# ECHA's approach to SMEs

## Ninth Stakeholders' Day

21 May 2014

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# 2013: studies and surveys

- **2013 studies** on the impact on SMEs
  - NL: *Impact REACH op MKB*
  - UK: Business Task Force *Cut EU Red Tape*; EEF-Manufacturers' Organisation *awareness, activity and perceptions*; DEFRA *survey on REACH business impacts*
  - 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-driven costs** (data-sharing, consultancy, SIEF management, etc.) **>> ECHA fees**
- **Mixed picture: burden** and **innovation,** lack of **awareness**

# REACH tops ‘Top ten’!

Most complex piece of EU legislation

However, 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***
- **Implementation also complex**
  - Many regulatory processes, many actors
- **SMEs responsible for good stewardship**
- **Focus: support** by ECHA, industry associations

# 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)
3. "Cost of **ignorance**": futile or belated efforts of taking the wrong route; cost of consultants; accessibility of public information
4. Obligations under **other** EU and national (environmental) **laws**

# SME registrants – specific challenges

- **Complexity** of their obligations
- Working in **English** (main working language of SIEFs and dossiers)
- **Complexity** of **SIEFs**
- **Cooperating with competitors**
- **Large companies** using their **power**
- Cost and quality of **consultants**

# Removal of substances from market

- **Uncertainties** regarding **actual registration** of certain substances; drivers: costs, substitution (authorisation)
- **Fragrance industry** (France and Mediterranean MS), driver: UVCBs – workshop in Brussels, 8 April 2014
- **Registrants of dyes**; driver: large numbers
- **Formulators' recipes** (e.g. detergents); driver: classification under REACH & CLP
- **Predictability** vs. **nervous market behaviour**

## ECHA aims to make

- **2018 REACH Registration**
- **Authorisation predictable processes**

*(see other presentations)*

# ECHA's challenges and dilemmas

- **Voices of SMEs** often **focus on legislation**
  - "REACH is burdensome!"
- Mandate of **ECHA** is **implementation**
  - "Managing the legislation", Article 75 of REACH
- **Cannot dispense SMEs** from compliance
- **Implementing REACH to 2018** and beyond relies on (affordable) **SME compliance**
- **Long-term gain vs. short-term pain**

# REACH on its way

A closer look

# 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

# ECHA’s support to 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 Help
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 exem**
- **A waste**
- **A substance used exclusively as a non isolated intermediate**
- **A "transported substance" (i.e. you exclusively transport the concerned substanc**

Yes
No

OK, next question >

HelpNet©

chesar

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GUIDANCE

## Guidance on registration

May 2012
Version 2.0
Guidance for the implementation of REACH


## 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.

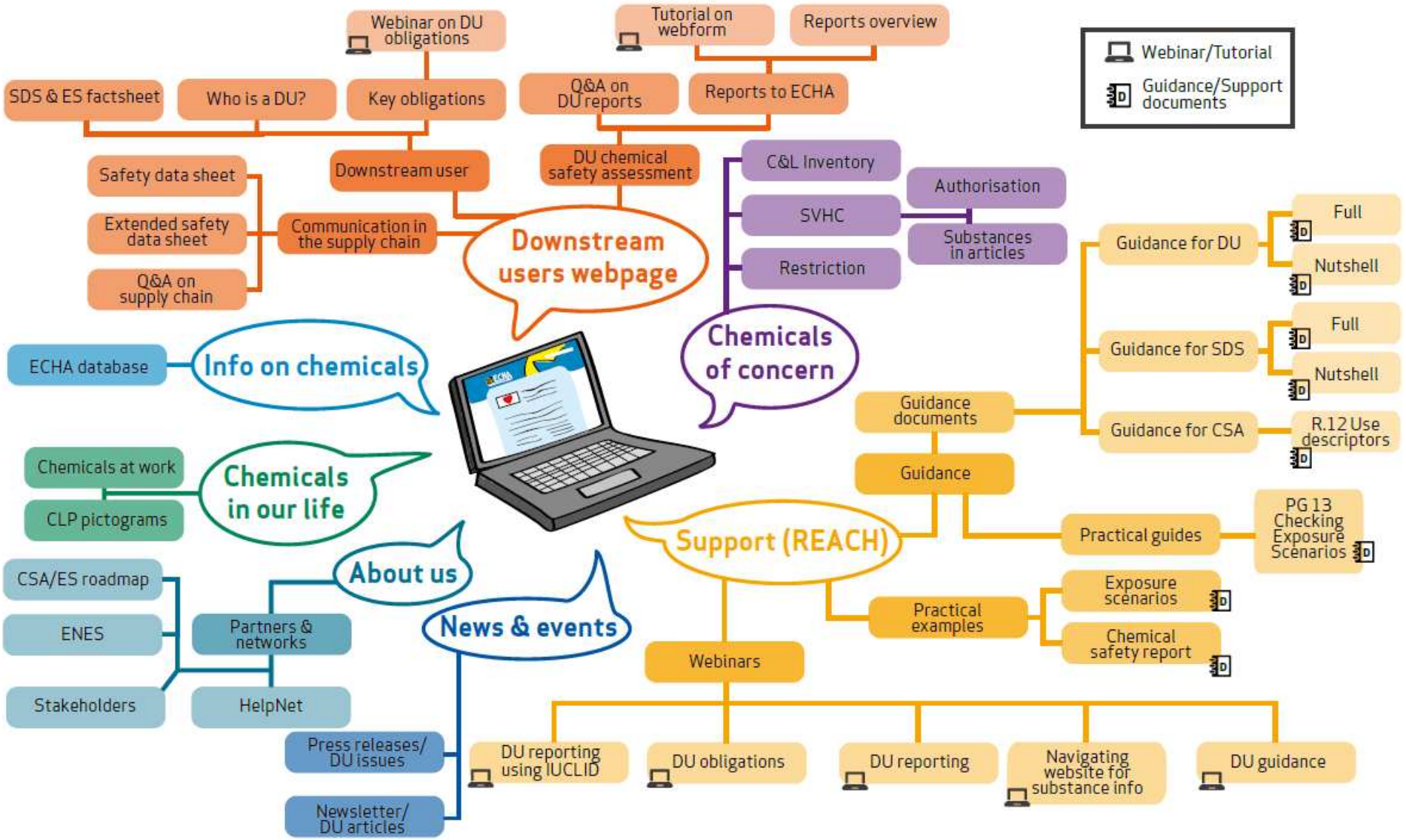
If there are data sharing disputes, ECHA has provisions in place to assist registrants. However, registrants are reminded that a dispute should be submitted only as a last resort. Further information and webforms to submit a dispute are available on ECHA's website.

**Key advice for dossier submission**

# *Simplification* of Guidance

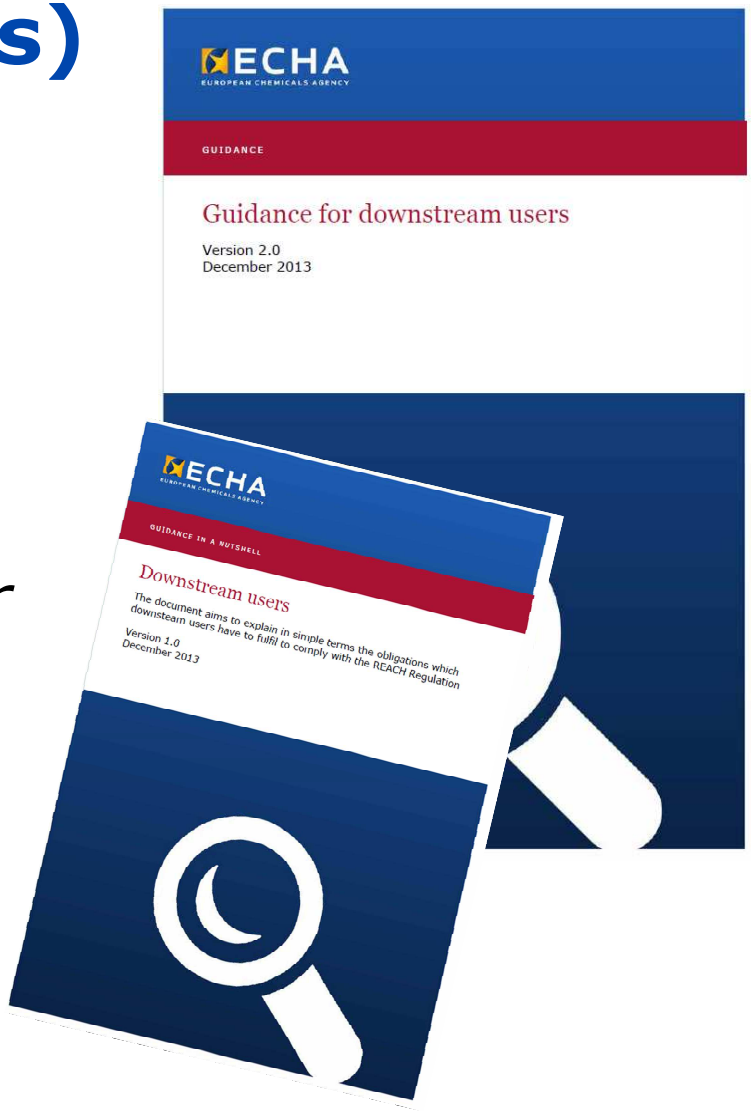

- = ***Simplification of access*** *to Guidance*
- ECHAs ***old*** **Guidance** partly lengthy, *heavy* and scientific
  - Started as European Commission RIP guidance
  - Focus on *first* duty holders: manufacturers of SVHCs and large volume industrial chemicals
- More ***recent*** **Guidance** targets *new* users
  - Guidance on registration, SDSs, downstream users (December 2013)
- Project: CLP Guidance → ECHA web pages

# Interactive map of information for downstream users on ECHA Website



# Recent Guidance (DUs)

- ***Guidance*** *for downstream users* (Version 2.0)
- A full revision of the structure and content of this guidance was published on 5 December 2013.
- *Guidance in a* ***Nutshell*** *for downstream users*
- This document was published (simultaneously in all official EU languages other than Gaelic) on 13 December 2013.

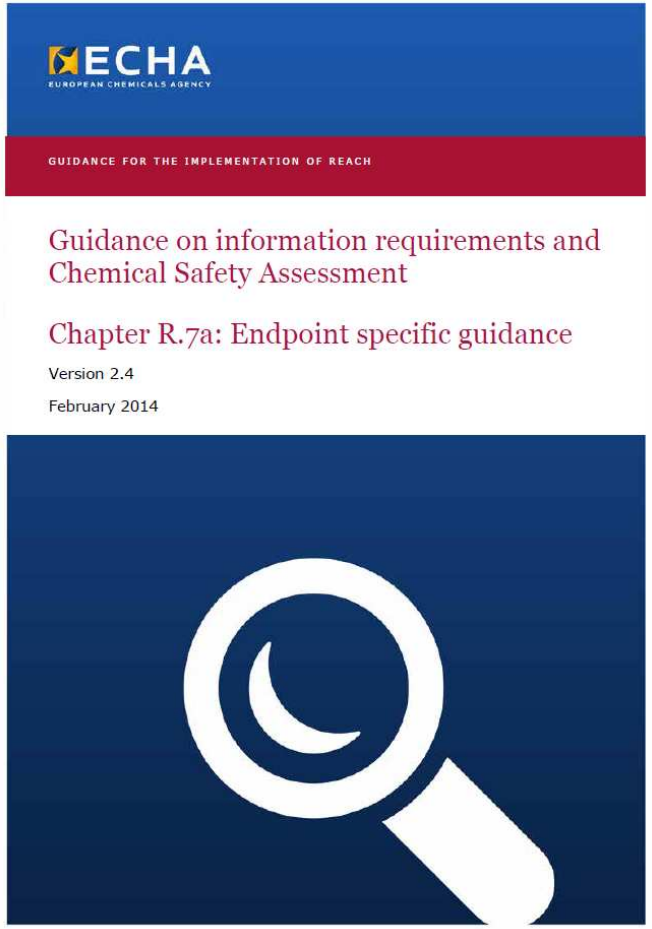


# Recent Guidance (SDSs)

- ***Guidance*** *on the compilation of safety data sheets*
- An update (Version 2.0/in English) of this guidance was published on 5 December 2013, covering in particular the extension of Appendix 2 of the guidance.
- *Guidance in a* ***Nutshell*** *on the Compilation of safety data sheets*
- This document was published (simultaneously in all official EU languages other than Gaelic) on 13 December 2013.

# Recent Guidance (CSA)

- ***Guidance*** *on IR & CSA, Chapter R.7a, Section R.7.1*
- Two further corrigenda to the guidance were published in December 2013 and February 2014 respectively.



- ***REACH Factsheet***
  *Toll manufacturer under REACH*
  - An English version of a REACH Factsheet explaining the responsibilities of toll manufacturers under the Regulation was published on 12 December 2013.
  - Translations in 22 additional languages were published in January 2014.

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REACH

Factsheet

ECHA-13-GF-06-EN

**Information for parties involved in contractual arrangements for toll manufacturing.**

## Toll manufacturer under the REACH Regulation

For business reasons (e. g. economic advantage, staying competitive, logistics) a company may decide to outsource (some of) its manufacturing operations to a third party. The nature of such contractual arrangements between companies is described using a broad range of terminology. "*Toll manufacturer*" is one of the most frequently used terms for describing a second company carrying out an activity on behalf of a first in cases where the activity is manufacturing. The activity is correspondingly described as *toll manufacturing* and is a common practice in the chemicals industry. The REACH Regulation does not have specific provisions on toll manufacturing. Nevertheless, toll manufacturers may have obligations under the Regulation.

The aim of this fact sheet is to explain the concept of a *toll manufacturer* and the responsibilities that he may have under the REACH Regulation. This document also briefly describes relevant REACH requirements. It additionally gives some initial advice on how compliance may be facilitated for toll manufacturers and for companies who are contracting others to toll manufacture on their behalf.

Toll manufacturing agreements may be very different in scope and arrangements. It is strongly recommended that such agreements explicitly address the REACH obligations related to manufacturing activities in the EU - as a minimum the registration obligation. Provisions for ownership of data, future updates, responsibility for compiling and providing Safety Data Sheets (SDSs), as well as other relevant REACH obligations should be clearly addressed in the contractual agreements. Similarly obligations for correct classification, packaging and labelling of the substances or mixtures subject to the agreement under the CLP Regulation should also be addressed in the agreements.

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# Other types of support

# Evaluation report


- Recommendations highlighted for easy reading

http://echa.europa.eu/documents/10162/13628/evaluation_report_2013_en.pdf

# *Low-tonnage* recommendations

http://echa.europa.eu/documents/10162/13628/eval_report_2013_facts_figures_en.pdf

KEY RECOMMENDATIONS TO REGISTRANTS

ECHA's recommendations to registrants shift the focus somewhat from previous years. Whilst reminding registrants to keep registrations consistent and up-to-date, ECHA urges them to substantiate robustly any adaptation of the standard testing requirements. This time, specific attention is paid to the chemical safety reports. As more cases go through evaluation in 2014, there is also advice about how to react when receiving a (draft) decision, requesting for more information.

These recommendations are **relevant both to future registrants** preparing their registration dossiers **and to existing registrants** who need to update.

Low-tonnage registrants (one to 10 tonnes/year) – pay attention to the following recommendations on yellow background.

1. Keep your dossier up-to-date

It is your duty to submit and maintain a compliant registration, so be proactive: Integrate REACH compliance into your quality management system.

Your registration dossier must be consistent and reflect the reality of your business.

Keep talking in the SIEF (substance information exchange forum) and in your supply chain, even after receiving your registration number.

Check REACH-IT regularly: This is ECHA's way of contacting you about issues found in your dossier. If you receive a message, you need to respond promptly.

When you prepare your dossier, use all available support material from ECHA including guidance, IUCLID plug-ins (particularly the Validation Assistant) and Chesar.

ECHA's webinars are an easy and interactive way to learn about common pitfalls and how to avoid them.

Relevant for low-tonnage registrants

2. Know how to react if you get a (draft) decision

Start to think carefully about how you will respond immediately after receiving a draft decision. The 30-day commenting period is your chance to give your views and bring your dossier into compliance.

It is even more important to keep talking in the SIEF if you receive a (draft) decision because it may impact on many registrants with the same substance: Endeavour to coordinate and respond to ECHA with one voice.

Understand the REACH decision-making procedure: The room for manoeuvre and the strict timing gets tighter as the process rolls on.

Remember ECHA and the Member States take regulatory action to help you and your customers to use the substance safely.

Relevant for low-tonnage registrants

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MOST FREQUENT SHORTCOMINGS

If ECHA finds information gaps when checking a dossier for compliance with the law, a decision is taken under REACH to request the missing information from the registrant. Most of these information requests in 2013 related to substance identity, physicochemical properties, sub-chronic toxicity studies, pre-natal developmental toxicity studies and exposure assessment.

3. Substantiate your reasoning if you adapt the standard testing regime

Be specific on the legal basis for any adaptations you make and state it clearly at each endpoint; then justify and document how you have fulfilled the conditions that allow such an adaptation.

The adaptation needs to be adequate for the risk assessment, with a comparable level of confidence as the test it aims to replace.

For QSAR (quantitative structure–activity relationship), this means attaching the documentation in the right format in the right place, justifying fully why the model is valid and how it was applied to the substance. Just providing a number from an unspecified model will not do.

For read-across and category approaches, this means showing that the substances are very likely to be similar (eco-) toxicologically, preferably with a data matrix. A read-across hypothesis without a proper justification and supporting data will not be accepted.

If you need to propose a new test after all, do so explicitly by selecting "experimental study planned" at the endpoint in your IUCLID file.

Relevant for low-tonnage registrants

4. The chemical safety report should reflect the actual uses and risks

If your substance is PBT (persistent, bioaccumulative and toxic) after careful assessment and checking the Candidate List, show clearly in the chemical safety report how you are minimising its release.

When you derive the DNEL (derived no-effect level), justify and document any deviation from the default assessment factors presented in REACH Guidance R.8 with scientific arguments that are specific to your substance.

When assessing the exposure, consider the scope of exposure assessment based on the hazards identified for the substance.

When using a model for estimating exposure, consider the domain of applicability of the model, use appropriate modelling parameters and justify their selection.

The exposure scenarios in the report must be transparent, have exhaustive coverage and each must be specific. The operational conditions and the risk management measures have to be provided in sufficient detail and should ensure safe use.

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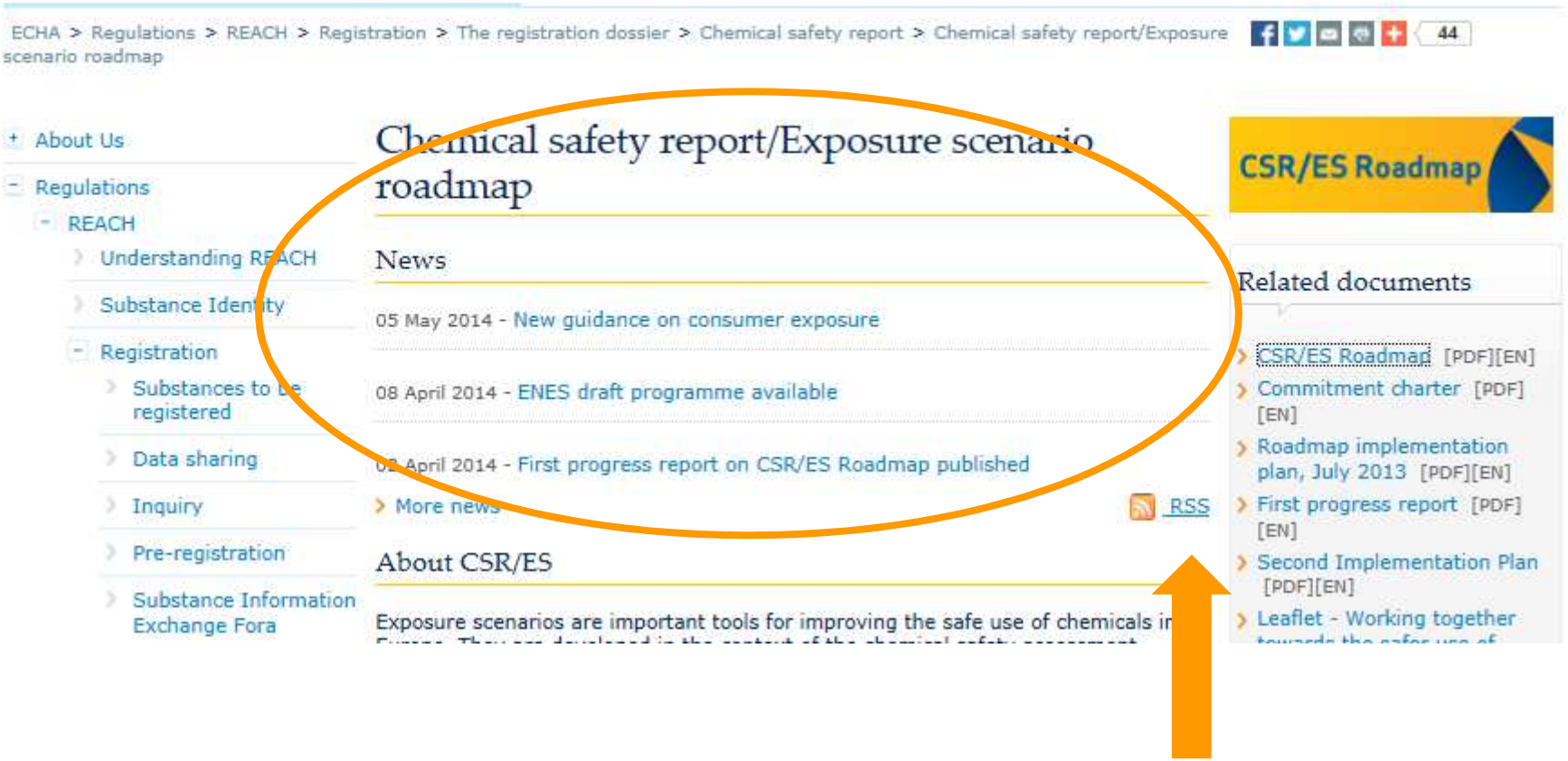
# Newsfeed and RSS

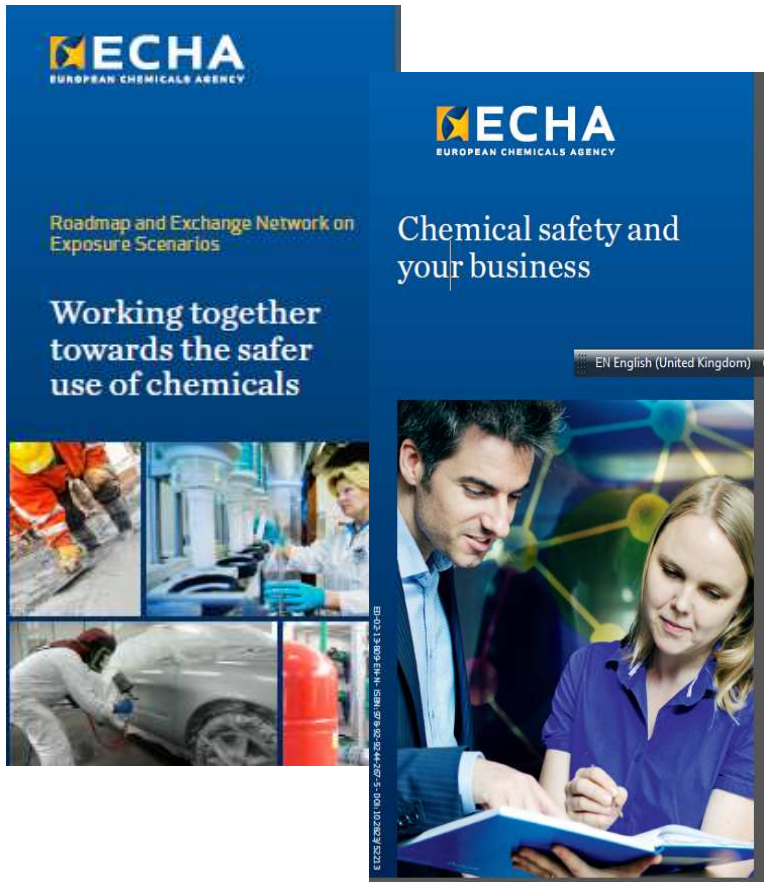


# Communications

- **ECHA e-News** (16 000 subscribers), **Newsletter**, **website**, multimedia products, social media
- **ECHA-term** (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

# Leaflets

- Awareness-raising
- Exposure scenarios
- Chemicals legislation in a nutshell
- ECHA's services
- HelpNet (Updated)
- Biocides (Updated)



# Working with partners

- Cooperation with **European Enterprise Network** (EEN), e.g. joint workshop with HelpNet in November 2013; EEN contact points
- **Communications network** (using partner platforms to reach SMEs)
- **Presentations** to various audiences
  - Also in **third countries** (from which ~50% of substances on Internal Market originate)

# DCG (Directors' Contact Group)

- **Third Terms of Reference (2014-2018)**
  - **Focus on supporting SMEs**
- **Next DCG meeting** (4 June 2014)
  - SIEF Letter of Access vs. Consortium membership
  - Checklist for hiring consultants
- European Commission preparing **Implementing Legislation**
  - Fair and transparent cost sharing in SIEFs
  - Recommendations on sound SIEF management

# Access to finance

# SMEs can make use of EU funds

- **COSME** (2014 – 2020), programming April 2014
- **Horizon 2020** – Research and Innovation
- EU Executive Agency for SMEs (EASME)
  - **http://ec.europa.eu/easme/**
- European Regional Development Fund (Member States mainly responsible for programming and delivering **EU structural funds**)
- ECHA SME Ambassador's interventions at:
  - SME Assembly Vilnius (Nov 2013), *Stoiber Group* Brussels (Dec 2013), SME Envoy meeting Munich (March 2014)

# Thank you

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