SMEs and REACH

Network of SME Envoys, Munich

11 March 2014

Andreas Herdina
SME Ambassador
European Chemicals Agency

Role of the ECHA SME Ambassador

REACH WILL BEACHAM LONDON

ECHA APPOINTS SME AMBASSADOR

LATE IN 2013, ECHA decided that it needed to improve communications with SMEs globally, especially as the 2018 smaller tonnage deadline approaches in 2018. Andreas Herdina (right), who is already ECHA's director of cooperation, has added the role of SME ambassador.

He says the new role has two main elements, inward facing and outward facing. "Inwardly, my role is to galvanise the attention of colleagues in all processes to the needs and concerns of SMEs. Outwardly, I have to look towards the voices of SMEs which are sometimes difficult to hear, and to make ECHA aware of their concerns."

Herdina has already attended several meetings where SMEs have voiced their concerns. He adds: "I need to hear more precisely the voices of SMEs on the implementation of Reach." Key concerns in his view are: disputes on costs of data-sharing in SIEFs, the fact that Reach costs are burdensome on SMEs in general, and disruption to supply chains caused by product withdrawal. ■

2013: more focus on SMEs

- **2013 Studies** on impact on SMEs
  - NL: "Impact REACH op MKB"
  - UK: EEF-Manufacturers' Organisation "awareness, activity and perceptions"; Business Task Force "Cut EU Red Tape"
  - EP: "The consequences of REACH for SMEs"
  - CEPS: "REACH: A killer whale for SMEs"
  - ECHA: "Survey of first-time successful SME registrants"
- **2014 Commission study** ("impact of REACH on innovation, competitiveness and SMEs")
- **Market costs** (data-sharing, consultancy, SIEF management, etc.) **>> ECHA fees**
- How can the **regulator influence** them?

ECHA's challenges and dilemmata

- **Voices of SMEs**
  - "REACH is burdensome!" **(legislation)**
- Mandate of **ECHA**
  - "Managing the legislation", Art. 75 REACH **(implementation)**
- **Long-term gain v. short-term pain**
- To sustain **success of REACH to 2018** and beyond, need to support SMEs to **make SME compliance affordable**
- **Cannot dispense SMEs** from compliance

Main cost factors for SMEs

1. Cost of data sharing, meeting information requirements, SIEF participation for **registration** (Letters of Access)
2. Cost of communicating in the **supply chain** (use of chemicals communicated)
3. "Cost of **ignorance**": futile or belated efforts of taking the wrong route; cost of consultants; accessibility of information
4. Obligations under **other** EU and national (environmental) **laws**

SME registrants – specific challenges

- **Complexity** of the **legislation**
- Working in **English** (main working language of SIEFs and dossiers)
- **Complexity** of substance information exchange forums **(SIEFs)**
- **cooperating with competitors**
- Cost and quality of **consultants**
- **Large companies** using their **power**

“REACH tops ‘Top ten’!”

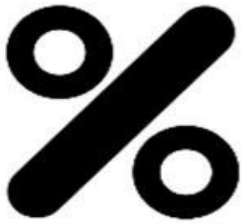
Most complex piece of EU legislation

But, REACH was intended
to have an impact

Regulatory burden = regulatory cost

- **REACH burdensome by design, not by default**
  - "The **most complex** [and most lobbied] piece of EU **legislation**"
  - "REACH put the **burden of proof** [for safe chemical management] **on industry**"
- **SMEs responsible for good stewardship**
- **Implementation also complex**
  - Many regulatory processes, many actors
  - Support by ECHA, industry associations can only help

NL study:



- Ca. 70% of companies claim not to be affected by REACH; for 60% of them this is not likely
- **Lack of awareness mainly of downstream users**
- Some companies may be compliant, not knowing that this is due to current legislation
- **REACH affects 4-6% of Dutch companies**; average **cost per company € 10,000**; strong sectoral differences
- **National cost (2012) € 425 million**

Companies' tasks

Manufacturers-Importers

Registration dossier (Incl. C&L)

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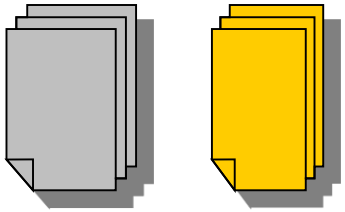
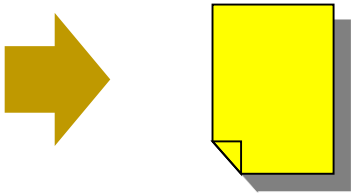


Chemical Safety Report Exposure Scenarios



Safety Data Sheet

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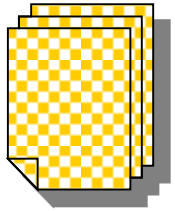

Exposure Scenarios

Information on uses

Safety advice

Customers (Downstream Users)

ECHA – EU Authorities

Public

IT tools for registration

- IUCLID, Chesar, REACH-IT
- Development done in cooperation with industry organisations
- Advance communication on the timelines to allow preparations in companies
- IT upgrade in 2016

Removal of substances from market

Examples:

- UK most vocal (recent Defra study); reason?
  - Large number of micro companies
  - Traders/distributors and Only Representatives > manufacturers
  - Public debate on "red tape" from Brussels
- French fragrance industry
- Formulators' recipes (e.g. detergents)
- SME voices confusing, **more clarity needed**
- **Predictability** v. **irrational market behaviour**

Why was REACH enacted?

Let’s recall the situation before REACH

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EUROPEAN CHEMICALS AGENCY

Protecting Human Health and the Environment

Status quo ante

- Difficult to **identify** and address **chemical risks**
  - Lack of information about chemicals
  - Burden of proof with public authorities
  - Difficult to deal with very hazardous substances
- **Lack of incentives** for newer, **safer chemicals**
- Lack of European **consumer confidence**
- **Health concerns** (e.g., worker exposure)
- **Environmental** damage, **bio-accumulation**

Expected benefits for society

- Higher **protection** for people and environment
- **Improved knowledge** about chemical risks
- **Substitution** of substances of very high concern
- **Consumer confidence** and demand for safer substances
- General **health benefits**; prevention of occupational skin and respiratory diseases
- **Environmental savings**

Expected benefits for public authorities

- **Burden of proof lies with those creating the risks**
- **Quicker response** to new and emerging risks
- **More information on chemicals** leads to stronger implementation of other laws on:
  - the environment
  - health
  - occupational health and safety

Expected benefits for business

- **More information from and to suppliers** on hazards and safe use
- **Level playing-field** between new and existing substances
- Coherent **internal market**
- **Incentives to innovate**
- **Competitiveness**

Commission's REACH review (2013)

- REACH **functions well** and delivers on all objectives that at present can be assessed
- Some needs for adjustments, but for the sake of **legislative stability and predictability** no changes to the enacting terms of REACH
- Need to **reduce the economic impact on SMEs**
- Benefit in **optimising implementation** at all levels
- **Commitment of all actors** is **necessary**

Commission General Report on the Operation of REACH, Feb 2013

…Commission's REACH Review…

- **Human Health and Environment: too early to quantify benefits** but positive initial **trend** for substances already registered:
  - More and **better** information available
  - Increased **information** on substances is resulting in changes on classification (mostly more stringent) and
  - Better targeted **risk management** measures
  - **Significant decrease in the risks**
- Moves towards **substitution** of SVHC
- Higher overall **costs** than estimated

…Commission's REACH Review

Internal Market and Competitiveness

- Positive effects for business through harmonisation, but:
- Sizeable registration costs have **increased market concentration**
- **SMEs more vulnerable and insufficiently aware (mainly Downstream Users)**

Innovation

- Increased communication in the **supply chain**
- **Suppliers more informed** about customer uses and needs
- **Substitution** of SVHCs as a **source of innovation**
- **Reorientation of R&D** expenditure towards regulatory compliance

REACH on its way

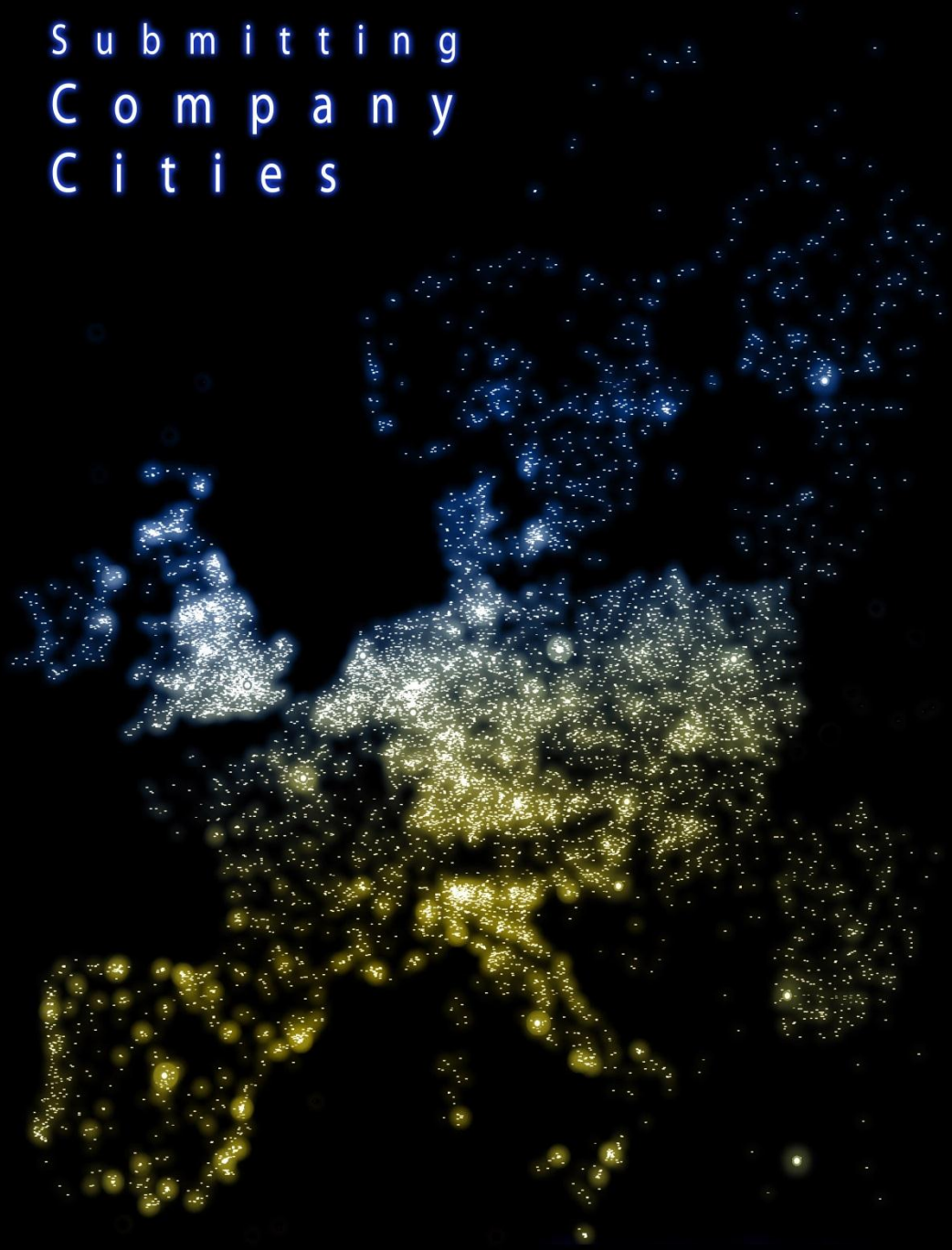
A closer look

Registrations and notifications

Submissions to ECHA so far

- 48,500 registrations (2,309 for new substances)
- 12,900 unique substances (1,000 new)
- 2 million study summaries on properties and effects of chemicals
- 4,500 substances with EU wide harmonised classification
- 125,000 substances classified
- 6 million notifications

Submitting Company Cities



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ECHA
Reporting
Service
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59
500
725
58
172
1
24
•Number of SME registrations by country.
•Data as of 01.03.2014

Expectations for 2018 registrations

	2010	2013	2018 ?
Substances	~ 3 400	~ 3 000	25 – 50 000 ?
Dossiers	~ 20 000	~ 9 000	40 – 70 000 ?

- Multitude of small SIEFs
- More individual registrants
- Higher % of SMEs
- Submission from 2016 onwards

Innovation

Is substitution actually happening?

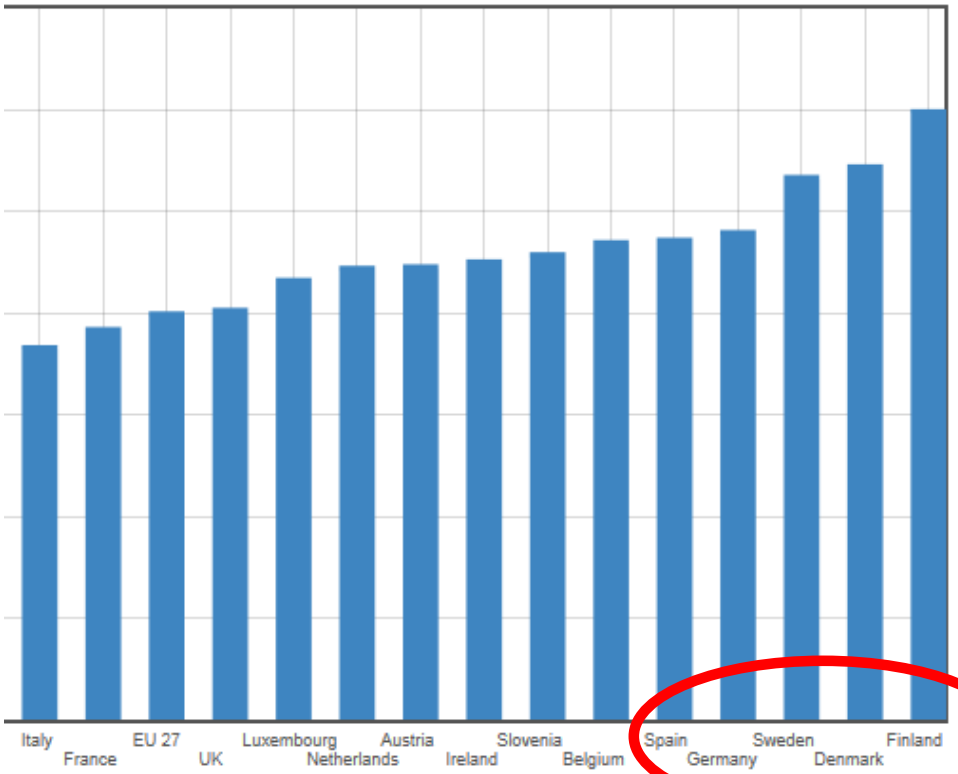
- **Yes**, seen for instance by:
  - Relatively low nr of CMRs registered
  - Relatively low nr of applications for authorisation
- But **difficult to quantify** for ECHA!
- When substitution is happening **ECHA does not necessarily know it**, e.g.:
  - Some registered uses might have been abandoned in practice but the registration dossier not (yet) updated
  - Current tonnages on the market cannot easily be compared with the situation 10 years ago

Are eco-innovation and competitiveness compatible?

Finland, Germany and Sweden are highly competitive, and leaders in eco-innovation

Entity	Rank	Score	Score and average (|)
2013-2014 » Global Competitiveness Index, 1-7 (best)			
Switzerland	1	5.67	
Singapore	2	5.61	
Finland	3	5.5[illegible]	
Germany	4	5.51	
United States	5	5.48	
Sweden	6	5.4[illegible]	
Hong Kong SAR	7	5.47	
Netherlands	8	5.42	
Japan	9	5.40	
United Kingdom	10	5.37	
Norway	11	5.33	
Taiwan, China	12	5.29	
Qatar	13	5.24	
Canada	14	5.20	
Denmark	15	5.18	
Austria	16	5.15	
Belgium	17	5.13	
New Zealand	18	5.11	

Entity
Series
Edition



Eco-Innovation Index 2012

How ECHA supports companies

Support

This section of the website provides tools and practical guidance to companies which have responsibilities under the EU chemicals legislatio

REACH

- Guidance documents
- Identify your obligations
- Practical examples of exposure scenarios
- Information Toolkit
- Information for registrants
- Restriction
- Authorisation
- Socio-economic analysis in REACH
- Small and Medium Enterprises

Publication
Document

ECHA Hel
National H

Navigator

Your Navigator ID is: 3835-3858-3066 - Name:

Questions History Restart Navigator

Question n°1

Is the substance any of the following?
- **A radioactive substance**
- **A substance under customs supervision**
- **A substance used exclusively in the interest of defence, covered by national exemption**
- **A waste**
- **A substance used exclusively as a non isolated intermediate**
- **A "transported substance" (i.e. you exclusively transport the concerned substance)**

Yes
No

OK, next question >

HelpNet©

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EUROPEAN CHEMICALS AGENCY

GUIDANCE

Guidance on registration

May 2012
Version 2.0
Guidance for the implementation of REACH

chesar

ECHA Webinar

HOW TO PREPARE AND SUBMIT THE MEMBER DOSSIER

05 MARCH 2013
11:00 - 14:00 HELSINKI TIME (GMT +2)

Final weeks before the 2013 registration deadline

ECHA/NA/13/17

ECHA provides final advice for companies registering by the registration deadline of 31 May 2013.

Helsinki, 14 May 2013 – With only a few weeks to go until the second REACH deadline, all registrants should be making the final arrangements for the submission of their dossier. At this stage, lead and member registrants should have already decided how to meet the relevant information requirements and the compensation for sharing data and related costs, allowing the lead to provide the members with the corresponding REACH-IT joint submission token.

The lead registrants of the SIEF are encouraged to submit their lead dossier as soon as possible to allow member registrants time to submit their own dossiers - members can only submit their own dossiers when the lead registrant has provided the members with the REACH-IT joint submission token and the lead dossier has passed the `business rules' step in REACH-IT.

Registrants who still have difficulties in meeting certain registration requirements can contact the ECHA Helpdesk, and ECHA will provide a response as soon as possible. Registrants that have an exceptional situation regarding their ability to register (e.g. scientific tests are still being conducted), and who potentially qualify for one of the Directors' Contact Group (DCG) exceptions, should urgently submit a request through the ECHA Helpdesk contact form and provide a justification of their situation. They will get their response within five working days.

If there are data sharing disputes, ECHA has provisions in place to assist registrants. However, registrants are reminded that a dispute should be submitted only as a last resort. Further information and webforms to submit a dispute are available on ECHA's website.

Key advice for dossier submission

Further ECHA support

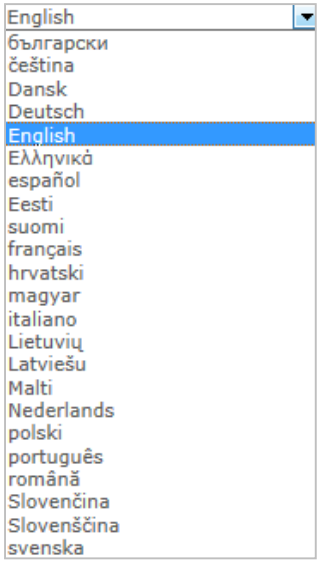
- Cooperation with **European Enterprise Network** (EEN), e.g. joint workshop with HelpNet in November 2013
- **Presentations** to various audiences
  - Also in **third countries** (from which ~50% of substances on Internal Market originate)
- **Publications** (leaflets, recommendations in annual Evaluation Report)
- **Communications network** (using partner platforms)

Directors' Contact Group

- **ECHA (chair)**, European Commission, industry associations (since January 2010)
- Informal **platform for exchanging information** on industry preparedness and potential practical obstacles to **registration**
- 28 issues identified, solutions developed in 2010
- **Third mandate** (Jan 2014 – Dec 2018)
  - **Focus on SME related issues** (registrants and downstream users); upfront: cost-sharing, consultants
- Directors supported by **Sherpas**

Further SME support

- **Simplification** - IT tools, guidance, manuals, registration procedure
- **Substance** identification and **sameness**
- Substance information exchange forum **(SIEF) best practice**
- **Helpdesk**
- **Multilingualism**
- Awareness raising and **outreach**



Help for downstream users

- Big challenge – information flow
- Exchange Network on Exposure Scenarios (ENES)
- CSR/ES Roadmap

Chemical safety report/Exposure scenario roadmap

CSR/ES Roadmap

Exposure scenarios are important tools for improving the safe use of chemicals in Europe. They are developed in the context of the chemical safety assessment undertaken as part of the REACH registration process. ECHA and several stakeholder organisations have developed a plan for improving the content and use of exposure scenarios during the years 2013-2018.

All stakeholder organisations are encouraged to make a commitment to this collaborative effort by signing the commitment charter. By doing this, stakeholders recognise the importance of generating and communicating accurate and clear information on the conditions of safe use of chemicals through the supply chain. They also commit to support the further development and implementation of the actions laid down in the roadmap.

› Action area 1: Increase common understanding among stakeholders

Achieving a common understanding among stakeholders on the purpose of the information in the CSR and the ES for communication.

› Action area 2: Information inputs for the chemical safety assessment

Identification of the information that registrants need from downstream users so that they can assess their uses.

› Action area 3: IT tools and standardisation

Related documents

› CSR/ES Roadmap [PDF][EN]
› Commitment charter [PDF] [EN]
› Roadmap implementation plan, July 2013 [PDF][EN]
› Leaflet - Working together towards the safer use of chemicals: Roadmap and Exchange Network on Exposure Scenarios [PDF] [EN]

Related links

› ENES
› Downstream user
› Chesar

Communications

- **ECHA Newsletter, e-news** (16000 subscribers), webpages, multi-media products, social media
- **ECHAterm** (multilingual terminology database)
- "Reaching the unreachables" – **outreach to** the **"unaware"** together with partners
- **Refining messages to SMEs:**
  - 2018 Registration
  - Authorisation
  - CLP mixture classification 2015
  - CSR/ES Roadmap

Close relations with stakeholders

73 accredited stakeholder organisations

REACH 2013 – Call to action

Workers' reps in companies manufacturing, importing or using chemicals

How can SME Envoys help?

Some suggestions…

- Mobilise **channels for spreading information** on REACH to SMEs (ministries, national business associations, etc.)
- Provide SMEs with **access to funding**
  - Linked to **innovation** (for substitution)
  - To overcome **cash-flow problems** due to REACH costs
  - National use of **EU Cohesion Policy** funds (spring 2014)
  - **National SME support**
- **Encourage a more concrete SME voice**

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