ATIEL Comments to REACH Revision 14 April 2022

Introduction

This presents additional comments aimed to provide explanations on the reasoning behind some specific answers chosen within the REACH public consultation questionnaire. The proposed REACH revision is very broad in scope and intend to modify many elements/processes, but at the same time, it brings forward notions that are not yet fully defined. As a result, it becomes challenging to properly understand or anticipate the real implications of the future regulatory landscape. In some instances, the way questions are formulated within the document requires comment, rather than a choice between the possible answers. This is due to question complexity and background implications.

Increased information on critical hazards / Information on substances marketed at the lowest tonnage level (Questions 1 to 4)

It is not justified to require additional information on critical hazards for all substances registered under REACH. On the contrary, the focus should be on the substances which could pose a concern ("flagged" either because of their classification, structure-activity relationship grouping analogy, indications resulting from other existing studies, high tonnages, wide dispersive uses, etc.). Small volumes substances are mainly produced by small or medium companies and for new substances. To require additional information to small volumes would limit innovation and put too much pressure on SME.
We would like to comment also question 1 (accept a higher level of uncertainty about the critical hazard properties of a substance, if in return some animal testing could be avoided through use of non-animal methods). In view of animal welfare, we support the use of validated non-animal methods if available. However, it remains unclear if a higher level of uncertainty would be accepted by regulators and authorities. This could lead to the implementation of additional compensatory safety factor, which we believe are not necessary because the present approach already includes many safety factors fueled by precautionary principle.

With regards to animal testing, we welcome the objective of the Commission to reduce and in time to replace them by alternative methods. In the current state, there are no validated NAMs for all critical hazards. It is very important to stress that in the future landscape, the NAMs should be robust and reliable. Implementing NAM too early just to follow political agenda, with the risk of having many false or equivocal results, could

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have major consequences, especially for low tonnage bands substances and for small and medium companies. In case of alerts or equivocal results, targeted testing should be developed rather than requesting full annex VII and annex VIII requirements for low tonnage substances.

A major point of concern for lubricant industry are the methods and approaches applicable for insoluble UVCB substances, for which deviating protocols should be put in place to cover the specificities of such complex substances.
Flexibility on the test types to be performed should be given to allow to choose the appropriate tests considering substances specificities.

Furthermore, for the purpose of Europe's Beating Cancer Plan, it is implied that all substances in REACH are potential threat for carcinogenicity. This claim is very surprising and disproportional. This unfounded assumption can potentially create a huge burden on companies, who will have to generate additional data, even in instances where no carcinogenic alerts exist. Instead, it is much more reasonable to focus on existing carcinogenicity alerts (from screening data, modelling) and to make the link with usage and exposure.

Information requirements to provide information on endocrine disruption (Questions 5 (incl 5a, 5b, 5c)

In the specific case of endocrine disruptors, even if the criteria for classification were agreed, there are still gaps to be addressed on too many levels.

First, the definition itself relies on identification on observed adverse effect(s) from in vivo studies which should be the key criteria, and which has to be confirmed with a specific link to an endocrine mode of action/activity (most of the times from *in vitro* studies). In practice this means to have different kind of information/tests to validate the assessment (*in vitro* studies cannot be sufficient *per se* to conclude). Where possible, a tiered testing approach should be based on adverse findings from all available "*in vivo* data", and which should trigger (or not) the type of necessary endocrine disrupting mode of action/activity studies. Therefore, more flexibility is needed to avoid unnecessary studies and to allow for more in-depth assessment only when warranted.

Secondly, there is complexity coming from consideration of different hormonal paths (EATS – estrogen, androgen, thyroid and steroids), their interferences/confluences and delimitation of endocrine secondary effects from other type of chronic toxicity. The assessment for this endpoint is in itself very complex, requires extensive knowledge expertise to assess data / results and it is prone to different interpretation. The *in vitro* and *in vivo* studies proposed for this endpoint were tested for a limited number of substances (especially for the in vitro studies assessing the mode of action), which makes not robust enough to apply on such huge number of substances and would lead to important false or equivocal results.

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To conclude on this topic, if additional information is needed to allow the identification of endocrine disruptors, the most suitable approach would be via the modification of the SIR (Substance Information Requirements) annexes. However, the requirements should be proportionate to the volume band. The strategy approach should be clear and reliable (including weight of evidence, waiving and flexibility to choose tests depending on type of substance). Testing "by default" all substances, especially for lower tonnage bands, with low exposure, is unjustified. On the contrary, a case-by-case endocrine disrupting assessment for each substance using available data, and additional investigations only when justified is more reasonable and pragmatic approach. Alternative tests (most likely *in vitro* tests) should be agreed internationally and should be preferred in low tonnages annexes.

Information requirements for polymers (Question 6)

Several previous reports (e.g., OECD (2009), COM (2012); COM (2015) and Wood (2020)) detail studies on identification of polymers requiring registration or of low concern (e.g., COM (2012); COM (2015) and Wood (2020)).
A previous study (COM, 2015) developed possible criteria for identifying polymers of low concern in relation to the REACH Regulation. These were based on a review of polymer registration schemes and requirements worldwide.
A polymer of low concern was based on the OECD Polymer Working group definition (OECD, 2009):

"Polymers of low concern are those deemed to have insignificant environmental and human health impacts. Therefore, these polymers should have reduced regulatory requirements."

The OECD (2009) study used data for 205 polymers collected from Australia, Canada, Japan, Korea, and United States and carried out an analysis to identify any correlations between the polymer characteristics and the potential for health or ecotoxicological concern. For the analysis, the polymers were classified into one of two categories - polymers of low concern (PLC) or non-PLC – based on the USEPA criteria.

A review of the experiences gained in the environmental assessment of polymers under the TSCA in the United States is available (Boethling and Nabholz, 1997). Around 10,000 premanufacture notices (PMN) have been reviewed by the United States Environmental Protection Agency and, based on this, a number of broad findings on polymers that are of no concern and polymers that may be requiring registration for the aquatic environment were reported by Boethling and Nabholz (1997).
In view of polymers under EU REACH, we agree with the general observations in these reviews and conclusions that the following polymers should be considered as polymers requiring registration:

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a) For polymers for which information on hazard classification under the EU CLP regulation is available, a polymer requiring registration e.g., Polymers classified for certain severe hazards (like e.g., mutagenicity, carcinogenicity, acute toxicity for humans and the environment, reprotoxicity)
b) Cationic polymers or polymers that can be reasonably expected to become cationic in a natural environment.
c) Polymers with low molecular weight (≤1000 Da) which are expected to behave similar to non-polymeric substances?
d) Polymers having reactive functional groups of concern.

Degradable Polymers:
The COM (2015) proposal for polymers of low concern excluded polymers that are degradable from being considered as a polymer of low concern. The fact that a polymer is itself degradable, either biologically or by other mechanisms, is itself not a parameter that would lead to a concern over the polymer. Indeed, in many respects, degradability of a polymer in the environment can be seen as a positive attribute.

The real concern here is if a polymer may degrade in the environment forming products that are more stable and hazardous and bioavailable than the parent polymer.
However, at this stage, it is not proposed to include any specific criteria based on polymer degradability for polymers requiring registration due to practical complications. However, hazards associated with degradability could be considered on a case-by-case in a safety net criterion.

Information on environmental footprint (Question 8 (incl. 8a, 8b, 8c)

We completely agree that assessing the environmental footprint of chemicals is essential for a safer planet. However, REACH is not the most appropriate legislation to obtain this information. The philosophy of environmental footprint is based on “potential impacts”, calculated (and not measured) through the whole life cycle and relative to a delivered function (and not to a quantity like kg or ton). A modulization of the reality is proposed and inputs/outputs flow through a supply chain are evaluated to obtain a picture of a footprint and to identify hotspots. Environmental footprint is calculated for a delivered function and not per kg or ton. Perimeter of the environmental footprint has also to be defined to have a real meaning. This all process is embedding the performance of the product put on the market. A comparison between ponderal quantities is not relevant.

The method for assessing environmental footprint is focused on flows linked to an activity, which is impossible to anticipate that early in the supply chain as when performing REACH registration. Information in a REACH dossier is focused on uses of a substance. It is highly unlikely to be able, at this stage, to include adequate information on the environmental footprint of all the complex mixtures and articles for which the substance is after that potentially used for.

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'Placing on the market' of a substance is a complex process. It would be very onerous for REACH registrants (manufacturers and importers) to gather all the information on how substances are being used by all further actors and subsequently to include all elements of the life cycle into a registration. Downstream users and other manufacturers are unlikely to share confidential business information, which would be required to feed into such an assessment. A simple example illustrating the complexity of this points is paraffin oil, a substance giving rise to a pervasive matrix in the supply chain: from pharmaceutical, to cosmetic, to different kind of articles, it can be found basically everywhere on the market – making impossible to express or quantify at the entry point of substance registration.

Information requirements on use and exposure (Question 9, specific 9d)

Reliable data on use and exposure is crucial, and industry should increase its efforts to improve it. Within the REACH dossier, the CSR is robust and already contains sufficient data on uses and exposure – the case of registrants who do not fulfill their obligations properly is more a matter of enforcement than of drawing a general conclusion and applying much stricter requirements.

Other actors in the supply chain like downstream users would have to provide this kind of information for substances of concern, which are those in high tonnage, dispersive use and classified. The regulatory process takes long and has many stages, not because of missing information on use and exposure as suggested in the questionnaire, but because it is necessarily to prove scientifically whatever a substance is safe or not for use, and this process requires data and takes time.
Use descriptors generated by consortia and other collective groups of companies tend to be well managed, specific and clear. In instances where use descriptors need further details on use maps, PROCs, ERCs and supporting narratives, consortia are already working to address these gaps.

Derived Minimal Effect Level for non-threshold substances (Question 9, incl. 9f, 9g, 9h)

The derivation of risk-based exposure limits for non-threshold carcinogenic substances is supported. However, these need to be balanced and substantiated by considering route of exposure, mode of action, technical feasibility of measurements and any resultant impacts. DMELs should not be extended to other hazard classes and data on routes of exposure should be utilized accordingly (i.e., an oral DMEL should not be derived from inhalational exposure data). What is deemed an acceptable level (e.g., agreement on an OEL) should be established by broad consensus between all interested parties.

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Introduction of a Mixture Assessment Factor (Question 10, incl. 10a, 10b, 10c)

A data review and assessment of surface water monitoring data shows that, only in a limited number of cases, environmental levels of chemicals might point to a potential combined exposure risk that would not be identified by applying current applicable assessments and regulatory regimes. Many substances identified in the study presented by RIVM are pharmaceuticals or biocides, which are out of scope of REACH.
The study provides evidence that a broad-brush approach such as one generic mixture assessment factor (MAF) to be applied to all chemicals, is not the right solution. It would not provide for the targeted work needed to identify combined exposures of potential concern.

The magnitude of the mixture assessment factor(s) that eventually would need to be applied, must be underpinned by data. Different methods to derive assessment factors using surface water monitoring data have been compared and reviewed.
A generic MAFof a level of 10 (or higher) can have significant impacts depending on the actual substances and uses. Therefore it is ATIEL's position that a MAF should only be applied to a limited group of chemicals meeting pre-defined criteria. Differentiated MAF values are required for environment and human health.

Reform of Authorisation and Restriction (Question 13, incl 13a to 13d)

The Essential Use concept that shall be introduced by the CSS, would allow the continued use of substances of concern, only when necessary for health, safety or for the functioning of society and if there are no suitable alternatives that are acceptable from a health & safety perspective. This would potentially lead to a wide scope ban o restriction of groups of chemically related substances, which will be particularly damaging to certain economic sectors, especially in applications where strict performance and safety requirements exist and substitution options are limited or non-existent.

Establishing what constitutes an Essential vs a Non-Essential Use will be hugely complex, subjective and likely to vary over time. Industry seeks predictability and stability via transparent, science/risk-based decision making that will be subject to challenge and periodic review. An acceleration of substitution of hazardous chemical substances purely on the basis of perceived "non-essentiality" as judged against poorly defined criteria should be avoided, as this could lead to "bad substitution"; in other words, substitution with potentially less hazardous substances but which come with sustainability downsides for the whole life cycle, so undermining the very objectives of the European Green Deal.

An assessment of Essentiality should only be considered as a last step in regulatory decision-making processes and only when risk cannot be adequately managed. An assessment of essentiality based on poorly defined/overly simplistic criteria should not form the basis of screening to fast-track the restriction of certain hazardous substances that may otherwise be beneficial to society and whose risks are well managed. Furthermore, the essential use concept must be applied in a transparent and predictable

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way, with decision-making involving all interested stakeholders. The proportionality principle enshrined in EU law should be respected, while competitiveness of the EU economy should be protected as one of the main aims of REACH

It should be clearly defined for each of the different options what are the desired results and whether the proposed changes would bring the anticipated results with regard to proportionality, efficiency, transparency and predictability.

Outcome of the reform must be a system that can, more effectively, identify the 'problem substances', and allows to choose and practically implement the best solution to control exposure or risks to humans and the environment.
Early prioritization for regulatory action is key. Prioritization should be done based on hazard, uses and exposure.

Existing generic exemptions from the authorisation requirement must be retained, including in a merged system (intermediates, biocides, thresholds for substances in mixtures, ... - see ECHA website)
We agree that merging the authorization and the restriction process could bring some benefits to authorities and industry. It could be designed as a tiered process with restriction of certain uses / applications would be the first level and authorisation would follow in case there is further need for regulatory actions. Harmonized information requirements need to be clearly defined.

Obtaining derogations/authorisations when safe use can be proven should always be an option.

Generic risk management approach (Question 14, incl. 14a and 14b)

The way extension of generic approach to risk management is being described by authorities leads to a switch in paradigm from risk to hazard assessment. The envisioned scale is unrealistically broad, considering the number and types of hazards under the scope and the addition of professional use. It is very important, on the various levels, to keep the proportionality and not to apply default prohibitive measures, only to satisfy the precautionary principle. Are the implications and effects behind this extended approach fully understood or predictable?

We think a step wise approach is best way forward. Regarding professional use, situations where risk is mitigated, and operational conditions and risk management measures are efficiently in place should constitute derogations from GRA. The essential use argument which seems to be interlinked with this approach is not yet defined, which makes the implications of GRA even more difficult to understand. Having an environment where blanket restrictions apply solely hazard based will create an instable socio-economic environment, where substitution and innovation would be inhibited rather than stimulated, due to uncertainties.

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Conclusion

If recent history taught us something so far, it is that misjudging the long-term consequences and putting forward ill tailored policies should be avoided. REACH revision is a crucial step for chemical legislation in Europe and beyond, with pervasive implications on all levels of society. We trust that the Commission will come up with long term best solution for the society, environment, industry, economic independency, innovation, and predictability.

About ATIEL:
ATIEL is a not-for-profit association (ASBL) representing the combined knowledge and experience of leading European and international engine oil manufacturers and marketers.

By drawing on the technical know-how of its membership, ATIEL promotes consensus on key technical, product stewardship and sustainability issues, ensuring that engine oils continue to contribute to improved wear protection, deposit control, lower emissions, and fuel economy C02 emissions efficiency[1].

[1] The lubricants industry researches, develops and delivers products for a wide variety of globally important applications:

- Automotive transport lubricants contribute to reducing vehicle emissions and costs of operation
- Off-highway applications such as construction, mining and quarrying or agriculture, lubricant products extend working time and durability of machinery and vehicles often in hostile environments
- Food and manufacturing industries rely on correct lubricants for metalworking, machinery operation and numerous processes
- Rail, shipping and aviation also uses many specialist lubricant products in safe and reliable fulfilment of their business

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