

# Joint Research Centre

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# Introduction to Regulation (EC) No 689/2008



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# Introduction

- ❖ The Rotterdam Convention (RC) on the Prior Informed Consent (PIC) procedure for certain hazardous chemicals and pesticides in international trade has been signed in Rotterdam on 11 September 1998 by 72 signatories.
- ❖ Currently, 153 Parties have joined the convention as of 17/07/2013
- ❖ Croatia accessed RC on 16/11/2007

# Objectives

To promote shared responsibility and cooperative efforts among Parties in the international trade of certain hazardous chemicals in order to protect human health and the environment from potential harm and 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

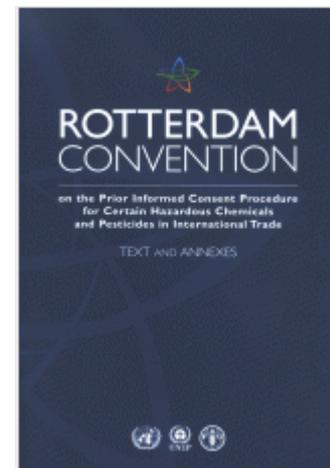
# History



<http://www.pic.int>

- ❖ **FAO (1985): “International Code of Conduct on the Distribution and Use of Pesticides”**
- ❖ **UNEP (1987): “London Guidelines for the Exchange of Information on Chemicals in International Trade”**

**text adopted in Rotterdam on 10/09/1998 and  
entered into force on 24/02/2004**



# Applicability

- ❖ Banned or severely restricted chemicals
- ❖ Severely hazardous pesticide formulations
- ❖ Narcotic drugs and psychotropic substances
- ❖ Radioactive materials
- ❖ Wastes
- ❖ Chemical weapons
- ❖ Pharmaceuticals, including human and veterinary drugs
- ❖ Chemicals used as food additives
- ❖ Food
- ❖ Chemicals in quantities not likely to affect human health or the environment provided they are imported:
  - for the purpose of research or analysis
  - by an individual for his or her own personal use in quantities reasonable for such use

# Prior Informed Consent (PIC)

## Annex III

- ❖ The chemicals listed in Annex III include pesticides and industrial chemicals that have been banned or severely restricted for health or environmental reasons by two or more Parties and which the Conference of the Parties has decided to subject to the PIC procedure.
- ❖ There are a total of 43 chemicals listed in Annex III, 32 are pesticides (including 4 severely hazardous pesticide formulations) and 11 industrial chemicals.

# Prior Informed Consent (PIC) procedure

- ❖ The Prior Informed Consent (PIC) Procedure is a mechanism for formally obtaining and disseminating the decisions of importing Parties as to whether they wish to receive future shipments of those chemicals listed in Annex III of the Convention and for ensuring compliance with these decisions by exporting Parties
- ❖ The European Community approved and implemented the Rotterdam Convention in the European Union by Council Decision 2006/730/EC with effect from 19 December 2002.

# Regulation (EC) No 689/2008

- ❖ Regulation (EC) No 689/2008 of the European Parliament and of the Council of 17 June 2008 concerning the export and import of dangerous chemicals
- ❖ Communication from the Commission 2011/C 65/01: Technical guidance notes for implementation of Regulation (EC) No 689/2008
- ❖ it affects all European Union based companies involved with the export or import of chemicals or articles containing chemicals
- ❖ it requires eventually the safety data sheet at least for the yearly first export

# Annexes of Regulation (EC) No 689/2008

Annex I → chemicals and articles with specific export controls

Annex V → chemicals and articles subject to export ban

- ❖ Part 1 of Annex I lists the chemicals subject to export notifications: chemicals that are banned or severely restricted within the Community within one or more categories or subcategories
- ❖ Part 2 of Annex I lists the chemicals qualifying for PIC notifications: chemicals that are banned or severely restricted within the Community or a Member State within one or more categories

# Annexes of Regulation (EC) No 689/2008

- ❖ Part 3 of Annex I lists the chemicals subject to the PIC procedure: chemicals that are listed in Annex III to the convention
  - 2 amendments in 2010 (Regulations 15 and 196)
  - 3 amendments in 2011 (Regulations 186, 214 and 834)
  - 1 amendment in 2012 (Regulation 71)
  - 1 amendment in 2013 (Regulation 73)
  
- ❖ On 1 March 2014 Regulation (EC) No 689/2008 will be substituted by Regulation (EU) No 649/2012

# Terminology in Regulation (EC) No 689/2008 and Directive 67/548/EEC

- ❑ Chemical means a substance, whether by itself or in a preparation, or a preparation whether manufactured or obtained from nature
- ❑ Substance ('pure substance') means chemical elements and their compounds as they occur in the natural state or as produced by industry
- ❑ Preparation means mixture or solution composed of two or more substances

# Categories of chemicals

- **industrial chemicals** means chemicals in either of the following subcategories:
  - chemicals for use by professionals
  - chemicals for use by the public
  
- **pesticides**, including severely hazardous pesticide formulations, means chemicals in either of the following subcategories:
  - pesticides used as plant protection products
  - other pesticides, such as biocidal products and such as disinfectants, insecticides and parasiticides

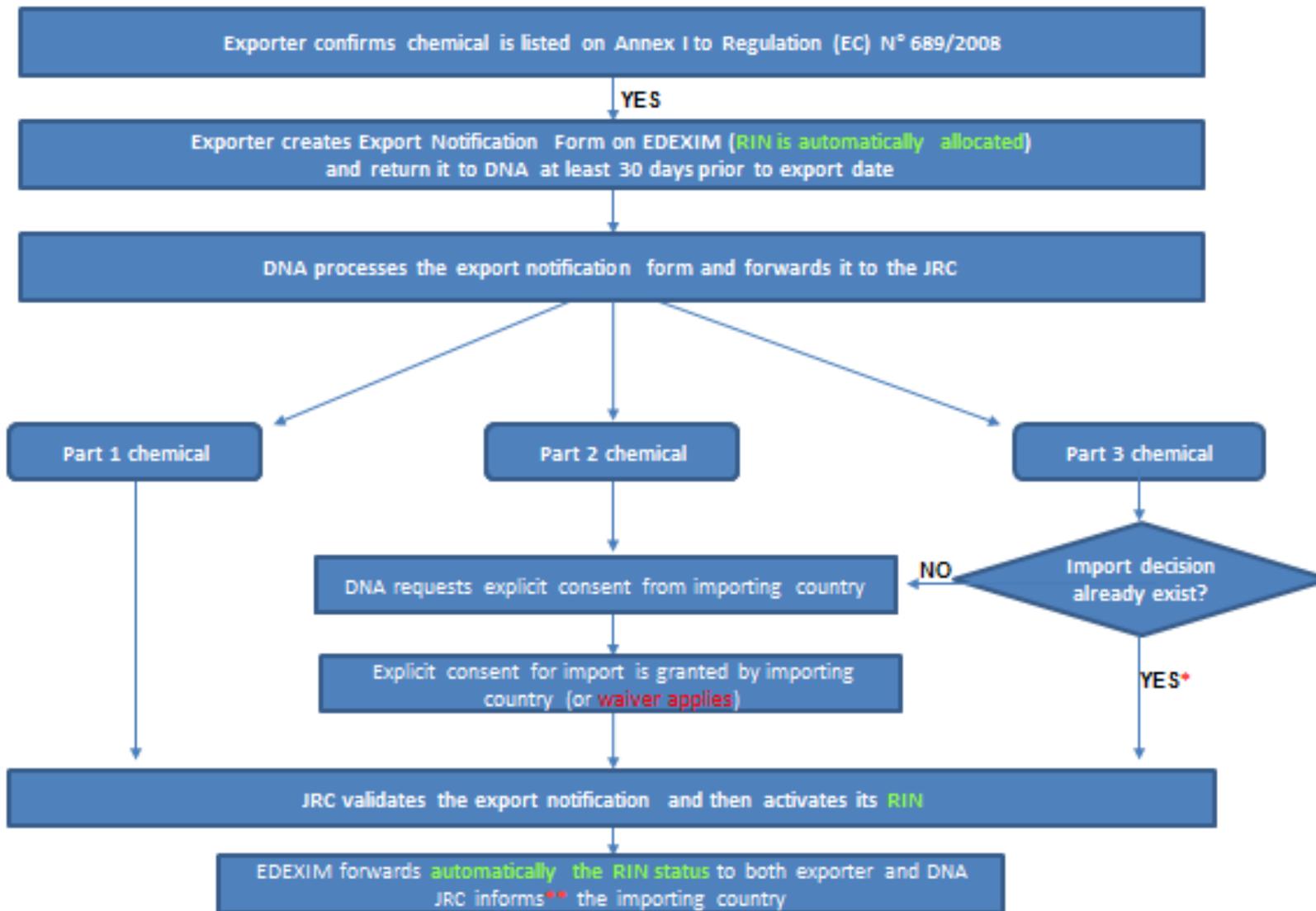
## Categories of chemicals (Cont'd)

- The category of **use** of exported chemical shall be inserted within the 'foreseen category in importing country' field of the export notification form
  - field 3.3 of section 3 'Information concerning the export'
- The category of **banned** or **severely restricted** exported chemical that is defined by Annex I shall be reported within the 'the final regulatory action has been taken for the category' field of the export notification form
  - field 6.2 of section 6 'Summary information on final regulatory action taken by the exporting Party (country)'

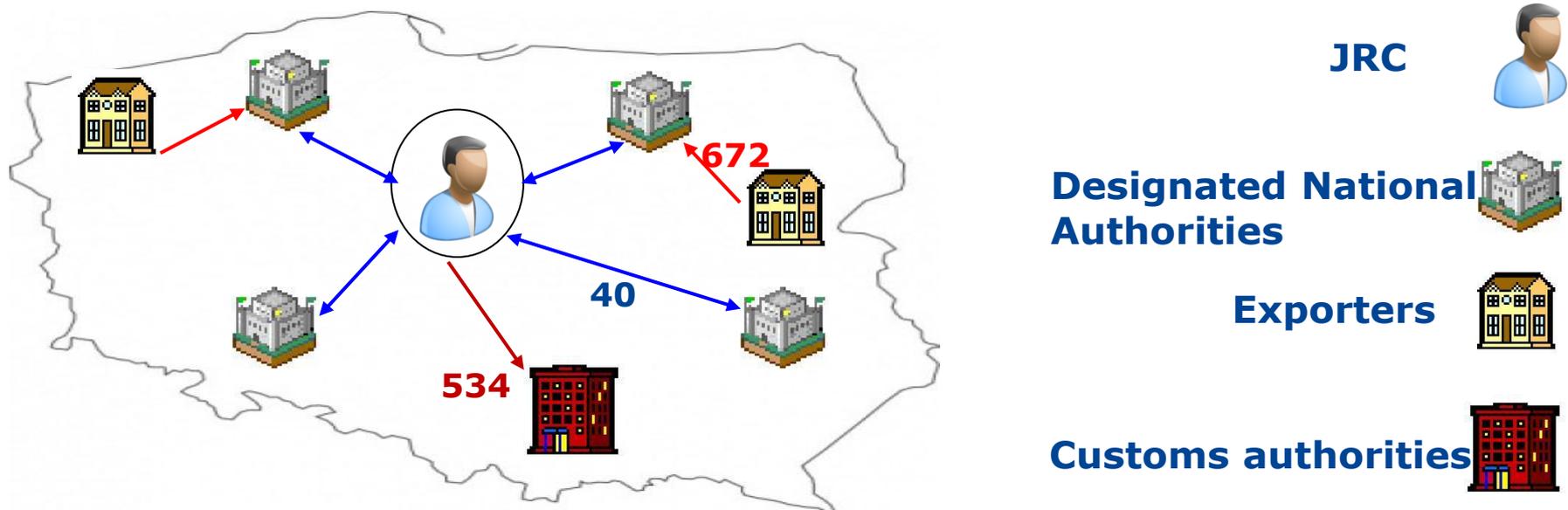
# Statistics on the database

- ❖ Total number of chemicals (substances and groups of substances) directly referred to within the Regulation is 183
- ❖ Total number of chemicals in Annex I is 162: 26 groups and 136 substances
- ❖ Total number of chemicals in Annex V is 21: 1 group of 20 substances
- ❖ Total number of substances is 960
- ❖ Total number of preparations is 2.798

# Chemicals of Annex I to Regulation (EC) No 689/2008



# Role of the Joint Research Centre (JRC) within the EU by using EDEXIM



- ❖ Developing and maintaining EDEXIM
- ❖ Export notifications verification, validation and management: EC & SDS
- ❖ EU interface with 214 importing DNAs: 125 Parties and 89 non-Parties to RC

**1,250 users  
as of Jul. 2013**

# Related legislations to Regulation (EC) No 689/2008

Source legislations within the EU determining the ban or severely restriction of chemicals therefore impacting their consideration within regulation (EC) 689/2008. These legislations are available in at least three main languages: EN, ES and FR

| Legislation                  | Description   |
|------------------------------|---|
| Regulation (EC) No 1107/2009 | Regulation (EC) No 1107/2009 of the European parliament and of the Council of 21 October 2009 concerning the placing of <b>plant protection products</b> on the market and repealing Council Directives 79/117/EEC and 91/414/EEC |
| Directive 98/8/EC            | Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of <b>biocidal products</b> on the market  |

# Related legislations to Regulation (EC) No 689/2008 (Continuation)

|                              |   |
|------------------------------|---|
| Regulation (EC) No 1907/2006 | Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorization and <b>Restriction of Chemicals</b> (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC |
| Regulation (EC) No 1272/2008 | Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on <b>classification, labelling and packaging</b> of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006   |