

NO DATA, NO MARKET?



EEB

European
Environmental
Bureau

Enforcement Forum
5 November 2019

Dolores Romano

EUROPEAN ENVIRONMENTAL BUREAU (EEB)

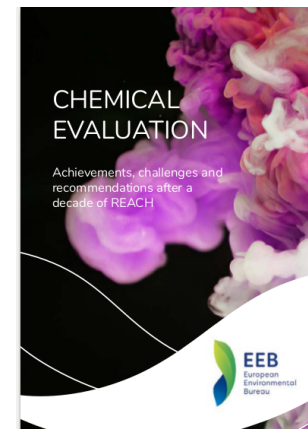
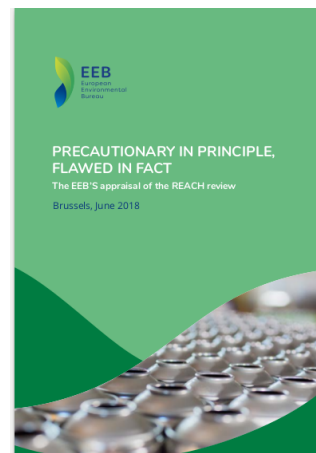
- Europe's largest network of environmental citizens' organisations
 - around **150 civil society organisations**... including a growing number of **European networks**
 - ...from more than 30 European countries
 -
- Over 40 years of EU environmental policy expertise

EEB: WHAT ISSUES DO WE FOCUS ON

- EEB tackles **Europe's most pressing environmental problems** by agenda setting, monitoring, advising on and influencing the way the EU deals with these issues.
-
- Our areas of work include:
 - **Climate and Energy**
 - **Nature and Sustainable Agriculture**
 - **Industry and Health**
 - **Resource Efficiency**
 - **Sustainability and Governance**
 - **Global and Regional Policies**

EEB & REACH

- The EEB participates actively at all ECHA Committees (MSC, RAC and SEAC) and nano and PBT expert groups as well as CARACAL.
- Follows closely REACH, ECHA, Commission and MS activities in order to ensure proper implementation.
- **Make proposals for improvement**



REACH REGULATION

Article 1. Aim and scope

1. The purpose of this Regulation is to **ensure a high level of protection of human health and the environment**, including the promotion of alternative methods for assessment of hazards of substances, as well as the free circulation of substances on the internal market while enhancing competitiveness and innovation.
3. This Regulation is **based on the principle that it is for manufacturers, importers and downstream users to ensure** that they manufacture, place on the market or use such substances that do not adversely affect human health or the environment. Its **provisions are underpinned by the precautionary principle.**

REACH REGULATION

- Article 5 **No data, no market**

Subject to Articles 6, 7, 21 and 23, substances on their own, in preparations or in articles **shall not be manufactured in the Community or placed on the market unless they have been registered in accordance with the relevant provisions** of this Title where this is required.

Information should be provided for registration according to Articles 10 to 12, 14, 19 and 24

REACH REGULATION

- Article 22 **Further duties of registrants**

1. Following registration, **a registrant shall be responsible on his own initiative for updating his registration** without undue delay with relevant new information and submitting it to the Agency in the following cases:

....

e) **new knowledge of the risks of the substance** to human health and/or the environment of which he may reasonably be expected to have become aware which leads to changes in the safety data sheet or the chemical safety report;

REACH REGULATION

- **Title XIV ENFORCEMENT**

-

Article 125 **Tasks of the Member States**

Article 126 **Penalties for non compliance**

Member States shall lay down the provisions on penalties applicable for infringement of the provisions of this Regulation and shall take all measures necessary to ensure that they are implemented. **The penalties provided for must be effective, proportionate and dissuasive.**

REGISTRATION IS THE PILLAR OF THE REACH REGULATION:

Should provide the information on hazards, uses and exposure needed to identify and control the risks and ensure safe use.

It is the basis for further regulatory action

It is the basis for ensuring proper information along the supply chain and to consumers.

COMPLIANCE WITH REACH REGISTRATION

- ECHA's Evaluation Progress Reports 2008-2017
- BfR & UBA project
- Enforcement Forum Projects
- REACH Review

ECHA's Evaluation Progress Reports 2008-2017

Percentage of non-compliant endpoints identified in compliance checks

Year	2009	2010	2011	2012	2013	2014	2015	2016	2017
N.º CCh	14	70	239	146	1130	283	183	184	222
% Non compliant	50	64	92	61	61	82	91	91	68

ECHA's Progress Report on Evaluation, 2017

Status of dossiers after submission of information requested in dossier evaluation	Percentage of endpoints
Compliant	85%
Non compliant	14%
2nd decision making process	1%

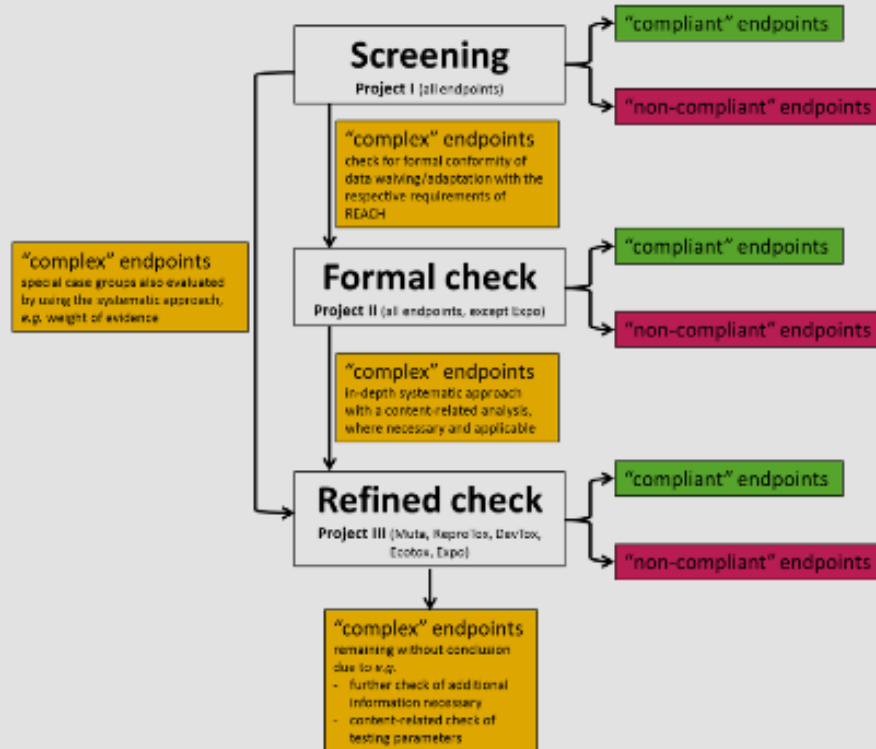
UBA/BfR project

- Checked 1,814 HPVC (>1000 t/y) plus 2053(>100t/y)
- Registered by 2014
- Focused on endpoints of “**highest significance for human health and environment**”: carcinogenicity, mutagenicity, persistence, bioaccumulation, reproductive and developmental toxicity.



UBA/BfR project

Figure 2-1: Overview of the stepwise approach in project I to III

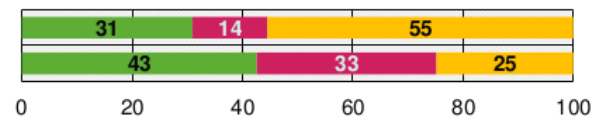
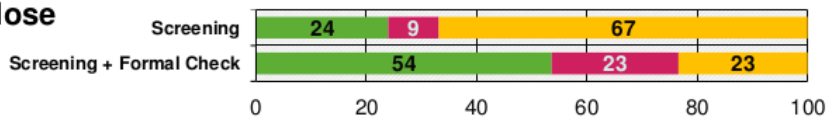


Human health endpoints – Results after Screening and Formal check

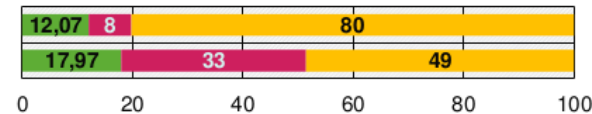
100-1000 tpa

≥1000 tpa

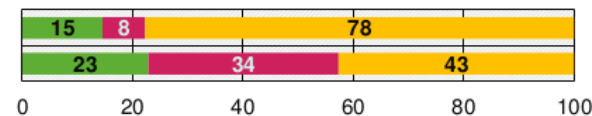
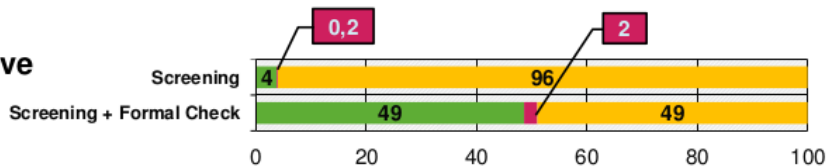
Repeated dose toxicity



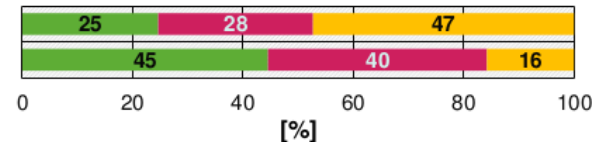
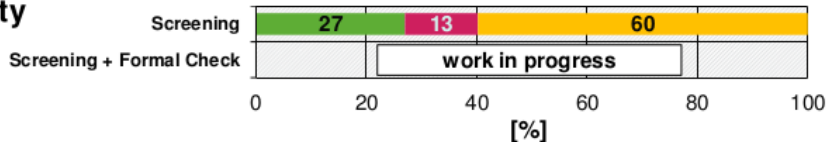
Developmental toxicity



Reproductive toxicity



Mutagenicity



■ "compliant" ■ "non-compliant" ■ "complex"

N= 2053/500

N= 1814

Research on BfR data:

940 substances not compliant (2014 data)

41 substance dossiers not updated since 2014

654 companies all over the EU

5 global top 10: BASF, Dow Chemical, SABIC, Ineos, ExxonMobil

Forum REACH-EN-FORCE 3 - Phase 1 Project Report

Registration obligation inspections:

first half of 2013 until August 2013.

528 inspected companies,

3065 substances

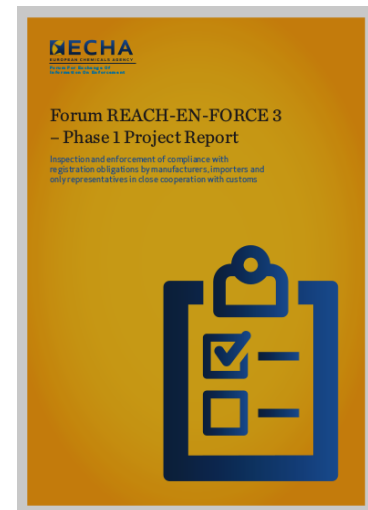
Non compliance:

75 of the 528 inspected companies

non-compliant companies in 19 countries

9 % (45) of the substances were missing registration

higher non-compliance rate for SVHCs and CLH substances



Forum REACH-EN-FORCE 3 - Phase 1 Project Report

Reason for non-compliance	Companies (N=75)*	Substances (N=143)*
Substance identity	5 (7%)	17 (12%)
Missing registration	56 (76%)	92 (64%)
Wrong tonnage band	2 (4%)	6 (4%)
Not all REACH obligations according to the applicable role M/I/OR	7 (9%)	16 (11%)
Criteria and/or obligation of an OR not fulfilled, missing evidence for appointment of an OR	15 (20%)	37 (26%)

* see section 3.7

Forum REACH-EN-FORCE 3 - Phase 1 Project Report

Measures taken

A high percentage of corrective measures taken to correct non-compliant companies took the form of **written and verbal advice**. Imposing measures are not always advisable as companies are obliged by law to comply in any case on their own initiative without an authority's order. **Altogether, the percentage of applied sanctions against an offender in the form of a fine or criminal complaint is low.**

REACH REVIEW

“However, the **shortcomings** in relation to the **high level of non-compliance** of the registration dossiers, the insufficient flow of information along the supply chain and the challenges associated with the evaluation, authorisation and the restriction processes are slowing down the delivery of those benefits.

(SWD, pages 126-127)

REACH REVIEW

-

“Work is still needed to rectify important data gaps or inappropriate adaptations in registration dossiers for specific endpoints and for information on uses and exposure. **The data gaps or data quality issues in dossiers hamper the identification of priority substances for SVHC identification or other regulatory action**”. (SWD, page 26)

The poor quality of information in registration is hampering REACH Implementation

REACH REVIEW

-

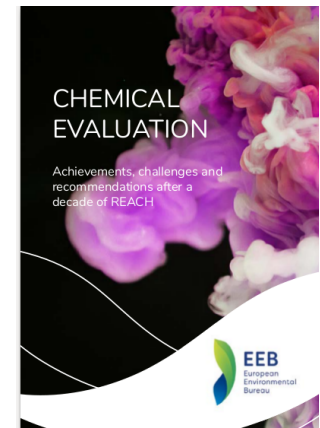
“... only 25% of dossier owners conduct a regular routine review of their REACH data and 50% of updates were requested by ECHA. ECHA concluded in 2016 that stronger incentives may be needed for companies to stimulate updates of registration dossiers, especially on the use, exposure and tonnage information.

The only incentive working in practice might be enforcement actions by the Member State Competent Authorities on dossiers which updates are overdue.” (SWD, page 26)

“systemic shortcoming in terms of a lack of incentives for registrants to update their files, despite an obligation to do so”

EEB PROPOSALS

- ✓ Improve transparency on non-compliant registration dossiers and decisions, enforcement activities and remediation of non-compliant status
- ✓ Reject registration of incomplete dossiers
- ✓ Accelerate regulatory risk management action
- ✓ **Improve, increase and speed-up enforcement activities** and remediation of the non-compliance status: increase and extend compliance checks, address misuse of data waiving and non-animal test methods ...



Challenges:

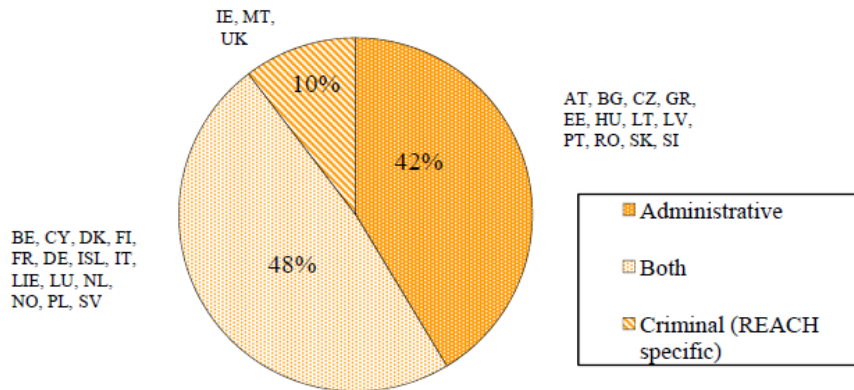
- ✓ Lack of resources
- ✓ Divergencies of enforcement measures and sanctions across the NEAs
- ✓ Priority widely given to soft measures
- ✓ Lack of transparency

Human and financial resources

- ✓ REACH REVIEW: “Overall, the **level of satisfaction of CAs** with the financial and human resources they can dedicate to REACH is **generally relatively low**.”
- ✓ No clear picture due to differences in data provided by Member States
- ✓ Resources vary a lot between NEAs, e.g.
 - ✓ ES, DE, NL no specific REACH or CLP units have been established;
 - ✓ BE 7 FTEs only for CLP;
 - ✓ FR 26 inspectors for REACH;
 - ✓ IT no specific REACH resources allocated

Divergent enforcement approaches and regimes

Chart 4.1 Regime of enforcement



- ✓ NEAs view on enforceable-subject to penalties varies greatly. e.g. breach of “no data, no market” (Art. 5) is subject to sanctions in all countries except for Romania and Italy.

- ✓ Enforcement methods vary quite from one country to another. e.g. Nordic Countries based on coercive measures while other countries enforce through administrative and criminal law or through administrative law only.

Type and level of sanctions

- ✓ There is a substantial **lack of consistency** from one country to another as to the
 - ✓ **type of penalties** (different administrative and criminal measures) e.g. fines, closure, withdrawal of permit, suspension activity or placing on the market, ban, destruction of the substance, pecuniary, deprivation of rights, prison, prohibitions) and
 - ✓ **level of penalties**
 - ✓ Administrative fines 1 000-2 500 000 EUR
 - ✓ Criminal fines 55 000 000 EUR-unlimited
 - ✓ Imprisonments 8 years - 3 months.

Enforcement should be a high priority of Member states (and without delay):

- ✓ Ensure **financial and human resources** equally allocated across NEAs
- ✓ Enforcement approaches, measures and sanctions should be **dissuasive, consistent and harmonised** across the EU and EEA
- ✓ **Increase transparency** on national enforcement activities, on sanctions following non compliance and on non compliance companies/substances
- ✓ **Clear and dissuasive measures are needed**: restrict market access if companies fail to comply with ECHA's evaluation decisions.

Do you agree that a more ambitious approach by ENFORCEMENT AUTHORITIES is needed?



EEB

European
Environmental
Bureau

THANK YOU!

Dolores.romano@eeb.org

www.eeb.org



[@Green_Europe](https://twitter.com/Green_Europe)



[@EuropeanEnvironmentalBureau](https://www.facebook.com/EuropeanEnvironmentalBureau)

eeb@eeb.org

The EEB gratefully acknowledges the financial support from the LIFE Programme of the European Union. This communication reflects the organizers' views and does not commit the donors.

