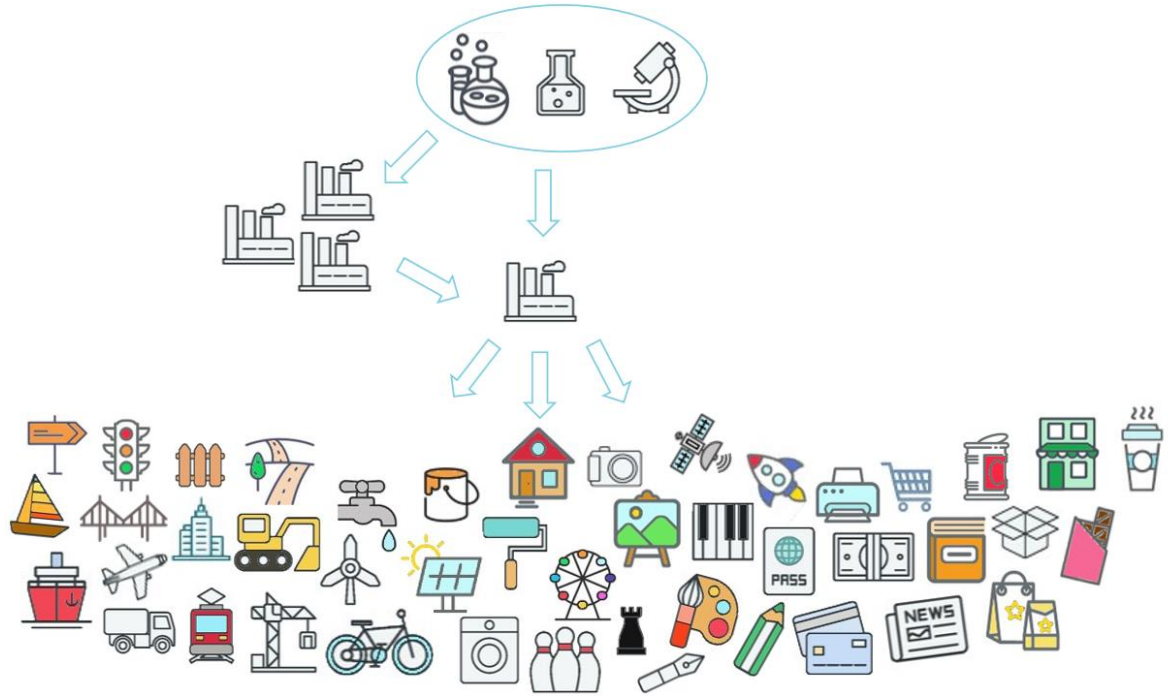
CEPE comments on the public consultation on the Inception Impact Assessment on the revision of REACH

CEPE, the European Council of Paint, Printing Ink and Artists' Colours Industry, welcome the possibility to comment on this initiative, which is of high interest to our industry.

Our industry depends on a broad raw material portfolio to ensure the functionality of the diverse products of the coatings and printing inks industry and is therefore concerned about the proposed development.

Indeed, CEPE member companies formulates chemical mixtures and is probably the downstream industry that uses the widest variety of chemicals (an estimated 5000-6000 REACH Registered substances – which includes monomers of resins). This is necessary to ensure all the required functions of the end use applications. Indeed, coatings are applied on a variety of substrates such as concrete, paper, plaster, wood, plastic, stone and metal for a variety of functions supporting societal needs (e.g. for well being, health and safety) and sustainability goals (e.g. by increasing service life of the treated objects).



Although the products may contain substances defined as hazardous our industry has the moral and legal obligation to place on the market only products that can be used safely.

General considerations

Today it is clear that the EU has one of the strictest and most advanced chemicals legislations in the world. REACH in particular has become a world standard, similarly implemented by many countries. This success is at the same time due to its high effectiveness.

REACH, for example, already offers a wide range of tools to respond to new findings and to regulate chemical products in a targeted manner and as needed. With the concepts of authorization and restriction, two very powerful instruments are available for the targeted regulation of the production, use and application of chemical substances.

The further development of chemicals legislation should be based on the precautionary principle in the sense of the corresponding "EU guideline" (EUR-Lex - l32042 - EN - EUR-Lex (europa.eu), which provides for comprehensive scientific assessments, risk assessments and the involvement of those affected.

The paints, coatings and inks industry relies on the diversity of chemical raw materials to ensure the functionality of its products.

In order to achieve the goals of the Green Deal, many of our industry's products are indispensable.

Combination effects of chemicals and mixture assessment factor

CEPE would like to highlight that an effective (regulatory) approach should be as targeted as possible, rather than applying a generic one-size-fits-all approach to the entire chemical universe. It is necessary to take in consideration the principle of proportionality from the Treaty of Lisbon, article 3b "*Under the principle of proportionality, the content and form of Union action shall not exceed what is necessary to achieve the objectives of the Treaties. The institutions of the Union shall apply the principle of proportionality as laid down in the Protocol on the application of the principles of subsidiarity and proportionality*"

Concerns for combination effect of chemicals should focus on unintentional mixtures such as ambient air, water and soil, not on intentional manufactured mixtures where the ingredients are known. This seems to be supported in the conclusion of the COMMISSION STAFF WORKING DOCUMENT "Progress report on the assessment and management of combined exposures to multiple chemicals (chemical mixtures) and associated risks" (https://op.europa.eu/en/publication-detail/-/publication/2e7f5564-0f02-11eb-bc07-01aa75ed71a1/language-en#) where it is stated that additional efforts are needed to adequately address the challenges posed by unintentional mixtures as knowledge and availability of toxicity and exposure information on unintentional mixtures and mixture components is, and will remain for a long time ahead, fragmented and insufficient. The application of a mixture assessment factor (MAF) is proposed as a mean to tackle these challenges. It may be that in some cases an unexpected exposure to the same chemical or to chemicals having the same mode of action through different routes can occur, but it should not be considered to be the rule. Safety factors are already intrinsically added when deriving an acceptable level, such as DNEL or PNEC and these are already conservative. The default application of an additional safety factor such as MAF (Mixture Assessment Factor) would result in unrealistically restrictive use of the precautionary principle. A MAF of 5 applied on an RCR (Risk Characterization Ratio) would mean that the exposure would be considered to be 5 times higher. This would result in many purely formal failures of risk assessment, which validity

is confirmed by current practice, due to the application of a blanket factor without a sound fact base.

For intentional mixtures, where ingredients and exposures are known, adding an additional safety factor on top of a number of other conservative safety factors assigned already does not seem to be justified nor necessary – even when interpreting the precautionary principle in a very conservative way. Our industry has been placing on the market safe products for decades based on current risk assessment procedures. The addition of a default MAF would make it very difficult to prove safe use for many products even when adding costly additional RMMs, when possible.

Generic risk management

We recognise the burden that the implementation of the restriction procedure places on authorities. However, the primarily hazard-based "generic approach to risk management" proposed in the Chemicals Strategy only seemingly brings the advantage of rapid feasibility without lengthy coordination processes and Risk Management Options Analyses (RMOA). Decisive for the protection of consumers is the safe use of a substance and not exclusively its intrinsic substance properties. Many substances that are classified as hazardous to health can be used safely. Also, past experience with downstream legislation shows that a direct link to classification is too simplistic and can often trigger unintended consequences (as shown, for example, by the current discussions on the classification of ethanol). A hazard-based approach may be, or appears to be, simpler and more transparent due to its lower complexity, but often only risk orientation allows for an equally effective, efficient and proportionate approach. For some regulatory areas, simple hazard-based approaches may be sufficient, but restrictions on the use of chemicals must necessarily be based on risk-based assessments. An RMOA can help with this.

Proposals to extend the generic approach by 2022/ Extension of Article 68(2) to professional users:
The term "professional uses" is often applied for uses that do not take place at an industrial site. Nevertheless, the conditions of use may be similar or even identical to those in the industrial sector. Compared to private end-users, professional users have specific qualifications and possibilities to limit risks during corresponding activities, e.g. through occupational safety measures. Professional users are covered by specific legislation taking into account their particular exposure and the chemical safety assessments in Reach covers many aspects of worker safety. If these regulatory instruments are not enough to ensure a safe work place, it should be clarified if it is the specific regulations that needs to be more strict or if it is a matter of low compliance and enforcement. Many products with functions vital for society used safely today by professionals would be lost if a generic approach is introduced. Therefore, in our view, professional uses should not be equated with consumer uses and should not be regulated as such.
If necessary, conditions of use and risk management measures can be selectively restricted through a regular restriction procedure in the current legal framework (REACH).

The complex, interdependent objectives of the Green Deal can only be achieved on the basis of holistic scientific analysis. This requires a balanced approach, taking into account the

sustainable product functionalities in the sense of the Green Deal and the current high level of protection. The achievement of the goals must not be thwarted by political urgency.

The evaluation of registration dossiers is complex

A registration dossier represents a comprehensive effort from an Industry Registrant to deliver information. The evaluation of such dossier is by nature complex and the EU can be proud to have the most comprehensive system in the world. This complexity requires resources and time and should not be taken as a problem as such. Proper scientific assessment should be always allowed. If the speed of evaluation should be increased, one could envisage to increase the resources allocated to such activity.

To date, comprehensive substance datasets have been submitted to the European Chemicals Agency (ECHA) for around 23,000 different substances in approximately 100,000 registration dossiers under REACH, thus creating a unique database worldwide. These dossiers are very complex and thus the evaluation of them is also a comprehensive and time-consuming process. However, this should be carried out conscientiously.

The European Commission has already revised the requirements for registration dossiers and data quality through an implementing regulation (EU 2020/1435). The annexes to the REACH information requirements have also been adapted several times, thereby defining the requirements more clearly. The basis for good, meaningful dossiers therefore already exists.

The authorization procedure is too heavy and inflexible

It is true that the Authorization procedure is burdensome for both Industry and Authorities. Perhaps it is again a matter of allocating the right resources.

Once a substance enters the Candidate list it does result in substitution (when possible) due to market forces. Thus, it can be considered that once a substance reaches Annex XIV of REACH most of its uses have already been stopped and the legislation has thereby achieved its objectives. The burden is high for industry to request an authorization so if a specific derogation/authorization is needed for a specific application, one could already consider that the application is for an essential use that cannot be easily substituted. When cost and administrative burden are involved industry endeavours to substitute where possible. The Plant Protection and the Biocide areas are systems that put a lot of pressure on these chemicals. If Industry is still supporting some chemicals it means that the remaining chemicals are essential, at least for a certain period. This is equivalent to a REACH Authorization system where continued use is limited in time and under certain conditions.

A simplification and revision of the authorization procedure should definitely be carried out without restricting the scientific assessments, risk evaluations and stakeholder consultations that have been possible up to now.

Essential use

As stated during the public consultation following the introduction of the concept of essential use end 2020, we believe that this concept cannot be implemented simply with categories of what is essential and what is not. This concept encompasses multiple considerations and will be defined by mere subjectivity and politics of the beholder. What is perceived as essential for one person may not be perceived as essential by another. Our industry places on the market decorative paints, printing ink and artist colours products that support the wellbeing and the

human creativity of our society. It would be too simplistic to state that any decorative products are non-essential. We refer to the examples provided in our contribution.
The lack of clarity on how this concept will be developed and implemented brings a lot of uncertainty to our Industry.

Restriction and authorization are the two main regulatory processes for addressing the "most harmful chemicals". These processes should remain and, as the Essential Use concept is linked to the management of such chemicals, inclusion of the Essential Use Concept complementing the existing Restriction and Authorization processes could make sense. Together with socioeconomic and availability of alternatives analyses, it can facilitate case specific discussions on whether to derogate a use of a substance subject to a ban or restriction.
The Chemicals Strategy is characterised by the precautionary principle and a regulatory approach based on the hazardous properties of chemicals. The nonetheless possible safe use of these chemicals is disregarded. REACH already offers the possibility of prioritising or restricting uses with instruments such as restriction and authorization. The pandemic events of recent months have shown that a use that is not essential today may be essential tomorrow. Therefore, inflexible definitions of essential uses must be avoided at all costs. Also, to achieve the goals of the Green Deal, many chemical substances are essential that may have a classification but can be used absolutely safely.

The current Restriction process is too slow

We recognize that the generation of an Annex XV dossier is a burden to the Authorities. If substances did not present a benefit for the society the decision would be easy, but most of the time there is a good justification for the use of certain hazardous chemicals. This illustrates that proper assessment is needed for complex situations.
The downstream user industry has a lot of technological knowledge and expertise and could bring value to be structurally involved in the dossier development. Perhaps Industry as a whole (i.e. not only the Registrants) should be more engaged with the concerned Authorities, be tasked to activities currently in the hands of the Authorities to relieve them, but under their control. This could be a way to lower the burden for Authorities, speed up the evaluation while maintaining proper scientific assessment.
The application of a simple "Risk Management approach" as is the case for CMRs Cat 1 (under REACH Annex XVII, entries 28-30) for other hazard categories would be a too simplistic approach as it would simply be based on hazard and not on risk, and thereby potentially leading to someh unknown consequences for society.

Enforcement

Proper enforcement is certainly desirable to ensure a level playing field between EU with non-EU made products/articles. This is true for the import of substances and mixtures, but also for the import of finished articles. The enforcement of chemicals legislation by the supervisory authorities should be uniform throughout Europe and take into account manufacturers, distributors, users, importers and only representatives. Otherwise, European companies will be at a competitive disadvantage vis-à-vis their non-European competitors, but also within Europe. The lack of resources to enforce imports of chemicals is a problem, and for finished products it is even more difficult.

Europe should not put a too high burden on the EU Industry if this burden cannot be applied outside Europe. A Restriction imposing a mandatory training for the users in Europe, such as the di-isocyanate one, is not applied beyond our borders, which means that the burden is higher to maintain the use of that chemistry within Europe. For instance, a Bicycle made in Turkey on which a polyurethane coating is applied can be imported as a finished article. We do support the EU restriction when it comes to real improvement of the protection of EU workers, but we cannot deny that this also means that there is no level playing field with manufacturers outside Europe.
With the revision of REACH the legislator should avoid that some hazardous chemicals are banned from use in EU when they can be incorporated in finished goods and imported as such from outside Europe. This is especially true for those substances that chemically react and disappear when curing and are not anymore present in finished goods as such.
We think it is the responsibility of EU to reassure our industry that this legislation will not unintentionally promote the import of finished products.

Polymers

The world of polymers is complex. Some polymers are hazardous, but most are not. Those that are might require registration, in which case the data requirements and testing methodology should be adapted. We would like to highlight that, as downstream users of chemicals so far we were not involved in REACH Registration, should some polymers be registered, our status might change to become Registrants, which would be potentially a significant new burden to our industry.

Supply chain communication

We welcome an improvement in supply chain communication. Any envisaged electronic exchange of data or e.g. safety data sheets should be done by means of a uniform, electronic format and in close cooperation with all stakeholders and software providers.

Additional suggestion to the IIA – Consumer education

Great emphasis is made on the need to protect consumers from substances of concern. A simple elimination of all substances of concerns simply based on hazard is a simplistic measure as it does not take into consideration exposure, and hence the consideration of safety in use through risk assessment (targeted towards specific end uses). Lack of consumer safety is often claimed because consumers do not read labels or do not follow the safety instructions, such as avoiding skin contact. Fundamentally this could lead to the disappearance of useful consumer products even to those who do follow the supplier's instructions. CLP exists to inform about hazard and should be part of basic knowledge of consumers in all Member States.

Reduction of administrative burden

The Inception Impact Assessment (IIA) touches upon the administrative burden for Industry. We would like to note that during the past years the regulatory activities with the existing chemical legislation has added significant burden to Industry with little benefit for the EU Society.

The first example is the Poison Center Notification. When the concept was first discussed we did support to have an EU Central portal instead of the many national systems in place. However, this turned out to be a massive database that requires the notification of millions of products with full detailed composition, which information is not needed for poison emergency action as the vast majority of poisoning cases are treated symptomatically.

The SCIP database under the Waste Framework Directive is another example. More than 5 million notifications have been received. Although we understand the need to track some substances of very high concerns (SVHCs) for their use throughout the supply chain for recycling purposes, it imposes an unnecessary burden for Industry, especially for objects composed of thousands of parts and substances. The SVHC identification is purely a hazard based process and again it does not mean that there is a risk in use. The tracking of SVHCs could have been focusing on what matters most but has also become a massive database.

The current development of the primary microplastic Restriction shows that ECHA suggest to the European Commission to setup a reporting obligation. We believe that this suggestion is an unnecessary additional burden for us with very minimal, if at all, benefit for the society. Waterborne dispersions used in waterborne paints are deemed to contain microplastics. The only relevant way for these to reach the environment is through consumers washing their brushers and rollers under the tap. This is a minor environmental release compared to other sources and it may not even reach the sea sediment as it may be trapped in sewage treatment plants. The reporting obligation would require all paint companies to report annually an estimate of the release to the environment using a generic descriptor of the type of microplastic (polymer) placed on the market. The estimation can only be done through the use of a default release factor as we cannot measure how much consumers will wash their brushes every year. Hence the expected amount will barely change throughout the years. We already have an estimate and this figure is not expected to change dramatically, therefore we think that this reporting obligation would be an unnecessary additional burden.

In fact the big data centres necessary for these information technology platforms require significant amounts of electricity, which in the world emits as much CO2 emissions as airplanes. At times when we aim at being carbon neutral by 2050 this aspect should also be taken into account, when creating big databases.

The IIA also touches upon the difficult flow of safety information through the supply. This is correct and we have invested resources together with other industry associations and ECHA during the past years in the ENES network. It is unfortunate that ECHA decided in December 2020 to 'pause' their work in this area due to other priorities (Green Deal…). The improvement of tools is a possible solution but again this has to be done carefully and not become another monster administrative burden.

The complexity cannot be solved through simple solutions. We should focus on what matters most and not create unwieldy systems that have limited societal values but create huge administrative burden.

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