

# Questions and Answers

FOR THE REGISTRANTS OF PREVIOUSLY NOTIFIED  
SUBSTANCES (RELEASE 5)



For latest news and most  
up-to-date information please  
consult the ECHA website

**Reference:** ECHA-08-QA-04-EN

**Date:** 1-10-2009

**Language:** English

If you have questions or comments in relation to this document please send those (quote the reference and issue date) using the information request form to ECHA helpdesk. The information request form can be accessed in the REACH helpdesk section of the ECHA website at:

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

# TABLE OF CONTENTS

<b>1. CLAIMING A REGISTRATION NUMBER FOR A NOTIFIED SUBSTANCE</b>	<b>4</b>
1.1. GENERAL PRINCIPLES	4
1.2. WHEN CAN I REQUEST MY REGISTRATION NUMBER?	5
1.2.1. General case	5
1.3. WHAT MUST I DO TO REQUEST A REGISTRATION NUMBER FOR MY NOTIFIED SUBSTANCE?	5
1.3.1. I notified as a Domestic Manufacturer AND/OR Importer under Directive 67/548/EEC	5
1.3.2. I notified as a Sole Representative under Directive 67/548/EEC and I will take up the duties of the Only Representative under REACH	6
1.3.3. I am a newly appointed Only Representative and will take the duties of an earlier Sole Representative	7
1.3.4. I notified as a Sole Representative AND as a Domestic Manufacturer AND/OR Importer under Directive 67/548/EEC	9
1.4. WHAT MUST I DO IN CASE OF CHANGE OF LEGAL ENTITY AND TRANSFER OF MY NOTIFICATION TO ANOTHER COMPANY?	9
1.5. OVERVIEW OF REGISTRATION NUMBER ALLOCATING PROCESS	11
<b>2. TRANSFER OF INFORMATION FROM NCD TO IUCLID 5</b>	<b>12</b>
<b>3. UPDATING A REGISTRATION, THAT WAS PREVIOUSLY A NOTIFICATION UNDER DIRECTIVE 67/548/EEC</b>	<b>13</b>
3.1. IN WHICH CASES SHALL I UPDATE MY NONS REGISTRATION?	13
3.2. WHEN SHALL I UPDATE MY NONS REGISTRATION DOSSIER?	14
3.3. HOW TO PREPARE MY IUCLID 5 SUBSTANCE DATA-SET IN CASE OF NONS UPDATE?	15
3.4. HOW TO SUBMIT MY NONS REGISTRATION UPDATE?	17
3.5. WHAT WILL HAPPEN NEXT?	18
<b>ANNEX 1</b>	<b>20</b>

# 1. Claiming a registration number for a notified substance

## 1.1. General principles

- ⇒ According to Article 24 of the REACH Regulation all notified substances under Directive 67/548/EEC (NONS) are considered already registered under the REACH Regulation at the relevant tonnage band.
- ⇒ A notification under Directive 67/548/EEC is **nominal** so that **only the notifier benefits from his notified substance as being considered registered**.  
(Cf. Section 1.6.5.3 of the Guidance on Registration available on [http://reach.jrc.it/docs/guidance\\_document/registration\\_en.htm](http://reach.jrc.it/docs/guidance_document/registration_en.htm))
- ⇒ In principle, any **other parties intending to manufacture or import a notified substance but who have not notified such substance themselves can not be assigned a registration number under Article 24 of the REACH Regulation. Such parties should submit an inquiry and subsequently register the substance in accordance with the provisions of 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**. ECHA has performed this task.
- ⇒ **This registration number** can be requested from ECHA by the **owner of the notification via the REACH IT system** using the “Claim Notified Substances” module. This procedure will confirm to ECHA the identity of the notifier and to whom the registration number should be sent to.  
In addition, 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.
- ⇒ 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 be able to allocate any registration number and **the notifier will have to contact its relevant Member State Competent Authority (MSCA)** to resolve this issue.
- ⇒ There are four potential types of claimant (role) that may request a registration number for a notified substance:
  - 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 (Sole Representative).

- ⇒ In case of a Sole Representative or newly appointed Only Representative, **one registration number will be allocated per non-Community manufacturer represented.**
- ⇒ In the case of a Sole Representative or newly appointed Only Representative, the claimant will have to submit, in REACH-IT, written evidence of the validity of his request (see sections 3.2. and 3.3 below). This provision is in line with the implementation already in place for an Only Representative in case of Registration.
- ⇒ Please note that the **claimants have to sign-up in REACH-IT for each type of claimant they are (role) for the notified substance in question** under Directive 67/548/EEC and submit a claim for NONS using the appropriate REACH-IT account.
- ⇒ On top of that, **Only Representatives have to sign-up in REACH-IT for each non-community manufacturer they represent** and submit a claim for NONS using the appropriate accounts. It is not possible to use the same legal entity object (having the same company UUID) for multiple accounts, but it is possible to use the same company identification information (name, VAT, etc.).

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

### **1.2.1. General case**

The distribution of registration numbers by ECHA will be done upon request via REACH-IT using the “Claim Notified Substances” module.

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

As already specified, a notification under Directive 67/548/EEC is **nominal** so that **only the notifier benefits from being considered registered according to Article 24 of the REACH Regulation.**

( Cf. Section 1.6.5.3 of the Guidance on Registration available on [http://reach.jrc.it/docs/guidance\\_document/registration\\_en.htm](http://reach.jrc.it/docs/guidance_document/registration_en.htm))

### **1.3.1. I notified as 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) appointed pursuant to Article 4 of the REACH Regulation. 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 data-sharing issues to other potential registrants of 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)

You can request the **notification migrated in IUCLID 5** format 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:

- ⇒ ECHA will not be able to allocate the registration number to you
- ⇒ **You are advised to contact your relevant Member State Competent Authority to resolve the situation.** ([http://echa.europa.eu/doc/reachit/msca\\_list.pdf](http://echa.europa.eu/doc/reachit/msca_list.pdf))

### **1.3.2. I notified as 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-Community manufacturer(s) you represent should be drawn up.

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

Please note that **Only Representatives have to sign-up in REACH-IT for each non-Community manufacturer they represent** for the same notification and submit a claim for NONS using the appropriate accounts.

#### 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-Community manufacturer to become the Only Representative under the REACH Regulation and that you are entitled to claim the registration number (tick the relevant box)
- Specify the non-Community manufacturer that you will represent as Only Representative for the notified substance.
- Attach the following document for **the non-Community manufacturer** you represent:
  - Individual letter(s)/contract(s) from the non-Community 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**.

#### What will then happen?

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

- ⇒ You will **get a submission number and a registration date and be allocated a registration number for the non-Community manufacturer you represent** via REACH-IT (look at your internal messages);

You can request the **notification migrated into IUCLID 5** format from your **relevant Member State Competent Authority**. ([http://echa.europa.eu/doc/reachit/msca\\_list.pdf](http://echa.europa.eu/doc/reachit/msca_list.pdf))

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:

- ⇒ ECHA will not be able to allocate any registration number to you
- ⇒ **You should contact your relevant Member State Competent Authority to resolve the situation.**

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

This situation occurs when a non-Community manufacturer 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.

Please note that **Only Representatives have to sign-up in REACH-IT for each non-community manufacturer they represent** for the same notification and submit a claim for NONS using the appropriate accounts.

#### 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-Community manufacturer to become the Only Representative under the REACH Regulation and that you are entitled to claim the registration number (tick the relevant box)
  - Specify the non-Community manufacturer that you will represent as Only Representative for the notified substance.
  - Attach the following documents:
    - Individual letter(s)/contract(s) **from the non-Community 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 and a registration date and be allocated a registration number per non-Community manufacturer you represent** via REACH-IT (look your internal message)

You can request the **notification migrated in IUCLID 5** format 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:

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



### 1.3.4. I notified as a Sole Representative AND as a Domestic Manufacturer AND/OR Importer under Directive 67/548/EEC

What do I have to do?

- ⇒ You shall first **sign-up in REACH-IT for each type of claimant you are (role) for the notified substance in question** under Directive 67/548/EEC and submit a claim for NONS using the appropriate REACH-IT account.
- ⇒ On top of that, as former **Sole Representative you have to sign-up in REACH-IT for each non-Community manufacturer you represent** and submit a claim for NONS using the appropriate accounts.
- ⇒ **You should then 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 requests to make via the REACH-IT module to claim registration number:	What will I get?
X			<b>1 request</b> as Manufacturer/Importer	<b>one</b> registration number
	X		<b>1 request</b> as Manufacturer/Importer	<b>one</b> registration number
		X	<b>1 request per non-Community manufacturer you represent</b> as Sole Representative	<b>one</b> registration number <b>per non-Community manufacturer</b> you represent
X	X		<b>1 request</b> as Manufacturer + Importer	<b>one</b> registration number
X		X	<b>1 request</b> as Manufacturer/Importer <b>+ 1 request per non-Community manufacturer you represent</b> as Sole Representative	<b>one</b> registration number as a domestic manufacturer/ importer <b>one</b> registration number <b>per non-Community manufacturer</b> you represent
	X	X		
X	X	X		

### 1.4. What must I do in case of change of legal entity and transfer of my notification to another company?

A notification under Directive 67/548/EEC is **nominal** so that **only the notifier benefits from being considered registered according to Article 24 of the REACH Regulation.** (Cf. Section 1.6.5.3 of the Guidance on Registration available on [http://guidance.echa.europa.eu/guidance\\_en.htm](http://guidance.echa.europa.eu/guidance_en.htm))

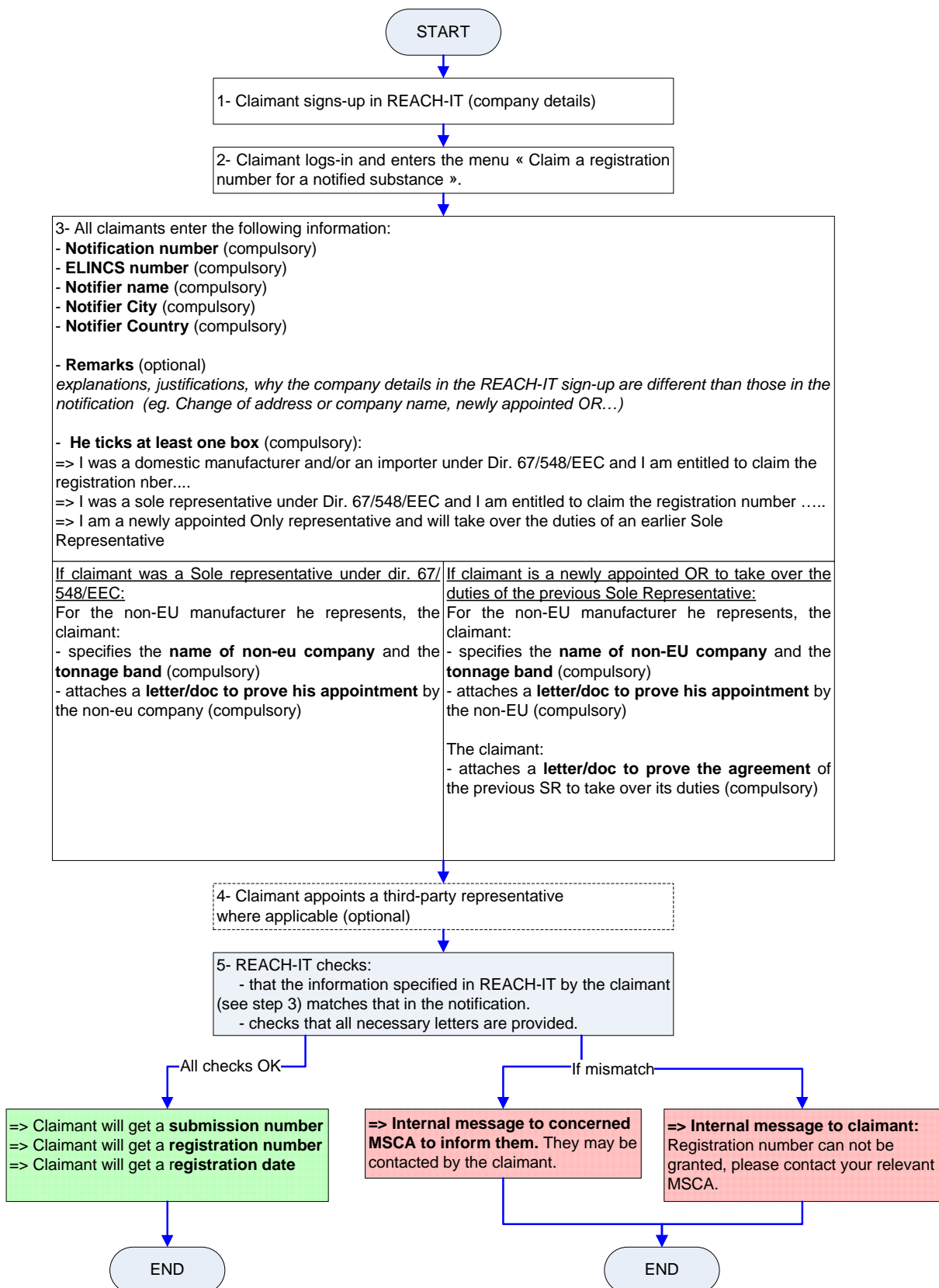
Nevertheless, it may happen that a company with legal personality that has notified a substance has transferred the responsibilities for manufacture and import of that substance to another company. In such circumstances the original notifier may have transferred its notification to the company that has taken over the original notifier's activities relating to the manufacture or import of the notified substance.

**Such event may happen for example after (i) a merger of two companies or (ii) company splits.**

For further information, please consult the REACH-IT fact-sheet on “Duties of companies that change their name or legal personality” available at:

[http://echa.europa.eu/doc/reachit/fact\\_sheets/reach\\_it\\_factsheet\\_legal\\_entity\\_change\\_20090417.pdf](http://echa.europa.eu/doc/reachit/fact_sheets/reach_it_factsheet_legal_entity_change_20090417.pdf)

## 1.5. Overview of registration number allocating process



## 2. Transfer of information from NCD to IUCLID 5

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 former European Chemicals Bureau (ex-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 have been 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 is also 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 the generated IUCLID 5 substance dataset carefully (eg. Legal entity(ies), confidentiality, endpoints, C&L...) before using it for updating your registration via REACH-IT.**

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

#### 3.1. In which cases shall I update my NONS 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. This would also include any update referring to the inclusion of the information required under Article 40 of the CLP Regulation (notification to the Classification & Labelling Inventory).

Please note that you shall first claim your registration number before updating your registration and please also note that Chapter 9 of the Guidance on Registration contains further details on when and how to update a registration dossier ([http://guidance.echa.europa.eu/guidance\\_en.htm](http://guidance.echa.europa.eu/guidance_en.htm)).

##### 1. *Tonnage updates*

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**. The update must include the additional required information under REACH corresponding to that tonnage threshold, as well as to all lower tonnage thresholds.

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(1) of the REACH 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 enforcement action by national authorities for placing a substance on the market for which not all information has been provided.

Please note that for substances that were previously notified in volumes of less than 1 tonne (**Annex VIIB/C substances under Directive 67/548/EEC**), a NONS registration update has to be submitted to ECHA under the REACH Regulation as soon as this substance reaches **the 1 tonne threshold**.

##### 2. *Updates other than tonnage updates*

Apart from the updates required when reaching the next tonnage threshold, updates at the registrant's own initiative and/or updates as a consequence of a decision made by ECHA or the European Commission must also be submitted if and when relevant. This includes updates following decisions made by national authorities according to national legislation implementing Article 16(1) or 16(2) of Directive 67/548/EEC.

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 the REACH 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 the REACH Regulation.

This means that the notifier (now a registrant) shall perform any study requested by the MSCA under the previous Directive 67/548/EEC. The **generated information should be sent to ECHA via an update of the registration by the deadline set by the MSCA.**

### **3.2. When shall I update my NONS registration dossier?**

- ⇒ Update of the registration dossier under **Article 22 or Article 24(2)** of the REACH Regulation shall be made **without undue delay**.
- ⇒ You are also recommended to update the registration dossier with the information required for notification to the Classification and Labelling Inventory according to Article 40 of Regulation 1272/2008 (CLP Regulation) by the timelines set out in that Regulation.
- ⇒ As for updates under **Article 135**, you have to submit your registration update to ECHA **by the deadline set by the MSCA**.
- ⇒ In the case of **multiple deadlines set in the request by the MSCA**:  
In many cases MSCAs requested information on several endpoints for a particular notified substance and gave more than one deadline for submission of this information. According to Article 22 of the REACH Regulation, the registrant should update his registration ‘without undue delay’ each time relevant new information becomes available. Compared to the previous legislation where the new information was sent directly to the MSCA, every submission of new information under the REACH Regulation requires the submission of an updated dossier to ECHA that needs to be processed and eventually evaluated.

REACH does not explicitly foresee any provision for ECHA to change the deadlines indicated in the decisions issued by the MSCA under the national legislation implementing Directive 67/548/EEC. Delays in providing requested information must therefore in principle be addressed at the enforcement level by national enforcement authorities. The MSCA may accept to receive different pieces of information deviant from previously taken decision(s) at a later time in order to allow the notifier to submit a single update.

Note that there may be situations where providing a new piece of information without delay after it has become available is not only a legal obligation but also necessary for safety reasons, for example when the new information changes the risk assessment or classification outcomes.

### **3.3. How to prepare my IUCLID 5 substance data-set in case of NONS update?**

A distinction should be made between updates due to a tonnage upgrade and other updates. In case of NONS registration updates due to increase in the tonnage band, a complete dossier in IUCLID 5 format has to be submitted like for any other registration. For other NONS updates, certain information is not required and may be waived until the next tonnage threshold is reached, provided that explanatory derogation statements are included. More detailed explanation on how to prepare the IUCLID 5 substance dataset is outlined below.

⇒ **Migrate the SNIF file to a IUCLID 5 substance dataset.**

You can request your notification migrated into IUCLID 5 format (IUCLID substance dataset) from your relevant Member State Competent Authority, or migrate it yourself using the SNIF migration plug-in tool available on the IUCLID web site <http://ecwbui5.jrc.it/>.

⇒ **Update the substance dataset according to the REACH requirements.**

Please note that all registration updates undergo a technical completeness check according to the requirements of Article 20(2) of the REACH Regulation. To be considered as complete, your dossier should be filled-in as specified below:

○ **Case 1: Tonnage band update.**

When updating a dossier due to an increase of tonnage band, the registrant must be aware that the updated dossier should fully comply with all REACH information requirements. The update should not only contain the information required by REACH which corresponds to that higher tonnage threshold, but also any information which corresponds to lower tonnage thresholds.

Please note that in case your update involves a registration at or above the 10 tonnes threshold, a complete chemical safety report (CSR) should be included in section 13 of your IUCLID 5 dossier unless the conditions for not submitting a CSR as set out in Article 14(2) of the REACH Regulation are met (in which case a justification should be provided in Section 13 instead).

Detailed information on how to submit a NONS dossier update in order to fulfil the completeness check requirements is described in Annex 4 of “Data Submission Manual 5: How to complete a technical dossier for registrations and PPORD notifications” available at [http://echa.europa.eu/reachit/registration-it\\_en.asp](http://echa.europa.eu/reachit/registration-it_en.asp).

○ **Case 2: Other updates.**

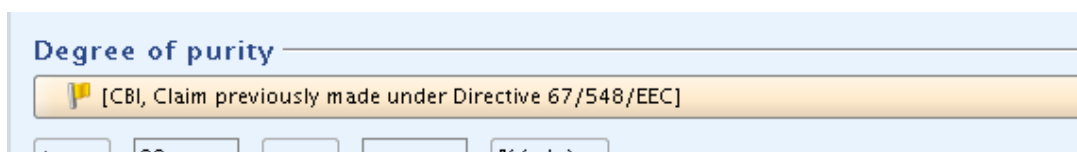
Other updates concern all other cases indicated under Article 22(1) of the REACH Regulation (except a tonnage band update indicated in Article 22(1)(c)) and updates following a decision made by the MSCA according to Article 16(1) or 16(2) of Directive 67/548/EEC.

For such updates, the dossier does not need to include information requested under the REACH Regulation that was not required under the previous legislation (i.e. Directive 67/548/EEC) at the time of the notification. Detailed information on the minimum of information which needs to be submitted in these types of updates is provided in **Annex 4 of “Data Submission Manual 5: How to complete a technical dossier for registrations and PPORD notifications”** available at [http://echa.europa.eu/reachit/registration-it\\_en.asp](http://echa.europa.eu/reachit/registration-it_en.asp).

⇒ **Update your confidentiality claims.**

Please note that ECHA will only charge a fee for those confidentiality claims associated with the new information submitted, or new confidentiality claims for the existing information i.e. there will be no fee for confidentiality claims successfully made under Directive 67/548/EEC, provided that this is confirmed by the registrant in their dossier as indicated below.

For the claims accepted under Directive 67/548/EEC, you are required to write in the justification field adjacent to each confidentiality flag the text "Claim previously made under Directive 67/548/EEC". This will allow ECHA to invoice correctly and validate the claims already presented under Directive 67/548/EEC.



ECHA may have in the past charged for existing claims under certain circumstances. Therefore, in a small number of cases some companies have previously paid a fee for confidentiality claims already accepted under Directive 67/548/EEC. If you believe that these circumstances apply to you, you may be in a position to request a refund. In this case, please contact our helpdesk, providing the relevant information and a brief explanation of the background and why you consider your claims to have been previously made and accepted under Directive 67/548/EEC. This can be done by using the web form at [http://echa.europa.eu/about/contact-form\\_en.asp](http://echa.europa.eu/about/contact-form_en.asp) and then selecting the menu item 'Enquiry on specific submission to ECHA'.

Please be aware that dissemination of information listed in Article 119(1) of the REACH Regulation includes the IUPAC names of substances included in Annex I to Directive 67/548/EEC and that, in general, information listed both in Articles 119(1) and 119(2) of the REACH Regulation must be disseminated. Note however that ECHA will not disseminate the information listed in Article 119(2) for which a party has submitted a justification, accepted as valid by the Agency, as to why such publication is potentially harmful for the commercial interests of the registrant or any other party concerned.

More information about the confidentiality claims which are possible under REACH and how to complete them in the IUCLID dossier is available in Annex III of the document "Data Submission Manual 5: How to complete a technical dossier for registrations and PPORD notifications" available at [http://echa.europa.eu/reachit/registration-it\\_en.asp](http://echa.europa.eu/reachit/registration-it_en.asp).

**TIP:**

*In section 1.3 of IUCLID **do not** forget to specify your notification number under Directive 67/548/EEC, as well as your registration number under the REACH Regulation (the one you get when claiming your registration number via REACH-IT)*

*If you are representing non-Community manufacturer: in section 1.7 of IUCLID **do not** forget to attach all necessary contractual agreement.*



### 3.4. How to submit my NONS registration update?

- ⇒ **Sign-up in REACH-IT (if not already done)**
- ⇒ **For a tonnage band increase (and only in this case)**, you are required to inform ECHA of the additional information you would need to comply with the information requirements for the new tonnage level (Article 12(2) of the REACH regulation). In order to facilitate this process and to accelerate the handling of your updated 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) of the REACH Regulation) 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.

The inquiry for a tonnage band increase should be submitted according to the procedures outlined at [http://echa.europa.eu/reachit/inquiry\\_en.asp](http://echa.europa.eu/reachit/inquiry_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 and section 1.2, 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/reachit/joint\\_submission\\_en.asp](http://echa.europa.eu/reachit/joint_submission_en.asp).*

- ⇒ **Create the IUCLID 5 registration dossier:**  
Create the IUCLID 5 dossier from the IUCLID 5 dataset prepared previously (see Part 3 – section 3 of the present Q&A).

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

- Tick the box “Is the submission an update?”
- Indicate the previous **submission number** (the one you get when you have claimed your registration number via REACH-IT) 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 note that if you need to indicate more than one reason for your spontaneous update (e.g. change of tonnage band **and** submission of requested tests), you should add more than one repeatable block under 'Spontaneous update'. In this case please refer to the data submission manual 4 "How to submit a valid dossier to ECHA and complete the dossier header" available on ECHA website at [http://echa.europa.eu/reachit/registration-it\\_en.asp](http://echa.europa.eu/reachit/registration-it_en.asp)

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-Community companies under the REACH Regulation you need to submit a separate updated registration for each of the non-Community manufacturers you represent.**

### 3.5. 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 an appropriate fee.

**Note:** ECHA will consider your dossier as complete, once ECHA has verified the completeness of the information you submitted and received the payment of the relevant fee in accordance with Article 20(2) of the REACH Regulation.

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

- ⇒ You will be requested to update your submission accordingly.

In the case of an update of a registration in accordance with **Article 135** of the REACH Regulation, the submitted information will be evaluated by ECHA pursuant to Article 42 or by the requesting MSCA pursuant to Article 48, depending on the legal basis of the original request of the MSCA under Directive 67/548/EEC.

## ANNEX 1

### UPDATE OF VERSION 1

Page	Change made
6	Integration of the claimed substance in a pre-SIEF was removed
7	Integration of the claimed substance in a pre-SIEF was removed
8	Integration of the claimed substance in a pre-SIEF was removed
9	The content of the table was rephrased
10	Update of the flow-chart

### UPDATE OF VERSION 2

Page	Change made
5	Precision on the fact that the claimants have to sign-up in REACH-IT for each role they represent and submit a claim for NONS using the appropriate REACH-IT account
5	Paragraph on urgent case has been removed
7	Precision on the fact that Only Representatives have to sign-up in REACH-IT for each non-community manufacturer they represent and submit a claim for NONS using the appropriate accounts
8	Precision on the fact that Only Representatives have to sign-up in REACH-IT for each non-community manufacturer they represent and submit a claim for NONS using the appropriate accounts
9	Update the table
13	Company shall first claim their registration number before updating their registration

### UPDATE OF VERSION 3

Page	Change made
4	Precision on the fact that a notification is nominal, and that the notifier only may benefit from article 24.
4	The REACH-IT module to claim registration number is now available
5	The REACH-IT module to claim registration number is now available
5	Paragraph on urgent case has been removed
10	Precision on what should be done in case of a notification transfer to another company
12	The SNIF migration tool is now available, and the migrated files have been distributed to the MSCAs.
14	New section about update deadline
15	New section added to explain how to prepare the IUCLID 5 substance data set
17	Precision on the details to specify in section 1.3 o the IUCLID 5 dossier
18	Update the screenshots

## UPDATE OF VERSION 4

<b>Page</b>	<b>Change made</b>
13-14	Clarification on the different types of updates
15-16	Precision on the content of a NONS registration dossier update
17	Precision on the content of an inquiry dossier
18	Text about the possibility of including in IUCLID 5 dossier header more than one reason for a spontaneous update.

