

Submission of a registration dossier via REACH-IT 2.0

5th May 2010

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Overview

- Pre-requisites for member registrants in REACH-IT 2.0

 The LEOX synchronisation
- Confirming membership in a Joint Submission
- Submitting the member registration dossier
- Full registration process overview
- What to do in order to avoid:
 - Account management problems
 - -- Business Rules and TCC problems
- Where to find further information



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Pre-requisites for member registrants in REACH-IT 2.0

The Lead Registrant, of the particular substance that the member registrant is about to register, must have already:

- Created a Joint Submission Object (JSO) in REACH-IT and distributed the joint submission information (name and token) to all member registrants in the SIEF (this happens outside the REACH-IT environment)
- Submitted the joint submission dossier via REACH-IT. The dossier must have successfully reached the end of the registration process and a registration number must have been assigned to the registration submission made by the lead registrant *

* Note that this process will change in the next major release of REACH-IT allowing MR to submit once LR dossier has passed, at least, Business Rules



LEOX Synchronisation

The LEOX used in REACH-IT must be the same as the one used in IUCLID 5.2 in order to create the substance dataset and the dossier

There are two ways to synchronise your LEOX:

- If you already have a REACH-IT account, export your LEOX from REACH-IT and import it into IUCLID 5.2 (most common case)
- If you still do not have an account in REACH-IT:
 - but you have one in the IUCLID 5 website that you are using in IUCLID 5.2 already, export it from the IUCLID 5 website and import it in REACH-IT during the sign-up.
 - nor in IUCLID 5, create a new REACH-IT account encoding your data manually and when the LEOX is created, export it from REACH-IT and import it in your IUCLID 5.2 installation





Welcome to REACH-IT

REACH-IT provides an online platform to submit data and dossiers (pre-registration, registration, C&L notification, ...) on chemicals. It also allows the Agency and Member States authorities to review the dossiers. The Agency will also use REACH-IT to make non-confidential information on chemicals accessible to public on its website.

What can you do?

To login to REACH-IT you first need to sign-up and provide information on your identity and set-up an account for a user who will have administrator privileges to manage your account. You can sign-up either as a company or as a third party.

. If you already have an account, you may login to the system.

If you have not created an account yet, you can do it here below.

Sign up as a company

- <u>Sign up as a Data Huider</u>
- Sign up as an interested third party
- Sign up as a third party representative

Need help with REACH-IT or with this site?

- REACH Frequently Asked Questions (FAQ)
- <u>The REACH legal text</u>
- Contact information



AE	LHA	-	Rea	ch-IT	ALE V
Company sign	-up Company Informati	ion			
User account	Company Information	Billing information	Contacts	Validation	

Please provide your company information below

Fields marked with an asterisk (*) are mandatory. Hovering over a (?) sign displays help informat

Company name:	Test Ispra Italy	
Company UUID:	ECHA-b26aef04-a68c-46eb-aaeb-5d7285e0124	4
D-U-N-S number:	Evample: 13, 9456, 799	
VAT number:	2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2	
	Format: Country code + Number; e.g. BE-111-22	22-333
Remarks:	~ ?	
Company Size		
*	I declare the information below to be correct size to be calculated according to Annex to Com Recommendation 2003/361/EC concerning the o small and medium-sized enterprises.	and the company mission Jefinition of micro,
• Company size:	Large Medium Small Micro	
General contact inf	ormation ?	
* Phone:	+39123123123	
Fax:		
Mobile phone:		
* E-mail:	peter.smith@test_ispra_italy.it Example: reach@domain.com	?
Company web site:	http://test_ispra_italy.it	
	Your website address must start with 'http://'	
Company address		
Street:	Via Esperia	
Street 2:		
* Postal code:	123123	
City / Town:	Ispra	
Region / County:		
- Country:	Italy 🔽	
Postal address:		
e e Previoue		Nextss







Opening ECHA 1271404793699.i5z	Enter name of file to save to	?×
You have chosen to open	Save in: 🗀 LEOX 💽 🥥 🥩 🖽 🗸	
 ECHA_1271404793699.i5z which is a: I5Z file from: https://industry-shared.reach.europa.local What should Firefox do with this file? Open with WinZip (default) Save File Do this automatically for files like this from now on. 	Wy Recent Documents Documents My Documents My Documents My Documents	
	File name: ECHA_1271404793699.15z	Save
	My Network Save as type:	Cancel



🔄 IUCLID 5	
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Tasks	
Legal entity Create and update company /organisation related information New, Update	Legal entity site Create and update legal entity sites <u>New, Update</u>
Substance Create and update substance related information New, Update	Mixture Create and update mixture related information <u>New, Update</u>
Template Create and update template related information New, Update	Category Create and update category related information <u>New, Update</u>
View dossier data View, <u>Compare</u>	
Inveniories	
View EC inventory related information View, Import	Literature reference View and exchange literature reference inventory related information <u>View, Exchange</u>
Reference substance Create and update reference substance related information New, Update	
Tools and administration	
Manage users, roles, preferences, etc. User preferences, Set password, User management, Role management	Import Import data from other IUCLID 5 systems Import, <u>Bulk import</u>
Bulk export Export multiple documents	



Export multiple documents

Run

Import assistant			
ase select the . <i>i5z</i> file to be imported rify content carefully before importing	4	lity site	
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ools and administration	File <u>N</u> ame:	ECHA_1271403141896.i5z	
Manage users, roles, preferences, etc. User preferences, Set password, User management, Role manageme	Files of <u>T</u> ype:	.152 IUCLID 5 data exchange container	OK Cancel



	1				
nport	Document	Endpoint	Last modification	Compared to da	Validation



			Welcome Logout	Peter Smith	(petersmith_	_test)
	IUCLID 5 Project	User Info	Download	Support	REACH	News
	User Info LEO	Creation You	ur LEOs			
Legal A Legal e organisat organisat here the created Organi	Entity Object (I ntity can be an indivisi ion (including SMEs), ion, a partnership (no data about a Legal er a LEO. sation informatic	LEO) Crea dual, an indu a university, on exhaustive ntity for whic on - Gener	ation strial or comm a research enumeration h you have a al	nercial). Edit Iready		
IUCLID 4 available	PIN (if					
Company	name (*): Test Is	pra				
DUNS n	mher:					



Organisat	ion information - Contact Person
Enter data ab the Legal Enti	out the person that will act as primary contact for ty.
Organisation:	Test Company
Title:	Mr
First name:	Peter
Region / County:	
Country:	— not specified —
	Exit from LEO Creation Submit
Press "Submit' For subsequer	for creation of the Legal Entity It downloading of the Legal Entity XML file (LEOX),
please go to s	Page 2 of 2



39 40 Y Zr 52 88.90 2 52			CAL INFORMAT		ABASE	Welcom Logout	e Peter Smith	(petersmith_	_test)
	SION Home	IUCLID 5	Project	User I	info	Download	Support	REACH	News
		User In	ifo LEO Cr	reation	Your	LEOs			
Your LEC	DS								
Your LEC Legal entity Name	UUID	Country	Address	Edit	LEOX				



	Save As						? 🔀
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Do you want to open or save this file? Image: Leox_041610090427.i5z Type: Unknown File Type, 1.27 KB From: iuclid.echa.europa.eu Image:	My Recent Documents Desktop My Documents	eox_041610	0090407.i5z				
	My Computer	File <u>n</u> ame: Save as <u>t</u> ype:	Leox_041610090448.i5z .i5z Document			×	<u>S</u> ave Cancel





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If you have not created an account yet, you can do it here below.

- Sign up as a company
- Sign up as a Data Holder
- Sign up as an interested third party.
- Sign up as a third party representative

Need belowith PEACH IT or with this site?



			^
Company sign-up	> User account		
User account C	ompany Information Billing information	Contacts Validation	
You need to specify (creation of addition requested informat	/ a REACH-IT administrator for your contrained to a REACH-IT users for your company on here below.	ompany account. This administrator will be granted special rights /, modification of company information, etc). Please provide the	
Fields marked with	an asterisk (*) are mandatory. Hoveri	ng over a (?) sign displays help information.	
User information	- General		
First Name:	Peter		
*Last Name:	Smith		
*E-mail:	peter.smith@test_ispra_italy.it	?	
* User ID:	petersmith ?		
	ID may consist of up to 20 letter	s [A-Z a-z], digits [0-9] or underscores	
* Password:	*******		
	The password must have at lease following character types: upper and non alphabetical.	st 8 letters and contain three of the rcase letter, lowercase letter, number	





Please import your IUCLID LEOX into REACH-IT. If you do not have any LEOX or do not intend to get one, you may encode your information into REACH-IT. REACH-IT will then attribute to your company a Universal Unique Identifier (UUID).

If you already have a company definition file in the IUCLID format (also known as the LEOX file format), and if you want to have the same UUID for your REACH-IT company definition as for your IUCLID LEOX, you should imperatively import your LEOX, and not enter your company information directly in REACH-IT.

Please load the file in which your company information has been saved.

Fields marked with an asterisk (*) are mandatory.

• File name:	Browse
	Load file
< < Previous	





Please import your IUCLID LEOX into REACH-IT. If you do not have any LEOX or do not intend to get one, you may encode your information company a Universal Unique Identifier (UUID).

If you already have a company definition file in the IUCLID format (also known as the LEOX file format), and if you want to have the same UUII LEOX, you should imperatively import your LEOX, and not enter your company information directly in REACH-IT.

Please load the file in which your company information has been saved.

Fields marked with an asterisk (*) are mandatory.







Please provide your company information below

Fields marked with an asterisk (*) are mandatory. Hovering over a (?) sign displays help information.

General informatio	n
* Company name:	
Company UUID:	IUC5-c2c0efb7-8f0b-49cc-bf95-fd1e187f84a0
D-U-N-S number:	Example: 12-3456-789
VAT number:	Pormat: Country code + Number, e.g. BE-111-222-333
Remarks:	



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The joint submission was successfu	lly created.		
Please keep track of the joint submi submission.	ssion name and tol	ken to be used by other members	of the joint
	Home > Confirm Memb	ership > Security Token	•
Name: JS formic acid	Token Contacts	Validation	
Token: 865-d34-c5f8-2978498145	Please enter the name membership Fields marked with an	e and the security token of the joint submissio asterisk (*) are mandatory. Hovering over a	n for which you wish to confirm (?) sign displays help information.
	• Name	JS formic acid	?
	• Token	865-d34-c5f8-2978498145	
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	esten to from a		



		Keach-LL
		You are connected as petersmith on behalf of Test Ispra Italy - Preferences - Log
	Home > Confirm Membe	ership > Select Contact > Add/Edit Contact
Company _	Token Contacts	Validation
Pre-registration	and the second second second second second second	
Pre-SIEF	Fill the form below to cr	reate a new contact person for your company. This person will have the type "pr
Online dossiers	registration and winde	e available for fullther pre-registration from the contact persons list.
Phase-in Information	Fields marked with an	asterisk (+) are mandatory. Hovering over a (?) sign displays help information.
Registration /		
notification	Contact information	
Joint submission	Title:	
Classification and	First Name:	Peter
Labelling	*Last Name:	Smith
Message box	* Phone:	+39123123123
Jser account	Fav	
Inventories		
Legal entity change	* E-mail.	peter.smith@test_ispra_italy.it
nvoices	Organisation	
Search	Organisation Name:	
	Department:	
	Address	



Reach-

	Home	
Company	Welcome Peter Smith.	REACH-IT News:
Pre-registration Pre-SIEF Online dossiers Phase-in Information Registration / potification	You have 0 <u>unread message(s) in your message box</u> . You last connected on 2010-03-09 10:33:18.0.	Shared environment unavailability 02/12/2009 Due to electrical works carried out in the building all REACH-IT environments need to be shutdown. REACH-IT shared environment will be shutdown on Friday December 14h00 EET. Normal service will resume on Monday at some point
leint submission	View joint	during the day.
Classification and Labelling	submissions Create joint	REACH-IT 1.5 migration testing in the shared environment
Message box 🛛 📲	submission	The shared environment will be used for
User account	Confirm	REACH-IT 1.5 migration testing since
Inventories	indiriberarily	December. Day to day planning is as



		M	
		Rea	ach-II (
		You are connected as petersmith on	behalf of Test Ispra Italy - <u>Preferences</u> - <u>Logout</u>
	Home > Confirm Memb	ership > Validation	
Company	Token Contacts	Validation	
Pre-registration			
Pre-SIEF	Please verify your info	ormation before submitting your joint sub	mission. You can go back to each section if
Online dossiers	corrections are neede	d.	
Phase-in Information	Substance identificatio	an Joint Submission	
Registration / notification	Substance iden	tification	
Joint submission	ousounoo nuon	unoucon	
Classification and	[200-579-1] formic a	cid	
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Message box	constituent(s):		
User account	EC Number	CAS Number	Name
Inventories	200-579-1	64-18-6	formic acid
Legal entity change	loint Submissi	20	
Invoices	Joint Submissio	511	
Search	Joint submission in	nformation	
	Name	JS formic acid	
	Description		
	Highest tonnage bar	id	
	Confirm members	riip Cancei	



Home > Messages

This internal message box is dedicated to the reception of messages sent by REACH IT (ECHA) to the user. You will not receive messages from REACH IT concerning your actions on this site in your private or professional email account. However, if you want to receive alerts when a message is received in this internal message system, you can define this as an option in your <u>User Preferences</u>.

The list below displays the internal messages that were sent to you the last 30 days. To view all internal messages click <u>here</u>.

Message box folder ? | User folder | Organisation folder | Role folder | Deleted | messages

elect A	All Selec	t None	1			
elect	Details	Read	Subject	Creation Date	Expire Date	Recipient
	<u>▼Hide</u>	Yes	Joint Submission membership confirmed.	09/03/2010 10:51		Party (EduCHEM)
	L L	oint Su oint Su	ubmission membership confirmed ubmission details:	d.		
	N C J A A F S A F F N	lame: J)escrip oint Me scting N ssigne Registra Registra Registra Party de lame: 1	IS formic acid tion: - embership details: Member: true ed to be Lead: false ation Date: 09/03/2010 gin: false ledgement date: 09/03/2010 ation Date: 09/03/2010 etails: Test Ispra Italy			



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(aec)	H/ Rea You are connected as u07015 or	ch-IT behalf of EduCHEM - Preferences - Logout
	Home	
Company	Welcome Alan Blacke	REACH-IT News:
Pre-registration		Shared environment unavailability
Pre-SIEF	You have U unread message(s) in your message box.	02/12/2009 Due to electrical works corriad out in
Online dossiers		the building all REACH-IT
Dhace in Information		environments need to be shutdown.
Fhase-III Information		REACH-IT shared environment will be shutdown on Friday 4 December
Registration /	View registration /	14h00 EET. Normal service will
loint cubmiccion	Subset	resume on Monday at some point
	registration /	during the day.
Classification and	notification	REACH-IT 1.5 migration testing in the
Massage hav	Claim Notified	shared environment
wessage box	Substance	01/12/2009 The shared environment will be used
User account	Cease Manufacture	for REACH-IT 1.5 migration testing
Inventories	Restart	since Wednesday 2 December until
Legal entity change	Manufacture	Friday 4 December. Day to day
Invoices		Wednesday: last day to submit test
Search		dossiers into the system Thursday: dossier submission will be



AEC	H/ Reach-IT
	You are connected as <u>u07015</u> on behalf of EduCHEM - <u>Preferences</u> - <u>Logout</u>
Company -	Registration / notification submission
Pre-registration Pre-SIEF Online dossiers	Here you can begin the submission process of your dossiers for the processes in the drop-down menu shown below. To submit an update you should use the same process as for the initial submission. The new dossier submitted as an update must also contain all the previously submitted required information.
Phase-in Information Registration / notification	Fields marked with an asterisk (*) are mandatory.
Joint submission	type:
Classification and Labelling	Registration Registration of on-site isolated intermediate
Message box User account	Product and Process Orientated Research and Development (PPORD) notification Classification and Labelling (C&L) notification
Inventories	Inquiry notification



Linux and Ordensite Description links

	Home > Submir	Dossier miro		
Company	Registration	notification submission		
Pre-registration	Here you can begin the submission process of your dossiers for the processes in the dron-down menu			
Pre-SIEF	shown below. To submit an update you should use the same process as for the initial submission. The			
Online dossiers	new dossier sui	omitted as an update must also contain all the previously submitted required.	information.	
Phase-in Information	Fields marked	with an asterisk (*) are mandatory.		
Registration / notification	*Submission	Registration	~	
Joint submission	Purchase			
Classification and Labelling	order.			
Message box		the submitting party declares the information above is correct and the company size to be calculated according to Annex to Commission		
User account	Declaration:	Recommendation 2003/361/EC concerning the definition of micro, small and medium-sized enterprises. The submitting party also		
Inventories		declares that, following careful verification, the substance subject of		
Legal entity change		notification under Regulation (EC) No 1907/2006		
Invoices	Joint submissio	n		
Search	Related to a joint submission:			
	submission	JS formic acid		
	name:			
	Opt-in for confi	dentiality claim(s)		
	Declaration:	I claim confidentiality according to Article 10(a)(xi) of the REACH Regulation for the following study summaries or robust study summaries for which confidentiality was claimed in the registration submitted by the lead registrant.		
	Proceed			



Registration	
Please pick here using the "Browse" button the file which contains your dossier (you been created using IUCLID 5 and have the extension "i5z")	ur file should have
 File C:\Documents and Settings\u07015\Desktop\Complete substance dataset.i5z * Enter 	Browse
the 2cgpp ? text shown:	
Can't read the text below? <u>Try another</u>	
Access code for large files	
For the submission of a file larger than 20 MB, please <u>request a large file access co</u> submission.	<u>ode</u> belore
If you have an access code for a large dossier, please, enter it here Large file access code:	
Submit dossier	



Confirm Dossier Submi	Ission
Dossier type:	Registration
Dossier file name:	Complete substance dataset.i5z
Organisation Name:	EduCHEM
Company size:	Medium
Invoice Contact Name:	Peter Smith
Joint submission	
Related to a joint submission:	Yes
Joint submission name:	JS formic acid
Confidentiality claim(s)	
Declaration:	No
Number of study summaries/robust study summaries for which a fee will be levied:	÷
List of study summaries/robust study summaries for which confidentiality is claimed:	¥1.
Submitting justification (s) for the above	
Connuentiality claim(s). Confirm submiss	ion Cancel submission



4

Submitting the member registration dossier

Reach-

<i>AECHA

	You are connected as <u>u0/015</u> on behalf of EduCHEM - <u>Preferences</u> - <u>Logout</u>		
	Home > Submit Dossier Intro > Dossier Submission Successful		
Company Pre-registration	Your dossier has been successfully submitted. Please find below the preliminary submission number.		
Pre-SIEF	Registration		
Online dossiers	Preliminary submission number		
Phase-in Information	Your dossier has received the following preliminary submission number: XU122516-07,		
Registration / notification	A report indicating the status of this dossier will be available in your <u>Message box</u> shortly. Please use this preliminary submission number if you need to contact the Agency about this dossier.		
Joint submission	until you receive a submission or reference number.		
Classification and Labelling	Your dossier is under examination by our IT systems to ensure that as a valid dossier it can be correctly processed. Following the successful completion of this task you will receive a subsequent message		
Message box	confirming the submission and providing you with a submission date and submission number.		
User account			
Inventories	You will receive the reference number upon successful processing of this dossier by ECHA's systems.		
Legal entity change	At any time you can also consult the status of your dossier and the report in the menu		
Invoices	"Registration/notification \ View registration/notification" and indicating your (preliminary) submission number to retrieve it.		
Search			



Select A	All Selec	t None				
Select	Details	Read	Subject	Creation Date	Expire Date	Recipient
	<u>.▼Hide</u>	Yes	File under examination (XU122516-07) - Registration (reg.)	09/03/2010 12:58		User(u07015)
) F C F	/our do Prelimin Dossier File nar	ossier is under examination by ou hary submission number: XU1225 type: Registration (regular) ne: Complete substance dataset	ir IT systems. i16-07 .i5z		
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	s F J A	∕our do and it c: Followir confirmi providir	ossier is under examination by ou an be processed correctly. Ing the successful completion of the Ing your submission and Ing you with a submission date an	ir IT systems to ens his task you will rec d submission numb	sure that it is a eive a subseq per.	valid dossier uent message



Passed Tasks

No.	Task	Remark	Result
1.	Virus check	-	Succeeded
2.	File format validation	-	Succeeded
3	Check XML structure	-	Succeeded
4.	Enforce Rules	-	Succeeded
5.	Store Dossier		Succeeded
6	Create Substance Identity		Succeeded
7.	Assign MSCAs		Succeeded
8.	Technical Completeness Check	÷.	Succeeded
9	Pay Submission Fee		Succeeded
10.	Overall Completeness Check	+	Succeeded
11.	Issue Reference Number	-	Succeeded
12.	End of Pipeline Activities		Succeeded
13.	Data Dissemination		Succeeded
14.	Trigger WorkFlow		Succeeded

Download submission report

Export submitted EC substance(s)



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Full overview of the registration process

Environment where things happen:



Process status bar:



1. LR and MR create REACH-IT accounts and synchronise the LEOX



The LEOX used in REACH-IT must be the same as the one used in IUCLID 5.2 in order to create the substance dataset and the dossier. Synchronise:

1) If you already have a REACH-IT account, export your LEOX from REACH IT and import it into IUCLID 5.2 (most common case)

IUCLID 5

INTERNATIONAL UNIFORM CHEMICAL INFORMATION DATABASE

2) If you still do not have an account in REACH-IT:

REACH-IT user & LEOX

REACH-IT

- but you have one in the IUCLID 5 website that you are using in IUCLID 5.2 already, export it from the IUCLID 5 website and import it in REACH-IT during the sign-up

- nor in IUCLID 5, create a new REACH-IT account encoding your data manually and when the LEOX is created, export it from REACH-IT and import it in your IUCLID 5.2 installation

2. Lead registrant (LR) and member registrant (MR) add an official LEOX to their user(s) in IUCLID 5.2 and install the TCC plug-in



- Import the Legal Entity Object (LEOX) created and exported from the IUCLID 5 website or from REACH-IT 2.0
- With the IUCLID 5.2 administrator user, assign the LEOX to the user(s) in IUCLID 5.2 who are going to work on the substance
- Login in IUCLID 5.2 with such user
- Install the TCC (Technical Completeness Check) plug-in from the IUCLID 5 website



3. Create Substance in IUCLID 5.2 (Part 1) (LR and MR minimum requirements)



- **New Substance** \rightarrow Give a name and assign the LEOX
- Section 1.1. Add a reference substance (i.e. formaldehyde), type, role
- **Section 1.2.** Add one substance composition to the substance, giving it a name and adding a constituent by selecting a reference substance (select formaldehyde)
- Sections 1.3, 1.4, (1.5 and 1.7)
- (LR) Section 2.2. Add a classification and labelling information
- Section 3.1. Methods of manufacture
- Section 3.2. Add tonnage and year
- Section 3.3. Add a new site, giving it a name and also indicating the address, postal code, town and country
- Sections 3.4 and 3.5



3. Create Substance in IUCLID 5.2 (Part 2)



- The LR creates the substance including all his/her endpoint study records
- The MR creates a substance dataset only indicating the information in sections 1 and 3.
 - If the MR decides to opt-out for some of the endpoints, he/she must include them in the relevant section in the substance. The rest of sections must be empty as they will be included by the LR in the joint submission dossier



INTERNATIONAL UNIFORM CHEMICAL INFORMATION DATABASE

info

UCLID 5.2 Create Exchange

Substance

REACH-I

user &

LEOX

user

The LR imports the endpoints into his IUCLID 5.2 installation and copies ۲ them to the joint submission substance dataset.

The LR substance dataset has now all the endpoints from the MRs

http://echa.europa.eu

If the MR still has endpoints to share with the LR, the MR goes through • the export wizard steps, exports the all his/her endpoints (except those that are part of the opt-out) and sends them to the LR



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5. Lead Registrant creates the joint submission in REACH-IT 2.0



- Create the joint submission giving it a meaningful name in order to facilitate handling it. (e.g JointSubmission_substance)
- Transmit the name of the joint submission and the token created by REACH-IT 2.0 to the MR (Outside REACH-IT)



6. Member Registrant confirms membership to the joint submission in REACH-IT 2.0

• Confirm membership to the **JointSubmission_substance** providing this name and the token given by the LR

After confirmation, the token is no longer needed



7. LR and MR may update section 1.5 in IUCLID 5.2 and create the IUCLID 5.2 dossier



- MR and LR may use Section 1.5 for their own administrative purposes but this information will not be verified against REACH-IT
- The LR creates a dossier selecting the dossier template: "REACH Registration above 1000 tonnes"
- the MR creates a dossier selecting one of the dossier templates:
 "REACH Registration member of a joint submission" for:
 - the general case
 - intermediates



8. LR and MR verify the completeness of the dossier with the TCC and export them



- Verify the completeness of the dossier running the Technical Completeness Check tool (TCC plug-in) in IUCLID 5 before submitting
- Once the dossier is ready, the LR and the MR can export the dossier in (.i5z) format



9. LR submits the dossier in REACH-IT 2.0



- Submit a new registration submission (**type**: Registration)
- Indicate the name of the joint submission and **confirm** the submission
- Go to the message box and check the status of the submission.

At this stage, MR cannot submit the MR dossier yet. The MR needs to wait until the LR's dossier has reached the end of the registration process in REACH-IT 2.0 *

This is to change in the next major release of REACH-IT



10. ECHA performs Business Rules, TCC and confirms fee has been paid



- Some manual checks are performed and after confirming all the business rules are valid, ECHA accepts the dossier for processing
- The dossier reaches the TCC step. ECHA staff review the dossier and after verifying that the conditions are met, the dossier is validated
- At the same time, the invoicing is reviewed. The invoice is issued and sent to the LR.
- Once the invoice is confirmed to be paid, ECHA sets the status to "consider paid".



11. LR confirms the dossier has reached the end of the registration process and informs MR to proceed



- LR may refresh the status of the dossier submission during the last steps to see how the dossier goes through all remaining steps. The value "Succeed" will indicate that everything goes well until the end of the registration process.
- After the invoice has been paid, ECHA will issue a registration number.
- MR will be able then proceed submitting the member registration dossier via REACH-IT 2.0 *



12. MR submits the member registration dossier via REACH-IT 2.0 and gets his/her registration number



- The MR submits now the registration dossier, indicating that the submission is part of a joint submission
- The MR may refresh the status of the dossier submission during the last steps to see how the dossier goes through all remaining steps. The value "**Succeed**" will indicate that everything goes well until the end of the registration process.
- When the fee has been paid (if needed) ECHA will issue a registration number and notify the registrant via the REACH-IT message box



Summary of internal tasks in REACH-IT 2.0

1.

Virus check

2.	File format validation		
3.	Check XML structure		
4.	Enforce Rules		
5.	Store Dossier	ECHA	
6.	Create Substance Identity	BR, TCC	
7.	Assign MSCAs	FCC	
8.	Technical Completeness Check		
9.	Pay Submission Fee		
10.	Overall Completeness Check		
11.	Issue Reference Number	FCH	Δ
12.	End of Pipeline Activities	confirm	ns
13.	Data Dissemination	registratio	on
14.	Trigger WorkFlow		



Overview

- Pre-requisites for member registrants in REACH-IT 2.0

 The LEOX synchronisation
- Confirming membership in a Joint Submission
- Submitting the member registration dossier
- Full registration process overview
- What to do in order to avoid:
 - - Account management problems
 - –- Business Rules and TCC problems
- Where to find further information



Avoiding REACH-IT account management problems

• Blocking the REACH-IT account

 The maximum number of attempts a user can make before blocking a REACH-IT account is 5. ECHA highly recommends users to use the "Forgot your User ID or password?" link available in the Login page before the account gets blocked.

* User ID:		
* Password:		
* Enter the text shown:	?	
	Can't read the text below? Try another	
	8cm3-	
Connect Cancel		



Avoiding Business Rules problems in REACH-IT 2.0

• Substance identification

 Full agreement on the substance identification and also on the way to indicate it in IUCLID 5 and REACH-IT. Special attention to the IUPAC name

• Tonnage Band

- The tonnage band indicated in the IUCLID 5.2 dossier must be either equal to or lower to the tonnage indicated by the lead in the joint submission. Tonnage is <u>only</u> indicated in IUCLID 5.2
- If the member registrant indicates an "opt-out" in the dossier, the tonnage can be higher than the one specified by the lead



Avoiding Business Rules problems in REACH-IT 2.0

- Token and Joint Submission (JS) name management
 - 5 attempts are allowed when confirming membership in a JS
 - Tokens have an expiry date of 30 days after they are issued *
 - Member registrants need to remember to click on the "Related to a submission" check box in order to submit the dossier

• Dossier management

- Only dossiers created in IUCLID 5.2 are accepted by REACH-IT
- Members need to use the appropriate dossier template
- Member registrants cannot submit their dossiers until the lead's joint submission dossier has been successfully processed *

^{*} Note that this process will change in the next major release of REACH-IT



Avoiding Technical Completeness Check (TCC) problems in REACH-IT 2.0

- Filling in information in IUCLID 5.2
 - IUCLID 5.2 sections 2, 4, 5, 6 and 7 (the C&L and the endpoints sections) of the member registrant dossier should be empty.
 Otherwise, this information will be considered as an opt-out
 - If the member registrant indicate in the dossier header that she/he is providing an individual 'Guidance on safe use' or a CSR, then the information in those sections (11 & 13) needs to be provided. Otherwise, those sections must remain empty
 - If a site is included in section 3.3, then it has to be identified with at least "Address", "Postal code", "Town" and "Country"
 - Check the lead's submission in order to confirm that all the information has been sent and there is nothing missing



Avoiding TCC problems in REACH-IT 2.0

 Use the TCC plug-in in order to verify that the dossiers are correct and that they will pass the TCC in REACH-IT 2.0.
 Available for download at <u>http://iuclid.echa.europa.eu/</u>

• Fees and invoicing

 Claims for confidentiality (opt-in) and opting-out for some sections will increase the fees to be paid to ECHA. Remember that the registration number is only provided once the invoice has been paid



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Where to find further information

Member Registrants can find further information at: http://echa.europa.eu/

- Industry User Manual Part 7: Joint Submission document and Data Submission Manual Part 4: How to Pass Business Rule Verification ("Enforce Rules") at <u>http://echa.europa.eu/reachit/supp_docs_en.asp</u>
- REACH-IT FAQ for general issues on fees, LEOX, etc... at http://echa.europa.eu/reachit/reachit_faq_en.asp
- Data sharing Guidance document (section 8), Guidance on information requirements and chemical safety assessment for further details on information requirements at <u>http://guidance.echa.europa.eu/guidance_en.htm</u>



Thank you for your attention