Citizen Petition

Date: February 28, 2024

The undersigned submits this petition under the auspices of:

907(a)(1)(B) of Section 907 of the Federal Food, Drug, and Cosmetic Act

and

https://www.fda.gov/tobacco-products/rules-regulations-and-guidance/section-904-federal-food-drug-and-cosmetic-act-submission-health-information-secretary#

to request that the Commissioner of Food and Drugs test for and, if found, to publicize and make broadly known the presence and concentrations of any residues of pesticide chemicals found in the Certified 1R6F Kentucky Reference Cigarettes that FDA distributes to researchers and research institutions worldwide for purposes of conducting tobacco and tobacco product-related research.

A. Action Requested

Petitioner requests that The Secretary conduct thorough, complete, and comprehensive testing for all classes and instances of pesticide residues on each manufacturing lot, if there is more than one, of the reported 50 million Certified 1R6F Kentucky Reference Cigarettes manufactured for FDA in 2015 by the University of Kentucky Center For Tobacco Reference Products (CTRP), and further:

Petitioner requests that The Secretary conduct thorough, complete, and comprehensive testing for all classes and instances of pesticide residues on each manufacturing lot of any previous Kentucky Reference Cigarettes, including any 1R1, 2R1, 2R1F, 1R3, 1R3F, 1R5F, 1A1, 2A1, 3A1, 1A2, 1A3, 1A4, 1R4F, 2R4F, or 3R4F which were distributed by FDA for research purposes, for which testable samples are still in the possession of FDA or CTRP, and further;

Petitioner requests that The Secretary conduct a scientifically valid sampling of the US tobacco product brand and sub-brand universe, and to report the results in a manner not misleading to lay persons, to determine if pesticide residue contamination in that universe is accurately represented by the pesticide contaminant profile of the Certified 1R6F Kentucky Reference Cigarettes manufactured for FDA by CTRP, and further;

Petitioner requests that The Secretary pro-actively report any pesticide residue findings on the 1R6F cigarettes to all recipients since 2015 of these Certified 1R6F Kentucky Reference Cigarettes from FDA, and that The Secretary pro-actively report any pesticide residue findings on any 1R1, 2R1, 2R1F, 1R3, 1R3F, 1R5F, 1A1, 2A1, 3A1, 1A2, 1A3, 1A4, 1R4F, 2R4F, and 3R4F Kentucky Reference Cigarettes that were distributed by FDA to any recipients of record of any of those Reference Cigarettes, as well as making these findings pro-actively available to any future recipients, users, or researchers and to the public in a transparent manner not misleading to lay persons.

B. Statement of Grounds

GROUNDS #1: NEED FOR RESEARCH DATA ACCURACY

1a. According to the American Chemical Society 2023 study " **Long-Term Storage Study of the Certified 1R6F Reference Cigarette**" :

> *"Reference tobacco products are crucially important to report, compare, and interpret the levels of HPHCs in tobacco products. The reporting or publication of data might be misinterpreted without the inclusion of certified reference materials in the communication."*

https://pubs.acs.org/doi/10.1021/acs.chemrestox.3c00004

1b. While no pesticide chemicals are yet included in FDA's HPHC list, within the classes of pesticide chemicals there are numerous chemicals that by published standards meet **one or more** FDA criteria for inclusion:

- They are IARC classified as known or probable human carcinogens.
- They are identified by ATSDR as having adverse respiratory or cardiac effects.
- They are designated reproductive or developmental toxicants by CEPA.
- They may have addictive properties (Central nervous system activity; Signs of withdrawal).

1c. Reference Cigarettes are seen by scientists and researchers as critical to assessing tobacco product-related effects, and that assessment will not be accurate unless all the relevant variables are disclosed and accounted for in the data. Since many pesticide chemicals have effects that are equivalent to those of chemicals already on the HPHC list, it may be reasonably assumed that they will have an equivalent if not similar impact on the smoke constituent data, although if their presence is unknown, their effects will be mis-attributed.

Mainstream Smoke Chemistry and In Vitro and In Vivo Toxicity of the Reference Cigarettes 3R4F and 2R4F
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6402302/

> *" Reference cigarettes play an important role in the identification and assessment of cigarette smoke-related effects. These cigarettes allow the replication and comparison of experiments performed in other laboratories.*
>
> *"Such comparisons can be performed by setting the values from reference cigarette data to 100% and expressing the values from other experimental cigarette as a percentage of the reference value."*
>
> *"In order to provide reference cigarettes that are easily available for all laboratories, all over the world, working in this field of research, the United States (U.S.) cigarette industry, on request of the Scientific*

Advisory Board of the Council for Tobacco Research, has provided such cigarettes since 1969. "*

* Petitioner notes that CTR and the Tobacco Institute were disbanded in 1999 as part of the Tobacco Master Settlement Agreement, but prior to that had served for 40+, years as the 'scientific' lobbying arm of the US Tobacco industry. Petitioner asserts that the fact that the Kentucky Reference Cigarette program was initiated, promoted and funded by these thoroughly discredited organizations from 1969 through 1999 makes FDA transparency about the current 2015 Certified 1R6F Kentucky Reference Cigarettes a scientific imperative.

1d. Because Reference Cigarettes are "crucially important to report, compare, and interpret the levels of HPHCs in tobacco products" (ACS), reporting and interpreting HPHC data in commercial brands and sub-brands using Reference Cigarettes that are contaminated with unrecognized, undocumented chemicals and chemical compounds that are scientifically certain to have multiple unrecognized impacts on the tobacco product smoke constituent data is not in the best interests of scientific accuracy or public health and safety.

The presence of pesticide residues as unrecognized but highly confounding variables would skew and potentially invalidate smoking and health research data to such an extent that to not correct this gap in public knowledge would be counter to the best interests of public health and safety, and counter to the clear intent of "Tobacco Product Standards" a3A-B. of Section 907 of the Federal Food, Drug, and Cosmetic Act

GROUNDS #2: SUPPORTS FDA HPHC PUBLIC AWARENESS GOALS

FDA has committed to "Making sure the public can clearly understand the real and potential risks of tobacco use is an important goal. Presently, **FDA is conducting research about how best to ensure that the public is made aware of the dangers of the chemicals and chemical compounds in tobacco products** and smoke and to communicate the levels of HPHCs in each brand and sub-brand of tobacco product. In the meantime, FDA is including messages about HPHCs in its ongoing public health campaigns."

https://www.fda.gov/tobacco-products/products-ingredients-components/harmful-and-potentially-harmful-constituents-hphcs

2a. FDA defines HPHCs in very clear terms: "HPHCs are chemicals or chemical compounds in tobacco products or tobacco smoke that cause or could cause harm to smokers or nonsmokers."

> In making the dual definitional distinctions between "chemicals or chemical compounds" and "... in tobacco products or tobacco smoke...", FDA points to the reality that there are potential HPHCs in both the smoke of pure tobacco and the smoke of tobacco products, and these HPHCs can be:
>
> (1) Naturally occurring or man-made.
> (2) Single or compound chemicals.
> (3) Occurring as a constituent in the smoke of BOTH uncontaminated tobacco leaf and tobacco products.
> (4) Occurring as a constituent ONLY in the smoke of tobacco products and NOT in the smoke of uncontaminated tobacco leaf.

2c. As of the date of this Petition, and to the best of Petitioner's knowledge, and according to FDA (See Exhibit 2), FDA has not conducted pesticide residue testing on tobacco products or on Kentucky Reference Cigarettes and has not determined their presence or absence in either.

2d. As of the date of this Petition and to the best of Petitioner's knowledge FDA has not conducted or funded research to determine the HPHC smoke constituents of tobacco that is free from contamination by pesticide chemicals, so there can be no informed discussion about the HPHC constituents of tobacco smoke, only of tobacco product smoke.

However if The Secretary acts on Petitioner's request and as a result of the requested investigation and testing finds pesticide residues to be widespread contaminants of tobacco products, and therefore based on scientific evidence of transfer of pesticides from tobacco into mainstream

smoke to be constituents of the smoke of these tobacco products, then there would be every reason under current FDA policies and regulations to classify qualifying pesticides as HPHCs and to ensure that the public is urgently informed and educated regarding their presence and extent in specific tobacco product brands and sub-brands, their potential health implications in tobacco product smoke, and their impact on the safety of smoking tobacco products.
https://www.fda.gov/tobacco-products/rules-regulations-and-guidance/section-907-federal-food-drug-and-cosmetic-act-tobacco-product-standards

GROUNDS #3: CLEAR HISTORY OF PESTICIDE RESIDUES EXISTS

Research data from all studies that have been conducted using Kentucky Reference Cigarettes since 1969 have been compromised to one degree or another by the unacknowledged presence of significant pesticide contaminants in every Kentucky Reference Cigarette series, beginning with high levels of organochlorine pesticides including DDT in the initial 1969 1R1 series, which was sourced from the commercial tobacco supply, which was known to have been heavily contaminated with organochlorine pesticides at the time. According to the UKCTRP website, all subsequent Kentucky Reference Cigarettes have also been sourced from the commercial tobacco supply at the time of manufacture, and apparently no effort has ever made to test for or record the presence of these critically important confounding variables.

3a. Chlorinated Insecticide Residues in The University Of Kentucky Reference And Alkaloid Series Cigarettes (1976)

https://www.coresta.org/sites/default/files/abstracts/Tobacco_Science_1976_20-8_p._22-25_ISSN.0082-4523.pdf

The chlorinated hydrocarbon insecticide content of the Research and Reference cigarettes produced by the Tobacco and Health Research Institute, University of Kentucky, has been examined. Total chlorinated insecticide residues on the cigarettes manufactured in 1969 ranged from 12.5 to 64.3 ppm with the 1R1 reference cigarette exhibiting the highest level. DDT-TDE residues accounted for >97% of the total content in this series. The remainder was composed of dieldrin and endrin residues. No endosulfan insecticide was detected. For the reference and research cigarettes manufactured in 1974, levels of chlorinated insecticide residues ranged from 3.6 to 7.1 ppm. Again, DDT-TDE accounted for the majority (62 to 77%) of the residues, with the balance composed of endosulfan. Smoke condensate derived from the 1R1 cigarette under standard smoking conditions contained an average of 8.3 μg of DDT-TDE residues/cigarette. Approximately 9.2% of the p,p′-DDT was transferred intact to the mainstream smoke.

3b. The authors of this 1976 study were clear in the need to assess the impact of pesticide residues in both the initial Kentucky Reference Cigarette and of the US commercial tobacco product supply:

> *"It has been well documented that cigarettes and other tobacco products contain insecticide residues. Most of these residues consist of the chlorinated insecticides, particularly DDT and more recently endosulfan. Moreover, appreciable quantities of these insecticide residues are transferred to the mainstream smoke.*
>
> *These studies suggest that residues of the chlorinated insecticides would be present on experimental cigarettes and in mainstream smoke from them. The present study was conducted to determine the nature and levels of chlorinated insecticides in the reference and research cigarettes and in 1RI smoke condensate.*
>
> *The actual health significance of these residues, if any, must await evaluations conducted with pesticide-free tobacco products."*

3c. In response to Petitioner's Open Records request in 2022, University of Kentucky has informed Petitioner that no UK entity including the Center For Tobacco Reference Products has conducted any pesticide residue testing on any of its Reference Cigarettes at any time since 1976 (see Exhibit 1).

FDA has told Petitioner that FDA has not communicated with UK regarding the presence or absence of pesticide residues in Kentucky Reference Cigarettes from 1976 to the present. (see Exhibit 2).

The clear implication is that some or all data from research conducted using Kentucky Reference Cigarettes since 1976 may have been skewed by the presence of various unknown combinations of pesticide residues on tobacco that, because the tobacco was sourced from the commercial US tobacco supply each time, it has contaminated successive editions of Reference Cigarettes since then - potentially compromising or invalidating 50+ years of research worldwide.

Petitioner is requesting that The Secretary move quickly, considering the impact on the body of science that depends on the data from these UK Reference Cigarettes, to correct this longstanding impediment to accurate assessment of the hazards of smoking by funding and implementing the requested comprehensive assessment and reporting of pesticide chemical residues in Certified 1R6F Kentucky Reference Cigarettes.

GROUNDS #4: PESTICIDE CHEMICALS IN THE US COMMERCIAL TOBACCO SUPPLY

While FDA has not conducted pesticide residue studies of the US tobacco product supply, and while manufacturers are not required to report pesticide residues as constituents of tobacco product smoke under Section 904 of the FFDCA, the limited published information available indicates the possibility of near-universal pesticide residue contamination. On the basis of both the historical record and contemporary data, there is a compelling indication that the pesticide residue sampling of the US tobacco product

universe requested by Petitioner will find a previously unrecognized and potentially remediable HPHC threat in commercial US tobacco products.

Hard Data On Pesticide Contaminants

1. In 2018 Petitioner commissioned testing of 5 US brands by a fully accredited lab with tobacco product substrate experience with results shown in Exhibit 3,

2. In 2022 The Ministry of Health of the Government of Saudi Arabia published a survey of all international brands sold in SA including a number of US brands, with results shown in Exhibit 4.

Petitioner submits to The Secretary that in light of these and other indicators, adherence to the Precautionary Principle makes it imperative to investigate and confirm or refute the potential compromise of the Certified 1R6F Kentucky Reference Cigarette program with unrecognized and undocumented pesticide residues and the potential exposure of American smokers and their families to chronic inhalation of multiple pesticide chemicals through smoking or exposure to the smoke of tobacco products, tobacco products that may have been tested by manufacturers or others and found, perhaps erroneously, to be in compliance with the Family Smoking Prevention and Tobacco Control Act standards using these potentially compromised Certified 1R6F Kentucky Reference Cigarette research materials.

C. Environmental Impact

N/A

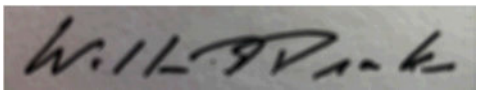
D. Economic Impact

N/A

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.

William D. Drake



(b) (6)

EXHIBIT 1