# Report on the operation of the Prior Informed Consent (PIC) Regulation 2017

August 2017

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| Version | Changes | |
|---|---|---|
| 1.0 | First publication | 30/03/2017 |
| 2.0 | Correction of data in Section 3.12 IT Related aspects.<br>Designated national authorities: 127 users<br>Commission: 1 user<br>National enforcement authorities: 388 users | 04/06/2018 |
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# 1. Foreword

This report covers the European Chemicals Agency's experiences on the first three years of implementing the Prior Informed Consent (PIC) Regulation.

In March 2014, ECHA took over the PIC-related tasks from the European Commission and started implementing new provisions, which had been added in the recast of the regulation. Later in the year, ECHA introduced a new IT tool, ePIC, which helps industry, national authorities, the European Commission, national enforcement authorities and customs to comply with their obligations under the legislation.

Since then, ECHA has established a close working relationship with stakeholders and offered high quality support. ECHA has also developed reports and published information about the export and import of PIC chemicals in order to make the data more easily accessible. Our input to the implementation of PIC within the EU and to the Rotterdam Convention on the prior informed consent procedure has been recognised both within the EU and at international level.

This report shows that, thanks to the continued efforts of and support from our stakeholders, we are on the right track towards achieving the key aims of PIC: to promote cooperation in the international trade of hazardous chemicals and protect human health and the environment. It also suggests further ways of improving how we can work together with the Commission on topics such as distributing or reallocating certain tasks, planning workloads and managing amendments to the regulation, as well as proposes potential changes to the legal text based on the experience that we have gained. ECHA seeks to discuss these points with the European Commission and the Member States should there be another recast of the regulation.

We also express our concern about the workload, which is already far higher than the original estimates at the time of the recast, and continues to increase. Without adequate resources, we cannot guarantee that the Agency will be able to continue to implement the provisions of PIC with the same level of quality as we have so far.

Finally, I would like to thank the European Commission, the Member State authorities, our accredited stakeholders and ECHA staff for their contributions in implementing the PIC Regulation so far and look forward to their continued support.

**Geert Dancet**
Executive Director

# 2. Three years of PIC – introduction

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

Within the EU, the 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 giving developing countries 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 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.

# 3. Questionnaire

The report is in the form of a questionnaire following the format adopted by the European Commission.

## 3.1 General information

1. Organisation: European Chemicals Agency (ECHA)

2. Period covered: 01 March 2014 – 31 December 2016

## 3.2 Information on the Agency

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

| | 2014 | 2015 | 2016 |
|---|---|---|---|
| Number of staff[1] working on PIC | 7 | 7 | 7 |

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

**4. 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 on the classification, labelling and packaging of substances and mixtures (CLP Regulation)
- 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)

Staff working on PIC collaborates with ECHA staff working on the above-mentioned pieces of legislation on the topics listed below, where there are synergies with processes that are run across the various pieces of legislation.

- Development and maintenance of the PIC submission system (ePIC); in order to benefit from synergies between all ECHA's IT tools, e.g. concerning login and account management
- Company support by means of the Helpdesk
- Substance identity check of substances added to the PIC Regulation by means of an amendment or in cases of substances belonging to groups (following ad-hoc requests from companies)
- Making relevant data publicly available on the ECHA website
- Data mining and reporting
- Safety data sheet (SDS) checks concerning inaccuracies in defining the concentration of a substance, a mixture composition, doubts on classification, etc.
- Providing support to the Commission in the drafting of notifications of final regulatory action for the Rotterdam Convention Secretariat
- Providing support to the Commission and the Member States by having a person nominated as a member of the Chemical Review Committee (CRC) of the Rotterdam Convention
- Drafting of the Guidance for the implementation of the PIC Regulation
- Legal advice
- Communications
- Human resources

**5. Is the Agency's workload in line with the predicted workload?**

☐ Yes

☒ No

Additional information:

The number of export notifications processed by ECHA has increased at a far greater rate than the original estimate of a ~10% yearly increase. The numbers below refer to the reporting period:

| | 2014 | 2015 | 2016 |
|---|---|---|---|
| No. of estimated notifications | 4 000 | 4 300 | 6 300 |
| Actual No. of notifications | 4 575 | 5 460 | 7 967 |

This increase in the number of export notifications implies a similar increase in the related number of associated processing tasks and in stakeholder support, in particular 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 processing team in Dossier Submission & PIC Unit spends between 30-40 % of their time on this task.

| | 2014 | 2015 | 2016 |
|---|---|---|---|
| No. of requests for technical/ regulatory support | 1 000 | 1 500 | 1 800 |

This increase has also led ECHA to continue enhancing the ePIC application and increasing automation of certain processes in order to enable all actors to cope with the increased workload and thus meet their legal obligations. IT development is resource-intensive as ECHA is involved in the analysis phase, testing, updating user manuals and subsequently training users on the new functionalities.

On top of the reporting obligations laid down in the legal text, PIC staff has also received a number of ad-hoc reporting requests from the Commission, ECHA's Management Board and the Rotterdam Convention Secretariat.

Furthermore, the nature of the work implies an uneven distribution of the workload throughout the year so that there is an annual peak during the winter months. 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 has to regularly hire interim staff for several months every year as the core staff is insufficient to cover these needs.

ECHA's implementation of the PIC Regulation was approved according to the ISO 9001 Standard in December 2015. In December 2016, it was further approved according to the ISO 14001 Standard. This confirms the quality and efficiency of the processes and the use of resources that have been put in place, whilst ensuring a regular review of their adequacy.

## 3.3 Support to exporters and importers

**6. 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:*
In conformity with the provisions of Article 6 (1) c and d, with the agreement of the Commission and after consultations with Member States (as well as other stakeholders), ECHA published version 1.0 of the *Guidance for implementation of Regulation (EU) No 649/2012 concerning the export and import of hazardous* chemicals ("Guidance on PIC") in December 2014 (in English only) and a corrigendum to it (version 1.1) in July 2015 (to take into account the end of certain CLP transition periods).

Translations of version 1.1 into 14 languages (Bulgarian, Croatian, Czech, Danish, Dutch, German, Finnish, French, Spanish, Italian, Polish, Portuguese, Slovenian and Swedish) were published in March 2016 and into the remaining 8 official EU languages (Estonian, Greek, Hungarian, Latvian, Lithuanian, Maltese, Romanian and Slovak) in October 2016.

*Web pages on Regulation (EU) No 649/2012 and ePIC:*
ECHA has published these pages and translated them in all official EU languages. They can be found here:
https://echa.europa.eu/regulations/prior-informed-consent-regulation
https://echa.europa.eu/support/dossier-submission-tools/epic

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

- To remind exports/importers of upcoming legal deadlines
- To advertise publication of updated user manuals, new factsheets, etc.
- To inform on policy changes
- To alert users in advance of maintenance breaks

*Awareness-raising campaign:*
ECHA reminds exporters/importers of PIC-related news such as upcoming legal deadlines or workload peaks by different communication means, for example, the ECHA Weekly or the ECHA Newsletter. These channels are also used for highlighting new substances added to Annex I or included in group entries.

*Support to individual companies:*
This is done by means of replies to Helpdesk incidents and/or support over the phone.

*Workshops, webinars and similar training events:*
ECHA has organised a number of workshops on PIC, mainly related to the initial development of ePIC. When ECHA was developing the ePIC IT system, three workshops were organised at ECHA (in June 2013, November 2013 and May 2014) with Member States and industry representatives in order to gather their feedback and allow them to contribute to the specifications. In parallel, a number of WebEx discussions were also hosted, in order to have further discussions. In September 2014 (just after go-live of ePIC) a training workshop was also held at ECHA. Furthermore, ECHA takes part in conferences/trainings, as they offer the opportunity to reach out to industry directly, to provide updates on ePIC/policy issues and to address specific concerns.

*IT user manuals, factsheets and Q&A (frequently asked questions):*
When ePIC went live, ECHA provided a fully-comprehensive user manual describing how to use the application. It was subsequently translated into all official EU languages and is updated every time there is a new release of the application. ECHA has also prepared factsheets dedicated to specific topics and has a Q&A document on ePIC, which is updated in parallel to new releases of the application.

**7. 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 EDEXIM (the IT tool initially used for PIC implementation). At the end of the reporting period, ePIC had 1 177 registered companies. Part of the increase is linked to new substances added to Annex I, which are exported by “new” PIC companies. On the other hand, the increased visibility given to PIC by ECHA, the information on ECHA’s website, the news items, ECHA’s participation in conferences, etc. have undoubtedly contributed to increasing awareness of and compliance with the PIC Regulation.

**8. 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 Q. 5) and are specific to PIC/ePIC.

| | 2014 | 2015 | 2016 |
|---|---|---|---|
| No. of requests[2] | 123 | 245 | 227 |

The largest number of requests ECHA receives is on the following topics:

- Exporters are not always certain whether their substance is subject to PIC or not.
- Exporters do not always understand why they have not been given the green light to export.
- What are exporters' obligations under PIC depending on which part of Annex I their chemical is listed in, on which country they should notify the export from (e.g. the legal entity holding the contract is in one Member State but the shipment is leaving from a different Member State), etc.
- During the first quarter of every year, ECHA receives a large number of requests from exporters/importers related to their obligations for reporting exact quantities of PIC chemicals exported/imported during the previous calendar year (pursuant to Article 10)

In addition to the above, the following are examples of more complex questions, of which the numbers are lower:

- ECHA has received questions related to the link between the PIC Regulation and Regulation 1102/2008 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).
- Exporters ask ECHA whether the PIC substance is present in their mixture in a high

2 Questions related to user accounts, access management, etc. are considered to be out of scope.

enough concentration to trigger labelling obligations under CLP (which is also the trigger for the PIC export notification, in accordance with Article 8(1)).

- Clarification when the manufacturer is based, for example, in Switzerland however, the chemicals are being shipped from the EU.

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

There are four FTEs working in the PIC Operations Team in the Dossier Submission & PIC Unit (C1). These are the people mainly involved in providing replies to the requests received from companies. On average, approximately 10 % of their time is spent on this task.

## 3.4 Coordination between the Agency and the Commission / designated national authorities (DNAs)

**10. Is the Agency satisfied with the collaboration with the Commission?**

☒ Yes

☐ No

Additional information:

ECHA and the Commission overall work well together. 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. They have been further elaborated upon in the section below. ECHA would like to highlight that many of the items listed below could be improved by enhancing ECHA's resources and role in processing tasks through a formal delegation by the Commission and by the Commission slightly increasing and focusing its capacity on policy-related activities.

**11. 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 some cases, the tasks have been assigned to ECHA with a short deadline and without pre-warning. Increased predictability and common planning would help ECHA to ensure timely development of good quality notifications.

*Technical preparation of meetings:*
In the context of the preparation for DNA meetings, the documents are often sent to ECHA for checking/drafting with a very short deadline to react. Taking into consideration the overall workload, it becomes a challenge for ECHA to comply with last-minute requests and to still produce good quality documentation.

Based on the first experience attending the Chemical Review Committee (CRC), there is a possibility to improve the preparation for the meetings by more collaboration between ECHA and the Commission/EU MS experts. The collaboration during the meeting was smooth.

*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. However, these decisions have an impact on other tasks falling under ECHA's responsibility. There is a relatively high number of cases in which ECHA needs to ask the Commission to verify and subsequently amend/reject the decision (when relevant) due to clerical errors (e.g. incorrect validity dates, translations of documents are missing, the nature of the supporting documentation is questionable). This slows down the process and, in many cases, triggers requests for clarification to ECHA from exporters. An enhanced role for ECHA in this process could improve its efficiency and effectiveness.

*Article 23 of Regulation (EU) No 649/2012 on updating annexes:*
As already mentioned to the Commission, ECHA believes it would be beneficial to be involved in the process concerning new amendments to the regulation at an early stage. For example, checking the substance identity of the chemicals proposed for inclusion in an amendment would ensure consistency with processes under other legislations managed by ECHA, thus providing clarity to companies and reducing the number of enquiries that ECHA receives. In addition, based on Article 6(1)(f), ECHA proposes that the Commission considers asking the Agency for support in identifying and proposing further candidate substances for inclusion in the PIC Regulation. ECHA's expertise on biocides and on REACH identification of substances of very high concern as well as related risk management actions could represent an added value in this context.

To the extent possible, ECHA would also like to contribute to the planning of the entry into application of amendments to the Regulation. As an example, both in 2014 and in 2015 the amendments (which resulted in a large number of new notifications) coincided with the annual export notification peak and represented an increased administrative burden for all actors at the busiest time of year. In 2014, the amendment became applicable on 1 December which meant that companies had to submit export notifications (and DNAs and ECHA had to process them) to cover exports just for the month of December. In parallel, they were also submitting the same notifications to cover their exports from January 2015 onwards.

*Other:*
With regards to the day-to-day exchanges between ECHA and the Commission, there is room for improvement concerning the timing for replies. Whereas delays are understandable for policy issues (which are often complex in nature and may require the involvement of other services in the Commission), they can create problems on operational issues which, for example, concern a specific export. In the latter cases, ECHA is often put under pressure by the exporter/exporter's DNA. The limited resources in the Commission are also a factor contributing to these delays; as a starting point, ECHA proposes that sufficient capacity is continuously available, including back-up, in order to ensure smooth running of PIC operations at all times.

**12. 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 at DNA meetings. Whenever there are differences, it is easy to discuss and to agree on a way forward. There are areas in which the collaboration could be more smooth and efficient and they have been further elaborated upon in question 13.

**13. 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, 19, 25, 26 and 28 below.

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

**14. 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)?**

| | 2014 | 2015 | 2016 |
|---|---|---|---|
| Export notifications handled[3] | 1 550[4] | 5 845 | 8 335 |
| Export notifications forwarded | 460 | 4 642 | 7 229 |
| Acknowledgments of receipt received | 190 | 3 077 | 4 575 |
| Export notifications forwarded a second time | 270 | 1 565 | 2 654 |

**15. 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

3 This number includes initial submission, re-submissions and rejections

4 Data available from 1 March 2014 (all the other data in this column available after go-live of the PIC submission system, i.e. 2 September 2014)

☐ 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 following (on top of the issues already listed for Q. 8, which raise Helpdesk incidents):

- If their chemical is not in ePIC, companies are not sure whether its export is subject to the PIC Regulation or not (this issue is specifically related to group entries, e.g. *cadmium and its compounds*, for which the list of cadmium compounds in ePIC is not necessarily fully-comprehensive).
- Some exporters confuse export notifications for substances/mixtures.
- Section 3.1 (foreseen category and foreseen use in importing country) of the export notification is often confused with Section 6.2 (category for which he final regulatory action was taken).
- The intended use and use category for exports of biocides can be problematic due to the fact that the EU considers a biocide as a sub-category of the pesticides category however, many non-EU countries consider biocides as industrial chemicals.
- Some companies insert controversial messages in section 6.1 on the final regulatory action (for example, that they disagree with the fact that the substance was banned or severely restricted in the EU) so ECHA has to ask for such statements to be removed.
- Not all companies provide safety data sheets (or equivalent information) in the official language of the importing country or in an appropriate language.

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

| Reason / Number per year | 2014[5] | 2015 | 2016 |
|---|---|---|---|
| Re-submission requested | 43 | 334 | 232 |
| Rejected | - | 51 | 124 |

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

Most frequent reasons for requesting re-submission of export notifications:

2014 Incorrect safety data sheets attached to the notification;
Safety data sheets unavailable as it was attached in the incorrect place in ePIC;

2015 Discrepancy between the data on the substance/mixture composition in ePIC and in the safety data sheet;
Issues with the data provided in Section 6.1 “Summary of and reasons for the final regulatory action and date of entry into force” (incorrect text/language);

2016 Amending the information entered under item 3.3 “Foreseen use in importing country”. More accurate information facilitates retrieving an explicit consent from the importing country;
Safety data sheet language;
Issues with the data provided in Section 6.1 “Summary of and reasons for the final regulatory action and date of entry into force” (incorrect text/language).

Most frequent reasons for rejecting export notifications:

2014 No rejections in 2014

2015 A large number of export notifications for didecyldimethylammonium chloride (CAS 7173-51-5) were rejected because the substance was notified in a mixture at a concentration level which did not trigger labelling of the mixture, irrespective of the presence of any other substance (in accordance with Article 8(1));

2016 The importing country has waived the requirement to receive export notifications for exports of certain chemicals from the EU;
Based on the information provided in the safety data sheet, the mixture has not been classified as hazardous.

5 Data only available after go-live of the PIC submission system, i.e. 2 September 2014

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

☒ Yes

☐ No

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

| Year | No. of late notifications | % of total yearly No. of notifications |
|---|---|---|
| 2014[6] | 6 | 1.2% |
| 2015 | 348 | 6.4% |
| 2016 | 371 | 4.7% |
| **Total** | **725** | **4.9%** |

Additional information:

When the Agency noticed that the exporter had submitted the export notification on time and that the delay was due to late processing by the DNA, ECHA (i.e. the PIC Operations Team in consultation with the Legal Affairs Unit) decided to process the late export notification in order not to further penalise the exporter and to allow the export process to continue.

The authority in the importing country is always 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).

**18. 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?:

6 Data only available after go-live of the PIC submission system, i.e. 2 September 2014

| Year | No of late notifications[7] | % of total yearly No. of notifications |
|---|---|---|
| 2014[8] | 4 (3) | 0.7 % |
| 2015 | 79 (18) | 1.4 % |
| 2016 | 88 (9) | 1.1 % |
| **Total** | **171 (30)** | **1.2 %** |

In a small number of cases (as clarified in the table above), it was actually the Agency which missed the legal deadline for processing, typically due to IT-related issues. Once again, ECHA decided to process the late export notification in order not to further penalise the exporter. The authority in the importing country is always informed accordingly.

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

**19. 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:

ECHA received a small number of 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)). The outcome of their processing was as follows:

- Most of them did not meet the criteria described in Article 8(5) and referred to exports that were considered urgent by the exporter. In these cases, ECHA rejected the export notification and asked the company to make a new “standard” submission.
- 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

7 ECHA-specific delays in brackets, as a portion of the total number.

8 Data only available after go-live of the PIC submission system, i.e. 2 September 2014.

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

**20. 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 large number of requests for clarification/additional information from the authorities in non-EU countries. The most frequent are the following:

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

## 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

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

| Year | Notifications received |
|---|---|
| 2014 | 209 |
| 2015 | 486 |
| 2016 | 410 |
| **Total** | **1 105** |

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

| Year | Acknowledgements sent[9] |
|---|---|
| 2014[10] | 3 |
| 2015 | 122 |
| 2016 | 92 |
| Total | 217 |

## 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)

**23. 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:

**24. 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:

Not all DNAs have understood which exports are/are not in scope for Article 10 reporting. Due to this, ECHA also receives data on exports of PIC chemicals exported for research and analysis purposes in quantities below 10 kg per year and per importing country. In accordance with Article 2(3) these exports are exempted from the provisions of the regulation and therefore also from the reporting obligation.

9 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.

10 Data only available after go-live of the PIC submission system, i.e. 2 September 2014.

The above-mentioned data refers to very small quantities, which complicate the aggregation of the overall report (whilst respecting the Eurostat recommendations on data confidentiality) which is mainly composed of high volume exports.

## 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)

**25. 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 of the interpretation of many explicit consents (which are diverse in format/language/approach based on the issuing non-EU country), in several cases ECHA asks the EU 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.

### 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)

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

☒ Yes

☐ No

Additional information:

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

Overall the process is working relatively smoothly. However, due to clerical errors by the DNAs/COM, ECHA has experienced the issues listed below. These have led to a decrease in speed and efficiency of the process:

- The waivers are assigned incorrect deadlines and therefore require revision (which has to be performed by COM after ECHA flags the issue);
- Incomplete/incorrect/expired documents are attached as documentary evidence to support the waiver (so the waiver needs to be amended/rejected by COM after ECHA flags the issue);
- The waiver document is in a non-EU language and the company has not provided a translation (although this was an agreed requirement). If ECHA is unable to understand whether the waiver is applicable, further clarification/follow-up actions are required with the DNA and/or the Commission.

Based on the above, ECHA believes it would simplify the procedure and reduce the burden on all actors if ECHA played a direct role in the waiver approval workflow (for example, if the approval could take place between the DNAs and ECHA directly). This would reduce the administrative burden on the Commission and would make the process faster and more effective. ECHA requests this proposal to be considered whenever the next recast of the PIC Regulation takes place. This would also require changes to ePIC and can therefore only be implemented once there is a clear legal basis for doing so and a new budget is made available for IT development.

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

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

| | First reminder | Second reminder |
|---|---|---|
| 2014 | 469 | 235 |
| 2015 | 826 | 627 |
| 2016 | 899 | 563 |
| **Total** | **2 194** | **1 425** |

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

**28. 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:

Initially there were some problems/misunderstandings linked to the interpretation of this provision and the cases it was applicable to. There were several case-by-case discussions with COM and the DNAs. The issue was then discussed at the 25th DNA Meeting (on 21 April 2015) and a common approach was identified. Once the way forward had been agreed, the related functionality in ePIC was also modified in order to better support the implementation of this provision.

Although this provision remains a challenging one to implement, by now the number of problematic cases (in which ECHA and the DNAs disagree on the interpretation) has been reduced to a very low number.

## 3.9 Exchange of information

### Exchange of information

**29. 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:

As outlined in the publicly available report (https://echa.europa.eu/regulations/prior-informed-consent-regulation/reporting-on-information-exchange), ECHA did not receive any requests falling in scope of Article 20 in 2014 and 2015. In 2016, ECHA received two such requests (from the authorities in the Syrian Arab Republic and from Canada). These two requests will be further elaborated upon in the next Article 20 report, which will cover the period 2016 – 2017.

### Reporting on the information transmitted

**30. 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:

The only minor challenge was linked to the fact that, as this report had never been compiled in the past, the scope of the report was unclear to many of the Member States. This was clarified between ECHA and the Commission and subsequently discussed with the DNAs at the 27th DNA Meeting (held on 26 April 2016).

At the 28th DNA Meeting (held on 14 December 2016), after the first report had been published, ECHA clarified the “lessons learned” from this reporting exercise with the aim to achieve more clarity in view of the reporting exercise for the next reporting period.

**31. 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: -

## 3.10 Technical assistance

### Cooperation

**32. 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 November 2015, ECHA participated in a Workshop to reinforce the cooperation on the implementation of the Rotterdam Convention between designated national authorities of the following countries: Burundi, Cameroon, Congo, Djibouti, Gabon and Rwanda. This was organised by the Rotterdam Convention Secretariat and had the aim of both clarifying the provisions of the Rotterdam Convention and highlighting the differences with the EU PIC Regulation and its specific provisions.

In November 2016, a similar event was organised for Benin, Burkina Faso, Cabo Verde, Cote d'Ivoire, Gambia, Guinée, Guinée – Bissau, Mali, Mauritania, Niger, Sénégal, Tchad and Togo. Unfortunately, at the last minute ECHA had to cancel its participation, but had still contributed to preparing the training material, presentations, etc.

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

Additional information:

ECHA's efforts in the above-mentioned events and in those listed in Q. 33 are highly appreciated by beneficiaries and often acknowledged publicly (for example, in the plenary session of the Conferences of the Parties to the Rotterdam Convention).

### Capacity building

**33. 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:

The European Chemicals Agency has contributed to the capacity building in sound management of chemicals mainly in the EU candidate countries and potential candidates for EU accession. The Agency's main goal is to assist these beneficiaries, at a technical level, in their alignment with the REACH, classification and labelling (CLP), biocides (BPR) and Prior Informed Consent (PIC) regulations.

In addition to the assistance that takes place under the EU Instrument for Pre-accession assistance (IPA), the Agency has also contributed through the European Neighbourhood and Partnership Instrument (ENPI), the Technical Assistance and Information Exchange instrument (TAIEX) and e.g. twinning projects. We also include PIC-related information in the programme of third country visit to ECHA when that is relevant to the work of visiting authorities.

For example, ECHA organised a workshop on PIC and ePIC for the EU candidate countries and potential candidates in 2014. In addition, in 2016 ECHA hosted a delegation from Turkey for three days to provide an overview on the Rotterdam Convention and the EU PIC Regulation and subsequently took part in a PIC and ePIC training that was organised by a technical assistance project for Turkey.

In May 2015, the Agency attended the Seventh Conference of the Parties to the Rotterdam Convention and had bilateral discussions with 47 non-EU countries at the margins of the meeting. The aim was to clarify the specific provisions of the EU PIC Regulation, to discuss problematic cases and to gather feedback from the authorities in the non-EU countries.

The Agency is also interested in continuing the collaboration with the RC Secretariat in this field in the future.

## 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)

**34. 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.

Additional information:

Exchange of information on PIC in the Forum does not yet happen on a regular basis however, it is part of the Forum's Multiannual Work Programme. The Forum decided in the course of 2016 to run a pilot project on PIC and prepared the specifications for the PIC form for the ICSMS tool (Commission owned IT platform for exchange of information in a secured way between national enforcement authorities).

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

☐ Yes

☒ No

If yes, please describe these activities:

In November 2016, the Forum decided to run a pilot project on PIC focusing on export notifications. The preparation and execution of this project will take place in the next reporting period. Additionally, the Forum has defined the requirements for the PIC form in the ICSMS tool.

**36. 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:

At this stage, the Forum activities on PIC are still in a starting phase. In the future ECHA expects that the number of PIC-related activities will increase. Due to the limited resources and many other priority areas for coordinated enforcement by the Forum, careful prioritisation of PIC activities is essential. One potential improvement would be to increase the number of PIC-related activities including integrated in other legislation-related enforcement projects.

**37. 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: -

## 3.12 IT-related aspects

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

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

- Industry: 1 836 users

- Designated national authorities: 127 users[11]
- Commission: 1 user
- Customs: 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:
    - 26 Member States consulted the application
    - 1 Member State checked >2 500 individual notifications
    - 1 Member State checked ~600 individual notifications
    - 5 Member States checked between 100-350 individual notifications
    - 7 Member States checked between 40-100 individual notifications
    - 12 Member States checked <20 individual notifications
- National enforcement authorities: 388 users

**39. Which new/enhanced features have been included in ePIC compared to the previous reporting period?**

The previous PIC IT submission system (EDEXIM) was used as the reference when implementing the first release of ePIC, i.e. all features in EDEXIM had to be replicated in ePIC.

The list below comprises the main additional features/improvements which were added in the reporting period:

- Article 10 reporting was previously completely managed outside the system (by email, excel, etc). Over three years we implemented the following, in an incremental way:
    - Submission of reports by exporters/importers.
    - Checking of the reports by DNAs.
    - Requesting re-submissions to industry of incorrect/incomplete reports.
    - Aggregation of national reports by DNAs and submission to ECHA.
    - Compilation of all the Member State data by ECHA.
    - Enhanced explicit consent metadata with the new “RIN match algorithm” functionality which matches the metadata from export notifications to potentially applicable explicit consents.
    - Waiver management (previously managed by email and uploaded to EDEXIM as explicit consents).
    - Bulk special RIN submissions available to industry (covering exports of PIC

[11] The number of DNA and NEA accounts refers to the existing number of accounts created and tokens issued (for ePIC) but does not necessarily refer to “active users” who then use the system.

chemicals which are exempted from the main provisions of the regulation and are exported in large numbers each month).

- Automated sending by ePIC of all email communication, including cover notes, for export notifications, second sendings of export notifications after 30 days (in the absence of an acknowledgement of receipt) and explicit consent reminders (enabling ECHA to deal with the increasing number of notifications).
- Pre-filled explicit consent request forms for DNAs (reducing their workload).
- Possibility for ECHA users to add/edit PIC chemicals in ePIC (previously only possible by means of database changes).
- Implementation of fully-fledged workflows with associated task items and deadlines (previously just web forms).
- Event history, submission history and message history available which allow traceability for audit purposes and for everyday follow-up of tasks/actions.
- Message box embedded in task items.
- Enhanced security of the application.

Additional information:

The above-mentioned new/improved features have reduced processing times, increased efficiency, enabled traceability and contributed to ensuring consistency and reliability of the data in the system. They have also enabled all stakeholders (industry, DNAs, Commission and ECHA) to manage an increasing number of tasks without significantly increasing staff numbers whilst still meeting legal deadlines (with a small number of exceptions linked to specific circumstances). Continuous improvements to the ePIC submission system should ensure that some of the identified issues get solved, that process efficiency keeps improving as well as the capacity to process an increasing number of tasks.

**40. How many releases of the system were delivered in the reporting period?**

| | 2014 | 2015 | 2016 |
|---|---|---|---|
| Number of main releases | 2 | 2 | 1 |
| Number of patch releases (to fix issues) | 6 | 4 | 3 |

**41. Please provide details on the availability of the system to external users:**

| | 2014 | 2015 | 2016 |
|---|---|---|---|
| ePIC Industry application | No data available | 99.9 % | 99.4 % |
| ePIC Authority application | No data available | 99.9 % | 99.4 % |

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

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

- Industry: the overall feedback we receive is positive. Based on the Stakeholder survey results, we have the following additional information:
    - 2014: no data (ePIC went live at the end of the year)
    - 2015: 87 % satisfaction rate
    - Some comments:
        - way better than the previous version
        - easy to understand, simple application
        - very convenient to have pre-filled data for many fields
    - 2016: 96.7 % satisfaction rate
- Designated national authorities: the overall feedback is always positive and is regularly mentioned at DNA meetings. Many of their suggestions for improvement have been prioritised and implemented during the reporting period.
- The Commission: overall positive feedback
- National enforcement authorities: no feedback (they only got access in Q2 2016)
- Customs: some countries have expressed the interest to link ePIC to their national customs applications in order to automate controls of these exports

**43. Please specify identified improvement needs for the IT system, if any:**

The main/largest improvement needs for ePIC that we are considering (pending availability of resources and budget) are listed below. In addition, there is an extensive backlog which includes many small improvements which have been requested mainly by DNAs/industry.

- Inclusion of generation of non-confidential Article 10 report in ePIC (which would reduce ECHA's work in generating the non-confidential report on a yearly basis).
- Change in the way acknowledgements of receipt are requested (please see the comment on Article 8(3) in section 13 below) if it is decided that we should change our current way of working in order to be aligned with the provisions of the legal text.
- Further improvements to the RIN match algorithms.
- Further improvement to management of our chemicals database to:
    - make the chemicals more easily searchable and editable;
    - simplify the insertion of new amendments;
    - make the breakdown of group entries more transparent to companies; and

  - facilitate data dissemination.

- Improve usability for exporters by improving data validation checks, standardising alerts and error messages, improving the document upload functionality and the options it provides.

- Further enhance our searches as the increased volume of data in the system calls for more refined search options.

- Improve/change the internal messaging so as to ensure (for traceability and for audit purposes) that as much communication as possible can happen within the system.

- Enhance ECHA's back-office functionality in order to reduce the number of manual tasks or tasks which even require database changes.

The improvements/new features listed above are examples of items that would either reduce processing times, reduce the occurrence of clerical errors, increase our compliance with our legal obligations and provide for an overall better user experience.

## Data dissemination

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

The legal text and all its amendments: https://echa.europa.eu/regulations/prior-informed-consent/legislation

Using this link (https://echa.europa.eu/information-on-chemicals/pic/chemicals) the following can be found:

- Chemicals subject to PIC.

- High-level information and statistics on export notifications.

- High-level information and statistics on import notifications.

- Non-confidential data on explicit consents received from non-EU countries.

- EU and non-EU DNA contact details.

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

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

In addition to the above, information on substances subject to the PIC regulation is also made available through ECHA's dissemination web pages which provides easy access to the information, via its three-layer structure: infocard, brief profile and detailed source data. https://echa.europa.eu/information-on-chemicals

### 45. Which new data has been made available since the last reporting period?

The report on actual quantities of PIC chemicals exported and imported (pursuant to Article 10) has been completely re-factored compared to previous years. The new approach enables

the disclosure of more data whilst respecting the Eurostat recommendations on data confidentiality. The data is presented in two levels of aggregation, one that is focused on the exported chemical(s) and one focused on the countries of export and of destination.

The report on information exchange was published for the first time in November 2016.

**46. 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:

A small number of companies and one of the main industry trade associations have highlighted that the chemicals subject to PIC (especially the breakdown of group entries) is not always clear on the website and could be improved. This is important as the list published by ECHA is the only consolidated list available with all chemicals/groups subject to PIC. This request for improvement has been noted and will be considered at a later stage.

Many authorities in non-EU countries find the information useful as they can find summaries of export notifications and explicit consents for their countries and other information.

## 3.13 Additional comments

**47. 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 after three years working on Regulation 649/2012, there are a number of issues that should be addressed.

Firstly, the following issues/articles in the legal text have led to workability issues or would appear to be incorrect (in addition to the issues mentioned in the other sections above). ECHA would welcome the opportunity to discuss these further, including whether they can be considered when the next review of the PIC Regulation is scheduled, or can be further solved in Guidance or through other means.

- 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. 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. ECHA's experience with the REACH Regulation is that such a definition would be beneficial.

- The obligation to notify the export of an article is set out in Articles 15 and 3(4). It is often unclear to exporters, DNAs and ECHA whether a given article is/is not subject to the PIC Regulation and it would be beneficial to all (and reduce questions/issues) if this could be clarified further.

- The definition of an exporter (Article 3(18)) could be improved as it is not easily applicable to cases in which, for example, the holder of the contract is in a non-EU country (Switzerland) but the export is physically being shipped from the EU.

- Article 8(3) states that "if the Agency does not receive […] an acknowledgement of receipt of the first export notification made after the chemical is included in Annex I […] it shall submit a second notification". Since the very first implementation of PIC in the EU (in 2003), an acknowledgement of receipt has been requested for all export notifications sent, not just the first one after Annex I inclusion. This is an important means 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.

- Article 9(1), second paragraph, states that "ECHA shall […] acknowledge receipt of the first export notification received for each chemical…". Certain non-EU countries (for example, the United States) do not wish to receive such acknowledgements so the text could be amended to read "Upon request, ECHA shall acknowledge…" in order to accommodate possible different needs from the non-EU countries.

- 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 data is therefore collected but not passed on further. 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 reality, in accordance with Article 10, the data is provided to ECHA. This should also be corrected.

- Article 14 describes how the EU should manage requests for explicit consent for affected chemicals. 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. 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, maybe in Article 13 on "Obligations in relation to import of chemicals".

Secondly, as explained in the answer to question 5 above, the workload has continued to increase during the past years. The experience from 2017 so far, as well as the projections for 2018 and beyond, confirm this trend. However, the PIC subsidy ceiling, as set in the MFF (multiannual financial framework), is foreseen to remain constant during 2018-2020 at the annual level of €1.142 million. The increasing workload (including processing, stakeholder support, etc) and the required IT development will require an annual rise in the human and financial resources. ECHA would like to discuss this further in the context of the budgetary exercise for 2018-2020.

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