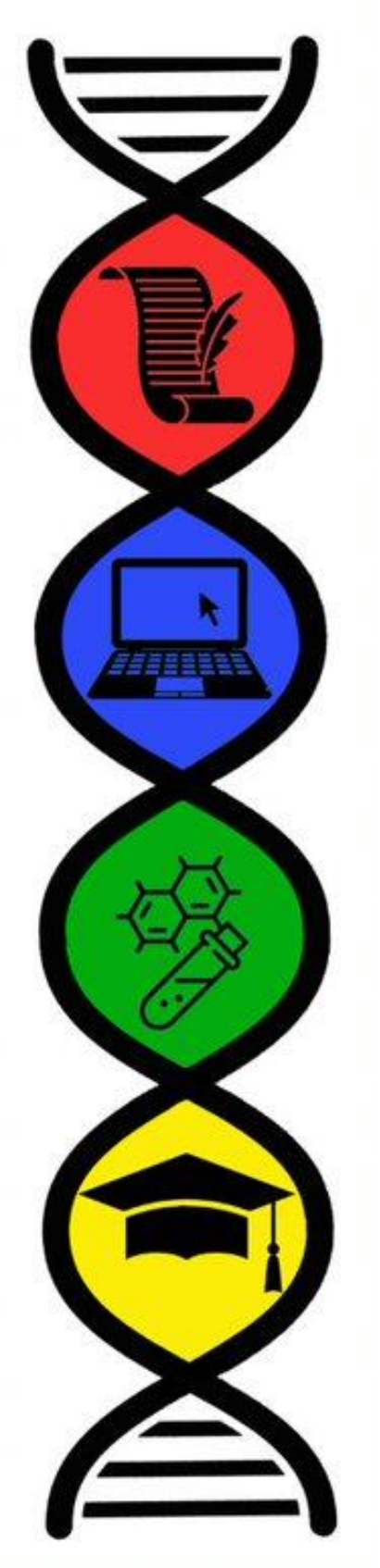


Decision making for High Throughput Sequencing used for biosecurity diagnostic purposes

A POLICY FOR APPLICATION TO AUSTRALIAN BIOSECURITY DIAGNOSTIC LABORATORIES

Version 1: October 2025

Decision making for High Throughput Sequencing used for biosecurity diagnostic purposes

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1. Purpose and scope

The purpose of this national policy document is to support the position of Australian Commonwealth and jurisdictional biosecurity authorities on the use of high throughput sequencing (HTS) technology for biosecurity diagnostics and describe best practices for where and how the use of HTS is accepted to support biosecurity risk management. This policy is for use by all biosecurity agencies and laboratories who seek to use HTS as part of evidence-based biosecurity risk management decision making.

The policy does not:

- detail HTS sampling and testing methodologies that are used to generate HTS data
- detail the use of HTS data analysis software packages and their interpretation
- limit or restrict the research and development of HTS and methods with the eventual aim of adopting these methods into biosecurity risk management decision making.

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Endorsements

This document has been reviewed and endorsed by the Subcommittee on Animal Health Laboratory Standards (SCAHLS), the Subcommittee on Plant Health Diagnostics (SPHD), the Animal Health Committee (AHC), the Plant Health Committee (PHC), and the National Biosecurity Committee (NBC).

3. Introduction

HTS is a powerful technology that, in recent years, has transformed the study of biology from a data-poor to a data-rich science. The use of biological data to identify, characterise and manage pests and diseases, which is a central goal of biosecurity, has been greatly enhanced through the use of HTS technology.

Judicious application of HTS in biosecurity allows the direct detection, identification, investigation and characterisation of the genome sequences of various infectious agents and destructive pests, including elucidation of their role, relatedness, spatial distribution, pathogenicity and evolutionary aspects of their biology. Furthermore, comparative sequencing studies of the genomes, exomes or transcriptomes of healthy and diseased cells and organisms provide more powerful diagnostic opportunities, as well as improved classification, forecasting and selection of chemical control for many pathogens and pests. HTS has applications also in the examination of pathogen species' composition where targeted loci can be sequenced simultaneously for detection, comparison of taxa, epidemiological analysis, and/or ecological studies. This can be applied equally to pest diagnostics specimens/parts of specimens, mixed contents of traps, or environmental samples. Early detection of many high priority pests and diseases is crucial to reducing the risk of entry into Australia and minimising the chance of spread if entry were to occur.

While HTS has many uses for biosecurity purposes, the data-rich outputs produced present challenges to reporting and policy. There is a responsibility for the reporting of diagnostic HTS results by biosecurity laboratories to provide assurance in the identification of pests and pathogens, including potentially new species. It is therefore critical that nationally agreed criteria are in place to establish minimum requirements needed before reporting the detection and identification of a biological species where HTS is the principal, or only, method of detection. Moreover, when diagnosing, identifying or naming an exotic pathogen or pest species through any detection method, the reporting laboratory is claiming the presence of the pathogen or pest in the sample. Government agencies must then be confident to defend any national and jurisdictional response.

Given the implications are large, the criteria for species detection and identification by HTS must be harmonised to fit for purpose principles across reporting laboratories nationally. Genomic findings from HTS examinations must be defensible and reproducible. Setting standards for reportable observations and the evaluation of findings by technical experts will lead to confident interpretation. Importantly, a robust framework that allows for skills transfer between diagnosticians must be in place to ensure the continuity of skilled staff without introducing variability in reporting. Establishing a harmonised approach to HTS use, reporting of results and data stewardship also will facilitate national confidence in individual laboratory results, in support of the intended testing purposes. Furthermore,

the establishment of clear and easily interpretable HTS reports should help respective decision making in response to a detection, such as movement controls, informed consent on destruction, re-export, or further testing.

3.1 Policy Statement

The implementation of this policy document will provide quality-assured reporting of HTS results and confidence to regulators who use HTS for diagnostics and biosecurity risk management decision making.

Biosecurity agencies responsible for regulatory biosecurity activities who wish to use HTS as part of their operational workflows must ensure the required validation/verification has been conducted and must comply with the HTS Standards and Guidelines.

It is not feasible to determine an all-encompassing policy regulating the downstream use of HTS to suit all circumstances and jurisdictions. The laboratory must develop supporting local-level policies, guidelines, standard operating procedures, work instructions, staff training and/or reference material as appropriate to meet the requirements in this policy. This document describes fit-for-purpose and best practices in an over-arching set of specifications upon which these local policies should be based.

4. Principles and implementation of this policy

HTS can be used in Biosecurity workflows including, but not limited to:

- surveillance,
- diagnostics,
- import/export compliance verification,
- area proof-of-freedom.

When using HTS in the above circumstances, the following principles must be considered and appropriately documented. As stated above, the laboratory must develop supporting local-level policies, guidelines, standard operating procedures, work instructions, staff training and/or reference material as appropriate to meet the requirements in this policy. This document describes an over-arching set of specifications upon which these local policies should be based.

4.1 Objectives and selection of appropriate methods

If undertaking HTS for the purpose of excluding notifiable pests or diseases, the testing laboratory must comply with existing policies that are applied to notifiable disease testing using any technique or discipline, such as requirements for prior approval by a CVO regarding notifiable disease of animals.

To optimise technical variables according to the goals, the objective(s) of the application of HTS in diagnoses must be clearly defined prior to commencing HTS. This includes selecting appropriate HTS methods, platforms and bioinformatics to suit the diagnostic objective. These selections must be based upon obtaining suitable metrics for the objective, according to the HTS Standards and Guidelines.

4.2 Sampling and collection

Samples and collection must comply with the HTS Standards and Guidelines and with the laboratory's standard protocols for sample collection and quality control for nucleic acid techniques (see also Guidelines for nucleic acid detection techniques).

4.3 Validation/verification

Validation/verification processes must comply with the HTS Standards and Guidelines and with the laboratory's standard protocols for assay validation. Any deviations from validated techniques must be documented and justified in the records as part of the retained data (see HTS Data below).

Laboratories must determine if there are any appropriate proficiency testing programs to demonstrate validity of their processes. If no formal programs are appropriate, the laboratory must have some means of demonstrating capability and staff competency and should consider an in-house or inter-laboratory demonstration of proficiency and inter-laboratory/inter-personnel comparison.

4.4 Accreditation

Accreditation by NATA is recommended for frequently used HTS techniques for a particular purpose. Although this is not mandated and is at the discretion of the laboratory, accreditation demonstrates quality assurance, thus generating trust and confidence. Accreditation may be required specifically if using HTS for some regulatory purposes, for example certain market assurance programs. Further information about the accreditation process can be found at https://nata.com.au/.

Key considerations for implementing this policy include:

- Ensuring a clear objective for the activity and understanding of actions and implications following a result that indicates a potential biosecurity risk
- Trust and acceptance of HTS by the decision makers and associated stakeholder groups
- Cost-benefit and value of using HTS versus existing or conventional tools or approaches
- The role and level of responsibility passed to any third-party service providers (such as sequence generation, sequence analyses or data storage provider)
    - Guidelines must be in place for selection of, and the expected policies of, any third-party service provider. A third-party provider should have quality management accreditation or other level of proven quality assurance, appropriate to the service being provided and for the HTS technique being considered, and demonstrate compliance with the laboratory/jurisdictional policy of quality standards and data confidentiality and management. Foremost, laboratories should consider accredited third parties compliant with appropriate ISO documentation
- Compliance with State and National regulations regarding off-shore cybersecurity for data creation and storage
- Legal considerations of confidentiality and handling/retention of client data
- Compliance with Commonwealth and jurisdictional governance framework for diagnostic activities
- Existence and documentation of agreed-upon documented protocols and sampling designs to meet the risk management objective
- Laboratory proficiency testing and quality assurance requirements
- Guidance on, and capability for, interpreting results and maintaining availability of appropriate infrastructure, systems and expertise

- Training requirements for staff involved at all stages of the workflow
- Data sharing requirements and agreements.

5. Reporting HTS results

The laboratory must have a standardised reporting format for biosecurity HTS processes. This might be reported to a case manager or be retained by the person(s) conducting the HTS depending upon the laboratory workflow. This report format should be retained as a record, in addition to work sheets, quality records and other work-flow documents, and is not intended to replace any standardised overall diagnostic test report but could be used as a basis for the final test report if no other test methods or pathological examinations were conducted. The case manager should determine the appropriate reporting to external parties/clients, which may include an option for requesting more detailed information from the HTS report.

The standardised report must include, at a minimum:

- Sample information, either an accession link to source sample/case through a laboratory information management system (LIMS), or details of material supplied for HTS
- Type of sample/subsample/test product etc. supplied for HTS
- Date of receipt of sample for initiation of HTS process (may be different from date of receipt by laboratory)
- Task/Objective/Aim/Query, what this HTS task is intended to achieve
- Main findings, summary of pertinent findings (not intended to replace detailed worksheets/analyses records)
- Interpretation and Conclusion summary, a lay-person summary of interpretation and conclusions
- Method parameters (including chemistry, hardware, software and reference database versions): not intended to replace worksheets but more to provide basic level information to reader of report who may compare with other reports
- Disclaimer/caveats/limitations about using current chemistry, software pipelines, reference databases that may be superseded at a later time, use of public databases that contain data that have not been verified or confirmed by the laboratory issuing this report
- Storage location of data and analyses if stored in single location long-term, or contact custodian of these records if later archived (refer to section 7.2).
- Name/signature of person completing the report and date of completing the report

It is recommended that the laboratory create a template report or a checklist for the reporting process. An example of a template is suggested in Appendix C.

5.1 Client data

The laboratory must have a policy regarding any reporting of client-identifiable data, including metadata and any identifiable sequence data (for example, patented or breeding identifier data), to third parties. Management of confidentiality and controlled release of information must be considered.

The laboratory must have a policy regarding which data are provided to clients.

Refer to section 7.1 Ownership.

5.2 High Priority Pest (HPP), Emergency Animal Disease (EAD) or other notifiable agent reporting

In addition to standard reporting, any detection of national-priority plant pests (NPPP), plant high-priority pests (HPP), emergency animal diseases (EAD) or other suspected or confirmed notifiable pests or diseases must be reported in accordance with relevant regulatory frameworks. This includes:

- Complying with jurisdictional reporting requirements, which vary by state/territory and agency.
- Following national response agreements, as applicable:

  Emergency Plant Pest Response Deed (EPPRD)

  Emergency Animal Disease Response Agreement (EADRA)

  Aquatic Emergency Animal Disease Response Agreement (Aquatic EADRA), pending

  National Environmental Biosecurity Response Agreement (NEBRA)

  Security-Sensitive Biological Agents (SSBA) regulatory scheme

These agreements outline:

- Who must be notified
- Timeframes for notification
- Required information and reporting pathways
- Triggers for initiating a formal biosecurity response

6. Incidental findings

Incidental findings are unsolicited genetic sequences or variations detected during genomic testing that were not the primary focus of the diagnostic inquiry. In the context of this document, the term incidental findings applies also to anything of interest detected through metagenomic/shot-gun sequencing. It is recognised that workflows/decisions in this context may become complicated, and it is recommended that laboratories or jurisdictions formulate decision trees for different scenarios. An example for the detection of novel taxa is included in this document as Appendix B as an illustration only.

6.1 Recognised taxa

Incidental detection of **previously described organisms** or viruses of significance to the case within the data must be confirmed using alternative methods, such as validated, targeted conventional diagnostic tests, and/or referral to reference or appropriately specialised laboratories where appropriate, before being reported in a diagnostic context. Further HTS to increase depth is not considered appropriate for confirmation of identity.

It is recommended that such incidental finding data comply with the HTS standards definition of a "high quality draft genome". Lower quality assemblies could be repeated using additional sequence data, in addition to the alternative methods of confirmation or processes. With metabarcoding, laboratories should apply this principle to the thresholds established through application of the HTS standards.

It is best practice that any suspected incidental pathogen or pest be described as **putative/indicative** until further evidence is found to support the finding. Putative detections may be most applicable if rapid reporting is required, for example at-border detections. Local policies can use a risk assessment approach in consultation with subject-matter scientific experts to determine what actions are taken using putative-labelled findings. The results must retain putative status in any reporting until confirmed. If the putative taxon resembles an EAD,HPP, exotic disease or zoonotic disease then the appropriate authorities (e.g. CPPO, CVO and/or CHO) should be informed of the putative finding. See Appendix B for an example decision tree.

A laboratory needs to acknowledge that HTS data from one field/discipline/specialist area may not be screened for sequences of importance/trade effects/other risk factors to other disciplines, unless requested. For example, metagenomic data screened for animal pathogens may require plant pathology specialists to detect and interpret any significant known plant pest or pathogen. Considering the scope of the objective of the case, incidental findings may not be always recognised and may require assistance from a specialist third party (refer to section 7.3 data sharing policy).

6.2 Unknown/undescribed detections

The incidental detection of novel, unknown, or previously undescribed organisms or viruses, believed to be of significance, must be confirmed using alternative methods and/or referral to reference or appropriately specialised laboratories prior to being reported in a diagnostic context.

It is recommended that such data comply with the HTS standards definition of a "high quality draft genome" as a minimum. Lower quality assemblies could be repeated using additional sequence data, in addition to the alternative methods of confirmation or processes.

Australian jurisdictional requirements may necessitate higher levels of confirmation and documentation for the formal publication and/or acceptance of novel taxa, and application to diagnoses, than those required by international nomenclatural codes/committees (see References section). For example, the International Committee for Virus Taxonomy (ICTV) can ratify novel viral taxa based upon sequence-only information with specified criteria (Minimum information about an uncultivated virus genome, MIUViG: Roux *et al.,* 2019). This is discussed also by Adriaenssens *et al.* (2023). These requirements may not always include confirmation using alternative technology or processes and may therefore be insufficient for application to Australian biosecurity without additional testing.

Where it is ascertained that there is no suitable confirmatory technique available currently, the finding must be marked as a **putative taxon** until confirmed otherwise. Local policies can use a risk assessment approach in consultation with subject-matter scientific experts to determine what actions are taken using putative-labelled findings. The results must retain putative status in any reporting until confirmed.

Any new/novel taxon with suspected **pathogen or pest status** must be described as putative until confirmed (for example, fulfill Koch's postulates or other widely accepted studies to confirm its pathogenic status). If the unknown entity might resemble an EAD,HPP, exotic or zoonotic agent, for example by taxonomic classification into a genus known to contain EAD/HPP/exotic/zoonotic and where the specimen displayed similar signs and symptoms, then the appropriate authorities (e.g. CPPO, CVO and/or CHO) should be informed of the putative finding. See Appendix B for an example decision tree.

7. HTS data

Unless otherwise stipulated, data in this document includes all metadata, HTS raw data, analysed data and interpreted data.

7.1 Ownership

Laboratories must determine a local or jurisdictional policy regarding ownership of HTS data (originating laboratory, secondary/service laboratory/sample submitter or owner, or other party) and document this ownership policy in user-guides and/or terms of reference; or otherwise inform submitters prior to initiating HTS work. Deviations from this may apply on a case-by-case basis according to agreement by involved parties, including compliance with Freedom of Information legislation. The local policies should consider ownership of raw data, quality trimmed data, run QC data, analysed data, mapped data, assembled data and any other associated data.

7.2 Data storage

The laboratory must have a policy regarding secure data storage and retention. This policy must comply with relevant Federal or State regulations. There is a range of legislation that requires businesses, researchers and clinical providers to retain documents and data for various purposes. Breach of any of the requirements can incur penalties, for the business and potentially also for individuals involved.

To meet the range of different purpose requirements, diagnostic HTS data must be normally retained for a **minimum of twelve years** unless State and Federal regulations state otherwise. This period has been determined to align with the Australian Government Department of Agriculture Fisheries and Forestry obligations to retention requirements for data obtained under the federal Biosecurity Act 2015 and hence is applicable to all jurisdictions. Some specialised cases may produce data with specific additional retention periods, for example data from what may be perceived as clinical trials should be retained for 15 years, or even indefinitely (Therapeutic Goods Act and NHMRC guidelines). A laboratory must determine if any specialised diagnostic investigations require extended data retention periods.

The local policy should define which data are mandatory and which data are recommended to be stored long-term. At a minimum, the raw data and methodology/software versions must be retained and the location recorded in the report (see section on reporting). It is recommended that pertinent processed data also is retained.

The policy must define HTS data security according to the local and/or jurisdictional cyber-security requirements.

7.3 Data transfer and sharing

Laboratories must comply with any National and jurisdictional data-sharing and data-reporting agreements or mandates, such as compliance with the Biosecurity Act 2015.

Where these do not apply, the laboratory should determine a local or agency policy regarding data transfer and sharing:

- **between jurisdictions**

  It is recommended that a laboratory use a **data transfer agreement** (DTA) to stipulate permitted purposes, a policy for previously unrecognised incidental findings, publication, passing to third parties, acknowledgement of data owner etc.

  The local policy must consider whether it is necessary to inform, and/or seek permissions from, the sample submitter and/or owner that the sample source and other metadata is being shared with another jurisdiction. This may be referred to in the terms of reference (see Ownership, above).

- **data transfer into the public domain and public databases**

  The jurisdiction, in consultation with the laboratory, must have a policy to address the distinction between submitting analysed target sequence data and submitting raw or metagenomic/metabarcoding data to public repositories. Such transfer must comply with any relevant legislation.

  The jurisdictional policy must consider potential issues and risks of raw data transfer into the public domain, including confidentiality, incidental findings, putative detections, non-standard quality of data analysis standards, or potential effects on market access. For example, publicly available sequencing data and metadata can be actively data-mined by third parties to report new-to-science pathogens or extensions of geographic range. The risks of this potential activity need to be considered:

  - Often, results from data mining by an external party are not confirmed by an alternative method.
  - There is no opportunity to assess the prevalence and biological implications of analyses conducted by an external party.
  - There may be no acknowledgement of the risk of the data being contaminated due to bleeding between runs, index hopping, sample collection or processing, or any other possible sources of contamination.
  - There may be no thought or care regarding the biosecurity or market impact.
  - Poor interpretation of the raw data can result in misidentification of a putative target (organism, virus, virus-like, genomic mutation, etc.).

- The owner of the genomic data, and/or a grower, breeder, farmer or a region is potentially at risk of being identified through proprietary markers, and intellectual property and/or breeding rights could be breached.
- Sometimes other parties publish after data mining without acknowledgement of the people who generated the data.

There is requirement from a range of initiatives and some peer reviewed journals that unfiltered raw high throughput sequencing datasets and associated metadata are made publicly available. Laboratories must consult with jurisdictional authorities (and data owners, if different) in this situation. The jurisdictional authorities and laboratory must consider the risks of sharing raw-read, unfiltered and/or metagenomic data. This may have biosecurity, privacy, data ownership and intellectual property implications that all need to be considered. The ownership of data submitted to databases must be determined and must be retained by the issuing laboratory.

Where the risks cannot be confidently managed, the raw data must not be released into public domains.

As an alternative, laboratories could consider submitting sequences pertaining to the target under study only, or assemblies or collections of filtered reads that have prior approval by jurisdictional authorities. The ownership of such data submitted to databases must be determined and must be retained by the issuing laboratory.

Related material

HTS Standards and Guidelines

EPPO PM 7/151 (1) Considerations for the use of high throughput sequencing in plant health diagnostics

IPPC Recommendation on Preparing to use high-throughput sequencing (HTS) technologies as a diagnostic tool for phytosanitary purposes

WOAH Standards for high throughput sequencing, bioinformatics and computational genomics

ISO - International Organization for Standardization

International Code of Nomenclature of Prokaryotes. Oren, A., Arahal, D., Goker, M., Moore, E., Rosello-Mora, R., Sutcliffe, I. (2022) International Code of Nomenclature of Prokaryotes. Prokaryotic Code (2022 Revision). *International Journal of Systematic and Evolutionary Microbiology* 73:5585 **https://doi.org/10.1099/ijsem.0.005585**

INTERNATIONAL CODE OF ZOOLOGICAL NOMENCLATURE: https://www.iczn.org/the-code/the-code-online/

International Code of Nomenclature for algae, fungi, and plants

Emergency Plant Pest Response Deed (EPPRD)

Emergency Animal Disease Response Agreement (EADRA)

Aquatic Emergency Animal Disease Response Agreement (Aquatic EADRA), pending

National Environmental Biosecurity Response Agreement (NEBRA)

Security Sensitive Biological Agents (SSBA) Regulatory Scheme

Guidelines for nucleic acid detection (NAD) techniques - DAFF

Data storage and processing

References

Adriaenssens, A.; Roux, S.; Brister, J.; Karsch-Mizrachi, I.; Kuhn, J.; Varsani, A.; Yigang, T.; Reyes, A.; Lood, C.; Lefkowitz, E.; Sullivan, M.; Edwards, R.; Simmonds, P.; Rubino, L.; Sabanadzovic, S.; Krupovic, M.; Dutilh, B. (2023) Guidelines for public database submission of uncultivated virus genome sequences for taxonomic classification. *Nature Biotechnology* 41: 898-902

Roux, S; Adriaenssens, E.; Dutilh, B. *et al.* (2019) Minimum information about an uncultivated virus genome (MIUViG). *Nature Biotechnology* 37: 29-37

Schmidt, A.M.; Abad, G.; Brearey, S.; Dinsdale, A.; Ho W.; Rabindran, S.; Rigano, L.; Rodoni, B.; Sultmanis, S. (2025) Managing regulatory issues arising from new diagnostic technologies: A case study using high throughput sequencing. *CABI Agriculture and Bioscience* 6:1

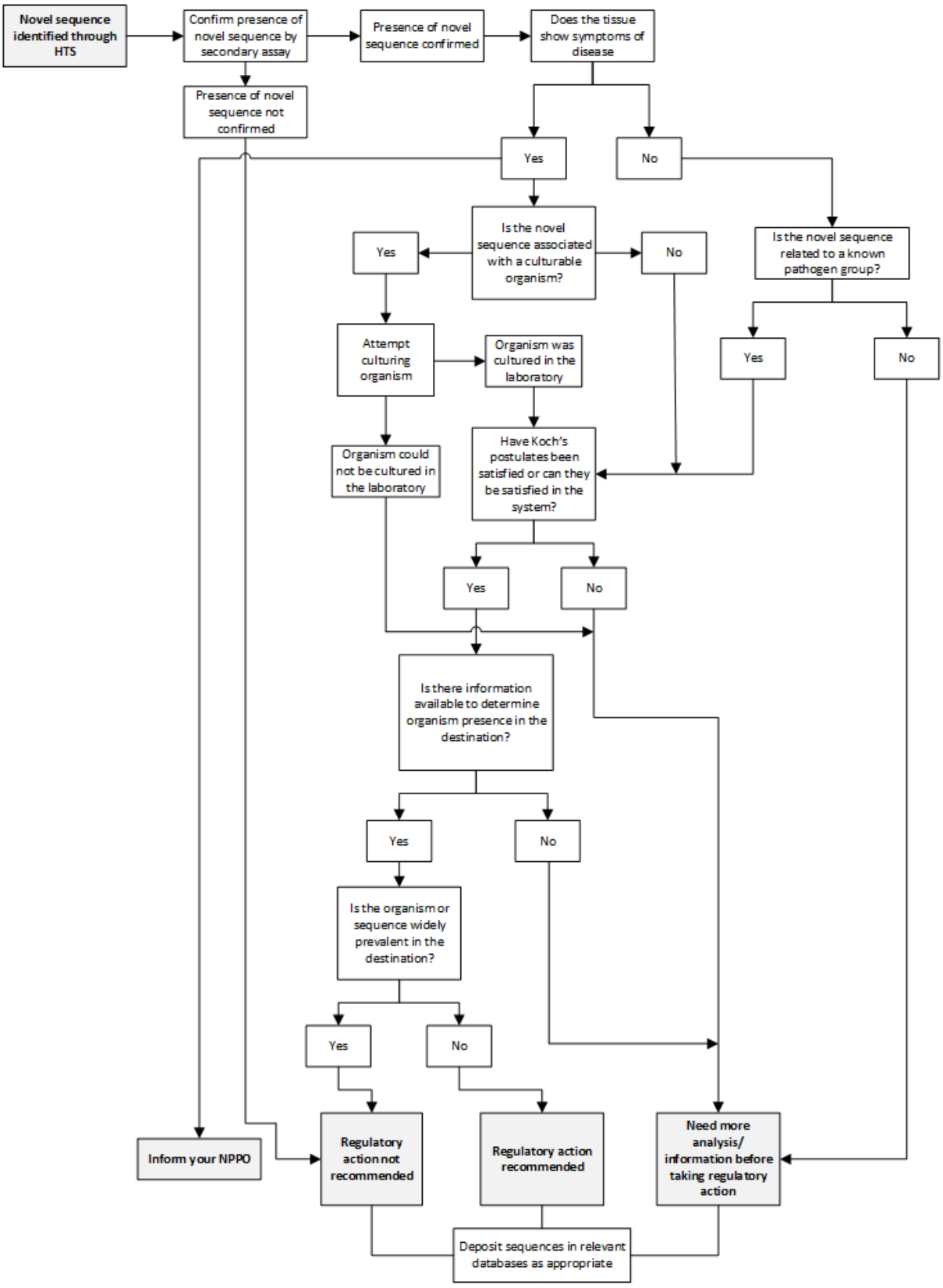
Appendix A: Definitions and abbreviations

The following defines the terms used in this document, in alphabetical order.

Term	Definition, as used in this document
Analysed data	Data arising from the raw data that has been manipulated in some way. In the context of this document, analysed data includes quality trimmed data, run QC data, mapped data, assembled data and any other manipulated data.
Bioinformatics	Collecting and analysing complex biological data using computers, databases, mathematics and statistics to collect, store, organise, analyse and interpret the data.
Biosecurity risk Management	Assessment, management and control of the likelihood of a disease or pest entering, establishing or spreading in Australian territory (or a part of Australian territory) and the potential for the disease or pest to cause harm to human, animal or plant health, or to the environment.
Data mining	Data mining is the process of searching and analysing a large batch of raw data with the aim of identifying patterns and extracting new information. In the context of this document, it includes bioinformatics, statistics, machine learning, and database systems.
EAD	Emergency Animal Disease
HTS	High Throughput Sequencing. HTS technologies are capable of sequencing multiple DNA molecules in parallel, enabling hundreds of millions of DNA molecules to be sequenced at a time.
HPP	High Priority Pest
Incidental findings	Unsolicited genetic sequences or variations detected during genomic testing that were not the primary focus of the diagnostic inquiry. In the context of this document, it includes also findings from metagenomic/metabarcoding data.
LIMS	Laboratory Information Management System. A software package to support laboratory operations such as sample management, data entry, workflows and reporting. LIMS are available from multiple commercial providers.
Metadata	A set of data that describes and gives information about other data. In the context of this document, metadata for a HTS dataset may include sample, location and submitter details in addition to technical information regarding the data. Hence, metadata may include sensitive or confidential information. In the context of this document, metadata is considered part of the entire dataset.
NATA	National Association of Testing Authorities
Platform	In the context of this document, Platform refers to a commercially available system for conducting HTS. Each platform has its own characteristics and methods for achieving high throughput sequencing and each has specific advantages and disadvantages.

Putative	In the context of this document, putative describes a sequence or taxon that is supposed or believed to be a specific entity, but its exact identity or role has not been confirmed or proven.
Raw data	Also known as source or primary data, refers to information in its most basic, unprocessed form. It is the data collected directly from its original source without any manipulation or cleaning.

Appendix B: Example of HTS Decision Making Flowchart



Reference: Schmidt *et al.* (2025)

Appendix C: Example template for internal reporting HTS

a.

HTS Summary Report	
Sample information	Identity/accession number XXXXX-XX Sample type Bacterial culture Date received XX/XX/XXXX from microbiology section of ***
Analyses/query	Whole genome sequence for comparison with YYYY, with particular reference to virulence genes ZZZZZZ
Interpretation & Conclusion summary	XXXXX sequence met the standard for complete coding sequence. XXXXX was identified as ****** (ID%) XXXXX contained FOUR of the FIVE reported virulence loci, lacking one of two adhesin genes XXXXX may have reduced virulence but will likely be a pathogenic strain of this bacterial species?
Main findings (dot points)	• 10,000,000 reads passed QC filtering • Kraken2 identified the input species as *** • Alignment with reference sequence (Accession) from YYYY showed 98% identity, coverage 99.5% and mean depth 102 • MLSA/MLST showed **** • Pathogenicity loci ******* were located • One locus *** was not located
Additional findings (optional)	One plasmid approximately 4 kbp, not identified from Genbank, no virulence genes noted on plasmid
Recommended follow-up/confirmations	Target specific PCR and Sanger sequence would confirm the lack of locus ****



Disclaimer/caveats/limitations: *Note about using current chemistry, software pipelines, reference databases that may be superseded at a later date*



Methods summary (including chemistry, hardware, software and reference database versions): *Summary only, not to replace worksheets but more to provide basic level info/knowledge to reader of report/pathologist/manager etc who may compare with other reports*



Storage location of data and analyses:



Prepared by: Date:

b.

HTS Summary Report	
Sample information	Identity/accession number XXXXX-XX Sample type tissue DNA extract Date received XX/XX/XXXX from molecular section of xxx
Analyses/query	Shotgun sequence for presumptive search of viruses
Interpretation & Conclusion summary	Comparison of data with virus accessions in Genbank identified presumptive partial sequences from *virus 1, virus 2* and *virus 3,* all below the level of the HTS standards. These viruses can be targeted for confirmation using targeted PCR and/or virus culture
Main findings (dot points)	• 10,000,000 reads passed QC filtering • NCBI virus RefSeq mapping identified potential: *virus 1* (0.5% reads, 30% coverage, 40X mean depth); *virus 2* (0.3% reads, 20% coverage, 45X mean depth); *virus 3* (0.9% reads, 35% coverage, 50X mean depth)
Additional findings (optional)	none
Recommended follow-up/confirmations	*Virus*-specific PCRs and/or appropriate virus culture should be progressed to investigate and confirm. Further sequencing required to meet HTS standards


Disclaimer/caveats/limitations: *Note about using current chemistry, software pipelines, reference databases that may be superseded at a later date*


Methods summary (including chemistry, hardware, software and reference database versions): *Summary only, not to replace worksheets but more to provide basic level info/knowledge to reader of report/pathologist/manager etc who may compare with other reports*


Storage location of data and analyses:


Prepared by: Date: