From ideation to execution: essential steps in industrial bioprocess development

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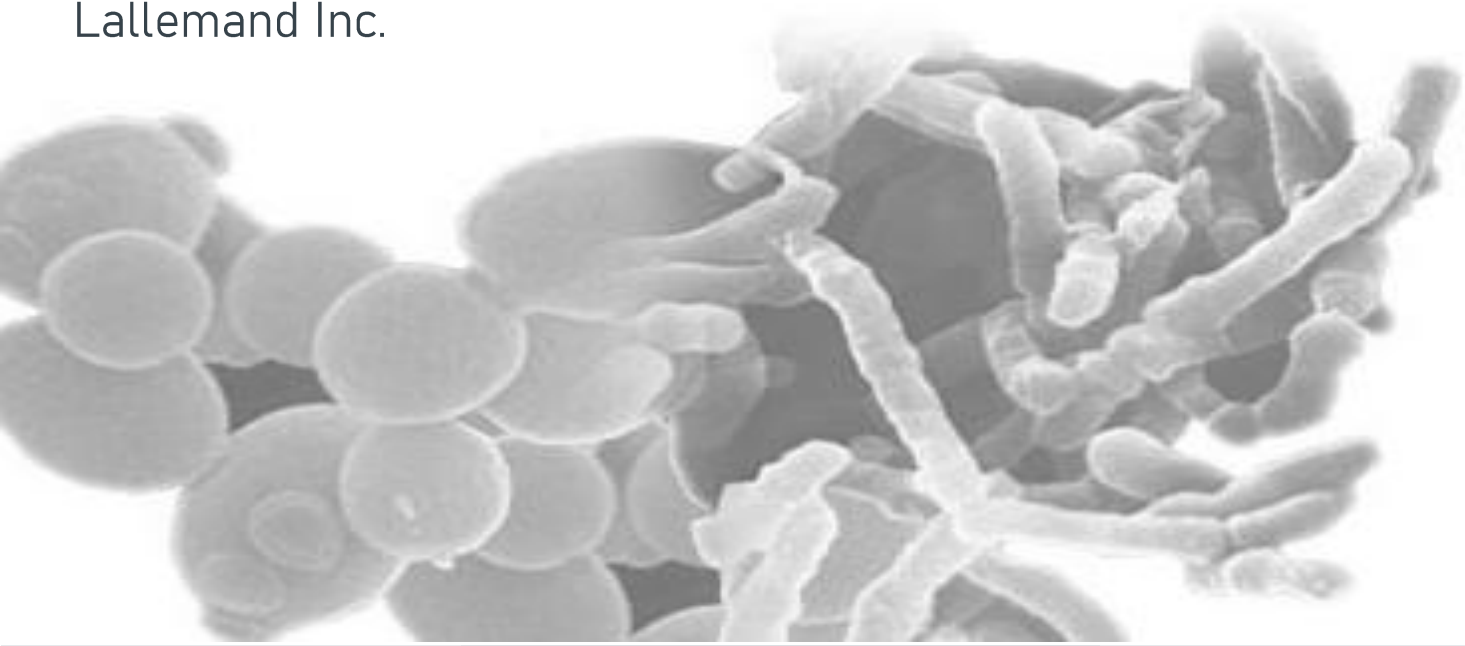
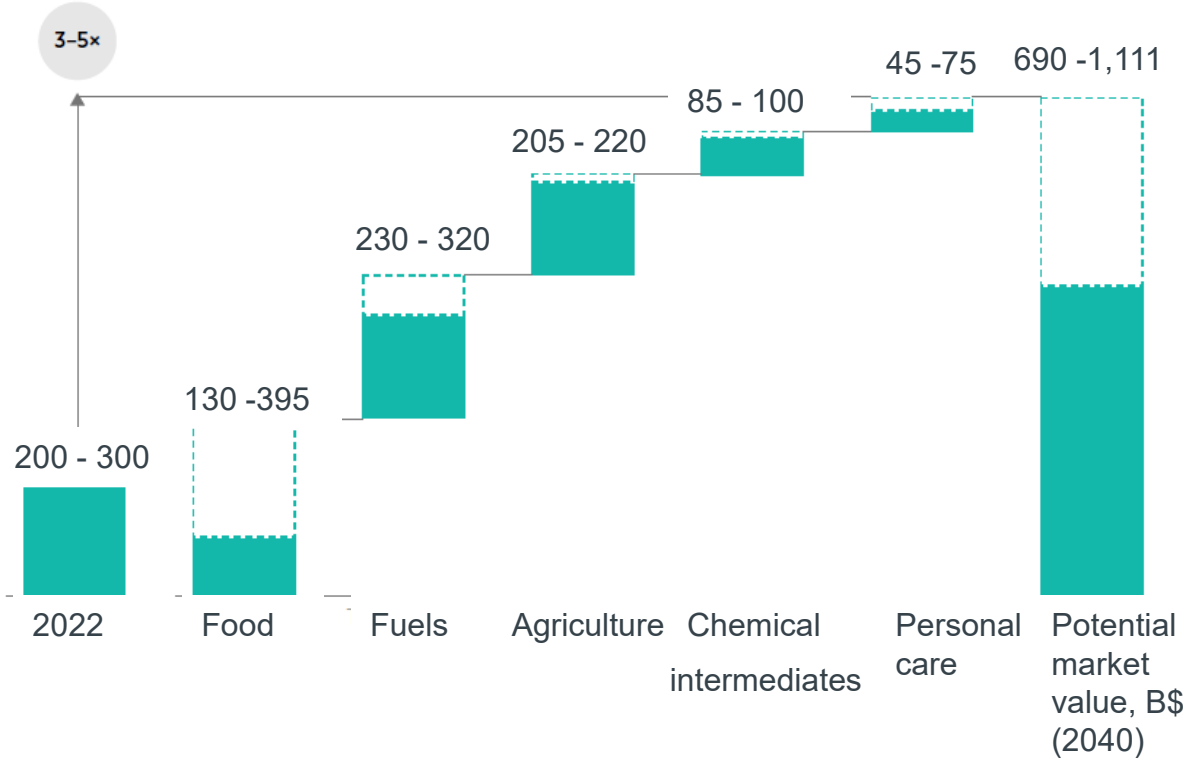


Biology is poised to drive commercial value…



Drivers:

- Vulnerabilities in the supply chain
- Increasing demand for bio-based molecules driven by regulatory shifts
- Limitations in performance (e.g., isomers)
- Rising cost trends

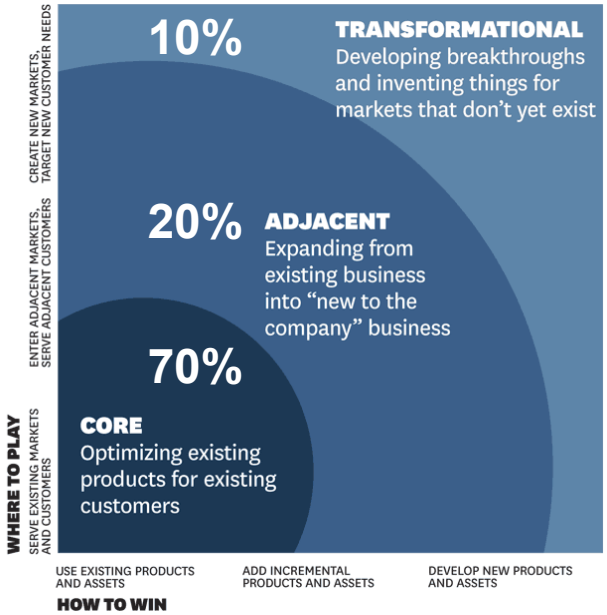
Source: Advanced Biotech for Sustainability, 2025

What bio-based products have potential to reach cost parity, and which ones will get there first?

Example> lysine from pharmaceutical specialty to mass market commodity

- 30 years of development
- COGS dropping from 80 – 90 $/kg to <1$/kg
- 3.6M tons/yr

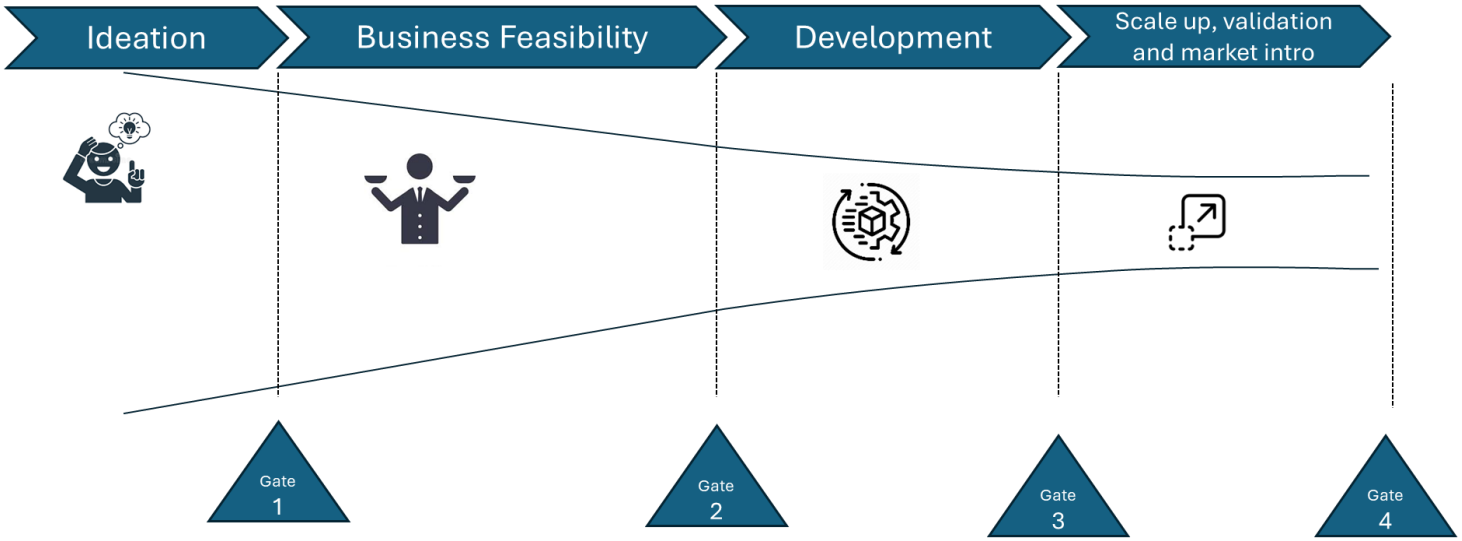
The innovation ambition matrix



Source: Nagji and Tuff, Harvard Business Review

- Outperforming industrial biotech firms typically execute at all three innovation levels
- Incremental and transformational innovation are both important

Critical steps in innovation pipeline

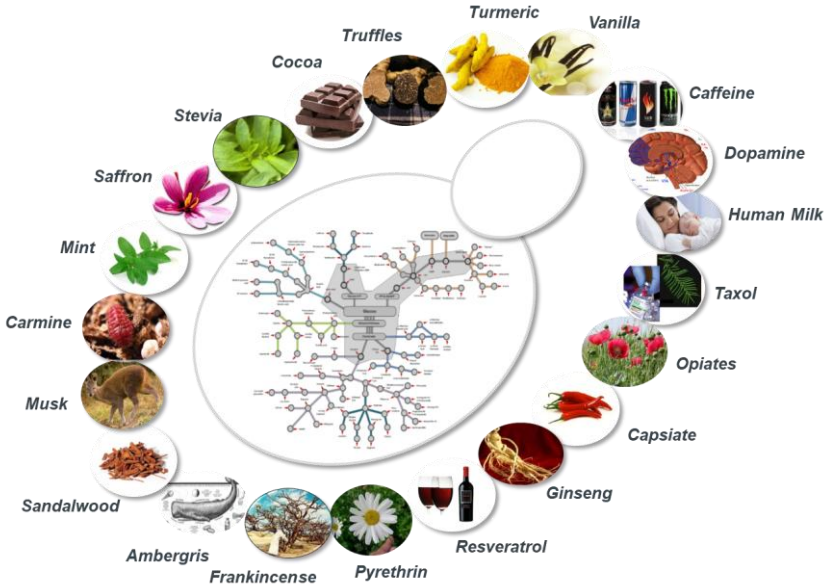


Pipeline management

- Periodic assessment of the progress
- (re)evaluation of the projectes ROI based on changes
- Go/Stop decisions

1. Ideation – the product idea portfolio

- Does it fit to existing business?
- New solution or incremental innovation
- Market (consumer) perception
- Other… (e.g., ESG impact)
- Preliminary technical approach

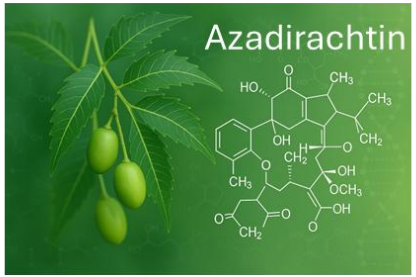


Preliminary technical approach is crucial

Transformational innovations are often challenging because the pathways and/or genes have not been fully elucidated

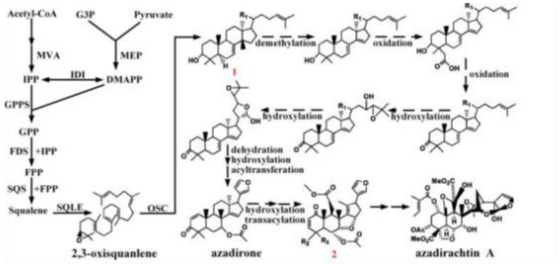
Natural source

Structure and functionality



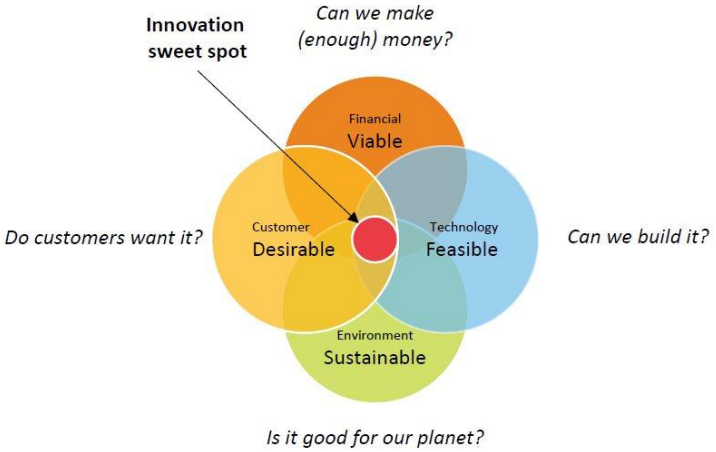
Insecticide in organic agriculture

Hypothetical pathway but no genes identified



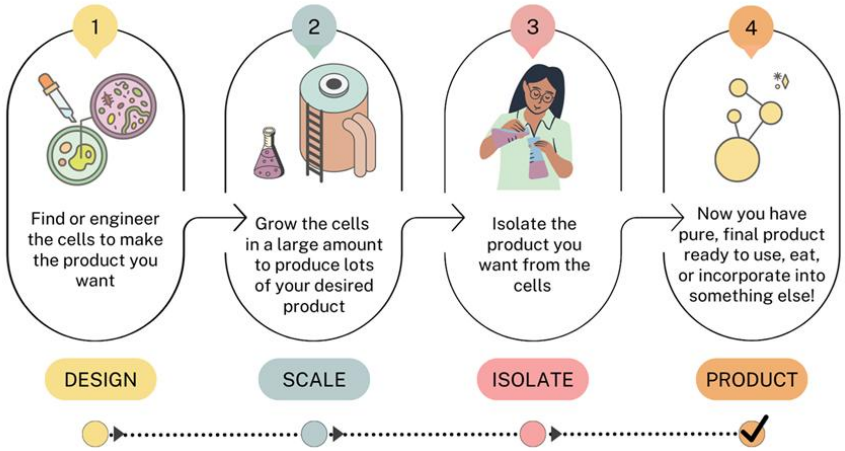
Source: Wang, Wang and Nuo. BMC Genomics 2020

2. Business feasibility assessment



- Value at stake (market demand assuming cost parity with existing alternatives, COGS vs market price)?
- IP landscape?
- Tehcnical feasibility (proven technology, viable supply chains, environmental risks)
- Favorable ecosystem (regulatory environment, consumer sentiment, market adoption risks)
- Incremental margin potential?

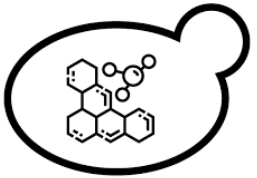
3. Development



Source: Angelica Guercio, UC Davis

- USP
  - microbial strain development
  - fermentation process development
- DSP
- Scale-up

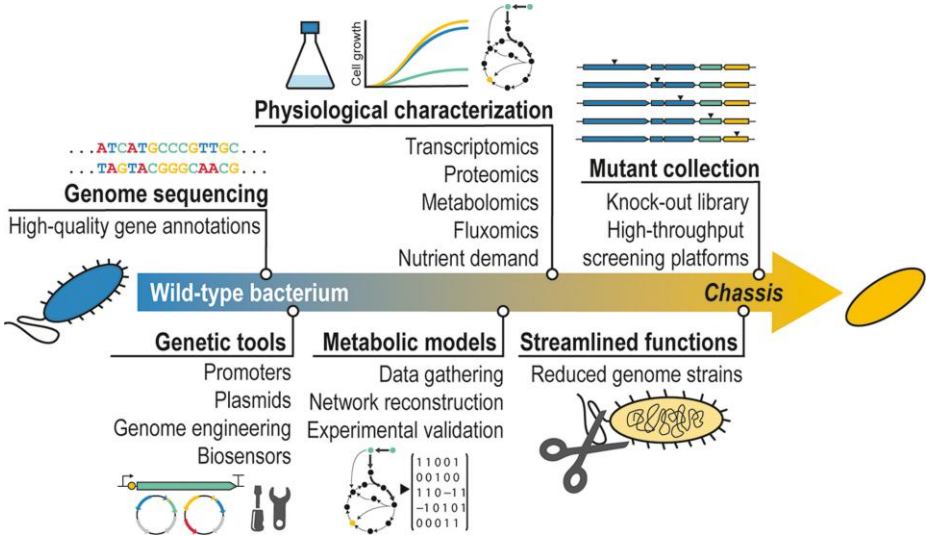
Microbial strain development



Compatibility with industrial capabilities is a must !!!

A good production host:

- High product yield/concentration
- Inexpensive and readily available substrates
- Genetically stable
- Non-pathogenic



Source: Calero and Nikel 2018

Fermentation process development – $T_{itre}R_{ate}Y_{ield}$

Trends in
Biotechnology

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Opinion

TRYing to evaluate production costs in microbial biotechnology

Oliver Konzock [1] and Jens Nielsen [1,2,*]

Microbial fermentations offer the opportunity to produce a wide range of chemicals in a sustainable fashion, but it is important to carefully evaluate the production costs. This can be done on the basis of evaluation of the titer, rate, and yield (TRY) of the fermentation process. Here we describe how the three TRY metrics impact the technoeconomics of a microbial fermentation process, and we illustrate the use of these for evaluation of different processes in the production of two commodity chemicals, 1,3-propanediol (PDO) and ethanol, as well as for the fine chemical penicillin. On the basis of our discussions, we provide some recommendations on how the TRY metrics should be reported when new processes are described.

Highlights

Microbial fermentations are widely used for the production of chemicals used as pharmaceuticals, food ingredients, materials, solvents, and biofuels.

Technoeconomic analysis of a given fermentation process is important to perform before scaling the process to levels that enable commercial production.

Titer, rate, and yield (TRY) of the fermentation process are key metrics that are

C_p [g/L]

$Q_{p/x}$ [g/kg/h]

$Q_{p/v}$ [g/L/h]

$Y_{p/s}$ [g/kg]

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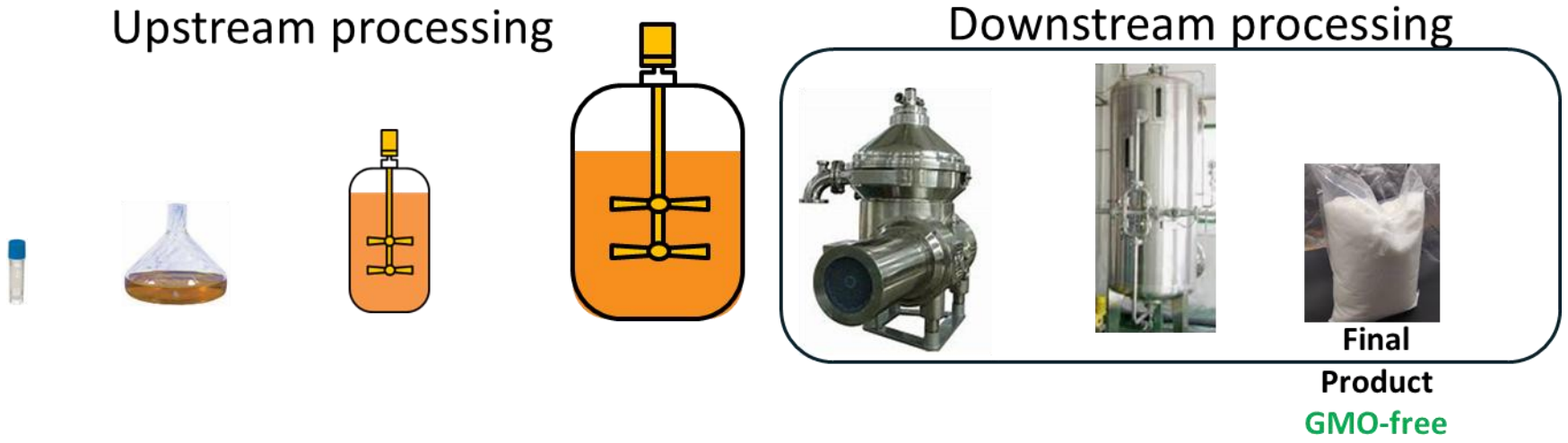
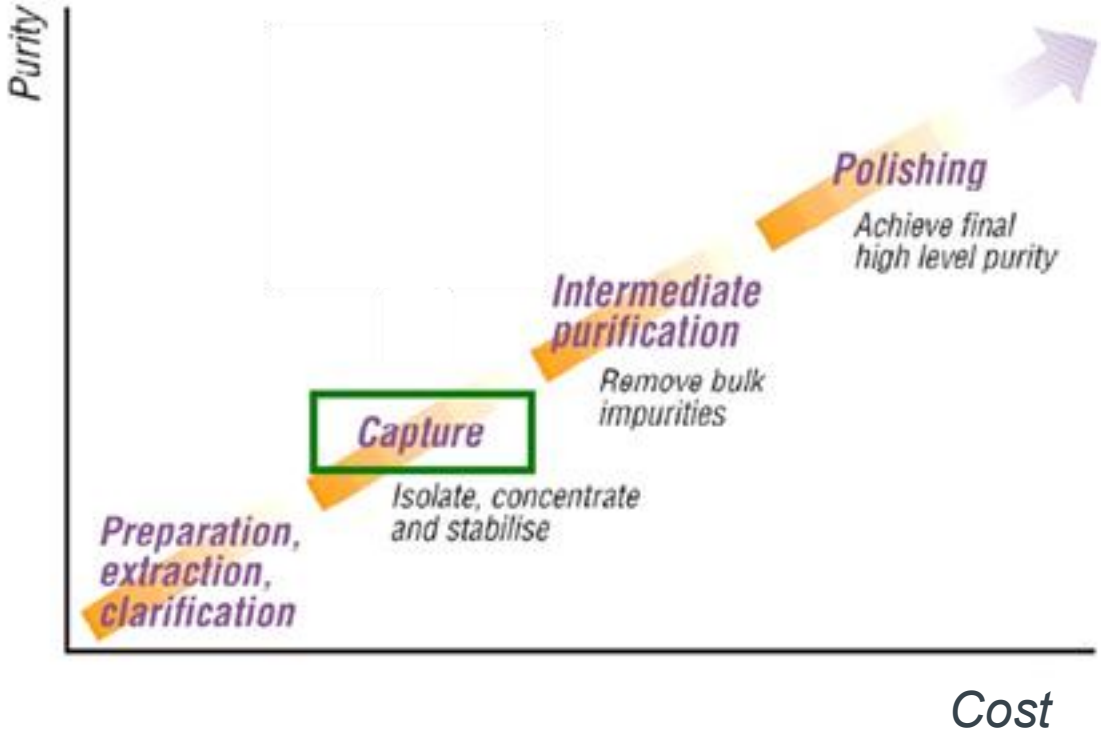
Downstream processing



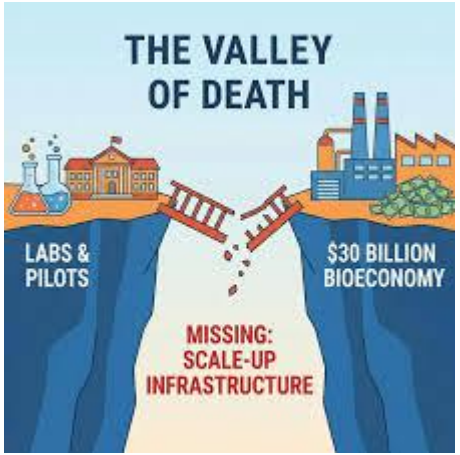
Main considerations for downstream processing

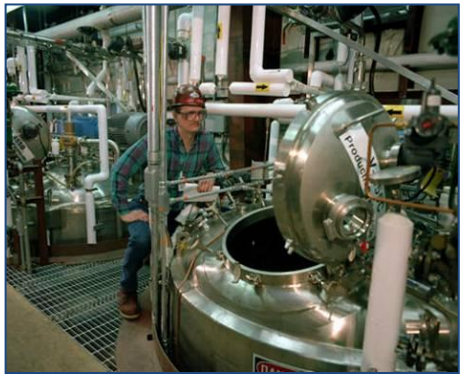


- Product intra- or extracellular?
- Final purity?
- rDNA free (≤10 ng/g)
- Formulation (liquid, powder, …)
- Stability during processing
- DSP yields

Key insights for infrastructure and scale-up

- Demand validation must precede infrastructure investment
- Hybrid production routes accelerate scale
- Downstream processing can be the primary cost driver
- Standardization (compatibility) across processes to streamline scaling





Last but not least…regulatory hurdles (and opportunities)

- Vary significantly by geography and molecule type
- Average time for regulatory compliance up to 6 years
- Approval process can be expensive
- Structural barriers in Europe

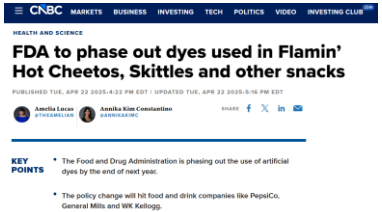
President Donald Trump signs an executive order to streamline the approval process for GMO crops, after speaking at Southwest Iowa Renewable Energy in Council Bluffs, Iowa, Tuesday, June 11, 2019.
AP Photo/Patrick Semansky

FOOD & BEVERAGE

Trump Orders Simpler Path for Genetically Engineered Food

Regulatory timelines for industrial biotech applications are a structural barrier to commercialization (EuropaBio, June 2026)

Application	EU approval	US / Singapore approval	EU disadvantage
Novel Food (fermentation products)	~6 years	~1 year	6× longer
Biocontrol products	7-8 years	2-3 years	3× longer



CNBC MARKETS BUSINESS INVESTING TECH POLITICS VIDEO INVESTING CLUB

HEALTH AND SCIENCE

FDA to phase out dyes used in Flamin' Hot Cheetos, Skittles and other snacks

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Amelia Lucas @THEAMELIAN · Annika Kim Constantino @ANNIKAKIMC

KEY POINTS

- The Food and Drug Administration is phasing out the use of artificial dyes by the end of next year.
- The policy change will hit food and drink companies like PepsiCo, General Mills and WK Kellogg.

Long delays in novel food approvals put Europe at risk of 'falling behind'

By Lauren Nicolle
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Thank you