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International Food & Agricultural Trade Policy Council

Innovative Agricultural Production Techniques Face Regulatory Barriers

The benefits from new agricultural production technologies risk being lost due to slow government decisions on policy, the high costs of regulation, and potential asynchronous global requirements according to speakers at an October 3, 2013 IPC-hosted discussion. The topic of "Innovative agricultural production technologies – a global approach to increasing production, enhancing food security and improving food safety?" was part of the World Trade Organization's Public Forum, an event for civil society, government, and business to discuss an aspect of trade. The focus this year was on innovation and trade.

New technologies, including plant breeding techniques, animal biotechnology and nanotechnology, can play an important part in meeting the challenge of increasing global food supplies by 70 percent to meet the anticipated world population of more than 9 billion in 2050 as well as the additional demand for meat and dairy products as millions more enter the middle class. They have the potential to increase production, reduce waste, enhance food security, and improve food safety. Gains can be made, too, by using technology to more precisely utilize fertilizers and pesticides.

"Fully utilizing these technologies and being able to trade products made from them will depend on governments' decisions about whether these need to be regulated, and if so, how," according to **IPC President Ellen Terpstra**. "Many governments are currently considering these questions, but if they reach contradictory conclusions, trade may be stifled and the benefits of these advances unrealized."

Throughout our history, plants have been genetically modified for desirable traits. Converting wild plants into crops through domestication is genetic modification. As science advanced, we cross bred crops in different species and different genera, and then created new genes in our crops through mutagenesis. Genetic engineering is the next step in a continuum of genetic modification techniques. New techniques have allowed improved precision and predictability to obtain the desired traits. New breeding technologies (NBTs) include zinc finger nucleases (ZFN), oligonucleotide directed mutagenesis (ODM), and induced DNA methylation. **Adrianne Massey, Ph. D., Managing Director, Science and Regulatory Affairs at BIO**, outlined the evolution of these technologies. She also indicated that the cost of going through the regulatory process is now between $15 million (for the U.S. market alone) and $36 million, making it nearly impossible for smaller companies or lesser valued commodities to benefit from new opportunities.

Dr. Emilio Rodríguez-Cerezo, with the Institute for Prospective Technological Studies of the European Commission's Joint Research Centre, reviewed technical innovations in plant breeding, the research and patent landscapes and outlook for commercial development, and discussed the regulatory and policy issues under consideration by governments. He classified the new plant breeding technologies in three families: 1) targeted mutagenesis/modification (genome editing); 2) techniques resulting in negative

(null) segregants; and 3) variants of genetic transformation. Techniques in the first category include oligonucleotide directed mutagenesis (ODM), and targeted mutagenesis techniques using nucleases such as zinc finger nucleases (ZFN), meganucleases, and TALEN nucleases. Reverse breeding and RNA directed DNA methylation are techniques resulting in negative segregants (i.e. techniques using a transgene in an intermediate step in the breeding process, while the transgene is segregated out in the commercial crop variety). Cisgenesis and intragenesis as well as grafting on GM rootstock are variants of plant transformation techniques.

He noted that in recent years there has been an increase in scientific publications on these technologies, mostly originating from academia and largely from institutions in the EU-27 or North America. The number of patents has also increased in recent years, with three-quarters being from industry, half based in North America and over a third in the EU-27. (For a full description of the techniques and the research/patent landscape he referred to the JRC report "New Plant Breeding Techniques: State-of-the-art and prospects for commercial development," free for download at http://ipts.jrc.ec.europa.eu/publications/pub.cfm?id=4679) and summarized in a JRC article in the journal Nature Biotechnology (Deployment of new biotechnologies in plant breeding, Nature Biotechnology 30 (3), 231-239.)

A survey of the plant breeding industry shows that these techniques are already adopted in breeding programs eventually resulting in commercial crop varieties. Drivers for adoption are the technical potential and the possibility to make breeding faster. Constraints, according to industry, are the need to increase efficiency of some techniques and the uncertainty of the regulatory status of these technologies. Dr. Rodríguez cited the JRC report "Comparative regulatory approaches for new plant breeding techniques: workshop proceedings", 12-13 September 2011 for more information on the policy considerations in recent years (http://ipts.jrc.ec.europa.eu/publications/pub.cfm?id=4959). Workshop participants included representatives from the governments of Argentina, Canada, the EU, Japan, South Africa, and Australia and included some input from the United States. The workshop revealed that regulatory decisions on these techniques are not yet taken in most cases and that the issue is being studied by expert groups. Although some common aspects were identified, the diversity in approach to regulation among the participants, including whether the regulation should be focused on the product trait or the technique as a process, suggests that differences in eventual regulatory classifications cannot be excluded.

Dr. Rodríguez also noted that a challenge for regulators is the availability of methods for detection/identification of crops produced from these techniques. Regarding detection methods it may or may not be possible to determine the existence of a change in the genetic material by reference to an appropriate comparator. A second area of challenge is whether it is possible to identify the genetic change as one that has been introduced by a new technique. In cases where the existence of a change in genetic material is not possible or if the genetic change cannot be identified with a new technique, then this raises questions about the ability to regulate the process or product.

Some of the techniques are now ready for crop plants but their future will depend on what governments decide about their regulatory status. These discussions are taking place in many countries with expert groups advising policy makers on the classification of the techniques and products vis-à-vis biotech crop legislation in the countries. However, much of the legislation and definitions are 20 years old and may not adequately consider the new technologies. There remains the possibility that government policy makers will reach contradictory decisions as to whether the techniques need regulation.

Catherine Moreddu, **Senior Agricultural Analyst, Trade and Agriculture Directorate** and an author of a recent **OECD** study on "Agricultural Innovation Systems: A Framework for Analyzing the Role of Government" (http://www.keepeek.com/Digital-Asset-Management/oecd/agriculture-and-food/agricultural-innovation-systems/executive-summary_9789264200593-2-en#page1) cited the benefits of agriculture innovation: improving farm income, productivity growth and competitiveness; lowering food costs to consumers; improving the sustainable use of natural resources and our ability to adapt to climate change;

reducing losses along the food chain; improving the nutritional attributes of food; and ensuring food traceability and safety. Governments' role in innovation may be as a funder and performer of research and development, technology transfer and farm advisory systems; providing the strategy and evaluation for innovation; having strong policies on intellectual property rights to protect knowledge innovators; and providing the infrastructure for knowledge, including information systems -- databases, modeling and forecasting tools, gene banks, etc. As many challenges are global, it is important to strengthen cross-country cooperation. Participation and support for international efforts such as CGIAR, GFAR, and the Global Research alliance on GHG is efficient as is regional cooperation on cross-boundary issues such as pests and diseases. On a national level, it is critical to align incentives for the agricultural sector and the innovation system to policy priorities, to ensure a supportive policy framework in terms of markets and trade policy, regulations, investment policy, etc; and to improve the governance of agricultural innovation systems by providing better information on outcomes and developing better evaluation methods.

Sal Amodeo, Trade Policy Advisor for Biotechnology with the U.S. Department of State, highlighted the U.S. Government's blueprint for the national bioeconomy. Realizing we will have to produce more food and are already using much of the world's land and water and that agriculture contributes significantly to green house gas emissions, technology will be a critical factor in meeting this challenge. Research and development investments will be the foundation of the future U.S. bioeconomy. Federal policy will have a role in the transition of bioinventions from the lab to market, including an increased focus on translational and regulatory sciences. The regulatory system must be reformed to reduce barriers, to increase the speed and predictability of the regulatory processes, and reduce costs while protecting human and environmental health. Finally, policy must support opportunities for public-private partnerships and precompetitive collaborations.

The bioeconomy is estimated to provide 2.7 percent to a global average GDP by 2030 according to OECD. While many governments are searching for ways to encourage economic growth, the regulatory burden on innovation stifles growth. New plant breeding technologies will be critical to more efficient food production but for this to happen, regulations must offer a speedy process, have a reasonable cost, and be harmonized among nations.

Additional information and presentations will be available on the IPC web site at www.agritrade.org.

The International Food and Agricultural Trade Policy Council promotes the role of trade in creating a more open, equitable, productive and sustainable global food and agricultural system. IPC makes pragmatic trade policy recommendations to help solve the major challenges facing the global food and agricultural system in the 21st century—the need to promote global food security, to sustainably increase productivity, and to contribute to economic growth and development.

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