Feedback from 2010

Lead Registrant Workshop

2 February 2012

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Outcome of registration in 2011

Registration 2010 in a nutshell

- ✓ Major co-operation effort
  - Excellent commitment by industry
  - Close cooperation between key players to narrow down uncertainties & clarify open questions (Directors' Contact Group)

- ✓ Successful management of the deadline
  - ca. 25 000 dossiers corresponding to 4300 (3300 phase-in) substances
  - Majority of large companies: 86 %
  - Submission by Only Representatives: 19 %
  - Joint Registrations: 94 %
  - 25% substances with intermediate use only

Lessons learnt from SIEF formation to submission of the joint dossier:

What worked?
What can be improved?

Registrations intentions

! 2010: Less substances registered than announced by industry in April 2010

- Reasons for non registration: later registration, better understanding of REACH obligations (e.g. exemptions), merge/split of SIEFs, etc.
- Results were published on ECHA website in September 2011

➔ Market surveys for next deadline early enough to identify difficulties

- Initiated by ECHA in Q4/2011, 18 months before the deadline
  - In total pre-registrants intend to register ~ 3,200 substances (28% already registered in 2010)
  - New phase-in substances for the 2013 deadline amount to ~ 2,300
  - Additional feedback will be sought from industry associations

SIEF formation and data-sharing

- Pre-registration in 2008 managed successfully but failed to meet its aims
  - Registrants: Large SIEFs difficult to administer
  - DUs: No certainty on which of their substances will be registered
- Challenges on data & cost sharing for smaller players or non EU manufacturers
  - 15 data sharing disputes lodged with ECHA
- Despite challenges in SIEF formation, 94% joint registrations

SIEF formation and data-sharing

- How to improve?

➔ Encourage companies to de-activate or remove pre-registration in REACH-IT if no intention to register in 2013

- Service provided by ECHA to de-activate/remove in bulk
- **40 000** pre-registrations removed in September 2011, **~100 000** more will soon be removed

➔ Start SIEF work for 2013 deadline early enough; Encourage early nomination of Lead Registrants

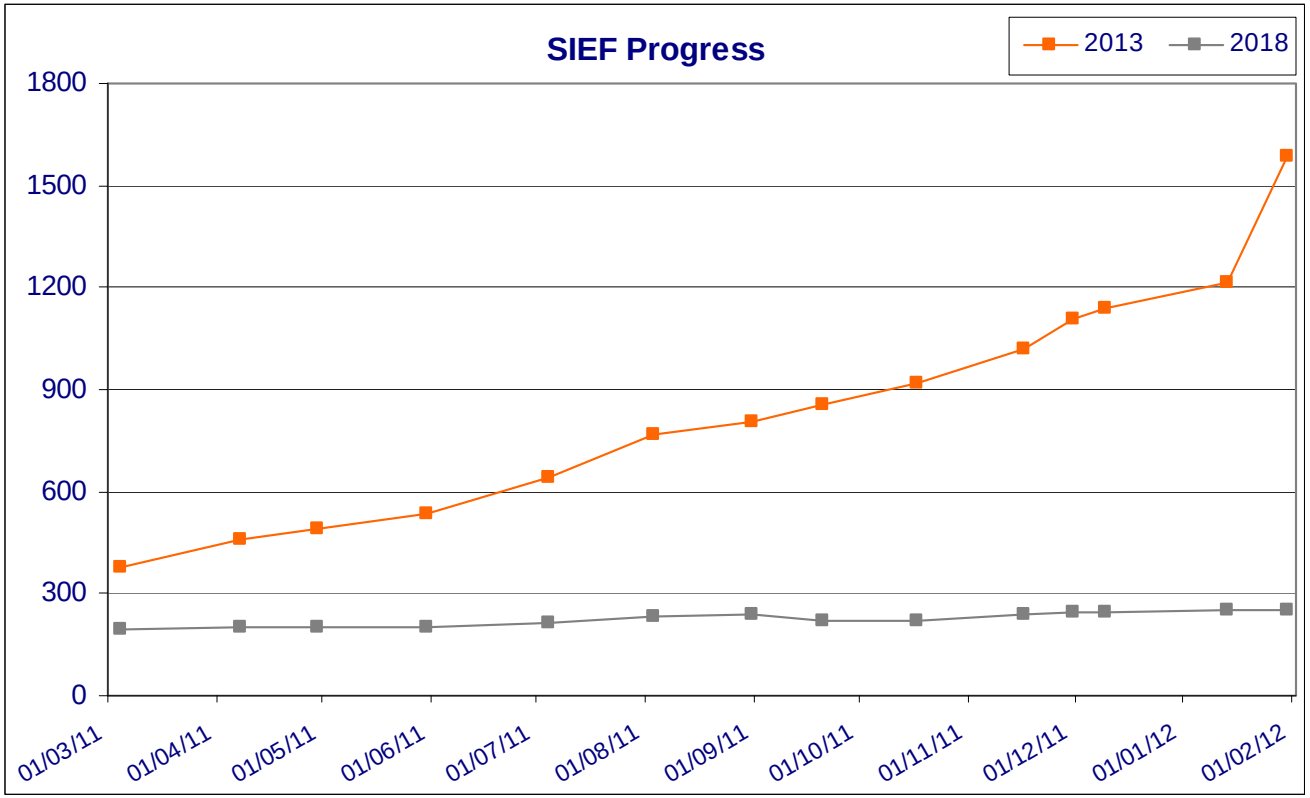
- **1583** Lead Registrants have identified within their SIEFs (surveys + ECHA Lead Registrants database)

➔ Increase transparency, promote best practice and fairness

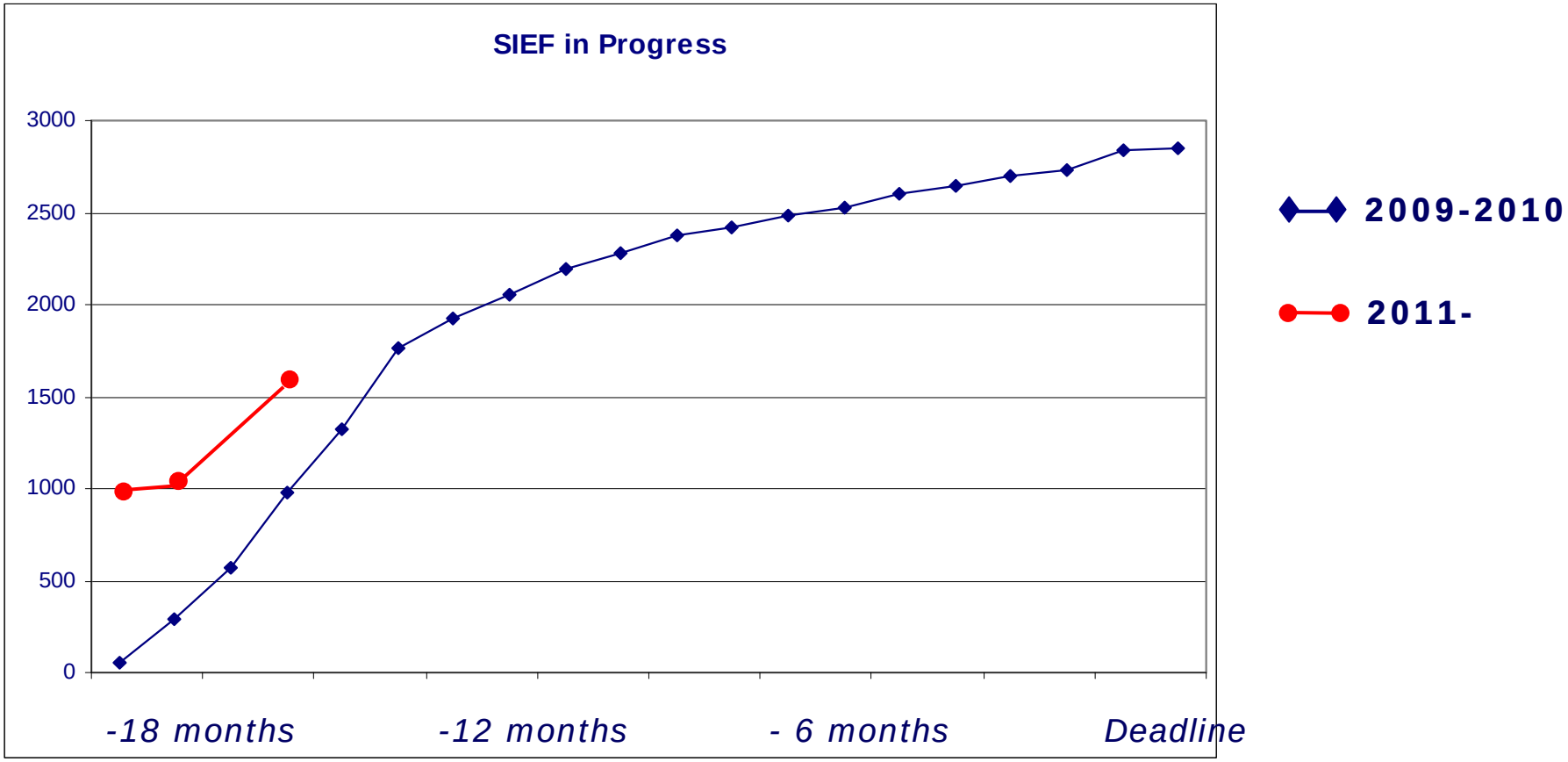
- Update of the Guidance on data sharing – Publication in **April 2012**

SIEF progress (2011 – 30 Jan 12)

Date	2013	2018
04/03/11	377	193
07/04/11	459	201
29/04/11	493	202
30/05/11	532	204
04/07/11	641	213
03/08/11	767	232
31/08/11	806	240
20/09/11	857	222
17/10/11	916	219
16/11/11	1021	238
30/11/11	1106	247
09/12/11	1138	248
13/01/12	1214	251
30/01/12	1583	253



SIEF formation in 2009-2010



Joint submission

- For 2010 registrations
  - Multiple joint submissions for the same substance observed
  - Individual submissions for substances with joint submissions observed

! Not in line with the REACH principle “one substance, one registration”

➔ Encourage Lead registrants to make their names known on ECHA web site for increasing transparency

➔ Already consulted those participating in the survey, and positive reactions received

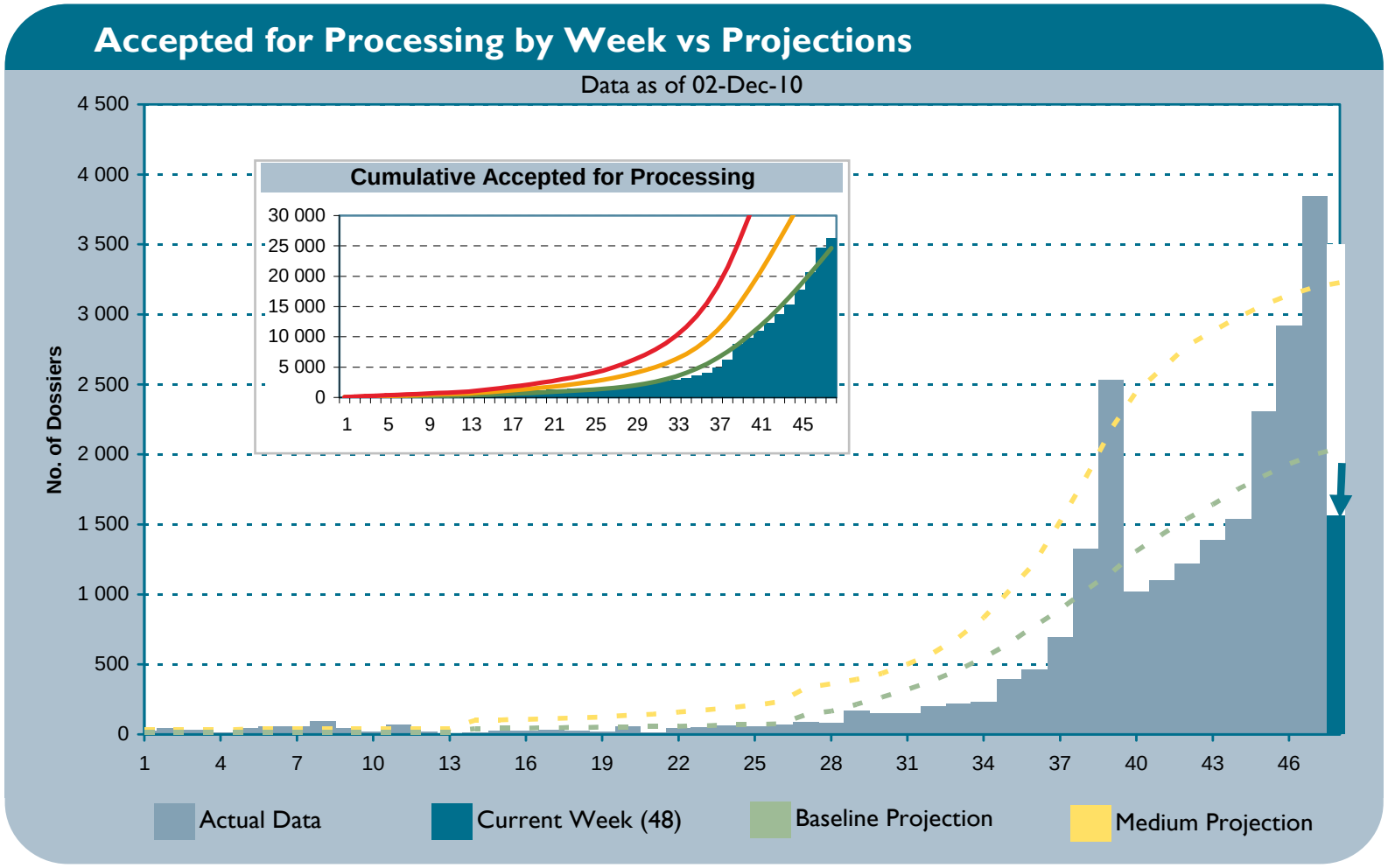
➔ More advice provided on the 2013 webpage at http://echa.europa.eu/reach2013

Registration

1. Ensure the substance identity for the whole joint submission
   - ➔ Critical for data sharing and compliance of data submitted
   - ➔ However, each member must identify his own detailed substance composition
2. Collect information on uses in organised manner
   - ➔ Ensure meaningful communication in the supply chain afterwards
3. Gather information on data available in the SIEF
   - ➔ Identify data gaps, agree who provides the missing information
4. Agree on classification and labelling
   - ➔ Opt-out from common classification needs to be justified
5. Decision whether to prepare CSR jointly or individually
   - ➔ Ensure that the CSR represents a safety assessment on realistic conditions of use
   - ➔ Consider forthcoming updates

- Keep the members up-to-date on the anticipated contents of the lead dossier

Submission timing in 2010



Dossier submission to ECHA

- IT tools and Guidance stabilised well ahead of deadline

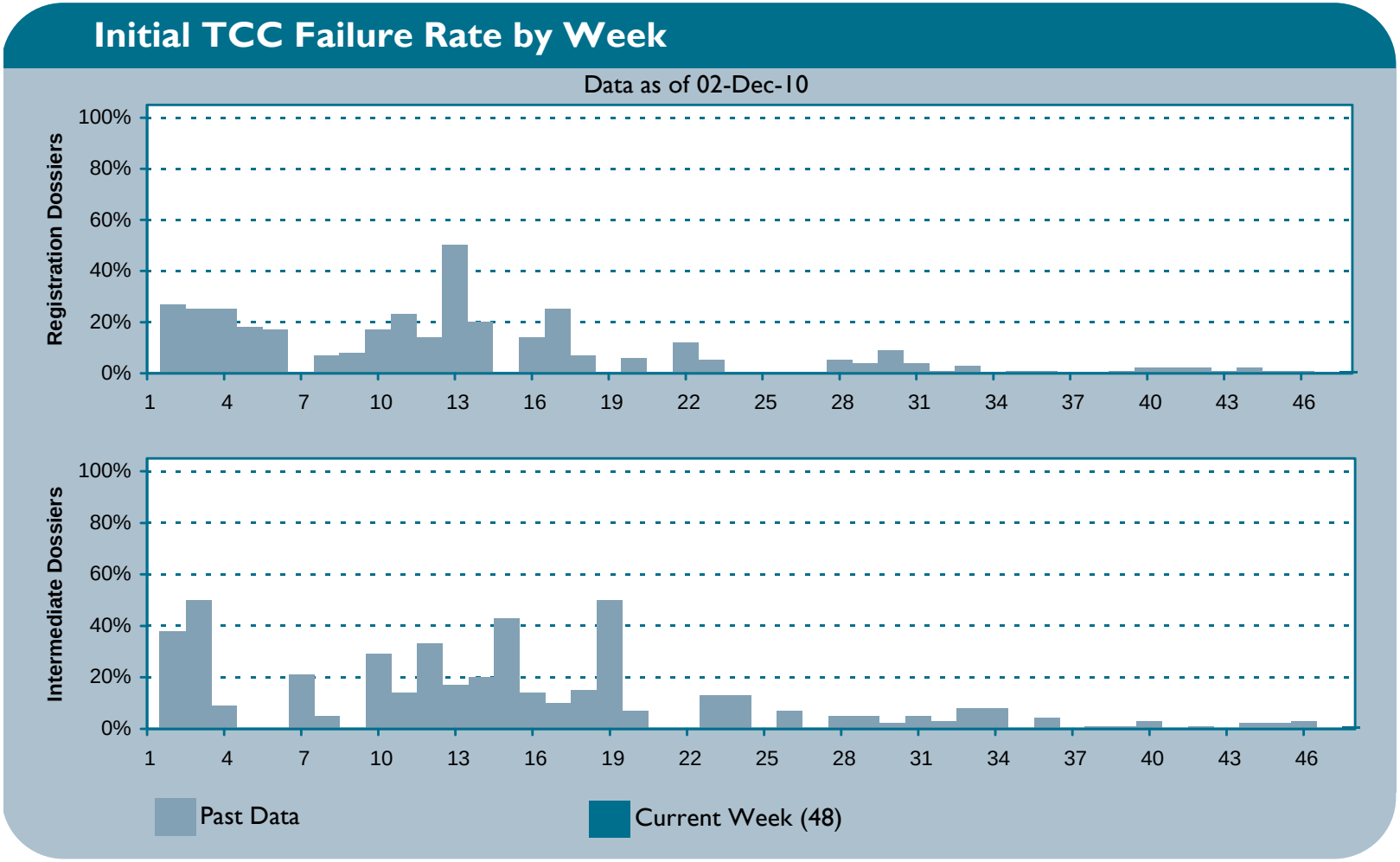
  ➔IUCLID 5.4 Q2/2012
  ➔Chesar Q3/2012
  ➔REACH-IT Q4/2012

  ➔Update of the Guidance on Registration – Publication in **April 2012**

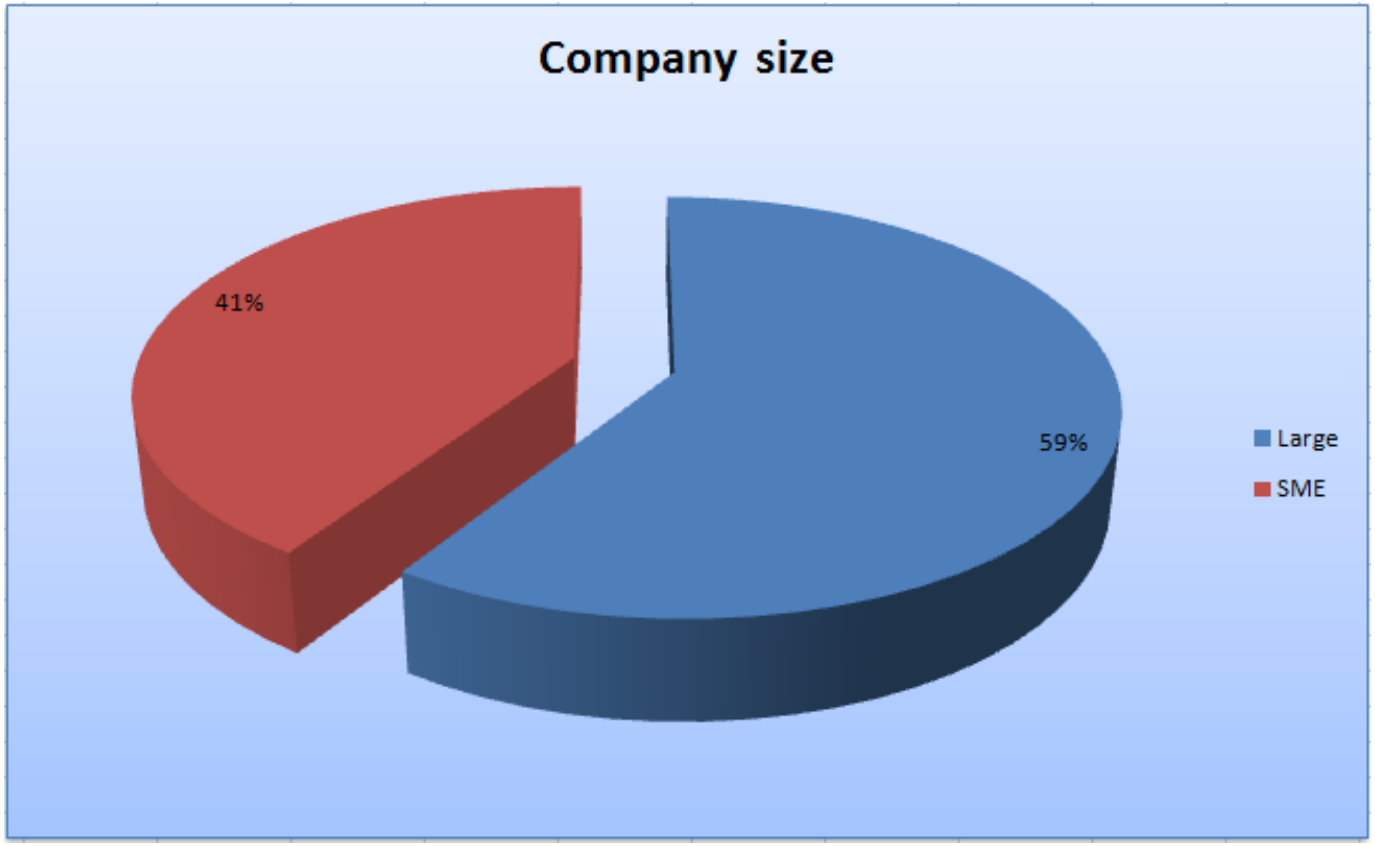
- ECHA support to registrants

  ➔Two Lead Registrant workshops
  ➔Webinar programme running through Q4/2011-Q2/2013
  ➔Helpdesks (ECHA Helpdesk and 30 national helpdesks)

Effect of publishing TCC plug-in in 2010



Business Rule Failures – Phone contact in 2010



Prepare for post registration

- Getting the registration number is not the end
  - The registration dossier must be kept up-to-date
  - Updates can be done spontaneously or requested by authorities
- Dossier compliance check will follow
- Dissemination
  - ECHA will make registration information available on its website at http://echa.europa.eu/web/guest/information-on-chemicals/registered-substances

Conclusions

- Registration is a big but manageable task
- Prepare in a timely manner and keep your SIEF members informed
- Be prepared for post-registration activities prior to the submission
- Make full use of ECHA support to the registrants

Thank You!

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