CME

Comparison of Imported European and US Infant Formulas: Labeling, Nutrient and Safety Concerns

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ABSTRACT

Objective: Infant formula in the United States is highly regulated. The American Academy of Pediatrics (AAP) has reported concerns over the use of non-Food and Drug Administration (FDA)-registered imported infant formulas. The purpose of this study is to identify Internet purchased and recommended imported European infant formulas and compare them with FDA labeling and nutrient requirements.

Study Design: We searched ''European infant formulas'' in Google and DuckDuckGo to identify vendors of European formulas and blogs discussing these formulas to determine the most frequently purchased and recommended brands. We then compared the identified European formula's label and listed nutrients to FDA labeling and nutrient requirements.

Results: Thirteen of 18 vendors responded to our inquiry of their top selling formula and 17 blogs were reviewed. Sixteen formulas were identified. None met all FDA label requirements. Listed nutrients fell within FDA requirements in 15 of 16 formulas.

Conclusions: Non-FDA-registered imported European formulas do not meet all FDA-labeling requirements. Although linoleic acid, which was not listed on all of the European formulas, could not be evaluated, all formulas except one met the remaining FDA nutrient requirements. These European infant formulas are being imported into the United States via third party vendors and are not FDA-regulated, limiting the notable consumer protections set by the FDA that ensure infant formula safety. Pediatric gastroenterologists and healthcare providers need to understand the composition, labelling and lack of FDA regulation and safety concerns of these formulas in order to better counsel parents.

Key Words: Hipp, Holle, infant formula act, infant nutrition, Lebenswert, Topfer, United States Food and Drug Administration

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What Is Known

- In the United States, many parents of infants are using imported European formulas purchased over the Internet from third party vendors.
- Healthcare providers, including pediatric gastroenterologists, may have limited knowledge on the nutrition of these formulas and their safety.

What Is New

- This article is the first article to compare these formulas to United States Food and Drug Administration nutrition and label requirements.
- This article is the first to review why these formulas are attractive to consumers.
- This information can be used to educate providers and parents on safety concerns on the use of these imported formulas.

Infant formula sold in the United States must meet the requirements of the Infant Formula Act (21 U.S.C. 350a) and associated regulations (21 CFR 106 and 107) (1–3). These require that any new formula provides data to support that it offers adequate nutrition for the healthy and adequate growth of infants (1–3), includes good manufacturing practices (2), with controls to prevent adulteration, including from microorganisms, and the establishment of an audit plan, including annual US Food and Drug Administration (FDA) inspections to confirm the formula meets nutritional and safety standards. Two components of this act include infant formula-labeling requirements (Table 1A) (1) and nutrient requirements (Table 1B) (3).

In May 2018, the American Academy of Pediatrics (AAP) issued a memorandum expressing concern over the increasing use of imported formulas that are not registered with the FDA (4). The FDA lists multiple formulas on an FDA Import Alert, takes enforcement action against third party sellers of formulas that are not in compliance with infant formula laws and regulations, and stops importation of nonnotified infant formulas (5). In one study conducted at a large private practice in New York City, it was found that approximately 20% of infants who were being fed formula were consuming a non-FDA registered imported European formula, that was primarily purchased over the Internet (6). In addition, a survey of pediatric gastroenterologists practicing in the United States demonstrated that although a majority of them have been asked about imported European formulas, specifically the brands HiPP, Holle, and Lebenswert, 81% did not feel

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TABLE 1. FDA nutrient and labeling specifications: (A) summary of reviewed US FDA powdered infant formula label requirements; (B) FDA minimum and maximum nutrient requirements per 100 kcal for infant formulas with specified units

(A)

The presence of the number of fluid ounces supplying the specified kilocalories
The required nutrients in the specified units of measurement
A statement whether the label indicated if additional iron was needed if the formula did not contain at least 1 mg of iron per 100 calories of formula, or if the label stated 'with iron' if it contained 1 mg or more of iron per 100 calories of prepared formula.
Directions of use, such as storage before and after the container was opened, sterilization steps, when needed for preparing formula
Mixing instructions for powder formula with the weight and volume to be reconstituted
Presence of a 'use by X date' on the package
A statement warning against improper preparation or use of the formula
A statement that parents should consult their physician on the use of infant formula
Pictograms for the formula-making steps

(B)

Nutrient (required unit of measurement)	Minimum level	Maximum level
Protein (g)	1.8	4.5
Fat (g)	3.3	6.0
Linoleic acid (mg)	300	
Carbohydrates (g)	NL	
Vitamin A IU (μg)	250 (75)	750 (225)
Vitamin D IU (μg)	40 (1)	100 (2.5)
Vitamin E IU (mg)	0.7 (0.5)	
Vitamin K (μg)	4	
Thiamine (Vitamin B1) (μg)	40	
Riboflavin (Vitamin B2) (μg)	60	
Vitamin B6 (μg)	35	
Vitamin B12 (μg)	0.15	
Niacin (μg)	250	
Folic acid (Folacin) (μg)	4	
Pantothenic acid (μg)	300	
*Biotin (μg)	1.5	
Vitamin C (ascorbic acid) (mg)	8	
*Choline (mg)	7	
*Inositol (mg)	4-	
Calcium (mg)	60	
Phosphorus (mg)	30	
Magnesium (mg)	6	
Iron (mg)	.15	3
Zinc (mg)	0.5	
Manganese (μg)	5	
Copper (μg)	60	
Iodine (μg)	5	75
Selenium (μg)	2	7
Sodium (mg)	20	60
Potassium (mg)	80	200
Chloride (mg)	55	150

Adapted from the FDA regulations 21 CFR 107.10: nutrient information (3) and 107.20: directions for use (1). Adapted from the FDA 107.100 nutrient specifications (3). FDA = Food and Drug Administration.
*Required only for nonmilk-based infant formulas.

knowledgeable on these formulas and 69% were not aware that these formulas were not FDA-regulated (7).

The purpose of this study is to identify the most commonly Internet-recommended and purchased imported European infant formulas in the United States and to determine if they meet FDA labeling and nutrient requirements as these are being sold and used within the United States.

METHODS

We chose to focus the source of our data to the information widely available to parents on the Internet, secondary to lack of information in the medical literature and no relevant reviews found in a PubMed search comparing imported European to FDA-registered infant formula. For the purposes of this study, European infant formula was defined as formula that can be used from birth to 6 months old (Stage 1); European follow-on formula (Stage 2), suitable for infants from 6 months to 1 year of age, was beyond the scope of this study. The soy formula was included in the study as it was marketed for use in infants from birth onward, as well as in infants older than 6 months. We used the search term ''European infant formula'' in the Google search engine and reviewed the first 5 pages of hits from this search. We identified all third-party vendors of European formulas selling to United States consumers and also all blogs that discussed European infant formulas in this search. For a more objective search and to determine reproducibility of information, we also used the same search term in DuckDuckGo, a search engine that does not personalize results and reports the same results for a search term to all of its users, which yielded 5 pages of search results, all of which were reviewed. Each vendor in both searches was contacted to determine their most popular selling European infant formulas. Each blog in the searches that discussed European infant formulas was reviewed for their infant formula recommendations and reasons for recommending these infant formulas. On the basis of this review, we then identified the most purchased and recommended brands of European infant formulas, reviewed the identified European manufacturers' websites, and grouped the available infant formulas according to the type of formula: intact cow milk-based, soy, partial hydrolysate, and anti-reflux formula (8–14). We then compared their labels and the listed nutrients on those labels or their manufacturer's website to FDA labeling and minimum and maximum nutrient level requirements (Table 1A and B). Google translate, when needed, was used to translate the European infant formula label. Units for each nutrient were converted to the units of the FDA guidelines so direct comparisons could be made. If the label or nutrition information was not available or clear on the manufacturer's website, we contacted the manufacturer directly through their website's E-mail or contact phone number for clarification. If European infant formula did not meet all of the FDA-labeling requirements, it was considered noncompliant with FDA-labeling requirements (1).

RESULTS

Eighteen total vendors were identified, 13 from the Google search and 9 from the DuckDuckGo search, though 4 of the 9 from the DuckDuckGo search were the same as identified in the Google search. Thirteen of the 18 vendors responded to our query of their top selling infant formula. Seventeen blogs discussing European infant formulas were reviewed, 11 from the Google search and 13 from the DuckDuckGo search, with 7 blogs appearing in both searches (Table 2). The majority (85%) of reasons given by the blogs for recommending European infant formulas was because of the belief that these formulas were held to stricter standards than US formulas, were made of higher quality ingredients, and were organic and lacked pesticides. Other reasons included that the

TABLE 2. European infant formulas blogs and third-party vendors identified via Google and DuckDuckGo searches and whether a response was obtained from third party vendors about most popular selling brands of formula

	Website	Search Engine
Blogs	Bettyruth.com	Google
	Gentlenursery.com	Google
	Nontoxicrobot.com	Google
	thrivalnutrition.com	Google
	Babyformulaexpert.com	DuckDuckGo
	Bewell.com	DuckDuckGo
	Cornucopia.com	DuckDuckGo
	Foodbabe.com	DuckDuckGo
	Mommyhood101.com	DuckDuckGo
	parenting.blogs.nytimes.com/2015/10/07/what-does-organic-mean-for-baby-formula	DuckDuckGo
	Healthyholisticliving.com	Google and DuckDuckGo
	Gimmethegoodstuff.com	Google and DuckDuckGo
	Mamanatural.com	Google and DuckDuckGo
	Mightymoms.club	Google and DuckDuckGo
	Mommytomax.com	Google and DuckDuckGo
	Pickyeaterblog.com	Google and DuckDuckGo
	Quora.com	Google and DuckDuckGo

			Response
Third party vendors	BeyondOrganicBaby	Google	No
	FormulaRUS.com	Google	No
	Mariposa Kids and Baby	Google	Yes
	My Organic Formula	Google	Yes
	Organic Baby Food Shop	Google	Yes
	Organic Baby Shop	Google	Yes
	Organic Formula World	Google	No
	ToraFoods.com	Google	No
	Udderly Baby Food	Google	Yes
	BuyOrganicFormula.com	DuckDuckGo	Yes
	HIPPformulausa.com	DuckDuckGo	No
	LWorganics.com	DuckDuckGo	Yes
	MyFirstOrganics.com	DuckDuckGo	Yes
	Organicstart.com	DuckDuckGo	Yes
	BabyKindMarket.com	Google and DuckDuckGo	Yes
	Formuland.com	Google and DuckDuckGo	Yes
	My-German-Depot.com	Google and DuckDuckGo	Yes
	Organic Baby Food24.de	Google and DuckDuckGo	Yes

European infant formulas emphasized gut balance (7.5%), treated colic (2%), provided more tailored nutrition as they are available in stages (2%,) had a goat milk option (2%) and that US infant formulas were tied to pharmaceutical companies (2%). From information gathered by contacting the third-party vendors of European formulas and from reviewing the European infant formulas recommended in the blogs, 4 most commonly imported and recommended brands of European Infant formula were identified, HiPP, Holle, Lebenswert, and Topfer (15–20). Review of these 4 manufacturers' websites revealed 16 distinct infant formulas.

Types of Formulas

There were 7 intact cow milk-based, 1 soy-based, 1 antireflux/added rice (AR) and 5 partial hydrolysate formulas identified. There were no extensively/completely hydrolyzed protein, amino acid-based, or premature imported European formulas identified. There were two imported European goat milk infant formulas found, though there is no FDA-registered US goat milk infant formula currently available in the United States for comparison with the imported European versions (Table 3).

Comparison of European to United States Food and Drug Administration Label Requirements

None of the 14 European labels met all of the FDA formula-labeling requirements. Nine of the 14 formula labels were not in English. All of the formulas had a statement of calories contained with the specified volume. None of the European formulas listed all of the nutrients in the FDA-required units of measurement. Ten of the 14 European formulas did not contain all the specified required nutrients based on their label; specifically, linoleic acid was not listed on these 10 labels. Eight of the identified European formulas contained less than 1 mg of iron per 100 calories and all of these formulas did not indicate on their label that additional iron may be necessary. The 6 formulas that contained 1 mg of iron or more did not state on their label that the formula was fortified ''with iron.'' Three of the 14 formulas did not state storage recommendations before and after the opening of the formula on their label. All formulas met the FDA guidelines of discussing sterilization, such as boiling of water or bottle parts, if needed, included an expiration date on the container and had statements about potential problems, if the formula is prepared improperly and the need to consult a

TABLE 3. Imported and internet recommended, non-Food and Drug Administration-registered, European infant formulas summarized by type of formula

Manufacturer	Type of Formula	Examples
Holle Holle baby food Riehen, Switzerland	Intact cow milk-based	Bio Pre Organic 1
Lebenswert Holle baby food Riehen, Switzerland	Intact cow milk-based	First Milk
Topfer Dietmannsried, Germany	Intact cow milk-based	Lactana Bio Pre Lactana Bio 1
	Soy protein isolate	Lactopriv dairy free
	Partial hydrolysate	Lactana Pre HA and HA 1
HiPP (UK, Dutch, and German) HiPP UK Ltd, Hurst, Reading, Babys HiPP GmbH & Co. Vertrieb KG, Pfaffenhofen an der Ilm, Germany	Partial hydrolysate	Combiotic Comfort HA Combiotik Pre and 1*
	Intact cow milk-based	Organic First Infant Milk 1 Organic Hungry Infant Milk Powder
	Anti-Reflux	Organic Anti-Reflux

Data from (15–20).

medical professional with questions of use. Scoop weights ranged from 4.3 to 4.6 g, and 13 formulas required mixing 1 scoop of formula with 1 ounce of water (15–20). Lebenswert First Milk had instructions to mix 3 scoops per 95 mL or approximately 1 scoop of formula with 31.7 mL of water. All 14 European formulas had pictograms illustrating the major steps in formula preparation on their label (Table 4).

Nutrient Requirements

European formula labels were examined to determine if the listed nutrients met FDA minimum nutrient requirements. All European formulas met FDA required nutrient levels except for 1 intact cow milk-based formula, Topfer Bio 1, which listed less than the FDA required amounts of vitamin A and copper. Linoleic acid levels were not listed on the manufacturer's websites or label for 10 of the 14 formulas, and thus could not be determined if they met FDA requirements. When listed, the linoleic acid levels did meet the minimum FDA nutrition requirement.

DISCUSSION

This is the first study to identify the most commonly recommended and imported European formulas used in the United States. As these formulas are being sold and used within the United States, we reviewed whether they meet FDA labeling and nutrient requirements as detailed under the US Infant Formula Act and associated regulations (1–3).

The results of this study demonstrate that none of the identified imported formulas met all of the FDA-labeling requirements, which have several important safety considerations (1). Although Europe has its own label requirements (21), legal importation of formula from one country to another always requires that the label comply with the local country's labeling requirements, including being in the receiving countries language. Nine of the 14 formula labels were not in English. Consumers may not be able to read either the expiration date or mixing instructions on imported European infant formulas if they do not follow common US formats and are not in English.

Although US FDA does not require a specific format for the ''use by date,'' standard date format differs in the United States and Europe. European formulas 'use by date'' are typically in a numerical day-month-year format whereas US formulas are in a month-day-year format. Using formula past the ''use by date'' poses a risk of insufficient nutrients as the manufacturer guarantees the nutrient content and the general quality of the formula only until this date (22).

In this study, mixing instructions were not available in English for 9 out of 14 formulas. The imported formulas are prepared with 1 ounce of water per 1 level scoop of powdered formula (1 scoop ranged from 4.3 to 4.6 g), which differs from how the majority of FDA-registered formulas are prepared (2 ounces of water with 1 unpacked level scoop of powdered formula, scoop range 8.2–9 g) (8–14). Use of a different scoop size or incorrect ratios of powdered formula to water can lead to a final product that is too dilute or concentrated. Formula that is too dilute or concentrated can potentially lead to electrolyte imbalances in infants, seizures, and if inadequate calories are consumed, poor weight gain.

Additional important safety concerns include that 3 formulas did not contain statements about storage before and after opening of the container on their label (1). Nutrients on European infant formula labels were not listed in the required units of measurement, as required by the FDA, for many of the nutrients. Sterilization statements, if needed, varied slightly from FDA requirements; European formulas statements included wording, such as ''store in a cool and dry place'' and did not specifically state to ''avoid extreme temperatures,'' a distinction that may be relevant in international transport and storage of the formulas by third party vendors. Powdered formulas are well tolerated and nutritionally stable when held at recommended temperatures. When stored at incorrect temperatures, there is some risk for premature product deterioration with loss of vitamins A and C as well as loss of protein solubility, with a potential reduction in digestibility and/or bioavailability of some essential amino acids (23).

Our study also sought to compare the nutrient values between the imported European Infant formulas and FDA requirements, a difficult comparison as, nutrient information on European labels (21) gives the average nutrient content whereas the US FDA (2) lists the minimal nutrient content that is guaranteed by the date of expiration. The listed nutrient levels of all the identified imported European formulas met the minimum and maximum nutrient level requirements of the FDA, with one exception, Topfer Bio 1. Topfer Bio 1 contained less than the FDA's minimum requirements for copper and vitamin A. Additionally, linoleic acid, required by the FDA, was not listed on 10 of the 14 European labels or

TABLE 4. Comparison of imported European Formulas' Labels (n = 14) to United States Food and Drug Administration Regulations

Formula	Label in English	Statement of calories/ volume	Contains all FDA nutrient requirements	Nutrients in required unit of measurement	Iron (mg per 1 00 calories) If <1, statement 'Additional Fe may be required'; if >1, statement 'Infant Formula with Fe)	Directions of Use • Storage pre and after opening • Sterilization, if needed • Mixing instructions • Date of expiration • Improper preparation statement • Consult pediatrician/ medical professional						Mixing instructions with number of scoops (g/scoop) per ounce of water	Pictogram of mixing instructions
HiPP Organic First Infant Milk 1	Yes	Yes	Yes	No	0.76, No	Y	Y	Y	Y	Y	Y	1 scoop (4.3 g)	Yes
HiPP Organic Hungry Infant Milk Powder	Yes	Yes	Yes	No	1, No	Y	Y	Y	Y	Y	Y	1 scoop (4.5 g)	Yes
HiPP HA Combiotic Infant Milk Stage Pre	No	Yes	Yes (except Linoleic)	No	0.77, No	Y	Y	Y	Y	Y	Y	1 scoop (4.3 g)	Yes
HiPP HA Combiotic Infant Milk 1	No	Yes	Yes (except Linoleic)	No	1.01, No	Y	Y	Y	Y	Y	Y	1 scoop (4.3 g)	Yes
HiPP Combiotic Comfort	Yes	Yes	Yes	No	1.0, No	Y	Y	Y	Y	Y	Y	1 scoop (4.4 g)	Yes
HiPP Organic Anti-Reflux	Yes	Yes	Yes	No	1.1, No	Y	Y	Y	Y	Y	Y	1 scoop (4.4 g)	Yes
Holle Bio pre	No	Yes	Yes (except Linoleic)	No	0.74, No	N	Y	Y	Y	Y	Y	1 scoop (4.5 g)	Yes
Holle Organic 1	Yes	Yes	Yes (except linoleic)	No	0.89, No	N	Y	Y	Y	Y	Y	1 scoop (4.4 g)	Yes
Lebenswert First Milk	No	Yes	Yes (except Linoleic)	No	1.04, No	N	Y	Y	Y	Y	Y	1 scoop (4.6 g)/ 31–31.7 mL	Yes
Toepfer Lactana Bio Pre	No	Yes	Yes (except Linoleic)	No	0.79, No	Y	Y	Y	Y	Y	Y	1 scoop (4.4 g)	Yes
Toepfer Bio 1	No	Yes	Yes (except Linoleic)	No	0.82, No	Y	Y	Y	Y	Y	Y	1 scoop (4.5 g)	Yes
Toepfer milk free-soy Lactopriv	No	Yes	Yes (except Linoleic)	No	0.8, No	Y	Y	Y	Y	Y	Y	1 scoop (4.3 g)	Yes
Topfer Lactana Pre-HA	No	Yes	Yes (except Linoleic)	No	1, No	Y	Y	Y	Y	Y	Y	1 scoop (4.4 g)	Yes
Topfer Lactana HA 1	No	Yes	Yes (except Linoleic)	No	0.9, No	Y	Y	Y	Y	Y	Y	1 scoop (4.4 g)	Yes

FDA = Food and Drug Administration.

manufacturer websites. The EU recommendations (24) for linoleic acid levels (minimum 500 mg/100 kcal, maximum 1200 mg/100 kcal) are comparable with the FDA (3) recommended levels (minimum 300 mg/100 kcal); therefore, it is likely that linoleic acid was present at adequate levels in these formulas. As it was not listed on the label in some instances, it could not be compared with FDA requirements. US infant formulas are also designed for infants from birth to 1 year of age, whereas European infant formulas are staged, 0–6 and 6–12 months, around the expected time of the introduction of complimentary feeding. Consumers in the United States may not be aware of these different stages and give their infant the incorrect stage formula, which may not provide the correct amount of nutrients for that age.

The majority of imported European formulas identified in our study were either partial hydrolysate or intact cow milk protein-based. None of the commonly imported European formulas were suitable for premature infants or infants with cow milk protein allergy (CMPA) as the latter, including extensively hydrolyzed protein and amino acid-based formulas, are typically available in Europe only through prescription and are not likely to be obtained by third party vendors and imported into the United States for sale. It is important to note that European regulations state that a formula can contain either partially or extensively hydrolyzed protein to be labeled hypoallergenic, such as HiPP HA. In the United States, FDA guidelines do not allow partially hydrolysate formulas to be labeled as hypoallergenic (25). In addition, the 1 soy-based formula, Topfer Lactopriv milk-free, an infant formula that can be used from birth onward, is marketed for use in infants with CMPA who are 6 months and older. Although soy-based formulas may be tolerated by those with CMPA, and the AAP allows their use after 6 months-of-age, they are not hypoallergenic. Extensively hydrolyzed and amino acid-based formulas are recommended as first-line management, especially for those with nonimmunoglobulin E-mediated CMPA where there is greater risk of co-reactivity to soy (25–27). Given how hypoallergenic is defined by the FDA and health professionals in the United States, formulas claiming to be used in the treatment of CMPA that contain soy and formulas that are only partially hydrolyzed that are labelled ''hypoallergenic,'' are mislabeled under US law. This difference may be misleading, resulting in potential misinformation to US consumers and providers alike and the improper treatment of CMPA.

To understand why parents may seek to use imported European infant formulas rather than US FDA-regulated formulas, we reviewed blogs discussing these formulas. The blogs based their recommendation for the use of European infant formula on the belief that the EU has stricter standards and uses higher quality ingredients. The US FDA Infant Formula Act was initially passed in 1980, and has had few updates on nutritional content and levels since this time. Updates have been made to revise quality control procedures (28), good manufacturing practices, record keeping, and recall requirements (29). In 2015, the US FDA focused on adding minimum and maximum levels of selenium to the list of required infant formula nutrients (30). In Europe, the EFSA (European Food and Safety Authority) Panel on Dietetic Products, Nutrition and Allergies (NDA) provides guidance on the requirements for the composition of infant formula and follow-on formula based on new scientific evidence (31), and was last comprehensively updated in 2014, with recommendations being implemented in 2015 (24). For example, the EU updated its requirements to include DHA and has adjusted iron to lower levels based on new recommendations (31). Therefore, European standards for formula production and safety are at least as stringent as US FDA standards. In addition, as infant formula is a food, it is also subject to US FDA regulations, which address good manufacturing practices and the distribution of food (32). When European formulas are purchased from third party sellers, however, and are imported outside their normal ''chain of control,'' they bypass these safety regulations, and create concerns for potential tampering and contamination of the formula with risks to US consumers.

According to the AAP, cases of infant sickness and death from nutritionally inappropriate and tainted formulas manufactured outside the United States have occurred (4,33). In 2017, the French dairy group Lactalis found that its infant formulas were contaminated with *Salmonella*, leading to a recall of more than 7000 tons of potentially contaminated products from more than 80 countries (34). In addition, a German infant formula, Remedia Super Soya 1, manufactured for Israel by the German company Humana, lacked thiamine and led to beriberi and fatalities among Israeli infants (35). Of note, at least 2 of the commonly identified imported European infant formulas are listed on a list of formulas on an FDA Import Alert (5). In 2016 to 2017, the FDA received notification of 6 adverse events on imported European formulas (3 from HiPP, 2 from Holle, and 1 from Lebenswert), which included complaints, such as fever, vomiting, diarrhea, lethargy, poisoning, and salmonellosis (36). Despite manufacturers' best efforts, there are rare instances of food safety concerns during the manufacture of infant formulas, both in the United States and abroad. If a European formula recall occurs abroad, however, it might not reach a US consumer or third-party supplier of the European formula in the United States in a timely manner.

This is the first study to identify and review infant formulas imported from Europe that are not registered with the FDA and compare them to the FDA's label and nutrient requirements. It was found that European formulas do not meet all FDA label requirements, including many not being in English, which may lead to the incorrect mixing of formula. The average listed nutrient levels of all but one of the identified imported European formulas fell within the minimum nutrient level requirements of the FDA. As the nutrient levels on the labels of European formula represents an average and not a minimal level, it is difficult to compare the actual contents with US formulas. In addition, it is important to note that hypoallergenic is defined differently in Europe than in the United States. Therefore, partially hydrolyzed European formulas may be labeled as ''hypoallergenic'' or HA, which is not appropriate for infants with CMPA and may lead to improper treatment of an infant with CMPA.

Future studies should compare actual nutrient levels at the time of the labeled expiration date of the formula, providing a more accurate comparison to FDA requirements. In addition, we used recommendations from blogs as a surrogate indicator of why these formulas may be chosen by parents. To gain more insight, future research should focus on surveying parents who have used these imported formulas to understand the reasons behind their choices. This study also did not evaluate the use of European infant formula or formula laws in other countries, including Canada. More data on the use and importation of these formulas to other countries would be an important topic for future studies.

Pediatric gastroenterologists and pediatric healthcare providers need to educate consumers that by purchasing imported European formulas from third party vendors, they are bypassing the notable consumer protections of infant formula as regulated by the FDA that ensure infant formula safety and protect against tampering and contamination. As European infant formulas are being illegally imported into the United States, there should be more aggressive regulatory enforcement of the Infant Formula Act and FDA regulations on infant formula distribution. This enforcement could be both at the level of European manufacturers and third-party vendors who import these formulas into the United States. Finally, perhaps, it is time to update the Infant Formula Act so that consumer choices in the United States can be informed by

the latest and most up-to-date scientific evidence for our infant population.

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