

REACH Restriction Process on PFAS:

Towards a Definition of "Essentiality"

Reflection Paper

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Definition

What is essential? According to the dictionary: "absolutely necessary", "extremely important" or "crucial", "key", "vital", "indispensable", "needed" or "required". The word "essential" comes from the Latin *essentialis*: the most important part of a thing. Composed of *essentia* and the adjectival suffix marking relationship, belonging, dependence, *alis*. The etymology takes us back to the fifth century Greek before the present era but does not allow us to grasp the meaning of what is 'essential'.

It is almost **impossible to define what is essential though decision-makers attempted to define it**, during the Covid crisis closing all shops but those considered essential. It led to a fierce debate whether, for instance, culture was essential. Any company such as a car maker has for its essential goal to make money but is that all? No, its primary objective is to fulfill societal goals such as for instance ensure mobility, inclusiveness, cultural exchanges, create jobs, among others.

Our hypermedia age is based on a complexity of words, images and thought in its most talkative form. It links news in rapid succession, all of which end up being the same or contradictory (e.g. Covid). It takes us into the abstract, out of reality... This malaise is symptomatic of an era where the major **experience is that of instantaneous experience**.

But it also comes as a reaction to a paradox of modern consumer society: the more we consume, the more we might expect to find satisfaction. But this is not what happens. **Consuming more only responds to our "lack of having"**.

This leads us to **search for what is really 'essential' to identify a real sense in things**. No doubt that the concept of essentiality evolves with time. What was essential a century ago is no longer meaning that no use is permanently essential.

Essential Use Concept in EU Regulations

Further to the adoption of the 2019 Council Conclusions "Towards a Sustainable Chemicals Policy Strategy of the Union" where the Member States called on the Commission to develop an action plan to eliminate all non-essential uses of PFAS" and the March 2021 conclusions "Sustainable Chemicals Strategy of the Union: Time to Deliver" where it was agreed that the **concept of 'essential uses'**

was a key element in the implementation of the Chemicals Strategy. Yet no definition is proposed so far.

One approach to the concept (let us call it a **negative** one) would be 'improving the protection against adverse effects of the most harmful chemicals': chemicals would *not* be allowed unless their use is deemed essential for society. However, our view is that the concept of essential use should rather be a **positive** one: a substance (or substances) *should* be allowed on the market even if the risk is not adequately controlled because of its importance to society.

The above conceptual dichotomy on what is essential or not (reflected in the ongoing debates in the Caracal and between the EU institutions) **is not new**. Other EU Regulations have already addressed derogations to 'ban' essentially based on hazard criteria.

Back in the early 2000s, the Commission agreed to refer to the concept of essential use (under the then Directive 91/414 now replaced by Regulation 1107/2009) to **approve some plant protection active substances despite the fact that they did not meet the conditions for approval under the Directive**.

Aldicarb (a Bayer active substance) is the reference. The substance was non-approved but the list of essential uses (referred for the first time) was so long that the non-approval was basically an approval to use the substance but only in some specific conditions and crops. The Commission decision on Aldicarb was confirmed by the European Court of Justice which stressed that a proper balance between the internal market and the environmental objectives of the Directive had to be found.

The Court concluded that because there were a limited number of essential uses, that those were applicable only for some Member States and that a monitoring programme was necessary to ensure no risk to human health or the environment of these uses were reasons enough to justify the 'non-approval' with essential uses.

Aldicarb remained on the market because there was no alternative to fight certain fungi on certain crops at the time of the risk assessment. And this, despite that Aldicarb was not considered safe.

The Aldicarb set a unique precedent in the EU law. This precedent was *de facto* formalized – this time with the formal blessing of the European Parliament and Member States – in the **new Plant Protection Products Regulation, PPPR (1107/2009)** and the **new Biocidal Products Regulations, BPR (528/2012)**, both referring to specific provisions about essentiality. This time, the substance would be approved because of its essentiality/need to the society.

In the PPR, the principle is that a substance that is not meeting the approval criteria may still be approved if necessary to control serious danger to plant health (art 4.7):

*'where on the basis of documented evidence included in the application an active substance is **necessary to control a serious danger to plant health** which cannot be contained by other available means including non-chemical methods*

such active substance may be approved for a limited period necessary to control that serious danger but not exceeding five years even if it does not satisfy the criteria set out in points 3.6.3, 3.6.4, 3.6.5 or 3.8.2 of Annex II, provided that the use of the active substance is subject to risk mitigation measures to ensure that exposure of humans and the environment is minimised. For such substances maximum residue levels shall be set in accordance with Regulation (EC) No 396/2005'

The BPR regulates the 'essential use' under art 5.2.c:

*'not approving the active substance would have a **disproportionate negative impact on society** when compared with the risk to human health, animal health or the environment arising from the use of the substance'.*

In the case of **pesticides**, the essentiality is based on resistance and the presence of alternatives within the same class of actives while as regards **biocides**, one might conclude that the derogation is based on a socio-economic assessment concluding that the substance is necessary or even more suitable than existing alternatives. What is interesting is that these derogations are valid when the substance is classified as CMR, ED, VPVB or PBT but not in case there is no hazard classification. This approach is in line with WTO rules since a pure hazard should not lead to ban without a proper risk assessment leading to an unacceptable risk.

The essentiality concept under **REACH** (which might have an impact on other sectorial legislation) should not mean that all substances are banned because of a hazard (is persistency alone a hazard?) and then approved for some uses just because they are essential.

Such an approach for the PFAS and in particular some of the sub-categories such as the Fluoropolymers or Perfluoropolyethers would be totally disproportionate given the lack of risk to the environment and public health and their importance in society.

A wrong policy/regulatory approach would lead the REACH Regulation to become another Plant Protection Regulation but with a much wider socio-economic impact.

Essentiality: in REACH of Consensus?

The Broad Restrictions Dilemma

Some will say that the REACH Restriction process has failed to improve human health, environmental protection and hence bring positive change to the society at large. **They would argue that substance-by-substance approach failed** to take into account 'regretful substitutes' for which there was less data or no data available at all at the time of banning the main compound.

It could therefore be assumed that by submitting a group restriction on PFAS, the 5 Member States would send a signal that the past approach was not satisfactory, disillusioned with the earlier restriction on PFOA or the (probably 'regretful') substitution of bisphenol A by bisphenol S in thermal paper.

Such **group restrictions require however substantial efforts** from authorities to gather and assess information, including on justification for grouping, uses and possible alternatives. It is also challenging in terms of defining properly the scope of the restriction. Enforceability might be questionable if at all realistic.

The **PFAS restriction expected proposal is so ambitious that necessary exemptions might very likely not be properly assessed**. Indeed, it requires a strong dialogue between all value chain players as a fluoropolymer or F-gas producers might not have all the relevant information about the essentiality of its product while the end user might not be aware of the importance of these chemicals. Information on use and exposure is often relatively general, and it is impossible to identify the exact uses and exposure patterns of the substance.

Member State Authorities and the European Commission seem to be inclined to simplify the restriction process by extending the generic approach to risk management (restrictions following the procedure of Article 68(2)). This means that the default assumption is that risks related to those uses cannot be controlled by the concerned actors, and hence there is no requirement for authorities to prove unacceptable risks, nor is there a requirement to submit a restriction dossier (Annex XV dossier). This would be seriously problematic as the burden of proof would be reversed, leading to a quasi-perpetual legal insecurity in the EU.

If the concept of 'essentiality' or essential use is construed in a negative manner (see previous section), namely that all uses are banned (default assumption) unless proven essential (i.e. necessary for health, safety or critical for the functioning of society and if there are no alternatives that are acceptable from the standpoint of environment and health), **it would then be an extreme interpretation of the precautionary principle.**

REACH already enshrines the use of a generic approach (i.e. assuming that the use constitutes a risk) for restricting certain carcinogenic, mutagenic or reprotoxic (CMR) substances in consumer products. But this procedure cannot CURRENTLY be used for other critical hazard classes including endocrine disruptors, **persistent**, bioaccumulative and toxic/very persistent and very bioaccumulative (PBT/vPvB) substances, immunotoxicants, neurotoxicants, respiratory sensitisers or substances that affect specific organs.

The lack of an adequate control of the risk and the demonstration that the ban of a substance will not lead to a disproportionate socio-economic impact must be established for every substance whether it is a polymerization aid, monomer if not an intermediate, a fluoropolymer or a F-Gas. Only if adequate control (risk assessment) and if the socio-economic analysis (quantitative approach) is not sufficiently clear, can a discussion on essentiality take place.

This is the essence of a positive approach to the concept of essentiality.

Is Performance the Essentiality?

Again, before there is any discussion on essentiality, **one must prove that there is a risk that cannot be adequately controlled**. Such control can and should take place at all levels of the value chain from the manufacturing of the chemical till the end of life of the product.

The **Montreal Protocol**, which phased out the use of ozone-depleting chloro-Fluorocarbons except for certain 'essential' uses, defined, for the first time, the concept of 'essential use' in Decision IV/25. In other words, and as indicated above an essential use is "necessary for health, safety or is critical for the functioning of society" **and** that "there are no available technically and economically feasible alternatives".

The discussions in ECHA on the broad Microplastics Restriction proposal also led SEAC to highlight that 'the cost-effectiveness of reducing microplastic emissions varies significantly depending on the sector/use as well as on the proposed measure (e.g. ban or technical means to reduce releases). In order to conclude if substitution of microplastics is proportionate or not, SEAC considers that the concept of 'essential use' could provide meaningful input to the decision-making process'. ECHA, for instance, concluded that In-Vitro Diagnostic products are important for the functioning of healthcare and thus can be considered as an 'essential use' of microplastics as there are currently no alternatives available.

Should we distinguish first the non-essential use? These uses would be related to a 'nice to have category'. These uses may relate more to consumer products but where there would be clear alternatives at a similar price. Very often, public media refer to PFAS when discussing cookware sets, ski waxes, cosmetic or textiles. As regards the latter, water & stain repellency, breathability could be considered as an essential performance requirement for the occupational protective clothing market (firemen, military, hospitals, high-tech sports equipment).

Fluorinated papers and board products might be considered non-essential but in some cases, these products are essential to provide repellency to oil, for instance for weeks to months (e.g. butter wrappers). A Long-time resistance/performance is key to ensure the product viability. Migration to food of whatever residual monomers, is regulated by the Food Contact Materials Regulation. A safe threshold is set. The concern is not about the essentiality but about the end of life -recycling need (or obligation) of plastics.

Fluoropolymers are used as coatings (Teflon, Viton) in catheters, stents and needles to reduce friction and improve clot resistance and to provide protein-resistance in tubing, O-rings, seals, and gaskets used in kidney dialysis machines and immunodiagnostic instruments. It is scientifically agreed that these fluoropolymers used into patients' bodies, does not pose an appreciable risk because they are not bioavailable. Are they essential, probably yes as they provide a serious benefit to society and public health. Should we address their disposal in the environment, definitely but through specific regulations such as the Waste EU legislation.

Without Fluoropolymer based Membranes large-scale chemical syntheses would not be possible (also reducing emissions of hazardous byproducts such as asbestos and mercury and therefore improving worker's safety). Moreover, in the case of the use as a proton exchange membrane (PEM) in fuel cells, the Nafion membranes are just essential and key for future green development within the automotive and energy sectors.

Clear essential uses given their contribution to society include the automotive industry, the semicons, green energy or telecommunications. These uses are far less mediatized whereas they are the ones that are really making the society to progress.

When performing an assessment on essentiality, the societal burden should not shift from the environment to public health....

The **conclusion** might be that the focus should be on the service the product should deliver (but which one: the fluoropolymer product, the molded product or the end-product, i.e. a car). The compound could therefore be evaluated for performance using the specifications required for the product but without excluding comparing an alternative to the PFAS in search to be replaced.

The above might be considered to assess essentiality but not outside a risk assessment and management approach where quantitative data are being used. An adequately controlled risk does not require that one reflects on whether the ultimate product is essential.

Essentiality but Not Outside an Objective Risk Management Approach

A discussion on whether a product is essential or not is a qualitative judgment, reason why the closing on non-essential places during Covid lockdowns was the result of a delicate and sometimes arbitrary decision.

If we would agree that only PFAS which are essential could be used, it would lead to the acceptance that PFAS are, by definition, problematic for the environment and/or public health and that they should be banned and assessed as group irrespective of the real risk posed and impact to the economy. If a dose is reduced, a manufacturing process improved, new protective equipment available or recycling guaranteed, should a product or substance be banned because they are not 'essential'? No!

The **REACH Regulation** (based on Article 114 TFEU, i.e. internal market) relies on an analytical, quantifiable and economic risk cost-benefit analysis and not to a more qualitative environmental or essential use test. Social and economic benefits of a restriction are to be considered but always in a very structured and quantifiable methodology. Depending on its interpretation, an essential use is not necessarily the same as an economic use. This explains why it is essential to define properly what is indeed essential and how the concept would be used and at what stage of the restriction process. Social considerations often require value-driven evaluations based on common normative perceptions (this is the role of the political level) cannot easily be quantified or objectively assessed by a regulator. Who would assess the essentiality? ECHA? Member States? The Commission when drafting its proposal

but without a democratic legitimacy? A scientific risk assessment or an economic cost-benefit analysis is measurable and subject to Courts scrutiny.

The **concept of substitution**, i.e. analysis of alternatives should remain. It would be an extreme interpretation of the precautionary principle to assess substitutes only for those uses which are essential but only temporally while the 'nice to have' category would fall automatically and the real essential one would remain untouched.

In short, if the **essential use approach goes beyond** analyzing the risk and economic cost-benefits to alternatives and include the societal value of the end-product to refine the assessment once adequate control and socio-economic considerations are finalized, then it may provide an added-value in case of borderline cases. Allowing or restricting substances solely based on just a qualitative judgment 'betterment of society' would go against legitimate principles such as non-discrimination and proportionality. Of course, WTO considerations would also have to be considered if not competitiveness of the EU industry.

The above means that essentiality has to be considered after the ECHA process came to an end and only if the risk is not adequately controlled and conclusions of the SEAC not sufficiently strong to avoid the restriction; that the Commission should conduct a specific public consultation (case-by-case approach) on those uses to be considered essential to not be restricted and that the decision be ratified by the REACH Committee.

Finally, the discussions on essentiality should also consider whether any alternative could be produced in time and sufficient quantity without having to rely on a very limited number of suppliers. EU industry should be protected from unreliable commercial partners.