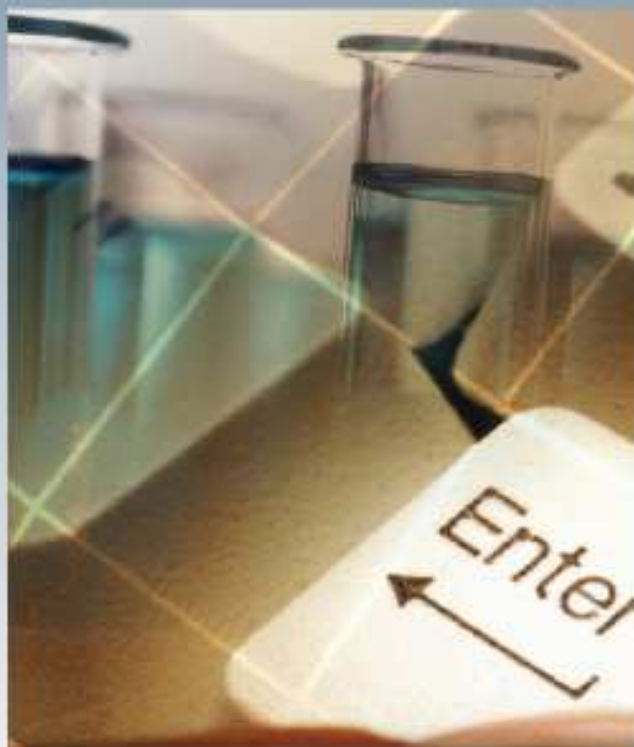


# Questions and Answers

FOR THE REGISTRANTS OF PREVIOUSLY NOTIFIED  
SUBSTANCES (RELEASE 1)



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up-to-date information please  
consult the ECHA website

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[http://echa.europa.eu/reach/helpdesk/echahelp\\_en.asp](http://echa.europa.eu/reach/helpdesk/echahelp_en.asp)

# TABLE OF CONTENTS

## **PART 1: CLAIMING A REGISTRATION NUMBER FOR A NOTIFIED SUBSTANCE 4**

- 1. GENERAL PRINCIPLES 4**
- 2. WHEN CAN I REQUEST MY REGISTRATION NUMBER? 5**
  - 2.1. General case 5
  - 2.2. Urgent case: The quantity of my notified substance reaches the next tonnage threshold before 1st December 2008 5
- 3. WHAT MUST I DO TO REQUEST A REGISTRATION NUMBER FOR MY NOTIFIED SUBSTANCE? 6**
  - 3.1. I was a Domestic Manufacturer AND/OR Importer under Directive 67/548/EEC 6
  - 3.2. I was a Sole Representative under Directive 67/548/EEC and I will take up the duties of the Only Representative under REACH 7
  - 3.3. I am a newly appointed Only Representative and will take the duties of an earlier Sole Representative 8
  - 3.4. I was a Sole Representative AND a Domestic Manufacturer AND/OR Importer under Directive 67/548/EEC 9
  - 3.5. Overview of registration number granting process 10

## **PART 2: TRANSFER OF INFORMATION FROM NCD TO IUCLID5 11**

## **PART 3: UPDATING A REGISTRATION, THAT WAS PREVIOUSLY A NOTIFICATION UNDER DIRECTIVE 67/548/EEC 12**

- 1. IN WHICH CASES SHALL I UPDATE MY REGISTRATION? 12**
- 2. WHAT DO I HAVE TO DO? 13**
- 3. WHAT WILL HAPPEN NEXT? 15**

# PART 1: Claiming a registration number for a notified substance

## 1. *General principles*

- ⇒ **All notified substances under NONS** (independent of the tonnage band) **are considered already registered under the REACH Regulation.**
- ⇒ According to Article 24 of the REACH Regulation, the European Chemicals Agency (ECHA) shall **assign** registration number(s) to all notifications made in accordance with Directive 67/548/EEC **by 1st December 2008.**
- ⇒ Even if there is no such provision in the REACH Regulation requiring notifiers to request for a registration number, the **owner of the notification** will have to request his registration number from ECHA.  
Indeed this protocol will confirm to ECHA the identity of the notifier and to whom the registration number should be sent to.  
In addition, thanks to this procedure, the REACH-IT database will be updated with the latest contact details of the notifiers, which will allow, for example, a proper data-sharing process.
- ⇒ There are four potential types of claimant that may request a registration number:
  - The claimant was a **Domestic Manufacturer** under Directive 67/548/EEC. (i.e. the Manufacturer was established within EU).
  - The claimant was an **Importer** under Directive 67/548/EEC.
  - The claimant was a **Sole Representative** under Directive 67/548/EEC.
  - The claimant is a **newly appointed Only Representative** and will take the duties of a previous notifier (e.g. Sole Representative or Importer).
- ⇒ **This registration number** can be requested from ECHA **via the REACH IT system** (as soon as the module to request a registration number for a notified substance will be available in REACH-IT).
- ⇒ Provided that the claimant's details specified in REACH-IT match those for the notification, ECHA will provide the registration number.
- ⇒ If the details do not match, ECHA will not grant any registration number and the notifier will have to contact its relevant Member State Competent Authority (MSCA) to resolve this issue.
- ⇒ In case of a Sole Representative or newly appointed Only Representative, **one registration number will be granted per non-EU manufacturer represented.**
- ⇒ In the case of Sole Representative or newly appointed Only Representative, the claimant will have to submit, in REACH-IT, all necessary contractual agreement as evidence of the validity of his request. This provision is in line with the implementation already in place for an Only Representative in case of Registration.

## **2. When can I request my registration number?**

### **2.1. General case**

**The distribution of registration number by ECHA will be done by 1<sup>st</sup> December 2008 upon request via REACH-IT.**

As soon as the module to request a registration number for a notified substance will be available in REACH-IT, you will be able to request your registration number.

**We therefore invite you to check regularly the ECHA website at <http://echa.europa.eu> to be informed of the latest news.**

### **2.2. Urgent case: The quantity of my notified substance reaches the next tonnage threshold before 1st December 2008**

If the quantity of the notified substance reaches the next tonnage threshold, as defined under Article 24(2) of the REACH Regulation, **before 1<sup>st</sup> December 2008**, ECHA invites you not to wait for the REACH-IT module to be available in order to request your registration number, but to submit as soon as possible **an Inquiry** for a tonnage band increase (Article 12(2)).

Afterwards an updated registration dossier for this notified substance must be sent to ECHA. Further information on this type of inquiry and on how to update a Directive 67/548/EEC Notification is provided later in this document.

### **2.3. Can I still request my registration number after 1st December 2008?**

Registration numbers can be requested after 1<sup>st</sup> December 2008 using the module available in REACH-IT. The process for providing a registration number will continue after 1<sup>st</sup> December 2008.

### **3. What must I do to request a registration number for my notified substance?**

#### **3.1. I was a Domestic Manufacturer AND/OR Importer under Directive 67/548/EEC**

##### What do I have to do?

Sign-up in REACH-IT and specify your company details (if not already done)

- ⇒ **Log-in to REACH-IT** to request your registration number for a notified substance:
  - Specify your **notification number (standard format) without the 2 last digits corresponding to the version of the notification** (for example, if your notification number is XX-XX-XXXX-YY you should specify **XX-XX-XXXX** in REACH-IT)
  - Specify the **ELINCS number** of the notified substance
  - Specify the **notifier name as it is** in the notification (section 0.2.10 of SNIF file)
  - Specify the **notifier city and country as it is** in the notification (section 0.2.10 of SNIF file)
  - If necessary specify in the “remark field” explanations, justifications as to why the company details in the REACH-IT sign-up are different than the one in the notified dossier (e.g. Change of address, of company name....)
  - Declare that you are “a Domestic Manufacturer” and/or an “Importer” under Directive 67/548/EEC and that you are entitled to claim the registration number (tick the relevant box(es))
  - Specify the name of a third party representative (if any). If you have appointed a third party representative for this notified substance, his/her name, contact details and company name will be made available in the pre-SIEF to others pre-registering this substance.

##### What will then happen?

If all the information specified is correct and matches with that in the notification dossier:

- ⇒ You will **get a submission number, a registration date and a registration number** via REACH-IT (check your internal messages)
- ⇒ Your substance will be **integrated in a pre-SIEF** under your company details (REACH-IT sign-up) or the one of the third-party representatives you have appointed.

Your **notification migrated in IUCLID 5** format can be requested from your **relevant Member State Competent Authority**.

You are a “**Manufacturer**”/ “**Importer**” **under the REACH Regulation**, and have to fulfil the duties of registrant under the REACH Regulation including any data-sharing obligations.

If the information specified does not match with that in the notification:

- ⇒ You will not get a registration number
- ⇒ You should contact your relevant Member State Competent Authority to resolve the situation.

### 3.2. I was a Sole Representative under Directive 67/548/EEC and I will take up the duties of the Only Representative under REACH

Any Sole Representative agreements are invalid after 31st May 2008. Where the intention is to appoint an Only Representative under REACH, new documentation/contract from the non-EU manufacturer(s) you represent should be drawn up.

The person claiming the registration number must indicate on the REACH-IT website, that he/she is entitled to act as the Only Representative.

#### What do I have to do?

- ⇒ **Sign-up in REACH-IT** and specify your company details (if not already done)
- ⇒ **Log-in to REACH-IT** to request your registration number
  - Specify your **notification number (standard format) without the 2 last digits corresponding to the version of the notification** (for example, if your notification number is XX-XX-XXXX-YY you should specify **XX-XX-XXXX** in REACH-IT)
  - Specify the ELINCS number of the notified substance
  - Specify the notifier name as it is in the notification (section 0.2.10 of SNIF file)
  - Specify the notifier city and country as it is in the notification (section 0.2.10 of SNIF file)
  - If necessary specify in the “remark field” explanations/justifications as to why the company details in the REACH-IT sign-up are different than those in the notification (e.g. Change of address or company name...)
  - Declare that you have the agreement and the consent of the non-EU manufacturer(s) to become the Only Representative under the REACH Regulation and that you are entitled to claim the registration number (tick the relevant box)
  - Specify all non-EU companies that you will represent as Only Representative for the notified substance.
  - Attach the following document for **each non-EU manufacturer** you represent:
    - Individual letter(s)/contract(s) from each non-EU manufacturer(s) declaring that you are entitled to become their Only Representative under the REACH Regulation for the notified substance. The letter(s) should be in **PDF format** and **written in one of the Community languages**.

#### What will then happen?

If all the information specified is correct and matches with that in the notification:

- ⇒ You will **get a submission number, a registration date and a registration number per non-EU company you represent** via REACH-IT (look at your internal message);
- ⇒ Your substance will be **integrated in a pre-SIEF** under your company details (REACH-IT sign-up) ;

Your **notification migrated into IUCLID 5** format can be requested from your **relevant Member State Competent Authority**.

You are an “**Only Representative**” under the **REACH Regulation**, and have to fulfil the duties of a registrant under the REACH Regulation including any data-sharing obligations.

If the information specified does not match with that in the notification:

- ⇒ You will not get any registration number

- ⇒ You should contact your relevant Member State Competent Authority to resolve the situation.

### **3.3. I am a newly appointed Only Representative and will take the duties of an earlier Sole Representative**

This situation occurs when a non-EU manufacturer(s) under Directive 67/548/EEC decides to change his Sole Representative to take care of his/their duties under the REACH Regulation.

If the Only Representative is not the same as the previous Sole Representative then evidence (contract/letter) should be provided in REACH-IT to support their claim for a registration number.

This evidence will be made available to the MSCA for future verification if necessary.

#### What do I have to do?

- ⇒ **Sign-up in REACH-IT** and specify your company details (if not already done)
- ⇒ **Log-in to REACH-IT** to request your registration number
  - Specify the notification number for which you request a registration number: **standard format of the notification number without the 2 last digits corresponding to the version of the notification** (for example, if your notification number is XX-XX-XXXX-YY you should specify **XX-XX-XXXX** in REACH-IT)
  - Specify the ELINCS number of the notified substance
  - Specify the notifier name as it is in the notification (section 0.2.10 of SNIF file)
  - Specify the notifier city and country as it is in the notification (section 0.2.10 of SNIF file)
  - Specify in the “remark field” explanations/justifications as to why the company details in the REACH-IT sign-up are different from those in the notified dossier (eg. change of Sole Representative to a new Only Representative)
  - Declare that you have the agreement and the consent of the non-EU manufacturer(s) to become the Only Representative under the REACH Regulation and that you are entitled to claim the registration number (tick the relevant box)
  - Specify all non-EU companies that you will represent as Only Representative for the notified substance.
  - Attach the following documents:
    - Individual letter(s)/contract(s) **from each non-EU manufacturer** declaring that you are entitled to become their Only Representative under the REACH Regulation for the notified substance. The letter(s) should be in **PDF format and written in one of the Community languages**.
    - Letter/contract from the previous Sole Representative declaring that he will no longer act a Sole Representative and that he agrees to transfer his duties to you as Only Representative under the REACH Regulation for the notified substance. The letter(s) should be in **PDF format and written in one of the Community languages**.

#### What will then happen?

If all the information specified is correct and matches with that in the notification:

- ⇒ You will **get a submission number, a registration date and a registration number per non-EU company you represent** via REACH-IT (look your internal message)

- ⇒ Your substance will be **integrated in a pre-SIEF** under your company details (REACH-IT sign-up).

Your **notification migrated in IUCLID 5** format can be requested from your **relevant Member State Competent Authority**.

You are an **“Only Representative” under the REACH Regulation**, and have to fulfil the duties of a registrant under the REACH Regulation including data-sharing obligations.

If the information specified does not match with that in the notification:

- ⇒ You will not get a registration number
- ⇒ You should contact your relevant Member State Competent Authority to clear-up the situation.

### 3.4. I was a Sole Representative AND a Domestic Manufacturer AND/OR Importer under Directive 67/548/EEC

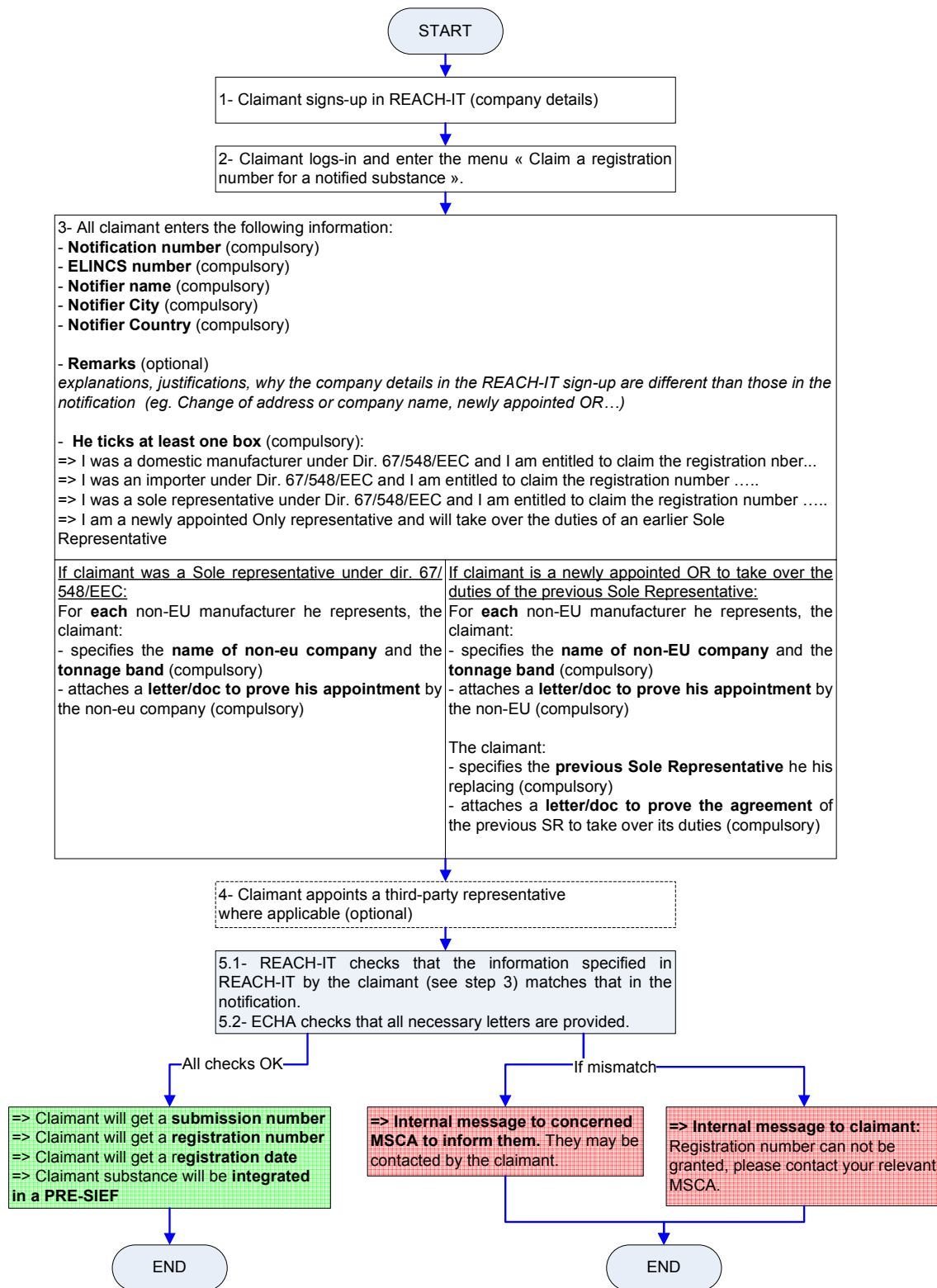
What do I have to do?

- ⇒ **You should first request your registration number as a domestic Manufacturer AND/OR Importer** (see the process described before)
- ⇒ **Then you should request your registration number as a Sole Representative.** (see the process described before)

In summary:

Domestic Manufacturer	Importer	Sole Representative	Number of request to make via the REACH-IT module to claim registration number:	What will I get?
X			<b>1:</b> as Manufacturer	<b>one</b> registration number
	X		<b>1:</b> as Importer	<b>one</b> registration number
		X	<b>1:</b> as Sole Representative	one registration number per non-EU company you represent
X	X		<b>1:</b> as Manufacturer + Importer	<b>one</b> registration number
X		X	<b>2:</b> one as Manufacturer and then another as Sole Representative	<b>one</b> registration number as a domestic manufacturer <b>one</b> registration number <b>per non-EU company</b> you represent
	X	X	<b>2:</b> one as Importer and then another as Sole Representative	<b>one</b> registration number as an importer <b>one</b> registration number <b>per non-EU company</b> you represent
X	X	X	<b>2:</b> one as Manufacturer + Importer and then another as Sole Representative	<b>one</b> registration number as manufacturer/importer <b>one</b> registration number <b>per non-EU company</b> you represent

### 3.5. Overview of registration number granting process



## **PART 2: Transfer of information from NCD to IUCLID5**

Information for a notification under Directive 67/548/EEC was initially submitted to the Member State Competent Authority in the Summary Notification Interchange Format (SNIF). Thereafter the SNIF was transmitted to the European Chemicals Bureau (ECB) in the Joint Research Centre, Ispra. This information was stored in a central database, called the new chemicals database (NCD) at ECB.

All SNIF files received by ECB are being migrated into IUCLID 5 format by ECB.

The migrated files will then be distributed back to the responsible Member State Competent Authority in 2 formats (read-only and editable) and to ECHA.

Claimants (owners of the notification) should refer to their Member State Competent Authority to receive their files in IUCLID 5 format. The editable format will enable them to fulfil their obligations under REACH, in particular when they need to update their registration in the case where the next tonnage threshold is reached.

In addition, the tool developed to migrate the SNIF to IUCLID 5 format will be made available to industry as an add-on to IUCLID 5 on the IUCLID web site <http://ecbwbiu5.jrc.it/>

Please note that you should pay attention to the migrated file results and check it carefully (eg. Legal entity(ies), confidentiality, endpoints...) before using it for updating your registration via REACH-IT.

## PART 3: Updating a registration, that was previously a notification under Directive 67/548/EEC

### 1. *In which cases shall I update my registration?*

Update of the registration dossier shall be performed if at least one of the cases described in **Article 22 or Article 24(2)** of the REACH Regulation applies. Please refer to Chapter 9 of the Guidance on Registration for further details ( [http://reach.jrc.it/guidance\\_en.htm](http://reach.jrc.it/guidance_en.htm) ).

In the case where your substance reaches the next tonnage threshold under Article 12, you shall, according to Article 24(2) of the REACH Regulation, update your registration dossier **without undue delay**.

As for registrations of substances made under Article 7 of the REACH Regulation, the update of the registration of a notified substance under Article 24(2) must be done pursuant to Article 22 of the REACH Regulation. Article 22(1) of the REACH Regulation provides that a registrant is responsible, on his own initiative, for updating his registration without undue delay with relevant new information. For example, in the case of a company that imports or manufactures a substance notified under Directive 67/548/EEC, this company should submit an update pursuant to Article 22 of the Regulation as soon as he has information that the substance he imports or manufactures will exceed or has exceeded a tonnage threshold. A company that does not submit such information without undue delay may be subject to possible enforcement action from national authorities for placing a substance on the market for which not all information has been provided.

On top of that, according to **Article 135** of the REACH Regulation (Transitional measures regarding notified substances):

- ⇒ The requests to notifiers to provide further information to the competent authority in accordance with Article 16(2) of Directive 67/548/EEC, shall be considered as decisions adopted in accordance with Article 51 of this Regulation.
- ⇒ The requests to a notifier to provide further information for a substance in accordance with Article 16(1) of Directive 67/548/EEC, shall be considered as decisions adopted in accordance with Article 52 of this Regulation.

This means that the notifier (now a registrant) shall perform any study requested due to an administrative act by the member state competent authority. The **generated information should be sent to ECHA via an update of their registration**.

Please note that **not only the additional information** (corresponding to the request or to the tonnage threshold reached...) has to be submitted, **but the complete dossier in IUCLID 5** format.

To do so please refer to the instructions provided in the manual “How to submit a valid dossier to ECHA and complete the dossier header” and in the manual “How to complete a technical dossier for registrations and PPORD notifications” available on ECHA website at [http://echa.europa.eu/reachit/registration-it\\_en.asp](http://echa.europa.eu/reachit/registration-it_en.asp).

Please note that you can update your registration even if you have not claimed yet your registration number.

## **2. What do I have to do?**

- ⇒ **Sign-up in REACH-IT (if not already done)**
- ⇒ **For a tonnage band increase (and only in this case)**, you are obligated to inform ECHA of the additional information you would require to comply with the information requirements for the new tonnage level (Article 12(2)). In order to facilitate this process and to accelerate the handling of your update dossier, we strongly recommend that you submit an inquiry to ECHA whenever you require such additional information. Upon receipt of this information, ECHA acts as in an inquiry process (Article 26(3) and (4)) and should inform the registrant of the names and addresses of the previous registrants (and any potential registrants) and of any relevant study summaries already submitted by them in order to share existing data and to ensure that studies on vertebrate animals are not unnecessarily repeated.

Until the inquiry functionality is available via the REACH-IT portal, the inquiry for a tonnage band increase should be submitted according to the temporary submission procedures outlined at [http://echa.europa.eu/reachit\\_en.asp](http://echa.europa.eu/reachit_en.asp). The only exception to this is that the notification or registration number can be given in Section 1.3 of the IUCLID 5 inquiry dossier in lieu of the substance identity information. This means that the IUCLID 5 inquiry dossier needs only to contain the IUPAC name and the EC number in section 1.1, the notification or registration number in section 1.3 and the completed inquiry information requirements form (available at [http://echa.europa.eu/reachit/inquiry\\_en.asp](http://echa.europa.eu/reachit/inquiry_en.asp)) in section 13. When creating your dossier be sure to make clear that this is an inquiry relating to an update of a registration by typing “Inquiry as a result of an update of a registration” in the dossier submission remark field during step 5 of the dossier creation wizard.

*Note: If you need to send a joint submission dossier please refer to the information available on ECHA website at <http://echa.europa.eu>*

- ⇒ **Migrate the SNIF file to a IUCLID 5 substance dataset.**
  - If the SNIF migration tool is not yet available, encode manually the information from your notification (SNIF file) into IUCLID 5 format by creating an IUCLID substance dataset.
  - If the SNIF migration tool is available, you can request your notification migrated into IUCLID 5 format (IUCLID substance dataset) from your relevant Member State Competent Authority.
- ⇒ **Update the substance dataset according to the REACH requirement. To do so please refer to the instructions provided in the manual “How to submit a valid dossier to ECHA and complete the dossier header” and in the manual “How to complete a technical dossier for registrations and PPORD notifications”.**

Please note that all registration updates undergo a technical completeness check according to the requirements of Article 20(2) of the REACH Regulation. Therefore, it

would not be sufficient to submit an IUCLID 5 dossier containing only the additional information required, because this dossier would not be regarded as complete. Additionally, when the 10 tonne threshold is reached we would like to underline that the update of the registration must also include a Chemical Safety Report (Article 10(b)).

**TIP:**

*In section 1.3 of IUCLID don't forget to specify your notification number!*

*If you are representing non-EU manufacturer: in section 1.7 of IUCLID don't forget to attach all necessary contractual agreement.*

⇒ **Create a registration dossier in IUCLID 5 format:**

**The IUCLID 5 dossier header of this “registration dossier” should be filled in as follow (see screen-shot below):**

- Tick the box “Is the submission an update?”
- Indicate the previous submission number (or the notification number under Directive 67/548/EEC if you do not have a REACH submission number) in the “last submission number” field
- Tick the box “Spontaneous update”
- Select the justification of the update (if you select ”other” indicate in the adjoining right field the reason for updating)

**TIP:**

*In the case of an update of a registration according to **Article 135** of the REACH Regulation (Transitional measures regarding notified substances), please indicate the following information in the remark field: “Article 135 of REACH – submission of xxx test”*

*Please refer also to the information on “How to submit a valid dossier to ECHA and complete the dossier header” available on ECHA website at <http://echa.europa.eu>*

**Figure: Dossier header in case of change of tonnage band**

**Figure: Dossier header in case of test request from the MSCA (Article 135)**

⇒ **Submit** to ECHA your registration dossier previously created (see guidance available on ECHA website at [http://echa.europa.eu/reachit/registration-it\\_en.asp](http://echa.europa.eu/reachit/registration-it_en.asp))

**Please note that if you are an Only Representative representing several non-EU companies under the REACH Regulation you need to submit a separate updated registration for each of the non-EU manufacturers you represent (via a joint submission for example).**

### 3. *What will happen next?*

Upon receipt of your updated registration dossier, ECHA will:

- ⇒ Send you an **acknowledgment of receipt** that includes a **submission number** and submission date
- ⇒ Initiate the procedures for the **dossier completeness check**
- ⇒ Send you an **invoice**, if applicable, for the appropriate registration fee
- ⇒ If you do not have yet a **registration number** for your notified substance then ECHA will send you one.

***Note:** ECHA will only communicate the registration number to you when your dossier is complete, i.e. once ECHA has verified the completeness of the information you submitted and received the payment of the relevant registration fee in accordance with Article 20(2) of the REACH Regulation.*

You are now a “**registrant**” under the **REACH Regulation**, and have to fulfil the duties of registrant under the REACH Regulation.

If the registration dossier submitted does not fulfil the requirement under the REACH Regulation:

- ⇒ You will not get any registration number
- ⇒ You will be requested to update your submission accordingly.

