

How can the REACH revision contribute to securing future-proof products for Europe?



15 June 2022

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Our Speakers – EU ambition for chemicals management



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Our Speakers - future registration of certain polymers



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Our Speakers - New Regulatory Management under REACH



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EU ambition for its future chemical management



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Deep dive on registration of certain polymers



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Registration of Certain Polymers



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Policy Officer, DG GROW
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Deep dive on future Registration of certain polymers

Digital Dialogue: How can the REACH revision contribute to securing future-proof products for Europe?

15 June 2022

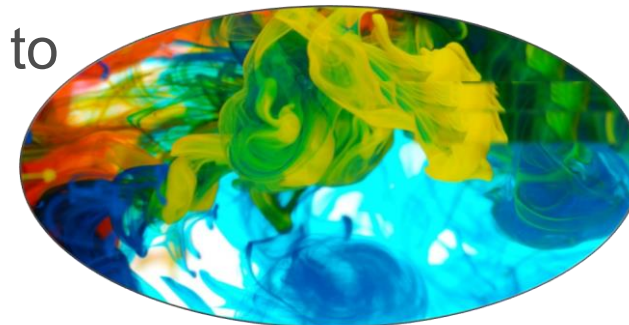
Lina Dunauskienė, DG GROW

Background – current polymer requirements in REACH

- Polymers, as defined in REACH Art. 3(5) are currently
 - exempt from REACH registration requirements and
 - evaluation (Titles II and VI).
- Monomers and oligomers not meeting the definition of Art.3(5) are subject to
 - the registration requirements, including risk assessments and CSR where more than 10 tonnes per annum are manufactured/imported.
- Article 138(2):
 - *“the Commission may present legislative proposals as soon as a practicable and cost-efficient way of selecting polymers for registration on the basis of sound technical and valid scientific criteria can be established, and after publishing a report on the following:*
 - a) the risks posed by polymers in comparison with other substances;*
 - b) the need, if any, to register certain types of polymer, taking account of competitiveness and innovation on the one hand and the protection of human health and the environment on the other”.*

Chemical strategy for Sustainability

- The EU's Chemicals Strategy for Sustainability (CSS) aims to
 - better protect citizens and the environment`
 - boost innovation for safe and sustainable chemicals
 - enhance the competitiveness of the EU chemical industry
- The CSS remarks the importance of



- **A comprehensive knowledge base on chemicals**

“...there is much knowledge to be acquired by authorities on the intrinsic properties of a vast majority of chemicals, including polymers....”

- **The improved availability of chemical data**

*“The EU is still **lacking a comprehensive information base on all substances** placed on the market <...>. **In particular polymers**, which are the fundamental building blocks of plastics, are not subject to registration under REACH”.*

- **The Commission will:**

- **make a proposal to extend the duty of registration under REACH to certain polymers of concern.**

Polymer registration

- Since 2012 the Commission has contracted three different studies to assist in the task related to the review of REACH with regard to the registration requirements on polymers (2012; 2015 & 2020).
 - About 23 300 substances (non-polymers) registered under REACH
 - The number of polymers on the EU-market estimated as 70 000 – 400 000 polymers, 200 000 as best estimate.
 - *Focus on Polymers Requiring Registration” (PRR) could lead to the registration of ~ 30 000 polymers, which could be grouped together into ~ 10 000 registration dossiers (Wood, 2020)*
- Definition of PRR since study by Wood (2020) has been developed further:
 - **“Polymers Requiring Registration”** - polymers that can be deemed to present some hazards on the basis of comparison against a set of PRR-Identification criteria.

Polymer registration (cont.)

- Several steps in overall registration process are envisioned and are currently Impact Assessed, such as:
 - **Identification of selected polymers for registration**
 - Industry checks polymers against PRR-criteria which should help select polymers that
 - are bioavailable estimated by size /MW
 - contain oligomers above certain thresholds (bioavailable)
 - have specific features in the polymer that may lead to toxicity to man or the environment (ionicity, reactive groups,...)
 - are likely to degrade into substances of concern
 - **Notification (not exhaustive)**
 - Would provide knowledge on the polymers market and the properties across the 'polymers universe'
 - Identifies individual polymers and their amounts as put on the market
 - Identifies polymer PRR/non-PRR status

Polymer registration (cont.)

- **Grouping process (not exhaustive)**
 - Should be based on clear and objective criteria that could withstand legal scrutiny
 - Limit number of registrations and burden on registrants
 - Limit (animal) testing
 - Allow for to perform risk management of polymers in groups
- **Submission of Standard Information requirements for registration**
- **Deadlines and more detailed arrangements for notification and registration processes**

Final remarks

- The Commission is aims to
 - *Increase knowledge on the number and exact nature of polymers on the EU-market*
 - *Create a system that offers the best chances to have compliant registrations with sufficient hazard information*
 - *Make use of all existing relevant data that would enable industry to properly describe individual polymers but also group them for Registration*
 - ***Overall, to create a fit-for-purpose, practical, and manageable framework from which authorities, industry and civil society could benefit.***

Thank you



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Registration of Certain Polymers



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How can the REACH revision contribute to securing future-proof products for Europe?

Polymers - the stakes, the concerns, the solutions - Polymer IT key messages



Aim

Enable EU industry to use a broad toolbox of polymers in the future to realise the green deal climate and sustainability objectives

Cefic supports the design of a process which maximises the balance between all three policy objectives of REACH

Status

Very high number of polymers AND majority of polymers is non-hazardous

Prioritisation is a real opportunity and key for a successful process

Challenge

change of mindset to prioritisation instead of maximised data collection

designing good criteria to allow screening of polymers with higher likelihood of hazard

Solution

Stakeholder to work together to develop a purpose-driven, step-wise, transparent process

Take time to develop a mature, ideally piloted solution presenting a win for all



Registration of Certain Polymers



JAN ROBINSON

Scientific and Regulatory Affairs Director
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KEY MESSAGES ON POLYMER REGISTRATION

- Formulators (downstream users) who produce or modify polymers face **registration obligations** – many for the first time
- Continued uncertainty on the approach for **grouping of polymers** is a cause for concern. Affected actors cannot start preparing, and the number of registrations – and hence the associated costs - may be greater than predicted
- **Information requirements** should suffice for the protection goal and avoid unnecessary testing and data generation (especially for notification of polymers not requiring registration)



Registration of Certain Polymers



EMILY MCIVOR

Senior Science Policy Advisor

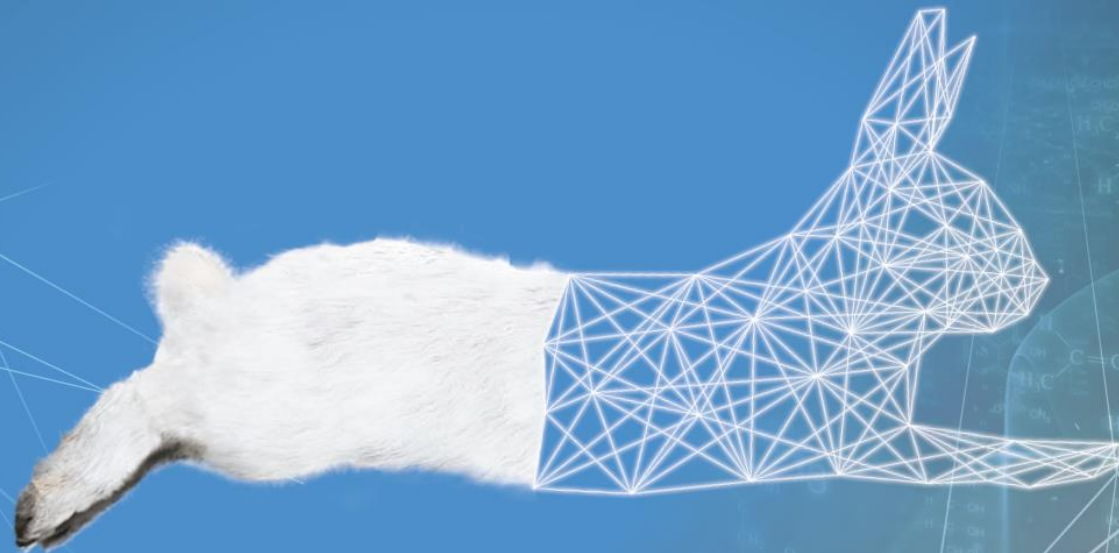
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How can the REACH revision contribute to securing future-proof products for Europe?



Emily McIvor
PETA Science Consortium International e.V.

Deep dive on future registration of certain polymers

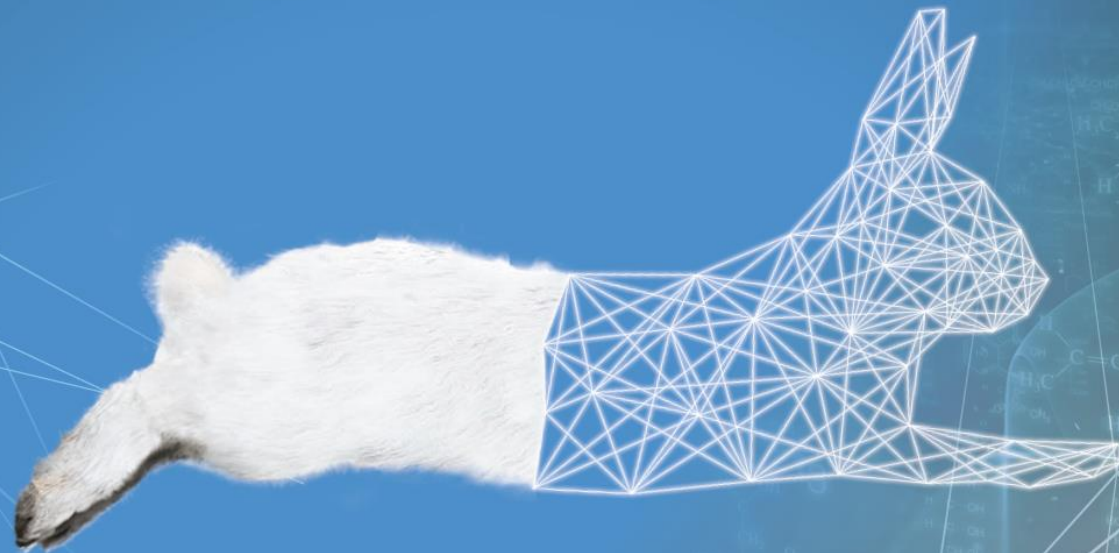
Animal testing as a last resort

- 1) Registration criteria to be clear, science-based to avoid redundant animal testing. Risk = millions of animal tests, questionable regulatory impact.
- 2) Maximum use of grouping, data sharing, pre-registration
- 3) But . . . to achieve 1 & 2, CSS R&I actions needed, eg:
 - * *Ensure polymer identity and composition is adequately determined and communicated, with new analytical methods and protocols developed as required*
 - * *Develop new and validate existing non-animal tests to assess polymer bioavailability*
 - * *Evaluate the applicability of existing tests to polymers*
- 4) Legislative action to be timely; changes without adequate knowledge cannot achieve stated objectives.

Further ideas and suggestions?

Keep in touch!

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Deep dive on New Regulatory Management under REACH



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New Regulatory Management under REACH



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EU Chemicals Strategy for Sustainability

EU Reform of the REACH
authorisation and restriction
systems

#ChemicalsStrategy

#EUGreenDeal

Cefic Digital Dialogue,
15 June 2022
Otto Linher, DG GROW



European
Commission

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Why a Reform of Authorisation and Restriction Processes?

- The **restriction** process is too slow to address new challenges, in particular endocrine disruptors and persistent substances
- The **authorisation/restriction** procedures are too burdensome
- The **existing decision making criteria** and procedures lead to getting lost in detail and missing main questions

Four steps in dealing with authorisation and restrictions

- **(1) Prioritisation** of substances for regulatory action
- **(2) Restricting** substance use (68(1), 68(2), Title VII, 69(2))
- **(3) Dealing with the need for continued use: processes** for granting **authorisation and derogations**
- **(4) Criteria** to assess justification of authorisations and derogations

(1) Prioritisation of substances for regulatory action

- Early steps of prioritisation: **(P)ACT**
- Confirmed substances of very high concern: **Candidate list**
 - Add new purposes:
 - Providing **more use and exposure information** upon candidate listing
 - Use candidate list also for **restriction**, measures under **OSH, IED** etc.
 - Involve **OSH authorities and stakeholders** in discussions on prioritisation for regulatory tools

(2) Restricting substances under REACH

- **Specific** restrictions (Article 68(1)):
 - **No major change** but continue **broader/grouped restrictions**
- **Generic** restrictions (Article 68(2)):
 - **Extension to new hazard classes** (ED, PBT/vPvB, STOT, respiratory sensitisers) and **professional uses**
- **Authorisation requirement** (Title VII):
 - **No change** (options 1 and 2) or **discontinuation** of Annex XIV listing (option 3)

REACH Revision – Generic Risk Management Approach (GRA)

- Extension of **empowerment** to Commission in Article 68(2)
- Exact **scope and timing** of restrictions to be decided
 - **Hazard classes** and categories
 - **Substances** on their own and in **mixtures; articles**
 - **Consumer** and **professional uses**
- **Work plan** and **transition pathways** to be elaborated in parallel

(3) Authorisations and Derogations from Restrictions

Baseline

Option 1

Keeping principles
but simplify details:

- Authorisation requirement:
industry application for authorisation
- Restrictions:
Part of authority restriction proposal

Option 2

One system:

- Part of authority proposal
- Industry request for derogations of general applicability
- Industry application for authorisation

Option 3

Only restrictions:

- Part of authority proposal

(4) Reform criteria to assess justification of authorisations and derogations

- Replace existing criteria by **essential use criteria** (Montreal Protocol):
 - A use is essential only if:
 - it is **necessary for the health, safety** or
 - is **critical for the functioning of society** and
 - there are **no available** technically and economically feasible **alternatives**
- Introduce a **screening step** to faster decide on clearly essential and clearly non-essential uses?
- Review the way **alternatives** are assessed and strengthen the role of substitution plans?

Thank you

EU Chemicals Strategy for Sustainability

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New Regulatory Management under REACH



STEVEN VAN DE BROECK

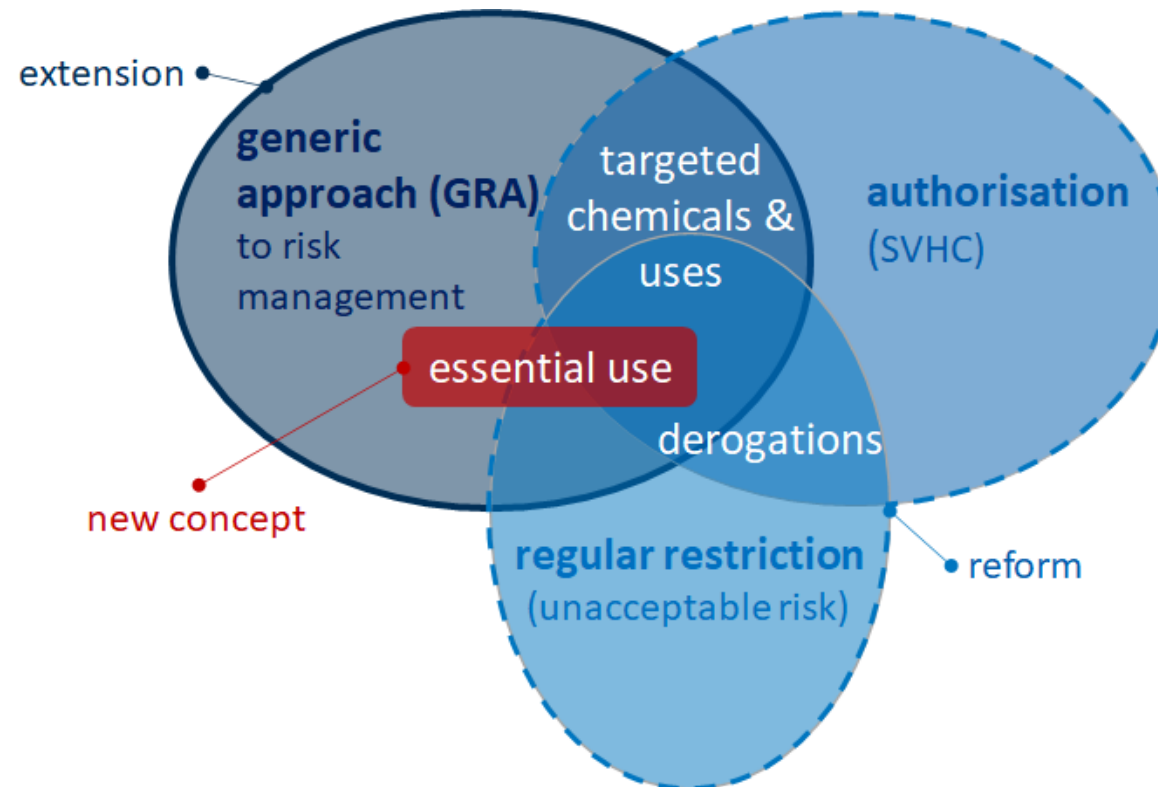
REACH and Chemicals Policy Director
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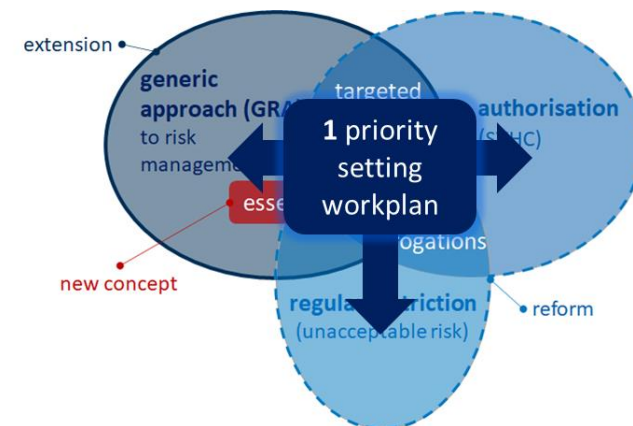
Generic Approach and Reform of Authorisation & Restriction

- Evaluate, discuss and revise restriction and authorisation processes holistically and not in isolation (including essential use)
- Improve efficiency and coordination of regulatory action



Generic Approach and Reform of Authorisation & Restriction

- One overarching priority setting workplan sequencing, prioritising and focussing action
 - Across different REACH and non-REACH tools (OSH | IED | ESPR | ...)
 - For all actors (Commission | ECHA | Member States | industry)
- Different elements underpinning such a workplan



GRA



Target consumer uses with high likelihood of exposure and focus on most severe hazards

- Substances & mixtures ED cat. 1 & PBT (down the drain)
- Articles with hard to mitigate exposure to CMRs cat. 1 & EDs cat. 1
- Subsequent phases, other hazard classes depending on lessons learned and GHS discussions

OSH legislation



Improve protection of professionals handling hazardous chemicals

- Strengthen workers protection legislation
- Step up efforts on training and communication for professionals with potential increased health risks

authorisation

regular restriction

OSH

IED



Focus on clear priorities making use of the whole regulatory toolbox



- Priorities based on hazard, use and exposure
- Targeted data collection on use & exposure from DUs to inform prioritisation
- Outcome prioritisation feeding into multiple EU regulatory processes (OSOA)

New Regulatory Management under REACH



DIDIER LEROY

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CEPE



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CEFIC Digital Event 15 June 2022



1. Downstream user just below CEFIC, thousands of chemicals used, potential high expected impact. Various chemistries designed to serve millions of applications with sustainable benefits
2. REACH revision is one of the many activities from Green Deal that could impact. Careful implementation of new concepts is needed to avoid the unexpected.
3. As DU we are part of the solution: we can substitute, but innovation takes time and robust analysis of alternatives is paramount.
4. Need a holistic approach within REACH revision (EUC, GRA, MAF, PRR...) AND between different initiatives (SSbD, ESPR, taxonomy...)

New Regulatory Management under REACH



TIMO UNGER

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How to fulfill the objectives of the CSS? The NOVAS Principle



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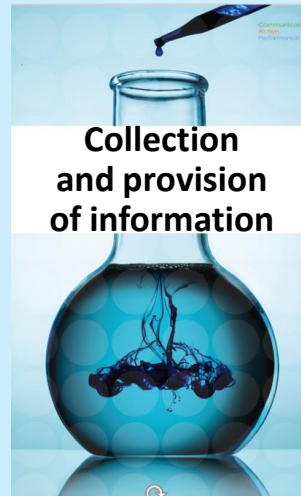
Where are the differences?



GRA



Essential Use



**Collection
and provision
of information**



**Avoiding SOCs
in Waste**

How to fulfill the objectives of the CSS?

The NOVAS Principle



NOFAS

...no one fits all solution...!

ONE SIZE
DOES NOT
FIT ALL

GB USA MEX

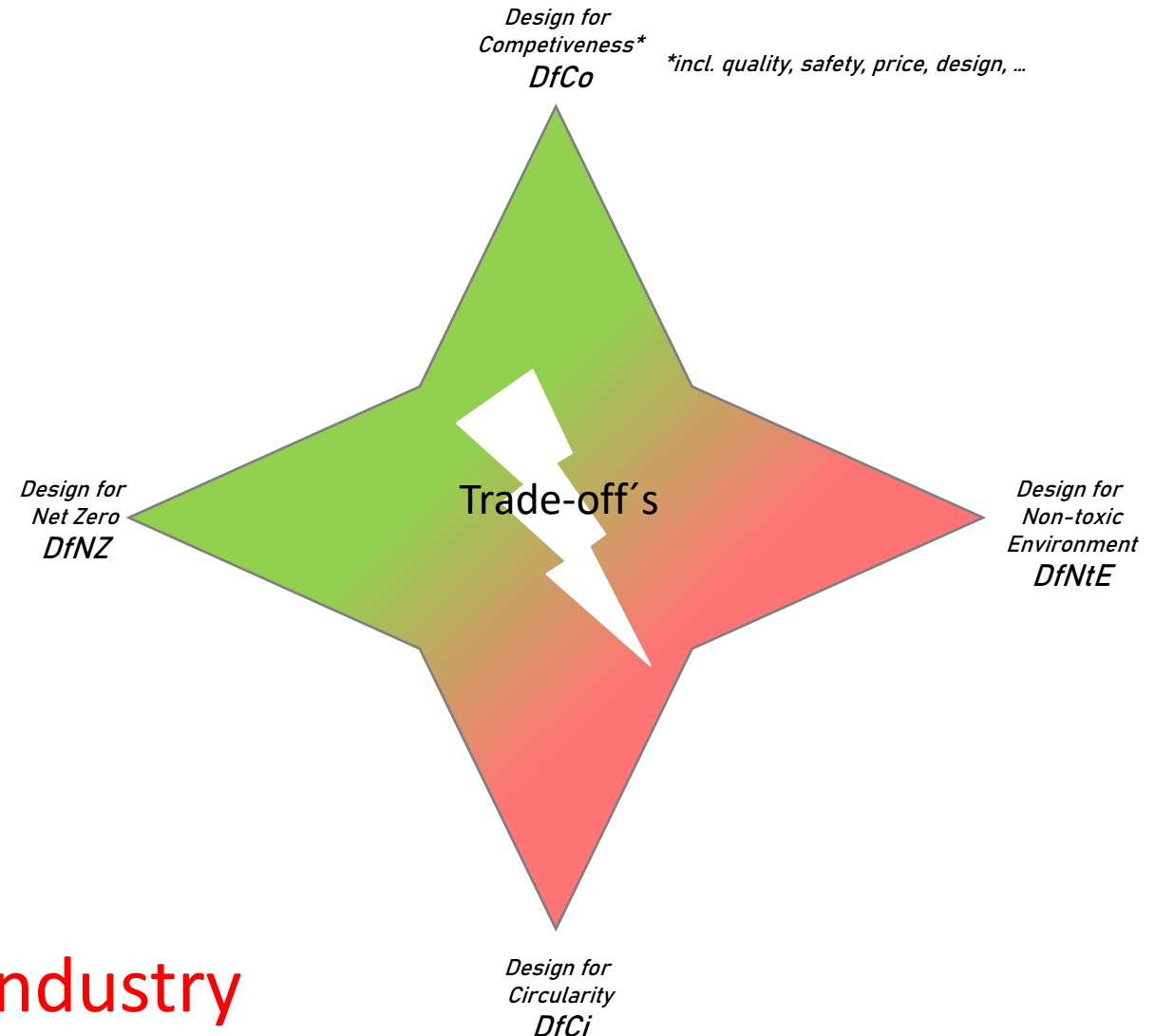
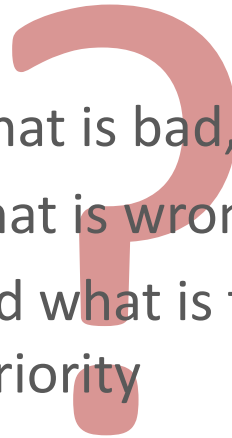
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How to fulfill the objectives of the CSS?

The Target Conflicts

- Industry and their products have to fulfill various objectives
- Some of these however are in contradiction to each other....
 - Example: Carbon fiber reinforced plastics
- So, what is
 - good and what is bad,
 - right and what is wrong,
 - the most and what is the least important priority



→ Very inefficient discussions in industry

New Regulatory Management under REACH



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REACH OSH INTERFACE

- REACH and OSH do complement each other and what is needed is to find synergies and try to avoid duplications.
- Key point for prevention is employers' liability to apply the appropriate measures taking into account the measures in the safety data sheets
- ETUC is strongly in favour of addressing MAFs to cover all currently registered substances.

Closing remarks



SYLVIE LEMOINE

Executive Director Product Stewardship
Cefic



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More legislation to be proposed – how to make it work in reality?

- > WE NEED TO GET IT RIGHT
- > FOCUS ON WHAT MATTERS
- > RISK OF POLICY BY DEROGATION (SLOWER, NOT FASTER)
- > SUPPORT NEW BUSINESS OPPORTUNITIES FOR SAFE AND SUSTAINABLE PRODUCTS

Europe: a global, competitive leader for future-proof products?



A Transition Pathway: an actionable plan to holistically look at all transition challenges through several lenses

Building Blocks



to help phase, prioritise and complement CSS actions

Timeline



A 10-point action plan for targeted and effective revision of REACH

1

Introduce a new safety assessment scheme where reliable and human-relevant **non-animal safety assessment methods** have a prominent place (New Assessment Methods).



Legislation reflects the latest advancements in the field of toxicology & Unnecessary animal testing is avoided.

2

Introduce a specific registration scheme for **polymers with a higher likelihood of hazard**.



Registration focuses on polymers that pose concerns & A “system overload” from processing hundreds of thousands of registrations is avoided

3

Make **essential use** a complementary tool for decision making but not the main driver for regulatory decisions.



This new and untested concept is smoothly integrated into existing legislation as an additional consideration, leading to better informed decision making.

4

Ensure **generic bans target consumer uses** with a high likelihood of exposure and focus on the most hazardous chemicals.



Consumers are better protected & Supply chains are less disrupted as priority-setting helps plan for substitution

5

Further improve **safe handling of chemicals** for professionals



Improved protection for professionals handling hazardous chemicals & No disruption of professional services



A 10-point action plan for targeted and effective revision of REACH

6

Enable the **Restriction & Authorisation reform** to prioritise actions bringing the biggest benefit for people and planet



A more agile and predictable system using the full EU regulatory toolbox in a more efficient way

7

Apply stricter environmental safety assessments rules (a so-called "**Mixture Assessment Factor**") for the chemical mixtures posing concerns.



Relevant "mixture effects" are addressed & Avoid disrupted supply chains for safe substances & Avoid risks of increasing reliance on imports of materials

8

Give ECHA an increased mandate to revoke REACH registration numbers of repeated offenders and address non-compliance with restrictions



The 'no data, no market' principle is enforced & Imports of non-compliant products (including via online platforms) are reduced & Level playing field for EU and non-EU producers is enforced

9

Secure a continuous **dialogue between industry and ECHA** during dossier evaluation process



Safety data is generated faster & Expectations for industry are clearer & Dossiers fulfil expectations of authorities

10

Ensure ECHA has resources at the level of declared ambition



ECHA can manage new tasks and has the manpower to provide necessary guidance on compliance for industry



Thank you for your attention

For more information, please contact
publicaffairs@cefic.be



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