Ministry for Primary Industries
Manatū Ahu Matua

Analysis of Submissions: Proposed new

Laboratory Specifications Notice

Date: 30 April 2015

MPI received 22 submissions on the proposal document(s). These submissions have been analysed in the following table. As a result of the consultation process, and where appropriate based on the analysis below, amendments have been made to the specification. MPI would like to thank those parties who have taken the opportunity to comment on the proposal(s).

Submission Analysis:

Points MPI would like feedback on	MPI Response
1. The proposed transition period is 2 years. Is this sufficient?	
Yes	General consensus is 2 years and fits with practicalities of IANZ assessments to permit every laboratory to have an opportunity to apply for recognition under the new notice. It is expected that it will take 2 years to cover all laboratories including close-out of any corrective actions. The 2 years also allows for the Dairy Cat 2 to ensure they can comply with 17025 and the Notice and be successfully assessed.
Two years is more than adequate for our laboratory. In fact, we would like to see the changes implemented more quickly if possible but understand why this is unlikely to happen.	
Yes	
Yes	
Yes	
We propose to extend the transition period to 3 years. This is to align with the IANZ three-yearly audit cycle.	
Yes	
Yes	
Yes	
Yes	
Provided the current LAS signatories are automatically transferred to KTP's.	
Yes	
Yes, I would have thought one year	LAS signatories are not automatically transferred as KTPs. It would be up to each laboratory to appoint KTPs.
Yes	
Yes, as this is compatible with the IANZ accreditation schedule.	
Yes	
Yes	
Probably it takes that length of time because of the size of the project, however how would this project impact on any overseas counterpart requirements and how would the overseas counterpart be informed of affected changes if required during the transition period?	
Yes – its sufficient	
2. The consolidated test list includes three programmes (Dairy, LAS and ELP). Should the ELP list be kept separate (this is currently the case)? A proposed combined list has been provided.	
It probably doesn't matter either way. The proposed list is easy to read and follow.	Whilst the consolidated test list has a mixed reaction, it is aligned with the intent of the consolidated lab notice to have a consolidated test list. However MPI needs to ensure it manages the consolidated list such that it meets the needs of all stakeholders and is clearly formatted. The procedure to achieve this will be based on the current internal procedures and will be reviewed. The consolidation of tests could be reviewed again after the consolidated list has been operational for a period of time.
We prefer the 'combined' list as currently proposed.	
Combined list of all three	
Yes it should be maintained separately	
Combined	

Points MPI would like feedback on	MPI Response
ELP List for endemic in NZ diseases could be consolidated; however, we would prefer to have a separate ELP list for exotic diseases to ensure it is closely monitored.	Noted.
Yes	
No	
As the ELP is targeted at live animals rather than product for consumption then yes a separate list is good for clarity.	
We have no preference but recommends that the option that is the easiest to update should be used.	
Simpler for industry labs if each of the three programmes are listed separately. Not sure what clarity the dairy test list adds – found the list confusing due to not being sure what the criteria was for inclusion on the list e.g. not all standard of identity tests are included.	
We do not have issue with this. Maintenance of the list may be onerous for MPI if there is a change to a test in any one program if the lists are combined. As in current LAS would be appropriate to have several appendices related to each specific class – Dairy, Meat, Honey, Potable water, Shellfish, etc. Separate lists may be easier to keep track of changes affecting only the specific list from the lab perspective.	
No. I think all should be combined preventing precedents for future programmes.	
Better to **keep separate** due to the products being very different in their matrices. Testing issues between the programmes are varied due to OMARs and food safety risks of these matrices.	
a. We see no reason why the lists shouldn't be merged, however we question the value of the list given it is guidance only of what a laboratory may need to perform and is not exhaustive and does not specify where testing is only required for specific products and markets. b. If the list is to be provided it should remain guidance and not be part of the notice as is currently proposed.	The list covers the regulatory tests that MPI recognises. Labs need to apply for recognition for one or many of these tests (scope of regulatory testing). They may (or may not) have other tests under their wider IANZ scope of accreditation, however MPI is only concerned with recognising the regulatory tests. The list is guidance and is not part of the Notice.
Combined is ok—one place with separate groups with the master list.	
A combined list would be good.	
List is fine. Prefer one list for all tests.	
Combined list is satisfactory but a number of test methods need to be updated so that more up to date International methods are recognised. This applies to Section 6 – Vitamins and Minerals and Section 7 – Methods which are on a lab's IANZ scope should be acceptable. Section 11.5.8 Histamine and 11.5.9 TVBN should just read "as per IANZ scope". A consistent approach to this would provide ease of use as well as credibility.	The consolidated test list at present has the necessary detail as advised by IANZ. Sometimes a method according to ISO17025 accreditation criteria is appropriate and sometimes the method is specified. The histamine and TVBN methods are specified according to EU requirements and that's why that detail needs to be there.
2. Should guidance for this new Notice be one document for all three programmes or should they be separate (this is currently the case)?	
One is good	The majority of stakeholders prefer the guidance document as one document. All concerns expressed will be considered as the guidance document is developed. The concerns will be checked against the draft guidance document as part of this process. It is intended that the drafting of the guidance document is done in collaboration between MPI and stakeholders. The document would be expected to separate the specific aspects of different lab programmes. A small electronic working group of MPI and Labs will draft the initial document before wider consultation with stakeholders.
We prefer all three programmes to be covered by a single notice. If need be, additional or supporting documentation specific to one of more of the programmes could also be issued. The 'wine for export' documentation does this with a 'notice' supplemented by a 'Notice of Direction' describing more detailed requirements for ILCPs.	
One document for all three programmes	
Happy with one criteria for all programmes	
Combined	
Agree with the approach of one Notice covering the three laboratory schemes.	
Yes	
One document.	

Points MPI would like feedback on	MPI Response
We are satisfied with the ELP programme as it currently stands but support the endeavours of MPI to facilitate streamlining of services across all regulated laboratory services.	
While it may be clearer for labs that handle multiple product types, it is simpler for industry labs if guidance for the three programmes is kept separate.	
One document should be sufficient as there should not be significantly different requirements between the three programmes.	
Separate. Prevents confusion between programmes.	
Combining into one document would work provided clauses that only apply to specific programs are clearly identified as such (e.g.: applies to STEC testing under the LAS Meat program only).	
One	
Should guidance for this new Notice be one document for all three programmes or should they be separate (this is currently the case)? A guidance can be one document for all programmes but there has to be sections for each programme as each industry it not the same; it does not make it easy to read for one industry when you are reading thru clauses that are not anything to do with your industry. It would also make it easier for updates it the guidance was one programme and the other sections were separate.	
One document	
One document. Prefer the avoidance of duplication to be read by staff.	
We see no reason that Dairy needs have separate guidance; the combination of these would support harmonisation work by MPI to date.	
Suggests one guidance with common requirements for the 3 programmes, then specifics for each of the programme.	

Overall Response	MPI Response
Our laboratory and its KTPs and Quality Staff approve of the concept of the changes and believe that they will simplify a number of our internal processes including; - the selection and training of KTPs - training of other Staff including those in our Quality Group - documentation describing MPI laboratory specifications - planning and preparations for annual IANZ Audits conducted at our various laboratory locations	Noted.
We withdrew from LAS because for the small customer base it applied to the costs were irrecoverable. Also, LAS was highly prescriptive & dictatorial. So due to past history I have some reservations about the proposal but am hopeful for a transparent and collegial merge. I am satisfied with ELP being on its own but support the endeavours of MPI to facilitate streamlining of services across all regulated laboratory services. The opportunity to participate in the consultative process is appreciated.	Noted.
We request provisions to recognise credible overseas laboratories and test methods where the Lab Notice has the effect of requiring companies to duplicate testing in highly regulated situations as occurs with animal products intended for use in medical or veterinary biologics industry. For example, BVDV testing is part of a panel of adventitious viruses tested for under regulations such as the USA Code of Federal Regulations Title 21 Food and Drugs or the European equivalent testing documents EMA/CHMP/BWP/457920/2012-Rev 1 Guideline on the Use of Bovine Serum in the Manufacture of Human Biological Medicinal Products. Adventitious virus testing (not just BVDV) is a global regulatory requirement for human and veterinary biopharmaceutical manufacturing. We consider it unnecessary duplication to repeat testing within New Zealand when BVDV is already always tested in a panel of adventitious viruses using a world recognized animal health laboratory.	It is not the intention for this Notice to recognise overseas labs as MPI does not have jurisdiction to apply the APA to a laboratory based overseas. However NZ labs can subcontract to overseas labs where needed as per 2.12 which provides the control. Further, 'products' that do not undergo NZ laboratory testing do not meet export requirements under the APA and products that do not meet export requirements cannot be issued with export certificates (or official assurances) unless subcontracted as per 2.12. There is no guarantee that satisfactory testing will subsequently take place. Although there may be a small chance, this could be damaging for New Zealand if the final product is later found to be unfit for purpose. Lack of oversight by NZ for NZ exports is not considered acceptable from many of our importing countries.

Overall Response	MPI Response
For the USA and European human and veterinary biopharmaceutical markets, detection of infectious viruses using viral cell culture methods followed by fluorescent antibody staining is considered the gold standard. The method is outlined in 9 CFR 113.53. In New Zealand there are no laboratories able to perform full 9 CFR virus testing due to restrictions on importing positive controls for the testing (such as rabies virus). Therefore, recognition of overseas laboratories is also required in cases where testing is not able to be performed in New Zealand.	As above.
Proposed new Animal Products (Specifications for Laboratories) Notice Context and Changes. Page 3 clause 2. "Providing a Legal basis for such requirements……..Notice support" We would like further clarification on this. How are competencies affected by legalising the requirements, etc. it appears to be out of context. The way the lab understands is that, publication of the notice will provide a legal basis on which labs will be required to inform MPI immediately upon identification of a food safety issue when testing rather than the industry/manufacturer doing this. This needs to be clarified.	The intent of this clause was to outline that the Notice does contain some of the existing requirements covered by 17025 and this was the approach explained here within the advisory document. Including some of the 17025 requirements is to ensure those small number of labs, e.g. with a MPI waiver from recognition, still need to meet these requirements of 17025.
We ask for confirmation that where the Requirements for Dairy Laboratories have been assessed as equivalent by our trading partners that this notice meets the same requirements and will meet their expectations.	Noted.
Support the amalgamation and simplification of the lab system.	Noted.

Clause	Comment	Proposed amendment	MPI Response
Other (3)	Please confirm that laboratories will be removed from the many dairy documents. Large amount of documents to read to find out what the laboratory requirements are. Some of these documents appear to be repetitive.	Remove laboratories from all other documents and include in current notice and guidance document.	Noted. MPI has a programme in place specifically aimed at having all its legislation and associated guidance documents into standard templates. As a result of this Notice and this programme 'dairy documents' will be reviewed and will provide the opportunity to streamline such information.
Other (3)	IANZ has specific criteria for the Dairy and LAS. Hopefully these will be streamlined as well into a MPI programme document. Large number of documents for Signatories and Laboratories to keep track off.	Recommend that IANZ has topic documents e.g. signatories, equipment, endorsement requirements etc. so that these are not repeated through all the Specific criteria. For laboratories with a number of programmes, it is repetitive to read the same information in the documents when potentially there could be a chemistry technical document vs. biological document vs. MPI programme document.	Noted.
1.2	Director General is used a number of times throughout the document, when it is not the real DG but a nominee. This should be clarified with a definition.	Director General means a representative from MPI with the nominated authority	The APA defines the "Director-General" to mean the chief executive of the Ministry for Primary Industries and the DG will delegate powers given under the Notice. It is MPI's approach not to repeat what is already explained in either an Act or Regulation. We can however explain this in the guidance document.
1.2	Test sample matrix: Unclear what this means, therefore a definition is suggested.		Agreed, the definition will be put into the guidance document.
1.2(1)	Phrasing for the disciplines does not align	Either change molecular biology to molecular biological or changes the others to chemistry, biology, parasitology and molecular biology. The latter is possibly the better option and aligns with the terminology used later in the document.	Agreed to change to 'chemistry, biology, parasitology and molecular biology'.
1.2(1)	Does it need to specify the DG or could it include 'or delegate'. Has anyone ever contacted the DG about any of the issues listed in the notice, or is this specified in other documents and a given?		The APA defines the "Director-General" to mean the chief executive of the Ministry for Primary Industries and the DG will delegate powers given under the Notice. It is MPI's approach not to repeat what is already explained in either an Act or Regulation. We can, however explain this in the guidance document.
1.2(1)	ILCP provider 'proficiency testing services for laboratory testing accredited to ISO/IEC 17043'. This currently could be read that the laboratory is accredited to 17043, not the proficiency testing provider.	'… for laboratory testing, accredited to ISO/IEC 17043'.	Agreed to change it to "...for laboratory testing who is accredited to ISO/IEC 17043".

Clause	Comment	Proposed amendment	MPI Response
1.2(2)	Guidance on terms KTPs are appointed by Senior Laboratory Management so the phrase 'apply to become a KTP' is not quite correct. Accrediting a laboratory that complies with the new notice will include ensuring KTP have been appointed as per the laboratory's documented procedures.	….Until the laboratory is under the scope of this notice and has appointed it's KTPs.	This is guidance text, nevertheless the text should be amended as suggested. The guidance boxes used in the consultation version of the Notice will be moved into the guidance document.
1.2(2)	Signatories should not have to apply to become KTPs after the transition period. I don't see the need for this to be conducted. Nothing is being achieved by doing this when the signatory status is at the higher level than KTPs. Is the purpose to generate some more revenue?	Apply common sense. Signatories are recognized as being at the same level as KTPs, and simply become KTPs when the new notice is applied.	Not all signatories will be KTPs. There will be no specific application process for KTPs as they will be appointed by laboratories, however laboratories will have to indicate who are their KTP(s) upon transition, and update MPI if the KTP(s) change.
2	I like the idea that we can accept our internal assessments of KTPs and IANZ' audit of our KTP's as acceptable replacing the terminology of "recognised persons"		Noted.
2.2	The document itself has been easy another to follow and most of the sections in the act or notice have been found to read; except for in this clause so if when you put section and acts in it needs to be more clearer or even have the site to go to as some of the labs are not site labs.	Make the sections easier to read where possible this one does not make sense and we could not find the section1.3	Agreed. This error has been corrected.
2.2	Sub clause (1) refers to tests as defined under clause 1.3, as this notice does not have a clause 1.3 is this meant to be the definition of Test in clause 1.2.		As above.
2.2	The Notice makes no provision for Special Approval for research laboratories that do not routinely conduct regulatory testing, as exists in the current LAS rules. Such laboratories may be engaged in specialist reference work for which a recognised approval is necessary. The WPC80 report identified such laboratories and the differences that exist between them and routine testing laboratories; we therefore request that the current provision for special approval is continued under LAS.	Include the existing clauses: 2.1 d. Includes provision for the recognition of laboratories that do not undertake any official tests by LAS special approval. Such laboratories will be nominated by the Deputy Director General (Regulation and Assurance). 4.3.3 f. LAS Special Approval – relates to laboratories under the LAS scheme that are not conducting any official tests and are thus not required to participate in the ILCP Programme as per section 6 or have signatories/recognised persons. 8.1 LAS Special Approval may be granted for laboratories not conducting any official testing. Such laboratories will be nominated by the Deputy Director General (Regulation and Assurance) and would usually be laboratories undertaking research functions only. 8.2 Laboratories applying for LAS Special Approval must apply the requirements specified by MPI and undergo assessment by a MPI designated Assessment Body. Note that this Assessment Body may be a different organisation from the one conducting assessment for general LAS approval. 8.3.1 e A LAS Special Approval laboratory must not issue test reports for NZ official assurances; except where approved by the Deputy Director General (Regulation and Assurance) as per clause 2.6.	Agreed and amended as: "… a research laboratory or reference laboratory whose functions include calibration, quality assurance and specific testing parameters."
2.2(1)	'….as defined under clause 1.3 must be recognised…….'	There is no clause 1.3	Agreed. This error has been corrected.
2.2(1)		No 1.3. Should be 1.2?	As above.
2.2(1)	Should "clause 1.3" state "clause 1.2"? Assume for a Dairy Company this is only scoped for tests carried out to demonstrate compliance with DPC1, OMAR and Standard of Identity testing, not e.g. customer tests)	Guidance clarifying that for dairy, clause is only scoped for those tests done to demonstrate standard of identity, and compliance with DPC1 and OMARs.	As above.
2.2(2)	IANZ does not give blanket accreditation but accreditation for activities at a laboratory. See submission document.		The purpose states that this Notice is about performing tests and is mentioned again in clause 2.1 – 'Application of this Part'. However the words "to perform test" has been inserted into 2.3(1).
2.2(3)	What does "subclause 2 and 3" refer to? Should this state "subclause 1 and 2"?	What does "subclause 2 and 3" refer to? Should this state "subclause 1 and 2"?	Agreed. This error has been corrected.
2.2(3)	'Notwithstanding subclause 2 and 3'	Should this read subclause 1 and 2?	As above.

Clause	Comment	Proposed amendment	MPI Response
2.3 & 2.4	As the notice is written, there seems to be some conflicting statements as highlighted in my email between section 2.3 and 2.4. regarding where a research lab may sit and this may well be because their position has not been fully determined yet. Possibly research labs could sit under section 2.2 (3) and that an individual set of criteria be designed for a research lab in collaboration with MPI to meet the specific set of requirements you are needing within the context of a research environment.		Agreed and amended as: "… a research laboratory or reference laboratory whose functions include calibration, quality assurance and specific testing parameters."
2.3	Dairy laboratories are all currently recognised as Category 1 Dairy Laboratories; as such we have no issue with the requirements in this section or the removal of Category 2 recognition.		Noted.
2.3(1)(a)		"is accredited to ISO/IEC 17025 by an accreditation body in accordance with ISO/IEC 17011"	Agreed and amended.
2.3(1)(c)	Superfluous as this is covered in 17025.	Delete.	Will need to keep some of the 17025 requirements for laboratories that will not be ISO 17025 accredited, but recognised by MPI e.g. a research or reference laboratory.
2.3 - 1c	This requirement is covered in ISO 17025 and is audited by the accreditation body	Delete this statement.	As above.
2.3(2)	It is unclear what type of changes might be deemed significant. It is unclear what is included under 'premises, equipment, facilities' – does this mean if new protein testing equipment is purchased MPI need to be notified??	Include a definition and examples of significant change Include scope covered by 'premises, equipment and facilities' (could be in form of guidance).	As above.
2.4	After the initial application for recognition, will we still have to apply yearly? Currently we have to re-apply yearly and pay a fee. There is mention of a fee, but not the time frame.		2.4(1)(c) The D-G specifies the period of recognition and this will be provided in the recognition documentation sent to the Lab. It is intended that all laboratories will be required to renew their recognition with MPI every 3 years.
2.4(1)(b)	'Where a KTP is required for a test….'. A laboratory accredited by IANZ is required to have at least one KTP for each method for which they have accreditation. The wording currently used implies this may be an option depending on the test method. And as per the previous comment, KTPs are appointed rather than nominated.	(b) The laboratory has appointed one or more KTP for the test; and	Agreed.
2.5	Agree with the KTP and this applies to all tests. There is nil mention of any tests being excluded and this is the preferred option. PIANZ does not want to see an exclusion for Campylobacter testing. This is a simple test.		Noted.
2.5	Want to go to a KTP recognised person. Going away from the signatory LAS which have to be accredited by IANZ staff. We feel that in a smaller lab a KTP would be easily noticed if they were not performing to this level. Were also easier to train in a smaller environment. Would be worried that the KTP system would become dumbed down and standards would drop; there would be no bench mark???		IANZ has a description for the role of the KTP and thus the Notice or Guidance Document do not need this included. IANZ annual assessments should prevent any 'dumbing down' as well as ILCPs, MPI and customer audits.
2.5	Sub clause (2) (b) allows the accreditation body to provide a dispensation where a KTP doesn't have a relevant tertiary qualification. Currently under ISO/IEC 17025 IANZ as the accreditation body provides criteria for when a KTP does not have a tertiary qualification and allows the laboratory to appoint and justify the appointment of a KTP without specific approval (excerpt of IANZ Specific Criteria for Accreditation - Dairy Testing 9 , Appendix 3(a) below *i. Key Technical Persons would be expected to have:* *(i) A tertiary qualification or equivalent professional recognition in the relevant discipline. Laboratories engaged in a restricted range of repetitive work may be able to appoint Key Technical Personnel with appropriate*	If the wording of (2)(b) was amended to something similar to the personnel meet the criteria specified by the accreditation body based on appropriate practical experience….this would align with currently accepted practice.	Agreed to amend (2)(b): "meet the criteria specified by the accreditation body from the requirements in paragraph (a) based on appropriate practical experience and specific training in that work without formal qualifications".

Clause	Comment	Proposed amendment	MPI Response
	practical experience and specific training in that work but without formal qualifications		
2.5 (2)	Are these two clauses necessary as clause 1 states "expertise in the technical areas". If 2b is included in the Notice would labs have to apply to IANZ before they could appoint any KTPs who do not have a tertiary qualification.		As above.
2.5(2)(b)	Dispensation by the accreditation body is no longer appropriate as it contradicts the Notice. It is understood that Laboratories (management) would be able to assess their own KTPs as per the Dairy and ELP programmes. This would continue to be an extra cost for the laboratory to then get approval from the accreditation body for additional assessment. Potential delay of appointing KTPs if required to wait for dispensation may be lengthy if this will require waiting for an audit.	Changed to management will demonstrate and assess KTPs to be capable to supervise the testing they will authorise and IANZ audit the KTP programmes to ensure that regulatory, technical, quality management system etc. requirements are clearly documented and the KTP programmes assess the understanding/competence of these areas. IANZ has KTP criteria already in each of their Specific Criteria. Recommend a standalone document to minimise duplication for programmes.	As above.
2.5.1	Where the Act or Regulations, Notices, Specifications or Directions issued under the Act require the laboratory to be responsible for sampling requirements and the qualification and status of sample takers for the test concerned it must: a) ensure samples are taken by sample takers in the manner specified in the Act or Regulations, Notices, Specifications or Directions issued under the Act; and b) ensure sample takers comply with any requirements issued under the Act or Regulations, Notices, Specifications or Directions issued under the Act; and c) maintain records of sample takers proficiency and qualifications; and d) undertake reviews of sampling and sample takers at least annually.	c) ensure records of sample takers proficiency and qualifications are maintained; and (where sampling is subcontracted, the lab has an audit role, it does not need to keep the records, only ensure they exist.	Disagree, and the term 'maintain' is being kept. This clause is about laboratories that undertake sampling "where sampling criteria are specified e.g. NMD".
2.5.1	Where sampling criteria are specified Sampling is an extremely critical component of testing and as with current LAS meat and Bivalve molluscan shellfish, samplers must be qualified so a scientifically robust criteria is applied and the sample is a true representation of the population/batch. This should apply to all industries.		Noted.
2.5.1	We would like confirmation that laboratories will not be responsible for any sampling not done by them i.e. that if the Laboratory was provided samples by a RMP Operator that they are not responsible for the sampling by the RMP Operator.	To clarify this, the wording for sub clause (1) could be amended to something similar to The laboratory is responsible for sampling requirements and the qualification and status of sample takers where these are under the direct control of the laboratory. For these sampling criteria the laboratory must	2.5.1(1) The wording in the clause includes "where the laboratory is responsible for sampling". However it has been amended to read: "Where the Act or Regulations or Specifications or Directions issued under the Act specifies that the laboratory is to be responsible for sampling requirements…." to clarify.
2.5.1	Assume sampling criteria is not applicable for dairy? This is an example where combining all requirements in one document is confusing.		As above.
2.5.1	Suggest that this section is not required as covered in 17025. Are there any cases that require the laboratory to be responsible for sampling? If so are these actual requirements of the person requiring the official assurance?		As above.
2.5.1(1)	a) ensure samples are taken by sample takers in the manner specified in the Act or Regulations, Notices, Specifications or Directions issued under the Act; and b) ensure sample takers comply with any requirements issued under the Act or Regulations, Notices, Specifications or Directions issued under the Act; and	a) **verify** samples are taken by sample takers in the manner specified in the Act or Regulations, Notices, Specifications or Directions issued under the Act; and b) **verify** sample takers comply with any requirements issued under the Act or Regulations, Notices, Specifications or Directions issued under the Act; and "Ensure" carrys the meaning : make certain that (something) will occur or be the case: "Verify" carries the meaning "substantiate or corroborate" A laboratory cannot "ensure" that samples are taken correctly without taking the samples themselves (or being there). Verification of sample taking suggests an audit function.	2.5.1(1) The wording in the clause includes "where the laboratory is responsible for sampling" such as NMD. Sampling and sample takers will be assessed annually by IANZ.

Clause	Comment	Proposed amendment	MPI Response
2.5.1(1) (d)	If this section is left in, requiring annual reviews is very prescriptive. The review period should be determined on a risk basis.	prepare and implement a procedure for the review of sampling and sample takers	Agreed. (d) has been removed as IANZ will assess this during their assessments.
2.5 .1 (1) d	This clause comes from LAS which only deals with NMD samplers. It is not practical for some of the other sectors to have labs review sample takers. For example in RCS this responsibility falls on the Animal Product Officer	This clause should be made specific to particular industries.	As above.
2.6	We agree with the audit frequency as set out in this notice. Year on year audits are finding fewer non-conformances or issues, a reduction in technical audits would be justified on this basis and performance of individual laboratories within their assessment cycle.		Noted.
2.6(2)(a)	Need to have some words that allow for labs that have received the relevant accreditation prior to the application		Agreed and amended.
2.6 (2) (b)	The DG receives the full initial assessment outcome….. IANZ will only be providing as we do currently for ELP and LAS, confirmation that the laboratory accreditation is granted and/or recommended, and the scope of testing for which the laboratory is accredited. This sort of implies the assessment report will be provided by the accreditation body – which is not the case, nor is planned to be. And/or, if reports from assessments are required to be provided by IANZ i.e. in the case of critical non-compliance, then there needs to be wording to this effect as the routine provision of reports to another party is not the norm for accreditation bodies.	The DG receives, from the accreditation body, confirmation of accreditation or continuing accreditation, and the scope of testing for which the laboratory is accredited. If, for example, critical non-conformances are identified during an assessment, MPI may request (in writing) for the Accreditation Body to provide a copy of the assessment report.	A new sub clause has been added to 2.6(3) “For continuation of recognition, the Director-General must receive any accreditation body assessment reports.”
2.6(3) guidance	The proposed wording should be a requirement and not just guidance. Additional assessments by the accreditation body are part of the 17025 accreditation and therefore not necessary to include here.	The laboratory must facilitate any additional assessment at the request of the Director General.	This guidance box was removed and the two clauses 2.6 and 2.8 have been amended to ensure clarity for the different purposes of assessments and are now clauses 2.6 Accreditation body assessment and 2.7 Audit or investigation requirements.
2.7(2)	WHY? Labs may wish to do this but it does not need to be regulated. An alternative could be that any notice of recognition must be available on request. This could be a listing on MPI’s website.		Agreed and amended to be “available”.
2.7(2)	Not clear what the purpose is for displaying the Notice of Recognition. Should be optional for laboratories. It is assumed it is only for overseas auditors. Most visitors don’t notice these documents on the wall. During external audits copies are supplied to the interested parties.	Recommend that it should be available at the Laboratory to be viewed by auditors and customers and that the mandatory requirement is removed.	As above.
2.7 (4) (a)	We question whether it is necessary for Staff to have to an up to date copy of the Act – all 160+ pages of it. Access to the other documentation referred to in this clause is both sensible and desirable.		Access can be through the internet e.g. assigning as a favourite or a bookmark.
2.7 – (4)a	Can updates to the Act in particular be included in the MPI’s email notification system. Previously only the section related to Responsibilities of Signatories was important to lab staff.		MPI does not manage updates to Acts or Regulations per se, this is managed by the Parliamentary Counsel Office, http://www.legislation.govt.nz/default.aspx, however legislation is required to be consulted on and the legislative changes are located at: http://www.mpi.govt.nz/news-and-resources/consultations/ and can be subscribed to.
2.7(5)		This is good operating practice and should not be regulated in the specification. If it is regulated there will be debate over what is: • Sound knowledge • Relevant industry, and • Operational processes. If absolutely necessary in the specification suggest that it could be in a guidance box.	Agreed and amended to “to demonstrate sound knowledge of the relevant industry practices.”

Clause	Comment	Proposed amendment	MPI Response
2.7(5)	Lab employees able to demonstrate sound knowledge of the relevant industry's operational processes.	Given the confidential nature of the dairy business practical application of this clause will be difficult for the laboratory unless this requirement is reciprocally enforced on the industry. Operational processes in some industries are much specialised. Unless there is industry buy-in making the laboratory responsible for acquainting themselves with industry operational processes will be difficult to implement. We do not believe this affects the laboratory's ability to conduct the testing using standard methods.	See above.
2.7(5)	It is unclear what is meant by "operational processes". Assume that where testing is subcontracted, if the subcontracted lab is "Recognised" by MPI this fulfils the requirement?	Include a definition of operational processes. Add guidance statement that where testing is subcontracted to a 'recognised' laboratory, this requirement is met.	See above.
2.7 (5)	This clause needs clarification and explanation of intention – what will this clause aim to achieve. Lab staff may have in-house knowledge of the processes or they may talk with the customer if there is a problem. Some processes are confidential and lab staff may not have access to the premises.	If this clause is necessary then add "employees should have access to knowledge of the relevant industry…."	See above.
2.10	Will we still have to send a yearly report to MPI regarding our internal audits and ILCP results? Or will the fact that IANZ audit us cover that? What about reporting the number of tests conducted (Pos and Neg)		Reporting regimes will be covered in guidance e.g. ELP is still expected to be annual. Providing reports on time will be a condition of recognition when issued by MPI Approvals Team.
2.10(1)	Reporting to MPI and other customers can be through web interface and Certificate of Analysis is not always provided to the customer. It can be generated by the Laboratory Information Management System, but it is not the results received by some customers as some customers do not require the actual Certificate of Analysis.	Consider electronic reporting as the standard format for an IANZ endorsed report is not represented in the electronic reporting systems.	Further clarity will be provided in guidance, this will cover both written and electronic reports.
2.10(1)	Assume "all reports for tests" only applies to tests stated in Part 2, 2.2 (1) and not to PAC's or COA's that are prepared for customers.		This Notice only covers the test(s) a lab is recognised for. A definition for test report has been added.
2.10(2) 2.11	These clauses are almost the same – is this intentional?		2.11(2) will include the words "not provided under clause 2.10" for clarification.
2.10(2)	This clause is the same as 2.8 (2) and 2.11 (2). These should all be consolidated into one clause.		There are different purposes for each clause and they will remain separate. 2.10(2) is about MPI being notified with information e.g. through regular reporting. 2.8 relates to e.g. facilities, audit assessments. 2.11 relates to e.g. exception reporting.
2.10(2)	What processes does MPI have in place to protect the intellectual property of our methods and validation reports?		MPI employees are required to maintain confidentiality and privacy and this is defined in job descriptions.
2.10 Guidance	This should not be guidance, but a separate section on ILCP.	ILCP requirements for recognised laboratories include: what must be undertaken to meet ISO/IEC 17025 requirements; and specific programmes as required by MPI under Notice, regs, etc. GUIDANCE. For some programmes MPI may contract an ILCP provider.	ILCP is a requirement of ISO 17025. Where there are specific requirements from importing countries, this will be described in other legal instruments e.g. OMARs. The guidance document will describe the current use of a contracted or designated ILCP provider for LAS.
2.11(3)	Are we still required to have a quality/technical manager? As it says that the KTP has to notify the Director-General		Yes. ISO 17025 requires the lab to have a quality manager and we have amended this clause accordingly. We have also added this role into clause 2.3 and a description of the role will be included in guidance.
2.11(3)	Recommend that this paragraph is split into Laboratory vs. KTP notifications. Some of the items listed may not in the scope of knowledge for the KTP who is responsible for technical conduct of the test and authorisation of results.	As per comment.	Agreed and the quality manager has been inserted where most of the references to KTP were used in this clause.
2.11(3)(b)	Suggest trade be added since DCD, HGP and BPQ are all examples of trade risks rather than public health or biosecurity.	as a result of its activities, the laboratory becomes aware of a situation which may pose a significant biosecurity, trade or public health risk; or	Agreed and amended.
2.11(3)(b)	Assume for a dairy company laboratory the Exception Reporting requirement covers this. If not, then more clarification is required.	More clarification is required around this sub-clause.	Exception Reporting is in relation to affected product rather than the test(s). Notification will still need to be made to MPI for test results. It is the

Clause	Comment	Proposed amendment	MPI Response
	Is it the intention that a subcontracted laboratory would notify MPI when they obtain any results outside the limits set in DPC1 e.g. a positive salmonella result? Would they be obliged to contact the manufacturer before disclosure to MPI? How will a subcontracted laboratory know what the final product use is of the sample they test is e.g. final product for human consumption or challenge testing for a research and development trial that will never be consumed?		contracting or original laboratory's responsibility to notify MPI not the sub-contracted laboratory.
2.11(3)(c)	Is the reporting structure within companies considered when judging "lacks impartiality"? E.g. a laboratory that reports through to Operations or Marketing functions within the Company.	Clarification how this affects laboratories that are part of the Company that also manufactures and markets the products.	Noted. This area is covered in ISO 17025, 4 Management requirements, 4.1 Organization, 4.1.4.
2.11(3)(d)	Assume this refers to IANZ audit CAR's and any PVB audit CAR's that relate to testing.		Clarification will be provided in guidance. Amended the Notice by removing the words "was found by an accreditation body or otherwise".
2.11 (3)d	The term" critical non-compliance" is not used by IANZ.	IANZ to provide suitable wording.	Critical non-compliance is defined under Definitions and clarification will be provided in guidance.
2.11(3)(d)	Critical non-conformances – please provide of list in guidance document to state clearly what type of non-conformance will trigger a reporting function.	As per comment.	As above.
2.13(1)	Could the requirement for record retention be amended to at least 4 years. Some laboratories have additional requirements that require records to be kept for at least up to 10 years i.e. for MOH work.	…at least four years….	Agreed. Amended as follows to include (2): "Records must be retrievable within two working days." Types of records will be described in Guidance e.g. electronic and backups.
2.13	The recognised laboratory must retain technical records (such as maintaining original test observations, copies of reports issued and other information necessary to maintain an audit trail) for four years.	The recognised laboratory must retain technical records (such as maintaining original test observations, copies of reports issued and other information necessary to maintain an audit trail) for at least four years or more as required by other legislation. Does this conform with other legislation (see http://www.aranz.org.nz/Site/resources/general/recordkeeping_legislation.aspx) given that contracts and financial information is linked to those reports. For example, **Goods and Services Tax Act 1985** This Act includes requirements for the keeping of records to support the administration of the Goods and Services Tax system (refer to section 75) and their retention for a period of at least seven years after the end of the taxable period to which they relate. Section 75 provides for the keeping of records. (The Goods and Services Tax Amendment Act (no 2) 1992 reduced the retention of records subject to this Act from 10 to 7 years.) **Limitation Act 1950** This Act establishes time limits within which certain types of civil actions may be brought and therefore effects how long records are kept. Generally, an action cannot be brought after the expiration of six years from the date on which the cause of action accrued. (The exception is contracts under seal which is 12 years). There may be instances where the 6 year expiry period does not begin until the person actually discovered a mistake or fraud and it has been deliberately covered up.	As above.
3	The Notice does not include any provision for a consultative panel, as exists in Part 5 of the existing LAS rules. The consultative panel is an integral part of the existing LAS administration and plays a vital role in method selection, validation and approval, as well as overseeing the accreditation and ILCP processes. We recommend it continues.	Restoration of Part 5.	MPI will continue to deliver a form of the 'LAS consultative panel' (but it may not be called that name). Industry forums are not legislated for nor are they compulsory to attend. Other programmes have forums that will continue as well.
3	In the *Animal Products (Dairy Recognised Agency and Persons Specification) Notice 2011 Number 2*, (RA&RP Spec) clause 9 states the tests that require approval by the Director-General. The *Proposed new Animal Products*		Approval for tests is provided for in clause 3.2 of the Notice, and specifically covered under other legal Notices, RMPs and OMARs as appropriate.

Clause	Comment	Proposed amendment	MPI Response
	(Specifications for Laboratories) Notice Context and Changes document advises that text relating to test methods within the RA&RP Spec will be deleted, and therefore there will not be any requirement for test methods for parameters specified in schedule 1 to be approved. Is this an oversight, or will the requirement for method approval either; remain in the revised RA&RP Spec or be moved to an alternative instrument under the *Animal Products Act 1999*. **9 Approval of test methods** (1) The prior approval of the Director-General must be obtained for — (a) test methods intended to measure parameters specified in Schedule 1 Schedule 1 **Inhibitory Substances** **Residues and Contaminants in raw milk** **Farm dairy water clarity** **Foreign Matter** (2) With the exception of those test methods covered under clause 9(1), Director General approval of test methods is not required provided — (a) analysis is undertaken in a dairy laboratory that is recognised by MAF in the appropriate category for the required test and (b) the test methodology used is specified within the scope of the laboratory accreditation/assessment and has been validated for the intended product type(s) (3) The exception in 9(2) does not apply where a particular method has been specified by way of Notice under the Animal Products Act 1999. (4) In situations where approval is required, the Director-General may approve test methods from the following sources provided they are used within their scope and are not modified significantly: (a) international standards: (b) methods published in reputable international texts: (c) national or regional standards or legislation: (d) any other sources that the Director-General considers acceptable. (5) For a test method to be approved as an acceptable alternative to a specified method under clause 9(1)(a) the method must be shown to be at least equivalent to the specified method in terms of performance characteristics, and the Director-General must have the freedom to accept an alternative.		
3	Acceptable test methods	With the rapid development of technologies, having methods specified for testing greatly restricts the laboratory's ability to employ some of the modern technologies that may have advantages to the industry including shorter turnaround times or being more cost effective. Currently, Dairy Recognised Laboratories, can use methods that are validated by the new technology manufacturers and subsequently verified by the laboratory for use on a specific matrix after the lab is accredited for the method. New Zealand industries are also developing new and unique value added products especially in the dairy industry for which verification and accreditation is required even to use existing methods. Several standards are not updated for years and will not have incorporated the latest technologies available. It may perhaps be appropriate to have referee methods for specific analytes and permit the labs to use methods for which labs can demonstrate equivalence or better results and have the methods accredited.	Noted. Where test methods are specified any equivalence needs to be agreed with our importing countries. Where test methods are not specified, clause 3.1(2) addresses this.
3.2	Use specified method without modification	Several dairy methods in the past have been based on NZTM references which are slight modifications of the ISO standards. However, data collected over several years is based on these modified references. For continuity it is necessary to use the same modified methods of analyses. This clause can therefore be difficult to implement if Dairy comes under the LAS scope. Eg: mesophilic aerobic/anaerobic spore testing. As above with testing, it should be possible to demonstrate equivalence. Test method choice could be a customer specification.	Modifications need both accreditation and trading partner agreement despite any benefits e.g. efficiencies.
3.2(1)	Assume for Dairy that this means the MPI spreadsheet of approved test method that is referenced in the 'Consolidated List of tests'.	A link to the 'Consolidated List of Tests' should be added (which in turn links out to the MPI spreadsheet of approved test methods).	A link to the Consolidated List of Tests will be in the guidance document.

Clause	Comment	Proposed amendment	MPI Response
	Note the 'Consolidated List of tests' adds confusion for dairy, as there are no test method references – not sure what value it is adding.		
3.2(2)	IANZ Scope Of Accreditation certificates need to be clearer. The scopes read that a laboratory has accreditation for all tests listed under a product type/s when this is sometimes not the case. This makes it difficult to be certain that the laboratory has the required accreditation when choosing to subcontract.	No amendment to notice required – just to how IANZ scope is specified.	Noted.
3.2(2)(a)	This should not be regulated as a responsibility of the laboratory as they may not know the purpose of the testing. This is the laboratory customer's responsibility. However the requirement is valid if the customer tells the laboratory that is a test required under the Act or the laboratory is sub-contracting the test.		Disagree. The laboratory takes responsibility for how they conduct the test, and the client and laboratory agree on what the test method is.
3.2(2)(b)		The test method used is specified within the scope of the laboratory's recognition	Disagree, the laboratory is accredited for the test method.
3.2(2)(c)	Clause 3.3. does not add anything as it just repeats this sentence.	The test method has been confirmed as suitable for the intended sample matrix.	Agreed, has been removed.
3.3	As ISO/IEC 17025 and laboratory accreditation against this standard covers validation of test methods appropriately (section 5.4 *Testing calibration methods and method validation*) it is suggested that this clause is removed.		Agreed, has been removed.
3.3(1)	Is this not part of the accreditation to 17025?		Yes it is however, parts of ISO 17025 need to be included for those labs who have special recognition by MPI but don't have ISO 17025 accreditation.
3.3(1)	Guidance As currently written a laboratory could assume that obtaining manufacturers validation information is sufficient, when in fact this is only part of the process and verification is still required to be carried out by the laboratory. Amend the second sentence to state the type of testing this refers to i.e. PCR, as most microbiological testing requires the use of positive and negative controls and this could be read as an option to reduce checks.	For example, for serological testing, the manufacturers' validation information may need to be obtained to confirm test kit suitability, prior to the laboratory performing its own method verification. On-going verification of test results may be achieved by using positive control material as an independent control, for example, for PCR and serology testing.	Agreed. Agreed.
4.2	Sub clause (1) requires that test results are released by the KTP, this contradicts the ability of a KTP in a large laboratory to delegate their responsibility as they are currently allowed to do under *IANZ Specific Criteria for Accreditation – Dairy Testing 9m Appendix 3 (c)* excerpt below. *Key Technical Personnel would normally be those individuals who authorise the release of all test results. However, in large laboratories such authorisations may be delegated to other supervisory staff on a day to day basis provided the delegations and the basis for them are clearly documented.* *Such delegation of authority does not absolve the Key Technical Person from taking full responsibility for the validity of the work. The authority to release results should not be confused with the authority to issue formal test reports. See Section 11.* We utilise this delegation within laboratories and removal of this ability would delay the release of testing information and would require additional KTPs to be trained. If the wording was amended to something similar to the following this would allow the current practice to continue.	The recognised laboratory must ensure that all test reports relating to that test are signed and issued (or, if in electronic form, are authorised for release) by the KTP responsible for those tests or their delegate, where the delegation meets the criteria specified by the accreditation body.	Agreed and amended.
4.2(1)	Delegation of KTP authority is only an option for electronically released results, in accordance with a documented laboratory policy. It does not absolve KTP of the responsibility and cannot be used to sign out reports on behalf of a KTP.	Another KTP may release results (electronically) when delegated to by a KTP (whom retains responsibility for the results). Endorsed test reports and certificates need to be signed by a KTP whose scope of responsibility includes some if not all the tests in the test report.	As above.

Clause	Comment	Proposed amendment	MPI Response
4.2(1)	Having the KTP just signing and issuing test reports adds no value. The KTP needs to take responsibility for the quality and accuracy of the test result and the report. This comment applies to 4.2(2) also.	The recognised laboratory must ensure that all test reports relating to that test are signed and issued (or, if in electronic form, are authorised for release) by the KTP responsible for those tests. Before signing and issuing test reports the KTP must be satisfied that the results reported are accurate. Another KTP can release results at the discretion of the KTP responsible for those tests.	As above.
4.2(1)	Assume for results from the Company's laboratory this refers to the initial release of results to the product grading department, not final PAC's or COA's to customers or MPI.	Definition of test report	As above.
4.2(1)	Authorisation of results – Another KTP can release results at the discretion of the KTP responsible for those tests. KTP's are appointed for their knowledge of the test, its limitations and trouble shooting. If a test results is not authorised by a KTP for that test, such results must not be released to maintain results integrity and validity. We do not believe this clause is acceptable otherwise any KTP can release any test result without adequate authorisation. It is however acceptable to have the final report with a set of several analytes results released by any one of the many KTP's, as long as each test is authorised by a suitable KTP for that test.		As above.
4.2(1)	Another KTP can release results at the discretion of the KTP responsible for those tests. This statement contradicts the extensive requirements that management have to meet to demonstrate KTP competence before appointing a KTPs. What process will be followed by this KTP to ensure that another KTP has the technical and regulatory knowledge to release the results when management has not appointed that KTP for the test?	Not clear what the purpose is of that statement and how this will be managed. Recommend removal as it is a risk to the laboratory and the MPI programmes if inappropriate KTPs release a MPI programme result.	As above.
4.2(2)	Is this meant for test labs external to the manufacturing Company, who may then subcontract the testing to another laboratory? IAs above, i this only in relation to release of individual test result reports and not PAC's or COA's for MPI or customers?	Definition of test report.	Agreed and amended.
4.2(2)	This expectation is not practical. The most the laboratory can do when subcontracting analysis would to ensure 1) the laboratory is IANZ ISO17025 accredited, 2) the specific test is on the IANZ schedule of accreditation and 3) approved by MPI and on the MPI website. It will be difficult to know whether another Laboratories signatory has correctly authorised the relevant. The IANZ schedules of accreditation are general which is appropriate for laboratories. It is the subcontractor's responsibility to meet IANZ (ISO17025) requirements and to ensure that the correct signatory has authorised the correct test.	The Laboratory to ensure that a suitable subcontractor is contracted to perform the analysis by ensuring they are ISO17025 accredited, the relevant test method is accredited and suitable for the specific sample matrix and finally MPI approved and listed on the website.	Agreed and amended.
4.2 (2)	This clause has "a KTP at the subcontracted lab that supervised the test" The other two clauses do not use the word supervised but released so it should be changed for consistency.	Clause should end "……..subcontracted lab that released the test report."	Agreed and amended.

Consolidated List of Tests

Ref	Comment	Proposed amendment	
MT	In the Consolidated List of Tests Numerical Reference 30.1 refers to Somatic Cells Raw Milk (cow)	What about sheep, goat etc milk?	Removed "cow" in the text but note that it is not the same standard for different species.
AHL	73.1 and 73.2 both Infectious Bovine rhinotracheitis (IBR) – Elisa – Ab, antibody detection i.e. both lines identical		Agreed and amended.

Ref	Comment	Proposed amendment	
PIANZ	55.3 Are all the test listed able to be tested by an approved lab? If so then cultivation of HPAI is permitted outside MPI lab. Upper Hutt.(clarification)		For the purpose of this notice all tests potentially done in export laboratories for export (in general) listed. Other legislation e.g. transitional facilities, Biosecurity Act etc. would prevent the culture of exotic organisms outside of MPI's IDC.
PIANZ	55.10 This is a very general test not applied to any other species, Why only avian viruses?		This has been removed.