

The deputy assistant administrator, Joel Beauvais, signed the following draft criteria document on May 19, 2016 and EPA is submitting it for publication in the *Federal Register* (FR). While we have taken steps to ensure the accuracy of this Internet version, it is not the official version of the health advisory. Please refer to the official version in a forthcoming FR publication, which will appear on the Government Printing Office's FDsys website (<http://fdsys.gpo.gov/fdsys/search/home.action>) and on Regulations.gov (<http://www.regulations.gov>) in Docket No. EPA-HQ-OW-2014-0138.

Once the official version of this document is published in the FR, this version will be removed from the Internet and replaced with a link to the official version.

ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OW-2014-0138; FRL_XXXX-X]

Lifetime Health Advisories and Health Effects Support Documents for Perfluorooctanoic Acid and Perfluorooctane Sulfonate

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of Availability.

SUMMARY: The Environmental Protection Agency (EPA) announces the release of lifetime health advisories (HAs) and health effects support documents for Perfluorooctanoic Acid (PFOA) and Perfluorooctane Sulfonate (PFOS). EPA developed the HAs to assist federal, state, tribal and local officials, and managers of drinking water systems in protecting public health when these chemicals are present in drinking water. EPA's HAs, which identify the concentration of PFOA and PFOS in drinking water at or below which adverse health effects are not anticipated to occur over a lifetime of exposure, are: 0.07 parts per billion (70 parts per trillion) for PFOA and PFOS. HAs are non-regulatory and reflect EPA's assessment of the best available peer-reviewed science. These HAs supersede EPA's 2009 provisional HAs for PFOA and PFOS.

FOR FURTHER INFORMATION CONTACT: Jamie Strong, Health and Ecological Criteria Division, Office of Water (Mail Code 4304T), Environmental Protection Agency, 1200 Pennsylvania Avenue NW, Washington, DC 20460; telephone number: (202) 566-0056; email address: strong.jamie@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. How Can I Get Copies of This Document and Other Related Information?

1. Docket. EPA has established a docket for this action under Docket ID No. EPA-HQ-OW-2014-0138. Publicly available docket materials are available either electronically through www.regulations.gov or in hard copy at the Water Docket in the EPA Docket Center, (EPA/DC) EPA West, Room 3334, 1301 Constitution Ave., NW, Washington, DC. The EPA Docket Center Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the Water Docket is (202) 566-2426.

2. Electronic Access. You may access this Federal Register document electronically from the Government Printing Office under the “Federal Register” listings FDSys (<http://www.gpo.gov/fdsys/browse/collection.action?collectionCode=FR>).

II. What are Perfluorooctanoic Acid and Perfluorooctane Sulfonate and Why is EPA Concerned About Them?

PFOA and PFOS are fluorinated organic chemicals that are part of a larger group of chemicals referred to as perfluoroalkyl substances. They were used to make carpets, clothing, fabrics for furniture, paper packaging for food and other materials (e.g., cookware) that are

resistant to water, grease or stains. They are also used for firefighting at airfields and in a number of industrial processes. Both PFOA and PFOS are persistent in the environment and in the human body. Over time both chemicals have become widely distributed in the environment and have accumulated in the blood of humans, wildlife, and fish. Studies indicate that exposure to PFOA and PFOS over certain levels may result in adverse health effects, including developmental effects to fetuses during pregnancy or to breast-fed infants (e.g., low birth weight, accelerated puberty, skeletal variations), cancer (e.g., testicular, kidney), liver effects (e.g., tissue damage), immune effects (e.g., antibody production and immunity), and other effects (e.g., cholesterol changes).

III. What are Health Advisories?

Under the Safe Drinking Water Act, EPA may publish HAs for contaminants that are not subject to any national primary drinking water regulation. SDWA section 1412(b)(1)(F). EPA develops HAs to provide information on the chemical and physical properties, occurrence and exposure, health effects, quantification of toxicological effects, other regulatory standards, analytical methods, and treatment technology for drinking water contaminants. HAs describe concentrations of drinking water contaminants at which adverse health effects are not anticipated to occur over specific exposure durations (e.g., one-day, ten-days, and a lifetime). HAs serve as informal technical guidance to assist federal, state and local officials, as well as managers of public or community water systems in protecting public health. They are not regulations and should not be construed as legally enforceable federal standards. HAs may change as new information becomes available.

IV. Information on the Drinking Water Health Advisories for PFOA and PFOS

EPA's HA levels, which identify the concentration of PFOA and PFOS in drinking water at or below which adverse health effects are not anticipated to occur over a lifetime of exposure, are: 0.07 parts per billion (70 parts per trillion) for PFOA and PFOS. Because these two chemicals cause similar types of adverse health effects, EPA recommends that when both PFOA and PFOS are found in drinking water the combined concentrations of PFOA and PFOS be compared with the 0.07 part per billion HA level.

EPA's lifetime HAs are based on peer-reviewed toxicological studies of exposure of animals to PFOA and PFOS, applying scientifically appropriate uncertainty factors. The development of the HAs was also informed by epidemiological studies of human populations that have been exposed to PFOA and PFOS. The HAs are set at levels that EPA concluded will not result in adverse developmental effects to fetuses during pregnancy or to breast-fed infants, who are the groups most sensitive to the potential harmful effects of PFOA and PFOS. EPA's analysis indicates that exposure to these same levels will not result in adverse health effects (including cancer and non-cancer) to the general population over a lifetime (or any shorter period) of exposure to these chemicals.

EPA's HAs for PFOA and PFOS are supported by peer reviewed health effects support documents that summarize and analyze available peer reviewed studies on toxicokinetics, human epidemiology, animal toxicity, and provide a cancer classification and a dose response assessment for noncancer effects. On February 28, 2014, EPA released draft versions of these health effects support documents for a 60-day public comment period and initiated a contractor-led, independent public panel peer review process (79 FR 11429). The peer review panel meeting occurred on August 21-22, 2014, and included seven experts in the following areas:

epidemiology, toxicology (liver, immune, neurological and reproductive and developmental effects), membrane transport, risk assessment, pharmacokinetic models, and mode-of-action for cancer and noncancer effects (79 FR 39386). Comments submitted to EPA's public docket during the 60-day public comment period were provided to the peer reviewers ahead of the meeting for their consideration. A peer review summary report and other supporting documents may be found at: <http://www.regulations.gov> under the docket EPA-HQ-OW-2014-0138.

Dated:

Joel Beauvais,

Deputy Assistant Administrator, Office of Water.