The Case for Horizon Scanning

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Outline

- 2018 National Academies' Study on Future Products of Biotechnology
- Horizon scanning activities carried out as part of the study
- New and ongoing efforts related to horizon scanning (syn bio focus)

Note: BioTech Regs slides have NASEM markings; see "Preparing for Future Products of Biotechnology" (NASEM, 2017) for details. All other slides are RMM's opinion and don't necessarily reflect the consensus opinion of the committee.

The National Academies of

SCIENCES • ENGINEERING • MEDICINE

BOARD ON LIFE SCIENCES • BOARD ON AGRICULTURE AND NATURAL RESOURCES • BOARD ON CHEMICAL SCIENCES AND TECHNOLOGY

Preparing for Future Products of Biotechnology

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nas.edu/biotech

Statement of Task

What will the likely future products of biotechnology be over the next 5-10 years? What scientific capabilities, tools, and/or expertise may be needed by the regulatory agencies to ensure they make efficient and sound evaluations of the likely future products of biotechnology?

(1) Describe the major advances and the potential new types of biotechnology products likely to emerge over the next 5-10 years.

(2) Describe the existing risk analysis system for biotechnology products … and each agency's authorities as they pertain to the products of biotechnology

(3) Determine whether potential future products could pose different types of risks relative to existing products and organisms. Where appropriate, identify areas in which the risks or lack of risks are well understood.

(4) Indicate what scientific capabilities, tools, and expertise may be useful to support oversight of potential future products of biotechnology.

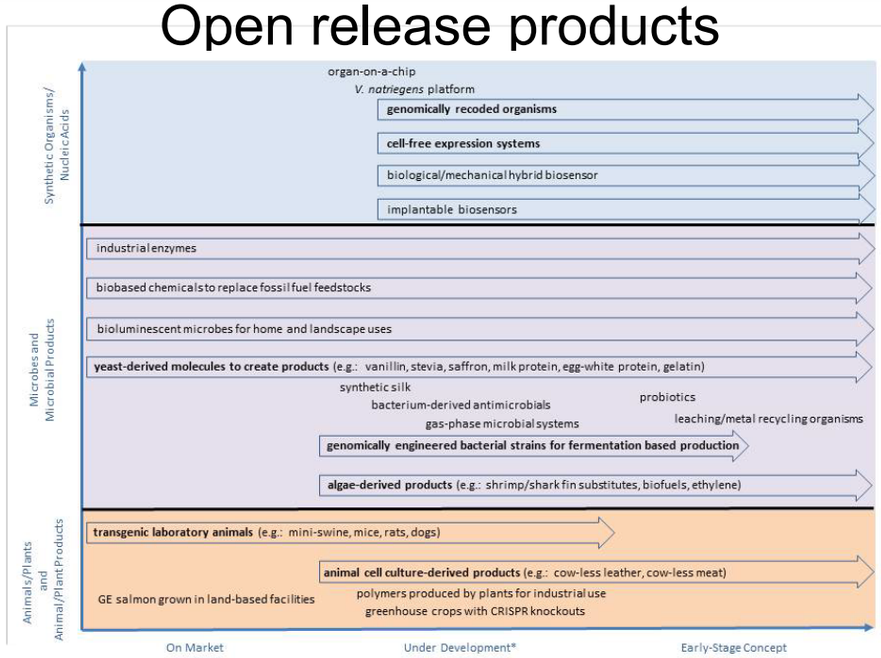
(Human drugs and medical devices are not in the purview of the study.)

What is a Biotechnology Product?

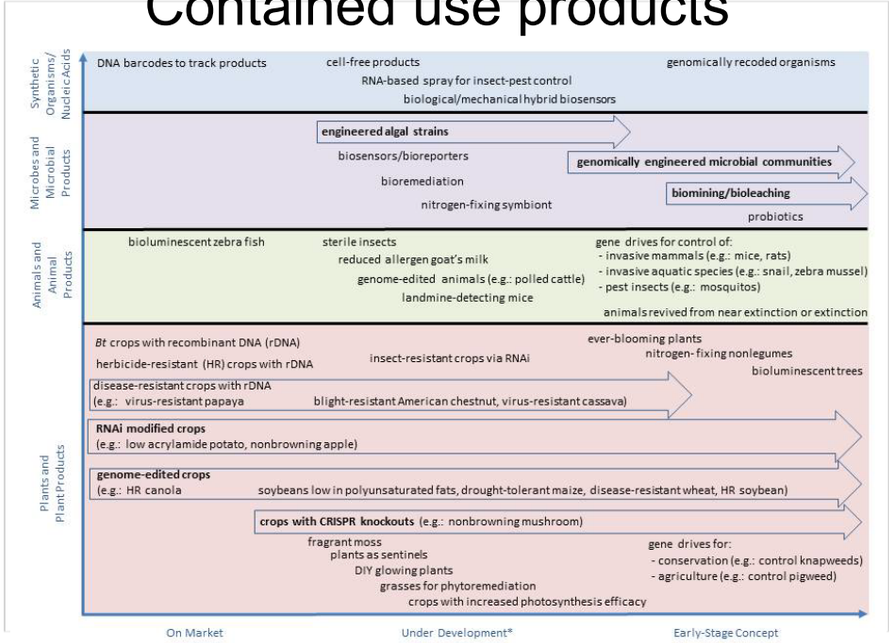
Products developed through genetic engineering or genome engineering or the targeted or *in vitro* manipulation of genetic information of organisms, including plants, animals, and microbes

- Includes products where the engineered DNA molecule is itself the "product" as in an engineered molecule used as a DNA information-storage medium
- Also covers some products produced by such plants, animals, microbes, and cell-free systems or products derived from all of the above

Open release products



Contained use products



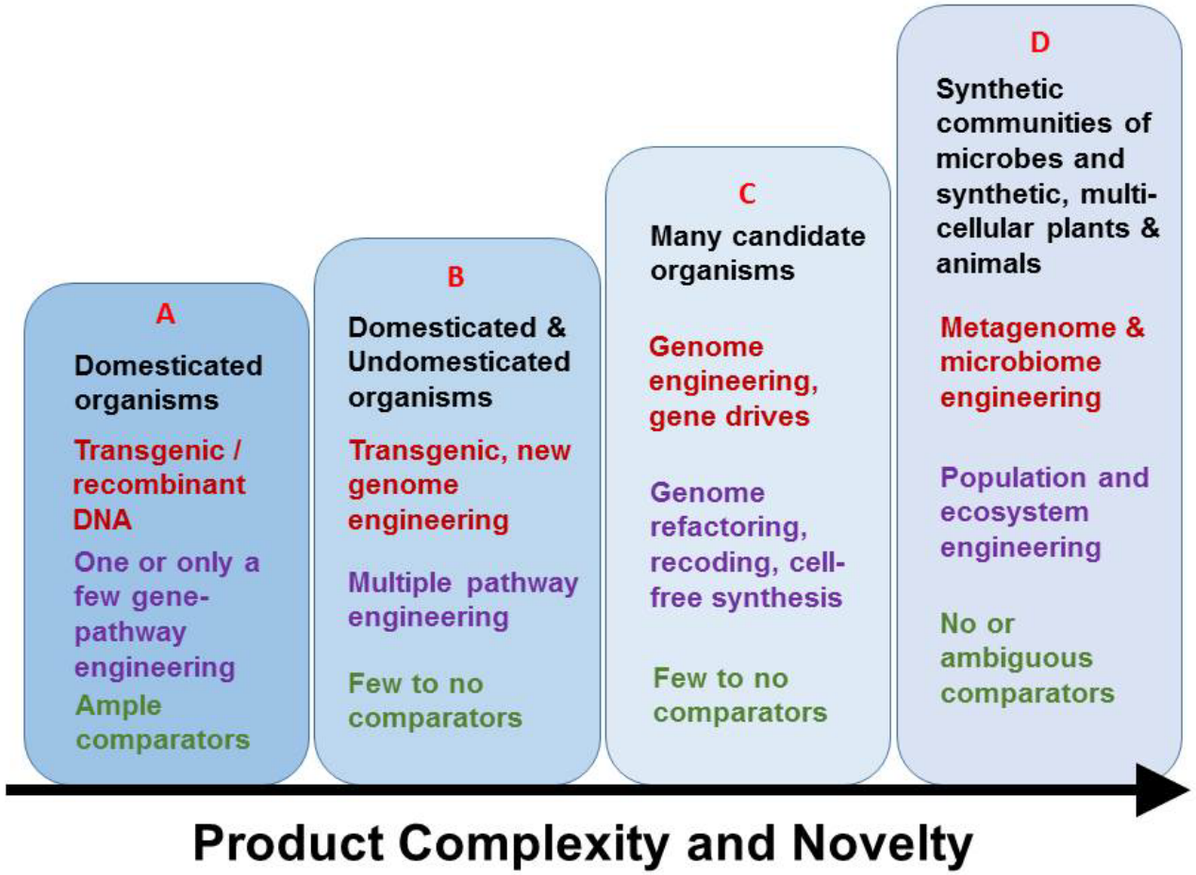
"Platforms"

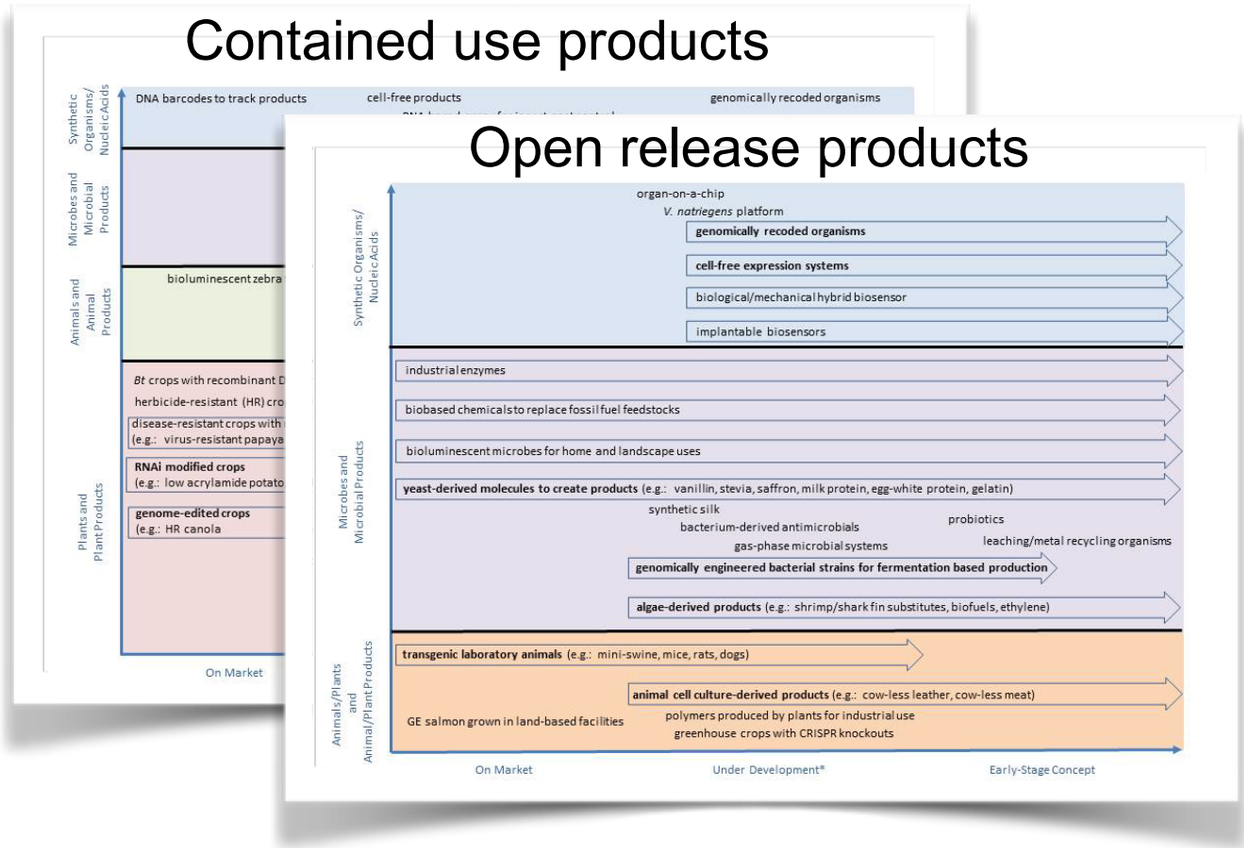
(products used to make other products)

Major Advances and New Types of Products

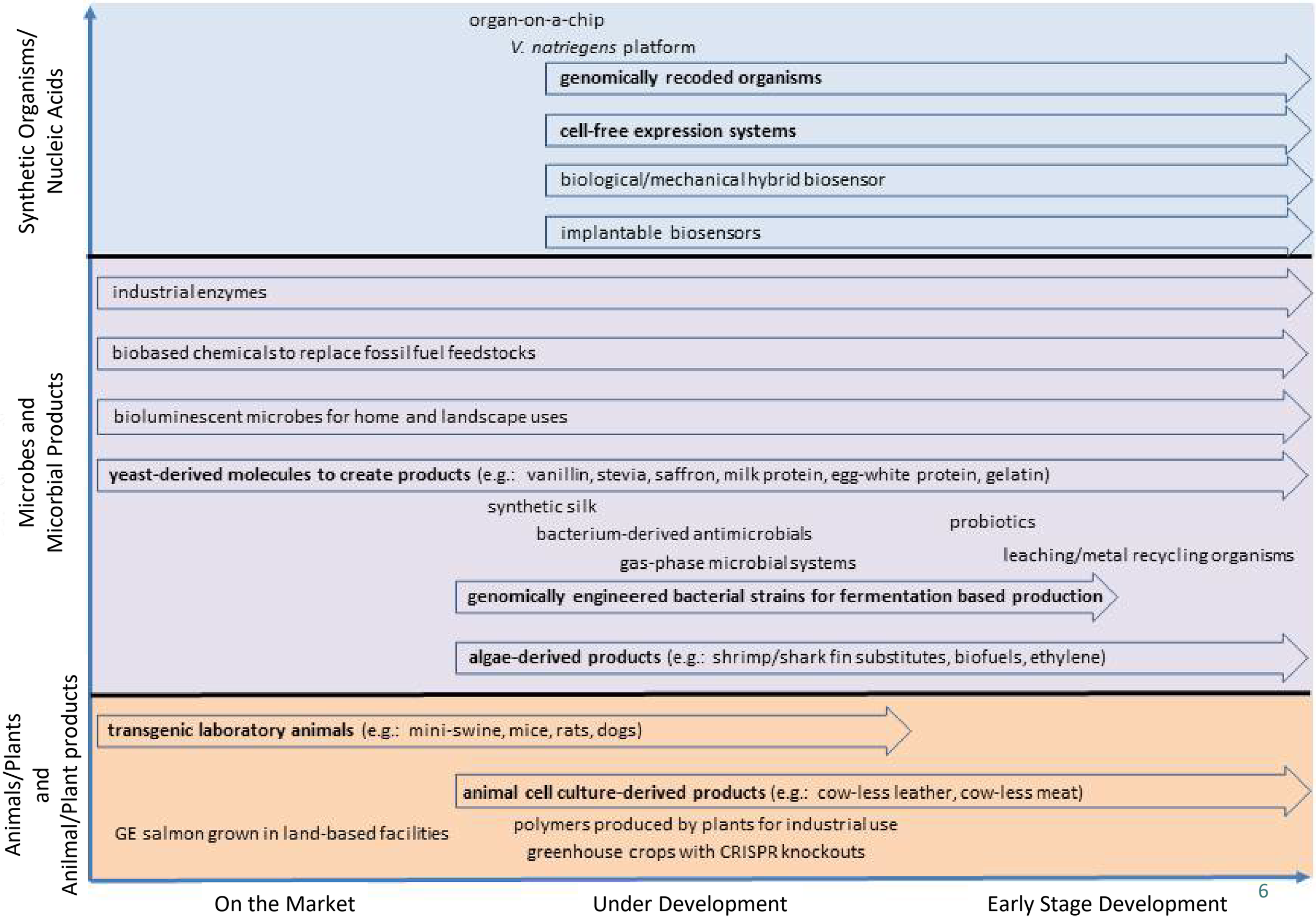
(1) Describe the major advances and the potential new types of biotechnology products likely to emerge over the next 5-10 years

- The *scale, scope, complexity, and tempo* of biotechnology products are *likely to increase* in the next 5–10 years. Many products will be similar to existing biotechnology products, but they may be created through new processes, and *some products may be wholly unlike products that exist today*

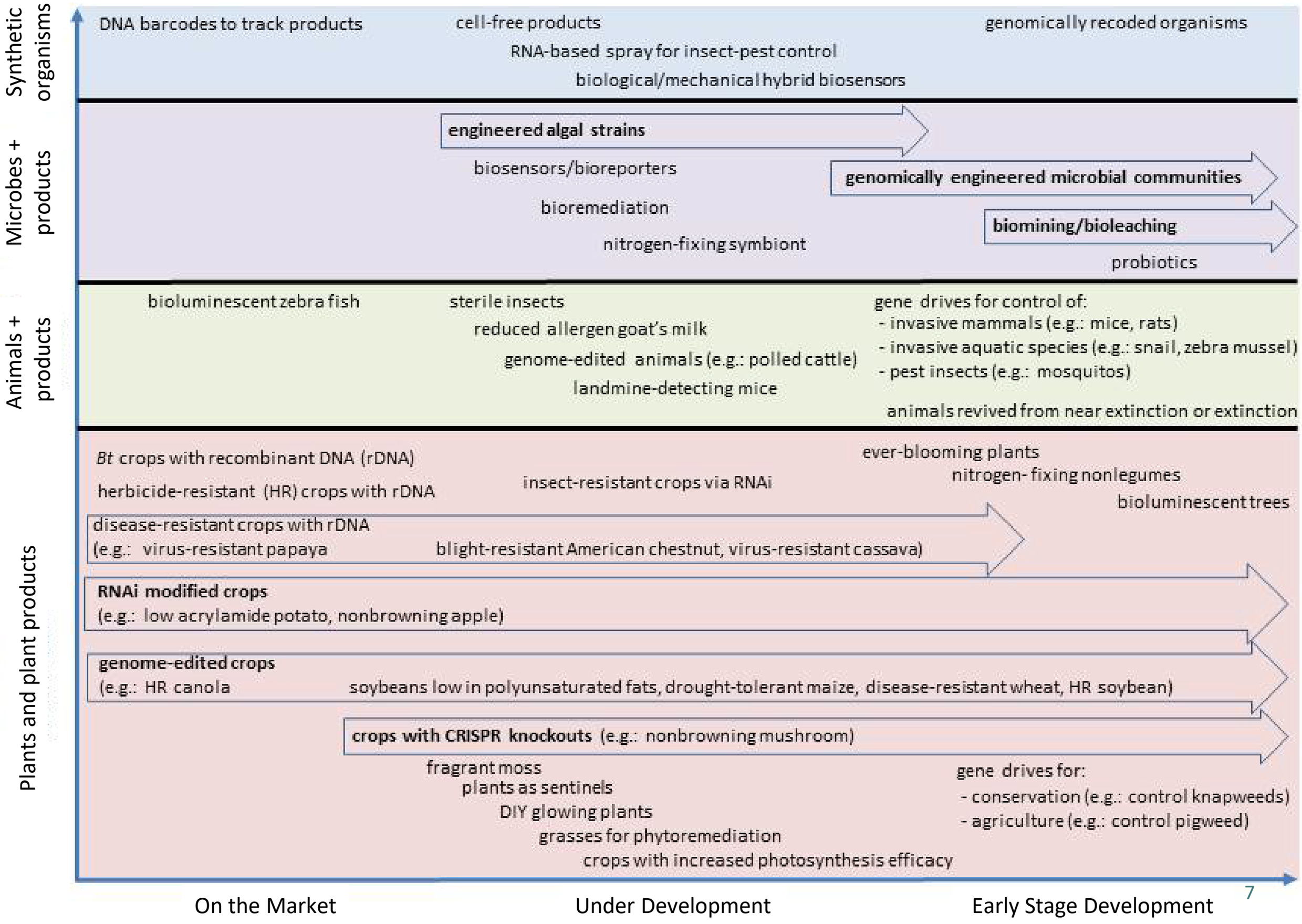




Contained Use Products



Open Release Products



Report Recommendations

1. EPA, FDA, USDA and other agencies involved in regulation of future biotechnology products should *increase scientific capabilities, tools, expertise, and horizon scanning in key areas of expected growth* of biotechnology, including *natural, regulatory, and social sciences*

2. EPA, FDA, and USDA should increase their use of *pilot projects* to *advance understanding and use of ecological risk assessments and benefit analyses* for future biotechnology products that are unfamiliar and complex and to *prototype new approaches for iterative risk analyses that incorporate external peer review and public participation*

3. The National Science Foundation, the Department of Defense, the Department of Energy, the National Institute of Standards and Technology, and other agencies that fund biotechnology research with the potential to lead to new biotechnology products should *increase their investments in regulatory science and link research and education activities to regulatory-science activities*

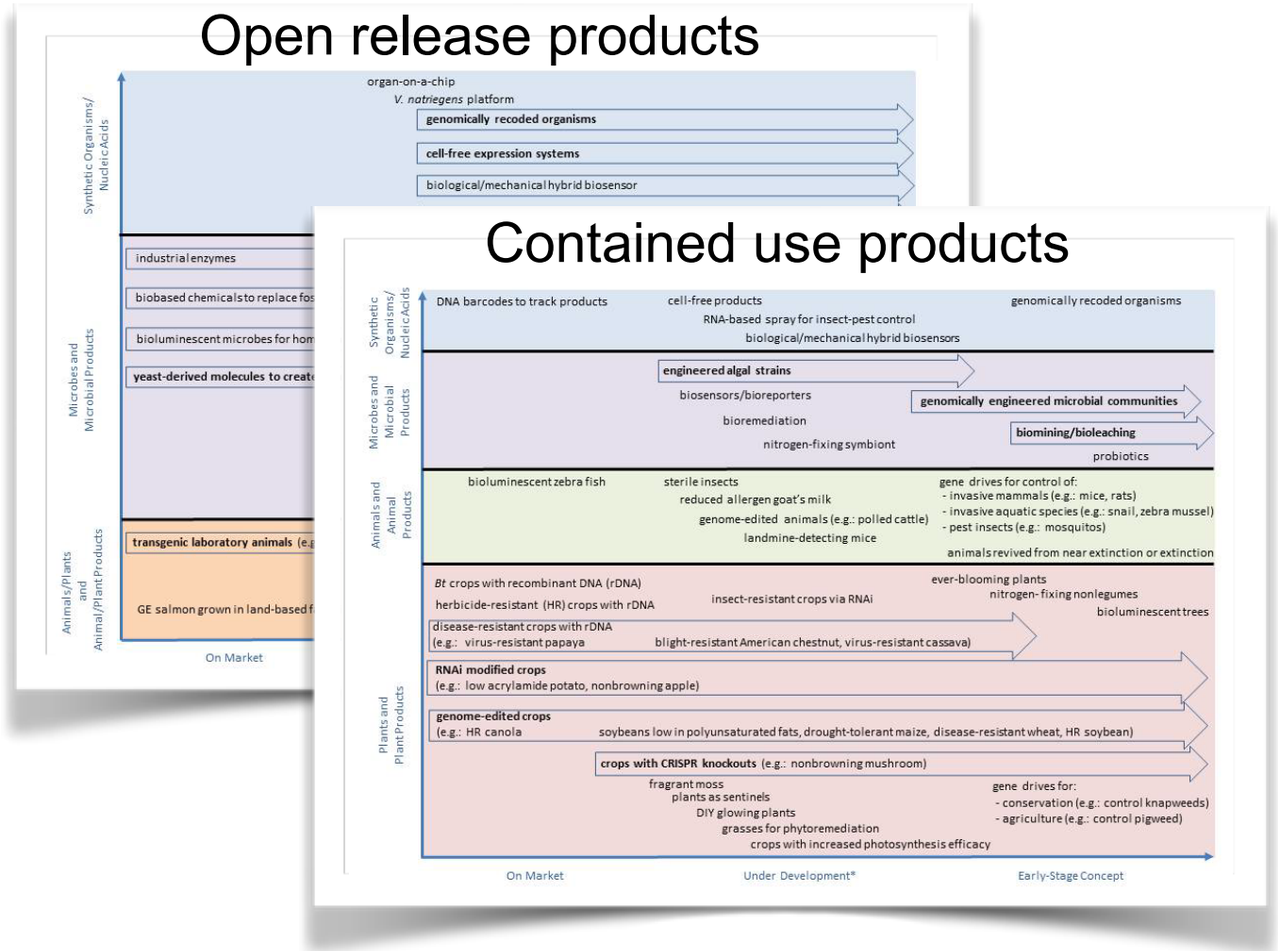
Horizon Scanning Activities for Report

Sources of input for "future products of biotechnology"

- Inviting product developers to speak at the committee meetings
- Reviewing submitted public comments
- Reading scientific literature, popular press reports, and patents
- Consulting previous reports by the National Academies
- Searching publicly available projects developed by international Genetically Engineered Machine teams
- Checking information available on regulatory agencies' websites and crowdfunding websites.
- Synthetic Biology Database (curated by the Woodrow Wilson Center): http://www.synbioproject.org/cpi/

Assignment of timelines

- On the market
- Under development
- Early stage development



Horizon Scanning Recommendations

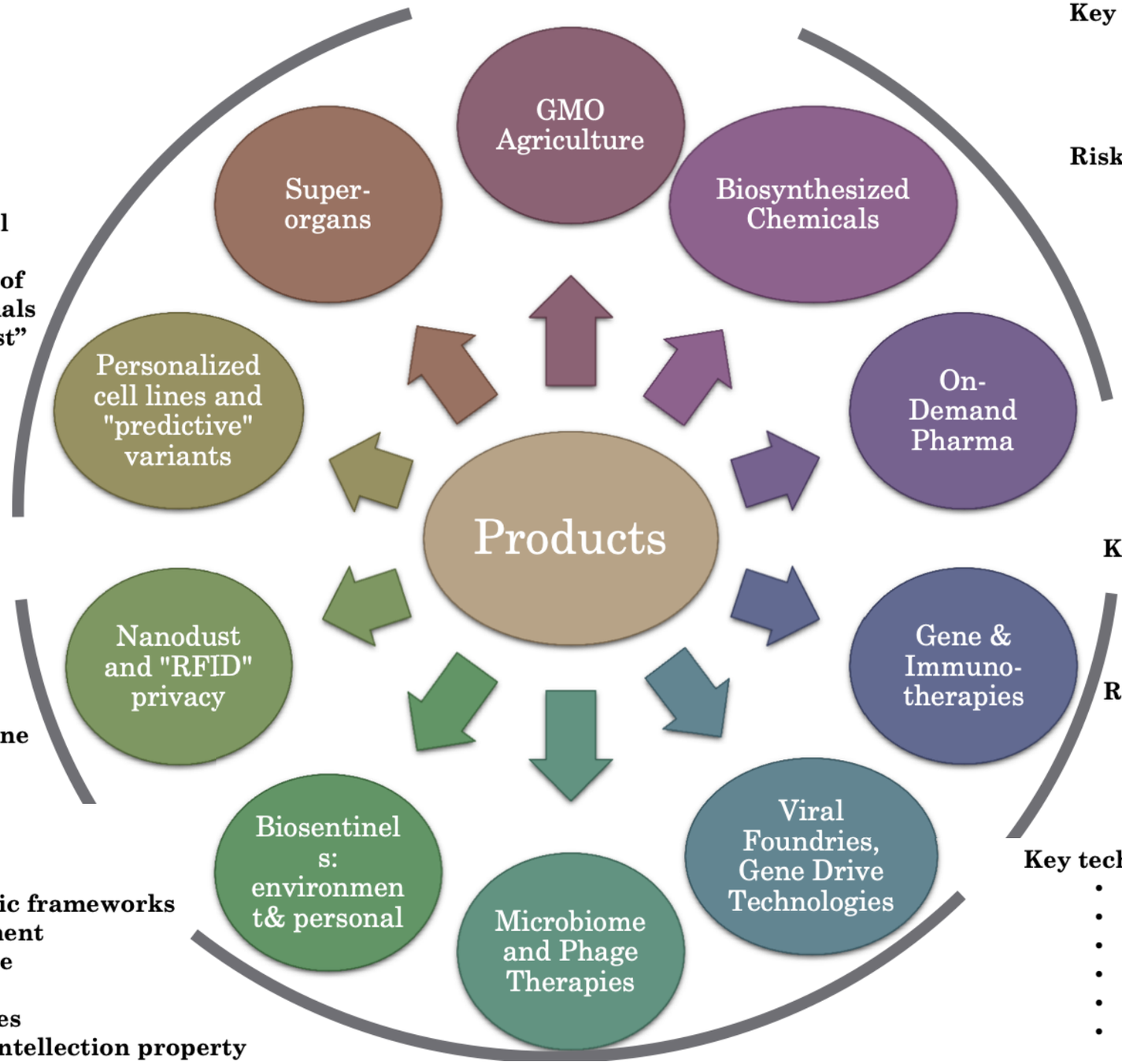
Recommendation #1: EPA, FDA, USDA and other agencies involved in regulation of future biotechnology products should increase scientific capabilities, tools, expertise, and horizon scanning in key areas of expected growth of biotechnology, including natural, regulatory, and social sciences

- Build and maintain capacity to rapidly triage products, focused on new pathways to risk-assessment endpoints
- Scan the horizon for new products that present novel risk pathways and develop new approaches to assess and address more complex risk pathways
  - Build and maintain internal expertise (eg, EPA Futures Network)
  - Make use of external advisory groups + extramural research
  - Team with other agencies: DHS, DOE, DoD, NIST, NASA, NSF
- EPA, FDA and USDA should work together to
  - Implement mechanisms for keeping aware of the emerging technologies
  - Pilot new approaches to problem formulation, uncertainty characterization, and risk-benefit assessments
  - Pool skills and expertise across the government for first-of-a-kind cases
- Pre-competitive “data commons” to provide information to developers
- Implement a more permanent, coordinated mechanism to measure progress

Other Things That Are Coming

Key tech:
- **Genome-editing**
- **Transgenic animals**
- **Precision Medicine**

Risks:
- **Expense cause social gap**
- **Diversity reduction of key plants and animals**
- **Social and Real "Cost" of predictions.**



Key tech:
- **Distributed manufacture,**
- **BioCAD tools,**
- **Maker-Compatible Local Bioprocessing Equipment**

Risks:
- **Easy transport and manufacture of organisms with controlled activities.**
- **Unauthorized modificatior**
- **Ecological hygiene**
- **Local enforcement of manufacturing standards**
- **Tracking/detection**

Key tech:
- **Novel organic, inorganic biosensors.**
- **Distance sensing**

Risks:
- **Privacy**
- **Environmental Hygiene**
- **Security**

Key tech:
- **Distributed manufacture,**
- **BioCAD tools,**
- **Immunology knowledge**

Risks:
- **Expensive with poor risk profile.**
- **Long-term safety needs study**

Risks:
- **Poor testing/economic frameworks**
- **Evolution a key element**
- **Environment hygiene**
- **Tracking/detection**
- **Strong dual-use issues**
- **Locking up genetic intellection property**

Key tech:
- **Distributed manufacture,**
- **BioCAD tools,**
- **Maker-Compatible Local**
- **Ubiquitous engineering**
- **Bioprocessing Equipment**
- **Genome scale recoding**

Adam Arkin, "No Surprise, No Control", Presentation to US National Academies Committee on Future Products of Biotechnology, 27 Jun 2016 (third public meeting)

New and Ongoing Efforts Related to Horizon Scanning

Environment Law Institute: Future Bioengineered Products

- Follow on activity to National Academies' BioTech Regs report
- https://www.futurebioengineeredproducts.org

Engineering Biology Research Consortium (EBRC) Roadmap

- Academic, Industry, Government partnership supporting synthetic biology community
- 100+ academic members, 10+ industry sponsors, 5+ government agency sponsors
- Primary activity: research roadmap for future technologies in synthetic biology

Some recent papers on emerging issues in biological engineering

- P. Shapira, S. Kwon, and J. Youtie. "Tracking the emergence of synthetic biology". *Scientometrics* 112(3):1439-1469, 2017.
- B. C. Wintle and C. R. Boehm *et al.* "A Transatlantic Perspective on 20 Emerging Issues in Biological Engineering". *Elife,* 6:e30247, 2017.
- P. Shapira and S. Kwon. "Synthetic Biology Research and Innovation Profile 2018: Publications and Patents". *bioRxiv* preprint, 2018. http://dx.doi.org/10.1101/485805.

Environment Law Institute

Explore bioengineered products

This website allows you to search data originally assembled by the National Academies of Science, Engineering and Medicine for their recent report on Future Biotechnology Products. The database is being updated to support inquiries by the public, academic and industrial researchers, businesses, investors, and others interested in better understanding advances in bioengineered products.

Begin exploring

→ Recently added products

Product categories

Market status

Production process

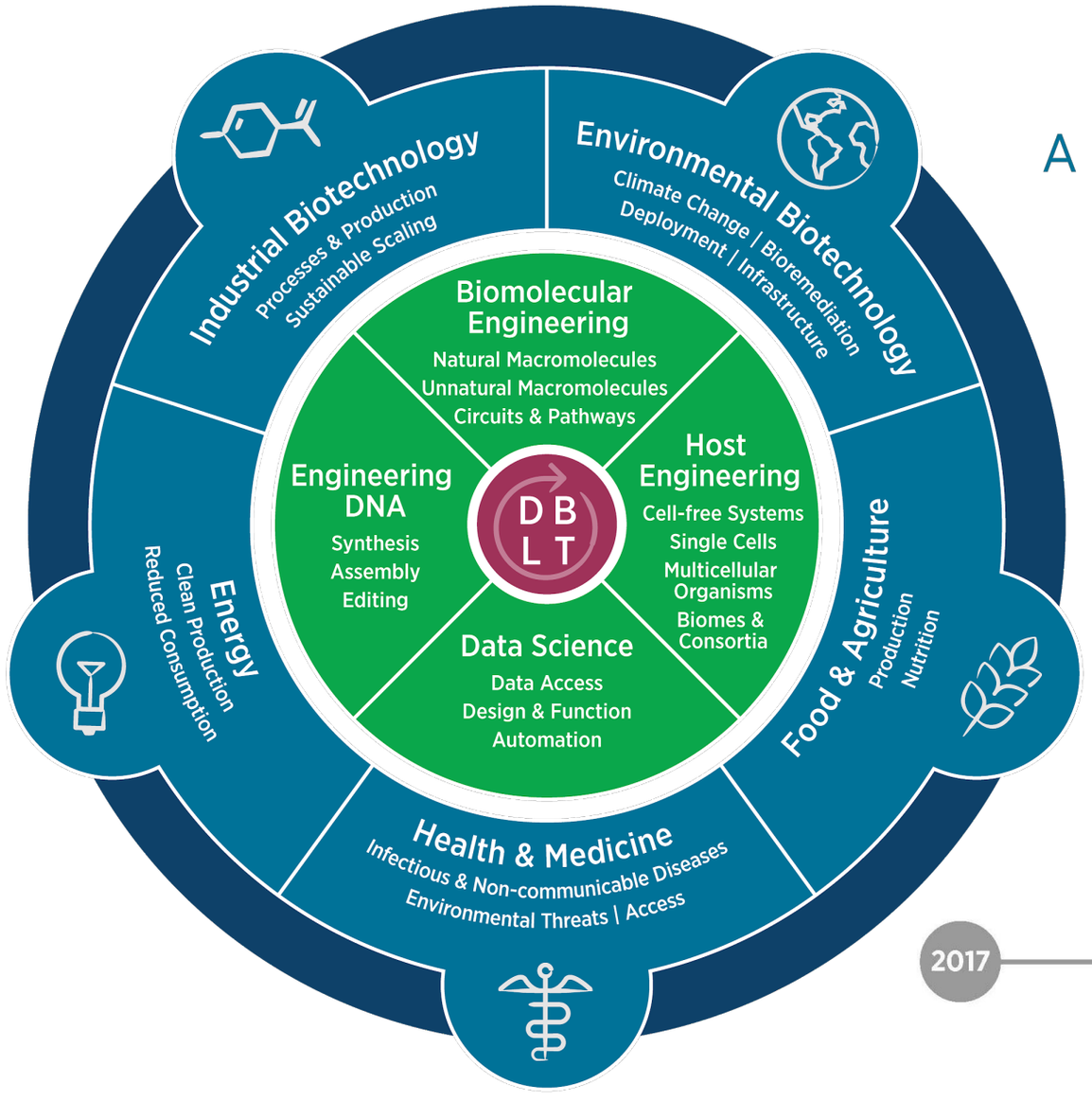
Find & filter 293 products

- Product categories ...
- Market status ...
- Production process ...
- Biotech components ...
- Business models ...
- Country of production ...
- Country of distribution ...
- Intended consumer ...
- Funding types ...
- Industry ...
- Organization type(s) ...
- Source ...
- Trading exchange ...
- Value chain stage ...

A list of products will display as soon as you select a filter above. You may continue to add as many additional filters as you'd like.

- Captures database from BioTech Regs report
- Has received some funding for updates (2018); not sure about current status…

Engineering Biology Research Consortium



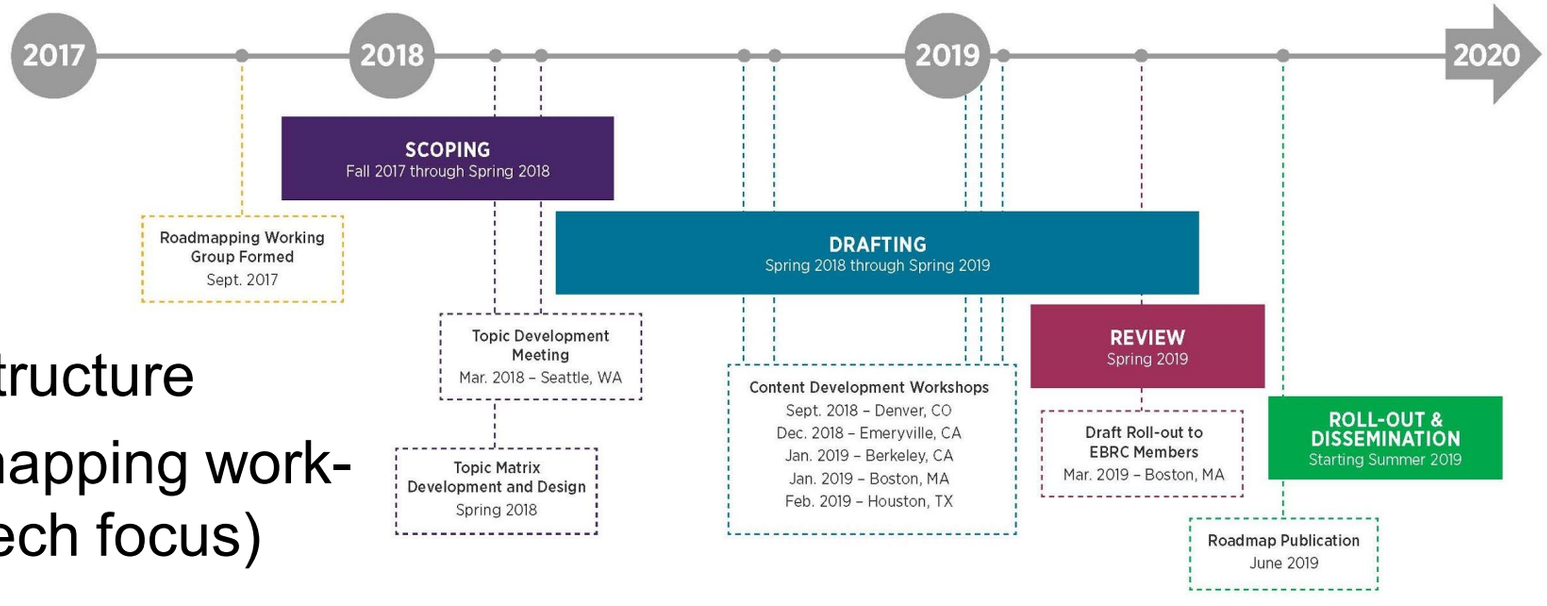
Engineering Biology

A Research Roadmap for the Next-Generation Bioeconomy

A critical assessment of the potential of engineering biology and a roadmap to help us get there.

Contributions from more than 80 scientists and engineers from a range of disciplines, representing more than 30 universities and a dozen companies.

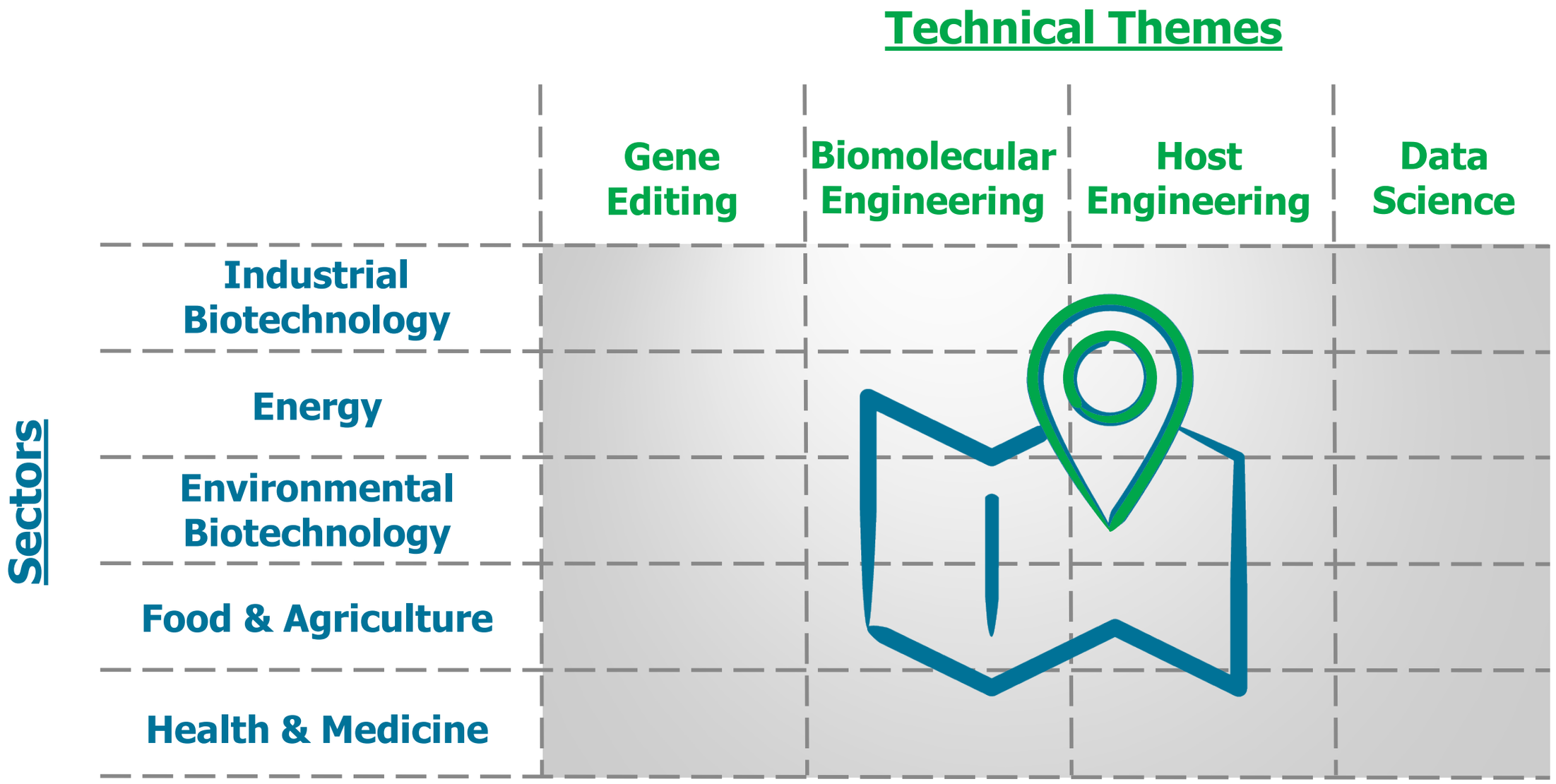
https://roadmap.ebrc.org



EBRC roadmap preparation

- Mar/Apr 2017: scoping and structure
- Sep 2018 - Feb 2019: roadmapping work-shops (~30 people, alt. app/tech focus)

EBRC Roadmap Organization



Sector Roadmap Elements

- Societal Goals
- Science/Engineering Aims
- Engineering Biology Objectives
- Technical Achievements

Technical Theme Roadmap Elements:

- Goals
- Breakthroughs
- Milestones (2, 5, 10, 20 years)
- Bottlenecks/Potential Solutions

Lessons Learned and Final Thoughts

What it takes to do Horizon Scanning

- Mechanisms for collecting input from broad variety of sources
  - Meetings, literature surveys, industry organizations (NASEM)
  - Structure for collecting input that exposes gaps in knowledge
- Substantial effort that engages industry, academia, government
  - Discussions with diverse groups that teases out what is possible
  - Sequence of meetings with both continuing and new participation
- Dedicated staff resources to help collect, organizer, filter, cajole, write, etc
  - Searchable databases that can be updated, maintained, queried
  - Might be able to leveral multi-agency efforts (eg, NSF-sponsored EBRC roadmap serving as starting point for DHS and DoD roadmaps/horizon scanning)

What it should look like if done right

- Complex issues get discussed *before* technology appears, not after
- Attention gets focused on parts of the future that are more complex, less understood
- Absolute timeframes can be wrong, but relative timeframes should be (roughly) right
- View of the future is regularly updated (annually?)