

What's the (Unregulated) Deal with Imported European Infant Formula?



In the US, infant formula is regulated by the U.S. Food and Drug Administration (FDA).^{1,2}

- Infant formula is one of the most highly regulated foods in the United States.
- This ensures the safety of your baby's soul source of nutrition and that the formula contains the proper nutrients for their growth and development.



Importing infant formula from Europe is a common practice among US parents.

- A recent study done at an urban private pediatric office showed that **20% of parents who were using formula, were using non-FDA registered imported European formula.**³
- These formulas are often obtained through online third party vendors.
- Why? Because many parents believe that Europe has stricter standards and use higher quality ingredients.

The Red List

- What's important to know is that there is an FDA Import Alert List (aka "The Red List") which calls out infant formula products that do not meet FDA requirements⁴.
- Many commonly imported European formulas are on this list because they do not meet the US infant formula nutrition and labeling requirements.
- **A 2019 research study identified 16 internet-purchased European-imported infant formulas. None met all FDA label requirements.**⁵



What are the risks associated with imported infant formulas?

Shipping & Storage Concerns



Imported formulas may not be shipped or stored correctly. If transported or stored at incorrect temperatures, for example, the formula can lose some of its nutritional value.

Language



If labels are not in English, it could lead to improper mixing of the formula (making it too diluted or too concentrated) or not reading the expiration date correctly

Definitions



ie. hypoallergenic is defined differently in the US vs. the EU

Aged-Based Stages



For routine and tolerance formulas, the EU offers staged products for age ranges, US infant formulas generally are not staged. If incorrect staged formula is offered to a baby, it might not provide the correct amount of essential nutrients.

Recall Notice Delays



If a formula is recalled in the country where it is produced, news might not reach the U.S. right away

US Recommendations and Position Statements:

In May 2018, the **American Academy of Pediatrics (AAP)** issued a memorandum expressing concern over the increased use of imported formulas.⁶

The **2020-2025 US Dietary Guidelines** calls out that infant formulas “improperly and illegally imported into the United States without mandated FDA review and supervision should not be used.”⁷

References:

¹ Infant Formula Act (21 U.S.C. 350a)

² 21 CFR 106 and 107

³ Du, Nan, et al. “Non–FDA-Reviewed Imported European Formula Use Among Parents in Urban Pediatric Private Practice.” *Clinical pediatrics* 59.6 (2020): 566-572.

⁴ U.S. Food and Drug Administration. Import Alert 40-05: Detention Without Physical Examination of Infant Formula Due to Failure to Meet Nutrient and Labeling Requirements. Silver Spring 2017.

⁵ DiMaggio, Dina M., et al. “Comparison of imported European and US infant formulas: labeling, nutrient and safety concerns.” *Journal of pediatric gastroenterology and nutrition* 69.4 (2019): 480-486.

⁶ Fuchs G. Imported infant Formula not reviewed by FDA may pose health risks. *AAP News*. May 11, 2018 ed: AAP; 2018.

⁷ U.S. Department of Agriculture and U.S. Department of Health and Human Services. *Dietary Guidelines for Americans, 2020-2025*. 9th Edition. December 2020. Available at [DietaryGuidelines.gov](https://www.dietaryguidelines.gov).