Research Update

Prospects and Issues of Industrialization of Smart Cells

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In a variety of bio-related areas, industrialization has rapidly progressed thanks to technological innovation for genome editing. This update describes prospects for new industry development using smart cells (i.e. cells artificially created using genome editing technologies), as well as issues that need to be solved.

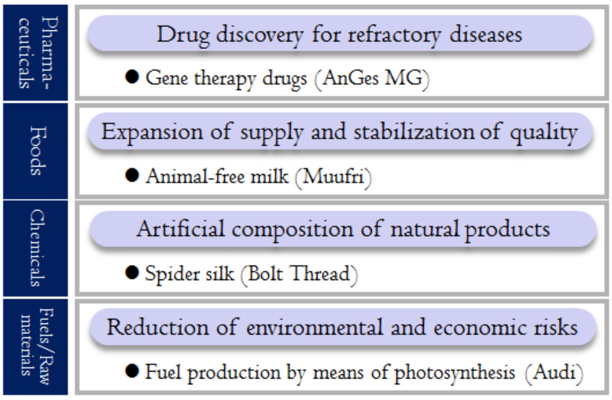
1. Evolution in the use of biofunctions: Current state and prospects

The use of biofunctions in material production has evolved from material extraction out of microorganisms to genetic recombination and to synthetic biology. Synthetic biology is defined as the artificial creation of smart cells that can discover the desired functions.

CRISPR/Cas9 technology invented in 2012 has brought innovation in genome editing. Thanks to this technology, DNA (deoxyribo nucleic acid: gene components) can be cut at desired points using enzymes, and it has become possible to edit genes very efficiently and at low cost. As a result, the world of smart cells is growing (i.e. use genome-editing technology to create microorganisms made up of smart cells having new functions and then let these microorganisms produce new substances).

Smart cell creation currently requires the elucidation of biofunctions from the natural world using an enormous amount of genetic information and the discovery of promising genes from among them. As a result, increasing cost burdens caused by prolonged development is becoming a problem. Other problems include variations and fluctuations in performance of artificially created products. The industrial use (industrialization) of smart cells is expected to expand in the design-type process that enables the efficient artificial design of smart cells using big data analyses and in the highly efficient production process that can reduce production fluctuations using AI (artificial intelligence) and automation technology.

Smart cells are currently used mainly for biopharmaceuticals but are expected to be also used in other business areas (i.e. foods, chemicals, and fuels) (see Diagram 1). Markets for chemicals and fuels are expected to expand rapidly. Global markets for biopolymers and biofuels/bio-based raw materials are forecast to account for 3.8 trillion yen in 2020 and 130 trillion yen in 2030.

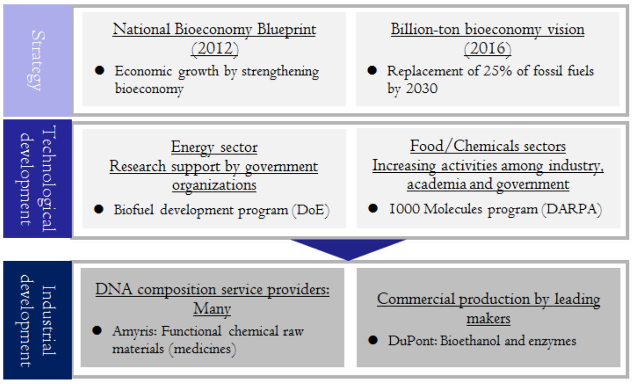


Source: Prepared by Hitachi Research Institute using various materials.
Diagram 1: Expanded use of smart cells in various business areas

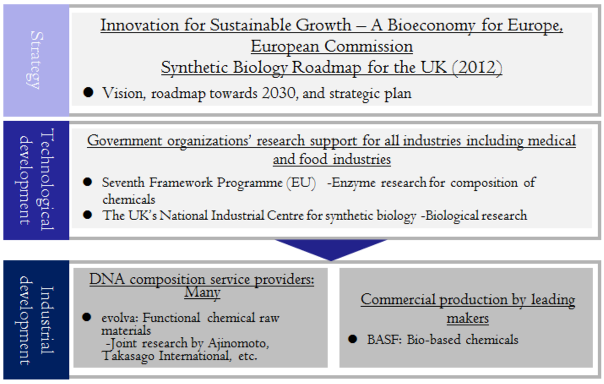
2. European and U.S. approaches: Government-led activities

In 2012, the U.S. announced the "National Bioeconomy Blueprint (2012), aiming for industrialization of gene technology (for industrial applications) (see Diagram 2). Based on this policy, the Department of Energy and other authorities have facilitated the energy industry's use of smart cells through tax incentives, and realized commercial production of next-generation biofuels. In addition, collaboration activities among industry, academia and government have increased, including JCVI (J. Craig Venter Institute), which is considering expanding technologies for the food sector (e.g., protein and supplements), DARPA (Defense Advanced Research Projects Agency), which aims at composition of key compounds in the chemicals sector, and University of Illinois that is developing synthetic biological systems through process automation.

In 2012, the EU announced Innovation for Sustainable Growth – A Bioeconomy for Europe, European Commission (see Diagram 3). The EU is highly interested in a post-petroleum society and in using forestry resources. For example, enzyme research has begun as part of the Seventh Framework Program for Research and Technological Development. In particular, the U.K. has prepared a roadmap toward 2030, defined the roles of industry, academia, and government in relevant sectors (i.e. the food, pharmaceutical, chemical, raw material, and fuel), and started many government-led research projects.



Source: Prepared by Hitachi Research Institute using various materials.
Diagram 2: U.S. strategy for industrialization of smart cells

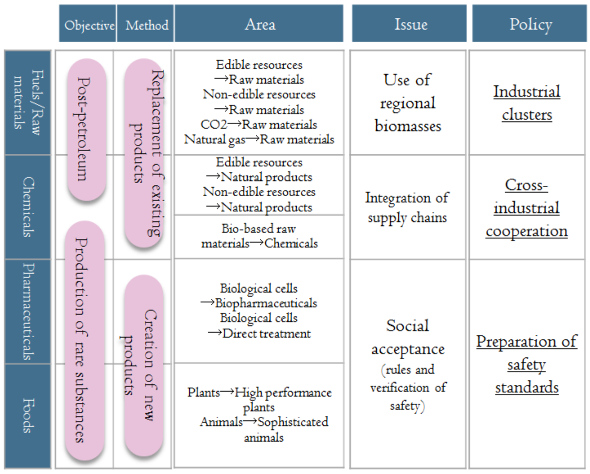


Source: Prepared by Hitachi Research Institute using various materials.
Diagram 3: EU strategy for using smart cells

3. Japan left behind in industrialization of smart cells

In January 2016, the National Institute of Technology and Evaluation, an independent administrative institution, issued the "Policy Proposal for New Phase of Biotechnology Industry Development," and summarized important policies mainly relating to four sectors: health/medical care, substance production, regional vitalization, and key DNA repository/BRC (biological resource center). Based on these policies, the Ministry of Economy, Trade and Industry reorganized its Bio-Industry Subcommittee (which is part of the Commerce, Distribution and Information Committee of the Industrial Structure Council) in March 2016. This subcommittee's mission is to investigate and deliberate important matters related to the industrial use of biotechnologies. However, although drug discovery, substance production (excluding drug discovery), and use and activation of regional resources are the issues to be considered, they have only been discussed individually, and policy integration for industrialization has not yet been considered. As a result, Japan has largely been left behind in the world in terms of industrialization.

The establishment of an integrated industrial system enabling the stable production and procurement of domestic biological resources and the inputting of these resources into an efficient production system are important for industrialization of smart cells. In addition, the completion of industrialization in future requires the implementation of a system to disclose reliability information and wider social acceptance of smart cells through rule establishment as essential activities from the beginning.



Source: Prepared by Hitachi Research Institute using various materials.
Diagram 4: Japan's policy issues

4. Policy issues to be resolved

The following three points are Japan's policy issues relating to the promotion of industrialization of smart cells (see Diagram 4).

The first issue is the promotion of industrial clusters aiming to use regional biomasses (biological resources). The effective use of a variety of low-density biomasses spreading extensively across Japan requires that industries (e.g. chemical, food, and fuel) are attracted to regions and neighborhoods where these biomasses are available. By doing so, it becomes possible to efficiently connect promising biomasses with commercial use and promote industrialization of smart cells based on regional characteristics.

The second issue is the establishment of an integrated supply chain system for the smart cell industry through cross-industrial cooperation. By establishing a supply chain system that manages the procurement of biomass raw materials, creation of smart cells, biological substance production process including cultivation plants, and distribution of bio-based products, the development and mass production of a variety of new synthetic bio-based materials, etc. become possible.

The third issue is the improvement of social acceptance through the preparation of safety standards. The verification of the safety of substances created using smart cells and the improvement of social acceptance require the segmentation of objects and ranges and the preparation of original safety standards suitable for safety trends in Japan. In addition, information about the social benefits of smart cells and the current global situation needs to be summarized and actively disseminated.

To contribute to the industrialization of smart cells in Japan, Hitachi Research Institute will continue to conduct researches on specific measures for addressing the above issues.