

US EPA ARCHIVE DOCUMENT

Q&A's - Perfluorochemical (PFC) Contamination of Biosolids near Decatur, AL

Prepared by U.S. Environmental Protection Agency

A. DECATUR-SPECIFIC Q&A's

Further questions about information contained within this section of the document should be directed to EPA Region 4, Dawn Harris-Young (404-562-8421) or Davina Marriccini (404-562-8293)

1. When did EPA learn about the levels of perfluorochemicals (PFCs) at agricultural sites near Decatur, Alabama where the biosolids from Decatur Utilities wastewater treatment were applied?

In October 2008, EPA received analytical results from a limited set of samples collected and analyzed by EPA from agricultural sites near Decatur, Alabama where sewage sludge (biosolids) from the Decatur Utilities wastewater treatment plant (Decatur Utilities) was applied. Decatur Utilities receives wastewater from municipal (i.e., residential) as well as industrial sources, including local facilities that utilize PFCs. Biosolids generated at the plant was land applied to approximately 5000 acres of privately owned agricultural fields in Lawrence, Morgan, and Limestone Counties from approximately 1995 to November 2008.

2. How long has EPA been investigating the PFC issue in Decatur, Alabama?

In 1999, a PFC manufacturer located in Decatur, Alabama, the 3M Corporation, conducted limited PFC sampling of the wastewater treatment plant sewage sludge from Decatur Utilities as part of its "multi-city" PFC study. The final report was submitted to EPA in 2001. Two Decatur Utilities' sewage sludge samples analyzed as part of this study indicated perfluorooctyl sulfonate (PFOS) levels of 2,840 parts per billion (ppb) [micrograms per kilogram] and 3,120 ppb respectively. 3M also sampled the local public water supplies in 1999. No PFOS or perfluorooctanoic acid (PFOA) were detected in public drinking water supplies. 3M conducted additional sampling of public drinking water in 2005 and 2006 as part of environmental monitoring done under a Memorandum of Understanding (MOU) with EPA. No PFOA, PFOS, perfluorobutane sulfonate (PFBS) or perfluorohexane sulfonate (PFHS) were detected in drinking water samples from the Decatur public drinking water system, although low levels were detected in the

West Morgan/East Lawrence public drinking water system which is located on the Tennessee River downstream from the 3M facility.

In 2007, EPA learned more about industrial discharges to the Decatur Utilities treatment plant, and obtained additional information on how the sewage sludge from the facility was being used. When EPA learned that biosolids from the Decatur Utilities plant was applied to agricultural fields, it collected a limited set of screening samples in a preliminary survey to investigate potential environmental concentrations of PFCs in soil and biosolids. The 2008 final report indicated the screening samples (taken in 2007) had elevated levels of PFOA and PFOS in biosolids and in soil that received biosolids when compared with other environmental sampling results from industrial and non-industrial sites. After learning of the PFC levels, Decatur Utilities made the decision to voluntarily cease land application of biosolids in November 2008.

3. Why did EPA collect samples in Decatur, Alabama?

Decatur Utilities receives wastewater from municipal (i.e., residential) as well as industrial sources, including local facilities that utilize PFCs. In 2007, one of the PFC manufacturers in Decatur notified EPA that it had unknowingly discharged PFCs to Decatur Utilities. This action led EPA to initiate an investigation to determine if the biosolids from Decatur Utilities were contaminated, and if the land application of these biosolids had resulted in a potential release of PFCs to the environment.

4. Are the levels of PFCs found in Decatur, Alabama high?

EPA regulations under the Clean Water Act (CWA) allow biosolids to be land applied as a soil amendment and fertilizer as long as certain monitoring requirements for regulated chemicals are performed and standard operating regulations are followed. PFCs are a class of man-made chemicals that, in most cases, are not regulated by EPA. Therefore, the testing of biosolids for these chemicals is typically not required.

In January 2009, EPA developed drinking water provisional health advisory levels for two PFCs: perfluorooctanoic acid (PFOA) and perfluorooctyl sulfonate (PFOS). The provisional health advisory level for PFOA is 0.4 parts per billion (ppb) [micrograms per liter] and the provisional advisory level for PFOS is 0.2 ppb.

The initial screening results (taken in 2007) indicated elevated levels of PFOA and PFOS in sewage sludge and in soil that received biosolids when compared with other environmental sampling results from industrial and non-industrial sites. Screening data for PFOS ranged from 715 -1296 ppb in four dried soil samples analyzed by the EPA lab in Georgia, and 589-708 ppb in five dried soil samples analyzed by the EPA lab in North Carolina. Screening data for PFOA ranged from 818-2531 ppb in four dried soil samples analyzed by the lab in Georgia, and 55-2144 ppb in five soil samples analyzed by the lab in North Carolina. Other PFCs were also analyzed. Because of the small sample size, it was not possible to make a definitive scientific interpretation of these numbers. However,

these data suggest that more investigation was warranted, and EPA conducted additional samples of public drinking water, private well and surface water, and soil.

The final results for the public drinking water, private well and surface water, and soil samples are available on the EPA Region 4 website:

www.epa.gov/region4/water/PFCindex.html

The analyses of samples collected by EPA and ADEM from the public water supply systems in Morgan and Lawrence counties in November 2008 found no detectable concentrations of PFCs in two of the three public water systems (Moulton and Decatur). The levels of PFCs detected in the West Morgan/East Lawrence system were below EPA's provisional health advisory levels of 0.4 ppb for PFOA and 0.2 ppb for PFOS in drinking water. In September 2009, EPA expanded its public water sampling event to include the public water systems of Limestone County and the Swann Creek Community. The sample results from the five public water systems sampled in September 2009 were below EPA's provisional health advisory levels.

EPA collected additional samples to determine if PFOA or PFOS has migrated over or through the soils to ground water or surface water and contaminated private drinking water supplies. Two of the six private drinking water wells sampled had PFOA concentrations above EPA's provisional health advisory level and none had concentrations above the PFOS provisional health advisory level. These two wells had PFOA levels of 2.2 ppb and 0.6 ppb respectively. Both of the residences with elevated PFOA levels were quickly provided with bottled water and connected to the public water supply system by Decatur Utilities and a group of local industries in the area. Other PFCs were also analyzed. The agency is evaluating the significance of the other PFCs detected.

PFOA, PFOS and other PFCs were also detected in many of the samples collected from ponds in the vicinity of the land application sites. These concentrations varied significantly: PFOA ranged from no detectable level to 11.0 ppb and PFOS ranged from no detectable level to 0.08 ppb.

In March 2009, 32 soil samples in or near the fields with the highest applications of biosolids were collected and analyzed. The final report indicated the following results:

- For PFOA, the results ranged from below the limit of quantization up to 317 ppb.
- For PFOS, the results ranged from below the limit of quantization up to 408 ppb.

In response to the detection of PFOA and PFOS in biosolids-applied soils, EPA released (in October 2009) residential soil screening guidance values for PFOA and PFOS that are protective of children who might incidentally ingest soils during play. These soil screening values are 16,000 ppb for PFOA and 6,000 ppb for PFOS. None of soil samples collected by EPA in 2007 or 2009 exceeded the soil screening values for protection of children's health (which are also protective of adult health.)

In August 2009, at the request of EPA, Decatur Utilities and the group of local industries conducted a comprehensive survey to identify any additional private drinking water wells located up to one mile from the biosolids application sites. Twelve wells were identified and a sampling plan was developed. Sampling results from August 2009 indicated that none of the wells have PFOA or PFOS levels above EPA's drinking water provisional health advisory. The report indicated the following results:

- For PFOA, the results ranged from no detectable levels up to 0.061 ppb.
- For PFOS, the results ranged from no detectable levels up 0.067 ppb.

In February and March 2010, the group of local industries continued their sampling protocol. In accordance with the sampling plan and, based on the results of the first sampling analyses, the industries sampled seven of the twelve initial drinking wells. The second quarter final sampling report indicated that one of these seven drinking water wells had PFOS levels of 0.339 ppb and 0.365 ppb (duplicate sample), which was above EPA's provisional health advisory. The residence with elevated PFOS levels was quickly provided with bottle water and connected to the public water supply system by Decatur Utilities and the group of local industries. The final second quarter sampling report indicated the following results:

- For PFOA, the results ranged from 0.0285 ppb up to 0.122 ppb.
- For PFOS, the results ranged from no detectable levels up to 0.365 ppb

In May 2010, the group of local industries conducted the third drinking water well sampling event in accordance with their sampling protocol. The final sampling report from this third set of samples indicated none of the six private drinking water wells sampled had PFOA or PFOS values above EPA's provisional health advisory. The final sampling report indicated the following results:

- For PFOA, the results ranged from no detectable levels up to 0.0398 ppb.
- For PFOS, the results ranged from 0.0100 ppb up to 0.0691 ppb.

In August 2010, the group of local industries conducted the fourth drinking water well sampling event in accordance with their sampling protocol. The final sampling report from this fourth set of samples indicated none of the six private drinking water wells sampled had PFOA or PFOS values above EPA's provisional health advisory. The final sampling report indicated the following results:

- For PFOA, the results ranged from no detectable levels up to 0.0524 ppb.
- For PFOS, the results ranged from no detectable levels up to 0.156 ppb.

5. What is the source of the elevated levels of PFCs found in Decatur, Alabama?

EPA and ADEM are investigating the sources of the elevated levels of PFCs found in Decatur, Alabama. Decatur Utilities receives wastewater from municipal (i.e., residential) as well as industrial sources, including local facilities that utilize PFCs. Municipal sewage sludge generated at the plant was land applied to approximately 5000 acres of privately owned agricultural fields in Lawrence, Morgan, and Limestone Counties from approximately 1995 to November 2008. To date, EPA has identified four

known sources of PFCs to the Decatur Utilities Plant: the 3M Company, Daikin America, Inc., Toray Carbon Fibers America, Inc., and the Morgan County Landfill leachate. Decatur Utilities and ADEM are currently collecting data and information to determine other sources of PFCs.

6. What is EPA doing about the levels of PFCs in Decatur, Alabama?

In January 2009, EPA issued national drinking water provisional health advisories for two PFCs, PFOA and PFOS. The provisional health advisory for PFOA is 0.4 ppb and for PFOS is 0.2 ppb. In November 2009, EPA released residential soil screening guidance values for PFOA and PFOS that are protective of children who might incidentally ingest soils during play. These soil screening values are 16,000 ppb for PFOA and 6,000 ppb for PFOS. The EPA's advisory levels for residential soils and drinking water are guidance values only and are not required to be met by federal or state regulations.

The analyses of samples collected by EPA and ADEM from the public water supply systems in Morgan and Lawrence counties in November 2008 found no detectable concentrations of PFCs in two of the three public water systems (Moulton and Decatur). The levels of PFCs detected in the West Morgan/East Lawrence system were below EPA's provisional health advisory levels of 0.4 ppb for PFOA and 0.2 ppb for PFOS in drinking water. In September 2009, EPA expanded its public water sampling event to include the public water systems of Limestone County and the Swann Creek Community. The sample results from the five public water systems sampled in September 2009 were below EPA's provisional health advisory levels.

EPA collected additional water samples from locations near the biosolids land application sites to determine if PFOA/PFOS has migrated over or through the soils to ground water or surface water and contaminated private drinking water wells. Two of the six private drinking water wells sampled had PFOA concentrations above EPA's provisional health advisory level and none had concentrations above the PFOS provisional health advisory level. These two wells had PFOA levels of 2.2 ppb and 0.6 ppb respectively. Both of these residents with elevated PFOA levels were quickly provided with bottled water and within days connected to the public water supply system by Decatur Utilities and a group of local industries in the area.

In August 2009, at the request of EPA, Decatur Utilities and a group of local businesses conducted a comprehensive survey to identify any additional private drinking water wells located within a specified distance from the biosolids application sites. Twelve wells were identified and a sampling plan was developed and implemented during August 2009. The final report from the August 2009 sampling event indicated that none of the wells had PFOA or PFOS levels above EPA's drinking water provisional health advisory. In February and March 2010, the group of local industries continued their sampling protocol. In accordance with the sampling plan and, based on the results of the first sampling analyses, the industries sampled seven of the twelve initial drinking wells. The final report from the second sampling event indicated that one of these seven drinking water wells had a PFOS level of 0.339 ppb and 0.365 ppb (duplicate sample), which was

above EPA's provisional health advisory. The residence with elevated PFOS levels was provided bottled water and connected to the public water supply system. In May 2010, the group of local industries conducted the third drinking water well sampling event in accordance with their sampling protocol. The final sampling report from this third set of samples indicated none of the six private drinking water wells sampled had PFOA or PFOS values above EPA's provisional health advisory. The final sampling report indicated the results for PFOA ranged from no detectable levels up to 0.0398 ppb and the results for PFOS ranged from 0.0100 ppb up to 0.0691 ppb. In August 2010, the group of local industries conducted the fourth drinking water well sampling event in accordance with their sampling protocol. The final sampling report from this fourth set of samples indicated none of the six private drinking water wells sampled had PFOA or PFOS values above EPA's provisional health advisory. The final sampling report indicated the results for PFOA ranged from no detectable levels up to 0.0524 ppb and the results for PFOS ranged from no detectable levels up to 0.156 ppb.

In May 2009, the U.S. Department of Agriculture (USDA) sampled blood and tissue from selected cows/steers from farms where Decatur Utilities biosolids were land applied in the past (seven animals associated with "high" application fields; two animals from "minimally" applied fields). The final analytical results from these tests indicate the values are below USDA's minimum proficiency level (MPL) of 20 ppb for both PFOS and PFOA; therefore, these samples are reported as not detectable for PFOS and PFOA. Based on USDA estimates for human health concerns using the MPL as an upper limit value and current Decatur area exposure patterns, this testing supports USDA's finding that there is no reason to believe there are human health concerns with consuming the meat processed from cattle grazed on lands receiving these biosolids.

Also in May 2009, the U.S. Food and Drug Administration (FDA) sampled and analyzed two milk samples, one from a single cow and one from a bulk milk tank, for PFOA and PFOS from a dairy farm located in the Decatur area that received limited application of Decatur Utilities biosolids. FDA testing found no PFOA or PFOS in the milk sample from the single cow. A very low level (0.17 ppb) of PFOS was detected in the bulk tank milk sample. FDA is currently testing retail milk samples collected throughout the U.S. for PFOA and PFOS to obtain additional information on background levels for PFCs in milk. To date, FDA testing found no PFOA in any of the 18 retail milk samples tested. A very low level of PFOS (0.042 ppb) was detected in one retail milk sample.

EPA will keep the public informed of what we are finding and our actions taken to limit human and environmental exposures.

7. What is EPA doing to determine if there is a problem with drinking water quality?

EPA has conducted ground and surface water sampling to determine if PFOA has migrated into drinking water supplies. EPA also collected water samples to determine if PFOA or PFOS has migrated over or through the soils to ground water or surface water and contaminated private drinking water wells. Two of the six private drinking water

wells sampled had PFOA levels above EPA's provisional health advisory level and none had levels above the PFOS provisional health advisory level. These two wells had PFOA levels of 2.2 ppb and 0.6 ppb respectively. Both of these residents with elevated PFOA levels were quickly provided with bottled water and within days connected to the public water supply system by Decatur Utilities and a group of local industries in the area. Other PFCs were also analyzed. The agency is evaluating the significance of the other PFCs detected.

In August 2009, at the request of EPA, Decatur Utilities and the group of local industries conducted a comprehensive survey to identify any additional private drinking water wells located up to one mile from the biosolids application sites. Twelve wells were identified and a quarterly sampling plan was developed. Sampling results from August 2009 indicated that none of the wells have PFOA or PFOS levels above EPA's drinking water provisional health advisory.

The report indicated the following results:

- For PFOA, the results ranged from no detectable levels up to 0.061 ppb.
- For PFOS, the results ranged from no detectable levels up 0.067 ppb.

In February and March 2010, the group of local industries continued their sampling protocol. In accordance with the sampling plan and, based on the results of the first sampling analyses, the industries sampled seven of the twelve initial drinking wells. The second quarter final sampling report indicated that one of these seven drinking water wells had PFOS levels of 0.339 ppb and 0.365 ppb (duplicate sample), which was above EPA's provisional health advisory. The residence with elevated PFOS levels was quickly provided with bottle water and connected to the public water supply system by Decatur Utilities and the group of local industries. The final second quarter sampling report indicated the following results:

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- For PFOA, the results ranged from no detectable levels up to 0.0524 ppb.
- For PFOS, the results ranged from no detectable levels up to 0.156 ppb.

8. What can residents in the area who rely on private wells for drinking water do to protect themselves from exposure?

If persons are concerned about PFC compounds in their drinking water, some water filtration devices (point-of-use devices that are installed at an individual tap, faucet, or outlet) may remove some of these compounds from water, based on a study conducted by the Minnesota Department of Health. Individuals should contact the company that makes the water filtration device to determine whether the device is effective in removing PFC compounds, and ask for advice on how often they should change their filters.

The environmental samples associated with the Decatur Utilities biosolids contain other PFCs for which EPA has not issued drinking water and residential advisory levels. EPA is currently working to establish a threshold value for PFCs, including PFOA and PFOS, in biosolids to protect public health through all exposure pathways, but has not yet completed this ongoing work. Therefore, it is not currently known if the levels of PFOA, PFOS and other PFCs in Decatur Utilities biosolids are protective of public health. EPA has not established guidance levels for PFCs, including PFOA or PFOS, in wastewater effluent, sewage sludge, compost, groundwater or surface water as it has for drinking water and residential soil.

9. Do residents in the area who rely on community water systems for drinking water need to take further precautions?

No. EPA has conducted public water sampling events in the Decatur area. In November 2008, the Agency sampled the public water supplies of Moulton, Decatur and the West Morgan / East Lawrence system. No detectable concentrations of PFCs were found in the Moulton and Decatur public water systems. Levels of PFCs detected in the West Morgan/East Lawrence system were at levels below EPA's drinking water provisional health advisory levels of 0.4 ppb for PFOA and 0.2 ppb for PFOS. In September 2009, EPA expanded its public water sampling event to include the public water systems of Limestone County and the Swann Creek Community. All sample results from the September 2009 sampling event are below EPA's provisional health advisory levels. Other PFCs were also analyzed as part of this review. Based on its current understanding, EPA believes residents may rely upon the public water systems in the area.

10. Will residents in the area be evaluated for exposure to PFCs?

In April 2010, ATSDR, in collaboration with EPA, voluntarily sampled and tested the blood of 155 residents in the Decatur area to determine the concentration of PFOA, PFOS and other PFCs in their blood. The testing was free to qualified participants and the individual's results will be kept. Participants received no other medical tests, diagnosis, or treatment. The ATSDR investigation targeted residents who have potentially been exposed to PFCs released by the biosolids-applied soils or from water sources containing PFCs. Eligible residents received a letter from the ATSDR inviting them to participate in the investigation. In February 2011, each participant received the test results of their

respective PFC blood levels and was invited to meet with an ATSDR toxicologist to discuss their individual blood test results. Participants were informed on whether their test results indicated PFC levels below or above the average of most people in the United States population as referenced in the Centers for Disease Control and Prevention (CDC) National Health and Nutritional Examination Survey (NHANES) for PFOA and PFOS. The ATSDR plans to publish the final summary report in 2011.

Scientists do not definitively know how PFC concentrations in the blood can affect a person's health, and until more research is completed, it is not possible to know:

- If the PFC levels in a person's blood will make the person sick now or later in life;
- If a person's current health problems are related to the PFC levels found in their body; or
- How or from where the PFCs entered their body.

Because of the wide spread use of PFCs, most people in the U.S. have some concentration of PFCs in their body. Once the PFCs are in a person's body, it takes several years for the level in the body to be reduced by one-half, even if no further exposures to PFCs occur. There is still much to learn about the health effects associated with PFCs. Some studies suggest that lower birth weight, increased cholesterol, and changes in liver function may be associated with PFCs. Yet, other studies have not shown the same associations. Therefore, there is still much debate about how exposures to PFCs may affect humans. Because many factors can contribute to health problems, it is difficult to link a person's health problem directly to any single measurement of PFCs in the blood. Testing of a person's PFC blood concentrations can be used to determine if exposures have occurred; however, these measurements do not tell the timing, magnitude, or duration of exposure.

Health-related information on PFCs may be found at the following ATSDR website:
<http://www.atsdr.cdc.gov/tfacts200.html>

ATSDR is best able to answer questions related to the PFC blood exposure investigation and can be contacted by phone or email as follows:

CAPT Bruce Tierney, M.D., U.S. Public Health Service
bgt2@cdc.gov, Phone: 1-888-529-1906 or 770-488-0771

11. Are my cattle/poultry/crops/feed safe?

In May 2009, USDA sampled blood and tissue from selected cows/steers from farms where Decatur Utilities biosolids were land applied in the past (seven animals associated with "high" application fields; two animals from "minimally" applied fields). The final analytical results from these tests indicate the values are below USDA's minimum proficiency level (MPL) of 20 ppb for both PFOS and PFOA; therefore, these samples are reported as not detectable for PFOS and PFOA. Based on USDA estimates for human health concerns using the MPL as an upper limit value and current Decatur area exposure patterns, this testing supports USDA's finding that there is no reason to believe

there are human health concerns with consuming the meat processed from cattle grazed on lands receiving these biosolids.

Also in May 2009, FDA sampled and analyzed two milk samples, one from a single cow and one from a bulk milk tank, for PFOA and PFOS from a dairy farm located in the Decatur area that received limited application of Decatur Utilities biosolids. FDA testing found no PFOA or PFOS in the milk sample from the single cow. A very low level (0.17 ppb) of PFOS was detected in the bulk tank milk sample. FDA is currently testing retail milk samples collected throughout the U.S. for PFOA and PFOS to obtain additional information on background levels for PFCs in milk. To date, FDA testing found no PFOA in any of the 18 retail milk samples tested. A very low level of PFOS (0.042 ppb) was detected in one retail milk sample.

At this time, there is not adequate data to provide advice to farmers/consumers regarding food grown on fields treated with biosolids from the Decatur wastewater treatment facility. Although the multiple components of feed and the subsequent dilution of the products exposed to the biosolids would likely contribute to reducing the risk associated with the feed and products derived from the animals, we do not have enough information at this time to make a definitive determination.

FDA and USDA are best able to answer these questions and can be contacted by e-mail or telephone as follows:

Brian Mabry, USDA – Questions about food safety (meat, poultry and certain egg products (not shell eggs))

Brian.Mabry@fsis.usda.gov Phone: 202-720-9113

Cindy N. Ragin, USDA - Questions about animal and plant health

Cindy.N.Ragin@aphis.usda.gov, Phone: 301-734-7280.

Mike Herndon, FDA – Questions about food (all food except meat, poultry and certain egg products (FDA is responsible for shell eggs))

Michael.Herndon@fda.hhs.gov, Phone: 301-796-4673

Ira Allen, FDA – Questions about animal feed

Ira.allen@fda.hhs.gov, Phone: 301-796-5349

B. PFC BACKGROUND

Further questions about information contained within this section of the document should be directed to EPA's Office of Public Affairs – Dale Kemery (202-564-7839) or Enesta Jones (202-564-7873).

1. What are PFCs?

PFCs are synthetic (man-made) chemicals that do not occur naturally in the environment. These compounds are used in a variety of industrial and consumer applications, including use as a processing aid in the manufacture of non-stick and stain-resistant surfaces and products and to impart water, stain, and grease resistance to carpets, paper and textiles. PFOS and PFOA are very persistent in the environment and have been found at very low levels both in the environment and in the blood of the general population of the United States. PFOS is no longer manufactured in the United States. Some PFCs have been determined to be degradable in the environment and to form PFOA, PFOS and related compounds.

2. How long has the Agency been looking into PFCs and their potential risks?

In the late 1990's, EPA received information from industry under the Toxic Substances Control Act (TSCA) Section 8(e) indicating that PFOS was widespread in the blood of the general population, and presented concerns for persistence, bioaccumulation, and toxicity. Following discussions between EPA and 3M, the manufacturer of PFOS, the company terminated production of these chemicals. Findings on PFOS led EPA to review similar chemicals, including PFOA, to determine whether they might present concerns similar to those associated with PFOS.

3. What are the concerns related to PFOA?

PFOA is very persistent in the environment and has been found at very low levels both in the environment and in the blood of the general population of the United States. Once the PFCs are in a person's body, it takes several years for the level in the body to be reduced by one-half, even if no further exposures to PFCs occur. There is still much to learn about the health effects associated with PFCs. Some studies suggest that lower birth weight, increased cholesterol, and changes in liver function may be associated with PFCs. Yet, other studies have not shown the same associations. All of these factors, taken together, prompted the Agency to investigate whether PFOA might pose a risk to human health and the environment at the levels currently being found, or at levels that might be reached in the future as PFOA continues to be released into the environment.

4. How are people exposed to PFOA?

EPA does not have a full understanding of how people are exposed to PFOA, which is used as a processing aid in the manufacture of fluoropolymers, and may also be a breakdown product of other related chemicals, such as some fluorinated telomers. In April 2003, EPA released a preliminary risk assessment for PFOA and started a public process to identify and generate additional information to better understand the sources of PFOA and the pathways of human exposure. Specifically, EPA is working with industry and other stakeholders to obtain additional environmental monitoring information on PFOA, exposures resulting from incineration or loss from products as they are used over time, and telomer biodegradation as a potential source of PFOA. The Agency has finalized TSCA Section 4 Enforceable Consent Agreements and MOUs for exposure-related studies with industry in a public process involving a large number of interested parties, and is cooperating with industry and other stakeholders on additional voluntary research activities. In addition, EPA is conducting research focused on the health effects and exposures to PFOA and other PFCs. This research is designed to generate enhanced science knowledge and high quality data that will help the Agency address these key uncertainties in pathways of exposure and potential risks from PFOA.

5. What steps has the Agency taken to reduce exposure to PFCs?

In January 2006, EPA invited the eight major companies in the industry to participate in the 2010/15 PFOA Stewardship Program. The companies agreed to participate and in so doing committed to reduce facility emissions and product content of PFOA and related chemicals by 95% by 2010, and to work toward eliminating emissions and product content by 2015. Commitment to the program is in addition to and does not replace existing commitments to enforceable consent agreements or MOUs. The first progress reports were received in October 2007, and showed significant reductions. For example, three companies reported greater than 98% reductions in emissions of PFOA in the United States, and five companies reported greater than 74% reductions of PFOA outside the United States.

There has also been considerable progress in the development and introduction of substitutes and alternates. For example, in early 2006, Asahi introduced a new line of products that were free of PFOA and PFOA precursors. In 2007, DuPont committed to “eliminate the need to make, buy or use PFOA by 2015.” In late 2007, Daikin announced intentions to “stop manufacturing, using and selling PFOA and eight-carbon or longer chain telomer-based water and oil repellent products by the end of 2012.” In early 2008, 3M announced intentions to introduce a PFOA substitute this year to be used in the manufacture of some of the products currently on the market. To date, companies have submitted more than 100 new chemical alternatives to EPA for review through the Premanufacture Notification (PMN) process. More information on the 2010/15 PFOA Stewardship Program is available at

<http://www.epa.gov/oppt/pfoa/pubs/pfoastewardship.htm>.

In December 2009, EPA released an Action Plan for Long-Chain Perfluorinated Chemicals (LCPFCs), announcing that EPA is considering initiating rulemaking under TSCA Section 6 to manage LCPFCs. TSCA Section 6 provides authority for EPA to ban or restrict the manufacture (including import), processing, and use of these chemicals. PFOA, PFOS, and their precursors, are part of LCPFCs. EPA will develop more detailed assessments to support the TSCA Section 6(a) “presents or will present an unreasonable risk” findings. If these more detailed assessments indicate that a different approach to risk management is appropriate, EPA will consider additional approaches. More information is available at <http://www.epa.gov/oppt/existingchemicals/pubs/actionplans/pfcs.html>.

6. What are the concerns related to PFOS?

Concerns with PFOS are similar to those with PFOA and include developmental, reproductive, and systemic toxicity. PFOS is highly persistent in the environment and has a strong tendency to bioaccumulate.

7. What recommendations does the Agency have for consumers who use products made with these PFCs?

Consumer products made with PFCs include some non-stick cookware and products such as breathable, all-weather clothing. PFCs are also employed in hundreds of other uses in almost all industry segments, including the aerospace, automotive, building/construction, chemical processing, electrical and electronics, semiconductor, and textile industries. Telomers are used as surfactants and as surface treatment chemicals in many products, including fire-fighting foams; personal care and cleaning products; and oil, stain, grease, and water repellent coatings on carpet, textiles, leather, and paper. These products are not PFOA; however, PFOA is used as a processing aid. The information that EPA has available does not indicate that the routine use of household products poses a concern. EPA does not have any indication that the public is being exposed to PFOA through the use of Teflon®-coated or other trademarked nonstick cookware. Teflon® and other trademarked products are not PFOA. At the present time, EPA does not believe there is any reason for consumers to stop using any products because of concerns about PFOA.

8. Is there a risk assessment on PFOA?

To ensure that the most rigorous science is used in the Agency's ongoing evaluation of PFOA, the EPA Office of Pollution Prevention and Toxics submitted in 2005 a draft risk assessment for formal peer review by the Agency's Science Advisory Board (SAB). That draft was preliminary and did not provide conclusions regarding potential levels of concern. The SAB reviewed the information that was available at the time, and suggested that the PFOA cancer data are consistent with the EPA guidelines descriptor "likely to be carcinogenic to humans." Since their review, additional research has been conducted pertaining to the carcinogenicity of PFOA. EPA is still in the process of evaluating this information, and has not made any definitive conclusions at this time.

9. What is the status of the Agency’s efforts regarding reducing exposure to PFOS?

Following the voluntary phase out of PFOS by the principal worldwide manufacturer, EPA took prompt SNUR regulatory action under the TSCA to limit any future manufacture or importation of 88 perfluoroalkyl sulfonates (PFAS) chemicals specifically included in that phase-out. PFAS is a generic term used to describe any fully fluorinated carbon chain length sulfonic acid, including higher and lower homologues as well as PFOS.

These TSCA SNURs allowed the continuation of a few specifically limited, highly technical uses of these chemicals for which no alternatives were available, and which were characterized by very low volume, low exposure, and low releases. Any other uses of these chemicals would require prior notice to and review by the Agency. Subsequently, EPA identified 183 more PFAS chemicals which it believed were no longer being manufactured, imported or used in the United States, with the possible exception of the same uses excluded from the earlier SNURs. However, based on comments received during the public comment period and related communications, EPA learned of additional limited uses of PFAS chemicals. Consequently, those uses for particular chemicals were excluded from the final SNUR. EPA published a Federal Register notice ([72 FR 57222, October 9, 2007](#)) finalizing the SNUR on these 183 chemicals.

In December 2009, additional actions on PFOS and related PFOS chemicals were proposed in the LCPFCs Action Plan.

10. Where can I find more information about PFOA and PFOS?

Basic information about PFOA is available at the EPA PFOA website:

<http://www.epa.gov/oppt/pfoa/pubs/pfoainfo.htm>.

Additional information about PFOS and other PFCs is also available at:

<http://www.epa.gov/oppt/pfoa/pubs/related.htm>.

Information on PFC contamination of biosolids applied near Decatur, Alabama and other related topics are available at the EPA Region 4 website at:

<http://www.epa.gov/region4/water/PFCindex.html>

C. BIOSOLIDS BACKGROUND

Further questions about information contained within this section of the document should be directed to EPA's Office of Public Affairs – Dale Kemery (202-564-7839) or Enesta Jones (202-564-7873).

1. What are Biosolids?

They are nutrient-rich organic materials resulting from the treatment of domestic sewage in a treatment facility. When treated and processed, these residuals can be recycled and applied as fertilizer to improve and maintain productive soils and to stimulate plant growth or as a soil amendment to improve soil quality.

2. Are there regulations for the land application of biosolids?

Yes. Under Clean Water Act (CWA) Section 405(d), EPA establishes numerical limits and management practices that protect public health and the environment from the reasonably anticipated adverse effects of chemical and microbial pollutants in sewage sludge. On February 19, 1993, EPA promulgated the 40 Code of Federal Regulations (CFR) Part 503 (Part 503) Standards for the Use or Disposal of Sewage Sludge, resulting in numerical standards for ten metals and operational standards for microbial organisms. The 1993 rule established requirements for the final use or disposal of sewage sludge when it is: (1) applied to land as a fertilizer or soil amendment; (2) placed in a surface disposal site, including sewage sludge-only landfills; or (3) incinerated. These requirements apply to publicly and privately owned treatment works that generate or treat domestic sewage sludge and to anyone who uses or disposes of sewage sludge.

Biosolids that are to be land applied must meet these regulations and quality standards. The Part 503 rule governing the use and disposal of biosolids contain numerical limits for metals, pathogen reduction standards, site restrictions, crop harvesting restrictions, monitoring, and record keeping and reporting requirements for land applied biosolids as well as similar requirements for biosolids that are surface disposed or incinerated.

Additionally, CWA Section 405(d)(2)(C) states that EPA shall review the sewage sludge regulations not less often than every two years. The purpose of such reviews is to identify additional toxic pollutants that may be present in sewage sludge and, if appropriate, to promulgate regulations for those pollutants consistent with the requirements set forth in the CWA. For Biennial Review 2003, EPA announced the final results of its review of existing sewage sludge regulations to identify additional toxic pollutants that may need to be regulated. In fulfilling this commitment for the Biennial Reviews 2005 and 2007, the Agency searched known databases and the published literature designed to capture available information on occurrence, fate and transport, and human health or ecological effects, as well as other relevant information for pollutants

that may occur in U.S. sewage sludge. The Agency subsequently analyzed the information identified by that search and determined that there is not sufficient information at this time on evaluated pollutants to conduct exposure and hazard assessment for deriving scientifically supportable numerical standards. EPA has completed Biennial Review 2009 and will summarize its results in 2010. The Agency will continue to assess the availability of sufficient information for pollutants during subsequent biennial reviews pursuant to the CWA Section 405(d)(2)(C).

In addition, EPA has completed the Targeted National Sewage Sludge Survey report and posted documents to EPA's Biosolids Web Site in January 2009. Reports are available at: www.epa.gov/waterscience/biosolids

Data from the survey will help determine exposure to target pollutants in biosolids and whether target pollutants may need to be evaluated for possible regulation pursuant to 40 CFR Part 503. Assessment and risk characterization of the 145 pollutants detected and quantified in the survey, where sufficient data exist, will be completed in 2010. Any regulatory decisions will be made subsequent to completing risk characterization and management decisions.

3. What is the difference between biosolids and sewage sludge?

Sewage sludge is defined in the Part 503 rule as the solid, semi-solid, or liquid residue generated during the treatment of domestic sewage in a treatment works. The term biosolids is not used in the Part 503 rule, but EPA often uses the terms “biosolids” interchangeably with “sewage sludge.” Others outside of EPA often use the term biosolids to describe sewage sludge that has had additional processing for land application.

4. How are biosolids generated and processed?

Biosolids are created through the treatment of domestic wastewater generated from sewage treatment facilities, and separation of liquids from solids. In many larger wastewater treatment systems, pre-treatment regulations require that industrial facilities pre-treat their wastewater to remove many hazardous contaminants before it is sent to wastewater treatment. This prevents these substances from getting into the sewage sludge.

Once the wastewater reaches the plant, the sewage goes through physical, chemical and biological processes that clean the wastewater and remove the solids. The solids may be treated with any number of options (e.g., treatment with lime to raise the pH or aerobic and aerobic digestion). The wastewater treatment processes sanitize solids to control pathogens (disease-causing organisms, such as certain bacteria, viruses and parasites). In addition, certain management options result in reduced vector attraction. Vectors are any living organism capable of transmitting a pathogen from one organism to another. Vectors for sewage sludge pathogens would most likely include insects, birds, and rodents.

5. Where are biosolids used?

Biosolids are used in agriculture. Agricultural uses of biosolids, that meet strict quality criteria (heavy metals, pathogens, and vector control) and application rates, have been shown to produce significant improvements in crop growth and yield. Nutrients found in biosolids, such as nitrogen, phosphorus and potassium and trace elements such as calcium, copper, iron, magnesium, manganese, sulfur and zinc, are necessary for crop production and growth. The use of biosolids reduces the farmer's production costs and replenishes the organic matter that has been depleted over time. The organic matter improves soil structure by increasing the soil's ability to absorb and store moisture and makes metals more available to plants.

Biosolids have also been used successfully at mining sites to establish sustainable vegetation and reclaim abandoned mine sites with little or no topsoil, and forestry sites to promote rapid timber growth, allowing quicker and more efficient harvest of an important natural resource. Other uses include ornamental gardens, golf courses, and parks.

6. How widespread is the use of sewage sludge, and how many farms use biosolids?

About 7.2 million dry tons of sewage sludge are used or disposed of annually in the United States. About 55% of that is applied to the land. The Agency estimates that sewage sludge is applied to less than 1% of available agricultural land in the United States annually. The remaining 45% is disposed of in municipal solid waste landfills, surface disposal units, or incineration facilities.

7. Are biosolids safe?

EPA believes that the Part 503 Standards for use or disposal of sewage sludge are protective of public health and the environment. In 1996, the National Academy of Sciences (NAS) reviewed practices, public health concerns and regulatory standards, and concluded that the use of these materials in the production of crops for human consumption when practiced in accordance with existing federal guidelines and regulations, presents negligible risk to the consumer, to crop production and to the environment. In 2002, the NAS again reviewed EPA's sewage sludge regulations and public health concerns and concluded that there is no documented scientific evidence that the Part 503 rule has failed to protect public health. However, the NAS also concluded that additional scientific work is needed to reduce persistent uncertainty about the potential for adverse human health effects from exposure to biosolids. The EPA believes that the current regulations are protective, but there is much we do not understand. EPA recognizes that uncertainty persists and new challenges are emerging so we are working proactively to strengthen the science and fill the gaps in our knowledge.

8. What is the Agency’s position on the use of biosolids?

EPA believes that the Part 503 standards for use or disposal of sewage sludge are protective of public health and the environment. EPA supports biosolids management in full compliance with the regulations. Biosolids management options allowable under Part 503 include land application, surface disposal, and incineration. The choices regarding which management options to use are local decisions subject to state and federal regulations.

9. Where can I find out more about the regulations?

The biosolids rule is described in the EPA publication [A Plain English Guide to the EPA Part 503 Biosolids Rule](http://www.epa.gov/owm/mtb/biosolids/503pe/index.htm) (<http://www.epa.gov/owm/mtb/biosolids/503pe/index.htm>). This guide describes the Part 503 rule for the general reader. The guide is also available in hard copy.

EPA has also prepared [A Guide to the Biosolids Risk Assessments for the EPA Part 503 Rule](http://www.epa.gov/owm/mtb/biosolids/503rule/index.htm) (<http://www.epa.gov/owm/mtb/biosolids/503rule/index.htm>) which shows the many steps followed to develop the scientifically defensible safe set of rules.