



Nov 19, 2021

Dockets Management Staff (HFA-305)
Food and Drug Administration
5630 Fishers Lane
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Re: Food and Drug Administration New Era of Smarter Food Safety Summit on E-Commerce; Public Meeting; Request for Comments (Sept. 7, 2021), Docket No. FDA-2021-N-0929

FMI- The Food Industry Association (FMI) appreciates the opportunity to provide comments to the Food and Drug Administration (FDA) regarding the summit on e-commerce in the food industry. As the food industry association, FMI works with and on behalf of the entire industry to advance a safer, healthier and more efficient consumer food supply chain. FMI brings together a wide range of members across the value chain — from retailers that sell to consumers, to producers that supply food and other products, as well as the wide variety of companies providing critical services — to amplify the collective work of the industry. www.FMI.org.

FMI strongly supports food safety compliance and sharing of best practices to provide consumers with safe and wholesome products and to protect public health. FMI members openly share food safety information to assist the entire industry with their food safety management programs.

Food delivery has a long history of meeting consumer needs

Food delivery is not a new concept. Many different food delivery models have been in existence for decades including pizza delivery, milk delivery and even delivery of frozen products directly to consumers at home. Consumer expectations and consumer satisfaction is at the root of e-commerce business models. Innovation and changing business practices are driven by the market and are necessary to retain customers in today's competitive environment. Companies work to meet the needs of their

customers and to ensure they receive food that is not only of the highest quality but is safe for families to consume and enjoy.

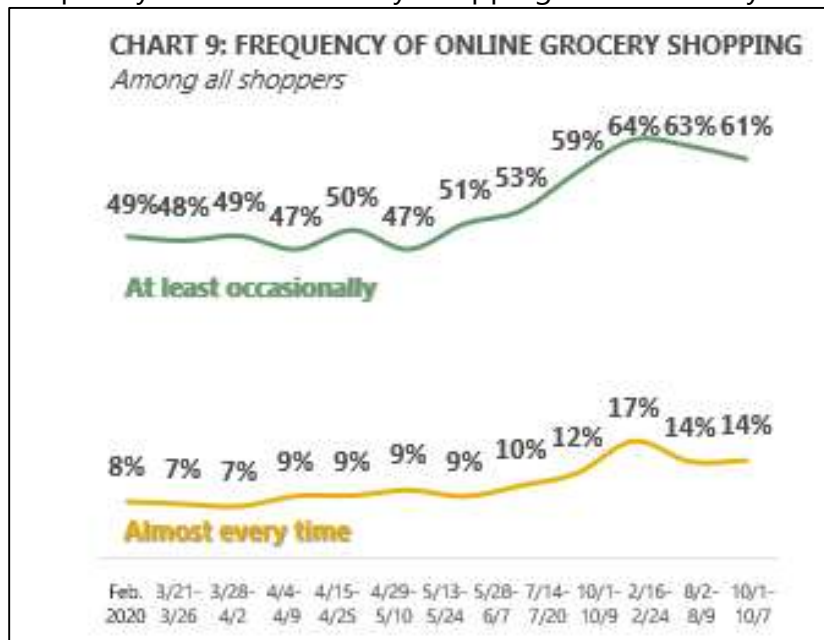
Business models are flexible, innovative and will continue to change

Business models will continue to evolve as technology advances and consumer expectations and preferences change. E-commerce models vary in many ways including, the types of facilities; operational processes (e.g., preparing, storing, sorting and staging); and how food products get to consumers (e.g., car, truck, bike, drone, mail, etc.). The introduction of new business models and the use of technology has enabled novel ways for retailers to engage consumers and provide them with flexibility in how they shop. For example, the rise of e-commerce has helped improve access to healthy and more affordable food options for many families living in food deserts and for individuals with a disability or lack of transportation. E-commerce models and the operational processes surrounding these models will continue to transform and adapt with the ever-changing needs of customers and their preferences for purchasing and obtaining food for their families.

For these reasons, the FDA and other public health regulatory agencies should focus their efforts on public health outcomes rather than the process of how food gets to consumers. Since early 2020, we have seen double digit growth in online shopping with almost 90% of FMI member companies report offering online shopping and alternative delivery methods for consumers.¹ Additionally, two thirds of consumers report that they have shopped for food online.

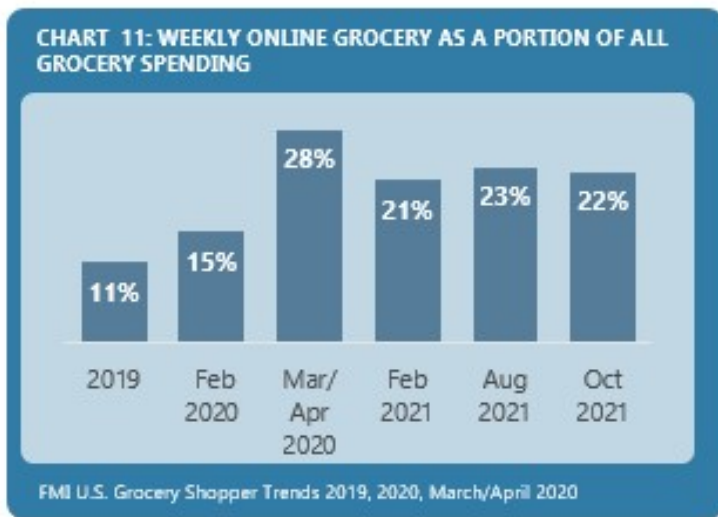
¹ FMI The Food Retailing Industry Speaks 2021 <https://www.fmi.org/our-research/research-reports/food-retailing-industry-speaks>

Frequency of Online Grocery Shopping from February 2020 – October 2020



FMI, U.S. Grocery Shopper Trends COVID-19 Tracker: Holidays October 2021

Weekly online grocery shopping spending as a percentage of total spending



FMI, U.S. Grocery Shopper Trends COVID-19 Tracker: Holidays October 2021

Existing food safety regulations provide regulatory oversight

All food establishments, including retail food establishments, have a responsibility to ensure that the food they prepare or sell is safe for consumption. The definition for

'food establishment'² in the FDA 2017 Food Code differs from the definition of 'retail food establishment' under 21 CFR 1.227. In the 2016 final rule for food facility registration, the FDA noted that establishments selling food directly to consumers through the internet or mail order are covered under the definition of retail food establishment as long as they meet the other criteria of the definition³. FDA's position on retail food establishments is also noted in the bioterrorism act⁴ and several FAQ documents for food facility registration published by the FDA.

Food facilities, including retail food establishments in the US are subject to regulatory oversight by FDA, USDA and/or regulatory agencies at the state, local, and/or tribal level. The foundational regulations for the facility should be based on the facility where the food originates because delivery models vary significantly. If companies are selling food directly to consumers, they should be subject to the appropriate regulatory requirements either as an extension of the food establishment where the product originates or as a separate entity operating as a retail food establishment.

The FDA Food Code definition for "food establishment" mentions delivery in section 1(b) and states that a food establishment "relinquishes possession of FOOD to a CONSUMER directly, or indirectly through a delivery service such as home delivery of grocery orders or restaurant takeout orders, or delivery service that is provided by common carriers." Additionally, transportation is mentioned in section 2(a) of the food establishment definition in the food code. Based on this definition of food establishment, food delivery is included, and this provides a regulatory framework for including delivery in the food establishment definition. The FDA and agencies regulating retail food establishments have authority through the definition of a food establishment in the 2017 FDA Food Code.

Food Establishment definition as stated in FDA 2017 Food Code ⁵ (emphasis added)

(1) "Food establishment" means an operation that:

(a) stores, prepares, packages, serves, vends food directly to the consumer, or otherwise provides FOOD for human consumption such as a restaurant; satellite or catered feeding location; catering operation if the operation provides FOOD directly to a CONSUMER or to a conveyance used to transport people; market; vending location; conveyance used to transport people; institution; or FOOD bank; and

(b) relinquishes possession of FOOD to a CONSUMER directly, or indirectly

² FDA 2017 Food Code (page 9) <https://www.fda.gov/media/110822/download> (accessed Nov 5, 2021)

³ 81 FR at 45924

⁴ 68 FR 58894 at 58914 to 58915

⁵ FDA 2017 Food Code (page 9) <https://www.fda.gov/media/110822/download> (accessed Nov 5, 2021)

through a delivery service such as home delivery of grocery orders or restaurant takeout orders, or delivery service that is provided by common carriers.

(2) "Food establishment" includes:

(a) An element of the operation such as a transportation vehicle or a central preparation facility that supplies a vending location or satellite feeding location unless the vending or feeding location is permitted by the REGULATORY AUTHORITY; and

(b) An operation that is conducted in a mobile, stationary, temporary, or permanent facility or location; where consumption is on or off the PREMISES; and regardless of whether there is a charge for the FOOD.

Under the regulations in the Food Safety Modernization Act, the FDA requires covered facilities to evaluate of the safety of products under several regulations including the Preventive Controls for Human Foods rule as well as more narrowly under the Sanitary Transportation rule. The FDA Preventive Controls for Human Foods rule requires that distribution and transportation current good manufacturing practices be in place (Subpart B, §117.93) and transportation practices must be considered when evaluating hazards (and subsequently controlled) under subpart C, §117.130 (iv)⁶.

The Sanitary Transportation of Human and Animal Food waivers for food establishments apply to permitted establishments or establishments that are otherwise authorized to sell human food.⁷ FDA has clarified that the scope of the food establishment waiver "applies to delivery services operated by the food establishment itself or by a third-party that is hired to deliver the food directly to the consumer."⁸

As FDA noted in the preamble of the Sanitary Transportation of Human and Animal Food proposed rule, we agree that "the regulatory programs of State and local agencies patterned upon the Food Code to be substantive, comprehensive, and effective in addressing food safety issues associated with retail food operations."⁹

⁶ Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food; Final Rule (80 FR 55907 – 56168)

⁷ FDA Clarification on Food Establishment Waiver from Requirements of the Sanitary Transportation of Human and Animal Food Rule: Guidance for Industry, August 2017.
<https://www.fda.gov/media/107146/download>

⁸ FDA Analysis of Comments Submitted to Docket FDA 2013-N-0013 Regarding Waivers from the Requirements of 21 CFR Part 1, Subpart O–Sanitary Transportation of Human and Animal Food, March 2017.

⁹ Sanitary Transportation of Human and Animal Food Proposed Rule, February 2014 (79 FR 7006 page 7031)

“Provisions of the Food Code address preventing food contamination and food holding temperatures for TCS foods or the use of time as a public health control, in the absence of temperature control, would apply to the transportation of foods from a food establishment to a site where the food would be relinquished to a consumer.”⁹

“State and local regulations modeled after the Food Code require that such establishments take the necessary steps to prevent food from becoming unsafe or being subject to temperature abuse during its preparation and service to the consumer, including during delivery to the consumer. Delivering food to customers under conditions that may render such products unsafe is a violation of these rules with which foodservice and retail establishments must comply as a condition of their permit to operate.”⁸ We encourage FDA to work with state, local, tribal and territorial partners to provide clarity on how e-commerce businesses should be regulated under existing regulatory frameworks. Furthermore, FDA should continue to work with these partners to achieve uniformity on how regulatory controls are applied and minimize inconsistency in how these business models are regulated across jurisdictions.

FMI supports uniform adoption of the FDA Model Food Code and encourages the use of the most recent Food Code published by the FDA. We rely on the consensus process through the Conference for Food Protection (CFP) for recommending changes to the Food Code, as well as, assist with the development of tools for various stakeholders. Therefore, FDA should leverage the work that has been done through CFP and utilize a recently released document from the CFP titled “Guidance Document for Direct-to-Consumer and Third-Party Delivery Service Food Delivery”¹⁰ as a starting point for education and evaluation. The CFP document was developed by a multidisciplinary committee within CFP and included broad consensus of food safety and public health professionals including representatives from CDC, FDA and USDA FSIS. The guidance document outlined the framework needed to deliver food directly to consumers or through a third party with program guidance related to identifying, assessing and controlling and validating and verifying risk based programs.

Food safety management practices extend beyond the physical store or facility

The food industry is committed to food safety and extends food safety practices to their e-commerce business models. The majority of FMI members report having standards of care in place to support food safety and extend their food safety management practices

¹⁰ CFP Guidance Document for Direct to Consumer and Third Party Delivery Service Food Delivery, 2020 http://www.foodprotect.org/issues/packets/2020Packet/attachments/III_004_content_c.pdf (accessed Nov 4, 2021)

to e-commerce operations or have agreements in place with e-commerce business partners addressing food safety. The industry will continue to innovate. Food safety is a priority in serving customers day in and day out.

Some of the programs reported by FMI members include, but are not limited to, the following

- Training for internal staff
- Required training for staff at third party companies
- Food safety expectations of third party business partners
- Temperature control throughout the process
- Control and tracking of time elapsed
- Proper labeling and allergen control
- Separation of raw and ready to eat products
- Separation of products based on allergens
- Tamper evident containers and/or packaging
- Employee health and hygiene training and procedures
- Customer feedback monitoring and procedures for correcting problems

Labeling

Labeling of foods online should be consistent with FDA’s current labeling regulations in that food labels should not be false or misleading to consumers. Labeling will vary based on the e-commerce model and the goal of providing accurate information for consumers should be the priority.

Consumer Food Safety Education

No matter how food is brought into the home, the role of consumers to reduce the risk of foodborne illness remains important. Leveraging consumer facing resources on food safety for e-commerce business models can help consumers keep food safety top of mind. FDA should work with trusted sources like the Partnership for Food Safety Education (PFSE), to develop and deliver consumer food safety education tools. Through the Prep Yourself¹¹ campaign, PFSE seeks to encourage safe food handling at home and educate consumers on what to consider when ordering from food delivery services.

Engage the food industry in solutions

Finally, we encourage the FDA to continue to engage with the food industry and food safety professionals to obtain information and share novel ideas and best practices that

¹¹ Partnership for Food Safety Education, *Prep Yourself* (2021) <https://www.fightbac.org/prep-yourself> (accessed Nov. 8, 2021)

will help protect public health. We encourage the FDA to continue to host forums, summits and public meetings. FMI heard from several members that they were not able to access YouTube as a platform for the summit held on October 19-21, 2021. We encourage the FDA to continue to hold meetings to obtain feedback and input utilizing meetings and technology platforms used by businesses and widely available to regulatory professionals.

Summary

FMI supports FDA's evaluation of e-commerce business models and the potential need to address new risks associated with these models. We encourage FDA to apply existing regulatory tools to these models and focus new efforts, if any, on areas where gaps in oversight or proven risks are identified. We hope the FDA will carefully evaluate existing regulations and exercise authority when appropriate rather than developing new or additional regulations for current and emerging business models.

We strongly encourage FDA to take a risk- and data-driven approach. FDA should focus its resources on areas where there are data, if any, supporting the presence of a public health risk, and it should evaluate new business models to determine whether existing regulatory controls are adequate.

Thank you again for hosting the summit and for inviting comments from the industry. We welcome the opportunity to work closely with the FDA as you advance food safety initiatives to protect consumers.

Regards,



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