

# Last minute tips

REACH 2018 Stakeholders' Day

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# Contents

- Ensure successful submission
- How to deal with difficult situations



# 120 days to the deadline...



# What is the best tool for you?



**ECHA** Cloud **S**ervices

- SMEs
- Consultants working for SMEs



- Member registrants
- Agree with all information submitted by the lead



- All others



REACH 2018

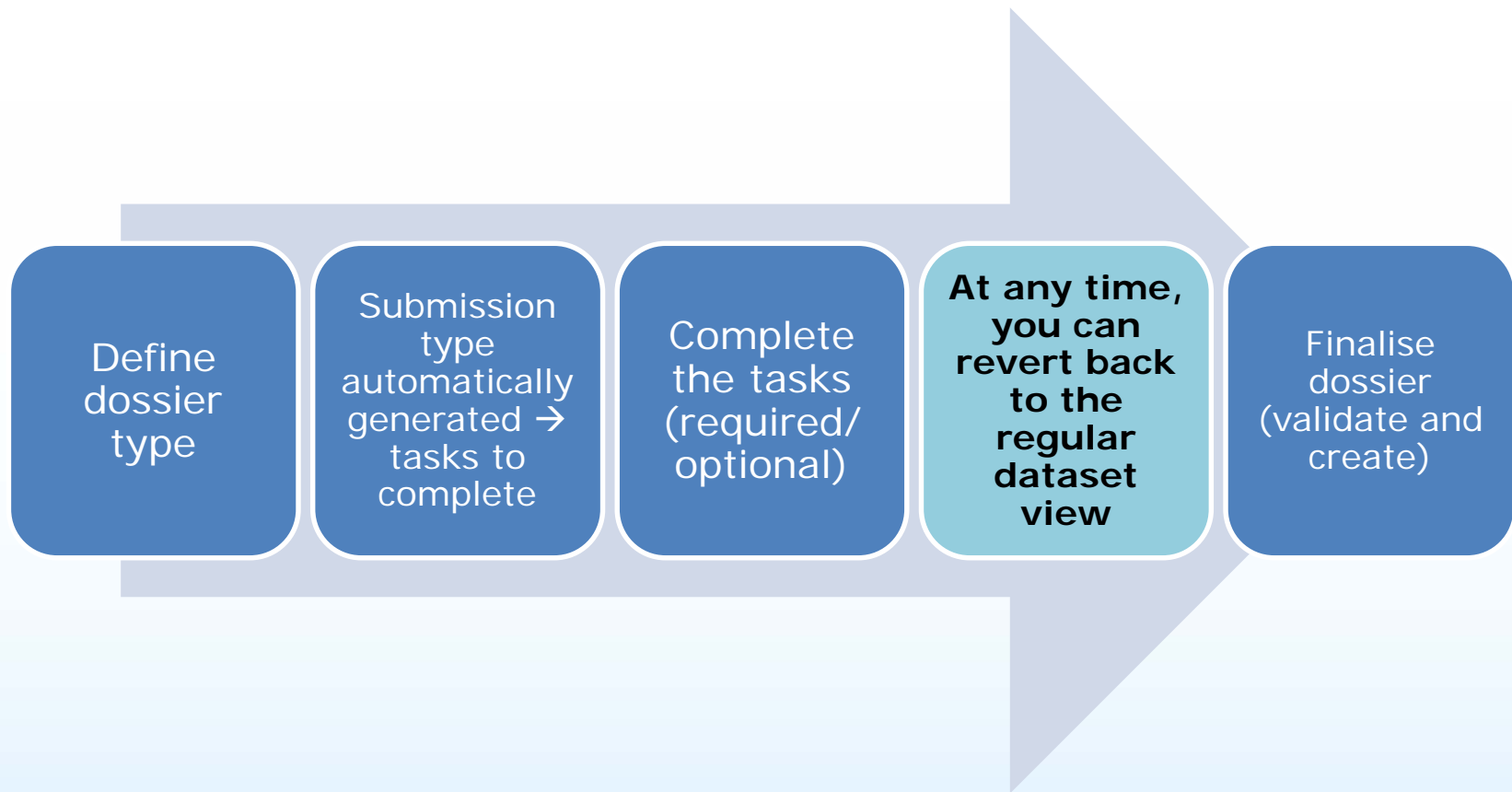
# IUCLID Cloud – simpler for SMEs





REACH 2018

# New in IUCLID Cloud: flow of dossier creation using a guided approach



# Review your dossier before submitting

- Run the **validation assistant** tool in IUCLID: a 'must' before submitting
- Consult our help: **tips** on manual verification
- See what information will be **disseminated** on ECHA's website
- Use the **fee calculator** to find out the expected registration fee



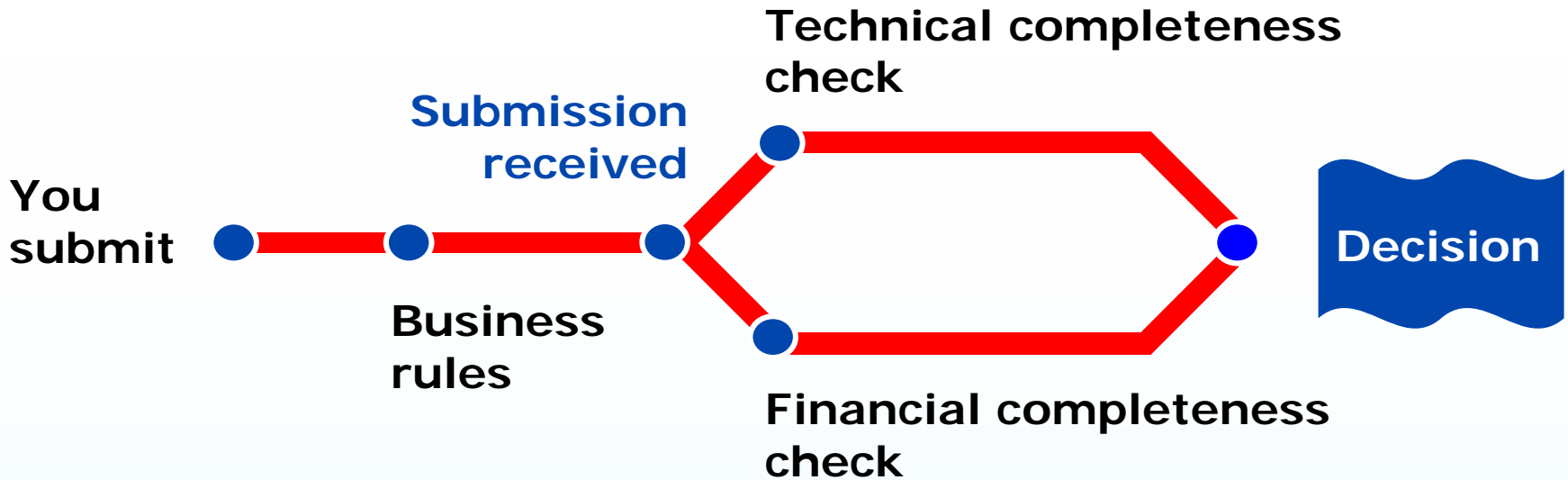
# Check these before submitting

- In REACH-IT
  - Company contacts
  - Company size
  - Billing address and VAT
- Within your company
  - Is a purchase order needed?





# Dossier's journey in ECHA





# Follow the progress

**Overview** | Request IUCLID file | Export assigned EC number | Download submission report

Submission status: **Complete** | Reference number: 01-2119967772-24-0003 | Reference date: 19/10/2016 | Initial submission  
Submission number: UB642823-38 | Submission date: 19/10/2016

Substance	Dossier type	Joint submission	Contact information	Submission processing steps
Name cineole	Registration	JS_207_431_5	Contact details +123 56789	1 ✓ Pre-validation
EC number 207-431-5	Tonnage band -	Company role Member	Third party representative	2 ✓ Business rules check
CAS number 470-82-6	On-site isolated intermediate 1-10 tpa	Registration type Full		3 ✓ Technical completeness check
	Transported isolated intermediate -			4 ✓ Financial completeness check
				5 ✓ Overall completeness check
				6 ✓ Submission outcome

Submitted information  
Submitting company information  
Dossier details

**Key documents**

- 19 Oct 2016 | Final submission result  
Outcome: Accept  
Annotation number: SUB-D-2114347086-49-01/F  
Submission number: UB642823-38  
Legislative status: Final | REGISTRATI...pdf
- 19 Oct 2016 | Invoice  
Type: Automatic invoice | Invoice

# Checks by ECHA

Business rules check	Completeness check
To make sure our system understands the dossier	To make sure all required elements are included
Must be passed for us to consider dossier submitted	Must be passed to get a registration number
	<ul style="list-style-type: none"> <li>• Technical and financial parts</li> </ul>
	<ul style="list-style-type: none"> <li>• One re-submission allowed</li> </ul>
Most rules in validation assistant	Automated rules in the validation assistant

# Incomplete dossier?

If 'technical completeness check' fails, check your tasks

- You will receive a letter – check the **key documents** section in REACH-IT
- Deadline to submit an improved dossier and instructions what to fix
- If not clear to you, contact us

Pay your invoice in time – fee payment is part of the completeness check

Submission processing steps		
1	✓	Pre-validation
2	✓	Business rules check
3	✗	Technical completeness check
4	⚙️	Financial completeness check
5		Overall completeness check
6		Submission outcome

# Manage the timelines

- Submit lead dossiers by the end of **March 2018**
  - Benefit from a shorter completeness check time
  - Allow enough time for member registrants to submit their registrations
  
- If you have several substances to register, complete one early to learn the process



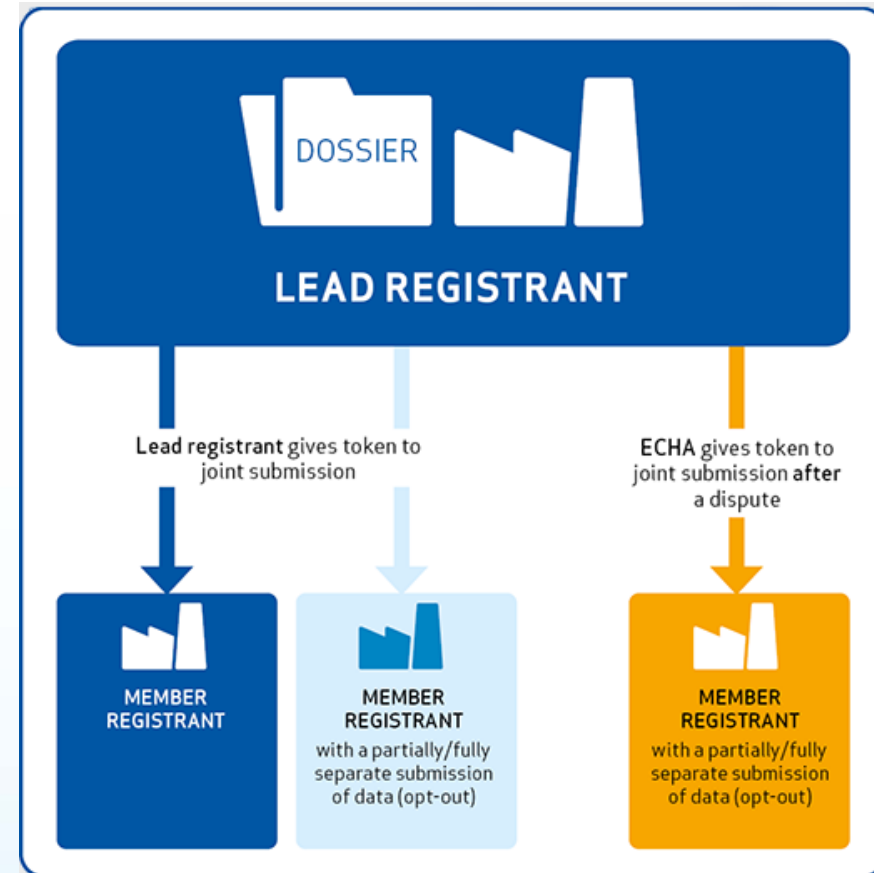
# How to deal with difficult situations





# Difficulties in the SIEF?

- Make sure the lead registrant has everyone's support
  - If not, contact ECHA
- Discuss the cost and data
  - Cost itemisation
  - Make every effort (justified claims)
- Justified opt-out possible
- Disputes at ECHA as last resort
  - On data
  - On access to the joint submission



## Slow or no progress in the SIEF?

- Only **few companies** to register
  - Agree to share the work equally
- Only **one active company** in the SIEF
  - Role of users of the substance critical
    - Make your need for the substance known to the supplier
    - Support the registrant in preparing the registration
- Substance pre-registered but **nobody plans to register** it
  - Users of the substance should make their need known to their association

→ When in doubt, register



# Directors' Contact Group (DCG)

- Informal group, founded in January 2010
  - monitors registration progress
  - finds solutions to practical obstacles to registration
- Directors of ECHA, European Commission and nine industry associations
- Outcome of the work
  - Factsheets
  - Recommendations
  - Solutions for companies in exceptional situations



## DCG publications

- Checklist to hire a good consultant
- Considerations to be made when joining an existing SIEF
- Recommendations on sound SIEF management
- Factsheet: SMEs – access to EU finance
- Recommendation on notifying registration intentions
- Recommendation to help small volume and SME registrants in registering for REACH 2018

# Recommendation to help small volume and SME registrants

Scope: Companies joining existing registrations

1. Explore if adequate to submit **only physico-chemical** information → reduced or no costs
2. Rely on **data sharing dispute** if negotiations come to a standstill. Submitting a registration dossier is possible.
3. Allow payment for letter of access in **instalments**
4. Offer a low-cost **affordable lump sum payment** option for 1-10 tonne registrants



## DCG solutions

Issue nr	Issue
10.2	Mixture importer does not obtain substance identification information from non-EU supplier
10.3	Delays in obtaining Annex VII and VIII test results
15.1-3	Legal entity change – one company without pre-registration
20.1	Lead registrant disappears after a failed completeness check, not completing the dossier
20.2	Lead registrant disappears before submitting the registration
21	SIEF without EU manufacturer/importer: Downstream user decides to start importing

# How to apply for the solutions?

Start from the DCG web page:

[echa.europa.eu/about-us/partners-and-networks/directors-contact-group](http://echa.europa.eu/about-us/partners-and-networks/directors-contact-group)

## DCG issues

In case you identify yourself as being in a situation described under is and solutions", you are advised to contact ECHA Helpdesk before you

To be eligible for a DCG solution, you must acknowledge that you have webforms. Specific instructions will be displayed for each one of the is

If you are not required to register your substance by 31 May 2013 the

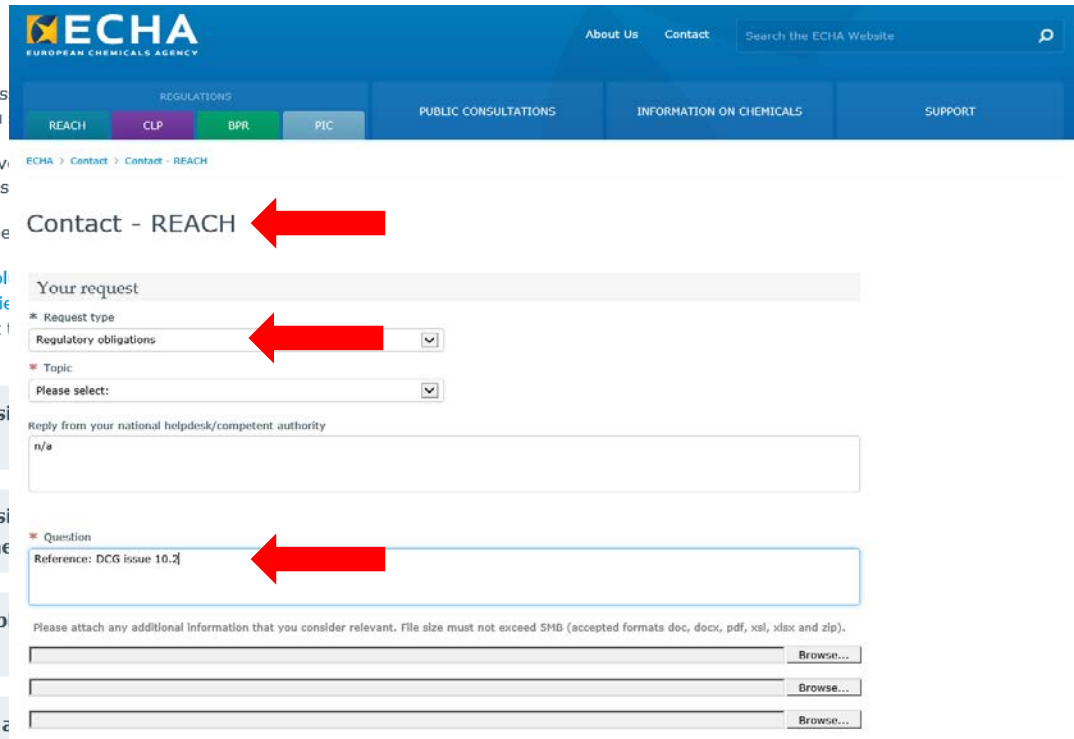
I declare that I have read the [Summary Paper on 28 issues and sol](#) provide information about being in an exceptional situation as identifi confronted by one of the scenarios outlined and I declare that I meet I form as set out in these documents.

**DCG issue 10.2 – Completeness of registration dossi substances in mixtures**

**DCG issue 10.3 – Completeness of registration dossi REACH not yet available by the registration deadline**

**DCG issue 15.1 – Legal Entity change – Company sp registration**

**DCG issue 15.2 – Legal Entity change – Transfer of a**



The screenshot shows the ECHA website interface for the 'Contact - REACH' form. The page title is 'Contact - REACH'. The form includes the following fields and elements:

- Your request** (text input field)
- \* Request type** (dropdown menu, with 'Regulatory obligations' selected)
- \* Topic** (dropdown menu, with 'Please select:' selected)
- Reply from your national helpdesk/competent authority** (text input field, containing 'n/a')
- \* Question** (text input field, containing 'Reference: DCG issue 10.2')
- Please attach any additional information that you consider relevant. File size must not exceed 5MB (accepted formats doc, docx, pdf, xls, xlsx and zip).** (three file upload fields with 'Browse...' buttons)

Red arrows point to the 'Contact - REACH' title, the 'Request type' dropdown, the 'Question' text input field, and the 'Regulatory obligations' dropdown option.

## Take home

- IUCLID Cloud guides you step-by-step through dossier preparation
- Use the available checks ahead of submission
- DCG solutions are now available for companies in exceptional situations
- Contact ECHA in case of difficulties
- Follow ECHA's one-stop-shop for REACH 2018:  
[echa.europa.eu/reach-2018](https://echa.europa.eu/reach-2018)

# Thank you

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