EXECUTIVE SUMMARY

Merck calls on the European Union to develop a balanced approach to the regulation of Per- and Polyfluoroalkyl substances (PFAS) that safeguards the environment while keeping the internal market of the EU a strong, resilient economy with a competitive industry.

Merck is a global company with its headquarters and roots in Europe. Established in 1668, our ambition is to become the global 21st century science and technology pioneer – and we are uniquely positioned to do so, thanks to our three diverse and **distinct sectors: Life Science, Healthcare, and Electronics.**

Merck is strongly committed to the European Union and supports the goals of the European Green Deal. To find the best strategy for a digital and sustainable future, politicians, authorities, and industries must work together and stay in constant dialogue. **We want to be part of this dialogue and contribute to the best possible solution.** The EU needs **a holistic approach to secure its resilience and competitiveness**, avoid supply chain disruptions and safeguard its strategic autonomy. The **proposal to ban virtually all PFAS in the EU** threatens to jeopardize this.

PFAS have several unique properties that make them very useful yet also difficult to replace with more sustainable solutions. At the same time, very persistent PFAS may lead to adverse effects for the environment and humans. We therefore support the search for substitutes for PFAS and conduct active research ourselves. Yet, we do not know whether alternatives with the same technical properties can be found in 5, 10 or 20 years from now or if a different technology is required.

Our three business sectors – Life Science, Healthcare and Electronics – are critical for society in different ways: From providing products and services that accelerate drug development and manufacturing as well as discovering unique ways to treat the most challenging diseases to enabling the intelligence of devices. Each business sector will therefore provide detailed, data-based, and substantiated input for applications where the use of PFAS is currently and in the near future without alternative to maintain the function and the purpose of specific critical products.

- **PFAS are critical for the European health systems, in drug and vaccine production and development** as well as other fields in life sciences. As a result, they enable innovation for a better life of mankind. Merck products are used by thousands of European companies in the pharmaceutical, medical device and biotechnology industry. This makes the availability of medicines and medical devices in the EU more independent from global supply chains and hereby increases our resilience and preparedness for the next public health emergency. Even if a more sustainable alternative with the same properties will be found,

substituting a material or substance from these uses often takes several years, due to regulatory approvals or quality management needs.

- **The draft restriction proposal recommends exemptions for Active Pharmaceutical Ingredients (APIs) – but not for pharmaceutical formulations, manufacturing or the necessary supply chain and packaging.** Not addressing PFAS materials in the entire value chain is a general problem in all exemptions or derogations within this proposal. Here, it would ban e.g., precursors, processing aids as well as production equipment, such as filters and primary packaging, which are all necessary to provide patients with much-needed medications. For regulated products, re-submissions and approvals must be regarded as well: On top of the time needed to find a substitute, it usually takes 5-10 years if sufficient resources are available on submitter and authority side. Ultimately, companies would be forced to stop producing and supplying important drugs in Europe. The same applies to the development of future treatments.

- **The initial proposal suggested a limited derogation for the use of PFA substances in the semiconductor industry** – however, the very complex production of chips is currently impossible without PFAS. For several applications (e.g., photolithography, plasma etching, wafer cleaning), a replacement that has the same technical properties would be very difficult or impossible to find. Either way, it would require a significant amount of time and in some cases even a completely new technology. Meanwhile, the EU Chips Act ambition to increase the EU's share of the global semiconductor production from 10% to 20% by 2030 cannot be achieved if semiconductor manufacturers can no longer manufacture, import and use key materials in the EU. A ban, including an import-ban, therefore threatens long-term investments in the region.

Merck supports the ambition for a smart and targeted PFAS regulation. Notwithstanding, **in its current form, the PFAS restriction proposal threatens the resilience of supply chains in several critical sectors and with that the competitiveness of the European Union** in a complex geopolitical environment. It also contradicts other European policies and legislative proposals aiming at increasing European competitiveness such as the EU Chips Act, the Net Zero Industry Act and the Green Deal Industrial Plan.

We therefore require smart derogations that

1. **include the complete value chains necessary for the production of critical products,**
2. **take into account regulatory timelines,**
3. **and with a review at the end of derogation periods to cover applications for which – despite best efforts – no alternatives could be found within the given timeframe.**