

GUIDANCE

Guidance for implementation of Regulation (EU) No 649/2012 concerning the export and import of hazardous chemicals

Version 1.1 July 2015



LEGAL NOTE

This document aims to assist users in complying with their obligations under Regulation (EU) No 649/2012 (the PIC Regulation). However, users are reminded that the text of the PIC Regulation is the only authentic legal reference and that the information in this document does not constitute legal advice. Usage of the information remains under the sole responsibility of the user. The European Chemicals Agency (ECHA) does not accept any liability with regard to the contents of this document.

Version	Changes
1.0	First edition (please note this was only published in the English language in December 2014)
1.1	Corrigendum to take into account the end of the transition period for classification, labelling and packaging mixtures according to the Dangerous Preparation Directive (DPD), and address the full implementation of the CLP Regulation:
	 in section 6.10: references to the Dangerous Substances Directive (DSD) and Dangerous Preparation Directive (DPD) have been deleted;
	 in sub-section 6.10.2: the text has been modified to address the full entry into force of the CLP Regulation from 1 June 2015;
	 in sub-section 6.10.3: the standard danger symbols according to DSD and DPD have been deleted; the CLP hazard pictograms have been replaced with pictograms compatibile with the format available on the website of United Nations Economic Commission for Europe (UNECE);
	 in sub-section 6.10.4: the reference to DPD classification for mixtures in the safety data sheet has been deleted;
	The references to the ePIC manuals have been added in sub-sections 6.1.5 and 6.6.1.

Guidance for implementation of Regulation (EU) No 649/2012 concerning the export and import of hazardous chemicals

Reference: ECHA-14-G-16.1-EN **ISBN:** 978-92-9244-893-6

Publ.date: July 2015 Language: EN

© European Chemicals Agency, 2015

If you have questions or comments in relation to this document please send them (indicating the document reference, issue date, chapter and/or page of the document to which your comment refers) using the Guidance feedback form. The feedback form can be accessed via the ECHA Guidance website or directly via the following link:

https://comments.echa.europa.eu/comments_cms/FeedbackGuidance.aspx

European Chemicals Agency

Mailing address: P.O. Box 400, FI-00121 Helsinki, Finland

Visiting address: Annankatu 18, Helsinki, Finland

Preface

This document describes specific provisions for export and import of certain hazardous chemicals under Regulation (EU) No 649/2012¹, the so-called Prior Informed Consent (PIC) Regulation (henceforth the "PIC Regulation").

The PIC Regulation gives ECHA a mandate to provide assistance and technical and scientific guidance on the PIC Regulation for industry and authorities². Two guidance documents³ for the previous regulation on import and export of dangerous chemicals⁴ had been drafted by the European Commission and endorsed by the REACH Committee. Part of the content of both documents remained to a large extent relevant after entry into operation of the new PIC Regulation. Therefore, ECHA has used this part of the content as a basis for some of the text of the present document. At the same time, the new information resulting from the changes introduced in the recast PIC Regulation has been included in this guidance.

All current ECHA guidance documents can be obtained via the website of ECHA (http://echa.europa.eu/support/guidance).

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 (recast); OJ L 201 27.07.2012 p 60.

Article 6 (1) (c) and (d) of the PIC Regulation: "where appropriate, provide, with the agreement of the Commission

and after consultations with Member States, assistance and technical and scientific guidance and tools for the industry in order to ensure the effective application of this Regulation" ... "provide, with the agreement of the Commission, the designated national authorities of the Member States with assistance and technical and scientific guidance in order to ensure the effective application of this Regulation".

^{3 (}i) <u>TECHNICAL GUIDANCE NOTES FOR IMPLEMENTATION OF REGULATION (EC) No 689/2008</u> - The general guidance for DNAs and industry, published in 22 official EU languages, excluding Croatian. This document was endorsed by the REACH Committee on 20 October 2010 and published in the Official Journal of the European Union on 1 March 2011;

⁽ii) Technical notes for guidance for Designated National Authorities for implementation of Regulation (EC) No 689/2008 – document which was available only in English and only to DNAs (once they had logged into the EDEXIM Database). This guidance was finalised in April 2012 by addressing the comments received from Member States during and after the DNA meeting.

⁴ Regulation (EC) No 689/2008 of the European Parliament and of the Council of 17 June 2008 concerning the export and import of dangerous chemicals; OJ L 204 31.7.2008 p 1.

Table of Contents

1. INTRODUCTION	6
2. UNDERSTANDING THE PIC REGULATION	6
2.1 The Rotterdam Convention	8
2.3.1 Notification of final regulatory action ("FRA notification")	9 10
2.4 Relationship to other international chemicals legislation2.5 Participation of the European Union in the Rotterdam Convention	10 11
3. DEFINITIONS	11
4. SCOPE	13
4.1 Chemicals included	
4.1.1 Chemicals subject to the PIC procedure 4.1.2 Banned or severely restricted chemicals	15 16 16
4.2 Chemicals exempted from the PIC Regulation	18
4.2.1 Narcotic drugs and psychotropic substances 4.2.2 Radioactive materials	18 19 19 19 19 19
5. KEY ACTORS	21
5.1 Designated National Authorities	
6. OBLIGATIONS UNDER THE PIC REGULATION	25
6.1 Export notifications forwarded to Parties and other countries	25
6.1.1 Who has to notify? 6.1.2 What to notify? 6.1.3 Information requirements. 6.1.4 Timelines 6.1.5 The procedure. 6.1.6 Incompliant export notifications 6.1.7 Following up export notifications 6.1.8 When is a new notification required? 6.1.9 Emergency situation 6.1.10 When is a notification no longer required? 6.1.11 Request for additional information	25 26 27 27 32 32 32 32 33 33
6.2 Export notifications from Parties and other countries	34
6.2.1 Obligations in relation to the import of chemicals	34
6.3 Information on quantities of chemicals exported and imported	

6.5 Information on banned or severely restricted chemicals not qualifying for PIC notification	7
6.6 Obligations in relation to export of chemicals other than export notification	
6.6.1 Explicit consent	
6.6.1.1 What chemicals are subject to explicit consent requirement?40	
6.6.1.2 Seeking an explicit consent)
6.6.1.3 Possible forms of explicit consent	L
6.6.1.4 The process of requesting explicit consent	L
6.6.1.5 Explicit consent for mixtures containing substances from Part 2 or 3 of Annex I42	<u> </u>
6.6.1.6 Timelines	5
6.6.1.7 Validity of the explicit consent	5
6.6.1.8 Waiver	5
6.7 Quality of exported products46.8 RIN in the customs declaration46.9 Information on transit movements56.10 Information to accompany exported chemicals5	8 0
6.10.1 Content of the label	2 2
6.11 Obligation of the authorities of the Member States to control exports	
6.12 Exchange of information	
6.14 Monitoring and reporting	
6.15 Updating of Annexes	
7. EPIC - AN IT APPLICATION FOR SUBMISSION OF INFORMATION	. 56
8. EXAMPLES	. 59
APPENDIX 1: ANNEX V TO REGULATION (EU) NO 649/2012	. 66
APPENDIX 2: OVERVIEW OF EXPORTERS' MAIN TASKS IN ORDER TO COMPLY WITH REGULATION (EU) NO 649/2012	
APPENDIX 3: EXAMPLES OF EVIDENCE THAT CAN JUSTIFY THE GRANTING OF A WAIVER TO THE REQUIREMENT FOR EXPLICIT CONSENT	. 69
APPENDIX 4. LIST OF OFFICIAL AND PRINCIPAL OTHER LANGUAGES FOR SDSS AND LABELLING OF EXPORTS TO CERTAIN COUNTRIES	. 71
APPENDIX 5. THE CUSTOMS TERRITORY OF THE UNION	
APPENDIX 6. GLOSSARY/LIST OF ACRONYMS	. 80
Table of Figures	
Figure 1: Export notification procedure for Annex I Part 1 chemicals to all countries (except exports pursuant to Article 8 (6))	1
Figure 2: Special RIN request procedure pursuant to Article 2 (3) or Article 8 (6) or an emergency export according to Article 8 (5)	
Figure 3: Article 14 (6) and (7) procedure for export of Annex I Part 2 and 3 chemicals to all countries (except those exports of Annex I Part 2 chemicals for which the waiver for OECD countries is applied) 4	4
Figure 4: Article 14 (6) procedure for Annex I Part 2 chemicals exported to OECD countries 4	6

1. INTRODUCTION

The aim of this document is to assist Designated National Authorities (DNAs), Customs authorities and industry in the effective application of the PIC Regulation.

The guidance opens in section 2 with an introduction to The Rotterdam Convention, including its basic principles and mechanisms. That section also includes information about the areas in which Regulation (EU) No 649/2012 goes beyond the requirements of the Rotterdam Convention. The guidance continues in section 3 and 4 with an explanation of key definitions and presentation of the scope of the Regulation. Section 5 defines the key actors (Designated National Authorities, exporters and importers). Subsequently, section 6 of the guidance outlines the obligations of exporters and authorities under the PIC Regulation by explanation of requirements of each provision. Section 7 then provides certain information about the ePIC application. Finally, section 8 provides some examples that demonstrate how the requirements of the PIC Regulation play out practically in a range of cases.

2. UNDERSTANDING THE PIC REGULATION

The PIC Regulation is the regulation of the European Parliament and of the Council concerning the export and import of hazardous chemicals. It applies to industrial chemicals and pesticides (including biocides)⁵ that are banned or severely restricted for health or environmental reasons. It places obligations on companies that wish to export these chemicals to non-EU countries. The export of such chemicals is subject to two types of requirements: **export notification** and **explicit consent**. The latter requirement applies only in certain cases (see sub-section <u>6.6.1</u> of this guidance document). The PIC Regulation also places obligations on importers of chemicals that are either banned or severely restricted by EU legislation or subject to the PIC procedure under the Rotterdam Convention. However, it should be noted that import of chemical substances is mostly covered by other EU legislation such as for example the REACH Regulation⁶ or Biocidal Products Regulation⁷.

The aim of the PIC Regulation is to promote shared responsibility and cooperation in the international movement of hazardous chemicals, and to protect human health and the environment by providing all importing Parties (as defined in the Regulation) and, additionally the relevant authorities in countries that are not Parties (particularly, developing countries) with information on characteristics of hazardous chemicals, and on how to store, transport, use and dispose of such chemicals safely. The PIC Regulation implements within the EU the Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade (henceforth the 'Convention'). The European Union (EU) ratified the Convention on 20 December 2002 and fully implemented its provisions

⁵ According to Article 2 (h) of the PIC Regulation proprietary medicinal products and veterinary medicinal products covered by Directive 2001/83/EC and Directive 2001/82/EC are excluded from the scope of the PIC Regulation unless they are 'other pesticides' within the meaning of Article 3(5)(b) of the PIC Regulation.

⁶ Regulation (EC) No 1907/2006 of the European Parliament and of the Council 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 omission of Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC.

⁷ Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products (The Biocidal Products Regulation (BPR))

through a series of regulations which were developed over time⁸.

To achieve a higher level of protection of human health and the environment the EU decided to include a number of additional provisions in the PIC Regulation that go beyond the Convention requirements. The scope of the PIC Regulation extends, for example, to requirements for export notification and for explicit consent (see sub-sections <u>6.1</u> and <u>6.6.1</u> of this guidance document) to all countries rather than applying only to those countries that are Party to the Convention.

Furthermore, an export notification for chemicals listed in Annex I to the PIC Regulation is required irrespective of their intended use in the importing country.

To fully understand the provisions and mechanisms of the PIC Regulation, the reader should be introduced to the basic principles and key elements of the Rotterdam Convention.

2.1 The Rotterdam Convention

The Convention was adopted on 10 September 1998 at the Diplomatic Conference held in Rotterdam. It entered into force on 24 February 2004 and became legally binding for its Parties⁹. The Convention is the response of the United Nations Environment Programme (UNEP) and the Food and Agriculture Organisation (FAO) to the concerns raised by the increased production, trade and use of chemicals during the 1960s and 1970s. These concerns related to the risk that the use of hazardous chemicals and pesticides could pose to human health and the environment. In addition, the regulatory systems and infrastructure of some countries (particularly developing countries) were not adequate to manage such chemicals safely.

The overall objective of the Convention is to promote shared responsibility and cooperative efforts among Parties in the international trade of certain hazardous chemicals in order to protect human health and the environment from potential harm and contribute to the environmentally sound use of chemicals. This objective is achieved with two key provisions of the Convention:

- the prior informed consent (PIC) procedure;
- information exchange.

Under the Rotterdam Convention the Parties designate one or more national authorities to perform administrative functions required by the Convention. The so-called Designated National Authorities (DNAs) are the contact points between a Party and the Secretariat of the Convention (provided jointly by UNEP and FAO) and between different Parties. DNAs have a crucial role in implementation of the Convention and dissemination of information about the Convention at the national level.

The chemicals covered by the Rotterdam Convention are pesticides and industrial chemicals that have been banned or severely restricted for health or environmental reasons by Parties. The chemicals explicitly identified as subject to Prior Informed Consent under the Rotterdam

⁸ Regulation (EC) No 304/2003; OJ L 63, 6.3.2003, p. 1., replaced by the Regulation (EC) No 689/2008; OJ L 204, 31.7.2008, p. 1., replaced by the Regulation (EU) No 649/2012 (recast); OJ L 201 27.07.2012 p 60.

⁹ Under the Convention Parties are countries or regional economic integration organisations that have ratified, accepted, approved or acceded to the Convention.

Convention are listed in <u>Annex III</u> to the Convention¹⁰.

The Convention also establishes a mechanism for including further chemicals into Annex III.

For the current list of chemicals included in Annex III please consult the Rotterdam Convention website www.pic.int ("Databases" at the bottom of the home page, click on Annex III chemicals to go to:

http://www.pic.int/TheConvention/Chemicals/AnnexIIIChemicals/tabid/1132/language/en-US/Default.aspx).

2.2 The PIC Procedure under the Convention

The **PIC procedure** is a mechanism for formally obtaining and disseminating the decisions of importing Parties as to whether or not they will allow for future import of certain chemicals. The key principle is that the shipment of those chemicals must not take place without the prior informed consent of the importing Party.

The prior informed consent (PIC) procedure applies to the chemicals listed in Annex III to the Convention. For each of the chemicals listed in Annex III to the Convention, a decision guidance document (DGD) is prepared by a subsidiary body - the Chemical Review Committee (CRC), composed of government-designated experts in chemical management. After approval by the Conference of Parties (COP)¹¹, the DGD is distributed to all Parties.

The DGD contains basic information about the chemical, i.e. its characteristics and a summary of information related to hazards and risks connected with the use of that chemical. It also includes details of the final regulatory actions that led to the chemical being included in Annex III to the Convention (see sub-section 2.3.1 of this guidance document). DGDs are available on the Convention website¹².

Information contained in DGDs helps Parties to evaluate the risks related to handling and use of chemicals taking into account the local conditions. Based on such an evaluation the Parties can take more informed decisions on whether to accept or refuse import or to allow import under certain conditions. These decisions are known as **import responses**¹³ and they are only related to the use category for which the substance has been listed under the Convention. Therefore, for example, if the importing Party has indicated that it does not wish to receive imports of a chemical X for use as pesticide, it does not mean that an export of the same chemical X for use as an industrial chemical cannot proceed. Parties should send import responses to the Secretariat as soon as possible.

Every six months the Secretariat informs all Parties of the import responses (as well as about the Parties that failed to respond) via so-called PIC Circulars. PIC Circulars also include:

¹⁰ Additional chemicals are subject to the Convention pursuant to Article 12(1), which requires the notification of the export of a chemical by a Party that banned or severely restricted that chemical.

¹¹ The Conference of Parties (COP) is the body responsible for making decisions concerning amendments to the Convention. It is composed of those countries or regional economic organisations that have ratified, accepted, approved or acceded to the Convention.

¹²http://www.pic.int/TheConvention/Chemicals/DecisionGuidanceDocuments/tabid/2413/language/en-US/Default.aspx

 $^{^{13}}$ Import responses can be either a "final decision" or an "interim response" as described in Article 10(4) of the Convention.

- information about notifications of Parties that have banned or severely restricted a chemical;
- proposals for listing of severely hazardous pesticide formulations submitted by Parties;
- an up-to-date list of the chemicals and severely hazardous pesticide formulations subject to the PIC procedure (updated Annex III to the Convention);
- DNA contact details.

PIC Circulars are published by the Secretariat twice a year (in June and December), sent to all DNAs and posted on the Convention website.

Import decisions taken by Parties must be neutral. This means that if a Party decides (based on a final regulatory action) to refuse imports of a chemical, it must also stop the domestic manufacture of that chemical for domestic use, as well as refuse imports from any other sources.

All Parties are obliged to ensure that their exporters comply with any import decision(s), i.e. export of chemicals subject to the PIC procedure is not contrary to a decision of an importing Party. This means that an export cannot proceed if the importing Party has indicated that it does not wish to receive imports of these chemicals¹⁴. Furthermore, if the importing Party has indicated that import into its territory is allowed under certain condition(s), the exporting Party must also comply with these condition(s). For more specific information on import responses from Parties to the Convention please consult the Database of Import Responses¹⁵ available on the Convention website.

2.3 Information exchange under the Convention

Information exchange under the Convention takes place through the notifications of final regulatory actions, DGDs, import responses, export notifications and PIC Circulars. The information is also exchanged via documents that accompany exports (for example safety data sheets) or via labels and harmonised system codes (where available).

2.3.1 Notification of final regulatory action ("FRA notification")

The other integral part of the Rotterdam Convention is the exchange of information among Parties. According to Article 5 of the Convention, Parties have to notify the Secretariat when they adopt a final regulatory action to ban or severely restrict a chemical for health or environmental reasons by submitting an FRA **notification**. The purpose of such a notification is to share the information on hazardous chemicals with the Secretariat and all Parties and to identify candidate chemicals for the PIC procedure.

The Secretariat verifies the completeness of the notification according to the information requirements of Annex I to the Convention. If the notification meets these requirements, a summary of the final regulatory action is prepared and published in the PIC Circular. Such a

¹⁴ For the exceptional circumstance of an importing party failing to transmit an import response or an interim response that does not contain an interim decision see Article 11 (2) of the Convention.

 $^{{\}color{blue}^{15}} \ \underline{\text{http://www.pic.int/Procedures/ImportResponses/Database/tabid/1370/language/en-US/Default.aspx}}$

summary includes a scope, reason for and expected effect of the regulatory action together with the information on hazards and risks posed by the chemical to human health and the environment.

After notifications for the same chemical from **at least two** different PIC regions¹⁶ have been submitted to the Secretariat, these notifications will be forwarded to the CRC if they meet the requirements set out in Annex I. The CRC reviews the notifications according to the criteria set out in Annex II to the Convention. In cases where the notifications meet the above-mentioned criteria, the CRC recommends to the COP that the chemical be listed in Annex III to the Convention and subject to the PIC procedure. The CRC then drafts a DGD, which is based on the information contained in the notifications and supporting documentation. The final decision to add the chemical to Annex III of the Convention and adopt the DGD is made by the COP. To learn how the notification of banned or severely restricted chemicals under the Convention functions at the EU level, please consult sub-section 6.4 of this guidance document.

2.3.2 Export notification

Another key pillar of the Convention relates to the exchange of information among Parties about potentially hazardous chemicals that may be exported. A Party that plans to export a chemical that is banned or severely restricted for use within its own territory must inform the importing Party that such export will take place. This must be done before the first shipment in each calendar year until the chemical becomes subject to the PIC procedure and the importing Party has provided an import response which has been distributed to all Parties. This procedure is known as an **export notification**.

The **export notification** differs from the PIC procedure, as it does not ask Parties for a decision related to future import of the chemical. It only informs Parties that the shipment of a chemical that is banned or severely restricted in the exporting Party's territory is foreseen.

In addition, exports of banned or severely restricted chemicals, as well as chemicals subject to the PIC procedure, need to be appropriately labelled and accompanied by basic health and safety information in the form of a safety data sheet (SDS).

2.4 Relationship to other international chemicals legislation

The **Stockholm Convention** on Persistent Organic Pollutants (POPs) is another international agreement in the field of chemicals management. It requires the elimination or restriction of production and use of POPs (i.e. certain industrial chemicals and pesticides). Some of these chemicals are also subject to the Rotterdam Convention, e.g. polychlorinated biphenyls (PCBs), aldrin, dieldrin, DDT, chlordane, hexachlorobenzene, toxaphene and heptachlor.

The substances are included in the Stockholm Convention based on their properties (toxicity, potential for bioaccumulation, environmental persistence, and transboundary movement to locations remote from their release) and not as a result of any national final regulatory action to ban or to severely restrict their use. Furthermore, certain chemicals can be subject to both Conventions since they apply independently and the listing of chemicals is based on different requirements and criteria. For more information about chemicals targeted by the Stockholm Convention please view the Stockholm Convention website at http://chm.pops.int.

¹⁶ The PIC regions (Africa, Asia, Europe, Latin America and the Caribbean, Near East, North America, Southwest Pacific) are used **only** for the determination of requirements given in paragraph 5 of Article 5 of the Convention.

2.5 Participation of the European Union in the Rotterdam Convention

Participation of the EU in the Convention is a joint responsibility of the European Commission and the Member States. The Commission acts as a common designated authority for the administrative functions of the Convention (the PIC procedure) and works in close cooperation with the DNAs of the Member States (see Article 5 of the PIC Regulation). These administrative functions include:

- transmission of EU export notifications to Parties and other countries¹⁷;
- submission of notifications of final regulatory actions concerning chemicals qualifying for PIC notification to the Secretariat;
- transmission of information concerning other final regulatory actions involving chemicals not qualifying for PIC notification;
- submission of EU import responses for chemicals subject to the PIC procedure to the Secretariat and
- exchange of information with the Secretariat.

The Commission also coordinates the EU input on all technical issues related to the Convention, the COP and its subsidiary bodies such as for example the CRC.

3. DEFINITIONS

Before continuing to describe in more detail the scope of the PIC Regulation it may be useful to clarify some of the terms:

Article 3 (1): 'chemical' means a substance, whether by itself or in a mixture, or a mixture, whether manufactured or obtained from nature, but does not include living organisms, which belongs to either of the following categories:

- (a) pesticides, including severely hazardous pesticide formulations;
- (b) industrial chemicals;

Note that the term 'chemical' covers both substances on their own or in mixtures.

Article 3 (2): 'substance' means any chemical element and its compounds as defined in point 1 of Article 3 of Regulation (EC) No 1907/2006.

The REACH Regulation defines substance as "a chemical element and its compounds in the natural state or obtained by any manufacturing process, including any additive necessary to preserve its stability and any impurity deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition".

¹⁷ 'other country' means any country that is not a Party to the Rotterdam Convention

Article 3 (3): 'mixture' means a mixture or solution as defined in point 8 of Article 2 of Regulation (EC) 1272/2008¹⁸.

Regulation (EC) No 1272/2008 (the CLP Regulation) defines mixture as "a mixture or solution composed of two or more substances". For the purposes of export notification and explicit consent requirements, mixtures fall within the scope of the PIC Regulation where one or more Annex I chemical(s) is/are present in a concentration that triggers labelling under the CLP Regulation, irrespective of the presence of any other substances. In contrast, the requirements of Article 17 (*Information to accompany exported chemicals*) insofar as they concern mixtures apply to <u>all</u> mixtures classified as hazardous under EU legislation, irrespective of whether or not this is due to the presence of Annex I chemicals.

Article 3 (4): 'article' means a finished product containing or including a chemical the use of which has been banned or severely restricted by EU legislation in that particular product (...).

The provisions of the PIC Regulation apply also to articles which contain certain chemicals and do not fall under the definition of 'substance' or 'mixture'. This definition is quite specific and needs to be read in conjunction with the relevant provisions applicable to articles (Article 15 of the PIC Regulation - *Export of certain chemicals and articles*), which further limit its scope. The requirements of the PIC Regulation for articles are described in more details in sub-sections 4.1.5 and 6.1 of this guidance document.

Article 3 (14): 'severely hazardous pesticide formulation' means a chemical formulated for use as a pesticide that produces severe health or environmental effects observable within a short period of time after single or multiple exposure, under conditions of use.

Severely hazardous pesticide formulations (SHPFs) are pesticide formulations found to cause serious problems (severe health or environmental effects observable within a short period of time after single or multiple exposures) under the conditions of use in a developing country or a country with an economy in transition.

Article 3 (10): 'banned chemical' means either of the following:

- (a) a chemical all uses of which within one or more categories or subcategories have been prohibited by final regulatory action by the Union in order to protect human health or the environment;
- (b) a chemical that has been refused approval for first-time use or has been withdrawn by industry either from the Union market or from further consideration in a notification, registration or approval process and where there is evidence that the chemical raises concern for human health or the environment;

In simple terms: a ban is where <u>all uses</u> of a chemical within one or more use subcategories¹⁹ or categories²⁰ have been prohibited (Article 3 (10) (a)), or where the chemical was never

¹⁸ Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.

¹⁹ Refer to use subcategories under the PIC Regulation (pesticides used as plant protection products, other pesticides, chemicals for use by professionals and chemicals for use by the general public).

²⁰ Refer to use categories under the Convention (pesticides and industrial chemicals).

approved or was withdrawn (Article 3 (10) (b)). Article 3 (10) (b) includes two conditions which must both be met:

- 1. The chemical has been withdrawn by industry;
- 2. Existence of evidence that the chemical raises concern for human health or the environment.

Article 3 (11): 'severely restricted chemical' means either of the following:

- (a) a chemical virtually all uses of which within one or more categories or subcategories have been prohibited by final regulatory action by the Union in order to protect human health or the environment, but for which certain specific uses remain allowed;
- (b) a chemical that has, for virtually all uses, been refused for approval or been withdrawn by industry either from the Union market or from further consideration in a notification, registration or approval process and where there is evidence that the chemical raises concern for human health or the environment;

In simple terms: a severe restriction is where <u>virtually all uses</u> of a chemical within one or more use subcategories or categories have been prohibited, approval was refused or the chemical was withdrawn, but for which certain uses are still permitted.

Whilst it is relatively easy to assess when a final regulatory action is a ban, it may be more difficult to determine when a final regulatory action is a severe restriction. Where some uses have been prohibited a case by case assessment is needed as to whether this may constitute a prohibition of virtually all uses. If all but one or two uses of an extensive range of uses have been prohibited and the remaining uses are relatively small, this may be considered as a severe restriction. However, if all but one or two uses of an extensive range of uses have been prohibited and those remaining are major uses, this may not constitute a severe restriction.

Article 3 (20): 'Party to the Convention' or 'Party' means a State or a regional economic integration organisation that has consented to be bound by the Convention and for which the Convention is in force

The definition refers to Parties to the Convention. However, it should be noted that the core provisions of the PIC Regulation, which relate to export notification, explicit consent, export bans and information to accompany exports (Articles 8, 14, 15 and 17 of the PIC Regulation) apply to exports to <u>all</u> countries irrespective of whether or not they are Parties to the Convention.

4. SCOPE

The scope of the PIC Regulation goes beyond the requirements of the Convention in order to achieve a higher level of protection of human health and the environment. The structure of the PIC Regulation is also different in that it also further divides the two use categories under the Convention (pesticides and industrial chemicals) into four subcategories:

• Pesticides - divided into

- pesticides used as plant protection products (PPPs) covered by Regulation (EC) No 1107/2009²¹;
- other pesticides, such as biocidal products under Directive 98/8/EC²² and disinfectants, insecticides and parasiticides covered by Directives 2001/82/EC and 2001/83/EC;

industrial chemicals – divided into

- chemicals for use by professionals;
- chemicals for use by the general public;

The use of these subcategories implies that under the PIC Regulation, more chemicals are subject to export notification than would be the case if only the Convention's use categories were followed. For example: Chemical X is prohibited within the EU as a plant protection product (PPP). However, the same chemical X has, within the EU, another important use as a biocide (and has been authorised within the EU in this subcategory). Consequently, chemical X is subject to export notification due to the ban at the level of the subcategory "pesticide in the group of plant protection products", although that chemical is not banned or severely restricted in the Convention use category "pesticide". To qualify as "banned or severely restricted" under the Convention, "all or virtually all uses" of the chemical X within the whole pesticide category would have to be prohibited.

Furthermore, EU exporters are obliged to send export notifications for chemicals listed in Annex I irrespective of the intended use declared on the export notification and whether or not that use is banned or severely restricted within the EU. The reasoning behind this is that the exporters cannot guarantee that the intended use declared in the export notification will correspond to how the chemical will actually be used in the importing country.

Finally, with regards to the requirement for explicit consent, the list of chemicals subject to this requirement extends beyond the list of chemicals subject to the PIC procedure under the Convention. Therefore, all chemicals which qualify for PIC notification²³ in any of the two Convention categories (pesticides and industrial chemicals) require the explicit consent of the importing country in order for their export to take place.

4.1 Chemicals included

The PIC Regulation covers the following chemicals:

- a) certain hazardous chemicals that are subject to the prior informed consent procedure under the Convention (the 'PIC procedure');
- b) certain hazardous chemicals that are banned or severely restricted within the Union or a Member State;

²¹ Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market;

²² The Biocidal Products Regulation (BPR, Regulation (EU) 528/2012) is applicable from 1 September 2013, with a transitional period for certain provisions. It repealed the Biocidal Products Directive (Directive 98/8/EC).

 $^{^{23}}$ 'PIC notification' in this context means the notification of banned or severely restricted chemicals under the Convention. See also Article 11 of the PIC Regulation.

c) chemicals when exported in so far as their classification, labelling and packaging are concerned.

The next sub-sections of this guidance document (4.1.1, 4.1.2 and 4.1.3) describe each of the above-mentioned groups of chemicals and briefly indicate the provisions that apply to each of them under the PIC Regulation.

4.1.1 Chemicals subject to the PIC procedure

Chemicals that are subject to the prior informed consent (PIC) procedure under the Rotterdam Convention (see sub-section $\underline{2.2}$ of this guidance) belong to this group. They are listed in Part 3 of Annex I to the PIC Regulation.

These chemicals require annual export notification according to Article 8 of the PIC Regulation, irrespective of the expected use of the chemical in the importing country, unless an applicable import response is shown in the latest PIC Circular or the importing country has waived the right to be notified.

Such chemicals also require the explicit consent of the importing country pursuant to Article 14 (6) of the PIC Regulation, unless the latest PIC Circular indicates that the importing country has provided a positive import response or a waiver to the explicit consent provision has been granted 24 . For further details on granting of a waiver, please refer to sub-section <u>6.6.1.8</u> of this guidance).

Legal reference: Article 2 (1) (a) of the PIC Regulation

4.1.2 Banned or severely restricted chemicals

The chemicals referred to in this sub-section are banned or severely restricted within the EU or a Member State (see also the explanation of the 'banned chemical' definition given in <u>section 3</u> of this guidance document). Such chemicals fall into the following groups:

 Chemicals banned or severely restricted within the EU in a Convention use category (for example category "pesticide").

These chemicals are listed in Part 2 of Annex I and they qualify for PIC notification. They are also subject to annual export notification, irrespective of the expected use of the chemical.

Furthermore, exports of such chemicals are subject to the explicit consent of the importing country according to Article 14 (6) of the PIC Regulation.

A waiver to the requirement for explicit consent may be granted under Article 14 (7) of the PIC Regulation (see sub-section <u>6.6.1.8</u> of this guidance).

In cases where such chemicals are to be exported to OECD countries²⁵ where they are known to be licensed, registered or authorised, the exporter's DNA may (at the request of the exporter and on a case-by-case basis) decide in consultation with the Commission, that no explicit consent is required and allow exports to proceed.

A list of the current member countries of the OECD is provided on the OECD website: http://www.oecd.org/about/membersandpartners/list-oecd-member-countries.htm. For a list of non-EU DNAs, please consult the ECHA website: http://echa.europa.eu/information-on-chemicals/pic/designated-national-authority (and

²⁴ The waiver can be granted in accordance with Article 14 (7) by the DNA, in consultation with the Commission assisted by ECHA, following unsuccessful attempts over 60 days to get a reply and provided that one of the conditions given by Article 14 (7) is met.

²⁵ Member countries of the Organisation for Economic Cooperation and Development (OECD).

select "non-EU").

 Chemicals banned or severely restricted within the EU in a subcategory of a Convention use category (e.g. subcategory "plant protection products" of the category "pesticides").

Such chemicals are listed in Part 1 of Annex I and they are subject to annual export notification, irrespective of the expected use of the chemical, unless the chemical is subject to the PIC procedure and an applicable import response is shown in the latest PIC Circular or the importing country has waived the right to be notified.

- Chemicals prohibited within the EU and banned from export

These are the chemicals that are prohibited within the EU in order to protect human health or the environment and are subject to an export ban according to Article 15 (2) of the PIC Regulation. These chemicals are either persistent organic pollutants subject to Regulation (EC) No 850/2004 and listed in Annexes A or B to the Stockholm Convention or they are banned for export by other Union legislation. Chemicals that are banned for export are listed in Annex V (Part 1 or 2) to the PIC Regulation.

Note however, that according to Article 2 (3) the export of chemicals listed in Annex V is possible if they are exported for the purpose of research or analysis in quantities of below 10 kilograms per exporter, per year and per importing country. In such cases the exporter must follow the special RIN 26 procedure. The provisions of Article 2 (3) and the special RIN procedure are described in sub-section 4.2.9 of this guidance.

- Chemicals banned or severely restricted by a Member State

Such chemicals may be subject to PIC notification or information exchange, i.e. the provision of relevant information to the PIC Secretariat for wider dissemination to other countries according to Articles 11 (8) and 12 of the PIC Regulation.

Legal reference: Article 2 (1) (b) of the PIC Regulation

4.1.3 All exported chemicals as regards their classification, labelling and packaging

When exported, chemicals must be packaged and labelled as though they were being placed on the EU market (see Articles 14 (10), 14 (11) and 17 of the PIC Regulation), unless those provisions would conflict with any specific requirements of importing Parties or other countries. To learn more about the information to accompany exported chemicals, please consult subsection $\underline{6.10}$ of this guidance document.

Legal reference: Article 2 (1) (c) of the PIC Regulation

4.1.4 Overview of Annex I to the PIC Regulation

The PIC Regulation applies to individual chemicals or groups of chemicals which are included in Annex I to the Regulation and to mixtures containing such chemicals in a concentration that triggers labelling obligations under the CLP Regulation.

The chemicals listed in Annex I are assigned to one or more of three groups set out as Part 1, Part 2 and Part 3 of that Annex. A different set of provisions apply to the chemical depending on its location in Annex I. Annex I also indicates the different use categories or subcategories for each entry.

For the current list of chemicals in each Part, see the following page on ECHA's website:

_

²⁶ Reference identification number.

http://echa.europa.eu/information-on-chemicals/pic/chemicals

(then select the appropriate tick-box "Annex I Part [1, 2 or 3]" and accept the legal notice).

Part 1: List of chemicals subject to export notification

This Part lists the chemicals or chemical groups that are subject to export notification. This comprises all of the chemicals that are banned or severely restricted within the EU in at least one of the use subcategories (i.e. pesticide used as a PPP, other pesticide such as a biocidal product, industrial chemical for use by professionals, or industrial chemical for use by the public). It also includes the chemicals that qualify for PIC notification and the chemicals subject to the PIC procedure (except some chemicals which are listed in part 3 but are excluded from Part 1 as they are subject to an export ban).

Part 2: List of chemicals qualifying for PIC notification

This Part lists chemicals that qualify for PIC notification because they are banned or severely restricted within the EU in a Convention use category (pesticide or industrial chemical). Apart from the export notification requirement, in order for export to be allowed the explicit consent of the importing country is also required (see sub-section <u>6.6.1</u> of this guidance document).

Part 3: List of chemicals subject to the PIC procedure

This Part lists the chemicals or chemical groups that are subject to the PIC procedure (being listed in <u>Annex III</u> to the Rotterdam Convention). The entries in Part 3 are subject to the export notification requirement, and additionally to explicit consent, except where an import response is published in the PIC Circular and certain criteria are met.

Please note that the lists of chemicals in the various parts of Annex I overlap. All the chemicals found in Parts 2 and 3 are also listed in Part 1 (except for POPs listed in Part 3 but excluded from Part 1 as they are subject to export ban according to the provisions of the Stockholm Convention). A list of chemicals subject to export ban can be accessed via the links in <u>Appendix 1</u> to this guidance document.

For chemicals that are banned or severely restricted within the EU, the most important sources of relevant regulatory actions currently are:

- Regulation (EC) No 1107/2009 concerning the placing of plant protection products on the market;
- Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products;
- Regulation (EC) No 1907/2006 on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH).

Annex I to the PIC Regulation is updated regularly as a result of regulatory actions under EU legislation, and developments under the Rotterdam Convention. An updated list is available on the ECHA website at: http://echa.europa.eu/information-on-chemicals/pic/chemicals (select the tick-box "Annex I" and accept the legal notice).

4.1.5 Articles

The export of articles containing certain Annex I chemicals is also subject to the export notification requirements. According to Article 15 (1) of the PIC Regulation, an export notification is required for finished products containing or including any of the following:

- substances listed in Part 2 or Part 3 of Annex I in unreacted form²⁷, the use of which has been banned or severely restricted by EU legislation in that particular product, or
- mixtures containing such substances in a concentration that triggers labelling obligations under the CLP Regulation irrespective of the presence of any other substances.

There are unlikely to be many such articles. An example might be fever thermometers and other measuring devices that contain mercury²⁸ and that are subject to restriction as set out in Annex XVII to the REACH Regulation²⁹. The concentration of the listed chemical within the article does not matter as an export notification is required irrespective of this concentration.

Furthermore, the export of certain chemicals and articles listed in Annex V of the Regulation, the use of which is completely prohibited in the European Union, is not allowed. As regards export bans, Article 15 (2) applies to articles that are listed in Annex V to the PIC Regulation. Part 2 of Annex V contains one type of such article, namely mercury-containing cosmetic soaps, which fulfil the definition of 'article' in Article 3 (4) of the PIC Regulation.

Please note that future decisions taken under the Stockholm Convention could lead to more chemicals and articles being listed in Annex V to the PIC Regulation.

Legal reference: Article 15 of the PIC Regulation

4.2 Chemicals exempted from the PIC Regulation

4.2.1 Narcotic drugs and psychotropic substances

Narcotic drugs and psychotropic substances covered by Regulation (EC) No 111/2005 laying down rules for the monitoring of trade between the Community and third countries in drug precursors.

Legal reference: Article 2 (2) (a) of the PIC Regulation

4.2.2 Radioactive materials

Radioactive materials and substances covered by Council Directive 96/29/Euratom laying down basic safety standards for the protection of the health of workers and the general public against the danger arising from ionizing radiation.

Legal reference: Article 2 (2) (b) of the PIC Regulation

4.2.3 Wastes

Wastes covered by Waste Framework Directive 2008/98/EC³⁰. The Directive defines waste as any substance or object which the holder discards or intends or is required to discard. This

²⁷ i.e., for example, where this form could present a risk of leaching out

²⁸ For export of metallic mercury and mercury compounds as such and products containing mercury the provisions of Regulation (EC) No 1102/2008 of the European parliament and of the Council of 22 October 2008 on the banning of exports of metallic mercury and certain mercury compounds and mixtures and the safe storage of metallic mercury [OJ L 304, 14.11.2008, p 75] should also be taken into account

²⁹http://echa.europa.eu/web/guest/addressing-chemicals-of-concern/restrictions/list-of-restrictions/list-of-restrictions-table

table

30 Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste and repealing certain Directives; OJ L 312, 22.11.2008, p. 3–30.

may be waste from households (e.g. newspapers or clothes, food, cans or bottles) or from professional business or from industry (e.g. tyres, slag, window frames that are discarded).

Legal reference: Article 2 (2) (c) of the PIC Regulation

4.2.4 Chemical weapons

Chemical weapons covered by Regulation (EC) No 428/2009 setting up a Community regime for the control of exports, transfer, brokering and transit of dual-use items.

Legal reference: Article 2 (2) (d) of the PIC Regulation

4.2.5 Food and food additives

Food and food additives covered by Regulation (EC) No 882/2004 on official controls performed to ensure verification of compliance with feed and food law, animal health and animal welfare rules.

Legal reference: Article 2 (2) (e) of the PIC Regulation

4.2.6 Feedingstuffs

Feedingstuffs covered by Regulation (EC) No 178/2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety, including additives, whether processed, partially processed or unprocessed, intended to be used for oral feeding to animals.

Legal reference: Article 2 (2) (f) of the PIC Regulation

4.2.7 Genetically modified organisms

Genetically modified organisms covered by Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms.

Legal reference: Article 2 (2) (g) of the PIC Regulation

4.2.8 Medicinal products

Proprietary medicinal products for human use and veterinary medicinal products covered by Directive 2001/83/EC on the Community code relating to medicinal products for human use and Directive 2001/82/EC on the Community code relating to veterinary medicinal products respectively. Please note that chemicals belonging to this category are excluded from the PIC Regulation provisions with the exception of biocidal products, disinfectants, insecticides and parasiticides that are considered pesticides within the meaning of the definition provided by the FAO International Code of Conduct on the Distribution and Use of Pesticides³¹. In cases of any doubts, it should be assumed that the PIC Regulation applies.

Legal reference: Article 2 (2) (h) and Article 3 (5) (b) of the PIC Regulation

³¹ http://www.fao.org/docrep/005/y4544e/y4544e00.htm

4.2.9 Chemicals exported for research or analysis

These are chemicals exported for research or analysis in quantities that are unlikely to affect human health or the environment³² and that in any event do not exceed 10 kilograms from each exporter to each importing country per calendar year.

Research and analysis should be understood as meaning analysis and scientific research by e.g. academia, authorities and companies. However, shipment of a chemical to be kept as stock to be subsequently sold in the importing country for that purpose is excluded.

Exporters of such chemicals must obtain a special reference identification number (RIN) and provide this number in their export declaration (box 44 of the Single Administrative Document). This administrative procedure is known as a **special RIN request**. The exporter first checks if Article 2 (3) applies to the export. If so, the exporter requests a special RIN from his DNA. Provided that Article 2 (3) of the PIC Regulation applies, the DNA approves the request and activates the RIN, which should be used by the exporter on the customs declaration. The special RIN request procedure is also illustrated by Figure 2 in section 6.6 below.

A **Reference identification number (RIN)** is generated by the ePIC application³³ as part of the export notification procedure. A RIN is the unique identifier for each export notification (and is associated to an exporter, a substance, an importing country and a calendar year). It is a string of 10 alphanumeric characters: nine randomly generated preceded by a first digit which is always either a "1" or a "0" and categorises the type of notification (in order to facilitate customs controls). "1" indicates a "standard" export notification whereas a "0" indicates a special RIN request. Note that RINs are not required for exports of chemicals that are not subject to the PIC Regulation.

The limit of 10 kg applies to the Annex I chemical by itself or 10 kilograms of the substance in a mixture, and also refers to an individual chemical within a generic group listed in Annex I. However, if the exporter expects to export larger quantities to the same importing country during the course of a calendar year, he is required to follow the provisions of the PIC Regulation, including the export notification provisions. Multiple exports of chemicals for research and analysis in quantities of below 10 kilograms may occur in high numbers at a given moment in time. In that case, the exporter may submit a so-called **bulk special RIN request**³⁴ whereby a submission for one substance for several countries, for several substances for one country, or for several substances for several countries can be made simultaneously. For provisions for Annex V chemicals at below 10 kg see sub-section 4.1.2.

Legal reference: Article 2 (3) of the PIC Regulation

³² It should be noted that in some cases quantities below 10 kilograms could affect human health and the environment despite the fact that chemicals for research and analysis will probably be intended for use only by trained personnel or by people supervised by such personnel.

³³ An IT application for processing and management of legal requirements of the PIC Regulation,

³⁴ Please note that a "bulk special RIN request" may also apply to Annex V chemicals exported in quantities at below 10 kilograms for research and analysis. However, a separate submission must be made for Annex V chemicals (i.e. Annex I and Annex V chemicals cannot be included in the same bulk request).

5. KEY ACTORS

Before explaining the obligations, it is important to have a clear understanding of the different roles under the PIC Regulation. The sub-sections below define the key actors.

5.1 Designated National Authorities

Article 4 (*Designated national authorities of the Member States*) requires Member States to designate one or more national authorities to act on their behalf with regard to carrying out the administrative functions required by the PIC Regulation. Designated National Authorities (DNAs) are requested to cooperate with the Commission (the common designated authority of the Union) in the implementation of the administrative functions of the Convention with reference to the PIC procedure.

The Member States are also obliged to designate the authorities such as customs authorities with the responsibility for controlling imports and exports of chemicals listed in Annex I (Article 18 of the PIC Regulation - *Obligations of the authorities of the Member States for controlling import and export*). See also sub-section <u>6.11</u> of this guidance document.

Given the highly technical nature of tasks allocated to DNAs under the PIC Regulation, the Member States usually nominate institutions of governmental administration or agencies that already have experience and responsibilities for managing chemicals and/or pesticides at a national level. For each exporter intending to export chemicals subject to the PIC Regulation, the relevant Designated National Authority (DNA) established in his Member State is the primary contact point. Similarly, DNAs are the key point of contact between Member States.

The tasks of the Member States (realised by their respective DNAs) can be divided into four groups:

Administrative

- Requesting explicit consents from the DNA/appropriate authority of the importing country for exports of chemicals listed in Parts 2 and 3 of Annex I. In case of export of Annex I Part 2 chemicals to OECD countries, deciding in consultation with the Commission whether the requirement for explicit consent may be waived on the basis of the chemical being licensed, registered or authorised in the OECD country (Article 14 (6));
- Consulting the Commission and taking decisions on granting of the waivers for export of chemicals listed in Parts 2 and 3 of Annex I in cases where no response has been received within 60 days of a request for explicit consent (Article 14 (7));
- Assisting the Commission in its periodic review of explicit consents and waivers (Article 14 (8));
- Forwarding export notifications received from third countries to ECHA (Article 9 (2));
- Where a Member State takes final regulatory action to ban or severely restrict a chemical, the DNA provides the Commission with sufficient information to allow it to consult the other Member States. The submitting Member State is also obliged to consider any comments received from other Member States before informing the Commission whether an FRA notification should be forwarded to the Secretariat or whether the information should instead be forwarded under the information exchange provisions (Article 11 (8));
- For PIC chemicals, where relevant, informing the Commission of national regulatory actions so that this information can be taken into account in EU import decisions (Article 13 (2)) and making available EU import decisions to those concerned within their competence (Article 13 (5));
- Forwarding to those concerned within its jurisdiction the information on chemicals and on

- decisions of importing parties regarding import conditions applicable to those chemicals (Article 14 (3) in conjunction with Article 14 (1));
- Handling of special RIN requests.

Enforcement

- Ensuring that exporters meet their obligations and to take measures to ensure compliance, including the establishment of penalties for infringements (Article 28);
- Checking compliance of export notifications with Annex II and forwarding these promptly to ECHA (Article 8 (2)).

Monitoring and reporting

- On the basis of reports from exporters and importers, providing ECHA with annual aggregated reports on trade in chemicals listed in Annex I using the format set out in Annex III (Article 10 (3));
- Providing the Commission with regular reports on the operation of the various procedures (Article 22), including activities controlling compliance of exporters (Article 18 (1)). See also sub-section 6.14 of this guidance document.

Provision and exchange of information

- On request, providing importing countries with additional information related to exported chemicals (Article 8 (7));
- On request, assisting the Commission in compiling additional information with respect to FRA notifications (Article 11 (6));
- Advising and assisting importing countries, upon request, in obtaining additional information to help them make an import response for PIC chemicals (Article 14 (5));
- Forwarding to the Commission (with a copy to ECHA) any information required by an importing Party to the Convention that has been provided by the exporter concerned prior to each transit movement of a chemical listed in Part 3 of Annex I (Article 16 (3));
- Facilitating, together with the Commission and with the support of ECHA, the exchange of information (Article 20) and cooperating in promoting technical assistance (Article 21).

The list of EU Designated National Authorities for Regulation (EU) No 649/2012 is provided on the ECHA website at: http://echa.europa.eu/information-on-chemicals/pic/designated-national-authority (and select "EU").

5.2 Exporters and importers

Article 3 (18): 'exporter' means any of the following persons, whether natural or legal:

- (a) the person on whose behalf an export declaration is made, that is to say the person who, at the time the declaration is accepted, holds the contract with the consignee in a Party or other country and has the power to determine that the chemical be sent out of the customs territory of the Union;
- (b) where no export contract has been concluded or where the holder of the contract does

- not act on its own behalf, the person who has the power to determine that the chemical be sent out of the customs territory of the Union;
- (c) where the benefit of a right to dispose of the chemical belongs to a person established outside the Union pursuant to the contract on which the export is based, the contracting party established in the Union;

An exporter of a chemical is a natural or legal person holding the export contract, or in the absence of a contract, is the person having the power to determine the export of the chemical from the customs territory of the Union³⁵ (irrespective of from which Member State the export is leaving the customs territory).

In cases where the exporter is not established in the EU, the contracting party established in the EU is responsible for fulfilling the obligations of the exporter. In simple terms, an exporter can be the person who:

- is shown on the shipping documents as the person that holds the export contract with the consignee in a Party or other country;
- provides the chemical to a person established outside of the EU who has the right to dispose of this chemical.

The application of the definition of exporter may be more complex in the context of Articles 8 (1) and 8 (2) of the PIC Regulation (*Export notifications forwarded to Parties and other countries*), which require the exporter to notify the DNA of the Member State in which he is established. Some chemical manufacturers (and possibly also distributors) may supply chemicals to traders who are not established in the EU and who may sell these on to customers in third countries. There appear to be two possible scenarios:

- 1) An EU chemical manufacturer or distributor supplies the chemical to a non-EU trader/dealer and delivers free on board to the ship.
- 2) An EU chemical manufacturer or distributor supplies the chemical to a non-EU trader/dealer ex works, i.e. the trader picks up the shipment at the factory.

In such circumstances the contracting party that is established in the EU, namely the chemical manufacturer or distributor, assumes responsibility for completing the export notification and delivering it to his national DNA. In order to complete the notification, the contracting party must have access to information on the identity and address of the importer. The information requirements for export notification are given in Annex II of the PIC Regulation.

Article 3 (19): '**importer**' means any natural or legal person who at the time of import into the customs territory of the Union is the consignee for the chemical;

An importer can be a person or a company that physically introduces a chemical into the customs territory of the Union. See $\underline{\text{Appendix 5}}$ of this guidance where the list of territories that comprises the customs territory of the Union is given.

³⁵ The 'customs territory of the Union' is determined in Article 3 of <u>Council Regulation (EEC) No 2913/92</u> establishing the Community Customs Code.

Import and export of chemicals subject to PIC from customs perspective

Import

Article 3 (17) of the PIC Regulation defines import as "physical introduction into the customs territory of the Union of a chemical that is placed under a customs procedure other than the external Union transit procedure for movement of goods through the customs territory of the Union".³⁶

The customs procedures other than the external Union transit procedures that are applicable to goods brought into the customs territory of the Union are the following (possible procedures codes given in brackets):

- release for free circulation (01, 02, 07, 40, 41, 42, 43, 45, 48, 49, 61, 63, 68);
- transit, other than external Union transit (T2, T2F, T2SM);
- customs warehousing (71);
- inward processing (51);
- processing under customs control (91);
- temporary admission (53).

Goods brought into the customs territory of the Union that are in temporary storage are not yet placed under a customs procedure and, therefore, should be considered out of the scope of the 'import' definition given in the PIC Regulation.

It should also be noted that placing goods that are brought into the customs territory of the Union into a free zone or a free warehouse (code 78) is **not** considered as a customs procedure and therefore it is not included in the current 'import' definition given in the PIC Regulation.

However, Regulation (EU) No 952/2013 laying down the Union Customs Code (UCC) will, as from 1 May 2016, specifically refer to free zones when defining the scope of special procedures (see Articles 5 (16) and 210 (b) of UCC). From that date, placing of goods in free zones will be a customs procedure. Therefore, it will fall under the 'import' definition given in the PIC Regulation.

Export

Article 3 (16) of the PIC Regulation defines export as:

- a) "the permanent or temporary export of a chemical meeting the conditions of Article 28 (2) TFEU" (i.e. Union goods). The following customs procedures are in line with this definition (possible procedures codes given in brackets):
 - customs procedure of export (10, 11, 22 and 23);
 - customs procedure of outward processing (21);

³⁶ The concept of import under the PIC Regulation is related to the customs territory of the Union whilst under REACH, by contrast, the concept of import relates to the territory of the European Economic Area (EEA).

- customs procedure of transit, other than external Union transit (T2, T2F, T2SM).
- b) "the re-export of a chemical not meeting the conditions of Article 28 (2) TFEU (i.e. non-Union goods) which is placed under a customs procedure other than the external Union transit procedure for movement of goods through the customs territory of the Union". The following customs procedure is in line with this definition (possible procedure code in brackets):
 - re-export (31) except when it takes place after external Union transit.

6. OBLIGATIONS UNDER THE PIC REGULATION

6.1 Export notifications forwarded to Parties and other countries

Export notification is a mechanism that enables exchange of information about banned or severely restricted chemicals among countries. Via such a notification, the importing country is alerted that a shipment of a chemical that has been banned or severely restricted in the exporting country is being sent to it. The provisions for export notification are outlined in Article 8 of the PIC Regulation (*Export notifications forwarded to Parties and other countries*).

6.1.1 Who has to notify?

The export notification obligation applies to each EU-based exporter intending to export a specific chemical subject to export notification from the EU to a third country (whether or not this country is a Party to the Convention). This obligation applies irrespective of the end-use of a chemical in the country of destination.

6.1.2 What to notify?

The export notification applies to:

- all chemicals listed in Part 1 of Annex I to the PIC Regulation³⁷;
- mixtures containing chemicals listed in Part 1 of Annex I, if the concentration of the chemical triggers labelling obligation under the CLP Regulation;
- articles as defined in Article 3 (4) of the PIC regulation, i.e. finished products containing or including in unreacted form:
 - a chemical listed in Part 2 or Part 3 of Annex I, the use of which has been banned or severely restricted by EU legislation in that particular product, or
 - mixtures containing such chemicals in a concentration that triggers labelling obligations under the CLP Regulation.

A separate export notification must be submitted to the importing country for each substance, mixture or article concerned and a separate RIN will subsequently be issued.

³⁷ Please note that although excluded from Annex I Part 1, certain chemicals listed in Annex V Part 2 can be exported under certain circumstances related either to their use or to their concentration.

6.1.3 Information requirements

The information required to accompany the export notification is specified in Annex II to the PIC Regulation. The text of Annex II is given below:

Annex II to Regulation (EU) No 649/2012 EXPORT NOTIFICATION

The following information is required pursuant to Article 8:

- 1. Identity of the substance to be exported:
- (a) name in nomenclature of the International Union of Pure and Applied Chemistry;
- (b) other names (e.g. ISO name, usual names, trade names, and abbreviations);
- (c) European Inventory of Existing Chemical Substances (EINECS) number and Chemical Abstracts Services (CAS) number;
- (d) CUS number (European Customs Inventory of Chemical Substances) and Combined Nomenclature Code;
- (e) main impurities of the substance, when particularly relevant.
- 2. Identity of the mixture to be exported:
 - (a) trade name and/or designation of the mixture
 - (b) for each substance listed in Annex I, percentage and details as specified under point 1;
 - (c) CUS number (European Customs Inventory of Chemical Substances) and Combined Nomenclature Code
- 3. Identity of the article to be exported:
 - (a) trade name and/or designation of the article;
 - (b) for each substance listed in Annex I, percentage and details as specified under point 1.
- 4. Information on the export:
 - (a) country of destination;
 - (b) country of origin;
 - (c) expected date of first export this year;
 - (d) estimated amount of the chemical to be exported to the country concerned this year;
 - (e) intended use in the country of destination, if known, including information on the category(ies) under the Convention under which the use falls;
 - (f) name, address and other relevant particulars of the natural or legal importing person;
 - (g) name, address and other relevant particulars of the exporter.
- 5. Designated national authorities:
 - (a) the name, address, telephone and telex, fax number or e-mail of the designated authority in the Union from which further information may be obtained.
 - (b) the name, address, telephone and telex, fax number or e-mail of the designated

authority in the importing country.

- 6. Information on precautions to be taken, including category of danger and risk and safety advice.
- 7. A summary on physico-chemical, toxicological and ecotoxicological properties.
- 8. Use of the chemical in the Union:
 - (a) uses, category(ies) under the Convention and Union subcategory(ies) subject to control measure (ban or severe restriction);
 - (b) uses for which the chemical is not severely restricted or banned (use categories and subcategories as defined in Annex I of the Regulation);
 - (c) estimation, where available, of quantities of the chemical produced, imported, exported and used.
- 9. Information on precautionary measures to reduce exposure to, and emission of, the chemical.
- 10. Summary of regulatory restrictions and reasons for them.
- 11. Summary of information specified in points 2 (a), (c) and (d) of Annex IV.
- 12. Additional information provided by the exporting Party because considered of concern or further information specified in Annex IV when requested by the importing Party.

6.1.4 Timelines

The exporter must follow the export notification procedure when exporting a chemical for the first time and for the first export in each subsequent year. Subsequent exports of the same chemical, to the same country within the same calendar year do not need to be notified, unless otherwise required by importing countries. However, the export of the same chemical to a different importing country will be considered as a "first export" and therefore subject to the export notification procedure.

The exporter must submit an export notification to his DNA (i.e. to the relevant designated national authority of the Member State in which he is established) at least **35 days before the first export** is due to take place. Thereafter the exporter must notify his DNA of the first export of the chemical each calendar year no later than 35 days before the export takes place. However, it is recommended to submit the notification as early as possible to the DNA to allow enough time for processing. Note that except in an emergency (see sub-section <u>6.1.9</u> of this guidance) the ePIC application will not allow submission of export notifications later than 35 days before the expected date of export specified in Article 8 (2) of the PIC Regulation.

Once the DNA has confirmed that the draft notification is complete, the DNA must forward it to ECHA no later than **25 days before the expected date of export**. After approval, ECHA transmits the final notification to the DNA or other appropriate authority of the importing country no later than **15 days before the first intended date of export** (and thereafter no later than **15** days before the first export in any subsequent calendar year).

6.1.5 The procedure

The export notification procedure consists of the following steps:

1) Submission of an export notification

The exporter creates and submits an export notification for a substance or mixture or article to

his DNA via ePIC. A reference identification number (RIN) is issued as a result of this process (for more information about RIN please refer to sub-section 4.2.9 of this guidance).

2) Processing by the DNA

The DNA checks the compliance of the submitted information with Annex II to the PIC Regulation (*Export notification*). The DNA should as far as possible verify the following:

Is the notification complete?

If not, the export cannot proceed. In such a situation the DNA should alert the exporter to enable any missing necessary information to be provided within the specified deadlines. At the stage of processing of export notification, the exporter is able to track the status of his export notification. A notification is only considered complete once it has been fully processed (i.e. checked and accepted by both his DNA and ECHA).

➤ <u>In the case of a chemical listed only in Part 1 of Annex I, has the country of destination</u> waived the right to be notified?

If so, the notification need not be forwarded and the exporter can be informed by the DNA that he need not submit any further notifications for export of that chemical to the country concerned (until further notice). However, the exporter **must** obtain a special RIN for that chemical and provide this number in his export declaration.

➤ <u>Is the notified chemical covered by a generic group listed in Annex I?</u>

The exporter should preferably identify the specific chemical involved and should forward the precise name with the notification. Separate notification should be submitted for individual chemicals within a generic group, if the classification and labelling is different from the respective generic group.

> Does the notification relate to a mixture?

Since mixtures tend to be differently composed and must therefore be classified and labelled individually, in principle every mixture containing an Annex I chemical(s) to the extent that this triggers labelling should be notified. However, a single notification covering several mixtures containing the same Annex I chemical(s) would be acceptable provided that the only difference between those mixtures is, for example, their colour and that there are no differences in the classification and labelling of the mixtures and the uses remain the same. Whenever changes in the concentration of Annex I chemical(s) in a mixture trigger new labelling requirements, a new notification is needed.

For a chemical qualifying for PIC notification listed in Part 2 of Annex I, has the country of destination given its explicit consent?

If not, and consent has not already been sought, the DNA should seek explicit consent from the DNA or another appropriate authority in the country of destination. The official export notification is forwarded to the importing country by ECHA. The DNA may attach a draft copy of the export notification to the request for consent to help the importing country in making a decision. The exporter is then informed accordingly. Note that in the absence of an explicit consent, the RIN for a part 2 chemical cannot be activated and export cannot proceed.

Version 1.1 July 2015

consent itself).

Please note that the explicit consent for a chemical or mixture obtained by one Member State is potentially also applicable to exports from another Member State from which the export of the same chemical or mixture is intended (depending on the terms of the

In cases where a chemical is listed in Part 3 of Annex I and the importing country is a Party to the Convention, does an import decision of the country of destination appear in the latest PIC Circular and if so, what does it say?

The first thing to be checked is whether the expected use on the export notification matches the use category for which the chemical is subject to the Rotterdam Convention. If the two do not match, an explicit consent is required. If the use categories match, the following scenarios can occur:

- If there is **no import decision** in the PIC Circular or the decision is otherwise unclear as to whether the importing country consents, explicit consent is required. If such consent has not already been obtained or sought (see status list of explicit consents on ePIC), the DNA should seek explicit consent from the DNA or another appropriate authority in the country of destination. In the absence of an explicit consent, the RIN for a part 3 chemical cannot be activated and export cannot proceed.
- If **the import decision in the PIC Circular gives consent**, export notification is no longer required for the respective use category, unless the country of destination has indicated that it still wishes to receive an export notification. In cases where the chemical is a double-use chemical, and the intended use is not covered by the import decision, an export notification still needs to be submitted and explicit consent sought.
- If there is a **negative import decision** (no consent for the respective Convention use category) and the intended use is for that category, the export cannot proceed. Please note that the negative import decision relates to the use category given in the Convention. Therefore, it is still possible to export for the other use category if the chemical is a double-use chemical (for example ethylene oxide³⁸) provided that the explicit consent was obtained.
- ➤ <u>Certain Annex I chemicals listed in case they have impurities (e.g. maleic hydrazine and its salts).</u>

For the above-mentioned chemicals an export notification is only required if the purity requirements are not met. Note also that some Annex I chemicals (e.g. benzene) may be present as impurities in other chemicals like petroleum distillates at concentrations that trigger labelling obligations and thus require notification.

If there are issues with any of the above-mentioned requirements (i.e. information is either missing or incorrect), the DNA returns the draft notification to the exporter without undue delay.

When assessing the completeness of a notification, the DNA also needs to take into account the following:

³⁸ Ethylene oxide is often exported for sterilisation purposes. For the PIC Regulation this is a biocidal use which is a subcategory of the 'pesticides' category.

The exporter is obliged to provide all the information required by Article 8 (as listed in Annex II). For information listed under points 6 and 7 of Annex II, the provision of a

safety data sheet (an SDS) would suffice;

- The exporter is not obliged to attach an SDS with the export notification. However, it is strongly recommended that when creating an export notification, the exporter provides a copy of the SDS in an official language or in one or more of the principal languages of the importing country as well as an English version (if available) in order to facilitate processing of the notification by the DNAs and ECHA;
- The exporter must send an SDS to each importer when the chemical is exported (see Article 17 (3) of the PIC Regulation). In this case the information on the label and on the SDS must as far as practicable be given in an official language, or in one or more of the principal languages, of the country of destination or of the area of intended use (Article 17 (4)). Appendix 4 to this guidance provides a list of official and principal other languages for SDSs and labelling of exports to certain countries.

Note that the DNAs may charge the exporter an administrative fee to cover the costs incurred in carrying out the export notification procedure.

3) Processing by ECHA

ECHA also checks the export notification and, if it is the first yearly EU notification for that chemical, it is transmitted to the importing country (otherwise it is stored in ePIC) along with the confirmation of the receipt form and, if submitted by the exporter, a copy of the SDS for the chemical. The final notification is stored on ePIC and is available to the exporter and DNAs. If the RIN can be activated at this stage, its active period will be communicated in the message sent (directly by ePIC) to the exporter and to his DNA.

In simple wording, an "active" RIN refers to an export which can proceed. Note however, that not all RINs are activated when the export notification is processed. For example, in case of chemicals also listed in Part 2 or 3 of Annex I, the RIN may not be activated, as the explicit consent of the importing country needs to be obtained first. The active period of the RIN may also be subject to changes during the calendar year due to the presence/absence of an explicit consent and to its validity period (see sub-section <u>6.6.1.7</u> of this guidance document).

Exporters are required to quote active RINs in their export declarations, thereby reducing the paper burden since supporting documents need no longer be submitted. The export can proceed upon expiry of the time limit specified in Article 8 (2) and as determined by the validity of the RIN. Figure 1 as well as Example 1 and Example 3 in section 8 of this guidance illustrate the procedure for an export notification for the chemicals listed in Part 1 of Annex I. The list of chemicals concerned is available to the public and DNAs on a dedicated section of the ECHA website 40. Additional information on how to technically fill in the information and submit the export notification is given in the ePIC User Manual available on ECHA website at: http://echa.europa.eu/support/dossier-submission-tools/epic/epic-manuals.

_

³⁹ 'Chemicals concerned' in this context means all the chemicals that are subject to the PIC Regulation.

⁴⁰ At: http://www.echa.europa.eu/information-on-chemicals/pic/chemicals

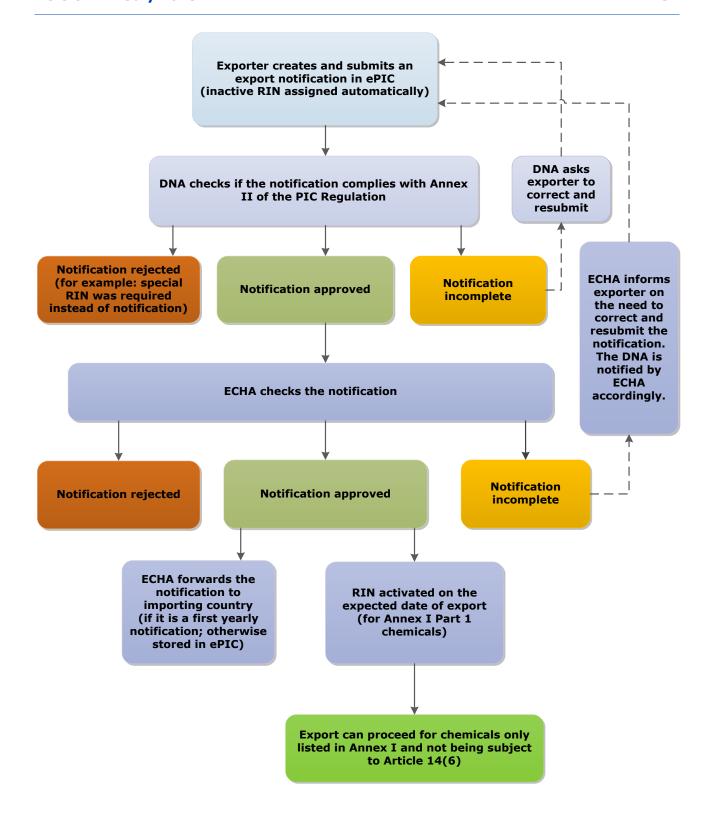


Figure 1: Export notification procedure for Annex I Part 1 chemicals to all countries (except exports pursuant to Article 8 (6)).

6.1.6 Incompliant export notifications

The exporter is responsible for the content of an export notification, therefore only the exporter can edit a notification (in case information is either missing or incorrect). The DNA is responsible for checking the notification's compliance with Annex II of the PIC Regulation but cannot modify the content of the notification. Therefore, in case of incompliance of the notification with the Regulation requirements, it needs to be sent back to the exporter.

In cases where an export notification is found to be incompliant, different scenarios are possible. These scenarios are mainly based on how far in advance of the export the notification is submitted and subsequently checked by the DNA.

It is possible for the DNA or ECHA to request a **re-submission of the export notification,** if the notification was submitted long in advance of the 35-day deadline and a re-submission is possible before this deadline. This implies that the RIN and the expected date of export remain the same.

Exceptionally, where the circumstances of the case allow, the DNA may allow the exporter to make a re-submission less than 35 days before the expected date of export, if the information can be re-submitted, checked and forwarded within the deadlines of the PIC Regulation.

The DNA will **reject an export notification** that is not required and request the submission of a special RIN request in its place. This could, for example, be the case if the importing country has waived the right to receive notifications or if the export is for <10kg per calendar year for research or analysis purposes.

The DNA will also reject an incomplete or incompliant export notification when:

- the notification cannot be re-processed within the legal timeframe, or
- the DNA had suggested an informal deadline to the exporter for correcting the export notification and this deadline was not met (once again, leading to the notification not being processed within the legal timeframe).

If one of the above-mentioned scenarios occurs, the exporter will have to submit a new export notification, a new RIN will be assigned to it and the day-count will go back to 35 days prior to the expected date of export as for any newly submitted export notification.

6.1.7 Following up export notifications

ECHA has to follow up notifications if there is no acknowledgement of receipt of a first export notification made after the chemical is included in Part 1 of Annex I from the importing country within **30 days** of the dispatch of the notification. In such cases, ECHA must submit a second notification and make (on behalf of the Commission) reasonable efforts to ensure that the DNA or other appropriate authority of the importing country receives the second notification. Note however, that this has no direct impact on the export proceeding.

Legal reference: Article 8 (3) of the PIC Regulation

6.1.8 When is a new notification required?

Whenever there is a change in EU legislation concerning the marketing and use or labelling of the chemical, or the composition of a mixture is changed insofar as the concentration of the chemical(s) concerned is different (for example to the extent that the required labelling is altered) a new export notification must be submitted. The new notification must indicate that it is a revision of a previous notification.

Legal reference: Article 8 (4) of the PIC Regulation

6.1.9 Emergency situation

If the export relates to a public health or environmental emergency, where a delay could worsen the situation in the importing country, the relevant DNA of the exporter's Member State (in consultation with the Commission and assisted by ECHA) may decide to waive entirely or partly the waiting period or notification requirements. Such an exemption can be granted at a reasoned request of the exporter or the importing country. If there is no dissenting response from the Commission within **10 days** of the DNA of the exporter's Member State sending it details of the request, a positive decision is considered to have been made.

Please note that exporters of chemicals exempted from the export notification obligation due to an emergency situation must anyway obtain a special RIN and provide that RIN in their export declaration. In order to distinguish these special RIN requests from those referring to exports to which the regulation does not apply (Article 2 (3) and 8 (6)) and to allow for the Commission to approve them, in ePIC these special RINs must be requested using the standard notification form as opposed to the special RIN request. There is a check-box in the notification form which allows the submission of these requests which do not need to be submitted 35 days before export and will not be subject to the explicit consent procedure; they will however be fully processed and sent to the importing country. Please consult Figure 2 which illustrates the procedure to make a special RIN request in an emergency situation.

Legal reference: Article 8 (5) and Article 19 (2) of the PIC Regulation

6.1.10 When is a notification no longer required?

The export notification obligations cease when **all** the conditions of Article 8 (6) are met, namely:

- a) a chemical becomes subject to the PIC procedure;
- b) the importing Party to the Convention has given an import response (indicating whether or not it consents to import);
- c) the Commission has been informed about that response by the Secretariat and has forwarded that information to the Member States and ECHA.

The exporter of chemicals for which the abovementioned obligations have ceased must nevertheless obtain a special RIN (if the import response exists and it is positive) and provide it in his export declaration. Note however, that an export notification will still be required if the importing Party to the Convention continues to require one. The requirement for export notification also ceases when the DNA of the importing Party officially waives the right to receive export notification. The Commission must receive such information from the Secretariat or from the DNA of the importing Party. The Commission subsequently forwards this information to ECHA (in order for it to be made available on ePIC) and to the Member States. Import responses are included in the latest PIC Circular accessible on the Rotterdam Convention website.

Legal reference: Article 8 (6) and Article 19 (2) of the PIC Regulation

6.1.11 Request for additional information

The authorities of the importing country may respond to an EU export notification and request additional information. This information must be provided by the exporter, the relevant DNA or ECHA.

Legal reference: Article 8 (7) of the PIC Regulation

6.2 Export notifications from Parties and other countries

When ECHA receives an export notification concerning the export of a chemical to the EU from a third country, the manufacture, use, handling, consumption, transport or sale of which is banned or severely restricted in the country of origin it will make it available within ePIC database within **15 days** of the receipt of such a notification. ECHA acknowledges receipt of the first notification received for each chemical from the third country on behalf of the Commission. ECHA will make the notification together with all accessible information available to the DNA of the Member States receiving the import within **10 days** of its receipt. Upon request, other Member States are entitled to receive copies of such export notifications.

If a DNA of a Member State receives an export notification from a third country directly, it must send this notification forthwith to ECHA together with all available information. However, the DNA need not forward the notification if it is incompliant with Article 9 (for example, because it has been triggered by "a significant new use rule" as under the US TSCA - Toxic Substances Control Act or because of non-registration in the country of origin, etc. rather than a ban/severe restriction for health or environmental reasons). In such cases, a summary of the notification may suffice if the Member State considers that other Member States should be informed. Where additional information is needed, the Member State concerned should seek this directly from the authorities in the exporting country (with a copy sent to ECHA for information).

Legal reference: Article 9 of the PIC Regulation

6.2.1 Obligations in relation to the import of chemicals

The PIC Regulation requires Member States to control the import of chemicals listed in Annex I and to designate authorities, e.g. customs, with this responsibility (Article 18 of the PIC Regulation). While the PIC Regulation does not include any detailed provisions on restrictions or prohibition at importation, it establishes a procedure through which the Commission, in close cooperation with the Member States, can evaluate and take import decisions regarding chemicals covered by the PIC procedure (i.e. those included in Part 3 of Annex I).

The Commission receives Decision Guidance Documents (DGDs) from the PIC Secretariat, which it circulates to the Member States and ECHA. The Commission adopts an EU import decision (by means of an implementing act) for the chemical concerned, and relating to the use category or categories for the chemical specified in the DGD. Before adopting the decision, the Commission obtains the opinion of the Member States using the advisory procedure in the committee established pursuant to Article 133 of the REACH Regulation (*Committee procedure*).

Existing EU legislation provides the legal basis for import decisions in the context of the Rotterdam Convention. The decision on whether a chemical is allowed to be imported and/or used and/or placed on the market of the EU territory is made in a legal act regulating the import, use or placing on the market of the chemical in question, e.g. the REACH Regulation or the legislation on plant protection or biocidal products. Therefore, the PIC Regulation does not include any detailed provisions as regards restriction or prohibition at importation.

The EU import decision is communicated to the Secretariat of the Rotterdam Convention and exporting Parties are requested to respect this decision. The decision is also made available to the public, in particular those concerned, by the DNAs in the Member States. It is also published in the regular PIC Circular, produced by the Secretariat and on the Convention website (http://www.pic.int).

Where relevant, the import decision will also mention different and more specific national rules if so requested by the Member State(s) concerned. Import decisions will relate to the use category or categories specified in the DGD for the chemical concerned. DNAs have to make import decisions available to those concerned within its competence, in accordance with its legislative and administrative measures. When evaluating the information contained in a DGD, the Commission in close cooperation with the Member States and ECHA will consider the need to propose EU measures to reduce risks to human health and the environment, if necessary.

Legal reference: Article 13 of the PIC Regulation

6.3 Information on quantities of chemicals exported and imported

During the first quarter of each year the exporter of:

- substances listed in Annex I to the PIC regulation;
- mixtures containing Annex I substances in a concentration that triggers a labelling obligation under the CLP Regulation irrespective of the presence of any other substances; or
- articles containing substances listed in Part 2 or 3 of Annex I in unreacted form, or mixtures containing such substances in a concentration that triggers a labelling obligation under the CLP Regulation irrespective of the presence of any other substances

has to inform the relevant DNA of the Member State in which he is established of the quantities of that chemical exported (as a substance, in mixtures and/or in articles) to each importing country for the previous year. The information should include a list of the names and addresses of each importer to which shipment took place. In cases of mixtures and articles it is the quantity of Annex I chemical(s) that should be reported⁴¹. As from the start of 2015 when the feature is available in ePIC, this information should be submitted to the DNA by using the dedicated feature in ePIC.

The definition of 'article' implies that information on export is only required if the use of the chemical in the particular article is banned or severely restricted by the EU legislation, and not for all other articles in which the substance might be used without restriction.

Any exports of chemicals listed under Parts 2 or 3 of Annex I that proceed with the approval of the DNA of the exporter and of the Commission assisted by ECHA but in the absence of explicit consent from the importing Party or other country shall be listed separately (see Article 14 (7) of the PIC Regulation).

Similarly, each EU-based importer is obliged to provide the same information for quantities of chemicals placed on the internal market. The DNAs, supported by the ePIC platform, compile and aggregate the information received from exporters and importers in accordance with the format set out in Annex III to the PIC Regulation. The aggregated reports for the preceding calendar year must then be submitted by the DNAs to ECHA within ePIC. This should be done by the end of September of the year following that to which the reports refer at the very

⁴¹ Quantities of Annex I chemical(s) should be reported in kilograms or liters. For the correct identification of the chemical, the relevant CAS number should be reported. Note also that it is the quantity of chemical for which an export notification has been made that needs to be reported and **not** the quantity relating to a group of chemicals such as for example 'mercury compounds'.

latest. Nil returns should also be reported to ECHA. ECHA will assist the DNAs in collecting the data by providing the necessary functionality in ePIC and will summarise the reports at Union level. An overall summary of the non-confidential information will be published on the dedicated section of the ECHA website.

Legal reference: Article 10 of the PIC Regulation

6.4 Notification of banned or severely restricted chemicals under the Convention

Chemicals that qualify for PIC notification (i.e. those banned or severely restricted in the EU within a Convention use category) are included in Part 2 of Annex I. After inclusion, they must be notified by the Commission to the Secretariat no later than 90 days after the date on which the final regulatory action is to be applied (FRA notification, see 2.3.1 above) . Such regulatory action may be underpinned by an EU risk evaluation identifying concerns for human health or the environment. The most important results of that risk evaluation will be reported in the notification in order to inform other Parties to the Convention and to allow them to use that information for their national decision-making on the use of that chemical.

The notification has to contain the information listed in Annex IV to the PIC Regulation (Notification of the Secretariat of the Convention of a banned or severely restricted chemical). If the Commission does not have this information at hand, it can request identified exporters or importers to provide such information within 60 days of the request. The notification has to be updated when there is a change in the regulatory action banning or severely restricting the chemical.

Proposed additions to Part 2 of Annex I will be made by a delegated act (Commission Delegated Regulation amending Annex I) formally adopted by the Commission and submitted to the Council and the European Parliament, which have the right to object. No EU FRA notification will be submitted unless and until the relevant amendment has been adopted. DNAs and relevant stakeholders will be consulted on draft notifications before the Commission submits the final versions to the Secretariat. See also section <u>6.15</u> of this guidance (Updating of Annexes).

Prioritisation for notification

In determining priorities for notification, the Commission will take into account:

- whether the chemical is already subject to the PIC procedure (i.e. is already listed in Part 3 of Annex I);
- the extent to which the information requirements of Annex IV to the PIC Regulation can be met;
- the severity of the risks presented by the chemical, in particular for developing countries.

Information on FRA notification from other Parties

When the Commission receives information from the Secretariat on chemicals notified as banned or severly restricted by other Parties to the Convention, it must circulate these immediately to all Member States and ECHA. Where appropriate, the Commission evaluates in close cooperation with Member States and ECHA the need to propose relevant EU measures to prevent any unacceptable risk to human health or the environment.

FRA notifications made by a Member States

Member States may adopt (in accordance with the relevant Union legislation) national final regulatory action to ban or severely restrict a chemical. If a Member State does so, it must provide relevant information to the Commission. The latter will make this information available to the other Member States, who may send comments on a possible FRA notification. The Member State that took the final regulatory action may request it to be notified to the Secretariat. In such cases, the procedure laid down in Article 11 of the PIC Regulation is followed. If the submitting Member State decides not to ask the Commission to forward the notification to the Secretariat, it asks the Commission to provide the Secretariat with information pursuant to Article 12 of the PIC Regulation.

Legal reference: Article 11(8) of the PIC Regulation

6.5 Information on banned or severely restricted chemicals not qualifying for PIC notification

Apart from an FRA notification, the Regulation provides other means for disseminating information about banned or severely restricted chemicals using the Convention's provisions on exchange of information. These alternative means are relevant, for example, to chemicals that are banned or severely restricted within the EU only in a use subcategory and thus do not qualify for PIC notification. These means are also relevant to chemicals banned or severely restricted by national regulatory actions in one or more Member States when those Member States concerned conclude, following the consultation procedure referred to above, that FRA notification would not be appropriate.

In such cases, instead of an FRA notification being made, the dissemination of information is ensured by the Commission providing relevant information to the PIC Secretariat so that other Parties to the Convention can be made aware. The information to be provided by the Commission will be essentially factual, including:

- identity of chemical;
- reference to the relevant regulatory action and underlying reasons for it, as stated in that action;
- (where appropriate) a summary of available underpinning risk evaluation, etc.
- (where appropriate) an explanation of why no FRA notification is being made pursuant to Article 11.

Legal reference: Article 12 of the PIC Regulation

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

EU exporters must comply with the import decisions (both interim and final) taken by importing Parties, which are published every six months in the PIC Circular issued by the Secretariat. The Commission forwards the PIC Circulars and any other relevant information it receives to the DNAs, ECHA and European industry associations.

The latest PIC Circulars will be publicly available on the dedicated section of the ECHA website. ECHA will also provide all interested parties with that information upon request. Import decisions are also available from the DNAs. The obligation to comply with an import decision starts six months after the Secretariat has distributed the information.

For the export to Parties to the Convention of chemicals listed in Part 3 of Annex I for which the import decision published in the latest PIC Circular consents to import and the PIC use category corresponds to the intended use, it is not necessary to notify the export, unless the importing Party requires otherwise (see Article 8 (6) of the PIC Regulation). However, exporters have to provide a RIN in their customs declaration. This RIN can be obtained by submitting a **special RIN request**⁴², namely:

- 1. The exporter first checks if Article 2 (3)⁴³ or Article 8 (6) applies to the export. If so, the exporter requests a special RIN from his DNA;
- 2. Provided that all requirements are met, the exporting DNA approves the request.

The RIN is then activated and has to be used by the exporter on the customs declaration.

Figure 2 below illustrates the procedure for requesting a special RIN.

⁴² Please note that in addition to the case described above, special RIN requests are also required:

for chemicals exported for the purpose of research or analysis in quantities not more than 10 kg per calendar year;

⁻ if the importing country has waived the right to receiving export notification;

in case of emergency export according to Article 8(5)

 $^{^{43}}$ Note that Article 2 (3) provisions cover Annex V chemicals. See also section 4.1.2 for more information on provisions for these.

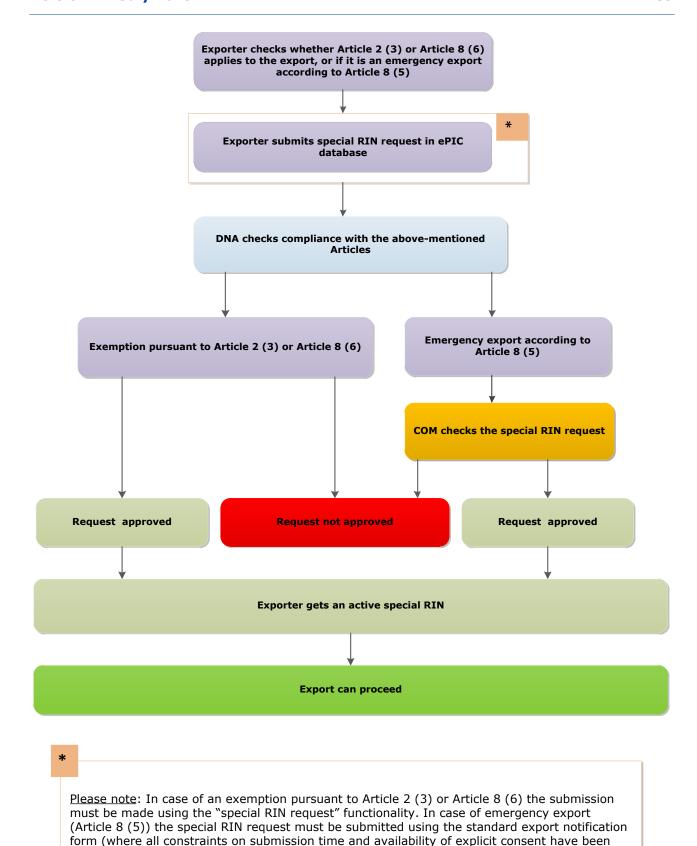


Figure 2: Special RIN request procedure pursuant to Article 2 (3) or Article 8 (6) or an emergency export according to Article 8 (5).

waived). This is in order to allow for the Commission assessment of the request.

6.6.1 Explicit consent

Article 14 of the PIC regulation requires the explicit consent of the country of destination prior to the export of chemicals listed in parts 2 or 3 of Annex I (unless a positive import response is available in the latest PIC Circular for chemicals listed in Part 3 of Annex I):

Article 14 (6):

Substances listed in Part 2 or 3 of Annex I or mixtures containing such substances in a concentration that triggers labelling obligations under Regulation (EC)1272/2008 irrespective of the presence of any other substances shall, regardless of their intended use in the importing Party or other country, not be exported unless either of the following conditions is fulfilled:

- (a) explicit consent to import has been sought and received by the exporter through the designated national authority of the exporter's Member State in consultation with the Commission, assisted by the Agency, and the designated national authority of the importing Party or an appropriate authority in an importing other country;
- (b) in the case of chemicals listed in Part 3 of Annex I, the latest circular issued by the Secretariat (...) indicates that the importing Party has given consent to import;

6.6.1.1 What chemicals are subject to explicit consent requirement?

With limited exemptions that are identified below, the PIC Regulation goes beyond the Convention and requires that the explicit consent of the importing country must be obtained before export of:

- chemicals subject to PIC procedure (i.e. those listed in Part 3 of Annex I);
- chemicals qualifying for PIC notification (i.e. those listed in Part 2 of Annex I);
- mixtures containing substances from Part 2 or 3 of Annex I in a concentration that triggers labelling obligations under the CLP Regulation.

6.6.1.2 Seeking an explicit consent

For some chemicals listed in Part 2 of Annex I there may be no applicable explicit consent or waiver available in the explicit consent list in ePIC. In such cases a new explicit consent is required in order for the export to proceed.

Additionally, for some chemicals listed in Part 3 of Annex I, the importing countries may have failed to provide an import response to the Convention Secretariat meaning that the latest PIC Circular may not indicate any response from the importing Party as to whether or not future imports of the chemical(s) in question is allowed. In the absence of an official import response, an explicit consent is required for the export to proceed.

Explicit consent has to be sought and received through the exporter's DNA and the DNA (or other competent authority) of the importing country. It is advised that the exporter or importer should not make any direct contact with the authorities of the importing country until after the exporter's DNA has made a formal approach.

Information on DNAs and (for non-Parties) other relevant authorities is available in ePIC. Where there are problems in identifying the authorities in the importing country, or when it is otherwise difficult to obtain a reply, the Commission may be able to assist. The DNA of the Member State of export should inform the Commission and ECHA if it receives updated information on DNAs from third parties.

To increase the probability of getting a reply to a request for explicit consent, DNAs are

encouraged to use as far as possible the official UN languages regime and to request explicit consent in whichever of these languages is the most relevant to the importing country. The templates for explicit consent request forms and the explanatory notes (describing the EU process) in the most common languages (English, French and Spanish) can be found in the dedicated section of ePIC.

6.6.1.3 Possible forms of explicit consent

Explicit consent can take different forms. For example, it could be in the form of an official import decision transmitted via the Secretariat giving the importing country's clear consent to imports (in the case of a chemical that is subject to the PIC procedure), or an e-mail or letter or confirmation from the appropriate authorities in the importing country.

Each document used as a basis for authorisation of an export of a chemical for which explicit consent is required gets a unique identifier (explicit consent identifier) and is uploaded and stored on ePIC. Once the explicit consent for a chemical is received by a DNA, the DNA uploads it on ePIC. If an applicable explicit consent is available, the DNA does not need to make a new request. If the terms of an explicit consent are broad enough, it may be applied to various matching export notifications and may form the basis for the activation of several RINs (from different exporters and/or Member States).

6.6.1.4 The process of requesting explicit consent

The process of requesting explicit consent always starts with an export notification that is created and submitted by the exporter in ePIC (see sub-section 6.1.5 of this guidance document). Subsequently, the process involves the following steps:

1) DNA checks if an explicit consent exists

The ePIC database will suggest potentially matching existing explicit consents (or existing negative responses). The DNA may select one, if applicable to the notification or propose another if it believes that there is a better option that was not proposed by the system.

If an applicable explicit consent exists:

There is no need to request a new consent from this importing country again. The DNA should approve the export notification (if the information requirements are met) and forward it to ECHA;

• If no explicit consent exists:

If no applicable explicit consent or positive import decision is available, the exporter's DNA needs to make a new request for consent to the appropriate DNA in the importing country.

In the meantime, ECHA will process and send the export notification⁴⁴. The RIN however will not be activated and the export cannot proceed until the consent is given.

2) In case a new request for explicit consent is needed:

- The DNA will find all the necessary forms and contact details in ePIC. A standard

⁴⁴ There is no direct link between the explicit consent and export notification requirements. Both obligations have to be fulfilled, but they are independent and can be met separately. There is thus no reason why the forwarding of an export notification should be delayed pending receipt of explicit consent, where required.

form (and explanatory note) that the exporter's DNA can use to seek the consent is available on ePIC:

- A request for explicit consent is sent by the DNA (outside ePIC) and is subsequently recorded in the ePIC system by the DNA⁴⁵;
- When sending the request to the importing country, the DNA should explain the context (e.g., that this is an internal EU requirement that goes beyond the obligation laid down in the Convention). A standard form (and explanatory note) that the exporter's DNA can use to seek the consent is available on ePIC;
- Should no response be received within 30 days of issuing the request, ECHA (on behalf of the Commission) will send a reminder to the DNA of the importing country. In the absence of a response, a second reminder will be sent by ECHA.

3) Once a consent is received:

- The DNA will upload the explicit consent to ePIC and extract as much metadata⁴⁶ as is relevant and/or available;
- ECHA will double-check the extracted metadata (as a one-off process). This step both (i) ensures that no human error was made and (ii) guarantees consistency in the interpretation of consents across all EU Member States. If there is no objection to the metadata, the consent will be published on the explicit consent list;
- The consent will then be available for RIN activation (or disabling if the consent is negative);
- The export can proceed for positive consent;
- The consent is applicable to the export notification for which it was requested but may also apply to other notifications.

More detailed information on how to fill in the necessary information and submit the request for explicit consent is provided in the ePIC User Manual which is available on the ECHA website at: http://echa.europa.eu/support/dossier-submission-tools/epic/epic-manuals.

Please consult <u>Figure 3</u> below, which illustrates the process of requesting an explicit consent.

6.6.1.5 Explicit consent for mixtures containing substances from Part 2 or 3 of Annex I

The obligation to get explicit consent also applies to the export of mixtures containing substances from Part 2 or Part 3 of Annex I in concentrations that trigger labelling obligations under the CLP Regulation. A separate explicit consent must be requested for each mixture and a separate explicit consent RIN is subsequently issued for each mixture.

In an effort to facilitate implementation of this provision, the explicit consent request includes various questions for the DNA in the importing country to answer. One of these questions is: "do you consent to the import of other mixtures containing the same Annex I substance?" In most cases the importing DNA answers "no" to this question, which then triggers the need for

 $^{^{45}}$ DNAs can use various ways of communication (fax, e-mail or post) to contact the DNA or other relevant authority in the importing country. The document recorded by the DNA in the system is the standard form used to seek an explicit consent.

⁴⁶ For example: explicit consent response (positive or negative), use category of the chemical (industrial or pesticidal), information on the identity of the chemical (substance or mixture?), validity period of the explicit consent, etc.

a separate explicit consent request for any other mixture, whereas in case of a positive reply, DNAs and ECHA can directly approve exports of other mixtures containing the substance.

Since a mixture includes more than one substance, it is necessary to check for each substance whether an obligation to obtain explicit consent exists. If at least one substance triggers that obligation, a request for explicit consent must be submitted. An importing country may give an unspecific reply that registered⁴⁷ chemicals are allowed to be imported.

Example: If substance A of a mixture AB is listed in Annex I of the PIC Regulation and is registered in the importing country, the export can proceed even if substance B is not registered, provided it is not listed in Annex I. The request for explicit consent was triggered by substance A, not substance B.

⁴⁷ "Registered" in this context means licensed or authorised in the importing Party or other country. See also Article 14 (6) and (7) of the PIC Regulation.

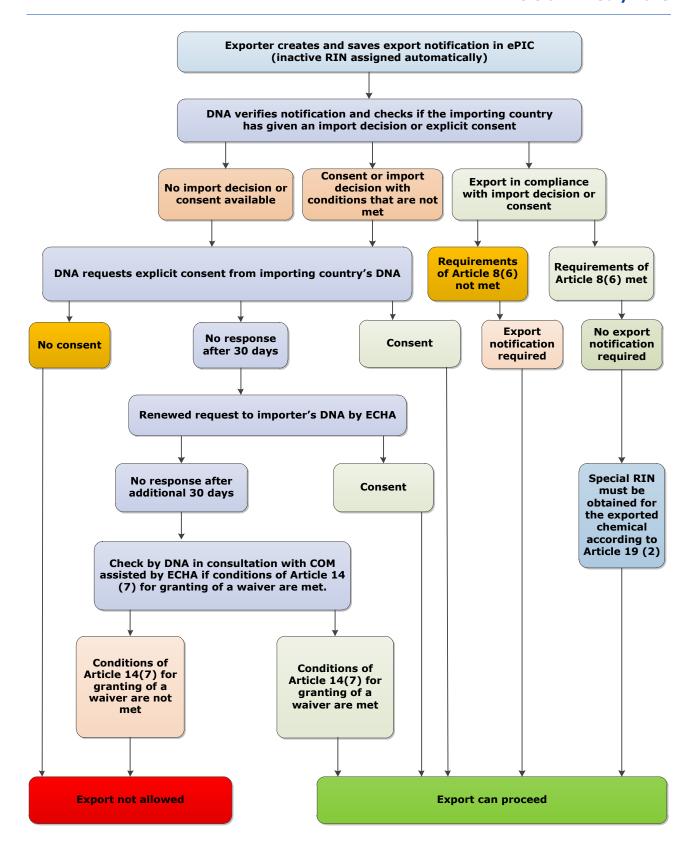


Figure 3: Article 14 (6) and (7) procedure for export of Annex I Part 2 and 3 chemicals to all countries (except those exports of Annex I Part 2 chemicals for which the waiver for OECD countries is applied).

6.6.1.6 Timelines

It is recommended that explicit consent be sought **as far in advance of export as possible**. Exporters of chemicals that require a request for explicit consent are encouraged to submit their export notifications to their DNAs well in advance of the intended date of export. A draft copy of the export notification (available on ePIC) would be a means of providing the necessary information to enable the importing country to take a decision. To facilitate the process for the DNA or other relevant authority in the importing country, it would be useful for exporters to submit copies to the DNA of the exporter of any registrations or authorisations which the importing country has issued for the chemical. The exporter's DNA could then upload this documentation on ePIC and attach it to the request for consent.

6.6.1.7 Validity of the explicit consent

Once explicit consent has been obtained by one exporter's DNA, it is potentially not necessary to make new requests for subsequent exports by any EU exporter, whilst that consent remains valid. To reflect the reality that an importing country's views could evolve over time, the validity of explicit consent is limited to three calendar years, unless otherwise specified in the explicit consent. At the end of the third year, a new request for explicit consent must be made to the DNA of the importing Party or the relevant authority of the other importing country by the DNA of the exporter. Pending response to the new request, exports of the relevant chemical may continue for an additional period of 12 months (see Article 14 (8) of the PIC Regulation).

In the case of chemicals for which an explicit consent is required in addition to submitting an export notification (i.e. Part 2 chemicals and certain Part 3 chemicals for which an import decision does not exist) the validity of the explicit consent may vary and will in most cases be different from the validity of the RIN. By default, a RIN remains valid until the 31 December of the year for which the notification was made, it will then expire. In this case, a new export notification must be made for the subsequent year and a new RIN will be issued. This new RIN will immediately be activated upon processing of the export notification, provided that all conditions are met. There will be no need to request a new consent until the explicit consent expires at the end of the third year from when it was obtained (unless otherwise stated by the terms of the consent).

6.6.1.8 Waiver

The Regulation provides for two possible exemptions to the requirement that explicit consent be obtained prior to export of chemicals listed in Part 2 or 3 of Annex I (i.e qualifying for PIC notification or subject to the PIC Procedure, respectively):

1) Export of chemicals from Part 2 of Annex I to OECD countries

Where a chemical qualifying for PIC notification is to be exported to OECD countries, the requirement for explicit consent may be waived. This decision is to be taken by the exporter's DNA, at the request of the exporter, in consultation with the Commission and on a case-by-case basis. The basis for the decision being that the chemical is, at the time of importation into the OECD country, licensed, registered or authorised in that OECD country. This procedure is illustrated by Figure 4. A list of the current member countries of the OECD is provided on the OECD website: http://www.oecd.org/about/membersandpartners/list-oecd-member-countries.htm. For a list of non-EU DNAs, please consult the ECHA website: http://echa.europa.eu/information-on-chemicals/pic/designated-national-authority (and select "non-EU").

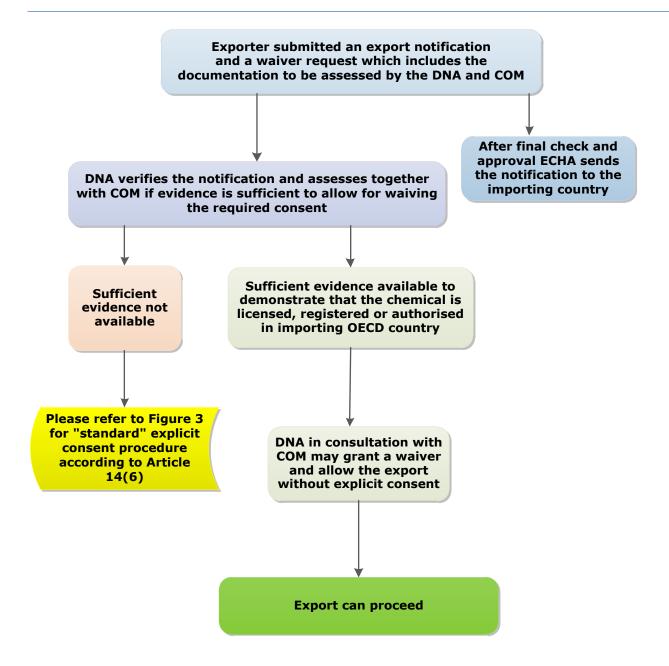


Figure 4: Article 14 (6) procedure for Annex I Part 2 chemicals exported to OECD countries.

2) Waiver under Article 14 (7) for chemicals listed in Part 2 or 3 of Annex I

The decision to waive the requirement for explicit consent may be taken by the exporter's DNA, in consultation with the Commission, assisted by ECHA and on a case-by-case basis, if:

- ➤ there is no evidence from official sources of final regulatory action to ban or severely restrict the use of chemical taken by the importing Party or other country, and if
- despite all reasonable efforts, no response has been received within 60 days of a request for an explicit consent for a chemical subject either to the PIC procedure or qualifying for PIC notification.

In addition, one of the two following conditions of Article 14 (7) must be met, namely:

Article 14 (7) (a) and (b):

- (a) there is evidence from official sources in the importing Party or other country that the chemical is licensed, registered or authorised; or
- (b) the intended use declared in the export notification and confirmed in writing by the importer is not a category for which the chemical was listed in Part 2 or 3 of Annex I, and there is evidence from official sources that the chemical has in the last five years been used in or imported into the importing Party or other country concerned.

For chemicals listed in Part 3 of Annex I, an export based on the fulfilment of the condition (b) is not allowed, if:

- the chemical has been classified as carcinogenic category 1A or 1B, mutagenic category 1A or 1B or toxic for reproduction category 1A or 1B (CMR Cat. 1A or 1B) according to the CLP Regulation; or
- the chemical fulfils the criteria of Annex XIII to the REACH Regulation for being persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB).

See <u>Figure 3</u> where the waiver request under Article 14 (7) for chemicals listed in Part 2 or 3 of Annex I is illustrated (as part of the explicit consent workflow). Examples of the type of evidence required to justify a waiver are provided in <u>Appendix 3</u> to this guidance document.

For further information on classification criteria of CMR substances and mixtures it is recommended to consult the <u>Guidance on the Application of the CLP Criteria</u> available on the ECHA website. For more information on PBT/vPvB identification, please consult Annex XIII of the REACH Regulation (*Criteria for the identification of persistent, bioaccumulative and toxic substances, and very persistent and very bioaccumulative substances*). It may be also useful to consult the ECHA <u>Guidance on Information Requirements and Chemical Safety Assessment Part C: PBT Assessment</u>.

When deciding on the export of chemicals listed in Part 3 of Annex I, the DNA must in consultation with the Commission assisted by ECHA take into consideration possible impacts on human health and the environment in the importing Party or other country and submit relevant documentation to ECHA, to be made available by ePIC.

Validity of the waiver

Waivers can be granted for a maximum period of 12 months, after which time explicit consent is required, unless a response to the initial request for explicit consent has been received in the meantime (see Article 14 (8) (b) of the PIC Regulation). The same period of 12 months applies for the validity of the "OECD waiver" granted pursuant to Article 14 (6) of the PIC Regulation.

After the maximum period of 12 months has expired, if no response to the request for explicit consent has been received, the exporter will once again need to seek explicit consent through the exporter's DNA, which means that the above-mentioned procedure starts again from the beginning. Please note that the above-mentioned period of 12 months starts at the date when the waiver is granted or on the day specified in the decision on granting the waiver.

6.7 Quality of exported products

Articles 14 (10) and (11) of the PIC Regulation impose requirements about the useful life of chemicals and their packaging, storage conditions and stability. These requirements are mainly relevant for pesticides.

An exporter must ensure that exported products are not exported within 6 months of their expiry date, when such a date exists or can be inferred from the production date, unless the chemical's intrinsic properties render this impracticable. In the case of pesticides, the size and packaging of containers must be optimised to reduce the risks of creating obsolete stocks, and the label has to contain specific information about storage conditions and stability under the climatic conditions of the importing country. In addition, the exported pesticide must comply with the purity specification laid down in the EU legislation.

6.8 RIN in the customs declaration

Exporters are obliged to include the relevant reference identification number (RIN) from their export notification in their customs declarations for export. This RIN (standard or special) should be entered either in box 44 of the Single Administrative Documents (SAD), or in the corresponding data element in an electronic export declaration, as referred to in Regulation (EEC) No 2913/92 establishing the Community Customs Code.

To facilitate customs controls of the export the requirement for a RIN in the customs declaration is integrated into TARIC⁴⁸ as an export control measure linked to a specific commodity code.

Please note that **Y915** is the TARIC certificate code indicating the requirement for a RIN. The exporter (who has submitted an export notification and obtained a RIN) must insert certificate code Y915 in box 44 of the SAD. Hence, Box 44 should contain the certificate code Y915 and a RIN.

There are other TARIC certificate codes associated with the PIC Regulation⁴⁹ that, depending on the type of the exported chemical, should be inserted by the exporter in box 44 of the SAD. These are listed below:

- Y916 This certificate code indicates that the chemical to be exported is not subject to the provisions of Regulation (EU) 649/2012, Annex I (relating to restrictions on export). No restriction applies. Note this certificate code is only used when the substance exported shares the same CN code as an entry in Annex I but is not the same chemical as that which gave rise to the entry.
- **Y917** This certificate code indicates that the chemical to be exported is not subject to the provisions of Regulation (EU) 649/2012, Annex V (relating to prohibitions on the export of certain chemicals). No prohibition applies. Note this certificate code is only used when the substance exported shares the same CN code as an entry in Annex V but is not the same chemical as that which gave rise to the entry.

⁴⁸ Tarif Intégré de la Communauté – i.e. Integrated Community Tariff is a multilingual database into which are integrated all measures relating to EU customs tariff, commercial and agricultural legislation. More information on tariff and non-tariff measures which are applicable for commodity codes is available at the website of Commission's Taxation and Customs Union Directorate-General:

http://ec.europa.eu/taxation_customs/customs duties/tariff_aspects/customs_tariff/index_en.htm

⁴⁹ Please note that TARIC does not only indicate that the PIC Regulation applies, but also indicates the Union codes to be used for declaring the RIN or special RIN in the customs declaration, or for declaring that the goods fulfill certain requirements. Customs must not allow the export unless the relevant TARIC certificate code is included and followed by the RIN or special RIN, if applicable.

Y919 - This certificate code indicates that the chemical to be exported is subject to the provisions of Article 2 (3) of Regulation (EU) 649/2012 which exempts the export from all provisions subject to the condition that the chemical is exported for the purpose of research or analysis in quantities not more than 10 kg. In the case of Y919, this should be accompanied by a 'special RIN' (see sub-section 4.2.9 of this guidance document).

If a RIN is entered in Box 44, customs officers can consult the customs interface of ePIC and check the status of the export.

The following information is available to the customs officer via the ePIC application (upon a successful match between a RIN and the corresponding country):

- RIN type (export notification/special RIN request);
- RIN validity period;
- Name of the chemical/mixture/article;
- CAS number;
- EC number;
- CUS number
- CN code;
- Exporting Member State;
- Name and details of the exporter;
- Importing country.

In addition to the above, customs authorities will have access to the full list of PIC chemicals and to all the EU DNA contact details. For **bulk** special RIN requests most of the information listed above will instead be available in a file attachment.

In case RIN and the importing country do not match (or the RIN does not exist) no information would be provided and an error message would be displayed.

If the RIN is active for the given export, the export can proceed. Where customs authorities have any doubt or identify any problem in a customs declaration regarding compliance with the PIC Regulation, the export should not be allowed and the DNA of the exporter's country should be duly notified. If these doubts remained unresolved the chemical would ultimately have to be taken back by the exporter.

The following checklist might be useful to customs as a basis for their list of what control of exports should cover:

- Is the chemical subject to the PIC Regulation?
- Is the chemical banned for export (i.e. included in Annex V to the PIC Regulation)?
- Is an active RIN provided in box 44?
- Do the chemical and the importing country correspond with the information provided in the export notification?
- Do packaging and labelling comply with the relevant provisions of Articles 14 (10), 14 (11) and 17 (hazard pictograms, precautionary statements, language, etc.)?
- Is the shipment accompanied by an SDS in a language that is expected to be understood in the importing country?
- Is the maximum quantity of 10kg respected in case of a special RIN?

Legal reference: Article 19 (1) of the PIC Regulation

6.9 Information on transit movements

In case a Party to the Convention requires information on transit movements of a chemical subject to the PIC procedure, the exporter must, insofar as possible, provide his DNA with the information laid down in Annex VI to Regulation (EU) No 649/2012 30 days before the first transit movement is due to take place, and at least 8 days before each subsequent movement.

The DNA of the exporter's Member State will forward the information, together with any available additional information, to the Commission (with a copy to ECHA), which will forward it to the DNA in the requesting importing Party no later than 15 days before the first transit movement and prior to each subsequent movement. Please note that at the time of drafting of this guidance **no** Parties to the Convention have indicated that they require such information.

Transit movements in relation to export and import concepts under PIC Regulation

In case of export or re-export, provisions of Article 16 should be understood as obligations towards the third countries whose territories are crossed during the transport between the country of dispatch and the country of destination.

It should be noted that external Union transit is excluded from the definition of export (Article 3 (16)) and import (Article 3 (17)), but not internal Union transit. In practice this means that chemicals which cross the customs territory of the Union under external transit, while they are sent from a third country A to another third country B, should not be treated as imported and re-exported.

On the other hand, movements of chemicals under internal transit going from one point in the customs territory of the Union to another point in the customs territory of the Union while crossing the territories of third countries fall under the definitions of export and import given by the PIC Regulation. In such cases the obligations under the PIC Regulation in relation to export and import apply. The communication of information on chemicals subject to the PIC procedure to the third country should follow the provisions of Article 16.

Legal reference: Article 16 of the PIC Regulation

6.10 Information to accompany exported chemicals

All chemicals that are intended for export must be packaged and labelled in the same way as if they were to be marketed in the European Union unless the importing country has its own specific requirements, taking into account also relevant international standards.

The relevant EU rules are laid down in the following legal acts:

- The CLP Regulation Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006;
- The Biocidal Products Regulation (BPR) Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products;
- The Plant Protection Products Regulation Regulation (EC) No 1107/2009 of the

European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market.

Furthermore, a safety data sheet in accordance with Article 31 and Annex II of the REACH Regulation must accompany exported hazardous chemicals. The exporter must send such an SDS to each importer when the chemical is exported. See also sub-section $\underline{6.10.4}$ of this guidance document.

6.10.1 Content of the label

According to Article 17 of the CLP Regulation, substances or mixtures classified as hazardous and contained in packaging must bear a label including the following information:

- the name, address and telephone number of the supplier(s)⁵⁰;
- the nominal quantity of the substance or mixture in the package made available to the general public, unless this quantity is specified elsewhere on the package;
- product identifiers for substance or mixture as specified in Articles 18 (2) or 18 (3) of the CLP Regulation; as a general rule, the same product identifier(s) as selected for the label must be used in the SDS for a substance or mixture;
- where applicable:
 - hazard pictograms, i.e. a pictorial presentation to communicate information on the hazard concerned (see also the definition provided in CLP Article 2(3));
 - signal words indicating the relative level of severity of a particular hazard (see also CLP, Article 20);
 - hazard statements describing the nature and severity of the hazards of a substance or mixture (see CLP Article 21);
 - precautionary statements giving advice on measures to prevent or minimise adverse effects to human health or the environment arising from the hazards of a substance or mixture (see CLP Article 22);
 - a section for supplemental information to incorporate additional labelling information over and above that listed in CLP Article 17(a) to (g);

The detailed legal requirements for labelling of substances and mixtures are provided in Title III of the CLP Regulation. It is also recommended to consult the <u>Guidance on labelling and packaging in accordance with Regulation (EC) No 1272/2008</u> available on the ECHA website.

Furthermore, according to Article 17 of the PIC Regulation the information on the label also has to include the expiry date (for different climate zones if necessary) and the production date, where appropriate.

⁵⁰ According to Article 2 (26) of the CLP Regulation '**supplier**' means "any manufacturer, importer, downstream user or distributor placing on the market a substance, on its own or in a mixture, or a mixture".

6.10.2 Timelines for classification, labelling, packaging and updating of CLP hazard labels

The CLP Regulation was introduced gradually in a phased manner before it started to apply fully, i.e. as of 1 June 2015. During this transitional period some of the rules of both CLP and the previous legislation on classification, labelling and packaging, i.e. the DSD and DPD directives, were applicable in parallel.

For substances, the obligation to classify, label and package according to the CLP Regulation had already applied since 1 December 2010. The same obligation now also apply for mixtures since 1 June 2015.

Therefore, **from 1 June 2015 both substances and mixtures must be classified, labelled and packaged according to CLP only**. This classification must be provided in the SDS for substances and mixtures. There is no longer a requirement to provide either DSD classifications of substances themselves or of component substances in mixtures or the DPD classifications for mixtures in the SDS. Only the corresponding information according to CLP need be provided (see also the ECHA <u>Guidance on the compilation of safety data sheets</u>).

Where a mixture is already classified, labelled and packaged according to the DPD rules and placed on the market before 1 June 2015, i.e. it was already in the supply chain by that date, the manufacturer, importer, downstream user or distributor may postpone its re-labelling and repackaging according to the CLP rules until 1 June 2017. This means that the mixture can be sold further in the supply chain with the DPD label until 1 June 2017.

Legal reference: Article 61 of the CLP Regulation

6.10.3 Hazard pictograms used in the EU

Hazard pictograms pursuant to the CLP Regulation, which implements the Globally Harmonised System of Classification and Labelling of Chemicals (GHS):

PHYSICAL HAZARDS:



HEALTH AND ENVIRONMENTAL HAZARDS:



The complete list of the CLP/GHS hazard pictograms for each hazard class and hazard category, is given in Annex V to the CLP Regulation. The GHS pictograms are provided free of charge for download from the website of United Nations Economic Commission for Europe (UNECE): http://www.unece.org/trans/danger/publi/qhs/pictograms.html.

6.10.4 Safety data sheet (SDS)

Article 31 (1) of the REACH Regulation requires the supplier of a substance or a mixture to provide an SDS whenever:

a substance or mixture:

Version 1.1 July 2015

- meets the criteria for classification as hazardous in accordance with the Regulation on classification, labelling and packaging of substances and mixtures (CLP Regulation); or
- is persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB) in accordance with Annex XIII of the REACH Regulation; or
- is included in the candidate list of substances which may be subjected to authorisation.

The PIC Regulation requires that an SDS formatted in accordance with Annex II of the REACH Regulation must accompany exported chemicals. The exporter must send an SDS to each importer together with the chemical. The information on the label and on the safety data sheet must, insofar as possible, be provided in the official languages, or in one or more of the principal languages, of the country of destination or of the area of intended use (see Appendix 4 to this guidance document).

For more detailed information please consult the <u>Guidance on the compilation of safety data</u> <u>sheets</u> available on the ECHA website.

Legal reference: Article 17 of the PIC Regulation

6.11 Obligation of the authorities of the Member States to control exports

The Member States have to designate authorities such as customs offices to control imports and exports of chemicals listed in Annex I. For more information on control of **imports** see section <u>6.2.1</u> below.

Together with the Commission supported by ECHA, Member States must coordinate their enforcement activities in relation to exporters and monitor exporters' compliance with the PIC Regulation. It is envisaged that Member States, the Commission and ECHA should act in a coordinated and targeted way.

ECHA is seeking to facilitate this through providing guidance on the PIC Regulation as well as IT manuals, webinars and training on the use of ePIC. The network of DNAs and other authorities responsible for enforcement is coordinated by the ECHA Forum for Exchange of Information on Enforcement.

The following checklist might be useful to enforcement authorities as a basis for their list of what control of exports should cover:

- Is the chemical banned for export (i.e. included in Annex V to the PIC Regulation)?
- Is the chemical being exported subject to export notification (specifically listed in Annex I or in a generic group listed in Annex I)?
- Has an annual export notification been submitted by the exporter and accepted by the DNA?
- Does the chemical appear in Part 3 of Annex I (*List of chemicals subject to the PIC procedure*)? Does the latest PIC Circular show the consent of the importing country or is there evidence that explicit consent has otherwise been given?
- Is the chemical listed in Part 2 of Annex I (*List of chemicals qualifying for PIC notification*)? Is there evidence that the explicit consent of the importing country has been given?
- Do packaging and labelling comply with the relevant provisions of Articles 14 (10), 14 (11) and 17 (hazard pictograms, precautionary statements, language, etc.)?
- Is the shipment accompanied by a safety data sheet (SDS) in a language that is expected to be understandable in the importing country?

Member States are also obliged to report on their enforcement activities through regular reports on the operation of procedures according to Article 22 (1) of the PIC Regulation.

Legal reference: Article 18 of the PIC Regulation

6.12 Exchange of information

The Commission assisted by ECHA and the Member States are to facilitate the provision of information to other countries about chemicals subject to the PIC Regulation. The Regulation acknowledges the need for certain confidentiality safeguards. However, in line with the Convention, Article 20 (3) of the PIC Regulation defines what information shall not be regarded as confidential. These are the following information:

- the information specified in Annex II (Export notification) and Annex IV (Notification to the Secretariat of the Convention of a banned or severely restricted chemical);
- the information contained in an SDS;
- the expiry date of the chemical;
- the production date of the chemical;
- information on precautionary measures, including hazard classification, the nature of the risk and the relevant safety advice;
- the summary results of toxicological and ecotoxicological tests;
- information concerning handling packaging after chemicals have been removed.

ECHA have to prepare a compilation of the transmitted information every two years. The names of individual exporters and importers are not shown (though this information will of course be included in the export notifications transmitted to importing countries). Similarly, summary reports produced by ECHA pursuant to Articles 10 and 22 will contain aggregated information so that individual exporters are not identifiable.

Legal reference: Article 20 of the PIC Regulation

6.13 Technical assistance

The Commission, the Member States and ECHA have to cooperate in promoting technical assistance, in particular with a view to enabling developing countries and countries with economies in transition to implement the Convention.

Legal reference: Article 21 of the PIC Regulation

6.14 Monitoring and reporting

Article 22 of the PIC Regulation (*Monitoring and reporting*) foresees monitoring and reporting on the functioning and implementation of the Regulation by Member States, the European Commission and ECHA.

Both the Member States and the Commission will monitor developments under the Regulation. The Member States and ECHA must regularly (every three years) send information on the operation of the various procedures to the Commission. These reports cover elements such as:

- the number of export notifications handled,
- the number of requests for explicit consent and their outcomes,
- the nature and extent of controls/inspections, problems and infringements,
- warnings and penalties issued,
- other measures taken, etc.

Based on these submissions, the Commission in turn compiles a report, incorporating a synthesis of the information provided in the reports from Member States and ECHA. Such summary report on the overall functioning of the Regulation is then forwarded by the Commission to the European Parliament and to the Council. Again, there are provisions to protect the confidentiality and ownership of data (see Article 22 (3)).

6.15 Updating of Annexes

According to Article 23 (1) of the PIC Regulation, at least once a year the Commission is required to review, on the basis of the development in EU law and under the Convention, the list of chemicals in Annex I to the PIC Regulation.

To amend Annex I, the Commission adopts a delegated act that adds further chemicals to or changes existing entries in this Annex. The power to adopt delegated acts was conferred to the Commission by the European Parliament and the Council for a period of five years (starting from 1 March 2014).

Prior to the adoption of a delegated act, the Commission will consult the relevant stakeholders on a draft amendment and will take into account their comments when finalising the drafting of that amendment of Annex I.When new chemicals are included in the relevant parts of Annex I this will then trigger as appropriate export notification requirements, submission of an FRA notification, explicit consent for export requirements, and the obligation to respect other countries' import decisions for chemicals subject to the PIC procedure.

The following measures to update Annexes have to be adopted by the same procedure:

 inclusion of a chemical in Part 1 or 2 of Annex I pursuant to Article 23 (2) following final regulatory action at EU level, and other amendments of Annex I, including modifications

- to existing entries;
- inclusion of a chemical subject to Regulation (EC) No 850/2004⁵¹ on persistent organic pollutants in Part 1 of Annex V;
- inclusion of a chemical already subject to an export ban at EU level in Part 2 of Annex V;
- modifications to existing entries in Annex V;
- amendment of Annexes II, III, IV and VI.

Inclusion of chemicals or articles not yet banned for export into Annex V Part 2 (meaning a ban of exports) will necessitate a co-decision by the European Parliament and the Council upon a proposal by the Commission.

Legal reference: Article 23 of the PIC Regulation

7. ePIC - AN IT APPLICATION FOR SUBMISSION OF INFORMATION

Many tasks relating to the day-to-day implementation of the PIC Regulation are carried out by using an IT application called ePIC. ePIC is an important IT-tool for fulfilling the obligations under PIC and for information exchange. The ePIC application is used by European stakeholders involved in the respective activities. In addition, certain information from ePIC will be published on the dedicated section of the ECHA website and will therefore be available to stakeholders from non-EU countries.

ePIC was built to replace the previous submission system, EDEXIM (the European Database for Export and Import of dangerous chemicals), due to the increasing numbers of notifications to process and to the increasing demand for additional features to facilitate the day-to-day work of stakeholders.

ePIC comprises four distinct interfaces which are tailored to the needs of the different user groups:

- i. the DNA interface for use by Member States, to manage implementation of the Regulation, in particular export notifications (Article 8), requests for explicit consent (Article 14), special RIN requests (Article 19 (2)), waivers (Article 14(6) and 14 (7)) and reporting pursuant Article 10;
- ii. the industry interface used by EU exporters to notify (and subsequently follow-up on) planned exports, submit special RIN requests, submit waiver requests, submit Article 10 reports and provide necessary information in accordance with the legal requirements of the Regulation;
- iii. the customs interface, designed to assist customs in controlling trade in hazardous chemicals;
- iv. the administrative interface (used by ECHA) for processing and storing import and export notifications as well as performing all related activities (including the Article 10 reporting).

⁵¹ Regulation (EC) No 850/2004 of the European Parliament and of the Council of 29 April 2004 on persistent organic pollutants and amending Directive 79/117/EEC; OJ L 158, 30.4.2004, p. 7.

The main objective of ePIC is to serve as a platform to fulfil obligations and to provide the user with information on the implementation of the PIC Regulation within the European Union related to:

- export notification for chemicals listed in Annex I of the Regulation;
- explicit consents given by countries on request for chemicals listed in Part 2 or 3 of Annex I of the Regulation;
- (indirect information only via a link to the Convention website) import decisions made by countries participating in the international PIC procedure under the Convention for chemicals listed in Part 3 of Annex I of the Regulation; and
- reports on actual exports and imports of chemicals subject to the regulation which took place in the previous calendar year(s).

The industry interface allows exporters to notify their DNAs directly and on-line of planned exports of Annex I chemicals. Once the exporter has created and saved an export notification, an inactive RIN is assigned to the export.

After submission by the exporter, the DNA will handle the export notification without undue delay and, if complete and correct, forward it to ECHA. Pending processing of the export notification by the DNA and ECHA, the exporter has the possibility of tracking the status of his export notification. ePIC informs the exporter after final approval of the notification, including the period of validity of the notification. For substances not requiring an explicit consent, the RIN will be active (i.e. the export will be allowed) as from the export date indicated by the exporter or the earliest possible date in compliance with the time limits prescribed by the Regulation. For those exports where explicit consent is required, the RIN will only be activated if the respective conditions are met.

The ePIC application also assigns each explicit consent an internal identification number which is associated with the notification during processing. DNAs and the Commission have access to the list of explicit consents. If no explicit consent is available, ePIC will notify the exporter that the export is not yet allowed.

The information taken from ePIC and published on the dedicated section of the ECHA website will be available to the general public. This information enables activities such as:

- a check for existing export notifications for the first annual export of certain hazardous chemicals to the country of destination;
- display of information on applicable explicit consent or waiver available for chemicals listed in Part 2 of Annex I to the PIC Regulation;
- display of information on third country import decisions for chemicals listed in Part 3 of Annex I to the PIC Regulation;
- display of statistics on registered export notifications from the European Union; and
- publication of the non-confidential EU report on exports and imports of chemicals subject to the PIC Regulation.

In an effort to facilitate procedures for the exporter, ePIC works on the basis of one single reference identification number obtained either by submitting a notification or by submitting a special RIN request. Submission of a notification is mandatory for Annex I Part 1 and Part 2 chemicals and for Annex I Part 3 chemicals for which no import decision exists.

Version 1.1 July 2015

For Annex I Part 3 chemicals for which an import decision that consents to the import is published in the PIC Circular, the option for retrieving the RIN that has to be provided in the customs declaration is the procedure called "special RIN request". A special RIN request should also be made for all exports falling under the Article 2 (3) exemption, i.e. chemicals exported for the purpose of research or analysis in quantities of 10 kg or less from each exporter to each importing country per calendar year.

In certain cases the use and terminology of the reference identification numbers in the ePIC application is for practical reasons different from that in the PIC Regulation. The details are as follows:

- the reference identification number mentioned in the Regulation is commonly referred to as the RIN and is obtained when submitting an export notification or a special RIN request;
- the reference identification number for an explicit consent/waiver mentioned in the Regulation is the unique identifier used in ePIC for each explicit consent and waiver. There is no need to provide this number in the customs declaration.

8. EXAMPLES

This section provides practical examples that outline the steps to be taken by exporters in a number of possible scenarios.

<u>Example 1</u> outlines several requirements concerning the information to be provided in customs declarations and to DNAs, as well as packaging and labelling obligations that must be respected whenever Annex I chemicals are exported. To avoid repetition, these requirements are not detailed in full after <u>Example 1</u> but simply referenced.

First, an exporter of an Annex I chemical will be allocated a RIN by ePIC and must include this number in his customs declaration. Secondly, during the first quarter of the following year the exporter must report to his DNA the quantities of:

- Annex I chemicals,
- certain mixtures containing Annex I substances
- certain articles containing substances listed in Parts 2 or 3 of Annex I,

which the exporting company has shipped pursuant to the PIC Regulation. Furthermore, the exporter must also report the names and addresses of each importer to whom the shipment was made.

Finally, exporters of all chemicals must package and label their products according to EU legislation, unless those EU provisions would conflict with any specific requirements of the importing country.

In addition, an SDS must be sent to each importer. The information in the SDS must (insofar as possible) be provided in the official language(s), or in one or more of the principal languages, of the country of destination or of the area of intended use (see Appendix 4 to this guidance document for a list of official and principal other languages for SDSs and labelling of exports to certain countries). It is also strongly recommended that the exporter attach an English-language version of the SDS (if available) when creating an export notification to facilitate processing of the notification by ECHA.

Example 1

An exporter in one of the EU Member States intends to export for the first time hexachloroethane to country A.

Hexachloroethane is listed in Part 1 of Annex I to the PIC Regulation, as it is severely restricted for industrial use.

- The exporter creates and submits an export notification via ePIC, supplying the information set out in Annex II to the Regulation to his DNA at least 35 days before the export. ePIC assigns the export notification an inactive RIN.
- The exporter provides an English version of the SDS when creating th export notification to facilitate processing of the notification by ECHA and the DNA.
- The DNA checks the export notification. As the notification is considered to be complete, the DNA forwards it to ECHA for further processing and (presumed) acceptance.

- Having verified that no EU export notification has already been made for that calendar year, ECHA sends the notification to country A.
- The exporter is informed by ePIC that the export notification has been processed and that the RIN will be activated (i.e. export can take place) as from the expected date of export which was declared on the export notification. This RIN must be included in the customs declaration together with the corresponding TARIC certificate code.
- The chemical is packaged and labelled as if it were to be marketed in the EU, as it has been established that the importing country does not have its own specific requirements. The exporter sends an SDS in the official language of Country A (whose official language is not English) to the importer.
- The information on the label is also provided in the official language used by country A (see Appendix 4 for further guidance on languages).
- The expiry and production dates are indicated on the label, which also contains specific information on storage conditions and stability under the climatic conditions of country A. The chemical is not exported later than six months before the expiry date.
- During the first quarter of the next year, the exporter informs his DNA of the quantities of the chemical shipped to country A during the preceding year.

Company "Chemoproducts" wants to export boron trichloride to country B.

Boron trichloride is not listed in Annex I to the Regulation, but it is classified as hazardous according to Annex VI of Regulation (EC) 1272/2008 (the CLP Regulation).

- The exporter does not need to provide any information to his DNA. The export may take place without export notification or consent from the importing country.
- The requirements relating to packaging and labelling of exports, the expiry date of the chemicals and provision of SDSs apply.

Example 3

"ABC Chemicals" intends to export chloroform to country C.

Chloroform is listed in Part 1 of Annex I to the PIC Regulation and has been exported to country C by another company earlier in the year, but was never exported by "ABC Chemicals" before.

- The exporter must submit an export notification supplying the information set out in Annex II to the PIC Regulation to his DNA at least 35 days before the export.
- After having saved and submitted the export notification, the exporter gets the RIN, which is not activated at this stage.
- Having established that the export notification is complete and correct the DNA forwards the export notification to ECHA for further processing. ECHA checks the notification and approves it, which activates the RIN for the export as from the expected date of export. Given that an EU export notification has already been made for that calendar year, the export notification is stored in ePIC without being sent to the importing country.

 The requirements relating to the information to be provided in customs declarations and to the relevant DNA, as well as to packaging and labelling of exports, the expiry date, the provision of SDSs and obligation to report on quantities of the chemical shipped to country C during the preceeding year apply, as outlined in Example 1.

Example 4

Company "LongShip" intends to export PCTs to country D, which is a Party to the Convention.

PCTs are subject to the PIC procedure under the Rotterdam Convention and therefore listed in Parts 1 and 3 of Annex I to the Regulation. Country D has reported an import decision in the latest update of the PIC Circular, giving consent.

- The exporter does not need to submit an export notification and can proceed with the export provided that the expected use in the importing country corresponds to the category for which the substance was listed in Annex III to the Convention.
- The exporter must submit a special RIN request to his DNA. Once it has been approved, the exporter will be provided with a RIN which he can add to his customs declaration.
- The requirements relating to the information to be provided in customs declarations and to the relevant DNA, as well as to packaging and labelling of exports, the expiry date, the provision of SDSs and obligation to report on quantities of the chemical shipped to country D during the preceding year apply, as outlined in Example 1.

Example 5

Company "KillingPest", based in one of the EU Member States, intends to import parathion from country E to produce a pesticide, and then export the mixture to country F.

Parathion is banned in the EU for use as a pesticide (both as plant protection product and as biocide). The substance is listed in Part 1 of Annex I to the PIC Regulation as well as Part 3 (being subject to the PIC procedure in the pesticides category). In the latest PIC Circular the import decision for the EU is 'no consent' for the pesticide use category. The import decision for country F is 'consent'.

- Notwithstanding the EU import decision, the company may import the substance for industrial processing to produce a pesticide as this will not be marketed within the EU.
- Since country F has given consent to import, the export may proceed. There is no need for an export notification.
- The exporter must submit a special RIN request to his DNA. Once it has been approved, the exporter will be provided with a RIN which he can add to his customs declaration.
- The requirements relating to the information to be provided in customs declarations and to the relevant DNA, as well as to packaging and labelling of exports, the expiry date, the provision of SDSs and obligation to report on quantities of the chemical shipped to country F during the preceding year apply, as outlined in Example 1. In addition the company must report the quantity of the chemical imported.
- The size and packaging of containers are optimised to minimise the risks of creating obsolete stocks.

An exporter wishes to export for the first time chlordimeform to country G, which is a Party to the Convention.

Chlordimeform is listed in parts 1 and 3 of Annex I to the PIC Regulation since it is subject to the PIC procedure in the pesticide category. No import decision for country G is listed in the latest PIC Circular.

- The exporter must submit an export notification supplying the information set out in Annex II to the PIC Regulation to his DNA at least 35 days before the export.
- After having saved and submitted the export notification, the exporter gets the RIN, which is not yet active at this stage.
- The export cannot proceed unless the DNA in country G has given its explicit consent to import of chlordimeform. The exporter's DNA establishes from ePIC that no such consent already exists. The exporter's DNA will have to seek this consent from the DNA in country G (the Commission is ready to help if needed).
- No response was received within 30 days and ECHA sent a reminder. In the absence of a response within a further 30 days, ECHA sent a further reminder.
- Despite all reasonable efforts, no response was received within 60 days.
- The exporter's DNA in consultation with the Commission assisted by ECHA decides that the export can proceed as there is no evidence from official sources of final regulatory action to ban or severely restrict the use of chlordimeform taken by country G, and one of the following conditions is met:
 - a) there is documentary evidence that chlordimeform is licensed, registered or authorised in country G for pesticidal use, or
 - b) the intended use declared by the exporter in the export notification and confirmed in writing by the importer from country G is not a category for which chlordimeform is listed in Part 2 or 3 of Annex I, and there is evidence from an official source that chlordimeform has in the last five years been used in or imported into country G.
- As authorisation for exports can only be granted for a maximum period of 12 months, upon expiry of this period explicit consent from country G will have to be requested again. The conditions outlined in this paragraph also apply to Example 7
 below.
- Depending on the final result of the request for explicit consent procedure, the export may be allowed and the RIN may be activated by ECHA. Otherwise the RIN will remain inactive.
- Annual export notification by the exporter will continue to be required, even if explicit consent is obtained, unless country G waived its right to receive such notifications.
- Should the export proceed, either under an explicit consent or under a waiver, the requirements relating to the information to be provided in customs declarations and to the relevant DNA, as well as to packaging and labelling of exports, the expiry date, the provision of SDSs and obligation to report on quantities of the chemical shipped to country G during the preceding year apply, as outlined in Example 1.
 - The size and packaging of containers are optimised to minimise the risks of creating obsolete stocks.

Company "Buy and Sell" wants to export for the first time a pesticide containing nitrofen to country H.

Nitrofen is listed in Parts 1 and 2 of Annex I to the Regulation. It is banned for plant protection use within the EU and the relevant regulatory action has been notified to the PIC Secretariat. Country H is a Party to the Convention. However since the chemical is not subject to the PIC procedure, no import decision for the chemical exists.

- The exporter submits an export notification supplying the information set out in Annex II to the PIC Regulation to his DNA at least 35 days before the export.
- After having saved and submitted the export notification, the exporter receives the RIN, which is not yet activated at this stage.
- As with <u>Example 6</u> above, the export cannot proceed unless the DNA in country H has given its explicit consent to importing nitrofen. The difference in this case is that, since the chemical is not subject to the PIC Procedure, an import decision has certainly not been published in the latest PIC Circular. The same conditions as outlined in <u>Example 6</u> apply, including the requirement to seek explicit consent, the possibility of requesting a time-limited waiver, and the need for explicit consent thereafter.
- Depending on the final result of the request for explicit consent procedure, the export may be allowed and the RIN may be activated by ECHA. Otherwise the RIN will stay inactive.
- Should the export proceed, the requirements relating to the information to be provided in customs declarations and to the relevant DNA, as well as to packaging and labelling of exports, the expiry date, the provision of SDSs and obligation to report on quantities of the chemical shipped to country H during the preceding year apply, as outlined in Example 1.
 - The size and packaging of containers are optimised to minimise the risks of creating obsolete stocks.
 - Annual export notification by the exporter will continue to be required, even if explicit consent is obtained, unless country H waived its right to receive such notifications.

Example 8

Company "Exterminator" wishes to export dimethenamid to country M, which is an OECD country.

Dimethenamid is banned in the EU for use as a pesticide. It is listed in Parts 1 and 2 of Annex I to the Regulation and therefore, explicit consent from the importing country would normally be required. Since the chemical is not subject to the PIC procedure, no import decision for the chemical exists.

- The exporter must submit an export notification supplying the information set out in Annex II to the PIC Regulation to his DNA at least 35 days before the export.
- After having saved and submitted the export notification to the DNA, the exporter gets the RIN, which is not yet activated at this stage.
- As DNA considers the export notification complete and correct, it is forwarded to ECHA for further processing and (eventual) acceptance. If the notification is correct and no EU export notification has been made yet for that calendar year, ECHA

- forwards it to country M. If the export notification has already been made for that year, the export notification is stored in ePIC without being sent.
- Dimethenamid is listed in part 2 of Annex I and consequently the export cannot proceed unless explicit consent to import has been sought and received.
- However, since the country M is an OECD country, the exporter may consider applying for a waiver and may, therefore, provide documentary evidence that the substance is licensed, registered or authorised in country M.
- Provided that this evidence was presented, the DNA may decide in consultation with the Commission that the export can proceed without the explicit consent of the importing country.
- Where the DNA, in consultation with the Commission, decides that explicit consent to import is required, it must be obtained from the DNA in country M, as per <u>Example 7</u> above.
- Depending on the final result of the request for explicit consent procedure, the export may be allowed and the RIN may be activated by ECHA. Otherwise the RIN will stay inactive, if no reply is received.
- The requirements relating to the information to be provided in customs declarations and to the relevant DNA, as well as to packaging and labelling of exports, the expiry date, the provision of SDSs and obligation to report on quantities of the chemical shipped to country M during the preceding year apply, as outlined in Example 1.
 - The size and packaging of containers are optimised to minimise the risks of creating obsolete stocks.
 - Annual export notification by the exporter will continue to be required, even if explicit consent is obtained, unless country M waives its right to receive such notifications.

Company "XYZ" intends to export 1,2-dibromoethane (EDB) to country J for industrial use.

EDB is listed in Parts 1 and 3 of Annex I to the Regulation. It is banned for plant protection use within the EU and is listed in the PIC procedure in the pesticides category. In the latest PIC Circular the import decision for country J is 'consent' for use as a pesticide.

- Since the substance is subject to the PIC procedure for pesticide use but not for industrial use, country J has not established a decision giving consent to import of EDB for industrial uses. Consequently, the exporter must submit an export notification and must obtain explicit consent to import for industrial use. In order to do so, the same procedure as outlined in Examples 6 or 7 should be followed.
- The requirements relating to the information to be provided in customs declarations and to the relevant DNA, as well as to packaging and labelling of exports, the expiry date, the provision of SDSs and obligation to report on quantities of the chemical shipped to country J during the preceding year apply, as outlined in Example 1.

Example 10

Company "Pest Products" intends to export "Fungicide X" - a fungicide mixture containing pentachlorophenol (60% active ingredient) to country K.

Pentachlorophenol is listed in Parts 1 and 3 of Annex I to the PIC Regulation, being subject to the PIC procedure in the pesticides category. Country K is not a Party to the Convention so there are no import decisions for that country listed in any PIC Circular. Another EU company has exported another mixture (with 30% pentachlorophenol) earlier in the year having

obtained through his DNA the explicit consent of country K's authorities. The explicit consent does not cover all mixtures containing pentachlorophenol, only that particular mixture.

- The exporter must submit an export notification supplying the information set out in Annex II to the Regulation to his DNA at least 35 days before the export. This will be forwarded to ECHA, who will submit it as an EU export notification.
- However, the export cannot proceed until the appropriate authorities in country K give a further explicit consent in respect of "Fungicide X" since the existing explicit consent was limited to a different formulation. To obtain such consent, the same procedure as outlined in Examples 6 or Texamples 6
- The requirements relating to the information to be provided in customs declarations and to the relevant DNA, as well as to packaging and labelling of exports, the expiry date, the provision of SDSs and obligation to report on quantities of the chemical shipped to country K during the preceding year apply, as outlined in Example 1.
 - The size and packaging of containers are optimised to minimise the risks of creating obsolete stocks.

Example 11

Company "Laboratory Analysis Products" intends to export 100g of nitrofen for use in analysis in a laboratory to country L.

Nitrofen is listed in Parts 1 and 2 of Annex I to the Regulation, and therefore explicit consent from the importing country would normally be required. Since the quantity of nitrofen intended to be exported in 2015 to country L is less than 10 kg and not considered likely to affect health or the environment as it is used under laboratory conditions for analysis, the export falls under Article 2 (3) of the PIC Regulation and is therefore exempted from its provisions.

However, a special RIN request must be submitted in order to obtain a RIN which will be used for customs clearance.

- The exporter submits (via ePIC) a special RIN request to his DNA before the export is intended to take place.
- After approval by the DNA, the exporter is provided with an active RIN.
- The exporter includes the RIN in his customs declaration.

Appendix 1: Annex V to Regulation (EU) No 649/2012

CHEMICALS AND ARTICLES SUBJECT TO EXPORT BAN

(referred to in Article 15)

Annex V Part 1 - Persistent organic pollutants (POPs) as listed in Annexes A and B of the Stockholm Convention on Persistent Organic Pollutants according to the provisions thereof.

For the current list, see the following page on ECHA's website:

http://echa.europa.eu/information-on-chemicals/pic/chemicals

(Select the tick-box "Annex VI part 1" and accept the legal notice)

Annex V Part 2 - Chemicals other than persistent organic pollutants as listed in Annexes A and B of the Stockholm Convention on Persistent Organic Pollutants according to the provisions thereof.

For the current list, see the following page on ECHA's website:

http://echa.europa.eu/information-on-chemicals/pic/annex-v-part-2

Appendix 2: Overview of exporters' main tasks in order to comply with Regulation (EU) No 649/2012

- 1. To notify their DNA (i.e. the relevant DNA of the Member State in which they are established) no later than 35 days prior to the first export of any chemical (either as substance itself or in mixture) listed in Part 1 of Annex I; to also notify no later than 35 days prior to the first export in each subsequent calendar year (Article 8), unless the conditions for waiving this obligation are fulfilled;
- 2. To notify their DNA within the same time limits prior to the first export of any article containing in unreacted form a chemical listed in Part 2 or 3 of Annex I; and the first export in each subsequent calendar year (Articles 15 (1) and 8 refer), unless conditions for a waiver are fulfilled;
- **3.** To respect the import responses of importing countries in relation to PIC chemicals listed in Part 3 of Annex I (Article 14 (4));
- **4.** Not to export chemicals and articles listed in Annex V (Article 15 (2)), unless such chemicals fall under the provisions of Article 2 (3) of the PIC Regulation (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). It should also be stressed that certain chemicals listed in Annex V Part 2 can be exported under specific conditions related to their use or concentration.
- **5.** Not to proceed with exports of chemicals (either as substances or in mixtures) listed in Parts 2 or 3 of Annex I without obtaining an authorisation from their DNA. This authorisation may be based on the explicit consent of the DNA/appropriate authority of the importing country or on the application of a waiver pursuant to Article 14 of Regulation (EU) 649/2012;
- **6.** To include the relevant (i.e. standard or special) reference identification number (RIN) in the customs declaration for the export box 44 of the Single Administrative Documents or corresponding data element in an electronic export declaration (Article 19 (1));
- **7.** To indicate the respective CUS number (Customs union and statistics number, identifier of the European Customs Inventory of Chemical Substances) and Combined Nomenclature Code on customs declarations;
- **8.** To provide to their DNA any information required by an importing Party to the Convention no later than 30 days before the first transit movement of a chemical listed in Part 3 of Annex I takes place and no later than eight days before each subsequent transit movement (Article 16);
- **9.** To ensure that all exported hazardous chemicals and mixtures are packaged and labelled in accordance with the provisions on packaging and labelling established in, or pursuant to the CLP Regulation, REACH Regulation, Biocidal Products Regulation or any other relevant EU legislation (Article 17 (1));
- **10.** Where appropriate, to indicate expiry and production dates on the label (Article 17 (2));
- **11.** Insofar as possible, to ensure that the information on the label and on the safety data sheet (SDS) is given in the official language(s), or in one or more of the principal languages of the importing country (Article 17 (4));

- **12.** To provide an SDS to each importer (Article 17 (3)). Insofar as possible, the information in the SDS should be given in the official/principal language(s) of the importing country;
- 13. Not to export chemicals later than six months before their expiry date, where applicable. In the case of pesticides, to ensure that the size and packaging of containers is such as to minimise risks of creating obsolete stocks. In addition, to include on the label appropriate information on storage conditions and stability. The purity specifications laid down in EU legislation must be respected (Articles 14 (10) and 14 (11));
- **14.** To provide on request the importing countries with available additional information on exported chemicals (Article 8 (7));
- **15.** Before 31 March of each year, to submit to their DNA an annual report for the preceding year on quantities of chemicals listed in Annex I exported from that Member State (similar obligation imposed on importers as regards imports). Exports made under waivers pursuant to Article 14 (7) are to be listed separately. Any additional necessary information also has to be provided upon request (Article 10);
- **16.** Where a chemical qualifies for PIC notification, but information is insufficient to meet the requirements of Annex IV, to provide all relevant available information to the Commission upon request within 60 days of the request (similar obligation imposed on importers) (Article 11 (4)).

Appendix 3: Examples of evidence that can justify the granting of a waiver to the requirement for explicit consent

Article 14 (7) provides for the granting of a waiver to the requirement for explicit consent in cases where, despite all reasonable efforts, no response is received to a request for explicit consent within a 60 day period. The decision to grant such a waiver must be based on evidence that the chemical is licensed, registered or authorised for use in the importing country. To provide guidance on what types of evidence may be used, examples drawn from experience and practice to date are identified below:

1. Registration certificate confirming that the chemical is authorised in the importing country

These certificates normally apply to pesticides. There are a number of different possibilities under this example since registration certificates can contain different conditions. The registration always relates to a specific active substance or mixture from a defined company, but sometimes the certificate is in the name of a local manufacturer only. In other instances it may specify not only a named foreign manufacturer but also a specific country of origin. Practice to date on how such registrations should be treated for the purposes of explicit consent has varied.

One Member State had accepted a registration of a specific mixture or named foreign manufacturer as explicit consent and posted the information on the Database as consent for that mixture (and concentration of the Annex I substance) without qualification. Another Member State had taken the view that as such registrations are limited to a particular source only; though they may have been accepted as explicit consent for that source, such information had not been listed on the Database and the requests were not listed at all or shown as 'pending'.

The latter approach could be considered to lack transparency and create a misleading picture of the situation. DNAs have agreed that such cases should be listed (if necessary with the identity of the exporter and the mixture name protected, if commercial confidentiality needs to be preserved). Such listings already occur for other similar cases where 'consent' is not generally applicable such as those where consent is limited to a specific shipment. DNAs also agreed that where the registration certificate is company-specific, this should be expressly stated in the Database listing so that it would be clear to all that the consent is not valid for other exporters.

For such certificates to be deemed a valid justification for granting a waiver to the requirement for explicit consent, the Annex I chemical(s) triggering the request for explicit consent should be explicitly mentioned in the registration document or certificate. Alternatively, if that is not the case (e.g. because the chemical concerned is not the active ingredient), there should be evidence provided by the exporter or importer demonstrating that the authority providing registration of the mixture was aware or actively informed that the mixture contains an Annex I chemical(s) (e.g. it is identified in the submitted registration application and supporting documents such as the relevant SDS, etc.).

In this regard particular care should be taken with so-called 'hygiene certificates' that are sometimes issued by the health authorities in importing countries, since 'hygiene certificates' may only confirm the conformity of production or product with certain sanitary requirements, without checking whether the chemical ingredients are specified and authorised.

2. Import licence issued for the chemical/mixture

One Member State reported a case that has many parallels with registration certificates. Since the licence was restricted to a named source of supply, it had elected to accept the licence as evidence that the chemical was used in the importing country, but not to post the information in the Database. The same approach should be followed as with registration certificates, i.e. that such cases should be listed in the Database and that in cases where the licence was company-specific this should be expressly mentioned in the Database listing so that it would be clear to all that the consent does not extend to other exporters.

In determining whether to accept such import licences as evidence upon which a decision to grant a waiver to the requirement for explicit consent can be based, DNAs should follow the same approach as that outlined above for registration certificates.

3. Statement from the importing country that the chemical is not subject to the PIC procedure and therefore no consent is required

In cases where, in response to a request for consent, the importing country has elected not to exercise its option to refuse import or impose any conditions but simply replied that none was needed as the chemical was not a PIC chemical, this can be interpreted as explicit consent provided that the exchanges are in writing.

4. Statement from the importing country that the chemical is not subject to any restrictions and that it can thus be imported without any requirements

In cases where, in response to a request for consent, the importing country has elected not to exercise its option to refuse import or impose any conditions but simply replied that the use of the chemical is not restricted in the importing country and that, therefore, imports can proceed without any requirements or with customs formalities only, this can be interpreted as explicit consent provided that the exchanges are in writing.

Appendix 4. List of official and principal other languages for SDSs and labelling of exports to certain countries

Country	Official language	Principal other languages used in international communication
Afghanistan	Pashto, Afghan Persian, Dari	English
Albania	Albanian	English
Algeria	Arabic	French
Andorra	Catalan	Spanish, French, Portuguese
Angola	Portuguese	French
Antigua and Barbuda	English	
Argentina	Spanish	English, Italian, German, French
Armenia	Armenian	English, Russian
Australia (and External Territories)	English	
Azerbaijan	Azerbaijani (Azeri)	English, Russian
Bahamas	English	
Bahrain	Arabic	English
Bangladesh	Bangla (Bengali)	English
Barbados	English	
Belarus	Belarussian, Russian	English, Polish
Belize	English	Spanish
Benin	French	
Bhutan	Dzongkha	English
Bolivia	Spanish, Quechua, Aymara	English
Bosnia and Herzegovina	Bosnian, Croatian, Serbian	
Botswana	English	
Brazil	Portuguese	English, Spanish

Brunei Darussalam	Malay	English
Burkina Faso	French	
Burundi	French, Kirundi	
Cambodia	Khmer	English, French
Cameroon	English, French	
Canada	English, French	
Cape Verde, Republic of	Portuguese	French
Central African Republic	French	
Ceuta, Melilla	Spanish	
Chad	French, Arabic	
Chile	Spanish	English, German
China (People's Republic of)	Standard Mandarin Chinese	English
Colombia	Spanish	English
Comoros	Arabic, French	
Congo (Republic of)	French	
Cook Islands	English, Cook Islands Maori (Rarotongan)	
Costa Rica	Spanish	English
Côte d'Ivoire	French	
Cuba	Spanish	English
Curação	Papiamentu, Dutch	
Democratic People's Republic of Korea	Korean	English
Democratic Republic of Congo	French	
Djibouti	French, Arabic	
Dominica	English	
Dominican Republic	Spanish	English
Ecuador	Spanish	English
Egypt	Arabic	English, French

El Salvador	Spanish	English
Equatorial Guinea	Spanish	French
Eritrea	Arabic, Tingrinya, English	
Ethiopia	Amharic, Arabic, English	French
Federated States of Micronesia	English	
Falkland Islands	English	
Faroe Islands	Faroese, Danish	
Fiji	English, Fijian	
French Polynesia	Polynesian, French	
Gabon	French	
Gambia	English	
Georgia	Georgian	English, Russian
Ghana	English	
Greenland	Greenlandic (East Inuit), Danish	English
Grenada	English	
Guatemala	Spanish	English
Guinea	French	
Guinea-Bissau	Portuguese	French
Guyana	English	
Haiti	French, Creole	English
Honduras	Spanish	English
Hong Kong	Cantonese, English	
Iceland	Icelandic	English
India	Hindi, English	
Indonesia	Bahasa Indonesia	English, Dutch
Iran	Persian	English, French
Iraq	Arabic, Kurdish	English

Israel	Hebrew	English
Jamaica	English	
Japan	Japanese	English
Jordan	Arabic	English
Kazakhstan	Kazakh, Russian	English
Kenya	Kiswahili, English	
Kiribati	English	
Korea, Democratic People's Republic of	Korean	
Korea, Republic of	Korean	English
Kosovo (under UNSCR 1244/99)	Albanian, Serbian	English
Kuwait	Arabic	English
Kyrgyzstan	Kyrgyz, Russian	English
Laos	Lao	English, French
Lebanon	Arabic	French, English
Lesotho	Sesotho, English	
Liberia	English	
Libya	Arabic	English
Liechtenstein	German	French
Macedonia	Macedonian, Albanian	English
Madagascar	French, Malagasy	English
Malawi	English, Chichewa	
Malaysia	Bahasa Malaysia	English
Maldives	Dhivehi	English
Mali	French	
Marshall Islands	Marshallese, English	
Mauritania	Arabic	French
Mauritius	English	
·	·	

Mexico	Spanish	English
	Moldovan	
Moldova, Republic of		English, Russian
Monaco	French	English, Italian
Mongolia	Khalkha Mongol	English, Russian
Montenegro	Montenegrin	English
Morocco	Arabic, Tamazight	French
Mozambique	Portuguese	English
Myanmar	Burmese	English
Namibia	English	German
Nauru	Nauruan	English
Nepal	Nepali	English
New Caledonia	French	
New Zealand (and Associated Territories)	English, Maori, New Zealand Sign Language	
Nicaragua	Spanish	English
Niger	French	
Nigeria	English	
Norway (and Dependency)	Norwegian	English
Oman	Arabic	English
Pakistan	Urdu, English	
Palestine, State of	Arabic	English
Panama	Spanish	English
Papua New Guinea	Tok Pisin, Hiri Motu	English
Paraguay	Spanish, Guarani	English
Peru	Spanish, Quechua, Aymara	English
Philippines, Republic of the	Tagalog (Philipino), English	
Puerto Rico	Spanish, English	
Qatar	Arabic	English

Russian Federation	Russian	English
Rwanda	Kinyarwanda, French, English	
Saint Kitts and Nevis	English	
Saint Lucia	English	
Saint Vincent and The Grenadines	English	
Samoa	Samoan	English
San Marino	Italian	French, English
Sao Tome and Principe	Portuguese	French
Saudi Arabia	Arabic	English
Senegal	French	
Serbia	Serbian	English
Seychelles	English, Creole, French	
Sierra Leone	English	
Singapore	Mandarin, Malay, Tamil, English	
Sint Maarten	Dutch, English	French, Spanish
Solomon Islands	Melanesian pidgin, English	
Somalia	Somali, Arabic	English, Italian
South Africa	IsiZulu, Afrikaans, English	
Sri Lanka	Sinhala	English
Sudan	Arabic, English	
Suriname	Dutch	English
Swaziland	Siswati, English	
Switzerland	French, German, Italian	English, Portuguese, Spanish
Syrian Arab Republic	Arabic	English, French
Taiwan	Mandarin Chinese	English
Tajikistan	Tajik	English, Russian
Tanzania, United Republic of	Swahili, English	

Thailand	Thai	English
Togo	French	
Tonga	Tongan, English	
Trinidad and Tobago	English	French, Spanish
Tunisia	Arabic	French
Turkey	Turkish	English
Turkmenistan	Turkmen	English, Russian
Tuvalu	Tuvaluan, English	
Uganda	English	
Ukraine	Ukrainian	English, Polish, Russian
United Arab Emirates	Arabic	English
United States of America (and External Territories)	English	
Uruguay	Spanish	English
Uzbekistan	Uzbek	English, Russian
Vanuatu	Bislama, English, French	
Vatican City State (Holy See)	Italian, Latin	
Venezuela, Bolivarian Republic of	Spanish	English
Vietnam	Vietnamese	English, French
Wallis and Futuna Islands	French	
Yemen	Arabic	English
Zambia	Bemba, English	
Zimbabwe	English	

Appendix 5. The customs territory of the Union⁵²

The territorial scope of the PIC Regulation is the Union territory, but the import and export concepts and subsequent obligations are related to the customs territory of the Union.

The customs territory of the Union comprises the territories listed in Article 3 of the Regulation (EEC) No 2913/92 establishing Community Customs Code:

- 1) The customs territory of the Union shall comprise the following territories, including their territorial waters, internal waters and airspace:
 - the territory of the Kingdom of Belgium,
 - the territory of the Republic of Bulgaria,
 - the territory of the Czech Republic,
 - the territory of the Kingdom of Denmark, except the Faroe Islands and Greenland,
 - the territory of the Federal Republic of Germany, except the Island of Heligoland and the territory of Büsingen (Treaty of 23 November 1964 between the Federal Republic of Germany and the Swiss Confederation),
 - the territory of the Republic of Estonia,
 - the territory of Ireland,
 - the territory of the Hellenic Republic,
 - the territory of the Kingdom of Spain, except Ceuta and Melilla,
 - the territory of the French Republic, except the French overseas countries and territories to which the provisions of Part Four of the TFEU apply,
 - the territory of the Republic of Croatia,
 - the territory of the Italian Republic, except the municipalities of Livigno and Campione d'Italia and the national waters of Lake Lugano which are between the bank and the political frontier of the area between Ponte Tresa and Porto Ceresio,
 - the territory of the Republic of Cyprus, in accordance with the provisions of the 2003 Act of Accession,
 - the territory of the Republic of Latvia,
 - the territory of the Republic of Lithuania,
 - the territory of the Grand Duchy of Luxembourg,
 - the territory of Hungary,

⁵² Please refer to Article 52 of TEU, Article 355 of TFEU and Article 3 of CCC. See also Article 4 of the Union Customs Code (UCC) which will come into force on 1 May 2016 (Regulation (EU) No 952/2013 (OJ L 269, 10.10.2013).

- the territory of Malta,
- the territory of the Kingdom of the Netherlands in Europe,
- the territory of the Republic of Austria,
- the territory of the Republic of Poland,
- the territory of the Portuguese Republic,
- the territory of Romania,
- the territory of the Republic of Slovenia,
- the territory of the Slovak Republic,
- the territory of the Republic of Finland,
- the territory of the Kingdom of Sweden, and
- the territory of the United Kingdom of Great Britain and Northern Ireland and of the Channel Islands and the Isle of Man.
- 2) The following territories, including their territorial waters, internal waters and airspace, situated outside the territory of the Member States shall, taking into account the conventions and treaties applicable to them, be considered to be part of the customs territory of the Union:

a) FRANCE

The territory of Monaco as defined in the Customs Convention signed in Paris on 18 May 1963 (Journal officiel de la République française (Official Journal of the French Republic) of 27 September 1963, p. 8679);

b) CYPRUS

The territory of the United Kingdom Sovereign Base Areas of Akrotiri and Dhekelia as defined in the Treaty concerning the Establishment of the Republic of Cyprus, signed in Nicosia on 16 August 1960 (United Kingdom Treaty Series No 4 (1961) Cmnd. 1252).

Appendix 6. Glossary/list of acronyms

BPR Regulation (EU) No 528/2012 of the European

Parliament and of the Council of 22 May 2012

concerning the making available on the market and use

of biocidal products (Biocidal Products Regulation)

C&L Classification and Labelling

CAS Chemical Abstracts Service Registry

CUS number Customs union and statistics number, identifier of the

European Customs Inventory of Chemical Substances

(ECICS) database

CN Combined Nomenclature

CLP Regulation (EC) No 1272/2008 on classification,

labelling and packaging of substances, mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No

1907/2006

CMR a substance or mixture that is carcinogenic, mutagenic

or toxic to reproduction

Convention Rotterdam Convention on the Prior Informed Consent

Procedure for Certain Hazardous Chemicals and

Pesticides in International Trade

COP Conference of Parties to the Rotterdam Convention

CRC Chemical Review Committee of the Rotterdam

Convention

DGD Decision Guidance Document

DNA Designated National Authority

DPD Dangerous Preparations Directive (1999/45/EC)

DSD Dangerous Substances Directive (67/548/EEC)

EC European Community

ECHA European Chemicals Agency

ECICS European Customs Inventory of Chemical Substances

EEC European Economic Community

ePIC IT application for processing and management of legal

requirements of the PIC Regulation

EU European Union

FAO Food and Agriculture Organization of the United Nations

Forum Forum for Exchange of Information on Enforcement

established by Regulation (EC) No 1907/2006

GHS Globally Harmonised System of Classification

and Labelling

Hazard Statement a phrase assigned to a hazard class and category that

describes the nature of the hazards of a hazardous substance or mixture, including where appropriate,

the degree of hazard

MSCA Member State Competent Authority

OECD Organisation for Economic Cooperation and

Development

PBT Persistent, Bioaccumulative, Toxic substances

PCBs Polychlorinated biphenyls

PCTs Polychlorinated terphenyls

PIC Prior Informed Consent

POPs Persistent Organic Pollutants

PPP plant protection product

Precautionary Statement a phrase (according to the CLP Regulation) that

describes recommended measure(s) to minimise or prevent adverse effects resulting from exposure to a

hazardous substance

or mixture due to its use or disposal

REACH Regulation (EC) No 1907/2006 concerning the

Registration, Evaluation, Authoriation and Restriction

of Chemicals

RIN Reference Identification Number

SDS Safety Data Sheet

SHPF severely hazardous pesticide formulation

TARIC Tarif Intégré de la Communauté – i.e.,

Integrated Community Tariff (of the European Union)

UNECE United Nations Economic Commission for Europe

UNEP United Nations Environment Programme

vPvB very Persistent and very Bioaccumulative substances

EUROPEAN CHEMICALS AGENCY ANNANKATU 18, P.O. BOX 400, FI-00121 HELSINKI, FINLAND ECHA.EUROPA.EU