Report on the operation of the Prior Informed Consent (PIC) Regulation 2020

August 2020

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1. Foreword

As an Agency, we have continued during 2017-19 to contribute to the success of implementing the PIC Regulation. In particular, we have focused on improving the efficiency of our processes and making sure that trade of hazardous chemicals is informed and transparent so that human health is protected and the environment in non-EU importing countries is safeguarded.

In line with the trends observed in the first reporting period (2014-16), the number of PIC export notifications submitted by EU exporters has continued to steadily increase – reaching a record of more than 10 000 notifications processed in 2019. With this increase, the number of associated tasks has also risen – this is seen by the upsurge in the amount of requests for technical or regulatory support from authorities both in the EU and outside our borders, as well as the number of helpdesk questions received from exporting and importing companies.

As the amount of resources available for PIC activities has not increased proportionally to the workload, we've had to put a considerable amount of effort in working with Member States and the European Commission to systematically identify ways to improve the practices, processes and tools we use.

Furthermore, we have developed several guidelines to help EU companies understand their obligations under PIC, so they are fully aware of what they are expected to provide. Our hope is that this action will reduce the number of dossiers rejected and resubmissions received, as well as improving the overall quality of information being provided to non-EU importing countries.

We have also continued to support the Commission on Rotterdam Convention activities. On these, we have been helping with substance identification activities, preparing notifications of final regulatory actions taken in the EU to severely restrict the use of chemicals, and taking part in various communication and capacity-building projects at the margins of the Conferences of the Parties to the Rotterdam Convention, and at dedicated workshops organised by its Secretariat.

Despite these achievements, I still have to express concern with the expected increase in our workload. With new PIC substances continuously being listed and our support to the Commission and designated national authorities becoming increasingly important, it is crucial that we have adequate staffing to carry out our tasks and enough budget in place to develop ePIC – the central IT tool used to implement the regulation. These will be critical to ensure that the important work under this regulation continues to be carried out successfully in the future.

Looking ahead, we are already providing some suggestions in this report for clarifications to be made to the legal text and adaptations to current practices that could bring further efficiencies and improvements to the PIC work. We have also identified some areas where further investment from the EU in general, and a deeper involvement of ECHA in particular, could result in a higher impact of the PIC Regulation and contribute to its objectives and those of the Rotterdam Convention.

Lastly, I would like to encourage you to read this report and to offer my thanks to the European Commission, Member State authorities, our accredited stakeholders and ECHA staff, without whom we would not have been able to successfully implement the regulation. We very much look forward to continuing to collaborate on this work in the future.

Bjorn Hansen
Executive Director

2. PIC Regulation - Introduction

This is the European Chemicals Agency's second *Report on the operation of the PIC Regulation*, for the period from 1 January 2017 to 31 December 2019, pursuant to Article 22 of Regulation (EU) No 649/2012 of the European Parliament and of the Council of 4 July 2012 concerning the export and import of hazardous chemicals (the "PIC Regulation").

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: 01.01.2017 – 31.12.2019

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:

	2017	2018	2019
Number of staff[1] 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).
- Contribution agreement 2018/703-813 (Instrument for Pre-accession Instrument (IPA)) on Preparatory measures of future participation of candidate countries and potential candidates in the work of the European Chemicals Agency in implementing REACH, CLP, BPR, PIC and POPs.

Furthermore, ECHA is involved in the implementation of:

[1] Temporary agents (TAs) and Contract agents (CAs)

- 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).

  Staff working on PIC collaborates 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: checking the appropriateness of the identification of substances to be added to the PIC Regulation by means of an amendment of Annex I or V, and addressing *ad-hoc* requests from companies via helpdesk (e.g. whether certain substances belong to group entries in the PIC Annex I).
  - 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.
  - Supporting the Commission and the Member States by having a person nominated as a member of the Chemical Review Committee (CRC) of the Rotterdam Convention, from June 2017 until June 2019 (*see further details in response to Question 11*).
  - 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 PIC staff is working in close cooperation with their expert colleagues of the ECHA IT Department as well as those in charge in the management of other IT tools in the various operational units.
- Making available of PIC data (dissemination)

- 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 it is responsible for.
- Legal advice, and in particular in the context of applications for access to document.
- 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 continued to increase over the whole reporting period, as illustrated by the numbers below:

	2017	2018	2019
No. of estimated notifications	8 900	10 700	11 400
Actual No. of notifications processed[2]	9 251	10 073	10 703

The long-term trend of an annual increase of circa 10 % in the number of export notifications continued. This implies a similar increase in the related number of associated processing tasks and in stakeholder support, towards the Member State Designated National Authorities (DNAs) and requests for clarification/additional information received from authorities in non-EU countries. The approximate figures on support provided to the Commission, EU- and non-EU DNAs are summarised 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.

	2017	2018	2019
No. of requests for technical/ regulatory support	2 080	2 550	3 100

This trend in submissions has also led ECHA to continue investing substantial human and financial resources in the enhancement of the ePIC application and in the automation of certain processes, in order to enable all actors to cope with an always higher workload, and thus meet their legal obligations. IT development is nevertheless resource intensive as ECHA is involved in the analysis phase, testing, updating user manuals and subsequently training users on the new functionalities.

Furthermore, the yearly export notification approach 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 up to 70 % of the total yearly submissions of export notifications. In order to meet its legal deadlines, to face the increased workload described above and to still provide the necessary level of stakeholder support, ECHA had to regularly hire interim staff for several months every year, as the core staff is insufficient to cover these "peak in workload" periods.

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.

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

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 published the following pages and translated them in all official EU languages. They can be found here:

- General introduction to the PIC Regulation: https://echa.europa.eu/regulations/prior-informed-consent/understanding-pic
- ePIC: https://echa.europa.eu/support/dossier-submission-tools/epic

More specifically, the direct links to all linguistic versions of 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 exporters/importers of upcoming legal deadlines (e.g. Article 10 reporting deadline).
- To alert or remind exporters of typical shortcomings or elements they should pay attention to in their export notifications.
- To advertise the publication of updated user manuals, new factsheets, 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.

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

- Upcoming legal deadlines (e.g. Article 10 reporting deadlines).
- New or clarified legal obligations: entry into application of a new amendment to Annex I and/or Annex V, new substances included in existing group entries.
- 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, which were also used to make the promotion of *ad hoc* activities such as the campaign for improving the quality of the information provided in Section 2 (Prohibited and Allowed uses) of export notifications.

Social media:
Since January 2018, ECHA has started to be more active on social media (LinkedIn, Twitter, Facebook) and published various posts 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, BREXIT, the ECHA Forum enforcement project on PIC, ECHA's participation in the meetings of the Parties to the Rotterdam Convention, or the publication of specific guidelines on how to provide information on prohibited and allowed uses in PIC export notifications.

Support to individual companies:
This support was mainly provided by means of replies to incoming Helpdesk incidents (*c.f. 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.

Workshops, webinars and similar training events:
During the reporting period, ECHA has not organised any specific in-house workshops, webinars or training events. However, the Agency has participated in several conferences during which the PIC Regulation and/or ePIC tool were presented and discussed with the participants from industry mainly. In November 2017 and October 2018 respectively, ECHA provided an update on relevant issues related to PIC and ePIC at a workshop on "*Technical Control on Trade of Chemicals*" (circa 50 participants in the room + circa 50 remote participants) and then a half-day training on the Rotterdam Convention, the PIC Regulation and ePIC (circa 20 participants in the room + remote participants), to representatives of the Spanish chemical industry, and both events took place in Madrid. In November 2019, ECHA talked about the PIC Regulation at the ChemCon Europe conference in Budapest, to which more than 250 representatives from industry took part in. In March 2019, ECHA also participated in a workshop on "*BREXIT and the implications on Supply and Use of Chemicals in Spanish Business*" and provided an update of the impact of the United Kingdom withdrawal from the EU in ECHA's activities, including PIC (circa 80 participants in the room + circa 140 remote participants).

IT user manuals, factsheets and Q&A (frequently asked questions):
ECHA has regularly updated the "ePIC User manual for Industry"[3], in order to reflect the successive improvements and new features brought to the ePIC tool.

More specifically, ECHA published during the reporting period four different guidelines ("In brief" documents) to assist exporting and importing companies on the following key aspects for the fulfilment of their obligations under the PIC Regulation:

[3] ECHA is also publishing and regularly updating specific ePIC User Manuals for DNAs, for NEAs for the Commission, and an ePIC User Guide for Customs – see at: https://echa.europa.eu/support/dossier-submission-tools/epic/epic-manuals.

- Special RIN requests (August 2017)
- Proposing waivers though ePIC (November 2017)
- Reporting on exports and imports of PIC chemicals (December 2017)
- How to provide information on prohibited and allowed uses in PIC export notifications (October 2018): the related section in the export notification has proven to be of particular importance for the authorities in the importing countries, but has always been a source of misunderstandings among exporters regarding what information is requested to be provided, and consequently led to a high number of requests for resubmission. It was therefore in the interest of all parties involved - EU exporters, EU processing authorities (MS DNAs, ECHA, and Commission) and importing countries – that the quality of the information provided in section 6.2 improves.

In addition, in 2018, ECHA conducted a major review of the existing legal texts developed by the Agency in three Rotterdam Convention languages (EN, ES, FR), with a focus on the texts for the 70 most exported PIC chemicals. ECHA provided these in ePIC for the exporters to use in Section 6.1 (*Summary of and reasons for the final regulatory action and date of entry into force*) of their export notifications.

Finally, in March 2019, ECHA established a temporary manual procedure for notifying PIC exports to the UK after UK's withdrawal. ECHA published a guideline on "*How to notify exports to the UK after the UK's withdrawal from the EU*", as well as some related PIC-specific information and Q&As, and a manual export notification form, until such export notifications can be made in the ePIC tool.

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:

When ECHA started working on the PIC Regulation in March 2014, there were 390 companies registered in the former IT tool used for PIC implementation (EDEXIM). At the end of the previous reporting period (2014-2016), ePIC had 1177 registered companies. At the end of this reporting period, ePIC had 2343 registered companies, of which 578 actively used ePIC in 2019 (i.e. submitted in ePIC at least one export notification, waiver proposal, Special RIN request or Article 10 import or export report). As also mentioned in the previous report, part of the increase is linked to new substances added to Annex I, which are exported by "new" *PIC companies* but the increased visibility given to PIC by ECHA (via information on ECHA's website, news items, ECHA's participation in conferences, social media, etc.) has also contributed to increasing awareness and compliance with the PIC Regulation.

ECHA is also of the opinion that the attention paid by the Member State DNAs and ECHA to the quality of the information provided in export notifications (e.g. in section 3.3 on foreseen category and foreseen use in the importing country, in section 3.4 on the importer name and details, in section 6 on the information on the final regulatory action taken at EU level), be it in the context of processing the export notifications or in the respective support and communication activities, has contributed to a substantial improvement in the compliance of information provided by exporters.

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.

	2017	2018	2019
No. of requests[4]	230	234	283

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

- Questions about or misunderstandings regarding the export notification and related procedures:
  - Why I have not been given the greenlight to export yet? (RIN activation): these enquiries relate in particular to misunderstandings on either the fact that PIC Annex I Part 2/3 substances require a positive Explicit Consent response from an importing country for their RIN to be activated and there is none, or the fact that an authority (DNA/ECHA), especially during the end-of-year peak submission period, does not necessarily process the export notification immediately but according to the legal deadlines and taking into account the foreseen first export date (i.e. so that the export notification is forwarded to the importing country DNA by latest 15 days before the export date).
  - Why has my export notification been rejected? (rejection)/ Why does it need to be amended? (resubmission request): these inquiries relate to the misunderstanding of when export notifications are (not) needed (e.g. duplicate notifications, export notifications for UVCB substances, etc.), or to what information is required to be provided in certain sections of an export notification.
  - What are exporters' obligations under PIC depending on which part of Annex I their chemical is listed in?
- Definitions/ concepts of "exporter" and transit under PIC: which country should I notify the export from, 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?
- Substance identification: e.g. exporters are not always certain whether their substance is subject to PIC or not, and especially when those are potentially falling within the scope of an

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

Annex I group entry (e.g. "*Arsenic compounds*", "*Cadmium and its compounds*", "*Lead compounds*") and when the PIC substance is a constituent (incl. as an impurity) of another substance.

- Article 10 reporting: during the first quarter of every year, ECHA receives requests from exporters/importers related to their obligations for reporting exact quantities of PIC chemicals exported/imported during the previous calendar year.

In addition to the above, the following are examples of more complex questions, of which the numbers are lower but usually require asking for the support of expert colleagues, being it within the Agency or in another organisation (e.g. European Commission):

- Link between the PIC Regulation and Regulation (EC) No 1102/2008 of the European Parliament and of the Council on the banning of exports of metallic mercury and certain mercury compounds and mixtures and the safe storage of metallic mercury (i.e. is their substance subject to PIC and therefore exportable or is it banned for export under the mercury regulation).
- Rules for classification and labelling of mixtures under CLP: is the PIC substance present in their mixture in a high enough concentration to trigger labelling obligations under CLP (which is also the trigger for the PIC export notification obligation, in accordance with Article 8(1))?
- Consequences of the withdrawal of the United Kingdom from the European Union for PIC exports to the UK (e.g. when and how to notify the exports/imports to the UK).

The questions related to the ePIC tool and its functionalities have always remained low in number (less than 10 per year) 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 directly involved in providing replies to the requests received from companies via the ECHA 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 Operations Team and the Commission, regular teleconferences (in every six weeks in average) have been established to discuss ECHA's PIC-related tasks/activities, and in particular when the involvement of other ECHA expert colleagues is needed (e.g. regarding the drafting of Final Regulatory Action notifications). These have already contributed to increase the necessary dynamism that the collaboration between the Commission and ECHA deserves, and could usefully be complemented by even more regular and informal contacts. 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:

Preparation of notifications of final regulatory action to the Rotterdam Convention Secretariat:
In 2017-2019 ECHA has prepared notifications of Final Regulatory Action for 25 pesticides and 5 industrial chemicals (listed in Annex XIV to REACH). The above mentioned regular teleconferences between ECHA and the Commission have helped to improve the predictability and planning of the work in this field in particular, although the planning of the work could be

even further improved and efficiency be increased by agreeing on near-term deadlines for the Commission to provide comments on notifications drafted by ECHA.

Technical preparation of meetings:

PIC DNA meetings:

ECHA believes 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. This would enable the Commission to take the full advantage of ECHA's insight to the daily processing and stakeholders' support activities, in the preparations and running of the discussions at the DNA meetings; as far as ECHA is concerned, it would support a better planning and use of its resources, and a better preparation for the discussions at the DNA meeting, in support to the Commission and in view of the necessary follow-up actions for the implementation of the decisions taken.

CRC:

ECHA supported the Commission and the EU experts, from mid-2017 to mid-2019, in two meeting cycles of the Chemical Review Committee (CRC) (including participating to two CRC meetings) by providing for two years an expert to the member seat of the United Kingdom. This covered contribution to several preparatory tasks groups including preparing of Draft Reports of four substances and for two intersessional drafting groups, including a co-chair/co-drafter responsibility on drafting group of Decision Guidance Document for phorate (now included in Annex III to the Rotterdam Convention). The work objectives were well predictable, but the workload appeared to be higher than estimated and than initially agreed between the Commission and ECHA. The collaboration between ECHA, the Commission and other EU participants, and also with other CRC members, was very fluent and constructive.

Decisions that the export can proceed in the absence of an explicit consent:

ECHA does not officially have a role in the approval of decisions that exports can proceed in the absence of an explicit consent (waivers). However, these decisions can have an impact on other tasks falling under ECHA's responsibility (such as management of explicit consents or helpdesk questions). As also reported previously, the final check performed by ECHA at the time of the activation of the related export notification leads in certain cases (circa 20 cases per year in the reporting period) to the revision of the initial decision, which in turn often triggers requests for clarification addressed to ECHA by the exporters due to the delay in the activation of the export notification. The experience also shows that the limited resources at the Commission can be a delaying factor in the processing of waiver proposals, while ECHA would have the capacity to process them within a maximum of 2 working days (an increase in efficiency of more than double if compared with the observed average processing time). A change in this process, with a reduction on the number of steps and actors, could reduce the administrative burden to all actors and make the process faster and more efficient. Moreover, ECHA has overall a better visibility than the Commission on the communications between the EU and non-EU DNAs, which usually should facilitate the decisions on the acceptance/rejection of the documentation proposed by the exporters, and in particular in case an explicit consent response is received from the importing country but its recording in ePIC is delayed, or clarifications are pending, and the Commission could unnecessarily process and possible accept a waiver proposal in the meantime. Therefore, an earlier and possibly enhanced role for ECHA in this process could improve its overall efficiency. ECHA is at the Commission disposal to reflect on how and under which conditions this could materialise.

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

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 is very valuable and much appreciated. In fact, 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. This also helps ECHA in better planning its activities and resources, and in particular for the timely preparations and adaptation of ePIC (new substance/group entries) and for the processing of any related new export notifications and all related activities (Explicit Consents-related, helpdesk questions, communication/awareness raising).

ECHA believes however that it can further support the Commission, should a need to make a prioritization among the substances that meet the criteria to be added to Annex I to the PIC Regulation appear. Criteria such as the uses, market importance, availability of alternatives could, among others, be taken into account to decide on which substances to be subjected to PIC first, with regard to the possible impact on protection of human health and the environment, as well as the associated expected workload for the DNAs, ECHA and the Commission. For instance, it may be of value to have a better understanding of the potential workload (i.e. number of submissions) that the listing of new substances under PIC may trigger, especially when there is a substantial number of candidates fulfilling the criteria, in order to be better prepared and possibly decide on a progressive listing over time.

ECHA's expertise in substances with biocidal uses and experience in the identification and prioritization of substances of very high concern under REACH, as well as in analysing and developing (regulatory) risk management strategies for individual and groups of substances, could represent an added-value in this context. Cooperation could also be sought with other national and European centres of expertise, such as EFSA for pesticides. Therefore, as also suggested in the previous report, ECHA proposes to work with the Commission on investigating whether and how the Agency could provide support in the prioritization of candidate substances for their inclusion in Annex I (and Annex V) to the PIC Regulation.

Furthermore, ECHA notes that the two main amendments to Annex I (and Annex V) to the PIC Regulation which were adopted during the reporting period (Commission Delegated Regulations (EU) 2018/172 and 2019/330) entered into application at an optimal period of the year, i.e. on 1 April 2018 and 1 May 2019 respectively. Unlike previous amendments in 2014 and 2015 which entry into application coincided with the end-of-year annual export notifications' submission peak period and represented an increased administrative burden for all actors at the busiest time of year, those latest amendments triggered a more manageable peak in the workload, at a period of the year with greater flexibility to reallocate resources. ECHA would recommend that this practice is maintained for the future amendments.

Finally, ECHA would like to stress that the clarity as to the reasons and regulatory basis for the listing of a (group of) substance(s) in Annex I to the PIC Regulation, as well as for the part of Annex I and the use limitation it is associated with, 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 in 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 and full understanding of the regulatory action restricting the placing on the market/use of a (group of) substance(s) within the EU as the basis for its inclusion to Annex I, 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 collaboration between ECHA and the Commission, and as also suggested in the questionnaire for the previous reporting period, the Agency would very much welcome the establishment of a proper backing-up system at the Commission, in order to ensure that ECHA can reach a PIC contact at the Commission, and ensure a smooth running of PIC operations, at all times; the summer period, during which the PIC operations continue (and may sometimes see increased workload due to e.g. the entry into application of an amendment to the list of substances subject to PIC) is particularly critical in this respect.

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

☐ Yes

☒ No

Additional information:

Overall, ECHA and the DNAs work together in a collaborative, efficient and friendly manner and this is often acknowledged by the DNAs as well at DNA meetings. Whenever different views arise between ECHA and a DNA, it is generally easy to discuss and to agree on a practical way forward. However, there are areas in which the collaboration could be even smoother and more efficient, and those have been further elaborated upon in the response to Question 13 and the following ones.

As an illustration of the good cooperation, a delegation of three colleagues from the German DNA visited ECHA for a one-day workshop, in September 2019. It gave the opportunity for the respective teams to know better each other, to exchange on the respective working approaches and methods, and to discuss some specific issues that could be better addressed in a physical meeting than by email. This initiative could be replicated with other Member State DNAs in the future.

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:

The operational issues related to the tasks highlighted in this section are further elaborated in the answers provided to questions 17, 18, 19, 25, 26 and 28 below.

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)?

	2017	2018	2019
Export notifications handled[5]	8 455	9 704	10 009
Export notifications forwarded	6 950	7 530	8 059
Acknowledgments of receipt received	4 583	5 062	5 387
Export notifications forwarded a second time	2 367	2 468	2 672

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:

When processing export notifications, ECHA has often noticed issues/ mistakes with the followings (in complement to the issues already listed in response to Question 8, which raised Helpdesk incidents):

- Duplicate notifications: some exporters still have not understood that they do not need to submit a new export notification for the export of the same chemical to the same importing country although they have already submitted a valid one for the same calendar year, in

[5] 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 2017 but processed in late 2016, are counted in 2017).

cases e.g. the expected yearly amount of the substance/ mixture or the importer(s) have changed, or the RIN active period expires during the calendar year.

- Scope: if the chemical they intend to export is not specifically listed in the list of "Chemicals" in ePIC, companies are not sure whether its export is subject to the PIC Regulation or not; as also mentioned in response to Question 8, this issue is specifically related to Annex I entries for groups of substances (e.g. "*Cadmium and its compounds",* or "*Lead compounds*" which does not cover "lead" (metal) itself) for which the lists of individual compounds associated in ePIC with these entries is not necessarily fully-comprehensive. As already mentioned in response to Question 8, the uncertainty of exporters whether an export notification should be submitted for export of the PIC substance as a constituent, and in particular as an impurity of another substance, has led to different approaches among exporters/Member States, and to the (mis)use of the "mixture" template in ePIC for such notifications.
- Templates: some exporters confuse export notifications for substances and for mixtures and use the wrong template.
- Use category and foreseen use(s) in the importing country:
  - The category and specific uses intended in the importing country as to be reflected in Section 3.3 under "*Foreseen category and foreseen use in importing country*" of the export notification, is often confused with the category for which the final regulatory action was taken and with the prohibited and allowed uses in the EU, as to be recorded under Section 6.2.
  - 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, in particular due to the fact that the field is provided as free text only, and therefore without any structured sub-categorization of uses which could help notifiers to describe the foreseen uses in a more clear and consistent way.
- Summary information on Final Regulatory Action taken by the exporting country (Section 6):
  - The prohibited uses and allowed uses described under Section 6.2 are often incorrect or misleading, and reflecting more the intended uses in the importing country (as mentioned above) than the regulatory status of uses within the EU; there is also sometimes product-related information inserted there.
  - The "Produced / Imported / Exported / Used" fields under Section 6.2 are usually left empty, but often filled in with incorrect data too, sometimes referring to quantities that are specific to the exporter instead of quantities that are to be reported at EU level.
- Importers' details: exporters often provide incomplete or incorrect contact details (e.g. PO Box addresses, wrong city/country), or even details of importers who cannot be identified/reached by the authorities of the importing country or who are not (yet) in contact with the EU exporter.
- Safety Data Sheets: not all companies provide SDSs (or equivalent information) in the official language of the importing country or in an appropriate language; ECHA has however noticed some improvement with regard to this issue, and in particular since new features were added in ePIC to raise the attention of the exporters.

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

	2017	2018	2019
Re-submission requested	570	1 251	937
Rejected	41	49	122

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

Reasons for requesting re-submission of export notifications:

2017 Most of the resubmissions were requested following the adoption by ECHA of a stricter approach in checking the content of export notifications, with the aim to ensure that the information in the notifications and the attached SDSs are provided at an appropriate level of quality and language to the authorities of the importing countries.

2018 Many notifications were received with unclear, irrelevant or incorrect information under section 6.2 (Prohibited and Allowed uses); also, many notifications had incorrect or insufficient contact details for the non-EU importers under Section 3.4, or not matching with the destination country.

2019 Similarly to 2018, most of the resubmissions were requested because of unclear or irrelevant information under section 6.2 (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 Safety Data Sheet.

Reasons for rejecting export notifications:

2017 Most of the rejections were made at exporters' request (e.g. exports cancelled; one already validated notification could cover similar mixtures for which other export notifications are not needed).

2018 The main reason for rejecting the export notifications was that the importing country has waived the right to receive export notifications for certain chemicals from the EU (Brazil); another representative reason for rejection was that the concentration of the PIC substance in the export notification did not trigger labelling obligations under CLP.

2019 Most of the rejections were 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) or a mismatch between the stated importing country and the importer's address.

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:

	2017	2018	2019	**Total**
No. of late notifications	312	880	594	**1 786**
% of total yearly No. of notifications	3.7 %	9.1 %	5.9 %	**6.3 %**

Additional information:

ECHA has noticed that the difficulties of certain Member States to cope with the legal timeframe for the checking export notifications usually appears during and right after peak submission periods, i.e. in November/December/January months, and especially when those coincide with holiday periods when very limited or no resources are available. Those can also arise when there is a temporary unavailability of the more experienced colleagues, or even change in staff and the need for newcomers to get acquainted with the PIC procedures and tasks. The advice generally given to the DNAs is to inform ECHA as early as possible about the possible or actual resources/processing issues, so that the necessary attention and *ad hoc* support can be given.

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.

In case of late notification, the authority in the importing country is systematically alerted by a separate communication as to the fact that the export notification was delivered less than 15 days before the expected date of export (as foreseen by Article 8(2) of the PIC Regulation).

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:

	2017	2018	2019	**Total**
No. of late notifications	44 (14)	95 (42)	71 (4)	**60**
% of total yearly No. of notifications	0.2 %	0.4 %	0.04 %	**0.2 %**

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).

For a number of cases, it was the Agency (and not the Member State DNA) who missed its legal deadline for processing, typically due to IT-related issues or a need for policy consultation. However, in many cases, this situation occurred because the tasks had been already processed late by the DNA and therefore ECHA received the task very close to the due date. In this case too, ECHA processed the late export notification in order not to further penalise the exporter, provided that all the required information has been submitted. The authority in the importing country has always been informed accordingly.

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:

Over the reporting period, ECHA received 15 export notifications flagged as referring to the export of a chemical related to an emergency situation in which any delay may endanger public health or the environment in the importing Party or other country, in accordance with Article 8(5) of the PIC Regulation. The outcome of their processing was as follows:

- Most of them (13) did not meet the criteria described in Article 8(5) and, when available, were providing justifications relating to economic considerations rather than to the protection of public health or the environment; in these cases, ECHA rejected the export notification and invited the company to submit a new "standard" export notification; the exporter's DNA

presumably did not realise that the export did not qualify as an emergency notification under the meaning of the PIC Regulation as they should have rejected the export notification instead of forwarding it to ECHA for further processing.

- Overall, only 2 export notifications under the "emergency situation" procedure were validated during the reporting period.

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:

ECHA receives a relatively high number of requests for clarification/additional information from the authorities in non-EU importing countries. The most frequent questions and requests are as follows:

- additional information on the importing company(ies): such requests come in particular from non-EU DNAs who (systematically) check with the importing company mentioned in the export notification that they are actually aiming at importing the chemical (and possible how they intend to ensure its safe use and disposal in the importing country), but fail to identify/get in contact with that company; the same DNAs may also request further information/contact details of the EU exporting company if, as it happens sometimes, the importing company mentioned in the export notification inform them that they are actually not aiming (yet) at importing the chemical or at least that they do not have yet a contact and/or contract with the EU exporter;
- further clarifications on the intended use of the chemical in the importing country – including further details on risk management measures (including disposal and waste management) to be implemented in the importing country, in order to ensure safe use of the chemical – or on the quantities exported;
- clarifications 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 (Annex I Part 1 only and Part 2 substances);
- ECHA may have sent the export notification to the incorrect authority, either based on the legislation in the importing country (e.g. a biocidal substance/product 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.

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?

	2017	2018	2019	**Total**
Notifications received	448	465	458	**1 371**

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

	2017	2018	2019	**Total**
Acknowledgements sent[6]	95	92	95	**282**

[6] ECHA does not send acknowledgements of receipt to the United States (based on a bilateral agreement) which is the country sending the most notifications to the EU

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: -

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:

Compared to the situation during the previous reporting period, the majority of the DNAs have understood which exports are/are not in scope for Article 10 reporting. As a consequence, ECHA receives less data on exports of PIC chemicals exported for research and analysis purposes in quantities below 10 kg per year and per importing country, which in accordance with Article 2(3) are exempted from the reporting obligation. These data indeed refer to very small quantities, which used to complicate the aggregation of the overall report (whilst respecting the Eurostat recommendations on data confidentiality) which is mainly composed of high volume exports.

However, some of the data aggregated and submitted by the DNAs to ECHA has contained mistakes derived from industry reporting. This has led to errors being spotted at a later stage (e.g. very high quantities due to mixing unit measures) requiring correction, re-aggregation and resubmission of the reports by the DNAs. In turn, this has led to inefficiencies and delays in the preparation of the overall report as well as to errors not being identified by ECHA and published, as ECHA's capacity to perform a quality check is very limited.

An increased verification of the data by DNAs before their 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:

To ensure a consistent interpretation of explicit consents across all EU Member States and to avoid clerical errors, it was agreed that ECHA would verify the metadata associated to explicit consent requests after it is uploaded to ePIC by the DNAs (and before it can be used for processing purposes).

Overall, this process is working smoothly and the above-mentioned goals are achieved. Due to the complexity in the interpretation of many explicit consents (which are diverse in format/language/approach depending 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 and a significant reduction in clerical errors compared to the past.

ECHA has however noticed that difficulties in interpreting responses to explicit consent requests may naturally arise when staff change in the DNAs and the newcomers need to familiarise themselves with this task and the sometimes quite complex cases; the Agency would like to stress that it remains at the disposal of the DNAs to provide them with the support and guidance they would need to be in the capacity to perform their tasks.

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/approval. Once approved, ECHA will then get a task to activate the related RIN(s).

In the previous report some issues have been identified – such as the attachment by exporters of incomplete/incorrect/expired documents as documentary evidence to support the waiver proposal or waiver documents in a non-EU language with no translation, or the assignment by DNAs/Commission of incorrect validity dates – that have led to a decrease in speed and overall efficiency of the process. Some improvements have already been noted towards the end of the reporting period and some of these issues are not appearing anymore (i.p. missing translations

and incorrect validity dates). However, the Agency is still having exchanges with the Commission, leading to the revision of the decision, on a regular basis as referred in Q11.

As indicated in response to Question 6, ECHA has published in 2017 guidelines ("In brief" document) to assist exporting companies in proposing waivers through ePIC, which has already led to a reduction in the number of problematic cases and needs for revisions/resubmissions/rejections. The Agency is also ready to consider any possible ways to provide further support to the Member States in the processing of waiver proposals, such as introducing alerts or checklists in ePIC.

As indicated in response to Question 11, ECHA nevertheless believes that it would simplify the procedure and further reduce the burden on all actors, and therefore improve the overall efficiency of the waivers process, if ECHA played an earlier and/or enhanced role in the waiver approval workflow.

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?

	2017	2018	2019	**Total**
First reminder	1 100	983	1 280	**3 363**
Second reminder	849	788	963	**2 600**

During the reporting period (2017-2019), 54 % 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 23 % of cases, the response is received after the first reminder and do not require a second reminder to be sent. If the overall response rate remains rather low, the system of reminders – of which the vast majority is triggered and sent automatically – is considered as 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:

As already indicated as part of the previous reporting, this provision is challenging to implement, but the number of problematic cases (i.e. in which ECHA and the DNAs disagree on the interpretation) has been substantially reduced after it was discussed at DNA meeting level (April 2015) and the related ePIC functionality was enhanced accordingly.

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 2018 and 2019, ECHA received requests falling within the scope of Article 20, from national authorities in 7 non-EU countries, namely Benin, Bosnia and Herzegovina, Iraq, Jordan, Lebanon, Sri Lanka (3 initial/follow-up requests in total) and Turkey.

The nature and topic of these requests will be further elaborated upon in the next Article 20 report, which will cover the period 2018 – 2019, and is due to be published by the end of 2020.

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: n.a.

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 May 2017 and May 2019, the Agency attended the Eighth and Ninth meetings 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[7], to which participated a high number of non-EU countries and delegates (e.g. circa 80 delegates from 40 to 50 non-EU countries each time). 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. Some specific issues such as the quality of the contact details of importers in non-EU countries, the limited capacity in non-EU countries to respond to EU's requests for explicit consents or the review by EU authorities of the documentation in support to waiver proposals were discussed and, where possible, led to concrete follow-up actions. Overall, the service provided by ECHA was very much appreciated and various calls for even further support to non-EU countries were made. In these occasions, ECHA also held a stand at the side "Technology fair", which was the opportunity to liaise with various stakeholders (more than 100 delegates from 55 countries and 13 organisations visited ECHA's stand in 2017) and promote and explain the PIC Regulation, and the EU legislation on chemicals more generally. ECHA also had one-to-one discussions with several non-EU country authorities, in particular with the aim to understand the reasons and find practical solutions to the issue of non-responding authorities in importing countries.

In September 2018, ECHA attended a side-event to the Basel Convention's 11th meeting of the Open-Ended Working Group (Geneva, Switzerland) on the implementation of the Bamako Convention on the ban on the Import into Africa and the Control of Transboundary Movement and Management of Hazardous Wastes within Africa ("*How can the effective implementation of the Bamako be accelerated?*"), organised by the French DNA.

In June 2019, ECHA participated in a "*Workshop on training and fostering collaboration between DNAs on the implementation of the Rotterdam Convention in the Maghreb countries: Algeria,*

[7] 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.

Morocco and Tunisia". This was organised by the Rotterdam Convention Secretariat and had as objectives to provide training on the key obligations under the Rotterdam Convention, to revise the implementation of the national action plan for complying with the Convention in each country, and to facilitate chemicals trade between EU and the Maghreb countries by promoting a better understanding of the EU PIC Regulation and the information received by the importing countries. For the preparation and delivery of this workshop, ECHA collaborated with the colleagues from both the Rotterdam Convention Secretariat and the Belgian DNA.

In September 2019, ECHA also provided support to the European Commission in the preparations for a regional training workshop to strengthen the capacity of countries in the African region to implement the Basel and Rotterdam Conventions, in Dakar, Senegal.

The Agency is interested in continuing the collaboration with the Rotterdam Convention Secretariat in this field in the future.

Please specify the countries benefiting from this cooperation: Please see above.

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, also support in beneficiaries efforts in aligning their national regulation for the provisions to implement Rotterdam Convention, with those in the EU. The list of ECHA's activities (EU events, study visits, workshops) under IPA until 2019 is available on its website at: https://echa.europa.eu/about-s/partners-and-networks/international-cooperation/support-to-eu-external-relations-policies/activities-under-ipa/

In addition, the Agency has noticed an increase in the number of requests for support from third countries on issues relating to developing a national legal framework for chemicals. In particular, third countries showed an increased interest in the use of data and information either submitted by industry to comply with REACH or generated by ECHA in operational processes such as e.g. restriction proposal.

Apart from the assistance under the EU Instrument for Pre-accession Assistance (IPA) and the participation in a limited number of events, ECHA has so far not formally or systematically engaged in projects with international organisations in relation to capacity building. Through requests for presentations, ECHA has however, after careful considerations and in close collaboration with the Commission, provided speakers for a selected number of (non PIC-specific) events outside the EU. During the Open Ended Working Group under SAICM in March 2019, ECHA hosted a lunch hour seminar to present an introduction on REACH, CLP and BPR as well as what information is publicly disseminated and its limitations. Similarly, ECHA receives regularly requests for visits from third countries to learn about REACH, ECHA databases, and for potential cooperation.

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.

During this reporting period, the PIC related discussions in Forum focused on:

- a pilot project on the control of PIC and a resulting guide for inspectors;
- the support to Commission in developing a PIC-related form for the ICSMS ("internet-supported information and communication system for the pan-European market surveillance");
- a discussion on the applicability of the PIC Article 8 notification duty to PIC substances exported as impurities of other substances;
- the review of the PIC Article 22(1) template for the Member State report to the Commission.

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:

During 2017-2018, the Forum prepared and conducted a pilot project on the control of PIC focusing on export notifications and information to accompany exported chemicals. One of the recommendations drawn from the project was for the European Commission to develop unique customs codes (CN) for all substances of PIC Annex I and V.

In 2019, following the completion of the project, the Forum prepared a "*Practical enforcement guide for the control of PIC obligations*" describing good practices in the enforcement of PIC Articles 8, 14, 15 and 17, as developed during the pilot project.

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

Involvement of the Agency in enforcement activities:

The Forum considered in its work programme 2019-2023 that inspections of PIC duties should become part of the NEAs' enforcement routine. However, due to the limited resources and many other priority areas for coordinated enforcement by the Forum, careful prioritisation of PIC activities is essential. In this reporting period (2017-2019) the Forum addressed PIC through a dedicated enforcement project and recommended to run another one in the future. One improvement would be to include PIC duties in an integrated enforcement project covering also

other legislations and involving close cooperation with the customs authorities.

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: 2 398 users
- Designated National Authorities: 137 users [8]
- European Commission: 1 user
- 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 23 Member States consulted the application:

  – 1 Member State checked > 2 200 individual notifications
  – 1 Member State checked ~850 individual notifications
  – 4 Member States checked between 200 - 600 individual notifications
  – 4 Member States checked between 100 - 200 individual notifications
  – 10 Member States checked between 10 - 50 individual notifications
  – 3 Member States checked < 10 individual notifications
- National enforcement authorities: 445 users [8]

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:

- Adaptations required in relation to BREXIT[9]:
  - Enabling submission of standard export notifications and special RIN requests for exports from EU-27 companies to the United Kingdom (UK).
  - Enabling registration of import notifications from the UK.
  - Maintenance of explicit consents requested by the UK.
  - Revocation of UK companies' and authorities' access rights.
  - Adaptation of all searches.
  - Disabling of UK export notifications.

- Improvements in Explicit Consent management:

[8] 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.
[9] The feature was not yet visible in ePIC during the reporting period and at the time of submitting this questionnaire as it requires a date of application of Brexit (i.e. after the end of the transition period) to be encoded.

  - DNAs: possibility to close several requests by one response; prevention of creating requests for part 1 substances.
  - ECHA: additional check on the terms and conditions of explicit consent responses (introduction of an internal Initiation-Validation cycle).

- "DLQ" (Dead Letter Queue): addition of a back-office functionality for ECHA to detect and resume "frozen" submissions.

- Improvements in RIN match algorithms, to cover cases under Article 14(8), second paragraph of the PIC Regulation (so called "*12-months extension of an expired response*").

- Improvements in PIC Annexes Amendments' management, to better manage cases of a substance moving from Part 1 to Part 2/3 of the Annex I to the PIC Regulation.

- Declarations of the language of the SDS files in an export notification.

- Improvements in data validation, such as:
  - Section 6.1 of an export notification filled-in automatically in the relevant language.
  - Business rules implemented to ensure fully comprehensive importer details in export notifications.

- Improved searches:
  - Search for substances that ECHA added to Annex I group entries after the group was originally introduced by an amendment.
  - Search for chemicals by amendment, Annex part and CAS-number.
  - Search for explicit consents by use category.
  - Search for article 10 reports and import notifications by ID.

- Terms and conditions revised for all user groups.

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 rather modest available budget for ePIC development 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:

	2017	2018	2019
Number of main releases	2	2	2
Number of patch releases (to fix issues)	1	3	4

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

	2017	2018	2019
ePIC Industry application	99.92 %	99.99 %	99.47 %
ePIC Authority application	99.92 %	99.94 %	99.47 %

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 overall feedback the Agency received was positive.

  Based on the results from the ECHA Stakeholder survey carried out in 2017 and 2018, the following additional information can be mentioned:

  - 2017: 93 % satisfaction rate, with some comments:
    - ePIC is very useful and easy to work with;
    - there is unfortunately no possibility for direct communication with ECHA inside the ePIC application.
  - 2018: 95 % satisfaction rate, with some comments:
    - ePIC is easy to use once familiar with the system;
    - an option for contacting ECHA in the ePIC tool directly should be offered;
    - error messages are difficult to understand.

  No ECHA Stakeholder survey was carried out in 2019 but the feedback received from Industry (representatives), e.g. in the margins of the DNA meetings, was positive. Nevertheless, some comments and suggestions for improvements were collected, such as:

  - an "*End-to-end system*" to support automated submissions from companies' internal systems to ePIC directly should be considered;
  - visibility of event history for explicit consent reminders should be added;
  - it is somehow difficult to find the reason for re-submission or rejection request.

- Designated National Authorities: the overall feedback was positive and the appreciation of the DNAs for a well-functioning, well-designed and efficient tool for the implementation of the PIC procedures is regularly mentioned at the DNA meetings. Many of the suggestions for improvement made by the DNAs have been prioritised and implemented during the reporting period, such as the improvement of the management of explicit consents with the possibility to close several explicit consent requests with one response, the introduction of several new searches (e.g. search of explicit consents by CAS number, search of import notifications or Article 10 reports by ePIC identification number) or a warning message relating to the maximum quantity of 10 kg to be exported for Special RIN requests under Article 2(3) of the PIC Regulation.

- European Commission: the overall feedback received from the Commission was positive.

- National Enforcement Authorities (NEAs): no specific feedback was received from NEAs during the reporting period; however, the interest expressed for the integration of PIC-related information into the "internet-supported information and communication system for the pan-European market surveillance" (ICSMS – see also response to Question 34) can be interpreted as a recognition of the importance and relevance of the data contained in ePIC.

- Customs: some Member States have expressed the interest to link ePIC to their national customs applications, in order to automate controls of these exports; related to that, it should be noted that, during the reporting period, initial contacts were initiated with the relevant European Commission services regarding the feasibility and conditions for connecting ePIC to a centralised application for automated checks by the customs authorities ("Single Window" project).

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

The main and most resources-intensive improvement needs for ePIC that have been identified and that ECHA is considering (pending availability of human resources and budget) are listed below. These improvements and new features would all contribute to either a further reduction of processing times, a reduction of the occurrence of clerical errors, an increase of compliance with legal obligations and timelines, or an overall better user experience of the ePIC tool.

Some of these items were already listed in the report for the previous reporting period but are repeated here as they remain relevant and have not been implemented yet; others are new as they have been identified or suggested during the reporting period subject to this questionnaire. However, it should be noted that some of the features listed below have already been prioritised for implementation in the years after the reporting period covered by this questionnaire; those are identified below with an *.

- Integration of Article 10 non-confidential report generation*, i.e. to generate the non-confidential Article 10 report in ePIC directly (and not outside of the application as it has been done so far), which would reduce ECHA's work in generating the non-confidential report on a yearly basis and take benefit of the fact that Article 10 data is already submitted by exporters/importers and checked/compiled by DNAs in ePIC.
- Messaging*: to improve/modify the internal and external messaging system in ePIC, for enhanced traceability and audit purposes in particular.
- Further improvement to the management of the chemicals database, in order to:
  - make the chemicals more easily searchable;
  - change the way chemicals listed in Annex V part 2 are introduced in the database;
  - facilitate data dissemination.

- Increased automation to reduce manual tasks (e.g. partial/full (pre-)validation of export notifications for Annex I, Part 1 substances, recording of acknowledgement of receipts), to enable further resources/efficiency gains.
- Legal entity change and asset transfer: currently, the system does not support legal entity changes and asset transfers from one account in ePIC to another. However, the implementation of such a feature may require legal clarifications and/or adaptations to the PIC Regulation (*see also response to Question 47*).
- Rules governing the verification and forwarding of export notifications and SRIN requests for substances belonging to a group entry: should the current approach be revised (c.f. response to Question 47) changes may be required/needed in ePIC for the processing of notifications

for group entries substances, and in particular regarding the estimated quantities declared for Special RIN requests (e.g. re-introducing the business rule on quantities) and the forwarding rules for standard export notifications.

In addition to the above listed items, it should be noted that there is a backlog of other items which includes many small possible improvements which have been identified by the various users.

Data dissemination

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

At this link: https://echa.europa.eu/information-on-chemicals/pic/chemicals, the following data and information can be searched (i.e. specific searching parameters/filters can be applied to the online search) and/or found (as non-dynamic information):

- **Chemicals subject to PIC**: the chemicals subject to PIC and listed in its Annex I (all Parts) or Annex V (Part 1 only), can be searched (full/sub-lists per chemical name, per EC or CAS number), with the possibility to apply specific filters (e.g. on use category, use limitation); the Annex V, part 2 is also published but not searchable (yet).
- **Export notifications**: non-confidential data on exports notifications can be searched, and high-level statistics (summaries by importing EU Member State, by exporting non-EU country, by chemical/ mixture/ article and per month) found.
- **Import notifications**: non-confidential data on import notifications can be searched, and high-level statistics (summaries by exporting EU Member State, by importing non-EU country) found.
- **Explicit consents**: non-confidential data on explicit consents received from non-EU countries can be searched.
- EU and non-EU **Designated National Authorities up-to-date contact details**.

In addition to the above, information on substances subject to the PIC Regulation is also made available through ECHA's public website which provides easy access to the information, via its three-layer structure: Infocard → Brief Profile → detailed source data, as well as an access to an overview of the "*Substance Regulatory Obligations*" under EU legislation: https://echa.europa.eu/information-on-chemicals

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

In addition to the disseminated data as described in response to Question 44 just above, as well as the information regularly updated on its website as mentioned e.g. in response to Question 6, ECHA has published the following reports:

- in each of the three years: 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

- in 2017: 1st Report on the operation of the PIC Regulation (pursuant to Article 22): https://echa.europa.eu/about-us/the-way-we-work/plans-and-reports

- in 2018: 2nd Report on information exchange (pursuant to Article 20): https://echa.europa.eu/regulations/prior-informed-consent-regulation/reporting-on-information-exchange

ECHA is also reporting on a yearly basis on its main activities and achievements, as well as on its workload and resources in the implementation of the PIC Regulation, as part of its annual General Reports, available at: https://echa.europa.eu/about-us/the-way-we-work/plans-and-reports

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:

The indirect feedback received from industry relates to the difficulty to get, in particular for open-ended group entries, the overview of substances subject to PIC. It usually materialises with helpdesk questions asking whether a given substance that has not been explicitly listed as falling within the scope of an entry yet, belongs to a certain PIC Annex I group entry. ECHA also received some feedback that it is not necessarily easy to identify newly added substances/entries. This issue was addressed in late 2017 by the addition of the "Chemicals latest" section in ePIC.

In the context of the various requests for Access To Documents under Regulation (EC) No 1049/2001 of the European Parliament and the Council regarding public access to documents ("ATD Regulation") received by ECHA during the reporting period, ECHA received valuable feedback – in particular from the applying Non-Governmental Organizations – on the availability and accessibility of the PIC data on the ECHA website. In addition to rather technical suggestions on how to improve the searching and display of the data that is already available on the ECHA website, the main suggestions were for the dissemination of more data and/or in a different manner than it is proposed to date. As far as the scope of the data to be published is concerned, the main suggestions related to information from individual export notifications (i.e. no aggregated data) on the foreseen uses of the chemicals in the importing country, the expected yearly amounts of chemicals to be exported, the name of the EU exporters and, when applicable, the names of the mixtures and the concentration of the PIC substances in them. The other main request related to the data stemming from the yearly Article 10 reporting procedure, which is asked to be published in a much less aggregated and different manner than it is today, in order to be able to identify the trade of PIC chemicals at the level of individual exporting EU Member States and non-EU importing countries.

Many authorities in non-EU countries find the information useful as they can find summaries of export notifications and explicit consents for their countries, as well as other information – in particular from the REACH, CLP and BPR regulations processes - on the intrinsic properties of the substances, on the regulatory (risk) assessments performed at EU level, as well as on their uses within the EU.

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 second reporting period, a number of issues that were already identified in the first *Report on the operation of PIC* still remain to be addressed, while others have emerged.

Firstly, in addition to other implementation issues already mentioned in the other sections above, the following issues/articles in the legal text have led to interpretation or workability issues. Some of them were mentioned in the previous report already, but are repeated here as they remain as issues and have not been addressed or solved since then; others are new as they have been identified or appeared during the reporting period subject to this questionnaire.

ECHA would welcome the opportunity to discuss these further, including whether they could be considered for the next review of the PIC Regulation, or should be addressed through other means (e.g. Q&As, factsheets, Guidance).

Definitions:

- Legal entities: the PIC Regulation mentions exporters and importers but never defines them as "legal entities". Such a definition would be welcome, especially if hand-in-hand with an approach on how to deal with legal entity changes and associated export notifications. This type of situation arises relatively often, and it is difficult for ECHA to provide guidance and assistance to the companies (both from a regulatory and from a technical perspective) in the absence of an adequate legal framework. 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.
- Exporter: the definition of an exporter (Article 3(18)) could be improved to explicitly address other 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 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. This situation also 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).

Scope:

- PIC substances as constituent of other substances: in accordance with Article 8(1) of the PIC Regulation, and as discussed and confirmed at a number of PIC DNA meetings, the export notification requirement does not apply to the export of a PIC substance when it is a constituent of an exported non-PIC substance, unless an entry of Annex I to the PIC Regulation specifically covers also non-PIC substances containing that PIC substance as a constituent. This means in practice that, in most cases, a PIC substance is not subject to the export notification requirement under the PIC Regulation when it is exported as a constituent of another (mono/multi-constituent) substance, and in particular of an UVCB. The specific case of PIC substances as "impurities" of other substances however remains undecided, and has led to discussions initiated in 2019 and which are still ongoing at the time of filling this questionnaire in. This is also irrespective of the concentration of the PIC substance in the exported substance, and whether or not it is at a concentration that triggers classification and labelling of the non-PIC substance or would trigger the labelling and therefore the export notification requirement of a mixture containing the PIC substance. The only exception to this is the case of group entries in Annex I (such as "*Arsenic compounds*", "*Cadmium and its compounds*" or "*Lead compounds*") which by definition covers UVCBs. Apart from policy questions and concerns raised by some Member States DNAs, this situation has led to doubts in the interpretation of the obligations and recurrent (helpdesk) questions from Industry, and in particular with regard to impurities. Questions from Industry received by ECHA have required the consultation of the Commission but a definite approach is required to ensure consistency on the handling of the requests. There are every year exports of PIC substances as constituents/impurities that are unnecessarily notified (usually using the mixture template in ePIC), processed and sometimes even validated and forwarded to importing countries. There also appears to be some inconsistencies among Member States DNAs on the way to communicate to Industry on this issue and/or process any submitted export notifications. Following possible policy discussions at PIC DNA meeting level, ECHA believes that it would be very beneficial to ensure a consistent approach among Member States, as well as to adopt a clear communication to Industry.

Procedures:

- Export notifications / Requests for 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 for the first one sent after Annex I inclusion. This is an important mean of ensuring that the information has been received, also in view of the frequent changes in contact details in the non-EU countries. As these reminders are managed by ePIC automatically in most cases (i.e. there is no impact on ECHA's workload – whereas changing this would imply IT changes and changes to all our reporting systems) and this practice is well-known and understood by non-EU countries, ECHA would recommend continuing with the current implementation. 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.
- 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*".

- Implementation of PIC Article 14(7) procedure ("waivers"): as explained in more detail in the responses to Questions 11 and 26, ECHA has identified the need for simplifying the procedure and reducing the burden on all actors. This could be achieved by a more active role of the Agency in the "waiver" approval workflow: ECHA, following the initial validation by the DNAs would give the final approval. Adaptations to ePIC would however be required, and necessary changes to the PIC Regulation legal text may also need to be considered.

- Annex I group entries: in accordance with Article 8(2) of the PIC Regulation, an "*[…] exporter shall notify [its] designated national authority of the first export of [a] chemical each calendar year*" and the "*The Agency shall […] transmit the notification to the national designated of the importing [country] […] to ensure that they receive that notification […] no later than 15 days before the first export in any subsequent year*. Furthermore, in accordance with Article 2(8), the PIC Regulation "*shall not apply to chemicals exported for the purpose of research or analysis in quantities that are unlikely to affect human health or the environment and that in any event do not exceed 10 kg from each exporter to each importing country per calendar year."* but exporters nevertheless " *[…] shall obtain a special reference identification number using [ePIC] and provide that reference identification number in their export declaration."* (the so-called "*Special RIN request*" procedure). In both cases, the application of the rules in case of the export within the same year of several individual substances that are falling within the scope of the same PIC Annex I "group entry" (e.g. "*Arsenic compounds*", "*Cadmium and its compounds*", "*Lead compounds*" or "*Mercury compounds […]*"), has raised questions and led to possible inconsistencies.

  On the first point, the question is firstly whether or not an exporter who submitted an export notification for the export of one member substance of an Annex I group entry, should submit another export notification for the export of a second substance falling within the scope of the same Annex I group entry, to the same importing country, within the same calendar year. Secondly, it should be clarified whether or not the notification of the foreseen export a second substance of an Annex I group entry, be it from the same exporter as for the first substance (if required so) or another one, should also be forwarded by ECHA to the importing country.

  When responding to these questions, it is important to also clarify whether or not the foreseen category (of uses) in the first and subsequent export notifications should be a criteria to decide whether or not subsequent notifications should be submitted.

  On the second, the question is whether the 10 kg-threshold shall, in the case of entries of Annex I to the PIC Regulation covering more than one substance, apply to each member substance of the group separately, or in total for all exported substances from the same Annex I group entry.

Information requirements:

- Format for information on foreseen uses as part of export notifications (Section 3.3): as mentioned in response to Question 15, the foreseen uses in the importing country are often inadequately described under sub-Section 3.3 of export notifications. This can trigger various issues that are impacting almost all actors of the PIC Regulation. For EU exporters, it can lead to requests from their Member States DNAs and/or ECHA to resubmit their export notification, and therefore to additional administrative burden and risks for missing their initial foreseen

date of exports; in turn, this create additional workload to the DNAs and/or ECHA. For the authorities of the importing country there might be difficulties in understanding what the foreseen use is, which in turn can have a negative impact on their capacity to ensure a safe use of the substance on their territory. Furthermore, the fact that the information on the foreseen uses in the importing countries is not structured further than at the level of the Rotterdam Convention use categories (i.e. pesticides / industrial chemicals) prevent an efficient identification of the uses at a lower level of granularity, and in particular to be able to distinguish pesticides uses in agriculture from other pesticides and biocidal uses. This has created difficulties to ECHA in the context of responding to Access To Document requests (under Regulation (EC) No 1049/2001 regarding public access to documents) which are mainly focusing on agricultural uses of PIC substances; it may also prevent an enhanced dissemination of PIC data in the future.

To address this issue, a more detailed and structured sub-categorization of foreseen uses could be introduced in the formats for export notifications in ePIC. Adaptations to ePIC and to the export notification template as sent to importing countries, would however be required.

- Information on how the exported chemical is regulated and used within the EU as part of export notifications (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 and resubmissions 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 to explore 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.

- Information reported in accordance with Article 10 and Annex III: according to Article 10(1) and (3), the data to be reported by exporters and importers of PIC substances as such, in mixtures or in articles, does not cover information on the (foreseen) uses of the substances that were exported from and imported into the EU. The availability of such information would enable an enhanced dissemination and communication on the actual exports and imports of PIC substances, and to address any specific requests – be it in the context of an Access To Document request under Regulation (EC) No 1049/2001 or not – for information on exports or imports for specific uses or use categories.

Adaptations to the PIC Regulation and to ePIC would however be required.

Reporting:

- Article 10: Article 10(1), penultimate subparagraph, mentions that the reports on exports "[…] *shall list separately exports pursuant to Article 14(7)*". Annex III, which defines the information to be provided by the Member State no longer mentions Article 14(7); the Article 14(7) specific data is therefore collected at Member State level, but not passed on further and used by the Agency for the purpose of the publication of the non-confidential summary, pursuant to Article 10(3). It would appear necessary to analyse if the Article 14(7)-specific information collected at Member State level should also be provided to the Agency and

possibly reflected in its annual non-confidential summary (Article 10 reports) and, if not deemed necessary, whether the Member States would still see a benefit in receiving this information. Depending on the outcome of this analysis, the reference to Article 14(7) should either be removed from Article 10 or added to Annex III.

In addition, Annex III mentions that information shall be "supplied to the Commission" but in fact, in accordance with Article 10, the data is provided to ECHA. This should also be corrected.

Secondly, as stressed in the response to Question 5 above, the workload has continued to increase over the whole reporting period. The nowadays regular annual update – and hence further population – of the list of substances subject to the PIC procedures (Annex I in particular) is expected to sustain this trend of a continuous increase in the submission of export notifications, and therefore of the overall workload of ECHA related to its own PIC processing tasks and to the support to be provided to the always more numerous stakeholders (exporters/importers, EU MS DNAs, non-EU DNAs, Commission).

The Withdrawal of the United-Kingdom from the EU, as well as the implementation of the related Northern Ireland Protocol, may also lead to an increase in the export notifications and/or workload. Furthermore, the apparent growing interest and capacity of (certain) importing countries to better manage their imports and use of hazardous chemicals opens 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 may require the EU to adapt its procedures, communications and/or support towards those countries; some regional policy development – such as the implementation of the Bamako Convention – may also trigger more exchanges – and possibly *ad-hoc* communications or procedures – with importing countries in the future. Finally, stakeholders – and in particular NGOs – appear to be always more interested in PIC data, and in particular regarding the export of EU banned pesticides to non-EU countries. The number of requests for Access To Documents (ATD) has substantially increased since 2019, and an enhanced dissemination of the PIC data may become one of the key challenges of the next years, if we wish to give to the EU PIC Regulation and the data it generates the accessibility and visibility it deserves with regard to its substantial contribution and great potential for a better management of the risks of hazardous chemicals at global level.

All of the above call for a permanent search of an always more efficient implementation of the PIC Regulation, but will also require that sufficient human and financial resources are allocated to ECHA.

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