Virtual breakout Group Session on Animal Biotechnology

Government Regulatory/Policy Officials

Asia and Oceania

Participants

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Challenges

- Definitions – lack of harmonization, need more clarity
- Clarity around regulatory pathways
- Regulatory experience - many countries do not have a lot of experience in safety assessment of GM animals.
- Limited R&D in some countries, particularly in agricultural products. R&D focus has been more on vaccines and disease diagnostics.
- Lack of real examples or precedents of animal biotech products that have been through the regulatory process (especially in food and agriculture).
- Public concerns – lack of public confidence in GM food safety and a lack of understanding among the public about the benefit of GM products. Producers often reluctant to commercialise in that environment, especially to be the first.

Recommendations to address challenges

- More opportunities to share experiences by different countries
- More case studies of animal products in regulation to share or inform international learning
- Some countries are in the process of developing or revising their regulatory frameworks for animal biotechnology. This work will hopefully provide greater regulatory clarity

Regulatory Cooperation

- Monitoring the international environment and trying to source information to share and understand has been a good approach.
- It would be useful to have more information sharing/cooperation activities between neighbouring countries – this would be useful for those countries still developing their regulations.
- There is a desire to work towards regional agreement among ASEAN countries. Something like this could take several years.
- Some examples of regulatory cooperation already exist – for e.g. the joint food standard setting system between Australia and New Zealand, GM food safety assessment sharing work being undertaken between FSANZ and Health Canada.
- It might be easier to harmonize human health and safety assessment within the region. Harmonizing environmental safety assessment may be more difficult because of the complexity and differences in environmental conditions.

Scope of regulation

- NZ - genome edited animals are considered to be GMOs. There are no exemptions.
- AU - SDN-1 edited organisms are not GMOs. Null segregant organisms are also excluded. Other forms of editing (requiring a template), and transgenics are GMOs. Situation in relation to food is still being clarified.
- PH - likely to define SDN-1 as excluded from GM definition, but SDN-2 and SDN-3 will be regulated as GM. Regulations arein development and will focus on the safety and qualities of the final product, most likely determined by equivalence with existing products. Null-segregants are excluded and not regulated
- MY is still working towards a framework for regulation.

Knowledge Gaps/Uncertainties

- There continues to be uncertainty in relation to genome editing because it is a relatively new technology with limited regulatory experience. There continues to be concern about off-target effects.
- Lack of familiarity with GE technology is a big challenge in Asia and many people are suspicious of gene editing technology. More effective communication will be needed to allay some of the concerns.
- MY – yet to establish their Biosafety Framework and engage all of the key Ministries. Foresee issues in identifying, monitoring and enforcing the regulation of GM technology.

Impacts on trade

- ASEAN - some countries have not begun to approach this issue yet. PH and MY are developing Biosafety Frameworks, laws relating to animals, food, derived materials, sharing information to aim for consistency in frameworks and guidance.
- AU and NZ have a joint food standard setting system, so the GM food regulations are the same for both countries. This does not extend to organisms - there is a lack of alignment in regulations because of the SDN-1 exemption in AU.
    - The trading system relies on appropriate declarations being made and compliance with the laws in the receiving country. Industry in AU is well equipped to deal with regulatory misalignment.

Preparing for innovation

- PH – seeking ways to reduce the regulatory burden on companies and on government, for implementation and compliance. However must maintain the confidence of the end-user, the public. Also looking at how the government agencies translate the confidence of the producers and sellers into outcomes.
- HK – consider the cost implications of developing new policy and regulation – understanding if the producers will have problems complying. Communication is seen as important in this process.
- AU/NZ – transparency is very important in creating a pathway for the regulation of new and different products. Proportionality of regulation is important and ensuring that the process is fit-for-purpose.

Next steps

- MY – has new laws coming to issue certificates for GM products and will need experts to help train/inform officials in the agriculture sector.
- PH – inter-agency working groups set up to establish appropriate regulations; National Biotech Week next month – targeting the public, activities to promote biotech.
- IN – Their process is still far behind some other ASEAN countries. Have been discussions on regulations and safety on the plant side.
- NZ – newly re-elected Government. Likely to be a review of the present arrangements.
- HK/AU – it will be very useful to invite industry/producers to share examples and information on the new technology. Case studies would be valuable as a means to share experience and lessons learned.
- Workshopping around examples of potential products, technology applications, outcomes and their interface with regulation could be a useful approach in next steps.