

REACH

Príprava a podanie registračných dokumentov

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Bešeňová 12. júna 2009

Obsah

- Príprava dossieru (IUCLID 5)
- Podanie dossieru (REACH-IT)
- Spracovanie dossieru v ECHA
- Doterajšie skúsenosti v ECHA

Príprava dossieru (IUCLID 5)

Príprava dossieru (IUCLID 5)

Podmienky:

nainštalovaný IUCLID5 a vytvorený účet na REACH-IT

1. Pripravte súbor údajov 'substance dataset' v IUCLID 5
2. Exportujte dossier z IUCLID 5
3. Vyberte -upload dossier cez REACH-IT
4. ECHA skontroluje 'business rules', zašle faktúru (ak je potrebné) a vykoná technickú kontrolu kompletnosti - Technical Completeness Check (TCC)
5. Možno bude potrebné podanie znova, ak sa vyskytnú formálne chyby (business rules a/alebo TCC)
6. Následne po uhradení faktúry vydá ECHA registračné číslo

Príprava dossieru (IUCLID 5)

- Štruktúra registračného dossieru
- 1-10 ton
 - technický dossier
- viac ako 10ton
 - technický dossier
 - správa o chemickej bezpečnosti

Príprava dossieru (IUCLID 5)

Technický dossier

Annex VI REACH: Identity of registrant, Identity of substance, Information about uses, C&L, Guidance on safe use ...

Annexes VII to X: Fyzikáno-chemické, toxikologické a ekotoxikologické štúdie sú požadované podľa tonáže :

1-10 ton: Annex VII

10-100 ton: Annex VII + VIII

100-1000 ton: Annex VII + VIII + IX

>1000 ton: Annex VII + VIII + IX + X

Annex XI: všeobecné pravidlá pre adaptovanie Annexov VII až X

Príprava dossieru (IUCLID 5)

Podmienky: nainštalovaný IUCLID5 a vytvorený účet na REACH-IT

Vytvorte a skompletizujte údaje o látke 'substance dataset' pre látku, ktorá má byť registrovaná

Vyexportujte dossier (select dossier type and fill 'dossier header')

Detaily o inštalácii IUCLIDu:

- <http://iuclid.echa.europa.eu/>

Príprava dossieru (IUCLID 5)

The screenshot displays the IUCLID 5 software interface. The main window is titled "Dossier: test for ECHA submission". The interface is divided into several sections:

- Dossier header:** A red box highlights this section, which is currently empty.
- Dossier template:** This section contains the following fields:
 - Name: REACH Registration 10 - 100 tonnes
 - Version: 2007-03-19
 - Name (given by user): test for ECHA submission
- Dossier subject:** This section contains the following fields:
 - Name: testchemical / test reference substance / 50-21-5 / test_2 / helsinki / Finland
 - Submitting legal entity: EUROPEAN COMMISSION - European Chemicals Bureau / vv / Italy
 - Dossier creation date/time: 2008-06-19 10:07:23 EEST
 - Dossier submission remark: dossier submitted to ECHA
 - used in category
- Type of submission:** This section is currently empty.

The left sidebar shows a navigation tree with the following items:

- Query results
- Components
- R_10-100 / Substance: testchemi
- 2008-06-19 / test for ECHA sum
- testchemical / test referenc
- test reference substance / 50-21
- EUROPEAN COMMISSION - Europe
- MadeSystems / Helsinki / Finland
- test_1 / Dortmund / Germany
- test_2 / helsinki / Finland

Príprava dossieru (IUCLID 5)

The screenshot shows the 'Dossier creation wizard' window. It is divided into four main sections, each highlighted with a colored background and a large red number. Yellow arrows point from these sections to the corresponding text on the right.

- Section 1 (Orange):** 'Dossier submission name and remarks'. It contains a text input field for 'Dossier submission name' and a larger text area for 'Remarks'.
- Section 2 (Purple):** 'Submission update information (only in case of update)'. It includes a 'Type of submission' dropdown set to 'Submission update', a 'Last submission number' field, and a 'Reason for updating' dropdown set to 'Further to a request from regulatory body'.
- Section 3 (Green):** 'Registration dossier specific information'. It contains several checkboxes and text areas for 'General', 'Documents', 'Endpoint concerned', 'Confidentiality', 'Data sharing', and 'Opt out from data submission'.
- Section 4 (Yellow):** 'Specific information for isolated intermediates'. It includes checkboxes for 'Transported > 1000 tonnes', 'Transported above 1000 tonnes', and 'Production and use under controlled conditions'.

1) Dossier submission name and remarks

2) Submission update information (only in case of update)

3) specific information related to the dossier: assessor revision, testing proposal, confidentiality, data sharing, opt out, fee waiver

4) specific information for isolated intermediates

Podanie dossieru (REACH-IT)

Step 1: Dossier Upload – Select dossier

1. Select the dossier type to submit

2. Browse to the file to submit

3

Access code is required to upload large files

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You are connected as **naqel** on behalf of **My Chemicals** - [Preferences](#) [Logout](#)

Company > [Dossiers](#) > [Submission](#)

Dossier submission

- Registration (regular) → Submit a regular registration dossier
- Registration (S.I.A) → Submit a substance-in-article registration dossier
- Registration (O.s.I.I.) → Submit an on-site is
- Registration (T.O.s.I.I.) → Submit a transport
- Pre-registration (bulk) → Pre-register a phas
- Inquiry → Submit an inquiry d
- C&L notification → Submit a C&L notifi
- DU report → Submit a downstre
- DU notification → Submit a downstre
- PPORD notification → Submit a PPORD n

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Company > [Dossiers](#) > [Submission](#) > [Registration](#)

Registration dossier submission

Registration dossier submission

Please select your registration dossier to submit

File name: **Browse...**

Note:

If you like to submit files bigger than this limit, please request a one time access code [here](#).

The Agency will check your request and may grant your upload by sending this one time access code to your personal inbox. This might last max. 24 hours.

Please consult your [inbox](#) for the decision.

One time access code

If you have an access code for large dossier, please enter it here

Access code

Submit dossier

[Legal notice](#)

Step 2: Dossier Upload – Confirm submission & obtain submission number

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You are connected as *jd (Jane Doe)* on behalf of *The Chemical Company, Inc.* [Preferences](#)

[Home](#) > [Dossiers](#) > [Submission](#) > PPORD Notification

External dossiers | **Internal dossiers**

Information page

You are submitting a PPORD notification with the following information:

File name	SuperFlux_no_123.i5z
Dossier type	PPORD notification
Company name	The flying company
Company size	5000+ employees
Invoice contact name	Marty McFly
Invoicing fax number	+39 333 444 5654

Like to submit this notification, please confirm the submission with the following information:

Like to cancel the submission, you might cancel the submission via the 'Cancel' button. Your data will be processed by the REACH IT system.

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You are connected as *jd (Jane Doe)* on behalf of *The Chemical Company, Inc.* [Preferences](#)

[Home](#) > [Dossiers](#) > [Submission](#) > Registration

Registration dossier submission

Your registration dossier has been submitted. Please find below your submission number.

Submission number

The registration dossier 'naphtalene.i5z' has been stored on the server.

Your submission has received the following submission number: **TN678451-98**. Please use this number for your next interaction.

Note: This number is *not* the registration number for your substance. This number will be communicated to you once your dossier passed completeness check.

As the submission process may take some time, please consult your [inbox](#) at a later stage to get the status of your submission process.

[Legal notice](#)

Submission number

Link to the inbox to consult the submission report

<http://echa.europa.eu>

Podanie dossieru (REACH-IT)

Viac informácií:

Industry User Manual - Part 1: Getting started with REACH-IT

- Part 2: Sign-up and account management
- Part 3: Login and Message Box
- Part 4: Online Pre-Registration
- Part 5: Pre-SIEF
- Part 6: Dossier Submission
- Part 7: Joint Submission
- Part 8: Invoices
- Part 10: Claim of a registration number for a notified substance

- http://echa.europa.eu/reachit_en.asp

Spracovanie dossieru v ECHA

Spracovanie dossieru v ECHA

Postupnosť

Kontrola Business Rules

(uistenie či dossier môže byť spracovaný systémom)

Kontrola úplnosti / Completeness check:

Technical Completeness Check (TCC)

Kontrola, či platba za faktúru bola prijatá v plnej výške

ECHA:

prejde - dostaneme registračné číslo

neprejde - zriedkavé prípady

Spracovanie dossieru v ECHA

Business rules je súbor podmienok, ktoré musia byť splnené predtým než ECHA ustanoví, že dossier môže byť správne spracovaný a požadované legislatívne postupy môžu byť úspešne vykonané.

3 hlavné dôvody:

Formát – (e.g. inquiry dossier in a registration template)

Administratívne- (e.g. registration update does not provide registration number)

Technické – REACH-IT „nerozumie substance identifiers“

Annexes

Annex I – List of automated business rules

	REACH-IT Business rule Code	REACH-IT Rule message	Explanation of the reason of failure	What to do to avoid a failure in your (next) submission
ALL SUBMISSION	SUB_GBL_UC02_F C030 SUB_GBL_UC02_F C010	There was no Reference substance in section 1.1 of your IUCLID 5 dossier and all constituents of the first composition of section 1.2 were not linked to a Reference substance.	You did not provide a Reference substance neither in IUCLID 5 section 1.1 nor in 1.2. A Reference substance should always be present in IUCLID 5 section 1.1 and in section 1.2. If not, the dossier cannot be linked to a substance and it cannot be processed by ECHA. This Business Rule also fails in case <u>an empty</u> repeatable block for "composition" and / or "constituent" is created in a dossier.	Ensure that <u>at least one</u> Reference substance is linked in section 1.1 and in section 1.2 under Constituents in the dossier that you are submitting in REACH-IT. A Reference substance cannot be defined by completing only the field "name". To be valid, a Reference substance should have at least one of the following identifiers: <ul style="list-style-type: none"> - EC number, or - CAS number and name, or - IUPAC name, or - Description <p>Note that in case the only available information is related to CAS, both the CAS number and name should be given.</p> <p>Ensure you indicate at least one 'valid' identifier in every Reference substances that you use in the dossier. In case you have an unknown impurity, you should write "unknown impurity" in the "IUPAC name" field of the corresponding Impurity Reference substance.</p> <p>Finally, in the subsequent Technical Completeness Check step, the presence of the molecular and structural information in each Reference substance (molecular formula, molecular weight range, and structural formula, or justification for not providing the information) will be checked. Please make the necessary modification and submit a new dossier.</p>

Skúsenosti v ECHA

- Do 1. júna 2008, 40% dossierov odmietnutých vo fáze kontroly *business rules*.
- Neúspešné podania sa zvýšili po podaní cez REACH-IT po 5. januári 2009.
- Preto ECHA pripravila
 - DSM 8: 'Business rule validation' jko dodatok k
 - DSM 4: How to submit a valid dossier to ECHA and complete the dossier header

Skúsenosti v ECHA

- **Zlyhania vo fáze „*Business Rules*“:**
- **Počiatočné versus Updatované podania:**
- Nesprávne predchádzajúce referenčné číslo (submission no. and previous communication no.) uvedené v hlavičke dossieru
 - **Regulatory identifiers:**
- Nesprávne predregistračné/inquiry/registračné čísla uvedené v sekcii 1.3
 - **Žiadosť o dôvernosť údajov bez uvedenia dôvodov:**
- Faktúra musí byť založená na položkách.
 - **Výrobný závod /Production site nedefinovaný (pre výrobcu):**
- REACH-IT nevie určiť ‘relevantný’ členský štát

Skúsenosti v ECHA

- **Kľúčové posolstvá:**
- Registračné dossiere by mali byť dobre predom pripravené
- Pozorne preštudujte relevantné príručky a manuály
- Preverte, že hlavička dossieru */dossier header/* a sekcie o identifikáciu látky */substance identity sections/* sú vyplnené podľa inštrukcií uvedených v Data submission manuals

http://echa.europa.eu/news/events/2nd_stakeholders_day_en.asp

Ďakujem za pozornosť