DEPARTMENT OF PUBLIC HEALTH AND ENVIRONMENT

Solid and Hazardous Waste Commission/Hazardous Materials and Waste Management Division

6 CCR 1007-3

HAZARDOUS WASTE

Addition of Perfluorooctanoic acid (PFOA) and its anion perfluorooctanoate, and Perfluorooctane sulfonic acid (PFOS) and its anion, perfluorooctane sulfonate, to the Part 261, Appendix VIII List of Hazardous Constituents.

1) Appendix VIII of Part 261 is amended by adding the listings for Perfluorooctanoic acid (PFOA) and its anion perfluorooctanoate, and Perfluorooctane sulfonic acid (PFOS) and its anion, perfluorooctane sulfonate to read as follows:

Appendix VIII -- Hazardous Constituents

Common name	Chemical abstracts name	Chemical abstracts No.	Hazardous waste No.
*******	*******	*******	*******
Pentachlorophenol	Phenol, pentachloro-	87-86-5	See F0276
Perfluorooctanoate		**45285-51-6**	
Perfluorooctanoic acid (PFOA)	**pentadecafluorooctanoic acid**	**335-67-1**	
Perfluorooctane sulfonate		**45298-90-6**	
Perfluorooctane sulfonic acid (PFOS)	**heptadecafluorooctane sulfonic acid**	**1763-23-1**	
Phenacetin	Acetamide, N-(4-ethoxyphenyl)-	62-44-2	U187
*******	********	*******	******

2) Section 8.90 {Statement of Basis and Purpose for the Rulemaking Hearing of February 20, 2018} is added to Part 8 of the Regulations to read as follows:

Statement of Basis and Purpose
Rulemaking Hearing of February 20, 2018

8.90 Basis and Purpose.

Listing Perfluorooctanoic acid and its anion perfluorooctanoate, and Perfluorooctane sulfonic acid and its anion, perfluorooctane sulfonate, in Part 261, Appendix VIII

These amendments to 6 CCR 1007-3, Part 261 are made pursuant to the authority granted to the Solid and Hazardous Waste Commission in § 25-15-302(2), C.R.S.

The Colorado Hazardous Waste Regulations, 6 CCR 1007-3, Part 261, Subpart B, allow substances to be added to the list of hazardous constituents in the regulations, Part 261 Appendix VIII, if they have been shown in scientific studies to have toxic, carcinogenic, mutagenic or teratogenic effects on humans or other life forms. Hazardous constituents listed in the regulations may have impacts to human health or other life forms when released into the environment, and many of the hazardous constituents form the basis for identifying solid wastes as listed or characteristic hazardous wastes under the regulations.

This rule amends existing regulations of the Colorado Hazardous Waste Regulations (6 CCR 1007-3) to add perfluorooctanoic acid and perfluorooctane sulfonic acid, as well as their anions, perfluorooctanoate and perfluorooctane sulfonate respectively, to the list of hazardous constituents in Appendix VIII to Part 261 of the Colorado Hazardous Waste Regulations (6 CCR 1007-3). Addition of these chemicals to the Appendix VIII Hazardous Constituent list ensures any hazards associated with the release of perfluorooctanoic acid and/or perfluorooctane sulfonic acid to the environment at facilities that are either under an existing permit or order for corrective action, or that may have a future release of hazardous waste to the environment and be subject to a permit or order, will be adequately characterized and remediated as necessary to ensure protection of human health and the environment.

Overview of PFOA and PFOS

Perfluorooctanoic acid (PFOA) and Perfluorooctane sulfonic acid (PFOS) are synthetic, eight carbon non-polymer organic compounds that are part of a group of toxic chemicals known as perfluoroalkyl and polyfluoroalkyl substances (PFAS). Perfluorinated alkyl substances like PFOA and PFOS are fully fluorinated carbon chain molecules with a basic structure consisting of a chain (or tail) of two or more carbon atoms with a charged functional group head attached at one end. Fluorine atoms are attached to all possible bonding sites along the carbon chain of the tail, except for one bonding site on the last carbon where the functional group head, a carboxylic acid for PFOA and a sulfonic acid for PFOS, is attached. PFOA and PFOA are extremely stable compounds, with their stability derived from the carbon-fluorine bond, the shortest and strongest covalent bond in organic chemistry. They are solid, white powders at room temperature and have low vapor pressures. These compounds possess hydrophobic, oleophobic and surfactant properties and are strong acids that readily dissociate in water. Once released into the

environment, PFOA and PFOS typically exist as their negatively charged anions, perfluorooctanoate and perfluorooctane sulfonate. The negative anions have different physical or chemical properties that generally control their fate and transport and potential for human health and ecological effects. For example, the perfluorooctanoate anion is highly water soluble with a negligible vapor pressure, whereas perfluorooctanoic acid has very low water solubility and a sufficient vapor pressure to partition out of water into air.

Due to their physical and chemical properties, PFOA and PFOS have a wide variety of uses, and have been produced in the United States since the 1940's. They are used in some industrial processes and a variety of consumer products to make them resistant to heat, oil, stains, grease and/or water. PFOS and PFOA are byproducts of other commercial products meaning they are released in the environment when other products are made, used, or discarded. PFOA has been used historically as a surfactant in the emulsion polymerization of fluoropolymers (e.g. manufacturing of Teflon) and as an additive in other protective coatings. PFOA is also generated as a degradation product of other perfluorinated compounds. PFOS is used in a variety of surface protection products, including textiles and leather, paper and food products, metal plating and clothing, and other materials to make them stain, soil and/or water resistant (e.g. Scotchguard). PFOS has also historically been an ingredient in firefighting foams (e.g. aqueous film forming foam (AFFF)) and alcohol-type concentrate foams.

Due to industry and regulatory concerns about the potential health and environmental impacts of these compounds, there has been a reduction in the manufacture and use of PFOA and PFOS in the United States. In May 2000, 3M the principal worldwide manufacturer and sole US manufacturer of PFOS announced a voluntary phase-out of perfluorooctanyl chemistries, which included PFOS and PFOA. Phasing out of these chemicals by 3M was reportedly nearly complete in 2002 with the remaining production terminated by 2008. Additionally, the US EPA initiated a PFOA Stewardship Program in 2006 aimed at committing eight major manufacturing companies to reducing PFOA and other related compound emissions and their use in manufacturing products. The Stewardship Program was very successful, meeting a 95% reduction by 2010 and elimination by 2015. Despite these phase out initiatives however, PFOA and PFOS continue to be produced internationally in China and Russia. Additionally, due to the long shelf life of PFOS-based AFFF foam, these compounds may still be stored and in use at various facilities. Exposure to PFOA and PFOS in the United States remains possible due to their legacy uses, existing and legacy uses on imported goods, degradation of precursors, and high persistence in the environment and human body.

Environmental releases of PFOS and PFOA include air emissions and dispersion from industrial sources, spills of chemical products or wastes, and the disposal of manufacturing or consumer wastes and wastewaters. For example, leachate from some municipal solid waste landfills has been shown to be a source of PFAS release to the environment, with the presence of some PFAS reportedly due to the disposal of consumer goods treated with water repelling or stain resistant coating. Additionally, discharges of consumer and industrial PFAS-containing wastes, including landfill leachates and firefighting foams, to wastewater treatment plants (WWTP) results in other possible releases to the environment. WWTPs generally do not treat PFAS like PFOA and PFOS, passing them through to surface and/or groundwater sources, or to the soil if sewage sludge is subsequently applied to agricultural land through biosolids application. Finally, firefighting foam used for extinguishing flammable liquid fires, including AFFF, comprise another significant

source of environmental release. These releases include not only use of the foam during firefighting or training exercises, but also releases due to equipment malfunctions, leaks in distribution systems and firefighting foam system testing and calibration checks.

PFOS and PFOA are mobile, persistent and bioaccumulative and are not known to degrade in the environment. They are considered terminal PFAS meaning other long chain PFAS will degrade to them, but no further degradation products will form from them under environmental conditions once they are released. PFOS and PFOA have been detected in water, wildlife, and humans worldwide. The primary way people come in contact with these compounds is through ingestion of food, and water (drinking, cooking, or incidental use of contaminated water). PFOA and PFOS are not removed by heating water and can increase in concentration when the water is boiled. Because these compounds generally have low vapor pressure, releases of them to the environment are not expected to be present in air and inhaled. However, inhalation can be a significant route of exposure if it occurs near large manufacturing sources of the compounds and some exposure may also occur through household dust inhalation, or ingestion through hand to mouth transfer for children. Additionally, dermal contact is not a significant pathway for human exposure.

Health Effects

The US EPA considers PFOA and PFOS to be emerging contaminants due to their perceived, potential, or real threat to human health and the environment. It issued Drinking Water Lifetime Health Advisories (HAs) for the compounds in 2016 (see https://www.epa.gov/ground-water-and-drinking-water/drinking-water-health-advisories-pfoa-and-pfos). EPA develops health advisories to provide information on contaminants that can cause human health effects and are known or anticipated to occur in drinking water. The HAs for PFOA and PFOS were based on best available peer-reviewed studies of the effects of PFOA and PFOS on laboratory animals (rats and mice) as well as epidemiological studies of human populations that have been exposed to PFAS. Scientists are not yet certain about the possible health effects resulting from human exposure to PFAS at levels typically found in our water and food, however PFOS and PFOA have been more widely studied than other PFAS. 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 breastfed infants, cancer, liver effects, immune effects, thyroid effects and other effects.

The scientific studies used by the US EPA in developing the HAs for PFOA and PFOS are available as "Health Effects Support Document for Perfluorooctanoic Acid (PFOA)" EPA 822-R-16-003 May, 2016 https://www.epa.gov/sites/production/files/2016-05/documents/pfoa_hesd_final_508.pdf and "Health Effects Support Document for Perfluorooctane Sulfonate (PFOS)" EPA 822-R-16-002 May 2016 https://www.epa.gov/sites/production/files/2016-05/documents/pfos_hesd_final_508.pdf. These documents detail the available scientific studies, risk assessment guidance and toxicological factors that show PFOA and PFOS have toxic, carcinogenic, mutagenic or teratogenic effects on humans or other life forms. Specific conclusions regarding the human health and animal studies in the support documents for PFOA and PFOS are briefly summarized below.

Adverse health effects observed following exposure to PFOA and PFOS are the same or similar and include effects in humans on serum lipids, birth weight, and serum antibodies. Additionally these compounds may affect the developing fetus and child, including possible changes in growth,

learning, and behavior. These effects also include decreased fertility and interference with the body's natural hormones, increased cholesterol, effects on the immune system, and increased cancer risk.

Human Studies

Human epidemiology data report associations between PFOA exposure and high cholesterol, increased liver enzymes, decreased vaccination response, thyroid disorders, pregnancy-induced hypertension and preeclampsia and cancer (testicular and kidney). Epidemiology data report associations between PFOS exposure and high cholesterol and reproductive and developmental parameters.

Animal Studies

Animal studies on PFOS and PFOA demonstrate similar health effects. Additionally, some of the animal studies show common effects on the liver, neonate development, and responses to immunological challenges. Long-term animal studies show that both compounds are also associated with tumors. For the most part, laboratory animals exposed to high doses of PFOA or PFOS have shown changes in the liver, thyroid, and pancreatic function, as well as some changes in hormone levels. Because animals and humans do not always process chemicals the same way, scientific methods are used to account for these differences and ensure their conclusions about chemicals are protective of the public. Neither PFOA nor PFOS are readily eliminated from the body; their respective half-lives are 4.1 and 8.67 years. Even short term exposures to these PFAS can result in a body burden that persists for years and that can increase with additional exposures.

EPA's risk assessment guidelines state that, as a general matter, a single exposure to a developmental toxin, at a critical time in development can produce an adverse effect. As such, EPA derived reference doses (RfDs) for both PFOA and PFOS based on developmental endpoints (reduced ossification and accelerated puberty in males for PFOA and decreased pup birth weight for PFOS). Because the RfDs for both PFOA and PFOS are based on similar developmental effects and are numerically identical, when these two chemicals occur at the same time and location in a drinking water source, a conservative and health-protective approach recommended by the EPA is to sum their exposure collectively.

While the associations for most epidemiology endpoints are mixed, the weight of evidence for human studies supports the conclusion that PFOS and PFOA exposure is a human health hazard. At this time, the US EPA concludes that the human health studies are adequate for use qualitatively in the identification hazard and are supportive of the findings in laboratory animals. PFOS and PFOA have been shown in scientific studies to be toxic and potentially carcinogenic to humans satisfying the regulatory criteria for listing.

<u>Regulatory Evaluation</u>

These amendments incorporate PFOA and PFOS and their respective anions into the list of hazardous constituents in the Colorado Hazardous Waste Regulations (6 CCR 1007-3), Part 261 Appendix VIII. Many hazardous constituents form the basis for characteristic and/or listed hazardous waste in the regulations (see 6 CCR 1007-3, Part 261 Appendix VII), and solid wastes may be listed if, after considering several factors, they contain any Appendix VIII hazardous constituents and pose a substantial present or potential hazard to human health or the environment

when improperly treated, stored, transported or disposed of, or otherwise managed in accordance with 6 CCR 1007-3, Section 261.11(3).

These amendments are designed only to incorporate PFOA and PFOS into the regulations as hazardous constituents. Additonal hazardous waste listings or characteristics based on PFOA or PFOS are not being proposed with these amendments. Under these amendments, if PFOA or PFOS are released into the environment, the release would not be considered a release of a hazardous waste unless the solid waste released was already a listed or characteristic hazardous waste as currently defined in the regulations.

However, a facility that is seeking, that has or had, or that should have had a hazardous waste permit, or that has had a release of hazardous waste to the environment, must complete corrective action at the facility as necessary to characterize and assess the release of any Appendix VIII hazardous constituents to the surface water, groundwater, or soil in accordance with 6 CCR 1007-3, Section 100.41(d) (RCRA 3004(u)) or 6 CCR 1007-3, Section 265.5 (RCRA 3008(h)). Listings of PFOS and PFOA as hazardous constituents in the Colorado Hazardous Waste Regulations (6 CCR 1007-3) under these amendments will therefore provide greater protection to human health and the environment at these facilities because these compounds will need to be considered and included as necessary in site-wide corrective action. That is, any release of PFOA or PFOS at a facility under a hazardous waste order or permit, must be characterized and assessed, and if necessary addressed though remedial action(s) to protect human health and/or the environment.

Corrective action at hazardous waste management facilities under these amendments will be implemented in accordance with the regulations using existing Hazardous Materials and Waste Management Division policy. No changes in corrective action policy are anticipated or needed to address the addition of PFOA and PFOS to Appendix VIII of the Colorado Hazardous Waste Regulations (6 CCR 1007-3). Sampling and analytical methods for the detection and identification of PFOS and PFOA in groundwater, surface water and soil are available using EPA Method 537 Liquid Chromotography Tandem Mass Spectroscopy, which possess detection limits equal to 10 ppt in drinking water. EPA's advisory level of 70 ppt for combined PFOA and PFOS in drinking water is also considered protective under unrestricted use or a level at which adverse health effects are not anticipated to occur over human lifetime. Additionally, advancement of analytical technologies, including real-time analysis are under development. Available treatement technologies for PFOS or PFOA soil contamination include excavation, in-situ binding to reduce leaching, and incineration. Available treatment technologies for surface and groundwater include membrane (reverse osmosis) and Granular Activated Carbon treatment.