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International Commercial & Trade
Tokyo

Client Alert
28 February 2024

Recent Developments on Regulations on Perfluoroalkyl and Polyfluoroalkyl Substances (PFAS) in Japan

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Perfluoroalkyl and Polyfluoroalkyl Substance ("PFAS") is a generic term used for approximately 10,000 organofluorine compounds. Because of various properties they possess that are not found in other substances — such as heat resistance, chemical stability and chemical resistance — they have been used in a wide range of applications, including lithium-ion batteries, semiconductor manufacturing, automotive parts, various machinery and equipment and medicine.

Perfluorooctanesulfonic acid ("PFOS") and perfluorooctanoic acid ("PFOA") have been the most widely used PFASs. They are not biodegradable and have high bodily accumulation potentials, prompting global discussion on curtailment of their use. Due to their toxicity and environmental persistence, PFOS and its salts have been listed in Annex B (Restricted) under the Stockholm Convention on Persistent Organic Pollutants ("POPs Convention"). It was decided at the 4th Meeting of the Conference of Parties to the POPs Convention in May 2009. PFOA and its salts and PFOA-related substances would be added to Annex A (Eliminated) of the POPs Convention at the 9th Meeting of the Conference of Parties in May 2019[1]. It was later decided that perfluorohexanesulfonic acid ("PFHxS") and its salts and PFHxS-related substances would be added to Annex A at the 10th Conference of the Parties in June 2022. Furthermore, restrictions on long-chain perfluorocarboxylic acids ("PFCAs") with 9-21 carbon atoms are currently under discussion by the POPs Convention's Review Committee ("POPRC"), which is scheduled to consider a risk management assessment of these substances at its next meeting.

1. Act on Regulation of the Manufacture and Evaluation of Chemical Substances[2]

The Act on Regulation of the Manufacture and Evaluation of Chemical Substances ("ARMECS") aims to prevent environmental pollution by chemical substances that may endanger human health or interfere with the habitats and growth of animals and plants. The Act stipulates regulatory measures to be taken in response to various properties of chemical substances (e.g. biodegradability, accumulation potential, toxicity and environmental persistence).

Under the Act, the following PFASs are currently controlled or scheduled to be controlled:

[1] https://www.meti.go.jp/shingikai/kagakubusshitsu/shinsa/pdf/233_01_00.pdf
[2] An English translation of the Act is available at:
https://www.japaneselawtranslation.go.jp/en/laws/view/3350

- PFOS and its salts: designated as a Class 1 Specified Chemical Substance in 2010.

- PFOA and its salts: designated as a Class 1 Specified Chemical Substance in 2021. Isomeric forms of PFOA and their salts are also scheduled to be designated as Class 1 Specified Chemical Substances in late 2024. PFOA-related substances are also scheduled to be designated as Class 1 Specified Chemical Substances in late 2024.

- PFHxS, isomeric forms of PFHxS and their salts: designated as a Class 1 Specified Chemical Substance on February 1, 2024[3].

- Other substances: the Ministry of Environment (MOE) explicitly mentioned in July 2023 that it will continue monitoring developments in the relevant discussions under the Stockholm Convention.

Engaging in the business of manufacturing or unlicensed importation of Class 1 Specified Chemical Substances is prohibited under the ARMECS[4]. Once a substance is designated as a Class 1 Specified Chemical Substance and Cabinet Order specifies products in which Class 1 Specified Substances is used, importation of the substance itself and any products specified by a Cabinet Order is prohibited[5]. In addition, use of a Class I Specified Chemical Substance for any purpose other than those specified by Cabinet Order ("Essential Use") is prohibited, except for testing and research[6]. To date, no Essential Use has been specified by Cabinet Order[7].

However, in order to strike a balance between the need for regulation and the impact of the sudden change on the market and businesses, the use of PFOS or PFOA-containing fire extinguishers (including firefighting foams) that are already installed or on the market will be permitted "for the time being" if they comply with the Ministerial Ordinance stipulating technical standards and labeling requirements[8]. Similarly, the use of fire extinguishers (including firefighting foams) containing isomeric forms of PFOA and their salts, PFOA-related substances, PFHxS or isomeric forms of PFHxS and their salts that are already installed or on the market are scheduled to be permitted if they comply with the Ministerial Ordinance stipulating technical standards and labeling requirements[9].

2. Water Pollution Prevention Act[10]

The Water Pollution Prevention Act ("WPPA") requires that water discharged from workplaces with specified facilities ("Specified Facilities") contain harmful substances in concentrations below effluent standards[11]. The effluent

[3] A prohibition on the importation of products designated by Cabinet order in which PFHxS is used is scheduled to come into force on June 1, 2024.
[4] Manufacture is prohibited under Article 17 while unlicensed importation is prohibited under Article 22.
[5] ARMECS, Article 24.
[6] ARMECS, Article 25.
[7] PFOA-related substances are scheduled to be designated for Essential Use (i.e., use of PFOI for the manufacture of PFOB for medical use and use of 8:2 FTOH for the manufacture of PFMA).
[8] ARMECS, Article 28 and Article 3 of the Supplementary Provisions of the ARMECS Enforcement Ordinance.
[9] https://www.meti.go.jp/shingikai/kagakubusshitsu/anzen_taisaku/pdf/2023_03_01_01.pdf
[10] An English translation of the Act is available at: https://www.japaneselawtranslation.go.jp/en/laws/view/2815
[11] Water Pollution Prevention Act, Article 12.

standards establish maximum permissible levels for specific harmful substances[12]. However, as PFASs are currently not designated as harmful substances, these obligations do not apply to Specified Facilities discharging water containing PFASs.

Furthermore, the WPPA obliges an operator of a factory or workplace with designated facilities ("Designated Workplace") to immediately take emergency measures to prevent the discharge of or permeation of the environment with water containing harmful substances or designated substances ("Designated Substances"). The WPA also requires that an operator promptly report any harm to public health or damage that is likely to negatively affect living conditions to the relevant prefectural governor[13]. In February 2023, the MOE added PFOA and PFOS and their salts to the list of Designated Substances, requiring operators of Designated Workplaces to take emergency measures to prevent the discharge of or permeation of the environment with water containing any of these substances in the event of an accident.

Finally, in May 2020, the MOE designated PFOS and PFOA as items requiring monitoring and established a provisional guideline concentration of no more than 50ng/l (0.00005 mg/l) for PFOS and PFOA in public drinking water and groundwater. Items requiring monitoring are defined as "substances relevant to the protection of human health, but for which environmental standards should not immediately be established in light of the status of their detection in public bodies of water, etc., and with regard to which efforts to accumulate knowledge should continue."[14] The provisional guideline concentration does not impose a statutory or regulatory obligation, and as such no penalty exists for exceeding it. As mentioned above, the MOE announced in July 2023 that they would continue to monitor relevant developments in the discussions of international forums.

Please note that if a court finds a causal relationship between the presence of PFOA/PFOS in drinking water / discharged water and damage to human health, a discharger may be held legally liable for any damage under the Civil Code of Japan[15] regardless of the regulatory status of PFAS under the Water Pollution Prevention Act.

3. Soil Contamination Countermeasures Act[16]

The Soil Contamination Countermeasures Act ("SCCA") regulates soil contamination by specified hazardous substances ("Specified Hazardous Substances") and stipulates measures that must be taken to prevent them from harming human health in Japan. It obliges (i) an owner, manager or possessor ("owner, etc.") of the site of a decommissioned Specified Facility at which a specified hazardous substance was used, (ii) a person that intends to change the characteristics of a parcel of land which is equal to or larger than 3000 m^2[17] and (iii) an owner, etc. of land contaminated with a Specified

[12] Water Pollution Prevention Act, Article 3(2).
[13] Water Pollution Prevention Act, Article 14-2(2).
[14] https://www.env.go.jp/water/impure/kanshi.html (Japanese only)
[15] An English translation of the Civil Code is available at: https://www.japaneselawtranslation.go.jp/en/laws/view/4314
[16] An English translation of the Act is available at: https://www.japaneselawtranslation.go.jp/en/laws/view/4448
[17] A “change in land characteristics” under Article 4 of the SCCA generally refers to any act that changes the characteristics of a parcel of land (e.g., residential development, excavation, soil extraction or land clearing).

Hazardous Substance that poses a risk of harm to human health to conduct an investigation of the state of the land's soil contamination and report the results thereof to the prefectural governor[18].

Furthermore, if a prefectural governor finds that the soil on a parcel of land does not conform to soil contamination standards set by the MOE or falls under standards specified by Cabinet Order as being harmful to or posing a risk of harm to human health, he/she is required to designate the parcel as contaminated by a Specified Hazardous Substance[19]. If the prefectural governor makes such a designation, he/she may, to the extent necessary to prevent the contamination from causing harm to human health, order the owner, etc. of the land to take remedial measures[20]. If the owner, etc. of land that has received such an order from a prefectural governor finds that the contamination of the soil with a Specified Hazardous Substance is due to an act by another person or entity, he/she can bring a claim for reimbursement of the costs of the remediation measures against that person or entity[21].

Importantly, no PFAS is currently specified as a Specified Hazardous Substance, nor is one specified under the soil contamination standards. Therefore, none of the above obligations currently apply to a case of soil contamination by a PFAS. However, a strong possibility exists that the MOE will establish guidelines and/or soil contamination standards for PFASs in the future as a result of its ongoing research and analysis. It will also consider global regulatory trends and the industrial impact of regulating PFASs under the relevant regulations, including the SCCA, as well as the possibility of mitigating these impacts by using alternative substances.

Even if an owner, etc. of land finds that it has been contaminated with a PFAS due to the owner, etc. 's activities, he/she is currently not required to conduct an investigation or remediate the contamination. However, if the contamination leaches into the groundwater and causes harm to the health of any third party (e.g., residents of surrounding land), the owner, etc. could be liable found liable in tort[22].

An owner, etc. of land is not legally required to include information on PFAS contamination in a land purchase/sale agreement in Japan. That being said, if the state of the land's soil contamination is found by a court to constitute a material factor that a potential buyer of the land must be able to consider, a fiduciary duty to inform and explain the contamination may be imposed on a seller under Article 1(2) of the Civil Code regardless of whether PFAS has been designated as a Specified Hazardous Substance under the SCCA. Alternatively, the seller may be found legally liable for the land's non-conformity with the intended purpose of its use by the buyer, and the seller may need to compensate the buyer for damage attributable to PFAS contamination[23].

[18] Soil Contamination Countermeasures Act, Article 3-5.
[19] Soil Contamination Countermeasures Act, Article 6.
[20] Soil Contamination Countermeasures Act, Article 7.
[21] Soil Contamination Countermeasures Act, Article 8.
[22] Civil Code, Article 709.
[23] Civil Code, Articles 415 and 564.