					P46 (E54); P47 (E55)	
	Vedhæftninger					
		VS Prep-call EFCTC webinar on PFAS & F-gases.eml				UNDTAGES
		2023 05 16_ PFAS webinar AGENDA.pdf				UNDTAGES
		2023 05 16_EFCTC WEBINAR QUESTIONS.docx				UNDTAGES
9704426	19-03-2024 22:54:45	VS: Request for Meeting: Implications of ECHA REACH Proposal on PFAS as Medical Propellants in Metered Dose Inhalers (MDIs)	364	2	DE (E1); (E1); P4 P5 (E6); ' P2 ' (E3); Peter Juhl Nielsen; Ida Svostrup Petersen	
	Vedhæftninger					
		VS Request for Meeting Implications of ECHA REACH Proposal on PFAS as Medical Propellants in Metered Dose Inhalers (MDIs).eml				
		IPAC IPAC-RS ECHA REACH Feedback FINAL Submission 20 September 2023.docx				
5860514	13-09-2022 08:31:02	WG: ChemSec - PFAS Restriction	110	1	Toke Winther; Tialda (E56)	UNDTAGES
	Vedhæftninger					
		WG ChemSec - PFAS Restriction.eml				
8403682	21-09-2023 08:43:36	WG: Fluoropolymers Product Group (FPG) has launched a new Manufacturing Programme for European manufacturing sites.	309	3	Sehbar Khalaf	
	Vedhæftninger					
		WG Fluoropolymers Product Group (FPG) has launched a new Manufacturing Programme for European manufacturing sites..eml				UNDTAGES
		FPG Manufacturing Programme for European Manufacturing sites - Final - September 2023.pdf				
		Letter to the 5 Competent authorities.docx				UNDTAGES
7332916	19-04-2023 17:13:58	WG: INFO_PFAS: Meeting DG ENV senior management on the PFAS proposal	158	1	P4 P5 (E6)	UNDTAGES
	Vedhæftninger					
		WG INFO_PFAS Meeting DG ENV senior management on the PFAS proposal.eml				

 # = antal relaterede dokumenter.

Miljøministeriet
Miljøstyrelsen

Den 12. juli 2024

Aktdetaljer

Akttitel: Bio-Rad question on PFAS restriction dossier and life-sciences analytical equipment
Aktnummer: 286
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Dokumenter:	• [1] Bio-Rad question on PFAS restriction dossier and life-sciences analytical equipment.eml (MEDTAGES IKKE) • [2] Bio-Rad Summary of Inquiry MST.pdf

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30 August 2023

Sandi Muncrief
Head of the Chemicals and Biocides Unit
Environmental Protection Agency
Denmark

Dear Ms Muncrief,

I am writing on behalf of Bio-Rad Laboratories[1] regarding the ongoing public consultation on the proposed restriction of per- and polyfluoroalkyl substances (PFAS) in Europe[2], on which the Danish EPA was a submitting authority.

Bio-Rad will be submitting a consultation response to the ECHA consultation and, in preparation, would like to ask for additional clarification on the categorisation of life science research and analytical laboratory devices in Bio-Rad's product portfolio, which are often critical to public health and related services across Europe.

Due to the sophistication and engineering requirements of some of our platforms, Bio-Rad products include limited quantities of compounds (fluorinated liquids) that qualify under the broad category of PFAS in the restriction proposal. In our interpretation of the proposed restriction, Bio-Rad's use cases, for devices in life sciences and public health domains that do not fall under IVD registered devices[3], do not conform to any of the identified main applications and sub-uses.

The specific PFAS provided by Bio-Rad are used for laboratory equipment functions. Notably, these products are not consumer products in design and are utilized by highly trained users in research and diagnostic laboratories, which themselves possess a level of sophistication in handling and disposing of chemically sensitive materials in accordance with local regulations.

Bio-Rad's non-IVD (Research Use Only - RUO) laboratory equipment consists of tools for the separation, amplification, and analysis of nucleic acids (DNA, RNA),

[1] Bio-Rad Laboratories is a global leader in developing, manufacturing, and marketing a broad range of innovative products for the life science research and clinical diagnostics markets. www.bio-rad.com
[2] https://echa.europa.eu/restrictions-under-consideration/-/substance-rev/72301/term
[3] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32021D1195&qid=1692632308119

proteins and cells. Examples include but are not limited to: Polymerase Chain Reaction (PCR), Real-Time Quantitative PCR (RT-PCR, QPCR, RT-QPCR), Droplet Digital PCR (ddPCR), Nucleic Acid Extraction and Purification, Flow Cytometry, Western Blotting, Electrophoresis and Gel Imaging, Electroporation, Lab Chromatography, Process Chromatography (Pharmaceuticals), Single-Cell Enrichment and Enumeration, Sequencing Library Preparation, Protein Detection and Quantification. Each of these laboratory devices also utilizes consumables and reagents during its operation, including but not limited to buffers, engineered fluids, analyze-specific reagents, and disposables.

Based on the above description of Bio-Rad's use case of relevant compounds we would, therefore, like to request clarification as to how our use case is covered by the restriction proposal, and on which industry sector we should base our consultation response.

Bio-Rad is currently participating in a consultation submission as a member of MedTech Europe for the parts of our business that fall under the existing proposed derogation for Diagnostic Laboratory Testing (Medical devices) given the sufficiently strong evidence that alternatives are not available.

Warmest regards,

P1

Penta Group
On behalf of Bio-Rad