THE VISION COUNCIL

PFAS GUIDANCE | DECEMBER 2023

Are FDA Regulated Medical Devices Exempt from the Reporting Requirements?

Yes. The PFAS reporting regulations are required under the Toxic Substances Control Act ("TSCA"). By statutory definition, medical devices regulated by the FDA are outside the scope of the TSCA. Thus, TVC members involved with FDA regulated medical devices or FDA regulated drugs need not comply; however, those with other products that are not regulated by the FDA will need to report.

What Obligations Do the New Regulations Create for PFAS in Articles?

The new regulations create reporting requirements for manufacturers and importers of PFAS **and** PFAS-containing articles, who must report certain required data regarding PFAS use, disposal and hazards to the EPA. The reporting requirement is a one-time submission covering the period January 1, 2011, through the last calendar year prior to November 13, 2023. This means that manufacturers and importers of optical products not regulated by the FDA as medical devices that contain PFAS from 2011 forward must use due diligence to report the required information for those products.

What PFAS are Covered by the Reporting Requirement?

The EPA will be providing a list of substances on its website that will trigger the reporting requirement. This list, however, is not dispositive, as the EPA has defined a PFAS as any substance containing at least one of the following three structures:

1. R-(CF2)-CF(R')R", where both the CF2 and CF moieties are saturated carbons;
2. R-CF2OCF2-R', where R and R' can either be F, O, or saturated carbons; or,
3. CF3C(CF3)R'R", where R' and R" can either be F or saturated carbons.

What Must an Importer of a Finished Product Report?

The EPA has created a "streamlined" reporting form option for article importers if they do not know or cannot reasonably ascertain information requested on the longer form. Thus, if a TVC member determines that merchandise it has imported since 2011 contains a covered PFAS, then at a minimum, they need to report: 1) the chemical identity (specific, generic and trade names; chemical identification number; representative molecular structure); 2) processing and use information (type of use; sectors and functional categories; percent of production volume per use; maximum concentration product), and 3) production volume (quantity of the imported product). To the extent that the reporter has information not requested on the streamlined form but would be necessary for completion of the longer form, then that information may be added in the "optional" information field.

No *de minimis* threshold exists for either production or import units or for the amount of PFAS found in a product. If the product contains PFAS, then it must be reported.

Since 2011? How Does One Get that Information?

The regulations only require an importer or manufacturer to be responsible for submitting information that is "known or reasonably attainable." This means information "in a person's possession or control, plus all information that a reasonable person similarly situated might be expected to possess, control, or know." Due diligence must be exercised when searching for relevant information, including third-party references like Dun & Bradstreet, the Chemical Abstract Services Registry, and the manufacturer's safety data sheet.

Timeline for Roll Out.

Everything is tied to the November 13, 2023, start date. The earliest anyone can report is one year later, on November 13, 2024, and the reporting period expires May 8, 2025. Small businesses, as defined under the EPA regulations, who are engaged solely in importing articles containing PFAS must report no later than November 12, 2025.

Any questions can be directed to Rick Van Arnam, The Vision Council's Regulatory Affairs Counsel, at rvanarnam@barnesrichardson.com