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Testimony
of
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Before the

U.S. House of Representatives

Energy and Commerce Committee
Subcommittee on Health

On the

"Keep Food Containers Safe from PFAS Act of 2019"

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Good morning, Chairwoman Eshoo, Ranking Member Burgess, and members of the Subcommittee. My name is Paul DeLeo, and I am a Principal at Integral Consulting Inc., which is an international science and engineering consulting firm, founded in 2002, serving a wide variety of clients across the public and private sectors. We have approximately 150 employees distributed nationwide, and I am based in Annapolis, Maryland. I am here today to express my scientific opinion, but no client or any other entity has retained me to offer this opinion.

I am pleased to be here today to share my perspective on H.R. 2827, the Keep Food Containers Safe from PFAS Act of 2019. H.R. 2827 would amend the Federal Food, Drug, and Cosmetic Act (FFDCA) to deem perfluoroalkyl or polyfluoroalkyl substances (PFAS) used as a food contact substance (FCS) to be unsafe and therefore treated as adulterated. My colleagues and I came to the attention of the Subcommittee based on our expertise with PFAS, in particular recent peer-reviewed scientific publications on the topic.[1,2] Additionally, I worked for six and a half years from 2000 to 2007 at the Food and Drug Administration (FDA) in the Office for Food Additive Safety, which is responsible for the regulation of food contact substances. So, I have firsthand knowledge of the regulatory process for the safety assessment of food contact substances and the staff who perform those safety assessments.

I testify today in opposition to H.R. 2827 as unnecessary, overly broad, and contrary to well-established scientific processes for the pre-market evaluation of chemical safety in the United States.

HR. 2827 Is Unnecessary

FDA has had responsibility for the regulation of food additives since 1938. As FDA notes on its website, "[p]rior to 2000, the FDA authorized the use of food contact substances through the food additive petition process, which resulted in a regulation establishing safe conditions of use in Title 21 of the Code of Federal Regulations. Consequently, there are a number of regulations for food contact substances as indirect food additives in the Code of Federal Regulations. Since 2000, the FDA authorizes the use of food contact substances through the Food Contact Notification (FCN) program.

The Inventory of Effective Food Contact Substance Notifications (FCN Inventory) is a publicly available database of all uses of food contact substances authorized through the

[1] Luz, A.L., J.K. Anderson, P. Goodrum, and J. Durda. 2019. Perfluorohexanoic acid toxicity, part I: Development of a chronic human health toxicity value for use in risk assessment. *Regulatory Toxicology and Pharmacology* 103:41-55. https://doi.org/10.1016/j.yrtph.2019.01.019.

[2] Anderson, J.K., A.L. Luz, P. Goodrum, and J. Durda. 2019. Perfluorohexanoic acid toxicity, part II: Application of human health toxicity value for risk characterization. *Regulatory Toxicology and Pharmacology* 103:10-20. https://doi.org/10.1016/j.yrtph.2019.01.020.

FCN program.[3] According to the FDA online database for the FCS Inventory,[4] FDA has received approximately 2,000 food contact notifications since the program was brought online in fiscal year 2000. According to research by the Environmental Defense Fund, as of October 22, 2019, there were 70 effective food contact notifications for PFAS, though seven of those have been voluntarily suspended by the manufacturer.[5] In addition, a search of the FDA database Indirect Additives Used in Food Contact Substances using the search term "fluor" returns 48 substances, some of which might not meet the PFAS definition in H.R. 2827. Consequently, the current universe of regulated PFAS food contact substances is approximately 100 substances. This is a modest number of substances, all of which have been evaluated by FDA staff for safety *prior* to being permitted to come to the market as a food contact substance.

It is important to note that there are substantial data requirement for an FCN and the agency has the authority to object to any FCN if it does not believe the proposed use of the food contact substance is safe. According to FDA guidance documents, an FCN may include a variety of short term and chronic toxicity studies such as those regarding carcinogenicity, or developmental and reproductive toxicity.[6,7] In addition, the agency has the discretion to request additional data from the notifier to confirm their safety assessment before the food contact substance is permitted on the market.

In addition to the FCN program, there are other provisions already in place to insure the safety of food contact substances. For example, the FFDCA gives the agency the authority under Section 409(h)(3) to require or accept submission of a food additive petition for the food contact substance in cases where it is necessary to provide adequate assurance of safety of that substance. It does not appear these provisions have been exercised for PFAS. Also, agency staff have the opportunity to request more information from the submitter of the food contact notification, or to object to that submission entirely.

Once food contact substances are on the market, FDA has the ability to track the safety of these chemicals and has a record of doing so for PFAS. For at least 15 years, scientists at

[3] https://www.fda.gov/food/chemicals/and-polyfluoroalkyl-substances-pfas
[4] https://www.accessdata.fda.gov/scripts/fdcc/?set=FCN
[5] http://blogs.edf.org/health/2019/11/13/think-again-pfas-food-packaging-safety/#_ftnref2 [Accessed January 24, 2020]
[6] Draft Guidance for Industry: Regulatory Submissions to OFAS, Part V Food Contact Substance Submissions, https://www.fda.gov/regulatory-information/search-fda-guidance-documents/draft-guidance-industry-regulatory-submissions-ofas-part-v-food-contact-substance-submissions
[7] Guidance for Industry: Preparation of Food Contact Notifications for Food Contact Substances (Toxicology Recommendations), https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-preparation-food-contact-notifications-food-contact-substances-toxicology

FDA have been publishing peer-reviewed scientific papers regarding the potential for PFAS to migrate from food contact substances and the safety of those exposures.[8,9,10,11]

Moreover, FDA has the ability to act on new science as it learns of it. According to FDA "[t]he FDA reviews updated scientific information on food contact substances as it becomes available. The agency can revoke food contact authorizations when scientific data demonstrate that the authorized uses of a food contact substance are no longer safe. In addition, the FDA can also work with industry to remove food contact substances from the market through voluntary agreements. For example, in 2011, the FDA obtained voluntary agreements with the manufacturers of certain "long-chain" PFAS compounds authorized under food contact notifications to remove those substances from food contact applications. "Long-chain" and "short-chain" refer to the number of carbon atoms in the molecular structure of a subset of PFAS. In 2016, the FDA revoked the regulations that authorized the remaining uses of these long-chain PFAS in food packaging."[12]

H.R. 2827 Is Overly Broad

H.R. 2827 would apply to any PFAS used as a food contact substance. While it appears that the universe of those PFAS currently approved by FDA is about 100 substances, according to FDA "[t]here are nearly 5,000 types of PFAS,"[10] and H.R. 2827 makes no distinction among them. It also does not make the important distinction between polymeric PFAS (e.g., fluoropolymers) and non-polymeric PFAS. For example, fluoropolymers are not bioavailable or bioaccumulative and satisfy the widely accepted assessment criteria to be considered as "polymers of low concern" around the globe.[13] Therefore, they are considered to be of low hazard to human health and the environment.

However, more importantly, the impacts of H.R. 2827 would be very broad because, although the number of individual chemicals may be modest, PFAS have been safely used through the food supply in a wide variety of applications for decades. Therefore, it is not possible to predict the implications for food safety and the potential unintended

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[8] Begley, T.H., K. White, P. Honigfort, M.L. Twaroski, R. Neches, and R.A. Walker. 2005. Perfluorochemicals, potential sources of and migration from food packaging. *Food Additives and Contaminants* 22(10):1023–1031.
[9] Begley, T.H., W. Hsu, G. Noonan, and G. Diachenko. 2008. Migration of fluorochemical paper additives from food-contact paper into foods and food simulants. *Food Additives & Contaminants: Part A* 25:384–390.
[10] Rice, P.A. 2015. C6-Perfluorinated compounds: The new greaseproofing agents in food packaging. *Curr. Envir. Health Rpt.* 2:33–40. https://doi.org/10.1007/s40572-014-0039-3
[11] Kabadi, S.V., J. Fisher, J. Aungst, and P. Rice. 2018. Internal exposure-based pharmacokinetic evaluation of potential for biopersistence of 6:2 fluorotelomer alcohol (FTOH) and its metabolites. *Food and Chemical Toxicology* 112:375-382. https://doi.org/10.1016/j.fct.2018.01.012.
[12] https://www.fda.gov/food/chemicals/and-polyfluoroalkyl-substances-pfas
[13] Henry, B.J., Carlin, J.P., Hammerschmidt, J.A., Buck, R.C., Buxton, L.W., Fiedler, H., Seed, J. and Hernandez, O. (2018), A critical review of the application of polymer of low concern and regulatory criteria to fluoropolymers. Integr Environ Assess Manag, 14: 316-334. doi:10.1002/ieam.4035

consequences such legislation might precipitate. Also, because there is compliance authority for food safety at the Federal level, the State level, and even at the local level (e.g., cities and counties), such changes with broad impacts will result in uneven application and confusion in the market without proper communication. Because the uses that would be prohibited have already been assessed for safety by FDA, it does not appear that there would be any benefit to H.R. 2827. However, these rapid and broad changes would lead to disruption and confusion in the food industry and potentially compromise the safety of the food supply.

H.R. 2827 Is Contrary to Well-Established Scientific Processes for the Pre-market Evaluation of Chemical Safety in the U.S.

Consumers in the U.S. benefit from a robust regulatory regime that requires new chemicals and new chemical applications to be evaluated for safety before they are permitted to be brought to market. Most of these programs are administered by FDA or the Environmental Protection Agency. Those programs have a long track record of success, and Congress has a track record of successful oversight and of reform or modernization when it is necessary to adapt those programs. The hallmark of safety regulation in the U.S. is a transparent, scientifically rigorous, risk-based process. The arbitrary declaration of an indeterminate number of PFAS chemicals as unsafe flies in the face of the track record of success of U.S. regulatory agencies and programs, with unpredictable, potentially wide-reaching disruptive consequences. While no process is perfect, U.S. regulatory agencies have been successful in addressing and adapting to limitations in these regulatory processes, and they should be allowed to be continued to do so.

Conclusion

In conclusion, my recommendation to Congress would be that, to the extent there is concern regarding PFAS used as food contact substances, it work closely with FDA to understand the safety of currently permitted uses of PFAS as food contact substances, to retrospectively analyze the assessment process, and to make sure the agency has the tools and resources necessary to fully address PFAS as food contact substances.

We appreciate the Subcommittee's vigilance and commitment to improve the safety and transparency in America's food and drugs, and we would be pleased to help in any way we can.

Thank you again for this opportunity to share my perspective. I look forward to your questions.