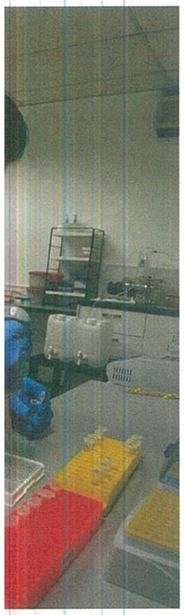

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BIOSAFETY MATTERS

The legal, scientific and policy-making aspects of biosafety put under the scope

MALAYSIAN biosafety experts who participated in the recent Asian Short Course on Agribiotech, Biosafety Regulation and Communication (ASCA5) share their thoughts with The Petri Dish (TPD) on the legal, policy, and science perspectives of Genetically Modified Organisms (GMOs). Dr Mohammad Firdaus Abdul Aziz, Senior Lecturer, Faculty of Law, Universiti Malaya shared on the legal aspects whereas Dr Nurzatil Sharleeza Mat Jalaluddin Postdoctoral Research Fellow, CEBAR Universiti Malaya spoke on policy-making. Dr Hoe Han Goh Deputy Director of INBIOSIS at Universiti Kebangsaan Malaysia shared the scientific aspects.

Dr Mohammad Firdaus Abdul Aziz, visiting International Rice Genebank.

TPD: As an academician in law who had initial training in biology, how did ASCA change your perception of the biosafety framework?
Dr Mohammad Firdaus Abdul Aziz: Previously, I developed my knowledge in biosafety law only through literature and interaction with scientists who are involved in modern biotechnology locally. By attending ASCA, I learned that the biosafety framework needs to be revisited from time to time to ensure the current existing framework stays relevant to the rapid development of modern biotechnology. It must be a living regulatory document that has a vital role in facilitating scientific development while ensuring the safety of human health and the environment.

For instance, in Malaysia, we currently have uncertainty about how to regulate gene editing. We need to move towards science-based approaches like many other countries, such as the Philippines, Australia, and Japan if Malaysia is serious about developing modern biotechnology. Without certainty, our scientists will be in a dilemma as to how they should proceed with their research work. They would perceive the regulation as a stumbling block. As someone who is trained in both law and science, I always promote regulatory approaches that are science-based, not risk-averse able to facilitate scientific breakthroughs in a safe, responsible, ethical manner.

TPD: How do you think dialogue between the legal fraternity and scientists can be improved on biosafety acts and regulations?
Dr Mohammad Firdaus Abdul Aziz: To ensure a legitimate regulation, it is important to first determine if the existing rules are clear and relevant. In doing so, there is a need for interaction between regulators and applicants/developers. Communication between the different stakeholders is key. I'd love to see an annual forum or conference on biosafety in Malaysia, whereby all stakeholders could convene and share with one another on the current scientific development and regulatory issues. The government through the mandated authority plays an important role to ensure that this initiative takes place for stakeholders from different backgrounds such as law and science to interact. If not, many of us work in silos and rarely share our work with anyone else except through publications, especially for academicians from law or science. Publications are important, but I think personal interactions and dialogue can have a greater impact, especially to work on policy and regulatory measures that capture the views of all interested parties. The communication process should be more inclusive with farmers, NGOs, and members of the public in any forum or conference. Such an effort would facilitate other groups of stakeholders to understand the law and scientific development better as the usual stakeholder engagements usually focus on scientists and lawyers.

TPD: Traditionally research breakthroughs are always ahead of regulations. However, the Philippines biosafety regulations are ahead of research. Do you think this is the way forward where regulations are future-proofed?
Dr Mohammad Firdaus Abdul Aziz: I must say that the regulators in The Philippines have shown an exemplary role in ensuring that the law in their jurisdiction is not lagging behind scientific progress. I believe this would not be possible if there is no dialogue or consistent communication between them and the local researchers. This can be seen from their presence at ASCA. They were very active in their participation and interacting with the participants who are mostly scientists. They demonstrate a high degree of commitment in making sure that their national regulation remains relevant and legitimate. I wouldn't say that any regulation can be future-proofed. Science is a complex realm and highly technical. I am not sure if we can establish a future-proofed law. However, regulators could ensure that appropriate regulation is in place. I think the key factor to doing this is communication between regulators and scientists would ensure that regulation remains relevant. One way of developing a regulatory framework is through comparison with other experienced countries. We could adopt regulations from countries with established regulations and adapt to our own local context instead of reinventing the wheel.

Dr Nurzatil Sharleeza Mat Jalaluddin sharing her point of view during the group discussion

TPD: Traditionally research breakthrough is always ahead of regulations. However, Philippines biosafety regulations are ahead of research. After learning from ASCA Do you think this is the way forward where regulations are future-proofed?
Dr Nurzatil Sharleeza Mat Jalaluddin: The Philippines is among the first mover in the Southeast Asia region that has recently clarified their regulatory decisions for gene-edited plants. The new regulations are grounded on science-based rules and minimally bureaucratic processes, which notably highlighted the commitment of the Philippines to modernize their agricultural sector and ensure sustainable food security through biotechnology. This is a great lesson and potentially a way forward for biosafety regulations in other countries, including Malaysia, to keep pace with technological developments and facilitate scientists to unleash the full potential of biotechnology.

TPD: What was the biggest key takeaway from ASCA?
Dr Nurzatil Sharleeza Mat Jalaluddin: The biggest key takeaway from ASCA is the importance of having clear, future-proofed, science-based regulations that will be able to support research, development, commercial use and trades of biotechnological products. As novel biotechnologies are emerging and rapidly evolving, regulators must keep abreast of latest technological advances and ensure that local regulations are current, relevant, and not unnecessarily burdensome to technological developers and traders.

Dr Hoe Han Goh visiting the International Rice Genebank which has thousands of rice seed varieties.

TPD: As a scientist, who develop GMOs what was the biggest takeaway from ASCA?
Dr Hoe Han Goh: I have been working on GMOs since 2008 while pursuing my Ph.D. in the United Kingdom. Returning to Malaysia as a principal investigator in 2011 introduced me to the bureaucracy when proposing a GMO-related research project as required by the Biosafety Act 2007. All researchers must submit a notification form to the institutional biosafety committee (IBC) for approval, while field trials must go through a public consultation which takes a much longer time. During one of the sessions in ASCA, the participants (researchers/policymakers) shared the current scenarios from their respective countries (Indonesia, Philippines, Thailand, and Vietnam). I realise that the biosafety risk assessment for Malaysian researchers is much more in-depth beyond just the environmental risks and includes risks to human health (occupational exposure). Another takeaway is that it remains challenging to bring a GMO such as golden rice to the field and market even in the Philippines, a country with a more permissive than precautionary approach like that of Malaysia. Continuous efforts are needed to encourage public acceptance by highlighting the benefits to all stakeholders, especially the farmers.

TPD: What is your wish list for the Malaysian biosafety framework after listening to the status of other Asian countries to support the R&D and commercialisation of GMOs?
Dr Hoe Han Goh: I wish that the Malaysian biosafety framework can be more permissive than precautionary to encourage more GMO researchers. The current scenario is not facilitating GMO research with constraints in the strict biosafety requirements and a lack of research funding. Most GMO research products are in the valley of death due to the lack of industrial uptake or public acceptance. In turn, this is discouraging further research in the field. Therefore, GMO-related researchers need to work with the policymaker and the public to instill awareness and a science-based approach to the acceptance of GMOs or GM products with the latest scientific advancements like gene editing and gene drive. For benchmarking, our policymakers should refer to success stories from our neighbors such as Indonesia and the Philippines in developing transgenic Bt sugarcane and brinjal, respectively. ●