Enzymes and Generic Risk Assessment (GRA)

July 7, 2022

amfep
association of manufacturers & formulators of enzyme products

Participants from AMFEP

[redacted] (AMFEP)

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[redacted] (IFF)

[redacted] (IFF)

[redacted] (AB Enzymes) - online

[redacted] (Novozymes)

[redacted] (Novozymes)

About AMFEP and Enzymes

Introduction to AMFEP and enzymes

AMFEP, is a non-profit European industry association

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

https://amfep.org/about-amfep/

Enzymes are

A special class of **proteins** produced by fermentation.

They **act as catalysts** that speed up the rate of specific chemical reactions

They are used to make and improve nearly 400 everyday consumer and commercial products.

All enzymes are

readily biodegradable and generally exhibit no specific environmental toxicity

Hence, they **are not classified for the environment**.

Enzymes **have an excellent safety profile**, with little ability to cause adverse responses in humans.

AMFEP in numbers

28

Full Members

2

Associated Members

80%

Of the global enzymes market

90%

Of the European Enzymes market

- €more than 50 million (4)
- €10 ~ 50 million (10)
- € below 10 million (14)

Why is AMFEP affected by GRA?

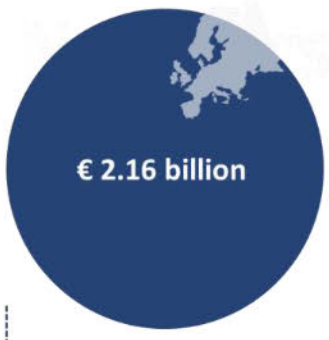
Enzymes are **Respiratory Sensitizers Cat 1**

- Most of enzymes are in harmonized classification (CLH), otherwise self-classified

There are no alternative to enzymes for downstream users. [redacted]

[redacted]

Market value of enzymes sector and jobs

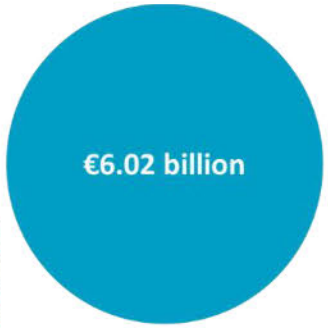


Sold production value of enzyme products EU27, 2020 - (*PRODCOM, 2022*)

Percentage share DK (58%), FI (14%), DE (8%), BE (4%)

Jobs in the enzyme sectors in EU 28, 2013 (*EuropaBio, 2016*)

4% of full-time jobs in biotechnology sector



Predicted Market value of the global enzymes sector, 2018 (*Bano et al. 2017*)

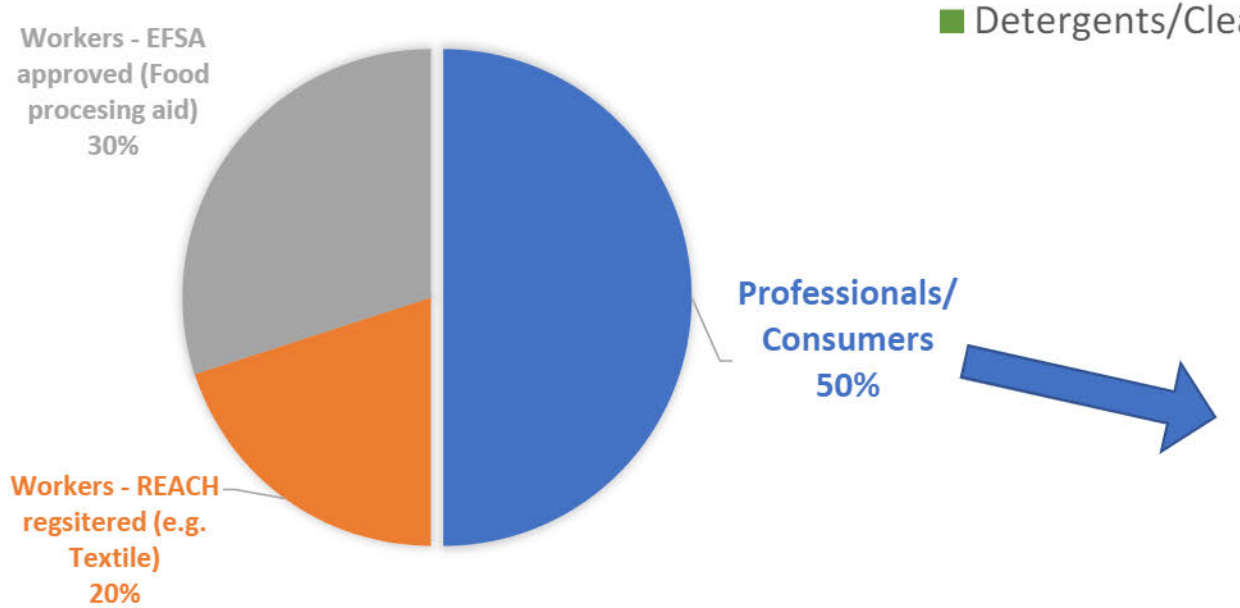
Figure 2.2: Sold production volume of enzyme products in the EU (by country), 2014 – 2018
Source: Produced based on PRODCOM (2019)

AMFEP is preparing a socio- economy study for GRA to deliver it to VVA by the end of August

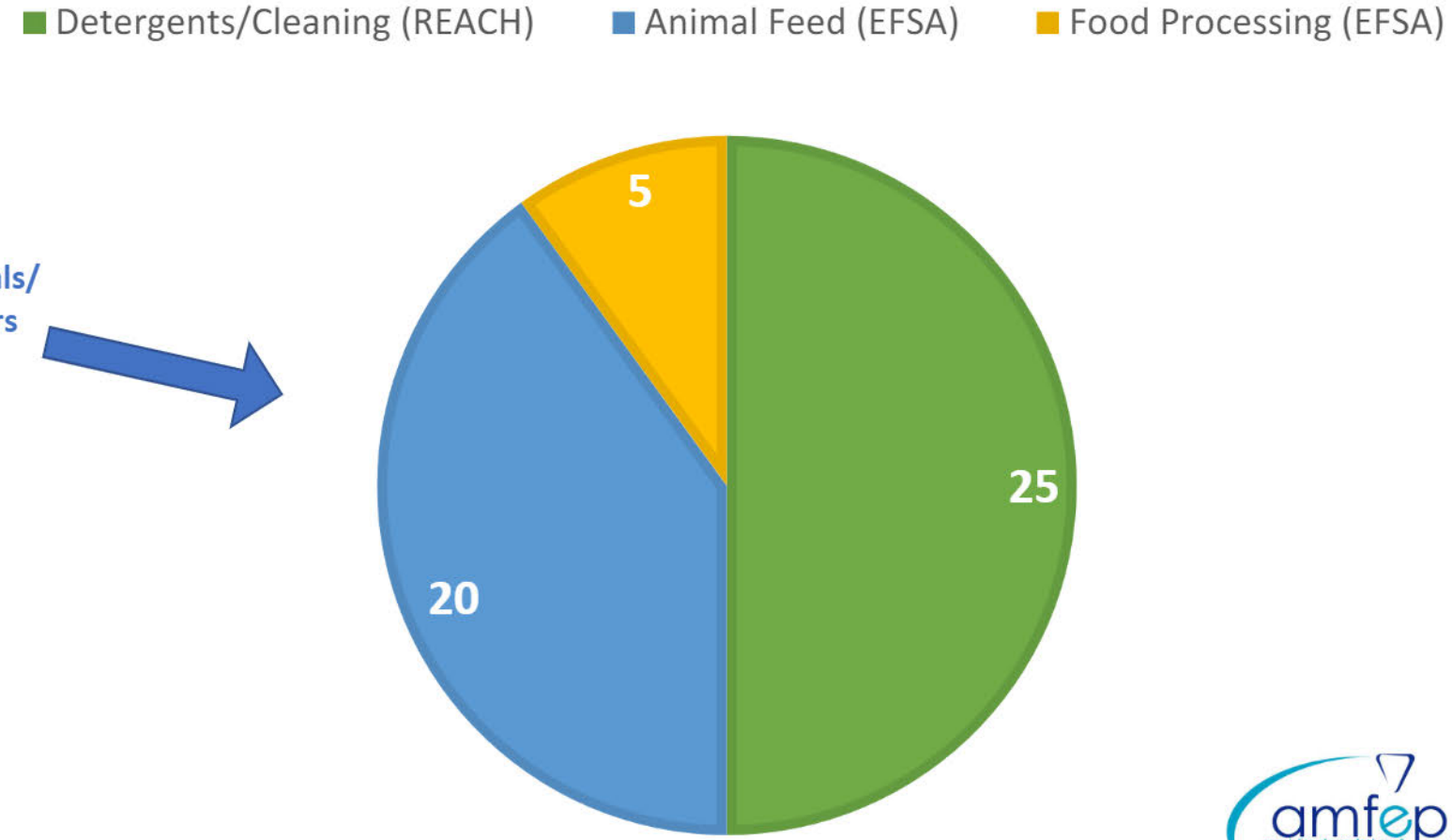
Enzyme uses -
Other than detergents

Various uses for professionals/consumers

GLOBAL MARKET SHARE



PROFESSIONALS/CONSUMERS



Source: Guerrand (2017)

AMFEP is preparing a socio- economy study for GRA to deliver it to VVA by the end of August 2022.

Enzymes are used by professionals and consumers

REACH uses

- Uses are registered in REACH dossiers (16 enzyme substances)
- e.g., contribute to reduce CO_2, energy and pollutants
- 25% (global value)

Consumer/professional use
REACH registered

- Detergents
- Cleaning
- *In vitro* diagnostic kit
- Medical device cleaning
- Cosmetics

Feed additive/EFSA

- Feed additives
- e.g., Reduction of phosphate in the environment
- 20% (global value)

Consumer/professional use
Not in REACH registration

- Animal Feed for farmers

Food/EFSA

- Processing aid for food
- e.g., Reduce acrylamide in food
- e.g., Long-lasting bread
- Unknown % (5%?) for professional and consumers - *AMFEP intend to deliver figure by the end of August.*

Consumer/professional use
Not in REACH registration

- Craft bakery
- Flour with enzyme(s) for consumers
- Craft brewery
- Winery

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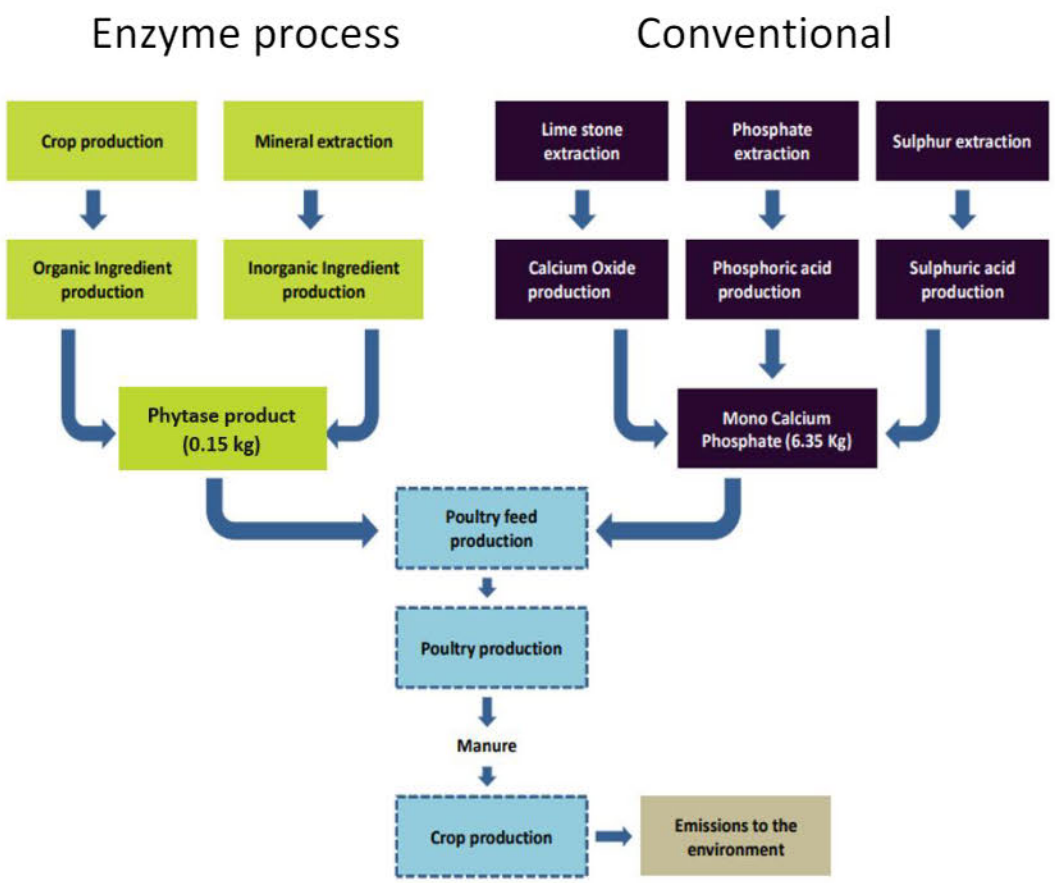
Animal Feed - example
Phytase for reduction of inorganic phosphate
(mono calcium phosphate (MCP))



- ✓ **A small amount of phytase (0.15kg) product can replace a large amount of inorganic supplement (6.35kg)**
- ✓ **Benefits of the enzyme**
  - global warming (CO_2)
  - acidification (SO_2)
  - nutrition enrichment (PO_4)
  - phosphate rock consumption
  - energy consumption
  - agricultural land

Impact category	Phytase	MCP	MCP/phytase
Global warming, g CO2 eq.	1900	32000	17
Acidification g SO2 eq.	4,8	530	110
Nutrient enrichment, g PO4 eq.	2,2	1500 (480-21000)	700 (220-9500)
Photochemical ozone formation, g C2H4 eq.	1,5	12	8,0
Phosphate rock, g	<0,1	24000	>240000
Primary energy, MJ	26	400	15
Agricultural land, m2*year	0,15	-	-

nvironmental impacts induced by phytase or inorganic phosphate (MCP) application. Figures are provided per functional unit (5·10⁶ FYT, i.e., one g phytase and 29 kg MCP) and refer generally to the 5% P-loss scenario, except figures in brackets which refer to the 0% and 100% scenarios, spectively).

Brewing - example
alpha-amylase, beta-glucanase and protease to skip malting

✓ Benefits of the enzyme

- Barley needs to be hydrolyzed prior to beer fermentation (Malting)
- **Malting can be skipped** with enzymes
- Enzymes can contribute to **full control in mashing - stable and less costly process**
- Beer is **just as tasty** as malt beer

Appendix 2: Tasting Test (Technical University of Berlin)

Result of sensory analyses conducted by a professional panel at Technical University of Berlin.

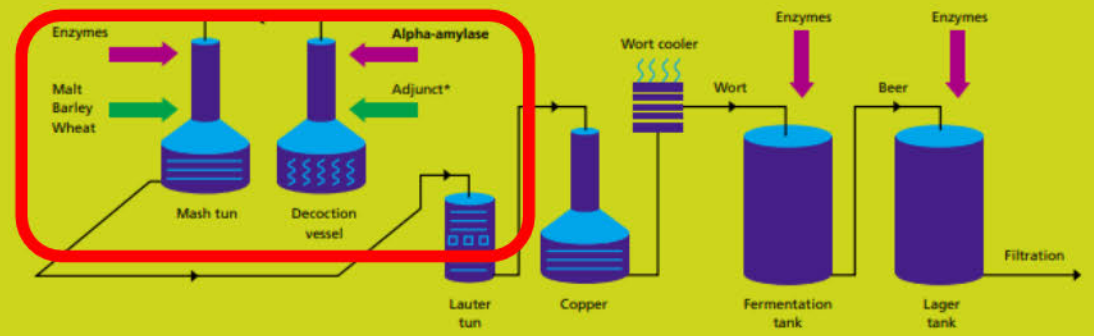
F0: 100% malt, F40: 40% barley + 60% malt beer, F100: 100% barley beer

Sensorische Analyse
(Ausgangswerte)

Prüfmerkmal	F0 (B0047TK) start value after filling and transport	F20 (B0048TK) start value after filling and transport	F40 (B0049TK) start value after filling and transport	F60 (B0050TK) start value after filling and transport	F80 (B0051TK) start value after filling and transport	F100 (B0052TK) start value after filling and transport
Geruch (aroma)	3,8	3,9	4,0	3,9	4,2	3,8
Reinheit des Geschmacks (flavour)	3,7	3,8	3,8	3,7	3,7	3,6
Vollmundigkeit (pallatefulness)	3,8	4,1	3,9	3,9	3,8	3,8
Rezenz	3,9	4,3	4,2	4,2	4,2	4,1
Qualität der Bittere (bitterness)	3,9	3,9	3,9	3,8	3,9	4,0
Kommentar (comment)						

TU Berlin – Prof. Dr.-Ing. Frank-Jürgen Methner, Thomas Kühz (030/4504[illegible]) ■ ■ ■ 16.03.2009 ■

Conclusion: No significant difference between the beers



* Adjuncts are starchy cereals such as corn, rice, wheat, sorghum, barley, or pure starch materials added to the mash.

✓ Contribution to the environment

- global warming (CO_2)
- acidification (SO_2)
- nutrition enrichment (PO_4)
- energy consumption
- agricultural land

Overview of net reductions in environmental impacts given per functional unit

Impact category	Global Warming	Acidification	Eutrophication	Photochem. ozone form.	Fossil energy	Agricultural land use
Net saving	1740	3.3	3.5	260	26	1380
Unit	kg CO_2 eq.	kg SO_2 eq.	kg PO_4^{3-} eq.	g C_2H_4 eq.	GJ	m^2·year

Source: Kløverpris, J.H., Spillane, D., 2010. Comparative LCA of malt-based beer and 100% barley beer. Brewing Beverage Industry International 2, 34 - 36.

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Is there any benefit from GRA?

Is there a benefit from GRA if enzymes are phased out ?

Human benefits

- **No benefit from or even downside because:**
  - No reduction in number of incidents of enzyme allergies among consumers or professionals, as no incidents have been documented for +50 years. Studies have shown no enzyme sensitization among the general population.
  - Incidents of enzyme allergy can occur among workers if the DMEL is not applied. **Enzyme allergy does not mean asthma!** Enzyme allergy will initiate sneezing, watery eyes or similar symptoms.
  - The general population will experience lower efficiency of e.g., laundry and cleaning products leading to less clean cloths.

Environmental benefits

- **Downside because**
  - More pollutants (from e.g. phosphate in manure) will be released to the environment
  - More energy will need to be used e.g., increasing temperature for laundry wash, food manufacture
  - More CO_2 will be released due to e.g. increasing temperature for laundry wash, more transport due to no compaction of laundry detergents, higher land use for food and livestock
  - Cloths would not be clean as before and would not last as long

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Safe use of enzymes is extensively documented

Safety - Facts

- Respiratory sensitization is **the only toxicological endpoint** of concern
- Consumers: **No documented incidents for +50 years**
- Workers: **Only few incidents when exposure is not in control**
- Enzymes have well-established **DMEL** (Derived Minimal Exposure Limit), established based on measured data and +50 years of experience
- alpha-amylase* **was concluded safe** under REACH Evaluation. The conclusion was **extended to all other enzymes** under RMOA.

* One of the most used industrial enzymes

Product Stewardship

- Engineering containments, good housekeeping, training and medical surveillance to ensure workers' safety
- Product designs to encapsulate low-dust solid enzymes and low volatile liquids ensuring limited aerosol formation for consumer products
- Continued efforts for implementation of safety across industries via the trade associations e.g.:

  Detergent industry
  Textile industry
  Pulp paper industry
  Baking industry

  Occupational Safety & sectoral guidelines (Safety - About enzymes) - AMFEP

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