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Exploring Challenges for E-Commerce and Novel Retail

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Food Retail Trends

- Direct to consumer
- Concierge convenience
- Micro food halls – combine restaurants and retail outlets
- Unmanned retail outlets



E-Commerce and The Food Industry

- Online food delivery sales >\$4 billion
- >1/3 consumers use online food delivery or reservations
- Trends:
 - Meal kits
 - Online grocery orders and delivery
 - Online restaurant orders and delivery
 - Online orders of dietary supplements (250K+ on Amazon)



Fitting Novel Retail Into Existing Regulatory Framework

- How do e-commerce and other novel retail methods fit into regulatory boxes designed for traditional commerce?
 - What type of facility? (retail vs. FDA registered)
 - What type of labeling? (NFP, menu labeling, allergens)
 - What about food safety?



Amazon

- FDA registered food facility vs. direct to consumer food establishment
- >300,000 food facilities registered with FDA; >100,000 are warehouses
- 2000: Amazon opens food storage facility
- 2008: FDA sends Amazon an untitled letter regarding food facility registration

Amazon

CIN	Amazon.com KYDC, LLC	Lexington	KY	40511	US	10/04/17	CFSAN	Foodborne Biological Hazards	VAI
CIN	Amazon.com KYDC, LLC	Lexington	KY	40511	US	05/18/10	CFSAN	Foodborne Biological Hazards	NAI
PHI	AMAZON FULFILLMENT SVCS INC	Breinigsville	PA	18031	US	01/05/17	CFSAN	Foodborne Biological Hazards	NAI
CIN	Amazon Fulfillment LLC	Hebron	KY	41048	US	10/19/12	CFSAN	Foodborne Biological Hazards	NAI
CIN	Amazon.com KYDC, LLC	Lexington	KY	40511	US	01/11/13	CFSAN	Foodborne Biological Hazards	NAI
PHI	Amazon Fulfillment Center PHL 7	Middletown	DE	19709	US	08/16/16	CFSAN	Foodborne Biological Hazards	NAI



FDA Food Code – Food Establishment

Food Establishment.

- (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 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.



FDA Food Facility Registration

- 21 CFR § 1.226:
 - Registration requirements do not apply to, among others, *retail food establishments* and *restaurants*



Restaurant or Retail Food Establishment?

- What is the impact of introducing a distribution center?
- *Restaurant* means a facility that prepares and sells food directly to consumers for immediate consumption. **“Restaurant” does not include facilities that provide food to interstate conveyances, central kitchens, and other similar facilities that do not prepare and serve food directly to consumers.**
 - Entities in which food is provided to humans, such as cafeterias, lunchrooms, cafes, bistros, fast food establishments, food stands, saloons, taverns, bars, lounges, catering facilities, hospital kitchens, day care kitchens, and nursing home kitchens are restaurants
- *Retail food establishment* means an establishment that sells food products directly to consumers as its primary function.
 - The term “retail food establishment” includes facilities that manufacture, process, pack, or hold food if the establishment's primary function is to sell from that establishment food, including food that it manufactures, processes, packs, or holds, directly to consumers.
 - A “retail food establishment” includes grocery stores, convenience stores, and vending machine locations.



Retail Food Establishment

- FDA:
 - “[W]e note that, in determining whether an establishment is a retail food establishment, our regulation has always allowed for establishments selling food directly to consumers via the Internet or mail order to be covered under the definition of “retail food establishment,” provided that they meet the other criteria of the retail food establishment definition....”



Labeling

- Threshold question of what type of establishment or facility produces the food also influences what type of labeling is required, and whether federal or state requirements apply.
- Online ordering introduces an additional wrinkle.



Nutrition Labeling

- 21 CFR § 101.9(j) – So long as the product does not have any nutrition claims or other nutrition information in any context on the label or in advertising, the following foods are exempt from this section or are subject to special labeling requirements:
 - Except as provided in §101.11, food products that are served in restaurants, or in other establishments in which food is served *for immediate human consumption* (e.g....food delivery systems or establishments where ready-to-eat foods are delivered to homes or offices)
 - Except as provided in §101.11, food products that are restaurant type foods or similar to the described food from other establishments [establishments in which food is served for immediate human consumption (e.g....food delivery systems or establishments where ready-to-eat foods are delivered to homes or offices)], if the food is ready for human consumption, offered for sale to consumers *but not for immediate human consumption*, processed and prepared primarily in a retail establishment, and not offered for sale outside of that establishment



Menu Labeling

- The FDA included establishments that provide food delivery (*e.g.*, pizza delivery or Chinese food delivery), but stated that
 - “For clarity, we are defining ‘location’ to mean ‘a fixed position or site.’”
 - A “‘location’ involves a specific or fixed position on land or portion of land.”



Allergen Labeling

- FALCPA only applies to packaged FDA-regulated foods
- State laws related to allergens
- Best practice – full and precise labeling of ingredients and/or products



Food Safety

- How should an e-commerce seller approach recalls and traceability?
 - Advantages of extensive customer information



Food Safety

- Cold Chain
- Product Adulteration and Tampering
- Customer Responsibility (Storage and Handling)



Marketing Challenges

- Claims
 - Applied to a single ingredient?
 - Applied to single product or menu item?
 - Applied to an entire meal?
 - Applied to an entire menu?
 - *E.g.*, McDonald's, Chipotle, Panera



Novel Retail – Unattended Markets

- There was speculation that the FDA would amend the Food Code to include requirements applicable to “unattended food establishments,” but this did not happen with the 2017 Food Code
- National Automatic Merchandising Association (NAMA) – unattended markets are “food establishments” under the current definition (unless they only offer pre-packaged foods that are not time/temperature controlled for safety)
- The Unattended Food Establishment Committee prepared a guidance document that outlines proposed amendments to the Food Code regarding unattended food establishments
 - Mirrors state requirements



Novel Retail – Unattended Markets

- Requirements vary by jurisdiction (typically at state level) and may require:
 - 24/7 video surveillance records
 - A responsible party that is available for inspections
 - Tamper evident products with an expiration date;
 - Display units that will shut-off and not dispense food if temperatures are not controlled
 - Sign that provides contact information to a responsible party
 - Controlled entry
 - That no bulk food be dispensed and that food preparation be limited to reheating food in a microwave
 - Beverage dispensers dispense beverage by individual servings only and be properly equipped with backflow prevention
 - Food contact surfaces to be cleaned regularly
 - Limits on the return of items
 - Procedures to handle recalled food items
 - Lease or other agreement to address maintenance, waste removal, pest control, etc.

