**COMMITTEE PAPER FOR DISCUSSION** **ACNFP/140/05**

**ADVISORY COMMITTEE ON NOVEL FOODS AND PROCESSES**

# EFSA GUIDANCE DOCUMENT FOR THE REQUIREMENTS FOR WHOLE GENOME SEQUENCE ANALYSIS OF MICROORGANISMS INTENTIONALLY USED IN THE FOOD CHAIN

## Issue

Members are invited to consider and provide feedback on a guidance document from the European Food Safety Authority on the requirements for whole genome sequence analysis of microorganisms intentionally used in the food chain.

## Background

1. Microorganisms, genetically modified or not, are often used in the food chain. In the cases in which this requires a pre-market authorisation process, a risk assessment has to be performed on the product to assess its safety. As part of the risk assessment process, it is necessary to identify the microorganism, for which whole genome sequence can provide very high-quality information on taxonomic identification. This can help identify traits such as virulence factors, antimicrobial resistant properties or production of toxic metabolites.

2. The European Food Safety Authority put up for public consultation a guidance document on the requirements for whole genome sequence analysis of microorganisms intentionally used in the food chain as part of the EU authorisation systems. The document provides recommendations on how to describe the whole genome sequence analysis, how to perform it and references on quality criteria. It is intended that the guidance applies to products managed under Regulations (EC) No 1829/2003, 1831/2003, 1924/2006, 1332/2008, 1333/2008, 1334/2008, 1107/2009, 2015/2283, and Directive 2001/18/EC including novel foods and GM.

3. The document is currently out for public consultation to gain input form stakeholders. The deadline for responses is the 28 February 2020.

## Guidance Document

4. It is stated that the guidance for whole genome sequencing must be used in combination with previous EFSA guidance specifying the requirements of identification of regulated products that require pre-market authorisation. The scope of the guidance is therefore to give further recommendations to applicants when providing whole genome sequence data in an application.

5. The following points are described in further detail in the document:

- The microorganism tested must be the one subject to the application for authorisation and must be cultivated before DNA extraction as a pure culture.
- The applicant is advised to describe the library construction method, DNA fragmentation method, sequencing strategy, instrumentation used and base-calling method. Contamination of the sequencing data should be investigated by a metagenomic classifier.
- In case an assembly-based approach is taken, the *de novo* assembly method, number of contigs and length and N50 metric should be provided.
- The microorganisms under assessment should be identified, and confirmation of the identity has to be provided.
- It is indicated that the presence of genes of concern coding for antimicrobial resistance, virulence, pathogenicity or toxigenicity, must be reported. In the case of antimicrobial resistance, similarity of at least 70% and 60% coverage should be reported. For toxigenicity and pathogenicity, similarity of 80% and 60% coverage should be reported.
- The raw reads should be submitted in FASTQ and the assembled sequence as electronic ASCII text files.
- Other relevant technical reports are provided for reference, as well as a checklist for the applicant to use.

**Committee Action Required**

- Members are invited to review the draft guidance document and provide feedback on its content.
- Members are asked whether the Committee would provide a response to the public consultation process.

**Secretariat**
**January 2020**

**Annexes Attached**

**Annex A –** (Draft) EFSA statement on the requirements for whole genome sequence analysis of microorganisms intentionally used in the food chain.