Guide for Assessing Investment Needs in Laboratory Capacities for Managing Food Safety, Plant Health, and Animal Health

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AGRICULTURE AND RURAL DEVELOPMENT
Sustainable Development Network

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THE WORLD BANK
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<tr>
<td>AVMA</td>
<td>American Veterinary Medical Association</td>
</tr>
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<td>AOAC</td>
<td>Association of Official Analytical Chemists</td>
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<tr>
<td>ASEAN</td>
<td>Association of Southeast Asian Nations</td>
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<tr>
<td>BSE</td>
<td>Bovine Spongiform Encephalopathy</td>
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<tr>
<td>CAADP</td>
<td>Comprehensive African Agricultural Development Program</td>
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<td>CAC</td>
<td>Codex Alimentarius Commission</td>
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<td>Codex</td>
<td>Codex Alimentarius</td>
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<tr>
<td>Cofrac</td>
<td>French Accreditation Committee (Comite Francais d'Accreditation)</td>
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<tr>
<td>DNA</td>
<td>Deoxyribonucleic acid</td>
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<tr>
<td>ELISA</td>
<td>Enzyme linked immunosorbent assay</td>
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<td>EC</td>
<td>European Commission</td>
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<td>EU</td>
<td>European Union</td>
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<tr>
<td>EurepGAP</td>
<td>Euro-Retailer Produce Working Group Good Agricultural Practice (now Global GAP)</td>
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<td>FAO</td>
<td>Food and Agriculture Organization of the United Nations</td>
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<td>FDA</td>
<td>Food and Drug Administration (United States)</td>
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<tr>
<td>FMD</td>
<td>Foot and Mouth Disease</td>
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<td>GAP</td>
<td>Good Agricultural Practices</td>
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<tr>
<td>GC-MS</td>
<td>Gas Chromatography with Mass Spectrometry</td>
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<tr>
<td>Global GAP</td>
<td>see EurepGAP</td>
</tr>
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<td>GLP</td>
<td>Good Laboratory Practice</td>
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<tr>
<td>GMO</td>
<td>Genetically Modified Organism</td>
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<td>GMP</td>
<td>Good Manufacturing Practices</td>
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<td>GTZ</td>
<td>German Agency for Technical Cooperation</td>
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<td>HACCP</td>
<td>Hazard Analysis and Critical Control Points</td>
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<td>IFAD</td>
<td>International Fund for Agricultural Development</td>
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<td>IFCC</td>
<td>International Federation of Clinical Chemistry</td>
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<td>IFI</td>
<td>International Financial Institution</td>
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<td>ILAC</td>
<td>International Laboratory Accreditation Cooperation</td>
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<td>IPPC</td>
<td>International Plant Protection Convention</td>
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<td>ISO</td>
<td>International Standard Organization</td>
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<tr>
<td>LS-MS</td>
<td>Liquid Chromatography – Mass Spectrometry</td>
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<tr>
<td>M&amp;E</td>
<td>Monitoring and evaluation</td>
</tr>
<tr>
<td>MRL</td>
<td>Maximum Residue Limit</td>
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<tr>
<td>NEPAD</td>
<td>New Partnership for African Development</td>
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<tr>
<td>NGO</td>
<td>Non Governmental Organization</td>
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<tr>
<td>NPPO</td>
<td>National Plant Protection Organization</td>
</tr>
<tr>
<td>O&amp;M</td>
<td>Operations and Maintenance</td>
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<tr>
<td>OECD</td>
<td>Organization for Economic Cooperation and Development</td>
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<td>OIE</td>
<td>Office of International Epizootics</td>
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<td>PAHO</td>
<td>Pan-American Health Organization</td>
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<tr>
<td>PCR</td>
<td>Polymerase Chain Reaction</td>
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<td>SADC</td>
<td>Southern Africa Development Council</td>
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<td>SANAS</td>
<td>South African National Accreditation System</td>
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<td>SOP</td>
<td>Standard Operating Procedures</td>
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<tr>
<td>SPS</td>
<td>Sanitary and Phytosanitary</td>
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<tr>
<td>STDF</td>
<td>Standards and Trade Development Facility</td>
</tr>
<tr>
<td>TBT</td>
<td>Technical Barriers to Trade</td>
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<tr>
<td>UEMOA</td>
<td>West African Economic and Monetary Union (Union Economique et Monétaire Ouest Africaine)</td>
</tr>
<tr>
<td>UK</td>
<td>United Kingdom</td>
</tr>
<tr>
<td>UNIDO</td>
<td>United Nations Industrial Development Organization</td>
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<td>WHO</td>
<td>World Health Organization</td>
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<td>WTO</td>
<td>World Trade Organization</td>
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Foreword and Acknowledgements

In their effort to protect public health, biodiversity, and the environment, while facilitating market access and supporting agricultural incomes, developing countries face challenges with respect to the verification of food safety and the management of plant and animal health issues. Laboratory testing is a crucial part of the agricultural production and marketing system, especially with respect to sanitary and phytosanitary (SPS) measures that support domestic commerce and foreign trade in agri-food products.

Many countries are making new investment in national laboratory systems, and donors are often approached for financial and technical support. While there are some examples of successful projects in this field, a disappointing number of investments have failed to achieve the desired results in terms of increased capacity, quality of results obtained, international recognition, customer service, or sustainability. Given the high cost involved in most laboratory development projects, inappropriate investment decisions often cause a huge waste of resources.

The purpose of the guide is thus to help policymakers and senior managers in developing countries, as well as staff in donor agencies and international organizations such as the World Bank, to make better decisions with regard to investing in laboratory establishment or upgrading. To achieve that goal, this guide sets out to inform decision makers of the broad range of factors that need to be considered when assessing the need for such investment. Typically these include: the structure, conduct, and performance of the agri-food sector; national trade and SPS policies; the relative importance of different subsectors and industries; regulations applicable to agricultural and related manufacturing activities; government institutions; the condition of laboratory infrastructure; and level of human skills. While this guide emphasizes public laboratory capacity, it also presents a number of alternatives, including outsourcing and encouraging private investment. Lessons from past projects are discussed throughout to help new projects avoid mistakes and pitfalls.

The development of this guide was led by the World Bank under the supervision of John Lamb. Substantial technical input came from the United Nations Industrial Development Organization (UNIDO), under the supervision of Steffen Kaeser. A first draft of the guide was prepared by Kees van der Meer and submitted on December 31, 2007. Important contributions were received from other World Bank and UNIDO consultants, including Maria Beug-Deeb, Tom Deeb, N.V. Rama Rao, Upali Samarajeewa, Tjaart W. Schillhorn van Veen and Xin Qin. Cees de Haan, Brian Bedard, and others provided useful comments and suggestions, for which the team is very grateful.

As part of the knowledge product preparation process, a consultative workshop was held by the World Bank and UNIDO at WTO headquarters in Geneva on November 15-16, 2007, to exchange views and experiences on the development of laboratory capacities in developing countries. Over 40 policymakers, laboratory managers, representatives from the private sector, donors and international organizations participated. We would like to thank the WTO-coordinated Standards and Trade Development Facility (STDF), and especially the then Secretary of STDF (Michael Roberts), for hosting the event. We also extend our thanks to the workshop participants for providing information on their own activities, sharing their insight on various issues regarding lab investment, and providing comments on the draft document and accompanying PowerPoint presentations.
Funding for the development of this guide comes from the World Bank, the World Bank Netherlands Partnership Program (BNPP) and UNIDO. However, the views and recommendations in this guide are those of the preparation team, and do not necessarily reflect the views and strategies of these agencies.

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Executive Summary

Background
Many developing countries have plans to expand or upgrade laboratory capacities that support food and agriculture, either to improve access to foreign markets through better compliance with Sanitary and Phytosanitary (SPS) requirements, or to improve plant and animal health (hereafter “agricultural health”) and food safety in their domestic market. Yet the outcome from such investments in the past has not been very satisfactory.

Intended uses of this guide
Although this note was prepared mainly to raise the awareness of issues and of lessons learned to improve lending operations prepared by World Bank task team leaders, it was deliberately written also to guide staff in donor agencies and international organizations as well as other decision-makers in developing countries. It is designed to be used as a tool for assessing investment needs in laboratory capacities, for analyzing the most viable and cost-effective way to provide the laboratory services required, or to evaluate the adequacy of existing national laboratory systems for food and agriculture.

Objective functions to guide investments
Although it is often the case that laboratory investment decisions are influenced by personal history, preferences, ambition, perceived crises, or other non-objective factors, this paper will argue in favor of more objective criteria.

Recommendation:
- Decisions about investment in agricultural laboratories should be based on the likely contribution to achievement of either: (1) better or safer agri-food products; (2) improved animal or plant health; (3) environmental protection; or (4) enhanced commerce or trade. The relative importance of these objective functions will vary from one situation to another. Usually more than one objective should be pursued at once.

Metrics for decision-making
In pursuit of any combination of the four objectives suggested above, decision-makers need some basis for judging whether to move forward at all, and if so, how to select among options that compete for scarce resources.

Recommendations:
- Decisions about investment in agricultural laboratories should be judged by the extent to which the investment would either measurably improve: (1) efficiency (including costs or turn-around time); (2) effectiveness (especially the quality and reliability of testing results, but also contribution toward opening new markets or other pathways to economic growth); or (3) service (including the types of analytical testing offered, the numbers of samples that can be handled at one time, and value-addition such as recommendations for action).
Improvements should be valued and evaluated in terms of increased net benefits in terms of reduced health and economic risks, balanced again incremental investment in fixed assets or human capital development as well as likely changes in net operational costs of major services.

Sustainability

Many investments in public laboratories for food and agriculture are not sustainable, at least from a financial standpoint, and sometimes technically as well. One reason is that the initial establishment or major upgrades are carried out in isolation from the broader food safety and agricultural health regulatory system of which they should form an integral part, so the investment may lack widespread support, even relevance. Another reason is that the decision process that led to significant investment may not have made sufficient provision for unrecoverable costs of operation as well as future staff development and service development. Still another reason—as this paper will argue forcefully—is that many public sector laboratories are not run in a business-like manner.

Recommendations:

- Make a thorough assessment of the strengths, weaknesses, opportunities and challenges of the overall food safety and agricultural health system before considering any major investment in laboratories.
- Consider and if appropriate initiate actions necessary to effect institutional and regulatory reforms so that laboratories will have a clear mandate and responsibilities, as well as a process for setting priorities that takes into account all relevant factors.
- Be sure that decisions on any significant investment in laboratories include plans for regular funding of operational, maintenance, and upgrade costs.

Public and private laboratories

While governments tend to focus on expanding the capacities of public laboratories, it should be noted that private laboratories can and do play important roles in the market for diagnostic and analytical services. Indeed, in some developed countries, outsourcing and contingent arrangements for surge situations are common. Ultimately what matters is the overall capacity of the national—and for very large countries, the sub-national—agricultural laboratory system, which is a mixture of public and private.

Suppliers to high-end markets that have demanding food safety standards often rely mostly on private laboratories. Many major retailers and importers in foreign markets now require independent third party certification, which can be provided either by governmental or private service providers.

Recommendations:

- Recognize that the government should not try to provide laboratory services that the private sector is capable of providing faster or more efficiently
- Don’t use public subsidies and regulatory power for unfair competition of public laboratories with private suppliers.
- Encourage the private supply of services, as well as friendly competition by providing: (i) a good investment climate; (ii) a level playing field for public and private laboratories with regard to taxation, subsidies, and
requirements for licenses, laboratory standards and quality control; and (iii) continuous public-private
dialogue.

Market access and export promotion
The government’s role in expanding market access and facilitating export growth varies much with
the products exported and requirements of destination markets. The role of public laboratories in
boosting exports and market access is often over-estimated.

The main responsibilities of government vis-à-vis trading partners are to provide: (i) information
about the pest and disease situation in the source country that might affect admissibility; (ii)
information about regulations for import of raw, transformed or manufactured food, feed, fiber or
industrial products that derive from agriculture; and (iii) where required, certification for
particular export products. Since most of the related inspection and diagnostic tasks can be
outsourced, that option should always be on the table.

It is commonly said that countries must adopt international SPS standards, for which WTO defers
to the international standard-setting bodies. Yet in reality the SPS Agreement allows ample room
for selectivity based on the country’s national interest and risk preferences.

In addition, over the last two decades there has been a realization that product safety cannot be
guaranteed by end product testing alone. From a regulatory standpoint, the emphasis has moved
away from market or product testing towards quality management systems and process evaluations.
The shift towards risk-based conformity assessments resulted in decreased sample loads for the
regulatory laboratories.

**Recommendations:**
- Work with stakeholders to clarify and build consensus regarding the proper role of agricultural laboratories
in terms of market access and export promotion.
- Selectively improve diagnostic capacities in line with a country’s evolving needs.

Limiting the scope of services
In many developing and transition countries there is artificial demand for diagnostic services in
international trade because of: (i) government-mandated testing or certification of export products,
which is not required by trading partners, or (ii) application of 100 percent inspections on
imported products, regardless of risks.

**Recommendation:**
- Introduce risk-based surveillance, monitoring and inspection, abolishing artificial demand, and reallocating
freed resources to priority areas with high risks.

Domestic food safety and agricultural health
The potential contribution of laboratories in boosting human and agricultural health is generally
underestimated.
In developing countries by far most of the work of public diagnostic laboratories relates to agricultural health and food safety in the domestic market. Since commercial demand for diagnostic capacities in the domestic market is small, private laboratories hardly invest in these markets.

**Recommendation:**
- Many diagnostic services for food safety in the domestic market and agricultural health management can be considered public goods; for such services, the government needs to assume responsibility for funding their provision, either through public laboratories or through outsourcing.

**Economies of scale**

In most small or poor countries the size of laboratories is insufficient to justify rapid turnaround of samples, offering sophisticated services, or aspiring to achieve international accreditation. Yet such countries do have other options for dealing with these constraints of economies of scale.

**Recommendations:**
- Create larger laboratories by consolidating the national laboratory infrastructure for food and agriculture, for instance by combining food safety, plant health and animal health testing facilities under a single roof.
- Make more selective investment in sophisticated equipment, use rapid detection kits, outsource part of the tests to other laboratories—both private and public, at home and abroad—or concentrate scarce resources in priority areas.

**Quality management**

Governments in developing countries generally give little attention to the quality of diagnostic services. Yet as the main buyer of diagnostic services and owner of public laboratories they have an interest and can play important roles in boosting quality. However, the cost of accreditation under ISO 17025 is high, and any decision on whether to seek this accreditation should be made on actual need. In the meantime, other forms of quality management can be implemented.

**Recommendation:**
- Governments should promote quality control in laboratories more often through requirements for quality programs, proficiency testing, training of staff, and supervision than by seeking accreditation through ISO 17025.

**Donor support**

Donors share responsibilities for lack of financial sustainability in past investment in laboratories because of supply-driven investments, inadequate needs assessment, a relative bias toward hardware procurement, insufficient provision for recurrent supply and maintenance costs, neglect of institutional mandates or limitations, and/or too short periods of external support for capacity building.

**Recommendation:**
- Improve performance of donor support through better donor coordination, improved preparation, better financial analysis upfront, and more effective monitoring and evaluation.

Business plan

However they may be owned, agro-food laboratories should function as businesses that must depend on revenue from services they provide and must therefore be customer-driven. Even if some or all of the funding for investment or user fees actually comes from other government agencies, operational and investment decisions should be assessed from this perspective. Strategic and business plans should be always be employed, whether to assess the feasibility and sustainability of any major new investments, or to guide annual operations for already existing facilities.

Recommendation:

- Public laboratories need to be given sufficient administrative and financial autonomy to function in as business-like manner as possible.

- Business plans for new or incremental investment in public laboratories should be based on thorough assessment of the policy and institutional framework, assessment of capacities, and assessment of demand under various policy and investment alternatives.

- Explicit attention should be given to possible consolidation of the infrastructure, policy reforms and capacity building in governance, funding, quality of services, and skills of staff.

- Benefit and risk analysis, supported by financial and economic analysis, should be used as the basis for priority setting in the formulation of investment plans.

- However, since public budgeting is always partly political as well, special efforts have to be made to explain to senior policymakers and other key stakeholders the benefits of the proposed investment(s).
1. Introduction

Why this guide?
Governments of developing countries often consider whether to expand laboratory capacities in support of agriculture and food. Goals may range from improving market access through demonstrable compliance with bilateral and multilateral sanitary and phytosanitary (SPS) requirements, to better control of food-borne pathogens and disease, animal diseases and plant pests, and to improving competitiveness of the private sector. Since development of laboratory capacities is expensive and technically demanding, they often seek grant and loan support from bilateral donors, international agencies, the World Bank and other international financial institutions (IFIs).

However, the outcome from developmentally-oriented investment in laboratories has often not been satisfactory. Throughout the developing world many laboratories created with outside support are underused, produce poor test results and experience great financial difficulties. In some cases laboratories or entire systems go from rescue to rescue (see Box 1).

Often the most direct cause for decline in services is inadequate recurrent funding by the government. However, in other cases it is inappropriate public regulations and policies that create major obstacles for successful operation of laboratories. Other factors may include deficient utilities (water and power) or lack of human skills.

Box 1. Kenya's veterinary labs

In the mid-1970s various donors helped the Government of Kenya set up a veterinary laboratory system with 22 clinical centers with small laboratories, 4 regional diagnostic centers and a central veterinary laboratory as well as laboratories at the Kabete veterinary school.

By the mid-1980s Kenya's veterinary laboratories had fallen into disrepair as operating expenses were inadequate. The Government obtained loans from the World Bank and IFAD for the Kenya Animal Health Services Rehabilitation Program (1984-1993) for improving the delivery of animal health services to small livestock owners nationwide. The project aimed to refurbish, equip and provide operating resources for Kenya's central and regional veterinary laboratories. Post project evaluation, however, showed that there was negligible improvement in the contribution the veterinary investigation laboratories made to disease control during the project period. The delays in the repair and re-outfitting of the Central Veterinary Investigation Laboratory meant that, by 1993, disease surveillance could not be carried out and the project failed to achieve the targets set in its appraisal report. Most of these failures were attributed to (i) the failure of the government to contribute to project funds, and (ii) the refusal of Department of Veterinary Service to implement the management changes considered essential during appraisal and recommended by follow-up supervision missions.

In 2004 the Kenya Government proposed another round of rehab to the Comprehensive Africa Agriculture Development Program, as “most of the equipment in the six veterinary investigation laboratories needs replacement.”

Sources: Feddema 1979; IFAD 1995; FAO 2004

In order to improve performance, investment decisions have to be well prepared and based on good analysis and planning. A number of key questions have to be thought through, such as
• What types and levels of laboratory capacity are most needed to improve food safety for consumers or to improve plant or animal health?

• What are the key diagnostic and analytical capacities required, and services needed, to expand agricultural exports?

• What is the relative importance of these different objectives, as well as the trade-offs or potential synergies between them?

• How much public and potential private resources can be allocated to pay for such services?

• What are the most cost effective ways to provide these services?

• Is there any room to make improvement in the existing laboratories through policy or administrative reform rather than incremental major investment?

• If new investment has to be made, will it be sustainable?

This guide provides a framework for feasibility assessment of investment in laboratory capacities. It recognizes that needs vary greatly with the level of development, the size of a country, its product mix, the domestic food safety situation, the pest and disease situation in agriculture, the requirements in its export markets and the perceived risks related to imports. Hence, it does not try to be a blueprint for laboratory capacity design, nor does it provide detailed TORs for designing investment plans. Instead, the purpose is to help to prepare for investment decisions by identifying the most important issues to consider and modalities for sustainable investment.

Many international agencies\(^1\), such as the AVMA, FAO, FDA, GTZ, IPPC, ISO, OIE, Seafood Council, and USAID, have developed and are applying capacity assessment tools and guidelines for laboratory assessments for a range of purposes. Regulatory agencies of the European Commission and the United States also have their own tools for assessing competence of laboratories in providing proof of compliance with SPS requirements in trade. The tools presented in this report focus on assessing demand and feasibility of investment and give less attention to detailed technical requirements. This report complements what other sources do and is not intended as an alternative.

For many developing countries, laboratories that support regulatory functions for food safety, plant and animal health form the core of national laboratory capacity of relevance to agriculture and food, and these are often the areas for which international support for investment is sought. But there are synergies to be taken into account with other functions such as promoting agricultural income and competitiveness, environmental health and human health.

The guide is primarily written for staff in international agencies, governments, IFIs, and donor agencies who either bear responsibility for the strategic planning of laboratory capacity development or who make investment decisions. However, it will also be useful for public sector managers who have policy responsibility or oversight over food safety, plant health or animal health, as well as the staff of government agencies mandated with promoting competitiveness in agriculture.

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What laboratory services are we talking about?

This guide is about laboratory services in the area of agriculture and food that generate data and information on either:

- the safety, quality or condition of agricultural products, especially those intended for use as food or feed;
- the safety and quality of pesticides, veterinary drugs, fertilizer, seed and planting material for propagation, and water for use in irrigation, food processing and drinking;
- the health status of plants and plant material;
- the health status of animals and animal products; and
- the chemical and other characteristics of soils and plants relevant for monitoring growth potential of crops.

The information and data generated by such labs is mainly used for regulatory and commercial purposes. Therefore, the discussion here may not apply to laboratories whose primary mandate is research and education, such as university laboratories or research institutes.

Although this guide focuses on public investment, it takes into full consideration the need for a balanced development of public and private capacities and, where possible, national and regional capacities.

The services covered by this guide fall into three main categories, which differ mainly by purpose:

1. diagnostic and analytical services relating to food safety, plant and animal health that support domestic laws and regulations;
2. services required for the government or private sector to comply with bilateral and multilateral agreements on food safety, plant and animal health; and
3. fee-for-service analytical activities and technical support offered to the farm, food and sometimes industrial sector, which typically provide information for farm and firm management that can help boost productivity, improve quality control, manage food safety and health of plants and animals, or provide verification of various health and quality parameters for commercial certification purposes.

Laboratory services for agriculture and food can be provided by a range of different laboratories, which form the so-called laboratory infrastructure. The laboratory infrastructure differs much between countries, depending on demand for laboratory services and such background factors as history, country size, production structure of agriculture, and level of development. Yet, there are similarities as well. Most countries have specialized laboratories for animal health, plant pest diagnostics, and food control; a few have combined laboratories for some of these services. Some countries also have specialized laboratories for food testing, analysis of soils, water, agrochemicals,

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2 In some cases analytical laboratories also perform research functions, which are not discussed here.
3 Laboratories can perform a range of these and other commercial services that are not the primary function of labs designated for regulatory services. Guidelines will be desirable to assure proper use of public resources and avoidance of conflicts of interest.
feed, or environmental health, but more often these services are also consolidated in laboratories with a broader mandate.

There are public and private laboratories. The main diagnostic laboratories for animal health, plant pest diagnostics and food safety are mostly government laboratories or autonomous not-for-profit laboratories, as are several of the specialized labs. In addition there are privately owned laboratories that operate for profit, providing services for fees. Such private laboratories specialize in tests with a high turn-over and a short turnaround time. Some enterprises, especially in food handling and processing, have in-house labs.

This guide is organized as follows. Section 2 looks at laboratory service in the context of a country’s overall system of food safety and agricultural health management. Section 3 aims to provide a clear understanding of the different requirements for lab services by various market segments. Section 4 focuses on the matter of financial viability (or the lack of it) of public laboratories, since this has been a major problem for many laboratory investment projects. To avoid making financially unsustainable investment, a number of options to obtain laboratory services should be considered by policymakers. These options are discussed in Section 5. Section 6 takes a close look at donors’ role in laboratory investment projects in recent years and offers some lessons learned from past experiences. Section 7 then provides a step-by-step guide for drafting a business plan for lab investment. It is supported by guides for structured interviews with stakeholders in the country’s food safety and agricultural health management system in Annexes I, II and III.
2. Understanding the role of laboratories in the national food safety and agricultural health management system

A laboratory for regulatory services does not function independently. It is part of the regulatory system of which the five main elements are (1) policies and regulations; (2) standards; (3) monitoring and inspection; (4) analytical services; and (5) outbreak response, which can involve quarantine, refusal of entry, fumigation, destruction, or other containment or mitigation measures.

The demand for laboratory services, as well as the cost-effectiveness of the services delivered, depends much on the policies and arrangements within the regulatory system. Policies determine priorities in work plans, define surveillance and inspection strategies, and directly affect the workload of laboratories. The regulatory framework provides the rules of the game.

Standards are needed for reference of quality and safety parameters demanded by the consumers and industry, or required under trade agreements.

If the inspection services don’t collect samples the laboratories have no work to do and the quality of tests will decline. If the quality of the surveillance and sampling is poor, no reliable conclusions can be made about compliance and safety parameters. Many quarantine measures also need to be backed by diagnostic services. In case of outbreaks policies, inspection services and quarantine need to be ready for emergency response.

Regulatory laboratories and inspectorates have two features in common. First, their volume of work is somewhat unpredictable and can suddenly increase if outbreaks or major calamities occur. Secondly, they also have to cover some areas for which risks are high yet demand is uncertain and generally low. Possible calamities require contingency planning to assure that surges in demand can be met. Solutions can involve temporary reduction of other programs and working up to 24 hours a day. Agreements can be made with other laboratories in the country and abroad to temporarily assist in part of the workload. For particular calamities some reserve capacity may be in place. Importantly, budgetary provisions need to be included in emergency plans.

Policies/regulatory framework and institutions

Government policies can have a major impact on the functioning of the laboratory system. They set many rules of the game and have major impact on demand for public and private laboratory services.

Public roles

Generally, governments have five distinctly different roles with regard to the laboratory infrastructure:

1. Bear and carry out overall responsibility for the development of an adequate laboratory infrastructure – this involves generic rules for laboratories and investment climate issues, as well as possible subsidization;

2. Ownership of part of the infrastructure – making sure that public property is properly maintained and used;
3. Regulation of food safety, plant and animal health – this largely shapes potential public and part of private demand;

4. Enforcement of food safety, plant and animal health regulations – chosen modalities are generating actual use of laboratory services;

5. Sponsoring the use of laboratory services by farms and enterprises in development projects.

It is important to institutionally separate these roles in a transparent way so that conflict of interest within units can be reduced as much as possible. The government in its overall responsibility should promote a level playing field for public and private laboratories. Competition among laboratories is in principle healthy and should be based on principles of fairness and equality. Government regulations should create a level playing field and not discriminate against private laboratories. Private investment in laboratories should be welcomed and full access to the lab service market should be granted to private laboratories irrespective of the origin of their ownership. No public resources should be used for unfair competition.

The regulatory and enforcement roles should be based on risk analysis and management as WTO principles require. Governments should guard against unnecessarily increasing the cost of doing business and the final cost to consumers, and should refrain from creating income for public laboratories through artificial demand for services. On the other hand, the ownership role should not be used to subsidize services through artificially low pricing schedules.

Major risks of mixing up these roles and responsibilities are that accountabilities become blurred, policy evaluation complicated and, most of all, that harmful policies are adopted.

Decisions to invest further in laboratories involve the general responsibility for the laboratory infrastructure and the regulatory and enforcement roles. Healthy competition can easily be jeopardized by overcapacity in the laboratory infrastructure. Therefore, public policy should avoid creating overcapacity and harmful overcapacity should be consolidated.

International good practice is that policy formulation, implementation and evaluation are as much as possible functionally separated. In most developing and transition countries such principles of transparent governance are not in place yet, but efforts need to be made to move in the right direction.

**Importance of mission**

Ideally, not only the entire national agri-food lab system, but each separate laboratory within it, should have a mission statement that describes its mandate, objectives, and scope. Management and staff at each level should be held accountable to perform activities in line with the mission.

However, shortfalls in public funding may tempt a lab executive to go outside that mission, in search of increased revenue or greater sample volume. As long as the core mission is not affected, there is nothing wrong with a laboratory accepting jobs outside its main field of work. For example, veterinary laboratories established to look after animal health and perhaps zoonoses, may elect to engage in side activities such as health care for pets. Although additional work tends to enhance the financial sustainability of the laboratory, there are risks that improper use is made of

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4 In dealing with risk, international good practice recommends the functional separation between risk assessment and risk management to ensure the scientific integrity of risk assessment process and reduce potential conflict of interest between risk assessment and risk management. See FAO 1997.
public resources and that the core mission of the laboratory gets diluted. These risks can be mitigated by requiring transparency and charging full cost tariffs. Moreover, in regulatory laboratories especially, conflicts of interest need to be prevented. Improper regulations can provide wrong incentives for staff and management and side activities may drive the agenda, having negative impact on the direction in which a laboratory develops.

Legal and financial status of laboratories

In developing countries most analytical work for government regulatory functions in food safety, plant and animal health management is carried out by public laboratories. Outsourcing to private laboratories is generally very limited.

Yet public ownership and governance rules can vary greatly and can have profound implications for the way laboratories operate and for their cost-effectiveness. Three stylized models of public laboratories with various ownership structure and levels of independence in management are discussed below and described in Table 1, but it should be remembered that in practice many hybrids exist.

Model 1: Laboratories that are part of core government services. Most government laboratories for food and agriculture in developing countries belong to the Ministries of Agriculture or Public Health, where they are often associated with line departments tasked with plant protection, animal health, public health and/or food safety. In such situations, they have very little formal autonomy in designing and implementing their work program, financial management, setting tariffs, purchasing goods and services, employing staff, and carrying out maintenance. In practice they may exercise some autonomy in decision making because of their expertise and incomplete oversight.

Model 2: Laboratories that are part of government services with some autonomy in management of day-to-day operations and finances. In many countries, those units in the government that are mandated with implementation of specialized tasks such as research, extension and laboratories services have more autonomy in financial management than policy units. Also possible is that specific statutes are given to laboratories, providing them some independence from their home agencies. However, since public funds are involved they remain under close financial supervision.

Model 3: Laboratories outside regular government services with high degree of autonomy in their management and finance, e.g. laboratories established as autonomous not-for-profit entities. These laboratories generally have been created by the government or with government support. Laboratories in universities and diagnostic laboratories associated with farmer organizations sometimes also have such an autonomous status.

Each of these models has implications for public funding and financial management. In the first model, laboratories have no fiscal autonomy and goods and services are procured under rules for core government agencies. All expenses—investments, labor, supplies, training and maintenance—are funded from the central budget, and, therefore, possible income has to go back to the central budget. In general, regulations for government services are far from optimal for carrying out business units such as analytical labs since they don’t provide the necessary flexibility for management.

In the second model some financial and management autonomy is given, especially for day-to-day cash management and small procurement. Unlike the first model, this one may show some problems of coordination related to its autonomy. This model provides in principle better scope
for managing a laboratory as business unit, but still with major constraints. In the first and second model the government is directly responsible for the performance and continuity of the laboratory. In both cases staffs have civil service status, and in some cases the bureaucratic culture may be an obstacle for discipline, quality of service and cost-effective operation.

In the third model the laboratory has its own governance structure and it has responsibility for its own income through its performance in selling services. This model, often found in OECD countries, is probably most suited for operating a public sector laboratory. However, it requires a somewhat sophisticated regulatory model for guiding its mission and for contracting public services.

**Table 1. Stylized models of governance of public laboratories for food control, animal and plant health**

<table>
<thead>
<tr>
<th>Feature</th>
<th>Model</th>
<th>Core government service</th>
<th>Peripheral government entity</th>
<th>Autonomous body</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ownership</td>
<td></td>
<td>Government</td>
<td>Government</td>
<td>Not-for-profit body; independent legal status</td>
</tr>
<tr>
<td>Responsibility for continuity of laboratory infrastructure</td>
<td></td>
<td>Government</td>
<td>Government</td>
<td>Board of Trustees, perhaps government role in securing basic infrastructure</td>
</tr>
<tr>
<td>Regulatory framework</td>
<td></td>
<td>Should govern all inspection, monitoring, quarantine activities, related testing and role of lab</td>
<td>Should govern all inspection, monitoring, quarantine activities, related testing and role of lab</td>
<td>Should govern all inspection, monitoring, quarantine activities and related testing; role lab need not be regulated</td>
</tr>
<tr>
<td>Autonomy</td>
<td></td>
<td>No autonomy from line management</td>
<td>Some autonomy given by government through internal mandate (or separate statute)</td>
<td>Full autonomy in operational and financial management</td>
</tr>
<tr>
<td>Supervision -- general</td>
<td></td>
<td>Direct supervision of management and staff by line managers</td>
<td>Direct supervision of management and staff in part by line managers and in part by central ministerial units</td>
<td>Supervision through Board of Trustees</td>
</tr>
<tr>
<td>Budgeting, operational management, procurement</td>
<td></td>
<td>No autonomy</td>
<td>Some autonomy granted by government, based on internal mandates</td>
<td>Full autonomy</td>
</tr>
<tr>
<td>Strategic decisions (mission, investment, appoint management, change mandate)</td>
<td></td>
<td>No autonomy</td>
<td>Some autonomy, based on internal mandates</td>
<td>Autonomy defined in statute; with Board of Trustees approval and perhaps subject to government approval</td>
</tr>
<tr>
<td>Auditing responsibility</td>
<td></td>
<td>Regular civil service</td>
<td>Regular civil service</td>
<td>Mandated by Board of Trustees, perhaps subject to government approval</td>
</tr>
<tr>
<td>Hire and fire</td>
<td></td>
<td>Civil service rules</td>
<td>Civil service rules</td>
<td>Autonomy with supervision by Board of Trustees</td>
</tr>
<tr>
<td>Base of carrying out testing for public needs</td>
<td></td>
<td>Order by line management</td>
<td>Order by government; performance management contracts</td>
<td>Basically through market-based contracts</td>
</tr>
<tr>
<td>Engaging in contracts, fee-for-service</td>
<td></td>
<td>No autonomy; requires line management decision and supervision, requires rules for tariff</td>
<td>Some autonomy based on internal mandates; requires rules for tariff</td>
<td>Full autonomy; generic rules for management of laboratories will apply</td>
</tr>
</tbody>
</table>
and rules for tariff setting  
setting and how to operate in market  

| Quality control and integrity assurance | No autonomy; requires line management decision and supervision | No autonomy; requires corporate management decision and supervision | Mandated by Board of Trustees, perhaps subject to government approval |

**Source:** Authors of this report

Line managers in ministries may not like this model because they have to follow contracting procedures rather than giving direct orders. Coordination between inspectorates and laboratories has to go through market-based contracts. Given the strategic interests of Government, there will be special contract clauses to ensure quality of services, timely delivery, special arrangements for dealing with outbreaks, transparency and minimizing risks of conflicts of interest. In principle government agencies have to pay full cost\(^5\) for services provided, just as private customers. Tendering contracts may seem attractive, but there are in practice often insufficient numbers of qualified suppliers. Moreover, shifting big contracts\(^6\) may threaten the continuity of the laboratory infrastructure. Therefore, long-term negotiated contracts based on real costs will be more common than tenders. Although the Government has redrawn itself from responsibility for operation of the laboratory, it will often still play a role in strategic decisions, both to ensure its own regulatory interest and availability of services for other users.

Funding mechanisms for public funded laboratories are mainly input funding and additional allocations for special programs. Such mechanisms have serious weaknesses for planning and accountability. Public funding of laboratories should preferably be output- or performance-based and not input-based.\(^7\) However, output-based funding requires more administrative sophistication and to develop and implement such systems may require external support.

Since administrative rules under which public laboratories operate are often a direct cause of inefficiencies and in some cases even the main cause of lack of functionality, reform of the administrative and financial status of laboratories is an important part of improving quality and output of services. Good guiding rules for operation of inspectorates and public laboratories are needed that clearly define the scope of work for laboratories (mission), prescribe publishing operational plans, set principles of price setting for tests and other services, and rules for reporting. Assessment of the administrative and financial status of a laboratory should therefore always be part of a business plan for new investment.

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\(^5\) With a discount for directly paid expenses, such as depreciation in case investment support is provided.

\(^6\) Smaller contracts may increase the processing and management costs to the government, but may be more conducive to broadening the number of participating labs including opportunities for private laboratories.

\(^7\) The preference for input funding over output- and performance-based funding is sometimes defended because of the unpredictability of demand because of outbreaks and calamities. However, the truth of the matter is that input funding usually means that there is no clarity about what to do in case of emergencies. An output-based contract forces parties to formulate principle and contingencies for the case when emergencies occur. Output-based funding is even an encouragement for preparing emergency plans.
3. Laboratory services and markets

Understanding SPS requirements of the WTO

Investment in laboratories has in recent years often been justified by making reference to WTO requirements. However, there is often confusion about what the WTO SPS/TBT requirements really are, and in particular about the status of international standards of Codex, OIE and IPPC.

The WTO has a number of principles that are in fact requirements for trade policies, because SPS measures taken by a country can be questioned in the WTO SPS Committee on the basis of these principles and interpretations can be subject to WTO panel cases. These principles include (1) providing transparency about sanitary and phytosanitary requirements; (2) use of a scientific basis for defining SPS measures; (3) non-discrimination between domestic and foreign products and between products from different countries; and (4) accepting other countries’ measures that provide equivalent health protection. A member country has little choice with regard to the adoption of these principles.

The WTO also recommends harmonization with standards set by international institutions, such as those of OIE, IPPC and Codex, but their adoption is not mandatory. Countries can, based on their perceived national interests, choose to adopt and implement fewer or less strict standards, as long as it does not conflict with the WTO principles. This is particularly important for small countries with limited international trade. Unfortunately many specialists in developing countries associate membership of WTO with mandatory adoption of international standards, and worse still technical “experts” sometimes present the recommendations as mandatory, which can cause confusion and misallocation of scarce resources. This has major implications because it puts the focus more on (supposedly) unavoidable costs rather than on selective choices taken to achieve trade opportunities and better protect health. What really matters in market access is, however, the standards and measures that importing countries require of imported agri-food products. That may be limited or extensive, easy or difficult to achieve, depending on what the countries agree bilaterally to be relevant trade-related risks and what to do about them.

This does not mean that there are no compliance issues with WTO principles. On the contrary. The regulators in many developing countries have serious difficulty explaining requirements to importers, partly because the regulations are so complex, partly because they are insufficiently precise, and partly contradictory. That leaves implementing agencies and inspectors with insufficient guidance and too much discretionary power on how to handle concrete cases. Laboratories can only conduct proper tests when the standards are clear.

Under the WTO Agreement, SPS measures should be based on risks identified by scientific methods, and not be more constraining on trade than necessary. Risk-based inspections should be proportionate to perceived risks. Yet many SPS measures in developing countries do not meet this criterion. For example, there may be 100 percent border controls regardless of the risks. Rent-seeking behavior can also play a background role in designing and implementing SPS measures. Official fees and informal payments from permits, inspections and tests can form an important source of revenue for laboratories, inspectorates and staff involved. In many countries one can easily find control activities that contribute little to health protection using resources that could be used for controlling real risks. The relevant point for this guide is that part of the actual demand for laboratory services can be artificial demand, which would disappear with a correct compliance with SPS/TBT principles.
Domestic food safety, plant and agricultural health policies and regulations in many respects need not to comply with international principles. In domestic markets there are also permits, inspections and surveillance activities that contribute little to protection of health, but do add to fee income of inspectorates and laboratories while adding to cost for farmers, enterprises and consumers. There are also cases where authorities require phytosanitary certificates for export, even though the importing country does not require them. These activities are undesirable from an economic and social point of view, although not violative of essential SPS/TBT principles. They do create artificial demand that would disappear with application of risk-based policies in domestic markets.

**Laboratory services and market access**
Promoting exports is often cited as the purpose or at least a major justification for developing countries to establish and upgrade their public laboratories. Yet the relationship between capacities of public laboratories and performance in foreign trade is not straightforward. Investment in public laboratories is not a guarantee for better trade performance and sometimes not even necessary.

The main SPS-related activities necessary for promoting exports are issuance of phytosanitary and veterinary certificates, support for the development and adoption of Good Agricultural Practices (GAP) and Good Manufacturing Practices (GMP), and monitoring the status of particular food safety, plant health and animal health parameters. This all involves some diagnostic testing but often not that much. Many activities are routine and not very difficult. There is for most products no strong direct relation between capacities in public laboratories and export performance. Sometimes the private sector assumes all responsibilities. For many animal diseases and plant pests the SPS market access constraints can be too difficult and too costly to solve and laboratory capacity does not make a difference (World Bank 2007c, 2007d, World Bank/USAID 2006). However, in selective cases specific laboratory capacities can make a difference (See Box 2).

In contrast to the often low public sector requirements for food safety, private importers, especially those with brand name, increasingly require from their suppliers conformity tests about quality and safety parameters as part of the contract conditions. In particular for the high-end markets in the OECD countries such requirements are common for most products. In many cases such tests are performed by certified or accredited third party private laboratories in the country or abroad and by certified in-house laboratories that can guarantee high reliability and rapid turn-around time. The actual arrangements depend on agreements between supply-chain partners, which can include technical support from the buyer (World Bank 2004a, 2004b).

The sequence of export and laboratory development is often a chicken-and-egg problem and can go in two ways. In many cases flourishing exports have developed without any back-up by public laboratory services. Initially exporters depend on testing in the target market country. Yet successful development of an export sector then allows public and private laboratories to grow in response to increased demand for services, which in turn helps reduce costs and risks. There are fewer cases in which the causality is reversed, i.e. where the existence of laboratory capacities made exports easier to emerge.
Box 2. Links between market access and public laboratory services for sectors

In the phytosanitary arena access to an export market is mostly country specific, depending on the proven pest and disease situation in both the source and target country. Many exports of plant products have only small risks that can be dealt with relatively easily. Once a country has gained initial access to an export market much of the government role is routine issuance of phytosanitary certificates at fees of a few dollars per lot. In part of the exports visual inspection of the absence of certain insects and pests plays an important role. In many cases issuance of phytosanitary certificates cannot be backed up by scientific evidence. As long as there are no violations in inspected imports in the country of destiny product flows are smooth. Specialized exporters for the top end of the export market have a strong commercial interest in protecting their export position, so they themselves will take preventive measures to control risks rather than depend too much on the roles of official or third-party inspectors. The role of plant pathology and quarantine laboratories is in diagnosis of the pest and disease situation in the source country or production area, assessment of samples sent by border inspectors, providing evidence in negotiations of market access, and in training of inspectors.

In cases where quarantine requirements of importing countries are difficult to meet, most developing countries can do little, either because the importer’s Pest Risk Analysis requirements are technically too demanding, or pest-free zones may be difficult to delineate or sustain, or there may not be a practical plant quarantine treatment available. Of course, cost-benefit considerations may also come into play.

In the veterinary sector the actual or suspected disease situation is a dominant factor in market access. Most developing countries have no realistic opportunities to export live animals and red meat to OECD countries because of their disease situation. Changing a country’s status of market access is very demanding, often expensive and beyond commercial perspective for nearly all developing and many transition countries. Moreover, exports are much constrained by hygiene and construction requirements for slaughter houses. Opportunities for developing countries are limited to some dairy products, honey, wool, hides and skins and processed products. Avian Flu has much reduced market access for poultry products; only few developing countries are able to meet market access requirements. For dairy products the processing plants play a major role in quality and food safety management, sometimes by employing veterinarians and use of in-house laboratory testing.

In most of the fisheries exports sanitary controls are of dominant importance for exports to OECD countries. The European Commission also requires pre-approvals for fish processing plants. Testing throughout the supply chain are public and private sector requirements for access to OECD markets. Often this is done in duplication by companies and public laboratories. Export safety certificates issued by public authorities are required although they cannot be backed up by laboratory services located within a realistic distance. Not surprisingly, Japanese importers in interviews a few years ago expressed that they depend much more on their trust in the exporting company than on public authorities (World Bank 2004a).

In food safety, other than for fisheries and livestock products, there are few public sector pre-requisites for market access other than proper registration as a food establishment, or none at all. As long as there are no serious violations of the food regulations of the target country that may jeopardize an entire industry, the responsibility is fully with the individual exporter. However, country or product-specific disruptions of market access do occur in cases of repeated serious violations of maximum residue limits (MRLs) and detection of residues of forbidden agrochemicals. For example, Japan banned all spinach exported from China after detecting residues of forbidden pesticides, and repeated violations of pesticides residues in grapes exported from India to the Netherlands disrupted trade till the supply side could guarantee compliance. It often takes long negotiations between governments and several preventive measures before a ban is lifted. However, policies can be lenient. Despite frequent violations of mycotoxin MRLs in nuts and dried fruit products from Iran and Turkey to the EU, no bans have been imposed, but intensive testing was adopted instead.

Source: Authors of this report.

Of course, laboratory services are not the only possible bottleneck in export development, and they are often far from the most important one. Competitiveness issues can be more constraining,
leaving laboratory capacities unused. Therefore, investment in generic laboratory capacities can have very low returns, especially in small developing countries. Selectivity in investment based on analysis is needed.

Active participation in international trade can have significant implications for the demand for laboratory services, whether public or private. Usually, international product standards and sanitary requirements of OECD importing countries, such as maximum residue limits (MRLs) and hygiene requirements, are stricter than the domestic standards in most developing countries. Also, the number of standards and requirements in target markets is much greater than what is enforced domestically. Equipment available for controls in the domestic market may not cover the range of diagnostics required and with the needed precision for export. Therefore, investment in capacities for complying with international SPS standards and procedures can be high. They can involve laboratory capacities and related human skills, and in some cases also policy, regulatory and institutional adjustments.

A dilemma for countries adopting WTO recommended international standards is whether to apply and enforce them in domestic markets. Because of high costs of adoption and enforcement for the private and public sectors alike, developing countries often opt for selective adoption and enforcement. Selectivity means just a limited number of standards and market segments are addressed. In practice this strengthens in many developing countries the three-tier system described in the next section.

**Difference in laboratory service requirement for various market segments**

Often attention about the role of laboratory services in developing countries focuses on promoting market access for exports. However, most of the volume of work of public regulatory laboratories is concerned with control over food safety, animal and plant pest and disease in the domestic market. Moreover, evidence indicates that more benefits can be gained by reducing the risks to human and agricultural health, than from expanding trade.

Developing countries generally have a three-channel marketing system: (1) the traditional informal markets; (2) the emerging modern urban markets; and (3) the demanding export markets. The varying economic and institutional characteristics of each channel and the differences in consumer and commercial demand pose quite different challenges to policy makers and regulators. Table 2 provides an overview of some health and control issues and the roles of the public and private sector in the three segments. The demand for safety and quality in demanding export markets is high and the private sector invests in preventive measures in supply chain control and in monitoring to guarantee selected quality and safety parameters. Still, the public sector has a number of mandatory international responsibilities such as verifying sanitary conditions and the pest and disease status for authorities in importing countries. In informal markets there is little scope for private investments and funding and government services are virtually the only providers of control measures. However, traditional food production and preparation methods often provide important safeguards. In the emerging modern urban market segment of developing countries willingness to pay for quality and safety assurances is still modest but increasing.

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8 Private sector requirements for full control of quality and safety throughout the supply chain are usually not more demanding from a diagnostic point of view, but they are more costly since they involve third party certification.

In general, the demand for quality of analytical laboratory services is low for Government provided and funded services. This is the case for most of the regulatory public services. In the export segment and parts of the modern urban segment the demand for quality is high and public laboratories often lack the capacity to provide what the market requires and are out-competed by private test service providers.

Table 2. Market segments and control services

<table>
<thead>
<tr>
<th></th>
<th>informal market</th>
<th>emerging modern urban market</th>
<th>demanding foreign market</th>
</tr>
</thead>
<tbody>
<tr>
<td>specific control issues</td>
<td>difficult control of pests and diseases</td>
<td>emerging demand for quality and food safety</td>
<td>high quality and safety assurance needs</td>
</tr>
<tr>
<td>public sector roles</td>
<td>pest and disease surveillance, food safety inspection</td>
<td>support for emerging modern food safety management, GAP, GMP, supply chain control</td>
<td>verifying pest / disease status, monitoring, verifying quality and safety parameters</td>
</tr>
<tr>
<td>private sector actors and roles</td>
<td>small farms and firms; little scope for commercial services</td>
<td>medium and large farms and firms; increasingly active in GAP, GMP, in-house testing</td>
<td>medium and large scale farms; verifying quality and safety parameters; private supply</td>
</tr>
<tr>
<td>demand for laboratory services</td>
<td>public demand and funding</td>
<td>mainly public demand and funding; emerging demand and funding private sector</td>
<td>indispensable public roles, public funding; private demand / funding market services</td>
</tr>
<tr>
<td>demand quality laboratory services</td>
<td>Low</td>
<td>low / moderate</td>
<td>moderate / high</td>
</tr>
<tr>
<td>consumer expectation about quality</td>
<td>Low</td>
<td>medium to high</td>
<td>high</td>
</tr>
</tbody>
</table>

*Source:* Authors of this report; World Bank 2006c
4. Financial aspects and sustainability

Financial sustainability of many public laboratories in developing countries is lacking. For private sector laboratories sustainability means not just coverage of the total cost of operation, including maintenance of equipment and buildings, keeping up with general trends of technology improvement, training of staff, and replacement of worn-out equipment and buildings, but also earning an acceptable return on investment after taxes. Of course, for government-owned laboratories no profit margin is needed, yet sustainability still implies that on an annual basis all operational costs have to be covered. Ideally reserves for replacement of equipment and supplies should be funded from fees as well, but if not, the central government must be willing to periodically provide additional budget for equipment replacement and major upgrades. For autonomous not-for-profit laboratories sustainability means about the same as for public laboratories, although arrangements for periodic upgrading may differ.

A major reason for lack of financial sustainability is that decisions about funding of investment and operational expenses are disconnected. Investment decisions are usually driven by the preferences or ambitions of professionals in the SPS area, whether in Government or international organizations, and justified by the belief that better laboratory services are necessary for market access and compliance with WTO SPS/TBT requirements. These preferences and beliefs are often exacerbated by supply-driven support from donors and international financial institutions. By contrast, funding for annual operational costs is generated by budget allocation decisions made by senior policy makers in Ministries of Finance, Agriculture and Public Health and in part also by commercial demand for laboratory services. There is apparently a difference in appreciation of the needs for laboratory services between both sides, which can lead to underutilization of infrastructure and human resources, problems covering recurrent operational costs such as reagents, and sometimes inability to fulfill part of the laboratories’ public mission.

For many public laboratories staff salaries represent as much as 80-90 percent of the operating budget, leaving little for maintenance, utilities, consumables, training etc. In a private laboratory, which has to cover all expenses from sales, cost of employees are generally below 50 percent (see Table 3 for an illustration). Since a public laboratory generally does not need a profit, the share of all cost components can be proportionally higher, yet shares of labor cost higher than 60 percent would certainly suggest that financial sustainability is lacking.
Table 3. Example of operating expenses as a percent of sales for a private laboratory in a developing country

<table>
<thead>
<tr>
<th>Item</th>
<th>Operating Budget as a percent of Revenues</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Human Resources</td>
<td>40 - 45%</td>
<td>Represents the total cost, including salaries, benefits, add-ons (housing allowance, telephone, etc.)</td>
</tr>
<tr>
<td>Maintenance &amp; Repair of Facilities</td>
<td>6%</td>
<td>Assumes that the facilities are generally in good repair.</td>
</tr>
<tr>
<td>Maintenance &amp; Repair of Equipment</td>
<td>6%</td>
<td>Again, assumes the equipment is in good repair.</td>
</tr>
<tr>
<td>Utilities</td>
<td>6%</td>
<td></td>
</tr>
<tr>
<td>Consumables</td>
<td>10%</td>
<td>Figure is high due to the fact that these items tend to cost more in developing countries.</td>
</tr>
<tr>
<td>Fuel</td>
<td>1%</td>
<td>Includes fuel for vehicles and back-up power.</td>
</tr>
<tr>
<td>Training</td>
<td>1%</td>
<td>Includes on the job training, training materials, and outside courses.</td>
</tr>
<tr>
<td>Office Supplies</td>
<td>1%</td>
<td>Includes paper, toner, notebooks, etc.</td>
</tr>
<tr>
<td>Reference Materials, Internet Access, Database access</td>
<td>2%</td>
<td></td>
</tr>
<tr>
<td>Travel</td>
<td></td>
<td>Often covered by donors</td>
</tr>
<tr>
<td><strong>Total Operating Cost</strong></td>
<td><strong>73 – 78%</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Earnings before interest and taxes</strong></td>
<td><strong>22-27%</strong></td>
<td>Includes depreciation for new investment.</td>
</tr>
<tr>
<td><strong>Gross revenue</strong></td>
<td><strong>100%</strong></td>
<td></td>
</tr>
</tbody>
</table>

**Source:** Beug-Deeb and Deeb 2007

**Note:** These values are illustrative for an on-going operation. Start-up costs can be and are significantly higher. The investment in equipment and facilities needed to run even a relatively small laboratory can be in the range of 1.5 – 3.0 million USD depending on the requirements. These percentages are aggregates based on laboratories operating in Africa, Eurasia and US and should only be seen as guidelines, as actual cost will vary.

**Advocacy for funding is weak**

While the human and agricultural health system in any country serves a dual role—part domestic and part international—as noted previously the bulk of its activity is inward-looking. In that regard, its key mission is to preserve public health by providing protection against food-, water-, or airborne hazards, and also to preserve plant and animal health and life by providing protection against hazards such as pests, diseases, toxins, and invasive species.

Funding support for any governmental activity is mainly influenced by public concern coupled with promise or proof of success. Yet there has been surprisingly little attention paid by professionals and public services involved in the three SPS domains to rigorously predicting *a priori* or evaluating *a posteriori* the efficacy of expenditures in terms of desired outcomes. While assessments of specific programs that seek to improve human health through preventive care, medical interventions or preventive care are commonplace, benefit-cost type analyses and evaluations of capacity-building activities—which include the strengthening of lab services-- are rare even in the field of human health. Some before-and-after analysis does occur for certain high profile animal and plant health programs—for instance, BSE for livestock and Medfly eradication
for susceptible crops—but little or no attempt has been made to assess the total or marginal return on additional investment in the overall SPS system. Cutting edge work on both regulatory impact assessment and the political economy of rule-making is sorely lacking, even in the developed world.

In the absence of more comprehensive data about outcomes and cost/benefit or cost effectiveness analysis, investments in all three SPS areas are usually “projectized”, which means narrowly defining their purpose, determining required inputs and expected outputs, then tracking and reporting against plan. While such progress indicators match well the scientific training of lead managers and technical staff, they do not readily convince the common man, nor the senior policy-makers who control fund allocations.

Whatever the reasons for this gap might be---the complexity of the system, the multiplicity of indicators, the need for a new methodological approach, or perhaps difficulty in finding common ground--the lack of rigorous prediction and evaluation deprives public and agricultural health system advocates of the hard data and arguments needed to build a strong constituency that would help ensure adequate funding over time.

The poor reputation that food safety and agricultural health control systems have in many countries with respect to perceived corruption and governance problems, especially in inspectorates, as well as the evident reality of many “white elephant” installations, can aggravate the financial situation, because politicians are reluctant to allocate more public budget to these agencies.

Thus more tangible and measurable outcomes, coupled with better governance, appear to be prerequisites to obtaining increased public funding for the human and animal health system, including but not limited to regulatory and diagnostic infrastructure such as agri-food labs.

**Other factors for sustainability**

Inadequate government funding is a direct reason but not the only reason for lack of sustainability. Many factors contribute to sustainability of laboratories, some of which are and some of which are not affected by policies, administrative rules and quality of management. A couple of examples will illustrate this.

1. “Overcapacity” of services within various agencies is another common problem. In particular food control and veterinary laboratories tend to have overlapping mandates and capacities. In Armenia, for example, both the veterinary laboratories and the regional Testing Center of the Hygienic and Anti-Epidemiological State Inspectorate, test meat for infectious diseases and parasites in municipal markets (World Bank 2007a).

2. In many cases there is adequate laboratory capacity but a lack of samples to analyze because inspection services don’t provide them. This leaves equipment and laboratory specialists idle and skills eroding. Low numbers of tests is a common problem in many laboratories in developing countries, simply because there are no or only very small monitoring, surveillance and inspection programs.

3. The functionality of a laboratory depends to a significant extent on the technical and management skills of senior staff. Many laboratories have major deficiencies in professional quality of their management and discipline of staff in following standard operating practice.

4. Training of laboratory staff of all levels is often insufficient. There is an imbalance between support for investment in equipment and training to use the equipment. Sometimes training of
laboratory staff sent abroad is ineffective since the equipment abroad and at home differs. The training needs are in part for hands-on training, and in parts for understanding issues such as risks, surveillance and epidemiology.

5. Some sophisticated equipment, for example Gas Chromatography coupled with Mass Spectrometry (GC-MS), has high requirements on staff and utilities and high maintenance cost, and thus may not suit the conditions and needs in many laboratories (see Box 3).

6. Policies and rules can also constrain operations. In many countries tariffs for tests in public laboratories are unrealistically low compared to those in private laboratories, in part because of the political and legal burdens to update them. In most countries Government laboratories have to forward at least part of their income from fee-for-service to the central budget. Government laboratories can face horrendous difficulties in timely procuring supplies and spare parts and as a result output of services can be seriously interrupted.

Box 3. Conditions for successfully operating GC-MS

<table>
<thead>
<tr>
<th>Requirement</th>
</tr>
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<tbody>
<tr>
<td>Skilled staff</td>
</tr>
<tr>
<td>A temperature controlled environment</td>
</tr>
<tr>
<td>A dust free environment</td>
</tr>
<tr>
<td>Access to carrier gasses such as Argon or Helium which had to be transported over long distances over the road and by sea</td>
</tr>
<tr>
<td>Power back-up</td>
</tr>
<tr>
<td>Uninterrupted power supply with sufficient power capacity to run the equipment through it’s shut down cycle</td>
</tr>
<tr>
<td>Freezers and refrigerators to store samples, regents, and standards</td>
</tr>
<tr>
<td>A clean and neat sample preparation area separate from the testing area. As one is detecting trace quantities of materials and one needs to prevent cross contamination</td>
</tr>
<tr>
<td>Staff that is trained on sample preparation, isolation, and operation of the equipment. This training can take up to 6 months to complete</td>
</tr>
<tr>
<td>Availability of calibration kits</td>
</tr>
<tr>
<td>Mass spectrometry library</td>
</tr>
<tr>
<td>Purchase the equipment, spare parts, installation which runs about 60,000 USD</td>
</tr>
<tr>
<td>A 3 year service contract which is about 36,000 USD.</td>
</tr>
</tbody>
</table>

Source: Beug-Deeb and Deeb 2007

Many deficiencies in functioning of laboratories can be solved, but not all. Demand for laboratory services is the most critical factor for sustainability, since without paid demand there is little chance for long-run sustainability of a lab. That is why effective demand is the dominant factor in private sector decisions for investing in labs. The actual demand for public and private laboratory services differs much between countries, depending among others on the quality of services provided, the level of economic development, market orientation, kinds of products covered, incidence and perceived risks of health hazards, competition from specialized laboratories abroad, public funding, and policy directives that directly affect labs. For investment decisions a demand analysis is necessary. Actual demand can be much affected by policies and regulations. Assessment
is needed of the potential demand in terms of number and range of services that have to be delivered, the revenues that will be generated and the cost that need to be covered.

Box 4 gives an example of how a private laboratory makes decisions about investing in building a new laboratory in developing countries. Given that public laboratories have different mandates from those of private laboratories, the issues to consider will be somewhat different. Nonetheless, enough attention should be paid to demand for services and financial viability. These will be discussed in more detail in the Section 7.

**Box 4. How does a private laboratory make investment decisions?**

The following describes the main issues considered by a private laboratory in assessing investment in a developing country.

1. Is there demand for quality control, food safety, animal or plant health in the country?
   -- Does the demand apply to the domestic market?
   -- Does the country export any product? Is there real demand for quality and safety in the export markets?
2. If there is a demand for laboratory service, is it sufficient? That is, does this demand assure a profitable return to the investment?
3. Will it be easy to set up our activities with regard to norms, national/local policies, permits, licenses, or is the legal system too cumbersome?
4. Equipment. Can local suppliers provide the needed equipment, and, more importantly, provide maintenance? Can they provide training?
6. Are basic provisions guaranteed in the country? Water, electricity, waste disposal.... If the answer to the above questions is negative, what are the additional costs for items such as generators, pressure bombs, water purifying units, residue treating units, and so on. What is the risk of damage in sophisticated equipments due to changes in the supply of basic provisions like electricity?
7. Staff. Is there trained and qualified labor in the country to join our staff? What is the extra training and knowledge transfer costs?
8. Accreditation. This cost is essential so as to generate confidence in the test result. Can we afford this cost?
9. What is competition like in the country? Are there public laboratories with lower costs offering quality control services to companies? Do they control prices of services? Are there competitive private labs?

**Source:** Salcedo 2007.

**Strategy and business plan**

A vision and strategy are needed for the possible and desirable development of the laboratory infrastructure in the medium to long run.

Investment analysis and planning for agri-food laboratories should take all of the factors mentioned above into account, then assess the likely effectiveness, service delivery capability, and sustainability of the proposed investment under different scenarios.

For major investments a business plan is needed that shows how the proposed investment fits within the strategy and how it can be sustainable given the various technical and financial alternatives and perceived health risks that need to be controlled. Based on well-done financial and sensitivity analyses, the business plan should not only make recommendations for decision making by policy-makers and executive management, but also provide a roadmap for execution.
5. Key issues that affect effectiveness, efficiency, and sustainability

Economies of scale

Trends in technology, quality management requirements, staff costs, and demand have significantly increased economies of scale for laboratories. The expanding range of tests demanded and the precision required are met by increasingly sophisticated and expensive test equipment. The increasingly sophisticated equipment poses higher requirements on infrastructural conditions, such as building materials, air conditioning and secure access to utilities, especially electricity and water. In parallel requirements for the range of skills and training of staff and management have increased. Quality management, using certification and accreditation, comes with high fixed costs. These factors all together mean that fixed cost have increased and can only be recovered by a higher turnover of tests. Maintaining quality of service at reasonable levels also requires a high volume of tests.

In response to these trends there is a much stronger need than in the past to create volume by consolidation of laboratories, sharing of expensive equipment and considering outsourcing of tests for which the volume is low. A good example of consolidation of laboratory capacity is provided by Lithuania’s upgrading of laboratory services as part of its preparation for the accession to the European Union (EU). The number declined from 50 laboratories in the area of food and veterinary services in 1994 to 11 in 2001 and a further decline to five is foreseen (World Bank 2007b; Paulauskas 2007). Similar trends in consolidation of the laboratory infrastructure are experienced in other new EU member countries that upgraded their capacities. These experiences provide useful lessons for developing and transition economies that are considering upgrading their laboratories, and donors interested in supporting investments in these laboratories.

Governments and donors face a dilemma because the volume of work in public laboratories in many countries is too small to allow for sophisticated equipment and international accreditation. The options available to cope with this dilemma include:

- Consider creating larger laboratories by consolidating the national laboratory infrastructure for food and agriculture
- Avoid investing in high levels of sophistication
- Consider outsourcing to other laboratories, both private and public, at home and abroad
- Consider making use of regional facilities
- Pursue quality control without seeking immediate accreditation if the ISO 17025 International Standard
- Consider making use of rapid detection kits

Levels of technical sophistication

Laboratories for regulatory purposes can be stratified in functions and level of sophistication. Bigger countries often have laboratories at three levels, national, regional and local. The national level has reference laboratories for the main areas of regulation – veterinary, plant health, food safety – which have the highest level of sophistication and offer a wide range of diagnostic tools. A reference laboratory is the ultimate authority in disputes over tests and plays a role in standardization of testing methods in the country. It usually also offers specialist services to
regulators such as in trade disputes and in standard setting. A reference laboratory can also provide training and support in quality management for other labs. Next to reference laboratories there are regional laboratories with a lower level of sophistication and a smaller range of diagnostic tools. Local laboratories are usually simple and offer a limited range of simple tests for first line animal health care, food control and extension services. Positive test results and complicated questions can in principle be forwarded to a regional or national lab. Small countries cannot afford a three-level system and various functions are carried out on two levels or can even be combined under one roof.

Private laboratories also have different levels of sophistication and range of tests performed. In-house laboratories in dairy factories can be simple wet laboratories whereas, for example, testing for pesticide residues or heavy metals in the export industry requires sophisticated equipment. Public reference laboratories may or may not be the most sophisticated laboratories in the country. In quite some cases private laboratories have equal or even better capabilities in certain specialist fields.

Industries in developed countries seeking quick test results have adopted sophisticated equipment that could process large volumes of test samples a day, as well as multiple analyses. Such modern testing facilities are, however, not required by the developing countries as the workloads are far below what this equipment demands. Moreover, the quality of utilities and buildings necessary to maintain such systems and cost of operation are much above the possible levels of sustenance in developing countries. The public laboratories in developing countries are mainly used for product certification, not for regular monitoring of product safety in large industries, and do not require such labor saving sophisticated high productivity systems.

However, there is room to accept some of the less sophisticated test methods marketed in the form of test kits for monitoring factory hygiene and testing specific microorganisms and mycotoxins (Box 5). The kits are becoming more popular in the food industry to carry out in-house monitoring of in-process product quality. Some of the test kits are validated by reputed international organizations forming reliable tools in ensuring food safety at farm or factory level.

### Box 5. Rapid test kits

A variety of test kits are available for rapid detection of antigens. They use a variety of technologies including enzyme linked immunoassays (ELISA), lateral flow immunochromatic assays, sandwich DNA hybridization assays etc.

Among the rapid test kits current on the market are
- Selected plant and animal disease detection kits
- Mycotoxin detection
- Pesticide detection kits
- GMO detection
- Detection of animal proteins in feed
- Sanitation test kit

These are marketed by a variety of companies, some offering only one or two specific tests, others with a comprehensive list; the costs varying from US$ 5 to US$ 50 per test or more.

**Source:** Schillhorn van Veen 2007.

A down-side for some cases is that the use of test kits along with the conventional tests methods is not encouraged by accrediting bodies for laboratories following ISO 17025.

Nonetheless, for smallholders and small enterprises there is a need for cheap and less sophisticated test kits. For example, high performance liquid chromatography equipment needed
for detecting pesticides cost approximately US$ 50 000. To make this investment pay requires either a high volume of tests per laboratory or a high price for the tests. A price of roughly $ 35/test (based on a low volume of 1000 tests/year, a 5 year write off, and a $ 20,000/yr operating and staff costs) will be too high for a small farmer delivering a few sacks of groundnuts, valued at maybe $100.¹⁰

The industry is responding by developing simpler and cheaper tests. The test kits increasingly provide viable options at low infrastructure costs to developing countries. Some developing countries such as Pakistan (Water Board) and Sri Lanka (private sector initiative) have developed their own low cost test kits through their own initiatives (Samarajeewa 2007). Although these test kits have not gone through rigorous validation they have begun to serve needs of national food safety. Some of the countries in the forefront in laboratory testing may develop test kits to serve the food industries. Combining the use of test kits with conventional testing at the level of the food industry may be a viable low-cost option. Of the samples examined by test kits at the level of the industry, 10 percent may be checked by the conventional test methods.

Investing in public laboratories or making use of private laboratories

Balanced development of the laboratory infrastructure

Private laboratories perform important roles in the food and agricultural sector, and their development requires an encouraging business environment. Yet, in many countries policies and regulations can seriously discourage private investment in laboratories. In many cases there is no fair competition between public and private labs. Directors of government laboratories with serious shortage of public funding, often try to mitigate their funding problems by advocating public monopoly for certain services and regulatory constraints for actual and potential private competitors. They often have a willing ear from superiors who see market protection for public laboratories as alternatives for allocating public resources. For these reasons it is important that policy making for developing and regulating a national laboratory infrastructure is not solely in the hands of units with direct responsibility for funding public laboratory services.

Subsidies and taxes may also contribute to unfair competition. Often public money is used by public laboratories to provide services at low prices. Moreover, private laboratories usually have to pay sales and profit taxes, whereas public laboratories are exempt, even for providing commercial services. For a balanced development of private and public facilities equal treatment is desirable.

Should public laboratories invest in commercial services for the export market?

Investment in public laboratories is often recommended as a way to serve the private sector in export markets. However, there is no reason why services from public laboratories would be intrinsically cheaper or better than from private laboratories if there is a level playing field; on the contrary, in many cases private laboratories have out-competed public laboratories in the quality segment of the export market. Experience from Kenya shows that although domestic capacity is available still many entrepreneurs send their samples to Europe (Wainwright 2007). Many private businesses don’t even consider using public sector capacities in developing countries, regardless of the sophistication and quality management in these laboratories.¹¹ Caution is needed in assuming that it will be easy to convince entrepreneurs to use local capacities. Therefore, careful analysis of actual and potential private sector demand is needed before decisions are taken. Are there really

¹⁰ Unfortunately, none of the present evaluation tools on laboratory capacity (Arellano et al., 1992; Pearson, 1998; Squarzoni et al., 2004; EC/DG SANCO, 2006; etc.) really address the issue of costs or financial sustainability.
¹¹ This is generally the case with A-brand companies and private schemes like Global GAP (EurepGAP).
important pockets of unmet demand in the private sector? Can services be supplied domestically at lower prices? And is supply from public laboratories the best answer? Samples sent to laboratories abroad are no proof of lack of capacity in the own country. Potential demand may not be matched by adequate supply of services in terms of kind of tests, quality of work, reliability of services and general trust in the laboratories, but that does not mean that it is economically feasible to create public domestic capacity to meet that demand. The case for public investment in serving the private sector in export to demanding markets is generally weak at best.

**Purchase of services from other laboratories**

If reliable capacities already exist, outsourcing to such laboratories can be a good strategy to cope with lack of economies of scale. By outsourcing these tests, the laboratory can maximize its resources and focus on those activities that it does best. The outsourced laboratory may be private, it may be another government laboratory, or it could be one located outside of the country. This outsourcing can be occasionally for low volumes, but it is also possible to sub-contract private laboratories for specialized services such as testing for pesticides or mycotoxins. Some form of contractual agreement will be needed for the services to be performed. Examples of outsourcing are given in box 6.

Within the context of the IPPC, OIE, and Codex, there is no restriction to outsource laboratory services to other organizations such as regional or provincial governments, other government agencies, or domestic or international private sector laboratories. It is even possible to outsource the complete service. The international organizations require that if outsourced services are to be used, then these organizations be designated by the recognized authority (NPPO, Veterinary services, Public Health). Therefore, from an international standpoint, the government is not required to directly conduct the diagnostic work. In fact, the diagnostic work need not even be conducted in country, but can be done by others outside of the nation.
Box 6. Examples of outsourcing laboratory services

Kenya, has outsourced a significant component of import and export conformity testing to SGS and Intertek, which are independent 3rd party private laboratories. These two private companies provide all of the conformity testing for all imports and exports and supply the information to the appropriate agency so that the export certificates can be issued. For conducting this conformity testing a fee is charged, a portion of which is retained by the service provider and the remainder is returned to the government. The laboratory provider is responsible for the complete operational costs including facilities, manpower, equipment, etc. The contracts typically have a fixed timeframe -- 5 to 10 years. At the end of the contract, the service provider may be required to turn over the complete operation to the government.

The National Agri-food Health and Quality Service of Argentina (SANASA) authorized two private laboratories – JLA Argentina and SGS Argentina – to test aflatoxin in peanuts intended for export to the EU.

The Indian government has contracted VIMTA Labs (a private laboratory in India) for several major projects. A recent example is the test of guar gum for export to the EU. The EU found PCP (penta chlorphenol) and dioxins in Guar Gum powder produced in India above maximum residue limits and imposed a ban.

Finally, it is also not uncommon for governments to contract with private veterinaries, para-professionals, private agricultural professionals, and provincial/regional employees to conduct surveillance and testing on behalf of the central government. Again, this is done by contract and allows the central government to pay for specific services on an as-needed basis in regions or areas that are not adequately covered by central government employees or services.


Outsourcing diagnostic capacity may not always be viable or even advisable. The logistics of shipping samples across poorly maintained roads, the lack of infrastructure to maintain the integrity of the sample, or the politics between the originating and receiving countries may all be impediments. Also risky disease agents cannot be transported internationally or need specific precautions and permits. Concerns about confidentiality and property rights may also limit outsourcing abroad. Another consideration is the priority or importance of the results. If, for example, a test for a specific disease or pest is outsourced to a laboratory in another region and that region experiences an outbreak, then the samples from that region will have priority. The outsourced samples shipped into the laboratory may not be analyzed at all or may be greatly delayed, and the spread of this disease or pest across the border may not be detected in time. Furthermore, as sample volume for a specific analysis increases, it may become more cost effective to bring the testing in-house. These types of factors should be taken into consideration in the business plan.

Quality management and accreditation

Reasons for low quality

Quality management in public laboratories is in many cases poor with weak incentives for improvement. Even in cases where much support has been received from donors quality management and quality results tend to decline after support is ended. There are a number of basic reasons for that. Most of the work of the laboratories and inspectorates is for the domestic market. Nearly all veterinary, plant protection and food safety services are demanded and paid by the public sector which generally does not demand high quality. The number of samples that can be handled depends on a fixed annual budget and since high quality services cost more than low quality services, there is incentive to have a high number of tests and to compromise on quality. Income from fees and informal payments are related to the number of transactions which strengthens the focus on volume of samples rather than on quality.
Most public laboratories are in-house government laboratories with a culture not conducive for running laboratories as efficient businesses. The incentive structure for quality is generally weak, and many government rules on procurement, hire and fire, setting of fees, and contracting can thwart the efficiency and effectiveness of service delivery. Revenues from fees often go back fully or in part to the central government budget. Under such conditions it is very difficult to serve two market segments with widely different quality requirements, i.e. a major domestic market segment with low requirements and a smaller export segment that has high and specific quality requirements.

Upgrading laboratories to achieve certification and accreditation can be expensive and requires strong and sustained efforts to develop a quality culture. As long as the demand for quality for the main domestic services is weak and the culture is not improved chances for sustainable improvements remain limited. Upgrading of quality of service in the absence of incentives for staff and management, renders in many cases limited benefits. Sustainable improvement of quality may require sustained attention from senior management in ministries and long-term support from abroad.

Quality control in autonomous not-for-profit laboratories is easier because the laboratory is at least in part responsible for its own survival and it can easily implement incentives for performance of staff and management. Quality management can be prescribed in the institution’s regulations and by main users through performance based contracts. For private sector laboratories quality is key for survival. High costs can only be recovered by serving markets that demand quality. Failure to meet quality requirements easily means end of business.

Quality of laboratory services is crucial for confidence in the results. Since quality cannot always be easily observed by the customer, systems of quality management have been developed, using internationally defined good laboratory practices (OECD), proficiency testing, certification and accreditation. In demanding international markets much weight is given to the adoption and accreditation of ISO 17025, a standard defined by the International Standards Organization (ISO).\(^\text{12}\) This standard is mandatory for EU reference laboratories for food and animal health. Yet, it is important to point out that adoption of these quality management tools does not automatically lead to trust in the laboratory with respect to independence, timely delivery and precision. In particular public sector laboratories in developing countries have to overcome suspicion and credibility challenges from potential private sector clients.

Upgrading a laboratory to the ISO 17025 standard requires significant investment in facilities, utilities, training and equipment. In addition to the initial investment, the costs of maintaining the accreditation status are in the range of tens of thousands US dollars per year. These costs are too high for the small annual workload of many public laboratories in developing countries. If there is a domestic accreditation body with international recognition the cost may be lower, but the existence of an accreditation body also requires a critical mass of laboratories, certification organizations, etc., which small countries do not have. So far not many low- and middle- income countries have accredited laboratories, even among those that are WTO members (see Annex V). Excluding the EU member countries, of the 98 low- and middle- income countries that are WTO members over 70 percent of them do not have

\(^{12}\) For plant health laboratories the standard is not yet generally applied (Beug-Deeb and Deeb 2007), but such accreditation is reportedly emerging in Europe.
internationally recognized accredited laboratories. Those countries that have internationally accredited laboratories are mainly bigger middle income countries.

A UNIDO survey among 343 responding laboratories involved in testing of food in Africa found that about one third (103) were nationally accredited of which 70 in SADC and 21 in northern Africa. Only 9 were internationally accredited (5 in northern Africa). There were virtually no internationally accredited laboratories in Sub-Saharan Africa (UNIDO 2007). Still, many of these countries do export, raising questions about the benefit/cost and urgency for broad accreditation. Many exporters use accredited laboratories abroad.

**Regional and international cooperation**

International cooperation is one way to deal with economies of scale and high cost for small numbers of samples. Sharing of resources, for a fee, allows each country and organization within a region to maximize the use of their limited resources.

Especially for small countries regional cooperation looks attractive for avoiding duplication through jointly operating regional laboratories and for specialization among countries. A good example is the network of 171 Reference Laboratories covering 93 diseases/topics in 30 countries, and 24 Collaborating Centers covering 22 topics in 14 countries with OIE certification for diagnostic tests for animal diseases (Box 7). Another example is the Pan-American Health Organization (PAHO) which supports the control of certain zoonoses and of foot and mouth disease in Latin America.

**Box 7. OIE’s reference laboratory program**

Reference laboratories are certified to pursue the scientific and technical problems relating to a named disease on the OIE lists. The role of the reference laboratory is to function as a center of expertise and standardization of diagnostic techniques for its designated disease. The expert, responsible to the OIE and its member countries with regard to these issues, should be a leading and active researcher helping the reference laboratory to provide scientific and technical assistance and expert advice on topics linked to surveillance and control of the disease for which the reference laboratory is responsible. They may also provide scientific and technical training for personnel from member countries, and also coordinate scientific and technical studies in collaboration with other laboratories or organizations (see OIE Mandate and Internal Rules for Reference Laboratories). Most laboratories are specialized in a single or a few diseases.

*Source:* Beug-Deeb and Deeb 2007

Although there is much talk about the option of regional cooperation in practice often the trend is even reverse. Several forms of regional specialization in the former Soviet Union 13, in former Yugoslavia and in colonial Africa fell into disarray with decolonization and independence of countries. Countries want to be self-reliant and have their own laboratories for regulatory purposes, just as they want their own airliner, even if the scope for sustainable exploitation is dim.

The private sector is more globally oriented in investment and use of laboratories than governments are (see Box 8). Perhaps the tide may turn among governments under influence of high cost, increased market requirements and lessons from failures. In Africa the harmonization of standards and collaboration in regional laboratories is on the agenda of several regional groupings, especially in the Western African Economic and Monetary Union (UEMOA). Many difficulties

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13 Not all have disappeared. For example the Vladimir laboratory in the Russian Federation is still serving CIS countries as the OIE regional reference laboratory for FMD.
have to be solved about rights, responsibilities, management and logistics, and not in the last place border crossings of samples.

**Box 8. Example of a regional private laboratory**

| In order to participate in the Aquaculture Certification Councils Best Aquaculture Practices (BAP) certification program, shrimp suppliers and growers must submit routine samples to a certified laboratory. While there are a few approved laboratories in Latin America, only BSI Inspectorate Lab – Ecuador has the volume, provides the turnaround time required by industry, and has the cost per test to meet the needs. While the cost of its services is relatively high, clients still find enough value to pay for these services. **Source:** Beug-Deeb and Deeb 2007. |

Within the context of laboratories that are used to support regulations and regulatory bodies, there are some basic elements that are required for regionalization of laboratory services to occur. These include: a demand for testing, legal framework, a common understanding and setting of test standards and laboratory operational systems, processes to transfer samples and materials, which in some cases may contain hazardous materials, and a system of compensation between organizations.

Obviously, the first and most critical element is the development of the demand for testing that will support the investment in the laboratory. This demand can be derived from many sectors, but the assumptions need to have a firm foundation. Then each party needs to come to agreement on several areas and this agreement should be embodied in an intergovernmental Memorandum of Understanding (MOU).

The MOU will help define the legal framework that the program will operate under and the relationship between the parties. This document will help outline what each party is committing to and will define the expectations and outcomes from this activity. In addition, the MOU should define at what point either or both parties can exit the agreement and what form exiting takes.

As a part of the MOU, or referenced documents, the organizations and countries will need to agree upon the test methods and standards to be used to conduct the tests. The parties will need to agree upon what operational systems and processes will be used to conduct the tests such as quality systems. Further, the laboratory will need to be accredited to conduct tests by each country as required by the OIE and Codex.

Because the samples are being moved across international borders, there will need to be agreements between the parties as to how the samples are to be shipped, how they are packaged, and who should receive the samples.

An alternative to MOU and other formal agreements is for the laboratory to simply outsource specific sample testing to other laboratories either in or outside their country. This provides the organizations involved with the greatest degree of flexibility. It also allows services to be purchased on an as needed basis. This works well in many cases for infrequent specialized tests for which there is a low demand that will not support investment in laboratory capacity.

The regionalization of testing services will need to be integrated into and managed as a part of ongoing regional disease control/surveillance programs. Because of the skills and investment required in equipment, supplies, and human resources, there is some movement towards regionalization as a part of the control programs related to Highly Pathogenic Avian Influenza. In at least one case in Africa, regional laboratory capacity is being used and recommended as a part of
the overall strategy. Regionalization allows for confirmation laboratories to be established without the excessive costs of having duplicative capacity in each country.
6. External support

In many developing countries donors provide a critical role in laboratory improvements. Most governments don’t want to invest large amounts of scarce budget in expanding laboratories, so the main resources for enhanced infrastructure come from grants and loans. Moreover, given the technical complexity of building an effective laboratory system, international support is necessary, especially for poor countries. Consequently, the aid community shares responsibility for unsustainable investments in laboratory capacity made in the past.

Once again, the main reasons for unsustainable outcomes of donor interventions have been:

1. Investment is often isolated from the policy and institutional environment in which laboratories operate. Most factors for success and failure are directly related to the regulatory system in which they operate.

2. In the design of many investment projects there is too much emphasis on technical preferences and inputs and relative neglect of outcomes of the investments in terms of prevention of risks, improved health outcomes, mitigation of problems, or realization of growth opportunities. Recommendations for adoption of international standards and investment in laboratory capacities are often insufficiently based on assessment of the related benefits and costs.

3. In many cases there is imbalance between support for hardware and software. There is insufficient appreciation of the need for long-term training of staff and management – much of which is on-the-job training – before good use can be made of all equipment and quality management is internalized.

4. Sometimes there is also a (perhaps unconscious) bias to the issues of donors’ own interest and concerns, which are actually low priorities from the recipient point of view. This is often the case in measures proposed to contain animal diseases and in bilateral trade relations.

5. There is an imbalance in qualifications of consultants guiding the investments; there is too little institutional and financial expertise. Many technical consultants from OECD countries have limited experience in developing and transition economies.

6. Lack of donor coordination can contribute to serious over-investment and a scattered laboratory infrastructure with much overlap. Box 9 provides an example.14

The failures of investment in laboratories have resulted in increased reluctance among donors in investing in labs.15 Yet, there has been little effort to evaluate experiences, and in the absence of evaluation results, there has been a tendency to blame institutional weakness for poor performance, ignoring deficiencies in the design.

Lessons from past experience suggest the following changes in emphasis:

- Rebalance attention between software and hardware; more input of institutional and financial expertise is needed;

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14 In fact this example also reflects lack of coordination by the receiving country.
15 Priority for Avian Flu has at least temporarily reversed the declining trend.
Better donor coordination;

Supportive projects should be of longer duration than common in the past. More support is needed for the preparatory phase and prolonged support is needed for the implementation phase with major attention to training on-the-job of all staff and management and establishing quality management. Twinning arrangements with more advanced laboratories can be a helpful tool.16

Lessons and experiences of World Bank laboratory investment projects in the past decade or so are summarized in Annex VI.

**Box 9. Lack of donor coordination leading to over investment**

In one country there were at least 10 different laboratories within the public and private sector that conducted analysis on plants and plant material, animal and animal materials as well as food stuffs. The two private laboratories were accredited to ISO 17025. The public sector laboratories were part of the Ministries of Trade, Justice, Agriculture (plant, fisheries, and veterinary services), Public Health (food control and drugs), and Environmental Resources. All of the laboratories were located within 20 kilometers of the capital city. Each of these organizations felt in order to meet its mandate it needed to be able to test for pesticide residues.

There are several ways to test for pesticide residues, but all of the laboratories felt that they needed to be able to conduct the assay using GC-MS (Gas Chromatography coupled with Mass Spectrometry). This is a sensitive technology that can provide excellent qualitative results and when coupled with other detection methods can provide quantitative results as well. However, as indicated in Table 3, there are many technical requirements that a laboratory must meet in order to successfully operate a GC-MS.

Each of the public laboratories worked with key donors to provide investment for the equipment, facilities and training which cost upwards of 150,000 USD per group.

In the period of one year, six of the public laboratories were able to raise the funds from donors in order to purchase a GC-MS. In some cases while the equipment was purchased, the facilities were not adequate and needed to be improved prior to installation. In all cases additional staff training was required before the systems could be used. The total expenditures in one year was about 900,000 USD. Yet the total sample load for this type of testing was about two to three samples per year for all of the laboratories combined.

Furthermore, none of the public laboratories were recognized by the buyers or the countries of destination as being competent and therefore results from these laboratories could not be used for exports even with the technology in hand.

*Source:* Beug-Deeb and Deeb 2007

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16 The consolidation and upgrading of laboratory capacity in the Baltic countries after the breakup of the Soviet Union was greatly enhanced by twinning with European institutions, as well as major funding by the European Union and lending institutions such as the World Bank. This still ongoing effort has taken over ten years.
7. Drafting a business plan

As part of the preparation of an investment proposal for upgrading or adding laboratory capacity a series of topics need to be considered that are important to the relevance and quality of the proposal and the cost-effectiveness of the new capacities. These topics include:

- general and specific policies and regulations
- description of the existing laboratory facilities and their quality
- assessment of the laboratory for which investment is proposed, including its capacities and operational performance
- assessment of trends in demand for laboratory services
- design of the investment proposal, including proposals for changes in
  - policies
  - governance and administration
  - quality management
- prioritization and financial and economic feasibility of the investment
- making the case for investment
- monitoring and evaluation

The best way to present this information is to write a business plan. This is common practice for investments in the private sector but much less so far in public investment. In the following sections the main topics of the proposed contents of a business plan are discussed.

Policy framework

Policies and the way they are framed in the legal framework provide the rules of the game for laboratories and they have direct impact on the functioning of laboratories vis-à-vis the control system and the market sector. This section of the business plan describes the main policies for laboratories and the control system with the specific aim to detect possible general and sector specific policies that hinder the development of the laboratory system and form an obstacle to cost-effectiveness of the control systems and efficient operation of public laboratories.

The higher level policy issues most likely to affect decisions on food and agricultural laboratory upgrading include: perceptions and resulting decisions with respect to acceptable levels of risk for food safety, plant health or animal health; competition and the role of the private sector; economic growth versus sustainability and consumer protection; and the relative importance of export versus domestic markets. Adequately covering such issues goes beyond the scope of this document.

One level down, however, national policies with respect to quality infrastructure, with regard to the role of government, and with respect to policy coordination between the health and agriculture ministries do have a direct impact on national agricultural laboratory infrastructure. If the main line ministries lack a working relationship and interagency process, it is hard to improve laboratory infrastructure and operations. Similarly a level playing field is important for a balanced development of public and private laboratories. Unfair competition can arise from tax treatment, subsidies, or unequal regulatory requirements such as for permits and licenses.

Sector specific policies and strategies for food safety, plant health and animal health have a direct
impact on demand for services and priorities in work programs. Individual ministries might also have strategies which affect demand for diagnostic services and certification; there can be ministerial investment plans as well. Contingency plans for outbreaks and food safety emergencies have to be taken into account in planning and work programs of laboratories. Ministries, or laboratories mandated by them, can have two kinds of bilateral and multilateral agreements: (1) mutual agreements about recognition of laboratory standards to be used in trade and health protection, and (2) agreements on outsourcing of tests for specific purposes to each other’s laboratories.

Crucial for the functioning of control systems are the programs for monitoring, surveillance and inspection. They form the main source of demand for most public laboratories in food and agriculture; they also dominate the demand for quality. In most developing countries the quality and effectiveness of these programs and their compliance with WTO and market efficiency requirements need significant improvement in the years ahead. With the evaluation of investment in laboratories a critical assessment of these programs and possibilities for improvement need to be included. Issues of interest are the strengthening of risk-based inspection and sampling strategies and reduction of rent-seeking tendencies, identification of areas of artificial demand and unnecessary inspection and sampling. Also important is how sampling strategies deal with particular characteristics and health risks of informal, modern urban and export markets. Last but not least, information is needed on public budgets for diagnostic services and likely developments in funding in the years ahead. A guide for structured interviews is added in Annex I.

**Description of the relevant national laboratory capacity**

The second step for the planning of upgrading of capacities of laboratories is the assessment of the relevant laboratory infrastructure and its output. Items to be described for each laboratory are mandate and scope, ownership, management model, governance issues, capacities in terms of equipment and human resources, range of services provided, the number of samples analyzed per year, and quality management. The description of quality management includes at least calibration, description of quality systems, GLP, SOPs, proficiency testing, certification, accreditation. Attention should be paid to possible expansion of public and private capacities in years ahead. A guide for structured interviews is added in Annex II.

**Assessment of the capacity of the laboratory seeking investment**

A third step for planning is an assessment of the capacity of the laboratory asking for investment. There are several assessment tools for laboratories. The one proposed here covers parts of the contents of other tools, but it gives relatively more attention to the business aspects of the laboratory: costs, revenue and administrative conditions for operating the laboratory as a business and less to the technical aspects. The assessment should provide a SWOT (Strengths, Weaknesses, Opportunities, Threats) analysis of the present situation, indicate issues to be addressed for better performance, and point at options for upgrading and expanding the laboratory. A guide for structured interviews is provided in Annex III.

A dominant factor for the performance of the laboratory and prospects for upgrading and expanding is the potential public and private demand for fee-based laboratory services for five years ahead. An assessment of demand brings together information collected in the Annexes I, II and III. The most important issues are discussed in the following sections.
Assessing demand for services in a public laboratory

Public demand
A description is needed of the monitoring, surveillance and border and domestic inspection programs that will generate demand. In addition there can be sponsored programs by extension and veterinary services for which the government pays part of the cost. What will be the number of samples, the range of tests, the precision required, and the number of tests? Will inspection programs be risk-based and WTO compliant? What capacity will be needed for outbreaks and emergencies? The likely amount of public funding for these laboratory services needs to be specified. The critical assumptions and the main risks for these assessments need to be analyzed. Particular points of special relevance to the assessment of the volume of demand are:

- Identification of artificial demand such as unnecessary inspections that violate WTO principles and/or negatively affect the investment climate.
- Identification of artificial demand for public laboratory services resulting from policies and regulations which create unfair competition with private laboratories.
- Logistics and quality management problems that reduce the number of samples that are actually tested.

Private demand
A description is needed of present and potential private demand for laboratory services five years ahead. A specification is needed of the kind of services, the required precision and turn-around time specified for the three market segments in Table 2. Analysis should be provided of the factors that drive the trends in private sector demand and uncertainties need to be mentioned.

Shortage and excess capacities
On the base of the description of present capacities and trends in demand a general assessment is needed of quantitative and qualitative shortage and excess of capacities in the country and more in particular for the laboratory that is seeking investment. The assessment should take into account the likely share of the public laboratory in total public and private demand. It should not overestimate the share of private demand that public laboratories will serve, and realistically assess the demand that will seek services abroad and private demand that is unlikely to go to public laboratories.

Drafting the investment plan
Before a plan can be drafted a mission should be formulated describing the purpose of the laboratory and the scope of work. Then, on the basis of information gathered and analysis of various factors that affect performance of the laboratory, a draft plan can be formulated, providing the scope of investment with a number of options for further assessment and prioritization. At this stage no detailed plan is needed yet.

Alternative investment options need to be explored. They will be related to crucial assumptions made regarding

- levels of demand
- possible reforms in governance and administration
- quality management options
• outsourcing to other labs, public and private in the country and abroad
• consolidation of laboratory infrastructure.

Explicit consideration needs to be given to alternatives to upgrading the laboratory. Countries with small-scale laboratories, a scattered laboratory infrastructure for food and agriculture and limited numbers of samples face serious limitations and trade-offs in (i) purchasing sophisticated equipment, (ii) choosing scope of operations and (iii) adopting advanced quality management systems. Serious considerations should be given to possibilities of mergers and consolidation of the laboratory infrastructure, cooperation and specialization, and outsourcing inside and outside the country.

**Governance and administration**

Where relevant, policy recommendations should be made to improve the scope for cost-effective management. Public laboratories need to have sufficient autonomy to be managed as efficient businesses. Procurement, financial management, incentives for staff and management need to be conducive for cost-effective operation. This means that laboratories should be moved out of core government services into peripheral entities with sufficient autonomy, preferably to a status of not-for-profit autonomous bodies (see Table 1 for description of models). This is in line with trends in management of laboratories in OECD countries.

Tariffs for laboratory services need to reflect real costs and should be adjusted periodically if changes in costs occur. Cost-based tariffs are needed for rational management and for fair competition. For external clients tariffs should be set on the basis of total cost. In case the government contributes directly to investment or other cost components the internal tariff should have a proportional discount. Estimation of cost for samples and tests is an important tool for rational management and funding decisions.

Assuming that the administrative systems provides managers with sufficient room to maneuver, general good practice is that public funding of laboratories should as much as possible be output--or better still--performance-based. Under performance-based systems staff and management can be made accountable and incentives could be added for quality of services delivered. Input funding should be reduced as much as possible.

**Quality management**

Quality management is a critical element in all successful laboratories. It follows that quality management provisions should be included in the business plan. Recommendations will depend on the size of the laboratory, its main source of demand and the level of quality management achieved in the past. Since the government is the main user of services in public laboratories and the main source of funding it has a special responsibility for promoting quality management. It can require quality management targets as part of the annual contract and provide incentives for meeting targets. Minimum standards of quality assurance and proficiency testing should be mandatory through policy directives or performance based management contracts. Active oversight is needed with annual audits to confirm that the management of laboratories complies with its mandate and tasks. Periodic peer review by independent experts is desirable. Needless to say, government requirements for quality management can be seriously undermined if the financial resources provided to the laboratory don’t allow quality management practices really to be implemented.
Accreditation against the ISO 17025 standard may be a long-term goal for many diagnostic food and veterinary laboratories. Yet for many poor countries the size of laboratories, the present level of capacities and the resources available make achievement of that goal impossible for the foreseeable future. Quality management plans should aim at measurable stepwise improvements over time.

Training is a crucial element in quality programs and especially in case of new investment. Twinning arrangements would generally be helpful for staff training and improving quality management. In particular in small countries it is not easy to recruit staff with sufficient skill mix and depth. Academic training in the country can be insufficient to provide the needed background expertise specified for pant health, animal health and food laboratories. This may constrain the range and quality of services a laboratory can produce.

**Feasibility of investment**

Financial analysis is a core part of the planning of investment in a laboratory. For a public laboratory not only the operational costs (supplies, training, maintenance and repair) but also anticipated expenses for gradual upgrading and quality management should be recovered, and liquidity should be sufficient to cover these expenses when needed.

Good practice for investment in infrastructure is to make cost-benefit analysis and to calculate the internal rate of return. Unfortunately, this practice is mostly not followed by donors and governments for investment in the laboratory infrastructure and therefore not many data sets are internationally available that can be used for reference. So, it is highly desirable that more efforts are made to assess direct and indirect economic benefits from increased market access and improved human, plant and animal health.

Assumptions on annual revenues from services provided and other sources need to be explicitly presented in the analysis and need to be discussed with staff in financial planning departments in the relevant line ministries and the Ministry of Finance.

Initial investment plans may not be financially sustainable or economically feasible and need to be adjusted in an iterative process by considering outsourcing and reducing tasks which will not receive sufficient paid demand to cover costs. In the iterative process also policy reform options and alternatives such as mergers or consolidation of the laboratory infrastructure need to be considered.

Explicit attention is needed to on-going and new donor activities in investing in the laboratory infrastructure. Other investments could have impact on the feasibility and relevance of the proposed investment.

**Making the case for investment – What are the benefits?**

Since willingness to provide annual funding for operational cost is a crucial variable for sustainability of the investment in laboratories major effort needs to be made to provide senior decision makers with relevant data on social and economic benefits and financial sustainability.

Plans should avoid making unproven assertions about benefits to be produced by generic capacities. Such claims could very well undermine credibility. Instead, efforts should be made to show real benefits as the outcomes of the investment, and preferably a full-fledged economic analysis should be provided. But efforts should go beyond figures and aim to provide concrete outcomes in the area of foreign trade, public health and agricultural income.
International obligations, such as membership in free trade areas or the WTO may form a political justification for investment in laboratories. However, claims on these grounds have to be precise and prove some urgency. Erroneous arguments about WTO and market access requirements can backfire.

Justifications for senior policy makers have to be focused and selective, and show real benefits.

**Monitoring and evaluation**

Given the poor performance of many investment projects in public laboratories continuous efforts should be made to identify and sharpen good practice. Monitoring and evaluation (M&E) tools are important for registering performance, improving learning from experiences and sharing experiences. M&E is the basis for good evaluation. Therefore, M&E needs to be part of all major investments in laboratories. Proposed performance indicators for M&E are presented in Box 10.

**Box 10. Proposed performance indicators**

The performance of laboratories can be measured in various ways (see for example FAO 2006). Indicators may include:

- Annual gross revenue (total operating income plus inflows from government budgetary plus grant received from third party sources)
- Net change in operating income and reserves
- Effective demand (numbers of samples, tests asked for)
- Output (i.e. quantity of total output, output per FTE, output per budget unit)
- Turn around time
- Percentage of demand not delivered
- Quality of output (scores in proficiency testing schemes)
- Rating of quality management (manuals of Standards Operational Procedures, calibration, participating in quality control and performance schemes)
- Training, library and internet access cost as a percentage of total gross revenue
- Maintenance and repair of equipment and facilities as a percentage of total gross revenue
- Salaries and benefits as a percentage of total gross revenue
- Percentage of output- and performance-based funding (fee income as percentage of total gross income)
- Rating of infrastructure and equipment (status, upkeep, performance, plans for servicing, calibration and repairs etc.)
- Staff numbers and their skills
- Rating of reporting and data management
- Indicators of stakeholders and end-users satisfaction (measured through surveys if possible)

*Source:* Authors of this report
8. The Building Block Approach

Analytical services are a highly technical area requiring, among other things, a highly trained workforce, well equipped facilities and sophisticated equipment. Analytical services support the regulatory system by providing the data on which legal and regulatory decisions are made. Therefore, the reliability and quality of the results (i.e. the data) are of utmost importance. Unreliable data can result in decreasing sample load or decreasing support and funding as trust in the facility is eroded. Unreliable data causing unjustified enforcement can become a national embarrassment. Therefore, the necessary processes and systems must be in place to ensure reliability and quality of the results, further adding to the required complexity and sophistication.

Putting a fully functional plant health, animal health, or food safety laboratory in place is not an easy task in any country. The long-term success of such a project is usually constrained either by financial or human resources or both. In less developed countries, this can be an especially difficult challenge. The answer to this challenge is to take a step back and take a long-term holistic approach based on 5 principles:

1. First of all, the government must provide sufficient on-going financial support. Without government support, public laboratories will not be fully funded, forcing them to either fail or compete with the private sector or into rent seeking behavior. The amount of the government support also defines the extent of analytical services that will be viable long term. This is the primary factor that defines the scope and size of the future analytical services.

2. The long-term goals of the analytical service function are defined using the business plan model outlined in the previous section of this report.

3. The path to achieving the long-term goals should be broken down into several achievable well-defined phases (3 to 5 year duration).

4. The initial laboratory project is designed to meet the goals of the initial phase, not unlike a starter kit for building blocks. This starter kit should include fully modern basic laboratory units with all the systems, processes, and support (including training, human resource, management and basic quality systems) in place to be fully operational and credible. It is recommended that additional technical resources are assigned to help these basic units to continue to grow.

5. Once such basic units are sustainable and self-sufficient, additional capacity or capabilities can be added. Adding to a well-functioning basic laboratory has a much higher chance of success than trying to build all systems at once. Sustainable and well functioning basic laboratories have the systems, processes, and human resources already established that make them successful.

For countries without current adequate analytical services the recommendation is to increase laboratory capacity in a stepwise fashion. This allows the countries to develop the necessary human and financial resources required for sustainability. The first step is building basic laboratory units sufficient for domestic and import surveillance with all necessary support to make them sustainable.
Stage 1: Basic Laboratory Building Blocks

Initial laboratory facilities are designed to provide the data to support domestic surveillance and import inspection efforts. The assumption is that there is no current export market and little or no commercial food processing.

There are two categories of requirements to consider when planning any laboratory: what is needed to start-up a turn-key laboratory and what continuous support, including technical expertise, be needed to grow in-country capabilities over time so that sustainability can be achieved? All of these elements must be included in the planning and funded with adequate budget. In fact, soft support (training and technical support) is often underestimated in planning the budgets for analytical services. Private sector service functions calculate a 2 to 1 budgeting ratio for soft support versus equipment. These elements are listed below and are described in more detail in Annex IV.

- **Required Start-up Elements:**
  - Facilities and Environmental Conditions
  - Equipment
  - Management Organization and Human Resources
  - Sample Volume
  - Test Methods
  - Quality Management Systems
  - Environmental Impact, including waste disposal
  - Start-up Technical Support
    - Laboratory and Equipment set-up so that the laboratory is fully operational
    - Training of all personnel on all methods, equipment, sample types, quality functions,...
    - Method validation on for all methods on the actual instruments installed in the new laboratory facility.

- **Elements for Continued Operations:**
  - Services and Supplies
  - On-going Technical Support
    - Training
    - Trouble shooting
    - New sample types/new method requirements
    - Quality Management support, as well as audits
    - Validation and Ring-testing efforts
    - Network of laboratories to outsource emergency sample volume and additional analyses.
Stage 2: Improved Laboratory Facilities

The additional needs of a sustainable and fully functioning basic laboratory are easily identifiable by the questions in Annex III and from the well-documented records kept by the laboratory. Areas of improvement may include more rigorous quality management systems, additional capacities and/or capabilities or even new facilities. Personnel competent in keeping the current laboratory fully functioning, not only by operating the equipment, but by maintaining the required calibration schedules, maintenance schedules, validation procedures, et cetera, will be ready to take on the challenges of some additional testing capabilities.

For example, quality management systems (QMS) is just one of the areas that can be built out over a longer time-frame in a step-wise fashion, like building blocks. QMS is needed in a laboratory and the current goal of most laboratories is to operate at ISO_17025 standards. Implementation of the ISO-17025 standard can be a daunting, if not impossible task for any laboratory, and even more so for laboratories in developing countries that have a number of additional challenges. The effort becomes much more manageable if it is approached in a step-wise fashion. This involves starting with the basic systems for a well functioning laboratory and then moving to an intermediate phase based on the principles of ISO-9000; 2000 before attempting to meet requirements for ISO-17025.

This stage can be repeated as often as necessary in easily incorporated step-wise fashion until all the required capacities and capabilities have been provided and the goals have been achieved. With each capacity or capability addition to an existing laboratory, all of the elements for start-up and for continuous operation should be included in the planning and funding process.
ANNEXES

Annex I. Guide for structured interviews for gathering information on the relevant policy framework

This annex is intended to be a guide to help collect information on the policy framework under which laboratories operate. The information is necessary to evaluate a laboratory request for investment in upgrading and expansion. It is not a comprehensive list of questions, but instead is designed to stimulate thoughts and further questions. This is only a guide and should be used by those who have experience in the evaluation of laboratory capacity.

The specific aim of this annex is to detect general and sector specific policies that form an obstacle for cost-effective control systems. Policy deficiencies can be an obstacle for the functioning of laboratories.

Generic policies

Is there a national policy / strategy for the development of the laboratory infrastructure?
- What does it include? Are there specific aims for the food and agricultural area?
- How and when was it developed? How is it implemented?

Has a government agency been assigned as the lead agency for the laboratory infrastructure?
- What are its roles?
- Does it have coordinating powers?
- Is it consulted when investments for sectoral laboratories are being prepared?

What generic laws and regulations are in place that are relevant for:
- developing the laboratory infrastructure?
- operating laboratories?

What are main issues?

Are there constraints for operating private laboratories? Is there a level playing ground?
- Taxes
- Subsidized supply of services of public laboratories (artificially low tariffs)
- Permits, licenses

Sector specific policies

Does the country have strategies / action plans for food safety, plant health, animal health?

What are the main issues of relevance for:
- Monitoring, surveillance and inspection
- Laboratories in food and agriculture?
Do Ministries of Agriculture, Public Health, Environment / Water, Industry / Trade have strategies in place for the development of the laboratory infrastructure relevant for the food and agricultural area?

What are the main issues of relevance for:
- Monitoring, surveillance and inspection
- Laboratories in food and agriculture?

Does the country have in place emergency plans for:
- Outbreaks of animal diseases
- Food safety calamities
- Outbreaks of plant pests and diseases

What are the main measures / interventions to be taken?
What role would laboratories have? Are there contingency budgets?

Does the country have agreements with other countries for the use of diagnostic capacities?
- Describe contents of the agreements (volumes, conditions, emergencies, mutual recognition)

Does the country have monitoring and surveillance programs for food safety, plant health and animal health?
Describe the programs (scope, number of visual observations, volume of samples, way of processing samples, data base of results, data analysis etc.)
- How are programs designed? Who are involved?
- Who decides on the programs?
- How are programs funded? By whom? Is there an earmarked budget for each program?
- Are programs based on risk analysis? If so, how?
- For what purpose are the collected data used and how?
- Is there a link between monitoring / surveillance and inspection programs?
- Are fees charged in any of the monitoring and surveillance programs?

Describe the inspection programs for food safety, plant health and animal health. (scope, number of visual observations, volume of samples, way of processing samples, database of results, data analysis etc.)
- How are inspection programs designed? Who are involved?
- Who decides on the inspection programs?
- How are programs funded? By whom? Is there an earmarked budget for each program?
- Are programs based on risk analysis? If so, how?
- For what purpose are collected data used and how?
- Is there a link between monitoring / evaluation and inspection programs?
- What are inspection rates and fees charged per inspection at each of the following categories?
  - Exports
  - Imports
  - Farm level
Food processing plants
- Trade and transport
- Wholesale markets
- Retail markets
- Restaurants
- Food retailers
- Other

- Are there differences in inspection policies between
  - informal markets,
  - modern urban markets
  - export markets

Does the possibility to recover inspection costs through a fee play a role in the design of inspection programs and the inspection rates?

Which percentage of samples collected is on average not analyzed or not properly analyzed? What are the reasons?

Are changes in policies expected in the next 3 years that will affect inspection programs (design, scope, numbers of samples)?

**Public Budget**
What are the relevant Government budgets for inspection and diagnostic services over the past three years for food safety, plant health and animal health?
Are changes expected in the next three to five years?
Annex II. Guide for structured interviews for evaluating national laboratory capacity

This annex is intended to be a guide to help collect information necessary to evaluate a laboratory request for investment in upgrading and expansion. It is not a comprehensive list of questions, but instead is designed to stimulate thoughts and further questions. This is only a guide and should be used by those who have experience in the evaluation of laboratory capacity.

Once this data has been collected, it needs to be analyzed to determine the current state of diagnostic testing as well as help define the future state. The future state is based on the overall goals and objectives. A gap analysis establishes the differences between the current state and the future state. Results from the gap analysis are used to evaluate and prioritize the various options. This prioritization process should start with establishing key metrics that will be used for evaluation, such as:

- Time to complete the task or option
- Degree of confidence that the task or option can be completed
- Cost
- Risks associated with not completing the activity relative to human, animal or plant health
- The relative risk to trade
- The relative risk to industry
- Political viability

Each option or task identified by the gap analysis needs to be evaluated versus the key metrics.

Market Demand

Market demand analysis, to some extent, can and should be conducted via literature searches and via the use of surveys. It is also critically important that face-to-face meetings be held as a part of the data collection process.

Questions for main users of laboratory services in public service and among enterprises
1. Currently, how many samples by type do you send for testing on a monthly or annual basis?
2. What data or information are you looking to obtain from these samples?
3. What testing do you request for the samples?
4. Where are the samples sent?
   - Government laboratory- which one(s)
   - Private laboratory- which one(s)
   - University- which one (s)
   - Research institute- which one(s)
   - Other- outside of the country
5. If samples are sent out of the country, can you tell how many and explain the reasons they are sent? E.g. lack of capability in the country, customer demands that samples be tested at specific laboratory, the client will only accept results from an accredited independent
6. Do you perform testing in-house as a part of your operations?
7. Why are these performed in-house?
8. As a part of your in-house testing, do you test samples for a fee for others?
9. What types of tests do you perform for others and how many samples per year?
10. What would it take to outsource your in-house sample testing?
11. What changes in sample type, volume, and testing requirements do you see over the next 5 years?
12. Are there new emerging requirements that must be met?
   - Government regulations
   - Importing requirements
   - Exporting requirements
   - Standards
   - Changes in buyer requirements
   - New products
13. What prices are you paying for specific tests?
   - pH
   - Total plate count
   - Water analysis
   - Pathogens -- \textit{E.coli}
   - Residues (pesticide, veterinary medicines …)
   - Heavy metals
   - Radionucleotides
   - Other

**Government Awareness**

Questions for policy makers

1. How important do they feel laboratory capacity improvement is for:
   - Protection of the population
   - Protection of crops, livestock
   - Protection of industry, and
   - Protection of exports?
2. What are some of the barriers that they have encountered in creating a laboratory system that meets the country’s needs?
3. What have been some of the difficulties they have encountered due to a lack of diagnostic capacity?
4. What is the mandate of the laboratories that are under your control?
5. Please describe what the laboratory system would be like in 5 years if the investment is successful?
Laws and Regulations

Questions for senior managers in veterinary service, national plant protection organization, food safety service, and inspection services
1. What is the mandate for your organization and what role does diagnostic capacity play in this mandate?
2. What is the legal framework or legislation that the laboratory operates under?
3. What is the official role of the laboratory as outlined by the legislation, regulation or decree?
4. Describe any potential areas of overlap between the various laboratories which provide testing services related to plant and plant products, animal and animal products, agrochemicals, veterinary drugs, feed, water and food.
5. What flexibility do the laboratories have to change fee structures and by what mechanism?
6. In the past, have there been any difficulties in changing fee structures?
7. What changes in regulations, legislation, or decrees are necessary as they relate to laboratories?
8. Which changes are in progress?

Inspection Systems

Questions for senior managers in veterinary service, national plant protection organization, food safety service, and inspection services.
1. What is the mandate of the inspectorate?
2. What role does the laboratory play in support of the inspectorate function today, and what role could it play in 5 years?
3. How is the inspectorate organized?
   • National
   • Regional
   • District levels
4. Does the inspectorate collect samples? If not, who does?
5. What types of samples are collected?
6. How many of each type of sample are collected?
7. What data and information are to be obtained from the analysis?
8. What analyses are to be conducted for each sample type?
9. What is the expected turn around time for the samples?
10. Are there any difficulties or delays in receiving samples?
11. Do these delays impact sample integrity?
12. Are there other areas within the inspectorate control that impact sample integrity such as:
   • Refrigeration
   • Sample containers
   • Sample preservation
   • Training
   • Sampling technique
How are these addressed?
13. In the next 5 years, what changes does the inspectorate envision that will impact diagnostic capacity?

14. Within the next 5 years, will there be changes in the inspectorate that impact the types of samples collected, the types of data required, and the analysis that need to be performed?

**Market Environment**

The purpose of this section is not to develop an in-depth assessment of capabilities, but instead to define which laboratories exist, what their functions are, who their clients are, their current fee structures, and what areas they see expanding into in the future.

Questions for senior managers in veterinary service, national plant protection organization, food safety service, and laboratories.

1. Which government organizations have laboratories that may be able to support specific or general diagnostic testing?
   - Trade – Standards Board
   - Public Health – food control and or drugs
   - Agriculture
     - Veterinary
     - Plant
     - Fisheries
   - Environment / Water
   - Science and Technology -- research institutes
   - Education -- universities
   - Regional, district, and border
   - Other

2. Which trade associations have laboratory or diagnostic capacity?
   - Feed associations
   - Meat or Poultry
   - Consumers Union
   - Dairy
   - Seafood
   - Horticulture
   - Other

3. Are there private laboratories that are providing testing services?

4. Which enterprises have sophisticated in-house laboratory capacities?

**General marketing questions for the laboratories**
1. Who are your primary customers? (government and private)
2. What services does the laboratory provide?
3. What types of analysis does the laboratory provide?
4. What are the fees that are charged?
5. What percentage of your revenues are derived from:
   - Government funding (including direct payments for personnel, maintenance buildings, maintenance equipment, investment in equipment, training, special budget for testing programs, other)
   - Internal operations funding (internal company laboratories)
   - Grants
   - Donor funds
   - Fee for samples
   - Consulting services
   - Other
6. What is the revenue from all sources for the laboratory?
   - 0 – 100,000 USD
   - 100,000 – 500,000 USD
   - 500,000 – 1,000,000 USD
   - 1,000,000 – 2,500,000 USD
   - 2,500,000 USD and greater
7. What has been the growth (positive or negative) in revenues over the last 3 years?
8. What have been the key contributors to this growth?
9. How do you differentiate yourself from other diagnostic services, and what makes your services different?
10. Over the next 5 years, what changes will occur to impact the revenues in the diagnostic sector?
11. How do you see the industry changing over the next 5 years, and what impact might that have on revenues?
12. What new services will your organization be offering in the next 5 years?

Certification and Standards
Questions for senior managers in veterinary service, national plant protection organization, food safety service, inspectorates and laboratories
1. Is there a need for certified or accredited diagnostic services in the country?
2. What is the driver for this need?
   - Exports
   - Imports
   - Regulations
   - Private sector
3. Is there a standard for laboratory certification within the country?
4. Which organization administers this certification or accreditation?
5. Which laboratories participate in proficiency testing?
6. Which laboratories are certified to ISO 9000:2000?
7. Which laboratories are accredited to ISO 17025?
8. Which organizations are providing the certification or accreditation, and are these internationally recognized bodies?

**Education and Training**

Questions for senior managers in inspectorates and laboratories

1. Are there programs within the University system that can provide the technical specialists required?
   - Veterinary
   - Plant
   - Chemical
   - Microbial
   - Food technology
2. Are there programs within the educational system that can provide the training required for technicians, such as a laboratory technician program?
3. Are there intra-laboratory training programs within the country or region?
4. Are there on-going forums for the sharing of information and training between the various laboratories?
5. Are there changes over the next 5 years that will impact the training of technical staff?
6. Is there a demand for training from the diagnostic community?
7. Are the other organizations, such as trade associations, technical associations that provide on-going training?
8. Are there programs from the government or donors to strengthen the training/education capabilities within the educational system?
9. What training is provided by equipment suppliers as part of delivery or maintenance contracts?

**Information Technology**

Questions for senior managers in veterinary service, national plant protection organization, food safety service, inspectorates and laboratories

1. Are there formats for sharing of information and data on diseases, pests, food safety calamities, early warning or emerging threats, within the country or regionally? Which countries are involved? Which international organizations are involved?
2. Do the various organizations use these technologies to share information?
3. What types of information would be of greatest value and would encourage information sharing?
4. What changes over the next 5 years do they see that will impact information sharing?

**Public Outreach**

Questions for senior managers in veterinary service, national plant protection organization, food safety service and laboratories
1. Are the laboratories involved in public outreach?
2. Do they advertise their services?
3. Do they have a recognized certification, approval mark, or seal?
4. Do they advertise these marks, seals, or certifications?
5. Do they participate in trade shows to market their services?
6. Do they communicate to the public the benefits of what they do?
7. Do they advertise in key trade literature or events?
8. Over the next 5 years, do they see the need for quality seal or certification programs in the country?

Donors

Questions for senior managers in veterinary service, national plant protection organization, food safety service and laboratories

1. Which donors have provided or are providing support to laboratory services?
2. What type of support is being provided?
   - Technical assistance and training
   - Equipment
   - Support of staff and vehicles
   - Budget support
3. In monetary terms how much support is being provided?
4. How long has the support been in place?
5. How long will this continue?
6. What are the objectives of the program?
7. What are the expected outcomes?
8. What barriers, issues, or difficulties have occurred during the time of the support?
9. What areas of additional support are required over the next 5 years and why?
10. Over the next 5 years, what additional support will be provided?
Annex III. Guide for structured interviews for assessing individual laboratories

After a general assessment of laboratory capacities in the country has been made a specific assessment is needed of the laboratory requesting investment for upgrading or expansion.

This annex is intended to be a guide to help collect information necessary to evaluate a laboratory requesting investment in upgrading and expansion. It is not a comprehensive list of questions, but instead is designed to stimulate thoughts and further questions. This is only a guide and should be used by those who have experience in assessing laboratories.

Questions are for management of the laboratory

Financial

1. What are the revenues for the laboratory for the last 3 years, including this year?
2. What are the sources of funding?
   - Government funding (including direct payments for personnel, maintenance buildings, maintenance equipment, investment in equipment, training, special budget for testing programs, other)
   - Internal operations funding (internal company laboratories)
   - Grants
   - Donor funds
   - Fee for samples
   - Consulting services
   - Other
3. What changes in revenue sources are envisioned over the next 3-5 years and why?
4. What percent of revenues are based on contracts versus on-demand testing?
5. What analytical services do you offer?
6. How many samples are tested per analysis?
7. What fees do you charge for each analysis?
8. What other services do you offer?
9. What are the prices for these services?
10. What are the estimated changes in service or analyses volume expected over the next 3-5 years and why?
11. Budget
   - Human Resources – this included base salary, taxes, housing allowance, fuel, cell phone, insurance, retirement, utilities allowance
   - Operational Costs
     - Utilities – power, water, telecommunications, waste disposal
     - Facilities maintenance and repair
     - Technical equipment maintenance and repair
     - Consumables – reagents, glassware, gases, cleaning materials
     - Fuel – vehicle and back-up power generation
     - Training
     - Conferences, seminars, and international travel
Facilities and Environmental Conditions

1. Are the facilities, generally, in good repair and operational?
2. Are the facilities well organized neat, clean, free of dust, and free of insects and vermin?
3. Does the laboratory have the needed heating and cooling required to operate specific tests or equipment?
4. Does the laboratory have the needed areas for sample receiving, preparation, testing, offices, chemical storage, sample storage?
5. Are the laboratories equipped with the appropriate materials?
   - Power
   - Water
   - Gases, if needed
   - Counters
   - Biological hoods
   - Chemical hoods
   - Safety equipment
   - Waste disposal
6. Does the laboratory have affordable access to the internet and computers from which to connect?
7. Does the laboratory have phone and fax connectivity?
8. Does the laboratory have the appropriate reference texts or access to the databases (AOAC, ISO, Codex or OIE test methods)
9. Is the laboratory secure?
10. Does the laboratory have appropriate waste disposal?
11. If needed, does the laboratory have back-up power and uninterrupted power supplies for key equipment?
12. Does the laboratory have a source of purified water (ion exchange resin or distillation)?
13. Over the next 3—5 years, are there planned investments or changes that are envisioned for the facilities, and how are these funded?
   - New roof
   - Improved water supplies
   - Improved electricity supply – power back-up
   - Windows

Management Systems

1. What is the mandate for the laboratory?
2. How does this mandate differ from other laboratories?
3. What is the organization structure for the laboratory?
4. What are the numbers of employees in each function?
5. Are the job descriptions (roles and responsibilities) clearly defined?
6. What key functions are currently open?
7. Does the laboratory have enough manpower to complete the tasks in the timeframes required?
8. Does the laboratory require overtime of its employees in order to meet the testing demand, and how much overtime is required?
9. Will the laboratory be adding additional employees? In what areas, and what is the drive for increased personnel?
10. Does the laboratory prepare written annual reports or summaries for the public, and or the ministry?

On-going Training and Learning

1. Is there a requirement for on-going training for the employees?
2. How many hours are required each year?
3. What systems are in-place to provide on-going learning and training to the staff?
4. Are there educational opportunities that are shared with other laboratories?
5. Does the university provide additional training that the staff can take advantage of?
6. Is there access to journals, texts, and internet to provide on-going training and learning?

Test Methods

1. What analyses are conducted by the laboratory?
2. Which test methods are used?
   - AOAC
   - OIE
   - ISO
   - Codex
   - Self-developed
   - Other
3. How were these selected?
4. Are these methods validated?
5. Are the methods in a form that is easy for the personnel to access and use?
6. Does the laboratory have SOPS for the methods?
7. Does the laboratory have single or multiple operator variability studies conducted?
8. Does the laboratory have sensitivity and selectivity information for each analysis to ensure the correct analysis is used?
9. If methods are used that are not national or international, has equivalency been established?
10. Does the laboratory have reference samples for all of the substances that are being analyzed?
    - Reference chemicals or standards
• Slides
• Insect library
• Plates
• Etc.

11. Are these standards certified (where applicable)?
12. Are the standards stored appropriately according to the manufacturer's recommendations for temperature, humidity, etc.?

Standard Operating Procedures (SOP)

1. Does the laboratory have documented standard operating procedures records for the following?
   • Receiving
   • Storage
   • Testing requests
   • Sampling
   • Conducting the tests
   • Reporting the results
   • Review of and issuing the results
2. Does the laboratory have SOPs and records for instrument operations, calibration, and maintenance?
3. Does the laboratory have SOPs for training and training records?
4. Does the laboratory have SOPs and records for waste disposal?

Quality Assurance

1. Does the laboratory have a basic quality assurance program? Describe the program with reference to:
   • Personnel
   • Test methods
   • Sampling procedures
   • Quality control documentation
   • Preventive maintenance procedures and schedules
   • Proper record keeping
   • Regularly scheduled internal audits
   • Management reviews
2. Does the laboratory participate in proficiency testing schemes?
3. Has the laboratory been certified by an internationally recognized body to ISO 9000:2000?
4. Has the laboratory been accredited by an internationally recognized body to ISO-17025?
5. What are some of the barriers to creating a basic quality assurance program?
6. What are some of the barriers to achieving ISO certification?
7. Does the laboratory intend to become ISO certified or accredited in the next 5 years?
8. If seeking accreditation, what are the major drivers for accreditation?

**Equipment**

There are numerous reports that contain lists of potential equipment that a laboratory could have. The choice of equipment is highly dependent on: the assays that will be conducted, the environment the equipment will operate in, and the needs of the inspectorate. The assessment team, or individual, has to take note of what is available and see if it meets the needs. Annex IV provides sample lists for illustration.

**General items**

1. Is the equipment operational, neat, and in good working order?
2. Is the equipment well maintained?
3. Is the equipment operating in the environment (temperature, vibrations, dust) it was intended for? For example, a vibration free area is required for micro-balances. There is no need to purchase or even attempt to use micro-balances if there are vibrations.
4. Is there an inventory list of the equipment?
5. Are there instructions for use, calibration, and maintenance?
6. How often are the machines calibrated or performance checked?
7. Are the calibrations or performance checks tied to international standards?
8. Does the laboratory have the proper supporting infrastructure for the equipment, including such things as power, reagents, solvents, gases and water?

**Services and Supplies**

1. Does the laboratory have on site maintenance for equipment?
2. Is maintenance carried out by employees or is this contracted out as needed?
3. What are the times for repair service delivery?
   - Hours
   - Days
   - Weeks
4. Is the time reasonable, and if not what are some of the factors that contribute to long time delays?
5. Has the lack of service caused delays in meeting critical analysis?
6. Are the systems in-place to use other laboratories as needed in case of an equipment service delay?
7. Are there local suppliers of reagents, consumables, gases, etc?
8. If not, where are the materials purchased from?
9. What level of inventory of key reagents, consumables and gases are kept on hand?
   - 1 day
   - 1 week
   - 1 month
   - Other
   - None – order as needed
10. How long does it take for a purchase order to be approved for reagents, consumables, etc.?
11. What is the typical timeframe from material request (purchase order being completed) to material arrival?
12. What are some of the main factors to the time involved?
13. Over the next 3-5 years, will there be a large enough concentration of laboratories in the area that a local equipment maintenance and laboratory supply company will be formed?
Annex IV. The Building Block Approach

The purpose of this annex is to describe the elements that should be considered when planning an investment in a country constrained either by financial or human resources or both. The goal of the investment is not only to improve the analytical capacity, but to develop the necessary human and financial resources required for sustainability in a step-wise fashion.

Stage 1: Basic Laboratory Building Blocks

There are two categories of requirements to consider when planning any laboratory: what is needed to start-up a turn-key laboratory and what continuous support, including technical expertise, be needed to grow in-country capabilities over time so that sustainability can be achieved?

Required Start-up Elements:

Facilities and Environmental Conditions

The condition of the facilities and the environmental conditions have significant impact on laboratory operations. The laboratories, offices, and storage spaces need to be clean, pest/vermin free, organized, and in good repair. The facilities and surfaces need to be constructed of materials that can easily be cleaned and sanitized. The facilities need to have staff amenities such as restrooms, dining areas, and wash facilities as needed. There must be adequate electrical power, operational back-up power generation, including fuel and un-interrupted power supplies (UPS) for critical equipment such as freezers, incubators, and computer operated/managed test equipment. There needs to be an adequate and reliable supply of clean portable water and equipment to provide de-ionized water. In order to facilitate the correct performance of the tests, the facility requires adequate environmental conditions including:

- proper heating and cooling
- a dust free environment
- biological sterility
- proper humidity and airflow
- appropriate sound and vibration levels (if necessary for sophisticated equipment)
- effective separation of areas to prevent cross contamination
- adequate security and access control to all areas that impact test results

Facilities need to be designed with the actual laboratory function in mind. Each laboratory building should have a designated sample receiving and storage room, with limited public access. The core laboratory area should be designed with the following features: separate sample preparation area should be designed to have sufficient spaces for sample preparation, sampling, wet chemistry equipment, and clean-up, separate instrumentation room(s), separate area with limited access for preparation and storage of calibration standards and/or reference standards, separate chemical storage area, separate records and documentation storage.
Microbiology laboratories have additional requirements. Collection, transport, and storage of the samples must occur under controlled and documented conditions to ensure sample integrity. The laboratories must have at least the following separate rooms with appropriate ventilation to avoid cross-contamination: sample receiving, sample preparation, media preparation, testing, decontamination and clean up, and a secure reference culture storage.

Facilities may need to be designed with future expansions in mind.

Equipment

The laboratory should have all the equipment necessary to provide the appropriate services. The equipment should be in good repair. The equipment should be identified and maintained properly and should have documented calibration and maintenance procedures and schedules. The laboratory also requires calibration traceability of all key measurements such as weight, volume, temperature, and pressure according to international standards.

New equipment should be selected on several criteria:
1. must meet a range of test methods,
2. the suitability for the laboratory environment,
3. its acceptability by scientific and regulatory bodies and to the clients,
4. in-country availability and price of replacement parts, maintenance and calibration services
5. in-country availability and price of consumables
6. staff capabilities

Management Organization and Human Resources

The laboratory should have a clearly defined organizational system and structure which includes job descriptions, roles, and responsibilities for all levels from the laboratory director to the support staff. The technical resources, skills, and competencies required for plant health, animal health, and food safety vary to some degree and will be outlined in Annex IV. The laboratory should have arrangements to ensure that all of its personnel are free from any potential conflict of interests. The laboratory should have on staff a quality manager that reports directly to senior management.

Sample Volume

All laboratories have an existing number of tests that are run per year. The test volume is the total number of samples submitted for specific analyses within a given timeframe (such as yearly). The submitted samples must be traceable from the collection point, to the receipt at the laboratory, to the diagnostic results, and to the final disposal. Test volume is one of the determining factors for upgrades required by a laboratory.
Test Methods
The laboratory should use appropriate test methods and related procedures for all diagnostic activities. The choice of test methods should include such factors as: the suitability of the test method, its acceptability by scientific and regulatory bodies, its acceptability to the clients, and its feasibility, given the available laboratory resources. The laboratory should have written instructions and procedures for all tests that include: calibrations and operation of the relevant equipment, collection, handling, transportation and storage of specimens, and sample preparation.

Test methods should be based on internationally recognized reference methods. These include methods provided by AOAC, OIE, ISO, Codex, IUPAC, ... The reference methods will need to be tested and adapted to the actual instruments installed in the new laboratory facility. The reference methods may also need to be translated. The instruments, the environment, and the reagents impacts the variability and error and reproducibility of the results. Method then need to be validated (if feasible) and Standard Operating Procedures adapted (or written) for the actual instruments and methods in the new laboratory facility.

Quality Management Systems (QMS)

Quality assurance systems or quality management programs are an integral part of any well functioning laboratory. Quality assurance systems provide the processes to assure accurate and reproducible results. Laboratories should implement quality assurance systems that are effective and meet their own as well as their customers’ needs and requirements. As part of the Standard Operating Systems (SOPs), the laboratory should have a method or system for document control to ensure that only the approved and current version of procedures are being used by the staff to perform their work. The laboratory should have a written policy, as well as written procedures and work instructions, for all activities that are related to the tests. Such activities would include: receipt of samples, labeling of samples, storage of samples, equipment monitoring and calibration, methods development, testing and validation, and reporting of results.

The basic quality assurance requirements include the following:

1. Personnel
   • Documented laboratory organization and responsibility
   • Documented job descriptions
   • Documented technical training, as well as responsibilities for the quality assurance program

2. Test Methods
   Documented standard operating procedures (SOP) detailing the analyses, instrument operations, quality control procedures, single operator and multiple operator (if applicable) variability, sensitivity and selectivity information to insure the correct method is used for a given analysis. The documented operating procedures should refer to national or internationally recognized test methods, or if these are not used, equivalency of the actual method in use should be documented.
3. Sampling procedures
Standard operating procedures (SOP) detailing the collection, preservation, containers, handling, shipping and storage of samples need to be documented. SOP for chain of custody must also be documented, allowing samples to be tracked from collection, to receipt by the laboratory through analysis to disposal.

4. Quality control documentation
- Instrument performance checks
- Appropriate calibration procedures, including standard source
- Controls, reagent blanks
- Corrective action contingencies

5. Preventive maintenance procedures and schedules

6. Proper record keeping procedures for results, analyses, samples and sample handling, personnel, quality control, environmental conditions of the laboratory, quality of reagents and consumables, equipment maintenance, etc.

7. Regularly scheduled internal audits to insure the procedures are being followed and meet the laboratories requirements. A management supported process must exist to implement recommendations from these audits.

8. Participation in Proficiency Testing programs coordinated and conducted either by the country or regional reference laboratory or by one of various scientific bodies like AOAC, ASTA, AACC, AOCS, FAPAS, ... in order to achieve repeatable and comparable testing data.

Environmental Impact, including waste disposal

Laboratory placement must take into account the needs of many constituents, including the general public, the agricultural industry, the Ministries that they serve, as well as their staff. For a laboratory to be successful, it must be within reasonable distance from where key samples are taken. It must be accessible via normal roads, highways, and if needed, airport facilities. In this way, samples can be collected and transported to the laboratory in a timely manner. Depending on the nature of the samples and the ability to preserve the samples, reasonable access may mean a significant distance and may take several hours to traverse.

The laboratory must be placed in an area where it can physically be isolated from the surrounding area, where access can be restricted and controlled for vehicles, the general population, and wildlife, and where bio-security measures can be administered.

Because of the bio-security risks posed by the laboratories involved with plant, animal and food safety diagnostcs, these facilities need to be located away from commercial farms and animal rearing facilities, as well as residential housing. While the laboratory will take every precaution
necessary to prevent the accidental release of an agent, a release can happen and lead to significant economic losses.

In addition to bio-containment issues, laboratories need to have facilities to ensure proper storage and disposal of chemicals, and to prevent contamination of ground water or surrounding land. In many countries, solvents can and are recovered and the wastes are transported to municipal treatment facilities for disposal. Further, the laboratories will need to construct incinerating facilities necessary to destroy samples, and in the case of veterinary laboratories, carcasses and remains. Again, the incineration facilities will need to be maintained and also placed away from residential housing facilities.

Technical Support for the Start-up Phase:

The amount of technical support required for a laboratory start-up is often seriously underestimated. The goal of the initial set-up and the supporting technical assistance is to achieve a turn-key laboratory. Turn-key laboratories are those where the set-up team can seamlessly turn over the facility and operations continue without interruption. The technical support required for a successful start includes:

- Equipment installation and start-up
- Selection of standard methods appropriate to the facility and type of samples
- Adaptation of standard methods to the actual instruments installed in the new laboratory facility. The instruments, the environment, and the reagents impacts the variability and error and reproducibility of the results.
- Method validation for all methods on the actual instruments installed in the new laboratory facility.
- Standard Operating Procedures adapted (or written) for the actual instruments and methods in the new laboratory facility. SOPs adapted (or written) for the maintenance and calibration procedures.
- Training of all personnel on:
  - Methods
  - Standard Operating Procedures
  - Equipment,
  - Sample types,
  - Quality functions,...
- Identification of and working agreements with laboratories that can provide surge capacity for emergency sample volume as well as those that can provide complementary analyses not offered at this facility.

Elements For Continuous Operations:

Services and Supplies
The laboratory should have access to supplies and services that impact the performance of the testing conducted. These may include: reagents, laboratory gasses, consumables, calibration standards and services, maintenance services reference libraries (such as CABI), spare parts, fuel for transportation vehicles, telephone service, internet access, computers, and databases. The laboratory should have access to trained and qualified maintenance and calibration services for testing equipment, as well as maintenance for the facilities. Storage facilities used to keep consumables and spare parts on hand need to be managed, giving special attention to expiration dates, required storage temperatures, light exposure, flammability, and safety.

To insure the continued support of services in the region, it is recommended that maintenance and calibration service contracts are negotiated with equipment suppliers at the time of the original purchase. An example of calibration services is the biannual recalibration of analytical balances often performed by balance manufacturers or their regional representatives. Many private laboratories negotiate maintenance contracts at the time of equipment purchase and the equipment manufacturer/supplier are often selected based on the continued maintenance support in the region. Public laboratories can achieve the same level of support by including maintenance contracts as part of the original purchase. In fact, if country-wide or even regional contracts are negotiated, the support for all the laboratories, including the smaller and more remote facilities, would greatly increase while the maintenance cost per equipment would decreases.

**Budget**

The overall budget for any laboratory is based on an evaluation of revenue and costs. In general, government laboratories are seen to operate on behalf of the public good and, therefore, funding is primarily derived from the government. Additional sources of income may include: fees from services, grants, and contracts. The cost of constructing and operating a laboratory can be quite high. The general budget items are:

- Salaries, including fringe benefits such as housing allowance, auto allowance, telephone
- Operating funds (utilities, telecommunications, transportation, internet access)
- Equipment purchases and support
- Facility maintenance and test equipment maintenance
- Education and training, including books, journals, databases access, and travel

**Training**

The laboratory should provide its employees with regularly scheduled training in new methodology, as well as initial training for new employees. All training should be documented. Training should cover technical topics as well as quality assurance, safety, and industry trends and standards. This training can be provided in many formats including on-line, train-the-trainer, educational seminars and classes, and on the job training in specific areas.

In addition, the laboratory should have access to journals, reference texts, reference libraries (such as for pests), international methods, and the internet. The ability to maintain access to current literature, new test methods, standards, and disease trends is critical to the overall effectiveness of the laboratory.
On-going Technical Support

On-going technical support can mean the difference between long-term viability for the laboratory versus stagnancy and decay. Especially in less developed nations, where the in-country educational system does not provide all of the needed expertise, the contributions of outside technical support can make a huge difference by allowing the facility to grow in-country expertise over time. This technical support can take many forms, including: twinning arrangements, expertise at local or regional universities, expertise in other local or regional laboratories (public or private), ...

The personnel providing the support should be available for routine laboratory visits either quarterly or at least semi-annually and should be available for regular phone consultation as well as for emergency issues. The types of contributions provided by such an arrangement should include:

- Training
- Provide advanced technical expertise, such as for new sample types/new method requirements
- Quality Management support, as well as audits
- Validation and Proficiency Testing efforts, including identifying and improving the laboratory based on how the laboratory performed in the proficiency testing schemes.
- Network of laboratories to outsource emergency sample volume and additional analyses.

Stage 2: Improved Laboratory Facilities

The additional investment needs for a sustainable and fully functioning basic laboratory are easily identifiable by writing a business plan. The investment plan for upgrading a facility should be much easier to prepare since the business plan for the original facility should be available and the laboratory will have a knowledgeable staff and good documentation and historical records.

Areas of improvement may include more rigorous quality management systems, additional capacities and/or capabilities or even new facilities. Adding capacity or capabilities to a well functioning laboratory can be repeated as often as necessary in easily incorporated step-wise fashion until all the required capacities and capabilities have been provided and the goals have been achieved. With each capacity or capability addition, all of the elements for start-up and for continuous operation should be included in the planning and funding process.
Annex V. Sample lists of expertise and equipment needed

The facility design, the equipment, reagents and standards, and the human resources/skills must be targeted for the specific laboratory functions: food (microbiological, chemical), animal health, and plant health testing. Again, the specific needs of each laboratory are determined by the assays to be conducted. In some instances, it may be advantageous to combine facilities for maximum effectiveness. For example, product quality and nutritional conformity assessments can be combined with the chemical testing facilities.

It is important to note that trace quantities should not be tested in the same laboratory as major components to avoid cross contamination. For example, pesticide residue testing needs to be kept separate from the laboratory identifying the major components of pesticides and fertilizers.

Need for expertise

Below is a list of the skills sets for plant health, animal health and food laboratories. This does not mean that there needs to be one person for each field of expertise. Within a laboratory, it is not uncommon for one person to have expertise in several areas, thus maximizing the utilization of the technical personnel. In addition, the laboratory, through its network of institutions, can access a variety of expertise on an as-needed basis. In addition, a laboratory will need support staff and technicians depending on the test volume.

Plant Health Laboratories

Plant health laboratories need to have access to the following expertise:

- General phytopathology (for symptom evaluation and diagnosis)
- Entomology
- Mycology
- Virology
- Bacteriology
- Nematology
- Weed-science
- Microbiology
- Analytical chemistry
- Molecular biology (in advanced labs)

Animal Health Laboratories

Animal health laboratories require specific knowledge and expertise, including:

- Clinical and general pathology
- Toxicology
- Bacteriology
- Virology
- Serology
• Histo-technology
• Microbiology
• Parasitology
• Analytical chemistry

**Food laboratories**

Food laboratories require specific knowledge and expertise, including:
- Analytical chemistry
- Food science
- Food technology
- Nutrition
- Toxicology
- Epidemiology
- Microbiology
- Parasitology
- Mycology
- Virology
- Bacteriology

**Need for equipment**

In general, plant health, animal health and food laboratories have somewhat similar equipment requirements. Sample lists of laboratory equipment are provided in the tables below. Please note that these are general equipment lists and the actual needs of a specific laboratory will be determined based on the tests the laboratory will perform. Equipment for advanced techniques, such as molecular and electron microscopes, GC-MS, LC-MS, and PCR, all have significant additional facility, training, and consumables requirements. These should only be incorporated into laboratories that have a sustainable longer term need to perform tests requiring these types of equipment.

In addition to the equipment outlined in laboratories need access to specific reference tools.

A plant health laboratory, for example needs access to an insect library, stained samples of specific diseases, and a weed library. These libraries and reference materials need not be contained within the national plant protection organization. Instead, these materials can be found at universities, research institutes, and regional facilities. All that is required is that the organization has access to the libraries as needed. In addition to reference materials, national plant protection organizations need to have access to greenhouse facilities. These facilities would be used for weed identification and propagation, and to test weed control mechanisms. Again, these need not be a part of the plant health organization, but instead could be shared with organizations such as the seed testing and plant registration branch of the NPPO.

The intent of the following equipment lists are as a starting point in the planning process. For example, the lists can be used to inventory existing equipment in current laboratory facilities. These lists do not imply that all of the equipment is required nor should this be interpreted in this...
manner. The actual needs have to be derived case by case. In addition to the larger (more expensive) items in these lists, the laboratories need to be equipped with a variety of glassware, pipettors, a source of deionized and distilled water, hot plates, magnetic stirrers, safety equipment... Laboratories also need reagents, standards, reference materials, and other consumables.

**Sample equipment list for plant health laboratories** (IPPC recommended equipment list)

<table>
<thead>
<tr>
<th>Equipment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Compound Microscope</td>
</tr>
<tr>
<td>Cold Light Source</td>
</tr>
<tr>
<td>Binocular Stereo Zoom Dissecting Microscope</td>
</tr>
<tr>
<td>Illuminated Magnifier</td>
</tr>
<tr>
<td>Insect rearing chamber</td>
</tr>
<tr>
<td>X-ray equipment, film, and safety equipment</td>
</tr>
<tr>
<td>Computers and internet access</td>
</tr>
<tr>
<td>Micropipettes</td>
</tr>
<tr>
<td>Hot Plates</td>
</tr>
<tr>
<td>Top Loading Balance</td>
</tr>
<tr>
<td>Magnetic Stirrer</td>
</tr>
<tr>
<td>Analytical balance</td>
</tr>
<tr>
<td>Blender</td>
</tr>
<tr>
<td>Laboratory Glassware</td>
</tr>
<tr>
<td>Refrigerator</td>
</tr>
<tr>
<td>Autoclave</td>
</tr>
<tr>
<td>Incubator</td>
</tr>
<tr>
<td>Deep Freeze (-20 C)</td>
</tr>
<tr>
<td>Laboratory Chemicals</td>
</tr>
<tr>
<td>Elisa Equipment</td>
</tr>
<tr>
<td>Lypolizer</td>
</tr>
<tr>
<td>Spectrophotometer</td>
</tr>
<tr>
<td>pH Meter</td>
</tr>
<tr>
<td>Rotary Shaker</td>
</tr>
<tr>
<td>High Speed Centrifuge</td>
</tr>
</tbody>
</table>
Source: IPPC
Note that this is not an all encompassing list, but will provide the laboratory and the evaluation team with a common basis from which to start. In addition, the listing of equipment such as GC-MS does not imply that this equipment is required nor should this be interpreted in this manner. The actual needs have to be derived case by case.

Sample equipment list for animal health laboratories

<table>
<thead>
<tr>
<th>Equipment</th>
</tr>
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<tbody>
<tr>
<td>Compound Microscope</td>
</tr>
<tr>
<td>Cold Light Source</td>
</tr>
<tr>
<td>Binocular Stereo Zoom Dissecting Microscope</td>
</tr>
<tr>
<td>Illuminated Magnifier</td>
</tr>
<tr>
<td>Water Baths</td>
</tr>
<tr>
<td>X-ray Equipment, Film, and Safety Equipment</td>
</tr>
<tr>
<td>Equipment</td>
</tr>
<tr>
<td>---------------------------------</td>
</tr>
<tr>
<td>Computers/Internet Access</td>
</tr>
<tr>
<td>Micropipettes</td>
</tr>
<tr>
<td>Hot Plates</td>
</tr>
<tr>
<td>Top Loading Balance</td>
</tr>
<tr>
<td>Magnetic Stirrer</td>
</tr>
<tr>
<td>Analytical Balance</td>
</tr>
<tr>
<td>Blender</td>
</tr>
<tr>
<td>Laboratory Glassware</td>
</tr>
<tr>
<td>Refrigerator</td>
</tr>
<tr>
<td>Autoclave</td>
</tr>
<tr>
<td>Incubator</td>
</tr>
<tr>
<td>Deep Freezers (-20°C) and (-80°C)</td>
</tr>
<tr>
<td>Laboratory Chemicals</td>
</tr>
<tr>
<td>Elisa Equipment</td>
</tr>
<tr>
<td>Lypolizer</td>
</tr>
<tr>
<td>Spectrophotometer</td>
</tr>
<tr>
<td>pH Meter</td>
</tr>
<tr>
<td>Rotary Shaker</td>
</tr>
<tr>
<td>Microwave Oven</td>
</tr>
<tr>
<td>Dissection Equipment</td>
</tr>
<tr>
<td>Bacterial Cell Counter</td>
</tr>
<tr>
<td>Near UV Lights</td>
</tr>
<tr>
<td>Electrophoresis Equipment</td>
</tr>
<tr>
<td>Culture Purification</td>
</tr>
<tr>
<td>Gas Chromatography (packed)</td>
</tr>
<tr>
<td>Gas Chromatography (capillary)</td>
</tr>
<tr>
<td>Thin Layer Chromatography</td>
</tr>
<tr>
<td>Gas Chromatography Mass Spec. (GC-MS)</td>
</tr>
<tr>
<td>Liquid Chromatography (LC)</td>
</tr>
<tr>
<td>High Performance Liquid Chromatography (HPLC)</td>
</tr>
</tbody>
</table>
IR Spectrophotometer
UV Spectrophotometer
Atomic Absorption (AA)
Soxlet Extractors
Automated Hematology and Biochemistry System
High Speed Centrifuge

*Source:* Beug-Deeb and Deeb 2007

Note that this is not an all encompassing list, but will provide the laboratory and the evaluation team with a common basis from which to start. In addition, the listing of equipment such as GC-MS does not imply that this equipment is required nor should this be interpreted in this manner. The actual needs have to be derived case by case.

**Sample list of equipment for chemical testing for food safety**

<table>
<thead>
<tr>
<th>Equipment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Atomic absorption Spectrophotometer with Hydride Generator and</td>
</tr>
<tr>
<td>Mercury Vapor Generator</td>
</tr>
<tr>
<td>Autoclave Vertical</td>
</tr>
<tr>
<td>Refractometer (quality conformity testing)</td>
</tr>
<tr>
<td>Conductivity meter (water testing)</td>
</tr>
<tr>
<td>Constant Temperature Water Circulating System</td>
</tr>
<tr>
<td>Refrigerators</td>
</tr>
<tr>
<td>Deep Freezer (-20 deg. C)</td>
</tr>
<tr>
<td>Analytical Balances</td>
</tr>
<tr>
<td>FT-IR Spectrometer</td>
</tr>
<tr>
<td>GC-MS, and Head Space attachment</td>
</tr>
<tr>
<td>Gas Generators for H₂, N₂/Air</td>
</tr>
<tr>
<td>General Purpose Centrifuge</td>
</tr>
<tr>
<td>High Speed Centrifuge</td>
</tr>
<tr>
<td>High Performance Liquid Chromatograph (HPLC) with UV, PDA, RI and Fluorescence detectors.</td>
</tr>
<tr>
<td>UV Visible Spectrophotometer</td>
</tr>
<tr>
<td>Thin Layer Chromatograph</td>
</tr>
<tr>
<td>Hot Air Ovens</td>
</tr>
<tr>
<td>Ion Chromatography</td>
</tr>
</tbody>
</table>

70
<table>
<thead>
<tr>
<th>Equipment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lab Blender/ Mixer</td>
</tr>
<tr>
<td>Microwave Digestion Unit</td>
</tr>
<tr>
<td>Muffle Furnace</td>
</tr>
<tr>
<td>Nitrogen Analyzer</td>
</tr>
<tr>
<td>Electrophoresis</td>
</tr>
<tr>
<td>pH Meter</td>
</tr>
<tr>
<td>Water Distillation Unit</td>
</tr>
<tr>
<td>Rotary Vacuum Evaporator</td>
</tr>
<tr>
<td>Soxhlet Extraction Unit</td>
</tr>
<tr>
<td>Thin Layer Chromatography Kit</td>
</tr>
<tr>
<td>UV Cabinet with long and short wave UV lamps</td>
</tr>
<tr>
<td>Vacuum Oven with Vacuum Pump</td>
</tr>
<tr>
<td>Water Bath Rectangular</td>
</tr>
<tr>
<td>Gel Permeation Chromatograph</td>
</tr>
<tr>
<td>Karl Fischer Titrator</td>
</tr>
<tr>
<td>Kjeldahl Digestion Unit</td>
</tr>
<tr>
<td>Kjeldahl Distillation Unit</td>
</tr>
</tbody>
</table>

# GC-MS can substitute for other detectors like FID, ECD, FPD, NPD etc.

**Sample equipment list for Food Microbiology laboratories:**

<table>
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<th>Equipment</th>
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<tbody>
<tr>
<td>Analytical balances</td>
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<tr>
<td>Autoclave</td>
</tr>
<tr>
<td>Waring blender</td>
</tr>
<tr>
<td>Stomacher blender</td>
</tr>
<tr>
<td>Water baths</td>
</tr>
<tr>
<td>Incubators</td>
</tr>
<tr>
<td>Vortex mixers</td>
</tr>
<tr>
<td>Refrigerator</td>
</tr>
<tr>
<td>Freezers (-20 C and -80 C)</td>
</tr>
<tr>
<td>Colony counter</td>
</tr>
<tr>
<td>Binocular microscope</td>
</tr>
<tr>
<td>pH meter</td>
</tr>
<tr>
<td>Equipment</td>
</tr>
<tr>
<td>---------------------------------</td>
</tr>
<tr>
<td>Compound Microscope with cold light source</td>
</tr>
<tr>
<td>Elisa Equipment</td>
</tr>
<tr>
<td>High Speed Centrifuge</td>
</tr>
<tr>
<td>Spectrophotometer</td>
</tr>
<tr>
<td>Rotary shaker</td>
</tr>
<tr>
<td>Microwave Oven</td>
</tr>
<tr>
<td>Near UV Lights</td>
</tr>
<tr>
<td>Electrophoresis Equipment</td>
</tr>
<tr>
<td>BSL-2 Hoods with UV sterilizer</td>
</tr>
<tr>
<td>Dissecting kit</td>
</tr>
<tr>
<td>Hot Air Oven</td>
</tr>
<tr>
<td>PCR</td>
</tr>
</tbody>
</table>
Annex VI. Accreditation of laboratories in the SPS area in middle- and low-income countries*

<table>
<thead>
<tr>
<th>Country</th>
<th>WTO member?</th>
<th>member of ILAC?*</th>
<th>accreditation bodies with ILAC membership</th>
<th>labs accredited by ILAC full member bodies? (name of lab, accredited field of testing, foreign accreditation body - if accredited by foreign bodies)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Afghanistan</td>
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<tr>
<td>Albania</td>
<td>Y</td>
<td>affiliate</td>
<td>Drejoria e Akreditimit</td>
<td></td>
</tr>
<tr>
<td>Algeria</td>
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<td>affiliate</td>
<td>Algeria Organization of Accreditation</td>
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<tr>
<td>American Samoa</td>
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<tr>
<td>Angola</td>
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<tr>
<td>Antigua and Barbuda</td>
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</tr>
<tr>
<td>Argentina</td>
<td>Y</td>
<td>full member</td>
<td>Argentina Organization of Accreditation</td>
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<td>Azerbaijan</td>
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<tr>
<td>Bangladesh</td>
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<tr>
<td>Barbados</td>
<td>Y</td>
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<tr>
<td>Belarus</td>
<td></td>
<td>affiliate</td>
<td></td>
<td>Yes. Belarusian State Institute for Metrology (BoGIM). Division of Agro-food testing in Minsk. Performs testing of physical-chemical, chemical, microbiological analyses of foodstuffs and tobacco products. Accredited by the German Accreditation Council.</td>
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<tr>
<td>Belize</td>
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<td>Bhutan</td>
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<td>Bolivia</td>
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<td>Bosnia and Herzegovina</td>
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<td>Botswana</td>
<td>Y</td>
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<tr>
<td>Brazil</td>
<td>Y</td>
<td>full member</td>
<td>CGCRE/INMETRO, General Coordination for Accreditation</td>
<td>yes</td>
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<td>Bulgaria</td>
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<td>Cape Verde</td>
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<td>Central African Republic</td>
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<td>Chad</td>
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<tr>
<td>Chile</td>
<td>Y</td>
<td>associate</td>
<td>National Institute of Standardization</td>
<td></td>
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<tr>
<td>China</td>
<td>Y</td>
<td>full member</td>
<td>China National Accreditation Service for Conformity Assessment</td>
<td>Yes</td>
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</table>

*Note: Y indicates Yes, N indicates No.
<table>
<thead>
<tr>
<th>Country</th>
<th>Membership</th>
<th>Status</th>
<th>Accreditation Body or Organization</th>
<th>Notes</th>
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</thead>
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<td>Colombia</td>
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<td>Comoros</td>
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<tr>
<td>Congo, Dem. Rep.</td>
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<tr>
<td>Congo, Rep.</td>
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<tr>
<td>Costa Rica</td>
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<td>Ente costarricense de Acreditacion</td>
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<td>Cote d'Ivoire</td>
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<td>associate</td>
<td>Croatian Accreditation Agency</td>
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<td>Cuba</td>
<td>Y</td>
<td>full</td>
<td>National Accreditation Body of Republic de Cuba</td>
<td>Yes</td>
</tr>
<tr>
<td>Czech Republic</td>
<td>Y</td>
<td>full</td>
<td>Czech Accreditation Institute</td>
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<td>Djibouti</td>
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<td>Ecuador</td>
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<td>Yes. A number of labs accredited by A2LC (US) for chemical or biological testing</td>
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<td>National Laboratories Accreditation Bureau</td>
<td>Yes. Also, Central Lab for Food and Feed is accredited by A2LC (US) for chemical testing</td>
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<td>El Salvador</td>
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<td>affiliate</td>
<td>National Council for Science and Technology</td>
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<td>Guatemala Accreditation Office</td>
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<td>Hungary</td>
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<td>associate</td>
<td>Nemzeti Akkreditalo Testulet</td>
<td>*** Yes. Laboratoire d'Analyse de la Direction (accredited by Cofrac); a few by the German Accreditation Council</td>
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<tr>
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<td>National Accreditation Board of Testing and Calibration Labs</td>
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<td>full</td>
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<td>Iran Accreditation System</td>
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<td>Accreditation Details</td>
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<td>---------------------------------------------------------------------------------------</td>
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<tr>
<td>Jamaica</td>
<td>Y</td>
<td>full member</td>
<td>Jordan Accreditation Unit, Jordan Institution for Standards and Metrology</td>
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</tr>
<tr>
<td>Jordan</td>
<td>Y</td>
<td>full member</td>
<td>Jordan Accreditation Unit, Jordan Institution for Standards and Metrology</td>
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</tr>
<tr>
<td>Kazakhstan</td>
<td>associate</td>
<td>National Center of Accreditation</td>
<td>Yes, JSC Biomedpreparat Engineering Center; chemical testing (pesticides, etc.) (by A2LA)</td>
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</tr>
<tr>
<td>Kenya</td>
<td>Y</td>
<td>affiliate</td>
<td>Kenya Accreditation Service</td>
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<tr>
<td>Kiribati</td>
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<td></td>
<td>Yes, Homegrown K Limited Testing Lab: microbiological analysis (accredited by SANAS); SGS Kenya chemical analysis (accredited by SANAS); and more</td>
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<td>Korea, Dem. Rep.</td>
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<td>Kyrgyz Republic</td>
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<td>National Institute for Standards and Metrology</td>
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<td>Lao PDR</td>
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<td>Libyan National Center for Standardization and Metrology</td>
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<td>Macedonia, FYR</td>
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<td>Madagascar</td>
<td>Y</td>
<td></td>
<td>Yes, Pasteur Institute of Madagascar. Microbiological analyses of agri-food products (accredited by Cofrac, France).</td>
<td></td>
</tr>
<tr>
<td>Malawi</td>
<td>Y</td>
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<td>Standards Malaysia</td>
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<td>Maldives</td>
<td>Y</td>
<td></td>
<td>Yes, University Science Malaysia; chemical testing (accredited by NATA, Australia)</td>
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<tr>
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<td>Mauritius Accreditation Service</td>
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</tr>
<tr>
<td>Mayotte</td>
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<td>Yes, SGS (Mauritius) Ltd - Food Testing Lab: meat and meat products (accredited by Singapore Accreditation Council)</td>
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<td>Mexico</td>
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<td>affiliate</td>
<td>Center of Accreditation in the Field of Conformity Assessment of Products</td>
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<tr>
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<td>Mongolian Agency for Standardization and Metrology; and Mongolian National Chamber of Commerce and Industry (affiliate)</td>
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<td>Country</td>
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<td>Membership</td>
<td>Accreditation Body</td>
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<tr>
<td>Morocco</td>
<td>Y</td>
<td>associate</td>
<td>Moroccan Committee for Accreditation</td>
<td>Yes. Central Analytical Laboratory; Physical-chemical analysis of water (accredited by Cofrac, France); Official Chemical Analysis and Research Laboratory: pesticide residue (accredited by Cofrac); Physical-chemical Analysis Laboratory - Agadir: pesticide residue (accredited by Cofrac); Etc.</td>
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<td></td>
<td>Yes. Global Conformity Services-Namibia: microbiological analysis (accredited by SANAS)</td>
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<td>Pakistan</td>
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<td>associate</td>
<td>Pakistan National Accreditation Council</td>
<td>Qarshi Research International (Pvt) Ltd Laboratories: some food and water testing (accredited by Norwegian Accreditation Agency)</td>
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<tr>
<td>Poland</td>
<td>Y</td>
<td>full member</td>
<td>Polish Center for Accreditation</td>
<td>*** yes. Central Laboratory for Milk Analysis (accredited by Cofrac)</td>
</tr>
<tr>
<td>Romania</td>
<td>Y</td>
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<td>Romania Accreditation Association</td>
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<tr>
<td>Russian Federation</td>
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<td>associate</td>
<td>Association of Analytical Centers &quot;Analitica&quot;</td>
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<td>Slovak National Accreditation Service</td>
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<tr>
<td>Slovenia</td>
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<td>Slovenia Accreditation</td>
<td>*** Yes. Also a few labs accredited by Cofrac.</td>
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<tr>
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<td>Sri Lanka</td>
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<td>Sri Lanka Accreditation Board for Conformity Assessment</td>
<td>yes. Five labs accredited by the Swedish Accreditation Authority in 2002****.</td>
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<tr>
<td>Country</td>
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<td>St. Vincent and the Grenadines</td>
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<tr>
<td>Suriname</td>
<td>Y</td>
<td>Bureau of Laboratory Accreditation, Dept. of Science Service; Bureau of Laboratory Standards; Thai Laboratory Accreditation Scheme (all three are full members)</td>
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<td>Venezuela, RB</td>
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<td>Vietnam</td>
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<td>Zimbabwe</td>
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</table>

**Notes and sources:**

- Bureau of Laboratory Accreditation, Dept. of Science Service;
- Bureau of Laboratory Standards;
- Thai Laboratory Accreditation Scheme (all three are full members);
- Yes. A few labs accredited by Cofrac.
- Yes. The Central State Veterinary Medicine Laboratory of the State Veterinary Medicine Department of the Ministry of Agrarian Policy of Ukraine: physical, chemical and microbiological analysis of raw materials, foodstuffs and feeding stuffs; determination of mycotoxins, vitamins, pesticides, antibiotics, radionuclides and trace elements in foodstuffs and feeding stuffs (Deutch Accreditation Council -DAR)
* This table is compiled from information on the websites of organizations/accreditation bodies with full ILAC membership. Full members are accepted as signatories to the ILAC Mutual Recognition Arrangement. They have been peer-reviewed and shown to meet ILAC criteria of competence.
** If a country has at least one organization that is a full member of ILAC, it is assumed that multiple laboratories in this country are accredited.
*** As member of the European Union, their official food control laboratory has to be ISO17025 accredited.
**** UNIDO 2006. "Building Up Trade Infrastructure: Lessons from strengthening the enabling environment for supply side development and conformity assessment."

**Summary:**
Of 154 low income and middle income countries,
- WTO members: 108
- WTO members that have at least one accreditation body with full members of ILAC: 21
- WTO members that have at least one laboratory in the SPS area accredited by internationally recognized accreditation body: 37, of which 10 are members of the European Union
- Low- and middle- income countries that are WTO members but have no internationally recognized accredited labs: 108-37=71
Annex VII. Lessons from World Bank lending for investment in laboratories for food and agriculture

Table Annex VI-1. Policy issues encountered in investment for laboratory capacity improvement

<table>
<thead>
<tr>
<th>Issue</th>
<th>Experiences in World Bank projects</th>
<th>Possible mitigation measures</th>
</tr>
</thead>
<tbody>
<tr>
<td>Supply-driven laboratory investment</td>
<td>Lack of proper assessment of (i) need/demand for services at local level, (ii) need for a sustained critical mass of skills, and (iii) appropriate budget.</td>
<td>Proper assessment of need and long-term sustainability, i.e., assessment of livestock population by geographic and disease control requirements (production and reportable diseases). Consulting with producer organizations may be useful in assessing demand for these services and whether it can be met by existing private and public labs.</td>
</tr>
<tr>
<td>Financial sustainability</td>
<td>Lack of financial sustainability in general has been a major issue in most projects. Most laboratories were in the public sector and – especially during the structural adjustment period – much of the public funding dried up.</td>
<td>Careful appraisal of demand for services from individual clients and contracts with government agencies and private sector.</td>
</tr>
<tr>
<td></td>
<td>Investment in laboratories based on belief of “build it and demand will come” without a system of passive or active sample collection or realistic assumptions about the volume of submissions.</td>
<td>Request an accurate estimate of sample volumes on a monthly and annual basis in concert with a realistic recurrent budget for surveillance and testing activities.</td>
</tr>
<tr>
<td></td>
<td>Lack of financial sustainability because of government budgeting rules prohibiting the retention of revenue from fees.</td>
<td>Allowing cost recovery and retaining part of revenue to purchase supplies etc. In some countries this may require a change of legal or tax status of the institutions. Good rules to prevent corruption and incorrect use of retained funds need to be in place.</td>
</tr>
<tr>
<td>Over-capacity</td>
<td>An over-extended laboratory infrastructure that cannot be maintained adequately. This is a common problem in countries of the former Soviet Union, but also exists elsewhere (Senegal, for example).</td>
<td>Conduct an inventory study that describes and assesses available laboratory space, capabilities, ownership and real estate value, of public and related laboratories in the private sector.</td>
</tr>
<tr>
<td>Unfair competition with private sector</td>
<td>The private sector can reasonably well provide the planned diagnostic services but has to compete with free or subsidized services from government laboratories. Creating more public sector capacity would mean increased unfair competition and will push the private laboratories out.</td>
<td>Avoid investment in public sector laboratories where the private sector can perform adequate services. Require a written policy on necessary State-executed services. Encourage government to contract with private laboratories, provided they participate in quality control programs. Bringing in the private sector as a matter of strategy and through specific mechanisms has great potential, and increases the dynamism and transparency of the project. Encourage fee-for-service in transitional systems to raise awareness of costs and benefits but with efficient results, turnaround, feedback and response.</td>
</tr>
<tr>
<td>Unnecessary conditions imposed on private or semi private labs</td>
<td>Unreasonable conditions are imposed on private providers – often at the advice of national laboratory directors who try to protect the monopoly position of the national laboratory or of government laboratories in general.</td>
<td>Encourage a system for sub-contracting of government work to private laboratories. Government laboratories focus on reportable diseases only. Diagnosis of production diseases should be left to the private sector.</td>
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</tr>
<tr>
<td>Competition for project financing between agencies for “their” laboratories.</td>
<td>Infighting and indecision about which laboratory will receive the investment.</td>
<td>Careful appraisal and solid arrangements before project approval without creating unwarranted expectations. Careful analysis of the needs of sectors and volume of samples; careful delineation of responsibilities of laboratories by geographic region, reportable disease priority and containment target, research priority, or level of technical sophistication.</td>
</tr>
</tbody>
</table>

*Source:* Derived from World Bank project completion reports and experiences.
Table Annex VI-2. Operational issues encountered in investment projects for laboratory capacity improvement.

<table>
<thead>
<tr>
<th>Type of issue</th>
<th>Experiences in World Bank projects</th>
<th>Possible mitigation measures</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Skills and skills development</strong></td>
<td></td>
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</tr>
<tr>
<td>Short-cutting training</td>
<td>Insufficient length of training. Sometimes the trainees sent are not prepared in knowledge and skills for the short intensive training.</td>
<td>For many skills a minimum of a 2 years Master’s level training will provide the most sustained benefit.</td>
</tr>
<tr>
<td>Selection of trainees</td>
<td>Wrong people were sent for training. Most common is to send laboratory directors or other staff that do not (no longer) do bench work. Sometimes trainees do not have enough skills in the language of instruction, which reduces effectiveness.</td>
<td>Carefully develop trainee selection criteria. Include laboratory technicians (intermediate level) for training to learn specific techniques. Evaluate language skills and needs.</td>
</tr>
<tr>
<td>Ascertain up to date information exchange</td>
<td>Laboratory technology is rapidly changing, requiring laboratory staff to keep up with new technological developments.</td>
<td>Include attendance of international meetings with peers (i.e. professional conferences) of bench-working technical staff. Twinning with foreign institutions has been successful in building long-term relations and self-sustained skills updates.</td>
</tr>
<tr>
<td>Timing of training and equipment purchase (see also under equipment below).</td>
<td>Laboratory was not able to become fully operational because the lack of adequate staff and training, after all equipment had arrived.</td>
<td>Preferably training should precede purchases in such a way that newly trained staff can participate in decision about laboratory remodeling and equipment purchase.</td>
</tr>
<tr>
<td>Using foreign consultants for technical training.</td>
<td>Very mixed results of using foreign consultants for longer-term training. Major issues are technical skills and commitment.</td>
<td>In view of mixed results the choice of sending national staff out (rather than bringing consultants in) has often proven to lead to more sustained skills improvement. This can be combined with visits from experts from the twinning institution.</td>
</tr>
<tr>
<td><strong>Infrastructure improvement</strong></td>
<td></td>
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<tr>
<td>Physical ownership of land or buildings</td>
<td>Delays because of disputes over ownership of land or buildings that housed the laboratory. This issue was especially prevalent in former Soviet countries where parts of the building(s) or the premises were privatized and where legal ownership or tenure was unclear. In the Middle East it may be an issue when proposing to build on unused land.</td>
<td>Careful appraisal and confirming legal ownership of land and buildings where the proposed laboratory will be housed.</td>
</tr>
<tr>
<td>Structural quality</td>
<td>Especially in the older projects when the Bank’s architectural review was done in-house, there was a reluctance to upgrade existing buildings because of problems with structure or lay-out.</td>
<td>Hire qualified architect, with experience in requirements for laboratory construction to assess structural soundness of proposed premises.</td>
</tr>
<tr>
<td>Lack of basic utilities</td>
<td>The lack of access to adequate (municipal) water and power is a main issue in many rural development related projects. Delay of lab. operation can occur when need for new main power line was not foreseen</td>
<td>This can temporarily be overcome by providing generators or water hauling/storage equipment (but this requires proper maintenance and repair skills).</td>
</tr>
<tr>
<td>Type of issue</td>
<td>Experiences in World Bank projects</td>
<td>Possible mitigation measures</td>
</tr>
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</tr>
<tr>
<td>Waste management</td>
<td>Necessary permits for waste (water) disposal cannot be obtained</td>
<td>Careful appraisal including Environment Management Plan; include the need for special waste water management (in case of chemical and pathogen) or scrubbers in incineration equipment in the project plan (even in case of “upgrade” or remodeling projects).</td>
</tr>
<tr>
<td></td>
<td>Laboratory security and biosafety standards not consistent with accepted international standards, including disposal of hazardous materials</td>
<td>Adhere to international standards in design (use architect specialized in laboratory construction).</td>
</tr>
<tr>
<td>Misuse of funds</td>
<td>Funds used for beautification of director’s etc. office, leaving budget short of financing essential improvements (in part because office remodeling can be purchase quickly without prior approval, whereas procurements such as lab equipment etc. may need longer process with prior Bank approval).</td>
<td>Clear description of proposed improvements with rough designs in order that everyone is clear on purpose and scope of expected improvement/remodeling plans.</td>
</tr>
<tr>
<td>Equipment purchase</td>
<td>Purchase equipment that is not needed for a variety of reasons (i.e. already available, no demand for the tests run with that equipment etc.)</td>
<td>Perform a realistic volume determination for passive and active sample submission, leading to an inventory of specific tests to be performed.</td>
</tr>
<tr>
<td></td>
<td>Consultant recommended purchase of equipment to run tests for which newer, more efficient and often cheaper tools are available.</td>
<td>Ask for specialist technical assistance (with current bench experience, and experience of working in developing countries). The use of professional generic consultants may not be conducive in this case.</td>
</tr>
<tr>
<td></td>
<td>Purchase equipment that need specific, often propriety, chemicals to operate (compare to HP printers needing HP ink), but these are not readily available.</td>
<td>Allow flexibility in procurement so project can respond to new developments, and prevent locking projects in by defining equipment needs in detail (describe expected function and outcome, not the equipment)</td>
</tr>
<tr>
<td></td>
<td>Government allocates equipment without proper needs assessment or plans, resulting in scattering of new equipment over (sometimes obsolete) labs vs. concentrating it in one or a number of centers of excellence.</td>
<td>Require inventory - and a quality - and needs assessment of all laboratories, as well as laboratory consolidation plans (if available) before approving the initiation of the equipment tendering process (condition in loan agreement).</td>
</tr>
<tr>
<td></td>
<td>Many projects last 4-8 years and most detection equipment also has a functional lifetime of 5-10 years. Generally most of the equipment is procured in the first few years of the project, often with no mechanisms to buy major hardware at the end of the project. Consequently by the time the project is handed over most equipment is at end of its functional lifetime.</td>
<td>Allow for new equipment or updates in later years of the project design.</td>
</tr>
<tr>
<td></td>
<td>Equipment is either not robust enough to function properly under local conditions (i.e. varying power supply, dust, lack of water), or the equipment was not matched by local operating, management or repair skills (this is a</td>
<td>Assure proper specifications in tender. Evaluate skills in equipment operation and repair at appraisal. Where appropriate include either a long term maintenance contract in the equipment tender, or include training or</td>
</tr>
</tbody>
</table>

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<table>
<thead>
<tr>
<th>Type of issue</th>
<th>Experiences in World Bank projects</th>
<th>Possible mitigation measures</th>
</tr>
</thead>
<tbody>
<tr>
<td>GENERIC IHS</td>
<td>Generic issue in many development projects)</td>
<td>Annual/bi-annual visits by (multipurpose) laboratory/equipment repair technicians in project budget.</td>
</tr>
<tr>
<td>Mismatch between skills improvement and laboratory functioning.</td>
<td>Excessive focus on equipment. Some projects (mainly FSU) were reluctant to invest in skills improvement, especially of technical staff, with the end result that equipment was delivered but was either misused or left idle.</td>
<td>Properly match skills improvement with equipment.</td>
</tr>
<tr>
<td>Timing gap between equipment arrival and available trained technical staff</td>
<td>Some projects reported a timing gap between ordering equipment and the improvement in skills (often graduate training), resulting in idle equipment.</td>
<td>In many projects the skills gap was initially solved by technical assistance, but it is often too short to adequately train local staff.</td>
</tr>
<tr>
<td>Supplies</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Delays in obtaining consumable supplies</td>
<td>Lack of operating budgets</td>
<td>See Table Annex VI-1 under financial sustainability</td>
</tr>
<tr>
<td></td>
<td>Lengthy delivery period (from abroad) and/or clearance at customs is a problem. In some cases this is generic, in others it happens because of lack of transparent arrangements (or waiver) of payment of taxes and custom duties.</td>
<td>Careful appraisal, including visiting with suppliers or other (medical) laboratory directors to evaluate experiences and solutions.</td>
</tr>
<tr>
<td>Waste of supplies</td>
<td>Supplies lost because of poor storage or dilapidated storage equipment (i.e. freezers etc.).</td>
<td>Match the need for delicate or perishable supplies with availability of proper storage conditions.</td>
</tr>
<tr>
<td>Management</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Management skills</td>
<td>Lack of management skills or absenteeism of director, leading to lack of quality and often misappropriation of funds</td>
<td>Proper selection and skills training.</td>
</tr>
<tr>
<td>Financial management</td>
<td>Lack of sound bookkeeping and accounting.</td>
<td>Include book keeping (and appropriate accounting programs) in project plan and training. Verify oversight responsibilities within government or project.</td>
</tr>
<tr>
<td>Quality control</td>
<td>Reluctance to verify lab results or participate in quality control program or performance testing.</td>
<td>Require such quality control up front and in M&amp;E of project. Standard laboratory quality control training for managers is available. Note: laboratory biosecurity depends largely on management, rather than facilities.</td>
</tr>
</tbody>
</table>

*Source:* Derived from World Bank project completion reports and experiences.
REFERENCES


American Association of Veterinary Laboratory Diagnosticians 2006. Essential Requirements for an Accredited Veterinary Diagnostic Laboratory, Version 4.1 (11/07/)


FDA. Laboratory Methods. See http://www.cfsan.fda.gov


