

# **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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**2018 IPPC Regional Workshop**

# The impact of plant pests



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



# IPPC

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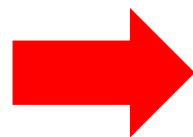
*Protecting the  
world's plant  
resources from  
pests*







**Early diagnosis and a rapid response**



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



**International Plant Protection Convention**  
Protecting the world's plant resources from pests

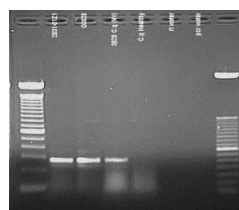
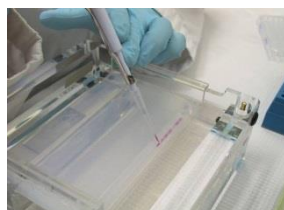


**Food and Agriculture  
Organization of the  
United Nations**



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***

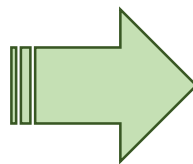
*“NGS technologies has very high potential for discovery of viruses and in diagnostics. As well as in research and development”.*



# 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)?



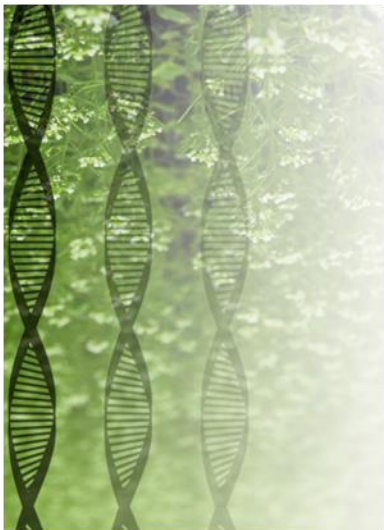


# NGS and the IPPC: regulatory aspects



- ✓ **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.	
<b>Date of this document</b>	2018-04-10
<b>Document category</b>	Draft CPM recommendation
<b>Current document stage</b>	To consultation (2018-05)
<b>Major stages</b>	<p>2018-03 Topic proposed to the IPPC work programme for a CPM Recommendation by Australia, EPPO and New Zealand</p> <p>2018-04 CPM-13 added the topic to the IPPC work programme for a CPM Recommendation</p> <p>2018-05 adjustments made following CPM-13</p> <p>2018-05 submitted to consultation period (15 May – 15 August 2018)</p>
<b>Notes</b>	<p>To be edited after the consultation period.</p> <p>This is a draft document and it will be presented for consultation period in English only</p>

### 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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of the United Nations



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