Non paper- EEB analysis of the REACH and CLP processes timeliness

The EEB would like to share an unpublished non-paper as evidence on the timeliness of the different REACH procedures for the ongoing public consultation on the REACH reform's impact assessment. The findings of our analysis show the need for the REACH revision to focus on speeding up the regulatory processes as a key priority.

The raw data used for our analysis is available upon request. The findings of our analysis and more detailed information will be published in May in the form of a report.

Analysis Summary

This analysis scrutinises the ability of the main EU chemicals control laws, REACH and its complementary CLP Regulation to limit the use of dangerous chemicals on the market as they were intended.

The European Environmental Bureau (EEB) analysed the publicly available data from the European Chemical Agency (ECHA) and looked at the time it has taken to the EU authorities to regulate over 300 chemicals under REACH and CLP since 2007, and at whether these processes managed to speed up regulatory action, as intended. The data also helped us calculate the average time spent on each regulatory step and identify the reasons for the bottlenecks at each stage, as well as the actors hampering the process.

Finally, the added value of this non paper is that it provides concrete recommendations for speeding up the regulation of chemicals of concern under REACH and CLP. Thanks to REACH, we are increasingly aware of products that contain harmful chemicals, while CLP has improved our understanding of the hazardous nature of chemicals, and the impact they have on our health and our environment.

But the findings of our analysis - covering from the moment ECHA allows chemicals onto the EU market until the prohibition of those deemed (potentially) hazardous - are shocking. They reveal that there is stark contrast between the short time it takes for companies to introduce a chemical onto the European market (no more than three weeks), and the many years it takes authorities to get the upper hand over the control of hazardous chemicals and also those already used on the market.

In the best-case scenario, it takes officials three and half years to identify and classify a hazardous chemical. In worse cases, it takes them almost twelve years. To put control measures in place (i.e.

Restriction and Authorisation processes) takes, on average, five and a half to nine and half years but in some cases it could take as long as 13 years.

At this pace, with almost 2,000 substances to be regulated or assessed, it may take no less than a century for the EU to ensure that chemicals on the market are safe. During this time, companies seeking to maximise their profits are free to produce and use high volumes of chemicals without proper control or even an understanding of the chemicals' potential negative human health and environmental impacts.

In this sense, the European authorities have failed to speed up the control of chemicals because of delays in the process which prolong the exposure of Europeans and the environment to the harmful effect of chemicals. These delays, which can take well over a decade, are as dangerous to people's health and the environment as they are unnecessary because, in our view, there's a lot that can be done to prevent hazardous chemicals from entering or staying on the market.

But there is also a positive example in REACH, the identification and listing of the Substances of Very High Concern (SVHCs) in the Candidate list, which takes around six months. This is a list at ECHA's disposal which, if properly managed, could be key to preventing the use of hazardous chemicals linked to cancer and other serious diseases, bioaccumulating in the food chain and stubbornly persisting in our environment for a long time. The Candidate list process is much more efficient than the other EU process to identify hazardous chemicals, the Harmonised Classification and Labelling (CLH) under CLP, which takes about 5 years and 9 months.

According to our analysis, there are several factors that slow down REACH significantly. To begin with, the industry resists requirements to provide relevant and adequate data on the chemicals that it uses or wants to use. ECHA itself is burdened by administration and ingrained in over analysis while many of the Member States have poor resources. Finally, the European Commission shows no real determination in making the hard decisions it takes to carry out its obligations to protect our health and environment and, sadly, it often gives in to lobbying pressure.

This analysis reveals that, so far, the European authorities have failed to speed up the control of chemicals.

An overview of the timeframes required for each regulatory process in connection to the chemicals analysed in this analysis.

- **Registering chemicals** takes no more than 3 weeks;
- **Compliance checks** of safety data provided by industry can take **more than 5 years** while **substance evaluation** can take up to **7 to 9 years**.
- **Assessment of Regulatory Needs of chemicals** takes from **less than a month to 10 years and 11 months**. Being **1 year and 8 months** (20 months) the median time;
- **Harmonised classification and labelling (CLH)** takes from **3 years and 9 months to 11 years and 10 month**. Being **5 years and 9 months** (69 months) the median time;
- **SVHC identification** takes from **3 months to 3 years and 7 months**. Being **6 months** the median time;
- **Authorisation** takes from **6 years and 2 months** to **13 years and 10 months**. Being **9 years and 8 months** (116 months) the median time;

- **Restriction** takes from **2 years and 4 months to 11 years and 5 months.** Being **5 years and 7 months** (67 months) the median time.

Please find more details on the different processes timeliness in Annex I

Our analysis also looked at **how efficient the different processes are to identify and regulate chemicals of concern**. We have demonstrated that in a decade's time, very few chemicals have ended up being controlled as a follow up of the evaluation and assessment of regulatory needs processes, mainly due to delays caused by poor safety data provided by industry. While in 9 years, Substance Evaluation has only resulted in two restrictions and one Annex XIV listing. The Expert groups set up to support the identification of SVHC have largely failed to doing so. In 10 years, only one PBT substance introduced in 2012 for assessment by the PBT Expert Group ended up in Annex XIV. In 8 years, not a single endocrine disruptor discussed by the EDC Expert Group has led to a restriction or inclusion in the Authorisation list (Annex XIV).

The Member States and ECHA assessments of regulatory needs analysis have only resulted in 2 restrictions in place, in 11 years.

An overview of the Efficiency of the REACH and CLP processes to identify and regulate chemicals of concern

- **Evaluation** is a rather slow and ineffective process. In 9 years, Substance Evaluation has resulted in two restrictions and one Annex XIV listing.
- In 11 years, **ARNs** have resulted in 2 restrictions.
- In 10 years, **only one PBT substance** introduced in 2012 for assessment by the PBT Expert Group **ended up in Annex XIV**, with a sunset date set for 2023.
- In 8 years, **not a single endocrine disruptor** discussed by the EDC Expert Group **has led to a restriction or inclusion in the Authorisation list** (Annex XIV).
- In 11 years, **CLP** has delivered 1 harmonised classification.
- In 13 years, REACH has delivered, 27 restrictions

Please find more details on the different processes timeliness in Annex II

After the lengthy and complex scientific opinions delivered by ECHA, the European Commission takes even longer to make regulatory action decisions. **The time for the Commission to make crucial decisions** such as regulating substances of very high concern (by its inclusion in annex XIV) or restricting chemicals for which the risk to human health and/or environment is known to be unacceptable **varies between 6 months and almost thirteen years in extreme cases**. The median time for SVHC inclusion in annex XIV is 1 year and 11 months (23 months) and 1 year and 5 months (17 months) for restriction decisions. Only a quarter of the known substances of very high concern have been added to the regulatory list (Annex XIV) by the Commission while in the last 9 years, the Commission has decided on half of the applications for authorisation received for

which ECHA has issued an opinion, meaning that half of the uses applied for of SVHCs remain allowed until the Commission decides.

In the meantime, people and the environment are unnecessarily exposed to known harmful chemicals.

An overview of the median times for ECHA developing opinions and recommendations and the Commission to make decisions.

Restriction

- The median time for ECHA, from submission of a restriction proposal to ECHA's final opinion is **14 months** (1 year and 2 months).
- The median time from opinions sent to Commision and date for Official Journal publication is **17 months** (1 year and 5 months).

Authorisation

- The median time, from ECHA recommendation of Annex XIV amendment to the Commission Annex XIV amendment is approximately **23 months** (1 year and 11 months)
- The median time for ECHA, from the receipt of an application for authorisation (payment date) until the sending of the RAC and SEAC opinions to the European Commission, is approximately **10 months**
- The median time for Commission decision after submission of opinion approximately **16 months** (1 year and 4 months)

CLH

- The median time from the date of intention to the date of receipt of the final dossier is **15 months** (1 year and 3 months).
- The median time for ECHA, from the date of receipt of the final dossier to ECHA's final opinion is **11 months**.
- The median time for the Commission, from the date of Adaptation to Technical Progress (ATP) publication to entry into force is **19 months** (1 year and 7 months).

Please find more details on the different processes timeliness in Annex III

Conclusions

This paper shows that despite some progress, REACH fails to duly address the large number of chemicals marketed and their potential risks to human health and the environment. The main problems identified are:

- The **'no data, no problem' approach**. Companies routinely submit incomplete or flawed data on the hazardous effects of their chemicals, yet they still gain market access (disrespecting the 'no data, no market' rule). As a consequence, the poor quality of

registration dossiers by industry creates a 'no data, no problem' situation that strongly hampers regulation and automatically places the responsibility of ensuring product safety on regulators.

- The **absence of deadlines** for member states and ECHA to conclude whether a substance or its use is potentially harmful and for the European Commission to make decisions. Now it can take over ten years from registration to go through compliance checks, and substance evaluation– that is, just to clarify the concerns of the substance. The Commission currently spends an average of two years, sometimes over a decade, to adopt regulatory actions for already known harmful chemicals.

- The **lack of accountability** by the competent authorities in finalising an Assessment of Regulatory Needs (ARN) and implementing their conclusions and recommendations. If an ARN indicates the need for a restriction or authorisation process, it indicates that risks to health or the environment do exist and need to be addressed. However, an ARN conclusion does not trigger an obligation to the authorities to act. The same applies to the conclusions of substance evaluations by the competent authorities.

- The **European Commission's inaction.** The Commission's apparent maladministration and disregard for years of the scientific opinion of ECHA for harmonised classification and labelling, recommendations for inclusion in Annex XIV and Restrictions and Authorisation procedures is a major bottleneck. The European Commission takes a longer time to make decisions than ECHA to develop scientific opinions. **Almost half (45%) of the decisions remain pending today.** In all these cases, the chemical industry is benefitting from the delays, while people and the environment are unnecessarily exposed to harmful chemicals for years.

Main Policy Recommendations

- **Apply the 'no data, no market' principle and 'zero tolerance to non compliance'** to quickly reverse this situation of wide-spread non-compliance and truly incentivise that industry provides data. Shift from a 'no data, no problem' practice to a 'no safety proven, no market' practice so chemicals for which safety is not demonstrated through adequate and reliable data, should not be allowed anymore on the market. The EU must impose dissuasive measures to non-compliant companies.
- **Put health before profits**. For doing so, the EU needs to use a precautionary approach and lower the level of evidence needed for identifying and regulating hazardous chemicals. Do not get lost in the details and paralysis by analysis when considering action against toxic chemicals. Incorporate grouping to make a conservative assessment of a substance's properties.
- **Deadlines should be written into law.** Introduce deadlines in REACH: to companies to provide data; to ECHA and member states to conclude regulatory needs and to adopt risk management measures for chemicals found as of concern; and to the Commission to make decisions without delay.
- **Speed up the regulation of hazardous chemicals**: by extending the fast-track restrictions; by adding additional SVHC categories and establishing automatic bans of SVHCs in everyday products; by incentivizing the restriction of groups of chemicals; and by establishing strict deadlines to each process.

- **Simplify the system** by allowing ECHA to perform compliance checks and substance evaluation in one go; by introducing a legal frame that allows evaluation and testing strategies based on group considerations; by applying the essential use concept to reduce the number of applications for authorisation and derogations for restriction; by reducing authorisation to one route, only for downstream users and individual or collective application for similar uses; and by changing the trigger of restrictions from demonstrating unacceptable risk to justifying high concern.
- **Ensure that the revision of REACH does not introduce additional complexity and delays:** Allow SVHC identification without the requirement of prior classification.

Annex I. REACH and CLP processes timeliness- summary table

REACH/CLP process	***Shortest* duration [substance]**	**Median duration**	***Longest* duration [substance]**	**Main bottleneck(s)**	**Main Problem(s)**
REACH REGISTRATION- completeness check	**< 3 weeks** data not available	**3 weeks** data not available	**3 weeks** data not available		
REACH EVALUATION					
Compliance check (CCh)	data not available	data not available	> 5 years (not concluded yet)	Industry	Lack of cooperation by the registrants to provide the necessary information Industry possibility of challenging ECHA's decisions
Substance Evaluation (SEv)			**7-9 years*****	Member States Industry	Substance evaluation paired with compliance checks Lack of cooperation by the registrants to provide the necessary information Industry possibility of challenging ECHA's decisions
ARN/RMOA*	**Less than a month**	**1 year and 8 months ****	**10 years and 11 months** (2-(2H-benzotriazo		

	(1,3-propanesultone)		l-2-yl)-4-(1,1,3,3-tetramethylbutyl)phenol)** (not concluded)		
Hazard identification					
CLH*	**3 years and 9 months** (tetrakis(2,6-dimethylphenyl)-m-phenylene biphosphate)	**5 years and 9 months**	**11 years and 10 months** (CU-HDO (Bis(N-cyclohexyl-diazenium-dioxy)-copper))	Commission	Delay in taking decisions
SVHC* identification	**3 months** (Dichromic acid)	**6 months**	**3 years and 7 months** (Nonadecafluorodecanoic acid)		
RISK MANAGEMENT MEASURES					
Authorisation *	**6 years and 2 months** (Bis(2-ethylhexyl) phthalate)	**9 years and 8 months**	**13 years and 10 months** (Sodium dichromate)**	**Commission**	**Commission's frequent inaction and delays in making decisions**

Restriction*	**2 years and 4 months** (Cadmium and its compounds)	**5 years and 7 months**	**11 years and 5 months** (PFNA; PFDA; PFUnDA; PFDoDA; PFTrDA; PFTDA; their salts and precursors)	**Commission**	**Commission's frequent inaction and delays in making decisions**

* From the date of intention to the date of Commission's decision/publication in the official journal/entry into force or inclusion in the candidate list by ECHA (in case of SVHCs identification).

** For substances that do not yet have a date on the Commission's decision. The analysis was conducted by using a hypothetical decision date (01/03/2022) for substances with different transitional periods. The latest date was considered as the entry into force. When the date of entry into force was not available we used the median between the Commission decision and entry into force to obtain a hypothetical date (01/09/2023) and extrapolate it to those substances without an entry into force date.

*** Substance evaluation can take from 7 to 9 years from their inclusion in CoRAP, and if further data generation is needed.

Annex II. Efficiency of the REACH and CLP processes to identify and regulate chemicals of concern-summary table

REACH / CLP process	Timeline (No years)	Number of substances assessed	Number of substances waiting for assessment conclusion (%)	Number of substances recommended for RMM (%)	Number of substances regulated – decision taken [RMM]
Dossier evaluation (compliance check)	2009 - 2022 (13 years)	6568 (4165)	2128 (32%)	data not available	data not available
Substance Evaluation	2012-2022 (10 years)	388	195 (50%)	50% of concluded SEv*	2 [restriction] 1 [Annex XIV]
ARN/RMOA	2011-2022 (11 years)	349	106 (30%)	173	2 [restriction]
PBT assessment	2012-2022 (10 years)	219	16 (7%)	24	1 [restriction]
ED assessment	2014-2022 (8 years)	105	84 (80%)	9 (9%)	0
CLH	2011-2022 (11 years)	361		14	1[1] [CLH]
Restriction	2009-2022 (13 years)	35	8 (23%)		27 (77% of restrictions assessed)
Annex XIV		223 SVHC	169		54 included in annex XIV (24% of SVHC)
Authorisation decisions	2013-2022	248 AfAs submitted by companies		352 ECHA opinions finalised	199 decisions by Commision

[1] Through ARN

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Substance Evaluation	2012-2022 (10 years)	388	195 (50%)	50% of concluded SEv*	2 [restriction] 1 [Annex XIV]
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CLH	2011-2022 (11 years)	361		14	1[1] [CLH]
Restriction	2009-2022 (13 years)	35	8 (23%)		27 (77% of restrictions assessed)
	(9 years)				(56,5% of adopted opinions by ECHA)

Annex III. Median times for ECHA developing opinions and recommendations and the Commission to make decisions

REACH/CLP process	***Shortest* duration** **(Substance)**	**Median duration**	***Longest* duration** **(Substance)**
CLH From date of submission to ECHA's final opinion	4 months	11 months	2 years and 1 month
CLH From date of ECHA's final opinion to Commission decision (ATP publication)	1 year and 3 months	1 year and 10 months	5 years and 5 months
SVHC From date of submission to MSC Agreement	2 months	4 months	4 months
SVHC From date of MSC Agreement to Inclusion in candidate list	Less than a month	Less than a month	2 years and 6 months
Authorisation From Annex XIV recommendation (by ECHA) to inclusion in Annex XIV (by COM)	1 year and 1 month (Diarsenic trioxide)	1 year an 11 months	12 years and 9 months (SCCP) ** (not concluded)
Authorisation From date of AfA submission to ECHA's opinion	5 months (Diarsenic trioxide)	1 year and 1 month	3 years (Chromium trioxide)
Authorisation From ECHA's opinion to Commission decision	4 months (Diarsenic trioxide)	1 year and 4 months	7 years (Bis(2-ethylhexyl) phthalate) **

Restriction From date of submission to ECHA's opinion sent to Commission	11 months (formaldehyde and formaldehyde releasers)	1 year and 3 months	2 years (4,4'-isopropylidenediphenol (Bisphenol A))
Restriction From opinion sent to Commission to Journal Publication	6 months (Cadmium and its compounds)	1 year and 5 months	3 years and 10 months (Lead and its compounds)