Update from ECHA

CEFIC REACH Implementation workshop

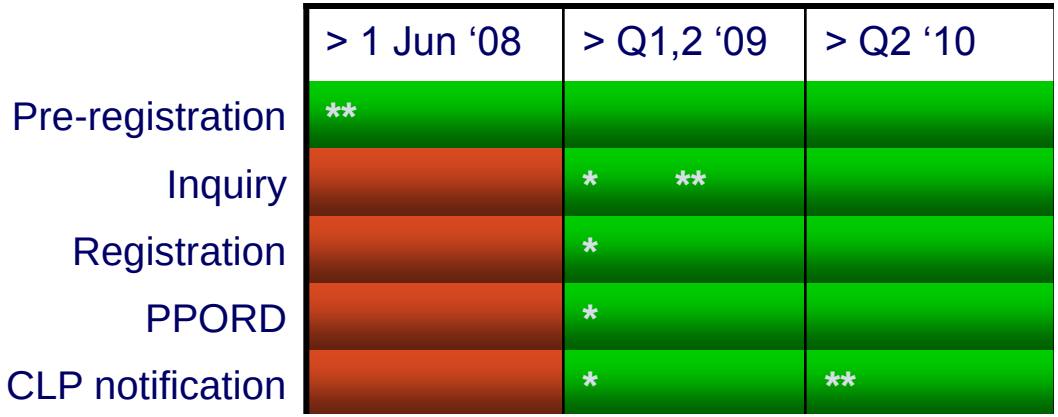
21 – 22 June 2011

Kevin Pollard
ECHA – Dossier Submission and Dissemination

Content

- **REACH industry submissions**
  - Summary of Industry REACH submission types
  - Update on submission numbers and dissemination
- ECHA priorities for 2011 – 2012
- 2013 REACH Deadline
  - 2010 Lead Registrants
  - 2013 Registrants
  - Recommendations

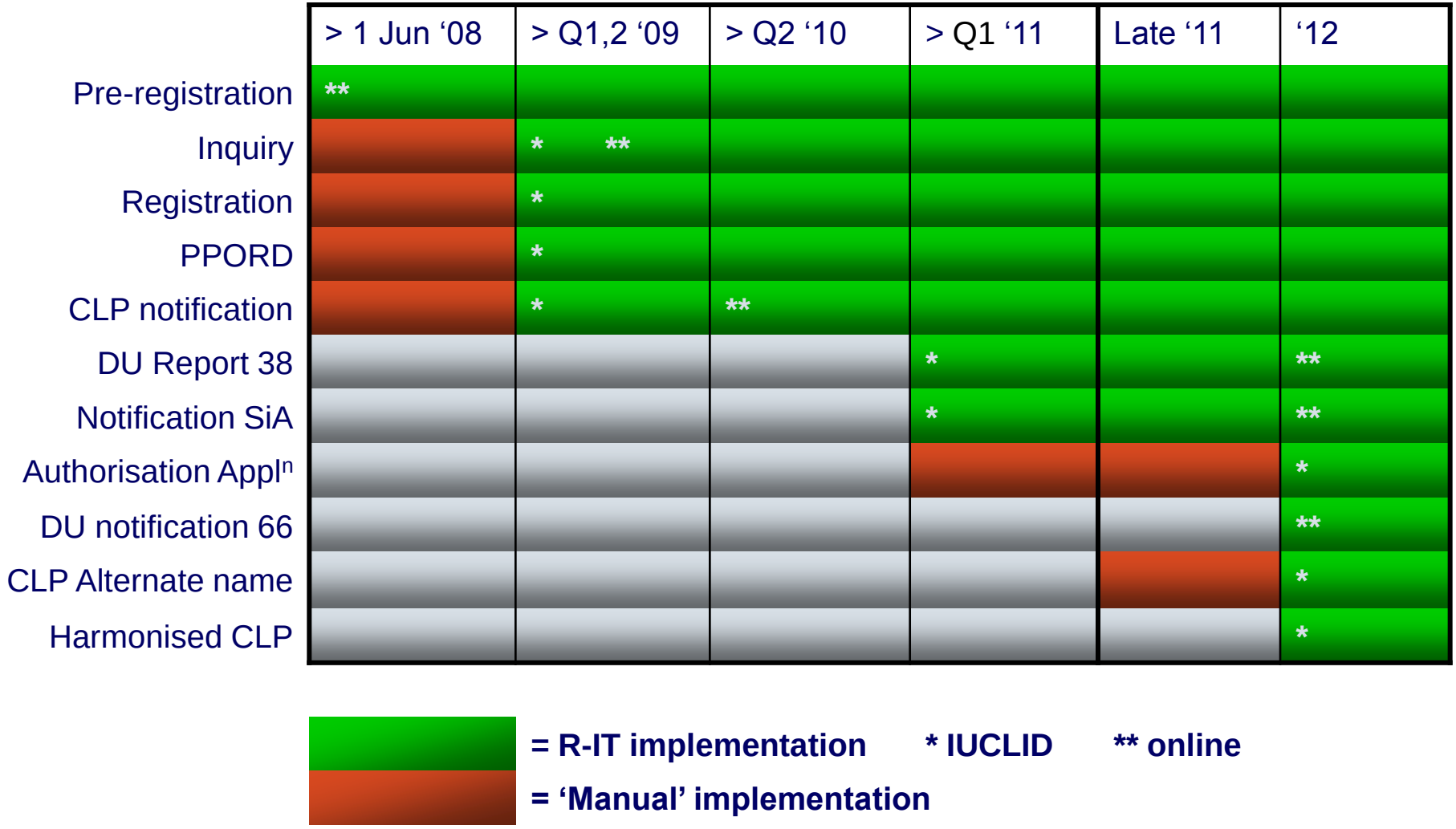
Industry REACH Submissions



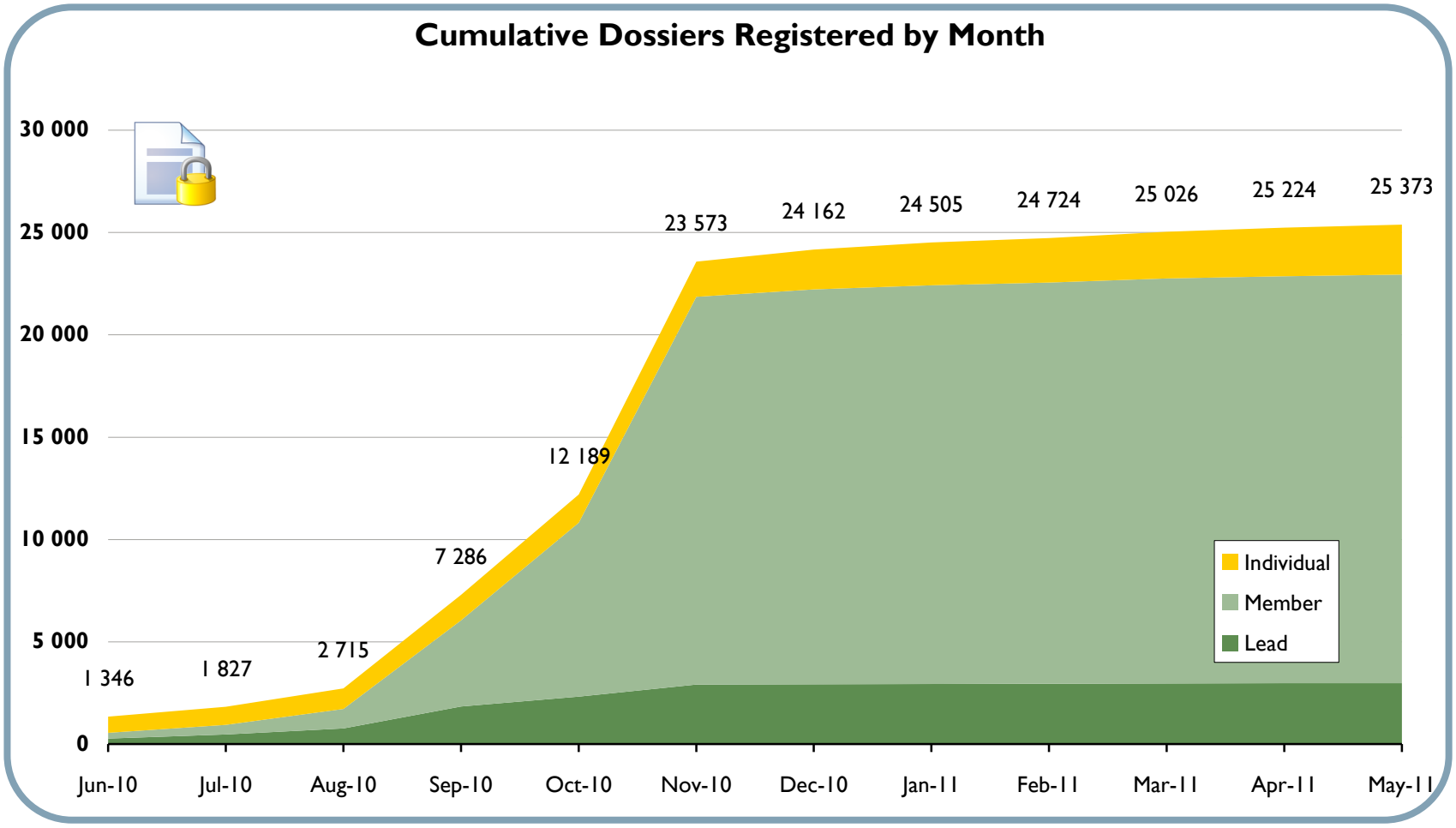
= R-IT implementation * IUCLID ** online

= 'Manual' implementation

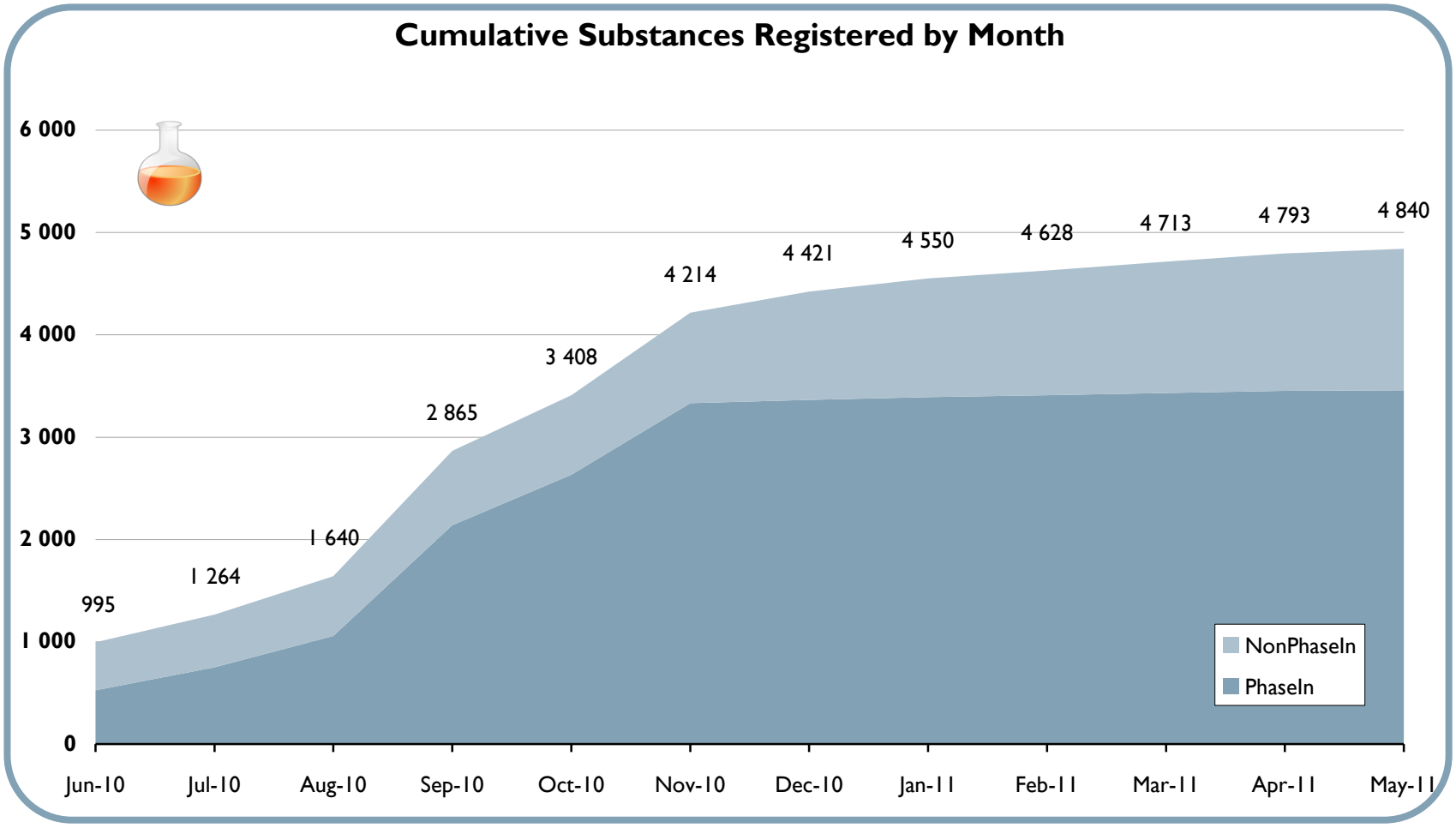
Industry REACH Submissions



Registration I



Registration II



Classification & Labelling

- By 3 January deadline:
  - more than 3 million notifications (3 114 835)
  - submitted by ca. 6600 companies
  - 107 000 distinct substances

Breakdown by country	
Germany	26%
United Kingdom	16%
France	9%
Italy	6%
Belgium	6%
Spain	4%
Poland	4%
The Netherlands	4%

Time period: 20/01/2009 – 03/01/2011

Since 3 January 2011

- Notifications have continued
  - more than 150000 additional notifications
  - ca. 3500 additional distinct substances
  - ca. 1000 additional notifiers

- Same distribution by country

Time period: 05/01/2011 – 13/05/2011

New submission types 2011

- DU report (Art 38) = 16 to date
- Notification of Substance in Article = 191
- Application for authorisation = 0

Dissemination Progress

ECHA Website > ECHA CHEM > Registered Substances

	Registered	Disseminated	
Substances §			
Phase-in	3 450	3 272	*95%*
Non-phase-in	1 390	422	*30%*
Total Substances	**4 840**	**3 694**	***76%***
Dossiers			
Lead	2 978	2 882	*97%*
Member	19 965	1	*0%*
Individual	2 430	1 188	*49%*
Total Dossiers	**25 373**	**4 071**	***16%***

Data as of 31st May 2011

§ The numbers for 'Substances' are determined automatically using unique substance identifiers (EC Number / Provisional List Number). As substance identities are verified the numbers for substances may change.

Content

- REACH industry submissions
  - New and future submission types
  - Update on submission numbers and dissemination

- **ECHA priorities for 2011 – 2012**

- 2013 REACH Deadline
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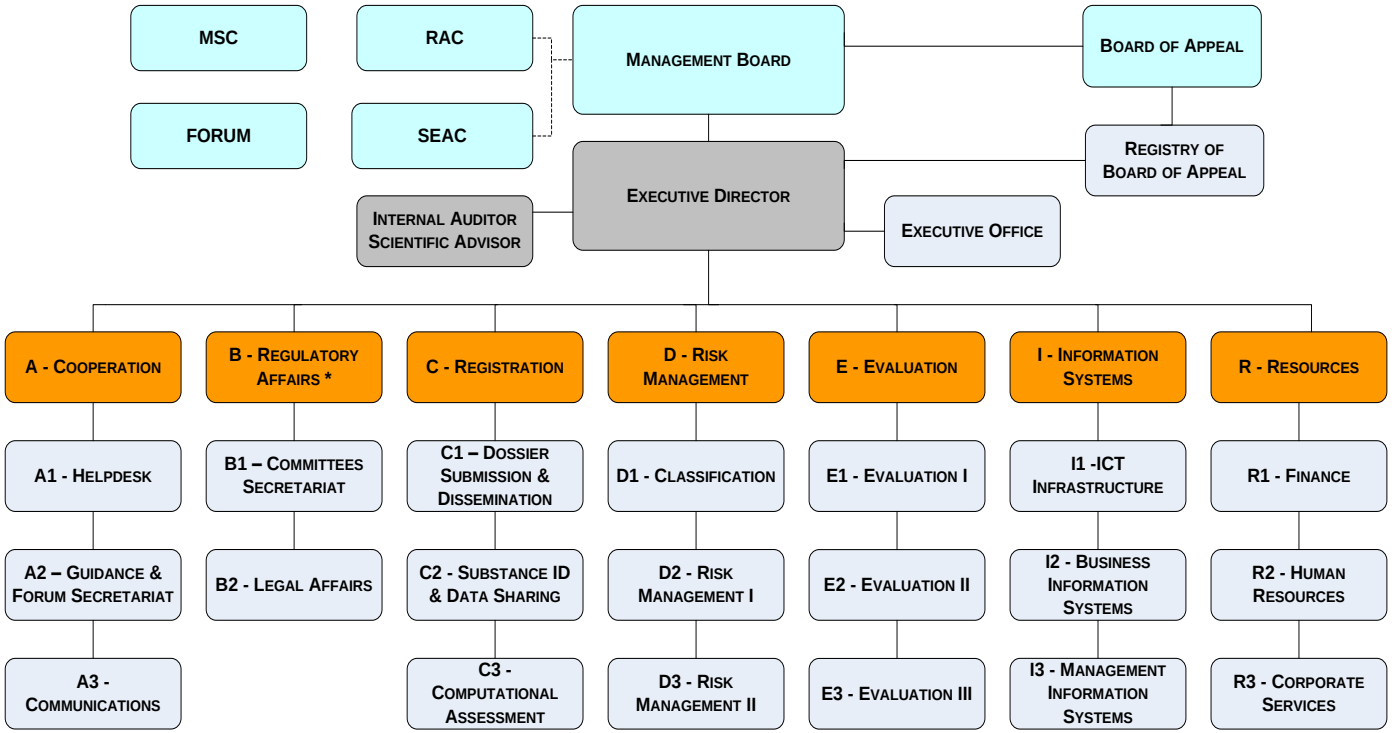
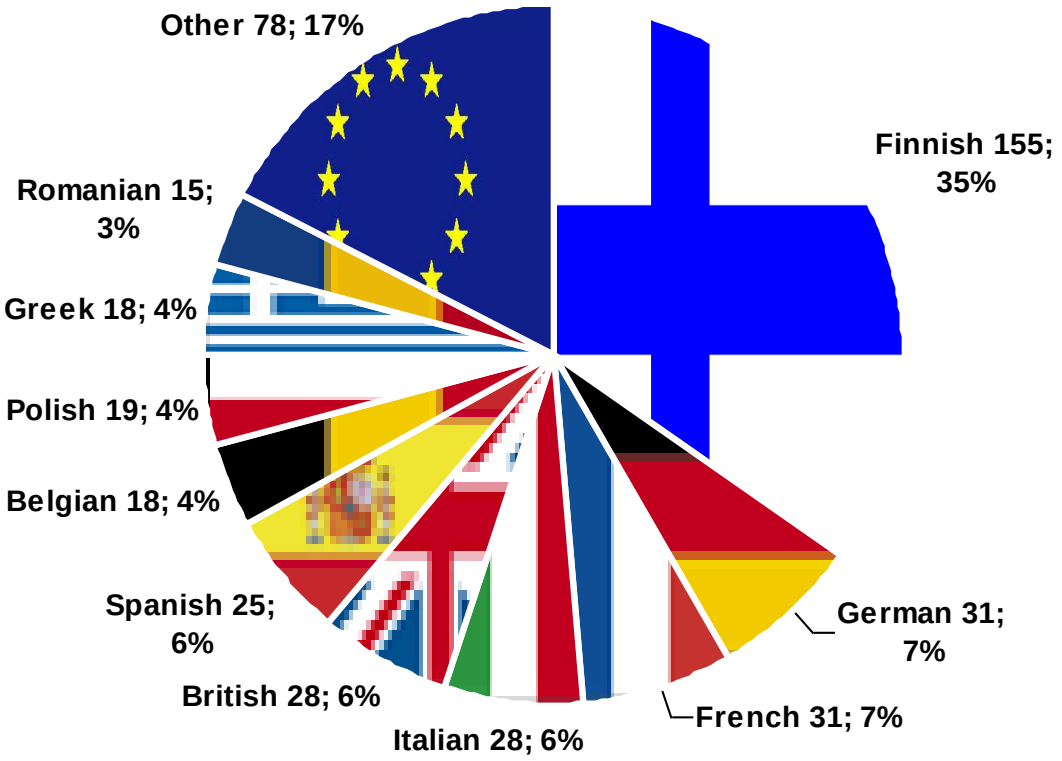
ECHA Organigramme 2011



* ALSO IN CHARGE OF COORDINATING REGULATORY OPINION- AND DECISION-MAKING

ECHA staff

- 446 (31 March 2011)
- From 25 EU countries (no Cypriots or Luxembourgish yet)



Priorities for 2011

- Focus on evaluations
  - Process 550 dossier evaluations with focus on testing proposals
  - First draft of the CoRAP list with up to 40 substances
- Dissemination
  - Publish public information from all registrations
  - C&L inventory
  - publish public version / maintain inventory after the deadline
- Substantial increase of Committee work on SVHC and CLH dossiers, restrictions and possibly authorisation

Priorities for 2011 - cont'd

- Authorisation
  - Two updates of the candidate list with up to 40 substances
  - 10 SVHC dossiers prepared by ECHA upon request of COM
  - New recommendation for the authorisation list
  - Readiness to process authorisation applications ensured
- Helpdesk & Guidance
  - Further development of advisory capacity in particular with a view to avoiding unnecessary animal testing and simplifying guidance
  - Emphasis will shift to helping "smaller" companies to prepare for 2013 deadline
  - Needs and feasibility study on translations for SMEs (incl IT tools)

Priorities for 2011 - cont'd

- Scientific IT tools – further development and/or revamping based on the experience gained in 2010
- Stepping up advice to COM and MS, in particular on nanomaterials & endocrine disruptors
- First 5-yr report on operation of the REACH Regulation
- First 3-yr report on non-animal test methods
- Rigorous budget discipline – fully self-financed by fees
- Prepare for new biocides regulation

Priorities 2012-2014

- **Optimise Guidance, IT tools and helpdesk** for 2013 deadline and drawing lessons for next deadline.
- **Complete the dissemination** portal & the assessment of confidentiality claims from the 2010 and 2013 deadlines
- Manage effectively the **proposals from MSCAs and industry for CLH** & maintain and improve the C&L Inventory
- **Focus on dossier evaluation** to meet deadlines and the compliance check target of 5% for highest tonnage bands
- Play **central role in substance evaluation** by prioritising substances, coordinating the process and supporting MSCAs
- **Implementation of authorisation processes** & capacity for up to 5 SVHC dossiers per year upon the COM request

Priorities 2012-2014 - cont'd

- Biannual update of the **Candidate List** & annual **recommendation to COM for the Authorisation List**
- Timely processing of increasing number of **authorisation applications**
- Support effective **enforcement via Forum**
- Interact and engage with the **academic and regulatory science communities**
- Enhance communications with the general public and SMEs & reinforce involvement of stakeholders
- Support COM in review/revision of REACH
- Prepare and implement the new **Biocides and PIC Regulations** (preparations subject to the availability of additional resources)

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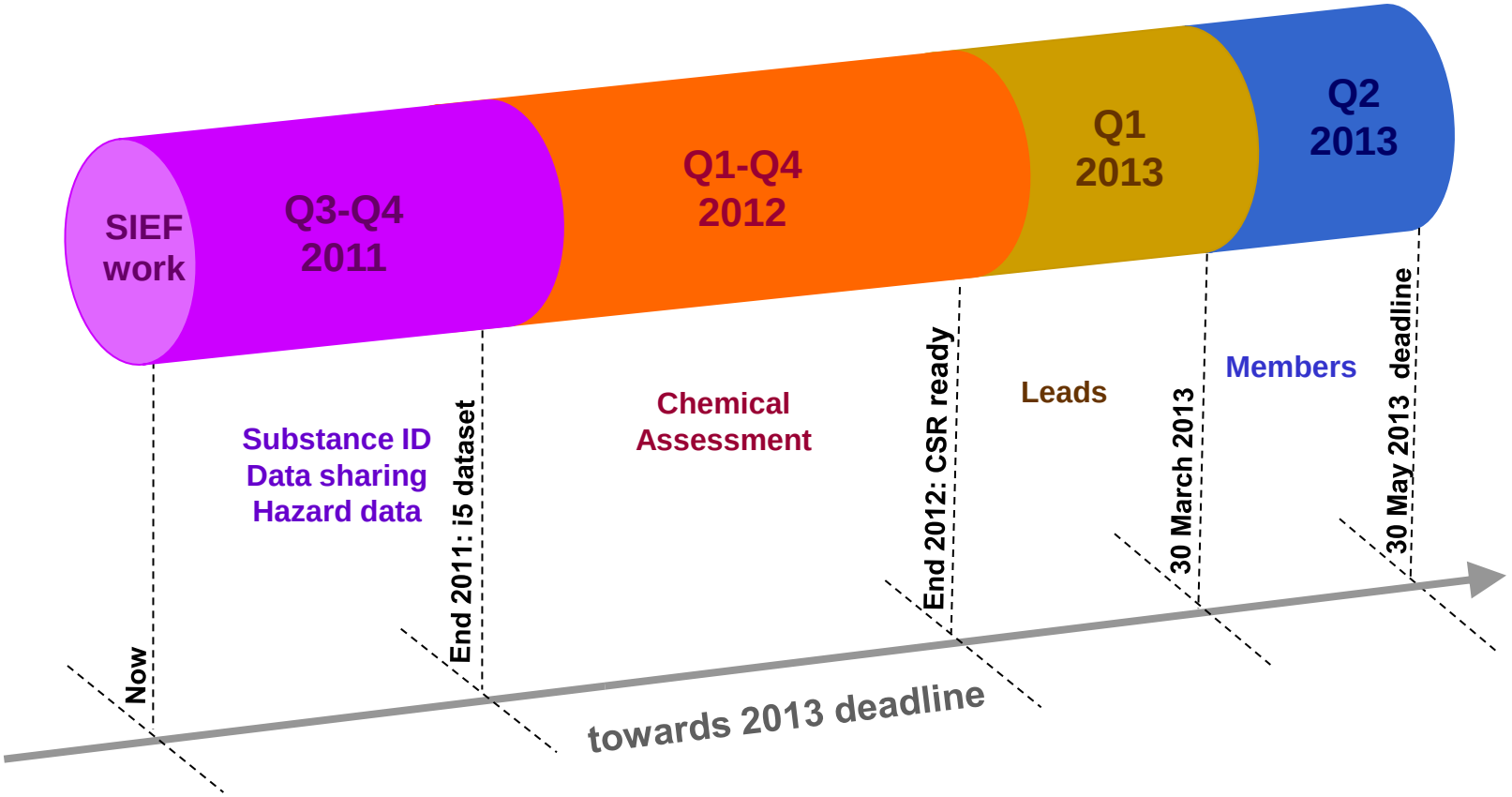
Two years to the next deadline!

- Substances concerned
  - Phase-in substances manufactured or imported in quantities **over 100 tonnes per annum** per manufacturer or importer

- If your substance falls into this category, start preparing immediately

- Non EU manufacturers, make sure that your Only Representative gets ready

Countdown: optimal situation



2010 Lead Registrants

- You hold obligations to the next registrants wishing to register the same substance as you
  - You remain Lead of the joint submission beyond 1 June 2018
  - Inform (pre-)SIEF members of your existence
  - Ensure that data sharing conditions are fair, transparent and non discriminatory
  - Newcomers only required to share costs of data needed for their tonnage band: **Annex 10 not required**
  - You will need to distribute the tokens to new registrants

2013 Registrants

- Is your substance already registered?
  - ECHA website:
    - http://apps.echa.europa.eu/registered/registered-sub.aspx
    - Some substances may not appear on the list, if the registrant has requested confidentiality on the name
  - Verify within SIEF or industry associations
  - Contact the Lead Registrant
  - Verify whether you have the same substance
  - Start data sharing negotiations
  - Ask for your token to join the “joint submission”

2013 Registrants

- Your substance is not registered yet
  - Some 2013 SIEFs already exist, the Lead may have been nominated already
    - Verify on ECHA website or with industry associations
  - If not, start the process of SIEF formation
    - Verify whether a SIEF Formation Facilitator (SFF) exists for your substance in REACH-IT (nb. some poor experiences in this area)
    - If not, contact pre-SIEF members to identify those registering in 2013

New SIEFs

- Verify substance sameness before forming the SIEF
- Nominate a Lead Registrant
- Collect data needed for Annexes 6-9
  - target **end 2011**
- Inform your downstream users
  - their uses must be known to you before **30 May 2012**
- Prepare Chemical Safety Assessment
  - target **end 2012**

New Leads

- Nominate yourselves to ECHA to benefit from special services, e.g. webinars https://comments.echa.europa.eu/Comments/LeadRegistrantNomination.aspx
- Inform the supply chain that your SIEF is functioning and your substance will be registered

Practical recommendations

- Make sure you are aware of all tools and guidance available
  - Some tools are critical to the success of your submission: IUCLID 5, Technical completeness check, fee calculator, & dissemination tools (http://www.iuclid.eu/)
  - Use Chesar for your chemical safety assessment and your CSR (http://chesar.echa.europa.eu/)
  - Dossier submission (http://echa.europa.eu/reachit_en.asp)
  - Data submission manuals (http://echa.europa.eu/reachit/dsm_en.asp)
  - Understanding of the dossier processing by ECHA (http://echa.europa.eu/reachit/dossier_processing_en.asp)

Thank you for your attention!