MedicalXpress

# Federal agencies need to prepare for greater quantity, range of biotechnology products

March 9 2017

A profusion of biotechnology products is expected over the next five to 10 years, and the number and diversity of new products has the potential to overwhelm the U.S. regulatory system, says a new report from the National Academies of Sciences, Engineering, and Medicine. The U.S. Environmental Protection Agency, the Food and Drug Administration, the U.S. Department of Agriculture, and other agencies involved in regulating biotechnology products should increase their scientific capabilities, tools, and expertise in key areas of expected growth, said the committee that conducted the study and wrote the report.

"The rate at which biotechnology products are introduced—and the types of products—are expected to significantly increase in the next five to 10 years, and federal agencies need to prepare for this growth," said committee chair Richard Murray, Thomas E. and Doris Everhart Professor of Control and Dynamical Systems and Bioengineering, California Institute of Technology. "We hope this report will support agency efforts to effectively evaluate these future products in ways that ensure public safety, protect the environment, build public confidence, and support innovation."

The U.S. biotechnology economy is growing rapidly, with the scale, scope, and complexity of products increasing. More types of organisms will likely be engineered, the report notes, and the kinds of traits introduced with biotechnology will also increase. Some future biotechnology products are likely to use genome-editing techniques such as CRISPR for familiar applications, such as modifying agricultural

crops. Other future products are expected to be entirely new—plants that can serve as sentinels of environmental contamination, for example, and collections of microorganisms that can produce chemical compounds efficiently. Engineered microbes, plants, and insects designed to live in the environment with little or no human management are likely to be more common. With few exceptions, products such as these have not yet been evaluated by the current regulatory system.

Current staffing levels, expertise, and resources available at EPA, FDA, USDA and other agencies may not be sufficient to address the expected scope and scale of future biotechnology products, the report says. It is critical that the agencies involved in regulation develop and maintain scientific capabilities, tools, and expertise in key evolving areas. Examples of such areas include understanding relationships between intended genetic changes and an organism's observable traits, the unintended effects of genetic changes on target and non-target organisms, predicting and monitoring ecosystem responses, and quantifying the economic and social costs and benefits of biotechnologies.

To respond to the expected increase and diversity of products, the agencies should develop risk-analysis approaches tailored to the familiarity of products and the complexity of their uses, the report says. For biotechnology products that are similar to products already in use, established risk-analysis methods can be applied or modified, and a more expedited process could be used. For products that have less-familiar characteristics or more complex risk pathways, new risk-analysis methods may need to be developed. Regulatory agencies should build their capacity to rapidly determine the type of risk-analysis approaches most appropriate for new products entering the regulatory system.

EPA, FDA, and USDA should identify products that could serve as pilot

projects to develop new approaches to assess risks and benefits and to inform regulatory decisions, the report says. Pilot projects could also be used by the agencies to evaluate future products as they move from laboratory scale, to field- or prototype-scale, to full-scale operation.

One challenge regulators will face is finding jurisdiction under existing statutes to regulate the diverse range of anticipated biotech products, the report says. The current collection of statutes and regulations that provide the basis for agencies' oversight, known as the Coordinated Framework for Regulation of Biotechnology, appears to have considerable flexibility to cover a wide range of biotechnology products, but in some cases the agencies' jurisdiction has been defined in ways that could leave gaps or overlaps in regulatory oversight. At times, FDA, EPA, and USDA may need to make use of the flexibility under their statutes to minimize gaps in jurisdiction.

Even when statutes do allow agencies to regulate products, the current statutes may not adequately equip regulators with the tools to regulate the products effectively, the committee said. For example, the statutes may not empower regulators to require product sponsors to share in the burden of generating information about product safety, and may place the burden of proof on regulators to demonstrate that a product is unsafe before they can take action to protect the public. This implies that adequate federal support for research will be crucial to protect consumer and occupational safety and the environment.

Biotechnology products on the horizon are likely to generate substantial public debate, the report notes. Many members of society have concerns over the safety and ethics of various biotechnologies, while others see prospects for biotechnology addressing social or environmental problems. The U.S. regulatory system will need to achieve a balance among competing interests, risks, and benefits when considering how to manage development and use of new biotech products.

In addition, more research may be needed to develop methods for governance systems that integrate ethical, cultural, and social implications into risk assessments in ways that are meaningful. This may not be feasible or even justified for all new biotechnology products—such as products with which there is already familiarity or products that will not be released into the environment. For example, genetically engineered organisms used in the research laboratory to develop new chemical synthesis methods are not likely to require the same level of public dialogue as products that have more uncertainty associated with them, such as organisms with gene drives, which enhance organisms' ability to pass certain genetic traits on to their offspring.

Overall, the federal government should develop a strategy that scans the horizon for new biotechnology products, identifying and prioritizing those products that are less familiar or that present a need for more complex risk analysis, the report says. The federal government should also work to establish appropriate federal funding levels for sustained, multiyear research to develop the necessary advances in regulatory science. To this end, the National Science Foundation, the U.S. Department of Defense, the U.S. Department of Energy, the National Institutes of Standards and Technology, and other agencies that fund biotechnology research should increase their investments in regulatory science.

Provided by National Academies of Sciences, Engineering, and Medicine