

Regulatory Monitoring of Unapproved/Unregulated Foods in the United States

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Abstract Foods from unapproved/unregulated food sources (UFS) pose complex public health challenges, and their contribution to foodborne illness remains insufficiently quantified. We conducted a cross-sectional survey from April 4 to May 5, 2024, that queried food safety regulatory agencies responsible for implementing, monitoring, and overseeing food safety programs. We assessed jurisdictional differences in monitoring practices, enforcement actions, and inspector training across retail and food service operations. The survey yielded 58 responses (22.3% response rate). Among respondents, 72.2% reported oversight of both retail and food service operations. Jurisdictions exhibited substantial variability in allowances for raw milk, along with additional jurisdiction-specific requirements or exemptions. Differences were reported in regulatory monitoring, documentation, training, and enforcement activities related to UFS. State-level allowances for UFS could create gaps in preventive food safety measures and impose additional burdens on regulatory jurisdictions. Additionally, these allowances could create conditions that increase foodborne illness among consumers. UFS entry into intrastate commerce increasingly challenges regulatory jurisdictions, heightens oversight variability, and strains the capacity to protect public health.

Keywords: unapproved/unregulated foods, foodborne illness, FDA model *Food Code*, food safety

Introduction

Unapproved/unregulated food sources (UFS) pose severe and complex public health risks. Outbreaks and clusters linked to UFS can be difficult to detect and investigate—often requiring jurisdictional determination, environmental assessments, identification of additional illnesses not captured through passive surveillance, and removal of implicated foods from commerce. UFS continue to challenge public health systems at the federal, state, and regional/local levels in the U.S.

The introduction of the hazard analysis critical control points (HACCP) process within the U.S. Department of Agriculture's Food Safety and Inspection Service, together with the Food and Drug Administration (FDA) Food Safety Modernization Act (2011), marked substantial progress in strengthening the U.S. food safety system by shifting the paradigm from response to prevention. These risk-mitigation strategies are intended to reduce foodborne illnesses, support regulatory monitoring and enforcement,

provide preventive-based requirements, and support guidance for industry partners (Lytton, 2019).

Recommendations made by the Conference for Food Protection, which are incorporated into the FDA model *Food Code*, include provisions addressing food from UFS in retail and food service operations (FDA, 2015). These restrictions aim to prevent unsafe food items from entering commerce and reduce foodborne illness among consumers. Recently, however, states have enacted laws with allowances for foods with varying risk profiles to be sold, used in permitted facilities, and marketed to consumers, which has created new challenges for oversight and public health protection measures.

Historically, the estimated incidence of foodborne illness associated with UFS has been low in the U.S. due to critical food safety measures (Scallan et al., 2011; Thomas et al., 2013). Food safety inspections are a vital protection layer that regulatory agencies employ to prevent foodborne illness (Barnes et al., 2022). Restrictions on UFS serve as a preventive measure to reduce the risk of contaminated raw ingredients and finished products entering commerce (Griffith, 2005). Food sources, however, represent only one dimension of risk. Even when raw ingredients are obtained from approved sources, the assembly and handling of foods—including temperature control and cooling practices—remain pivotal factors to achieve a safe finished product. Additional determinants include the health and hygiene of food handlers and the sanitary conditions under which foods are prepared, packaged, and held prior to sale.

FDA has identified five critical risk factors for foodborne illness: 1) improper holding

TABLE 1

Examples of Unapproved/Unregulated Foods

Category	Examples
Non-potential hazardous foods	Canned jams/jellies, dried herbs/herb mixes, candy, breads/pastries, popcorn, honey/raw honey, dried fruits, roasted nuts, fruit butters, chocolate-covered snacks, granolas, cereals/trail mixes, vinegar, mustard, dried teas, roasted coffee
Potential hazardous foods	Pickled fruits/vegetables, salsa, fresh eggs, acidified foods (e.g., sauces, hot sauces), canned vegetables, custom meats, raw/unpasteurized milk and dairy products, low-acid canned green beans, meat jerky, dried fish

temperatures, 2) inadequate cooking, 3) contaminated equipment, 4) unsafe sources, and 5) poor personal hygiene (FDA, 2015; World Health Organization, 2006). These high-priority factors are, in principle, closely monitored in permitted facilities through regulatory inspections.

Policy Context and Recent Trends

State laws have expanded allowances for individuals to process and manufacture foods in noncommercial private residences. Although the U.S. food system is robust and multifaceted, pre- and post-COVID-19 supply disruptions affected ingredient availability and consumer confidence. In response to concerns raised by small processors in particular, advocates supported deregulation, which permitted small-scale processing and manufacturing in private residences and noncommercial settings.

Although these policies were intended to address economic hardship and expand market access, these policies also have introduced new burdens for regulatory agencies and consumers. Further research is needed to determine the full impact of permitting UFS in intrastate commerce and identify the effect these laws have on incidence of foodborne illness. Historically, state food codes and related statutes restricted UFS to direct-to-consumer channels and limited permissible products by risk (e.g., pH, water activity). Across the U.S., state legislators have enacted exemptions and amendments that have increasingly allowed UFS of variable risk products to enter intrastate commerce.

Raw Milk as an Illustrative Case

States have separately addressed raw milk and dairy products, adopting varied approaches such as animal-share arrangements, on-farm

sales, and, in some jurisdictions, sales within permitted facilities. A state-level needs assessment reported increased outbreaks associated with raw milk and highlighted resource constraints for state and local agencies that investigate these adverse events (Ablan et al., 2024). These findings underscore the oversight burden from a regulatory perspective. Similar and parallel trends in UFS legislation are now occurring in every state in the U.S., with the purpose of expanding consumer access to a broader array of food products.

Public Health Practice and Consumer Behavior

Household-level food safety practices are strongly influenced by consumer knowledge and behaviors. Identifying modifiable risk factors and implementing policies that reduce those risks among both food service workers and consumers remains a long-term persistent challenge. These food freedom and cottage food laws challenge established, evidence-based policies and safe food practices that were developed to prevent foodborne illness and ensure a safe food supply and wholesomeness of the food. Examples of UFS product allowances vary by state and encompass many categories of foods (Table 1). As state-level laws increase access and deregulate specific food safety preventive measures, the effect these laws will have and potential gaps that will emerge in preventive public health measures have yet to be fully understood.

Regulatory Jurisdiction and the Model Food Code

Regulatory jurisdiction is determined by state law, with some states assigning authority through cooperative or contractual agreements with local governments. FDA recom-

mends that jurisdictions follow the FDA model *Food Code*, which does not permit UFS to be sold or used in permitted facilities. State legislature can modify, revise, or remove specific provisions of the *Food Code* (DeWaal & Dahl, 1997). Many jurisdictions have enacted exemptions or amendments that allow UFS to be sold within intrastate commerce (Farquhar, 2020). In this context, regulatory monitoring and enforcement remain essential to protecting the food supply and public health food safety preventive measures.

The aim of our cross-sectional survey was to understand how regulatory food safety jurisdictions in the U.S. address allowances for UFS and evaluate jurisdictional practices related to UFS, including allowances, monitoring, enforcement, and training. Our study objective was to identify differences across jurisdictions in policies and practices related to UFS and further characterize the regulatory landscape and understanding of UFS in the U.S. food supply.

Methods

Survey Design

The 17-item survey included four sections: 1) respondent demographics and jurisdictional allowances, 2) UFS in permitted facilities, 3) regulatory monitoring and enforcement actions, and 4) field staff training and awareness of foodborne illness. We created and administered the survey instrument in Microsoft Forms. We developed all survey questions to measure and quantify differences in food safety policies and monitoring practices across U.S. jurisdictions. The survey questions addressed UFS allowances under state law: handling, documentation, and disposition of noncompliant foods; types of enforcement actions; training for field operations personnel; and if respondents were aware of suspected or confirmed UFS-related illnesses. All survey items were original to our study, and to our knowledge, this survey is the first to be administered on this topic.

Study Population and Sampling Frame

Eligible participants were state-level contacts who are responsible for implementing and overseeing food safety programs within regulatory agencies across the U.S. We identified prospective participants primarily from state

health and agriculture departments, with the use of the Association of Food and Drug Officials (AFDO) directory database, using filters to identify individuals in implementation of food safety programs and program areas where UFS would be present. We queried the AFDO directory to identify individuals involved in program areas in which UFS could be present (e.g., raw milk, retail food, food service, grocery/retailers, manufactured food, home-based processing).

Tribal jurisdictions were excluded from the sampling frame due to statutes of funding mechanisms across various programs that required tribal jurisdiction to adopt the FDA *Food Code* by reference. Target roles included mid- and upper-level managers, administrators, and program directors with oversight of relevant food safety program areas. Institutional review board (IRB) review was not required, as our study was determined not to constitute human subjects research by the institutional IRB.

Recruitment and Administration

Invitations were sent to 273 individuals whose roles included regulatory oversight and compliance. Individuals in both health and agriculture agencies had relevant personnel, and multiple individuals received invitations to participate. The self-administered web survey was open from April 4 to May 5, 2024. Participation was voluntary and anonymous. We sent email reminders 2 weeks after deployment and 3 days before the survey closed.

Data Management and Analysis

Survey data were collected in Microsoft Forms and exported for analysis. Responses were deidentified prior to coding, with any text that could identify a jurisdiction removed. Closed-ended items used preset response options, while “Other” allowed descriptive text. During coding, free-text “Other” responses were reviewed and consolidated into appropriate categories using a codebook and response matrix. Unless otherwise noted, percentages are calculated from the number of respondents to each item totals and therefore might not sum to the overall sample due to item nonresponse and rounding.

After categorization, descriptive analyses were conducted in SAS 9.4 to examine differences across the four sections. Results were cross-tabulated to determine associa-

TABLE 2

Roles of Regulatory Authorities Who Completed the Survey

Role	#	%
Program division director	1	1.7
Program administrator or chief	15	25.9
Program director or coordinator	26	44.8
Regional manager or program manager and supervisor	8	13.6
Supervisor or specialist	7	12.0

TABLE 3

Allowances of Custom Meat and Poultry, Temperature Control for Safety (TCS), and Low Acid Canned Food (LACF)/Acidified Foods in Both Retail and Food Service Operations (N = 58)

Allowance	Category	#	%
Retail meat and poultry	No	27	46.5
	Yes	6	10.3
	Yes, with CE	13	22.4
	Yes, with restrictions	12	20.7
Food service meat and poultry	No	28	48.3
	Yes	10	17.2
	Yes, with CE	11	18.9
	Yes, with restrictions	9	15.5
Retail TCS	No	51	87.9
	Yes	1	1.7
	Yes, with restrictions	6	10.3
Food service TCS	No	53	92.9
	Yes	1	1.7
	Yes, with restrictions	3	5.3
Retail LACF/acidified foods	No	48	84.2
	Yes	2	3.5
	Yes, with restrictions	7	12.3
Food service LACF/acidified foods	No	51	87.9
	Yes	2	1.8
	Yes, with restrictions	6	10.3

Note. CE = custom exemption for meat and poultry.

tions between retail and food service operations among variables. Descriptive analyses were based on available responses (i.e., complete case analysis), with missing data excluded for calculating item-level and overall response rates.

Results

Sample and Response Rate

Of 273 invitations, 13 emails were undeliverable, yielding 260 eligible survey participants. Respondents were asked to complete the sur-

TABLE 4

Allowance for Raw Milk, Methods for Documenting Unapproved/Unregulated Food Sources (UFS), Types of Enforcement, Training to Identify UFS, and Awareness of Foodborne Illness Associated With UFS (N = 58)

Action	Category	#	%
Allowances for raw milk	Allowed	16	28.8
	Not allowed	21	36.8
	Allowed, with restrictions	20	35.1
Actions for UFS	Actions	52	89.7
	No actions	3	5.2
	Actions, with restrictions	3	5.2
Methods to document UFS	Methods	53	91.4
	No methods	5	8.6
Types of enforcement	Embargo	8	13.8
	Hold/stop-sale order	5	8.6
	Combination of enforcement*	45	77.6
Training to identify UFS	Written training	14	24.6
	Knowledge of the law	37	64.9
	No training	6	10.5
Awareness of illnesses associated with UFS	Aware	25	43.1
	Unaware	33	56.9

* Combination of enforcement included: embargo, hold/stop-sale order, and legal enforcement actions such as injunctions, civil penalties/fines, suspension of operations, criminal proceedings, and destruction of food.

vey only once. In total, 58 individuals completed the survey, for a response rate of 22.3%.

Respondent Characteristics and Program Oversight

Among respondents, 98.3% represented state jurisdictions. Regarding program scope, 16.7% reported oversight of retail food facilities only, 11.1% reported oversight of food service operations only, and 72.2% reported oversight of both retail and food service facilities. Roles varied by state organizational structure, but respondent positions were categorized as shown in Table 2.

Allowances by Operation Type

In retail operations, 65.5% reported that UFS were not allowed to be sold to consumers, 8.6% reported UFS were allowed, and 25.9% reported UFS were allowed with restrictions (Table 3). In food service operations, 84.5% reported UFS were not allowed to be used, 3.5% reported UFS were allowed,

and 12.1% reported UFS were allowed with restrictions (Table 3).

Unapproved/Unregulated Sources in Permitted Facilities

This section of the survey included selected activities governed by state law (e.g., custom-exempt meat and poultry, temperature control for safety [TCS] foods, low-acid/acidified products) (Table 3). Responses indicated variation in the reported allowance of UFS products across retail and food service operations. In retail operations, 46.5% reported bans on the sale of meat and poultry from UFS, while 53.4% reported allowing sales, either full allowances, under custom exemption, or with restrictions. Similar percentages of allowances were reported in food service operations for meat and poultry from UFS. For TCS foods and low-acid canned foods/acidified foods, more respondents reported full bans in retail (87.9% and 84.2%, respectively) and food service operations (92.9% and 87.9%, respectively).

Raw Milk Allowances

Regarding raw milk for human consumption (not distinguished by food service and retail operations in this item), 36.8% reported their jurisdiction does not permit sale, 28.8% reported sale is allowed, and 35.1% reported sale is allowed with restrictions or additional requirements (Table 4).

Enforcement Actions and Documentation

For enforcement actions addressing UFS found out of compliance, 89.7% reported that actions are in place, 5.2% reported actions with restrictions or additional requirements, and 5.2% reported no actions in place. In open-ended responses describing specific actions, 6.9% reported the use of embargo, 8.6% reported hold/stop-sale orders, and 84.5% reported a combination of embargo, hold/stop-sale orders, and legal actions (e.g., injunctions, civil penalties/fines, suspension of operations, criminal proceedings, destruction of food). For documentation of UFS identified during routine monitoring, 91.4% reported established methods for official documentation, and 8.6% reported no methods in place (Table 4).

Training and Foodborne Illness Awareness

With respect to field staff training on UFS, 10.5% reported no training, 64.9% reported training focused on jurisdictional law related to UFS, and 24.6% reported written training materials for field staff. Regarding awareness of illnesses associated with UFS, 43.1% were aware of suspected or confirmed cases, and 56.9% were not aware (Table 4).

Discussion

We assessed how U.S. food safety jurisdictions handle and monitor UFS. Most jurisdictions reported having actions in place to document UFS and to take enforcement steps when products were found out of compliance with jurisdictional law. Allowances varied by jurisdiction and food type, with many jurisdictions reporting additional requirements or exemptions. Compared with food service operations, retail operations had more reported allowances, reflecting the sale of finished, labeled products that enable consumers to make informed choices. Labeling requirements were commonly reported but varied in phrasing and information display across jurisdictions.

Allowances within food service depend on how foods are sourced and used, and sources might not be apparent at the point of preparation. Effective monitoring, therefore, requires inspectors to identify UFS before combining or preparing foods, verify packaging or labels when present, and inquire about suppliers during routine monitoring. The greatest differences across jurisdictions were observed in the “allowed with restrictions” category. Although respondents indicated that specific foods were permitted with additional restrictions, these restrictions could include other statute exemptions, internal guidance, or jurisdictional policy. Allowance with restrictions would be based on state-level statutes that permit historically categorized high-risk food products and meet specific safety requirements that would render the products safe.

Other allowances with restrictions among jurisdictions are grounded in decisions of evidence-based justification and shifts in guidelines that revise earlier assumptions about the safety of specific foods. Identifying these food types in detail, however, was outside the scope of our survey. Many jurisdictions reported training field staff to identify UFS during routine monitoring.

Little research has examined the broader impact of UFS entering the U.S. food supply. Ablan et al. (2024) highlighted the challenges faced by state and local health departments when responding to raw milk-associated outbreaks. Their findings suggest that raw milk can strain public health resources and increase the complexity of investigating and mitigating foodborne illness risks. Although the raw milk example reflects only a small niche category of UFS among a specific consumer base, the broader scope of UFS entering intrastate commerce across multiple jurisdictions extends beyond the highly regulated dairy sector. Findings from our study illustrate that variation across jurisdictions contribute to inconsistent monitoring and

enforcement, underscoring the need for further research to more fully characterize the complex, adaptive nature of the U.S. food safety system as it relates to UFS.

Limitations

Our study had several limitations. The sample size was modest and composed primarily of respondents from state health and agriculture departments. Given the sensitive nature of UFS policy, we anticipated a lower response rate. Responses were anonymous to encourage participation and reduce response bias. Nonetheless, nonresponse and social-desirability biases remain plausible, reflecting the policy’s political origin. Moreover, our survey was conducted at the state level, and depending on the jurisdiction, might not reflect local implementation as it relates to UFS. Expanding the sampling frame to include local and regional program contacts would increase representation and improve understanding of monitoring, documentation, and enforcement during routine inspections.

Future work should examine implementation from the field inspector’s perspective, as inspectors conduct routine monitoring in permitted facilities. Subsequent surveys should prioritize higher response rates among regional and local jurisdictions.

Conclusion

Findings from our survey indicate heterogeneity in allowances, documentation practices, and enforcement activities related to UFS across jurisdictions. Retail settings reported more allowances than food service settings, reflecting product labeling and point-of-sale practices. Overall, the entry of UFS into intrastate commerce presents ongoing oversight challenges for regulatory authorities. Although our survey did not directly link any foodborne illness outcomes, the way that jurisdictions monitor, enforce, and conduct

regulatory activities related to UFS could affect the incidence of foodborne illness.

Importance

Understanding how recent state laws affect regulatory practice is essential to anticipating the impact of UFS on foodborne illness. Passive surveillance will remain an important indicator for detecting UFS-related illness. UFS are limited to intrastate commerce; however, outbreak investigations still face substantial challenges, including source identification, case finding, environmental assessment, laboratory coordination, and removal of implicated products from commerce. These activities vary by state and are influenced by jurisdictional authority and capacity.

Public Health Impact

UFS entry into intrastate commerce presents a clear and growing challenge for regulatory jurisdictions, which must balance established food safety protections with state laws that expand allowances and could weaken food safety safeguards. Our findings underscore that much remains unknown about the overall impact of these laws on the incidence of foodborne illness, particularly from the perspective of regulatory food safety agency oversight. Without commensurate monitoring, labeling, and enforcement, preventive measures across food safety jurisdictions could erode, leading to an increased likelihood of adverse health outcomes and an increase in the incidence of foodborne illness across the U.S. 🌸

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