

How can regulatory oversight keep up with the pace of bioscience innovation ?

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Microbes used in human or animal food for:

- **Manufacture of GRAS substances:**
 - enzymes, vitamins, amino acids, oligosaccharides, sweeteners, proteins
 - Some of these may be regarded Novel Foods in some jurisdictions

- **Production of a range of fermented/preserved foods:**
 - bread, cheese, yoghurt/kefir, beer, tofu, kimchi, etc.

- **Probiotic function:**
 - Dietary supplements / health foods
 - Direct Fed Microbial Products in animal feed

Innovation in Nutritional Microbial Products is rapid accelerating

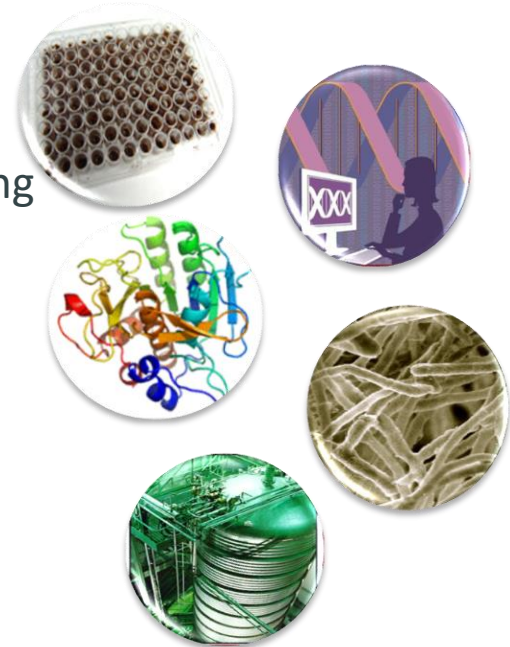


✓ Increased understanding of the microbiome

- **Nutribiosis**: interaction between nutrition, gut microbiota, and immune response

✓ Modern methods of improvement & production:

- New genetic techniques (rDNA, CRISPR)
- High-throughput screening for protein engineering
- Efficient scale-up
- Enabling products not feasible before
 - Novel proteins from exotic sources
 - Tailored for application conditions
 - Cost-effective, from renewable resources
- Better for people, animals & planet





One fermentation run produces millions of grams of protease or amylase

Enabling billions of loaves of bread baked that don't stale

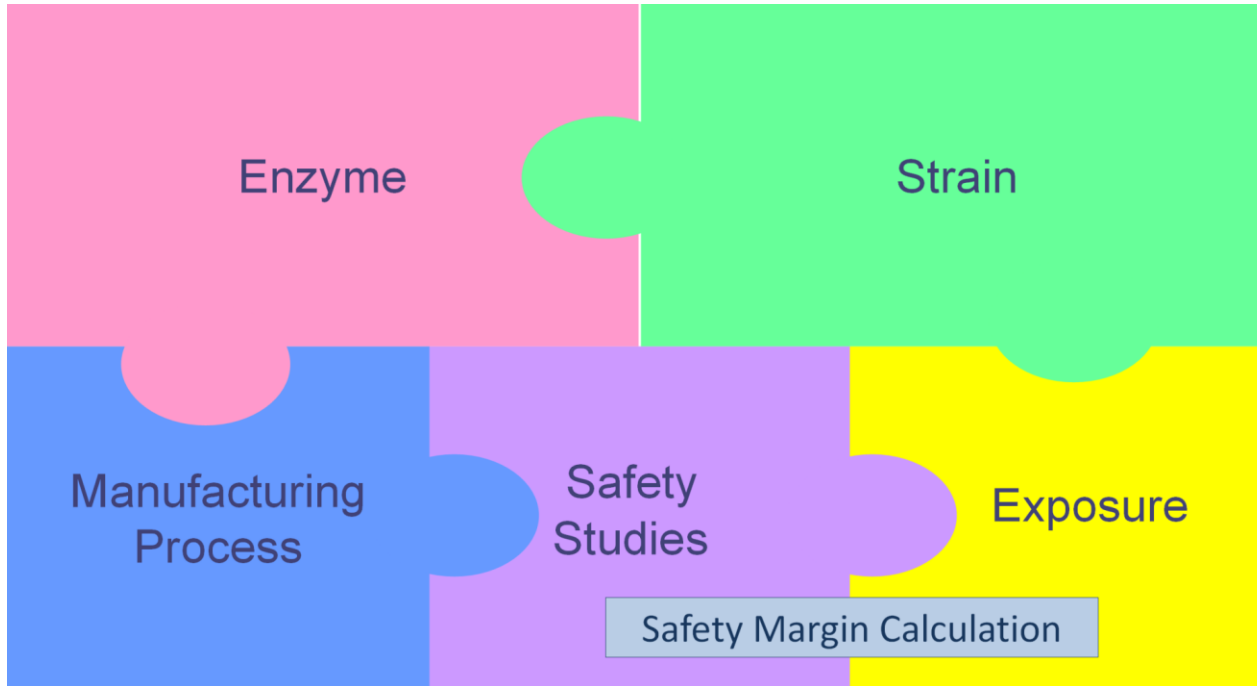


Enzymes as example for other microbial products:

- Used in very small quantities
- Made with modern biotechnology
- Long history of safe use
- Well-defined yet evolving safety evaluation methodology

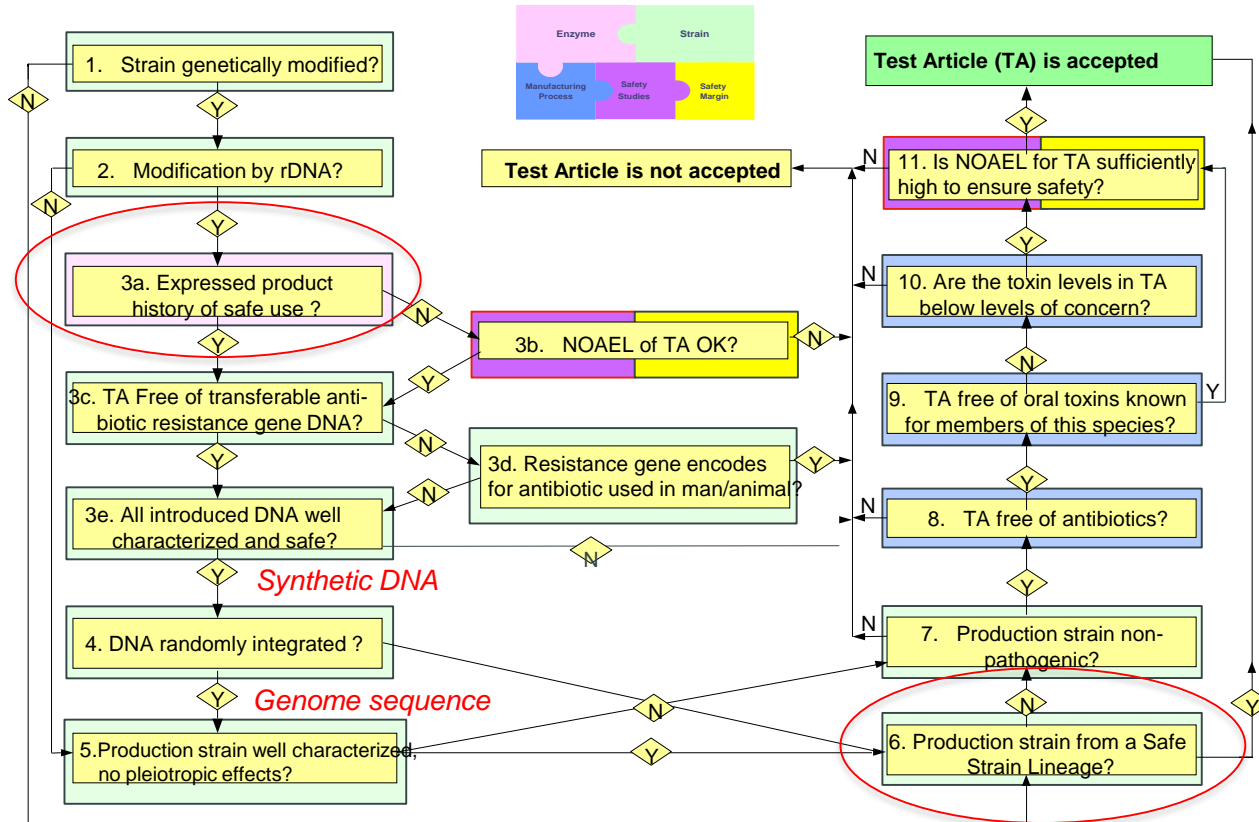
Safety Evaluation of Microbial Enzymes...

5 essential elements



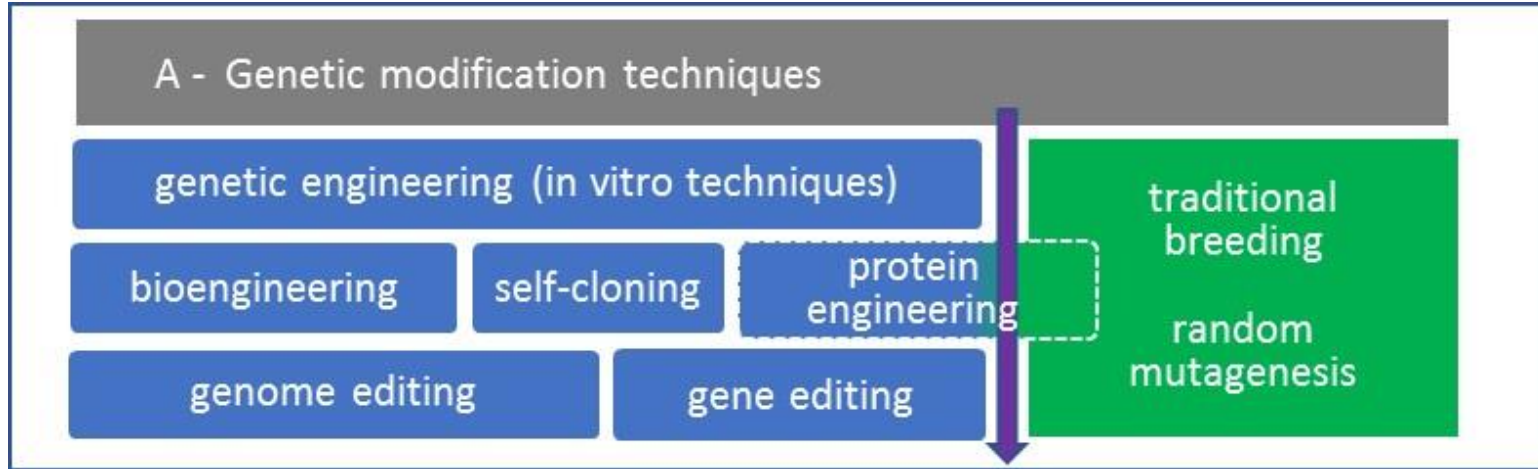
Sewalt V., Shanahan D., Gregg L., La Marta J., and Carrillo R. 2016. The Generally Recognized as Safe (GRAS) Process for Industrial Microbial Enzymes. *Indust. Biotechnol.* 12: 295-302. <https://doi.org/10.1089/ind.2016.0011>

Pariza & Johnson (2001) Decision Tree



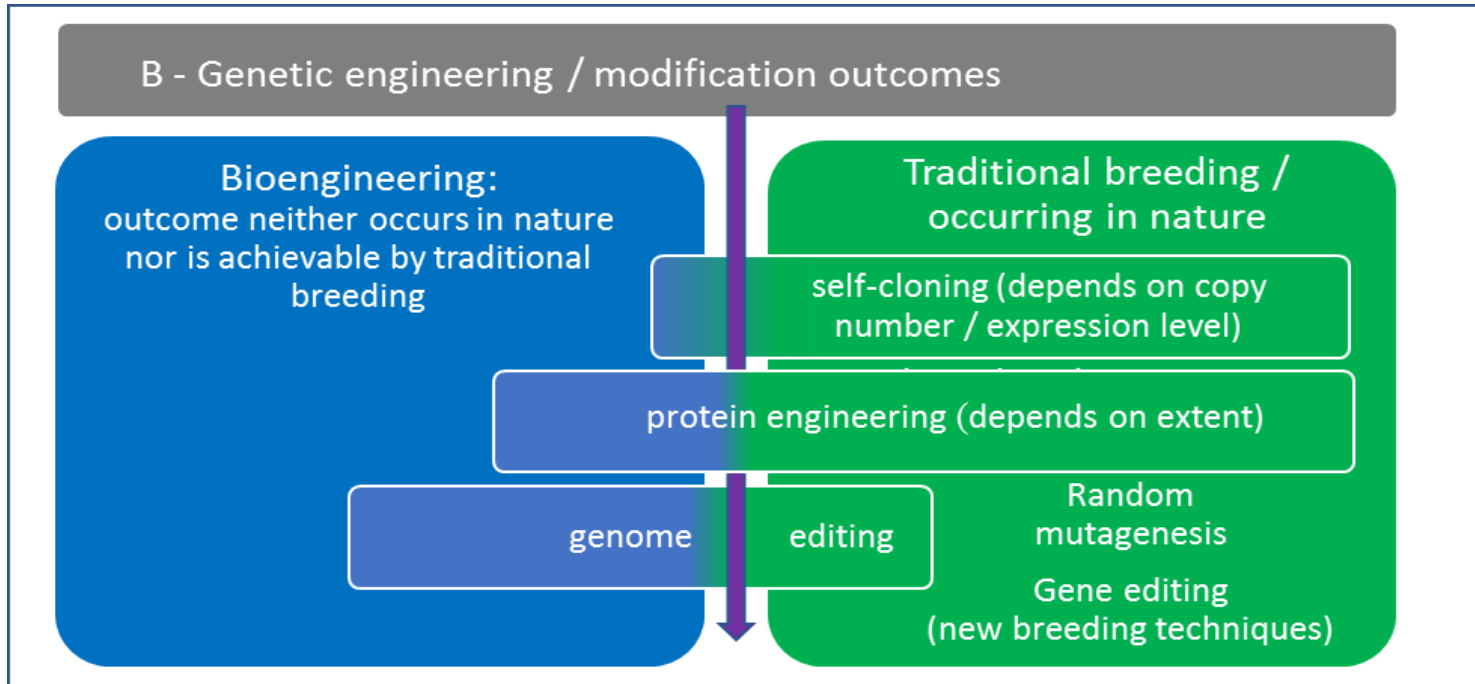
Pariza M.W. and Johnson E.A. 2001. Evaluating the safety of microbial enzyme preparations used in food processing: Update for a new century. Regul. Toxicol. Pharmacol. 33: 173–186. <https://doi.org/10.1006/rtp.2001.1466>

Delineation of genetic modification techniques - EU way of looking at GMO



EU way of looking at GMO – based on technique, not outcome

*Hanlon and Sewalt, 2020. GEMs: regulatory oversight of their uses in modern food production. IFT (submitted)



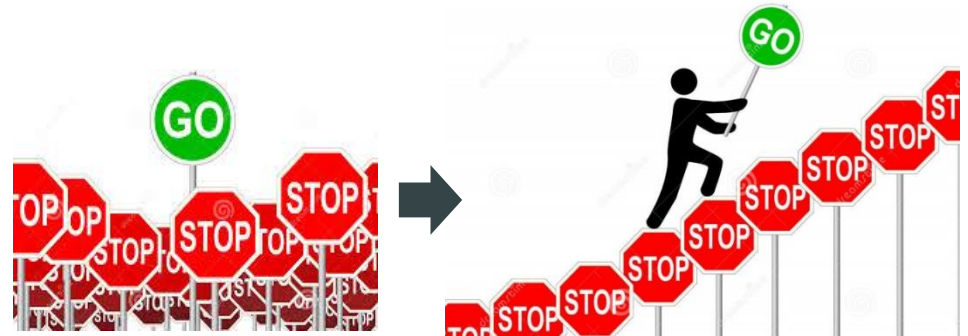
US way of looking at GMO – based on outcome, not technique

*Hanlon and Sewalt, 2020. GEMs: regulatory oversight of their uses in modern food production. IFT (submitted)

Achieving acceptance for modern biotechnology products

Enzymes serve as a great example that can be duplicated

- Long history of safe use in food (bread, beer, dairy)
- Use of GE microbes enabled more sustainable enzyme production
- Use of well-characterized microbial production platforms → Safe Strain Lineage
- Standard manufacture process & specifications
- Published safety evaluation methodology with decision tree
- Safety publications
- Regulator engagement
- GRAS Notification track record:
 - High success rate (~95%)
 - Transparency to stakeholders



Other Food categories can duplicate this!