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Helping Life Science Firms Navigate the Complex PFAS Risk Landscape

Oliver Fudge • November 30, 2023

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Perfluoroalkyl and polyfluoroalkyl substances, commonly referred to as PFAS, are attracting increasing levels of attention owing to their possible association with human health concerns[1]. This family of over 15,000 substances, dubbed the 'forever chemicals' due to their lack of degradation, have several attractive chemical properties, including their resistance to moisture and heat and their durability[2]. This has made these substances an appealing option in a variety of different applications for many years, including within the Life Science industry.

As health concerns associated PFAS continue to grow and grab media headlines, so too does the likelihood of heightened regulatory scrutiny and an increase in potential litigation. With PFAS risk in the spotlight, it is vital that Life Science organisations understand the implications that products which contain PFAS may have on both consumers and the environment and that they establish robust, proactive risk management practices to effectively mitigate this emerging risk.

PFAS and the life sciences industry

Cosmetics:

PFAS are used to create longer-lasting skincare products due to their water and oil-resistant chemicals. In particular, they have been identified in a broad range of cosmetic products, including lip products, foundation, concealers and mascara[3].

Medical Devices:

A number of products containing PFAS have been used extensively within hospital and healthcare settings. Many medical devices are coated with Polytetrafluoroethylene (PTFE), comprised of PFAS, to make device surfaces more water-repellent and avoid adherence of cells, fluids, or blood components to the device. Equally, these chemicals are also utilized in catheters, stents, and needles to provide clot-resistant coatings[4].

Active Pharmaceutical Ingredients (API):

APIs are the components of a drug responsible for its therapeutic effect in a product. PFAS have been used as the 'building blocks' in API manufacturing, with an estimated 30% of all APIs manufactured containing . Over 300 fluorinated compounds have been launched as drugs over the last few decades and over 500 more are in late-stage clinical trials[5].

Pharmaceutical Packaging:

PFAS are used in blister packaging for solid-dose medication products and are also in film-coated packaging for injectable drugs, including stoppers and plungers[6].

Potential litigation

As the understanding of potential health concerns linked to PFAS develops, the number of civil lawsuits filed involving damages allegedly caused by or related to these substances is on the increase[7].

Although predominately originating in the US, greater litigation activity across other jurisdictions, including Europe, remains a possibility. The key sources of civil liability for persons who have conducted activities involving PFAS are the torts of nuisance and negligence, namely public nuisance allegations from contamination of water systems, along with personal injury losses attributed to PFAS exposure. There is also the possibility of litigation for those involved in the testing of samples for PFAS contamination, and the potential for errors or omissions in the conducting of such activities worldwide.

Public Nuisance Allegations:

Several sizable legal awards have been made recently against chemical companies for their involvement in PFAS contamination of public water systems. In June 2023, 3M entered into a class resolution to support PFAS remediation for US public water supplies with a contribution of US$ 10.3bn . Similarly, The Chemours Company, Dupont de Nemours Inc and Corteva Inc collectively agreed in principle to a settlement fund of US$1.185bn to resolve all PFAS-related drinking water claims of a defined class of public water systems that serve the vast majority of the population of the United States. The size of such funds highlights the potential scale of such allegations and the need to remain diligent about PFAS exposure within the supply chain[9].

Personal Injury:

Given that PFAS were detected in over 30,000 umbilical cord blood samples across 40 studies conducted in the past five years[10], there is

a heightened focus on the implications of these chemicals on human health. This is particularly apparent given the long half-life (the time taken for the chemical concentration to decrease by half) of PFAS in the body at over four years, and thus an individual's prolonged exposure to such chemicals. Personal injuries alleged include fertility complications, endocrine dysfunction and the onset of cancer[10].

Managing exposure to PFAS

A big challenge in PFAS litigation is inevitably going to be in the context of causation when establishing liability with allegations to date largely based on the association between exposure and resultant health implications. Equally, owing to the variety of potential exposure sources to such chemicals, it is very difficult to completely eradicate exposure. This is compounded by the longevity of these chemicals, meaning that even if exposure is removed, it would take years for levels in the body to be fully eliminated.[12] These factors mean that Life Science businesses need to ensure that robust risk management procedures are in place in respect of their PFAS exposure to mitigate allegations of negligence. It is important that this stems across the entire product lifecycle from design through to disposal.

Understand what exposure your business operations have to PFAS

In order to manage and mitigate exposure to PFAS, it is first important to understand your business' exposure across your product lifecycle. This has a number of important implications, including ensuring appropriate labelling of products and adequate guidance being provided to consumers, and also in the disposal of PFAS related products.

Remain vigilant to regulatory changes to ensure compliance

Regulators worldwide are responding to increased attention on PFAS, with increasing responsibilities on clients to maintain regulatory compliance. The US Environmental Protection Agency (EPA) and the US Food and Drug Administration (FDA) in particular are accelerating regulatory action in an attempt to contain PFAS exposure placing a greater onus on clients to disclose the presence of PFAS in their materials, and consider the use of alternative materials where possible[13]. Similarly, in Europe, greater regulatory action is being taken to broaden the current PFAS restrictions in place under the REACH and POP legislation[14], emphasising the need for clients to remain diligent to the evolving restrictive actions being taken against consumer products.

Develop a mitigation plan to address PFAS exposure

Be proactive and engage with feasibility assessments and wider analytics to understand how best to proceed. This may involve the identification and evaluation of possible PFAS-free product substitutes that achieve similar end results. It is recognized that there are likely to be significant cost-implications of such actions and it is important that PFAS risk is considered with objectivity to help make informed decisions that bring about positive actions, both for your business and

consumers.

With the heightened level of scrutiny being placed on the use of PFAS throughout the supply chain there is, and will continue to be, a greater level of responsibility put on Life Science companies to ensure they are compliant with PFAS regulatory practices. This is a risk that needs to be high on Life Science organizations' risk radars as it has the potential to become a significant issue that could require careful navigation through this new, complex risk landscape.

If you would like to find out more about insurance coverage for PFAS exposure, please contact our Life Sciences and Environmental teams for more information.

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Underwriter - Int Miscellaneous Medical - Specialty Risks

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[2] 'Forever chemicals': what are PFAS and what risk do they pose? | PFAS | The Guardian

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[5] European PFAS ban would burden manufacturers (pharmaceutical-technology.com)

[6] European PFAS ban would burden manufacturers (pharmaceutical-technology.com)

[7] PFAS Update: Litigation trends in PFAS consumer product litigation from 2021 to 2022 | Bryan Cave Leighton Paisner (bclplaw.com)

[8] 3M pays $10.3bn to settle water pollution suit over 'forever chemicals' | PFAS | The Guardian

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[10] 'Forever chemicals' detected in all umbilical cord blood in 40 studies | PFAS | The Guardian

[11] Per- and poly-fluoroalkyl substances (PFAS) and female reproductive outcomes: PFAS elimination, endocrine-mediated effects, and disease - PubMed (nih.gov)

[12] PFAS Exposure Reduction - Guidance on PFAS Exposure, Testing, and Clinical Follow-Up - NCBI Bookshelf (nih.gov)

[13] Key EPA Actions to Address PFAS | US EPA

[14] EU Sets PFAS Restrictions in Consumer Products | UL Solutions

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