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Cos. Should Prepare Now For European PFAS Regs

By **John Gardella** (July 16, 2020, 4:25 PM EDT)

Per- and poly-fluoroalkyl substances, or PFAS, are a collection of over 7,000 synthetic chemicals. PFAS were introduced to consumers in 1946 with the invention and sale of Teflon; thousands of additional PFAS chemicals were developed over time, and remain in use today.

PFAS have unique physical properties, including high resistance to heat and degradation, and an ability to repel water and oil — all of which led to PFAS being nicknamed the "forever chemicals." However, the beneficial characteristics that make PFAS useful in a multitude of commercial applications are also the reason PFAS are the subject of biopersistence and human health concerns.



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Much attention has been given to the U.S. Environmental Protection Agency's efforts to regulate PFAS, including establishing permissible limits for drinking water, potential classification of PFAS as hazardous substances under the Comprehensive Environmental Response, Compensation and Liability Act — also known as the Superfund law — and standardization of testing methodology for PFAS.

However, over the past several months, the European Union has stepped up its own efforts to regulate PFAS chemicals in a way that has the potential to be more far-reaching than the efforts underway in the U.S. At the end of June, the European Commission — the executive branch of the EU that proposes legislation — provided a glimpse of the action steps that it may soon propose on PFAS, with the possibility of legislative debate beginning as early as this fall.

Regardless of the final scope of the European Commission's proposals or actions, the EU's PFAS regulations promise to have a significant impact on companies in, and doing business with, EU nations.

The Current Landscape of EU Regulations

Just as there is an assortment of enacted and proposed PFAS regulations at both the federal and state levels in the U.S., the EU landscape with respect to PFAS regulations requires knowledge of several different sources to navigate.

Stockholm Convention

The Stockholm Convention on Persistent Organic Pollutants, or POPs, is an international environmental treaty signed in 2001 that aims to eliminate or restrict the production and use of alleged pollutants. Since 2009, perfluorooctane sulfonate, or PFOS — one form of PFAS — has been restricted under POPs regulations.

There are ongoing discussions among Stockholm Convention signatories to completely eliminate the use of PFOS and perfluorooctanoic acid, or PFOA, another PFAS chemical. Recently, Stockholm Convention signatories began discussions to include perfluorohexane sulfonic acid, or PFHxS, another PFAS chemical, in future lists of PFAS for global elimination.

It is notable that 184 parties — 183 nations and the EU — are signatories to the Stockholm

Convention, but Italy and the United States have not ratified the convention's statements concerning PFAS. While the Stockholm Convention has not yet passed legislation formally eliminating some or all PFAS chemicals from manufacture or sale, PFAS are regulated by several key organizations and regulatory bodies in the EU.

REACH

The Registration, Evaluation, Authorization and Restriction of Chemicals, or REACH, regulation was created as a legislative framework for the EU in 2007. REACH's goals include ensuring a high level of protection for human health and the environment, including by promoting of alternate testing methods.

Instead of placing responsibility on government authorities to accomplish these goals, REACH shifts the responsibility to industry to assess and manage the risks posed by chemicals, as well as provide safety information to consumers. By shifting the responsibility to companies, REACH aims to improve communication along the supply chain.

Under REACH, the manufacture and use of some PFAS chemicals are already restricted. For example, PFOA is listed on REACH's restriction list, which restricts PFOA use in products made in, or sold to, EU countries. However, the REACH restriction does not equate to a complete ban, as is contemplated under the Stockholm Convention. Such a ban under the Stockholm Convention would supersede the REACH restrictions.

Several other PFAS are included on REACH's list of substances of very high concern, or SVHC. Chemicals are included on this list if it is determined that their persistence, mobility and toxicity pose a threat to human health and wildlife through environmental means.

As recently as June 2019 and January 2020, two PFAS were identified as SVHCs: perfluorobutane sulfonic acid, or PFBS, and 2,3,3,3-tetrafluoro-2-(heptafluoropropoxy)propionic acid, or HFPO-DA. The SVHC designation for these two PFAS chemicals is notable for two reasons.

First, the SVHC identification is a recognition that the two substances have an equivalent concern as carcinogens, a conclusion that may lack scientific support at such an early stage in science's understanding of the carcinogenicity of PFAS chemicals. Second, both PFBS and HFPO-DA were created as "next generation" PFAS — meant to substitute for PFOA and PFOS.

This is especially noteworthy to companies that are looking to quickly replace PFOA and PFOS with next generation PFAS. Such changes in manufacturing can be time-consuming and costly, yet REACH's SVHC conclusions show that even substitutes for the most pervasive PFAS may be in danger of being regulated more quickly than anticipated.

Finally, REACH has added several PFAS to its list for evaluation in the coming years, with the aim being to clarify concerns about the risks to human health and the environment that these chemicals pose.

Several EU countries have also submitted proposals through REACH for regulation or restriction of various PFAS, with many set to be decided upon in 2020 through REACH or the Stockholm Convention. These PFAS include a group of six C9-14 PFCAs; PFHxS; and PFHxA. Also under consideration is a global PFAS regulation, restriction or ban.

Classification, Labeling and Packaging Regulation

In 2008, the EU created the Classification, Labelling and Packaging, or CLP, regulation to introduce a new system of classification criteria, uniform hazard symbols and uniform risk and safety statements for product labels. The CLP aims to create greater uniformity in product packaging in the EU, with the ability to require companies to appropriately classify, label and package products before the products hit the market.

A few PFAS have already been included on the CLP regulations, including PFOA, APFO, PFNA and PFDA. There are other PFAS in the proposal stage under CLP for classification and hazard label creation.

Drinking Water Regulations

The provisional agreement by the European Parliament and the European Council in December 2019 on PFAS drinking water limits includes a limit of 0.5 micrograms per liter for all PFAS.

This agreement is now subject to formal approval by the parliament and the council. Following approval, the regulation will be published in the EU's official journal, and enter into force 20 days later.

Individual Countries

Several European countries have independently monitored PFAS, and established regulations related to PFAS specific to their countries. Denmark, Germany, the Netherlands and Sweden, for example, have established limit values for PFAS in water and soil.

Norway established a limit value for PFAS in textiles. In 2019, Denmark established a limit value for food contact materials, which in 2020 became a full ban on PFAS chemicals in any food contact materials. Finally, several EU member states have set drinking water limits for various types of PFAS.

European Commission's Proposed Action Steps

The European Commission has been involved in virtually all of the above-mentioned regulations, action steps and proposals related to PFAS. Separately, the European Commission is currently carrying out several studies related to PFAS used in fire-fighting foams and textiles. The data obtained from these studies will inform future regulations put forth by the European Commission and above-mentioned EU entities.

In June, the European Commission signaled its intention to develop and implement an action plan regarding the use of PFAS in all European countries. The commission revealed that six primary action items were being considered in order to phase out all but "essential uses" of PFAS.

It is expected that the commission will publish its action steps by the fall of 2020. However, the publication of these steps is not the final step in the legislative process, and there are no set deadlines for later milestones in the commission's decision-making at this point in time.

What is not clear at this stage is what the European Commission will consider an essential use, or how that term will be defined. However, regardless of the commission's decision, there will undoubtedly be considerable lobbying, debate and disagreement regarding the commission's recommended definition.

For now, the commission has outlined the following action points for PFAS:

- Ensure through legislation that PFAS use is allowed in the EU only when essential for society.
- Step up initiatives to address PFAS with a group approach with legislation on water, sustainable products, food, industrial emissions and waste.
- Use the expertise of EU member states, the Strategy for a Sustainably Built Environment, the Zero Pollution Action Plan and the revision of the thematic strategy for soil protection to address soil contamination with PFAS.
- Continue working internationally with relevant groups (the Stockholm Convention, the Basel Convention and the United Nations Globally Harmonized System) to address PFAS concerns on a global scale.

- Establish an EU-wide approach and adequate funding to identify and remediate cases of PFAS contamination in the environment, as well as legacy PFAS presence in products and materials, to monitor PFAS presence in humans and the environment, and to guarantee safe PFAS disposal.
- Provide research and innovation funding for safe substitutes for PFAS and facilitate environmental remediation.

The European Commission's initiatives will impact not only businesses based in the EU, but also global businesses selling to EU member states. With an aggressive timetable to begin the process of debating proposed legislation as early as this fall, and with pressure from EU member states building for the European Commission to take action quickly, companies may not have the luxury of extended periods of time to prepare for a sweeping ban of PFAS in the EU.

The number of products that typically contain PFAS is staggering. To name a few:

- Grease-resistant paper products (fast food packaging, pizza boxes, popcorn bags, etc.);
- Nonstick cookware;
- Stain-resistant upholstery and carpets;
- Water-resistant or water-repellent clothing and shoes;
- Cleaning products;
- Personal care products;
- Cosmetics;
- Children's items (toys, bottles, clothing, etc.);
- Paints, varnishes and sealants;
- Medical devices and personal protective equipment;
- Automotive parts;
- Airplane parts; and
- Ski waxes.

Hundreds of thousands of products commonly sold in and to the EU may therefore be subject to a PFAS ban, which will disrupt the entire supply chain in the EU for consumer goods (not to mention commercial and industrial goods) unless companies prepare now. While exceptions will be granted for essential use, the process of receiving approval for essential use status will certainly take time and may become a quagmire, given a likely deluge of applications.

Early compliance initiatives, risk management assessments and prudent planning are essential for companies doing business in or with EU member states to avoid costly last-minute efforts and potential products liability litigation. Manufacturers and distributors alike can take several simple steps now to prevent business interruption, avoid unnecessary costs down the road and have a competitive advantage over companies that may not be as well-prepared:

- Determine the exact scope of PFAS use in products. With over 7,000 PFAS chemicals in use, and the EU contemplating a complete chemical class ban, simply determining whether the most common PFAS are used in products is not enough. Contact component part suppliers for detailed information of PFAS use.
- As part of any compliance initiative, determine whether substitutes exist for PFAS used in products, and whether it is economically viable to switch to such substitutes.

- Determine potential litigation risks for products already on the market or in the stream of commerce, assuming that a PFAS ban is enacted. Manufacturers and distributors need to assess whether they have adequately warned or provided disclosure information to downstream consumers or users in advance of the ban that would enable them to demonstrate prudent corporate behavior.

- Gather supporting materials and develop arguments as to why products are essential, and should be exempt from a PFAS class ban.

While the above steps will certainly require investments of both time and money, these short-term preparedness costs will certainly outweigh the long-term costs of being caught unprepared.

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