

September 20, 2023

Dr. Donald A. Prater
Acting Director, Center for Food Safety and Applied Nutrition (CFSAN)
Food and Drug Administration (FDA)
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Dear Dr. Prater:

We write with concerns and questions about the conclusion reached by the FDA regarding the safety of cell-cultured chicken products produced by UPSIDE Foods. The concerns outlined in this letter are focused on the levels of heavy metals, especially lead and cadmium, which may be too high and not safe for consumption.

In a November 14, 2022 [memorandum](#), the FDA stated, “We did not identify any substances that would lead us to question UPSIDE’s conclusion regarding the safety of its food given available information, existing uses or authorizations in food, and anticipated exposure. ... We evaluated the firm’s specifications for toxic heavy metals to ensure they were as low as reasonably possible and were consistent with food safety.” Given this declaration, FDA appears to conclude that UPSIDE Foods’ *specifications* for toxic heavy metals are both consistent with food safety and as low as reasonably possible.

UPSIDE Foods notes in its [submission](#) to the FDA that “Batch release specifications have been developed for UPSIDE Foods’ cultured poultry meat (CPM) product to ensure the safety and suitability of product that is released for further food processing pursuant to USDA oversight.” The specifications for UPSIDE Food’s CPM for lead, arsenic, and cadmium are <2,000 ppb, <1,000 ppb, and <2,000 ppb, respectively. This would seem to indicate that a batch of CPM with levels just below these specifications – 1,000 to 1,999 ppb of lead; 900 to 999 ppb of arsenic; and 1,000 to 1,999 ppb of cadmium – would be considered acceptable to be processed into a final food product and sold to consumers.

It should be noted that the cell-cultured chicken product produced by GOOD Meat has [specifications](#) for lead, arsenic, and cadmium of < 200 ppb, < 100 ppb, and < 20 ppb, respectively. Thus, the specifications for GOOD Meat cell-cultured chicken for these three heavy metals are 10 to 100 times lower than for the UPSIDE Foods’ CPM. In fact, testing showed that levels of lead, arsenic and cadmium in the cultured product were < 10 ppb, < 10 ppb, 1 ppb or lower, respectively.

In addition to the specifications for heavy metals for UPSIDE Foods’ CPM being excessively high, the actual levels in their CPM, although much lower than the respective specification level,

raises safety concerns because they are still much higher than would be found in current retail chicken products.

UPSIDE Foods produces two types of CPM, one made using fetal bovine serum, and one made without serum. UPSIDE sampled three independent lots of CPM made using serum and three made without serum,¹ and it appears the levels of lead, arsenic, and cadmium in the CPM differ based on whether the growth medium contains serum. For serum-containing CPM, the average levels of lead, arsenic, and cadmium are 16.9 ppb, 11.2 ppb, and 8.1 ppb, respectively.

For serum-free CPM, the average levels of lead, arsenic, and cadmium are 47.6 ppb, < 5 ppb, and 14.8 ppb, respectively. Thus, the average levels of lead and cadmium are significantly higher and the levels of arsenic significantly lower in the serum-free CPM compared to the serum-containing CPM. For lead and cadmium, the levels in the CPM (whether serum-containing or serum-free) are significantly higher than found in retail chicken. UPSIDE Foods also tested ground chicken that was bought at a local retail store and the level of lead and cadmium were 2.4 ppb and < 1.3 ppb, respectively. Therefore, the level of lead in the serum-free CPM is 20 times higher and the cadmium levels 10 times higher than those levels found in retail ground chicken.

Data from the FY2018 – FY2020 Total Dietary Study (TDS) on chicken show that lead and cadmium are infrequently found in chicken products and when found, are present at much lower levels. For example, for chicken breast without skin (TDS food number 240), of 27 samples only one had detectable levels of lead (7.3 ppb), and 6 of 27 samples detectable levels of cadmium, with average level of 0.75 ppb. For chicken breast with skin, fried, fast food (TDS number 336), of 27 samples, only one had detectable levels of lead (7.8 ppb), and all samples had detectable levels of cadmium, with a mean of 0.99 ppb. For chicken leg, fried with skin, fast food (TDS food number 338), of 27 samples only one had detectable levels of lead (4.4 ppb), and none of the 27 samples had detectable levels of cadmium. For chicken nuggets (TDS number 241), of 27 samples, only one had detectable levels of lead (4.3 ppb), and all samples had detectable levels of cadmium, with a mean of 0.83 ppb.

Given that some cell-cultured chicken products have lead and cadmium content that is approximately 10 times higher than current retail chicken products, we hope you are able to provide information on the following questions.

- **Does the FDA believe that the following specifications for cultured poultry meat are considered safe levels and are consistent with the goals of the Closer to Zero initiative?**
 - < 2,000 ppb for lead
 - < 1,000 ppb for arsenic
 - < 2,000 ppb for cadmium

¹ See Table 5.5-1, pg 34 in <https://www.fda.gov/media/163262/download?attachment>

- **Explain the agency’s assertion that these specifications for lead, arsenic, and cadmium “are as low as reasonably possible” for a product, especially given that another product has specifications that are 10 to 100 times lower.**
- **As outlined above, recent TDS data demonstrates that lead and cadmium are infrequently found in current retail chicken products and when found, are present at much lower levels. However, in its memorandum to UPSIDE, the FDA indicated that it agreed with the company’s conclusion that food comprised of or containing cultured chicken cell material “are as safe as comparable foods.” What factors led the agency to agree with UPSIDE’s conclusion?**

We support the goal of FDA’s Closer to Zero initiative to reduce dietary exposure to contaminants such as arsenic, lead and cadmium to levels as low as possible and urge the agency to apply this approach in regulating cell-cultured food products.

If you are able to provide a response to this letter in a timely manner, it would be greatly appreciated. Alternatively, we would be pleased to meet with you or designees to discuss. Thank you for your attention to this important matter.

Sincerely,

Brian Ronholm
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Consumer Reports

Dr. Michael Hansen, Ph.D.
Senior Scientist
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