

Factsheet on the Prior Informed Consent (PIC) Regulation (EU Regulation no: (EU) 649/2012)

[A] Dates

- PIC regulation will apply from 1st March 2014.
- From this date, ECHA will be responsible for the administrative and technical tasks related to the new Regulation. The main task will be to process and send export notifications to the importing countries outside the EU, and keep a database of the notifications and the explicit consents given by the importing countries.

[B] Objectives

- Manages imports and exports of hazardous chemicals and is an obligation to companies exporting to non EU countries.
- The PIC Regulation applies to banned or severely restricted chemicals listed in Annex I, containing industrial chemicals, pesticides and biocides.

[C] Scope

The regulation applies to

- PIC notification applies to chemicals which are listed in Annex I (Part 1) of the regulation and the explicit consent requirement are applicable to Parts 2 and 3. This list is updated regularly as result of regulatory actions under EU legislation, and developments under the Rotterdam Convention.

[D] Exemption

- PIC does not apply to R&D substances provided it is unlikely to affect human health & environment and do not exceed 10 kg from each exporter to each importing country per calendar year.
- Chemicals listed in Annex V of this regulation (which are Persistent organic pollutants) are banned for export.
- Chemicals found in drugs, radioactive materials, wastes, chemical weapons, food and food additives, feeding stuffs, genetically modified organisms, and pharmaceuticals (except disinfectants, insecticides and parasiticides) are regulated by other EU legislation and therefore do not fall within the PIC Regulation.

[E] Implication

- Exporters have to notify their intention to export their chemicals
- In additions to notification (for part 2 & 3 of annex I) there exists a valid consent which has to be taken from national authority.
- All chemicals that are exported have to comply with rules on packaging and labelling pursuant to the CLP Regulation (EC) 1272/2008 or any other relevant EU legislation.
- Exports of the chemicals mentioned in Annex I (Part 1, 2 and 3) are subjected to 2 types of requirement
 - ✓ Export notification
 - ✓ Explicit consent

[F] Action required

- **Notification:** PIC Regulation applies to a list of entries (for individual chemicals or groups of chemicals), which are included in Annex I, and to mixtures containing such chemicals in a concentration that triggers labelling obligations under the CLP Regulation (EC) No 1272/2008 (irrespective of the presence of any other substance), as well as to articles containing these chemicals in an unreacted form.
- This list is divided into three parts that define the different obligations applied to the chemicals.
 - Part 1: This is
 - Subjected to export notification procedure
 - Includes all the chemicals that are banned or severely restricted within the EU in at least one of the four use subcategories:
 - ✓ Industrial chemical for professional use
 - ✓ Industrial chemicals for consumer use
 - ✓ Pesticide used as PPP
 - ✓ Other pesticide such as biocides products
 - Part 2: Other than export notification, part 2 chemicals will also require a statement from the authorities of the importing countries which shows that they agree to import of the chemical – This is called explicit consent. So, this list had export notification and explicit consent.
 - Part 3:
 - ✓ This includes notification requirement plus additional explicit consent. Except where positive import response is already published in the PIC regulation and certain criteria are met for the same.
 - ✓ Also includes substance which are organic pollutants and are totally banned for exports
 - ✓ Chemicals subjected to PIC regulation which exists in the Rotterdam convention are also listed in Annex III of the convention.
- **Export notification procedure:**
 - Exporters will have to notify to the designated national authorities of the countries from which the exports will originate
 - This has to be done before 1st exports as well as before the 1st exports in each subsequent calendar year.

- Each notifier will be assigned a unique identifier called REFERENCE IDENTIFICATION NUMBER.
- **Annex II:** contents of export notification
 - ✓ Identity of the chemical
 - ✓ Information on exports
 - ✓ Information and precautions to be taken
 - ✓ Summary of physico-chemical, toxicological and eco toxicological properties
 - ✓ Uses & summary of the regulatory restrictions & reason for the same.
- Notification should have the following schedule:
 - ✓ 35 days before the export is due to take place: Exporter must notify the designated national authority of the Member State in which he is located.
 - ✓ 25 days before the export is due to take place: The designated national authority validates the notification and forwards it to ECHA.
 - ✓ 15 days before the export is due to take place: ECHA sends the notification to the non-EU designated national authority in the importing country.
- **Explicit consent requirement :**
 - In addition to the notification requirement, the export of chemicals included in parts 2 and 3 of Annex I to the PIC Regulation are also subject to the existence of a valid explicit consent given by the designated national authority of the importing country outside the EU. A waiver might be granted only under exceptional circumstances.
 - This requirement is not applied for part III of the Annex I if positive import response is published in PIC circular & certain criteria are met.
 - An explicit export remains valid for subsequent exports during a period 3 calendar year unless otherwise specified.
 - So, for 3 years company can export the same chemical to that country but still needs to meet the annual notification & reporting requirement

[H] Action required by Non – EU companies

- The basic obligation of the non-EU industry is to check for the substances if present in the Annex I of the PIC regulation.
- In case the substance appears in the Annex I then the EU importer (SSS can qualify as importer for regulatory compliance activity) will have to notify to the designated national authorities of the countries from which the exports will originate
- Similarly imports of severely restricted chemicals (covered within the Annex XVII of the REACH Regulation) can also be considered for notification obligation.
- Further the substance due for export will also require to be checked in Annex V list of the PIC regulation, if present then the exports of this substance will not be possible as the substances are banned within the EU countries.

As mentioned that the non EU companies will have to evaluate if the PIC regulation is relevant for the exports to Europe and this applicability assessment of regulation to your product can be provided to your company.

Contact us (Europe)

Sustainability Support Services (Europe) AB
Markaskälsvägen 6, Lund – 22647, Sweden,
Contact no.: +46 46 2114615
Email: sk@reach-onlyrep.eu;
Website: www.reach-onlyrep.eu

(India)

Nagpur Sustainability Support Services Pvt. Ltd.
301, Samved Sankul, Near MLA Hostel, Civil Lines, Nagpur - 440001,
Contact no.: +91 712 2552725/26; +91 712 2562723
Email: advisor@or-reach.com;
Website: www.reach-or.com