Current Status and Enforcement of REACH

Get ready for REACH Registration
Shanghai
2 December 2009

Eva Sandberg
International relations
European Chemicals Agency
Helsinki, Finland

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 presently ~ 340 will grow by the end of 2010 to ~ 480
- ECHA is managing the implementation of the
  - REACH Regulation 1907/2006
  - Regulation 1272/2008 on the classification, labelling and packaging of substances and mixtures

ECHA – the coordinator of REACH Implementation

ECHA European Chemicals Agency

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

ECHA: Mission details

ECHA European Chemicals Agency

- Providing ECHA Help desk and Guidance
- Providing IT tools for use by industry and MSCA
- Running multilingual ECHA Website
  http://echa.europa.eu/home_en.asp
  - Guidance for industry and authorities on how to comply with REACH requirements and how to use REACH IT
  - Registry of Intention incl. info on Annex XV dossier supplied
  - Public consultations on the proposals for implementing REACH requirements (C&L, identification of substances of very high concern, substances to be subject to authorisation, restrictions)
  - List of pre-registered substances
  - Guidance IT systems & work processes gradually operational starting 1 June 2008

REACH processes; timing

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➢ Communication obligations	from 1 June 2007
➢ Pre-registration	1 June – 1 December 2008
➢ Registration	
❑ Phase in substances	2010 / 2013 / 2018
❑ New substances	from 1 June 2008
➢ Evaluation:	
❑ dossiers & testing proposals	from 1 June 2008
❑ Substance evaluation	from 2012
➢ Notification of substances in articles	from 2011
➢ Authorisation	
❑ Candidate list	from 2008
❑ Applications	from ~ 2011
➢ Restrictions	from 1 June 2009

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Pre-registration and SIEF

Pre-registration to pre-SIEF

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- **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

pre-SIEF to SIEF

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- What a SIEF is for
  - Formed by companies intending to register the same substance
  - Facilitate data sharing, avoid duplication of studies
  - Provide each other with existing studies
  - "Collectively identify needs" for further studies
  - Arrange for them to be carried out
  - Agree classification and labelling
- Sameness, important to be in the right pre-SIEF!
  - Splitting or merging of pre-SIEFs
- One substance one registration
- Document what you do

Forming SIEFs – a challenge

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- 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"
- new web section for support
  http://echa.europa.eu/sief_en.asp
  - *Getting Started in SIEFs – Top Tips*
  - *SIEF – key principles*.
  - ….

"The clock is ticking – form your SIEF now" - campaign

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Elements

- Trying to remove the barriers
- Raising awareness of the urgency
- Supporting Lead Registrants

Removing the barriers

- Developing clearer lines and recommendations
- Translation of key materials
- Helpdesk support

Raising awareness of the urgency

- The ”clock is ticking” campaign banner on websites with links to info
  - EU and national trade associations
  - National helpdesks
  - European Commission
  - Chemical media
- Direct email to pre-registrants
- PR campaign - autumn through to spring
- EU and ECHA publications
- Coverage by industry associations

Lead registrants support (1)

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Support from ECHA for LRs registered with us

- LR nomination form and publication of weekly updates
- LR workshop, Brussels September 11

- Lead Registrant Forum
  - Platform of exchange provided by ECHA to lead registrants to "discuss" SIEF-related issues and promote best practice for successful SIEFs (**http://lr.echa.europa.eu**)
  - Exclusively for LR identified on the LR database (from the webform)
  - Started in September 2009

Lead registrants support (2)

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- Webinars program (for LRs)
  - Monthly
  - Will address requests for clarifications / technical issues
  - Interactive
  - No 1 – 'General principles of dossier preparation and submission'; 4 November;
  - No 2 – 'Fulfilling Information requirements I: Gathering and evaluating information on intrinsic properties'; 30 November
  - No 3 – 'Fulfilling Information requirements II: QSARs, read-across, categories and in vitro
  - 2010 timeline will be announced on ECHA website
  - All will be available for everyone on website ~1 week later (http://www.echa.europa.eu/news/webinars_en.asp)

Lead registrants support (3)

ECHA European Chemicals Agency

- 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
- Database created on “Key Issues for LRs and Best Practices for SIEFs” using the web form available at:(https://comments.echa.europa.eu/comments/SIEFBestPractices.aspx)

Lead Registrant status (18 Nov 09)

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- 2025 SIEFs active or in progress
- Approx. 630 legal entities informed to ECHA
- Approx. 1600 substances indicated for the 2010 registration deadline
  - 127 for 2013
  - 133 for 2018
  - 189 substances still no deadline

SIEFs in 2010: Main challenge

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55 350 substances indicated by companies to be registered by **2010**

ECHA expects the number of substances to be closer to the EC's estimates (< 10.000)

~ 17,5% * have nominated the Lead Registrant to ECHA

Awareness campaign:

The clock is ticking

70% of the **55 000 pre-SIEF's** have between **10-99** potential registrants (93% - 1-99)

Substance Exchange Information Forum (SIEF)

* Of 2010 expected registrants

- **Try to get SIEFs working**
- **Encourage Lead registrant to come forward**

Lead Registrants update

Published on ECHA website by 11 November 2009

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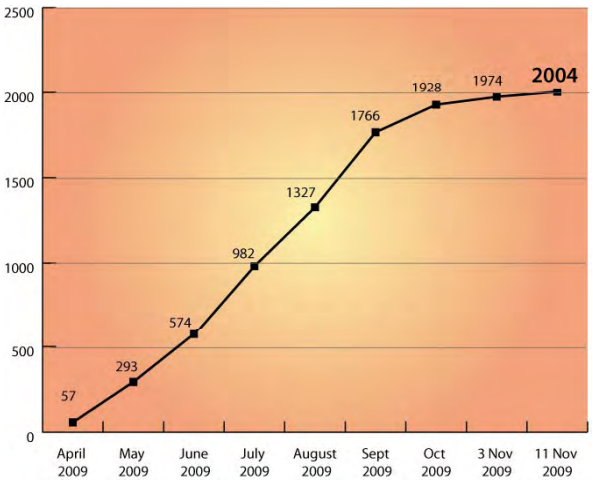
- 8.1 % of these 2025 are candidate lead registrants =where a company is interested in taking up the role as lead registrant, but has not yet been nominated within the (pre-)SIEF.
- ~17,5% of the SIEFs seem to have effectively overcome the pre-SIEF stage (for the 2010 deadline)



Consortia

- Consortia and cost sharing
  - Consortium members still have co-operation and data sharing obligations with other SIEF members who are not part of in the consortia
  - Consortia are encouraged to operate in an open and transparent way and apply best practice on cost sharing highlighted in the Guidance on data sharing
  - SMEs are recommended to take part in a consortium's activities as early as possible (participate and influence consortium orientation and discussions)
- Specific challenges for SMEs to meet REACH requirements
  - Lack of information and knowledge, partly due to the lack of resources and internal expertise > guidance in a Nutshell
  - Language barrier > translations of core guidance documents / national initiative
  - Costs > reduced fees for SMEs and joint registrations

Registration and dossier submission

ECHA 2010 estimates

- The number of registrations is expected to remain close to original estimates
  - 9200 vs. 8700, but it can also be lower
  - It includes HPV substances, intermediates and some categories of substances of concern
- Total number of registrations remains uncertain
  - Particularly for intermediates, where the Commission assumed 1 dossier per substance
  - Also the average number of legal entities submitting HPV dossiers may be significantly higher than 5.4 (eg. 1 LR+ 4-5 members)
  - We source for 25,000 dossiers but have contingency plans up to 75,000 dossiers
  - Monitoring is done by getting feedback from chemical associations

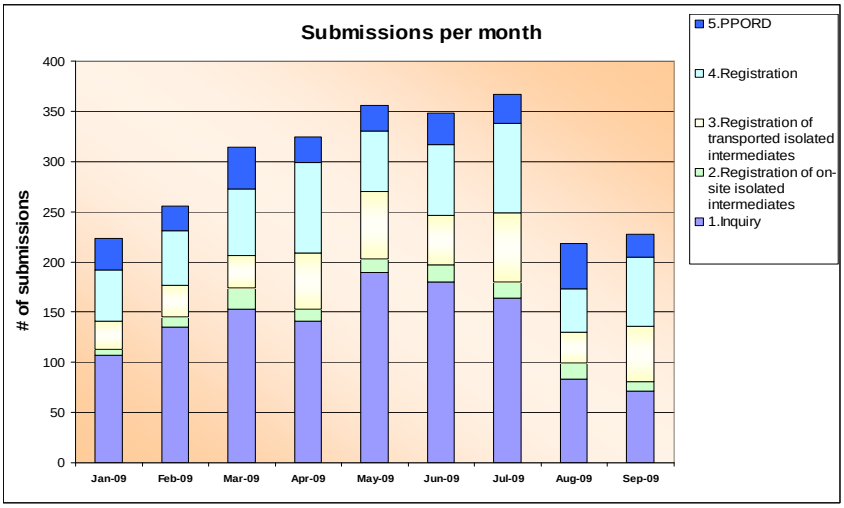
State of Play of Registration (1)

Number of registrations in 2009 up to 19 October

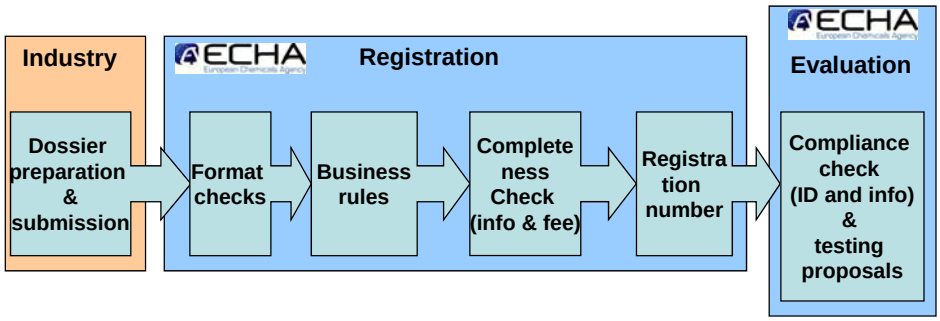
Type of registrations	Type substances	Submitted	Format check / BR passed	Technically complete	Registration n° assigned (i.e. invoice received)
On-site isolated intermediates	1. Phase-in	62	38	24	24
	2. Non Phase-in	67	35	26	26
	Total:	129	73	50	50
Transported isolated intermediates	1. Phase-in	63	32	18	15
	2. Non Phase-in	417	192	138	138
	Total:	480	224	156	153
Registrations	1. Phase-in	178	76	49	46
	2. Non Phase-in	510	172	84	82
	Total:	688	248	133	128

- Out of 1297 total submissions
  - >75% are relating to non-phase-in substances
  - Current rate of success: 25% (already 58% fail before format/ BR check)

State of Play of Registration (2)



Registration process



Dossier submission: Critical reminders

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- Registration dossiers should be prepared **well in advance**
- Carefully consult the relevant **guidance and manuals**
- Take care to ensure that the **dossier header** and **substance identity sections** are completed according to the instructions in the data submission manuals

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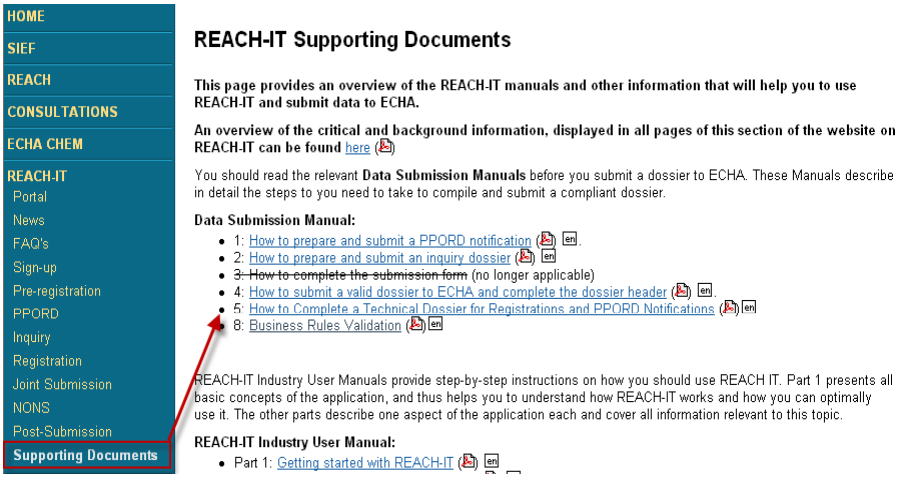
Data Submission Manuals are available on ECHA website



Dossier processing workflow at ECHA

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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 + 2nd Completeness Check)

pass → Registration number

fail → Rejection (rare cases)

Business rules

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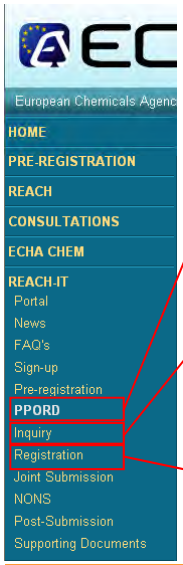
= Set of pre-requisites that must be fulfilled before ECHA can establish whether the dossier can be handled properly and whether the required regulatory processes can be successfully carried out.

Three main criteria:

- **Format** - e.g. inquiry dossier in a registration template
- **Administrative** - e.g. registration update does not provide registration number
- **Technical** – REACH-IT cannot ‘understand’ the substance identifiers

Technical Completeness Check (TCC)



Current supporting tools for industry:

- PPORD: TCC tool
  http://iuclid.echa.europa.eu/index.php?fuseaction=home.completenesscheck&type=public
- Inquiry: Preliminary Check Tool
  http://iuclid.echa.europa.eu/index.php?fuseaction=home.inquiry&type=public
- Registration: Data Submission Manuals

The clock is ticking

Technical Completeness Check (TCC)

TCC Tool for Registration Dossiers:

- It will offer the possibility to companies to check on their own the completeness before submitting to ECHA
- Tool is developed as a IUCLID 5 plug-in
- Release to the public at ECHA website **before end 2009**

The clock is ticking

Further information on registration

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- Forthcoming webinars
- Guidance and Manuals
- ECHA Helpdesk

The clock is ticking

Next Steps

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- Dissemination website: first release end of 2009
  - Only public data
  - Data claimed to be confidential will be filtered first
- Further IT development to support smooth registrations
  - TCC tool: release end of 2009 (plug-in of IUCLID 5.2)
  - CSA/ CSR (Chesar): first release end of 2009 (plug-in of IUCLID 5.2)
  - IUCLID 5.2: important upgrade early 2010
  - REACH-IT: important upgrade early 2010 (to improve internal processing of expected workload)

Authorisation, SVHC and the Candidate list

Authorisation

- Scope: substances of very high concern (SVHC)
  - CMR 1 and 2, PBT, vPvB, 'scientific evidence of probable serious effects'
- Substance cannot be placed on the market* for use unless authorised for specific uses and if
  - risks are adequately controlled
  - and/or socio-economic benefits outweigh risk
- Prioritised - Substances progressively authorised (as resources allow)

Ultimate objective: substitute SVHC by less hazardous substances or technologies

*Import of a substance is placing on the market

Authorisation procedure

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3 main steps:

1. Identification of SVHCs → ***"candidate list"***
   Who?: MSCAs / Commission; ECHA (Secretariat + MSC)
   + *public consultation*
2. Prioritisation of substances → ***"recommendation"***
   Who?: *ECHA (*Secretariat + MSC*)* + *public consultation*
3. Inclusion in Annex XIV → ***"authorisation list"*** (Annex XIV)
   Who?: European Commission and MS

Website publication

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- After Each Step a Publication is made on ECHA website
- Comments invited from all interested parties
  - Proposals for identification as a SVHC – 45 days
  - Draft recommendation for authorisation – 3 months

Information obligations

From the **date of inclusion** on the Candidate list of Substances identified as being of Very High Concern (SVHC), **Information Obligations** regarding the use of these substances in articles come into force

1st list containing 15 substances adopted 28 October 2008

Information obligations

Any supplier of an article which contain substances on the Candidate List in a concentration above 0.1% (w/w) have to provide sufficient information, available to them,

- to the recipients (professional and industrial users, distributors) and
- on request, to a consumer - free of charge - within 45 days of the receipt of the request

This information must ensure safe use of the article including as minimum the name of the substance.

Time schedule for submission of Annex XV dossiers for SVHC

- Annex XV dossiers will be submitted by the MS's twice a year
  - By 3 August 2009
  - By 8 February 2010
  - By 2 August 2010
- Candidate list will be updated twice a year immediately after the MSC has agreed on the identification of SVHC's
- Information requirements will follow from inclusion of the substance in the candidate list

Enforcement

Enforcement

- Enforcement and penalties are the responsibility of the Member states
- 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
  - 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
  - WG with Customs

Forum Current Work

- **1st Enforcement Project (REACH-EN-FORCE 1)**
  - Pre-registration, registration & SDS
  - 28 countries participate
  - Progress report at Forum-5
    - Coordinated approach to enforcement of Article 5 needed
    - Liaisons with stakeholders continue – new ways of interaction will be investigated (e.g. workshop)
  - Final report in early 2010
- **Preparation of Forum enforcement project for 2010**
  - Setting priority for next projects and preparing project for 2010
  - Prioritisation criteria adopted at Forum-5
  - WG meeting 29 October

Classification and labelling

Classification & Labelling

- Classification and labelling is the first step to define the hazards of chemicals and thus to ensure that the substances are manufactured, used and disposed of safely

- CLP Regulation (EC) No 1272/2008 entered into force on 20 January 2009
  - Implementation of agreed UN-wide system (GHS)
  - Transitional period 2010–15; both classification systems to be used

CLP: ECHA's main tasks

- Developing and managing a C&L inventory
  - a high number of C&L notifications expected by the end of 2010
  - to be made publicly available
- Managing proposals for harmonised C&L
  - ECHA opinions provide scientific basis for COM decisions
- Supporting national helpdesks
- Providing Guidance to industry and MSCAs
- Coordinating enforcement activities via the Forum
- Handling requests for the use of alternative names
- Carrying out a study on the communication of safe use

Information sources

Information sources on ECHA Website

- ECHA Helpdesk – questions via web form
  - Basic information for non EU inquirers
  - Question related to REACH IT, IUCLID and other ECHA tools
  - Questions related to REACH and CLP requirements (non EU inquirers)
- Frequently asked questions, FAQ
- Guidance website
  - Navigator
  - Guidance Documents related to the REACH processes
  - Guidance Fact Sheets
  - Glossary
  - Guidance feedback form
  - Formats, templates (e.g. CSR)

The world is watching…

ECHA website – Sept 2009

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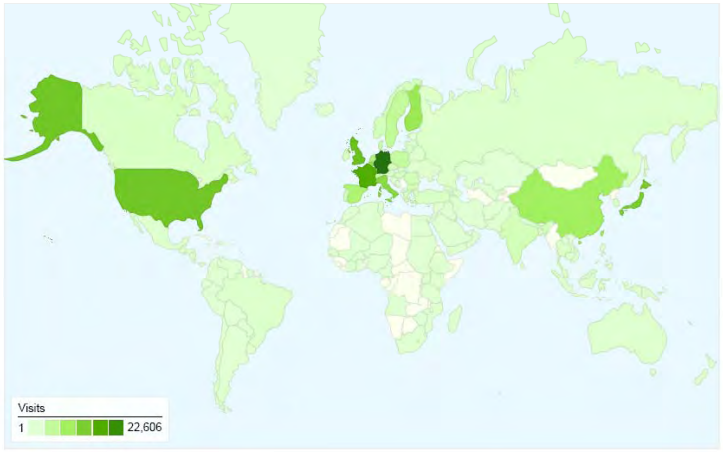
165 501 visits from 156 countries/territories
Top visiting countries: Germany, France, UK and the US



The world is watching…

ECHA European Chemicals Agency

6k cities

Top cities: Paris, London, (Helsinki) and Tokyo

Questions from non-EU countries

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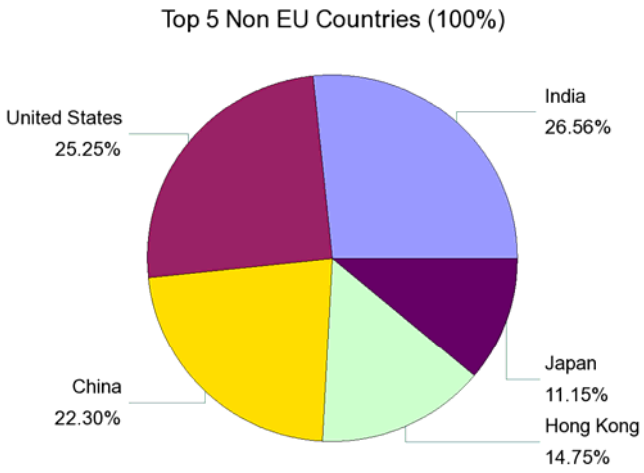

Shows Jan-Oct 2009; 1164/6632 questions from Non EU-countries

Dissemination of information

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- ECHA provides **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**

To conclude

Achievements

- 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
- CLP regulation EiF 20 January 2009
  - Guidance published 28 of August 2009
- SIEF awareness campaign launched in May 2009
- First recommendation for authorisation sent to COM 1 June 2009
  - 7 substances
- Two public consultations on proposals for harmonised C&L
  - 2 + 3 substances
- Second public consultation on proposed SVHC
  - 15 substances - Commenting period until 15 October
- Lead registrants activities launched

Current main challenges/1

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- **Getting ready for crucial deadlines**
  - 30 November 2010: 1st registration deadline (> 1000t + priority substances)
  - 3 January 2011: notifications for C&L
    - Staff and IT systems need to be ready to handle workload peaks incl. plan B
    - Industry needs advice and assistance to fulfil their obligations (SIEF & C&L campaigns)
    - High uncertainly about number of dossiers, TCC failure rate and peak submission times

Current main challenges/2

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- **Prepare for dossier evaluation**
  - Major scientific task for ECHA (target for 2010: 600 evaluations started (compliance checks and testing proposals) & 70 decisions taken
    - Build up sufficient scientific competence
    - Ensure that staff is trained well for fully exploiting the possibilities of non-animal testing methods, like categories, read across and (Q)SAR approaches
  - Explore mechanisms to promote improved quality of technical dossiers and CSRs
  - Stringent deadlines for decisions (testing proposals - by 1 Dec 2012, if received by 1 Dec 2010; >1000 tonnes p/a)

Current main challenges/3

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- **Update candidate list & new recommendations for authorisation list**
  - New process with many unknown factors
  - Type and quality of information available not yet known
  - SEA for chemicals is a relatively new area that needs new skills and expertise
  - Long process but tight deadlines for most parts
- Authorisation is a complex and heavy process
- The candidate list is a 'living' list

Current main challenges/4

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- **Setting up a high quality database on C&L and disseminating the information efficiently**
  - Process the high number of classification and labelling dossiers (at least 2 million)
  - Implement efficient working procedures for harmonising C&L with all actors involved
  - Develop appropriate scientific capacity for providing support to the drafting of RAC opinions
- A '**dissemination' website** is rolled out in 2010 (after piloting in 2009) which will include (non-confidential) information
- **Increase of staff by over 100 in 2010**

ECHA Welcomes All To Its 3rd Stakeholder's Day

WHEN: 7 December 2009,

WHERE: Helsinki and www.echa.europa.eu

WHO: participants worldwide from industry, national authorities and interest groups

COST: Free of charge.

THEME: CLP, Enforcement, Registration, dossiers and compliance

INFO: http://echa.europa.eu/home_en.asp

ECHA website

For any information about REACH and ECHA

http://echa.europa.eu

Follow the news on our home page

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Thank you for your attention!

谢谢大家！

The clock is ticking