Report on Utilization of Next Generation Sequencers in Safety Assessment of Genetically Modified Plants

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<Summary>

The safety assessment of genetically modified plants (GM plants) for regulatory approval currently requires a detailed molecular characterization of the DNA sequence and integrity of the transgene locus. Typically, molecular characterization has relied on southern blot analysis to establish locus and copy number along with targeted sequencing of polymerase chain reaction (PCR) products spanning any inserted DNA to complete the characterization process. The next generation sequencing (NGS) technology can provide dramatically increased sequencing throughput compared with capillary electrophoresis sequencing technologies, comprehensive coverage of complex genomes when a sufficient sequencing depth is given, and a basis for accurate whole-genome studies. In this research, we collected and analyzed the information about characteristics of each sequencer based on NGS technology, comparison between the traditional method and NGS technology used for safety assessment of GM plants, and GM plants study based on NGS data in order to contribute to the safety assessment of GM plants in Japan.

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Recent Advances on the Involvement of Lipids in NAFLD/NASH

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<Summary>

Non-alcoholic fatty liver disease (NAFLD) and non-alcoholic steatohepatitis (NASH) are recognized as one of the phenotypes of lifestyle-related diseases in the liver. While hepatocellular damage and inflammation, derived from toxic effects of excess lipids, have been elucidated to be one of the major causes of NASH, recently accumulating data indicate that the major determinant of lipotoxicity is not (a total amount of) triglyceride stored in hepatocytes, but the specific classes of lipid damaging hepatocytes. It is essential, therefore, to elucidate key lipid classes and their functions, for the understanding mechanisms underlying NAFLD/NASH and the development of novel strategies of their therapy and prophylaxis. In particular, roles of free saturated fatty acids, such as palmitic acid, and cholesterol have recently been emerged, and these lipotoxic agents impair hepatocytes via mitochondrial dysfunction and oxidative stress. On the other hand, n-3 long-chain polyunsaturated fatty acids ameliorate liver steatosis and inflammation via various mechanisms. In addition, it has recently been suggested that the balance of the chain-lengths of fatty acids is another important factor for the development of NAFLD/NASH. In this article, we discuss these and the other latest topics with regard to trans fatty acids and phospholipids, to review recent advances on the involvement of lipids in NAFLD/NASH.

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Present Situation and Perspectives of a Technical Innovation on an Alternative to Animal Test Method for a Safety Assessment of Chemicals and Pharmaceuticals

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<Summary>

As safety evaluation test methods without experimental animals, in vitro and in chemico test methods have been developed to date. Recently the Organisation for Economic Co-operation and Development (OECD) has officially adopted more than 20 non-animal test methods guidelines. However, the officially adopted methods are limited to those for local toxicity (such as ocular irritation, skin corrosion & skin irritation, skin sensitization), genotoxicity, endocrine disrupter screening etc.; there is no officially adopted test methods which replace the existing systemic toxicity test methods.

In such circumstances, new projects and organizations have been activated in these few years in Japan in order to develop non-animal test methods and in silico which predict cardiotoxicity, neurotoxicity, hepatotoxicity, nephrotoxicity, etc. supported by the Japan Agency for Medical Research and Development (AMED) and Ministry of Economy, Trade and Industry (METI). By new non-animal test methods and in silico been developed through technological innovations in such large projects, new toxicity evaluation methods are expected to emerge.

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< Research Institute of ILSI Japan Members >
Research Introduction of "Research Village Kyoto" That Is Rohto Pharmaceutical R&D Center.
Our Challenge to Contribute to Society through Health Promotion of "Eye Care", "Skin Care", "Food" and "Regenerative Medicine".

Yoichi Honma
ROHTO Pharmaceutical Co., Ltd.
Director of Corporate Strategy Promotion Headquarters
R & D business special manager
Director of the basic research and development department

<Summary>

ROHTO started the manufacture and sale of stomach medicine and eye drops, and "skin care" is also one of major pillar of business now. After exclusively acquiring the right to use the trademark of the Mentholatum Company in USA, we entered the skin care field. After that, we increased sales and acquired management rights. Several factors overlapped and we were able to enter the skincare field newly. For example, research using corneal cells cultivated in eye care could be applied to skin research. We have made markets with stores before drug store sells cosmetics. In laboratories that make use of open innovation, in addition to the active participation of many researchers regardless of gender and nationality, we are also proactively promoting collaboration with other companies. Following "Eye care" and "Skin care" in the future, we are also expanding into "food" and "regenerative medicine" as new businesses. We will challenge making the world healthy with the spirit of our corporate slogan "Never Say Never".

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ILSI Japan Biotechnology Research Committee: ERA Study Meeting

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<Summary>

ILSI Japan Biotechnology Research Committee held ERA study meeting on April 25th, 2018 at Fukuracia Marunouchi Oazo.

More than 170 different events of Genetically Modified crops have been evaluated for environment risk (adverse effects on biodiversity) and approved in Japan since enforcement of Japanese Cartagena law in 2004. At the same time, review process has been reviewed and improved to conduct environmental risk assessment more effectively. The ERA study meeting was held to contribute further progress of science based ERA through review of a current concept of environmental risk assessment in Japan and discussion on data transportability of confined field trial data.

Five presenters talked about a concept of ERA of GM crops in Japan, a concept of data transportability and its status in/outside Japan and current activities on data transportability of confined field trials in ILSI Japan. Total of 59 people participated the study meeting from industry, academia and regulators and conducted an active discussion during QA sessions and panel discussion.