

Commission Implementing Decision (EU) 2016/1115 of 7 July 2016 establishing a format for the submission by the European Chemicals Agency of information concerning the operation of the procedures pursuant to Regulation (EU) No 649/2012 of the European Parliament and of the Council concerning the export and import of hazardous chemicals (notified under document C(2016) 4141)

COMMISSION IMPLEMENTING DECISION (EU) 2016/1115

of 7 July 2016

establishing a format for the submission by the European Chemicals Agency of information concerning the operation of the procedures pursuant to Regulation (EU) No 649/2012 of the European Parliament and of the Council concerning the export and import of hazardous chemicals

(notified under document C(2016) 4141)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) No 649/2012 of the European Parliament and of the Council of 4 July 2012 concerning the export and import of hazardous chemicals⁽¹⁾, and in particular Article 22(1) thereof,

After consulting the Committee established by Article 133 of Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC⁽²⁾,

Whereas:

- (1) In order to ensure that the information provided to the Commission by the European Chemicals Agency pursuant to Article 22(1) of Regulation (EU) No 649/2012 is of an appropriate standard, it is necessary to lay down a format to be used for the provision of such information.
- (2) In order to ensure clarity and consistency, it is appropriate to specify the exact reporting periods for the provision of information by the European Chemicals Agency pursuant to Article 22(1) of Regulation (EU) No 649/2012,

HAS ADOPTED THIS DECISION:

Article 1

The format for submission by the European Chemicals Agency of the information required under Article 22(1) of Regulation (EU) No 649/2012 shall be a questionnaire as set out in the Annex to this Decision.

Changes to legislation: There are outstanding changes not yet made to Commission Implementing Decision (EU) 2016/1115. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) [View outstanding changes](#)

Article 2

The first report to be submitted by the European Chemicals Agency pursuant to Article 22(1) of Regulation (EU) No 649/2012 shall cover the calendar years 2014, 2015 and 2016.

Article 3

This Decision is addressed to the European Chemicals Agency.

Done at Brussels, 7 July 2016.

For the Commission

Karmenu VELLA

Member of the Commission

Changes to legislation: There are outstanding changes not yet made to Commission Implementing Decision (EU) 2016/1115. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes

ANNEX

QUESTIONNAIRE

Section 1: General information

1. Organisation:
2. Period covered:

Section 2: Information on the Agency

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

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

Yes

No

Additional information:

Section 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)

Changes to legislation: There are outstanding changes not yet made to Commission Implementing Decision (EU) 2016/1115. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) [View outstanding changes](#)

Others

Additional information, if relevant:

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:

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.

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

Section 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:

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)

Document Generated: 2024-06-18

Changes to legislation: There are outstanding changes not yet made to Commission Implementing Decision (EU) 2016/1115. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) [View outstanding changes](#)

- # 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:

12. Is the Agency satisfied with the collaboration with the DNAs?

- # Yes
- # No

Additional information:

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:

Section 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)?

	Year 1	Year 2	Year 3
--	---------------	---------------	---------------

Changes to legislation: There are outstanding changes not yet made to Commission Implementing Decision (EU) 2016/1115. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes

Export notifications handled			
Export notifications forwarded			
Acknowledgments of receipt received			
Export notifications forwarded a second time			

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
- # 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:

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	Year 1	Year 2	Year 3
Re-submission requested			
Rejected			

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

Document Generated: 2024-06-18

Changes to legislation: There are outstanding changes not yet made to Commission Implementing Decision (EU) 2016/1115. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes

Reasons for requesting re-submission of export notifications:

Reasons for rejecting export notifications:

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
Year 1		
Year 2		
Year 3		
Total		

Additional information:

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:

Year	No of late notifications	% of total yearly No of notifications
Year 1		
Year 2		
Year 3		
Total		

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:

Changes to legislation: There are outstanding changes not yet made to Commission Implementing Decision (EU) 2016/1115. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes

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:

Section 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?

	Notifications received
Year 1	
Year 2	
Year 3	
Total	

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

	Acknowledgements sent
Year 1	
Year 2	
Year 3	
Total	

Section 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:

Changes to legislation: There are outstanding changes not yet made to Commission Implementing Decision (EU) 2016/1115. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) [View outstanding changes](#)

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:

Section 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:

DNA's 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:

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
Year 1		
Year 2		
Year 3		
Total		

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 subparagraph of Article 14(8) of Regulation (EU) No 649/2012?

Changes to legislation: There are outstanding changes not yet made to Commission Implementing Decision (EU) 2016/1115. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) [View outstanding changes](#)

Yes

No

Additional information:

Section 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:

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:

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:

Section 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

Changes to legislation: There are outstanding changes not yet made to Commission Implementing Decision (EU) 2016/1115. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) [View outstanding changes](#)

Other

If other, please specify.

Please specify the countries benefiting from this cooperation:

Additional information:

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:

Section 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:

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

Yes

No

If yes, please describe these activities:

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

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:

Section 12: IT-related aspects

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

Changes to legislation: There are outstanding changes not yet made to Commission Implementing Decision (EU) 2016/1115. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) [View outstanding changes](#)

38. How many external organisations/users are using ePIC for each of the following categories?
- Industry:
 - Designated National Authorities:
 - Commission:
 - Customs:
 - National Enforcement Authorities:

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

Additional information:

40. How many releases of the system were delivered in the reporting period:
41. Please provide details on the availability of the system to external users:
42. High-level summary of feedback received by the Agency on ePIC from the following user communities:
- Industry:
 - Designated National Authorities:
 - Commission:
 - National Enforcement Authorities:
 - Customs:

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

Data dissemination

44. Which data originating from implementation of Regulation (EU) No 649/2012 is made publicly available on the Agency's website:
45. Which new data has been made available since the last reporting period:
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:

Section 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.

Changes to legislation: There are outstanding changes not yet made to Commission Implementing Decision (EU) 2016/1115. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) [View outstanding changes](#)

- (1) [OJ L 201, 27.7.2012, p. 60.](#)
- (2) [OJ L 396, 30.12.2006, p. 1.](#)

Changes to legislation:

There are outstanding changes not yet made to Commission Implementing Decision (EU) 2016/1115. Any changes that have already been made to the legislation appear in the content and are referenced with annotations.

[View outstanding changes](#)

Changes and effects yet to be applied to :

- Decision revoked by [2023 c. 28 Sch. 1 Pt. 2](#)