



*Cefic Action Plan for Review/Improvement
of Registration Dossiers
& 2 industry examples*

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3 (different) parts presentation:

**Part 1 – Cefic Action Plan for
Review / Improvement of
Registration Dossiers**

Part 2 – Illegal imports of HFCs

Part 3 – Online sales of GBL



Part 1 - *Cefic Action Plan for
Review / Improvement of
Registration Dossiers*





We want REACH to work

We want people and the environment to be **safe** when handling and using chemicals.

- ⇒ Confidence in EU chemical legislation framework
- ⇒ Confidence in chemicals

How?

- Demonstrate safe use with **data on hazards and exposure**.
- Identify substances that cannot be used safely and uses that are not appropriate; and determine the most appropriate RMM.



We are proud of what has been achieved 2008-2018

- > 22.000 substances registered;
- > 95.000 registrations;
- 80% of lead registrants have already made an update (high-volume substances).



The EU is a trail blazer

REACH:

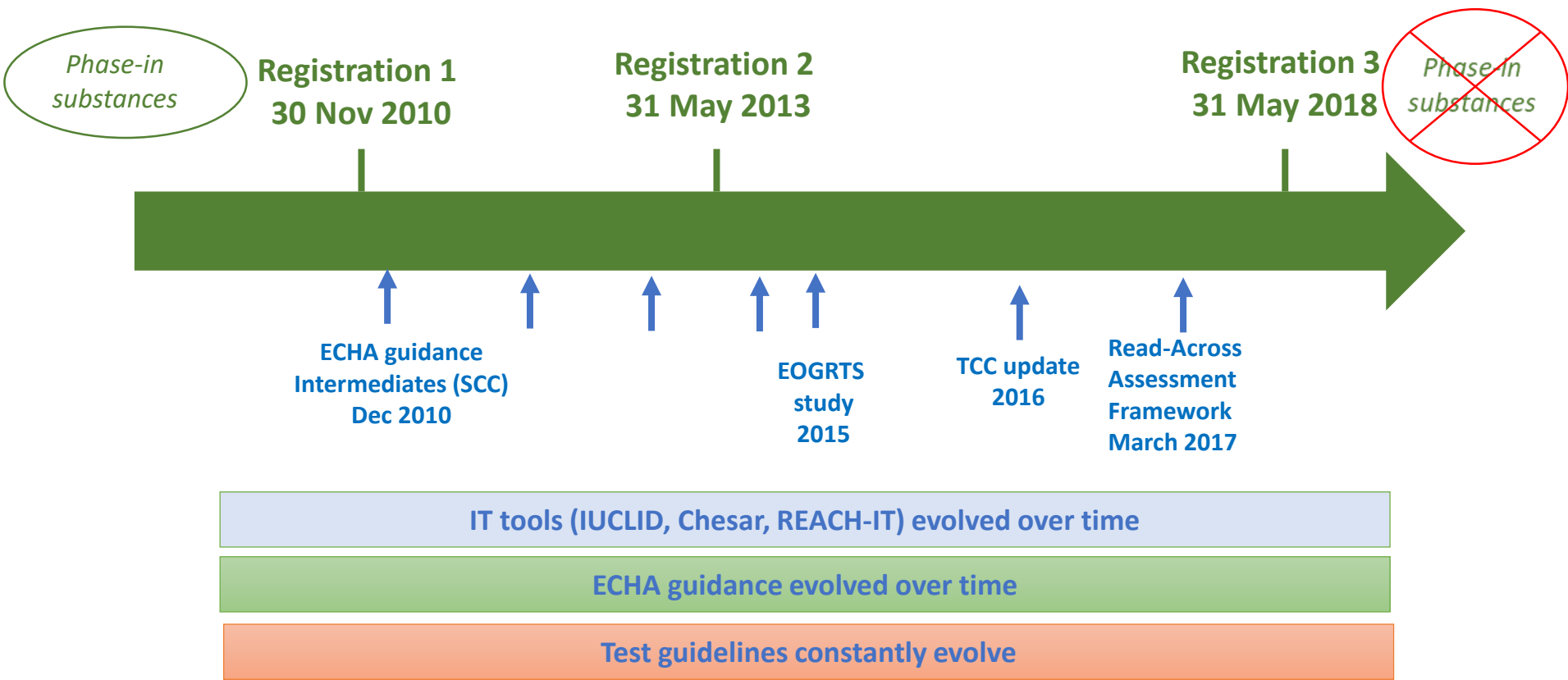
- is the **most ambitious, most extensive** chemical legislation in the world;
- introduced **novel and unique features**, e.g. SIEFs, burden of proof on industry, exposure scenarios, authorisation;
- **extensively** covers substance hazards and uses;
- is **complex**, subject to interpretation, both legally and scientifically;
- There is **no one-size-fits-all** model.

With sophistication comes complexity

One (full) registration is:

- ✓ > 2.000 data fields in IUCLID;
- ✓ Up to 70 phys-chem, tox and ecotox studies/tests;
- ✓ 100-150 hours of work (when all studies/info has been gathered);
- ✓ Complex consortia/SIEF dynamics;
- ✓ Some studies take 1-2 years to run;
- ✓ Complex use and exposure assessment;
- ✓ A lot of maintenance: requires update when new information is available.

REACH is an on-going improvement process



We all learnt a lot in the last 10 years
Guidance and tools evolved

A difficult balance

particularly for long-term endpoints



Generate new data

Standard requirements:
One registration for > 1000T substance requires about 6000 rats and rabbits and 100 fish.



Animal testing as a last resort

Adaptation of standard requirements:

- predictive methods;
- “sufficient” weight-of-evidence;
- waiving based on “negligible exposure”.

**Read-across/grouping and waiving are essential but complex.
Common understanding needs to be further developed.**



REACH Dossier Improvement Action Plan



Cefic launches Action Plan to help REACH registrants review chemical safety data

In June 2019 the European chemical industry launched an unprecedented action to help its members proactively and systematically review and update data in previously submitted REACH registration dossiers. This initiative comes in response to the recent conclusion by the European Chemicals Agency (ECHA) that many REACH registration dossiers require additional information.

To this end Cefic has developed a multi-annual Action Plan, which provides a framework for REACH registrants to evaluate the safety data in a stepwise manner. The Action Plan outlines the timeline, roles and responsibilities, substance prioritisation criteria, critical issues, and explains how progress will be reported.

<https://cefic.org/our-industry/reach-dossier-improvement-action-plan>

Cefic developed an Action Plan for Review/Improvement of Registration Dossiers



Objectives

Proactive re-assessment of registration dossiers content, and effectively and efficiently identify/address data or information gaps (staged priority setting), if needed.

The commitment is open to all Cefic member companies, including national Association members.





Key elements of the initiative?

Action Plan

- Timeline: 2019-2026;
- KPIs (on Action Plan implementation);
- Roles and responsibilities: Cefic / companies;
- Criteria to prioritise substances for re-evaluation;
- Annual Reporting (template).



Declaration of Intent, *signed by individual companies*

- Re-evaluate dossiers and provide further information, where appropriate;
- Report to Cefic on KPIs → Cefic annual reports.

Cooperation framework with ECHA

- Further cooperation with ECHA, under the umbrella of the June 2018 Cefic-ECHA Joint Statement.

Cooperation framework with ECHA: activities



- **Development of material to guide registrants** towards a clearer understanding of what is expected under Article 41 of REACH (CCH procedure)
 - **Case studies** to illustrate practical application of the Read Across Assessment Framework
 - Examples of **testing strategies** or **waiving justifications** that have helped registrants successfully pass a compliance check, both for human health and the environment, while ensuring new vertebrate animal studies are performed only as a last resort
- Identification and notification of **priority substances**
- Progress tracking
- Dissemination



Transparent communication and progress reporting



Via Cefic's website

- Action Plan and related material;
- Guidance/tools produced during implementation;
- Workshop summaries;
- Annual progress reports.

<https://cefic.org/our-industry/reach-dossier-improvement-action-plan>

Information to stakeholders



Role of Cefic

- Act as a **platform to support, coordinate and streamline** companies' efforts for the review/improvement of dossiers.
 - Cefic does not run consortia and does not work on specific substances or dossiers;
 - Help generate common learning;
 - Develop and publish material, including progress reports;
 - Facilitate interaction with ECHA (technical and scientific challenges).
- **Promote** the initiative and **engage** as many companies as possible.



What does it entail for companies?

- Prioritisation process;
- Resources and costs (more testing is expected);
- Company implementation plan;
- Further work with consortia / SIEFs.

Cefic is not and will not be involved in individual dossier assessment. It is for each individual company to proactively review/ improve their dossiers, and to coordinate with consortia/SIEFs as applicable.



What are the next steps?

- Implementation of the Action Plan.
- Signatures – **companies** commitment:
 - Cefic member companies;
 - National Associations member companies.
- **National Associations** engagement.
- Dialogue with other registrants' associations.

More than 140 companies have
joined the Action Plan.



Enforcement Authorities (EA)

- How are EA applying the new ECHA's practice (i.e. draft Decisions sent to all registrants)? How are EA coordinating in different MSs?
- How do EA consider the lab capacity issues? How to deal with the shortage of available labs? What are the implications?
- How could EA help to raise awareness?

Part 2 – *Industry example 1*

Illegal imports of HFCs





What are hydrofluorocarbons?

Hydrofluorocarbons (HFCs) are greenhouse gases, widely used in air-conditioning and for refrigeration.

⇒ Phase-down schedule under F-Gas Regulation:

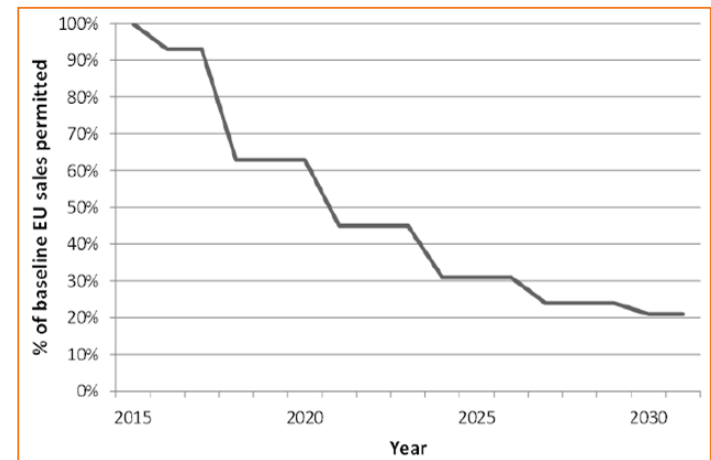
- 37% reduction by 2018
- 55% reduction by 2021
- 69% reduction by 2024
- 76% reduction by 2027
- 79% reduction by 2030



Commercial refrigeration



Air-conditioning

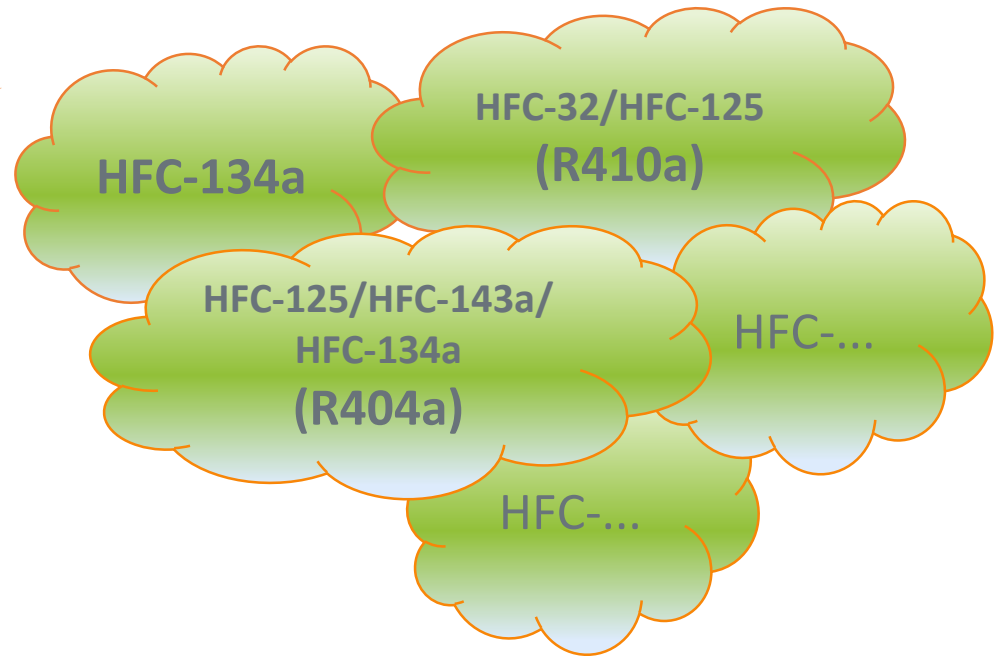


Historically replaced chlorofluorocarbons
(ozone depleting substances)



What is the concern?

**MID-2018
ILLEGAL IMPORTS
OF HFCs**



Countries affected by illicit market practices identified.



Illegal imports of HFCs - implications

F-Gas Regulation:

- Phase-down of HFCs via EU quota system.
- 37% reduction vs baseline in 2018.
- Successful programme until mid-2018.

Mid-'18: illegal imports of HFCs

Transport Regulation (ADR):

- Illegal HFC shipments in non-ADR compliant cylinders.
- Arriving in major ports & land borders (Central EU).
- Trade via internet/express delivery services.



REACH:

- Many illegally imported HFCs not REACH compliant.
- Quantities > 1 tonne/year;
 - Illegally imported HFCs (including confiscated material) currently not on REACH enforcement radar?



European Fluorocarbons Technical Committee (EFCTC), a Sector Group of Cefic



<https://www.fluorocarbons.org/illegal-trade-of-hfcs/>

EFCTC action plan:

- Private investigator at borders; provides evidence to national enforcement agencies.
- Close contact with OLAF.
- Proposal to support MS customs' trainers.
- ...

EFCTC information campaign:

- ADR competent authorities.
- Logistics and delivery companies.
- Environment competent authorities.

EFCTC raises awareness:



Let's protect the environment and stop these illegal imports together!!

For further information, please contact
A. Candido (anc@cefic.be), EFCTC Manager

Part 3 – *Industry example 2*

Online sales of GBL



The chemical GBL is essential to society

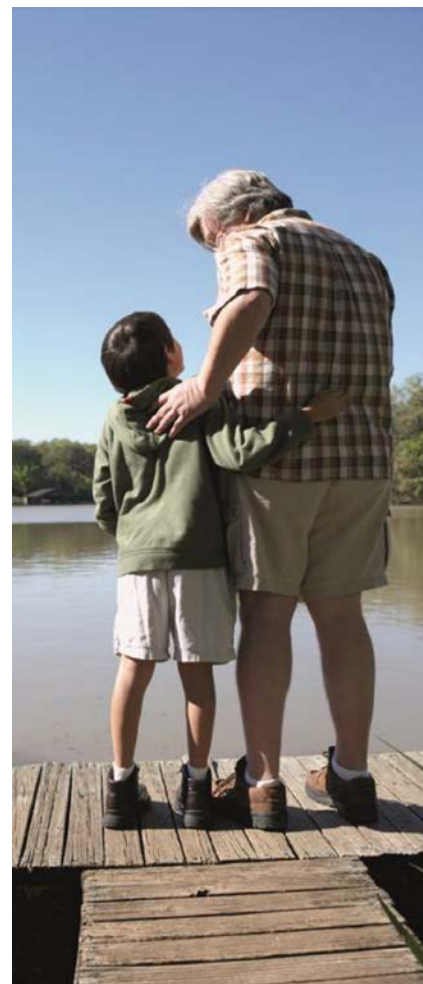
(Process solvent, raw material for chemical synthesis)



GBL (γ -Butyrolactone) down stream product is essential for:

- Antibiotics, Alzheimer-medication
- Wound disinfection, essential Vitamin B1
- Plant protection (insecticide, fungicide)
- Production of semi-conductors
- Filters for drinking
- Cosmetic product

European manufacturers clearly “**advice against use**” of GBL in cleaners for consumer use in their safety data sheets.

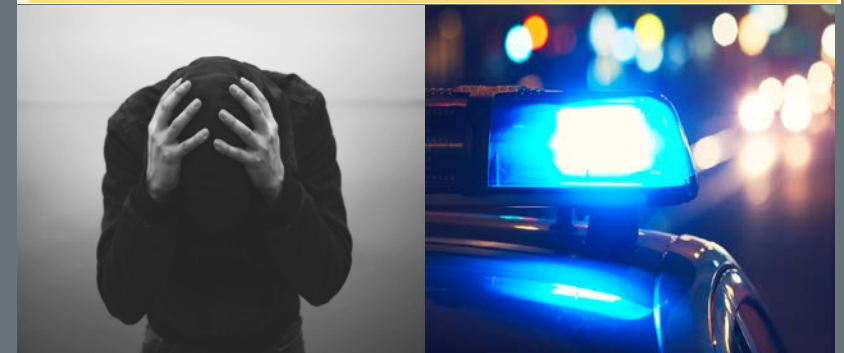


GBL – What can we do?

Actual use
Legitimate intention



Public perception
Criminal intention



ICCA GBL Task force (Chaired by Cefic)



Voluntary product stewardship practices offer one of the most effective means to prevent diversion into illicit trade.



- Cefic had developed voluntary practices in 2005.
- ICCA task force has been working closely with affiliated associations to develop an international voluntary Product Stewardship Code .
- ICCA Steering committee endorsed the code on 5th of April 2017.



<https://www.petrochemistry.eu/sector-group/bdo-derivatives/>



Voluntary Product Stewardship Practices to Prevent Diversion of GBL

1. Implement procedures
- 2. Check Customers credibility**
- 3. Collect End-use declarations**
4. Require distributors to join
- 5. Notify authorities of suspicious orders**
- 6. Prevent tampering with containers**
- 7. Same procedures for samples**
8. Monitor and review procedures

Internet Sales an area of conflict



Google search “*buy GBL*” provides anybody with several hits on internet shops.

Web shops do look professional and make any claim to look trustworthy.

Customer portals and reviews on web shops are available.

Web shops sell GBL 99.9% as cleaner to consumers (rims, wall, etc.).

Price is clearly way above the price you would pay for a cleaner.

Shops accept bitcoins etc. or provide strange payment instruction

Looking for solutions



- **Industry goal:** we act responsibly as an integral part of society.
- **Cooperation is a corner stone of our approach:**
 - Ensures a good understanding of the respective difficulties;
 - Ensures effective, appropriate and proportionate measures.
- **Proactive discussion with authorities to regulate GBL under REACH (Restriction) to restrict any consumer use of GBL and enable enforcement.**



For further information, please contact
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Thank you!

