







## **WEBINAR SERIES ON**

# Applications of Gene Editing in Sustainable Agriculture and Food Security in Asia-Pacific Region

### **WEBINAR**



Enabling Policies for Genome Editing in Agriculture

Date:
August 18, 2021, 10.30 AM - 12.30 PM
ICT (Bangkok time)

Registration
https://zoom.us/meeting/register/
tJAqdumsqDooGNApndwbg1Zt6ldtYcsrLM5y

Dr. Kanokwan (May) Chodchoey

Dr. Roland Schafleitner

Flagship Program Leader -

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Dr. Okjae Koo Director, Business Development, Plant and Animal Genome Editing, ToolGen Inc. Co-founder, PLANTeDIT

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**Dr. William D. Dar**Secretary,
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#### **PRESENTERS**



Mr. Fabrice Mattei
Patent Attorney and
Co-head, Rouse's Patent Group

#### **PANELLISTS**



Prof. Masahi Tachikawa Nagoya University, Japan



Dr. Ravi Khetarpal
Executive Secretary,
Asia Pacific Association of
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# Webinar Series on Applications of Gene Editing in Sustainable Agriculture and Food Security in Asia-Pacific Region

Webinar 3: Enabling Policies for Genome Editing in Agriculture

Date: August 18, 2021; 10:30 AM ICT (Bangkok time)

#### **ABSTRACTS**

Need for harmonized policies on research, utilization and trade of genome-edited plants

Dr. Kanokwan (May) Chodchoey, Executive Director, Asia and Pacific Seed Association (APSA), Thailand

Today's plant breeding methods are based on the gradual accumulation of knowledge and understanding over centuries about plant physiology and more recently genetics. The latest tools that have become available to breeders today enable very efficient and precise trait generation and selection, as well as more efficient integration of genetic diversity in breeding programs. Many of these tools are commonly referred to collectively as "plant breeding innovation" (PBI) or "new breeding techniques" (NBT). The technique of "gene editing" or "genome editing" refers to the use of a specialized enzyme to insert, replace or remove DNA from a genome, which is done with a high degree of specificity. This technique can help breeders produce novel traits through the introduction of genetic changes that are predetermined and not random, which helps breeders to add speed, precision and efficiency to their breeding programs. In order to facilitate the use of this technique to address all challenges faced by farmers (diseases and pests, agronomic performance, abiotic stresses such as drought, salinity, heat, etc.), the Asia-Pacific seed industry believes that the adoption of consistent, science-based, policies for the regulation of products derived from the latest plant breeding methods (e.g. CRISPR-mediated genome editing) across the region would facilitate the development and uptake of advanced, innovative breeding applications by private and public breeders. This would in turn benefit the region's agriculture-based sectors of the economy, strengthening the entire agrofood value chain, from farmers to consumers. "It is therefore crucial for regulators drafting or considering new legislation related to new breeding technologies to apply logic- and science-based reasoning, and thus adhere to the concept that "Plant varieties developed through the latest breeding methods should not be differentially regulated if they are similar or indistinguishable from varieties that could have been produced through earlier breeding methods." This concept, as outlined in a position paper adopted by the Asia and Pacific Seed Association and International Seed Federation, has been adopted by and amongst all key stakeholders in various international seed sector organizations, and will be elaborated on in this presentation. Examples of regulatory-processes concerning gene editing technology in different countries and regions will be shared. Moreover, insights, and the conclusion from the recent "OECD Conference on Genome Editing: Applications in Agriculture - Implications for Health, Environment and Regulation" will also be highlighted.









Mr. Fabrice Mattei, Patent Attorney and Co-Head, ROUSE's Patent Group, Bangkok

Despite its promise, gene editing tools remains hampered by a complex and uncertain patent landscape. With more than 1,500 patent families with claims including CRISPR, it is critical to assess third-party rights before using this technology. In this presentation we will review pending patent disputes, identify key patent families and applicants, highlight patent filing trends and point out drafting tips to overcome patent offices' objection

#### The legal situation for site-directed genome editing for breeding of vegetable crops

Dr. Roland Schafleitner, Head-Molecular Genetics, Flagship Program Leader – Vegetable Diversity and Improvement, World Vegetable Centre, Taiwan

Genome editing is an attractive method to alter gene functions for improving crops. It is particularly useful for crops with complex genomes and long generation times, and for traits that are difficult to breed for using traditional methods. The policies for meeting ethical, safety, economical and technical concerns associated with this technology in plant breeding vary among countries. The regulations also depend on the kind of the modification introduced into the genome, such as small deletions or insertions, oligonucleotide-mediated mutagenesis or site-directed insertion of a native or foreign DNA sequences.

Vegetable crops are affected by a wide range of biotic and abiotic stresses, and climate change is likely to make these constraints even more severe. Genome editing contributes to the development of stress tolerant varieties and regulations should be put in place to ensure the safety of genome edited crops, but also encourage the use of this technology in plant breeding. Many countries have introduced policies that keep the regulatory burden for low-risk genome editing applications low enough to allow small and medium-sized enterprises and academic research institutes to clear the regulatory hurdles. This will likely favor the cost-effective development of improved crop varieties for food and nutrition security.

Dr. Okjae Koo, Director, Business Development, Plant and Animal Genome Editing, ToolGen Inc. and Cofounder, PLANTeDIT

Genome editing is a revolutionary tool that can be used in all fields of biotechnology. In particular, CRISPR/Cas technology is overwhelmingly convenient, efficient, accurate and even significantly cost-effective compared to former genome editing technologies such as ZFN and TALEN. For this reason, competition over IP rights for CRISPR/Cas9 technology is unprecedentedly fierce. In 2012, at least five organizations filed fundamental IP underlying CRISPR/Cas9 technology, and the IP competition is still undergoing now in 2021. However, the patent competition over CRISPR/Cas9 is mainly related to human therapeutics development. In the area of agriculture, the joint licensing framework for at least 3 major IPs has already begun and the first product was commercialized this year based on this joint-license. On the other hand, several alternative CRISPR systems, such as Cpf1, Mad7 and CasX, continue to be reported. Most of these Cas alternatives have been also patented, however, they are not in the same complex situation as in Cas9. From an IP perspective, CRISPR-based agricultural products are ready for commercialization. It is time to establish clear and scientific regulatory policies, which will open up enormous potential for agriculture in the Asia-Pacific region.









#### Prof. Masahi Tachikawa, Graduate School Environmental Science, Nagoya University, Japan

Genome editing is being applied in various fields of life sciences, such as medicine, agriculture, food and energy. Regarding the regulatory status of genome editing in Japan, policies are being issued by the relevant competent authorities, and applications to the fields of agriculture and food are being widely considered. However, there has been little discussion on the perceptional differences between applications for plants and animals. In our study based on a web-based survey, we asked respondents to respond to each questionnaire regarding their expectations and concerns about genome editing, and we observed differences in the tendency of responses between the group that was shown a crop (tomato) and the group that was shown an animal (pig). In particular, statistically significant differences were observed in items such as "I feel there are bioethical issues". When the participants were asked to answer the questions while being shown livestock as an image, they tended to show more negative attitude than the crop group. In order to promote the use of genome editing technology in animals, various issues still exist, such as animal welfare, consumer awareness, and dependence on foreign countries for genetic resources.

Dr. Ravi Khetarpal, Executive Secretary, Asia Pacific Association of Agricultural Research Institutions

Regulatory policy cannot keep pace with the fast-moving scientific advances. Many countries are still in the process of developing regulatory approaches for products of Genome edited plants, so the opportunity remains for enhancing global regulatory coordination. The resulting different regulatory processes in different countries can have large impacts on trade and innovation. They can shape which products are developed, which products are available for farmers to grow, and what types of products are available for consumers. Asia-Pacific countries need to share their experiences and support those countries within the region who need to have an enabling policy environment for genome edited plants. APAARI is committed to take this forward in the region.