

IFST are the UK's leading professional body that aims to advance the application of food science and technology for the benefit, safety and health of the public. Thank you for inviting comments regarding monitoring of and reporting on molecular analytical data for foodborne outbreaks.

There are several points which we think need to be clarified regarding implementation of this regulation:

- 1) Although outbreaks have been identified using whole genome sequencing (WGS) for several years now, there is one issue which is a barrier to solving incidents, namely there does not appear to be a common approach to naming genetic variations., this could cause confusion and incorrect attribution of risk unless this can be agreed. IFST suggest that an ISO type standard is discussed and agreed to avoid these issues.
- 2) As we understand, small variations in genetic sequence may not be classified as new genetic variants of a pathogen. This could lead to inadvertent implication of the foodborne outbreak, and subsequent risk to a Food Business Operator that food products are wrongly attributed as the cause of an outbreak.
- 3) Article 2.2(a) states that the WGS should have a unique reference number of the genome sequence of the isolate from which the sequence has been generated and of the sample from which the isolate was obtained. There should be an agreed method of nomenclature to avoid confusion and aid cross-match of closely related outbreaks.

Additional concerns that should be borne in mind relate to government agency pressure on companies to share their WGS data. In many countries, the information on WGS results (when shared with government) is open to freedom of information requests of media and NGOs to have insight of the data and names of companies concerned. This could and will undoubtedly lead to unwarranted negative publicity and consumer concerns. This data would remain on record forever, so if a match is found in the distant future the company having submitted the data can be (and has previously been) implicated in a current/recent outbreak, with unsubstantiated allegations made of persistent contamination. Hence only food business operators (FBO) with technical resource to carry out WGS would be most likely to have the best controls in place but would be most likely to be implicated in an issue compared with other companies with less resource to conduct WGS. Therefore, all FBO should be required to conduct WGS and submit data, or this should be a voluntary system.