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Memo to ASTA Membership on Consumer Reports Testing Methodology

Consumer Reports published an article, entitled "Your Herbs and Spices Might Contain Arsenic, Cadmium, and Lead" on November 9, 2021. The article concluded that almost a third of the 126 spices tested had heavy metal levels high enough to raise health concerns.

ASTA followed up with Consumer Reports to learn more about the methodology used in their study. We spoke to Jen Shecter, the Senior Director of Content Impact and Outreach, Michael McCauley, the Associate Director of Strategic Partnerships, and several members of the science team, including the James Dickerson, the Chief Science Officer and Tunde Akinleye, who was the lead on the spices testing project. During the conversation, ASTA raised several questions and concerns about their approach.

We identified several problematic ways in which Consumer Reports evaluated the risk to consumers of the products that it tested, which we believe resulted in an inaccurate determination:

- ***Unclear Indication of Risk -*** In the article, "levels of concern" are denoted by red and green dots next to products that were tested. One red dot refers to "some concern", two red dots refers to "moderate concern," and three red dots refers to "high concern". A green dot denoted no concern. Only a few products received two red dots or three red dots. However, the article is unclear as to what these dots actually refer to in terms of risk level.

  Consumer Reports has confirmed in follow up with ASTA that the concern levels correspond to the Hazard Index (HI) calculations as follows:

  1 green dot (no concern) – HI of <1
  1 red dot (some concern) – HI of 1-2.9
  2 red dots (moderate concern) – HI of 3-4.9
  3 red dots (high concern) – HI of 5+

- ***Invalid Safety Assessment –*** Consumer Reports determined the possibility of adverse health effects by the HI approach as explained in their methodology section. Their HI approach was based on the addition of each of the Hazard Quotients (where a hazard quotient is equal to the estimated daily intake / reference dose) from lead, cadmium, and arsenic.

  There is interest amongst the scientific community in understanding the impact of the combination of heavy metals in the diet. However, the scientific evidence for how to evaluate this is still emerging. The addition of risk levels from lead, cadmium, and arsenic is not a recognized approach to the evaluation cumulative risk for these toxins. Since each heavy metal has a different mode of action and different health endpoints upon which the reference doses are based, it is not correct to simply add the risk levels together. This would be an "apples to

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oranges" approach, as the levels are measuring different and unrelated issues. There is no known regulatory or scientific basis for using this approach.

FDA does not conduct cumulative exposure assessment for different metals. This approach is only recognized when compounds being added have the same mode of action (MOA). Further, if toxins are determined to have the same MOA, different potencies need to be accounted for with toxicity equivalency factors, which was not done in the Consumer Reports assessment.

It should also be noted that although Consumer Reports states that a reference dose is used in the calculation, the only actual reference doses (as defined by USEPA) used are for arsenic and methyl mercury. The cadmium reference dose is 1 ug/kg bw/day (as opposed to the lower EFSA value of 0.36 ug/kg bw/day used by Consumer Reports). There is no reference dose for lead, rather it is evaluated by estimating the increase in blood lead level associated with a certain amount of exposure. Where multiple limits are listed in the methodology section, the Hazard Quotients were calculated using the more conservative limit.

- ***Inaccurate Consumption Levels*** - The consumption value that was used to conduct the risk assessment was arbitrarily selected to be three times the Reference Dose Customarily Consumed (RACC) of ¼ teaspoon (i.e., three servings per day for a total of ¾ teaspoon). This is not in line with the pattern of consumption nor the current consumption data for spices. ASTA has conducted dietary intake assessments for spices, demonstrating that even at the 90th percentile of consumption, consumers are eating less than 0.5 g or ¼ teaspoon per day. The consumption amount used by Consumer Reports is random and would overestimate risk.

Consumer Reports also shared ranges of data observed in the samples tested in their study, which are available here.

It appears that if risk was determined based on each heavy metal individually, using standard risk assessment methods, many of the spices denoted as having unsafe levels would not have been identified as having levels of concern.

It is clear that this risk assessment did not follow the regulatory risk assessment guidance or scientific protocols. Other considerations regarding the publication are that there were only 126 products tested and their methodology notes that 2-3 samples of each product were tested from three states in the US. This is a limited number of samples to determine safety for the entire industry.

Consumer Reports also noted that positive information about the industry was included, such as the absence of *Salmonella* in any spice products. Also, Consumer Reports opted not to include information on Aerobic Plate Count numbers based on the information provided by the industry explaining that this is not a food safety metric.

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In summary, it is clear that the approach that Consumer Reports took to evaluate the risk from heavy metals in spices is deeply flawed. ASTA will continue to work with the Task Force on Heavy Metals to discuss the best way of addressing errors in this evaluation and continue to keep the membership informed on updates.