explored.
- Export notifications / Acknowledgment of receipt: Article 8(3) states that "*if the Agency does not receive […] an acknowledgement of receipt of the first export notification made after the chemical is included in Annex I […] it shall submit a second notification*". Since the very first implementation of PIC in the EU (in 2003), an acknowledgement of receipt has been requested for all export notifications sent, not just the first one after Annex I inclusion. This is an important mean of ensuring that the information has been received, also in view of changes in contact details in the non-EU countries. The legal text could be amended accordingly, in order to reflect the actual working practice.
- Import notifications / Acknowledgment of receipt: Article 9(1), second paragraph, states that "*ECHA shall […] acknowledge receipt of the first export notification received for each chemical…*". However, certain non-EU countries, such as the United States, do not wish to receive such acknowledgements. The legal text could therefore be amended so that more flexibility is given in order to accommodate the specific need of the non-EU countries.
- Information of the use of the chemical in the Union: (Section 6): Section 6 of a PIC export notification (*Summary information on final regulatory action taken by the exporting country*) is meant to provide information to the authorities in the importing

country on how the chemical is regulated in the EU under the PIC Regulation; sub-Section 6.2 more specifically highlights the use category for which the final regulatory action (FRA) was taken and should provide intelligible and useful information on the uses of the PIC chemical in the EU. As indicated in the response to Question 15, the sub-Section 6.2 of export notifications is one of those for which exporters experience most difficulties in providing the requested information. This has as consequences a substantial number of requests for updates from the DNAs or ECHA. Since the authorities have also legal and resources constraints in requesting the improvement of the provided (or missing) information, despite best efforts sometimes the provision of information remains of limited quality or usefulness to the importing country. ECHA would therefore suggest exploring the possible ways and means to improve the overall efficiency and usefulness of the information provided under this sub-Section, namely through improved data structure. Since these information requirements in ePIC are derived from Article 8, paragraph 2 and Annex II to the PIC Regulation, necessary changes to the PIC Regulation legal text may however be needed. Depending on the changes considered, adaptations to ePIC and to the export notification template as sent to importing countries, may be required too.

- Imports to the EU / Requests for Explicit Consent: Article 14 describes for which substances and how the EU should trigger requests for explicit consent from non-EU importing countries and manage their (non-)responses. The PIC Regulation does not clarify what the EU should do in case it receives a request for explicit consent from a non-EU country, for an import to the EU. When this happened (as a number of non-EU countries have included pieces of legislation similar to the PIC Regulation in their national legislation) an *ad-hoc* procedure was agreed between the Commission, ECHA and the EU DNAs; however, this could be reflected in the legal text in Article 13 on "*Obligations in relation to import of chemicals*".
- Article 8 defines the timelines of export notifications for all actors however, the legal text is not addressing a possibility for a re-submission, i.e. a situation when a notification is found incompliant and therefore sent back to the exporter for revision. The implementation in ePIC since September 2014 allows updates of export notifications if requested by exporter's DNA/ECHA so that companies do not have to start the whole process again but can edit the already notified submissions. When a company re-submits their notification following request either from ECHA or the DNA, the timelines of the initial submissions are being followed. This means that both the DNA and ECHA has less time to process the re-submission and in certain cases, as outlined in question 18, notifications are forwarded overdue to the importing countries. This means that in those cases the authorities in the importing countries have less time to react to the export notifications. It could be appropriate that the re-submission scenario is specified in the legal text to align with the current practice and the timelines for the actors involved clarified.
- Certain provisions of the PIC Regulation are applicable to all chemicals when exported (e.g. Article 17) and not only for chemicals listed in Annex I. For clarity, it is suggested that those provisions would be clarified and/or explicitly referred in the legal text.

Secondly, substantial improvements to the PIC Regulation legal text with regard to the **availability and publication of the data** on imports and exports of PIC chemicals should be sought, with the aim to better address the recent increased interest of media and NGOs on such data, and for that provide a clearer and more solid legal basis for the authorities - and in particular ECHA and the Member State DNAs – to upfront make more and more useful information available to the public, and at the same time limit as much as possible the use of their scarce resources to the processing of ATD requests.
The PIC Regulation has no explicit provisions regarding the dissemination of export notifications. Article 8(2) only states that "*the Agency shall also make available to the public and the designated national authorities of the Member States, as appropriate, an updated list of the chemicals concerned and the importing Parties and other countries for*

each calendar year by means of the Database." Beyond the requests received from media and NGOs, certain Member States have also expressed interest in enlarging the number of public elements of export notifications. Some have even made reference to Article 20(3), interpreting that this specific provision already gives grounds to consider information requirements provided in Annex II non-confidential. ECHA recommends that the elements of export notifications that should always be considered as public, and on the contrary those which release to the public should still be subject to *ad hoc* assessment as part of ATD requests, are explicitly specified in the legal text.

Similarly, in accordance with Article 10(3) ECHA compiles annually a report on actual quantities exported/imported during previous year "*at Union level and shall make* the non-confidential information publicly available". In the absence of more explicit provisions in the PIC Regulation legal text, ECHA has so far published the received information following Eurostat recommendations on data confidentiality and applied certain aggregation rules which were formalised in 2015. Due to the diversity of the volumes reported/number of operators, the information published is necessarily not providing sufficiently clear picture on trade at chemical/exporting-importing country, as expressed in the numerous requests received from stakeholders in the context of ATD requests. In light of the public interest, it should be considered whether the current approach/format still continues to be appropriate and whether the aggregation rules should be changed to present the data differently, in particular for exports of pesticides relating to emissions to the environment in accordance with Aarhus Regulation. The legal text should ideally specify the format/summary of the information of the EU-level report (similarly to Annex III for the data requirements supplied by DNAs).

To be noted that such modifications of the legal text and their implementation may require some adaptations to the current procedures, templates (e.g. an additional flag in export notification template in ePIC for exports falling under the Aarhus) and to the ePIC application.

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