# University of Maryland –JIFSAN-

## Laboratory Capacity Building Needs at FSSAI.

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# Table of Contents

# Laboratory Capacity Building Needs at FSSAI

## Objectives of Laboratory Capacity Building

The objective of the GFSP program for laboratory capacity building is to develop training resources for long-term impact. We aim to develop skills where they are needed and verify that the skills are acquired through proficiency testing. Finally, we want to support the reproduction of training workshop and the implementation of sustainable training resources to ensure impact in the long term.

## Methodology

In order to design a human resources capacity building plan with FSSAI, we needed to understand the structure of the food control system and the place of laboratories. Furthermore, we considered the expansion of infrastructure around the country that is ongoing a result of a gap analysis performed internally in 2015 (outcomes reported in the 16th Meeting of Central Advisory Committee of FSSAI on February 3rd, 2016) following (largely) the "Maggie noodle" problem.

This evaluation needed to be performed within a 2-month period and without visits in India. Tools used:

- An online survey of participants in GFSP training
- Media survey (desk work)
- Informal interviews participants in GFSP training (face to face meetings)
- Additional informal interviews with stakeholders (face to face)
- The list of persons involved and dates of meetings is available in Appendix 1.

The methodology used for prioritization was developed as part of an Asia Pacific Economic Cooperation (APEC) project under the Food Safety Cooperation Forum's Partnership Training Institute Network (PTIN) in 2013. The laboratory collaboration program in APEC consists of five critical components:

1. **Accreditation**. 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 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.

## APEC Food Safety Cooperation Forum Tool

Facing the challenge of investing in a single activity each year, 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 Spring 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" reflected the public-private partnership model of the PTIN and was composed of experts from USDA (Dr. Charles Pixley and Dr. Emilio Esteban, Mrs. Cathy McKinnel, 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 of 3M, Dr. Wayne Wargo of Abbott Nutrition).

The team developed a capacity assessment tool to enable a better understanding of 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 [1]and STDF P-IMA[2].

### Framework for Prioritization

The objective of the decision 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"[3] from now on referred to as "the Guide".

As explained in the Guide, "the framework is designed for application 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 seven 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. For this section,

[1] http://www.oie.int/support-to-oie-members/pvs-evaluations/oie-pvs-tool/
[2] http://www.standardsfacility.org/sites/default/files/P-IMA_Guide_EN.pdf
[2] http://www.standardsfacility.org/sites/default/files/P-IMA_Guide_EN.pdf

the list of indicators developed by regulators and industry for the APEC work was used here as the basis for comparison of options. The hierarchy of factors and criteria used for comparison is illustrated in Figure 2 and briefly described below.

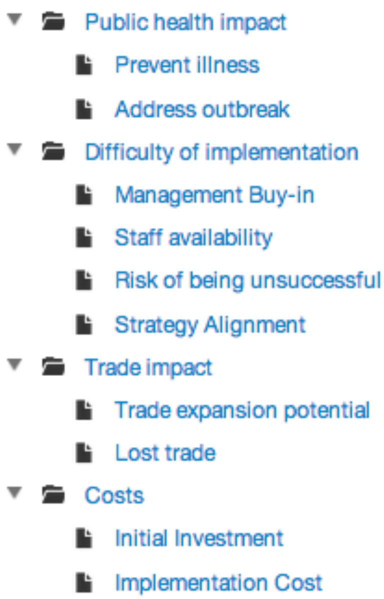


*Figure1: Indicators and criteria to compare options.*

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 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 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)

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, 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 can 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). In the case of this activity, we used trade loss information from statistics published by the US and EU on import rejection.

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. In this particular activity, the ongoing infrastructure development of FSSAI was considered an important factor and the costs associated with this plan were perceived as already incurred.

**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 related to developing human resources (i.e. training). The complete set developed in the APEC project was proposed, but the participants refined the options.

During the conversations, participants were asked questions about the different options and were given the opportunity to discuss them casually.

**Stage 3: Define Decision Criteria and Weights**

Decision criteria, indicators the importance of each, which will translate into their weights, were organically selected through the pilot work in APEC and applied here with consideration of the context, especially as it relates to FSSAI infrastructure expansion plans.

**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 felt about the information by the implementer (JIFSAN).

Stages 5-7 concern the analysis of this information, either manually of using statistical software, and decisions. Statistical software is more appropriate when detailed information about health impact, available resources, costs and trade values are considered. The short period allocated for this prioritization activity did not permit a compilation of detailed information therefore a simple manual analysis was preferred.

# FSSAI Laboratory Capacity Building Prioritization

## 1- Information Dossier

1.1 Food Control System in India

The structure of the food control system is based on the Food Safety and Standards Act of 2006. The Food Safety and Standards Authority (FSSAI) is responsible for the control of domestic and imported foods. Its Commissioner of Food Safety appoints food-testing laboratories, which play roles in a three-level system. Both public and privately owned laboratories may become FSSAI notified laboratories, but Referral Laboratories are part of the FSSAI.
Types of FSSAI Notified Laboratories:

- Level 1: Food Products Standards and Food Additives
- Level 2: Contaminants, Toxins and Residues
- Referral: R&D capabilities, training facilities, analytical capacity and investigation

Finally, all FSSAI notified laboratories must be accredited by the National Accreditation Board for Testing and Calibration (NABL) according to the standard ISO 17025.

1.2 Recurring Problems at Export as an Indicator

This prioritization is largely based on opinions from analysts. However, beyond interviews with analysts in the FSSAI jurisdiction, it is useful to look at trade data to evaluate the types of laboratory tests that would respond to the greatest sources of import rejections. Rejection of exported commodities is typically indicative of problems that are widespread in the domestic production as well. Export rejections from the European Union were used to prioritize the first step of the project in India, where pesticide residues, veterinary drugs and mycotoxins were selected. US FDA import rejection data from 2005 to 2013 was evaluated by the USDA Economic Research Service and they identified that the main problems with Indian food commodities presented for importation into the United States were *Salmonella* contamination, pesticide residues and the presence of filth. This data does not include meat and poultry, for which there is essentially no trade between the two countries. Similar information was compiled by UNIDO for the US and EU for 2002-2008 in a working paper entitled " What do Border

Rejections tell us about Trade Standards Compliance of Developing Countries?" [4] and reproduced in Figures 1 and 2.

| Country | Mycotoxins | Microbiological contaminants | Veterinary drug residues | Heavy metals | Unauthorized food additives | Product composition | Pesticide residues | Migration | Industrial contaminants | GMO/novel food | Foreign bodies | Biotoxins/contaminants | Radiation | Organoleptic | Bad or insufficient controls | Parasitic infestation | Labelling | Packaging | Other chemical contamination | Allergens | Feed additives | Not determined/other | Total |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| India | 193 | 148 | 179 | 77 | 48 | 139 | 65 | 9 | 5 | 7 | 7 | 3 | 7 | 18 | 1 | 0 | 3 | 0 | 1 | 2 | 0 | 16 | 928 |

Figure 1: Largest sources of import rejections of Indian commodities by the EU 2002-2008.

| Country | Labelling | Unregistered process/ manufacturer | Filthy/unsanitary | Unauthorized food additives | Microbiological contaminants | Pesticide residues | Veterinary drug residues | Poisonous | Biotoxins/contaminant | Product not approved/ no import permit | HACCP | Mycotoxins | Product composition | Foreign bodies | Other chemical contamination | Packaging | Allergens | Adulteration | Quality standards | Inadequate information | Radiation | Total |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| India | 3,829 | 1,246 | 1,722 | 1,346 | 1,532 | 454 | 16 | 48 | 2 | 28 | 0 | 37 | 15 | 38 | 10 | 4 | 4 | 1 | 1 | 0 | 0 | 10,333 |

Figure 2: Largest sources of import rejections of Indian commodities by the US 2002-2008.

A closer look at rejections and import alerts from 2016 indicates that spices, processed food and feed, rice, seafood and produce show the most problems (table 1).

Shipment rejections indicate the rejection of individual consignments, while import alerts indicate that the FDA suggests that particular commodities imported by specific firms not be accepted for import without evidence provided by the firm that the products comply. So an import alert may list 1 firm, or 50 firms. Put simply, import alerts are indicative of recurring problems, as opposed to rejected shipments which concern only one shipment at a time.

[4]

| Commodity | US FDA Import Alerts | US Shipment Rejections 2016 |
|---|---|---|
| Dairy | 1 | 34 |
| Honey | 1 | NA |
| Dietary suppl. | 2 | 43 |
| Processed foods/feed | 16 | 904 |
| Fish & Seafood | 10 | 320 |
| Spices | 3 | 1117 |
| Produce | 2 | 290 |
| Rice | | 626 |

Table 1: Import alerts and rejection data for Indian commodities by US FDA (2016). Note that there were no import alerts on rice.

1.3 Relevant Issues Identified in 2015

The review of the food control system conducted internally in FSSAI in 2015 is largely reported in the minutes of the 16th Meeting of Central Advisory Committee of FSSAI on February 3rd, 2016. The observations related to laboratories, while in the process of being addressed, are still relevant:

- Lack of adequate human resources
- Outdated infrastructure
- Shortage of reagents and supplies to carry out tests
- Most state laboratories are not fully functional and cannot perform all three wings of mandate (chemical, microbiological and heavy metals analyses)
- Financial constraints in most of the state laboratories
    - High sample load
    - Lack of appropriate equipment for contaminants and sample load
    - State labs have little to no capacity in microbiology

First, laboratories lack sufficient numbers of trained analysts and scientists to review the data. They often operate in inadequate infrastructure that cannot support the installation of the laboratory equipment needed to test against modern standards. The media widely reported that most laboratories at the State level cannot perform all of their functions due to the infrastructure and staff shortcomings. State laboratories (especially) are not adequately funded to purchase the supplies they need to handle the sample throughput expected from them. It is not clear that the new partial central control of funds will resolve this issue because of an overall underfunding of the functions.

Finally, the media also reports that focus of most laboratories has been chemical contaminants, but the changing demographics (more ready-to-eat foods in urban centers, less time to cook, less traditional foods that are boiled for long periods) will very rapidly emphasize the deficiencies in the capacity to test for microbial pathogens in food.

1.4 Opinions of Analysts and M

JIFSAN, on behalf of the GFSP's Laboratory Capacity Building Program conducted a short review of priority capacity building needs in food control laboratories in the 3 months between the first GFSP-sponsored training in Singapore, and this meeting.

a. Perception of Support

We first asked analysts how they felt about their work and their laboratories. Most analysts (the exception being in referral labs) feel isolated in their laboratory; they feel that they do not have a group of peers that they can reach out to when they need support. Analysts also feel that the workload is disproportional with the infrastructure and equipment. Long hours, far beyond the "normal workday" are needed to meet the sample throughput demand.

b. Perception of Skills

In terms of technical skills, we found analysts confident about their skills and also realistic about the scope of their technical skills. A difference it seen between highly skilled analysts and newer recruits in terms of their priorities.

Lower skilled analysts show a strong desire to learn and increase both the breadth skills and their network of peers, while the (often more senior) highly skilled analysts feel somewhat frustrated by a lack of inclusion of scientists in management decisions. They also focus their concerns on the mission of their laboratory when asked about growth and feel that the lack of infrastructure and latest technologies is preventing them from achieving their goals.

This indicates that the desire for training is a very personal one among newer analysts and lack of training opportunities for their staff not perceived as a roadblock by the managers who are more concerned with infrastructures. Managers feel that provided the instruments, they will be able to train their analysts.

The review did not dive into the individual laboratory needs in microbiology in large part because the interviewees in public labs were all chemists. Nevertheless, we wished to look into the needs in microbiology in order to plan capacity building activities in the medium term, so we initiated discussions in the groups and an interview with an Advisor to FSSAI. We also used the trade data, more specifically the reasons for import rejections related to microbiology.

## 2- Capacity Building Choice Set

The second stage of the prioritization activity is to define a set of workforce capacity building options to prioritize. The list compiled by the APEC group for general use was considered adequate:

- Screening (rapid) methods for mycotoxins
- Confirmation methods for multi-mycotoxins
- Methods for multi-residues of veterinary drugs
- Methods for multi-residue testing of pesticides
- Non-targeted contaminants analysis
- Screening methods for industrial chemicals
- Advanced mass spectrometry (for contaminants)
- Validation of chemical methods (including matrix extension)
- General food microbiology training
- Rapid (molecular) methods for food microbiology (rtPCR-based)
- Whole genome sequencing to replace PFGE (PulseNet for outbreaks)
- Screening methods in food microbiology
- Methods for the determination of filth
- Methods for the determination of *Salmonella*
- Methods for the determination of *E.coli* (STEC)

## 3- Define Decision Criteria and Weights

The criteria of public health impact, ease of implementation, trade impact and costs as defined in the APEC project were used without changes.

Weights for the criteria were not predefined and all criteria were considered equal.

## 4- Information Cards

An information card is the collection of data, discussion points and relevant information about each option on the choice set. The information is by definition biased by the participants in a consultation, whom in this case were almost exclusively chemical analysts. The trade impact information was also limited to trade with the EU and US. Finally, the cost and ease of implementation were approached from a GFSP perspective, where we considered both in-country resources and access to GFSP partners.

The information cards for each option are available in Appendix 2.

## 5- Selection of Priorities

Phase of the laboratory capacity building project at the GFSP focused on chemical analysis and addressed the topics of methods of determination for pesticides, mycotoxins and veterinary drugs in food. They are identified in Table 2.

**Priorities for Phase 2 of Laboratory Capacity Building**:
1- Chemistry
- Screening methods for industrial chemical residues in food
- Advanced training in mass spectrometry (for contaminant residues in food)
- Training on method validation, including matrix extension

2- Microbiology
- Training in rapid (focus on molecular) methods for microbial contaminants in food
- Methods of determination of *Salmonella* in food
- Standard methods for the determination of filth

These priorities were determined based on the scores obtained using the multi-criteria decision analysis described above. Table 2 summarizes the scores.

Table 2: Score and selection of priorities for phase 2 of the GFSP project.

| Laboratory Capacity Building Options | Total score | Proposed Phase 1-2 |
|---|---|---|
| "Chemistry" | | |
| Screening methods for mycotoxins | 10 -$ | |
| Confirmation methods for multi-mycotoxins | 14 -$ | Phase 1 |
| Methods for multi-residues of veterinary drugs | 12 -$ | Phase 1 |
| Methods for multi-residue testing of pesticides | 15 -$ | Phase 1 |
| Non-targeted contaminants analysis | 6 -$ | |
| Screening methods for industrial chemicals | 12 -$ | Phase 2 |
| Advanced mass spectrometry (for contaminants) | 12 -$ | Phase 2 |
| Validation of chemical methods (incl. matrix extension) | 11 -$ | Phase 2 |
| "Microbiology" | | |
| General food microbiology training | 9 -$ | |
| Rapid (molecular) methods for food microbiology (rtPCR-based) | 11 -$$ | Phase 2 |
| Whole genome sequencing to replace PFGE | 8 -$ | |
| Screening methods in food microbiology | 11 -$$ | |
| Methods for the determination of filth | 12 -$ | Phase 2 |
| Methods for the determination of Salmonella | 13 -$ | Phase 2 |
| Methods for the determination of E. coli (STEC) | 11 -$ | |
| Validation of microbiological methods | 5 -$ | |

**Rationale for the Specific Training Needs in Chemistry**

The scores obtained in the evaluation of options are used to determine priorities. The three priorities addressed in the first phase of the GFSP-FSSAI project are indicated in the table and correspond to some of the highest scoring options.

The additional training needs emphasized by the participants included both analytical methods and skills to use the data generated by these methods, a topic that was raised as part of the method validation option. There is a desire to be able to review data for conformance as a means of accessing promotions, but also a desire by higher-level managers to use the data in risk analysis to develop Indian standards for domestic foods. These aspects were not part of the criteria for selection, but are worth mentioning here.

Analysts also indicated that they did not know of, or completely understand, the sampling plans that lead to the samples they receive in the laboratories, which in turn leads them to question how representative the samples are. Methods validation would include the subject of sampling.

Finally, bench analysts do not feel confident about writing Standard Operating Procedures and wish to rely on SOPs written by others. While this process works well in highly hierarchical organizations such as FSSAI and its referral labs, it is a significant hurdle for smaller organizations like State laboratories. Private sector laboratories did not share the need for training in QA or scientific principles. These topics were deemed part of the methods validation option.

The principles of the analytical techniques as well as the biochemistry of the commodities and foods themselves were considered a need that may be fulfilled with literature, but analysts don't know where to find it. We included these topics in the option of advanced mass spectrometry training.

As a means of comparison for the demand placed on the analysts, we can look at the US and EU systems. In the US, regulatory laboratories almost exclusively test agricultural commodities… Commodities are relatively simpler with either high water OR high fat content, acid or alkaline pH, and a need to test for either pesticides or veterinary drugs for example. In the EU, a large network of reference laboratories is heavily funded to develop and see to the validation and deployment of fit-for-purpose methods. The Indian system, which has a large component of testing on finished foods, requires analysts to test complex food products combining many agricultural commodities and consequently requiring testing for many classes of contaminants. Analysts felt that the Indian system was similar to the EU when the FSSAI methods manual was prescriptive and very detailed, but that the current manual doesn't provide them with the methods that they need.

Since Western scientists who largely do not deal with finished foods publish most analytical methods in the peer-reviewed literature, there is very little information available on methods adaptation for complex matrices. This had a large influence on the desire to see the option of methods validation get implemented.

Specific Training Needs in Microbiology

Similarly to the observation in chemistry, microbiological labs feel that the food control system will not be able to meet the sample throughput needs with traditional microbiological methods, supporting the higher score obtained for the option of training in rapid molecular-based methods. This private laboratories mentioned already being equipped with molecular methods and look to move into whole genome sequencing in the future to match the data available in the West for outbreak investigation (as a fee-for-service to exporters). The public health laboratories see the global PulseNet system moving to Whole Genome Sequencing, but it is still not perceived as essential (among the group interviewed).

Interestingly, filth analysis was a top reason for import rejection, but interviewees did not believe these analyses are done in their laboratories. Filth analysis and Salmonella scored high because of the trade concerns and ease of implementation, while this group did not recognize a high public health impact.

The needs identified were:
1. Screening (rapid) methods based on molecular testing
2. Adapted confirmation methods, probably using traditional selective culture methods (to keep costs low) and the organism of greater interest for initial training: *Salmonella*
    - Whole genome sequencing in Referral Labs for outbreak investigation
3. Filth analysis to reduce trade impact

Specific Needs in Laboratory Operations Support

Last but not least, analysts raised the issues associated with modern instrument maintenance. While analysts do not feel it should be their job to maintain instruments, they do wish to have access to trained engineers who would perform this maintenance for them. Skills for basic troubleshooting should be developed at each laboratory, and analysts feel that centrally located resources could support for more complex issues.

To be clear, analysts realize that internal support cannot replace service engineers from the vendors for repairs, but they feel that the in-house service should deal with what is perceived in Western labs as in-house maintenance.

Finally State labs especially feel that the development and maintenance of a sourcing system for reagents and kits would help meet workload requirement by avoiding downtime. Among the many advantages perceived by analysts, avoiding downtime due to delays in deliveries, lowering costs and also aligning methods with other labs through the decision-making process of selecting what to keep in

## Conclusions

Laboratory training needs are broad in scope, but analysts now feel that the expertise is available in India in many areas of need (especially those addressed in phase 1 of the GFSP-FSSAI project), and only requires to be managed for effective deployment across agencies and laboratories through train-the-trainer programs.

A set of three additional training topics was selected to propose for the second phase of the project based on the relevance to both trade and health, and in general, the difficulty of implementation was not perceived as a hurdle.

There was not an equivalent confidence in the availability of trainers in microbiology, but it could be due to the interview pool that was composed largely of chemists and a few laboratory managers.

Discussions indicated that analysts want more networking opportunities and modern instruments to meet the desired sample load. Analysts want more standard methods fit for the commodities they are given (especially for processed foods). Finally, a support system in terms of instrument maintenance and procurement was suggested that could facilitate the expansion of the FSSAI portfolio of analyses.

# Appendix 1: Participants in discussions for prioritization

| Date: December 9, 2016 | Group discussion |
|---|---|
| Mr. M.A. Sreenivasa | CSIR- Central Food Technological Research Institue, Mysore |
| Mrs. Aruna Bandil | Food Safety & Standards Authority of India, Delhi |
| Mr. Surender Singh Raghav | FSSAI,Ghaziabad |
| Mr. Hemant Kulkarni | State Public Health Laboratory, Pune |
| Dr. Rajesh .R | Export Inspection Agency, Kolkota |
| Dr. Priti Amritkar | Envirocare Labs Pvt Ltd, Thane |
| Dr. Archna Tiwari | Food Safety & Standards Authority of India, Delhi |
| Dr. Aparna Pharande | Ashwamedh Engineers & Consultants-Laboratory Services Division, Nashik |
| Dr.Debadutta Mishra | Central Food Laboratory (FSSAI), Kolkata |
| Dr. Cherukuri Sreenivasa Rao | Director , National Institute of Plant Health Management, Hyderabad |

| Date: April 27, 2017 | Group discussion |
|---|---|
| Dr. Satyen Kumar Panda | Indian Council of Agricultural Research, Cochin |
| Dr. Anoop A. Krishnan | Export Inspection Agency, Kolkata |
| Dr. Prasanna Kumar Patil | Central Institute of Brackish Water Aquaculture, Chennai |
| Anupam Gogoi | Govt. of Assam, State Public Health Laboratory, Guwahati |
| Ms. Kanika Aggarwal | Food Safety & Standards Authority of India, New Delh |
| Dr. Rakesh Kumar Tirpude | Food and Drug Laboratory, Mumbai |

| Date: April 28, 2017 | Private meeting |
|---|---|
| Dr. Bhaskar Narayan | ADVISOR, FOOD SAFETY & STANDARDS AUTHORITY OF INDIA (FSSAI), NEW DELHI |
| Dr. Shrinivas Joshi | Waters Pvt Ltd, Bangalore |

| Date: June 1, 2017 | Group discussion |
|---|---|
| Mr. Zavier T.V. | Spice Board Quality Evaluation Laboratory, Kochi |
| Dr. Prasanna Vasu | CFTRI, Mysore |
| Ms. Vanajakshi | CFTRI, Mysore |
| Sri. Chabungbam Sanajaoba Meitei | State Public Health, Manipur |
| Dr. Chetan T.P. | State Food Laboratory, Bangalore |
| Ms. Sharada H. Roddammanavar | State Food Laboratory, Bangalore |
| Ms. Ajini A.S. | CEPCI Laboratory, Kollam |
| Dr. Jayrajsinh Sarvaiya | Gujarat Forensic Science University, Gandhinagar |
| Ms. Kavitha M. | FSSAI, New Delhi |
| Sri. Balamurali Krishna Kondapalli | Intertek Pvt Ltd, Hyderabad |
| Ms. Elizabeth M. Gomes | Bangalore Testing Laboratory Pvt Ltd, Bangalore |
| Dr. D.P. Gurumoorthi | Scientific Food Testing Services (P) Ttd, Chennai |
| Manoranjan Kumar | State Food and Drug Testing Laboratory, Rudrapur |

## Appendix 2: Information Cards

Each option was discussed and pros and cons were noted. A score, between 1 and 5, was assigned based on the comments, where 1 is low and 5 is high priority.

"Chemistry"
Option 1: Screening methods for mycotoxins

| Criteria | Information | Score |
|---|---|---|
| Public Health Impact | - Low: Found in spices, but reduced by cooking (presumably)<br>- Many deaths in 1970s but no recent outbreaks<br>- Low in staple food rice | 2 |
| Ease of Implementation | Screening not common in labs, mostly confirmation and quantitation<br>Would not be very expensive to start screening, training partners and facilities are available. | 5 |
| Trade Impact | - Priority cause of rejects in EU, but screening insufficient in trade, require confirmation<br>- Could help prioritize use of resources for confirmation | 3 |
| Costs (training only) | - Low because of ease and kits are cheap | low |

Option 2: Confirmation methods for mycotoxins

| Criteria | Information | Score |
|---|---|---|
| Public Health Impact | - Same as screening | 4 |
| Ease of Implementation | Easy because part of FSSAI infrastructure plan and training partners and facilities available | 5 |
| Trade Impact | - Priority cause of rejects in EU | 5 |
| Costs (training only) | - Low because of ease and infrastructure resources already allocated | low |

Option 3: Methods for multi-residue of veterinary drugs

| Criteria | Information | Score |
|---|---|---|
| Public Health Impact | - Unknown, although fears of antimicrobial resistance warrant better control of veterinary drug use | 2 |
| Ease of Implementation | - Easy because part of FSSAI infrastructure plan and training partners and facilities available<br>-Medium because methods not common for processed foods | 5 |
| Trade Impact | - Priority cause of rejects in EU | 5 |
| Costs (training only) | - Low because of ease and infrastructure resources already allocated | low |

Option 4: Methods for multi-residue of pesticides

| Criteria | Information | Score |
|---|---|---|
| Public Health Impact | - Very high for applicators, farming families<br>- Great fear of misuse due to lack of education<br>- Great fear due to casual marketing practices (unlabeled containers, dosage unspecified, etc) | 5 |
| Ease of Implementation | -Easy because part of FSSAI infrastructure plan and training partners and facilities available<br>- Medium because methods not common for processed foods | 5 |
| Trade Impact | - Priority cause of rejects in EU | 5 |
| Costs (training only) | - Low because of ease and infrastructure resources already allocated | low |

Option 5: Non-targeted contaminants analysis

| Criteria | Information | Score |
|---|---|---|
| Public Health Impact | - Medium: Important fear from educated population but "over-rated"<br>- Low don't feel that people get sick from unknowns | 2 |
| Ease of Implementation | - Difficult because no FSSAI facility is equipped, but training could be easy because training partners and facilities are available<br>- Difficult because of matrix variety presented to labs, methods not adapted | 1 |
| Trade Impact | - Low because completely unexpected substances are not such a big concern in India<br>- Also because we know what we want to look for so we could use targeted tests<br>- High because feel like it would help build trust | 3 |
| Costs (training only) | - Low because of available training partners and facilities | low |

Option 6: Screening methods for industrial chemicals

| Criteria | Information | Score |
|---|---|---|
| Public Health Impact | - Low, not perceived as large problem (like China)<br>- High, would like to know if it is a problem<br>- High because techniques really includes all chemical contaminants, not just industrial | 4 |
| Ease of Implementation | - Easy because part of infrastructure plan<br>- Hard because not many laboratories have specialists in industrial chemicals (analysts don't know what they should look for)<br>- Easy because it also works for pest., vet. drugs, additives, etc. | 5 |
| Trade Impact | - Low in EU and US<br>- High because of fear that if someone starts looking, they may find it<br>- High because may reduce problems with agric. contaminants | 3 |
| Costs (training only) | - Low because of available training partners and facilities | low |

Option 7: Advanced mass spectrometry (for contaminants)

| Criteria | Information | Score |
|---|---|---|
| Public Health Impact | - Medium because methods can be applied already | 3 |
| Ease of Implementation | - Easy because part of infrastructure plan<br>- Easy because access to training partners | 5 |
| Trade Impact | - Medium since touches on problems in EU and US<br>- High because of fear that unknown problem may exist | 4 |
| Costs (training only) | - Low because of available training partners and facilities | low |

Option 7: Validation of chemical methods (including matrix extension)

| Criteria | Information | Score |
|---|---|---|
| Public Health Impact | - Low because we can use validated methods | 2 |
| Ease of Implementation | - Easy, just classroom training and many training partners available for validation part<br>- Medium because need to address different matrices, but easy because expertise is available | 5 |
| Trade Impact | - Low because we can use validated methods<br>- High because validated methods don't work for all matrices, especially processed foods | 4 |
| Costs (training only) | - Low because of available training partners and infrastructure within FSSAI development plan | low |

"Microbiology":

Option 1: General Food Microbiology

| Criteria | Information | Score |
|---|---|---|
| Public Health Impact | - Low for general food microbiology<br>- Not sure what it means<br>- Feel there are plenty of food micro courses in universities | 1 |
| Ease of Implementation | - High because very basic and plenty of training partners available<br>-Low because too general to get time for training | 3 |
| Trade Impact | - Low, too basic to have relevance with trade<br>- High because lots of rejections in US and EU because of microbiology<br>- High if industry was the target instead of FSSAI | 5 |
| Costs (training only) | - Low because of ease | low |

Option 2: Rapid (molecular) methods for food microbiology

| Criteria | Information | Score |
|---|---|---|
| Public Health Impact | - Medium, don't feel so many people get sick in India | 3 |
| Ease of Implementation | - Hard, very few labs have equipment, not sure it is in infrastructure plan<br>- Easy because training partners are available | 3 |
| Trade Impact | - High because of EU and US rejections<br>- High to accelerate release of exports | 5 |
| Costs (training only) | - Low because of availability of training partners | medium |

Option 3: Whole genome sequencing to replace PFGE (PulseNet for outbreaks)

| Criteria | Information | Score |
|---|---|---|
| Public Health Impact | - High when an outbreak happens<br>- Not sure how often outbreaks happen<br>- Current tools may be enough (?) (not right group to discuss) | 4 |
| Ease of Implementation | - Low because instrumentation not available and not part of FSSAI infrastructure plan<br>- Training partners available, but facilities abroad only | 2 |
| Trade Impact | - No right group to ask<br>- Perceived as high if can "clear" India as cause of outbreak...<br>- Perceived as medium to create trust in system | 2 |
| Costs (training only) | - High but has to be abroad, facilities not available for reproductions | high |

Option 4: Screening methods in food microbiology

| Criteria | Information | Score |
|---|---|---|
| Public Health Impact | - High as a preventative measure, especially for cities<br>-Low because all food is cooked<br>- Low because people don't seem to get sick from food in India | 4 |
| Ease of Implementation | - High because many labs have facilities for screening methods<br>- High because many training partners available<br>- Low because reference strains not available | 4 |
| Trade Impact | - Unknown, seems to vague to have measurable impact<br>- Not right audience for this question<br>- Could be high if addresses US and EU rejections | 3 |
| Costs (training only) | - Low because many labs and training partners available<br>- High because reference strains are not available and are difficult to import | medium |

Option 5: Methods for determination of filth

| Criteria | Information | Score |
|---|---|---|
| Public Health Impact | - Low, people don't know what filth is<br>- Indians are used to washing commodities, expect physical contaminants | 2 |
| Ease of Implementation | - High because training partners available<br>- High because requires "usual" equipment like microscopes | 5 |
| Trade Impact | - High because of rejections from US | 5 |
| Costs (training only) | - Low because of availability of training partners and no requirement for special equipment | low |

Option 6: Methods for determination of *Salmonella*

| Criteria | Information | Score |
|---|---|---|
| Public Health Impact | - High for cities where people each differently<br>- High for children<br>- Low because most traditional food is cooked | 4 |
| Ease of Implementation | - High because labs exist who do these tests<br>- Low because labs are overloaded, no time for training<br>- High because training partners are available<br>- Low if we need a lot of reference strains | 4 |
| Trade Impact | - High because of rejections from US | 5 |
| Costs (training only) | - Low because of availability of training partners and facilities available in India | low |

Option 7: Methods for determination of *E. coli*

| Criteria | Information | Score |
|---|---|---|
| Public Health Impact | - High for cities where people each differently<br>- Low because many Indians are vegetarian<br>- Low because traditional food is cooked | 2 |
| Ease of Implementation | - High because labs exist who do these tests<br>- Low because labs are overloaded, no time for training<br>- High because training partners are available<br>- Low if we need a lot of reference strains | 4 |
| Trade Impact | - High because of rejections from US<br>- High, we think it is a growing problem in aquaculture | 5 |
| Costs (training only) | - Low because of availability of training partners and facilities available in India | low |

Option 8: Validation of microbiological methods

| Criteria | Information | Score |
|---|---|---|
| Public Health Impact | - Low because we can use validated methods | 1 |
| Ease of Implementation | - High because classroom training and training partners available<br>- Low because labs don't have statisticians on staff | 3 |
| Trade Impact | - Low because we can use validated methods<br>- (Not right group to ask, not aware of lack of methods) | 1 |
| Costs (training only) | - Low because only classroom | low |