

Meeting with BioPhorum on PFAS restriction
 Commission premises, N105 [REDACTED] 13:00-14:30

Participants

BioPhorum and member representatives:

- BioPhorum, [REDACTED]
- Cytiva, [REDACTED]
- Sartorius, [REDACTED]
- Watson Marlow Fluid Technology Solutions, [REDACTED]
- Thermo Fisher Scientific, [REDACTED]
- Eli Lilly, [REDACTED]
- Roche, [REDACTED]

Commission (GROW.F.1): [REDACTED]

BioPhorum and its members introduced themselves covering the development, manufacture and supply of medicinal products.

BioPhorum and its members indicated that their main concern is about the inclusion of fluoropolymers in the scope of the restriction. They consider that PFAS group restriction too broad. Fluoropolymers are used in several applications in the biopharma industry, including in R&D for which there is no exemption proposed in the current dossier, and in packaging. They pointed out that any changes need regulatory approval by EMA. The transitional periods as proposed in the current dossier are not feasible for pharma industry, due to regulatory approvals and R&D needed.

In addition to the use of fluoropolymers, the use of PFAS as starting material or intermediates was raised (especially trifluoroacetic acid). Although the Dossier Submitters excluded the active ingredients of the pharmaceuticals from their restriction proposal, co-formulants and other ingredients are not.

Further issues raised:

- There are supply chain risks if there is a restriction is for manufacturing upstream and pharma is a niche use.
- Undermining of EU competitiveness if companies relocate outside the EU and products are reimported in the EU (fluoropolymers used only in the production phase).

Finally, they also pointed to the lack of clarity in ECHA guidance for the consultation.

GROW.F1 explained the REACH restriction process, which applies also to the PFAS restriction, and pointed out that information should now be submitted to ECHA.

More information see powerpoint slides and BioPhorum response to ECHA's consultation.



BioPhorum_EC slide deck 19-07-23.pptx BioPhorum PFAS Response Submission