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Standard Operating Procedure for the PIC Content Management

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Executive summary

The Rotterdam Convention that was signed in Rotterdam on 10 September 1998 and entered into force on 24 February 2004 regroups currently 154 Parties. It introduced the Prior Informed Consent (PIC) procedure for certain hazardous chemicals and pesticides in International trade. The convention aims to promote shared responsibility and cooperative effort among Parties in order to protect human health and the environment from potential harm and to contribute to their environmentally sound use, by facilitating information exchange about their characteristics, by providing for a national decision-making process on their import and export and by disseminating these decisions to Parties.

The European Union adopted the Rotterdam Convention by Council Decision 2006/730/EC of 25 September 2006. Furthermore, Regulation (EC) No 689/2008 of the European Parliament and the Council of 17 June 2008 concerning the export and import of dangerous chemicals is the latest in a series of measures over the years that seek to address international trade with dangerous chemicals. This Regulation reaffirms the EU commitment towards ensuring proper control in the trade and use of dangerous chemicals at the global level, based on the principle that it should help to protect human health and the environment beyond its borders as well as within.

Two linked processes were identified as characterising the PIC content management activities. They are analysed separately: the export notifications process and the explicit consents process. The export notifications process aims to identify uniquely the single administrative document clearing customs. The explicit consents process aims to explicitly exchange risk management information, between an exporting designated national authority and an importing one, prior to export of chemicals. Each process is first described. The functionalities supporting the process are listed and explained. The specific implication of the administrator in the process is then identified. Finally the liaison between both processes is analysed.

Several working documents are annexed in order to transparently manage the hand over of the PIC content management activities to the European Chemicals Agency - ECHA.

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I - Introduction

The European Database for the EXport and IMport of (certain) dangerous chemicals (EDEXIM) has been developed by the Institute for Health and Consumer Protection (IHCP) of the Joint Research Centre (JRC) since May 1996. This database implements the Regulation (EC) No 689/2008 concerning the export and import of dangerous chemicals and thus manages its both annexes I (listing of chemicals covered by the provisions of this Regulation relating to export notification, Prior Informed Consent (PIC) notification and the PIC procedure respectively) and V (listing of chemicals and articles subject to export ban). It is a web application programmed by using the hypertext pre-processor PHP scripting language (originally called Personal Home Page) and data are stored into an Oracle database. It delivers five different interfaces: public, customs, exporters, designated national authorities (DNAs) and administrators through any browser. Currently, it is characterised by roughly 183 chemicals directly referred within the Regulation (EC) No 689/2008, 977 substances, 2,798 preparations, 1,250 registered users and 214 importing DNAs: 125 Parties and 89 non-Parties.

EDEXIM is maintained by the IHCP. In addition, it is updated according to the DNA meetings (twice per year) and to the amendments of the Regulation (EC) No 689/2008.

This document focuses on the validation of export notifications of substances and of preparations containing active substances listed in Annex I Part 1, Part 2 and Part 3. Export notification for certain hazardous chemicals and pesticides listed in Annex I of Regulation (EC) No 689/2008 is uniquely identified by its Reference Identification Number (RIN) according to the Regulation. EDEXIM generates randomly and uniquely 10 digits number for each RIN. Export notification has also an Export Reference Number (ERN) inherited from the previous legislation. In the ERN of an export notification of a substance (*e.g.* ../EC/**200-663-8**/**XY**/**2012**), it is possible to identify the following information:

1. the European Inventory of Existing Commercial Chemical Substances (EINECS) number (*e.g.*, **200-663-8**)
2. **XY** stands for the code of importing country (*e.g.*, **AO** for Angola)
3. year of export (*e.g.*, **2012**).

The ERN of a group of chemicals such as Nonylphenol ethoxylates $(C_2H_4O)_nC_{15}H_{24}O$ contains thus the EINECS number followed by the letter **a**. For example, 205-632-2**a** and 236-855-3**a**. Sometimes, the Combined Nomenclature (CN) code can also be used (*e.g.*, 34021300**a**). In case the EINECS does not exist, the Chemical Abstracts Service (CAS) number of the American Chemical Society can thus be used followed by the letter **b**. For example, 82560-54-1**b**, 77536-68-6**b** and 82657-04-3**b**.

According to the chemical, export notification has its validity period within the year of its export date. It is the end of the year for chemicals of Part 1.

After a brief introduction to the main concept of export notifications, the export notification process is analysed separately for the following five cases: **(i)** substances of Part 1; **(ii)** substances of Part 2 & Part 3; **(iii)** preparations containing substances of Part 1; **(iv)** preparations containing substances of Part 2 & Part 3 and **(v)** subsequent notifications. It is followed by the analysis of the explicit consent process. Its ramification with the adequate export notification process is explained either for the cases of substances of Part 2 & Part 3 than for

preparations containing substances of Part 2 & Part 3. The emailing templates for importing country DNA are annexed (see Annexes II and III) as well as the accompanying explanatory note (see Annex V). The forms used for export notification and for explicit consent are annexed as well (see Annexes I and IV respectively).

II – Principles of export notifications

Export notification is created generally by the exporter but can also be created by the designated national authority (DNA). Annex I shows the form for export notification in accordance with Article 12 of the Rotterdam Convention and pursuant to Article 7 and Annex II of the Regulation (EC) 689/2008.

Exporter notifies its (the member State in which he is established) DNA **for the first time** no later than **30 days** before the export of the chemical is due to take place. The notification shall take place no later than 15 days prior to the export in any subsequent calendar year. DNA can also create the export notification on behalf of the exporter. Then it is sent to IHCP. One of the main operation of the IHCP is validating export notifications within the timeframe foreseen by the legislation, *i.e.* at least **15 days** before the exporting date indicated on the notification (see Figure 1a) and thereafter before the export date in any subsequent calendar year (see Figure 1b). The export notification is then saved as pdf file in at least one common language of {EN, ES, FR} according to the importing country. When it is available[1], the IHCP annexes the Safety Data Sheet (SDS) within the same pdf file of the export notification.

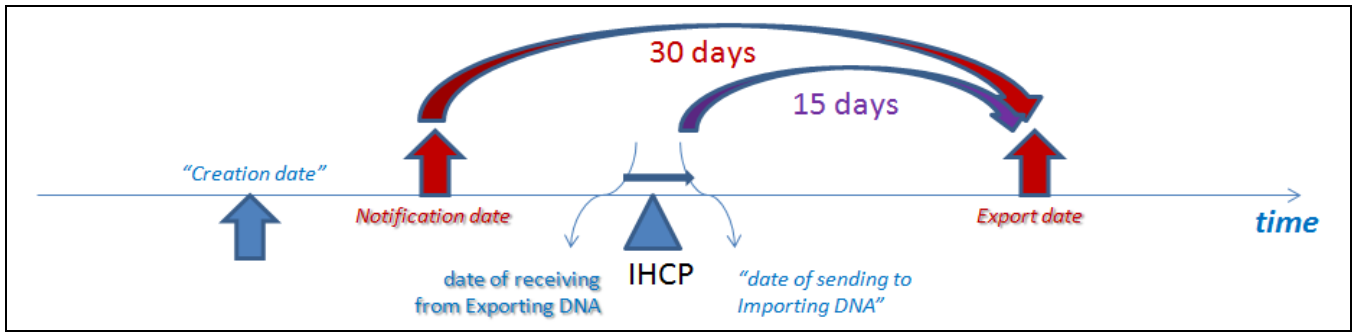

Figure 1a: export notification of a chemical of Annex I from the European Union to an importing DNA for the first time ever

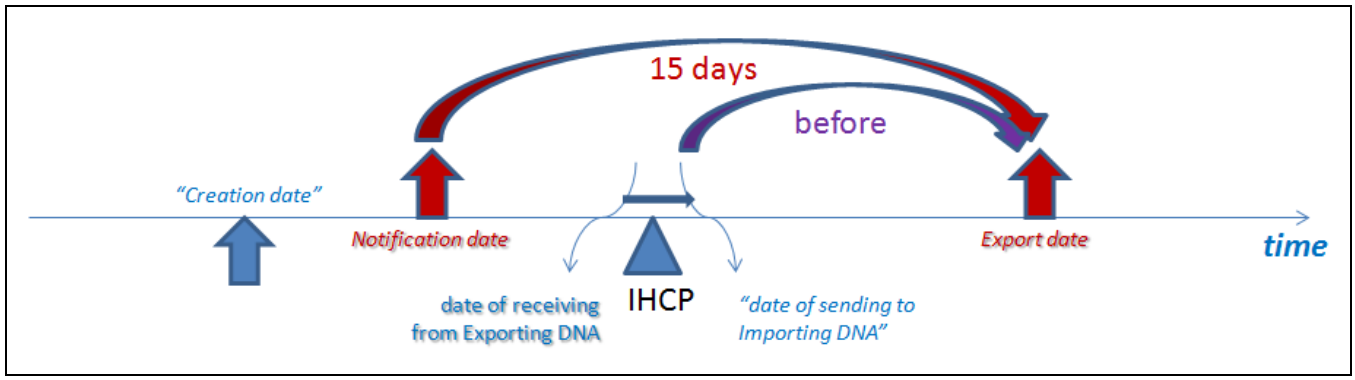

Figure 1b: export notification of a chemical of Annex I from the European Union to an importing DNA in any subsequent calendar year

[1] If the exporter does not provide a SDS the relevant fields within the export notification itself must be filled in with all the required information.

In order to respect the Regulation (EC) 689/2008, and even if EDEXIM does not recognise it automatically, the administrator shall check if an exporter is exporting the considered substance of the preparation to the considered importing country for the **absolute first time since 2003**.

For example, we have five export notifications ERN EC/**P**nnnn/**XY**/**2008**, RIN C6T3R7IHW1 (ERN EC/**P**nnnn/**XY**/**2009**), RIN QT3BDB2MQJ (ERN EC/**P**nnnn/**XY**/**2010**), RIN 5247GIU8LZ (ERN EC/**P**nnnn/**XY**/**2011**) and RIN DG7YK6VNHR (ERN EC/**P**nnnn/**XY**/**2012**) exporting the preparation Alpha , identified as **P**nnnn, containing 4.85% of the active substance Nonylphenol ethoxylates $(C_2H_4O)_nC_{15}H_{24}O$ by Exporter A from an EU member state to the same importing country (encoded as **XY**) in **2008**, **2009**, **2010**, **2011** and **2012** respectively.

These five export notifications are **relative**. They cannot be subsequent according to EDEXIM because they do not occur within the same calendar year. Only for **the absolute first one**, *i.e.* in **2008** the delay between notification and export is **30 days** according to Figure 1a. For all other relative notifications, the delay between notification and export is 15 days according to Figure 1b.

When several export notifications are ready for one importing country, then the IHCP is sending them, together with an explanatory note, to the DNA of the importing country via email. We use a template (see Annex II) for this emailing. In case it is not possible to communicate with the importing country by e-mail, the export notifications can be sent by fax or by post. The IHCP ensures that the DNA of the importing Party receives the notification(s) no later than **15 days** before the **first intended export** of the chemical and thereafter before the first export in any subsequent calendar year.

If the IHCP does not receive from the importing Party or other country an acknowledgement of receipt of the first export notification given after the chemical is included in the Part 1 of Annex I within 30 days of the dispatch of such notification, it shall send the notification for the second time.

III - Export notifications concerning substances of Annex I Part 1

For simplifying the text, we assume the consideration of **absolute first** export notification of (pure) substance/chemical referred to in Annex I from the European Union to an importing DNA. We also assume that the export notification deals with a (pure) substance that listed within Annex I Part 1 (*e.g.*, Chloroform (EC# (also EINECS No) 200-663-8; CAS# 67-66-3 and Index No 602-006-00-4)).

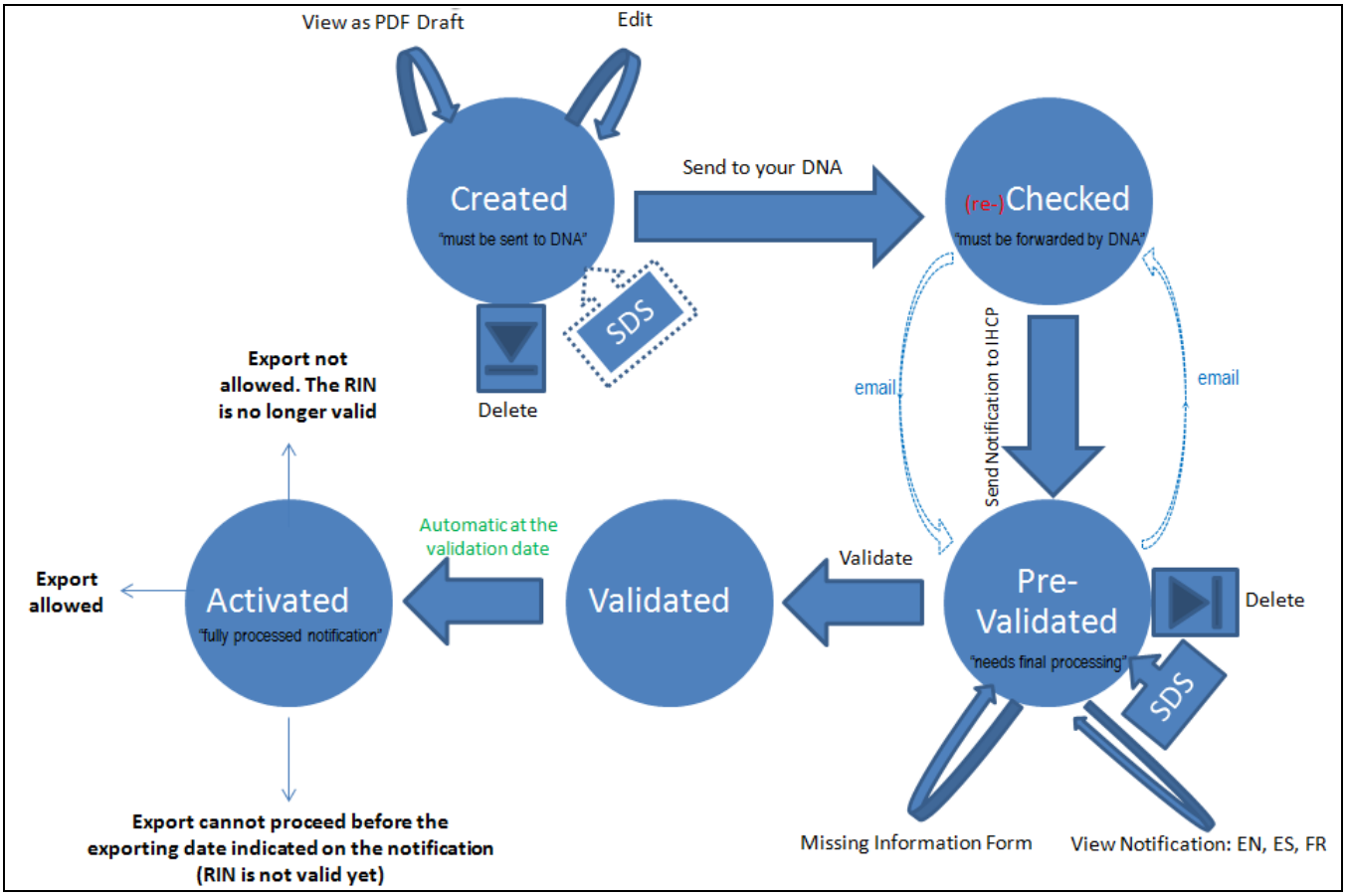

Figure 2: the state-command diagram of the full export notification process for substances in Annex I Part 1

1 - Description of the export notifications process

The export notifications concerning substances of Annex I Part 1 have to go through the following five steps:

1) **Created** by either the exporter or by the DNA of the exporter country: this status can be seen as "must be sent to DNA" within EDEXIM; an associated SDS shall be prepared; the export notification can be edited, viewed and deleted and then it has to be sent to the DNA;
2) **Checked** by the DNA of the exporter country: this status can be seen as "must be forwarded by DNA" within EDEXIM; an email exchanging can take place between the DNA and the IHCP in order to complete this operation and then send the notification to IHCP;

From this step onwards, the IHCP is the main actor of the process. Three main steps can be identified:

3) **Pre-Validated** by the IHCP: this status can be seen as "needs final processing" within EDEXIM; Administrator can exchange emails with the DNA, can view or delete the notification, can attach information in a specific form, visible to the administrator only; administrator must attach the SDS to the export notification before validating it;
4) **Validated** by the IHCP: this status is reachable after the validation;
5) **Activated** by the IHCP: this status can be seen as "fully processed notification" within EDEXIM and is automatically reachable after the validation;

After the validation, the status of an export notification evolves from "Pre-Validated" to "Validated". For Part 1 chemicals, this status (*i.e.*, "Validated") is automatically evolving toward "Activated" directly at the date of validation.

The state-command diagram of the full export notification process for substances in Part 1 is shown in Figure 2.

The workflow of the export notification procedure for Annex I Part 1 chemicals, as from the export date, to all countries pursuant to Article 7 of the Regulation (EC) No 689/2008, is on Figure 3 (Annex 4 to the Communication 2011/C 65/01). The Annex II to Regulation (EC) No 689/2008, referred to within Figure 3, relates to the information required pursuant to Article 7 of the European Regulation (EC) No 689/2008. The notification shall comply with the following twelve requirements (Annex II to Regulation (EC) No 689/2008) pursuant to Article 7:

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 preparation to be exported:
   (a) trade name and/or designation of the preparation;
   (b) for each substance listed in Annex I, percentage and details as specified under item 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 item 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 Rotterdam Convention under which the use falls;
   (f) name, address and other relevant particulars of the importer or importing company;
   (g) name, address and other relevant particulars of the exporter or exporting company.
5. Designated national authorities:
   (a) the name, address, telephone and telex, fax number or e-mail of the designated authority in the European 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 physicochemical, toxicological and ecotoxicological properties.
8. Use of the chemical in the European Union:
   (a) uses, category(ies) under the Rotterdam Convention and Community 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 related to
    (a) information specific to the final regulatory action
       (i) summary of the final regulatory action;
       (ii) reference to the regulatory document;
       (iii) date of entry into force of the final regulatory action;
       (iv) indication of whether the final regulatory action was taken on the basis of a risk or hazard evaluation and, if so, information on such an evaluation, covering a reference to the relevant documentation;

(v) reasons for the final regulatory action relevant to human health, including the health of consumers and workers, or the environment;
(vi) summary of the hazards and risks presented by the chemical to human health, including the health of consumers and workers, or the environment and the expected effect of the final regulatory action;

(b) an indication, to the extent possible, of the likely relevance of the final regulatory action to other States and regions;

(c) other relevant information that may cover:
(i) assessment of socioeconomic effects of the final regulatory action;
(ii) information on alternatives and their relative risks, where available, such as:
— integrated pest management strategies,
— industrial practices and processes, including cleaner technology.

12. Additional information provided by the exporting Party because considered of concern or further information when requested by the importing Party.

2 - EDEXIM functionalities supporting the export notifications process

The export notification form has a standard format (see Annex I). It corresponds to Annex II to the Regulation (EC) 689/2008. It contains twenty nine fields to be filled in: **(i)** three mandatory fields filled in when the chemical is selected, *i.e.* common name, CAS number and EINECS number, **(ii)** other nine mandatory fields, **(iii)** five fields automatically filled in by EDEXIM and **(iv)** twelve fields containing information which is mandatory according to the Regulation but can be left empty in EDEXIM provided a SDS (which typically contains this information) is attached to the notification.

The exporter or the DNA eventually fills in the export notification form. It is composed of two main parts:

1. Form for Export Notification
2. Form for Acknowledging Receipt of Export Notification

The first part defines the export notification while the second one is to be used by the importing DNA to acknowledge receipt of the export notification. We focus on the first part because the acknowledging receipt part that is composed of four fields (*i.e.*, name of the importing country, reference number of the export notification, chemical name and name & address of the exporting party) is completely filled in automatically.

The first part is composed of the following six sections:

1. Identity of the chemical subject to the export notification
2. Information concerning the export
3. Information on hazards and/or risks of the chemical and precautionary measures
4. Information on physico-chemical, toxicological and ecotoxicological properties of the chemical
5. (Summary) information on final regulatory action taken by the exporting party (Country)
6. Designed National Authorities (DNAs)

From the second section onward, the section numbering within the export notification form is increased by 1.

The following twelve fields of the export notifications form are mandatory:

1. Importing Party/Country
2. Common name
3. CAS number
4. EINECS number
5. CN code
6. CUS code
7. Expected date of export, expressed as dd-mm-yyyy
8. Expected amount of the substance/preparation, expressed as a number and a unit to be selected between Kg and l
9. Name, address, **(**telephone, fax and email**)** of the importer. Note that the telephone, the fax and the email are optional

10. Summary of and reasons for the final regulatory action and date of entry into force
11. The final regulatory action has been taken for the category, expressed as a tick box on "Pesticide" or "Industrial chemical''
12. The final regulatory action has been taken for the category, expressed as use(s) prohibited, use(s) that remain allowed and, where available, estimated quantity of the chemical produced, imported, exported and used

The following five fields of export notification form are automatically filled in.

1. Reference Number
2. Exporting Party
3. Identification of the exporter (*i.e.*, Name, address, telephone, fax and email)
4. Identification of the notifying DNA in the exporting Party (*i.e.*, Name, address, telephone, fax and email)
5. Identification of the DNA in the importing Party (*i.e.*, Name, address, telephone, fax and email – based on the availability of this information)

The following twelve fields of the export notifications form are:

1. Chemical name according to an internationally recognized nomenclature
2. Harmonized system customs code
3. Other numbers
4. Foreseen category (industrial chemical or pesticide) and foreseen use in importing country
5. Hazard classification
6. Information on hazards and/or risks
7. Information on precautionary measures to reduce exposure to and emission of the chemical
8. Further information that may be useful to the importing country or has been requested by it
9. Reference (under section 4)
10. Summary information
11. Reference (under section 5)
12. Reference to the regulatory document

The administrator manages the filled in export notification form throughout the following nineteen characteristics fields:

1. ID
2. ERN Reference
3. Export Code, *i.e.* RIN
4. Chemical
5. Einecs
6. Export Date
7. Expected Use
8. Expected Amount
9. Importing Country
10. Created By
11. Date Received By DNA
12. Date Received By EC
13. View Documents
14. DNA Importing Country
15. Importer
16. DNA Exporting Country
17. Exporter
18. Validation period: From
19. Validation period: To

3 - Administrator implication within the export notifications process

The two main functions of the administrator consist of validating and then activating the export notifications.

1) Validating

Validating an export notification consists of checking three main issues: (i) the 'Notification Validation' window; (ii) the export notification and the (iii) SDS. When an export notification is validated by the IHCP, both exporter and exporting DNA are informed by means of an automated e-mail.

1.1 - validating the 'Notification Validation' window

This validation consists of checking the following **five** points:

1) the nineteen elementary fields composing the 'Notification Validation' window are filled in;
2) the substance is listed within Annex I of EDEXIM according to the latest amendment in force but not listed within Annex V of EDEXIM;
3) the content of the 'Export Date' field shall be at least 15 days greater than the content of the 'date Received By EC' field;
4) sending the export notification to the importing DNA shall be within the maximum duration of 15 days, when possible, after the reception of complete notification;

N.B. for the **absolute first export** of one chemical (*e.g.*, Chloroform) from an exporter (*e.g.*, Exporter B) from an EU member state to an importing country starting from 2008, the total duration of **30 days** between the date of notifying the export notification (from the exporter to the designated national authority of the Member State in which it is established) and the date of export (see Figure 1a) shall be strictly respected.

5) both fields of 'DNA Importing Country' and 'Importer' shall be within the same Country.

1.2 - validating the export notification

The validation of the export notification consists of checking the following **three** points:

6) the foreseen category and use in importing country is allowed according to the EU Regulation. It is checked to send the notifications to the correct DNA (Industrial Chemicals or Pesticides);
7) the **full** name, address, (telephone, fax and email) of the importer is filled in. Note that the telephone, the fax and the email are optional;
8) the information required under sections 3 (information on hazards and/or risks), 4 (information on physic-chemical, toxicological and ecotoxicological) and eventually 5 (information on final regulatory action) are provided if the SDS is missing.

The sixth criteria can be extremely flexible for substances from Annex I Part 1.

1.3 - validating the safety data sheet

The SDS is not mandatory. However, when missing, all fields of the export notification are required (*e.g.*, under sections 4, 5 and 6). When available, validation the SDS consists of checking the following **two** points:

9) the existence of the SDS to be used by the importing country. Selecting the SDS in the language of the importing country if available is recommended;
10) the correspondence between the SDS and the export notification with regard to the same chemical.

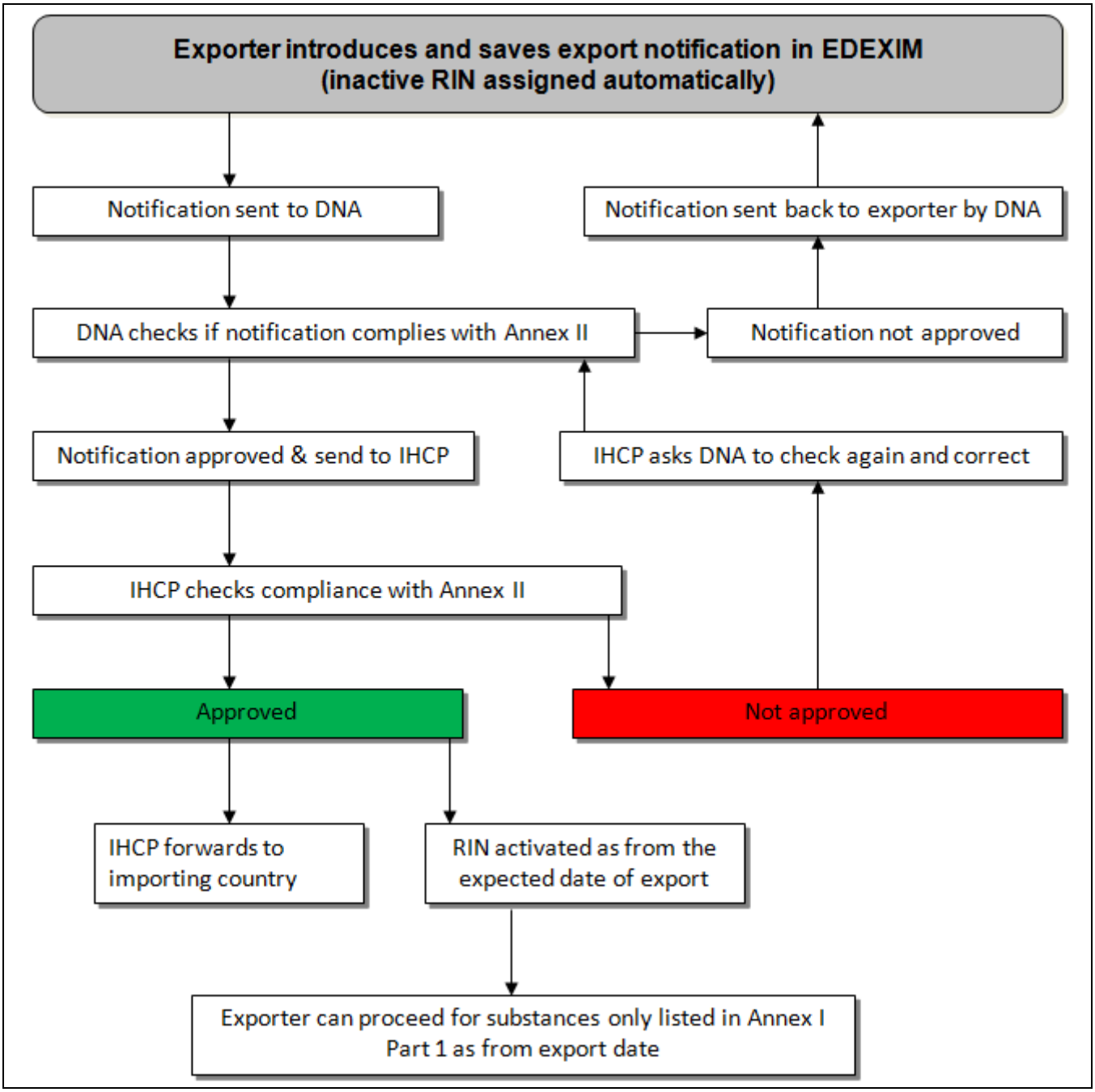

Figure 3: the flowchart of the full export notification process

2) Activating

The activation of an export notification of Part 1 chemicals is automatic. It is done by the validation. Two additional statuses can be found: "Export cannot proceed before the exporting date indicated on the notification (RIN is not valid yet)" and "Export not allowed. The RIN is no longer valid". The status "Export cannot proceed before the exporting date indicated on the notification (RIN is not valid yet)" can occur between the validation date and the export date. Finally, the status "Export not allowed. The RIN is no longer valid" occurs after the expiry date of the RIN.

IV - Export notifications concerning substances of Annex I Part 2 & Part 3

For simplifying the text, we assume the consideration of **absolute first** export notification of (pure) substance/chemical referred to in Annex I from the Community to an importing DNA. We also assume that the export notification deals with a (pure) substance listed within Annex I Part 2 - qualifying for PIC notification - (*e.g.*, Carbosulfan (EC# (also EINECS No) 259-565-9; CAS# 55285-14-8 and Index No 006-084-00-5)) or within Annex I Part 3 - subject to the PIC procedure under the Rotterdam Convention - (*e.g.*, Ethylene oxide (oxirane) (EC# (also EINECS No) 200-849-9; CAS# 75-21-8 and Index No 603-023-00-X)).

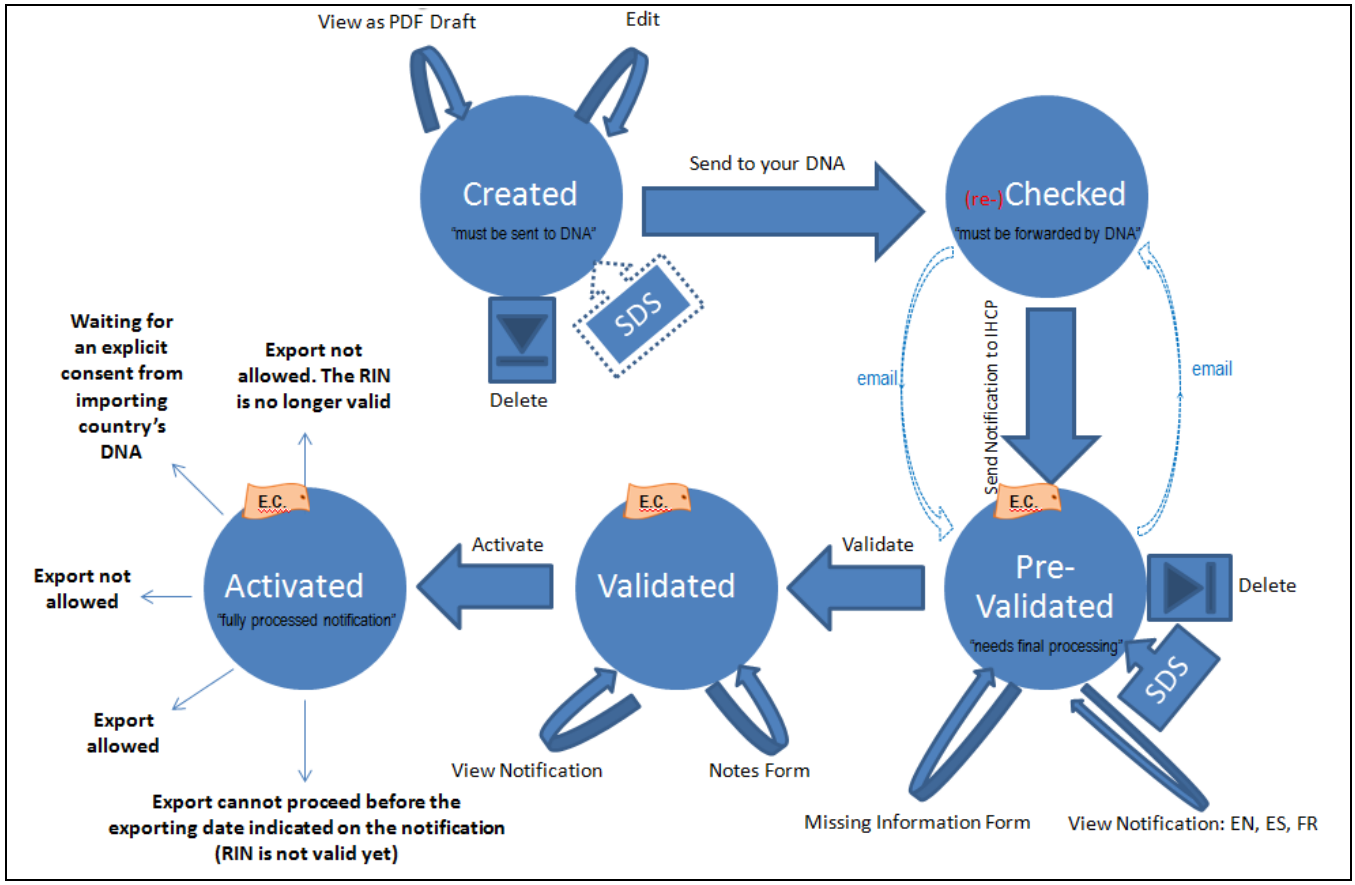

Figure 4: the state-command diagram of the full export notification process for substances in Annex I Part 2 and Part 3

The same E.N. process applies and the same functionalities of EDEXIM apply to substances in Annex I Part 2 and Part 3. However, three main differences characterise the export notifications of substances in Annex I Part 2 and Part 3:

1) The evolution from the "Validated" phase to the "Activated" phase (This status can be seen as "fully processed notification" within EDEXIM) of the export notification takes place by the explicit intervention of the Administrator, namely the activation; four Administrator actions are possible at the "Validated" status: (i) select an adequate explicit consent; (ii) view notification; (iii) attach information in a specific form and (iv) activate the export notification when the eleven validation criteria are met;

2) The validation of the export notification follows strictly the ten described criteria (see chapter III.3.1). In addition, one additional critical step is foreseen: selecting the explicit consent (E.C.) for the selected export notification to the corresponding importing DNA. The explicit consent can be added as soon as it is available. Selecting an adequate explicit consent can happen at the "Pre-Validated", "Validated" or "Activated" states of the export notification. Even if its output is embedded in the E.N. process, the explicit consent process and its associated workflow are explained separately. The sixth criterion of the validation becomes strictly applicable for substances in Annex I Part 3;

3) A new final status of the export notification "**Waiting for an explicit consent from importing country's DNA**" is possible. Furthermore, the status of "**Export not allowed**" becomes possible.

The state-command diagram of the full export notification process for substances in Part 2 and Part 3 is shown in Figure 4. These three issues are under the responsibility of the Administrator, *i.e.* IHCP.

V - Export notifications concerning preparations containing substances of Annex I Part 1

For simplifying the text, we assume the consideration of **absolute first** export notification of a preparation (*e.g.*, Mixt A) containing an active substance referred to in Annex I Part 1 (*e.g.*, Chloroform having EC# (also EINECS No) 200-663-8; CAS# 67-66-3 and Index No 602-006-00-4) with a specific concentration (*e.g.*, 79%) from an exporter (*e.g.*, Exporter B) from an EU member state to an importing country DNA.

In the ERN of an export notification of a preparation (*e.g.* ../EC/**P**nnnn/**XY**/**2011**) it is easy to identify:

1. the letter **P** with the identification code of the preparation (*e.g.*, nnnn),

Likewise the ERN of an export notification concerning substances, the ERN of an export notification of a preparation contains the following information:

2. **XY** stands for the code of importing country (*e.g.*, **MY** for Malaysia),
3. year of export (*e.g.*, **2011**).

1 – Description of the export notifications process

The export notification process of preparations starts with creating the preparation and saving it within EDEXIM database. The following four fields are mandatory for creating a preparation:

1. the name of the preparation;
2. the CN code of the preparation;
3. the substance(s) or chemical(s) composing the preparation;
4. its percentage

Since its creation, the preparation can have a SDS associated to. In other words, each preparation has a specific SDS. The preparation, its SDS and its export notification are created generally by the exporter. The same SDS will be attached, by the administrator, to the export notification at the “Pre-validated” step before validating it.

This specific step to the E.N. process of preparations is entitled “**preparation created**”. The state-command diagram of the full export notification process of preparations containing substance(s) in Part 1 is shown in Figure 5.

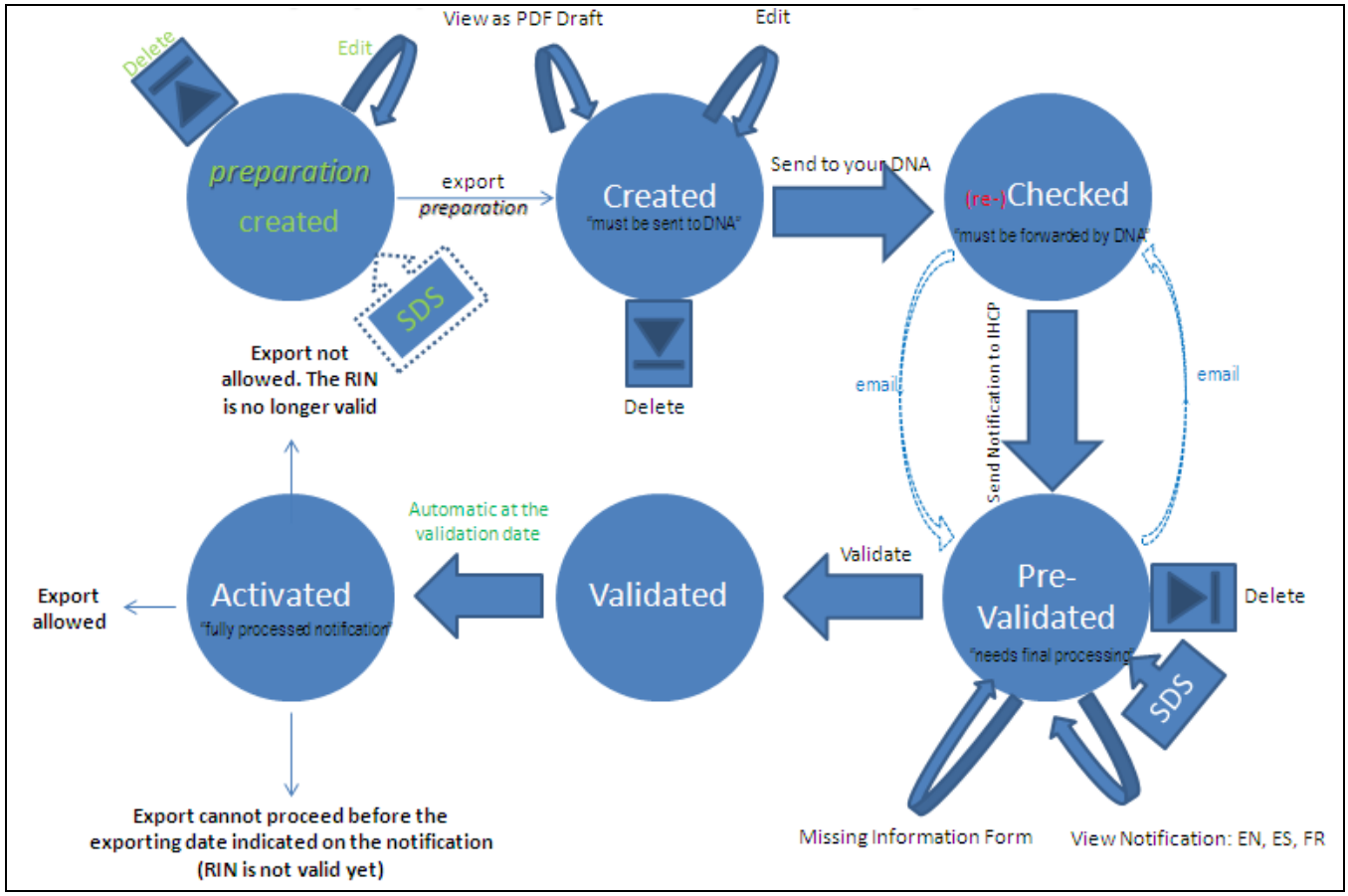

Figure 5: the state-command diagram of the full export notification process for preparations containing substances in Annex I Part 1

Likewise the export notification procedure for substances in Annex I Part 1, the workflow of the export notification procedure for preparations containing substances in Annex I Part 1 is shown in Figure 3 (Annex 4 to the Communication 2011/C 65/01).

2 – EDEXIM functionalities supporting the export notifications process

For allowing exporters to create their preparations, EDEXIM offers the following eight main fields:

1) Name of the preparation
2) Alias of the preparation:
   This alias will appear only in the public version instead of the trade name of the preparation.
   If the alias is left blank, then EDEXIM will automatically create an alias as "PreparationName_ID"
   (where ID is the identification code of the preparation).
3) Harmonised system customs code
4) CN Code:
5) CUS Code:
6) Classification:
7) Select the chemicals present in the preparation (Listed in the Annex I Part I)
   (Hold Ctrl to select multiple items)
8) Select a SDS
   8.1) Select Language: EN, CN, ES, FR, JP, PT, RU, TR
   8.2) Send SDS (max: 1MB)

The confidentiality of the preparation aims to protect exporters. EDEXIM allows exporters to completely defining their preparations. The information is confidential except to the exporter. However, an alias of the preparation has been added in order to share it publicly.

The form of export notification for preparations that is a standard format (see Annex I) like substances is composed of seven sections. It is characterised by adding section 2 entitled “Identity of the preparation to be exported”:

1. Identity of the chemical subject to the export notification
2. Identity of the preparation to be exported
3. Information concerning the export
4. Information on hazards and/or risks of the chemical and precautionary measures
5. Information on physico-chemical, toxicological and ecotoxicological properties of the chemical
6. (Summary) information on final regulatory action taken by the exporting party (Country)
7. Designed National Authorities (DNAs)

Filling section 1 entitled “Identity of the chemical subject to the export notification” is reduced to the name of substance(s) or chemical(s) composing the considered preparation.

Section 2 entitled “Identity of the preparation to be exported” that is filled in only in case of a mixture or preparation is composed of the following five fields:

2.1 Trade name and name of the preparation/mixture
2.2 Harmonized system customs code
2.3 CN code of the preparation
2.4 CUS code of the preparation
2.5 For each substance in the preparation that is subject to the export notification, concentration (%) and information as specified under SECTION 1

In addition to the twelve mandatory fields of the form of export notification for substances, the form of export notification for preparations has two more fields: “Trade name and name of the preparation” and “CN code of the preparation”. The full fourteen fields are the following:

1. Reference Number
2. Importing Party/Country
3. At least one of the following three fields for characterising the active substance is mandatory: 'Common name'; 'CAS number' and 'EINECS number'
4. CN code of the active substance composing the preparation
5. CUS code of the active substance composing the preparation
6. Trade name and name of the preparation
7. CN code of the preparation
8. Expected date of export, expressed as dd-mm-yyyy
9. Expected amount of the substance/preparation, expressed as a number and a unit to be selected between Kg and l
10. Name, address, telephone, fax and email of the importer
11. Name, address, telephone, fax and email of the exporter
12. Summary of reasons for the final regulatory action and date of entry into force
13. The final regulatory action has been taken for the category, expressed as a tick box on "Pesticide" or "Industrial chemical''
14. The final regulatory action has been taken for the category, expressed as use(s) prohibited, use(s) that remain allowed and, where available, estimated quantity of the chemical produced, imported, exported and used

The same fields automatically filled in for export notification of substances are automatically filled in for export notification of preparations.

Instead of managing the following two fields characterising the export notification of substances (*i.e.*, “Chemical” and “Einecs”), EDEXIM allows the administrator to substitute them by the fourth field “Preparation” with its active substance “Chemical” composing it. Thus the administrator manages the filled in export notification for preparations throughout the following eighteen characteristics fields:

1. ID
2. ERN Reference
3. Export Code, *i.e.* RIN
4. Preparation
   <Chemical>, *i.e.* active substance composing the preparation
5. Export Date
6. Expected Use
7. Expected Amount
8. Importing Country
9. Created By
10. Date Received By DNA
11. Date Received By EC
12. View Documents
13. DNA Importing Country
14. Importer
15. DNA Exporting Country
16. Exporter
17. Validation period: From
18. Validation period: To

3 - Administrator implication within the export notifications process

Validating export notifications for preparations is similar to validating export notifications for substances. However, the preparation has three main characteristics to be validated:

1. the trade name of the preparation
2. the substance or chemical name(s) included in the preparation
3. the concentration of each substance or chemical included in the preparation

Activating export notifications for preparations is identical to activating export notifications for substances.

1) Validating

As for substances, validating an export notification for preparations consists on checking three main issues: (i) the 'Notification Validation' window; (ii) the export notification and the (iii) SDS. When an export notification is validated by the IHCP, both exporter and DNA receive a confirmation of this validation.

1.1 - validating the 'Notification Validation' window
This validation consists of checking the following **five** points:

1) the eighteen elementary fields composing the 'Notification Validation' window are filled in;
2) the active substance composing the preparation is listed within Annex I of EDEXIM according to the latest amendment in force but not listed within Annex V of EDEXIM;
3) the content of the 'Export Date' field shall be at least 15 days greater than the content of the 'date Received By EC' field;
4) sending the export notification to the importing DNA shall be within the maximum duration of 15 days, when possible, after the reception of complete notification;

N.B. for the **absolute first export** of a preparation (*e.g.*, Mixt A) containing an active substance referred to in Annex I Part 1 (*e.g.*, Chloroform having EC# (also EINECS No) 200-663-8; CAS# 67-66-3 and Index No 602-006-00-4) with a specific concentration (*e.g.*, 79%) from an exporter (*e.g.*, Exporter B) from an EU

member state to an importing country DNA starting from 2008, the total duration of **30 days** between the date of notifying the export notification (from the exporter to the designated national authority of the Member State in which he is established) and the date of export (see Figure 1a) shall be strictly respected.

5) both fields of 'DNA Importing Country' and 'Importer' shall be within the same Country.

1.2 - validating the export notification

The validation of the export notification consists of checking the following **four** points:

6) for each active substance composing the preparation that is subject to the export notification, its concentration, expressed in {percentage (%), mass fraction w/w, mass concentration w/v, volume concentration v/v or g/l}, shall be explicitly specified;
7) the foreseen category and use in importing country is allowed according to the EU Regulation. It is checked to send the notifications to the correct DNA (*i.e.*, Industrial Chemicals or Pesticides);
8) the **full** name, address, (telephone, fax and email) of the importer is filled in. Note that the telephone, the fax and the email are optional;
9) the information required under sections 4 (information on hazards and/or risks), 5 (information on physic-chemical, toxicological and ecotoxicological) and eventually 6 (information on final regulatory action) are provided if the SDS is missing.

The seventh criteria can be extremely flexible for preparations containing active substances from Annex I Part 1.

1.3 - validating the safety data sheet

The SDS is linked to the preparation instead of being associated to the export notification. Validation of the SDS, when available, consists of checking the following **two** points:

10) the existence of the SDS to be used by the importing country. Selecting the SDS in the language of the importing country if available is recommended;
11) the correspondence between the SDS and the export notification with regard to the same trade name of the preparation, the same substance or chemical composing the preparation and the same concentration of each substance or chemical composing the preparation.

2) Activating

The activation of an export notification for preparations containing substance(s) or chemical(s) of Part 1 is automatic. It is done by the validation. It is practically the same than for Part 1 chemicals. Then the notification status can be either "**Export allowed**" , "**Export not allowed**", "Export cannot proceed before the exporting date indicated on the notification (RIN is not valid yet)" or "Export not allowed. The RIN is no longer valid". However, it is practically impossible to find the status "**Export not allowed**" for preparations containing substance(s) or chemical(s) of Part 1.

VI - Export notifications concerning preparations containing substances of Annex I Part 2 & Part 3

For simplifying the text, we assume the consideration of **absolute first** export notification of a preparation (*e.g.*, Mixt B) containing an active substance referred to in Annex I Part 2 - qualifying for PIC notification - (*e.g.*, Carbosulfan (EC# (also EINECS No) 259-565-9; CAS# 55285-14-8 and Index No 006-084-00-5)) with a specific concentration (*e.g.*, 25%) from an exporter (*e.g.*, Exporter C) from an EU member state to an

importing country DNA. Similarly, we assume the consideration of **absolute first** export notification of a preparation (*e.g.*, Mixt C) containing an active substance referred to in Annex I Part 3 - subject to the PIC procedure under the Rotterdam Convention - (*e.g.*, Ethylene oxide (Oxiranne) (EC# (also EINECS No) 200-849-9; CAS# 75-21-8 and Index No 603-023-00-X)) with a specific concentration (*e.g.*, 20%) from an exporter (*e.g.*, Exporter D) from an EU member state to an importing country DNA.

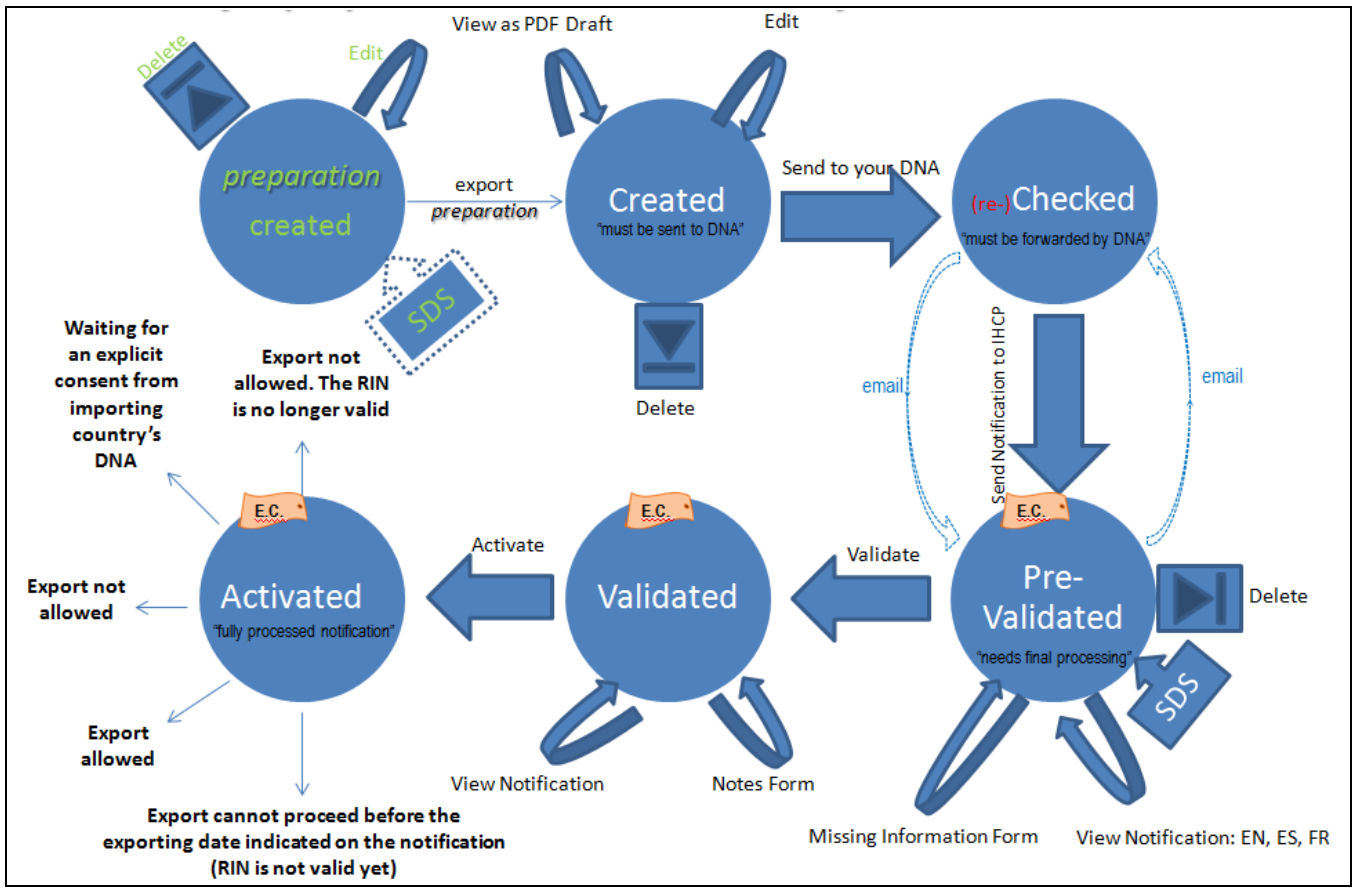

Figure 6: the state-command diagram of the full export notification process for preparations containing substances in Annex I Part 2 and Part 3

The E.N. process for preparations containing substance(s) in Annex I Part 1 applies and the same functionalities of EDEXIM apply to preparations containing substance(s) in Annex I Part 2 and Part 3. However, three main differences characterise the export notifications of preparations containing substance(s) in Annex I Part 2 and Part 3:

1) The evolution from the "Validated" phase to the "Activated" phase (This status can be seen as "fully processed notification" within EDEXIM) of the export notification takes place by the explicit intervention of the Administrator, namely the activation; this is exactly similar to the export notifications of substances in Annex I Part 2 and Part 3;

2) The validation of the export notification follows strictly the nine criteria described for the E.N. process for preparations containing substance(s) in Annex I Part 1. In addition, likewise the export notifications of substances in Annex I Part 2 and Part 3, one more critical step is foreseen: selecting the explicit consent (E.C.) for the considered export notification to the considered importing DNA. The seventh criterion of the validation becomes strictly applicable for preparations containing substance(s) in Annex I Part 3;

3) Likewise the export notifications of substances in Annex I Part 2 and Part 3, the new final status of the export notification of preparations containing substance(s) in Annex I Part 2 and Part 3 "**Waiting for an explicit consent from importing country's DNA**" is possible. Furthermore, the status of "**Export not allowed**" becomes possible.

The state-command diagram of the full export notification process for preparations containing active substance(s) in Part 2 and Part 3 is shown in Figure 6. These three issues are under the responsibility of the Administrator, *i.e.* IHCP.

VII - Subsequent export notifications

As soon as an export notification is created, EDEXIM checks the following three criteria:

1. within the **same** calendar year, EDEXIM checks the existing export notifications;
2. if the **same** substance (or the **same** identification of the preparation) has been used;
3. if the **same** importing country has been selected

Then the new created export notification becomes a subsequent export notification. This will allow importing country to receive only one notification, *i.e.*, the first one created from the European Union, irrespective of which Member State the notification originates from.

Obviously, the exporting country cannot be aware if its export notification is subsequent or not. Only the administrator is aware of the subsequent information.

There are two main differences between an export notification and its various subsequent notifications:

1. the ERN containing the EINECS number (or the **P** and the identification of the preparation) is ending with an **S:mmmmm** where the **S** represents the subsequent export notification and the **mmmmm** represents a sequential number in five digits. This ERN is not visible to the exporting country nor, obviously, to the importing country but only to the administrator;
2. the export notification and eventually its associated SDS is sent to some importing DNA countries. Bolivia and Malaysia have requested to send all subsequent notifications refer to chemicals or substances of Part 2 and Part 3.

For example, the ERN ../EC/**200-663-8**/**XY**/**2012**/**S:**mmmmm is a subsequent export notification of the Chloroform substance, which EINECS number is **200-663-8**, to an importing country encoded as **XY** within **2012**. The ERN ../EC/**P**nnnn/**XY**/**2012**/**S:**mmmmm is a subsequent export notification of the Mixt D preparation with identification number nnnn, containing Nonylphenols $C_6H_4(OH)C_9H_{19}$ to an importing country encoded as **XY** within **2012**.

A part from the three mentioned exceptions, the subsequent export notification follows exactly the already specified process including validation, activation when applicable and explicit consent when needed.

VIII – Principles of explicit consents

In addition to export notification, the export of chemicals listed in Part 2 and Part 3 also require the explicit consent of the importing country. The explicit consent aims to explicitly exchange risk management information between an exporting DNA and an importing one prior to export of chemicals or preparations. When chemicals are also listed in Part 2 or Part 3 of Annex I, the RIN will not be activated because the explicit consent of the importing country needs to be obtained prior to export of chemicals or preparations pursuant to Article 13 of Regulation (EC) No 689/2008.

Exporters and Customs users of EDEXIM do not have access to the explicit consents process. It is mainly reserved to DNA. The Administrator can also access it.

Later the explicit consent process is described and the EDEXIM functionalities supporting this process are listed. The specific implication of the administrator within the explicit consent process is explained. Finally, two special cases are described: waiver and reminder.

1 – Description of the explicit consents process

Explicit consent has to be sought and received through the exporter's DNA and the DNA (or other competent authorities) of the importing country. The Explicit Consent (E.C.) process aims to request first and then to receive from importing DNA (or other competent authorities) a filled in form (*i.e.* a response), see Annex IV. The status of the E.C. can be either 'Requested', 'Yes' or 'No'. The evolution of the status from 'Requested' to 'Yes' or 'No' is shown in Figure 7 according to EDEXIM commands.

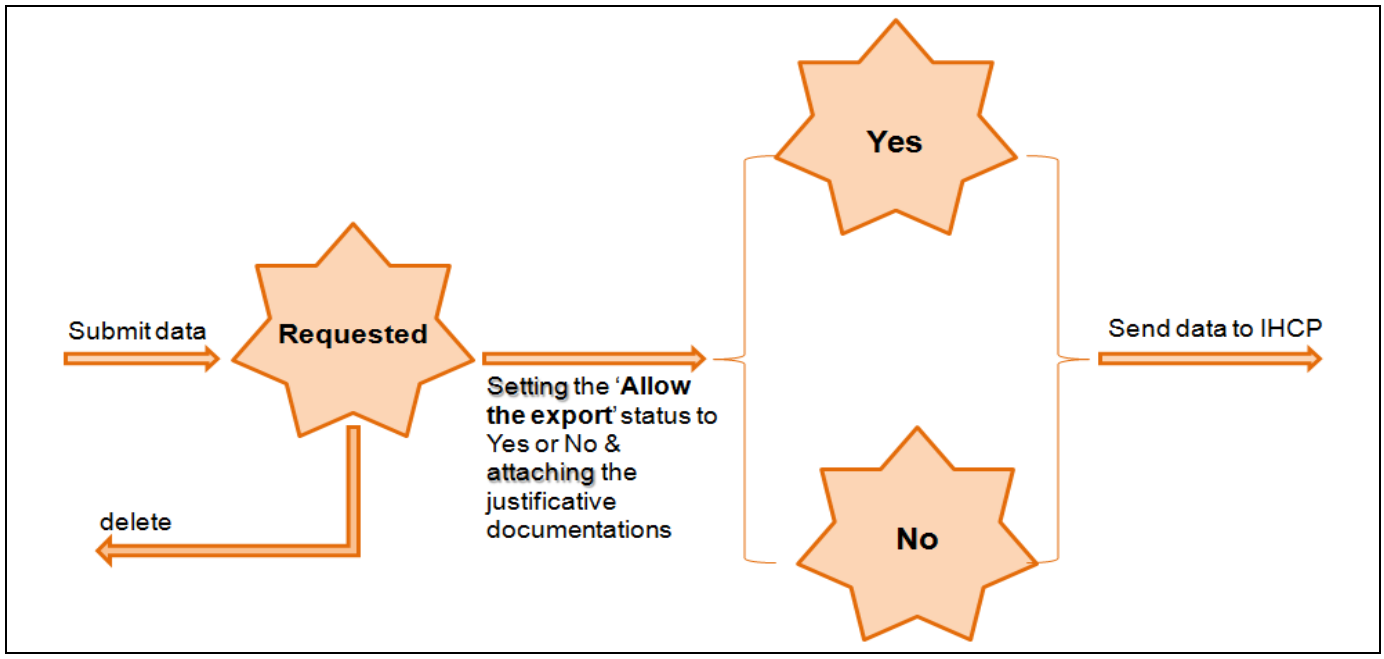

Figure 7: Status of the explicit consent under the supervision of the exporting DNA

The full E.C. process is described in three main phases: (i) the request phase under the supervision of the DNA exporting, see figure 8a, (ii) the beginning of the response phase under the supervision of the DNA exporting, see figure 8b and (iii) the ending of the response phase under the supervision of the IHCP, see figure 8c.

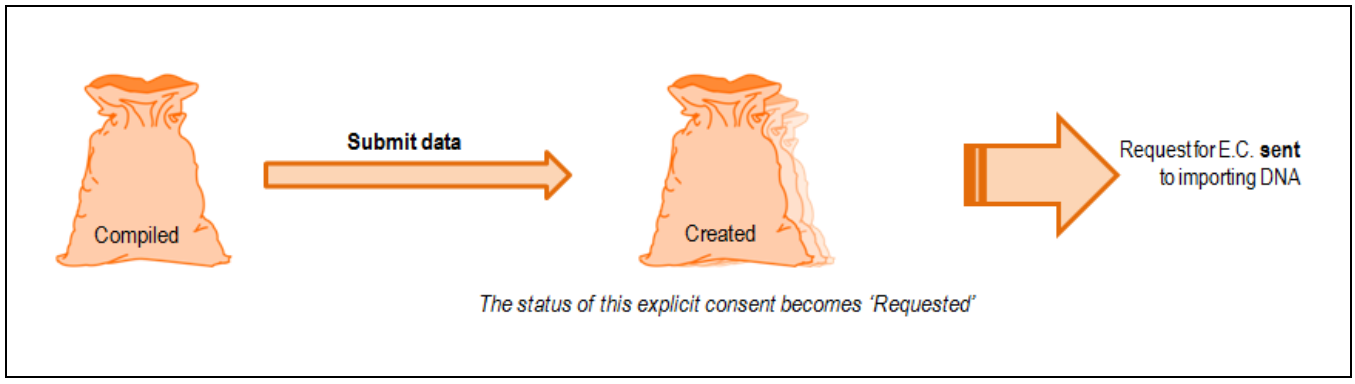

Figure 8a: EDEXIM state-command diagram of the explicit consent process for substances (or preparations containing substances) in Part 2 & Part 3: the request phase under the supervision of the exporting DNA

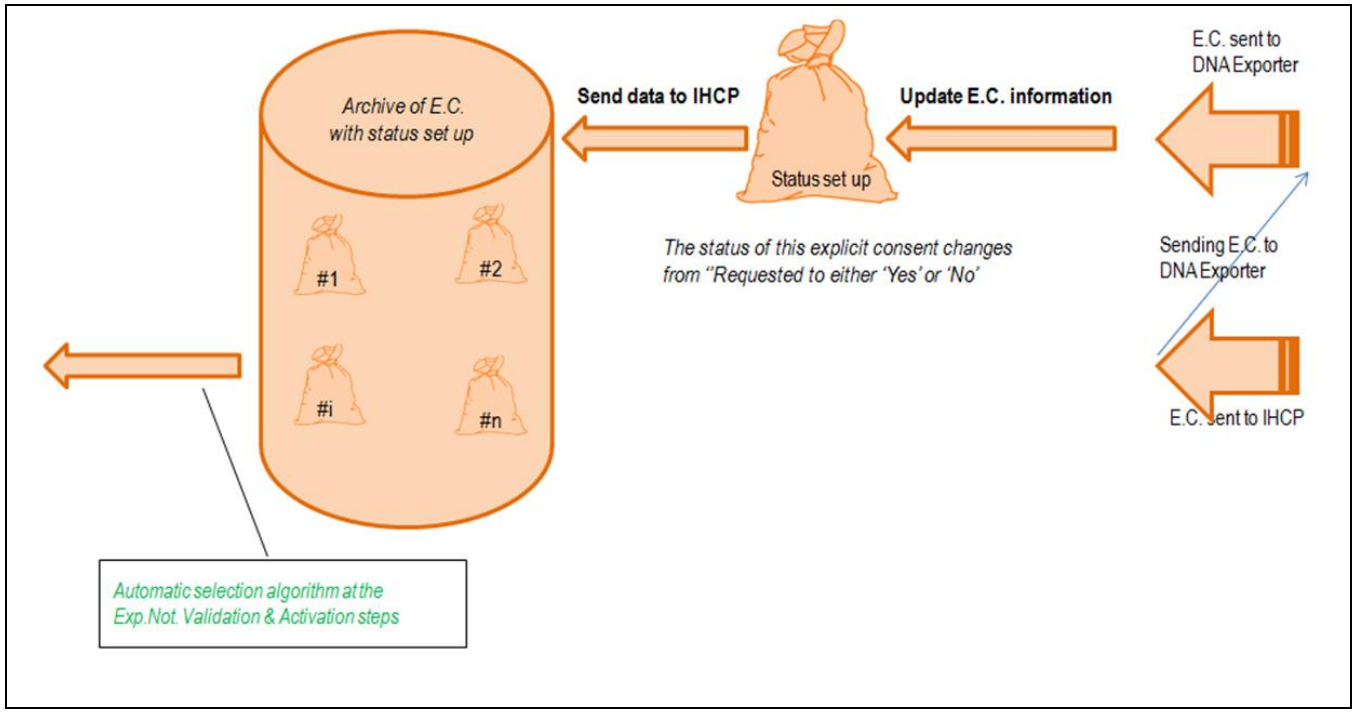

Figure 8b: EDEXIM state-command diagram of the explicit consent process for substances (or preparations containing substances) in Part 2 & Part 3: the beginning of the response phase under the supervision of the exporting DNA

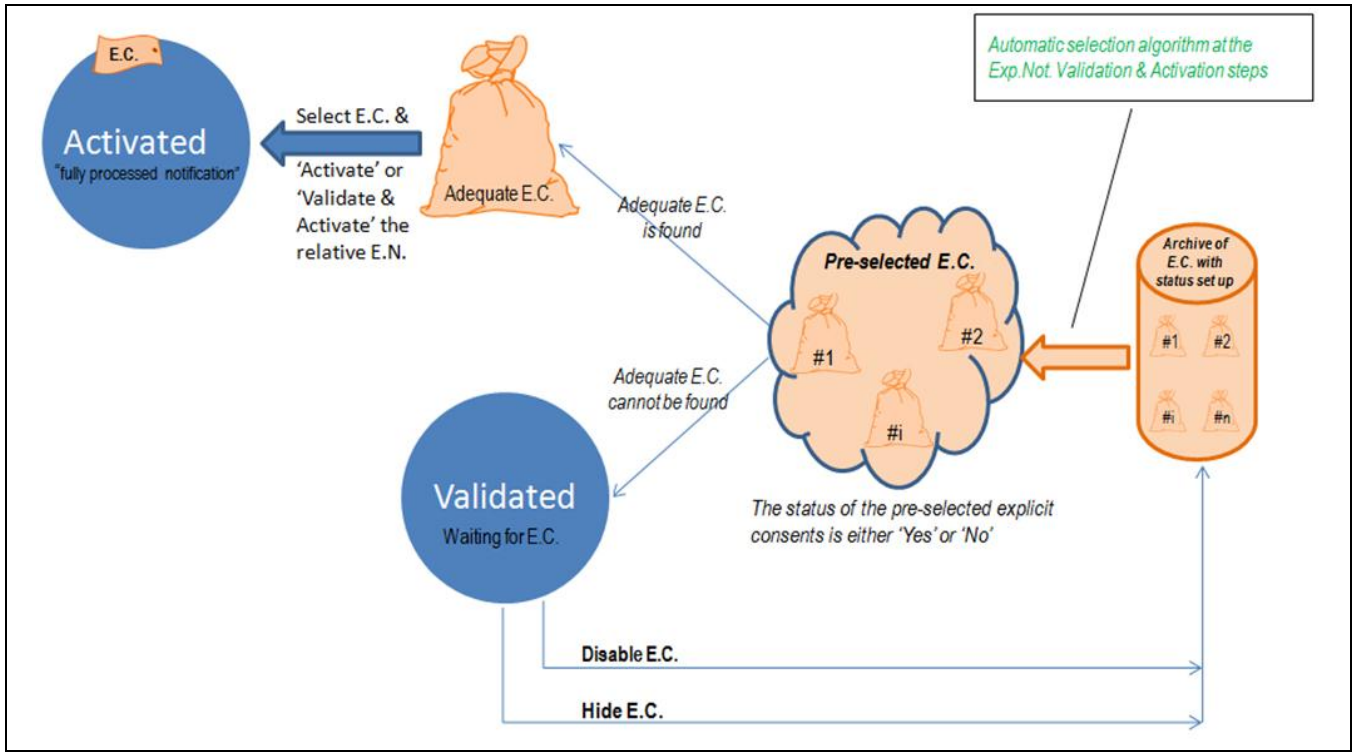

Figure 8c: EDEXIM state-command diagram of the explicit consent process for substances (or preparations containing substances) in Part 2 & Part 3: the ending of the response phase under the supervision of the IHCP

It appears clearly that ending the explicit consents process is embedded within the export notification process.

The workflow of the explicit consent procedure for Annex I Part 2 and Part 3 chemicals follows article 13 of the Regulation when both export notifications and explicit consents are required, see Figure 9 (Annex 4 to the Communication 2011/C 65/01).

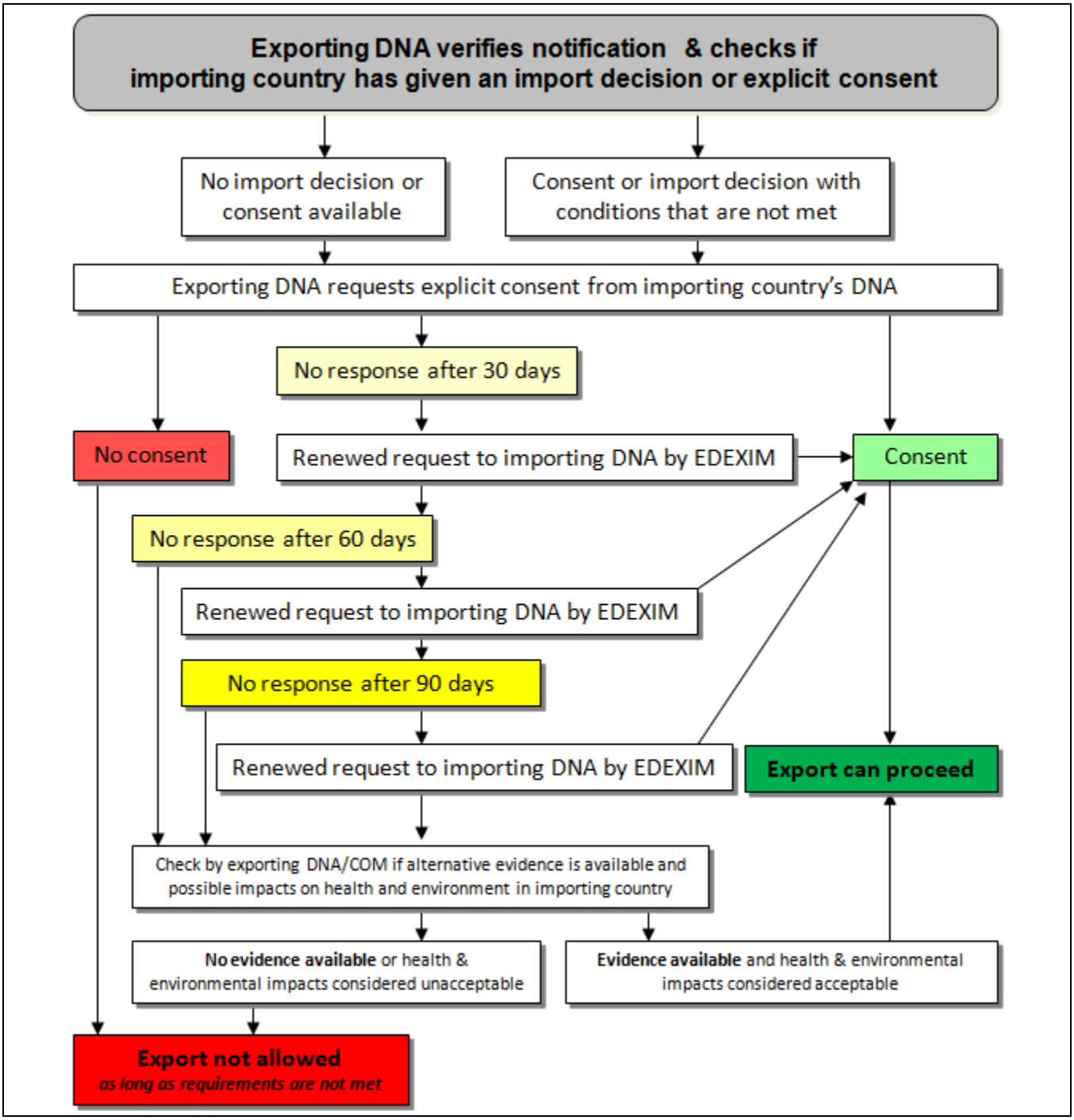

Figure 9: the flowchart of the explicit consent process for Annex I Part 3 (PIC Convention) chemicals to all countries and for Annex I Part 2 chemicals for non-OECD countries when both export notifications and explicit consents are required

2 – EDEXIM functionalities supporting the explicit consents process

In EDEXIM, each explicit consent has a unique identifier composed of five digits **ddddd**. An explicit consent for a chemical remains valid for subsequent exports by any EU exporter for a period of three calendar years, unless otherwise specified in the explicit consent itself. The E.C. is generally characterised by the following fifteen fields:

1) Explicit Consent Identifier – it contains the explicit consent identification number;
2) Type – it can be either "Chemical" (abbreviated C) or "Preparation Name" (abbreviated P) or "Article Name" (abbreviated A);
3) Chemical name or Preparation name or Article name;
4) Chemical name in case of Preparation;

5) Request by/Country – name of the member state who made the explicit consent request;
6) Importing Country – mandatory field;
7) Request Date
8) Explicit Consent request delivery method – it can be either 'default', 'surface mail', 'fax' or 'email';
9) Response Date – it contains the date of the answer given for the explicit consent request;
10) Status/Result – it contains the answer given for the explicit consent request, it can be either 'requested', or 'yes' or 'no';
11) Category – category for which the explicit consent is requested; it can be either 'industrial', 'pesticide' or 'all';
12) RIN – when the explicit consent refers to a specific RIN and not to other exports;
13) Notes – free text field of maximum size of 1,000 characters;
14) Enclosure DNA Version Documents sent to importing DNA of maximum size of 10M – mandatory field when status is 'yes' or 'no';
15) Enclosure Public Version Documents of maximum size of 10M – mandatory field when status is 'yes' or 'no'.

When four dates are listed at the maximum within the "Request Date" field, they correspond to the "Request Date" and the maximum value of three "Reminders Date". Sometimes, the field "Request Date" is separated from the field "Reminders Date" – see the explicit consent details while searching by identifier.

The explicit consent reminder status lists the explicit consents that are still in "requested" status and the maximum number of reminders (*i.e.*, 3) has been reached. In this list, the "Status" is always "requested" and the date of "Last Reminder" is the main focus.

When uploading the documents sent to importing DNA, the "Document Language" contains the most common languages, either "EN", "FR" or "ES".

Both DNA and Administrator have the following commands for managing the Explicit Consent (E.C.) process:

1. Search & Edit & Delete E.C. and Search E.C. by id;
2. New Substance/Preparation/Article E.C.;
3. View & Edit (DNA) Contact information / Insert New (DNA) Contact for E.C. reminders;
4. E.C. Reminder Status;
5. Download forms where DNAs can find templates of explicit consent forms in the most common languages English (EN), French (FR) and Spanish (ES), see Annex III;
6. E.C. Statistics.

In addition, the Administrator has two extra searching commands: 'Search all E.C. by Country' and 'Search all E.C. by Chemical'.

3 – Administrator implication within the explicit consents process

Under the Explicit Consent Information part of the Notification Activation window, the Administrator can do the following:

1) setting the "Allow the export" field to either 'Export allowed' , 'Export NOT allowed' or 'Waiting for explicit consent';
2) ticking the "EC manual selection" box ();
3) writing an identification number within the "EC ID" box;

For each export notification at the validation or at the activation steps, EDEXIM proposes a list of pre-selected explicit consents where status is either 'yes' or 'no'.

At the validation step of the export notification process, EDEXIM lists a pre-selection of potentially matching explicit consents. This pre-selection consists of items which need to strictly match all the four criteria listed between (i) to (iv). The first criteria (*i.e.*, '(i)') can have one of the following four formats listed between a. to d.

(i) The substance(s) of the considered export notification is identical to the substance(s) of the selected explicit consent;
   a. The substance of the considered export notification is identical to the substance of the selected explicit consent;
   b. The substance of the considered export notification is identical to the substance or chemical composing the preparation of the selected explicit consent;
   c. The (substance or chemical composing the) preparation of the considered export notification is identical to the (substance or chemical composing the) preparation of the selected explicit consent;
   d. The substance or chemical composing the preparation of the considered export notification is identical to the substance of the selected explicit consent;

(ii) The status of the selected explicit consent is either 'yes' or 'no' (*i.e.*, different from 'Requested');

(iii) The selected explicit consent has not been hidden by the Administrator;

(iv) The selected explicit consent has not been disabled by the Administrator;

The Administrator examines the pre-selected lists of explicit consents in order to select, when available, the adequate explicit consent and then setting the 'Allow the export' field to either 'Export allowed' or 'Export NOT allowed'. Generally, the Administrator manages the pre-selected lists by using both commands of **(a)** Hide E.C. and **(b)** Disable E.C. aiming at filtering the pre-selected explicit consents list. Obviously, the Administrator updates the 'Allow the export' field to 'Waiting for explicit consent' when an adequate explicit consent cannot be found. Consequently, the associated export notification disappears from the activation list of export notifications. It appears back only when a new and potentially matching explicit consent has been uploaded.

The following four commands are available to the Administrator for managing the list of pre-selected explicit consents:

1) select a tick box "" corresponding to the adequate explicit consent;
2) **Disable** – it disables the selected explicit consent for all notifications (*e.g.*, when the validation period of the explicit consent is over);
3) **Hide** – it hides the selected explicit consent only for the considered notification (*e.g.*, valid explicit consent for different concentration or valid explicit consent for a pure substance when the export notification deals with a preparation);
4) setting the export notification "Allow the export" field to either 'Export allowed' or 'Export NOT allowed' or 'Waiting for explicit consent' (*i.e.*, the default value).

When several explicit consents are available, we generally give the top priority to the explicit consent with the identical CAS number of the export notification or of the associated safety data sheet when possible. For example, notification **7KFFD0YF9L** for the Mixt E preparation (with CAS No. **68412-54-4** in the SDS) is using the explicit consent identifier **ddddd** (with CAS No. **68412-54-4**).

If the CAS number is not mentioned within the explicit consent, then the same explicit consent can be used for a group of chemicals (*e.g.*, Nonylphenol ethoxylates $(C_2H_4O)_nC_{15}H_{24}O$). For example, notification **OAXH13TYCG** for the Mixt F preparation (with CAS No. **68412-54-4** in the SDS) and notification **PX34BNR2O1** for the Nonylphenol, branched, ethoxylated substance (with CAS No. **68412-54-4** in the E.N.) have been given the explicit consent identifier **ddddd** (without CAS No.).

When an adequate explicit consent cannot be found, both commands 'Disable E.C.' and 'Hide E.C.' allow the administrator to remove the proposed consents from the pre-selected list, *i.e.* to filter this list in order to avoid checking them once again during a subsequent activation.

4 – Special cases

1) Waivers

A waiver may be granted on a case-by-case basis under Article 13(7), where, despite all reasonable efforts, no response has been received within 60 days of a request for explicit consent for a chemical subject either to the PIC procedure or qualifying for PIC notification (chemicals listed in Parts 2 or 3 of Annex I). The decision to waive the requirement is taken by the DNA of the exporter in consultation with DG ENV, and must be based on evidence from official sources in the importing Party or other country that the chemical in question is licensed, registered or authorised in that country. When deciding on the export of chemicals listed in Part 3 of Annex I, the decision must also take into consideration possible impacts on human health and the environment in the importing Party or other country. Such 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. 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.

Waivers can only be used by the Member State that requested it. From EDEXIM point of view, the waiver behaves exactly like an specific explicit consent.

2) Reminders

30 days after the first request (or the latest reminder) the system will automatically generate a reminder based on a template letter in EN, ES and FR. If communication with this particular importing country takes place by e-mail, EDEXIM will automatically send the letter to the address(es) specified with the original documents posted by the DNA as attachments. If communication with this particular importing country takes place by fax or surface mail, EDEXIM will assemble the package and send it to DG ENV who will take care of the sending. The exporting DNA will receive a copy of the e-mail from EDEXIM to DG ENV. They will also receive a copy of the e-mails sent directly to the importing countries.

A maximum number of 3 reminders will be sent after which the cycle will be stopped even if no answer has been received (see Figure 9).

IX - Conclusion

It is possible that importing country designated national authority get confused by the current Institute for Health and Consumer Protection processing of export notifications simultaneously with the exporting country designated national authority processing of explicit consents for substances, or preparations containing substances, of Part 2 and Part 3 of Annex I. In fact, it is common that an importing country receives, at time t_1, from the exporting country designated national authority an earlier version of the export notification, *i.e.*, not yet validated, together with the request for an explicit consent. This version of the export notification is tagged **Preliminary**. Later on, *i.e.* at time $t_1 + \Delta$, the same importing country designated national authority receives from the Institute for Health and Consumer Protection the official version of the notification together with the associated safety data sheet which means that the notification has been validated.

Annex I: form for export notification

ROTTERDAM CONVENTION

SECRETARIAT FOR THE ROTTERDAM CONVENTION ON THE PRIOR INFORMED CONSENT OPROCEDURE FOR CERTAIN HAZARDOUS CHEMICALS AND PESRTICIDES IN INTERNATIONAL TRADE

Form for Export Notification

Note for the importing Party: This export notification is sent by the European Commission on behalf of the exporting Member State in accordance with Article 12 of the Rotterdam Convention. The European Commission will only notify the first yearly export from the European Community to your country of the chemical or preparation identified below. You are kindly requested to **acknowledge** receipt of this export notification within 30 days of the date indicated in section 7, preferably by using the attached form. Please note that this export notification form deviates from the form established under the Convention in order to comply with legal requirements in the European Union. All changes stemming from European Union legislation are marked with an asterisk*.

Reference Number

Exporting party
Importing party

SECTION 1 IDENTITY OF THE CHEMICAL SUBJECT TO THE EXPORT NOTIFICATION

1.1 Common name
1.2 Chemical name according to an internationally recognized nomenclature (*e.g.* IUPAC)
1.3 Code numbers
- 1.3.1 CAS number
- 1.3.2 EINECS number*
- 1.3.3 Harmonized system customs code
- 1.3.4 CN code*
- 1.3.5 CUS code*
- 1.3.6 Other numbers (if applicable, specify the numbering system)

SECTION 2 IDENTITY OF THE PREPARATION TO BE EXPORTED

2.1 Trade name and name of the preparation/mixture
2.2 Harmonized system customs code
2.3 CN code of the preparation
2.4 CUS code of the preparation
2.5 For each substance in the preparation that is subject to the export notification, concentration (%) and information as specified under SECTION 1

SECTION 2b IDENTITY OF THE ARTICLE TO BE EXPORTED

2.1 Trade name and name of the article
2.2 For each substance in the article that is subject to the export notification, concentration (%) and information as specified under SECTION 1

SECTION 3 INFORMATION CONCERNING THE EXPORT

3.1 Expected date of first export (dd.mm.yy)
3.2 Expected amount of the substance or preparation (kg/l per year)
3.3 Foreseen category (industrial chemical or pesticide) and foreseen use in importing country
3.4 Name, address, telephone, fax and email of the importer
3.5 Name, address, telephone, fax and email of the exporter

SECTION 4 INFORMATION ON HAZARDS AND /OR RISKS OF THE CHEMICAL AND PRECAUTIONARY MEASURES

(Please provide information in the table below or attach a copy of the safety data sheet that covers the information required.)

4.1 Hazard classification (*e.g.* GHS, WHO, IARC, EU)
4.2 Information on hazards and/or risks
4.3 Information on precautionary measures to reduce exposure to and emission of the chemical
4.4 Further information that may be useful to the importing country or has been requested by it, *e.g.* on relevant impurities
4.5 Reference (*e.g.* safety data sheet)

SECTION 5 INFORMATION ON PHYSICO-CHEMICAL, TOXICOLOGICAL AND ECOTOXICOLOGICAL PROPERTIES OF THE CHEMCIAL

5.1 Summary information
5.2 Reference

SECTION 6 SUMMARY INFORMATION ON FINAL REGULATORY ACTION TAKEN BY THE EXPORTING PARTY (COUNTRY)

6.1 Summary of and reasons for the final regulatory action and data of entry into force
Regulatory Restrictions
selecting a language between EN, FR and ES
6.2 The final regulatory action has been taken for the category
☐ Pesticides ☐ Industrial chemical
Please indicate
- use or uses prohibited
- use or uses that remain allowed
- where available, estimated quantity of the chemical produced, imported, exported and used

6.3 Reference to the regulatory document

SECTION 7 DESIGNATED NATIONAL AUTHORITIES (DNAs)

7.1 Name, address, telephone, fax and email of the notifying DNA in the exporting Party
7.2 Name, address, telephone, fax and email of the DNA in the importing Party

Date, signature of the notifying DNA in the exporting Party and official seal:

ATTACHMENTS
Upload first SDS
Upload second SDS
selecting a language and then browse the file

Form for Acknowledging Receipt of Export Notification

This is to acknowledge the receipt of the export notification

Name of the importing country
Reference number of the export notification
Chemical name

Date, signature of the designated authority in the importing Party and official seal:

Please send the acknowledgment within 30 days of the date indicated in section 7 to the exporting Party at the following address:
Name and address

Annex II: emailing importing country DNA

A concrete example of an email sent to importing country is attached below in both cases: single chemical or plural chemicals. Obviously, two other linguistic versions, FR and ES, are also available. The letters sent by fax and post are also attached in three languages.

A - Letters for email

1) English

1.1 - Single case

Subject: Export Notification for XXXXXXXXXXX from the EU

Dear Sir/Madam,

please find one export notification attached to this email:

XXXXXXXXXXX – substance "A"

together with its Safety Data Sheet regarding intended export of this chemical from the European Union to Yyyyyy. When you receive the export notification (and in any case within 30 days), could you please be so kind as to send us back a signed copy of the confirmation of receipt form which is generally the fifth/sixth page of an export notification?

I would like to remind you that there are no further implications involved, it is just to let us know that the notification has been received by the correct person otherwise we must send it again.

However, for certain chemicals the DNA of the exporting country will send you a request to provide your decision on their import into your country, if you have not already done so recently.

As always, I have also attached a note that we prepared explaining the EU procedure and legislation and how it differs from the PIC procedure, we hope it will help the authorities in importing countries to understand our requests.

Thank you in advance for your kind collaboration and please do not hesitate to contact us if further clarification is necessary.

Kind regards,

PIC team

European Commission
Joint Research Centre
Institute for Health and Consumer Protection
Via E. Fermi, 2749
I-21027 Ispra (VA), ITALY
TP xxx

Phone: +39 0332 78 xxxx
Fax: + 39 0332 78 xxxx
JRC-IHCP-EDEXIM@ec.europa.eu

"Disclaimer required under the terms and conditions of use of the internet and electronic mail from Commission equipment: "The views expressed are purely those of the writer and may not in any circumstances be regarded as stating an official position of the European Commission"".

1.2 – Plural case

Subject: Export Notifications for Banned or Severely Restricted Chemicals from the EU

Dear Sir/Madam,

please find two export notifications attached to this email:

XXXXXXXXXXX – substance "A"
XXXXXXXXXXX – substance "B"

together with their Safety Data Sheets regarding intended export of these chemicals from the European Union to Yyyyyy. When you receive the export notifications (and in any case within 30 days), could you please be so kind as to send us back a signed copy of the confirmation of receipt form which is generally the fifth/sixth page of an export notification?

I would like to remind you that there are no further implications involved, it is just to let us know that the notification has been received by the correct person otherwise we must send it again.

However, for certain chemicals the DNA of the exporting country will send you a request to provide your decision on their import into your country, if you have not already done so recently.

As always, I have also attached a note that we prepared explaining the EU procedure and legislation and how it differs from the PIC procedure, we hope it will help the authorities in importing countries to understand our requests.

Thank you in advance for your kind collaboration and please do not hesitate to contact us if further clarification is necessary.

Kind regards,

PIC team

European Commission
Joint Research Centre
Institute for Health and Consumer Protection
Via E. Fermi, 2749
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"Disclaimer required under the terms and conditions of use of the internet and electronic mail from Commission equipment: "The views expressed are purely those of the writer and may not in any circumstances be regarded as stating an official position of the European Commission"".

2) French

2.1 – Single case

Subject: Notification d'exportation en provenance de l'Union Européenne

Madame, Monsieur,

Je vous invite à prendre connaissance de la notification d'exportation ci-dessous:

XXXXXXXXXXX – substance "A"

jointe à ce courriel accompagnée de la fiche de données de sécurité (FDS) relative à l'exportation d'un produit chimique interdit ou strictement réglementé, en provenance de l'Union Européenne à destination de votre pays.

Lors de la réception de la notification d'exportation, pourriez-vous avoir, s'il-vous-plaît, l'amabilité de me renvoyer, sous 30 jours, une copie signée du formulaire d'accusé de réception figurant à la 5ème ou 6ème page de la notification d'exportation ? Notez bien, je vous prie, que le renvoi de l'accusé de réception signé nous informe seulement que vous avez reçu la notification et qu'il n'a pas d'autres implications.

Toutefois, pour certains produits chimiques, l'Autorité Nationale Désignée (AND) du pays exportateur vous enverra une requête sollicitant la communication de votre décision concernant l'importation desdits produits chimiques dans votre pays, si vous ne l'avez pas déjà faite.

Comme d'habitude, je joins également une brève note explicative qui peut vous aider à comprendre notre procédure et en quoi celle-ci diffère de la procédure CIP.

N'hésitez pas à me contacter pour tout complément d'information.

En vous remerciant de votre obligeance, je vous prie d'agréer, Madame, Monsieur, l'expression de mes salutations distinguées.

2.2 – Plural case

Subject: Notifications d'exportation en provenance de l'Union Européenne

Madame, Monsieur,

Je vous invite à prendre connaissance des notifications d'exportation ci-dessous:

XXXXXXXXXXX – substance "A"
XXXXXXXXXXX – substance "B"

jointes à ce courriel accompagnées des fiches de données de sécurité (FDS) relatives à l'exportation de certains produits chimiques interdits ou strictement réglementés, en provenance de l'Union Européenne à destination de votre pays.

Lors de la réception des notifications d'exportation, pourriez-vous avoir, s'il-vous-plaît, l'amabilité de me renvoyer, sous 30 jours, une copie signée des formulaires d'accusés de réception figurant à la 5ème ou 6ème page de chaque notification d'exportation ? Notez bien, je vous prie, que le renvoi de l'accusé de réception signé nous informe seulement que vous avez reçu la notification et qu'il n'a pas d'autres implications.

Toutefois, pour certains produits chimiques, l'Autorité Nationale Désignée (AND) du pays exportateur vous enverra une requête sollicitant la communication de votre décision concernant l'importation desdits produits chimiques dans votre pays, si vous ne l'avez pas déjà faite.

Comme d'habitude, je joins également une brève note explicative qui peut vous aider à comprendre notre procédure et en quoi celle-ci diffère de la procédure CIP.

N'hésitez pas à me contacter pour tout complément d'information.

En vous remerciant de votre obligeance, je vous prie d'agréer, Madame, Monsieur, l'expression de mes salutations distinguées.

3) Spanish

3.1 - Single case

Subject: Notificación a la exportación desde la Unión Europea

Estimado Señor, Estimada Señora:

En este correo electrónico se adjunta la siguiente notificación a la exportación:

XXXXXXXXXXX – Substancia "A"

junto con su Ficha de Datos de Seguridad asociada correspondiente a la exportación de esta substancia desde la Unión Europea hacia su país. Cuando reciba la notificación a la exportación, rogamos sea tan amable de enviarnos una copia firmada del acuse de recibo, a ser posible en el plazo de 30 días desde la recepción de la notificación, que se encuentra en la quinta/sexta página de la notificación a la exportación. El acuse de recibo firmado únicamente nos informa que la notificación ha sido recibida por la persona correcta – sin posteriores implicaciones. De lo contrario debemos enviarla de nuevo.

Para ciertos productos químicos, el AND del país exportador enviará una petición solicitando su decisión a la importación en su país, si no ha contestado ya recientemente.

También se incluye una breve nota explicativa que puede ayudarle a comprender nuestro procedimiento y las diferencias existentes respecto al procedimiento CFP.

Agradeciendo de antemano su colaboración, no dude en contactar con nosotros para cualquier aclaración.

Saludos cordiales,

3.2 - Plural case

Subject: Notificaciones a la exportación desde la Unión Europea

Estimado Señor, Estimada Señora:

En este correo electrónico se adjuntan las siguientes notificaciones a la exportación:

XXXXXXXXXXX – Substancia "A"

XXXXXXXXXXX – Substancia "B"

junto con sus Fichas de Datos de Seguridad asociadas correspondientes a la exportación de estas substancias desde la Unión Europea hacia su país. Cuando reciba las notificaciones a la exportación, rogamos sea tan amable de enviarnos una copia firmada de los acuses de recibo, a ser posible en el plazo de 30 días desde la recepción de la notificación, que se encuentra en la quinta/sexta página de las notificaciones a la exportación. Los acuses de recibo firmados únicamente nos informan que las notificaciones han sido recibidas por la persona correcta – sin posteriores implicaciones. De lo contrario debemos enviarlas de nuevo.

Para ciertos productos químicos, el AND del país exportador enviará una petición solicitando su decisión a la importación en su país, si no ha contestado ya recientemente.

También se incluye una breve nota explicativa que puede ayudarle a comprender nuestro procedimiento y las diferencias existentes respecto al procedimiento CFP.

Agradeciendo de antemano su colaboración, no dude en contactar con nosotros para cualquier aclaración.

Saludos cordiales,

B - Letters for fax and post

1) English

1.1 - Single case

Subject: Export of dangerous chemicals from the EU according to Regulation 689/2008

Dear Madam/Sir,

Please find one export notification attached to this letter:

XXXXXXXXXXX – substance "A"

together with its Safety Data Sheet regarding intended export of this chemical from the European Union to Yyyyyy. When you receive it (and in any case within 30 days), could you please be so kind as to send us back a signed copy of the confirmation of receipt form which is generally the fifth/sixth page of an export notification?

I would like to remind you that there are no further implications involved, it is just to let us know that the notification has been received by the correct person otherwise we must send it again.

However, for certain chemicals the DNA of the exporting country will send you a request to provide your decision on their import into your country, if you have not already done so recently.

As always, I have also attached a note that we prepared explaining the EU procedure and legislation and how it differs from the PIC procedure, we hope it will help the authorities in importing countries to understand our requests.

Thank you in advance for your kind collaboration and please do not hesitate to contact us if further clarification is necessary.

Best regards,

1.2 – Plural case

Subject: Export of dangerous chemicals from the EU according to Regulation 689/2008

Dear Madam/Sir,

Please find two export notifications attached to this letter:

XXXXXXXXXXX – substance "A"
XXXXXXXXXXX – substance "B"

together with their Safety Data Sheets regarding intended export of these chemicals from the European Union to Yyyyyy. When you receive the export notifications (and in any case within 30 days), could you please be so kind as to send us back a signed copy of the confirmation of receipt form which is generally the fifth/sixth page of an export notification?

I would like to remind you that there are no further implications involved, it is just to let us know that the notification has been received by the correct person otherwise we must send it again.

However, for certain chemicals the DNA of the exporting country will send you a request to provide your decision on their import into your country, if you have not already done so recently.

As always, I have also attached a note that we prepared explaining the EU procedure and legislation and how it differs from the PIC procedure, we hope it will help the authorities in importing countries to understand our requests.

Thank you in advance for your kind collaboration and please do not hesitate to contact us if further clarification is necessary.

Best regards,

2) French

2.1 - Single case

Sujet: Exportation de produits chimiques interdits ou strictement réglementés selon le Règlement (UE) No. 689/2008

Madame, Monsieur,

Je vous invite à prendre connaissance de la notification d'exportation ci-dessous:

XXXXXXXXXXX – substance "A"

jointe à ce courrier accompagnée de la fiche de données de sécurité (FDS) relative à l'exportation d'un produit chimique interdit ou strictement réglementé, en provenance de l'Union Européenne à destination de votre pays.

Lors de la réception de la notification d'exportation, pourriez-vous avoir, s'il-vous-plaît, l'amabilité de me renvoyer, sous 30 jours, une copie signée du formulaire d'accusé de réception figurant à la 5ème ou 6ème page de la notification d'exportation ? Notez bien, je vous prie, que le renvoi de l'accusé de

réception signé nous informe seulement que vous avez reçu la notification et qu'il n'a pas d'autres implications.

Toutefois, pour certains produits chimiques, l'Autorité Nationale Désignée (AND) du pays exportateur vous enverra une requête sollicitant la communication de votre décision concernant l'importation desdits produits chimiques dans votre pays, si vous ne l'avez pas déjà faite.

Comme d'habitude, je joins également une brève note explicative qui peut vous aider à comprendre notre procédure et en quoi celle-ci diffère de la procédure CIP.

N'hésitez pas à me contacter pour tout complément d'information.

En vous remerciant de votre obligeance, je vous prie d'agréer, Monsieur, Madame, l'expression de mes salutations distinguées.

2.2 - Plural case

Sujet: Exportation de produits chimiques interdits ou strictement réglementés selon le Règlement (CE) No. 689/2008

Madame, Monsieur,

Je vous invite à prendre connaissance des notifications d'exportation ci-dessous:

XXXXXXXXXXX – substance "A"
XXXXXXXXXXX – substance "B"

jointes à ce courrier accompagnées des fiches de données de sécurité (FDS) relatives à l'exportation de certains produits chimiques interdits ou strictement réglementés, en provenance de l'Union Européenne à destination de votre pays.

Lors de la réception des notifications d'exportation, pourriez-vous avoir, s'il-vous-plaît, l'amabilité de me renvoyer, sous 30 jours, une copie signée des formulaires d'accusés de réception figurant à la 5ème ou 6ème page de chaque notification d'exportation? Notez bien, je vous prie, que le renvoi de l'accusé de réception signé nous informe seulement que vous avez reçu la notification et qu'il n'a pas d'autres implications.

Toutefois, pour certains produits chimiques, l'Autorité Nationale Désignée (AND) du pays exportateur vous enverra une requête sollicitant la communication de votre décision concernant l'importation desdits produits chimiques dans votre pays, si vous ne l'avez pas déjà faite.

Comme d'habitude, je joins également une brève note explicative qui peut vous aider à comprendre notre procédure et en quoi celle-ci diffère de la procédure CIP.

N'hésitez pas à me contacter pour tout complément d'information.

En vous remerciant de votre obligeance, je vous prie d'agréer, Madame, Monsieur, l'expression de mes salutations distinguées.

3) Spanish

3.1 - Single case

Asunto: Notificación a la exportación desde la Unión Europea, Reglamento (EEC) No. 689/2008

Estimado Señor, Estimada Señora:

En esta carta se adjunta la siguiente notificación a la exportación:

XXXXXXXXXXX – Substancia "A"

junto con su Ficha de Datos de Seguridad asociada correspondiente a la exportación de esta substancia desde la Unión Europea hacia su país. Cuando reciba la notificación a la exportación, rogamos sea tan amable de enviarnos una copia firmada del acuse de recibo, a ser posible en el plazo de 30 días desde la recepción de la notificación, que se encuentra en la quinta/sexta página de la notificación a la exportación. El acuse de recibo firmado únicamente nos informa que la notificación ha sido recibida por la persona correcta – sin posteriores implicaciones. De lo contrario debemos enviarla de nuevo.

Para ciertos productos químicos, el AND del país exportador enviará una petición solicitando su decisión a la importación en su país, si no ha contestado ya recientemente.

También se incluye una breve nota explicativa que puede ayudarle a comprender nuestro procedimiento y las diferencias existentes respecto al procedimiento CFP.

Agradeciendo de antemano su colaboración, no dude en contactar con nosotros para cualquier aclaración.

Saludos cordiales,

3.2 - Plural case

Asunto: Notificaciones a la exportación desde la Unión Europea, Reglamento (EEC) No. 689/2008

Estimado Señor, Estimada Señora:

En esta carta se adjuntan las siguientes notificaciones a la exportación:

XXXXXXXXXXX – Substancia "A"
XXXXXXXXXXX – Substancia "B"

junto con sus Fichas de Datos de Seguridad asociadas correspondientes a la exportación de estas substancias desde la Unión Europea hacia su país. Estas notificaciones se han enviado también por correo electrónico. Cuando reciba las notificaciones a la exportación, rogamos sea tan amable de enviarnos una copia firmada de los acuses de recibo, a ser posible en el plazo de 30 días desde la recepción de la notificación, que se encuentra en la quinta/sexta página de las notificaciones a la exportación. Los acuses de recibo firmados únicamente nos informan que las notificaciones han sido recibidas por la persona correcta – sin posteriores implicaciones. De lo contrario debemos enviarlas de nuevo.

Para ciertos productos químicos, el AND del país exportador enviará una petición solicitando su decisión a la importación en su país, si no ha contestado ya recientemente.

También se incluye una breve nota explicativa que puede ayudarle a comprender nuestro procedimiento y las diferencias existentes respecto al procedimiento CFP.

Agradeciendo de antemano su colaboración, no dude en contactar con nosotros para cualquier aclaración.

Saludos cordiales,

Annex III: second sending email to the importing country DNA

A concrete example of an email sent to importing country is attached below. Obviously, two other linguistic versions, ES and FR, are also available. The letters sent by fax and post are also attached in three languages.

A - Letter for email

1) English

Subject: Export Notifications for Banned or Severely Restricted Chemicals from the EC - second sending

Dear Sir,

Regulation (EC) 689/2008 foresees that we must be sure that the Designated National Authority in the importing country has received our export notifications and that if we are not certain of this we must send a second copy. As we never received confirmation of receipt forms from your country, please find attached a second copy of the following Export Notifications and related Safety Data Sheets related to exports from the European Community:

XXXXXXXXXXX – sent on dd.mm.yyyy
XXXXXXXXXXX – sent on dd.mm.yyyy

We would be grateful if you could send the signed form back to us, it is generally the third/fourth page of an export notification. Please bear in mind that sending us the signed confirmation of receipt form only informs us that you have received the notification – there are no further implications.

However, for certain chemicals the DNA of the exporting country will send you a request to provide your decision on their import into your country, if you have not already done so recently.

Another e-mail will follow with more export notifications as the files are too big to attach here.

Please don't hesitate to contact us if you need any further specifications.

Thank you in advance for your kind collaboration.

Kind regards,

2) French

Subject: Notifications d'exportation en provenance de la CE - deuxième envoi

Madame, Monsieur,

La Réglementation (CE) 689/2008 prévoit que nous devons nous assurer que l'Autorité National Désigné (AND) du pays importateur a reçu nos notifications en matière d'exportation, et que si nous n'avons pas cette certitude, nous devons alors envoyer une ultérieure copie. N'ayant jamais eu confirmation de la part de votre pays que vous avez bien reçu ces documents, je vous prie de bien vouloir trouver ici en pièce jointe une seconde copie des Notifications d'exportation, ainsi que les fiches de données de sécurité connexes aux exportations depuis la Communauté Européenne.

XXXXXXXXXXX – envoyé le jj.mm.aaaa
XXXXXXXXXXX – envoyé le jj.mm.aaaa

Par ailleurs, nous vous serions reconnaissants de bien vouloir nous renvoyer ces documents signés afin d'attester que vous les avez bien reçus (il s'agit généralement de la troisième/quatrième page de la notification d'exportation). Je me permets de vous rappeler en outre que la réception de l'accusé de réception signé nous informe simplement que vous avez reçu la notification, cela n'implique aucun type d'engagement.

Toutefois, pour certains produits chimiques, l'Autorité Nationale Désignée (AND) du pays exportateur vous enverra une requête sollicitant la communication de votre décision concernant l'importation desdits produits chimiques dans votre pays, si vous ne l'avez pas déjà faite.

N'hésitez pas à me contacter, SVP, pour tout complément d'information.

Je joins également une brève note explicative qui peut vous aider à comprendre notre procédure et en quoi celle-ci diffère de la procédure CIP.

En vous remerciant de votre obligeance, je vous prie de recevoir mes meilleures salutations.

3) Spanish

Subject: Notificaciones a la exportación desde la Unión Europea - segundo envío

Estimado Señor, Estimada Señora:

El Reglamento 689/2008 establece que debemos asegurarnos que la Autoridad Nacional Designada del país importador ha recibido las notificaciones de exportación y en caso contrario se debe realizar un segundo envío. Debido a que nunca recibimos de su país los acuses de recibo, le adjunto una segunda copia de las siguientes Notificaciones a la Exportación con sus correspondientes Hojas de Datos de Seguridad relacionadas con las siguientes exportaciones de la Unión Europea:

XXXXXXXXXXX – enviada el dd.mm.aaaa
XXXXXXXXXXX – enviada el dd.mm.aaaa

Le estaríamos agradecidos si nos devolviese firmados los formularios. Normalmente se encuentran en la tercera/cuarta página de la notificación de exportación. Le rogamos tenga presente que devolviéndonos los acuses de recibo firmados, únicamente nos informa que han recibido la notificación - no hay implicaciones posteriores.

Para ciertos productos químicos, el AND del país exportador enviará una petición solicitando su decisión a la importación en su país, si no ha contestado ya recientemente.

Agradeciendo de antemano su colaboración, no dude en contactar con nosotros para cualquier aclaración.

Saludos cordiales,

B - Letter for fax and post

1) English

Subject: Export Notifications for Banned or Severely Restricted Chemicals from the EC – second sending

Dear Sir/Madam,

Regulation (EC) 689/2008 foresees that we must be sure that the Designated National Authority in the importing country has received our export notifications and that if we are not certain of this we must send a second copy. As we never received confirmation of receipt forms from your country, please find attached a second copy of the following Export Notifications and related Safety Data Sheets related to exports from the European Community:

XXXXXXXXXXX – sent on dd.mm.yyyy
XXXXXXXXXXX – sent on dd.mm.yyyy

We would be grateful if you could send the signed form back to us, it is generally the third/fourth page of an export notification. Please bear in mind that sending us the signed confirmation of receipt form only informs us that you have received the notification – there are no further implications.

However, for certain chemicals the DNA of the exporting country will send you a request to provide your decision on their import into your country, if you have not already done so recently.

Please don't hesitate to contact us if you need any further specifications.

Thank you in advance for your kind collaboration.

Kind regards,

2) French

Sujet: Exportation de produits chimiques interdits ou strictement réglementés selon le Règlement (CE) No. 689/2008

Monsieur, Madame,

La Réglementation (CE) 689/2008 prévoit que nous devons nous assurer que l'Autorité National Désigné (AND) du pays importateur a reçu nos notifications en matière d'exportation, et que si nous n'avons pas cette certitude, nous devons alors envoyer une ultérieure copie. N'ayant jamais eu confirmation de la part de votre pays que vous avez bien reçu ces documents, je vous prie de bien vouloir trouver ici en pièce jointe une seconde copie des Notifications d'exportation, ainsi que les fiches de données de sécurité connexes aux exportations depuis la Communauté Européenne.

XXXXXXXXXXX – envoyé le jj.mm.aaaa
XXXXXXXXXXX – envoyé le jj.mm.aaaa

Par ailleurs, nous vous serions reconnaissants de bien vouloir nous renvoyer ces documents signés afin d'attester -comme prévu par la réglementation- que vous les avez bien reçus (il s'agit généralement de la troisième/quatrième page de la notification d'exportation). Je me permets de vous rappeler en outre que la réception de l'accusé de réception signé nous informe simplement que vous avez reçu la notification, cela n'implique aucun type d'engagement.

Toutefois, pour certains produits chimiques, l'Autorité Nationale Désignée (AND) du pays exportateur vous enverra une requête sollicitant la communication de votre décision concernant l'importation desdits produits chimiques dans votre pays, si vous ne l'avez pas déjà faite.
N'hésitez pas à me contacter, SVP, pour tout complément d'information.

Je joins également une brève note explicative qui peut vous aider à comprendre notre procédure et en quoi celle-ci diffère de la procédure CIP.

En vous remerciant de votre obligeance, je vous prie de recevoir mes meilleures salutations.

3) Spanish

Asunto: Notificaciones a la exportación desde la Unión Europea, Reglamento (EC) No. 689/2008

Estimado Señor, Estimada Señora:

El Reglamento 689/2008 establece que debemos asegurarnos que la Autoridad Nacional Designada del país importador ha recibido las notificaciones de exportación y en caso contrario se debe realizar un segundo envío. Debido a que nunca recibimos de su país los acuses de recibo, le adjunto una segunda copia de las siguientes Notificaciones a la Exportación con sus correspondientes Hojas de Datos de Seguridad relacionadas con las siguientes exportaciones de la Unión Europea:

XXXXXXXXXXX – enviada el dd.mm.aaaa
XXXXXXXXXXX – enviada el dd.mm.aaaa

Le estaríamos agradecidos si nos devolviese firmados los formularios. Normalmente se encuentran en la tercera/cuarta página de la notificación de exportación. Le rogamos tenga presente que devolviéndonos los acuses de recibo firmados, únicamente nos informa que han recibido la notificación - no hay implicaciones posteriores.

Para ciertos productos químicos, el AND del país exportador enviará una petición solicitando su decisión a la importación en su país, si no ha contestado ya recientemente.

Agradeciendo de antemano su colaboración, no dude en contactar con nosotros para cualquier aclaración.

Saludos cordiales,

Annex IV: Explicit Consent letter and form

Subject: **Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade: Request for explicit consent to export a chemical to your country in accordance with EC implementing legislation**

Company ….. wishes to export the chemical ….. to your country

The chemical is to be exported as a substance by itself*/ in a preparation (concentration ….%)* for use as …… Additional information can be found in the attached export notification/ advanced copy of the export notification*, which has been produced in accordance with Article 12 of the Rotterdam Convention.

In addition to the rules provided for in the Rotterdam Convention, the European Community (EC) has introduced a domestic requirement that export from the European Community of this chemical cannot proceed without the explicit consent of the importing country[2]. Enclosed is an explanatory note that explains the EC procedures in more detail*.

Accordingly could you please answer the attached questionnaire to inform us whether or not you consent to the import of this chemical. If you need time to give a response, please inform us as soon as possible when we can expect your answer. Also, if you are not the relevant authority, please let us know who we should contact.

You may reply by letter, fax or email to the address below.

The European Community has a website[3] that provides information about chemicals subject to its legislation. Your response will be listed on the website so that all interested parties are made aware of your decision.

Thank you in advance for your co-operation.

Name and address of EC Member State exporting Designated National Authority (DNA):

Contact name:
Phone/fax:
Email address:

Date:

* delete as appropriate

[2] Regulation 689/2008 concerning the export and import of dangerous chemicals, Article 13.6 thereof

[3] http://edexim.jrc.ec.europa.eu

IMPORTING COUNTRY RESPONSE TO REQUEST FOR EXPLICIT CONSENT

SECTION 1A. CHEMICAL IDENTITY, IF IN FORM OF SUBSTANCE (TO BE COMPLETED BY EXPORTING DNA)	
Name of chemical	
CAS No.	

SECTION 1B. CHEMICAL IDENTITY, IF IN FORM OF PREPARATION (TO BE COMPLETED BY EXPORTING DNA)	
Name of preparation	
Name of chemical and % concentration	
CAS No.	

SECTION 2. RESPONSE TO THE REQUEST FOR EXPLICIT CONSENT
Do you consent to import?
❑ **YES (Please complete sections 3 to 9)** OR ❑ **NO (Please complete sections 3 and 7 to 9)**

SECTION 3. TO WHICH OF THE FOLLOWING USE CATEGORIES DOES YOUR RESPONSE APPLY?				
(A) Pesticide	❑ Yes ❑ No		(B) Industrial chemical	❑ Yes ❑ No

SECTION 4. IF CONSENT IS GIVEN IN SECTION 2, AND THE CHEMICAL IS IN THE FORM OF A PREPARATION, DOES CONSENT GO WIDER THAN THE SPECIFIC PREPARATION LISTED IN SECTION 1B?	
Is consent valid for other preparations containing the same chemical at different concentrations?	❑ Yes ❑ No
The concentrations that are allowed are :	
Does consent extend to the chemical in the form of a pure substance?	❑ Yes ❑ No

SECTION 5. IF CONSENT IS GIVEN IN SECTION 2, ARE THERE ANY RESTRICTIONS/CONDITIONS ?	
Are there any restrictions or conditions attached to consent?	❑ Yes ❑ No
The specified restrictions or conditions (including any limitations on the use of the chemical) are:	

SECTION 6. IF CONSENT IS GIVEN IN SECTION 2, HOW LONG DOES IT APPLY?	
Is the consent time-limited?	❑ Yes ❑ No
If consent is time-limited, the length of time it applies is:	

SECTION 7. WOULD USE OF THE CHEMICAL FROM ALL SOURCES (DOMESTIC PRODUCTION FOR DOMESTIC USE AND IMPORTS FROM OTHER COUNTRIES) BE TREATED THE SAME AS THE PROPOSED EXPORT FROM THE EU?
❑ **YES** OR ❑ **NO**
If 'No', the reasons why are:

SECTION 8. ANY OTHER RELEVANT INFORMATION

SECTION 9. NAME AND ADDRESS OF IMPORTING DNA	
Institution	
Address	
Contact name	
Telephone	
Telefax	
E-mail address	
Date	

Annex V: Explanatory note

The explanatory not is attached in three languages.

1) English

EUROPEAN COMMISSION
JOINT RESEARCH CENTRE
Institute for Health and Consumer Protection (Ispra)

Explanatory Note concerning the EU Export notification Procedure and Explicit Consent Provision

The EU legislation (Regulation 689/2008 concerning the export and import of dangerous chemicals) implements the Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade. However it goes further than the requirements of the Convention itself. The purpose of this note is to explain the EU procedures.

There are two main procedures:

1. **Yearly Export Notification (using document 'EU Yearly Export Notification') – made by the European Commission as the common EU Designated National Authority (DNA)**

2. **Explicit Consent (using document 'Request for Explicit Consent Form') – managed by the DNA in the exporting EU Member State**

1.Yearly Export Notification

ROTTERDAM CONVENTION

Under Article 12, an exporting Party must send annual export notifications for any chemical that it has banned or severely restricted domestically in a Convention use category (pesticides or industrial chemicals). The exporting Party's obligations in relation to that chemical end with the export notification. The importing Party is requested to send an acknowledgement of receipt of the first export notification received after adoption of the ban/severe restriction of the chemical in the exporting Party. For chemicals listed in Annex III to the Convention as being subject to the PIC procedure, the obligation to notify export ceases when the importing Party has given a clear import response in accordance with Article 10.

EU REGULATION

Under the EU Regulation, export notification extends to exports to all countries, not only to Parties of the Convention.

In addition, the scope of the EU Regulation is not limited only to chemicals that are banned or severely restricted under the Convention, but also to

- Chemicals that are banned or severely restricted at EU level even if not banned or severely restricted within the meaning of the Convention, i.e. the chemicals do not qualify for PIC notification pursuant to Article 5 of the Convention but the restrictions are such that the EU would like to alert other countries to EU exports so as to facilitate the safe handling of these chemicals.

  In order to determine which chemicals should be subject to export notification from the EU, the two Convention use categories have been divided into subcategories. The pesticides category is divided into 2 subcategories: agricultural pesticides and non- agricultural pesticides ; the industrial chemicals are divided into chemicals for professional use and chemicals for consumer use. Therefore under the EU Regulation a chemical can be banned or severely restricted at subcategory level but not at Convention use category level, and still trigger export notification.

  Furthermore, the EU makes export notifications irrespective of the intended use and whether or not that use is banned or severely restricted within the EU. This is because it cannot be guaranteed that the intended use is identical to the final use in the importing country.

- Chemicals listed in Annex III to the Convention as being subject to the PIC procedure

  Export notifications are made until the importing country has given a clear import response covering the intended use in accordance with Article 10 of the Convention, unless it asks to continue to receive export notifications.

For chemicals that are banned or severely restricted within the EU in a Convention use category and for Annex III chemicals, unless the importing country has already given explicit consent (see below), the export notification will specify that the export will not proceed unless explicit consent is given by the importing country.

Export notifications from the EU are sent out from the common EU Designated National Authority (DNA), the European Commission. Currently the Export Notification procedure and the related database EDEXIM http://edexim.jrc.ec.europa.eu) are administered within the European Commission by the IHCP – Institute for Health and Consumer Protection in Ispra, Italy.

A confirmation of receipt form is included in the export notification (normally the third/fourth page) that can simply be filled in and sent back to the address given. Returning this form does not imply the acceptance of the import, it simply informs us that the notification has been received.

If the importing country fails to return the confirmation of receipt of the first export notification within 30 days, the IHCP will send a second export notification.

2. Explicit Consent

ROTTERDAM CONVENTION

For chemicals listed in Annex III, Article 11 requires exporting Parties to respect the import responses of importing Parties as listed in the latest PIC circular.

EU REGULATION

The EU Regulation includes an explicit consent procedure for such chemicals exported to all countries since import responses in the PIC circular relate only to the use category listed in Annex III to the Convention and in many cases importing Parties have failed to provide import responses and are thus unprotected by Article 11 of the Convention. The EU explicit

consent procedure also extends to chemicals that are banned or severely restricted in the EU within a Convention use category and thus qualify for PIC notification pursuant to Article 5 of the Convention even though the chemicals are not yet listed in Annex III.

The requests for explicit consent are made to the importing country DNA by the DNA in the exporting EU Member State (who will often provide an advance copy of the export notification). The request will be repeated if there is no response within a certain period. If the request has not been sent to the appropriate DNA in the importing country, it would be helpful if it could be forwarded to the responsible DNA. If changes to the relevant national legislation are expected or planned, it would be helpful if you could in the meantime give an interim response.

We would expect the importing county's response to a request for explicit consent to reflect its domestic legislation for the chemicals concerned and to respect the 'non-discrimination' provisions of Article 10.9 of the Convention and World Trade Organisation rules, *i.e.* if import from EU is banned, imports from other sources and any domestic production should likewise not be allowed.

For any chemical for which explicit consent is requested from the importing country DNA, an export notification is also submitted from the European Commission, the common EU DNA. This export notification will specify that exports will not proceed unless explicit consent is obtained. Explicit consent requests from the EU Member States and replies from importing countries are all registered in the EDEXIM database, available at http://edexim.jrc.ec.europa.eu

When a chemical is intended to be exported in its pure form, the Request for Explicit Consent Form asks the importing country DNA to state whether the response given also applies to imports of preparations containing the notified chemical. Likewise, when a chemical is intended to be exported as a preparation, the form asks for the importing country to state whether its response extends to preparations containing the same chemical at different concentrations and whether it is applicable for exports of the pure chemical in itself. The importing DNA is further asked to state any conditions, such as limited use categories, time-limits or other restrictions.

EDEXIM
European Database on Export and Import of Dangerous Chemicals

In case you have any queries or comments, please consult our homepage (http://edexim.jrc.ec.europa.eu) for further information or address your query directly to one of the colleagues at the IHCP (JRC-IHCP-EDEXIM@ec.europa.eu) or to the DNA of the exporting EU Member State.

[1] mainly chemicals evaluated under Regulation (EC) No 1107/2009 on authorisation of plant protection products

[2] mainly chemicals evaluated under Regulation (EU) 528/2012 on authorisation of biocidal products

2) French

Note explicative concernant la procédure de notification d'exportation de l'UE et la disposition de consentement explicite

La législation de l'UE (Règlement 689/2008 concernant l'exportation et l'importation de substances chimiques dangereuses) met en œuvre la convention de Rotterdam sur la Procédure de Consentement Préalable en connaissance de cause applicable à certains produits chimiques et pesticides dangereux qui font l'objet d'un commerce international. Toutefois, elle va au-delà des dispositions prévues par la convention. Le but de cette note est d'expliquer les procédures de l'UE.

Il y a deux procédures principales :

1 **Notification d'Exportation Annuelle (utilisant le document « Notification Annuelle d'Exportation UE » fait par la Commission Européenne en qualité d'Autorité Nationale Désignée (AND) commune de l'UE**

2 **Consentement explicite (utilisant le document `Formulaire pour la demande de consentement explicite`) géré par l'AND de l'État membre exportateur de l'UE.**

1. Notification d'Exportation Annuelle

CONVENTION DE ROTTERDAM

En vertu de l'article 12, une Partie exportatrice doit envoyer des notifications d'exportation annuelles pour tout produit chimique interdit ou strictement réglementé dans une catégorie d'utilisation prévue par la convention (pesticides ou substances chimiques industrielles). Les obligations de la Partie exportatrice en rapport à ce produit chimique se terminent avec la notification d'exportation. La Partie importatrice est invitée à envoyer un accusé de réception de la première notification d'exportation reçue après l'adoption de l'interdiction/la réglementation stricte du produit chimique dans la Partie exportatrice. Pour les substances chimiques énumérées à l'Annexe III de la convention, soumises à la procédure CIP, l'obligation de notifier l'exportation cesse quand la Partie importatrice a donné une réponse d'importation claire, conformément à l'article 10.

RÈGLEMENT DE L'UE

En vertu du règlement de l'UE, la notification d'exportation s'étend aux exportations vers tous les pays, non seulement aux Parties de la convention.

En outre, le champ d'application du règlement de l'UE ne se limite pas seulement aux substances chimiques qui sont interdites ou strictement réglementées en vertu de la convention, mais également aux

- Substances chimiques qui sont interdites ou strictement réglementées au niveau de l'UE, même si elles ne sont pas interdites ou strictement réglementées au sens de la convention, c'est-à-dire les substances chimiques ne remplissant pas les conditions pour la notification CIP, conformément à l'article 5 de la convention : les réglementations sont telles, que l'UE souhaiterait alerter d'autres pays sur les exportations de l'UE afin de faciliter une manipulation sans danger de ces substances chimiques.

  Afin de déterminer quelles substances chimiques soumettre à la notification d'exportation de l'UE, les deux catégories d'utilisation prévues par la convention ont été subdivisées en sous-catégories. La catégorie des pesticides est subdivisée en 2 sous-catégories :

pesticides agricoles[1] et pesticides non agricoles[2]; les substances chimiques industrielles sont subdivisées en substances chimiques à usage professionnel et substances chimiques destinées au grand public. Par conséquent, en vertu du règlement de l'UE, une substance chimique peut être interdite ou être strictement réglementée au niveau de sous-catégorie mais non au niveau de catégorie d'utilisation prévue par la Convention, et déclencher toujours la notification d'exportation.

En outre, l'UE fait des notifications d'exportation indépendamment de l'utilisation prévue et du fait que cette utilisation soit interdite ou strictement réglementée au sein de l'UE. Ceci parce qu'il ne peut être garanti que l'utilisation prévue soit identique à l'utilisation finale dans le pays importateur.

- Substances chimiques énumérées à l'Annexe III de la convention comme étant soumises à la procédure CIP.

Les notifications d'exportation sont faites jusqu'à ce que le pays importateur ait donné une réponse d'importation claire couvrant l'utilisation prévue, conformément à l'article 10 de la convention, à moins qu'il demande de continuer à recevoir des notifications d'exportation.

En ce qui concerne les substances chimiques qui sont interdites ou strictement réglementées au sein de l'UE dans une catégorie d'utilisation prévue par la convention et les substances chimiques à l'Annexe III, à moins que le pays importateur ait déjà donné le consentement explicite (voir ci-dessous), la notification d'exportation spécifiera que l'exportation ne procédera pas sans que le consentement explicite ne soit donné par le pays importateur.

Les notifications d'exportation de l'UE sont envoyées par l'Autorité Nationale Désignée (AND) commune de l'UE, la Commission européenne. Actuellement la procédure de notification à l'exportation et la base de données connexe EDEXIM (http://edexim.jrc.ec.europa.eu) sont administrées au sein de la Commission européenne par l'institut IHCP – Institute for Health and Consumer Protection à Ispra, en Italie.

Un formulaire d'accusé de réception est inclus dans la notification d'exportation (normalement, à la troisième/quatrième page), qui peut être simplement rempli et renvoyé à l'adresse donnée. Le renvoi de ce formulaire n'implique pas l'acceptation de l'importation, il nous informe simplement du fait que la notification a été reçue.

Si le pays importateur ne renvoie pas l'accusé de réception de la première notification d'exportation dans les 30 jours, le IHCP enverra une deuxième notification d'exportation.

2. Consentement Explicite

CONVENTION de ROTTERDAM

Pour les substances chimiques énumérées à l'Annexe III, l'article 11 exige que les Parties exportatrices respectent les réponses d'importation des Parties importatrices énumérées dans la circulaire CIP la plus récente.

RÈGLEMENT de l'UE

Le règlement de l'UE comprend une procédure de consentement explicite pour les substances chimiques exportées vers tous les pays puisque les réponses d'importation dans la circulaire CIP se rapportent seulement à la catégorie d'utilisation énumérée à l'Annexe III de la convention et dans de

nombreux cas les Parties importatrices n'ont pas fourni de réponses d'importation et ne sont donc pas protégées par l'article 11 de la convention. La procédure de consentement explicite de l'UE s'étend aussi aux substances chimiques qui sont interdites ou strictement réglementées dans l'UE dans une catégorie d'utilisation prévue par la convention et remplissent les conditions pour la notification CIP conformément à l'article 5 de la convention, même si les substances chimiques ne sont pas encore énumérées à l'Annexe III.

Les demandes de consentement explicite sont faites à l'AND du pays importateur par l'AND de l'État membre exportateur de l'UE (qui fournira souvent un exemplaire avant tirage de la notification d'exportation). La demande sera renouvelée s'il n'y a aucune réponse pendant une certaine période. Si la demande n'a pas été envoyée à l'AND approprié dans le pays importateur, il serait utile qu'elle puisse être transmise à l'AND responsable. Si des changements à la législation nationale pertinente sont attendus ou prévus, ce serait utile si vous pouviez donner une réponse provisoire en attendant.

Nous attendons la réponse du pays importateur à une demande de consentement explicite pour refléter sa législation nationale sur les substances chimiques concernées et pour respecter les dispositions de 'non-discrimination 'de l'article 10.9 de la Convention et les règles de l'Organisation Mondiale du Commerce, c'est-à-dire si l'importation en provenance de l'UE est interdite, l'importation d'autres sources et toute production nationale ne devraient également pas être permises.

Pour tout produit chimique pour lequel un consentement explicite est demandé à l'AND du pays importateur, une notification d'exportation est également soumise à la Commission Européenne, l'AND commune de l'UE. Cette notification d'exportation spécifiera que les exportations ne procéderont pas à moins que le consentement explicite ne soit obtenu. Les demandes de consentement explicite des États membres de l'UE et les réponses des pays importateurs sont enregistrées dans la base de données EDEXIM, disponible à l'adresse http://edexim.jrc.iec.europa.eu.

Quand une substance chimique est destinée à être exporté dans sa forme pure, le formulaire pour la demande de consentement explicite demande à l'AND du pays importateur d'énoncer si la réponse donnée s'applique également aux importations des préparations contenant la substance chimique notifiée. De même, quand une substance chimique est destinée à être exportée en tant que préparation, le formulaire demande au pays importateur d'énoncer si sa réponse s'étend aux préparations contenant la même substance chimique aux différentes concentrations et si elle s'applique aux exportations de la substance chimique pure. L'AND d'importation est encore invitée à énoncer toute condition, telle que les catégories limitées d'utilisation, les limites temporelles ou d'autres restrictions.

Si vous avez des questions ou des commentaires, veuillez consulter notre page d'accueil (http://edexim.jrc.ec.europa.eu) pour des informations complémentaires ou adressez votre question directement à l'un des collègues du IHCP (JRC-IHCP-EDEXIM@ec.europa.eu) ou à l'AND de l'État membre exportateur de l'UE.

[1] surtout les produits chimiques évalués sous le Règlement (EC) No 1107/2009 de l'UE concernant l'autorisation de mise sur le marché de produits phytopharmaceutiques

[2] surtout les produits chimiques évalués sous le Règlement (EU) No 528/2012 de l'UE concernant l'autorisation des produits biocides

3) Spanish

Nota Explicativa sobre el Procedimiento de la Notificación a la Exportación y el Consentimiento Explícito en la UE

La legislación de la UE (Reglamento 689/2008 sobre la exportación y la importación de productos químicos peligrosos) implementa el Convenio de Rotterdam sobre el Procedimiento de Consentimiento Fundamentado Previo Aplicable a Ciertos Plaguicidas y Productos Químicos Peligrosos Objeto de Comercio Internacional. Sin embargo va más allá que los requerimientos del Convenio mismo. El propósito de esta nota es explicar el procedimiento de la UE.

Hay dos procedimientos principales:

1. **Notificación Anual a la Exportación (ver documento "Notificación Anual a la Exportación UE") – elaborado por la Comisión Europea como Autoridad Nacional Designada de la UE (AND).**
2. **Consentimiento Explícito (ver documento "Solicitud de un formulario para Consentimiento Explícito") – gestionado por las AND de los Países Miembros exportadores.**

1. Notificación Anual a la Exportación

CONVENIO DE ROTTERDAM

Según el Artículo 12, una Parte exportadora debe enviar la notificación anual a la exportación para cualquier producto químico que haya sido prohibido o severamente restringido en su territorio en alguna de las categorías de uso indicadas en el Convenio (plaguicidas o productos químicos industriales). Las obligaciones de la Parte exportadora terminan con la notificación a la exportación. A la parte importadora se le solicita un acuse de recibo de la primera notificación a la exportación recibida después de la adopción de prohibir o restringir severamente al producto químico en la Parte exportadora. Para los productos químicos listados en el Anexo III del Convenio, sometidos al procedimiento PIC, la obligación de la notificación cesa cuando la Parte importadora haya dado una clara respuesta de acuerdo con el Artículo 10.

REGLAMENTO UE

Según el Reglamento de la UE, la notificación a la exportación se extiende a todos los países y no únicamente a las Partes del Convenio.

Además el objetivo del Reglamento de la UE no se limita únicamente a los productos químicos que han sido prohibidos o severamente restringidos, sino que también a

- Los productos químicos que han sido prohibidos o severamente restringidos en la UE incluso si esta prohibición o restricción severa queda fuera de las categorías del Convenio por ejemplo los productos químicos no calificados para la notificación PIC según el Artículo 5 del Convenio pero las restricciones son tales que la UE quiere alertar sus exportaciones para facilitar el manejo seguro de estos productos químicos.

Para determinar cuales productos químicos estarían sometidos a la notificación de la UE, las dos categorías de uso del Convenio han sido divididas en subcategorías. La categoría de plaguicida ha sido dividida en dos subcategorías: plaguicidas agrícolas[1] y plaguicidas no agrícolas[2]; los productos químicos industriales se dividen en productos químicos para uso

profesional y para uso ciudadano. Por consiguiente en el Reglamento UE un producto químico que sea prohibido o severamente restringido solo en una subcategoría de uso del Reglamento pero no en una categoría de uso del Convenio, también originaria una notificación a la exportación.

Además, la UE realiza las notificaciones a la exportación independientemente del uso que vaya a realizarse y si o no este uso se encuentra prohibido o severamente restringido en la UE. Esto sucede al no poder garantizarse que la intención del uso sea idéntica al uso final en el país importador.

- Los productos químicos listados en el Anexo III del Convenio están sometidos al procedimiento PIC.

Las notificaciones a la exportación son realizadas hasta que el país importador haya dado una respuesta clara relativa la intención de uso de acuerdo con el Artículo 10 del Convenio, exceptuando el caso que solicite seguir recibiendo las notificaciones a la exportación.

Para los productos químicos que hayan sido prohibidos o severamente restringidos en la UE en una categoría de uso del Convenio y para los productos químicos del Anexo III, a menos que el país importados haya ya concedido el consentimiento explícito (ver más adelante), la notificación a la exportación especificará que la exportación no se realizará hasta que el país importador conceda el consentimiento explícito.

Las notificaciones a la exportación procedentes de la UE son enviadas a través de la Autoridad Nacional Designada de la UE (AND), la Comisión Europea. El procedimiento de las Notificaciones a la Exportación y la base de datos relacionada EDEXIM (http://edexim.jrc.ec.europa.eu) son administradas en la Comisión Europea por el Instituto IHCP – Institute for Health and Consumer Protection en Ispra, Italia.

Se incluye en la notificación a la exportación (normalmente 3/4 páginas) un acuse de recibo para ser rellenado sin dificultad y enviado a la dirección indicada. La devolución de este formulario no implica la aceptación de la importación, sino simplemente nos informa que la notificación se ha recibido.

Si el país importador no devuelve el acuse de recibo de la primera notificación a la exportación dentro de 30 días, el IHCP enviará una segunda notificación.

2. Consentimiento Explícito

CONVENIO DE ROTTERDAM

Para los productos químicos listados en el Anexo III, el Artículo 11 requiere que las Partes exportadoras respeten las respuestas a la importación de las Partes importadoras publicadas en la última circular PIC.

REGLAMENTO EU

El reglamento de la UE incluye un procedimiento de consentimiento explícito para aquellos productos químicos exportados a todos los países debido a que las respuestas de los países en la circular PIC indican únicamente la categoría de uso del Anexo III del Convenio y en muchos casos las Partes importadoras no han proporcionado una respuesta a la importación y por consiguiente se encuentran desprotegidas por el Artículo 11 del Convenio. El procedimiento de consentimiento explícito se extiende también a los productos químicos que han sido prohibidos o

severamente restringidos en una de las categorías del Convenio y por consiguiente se califican para la notificación PIC siguiendo el Artículo 5 del Convenio incluyendo incluso aquellos no todavía listados en el Anexo III.

Las solicitudes de consentimiento explícito se realizan a la AND del país importador por la AND del Estado Miembro exportador de la UE (quien a menudo proporciona una copia de la notificación a la exportación por adelantado). La solicitud se repetirá en el caso que no se produzca una respuesta dentro de un cierto periodo. Si la solicitud no hubiera sido enviada a la AND adecuada en el país importador, sería útil si se pudiese re-enviar a la AND responsable. En el caso que se esperen cambios relevantes en la legislación nacional sería útil mientras tanto si se pudiese dar una respuesta provisional.

Nosotros esperaríamos en la respuesta del país importador a una solicitud de consentimiento explícito que se reflejase la legislación del país para los productos químicos implicados y respecto a las disposiciones de "no-discriminación" según el Artículo 10.9 del Convenio y de las reglas de la Organización Mundial del Comercio ej. si la importación desde la UE está prohibida, las importaciones desde otros orígenes y cualquier producción interna no debería permitirse.

Para cualquier producto químico que se haya solicitado el consentimiento explícito a la AND del país importador, se enviará una notificación a la exportación desde la Comisión Europea (AND común para la UE). Esta notificación a la exportación especificará que las exportaciones no procederán hasta que no se haya obtenido el consentimiento explícito. Tanto las solicitudes de consentimiento explícito de los Estados Miembros de la UE como las respuestas de los países importadores se registraran en la base de datos EDEXIM, disponible en la dirección http://edexim.jrc.ec.europa.eu.

Cuando un producto químico va a ser exportado en su forma pura, el Formulario para la Solicitud del Consentimiento Explícito pregunta a la AND del país importador si la respuesta se aplica también a las importaciones de preparados que contengan el producto químico notificado. Análogamente, cuando se vaya a proceder a la exportación de un producto químico contenido en una preparación, el formulario solicita al país importador que establezca si su respuesta se extiende a las preparaciones que contienen el mismo producto químico a otras concentraciones y si es aplicable al mismo producto químico en forma pura. Se solicita a la AND importadora que establezca las condiciones, tales como limitaciones en las categorías de uso, periodos de validez y otras restricciones.

En el caso que tuviese algunas preguntas o comentarios, por favor consulte nuestra página (http://edexim.jrc.ec.europa.eu) y para una información más detallada dirigase directamente a alguno de los colegas del IHCP (JRC-IHCP-EDEXIM@ec.europa.eu) o a la AND del País Miembro exportador de la UE

[1] principalmente productos químicos evaluados en el Reglamento (EC) 1107/2009 sobre productos fitosanitarios.

[2] principalmente productos químicos evaluados en el Reglamento (EU) 528/2012 sobre biocidas.

LEGEND

A:	Article
AND	Autorité Nationale Désignée (French) & Autoridad Nacional Designada (Spanish)
C:	Chemical
CAS:	Chemical Abstracts Service registry number
CFP	Consentimiento Fundamentado Previo (Spanish)
CIP	Consentement Informé Préalable (French)
COM:	European Commission, Directorate-General for the Environment
CN:	Chinese
CN:	Combined Nomenclature code of the European Union
CUS:	Customs Union and Statistics number
dd:	day
DG:	Directorate-General
DNA:	Designated National Authority(ies)
EC:	European Commission
EC:	European Community(ies)
E.C.:	Explicit consent (*also* Ex. Con.(s))
EDEXIM:	European Database for the EXport and IMport of (certain) dangerous chemicals
EINECS:	European Inventory of Existing Commercial Substances
EN:	English
E.N.:	Export notification (*also* Exp. Not.)
ENV:	Environment
ERN:	Export Reference Number
ES:	Spanish
EU:	European Union
FDS	Fiche de Données de Sécurité (French) & Ficha de Datos de Seguridad (Spanish)
FR:	French
g:	gram
GHS:	Globally Harmonised System
IARC:	International Agency for Research on Cancer
ID:	identifier
IHCP:	Institute for Health and Customer Protection of the JRC
IUPAC:	International Union of Pure and Applied Chemistry
JP:	Japanese
JRC:	Joint Research Centre of the European Commission
Kg:	kilogram(me)
l:	litre
MB:	Megabyte
mm:	month
OECD:	Organisation for Economic Co-operation and Development
P:	Preparation
PDF:	Portable Document Format
PHP:	Hypertext Processor, *originally Personal Home Page*
PIC:	Prior Informed Consent
PT:	Portuguese
RIN:	Reference Identification Number
RU:	Russian
SDS:	Safety Data Sheet
TR:	Turkish
UE	Union Européenne (French) & Unión Europea (Spanish)
v:	volume
w:	weight
WHO:	World Health Organization
yyyy:	year

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Abstract

The Rotterdam Convention that was signed in Rotterdam on 10 September 1998 and entered into force on 24 February 2004 regroups currently 154 Parties. It introduced the Prior Informed Consent (PIC) procedure for certain hazardous chemicals and pesticides in International trade. The convention aims to promote shared responsibility and cooperative effort among Parties in order to protect human health and the environment from potential harm and to contribute to their environmentally sound use, by facilitating information exchange about their characteristics, by providing for a national decision-making process on their import and export and by disseminating these decisions to Parties.

The European Union adopted the Rotterdam Convention by Council Decision 2006/730/EC of 25 September 2006 on the conclusion, on behalf of the European Community, of the Rotterdam Convention on the Prior Informed Consent Procedure for certain hazardous chemicals and pesticides in international trade. Furthermore, European Regulation (EC) No 689/2008 of the European Parliament and the Council of 17 June 2008 concerning the export and import of dangerous chemicals is the latest in a series of measures over the years that seek to address international trade with dangerous chemicals. This Regulation reaffirms the EU commitment towards ensuring proper control in the trade and use of dangerous chemicals at the global level, based on the principle that it should help to protect human health and the environment beyond its borders as well as within.

Two interlinked processes were identified as characterising the PIC content management activities. They are analysed separately: the export notifications process and the explicit consents process. The export notifications process aims to identify uniquely the single administrative document clearing customs. The explicit consents process aims to explicitly exchange risk management information, between an exporting DNA and an importing DNA, prior to export of chemicals. Each process is first described. The functionalities supporting the process are listed and explained. The specific implication of the administrator in the process is then identified. Finally the liaison between both processes is analysed.

Several working documents are annexed in order to transparently manage the handover of the PIC content management activities to ECHA.

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