



November 19, 2021

Dockets Management Staff (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

RE: Docket ID: FDA-2021-N-0929

Submitted via: <https://www.regulations.gov>

Dear Sir or Madam:

IFT, founded in 1939, is a non-profit, scientific individual member institute whose mission is to connect global food system communities to promote and advance the science of food and its applications. IFT has more than 12,000 individual food scientist members from across industry, academia, government, and non-profit organizations. Organized around the core values of community, integrity, passion, progress, respect, and inclusion, IFT's members and staff are focused on overcoming barriers to feed our future safely by developing scientifically sound solutions.

IFT appreciates the opportunity to comment on possible food safety risks related to foods sold through Business to Consumer (B2C) e-commerce and discuss what additional courses of action may be necessary to address any food safety vulnerabilities. We commend efforts to further enhance and clarify requirements for safe, transparent e-commerce.

As with IFT's previous foundational piloting work to support FSMA and enhance food safety, IFT recognizes a suite of stepwise needs to achieve the FDA's articulated goals of understanding B2C e-commerce's possible food safety risks and needed additional action. These include: 1) **classification of sub-types of similar B2C entities** (e.g., restaurant delivery, online grocery, meal kits); 2) **supply chain mapping** to describe how product moves and who handles the product in each type of the various B2C e-commerce, 3) modifying current outbreak investigation and reporting to enable **risk quantification** associated with B2C e-commerce supply chains, and 4) then developing a **risk ranking model** to support any additional action. Following this stepwise approach will clarify **food safety risks** and what may be warranted to address them.

Thank you for considering our comment on this important activity. If IFT may provide further assistance, please contact Bryan Hitchcock, Executive Director, GFTC, (bhitchcock@ift.org; 312-604-0225).

Sincerely,

A grey rectangular box containing a handwritten signature in cursive script that reads 'Bryan W. Hitchcock'.

Bryan Hitchcock



Vice President Science, Policy and Learning and Executive Director Global Food Traceability Center

Four Stepwise Recommendations

1. **Classify sub-types of B2C e-commerce** by structural attributes to support additional risk assessment (e.g., meal kits, app-based restaurant delivery, online grocery, specialty food delivery)
2. Map **supply chains of several of each sub-type** to explicitly identify how product moves and who handles the product in each of the various B2C e-commerce supply chains from business to end consumer.
3. Modify current outbreak investigation and reporting to enable **risk quantification** associated with B2C e-commerce supply chains.
4. Develop a **risk ranking model** to support any additional action.

Four Findings

1. **The sector merits additional attention.** The sector has grown to represent a significant, stable, and growing segment of our food system, particularly restaurant delivery and online grocery, followed by meal kits and perishable specialty food boxes.
2. **Temperature abuse is the chief concern.** Within the sector, temperature abuse between the food business and end consumer is the most significant risk. Meal kits and perishable boxes may be exposed to non-refrigerated conditions ranging from -80 to 160 °F for up to 60 hours or more. This is reflected in research that shows product temperatures in the danger zone (>40°F) upon receipt or unboxing by the consumer are particularly widespread in the meal kit and meat/seafood box categories.
 - a. Consumers' perceptions, consumer education, and company policies do not reflect this risk.
 - b. Packaging is the primary standard of care used to mitigate this risk in those two categories (meal kits and perishable food boxes), though (see #2 above) it does not seem to be sufficient.
 - c. Restaurant delivery and online grocery typically rely on time to minimize temperature abuse risk. Current industry objectives range from 40 minutes to 2 hours, though these are not requirements, and they may or may not be sufficient depending on outdoor temperatures.
3. **Foodborne illness data capture and reporting needs to include B2C e-commerce.** Understanding the risk posed by these categories is not possible through the current foodborne illness tracking dashboard, NORS, which does not include these categories under settings. For example, multiple types of restaurants are included under 'Setting' but not 'restaurant delivery'. ***Adding these growing categories would improve understanding of the risk they pose and aid in guiding any future risk-based regulatory action.***
4. **Existing regulations need to be extended** to include B2C e-commerce.
 - a. **Labeling.** Existing regulations for labeling are appropriate for B2C e-commerce, However, since the point of sale is online, critical label information should be provided to consumers



at the point of purchase as well as on package, consistent with The Federal Food, Drug, and Cosmetic Act (FD&C Act) and the Fair Packaging and Labeling Act, and the Nutrition Labeling and Education Act. The FDA should update guidance for industry to clarify requirements in the context of online transactions, which are currently absent from existing guidance published in 2013.

- b. **FSMA for business registration.** FSMA also provides sufficient framework for registering food business establishments, however the exemption for retailers does not make sense in the context of B2C e-commerce, where actors, like meal kits, frequently act more like a processor or manufacturer within their facilities. Including these businesses within the existing registry would aid transparency and management of this sector.

Categories, Prominence, and Relevance of B2C e-Commerce

B2C food e-commerce was a fast-growing segment of food sales in the US prior to the beginning of the pandemic. Boosted further by the pandemic, the segment includes several subsegments characterized by different scales, growth rates, and risk factors. The primary sub-segments include online grocery (\$96B in sales in 2020)¹, meal kits (\$6.9B in 2021)², restaurant delivery (\$220B expected in 2020)³, and specialty food boxes (e.g., produce boxes or meat/poultry/seafood boxes⁴). While it is true that food delivery and some of these sub-segments have been around for much of the last decade, it is only in the last 2 years that they began to account for a significant portion of food sales. In 2020, online grocery grew by 54%, meal kits by 70%, and restaurant delivery grew more than 300%, well faster than the 8% that subsector had been maintaining over the last 5 years. While vaccine rollouts and re-openings have cooled growth expectation for 2021 to 5%, 18%, and 8% respectively, all are expected to retain and continue expanding the market share that they so rapidly attained during the pandemic. These statistics and trends affirm the importance and relevance of the B2C e-commerce sector within the American food system.

Across these categories, restaurant delivery and online grocery are both the largest and represent a smaller departure in structure from their brick-and-mortar versions than some other models, like meal kits or meat boxes. While B2C e-commerce may mean consumers are now purchasing these goods online, the delivery distance from restaurant or grocer to consumer is typically relatively short, ranging from the consumer picking up the goods themselves curbside to local delivery by bike, van, or car feasibly within an hour or two. Restaurant delivery, the oldest and largest segment, has achieved the

¹ eMarketer. 2021. In 2021, online grocery sales will surpass \$100 billion. Available from: <https://www.emarketer.com/content/2021-online-grocery-sales-will-surpass-100-billion>

² Moran and Wells. 2021. Meal kit sales growth will sharply decelerate this year, report predicts. Available from: <https://www.grocerydive.com/news/meal-kit-sales-will-sharply-decelerate-this-year-report-predicts/602620/>

³ Littman. 2019. Why the delivery market will look different in 5 years. Available from: <https://www.restaurantdive.com/news/why-the-delivery-market-will-look-different-in-5-years/546936/>

⁴ Hallman, Senger-Mersich, Godwin. 2015. Online Purveyors of Raw Meat, Poultry, and Seafood Products: Delivery Policies and Available Consumer Food Safety Information. *Food Protection Trends* Available from: [link](#).



greatest degree of market penetration and analysts estimated it would account for 40% of restaurant sales in 2019, prior to the emergence of the pandemic³. Platform-to-consumer (app-based) restaurant delivery is a smaller subsegment, estimated at ~\$13B, with estimates varying across sources. Online grocery is the next largest segment, albeit with more modest market penetration estimated at 7.4% of grocery sales with ~\$112B in sales in 2021, growing to more than 10% of grocery sales at \$188B by 2024¹. Additionally, while most consumers are still grocery shopping both in-person and online, analysts expect more than half of the US population will buy at least some of their groceries online¹. These two (online grocery and restaurant delivery) subsegments' scales and expected on-going growth necessitate closer evaluation of the structure, risk factors, and risk mitigation necessary to protect the nearly half of Americans expected to access their food from these channels from foodborne illness.

Meal kits, a category that emerged in the early 2010s, has matured, experienced significant consolidation, with a single company, Hello Fresh, now accounting for 42% of sales. While there is an array of meal kit types, ranging from packages of uncooked raw ingredients ordered online and delivered to customers homes (e.g., Hello Fresh, Blue Apron, etc.) to fully cooked ready to heat and eat meals (e.g., Freshly), to prepped, uncooked refrigerated kits available in traditional brick-and-mortar retail; the first type accounts for most of the sub-segment's sales of ~\$7B. This segment is also most similar in structure and risk factors to the meat/poultry/seafood boxes assessed by Hallman et al. (2015)⁴. In contrast to the restaurant and grocery B2C e-commerce category addressed above, this prevailing meal kit model as well as the meat/poultry/seafood boxes described by Hallman et al. (2015) typically spend up to 2 days in unrefrigerated transit environments ranging from -80°F to 160°F managed by third parties such as UPS, FedEx, local carriers, and/or the USPS between the facility where the goods were packed and the ultimate consumer. Even after delivery to the end consumer, these boxes may sit outside on a porch, sidewalk, or unrefrigerated mailroom for 12 hours or more. Thus, these sub-segments are characterized by some greater structural challenges to standard FDA time and temperature guidance⁵ than the other two sub-segments where distance from store or restaurant to consumer is closer to a mile or a few miles as opposed to thousand(s) of miles as may be the case with meal kits, meat, and perishable produce boxes.

Safety risks associated with foods sold through B2C e-commerce and the standards of care used by industry to control these safety risks

Foods sold through B2C e-commerce include everything from raw, highly perishable raw meats, poultry, seafood to perishable prepared foods, to complex multi-ingredient shelf stable items. These foods are vulnerable to the same pathogen contamination, temperature abuse, and mis-labeling risks that impact more traditional retail and food service channels. However, these new channels present new cold chain challenges that typically occur outside of the direct custody of either the e-commerce business or their

⁵ FDA. [Safe Food Handling](#). "Refrigerate meat, poultry, eggs, seafood and other perishables below 40°F within 2 hours of purchasing. Refrigerate within 1 hour if the temperature outside is above 90°F."



customer. The custodian varies between segment categories but can be a national carrier like FedEx UPS or the USPS in the case of meal kits or produce/protein boxes, or a local delivery contractor like DoorDash, UberEats, Grubhub or Instacart in the case of restaurant and/or grocery delivery (Hallman et al. 2015; Mickanuck 2020; Ahuja et al. 2021). Lack of cold chain challenges both categories, but the duration of that lack of cold chain and how extreme the unrefrigerated temperatures may differ. Meal kits and protein/produce boxes are subject to both longer durations of temperature abuse (up to 60 hours in some cases) as well as more extreme ambient temperatures (-80°F to 160°F). This poses significant challenges to maintaining product safety and quality. Industry uses packaging to mitigate these risks, but consumer concerns about the type and quantity of packaging associated with these products presents a competing challenge, inspiring industry efforts to reduce packaging to retain customers (McGoff 2021). McGoff (2021) estimates that packaging for meal kit shipping constitutes two thirds of meal kits' shipping weight.

Despite industry's adoption of substantial packaging to maintain perishable product quality and safety recent evidence indicates it still may not be sufficient, even in higher latitude locales with presumably less challenging ambient temperatures. Research on both meat/seafood boxes (Hallman et al. 2015) and meal kits (Mickanuck 2020) which found that 47% and 76% of the surface temperatures of high-risk items such as meat, poultry, seafood, and leafy greens exceeded 40°F or 4°C. For the meal kits, this was true even after just 8 hours, less than the 12-hour delivery window typical for these deliveries (Mickanuck 2020). Despite the prevalence of apparent temperature abuse in this category, few companies (n=500+) in either study (n=3) provided any information "recommending that the temperatures of high-risk food products should be received at temperatures below 4°C or recommend visually inspecting the food products upon receipt." Additionally, no companies or even general consumer education campaigns (e.g., Partnership for Food Safety Education) recommend disposing of high-risk food products if their temperature was >40°F/4°C prior to receipt/refrigeration by the consumer because of the increased risk of foodborne illness due to microbial growth enabled by temperature abuse.

Online grocery and restaurant delivery also struggle with maintaining product safety and quality between store, restaurant, or prep and pack facility and the consumer. However, their primary management approach centers around minimizing the duration of this time of temperature abuse. The recent McKinsey & Co. (2021) report indicates restaurants strive to keep the delivery period under 40 minutes, which would be consistent with FDA recommendations, however there is no visibility to compliance for consumers beyond the time that has elapsed between placing and receiving their order, nor is this an enforceable threshold. This is a similar challenge for online grocery services like Instacart, where recent changes cause Instacart shoppers to have to collect and then deliver multiple orders, potentially extending the amount of time product is outside of refrigeration (Schweizer 2021). Standardizing delivery time expectations to be consistent with existing FDA guidance (e.g., less than 2 hours if <90 °F or < 1 hour if > 90°F) is an appropriate standard of care for the restaurant and online grocery categories that operate without supplementary product packaging.



Given the prominence and market penetration of B2C e-commerce, segment actors have been implicated in several recent foodborne illness outbreaks, including both recent onion-linked *Salmonella* (references 18 to 21) and online grocery retailers some of the salad-linked *Salmonella* and *Listeria* outbreaks in 2021. With 17 to 36 possible multistate foodborne illness outbreaks each week (CDC 2021), and the increasing scale of B2B e-commerce, they are increasingly implicated as actors in these recalls. Ensuring the industry's standards of care are appropriate, sufficient, and consistently adopted across all actors will be critical to protecting consumers' health as they increasingly access food through these channels.

Regulatory approaches to food sold through B2C e-commerce

Existing regulations for the registration of food businesses (FSMA, rule finalized in 2020) explicitly exclude e-commerce businesses, grouping them in with brick-and-mortar retailers.

Exemption of 'retail food establishments' under the FSMA Food Facility Registration Final Rule, p. 14:

"At other such direct-to-consumer sales platforms, including door-to-door sales; mail, catalog and Internet order, including online farmers markets and online grocery delivery; religious or other organization bazaars; and State and local fairs."

Given the range of actors within the category, that may be appropriate for some, but not all actors in the category. Meal kit businesses, specialty perishable food box sellers, and some models of online grocery delivery have facilities and operations that also include packing, processing, or manufacturing to different degrees. For example, meal kit fulfillment centers portion perishable sauces from 5-gallon buckets and 50-gallon drums using piston fillers and cup fillers into individual packages that are then bundled with other perishable, refrigerated items prior to shipment to consumers. They also fabricate produce items into recipe portions, either by weighing and bagging whole produce items such as brussels sprouts or mini sweet peppers, or by breaking down larger items like heads of cabbage. These activities involve more handling and processing than traditional brick-and-mortar grocery. Given their greater similarity to manufacturing facilities, it may be important to manage them through that registry. FDA should review the appropriateness of this exemption for each of the 4 sub-types of e-commerce.

Labeling of foods sold through B2C e-commerce

Point of sale labeling requirements for food are clearly articulated in The Federal Food, Drug, and Cosmetic Act (FD&C Act) and the Fair Packaging and Labeling Act, and the Nutrition Labeling and Education Act. However, existing guidance is developed for sales that take place with physical packaged in stores. Given that the intent of the regulations is to provide critical product content (nutrition, allergens, ingredients, quantity) at the point of sale, guidance should be updated to clarify the responsibility of online B2C businesses to offer that information at the point of sale, as well as on the physical food products they ultimately deliver or have delivered to their customers.



Summary and Conclusions

B2C e-commerce is a diverse, significant, and growing segment of our food system. IFT recommends four key steps to improve understanding and management of food safety risks that may exist within the category. Those steps include:

1. **Classify sub-types of B2C e-commerce** by structural attributes to support additional risk assessment (e.g., meal kits, app-based restaurant delivery, online grocery, specialty food delivery)
2. Map **supply chains of several of each sub-type** to explicitly identify how product moves and who handles the product in each of the various B2C e-commerce supply chains from business to end consumer.
3. Modify current outbreak investigation and reporting to enable **risk quantification** associated with B2C e-commerce supply chains.
4. Develop a **risk ranking model** to support any additional action.

In addition to unique structural risks that may characterize B2C e-commerce supply chains, IFT recognizes that these retailers have a unique set of challenges that diverge in important ways from conventional food retailers. IFT encourages the FDA to work with neutral technical service providers to convene key stakeholders, understand their educational needs, and support development of educational materials that recognize and speak to these differences and needs. IFT believes this will be critical to mitigating food safety risks in this sector.

IFT looks forward to improving e-commerce food safety and stands ready to partner with the FDA and private enterprise in quantifying possible food safety risks and supporting efforts to design and implement methods to mitigate them. Just as in any other channel, e-commerce consumers are counting on us to provide them with great tasting, nutritious, and most importantly, safe food. Thank you for considering our comment on this important initiative.

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