

ECHA and the implementation of REACH, CLP and other tasks

Eva Sandberg

International Unit

ECHA, its tasks and organisation

European Chemicals Agency



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; biocide tasks after that
 - Number of staff ~ 600
 - ECHA is managing the implementation of the
 - REACH Regulation 1907/2006
 - Regulation 1272/2008 on the classification, labelling and packaging of substances and mixtures
 - Biocides regulation (since 1 Sep 2013)
 - Prior informed consent regulation (Rotterdam convention, since 1 March 2014)
-

Rationale behind agencies



- Harmonise implementation of EU law
- Contribute to European governance / Strengthen the European executive
 - Decentralisation and dispersal of the Union's activities
 - Allow Commission to focus on core tasks - policy
 - Visibility for the public / stakeholders
- Higher profile to the tasks that are assigned to them
- Some agencies, like ECHA, contribute to the development of scientific or technical know-how

N.B. Policy issues remain with the Commission!

ECHA is a Regulatory agency

- Takes certain decisions, most of which can be appealed to the ECHA Board of Appeal
- Gives opinions to the Commission
- Largely fee-financed by registration and other fees

What is ECHA?

- **ECHA comprises (Art. 76)**
 - ❑ The Management Board
 - ❑ The Committees:
 - a Committee for Risk Assessment
 - a Committee for Socio-Economic Analysis
 - a Member State Committee
 - a Forum for Exchange of Information on Enforcement
 - ❑ The Board of Appeal
 - ❑ The Secretariat
-

ECHA's Tasks for REACH

- Manage and carry out REACH tasks
 - Ensure consistency at Community level
 - Provide Member States & EU institutions with best possible advice on chemicals which fall under REACH
 - Manage guidance, IT tools and data bases
 - Support national helpdesks and provide advice to registrants
 - Make info on chemicals publicly accessible
-

ECHA's Tasks cont'd

Running multilingual [ECHA Website](http://echa.europa.eu/home_en.asp)

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, info on submitted proposals Annexes XV (REACH) and VI (CLP)
 - **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)
– comments from all possible
 - Dissemination webpage
-

ECHA's tasks under CLP

Regulation 1272/2008 on the classification, labelling and packaging of substances and mixtures (CLP)

- Managing proposals for harmonised C&L
 - Developing and managing the C&L inventory
 - Support national helpdesks
 - Providing guidance to industry
 - Providing guidance and support to MS-CAs
 - Co-ordinate enforcement activities via Forum
 - Receiving reports from MSs on control & enforcement
 - Carrying out a study on communication on safe use of substances and mixtures
 - Handling requests for use of alternative names
-

ECHA: Organisation

- Management Board
 - 1 per Member State (+ observers EEA/EFTA), 2 by EP and 3 by COM
 - 3 interested party observers nominated by COM
- Secretariat lead by Executive Director
 - 7 different directorates
- Committees
 - Committee for Risk Assessment
 - Committee for Socio-economic Analysis
 - Member State Committee
- Forum for Exchange of Information on Enforcement
- Several Networks: HelpNet, SON, RCN
- Board of Appeal: independent from the Secretariat

Committee for Risk Assessment (RAC)

Consists of scientific experts nominated by Member States and appointed by the Management Board

Tasks:

- Prepares Agency's opinions for the Commission on
 - Classification and Labelling proposals in accordance with the CLP Regulation 1272/2008
 - Restriction proposals
 - Authorisation applications
 - Provides opinions on any other questions relating to REACH and risks to human health or the environment at the request of the Executive Director
-

Committee for Socio-economic Analysis (SEAC)

Consists of scientific experts nominated by Member States and appointed by the Management Board

Tasks:

- Prepares Agency's opinions for the Commission on
 - Restriction proposals based on
 - consideration of socio-economic factors of the proposal and evaluation of the socio-economic impact
 - Authorisation applications based on
 - assessment of socio-economic factors and the availability, suitability and technical feasibility of alternatives
 - Provides opinions on any other questions relating to REACH and socio-economic impact of possible legislative action on substances at the request of the Executive Director
-

Member State Committee (MSC)

Consists of members appointed by the Member States

Tasks:

- Seeks *unanimous agreement* on draft decisions concerning evaluation
 - Dossier evaluations: testing proposals and compliance checks
 - Substance evaluations
- Seeks *unanimous agreement* on identification of substances of very high concern (SVHC)
- Gives opinions on
 - ECHA's draft recommendation for Annex XIV (authorisation list)
 - Community Rolling Action Plan established for substance evaluation
 - Safety of substances at the request of the Executive Director

ECHA and biocides

- A new 'area' for ECHA
- Preparatory activities started in 2011
- Hand-over from 'old' (BPD) to 'new' (BPR) system
- Objective is to create synergies between REACH and biocides

Role of ECHA -Biocides

- Creating an organisation structure
- Set-up the ECHA Secretariat for Biocides, the Biocidal Products Committee including sub-groups and a Board of Appeal
- Develop IT System: Register for Biocidal Products
- Budget: Community subsidy and fees

The Biocidal Products Committee

Consists of members appointed by the Member States

Tasks:

- Prepares the opinions of ECHA related to several BPR processes. The final decisions are taken by the European Commission.
 - Applications for inclusion in Annex I of active substances as well as review of the included substances
 - Identification of active substances which are candidates for substitution
 - Union authorisation of biocidal products and for renewal, cancellation and amendments of Union authorisations

Board of Appeal

- To decide on appeals against decisions taken by Agency
- Independent and impartial
- No other duties inside the Agency
- Not against all ECHA decisions
- Appeal fee – which may be refunded

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

http://echa.europa.eu/reach_enforcement_en.asp

The Forum

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 (i.a. with customs)
- Liaison with industry
- Advising on enforceability of restriction proposals

ECHA Helpdesk

- Operational since 1 June 2007
 - Coordination of REACH and CLP national helpdesks in each Member State: 1st point of contact for EU industry
 - Service to registrants and MSCAs
 - 1st point of contact for **non-EU** industry
- ECHA chairs and has secretariat of the **HelpNet**, represented by the helpdesk correspondents network
Aim of the network: achieve consistent and harmonised advice to stakeholders across EU

Information sources on ECHA Website

- ECHA Helpdesk – questions via web form
 - Basic REACH and CLP information for non-EU inquirers
 - Question related to REACH IT, IUCLID and other ECHA tools
 - Questions related to REACH 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



Advanced search »

About Us

Regulations

Addressing Chemicals
of Concern

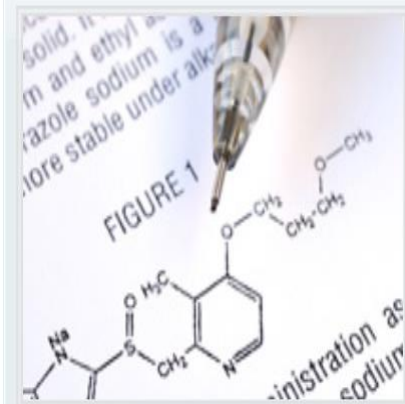
Information on
Chemicals

Chemicals in our Life

Support

ECHA > Homepage

For any information about REACH, CLP and ECHA



24 July 2012

Additional information on chemical substances to be published

More information from registration dossiers will be published on ECHA's website as from November. Registrants can request that the information be kept confidential by updating their dossiers before the end of October.

Search for Chemicals

I have read and I accept the [Disclaimer](#)

Name, EC or CAS No



News Alerts

16/09/2014

31 July 2012

[ECHA publishes Guidance in a Nutshell on](#)

Press Releases

17 July 2012

[New Biocides Regulation enters into force](#)

ACT NOW!

REACH
2013



23

Dissemination of information

Dissemination of information

- According to REACH legislation, ECHA will have to provide free public access to information on registered substances
 - Accessible and useful also to countries outside the EU
- Even publicly available information will be highly technical
- ECHA initiative: hosting the OECD Global Portal

Dissemination of information

- A dissemination website has been developed
- The dissemination website includes (non-confidential) information
 - on notified substances collected under previous legislation
 - the REACH processes and registered substances
 - C&L data for notified substances in the C&L inventory
 - A Consumers section etc
- The information on the same substance is aggregated
 ➔ one point of entry for each substance

<http://apps.echa.europa.eu/registered/registered-sub.aspx#phasein>

ECHA Website



Advanced search »

About Us

Regulations

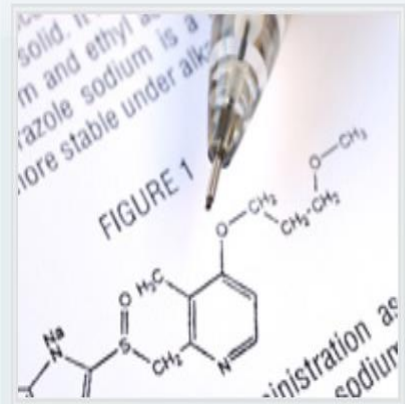
Addressing Chemicals of Concern

Information on Chemicals

Chemicals in our Life

Support

ECHA > Homepage



24 July 2012

Additional information on chemical substances to be published

More information from registration dossiers will be published on ECHA's website as from November. Registrants can request that the information be kept confidential by updating their dossiers before the end of October.

Search for Chemicals

I have read and I accept the [Disclaimer](#)

News Alerts

16/09/2014
31 July 2012

[ECHA publishes Guidance in a Nutshell on](#)

Press Releases

17 July 2012

[New Biocides Regulation enters into force](#)

ACT NOW!
REACH 2013

Public C&L inventory

- new database with more than 5 million classification and labelling records on more than 100.000 substances
- contains
 - substance name and identifiers
 - harmonised classification and labelling
 - classification and labelling according to CLP criteria from notifications and registration dossiers (industry data)
- searchable by substance, by hazard category and by hazard statement

OECD eChemPortal and registration data

- Gateway to ECHA Dissemination website where currently ~ 4000 substances disseminated
- Allows search per substance properties

The screenshot shows the OECD eChemPortal website. At the top left is the OECD logo (Organisation for Economic Co-operation and Development). To the right is a 'Print' button and a language dropdown menu set to 'English'. The main header features the text 'The Global Portal to Information on Chemical Substances' and the 'eChemPortal' logo. A navigation menu on the left lists: Home, Substance Search, Property Search, General Information, Participating Databases, Roles & Responsibilities, Extension of the Portal, What's new?, Other useful information, FAQ, Help, Contact Us, and Disclaimer. The main content area has two search buttons: 'Chemical Substance Search' and 'Chemical Property Data Search'. Text next to these buttons states: 'Nineteen data sources participate under Chemical Substance Search. Two databases participate under Chemical Property Data Search. The list of data sources participating in eChemPortal is continuously expanding.' Below this is a 'Welcome to eChemPortal' section. It states: 'eChemPortal provides free public access to information on properties of chemicals:' followed by a list: Physical Chemical Properties, Environmental Fate and Behaviour, Ecotoxicity, and Toxicity. A final paragraph explains: 'eChemPortal allows simultaneous searching of reports and datasets by chemical name and number and by chemical property. Direct links to collections of chemical hazard and risk information prepared for government chemical review programmes at national, regional and international levels are obtained. Classification results according to national/regional hazard classification schemes or to the Globally Harmonized System of Classification and Labelling of Chemicals (GHS) are provided when available.'

<http://echa.europa.eu>

Global Portal to Information on Chemical Substances, eChemPortal)

- eChemPortal offers free public access to information on properties of chemicals:
 - Physical chemical properties
 - Environmental Fate and Behaviour
 - Ecotoxicity
 - Toxicity
- eChemPortal allows for simultaneous search of multiple databases and provides clearly described sources and quality of data.
- eChemPortal gives access to data submitted to government chemical review programmes at national, regional, and international levels.

<http://www.oecd.org/ehs/eChemPortal>; or link via ECHA Website

OECD: Collecting and/or generating data

- Existing information: Global Portal to Information on Chemical Substances <http://www.oecd.org/ehs/eChemPortal>
- Estimating properties: (Q)SARs
<http://www.oecd.org/env/existingchemicals/qsar>
- Testing: Test Guidelines and Good Laboratory Practices
<http://www.oecd.org/env/testguidelines>
<http://www.oecd.org/env/glp>
- Reporting: Harmonised Templates
http://www.oecd.org/site/0,3407,en_21571361_43392827_1_1_1_1_1,00.html

ECHA and non-EU countries

ECHA contacts with countries outside the EU

- ECHA Helpdesk important contact point
 - ECHA Website
 - In certain cases meetings with ECHA or ECHA makes presentations for larger audiences in other countries
 - The Commission Delegation one contact point
 - Participates in OECD WGs, TFs
 - Scientific and technical cooperation with some countries
 - IPA projects, participates in TAIEX events
 - Some Observers in HelpNet
-

REACH and CLP for non-EU companies

- Non-EU companies are not directly impacted (i.e. do not have direct legal obligations)
but imports to the 27 EU-Member States are under the scope of REACH and CLP
- EU-importers and/or Only Representatives (OR) must fulfill all REACH and CLP obligations for imported substances, preparations, articles;

REACH and CLP for non-EU companies

AND

EU-importers/OR rely on their suppliers in third countries for hazard data and safe use information that is required by REACH and CLP

- in practice, non-EU companies have to provide data of sufficient quality (e.g. OECD GLP certified labs) and in time to enable their importers/OR to fulfill the obligations in the EU legislation

Looking forward

ECHA work continues

- Dossier Evaluations
- Substance evaluations
 - Three CoRAP list of substances agreed since 2012
 - Identify need for further information within 1 year
 - The list will be updated annually
 - Member States split the evaluations between each other
- Continuous update of candidate list
 - 155 substances there now
- Authorisations has started
- Restrictions
- Last registration deadline 1 June 2018

ECHA work continues

- Harmonised C & L
- Dissemination website
 - More information added
 - More functionalities improving searchability
 - Single-point of access per substance
- Biocides has recently started
 - Regulation applicable from 1 September 2013
- PIC-regulation applicable from 1 March 2014
 - ECHA takes over the handling of the IT system for information to other countries

Thank you!

Questions?