

Next Generation Sequencing (NGS) or high throughput sequencing (HTS) in the context of the International Plant Protection Convention (IPPC): the regulatory aspect

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The impact of plant pests



Loss: 10–16% of global harvest, **40%** of global food supply
Cost: at least 220 billion USD

IPPC

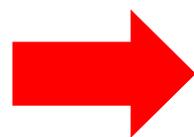
*Protecting the
world's plant
resources from
pests*



Protecting the world's plant resources from pests



Early diagnosis and a rapid response

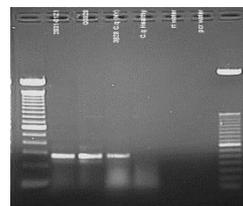
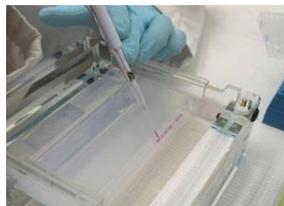


Crucial to reduce the risk of entry and spread of plant pests into an area.



The ability to detect plant pests varies with the sensitivity and specificity of the detection tools used.

National Plant Protection Organizations (NPPOs) routinely perform pest diagnosis to support export certification, import inspections, pest surveillance and eradication programs.



The promise of NGS in diagnostics:



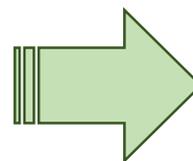
- Faster
- Less expensive (in near future)
- More sensitive
- More accurate
- Greater specificity
- Improved new virus detection
- ***Replace the bioassay? NO***

“NGS technologies has very high potential for discovery of viruses and in diagnostics. As well as in research and development”.

NGS and molecular technologies within the IPPC: regulatory aspects



Detection and identification of pests



Evidence of living pests or damage to the plant/plant products??



Does the pest represents a risk for production and trade?

Interpretation of results: Beyond detection and identification



How NGS can be used to help taking appropriate regulatory decisions for phytosanitary purposes?



NGS and the IPPC: regulatory aspects

Diagnostic opportunities examples:

- 1) Post-entry quarantine tests
- 2) Certification of nuclear stocks and plant propagation material
- 3) Surveillance programmes
- 4) Monitoring of imported commodities for new potential risks



NGS and molecular technologies within the IPPC: regulatory aspects

- ISPM 2 (*Framework for pest risk analysis*)
- ISPM 6 (*Guidelines for surveillance*)
- ISPM 8 (*Determination of pest status in an area*)
- ISPM 11 (*Pest risk analysis for quarantine pests*)
- ISPM 17 (*Pest reporting*)
- ISPM 27 (*Diagnostic protocols for regulated pests*)



NGS and the IPPC: regulatory aspects

- Do the newly detected organisms present an economic or trade risk?
- What is the biological significance (e.g. host range) of the newly detected organism?
- How to determine the geographic distribution of this organism if the organism is recently discovered and is cryptic or latent in nature?
- What type of actions would be appropriate following findings based on NGS technologies (e.g. destruction of an imported consignment, further testing using other methodologies)?

NGS and the IPPC: regulatory aspects



- ✓ **Interpretation of results is the biggest challenge** in the phytosanitary context.
- ✓ NGS for phytosanitary purposes: significant **validation data** would have to be available **and criteria** for its use and policies for the **interpretation of the results** would need to be developed to enable appropriate regulatory decisions.

NGS and the IPPC: regulatory aspects



- ✓ **Not all organisms associated with plants are pests:** some may be mutualists or commensal agents.
- ✓ **Guidance on the interpretation of the NGS results has not been developed yet:** these technologies may currently be used for screening consignments, but not to form the basis for final decisions (e.g. destruction or rejection of consignments).

NGS and the IPPC: regulatory aspects

Standards Committee (2017)

- ✓ NGS: broader than pest diagnosis – PRA and surveillance
- ✓ Further work is needed on NGS technologies before they can be considered as the sole method for pest detection

CPM-13 (2018)

- ✓ Noted the challenges associated with the use of NGS technologies as a diagnostic tool for phytosanitary purposes
- ✓ Agreed to develop a CPM Recommendation on “Next Generation Sequencing technologies as a diagnostic tool for phytosanitary purposes”: for adoption in 2019 (link to draft)
- Side session: “Gene sequencing and molecular technologies”

NGS and the IPPC: regulatory aspects

What is needed?



NGS and the IPPC: regulatory aspects

- ✓ **Framework for evaluation of regulatory impacts** is needed
- ✓ **International efforts** in developing and finalising standardised operational guidelines for NGS
- ✓ **Obtain more scientific evidence** on reliability and accuracy of NGS: **validation data and criteria for its use**
- ✓ **Share knowledge and expertise** with other countries where possible and support the development of NGS training programs
- ✓ **The TPDP is developing guidance** for authors of IPPC DPs on criteria for inclusion of an NGS method in IPPC protocols.



CPM recommendation: Next Generation Sequencing technologies as a diagnostic tool for phytosanitary purposes

Status box

This is not an official part of the CPM Recommendation and it will be modified by the IPPC Secretariat after adoption.	
Date of this document	2018-04-10
Document category	Draft CPM recommendation
Current document stage	To consultation (2018-05)
Major stages	2018-03 Topic proposed to the IPPC work programme for a CPM Recommendation by Australia, EPPO and New Zealand 2018-04 CPM-13 added the topic to the IPPC work programme for a CPM Recommendation 2018-05 adjustments made following CPM-13 2018-05 submitted to consultation period (15 May – 15 August 2018)
Notes	To be edited after the consultation period. This is a draft document and it will be presented for consultation period in English only

Background

In December 2017, the CPM Bureau considered a paper prepared by the Standards Committee (SC) which reflected discussion by the IPPC Technical Panel on Diagnostic Protocols (TPDP) on opportunities and challenges in relation to the use of Next Generation Sequencing (NGS) technologies as a diagnostic tool for phytosanitary purposes. The Bureau was asked to agree that the background paper be presented to CPM-13 with a request that the CPM note the challenges associated with the use of NGS technologies and that further work is needed on NGS technologies for pest detection and identification.

Link to the draft CPM recommendation: <https://www.ippc.int/en/core-activities/governance/cpm/current-consultations-for-cpm-recommendations/>





A Framework for the Evaluation of Biosecurity, Commercial, Regulatory, and Scientific Impacts of Plant Viruses and Viroids Identified by NGS Technologies

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High-throughput sequencing technologies for plant pest diagnosis: challenges and opportunities

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