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## Unintended Consequences of Allergen Food Labeling

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An estimated 6.2% of U.S. adults and 5.8% of U.S. children – more than 20 million people – have food allergies (Ng and Boersma, 2023; Zablotzky, Black, and Akinbami, 2023). For consumers with food allergies, labels indicating the presence of an allergen in a product can reduce information asymmetry and enhance the safety of purchasing decisions (Simons, et. al, 2005). For producers, however, ensuring that food products with and without major allergens are kept separated in production and distribution can be a significant challenge. The costs associated with mislabeling and cross-contamination, driven by costs of recalls and related civil litigation, can be large (Gupta et al., 2017). Indeed, the current most common reason for recalls of food products in the United States is the incorrect labeling of allergens (Gendel and Zhu, 2013).

For the last two decades, U.S. statutes have required that the presence of any of the “big eight” major allergens – milk, eggs, fish, crustacean shellfish, tree nuts, wheat, peanuts, and soybeans – be clearly labeled on the packaging of food products. Recently, new statutes required the inclusion of a ninth major allergen, sesame, first at a state level (2019) and later at the federal level (passed in 2021 and enacted in 2023).

Strikingly, media reports indicated that some food manufacturers began adding sesame to products that previously did not contain the ingredient following the implementation of the new allergen labeling requirements (Aleccia, 2022; Chatman, 2023; Hughes, et al., 2023). Statements from U.S. Food and Drug Administration (FDA) officials also noted the prevalence of such unexpected responses by producers (Califf, 2023). To our knowledge, however, there has not yet been any systematic examination of food manufacturers’ responses to the regulatory change. To address this gap, we use ingredient label data to evaluate the timing and frequency of firm responses, thus illuminating some of the unintended consequences of the change in allergen labeling requirements for sesame.

### U.S. Allergen Labeling Policies

In 2004, the Food Allergen Labeling and Consumer

Protection Act (FALCPA) established federal rules on the labeling of allergens. The Act required that labels on packaged foods containing any of the “big eight” declare the presence of allergens on the package using the allergen’s common name and identify the allergen specifically below the product’s ingredient list. These requirements implied that even the presence of small amounts of an allergen, for example, in a spice mix, would need to be explicitly indicated. In the following years, efforts to include a ninth major allergen – sesame – gained momentum.

An estimated 0.23% of consumers have sesame allergies (Warren, et. al, 2019). Although the group is relatively small, there has been concerted public interest in adding sesame to the major allergen list for some time. For example, in 2014 a consumer advocacy group, Center for Science in the Public Interest, petitioned the FDA requesting that sesame be included as a major allergen (CSPI, 2014). Additionally, other nations, including members of the European Union, have required allergen labeling for sesame for some time (EUR-Lex, 2011).

For its part, the FDA began to compile data and information on sesame allergies and products containing sesame in the United States in 2018 (FDA, 2018), and in 2020, the agency released draft guidance encouraging firms to voluntarily add labels to products indicating the presence of sesame (FDA, 2020).

Legislative interest in adding sesame to the list of allergens with labeling requirements also gained momentum over time. At the state level, Illinois lawmakers in 2019 passed a law (HB2123) requiring sesame allergen labeling for products sold within the state. At the federal level, both the House (HR2117) and the Senate (S3451) passed comparable bills the following year, but neither were signed into law. In 2021, the issue was settled when Congress passed the Food Allergy Safety, Treatment, Education, and Research Act (S.578/FASTER), which established a federal requirement on the labeling of sesame in packaged food products. The legislation mandated that food

manufacturers comply with the new labeling rules by 2023.

## Food Manufacturers and Allergen Labeling

Allergen labeling requirements create new sources of risk for manufacturers. As noted above, incorrect allergen labeling is the most common reason for product recalls, often due to inaccurate information on labels or the use of the wrong packaging during production (Gendel and Zhu, 2013). Recalls can impose many costs on food manufacturers, including product retrieval and disposal, transportation, warehousing, legal expenses, and penalties (Gupta et al., 2017). More broadly, the literature evaluating the consequences of food safety recalls has found that these events can be associated with reduced consumer demand, decreased stock market valuations of affected firms, and diminished brand reputations (for example, Pozo and Schroeder, 2016; Bakhtavoryan, Capps, and Salin, 2014). Additional research is needed to assess whether and to what degree firms facing allergen recalls experience these sorts of costs.

To mitigate the risk of having to recall a product over the presence of an allergen, firms that manufacture products both with and without major allergens can either (1) remove allergens from all products to eliminate the chance of cross-contamination, (2) add allergens and the associated allergen labels to all products, or (3) continue to produce both types of products and take steps to avoid cross-contamination. Previous research has found that employee training, cleaning procedures, and managing cross-contamination were the most important aspects of allergen management efforts for firms (Gupta et al., 2017).

For products at risk of cross-contamination, firms often include precautionary allergen labeling warnings (for example, “may contain [allergen]” or “manufactured in a facility that processes [allergen]”). Such labels are voluntary and have become more common (Allen and Taylor, 2018). However, current FDA guidance underscores that precautionary allergen labeling “should not be used as a substitute for adhering to current good manufacturing practices,” meaning that firms can still be held responsible for cross-contamination that occurs due to inadequate preventative measures (FDA, 2024). Products sold without allergen labels that produce allergic reactions from cross-contamination can lead to both recalls and litigation.

Adding an allergen to a product that did not originally contain the allergen allows firms to fall under the federal allergen labeling regulatory umbrella, rather than relying on a combination of precautionary labeling and “good manufacturing practices” that expose manufacturers to possible risk. The new labeling requirements thus established an incentive for food manufacturers to intentionally *increase* the prevalence of allergens in their products as a strategy for reducing exposure to legal

risk. Indeed, following the 2004 passage of FALCPA, the FDA surveyed representatives from 59 food manufacturing companies about their anticipated reactions to the newly introduced labeling requirements for the original eight major food allergens. The resulting report highlighted that allergen labeling was likely to be used with “increased frequency” to identify products with “intentionally added allergen-containing ingredients” (Taylor et al., 2007).

Such an outcome was observed in a handful of cases after FALCPA’s passage. For example, media reports from 2016 described that Kellogg’s planned to add small amounts of peanut flour to several cracker products that did not previously contain any peanut-based ingredients (Bloom, 2016; Crawford, 2016). However, following the more recent passage of federal sesame allergen labeling requirements, reports of this behavior have proliferated. Several major restaurant chains, including Olive Garden and Chick-fil-A, made headlines after announcing plans to add small amounts of sesame to their products in response to the law (Aleccia, 2022; Chatman, 2023; Hughes, et al., 2023). Although most food sold at restaurants is not subject to FALCPA’s rules for packaged food products, it is possible the restaurants’ suppliers sold the same product through multiple channels, some of which (for example, grocery) would be subject to the new sesame disclosure requirements. The establishment of federal allergen labeling requirements for sesame thus resulted in some manufacturers adding the ingredient to their products.

The purpose of adding sesame to the major food allergen list was to improve consumer safety through labeling. However, the unintentional consequence of this change was the addition of sesame to existing products by some manufacturers. Such an outcome fell outside the intended purpose of the statute to reduce allergen exposure, particularly in cases of products for which sesame is not an integral ingredient (for example, products for which sesame does not contribute to the good’s taste, texture, or appearance).

Reports of manufacturers adding sesame to their products spurred consumer complaints over the practice. The FDA’s Commissioner of Food and Drugs responded with a public statement indicating that

“...we are seeing a number of manufacturers, after the FASTER Act, dedicating their facilities, space within their facilities, or equipment, as sesame-free. ... At the same time, we have become aware of a practice with an outcome we do not support. Some manufacturers are intentionally adding sesame to products that previously did not contain sesame and are labeling the products to indicate its presence. This keeps manufacturers in compliance with our law for disclosing the presence of a major food allergen, but limits options for consumers who are allergic to sesame. ... I don’t think

anyone envisioned there being a decrease in the availability of products that are safe choices for sesame allergic consumers” (Califf, 2023).

To the best of our knowledge, the responses of food manufacturers to the allergen labeling regulation have not yet been systematically analyzed. Here, we examine changes in the presence of sesame in food products’ listed ingredients to investigate how firms responded to the new requirements.

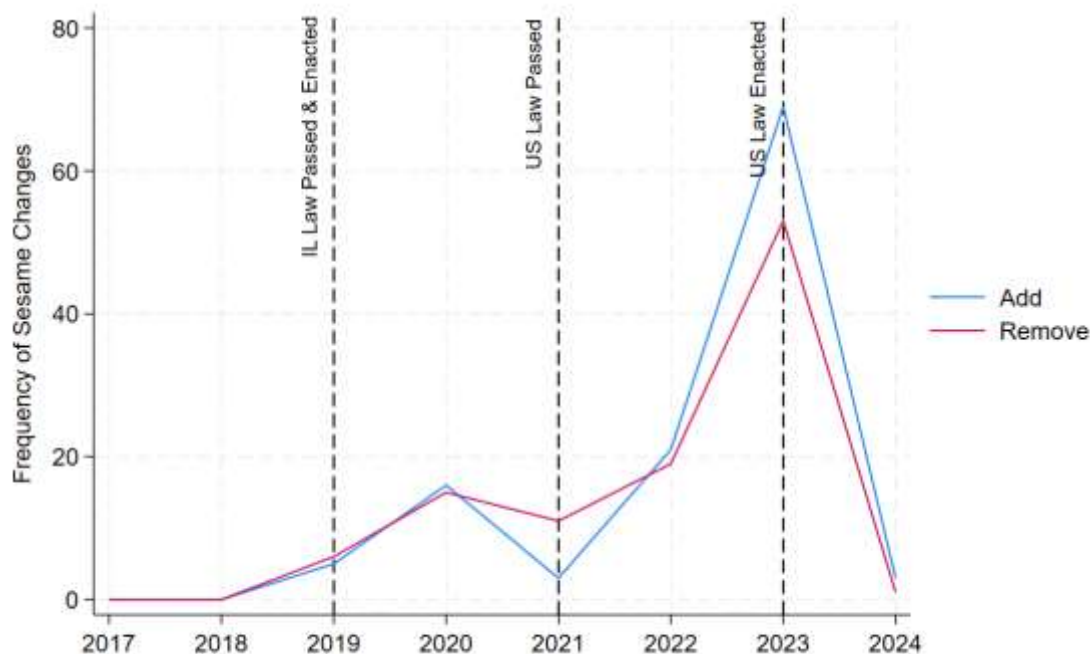
## Data & Methods

To assess firms’ responses to the sesame labeling laws, we use data on ingredients in food products from the U.S. Department of Agriculture (USDA) Global Branded Food Products Database (2024). The database records information on nutrients and ingredients for the near-universe of branded and store-brand food products sold in the United States. The database provides substantial coverage in recording the nutritional information for hundreds of thousands of products, which together account for around 85% of U.S. food and beverage sales (Larrick, Kretser, and McKillop, 2022). The database was launched in 2016 and included over 315 thousand entries by October 2017 (USDA, Version 4.4) and currently extends through October 2024. As FALCPA was passed in 2004, we are not able to utilize the database to evaluate responses to the labeling requirements of the original “big eight” allergens.

Importantly, as firms update food products (for example, add new ingredients) and log changes to their nutritional information or ingredient list, the database connects the product ID (GTIN/UPC ID) with an update ID (FDC ID) and a date associated with the formulation. These data allow researchers to investigate changes in nutritional compositions or ingredients for specific products over time (Larrick, Kretser, and McKillop, 2022).

The database includes over 50 thousand unique products with ingredient lists that include sesame. Here, we limit the data to products sold in the United States that include sesame (either sesame seeds or sesame-derived products such as oil or flour) as an ingredient during at least one of the product’s appearances in the database. Products that did not contain sesame in any iteration were omitted from this analysis. As multiple firms provide data for the database, duplications of updates can occur, and to ensure data quality we limit our analysis to the first logged change if products were updated on the same date. Thus, our dataset is limited to products that contained sesame as an ingredient for part or all of the sample period. We focus primarily on the products that added or removed sesame during the sample period. Previous research has employed similar methods to identify products with relevant ingredients (Ahuja, et al., 2021). In doing so, we are able to analyze the frequency with which firms added sesame to products following the introduction of the new allergen labeling requirements.

**Figure 1: Changes in sesame as an ingredient during period of regulatory change (2017–2024)**



Source: Global Branded Food Products Database.

Note: Data for 2024 reflects changes reported through October 2024.



To supplement this discussion, we also assess how the change in regulation affected the frequency of FDA-initiated product recalls. Recall data is publicly available through the FDA Recall Dashboard, which can be found at <https://datadashboard.fda.gov/ora/cd/recalls.htm>. We restrict the data to analyze sesame-related recalls of food products occurring between January 2012 and September 2024.

## Results

### *Firm Decisions*

First, we find that the vast majority (over 95%) of the products that contained sesame during the sample period contained the ingredient in every iteration. For these products, the law seems to have had no effect.

Notably, however, a number of firms modified their products' ingredients following the regulatory change, either by removing sesame from a product that previously contained the ingredient (one expected response to the law) or adding sesame to a product that was previously sesame-free (an unexpected response to the law). In total, we identify 240 additions of sesame and 182 removals of sesame during the sample timeframe. Importantly, many of these products were major brands or store brands – these changes were thus likely to have had nationwide impacts. Figure 1 shows how these changes evolved across the period of regulatory change. For example, the year the national

law went into effect (2023) accounted for 59% of sesame additions and 50% of the removals. To evaluate changes in product ingredients, at least two versions of a product's ingredient list must be present; consequently, our analysis may underestimate the frequency of changes in early years, particularly 2017.

### *Recalls*

The expansion of allergen labeling to include sesame is also likely to have impacted the frequency of recalls. The FDA recorded 115 sesame-related recalls affecting 55 firms between January 2012 and September 2024.

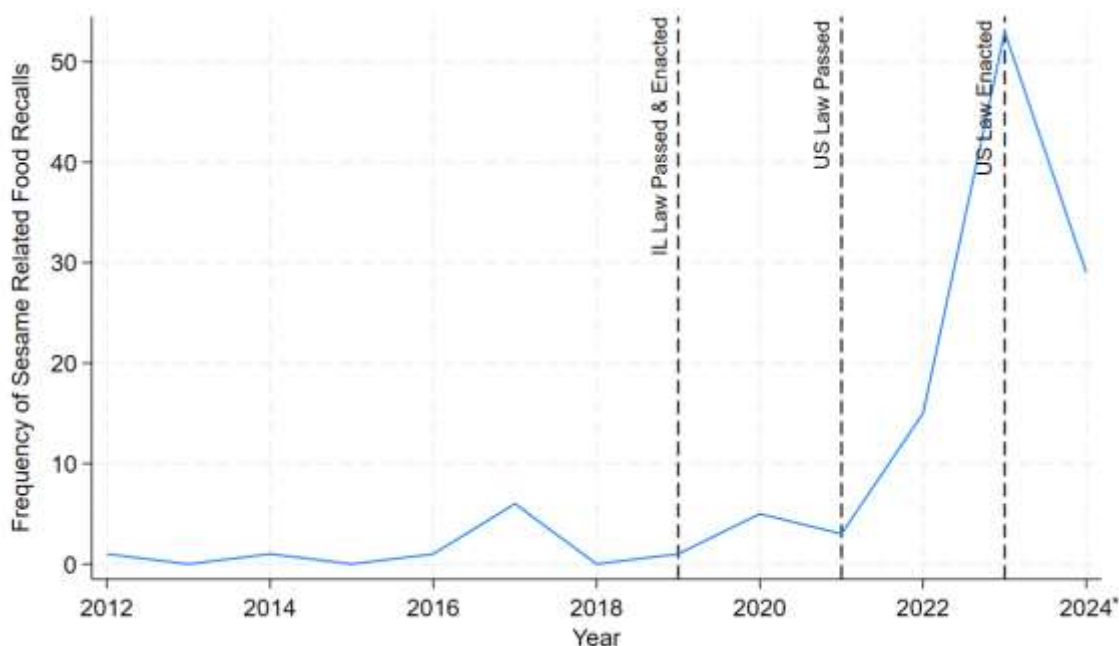
Figure 2 shows the number of recalls by year. As might be expected, the bulk of these recalls (46%) occurred in 2023, when the federal labeling law went into effect. We also see that sesame recalls remained high in 2024.

Similarly, a much larger number of firms were affected by recalls in the wake of the law as 26 firms undertook sesame-related recalls in 2023 and 14 firms conducted recalls in 2024. Some of the recalls in earlier years were for products with some sales in areas with previously existing sesame allergen labeling (for example, Canada).

### *Products*

Using USDA Branded Food categories, we can learn more about what products were likely to be reformulated. Overall, 20 food categories added sesame and 32 categories removed sesame. These categories included

**Figure 2. Number of FDA Sesame Recalls**



Source: [FDA Recall Dashboard](https://datadashboard.fda.gov/ora/cd/recalls.htm)

Note: \*Data for 2024 reflects changes reported through 9/2024.

**Table 1. Proportion of changes in sesame as an ingredient across product types**

Product Type	% of Sesame Additions	% of Sesame Removals	% of Sesame Recalls
<b>Bread/Buns</b>	69%	30%	34%
<b>Baking Mixes</b>	1%	10%	0%
<b>Snacks</b>	8%	17%	16%
<b>Cereal</b>	3%	5%	0%
<b>Soups</b>	3%	6%	0%
<b>Meat/Seafood</b>	1%	8%	7%
<b>Frozen Meals</b>	7%	8%	0%
<b>Condiments</b>	0%	4%	1%
<b>Seasonings</b>	2%	0%	6%
<b>Other</b>	7%	14%	37%

Sources: [Global Branded Food Products Database](#) and [FDA Recall Dashboard](#)

Notes: The first and second columns show results from the USDA Branded Food Database between 2017 and 2024. The third column shows results from the FDA recall data between 2012 and 2024. To discuss product categories for each, we condense USDA Branded Food Database categories into ten groups: Bread/Buns includes Breads & Buns and Bread. Baking Mixes includes Cake, Cookie & Cupcake Mixes; Baking/Cooking Mixes/Supplies; and Bread & Muffin Mixes. Snacks includes Chips, Pretzels & Snacks; Crackers & Biscotti; Snack, Energy & Granola Bars; Popcorn, Peanuts, Seeds & Related Snacks; Cookies & Biscuits; and Other Snacks. Cereal includes Processed Cereal Products and Cereal. Soups includes Prepared Soups; Canned Condensed Soup; Canned Soup; and Chili & Stew. Meat/Seafood includes Frozen Fish & Seafood; Frozen Patties and Burgers, Meat/Poultry/Other Animals Prepared/Processed; Canned Tuna; Other Frozen Meats, Other Meats; and Vegetarian Frozen Meats. Frozen Meals includes Frozen Dinners & Entrees and Frozen Appetizers & Hors D'oeuvres. Condiments includes Salad Dressing & Mayonnaise; Sauces/Spreads/Dips/Condiments; Sauces/Spreads/Dips/Condiments; and Ketchup, Mustard, BBQ & Cheese Sauce. Seasonings includes Seasoning Mixes, Salts, Marinades & Tenderizers. Other includes Pre-Packaged Fruit & Vegetables; Ready-Made Combination Meals; Pasta by Shape & Type; Dips & Salsa; Pizza; Cheese; Prepared Subs & Sandwiches; Other Frozen Desserts; and Energy, Protein & Muscle Recovery Drinks. We categorize recalls using the same ten groups based on the recall's product description. Recalled bagels, pitas, cakes, and rolls are also categorized as Breads/Buns. Recalls corresponding to an ambiguously defined product are categorized as Other.

baked goods (breads, buns, etc.), snacks (crackers, pretzels, etc.), frozen entrees, and others. We summarize these into ten major categories: breads/buns, baking mixes, snacks, cereal, soups, meat/seafood, frozen meals, condiments, seasonings, and other (see Table 1, columns 1 and 2). The breads and buns category was the most affected, accounting for nearly 70% of the additions and 30% of the removals. Cereal was also one of the most commonly reformulated product categories. To compare these results to recall data, we categorize recalls using the product description provided in the recall notice (see Table 1, third column). We find that, in line with the literature, products like breads, buns, and cakes accounted for many of the recalls (Gendel and Zhu, 2013).

Firms that produce both sesame and non-sesame products in a single facility would have the highest cross-contamination risk. Accordingly, some firms may respond to the law by removing sesame from their products to avoid this risk while others may add sesame to products without sesame (including a label) to avoid the risk. Previous research has found that bakery items are the most common products to be subject to allergen recalls, which may also explain the variation in category responses (Gendel and Zhu, 2013).

Products that underwent changes related to sesame generally added or removed sesame oil, flour, or seeds from their ingredient list. Sesame seeds were the most commonly added or removed ingredient, accounting for 66% of additions and 80% of removals. Sesame oil accounted for 13% of additions and 19% of removals, and sesame flour accounted for 20% of additions and 1% of removals. Many of the additions were small quantities of the ingredient. For example, the box below depicts a change in the ingredient label for a large, private label's bread product. As ingredients are ordered according to the amount of the ingredient present in the product, the updated list reflects the firm's decision to add a small quantity of sesame seeds to the product.

Ingredients differ in relation to the difficulty of preventing of cross-contamination. Flour, for example, is particularly difficult to manage. At the time of the law, a representative of Commercial Food Sanitation reflected on this stating, "It's as if we've suddenly asked bakers to go to the beach and remove all the sand" (Aleccia, 2022). Ingredients also differ in the way they affect other aspects of the food product, including taste and visual appeal. For example, a small amount of sesame flour in a bread product is unlikely to affect taste or have a visual impact.

## Box: Example of ingredient changes (emphasis added)

### Original Ingredient List:

Whole wheat flour, water, cellulose fiber and/or sugarcane fiber, yeast, wheat gluten, rolled oats, sugar, salt, monoglycerides, sunflower oil, (calcium propionate, sorbic acid [to retard spoilage]), vinegar.

### Updated Ingredient List:

Whole wheat flour, water, cellulose fiber and/or sugarcane fiber, yeast, wheat gluten, rolled oats, sugar, salt, monoglycerides, sunflower oil, (calcium propionate, sorbic acid [to retard spoilage]), vinegar, **sesame seeds**.

Source: [Global Branded Food Products Database](#)

## Discussion & Conclusions

In this paper we explore the implications of the expansion of allergen labeling laws from the “big eight” allergens to the “big nine.” The inclusion of sesame as a major allergen, first mandated by the state of Illinois and later by the federal government, was undertaken with the intent of providing more detailed information to consumers with sesame allergies. For consumers with sesame allergies, the law had positive, intended impacts of reduced exposure risk through increased labeling and through the removal of sesame from some products. The regulation, however, led to the unintended consequence of reduced choice for consumers with allergies, as some firms reformulated products to add sesame, likely to avoid recall and litigation risk. We use a unique dataset, the USDA Global Branded Food Database, to evaluate changes in product ingredients following the change in regulation at the state, and later federal, levels.

Our results indicate that, first, the vast majority of products already containing sesame as an ingredient were not impacted by the regulation. Most products that contained sesame at some point during the sample period included and labeled the ingredient in every iteration of the product. Second, we document that, following the enactment of the federal law, some food manufacturers engaged in risk mitigation by adding small amounts of sesame to products that previously did not contain the ingredient. Doing so allowed firms to use the safe harbor provided by the allergen labeling rule rather than the ambiguous and non-protective “may contain” precautionary labeling. This was most observed in the breads and buns category, products for which the prevention of cross-contamination may have been more challenging and the likelihood of a recall or litigation higher. Finally, we highlight that recalls for undeclared sesame increased substantially following the federal law.

While our work provides important context for firms, consumers, and policymakers, more research assessing the impact of allergen labeling laws is needed. For consumers with allergies, accurate allergen labeling laws provide important information (Simons, et al., 2005). For firms, undeclared allergens continue to be the most common reason for recalls of food products in the United States, which can be costly (Gendel and Zhu, 2013). Additional analysis would be likely to provide valuable insights towards understanding how firm characteristics inform responses to allergen labeling. For example, firm size is likely related to both actual risk of cross-

contamination and risk preferences, both of which would influence firm decision making. Larger firms are more likely to sell many products than small firms (which can increase risk of cross-contamination), but also may have separate, internally-controlled production lines (which can decrease risk of cross-contamination) (Allen and Taylor, 2018). Larger firms also tend to have greater access to robust legal resources, which may influence perceived risk. Similarly, additional research is needed to understand how firms’ responses may differ across ingredients. For example, it is conceivable that the addition of an allergen to a product would be a less preferred strategy for allergens that are less prone to cross-contamination or if the inclusion would alter other important attributes, such as taste.

While we evaluate responses to sesame’s inclusion in U.S. food allergen labeling requirements, it is worth also noting that required allergen labeling covers a larger number of ingredients in other countries and that regulation in the United States is likely to evolve in the future (Gendel, 2012). Similarly, there is an active debate about the use of precautionary labels, as research has found that consumers with allergies can misinterpret the non-standardized information that they provide (Gupta et al., 2017; Marchisotto, et al., 2017). Besnoff (2014) criticizes precautionary labels as providing poor signals of actual levels of risk and describes that the labels can be an indication of potential risk to the consumer or “a nervous legal department,” advocating instead for the use of adventitious presence limits and stronger prevention mechanisms in production processes. However, some consumers are allergic to very small amounts of allergens and complying with thresholds in food production is often very expensive. For example, previous literature has found threshold requirements related to genetically modified organisms to be very costly (Kalaitzandonakes, Kaufman, and Miller, 2014).

Finally, while the literature has acknowledged the important role of state food regulation (McCabe, 2010; Kalaitzandonakes and Ridley, 2025), it has been understudied to date how firms respond to state versus national regulations. Here, we identify a relatively modest response by firms to Illinois’ state laws on sesame labeling in 2019 and a more concerted response to the federal sesame labeling standard established by the FASTER Act in 2023. Additional research on the role

of federalism in the food system is needed in order to better understand these policy dynamics.



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