

26 October 2023

Mona Blomdin Persson

Head of Department – Development of legislation and other policy instruments
Swedish Chemicals Agency, Sweden

Dear Ms Blomdin Persson,

I am writing on behalf of Bio-Rad Laboratories to request a meeting to discuss the proposed restriction of per- and polyfluoroalkyl substances (PFAS) in Europe. Our concerns stem from the fact that our products and use-cases, particularly analytical laboratory devices serving the Life Sciences industry, due to their innovative nature, are not adequately represented by any industry body.

There are currently tens of thousands of devices in Europe, providing vital services to life science and translational research, pharmaceutical and biopharmaceutical, metrology, medical diagnostic, environmental and food safety sectors.

These technologies play a predominant role as decision-making tools for patient care in cancer and other human health conditions, quality control devices to ensure the safety and efficacy of gene therapies and biologics, critical surveillance tools in the pursuit of public safety from infectious diseases and pandemics, and as gold standards in the field of metrology.

Bio-Rad has submitted a consultation response to the ECHA consultation. However, due to the unique approach taken by some of Bio-Rad's technologies, there are no ECHA accredited stakeholder organisations in the life sciences sector able to support ECHA's work on the proposed restriction and how it impacts these devices. This could lead to a lack of clarity about use cases similar to those employed by Bio-Rad products, which are integral to advanced laboratory analytics throughout Europe.

Bio-Rad Laboratories stands as a global frontrunner in developing, manufacturing, and marketing a diverse array of innovative products tailored for the life science research and clinical diagnostics markets. Notably, there are analytical laboratory devices across Europe in academic research institutions, university hospitals, and a spectrum of labs in the pharmaceutical and biopharmaceutical sectors.

It's crucial to note that Bio-Rad laboratory equipment and reagents aren't consumer products, but specialized tools wielded by highly trained professionals in research and diagnostic laboratories. Given the intricate engineering and sophistication of some of our platforms, they contain limited quantities of compounds that fall under the broad PFAS category in the restriction proposal. We firmly believe that under the proposed restriction, Bio-Rad's use cases don't align with any of the identified primary applications and sub-uses.

Further, given the limited presence and niche role of PFAS in the Bio-Rad products, the transition to viable alternatives requires balancing technical performance with financial and logistic considerations. Our comprehensive strategy for this transition is already underway. We are seeking support for a derogation that will allow for the necessary time to identify design replacements and validate the performance of these redesigns to ensure the consistency of our product performance.

Our commitment to minimizing our reliance on PFAS chemicals is unwavering. Yet, the looming restriction, if enforced without considering a derogation for such products, threatens to disrupt the operations of all labs in Europe that rely on our systems.

Therefore, Carolyn Reifsnnyder, Senior Director of Global Product Marketing at Bio-Rad, who has over 15 years of experience in the life sciences industry, would welcome the opportunity to meet with you and discuss the company's use of PFAS and possible solutions for a transition period.

We would be delighted if you or someone in your office could take the time to meet Mrs. Reifsnnyder either in person or online.

Thank you and we very much look forward to your response.

Best regards,

Simon May, Ph.D.
EVP & President, Life Sciences Group
Bio-Rad Laboratories, Inc.
2000, Alfred Nobel Drive
Hercules, CA 94547

TEL: [REDACTED]
[REDACTED]@bio-rad.com

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