

REACH 10 Year Anniversary Conference



June 15th 2017
Spencer Hotel, IFSC, Dublin 1

REACH: the story so far and the next ten years

Dublin, 15 June 2017

Geert Dancet
Executive Director







QSAR TOOLBOX



Substance Infocard

Formaldehyde

Other names: [Regulatory processes names \[2\]](#) [Trade names \[53\]](#) [IUPAC names \[6\]](#)



Substance identity

EC / List no: 200-001-8
CAS no: 50-00-0
Mol. formula: CH_{2O}



Hazard classification & labelling



Danger! According to the **harmonised classification and labelling (ATP06)** approved by the European Union, this substance is toxic if swallowed, is toxic in contact with skin, causes severe skin burns and eye damage, is toxic if inhaled, may cause cancer, is suspected of causing genetic defects and may cause an allergic skin reaction.

Additionally, the classification provided by companies to ECHA in **REACH registrations** identifies that this substance is fatal if inhaled and causes serious eye damage.

Properties of concern



Important to know

- Substance included in the [Community Rolling Action Plan \(CoRAP\)](#).

About this substance

This substance is manufactured and/or imported in the European Economic Area in 1 000 000+ tonnes per year.

This substance is used by consumers, in articles, by professional workers (widespread uses), in formulation or re-packing, at industrial sites and in manufacturing.

Consumer uses

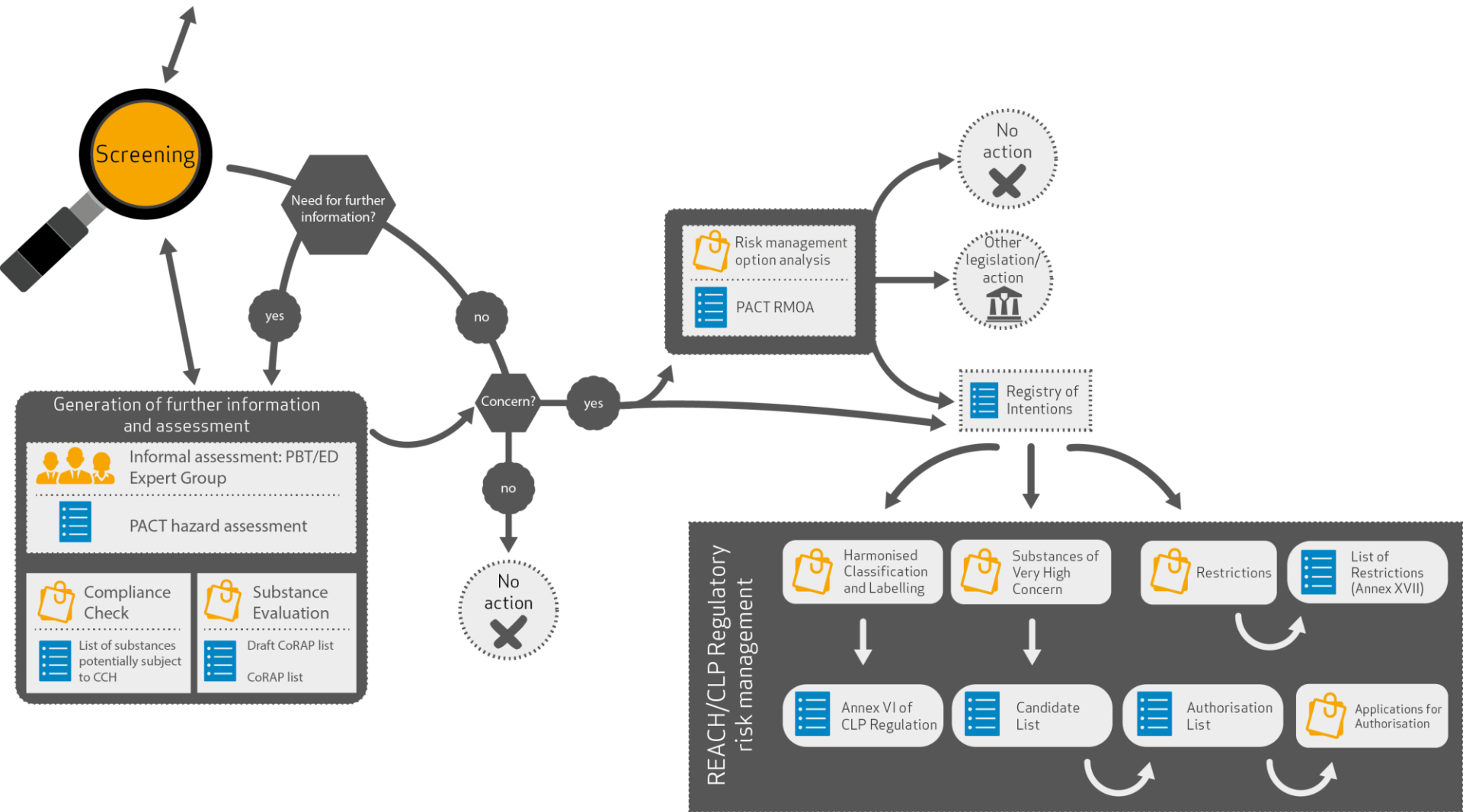
This substance is used in the following products: adhesives and sealants, coating products, fillers, putties, plasters, modelling clay, inks and toners, polymers, fuels, biocides (e.g. disinfectants, pest control products), polishes and waxes, washing & cleaning products and cosmetics and personal care products. Other release to the environment of this substance is likely to occur from: indoor use (e.g. machine wash liquids/detergents, automotive care products, paints and coating or adhesives, fragrances and air fresheners), outdoor use, outdoor use in long-life materials with low release rate (e.g. metal, wooden and plastic construction and building materials) and indoor use in long-life materials with low release rate [...]

How to use it safely

- ECHA has no data from registration dossiers on the precautionary measures for using this substance.
- [Guidance on the safe use of the substance](#) provided by manufacturers and importers of this substance.



SVHC Coordination Group
for Human Health



● Information on regulatory processes and activities

● Substance lists

- Classification information on **130,000** substances
- **11 560** companies have registered substances
- **60 134** registration dossiers for 16 124 substances
- **173** substances of very high concern
- **31** substances of concern require prior authorisation
- **20** new restrictions on use of dangerous substances to reduce risks
- **236** CLH opinions delivered by RAC

REACH 2018



Thank you!

Geert.Dancet(at)echa.europa.eu

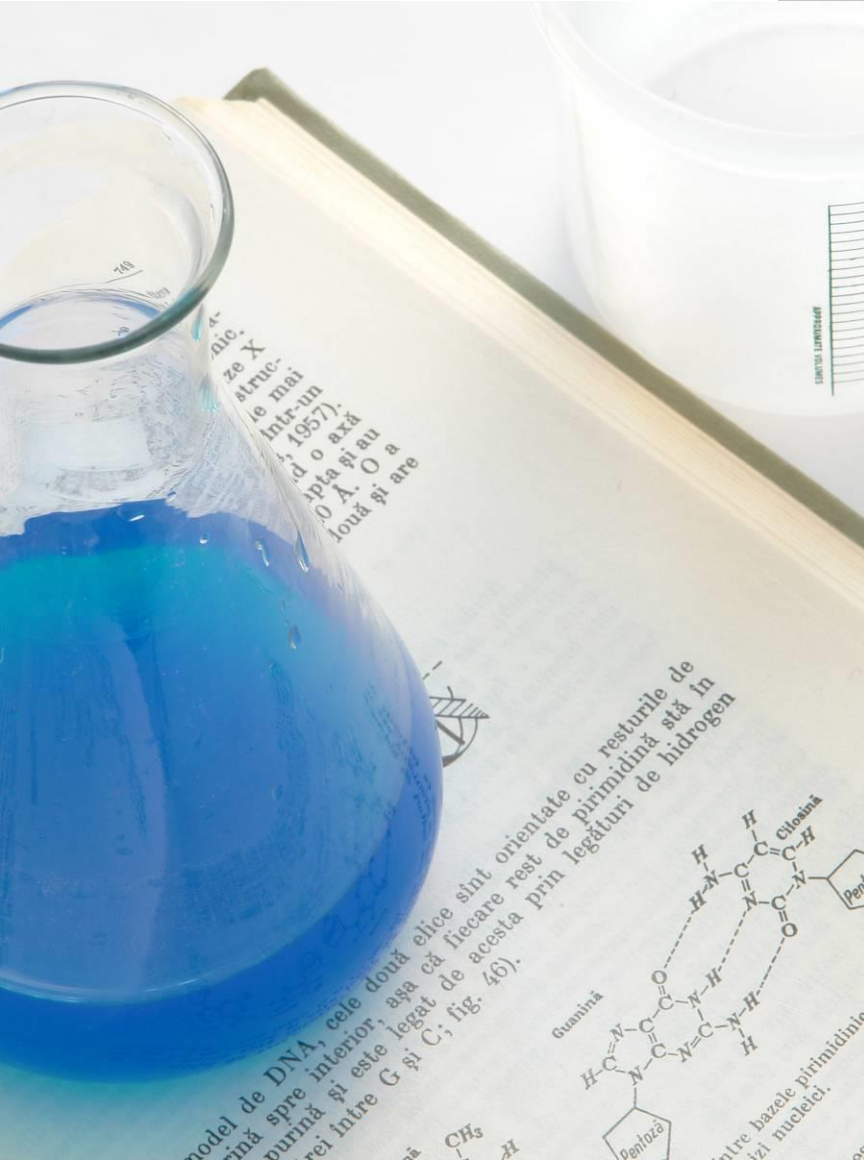
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European
Commission



REACH REFIT evaluation

*REACH 10 Year
Anniversary Conference
Dublin, 15 June*

*Klaus Berend
Directorate-General for Internal Market,
Industry, Entrepreneurship and SMEs
European Commission*

REACH REFIT evaluation

Legal obligation (Art 117 REACH) with input from:

- **Member States reports – June 2015**
- **ECHA reports – June 2016, 2017 (advanced)**
- **Commission, including thematic studies carried out between 2014 and 2017**
- **Open public consultation**
- **SME panel**
- **Eurobarometer on the perception of chemical safety by EU citizens**

REACH REFIT evaluation

Evaluation and Better Regulation Agenda

- Full-fledged evaluation according to Better Regulation requirements
- Evidence-based policy making
- improved transparency and stakeholder involvement.

Evaluation questions to be addressed

- To what extent has REACH been effective and efficient?
- To what extent is REACH relevant for the EU and its citizens?
- How coherent is REACH both internally and with other EU policies?
- Has REACH achieved EU added-value?

Latest developments

- ✓ *Online Public Consultation: 28 October 2016 and 28 January 2017*
- ✓ *SME specific consultation via the Europe Enterprise Network carried out*
- ✓ *Eurobarometer on perception of chemical safety published on 8 June*

http://ec.europa.eu/growth/tools-databases/newsroom/cf/itemdetail.cfm?item_id=9162

- ✓ *REACH Review 2017 website:*

http://ec.europa.eu/growth/sectors/chemicals/reach/review_en
http://ec.europa.eu/environment/chemicals/reach/review_2017_en.htm

Roadmap, consultation strategy, list of thematic studies, Results of consultations

Online Public consultation (1/3)

Objectives:

- **Collect stakeholders views on strengths and weaknesses of REACH**
- **Identify any possible missing element**
- **Ensure transparency and stakeholder engagement**

Questionnaire:

- **Questions for general public**
- **Specific questions concerning evaluation criteria and REACH procedures/mechanisms**

Online Public consultation (2/3)

Feedback expected:

- **Evidence (facts and figures) to identify and quantify effects (both positive and negative) of REACH**
- **Evidence-based description of main challenges for your sector**
- **Suggestions for burden reduction while preserving REACH objectives**

Online public consultation (3/3)

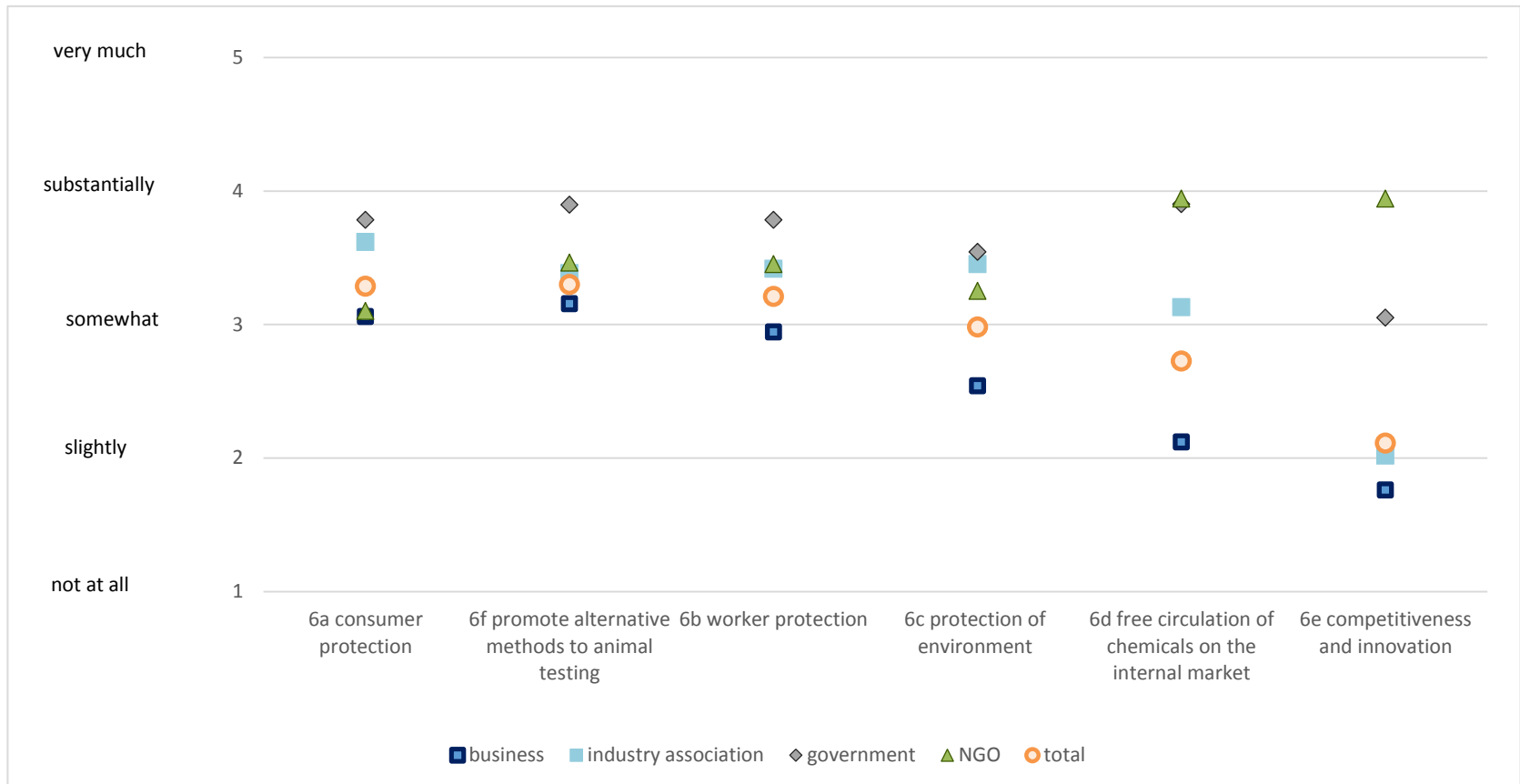
✓ *455 replies*

- **208 businesses, 142 industry associations,**
- **26 public authorities,**
- **21 NGOs, 8 academia, 6 consumer associations, 5 trade unions**
- **20 citizens, 17 other**

✓ *200 documents including position papers, academic articles, studies, presentations, test reports*

http://ec.europa.eu/growth/tools-databases/newsroom/cf/itemdetail.cfm?item_id=8952

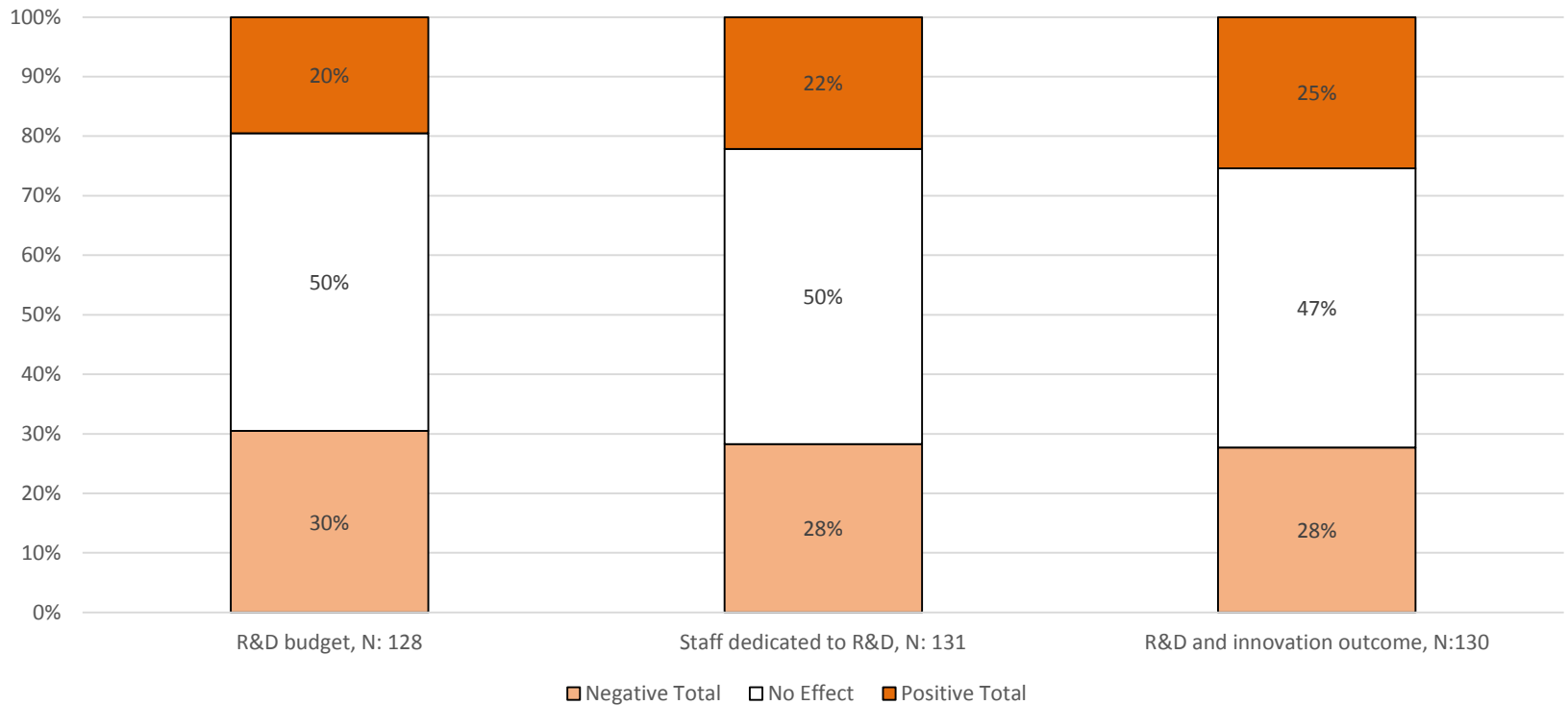
One example of results: To what extent do you think REACH is achieving the following objectives?



SME consultation

- ✓ Specific questionnaire addressing issues relevant for SMEs: sources of information used, effects of REACH, links with national authorities
- ✓ 181 replies
 - **32 large enterprises**
 - **63 medium-sized enterprises**
 - **63 small enterprises**
 - **23 microenterprises**
- ✓ Respondents profiles balanced in size and covering several REACH roles and sectors

Example of results: REACH impact on research & innovation



Finalised studies

Study on low tonnages (1 to 10 tpa) – Final report adopted in March 2015

<http://ec.europa.eu/environment/chemicals/reach/pdf/1-10t%20InfReq%20Final.pdf>

Study on polymers – Final report adopted in February 2015

<http://ec.europa.eu/environment/chemicals/reach/pdf/FINAL%20REPORT%20POLYMER%20SI671025.pdf>

Monitoring the impacts of REACH on competitiveness, innovation and SMEs – final report adopted in December 2015

<http://ec.europa.eu/DocsRoom/documents/14581/attachments/1/translations>

Study on development of enforcement indicators for REACH and CLP – final report adopted in April 2015

<http://ec.europa.eu/DocsRoom/documents/10364/attachments/1/translations>

Study on impacts of REACH and corresponding legislation governing the conditions for marketing and use of chemicals in different countries/regions on International competitiveness of the EU industry – final report adopted in December 2016

<http://ec.europa.eu/DocsRoom/documents/20001>

Study on Substance Identity (SID) in REACH. Analysis of SID and substance sameness of complex substances

<http://ec.europa.eu/DocsRoom/documents/17805/attachments/1/translations/en/renditions/native>

Ongoing studies

Study on costs and benefits of REACH authorisation – launched in September 2016; targeted survey ongoing; feedback to be gathered by end of March; Interim report submitted by end of April and final report expected in September

Next steps

Publication of the summary of the open public consultation in the REACH REFIT evaluation webpages

Submission of the Evaluation Report (Staff Working Document) to the Regulatory Scrutiny Board

Commission Report and Staff Working Document to be adopted and published in autumn 2017

One important element in the evaluation is coherence – within REACH and with other legislation

Among these, the interface between REACH and OSH has a lot of attention:

- *Commission Workshop in November 2014*
- *Submission by the Cross-Industry Initiative to the REFIT platform*
- *Commission Communication on the outcome of the OSH REFIT (COM (2017) 12 final)*
- *Commission mandates to SCOEL and RAC on their methodologies to derive limit values or dose/response curves*

Thank you

For further information on REACH and the REACH REFIT evaluation, please visit:

ec.europa.eu/growth/sectors/chemicals/reach/

ec.europa.eu/environment/chemicals/reach

echa.europa.eu

http://ec.europa.eu/growth/sectors/chemicals/reach/review_en

http://ec.europa.eu/environment/chemicals/reach/review_2017_en.htm

Article 138

Review

From 1 June 2019, the Commission shall carry out a review to determine whether or not to extend the application of the obligation to submit a chemical safety assessment and to document it, for substances not covered by this Directive because they are not subject to registration or subject to registration but manufactured or imported in quantities of more than one tonne per year. However, for substances meeting the criteria set out in Article 137(1) of the Directive, in accordance with Directive 2008/104/EC, referred to in Article 137(1) of the Directive, the Commission shall carry out a review by 1 June 2019.

This presentation does not necessarily reflect the official opinion of the Commission.

The Competent Authority view - past and future

Sharon McGuinness

15 June 2017



In the beginning.....



REACH adopted on 18 December 2006

The purpose of the Regulation:

- Ensure a high level of protection of human health and the environment
- Promote alternative methods for assessment of hazards of substances
- Promote the free circulation of substances on the internal market
- Enhance competitiveness and innovation

Introduced a sea-change in chemical regulation

- Reversal of the burden of proof - Industry responsible for their own substances
- Level playing field between old and new substances
- Animal testing as a last resort
- Communication required up/down the supply chain
- Central agency (ECHA)

What would it really mean.....

- More data on chemicals
- Focus on risk management rather than hazard identification
- Focus on substances of very high concern (SVHCs)
- Faster and more transparent decision making

In preparing for REACH, Ireland...

- Introduced the Chemicals Act 2008 – 3 Competent Authorities
- Health and Safety Authority – lead CA and enforcement agency
- Established the REACH Helpdesk

As lead CA, our priorities were & remain the same

- Fulfil our CA functions with a view to ensuring hazards (SVHCs) are correctly identified and risks properly controlled
- Support IE stakeholders, particularly SMEs
- Enforce

Some facts and figures.....



REACH and CLP facts and figures.....

- Classification information on **130,000** substances
- **11,560** companies have registered substances
- **60,134** registration dossiers for **16,124** substances
- **319** substances subject to evaluation
- **173** substances of very high concern
- **31** substances of concern require prior authorisation
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REACH & CLP facts and figures - IE

- Ireland is **8th** overall in number of registrations
- **1735** registrations for **851** substances (3.46% of EEA total)
- **1352** are OR registered substances – **11.63%** of EEA
- **427** Intermediate registrations – **3.92%** of the EEA

Breakdown of IE Registrations - Company Size

- Large - 1426 registrations - 3.31% of EEA total
- SME - 308 registrations - 4.38% of EEA total
 - 150 - Medium company (3.90% of EEA)
 - 112 - Small company (4.90% of EEA)
 - 47 - Micro company (5.04% of EEA)

REACH & CLP facts and figures - IE

- 3 companies have applied for authorisation to-date
- 1 company has had an authorisation application approved

As Lead CA, we have.....

- **Evaluated** 3 substances under substance evaluation
- **Participated** in relevant ECHA committees and groups - MSC, RAC, Forum on Enforcement, Helpnet
- **Represented** IE at CARACAL and REACH Article 133 Committee
- **Acted as rapporteurs** for authorisations, restrictions & MSC recommendations
- **Contributed** to the SVHC Roadmap

As Lead CA, we have.....

- **Answered** 2,299 REACH and 1,192 CLP queries
- **Advised** 1000s of stakeholders through seminars, workshops, bulletins
- **Held meetings** with 100s of trade bodies and companies
- **Published** 60+ information sheets and guidance docs

Stakeholder Guidance

Safety Data Sheets for Hazardous Chemicals Information Sheet

An overview of the REACH Regulation (EC) No. 1831/2003, which sets out the obligations for manufacturers and importers of hazardous chemicals, and the requirements for the preparation and distribution of Safety Data Sheets (SDS) for hazardous chemicals, is provided in this information sheet. The information sheet is available in English, Irish and Gaelic. It is available in other languages on request. For more information, please contact the Health and Safety Authority at the following telephone number: 1800 455 611.

The Safety Data Sheet must contain the following information:	
1. Identification of the substance	8. Hazardous ingredients
2. Hazards of the substance	9. Physical and chemical properties
3. Health hazards	10. Exposure controls
4. Environmental hazards	11. Transport and handling
5. Regulatory information	12. Stability and reactivity
6. Safety, health and environment	13. Other information
7. Safety, health and environment	

- Safety Data Sheets must be available for:**
- 1. Manufacturers of substances
 - 2. Importers of substances
 - 3. Suppliers of substances
 - 4. Distributors of substances
 - 5. Retailers of substances
 - 6. Users of substances
 - 7. Importers of substances
 - 8. Exporters of substances
 - 9. Suppliers of substances
 - 10. Distributors of substances
 - 11. Retailers of substances
 - 12. Users of substances
 - 13. Importers of substances
 - 14. Exporters of substances
 - 15. Suppliers of substances
 - 16. Distributors of substances
 - 17. Retailers of substances
 - 18. Users of substances
 - 19. Importers of substances
 - 20. Exporters of substances
 - 21. Suppliers of substances
 - 22. Distributors of substances
 - 23. Retailers of substances
 - 24. Users of substances
 - 25. Importers of substances
 - 26. Exporters of substances
 - 27. Suppliers of substances
 - 28. Distributors of substances
 - 29. Retailers of substances
 - 30. Users of substances



Hazard Labelling & Packaging according to the CLP Regulation

Information Sheet May 2014



The Classification, Labelling and Packaging (CLP) Regulation covers hazardous chemicals sold to professional users and consumers. This information sheet outlines the key requirements for the labelling and packaging of hazardous chemicals under the CLP Regulation.

All hazardous chemicals (substances and mixtures) placed on the market must be classified, labelled and packaged according to the CLP Regulation (EC) No. 1272/2008 by 1st June 2015. The responsibility for labelling and packaging of hazardous substances and mixtures rests with:

- manufacturers of substances,
- importers of substances or mixtures,
- formulators of mixtures, and
- distributors or Downstream Users, who do not reformulate or change the substance or mixtures but relabel/package them.

Exemptions from CLP
Vet and cosmetic, medicinal, medical device, veterinary products, foodstuffs or animal feed intended for use in their finished state, intended for the final user or not covered by the CLP Regulation.

Classification of Hazardous Substances/Mixtures
The physical properties along with health and environmental effects of chemicals must be identified and evaluated to determine if they need to be classified. Some hazardous chemical substances have

CHEMICAL IMPORTERS Information Sheet

October 2013

Under EU Chemical Regulations, those who import chemicals from outside the EU have a number of duties to fulfil. This information sheet aims to outline the key responsibilities for EU importers of chemical substances and mixtures under the REACH, CLP and Rotterdam Regulations, for which the Health & Safety Authority are the relevant Competent Authority in Ireland.

Who is legally responsible for the importation of chemical substances and mixtures into the EU?
Import means the physical introduction into the customs territory of the EU.

• An importer, in accordance with the REACH and CLP Regulations, is defined as any natural or legal person established in the EU who is responsible for import. Under REACH and CLP, import is deemed to be placing on the market.

Companies who source their chemicals from within the EU are not importers and do not have any importer duties as they are considered to be downstream users.



Exporters Duties under the Rotterdam Regulation (EU) No 649/2012 on the Export and Import of hazardous chemicals

Information Sheet Updated May 2015

For certain hazardous chemicals and articles containing them, the export to countries outside of the EU is prohibited under Regulation (EU) No 649/2012. Strict administrative procedures are in place to ensure their export is legitimate. This information sheet provides exporters with information to help them identify whether they are likely to have duties under Regulation (EU) No 649/2012 and to assist them with the steps involved in meeting their obligations prior to chemical export.

What Chemicals are covered under this Regulation?
Regulation (EU) No 649/2012 applies to hazardous chemicals (individual chemicals, pesticides and biocides) that are already severely restricted for sale or banned within the EU, for example, barbitone and diazinofluthrin.

If the chemical contains a substance listed in Annex I of Regulation (EU) No 649/2012, exporters of such chemicals to countries outside the EU must notify their intent to export the chemical to the Designated National Authority (DNA) and in certain cases obtain explicit consent from the importing country before the export can proceed. The Health and Safety Authority (HSA) is the DNA for Ireland as chemical only under the Regulation.

Annex I that these parts and is regularly updated as a result of ongoing regulatory actions under EU legislation, and developments under the Rotterdam Convention. Chemicals listed in the individual parts of the Annex are subject to different procedures.



Information for Retailers on Hazard Labelling & Packaging of Chemical Products

July 2013

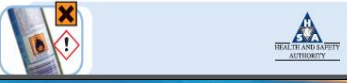
Hazardous chemical products must be labelled and packaged according to rules set out in specific classification, labelling and packaging legislation. Manufacturers, importers and formulators must ensure that such products are labelled and packaged correctly before being placed onto the market for sale. Retailers who supply chemical products do not themselves have responsibility for labelling chemicals with hazard information, unless they are selling their own brand products. They are, as suppliers of chemicals, responsible for ensuring that the hazardous chemicals for sale on their shelves are correctly labelled with the relevant hazard information and packaged accordingly.

What is a Chemical Product?
A chemical product may be any chemical ranging from an everyday household cleaning chemical to a chemical used in the industrial setting. Products include paints, lubricating oils, glues, detergents such as dish cleaners, toilet deodorants, window cleaners, oven cleaners and bleach. A chemical product may be a substance or a mixture of substances or a mixture of substances in a pack and underlying detergent.

When does a Chemical Product require a Hazard Label?
A chemical product must have a hazard label when it is classified as hazardous from a physical, chemical, health or environmental hazard.

Role of the Retailer in Hazard Labelling
Hazardous chemicals are not permitted to be imported or marketed unless they are classified, labelled and packaged correctly. Retailers of chemical products who sell on the product for the professional and/or the consumer or general consumer use, should ensure that the correct hazard label is shown on the label of the product (although they themselves have not produced the product).

Who is responsible for Hazard Labelling?
Manufacturers, Importers and Downstream Users (Consumers) all have responsibilities in relation to the labelling of chemical products which are classified as hazardous. Importers, distributors, including retailers, who re-label or change hazardous chemicals with their own label, must ensure that the correct hazard information on the label of the chemical product, following the applicable rules.



Labelling and Packaging requirements for Detergents & Biocidal Detergent Products

July 2014

The Detergent Regulations cover the manufacture, placing, making available on the market and use of detergent products. In addition, detergents with a biocidal action are also regulated by the Biocidal Products Regulation (BPR) which includes disinfectants, sanitizers, antimicrobials, antifungals and any detergents with biocidal activity. This information sheet covers the packaging and labelling requirements of detergents and biocidal detergents.

All detergents on the EU market must be labelled and packaged according to the Detergent Regulations. Detergents that contain biocidal active substances must also comply with the Biocidal Products Regulation. The responsibility for labelling and packaging of detergents and biocidal detergents lies with:

- all manufacturers/producers and importers of detergent/biocidal detergent products,
- any person changing the formulation (composition) of a detergent/biocidal detergent, and
- any person who changes the labelling or packaging of a detergent product including retailers and distributors who sell their own label detergent.

Distributors, including retailers, who only supply the market have a responsibility to ensure the detergents they "make available" to the market are compliant.



HEALTH AND SAFETY AUTHORITY

2012 Survey of Chemical Usage in Irish Workplaces

Final report

4/30/2013

The Consumer

Liquitabs can damage your child's eyes.



Store them safely.



15:56 30%

Tweet

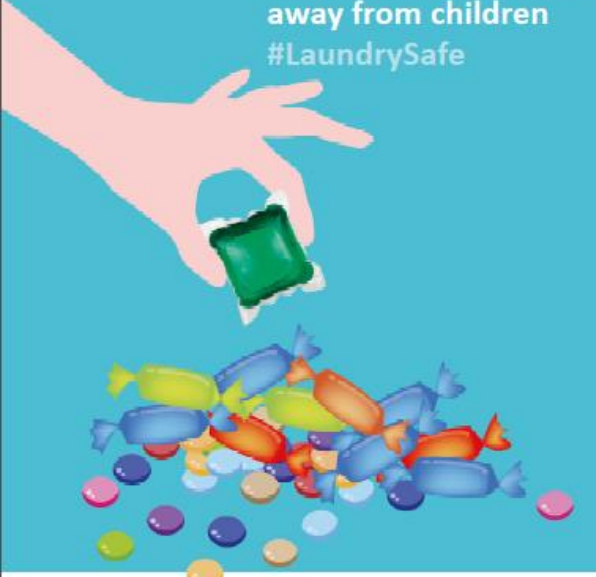
HSA @TheHSA

Liquitabs can be attractive to children and pose serious dangers! Keep laundry capsules away from children!
ow.ly/8Oy6304loP9



Kids don't see the difference

Keep laundry capsules away from children
#LaundrySafe



OECD | European Commission

Global Awareness-raising Campaign on Laundry Detergent Capsules/packets
16-23 March 2015

As enforcement authority, we have.....

- **Conducted** 7826 REACH & CLP related inspections
- **Integrated** REACH inspection into other enforcement areas – Seveso, Occupational H&S
- **Developed** market surveillance programme and checked >1000 chemical products including Liquitabs, E-liquids etc.
- **Engaged** in 5 REACH Enforcement Projects (REF), pilot projects and working groups in the Forum on Enforcement

Chemical Enforcement Findings 2016

260
REACH/CLP
inspections

14 detailed
REACH/CLP
Audits

3
Manufacturers
1 O/R

8
Importers

199
Downstream users
incl. 17 formulators
87 distributors

Market
Surveillance
281 Chemical
Products

31
Carcinogens
Cat. 1A and 1B

10 Mutagens
Cat. 1A and 1B

43 Reproductive
toxins

58 Sensitisers

4 SVHC, 2 of which subject to authorisation

160 Rapex Alerts

- 74 China
- 23 India
- 11 USA
- 8 Pakistan

- Covered by an authorisation application further up supply chain

Future Challenges



Within REACH....

- Meeting 2018 Registration deadline – SMEs
- 2018 registration is not the end
- Quality of data
- OSH-REACH overlaps
- Substances in articles/products
- Downstream Users – niche sectors & SMEs
- Nanomaterials and Endocrine disruptors
- Use of the data generated in REACH more widely

Other issues

- REACH Evaluation
- Circular Economy – Chemicals/Products/Waste
- Non-toxic Environment
- Brexit

Thank You



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June 15th 2017
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