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NAVIGATING IN THE FOOD AND FEED REGULATORY JUNGLE

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AGENDA

Welcome

Bridging boundaries: EU food and chemical legislation interconnections

- Iida Saarela, Sweco Finland

How do I prepare for launching a new food or feed ingredient by exploring its EU regulatory positioning and regulation requirements?

- Mari Eskola, Medfiles

Microbes on the menu: Bringing regulated innovations to market

- Pauliina Halimaa, Biosafe - Biological Safety Solutions

Case example: A novel food authorisation procedure

- Elisa Arte, Enifer

Thank you and contacts

FOOD 2.0 ECOSYSTEM – NOVEMBER 2025

AND LINKS TO THE OTHER VETURI COMPANIES

ENERGY AND TRANSPORT

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Patria eALLIANCE
st1
Kuljetusliike Järvimäki Oy
Suomen Lantakaasu
XYLO GAS
WÄRTSILÄ ZERO EMISSION MARINE 2030
nokian TYRES FUTUREPROOF
NESTE Novel sustainable & scalable solutions for transportation and chemicals

MATERIALS AND CHEMICALS

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KAPASITY
AB Enzymes
WOODGROW
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FOOD AND FEED, PROCESS TECHNOLOGY

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linseed
Lantmännen
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AISTILA
Alimetrics RESEARCH
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ALUKE
BioName DNA analyses as turnkey solutions
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eurofins
KeinoX
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Food 2.0 ecosystem: Energy, Food, Materials, Feed; water, nitrogen, carbon, phosphorus; Animal-based, Plant-based, Cell-based

DIGITAL, DATA, AI

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code.
ORION A Digital Boost for the Pharmaceutical R&D
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kpedu
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TF TAK
RUOKAVIRASTO Livsmedelsverket • Finnish Food Authority
SAVONIA
SOKERIJUURIKKAAN TUTKIMUSKESKUS
Sven Hallinin tutkimussäätiö

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BUSINESS FINLAND
Maa- ja metsätalousministeriö
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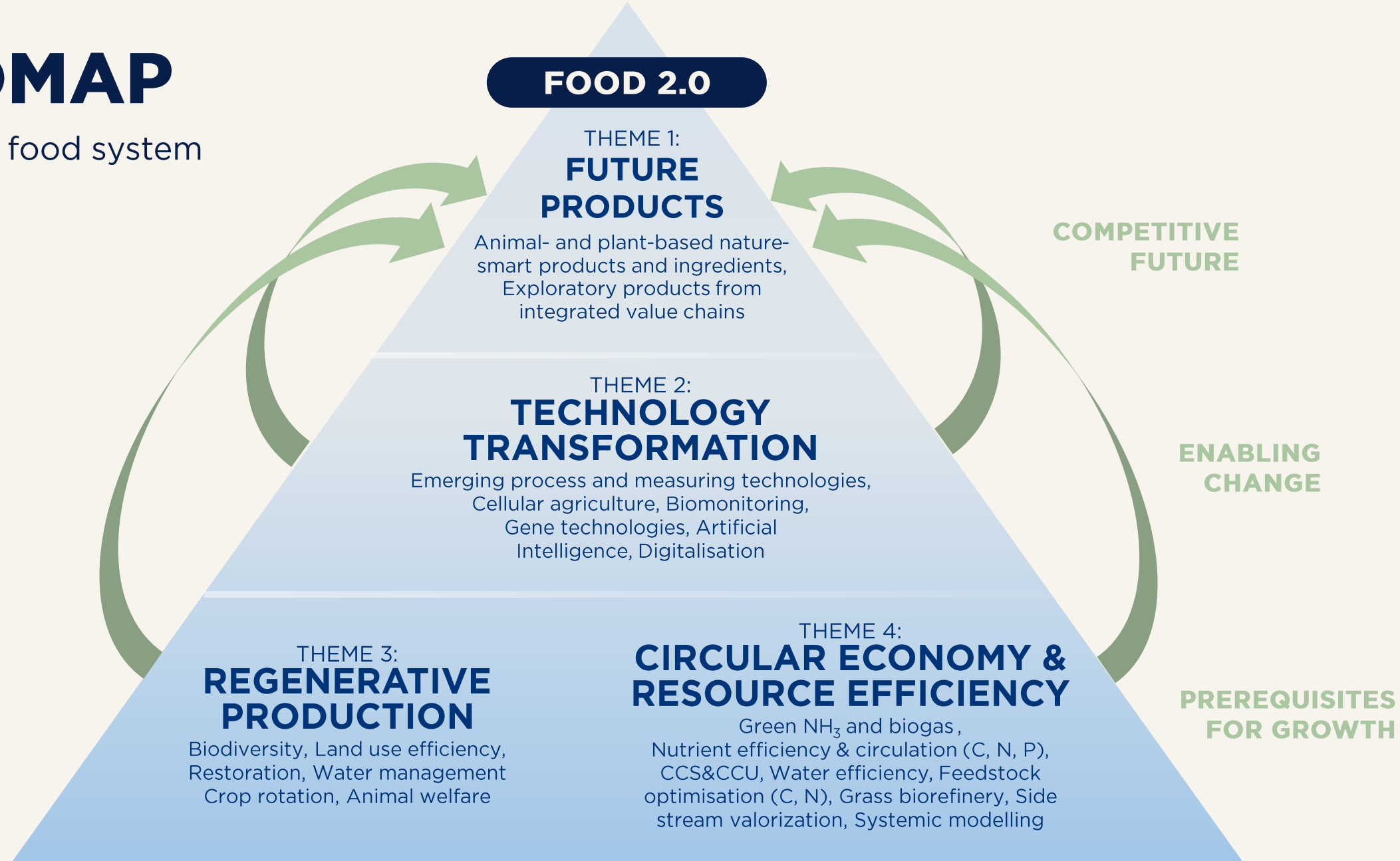
ORGANIZATIONS

BSAG Baltic Sea Action Group
ETL
ETT
MTK
ProAgria
KEHITTYVÄ ELINTARVIKE
SLC
ETELÄ-POHJANMAAN LIITTO Regional Council of South Ostrobothnia
ETS ELINTARVIKETIETEIDEN SEURA RY
SALAOJITUKSEN TUTKIMUSYHDISTYS RY
DYNAMO Närpes
Pyhäjärvi-instituutti
AgriFood
Satafood
PIETARSAAREN SEUTU JAKOBSTADSREGIONEN
into SEINÄJOKI
Posintra
BUSINESS VANTAA
ROVANIEMI

ROADMAP

Nature-smart food system



BRIDGING BOUNDARIES: EU FOOD AND CHEMICAL LEGISLATION INTERCONNECTIONS

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Bridging boundaries: EU food and chemical legislation interconnections

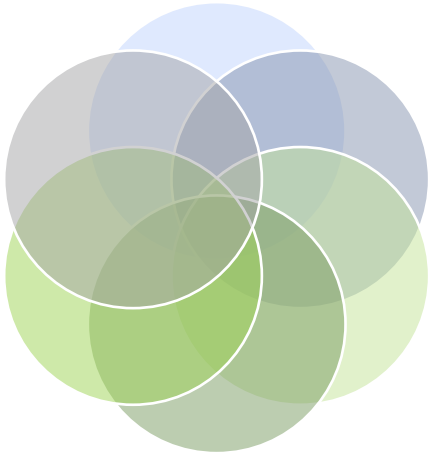
Iida Saarela
Legal Specialist
Sweco

Chemical and food legislation in a nutshell

Chemicals

Food Contact Materials

Biocides



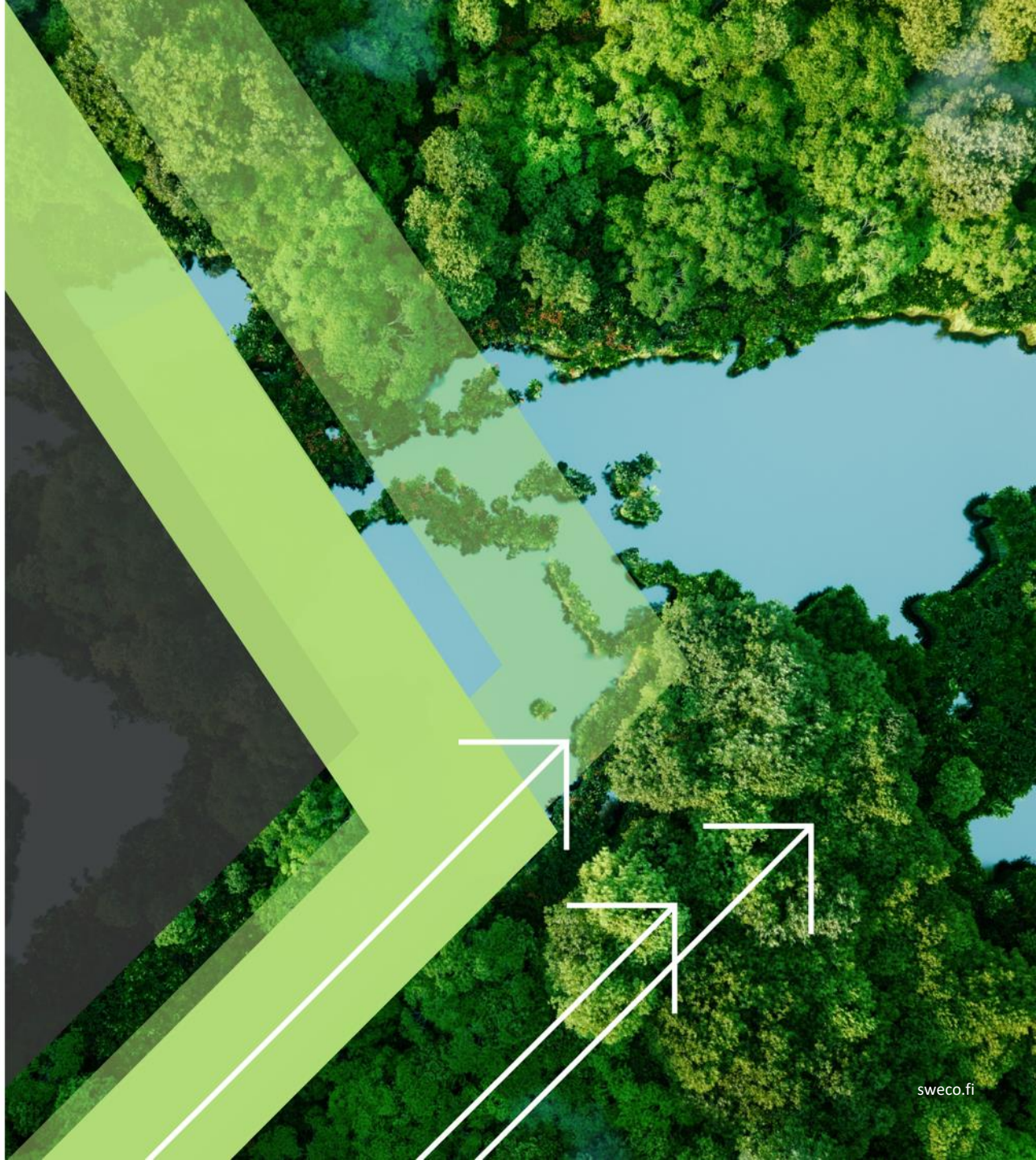
Food additives, entsymes

Novel Food

Food and feed

Chemical and food legislation in a nutshell

- Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)
- Regulation(EU) No 528/2012 of the European parliament and of the Council concerning the making available on the market and use of biocidal products (BPR)
- Regulation (EC) No 178/2002 of the European Parliament and of the Council laying down the general principles and requirements of food law
- Regulation (EC) No 1935/2004 of the European Parliament and of the Council on materials and articles intended to come into contact with food
- Regulation (EC) No 1333/2008 of the European Parliament and of the Council on food additives
- Regulation (EU) 2015/2283 of the European Parliament and of the Council on novel foods
- Regulation (EC) No 1332/2008 of the European Parliament and of the Council on food enzymes
- etc



Collisions of legislation

- While many regulations govern different scopes; they also have a lot of overlap.

- Couple of examples:
  1. REACH exemptions
     - As a basic principle, REACH exempts food and feed from its scope (*Art 2.5*.).
     - However, not all exceptions come directly from the Regulation → E.g. enzymes are not considered as food directly according to the Food Regulation 178/2002. However, the inclusion of enzymes in the food definition can only be found in the preamble of the Enzyme Regulation. → Enzymes are exempted from REACH

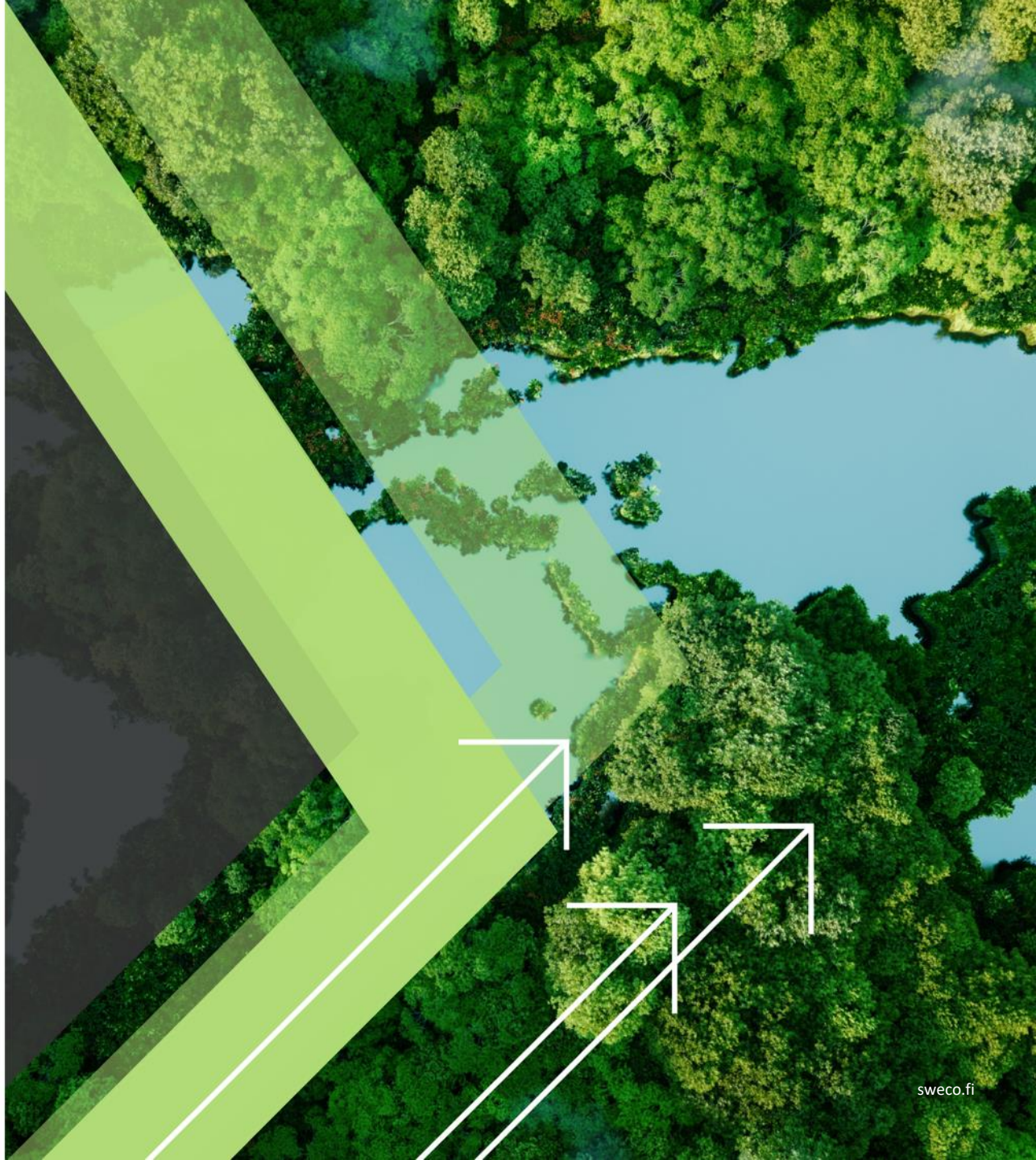
Collisions of legislation

2. Situation when a new food is invented from side stream
   - Preparing food from atypical raw material → under Novel food Regulation versus REACH.

3. The case of Ethanol
   - Ethanol is currently an active substance under BPR.
   - The proposal of the working group for reviewing the classification was to classify Ethanol as a CMR substance category 1A or 1B. → Indirect but severe impact also on food industry.
   - Originating from a procedure according to product- specific BPR, ethanol is at risk to disappear from the market for more than BPR-related applications

What to do?

- Define whether your material is food, additive, enzyme, a chemical under REACH, or something else?
- Familiarize yourself with the relevant regulations.
  - In food sector, it is also necessary to know relevant chemical law regulations; be aware of the chemical's restrictions in case you use them in your food production
- Authorities and external specialists help operators with compliance



Food and product safety services

Food and FCM Safety and Compliance

Self-monitoring and management systems (HACCP, ISO 22000)

Company-specific food legislation monitoring

Safety assessments of food contact materials (FCM)

Declaration of Compliance (DoC) for food contact materials

Product Safety

Biocides, RoHS, Battery Regulation, Drinking Water Directive (DWD), General Product Safety Regulation (GPSR)

Cosmetic safety assessments and CPNP notifications

Safe and Sustainable by Design (SSbD)

Toxicological and ecotoxicological assessments

Chemical Legislation and Registrations

REACH and CLP obligations

Registrations and notifications (PCN, SCIP)

Safety data sheets and classifications

Consortium management and permit procedures

BPR authorizations

Legal Services and Regulatory Advice

Legislative reviews and statements

Permit processes and appeals

Legal overviews and training

REACH and food legislation monitoring services

Thank you for your attention!

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HOW DO I PREPARE FOR LAUNCHING A NEW FOOD OR FEED INGREDIENT BY EXPLORING ITS EU REGULATORY POSITIONING AND REGULATION REQUIREMENTS?

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HOW DO I PREPARE FOR LAUNCHING A NEW FOOD OR FEED INGREDIENT BY EXPLORING ITS EU REGULATORY POSITIONING AND REGULATORY REQUIREMENTS?

Navigating in the food and feed regulatory jungle webinar / Valio 2.0

Mari Eskola, Senior Regulatory Affairs Expert; Team leader Regulatory Science and Reports

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WHY REGULATORY POSITIONING IS IMPORTANT?

Companies / distributors are well aware of regulations, e.g. novel food regulation

→ Inquiries of regulatory status
→ Statements / documents on regulatory status

Unauthorised / not registered food or feed ingredients on the market are illegal

→ Withdrawal
→ Enforcement; Rapid Alert System for Food and Feed (RASFF) notification

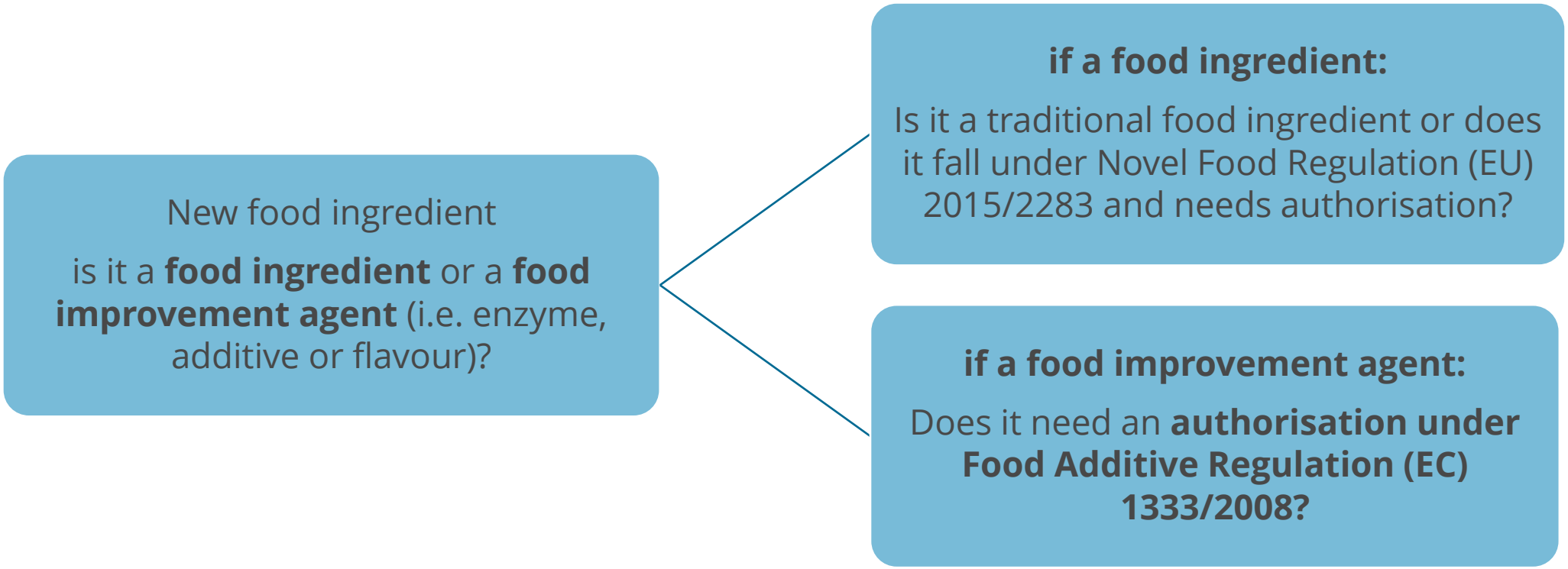
Business plans can be done to correct direction

- fundings, resources

→ It is essential to evaluate and define the regulatory positioning of a new ingredient

REGULATORY POSITIONING OF A NEW FOOD INGREDIENT (1)

- It is the responsibility of food/feed business operator (FBO) to clarify the regulatory positioning of their new food ingredient under EU law



TRADITIONAL VS. NOVEL FOODS

NOVEL FOOD REGULATION (EU) 2015/2283: KEY DEFINITIONS

- **Novel food'** means any food that was not used for human consumption **to a significant degree** within the Union **before 15 May 1997**, irrespective of the dates of accession of Member States to the Union
- **'Traditional food from a third country'** is a novel food derived from primary production (plants/animals/micro-organisms etc., processed/unprocessed) with a history of safe use in a third country.
    - **'History of safe food use in a third country'** means that the safety of the food in question has been confirmed with **compositional data** and from **experience of continued** use for at least **25 years** in the customary diet of a significant number of people in at least one third country."

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A 1st Finnish example: DEFATTED RAPESEED POWDER IN THE UNION LIST OF NOVEL FOODS (Regulation (EU) 2017/2470) (1)

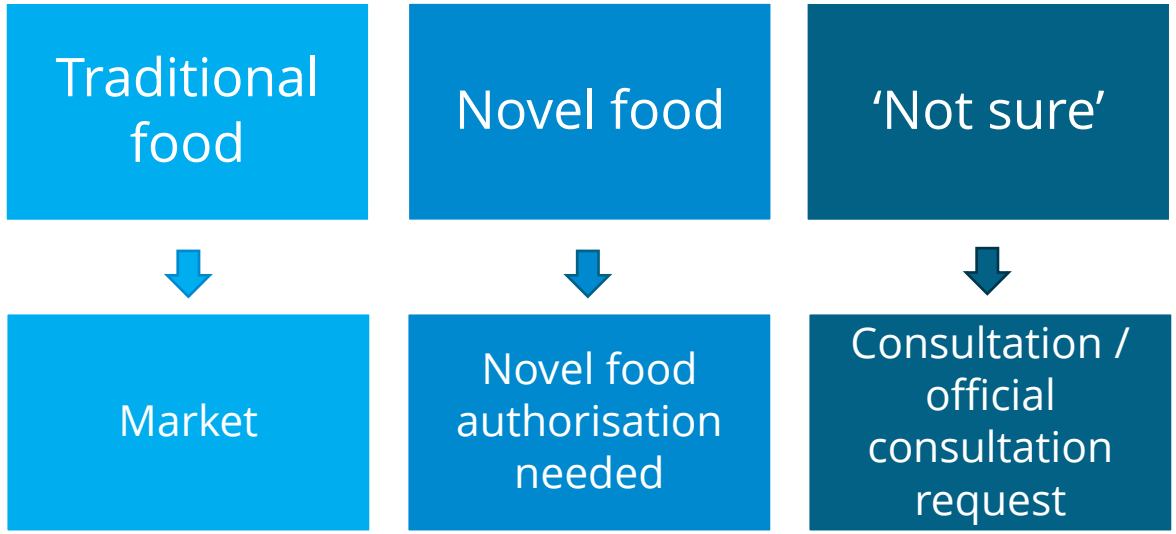
	Specified food category	*Maximum levels*	
Partially defatted rapeseed powder from *Brassica rapa* L. and *Brassica napus* L.	Cereal bars mixed	20 g/100 g	The designation of the novel food on the labelling of the foodstuffs containing it shall be 'Partially defatted Rapeseed powder'. Any foodstuff containing 'Partially defatted Rapeseed powder' from *Brassica rapa* L. and *Brassica napus* L.' shall bear a statement that this ingredient may cause allergic reaction to consumers who are allergic to mustard and products thereof. That statement shall appear in close proximity to the list of ingredients.
	Muesli and similar breakfast cereals	20 g/100 g	
	Extruded breakfast cereal products	20 g/100 g	
	Snacks (excluding potato crisps)	15 g/100 g	
	Breads and rolls with added special ingredients (such as seeds, raisins, herbs)	7 g/100 g	
	Brown breads bearing statements on the absence or reduced presence of gluten in accordance with the requirements of Commission Implementing Regulation (EU) No 828/2014	7 g/100 g	
	Multigrain bread and rolls	7 g/100 g	
	Meat substitutes	10 g/100 g	
	Meat balls	10 g/100 g	

DEFATTED RAPESEED POWDER (Regulation (EU) 2017/2470) IN THE UNION LIST OF NOVEL FOODS (2)

Partially defatted rapeseed powder from *Brassica rapa* L. and *Brassica napus* L.	**Definition:** The powder is produced from the partially defatted seeds of non-genetically modified ***Brassica rapa*** L. and ***Brassica napus*** L. double low (00) cultivars through a series of processing steps to reduce glucosinolates and phytates. **Source:** ***Brassica rapa*** L. and ***Brassica napus*** L. seeds **Characteristics/Composition:** Protein (N × 6,25): 33,0-43,0 % Lipids: 14,0 – 22,0 % Total Carbohydrates(*): 33,0 – 40,0 % Total Fibre(**): 33,0 – 43,0 % Moisture: < 7,0 % Ash: 2,0–5,0 % Total Glucosinolates: < 0,3 mmol/kg (≤ 120 mg/kg) Phytate: < 1,5 % Peroxide value (in novel food weight): ≤ 3,0 mEq O_2/kg **Heavy Metals:** Lead: < 0,2 mg/kg Arsenic (inorganic): < 0,2 mg/kg Cadmium: < 0,2 mg/kg Mercury: < 0,1 mg/kg Aluminium: < 35,0 mg/kg **Microbiological criteria:** Total plate count (30 °C): < 5 000 CFU/g ***Enterobacteriaceae***: < 10 CFU/g ***Salmonella*** sp.: Negative/25 g Yeast and mould: < 100 CFU/g ***Bacillus cereus***: < 100 CFU/g (*) By difference: 100 % – [protein % + moisture % + fat % + ash %] (**) AOAC 2011.25 (Enzymatic gravimetry) CFU: Colony Forming Units, AOAC: Association of Official Agricultural Chemists

REGULATORY POSITIONING OF A NEW FOOD INGREDIENT

- Always **case-by-case evaluation**
  - The key point: significant use by humans in the EU prior to 15 May 1997
  - Searches in
    - Union list of novel foods (Regulation (EU) 2017/2470)
    - Consultation request statements for novel foods (EC website)
    - EC Novel food status catalogue (EC website)
    - Other public lists in the EU and Member States
  - Internal investigations from the literature etc.



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OFFICIAL CONSULTATION PROCESS TO DEFINE THE NOVEL FOOD STATUS

Consultation request to authorities

- If the company is unsure on the food's novel food status, the company may compile a consultation request the Member State where they first intend to place the novel food, in accordance with Regulation (EU) 2018/456
- After validation - legal timeline 4 months (+ 4 months)
- Member States may consult the other Member States and the Commission
- The result will be published on Commission's website, i.e. it is public

By 14 November 2025, **175 published results**:

- **~65 non-novel foods**
- **~90 novel foods**

Note! Some novel foods are not novel foods if used in food supplements

2nd EXAMPLE FROM CONSULTATION REQUEST PROCEDURE: NOT NOVEL

Hard tissue mass from Atlantic salmon (Salmo salar) or from Rainbow trout (Oncorhynchus mykiss)	6 December 2023	Not Novel

Hard tissue mass is produced from the side-stream material of fish filleting production of Atlantic salmon or rainbow trout. The raw material is typically the fish bones together with fish flesh leftovers together with fins and fish head. The bone content of the hard tissue mass is approximately 70 %. The fish hard tissue mass is not to be eaten as such but is further processed with other traditional ingredients into a softer paste. The content of hard tissue mass in the paste is 70 %. The paste is intended to be used as an ingredient in processed foods.

Status

Not novel.

Reasons statement

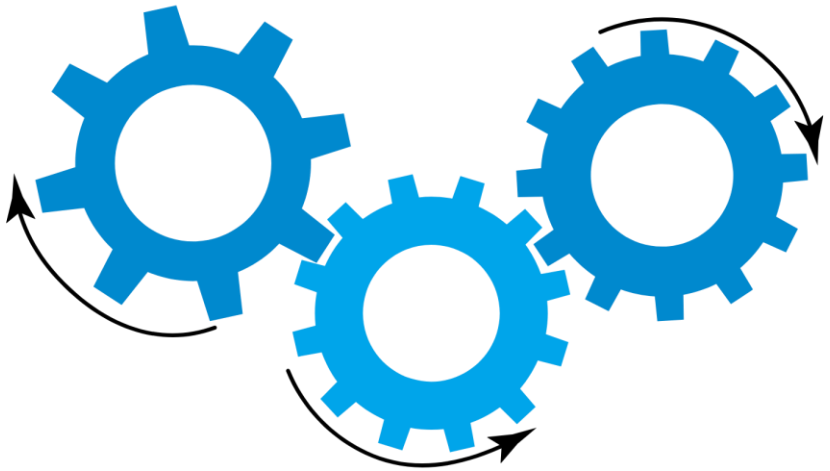
The competent authorities of the EU Member States and the European Commission were consulted.

Atlantic salmon (*Salmo salar*) and rainbow trout (*Oncorhynchus mykiss*) have been used as food to a significant degree in Europe and have also been used extensively in the production of various fish products for a long time before 1997. For example, fish bones have been used in the production of gelatin, collagen and fish stock. Different fish with bones have also been eaten in various EU Member States as such (e.g. vendace, herring, sardine or mackerel) or as minced to prepare fish loafs or fish balls. In addition, bone powder produced from the bones of Atlantic salmon (*Salmo salar*) was concluded to be *not novel* by the Norwegian Food Safety Authority. The bone powder, like fish hard tissue mass in question, is produced from the side-stream material of salmon filleting production, which includes the bones of the fish.

WHAT DOES IT MEAN IF A NEW INGREDIENT IS CLASSIFIED AS A NOVEL FOOD?

- Safety of the product need to be demonstrated extensively
- Authorisation procedure of a novel food
  - Novel food application / notification
  - EFSA risk assessment
  - Commission risk management

  → authorisation



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FEED MATERIALS VS. FEED ADDITIVES

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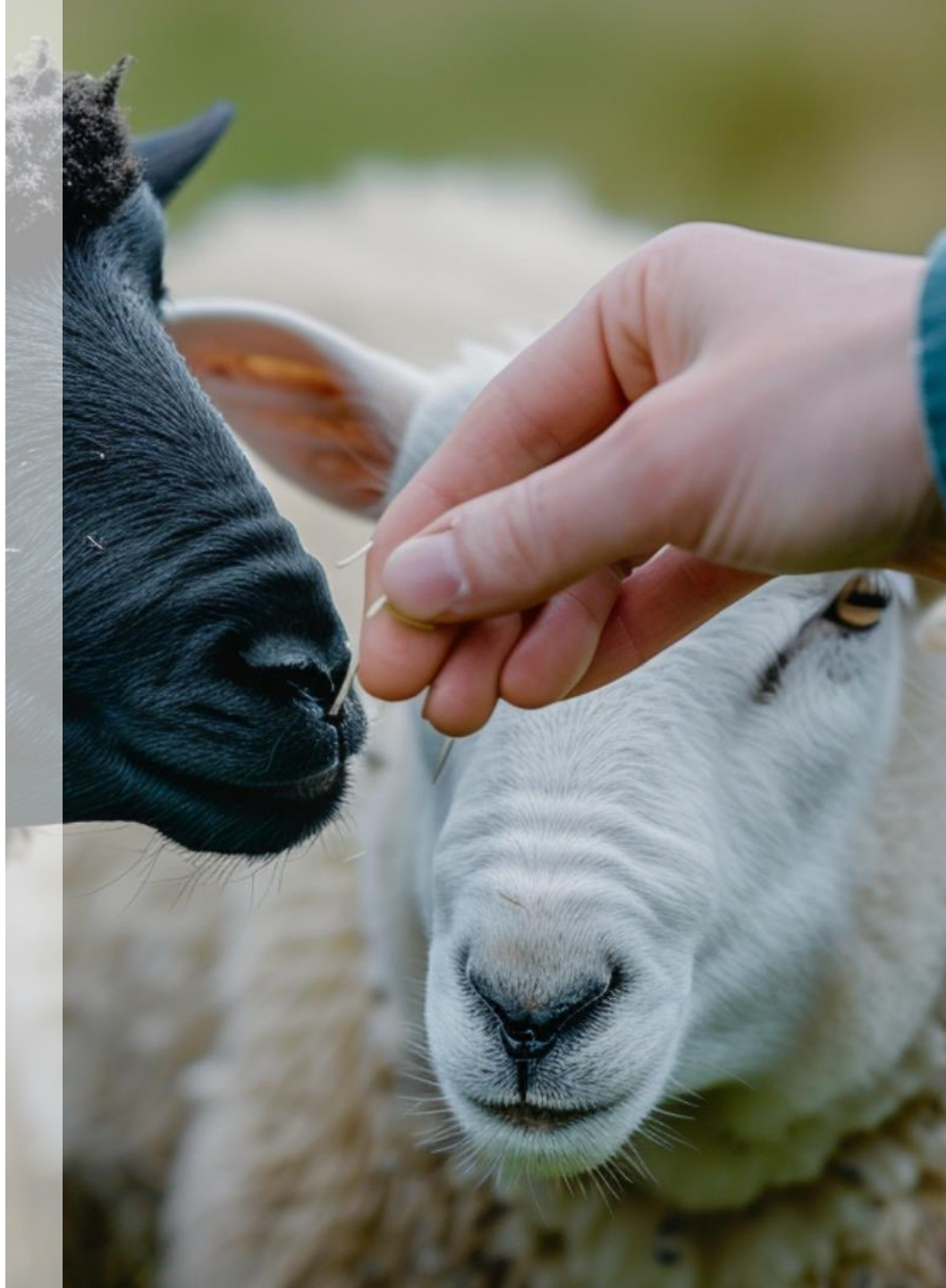
REGULATORY POSITIONING OF A NEW FEED INGREDIENT (2)

- NEW FEED INGREDIENT
  - Is it **a feed material** or **a feed additive**?
    if a feed material →
    - Is it a registered feed material in accordance with Regulation (EC) 767/2009 or does is need safety assessment and registering?

    if a feed additive →
    - Does it need an authorisation under Feed Additive Regulation (EC) No 1831/2003?



FEED REGULATION (EC) No 767/2009 AND FEED ADDITIVE REGULATION (EC) No 1831/2003: KEY DEFINITIONS

- **Regulation (EC) No 767/2009:**

'*Feed materials' means products of vegetable or animal origin, whose principal purpose is to meet animals' nutritional needs*, in their natural state, fresh or preserved, and products derived from the industrial processing thereof, and organic or inorganic substances, whether or not containing feed additives, which are intended for use in oral animal-feeding either directly as such, or after processing, or in the preparation of compound feed, or as carrier of premixture

- **Regulation (EC) No 1831/2003:**

'Feed additives' means substances, micro-organisms or preparations, other than feed material and premixtures, which are *intentionally added to feed or water in order to perform*, in particular, one or more of the *functions…:*

(a) technological additives:

(b) sensory additives (improves the organoleptic properties or the visual characteristics;

(c) nutritional additives;

(d) zootechnical additives: any additive used to affect favourably the performance of animals in good health or used to affect favourably the environment;

(e) coccidiostats and histomonostats

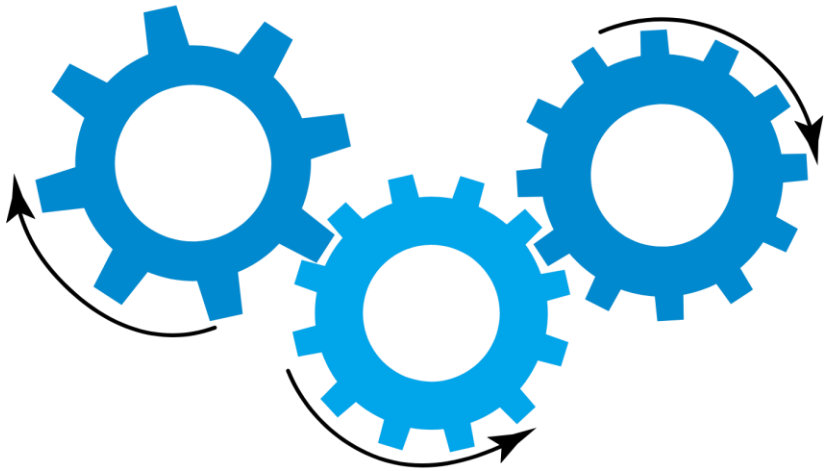
WHAT DOES IT MEAN IF A NEW INGREDIENT IS CLASSIFIED AS A **FEED MATERIAL**?

- To be checked it does not contain or consist of prohibited materials, e.g.
  - Wood, including sawdust or other materials derived from wood, which has been treated with wood preservatives as defined in Annex V to Directive 98/8/EC concerning the placing of biocidal products on the market
  - Solid urban waste, such as household waste.
- Safety of the product need to be demonstrated and documentation saved in-house
- A notification to Feed Material Register maintained by European feed business sector

WHAT DOES IT MEAN IF A NEW INGREDIENT IS CLASSIFIED AS A **FEED ADDITIVE**?

- Safety and efficacy of the feed additive need to be demonstrated extensively
- Authorisation procedure of a feed additive
  - Feed additive application
  - EFSA risk assessment
  - Commission risk management

  → authorisation



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THANK YOU!

TIME FOR QUESTIONS

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MICROBES ON THE MENU: BRINGING REGULATED INNOVATIONS TO MARKET

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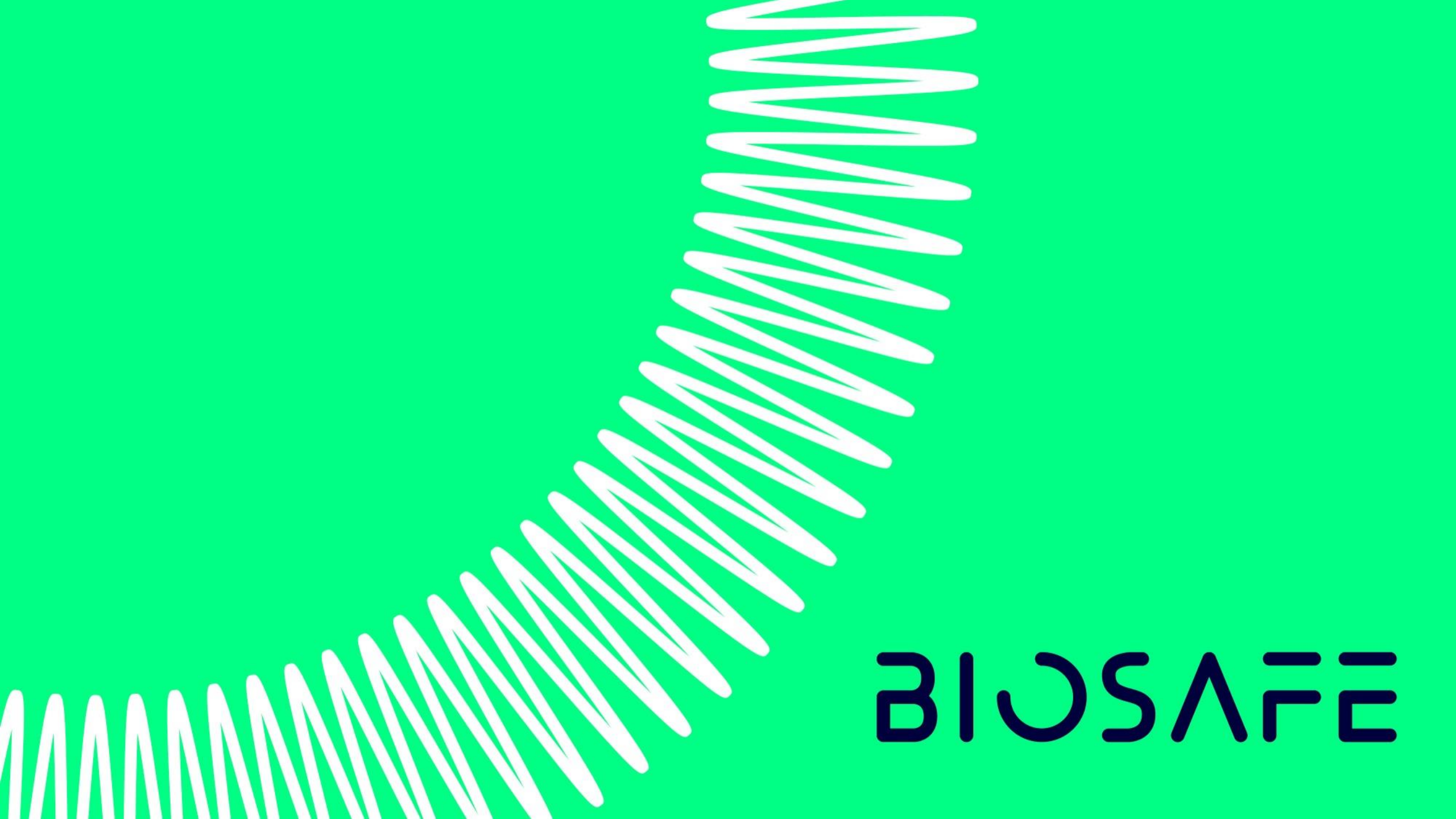
BIOSAFE

BIOSAFE

Bringing a novel food or feed product to market is complex. You need scientific, regulatory, and laboratory expertise aligned with both EFSA and FDA.

That’s where Biosafe comes in.

- One team.
- One process.
- From genome to global launch.

Microbes on the menu: Bringing regulated innovations to market

Pauliina Halimaa 24.11.2025

BIOSAFE

EU Regulatory pathways

1. **Novel foods**
   Regulation (EU) 2015/2283
2. **Food additives**
   Regulation (EC) No 1333/2008
3. **Food flavourings**
   Regulation (EC) No 1334/2008
4. **Feed additives**
   Regulation (EC) No 1831/2003
5. **Feed materials**
   Regulation (EC) No 767/2009
6. **Genetically modified food**

Guidance documents for each sector

One guidance for all microorganisms used in the food chain

- Active agents
  - A genetically modified (GM) or a non-GM microorganism capable of multiplication, used as such in product
- Biomass
  - Produced from a GM or a non-GM microorganism, cells inactivated
- Production strain
  - GM or a non-GM microorganism that produces substances of interest ('product'), microorganism removed

Adopted: 24 September 2025

DOI: 10.2903/j.efsa.2025.9705

efsa JOURNAL

GUIDANCE

Guidance on the characterisation of microorganisms in support of the risk assessment of products used in the food chain

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Abstract

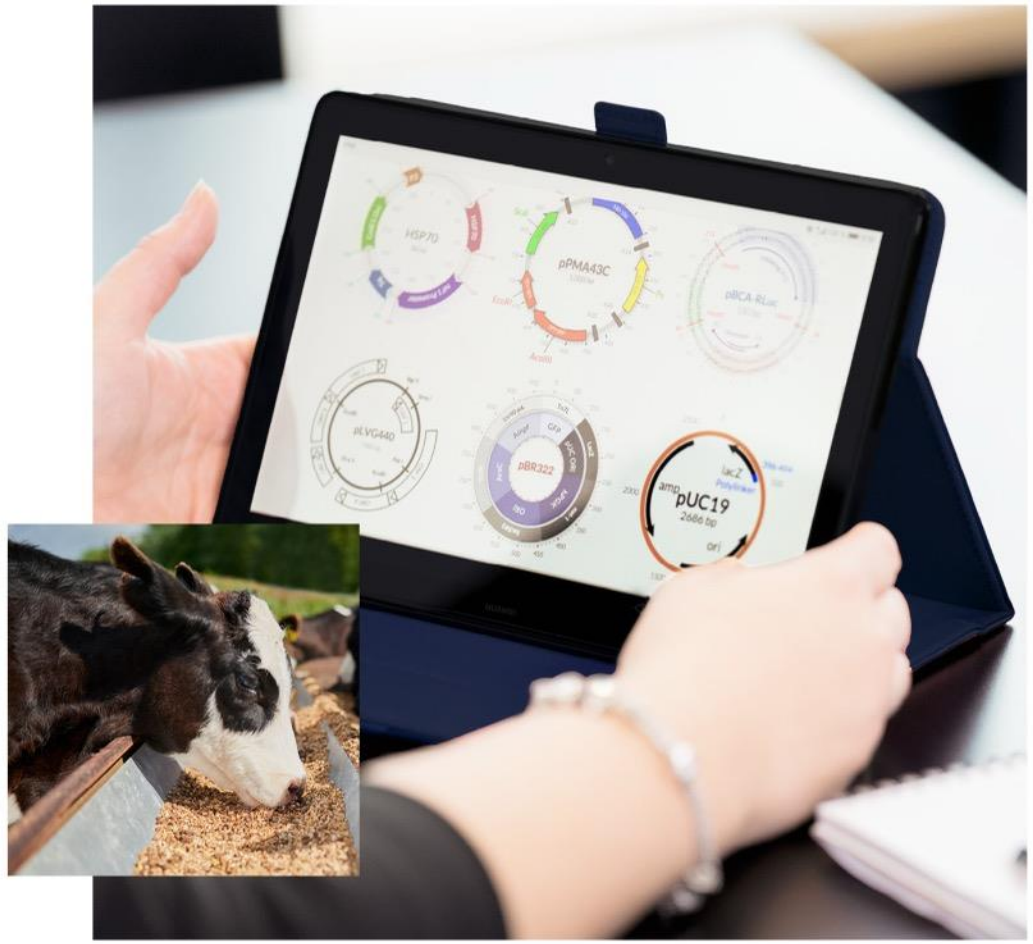
This document provides guidance to assist in the preparation of applications for regulated products to be used in the food chain containing, made from or produced by using microorganisms, genetically modified or not, that are subject to risk assessment within EFSA's remit before their placement on the EU market. This guidance focuses on the scientific requirements to characterise the microorganisms and, to some extent, their products. It provides the basis for hazard identification in support of the risk assessment of microorganisms and establishes the data requirements to conduct the risk assessment.

KEYWORDS

food chain, hazard, microorganisms, regulated products, risk assessment

1. Taxonomic identification

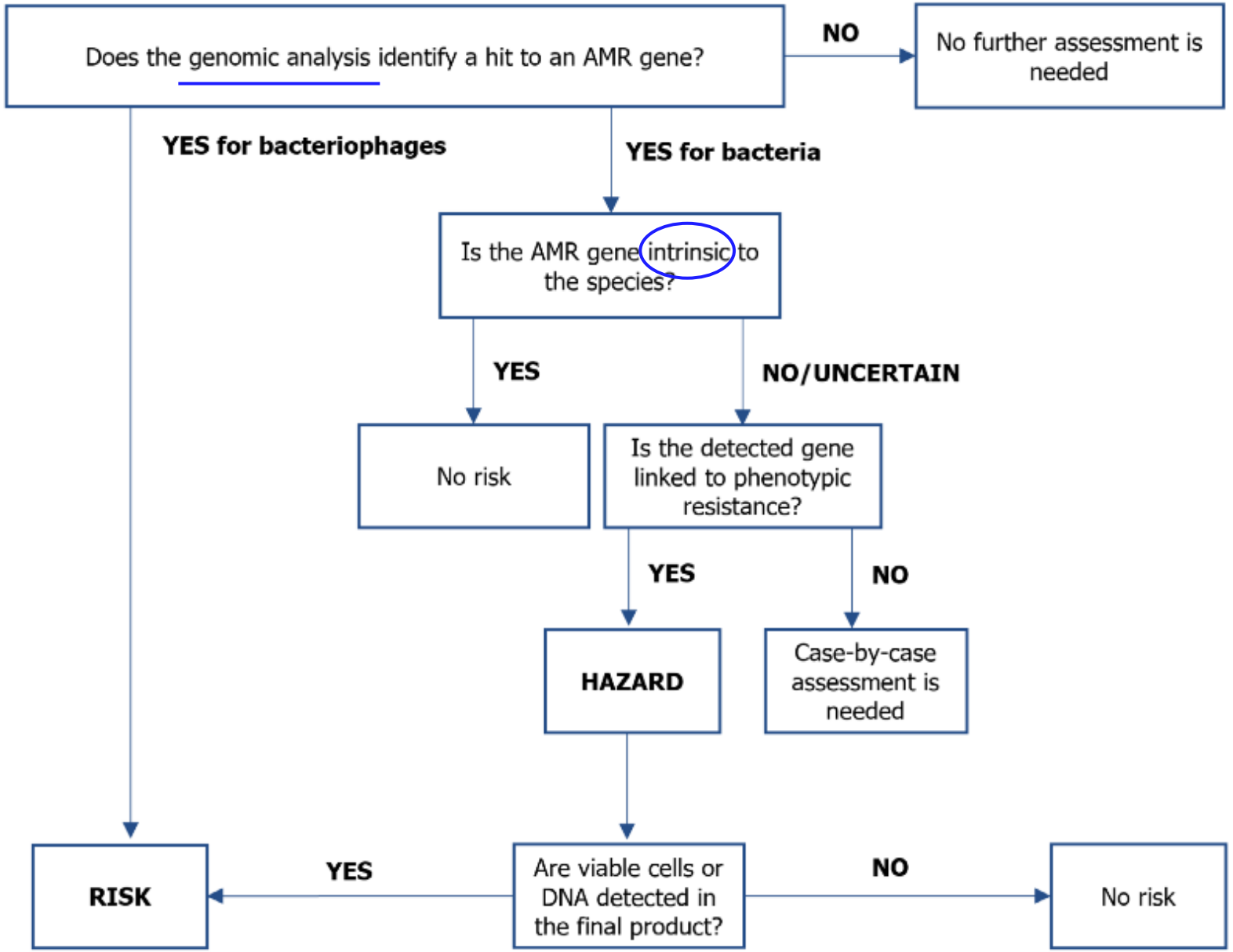
- Bacteria, yeasts, filamentous fungi and viruses
  - ➢ Whole genome sequencing
- Microalgae and other protists
  - ➢ Combination of morphological and DNA sequencing information of selected genetic markers



2. Antimicrobial resistance

Yeasts and filamentous fungi used as active agents: phenotypic testing to find treatment options

Bacteria and bacteriophages: risk for horizontal gene transfer



3. Production of antimicrobial substances

- WGS-based assessment
  - If the presence of gene clusters involved in the biosynthesis of therapeutic antimicrobials is detected, the antimicrobial compound(s) should be quantitatively analysed

AND

- Phenotypic tests
  - If antimicrobial activity is observed, exclude the production of therapeutic antimicrobials

4. Toxigenicity and pathogenicity

- Bacteria
  - WGS
  - Special cases: *Bacillus*, *Enterococcus faecium* and *Enterococcus lactis*
- Yeasts and filamentous fungi
  - Literature search + WGS
- Viruses
  - Host range/infectivity, for bacteriophages also WGS
- Microalgae and other protists
  - Literature search

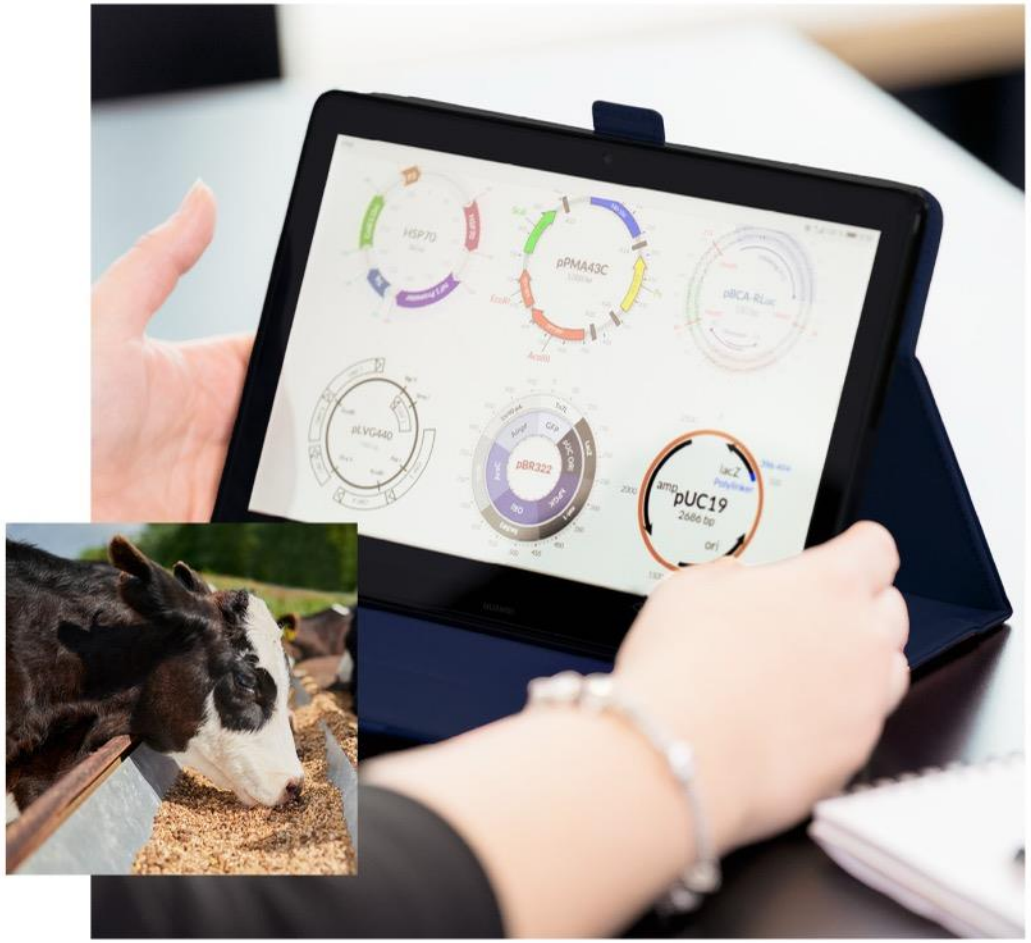
➢ If hazards identified, phenotypic testing, toxicological studies case by case

5. Genetic modifications

- Description of inserted sequences and other modifications (deletions, substitutions, frameshift mutations, and their intended effect
- Structure of the modification by comparison with parental strain

- Further details in *EFSA statement on the requirements for whole genome sequence analysis of microorganisms intentionally used in the food chain, 2024*

  https://www.efsa.europa.eu/en/efsajournal/pub/8912



6. Presence of viable cells and DNA in the final product

- **Presence of viable cells**
  - For biomasses, fermentation products and bacteriophages
  - Culture-based method
  - On solid medium
  - Method should consider the recovery of stressed cells, contaminating microorganisms and spore formation
  - Positive (the strain must grow in the presence of the concentrated sample) and negative controls
- **Presence of DNA**
  - For biomasses, fermentation products and bacteriophages where the production strain carries genes of concern, GM production strains
  - PCR method
  - Positive and negative controls
    - Check factors causing PCR inhibition
  - Semi-quantitative PCR: DNA spiked in samples in different dilutions to calculate the limit of detection
    - LOD ≤ 10 ng/ g or mL of product

Part of the dossier

Table 1: Information required in the technical dossier and recommended format for novel food applications

CONTENT OF THE TECHNICAL DOSSIER	INFORMATION TO BE PROVIDED	EXPECTED ACTION	FORMAT
Pre-application information	Pre-application ID(s)	Insert all relevant pre-application ID(s) received by EFSA in the pre-submission phase for the novel food which is the subject matter of the application.	Free text
	Information on studies that have been notified in EFSA's database of study notifications, but not submitted in the application	Insert study ID generated by EFSA's database of study notifications for each study notified, and justification for non-inclusion in the application, if relevant.	Free text
Identity of the novel food	Identity and description of the novel food according to the classification proposed by the NDA Panel.	Upload a file containing the main text of the section.	PDF
The production process	Detailed description of the production process. Measures of production control and quality and safety assurance. Flow chart of production process.	Upload a file containing the main text of the section.	PDF
Compositional data	Characterisation of the novel food. Qualitative and quantitative data on the composition. Information on impurities/contaminants and stability of the novel food.	Upload a file containing the main text of the section.	PDF
Specifications	Key parameters that characterise the novel food. Limits and information on the method of each selected parameter. Rationale for the selected parameters.	Upload a file containing the main text of the section.	PDF
The history of use of novel food and/or its source	Comprehensive literature review on history of use and human studies on relevant safety outcomes. Information on the search strategy used to retrieve the studies.	Upload a file containing the main text of the section.	PDF
The proposed use(s) and use levels and anticipated intake	Target population. Form of uses, food categories, maximum amounts as consumed. Anticipated and Combined intake of the novel food from other sources. Exposure to undesirable substances and Precautions and restrictions of use.	Upload a file containing the main text of the section.	PDF

Thank you!

Questions?

CASE EXAMPLE: A NOVEL FOOD AUTHORISATION PROCEDURE

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FOOD2.0 | Valio

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Valio
THANK YOU
Have a great day!