

VdMi statement on the REACH restriction project for polyfluoroalkyl substances (PFAS)

On 7 February 2023, ECHA published a restriction proposal in accordance with Annex XV of the REACH Regulation, based on the proposal of 5 Member States (Denmark, Germany, Netherlands, Norway, Sweden). VdMi fully supports efforts to minimize the impact of hazardous substances on human health and the environment. However, the current restriction project goes far beyond that.

The current restriction proposal for polyfluoroalkyl substances (PFAS) is based on a revised OECD definition from 2021^[1]. **The OECD itself states in the document that this definition is not suitable for regulatory purposes.**

The definition used for PFAS covers several thousand different fluorinated substances, polymeric and non-polymeric substances. PFAS are therefore defined as fluorinated substances that contain at least one fully fluorinated methyl or methylene carbon atom (without an H/Cl/Br/I atom attached to it). By applying this definition to the restriction, with a few exceptions, any chemical containing at least one perfluorinated methyl group (-CF₃) or one perfluorinated methylene group (-CF₂-) is a PFAS. **We reject this too general and not very scientific definition.**

The term "PFAS" does not indicate whether a substance is persistent, mobile, or toxic, it only conveys that the substances have similar structural features. **In general, it is not possible to draw conclusions about the toxicological or ecotoxicological properties from the structure.**

We would like to point out that the used definition of PFAS, which is based only on molecular structure, classifies various substances as PFAS based on assumptions, simplifications and extrapolations, even though they do not have the environmental and toxicological characteristics on which the restriction focuses.

Furthermore, an unacceptable risk to human health or the environment is necessary for a restriction within the REACH regulation. This risk cannot be derived from a structural feature, it needs a deeper analysis. Such an evaluation can be carried out for individual substances or for small groups of substances, but not for such an extensive group of substances as PFAS, as currently defined in the EU Commission's proposal.

In the United States, there is already a restriction on PFAS, but individual substances are banned, no general ban is imposed. In addition, in some U.S. states, drinking water is tested for PFAS, whereby appropriate limit values must be observed. The definition of PFAS chosen is more precise and not as broad as the current definition of the EU Commission.

^[1] Organization for Economic Co-operation and Development (OECD). 2021. Reconciling Terminology of the Universe of Per- and Polyfluoroalkyl Substances: Recommendations and Practical Guidance. Series on Risk Management No. 61.

We can understand that the EU Commission wants to avoid the replacement of PFAS through so-called "regrettable substitutions". Nevertheless, we do not see the demonization of an entire group of substances as the right way. A more precise restriction, which does not cover all PFAS, should be limited only to the detected substances with PBT, vPvB, PMT and vPvM properties as well as toxic properties.

Some colorants (organic pigments and dyes) containing an aromatic CF_3 group are non-toxic, non-bioavailable, non-water-soluble, and therefore do not meet the PBT, vPvB, PMT, and vPvM criteria. The dossiers on REACH registration on the dissemination platform accessible to the EU Commission show that these colorants have no significant impact on the environment and human health.

In the confidential section, we have indicated the corresponding colorants registered under REACH.

Colorants that are imported or manufactured in Europe more than 1 ton/year are REACH-registered. Their physical, toxicological and ecotoxicological properties are very well documented. These colorants are non-toxic, non-bioavailable, non-water-soluble, and therefore do not meet PBT, vPvB, PMT, and vPvM criteria. In contrast to the applications in focus, such as oil and water repellence, temperature and chemical resistance, and surfactant properties, colorants and their raw materials have uses and applications that are not the focus of the restriction.

Colorants with an aromatically bound CF_3 -group have unique colour properties, properties that are very important in certain applications and cannot be replaced. This CF_3 -group is essential for maintaining these coloristic characteristics.

Because of colorants have significantly different properties, **we urgently call for an exemption from the restriction for the colorants sector** to avoid an unnecessary restriction of colorants in question and an interruption in many supply chains.

The EU proposal for restrictions aims at a complete ban on PFAS as defined by the EU in various applications, with exemptions granted for certain uses.

We consider the use of the new Essential Use concept to be very critical. First, there is too much general restriction for substances, followed by temporary exemptions. **The Essential Use concept should only be used as an option, if at all, and should not be used as the main trigger for regulatory decisions.**

The restriction of PFAS is also a major problem for production facilities in the European Union. In almost all high-tech industrial plants. PFAS can be found in the form of seals, pipes, reactor linings, valves or membranes. Fluorinated polymers are the safest materials for handling corrosive media and are the global industry standard. Without these substances, the safe production of many products would no longer be possible. Such a ban would also affect the manufacture of downstream products and commodities, as they could be intermediate products or essential components. For this reason, the restriction of all PFAS not only has a direct negative impact on the European economy, but also an indirect impact on the production of a variety of other substances. **Both effects, direct and indirect effects, must be considered in the restriction proposal, otherwise there is a risk of serious damage to the economy.**

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The Verband der Mineralfarbenindustrie e. V. represents German manufacturers of inorganic (e. g. titanium dioxide, iron oxides), organic and metallic pigments, fillers (e. g. silica), carbon black, ceramic and glass colours, food colourants, artists' and school paints, masterbatches and products for applied photocatalysis.

The VdMi is listed in the Lobbying Register for the Representation of Special Interests vis-à-vis the German Bundestag and the Federal Government (Lobbyregister des Deutschen Bundestags, number R000760) as well as in the Transparency Register of the EU Commission (number 388728111714-79).