REACH 2013: Update of current activities

ECHA's seventh Stakeholders' Day

23 May, 2012

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REACH 2013

- **Registration key messages and expectations**
- Steps to successful registration
- New IUCLID in 2012

Just over one year to the next deadline!

- Phase-in substances **over 100 tonnes per annum**
- Preparations should be well underway!
- Non EU manufacturers: make sure that your Only Representative gets ready

Registration key messages

- Registration is a big but manageable task:

Already 26 382 new registrations under REACH from approx. 6 800 legal entities for 4 335 substances*

- Is your substance already registered?

Already registered: contact the lead registrant to verify substance sameness, make the SIEF agreement and to obtain your REACH-IT member token

Not already registered: contact (pre)SIEF to establish sameness and agree on a lead registrant

- Members still need to submit their dossiers by 31 May 2013.

* data as of 15 May 2012, excludes transitional NONS registrations

2013 Expectations – Number of substances

Substances relevant for 2013 deadine	**3 551**
Of which are 'new' substances to be registered for 2013	*2 685*
Of which were registered for 2010 deadline by a Lead	*866*

'New' substances to be registered for 2013 deadline	**2 685**
For which a Lead Registrant is known to ECHA	1 919
Of which are already registered by a Lead Registrant	141

'New' substances which are not yet registered and for which no LR nomination has been received by ECHA	**746**

Data as of 22 May 2012

http://echa.europa.eu/web/guest/information-on-chemicals/registered-substances/identified-substances-for-registration-in-2013

2013 Expectations – SIEF Activity

- To support SIEF activities, ECHA aims to collect the best possible information on the Lead Registrant status

- List of lead registrants on the ECHA Website is one of the best possible sources of information concerning the SIEF progress. The list provides information on:
  - Whether a lead registrant has made themself known to ECHA (i.e. SIEF is active)
  - Whether a registration has been submitted by the same lead or by another company
  - Whether a registration has been submitted by the lead of the joint submission.

- ECHA urges companies to continue to actively participate in the Lead Registrant Nomination on the website to ensure accurate administration and information of the SIEF formation activities for the 2013 deadline.
- Please, when participating, consent to the publication of your identity.

https://comments.echa.europa.eu/comments_cms/LeadRegistrantNotification.aspx

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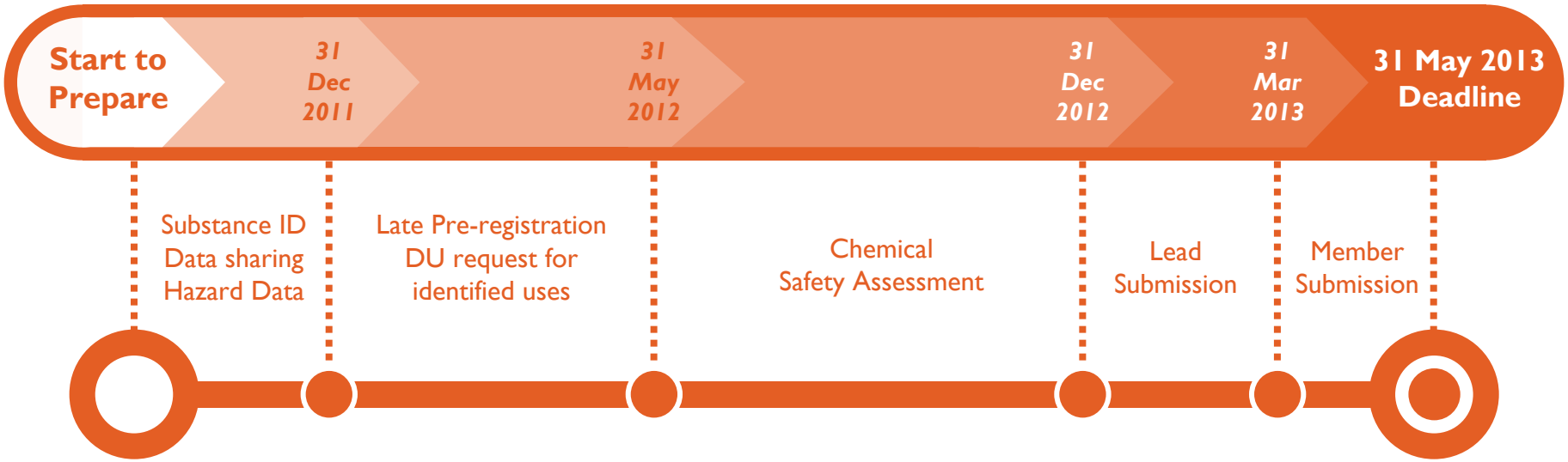
Countdown: optimal situation



The main SIEF tasks

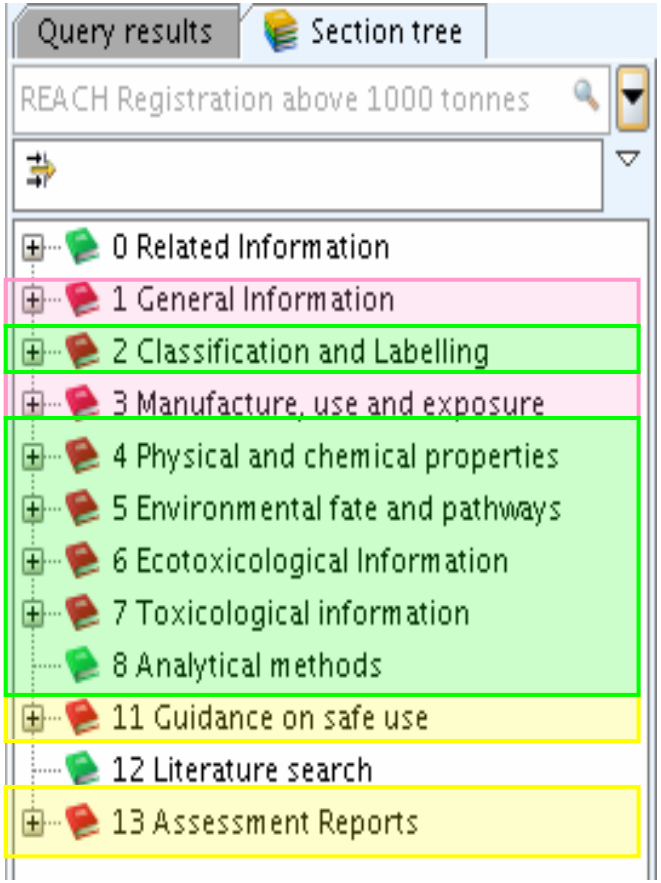
Obligatory steps for SIEF	Standard /recommended practice
(SIEF) Agrees on substance sameness (and decides own analytical requirements)	Generate SIEF agreement
(SIEF) Data sharing: vertebrate data must be shared. Other data must be shared if requested	Generate letters of access
(SIEF) Assess data gaps and agree strategy to fill them	
(SIEF) Agree on common classification and labelling	

The main for Lead / Member tasks

Obligatory steps for LEAD	Standard /recommended practice
Perform own CSA and document in CSR	Perform CSA on behalf of SIEF and document in joint CSR
Create REACH-IT joint submission and transfer the 'token' to members	
Prepare and submit IUCLID dossier	Provide members with IUCLID data set. Coordinate 'Guidance on Safe use' section
Follow REACH-IT to verify successful submission and payment	Give best practice advice to members
Perform post-registration activities (updates)	Use SIEF agreement (or equiv.) to specify post-registration coordination e.g. response to compliance check

Building the dossier in IUCLID

Lead

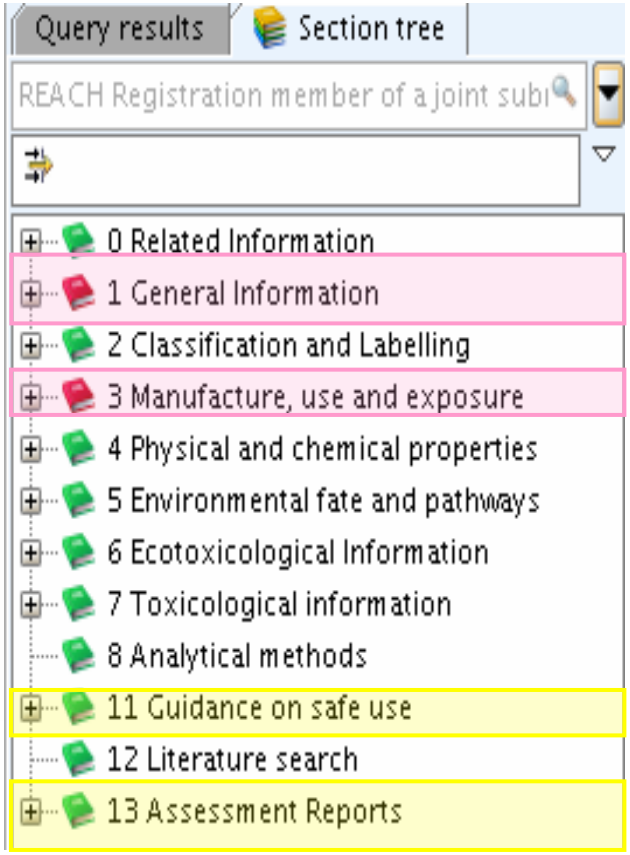


Private data submitted by the LEAD and the MEMBER

Data submitted only by the LEAD (if not opted-out)

Data submitted either by the LEAD or individually

Member



Key steps for 'member' registrants

- Make sure that you are in the correct SIEF and substance ID is sufficiently clear in the registration dossier
- Verify what the SIEF agreement will deliver (previous slides)
- If SME, carefully verify your status: ECHA website > Support > SME's
- Ensure that you have resources in place to:
  - negotiate within the SIEF
  - prepare and submit the member dossier (making use of the TCC, dissemination and fee calculator IT tools)
  - be ready to pay the fee within the deadline
  - maintain and update the dossier when e.g. new information is received

Post-registration considerations

- **Requirements to spontaneously update dossier include**:

Change in status/identity	Change in composition	Changes in tonnage band
New identified uses/uses advised against	New knowledge on risks (impacting CSR and/or SDS)	Change in classification and labelling
CSR/Safe Use amendments	Testing proposal needed	(Respond to Quality Observation Letter)

- **Regulatory updates:**
  - Responding to compliance check (draft/final) decision
  - Responding to request for further information on confidentiality claim
  - Responding to TCC failure of a submitted spontaneous update

- **Be prepared and invest resources in this**

Post-registration considerations

- **Based on experience; proactive spontaneous updates recommended in the following areas:**

  - **Dossier evaluation**: Completeness ≠ Compliance:
    - Read the Article 54 Evaluation Report and invest in a spontaneous update to address potential issues prior to compliance check
    - Take care to correctly enter <u>all</u> testing proposals in the dossier

  - **Intermediate status**: Screening of intermediate dossiers under 'Article 36' provisions showed that 86% of dossiers screened had insufficient information to confirm intermediate status. Formal updates have been requested and work is ongoing.

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Launch of IUCLID 5.4 and REACH-IT upgrade

- **New IUCLID 5.4 to be released end of May / early June 2012**

- Changes mainly relate to new fields for reporting information from the Chemical Safety Report (CSR), and to facilitate the publication of certain information contained in the Safety Data Sheet (SDS):

- PBT (Persistent, Bioaccumulative and Toxic chemicals) assessment
PBT / vPvB status of the substance assessed; likely routes of exposure outcome of the assessment for each criterion (Persistence, Bioaccumulation, Toxicity).

- Modification of IUCLID section 3 (Manufacture, use and exposure): More standardised documentation of information on manufacture and use of a substance and the related exposure and risk assessments: conditions of use; exposure estimates; methods and tools used for the assessment.

- Endpoint summary of IUCLID section 7 (DNEL) enhanced

Launch of IUCLID 5.4 and REACH-IT upgrade

Impact for existing registrants - 'SDS information' to be published and action required:

- Implementation already included basic information on uses
- Now also includes:
  - ***Company name, Registration number, PBT assessment***

- Read the Questions and Answers document (below) and decide whether to make an update claiming confidentiality on the above items (which needs to be supported by an adequate justification).

More information: ECHA > Support > FAQs > Questions and answers on upcoming IUCLID 5.4 changes and impact on submission and dissemination of information. Additional briefing note on the SDS information (including precise timelines) to be published soon.

Launch of IUCLID 5.4 and REACH-IT upgrade

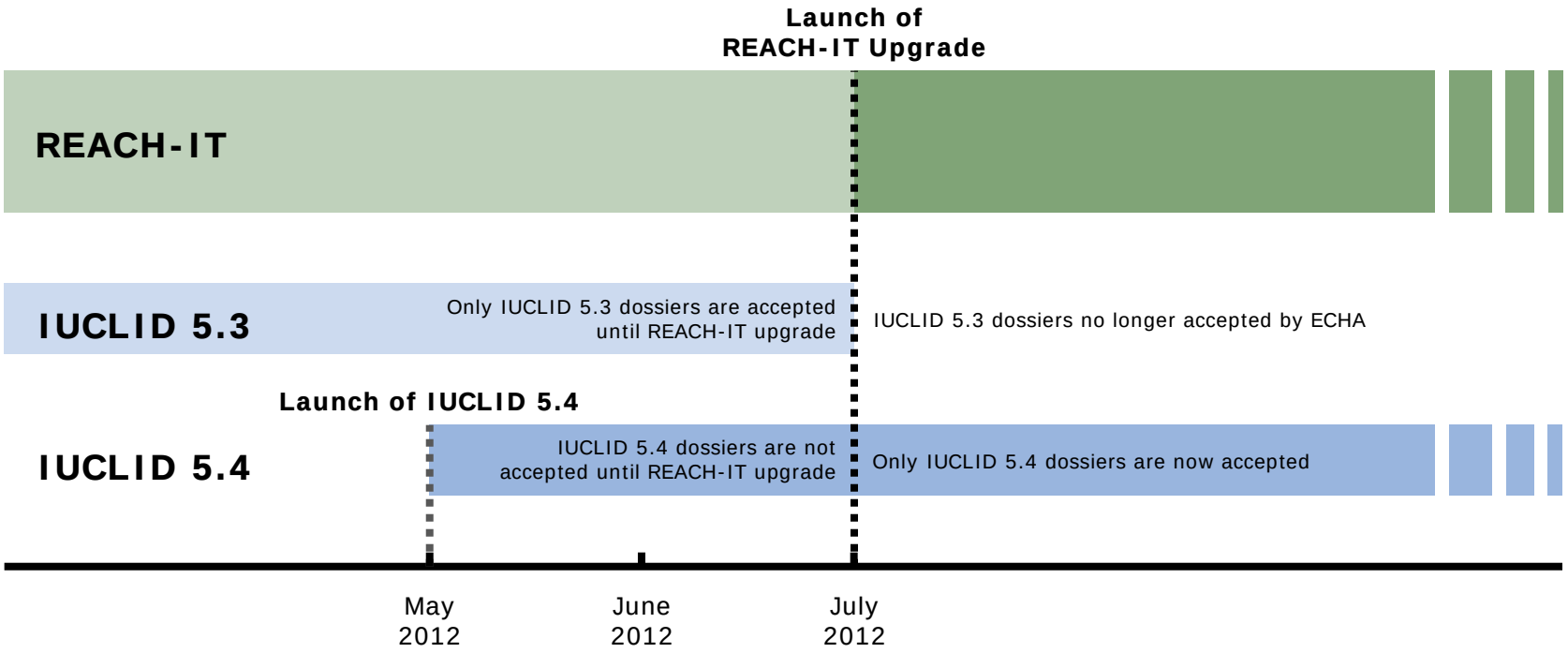
Impact for new registrations

No new technical completeness check (TCC) rules at this stage (IT stabilised 12 months before 2013 deadline); these will be developed in consultation with stakeholders for the future. However, it will be mandatory to include the outcome of the PBT assessment.

New registrants are strongly encouraged to fully complete the relevant sections already in 2012/2013 to avoid having to update in 2014 when the TCC and dissemination rules are further enhanced after stakeholder consultation.

More information: ECHA > Support > FAQs > Questions and answers on upcoming IUCLID 5.4 changes and impact on submission and dissemination of information

Launch of IUCLID 5.4 and REACH-IT upgrade



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Thank you.

Let’s work together for another successful deadline!

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