Infant Formula Rules and Systems
Breaking Down US Regulations for Infant Formula

Editor's Note: This is a transcript of an online course released in May 2025. It has been edited for clarity.

Karla Gil, MD: My name is Dr. Carla Gill and I'm having fun picking the brain of my friend and colleague, Dr. Jessica Kalia, a neonatologist and our infant formula expert who's been bringing me up to date on the huge variety of infant formulas on our shelves in the last 3 years. But, to truly help our patients navigate these changes, we have to understand what's in the formulas. So, can we dive a little deeper, Jess, into how infant formula is regulated in the US?

Jessica Kalia, MD: Sure! So, the FDA doesn't approve infant formula; it regulates it. The Infant Formula Act of 1980 provides guidelines for safety, nutritional adequacy, packaging and labeling requirements of infant formula. However, during the formula shortage of 2022, the FDA started to allow imported and foreign manufacturers of formula to bring new products into the United States as long as they met certain requirements. They also allowed for some enforcement discretion with these new products. So, if the companies had minor issues with their products, so say, for example, the package labeling didn't list the ingredients in the appropriate order that the FDA requires, the FDA would still allow them to sell their product because they were safe and they had been looked at. However, these companies only have until October of 2025 to comply with all these requirements and make the necessary changes. And, in addition to these companies, just like the traditional US formula manufacturers, they need to show growth and efficacy studies for their products, also by that October 2025 deadline.

Karla Gil, MD: So pretty soon we should have a good idea of how these formulas from the US and the imported formulas compare with respect to growth and efficacy and things like that. How about the regulations? How do US infant formula regulations compare to those of Europe?

Jessica Kalia, MD: Formula production is regulated a lot like the pharmaceutical industry. It's highly regulated and sometimes a slow process. In contrast, the European formula production is regulated like the dairy industry. So, as a result, European formulas come to market sooner than US products, but sometimes have more recalls than US products and often have contaminants not seen in US products, things like salmonella.

Karla Gil, MD: Salmonella always sounds scary to me, especially for our youngest babies where a nasty bug like salmonella can easily cross the blood-brain barrier. So, that's really important to tell our caregivers when they're considering a European formula. Obviously, when parents see a new formula on the shelf, they're going to get most of their information from the labels on the formula. So, how do differences in regulation lead to differences in labeling of those products?

Jessica Kalia, MD: In the US, as per the FDA, you can't use the term "hypoallergenic" on a label unless the protein is extensively hydrolyzed. This is not the case in Europe and other countries. Many cans will say hypoallergenic or HA, you may have seen on labels, but it may only be partially hydrolyzed. So, an example is that HiiP-HA. This is important if you have a baby with a cow's milk protein allergy, you want them to have an extensively hydrolyzed product, like Alimentum or Nutramigen, not something that's only partially hydrolyzed. So, this is really important.

Karla Gil, MD: Very, important for healthcare providers to know and very important for caregivers to know. I also get a lot of questions about iron content, DHA, do differences in regulations lead to differences in amounts of those, of iron and DHA in the formula?

Jessica Kalia, MD: Yes, they absolutely do. So, nutrients in the US, in US infant formulas, are regulated under the 1980 Infant Formula Act. Nutrients in Europe, those are regulated by the European Commission. So, looking at kind of 2 big elements of infant formula that parents are talking about a lot, caregivers are talking about a lot, the first one being iron. So, iron is important for brain development, preventing anemia and supporting growth. The American Academy of Pediatrics, kind of our gold standard, recommends 1.5 to 1.8 mg/100 Kcal of iron in infant formula for our US babies. This AAP requirement is met in all of those traditional US formulas, Similac, Enfamil, Gerber. However, this goal is not met in many of the imported and what we call European style formulas. So, you might wonder why these formulas were allowed to be sold in the US if they didn't meet these AAP requirements. Well, AAP requirements and the FDA requirements are different from each other. The FDA minimum requirement is much

lower. So, these products do meet the FDA requirement; they just don't meet our AAP requirement. And it's also important to realize these standards were set over 40 years ago and a lot has changed in the US newborn population since that time. So, hopefully we will have some changes to these guidelines, but this is what we have for now.

US infants are different from European infants. In the US, we have a high maternal mortality rate, maternal morbidity rate, many moms have babies that have been exposed to their own underlying health conditions, like gestational diabetes, gestational hypertension. We have growth-restricted babies, moms who suffer from chronic anemia. So, these conditions put the babies at risk for anemia and inadequate iron stores when they're born. So, it's important to choose a formula that has the appropriate amount of iron for their baby.

Karla Gil, MD: That's a good point because we do expect that US pregnant women are different from their European counterparts, so we would expect their infants to be different and have different nutritional needs. So, yeah, I understand that.

Jessica Kalia, MD: Then you had asked about DHA and ARA. So, this is different in the US formulas vs the European and imported formulas. So, just to give you some background, DHA is an omega-3 fatty acid, ARA is an omega-6 fatty acid. We call them the long-chain polyunsaturated fatty acids or the L-PUFAs. So, nonhuman mammalian milk doesn't have the same fatty acid profile as human milk. So, certain fatty acids need to be added to the infant formula to create a milk product that is as close as possible to human milk because, remember, that's the goal of these formula companies, to really replicate human milk as best they can. So, DHA and ARA, we know are important, they're transferred to the growing fetus during gestation. They're also transferred after birth in breast milk. They've been shown to have beneficial effects on neurodevelopment, visual acuity and cognition and there's no FDA requirement for DHA and ARA, however the FDA says, if you're going to add DHA, you also need to add ARA and they have a ratio that they want, either a 1:1 or a 1:2 DHA to ARA ratio, because they know that these 2 fatty acids work together and this will help maximize their benefits.

The waters get a little muddy because there's many studies related to these L-PUFAs and their benefits, but some are conflicting with respect to the amount of DHA that an infant needs. So, most of the traditional US formulas use an amount of DHA that is similar to the average amount found in breast milk. In contrast to the FDA, the European Commission does have a requirement for DHA. They love DHA. Their requirement is higher than what we find in breast milk. So, unlike the US, the European Commission has a requirement for DHA, but interestingly they do not have a requirement for ARA. So, you won't find ARA in all of those European or imported formulas and you also won't always find ARA in those what we call European style formulas because they're following recipes just like the European formulas.

Karla Gil, MD: Usually when parents ask about those nutrients and the different DHA, ARA, all the different things that are added now to promote neurodevelopment, parents are looking for what's the healthiest. So, what if you have a parent that insists on using a European formula because they read that this is the healthiest way to feed their babies? How do you counsel them?

Jessica Kalia, MD: That's important. They all want the healthiest formula for their baby. So, I go through many of the things we've talked about here. I look at each baby and look at their nutritional risk factors. So, for a healthy term infant that was born to a mom with no medical issues, the European formulas and European style formulas should be fine to use. If a baby was born prematurely, I steer them away from these formulas because those formulas really don't have adequate calcium, phosphorous, iron or protein needed to optimize the growth of that baby that missed out on so much of gestation.

Then, if the infant's mother was a gestational diabetic or suffer from chronic anemia, I counsel them towards the traditional US infant formulas to make sure that they're getting the AAP-recommended requirement of iron. And I feel like the best thing we can do is educate our families and give them the information they need to make an informed decision.

Karla Gil, MD: Yes, that's why I appreciate all this information that you're giving me because I can use all of this for my caregiver education. So, do you think that there's going to be changes now for regulation of formulas based on the shortage that we had in 2022?

Jessica Kalia, MD: FDA regulation of infant formula really remains the same as it did prior to the formula shortage, using the Infant Formula Act of 1980 as its guideline. However, there have been some new government initiatives, and the government has been looking at the formula shortage and evaluating it and looking for ways to

prevent this from happening again. So, more recently, we have an initiative called the Operation Stork Speed and it'll be looking at improving the safety, quality and nutritional adequacy of the US infant formula supply because, remember, 1980 was a long time ago and babies have changed a lot. So, we could use some updates to that. And then, to help prevent another national formula shortage, experts from the National Academies of Science, Engineering and Medicine published a 400-page report just this past December of 2024 to kind of help create resiliency and redundancy in the market. So, they came up with some guidelines for plans and they're based on really 5 areas of vulnerability. The first one being having these companies consider some risk management planning and trying to create redundancy risk management plans. So, if there's a recall or a natural disaster affecting their plant, they can accommodate and continue to provide their formula product because we know these babies need it.

Then another thing is looking at market concentration. So, if there's a large share of 1 particular type of formula coming from a specific facility or line, they should make modifications to help diversify this risk. I know right now some companies—US formula manufacturers— are updating and remodeling their factories to make it more amenable so that if there's a problem with 1 line, they could shut it down and it won't affect the whole facility. They could continue to produce on the other lines. So, things like that are important. Another area that needs improvement has to do with supporting a speedy supply recovery. Currently, the FDA lacks oversight over manufacturing and there are regulatory requirements that prevent rapid importation of formula in a real emergency. So, these things should be worked on at the national level. For example, Congress could require infant formula companies to develop these redundancy risk management plans and be subject to inspections, especially companies that are WIC contract holders because that takes, they support a large proportion of our population.

Then that report also identified some poor governmental management of adverse effects. So, they were highlighting that there really had been poor communication with the public and poor communication between government and industry prior to this formula shortage. So, kind of fixing that, improving engagement, the FDA and government's engagement with the formula companies are, would be important going forward. And last, they noted improvement, and this is huge, we need to support breastfeeding mothers in the US. You know, the US society has so many structural barriers to breast feeding and that really is the gold standard of infant nutrition. We really want more parents to breast feed their infants. So, things like lack of paid maternity leave, core access to lactation support and really lack of social support contributes to this problem. So, efforts to support breastfeeding are really important to help in any future formula shortage that we might see.

Karla Gil, MD: Absolutely! You never think about all the things that are happening behind the scenes when you look at a can of formula, but that was a lot of great information that you covered. So, thank you again and I'm excited to hear all about nutrition in our next segment. Thank you.

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