AMFEP experience with development of guidance documents

Dr Céline Benini
AMFEP Secretary General

EFSA Stakeholder Forum

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AMFEP is the representative association of the European enzyme industry

Members of AMFEP produce and sell enzymes for use in **food**, **feed**, **detergents** and other **non-food industries.**

27	15	80%	90%
members	EU turnover < 10Mio euro	of the global enzymes market	of the European enzymes market

AMFEP | Association of Manufacturers and Formulators of Enzyme Products

Our main partners:

A·I·S·E   FOODDRINK EUROPE   EuropaBio   fedima   aci   FEFANA

AMFEP members

Full members

AB Enzymes — an ABF Ingredients company

Eat Well, Live Well. Aj AJINOMOTO.

AMANO

BASF — We create chemistry

BIOCATALYSTS

bioseutica

biovet PESHTERA

c-LEcta — for tomorrow's industry

CAGLIFICIO CLERICI

dsm-firmenich

Enzybel — The Reference for Natural Enzyme Solutions

ERBSLÖH — Fortschritt macht Zukunft

evoXX — a division of advanced enzymes

iff

KERRY

LALLEMAND

NAGASE

novonesis

ORBA

puratos — Food Innovation for Good

GROUPE Soufflet

SternEnzym — The Enzyme Designer

 Is

TAKABIO — Bio solutions for life

tega ferm

Associated members

BDF — Smart Food · Better Health · Active Life

Linzyme
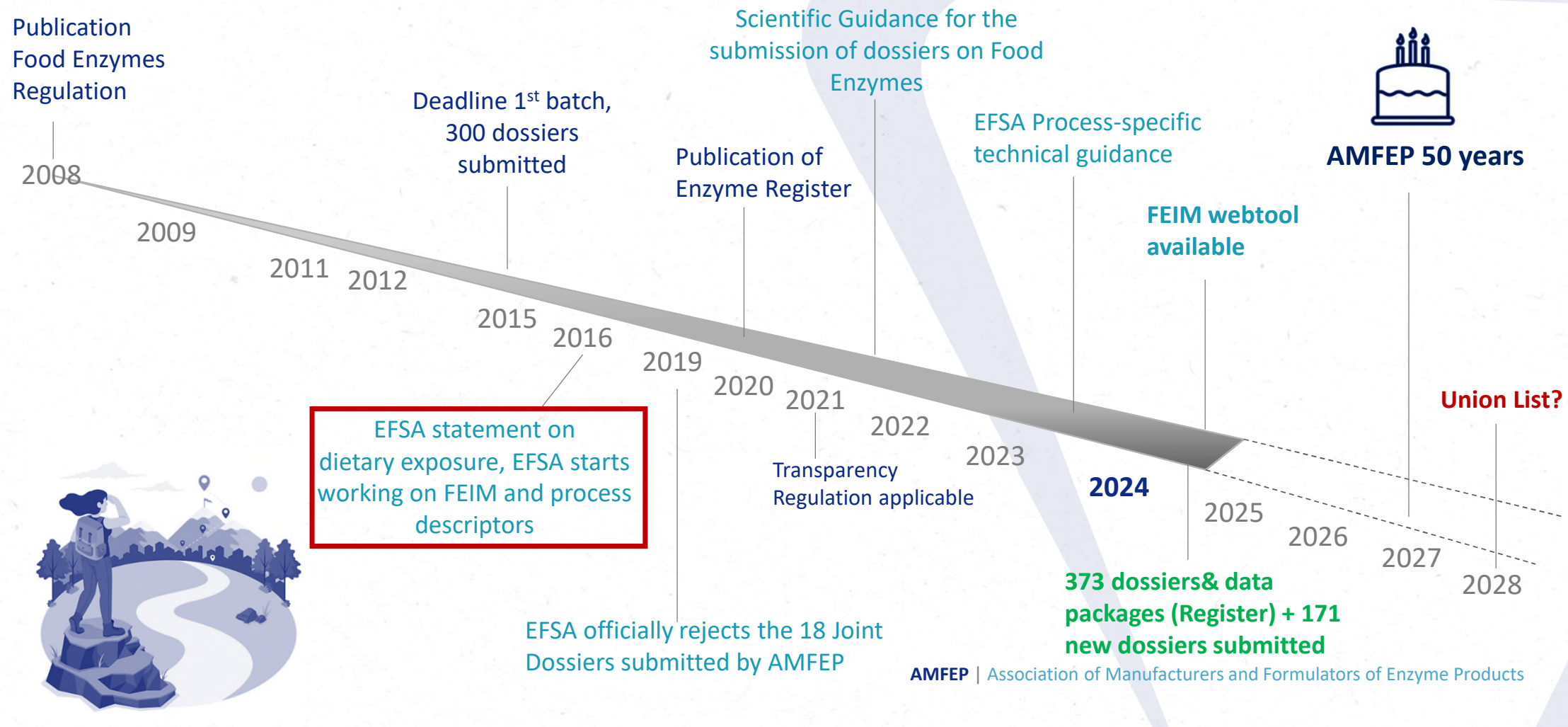
Companies only!

The Food Enzymes Regulation journey in the EU

Note: pending the Union List, enzymes can be legally placed on the market according to existing national laws and GFL provisions

Publication Food Enzymes Regulation

2008

2009

2011

2012

2015

2016

Deadline 1st batch, 300 dossiers submitted

EFSA statement on dietary exposure, EFSA starts working on FEIM and process descriptors

2019

2020

2021

2022

2023

Publication of Enzyme Register

Transparency Regulation applicable

EFSA officially rejects the 18 Joint Dossiers submitted by AMFEP

Scientific Guidance for the submission of dossiers on Food Enzymes

EFSA Process-specific technical guidance

FEIM webtool available

2024

2025

2026

2027

2028

373 dossiers& data packages (Register) + 171 new dossiers submitted

AMFEP 50 years

Union List?

AMFEP | Association of Manufacturers and Formulators of Enzyme Products

Since 2008... Not always an easy ride...

Many changes → high level of adaptation needed

AMFEP tried to make the best out of it!

Our 'recipe' for good collaboration

Mutual trust established over the years, based on science

Continued efforts to address both EFSA and the Commission coherently

Good collaboration

Very good alignment and preparation within AMFEP & with other stakeholders

Clear willingness from both parties to be open about issues

Interactions with EFSA

Case study:

- Food manufacturing processes and technical data used in the exposure assessment of food enzymes (July 2023)

Food manufacturing processes and technical data used in the exposure assessment of food enzymes (July 2023)

▽ Budget method replaced by an alternative assessment methodology in 2016 (link)

▽ EFSA mandating a self-task in 2017

1. Collate technical data for the originally identified 18 food manufacturing processes

2. Develop simple Excel-based exposure calculators for each process (FEIM calculators)

3. Develop a web-based multi-process exposure tool (FEIM-web).

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Food manufacturing processes and technical data used in the exposure assessment of food enzymes (July 2023)

▽ **Two types of calls for data and process**

1. **Building of FEIM**: calls in which EFSA collected data on the process itself from the raw material (which may be treated with enzyme) to the final product (ready for consumer use, on which EFSA has collected consumption data in several Member States).

   - AMFEP alerted of the calls by EFSA

   - AMFEP supported EFSA in identifying the sector associations and contact points

   - AMFEP supported sector associations in better understanding how to answer the calls for data (+ clarification calls with EFSA jointly with sectors)

2. **Transfer of enzymes to food**: to provide data showing there is no TOS remaining in the food (99% removal) → no need for exposure assessment and no need to develop FEIM models.

   - Letter sent to AMFEP by EFSA

   - AMFEP liaised with concerned food sectors

   - Coalitions of AMFEP relevant members and food sector association generated the data (alignment internally and externally + clarification calls with EFSA)

Food manufacturing processes and technical data used in the exposure assessment of food enzymes (July 2023)

▽ **From "annex B" to the guidance on food manufacturing process**

- 8-week public consultation of narrative and its 30 annexes in March 2023 (deadline 9 May 2023)
  - Creation of a dedicated Task Force in AMFEP: several meetings and rounds of comments to agree on the most relevant contribution
    - Priority given to important comments, not details!
  - Encouraging sister associations (incl. users) to contribute
  - Alignment when needed with other associations

- Information session on FEIM on 18 April (foreseen before the launched of the consultation)
  - AMFEP invited to deliver presentation
  - Dedicated Task Force worked on concrete input + reach out to sister associations
  - AMFEP prepared slide decks to discuss the most urgent comments on the document and to address a specific technical concerns already addressed during calls for data
    - Information shared with EFSA well in advance of the event
  - **Open scientific discussion between EFSA and AMFEP leading to better understanding from both sides!**
  - Adaptation of AMFEP comments to the consultation based on the discussion in the event

Food manufacturing processes and technical data used in the exposure assessment of food enzymes (July 2023)

▽ **FEIM webtool**

- Pilot testing with call for interest (around 3 weeks)

  - Only AMFEP members participated (not Secretariat) → technical input from users needed

  - Creating of a Task Force to exchange experience from the testing and agree on the most important messages to convey (on top of individual input)

- In-person workshop on 14 May

  - Only testers attended

  - Agreement in advance in the Task Force about the main messages

For AMFEP, the work on FEIM (and narrative) is one of the best examples of scientific collaboration that the sector ever experienced!

Ideas for further improvement

What could be further improved...
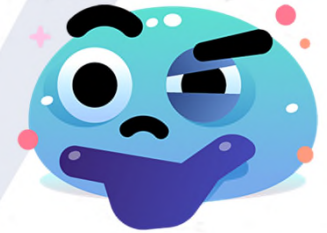
▽ Guidance content:

- Generating data: cost / time >>>
    - Request to **specifically** support risk assessment and clear justification
- Sensitivity of data
    - Certain data are critical from IP/confidentiality viewpoint → they should be required only when there is a **confirmed** need for additional data

▽ Guidance / tools development process

- Discussion / input at the mandate step
- Pilot testing
- Events to discuss applicants' input (allow better understand of every parties' stance)

▽ Scientific advice

- Applicant's assumptions for testing and data generation

Thank you for your attention!

Any questions?

www.amfep.org

amfep@kellencompany.com

+32 (0)2 761 16 77

https://www.linkedin.com/company/amfep