NO DATA, NO MARKET?

What citizens and workers need to know about REACH compliance

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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.

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REGISTRATION UNDER REACH

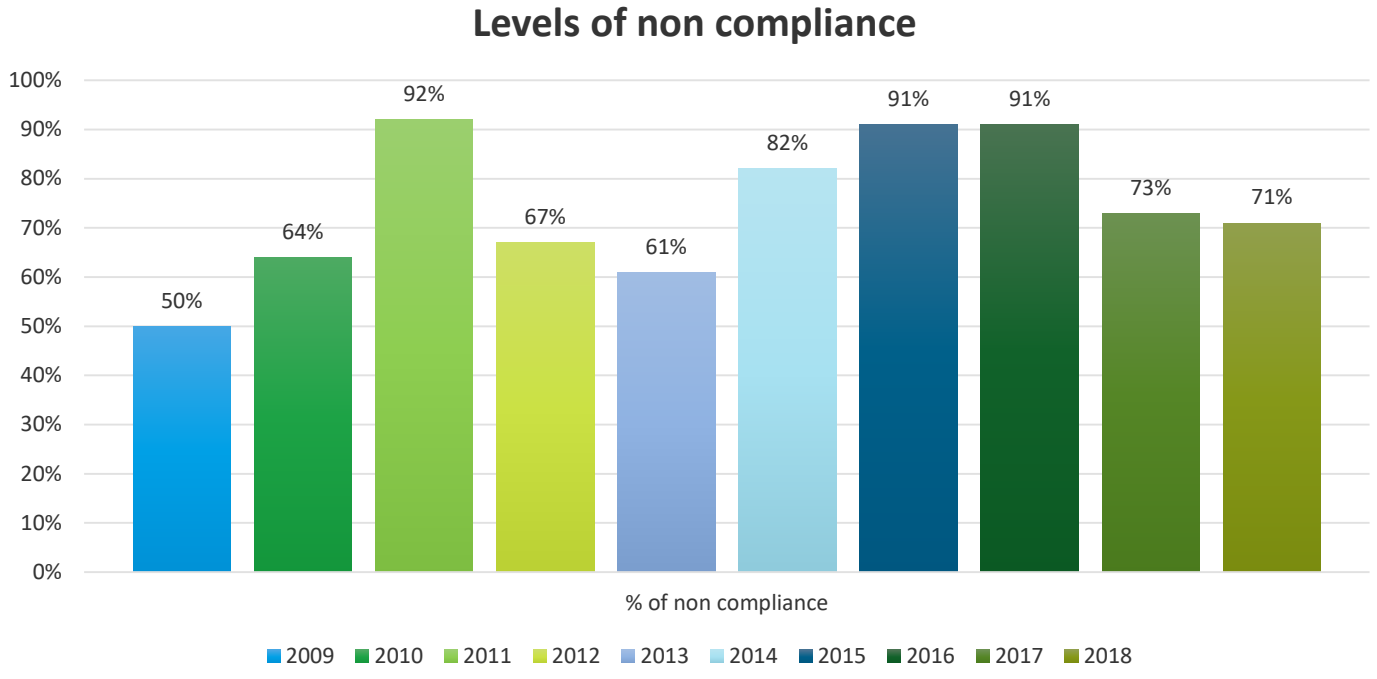
Article 5. No data, no market

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.*

Registration is the pillar of the REACH Regulation:

- Should provide the information on hazards, uses and exposure needed to identify and control the risks.
- It is the basis for further regulatory action and ensuring safe use
- It is the basis for ensuring proper information along the supply chain and to consumers.

10 YEARS OF NON COMPLIANCE



ECHA (2016) 64% of 29,000 dossiers have never been updated since registration

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QUALITY? REALLY?

Compliance is not about quality, it is about legality

New tool to support registrants in improving dossier quality now available

ECHA/NA/13/05
News alert
Media enquiries: ECHA Press

Executive summary

The report describes the results of ECHA's evaluation activities in 2016 and provides recommendations to registrants to foster improvement in the quality of registrations.

Registrants are encouraged to consider them and to be proactive in updating and improving their dossiers with any new and/or relevant information. Continuous improvement of the hazard, use and exposure information in the registration dossiers will lead to more accurate risk assessments and safer use of the chemicals.

The annual report explains ECHA's evaluation activities in 2013, highlighting the most common shortcomings in registration dossiers and providing recommendations to registrants. To further improve the quality of registration dossiers, registrants are requested to proactively update their dossiers.

FOREWORD FROM THE EXECUTIVE DIRECTOR

Dear reader,

This is the seventh annual report on our activities in evaluating dossiers and coordinating substance evaluation, ending with a list of recommendations for registrants. It shows how the collective efforts of gistrants, ECHA and Member States are improving the quality of Europe's chemical knowledge and safety formation.

eximising the availability of high-quality data is one of ECHA's strategic objectives. The annual evaluation ports allow us to see where improvements can be made. Through better information in registration ssiers, registrants and authorities can work together for the safer manufacture and use of chemicals in rope.

2014, we developed a new compliance check strategy to maximise the impact on the safe use of emicals. The aim is to identify those substances that matter the most for the protection of people and the vironment. These are substances produced in high volumes with data gaps in human health or environment dpoints and with high potential for exposure of workers or the general public.

increase transparency, ECHA will start to periodically publish a list of likely cases for compliance checks. the same time, we will tighten deadlines with dossier updates to reduce processing times and increase ficiency.

'HA was successfully awarded the ISO 9001 certificate in relation to our REACH and CLP tasks. This monstrates that in evaluating registration dossiers ECHA applies internationally recognised good siness practices.

e findings of this report and the first measurements of dossier quality improvement that will be ported in the next general report show improvement in dossier quality. Registrants have taken evaluation cisions seriously and improved their dossiers accordingly. The increased number of cases where quested information was provided after involvement of the Member State authorities also shows that the operation between ECHA and the enforcement agencies is working and delivers results. As in previous ars, the information quality and consistency of registration data still need to improve, especially related exposure assessment, risk characterisation and substance identity. That is why recommendations on how dustry can improve dossier quality forms an integral part of this annual report.

ith this in mind, I want to remind registrants that the registration process does not stop with a registration mber. Please be proactive and update your dossiers. I also want to encourage all the registrants preparing r the 2018 deadline to start their preparations early and make use of this report and existing support. 'HA's REACH 2018 web section is a good starting point for newcomers.

y sincere thanks go to all staff involved in the Member States and at ECHA – d to registrants for their work on improving registration dossiers. Please take e time to carefully read the recommendations of this report.

INNEFECTIVE ‘SOFT’ MEASURES

ECHA launched a varied set of ‘soft measures’ since 2009, such as:

- (targeted) letter campaigns to registrants,
- quality observation letters,
- informal contact with companies,
- lists of substances that are likely to face compliance checks, and
- REACH guidance updates.

Bottom line: compliance has not improved in 10 years

BFR PROJECT

- checked 1,814 HPVC, registered by 2014.

- focused specifically on endpoints of "highest significance for human health and environment", including carcinogenicity, mutagenicity, persistence, bioaccumulation, reproductive and developmental toxicity.

- Results: **52% HPVC dossiers in breach REACH legal requirements**

- established that ECHA failed to apply the 'no data, no market' rule, by allowing chemicals with missing safety data onto the market.

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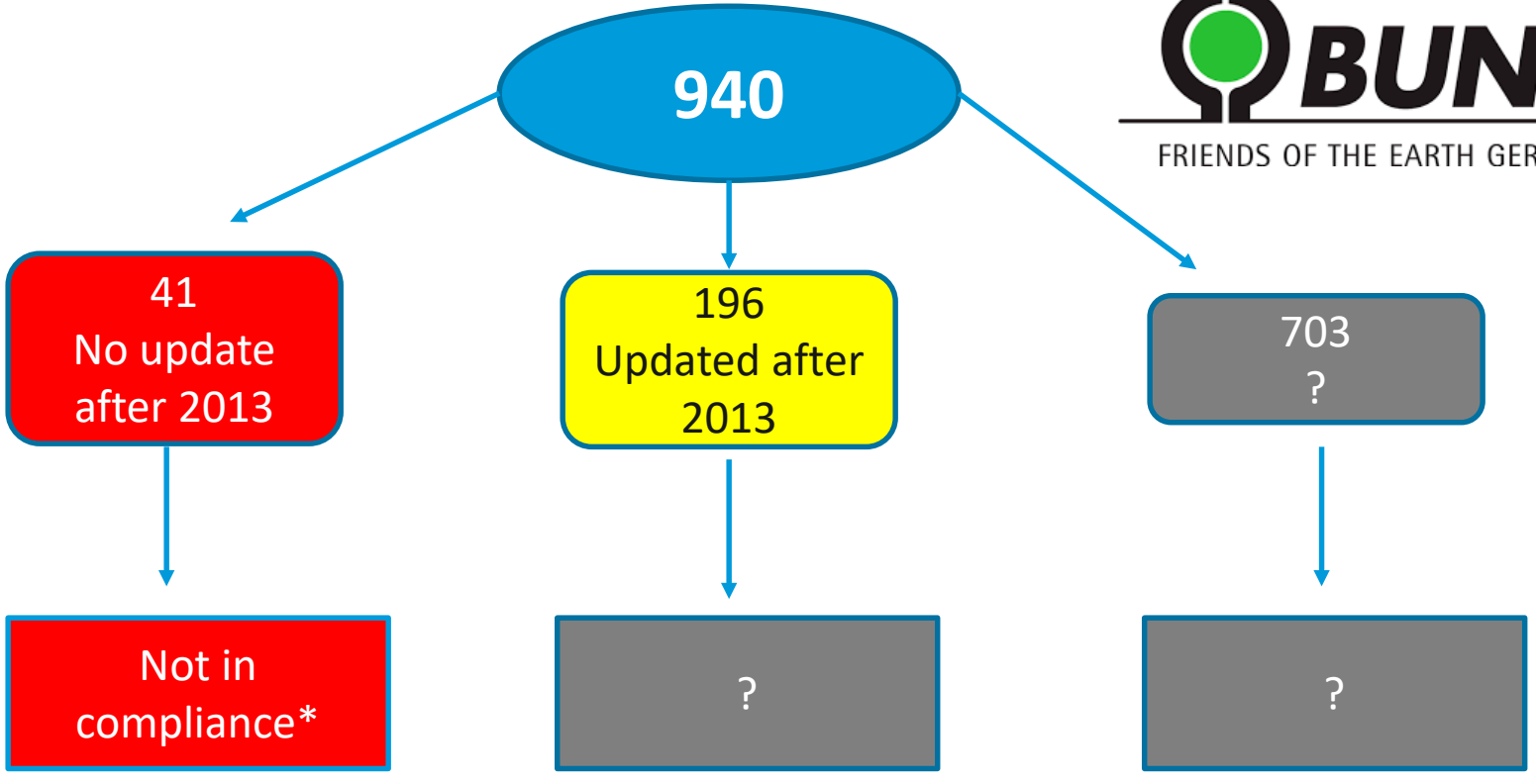
BUND PROJECT – TIP OF THE ICEBERG

- ATD request to BfR-> substances “assessed as non-compliant”



BUND
FRIENDS OF THE EARTH GERMANY

* according to BfR’s analysis

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CITIZENS IN THE DARK

- Non compliant substances/dossiers highly unclear
- Non compliant companies blanked out (draft decisions)
- Lead registrant identity not available most of the times
- Nature of the updates unavailable
- Status of compliance/evaluation process/enforcement not available

LOOSING TRUST

What citizens and workers need to know

• 12 -121 millions tonnes 41 HPV chemicals are used in Europe every year, some end up in in toys or food contact products

• companies happy to sell their products without knowing if they cause serious health and environmental impacts

• authorities are allowing these chemicals in the market without crucial information provided regarding its potential to cause cancer, developmental disorders, infertility ….

• Tip of the iceberg? We don’t know for 703 + 196 HPVC

• we are in the dark, but we know enough to be concerned

IMPACT OF NON COMPLIANCE

"*the lack of compliant information in the registration dossiers hampers the functioning of other REACH processes and slows down the achievement of the REACH objectives for human health and environment.*" (REACH review 2017)

Non-compliance is a serious problem:

- causes delays and hampers the whole implementation of REACH
- causes a waste of time and resources for ECHA and MS
- new information on hazardous properties is not generated
- results in less substances of very high concern (SVHC) identified
- leads to a lower level of protection of human health and the environment

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RECOMMENDATIONS/MESSAGES

to industry: chemical/product safety is your responsibility, and starts by information

to ECHA:

• retrospectively check non-compliant dossiers identified by BfR for completeness - > revoke if needed

• improve, increase and speed up completeness/compliance checks

• more transparency is needed to protect citizens and support informed purchasing choices

to National authorities: enforce and increase transparency

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CONCLUSIONS

- **Non-compliance "can result in damage to human health and the environment**" (REACH, recital 122)
- Only substances for which full information requirements are provided should be allowed on the market ('no data, no market' principle)
- Need for stricter measures and sanctions to increase compliance
- Transparency is key to ensure protection, information, scrutiny, fair competition, incentives for compliance
- Industry is responsible for their products- duty of care

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