November 9, 2022

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Commissioner Melanie Loyzim
Maine Department of Environmental Protection
State of Maine
17 State House Station
Augusta, Maine 04333

Re: Maine Department of Environmental Protection Second Concept Draft, Maine PFAS in Products Program

Dear Commissioner Loyzim:

Merck & Co. appreciates the opportunity to comment on the Maine Department of Environmental Protection's (DEP's) Second Concept Draft for the Maine PFAS in Products Program implementing **LD 1503, "An Act to Stop Perfluoroalkyl and Polyfluoroalkyl Substances Pollution."**

Merck & Co. manufactures both human and animal health products regulated by the U.S. Food and Drug Administration, the U.S. Environmental Protection Agency, or the U.S. Department of Agriculture under federal laws including the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 et seq., the Public Health Service Act, 42 U.S.C. § 201 et seq., the Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. § 201 et seq., and their respective implementing regulations. While regulatory responsibility is divided between the above agencies, these products are all regulated with strict pre-market product reviews focusing on product safety and are subject to intense federal oversight.

Under 38 MRS § 1614(4)(a), the following are exempt from all requirements of 38 MRS § 1614: "product[s] for which federal law governs the presence of PFAS in the product in a manner that preempts state authority." Under this section of the Maine law, as well as general principles of federal preemption, drugs, biologics, and devices – for humans and animals – regulated by the federal government are out of scope of 38 MRS § 1614, as is their packaging. This includes an exemption from Maine's reporting requirement with a current statutory deadline of January 1, 2023.

On an October 27, 2022 webinar, Department of Environmental Protection ("Department") officials invited the public to engage with the Department on whether it has thus far correctly interpreted the scope of its legal authority and obligations under 38 MRS § 1614. A Department official stated that "at this time" the Department believes drugs, medical devices, and packaging are in scope of the statute. This is an incorrect interpretation of the Department's authority and the statute as written.

We would appreciate clarification from the DEP, including legal rationale, as to the exemption language. As we share above, we believe the exemption language included in LD 1503, exempts our human and animal health products.

Merck & Co. appreciates the regulatory challenges that come with implementing LD 1503, especially given the broad definition of PFAS, and is committed to working with the state. We look forward to DEP's consideration of these comments in its forthcoming rulemaking processes and would be happy to schedule a meeting or discussion should any clarification or further information be needed.

Sincerely,

Joan Tell, Ph.D.

Joan Griffith Tell, Ph.D.
Director, Product Stewardship
Merck & Co., Inc.