SYDDANSK UNIVERSITET
UNIVERSITY OF SOUTHERN DENMARK

Institut for Sundhedstjenesteforskning
Forskningsenheden Miljømedicin
J.B. Winsløws Vej 17A, 2. sal
DK-5000 Odense C

Tel. +45 6550 1000
Fax +45 6550 3980
www.sdu.dk/ist/environ

ECHA

Re: Per- and polyfluoroalkyl substances (PFAS) [#RESTOD-PFAS-1#]

30 June 2023

Dear Sir/Madam,
We are aware of ECHA's current consideration of a restriction proposal in regard to the per- and polyfluoroalkyl substances (PFASs).
In this connection, we wish to draw your attention to the fact that the tolerable exposure limits for the most prevalent of these compounds, as developed by the European Food Safety Authority (EFSA) are erroneous, i.e., much too high for the two main compounds, PFOS and PFOA.
We made EFSA aware of the problems early in the preparation of the EFSA opinion, but EFSA decided nonetheless to stick to an original plan. We have therefore submitted our concerns to a scientific journal, where they have now been published:
https://ehjournal.biomedcentral.com/articles/10.1186/s12940-023-00985-w.
Briefly, EFSA disregarded a large study, conducted by us and other colleagues, a individual data points could not be extracted by scanning a data plot. Instead EFSA relied on a smaller study of younger children that resulted in higher benchmark results, in part because EFSA chose to ignore the outcome variable associated with the lowest BMDs.
EFSA also assumed equal weight-based toxicity of the four PFAS compounds considered, which is of dubious validity. We instead provided statistical approaches to determine data-based potency differences.
In addition to submitting our comments to EFSA in 2020, we have of course now shared our published article with EFSA. We have not received a reply so far.
More recently, the U.S. Environmental Protection Agency (EPA) has calculated benchmark dose results individually for PFOS and PFOA. The findings were published last year:
https://www.epa.gov/sdwa/drinking-water-health-advisories-genx-chemicals-and-pfbs. We have contributed to EPA's calculations by providing results that the EPA could insert into the algorithms used by the agency. Part of the default procedures includes a 10-fold uncertainty factor. The EPA limits for PFOS and PFOA are much lower than EFSA's. Part of the difference is due to the uncertainty factor, but a larger part is due to the different analytical approaches. We believe that the EPA has appropriately applied the data available, and by the most appropriate methods.
In conclusion, we wish to make ECHA aware that EFSA's proposed tolerable limits for the four PFASs are too high and that a more appropriate use of the benchmark approach and available data will result in much lower exposure limits, at least for the PFASs that have been studied in most detail.
We are of course willing to answer any questions that you may have in this regard.

Thank you,
Esben Budtz-Jørgensen, PhD, Professor of Biostatistics (email: [redacted]@sund.ku.dk)
Philippe Grandjean, MD, Professor of Environmental Medicine (email: [redacted]@sdu.dk)