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June 3, 2021

Division of Dockets Management
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane, Room 1061
Rockville, MD 20852

RE: Citizens petition requesting that the agency take more aggressive action to protect consumers from per- and poly-fluoroalkyl substances (PFAS) by banning all forms that biopersist in the human body

Dear Commissioner:

The United States is awash with per- and poly-fluoroalkyl substances (PFAS). Their widespread use and their ability to remain intact in the environment means that over time PFAS levels from past and current uses can result in increasing levels of environmental contamination, and accumulation of certain PFAS has also been shown in humans and animals.[1] Thousands of these substances have been used across various industries and goods,[2] including in firefighting foam,[3] food packaging,[4] and household products.[5] People are exposed to PFAS from products we use, the food we eat, the air we breathe, and the water we drink, especially in communities near where the chemicals are produced, processed, used or disposed. As a result, PFAS have been measured in the bodies of virtually every person that has been tested in the US[6] and in thousands of drinking water sources.[7] The Biden-Harris Campaign's Environmental Justice Plan identified tackling PFAS contamination as one of the new administration's top priorities.[8]

The scientific evidence showing widespread harm to health, especially to children, from the most studied forms of PFAS is overwhelming.[9,10,11] And, the more PFAS are studied, the more we learn that substances misleadingly touted by the chemical industry as safer forms of PFAS[12] are linked to harm and contamination.[13,14,15] The cumulative effect of PFAS from all these sources on our health, including our risk of cancer, harm to our immune system and impaired development of our children, has resulted in a national outcry for comprehensive action; states have been compelled to take action because the federal government's piecemeal approach has left residents at risk.[16,17,18,19]

The Food and Drug Administration (FDA) has been a significant contributor to the consumer's exposure based on past approvals, but the extent of the food contamination from the substances the agency currently allows is largely unknown because the agency does not test for them. It wasn't until 2012 – long after the Environmental Protection Agency (EPA) began to act – that the FDA first took steps, albeit incomplete, to remove long-chain PFAS from food packaging.[20,21] However, FDA continued authorizing food contact substances (FCSs) made from short-chain PFAS and treating them as a safer alternative despite the lack of information[22] on their potential biopersistence, toxicity and cancer risk. Only in 2020 did the agency begin a five-year process to phase out some short-chain PFAS[23] after the chemicals' manufacturers balked at conducting the cancer, reproductive, and developmental toxicology studies that FDA said were necessary to determine whether the uses might be safe.[24]

Adding to these failures, the agency continued to authorize FCSs made from other types of PFAS even though it knew those substances had also not been adequately studied. As recently as April 2021, FDA's

scientists published a study reviewing the toxicology of ether-PFAS that acknowledges little is known about their ability to biopersist in the human body and that these materials have major toxicity data gaps.[25] Studies recently made public indicate that a PFAS-ether compound used to manufacture food packaging outside the US has a half-live similar to PFOA and PFOS.[26]

FDA has a duty to take broader and more aggressive action under the Federal Food Drug and Cosmetic Act (FFDCA) to ensure food is safe. The law demands that no use of PFAS – or any other food contact substance – be allowed unless there is "a reasonable certainty in the minds of competent scientists that the substance is not harmful under the intended conditions of use" after considering three factors including "[t]he cumulative effect of the substance in the diet, taking into account any chemically or pharmacologically related substance or substances in such diet."[27]

Therefore, we now petition the agency to protect consumers from further harm by banning all long- and short-chain PFAS as FCSs and systematically reassessing its past actions based on a presumption that all per and poly-fluorinated compounds (PFCs) biopersist in the human body unless there is affirmative evidence to the contrary. PFC is a broad term that FDA has used previously and comprises not just those chemicals with alkyl chains but also other forms including cyclic chemicals. Based on this presumption, FDA should take aggressive action to protect consumers from all PFCs.

A. FDA regulation of PFAS as food contact substances

The FDA has designated short-chain and long-chain PFAS as two distinct classes of chemically-related substances.[28] For each class, the agency has determined that there is sufficient evidence that one or more members are absorbed by the gut, are distributed in the blood, and accumulate in the human body ("biopersist"); likewise, for each class there is a lack of toxicology studies necessary to demonstrate safety. Therefore, the chemicals within these classes and FCS that contain or release these chemicals into food cannot be considered safe.

For the long-chain PFAS (LC-PFAS) class, in 2008 FDA treated them as a class due to their biopersistence, carcinogenicity, and reproductive and developmental toxicity and identified seven FCS notifications (FCNs) for substances that the agency classified as members of this class. In response, the manufacturers of those PFAS agreed to phase out their use in food in 2011.[29] Today, the seven FCNs remain effective with a flag stating that they have been "voluntarily ceased by the manufacturer." This status is not recognized by the FFDCA or the agency's regulations and is not binding on food manufacturers; FDA essentially put the substances in a limbo. In 2016, in response to a food additive petition by several of those joining on this petition, the agency revoked its prior regulatory approvals of other LC-PFAS due to similar safety concerns but took no action on the seven FCNs that still remain in limbo.

For the short-chain PFAS (SC-PFAS) class, on October 1, 2019, FDA sent letters to three companies that have effective FCNs for these substances.[30] In the letters, the agency stated that a member of the class known as 6:2 fluorotelomer alcohol (6:2 FTOH) biopersists in the body. FDA said that because biopersistence increases the internal dose, additional, long-term cancer, reproductive, and developmental toxicology studies were needed to demonstrate safety of 6:2 FTOH monomer and associated low molecular weight oligomers, with specific evaluation of impacts on the immune system, nervous system, and reproductive tract after birth. Without this evidence, all members of the SC-PFAS class should be considered unsafe consistent with the precedent set by FDA in its 2016 decision on LC-PFAS and with 21 C.F.R. § 170.18.

Through FDA's December 2020 response to a Freedom of Information Act (FOIA) request by the Environmental Defense Fund and Environmental Working Group, we learned that the agency:

- Rejected one company's offer to conduct the necessary studies because the time to perform them (at least two years) "would take too long to complete", in an attempt to accelerate the market removal of these chemicals in light of the risk posed by their biopersistence;[31] and
- Accepted, without apparent negotiation, a unified offer made by the companies to a five-year phase-out of their products for food use. This is a clear contradiction to the urgency it conveyed to the one company that two years was too long to wait for studies.

The phase-out plan FDA agreed to is described on the agency's webpage[32] as follows:

- "Beginning in January 2021, three manufacturers will begin a 3-year phase-out of their sales of certain substances that contain 6:2 FTOH for use as food contact substances in the U.S. marketplace.
- After the phase-out period, it is anticipated that it may take up to 18 months to exhaust existing stocks of paper and paperboard products containing these food contact substances from the market."

The agency added that it will monitor "the progress of the phase-out of these short-chain grease-proofing agents through annual updates provided by the three remaining manufacturers." It did not indicate how it will approach any deviation from the proposed plan.

Despite the determination that FDA lacks sufficient information to demonstrate the safety of SC-PFAS, FDA has taken no apparent action on FCSs in the class other than those associated with 6:2 FTOH. In addition, other forms of PFAS and PFCs that do not fit the LC- and SC-PFAS classes remain authorized by FDA.

Despite its past flawed assessments of the risks posed by LC- and SC-PFAS, we have seen no indication that FDA has systematically reviewed its approvals and authorization for all PFCs including PFAS, polymers and oligomers, to determine whether there is sufficient evidence of safety in light of the new information. In addition, the agency has taken no action to prohibit companies from determining that uses of these substances are generally recognized as safe (GRAS). Because FDA allows companies to make these safety determinations in secret without notifying the agency, it would have no way to ensuring that PFAS and PFCs are not used as FCSs without banning all forms of PFCs, including all PFAS in regulations.

B. Action requested

We specifically request that FDA comply with the FFDCA and its implementing regulations by:

- Revoking the effectiveness of all FCNs that contain a member of either the LC-PFAS or the SC-PFAS classes as an ingredient, manufacturing byproduct, impurity, breakdown product or metabolite pursuant to 21 C.F.R. § 170.105;
- Evaluating its food additive or GRAS regulations at 21 C.F.R. Parts 172 to 188 and removing any approvals that contain a member of either the LC or SC-PFAS classes;
- Issuing a regulation in 21 C.F.R. Part 189 banning use of SC-PFAS and LC-PFAS in food contact materials whether packaging or food handling equipment; and
- Requiring that industry provide sufficient information to affirmatively demonstrate that all PFCs, including all PFAS that are not in the SC-PFAS or LC-PFAS classes, their impurities, byproducts, and metabolites do not biopersist or may cause cancer by non-genomic means in order for their continued use in food contact materials to remain authorized. If the evidence is not

provided, then FDA should remove all approvals and authorizations. In case FDA determines that their uses are safe, the companies must submit an environmental assessment evaluating the impacts from production, processing, use, recycling, and disposal of these substances per the National Environmental Policy Act.

C. Statement of grounds

The FDA is responsible for ensuring food is safe.[33] For food additives and food contact substances, safety means there is "a reasonable certainty in the minds of competent scientists that the substance is not harmful under the intended conditions of use" after considering three factors including "[t]he cumulative effect of the substance in the diet, taking into account any chemically or pharmacologically related substance or substances in such diet."[34] Despite determining that there is sufficient evidence that the use of LC-PFAS and SC-PFAS are no longer safe due to biopersistence and toxicity, the agency has taken only limited action and that action falls short of its responsibilities under FFDCA.

In the analysis below we provide a detailed explanation of the grounds on which FDA should take the requested action.

1. FDA has designated SC- and LC-PFAS as two distinct classes of chemically-related substances.

2. For each of the PFAS classes, the agency has determined that there is sufficient evidence that one or more members of the class biopersist, and that the available toxicology data is inadequate to establish safety, and therefore, the use of any member in the class cannot be considered safe.

3. Despite acknowledging that LC- and SC-PFAS classes are not considered safe, FDA improperly allows food contact materials containing members of those classes to remain in use.

4. The agency's failure to anticipate that these two classes of PFAS are biopersistent and carcinogenic when it authorized their use underscores the need for FDA to reassess other PFCs, including PFAS, as the agency's initial assessments for these substances may be similarly flawed.

We explore each of these findings in more detail below.

B.1 FDA has designated SC- and LC-PFAS as two distinct classes of chemically-related substances.

B.1.1 FDA has designated LC-PFAS as a class of chemically-related substances.

In its January 4, 2016 rulemaking, FDA removed its prior approval of three LC-PFAS[35] to repel oil and water in paper and paperboard contacting aqueous and fatty foods because it concluded there was "no longer a reasonable certainty of no harm for the food contact use of these FCSs."[36] In essence, the agency found the use of these FCSs was no longer safe as that term is defined in 21 C.F.R. § 171.3(i).

The agency reached this conclusion because it found that the three FCSs were members of a class of LC-PFAS (a type of long-chain perfluorinated compounds (long-chain PFCs))[37] that were not safe. Specifically, FDA stated that:

> As a result of this review, we concluded that data for subsets of long-chain PFCs (demonstrating biopersistence and reproductive and developmental toxicity) are applicable to long-chain PFCs on a general basis and that this data raises significant questions as to the safety of the authorized uses of the three FCSs subject to the petition.[38]

FDA defined the class as having "extended alkyl chains where all of the hydrogens are replaced by fluorine (hence the FCSs are "perfluorinated")" with the "perfluorinated alkyl chains greater than or equal to eight carbons in length . . ."[39] In other words, LC-PFAS are substances with alkyl chains of eight or more carbons with all of the hydrogens on those carbons replaced with fluorine.

B.1.2 FDA designated SC-PFAS as a class of chemically-related substances.

In a 2020 letter to Daikin,[40] FDA states, in part:

> Recently available toxicological data on 2-(perfluorohexyl)ethyl alcohol (CAS Reg. No. 647-42-7) (6:2 fluorotelomer alcohol (FTOH)), one of the impurities listed for the FCS in FCN 1493, reveals concerns for biopersistence of a key metabolite, 2H, 2H, 3H, H-perfluorooctanoic acid (5:3 acid) (CAS Reg. No. 914637-49-3).

These chemicals, 6:2 FTOH and 5:3 acid, fit the definition of "short-chain per- or polyfluorinated substances (short-chain PFAS)" as defined by FDA in footnote 1 of the same letter. The footnote says "'Short-chain PFAS' refers to PFAS with seven or fewer carbons in an alkyl chain (n-1 carbons are perfluorinated)."[41]

In addressing Daikin's products, FDA said:

> The subject FCS in FCNs 820, 827, 888, 933, 1044, 1360, and 1451 are intended for use as grease-proofing agents to be applied to paper and paperboard for use in contact with food. **Due to the chemical structure of these FCSs, the Food and Drug Administration (FDA) considers them to belong to a class of chemicals termed "short-chain per- or polyfluorinated substances" (short-chain PFAS)** [*Emphasis added*].

That means that Daikin's FCSs, 6:2 FTOH and 5:3 acid are members of the same class of SC-PFAS because their chemical structure is similar and therefore, they are chemically-related.

FDA also treated as members of the class "the SC-PFAS monomers and the low molecular weight oligomers (LMWO) which are constituents or impurities of short-chain PFAS FCS."[42] FDA typically defines LMWOs as those below 1000 Daltons.[43] However it treats fluorinated compounds as an exception that raises the limit on Daltons to up to 2500.[44]

In other words, the SC-PFAS class consists of chemically-related substances containing alkyl chains with seven or fewer carbons where all but one of the carbons are perfluorinated. It also includes LMWOs made from or containing impurities that are SC-PFAS.

B.2. For each of the PFAS classes, the agency has determined that there is sufficient evidence that one or more members of the class biopersist, and the available toxicology data is inadequate to establish safety, and therefore the use of any member in the class cannot be considered safe.

According to 21 C.F.R. § 170.18(a), "[f]ood additives that cause similar or related pharmacological effects will be regarded as a class and in the absence of evidence to the contrary, as having additive toxic effects and will be considered as related food additives." In essence, the toxicological information for members of the class that have been studies are presumed to apply to all members of the class. FDA took this approach when it created the two classes of LC-PFAS and SC-PFAS.

B.2.1 LC-PFAS class is biopersistent and poses reproductive and developmental risks.

In defining the LC-PFAS class in 2016, the agency said it "formulated a safety assessment approach" based on:

- "structural similarities of that class to long-chain PFCAs [perfluorocarboxylic acids] and FTOHs [fluorotelomer alcohols] and
- available toxicity information on long-chain PFCAs and FTOHs that indicate a concern for reproductive/developmental toxicity."[45]

FDA relied on "published studies demonstrating metabolic conversion of FTOHs and PFCs [perfluorinated chemicals] similar in structure to the FCSs herein (perfluoroalkyl phosphate surfactants (PAPs)) to PFCAs *in vitro* and in animals."[46] It justified the approach based on the Organisation for Economic Co-operation and Development (OECD)'s Guidance for Grouping of Chemicals that essentially organized chemicals based on any one of five criteria including the:

1. Existence of common functional groups, and
2. The likelihood of common precursors and/or breakdown products, via physical or biological processes, which result in structurally-similar chemicals (e.g., the "metabolic pathway" approach of examining related chemicals such as acid/ester/salt).[47]

In the 2016 action removing its prior approval of three members of the LC-PFAS class,[48] the agency found these FCSs were no longer safe because "data for subsets of long-chain PFCs (demonstrating biopersistence and reproductive and developmental toxicity) are applicable to long-chain PFCs on a general basis and that this data raises significant questions as to the safety of the authorized uses of the three FCSs subject to the petition."[49]

In short, FDA determined that some members of the LC-PFAS were unsafe due to biopersistence and reproductive and developmental risks. Therefore, in the absence of evidence to the contrary, all members of the class should be considered unsafe.

B.2.2 SC-PFAS class is biopersistent and poses cancer, reproductive, developmental, immunological, and neurological risks.

In 2019, FDA made a similar determination for SC-PFAS as it had done for LC-PFAS, finding that SC-PFAS were biopersistent in the human body and that there was not enough data to demonstrate their safety.[50] Specifically, the agency sent correspondence to three companies stating that "FDA has recently become aware of toxicological data that is relevant to short-chain (SC) PFAS as a class" indicating that the new data revealed "safety concerns for SC-PFAS which are applicable" to the food contact uses authorized under FCNs 820, 827, 888, 933, 1044, 1360, and 1451 for Daikin;[51] FCN 1493 for Archroma;[52] and FCNs 599, 604, 1186 and 1676 for Asahi.[53]

The agency found that the information:

> Provides evidence that the 5:3 acid, a key metabolite of the 6:2 FTOH, is biopersistent in rodents; 6:2 FTOH may also be carcinogenic in the livers of rodents, based on data from repeated-dosing oral toxicity studies conducted with 6:2 FTOH in mice and rats; concerns for immunotoxicity and

postnatal toxicity for the 6:2 FTOH and, by extension, for the SC-PFAS monomers and the low molecular weight oligomers (LMWO) which are constituents or impurities of short-chain PFAS FCS.[54]

Due to biopersistence, FDA specifically requested more information on:

- "[Toxicokinetic] studies in rodents, hepatocytes, and kidney cells are needed to derive critical toxicokinetic parameters necessary for calculating systemic steady-state body burdens for 6:2 FTOH and its metabolites in humans and animal models."[55]
- "Longer-term repeated dose studies of at least one-year in duration are necessary to potentially derive reliable points of departure for quantitative risk assessment. Specialized studies examining functional and physiological endpoints for the immune system are recommended to fully-characterize the effects of the 6:2 FTOH on the immune system."[56]
- "[A]n extended one-generation reproductive toxicity study . . . in mice, the more sensitive species, with the 6:2 FTOH to characterize the effects of postnatal exposure on development of the immune system, nervous system, and reproductive tract."[57]
- "[C]onduct of a two-year bioassay in mice, the more sensitive species, with the 6:2 FTOH" in order "[t]o fully-characterize the carcinogenic potential of the 6:2 FTOH."[58]

In summary, FDA found that SC-PFAS as a class were biopersistent and pose cancer, reproductive and developmental risks and that the available toxicology data the companies provided to FDA was inadequate to establish safety. Therefore, as the agency concluded for LC-PFAS, all members in the class should be considered unsafe.

B.3. Despite acknowledging that LC- and SC-PFAS classes are not considered safe, FDA improperly allows food contact materials containing members of those classes to remain in use.

FDA has taken ineffective or incomplete action to stop the use of LC-PFAS and SC-PFAS despite its findings that the classes cannot be considered safe. Specifically, it:

- Allows 22 FCNs to be "voluntarily ceased" for LC-PFAS and some SC-PFAS[59] – a status that is not recognized in the law;
- Allows other FCNs to remain effective even though they contain SC-PFAS;
- Has not reviewed its existing approvals of food additives and GRAS substances to revoke uses involving LC- and SC-PFAS; and
- Has not explicitly prohibited use of LC- and SC-PFAS by issuing a regulation at 21 C.F.R. Part 189.

B.3.1 Allows 22 FCNs to be "voluntarily ceased" for LC-PFAS and some SC-PFAS – a status that is not recognized in the law.

FDA's rules at 21 C.F.R. § 170.105 provide a specific process that the agency is to follow when it determines that the intended use of a food contact substances covered by an FCN is no longer safe. According to the rules:

> (a) If data or other information available to FDA, including data not submitted by the manufacturer or supplier, demonstrate that the intended use of the food contact substance is no longer safe, FDA may determine that the authorizing FCN is no longer effective.
>
> (b) If FDA determines that an FCN is no longer effective, FDA will inform the manufacturer or supplier in writing of the basis for that determination. FDA will give the manufacturer or

supplier an opportunity to show why the FCN should continue to be effective and will specify the time that the manufacturer or supplier will have to respond.

(c) If the manufacturer or supplier fails to respond adequately to the safety concerns regarding the notified use, FDA will publish a notice of its determination that the FCN is no longer effective. FDA will publish this notice in the Federal Register, stating that a detailed summary of the basis for FDA's determination that the FCN is no longer effective has been placed on public display and that copies are available upon request. The date that the notice publishes in the Federal Register is the date on which the notification is no longer effective.

(d) FDA's determination that an FCN is no longer effective is final agency action subject to judicial review.[60]

For seven LC-PFAS in 2010 and fifteen SC-PFAS in 2019,[61] FDA took the first step of informing the manufacturers that new evidence was available to the agency regarding safety concerns for their products. The letters detailed the information the agency needed to assess whether the use of their substances continue to be safe and gave the companies an opportunity to show why the FCNs should continue to be effective.

In response to the letters, the companies provided answers that did not adequately address the safety concerns. There were three types of responses from the companies:

- Asahi offered to conduct the necessary studies but needed at least two years to perform them.[62] Citing the urgency of the risk posed by the use, Asahi stated that FDA rejected this offer.
- Chemours claimed it had permanently abandoned its three FCNs.[63]
- For LC-PFAS, BASF,[64] DuPont,[65] and Clariant [66] opted not to conduct the requested studies and offered to phase-out the use of the FCNs. For SC-PFAS, Archroma and Daikin, joined by Asahi, presented FDA with a market-based voluntary phase-out plan.[67]

Despite inadequate responses and determination of unsafe uses for all of the FCNs, FDA retained the effectiveness of all 22 FCNs and identified them as follows in its online database:

- For 10 FCNS, it says: *Introduction into interstate commerce and delivery for introduction into interstate commerce voluntarily ceased by the manufacturer*
- For 12 FCNs, FDA says: "*Introduction into interstate commerce and delivery for introduction into interstate commerce will be voluntarily ceased by the manufacturer*" (hereinafter "voluntarily ceased").[68]

This approach is inconsistent with the law and FDA's regulations and leaves the FCNs in a limbo. No one using the PFAS would be violating the law, and the manufacturers could resume the use at any time. Without delay, FDA needs to formally act to remove the effectiveness of all 22 FCNs.

B.3.2 Allows other FCNs to remain effective even though they contain SC-PFAS.

FDA designated SC-PFAS as a class of chemically-related substances with seven or fewer carbons in an alkyl chain (n-1 carbons are perfluorinated) and their LMWO which are constituents or impurities. However, the agency appears to have only focused on FCNs associated with the one member of the class – 6:2 fluorotelomer alcohol (FTOH) that it said:

> Reveals concerns for biopersistence of a key metabolite, 2H, 2H, 3H, H-perfluoroctanoic acid (5:3 acid). (CAS Reg. No. 914637-49-3). Our review of newly available toxicological data provides evidence that the 5:3 acid, a key metabolite of the 6:2 FTOH, is biopersistent in rodents; 6:2 FTOH may also be carcinogenic in the livers of rodents, based on data from repeated dosing

oral toxicity studies conducted with 6:2 FTOH in mice and rats. Our review also identifies concerns for immunotoxicity and postnatal toxicity for the 6:2 FTOH and, by extension, for the SC-PFAS monomers and the low molecular weight oligomers (LMWO) which are constituents or impurities of short-chain PFAS FCS.[69]

Unfortunately, we have seen no evidence that FDA has taken similar action on other FCNs that contain SC-PFAS. In addition, it seems to have ignored those FCNs that involve use of SC-PFAS as a processing aid in the manufacturing of plastic food packaging and food contact materials, despite the evidence that the use results in SC-PFAS migrating into food.

B.3.3 Has not reviewed its existing approvals of food additives and GRAS substances to revoke uses involving LC- and SC-PFAS.

We have seen no evidence that FDA has reviewed its food additive and GRAS approvals in its regulations at 21 CFR Part 172 to 186 for use of substances that might be members of either LC-PFAS or SC-PFAS, especially since its definition of SC-PFAS includes alkyl chains that are poly- and not necessarily perfluorinated. Given the growing evidence of a problem, such a public review is long overdue. We ask that the agency conduct that review and publicly report its findings.

B.3.4 Has not explicitly prohibited use of LC- and SC-PFAS by issuing a regulation at 21 C.F.R. Part 189.

Since both LC-PFAS and SC-PFAS were allowed for years before FDA acted, there is every reason to believe that companies self-certified their use as GRAS without notifying FDA pursuant to 21 C.F.R. Subpart E. It is particularly likely since the agency created a regulatory limbo by never publishing the notice required by 21 C.F.R. § 170.105 in the Federal Register announcing removal of effectiveness of FCNs. Since the FCNs are technically still effective, the agency would have difficulty taking enforcement action against someone using the products in food. Therefore, it is only reasonable that FDA explicitly prohibit LC-PFAS and SC-PFAS as classes by adopting a regulation in 21 C.F.R. Part 189 to protect the public from unsafe PFAS.

B.4. The agency's failure to anticipate that these two classes of PFAS were biopersistent when it authorized their use, underscores the need for FDA to reassess other PFCs, including PFAS, as their initial assessments may be similarly flawed.

There were two fundamental flaws in the FDA's assessment of SC-PFAS:

- **SC-PFAS do not biopersist.** Now we know that was just assumption based on an artificial bright line FDA drew between substances with fewer or greater than seven fully fluorinated carbons. There was not strong scientific evidence supporting that distinction as demonstrated by FDA's scientists most recent peer-reviewed publications.
- **SC-PFAS are not genotoxic and therefore there is no risk of cancer.** This is not the case. According to FDA's scientists "PFAS as a class are generally negative for activity in traditional genotoxicity tests and act primarily through non-genotoxic mechanisms of action: FDA's assessment of the endpoint of carcinogenicity for PFAS in general focused on data indicative of ability to cause peroxisome proliferation and xenobiotic-metabolism enzyme induction in the liver, which appear to be key mechanisms of action for tumor induction for PFAS compounds."[70]

We ask the agency to conduct a thorough reassessment of prior PFCs determinations and stop assuming safety based on decisions made decades ago on what is clearly an incomplete understanding of biopersistence and carcinogenicity.

PFCs to be reviewed should include those used in FDA's authorized uses in food contact applications:

- Non-stick cookware: substances may be used as a coating to make cookware non-stick.
- Gaskets, O-Rings, and other parts used in food processing equipment: substances may be used as a resin in forming certain parts used in food processing equipment that require chemical and physical durability.
- Processing aids: substances may be used as processing aids for manufacturing other food contact polymers to reduce build-up on manufacturing equipment.
- Paper/paperboard food packaging: substances may be used as grease-proofing agents in fast-food wrappers, microwave popcorn bags, take-out paperboard containers, and pet food bags to prevent oil and grease from foods from leaking through the packaging.

Other PFCs used as processing aids in the production of materials used in food contact applications should also be reviewed. Examples of these PFCs processing aids include but are not limited to propanoic acid, 2,3,3,3-tetrafluoro-2-(1,1,2,2,3,3,3-heptafluoropropoxy)-, (HFPO-DA) also known as a substance within GenX; propanoic acid, 2,2,3,-trifluoro-3-[1,1,2,2,3,3-hexafluoro-3-(trifluoromethoxy)propoxy]-(DONA); acetic acid, 2,2-difluoro-2-[1,1,2,2-tetrafluoro-2-(1,1,2,2,2-petafluoroethoxy)ethoxy]-, (EEA-); and propanoic acid, 2,3,3,3-tetrafluoro-2-[1,1,2,3,3,3-hexafluoro-2-(1,1,2,2,3,3,3-heptafluoropropoxy)propoxy]-(HFPO-TA). [71]

Unless there is an affirmation of safety by the agency, the use of these PFCs should be presumed unsafe and FDA should take aggressive, legally required action to protect human health.

C. Environmental impact

This citizens petition is categorically excluded from the need to prepare an Environmental Assessment under 21 CFR § 25.30(h) as an "Issuance, amendment, or revocation of procedural or administrative regulations and guidance documents, including procedures for submission of applications for product development, testing and investigational use, and approval." The requested regulations and guidance documents clarify an existing statutory requirement to ensure compliance.

There is ample evidence that the chemicals persist in the environment for decades and contaminate the environment from their production, processing, use, recycling, and disposal. FDA acknowledges this when it states that "the widespread use of PFAS and their ability to remain intact in the environment means that over time PFAS levels from past and current uses can result in increasing levels of environmental contamination."[72] Therefore, stopping their use is expected to provide long-term benefits by limiting additional release of PFAS.

We have identified no extraordinary circumstances as defined at 21 CFR § 25.21 for the action requested in this petition which would require the submission of an Environmental Assessment.

D. Economic impact

Not requested by FDA.

E. Certification

The undersigned certifies, that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.

For more information or communications about this petition, please contact Tom Neltner at tneltner@edf.org and Maricel Maffini at drmvma@gmail.com.

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