Background Document for
FDA New Era of Smarter Food Safety Summit on E-Commerce:
Public Meeting and Request for Comments

The FDA New Era of Smarter Food Safety Summit on E-Commerce: Ensuring the Safety of Foods Ordered Online and Delivered Directly to Consumers ("Summit") will take place virtually October 19-21, 2021. In conjunction with the Summit, FDA has opened a docket for comments on this topic. The summit and docket are designed to help the agency improve its understanding of how human and animal foods are sold through Business to Consumer (or B2C for short) e-commerce models across the U.S. and globally. This background document is intended to focus our stakeholders on the questions on which FDA is seeking additional information and data.

Background

In July 2020, FDA released the New Era of Smarter Food Safety Blueprint (Blueprint), outlining a new approach to food safety that leverages technology and other tools to create a safer, more digital, traceable, food system. The Blueprint contains Four Core Elements that outline our efforts to ensure the safety and security of the food supply through simpler, more effective, and modern approaches and processes.

Core Element 3 of the Blueprint -- New Business Models and Retail Modernization -- looks to address how to protect foods from contamination as new business models emerge and change to meet the needs of the modern consumer. One area of focus within Core Element 3 is human and animal foods sold through Business to Consumer e-commerce. B2C e-commerce is the manufacturing, packaging, labeling, storage, and delivery of human and animal foods sold directly to consumers, through commercial transactions conducted electronically on the internet.

The Coronavirus Disease 2019 (COVID-19) pandemic and changes in consumer shopping behavior accelerated the transition to B2C e-commerce. Before the pandemic, online grocery shopping[1] was already growing. In 2019, the U.S. spent $62.2 billion on online grocery sales. In 2020, online grocery sales grew 54 percent, reaching $95.8 billion and accounting for 7.4 percent of all grocery sales. Online grocery sales are expected to make up 11.2 percent of all U.S. grocery sales in 2023.[2] This may reflect consumer behavior for the long-term, making both the safety and labeling of these foods important priorities. On the latter point, consumers need sufficient information (e.g., nutrition information, allergen information, ingredient information) at point of purchase to make informed decisions about the food they are purchasing.

The use of B2C e-commerce is expanding within the produce, manufacturing, and retail food industries (e.g., produce and meal kit subscription and delivery services, ghost kitchens[3], dark stores[4]). Some human and animal food producers and manufacturers are shifting from a traditional business-to-business model, to a B2C e-commerce model. These B2C e-commerce businesses historically shipped food products directly to consumers using postal and parcel delivery services but are now incorporating other third-party models such as third-party delivery service companies that transport food to customers. Third-party delivery service companies primarily conduct business through e-commerce, and many are "digitally native brands" (i.e.,

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[1] For the purposes of this document, the term "online grocery" refers to foods ordered through grocery (e.g., supermarket) websites, directly from the grocery manufacturers' websites and from third-party online grocery providers. It does not include restaurant type, ready-to-eat meals that are ordered online for pick-up or delivery.
[2] Marketer Editors. "In 2021, Online Grocery Sales Will Surpass $100 Billion" Insider Intelligence. February 24, 2021. Available at: https://www.emarketer.com/content/2021-online-grocery-sales-will-surpass-100-billion.
[3] Ghost kitchens, also referred to as dark kitchens, blackbox kitchens, cloud kitchens and virtual kitchens, are food production spaces that do not have a storefront or a dining area and are used mainly for delivery and/or catering. JDSupra. "The Rise in Ghost Kitchens," August 28, 2020. Available at: https://www.jdsupra.com/legalnews/the-rise-in-ghost-kitchens-95397/.
[4] Dark stores are traditional retail stores that have been converted to local fulfillment centers to fulfill delivery and pickup orders Morgan, Blake. "Dark Stores are the Future of Post-Pandemic Retail," April 25, 2020. Available at: https://www.forbes.com/sites/blakemorgan/2020/04/25/dark-stores-are-the-future-of-post-pandemic-retail/.

companies that operate primarily online with online sales making up most or all of their sales).[5] These third-party delivery service companies provide ordering, selection (such as by a grocery delivery service), and/or food delivery services. Also, some retail food companies are using technology to explore and pioneer new delivery modes (e.g., drones, parachutes, robots).

We note that B2C e-commerce is growing in the animal food market, where pet companies and online private brands are selling their pet food products directly to the end-consumer through online platforms.[6] In addition, some retail food establishments, such as grocery stores, may sell both human and pet food online and use third-party delivery services to deliver that food to consumers. Digitally native brands of pet food are on the rise and operate primarily online, with some specializing in niche pet food, pet treats and made-to-order diets. Not all pet foods are shelf-stable, and many customers are opting for fresh or frozen pet foods, which adds more complexity to the safe transportation and delivery of these products. We also note that animal food has a different regulatory framework than human food. For example, the model FDA Food Code does not apply to animal food, and there is not a similar federal animal food model code for state or local regulation of retail animal food establishments.

This shifting landscape requires a wholistic look at these emerging business models. The Summit and docket are intended to solicit ways to address the food safety risks associated with the manufacturing, packaging, labeling, storage, and delivery of human and animal foods sold directly to consumers through e-commerce.

Meeting Overview

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[5] Hollingsworth LLC. 50+ Digitally Native Companies. October 2019. Available at: https://www.hollingsworthllc.com/50-digitally-native-companies/.

[6] Phillips-Donaldson, D. "Pet food e-commerce 'on steroids' in 2020 and beyond" Pet food Industry. December 2020. Available at: https://www.petfoodindustry.com/blogs/7-adventures-in-pet-food/post/9838-pet-food-e-commerce-on-steroids-in-2020-and-beyond

This 3-day virtual Summit is an opportunity for us to further our collaboration with federal, state, and local regulatory partners, and a broad array of stakeholders, including industry, consumers, consumer and public health organizations, and academia, to identify what, if any, actions may be necessary to address potential food safety vulnerabilities. When announcing the Summit, in the *Federal Register*, we opened a docket where stakeholders can submit written comments on the specific topics outlined below, and provide additional data and other information on topics raised during the Summit.

On Day 1, representatives from industry engaged in B2C e-commerce will discuss the procedures and the standards of care that they use to ensure the safety of human and animal food from production, harvest, or manufacture, through delivery to consumers. The panels on Day 1 will also feature representatives from academia and consumer organizations to discuss their perspectives on the safety of foods sold through B2C e-commerce.

On Day 2, regulators from federal, state, and local governments will discuss regulatory frameworks, provide an overview of regulatory oversight and challenges, and discuss opportunities to help strengthen the safety of foods sold through B2C e-commerce.

On Day 3, foreign regulators from around the world will discuss international approaches to the regulation of foods sold through B2C e-commerce.

Each day, there will also be an opportunity for registered participants to ask questions and engage with these experts, as well as to offer open public comment for those who select this option when registering (see III Participating in the Public Meeting). Questions can also be submitted for the panels prior to the Summit. For more information, including the agenda, visit the FDA New Era of Smarter Food Safety Summit on E-Commerce Event Page.

Topics of Interest

During the Summit, experts from FDA, industry, academia, consumer and public health organizations, and domestic and foreign governments will be asked to address a variety of topics. While we seek to have a broad array of perspectives on the panels, we are interested receiving additional comments during the Summit, as well as through the associated docket, from other stakeholders on these issues. We will use the information provided as we consider what, if any, actions may be necessary to ensure the safety of human and animal foods sold through B2C e-commerce. The following are subjects of interest to FDA and questions on which we request stakeholder data and other information as we proceed in this area:

- Types of B2C E-commerce Models
    - What models other than the existing B2C e-commerce models for human and animal food (e.g., on-line ordering, produce and meal kit subscription services, ghost kitchens, dark stores) currently exist or are being developed?
- Food Safety Risks
    - Are there unique chemical (including allergen), physical, and/or microbiological that relate to the manufacturing, packaging, labeling, storage, and delivery of human foods sold through B2C e-commerce models? We are particularly interested in the "last mile" of B2C e-commerce to its final destination.
    - What, if any, are the unique food safety risks associated with emerging autonomous food delivery models (e.g., drones, parachutes, robots)?
    - Are there food safety risks unique to animal food sold through B2C e-commerce compared to animal food sold business to business or in traditional retail settings?
- Standards of Care

  - What additional practices or standards of care, beyond those used for food sold in traditional manufacturing and retail operations, are being used by industry for human foods sold through B2C e-commerce to manage food safety risks? We are particularly interested in how those risks are managed during the "last mile" of delivery to its final destination using third-party delivery services and autonomous delivery models.
  - What technologies are available to help control the food safety risks of human and animal food sold through B2C e-commerce, particularly during delivery?

- Regulatory Framework
  - Are there unique food safety issues associated with human and animal food sold through B2C e-commerce that require a different regulatory approach than food sold business-to-business or in traditional retail settings?
  - What regulatory and compliance gaps and challenges exist with respect to the current federal, state, local, territorial, and tribal (SLTT) regulatory structure for B2C e-commerce businesses that sell human food? What regulatory approaches have been effective and are there lessons learned you can share?
  - What additional actions (e.g., training, outreach, guidance, or revisions to the FDA Food Code), if any, could FDA and its SLTT partners undertake to help ensure the safety of human and animal food sold through B2C e-commerce?

- Labeling for Online Grocery Shopping Platforms
  - What labeling information is being presented to consumers in online grocery shopping platforms, such as websites and mobile applications?

- How is labeling information presented on these platforms (e.g., on the same page as the product, using web links)? When provided, is the nutrition information and other labeling information (e.g., allergen and ingredient labeling) legible and consistent with the label on the actual product?
- What challenges, limitations, or advantages do online grocery retailers, manufacturers and third-party online grocery providers encounter when displaying labeling information online?
- What labeling information is important for consumers to have access to when using the online grocery shopping platforms (e.g., nutrition facts label, ingredient declaration, allergen information, food safety information)?