A New Zealand Reference Collection for Food Safety/Spoilage Trials: Opportunities and Obstacles

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Prepared by:

Jan Powell

Beverley Horn

Joanne Kingsbury

PREPARED FOR: NZ Food Safety Science & Research Centre

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REVIEWED BY: Rob Lake

Manager and Peer Reviewer	Author
	
Rob Lake	Beverley Horn
Manager, Risk Assessment and Social Systems, ESR	Senior Scientist

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SUMMARY

Food producers must find ways to control or remove microorganisms from the food production chain that can cause illness in people or food spoilage issues. Microbial challenge studies are used to validate control measures and to provide the scientific evidence to ensure that food is safe and suitable for human consumption throughout shelf-life.

Microorganisms can be eliminated, reduced or limited in their cell growth by intrinsic food properties such as pH or water activity, or by extrinsic mechanisms such as temperature or pressure. In designing a challenge study, a cocktail of strains of a microorganism should be chosen which are (i) representative of the likely strains the food is exposed to and (ii) from the strains that are most resilient to the conditions the food will be exposed to.

The purpose of the current project was to assess the current status of the microbial challenge study landscape in New Zealand. Specifically, the project was to determine whether a reference culture collection of microorganisms that could be used for challenge testing would be of benefit across the food industry. The culture collection would house strains of microorganisms that had been validated for specified intrinsic and extrinsic conditions.

Potential stakeholders were engaged through outreach at industry conferences and through professional networks. Follow-up with stakeholders from regulatory authorities, and large and small producers/industries revealed that there is a range of needs and issues relating to the execution of challenge testing in New Zealand. Conducting the necessary challenge studies can be a barrier to new product development or to exporting overseas, especially for small or new businesses.

The outcomes from this study are:

- Industry would use such a reference collection, if it was accessible at an acceptable cost and with appropriate privacy controls.
- Scientifically it would be possible to produce a robust reference library, and there is the expertise in New Zealand to support its development and maintenance.
- A one-size-fits-all strategy for funding the development of a reference collection is unlikely to be successful. For larger food producers, this would not be a priority as many have systems in place to support challenge trials. Smaller producers are unlikely to have these resources.
- A staged approach to building the collection may be appropriate, starting with a high priority species.
- Concerns over ownership and confidentiality of strains, resources, and data will need to be resolved for the collection to a successful New Zealand resource for the food industry.

1. INTRODUCTION

1.1 CHALLENGE STUDIES

Food for commercial retail must be safe and suitable for human consumption. Principally, this means that the food is produced as specified under a validated food safety risk management plan and that foodborne pathogens are absent, or within specified regulatory limits (MPI, 2017). Additional requirements are placed on processed foods to ensure that processing conditions are validated and do not add additional food safety risk to the product. Product shelf-life must also be validated to ensure that food remains safe during the prescribed storage period.

Microbial challenge studies are designed and executed under controlled conditions to provide the scientific evidence to validate the food formulation, production, processing, packaging, and/or storage conditions needed to remove, reduce or prevent the growth of risk microorganisms. Challenge studies may also be undertaken as part of good manufacturing and food safety programmes, to meet market access requirements, required as a result of process/product failure or product recall due to identification of pathogens, or as a result of an outbreak linked to a specific food.

In New Zealand microbial challenge studies are performed at a variety of institutions. Large food producers and multinational companies are likely to have access to in-house facilities/laboratories where challenge studies can be undertaken. Contract research laboratories such as Hills Laboratories, AsureQuality, Eurofins, Crown Research Institutes (e.g. ESR, Plant & Food and AgRresearch), and academic laboratories undertake studies on a fee-for-service basis. Studies need to be designed specifically for the risk microorganism, food matrix, and process or storage conditions being validated. For example, growth kinetic studies may be performed to assess the behaviour of a particular microorganism in a food matrix under intrinsic (e.g. water activity (a_w), pH, preservative) or extrinsic (e.g. temperature, gas composition) conditions (NACMCF Executive Secretariat, 2010). The shelf-life of a product may also be explored by inoculated pack studies held under different storage conditions. The studies must be designed to provide robust data that can provide sufficient evidence to regulatory authorities that food safety risks are being managed. Data from challenge studies can also be used to provide customer assurance and to determine whether new or innovative products are safe. The use of accredited laboratories which undertake studies using International Organisation for Standardisation (ISO) methods provides additional confidence that the results are valid.

Selection of the microorganism(s) to be used in a challenge study requires particular consideration. Studies with human pathogens such as *Listeria monocytogenes* are often restricted to laboratories that can contain the microorganism to ensure that the food processing plant or lines do not become contaminated. However, this can make it difficult to replicate plant or process conditions to fully assess microbial behaviour (Scott, 2005). Surrogate microorganisms may be used but must be carefully selected to ensure they mimic the behaviours of the pathogen. In some circumstances it may be equally difficult to justify the use of non-pathogenic surrogates for in-plant studies due to potential contamination risk.

Isolates used in challenge studies come from a variety of sources such as reference culture collections including clinical isolates, academic collections, and industry-isolated strains, the latter of which may be considered proprietary. There are a few examples where collections of isolates from a particular food have been made available for use by external customers. A collection of *Staphylococcus aureus* isolates is available from the University of Melbourne for the use in cheese challenge studies, while a selection of non-pathogenic Enterohaemorrhagic *Escherichia coli* (EHEC) isolates is available for fermented meat product challenge studies at the CSIRO in Australia (Ross, 2001)

1.2 RATIONALE FOR THE CURRENT PROJECT

A number of projects conducted at ESR and participation in industry meetings have identified a hurdle for industry in performing validation challenge studies for food safety. New Zealand Food Safety (MPI) and overseas market access require justification of the choice of microbial pathogens and particular strains used for these studies. The choice of test strains is dependent on:

- The food matrix.
- Critical control processes.
- New Zealand relevance.
- May need to meet overseas requirements and standards.
- If appropriate surrogates can be identified and validated.

1.3 PROJECT AIM

The aim of this project was to characterise the need for a NZ Reference Collection of challenge study microbial pathogens/surrogates/spoilage micro-organisms. The project starts to establish a network of industry, regulatory, and science providers who could take part in the development of the reference collection, the scope of current and future needs, and a high-level protocol used to inform the choice of microorganisms in the Reference Collection.

This information would then support the preparation of a NZFSSRC project brief for further development of the Reference Collection. This would develop evidence and justify the selected microorganisms for their use in different food types (e.g. matrix parameters, high/low acidity, low or high water activity), product processing and storage conditions (freezing, refrigeration, heating) and product types (meat, vegetables, dairy).

The endpoint goal of the Reference Collection would be for it to be recognised by overseas regulatory authorities and MPI, providing a ‘tick in the box” option for validated challenge study microorganisms.

2. METHODS

2.1 IDENTIFICATION OF STAKEHOLDERS/COLLABORATORS

Stakeholders/collaborators were identified as any individual, industry, or government agency who may undertake microbial challenge studies or who may use data from challenge studies for regulatory or other decision making. Such people/organisations were identified through professional networks and the NZFSSRC database.

It was anticipated that there may be some sensitivity around confidentiality around how any information gathered during this project may be used. For this reason, information has been generalised to provide a broad overview of feedback.

2.2 STAKEHOLDER ENGAGEMENT

A variety of methods were used to collect stakeholder feedback. Materials were prepared for use at the NZFSSRC and NZIFST conferences held in July 2019. Copies are provided in the Appendix. At both conferences, ESR staff were available to speak with anyone who was interested in the project.

ESR has also worked with a variety of industry stakeholders on other projects and individuals were contacted and asked if they would be willing to provide information relevant to their organisation. Phone interviews lasting approximately 30 minutes each were undertaken. Participants were asked about their knowledge, current involvement in, and future need for challenge studies in their company. The idea of a reference culture collection was presented and participants provided feedback on the idea.

Meetings were also held with representatives from NZ Food Safety and Food Safety Australia New Zealand (FSANZ).

3. OUTCOMES

3.1 CONFERENCE ENGAGEMENT WITH INDUSTRY

Outreach at the NZFSSRC and NZIFST conferences resulted in a limited number of contacts which were followed up directly by phone. It was established at the conferences that industry people had different interpretations of what was meant by a challenge study. Any future communications regarding the reference collection, should be careful to make the scope and purpose of the collection clear.

It may have been that there were additional individuals/organisations who might have engaged in this project but they missed seeing the information while they were at the conference(s) or misinterpreted what was being suggested.

Consequently additional feedback may occur as a result of this report being shared by the NZFSSRC.

3.2 NETWORK OF POSSIBLE COLLABORATERS

The network of possible collaborators covers government, research and end users (food industries or research).

The government collaborators include New Zealand Food Safety (Ministry for Primary Industries) and Food Safety Australia New Zealand. If specific target overseas countries were identified for export requirements, these could also become end users or approvers of the reference collection.

The provision of micro-organisms for consideration for the reference collection may come from research institutes, industry sources or national reference collections.

The testing of the micro-organisms would need to be carried out in laboratories with appropriate controls and containment. For pathogenic strains this is more likely to be possible at research institutes rather than product development organisations (such as Food HQ) or tertiary educational departments. Such research institutes include AgResearch, Cawthron, ESR and Plant and Food.

Tertiary Education Institutes provide expertise, potential strains of micro-organisms and possible student projects to support a reference collection. Potential educational departments include

- Lincoln University (Centre of Food Research and Innovation)
- Canterbury University (School of Biological Sciences)
- Massey University (Hopkirk and Riddet Institutes)
- Auckland University (Food and Health Programme)

There are also commercial service providers who may wish to collaborate in establishing or would use the proposed reference library. These include AsureQuality, Eurofins Food Analytics, Hill Laboratories, SGS and CAIQTEST.

The team has also identified potential for Australian collaborators with the CSIRO Food Safety and Stability Group or the Food Safety Centre based at the University of Tasmania.

3.3 SCOPE OF CURRENT AND FUTURE INDUSTRY NEEDS

3.3.1 Regulatory Agencies

Government agencies, including ministries and statutory authorities, use data and information from microbial challenge studies to support regulatory decision-making. Information from such studies may also be used in risk assessments. In New Zealand it is the responsibility of the producer to ensure that the food product is 'safe and suitable' for human consumption. Therefore, each industry or producer has to undertake studies and provide the supportive evidence applicable and specific to each product or process.

The development of a reference culture collection of challenge study isolates would need to be supported by industry and be designed to meet their needs. The onus is on industry to design and conduct their challenge studies to provide data that meets all necessary regulatory requirements as well as design and formulation requirements.

3.3.2 Large producers and industries

Large industries/producers and/or multinational companies appear to be well supported in meeting any challenge study requirements they might have. Some have in-house laboratories and scientists on staff able to complete relevant challenge studies and provide the appropriate documentation required by regulatory agencies. In addition, they may have well-established relationships with external contract research laboratories or crown research institutes which may perform challenge study work on a fee-for-service basis. Some producers also have strong linkages to academic research groups in NZ or in other countries who have specialised knowledge, and who can provide further support.

Data from challenge studies, including company-specific microbial isolates, are likely to be considered proprietary and confidential, and are less likely to be shared publically, particularly if the work is to support new or novel products/processes.

A reference culture collection of isolates for challenge studies would provide the benefit of easily accessible New Zealand-relevant strains accompanied by validated documentation. Studies that provide data around 'worst-case-scenarios' would be of particular interest.

3.3.3 Small or new producers and industries

In contrast to large producers, small or new producers face a number of significant barriers in being able to undertake appropriate challenge studies:

- They are less likely to have in-house laboratories and will require external support.
- They may have difficulty finding relevant information within the industry if it is proprietary or confidential.
- Getting the right advice on what evidence is needed to determine their product is safe and suitable, particularly if it is a new product, risk or process, can be challenging.
- The costs of contracting out challenge studies to an external provider can be significant and may end up being prohibitive.

Therefore, small businesses may be more likely to seek out alternative relationships such as partially supporting a graduate student to perform research in a specific area.

This sector appeared to be most interested in the concept of a centralised reference culture collection of microorganisms that could be used for challenge studies. A major benefit is having access to isolates and pre-validated background data/information that can be used as a starting point.

3.4 IDENTIFYING RELEVANT CHALLENGE STUDY MICROORGANISMS

The underlying principle for challenge studies is that the trials must accurately reflect the conditions the risk microorganism would experience in the food or product throughout the production chain from source to consumer (Ross, 2001). Some considerations when designing a challenge study are given in Appendix B.

From a risk averse point of view we want to choose microorganisms and strains of microorganisms that will be most resilient to the hurdles in place to control them for challenge studies. If the challenge study shows these resilient strains are effectively controlled, then less resilient strains should also be controlled.

Figure 1 is designed to serve as a high-level protocol as a starting point for selecting appropriate microorganisms to include in the reference collection. This protocol would need to be refined and reviewed by industry and regulators as part of the planning phase for the reference collection.

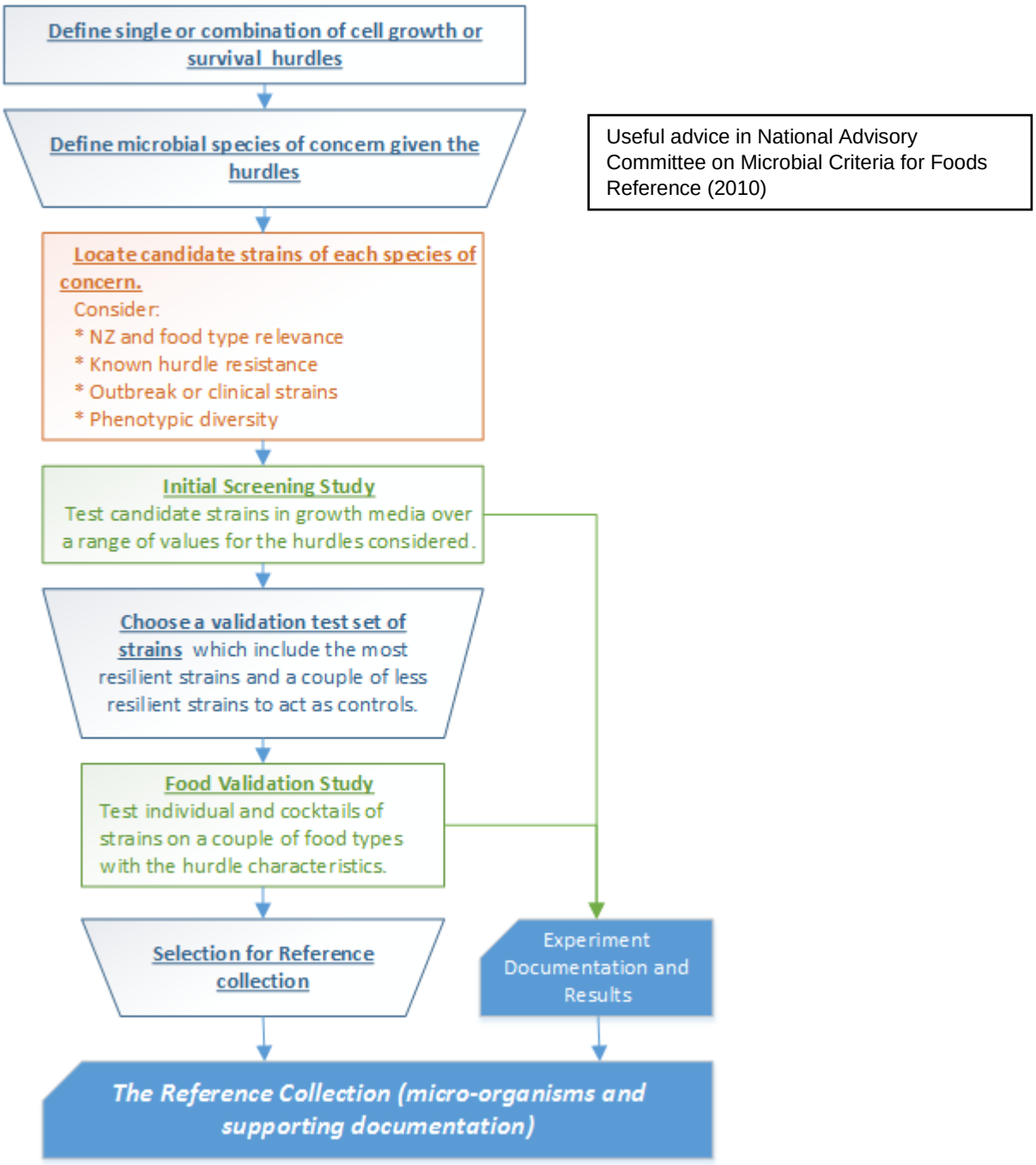

Figure 1: Overview of a suggested approach for populating the reference collection.

4. CONCLUSIONS

4.1 CONCLUSIONS

The stakeholders/collaborators we engaged with were genuinely interested in the outcome of this project. As expected, there were varying degrees of support for the development of a reference library of microorganisms that could be made available for challenge studies. While it was generally recognised that a reference culture collection might be useful, there were a number of questions raised including:

- Where the reference library would be housed?
- Who would have access to the microorganisms and associated documentation?
- What microorganisms would be in the collection? The breadth of hazard-food-process combinations may be too large.
- How would proprietary or confidential information/data be managed?
- How would the reference library be funded and supported?
- What parameters the microorganisms would be screened for e.g. pH, a_w, salt etc.

Regulatory agencies require the information/data generated by challenge studies for making decisions around the safety and suitability of food, and for risk assessments. The development of a reference culture collection would be of benefit as it would potentially provide standardised strains and validated data that could be used. To have the most impact the collection and associated data would need to be made publicly available at a reasonable cost.

Large producers/industries appear to have well established resources, including in-house and/or external contract laboratories to meet their challenge study needs. A reference library of microorganisms may be useful, but not necessary, for these organisations.

Small producers/industries would appear to gain the most benefit from having access to a reference culture collection. Being able to source panels of strains that had been pre-validated for defined conditions could save significant time from having to start at the beginning to determine which strains are appropriate.

It is possible that a component of the reference collection could be a collection of documented challenge studies using the reference strains, which would provide extra evidence to support food safety and shelf life claims.

Across all organisations there was concern over confidentiality, ownership of strains and data, and how information might be used.

While the main hurdle to creating the proposed reference collection is the funding source to develop it, the feedback from industry was that such a resource would be useful and likely to be used once established.

4.2 NEXT STEPS

The following next steps are proposed:

1. Circulate this report to potential stakeholders and collaborators for additional feedback
2. Identify a funding model to support the development of the reference culture collection library. It is not clear if the NZFSSRC funding model would support such a project.
    - The model needs to support small producers/industry as well as large producers/industry. Small producers across food product types would need to come together to support the development of the library.
    - Consider a staged approach, with a number of funding steps and the incorporation of student projects.
    - Determine whether there are synergies with the Australian food industry that could be leveraged and engage with researchers at CSIRO.

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APPENDIX A: STAKEHOLDER ENGAGEMENT

NZFSSRC Annual Conference and NZIFST materials

A.1 Project information handout

New Zealand FOOD SAFETY SCIENCE & RESEARCH CENTRE

ESR Science for Communities

Are you or your organisation involved in microbial challenge studies?

Microbial Challenge Studies are scientifically designed and executed studies to determine whether a process reduces or inhibits microbes which are a food safety risk or affect shelf life.

Challenge studies may be required to show compliance with food standards and/or meet market access requirements.

We are currently developing a cross-industry New Zealand Food Safety, Science and Research Centre project proposal to build an internationally and New Zealand Food Safety-validated reference collection of microorganisms that can be used for food-related challenge studies.

A reference library would eliminate the need for you to locate or justify your choice of suitable microorganisms.

Please fill out the attached questionnaire and return to the ESR booth or e-mail Jan

Would you like to know more

Contact: Jan Powell
jan.powell@esr.cri.nz
03 351 0155

A.2 Questionnaire

New Zealand FOOD SAFETY SCIENCE & RESEARCH CENTRE

ESR Science for Communities

Food Safety Challenge Study Questionnaire

1. Where do you work?

- ☐ Food Company
- ☐ Packaging Company
- ☐ Industry Body
- ☐ Testing Laboratory
- ☐ Research / Tertiary Education Institute

2. Which industry/ies do you represent or do you work with?

- ☐ Meat
- ☐ Poultry
- ☐ Dairy
- ☐ Fruit/Vegetable
- ☐ Shellfish
- ☐ Secondary Processed foods
- ☐ Other (please describe): _____

3. What type of challenge testing is performed or will be performed?

- ☐ Growth inhibition studies
- ☐ Inactivation studies
- ☐ Shelf life studies
- ☐ No immediate intention to do challenge studies
- ☐ Other (please describe): _____

4. Who performs your challenge studies?

- ☐ Performed in-house
- ☐ Commercial testing laboratory
- ☐ CRI/Research Institute
- ☐ Tertiary Education Institute
- ☐ Other (please describe): _____

5. Would having access to a validated reference library of test microorganisms that can be used for challenge studies be a benefit to your organisation?

- ☐ Yes
- ☐ No

If yes, please suggest microorganisms/processes/foods/food properties (e.g. HPP, high acid) to include in the reference library.

_____

_____

_____

6. Interested in collaborating in the proposed project? Happy to provide more information? Like to keep up to date on progress of the proposal? Please provide contact details (Name / Company / E-mail).

_____

Please return answers to the ESR booth, or Jan Powell: jan.powell@esr.cri.nz Tel: 03 351 0155

APPENDIX B: CHALLENGE STUDY ASPECTS

The following references were reviewed; (Ross, 2001); (NACMCF Executive Secretariat, 2010); (Brackett *et al.*); (CODEX, 2008); (Notermans *et al.*, 1993); (International Organization for Standardization, 2019); (Syamaladevi *et al.*, 2016)

Before undertaking a challenge study

1. Define the process or product including packaging and shelf-life requirements
   e.g. intrinsic properties including chemical composition, water activity, pH, organic acids
2. Identify the microorganism(s) of concern
   e.g. process of contamination, species, microbial load
3. Define the conditions that affect the growth and/or persistence of the risk microorganism(s)
4. Define the critical control/prevention point(s)
   e.g. extrinsic factors including temperature, pressure, modified atmosphere, preservatives/additives
5. Define the performance standard required
   e.g. risk organism below limit of detection, reduction of risk microorganism viability by 5 log, pass/fail criterion
6. Determine what data currently exist and identify any gaps that need to be filled by experimental trials/challenge testing
   e.g. review scientific publications & models, industry reports, regulatory documents, operational data, historical knowledge

Selection of challenge organisms

- If possible, use strains that have been isolated from the food/product of interest
- Include clinical isolates, particularly from outbreaks, if available and relevant
- Include reference strains if applicable
- Consider whether surrogates should/could be used (in the case of significant human pathogens)

Challenge study parameters

- Length of the study and the number of sampling points
- Use a cocktail of 5 or more strains of the same species (risk microorganism)
- Check that there is no antagonism between strains
- Adapt the strains to the product/food environment prior to initiating the challenge testing
- Choose the “worst-case” process parameters identified during food production to test in the study
- Monitor both microorganism growth or inactivation profiles (kinetic, presence/absence)
- Ensure that the study includes enough samples and replicates to meet statistical rigour

INSTITUTE OF ENVIRONMENTAL SCIENCE AND RESEARCH LIMITED

Kenepuru Science Centre
34 Kenepuru Drive, Kenepuru, Porirua 5022
PO Box 50348, Porirua 5240
New Zealand
T: +64 4 914 0700 **F:** +64 4 914 0770

Mt Albert Science Centre
120 Mt Albert Road, Sandringham, Auckland 1025
Private Bag 92021, Auckland 1142
New Zealand
T: +64 9 815 3670 **F:** +64 9 849 6046

NCBID – Wallaceville
66 Ward Street, Wallaceville, Upper Hutt 5018
PO Box 40158, Upper Hutt 5140
New Zealand
T: +64 4 529 0600 **F:** +64 4 529 0601

Christchurch Science Centre
27 Creyke Road, Ilam, Christchurch 8041
PO Box 29181, Christchurch 8540
New Zealand
T: +64 3 351 6019 **F:** +64 3 351 0010

www.esr.cri.nz