IMPACT OF NEXT GENERATION SEQUENCE (NGS) ON POLICY REGULATIONS

A CASE STUDY IN NEW ZEALAND

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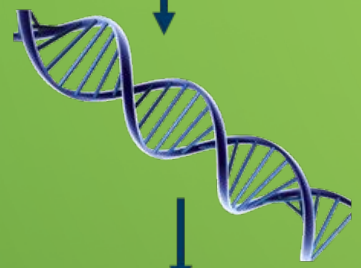
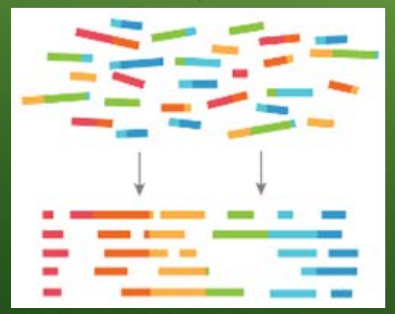
- The New Zealand horticulture industry has a gross value of $7.16 billion, with global exports worth $4 billion annually
- New Zealand is at the forefront of biosecurity worldwide owing to our rigorous post entry quarantine scrutiny of imported plants
- Preventing entry of exotic pests into New Zealand is pivotal to not only maintain and gain access to high-value markets but also to protect domestic plant industries and native biodiversity





1. Existing quarantine processes are laborious, resource hungry and time consuming
2. Technological advances such as NGS have demonstrated that it's possible to detect a high number of pathogenic viruses and viroids in **one diagnostic test**
3. An appropriate regulatory framework is required that considers the constraints with the existing diagnostic platforms used in Post-Entry Quarantine (PEQ) against the benefits and limitations of NGS technology

CHALLENGES OF NGS TECHNOLOGIES FOR PEQ SCREENING

1. Sample collection and NGS data generation (i.e. sample time, tissue, quality, and cross-contamination)
2. Data Storage (including backups) – data security
3. Data analysis (bioinformatics) – long-term access, collection of comparative testing data, assembly of viral sequences, and training of staff
4. Data sharing - stakeholders

RESULTS SO FAR:

- Actinidia – new Betaflexiviridae = decision non-regulated
- Camellia – new Betaflexiviridae = General surveillance sample; non-regulated
- Daphne – Turnip yellows virus (new host) + possible new Carlavirus = General surveillance sample; non-regulated
- Hemerocallis – new Luteovirus = General surveillance sample; non-regulated

- Lavandula – Raspberry ringspot virus (unexpected association), Phlox virus M = General surveillance sample; non-regulated for the phlox virus but RpRSV is regulated in BORIC (does not mention at strain level though)
- Prunus – Strawberry latent ringspot virus (new isolate) = General surveillance sample; SLRSV regulated at strain level
- Rosa – new Secoviridae = General surveillance sample; non-regulated
- Vietnamese mint – two new Carmoviruses = General surveillance sample; non-regulated

QUADS GROUP
(NEW ZEALAND, CANADA, USA AND AUSTRALIA)

- Aim: to develop a simple but robust regulatory framework which will provide harmonisation in decision making illustrated with case studies for each major group of organisms






REGULATORY CHALLENGES

1. Uncertainty of data quality
2. Implementation of guidelines - collides with individual demands and issues of single laboratories as well as organizations and many research units have little or any experience with quality management (QM) and quality assurance (QA)
3. NGS standards - evaluation of appropriate platform-dependent and independent information as well as comparative analysis of different sequencing systems

4. Is the presence of a sequence that matches a virus enough to make a decision?

5. How much of the sequence is needed?

6. Is NGS data more of a screening tool and a PCR test is still needed for confirmation?

7. Or can we work towards sufficient QA/QC for NGS such that it becomes the gold standard?

FINAL THOUGHTS

- More comparative side-by side data between NGS against existing PEQ protocols to demonstrate reliability and assurance
- Agreed quality control measures around NGS data
- Development of a national protocol that would be acceptable for policy adoption for PEQ testing
- Development of an appropriate regulatory framework to aid decision making based on NGS data
- Secure sustainable access to the optimised bioinformatics toolkit

THANK YOU