

# FDA Acts on Final Action Levels for Lead in Baby Food

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January 16, 2025 Suzie Trigg, Carleigh Lenz

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**PRACTICES** FDA Regulatory and Compliance, Food, Beverage and Restaurant

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FDA progressed its *Closer to Zero* initiative by releasing final [Action Levels for Lead in Processed Food Intended for Babies and Young Children](#). The final action levels are the same as the draft action levels that FDA proposed in 2023 but create a clearer path for FDA to take action if processed foods for infants and young children contain lead in excess of the applicable action level. The final action levels also trigger a requirement under California law to not only test each production lot for lead (and other heavy metals), but to also place a QR code on packaging through which consumers can access the information, a step which much or most of the industry had already taken in anticipation of FDA’s final guidance.

## What is an action level?

If a contaminant cannot be entirely excluded from food, FDA can, under 21 CFR 109.6(d), establish an action level for a “poisonous or deleterious substance” at which FDA may consider a food adulterated. It is not a safety threshold, since, for example, there is no known safe level of lead exposure for infants and young children. This is the first final action level to come out of FDA’s *Closer to Zero* initiative, which FDA launched to reduce the amount of toxic heavy metals that young children are exposed to through foods. The risks of exposure to lead and other toxins are particularly concerning for children because of their small bodies and physical and mental development.

## What are the final action levels?

When intended for children under two years old, the following processed foods should have **less than** the amount of lead referenced below. Industry should increase testing of foods known to be at risk of high levels of lead contamination, according to FDA, and must test representative samples from each production aggregate, according to California. Manufacturers should also be cognizant of state laws, like California’s AB 899 and Maryland’s Rudy’s Law, that impose additional requirements for baby food sold in those states. For more information on AB 899 and Rudy’s Law, see our articles on each available [here](#) and [here](#), respectively.

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Fruits

Vegetables (excluding single-ingredient root vegetable products)

Mixtures

**10 parts per billion (“ppb”)**

Yogurts

Custards/puddings

Single-ingredient meat

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Single-ingredient root vegetables

**20 ppb**

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**Did FDA make any significant changes between the proposed and final guidance?**

As noted above, the action levels are the same as those previously proposed by FDA. FDA did clarify that a “single-ingredient root vegetable” means carrots or sweet potatoes, with or without additional ingredients, such as water or preservatives. FDA also clarified throughout the guidance that the action levels apply to “processed” foods.

**When are the action levels effective?**

The action levels are immediately effective, but FDA will consider multiple factors on a case-by-case basis when deciding whether to act on specific impacted products.

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Prepared by Suzie Trigg and Carleigh Lenz as of January 16, 2025. See FDA, [Action Levels for Lead in Processed Food Intended for Babies and Young Children: Guidance for Industry \(Jan. 6, 2025\)](#) (“**Final Guidance**”).