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# **Action Level for Inorganic Arsenic in Apple Juice: Guidance for Industry**

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Office of Food Safety, HFS-300  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
5001 Campus Drive  
College Park, MD 20740  
(Tel) 240-402-1700  
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**U.S. Department of Health and Human Services  
Food and Drug Administration  
Center for Food Safety and Applied Nutrition**

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# Action Level for Inorganic Arsenic in Apple Juice: Guidance for Industry<sup>1</sup>

This guidance represents the current thinking of the Food and Drug Administration (FDA or we) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff responsible for this guidance as listed on the title page.

## I. Introduction

This guidance provides information to manufacturers on the action level<sup>2</sup> of 10 parts per billion (ppb) or 10 micrograms/kilogram ( $\mu\text{g}/\text{kg}$ ) for inorganic arsenic in apple juice<sup>3</sup> that is intended to help protect public health by reducing exposure to inorganic arsenic and that is achievable by industry with the use of current good manufacturing practices. This guidance presents the background and rationale for FDA's action level.

Consistent with 21 CFR 109.6(d), this action level reflects the level of inorganic arsenic at which FDA may regard apple juice as adulterated within the meaning of section 402(a)(1) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 342(a)(1)). We intend to consider this action level, in addition to other factors, such as our confidence in a measured analytical value, when considering whether to bring enforcement action in a particular case.

In general, FDA's guidance documents do not establish legally enforceable responsibilities. Instead, guidances describe our current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word should in FDA guidances means that something is suggested or recommended, but not required.

## II. Background

Arsenic is an element that occurs in the environment from both natural and manmade sources,

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<sup>1</sup> This guidance has been prepared by the Division of Plant Products and Beverages, Office of Food Safety, in the Center for Food Safety and Applied Nutrition at the U.S. Food and Drug Administration.

<sup>2</sup> Under 21 CFR 109.4, when certain conditions are met, FDA may establish an action level for an added poisonous or deleterious substance to define a level of contamination at which a food may be regarded as adulterated, within the meaning of section 402(a)(1) of the Federal Food, Drug, and Cosmetic Act (FD&C Act). In this context, "added" does not mean added by the manufacturer, but rather resulting from the hand of man; for example, from previous pesticide use (see *United States vs. Anderson Seafood, Inc.* 622 F.2d 157 (5th Cir. 1980)). Action levels serve as guidance to FDA field staff and industry. We will establish an action level, as opposed to a tolerance or regulatory limit (which must be established by rulemaking), when technological or other changes that might affect the appropriateness of the tolerance are foreseeable in the near future (21 CFR 109.6(d)). Consistent with 21 CFR 109.6, we will consider action levels, in addition to other factors, when considering whether to bring enforcement action in a particular case.

<sup>3</sup> Including apple cider.

including erosion of arsenic-containing rocks, volcanic eruptions, contamination from mining and smelting ores, and previous or current use of arsenic-containing pesticides (Ref. 1).<sup>4</sup> Arsenic is found in both inorganic and organic forms (together referred to as total arsenic), and inorganic arsenic is generally considered more toxic than organic arsenic (Ref. 4).<sup>5</sup> Consumption of inorganic arsenic has been associated with cancer, skin lesions, cardiovascular disease, and diabetes in humans (Refs. 4-5). A report by the National Research Council (NRC) (Ref. 5) also listed adverse pregnancy outcomes and neurodevelopmental toxicity as adverse health effects of concern for exposure to inorganic arsenic. The Joint Food and Agriculture Organization/World Health Organization (FAO/WHO) Expert Committee on Food Additives (JECFA) (Ref. 4), which includes participation by FDA scientists, concluded that food can be a major contributor to inorganic arsenic exposure, and the European Food Safety Authority (EFSA) (Ref. 6) concluded that dietary exposure to inorganic arsenic should be reduced.<sup>6</sup>

These findings support our initiatives to assess and reduce exposure to inorganic arsenic in food. For example, in April 2016, we released a risk assessment on arsenic in rice and rice products (Ref. 7) and a draft guidance for industry with an action level for inorganic arsenic in infant rice cereal (81 FR 19976). In August 2020, we finalized the approach presented in the 2016 draft guidance (85 FR 47797). We also conducted surveys in 2013, 2016, and 2018 of arsenic in other foods (Refs. 8-10), focusing primarily on rice and rice products, and released consumer information on consumption of rice and rice products, available online at <https://www.fda.gov/consumers/consumer-updates/consumers-seven-things-pregnant-women-and-parents-need-know-about-arsenic-rice-and-rice-cereal>. We also posted analytical results for arsenic in foods intended for babies and young children sampled under the FDA's Toxic Elements in Food and Foodware, and Radionuclides in Food Program from FY2008-FY2021 (Ref. 11).

On July 15, 2013, we published in the *Federal Register* (78 FR 42086) a notice of availability for a draft guidance for industry entitled "Arsenic in Apple Juice: Action Level," a supporting document entitled "Supporting Document for Action Level for Arsenic in Apple Juice," and a risk assessment report entitled "A Quantitative Assessment of Inorganic Arsenic in Apple Juice" (Ref. 12). The 2013 risk assessment focused on cancer effects, but a growing body of literature suggests an association with adverse neurodevelopmental effects in infants and children from exposure to inorganic arsenic (Refs. 5, 7).

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<sup>4</sup> Generally, it is not possible for FDA to identify the specific source of any arsenic that may be found in a particular type of food, including apple juice. Therefore, for purposes of this guidance, FDA is not distinguishing the presence of arsenic that may be due to prior pesticide use, such that the residues are pesticide chemical residues subject to a tolerance or tolerance exemption by the Environmental Protection Agency (EPA) under section 408 of the FD&C Act (21 U.S.C. 346a), or other environmental contamination. Our understanding from EPA information is that currently arsenical pesticide use in the United States is limited to the organic arsenical monosodium methanearsonate (MSMA) for use on sod farms, golf courses, highway rights-of-way, and to control weeds in cotton fields (Ref. 2), and to chromated copper arsenate (CCA) for use by certified pesticide applicators using specialized high-pressure equipment in wood treatment facilities (Ref. 3).

<sup>5</sup> Organic in this sentence refers to arsenic molecules that contain carbon. Inorganic arsenic molecules do not contain carbon. Use of the term "organic" here does not refer to organically grown food.

<sup>6</sup> The Codex Alimentarius Commission (Codex), an international food standards organization, has established maximum levels (MLs) for toxic elements, including inorganic arsenic, in certain foods in international trade. At this time, Codex has not established a ML for inorganic arsenic in apple juice.

Apple juice is one source of exposure to inorganic arsenic from food. Apple juice is a greater potential source of dietary inorganic arsenic exposure for children than for adults, because children's dietary patterns are often less varied than those of adults, and they consume more apple juice relative to their body weight than do adults (Ref. 13).

FDA has conducted routine surveillance for total arsenic in apple juice for many years; surveillance results are described in Section III below. Total arsenic levels in apple juice samples have routinely been below 10 ppb; for example, more than 95 percent of total arsenic levels in a set of 94 apple juice samples collected at retail as part of a fiscal year (FY) 2011 assignment were below 10 ppb (Ref. 14). The remaining four samples in that assignment with total arsenic levels above 10 ppb had inorganic arsenic levels below 10 ppb. However, we occasionally find apple juice samples with inorganic arsenic levels above 10 ppb as part of our surveillance efforts.

FDA considers that it is possible to further reduce public exposure to inorganic arsenic from apple juice in general, and specifically from apple juice that currently may contain inorganic arsenic at levels above 10 ppb. Therefore, we are issuing this final guidance to manufacturers on an action level for inorganic arsenic in apple juice of 10  $\mu\text{g}/\text{kg}$  or 10 ppb. This guidance finalizes the approach presented in the July 2013 draft guidance.

### **III. Data on Arsenic in Apple Juice**

FDA routinely monitors total arsenic in apple juice through its Toxic Elements in Food and Foodware, and Radionuclides in Food Program (TEP).<sup>7</sup> The TEP is a targeted monitoring program that monitors levels of certain toxic elements, including arsenic, in foods and foodware in domestic and imported products. Foods selected for analysis include those that are suspected of having elevated levels of toxic elements based on historical data or other information available to us. Apple juice is one of the foods sampled under the TEP program. FDA has published TEP data on arsenic in apple juice from 2005-2011 (Ref. 15) and 2013-2022 (Refs. 16-17). In October 2011, FDA issued a supplemental assignment to the TEP resulting in the collection of 94 retail apple juice samples. FDA published these data in 2013 (Ref. 14).

Table 1 summarizes results from the FY2011 retail sample survey. These samples, all of which were speciated for inorganic arsenic, had a mean of 4.4 ppb inorganic arsenic and a standard deviation of 2.4 ppb inorganic arsenic, with a range of 0 to 9.8 ppb inorganic arsenic. Of the 94 samples, 90 had total arsenic levels of 10 ppb or less; the other four samples had total arsenic levels ranging from 11 to 36 ppb. All samples had inorganic arsenic levels below 10 ppb and 51 samples had inorganic arsenic levels below 5 ppb.<sup>8</sup>

Table 2 summarizes TEP data collected from FY2013-2022, consisting of 160 single-strength apple juice samples (Ref. 16). These samples had a mean of 4.6 ppb total arsenic and a standard deviation of 6.6 ppb total arsenic, with a range of 0 to 44 ppb total arsenic. Of the 160 samples,

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<sup>7</sup> <https://www.fda.gov/food/chemical-contaminants-pesticides/toxic-elements-foods-and-foodware>.

<sup>8</sup> In addition to inorganic arsenic, methods for speciating arsenic can also quantify organic arsenic species including monomethylarsonic acid (MMA) and dimethylarsinic acid (DMA). Because only three of the 94 samples had levels of MMA or DMA above trace amounts (i.e., above 2 ppb, Ref. 14) and because inorganic arsenic is considered more toxic than organic arsenic (see Section II), FDA concluded that the action level for arsenic in apple juice should be based on inorganic arsenic.

143 samples had total arsenic levels of 10 ppb or less, and 125 samples had total arsenic levels of 5 ppb or less. Speciation analysis was conducted on 14 of these 160 TEP samples, and these speciated samples had a mean of 20.6 ppb inorganic arsenic and a standard deviation of 10.1 ppb inorganic arsenic, with a range of 8.3 to 39 ppb inorganic arsenic (Ref 17).<sup>9</sup> Of the 14 speciated samples, 12 were confirmed to have inorganic arsenic levels above 10 ppb.

FDA also monitors apple juice through the Total Diet Study (TDS) (Ref. 18). The TDS is an ongoing market basket study representative of the U.S. diet that includes analysis of toxic elements such as arsenic. Table 2 summarizes TDS data on arsenic in apple juice collected from FY2013-2020, consisting of 47 single-strength apple juice samples for babies and for general consumption. The TDS data had a mean of 2.7 ppb total arsenic with a standard deviation of 2.0 ppb total arsenic and ranged in concentration from 0 to 10 ppb total arsenic. Most TDS samples are not samples of individual foods; they are composites (“averages”) of three retail samples, all from different cities. Because the compositing provides an “average” result, and our achievability assessment is based on percentiles of arsenic concentrations in individual samples, we did not use the TDS data in the achievability assessment or other assessments in Section IV.

Because FDA analyses indicate the majority of arsenic in apple juice is inorganic arsenic, total arsenic can closely approximate inorganic arsenic in apple juice (Ref. 14). FDA used the total arsenic data collected from FY2013-2022 to recalculate the disease rate and achievability estimates from FY2011, as well as to estimate the reduction in inorganic arsenic exposure from apple juice to children based on the 10 ppb action level. We discuss our evaluation in the next section.

## **IV. Risk Assessment, Achievability Assessment, and Exposure Assessment**

**a. Risk Assessment:** In 2008, we established a level of concern (Ref. 19) of 23 ppb for inorganic arsenic in single-strength (ready-to-drink) apple juice as part of a hazard assessment. This level of concern, which is no longer in use, focused on non-cancer endpoints and average consumption of apple juice with higher levels of arsenic for a limited (not lifetime) period of time.

In 2011, to facilitate development of an action level for inorganic arsenic in apple juice, FDA conducted a quantitative assessment of the risk for cancer associated with exposure to inorganic arsenic in apple juice. Detailed information on the risk assessment process can be found in the risk assessment document (Ref. 12). Briefly, FDA used data on lung and urinary tract cancer cases from a Taiwanese population exposed to high levels of inorganic arsenic in drinking water (Ref. 20-21) to develop a dose-response model for inorganic arsenic and cancer. FDA used data from the National Health and Nutrition Examination Survey to estimate apple juice consumption rates for children (ages 0-6 years) and for all persons (ages 0-50 years and for lifetime), both for average consumption and for high consumption (three times average consumption). The dose-response

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<sup>9</sup> FDA uses an inductively coupled plasma mass spectrometry (ICPMS) method for total arsenic (<https://www.fda.gov/downloads/Food/FoodScienceResearch/LaboratoryMethods/UCM377005.pdf>) and a high performance liquid chromatography-inductively coupled plasma mass spectrometry (HPLC-ICPMS) method for speciation analysis (<https://www.fda.gov/media/86499/download>). Measurement of total arsenic is considered simpler and easier to perform than speciation analysis, in which the inorganic and organic forms of arsenic present in a sample are identified and quantified. Therefore, in the past, FDA has screened apple juice samples for total arsenic, and then speciated samples with elevated total arsenic to determine inorganic arsenic levels. We intend to continue this practice.

model was then used to model disease rates based on the estimated average inorganic arsenic concentrations in apple juice collected by FDA in FY2011 (Table 3).

To update the disease rate calculations in the risk assessment, FDA estimated total arsenic concentrations in apple juice from FY2013-2022 TEP data (Ref. 16). We modeled average total arsenic concentrations in juice at or below hypothetical inorganic arsenic maximum limits (3, 5, and 10 ppb), where juices with arsenic concentrations exceeding these maximum limits were hypothetically eliminated from the food supply.

Based on FY2013-2022 sampling data and assuming chronic exposure (0-50 years), the modeled bladder and lung cancer disease rates at the hypothetical maximum limits ranged from 2.5 to 4.2 cases per million people for the average consumer and 7.5 to 12.8 cases per million people for high-level consumers (see Table 4). Comparison of risk estimates between lifetime exposure and childhood exposure indicate that much of the risk from apple juice is incurred during childhood because the majority of exposure occurs during childhood (Ref. 12).

**b. Achievability Assessment:** To assess achievability, or manufacturers' ability to achieve the hypothetical maximum limits on inorganic arsenic, we used survey results to determine the percentage of apple juice samples in the market that would fall at or below each of the hypothetical maximum limits. The initial analysis from samples collected in FY2011 (Table 3) demonstrated that at 3, 5, and 10 ppb, achievability was 31, 54, and 100 percent, respectively.

We repeated this analysis on the 160 single-strength TEP samples collected from FY2013-2022 to examine arsenic levels in apple juice since the 2013 draft guidance (Ref. 16). Table 4 shows that 63, 78, and 89 percent of TEP samples had total arsenic levels below 3, 5, and 10 ppb, respectively. These results reflect a trend toward improved achievability at lower levels (i.e., 3 and 5 ppb) since the FY2011 survey, but decreased achievability at 10 ppb.

**c. Exposure Assessment:** To examine the effect of a 10 ppb action level for apple juice on inorganic arsenic exposure in children, we compared estimated dietary exposure for total arsenic from apple juice with and without a 10 ppb action level. To estimate dietary exposure, we used the mean concentration of total arsenic in apple juice and the 90th percentile consumption (representing an upper bound) for children. This upper bound percentile (90th percentile) was chosen as a health protective measure to account for children who consume larger amounts of apple juice and would therefore have higher exposures. For the FY2013-2022 dataset, an action level of 10 ppb for single-strength (ready-to-drink) apple juice reduces dietary exposure to total arsenic for children by 42% at the 90th percentile consumption level.

## V. Action Level

FDA previously identified 23 ppb as the level of concern for inorganic arsenic in apple juice for the purpose of a hazard assessment based on short-term exposure and non-cancer endpoints. Based on the quantitative risk assessment using chronic exposure (0-50 years) and cancer endpoints, as well as considerations including additional information on neurodevelopmental effects, data on total and inorganic arsenic levels, manufacturer achievability, and reduction in exposure, FDA is setting an action level for inorganic arsenic in single-strength apple juice of 10 µg/kg or 10 ppb. The action level of 10 µg/kg or 10 ppb, based on chronic exposure, will be protective against adverse effects associated with short-term exposure that were the basis for the level of concern of 23 ppb.

Because of the potential for human health risks associated with exposure to inorganic arsenic, human exposure to inorganic arsenic in apple juice should not exceed levels achievable with the use of good manufacturing practices. FDA considers that it is possible to further reduce public exposure to inorganic arsenic from apple juice in general, and specifically from apple juice that currently may contain inorganic arsenic at levels above 10 ppb.

Possible sources of inorganic arsenic in apple juice include processing aids, prior use of arsenic-based pesticides on land currently used for apple orchards, current use of arsenic-based pesticides in other countries, naturally high levels of arsenic in soil or water, and atmospheric deposition from industrial activities. It may be possible in some cases for manufacturers who have found elevated inorganic arsenic in sources of apples or apple juice concentrate to reduce or limit inorganic arsenic in apple juice by choosing sources of apples or apple juice concentrate with lower inorganic arsenic levels or no detectable inorganic arsenic.

Another potential source of inorganic arsenic in apple juice is water used by manufacturers to dilute concentrate to prepare ready-to-drink juice. Municipal water supplies in the United States are required to meet a maximum contaminant level of 10 ppb arsenic established by EPA (40 CFR 141.62). However, well water from areas of the U.S. with naturally high arsenic levels in groundwater could contain higher levels of arsenic.<sup>10</sup> It may be possible in some cases for manufacturers who have found arsenic in water used to dilute concentrate to reduce or limit levels of inorganic arsenic in ready-to-drink apple juice by examining and controlling arsenic levels in water used for dilution of juice concentrate.

With regard to processing aids, recent research by FDA shows that the use of some filtering aids to remove sediments in juice can contribute to elevated arsenic levels. Changing or treating filtering aids may reduce the levels of arsenic in filtered juices (Refs. 22-23).

FDA has made the determination that a level of 10 µg/kg or 10 ppb inorganic arsenic is achievable under good manufacturing practices based on evaluation of recent FDA data on arsenic levels in apple juice samples. FDA considers the action level for inorganic arsenic in apple juice to be protective of public health. The action level can reduce human exposure to inorganic arsenic that may be found in apple juice.

We note that achievability at lower levels has been increasing rapidly in recent years. For instance, achievability at 5 ppb improved from 54 percent for samples collected in FY2011 (based on inorganic arsenic) to 78 percent for samples collected from FY2013 to FY2022 (based on total arsenic). Continued improvement with respect to achievability is likely possible over the next several years. We further note that lower arsenic levels are more protective of public health. Modeled cancer rates based on average juice consumption decline from 4.2 cases per million at 10 ppb to 3.2 cases per million at 5 ppb based on FY2013-2022 data. As we collect additional data with respect to achievability and dietary exposure, we expect to revisit action levels as part of FDA's "Closer to Zero" action plan<sup>11</sup> (Ref. 24).

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<sup>10</sup> Water used for dilution must be of safe and sanitary quality (21 CFR 117.37(a)).

<sup>11</sup> FDA's *Closer to Zero* action plan is a science-based, iterative approach to decreasing levels of toxic elements, including arsenic, in foods over time, including by setting action levels.



## VI. Conclusion

For the reasons discussed above, we have concluded that a level of 10 µg/kg or 10 ppb inorganic arsenic is achievable under good manufacturing practices based on evaluation of recent FDA data on arsenic levels in apple juice, which highlights industry progress in lowering levels of inorganic arsenic in apple juice. We intend to take the following sampling and enforcement approach to arsenic in apple juice. We intend to initially analyze apple juice samples for total arsenic. We intend to speciate samples containing more than 10 µg/kg or 10 ppb total arsenic to determine inorganic arsenic levels. We intend to consider the action level of 10 µg/kg or 10 ppb inorganic arsenic as an important source of information for determining whether apple juice is adulterated within the meaning of section 402(a)(1) of the FD&C Act (21 U.S.C. 342(a)(1)). FDA considers on a case-by-case basis whether a food that contains a contaminant is adulterated. When considering whether to bring an enforcement action in a particular case, we will consider whether the inorganic arsenic causes apple juice to be adulterated under section 402(a)(1) of the FD&C Act.

## VII. References

The following references marked with an asterisk (\*) are on display at the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they also are available electronically at <https://www.regulations.gov>. References without asterisks are not on public display at <https://www.regulations.gov> because they have copyright restriction. Some may be available at the website address, if listed. References without asterisks are available for viewing only at the Dockets Management Staff.

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**Table 1. Summary of Data on Total and Inorganic Arsenic in Apple Juice Collected in FY2011 Retail Sample Survey - Number of Samples: 94**

Data Set	Fiscal Year	Arsenic	Mean±std. dev (ppb)	Range (min-max) (ppb)
Retail survey	2011	Total Arsenic*	6.4±4.7	1.3-36
Retail survey	2011	Inorganic Arsenic	4.4±2.4	0-9.8

\* One retail survey was conducted and all of the total arsenic samples were speciated.

**Table 2. Summary of Data on Total Arsenic in Apple Juice Collected from FY2013-2022**

Data Set	Fiscal Year	Number of Samples	Mean±std. dev (ppb)	Range (min-max) (ppb)
Toxic Element Program (TEP)	2013-2022	160	4.6±6.6	0-44
Total Diet Study (TDS)	2013-2020	47	2.7±2.0	0-10

**Table 3. Effects of Three Hypothetical Limits on Arsenic in Apple Juice: Modeled Disease Rates and Manufacturer Achievability from FY2011 Dataset<sup>1</sup>**

Limit (inorganic arsenic, ppb)	Average inorganic arsenic level in juices below specified limit <sup>2</sup>	Disease rates <sup>3</sup> based on average juice consumption <sup>4</sup>	Disease rates based on three times average juice consumption (high consumer)	Percentage of 94 FY11 retail samples with inorganic arsenic levels at or below specified limit <sup>5</sup>
3	1.4	2.5 (0.0, 6.8)	7.7 (0.0, 20.3)	31 %
5	2.7	4.8 (0.0, 12.8)	14.9 (0.1, 38.5)	54 %
10	4.4	8.0 (0.0, 21.3)	24.9 (0.2, 63.8)	100 %

<sup>1</sup> Disease rates for total lung and bladder cancer are from Ref. 12. Disease rates are based on chronic (0-50 years) exposure. Inorganic arsenic levels are based on FY11 retail apple juice data (Ref. 14).

<sup>2</sup> Average inorganic arsenic level based on 94 samples. For the purpose of calculating average levels, levels below the limits of quantitation (LOQ, 2.8 ppb for each arsenic species) were set to 1.4 ppb.

<sup>3</sup> Number of cases per million. Numbers in parentheses represent lower and upper bounds.

<sup>4</sup> Average per capita juice consumption for all persons aged 0-50 years is 0.83 g apple juice/kg bw/day (see Ref. 12, pp. 17-19). Consumption data are from the National Health and Nutrition Examination Survey, 2007-2008.

<sup>5</sup> Percentages calculated by dividing the number of samples with inorganic arsenic levels at or below the proposed limit by 94 total number of samples.

**Table 4. Effects of Three Hypothetical Limits on Arsenic in Apple Juice: Modeled Disease Rates and Manufacturer Achievability from FY2013-2022 Dataset<sup>1</sup>**

<b>Limit (inorganic arsenic, ppb)</b>	<b>Average total arsenic level in juices below specified inorganic arsenic limit<sup>2</sup></b>	<b>Disease rates<sup>3,4</sup> based on average juice consumption<sup>5</sup></b>	<b>Disease rates based on three times average juice consumption (high consumer)</b>	<b>Percentage of 160 FY13-FY22 samples with total arsenic levels at or below specified inorganic arsenic limit<sup>6</sup></b>
3	1.6	2.5 (0.0, 6.2)	7.5 (0.1, 18.6)	63 %
5	2.1	3.2 (0.0, 8.1)	9.8 (0.1, 24.3)	78 %
10	2.7	4.2 (0.0, 10.6)	12.8 (0.2, 31.7)	89 %

<sup>1</sup> In Table 4, disease rates for total lung and urinary tract cancer are calculated based on dose-response model from Ref. 12. Disease rates are based on chronic (0-50 years) exposure. Arsenic levels are based on FY2013-2022 data.

<sup>2</sup> Average total arsenic level based on 160 samples. For the purpose of calculating average levels, non-quantified levels below the LOQ were set to the LOQ (2 or 4 ppb) and levels below the LOD (limit of detection) were set to zero.

<sup>3</sup> The risk estimates presume that all of the arsenic is inorganic. This is a conservative approach, since based on the FY2011 94-sample survey, the median percentage of inorganic/total arsenic is 75 percent.

<sup>4</sup> Number of cases per million. Numbers in parentheses represent lower and upper bounds.

<sup>5</sup> Average per capita juice consumption for all persons aged 0-50 years is 0.69 g apple juice/kg bw/day based on consumption data from What We Eat in America (WWEIA), the food consumption portion of the National Health and Nutrition Examination Survey (NHANES), 2003-2018.

<sup>6</sup> Percentages calculated by dividing the number of samples with total arsenic levels at or below the proposed limit by 160, the total number of samples. Most of these samples were not speciated because they contained  $\leq 10$  ppb total arsenic.