

## 2018 CONSULTATION

15 May – 15 August 2018

### Compiled comments for "CPM recommendation: Next Generation Sequencing technologies as a diagnostic tool for phytosanitary purposes"

T (Type) - B = Bullet, C = Comment, P = Proposed Change, R = Rating

| FAO sequential number | Para | Text              | T | Comment                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
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| 1                     | G    | (General Comment) | C | <b>Guyana</b><br>We accept the draft document in its entirety.<br><i>Category : SUBSTANTIVE</i>                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| 2                     | G    | (General Comment) | C | <b>Canada</b><br>The document is well written covering the technology and the technical issues at a high enough level without getting bogged down in the details. In terms of using NGS, an emphasis must be placed on Quality Assurance and this is addressed in the recommendations.<br>Key concern is that one expects to hear about NGS for pathogens and pests and it is all about viruses.<br><i>Category : SUBSTANTIVE</i>                                                                                                          |
| 3                     | G    | (General Comment) | C | <b>Peru</b><br>We consider that NGS technologies need to be further investigated before adopting a CPM Recommendation.<br>As stated in the draft under consultation further work is needed on NGS technologies before they can be considered as an alternative method for pest detection and identification as the basis for applying phytosanitary regulations. Therefore, before CPM adopts a recommendation it would be advisable an analysis on the impact of this technology on regulatory issues.<br><i>Category : TECHNICAL</i>     |
| 4                     | G    | (General Comment) | C | <b>Brazil</b><br>We consider that NGS technologies need to be further investigated before adopting a CPM Recommendation.<br>As stated in the draft under consultation further work is needed on NGS technologies before they can be considered as an alternative method for pest detection and identification as the basis for applying phytosanitary regulations. Therefore, before CPM adopts a recommendation it would be advisable an analysis on the impact of this technology on regulatory issues.<br><i>Category : SUBSTANTIVE</i> |
| 5                     | G    | (General Comment) | C | <b>COSAVE</b><br>We consider that NGS technologies need to be further investigated before adopting a CPM Recommendation.<br>As stated in the draft under consultation further work is needed on NGS technologies before they can be considered as an alternative                                                                                                                                                                                                                                                                           |

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|    |   |                   | method for pest detection and identification as the basis for applying phytosanitary regulations. Therefore, before CPM adopts a recommendation it would be advisable an analysis on the impact of this technology on regulatory issues.<br><i>Category : SUBSTANTIVE</i>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| 6  | G | (General Comment) | C <b>Uruguay</b><br>We consider that NGS technologies need to be further investigated before adopting a CPM Recommendation.<br><br>As stated in the draft under consultation further work is needed on NGS technologies before they can be considered as an alternative method for pest detection and identification as the basis for applying phytosanitary regulations. Therefore, before CPM adopts a recommendation it would be advisable an analysis on the impact of this technology on regulatory issues<br><i>Category : SUBSTANTIVE</i>                                                                                                                                                                                                                                                                                                           |
| 7  | G | (General Comment) | C <b>Argentina</b><br>We consider that NGS technologies need to be further investigated before adopting a CPM Recommendation.<br>As stated in the draft under consultation further work is needed on NGS technologies before they can be considered as an alternative method for pest detection and identification as the basis for applying phytosanitary regulations. Therefore, before CPM adopts a recommendation it would be advisable an analysis on the impact of this technology on regulatory issues.<br><i>Category : SUBSTANTIVE</i>                                                                                                                                                                                                                                                                                                            |
| 8  | G | (General Comment) | C <b>Japan</b><br>We have clear expectation for new technologies to be tools to improve plant health efforts. Diagnostics technique of DNA level is already broadly in use and this is one of the promising areas to be further developed in the future. Next Generation Sequencing Technologies have been developed and become technically close to actual use. At the same time there is still a serious cost issue to introduce the technologies in the practical use. At present, it is also difficult for NPPOs to use NGS technologies as the sole method for pest detection and identification as the basis for applying phytosanitary regulations. For the time being, we should consider to use NGS as one of complementary methods for the current major pest detection and identification methods such as PCR.<br><i>Category : SUBSTANTIVE</i> |
| 9  | G | (General Comment) | C <b>Iraq</b><br>No comment<br><i>Category : TECHNICAL</i>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| 10 | G | (General Comment) | C <b>Colombia</b><br>It's necessary to talk about molecular entities of plants. Molecular                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |

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|    |   |                   | <p>entities of plants are pathogenic or no-pathogenic agents that only they have nucleic acid and need their host for survive (virus, viroid, phytoplasma, spiroplasma).</p> <p>In general, molecular plant entities are poorly characterized, and their pathogenic effect in plants as well. NGS becomes a method to identify different organisms using genetic information.</p> <p>We recommended to change the scope in the NGS application in all document.</p> <p><i>Category : SUBSTANTIVE</i></p>                                                                                                                                                                                                                                                                                         |
| 11 | G | (General Comment) | <p>C <b>New Zealand</b><br/>New Zealand is very supportive of this initiative. It is great to see it going ahead.<br/>One comment for consideration is that this paper refers to viruses and viroids but not fungi and bacteria to which NGS would also be valuable, and similar challenges to viruses and viroids also apply.<br/><i>Category : TECHNICAL</i></p>                                                                                                                                                                                                                                                                                                                                                                                                                               |
| 12 | G | (General Comment) | <p>C <b>Chile</b><br/>As stated in the draft under consultation further work is needed on NGS technologies before they can be considered as an alternative method for pest detection and identification as the basis for applying phytosanitary regulations. Therefore, before CPM adopts a recommendation it would be advisable an analysis on the impact of this technology on regulatory issues.<br/><i>Category : SUBSTANTIVE</i></p>                                                                                                                                                                                                                                                                                                                                                        |
| 13 | G | (General Comment) | <p>C <b>Panama</b><br/>Panama supports the importance of data interpretation as the fundamental basis for the decision making of a phytosanitary measure.<br/><i>Category : TECHNICAL</i></p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| 14 | G | (General Comment) | <p>C <b>European Union</b><br/>We recommend the use of High Throughput Sequencing ('HTS') as the main designation and not Next Generation Sequencing ('NGS'). Indeed, there is no sense of "next generation" anymore. Current technologies are already the 3rd next generation. High throughput is more accurate.</p> <p>NGS is a method that requires careful interpretation of the data; which requires in depth knowledge on the biology, taxonomy and molecular aspects of the pathogen. All of these differ among fungi, bacteria and viruses. Thus, it is very unlikely that one can have a standardized NGS platform that comprises "all organisms". It should be divided into bacteria, fungi and viruses; and be developed independently by those who dominate the respective area.</p> |

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|    |   |                   |   | <i>Category : SUBSTANTIVE</i>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| 15 | G | (General Comment) | C | <b>Malawi</b><br>There is no comment<br><i>Category : TECHNICAL</i>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| 16 | G | (General Comment) | C | <b>United States of America</b><br>Suggest replacing Next Generation with High Throughput (HTS), here and throughout the document. HTS is a broader term that includes all technologies available.<br><i>Category : TECHNICAL</i>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| 17 | G | (General Comment) | C | <b>Slovenia</b><br>Our comments were submitted to EPPO and considered there, so please ignore the comments below to certain paragraphs. I do not know, how to revoke them. We do not have additional comments to the EPPO common position. Sorry for the inconvenience.<br><i>Category : EDITORIAL</i>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| 18 | G | (General Comment) | C | <b>Benin</b><br>No comment<br><i>Category : TECHNICAL</i>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| 19 | G | (General Comment) | C | <b>Korea, Republic of</b><br>NPPO of Rep. of Korea does not support to adopt a CPM recommendation on NGS technologies after review of the draft, even though CPM-13 agreed to develop a CPM recommendation on "NGS technologies as a diagnostic tool for phytosanitary purposes" (CPM 13 report Agenda 8.6 CPM decision point (3)).<br><br>Rep. of Korea agrees NGS technology has potential to be utilized in phytosanitary related area but may not be appropriate for diagnostic tool for daily inspection. Rep. of Korea considers this topic is not appropriate as CPM recommendation because;<br><br>1. The topic is not relevant for CPM recommendation; NGS technology is one of techniques which have been developed or will be developed in future and it has potential and challenges at the same time to be applied in phytosanitary area which is still under discussion and review.<br><br>2. As the draft mentioned, NGS technologies 'should be introduced cautiously' and 'existing challenges and further work is needed before they can be considered. . .', this means NGS may not be feasible yet to the phytosanitary area. However the recommendation points a)~e) seem encouraging participation and information sharing forward application of NGS which is not aligned with introduction.<br><br>3. Most of the recommendation points are beyond NPPO's authority which may not lead concrete action by NPPOs.<br><br>4. NGS is expensive, high technology and time consuming |

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|    |   |                                                                                                                    | <p>and the accessibility and use of data base is not possible to many countries especially developing countries.</p> <p>5. NGS can be a useful tool for detection of unknown virus, viroid etc., from nursery stocks which do not have symptom during post-entry quarantine or germplasm management or research purpose rather than phytosanitary inspection including diagnosis at port of entry. However a country can detect a new pest with NGS technology and if it is technically justified, nothing can prevent use of NGS for phytosanitary purpose anyway as other new technical tools which have been introduced for diagnosis for phytosanitary purpose.</p> <p>As conclusion, Rep. of Korea proposes to have discussion during CPM-14 on NGS based on comments from CPs as an agenda rather than adopt CPM recommendation at this time.<br/><i>Category : SUBSTANTIVE</i></p> |
| 20 | G | (General Comment)                                                                                                  | <p>C <b>NEPPO</b><br/>No comment<br/><i>Category : EDITORIAL</i></p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| 21 | G | (General Comment)                                                                                                  | <p>C <b>EPPO</b><br/>We recommend the use of High Throughput Sequencing as the main designation and not Next Generation Sequencing. Indeed, there is no sense of "next generation" anymore. Current technologies are already the 3rd next generation. High throughput is more accurate.</p> <p>NGS is a method that requires careful interpretation of the data; which requires in depth knowledge on the biology, taxonomy and molecular aspects of the pathogen. All of these differ among fungi, bacteria and viruses. Thus, it is very unlikely that one can have a standardized NGS platform that comprises "all organisms". It should be divided into bacteria, fungi and viruses; and be developed independently by those who dominate the respective area.<br/><i>Category : SUBSTANTIVE</i></p>                                                                                  |
| 22 | 1 | <b>CPM recommendation: Next Generation Sequencing technologies as a diagnostic tool for phytosanitary purposes</b> | <p>C <b>Colombia</b><br/>It's necessary to talk about molecular entities of plants. Molecular entities of plants are pathogenic or no-pathogenic agents that only they have nucleic acid and need their host for survive (virus, viroid, phytoplasma, spiroplasma).</p> <p>In general, molecular plant entities are poorly characterized, and their pathogenic effect in plants as well. NGS becomes a method to identify different organisms using genetic information.</p>                                                                                                                                                                                                                                                                                                                                                                                                              |

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|            |    |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |   | We recommended to change the scope in the NGS application in all document.<br><i>Category : SUBSTANTIVE</i>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| 23         | 1  | <b>CPM recommendation: Next Generation Sequencing technologies as a diagnostic tool for <del>phytosanitary</del> <u>Phyotosanitary</u> purposes</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                               | P | <b>Ghana</b><br>phytosanitary should be capitalized Phyotosanitary<br><i>Category : EDITORIAL</i>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| 24         | 1  | <b>CPM recommendation: Next Generation Sequencing (<u>NGS</u>) technologies as a diagnostic tool for phytosanitary purposes</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | P | <b>Ghana</b><br>The abbreviation NGS must be added to the topic<br><i>Category : EDITORIAL</i>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| 25         | 12 | 2018-04 CPM-13 added <del>the</del> <u>this</u> topic to the IPPC work programme for <del>a</del> -CPM Recommendation                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | P | <b>Sierra Leone</b><br><i>Category : EDITORIAL</i>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| 26         | 17 | This is a draft document and it will be presented for consultation period in English only                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | C | <b>Nicaragua</b><br>Nicaragua considera estar interesado en la aplicación de este documento como un protocolo de diagnóstico que permita dar respuesta rápida y a su vez confiables en la identificación de patógenos (Virus, Viroides, Bacterias) y plagas. Así le permita garantizar la adopción de tecnologías modernas de secuenciación de primera generación (NGS) con enfoques armonizados internacionalmente. Esta "Tecnologías de secuenciación de primera generación como herramienta de diagnóstico fitosanitarios" proporcionará la seguridad, y confianza de los resultados. La aplicación de estas tecnologías ha dado lugar recientemente al descubrimiento de microorganismos no detectados previamente, en particular virus en los que el uso de la tecnología es más avanzado que para otros patógenos.<br><i>Category : EDITORIAL</i> |
| Background |    |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |   |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| 27         | 19 | 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. | C | <b>Nicaragua</b><br>Consideramos la necesidad de continuar con investigaciones que contribuyan a la mejora de obtener protocolos de diagnostico que apoyen la NGS.<br><i>Category : TECHNICAL</i>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| 28         | 19 | 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 <u>Next Generation Sequencing (NGS)-with High Throughput (HTS)</u> 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                                                                                                                                       | P | <b>United States of America</b><br>HTS here and global change through the document<br><i>Category : TECHNICAL</i>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |

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|    |    | 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.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |   |                                                                                                                                                                                                                                                                                                                                                                   |
| 29 | 19 | 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.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | C | <b>International Seed Federation</b><br>NGS is considered by some authors as second generation technology such as Illumina, and does not include the 3rd generation (e.g. Nanopore). As the scope of NGS in the CPM's recommendation is not clearly identified, ISF concerns apply to all high-throughput sequencing technologies.<br><i>Category : TECHNICAL</i> |
| 30 | 19 | 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.<br><br><u><a href="#">Standards Committee (SC) prepared a paper on the use of Next Generation Sequencing (NGS) technologies as a diagnostic tool for phytosanitary purposes based on the outcomes from the IPPC Technical Panel on Diagnostic Protocols (TPDP) discussion on its opportunities and challenges.</a></u><br><u><a href="#">In December, 2017 the CPM Bureau was asked to agree that the background paper will be presented to CPM-13 with a request that CPM will note the challenges associated with the use of NGS technologies with further work needed on NGS technologies for pest detection and identification.</a></u> | P | <b>Sierra Leone</b><br><br><i>Category : SUBSTANTIVE</i>                                                                                                                                                                                                                                                                                                          |
| 31 | 20 | The CPM Bureau agreed that since this was an emerging issue that would be of interest to <del>contracting</del> <b>Contracting</b> parties, a CPM Recommendation should be drafted to provide policy advice and guidance to Contracting parties and Regional Plant Protection Organizations (RPPOs) on the use of NGS technologies as a diagnostic tool for phytosanitary purposes.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | P | <b>Ghana</b><br>The contracting should be capitalized to read Contracting to match with the others<br><i>Category : EDITORIAL</i>                                                                                                                                                                                                                                 |
| 32 | 20 | The CPM Bureau agreed that since this was an emerging issue that <b>it</b> would be of interest to contracting parties, <del>a</del> CPM Recommendation should be drafted to                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | P | <b>Sierra Leone</b>                                                                                                                                                                                                                                                                                                                                               |

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|                                                               |    | provide policy advice and guidance to Contracting <del>parties</del> <b>Parties</b> and Regional Plant Protection Organizations (RPPOs) on the use of NGS technologies as a diagnostic tool for phytosanitary purposes.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |   | <i>Category : EDITORIAL</i>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| 33                                                            | 21 | <del>At the Thirteenth session of the CPM, a draft CPM recommendation was presented by Australia, New Zealand, European and Mediterranean Plant Protection Organization (EPPO) and New Zealand presented a draft CPM recommendation during CPM 13, and the CPM 13 (2018)-it was</del> agreed to include the topic <del>to in</del> the IPPC work programme for a CPM Recommendation on “Next Generation Sequencing technologies as a diagnostic tool for phytosanitary purposes”.                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | P | <b>Sierra Leone</b><br><i>Category : EDITORIAL</i>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| What is NGS and how is it different to other testing methods? |    |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |   |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| 34                                                            | 23 | Next Generation Sequencing (NGS) or high throughput sequencing or deep sequencing technologies allow the sequencing of the whole genome and can be used for all types of organisms. NGS technologies can be used for targeted detection of regulated pests and also allow the detection of unknown organisms (i.e. without a priori knowledge). Indeed, application of these technologies has recently resulted in the discovery of previously undetected microorganisms, in particular viruses where the use of the technology is more advanced than for other pathogens (examples provided in this document are for viruses and viroids). Researchers and diagnosticians using NGS technologies will continue to identify and describe new taxa from among the large volume of as yet undiscovered organisms. These technologies therefore enable a new and comprehensive approach to the detection and characterization of pests in a biological sample. | C | <b>Nicaragua</b><br>Es de mucha importancia tecnología accesible y moderna (NGS) que permitan identificar el genoma de microorganismos de interés fitosanitario que actualmente con las tecnología tradicionales no se han logrado identificar<br><i>Category : TECHNICAL</i>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| 35                                                            | 23 | Next Generation Sequencing (NGS) or high throughput sequencing or deep sequencing technologies allow the sequencing of the whole genome and can be used for all types of organisms. NGS technologies can be used for targeted detection of regulated pests and also allow the detection of unknown organisms (i.e. without a priori knowledge). Indeed, application of these technologies has recently resulted in the discovery of previously undetected microorganisms, in particular viruses where the use of the technology is more advanced than for other pathogens (examples provided in this document are for viruses and viroids). Researchers and diagnosticians using NGS technologies will continue to identify and describe new taxa from among the large volume of as yet undiscovered organisms. These technologies therefore enable a new and comprehensive approach to the detection and characterization of pests in a biological sample. | C | <b>Colombia</b><br>Complete the scope of NGS application with fungi and bacterial and the policies of international trade of plant material.<br><br>The contribution of Universities, Agricultural Research Centers and National Plant Protection Organizations have been important to build phytosanitary regulations in international trade of plant material. The interchange of information from different parts of the world strengthens the policies of the international trade of plant material. Harmonize the protocols for NGS method is stronger mandate in the Free Trade Agreement (FTA) between countries (Olmos et al, 2018).<br>Also include others NGS methods as pyrosequencing to identify genes in fungi (Gao & Zhang, 2013) and bacteria as well. In this sense, the majority of plant pathogens diagnosis is completed by NGS. |

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|    |    |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | <p>We suggested this reference:</p> <p>Olmos A., et al., (2018) High-throughput sequencing technologies for plant pest diagnosis: challenges and opportunities. Bulletin OEPP/EPPO. 48 (2):219–224.</p> <p>Gao, R., and Zhang, G. 2013. Potential of DNA barcoding for detecting quarantine fungi. Phytopathology. 103:1103-1107.<br/><i>Category : SUBSTANTIVE</i></p> |
| 36 | 23 | <p>Next Generation Sequencing (NGS) or high throughput sequencing or deep sequencing technologies allow the sequencing of the whole genome and can be used for all types of organisms. NGS technologies can be used for targeted detection of regulated pests and also allow the detection of unknown organisms (i.e. without a priori knowledge). Indeed, application of these technologies has recently resulted in the discovery of previously undetected microorganisms, in particular viruses where the use of the technology is more advanced than for other pathogens (examples provided in this document are for viruses and viroids). Researchers and diagnosticians using NGS technologies will continue to identify and describe new taxa from among the large volume of as yet undiscovered organisms. These technologies therefore enable a new and comprehensive approach to the detection and characterization of <u>potential</u> pests in a biological sample.</p>                                                                                                                                         | <p>P <b>European Union</b><br/>By only identifying a genome, one does not know if the organism is a pest (nor the associated risks) or not.<br/><i>Category : TECHNICAL</i></p>                                                                                                                                                                                         |
| 37 | 23 | <p>Next Generation Sequencing (NGS) or high throughput sequencing or deep sequencing technologies allow the sequencing of the whole genome and can be used for all types of <del>organisms</del><u>organisms and is of particular interest for non-culturable organisms (e.g. viruses and viroids, and some bacteria, oomycetes and fungi).</u> NGS technologies can be used for targeted detection of regulated pests and also allow the detection of unknown organisms (i.e. without a priori knowledge). Indeed, application of these technologies has recently resulted in the discovery of previously undetected microorganisms, in particular viruses where the use of the technology is more advanced than for other pathogens (examples provided in this document are for viruses and viroids). Researchers and diagnosticians using NGS technologies will continue to identify and describe new taxa from among the large volume of as yet undiscovered organisms. These technologies therefore enable a new and comprehensive approach to the detection and characterization of pests in a biological sample.</p> | <p>P <b>European Union</b><br/>The potential of these technologies in particular for not culturable organisms or organisms difficult to culture (e.g. viruses, viroids, phytoplasma, and some bacteria, oomycetes and fungi) is particularly noteworthy and should be highlighted.<br/><i>Category : SUBSTANTIVE</i></p>                                                |

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| 38 | 23 | Next Generation Sequencing (NGS) or high throughput sequencing or deep sequencing technologies allow the sequencing of the whole genome and can be used for all types of organisms. NGS technologies can be used for targeted detection of regulated pests and also allow the detection of unknown organisms (i.e. without a priori knowledge). Indeed, application of these technologies has recently resulted in the discovery of previously undetected microorganisms, in particular viruses where the use of the technology is more advanced than for other pathogens (examples provided in this document are for viruses and viroids). Researchers and diagnosticians using NGS technologies will continue to identify and describe new taxa from among the large volume of as yet undiscovered organisms. These technologies therefore enable a new and comprehensive approach to the detection and characterization of pests in a biological sample.                        | C | <b>United States of America</b><br>Most of us are doing RNA-Seq for the identification of viruses. Therefore, we are not really sequencing the whole genome. Maybe say something more general, like allow the sequencing of the genetic material...<br><i>Category : TECHNICAL</i> |
| 39 | 23 | Next Generation Sequencing (NGS) or high throughput sequencing or deep sequencing technologies allow the sequencing of the whole genome and can be used for all types of organisms. NGS technologies can be used for targeted detection of regulated pests and also allow the detection of unknown organisms (i.e. without a priori knowledge). Indeed, application of these technologies has recently resulted in the discovery of previously undetected microorganisms, in particular viruses where the use of the technology is more advanced than for other pathogens (examples provided in this document are for viruses and viroids). Researchers and diagnosticians using NGS technologies will continue to identify and describe new taxa from among the large volume of as yet undiscovered organisms. These technologies <del>therefore therefore</del> , enable a new and comprehensive approach to the detection and characterization of pests in a biological sample. | P | <b>Ghana</b><br>therefore must be punctuated to read therefore,<br><i>Category : EDITORIAL</i>                                                                                                                                                                                     |
| 40 | 23 | Next Generation Sequencing (NGS) or <del>high throughput sequencing</del> <u>High Throughput Sequencing (HTS)</u> or deep sequencing technologies allow the sequencing of the whole genome and can be used for all types of organisms. NGS technologies can be used for targeted detection of regulated pests and also allow the detection of unknown organisms (i.e. without a priori knowledge). Indeed, application of these technologies has recently resulted in the discovery of previously undetected microorganisms, in particular viruses where the use of the technology is more advanced than for other pathogens (examples provided in this document are for viruses and viroids). Researchers and diagnosticians using NGS technologies will continue to identify and describe new taxa from among the large                                                                                                                                                          | P | <b>Ghana</b><br>high throughput sequencing should read High-Throughput Sequencing (HTS) as well as deep sequencing as Deep Sequencing. Thus the initial letters must be capitalized and the High Throughput be hyphenated<br><i>Category : EDITORIAL</i>                           |

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|    |    | volume of as yet undiscovered organisms. These technologies therefore enable a new and comprehensive approach to the detection and characterization of pests in a biological sample.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |   |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| 41 | 23 | Next Generation Sequencing (NGS) or high throughput sequencing or deep sequencing technologies allow the sequencing of the whole genome and can be used for all types of organisms. NGS technologies can be used for targeted detection of regulated pests and also allow the detection of unknown organisms (i.e. without a priori knowledge). Indeed, application of these technologies has recently resulted in the discovery of previously undetected microorganisms, in particular viruses where the use of the technology is more advanced than for other pathogens (examples provided in this document are for viruses and viroids). Researchers and diagnosticians using NGS technologies will continue to identify and describe new taxa from among the large volume of as yet undiscovered organisms. These technologies therefore enable a new and comprehensive approach to the detection and characterization of pests in a biological sample. | C | <b>International Seed Federation</b><br>Not everything that is found on seed is a pest; the mere presence of a known pathogen does not mean that it can or will cause disease. Multiple pathogens and secondary organisms such as saprophytes that have morphological or genetic similarities to the target pathogen may be present on the seed. The pathogenic nature of what has been detected must be confirmed first (Massart et al. (2017)).<br><i>Category : TECHNICAL</i> |
| 42 | 23 | Next Generation Sequencing (NGS) or high throughput sequencing or deep sequencing technologies allow the sequencing of the whole genome and can be used for all types of organisms. NGS technologies can be used for targeted detection of regulated pests and also allow the detection of unknown organisms (i.e. without a priori knowledge). Indeed, application of these technologies has recently resulted in the discovery of previously undetected microorganisms, in particular viruses where the use of the technology is more advanced than for other pathogens (examples provided in this document are for viruses and viroids). Researchers and diagnosticians using NGS technologies will continue to identify and describe new taxa from among the large volume of as yet undiscovered organisms. These technologies therefore enable a new and comprehensive approach to the detection and characterization of pests in a biological sample. | C | <b>International Seed Federation</b><br>ISF is of the view that the required higher sensitivity, the need to detect defined pathogens, and the need for appropriate test validation all render sequencing approaches more appropriate for targeted pests than non-targeted ones.<br><i>Category : TECHNICAL</i>                                                                                                                                                                  |
| 43 | 23 | Next Generation Sequencing (NGS) or high throughput sequencing or deep sequencing technologies allow the sequencing of the whole genome and can be used for all types of organisms. NGS technologies can be used for targeted detection of regulated pests and also allow the detection of unknown organisms (i.e. without a priori knowledge). Indeed, application of these technologies has recently resulted in the discovery of previously undetected microorganisms, in particular viruses where the use of the technology is more advanced than for other pathogens (examples provided in this document are for viruses and viroids).                                                                                                                                                                                                                                                                                                                 | C | <b>International Seed Federation</b><br>In relation to using the technology for the detection of unknown organisms, full validation of a method to detect non-target organisms is not feasible (Roenhorst et al., 2018). For instance, how should the limit of detection (LOD) for an unknown target be determined?<br><i>Category : TECHNICAL</i>                                                                                                                               |

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|    |    | Researchers and diagnosticians using NGS technologies will continue to identify and describe new taxa from among the large volume of as yet undiscovered organisms. These technologies therefore enable a new and comprehensive approach to the detection and characterization of pests in a biological sample.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |   |                                                                                                                                                                                                                                                                                                     |
| 44 | 23 | Next Generation Sequencing (NGS) or high throughput sequencing or deep sequencing technologies allow the sequencing of the whole genome and can be used for all types of <del>organisms</del> <u>organisms and is of particular interest for non-culturable organisms (e.g. viruses and viroids, and some bacteria, oomycetes and fungi)</u> . NGS technologies can be used for targeted detection of regulated pests and also allow the detection of unknown organisms (i.e. without a priori knowledge). Indeed, application of these technologies has recently resulted in the discovery of previously undetected microorganisms, in particular viruses where the use of the technology is more advanced than for other pathogens (examples provided in this document are for viruses and viroids). Researchers and diagnosticians using NGS technologies will continue to identify and describe new taxa from among the large volume of as yet undiscovered organisms. These technologies therefore enable a new and comprehensive approach to the detection and characterization of pests in a biological sample. | P | <b>EPPO</b><br>The potential of these technologies in particular for not culturable organisms or organisms difficult to culture (e.g. viruses, viroids, phytoplasma, and some bacteria, oomycetes and fungi) is particularly noteworthy and should be highlighted.<br><i>Category : SUBSTANTIVE</i> |
| 45 | 23 | Next Generation Sequencing (NGS) or high throughput sequencing or deep sequencing technologies allow the sequencing of the whole genome and can be used for all types of organisms. NGS technologies can be used for targeted detection of regulated pests and also allow the detection of unknown organisms (i.e. without a priori knowledge). Indeed, application of these technologies has recently resulted in the discovery of previously undetected microorganisms, in particular viruses where the use of the technology is more advanced than for other pathogens (examples provided in this document are for viruses and viroids). Researchers and diagnosticians using NGS technologies will continue to identify and describe new taxa from among the large volume of as yet undiscovered organisms. These technologies therefore enable a new and comprehensive approach to the detection and characterization of <u>potential</u> pests in a biological sample.                                                                                                                                           | P | <b>EPPO</b><br>By only identifying a genome, one does not know if the organism is a pest (nor the associated risks) or not.<br><i>Category : TECHNICAL</i>                                                                                                                                          |
| 46 | 23 | Next Generation Sequencing (NGS) or high throughput sequencing or deep sequencing ( <u>HTS</u> ) technologies allow the sequencing of the whole genome and can be used for all types of organisms. NGS technologies can be used for targeted detection of regulated pests and also allow the detection of unknown organisms                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | P | <b>Slovenia</b><br>Clear message for NPPOs and other non-specialists that NGS and HTS acronyms are synonyms<br><i>Category : TECHNICAL</i>                                                                                                                                                          |

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|    |    | (i.e. without a priori knowledge). Indeed, application of these technologies has recently resulted in the discovery of previously undetected microorganisms, in particular viruses where the use of the technology is more advanced than for other pathogens (examples provided in this document are for viruses and viroids). Researchers and diagnosticians using NGS technologies will continue to identify and describe new taxa from among the large volume of as yet undiscovered organisms. These technologies therefore enable a new and comprehensive approach to the detection and characterization of pests in a biological sample.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |   |                                                                                                                                                                                                                                                            |
| 47 | 23 | Next Generation Sequencing (NGS) or high throughput sequencing or deep sequencing technologies allow the sequencing of the whole genome and can be used for all types of organisms. NGS technologies can be used for targeted detection of regulated pests and also allow the detection of unknown organisms (i.e. without a priori knowledge). <del>Indeed, application of</del> <u>Applying</u> these technologies has recently resulted in <del>the the</del> discovery of previously undetected microorganisms, <del>in particular particularly</del> viruses where <u>using</u> the <del>use of the</del> technology is more advanced than for other pathogens (examples provided in this document are for viruses and viroids). Researchers and diagnosticians using NGS technologies will continue to identify and describe new taxa from among the large volume of as yet undiscovered organisms. These technologies therefore enable a new and comprehensive approach to the detection and characterization of pests in a biological sample.                                                                                  | P | <b>Sierra Leone</b><br><i>Category : EDITORIAL</i>                                                                                                                                                                                                         |
| 48 | 24 | Phytosanitary testing for viruses and viroids in plants and plant products moved around the globe currently relies on a combination of specific (molecular and serological) and generic (visual, electron microscopy and biological indicators or bioassays) approaches. Whilst these methods are currently the best available they have a number of inherent weaknesses. The specific tests usually require a priori knowledge of the viral pathogens and each test needs to be developed and validated (including validation of the test for different pest/host combinations), making resource demands on national plant protection organisations (NPPO). The host range of many pathogens is not well defined and exotic viruses and viroids may not be detected in new pest-host combinations. Whilst bioassays have traditionally been used to detect unknown viruses, further molecular or serological testing is usually required to confirm the identity of the causal agent when disease symptoms are observed. Bioassays are heavily reliant on environmental conditions for symptom expression and often produce ambiguous | C | <b>Nicaragua</b><br>El Uso de tecnología tradicional demanda tiempo y recursos que en la actualidad se deben maximizar con tecnologías de primera generación, como NGS, esto permite a las ONPF tomar decisiones acertadas.<br><i>Category : TECHNICAL</i> |

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|    |    | results as false positives and false negatives. The time taken for bioassays means that plants spend extended periods of time in post entry quarantine stations, significantly adding to costs and delays for importers. A further drawback with bioassays is that strains may not be detected if they are asymptomatic on the indicator host.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |   |                                                                                                                                                                                                                                           |
| 49 | 24 | Phytosanitary testing for viruses and viroids in plants and plant products moved around the globe currently relies on a combination of specific (molecular and serological) and generic (visual, electron microscopy and biological indicators or bioassays) approaches. Whilst these methods are currently the best available they have a number of inherent weaknesses. The specific tests usually require a priori knowledge of the viral pathogens and each test needs to be developed and validated (including validation of the test for different pest/host combinations), making resource demands on national plant protection organisations (NPPO). The host range of many pathogens is not well defined and exotic viruses and viroids may not be detected in new pest-host combinations. Whilst bioassays have traditionally been used to detect unknown viruses, further molecular or serological testing is usually required to confirm the identity of the causal agent when disease symptoms are observed. Bioassays are heavily reliant on environmental conditions for symptom expression and often produce ambiguous results as false positives and false negatives. The time taken for bioassays means that plants spend extended periods of time in post entry quarantine stations, significantly adding to costs and delays for importers. A further drawback with bioassays is that strains may not be detected if they are asymptomatic on the indicator host. | C | <b>Kenya</b><br>The initial part is true on currently applied diagnostic methods. However, there seems over-exaggeration of limitation of conventional diagnostic assays especially in quarantine context.<br><i>Category : TECHNICAL</i> |
| 50 | 24 | Phytosanitary testing for viruses and viroids in plants and plant products <del>moved around the globe</del> currently relies on a combination of specific (molecular and serological) and generic (visual, electron microscopy and biological indicators or bioassays) approaches. Whilst these methods are currently the best available they have a number of inherent weaknesses. The specific tests usually require a priori knowledge of the viral pathogens and each test needs to be developed and validated (including validation of the test for different pest/host combinations), making resource demands on national plant protection organisations (NPPO). The host range of many pathogens is not well defined and exotic viruses and viroids may not be detected in new pest-host combinations. Whilst bioassays have traditionally been used to detect unknown viruses, further molecular or                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | P | <b>European Union</b><br>Not really relevant in this paragraph. Moreover, this deletion makes the sentence easier to read.<br><i>Category : EDITORIAL</i>                                                                                 |

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|    |    | serological testing is usually required to confirm the identity of the causal agent when disease symptoms are observed. Bioassays are heavily reliant on environmental conditions for symptom expression and often produce ambiguous results as false positives and false negatives. The time taken for bioassays means that plants spend extended periods of time in post entry quarantine stations, significantly adding to costs and delays for importers. A further drawback with bioassays is that strains may not be detected if they are asymptomatic on the indicator host.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |   |                                                                                                                                                                                |
| 51 | 24 | Phytosanitary testing for viruses and viroids in plants and plant products moved around the globe currently relies on a combination of specific (molecular and serological) and generic (visual, electron microscopy and biological indicators or bioassays) approaches. Whilst these methods are currently the best available they have a number of inherent weaknesses. The specific tests usually require a priori knowledge of the viral pathogens and each test needs to be developed and validated (including validation of the test for different pest/host combinations), making resource demands on national plant protection organisations (NPPO). The host range of many pathogens is not well defined and exotic viruses and viroids may not be detected in new pest-host combinations. Whilst bioassays have traditionally been used to detect unknown viruses, further molecular or serological testing is usually required to confirm the identity of the causal agent when disease symptoms are observed. Bioassays are heavily reliant on environmental conditions for symptom expression and often produce ambiguous results as false positives and false negatives. The time taken for bioassays means that plants spend extended periods of time in post entry quarantine stations, significantly adding to costs and delays for importers. A further drawback with bioassays is that strains may not be detected if they are asymptomatic on the indicator host. <a href="#">Studies conducted so far have demonstrated NGS to be equivalent to or better than biological indexing assays in detecting viruses and viroids of agronomic significance (Rott et al. 2017; Rwahni et al., 2015; Mackie et al., 2017; Barrero et al., 2017). Most importantly, the studies are demonstrating that NGS is able to produce results significantly quicker than bioassays.</a> | P | <b>European Union</b><br>Text moved from para 25 as it fits better here as the text in this paragraph is mainly focused on biological indexing.<br><i>Category : TECHNICAL</i> |
| 52 | 24 | Phytosanitary testing for viruses and viroids in plants and plant products moved around the globe currently relies on a combination of specific (molecular and serological) and generic (visual, electron microscopy and biological indicators or bioassays) approaches. Whilst these methods are currently the best available they                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | P | <b>Ghana</b><br>post-entry<br><i>Category : EDITORIAL</i>                                                                                                                      |

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|    |    | <p>have a number of inherent weaknesses. The specific tests usually require a priori knowledge of the viral pathogens and each test needs to be developed and validated (including validation of the test for different pest/host combinations), making resource demands on national plant protection organisations (NPPO). The host range of many pathogens is not well defined and exotic viruses and viroids may not be detected in new pest-host combinations. Whilst bioassays have traditionally been used to detect unknown viruses, further molecular or serological testing is usually required to confirm the identity of the causal agent when disease symptoms are observed. Bioassays are heavily reliant on environmental conditions for symptom expression and often produce ambiguous results as false positives and false negatives. The time taken for bioassays means that plants spend extended periods of time in <del>post-post</del>-entry quarantine stations, significantly adding to costs and delays for importers. A further drawback with bioassays is that strains may not be detected if they are asymptomatic on the indicator host.</p>                                                                                                                                                                                                                                                                                                                                           |   |                                                        |
| 53 | 24 | <p>Phytosanitary testing for viruses and viroids in plants and plant products moved around the globe currently relies on a combination of specific (molecular and serological) and generic (visual, electron microscopy and biological indicators or bioassays) approaches. Whilst these methods are currently the best available they have a number of inherent weaknesses. The specific tests usually require a priori knowledge of the viral pathogens and each test needs to be developed and validated (including validation of the test for different pest/host combinations), making resource demands on national plant protection organisations (NPPO). The host range of many pathogens is not well defined and exotic viruses and viroids may not be detected in new pest-host combinations. Whilst bioassays have traditionally been used to detect unknown viruses, further molecular or serological testing is usually required to confirm the identity of the causal agent when disease symptoms are observed. Bioassays are heavily reliant on environmental conditions for symptom expression and often produce ambiguous results as false positives and false negatives. The time taken for bioassays means that plants spend extended periods of time in <del>post-entry-post-entry</del> quarantine stations, significantly adding to costs and delays for importers. A further drawback with bioassays is that strains may not be detected if they are asymptomatic on the indicator host.</p> | P | <p><b>Ghana</b></p> <p><i>Category : EDITORIAL</i></p> |

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| 54 | 24 | Phytosanitary testing for viruses and viroids in plants and plant products moved around the globe currently relies on a combination of specific (molecular and serological) and generic (visual, electron microscopy and biological indicators or bioassays) approaches. Whilst these methods are currently the best available they have a number of inherent weaknesses. The specific tests usually require a priori knowledge of the viral pathogens and each test needs to be developed and validated (including validation of the test for different pest/host combinations), making resource demands on national plant protection organisations (NPPO). The host range of many pathogens is not well defined and exotic viruses and viroids may not be detected in new pest-host combinations. Whilst bioassays have traditionally been used to detect unknown viruses, further molecular or serological testing is usually required to confirm the identity of the causal agent when disease symptoms are observed. Bioassays are heavily reliant on environmental conditions for symptom expression and often produce ambiguous results as false positives and false negatives. The time taken for bioassays means that plants spend extended periods of time in <del>post-entry-post-entry</del> quarantine stations, significantly adding to costs and delays for importers. A further drawback with bioassays is that strains may not be detected if they are asymptomatic on the indicator host. | P | <b>Ghana</b><br><br><i>Category : EDITORIAL</i>                                                                                                                                        |
| 55 | 24 | Phytosanitary testing for viruses and viroids in plants and plant products moved around the globe currently relies on a combination of specific (molecular and serological) and generic (visual, electron microscopy and biological indicators or bioassays) approaches. Whilst these methods are currently the best available they have a number of inherent weaknesses. The specific tests usually require a priori knowledge of the viral pathogens and each test needs to be developed and validated (including validation of the test for different pest/host combinations), making resource demands on national plant protection organisations (NPPO). The host range of many pathogens is not well defined and exotic viruses and viroids may not be detected in new pest-host combinations. Whilst bioassays have traditionally been used to detect unknown viruses, further molecular or serological testing is usually required to confirm the identity of the causal agent when disease symptoms are observed. Bioassays are heavily reliant on environmental conditions for symptom expression and often produce ambiguous results as false positives and false negatives. The time taken for bioassays means that plants spend extended periods of time in post entry quarantine stations,                                                                                                                                                                                                     | C | <b>United States of America</b><br>This is also true for NGS. Labs validate NGS results with PCR data and/or ELISAs. We are following the same approach<br><i>Category : TECHNICAL</i> |

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|    |    | significantly adding to costs and delays for importers. A further drawback with bioassays is that strains may not be detected if they are asymptomatic on the indicator host.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |   |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| 56 | 24 | Phytosanitary testing for viruses and viroids in plants and plant products moved around the globe currently relies on a combination of specific (molecular and serological) and generic (visual, electron microscopy and biological indicators or bioassays) approaches. Whilst these methods are currently the best available they have a number of inherent weaknesses. The specific tests usually require a priori knowledge of the viral pathogens and each test needs to be developed and validated (including validation of the test for different pest/host combinations), making resource demands on national plant protection organisations (NPPO). The host range of many pathogens is not well defined and exotic viruses and viroids may not be detected in new pest-host combinations. Whilst bioassays have traditionally been used to detect unknown viruses, further molecular or serological testing is usually required to confirm the identity of the causal agent when disease symptoms are observed. Bioassays are heavily reliant on environmental conditions for symptom expression and often produce ambiguous results as false positives and false negatives. The time taken for bioassays means that plants spend extended periods of time in post entry quarantine stations, significantly adding to costs and delays for importers. A further drawback with bioassays is that strains may not be detected if they are asymptomatic on the indicator host. | C | <b>United States of America</b><br>This is also true for NGS, since it needs to be validated for each crop. Samples need to be collected, sequenced and analyzed at different points of the plant life cycle to identify when would be the optimal time for when all viruses/viroids would be identified. Also the sequencing depth and number of reads that is needed for accurate diagnostics needs to be validated for each crop. We are currently doing this work for the different crops we process and each crop is a completely different system.<br><i>Category : TECHNICAL</i> |
| 57 | 24 | Phytosanitary testing for viruses and viroids in plants and plant products moved around the globe currently relies on a combination of specific (molecular and serological) and generic (visual, electron microscopy and biological indicators or bioassays) approaches. Whilst these methods are currently the best available they have a number of inherent weaknesses. The specific tests usually require a priori knowledge of the viral pathogens and each test needs to be developed and validated (including validation of the test for different pest/host combinations), making resource demands on <del>national plant protection organisations</del> <u>National Plant Protection Organisations</u> (NPPO). The host range of many pathogens is not well defined and exotic viruses and viroids may not be detected in new pest-host combinations. Whilst bioassays have traditionally been used to detect unknown viruses, further molecular or serological testing is usually required to confirm the identity of the causal agent when disease symptoms are observed. Bioassays are                                                                                                                                                                                                                                                                                                                                                                                     | P | <b>Ghana</b><br>national plant protection organization should capitalized to read National Plant Protection Organization<br><i>Category : EDITORIAL</i>                                                                                                                                                                                                                                                                                                                                                                                                                                 |

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|    |    | heavily reliant on environmental conditions for symptom expression and often produce ambiguous results as false positives and false negatives. The time taken for bioassays means that plants spend extended periods of time in post entry quarantine stations, significantly adding to costs and delays for importers. A further drawback with bioassays is that strains may not be detected if they are asymptomatic on the indicator host.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |   |                                                                                                                                                                                        |
| 58 | 24 | Phytosanitary testing for viruses and viroids in plants and plant products moved around the globe currently relies on a combination of specific (molecular and serological) and generic (visual, electron microscopy and biological indicators or bioassays) approaches. Whilst these methods are currently the best available they have a number of inherent weaknesses. The specific tests usually require a priori knowledge of the viral pathogens and each test needs to be developed and validated (including validation of the test for different pest/host combinations), making resource demands on national plant protection organisations (NPPO). <a href="#">Moreover, such specific tests can also detect nucleic acid or protein traces of disintegrated pathogen particles, resulting in an overestimation of actual pathogen presence.</a> The host range of many pathogens is not well defined and exotic viruses and viroids may not be detected in new pest-host combinations. Whilst bioassays have traditionally been used to detect unknown viruses, further molecular or serological testing is usually required to confirm the identity of the causal agent when disease symptoms are observed. Bioassays are heavily reliant on environmental conditions for symptom expression and often produce ambiguous results as false positives and false negatives. The time taken for bioassays means that plants spend extended periods of time in post entry quarantine stations, significantly adding to costs and delays for importers. A further drawback with bioassays is that strains may not be detected if they are asymptomatic on the indicator host. | P | <b>International Seed Federation</b><br>Sentence added to emphasize the risk of using the technology for phytosanitary testing for viruses and viroids.<br><i>Category : TECHNICAL</i> |
| 59 | 24 | Phytosanitary testing for viruses and viroids in plants and plant products moved around the globe currently relies on a combination of specific (molecular and serological) and generic (visual, electron microscopy and biological indicators or bioassays) approaches. Whilst these methods are currently the best available they have a number of inherent weaknesses. The specific tests usually require a priori knowledge of the viral pathogens and each test needs to be developed and validated (including validation of the test for different pest/host combinations), making resource demands on national plant protection organisations (NPPO). The                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | P | <b>EPPO</b><br>This paragraph fits better here as the text in this paragraph is mainly focused on biological indexing.<br><i>Category : TECHNICAL</i>                                  |

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|    |    | <p>host range of many pathogens is not well defined and exotic viruses and viroids may not be detected in new pest-host combinations. Whilst bioassays have traditionally been used to detect unknown viruses, further molecular or serological testing is usually required to confirm the identity of the causal agent when disease symptoms are observed. Bioassays are heavily reliant on environmental conditions for symptom expression and often produce ambiguous results as false positives and false negatives. The time taken for bioassays means that plants spend extended periods of time in post entry quarantine stations, significantly adding to costs and delays for importers. A further drawback with bioassays is that strains may not be detected if they are asymptomatic on the indicator host. <u>Studies conducted so far have demonstrated NGS to be equivalent to or better than biological indexing assays in detecting viruses and viroids of agronomic significance (Rott et al. 2017; Rwahni et al., 2015; Mackie et al., 2017; Barrero et al., 2017). Most importantly, the studies are demonstrating that NGS is able to produce results significantly quicker than bioassays.</u></p>                                                                                                                                                                                                                                                                                |   |                                                                                                                                                          |
| 60 | 24 | <p>Phytosanitary testing for viruses and viroids in plants and plant products <del>moved around the globe</del> currently relies on a combination of specific (molecular and serological) and generic (visual, electron microscopy and biological indicators or bioassays) approaches. Whilst these methods are currently the best available they have a number of inherent weaknesses. The specific tests usually require a priori knowledge of the viral pathogens and each test needs to be developed and validated (including validation of the test for different pest/host combinations), making resource demands on national plant protection organisations (NPPO). The host range of many pathogens is not well defined and exotic viruses and viroids may not be detected in new pest-host combinations. Whilst bioassays have traditionally been used to detect unknown viruses, further molecular or serological testing is usually required to confirm the identity of the causal agent when disease symptoms are observed. Bioassays are heavily reliant on environmental conditions for symptom expression and often produce ambiguous results as false positives and false negatives. The time taken for bioassays means that plants spend extended periods of time in post entry quarantine stations, significantly adding to costs and delays for importers. A further drawback with bioassays is that strains may not be detected if they are asymptomatic on the indicator host.</p> | P | <p><b>EPPO</b><br/>Not really relevant in this paragraph. Moreover, this deletion makes the sentence easier to read.<br/><i>Category : EDITORIAL</i></p> |

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| 61 | 24 | Phytosanitary testing for viruses and viroids in plants and plant products moved around the globe currently relies on a combination of specific (molecular and serological) and generic (visual, electron microscopy and biological indicators or bioassays) approaches. Whilst these methods are currently the best available they have a number of inherent weaknesses. The specific tests usually require a priori knowledge of the viral pathogens and each test needs to be developed and validated (including validation of the test for different pest/host combinations), making resource demands on <del>national plant protection organisations</del> <a href="#">National Plant Protection Organisations</a> (NPPO). The host range of many pathogens is not well defined and exotic viruses and viroids may not be detected in new pest-host combinations. Whilst bioassays have traditionally been used to detect unknown viruses, further molecular or serological testing is usually required to confirm the identity of the causal agent when disease symptoms are observed. Bioassays are heavily reliant on environmental conditions for symptom expression and often produce ambiguous results as false positives and false negatives. The time taken for bioassays means that plants spend extended periods of time in post entry quarantine stations, significantly adding to costs and delays for importers. A further drawback with bioassays is that strains may not be detected if they are asymptomatic on the indicator host. | P | <b>Sierra Leone</b><br><br><i>Category : EDITORIAL</i>                                                                                                                                                      |
| 62 | 25 | Due to the limitations with traditional diagnostic methods, new robust, reliable and cost-effective methods are required to rapidly and reliably screen plants and plant products for viruses and viroids. Studies conducted so far have demonstrated NGS to be equivalent to or better than biological indexing assays in detecting viruses and viroids of agronomic significance (Rott <i>et al.</i> 2017; Rwahnih <i>et al.</i> , 2015; Mackie <i>et al.</i> , 2017; Barrero <i>et al.</i> , 2017). <a href="#">Metabarcoding or NGS applied to PCR amplicons of a DNA barcode region also have diagnostic applications for phytosanitary purposes. Outside viruses, this could be more likely the NGS approach that will have a diagnostic impact.</a> Most importantly, the studies are demonstrating that NGS is able to produce results significantly quicker than bioassays.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | P | <b>Canada</b><br>Outside viruses, this could be more likely the NGS approach that will have a diagnostic impact.<br><i>Category : SUBSTANTIVE</i>                                                           |
| 63 | 25 | Due to the limitations with traditional diagnostic methods, new robust, reliable and cost-effective methods are required to rapidly and reliably screen plants and plant products for viruses and viroids. Studies conducted so far have demonstrated NGS to be equivalent to or better than biological indexing assays in detecting viruses and viroids of agronomic significance (Rott <i>et al.</i> 2017; Rwahnih                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | C | <b>Kenya</b><br>Need to be clear if traditional methods here refers to biological assays or includes PCR others like ELISA<br><br>There is need also to mention the advantages and limitations of NGS here. |

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|                                      |    | <i>et al.</i> , 2015; Mackie <i>et al.</i> , 2017; Barrero <i>et al.</i> , 2017). Most importantly, the studies are demonstrating that NGS is able to produce results significantly quicker than bioassays.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |   | NGS process including delivery of results and data analyze can take from 1 to 3 months. To fast track results, companies charge extra price. In theory, NGS is faster but in practicality, it takes longer time unless the organization owns NGS facilities/equipment. Although this might change in future, CPM should therefore realize that this is a limitation.<br><i>Category : TECHNICAL</i>                                                                                                                                                                                                                 |
| 64                                   | 25 | Due to the limitations with traditional diagnostic methods, new robust, reliable and cost-effective methods are required to rapidly and reliably screen plants and plant products for viruses and viroids. Studies conducted so far have demonstrated NGS to be equivalent to or better than biological indexing assays in detecting viruses and viroids of agronomic significance (Rott <i>et al.</i> 2017; Rwahnihi <i>et al.</i> , 2015; Mackie <i>et al.</i> , 2017; Barrero <i>et al.</i> , 2017). <u>Most importantly, the studies are demonstrating that NGS is able to provide genetic information as sequence nucleotide information in a laboratory routine diagnosis and complement with bioassays to produce results significantly quicker than bioassays determine the potential pathogenic effect in crops</u> | P | <b>Colombia</b><br>NGS is a genetic method to identify results significantly quicker than bioassays. However, test the pathogenic effect in plants is the key to understand its role in crops and the environmental conditions.<br><br>Using the Integrated Pest Management concept, the diagnosis of pest in plant should be characterized from different views. NGS is one of them as powerful genetic tool to identify the genome sequence of pathogens. This information, combine with bioassays, will contribute in the complete view of epidemiological effect in crops.<br><br><i>Category : SUBSTANTIVE</i> |
| 65                                   | 25 | Due to the limitations with traditional diagnostic methods, new robust, reliable and cost-effective methods are required to rapidly and reliably screen plants and plant products for viruses and viroids. <u>Studies conducted so far have demonstrated NGS to be equivalent to viroids but also for other non-culturable or better than biological indexing assays in detecting viruses fastidious pests and viroids of agronomic significance (Rott HTS technologies open such perspectives. et al. 2017; Rwahnihi et al., 2015; Mackie et al., 2017; Barrero et al., 2017). Most importantly, the studies are demonstrating that NGS is able to produce results significantly quicker than bioassays.</u>                                                                                                                | P | <b>European Union</b><br>1) Although mainly used for viruses there is potential for other organisms.<br>2) To complete the sentence and replace the paragraph moved<br><br><i>Category : TECHNICAL</i>                                                                                                                                                                                                                                                                                                                                                                                                              |
| 66                                   | 25 | Due to the limitations with traditional diagnostic methods, new robust, reliable and cost-effective methods are required to rapidly and reliably screen plants and plant products for viruses and viroids. <u>Studies conducted so far have demonstrated NGS to be equivalent to viroids but also for other non-culturable or better than biological indexing assays in detecting viruses fastidious pests and viroids of agronomic significance (Rott HTS technologies open such perspectives. et al. 2017; Rwahnihi et al., 2015; Mackie et al., 2017; Barrero et al., 2017). Most importantly, the studies are demonstrating that NGS is able to produce results significantly quicker than bioassays.</u>                                                                                                                | P | <b>EPPO</b><br>1) Although mainly used for viruses there is potential for other organisms.<br>2) To complete the sentence and replace the paragraph moved<br><br><i>Category : TECHNICAL</i>                                                                                                                                                                                                                                                                                                                                                                                                                        |
| Regulatory and scientific challenges |    |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |   |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |

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| 67 | 26 | <b>Regulatory and scientific challenges</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | C | <p><b>United States of America</b></p> <p>Perhaps it should start with stating that many of the challenges of HTS are not new, and are the same we have been dealing with when using molecular detection or sequence based detection. This is no different than most DNA-based detection methods, and with viruses it is often RNA that is being sampled which might suggest more active-transcription or viability</p> <p><i>Category : SUBSTANTIVE</i></p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| 68 | 27 | Research findings based on NGS technologies have significant implications within a phytosanitary framework. For example, there is a risk that plant material may be restricted in movement due to the perceived presence of a (previously unknown) microorganism (e.g. virus) that does not have the potential to be pathogenic to its host(s). Not all organisms associated with plants are pests; some may be mutualists providing benefit to the host plant or commensal agents. There is also the issue, as with other indirect methods, that NGS technologies will detect non-viable organisms.                                                            | C | <p><b>Colombia</b></p> <p>Virus and viroid are the main objective of NGS. Other pathogens are important to characterize by NGS as phytoplasma and spiroplasma). These pathogens are poorly characterized in several host.</p> <p>Phytoplasma and spiroplasma are genera of bacteria that lack cell walls related as pathogens restricted to the host tissues. Their behavior is similar than virus and viroid, keeping the proportions. In consequence, NGS could be provide important genetic information for diagnosis of these possible pathogens in trade international plant material.</p> <p>In general, in the document is possible refer phytoplasma and spiroplasma as examples in the NGS applications. We suggested this reference:<br/>Kakizawa, S. and Yoneda, Y. (2015) The role of genome sequencing in phytoplasma research. Phytopathogenic Mollicutes. 5(1): 19-24. This document is attachment.</p> <p><i>Category : SUBSTANTIVE</i></p> |
| 69 | 27 | Research findings based on NGS technologies have significant implications within a phytosanitary framework. For example, there is a risk that plant material may be restricted in movement due to the perceived presence of a (previously unknown) microorganism (e.g. virus) that does not have the potential to be pathogenic to <del>its host(s)</del> <a href="#">this plant</a> . Not all organisms associated with plants are pests; some may be mutualists providing benefit to the host plant or <a href="#">are</a> commensal agents. There is also the issue, as with other indirect methods, that NGS technologies will detect non-viable organisms. | P | <p><b>European Union</b></p> <p>Self-explanatory.</p> <p><i>Category : EDITORIAL</i></p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| 70 | 27 | Research findings based on NGS technologies have significant implications within a phytosanitary framework. For example, there is a risk that plant material may be restricted in movement due to the perceived presence of a (previously unknown) microorganism (e.g. virus) that does not have the potential to be pathogenic to its host(s). Not all organisms associated with plants are pests; some may be                                                                                                                                                                                                                                                 | P | <p><b>United States of America</b></p> <p><i>Category : TECHNICAL</i></p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |

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|    |    | mutualists providing benefit to the host plant or commensal agents. <u>There Ensuring that regulatory decisions are made on pathogens is also a key criteria to the issue, as with other indirect methods, that NGS technologies will detect non-viable organisms- adoption of whole genome sequencing</u>                                                                                                                                                                                                                                                                                                                                                       |   |                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| 71 | 27 | Research findings based on NGS technologies have significant implications within a phytosanitary framework. For example, there is a risk that plant material may be restricted in movement due to the perceived presence of a (previously unknown) microorganism (e.g. virus) that does not have the potential to be pathogenic to its host(s). Not all organisms associated with plants are <u>pests</u> and instead are <u>part of the plant microbiome</u> ; some may be mutualists providing benefit to the host plant or commensal agents. There is also the issue, as with other indirect methods, that NGS technologies will detect non-viable organisms. | P | <b>United States of America</b><br>This is not always true and this is one of the reasons why many labs do RNA-Seq (including us), to avoid sequencing inactive or dead microorganisms, and only sequence metabolic active microbes. See Nature paper where they address some this issue: <a href="https://www.nature.com/articles/s41522-017-0046-x">https://www.nature.com/articles/s41522-017-0046-x</a><br>Category : <i>TECHNICAL</i> |
| 72 | 27 | Research findings based on NGS technologies have significant implications within a phytosanitary framework. For example, there is a risk that plant material may be restricted in movement due to the perceived presence of a (previously unknown) microorganism (e.g. virus) that does not have the potential to be pathogenic to its host(s). Not all organisms associated with plants are pests; some may be mutualists providing benefit to the host plant or commensal agents. There is also the issue, as with other indirect methods, that NGS technologies will detect <u>non-viable-non-viable, dead, and fragments of</u> organisms.                   | P | <b>International Seed Federation</b><br>Added to emphasize the risk of detecting traces of organisms as well as dead organisms.<br>Category : <i>TECHNICAL</i>                                                                                                                                                                                                                                                                             |
| 73 | 27 | Research findings based on NGS technologies have significant implications within a phytosanitary framework. For example, there is a risk that plant material may be restricted in movement due to the perceived presence of a (previously unknown) microorganism (e.g. virus) that does not have the potential to be pathogenic to <u>its host(s) this plant</u> . Not all organisms associated with plants are pests; some may be mutualists providing benefit to the host plant or <u>are</u> commensal agents. There is also the issue, as with other indirect methods, that NGS technologies will detect non-viable organisms.                               | P | <b>EPPO</b><br>Category : <i>EDITORIAL</i>                                                                                                                                                                                                                                                                                                                                                                                                 |
| 74 | 28 | The correct interpretation of results is one of the major challenges in using NGS. Very large and well curated databases of the whole genomes of known pests and micro-organisms are required as the reference for comparison with NGS generated sequence data. NPPOs will face the challenge to make decisions on the basis of data analysis but incomplete information about the biological significance of the finding and the ability of the micro-organism to infect. This decision-making process distances the diagnostic outcome from any analysis of pathogenicity and                                                                                  | C | <b>Nicaragua</b><br>Es importante la secuenciación de primera generación NGS en vista en las bases de datos Gen BANK no existen todos los oligonucleótidos necesarios que sirva de referencia comparativa.<br>Category : <i>TECHNICAL</i>                                                                                                                                                                                                  |

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|    |    | poses questions in deciding whether the data is linked to the actual presence of a viable biological entity that is a quarantine pest. However this same challenge is presented with current molecular sequencing methods and particularly for 'new to science' viruses, so this is not a new problem. Other challenges in using NGS for regulatory purposes are noted by Massart <i>et al.</i> (2017) and Martin <i>et al.</i> (2016).                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |   |                                                                                |
| 75 | 28 | The correct interpretation of results is one of the major challenges in using NGS. Very large and well curated databases of the whole genomes of known pests and micro-organisms are required as the reference for comparison with NGS generated sequence data. NPPOs will face the challenge to make decisions on the basis of data analysis but <a href="#">incomplete without complete</a> information about the biological significance of the finding and the ability of the micro-organism to infect. This decision-making process distances the diagnostic outcome from any analysis of pathogenicity and poses questions in deciding whether the data is linked to the actual presence of a viable biological entity that is a quarantine pest. However this same challenge is presented with current molecular sequencing methods and particularly for 'new to science' viruses, so this is not a new problem. Other challenges in using NGS for regulatory purposes are noted by Massart <i>et al.</i> (2017) and Martin <i>et al.</i> (2016). | P | <b>Canada</b><br>Adding clarity<br>Category : <i>EDITORIAL</i>                 |
| 76 | 28 | The correct interpretation of results is one of the major challenges in using NGS. Very large and well curated databases of the whole genomes <a href="#">or barcodes</a> of known pests and micro-organisms are required as the reference for comparison with NGS generated sequence data. NPPOs will face the challenge to make decisions on the basis of data analysis but incomplete information about the biological significance of the finding and the ability of the micro-organism to infect. This decision-making process distances the diagnostic outcome from any analysis of pathogenicity and poses questions in deciding whether the data is linked to the actual presence of a viable biological entity that is a quarantine pest. However this same challenge is presented with current molecular sequencing methods and particularly for 'new to science' viruses, so this is not a new problem. Other challenges in using NGS for regulatory purposes are noted by Massart <i>et al.</i> (2017) and Martin <i>et al.</i> (2016).      | P | <b>Canada</b><br><br>Category : <i>TECHNICAL</i>                               |
| 77 | 28 | The correct interpretation of results is one of the major challenges in using NGS. Very large and well curated databases of the whole genomes of known pests and micro-organisms are required as the reference for comparison with NGS generated sequence data. <a href="#">Because of the increased rate of new microorganism</a>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | P | <b>European Union</b><br>to explain the context<br>Category : <i>TECHNICAL</i> |

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|    |    | <a href="#">discovery</a> , NPPOs will face the challenge to make decisions on the basis of data analysis but incomplete information about the biological significance of the finding and the ability of the micro-organism to infect. This decision-making process distances the diagnostic outcome from any analysis of pathogenicity and poses questions in deciding whether the data is linked to the actual presence of a viable biological entity that is a quarantine pest. However this same challenge is presented with current molecular sequencing methods and particularly for 'new to science' viruses, so this is not a new problem. Other challenges in using NGS for regulatory purposes are noted by Massart <i>et al.</i> (2017) and Martin <i>et al.</i> (2016).                                                                                                                                                                                                                                                                                                                                                                                      |   |                                                                                                                                                                        |
| 78 | 28 | The correct interpretation of results is one of the major challenges in using NGS. Very large and well curated databases of the whole genomes of known pests and micro-organisms are required as the reference for comparison with NGS generated sequence data. NPPOs will face the challenge to make decisions on the basis of data analysis but incomplete information about the biological significance of the finding and the ability of the micro-organism to infect. This decision-making process distances the diagnostic outcome from any analysis of pathogenicity and poses questions in deciding whether the data is linked to the actual presence of a viable biological entity that is a quarantine pest. However this same challenge is presented with current molecular sequencing methods and particularly for 'new to science' viruses, so this is not a new problem. Other challenges in using NGS for regulatory purposes are noted by Massart <i>et al.</i> (2017) and Martin <i>et al.</i> (2016).                                                                                                                                                  | C | <b>European Union</b><br>"This decision-making process (...)": It needs to be clarified which decision making process is referred to.<br><i>Category : SUBSTANTIVE</i> |
| 79 | 28 | The correct interpretation of results is <del>one of the another</del> major <del>challenges</del> <a href="#">challenge</a> in using NGS. Very large and well curated databases of the whole genomes of known pests and micro-organisms are required as the reference for comparison with NGS generated sequence data. NPPOs will face the challenge to make decisions on the basis of <a href="#">nucleic acid</a> data analysis but incomplete information about the biological significance of the finding and the ability of the micro-organism to <del>infect</del> <a href="#">infest plants or plant products</a> . This decision-making process distances the diagnostic outcome from any analysis of pathogenicity and poses questions in deciding whether the data is linked to the actual presence of a viable biological entity that is a quarantine pest. However this same challenge is presented with current molecular sequencing methods and particularly for 'new to science' viruses, so this is not a new problem. Other challenges in using NGS for regulatory purposes are noted by Massart <i>et al.</i> (2017) and Martin <i>et al.</i> (2016). | P | <b>European Union</b><br>To be more precise and consistent with IPPC terminology.<br><i>Category : EDITORIAL</i>                                                       |

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| 80 | 28 | The correct interpretation of results is one of the major challenges in using NGS. Very large and well curated databases of the whole genomes of known pests and micro-organisms are required as the reference for comparison with NGS generated sequence data. NPPOs will face the challenge to make decisions on the basis of data analysis but incomplete information about the biological significance of the finding <u>and e.g.</u> the ability of the micro-organism to infect. This decision-making process distances the diagnostic outcome from any analysis of pathogenicity and poses questions in deciding whether the data is linked to the actual presence of a viable biological entity that is a quarantine pest. However this same challenge is presented with current molecular sequencing methods and particularly for 'new to science' viruses, so this is not a new problem. Other challenges in using NGS for regulatory purposes are noted by Massart <i>et al.</i> (2017) and Martin <i>et al.</i> (2016).                                   | P | <b>European Union</b><br>The end of the sentence is one example of the biological significance so 'and' is not appropriate. We consequently propose to replace 'and' by 'e.g.'.<br><i>Category : TECHNICAL</i>                                                                                                                                                                                                |
| 81 | 28 | The correct interpretation of results is one of the major challenges in using NGS. Very large and well curated databases of the whole genomes of known pests and micro-organisms are required as the reference for comparison with NGS generated sequence data. NPPOs will face the challenge to make decisions on the basis of data analysis <u>but-with</u> incomplete information ( <u>or even no information</u> ) about the biological significance of the finding and the ability of the micro-organism to infect. This decision-making process distances the diagnostic outcome from any analysis of pathogenicity and poses questions in deciding whether the data is linked to the actual presence of a viable biological entity that is a quarantine pest. However this same challenge is presented with current molecular sequencing methods and particularly for 'new to science' viruses, so this is not a new problem. Other challenges in using NGS for regulatory purposes are noted by Massart <i>et al.</i> (2017) and Martin <i>et al.</i> (2016). | P | <b>European Union</b><br>More precise as there are situations where no information is available.<br><i>Category : TECHNICAL</i>                                                                                                                                                                                                                                                                               |
| 82 | 28 | <del>The correct interpretation of results is one of the major challenges in using NGS. Very large and well curated databases of the whole genomes of known pests and micro-organisms are required as the reference for comparison with NGS generated sequence data. NPPOs will face the challenge to make decisions on the basis of data analysis but incomplete information about the biological significance of the finding and the ability of the micro-organism to infect. This decision-making process distances the diagnostic outcome from any analysis of pathogenicity and poses questions in deciding whether the data is linked to the actual presence of a viable biological entity that is a quarantine pest. However this same challenge is</del>                                                                                                                                                                                                                                                                                                      | P | <b>United States of America</b><br>Another major challenge: how depending of the bioinformatic tool or pipeline and parameters used, pathogen identification can completely vary. Suggest re-writing the paragraph as proposed since it pointing NGS problems specifically but at the end briefly mentions that we already have these problems with other molecular methods.<br><i>Category : SUBSTANTIVE</i> |

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|    |    | <p><del>presented with current molecular sequencing methods and particularly for ‘new to science’ viruses, so this is not a new problem. Other challenges in using NGS for regulatory purposes are noted by Massart <i>et al.</i> (2017) and Martin <i>et al.</i> (2016). Correctly identifying or predicting pathogens from whole genome sequences are two separate but important challenges using these technologies. With more nucleic acid information generated from HTS, it is important that identification is not made from portions of genomes, and to help avoid this mistake it is beneficial to have well-curated databases of a wide-array of microorganisms (both pathogenic and non-pathogenic). Without definitive research identifying specific disease-causing genes, NPPOs will face the same current challenge of making decisions on the basis of microbial identification without the functional data, and may at times have to rely on using specific gene sequence rather than whole genome. Without the research, whole genome sequence alone does not solve the current decision-making problem that diagnostics does not equate pathogenicity. This same challenge is presented with current molecular sequencing methods and particularly for ‘new to science’ viruses, so is not a new problem</del></p> |   |                                                                                                                                                                                                                                                     |
| 83 | 28 | <p>The correct interpretation of results is one of the major challenges in using NGS. Very large and well curated databases of the whole genomes of known pests and micro-organisms are required as the reference for comparison with NGS generated sequence data. NPPOs will face the challenge to make decisions on the basis of data analysis but incomplete information about the biological significance of the finding and the ability of the micro-organism to infect. This decision-making process distances the diagnostic outcome from any analysis of pathogenicity and poses questions in deciding whether the data is linked to the actual presence of a viable biological entity that is a quarantine pest. <del>However-However</del>, this same challenge is presented with current molecular sequencing methods and particularly for ‘new to science’ viruses, so this is not a new problem. Other challenges in using NGS for regulatory purposes are noted by Massart <i>et al.</i> (2017) and Martin <i>et al.</i> (2016).</p>                                                                                                                                                                                                                                                                                    | P | <p><b>Ghana</b><br/>However should be punctuated to read However,<br/>Category : <i>EDITORIAL</i></p>                                                                                                                                               |
| 84 | 28 | <p>The correct interpretation of results is one of the major challenges in using NGS. Very large and well curated databases of the whole genomes of known pests and micro-organisms are required as the reference for comparison with NGS generated sequence data. NPPOs will face the challenge to make decisions on the basis of data analysis but incomplete information about the biological significance of the finding and the ability of the micro-organism to infect. This decision-making process distances the diagnostic outcome from any analysis of pathogenicity and poses questions in deciding whether the data is linked to the actual presence of a viable biological entity that is a quarantine pest. However this same challenge is presented with current molecular sequencing methods and particularly for ‘new</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | C | <p><b>International Seed Federation</b><br/>A comment on the second to last sentence: The question of how the challenge is being addressed with PCR and first generation sequencing methods is still not clear.<br/>Category : <i>TECHNICAL</i></p> |

|    |    |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |   |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
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|    |    | to science' viruses, so this is not a new problem. Other challenges in using NGS for regulatory purposes are noted by Massart <i>et al.</i> (2017) and Martin <i>et al.</i> (2016).                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |   |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| 85 | 28 | The correct interpretation of results is one of the major challenges in using NGS. Very large and well curated databases of the whole genomes of known pests and micro-organisms are required as the reference for comparison with NGS generated sequence data. NPPOs will face the challenge to make decisions on the basis of data analysis but incomplete information about the biological significance of the finding and the ability of the micro-organism to infect. This decision-making process distances the diagnostic outcome from any analysis of pathogenicity and poses questions in deciding whether the data is linked to the actual presence of a viable <a href="#">and pathogenic</a> biological entity that is a quarantine pest. However this same challenge is presented with <a href="#">current molecular-PCR and first generation</a> sequencing methods and particularly for 'new to science' viruses, so this is not a new problem. Other challenges in using NGS for regulatory purposes are noted by Massart <i>et al.</i> (2017) and Martin <i>et al.</i> (2016). | P | <p><b>International Seed Federation</b><br/> Addition of 'pathogenic', as confirmation of the presence of a viable and pathogenic organism is necessary to fulfil Koch's postulates, and to be able to conduct a fit-for-purpose risk assessment of a specific seed lot.</p> <p>The term "current molecular sequencing technologies" is unclear and time-bound (in 10 years nobody will understand). First generation sequencing or even "Sanger sequencing" is a better term.<br/> Category : <i>TECHNICAL</i></p>                               |
| 86 | 28 | The correct interpretation of results is one of the major challenges in using NGS. Very large and well curated databases of the whole genomes of known pests and micro-organisms are required as the reference for comparison with NGS generated sequence data. NPPOs will face the challenge to make decisions on the basis of data analysis but incomplete information about the biological significance of the finding and the ability of the micro-organism to infect. This decision-making process distances the diagnostic outcome from any analysis of pathogenicity and poses questions in deciding whether the data is linked to the actual presence of a viable biological entity that is a quarantine pest. However this same challenge is presented with current molecular sequencing methods and particularly for 'new to science' viruses, so this is not a new problem. Other challenges in using NGS for regulatory purposes are noted by Massart <i>et al.</i> (2017) and Martin <i>et al.</i> (2016).                                                                         | C | <p><b>International Seed Federation</b><br/> In response to second sentence: As very large and well curated databases are required for known pests, won't the absence of these databases for unknown pests make it hard to detect unknown organisms? What does one do with sequences that do not match?<br/> Category : <i>TECHNICAL</i></p>                                                                                                                                                                                                      |
| 87 | 28 | The correct interpretation of results is one of the major challenges in using NGS. Very large and well curated databases of the whole genomes of known pests and micro-organisms are required as the reference for comparison with NGS generated sequence data. NPPOs will face the challenge to make decisions on the basis of data analysis but incomplete information about the biological significance of the finding and the ability of the micro-organism to infect. This decision-making process distances the diagnostic outcome from any analysis of pathogenicity and poses questions in deciding whether the data is linked to the actual presence of a                                                                                                                                                                                                                                                                                                                                                                                                                              | C | <p><b>International Seed Federation</b><br/> The correct interpretation of results first depends on having high quality results, and this is a bigger challenge: what and where to sample, the processing, the NGS machine used (each platform generates different quality data), and the bioinformatic software used to interpret the data (as every software has advantages and disadvantages, several software programmes are needed for an optimal analyses; developing or finding this is challenging).<br/> Category : <i>TECHNICAL</i></p> |

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|    |    | viable biological entity that is a quarantine pest. However this same challenge is presented with current molecular sequencing methods and particularly for 'new to science' viruses, so this is not a new problem. Other challenges in using NGS for regulatory purposes are noted by Massart <i>et al.</i> (2017) and Martin <i>et al.</i> (2016).                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |   |                                                                                                                                                                                                      |
| 88 | 28 | The correct interpretation of results is one of the major challenges in using NGS. Very large and well curated databases of the whole genomes of known pests and micro-organisms are required as the reference for comparison with NGS generated sequence data. NPPOs will face the challenge to make decisions on the basis of data analysis <u>but-with</u> incomplete information <u>(or even no information)</u> about the biological significance of the finding and the ability of the micro-organism to infect. This decision-making process distances the diagnostic outcome from any analysis of pathogenicity and poses questions in deciding whether the data is linked to the actual presence of a viable biological entity that is a quarantine pest. However this same challenge is presented with current molecular sequencing methods and particularly for 'new to science' viruses, so this is not a new problem. Other challenges in using NGS for regulatory purposes are noted by Massart <i>et al.</i> (2017) and Martin <i>et al.</i> (2016). | P | <b>EPPO</b><br>More precise as there are situations where no information is available.<br><i>Category : TECHNICAL</i>                                                                                |
| 89 | 28 | The correct interpretation of results is one of the major challenges in using NGS. Very large and well curated databases of the whole genomes of known pests and micro-organisms are required as the reference for comparison with NGS generated sequence data. NPPOs will face the challenge to make decisions on the basis of data analysis but incomplete information about the biological significance of the finding <u>and-e.g.</u> the ability of the micro-organism to infect. This decision-making process distances the diagnostic outcome from any analysis of pathogenicity and poses questions in deciding whether the data is linked to the actual presence of a viable biological entity that is a quarantine pest. However this same challenge is presented with current molecular sequencing methods and particularly for 'new to science' viruses, so this is not a new problem. Other challenges in using NGS for regulatory purposes are noted by Massart <i>et al.</i> (2017) and Martin <i>et al.</i> (2016).                                 | P | <b>EPPO</b><br>The end of the sentence is one example of the biological significance so 'and' is not appropriate. We consequently propose to replace 'and' by 'e.g.'.<br><i>Category : TECHNICAL</i> |
| 90 | 28 | The correct interpretation of results is <u>one-of-the-another</u> major <u>challenges</u> <u>challenge</u> in using NGS. Very large and well curated databases of the whole genomes of known pests and micro-organisms are required as the reference for comparison with NGS generated sequence data. NPPOs will face the challenge to make decisions on the basis of <u>nucleic acid</u> data analysis but incomplete                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | P | <b>EPPO</b><br>To be more precise and consistent with IPPC terminology<br><i>Category : EDITORIAL</i>                                                                                                |

|    |    |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |   |                                                                                                                                                              |
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|    |    | information about the biological significance of the finding and the ability of the micro-organism to <del>infect</del> <u>infest plants of plant products</u> . This decision-making process distances the diagnostic outcome from any analysis of pathogenicity and poses questions in deciding whether the data is linked to the actual presence of a viable biological entity that is a quarantine pest. However this same challenge is presented with current molecular sequencing methods and particularly for 'new to science' viruses, so this is not a new problem. Other challenges in using NGS for regulatory purposes are noted by Massart <i>et al.</i> (2017) and Martin <i>et al.</i> (2016).                                                                                                                                                                                                                                                                                                                                                                                |   |                                                                                                                                                              |
| 91 | 28 | The correct interpretation of results is one of the major challenges in using NGS. Very large and well curated databases of the whole genomes of known pests and micro-organisms are required as the reference for comparison with NGS generated sequence data. NPPOs will face the challenge to make decisions on the basis of data analysis but incomplete information about the biological significance of the finding and the ability of the micro-organism to infect. This decision-making process distances the diagnostic outcome from any analysis of pathogenicity and poses questions in deciding whether the data is linked to the actual presence of a viable biological entity that is a quarantine pest. However this same challenge is presented with current molecular sequencing methods and particularly for 'new to science' viruses, so this is not a new problem. Other challenges in using NGS for regulatory purposes are noted by Massart <i>et al.</i> (2017) and Martin <i>et al.</i> (2016).                                                                      | C | <b>EPPO</b><br>"This decision-making process (...)": It needs to be clarified which decision making process is referred to.<br><i>Category : SUBSTANTIVE</i> |
| 92 | 28 | The correct interpretation of results is one of the major challenges in using NGS. Very large and well curated databases of the whole genomes of known pests and micro-organisms are required as the reference for comparison with NGS generated sequence data. <u>Because of the increased rate of new microorganism discovery,</u> NPPOs will face the challenge to make decisions on the basis of data analysis but incomplete information about the biological significance of the finding and the ability of the micro-organism to infect. This decision-making process distances the diagnostic outcome from any analysis of pathogenicity and poses questions in deciding whether the data is linked to the actual presence of a viable biological entity that is a quarantine pest. However this same challenge is presented with current molecular sequencing methods and particularly for 'new to science' viruses, so this is not a new problem. Other challenges in using NGS for regulatory purposes are noted by Massart <i>et al.</i> (2017) and Martin <i>et al.</i> (2016). | P | <b>EPPO</b><br>to explain the context<br><i>Category : TECHNICAL</i>                                                                                         |
| 93 | 28 | The correct interpretation of results is one of the major challenges in using NGS. Very large and well curated databases of the whole genomes of known pests and                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | P | <b>Slovenia</b><br>More specific text: the position is not much different than in usnig                                                                      |

|                      |    |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |   |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
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|                      |    | micro-organisms are required as the reference for comparison with NGS generated sequence data. NPPOs will face the challenge to make decisions on <del>because of the basis-increased rate of the discovery of data analysis but</del> <u>microorganisms with</u> incomplete information about the biological significance of the finding and the ability of the micro-organism to infect. This decision-making process distances the diagnostic outcome from any analysis of pathogenicity and poses questions in deciding whether the data is linked to the actual presence of a viable biological entity that is a quarantine pest. However this same challenge is presented with current molecular sequencing methods and particularly for 'new to science' viruses, so this is not a new problem. Other challenges in using NGS for regulatory purposes are noted by Massart <i>et al.</i> (2017) and Martin <i>et al.</i> (2016).     |   | other molecular methods for the discovery of microorganisms. However, due to its high resolution and universality, the pace of discovery is now accelerated with the high-throughput sequencing.<br><i>Category : SUBSTANTIVE</i>                                                                                                                                                                                                                                                                     |
| 94                   | 29 | To give confidence to NPPOs in adopting NGS technologies for pest diagnosis, internationally harmonized approaches are required, including development of operational guidelines to reliably and repeatedly perform NGS including quality controls and validation data to interpret NGS outputs (Boonham <i>et al.</i> , 2014). Validation of the technology against existing methods, which also takes into account the limits of current procedures, is also needed. <u>NGS techniques need to be thoroughly validated for each target pathogen and matrix to demonstrate that they are fit-for-purpose. Lab protocols should be made available along with a description of sample preparation, process for data analysis and the sequence databases utilized.</u><br><u>In addition, clear guidance on whether NGS is a valid technique for the detection of non-target organisms should be provided along with validation criteria.</u> | P | <b>International Seed Federation</b><br>ISF is of the view that the required higher sensitivity, the need to detect defined pathogens, and the need for appropriate test validation render sequencing approaches more appropriate for targeted pests than non-targeted ones. Full validation of a method to detect non-target organisms is not feasible (Roehorst <i>et al.</i> (2018). How should the limit of detection (LOD) for an unknown target be determined?<br><i>Category : SUBSTANTIVE</i> |
| 95                   | 29 | To give confidence to NPPOs in adopting NGS technologies for pest diagnosis, internationally harmonized approaches are required, including development of operational guidelines to reliably and repeatedly perform NGS including quality controls and validation data to interpret NGS outputs (Boonham <i>et al.</i> , 2014). Validation of the technology against existing methods, which also takes into account the limits of current procedures, is also needed.                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | C | <b>International Seed Federation</b><br>Comment on "Validation of the technology against existing methods, which also takes into account the limits of current procedures, is also needed": The limits of both PCR and NGS technology to determine viability must be resolved.<br><i>Category : TECHNICAL</i>                                                                                                                                                                                         |
| Global collaboration |    |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |   |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| 96                   | 31 | There are a number of initiatives underway in different regions of the world that are exploring the use of NGS technologies as a diagnostic tool for <del>phytosanitary</del> <u>Phytosanitary</u> purposes (for example in Australasia, Europe and North America). These include discussions on associated policies that may be developed. Co-ordination of outcomes from these initiatives is required to progress the timely                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | P | <b>Ghana</b><br>phytosanitary should be capitalized to read Phytosanitary<br><i>Category : EDITORIAL</i>                                                                                                                                                                                                                                                                                                                                                                                              |

|                                                                                                            |    |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |   |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
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|                                                                                                            |    | development of internationally harmonised standards to use NGS in a regulatory setting.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |   |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| 97                                                                                                         | 31 | There are a number of initiatives underway in different regions of the world that are exploring the use of NGS technologies as a diagnostic tool for phytosanitary purposes (for example in Australasia, Europe and North America). These include discussions on associated policies that may be developed. Co-ordination of outcomes from these initiatives is required to progress the timely development of internationally harmonised standards to use NGS in a regulatory setting.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | C | <b>Nepal</b><br>The proposal is fine. But the problem is that in most of the developing countries like Nepal we are not adopting conventional current generation sequencing (CGS) technologies for phytosanitary purposes. To be honest CGS is still too far for us, and even conventional technologies are not in place for phytosanitary purposes. So, timely development of internationally harmonized standards to use NGS is fine but to be adopted in regulatory setting would be too early<br><i>Category : SUBSTANTIVE</i> |
| Recommendation on: Next Generation Sequencing technologies as a diagnostic tool for phytosanitary purposes |    |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |   |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| 98                                                                                                         | 43 | <b>Recommendation on: Next Generation Sequencing (NGS) technologies as a diagnostic tool for <del>phytosanitary</del> Phytosanitary purposes</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | P | <b>Ghana</b><br>The abbreviation (NGS) must be included in the heading as well as capitalizing Phytosanitary<br><i>Category : EDITORIAL</i>                                                                                                                                                                                                                                                                                                                                                                                        |
| 99                                                                                                         | 45 | The Commission on Phytosanitary Measures (CPM) recognizes that accurate and timely pest diagnosis underpins export certification, import inspections and the application of appropriate phytosanitary measures <sup>1</sup> . It is widely accepted that the ability to detect and identify a plant pest varies with the accuracy and reproducibility and specificity of the detection tools.<br><br><u>Next Generation Sequencing (NGS) technologies, also known as high throughput or deep sequencing, have provided a powerful alternative to the detection and identification of organisms. However, the NGS-based diagnostic outcomes may not be associated with evidence of living pests or damage to the plant or plant products by these organisms. As such, the use of highly sensitive technologies, such as NGS for the detection and identification of plant pests should be introduced cautiously and with due consideration of the risks and consequences of applying NGS-diagnostic outcomes to regulate phytosanitary risks. Furthermore, NGS technologies may not suit all NPPOs due to the high cost in platform and operating. It should be also noted that each NPPO may use different NGS platforms.</u> | P | <b>Japan</b><br>It should be noted that there are several kinds of NGS platforms and NPPOs can use not necessarily a specific NGS platform but other NGS platforms or methods for pest detection and identification.<br><i>Category : SUBSTANTIVE</i>                                                                                                                                                                                                                                                                              |
| 100                                                                                                        | 45 | The Commission on Phytosanitary Measures (CPM) recognizes that accurate and timely pest diagnosis underpins export certification, import inspections and the application of appropriate phytosanitary measures <sup>1</sup> . It is widely accepted that the ability to detect and identify a plant pest varies with the accuracy and reproducibility and specificity of the detection tools.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | P | <b>European Union</b><br>We want to provide the following comments on paragraph 47, which is missing in the OCS version.<br>1. Substantive ( ~ interpretation of results): It is the interpretation of the outputs which should be considered cautiously, not the use of the method.<br>2. Editorial: HTS is not used to regulate but take measures.<br>Bold: added text; Italics: to be deleted<br><i>Category : SUBSTANTIVE</i>                                                                                                  |

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|            |    | <a href="#">[47]Next Generation Sequencing (NGS) technologies, also known as high throughput or deep sequencing, have provided a powerful alternative to traditional diagnostic methods for the detection and identification of organisms. However, the NGS-based diagnostic outcomes may not be associated with evidence of living pests or damage to the plant or plant products by these organisms. As such, the use interpretation of the results of highly sensitive technologies, such as NGS for the detection and identification of plant pests should be introduced cautiously and with done cautiously. In particular, due consideration of should be given to the risks and consequences of applying NGS-diagnostic outcomes to regulate take phytosanitary risks measures.</a> |   |                                                                                                                                                                                                                                                     |
| 101        | 45 | The Commission on Phytosanitary Measures (CPM) recognizes that accurate and timely pest diagnosis underpins export certification, import inspections and the application of appropriate phytosanitary measures <sup>1</sup> . It is widely accepted that the ability to detect and identify a <del>plant</del> -pest varies with the <del>accuracy and accuracy</del> , reproducibility and specificity of the detection tools.                                                                                                                                                                                                                                                                                                                                                            | P | <b>European Union</b><br>See definition of pest in ISPM 5.<br>Category : EDITORIAL                                                                                                                                                                  |
| 102        | 45 | The Commission on Phytosanitary Measures (CPM) recognizes that accurate and timely pest diagnosis underpins export certification, import inspections and the application of appropriate <del>phytosanitary</del> <del>Phytosanitary</del> measures <sup>1</sup> . It is widely accepted that the ability to detect and identify a plant pest varies with the accuracy and reproducibility and specificity of the detection tools.                                                                                                                                                                                                                                                                                                                                                          | P | <b>Ghana</b><br>phytosanitary should read Phytosanitary<br>Category : EDITORIAL                                                                                                                                                                     |
| 103        | 45 | The Commission on Phytosanitary Measures (CPM) recognizes that accurate and timely pest diagnosis underpins export certification, import inspections and the application of appropriate phytosanitary measures <sup>1</sup> . It is widely accepted that the ability to detect and identify a plant pest varies with the accuracy and reproducibility and specificity of the detection <del>tool</del> <del>tools</del> and whether the latter is <del>fit-for-purpose</del> .                                                                                                                                                                                                                                                                                                             | P | <b>International Seed Federation</b><br>From the seed industry's point of view, it is important to add this as reproducibility and specificity cannot be enough to accept a test and make decisions that affect seed trade.<br>Category : TECHNICAL |
| 104        | 45 | The Commission on Phytosanitary Measures (CPM) recognizes that accurate and timely pest diagnosis underpins export certification, import inspections and the application of appropriate phytosanitary measures <sup>1</sup> . It is widely accepted that the ability to detect and identify a <del>plant</del> -pest varies with the <del>accuracy and accuracy</del> , reproducibility and specificity of the detection tools.                                                                                                                                                                                                                                                                                                                                                            | P | <b>EPPO</b><br>See definition of pest in ISPM 5<br>Category : EDITORIAL                                                                                                                                                                             |
| BACKGROUND |    |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |   |                                                                                                                                                                                                                                                     |
| 105        | 47 | <a href="#">Next Generation Sequencing (NGS) technologies, also known as high throughput or deep sequencing, have provided a powerful alternative to the detection and identification of organisms. However, the NGS-based diagnostic outcomes may not be associated with evidence of living pests or damage to the plant or plant</a>                                                                                                                                                                                                                                                                                                                                                                                                                                                     | P | <b>Ghana</b><br>phytosanitary should be capitalized as Phytosanitary<br>Category : EDITORIAL                                                                                                                                                        |

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|     |    | <u>products by these organisms. As such, the use of highly sensitive technologies, such as NGS for the detection and identification of plant pests should be introduced cautiously and with due consideration of the risks and consequences of applying NGS-diagnostic outcomes to regulate Phytosanitary risks.</u>                                                                                                                                                                                                                                                                                                                                                                                            |   |                                                                                                       |
| 106 | 47 | Next Generation Sequencing (NGS) technologies, also known as <del>high-throughput</del> <u>High-Throughput (HTS)</u> or <del>deep-sequencing</del> <u>Deep Sequencing</u> , have provided a powerful alternative to the detection and identification of organisms. However, the NGS-based diagnostic outcomes may not be associated with evidence of living pests or damage to the plant or plant products by these organisms. As such, the use of highly sensitive technologies, such as NGS for the detection and identification of plant pests should be introduced cautiously and with due consideration of the risks and consequences of applying NGS-diagnostic outcomes to regulate phytosanitary risks. | P | <b>Ghana</b><br>high throughput should read High-Throughput (HTS)<br><i>Category : EDITORIAL</i>      |
| 107 | 47 | Next Generation Sequencing (NGS) technologies, also known as high throughput or deep sequencing, have provided a powerful alternative to the detection and identification of organisms. However, the NGS-based diagnostic outcomes may not be associated with evidence of living pests or damage to the plant or plant products by these organisms. As such, the use of highly sensitive technologies, such as NGS for the detection and identification of plant pests should be introduced cautiously and with due consideration of the risks and consequences of applying NGS-diagnostic outcomes to regulate phytosanitary risks.                                                                            | C | <b>Ghana</b><br>high-throughput must be edited to read High-Throughput<br><i>Category : EDITORIAL</i> |
| 108 | 47 | Next Generation Sequencing (NGS) technologies, also known as high throughput or deep sequencing, have provided a powerful alternative to the detection and identification of organisms. However, the NGS-based diagnostic outcomes may not be associated with evidence of living pests or damage to the plant or plant products by these organisms. As such, the use of highly sensitive technologies, such as NGS for the detection and identification of plant pests <u>in tissue and especially seed</u> should be introduced cautiously and with due consideration of the risks and consequences of applying NGS-diagnostic outcomes to regulate phytosanitary risks.                                       | P | <b>International Seed Federation</b><br><i>Category : TECHNICAL</i>                                   |
| 109 | 47 | Next Generation Sequencing (NGS) technologies, also known as high throughput or deep sequencing, have provided a powerful alternative to <u>traditional diagnostic methods for</u> the detection and identification of organisms. However, the NGS-based diagnostic outcomes may not be associated with evidence of living pests or damage to the plant or plant products by these organisms. As such, the use of                                                                                                                                                                                                                                                                                               | P | <b>EPPO</b><br>HTS is not used to regulate but take measures<br><i>Category : EDITORIAL</i>           |

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|     |    | highly sensitive technologies, such as NGS for the detection and identification of <del>plant</del> pests should be <del>introduced cautiously and with</del> <u>done cautiously. In particular,</u> due consideration <del>of should be given to</del> the risks and consequences of applying NGS-diagnostic outcomes to <del>regulate</del> <u>take</u> phytosanitary <del>risks</del> <u>measures</u> .                                                                                                                                                                                                                                                                                                                                                                                                                                         |   |                                                                                                                                                                                                                                                       |
| 110 | 47 | Next Generation Sequencing (NGS) technologies, also known as high throughput or deep sequencing, have provided a powerful alternative to the detection and identification of organisms. However, the NGS-based diagnostic outcomes may not be associated with evidence of living pests or damage to the plant or plant products by these organisms. As such, the <del>use</del> <u>interpretation</u> of <u>the results of</u> highly sensitive technologies, such as NGS for the detection and identification of plant pests should be introduced cautiously and with due consideration of the risks and consequences of applying NGS-diagnostic outcomes to regulate phytosanitary risks.                                                                                                                                                        | P | <b>EPPO</b><br>It is the interpretation of the outputs which should be considered cautiously, not the use of the method.<br><i>Category : SUBSTANTIVE</i>                                                                                             |
| 111 | 47 | Next Generation Sequencing (NGS) technologies, also known as high throughput or deep <del>sequencing</del> <u>sequencing (HTS)</u> , have provided a powerful alternative to the detection and identification of organisms. However, the NGS-based diagnostic outcomes may not be associated with evidence of living pests or damage to the plant or plant products by these organisms. As such, the use of highly sensitive technologies, such as NGS for the detection and identification of plant pests should be introduced cautiously and with due consideration of the risks and consequences of applying NGS-diagnostic outcomes to regulate phytosanitary risks.                                                                                                                                                                           | P | <b>Slovenia</b><br>Clear message for NPPOs and other non-specialists that NGS and HTS acronyms are synonyms.<br><i>Category : TECHNICAL</i>                                                                                                           |
| 112 | 47 | Next Generation Sequencing (NGS) technologies, also known as high throughput or deep sequencing, have provided a powerful alternative to the detection and identification of organisms. However, the NGS-based diagnostic outcomes may not be associated with evidence of living pests or damage to the plant or plant products by these organisms. As such, the use of highly sensitive technologies, such as NGS for the detection and identification of plant pests should be introduced cautiously and with due consideration of the risks and consequences of applying NGS-diagnostic outcomes to regulate phytosanitary risks.<br><br><u>Please specify the organisms that can be identify by the NGS for clarity. It can not be used to identified insect eggs, larvae, pupa stages and the type of adult insect of phytosanitary risk?</u> | P | <b>Sierra Leone</b><br>Please specify the organisms that can be identify by the NGS for clarity. It can not be used to identified insect eggs, larvae, pupa stages and the type of adult insect of phytosanitary risk?<br><i>Category : TECHNICAL</i> |

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|                 |    | <a href="#">Can NGS be used for bacteria, fungi and other pathogens or only viruses? this is not clear here, please explain.</a>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |   |                                                                                                                                                                                 |
| 113             | 47 | <p>Next Generation Sequencing (NGS) technologies, also known as high throughput or deep sequencing, have provided a powerful alternative to the detection and identification of organisms. However, the NGS-based diagnostic outcomes may not be associated with evidence of living pests or damage to the plant or plant products by these organisms. As such, the use of highly sensitive technologies, such as NGS for the detection and identification of plant pests should be introduced cautiously and with due consideration of the risks and consequences of applying NGS-diagnostic outcomes to regulate phytosanitary risks.</p> <p><a href="#">Can NGS be used for bacteria, fungi and other pathogens or only viruses? this is not clear here, please explain.</a></p> | P | <p><b>Sierra Leone</b><br/>Can NGS be used for bacteria, fungi and other pathogens or only viruses? this is not clear here, please explain.<br/><i>Category : TECHNICAL</i></p> |
| ADDRESSED TO    |    |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |   |                                                                                                                                                                                 |
| 114             | 49 | Contracting parties and <del>regional plant protection organizations</del> <a href="#">Regional Plant Protection Organizations</a> .                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | P | <p><b>Ghana</b><br/>regional plant protection organizations should show as Regional Plant Protection Organizations.<br/><i>Category : EDITORIAL</i></p>                         |
| 115             | 49 | Contracting parties and regional plant protection organizations.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | C | <p><b>Ghana</b><br/>regional plant protection organizations must be edited to read Regional Plant Protection Organizations (RPPO)<br/><i>Category : EDITORIAL</i></p>           |
| 116             | 49 | Contracting <del>parties</del> Parties, IPPC Secretariat and <del>regional plant protection organizations</del> <a href="#">Regional Plant Protection Organizations</a> .                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | P | <p><b>Sierra Leone</b><br/><i>Category : EDITORIAL</i></p>                                                                                                                      |
| RECOMMENDATIONS |    |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |   |                                                                                                                                                                                 |
| 117             | 51 | <p>The Commission notes findings based on NGS technologies of an unknown microorganism need to be further investigated to demonstrate the potential of that microorganism to be a plant pest that would qualify as a regulated pest. The Commission notes that there are existing challenges and further work is needed on NGS technologies before they can be considered as the sole method for pest detection and identification as the basis for applying phytosanitary regulations.</p> <p><del>Findings based on NGS technologies of an unknown microorganism need to be further investigated to demonstrate the potential of that microorganism to be a plant pest and that would qualify as a regulated pest.</del></p>                                                      | P | <p><b>Canada</b><br/>The first and last sentences are the same.<br/><i>Category : SUBSTANTIVE</i></p>                                                                           |

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| 118 | 51 | The Commission notes findings based on NGS technologies of an unknown microorganism need to be further investigated to demonstrate the potential of that microorganism to be a plant pest that would qualify as a regulated pest. The Commission notes that there are existing challenges and further work is needed on NGS technologies before they can be considered as the sole method for pest detection and identification as the basis for applying phytosanitary regulations.<br><del>Findings based on NGS technologies of an unknown microorganism need to be further investigated to demonstrate the potential of that microorganism to be a plant pest and that would qualify as a regulated pest.</del> | P | <b>Japan</b><br>Overlap with the first sentence.<br><i>Category : EDITORIAL</i>                                |
| 119 | 51 | The Commission notes findings based on NGS technologies of an unknown microorganism need to be further investigated to demonstrate the potential of that microorganism to be a plant pest that would qualify as a regulated pest. The Commission notes that there are existing challenges and further work is needed on NGS technologies before they can be considered as the sole method for pest detection and identification as the basis for applying phytosanitary regulations.<br><del>Findings based on NGS technologies of an unknown microorganism need to be further investigated to demonstrate the potential of that microorganism to be a plant pest and that would qualify as a regulated pest.</del> | P | <b>Panama</b><br>The text is deleted as it is repeated in the same paragraph.<br><i>Category : EDITORIAL</i>   |
| 120 | 51 | The Commission notes findings based on NGS technologies of an unknown microorganism need to be further investigated to demonstrate the potential of that microorganism to be a plant pest that would qualify as a regulated pest. The Commission notes that there are existing challenges and further work is needed on NGS technologies before they can be considered as the sole method for pest detection and identification as the basis for applying phytosanitary regulations. Findings based on NGS technologies of an unknown microorganism need to be further investigated to demonstrate the potential of that microorganism to be a <del>plant pest and</del> that would qualify as a regulated pest.    | P | <b>European Union</b><br>Self-explanatory.<br><i>Category : EDITORIAL</i>                                      |
| 121 | 51 | The Commission notes <del>findings based on NGS technologies of an unknown microorganism need to be further investigated to demonstrate the potential of that microorganism to be a plant pest that would qualify as a regulated pest. The Commission notes that</del> there are existing challenges and further work is needed on NGS technologies before they can be considered as the sole method for pest detection and identification as the basis for applying phytosanitary regulations. Findings based on NGS technologies of an unknown microorganism need to be                                                                                                                                           | P | <b>European Union</b><br>Same idea than in the last sentence of this paragraph.<br><i>Category : EDITORIAL</i> |

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|     |    | further investigated to demonstrate the potential of that microorganism to be a plant pest and that would qualify as a regulated pest.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |   |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| 122 | 51 | The Commission notes findings based on NGS technologies of an unknown microorganism need to be further investigated to demonstrate the potential of that microorganism to be a plant pest that would qualify as a regulated pest. The Commission notes that there are existing challenges and further work is needed on NGS technologies <del>before they can be considered as the sole method</del> for pest detection and identification as the basis for applying phytosanitary regulations. Findings based on NGS technologies of an unknown microorganism need to be further investigated to demonstrate the potential of that microorganism to be a plant pest and that would qualify as a regulated pest.           | P | <b>European Union</b><br>This sentence is misleading and could be interpreted in the sense that only HTS needs confirmation with another method for pest identification. Already established test also need confirmation with a second test in a diagnostic procedure. In this sense HTS is not different.<br>In addition, the way it is written is misleading NGS technologies do not have to be the sole method. Other methods will still be used.<br><br><i>Category : SUBSTANTIVE</i> |
| 123 | 51 | The Commission notes findings based on NGS technologies of an unknown microorganism need to be further investigated to demonstrate the potential of that microorganism to be a plant pest that would qualify as a regulated pest. The Commission notes that there are existing challenges and further work is needed on NGS technologies before they can be considered as <del>the sole a primary</del> method for pest detection and identification as the basis for applying phytosanitary regulations. Findings based on NGS technologies of an unknown microorganism need to be further investigated to demonstrate the potential of that microorganism to be a plant pest and that would qualify as a regulated pest. | P | <b>International Seed Federation</b><br>This part mainly focuses on new findings and thus potential new regulations. Nothing is said about routine application of NGS for targeted detection of regulated pests and what to do with the findings (Quality standards, number of reads cut off, coverage ...).<br><br>ISF would like to see recommendations on how to use NGS for diagnostic and detection purposes.<br><i>Category : TECHNICAL</i>                                         |
| 124 | 51 | The Commission notes findings based on NGS technologies of an unknown microorganism need to be further investigated to demonstrate the potential of that microorganism to be a plant pest that would qualify as a regulated pest. The Commission notes that there are existing challenges and further work is needed on NGS technologies <del>before they can be considered as the sole method</del> for pest detection and identification as the basis for applying phytosanitary regulations. Findings based on NGS technologies of an unknown microorganism need to be further investigated to demonstrate the potential of that microorganism to be a plant pest and that would qualify as a regulated pest.           | P | <b>EPPO</b><br>This sentence is misleading and could be interpreted in the sense that only HTS needs confirmation with another method for pest identification. Already established test also need confirmation with a second test in a diagnostic procedure. In this sense HTS is not different.<br>In addition, the way it is written is misleading NGS technologies do not have to be the sole method. Other methods will still be used.<br><br><i>Category : SUBSTANTIVE</i>           |
| 125 | 51 | The Commission notes <del>findings based on NGS technologies of an unknown microorganism need to be further investigated to demonstrate the potential of that microorganism to be a plant pest that would qualify as a regulated pest. The Commission notes that</del> there are existing challenges and further work is needed on NGS technologies before they can be considered as the sole method for pest detection and identification as the basis for applying phytosanitary regulations.                                                                                                                                                                                                                            | P | <b>EPPO</b><br>Same idea than in the last sentence of this paragraph.<br><i>Category : EDITORIAL</i>                                                                                                                                                                                                                                                                                                                                                                                      |

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|     |    | Findings based on NGS technologies of an unknown microorganism need to be further investigated to demonstrate the potential of that microorganism to be a plant pest and that would qualify as a regulated pest.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |   |                                                                                                                                                                                                                                                                                                       |
| 126 | 51 | The Commission notes findings based on NGS technologies of an unknown microorganism need to be further investigated to demonstrate the potential of that microorganism to be a plant pest that would qualify as a regulated pest. The Commission notes that there are existing challenges and further work is needed on NGS technologies before they can be considered as the sole method for pest detection and identification as the basis for applying phytosanitary regulations. Findings based on NGS technologies of an unknown microorganism need to be further investigated to demonstrate the potential of that microorganism to be a <del>plant pest and</del> that would qualify as a regulated pest.                                    | P | <b>EPPO</b><br><i>Category : EDITORIAL</i>                                                                                                                                                                                                                                                            |
| 127 | 51 | The Commission notes findings based on NGS technologies of an unknown microorganism need to be further investigated to demonstrate the potential of that microorganism to be a plant pest that would qualify as a regulated pest. The Commission notes that there are existing challenges and further work is needed on NGS technologies <del>before they can be considered as the sole method for pest detection and identification as the</del> basis for applying phytosanitary regulations. Findings based on NGS technologies of an unknown microorganism need to be further investigated to demonstrate the potential of that microorganism to be a plant pest and that would qualify as a regulated pest.                                    | P | <b>Slovenia</b><br>This sentence is misleading that only NGS needs confirmation with another method of pest identification. Already established methods also need confirmation with the second method in a diagnostic procedure. In this sense NGS is not different.<br><i>Category : SUBSTANTIVE</i> |
| 128 | 51 | The Commission notes findings based on NGS technologies of an unknown microorganism need to be further investigated to demonstrate the potential of that microorganism to be a plant pest that would qualify as a regulated pest. The Commission notes that there are existing challenges and further work is needed on NGS technologies before they can be considered as the sole method <u>“or in combination with other methods”</u> for pest detection and identification as the basis for applying phytosanitary regulations. Findings based on NGS technologies of an unknown microorganism need to be further investigated to demonstrate the potential of that microorganism to be a plant pest and that would qualify as a regulated pest. | P | <b>Singapore</b><br>To include “ or in combination with other methods” as DPs have advocated use of combination of methods ie morphological and molecular for pest identification. To be consistent with approach in DPs.<br><i>Category : SUBSTANTIVE</i>                                            |
| 129 | 52 | To improve the capacity and capability of contracting parties to adopt NGS <del>technologies</del> <u>technologies and use their results</u> , the Commission <i>encourages</i> contracting parties and regional plant protection organizations to:                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | P | <b>European Union</b><br>It is essential to mention the use of results.<br><i>Category : SUBSTANTIVE</i>                                                                                                                                                                                              |

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| 130 | 52 | To improve the capacity and capability of contracting parties to adopt NGS technologies, the Commission <i>encourages</i> contracting parties and regional plant protection organizations to:                                                                                                                                                                                                                                                                   | C | <b>Ghana</b><br>contracting should read Contracting and regional plant protection organizations edited to read Regional Plant Protection Organizations<br><i>Category : EDITORIAL</i>                                                                                            |
| 131 | 52 | To improve the capacity and capability of contracting parties to adopt NGS technologies, the Commission <i>encourages</i> contracting parties and regional plant protection organizations to:                                                                                                                                                                                                                                                                   | C | <b>Ghana</b><br>regional plant protection organizations must be edited to read Regional Plant Protection Organizations (RPPR)<br><i>Category : EDITORIAL</i>                                                                                                                     |
| 132 | 52 | To improve the capacity and capability of contracting parties to adopt NGS <del>technologies</del> <i>technologies and use their results</i> , the Commission <i>encourages</i> contracting parties and regional plant protection organizations to:                                                                                                                                                                                                             | P | <b>EPPO</b><br>It is essential to mention the use of results<br><i>Category : SUBSTANTIVE</i>                                                                                                                                                                                    |
| 133 | 53 | <i>Actively engage in and support</i> international efforts in developing <del>and finalising</del> standardised operational guidelines for NGS including proper interpretation of results and agreed quality control measures to ensure NGS data outputs are robust and accurate;                                                                                                                                                                              | P | <b>European Union</b><br>Finalizing is not necessary as it is included in 'developing'.<br><i>Category : EDITORIAL</i>                                                                                                                                                           |
| 134 | 53 | <i>Actively engage and support</i> international efforts in developing and finalising standardised operational guidelines for NGS including proper interpretation of results and agreed quality control measures <i>(e.g. procedure controls)</i> to ensure NGS data outputs are robust and accurate;                                                                                                                                                           | P | <b>European Union</b><br>It is important to mention which part of the quality control system bears the highest relevance.<br><i>Category : TECHNICAL</i>                                                                                                                         |
| 135 | 53 | <i>Actively engage and support</i> international efforts in developing and finalising standardised operational guidelines for NGS including proper interpretation of results and agreed quality control measures to ensure NGS data outputs are robust and <del>accurate</del> <i>accurate and implemented in a harmonized way;</i>                                                                                                                             | P | <b>European Union</b><br>Harmonized implementation is essential.<br><i>Category : SUBSTANTIVE</i>                                                                                                                                                                                |
| 136 | 53 | <i>Actively engage and support</i> international efforts in developing and finalising standardised operational guidelines for NGS including proper interpretation of results and agreed quality control measures to ensure NGS data outputs are robust and accurate;<br><br><i>b) Establish guidelines on what actions should be taken after detection of an unknown organism (for example virus) or detection of non-viable organisms in a plant material;</i> | P | <b>European Union</b><br>Clear guidelines for specific situations presenting risks are needed. This is marked as a substantive comment but we recognize that this is a more general issue valid for other diagnostic methods, not only for HTS.<br><i>Category : SUBSTANTIVE</i> |
| 137 | 53 | <i>Actively engage and support</i> international efforts in developing and finalising standardised operational guidelines for NGS including proper interpretation of results and agreed quality control measures to ensure NGS data outputs are robust and <del>accurate</del> <i>accurate and implemented in a harmonizes way;</i>                                                                                                                             | P | <b>Latvia</b><br>Harmonized implementation is essential.<br><i>Category : SUBSTANTIVE</i>                                                                                                                                                                                        |

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| 138 | 53 | Actively engage and support international efforts in developing and finalising standardised operational guidelines for NGS including proper interpretation of results and agreed quality control measures to ensure NGS data outputs are robust and accurate;<br><a href="#">b) Establish guidelines on what actions should be taken after detection of an unknown organism (for example virus) or detection of non-viable organisms in a plant material</a> | P | <b>Latvia</b><br>Clear guidelines for specific risky situations are missing.<br><i>Category : SUBSTANTIVE</i>                                                                                                                                                          |
| 139 | 53 | Actively engage and support international efforts in developing and finalising standardised operational guidelines for NGS including proper interpretation of results and agreed quality control measures to ensure NGS data outputs are robust and accurate;<br><a href="#">b) Establish guidelines on what actions should be taken after detection of an unknown organism (for example virus) or detection of non-viable organisms in a plant material</a> | P | <b>EPPO</b><br>Clear guidelines for specific situations presenting risks are needed. This is marked as a substantive comment but we recognize that this is a more general issue valid for other diagnostic methods, not only for HTS.<br><i>Category : SUBSTANTIVE</i> |
| 140 | 53 | Actively engage and support international efforts in developing and finalising standardised operational guidelines for NGS including proper interpretation of results and agreed quality control measures to ensure NGS data outputs are <del>robust</del> robust, accurate and <del>accurate</del> have biological significance;                                                                                                                            | P | <b>International Seed Federation</b><br>Added as it is important for seed trade.<br><i>Category : TECHNICAL</i>                                                                                                                                                        |
| 141 | 53 | Actively engage and support international efforts in developing and finalising standardised operational guidelines for NGS including proper interpretation of results and agreed quality control measures to ensure NGS data outputs are robust and <del>accurate</del> accurate and implemented in a harmonized way;                                                                                                                                        | P | <b>EPPO</b><br>Harmonized implementation is essential<br><i>Category : SUBSTANTIVE</i>                                                                                                                                                                                 |
| 142 | 53 | Actively engage and support international efforts in developing and finalising standardised operational guidelines for NGS including proper interpretation of results and agreed quality control measures ( <a href="#">e.g. procedure controls</a> ) to ensure NGS data outputs are robust and accurate;                                                                                                                                                    | P | <b>EPPO</b><br>It is important to mention which part of the quality control system bears the highest relevance.<br><i>Category : TECHNICAL</i>                                                                                                                         |
| 143 | 53 | Actively engage <a href="#">in</a> and support international efforts in developing <del>and finalising</del> standardised operational guidelines for NGS including proper interpretation of results and agreed quality control measures to ensure NGS data outputs are robust and accurate;                                                                                                                                                                  | P | <b>EPPO</b><br>Finalizing is not necessary as it is included in 'developing'<br><i>Category : EDITORIAL</i>                                                                                                                                                            |
| 144 | 53 | Actively engage and support international efforts in developing and finalising standardised operational guidelines for NGS including proper interpretation of results and agreed quality control ( <a href="#">e. g. procedure controls</a> ) measures to ensure NGS data outputs are robust and accurate;                                                                                                                                                   | P | <b>Slovenia</b><br>It is important to mention which part of the quality control system bears the highest relevance.<br><i>Category : TECHNICAL</i>                                                                                                                     |

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| 145 | 53 | Actively engage and support international efforts in developing and finalising standardised operational guidelines for NGS including proper interpretation of results and agreed <a href="#">on</a> quality control measures to ensure NGS data outputs are robust and accurate;                                                                                     | P | <b>Sierra Leone</b><br><i>Category : EDITORIAL</i>                                                                                                                                                                                                                                                                                                                                                                   |
| 146 | 54 | Support international efforts in obtaining more scientific evidence on reliability and accuracy of NGS by conducting trials comparing NGS against existing diagnostic platforms;<br><br><a href="#">d) Share knowledge and experience on the interpretation of NGS results and especially on the conclusions of the phytosanitary risk of the organism detected;</a> | P | <b>European Union</b><br>It is important to specify that sharing of knowledge should be ensured.<br><i>Category : SUBSTANTIVE</i>                                                                                                                                                                                                                                                                                    |
| 147 | 54 | Support international efforts in obtaining more scientific evidence on reliability and accuracy of NGS by conducting trials comparing NGS <a href="#">against-with</a> existing diagnostic platforms, <a href="#">preferably using assays/methods that determine viability of the target pathogen and its pathogenicity;</a>                                         | P | <b>International Seed Federation</b><br>Added as a recommendation, see ISF's view on the use of "indirect" tests ( <a href="http://www.worldseed.org/wp-content/uploads/2015/10/Indirect_Seed_Health_Tests_2013.pdf">http://www.worldseed.org/wp-content/uploads/2015/10/Indirect_Seed_Health_Tests_2013.pdf</a> ).<br><i>Category : TECHNICAL</i>                                                                   |
| 148 | 54 | Support international efforts in obtaining more scientific evidence on reliability and accuracy of NGS by conducting trials comparing NGS against existing diagnostic platforms;<br><br><a href="#">c) Share knowledge and experience on the interpretation of NGS results and especially on the conclusions of the phytosanitary risk of the organism detected.</a> | P | <b>EPPO</b><br>It is important to specify that sharing of knowledge should be ensured<br><i>Category : SUBSTANTIVE</i>                                                                                                                                                                                                                                                                                               |
| 149 | 54 | Support international efforts in obtaining more scientific evidence on <a href="#">the</a> reliability and accuracy of NGS by conducting trials comparing NGS against <a href="#">other</a> existing diagnostic platforms;                                                                                                                                           | P | <b>Sierra Leone</b><br><i>Category : EDITORIAL</i>                                                                                                                                                                                                                                                                                                                                                                   |
| 150 | 56 | Share agreed international NGS <del>protocols</del> <a href="#">protocols (developed for corresponding NGS platforms), after reviewed by relevant IPPC subsidiary bodies,</a> guidelines and training material on the IPPC phytosanitary resources page once finalised;                                                                                              | P | <b>Japan</b><br>NGS protocols should be reviewed by appropriate IPPC forums (i.e. IC or TPDP) before published on the Phytosanitary resource page.<br>There are various NGS platforms while the products of a major company are widely used at present. There is a possibility that other NGS platforms and the corresponding NGS protocols might be widely used in the future.<br><br><i>Category : SUBSTANTIVE</i> |
| 151 | 56 | Share agreed international NGS protocols, guidelines and training material on the IPPC phytosanitary resources page once finalised;<br><a href="#">;</a>                                                                                                                                                                                                             | P | <b>Japan</b><br>Based on Scope of CPM recommendation (CPM5; 2010), the contracting Parties should explore lower-cost and more simple techniques of NGS.                                                                                                                                                                                                                                                              |

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|     |    | <a href="#">e) Explore lower-cost and more simple techniques of NGS which make available for more NPPOs.</a>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |   | Solution of cost problem encourage the use of NGS to be able to implement for all NPPOs.<br><i>Category : SUBSTANTIVE</i>                                                                                                                                                                                                                                      |
| 152 | 56 | Share agreed international NGS protocols, guidelines and training material on the IPPC <del>phytosanitary</del> <a href="#">Phytosanitary</a> resources page once finalised;                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | P | <b>Ghana</b><br>phytosanitary must be capitalized to read Phytosanitary<br><i>Category : EDITORIAL</i>                                                                                                                                                                                                                                                         |
| 153 | 57 | <i>Establish</i> plans for appropriate infrastructure and investments in Information Technology and bioinformatics, and education/trainings on bioinformatics, for the appropriate interpretation of test results and to support effective implementation of these technologies-<br><br><a href="#">f) Take into account the rapidly advancing nature of NGS technologies and reflect the most updated situations appropriately in actual application.</a>                                                                                                                                                                                           | P | <b>Japan</b><br>NGS is rapidly advancing and changing technologies. NPPOs should take into account it and accommodate the changes appropriately in actual operation at that time.<br><i>Category : SUBSTANTIVE</i>                                                                                                                                             |
| 154 | 57 | <i>-Establish</i> plans for appropriate infrastructure and investments in Information Technology and bioinformatics, and education/trainings on bioinformatics, for the appropriate interpretation of test results and to support effective implementation of these technologies;<br><br><a href="#">h) Stimulate the scientific community to register and exchange information on the unexpected biological associations of quarantine organisms in plants and plant products that are revealed by NGS. These data can have important phytosanitary consequences;</a><br><br><a href="#">i) fund research projects in the above mentioned area.</a> | P | <b>European Union</b><br>It is important to specify that sharing of experience should be ensured and also it is an important aspect to encourage countries to promote research.<br><i>Category : SUBSTANTIVE</i>                                                                                                                                               |
| 155 | 57 | <i>Establish</i> plans for appropriate infrastructure and investments in Information Technology and bioinformatics, and education/trainings on bioinformatics, for the appropriate interpretation of test results and to support effective implementation of these technologies-<br><br><a href="#">f) Establish plans to secure the confidentiality of data generated by NGS and to ensure the enforcement of intellectual property rights on data and seeds</a>                                                                                                                                                                                    | P | <b>International Seed Federation</b><br>It is important to ensure the genetic sequences of plant varieties (parental lines and commercial material) and the intellectual property of the exporter remain confidential as such information falls into the scope of other international conventions and agreements (e.g. UPOV).<br><i>Category : SUBSTANTIVE</i> |
| 156 | 57 | <i>Establish</i> plans for appropriate infrastructure and investments in Information Technology and bioinformatics, and education/trainings on bioinformatics, for the appropriate <a href="#">data storage and comparisons</a> , interpretation of test results and to support effective implementation of these technologies.                                                                                                                                                                                                                                                                                                                      | P | <b>International Seed Federation</b><br>Data quality, storage, and analysis are important aspects of the application as well.<br><i>Category : TECHNICAL</i>                                                                                                                                                                                                   |
| 157 | 57 | <i>Establish</i> plans for appropriate infrastructure and investments in Information Technology and bioinformatics, and education/trainings on bioinformatics, for the                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | P | <b>EPPO</b><br>It is important to specify that sharing of experience should be                                                                                                                                                                                                                                                                                 |

|     |    |                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |   |                                                                                                                                   |
|-----|----|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---|-----------------------------------------------------------------------------------------------------------------------------------|
|     |    | <p>appropriate interpretation of test results and to support effective implementation of these technologies_</p> <p><u>h) Stimulate the scientific community to register and exchange information on the unexpected biological associations of quarantine organisms in plants and plant products that are revealed by NGS. These data can have important phytosanitary consequences.</u></p> <p><u>i) fund research projects in the above mentioned area.</u></p> |   | <p>ensured and also it is an important aspect to encourage countries to promote research</p> <p>Category : <i>SUBSTANTIVE</i></p> |
| 158 | 57 | <p><i>Establish</i> plans <del>for</del> <u>to support</u> appropriate infrastructure and investments in Information Technology and bioinformatics, and education/trainings on <del>bioinformatics</del> <u>bioinformatics for Contracting Parties lacking or with inadequate facilities</u>, for the appropriate interpretation of test results and to support effective implementation of these technologies.</p>                                               | P | <p><b>Sierra Leone</b></p> <p>Category : <i>SUBSTANTIVE</i></p>                                                                   |