Frequently Asked Questions (FAQs)

Assembly Bill (AB) 899: Food Safety – Baby Food

What is Assembly Bill 899 (AB 899)?

AB 899 is a California legislative bill signed into law and enacted on October 10, 2023. AB 899 requires manufacturers of baby food to test and disclose the levels of four toxic elements that may be present in baby food, and to meet particular labeling requirements. These changes were made to the California Health and Safety Code (H&SC) sections 110962 and 110963 which went into effect January 1, 2024. The <u>full text of AB 899</u> is available.

What is the goal of AB 899?

The goal of AB 899 is to enhance the safety of baby food products by publicly disclosing information to consumers about levels of the four toxic elements in the products; promoting transparency in the industry and enabling consumers to make educated decisions associated with their health.

What is California's definition of a "manufacturer" of baby food?

Per California's Health and Safety Code, Section 109970.

"Manufacture" means the preparation, compounding, propagation, processing, or fabrication of any food, drug, device, or cosmetic. The term "manufacture" includes repackaging or otherwise changing the container, wrapper, or labeling of any food, drug, device, or cosmetic in furtherance of the distribution of the food, drug, device, or cosmetic. The term "manufacture" does not include repackaging from a bulk container by a retailer at the time of sale to its ultimate consumer.

What are the four toxic elements required by AB 899 that baby food manufacturers must test for?

Arsenic, cadmium, lead, and mercury are the four toxic elements under AB 899.

Does AB 899 apply only to California baby food manufacturers or imported baby foods as well?

AB 899 applies to final baby food products that are sold, manufactured, delivered, held, or offered for sale in California. Imported baby food products to be sold, delivered, held, or offered for sale in California are not excluded.

Does AB 899 have compliance dates for baby food manufacturers?

Yes. AB 899 provides two compliance dates for set requirements under the law as follows:

Beginning January 1, 2024, baby food manufacturers must test a representative sample of their final baby food products for levels of arsenic, cadmium, lead, and mercury at least once a month. Manufacturers must keep records and provide them to the California Department of Public Health (CDPH) upon request.

Beginning January 1, 2025, manufacturers must disclose on their internet website the following for baby food products sold, manufactured, delivered, held, or offered for sale in the state:

- The name and level of the toxic elements (arsenic, cadmium, lead, and mercury) present in each production aggregate of their final baby food product.
- Descriptive information (e.g., product name, universal product code, size, lot numbers, or batch numbers) to enable accurate identification of the final baby food product by consumers.

Additionally, if the toxic heavy metal is subject to an action level, regulatory limit, or tolerance established by the U.S. Food and Drug Administration (FDA) pursuant to Title 21 Code of Federal Regulations, Part 109, the manufacturer must include the following two items on their label:

1. A statement that reads: "For information about toxic element testing on this product, scan the Quick Response (QR) code."

2. A QR code or other machine-readable code, which will allow consumers to access the manufacturer's website and view the following information:

- Test results for the toxic element for final baby food products
- An internet website link to a website of the FDA where consumers can find the most recent FDA guidance and information about the health effects of the toxic element on children.

Does the January 1, 2024, compliance date for the product testing requirements apply to products manufactured on or after that date, and does not apply retroactively to products manufactured before that date that may still be on store shelves/in the supply chain?

This applies to products manufactured on or after January 1, 2024.

Does the January 1, 2025, compliance date for the public disclosure and QR code/product labeling requirements apply to products manufactured and labeled on or after that date and does not apply retroactively to products manufactured and labeled before January 1, 2025, that may still be on store shelves/in the supply chain.

January 1, 2025, is the date when the requirements listed under California H&SC, section 110962(b)(2) go into effect. These requirements apply to products manufactured and labeled on or after January 1, 2025, and do not retroactively apply. Therefore, there may be products in

the supply chain manufactured and labeled before January 1, 2025, that would not be subjected to these requirements.

What products are covered given the definition of Baby Food?

AB 899 incorporates all food specifically for babies and young children less than two years old. This includes food packaged in jars, pouches, tubs and boxes. Infant formula is not included in the definition of baby food.

Does the testing requirement under AB 899 mean all covered final baby food products have to be tested for all four toxic elements (i.e., lead, mercury, cadmium, and arsenic) regardless of the risk profile, or can the industry take an appropriate science- and risk-based approach to which toxic elements are tested?

AB 899 requires testing of all four toxic elements regardless of the risk profile. CDPH does not have the ability or authority to make changes to this statutory requirement.

For final baby food products, AB 899 requires testing of the four toxic elements "at least once per month." Can this testing frequency be adjusted?

No. AB 899 does not allow for less frequent testing. The requirement for testing at least once per month was set by the California Legislature.

Is product labeling the primary determining factor on whether a food is "represented or purported to be specifically for babies and children less than two years of age"?

No. When CDPH determines the intended use of any product under its jurisdiction, labeling is an important factor, but not the only factor.

Do manufacturers have the flexibility to disclose the required product information on thirdparty websites that agree to host the information instead of their own company websites?

No. AB 899 states that the information must be made publicly available on the manufacturer's internet website.

Does the QR code and labeling requirement apply to both final and draft FDA action levels, regulatory limits, or tolerances?

If a product is tested for a specific toxic element that has a final FDA action level, regulatory limit, or tolerance, AB 899 requires manufacturers to include a QR code on the product label that links to a page to the manufacturer's internet website containing test results for the toxic element and a link to FDA guidance and information about the health effects of the toxic element on children. This requirement does not apply if the FDA action level, regulatory limit or tolerance is only in draft stage.

Will CDPH permit the statement and QR code to be placed at the point-of-sale versus on actual product labels?

No. CDPH does not have the discretion to change this statutory requirement and it must remain on the actual product labels.

Is it acceptable to post an internal Certificate of Analysis rather than third party lab analysis report to a consumer-facing website?

Yes, it is acceptable as long as the internal ("in-house") laboratory is in compliance with AB 899 requirements for the testing laboratory per H&SC Section 110962 (c).

Are there any concerns with the website being hosted and managed by the manufacturer?

There are no concerns as long as the manufacturer is in compliance with AB 899 requirements set forth under H&SC Section 110962 (b).

Is it acceptable to use Smart Label QR code?

Yes. Per AB 899, a QR code is defined as a machine-readable code, consisting of an array of squares, used for storing an internet website to access a web page.

Is it acceptable the Smart Label will take consumers to a smart label site, which would contain a link to the toxic elements testing results and guidance?

No. AB 899 specifies the QR code must link to a page on the manufacturer's internet website.

Is it acceptable to have the Smart Label QR code on the package Principal Display Panel (PDP), linked by asterisk to the statement on the back panel?

The placement of the QR code should be clearly visible and accessible by the consumer.

Can CDPH advise on the placement of required QR code statement "For information about toxic element testing on this product, scan the QR code"?

The statement may be placed wherever it is clearly visible and accessible by the consumer.

Can CDPH advise on the wording of the required QR code statement "For information about toxic element testing on this product, scan the QR code"?

This language is in statute and cannot be modified by CDPH or the industry.

AB 899 defines "Production Aggregate." Are "production lots" covered under this definition of Production Aggregate?

Yes. This definition includes, but is not limited to, what the food industry commonly calls "product lots."

Does CDPH plan to initiate rulemaking prior to the implementation and enforcement of AB 899?

CDPH does not plan to initiate rulemaking to implement or enforce the provisions of AB 899.

What is the U.S. Food and Drug Administration's "Closer to Zero" Initiative?

In 2021, the FDA released its <u>Closer to Zero</u> initiative, which aims to decrease the exposure of babies and young children to harmful substances such as lead, arsenic, cadmium, and mercury in food. The initiative includes conducting and evaluating research, proposing draft action levels, consulting with stakeholders, and finalizing regulatory action levels.

What penalties or enforcement actions will be administered against manufacturers that do not comply with the provisions of AB 899?

CDPH will consider various enforcement options if food manufacturers are determined to be non-compliant with the requirements in AB 899. For example, misbranded baby food products may be subject to embargo and court ordered destruction. In addition, civil penalties may be considered depending on the nature of the violations.

How will baby food manufacturers be able to prevent non-compliant products from being sold in California?

If someone is aware of a manufacturer who is not compliant with AB 899, please report the matter to the complaint form on our website.

What is a good contact for questions related to AB 899?

If you have questions related to AB 899, please contact FDB directly by emailing <u>FDBFood@cdph.ca.gov</u>, and include in the subject line AB 899 and inquiry topic.