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FDA Issues Final Guidance for Inorganic Arsenic in Apple Juice

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- On June 1, 2023, the FDA announced a final guidance for industry titled "Action Level for Inorganic Arsenic in Apple Juice." The final guidance adopts an action level of 10 parts per billion (ppb) for inorganic arsenic in apple juice, which is the same action level as initially proposed in the agency's July 2013 draft guidance. The final guidance reflects FDA's continued efforts to reduce levels of heavy metal contaminants in food commonly consumed by babies and young children.

- Inorganic arsenic is associated with adverse human health effects such as cancer, skin lesions, diabetes, detrimental birth effects, and cardiovascular and neurodevelopment toxicity. Although current FDA testing indicates an overall reduction of inorganic arsenic in apple juice, with many samples testing below 5 ppb, the agency considers a 10 ppb level to be protective of public health and widely achievable within the industry. The guidance is not legally binding and therefore if apple juice is found to contain inorganic arsenic above the action level, FDA will consider the level in addition to other factors, such as the agency's "confidence in a measured analytical value," to determine whether the food is adulterated within the meaning of section 402(a)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 342(a)(1)).

- 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, atmospheric deposition from industrial activities" and "water used by manufacturers to dilute concentrate to prepare ready-to-drink juice." FDA notes manufacturers may lower the level of inorganic arsenic in their apple juice by sourcing from apples or apple juice concentrates with lower inorganic arsenic levels, controlling the amount of inorganic arsenic in the water used to dilute concentrate, or changing filtering aids used to filter juices.

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