

Infant Formula

Navigating Nutritional Differences, Labels, and Marketing

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

Karla Gil, MD: Hello my name is Dr. Carla Gill and I've been chatting with my friend and colleague, Dr. Jessica Kalia, a neonatologist and our infant formula expert who's been giving us some important and actionable information about the current formula landscape in the US. So, Jess, let's get right into it because there's a lot I want to know. In our first segment, you outlined the major categories of infant formula, and we'll run through them in detail in a few minutes, but there are also numerous differences in macronutrients. Can you talk about the key nutritional differences we have to be aware of?

Jessica Kalia, MD: Sure! Most formula manufacturers start with either whole milk or skim milk and modify their product based on their own proprietary processes and formulations. All infant formulas must be processed to more closely match the composition of breast milk because we know cow's milk and goat milk is very different than breast milk. Infant formula is an ultraprocessed product, so no matter how natural the can says it is, it's still an ultraprocessed product. It has to be. So, no formula company can get around that.

Look at the components of infant formula. The major macronutrients in infant formula are protein, carbohydrates and fat. So, as far as protein, most infant formulas use a 60 to 40 whey to casein ratio, similar to breast milk. Cow's milk has both A1 and A2 casein protein. When you compare that to goat's milk, goat's milk has more A2 than A1 casein protein and the reason why this is important is because the A2 protein forms a looser curd and is more easily digested. However, there have been no studies that show goat's milk formula is more gentle than cow's milk formula, but I'm sure we've both had families tell us that goat's milk formula was well tolerated by their babies.

Now, as far as the basic carbohydrate source for all term infant formulas—not the specialty formulas, but your basic term formula—is lactose. However, we know that some newborns have decreased lactase enzyme activity at birth and they have difficulty digesting lactose. It doesn't mean they're lactose-intolerant. It just means they're just not used to it yet and kind of need to get adjusted to having that level of lactose in their formula. So, formula companies have created some specialized formulas, things like Gentlease or

Similac Sensitive, which have lower levels of lactose. However, if they take some of that lactose out, they have to replace it with another carbohydrate. There are alternative carbohydrate sources that are used. You may have heard of corn syrup solids, maltodextrin or sucrose. So, it's important to understand that the European-style US formulas, things like Bobbie, ByHeart or Baby's Only, they are manufactured in the US but they follow the European style, as well as those truly imported European formulas. Those are all basic term infant formulas. They don't have any specialty versions available right now in the US, therefore they all use lactose as their carbohydrate source.

The third macronutrient that's important and that's required in all infant formula is fat. So, the fat in whole cow's milk is not suitable for human infants. Like we said, it needs to be modified, and you modify it by adding different oils into it to make it more closely resemble breast milk.

Karla Gil, MD: That was a good overview. I do have a few questions about some of the things that you just brought up. With regard to proteins, if I have a patient with a cow's milk protein allergy, I know there's a cross-reactivity with soy protein, so I counsel against soy formula. But could they use goat's milk-based formula instead?

Jessica Kalia, MD: No. There also is a significant amount of cross-reactivity, greater than 90%, between cow's milk protein and goat's milk protein. So, that would not be a good option. You would have to steer them to those extensively hydrolyzed formulas.

Karla Gil, MD: Good to know. About carbohydrate sources, I know you said, for example, the soy formula doesn't generally contain lactose, so you mentioned that a carbohydrate source is likely going to be from a corn syrup solid. So, is that high fructose corn syrup?

Jessica Kalia, MD: Good question! Everybody gets this mixed up. No. Corn syrup solids are glucose polymers; they're not fructose. It has nothing to do with high fructose corn syrup, but parents very often confuse the 2 and they get all freaked out when you say corn syrup solids. They don't want high fructose corn syrup. It's not high fructose corn syrup.



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Karla Gil, MD: Absolutely, absolutely, yeah, the difference is very nuanced and they certainly haven't added biochemistry into any of the prenatal classes around here yet, but let's get a little deeper into some of the biochemistry of the formulas. What are the micronutrient differences between the different types of infant formula that we should be paying attention to?

Jessica Kalia, MD: Important micronutrients, such as iron and DHA, are found in infant formula. So, let's talk about iron. Iron is important for brain development, preventing anemia and supporting growth. The imported and the European style formulas are lower in iron and don't meet the American Academy of Pediatrics recommendation for iron. However, they can be sold and marketed in the US because they do meet the FDA's minimum requirement for iron which is less than the AAP requirement. And it's important to remember US infants are different from European infants. In the US, many infants are born to mothers with underlying health conditions, gestational diabetes, chronic hypertension, chronic anemia, and these conditions put the babies at risk for anemia and inadequate iron stores. So, if I have a parent that wants to use a European or imported formula that doesn't have the AAP recommended amount of iron in it, I review the infant and mother's medical history, and see if that formula supplies enough iron for their needs. And if not, I discourage its use.

We all have parents that insist, you know, I really want to use this. And it's their option to do that, but if I do have a parent like that, then I recommend an iron supplement and I explain why. And usually, they're on board with it.

Karla Gil, MD: Yeah, that's a perfect example of patient-centered care.

Jessica Kalia, MD: Another important micronutrient is DHA and ARA, or those long-chain polyunsaturated fatty acids. So, we know that both are transferred to the growing fetus during gestation and are found in breast milk in various concentrations. They have been shown to have beneficial effects on neurodevelopment, visual acuity and cognition. So, there is no FDA requirement for DHA and ARA, however many traditional US formulas do include them because they know they're important.

The FDA's only requirement is that if the formula company adds DHA, then ARA should be added too, since both of them work together synergistically to affect neurodevelopment.

The studies related to the amount of long-chain polyunsaturated fatty acids, like DHA and ARA, are vast and often conflicting, and this is where the traditional US formulas and the European style formulas differ. The European Commission does have a requirement for DHA, unlike the FDA. But in Europe, there is no requirement for ARA. And the European Commission's DHA requirement is higher than what is found in average breast milk.

Karla Gil, MD: So, when we're talking about DHA, the European formulas, they're not quite as similar to breast milk as the US formulas that do have the DHA in them. They have more, they're more comparable to breast milk. Well, okay, in fact, even though DHA isn't required here in the US, I feel like I'm having a hard time thinking of a US-manufactured formula that doesn't have DHA on its label.

Jessica Kalia, MD: Yes, you're absolutely right. Most of them do have DHA because we know it's important.

Karla Gil, MD: Speaking of labels, can we get into label terminology? There are so many different things that I see on labels. If I ask you about some of those terms, can you give me a little bit of info about what they mean?

Okay, great. Let's start with natural and organic. What does that really mean on a label? Natural, organic?

Jessica Kalia, MD: So, natural really only means that nothing artificial has been added. It doesn't address the use of pesticides and, more importantly, it doesn't really describe any health benefit. I know we all think natural means healthy, but that's not necessarily true, and everyone gets all caught up in that natural label, but it really doesn't mean that it's healthy. And as far as organic, when you see organic on a US infant formula vs imported or European formula, there, the term organic really means about the same thing in both areas. They must conform to the rules for production of processed food and use at least 95% organically produced ingredients. And again, some people focus more on the organic label than the amount and type of ingredients that are best for their babies. So, it's just something to be aware of.

Karla Gil, MD: How about this one? Clean Label Project. What does that mean?

Jessica Kalia, MD: Yes, so we do see this on a lot of infant formulas. So, the Clean Label Project is a nonprofit organization that tests products for purity and compares



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them to high-risk chemicals listed on the California Prop 65 list. Now, that sounds great, and it may be. The only concern—you know we have to critically think about things—is that their studies are not peer-reviewed and they're not very transparent with their methodologies. So, we really don't know. It's probably fine, but we can't really make it out to be more than it is without being able to see the studies and having them explained to us how they came to these conclusions. So, that's really what Clean Label Project is.

Karla Gil, MD: That's true. Okay, let's go with some that I think are a little easier. Can you talk about the non-GMO or the no-antibiotics, the palm oil-free on the labels?

Jessica Kalia, MD: Sure! Non-GMO means that it has not been genetically modified or derived from anything that underwent genetic engineering. So, most GMO crops were developed to resist disease, insects and pests and the benefit of that is they didn't need to use as many pesticides on those crops. So, this could actually be a good thing rather than something that people are suspicious of. So again, it's kind of pros and cons and really understanding what it means. That's your non-GMO. No antibiotics, this can be a little confusing because it really only refers to the fact that no antibiotics were present in that milk at the time of sale. It doesn't mean that that animal was never given antibiotics and there's a high likelihood the animal had received antibiotics because these are lactating cows. They're at risk for mastitis, just like we are, and humanely, they need treatment for that. So, you have to kind of take that with a grain of salt when you see no antibiotics on the label.

Then you mentioned palm oil-free, so we talked earlier that different oils have to be added into infant formula to more closely resemble breast milk. Well, palm oil, or they call it palm olein oil, is actually one of those oils and 20% of the fatty acids in breast milk are palmitic acid. So, this is just 1 of the oils that is added to more closely replicate breast milk and they have looked at this. The European Society of Pediatrics GI, Hepatitis and Nutrition say that palm oil is safe. They just make a recommendation to source it sustainably because of the environmental impact.

Karla Gil, MD: We cannot leave this one out. What about the use of the term hypoallergenic on the label?

Jessica Kalia, MD: This is important to understand, especially when we're seeing patients using foreign formulas, things like HiiP and Holle, that have not been reviewed by the FDA

and these are ones that families purchase online. So, as per the FDA, you can't use the term "hypoallergenic" on a label unless the protein is extensively hydrolyzed. So, Europe and other countries don't have this requirement. They can use the term hypoallergenic even if the product is only partially hydrolyzed. So, like I said, with that HiiP-HA, I've seen this on their advertisement, it says hypoallergenic and it can get confusing because if you have a baby with a cow's milk protein allergy and a parent asks to use this hypoallergenic formula, you have to explain that it may not be extensively hydrolyzed or hydrolyzed enough to treat their condition. So, it does create some confusion for parents and caregivers. It's important to make that distinction.

Karla Gil, MD: Absolutely, and even for healthcare providers who haven't been getting all this wonderful information from you. Because prior to all this education, I don't think I would've known that HiiP-HA isn't equivalent to the HA formulas that we have here. So, obviously, when a parent is thinking about bringing their precious newborn into the world, they want only the best of everything. What would you say to a parent or caregiver that asks for the best infant formula? Are there some formulas that are nutritionally better than others?

Jessica Kalia, MD: There really isn't 1 best formula out there. There are a few different types and what is best for 1 infant might not be best for another. It's very individual. So, I try to counsel and educate parents based on the needs of their infant and the needs of the family. So, obviously, breast milk is our gold standard, but when breast milk isn't available, our traditional US infant cow's milk-based formulas are still the gold standard for infant formula. The US infant formulas are precisely made and are regulated similarly to the pharmaceutical industry and this industry is heavily invested in research and development of these formulas to optimize nutrition for our babies. Due to the formula shortage, these new infant formulas appeared on our store shelves and the brands sold and marketed in the US stores have gone through the FDA's process of ensuring their safety and nutritional adequacy. So, it is important for caregivers to choose something that is available here in the US on store shelves because we know that they've been reviewed by the FDA and are considered safe.

Karla Gil, MD: There's so much to navigate when it comes to infant formulas. How can we, as healthcare providers, help guide our parents and caregivers on choosing the best option across all the major categories of formulas for infants?



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Jessica Kalia, MD: These are the important things to know about the available infant formulas, and in order for me to help remember them, I break them down into 4 categories to help keep them straight. So, first we have those traditional US formulas. Examples would be Enfamil, Similac, Gerber. So, these have been around for years. They're well known to the public. They're well known to us providers. They have the recommended nutritional requirements of iron and DHA and ARA for the US infant population.

Karla Gil, MD: Absolutely, and those are the ones that are often covered by WIC.

Jessica Kalia, MD: Yes. The next category we have are the US-made European style formulas. Things like Bobbie, Baby's Only or ByHeart. And the third category would be the European or the imported formulas, things like Kendamil which is from the UK, Kabrita, which is goat's milk infant formula, from the Netherlands, and Bubs which is from Australia. And so, both the US-made European-style formulas and the European or imported formulas, these categories together, are basic infant formulas for full-term infants. So, we said some companies have goat's milk-based formulas. As far as I know, in the United States, we don't have any companies that are manufacturing goat's milk formula yet, I don't know if they're going to do that in the future. So, your option for goat's milk infant formula would be from a company like Kabrita or Kendamil or Bubs. They have those options. This classification of formulas, though, the imported formulas, the US-made European-style formulas, don't have any specialty formulas. So, there's no preemie version available here, there's no fully hydrolyzed versions here. They tend to be lower in iron than the traditional US formulas and they don't meet the American Academy of Pediatrics recommendations for iron.

They do have more DHA than the traditional US formulas. Like I mentioned in a previous segment, we have no conclusive evidence that more DHA is better. We just don't know, and the US products do more closely resemble the amount of DHA in breast milk. Some of these products also don't contain ARA, and we know that DHA and ARA do work together to optimize neurodevelopment and mature the immune system. This category of formulas is often not covered by WIC, so it is less accessible to everyone which can be an issue. And in general, they're more expensive than the traditional US formulas.

The fourth category, which I call the foreign formulas, I'm sure you've seen them, HiP, Holle, these formulas have not

been reviewed by the FDA and are not approved to sell in the stores in the United States. So, families are getting them online through third party vendors and I always caution families against these products. We can't vouch for their safety and their nutritional components and just remember, babies that are using infant formula, it's their sole source of nutrition for the first 6 months of life. It's vital that we give them adequate nutrition to maximize their growth and development at this time. And if we can't verify these products, I feel it's too risky to take that chance.

I say if parents want to use something other than the traditional US formulas, I encourage them to choose a product that is at least sold in US stores because then we know it's been looked at by the FDA.

Karla Gil, MD: You know, in particular, the population that I care for. My population uses WIC a lot and especially during the formula shortage, they asked a lot about generic infant formulas, what other options do they have and they see generic infant formulas, like at CVS or at Walmart, what can I tell families about these?

Jessica Kalia, MD: The generic infant formulas, interestingly, are all made by 1 company in the US. So, there's really no store brand differences between them. They have been approved, well, they have been *regulated*, by the FDA. They meet those FDA requirements, and these formulas will be more like the traditional US infant formulas and have the recommended nutritional requirements for US infants. They may not have the newest proprietary ingredients that some of the traditional formula brands have, however they're safe and they're generally less expensive than the name brand formulas.

Karla Gil, MD: That's good information. That was an excellent education you gave me on everything I ever needed to know about infant formulas. I feel so empowered. My patients and I thank you so much for sharing your time to talk about this important nutritional topic.

This activity is supported by an educational grant from **Mead Johnson Nutrition**.