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3M Key Considerations on PFAS

3M understands that the European authorities are concerned by the presence of PFAS in the environment due to their persistent character, and that they wish to address this concern. 3M would like to point out that Persistence is what enables durability and high performance of applications of high societal value and contributes to the European Green Deal goals such as circular economy and fight against climate change. It is thus essential to allow the use of persistent chemicals while minimizing their potential impact on human health and the environment. As a company committed to innovation and sustainable development, 3M supports clear and proportionate regulations based on sound science.

In light of the upcoming REACH Annex XV Restriction on PFAS, signaled by the Netherlands, Germany, Sweden, Denmark and Norway, as well as the upcoming PFAS Action Plan under the Sustainable Chemicals Strategy prepared by the European Commission, 3M would like to contribute to the debate by outlining some elements below:

- A restriction under REACH (Article 68) requires demonstration by the authorities that the substances involved present an unacceptable risk to human health and the environment and the burden of proof of that demonstration is on the authorities. 3M believes that Persistence (P) on its own is not enough to assess or demonstrate an unacceptable risk to human health and environment and therefore to ban or restrict substances being manufactured, imported or used in products. An overly narrow regulatory focus on Persistence only will undermine innovation to produce durable and high performing materials that may support societal sustainability goals. As regards other potential effects on human health or the environment, if any, they need to be determined on the basis of state of the art, generally agreed scientific principles, which requires substance specific determinations.

- Furthermore, 3M is concerned that the Commission and the REACH Competent Authorities may be seeking to adopt a very broad regulatory action that would restrict all PFAS under a very broad definition. Trying to restrict PFAS as one group of +/- 4700 substances with different chemical structure (e.g. polymeric versus non-polymeric, perfluorinated versus polyfluorinated, reactive versus non-reactive etc.) and physico-chemical properties (e.g. gas versus liquids versus solid, hazardous versus non-hazardous etc.) is not scientifically appropriate.

- High molecular weight fluoropolymers, for example, are a class by themselves. They are to be considered according to the OECD assessment criteria[1] as 'polymers of low concern (PLC)' meaning being of low hazard to human health and environment, and therefore to be separated from the other PFAS for hazard assessment or regulatory purposes.[2] Consequently, high molecular weight fluoropolymers should not fall under the scope of the REACH restriction currently under consideration.

- Lastly, applying the essential/non-essential use concept should allow the continuous use of substances presenting a demonstrated unacceptable risk to health or the environment.

[1] e.g. high molecular weight, low residual monomers, low molecular weight leachables, low water solubility (very limited long-range transport), high stability, etc.

[2] ref. Henry, B. J., et al: 'A critical review of the application of polymer of low concern and regulatory criteria to fluoropolymers' (2018).

- Article 68 of REACH requires authorities when adopting a restriction for substances posing an unacceptable risk to take due account of the socio-economic impact of the restriction, including the availability of alternatives. This is the legal framework that needs to be applied. Applying the essential/non-essential use concept in the absence of a demonstrated unacceptable risk would mean that products would be banned on the basis of unnecessarily intrusive judgements of what is good or bad for society, which is by nature relative and must remain evolutionary.

- Further use should be allowed when the benefits to society, including socio-economic benefits, exceed the demonstrated risks, and for which there are no equally performing, technically and economically feasible alternatives available, also from a life cycle assessment point of view. Any restriction should be very carefully considered and regrettable substitution avoided.

- When considering essential uses of those PFAS that are demonstrated to cause an unacceptable concern, authorities should also apply the following criteria:

    - The standard or review of alternatives or substitutes from the standpoint of environment and health must be the same as the standard applied to the substance considered to be substituted.
    - Essential uses must be authorized until technically and economically suitable alternatives become available with also due consideration of the time required for companies to adapt their products and have such adapted products validated under applicable regulatory regimes.

The majority of PFAS uses today are in applications of high societal value and part of our modern life i.e. electronics, cars, airplanes, solar panels, imaging, surgical drapes and medical devices, medicines, buildings, and many others. 3M-manufactured PFAS products are used in many critical mainly industrial applications where they present significant socio-economic benefits and have no technically and economically feasible alternatives equally performing.

3M will be submitting more detailed information during the current Call for Evidence supporting an analysis of restriction options for PFAS and would like to remain an active contributor in the upcoming policy discussions and regulatory developments on this topic.

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