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Data Submission Manual 4

How to submit a valid dossier to ECHA and complete the dossier header **(RELEASE 1)**

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1. INTRODUCTION

Aim of the document

This document explains how the information needs to be presented to ECHA to ensure that a dossier can be accepted for further processing (like invoicing procedure, technical completeness check, evaluation of the dossier). When REACH IT is available it will not be possible to submit a dossier without fulfilling certain requirements. Until then, manual procedures have been put in place to replicate those requirements and to ensure that the dossier can be further processed. This document describes those requirements and how to fulfil them.

Dossiers submitted using the temporary submission procedures (i.e. PPORD notifications, registrations and inquiries) undergo some basic checks before being accepted for further processing.

These checks are carried out for a number of reasons, for example to ensure that:

(i) a genuine submission has been made by supplying:
  - a dossier
  - a submission form duly completed (see data submission manual);

(ii) the dossier is in the correct format (i.e. it is a genuine IUCLID 5 dossier) and does not contain a virus;

(iii) the information in the submission form and 'dossier header[1]' is sufficient to allow the dossier to be processed correctly.

For points (i) and (ii) the check is quite straightforward, but the information related to point (iii) can be complex and result in dossiers not being accepted for further processing. For example, it might be unclear whether the dossier is intended as an update of a previous registration due to a tonnage band increase, or an update due to a request for further information after a first completeness check under Article 20 of REACH.

Because it is critical that ECHA understands both the type of the dossier and the specific circumstances behind the submission, dossiers cannot be processed if this information is unclear.

The present document is divided in two different parts:

- the first one describes the initial processing steps of dossiers submitted to ECHA in order to determine whether further processing can take place or not
- the second one gives detailed explanations on how to prepare an appropriate dossier header.

[1] The dossier header of a IUCLID 5 dossier consists in information used for administrative purposes and is completed by the applicant when preparing his dossier from the substance data set.

2. HOW TO SUBMIT A VALID DOSSIER TO ECHA

Once the dossier arrives in ECHA (by email, mail or courier), both the IUCLID 5 dossier and the submission form are subject to the following procedure before the technical completeness check can be performed:

- technical and administrative verification

- fee determination and invoice preparation

In the following paragraphs these verifications are explained in detail to ensure that dossiers are submitted properly and can be further processed.

2.1. Technical and administrative verification

The technical and administrative checks are performed in two steps within ECHA for practical reasons. A refusal to accept a dossier for further processing can occur at either of the two steps and will result in a communication from ECHA.

The explanations below follow those two steps and show how the communication is done in case of a failure.

1) During the first step of technical and administrative verification several points are checked; the most important ones are:
   - do the submitted files not contain any virus
   - is the submission form available, readable and duly filled in (e.g. company and dossier UUID, submission type, company information, additional compulsory information if applicable)
   - does the submission contain a valid IUCLID 5 dossier (i.e. a valid dossier with an '.i5z' extension)
   - is the information indicated in the submission form in line with the content of the IUCLID 5 dossier (particularly with the content of the dossier header)
   - does the UUID (Universal Unique IDentifier) of the IUCLID 5 dossier submitted match the one reported in the submission form
   - does the UUID of the company match with:
     - the one reported in the submission form
     - the one coming from the REACH-IT sign-up (reach IT sign-up and account creation)

If all checks are valid, an "**Acknowledgement of receipt**" email is sent to the email address indicated during the REACH-IT sign-up.

The text of the "Acknowledgement of receipt" reports the following information:

- the submission number assigned to the dossier (unique for each submission)
- the submission date (date & time in which ECHA started to process the dossier)

- the “dossier type” of the dossier (e.g. PPORD notification, Registration dossier)
- the UUID of the submitted dossier

An example of “Acknowledgement of receipt” email is given below (please note that in this case the email refers to a PPORD notification submission):

Subject: Acknowledgement of receipt (xxxxxxxx-xx)

Acknowledgement of receipt of information under regulation (EC) no 1907/2006:

The European Chemicals Agency (ECHA) has received your file. You will find hereafter your submission number and date.

Submission number: xxxxxxxx-xx

Submission date: 02/06/2008 18:59:05

Dossier type: PPORD notification

Dossier UUID: xxxx-xxxxxxxx-xxxx-xxxx-xxxx-xxxxxxxxxxxx

If you have a specific concern about the content of this message you can contact ECHA using the webform at http://echa.europa.eu/about/contact-form_en.asp and then selecting the menu item 'Enquiry on specific submission to ECHA'.

Note that because of ECHA's security policies it is not possible to reply to this mailbox.

If at least one of the checks failed a “**Communication on your submission**” email is sent to the submitting company indicating that the dossier cannot be processed by ECHA.

This “Communication on your submission” email reports:

- the UUID of the submitted dossier, when available

- the submission number assigned to the dossier (unique for each submission)
- the submission date (date & time in which ECHA started to process the dossier)
- the reason(s) for which the dossier cannot be processed by ECHA

An example of a “Communication on your submission” email is given below (please note that in this case the UUID of the IUCLID 5 dossier was not matching the one indicated in the submission form).

Subject: Communication on your submission under regulation (EC) no 1907/2006 (xxxxxxxx-xx)

Your dossier UUID: xxxx-xxxxxxxx-xxxx-xxxx-xxxx-xxxxxxxxxxxx

This email provides the acknowledgement of receipt of information under regulation (EC) no 1907/2006. The European Chemicals Agency (ECHA) has received your file and you will find hereafter your submission number and date.

Submission number: xxxxxxxx-xx

Submission date: 04/06/2008 15:17:14

However, the information you have submitted does not meet the conditions as set by the regulation for the following reasons:

- The dossier UUID mentioned in your submission form was not consistent with the UUID of the IUCLID 5 dossier you submitted.

The file can therefore not be processed by ECHA and will automatically be removed from our system. You are requested to address the deficiencies as listed above and re-submit your dossier as a new submission to ECHA.

If you have a specific concern about the content of this message you can contact ECHA using the webform at http://echa.europa.eu/about/contact-form_en.asp and then selecting the menu item 'Enquiry on specific submission to ECHA'.

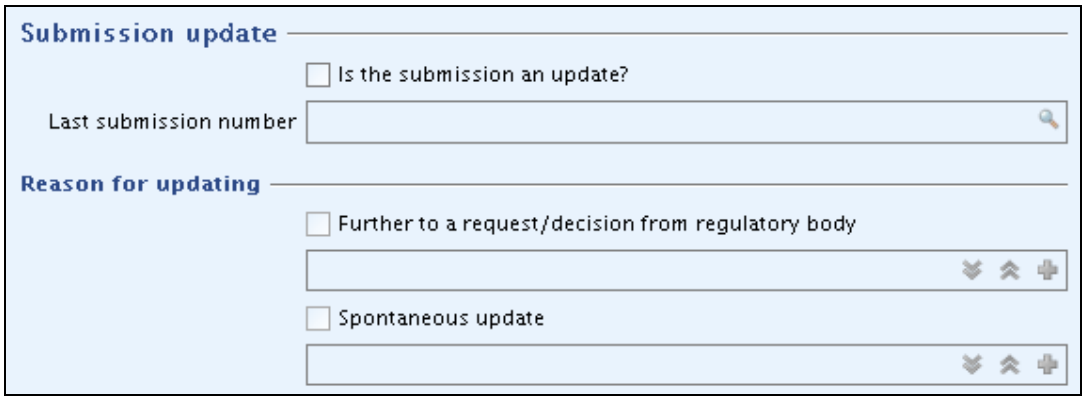
Note that because of ECHA's security policies it is not possible to reply to this mailbox.

Important note: If you receive a "Communication on your submission", you should correct the deficiencies and submit again your dossier as a NEW submission to ECHA (i.e. you should not treat this new submission as an update of the previous one and you should not mention in your IUCLID 5 dossier any reference to the previous submission number).

When the submission of a dossier fails at this stage, the corresponding file is removed from ECHA system. Consequently, the company must not refer to this dossier (or mention the associated submission number) anymore.

The two following scenarios show the necessary steps in preparing the NEW submission in case a previous dossier could not have been processed by ECHA.

→ If the dossier submitted that could not be processed by ECHA was an initial one, a new initial dossier shall be submitted to ECHA without any reference to the dossier that was previously rejected and for which you received a "Communication on your submission" email. The dossier header of your new initial dossier should be empty in the "Submission update" section, as shown in the following screenshot.



→ If the dossier submitted that could not be processed by ECHA was an update, a new update dossier should be submitted without including any reference to the former one. The last submission number to indicate in the new update, should be the one attributed to the last dossier processed by ECHA for this substance.

For example if the first dossier submitted to ECHA (AA111111-11) passed the administrative and technical verification (i.e. can be processed by ECHA) but failed the technical completeness check, an updated one must be submitted (in which the last submission number, i.e. AA111111-11, should be reported in the dossier header). Once this update is submitted to ECHA a new submission number is allocated (e. g. BB222222-22). If this dossier does not pass the administrative and technical verification (i.e. cannot be processed by ECHA), the company should resubmit a new update indicating in the dossier header the last 'valid' submission number (AA111111-11).

More details on how to complete the dossier header in case of an update are available here.

2) The second step of the technical and administrative verification consists in checking, for example, that:

– the dossier template appearing in the dossier header (e.g. REACH PPORD; REACH Registration 10 - 100 tonnes; REACH Registration above 1000 tonnes)

matches with the one indicated in the submission form;

- in case the submission is an update (see submission update), the indication that the dossier is an update is correctly reported in the dossier header and matches with the information that is already present in the ECHA database for the linked company/substance;
- the submitted IUCLID 5 dossier contains a valid Reference Substance in section 1.1 and in 1.2, in which at least one chemical identifier is present (EC number, CAS number, CAS name or IUPAC name);
- the IUCLID 5 dossier was not prepared using the Mixture data set feature of IUCLID 5 (this is not allowed because the dossier should be for a substance, not a mixture);
- for initial registration dossiers only (i.e. not for updates), the same substance was not already registered or still processed by ECHA for the same company.

Note: The list of the checks here above indicated is not exhaustive, as the technical and administrative verification is strictly related to the typology of the submission (single/joint submission, spontaneous/further to a communication-decision update and so on).

If one of the previous verifications fails, the dossier cannot be processed by ECHA. A "**Communication on your submission**" email is sent to the submitting company indicating that the dossier cannot be processed by ECHA. The email text is given below.

Subject: YOUR SUBMISSIONS UNDER REGULATION (EC) NO 1907/2006

The information you have submitted to the European Chemicals Agency (ECHA) does not meet the conditions as set by the regulation (see details in the attached communication).

The information cannot be processed by ECHA and will be automatically removed from our system.

You are requested to submit the information in the format specified by ECHA as a new submission.

If you have a specific concern about the content of this message you can contact ECHA using the webform at http://echa.europa.eu/about/contact-form_en.asp and then selecting the menu item 'Enquiry on specific submission to ECHA'.

Note that because of ECHA's security policies it is not possible to reply to this mailbox.

In this type of communication, the explanation of the failure of the verification is provided as a PDF file attached to the email. The PDF document states the reason(s) why the dossier does not meet the conditions as set by the REACH regulation. This document reports:

- the submission date (date & time in which ECHA started to process the dossier);
- the submission number assigned to the dossier (unique for each submission);
- the communication number (to be used for all correspondence regarding this communication);
- the reason(s) for which the dossier cannot be processed by ECHA.

Important note: as for step 1, if you receive a “Communication on your submission” with a communication as a pdf attachment, you should correct the deficiencies and submit again your dossier as a NEW submission to ECHA (i.e. you should not treat this new submission as an update of the previous one and you should not mention in your IUCLID 5 dossier any reference to the previous submission number) – see detailed explanation given for dossiers not accepted by ECHA at step 1.

2.2. Fee determination

Fee determination relates only to dossiers submitted for PPORD notifications and registrations.

The fee determination and the preparation of the invoice are based on:

- the information reported in the dossier header (see Section 3 for more information);
- the information in the submission form. For registration, the information submitted in the submission form relates to:
    - the tonnage band of the registration
    - the indication of intermediate use (if the tonnage for such a use is not covered by the tonnage band given above – see for more information data submission manual 3)
    - the statement that a full annex VII is submitted (related to fee waiver reasons), for registration of less than 10 tonnes of substance;
- the information contained in the substance data set such as the confidentiality requests. Please note that a fee is requested only for those confidentiality requests which are falling under Art. 119(2) of REACH and Annex IV of the fee regulation ((EC) 340/2008 (for more details, see Annex 1 in the present manual).

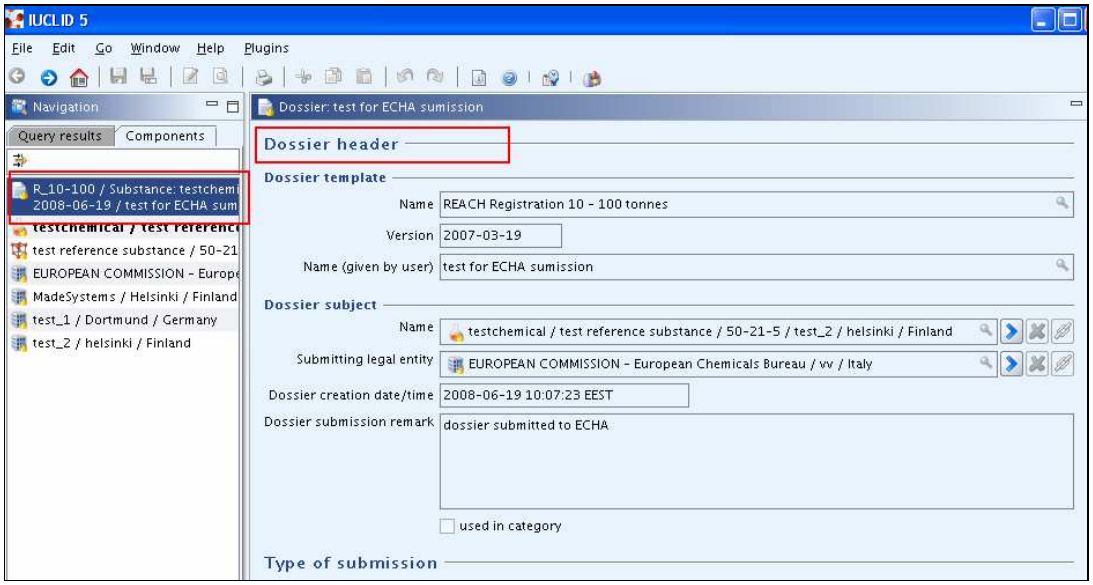
Note: the justification for a confidentiality claim will be checked only before information is published. In case a confidentiality request would then be rejected by ECHA, the fee would not be reimbursed.

3. IUCLID DOSSIER HEADER

As already pointed out in Section 2, the dossier header has a significant impact:

- on the processing of the dossier before the technical completeness check
- on the calculation of fees and preparation of the invoice.

During the IUCLID 5 dossier creation procedure[2], the dossier creation wizard requests the user to "*Enter additional administrative information concerning your dossier*" in the 6th step[3]. This information will then be contained in what is called the "IUCLID 5 dossier header". The dossier header is the part of the dossier that reports information fundamental to pass the administrative/technical verification and on which a part of the fee calculation is based.

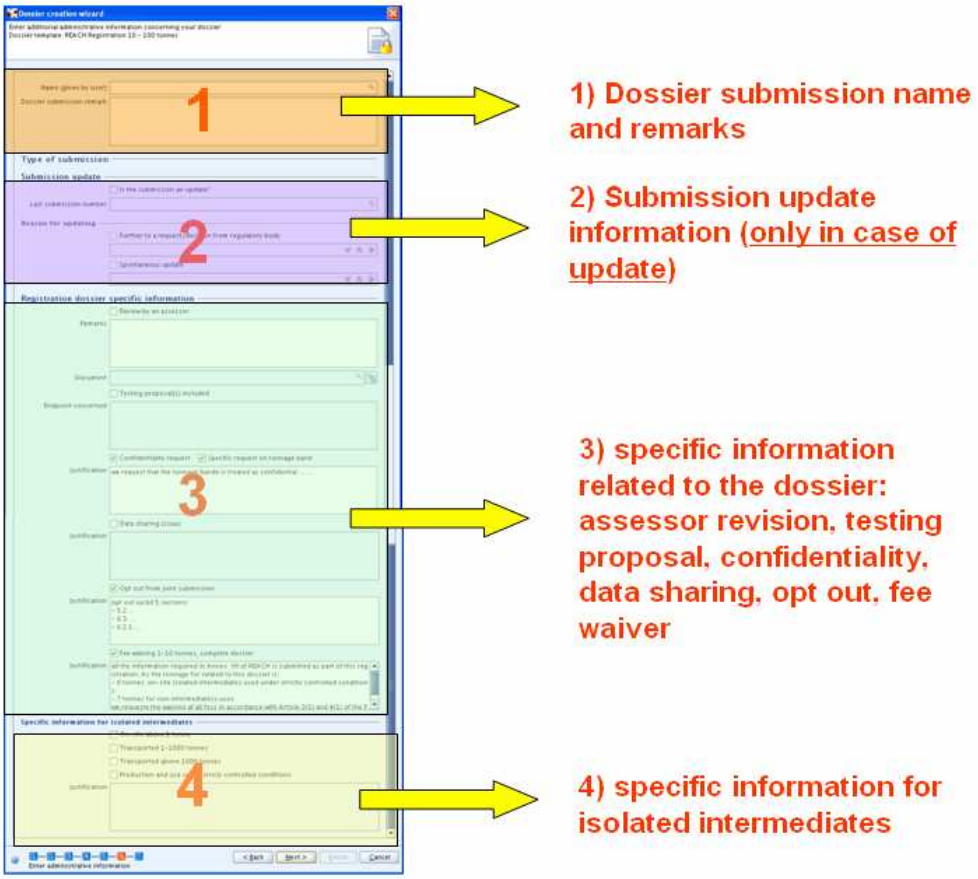


Note: for general guidance on dossier creation, refer to the IUCLID 5 User manual.pdf, section C.6 "Creating a dossier" and section D.8.2 "Creating dossiers".

[2] To create a dossier in IUCLID 5, you should start from the IUCLID 5 substance dataset, select the template corresponding to your submission (for ex. REACH Registration 10 - 100 tonnes, REACH PPORD, …), follow the dossier creation wizard guide, export the dossier and save it in on your PC (from where then you can easily copy & paste it to a CD or DVD or attached it to an email to be submitted)

[3] For dossier creation containing a category, the wizard step related to the dossier header is the 7th

In the following pages, a detailed guide on how to fill in properly the information requested during the 6th step[4] of the dossier creation wizard is given. The screen at this step is divided in four parts, as shown in the figure below:



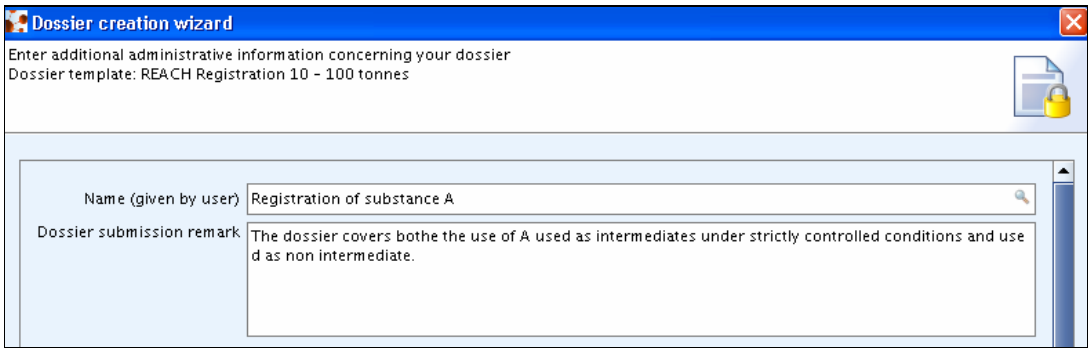
Note: for the creation of a dossier, different from a registration one (PPORD notification, C&L notification, notification of substance in article, inquiry…) a reduced set of information is needed to prepare a proper dossier header.

For registrations, the person compiling the IUCLID 5 dossier before the submission to ECHA should complete the information related to the four parts described above. However, unless the dossier is an update no information on submission update should be reported.

[4] For dossier creation containing a category, the wizard step related to dossier header is the 7th

3.1. *Dossier submission name and remarks (dossier header part 1)*

The first part allows the registrant to specify the name of the dossier as well as any additional information needed.



3.2. *Submission update information (dossier header part 2)*

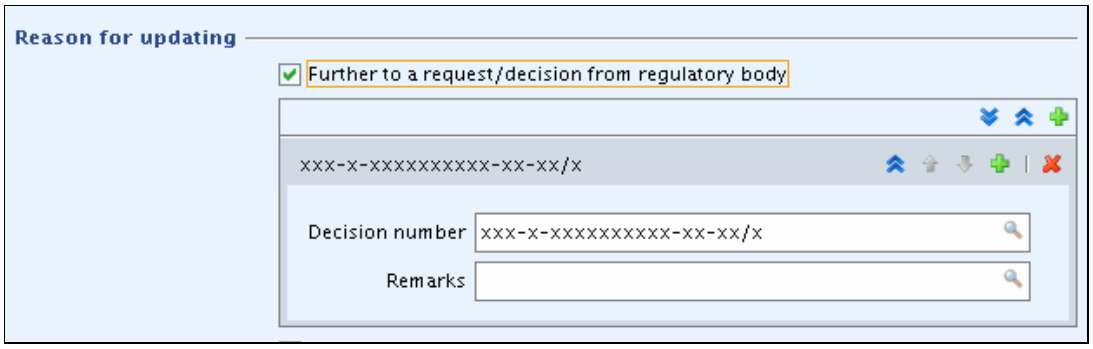
It is important to identify whether the dossier is an update of a previous dossier or not as

- if it is submitted as an update although it is not, then it cannot be processed by ECHA;
- if it is not submitted as an update although it should be one, the fees will not be correct and this could lead to administrative problems later on.

The following situations are the only situations where the submission should be considered as an update:

1. A registration dossier has been sent for the substance but, although it passed the technical and administration verification steps, the registration was considered as incomplete by the Agency during completeness check. The submission of an updated dossier in this case is meant to fulfil the request for further information made by the Agency within a set deadline. Under these circumstances: the last submission number (i.e. the one attributed to the dossier which resulted in the request for further information) must be reported in the "Last submission number" field; the checkbox "Further to a request/decision from regulatory body" must be selected, and the communication number indicated in the request for further information must be entered in the adjacent "Decision number" field.

> **Note:** This only applies to submissions which were considered incomplete by the Agency during the completeness check and which resulted in a letter entitled 'Request for further information on your registration under Regulation (EC) No. 1907/2006'. If you receive a 'Communication on your submission' you should follow the instructions in Section 2.1.

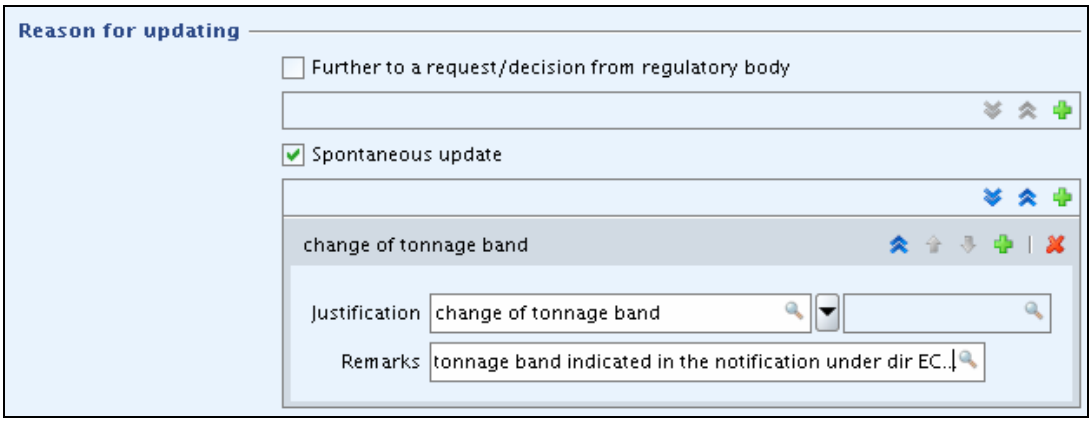


2. The substance is a notified substance under Directive 67/548/EEC (considered as being registered under REACH).

    - if a registration number has not been assigned yet, the notification number under Directive 67/548/EEC should be reported in the "Last submission number" field as well as in section 1.3 of the IUCLID 5 dossier;

    - If a registration number has been assigned then the submission number linked to the registration number request should be reported in the "Last submission number" field. In addition, the registration number AND the notification number under Directive 67/548/EEC should also be indicated in section 1.3 of the IUCLID 5 dossier.

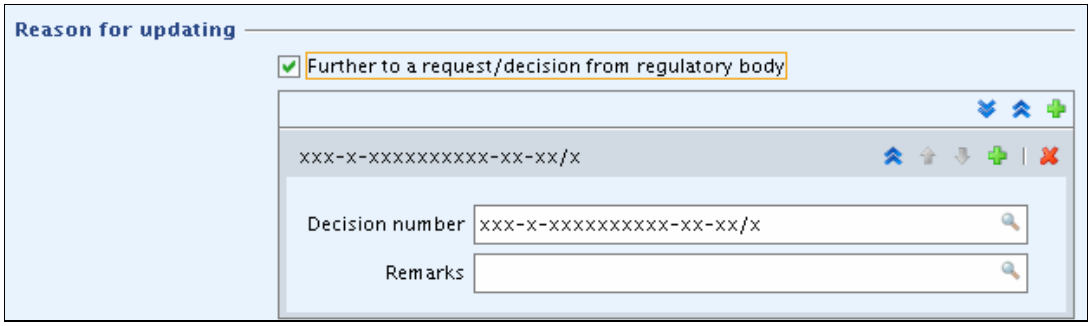
In these cases the checkbox "Spontaneous update" should be selected and the reason for the update should be chosen from the drop down list in the "Justification" field.



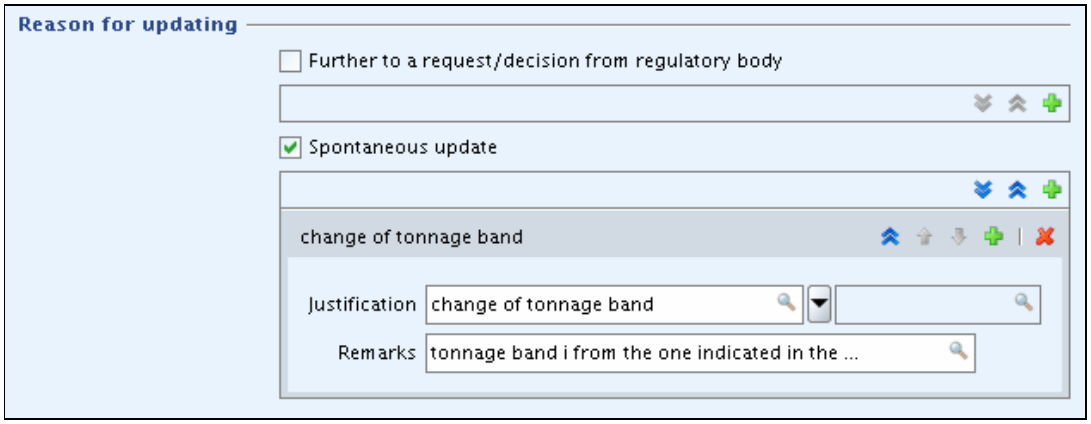
3. The substance was previously registered by your company under REACH. In this case the submission number of the last complete dossier submitted for this substance should be reported in the "Last submission number" field and the registration number should be indicated in the section 1.3 of the IUCLID 5

dossier. It should also be reported whether the update is an update made on “request from regulatory body” (for example when an update should be submitted following an ECHA compliance check decision) or whether it is a spontaneous update.

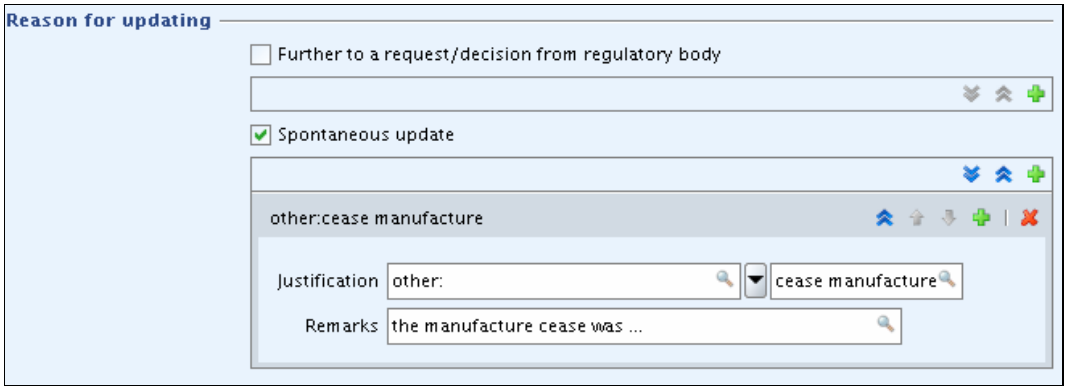
a. In case of an update made on request of a regulatory body, the checkbox “Further to a request/decision from regulatory body” must be selected and the communication number in the request letter must be entered in the adjacent “Decision number” field.



b. In case of spontaneous update, the checkbox “spontaneous update” should be selected and the reason for the update should be chosen from the drop down list in the “justification” field.



If the reason of the spontaneous update is not listed in the drop down list (for example in case of manufacture cease), the entry “other:” should be selected and the information should be indicated in the adjacent field, as indicated in the following screenshot.



As soon as the dossier is an update this should be identified by all of the following information, otherwise it will not be possible for ECHA to process the dossier:

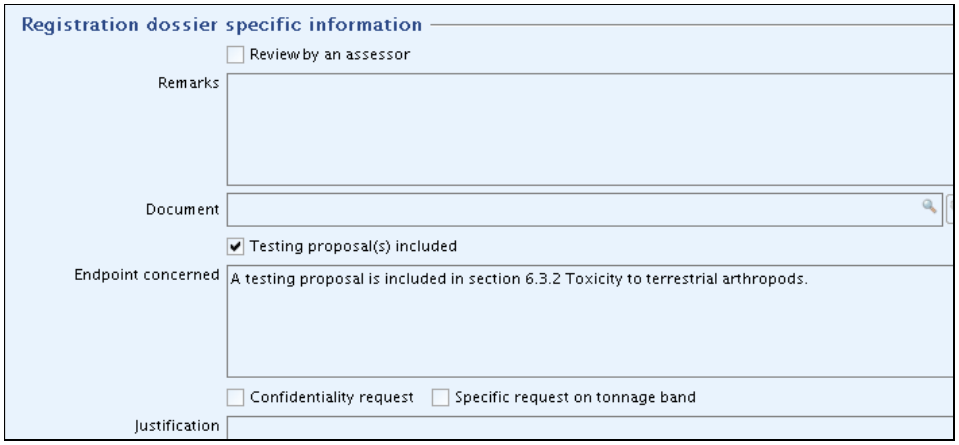
- ticking the box “is the submission an update”
- including a “last submission number” (the number to be given depends on the circumstances described in the preceding paragraphs)
- filling the “reason for updating”

Note: For more information on different types of registration dossiers and the related requirements, refer to the “Guidance on registration” - section 9 (guidance on update of dossier).

3.3. Specific information related to the dossier (dossier header section part 3)

This part of the dossier header allows the registrant to give general information on the IUCLID 5 dossier submitted.

As a general rule when one of the boxes of the block “registration dossier specific information” (review by an assessor, testing proposals, confidentiality request, fee waiving…) is ticked then the associated free text field below the box should be filled in.



Some of the information reported in this block has a direct influence on the fee calculation (in bold in the list here below), others are instead for providing a quick overview on the data/information present in the dossier.

The specific information reported in this part of the dossier header is whether the:

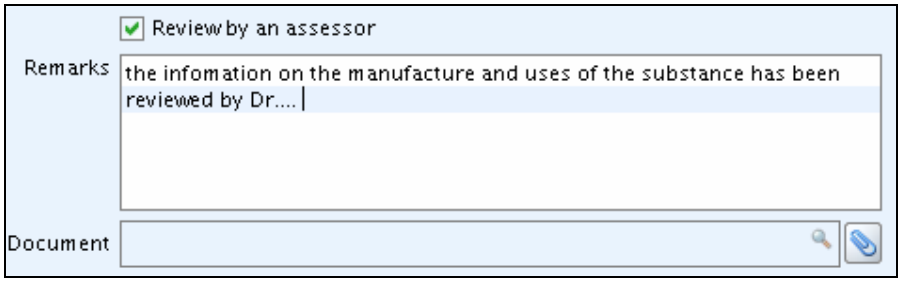
- the dossier has been reviewed by an assessor
- testing proposals are included
- **confidentiality request is made in the dossier**
- there is an issue regarding data sharing
- **there is an opt out from a joint submission**
- **there is a request of fee waiving**

The specific information reported in bold above has an influence on the fee calculation:

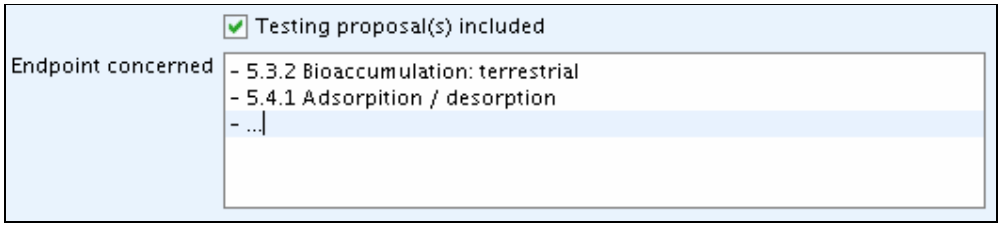
- an additional fee will be levied for each confidentiality request (see Annex 1) in the dossier in accordance with article 6 and Annex IV of the fee regulation.
- an different fee will be levied in accordance with Article 3(3), 4(3), 5(3) of the fee regulation if the registrant opts out from the joint registration, by submitting separately part of (or all) the relevant information referred to in Article 10(a)(iv), (vi), (vii) and (ix) or 17(2)(c) and (d) or 18(2)(c) and (d) of REACH Regulation.
- fees are exempted for registrations of substances in the 1-10 tonnes tonnage band if all the information required in Annex VII of REACH is submitted in accordance with Article 3(1) and 4(1) of the fee regulation.

In detail the registration specific information that might/should be reported is:

- Reviewed by an assessor: by ticking the checkbox “Review by an assessor” the registrant declares that the dossier has been reviewed by an assessor having an appropriate experience (in accordance to Art 10 (a) (viii)). A document can also be attached if necessary.



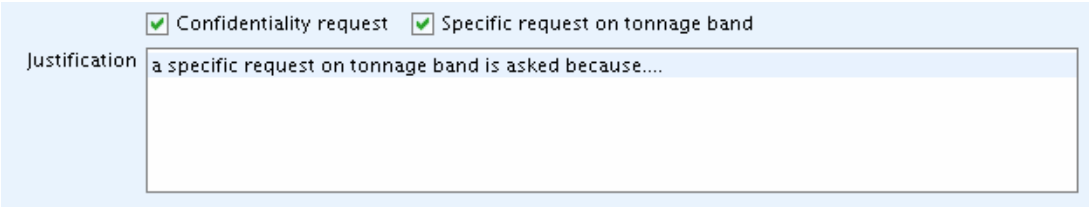
- Testing proposal included: by ticking the checkbox “Testing proposal included” the registrant declares that at least one testing proposal is present in the endpoint section of the dossier submitted. It should be stated in the “endpoint concerned” text box, which endpoint(s) is (are) concerned in the dossier.



- Confidentiality request: the confidentiality request in the dossier header shall be used only to indicate the following cases:

1) Confidentiality request on the tonnage band

If the registrant wants to keep the tonnage band for which he registers confidential, the checkbox “Specific request on tonnage band” should be selected as this is the only way to request this confidentiality. A justification should be provided.



Note: the confidentiality flag in section 3.2 of IUCLID 5 cannot be used to request confidentiality for your tonnage band, because that section relates to the actual tonnage which is anyway confidential information.

2) Confidentiality requests which cannot be made in the detailed sections of the IUCLID dossier.

A registrant can request that information that is submitted to the Agency according to Art. 10 of the REACH regulation is not published on the internet because publication could be harmful for his or any other concerned party’s commercial interests. Further information on confidentiality requests can be found in Annex 1.

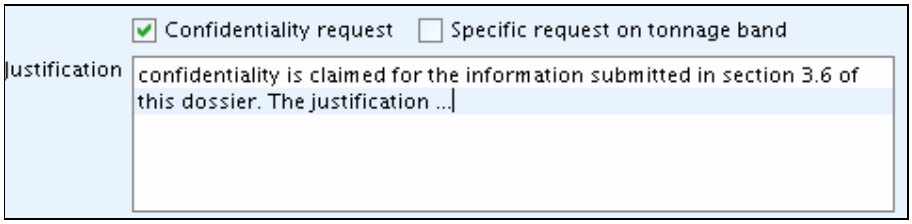
Some of these confidentiality requests cannot be made in the detailed sections of the IUCLID dossier, and so the dossier header must be used as follows.

Parts of IUCLID 5 dossier sections 3.5 and 3.6 fall under the Art. 119(2)(d) of the REACH Regulation and thus are subject to a confidentiality request and payment of fee. The current version of IUCLID 5 does not offer the possibility to claim confidentiality directly in these sections. Art. 119(2)(d) refers to information contained in the safety data sheet, that is not already published by ECHA according to Art. 119(1).

The following information falls into this category:

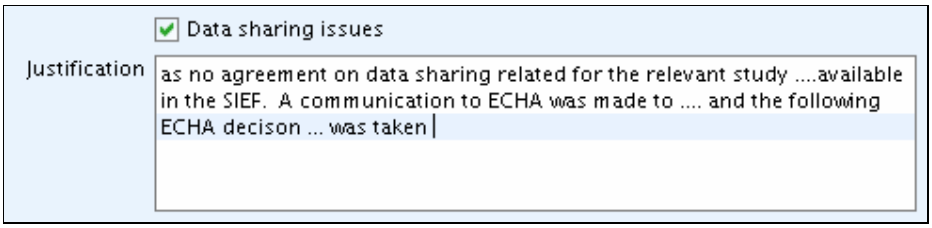
- 3.5 Identified uses and exposure scenarios: Main use category and Specification for industrial and professional use
- 3.6 Uses advised against

Consequently if confidentiality is claimed on information reported in sections 3.5 and/or 3.6 of IUCLID 5 the checkbox “Confidentiality request” should be selected and a justification for those requests should be provided in the “Justification” field.

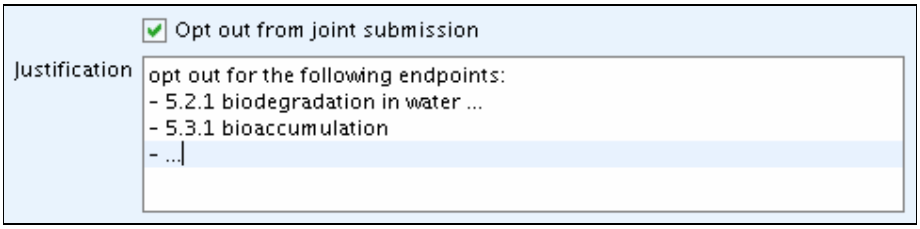


Note: All other confidentiality requests shall be made in the foreseen places in the technical dossier (see Manual on completion of a technical dossier)

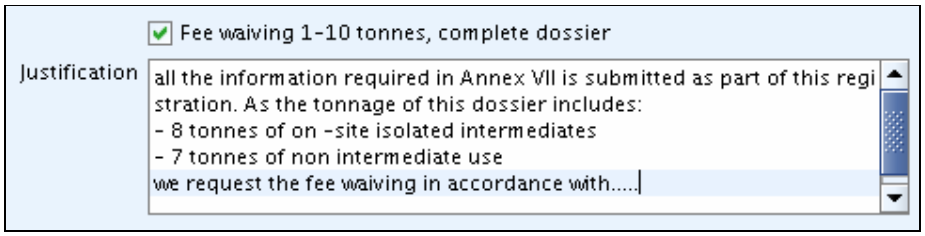
- Data sharing issues: if during the data sharing process any issues arises in obtaining information/data (after a regular inquiry to ECHA) from the data owner, the registrant can indicate the problem in this section. A justification should also be made available and, if available, the ECHA decision number on this particular sharing situation.



- Opt out from a joint submission: if the registrant is part of a joint submission and he wants to opt out (according to Article 11(3) of the REACH Regulation) by submitting separately information which should normally be submitted jointly, he should select the checkbox “Opt out from joint submission”. A justification should be provided, indicating also in which section of the dossier the opt out is requested.



- Request of fee waiving: In case a registration is made for a tonnage below 10 tonnes, an exemption of the fee can be requested if all information required by Annex VII of REACH is provided in accordance with Art 3(1) and 4(1) of the Fee Regulation (EC 40/2008). In this case the checkbox “Fee waiving 1-10 tonnes, complete dossier” should be selected and a justification should be provided in the appropriate text box.

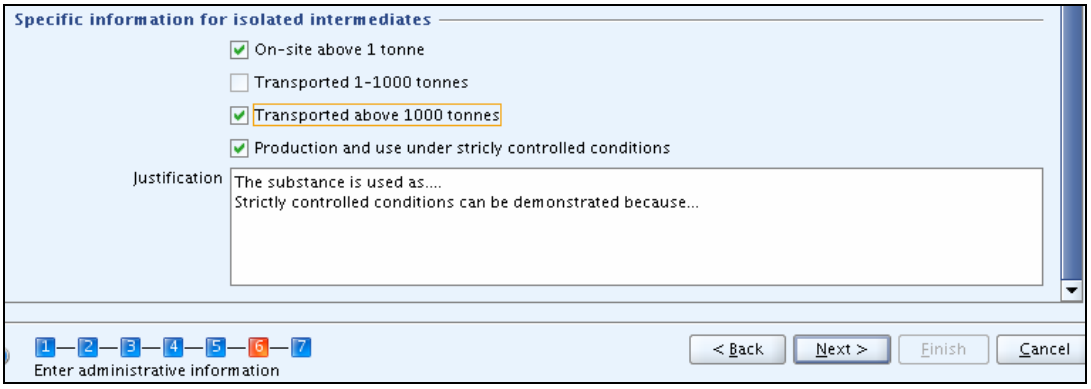


3.4. Specific information for isolated intermediates (dossier header part 4)

When the dossier covers also a volume used as an isolated intermediate specific information should be reported. This information should be consistent with the information reported in the submission form.

The exemption from standard information requirements only applies to isolated intermediates that are manufactured or used under strictly controlled conditions and this

will be regarded as claimed by the registrant only if the appropriate checkbox is selected[5]. In addition, different information requirements apply to on-site and transported intermediates and more information can be found in the Guidance for intermediates.



When a dossier is made for a substance used both as isolated intermediates under strictly controlled conditions and as non intermediates, the fees will be calculated as the sum of individual fees for intermediate and non intermediate, as specified in the submission form (as if separate dossiers had been submitted).

[5] Please note that the strictly controlled conditions will have to be carefully documented. This can be done in the justification field in Section 11 of IUCLID 5.

ANNEX 1

A registrant can request that information submitted to the Agency according to Art. 10 of the REACH regulation is not published on the internet because publication could be harmful for his or any other concerned party's commercial interests. Article 119(2) specifies which information requires publication by ECHA. If the information falls under Article 119(2) of the REACH regulation and Annex IV of the Fee Regulation[6], then the Agency will request a fee payment for these confidentiality requests. Note that the fee has to be paid for the request but it is not a guarantee that the information is not published. The Agency will decide based on the provided justification if the reasoning is sufficient to not publishing the information.

Confidentiality requests which are subject to a fee and that appear in the dossier header are:

Relevant tonnage band (corresponds to Art. 119(2)(b) of REACH)

Requests in IUCLID 5:

- Dossier header: Request for the tonnage band (checkboxes "Confidentiality request" and "Specific request on tonnage band" are selected and a justification is provided.)

Information in the safety data sheet (corresponds to Art. 119(2)(d) of REACH)

Requests in IUCLID 5:

- Dossier header: Request for sections
  - 3.5 Identified uses and exposure scenarios: Main use category and Specification for industrial and professional use
  - 3.6 Uses advised against

  Requests have to be made in the dossier header as there is no possibility in sections 3.5 and 3.6 to flag the information directly. The box "Confidentiality request" should be ticked and in the justification field the item for which confidentiality is requested should be mentioned and a justification given.

[6] COMMISSION REGULATION (EC) No 340/2008 of 16 April 2008 on the fees and charges payable to the European Chemicals Agency pursuant to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)

European Chemicals Agency Annankatu 18, P.O. Box 400, FI-00121 Helsinki, Finland
Tel.: +358 9 6861 80 | Fax +358 9 6861 8210 | http://echa.europa.eu | info@echa.europa.eu