EPA Continues to Approve Toxic PFAS Chemicals Despite Widespread Contamination

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Even as the Environmental Protection Agency has been trumpeting its efforts to find and clean up contamination from industrial chemicals known as PFAS, it has been allowing new chemicals in this class to enter into commerce, according to data from the agency. The EPA has allowed more than 100 new PFAS compounds to be made and imported in large quantities in the U.S. after it became aware of the health risks associated with them, and many more have entered commerce through loopholes that allow them to be omitted from the official inventory of chemicals and to bypass a basic safety review.

Since 2002, the agency has allowed 112 new PFAS chemicals to be made or imported in very large quantities, according to a list of compounds kept by the agency known as the Chemical Data Reporting database, or CDR. Companies have to report a chemical on the CDR if they make 25,000 pounds or more of it in a year in a single location. At that point, the agency was already working on a risk assessment of PFOA, which it released the next year with the grim warning that the chemical "raised a number of potential toxicity concerns," and required additional study. "To ensure consumers are protected from any potential risks, the Agency will be conducting its most extensive scientific assessment ever undertaken on this type of chemical," the EPA assistant administrator said at the time.

Yet, in 2006, just three years later, when the CDR was next updated, the EPA had allowed four more PFAS compounds to be added to the list of chemicals made or imported in large quantities. That year, the EPA arranged to phase out PFOA and PFOS, two of the best-known chemicals in the class, due to evidence that they caused health problems in people and animals and persisted indefinitely in the environment. By 2012, when it had become clear that PFAS had contaminated water near several industrial and military sources, the list included an additional 14 new PFAS compounds made in large amounts. Last year, when PFAS contamination was so widespread that it was described as a nationwide crisis, the latest CDR was released with 19 more new PFAS chemicals

In all, 203 PFAS have been made in or imported to the U.S. in large quantities since 1986, when the first CDR was published, according to EPA data. Ninety-six chemicals in this class are still being used in large quantities, according to the most recent list, which came out in 2016. The total number of PFAS compounds on the market with the EPA's permission is likely far larger, since the CDR lists only a fraction of chemicals in use. A tally of chemicals kept by the agency known as the TSCA inventory currently includes 1,223 PFAS, 1,013 of which are in active use, according to an EPA spokesperson. These numbers are expected to grow because the inventory is being updated. Of these, 674 were already in use when the agency began tracking chemicals and didn't undergo any initial scrutiny before being made or used in the U.S.

The CDR, which listed 8,707 chemicals in 2016, represents just over 10 percent of the most recent TSCA inventory, which included some 85,000 chemicals, though that proportion may change after the update of the inventory is completed in a few months. A recent study by the Organization for Economic Cooperation and Development identified 4,730 unique identifying numbers associated with PFAS chemicals currently in use worldwide.

Convenient Loopholes

Whatever the final number of PFAS on the EPA's updated inventory, it will fall short of the actual number of these compounds in use because several loopholes allow chemicals to be used and made here without undergoing a standard safety review and being included on that official list.

The law exempts certain chemicals, including some mixtures, byproducts, and substances unlikely to be released in large quantities, from these basic requirements. The most often used of these alternate paths to market, the low-volume exemption, allows companies to begin producing less than 10,000 kilograms per year of a substance without having to undergo a full safety review. The EPA has reviewed 722 PFAS chemicals submitted for such low-volume exemptions, according to the EPA. An agency spokesperson declined to say how many of the chemicals submitted for the exemption were ultimately approved for use and import. But the EPA website shows that since June 2016, when the new chemicals law went into effect, the EPA granted low-volume exemptions for more than 80 percent of all chemicals submitted.

The EPA has had clear evidence of the dangers of PFOA and PFOS since at least 2000, when 3M sent the agency results of its internal research, showing that the chemicals accumulated in blood and caused health problems in people and animals. 3M, which first produced PFOS and PFOA, shared documentation of the harms of both chemicals, including two troubling monkey studies in which the exposed animals had immune impacts and some died. The next year, attorney Rob Bilott, who was suing DuPont on behalf a West Virginia farmer whose entire herd of cattle had died after PFOA contaminated their drinking water, mailed a packet of more than 100 documents to the EPA detailing evidence of the association between PFOA exposure and tumors, hormonal changes, and reproductive issues and other health problems.

"Every PFAS that has been studied is causing problems."

In recent years, scientists have found other PFAS to be associated with harms, including cancers, hormonal disruption, obesity, and immune and reproductive dysfunction. "Every PFAS that has been studied is causing problems," Linda Birnbaum, director of the National Institute of Environmental Health Sciences, told the audience at a PFAS conference last year.

The 2016 update of the Toxic Substances Control Act was meant to strengthen public health protections by increasing the scrutiny of chemicals. And right after the new law went into effect, oversight of new chemicals did improve, according to Richard Denison, lead senior scientist at the Environmental Defense Fund.

"During the first year, between 60 and 80 percent of new chemicals were having some kind of restriction, whether testing requirements, limits on their production, or use put on them," he said. "That's all going away now," continued Denison, who went on to describe a recent easing of restrictions that allows new chemicals to clear the review process laid out by the law while providing only minimal information.

And while the standard review process in which manufacturers submit pre-manufacture notifications, or PMNs, to the EPA may be becoming more lax, many chemicals are circumventing this route altogether. Of the new compounds allowed onto the market since the new chemicals law went into effect in June 2016, more have bypassed the safety review the law put in place than have undergone it. Since then, the EPA has approved 570 chemicals for commercial use after receiving PMNs, which require the submission of basic safety information, such as how much companies plan to make, details of expected worker exposure, and any studies of the health effects of the chemical.

During that same period, the agency granted 667 chemicals low-volume exemptions, a process that involves a more truncated review process and leaves them off the EPA's official chemical inventory. Data on the number of chemicals newly allowed to be made and sold through other exemptions during that period were not available.

The exemption path to commerce is preferable to many companies in part because of the lower level of scrutiny it involves. "The advantage of filing [a low-volume exemption] application is that it undergoes only a 30-day review," explains a blog post from Keller & Heckman LLP, a law firm that represents many chemical manufacturers. The post described the process as "an attractive option for high-toxicity substances." The same substance "might well wind up being regulated" under the standard review process.

No Public Record

Allowing PFAS compounds to be made, used, and imported without first undergoing a standard safety review may be a violation of the Toxic Substances Control Act, according to Eve Gartner, who heads Earthjustice's toxic chemicals program. "The statute only allows EPA to allow chemicals to bypass the usual approval process if EPA is confident that the chemical will not present unreasonable risk of injury," said Gartner. "But there's no way EPA can make that determination for a PFAS chemical since it's been known since 2006 or earlier that at least some of the chemicals in this class pose very serious health harms."

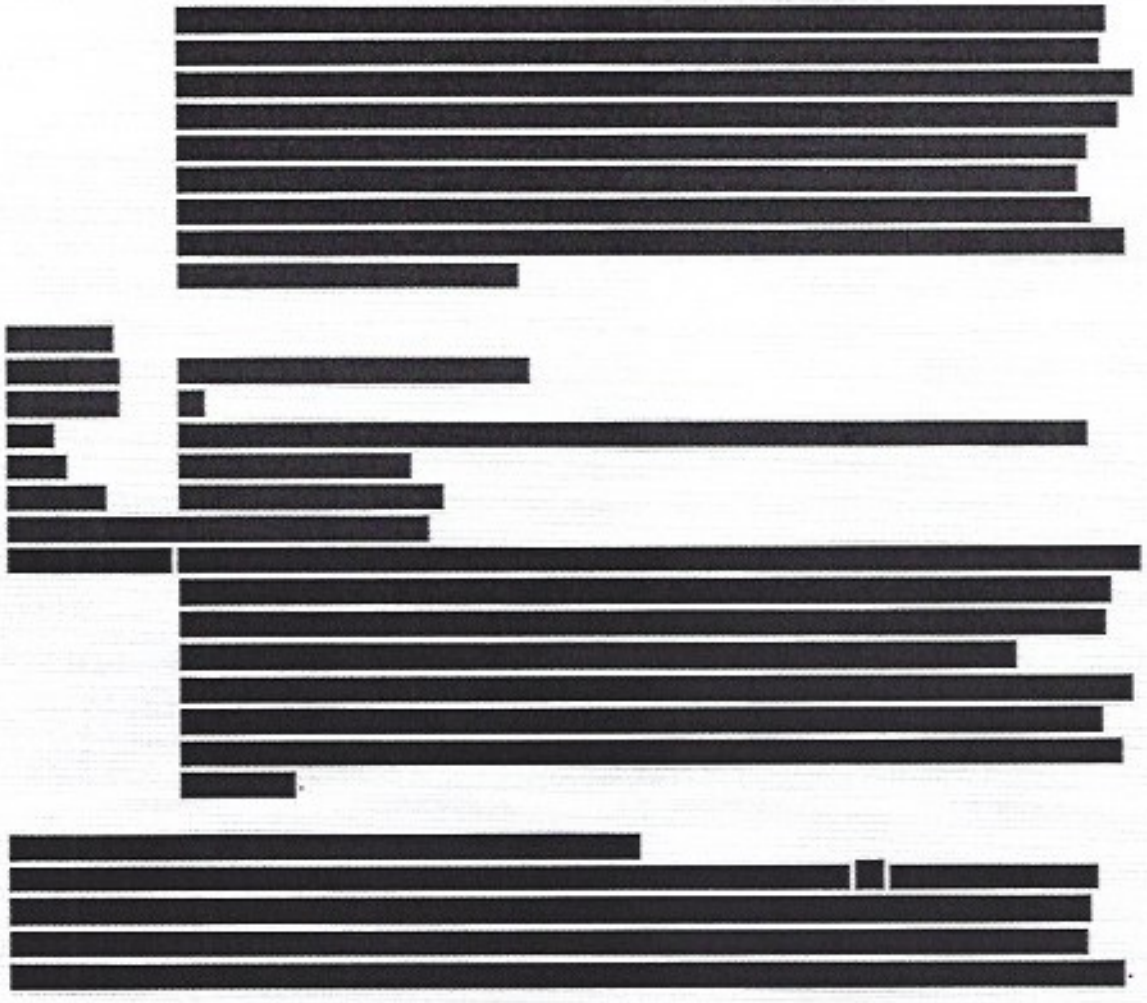
The exemptions also present an enforcement conundrum. Because there is no public record of chemicals that have been approved through the low-volume and other exemptions, there is no way to independently verify that they have met the requirements to keep them off the public list. It's very difficult to check whether chemicals are in fact produced in quantities below the low-volume exemption's 10,000 kg per year threshold, for instance, or released to the environment in amounts that qualify them for the Low Release and Low Exposures Exemption without knowing their names. The EPA did not respond to a question about what steps it takes to ensure that chemicals granted the low-volume exemption are not produced in quantities that exceed the allowed threshold.

Meanwhile, hundreds of chemicals that do undergo the standard safety review and are entered into the official inventory are listed without making the basic facts about them public. According to the EPA, manufacturers have withheld the name, quantities to be produced, and location of production facilities or other data for 396 PFAS chemicals on the grounds that such information is "confidential business information," or CBI.

Consider the unnamed PFAS chemical the EPA allowed the Agfa Corporation to begin importing last year. In a consent order it issued at the time, the EPA acknowledges that the "substance may be a persistent, bioaccumulative, and toxic (PBT) chemical" and that the substance may "cause liver toxicity, blood toxicity, and male reproductive toxicity." The document also noted that "the Ecotoxicity hazard concerns are high for effects of the potential degradation products to terrestrial wild mammals and birds," and concluded that the "EPA is unable to determine whether the PMN substance will present an unreasonable risk to health or the environment."

Nevertheless, on September 1, 2017, just days after state officials from New York, Alaska, Michigan, Pennsylvania, New Hampshire, and Vermont wrote to the Centers for Disease Control asking for help with PFAS, which were causing health crises in their states, and as extensive contamination with the chemicals from the Wolverine shoe manufacturing factory in Michigan was coming to light, the EPA approved the new PFAS chemical's import while withholding its name from the public. The agency did ask for a limited standard review of the chemical, which notes that it will be used at "800

unknown sites" around the country. But with critical information shielded, the report is of questionable use to the public.



From a heavily redacted review of a PFAS chemical the EPA approved for import in 2017. According to the review, the chemical will be used at "800 unknown sites."

Source: EPA

The cloaking of basic facts about chemicals is par for the course, according to the Environmental Defense Fund's Richard Denison, who asked the EPA for more than 90 new chemical applications over the past year. "The information we got back was spotty, almost everything was claimed confidential," said Denison. "With the vast majority of new chemicals, the identity of the chemical is claimed CBI, but so is the great majority of the other information the company submits — the manufacturing process, how many sites the chemical is being processed at, worker exposure."

Even health information, which is required by law to be public, was missing in some cases, according to Denison. "You'd see in attachment list that there's a 78-page study. And, in the file, there was a document labeled 'acute toxicity in mice,' but when you opened it up, it was just one blank page. Someone had made the decision to redact that study even though it's a health study, and it's not eligible to be redacted."

Companies are only allowed to shield their data in certain circumstances and are required to file a form explaining the reasons for their CBI claims. But in many cases they don't provide that information, according to Denison. "We see massive levels of redaction with no substantiation or insufficient substantiation and no evidence that EPA has reviewed any of those claims," he said.

The EPA declined to comment on the record.

The inaccessibility of information about chemicals complicates the work of scientists hoping to prevent and clean up PFAS contamination because it's almost impossible to look for a compound without knowing its name and where it's made. Detlef Knappe, an environmental engineer, co-authored a 2016 study that identified 17 PFAS, including GenX, in drinking water that originated in the Cape Fear River in North Carolina. But Knappe fears there are many more.

"Have we identified all of the PFAS in the water?" asked Knappe. "That question right now is impossible to answer in part because there is confidential business information surrounding the production of these compounds."

It's clear that at least one of the PFAS chemicals found in the river got there through yet another loophole that allowed it to bypass safety testing and inclusion on the EPA's official list of chemicals in use. When DuPont began releasing what is now known as GenX in 1980, the compound wasn't listed on the TSCA inventory because it was made in the course of manufacturing another chemical — and thus spared from reporting and a basic safety review requirements through the "byproducts exemption." The chemical first appeared on the list in 2010, a year after the company introduced it as a replacement for PFOA and entered a legal agreement with the EPA that included restrictions on its production.

While the 2009 agreement required DuPont — and later its spinoff, Chemours — to capture and recycle much of the chemical, up until that point, it had been dumping the very same chemical for decades directly into the Cape Fear River, which is the source of drinking water for hundreds of thousands of people. The loophole allowed GenX to escape regulation because it, at first, wasn't produced with the intent to sell.

In response to inquiries for this article, DuPont provided the following statement:

"DuPont worked closely with regulatory agencies to develop replacement materials that provide comparable properties and benefits with more favorable toxicological profiles. Throughout the time we introduced and used GenX, we always acted responsibly based on the health and environmental information that was available, and our commitment to safety, health and environmental stewardship is essential to everything we do."

Chemours did not respond to requests for comment.

Almost 40 years after DuPont began quietly dumping that chemical into the river, the mess it has made is proving extremely difficult to clean up. "What mystifies me is the barrier for chemicals' entry seems to be very low," said Knappe, who has spent much of the past two years consumed with finding and cleaning up the PFAS compounds in drinking water. "But when it comes to thinking about developing regulation, the barrier is really high."

The EPA says it is working to solve the problem. After holding a series of local meetings about PFAS contamination this summer, the agency announced that it will be releasing a plan to manage the chemicals later this year. The LPA website points to the work it's already done studying the health impacts of the chemicals, monitoring their presence in drinking water, and coordinating with states and tribes dealing with contamination. But it's hard to see how it can fix the country's massive PFAS problem without addressing how these chemicals come onto the market in the first place.