CITIZEN'S PETITION FOR TEMPORARY TOLERANCE SETTING AT THE METHOD DETECTION LIMIT FOR 30 OR 26 PFAS IN/ON VARIOUS FRUITS, VEGETABLES, MILK, EGGS, FISH AND BREAD

PETITIONERS:

TUCSON ENVIRONMENTAL JUSTICE TASK FORCE,
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SUBMITTED VIA ELECTRONIC FILING TO:

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CITIZEN PETITION

Tucson Environmental Justice Task Force, Arno Krotzky, Ph.D., independent consultant, and The Law Office of Sandra T. Daussin, PLLC (hereafter, Petitioners) submit this petition under Section 406 of the Federal Food Drug and Cosmetic Act ("FFDCA"), codified at 21 USC 301 et seq., and more specifically under 21 USC 346, ***Tolerances for poisonous or deleterious substances in food regulations***.

Petitioners request that the Commissioner of the Food and Drug Administration ("FDA") establish tolerances at the **m**ethod **d**etection **l**imit ("**MDL**"), which is 0.05 µg/kg (0.05 ppb) according to the data available as of November 2023 from the FDA, for residues of either twenty-six (26) or thirty (30) PFAS in a variety of foods, as set forth below.

As detailed herein, PFAS are food additives which have been transferred to foods, through acts of man, by his contamination of the water, air, and soil. PFAS are demonstrably toxic. FDA has granted a *de-facto* pre-market approval for the manufacture and use of PFAS, without the benefit of the normal safety data that are required for food additives which are not generally regarded as safe ("GRAS"). Action levels permit FDA to "take enforcement action on a case-by-case basis" and are not legally binding.[1] Temporary tolerances, on the other hand, must be enforced.[2] Therefore, Petitioners expressly and exclusively seek mandatory enforceable *temporary tolerances*, rather than *action levels*, for the PFAS indicated herein.

This petition meets the requirements for a citizen filing provided in 21 CFR § 10.30 "Citizens petition," which gains its statutory authority from the Administrative Procedures Act (5 USC 551 et seq (2020)).[3]

I. ACTION REQUESTED.

A. Set New Temporary Tolerances Under 21 CFR Subpart B - *Tolerances for Unavoidable Poisonous or Deleterious Substances*, § 109 for PFAS Residues.

Petitioners request the Commissioner to establish new temporary tolerances at the MDL arising from the inadvertent transfer of certain PFAS to lettuce (head and leaf), blueberries, ready-to-eat bread, milk, eggs, salmon, clams, corn silage, and corn snaplage due to the unavoidable environmental contamination of the soil, air, and water. Petitioners additionally request that these temporary tolerances are lowered as new

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1 *See* US FDA, *Pesticide Residue Monitoring Program Questions and Answers*, February 25, 2022, https://www.fda.gov/food/pesticides/pesticide-residue-monitoring-program-questions-and-answers.

2 *Id*.

3 Administrative Procedures Act, 79 PUB. L. NO. 404, 60 STAT. 237 (ENACTED 1946).

validated MDLs are achieved, and that all PFAS tolerances are revoked as soon as practicable after there is no longer any environmental contamination with PFAS.

1. Set Tolerances at the MDL (currently 0.05 PPB) for 30 PFAS in/on Lettuce (head and leaf) and Blueberries.

Temporary tolerances should be set nondetectable, or the MDL, for each of the thirty (30) PFAS listed below, and their associated free acid or salt, as applicable, in/on lettuce (head and leaf) and blueberry. The available data from FDA at the time of the submission of this Citizens' Petition indicates the current enforceable MDL for these analytes in these matrices is 0.05 µg/kg (0.05 ppb).

Table 1. Proposed PFAS Tolerances.

COMMON NAME	CHEMICAL NAME	CAS NO.	CHEMICAL FORMULA
PFBA	Perfluorobutanoic Acid	375-22-4	$C_4\,H\,F_7\,O_2$
PFBS	Perfluorobutanesulfonic Acid	375-73-5	$C_4\,H\,F_9\,O_3\,S$
PFPeA	Perfluoropentanoic Acid	2706-90-3	$C_5\,H\,F_9\,O_2$
PFPeS	Perfluoropentanesulfonic Acid	2706-91-4	$C_5\,H\,F_{11}\,O_3\,S$
PFHxA	Perfluorohexanoic Acid	307-24-4	$C_6\,H\,F_{11}\,O_2$
PFHxS	Perfluorohexanesulfonic Acid	335-46-4	$C_6\,H\,F_{13}\,O_3\,S$
HFPO-DA (GenX)	Hexafluoropropylene Oxide Dimer Acid	13252-13-6	$C_6\,H\,F_{11}O_3$
4:2 FTS	Perfluorohexane Sulfonic Acid	355-46-4	$C_6\,F_{13}\,S\,O_3\,H$
PFHpA	Perfluoroheptanoic Acid	375-85-9	$C_7\,H\,F_{13}\,O_2$
PFHpS	Sodium Perfluoroheptanesulfonate	21934-50-9	$C_7\,F_{15}\,O_3\,S\cdot Na$
NaDONA	Sodium Dodecafluoro-3H-4,8-Dioxanonanoate	958445-44-8	$C_7\,H_5\,F_{12}\,NO_4\cdot Na$
PFOA	Perfluorooctanoic Acid	335-67-1	$C_8\,H\,F_{15}\,O_2$
PFOS	Perfluorooctanesulfonic Acid	1763-23-1	$C_8\,H\,F_{17}\,O_3\,S$
FOSA	Perfluorooctane Sulfonamide	754-91-6	$C_8\,F_{17}\,S\,O_2\,N\,H_2$
9Cl-PF_3ONS	Potassium 9- Chlorohexadecafluoro-3 Oxanonane-1-Sulfonate	73606-19-6	$C_8\,Cl\,F_{16}\,K\,O_4\,S$
6:2 FTS	Perfluorooctane Sulfonic Acid	1763-23-1	$C_8\,F_{17}\,S\,O_3\,H$
PFNA	Perfluorononanoic Acid	375-95-1	$C_9\,H\,F_{17}\,O_2$

Table 1. Proposed PFAS Tolerances.

COMMON NAME	CHEMICAL NAME	CAS NO.	CHEMICAL FORMULA
PFNS	Perfluorononanesulfonate	474511-07-4	$C_9 F_{19} O_3 S$
PFDA	Perfluorodecanoic Acid	335-76-2	$C_{10} H F_{19} O_2$
11Cl-PF3OUdS	Potassium 11- Chloroeicosafluoro-3-Oxaudecane-1-Sulfonate	83329-89-9	$C_{10} Cl F_{20} K O_4 S$
PFDS	Perfluorodecanesulfonate	126105-34-8	$C_{10} F_{21} O_3 S$-
8:2 FTS	Perfluorodecane Sulfonic Acid	335-77-3	$C_{10} F_{21} S O_3 H$
PFUdA	Perfluoroundecanoic Acid	2058-94-8	$C_{11} H F_{21} O_2$
PFUdS	Perfluoroundecane Sulfonate	441296-91-9	$C_{11} F_{23} S O_3$-
PFDoA	Perfluorododecanoic Acid	307-55-1	$C_{12} H F_{23} O_2$
PFDoDS	Perfluorododecane Sulfonate	343529-43-6	$C_{12} F_{25} S O_3$-
10:2 FTS	Perfluorododecane Sulfonic Acid	79780-39-5	$C_{12} F_{25} S O_3 H$
PFTrDA	Perfluorotridecanoic Acid	72629-94-8	$C_{13} H F_{25} O_2$
PFTrDS	Perfluorotridecane Sulfonate	None	$C_{13} F_{27} S O_3$-
PFTeDA	Perfluorotetradecanoic Acid	376-06-7	$C_{14} H F_{27} O_2$

2. Set Tolerances at the MDL (currently 0.05 PPB) for 26 PFAS in/on Ready-to-Eat Bread, Milk, Eggs, Salmon, Clams, Corn Silage and Corn Snaplage.

Temporary tolerances should be set at nondetectable, or the MDL, for each of the following twenty-six (26) PFAS, and their associated free acid or salt, as applicable, in/on ready-to-eat bread, eggs, milk, salmon, clams, corn silage and corn snaplage: PFBA, PFBS, PFPeA , PFPeS , PFHxA , PFHxS, HFPO-DA (GenX), 4:2 FTS , PFHpA, PFHpS, NaDONA, PFOA, PFOS, FOSA , 9Cl-PF_3ONS, 6:2 FTS , PFNA, PFNS , PFDA, 11Cl-PF3OUdS , 8:2 FTS , PFUdA , PFDoA , 10:2 FTS , PFTrDA , PFTeDA. The chemical name, CAS No. and chemical formula for these twenty-six (26) PFAS are provided in **Table 1** above. The available data from FDA at the time of the submission of this Citizens' Petition indicates the current enforceable MDL for these analytes in these matrices is 0.05 µg/kg (0.05 ppb).

3. All Tolerances Requested Herein Are Temporary.

All tolerances requested herein *are temporary* and must be lowered as better analytical methodology is developed and to allow lower validated MDLs. In addition,

these tolerances must be revoked when there is no longer a reasonable risk of PFAS residues transferring to foods arising from environmental contamination.

II. STATEMENT OF GROUNDS.

A. FACTUAL BACKGROUND

1. PFAS Chemical Properties and Uses.

The US FDA defines PFAS as per- and polyfluoroalkyl substances.[4] The Organization for Economic Cooperation and Development("OECD") has defined PFAS as "[a]ny substance that contains at least one fully fluorinated methyl (CF3-) or methylene (-CF2-) carbon atom (without any H/Cl/Br/I attached to it."[5] PFAS can be more plainly described as a class of synthetic compounds wherein the members of the class are made from carbon atoms linked in a chain with fluorine atoms attached to the carbons. [6] The carbon-fluoride bonds in PFAS are one of the strongest chemical bonds known to mankind.[7] It is this trait which gives PFAS the apt nickname "forever chemicals," as they are very resistant to breakdown.

PFAS have a wide variety of industrial and commercial applications because they are resistant to heat, grease, water, and oil.[8] For example, PFAS are used to make water-repellent clothing, stain-resistant fabrics, firefighting foams, non-stick cookware, food packaging materials, and cosmetics and other personal care products such as lotions and shaving cream.[9]

As of the date of filing this petition, there are a total of 14,735 individual PFAS in existence according to a US EPA public database.[10] This number has almost doubled in

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4 *See* US FDA, *Per- and Polyfluoroalkyl Substances (PFAS)*, May 31, 2023; available at https://www.fda.gov/food/environmental-contaminants-food/and-polyfluoroalkyl-substances-pfas#.

5 *See* European Chemical Agency, "ECHA", *Per- and polyfluoroalkyl substances (PFAS),* https://echa.europa.eu/hot-topics/perfluoroalkyl-chemicals-pfas, last visited on October 29, 2023.

6 See *id*.

7 *See id*.

8 *See* ATSDR, Agency for Toxic Substances and Disease Registry, *What Are PFAS*, November 1, 2022; available at https://www.atsdr.cdc.gov/pfas/health-effects/overview.html. *See also supra* at 2, US FDA, *Per- and Polyfluoroalkyl Substances (PFAS)*.

9 *See* US FDA, *Per and Polyfluoroalkyl Substances (PFAS) in Cosmetics*, February 25, 2022*;* available at https://www.fda.gov/cosmetics/cosmetic-ingredients/and-polyfluoroalkyl-substances-pfas-cosmetics)

10 *See* US EPA*, CompTox Chemicals Dashboard v2.2.1*, https://comptox.epa.gov/dashboard/chemical-lists/PFASSTRUCT, last visited on October 29, 2023. *See also* US EPA*, CompTox Chemicals Dashboard: About*, https://www.epa.gov/comptox-tools/comptox-chemicals-dashboard-about, last visited on October 1, 2023.

the past three years. In January 2020, a total of 7,866 individual PFAS substances were in existence according to this same US EPA database.[11]

2. Environmental Contamination with PFAS is Widespread.

It is well-known that PFAS are persistent in the environment, and that because they are aqueous soluble water is readily contaminated.[12] In fact, the US Geologic Survey has determined that at least 45% of the US drinking water is now contaminated with PFAS.[13]

The US EPA has determined that "[b]ecause of their widespread use … PFAS … are present at low levels in a variety of food products and in the environment."[14] FDA has also found that there is an "increasing level[] of [PFAS] contamination [in] the air, water, and soil" and that PFAS bioaccumulate in humans and animals.[15]

Furthermore, it is well-accepted common knowledge that PFAS contaminates food crops and livestock, including dairy farms, through contaminated irrigation water, contaminated rainwater, or even contaminated biosolids which are used as fertilizers.[16] PFAS has also been found as a contaminate in some pesticides which are directly applied to food crops.[17]

3. Adequate Methods for Tolerance Enforcement Are Available.

In August 2023, FDA issued a method, along with validation data, for the analysis of the thirty (30) PFAS which are the subject of this petition in or on lettuce (head and leaf), blueberries, ready-to-eat bread, milk, eggs, salmon, clams, corn silage and corn snaplage. The method and its validation data are included here as **Appendix 1.** The

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[11] U.S. EPA, *ChemTox database*, https://comptox.epa.gov/dashboard/chemicallists, lasted visited on Jan. 26, 2020.

[12] *See* Alaska Division of Spill and Prevention Response, *PFAS*, https://dec.alaska.gov/spar/csp/pfas/, last visited on October 8, 2023.

[13] USGS, *Tap water study detects PFAS 'forever chemicals' across the US*, July 5, 2023; available at https://www.usgs.gov/news/national-news-release/tap-water-study-detects-pfas-forever-chemicals-across-us.

[14] *See* US EPA, *PFAS Explained*, https://www.epa.gov/pfas/pfas-explained, last visited on October 8, 2023.

[15] *See id*.

[16] *See* US FDA, *Testing Food for PFAS and Assessing Dietary Exposure*, August 29, 2023; available at https://www.fda.gov/food/process-contaminants-food/testing-food-pfas-and-assessing-dietary-exposure. *See also,* NewYorkTime.com, *PFAS: The 'Forever Chemicals' You Couldn't Escape if You Tried*, April 12, 2022; available at https://www.nytimes.com/2022/04/12/us/pfas-chemicals-fast-food.html. *Also see* National Resources Defense Counsel (NRDC.org), S. Cosier, *America's Dairyland May Have a PFAS Problem, 2019***,** October 11, 2019; available at https://www.nrdc.org/stories/americas-dairyland-may-have-pfas-problem**.**

[17] *See* Lasee et al, *Targeted analysis and Total Oxidizable Precursor assay of several insecticides for PFAS*, Journal of Hazardous Materials Letters, Volume 3, November 2022 (100067).

method (hereinafter, the "*PFAS 30 Method*") uses liquid chromatography/high resolution mass spectrometry detection (LC-HRMS) for PFBA and PFPeA, and LC-MS/MS detection for the remaining target analytes.[18]

As detailed below, the *PFAS 30 Method* was adequately validated for tolerance enforcement purposes for all thirty (30) analytes in all matrices tested, with the exception of four PFAS (PFDS, PFUdS, PFDos, PFTrDS) in/on ready-to-eat bread, eggs, milk, salmon, clams, corn silage and corn snaplage. As the Petitioners seek enforceable tolerances, this petition does not seek tolerance setting for PFDS, PFUdS, PFDos, PFTrDS in/on ready-to-eat bread, eggs, milk, salmon, clams, corn silage and corn snaplage.

The *PFAS 30 Method* was developed in response to increasing regulations in Europe. In 2022, the European Commission issued more expansive monitoring requirements, and established maximum levels for four PFAS analytes (PFOS, PFOA, PFNA, and PFHxS) in a variety of foods, as discussed further below.[19] Thus, FDA needed to align with these more stringent requirements in order not to disrupt global trade of agricultural commodities. Prior to the *PFAS 30 Method*, FDA was using methods validated only for sixteen (16) PFAS analytes in processed foods (hereinafter, the *PFAS 16 Method*) and twenty (20) target PFAS analytes in fish.[20]

Validation of the *PFAS 30 Method*

The *PFAS 30 Method* was validated following FDA guidelines as follows. Samples of lettuce, blueberries, chocolate milk, eggs, salmon, clams, bread, corn silage and corn snaplage were spiked in triplicate with each of the thirty (30) target analytes at levels ranging from 0.05 µg/kg to 15 µg /kg.[21] The data provided indicate that the 0.05 µg /kg level was used to establish MDL, and the next highest level of spiking (1 µg/kg) was used to set the limit of quantitation (LOQ).[22] Adequate recoveries at the LOQ were defined as 40-120% with a %RSD of less than or equal to 22%.[23] Analytical reference standards were purchased from commercial vendors.[24]

The results demonstrated that the *PFAS 30 Method* was adequately validated in lettuce, blueberries, and chocolate milk for all thirty (30) target analytes, with the MDL at

[18] *See id*.
[19] *See* EU Commission Regulation 2022/1431, August 26, 2022; available at https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32022H1431. *See also* EU Commission Regulation 2022/2388, December 7, 2022; available at http://data.europa.eu/eli/reg/2022/2388/oj.
[20] *See* US FDA, *Testing Food for PFAS and Assessing Dietary Exposure*, August 29, 2023.
[21] *See* Appendix 1 at 4.
[22] *Id*.
[23] *Id*.
[24] *Id*.

0.05 µg/kg.[25] In eggs, salmon, clams, corn silage, corn snaplage and bread, low recoveries were found for four of the target analytes (PFDS, PFUdS, PFDoS, and/or PFTrDS).[26] Adequate validation data were obtained for the remaining twenty-six (26) analytes in eggs, salmon, clams, corn silage, corn snaplage and bread, with the MDL at 0.05 µg/kg.[27]

Additional work was performed in conjunction with the experiments discussed above to obtain a lower LOQs in certain matrices for certain PFAS analytes which are the subject of EU regulations. The results of this additional work demonstrate that a modification of *PFAS 30 Method* achieved better results for PFOS, PFOA, PFNA, and PFHxS in lettuce and blueberries (LOQ of 0.005 µg/kg) and in chocolate milk (LOQ of 0.010 µg/kg).[28]

These data show that FDA's *PFAS 30 Method* is adequate to detect residues of lettuce, blueberries, chocolate milk, eggs, salmon, clams, bread, corn silage and corn snaplage to an MDL of ≤ 0.05 µg/kg for all target analytes except PFDS, PFUdS, PFDoS, and/or PFTrDS. Based on the data as reported, no adequate enforcement method is available for PFDS, PFUdS, PFDos, PFTrDS in/on ready-to-eat bread, eggs, milk, salmon, clams, corn silage and corn snaplage as the recoveries were too low. Therefore, as stated earlier, petitioners exclude these four analytes in the tolerance setting request for ready-to-eat bread, eggs, milk, salmon, clams, corn silage and corn snaplage.

4. The Available Data Show PFAS from the Environment Contamination Transfers to Foods.

The available data from studies conducted by FDA show that environmental contamination with PFAS does in fact transfer to food at quantifiable levels in milk and agricultural crops. For example, FDA has analyzed milk produced/collected from an inadvertently contaminated dairy farm in New Mexico in 2018 to 2021 using the *PFAS 16 Method*. Milk from the contaminated farm bore detectable residues of ten (10) of the sixteen (16) target analytes, and FDA deemed the levels unsafe. These data are included here as **Appendix 2**. However, what is most troubling from this study is that "control" milk and "retail" milk also bore residues of PFAS. For example, in two such milk samples collected on September 17, 2019 bore PFOA residues at 0.064 and 0.066 µg/kg, which is more than six times the current 0.010 µg/kg monitoring level recommended by the EU Commission in August 2022.[29]

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[25] *Id*. at 4-5.
[26] *Id*.
[27] *Id*.
[28] *See id*. at 6.
[29] *See* **Appendix 2** at 31. *See also* EU Commission Regulation 2022/1431 at 108.

In another study conducted in North Carolina, FDA found that sixteen (16) of twenty (20) produce samples collected bore residues of PFAS. Corn, blueberries, tomatoes, a variety of leafy vegetables and cabbage were analyzed using the *PFAS 16 Method*. These data are presented here in **Appendix 3**. Quantifiable residues of seven (7) of the sixteen (16) target analytes were found in the leafy vegetables and cabbage, at levels up to 0.566 µg/kg.[30] One of the target analytes (PFNA) was also detected in corn at 0.029 µg/kg.[31]

In addition, other studies conducted by FDA, universities or other non-governmental organizations have found freshwater fish caught in US bear significant PFAS residues, and that honey collected in Europe is also widely contaminated with PFAS; see **Appendix 4** and **5**.

In sum, the available data demonstrate that PFAS contamination of the food supply is not just reasonably foreseeable. It has already happened.

5. The FDA is Not Aligned with Other Regulatory Authorities.

FDA currently relies on a divide-and-conquer approach to risk assessment for PFAS, refusing to assess any "possible additive effects of PFAS exposure in samples where more than one type of PFAS is detected."[32] That is, FDA only considers the risk of exposure to one PFAS substance at a time when evaluating the overall health risk.

EPA's proposed maximum contamination levels ("MCLs") for PFNA, PFHxS, PFBS, and GenX in water were developed using a "Hazard Index" which takes into account the **combined levels** of these contaminates.[33] The European Food and Safety Authority ("EFSA") uses the same additive approach that EPA used to evaluate risk. In December 2022, the European Commission adopted EFSA's recommendation to establish maximum levels for the **combined residues** of PFOS, PFOA, PFNA, and PFHxS in a variety of foodstuffs.[34] Thus, FDA is not aligned with either the EPA or EFSA.[35]

What's more, several EU countries (Germany, the Netherlands, Denmark, Norway, and Sweden) have recognized that it is a more than reasonable inference that people are exposed to more than one PFAS at time, especially because they

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30 *Id*.
31 *Id*.
32 *See* US FDA, *Per- and Polyfluoroalkyl Substances (PFAS),* May 31, 2023.
33 *See* US EPA, *Proposed PFAS National Primary Drinking Water Regulation*, September 22, 2023; available at http://epa.gov/sdwa/and-polyfluoroalkyl-substances-pfas.
34 *See* EU Commission Regulation 2022/2388, December 7, 2022.
35 *See* US EPA *News Release*, March 14, 2023; available at https://www.epa.gov/newsreleases/biden-harris-administration-proposes-first-ever-national-standard-protect-communities

bioaccumulate and persist in the environment. As a result, these EU countries have called for restriction of the manufacture of over 10,000 PFAS.[36]

In addition, twelve states (CA, CO, CT, HI, MD, ME, MN, NY, OR, RI, VT, and WA) also have recognized the substantial risks arising from PFAS and have enacted legislation or promulgated regulations to ban or phase out PFAS entirely in their states.[37]

Notwithstanding these decisions taken by the States, US EPA and EFSA, FDA continues to ignore cumulative risks from exposure to multiple PFAS at one time. In addition, FDA has failed to consider all of the various routes and sources of exposure to PFAS, including contaminated drinking water, showering in contaminated water, and breathing contaminated dust or water particles. This not only defies logic; it also does not comport with the requirements of the Food Quality Protection Act, as discussed further below.

6. FDA Uses Very Limited Toxicity Data for PFAS, all of which Unequivocally Show Alarming Health Affects Including Cancer.

FDA acknowledges toxicity data for only seven (7) of the 14,754 PFAS in existence.[38] From the FDA website:

> There are currently seven PFAS (PFOA, PFOS, PFNA, PFHxS, HFPO-DA [GenX], PFBS, and PFBA) from environmental contamination for which the FDA can assess the potential human health concern for levels found in food.
>
> ….
> The agency is currently using the finalized minimal risk levels (MRLs) from the Agency for Toxic Substances and Disease Registry's May 2021 Toxicological Profile for Perfluoroalkyls, along with EPA reference doses for PFBS, HFPO-DA (GenX) and PFBA, in our evaluations of the exposure to certain PFAS detected in foods.[39]

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[36] *See* ECHA, *Consultation on a proposed restriction on the manufacture, placing on the market and use of per- and polyfluoroalkyl substances (PFAS),* https://echa.europa.eu/documents/10162/aea5537d-b698-3b75-4b67-0cadd0fd11d3, last visited on October 1, 2023.

[37] *See* Saferstates.org, *First-in-nation ban on PFAS "forever chemicals" in menstrual products, cleaning ingredients, cookware, and dental floss signed by Minnesota Governor,* May 25, 2023; available at https://www.saferstates.org/news/first-in-nation-ban-on-pfas-forever-chemicals-in-menstrual-products-cleaning-ingredients-cookware-and-dental-floss-signed-by-minnesota-governor-today.

[38] *See* US FDA, *Per- and Polyfluoroalkyl Substances (PFAS),* May 31, 2023.

[39] *See* US FDA*, Testing Food for PFAS and Assessing Dietary Exposure*, August 28, 2023.

The available data, relied upon by FDA, show that oral exposure to even one of these seven compounds (PFOA, PFOS, PFNA, PFHxS, GenX, PFBS, or PFBA) can cause serious life-threatening health effects including damage to major organs (liver, kidneys), cancer, neurotoxicity, immunotoxicity, and adverse effects to developing offspring and the reproductive system.[40] Furthermore, these data show that adverse effects on the thyroid and development of offspring has been found for all of the PFAS which have been adequately studied.[41] And, for most of the PFAS studied, adverse effects on the liver and reproductive system is noted.[42] Thus, from these data, it is a reasonable inference that all PFAS share a similar or even common mechanism of toxicity as they cause similar adverse effects. Moreover, three of the seven PFAS studied are carcinogenic; these are PFOA, PFOS, and GenX.[43]

B. APPLICABLE LAWS AND ANALYSIS

1. The FFDCA and Delaney Govern While the FQPA is Instructive.

A *food additive* under the FFDCA is any substance that is *reasonably expected to become part of food, either directly or indirectly*, as a result of the intended use of that substance (emphasis added).[44] An adulterated food is one that contains an unsafe food additive, or a poisonous or deleterious ingredient present at unsafe levels.[45] The FFDCA prohibits the introduction, manufacture, *or* transport any adulterated food in interstate commerce.[46]

The Delaney Clause of the FFDCA, named after Rep. James Delaney (D-N.Y.),

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[40] *See* US EPA: *Technical Fact Sheet– Perfluorooctane Sulfonate(PFOS) and Perfluorooctanoic Acid (PFOA)*, November 2017; available at https://19january2021snapshot.epa.gov/sites/static/files/2017-12/documents/ffrrofactsheetcontaminantspfospfoa11-20-175080.pdf. *See also Human Health Toxicity Assessment for GenX Chemicals*, March 2023; available at https://www.epa.gov/system/files/documents/2023-03/GenX-Toxicity-Assessment-factsheet-March-2023-update.pdf. *See also Technical Fact Sheet: Toxicity Assessment for PFBS*, September 6, 2023; available at https://www.epa.gov/chemical-research/learn-about-human-health-toxicity-assessment-pfbs. *See also IRIS Toxicological Review of Perfluorobutanoic Acid (PFBA, CASRN 375- 22-4) and Related Salt*s at 4-4, December 2022; available at https://iris.epa.gov/static/pdfs/0701tr.pdf at 4-4. *See also* ATSDR, *Toxicological Profile for Perfluoroalkyls*, May 2021; available at https://www.atsdr.cdc.gov/toxprofiles/tp200.pdf.

[41] *See IRIS Toxicological Review of Perfluorobutanoic Acid (PFBA, CASRN 375- 22-4) and Related Salts* at 4-4.

[42] *See id.*

[43] *See Technical Fact Sheet– Perfluorooctane Sulfonate(PFOS) and Perfluorooctanoic Acid (PFOA)* at 3; *Human Health Toxicity Assessment for GenX Chemicals* at 2; and *IRIS Toxicological Review of Perfluorobutanoic Acid (PFBA, CASRN 375- 22-4) and Related Salts* at 4-4.

[44] 21 USC § 321 (s).

[45] 21 USC § 342; 21 USC § 348 (a); and 21 CFR § 109.6.

[46] 21 USC § 331.

prohibits any food additive which can cause cancer, as below:

> … no additive shall be deemed to be safe if it is found to induce cancer when ingested by man or animal, or if it is found, after tests which are appropriate for the evaluation of the safety of food additives, to induce cancer in man or animal.[47]

Tolerance Setting for Pesticides

In general, tolerance setting activities by US authorities have been largely focused on pesticides because these chemicals are anticipated to be toxic and present in foods as they are deliberately applied to agricultural crops or livestock.[48] EPA has the authority to set pesticide tolerances under the Section 408 of the FFDCA.[49] EPA's authority includes the power to set a "zero tolerance" for any pesticide which is "chemical is carcinogenic to or has other alarming physiological effects upon one or more of the species of the test animals used, when fed in the diet of such animals."[50]

While EPA's authority for tolerance setting arises under the FFDCA, most of EPA's current regulations for the safety assessments of pesticides in foods have been promulgated under the Federal Insecticide, Fungicide, Rodenticide Act ("FIFRA"), as amended by the Food Quality Protection Act ("FQPA").[51] The FQPA was enacted in 1996 to address the failure of EPA to enforce the zero-tolerance for cancer requirements of the FFDCA Delaney Clause, and to establish more realistic achievable risk assessments with the recognition that zero risk is not practicable.[52] Prior to the passage of the FQPA, all food additives, including pesticides, were subject to the Delany Clause. However, with the FQPA carve-out only for pesticides, this left FDA's tolerance setting for environmental contaminants still subject to Delaney.

The safety assessments under the FQPA are instructive for PFAS, as these processes are more sensitive to the impossibility of achieving a zero risk under all circumstances. Under the FQPA, safety data assessments are performed using a cumulative risk approach whenever there is concurrent exposure to structurally similar

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47 21 USC § 348 (c)(3).

48 S. Daussin, D. Carter, and M. Moore (2020), *Longstanding Regulatory Loophole Leaves Minority Pesticide Applicators Unprotected*, NCCU Environmental Law Review: Vol. 2, Article 5 at 48, citing FEDERAL FOOD, DRUG, AND COSMETIC ACT, AMENDMENT., PUB. L. NO. 83-518, 68 STAT. 511 (1954); available at: https://archives.law.nccu.edu/nccuelr/vol2/iss1/5.

49 *See* US EPA, *Summary of the Federal Food, Drug, and Cosmetic Act*; available at https://www.epa.gov/laws-regulations/summary-federal-food-drug-and-cosmetic-act. *See also* 21 USC § 348 and 21 CFR § 109.

50 *See* 40 CFR 180.5.

51 *See* US EPA, *Summary of the Federal Food, Drug, and Cosmetic Act*.

52 *See* USDA, *What is the Delany Clause*?; https://ask.usda.gov/s/article/What-is-the-Delaney-Clause, last visited on October 15, 2023.

compounds.[53] In addition, the FQPA requires that the exposure assessments conducted must take into account the actual exposure levels, and even consider regional differences. Furthermore, exposure is measured by looking at all routes (i.e., dermal, inhalation, and oral) from all sources including air, water, and dietary exposure.[54] The FQPA also requires a 10-fold safety factor to account for the higher vulnerability of infants and children.[55] That is, when EPA sets a tolerance on a pesticide, an accurate exposure assessment is determined, taking into account both food *and* water, before the tolerance level is set.

Tolerance Setting for Chemicals that are Not Pesticides

FDA has the authority under Section 406 of the FFDCA to set tolerances for unavoidable poisonous or deleterious substances which are not pesticides, including those which arise from environmental contaminants.[56] Furthermore, FDA is empowered to set tolerances for poisonous or deleterious substance in food "[t]he tolerance established is sufficient for the protection of the public health, *taking into account* the extent to which the presence of the substance cannot be avoided and *the other ways in which the consumer may be affected by the same or related poisonous or deleterious substances*."[57] Furthermore, like EPA, FDA's authority also includes the power to set a tolerance to "*prohibit any detectable amount of the substance in food*" (emphasis added) when if this is the level that is required in order to be protective of health.[58]

Thus, current FDA's regulations, like EPA's regulations, require an assessment of *all* routes of exposure of the same *or related* chemicals, and permit tolerance setting *at the detection limit* if this is required to be protective of health.

2. Tolerances Must be Enforceable.

Tolerance setting enables regulatory action, such as seizure of adulterated foods, which keeps the food supply safe.[59] Validated methods are necessary for tolerance setting as FDA and USDA share the responsibility for testing and seizing of any commodity

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[53] *See* US EPA, *Overview of Risk Assessment in the Pesticide Program*, https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/overview-risk-assessment-pesticide-program.

[54] *See id*.

[55] *See* U.S. EPA, *Determination of the Appropriate FQPA Safety Factor(s) in Assessing Pesticide Tolerances,* https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/determination-appropriate-fqpa-safety-factors (last visited Dec. 29, 2018).

[56] *See* US EPA, *Summary of the Federal Food, Drug, and Cosmetic Act*; available at https://www.epa.gov/laws-regulations/summary-federal-food-drug-and-cosmetic-act. *See also 21 USC* § 348 and 21 CFR § 109.

[57] 21 CFR 109.6(b).

[58] *See* 21 CFR § 109.4.

[59] *See* US EPA *Setting Tolerances for Pesticide Residues in Foods*, https://www.epa.gov/pesticide-tolerances/setting-tolerances-pesticide-residues-foods, last visited on October 1, 2023.

found to bear over-tolerance residues.[60] That is, tolerance setting is only meaningful if it is enforceable. Therefore, this Petition is only for PFAS residues which are measurable by FDA's validated *PFAS 30 Method* on the matrices which have a validated detection limit.[61]

3. Under the FFDCA Delaney Clause, the FQPA, and the Existing FDA Regulations, Tolerance for PFAS Residues Must be Set at the MDL.

Here, there is good cause shown to establish temporary tolerances for following the FQPA risk-assessment processes, taking into account exposure to and from all sources, and evaluating similarly structured compounds as to be presumptively of similar toxicity.

First, as above, the available data collected by FDA and others, clearly demonstrate that environmental contamination with PFAS has and will transfer to agricultural produce, milk, fish, and ready-to-eat foods. Furthermore, US authorities have acknowledged that because PFAS do not break down, the widespread environmental contamination is a growing problem and can only worsen unless all manufacture of these chemicals is stopped – which it has not. Therefore, the prevalence of foods adulterated with PFAS due to environmental contamination is necessarily increasing.

Second, the available toxicology data unequivocally demonstrate that GenX, PFOS, and PFOA are carcinogenic. Under Delaney, tolerance for at least these PFAS must be set at zero or the MDL. Still, FDA has failed to take appropriate measures, and the result is alarming. For example, as above, PFOA residues were found in milk randomly purchased by FDA in September 2019 at 0.064 and 0.066 µg/kg.[62] Under Delaney, this milk was adulterated. Young children and pregnant mothers rely on drinking dairy milk for adequate bone development. PFOA is not only carcinogenic, but it causes developmental problems. Yet, FDA's response to finding PFOA in retail milk has been woefully inadequate.

FDA should have immediately set a tolerance prohibiting any detectable residues of PFOA in milk and begun a targeting monitoring program so that adulterated milk

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[60] *See* US EPA, *Summary of the Federal Food, Drug, and Cosmetic Act*; available at https://www.epa.gov/laws-regulations/summary-federal-food-drug-and-cosmetic-act, last visited on October 29, 2023. *See also* US FDA, *Pesticide Residue Monitoring Program Questions and Answers*; https://www.fda.gov/food/pesticides/pesticide-residue-monitoring-program-questions-and-answers, last visited on October 29, 2023.

[61] *See* Genualdi,·S., et al, *Analyte and matrix method extension of per- and polyfluoroalkyl substances in food and fee,* Analytical and Bioanalytical Chemistry, 29 June 2023; available at https://doi.org/10.1007/s00216-023-04833-1, also at https://www.fda.gov/food/process-contaminants-food/analytical-results-testing-food-pfas-environmental-contamination.

[62] *See* **Appendix 2** at 31.

could be removed from store shelves. FDA had the authority to do so under Section 406 of the FFDCA.[63] Instead, FDA analyzed a mere twenty-four (24) milk samples in data gathered over a four-year period, between 2019 and 2022, as part of its Total Dietary Study. *See* **Appendix 6**. Only four (4) of these samples were whole milk, with the milk samples processed in some way (i.e., skim, low fat, or chocolate). That is, since finding PFOA, a carcinogen, at measurable levels in randomly purchased milk in 2019, FDA has analyzed only one (1) whole milk samples per year. Based on these meagre efforts, FDA has re-assured the US public that the milk supply is safe. However, with no actual monitoring, this re-assurance carries no weight. Had milk been monitored for PFOA using the MDL as the tolerance level, it is highly likely that adulterated milk would have been found and appropriately removed from store shelves.

Third, a zero tolerance is also permitted under federal law for chemicals which either are carcinogenic *or* cause "other alarming physiological effects."[64] However, as above, a tolerance of "zero" *per se* is meaningless because zero cannot be measured. FDA's existing regulations have addressed this by allowing tolerance setting at the MDL if that is what is required to be protective of health, when taking into account the unavoidable and inevitable exposure to the chemical from all sources, including but not limited to food.[65] Here, the available toxicity data show PFAS case alarming carcinogenic and non-carcinogenetic effects, including developmental toxicity and neurotoxicity. Also, as discussed above, US authorities, including, FDA have acknowledged that PFAS exposure is through water, food, soil, and air. Thus, under the current federal law (Section 406 of the FFDCA) and existing FDA's regulation (21 CFR § 109), FDA has the authority to set tolerances at the requested MDL tolerances that are the subject of this petition.[66]

Fourth, FDA's reliance on the Total Diet Study ("TDS") program to monitor the food supply, with no enforceable tolerance levels, is inadequate. The TDS, begun in 2019, is currently only one-quarter complete.[67] So far, the results show that the highest PFAS residues are in seafoods.[68] However, even by FDA's own admission, if the methods target more analytes, or if more samples were analyzed, more PFAS could be found in foods.[69]

Fifth, FDA has failed to align with the FQPA by refusing to assess the cumulative exposure to more than one PFAS at a time, even though the data show that they are similarly toxic, similarly structured, persistent in the environment, and levels are simply

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63 *See* 21 CFR § 109.4.
64 *See* 40 CFR 180.5.
65 *See* 21 CFR § 109.4 and 21 CFR 109.6(b).
66 *See id.*
67 *See* FDA, *Testing Food for PFAS and Assessing Dietary Exposure*, August 28, 2023.
68 *See id*.
69 *See id.*

rising over time. Furthermore, because EPA's proposed MCLs for certain PFAS were set without any accounting for oral intake of contaminated foods, it is necessary to set the tolerance level at zero for at least these PFAS in order to avoid creating a total exposure which is above a safe limit already determined by EPA.

Finally, EFSA has established maximum levels for PFAS in foods. Therefore, US foods which are imported into EU are subject to seizure if they do not comply with these limits. By failing to set tolerances for PFAS residues in food, FDA is not only showing a conscious disregard for the risk that the US population is exposed to from PFAS residues in food, but also failing to protect international trade of agricultural goods.

4. There is Legal Precedence to Set Temporary Tolerances for PFAS Residues in Food Resulting from Environmental Contamination.

FDA has in the past set tolerances for inadvertent residues arising from unavoidable environmental contamination.[70] Specifically, this was done for polychlorinated biphenyls (PCBs). Similar to PFAS, PCBs are a class of toxic synthetic chemicals, which have contaminated the environment because of their widespread use and persistent chemical nature.[71] Recognizing that PCBs bioaccumulate and are an unavoidable environmental contaminant, FDA set tolerances for PCBs at 21 CFR Subpart B - *Tolerances for Unavoidable Poisonous or Deleterious Substances*, §109.30(a), as below:

> (a) Polychlorinated biphenyls (PCB's) are toxic, industrial chemicals. *Because of their widespread, uncontrolled industrial applications, PCB's have become a persistent and ubiquitous contaminant in the environment. As a result, certain foods and animal feeds, principally those of animal and marine origin, contain PCB's as unavoidable, environmental contaminants ….*
>
> …. Therefore, temporary tolerances for residues of PCB's as unavoidable environmental or industrial contaminants are established *for a sufficient period of time following the effective date of this paragraph to permit the elimination of such contaminants at the earliest practicable time* (emphasis added).[72]

PFAS, in the manner of diligence applied to addressing the environmental catastrophe posed by PCBs, must have post-market temporary tolerances set for residues of these chemicals in or on foods.

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[70] *See* 21 CFR §109.30(a). *See also* US EPA, "*Inadvertent PCBs,*" November 12, 2022; available at https://www.epa.gov/pcbs/inadvertent-pcbs.

[71] *Id*.

[72] *Id*.

Furthermore, under federal case law PFAS residues, although unintentionally added to food via environmental contamination, are, in fact food additives subject to regulation under the FFDCA. Intent is not determinative, rather, all that is needed is if the contamination was due to an act of man. Three federal cases show this principle in different factual circumstances:

First, in *Gerber Products Co. v. Fisher Tank Co*., the Fourth Circuit held that food was adulterated when an unsafe ingredient was accidentally and indirectly added to baby food.[73] The incident happened when a subcontractor inadvertently used the wrong liner for a hot water tank and this water was used during the processing of the baby food.[74] Substances leached off of the liner and gave the food a metallic taste.[75] This was deemed an unapproved food additive, and the food was deemed adulterated as a result.[76]

Second, in *United States v. Ewig Bros. Co*, the Seventh Circuit held that fish caught in the Great Lakes bearing residues of DDT were adulterated food when the contaminant was added through environmental exposure.[77] The defendant, a food producer, argued since the DDT was an environmental contaminant and not intentionally put into the fish, the fish were not adulterated.[78] However, the Seventh Circuit disagreed. The court reasoned that since DDT is a pesticide, which are presumably harmful, the fish were adulterated as a matter of law.[79]

Third, in *United States v. Anderson Seafoods, Inc.,* the Firth Circuit held that swordfish from Florida were adulterated with mercury under the FFDCA when only a portion of this environmental contaminate was added by man.[80] The defendant, a seafood processor, argued the food could not be adulterated under the FFDCA because not all of the mercury present in the fish was attributable to acts of man, therefore it was not an "added" substance under the law.[81] However, the court disagreed, holding that since there was sufficient evidence to show *some* of the mercury present in the fish was attributable to man's acts, it was "added" and the fish were adulterated under the FFDCA.[82]

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[73] *Gerber Products Co. v. Fisher Tank Co*., 833 F.2d 505 (4th Cir. 1987).
[74] *Id.*
[75] *Id.* at 507.
[76] *Id.* at 508.
[77] *United States v. Ewig Bros. Co*., 502 F.2d 715 (7th Cir. 1974).
[78] *Id.*
[79] *Id.* at 723-24.
[80] *United States v. Anderson Seafoods, Inc*., 622 F.2d 157, 158-162 (5th Cir. 1980)
[81] *Id*.
[82] *Id.*

Thus, under federal existing law, there is precedent to set temporary tolerances for PFAS residues present in food through inadvertent transfer via environmental contamination.

C. CONCLUSION

Tolerances for unsafe food additives are set at the federal level by the Secretary of Health and Human Services.[83] Tolerance setting is generally at the discretion of the Secretary; however, as the U.S. Attorney General opined in 1979, that if the additive is a carcinogen no discretion can be allowed.[84] However, FDA's current strategy for PFAS is dysfunctional and has left other authorities, including State governments, to take the lead.

As detailed herein, there are close to 15,000 individual PFAS in existence today; double what there was two years ago. FDA is relying on the toxicity assessment that is available for only seven of these 15,000. FDA's current strategy of wait-and-see turns the precautionary principle on its head. At this rate, by the time the adequate toxicity data are available for the next seven PFAS, there could be 15,000 *more* PFAS in existence. Even with only seven PFAS studied, the data show that almost half are carcinogenic. Therefore, under either the Delaney or the FQPA, FDA must set temporary tolerances for PFAS residues in food. The failure of FDA to set tolerances is a reckless and conscious disregard of their duty of care owed to the American public to ensure the US food supply is safe to eat.

Adequate enforcement methods are available for the analysis of the thirty (30) PFAS identified herein in/on blueberries and lettuce; and for the twenty-six (26) PFAS identified herein in/on ready-to-eat bread, eggs, milk, salmon, clams, corn silage and corn snaplage. As tolerances must be enforceable, this petition is only for these compounds and these commodities, even though Petitioners recognize this action will not provide full protection from food adulteration by the nearly 15,000 PFAS in existence. Nevertheless, based on the best available technology and science, these temporary tolerances should be established for the reasons set forth herein.

Petitioners reserve the right to supplement this Citizen's Petition with any relevant new data or information as it becomes available during FDA's review process.

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[83] 21 U.S. Code § 346. (2019). "… *the Secretary shall promulgate regulations limiting the quantity (emphasis added)* therein or thereon to such extent as he finds necessary for the protection of public health…. In determining the quantity of such added substance to be tolerated in or on different articles of food the Secretary shall take into account the extent to which the use of such substance is required or cannot be avoided in the production of each such article, and the other ways in which the consumer may be affected by the same or other poisonous or deleterious substances."

[84] 43 Op. Att'y Gen. 163 (1979).

III. Environmental Impact

Petitioners claim a categorical exclusion from the requirement of an Environmental Impact Statement in relation to an amendment of a food standard pursuant to 21 CFR § 25.32 (e).

IV. Economic Impact

A statement of economic impact will be provided to the extent requested by the Commissioner of Food and Drugs.

V. 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.

Respectfully Submitted,

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LIST OF APPENDICES