Directorate-General for Health and Food Safety,
European Commission Re: European Commission's public consultation, Foodborne outbreaks – monitoring of and reporting on molecular analytical data

The United States Food and Drug Administration (US FDA) supports the European Commission's proposal for monitoring and reporting molecular analytical data to improve food safety outcomes across the European Union. The genomic sequence of isolates collected from clinical, food, or environmental samples in the United States of America are publicly available (with limited metadata) through the National Center for Biotechnology Information (NCBI) on NCBI's Pathogen Detection platform (Home - Pathogen Detection - NCBI (nih.gov). This has been a keystone resource of the United States' food safety program for the past decade and an invaluable resource to support public health. So too will be the European Food Safety Authority (EFSA)/European Centre for Disease Prevention and Control (ECDC) One Health Database should the sharing of pathogen data (collected by Member States) be mandated. Such a mandate will significantly impact and improve food safety and public health within the European Union.

Genomic data from foodborne pathogens isolated from food, feed, and the environment, by itself and in combination with other information, is a robust resource that can help public health officials identify and understand the source of foodborne illness outbreaks when linked to clinical isolates. Although public health officials sequence foodborne pathogens after a foodborne illness outbreak or event has occurred, it isn't the only time. Genomic sequencing information can be used for more than just determining the scope of outbreaks and speeding traceback investigations. It can be used as: an industry tool for monitoring ingredient supplies and the effectiveness of preventive and sanitary controls, and to develop new rapid method and culture independent tests; to determine the persistence of pathogens in the environment; to monitor emerging pathogens; and as a possible indicator of antimicrobial resistance.

Therefore, and to make this proposal even more effective in maximizing the usefulness of pathogen data being collected around the world, the US FDA suggests an additional requirement that the data being submitted to ECDC/EFSA's One Health Database also be uploaded to the International Nucleotide Sequence Database Collaboration (INSDC; of which European Nucleotide Archive (ENA) and NCBI are part). The inclusion of sequence data plus limited metadata (e.g., date of collection, isolate source, and geographic area) collected from samples in the European Union in the INSDC could make a greater impact when combined with data from the rest of the world on food safety both within the European Union and globally, allowing public health professionals and food safety authorities to more rapidly detect and address foodborne illness affecting multiple countries or regions.

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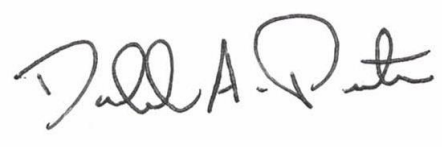
The food supply chain is becoming increasingly global and the United States and the European Union share many common importers of food; thus, having integrated data systems and working together greatly benefits consumers in the United States and European Union.
In summary, we applaud the European Union for pursuing greater data expectations and information sharing to modernize your food safety oversight system.

Sincerely,



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