EFSA FEEDAP Panel: Frequently asked questions from EFSA to applicants

Trusted science for safe food

efsa
European Food Safety Authority

FEED Additives assessment - Q&A

- EFSA analysed the questions asked to applicants in the period from 2017 until 2020 during the assessment of the FEED additives dossiers

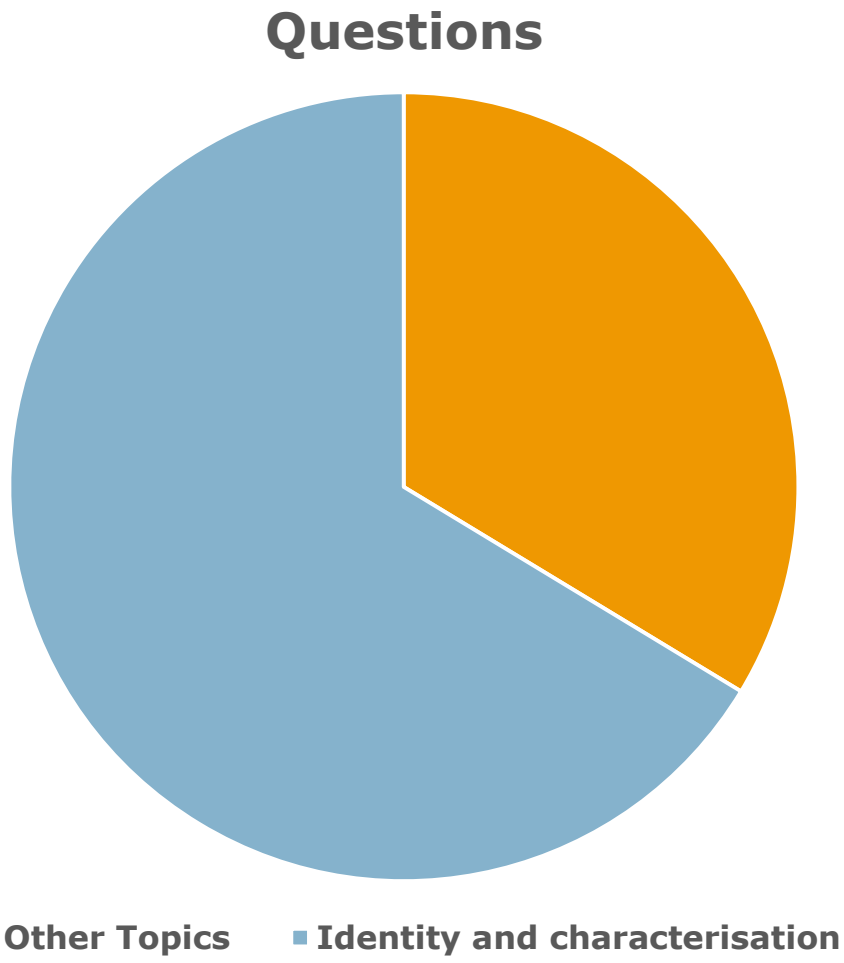
- Most frequently asked questions that highlighted recurring problems for the identity and characterisation of the additive were selected

FEED Additives assessment - Q&A

- **Answers were provided in the Q&A document**
- **https://www.efsa.europa.eu/sites/default/files/2021-05/frequently-asked-questions-applicants-assessment-feed%20additives.pdf**
- **The aim is to give the applicants useful tips that help in building feed additives dossiers**
- **The requirements are described in the guidance documents**

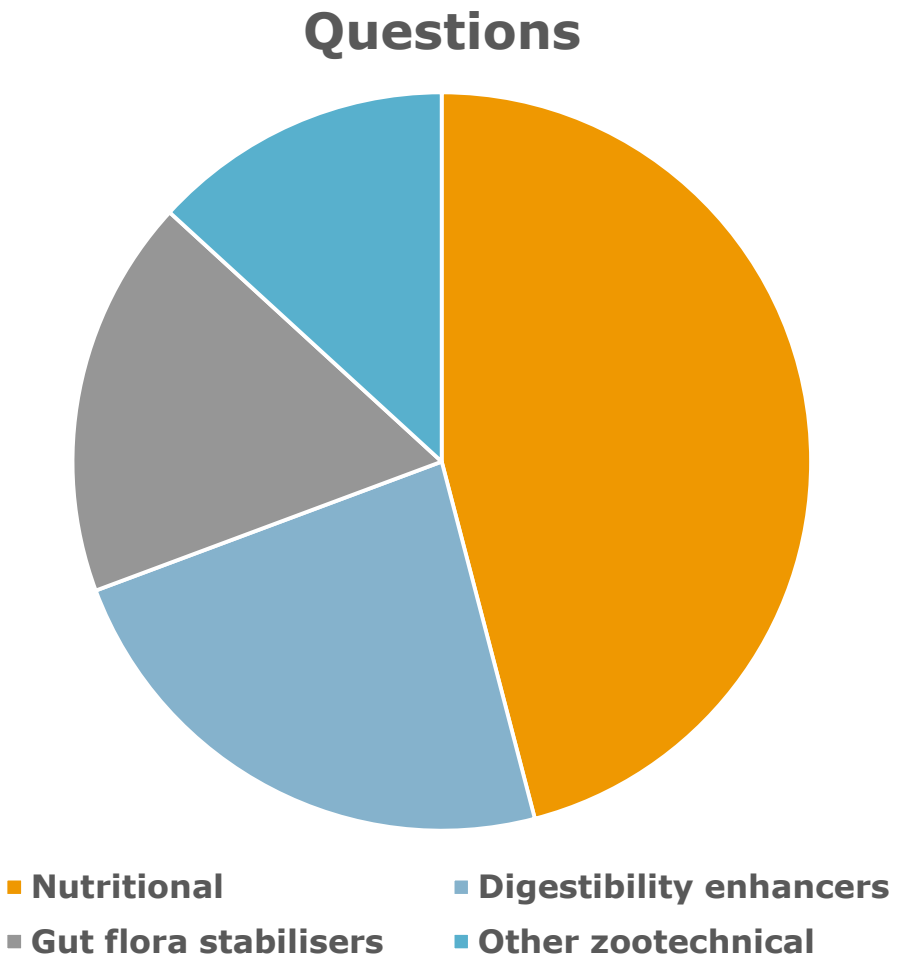
Frequency of questions

- **EFSA screened the topics for which questions were requested to the applicants with a higher frequency for the period 2017-2020**



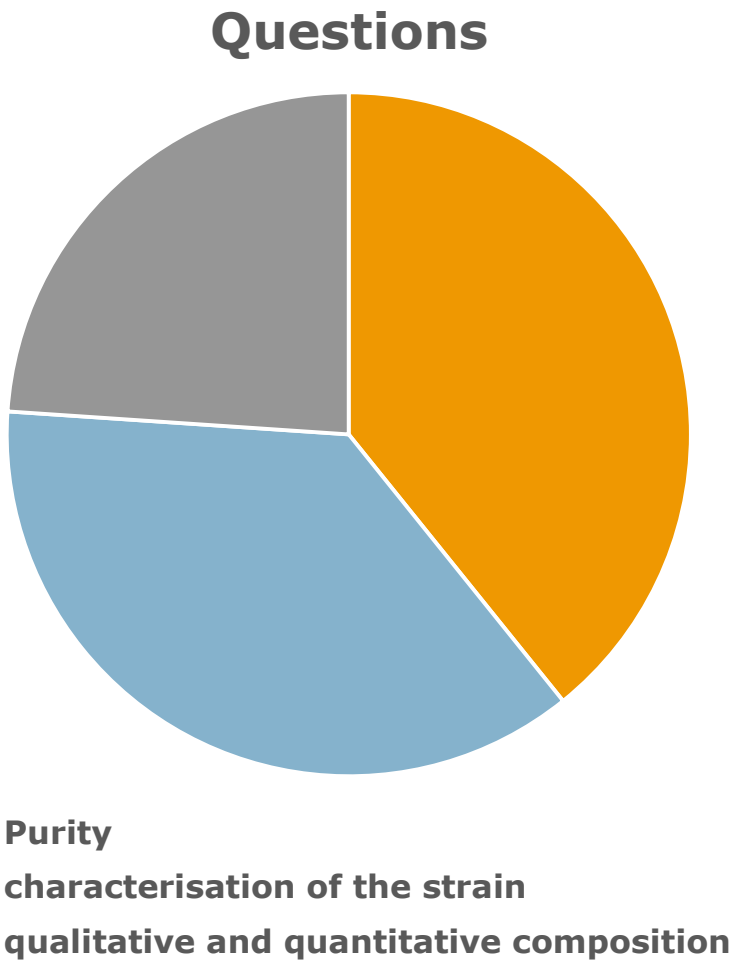
Which categories?

- **The categories/functional groups with most questions were submitted**



Which topics?

- **The questions were further classified depending on subtopics**



Taxonomic identification of microorganisms

Limitations

- **Incomplete reporting**
- **Wrong reference strain used for analysis**

Tips

- **Database used for comparison, sequences, raw data**
- **Type strains for the expected species, type strains or well-and widely-recognised strains of related species**

History of modifications of microorganisms

Limitations

- **Incomplete reporting**

Check the Guidance on the characterisation of microorganisms used as feed additives or as production organisms (par. 2.1 and 2.1.1)
https://efsa.onlinelibrary.wiley.com/doi/pdf/10.2903/j.efsa.2018.5206

Tips

- **Origin of the strain**
- **Description of techniques used**
- **Steps followed to select/obtain the strain**
- **Genetically Modified Microorganisms structure using the Whole Genome Sequences (where relevant)**

Presence of viable cells of production strain in the additive

Limitations

- **Suitability of test item**
- **Amount of sample analysed**
- **Representativeness of the additive under assessment**
- **Wrong methodology**

Check the Guidance on the characterisation of microorganisms used as feed additives or as production organisms (par. 3.1) https://efsa.onlinelibrary.wiley.com/doi/pdf/10.2903/j.efsa.2018.5206

Tips

- All final formulations or a representative intermediate
- At least 1 gram/mL of the product
- at least 9 samples (of at least 10 gram or mL) from a minimum of 3 independent batches
- Any dilution made should be stated. The amount of product plated should correspond to at least 1 gram/mL of starting material

Presence of DNA of production strain in the additive

Limitations

- **Suitability of test item**
- **Amount tested**
- **Wrong methodology**
- **Suitable sensitivity tests**

Check the Guidance on the characterisation of microorganisms used as feed additives or as production organisms (par. 3.1) https://efsa.onlinelibrary.wiley.com/doi/pdf/10.2903/j.efsa.2018.5206

Tips

- **All final formulations or a representative intermediate**
- **1 g/mL tested (see previous slide)**
- **Suitable lytic agent in DNA extraction phase**
- **Appropriate targeted sequence**
- **Raw data**
- **LOD determined by spiking prior to DNA extraction**

Manufacturing process

Limitations

- **Impurities to be addressed**

Check the Guidance on the identity, characterisation and conditions of use of feed additives (par. 2.1.4 and 2.3.2) https://efsa.onlinelibrary.wiley.com/doi/pdf/10.2903/j.efsa.2017.5023

Tips

- e.g. solvents (toluene, hexane) that may impact the safety
- Analytical data
- Details on antimicrobials used

Questions are welcome

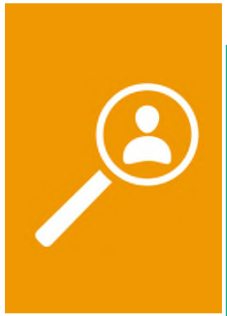
One2022.eu

#OneEU2022

Stay connected

Subscribe to

efsa.europa.eu/en/news/newsletters
efsa.europa.eu/en/rss



Receive job alerts

careers.efsa.europa.eu – job alerts

Follow us on Twitter

@efsa_eu
@plants_efsa
@methods_efsa
@animals_efsa

Follow us Linked in

Linkedin.com/company/efsa

Contact us

efsa.europa.eu/en/contact/askefsa