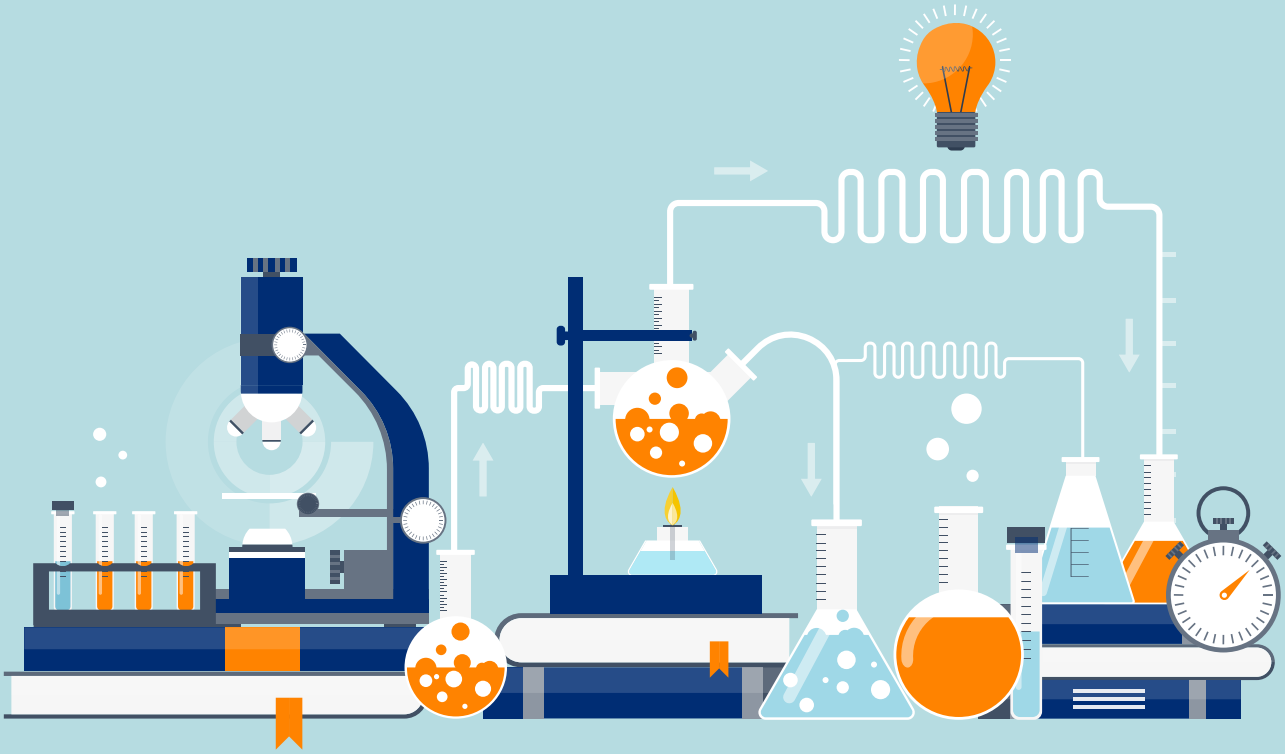


Framework for Self-Assessment of Laboratory Capacity Building Needs and Prioritization

Asia-Pacific Economic Cooperation

FSCF Food Safety Cooperation Forum
PTIN Partnership Training Institute Network

BACKGROUND

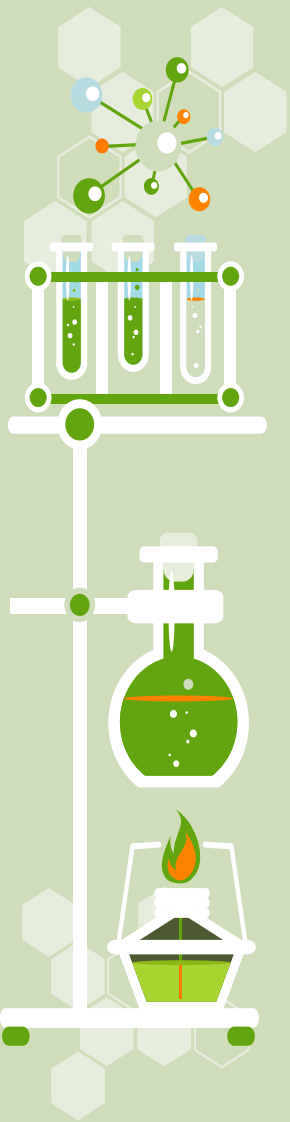
The Asia-Pacific Economic Cooperation, or APEC, is a forum for facilitating economic growth, cooperation, trade and investment in the Asia-Pacific region. APEC also works to create an environment for the safe and efficient movement of goods, services and people across borders in the region through policy alignment, and economic and technical cooperation.

APEC and Food Safety

APEC advances cooperation on food and agricultural issues. APEC activities promote productivity and growth in the processed food and agricultural sectors, encourage the development and adoption of new technologies and facilitate food trade. The Committee on Trade and Investment's Subcommittee on Standards and Conformance (SCSC) is the focal point for efforts relating to food safety and consumer product standards and conformance matters. The Food Safety Cooperation Forum (FSCF), which reports to the SCSC, is a forum of food safety regulators which sets food safety capacity building priorities for the region.

The FSCF Partnership Training Institute Network (PTIN) was created to address the need to engage the food industry, academics and regulators to strengthen capacity for food safety across the APEC region. APEC leaders endorsed the FSCF PTIN initiative in 2008. An APEC/PTIN Expert Working Group held a meeting in May 2010 in Washington, DC, where policy officials met to discuss gaps in knowledge across the APEC communities and prioritized areas for possible collaboration. During the discussion, the group emphasized the need to focus on laboratory capacity building efforts. Specifically, the following eleven priority areas were identified as critical laboratory capacity priorities:

- Critical Role of Laboratories in National Food Safety Progress
- Assessing needs of laboratories
- Safety (personnel and laboratory)
- Quality Assurance/Validation
- Metrology
- Sampling
- Laboratory Management
- Lab Accreditation
- Analytical Methods
- Data Analysis and Interpretation
- Maintenance and Troubleshooting



Since the Expert Working Group convened in May 2010, stakeholders have worked to carry out the Working Group's recommendations, develop and disseminate a survey tool, and organize a lab competency workshop which brought together technical experts from 17 APEC economies in Bangkok in August 2011. Post-workshop follow-up activities led to the conclusion that a collaborative approach was the optimal way to advance the competency building activities. The laboratory collaboration program consists of five critical components:

1. Establishing or leveraging existing **Lab Accreditation/Quality Assurance** measures. This includes sharing SOPs, best practices, identifying scope of accreditation and recommending sources for gap analysis. Laboratories can range from no quality assurance system to highly rigorous systems (for example, ISO 10725 accredited). Current laboratory status will dictate needs assessment.
2. **Proficiency Testing** (PT). This includes the identification of programs and leveraging of available resources and reference materials. While usually included under laboratory accreditation/quality assurance, it is separated to emphasize the importance of participation in a PT program. PT samples are a direct measure for demonstrating laboratory testing competency.
3. **Training**. Utilizing current programs, including government sponsored training courses, and international training laboratories, among others. Training will cover screening and confirmatory testing. Prerequisites can be satisfied by developing web-based modules or through existing training material available from government agencies and other organizations.
4. **Laboratory Infrastructure**. This includes recommendations for current and new technologies and equipment utilized by regulatory laboratories. Based on current testing methodologies, guidance can be provided as to what equipment, standards and reagents are most suitable for test methods. Although flexibility in method selection exists, eventually, equipment platforms for testing will harmonize.
5. **Methods**. This includes sharing current food testing methods (microbiological and chemical) and method validation protocols, as well as participation in collaborative studies. Method validation criteria can also be captured under laboratory accreditation/quality assurance but is included here to highlight the importance of methods, their intended use and performance.

Facing the challenge of investing in a single activity again in 2013, it was obvious that the task of selecting such activity demanded an evaluation of many factors that were not seen as equally important by different stakeholders and across the region. To this effect, a Scientific and Technical Advisory Group (STAG) was gathered in the March 2013 to develop a tool for the prioritization of laboratory capacity building activities that could be used independently by national or regional governments or stakeholders groups to decide their own priorities for investments.

A "mini-STAG" was composed of experts from USDA (Dr. Charles Pixley and Dr. Emilio Esteban, Mrs. Cathy McKinnell, Ms. Kelly McCormick and Mrs. Fania Yangarber), U.S. FDA (Dr. Elizabeth Calvey, Dr. Palmer Orlandi, Mr. Carl Sciacchitano), academia (Dr. Janie Dubois, University of Maryland JIFSAN), and industry (Dr. DeAnn Benesh, 3M, Dr. Wayne Wargo, Abbott Nutrition).

The team developed the structure for a capacity assessment tool to enable a better understanding current and desired capacity. The draft tool was presented and discussed at

a STAG meeting in November 2012 in Washington DC. It was agreed that economies would volunteer to conduct a pilot application of the prioritization tool to support further development. Chile and China were announced as the pilot economies at the APEC SOM II meeting in Indonesia in April 2013.

There were strong imperatives to avoid duplicating existing resources in this project, so assessment and prioritization tools used by international organization were investigated by JIFSAN (University of Maryland's Joint Institute for Food Safety and Applied Nutrition), the program implementation organization.

The World Organization for Animal Health Tool for the Evaluation of Performance of Veterinary Services (OIE PVS) tool was selected as a good model for assessment, and the Multi Criteria Decision Analysis developed to prioritize Sanitary and PhytoSanitary capacity building needs at the Standards and Trade Development Facility (STDF) could be tailored to fit the purpose of prioritization for laboratory capacity. More information may be found using these links: OIE PVS and STDF MCDA

PTIN Regional Workshop on Strengthening Laboratory Capacity in Food Safety

The Regional Workshop was held at the University of Maryland and hosted by JIFSAN, with financial support from the USDA Emerging Markets Program, the University of Maryland's Division of Research and Division of University Relations, and 3M.

Among other activities, round-table discussions on capacity building needs and process of prioritization were held. Each economy was asked to contribute an opinion on capacity building needs, and discussions about why and how these needs may be addressed led to a prioritization for one particular need to be drafted by each team.

At the end of the meeting, the questions discussed and the paths proposed from various teams enabled additions to be made to the basic decision tree presented by Janie Dubois for one particular aspect of capacity building needs (personnel training) (Figure 1).

Figure 1: Decision tree for capacity building activities related to the implementation of new testing methods and the need for personnel training.

The decision tree was found to be difficult to implement in large part because food safety issues don't always have comparable reasons for being considered priorities. It was concluded that the tree works well to define specific activities that should be prioritized for a particular food safety issue, but does not enable stakeholders to prioritize the issues themselves. It was also realized that designing a decision tree that would encompass both aspects would become too complicated, so it was decided that a software assisted approach based on Multi-Criteria Decision Analysis (MCDA) would be proposed.

FRAMEWORK FOR PRIORITIZATION

The objective of the MCDA framework is to provide a transparent tool to prioritize laboratory capacity building activities and the underlying food safety issues. The development is based on work by Henson and Masakure detailed in the document "Establishing Priorities for SPS Capacity-building: A Guide to Multi-Criteria Decision-Making", from now on referred to as "the Guide".

As explained in the Guide, "the framework is designed to be applied to choices between relatively large numbers of options that can differ markedly in their characteristics and the associated flow of costs and benefits over time, including various elements of food safety, (…). Further, it permits priorities to be defined on the basis of multiple criteria which might be measured in a disparate manner and assigned differing weights."

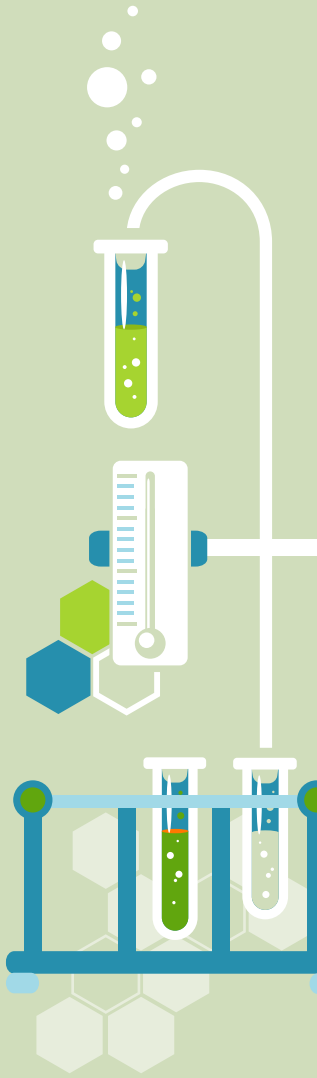
The framework is designed using stages.

Stage 1: Compile Information Dossier

The information dossier is a collection of information that should be used to define capacity building options and rank them. It incorporates economic, trade, health and other relevant data. In this particular case, an information dossier was not gathered *per se* for two reasons. First, the work of the APEC FSCF and PTIN over the years has already led to identified priorities and critical components (above). Second, the participants in the Regional Workshop were selected by the Secretariats of their economies and therefore assumed to be well informed about the relevant information for their economy.

One aspect of the information dossier that was compiled at the Regional Workshop was a list of indicators that should be the basis for comparison of options. The hierarchy of factors and criteria used for comparison is illustrated in Figure 2 and briefly described below.

- Public health impact is an indicator that will be measured using two criteria: The potential to prevent illness and the need to address an outbreak. The data used to evaluate these criteria shall include
- A quantitative, or at least semi-quantitative evaluation of the disease burden that may be addressed by the option (*i.e.* is there a health problem?)
- Data from the region (ideally) about the impact of the option on disease burden (*i.e.* has this option shown an impact on disease burden somewhere?)
- Data on the extent of a current outbreak and the likelihood that it will be resolved without the application of the option (*i.e.* will this option at least positively influence the resolution of the outbreak)
- Regional.



Difficulty of implementation is an indicator of the likelihood that the option will actually be applied if it is found to be a priority. Criteria for this evaluation address management buy-in, availability of personnel required to apply the option, a qualitative evaluation of the chances that the option will not yield the desired outcome (*i.e.* solve the food safety issue it is meant to address), and a qualitative measure of alignment with the overall strategy. The latter criterion is essential to ensure that the resources needed for the realization of the capacity building option will be available and for long enough to be able to reach the desired outcome.

Trade impact is an indicator that will be measured with two criteria: Trade expansion potential (opening new markets) and trade loss that will be regained as a result of this option being applied and successful. These criteria are best represented by quantitative data (in U.S. dollars to facilitate discussions across economies).

Finally, the costs associated with the option are measured quantitatively and divided into the two categories of initial investment and implementation (and continuous application) of the option. The second category shall be evaluated on a per-year basis considering the load of samples now and in the future, the savings resulting from switching to this option if it replaces another option and other similar factors.

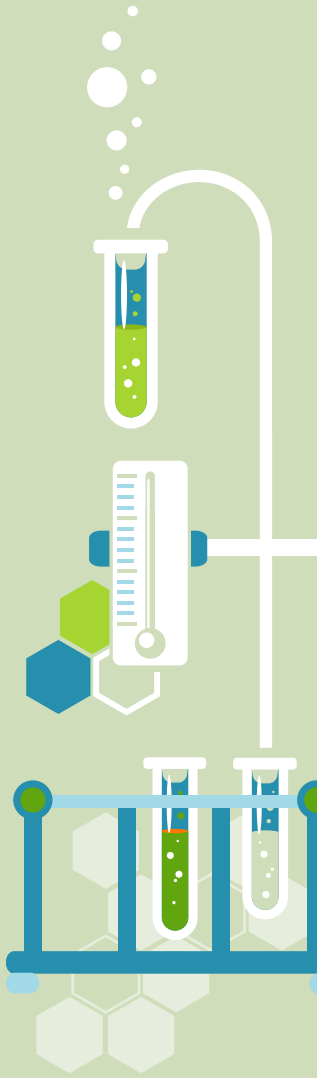
Stage 2: Define Choice Set

The second stage of the prioritization activity is to define a set of capacity building options. In the current exercise, only laboratory capacity building options are considered and the set was defined both using input from the pilot work done with Chile and China, and from options proposed at the Regional Workshop. In the terminology of the Guide, the choice set was obtained from a stakeholder workshop.

During the workshop, participants presented options and were given the opportunity to discuss them using qualitative estimated for the indicators proposed in Figure 2. Participants were also invited to introduce criteria for the indicators, which resulted in the list presented in this document. The activity options proposed, the need they address and the food safety challenge are presented in Tables 1 and 2.

Table 1: Challenges identified by team 1, needs defined and activities proposed to address these needs.

Food Safety Challenge	Needs	Proposed Activities
Organic contaminants in seafood, from effluents, persistent	• Training in analytical chemistry • Infrastructure • Training on how to approach the problems • Communications about non-fit-for-purpose methods being applied	1. Webinar series on screening non-targeted components, to cover pesticides, persistent contaminants, allergens, mycotoxins, etc. A series by manufacturers of instruments (like done in micro in the Chile pilot) was proposed. 2. Webinar or written document on "how to approach the problem of non-targeted ID", to include discussions of what technologies are used, the level of expertise required, flags for what "looks right" or "looks wrong." It was suggested that webinar should be presented by a government expert, and should include the concept of "broadly targeted methods" to ensure the understanding that we are still targeting some chemical groups.
Unavailability of reference/ standard materials and reference methods, proficiency testing	• Local control matrix • Food safety control materials (incurred materials are not addressed by metrology institutes)	1. Mexico is already involved in a project for the production of local control materials and has proposed to make them available to APEC economies. 2. Training on how to prepare food safety control materials (Mexico to see if they can do this following the first phase of their project)
Non-targeted identification	Same as first row	Addressed in activities in first row
Allergens determination	Same as first row	Addressed in activities in first row
Validated methods of nutritional value/ label claims	Could not define specific needs	Nothing proposed
Disconnected authority within governments	Implement collaborative approaches among government organizations	1. Webinar by Chile to present how ACHIPIA reached their objective of coordinating food safety efforts across multiple government organizations (to be organized as part of China pilot and recorded for posting on APEC FSCF PTIN website)



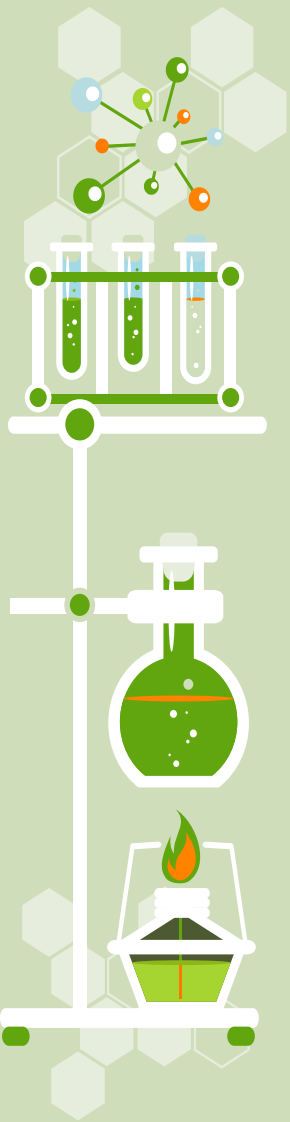


Table 2: Challenges identified by team 2, needs defined and activities proposed to address these needs.

Food Safety Challenge	Needs	Proposed Activities
Lack of understanding of PAH testing	Training on PAH testing	1. Hands-on train-the-trainer workshop with experts on preparing samples and analyzing for PAH. (JIFSAN proposed to lead) 2. Trainees selected for ability to reproduce in their sub-region 3. Redelivery in sub-regions with a team of 3 instructors: 1- leader from the host country, 2- expert from activity 1, and 3- young analyst in the field to ensure continuity
Inadequate infrastructure	Understand how to develop infrastructure efficiently	Find a way to share experience in infrastructure development. No specific activity could be defined
Unavailability of PT Material	Training on how to prepare PT samples	No activity was identified as a priority since this service exists from the private sector.
Lack of understanding of each other's system and other info available	Ahead of APEC meetings, someone should gather information about the food safety regulatory systems of all participants, include international organizations such of OIE, WHO, SPS, IPPC, Codex (in particular risk assessments)	1. Each economy to prepare a 5-10 minute web-delivered recording explaining their food safety regulatory system ahead of the APEC meeting (hosted on APEC FSCF PTIN website) 2. Develop a resource (web-based) on where to find various info from international organizations. It was proposed that this could be part of the GFSP information platform
Uncertainty of measurement (in micro and chemistry)	• Training on the measurement of uncertainty and its interpretation • Better visibility of guidelines on sampling	1. Webinars on the measurement of uncertainty, separate for micro and chem including a review of guidelines offered by different organizations, data distributed ahead of the webinar and the webinar should show the steps of the calculation (using data distributed) 2. Web-based training on designing a sampling plan (in China, contract labs design the sampling plan)

Stage 3: Define Decision Criteria and Weights

As mentioned previously, the criteria and indicators were organically selected through both the pilot work and the Regional Workshop. However, the importance of each, which will translate into their weights, was included in the discussion. The intent was not to decide on weights at the time, but rather gain a better understanding of the relative weight values favored by different economies as well as by stakeholders with different functions in the food safety system. A qualitative scale was determined to be more appropriate for some of the criteria that could actually be evaluated using quantitative data because of the fact that this was done in a large Regional Workshop with representatives from many economies with quite different economic situations, import/export markets and infrastructures. Further deployment at a single economy or even small region level would benefit from the use of quantitative data.

Scope and Intent of Criteria

One of the most challenging aspects of the discussions with stakeholders revolved around defining the scope and the intent of the criteria. In some cases, the criteria appeared clear, but in other cases, no agreement could be reached and decisions were made to use a particular definition.

Public health included two criteria: Addressing an outbreak and preventing illness. The former was determined to require that an outbreak be ongoing at the time of the assessment, while the latter regarded any potential isolated cases and outbreaks. These criteria would best be measured with economic data or disease burden statistics, but it was determined that such data is not available and would be difficult to evaluate for the full APEC region, so a qualitative scale would be used. A pairwise comparison of values (low, medium of high) would be done using a linear function. The indifference was set to low because it is not a direct goal of APEC to address outbreaks (an indifference set higher would risk ranking options with high results against other criteria at a low rank if they did not address an outbreak). Preference was set to medium, so that if there is indeed an outbreak in progress, options that address this type of crisis are ranked higher.

Trade impact was another category that would best be represented by economic data, but it was determined that data for the entire APEC region were not available.

Weights

It is expected that the relative weights will be one of the factors that economies and organizations will adjust when using the prioritization framework depending on their role in the food safety system. For example, public health laboratories will likely wish to give a higher weight to the public health impact than the trade impact. Similarly, smaller organizations operating on funds secured for targeted tactical activities may not give as much weight to the costs compared to the difficulty of implementation. The initial allocation of weights for the criteria was set as presented in Table 3.

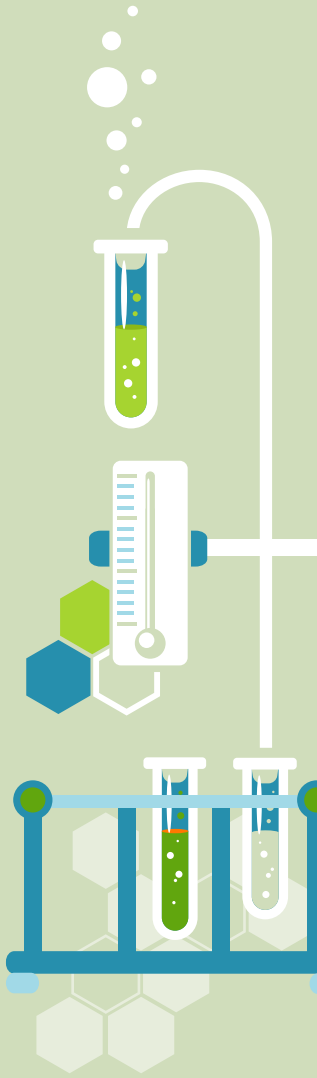
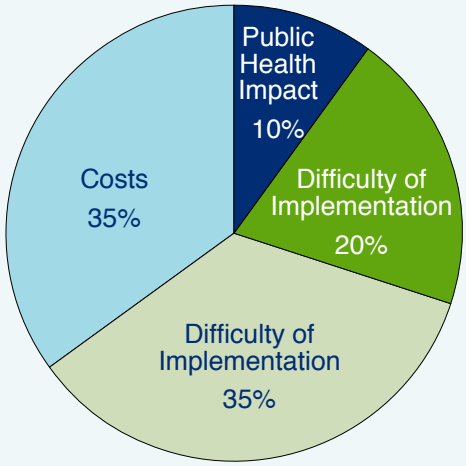


Table 3: Criteria Weighting

Public Health Impact	**10%**
1. Prevent illness	20%
2. Address outbreak	80%
Difficulty of Implementation	**20%**
1. Management buy-in	15%
2. Staff availability	25%
3. Risk of being unsuccessful	50%
4. Strategy alignment	10%
Trade Impact	**35%**
1. Trade expansion potential	25%
2. Lost Trade	75%
Costs	**35%**
1. Initial investment	60%
2. Implementation cost	40%



The weights were biased towards trade impact and considerations of costs because this is an APEC project, and consequently, is focused on facilitating trade in the region. The costs were weighted toward a heavier weight for the initial investment because of the known limited funds available for this phase. The implementation costs were seen as less critical because savings made by replacing outdated laboratory procedures or systems already present in budgets typically offsets them.

More details about the interpretation of the criteria are provided in the information cards.

Stage 4: Construction of Information Cards

The information cards are the gathering place for all the information briefly introduced before, where each indicator and criteria are evaluated for each option. The criteria encompass both quantitative and qualitative data, and the discussions that led to the information included in the cards also considered the level of confidence that the Regional Workshop participants felt about the information.

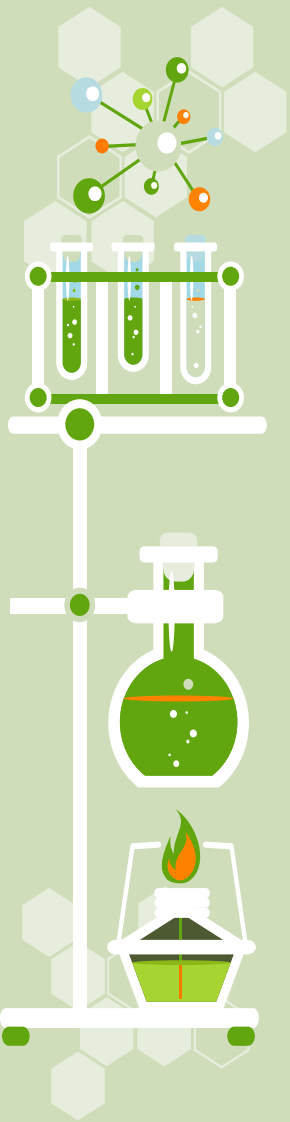
The information cards are not quite as specific as they will need to be for application at a single economy level because consensus could only be obtained on broad points of view from the numerous economies represented.

Example of an information card compiled from discussions held at the Regional Workshop is presented in Appendix 1.

The information from the cards enables participants to fill the evaluation table for each option and all criteria.

Evaluate Alternatives

	Address outbreak	Prevent illness	Lost trade	Trade expansion potential	Initial Investment	Implementation Cost	Management Buy-in	Staff availability	Strategy Alignment	Risk of being unsuccessful
Micro methods validation	Low	Low	High	Medium	7000	0	High	Medium	High	Medium
Chemical methods validation	Low	Low	High	Medium	9000	0	High	Medium	High	Low
Rapid methods food microbiology	Low	Low	Medium	Medium	7000	0	Medium	High	High	Low
Non-targeted contaminants using GC/MC/MS	Low	Medium	Medium	Medium	9000	0	Medium	High	High	Low
Non-targeted contaminants using LC/MS/MS	Low	Medium	Medium	Medium	9000	0	Medium	High	High	Low
Non-targeted analysis using TOF	Low	Low	Medium	Low	9000	0	Low	Medium	Medium	High
Approaching identification of unknowns	Low	Low	High	Low	9000	0	High	High	High	Low
purchase GC/MS/MS	Low	Medium	High	High	100000	20000	Medium	Medium	High	Medium
Purchase LC/MS/MS	Low	Medium	High	High	350000	45000	High	Medium	High	Medium
Invest in PT from service provider	Low	Low	High	High	50000	20000	Medium	Medium	High	Low
Develop PT for country (gov as provider)	Low	Low	Low	Low	100000	50000	Medium	Low	Low	High
Purchase standards	Low	Low	High	Medium	0	30000	Low	High	High	Medium
Purchase CRMs in food matrix	Low	Low	High	High	0	30000	Medium	Medium	High	Low
Develop CRM in food matrix	Low	Low	High	High	50000	10000	Low	Low	Medium	High
Mycotoxins analysis training	Low	High	High	High	9000	0	Low	High	High	Low
General food microbiology training	Low	High	Medium	High	6000	0	Low	High	High	Low
Vet drug residue analysis	Low	Medium	High	High	9000	0	Medium	High	High	Low
PAH analysis	Low	Low	Medium	Medium	9000	0	Medium	Medium	High	Low
Pesticide residue analysis	Low	Low	High	High	9000	0	Medium	Low	Low	High
Viruses in food training	Low	High	High	High	7000	0	Medium	Medium	High	Low
E coli (STEC) training	High	High	High	High	9000	0	Medium	High	High	Low
Salmonella training	High	High	High	High	7000	0	Medium	High	High	Low



Stage 5: Derive Quantitative Priorities

This stage is where the multiple criteria are used together for decision-making. A score is computed from the response for each of the criteria using the relative weights assigned.

Table 4: Ranking of capacity building options based on data collected during the Regional Workshop.

Rank	Alternative	Score
1	Salmonella training	63.548
2	E coli (STEC) training	60.548
3	Purchase CRMs in food matrix	60.210
4	General food microbiology training	58.946
5	Viruses in food training	57.095
6	Rapid methods food microbiology	56.821
7	Purchase standards	56.275
8	Vet drug residue analysis	55.881
9	Mycotoxins analysis training	55.071
10	Non-targeted contaminants using GC/MC/MS	54.631
11	Non-targeted contaminants using LC/MS/MS	54.631
12	Chemical methods validation	53.399
13	Approaching identification of unknowns	53.161
14	Micro methods validation	52.113
15	PAH analysis	51.560
16	Pesticide residue analysis	44.048
17	Invest in PT from service provider	43.943
18	Non-targeted analysis using TOF	40.631
19	purchase GC/MS/MS	38.467
20	Purchase LC/MS/MS	36.348
21	Develop CRM in food matrix	34.819
22	Develop PT for country (gov as provider)	17.856

Stage 6: Validation

Not performed.

APPENDIX 1: INFORMATION CARD

Option: Training in Microbiology Methods Validation

Description of the issue and proposed option

Many representatives at the Regional Workshop considered method validation in microbiology an issue. A disparity of understanding of what is meant by the term was addressed by the presentation delivered by Dr. Benesh at the Regional Workshop, so this particular aspect was kept out of this discussion.

Regional Workshop attendees expressed concern about the ability of many organizations to perform method validation and bear the cost both in time and financial resources to do it. Once there was clarification about what method validation meant and also the differences arising from matrix extension versus full validation, it became clear that some organizations were staying away from new methods for reasons associated with a misunderstanding of what actually needs to be done in a method validation activity.

The topic had also surfaced at the private sector stakeholders workshop in Chile; specifically, the poultry and pork industry in Chile indicated a difficulty to adjust to new requirements, with the example of the “big six” STEC and implement the new methods needed to address the requirement in a “short time frame”. Further discussions to clarify the problem led to narrowing the issue to a desire by the industry to see the export country government putting in the new requirements validate the method(s) that should be used.

Considering that the approach favored in the APEC region is not to see economies impose on each other but rather align their efforts to reach a common goal, it was decided that a solution to this issue would be to train the workforce to perform method validation so that each economy could select methods that fit their situation (infrastructure, staff, availability of instrumentation, workload, cost, *etc.*) and validate them. This validation could be done for a group of laboratories, or by individual laboratories as dictated by the structure of the food safety system, so this training needs to be broadly available.

Decision Category	Decision Criteria	Value	Details	Confidence
Public Health Impact	Address outbreak	Low	The option is driven by new trade requirements, not outbreaks	**high**
	Prevent illness	Low	Illnesses are prevented by the application of the rule, and to an extent, by the proper use of a method, but it was determined that this was under the umbrella of operating under a valid QA system and not directly linked to the act of being able to validate a method	**high**
Trade Impact	Lost trade	High	This was a difficult question to address because there were two perceptions of the question: How much trade is lost because of not being able to validate a method (valued through import rejections) versus how much trade may be lost due to not being able to validate methods needed to address changing requirements. The second perception was selected for this exercise. It was determined that not being able to validate a method, and consequently not having a validated method, can lead to lost trade so the act of validating a method is related to the maintenance of current trade. The impact of adopting the option was perceived as high in avoiding lost trade.	**medium**
	New trade	Medium	The impact of being able to validate methods on opening new trade markets was perceived as low by some because there was a feeling that the development of new markets happens over a longer timescale where the pressures to validate a method are not immediate. Others believed that the impact was high because not being able to validate a method could mean not being allowed as an importer, or exporting product that is then rejected by the importer. Further specification of the meaning of this criterion will be needed to implement at single economy level and either interpretations were thought to have a strong rationale.	**high**

Costs	Initial Investment	$7,000	This criterion very specifically relates to the cost of the option itself, i.e. the cost of training…	**high**
	Implementation	$0	It was difficult for stakeholders to differentiate between the cost of implementation of training for the act of validation, versus the implementation of a method needed to meet new trade requirements… For example, the estimate of cost of implementation of testing for the "big six" STEC on the beef industry would be $10 Million/year as estimated by USDA, but between $72 and 144M estimated by the American Meat Institute, but the long term cost of training on validation (or even of validating a method) is zero beyond the initial investment. It was decided that the position used in the current exercise in that training the workforce to be able to perform validation has no cost of implementation and only an initial investment cost. This is a decision that affects the outcome dramatically and due to inability to come to an agreement, we indicate a low confidence in this value.	**low**
Difficulty of implementation	Management buy-in	High	Management supports the use of validated methods and the development of staff that will be able to make it happen. There was discussion however about management being prepared to take other duties away from the people who would need to be trained and do the validation activities.	**medium**
	Staff availability	Medium	This activity requires highly technical staff, a group that already has a lot of other responsibilities. It will require a dedicated effort to give these people time to learn the process.	**high**
	Strategy alignment	High	Completely in-line with APEC strategies	**high**
	Risk being unsuccessful	Low	Because there is high management buy in, there is minimal risk of not being successful	**high**

For further information on PTIN laboratory capacity building activities, please visit

http://fscf-ptin.apec.org