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AGRIBUSINESS AND FOOD ISSUES TO WATCH FOR 2022

In 2022, the Food and Drug Administration (FDA) and related regulatory bodies will continue to balance emergent public health issues related to the COVID-19 pandemic with "conventional" oversight obligations. Our Agribusiness and Food industry team has compiled its annual overview of key issues that may impact related industries throughout the year.

COVID-19 RELATED MATTERS

Stating the obvious, the pandemic will continue to impact individuals and companies in immeasurable ways. Some of the explicitly related regulatory matters in 2022 will include:

- Recent extension of the Public Health Emergency (PHE), effective Jan. 16, 2022, through April 16, 2022. The PHE has been renewed more than half a dozen times. The PHE triggers increased access to categories of federal funding for local authorities and allows for the waiver of certain regulatory requirements.
- Attention to economically motivated raw material adulteration in the face of ongoing supply chain delays and disruptions.
- Ongoing use of FDA's authority to issue Emergency Use Authorizations (EUAs) to accelerate the development of treatment therapeutics, vaccines and tests. EUA review is a mechanism used to facilitate the availability of medical treatments and countermeasures during public health emergencies. Although EUA authority enables the FDA to allow the use of unapproved medical products, or unapproved uses of approved medical products, in emergency circumstances, it does not obviate rigorous testing of such products.
- Continued emphasis on production of Personal Protective Equipment (PPE) and over-the-counter testing options.

PENDING EXPORT ISSUES FOR DOMESTIC PRODUCERS

Epic supply chain disruptions, border closings, enhanced emphasis on supplier qualification and traceability—it is a vast understatement to suggest the international flow of food and agricultural products is in a state of flux. Notably, with respect to certain key export markets for domestic producers, there are still more challenges to reaching those markets in 2022.

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SERVICES AND INDUSTRIES

Agribusiness and Food

International

China: Effective Jan. 1, 2022, the General Administration of Customs of China (GACC) issued Decrees Nos. 248 and 249 (Decrees), which set out new requirements for the registration of qualified foreign food producers that are allowed to export food products to China. Decree No. 248 requires all overseas food manufacturers, processors, and storage facilities to be registered with the GACC. Under Decree 248, 18 categories of food, such as meat and aquatic products are subject to registration as recommended by the competent authority of the home country of the exporter. In addition, the GACC issued Decree No. 249 which provides new enforcement tools for the GACC to inspect food imports, and suspend or prohibit food imports into China when violations are identified. At this point there is no indication of an interim safe harbor to allow exporters who have not already begun the registration process to come into compliance, effectively halting imports of those products. The GACC Decrees make it apparent that the Chinese government intends to expand its scope of supervision over food supply chains to include operations outside of China. In looking forward, in addition to the compliance challenges which arise from the new Decrees, companies exporting food need to focus on the compliance risks and challenges involved in such pre-importation operations.

Canada: The transition period for the 2016 nutrition labeling changes were set to end on Dec. 14, 2021. Given, however, the challenges imposed by COVID-19, the Canadian Food Inspection Agency (CFIA) will focus its efforts on education and compliance promotion for the first year, until Dec. 14, 2022. As of Dec. 15, 2022, CFIA will verify compliance and apply enforcement discretion in cases where noncompliant companies have detailed plans showing how they intend to meet the new requirements at the earliest possible time. Other regulatory initiatives (like Front of Package Labeling) continue to be on hold. Delayed enforcement was extended for Safe Food for Canadians Regulations requirements that came into force in July 2020 for the manufactured food sector. United States-Mexico-Canada Agreement (USMCA) certification of origin requires the certifier (importer, exporter or producer) to cover nine mandated minimum data elements, replacing the old North American Free Trade Agreement (NAFTA) certificate of origin.

Effective March 1, 2022, amendments to the Canadian Medical Device Regulations (CMDR) will require Medical Device License (MDL) and Medical Device Establishment License (MDEL) holders for certain Class I, II, III and IV devices to report shortages of their devices and/or device components and accessories to Health Canada. The amendments will also authorize the Canadian Minister of Health to require manufacturers, importers and/or distributors to provide data regarding device shortages.

Mexico: Effective June 1, 2021, Mexico made amendments to the Health Supplies Regulation (*Reglamento de Insumos para la Salud RIS*, which also includes the regulations for Medical Devices). These amendments (1) eliminate

the obligation to translate English documents into Spanish and (2) allow for more simplicity in the renewal process. Prior to these changes, any registration had to be renewed every five years. Currently, no further renewals are required unless there are safety issues with the product.

EU: On May 26, 2021, a new EU medical device regulation (MDR) entered into force. The EU MDR is greatly expanded to cover more devices, including Software as Medical Device, implantable devices, contact lenses, and many digital health technologies. It also promotes a lifecycle approach to regulation. EU MDR requires improved device traceability by introduction of a unique identification system, or UDI, for medical devices approved for use in the EU. To keep track of devices through every lifecycle stage, a device identifier (UDI) will be assigned, and all production series will be marked with a production identifier. The regulations also tighten the rules for testing medical devices on patients to ensure the availability of documentary evidence of device testing. In addition, manufacturers of medical devices must meet stricter requirements with regard to following up on the quality, performance and safety of devices. A new in vitro diagnostic medical devices regulation (IVDR) will follow this year, entering into force on May 26, 2022. In vitro diagnostics are tests done on samples such as blood or tissue and can be used to detect diseases or other conditions.

CONSUMER FRAUD CLAIMS

Class actions targeting highlighted ingredients (ex. vanilla), health representations, and—the perennial favorite—"all natural" statements on human food and animal food product labels will likely remain a plaintiffs' bar darling in 2022. These types of cases exploit broad state consumer protection laws (with attractive attorneys' fees allocations) to claim that consumers have been deceived, misled or otherwise damaged by food, beverage, supplement or pet food manufacturers. Although these lawsuits have typically focused on labeling claims that fall within definitional gray areas or silence from the FDA, plaintiffs' attorneys have also increasingly targeted "healthy" food products. Although products may technically meet the FDA's metric for a healthy product (low in sodium, fat, and cholesterol), certain lawsuits have made a more holistic assessment as to whether a product is healthy.

Oftentimes, when food and beverage companies receive a demand letter threatening a consumer fraud class action as a result of a labeling claim, the calculus whether to fight an unreasonable demand or settle is frustrating because the case could easily survive motion to dismiss and result in significant fees. As result, even though clarified regulatory standards around the terms "natural" and "healthy" would be helpful, it may be equally useful for food and beverage companies if federal judicial circuits like the Ninth and Second circuits opt to dismiss unreasonable consumer fraud claims early and further develop a

"reasonable consumer" standard.

ENFORCEMENT ACTIONS FOR MARKET OPPORTUNISTS

In 2022, we will likely see fallout from the proliferation of personal and surface area cleaning products on the market. The COVID-19 pandemic motivated companies to rush to market with sanitizing products to satisfy consumer demand. Depending on the purpose of the products and nature of claims made, these products are subject to extensive regulation by the EPA, FDA, and state bodies. Regulators and plaintiff's attorneys have already begun to target producers and distributors of these products who were less than rigorous in evaluating and supporting labeling claims (ex. "kills 99.9% of bacteria") and meeting defined product formulations (ex. limits on volatile organic compounds (VOCs)).

In particular, violators of the Federal Insecticide, Fungicide and Rodenticide Act, known as FIFRA, may hear from the EPA in 2022; new market entrants making pesticidal claims are often not familiar with EPA's strict regulation of requirements. New pesticide products require a significant lead time to get through the FIFRA approval process and, although EPA has an expedited review process for COVID-19 disinfectants, it continues to closely regulate labels and claims, including the iconography.

ENHANCED REGULATION OF DIETARY SUPPLEMENTS

Consumer safety advocates want the FDA's supplement regulatory capabilities to keep pace with the growth of the dietary supplement industry. They may make headway on this goal in 2022 by securing funding for the Office of Dietary Supplement Programs within the FDA and by developing a framework requiring "mandatory product listing."

The FDA has been active in issuing Public Notifications with respect to products making unsubstantiated health and benefit claims in violation of the Food, Drug and Cosmetic Act. Some of these Public Notifications focus on dietary supplements the FDA believes to contain "hidden drug ingredients." Specifically, the FDA continues to object to cannabidiol (CBD) infused products to be sold as dietary supplements. Unfortunately for manufacturers—and consumers—of such products, there remains uncertainty as to the market viability of CBD products and any notion of a standard for safe levels of consumption of CBD. Although the FDA continues to tout its Cannabis-Derived Products Data Acceleration Plan (last updated in October 2021), there is clear hesitancy from the FDA to issue any new regulation to allow CBD-infused products to be marketed as dietary supplements. The lack of clarity in regulatory oversight has likely led to a flood of products on the market of varying potency and quality. Circumstances may not change absent

congressional action.

At the state level, certain legislatures are moving to address what they see as an unfettered marketplace for dietary supplements. In one specific instance, there is an effort to limit the sale of dietary supplements that are targeted for weight loss or muscle building to minors. State legislators in California, Illinois, Massachusetts, Missouri, New Jersey, and New York cite eating disorders and constant content on social media as contributing reasons for introducing such legislation.

COMPLIANCE DEADLINE FOR USDA'S NATIONAL BIOENGINEERED FOOD DISCLOSURE STANDARD

The National Bioengineered Food Disclosure Standard (NBFDS) promulgated by the USDA outlines labeling and disclosure requirements for bioengineered (BE) food products. 7 CFR Part 66. As noted in previous updates, the labeling compliance deadline for producers, importers and retailers with human food products subject to NBFDS was Jan. 1, 2022.

With respect to the NBFDS, the USDA's enforcement options are effectively limited to public disclosure of the results of an investigation following a hearing for a noncompliant regulated entity. In other words, as of now, USDA may not require a recall or issue fines for failure to make a BE labeling disclosure. However, it should be noted that public disclosures of noncompliance with NBFDS will likely be closely watched by competitors and plaintiffs' attorneys.

ANTICIPATED GUIDANCE FOR STANDARDS OF IDENTITY AND FAIR LABELING

Plant-Based Milk: In June 2021, the FDA indicated that by June 2022, it intended to issue guidance on "Labeling of Plant-based Milk Alternatives." This includes soy milk, almond and the increasingly popular oat milks. The comment period is still open. The "milk" debate has continued for years, especially as more plant-based milk products have come to market. Dairy producers seek to enforce the standard of identity for milk, which is limited to lacteal secretions of cows as—in their view—plant-based beverages identified as "milk" have implied nutritional equivalency with milk. Proponents of dairy milk alternatives claim that it is unlikely consumers are misled when "almond" or "oat" appears before milk.

Alternative Proteins: In September 2021, the USDA's Food Safety and Inspection Service (FSIS) issued an advance notice of proposed rulemaking (ANPR), seeking comments regarding the labeling of meat and poultry products made using cultured cells derived from animals. The USDA and FDA entered an agreement to oversee products made using animal cell culture technology derived from cells of poultry and livestock. The FDA will oversee the cell collection and growth. Cell harvest, processing, packaging and labeling will fall

to FSIS. Those in the agribusiness and food industry are awaiting guidance from the USDA and FDA following the comment period, which has now ended. The industry is particularly focused on the standards of identity for these products.