REACH 2013: Update on registration and dissemination

REACH Implementation Workshop XI

18 June, 2012

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ECHA

REACH 2013

- **Registration key messages and expectations**
- New IUCLID in 2012
- Dissemination of SDS information
- Dissemination of NONS

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*

- 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 30 May 2013.

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

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Registered Substances

5 686
Registered Substances
(for which a REACH registration dossier has been received)

+ 2 318
Registered Substances
(Notified under Directive 67/548, claimed since Jun 2008)

Only as Full *	3 022
Only as OSII *	480
Only as TII *	1 141
Full & OSII	118
Full & TII	363
OSII & TII	287
Full, OSII & TII	275

Registered as Full Registration	3 778
Registered as Intermediate Only	1 908

Registered substances by registration type *

Phase-in substances	3 854
Non-phase-in	1 832
Total	**5 686**
Of which are NONS ¶	1 265
EINECS substances	2 930
Substances from Joint Submissions	3 244
Substances from Individual Subm.	2 442

Registered substances by category / class / source

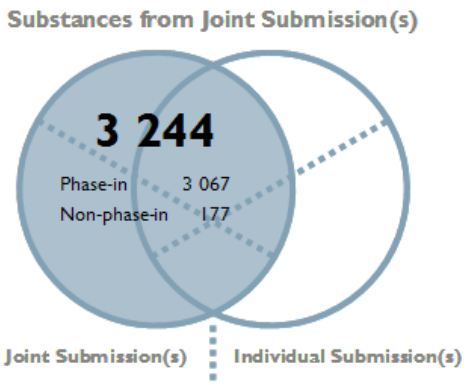
Germany	3 161
United Kingdom	1 397
Belgium	1 189
France	1 139
The Netherlands	1 099
Italy	985
Spain	874
Ireland	413
Sweden	393
Finland	386

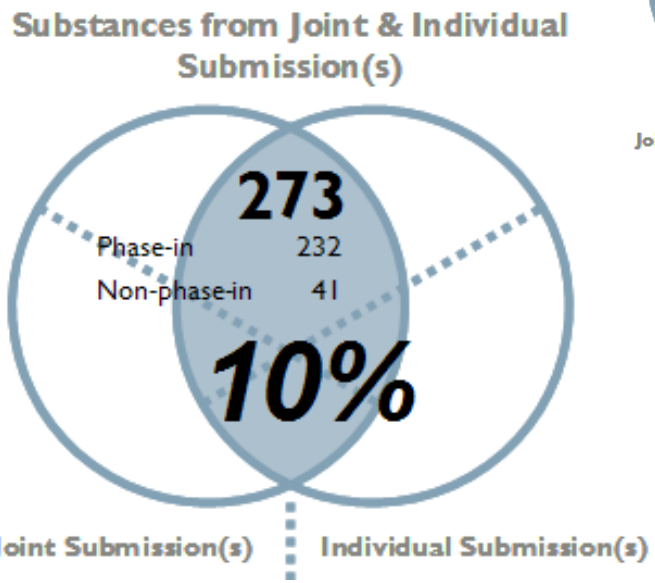
Top 10 countries by number of substances registered •

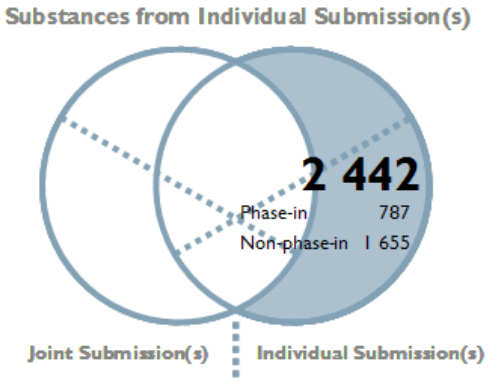
§ All numbers for 'Substances' are determined automatically using unique substance identifiers (EC Number / List Number). As substance identities are verified the numbers reported for substances may change.
* 'Full' indicates a registration under REACH Article 10 as a full dossier; 'OSII' under REACH Article 17 as an on-site isolated intermediate; 'TII' under REACH Article 18 as a transported isolated intermediate.
¶ Substances previously notified under Directive 67/548/EEC ('NONS' substances) which have been claimed and updated with a REACH registration dossier; these are counted with the 5686 REACH registrations
• Numbers indicated in this table are the number of substances registered in a country (by at least one legal entity) from the total figure of 5686 substances for which REACH registrations have been received.

Data as of 05 Jun 2012

Registered Substances Overview







% of individual submissions for which there is a 'matching' joint submission

2013 Expectations – Number of substances

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

'New' substances to be registered for 2013 deadline	**2 685**
Of which are already registered by a Lead Registrant (LR)	141
For which a LR nomination has been received by ECHA	1 919

'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

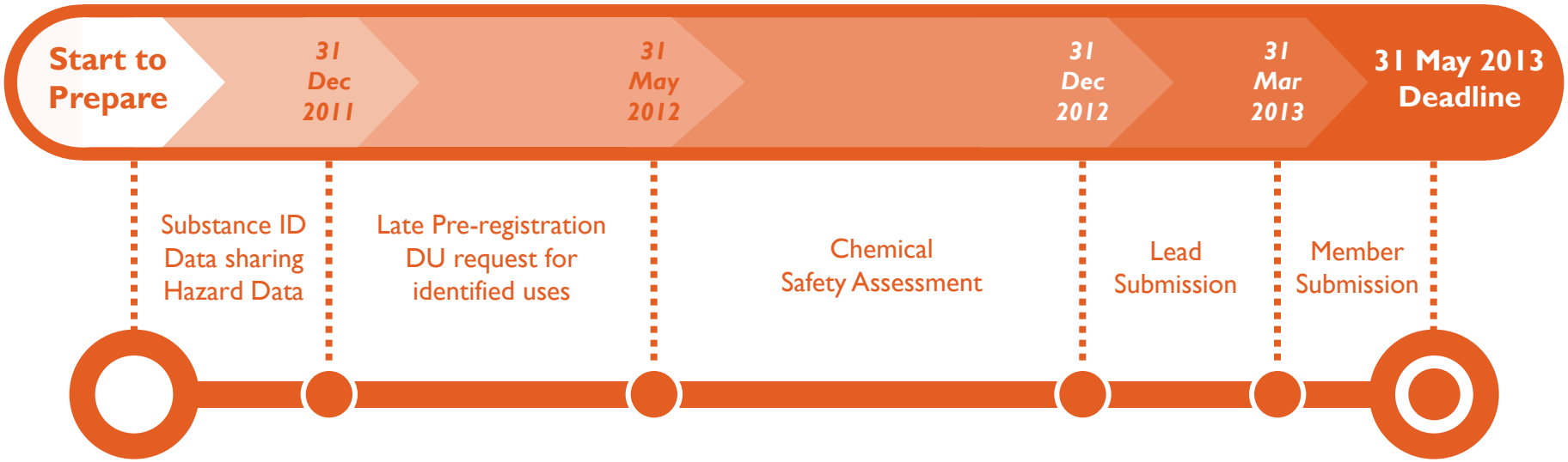
- To support SIEF activities, ECHA aims to collect the best possible information on the Lead Registrant status

- 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 himself 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 at 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

Countdown: optimal situation



Key steps for new lead registrants

- Check if your registration preparations are according to ECHA's recommended timeline
- Inform ECHA of your nomination as lead registrant
- SIEF agreements – there are standard documents available
- Make sure that all SIEF members are informed:
  - Timeline
  - Scope (e.g. joint chemical safety report or not)
  - Progress
- Submit the lead dossier well in advanced to allow time for member submissions

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
- 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

- **Requirement 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 decisions on compliance check, testing proposals, or substance evaluation
  - Responding to request for further information (e.g. on confidentiality claim, Art 36)
  - Responding to TCC failure

- **Be prepared and invest resource 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 all 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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New IUCLID in 2012

- **New IUCLID 5.4 released on 5th June 2012**

- Changes are mainly related 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

New IUCLID in 2012

Impact for new registrations

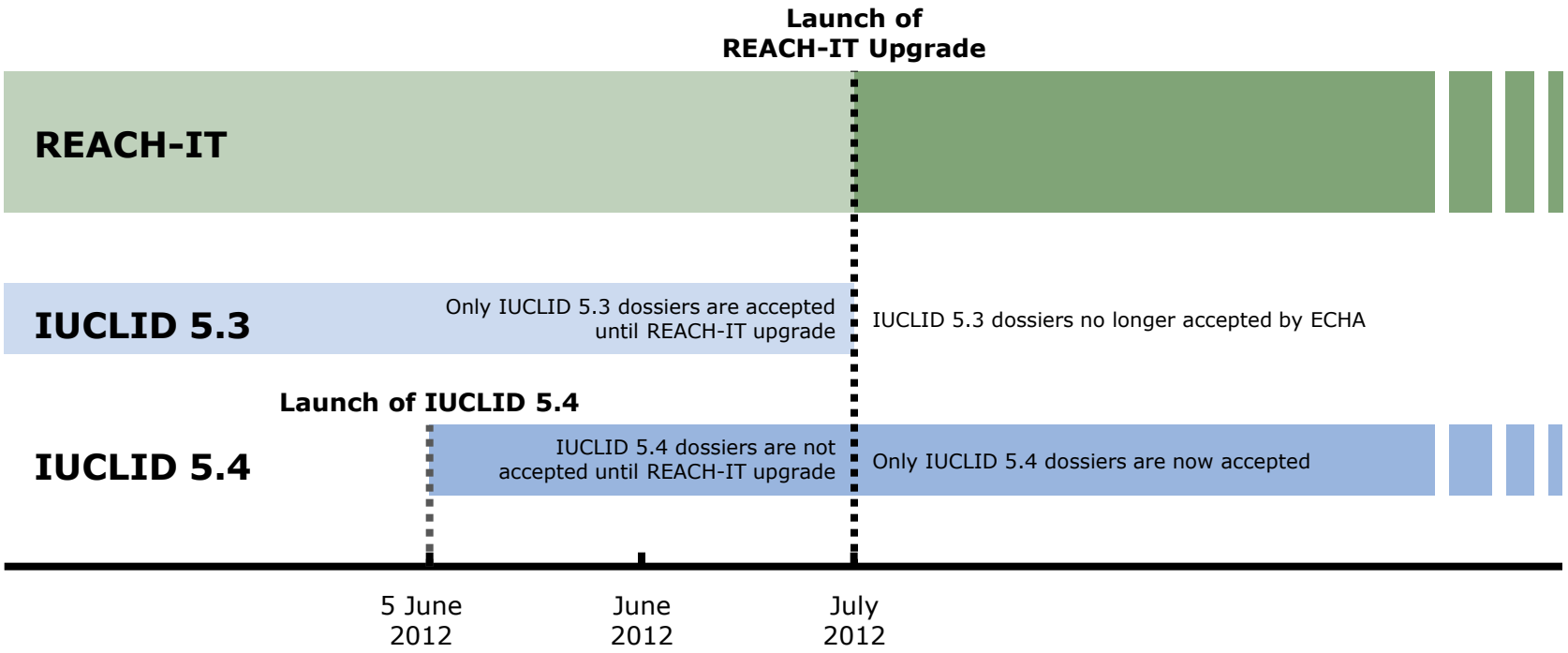
No new technical completeness check (TCC) rules at this stage.

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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Dissemination of 'SDS information'

- Implementation already included basic information on uses
- With IUCLID 5.4, now also includes:
  - ***Company name, Registration number, PBT assessment***
- Information will be published from all registration dossiers unless claimed confidential
- Confidentiality claim needs to be supported by adequate justification and attracts a fee if:

  ✓ SDS is required (registration number, company name)
  ✓ SDS and CSR required (PBT assessment)

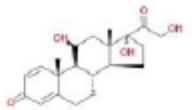
Dissemination of 'SDS information'

Example of dissemination of company names and registration numbers

Substance identification

Substance example

EC Number	200-123-4
EC Name	Substance example
CAS Number	12-34-5
Molecular formula	C21H28O5
IUPAC Name	11,17,21-trihydroxypregna-1,4-diene-3,20-dione



Type of substance

Composition	mono constituent substance
Origin	organic 12

Trade names

Substance

Total Tonnage Band

100 – 1 000 tonnes per year

Registrants

A company	123 Mannerheimintie, 00123 Helsinki, Finland	040 9736 1237
Be Chemicals	123 Mannerheimintie, 00123 Helsinki, Finland	040 9736 1237
Example Corp	123 Mannerheimintie, 00123 Helsinki, Finland	040 9736 1237
Finchem	123 Mannerheimintie, 00123 Helsinki, Finland	040 9736 1237
Zetec Chemicals Inc	123 Mannerheimintie, 00123 Helsinki, Finland	040 9736 1237
[Confidential]		

Registration Numbers

01-211457123-45-0000	01-211457123-45-0001	01-211457123-45-0002
01-211457123-45-0003	01-211457123-45-0004	01-211457123-45-0007
01-211457123-45-xxxx	[Confidential]	

Contact Persons Responsible for SDS

A company	123 Mannerheimintie, 00123 Helsinki, Finland	040 9736 1237
Be Chemicals	123 Mannerheimintie, 00123 Helsinki, Finland	040 9736 1237
Example Corp	123 Mannerheimintie, 00123 Helsinki, Finland	040 9736 1237
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[Confidential]		

Dissemination of 'SDS information'

Actions for existing registrations:

- Read the Questions and Answers document (below) and decide whether to make an update claiming confidentiality on these items
- Resubmission of updated dossier by **31st October 2012** latest. ECHA will start disseminating the information after that date.

More information: ECHA > Support > FAQs > Questions and answers on dissemination and confidentiality claims of SDS

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- **Dissemination of NONS**

Dissemination of NONS

- Information included in NONS will be published

- All previous notifiers are individually informed and given an adequate deadline to review their dossiers

- NONS with registration number claimed will be disseminated first. Those not yet claimed will follow later on.

  ✓ Dissemination will follow a stepwise approach (next slide)

- If tonnage band is updated or testing proposal included, dissemination as any other REACH dossier

Dissemination of NONS

- Stepwise approach:

Step 1 – Publication of reduced set of data. Started in May 2012.

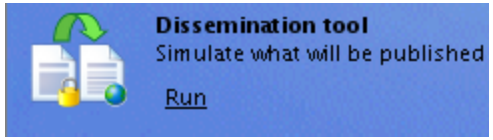
Step 2 – Publication of information which could not be claimed confidential under NONS (e.g. 'SDS information').

- ✓ Deadline for submitting updated dossier with claims is **31 October 2012**. Fee will apply and claims will need to be justified.

Step 3 – Full publication according to Article 119 of REACH.

- ✓ Deadline for submitting updated dossier with claims is **31 August 2013**.

Action needed: Review your dossier; edit and insert claims if appropriate, and resubmit.



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Thank you.

Let’s work together for another successful deadline!