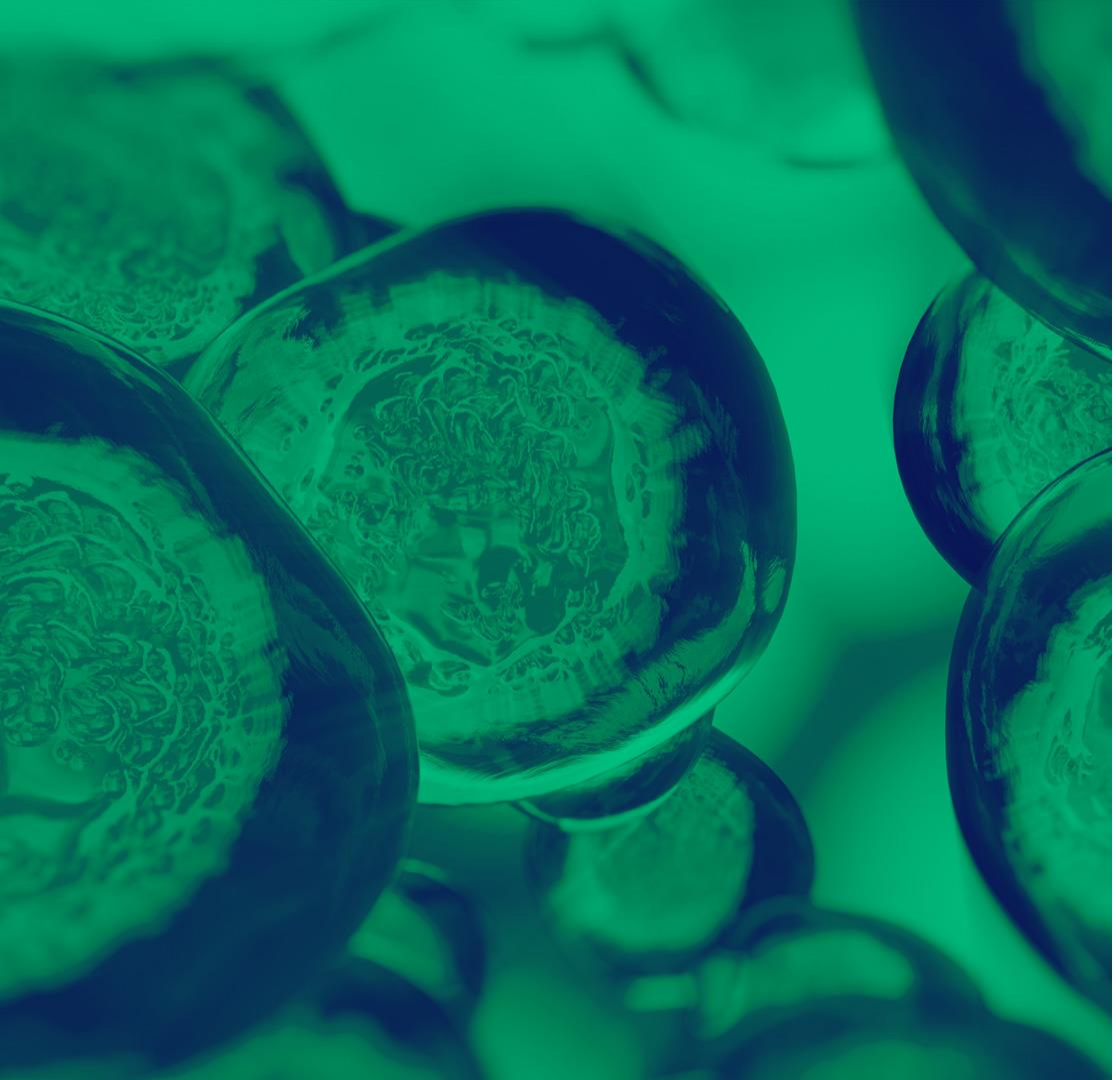

Market entry and barriers for microbial foods and how to overcome them

Dr Pauliina Halimaa
CEO, Biosafe

23.10.2023

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1. Overview of EU regulatory pathways for alternative proteins or other fermentation products

2. The use of genetically modified microorganisms in the EU

3. Transparency regulation and QPS – understanding concepts specific to the EU

EU regulatory pathways

1. Novel foods

Regulation (EU) 2015/2283

- Food not consumed before 1997
  - Novel structure
  - Consisting of, isolated from, or produced from microorganisms, minerals, plants, animals, cell or tissue culture
  - New production process
  - Nanomaterials

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2. Food additives

Regulation (EC) No 1333/2008

- Sweeteners, colours, preservatives, antioxidants, thickeners, acids...

3. Food flavourings

Regulation (EC) No 1334/2008

- Not consumed as such, added to food to impart or modify odour and taste
- Can be obtained from microbiological processes

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4. Feed additives

Regulation (EC) No 1831/2003

- Sensory additives (e.g. flavourings, colourants)
- Nutritional additives (e.g. vitamins, amino acids)

5. Feed materials

Regulation (EC) No 767/2009

- Principal purpose is to meet animals' nutritional needs
- No premarket authorization required for non-GMMs

GMO/GMMs in the EU

21.10.2023

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GMO/GMMs in the EU

Regulation 1829/2003 on genetically modified food and feed

Directive 2001/18/EC on the deliberate release of GMOs into the environment

- Genetically modified microorganisms used widely by the biotechnology industry
- No genetically modified microorganisms (GMMs) or fermentation products labelled as GMOs in the EU market

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2011 EFSA Guidance

on the risk assessment of genetically modified microorganisms and their products intended for food and feed use

Category 3

Products derived from GMMs in which GMMs capable of multiplication or of transferring genes are not present, but in which newly introduced genes are still present

- Investigate whether DNA is detected in analyses having detection threshold of 10 ng of DNA per gram or mL of product or lower

BIOSAFE

2011 EFSA Guidance

on the risk assessment of genetically modified microorganisms and their products intended for food and feed use

Category 4

- Products consisting of or containing GMMs capable of multiplication or of transferring genes

EFSA and GMMs

GMO EFSA-Q-2023-00046

Application of L-tryptophan as a GMM in the European Union to be used as feed additive

Last updated on: 19/04/2023
Status: Intake

GMO EFSA-Q-2023-00047

Application of L-threonine as a GMM in the European Union to be used as feed additive

Last updated on: 19/04/2023
Status: Intake

GMO EFSA-Q-2019-00651

Request for placing on the market of Soy Leghemoglobin produced from genetically modified Pichia pastoris (EFSA-GMO-NL-2019-162)

Last updated on: 20/12/2022
Status: Ongoing Risk Assessment

Clockstop expected until 31/12/2023

GMO EFSA-Q-2023-00507

Application for authorisation of L-lysine sulphate from genetically modified Corynebacterium glutamicum KCCM 80368 in accordance with Regulation (EC) No....

Last updated on: 12/10/2023
Status: Intake

GMO EFSA-Q-2023-00538

Application for authorisation of L-valine from genetically modified Corynebacterium glutamicum KCCM 80365 in accordance with Regulation (EC) No. 1829/2003 (AP186)

Last updated on: 09/10/2023
Status: Intake

Concepts specific to the EU

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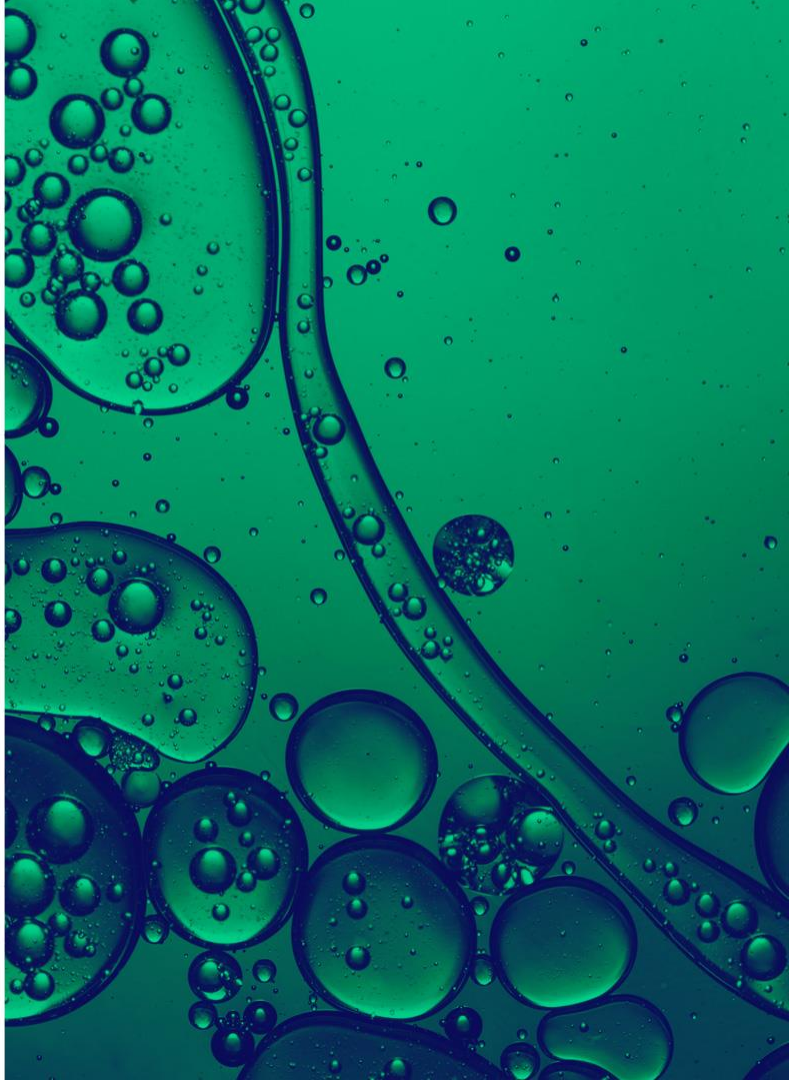
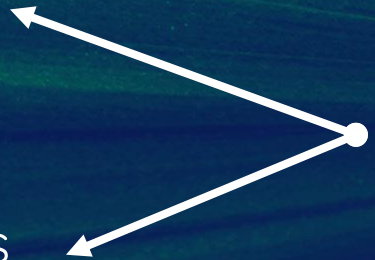
Transparency Regulation

(EU) 2019/1381

- Increasing the independence of studies
- Strengthening the governance and the scientific cooperation
- Developing comprehensive risk communication



- Pre-submission advice
- Notification of studies
- Public consultation
- Verification studies
- Confidentiality requests
- Fact-finding missions



Suitability check, confidentiality decision making

> DELAYS

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QPS – Qualified presumption of safety

- The QPS assessment process is only triggered by submitted dossier for regulated product to EFSA

- QPS list updated every six months

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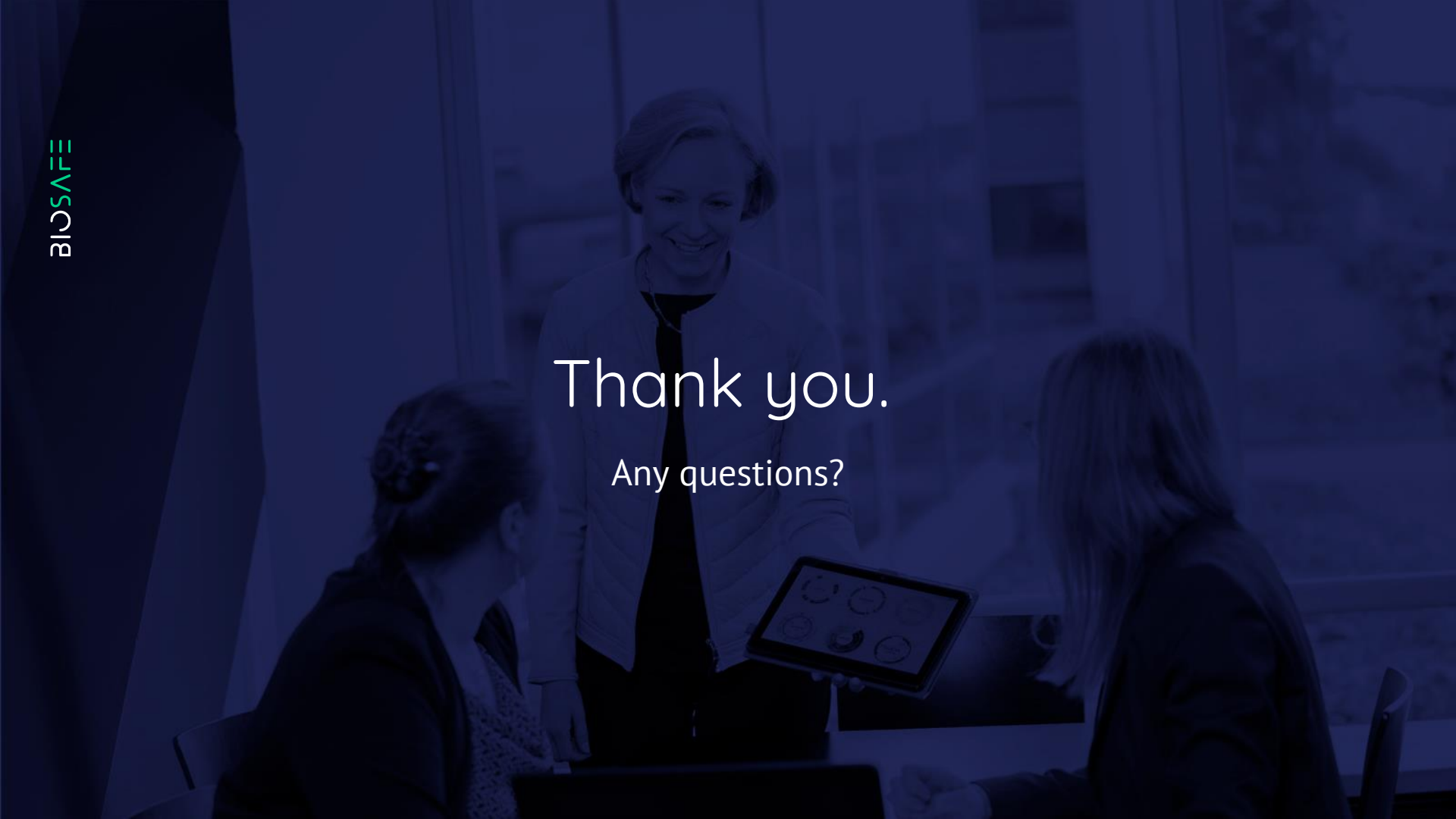
QPS – Qualified presumption of safety

Microorganisms with QPS status require less data on potential risks (no toxicological studies)

The following are assessed at a taxonomic unit (species) level:

- taxonomic identity
- body of knowledge
- potential safety concerns (including acquired antimicrobial resistance - for bacteria)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Thank you.
Any questions?