

EFSA technical meeting with stakeholders on applications for food enzymes

Brussels, 19-20 June 2019

AMFEP's input

Characterization of microbial strains

Guidance on the Characterization of Microorganisms

Ambition: harmonized guidance for feed and food

Specific requirements could be waived, e.g. due to typically lower use rates of food-processing enzymes

Also to be taken into account:

Previous discussions on the guidance for feed, e.g. Meeting EFSA-Stakeholders of 20 November 2018

Guidance on the Characterization of Microorganisms

QPS status and consequences

Antibiotic resistance – MIC

Whole Genome Sequencing

Presence of rDNA

Taxonomic changes

QPS status

(N.B.: to be covered in-depth in a later slide)

Clarity

Data needed for the specific production organism

Predictability

Waiving of requirements

Antibiotic resistance

How: whole genome sequencing + MIC value determination

Challenges MIC

- Values at species level

- Cutoff levels

- Update frequency of cutoff levels

- Data needed for requesting a change

Antibiotic resistance

- Only risk if clear resistance gene found + phenotypic resistance

- Only acquired resistance genes which were introduced

Whole genome sequencing

Challenges for WGS

Up-to-date databases

Meaningful annotation of genes

Homology values

Cut-off values of hits

False positives

Submission of proof that WGS analysis has been properly performed, no need for submission of FASTA files

Presence of rDNA

Safety: rDNA presence is not a safety issue

(if no sequences of concern are present)

Points of attention

PCR inhibition

DNAses

Matrix effect

Dilution factor intermediate product and final product

LOD not always attainable

Taxonomic changes

Issue: Taxonomic change of production organism after submission

Points of attention

- Impact on the risk assessment

- Mention old and new taxonomy in the opinion

- Keep link between submission and opinion for the EC

Importance for industry

- Internationally approvals under old organism name

- Labels, documentation, trade