SPECIAL GUEST EDITOR SECTION: FOOD ALLERGENS SURVEYS

Undeclared Food Allergens and Gluten in Commercial Food Products Analyzed by ELISA

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Undeclared allergen(s) in commercial food products are responsible for many food recalls, as reported by regulatory agencies in various countries, including the United States. Correct allergen labeling practices are essential for the safety of food-allergic consumers. However, this practice may be hindered by the introduction of allergens all along the food supply chain, including unintentionally through cross-contact. To understand the pervasiveness of undeclared allergen(s) in commercial food products, the objective of this review is to summarize the prevalence of undeclared milk, egg, hazelnut, peanut, soy, and gluten as detected by ELISA from previously published surveys. The prevalence of undeclared allergen(s) in products with or without an advisory statement was also summarized and compared. As compiled by this review, there are some food categories that may be at higher risk for containing undeclared allergen(s). However, the data on prevalence and amount of allergen present may vary widely within any particular allergen or food category. Factors, such as food survey product selection, geography, awareness of allergen/gluten issues, and/or the choice of ELISA method, may be responsible for such differences.

Food allergy is a prominent health issue, and it is estimated to affect 3% of the U.S. population (1). The clinical symptoms of an allergic reaction can range from hives to anaphylaxis (2). There are currently no available treatments for preventing allergic reactions from food. Thus, avoidance of allergen hazards through proper identification of allergenic ingredients in food products is important. Commercial food products, such as packaged or processed foods, are a part of most consumer diets as they not only have consistent quality and shelf-life, but also offer convenience to consumers. Labeling regulations were enacted in various countries to help allergic patients avoid the consumption of packaged food products that contain priority food allergens. In the United States, the Food Allergen Labeling and Consumer Protection Act (FALCPA) was enacted in 2004, requiring specific declaration of the eight major food allergens—egg, milk, peanut, soy, fish, crustacean shellfish, tree nuts, and wheat—when added as ingredients in labeled food products. Similar legislation also exists in other countries or regions, such as Canada, Australia, New Zealand, Japan, and the European Union (EU) (3). However, depending on the jurisdiction, additional food allergens, such as sesame, mustard, etc., also require declaration. More recently, in 2013, a rule for the voluntary use of gluten-free labels on foods was published in the United States. Similar requirements for gluten-free labeling also exist in many other countries. Gluten is found predominantly in wheat, rye, and barely and their cross-bred hybrids. A 20 ppm maximum limit of gluten has been established in foods labeled gluten-free by most countries and the Codex Alimentarius.

According to Reportable Food Registry (RFR) reports by the U.S. Food and Drug Administration (FDA), the annual number of reportable foods (that meet the same definition of a class I recall) due to undeclared allergens has steadily increased between 2009 and 2014 (4). Undeclared allergens constituted 47% of all reportable foods in 2013–2014 (4), making undeclared allergens the most common cause of reportable foods for that year. Further, this report identified bakery, chocolate/confections/candy, dairy, and snack foods as the four food categories involved in the majority (53.1%) of allergen RFR entries. Bucchini et al. (5) compared the food allergen recalls between 2011 and 2014 from various countries and identified bakery as the food category with most recalls from the European Commission Rapid Alert System for Food and Feed, U.K. Food Standards Agency, FDA, and Canadian Food Inspection Agency (CFIA). There are multiple reasons for the presence of undeclared allergens, including the use of an incorrect food package or label, allergen terminology issues, or cross-contact (6).

Cross-contact can be defined as the unintentional incorporation of a food allergen into a food and may occur at any stage of food production, from raw material to finished product. It often occurs when there is failure to adequately clean equipment between production runs of allergen- and nonallergen-containing food products. Despite precautions being taken to avoid the introduction of an unintended allergen during manufacture, cross-contact may sometimes be inevitable. Many countries have no regulations or rules requiring labeling of foods that may have allergens present due to cross-contact (7). Thus, food manufacturers may voluntarily warn consumers of the possible presence of undeclared allergen(s) through the use of advisory or precautionary allergen labeling statements, such as "may contain....", "made in a facility....",

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"produced on shared equipment...." etc. A 2009 study (8) found that 17% of 20 241 commercial food products in the United States contained some sort of allergen advisory statement, and these statements were found in over 50% of food categories, such as chocolate candy and cookies.

Critical to the reduction of cross-contact or mislabeling during food production is the implementation of good manufacturing practices. Many manufacturers may have an allergen control plan, or Hazard Analysis and Critical Control Points plan, to help streamline and mitigate allergen-related issues. In the United States, as part of the Food Safety Modernization Act of 2010, the FDA requires certain manufacturers to have a plan to control for allergens under the rule for Preventive Controls for Human Food (9). In order to detect or monitor for the presence of allergen(s) in finished commercial products or anywhere along the production chain, an ELISA is often the method of choice. ELISAs are considered as having high sensitivity and specificity (10). Most immunochemical-based assays use polyclonal or monoclonal immunoglobulin G antibodies developed against a specific allergen or intrinsic allergenic proteins (e.g., in peanut, Ara h1, Ara h2, etc.) to detect and quantify the allergen. The choice of antibody can affect the sensitivity and specificity of the assay (11). The method also involves an extraction step in which protein is solubilized from the food matrix using an extraction buffer. The food matrix and processing procedures can make the extraction process difficult and can, therefore, affect allergen quantitation by ELISA (11, 12). Moreover, protein modifications due to food processing can also alter interactions of the antibody to the target allergen, further affecting ELISA results.

This review seeks to examine the reported prevalence of undeclared major food allergens and gluten found in commercial food products from published product surveys using ELISA as the analytical method. Because surveys routinely collect and analyze products from certain food categories that carry a higher risk for the presence of undeclared allergen, the prevalence of undeclared allergens in products from these select food categories was compared. In addition, this review explores the relationship between an allergen advisory statement and the prevalence of allergens in such products.

Review and Classification of Survey Data

Survey data included a wide range of allergens, product types, sampling approaches, and ELISA methodologies. Insufficient survey information was available for certain allergens (undeclared fish; crustacean shellfish; tree nuts, except hazelnut; and wheat); thus, this review is focused on the following major allergens: milk, egg, hazelnut, peanut, soy, and gluten. The lack of information on the prevalence of undeclared fish and crustacean shellfish is possibly because they are less often associated with allergen-related recalls (6), whereas wheat is more likely covered in the surveys involving undeclared gluten. Among tree nuts, the high prevalence of hazelnut allergy in Europe (13) may explain why undeclared hazelnut was most commonly studied in surveys, most of which were from Europe. Survey data were categorized into four groups: (*1*) an overall prevalence of undeclared allergen in all products analyzed by individual surveys, which includes multiple food categories (Table 1); (*2*) an overall prevalence of undeclared allergen in surveyed products from select food categories (Table 2); (*3*) prevalence of an allergen among multiple food categories that contained an advisory statement for the undeclared allergen of interest (Table 3); and (*4*) prevalence of an allergen among multiple food categories that did not mention the undeclared allergen of interest anywhere on the label and had no advisory statement (Table 4). Surveillance studies conducted as a result of an isolated or recall event were excluded, as well as small surveys often conducted to support the development of an ELISA method. Also, surveys with a very small sample size (<10) were not reviewed. Within these four survey groups, if information regarding certain food categories was available, it was also included.

Milk

Undeclared milk ranks the highest in allergen-related food recalls (16–31%) across the world (5). According to the RFR reports (4), undeclared milk accounted for 8.7–15.6% (excluding entries having multiple undeclared allergens) of reportable foods in 2009–2014. Within food categories in the United States, the highest frequency of milk-related recalls was associated with bakery, followed by snack and candy (6). The identification of undeclared milk allergen is challenging because a variety of milk-derived ingredients (cheese, butter, and cream) and proteins (caseinates, whey protein, and protein hydrolysates) are used in many types of foods, increasing the potential for cross-contact when nonmilk-containing products are produced on the same production line. Furthermore, many labeled ingredients may not be readily identifiable as milk proteins (i.e., casein, whey, or β-lactoglobulin). Milk-allergic children have been reported to have unintentional adverse reactions to prepacked and non-prepacked products with no indication of milk as an ingredient (14, 15).

Survey studies of various food products (Table 1) showed that the overall prevalence of undeclared milk ranged from 0.8 to 14.8% (16–21), with the highest prevalence of 14.8% noted by Surojanametakul et al. (21) in the analysis of commercial Thai products, at which time a food allergen-labeling regulation was lacking in Thailand. Dark chocolate-containing products are among the high-risk foods for milk allergen, with a wide prevalence rate of 1.5–77.8% (Table 2; 12, 17, 22, 23). The highest prevalence of 77.8% is from a survey that examined only those chocolate products that contained an advisory statement (23). However, lot-to-lot variation in the presence of undeclared milk was observed in different surveys, indicating inadequate cleaning of shared manufacturing lines as a source of cross-contact or the irregular distribution of milk residues within a lot (12, 23). A 36% prevalence of undeclared milk in the confectionary category has been reported by Hirst (18).

Various surveys have consistently shown the bakery category to account for a notable prevalence of undeclared milk in products (Table 2). When analyzing prepackaged bakery foods, Ford et al. (17) reported 4.2% of products had undeclared milk protein. A targeted survey of prepackaged cookies without advisory statements by the CFIA in Canada reported a 2.4–3.3% prevalence of undeclared milk (24). In a small study of non-prepackaged bakery foods (sold as cow's milk-free) by Trendelenberg et al. (15), 43% of the bakery products had detectable undeclared milk protein. Meat-, chicken- or fish-based products have also tested positive for

Table 1. Prevalence of select undeclared food allergens and gluten in foods based on multiple food categories

Allergen	Food categories	Survey size	Prevalence, %	Level, ppm[a]	Ref.
Milk	Baking mixes, chocolate candies, nonchocolate candies, cookies, salty snacks, cold cereals, others	193	5.2	1.4–78[b]	(17)
	Instant noodles, sauces, snacks, rice flour products, fish/meat balls, salad dressings, others	142	14.8	10–30 000	(21)
	Desserts, snacks, ready-to-eat meals, spices and flavor packets	650–652	0.8–1.1	0.4–9[b]	(19)
	Meat-based products, snacks, baby foods, ready-to-eat products, others	285	2.8	NA[c]	(16)
	Cereal products, confectionery, chilled desserts, meat, fish, ready meals, others	474[d]	8.2	4–4400	(18)
	Meat- or fish-based products, bakery products, pasta, dumpling, infant foods	791	2	14 to >135[b]	(20)
Egg	Baking mixes, chocolate candies, nonchocolate candies, cookies, salty snacks, cold cereals, others	174	2.3	1–4[b]	(17)
	Cakes, biscuits, confectionery, ready meals, breads, baby foods, others	214	2.6	Up to >920[b]	(30)
	Instant noodles, sauces, snacks, rice flour products, fish/meat balls, salad dressings, others	142	12	33–35 250	(21)
	Desserts, snacks, ready-to-eat meals, spices and flavor packets	945	0.2	2.2	(19)
	Meat-based products, snacks, baby foods, ready-to-eat products, others	234	4.7	NA	(16)
	Meat- or fish-based products, bakery products, pasta, dumpling, infant foods	775	3.6	0.4 to >6[b]	(20)
	Bakery (breads, cakes, cookies, others) and snack (chips, pretzels, crackers, others) products	835	5	0.3–74 085	(29)
Hazelnut	Cookies, breakfast cereals, milk chocolates, dark chocolates, ice creams, yogurts	383	19.8	NA	(36)
	Desserts, snacks, ready-to-eat meals, spices and flavor packets	1029	0	NA	(19)
	Ready meals, confectionery, cereal and cereal products, dried sauces, gravies and mixes, chilled and frozen desserts, others	988[d]	2.9	1–170	(18)
Peanut	Cookies, breakfast cereals, milk chocolates, dark chocolates, ice creams, yogurts	383	4.4	NA	(36)
	Baking mixes, chocolate candies, nonchocolate candies, cookies, salty snacks, cold cereals, others	232	2.2	1–40[b]	(17)
	Cakes, biscuits, confectionery, ready meals, breads, baby foods, others	181	3.9	NA	(30)
	Instant noodles, sauce, snacks, rice flour products, fish/meat balls, salad dressing, others	142	0	NA	(21)
	Desserts, snacks, ready-to-eat meals, spices and flavor packets	1059	0.1	0.4	(19)
	Ready meals, confectionery, cereal and cereal products, dried sauces, gravies and mixes, chilled and frozen desserts, others	950[d]	0.2	11–18	(18)
	Biscuits and pastry, chocolate tablets or spreads, bread and bakery products, other chocolate products, appetizer products, ice cream and sorbets, others	899	1	0.2–5[b]	(38)
Soy	Desserts, snacks, ready-to-eat meals, spices and flavor packets	561	5.3	0.6–50	(19)
	Bakery (bread, cookies, cake, other) and snack (chips, crackers, popcorn, others) products	558	16.8	1–61	(45)
Gluten (gluten-free-labeled)[e]	Gluten-free foods (food categories unknown)	3088	34.7	20 to >200	(51)
	Cereal foods (flour, breakfast, chips, others)[f]	77	9.1	24–316	(54)
	Bread, pasta, pastry, biscuits, pizza, breakfast cereals	205	0.5	28	(55)
	Snacks, cookies, baking mixes, flours, ready-to-eat cereals, hot cereals, others	112	3.6	≥20	(62)

Table 1. (*continued*)

Allergen	Food categories	Survey size	Prevalence, %	Level, ppm[a]	Ref.
	Flours and starches from grains, nuts, seeds, and others	268	1.1	>20	(56)
	Breakfast cereals, pasta, bread, tortilla, bars, snacks, baking mixes	78	20.5	20–60	(64)
	Snacks, baked foods, meat/meat substitute/ refrigerated or frozen foods, breakfast cereals, condiments/sauces, curry/soup/soup mixes, others	275	1.1	>20 to 554	(61)
	Baking ingredients, beverages, breads, chili, condiments, cookies, others	158	5.1	≥20	(60)
	Snacks, flours/starches, cookies/muffins, seasonings/herbs/spices, maize flakes/granola, potato chips, others	~307	11.0	>20	(63)
	Grains, pasta products, soups, baking mixes, baked foods, breakfast cereals, others	173	5.8	>20	(58)
	Dry pasta and flours from maize, rice, quinoa, and buckwheat	12419[g]	0.9	≥20	(57)
	Flours, pasta, snacks, cookies, muesli, breakfast cereals, others	93	2.2	>20	(59)
	Flours, breakfast cereals/bars, pasta products, breads, dough/pastry/pizza, bakery, others	1652	3.2	>20	(52, 53)
	Cereal-based foods (breakfast, snack, bakery), grain bars, flours and meals	>250	<0.5	24–43	(65)
Gluten (nongluten-free-labeled)[e]	Cereal-based products (rice, maize, buckwheat, millet, oat)	110	43.6	20 to >200	(66)
	Cereal foods (flour, breakfast, chips, cookie, granola bar, others)[h]	71	22.5	22–2827	(54)
	Flours–cereals, dairy (milk drinks, yogurt, ice cream, cheese), sweets, processed meats, pasta, tomato sauce	41	9.8	21–39	(67)
	Flours and starches from grains, nuts, seeds and others	372	15.6	>20	(56)
	Breakfast cereals, grains/seeds/nuts/legumes, snack foods, meat/meat substitute/refrigerated or frozen foods, condiments/sauces, granola/bars, others	186	19.4	>20 to 1566	(61)
	Breakfast cereals, spices, snacks, seasoning mixes, oat cereal, green tea leaves, others	101	5.0	≥20	(68)
	Bread, biscuit, cake[i]	130	21.5	>20	(69)
	Flours, pasta, snacks, cookies, muesli, breakfast cereals, others	107	15	>20	(59)
	Snacks, noodles, Thai desserts, fish and meat products, precooked rice, sauce, others	129	7.8	62–28 713	(70)
	Flours, breakfast cereals/bars, pasta products, breads, dough/pastry/pizza, bakery, others	962	8.0	>20	(52, 53)

[a] Measured allergen protein.

[b] Allergen converted to protein concentration using one of the following: nonfat dried milk, 35.1% protein (81); casein and β-lactoglobulin are 85 and 10% of total milk protein, respectively (82); dried whole egg, 46% protein (81); or peanut, 25% protein (81).

[c] NA = Not available/applicable.

[d] Prevalence is based on the number of samples, which may be higher than the number of products used in the study.

[e] Prevalence is based on >20 ppm gluten.

[f] Wheat-free samples were also included.

[g] Includes 180 environmental swabs.

[h] Some products included minor ingredients, such as barley malt, wheat starch, etc.

[i] Most products did not contain a gluten-free claim, but were conveyed to be gluten-free verbally.

undeclared milk protein, with a prevalence of 3.1–14.2% (16, 18, 25). An exception was the survey of Bianchi et al. (20) in which the incidence of undeclared milk was 75%. However, Bianchi et al. (20) analyzed only 16 meat products for undeclared milk protein, compared with the other surveys in which 195–696 products were analyzed (16, 25).

A number of surveyed products also had various forms of milk advisory statements (12, 17, 18). Approximately 10.2–42%

Table 2. Prevalence of undeclared allergens in select high-risk food categories

Allergen	Food categories	Survey size	Prevalence, %	Level, ppm[a]	Ref.
Milk	Dark chocolate and/or chocolate products	18[b]	77.8	1–5265[c]	(23)
		68	1.5	NA[d]	(17)
		152[e]	16.4–18.4	0.9–12 000[c]	(22)
		88	58	0.9 to >1755[c]	(12)
	Bakery products (bread, baking mixes, cookies, others)	167	4.2	NA	(17)
		123[e,f]	2.4–3.3	0–1177[c]	(24)
		73[g]	43	0.7 to >68	(15)
		16	6.3	90.5[c]	(20)
Egg	Bakery products (bread, baking mixes, cookies, others)	167	2.4	NA	(17)
		335[e,f]	0.3	24	(24)
		28	14.3	1[c]	(20)
		443	7.5	0.3–74 085	(29)
	Meat-, chicken-, or fish-based products	726	13.1	0.1–12	(25)
		185	4.9	NA	(16)
		56	39.3	0.4 to >6[c]	(20)
Hazelnut	Chocolate (milk and/or dark)	248	65.3	0.2 to >3[c]	(37)
		116	33.6	NA	(36)
		210[e]	1.4	1–91	(22)
	Cookies	278	27.7	0.2 to >3[c]	(37)
		131	23.7	NA	(36)
		305[e]	0.3	0.3	(24)
Peanut	Chocolate (milk and/or dark)	92	27.2	4–245	(39)
		248	37.1	0.2 to >5[c]	(37)
		116	7.8	NA	(36)
		68	4.4	NA	(17)
		305[e]	0.7	2–3	(22)
		140	1.4	0.2–0.8[c]	(38)
		78	9.4	1–138[c]	(12)
	Cookies	278	24.5	0.2 to >5[c]	(37)
		131	3.1	NA	(36)
		318[e]	1.6	0.4–19	(24)
Soy	Meat	131	84	NA	(44)
		116	28.4	<53 to >530[c]	(48)
		58	86.2	Up to 0.9	(50)
	Wheat flour	35	62.8	2–236	(47)
		~26[e]	54	0.8–30	(46)
Gluten (gluten-free-labeled)[h]	Cereals (breakfast, hot, ready-to-eat)	18	0	NA	(55)
		22	4.5	28–78	(61)
		14	7.1	≥20	(62)
	Grains/nuts/seeds/legumes/flours/starches	268	1.1	>20	(56)
		17	0	NA	(61)
		15	0	NA	(62)
		10	10	>20	(58)
Gluten (nongluten-free-labeled)[h]	Oat-based products	109	70.6	22–10 380	(71)
		88	44.3	22 to >200	(66)
		12	75	23–1807	(72)
		133	93.2	21–3784	(74)
	Grains/nuts/seeds/legumes/flours	22	31.8	25–2925	(73)
		372	15.6	>20	(56)
		30	20	21–711	(61)

[a] Measured allergen protein.

[b] All samples studied had an advisory statement.

[c] Allergen converted to protein concentration using one of the following: nonfat dried milk, 35.1% protein (81); casein and β-lactoglobulin are 85 and 10% of total milk protein, respectively (82); dried whole egg, 46% protein (81); peanut, 25% protein (81); hazelnut, 15.7% protein (81); or soy flour, 53% protein (81).

[d] NA = Not available/applicable.

[e] All samples studied had no advisory statement.

[f] Only cookie samples were surveyed.

[g] Non-prepacked foods sold as cow's milk-free.

[h] Prevalence is based on >20 ppm gluten.

of surveyed products with milk advisory statements contained milk protein (Table 3; 17, 23). In a survey of various foods having no milk reference on the label (Table 4), 3% of products tested positive for undeclared milk protein (17). Among dark chocolate products with advisory statements, 75–78% were found to have undeclared milk protein (12, 23). On the other hand, in surveys of chocolate products without a milk advisory statement, 16–33% undeclared milk prevalence was observed (12, 22). One of these chocolate surveys also analyzed products labeled as dairy-free, lactose-free, or vegan and found 15–25% products had milk protein (12). These surveys provide evidence that dark chocolate products, especially bars with (or even without) advisory statements, have a comparatively high risk for undeclared milk compared with other products. There is limited information from these surveys to determine whether a chocolate ingredient may be one of the causes of undeclared milk in other product categories (e.g., bakery) as well.

Egg

Undeclared egg represented 52% of total FDA class I recalls in fiscal year 1999 (26) and 3.1–7.5% of reportable foods (excluding reportable foods involving multiple allergens) annually between 2009 and 2014 (4). According to Gendel and Zhu (6), for fiscal years 2007–2012, egg ranked fifth among FDA allergen-related recalls. The desirable functional properties of egg-white and yolk proteins (e.g., foaming, gelling, binding adhesion, and emulsion) makes their use common in foods such as bakery products, cookies, meat, pastries, ice cream, sauces, cheese, etc. (27, 28). In addition, the extensive use of egg components (e.g., egg powder, ovalbumin, or lysozyme) as food ingredients increases the potential for undeclared egg and unintentional egg allergen exposure.

Based on existing data of survey studies of broader food categories (Table 1), the prevalence of undeclared egg was 0.2–12% of tested products (16, 17, 19–21, 29, 30). Among different food categories in the United States, undeclared egg was found to be highly associated with bakery products, followed by dairy, dressing, candy, and snacks (6). In Table 2, surveys of food commodities suggest an overall prevalence of undeclared egg in 0.3–14.3% of bakery

Table 3. Prevalence of undeclared allergens based on multiple food categories among products with advisory labels

Allergen	Food categories	Survey size	Prevalence, %	Level, ppm[a]	Ref.
Milk	Baked goods/mixes, dark chocolate candy, other candy/ confectionery, cereals, frozen desserts, instant meals, others	81	42	1–5265[b]	(23)
	Baking mixes, chocolate candies, nonchocolate candies, cookies, salty snacks, cold cereals, others	59	10.2	1–78[b]	(17)
Egg	Baking mixes, chocolate candies, nonchocolate candies, cookies, salty snacks, cold cereals, others	57	1.8	3[b]	(17)
	Cakes, biscuits, confectionery, ready meals, breads, baby foods, others	18	6	NA[c]	(30)
	Chocolates, breakfast cereals, muesli bars, savory biscuits, sweet biscuits (cookies)	128	0	NA	(31)
	Bakery (breads, cakes, cookies, others and snack (chips, pretzels, crackers, others) products	101	10.9	0.3–36 436	(29)
Peanut	Confectionery/candy, bakery products/mixes, nutrition/meal bar, cereal/cereal bars, snack foods, baking ingredients, others	179	7.3	0.8–1000[b]	(42)
	Baking mixes, chocolate candies, nonchocolate candies, cookies, salty snacks, cold cereals, others	112	4.5	1–40[b]	(17)
	Cakes, biscuits, confectionery, ready meals, breads, baby foods, others	75	6.7	NA	(30)
	Baked good/mixes, candy/confectionary, snack foods, nutritional/meal bars, cereal/cereal bars, instant meals, others	186	8.6	0.8–128[b]	(41)
	Baked good, biscuits, cereal/granola bars, chocolates, nutrition/ meal bars	29	6.9	0.7–6[b]	(40)
Soy	Bakery (breads, cookies, cakes, others) and snack (chips, crackers, popcorn, others) products	151	13.9	1–43	(45)
Gluten (not labeled gluten-free)[d]	Flours and starches from grains, nuts, seeds and others	74	37.8	>20	(56)
	Breakfast cereals, grains/seeds/nuts/legumes, snack foods, meat/meat substitute/refrigerated or frozen foods, condiments/sauces, granola/bars, others	53	34.0	>20	(61)
	Beverage mixes, candy, nut, snacks, oat fiber, bakery products, others	14	7.1	≥20	(68)
	Flours, pasta, snacks, cookies, muesli, breakfast cereals, others	36	11.1	>20	(59)

[a] Measured allergen protein

[b] Allergen converted to protein concentration using one of the following: nonfat dried milk, 35.1% protein (81); dried whole egg, 46% protein (81); or peanut, 25% protein (81).

[c] NA = Not available/applicable.

[d] Prevalence is based on >20 ppm gluten.

products (17, 20, 24, 29), including the 0.3% prevalence found in a report that examined only cookies without an egg advisory statement (24). The highest prevalence of 14.3% reflected one relatively small survey of 28 bakery products in which 4 were found to contain undeclared egg (20). Other food categories were also found to be positive for undeclared egg with the following prevalence: 7.1% in pasta and dumpling products (20) and 1% in snack products (29). The low prevalence of undeclared egg in snack products is reflected in the low number of egg-related recalls in the snack food category compared with the bakery category (6, 29).

Though the prevalence of undeclared egg in meat products is not known in the United States, Bucchini et al. (5) reported that egg was responsible for 12% of total allergen recalls by the U.S. Department of Agriculture (USDA) Food Safety and Inspection Service (FSIS) from years 2011 to 2014. The allergen-related recalls for meat products are not reflected in the Gendel and Zhu study (6), as most meat products are regulated by the USDA and, therefore, not registered in the FDA's recall database. In meat- or fish-based foods, Barbaro et al. (16) found 4.9% prevalence when surveying 185 meat-based products, whereas Bianchi et al. (20) showed 39.3% (67.9% in meat- and 10.7% in fish-based products separately) when surveying 56 meat- and fish-based products. A 13.1% prevalence rate of undeclared egg was reported for 726 products of animal origin (meat, chicken, or fish) in the Piedmont region of Italy (25).

As seen in Table 3, surveys of various foods with egg advisory statements demonstrated the prevalence of undeclared egg to be in 0–10.9% of tested products (17, 29–31). The frequency of undeclared egg in bakery and snack products that contained an advisory statement was reported as 12 and 5%, respectively (29). In the surveys of the broader group of commercial food products without egg as an ingredient and without an egg advisory statement, the percentage of the products testing positive for egg protein was 2.6–5% (Table 4; 17, 29, 30). Among bakery and snack products that did not declare egg as an ingredient, undeclared egg protein was detected in 6 and 2% of the products without an egg advisory statement, respectively (29).

Hazelnut (Tree Nut)

Tree nuts represented 3.6–7.9% of reportable foods in the RFR reports between 2009 and 2014 (4) and ranked fourth

Table 4. Prevalence of undeclared allergens based on multiple food categories among products without advisory labels

Allergen	Food categories	Survey size	Prevalence, %	Level, ppm[a]	Ref.
Milk	Baking mixes, chocolate candies, nonchocolate candies, cookies, salty snacks, cold cereals, others	134	3	6–44[b]	(17)
Egg	Baking mixes, chocolate candies, nonchocolate candies, cookies, salty snacks, cold cereals, others	117	2.6	1–4[b]	(17)
	Cakes, biscuits, confectionery, ready meals, breads, baby foods, others	106	5	NA to >920[b,c]	(30)
	Bakery (breads, cakes, cookies, others) and snack (chips, pretzels, crackers, others) products	734	4.2	0.3–74 085	(29)
Peanut	Baking mixes, chocolate candies, nonchocolate candies, cookies, salty snacks, cold cereals, others	120	0	NA	(17)
	Cakes, biscuits, confectionery, ready meals, breads, baby foods, others	106	1.9	NA	(30)
Soy	Grain-based flours, baked goods, baking mixes, breads, cookies, others	388	44.1	0.5–520	(46)
	Bakery (bread, cookies, cake, others) and snack (chips, crackers, popcorn, others) products	407	17.9	1–61	(45)
Gluten (not labeled gluten-free)[d]	Grains, seeds, flours	15	26.7	25–2925	(73)
	Flours and starches from grains, nuts, seeds and others	298	10.1	>20	(56)
	Breakfast cereals, grains/seeds/nuts/legumes, snack foods, meat/meat substitute/refrigerated or frozen foods, condiments/sauces, granola/bars, others	133	13.5	>20	(61)
	Breakfast cereals, spice, seasoning mixes, oat fiber/cereal, green tea leaves, legumes, others	87	4.6	≥20	(68)
	Flours, pasta, snacks, cookies, muesli, breakfast cereals, others	71	16.9	>20	(59)

[a] Measured allergen protein.

[b] Allergen converted to protein concentration using one of the following: nonfat dried milk, 35.1% protein (81); or dried whole egg, 46% protein (81).

[c] NA = Not available/applicable.

[d] Prevalence is based on >20 ppm gluten.

among allergen-related recalls for fiscal years 2007–2012 (6). The tree nuts mandated for allergen labeling vary by country/region. Although there are a wide variety of tree nuts, the majority of surveys on the prevalence of undeclared tree nuts focused on hazelnut. One possible reason for this narrow focus may be due to the fact that hazelnut is commonly found in commercial food products, such as chocolate, pastries, and ice cream (32, 33). Another reason may be due to the high prevalence of hazelnut allergy among Europeans (13) in which about 0.1–0.5% of the population are affected (34, 35).

The presence of undeclared hazelnut in foods, as determined by ELISA, was reported to be 0–19.8% (Table 1; 18, 19, 36). The higher prevalence of 19.8% observed by Baumgartner et al. (36) could be attributed to the disparity in prevalence between the European countries surveyed. For example, 3% of products were found to be positive in Norway compared with 35 and 51% in Greece and Slovenia, respectively. Based on the survey data, the food categories with a high risk of undeclared hazelnut include cookies and chocolate products with reported occurrences of 0.3–27.7% and 1.4–65.3%, respectively (Table 2; 22, 24, 36, 37). The low prevalence of 0.3 and 1.4% in the CFIA reports for cookies and chocolate products, respectively, focused on only those products that did not carry an advisory statement (22, 24). Among the other food categories, undeclared hazelnut was also observed in breakfast cereal (8.2%), ice cream (9.4%), and yogurt (3.2%) (36).

Pieretti et al. (8) found that of 98 products from multiple food categories, 61% had an advisory statement for some kind of tree nut. As expected, a high number of products surveyed for hazelnut had advisory statements for tree nuts. As noted by at least one survey, advisory statements were about five times more likely to list the more generic reference of "nut" rather than "hazelnut"; i.e., 36% of surveyed products contained a nut advisory versus 7% that specified hazelnut (37). Thus, surveys examined hazelnut in products with advisory statements that either specified hazelnut or contained an advisory for "nut" or "tree nut" (18, 36, 37). A survey of chocolate and cookie products with either hazelnut or tree nut advisory statements found a prevalence of hazelnut in 77.5 and 31.2% of products, respectively (37). Among food products that did not declare hazelnut as an ingredient and had no hazelnut advisory statement, 1.4–53% of chocolate products and 0.3–25% of cookies had detectable levels of hazelnut (22, 24, 37). The lowest prevalence of 1.4 and 0.3% resulted from products collected from Canadian retail stores (22, 24), whereas the highest prevalence of 53 and 25% resulted from the products collected from European countries (37).

Peanut

Undeclared peanuts represented 3.5–5.7% of reportable foods per the RFR reports between 2009 and 2014 (4) and ranked sixth among allergen-related recalls for fiscal years 2007–2012 (6). Peanuts are often included as ingredients in cracker sandwiches, granola bars, cookies, chocolate, and confectionary products,

appearing in the form of whole/pieces of peanut or peanut butter. According to the FDA recall database, foods categorized as snacks were involved in most peanut allergen-related recalls in the United States for years 2007–2012, followed by those in the candy and bakery categories (6).

In several comprehensive surveys, the prevalence of food products with undeclared peanut was reported to be 0–4.4% (Table 1; 17–19, 21, 30, 36, 38). It should be noted that the study by Zagon et al. (38) used a cascade approach in which the peanut-positive sample was tested by ELISA only after screening with lateral-flow device and PCR methods. Based on survey data, the prevalence of chocolate (milk and/or dark) and cookie products containing undeclared peanut ranged from 0.7 to 37.1 and 1.6 to 24.5%, respectively (Table 2; 12, 17, 22, 24, 36–39). The low prevalence reported in these categories resulted from the CFIA reports that surveyed only those food products that did not contain an advisory statement (22, 24). Among other food categories, the prevalence of products found to have undeclared peanut were as follows: cereal, 4.7% (36); and appetizers, 12.1% (38). Specifically, among milk chocolate products, 8.3% tested positive for peanut (36); and for dark chocolate, the prevalence was 6.3–9.4% (12, 36). The high overall prevalence of 37.1% undeclared peanut among chocolate products in the EU found by Pele et al. (37) could be explained by the reported survey difference in prevalence between the older member states' who joined the EU before 2004 (13%) and the newer members (79%).

Pieretti et al. (8) found that peanuts ranked second in terms of the most prevalent allergen (tree nuts ranked first) identified in advisory statements, accounting for 48% of surveyed products that contained an advisory statement. Bedford et al. (12) found 65% of the surveyed dark chocolate products contained the word "peanut" in their advisory statements. The authors also reported undeclared peanuts in chocolates that had an advisory statement for nuts but not peanuts. They indicated the possibility of confusion relating to the use of the word "nuts" versus "peanuts" in advisory statement (12). Among commercial products with a peanut advisory statement, 4.5–8.6% were found to be positive for peanut (Table 3; 17, 30, 40–42). Among various food categories with advisory statements, the prevalence of undeclared peanut was as follows: among chocolate products in the majority of studies, 1.1–17.8% (17, 39, 40), except in one study with 40.3% (37); dark chocolate, 8.4% (12); cookies, 31.2% (37); cereal/cereal bars, 7.7–10% (41, 42); confectionary/candy, 12.5–19.4% (41, 42); and nutrition/meal bars, 7.5–14.3% (41, 42).

Among broad surveys of commercial food products (Table 4), the prevalence of undeclared peanut was 0–1.9% in food products that did not declare peanut as an ingredient nor included a peanut advisory statement (17, 30). The following prevalence was observed within certain food categories: chocolate products, 0.7–36.2% (22, 37, 39); dark chocolate, 17% (12); and cookies, 1.6–11% (24, 37). It is worth noting that foods labeled "allergen-free," "peanut-free," "peanut-free facility," or other such claim contained no detectable peanut in a survey of 15 bar products (41) and 989 products containing bars, chocolate, and cookies (43). Further surveys on other food types and from various regions are needed before making a general statement that products bearing peanut-free claims are indeed free from peanut residues.

Soy

Undeclared soy represented 2.2–5.3% of reportable foods per the RFR reports between 2009 and 2014 (4) and ranked third among allergen-related recalls for fiscal years 2007–2012 (6). Soy is commonly found in many processed foods and is often an alternative to meat for those on a vegetarian or vegan diet. The surveys conducted on the prevalence of undeclared soy in food products are somewhat different from other major allergens. There appeared to be a focus on single-ingredient products, such as wheat flour, and commodities found in the meat category. Plausible reasons for this narrow focus may be the increased incidences of commingling for soy and other raw agricultural commodities, as well as the use of soy in meat-based products. Soy is often added to meat products because of its ability to increase water-binding capacity, leading to improved product durability (44). Its frequent use has led to issues with undeclared soy, as documented by Bucchini et al. (5) who found that 45% of the allergen-related recalls and alerts by the USDA-FSIS (responsible for regulating most meat products in the United States) were related to soy.

The overall prevalence of undeclared soy in foods is not well-studied. However, in two surveys, the prevalence of undeclared soy (Table 1) was estimated to be 5.3–16.8% (19, 45). The relatively high prevalence was attributed by one of the survey authors (45) to be due to possible commingling of soy with wheat, a main ingredient for many bakery and snack products. Khuda et al. (45) found that, among bakery and snack food categories, products having the highest prevalence of undeclared soy were bread (16–28%) and crackers (18–26%), respectively. In studies that examined the prevalence of undeclared soy in wheat flour (Table 2), the prevalence was 54–62.8% (46, 47).

In a study that examined the prevalence of undeclared soy among commercial food products with advisory statements, 19% of bakery items (e.g., bread, cake, cookies, and pastries) and 9% of snack items (e.g., chips, crackers, and pretzels) contained undeclared soy (45). For products without advisory statements, 25% of bakery products and 11% of snack products were found to be positive for soy (45). Undeclared soy was also found in 3.3% of products with an advisory statement and 4.7% of those without an advisory statement in a survey by the Ireland Food Authority, although a PCR method was used because an ELISA test for soy was not available at that time (30). In a report by the CFIA, 44% of prepackaged grain-based foods without soy as an ingredient and with no advisory statement contained soy (46).

In addition to these categories of processed foods, processed meat products with undeclared soy are also of concern. Undeclared soy can often be found in meat products due to cross-contact or, in some cases, as a result of economic adulteration (48). Researchers have pointed out that, due to rising prices of meat commodities, the intentional introduction of soy for economic gain is probable (49). In studies examining a select number of meat products (Table 2), soy was found in 28.4–86.2% of meat products that had no soy declaration (44, 48, 50).

Gluten/Wheat

In fiscal year 1999, there were only two recall actions (three products recalled) in the United States that involved wheat

allergen (excluding recalls involving multiple allergens), which represented 3% of total recall actions (26). Following the implementation of FALCPA, wheat ranked second among recalls, representing about 18% of food allergen-related recalls for the years 2007–2012 (6). Similar percentages of recalls have been reported during the years 2011–2014 in the European Union (17–19%), and Canada (14%) for cereals containing gluten (5). Currently, there is no commercial ELISA kit available for the exclusive quantitation of wheat, as the antibodies used in these assays also react to the proteins (gluten) from rye and barley. Thus, this section focuses on the prevalence of gluten in foods.

The studies involving detection of undeclared gluten have broadly categorized foods into gluten-free-labeled and nongluten-free-labeled (no explicit gluten-free label and no declaration of a gluten-containing ingredient/grain, e.g., wheat, rye, or barley). Because most countries have established a maximum threshold of 20 ppm for the unintentional presence of gluten in foods labeled gluten-free, many studies have assessed gluten-free-labeling compliance using this threshold level. Though most surveys on gluten estimation have used an R5 antibody-based ELISA method, ELISAs that use other antibodies, such as the Skerritt antibody, have also been used in select surveys. The variability in gluten quantitation associated with the antibody used in ELISA is well known and could also contribute to the disparity in the prevalence of >20 ppm gluten in foods between surveys.

Studies surveying gluten-free-labeled foods found wide variation in the incidence of foods containing >20 ppm gluten, ranging from <0.5 to 34.7% (Table 1; 51–65). Only 3 out of 14 surveys listed in Table 1 found a >10% prevalence in gluten-free-labeled foods having >20 ppm gluten. Among them, the highest prevalence (34.7%), reported by Valdés et al. (51), used gluten-free foods in the survey, but it is not clear if they were labeled gluten-free or inherently gluten-free. It is difficult to identify the specific reason for the high prevalence in those surveys. Among gluten-free-labeled foods, the prevalence of >20 ppm gluten in cereals, such as breakfast, hot, or ready-to-eat, was found to be 0–7.1%, whereas that in grains/nuts/seeds/legumes/flours/starches was 0–10% (Table 2; 55, 56, 58, 61, 62). A recent compilation of the data from previous surveys on gluten-free-labeled foods by Miranda and Simón (53) noted a reduced prevalence rate of foods with >20 ppm gluten over the years (15–20% in 2003–2008 versus <5% in 2009–2016).

Surveys analyzing nongluten-free-labeled foods identified foods with >20 ppm gluten at a prevalence ranging from 5 to 43.6% (Table 1; 52–54, 56, 59, 61, 66–70). Among the 10 surveys, 3 found >20 ppm gluten in more than 20% of the surveyed foods. Two of these three surveys focused on cereal or cereal-based foods (54, 66), whereas one survey analyzed bread, biscuits, and cake from bakeries in Brazil (69). Also, some of the cereal foods surveyed by Gelinas et al. (54) contained minor ingredients, such as wheat starch and malt extract, which may have been a potential source of gluten in those foods. Cawthorn et al. (48) surveyed 94 meat-based products with undeclared gluten in South Africa and detected gluten in 40% of samples, and about 27% of samples contained >20 ppm gluten, with the highest prevalence in sausages. Undeclared gluten concentrations at high levels have been reported in many food categories, including breakfast cereals, flours and meals, and oat-based products (e.g., oat grains/flours, oatmeal, rolled oats, etc.) (56, 61, 70–74). Oat-based products appear to be one of the food categories in nongluten-free-labeled foods that are at a high risk for gluten cross-contact, with >20 ppm gluten prevalence in 44.3–93.2% of surveyed products (Table 2; 66, 71, 72, 74). Sharma et al. (61) found that 61% of breakfast cereals and 24% of bars had >20 ppm gluten, and all of those products with >20 ppm gluten had oat as an ingredient. In the grains/nuts/seeds/legumes/flours category, >20 ppm gluten have been reported in 15.6–31.8% of foods (Table 2; 56, 61, 73). As with the gluten-free-labeled foods, based on the compilation of data from previous studies, Miranda and Simón (53) also reported a reduction in the incidence of >20 ppm gluten in foods not labeled gluten-free from the time period 2003–2008 (20–25%) to 2009–2016 (about 10%).

Many gluten-free-labeled foods also bear an advisory statement for wheat. Wheat/gluten advisory statements were found on 10.5% of the gluten-free-labeled foods, of which only one food had >20 ppm gluten (3.4% prevalence) (61). Thompson et al. (68) reported wheat advisory statements on 25% of gluten-free-labeled snack bars tested, and all the bars had <20 ppm gluten. There is scarce information on risk associated with foods that do not declare a gluten-containing ingredient, but have an advisory statement for wheat or gluten. Among foods without a gluten-free claim and no gluten-containing ingredients listed, 7.1–37.8% of foods containing wheat/gluten advisory statements had ≥20 ppm gluten (Table 3; 56, 59, 61, 68). The prevalence of >20 ppm gluten in nongluten-free-labeled foods that do not have an advisory statement for wheat or gluten ranged from 4.6 to 26.7% (Table 4; 56, 59, 61, 68, 73). Koerner et al. (56) found a high gluten-associated risk in flours and starches that had an advisory statement, with 37.8% of samples containing >20 ppm gluten as compared with those with no advisory statement (10.1%). Similarly, among foods with wheat/gluten advisory statements, a significant number of products with >20 ppm gluten were reported by Sharma et al. (61) and Thompson et al. (68). Only Verma et al. (59) found >20 ppm gluten in fewer foods with wheat/gluten advisory statements (11.1%), as compared with those without an advisory statement (16.9%).

Limitations and Challenges in Prevalence Estimation

As shown by this review, there is a wide variation in the prevalence of undeclared allergens and gluten in commercial food products from published surveys. This variation makes it difficult to make any firm conclusions of hazard or risk posed by undeclared allergens in food products. Various factors listed below may be responsible for this variability.

Food Group Selection

The results for prevalence may be biased if the number and type of products selected in the food categories do not represent the products' market share. In addition, certain food categories may be chosen by surveys, as they may be perceived as being at high risk for containing undeclared allergens because of a greater potential for cross-contact due to shared equipment or commingling. If more products are selected for testing from high-risk food categories (e.g., chocolate products for milk and hazelnut or oat-based products for gluten), then the

overall prevalence of undeclared allergen could be overestimated. Further, the origin of the selected food within the food category may affect the prevalence of undeclared allergens. Depending on the store where the product was purchased (general or specialty) or the company where the product was produced, biases may be introduced. In terms of the company, larger companies may have the means for more extensive QC procedures or the ability to perform more routine allergen testing. In a study by Ford et al. (17), undeclared allergens (egg, milk, and peanut) represented 5.1% of products originating from small companies and 0.75% of those from large companies.

Geography

A pattern in some of the surveys indicates that geography may play an important role in the prevalence of undeclared allergens in some foods. It is well known that the prevalence of specific food allergy is dependent on the geographical region. For example, peanut allergy is found more in North America and Europe as compared with Israel and Asia, where allergy to sesame and shellfish, respectively, is comparatively more prevalent (75, 76). Allergy prevalence and consumption patterns may guide the survey studies for undeclared allergen in foods. For example, hazelnut is studied more often in the EU due to the higher prevalence of hazelnut allergy. This could bias the frequency of undeclared allergen detection toward the geographical region where more studies for a specific allergen are conducted, whereas studies in other regions may be under-represented for the same allergen. Manufacturing practices and regulations may also vary by geographical region (countries), which further widens the range of prevalence and concentrations of undeclared allergen. In a survey by Vadas and Perelman (39) testing 92 chocolate bars from North America and Europe, none of the 32 chocolate bars manufactured in North America (Canada and the United States) contained peanut, whereas 25 out of the 60 chocolate bars manufactured in Europe were positive for peanut. In a separate study, products surveyed from the United Kingdom, France, Norway, Portugal, and Spain did not contain undeclared peanuts, whereas, in the Czech Republic, the prevalence rate of undeclared peanut was 14% (36).

Awareness of Allergen/Gluten Issues

Awareness of good manufacturing and allergen control practices can help reduce cross-contact with allergens and lead to a lower prevalence of undeclared allergens or gluten in foods. Greater awareness of peanut as an allergen and a potentially serious health hazard may have resulted in better industry controls to prevent peanut cross-contact (12, 18). However, Hirst (18) also noted that a low prevalence may occur in a heterogeneously distributed allergen (such as peanut) compared with a homogeneously distributed allergen (such as milk) possibly due to reduced detection of the former. Multiple surveys show the prevalence of undeclared peanut in various products to be 1% or less (18, 19, 21, 38). Of the eight major allergens, peanut ranked sixth among allergen-related recalls in the United States (6). The understanding of allergen cross-contact and the use of preventive measures have also increased over the years. Many surveys conducted before allergen- or gluten-free-labeling regulations may have different prevalence results than those surveys conducted after the implementation of such regulations. Some of the published survey studies are more than a decade old and may not reflect improvements in manufacturing controls. For example, undeclared gluten prevalence was shown to decrease significantly over the years, possibly due to implementation of gluten-free regulations and better controls by the food industry (52, 53).

ELISA of Choice

Variability between the kits used in the surveys can affect allergen prevalence. One aspect of variability is associated with the antibody used to detect the targeted allergen. For example, an ELISA kit for milk can target β-lactoglobulin or a different milk protein (e.g., casein). If the β-lactoglobulin kit is used to analyze commercial food products with an undeclared milk component, such as casein, the kit may underestimate the milk concentration or yield a false-negative result. In a report by the CFIA on undeclared milk, one chocolate-covered almond product contained 1200 ppm of β-lactoglobulin (equivalent to about 12 000 ppm total milk protein) when the product was tested using a β-lactoglobulin antibody-based ELISA, but only 8.2 ppm casein (equivalent to about 10 ppm total milk protein) when a casein antibody-based kit was used (22). In addition, due to the processed nature of many of these food products, end users may choose kits that may be more effective at detecting processed proteins. For example, the Morinaga egg kit specifically targets chemically denatured ovalbumin, and the Neogen Veratox kit targets heat-processed egg-white protein (77, 78). Some kits may also contain extraction buffers with denaturing and reducing agents, making them more effective at extracting heat-treated proteins, leading to higher levels of quantitation (79, 80). Thus, ELISA methods can greatly differ in the quantitation of an allergen in a specific food. Apart from the analytical variability of the ELISA method, allergen quantitation can also be affected by the nature of allergen distributed in the food. Depending on the sample used for analysis, heterogeneous allergen distribution can result in variable results between lots or within a lot. For example, Hefle et al. (42) found variable peanut concentrations in nutrition bars from different lots. Lot-to-lot variability was also reported by Bedford et al. (12) for milk and peanut concentrations in dark chocolate products.

Conclusions

Undeclared allergens or gluten can occur and lead to product recalls or other potential hazards. Multiple surveys show wide variability in the prevalence of undeclared milk, egg, hazelnut, peanut, soy, or gluten, as detected by ELISA, in commercially available food products. This review also compiled the data on the prevalence of an undeclared allergen or gluten in products with and without an advisory statement. The intended purpose of an advisory statement is to warn allergic consumers of possible undeclared allergens, but when or how it is used is not regulated and may not reflect the presence of allergen levels in the product. Although many survey studies found comparatively higher prevalence of undeclared allergen in

products with an advisory statement, systematic surveys are still needed to establish a more definitive relationship between the use of an advisory statement and the presence or absence of the undeclared allergen. Survey studies appear to identify certain food products with higher prevalence of undeclared allergens and those likely to present allergen hazards (e.g., undeclared milk in dark chocolate products). Increased awareness of the prevalence of undeclared allergen(s) and possible root causes will lead to better preventive and labeling controls. This will in turn lead to safer foods for consumers who have food allergies and/or are gluten intolerant.

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