PFAS and the Essential Use Concept
Audience Q&A

SK: Stephen Korzeniowski (ATCS & PFP); **JI:** Jenny Ivarsson (KemI); **AL:** Anna Lennquist (ChemSec); **JT:** Joel Tickner (UMass Lowell)

Industry Rep, Europe: Regarding a remark made by Anna Lennquist: Is a PFAS restriction possible on imported good in terms of WTO-rules?
JI: *Restrictions in REACH do in general also include imported articles so that will be the same for an up-coming broad restriction for PFAS. This is important since many of the articles that are consumed (e.g. textiles) are produced outside EU.*
AL: *In general restrictions should apply also to imported articles, so I definitely hope so. On the issue I think we have much in common with Cefic, while EU companies mainly are legally compliant, much problematic chemicals come via the imported articles, and this must be changed.*

Private consultant, Europe: Would one possibility be to link the "functioning of society" aspect from the Montreal Protocol with the "critical sectors/professions" definitions that both on EU-level and by the Member States have been defined and include, next to the obvious health sector, also ICT, transport or energy, for example?
SK: *First and foremost, we will need to agree on a definition of essential use (aside from the Montreal Protocol) along with specific criteria and guiding principles in how to effectively employ this concept; if at all.*
JI: *The concept essential uses must be clarified. The definition in the Montreal Protocol could be used as a starting point.*
AL: *It's an interesting idea and we need to learn as much as possible from the implementation of the Montreal protocol. Crucial through is that whatever is defined: uses, products or sectors – it should be narrow and specific.*

Industry Rep, Europe: The Montreal Protocol focuses on one purpose to control specific substances that deplete the ozone layer. Therefore, using the same approach for a broad and chemically diverse overall PFAS group of compounds seems problematic.
SK: *Please see the answer above.*
JI: *As stated in the elements for an EU-strategy for PFAS that was sent to the Commission by several Member States in December 2019 there are several reasons why PFAS should be assessed and managed as a group:*
a) Regulating individual substances or arrowhead substances (subgroups) will take too long to effectively manage the risk from these substances.
b) All PFAS, in themselves or their degradation products, are extremely stable in the environment.
c) Some PFAS have documented toxicity. With the present knowledge, and based on similarities between PFAS, concerns are raised for the whole group.
d) Human and environmental exposure to many PFAS occur and combination effects can be expected.
e) A group approach is needed to avoid regrettable substitution. PFAS that are regulated are often replaced by similar, but not yet regulated, PFAS.
AL: *While the group is broad and diverse, it is united by the property extreme persistence. One could also focus on this property instead, and apply the concept to all chemicals sharing extreme persistence.*
JT: *An option here may be to within a class of chemicals look at those functions that pose the greatest potential for exposure/impact and then prioritize those for consideration of essentiality based on function. Schemes to prioritize using some objective criteria can help to "test" the concept with a more targeted sub-group of PFAS chemicals as was the case of CFCs.*

Industry Rep, Europe: Also the concept of essential use raises many unanswered questions: Which objective parameters should be considered to assess essentiality of a chemical use in practice? Can we limit "essentiality" only to health and safety aspects? Whether to include a time dimension in judging the essentiality of use? What European authorities determine as being essential may not be assessed as being so in other regions of the world, and vice-versa.
SK: *Please see answer above. Some principles to consider are: substance needs to be able to deliver critical functionality required; consider regional and sub-populations; availability of alternatives providing equivalent functionality; socioeconomic impact considerations; safety and efficacy of alternatives; consider production asset impact and capability if withdrawn; be enforceable*
JI: *Important question, and this needs to be discussed further.*
AL: *Yes, here we can expect tough negotiations as this need to be defined.*
JT: *Functionality is a key consideration which can be debated but is generally implementable by governments. By defining essentiality in terms of functionality, it may be possible to define more "objective" criteria for defining essential uses. Trying to develop a generic approach that can be applied to multiple chemical classes/applications may help. Societal needs tend to be defined by legislative bodies.*

Fluorochemical Industry, Global: Uses can become essential over time e.g. mobile phones as a gadget in the beginning but now as an emergency tool. How does that fit the concept that was presented?

JI: *Or the other way around. Essential uses should be assessed with regard to the availability of alternatives on a regular basis to ensure future replacement and phasing out of PFAS. Thus, essential uses that have been agreed upon should be regularly reviewed to ensure that alternatives are developed.*
AL: *It is proposed that essentiality should be re-evaluated over time, so this would cover this aspect I think?*
JT: *As Steve pointed out, these chemistries were made for their functionality and not their essentiality. The question then is how to think about functional needs and be more nuanced with "fit for purpose" functionality and having regular processes to update as knowledge or technology evolves. For example, fuel types have changed over time which changes the essential function of AFFF for many fires.*

Academic, Europe: regarding the topic of regulating PFAS as a group: do we necessarily see PFAS as 1 group or is there also a discussion on regulating them in smaller subgroups of more similar properties?
SK: *PFAS have one thing in common – C-F bond and in most cases they are persistent. That said – PFAS need to be discussed in clear, specific and descriptive terms and clearly not as one group. There are very significant property and physiochemical differences that make this 'group as one' scientifically unsound.*
JI: *See answer to question three above.*

Regulator, Europe: if a substance use is identified as essential, what does that mean for regulation? 1. Does this mean we should just ban all non-essential uses without assessing the impacts? or 2. does it mean we should derogate essential uses without assessing the impacts of not regulating them? To me it seems the concept is differently interpreted at the moment and its implications need to be clarified, otherwise I don't see that it can be useful for regulating PFAS.
AL: *It remains to be discussed and defined I believe, although I would favor no 1, which is more similar to the pheaseout of SVHCs, as I read it.*
JT: *It seems that there needs to be transparent, consistent and clear regulatory processes to determine this. If "essential" this should be linked to R&D to identify potential alternatives, if indeed a class-based approach is being taken.*

Anonymous: Have PFAS been classified as carcinogenic substances to human based on some evidences in human organs?
JI: *Increased risk for cancer has been associated with exposure to certain PFAS. Other health effects in humans are increased cholesterol levels, impact on infant birth weights, effects on the immune system and thyroid hormone disruption. Data are available for some PFAS, however based on similarities between PFAS, concerns are raised for the whole group.*
AL: *Some PFAS are officially classified for being potentially carcinogenic, such as PFOA. Much of the legal case against DuPont in the US was also about different forms of cancer having affected the workers.*

Research institute, Europe: Where do you see the comparative advantage(s) of using the concept of essential use compared to the existig procedures?
SK: *Until this concept is better defined with bona fide criteria for its use and tested in real life scenarios, I am not sure we can say this will be an 'advantaged' concept.*
JI: *This is something we are discussing at KEMI.*
AL: *It places (or should ideally place) the burden of proof on industry to show that specific uses are essential, rather than having authorites needing to prove the problems with seach pecific PFAS in each specific uses.*
JT: *It allows addressing a broader range of chemistries rather than the one chemical at a time approach by focusing on the functionality and need for the substance rather than assessing the risk of each one individually an debating risk management measures.*

Research institute, Europe: How can in your opinion key terms such as 'necessary', 'critical' and 'feasible' be defined?
SK: *It all starts with what function a product provides, what is the benefit of that function, are there alternatives to the product that perform as well, is it an enabling technology that provides unique benefits. The key terms you note often evolve over time as consumers and industries use these products and fully understand their unique benefits.*
JI: *This is something we are discussing at KEMI.*
JT: *There would need to be clear, transparent government processes to define these terms and their application so that their use in decision-making is consistent and objective and defensible. Governments define such terms regularly. Ideally this would be done in the context of the new chemicals strategy.*

Public Relations, Europe: What European authorities determine as being essential may not be assessed as being so in other regions of the world, and vice-versa. How do we ensure a harmonized approach?
JI: *Important question, we need to discuss this at an EU-level, but also globally.*
JT: *This is a difficult question as few policy thresholds are globally harmonized. Yet, this is important for industry and critical to leveling the playing field globally. Ideally, discussion would happen for example in the OECD context around PFAS but this concept should be defined beyond PFAS.*

Anonymous: A question to Stephen: do you consider PFAS in food packaging as an essential use?
SK: *First, we have not agreed on a definition of essential use and the criteria needed to apply it in the commercial marketplace. While the Montreal Protocol exists for Ozone Depleting substances, it is not clear those concepts apply here. As noted in the webinar, the marketplace and consumers make buying choices. And we all recognize*

that many paper product uses are being phased out where substitutes have been found to be functional. And we expect that trend to continue.

Public Affairs consultant: What about uses of PFAS as precursors, would the essentiality criterion be based on precursor function or on end use of the product, what do Chemsec and Kemi think?
JI: *Important question, I guess both should be considered.*
AL: *Good question, in general intermediates are exempted from REACH authorization and the end product is considered. Then the problem could instead be for workers health and also accidental releases, what needs to be covered by additional regulation. I do not know right now if PFAS precursors are used to produce non-PFAS chemicals or products?*

Academic, Europe: Do you think that economic disincentivizing would effectively reduce the consumption of non-essential PFAS products, or is regulation more important?
JI: *In general regulation is a strong driver for phasing out hazardous substances. But this could be complemented with other measurements.*
AL: *Regulation seem to be the strongest driver in most cases, but other tools, such as what you propose could definitely be considered to pave the way.*
JT: *Both are important, particularly support for substitution to safer alternatives which has been suggested as part of the Chemicals Strategy.*

Government, Europe: Soon the new European Chemical Strategy will be presented and it is currently in the hot phase. There´s a lot of discussion on whether to use a grouping approach or looking at each chemical on its own. In the current system we need a lot of time to regulate and ban/restrict different substances. What would the panelists propose to speed up the process?
SK: *Given the significant diversity of the compounds in the PFAS group, efforts should be made to find logical small groups of PFAS compounds that make sense to assess as a small group. Assessing as one makes no sense given the huge differences in properties and physiochemical behavior. And some maintain that the actual number of compounds in actual commerce is in the hundreds not the thousands.*
JI: *I believe a big step to speed up the process is a REACH restriction with a broad group approach.*
AL: *It is clear we need to move towards more and more groupwise restrictions.*
JT: *We need new approaches that can address multiple chemicals at a time. Grouping by function and class offers an overlapping approach where one could look at particular functions – such as solvency – and then identify the safest and less safe options for that.*

Academic, Europe: If nobody knows the uses of PFAS (or any chemicals) how can producers do a responsible risk assessment? Doesn't that situation require that we do hazard-based assessment instead?
SK: *The large majority of PFAS products in commerce have known uses. Therefore for the majority of major end-uses, a classic risk assessment should be possible.*
JI: *They should demand information from their supplier. There is a need for better sharing of information on PFAS and other chemicals throughout the value chain.*
AL: *I definitely agree. Also some parts of industry has claimed for ages that they act responsibly and take measures based on risk assessment. But still we find these chemicals in all of us and in the environment, so something obviously this do not work.*
JT: *There is a clear need in product stewardship to understand where chemicals are being used and ending up through their lifecycles. For most chemistries this has not happened and should occur. You can't manage what you can't measure is a typical saying in pollution prevention.*

Law firm, Global: Several panelists suggest that the essential use concept should be applied to all PFAS because they all present the same risk concerns – primarily persistence. But the data show very different toxicity profiles – with some PFAS chemistries being essentially non-toxic. Why should these essentially non-toxic chemistries be eliminated simply because they don't satisfy someone's definition of what's essential -- particularly if emissions from their production are adequately controlled?
JI: *KEMI sees many reasons why PFAS should be handled on a group level:*
1. All PFAS, in themselves or their degradation products, are extremely stable in the environment.
2. Many are mobile in the environment which can pose a problem for the groundwater and drinking water supplies.
3. Some PFAS have been documented as toxic and bioaccumulative substances. With the present knowledge, and based on similarities between PFAS, concerns are raised for the whole group.
4. Human and environmental exposure to many PFAS occur and combination effects can be expected.
AL: *The idea to act strongly on persistence alone would cover both toxicity that has not yet been discovered – as many of these chemicals are not well studied, and also the constant build-up in environment and biota to toxic levels, even if toxicity is low. Simply, persistent chemicals cannot be "regretted", we need to live with them.*

Academic, Europe: What does the host and panelist think of these two phrasings? "In the draft text for the EU chemical strategy for sustainability, it was stated (and I am paraphrasing here, based on leaked documents to ChemWatch not direct quotes) that "substances of concern" should be avoided for "non-essential societal uses". DG Grow, who represent SMEs and innovation, requested to rephrase "substances of concern" to "SVHC" (which is defined under REACH) and "avoided for non-essential societal uses" to "avoid for uses where alternatives are technologically or economically feasible".

SK: *Good questions. However, EU regulations (REACH) do not have an agreed to Essential Use definition. Nor are there well-defined and agreed-to criteria and/or guiding principles to apply the concept.*
AL: *I do see a need for the term "essential use" as the terminology "technologically and economically feasible" has been so terrible misused, also because nobody but industry could claim to know what is technologically and economically feasible. Essential could be defined and agreed by a broader set of stakeholders.*

Academic, Europe: Is there a basis for classifying and regulating PFAS by taking into account their transformation end-products and persistence? (e.g. long-chained vs short-chained)
JI: *When now working on a proposal for a broad PFAS restriction we are considering both the precursors and their persistent end products.*

Academic, Europe: If we go into essiential use of PFAS, would the prodfucts we still want to use noy become very expansive because the prices are low due to the current bulk production. At the end the essential products would maybe not be available anymore."
SK: *This notion is the reason we and others suggest doing a socio-economic analysis, among other analyses) when alternatives are assessed.*
AL: *Along with identifying something as essential for society it might also be needed with measures to assure continuous supply beyond market forces.*
JT: *PFAS chemistry is relatively expensive and used for its functionality. Reducing bulk production hence may or may not impact the marginal price of essential uses.*

Contract Research Organization, Europe: Essential use concept as you mentioned I think should not be applied to PFAS as a whole group by default. But essential use as a concept to decide on REACH restriction and/or authorisation for similar use PFAS, is that an option?
SK: *Please see answers above. Need to define and need criteria/guiding principles to begin using this essentiality concept.*
JI: *This is something we are discussing at KEMI.*
AL: *I think so, yes.*

Research institute, Europe: Joel and Steve, in your opinion, what are the minimum criteria to define essential use? To make the Montreal criteria less vague?
SK: *Great question. There is no magic to number of criteria. However, we suggest that a proper risk evaluation be carried out according to REACH requirements and then be assessed based on the criteria (among others) noted in the response to Nicolas R. above. This assumes that an agreed to definition has been developed for Essential Use/Essentiality.*
JT: *This is a good question. I would think this should at a minimum describe some functionality that is needed and cannot be achieved via other chemical or technical needs. How necessary functionality is defined would have to be thought through more. We need to go from broad concept here to more specific language that can be applied consistency in a policy environment and reviewable by courts which is no easy matter.*

Academic, Europe: How do you even approach the regulation of products that contain PFAs and in which quantities the PFAs would persist in the case of recycling/reuse in a circular economy? a) to avoid contamination to other recycled products, b) to reuse PFAs products so that they are not produced again, introducing more PFAs into the environment.
JI: *I believe a broad PFAS restriction (as well as other REACH restrictions and tough chemical regulations) are crucial to achieve a circular economy. It is important to think non-toxic in the beginning, at the design phase. KEMI's view is that products containing SVHC should not be recycled.*

Government, Europe: Agree with Jenny, PFAS group restriction at the moment is already speeding up the process!!
SK: *Many do not agree with a group approach as the PFAS category has many diverse compounds with very different properties spanning solids, liquids and gases. Many would argue expediency in science assessments should be carried out with an abundance of caution as speed often does not produce a scientifically sound outcome.*

Anonymous: is there any standardized method for monitoring total PFAS's concentration?
SK: *As noted in EEB Webinar #4, there are methods available for a number of PFAS (i.e. 25-75) in a variety of matrices. However, there is no single general method for broad quantification and speciation.*

Contract Research Organization, Europe: We need to avoid the thousands of PFAS that according to Steve do not need risk assessment yet to become also high production volume chemicals with diffuse emission as a consequence and accumulation in man and the environment and potential risk before we start to act. Precautionary principle based on P and T criteria next to essential use should be important leading principle here.
SK: *It should be noted that what was said in the webinar is that risk assessment can be carried out on a smaller number of PFAS as the 4730 represents a list of CAS numbers from 2018, not a list of current compounds in commerce. And that risk assessments considering hazard and exposure, in some form, do need to be carried out.*
AL: *Very true – we must avoid regrettable substitution, which has already proven to have happened for PFAS.*

Academic, US. Would industry agree that PFAS are important enough problem to mandate their customers through the supply chain to indicate which chemicals or class of PFAS chemicals are in any given product?
SK: *It can be argued that most primary uses of PFAS categories are well known as well as which Class of PFAS chemical is likely used: Perfluoro, Polyfluoro, Fluoropolymer, Perfluoropolyether and Side-chain polymer. Many publications including one that is due out any day address the Uses for the various PFAS compounds. It was also*

noted in our webinar, that this upcoming Uses paper has no industry representatives on its author line and that maybe a mutual conversation between all parties would be beneficial.