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Emerging pollutants: What solutions beyond reactive regulation?

Summary

Chemicals are now an integrated part of our environment, present in almost all manufacturing products, especially Personal Care Products and Household Products. As a result of decades of negotiations, the EU has adopted one of the most stringent chemical policy in the world, centred on the REACH Directive. However, concerns are growing regarding the high number of substances with low restriction and monitoring, whose new presence is now increasingly evidenced in environmental matrices. Scientific studies are needed to better understand interactions and pathways, but reducing the chemical cocktail has to be considered from now on in a pro-active approach. This is already possible with the help of existing data and tools from early stages of risk assessment and product development, such as qualitative exposure and hazard assessment or sustainability tools.

KEY POINTS

1. Although REACH reframed EU chemical policy, grey areas remains to allow flexible management of risks.

2. Combination effects and repeated exposure are underestimated in regulatory risk assessment, so is the role of remaining historical pollution.

3. Improved use of existing data and tools could help reducing pollution along product life cycle.

Institut d'études européennes
Institute for European Studies
UNIVERSITÉ SAINT-LOUIS - BRUXELLES

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Chemicals of Emerging concern in consumer products: a public health issue still barely harnessed

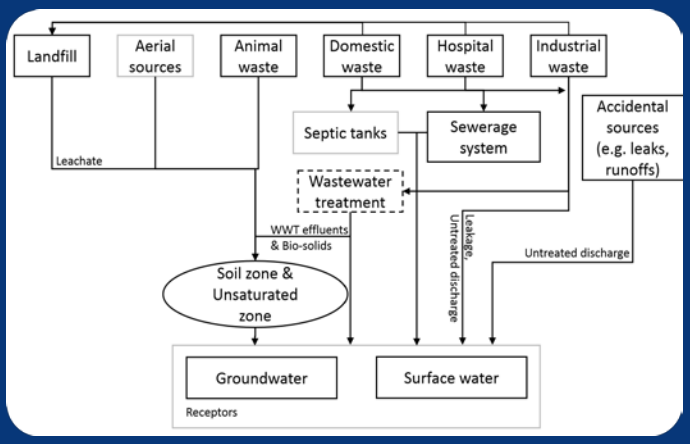
Food additives, synthetic textiles, detergents, personal care products, surface treatment, the list goes on and on: chemicals have progressively invaded our day life far beyond industrial usages. With the multiplication of environmental contests and health scandals in the past decades, their use has raised public awareness in civil society, as yet another pressure on politicians to recognize the need for more stringent chemicals regulation. This process is however under development and the European Union, with the multiplication of directives at all levels and the development of a comprehensive chemicals regulation policy, is now playing a key role in its enforcement. Nevertheless, some grey area remains, especially regarding emerging contaminant, located in the margin of existing regulatory frameworks. In our consuming society, the products containing chemicals have boomed, exposing everyone daily to a tremendous number of substances. Especially, concerns are raising regarding Personal Care Products (PCP) and Household Products (HHP), such a cosmetics, hygiene products, detergent and ambient air products. Considering the limits of knowledge and implementation feasibility, as a researcher on environmental science, law and policy, I want through this brief to encourage policy-makers, regulators and industrials involved at all phases of product life to adopt more integrated approach to chemicals risks in order to take into account effective exposure in correlation with the real use of product by consumers overall its life, from conception to waste management.

Chemical of Emerging Concern (CEC), also known as Emerging Pollutants, or Emerging Substances, represent the massive number of chemicals that are not currently regulated, or at least not adequately, and are increasingly suspected to have potential adverse effects on human health and the environment. Their denomination as “emerging” is not based on a new use or recent development of these chemicals, but on the fact that numerous molecules from human manufacturing sources are now found in the environment, which was not the case since then or at significantly lower concentrations, as for neonicotinoids from agricultural products. CEC being used in most manufacturing products, consumers are exposed daily to an accretion of molecules which may develop into a toxic cocktail, raising significantly public awareness.

Regulating chemical use raises a problem of numerous competing dimensions, torn between scientific debate, political feasibility, and socio-economic benefits. Indeed, considering scientific accuracy alone, disputes are vivid regarding adequacy of testing methods and effectiveness of lab-proven impacts in real-life conditions, especially when considering the huge number of chemicals to be considered and the complexity of their pathways from anthropogenic sources, as shown in Figure 1. This has been emphasized by the preliminary REACH debates around the dedicated White Paper published in 2001 and the continuous

to be adopted. Furthermore, the focus has been given to intrinsic hazards of each molecules. This approach is now questioned has it does not comprehensively integrated the various notions of exposure and combination effects (Assmuth et al, 2010). Difficulties towards procedure application, coordination between authorities and supply chain stakeholders, and market pressures are adding further complexity to the regulatory process, which may leave room for potential conflict of interests.

Figure 1. Chemicals from anthropogenic sources: pathways in the environment



In some case, gathered under the CEC appellation, regulation is either inefficient due to an underestimation of chemicals' impact, leading to inappropriate risk management measures, or inexistent in the case of molecules used in low yearly tonnage under the lowest REACH threshold. In regards to the presence of such substance in a massive number of consumption products used without any specific handling warnings for consumers, repeated exposure is even more accentuating the risk of bioaccumulation (when applicable) and of activating adverse effects, and considerably increases the possibility of combination effects. Dealing with the limits of knowledge and scientific demonstrations, these impacts are hard to identify and track back to understand triggering mechanisms (Naidu et al, 2016). Therefore, chemical risk management become as much question of anticipating impacts identification as dealing with risk perception. For instance, the requirement for strict regulation of GMOs, pesticides and nanomaterials is driven by experts debates as much as public's anxiety towards technological experimentation.

What regulatory provision for protecting human health and the environment from chemicals risks?

The EU has one of the most constraining regulation policy towards chemicals since the introduction of the REACH regulation. However, even though this directive contributed to simplify the regulatory framework, it is can still be quite complicated for their users to find their way.

- ***Protection of human health and the environment***

European legislation related to environmental release (such as the Water Framework Directives (WFD), and other directives associated to water, or Air Pollution Directive) are defining physicochemical conditions and standard values of listed chemicals for industrial and domestic discharges into environmental matrices.

For instance, the WFD includes several lists of pollutants to be monitored: the list of

main pollutants and quality standards (Annex VIII), the emission limit values and environmental quality standards (Annex IX) and a stricter Priority list (Annex X), including classification of the most dangerous substances has "hazardous substances". The latter lists 33 priority substances in its 2008 revision, including 20 priority hazardous substances, and 8 other pollutants. This number of chemicals targeted may sound small, but this can be explained by the limited capacity for monitoring at large scale.

Some other tools have been implemented to promote a better integration of environmental protection in industrial activities, like Environmental Impact Assessments (EIA), Strategic Environmental Assessment (SEA),or the European Environmental Liability Directive, as well as some additional tools on voluntary basis (certification based on ISO 14000 regulations, eco-management and audit scheme (EMAS), eco-label award scheme) (Lee et al, 2013).

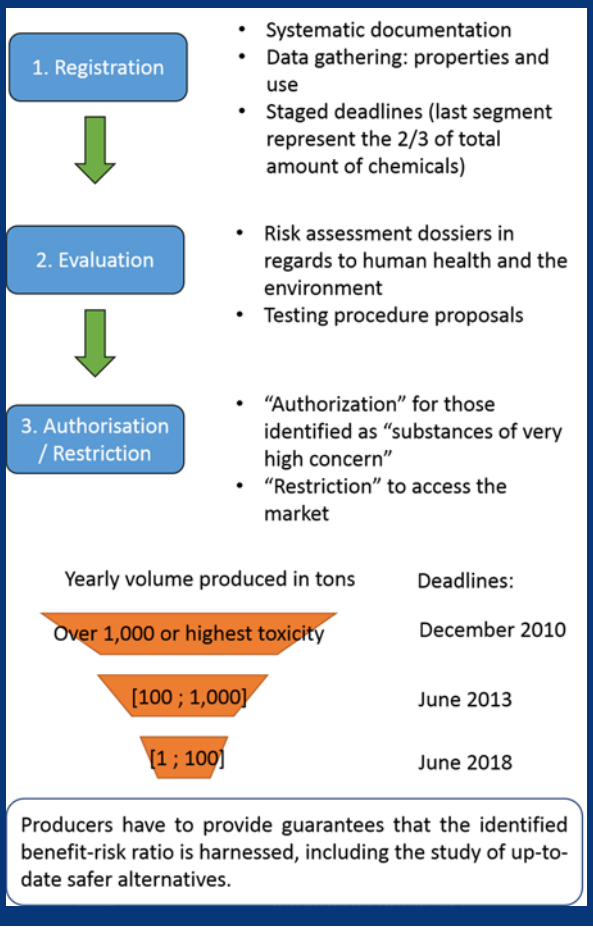
- **Control of chemicals use**

Regarding product manufacturing itself and the use of chemicals, European legislations is centred on one main directive, centralising information requirement, but supported by other regulatory legislations.

The Registration, Evaluation, Authorisation and Restriction of Chemicals Directive (REACH)

This highly procedural directive provides a comprehensive framework for the registration and risk assessment of chemicals. Although the subject of numerous critics (e.g. potential influence of industrial lobbying during the discussions, high level of complexity not adapted to companies with low technical capacity), this directive entered into application in 2007 revolutionized the European chemical policy by its systematic approach of all chemicals without distinguishing "new" and "existing" substances contrary to former regulations *(see supporting legislations below)*. A prioritisation has been implemented based on yearly tonnage of substances manufactured or imported for a staged approach with the focus on highest volumes as described on Figure 2. Therefore, chemicals used below one ton per year would not be subject to a registration procedure.

Figure 2. Summary of REACH registration procedure.



Other legislations supporting REACH

Developed to simplify and clarify the existing pre-REACH regulatory framework, such as the Dangerous Substances Directive, the Dangerous Preparations Directive or Existing Substances Regulations (Gebel et al, 2009), the REACH nevertheless relies on their former findings. It however made possible the systematization of the risk assessment and information collection process, even though the increase of data available may only be a deepening of the existing ones more than a generation of new data according to the analysis of Oltmanns et al in 2014.

Additionally, the registration process is supported by the Classification, Labelling and Packaging Directive (CLP), which is the European Union application of the Globally Harmonized System (GHS) provided by the United Nations. This regulation ensures classification of substances and mixtures by hazard types, e.g. toxic, carcinogenic, irritant, or mutagenic. As a result, specific instructions are specified to ensure safe handling of chemicals along process and use, transparency and traceability, such as safety pictograms and hazard sentences.

Specific regulations (e.g. Cosmetic Regulation (EC) No 1223/2009) can also provide further constraints, such as by limiting the amount of certain substances in products.

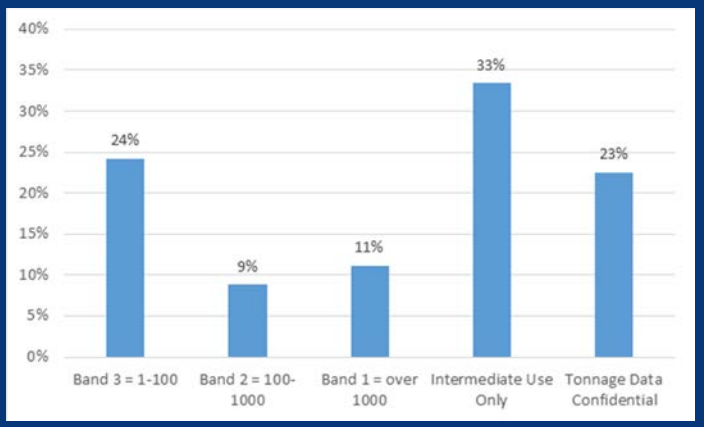
The urgent need for a better integration of exposure and combination issues in risk management

Even though the REACH directive has completely reframed EU chemical policy, providing better transparency and tracking of substances, numerous challenges remain to ensure the safer production modes.

- **Chemicals produced in low tonnage**

21144 substances have been registered for REACH on 3rd May 2018 according to ECHA website, the European authority coordinating and controlling registration dossiers. As shown on Figure 3, the lowest band (1 to 100 tons per year per producer), whose registration deadline is the last (June 2018), represents the highest number of chemicals in direct use, excluding volume kept confidential, demonstrating the partial inadequacy of this volume criteria. Indeed, there is no correlation between number of chemicals, harmfulness and volume of chemicals used. Many potentially hazardous molecules, included in CEC denomination, can hence overpass the procedure as long as they are used in low quantity, with no guarantee that this would be sufficient to avoid having health or environmental impact.

Figure 3. Distribution of REACH registrations by volume produced, based on ECHA, 03/05/2018



- **Limits of risk assessment requirement in registration**

In terms of risk assessment method used, the procedure being focussed on single chemicals entry, little consideration is given to “cumulative risks from long-term accumulation of dispersive chemicals in the environment" (Jihyun et al, 2013).

Exposure is additionally under covered by REACH exposure scenarios. Indeed, such assessment, together with risk characterisation, is required for a limited number of chemicals only, those classified as "dangerous substances", “Persistent, Bioaccumulative and Toxic substances” (PBT), or “very Persistent, very Bioaccumulative substances” (vPvB). However, in regards to the frequency of use of PCP and HHP, repeated exposure can be a major triggering factor for numerous chemicals, such allergens, beyond existing testing capacity. Therefore, anticipated studies of exposure scenarios should be considered for PCP and HHP, at least qualitatively and regardless hazard classification prioritisation.

- **Low integration of historical pollution**

Existing pollution can interact with the new releases to increase background exposure. A comparative study of Denmark and Korea in 2013 hence highlighted the impact of common air pollutants from historical accumulation in addition to current emissions in regards to the past industrial specificities of these countries. Subject to similar regulatory constraints as South Korea chose to apply the REACH directive for trade reasons, and with comparable standards of living, background pollution proved have noticeable effects.

Solutions proposed to improved safety of PCP and HHP

While REACH is arriving at its last deadline, the case of lowly regulated chemicals with a raising suspicion of harmful potential, known as CEC, should gain further audience. In regards to their massive number, procedural case-by-case study, as the one which led to the restriction of use of triclosan, and antibacterial used in many PCP and HHP, are no longer the solution. Combination effects, repeated exposure and accumulation of substances into the environment along the time are indeed suspected to significantly increase the risks to trigger uncontrolled hazards. A broader policy is needed to ensure suitable application of the precautionary principle and compel industrials to take their responsibility in reducing the chemical mix, such as:

- Encourage incorporation of geographical specificities, such as existing pollution background, in defining emission limits. This can be supported by existing monitoring programs (e.g. the European Pollutant Release and Transfer Register);

- Promote integrated risk management solutions including exposure assessments, at least qualitatively, at early stage of development.
- Advocate for increased use of sustainability tools in industrial sector along product life cycle, from regulatory risk assessment to waste management, for example: Life Cycle Assessment (LCA), eco-conception and green chemistry principles;
- Incite consumer to question their behaviours by providing simpler qualitative labelling, following the example of Que Choisir (French consumer association) summary sheets.

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Author: Lucille GROULT, PhD student at the University of Dundee, Centre for Water Law, Policy and Science (Scotland, United Kingdom).

With three master's degree in chemical engineering for the environment, water management and international relations, Lucille worked for 8 years as an industrial and environmental risk engineer in the industrial sector. She thus conducted studies for the energy sector (oil, gas, nuclear) and the chemical industries. She now work on exploring socio-legal solutions to better reduce exposure to CEC as part of the Hydro Nation Scholars program, funded by the Scottish government.

E-mail: lgroult@dundee.ac.uk

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