

# Questions and Answers

For Croatian Companies Pre-registering and Registering under  
REACH



Version	Changes
1.1	04/2013 Submission window information added for Applications for Authorisation (section 7).
1	First version

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### **European Chemicals Agency**

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

Visiting address: Annankatu 18, Helsinki, Finland

## 1 Introduction

Croatia will join the European Union on 1 July 2013 and therefore the REACH and CLP Regulations will apply to companies established in Croatian territory from that date. The application of some provisions of these Regulations is subject to a series of transitional measures as laid down in the Accession Treaty (Treaty concerning the accession of the Republic of Croatia).

In order to comply with the obligations to register and notify chemical substances to the European Chemicals Agency, Croatian companies will have access to the related IT tools: IUCLID 5 and REACH-IT.

Technical manuals on how to use those IT tools as well as other supporting material are available in the ECHA website at: <http://echa.europa.eu/support>. The ECHA Helpdesk can also be accessed through that link.

The technical manuals are organised into two different series:

- Data Submission Manuals. These manuals provide instructions on how to use IUCLID 5 in order to build and create dossiers.
- REACH-IT Industry User Manuals. These manuals provide step-by-step instructions on how to use the different functionalities of REACH-IT, e.g. how to submit dossiers to ECHA, indicate changes of legal entity, etc.

Those manuals are applicable to Croatian companies having obligations under the REACH and CLP Regulations. However, certain specific instructions applying only to Croatian companies during the transitional period are covered in the present Q&A document. In particular, specific instructions cover technical advice on how to pre-register (Question 3 below), and how to transfer registrations previously managed by an Only Representative (Question 6 below).

In summary, the purpose of the present Q&A document is to provide a concise overview of the main specific issues affecting Croatian companies during the transitional period.

## 2 What are the relevant deadlines for Croatian companies regarding pre-registration of substances?

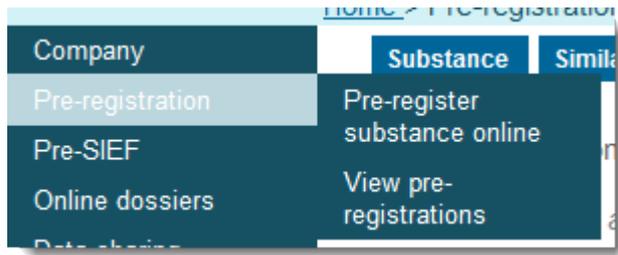
The Accession Treaty grants Croatian manufacturers and importers and producers of articles a special pre-registration period for their phase-in substances. The special period starts from 1 July 2013 which is the date of accession, and lasts for six months ending on 1 January 2014.

Pre-registration is a requisite to benefit from the extended registration deadlines foreseen for phase-in substances.

## 3 How to pre-register a phase-in substance in REACH-IT?

You can find detailed instructions on how to pre-register your substances through REACH-IT in the document "REACH-IT Industry User Manual – Part 4: Online Pre-registration". However, for specific adaptations concerning Croatian companies, please follow the instructions provided here below.

Once you have signed-up in REACH-IT, please select 'Pre-registration' > 'Pre-register substance online' in the REACH-IT menu.



You will need to declare that you are pre-registering a phase-in substance and you are entitled to benefit from the transitional measures that are laid down in the Croatian Accession Treaty.

Then find and select the substance you need to pre-register. You may also add any similar substances.

Under the Tonnage/deadline tab, select the tonnage band you intend to register.

The REACH Regulation set three major deadlines for registration of chemicals, depending on the tonnage and hazardous properties of the substance. In the second pick list, select the relevant registration deadline according to the type of substance you intend to register.



As you can see, the pick list displays only the standard registration deadlines established in REACH. Due to technical reasons, it does not display the transitional registration deadlines established for Croatian companies.

Therefore, when pre-registering your substances, please follow the table below to identify which value to select. Detailed information on transitional registration deadlines is provided under Question 4.

Type of substance	Registration deadline to be selected when pre-registering
<ul style="list-style-type: none"> <li>- Phase-in substances classified<sup>1</sup> as carcinogenic, mutagenic or toxic to reproduction, category 1 or 2, in accordance with Directive 67/548/EEC, and manufactured or imported in quantities reaching one tonne or more per year.</li> <li>- Phase-in substances classified as very toxic to aquatic organisms which may cause long-term adverse effects in the aquatic environment (R50/53) in accordance with Directive 67/548/EEC and manufactured or imported in quantities reaching 100 tonnes or more per year.</li> <li>- Phase-in substances manufactured or imported in quantities reaching 1 000 tonnes or more per year.</li> </ul>	1 December 2010
Phase-in substances manufactured or imported in quantities reaching 100 tonnes or more per year.	1 June 2013
Phase-in substances manufactured or imported in quantities reaching 1 tonne or more per year.	1 June 2018

<sup>1</sup> Classified in accordance with Directive 67/548/EEC refers to substances listed in Annex VI of the CLP Regulation with a harmonised classification and labelling and substances self-classified by the registrant.

You will then need to enter the first date of manufacturing, importing or using the substance in quantities of 1 tonne or more per year.

Follow the subsequent steps to proceed to the validation of the pre-registration submission. When you have all the information in place, submit your pre-registration to ECHA.

#### 4 *What are the relevant deadlines for Croatian companies regarding registration of substances?*

According to the Accession Treaty, the dates for the first and second registration deadline set out in Article 23(1) and (2) of the REACH Regulation shall be 12 months from the date of accession. The registration deadlines affecting companies established in Croatia are the following:

Type of substance	The Registration must be submitted by
<ul style="list-style-type: none"> <li>- Phase-in substances classified<sup>2</sup> as carcinogenic, mutagenic or toxic to reproduction, category 1 or 2, in accordance with Directive 67/548/EEC, and manufactured or imported in quantities reaching one tonne or more per year.</li> <li>- Phase-in substances classified as very toxic to aquatic organisms which may cause long-term adverse effects in the aquatic environment (R50/53) in accordance with Directive 67/548/EEC and manufactured or imported in quantities reaching 100 tonnes or more per year.</li> <li>- Phase-in substances manufactured or imported in quantities reaching 1 000 tonnes or more per year.</li> </ul>	1 July 2014
Phase-in substances manufactured or imported in quantities reaching 100 tonnes or more per year.	1 July 2014
Phase-in substances manufactured or imported in quantities reaching 1 tonne or more per year.	31 May 2018

#### 5 *What is the deadline for Croatian companies to notify classification and labelling for substances?*

After 1 December 2010, according to Article 40 of the CLP Regulation the deadline for notification to the C&L inventory is one month after a substance has been placed on the

<sup>2</sup> Classified in accordance with Directive 67/548/EEC refers to substances listed in Annex VI of the CLP Regulation with a harmonised classification and labelling and substances self-classified by the registrant.

market. The one month period has to be calculated from the date a substance is placed on the market. This refers to the market in the EU, which includes Croatia as of 1 July 2013.

No special transitional deadline has been established for Croatian companies. Therefore, companies established in Croatia are required to submit a classification and labelling notification within one month of its placement in the market. This means that all substances which are on the market at the moment of accession to the European Union need to be notified by 1 August 2013.

Please consult the following webpage for further information on notification of classification and labelling:

<http://echa.europa.eu/web/guest/regulations/clp/cl-inventory/notification-to-the-cl-inventory>

**6 My company is a manufacturer/importer established in Croatia. We appointed an Only Representative before accession of Croatia to the EU. How can I take over the registrations of the Only Representative?**

You can transfer all the registrations carried out by your Only Representative by using the Legal Entity change functionality in REACH-IT. Detailed instructions on how to use this functionality are available in the document "REACH-IT Industry User Manual – Part 17: Legal entity change". However, for specific adaptations concerning Croatian companies, please follow the instructions provided here below.

**Actions to be performed by the Only Representative:**

The Only Representative will need to sign into its REACH-IT account. Then select 'Legal entity change' > 'Create legal entity change' in the REACH-IT menu.

The option 'Create a new legal entity change' needs to be selected (or 'Continue creating an existing legal entity change' in case you have interrupted your legal entity change before submitting).

Name the legal entity change and enter the legal successor's legal entity UUID (the Croatian company that becomes a manufacturer/importer). UUID stands for "Universal Unique Identifier" and it is a string of characters link to each legal entity existing in REACH-IT. The UUID can be found in REACH-IT under the menu 'Company' > 'View'.

Legal entity change details	
* Legal entity change name:	OR_to_manufacturer
Originating legal entity UUID:	IUC5-a620a92d-32c6...
Originating legal entity name:	[blurred]
* Legal successor UUID:	ECHA-7d510af4-00d7-4585-a3...
Legal successor name:	

In the following steps the Only Representative will need to add supporting documentation regarding the legal entity change. Supporting documentation could be e.g. the appointment of the Only Representative by the Croatian company. Select a contact person and, in the following step, select 'Only representative change' as type of legal entity change (see figure below). The Only Representative needs then to select also the way to define the items to be transferred (manual selection or bulk upload).

Home > Legal Entity Change Instance > Type

Details Add Attachments Contact **Type** Items Validation

Please select the type of legal entity change. [?](#)

Merger  
 Split  
 Only representative change

Please select below how you wish to define the items to be transferred. [?](#)

Manual selection of items in REACH-IT  
 Bulk upload of identified items

<< Previous

In the next step under 'All items' tab, find and select the items to be transferred from the Only Representative to the Croatian company that is taking over the activities.

All items Selected items

This page allows you to search all your items which may be transferred. You can view the current item list on the **Selected items** tab.

**Search available items criteria**

Asset type: All

Reference number: |

Submission date from:  

Submission date to:  

EC number:

CAS number:

Chemical name:

Search Clear

[Select All](#) | [Select None](#)

Select	Item type	EC number
<input type="checkbox"/>	Registration	406-040-9
<input type="checkbox"/>	Registration	448-090-4

Add selected items

Once you have clicked 'Add selected items', open the 'Selected items' tab. Under this tab you can view and remove the items you have selected for the transfer.

Home > Legal Entity Change Instance > Available items

Details Add Attachments Contact Type **Items** Validation

**The item(s) you have selected have been added to your list**

All items **Selected items**

This page allows you to search all your items which may be transferred. You can view the current item list on the **Selected items** tab.

**Search available items criteria**

Asset type: All

Reference number:

When all the items to be transferred are listed in this step, proceed to the validation page. Verify that all the information is correct, and click 'Create legal entity change' button.

On the following page, and as a REACH-IT message, the Only Representative will be provided a token number that they will need to communicate to the Croatian company.

Your legal entity change has been successfully initiated in REACH-IT. In order to validate the contents of the legal entity change.

**Legal entity change name: OR\_to\_manufacturer**

**Token: 1361438181588**

Following successful validation of the legal entity change by the legal successor, the listed items will be transferred to the legal successor.

OK

#### **Actions to be performed by the Croatian manufacturer/importer (done after the Only Representative's actions):**

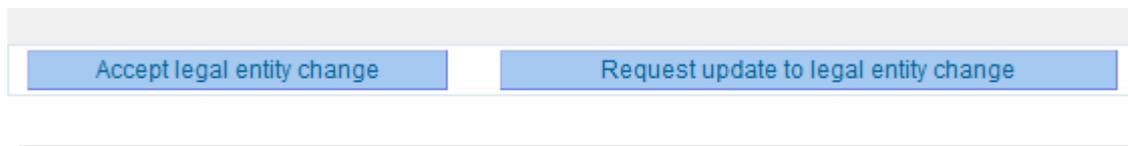
After receiving the token from the Only Representative, the Croatian company will need to sign into its REACH-IT account. Then select 'Legal entity change' > 'View legal entity change' in the REACH-IT menu.

You will be then directed to the search for legal entity page. In that page, select claim status 'Created' and search for legal entity changes. Select the correct legal entity in the search results and click 'Edit'.



change, joint submission and pre-SIEF matters. You may also appoint a third party representative for the items that are being transferred in the legal entity change.

Proceed to the validation page where you have the choice either to accept the legal entity change or request an update to the legal entity change.



If you request the Only Representative to update the legal entity change, you will need to communicate the required changes to the Only Representative, and verify the changes afterwards until you are ready to accept the legal entity change.

In case you accept the legal entity change, you are asked to declare the correctness of the information that has been provided in the legal entity change.

### *Legal entity change details*

 A screenshot of a form titled "Legal entity change details". It contains a declaration section with a checkbox checked, followed by the text: "The user declares that the information provided herein as evidence of the legal entity change is true, correct and not misleading." Below this, there is a label "Legal entity change" and a dropdown menu showing "OR\_to\_manufacturer".

Check your REACH-IT message box regularly after accepting the legal entity change. If an invoice is issued for the legal entity change of type 'Only representative change', please do not pay it. Contact ECHA Helpdesk (<http://echa.europa.eu/web/guest/support/helpdesks/echa-helpdesk>) immediately to request to have the invoice cancelled.

For more information about legal entity changes, including step-by-step instructions and screenshots, please refer to Industry User Manual - Part 17: Legal entity change available at:

<http://echa.europa.eu/web/guest/support/dossier-submission-tools/reach-it/data-submission-industry-user-manuals>

## **7 What kind of transitional measures there are regarding Applications for Authorisation?**

After their "sunset date", substances included in Annex XIV of the REACH Regulation will require an authorisation before they can be placed on the market or used.

To applicants established in Croatia, the Accession Treaty grants an adaptation period of six months from the date of accession by the end of which applications for authorisations must be received, if the latest application date falls before the date of accession or less than six months after that date.

To better plan the committees' workload, ECHA has established a specific submission window for Croatian companies to submit applications for authorisation. Uploading your

application within this window can ensure the minimum processing time for your application by ECHA and its Committees.

According to the Accession Treaty, the adapted deadlines and the recommended submission window for Application for Authorisation affecting companies established in Croatia are the following:

Substance	Sunset date	Latest application date	Submission window
Musk xylene (EC 201-329-4) MDA. (EC 202-974-4)	21 August 2014	1 January 2014	07/11/2013 – 21/11/2013
DEHP (EC 204-211-0) BBP (EC 201-622-7) DBP (EC 201-557-4) DIBP (EC 201-553-2)	21 February 2015	1 January 2014	07/11/2013 – 21/11/2013
Diarsenic trioxide (EC 215-481-4) Diarsenic pentaoxide (EC 215-116-9) Lead chromate (231-846-0) Lead sulfochromate yellow (C.I. pigment yellow 34) (EC 215-693-7) Lead chromate molybdate sulphate red (C.I. pigment red 104) (EC 235-759-9)	21 May 2015	1 January 2014	07/11/2013 – 21/11/2013

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