REACH Registration

9th CONCAWE Symposium

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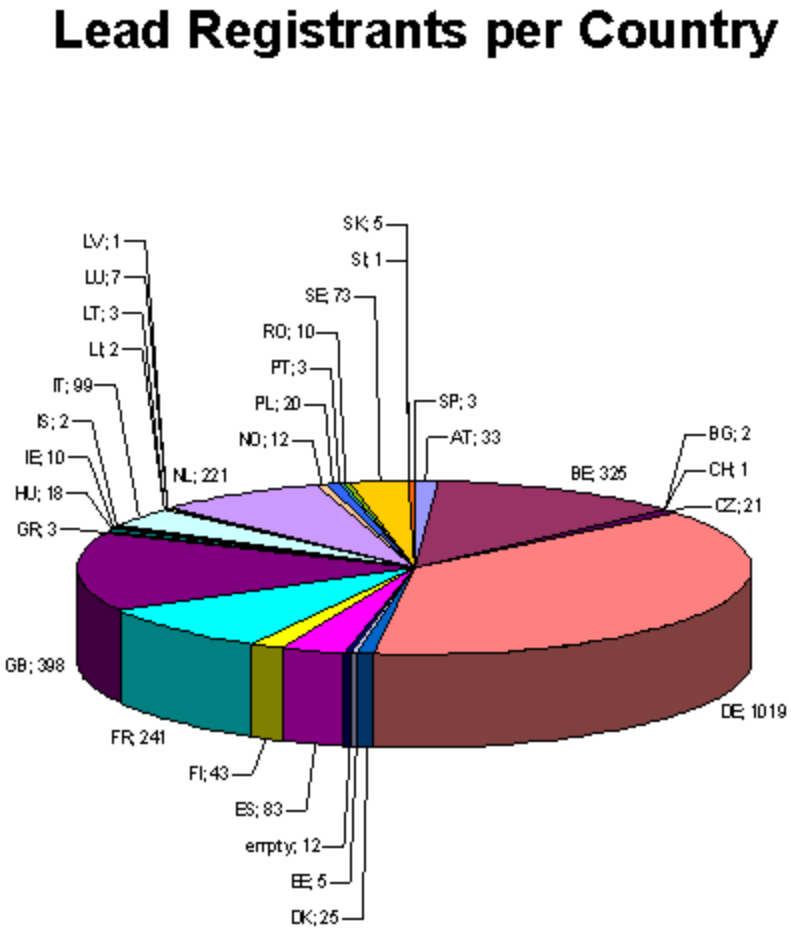
REACH - groundbreaking legislation

- REACH Regulation is a product of an almost 10 years legislative process
- Past: Authorities to prove chemicals pose risk
- REACH: Industry to prove chemicals are safe
- Ensures high level of protection of human health and the environment
- Promotes alternative methods for assessment and testing of chemicals
- Enhances competiveness and innovation
- Most ambitious chemicals legislation in the world
- Benchmark for our OECD partners

Registrations outlook for 2010

- Lead Registrants
  - ~ 2500 notified to ECHA
  - – Germany, UK, Belgium, France Netherlands most active
- Substances
  - ~ 4900 phase-in substances expected (inventory on ECHA‘s website)
- Dossiers
  - ~ 25 000 dossiers planned
  - ~ 38 000 dossiers estimated



Number of Submissions

Dossier type	Accepted for Processing		Successfully Completed	
	Total*	For the 2010 deadline**	Total*	For the 2010 deadline**
Registration	19,702	17,174	14,265	12,312
Transported Isolated Intermediate	3,544	2,692	2,699	1,979
On-Site Isolated Intermediate	1,429	857	1,037	492
Total	24,675	20,723	18,001	14,783

*Total includes dossier updates during the period.

**Dossiers submitted by companies indicating a phase-in substance meeting the criteria for the 2010 deadline

Number of Substances

Substances Registered under REACH & submitted before 1 Dec 2010 §

	From 1 Jun '08 to 30 Nov '10 Total	Phase-in	
Subtotal - Substances as Full Registrations *	2 773	2 274	82%
Subtotal - Substances Registered as OSII *	900	827	92%
Subtotal - Substances Registered as TII *	1 487	1 170	79%
Total Unique Substances Registered	**4 074**	**3 218**	**79%**

Data as of 03-Mar-11 at 02:30

§ **NB:** Substances Registered indicates substances fully processed by ECHA after 1 Jun '08 and issued with a reference number

* **Note:** Substances can be registered as full registrations and / or OSII and / or TII

Breakdown of Submissions

	% Accepted for Processing	Ratio Member/Lead**
Joint - Lead Registrant	**12%**	
Joint - Member Registrant	**82%**	**6.7**
Individual Registrant*	**6%**	

* Includes individual submissions for non-phase in substances

** Number of Member Registrants for every Lead Registrant

Technical Completeness Check Failure Rates

Dossier type	For the 2010 deadline*
Registration	1%
Transported Isolated Intermediate	2%
On-Site Isolated Intermediate	1%

* Dossiers submitted by companies indicating a phase-in substance meeting the criteria for the 2010 deadline

Dossiers by Company Size & by Only Representatives

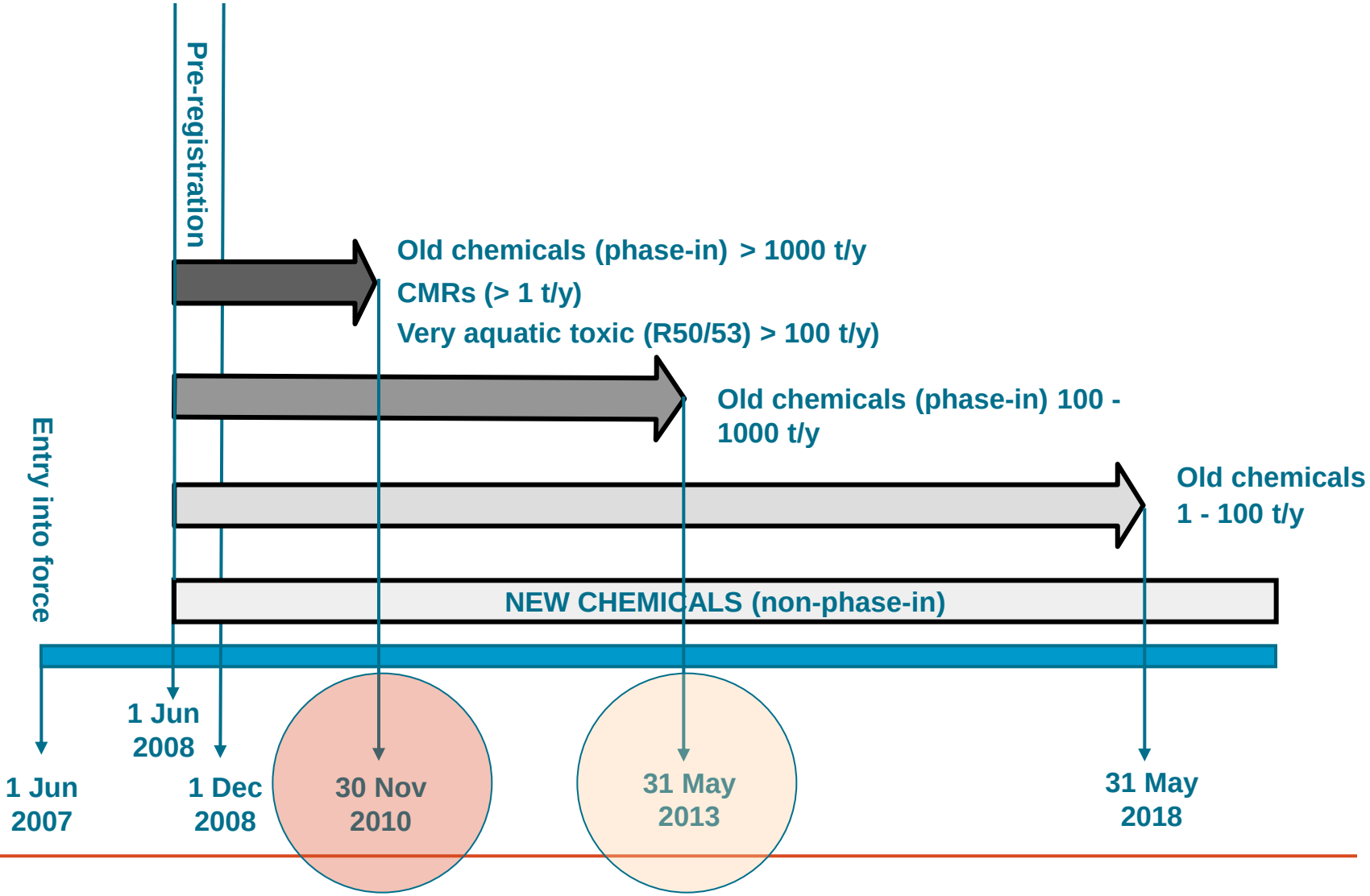
Company size	Accepted for Processing For the 2010 deadline*
Large	86%
Medium	9%
Small	4%
Micro	1%

* Dossiers submitted by companies indicating a phase-in substance meeting the criteria for the 2010 deadline

	Accepted for Processing For the 2010 deadline*
Only Representative	19%

* Dossiers submitted by companies indicating a phase-in substance meeting the criteria for the 2010 deadline

Next registration deadlines looming



Registration experiences

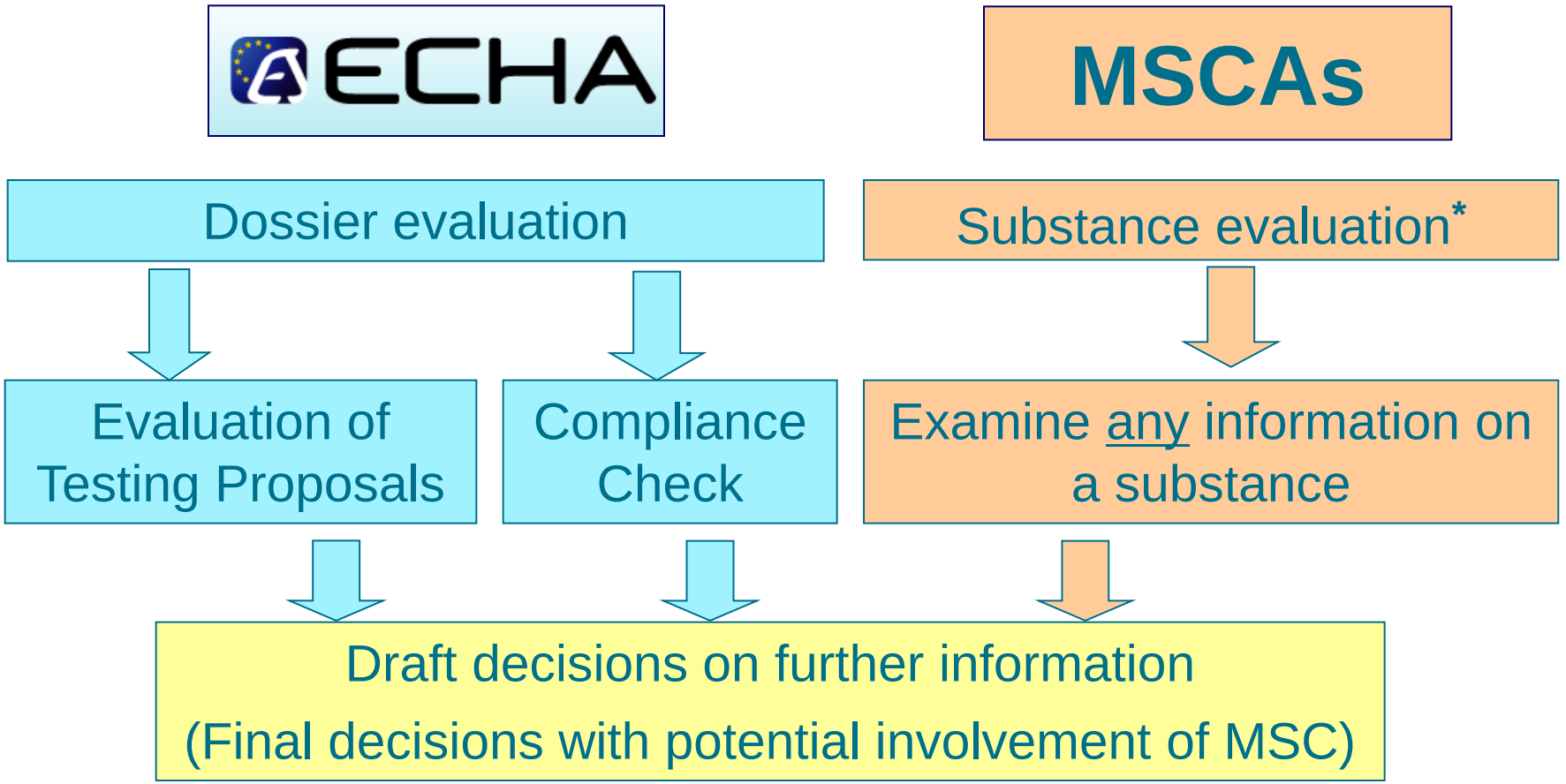
- Major challenge – major success
- Huge work for industry – excellent commitment
  - Especially cooperation in SIEF's very demanding
- In ECHA key challenges of 2010 accomplished
  - Stability of IT tools ensured
  - Well trained staff
  - Contingency planning in place
- Joint effort
  - ECHA, MSCA's, national helpdesks & Commission with close cooperation with industry associations via Directors Contact Group

Lessons learned

- DCG to be continued with a new mandate
- Estimations/predictions – a new strategy to estimate the numbers of substances and dossiers is needed → DCG
- DCG document also under development on lessons

  Key areas include:
  - Stability of the Guidance = ≥ 6 months moratorium recommended
  - Stability of interpretation and therefore IT requirements
  - Further work needed to simplify process and IT tools for SME's; under analysis
  - SIEF operation to be improved by best practices
  - Improve workability of solutions for exceptional situations
  - Improve communication in supply chains & address shortcomings

Evaluation



* Process in preparatory phase, evaluation to be started in 2012

MSCA = Member State Competent Authority; MSC = Member State Committee

Dossier Evaluation – challenge of next years

- About 1000 Compliance Checks on HPV's to meet the 5 % target
  - Selection is concern driven & random
- 580 dossiers with Testing Proposals received
  - Covering 1500 hazard endpoints
  - All of these to be examined by Dec 2012
- ECHA carries out scientific evaluation & submits draft Decisions requesting further data from registrants
- Industry and, later, MSCAs can comment on draft Decision
- MSC process if MSCA's submit comments
- Major workload for ECHA Secretariat, MSCA's, and MSC

Tips for successful registration

- Identity of registered substance shall be clearly described
- Adaptation to standard testing regime must meet conditions of Annex XI or column 2 of Annexes VII – X of REACH ➔ sufficient justification should be provided
- Robust study summaries should contain sufficient level ➔ allow independent assessment
- Classification and labelling should be in line with hazards identified or harmonized classification and labelling
- Testing proposal shall be submitted for tests of Annex IX and X before undertaking it ➔ potential enforcement actions
- Obligation to share data and costs on vertebrate testing before registering
- Use Chesar for arriving at DNEL's and PNIC's

Substance evaluation will start

- ECHA is developing the first list of substances
  - MSCAs can identify candidates & ECHA add others from other REACH processes based on a priority setting
  - CoRAP ‘rolling’ 3-year list – proposal by end of 2011 – adoption Feb 2012
- MSCA’s to inform ECHA about capacity for evaluation
- Substance evaluation is to clarify risk (i.e. to get extra hazard &/or exposure data) with a view to using regulatory instruments

ECHA Helpdesk, Guidance & Communication

- **Helpdesk peak workload in 2010**
  - **9953 questions resolved**
    - 15.1% REACH and 3.8% on CLP matters
    - 60.7% on IT tools (REACH-IT, IUCLID 5, CHESAR)
    - Rest (20.4%) on standard cases of dossier submissions
- **HelpNet Secretariat – supporting national helpdesks:**
  - **Frequently Asked Questions: 7 Q&As published in 2010**
  - **Meetings and trainings**
- **ECHA publishes guidance documents for national authorities and industry see: http://guidance.echa.europa.eu/**
- **Communications – Translations**: 190 documents available online in EU languages

FORUM - For Exchange of Information on Enforcement

- Network of national enforcement authorities
- Exchange of information: share good practice
- Coordinate harmonised activities related to enforcement

- Increased momentum for effective enforcement in 2011
  - REACH-EN-FORCE 2 focused on formulators for supply-chain related REACH & CLP obligations
  - Preparation of 3th joint project with customs
- Roll-out of RIPE IT tool for enforcers in June

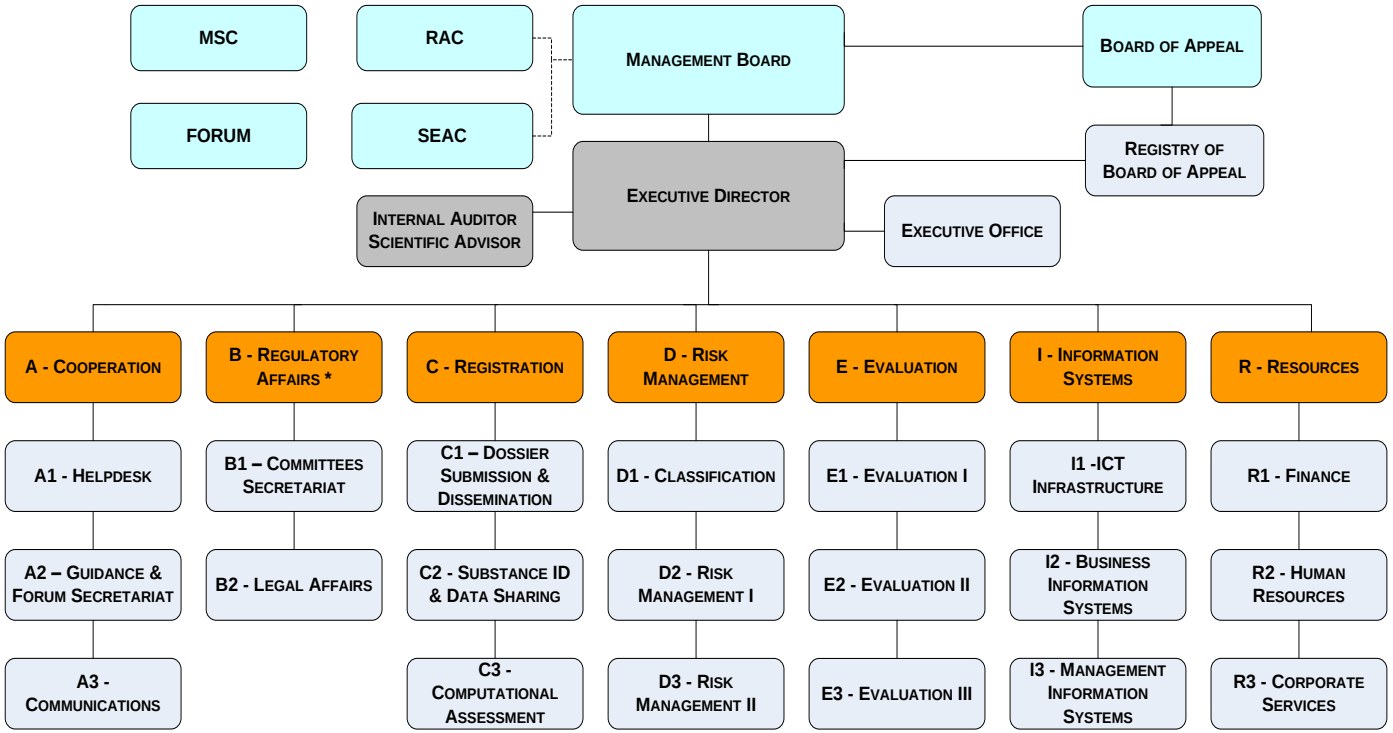
Reviews & reports on REACH

- First set of MSCAs Article 117(1) 5-year reports submitted to Commission in 2010
- First ECHA Article 117(2) 5-year report to Commission by 1/6/11 on operation of REACH with proposals on improving operability
- First ECHA Article 117(3) 3-year report to Commission by 1/6/11 on non-animal test data
- Larger review initiated by Commission including lessons learnt with attention to costs & administrative burden & impacts on innovation
- Commission first Article 117(4) report by 1/6/12 on experience on operation of REACH & funding for alternative test methods
- Review of ECHA by 1/6/12 under Article 75(2)
- Article 138 reviews by Commission: e.g scope of REACH & data for low tonnage registration (by 1/6/12), polymers (as soon as practicable) etc

Future work for ECHA

- New tasks for ECHA
  - Proposal for Biocides Regulation in co-decision
  - Export and import of dangerous chemicals (PIC)
- Co-operation with other EU agencies & non-EU regulators: US EPA Statement of Intent & Canada signed & Australia, Japan planned
- Scientific challenges
  - Non-test methods
  - Nanomaterials
  - Endocrine disruptors
  - Mixture toxicity

ECHA Organigramme 2011



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

Thank you for your attention!