

# **REACH - Registration and enforcement**

***Latest trends in REACH  
and CLP***

*Tokyo 30 March 2010*

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ECHA – Guidance and helpdesk*

# REACH and ECHA

- REACH Regulation entered into force 1 June 2007
- ECHA was created in this regulation
- ECHA became operational 1 June 2008
- Building up phase till 2010
  - Number of staff now ~ 380 will grow by the end of 2010 to ~ 490
- ECHA is managing the implementation of the REACH Regulation 1907/2006
  - ECHA is not a policy maker

# ECHA – the coordinator of REACH implementation

## MISSION

- **Manage REACH and CLP tasks**
- **Ensure a consistent implementation at EU/EEA level**
- **Provide with the best possible scientific advice on safety and socio-economic aspects of the use of chemicals**
- **Ensuring a credible decision-making process, using the best possible scientific, technical and regulatory capacities**
- **Manage guidance, IT tools and data bases**
- **Support national helpdesks and provide advice to registrants**
- **Make info on chemicals publicly accessible**

## ORGANISATION

- **Management Board**
- **Executive Director**
- **Secretariat (currently staff of 350)**
- **Three Scientific Committees**
- **Forum on Enforcement**
- **Networks (Help Net, RCN, SON)**
- **Board of Appeal**

# REACH: Main features

- New registration requirements for old substances.
- Data sharing as a general principle.
- Industry to generate information about substances and adopt risk management measures.
- Increased obligations to transmit information down the supply chain.
- New authorisation procedure.

# REACH – Registration

## Current status


# Registration of phase-in substances

## First deadline **30 November 2010**

- Substances  $\geq 1000$  tonnes per year
- CMR category 1 and 2 substances  $\geq 1$  tonne per year
- Very toxic to the aquatic environment (R50/53)  $\geq 100$  tonnes per year

Need to have pre-registered the substance to benefit from extended registration deadline(s)

# REACH: Registration in practise



Create the  
Dossier in  
IUCLID 5



Submit the  
Dossier in  
REACH-IT

Business  
Rules

TCC and  
Invoicing

Pass/Fail  
Decision

**INDUSTRY**

**ECHA**

**Business rules** are a set of pre-requisites that must be fulfilled before REACH-IT can establish that the dossier can be handled properly and that the required regulatory processes can be successfully carried out.

Three main reasons for failure:

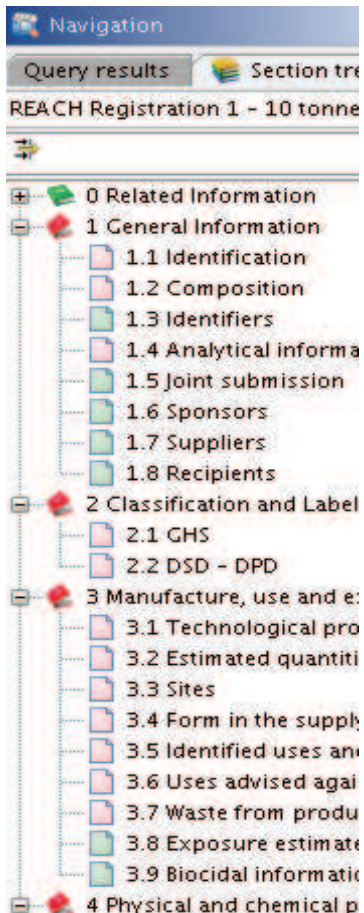
- **Format** - e.g. wrong IUCLID 5 template
- **Administrative** - e.g. registration update does not provide a valid reference number
- **Technical** – REACH-IT cannot ‘understand’ the substance identifiers



## Further information:

- Data Submission Manual 8: Business Rules validation
  - Provides list of all business rules and how to avoid failures
- Forthcoming webinar on business rules on 22 April 2010

# Technical Completeness Check



- The minimum information required in a dossier is dependant on the tonnage band covered by the registration.
- In case the registration is incomplete (TCC fails), ECHA sends a request for further information and sets a deadline to resubmit a complete dossier.

# Dossier processing at ECHA

## Check of Business Rules

(ensure that dossiers can be processed by the system)



Completeness check:

**Technical Completeness  
Check (TCC)**

**+ Check if payment was  
received in full**



(Request to complete dossier, if needed  
+ 2<sup>nd</sup> Completeness Check)

pass ↓

↓ fail

**Registration number**

**Rejection**

# Registration Dossiers

Phase-in	Dossier Type	Accepted for processing	Technically complete	Invoice paid + reg. no. given
1.Phase-in substances	2.Registration of on-site isolated intermediates	101	83	70
	3.Registration of transported isolated intermediates	93	70	57
	4.Registration	215	170	146
	<b>Total</b>	<b>409</b>	<b>323</b>	<b>273</b>
2.Non Phase-in substances	2.Registration of on-site isolated intermediates	67	46	42
	3.Registration of transported isolated intermediates	349	249	230
	4.Registration	340	197	183
	<b>Total</b>	<b>756</b>	<b>492</b>	<b>455</b>
<b>Overall total</b>		<b>1165</b>	<b>815</b>	<b>728</b>

# Registrations by tonnage

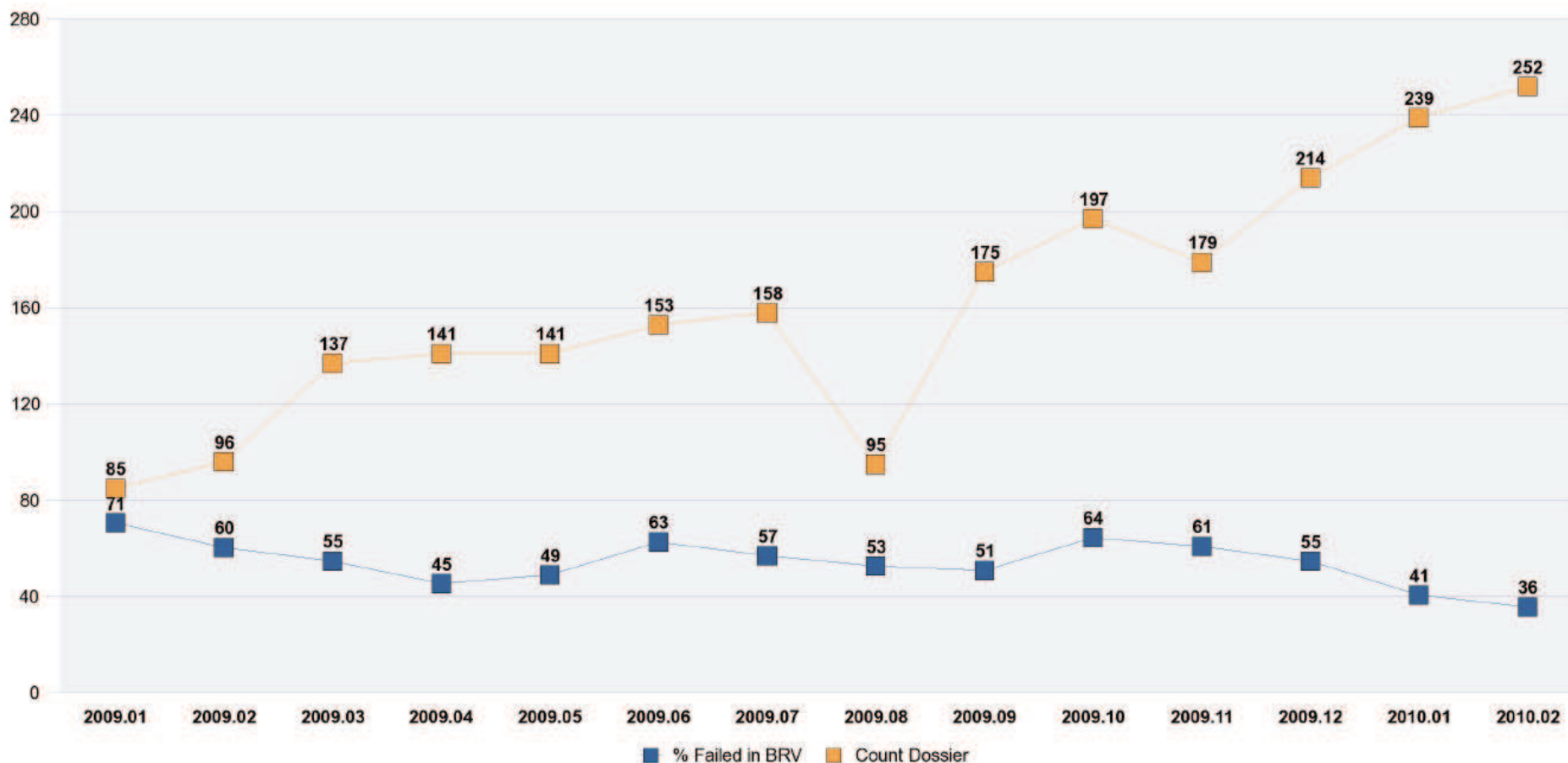
Registration type	Tonnage	Accepted for processing	TCC Passed	Complete
OSII	1to10	23	14	14
	Over10	153	123	102
Reg	100to1000	47	32	29
	10to100	75	47	43
	1to10	284	163	154
	Over1000	142	118	100
	10to1000	236	175	157
TOSII	1to10	160	112	103
	Over1000	61	44	35
	<b>Sum:</b>	<b>1181</b>	<b>828</b>	<b>737</b>

**Data from 01/06/2008 till 22/02/2010**

Note: registration dossiers that combine a registration for e.g. an on-site isolated intermediate (OSII) and/or transported isolated intermediates (TOSII) were counted as separate registrations, data is indicative.

# Registration dossiers – accepted for processing

% failed BRv by 'Submitted registrations' and 'Month' (till 22/02/2010)



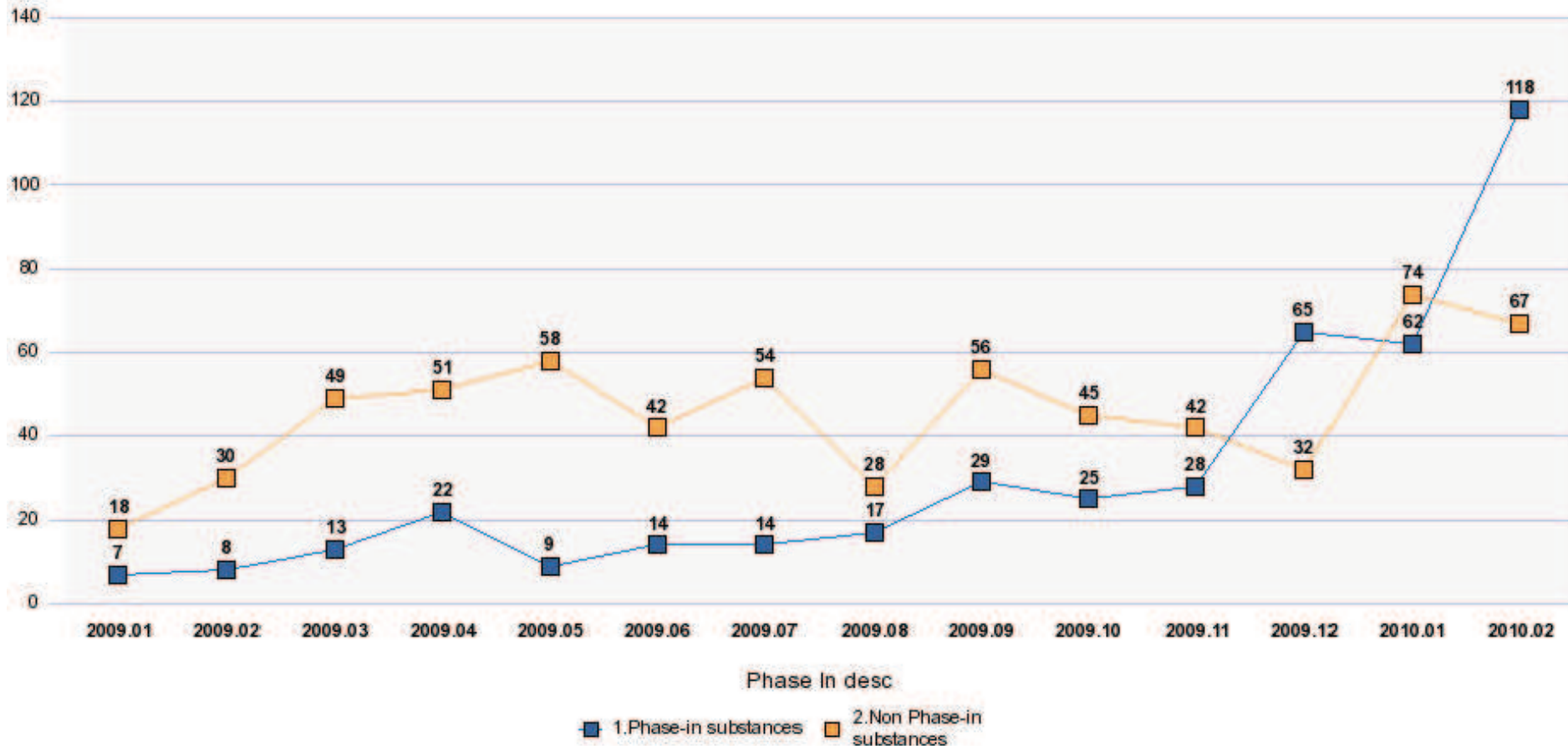
Note: the % failed in BRV is calculated from the number of submitted dossiers, data is reported by submission date, data is indicative.

<http://echa.europa.eu>

The clock  
is ticking

# Registration dossiers

Registration dossiers received by Phase-in and Month (till 24/02/2010)

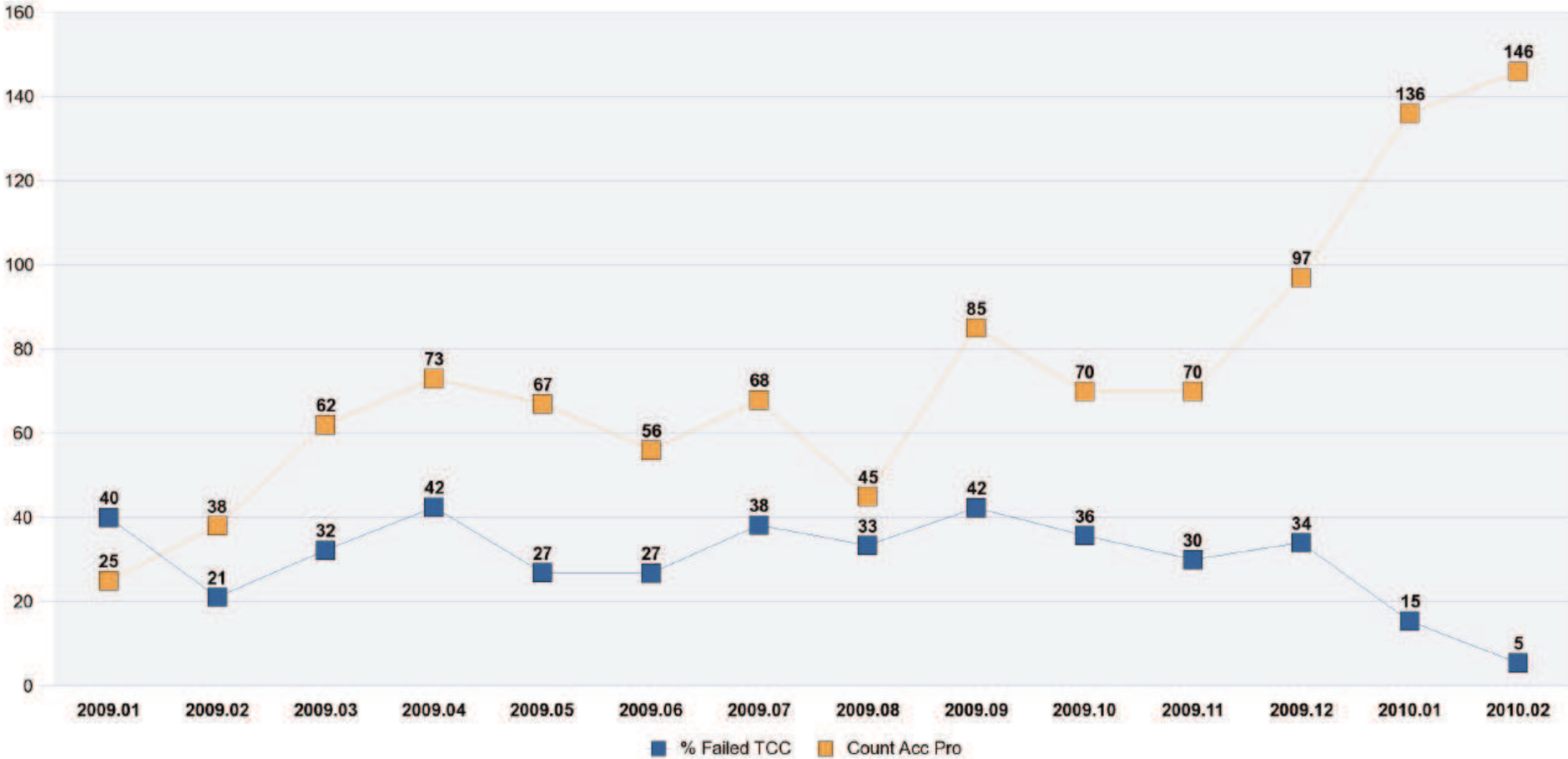


Note: numbers are derived from registration dossiers accepted for processing (after BRv).

# Registration dossiers and TCC



% failed TCC by 'Registrations accepted for processing' and 'Month' (till 22/02/2010)



Note: the % failed in TCC is calculated from the number of dossiers accepted for processing, data is reported by submission date, data is indicative.

<http://echa.europa.eu>

The clock is ticking



## ➤ Aim

- Verify compliance with information requirements
- Check adequate justifications for adaptations

## ➤ Which dossiers

- Only selected dossiers (Article 41)
- At least 5% of dossiers from each tonnage band

# Key messages - Recommendations/1

## Evaluation Report 2009 published 1 March 2010

- The identity of the registered substance and the substance used for testing were not clearly described (precise composition and impurities)  $\implies$  Provide sufficient information on substance identity
- Testing was omitted based on inappropriate or poorly justified scientific arguments  $\implies$  Provide adequate justification for QSAR, Read across, grouping and weight of evidence cases

# Key Messages - recommendations/2

## Evaluation Report 2009 published 1 March 2010

- The summaries of test reports did not include enough detailed information ⇒ Ensure good quality for robust study summaries
- Shortcomings related to the risk assessment and the recommended risk management measures ⇒ Check the exposure scenarios and CSR for consistency and completeness
- Omission of the classification and labelling information specified by the CLP Regulation.

# REACH – Dissemination of information

- According to REACH legislation, ECHA will provide public access to (non-confidential) information on registered substances
  - Accessible and useful also to countries outside the EU
- Even publicly available information will be highly technical
- A dissemination website is being developed for 2010
- Other ECHA initiative: hosting the OECD Global Portal

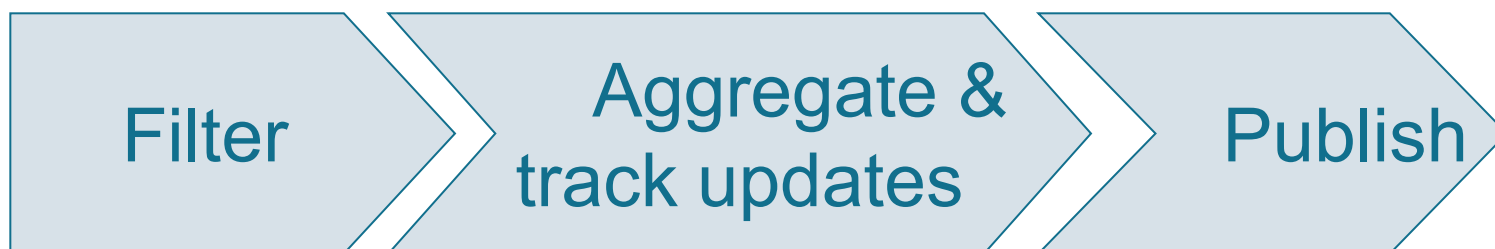
# Dissemination of information

- ECHA shall provide **free public access** to information on registered substances
- A '**dissemination**' website is being produced for 2010 which will include (non-confidential) information
  - ❑ from registration dossiers
  - ❑ on notified substances
  - ❑ collected under previous legislation
  - ❑ other REACH processes
  - ❑ C&L data
- Other ECHA initiative:  
future hosting **OECD Global Portal**

Substance identification			
Substance name	CAS number	EC number	Responsible MS
<a href="#">Tetrachloroethylene</a>	127-18-4	204-825-9	UK
<a href="#">Styrene</a>	100-42-5	202-851-5	UK
<a href="#">Ethylbenzene</a>	100-41-4	202-849-4	DE
<a href="#">Chloroform</a>	67-66-3	200-663-8	FR
<a href="#">2-ethoxyethanol</a>	110-80-5	203-804-1	DE
<a href="#">Amines, tallow alkyl</a>	61790-33-8	263-125-1	DE
<a href="#">Trisodium nitriotriacetate</a>	5064-31-3	225-768-6	NL
<a href="#">Tert-butyl hydroperoxide (TBHP)</a>	75-91-2	200-915-7	NL
<a href="#">Pitch, coal tar, high-temp.</a>	65996-93-2	266-028-2	NL
<a href="#">4,4'-isopropylidene-diphenol (Bisphenol-A)</a>	80-05-7	201-245-8	UK
<a href="#">Trisodium hexafluoroaluminate (Synthetic)</a>	13775-53-6	237-410-6	DE
<a href="#">Trisodium hexafluoroaluminate (Natural)</a>	15096-52-3	239-148-8	DE

# How are dossiers processed

- IT-application for dissemination of information from registration dossiers is developed in-house



- 129 substances, registered before 01.10.2009, listed in EINECS or dangerous without a confidentiality claim on the substance name published on 18 December 2009

# Tips for registrants

- Discuss dissemination in the SIEF
- Do not include confidential information (e.g. company name) in public fields (e.g. guidance on safe use)
- Avoid referring to attachments in public fields (e.g. in guidance on safe use)
- Carefully review your dossier before submission: ECHA cannot make changes to the filtered dossier; resubmission is needed if you have concerns about publication
- The manual for dissemination (Q1 2010) and the IUCLID plug-in for dissemination (Q2 2010) will be available soon



# REACH – Review of Annex II

# Review of Annex II of REACH

- Draft by the European Commission
- Positive vote in the REACH Committee 9 Dec 2009
- Scrutiny of the European Parliament and the Council until 13 Apr 2010
- If no opposition, swift adoption by the Commission

# Review of Annex II of REACH

## ➤ Proposed section 1.1 of Annex II

- Part of registration number referring to individual registrant may be omitted by distributor or a downstream user if this supplier
- assumes the responsibility to provide the full registration number upon request for enforcement purposes, or if not available to him, to forward the request to his supplier

and

- provides the full registration number to the enforcement authority within seven days (upon request of this authority or forwarded by his recipient), or, if not known to him, shall forward the request to his supplier and at the same time inform the enforcement authority thereof

# REACH – ECHA support for registrants

# From pre-registration to pre-SIEF

## ➤ **At the end of pre-registration**

- ❑ 2 750 000 pre-registrations
- ❑ 65 000 companies
- ❑ 146 000 substances pre-registered

## ➤ **The list of substances**

- ❑ Published 19 December 2008, updated 27 March 2009
- ❑ Information from data holders

## ➤ **Starting from a pre-SIEF**

- ❑ REACH-IT brings companies that pre-registered the “same” substance together in a “pre-SIEF” webpage
- ❑ You can see contact details of other pre-registrants and data holders
- ❑ You can start to look for “similar to” substances

# Forming SIEFs – a challenge

- Crucial to the success of REACH
- Essential if we are to minimise unnecessary testing and costs to industry
- Getting started is a challenge and is urgent
- ECHA is doing what we can but industry to lead
- New awareness campaign “the clock is ticking... form your SIEF now”
- Dedicated web section for support

[http://echa.europa.eu/sief\\_en.asp](http://echa.europa.eu/sief_en.asp)

- ❑ *Getting Started in SIEFs – Top Tips*
- ❑ *SIEF – key principles.*
- ❑ ....

# SIEF Awareness Campaign

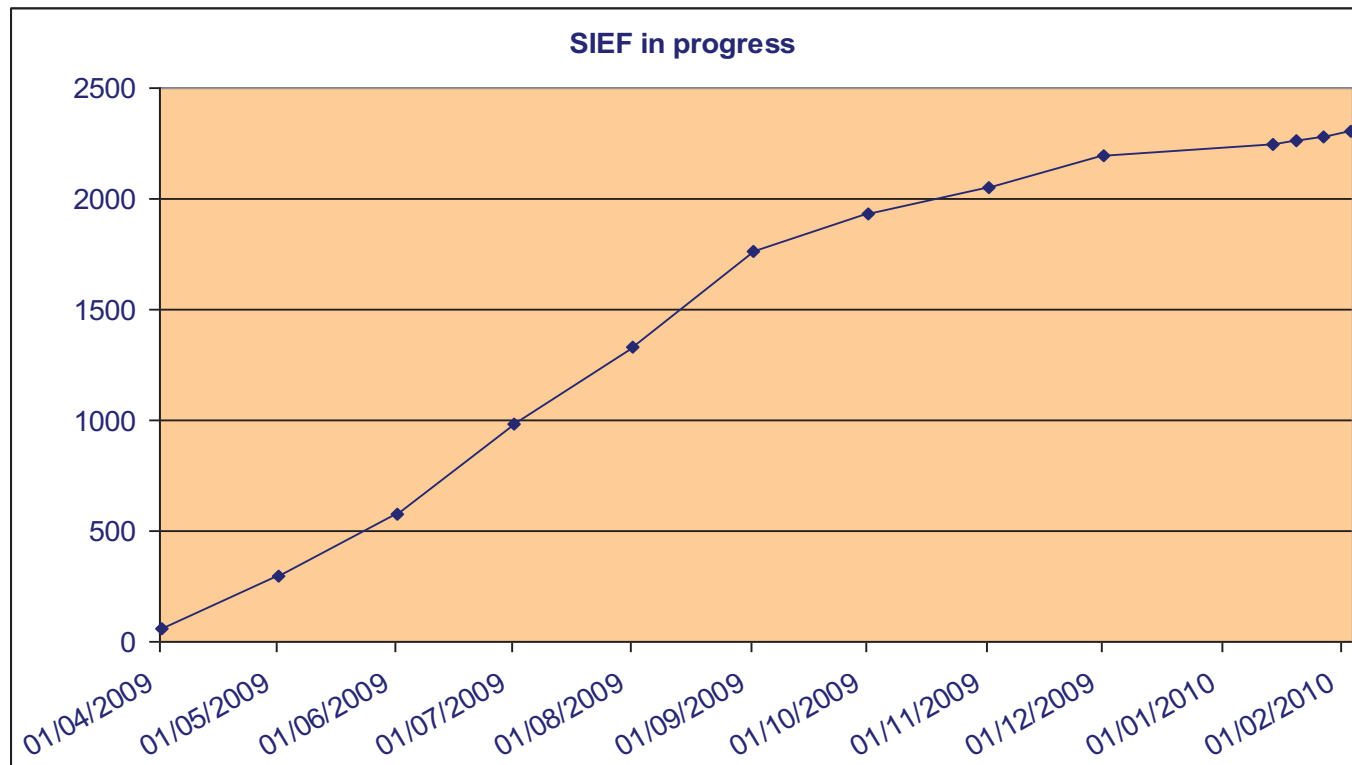
- Aims

- SIEFs formed and Lead Registrants nominated
- Early submission from Lead Registrants of high quality dossiers
- Submission of all dossiers before the deadline
- Removing the barriers
  - Developing clearer lines and recommendations
  - Translations
- Raising awareness of the urgency "The clock is ticking"
  - Trade associations and Helpdesks
  - Emails to all pre-registrants
- Supporting Lead Registrants- Lead Registrants' Workshop on 11Sep09  
[http://webcast.ec.europa.eu/dgenttv/portal/\\_vi\\_fl\\_300\\_en/index.html?viewConference=7497](http://webcast.ec.europa.eu/dgenttv/portal/_vi_fl_300_en/index.html?viewConference=7497)
  - Lead Registrant Forum (<http://lr.echa.europa.eu>)
  - Monthly webinars ([http://www.echa.europa.eu/news/webinars\\_en.asp](http://www.echa.europa.eu/news/webinars_en.asp))
  - Special Helpdesk support

# Weekly update of SIEF Formation

Approx 10% of the total number are candidate lead registrants

Date	SIEF in progress
Apr-09	57
May-09	293
Jun-09	574
Jul-09	982
Aug-09	1327
Sep-09	1766
Oct-09	1928
Nov-09	2051
Dec-09	2195
Jan-10	2282
03/02/10	2306
17/02/10	2374





# Lead Registrant status (17Feb10)

- 2352 SIEFs active or in progress
- Approx. 650 legal entities informed ECHA
- 1932 substances indicated for the 2010 registration deadline
  - 177 for 2013
  - 160 for 2018
  - 45 substances still no deadline

# Lead Registrant Support

- **Monthly webinars** ([http://www.echa.europa.eu/news/webinars\\_en.asp](http://www.echa.europa.eu/news/webinars_en.asp))
  - Targeted to help the LR; clarifications / technical issues
  - From Nov 2009 until Apr 2010
  - Available online to all afterwards
- **Special helpdesk support**
  - Focus on LRs (National HD will support others)
  - No individual service, but response to collective concern
  - Provide time-limited phone service (outbound only) close to the deadline
- **Facilitation of communication within SIEF**
  - New process to put in place soon to facilitate contacts between REACH actors and lead registrants in LR database
- **Further Support**
  - Analysis of the intentions to register by 2010 deadline and of SIEF progress
  - Inventory of issues compiled by industry: replies/ proposals prepared to facilitate prioritisation

# SIEF / LR Conclusions

- ECHA committed to provide support to industry
- Communication is key both within SIEFs and towards ECHA
- Companies are making progress
- Companies may learn from each other (Forum, Trade associations)
- Need to know Lead Registrants for Special support
- Further activities to support LR progress and success of SIEFs
- Recently: **Directors Contact Group (IND, COM, ECHA)**

# OVERVIEW OF WEBINARS IN 2009

<b><u>WEBINAR</u></b>	<b><u>DATE</u></b>
<b><i>General Principles of Dossier Preparation and Submission</i></b>	<b>4 November</b>
<b><i>Information Requirements I</i></b>	<b>30 November</b>
<b><i>Information Requirements II</i></b>	<b>10 December</b>
<b><i>Substance Identity</i></b>	<b>25 January</b>

# WEBINAR PLAN 2010

<b><u>WEBINAR</u></b>	<b><u>DATE</u></b>
<b><i>Technical Completeness Check Tool (TCC)</i></b>	<b>25 February</b>
<b><i>Chemical Safety Report (CSR) and CSA – part I</i></b>	<b>09 March</b>
<b><i>Chemical Safety Report (CSR) and CSA – part II</i></b>	<b>26 March</b>
<b><i>Classification and Labelling</i></b>	<b>09 April</b>
<b><i>Business rules</i></b>	<b>22 March</b>
<b><i>Data sharing</i></b>	<b>30 April</b>

# REACH - Enforcement

# Enforcement

- Enforcement and penalties are the responsibility of the Member States (Article 125 and 126 of REACH)
- Member States are obliged to establish the necessary arrangements for the implementation of REACH
- Some legal instrument is required at national level

# The Forum for Information Exchange on Enforcement

- Coordinates a **network of Member States' competent authorities responsible for enforcement**
- Tasks include:
  - ❑ Promotion of best practices & tools (Minimum criteria for inspections adopted)
  - ❑ Development of electronic info exchange procedures
  - ❑ Identification of enforcement strategies
  - ❑ Coordination and evaluation of harmonised enforcement projects
  - ❑ Liaison with industry
  - ❑ Advising on enforceability of restriction proposals



# Establishment of FORUM

## Members

- One per Member State
- 3-year term, renewable
- Contact with MS and CAs
- Broad range of relevant expertise
- FORUM members are independent

# FORUM Working Methods

- **Decisions and Conclusions**
  - Plenary meetings 2-3 times each year
  - Written procedures
- **Work Programme**
- **Working Groups**
  - Specific in-depth discussions chaired by one Forum member; composed of Forum members and invited experts
  - Documents as basis for discussions of the Forum, to prepare conclusions, statements, positions

## Working Groups - finalised

- Forum Work Programme
- Advice on enforceability of revised Annex XVII
- Enforcement strategies, best practice
- Report to the Commission under Article 117
- Minimum criteria for inspections
  - Ensuring a level playing field within the Internal Market and better coordination of REACH enforcement within EU/EEA

- **1<sup>st</sup> Enforcement Project (REACH-EN-FORCE 1)**
  - ❑ Pre-registration, registration & SDS
  - ❑ 26 countries participate **>1000 inspections**
  - ❑ Report will be ready in Q3 2010 at the latest
  
- **Preparation of Forum enforcement project for 2010**
  - ❑ Another major enforcement project will focus on formulators of mixtures and their Downstream User obligations

## ➤ **Cooperation with custom authorities**

- ❑ Draft recommendation to customs on how customs can be involved in control of REACH (imports)
- ❑ Preparing recommendation for procedure for control of Article 5 by customs and REACH enforcers
  - ❑ Customs and REACH enforcers will work together to stop un-registered substances from being released for free circulation
- ❑ Once recommendations are finalised, Forum will approach Member State customs authorities via DG Taxation and Customs Union

# Practical enforcement?

- Limits of coordination...
  - Enforcement Structures in Member States
- Possibilities for coordination...
  - Enforcement approaches
    - Key to ensure same situation on the market
  - Strategies
- **Practical experiences from enforcement discussed at every meeting**

# FORUM Conclusions

- Important to have coordinated enforcement
- Successful in coordinating enforcement in 30 EU/EEA states
- Ensures an equal treatment of companies throughout the EU/EEA
- Composition is stable
- Atmosphere is constructive, active contributions
- Members discuss practical issues and aim towards achievable solutions

## To conclude



- First candidate list published 28 Oct 2008
  - ❑ 15 substances – Information obligations
- Pre-registration closed 1 December 2008
  - ❑ 2,750,000 pre-registrations received
  - ❑ 146,000 different substances pre-registered
- SIEF awareness campaign launched in May 2009
- First recommendation for authorisation sent to COM 1 June 2009 - 7 substances
- Second candidate list published 13 Jan 2010
- Lead registrants activities launched

# Main challenges for 2010

- Handling submitted registration dossiers - first REACH deadline 30 November 2010
- Handling hundreds of test proposals and compliance checks within legal deadlines
- Upgrading REACH-IT and IUCLID 5
- Providing guidance and help to registrants

# Welcome to Helsinki

## 4th ECHA Stakeholders' Day

# Do not miss....

## Stakeholders' Day 19 May 2010 (just ahead of HCF)

- IT Tools for Industry (including CHESAR)
- C&L notification and campaign
- Lead registrants can meet ECHA dossier handlers
- Dissemination of information from registration dossier

# Helsinki Chemicals Forum

## 20-21 May 2010 - Programme



### 1. Opening comments

- Antonio Tajani, Vice President, European Commission - invited
- Jussi Pajunen, Mayor of Helsinki
- Geert Dancet, Executive Director, ECHA

### 2. Chemicals Regulation –Global Challenges

### 3. Chemical Policies – Emerging Economies

### 4. Competitiveness – Financial Constraints

### 5. Green Chemistry – Solution Provider

Keynote speakers:

President **Martti Ahtisaari**, the 2008 Winner of the Nobel Peace Prize, and Professor **Paul J Crutzen**, the 1995 Winner of the Nobel Prize for Chemistry

<http://finnexpo.multiedition.fi/wwwcem/cem/index.php>

<http://echa.europa.eu>

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is ticking

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# ECHA website



For any information about REACH, CLP and ECHA

<http://echa.europa.eu>

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**Follow the news on our home page**

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# Thank you for your attention!

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These slides represent the opinion of the author and do not constitute the official position of ECHA

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