Discussion Paper

# Developing a Global Curriculum for Regulators

**Charles Preston, Samvel Azatyan, Tammie Bell, Katherine Bond, Julia Bradsher, Martha Brumfield, Gillian Buckley, Thomas Hughes, Stacy Kane, Sherry Keramidas, Margaret Miller, Mary Morrison, Lembit Rägo, Jim Riviere, Mary Lou Valdez, and Gerald Wojtala***

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**Participants in the dissemination meeting for the IOM report Ensuring Safe Foods and Medical Products through Stronger Regulatory Systems Abroad*



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Charles Preston, U.S. Food and Drug Administration; Samvel Azatyan, World Health Organization; Tammie Bell, U.S. Food and Drug Administration; Katherine Bond, U.S. Food and Drug Administration; Julia Bradsher, Global Food Protection Institute; Martha Brumfield, Martha A. Brumfield LLC; Gillian Buckley, Institute of Medicine; Thomas Hughes, U.S. Food and Drug Administration; Stacy Kane, U.S. Food and Drug Administration; Sherry Keramidas, Regulatory Affairs Professional Society; Margaret Miller, U.S. Food and Drug Administration; Mary Morrison, U.S. Food and Drug Administration; Lembit Rägo, World Health Organization; Jim Riviere, Kansas State University; Mary Lou Valdez, U.S. Food and Drug Administration; and Gerald Wojtala, International Food Protection Training Institute[1]

## CONTEXT

Globalization has resulted in countries importing foreign products in numbers never before seen. For example, the U.S. Food and Drug Administration (FDA) estimates that the products it regulates now originate in more than 150 countries and 300,000 foreign facilities (FDA, 2011). Eighty percent of seafood consumed in the United States comes from abroad and 40 percent of finished drugs originate from overseas (FDA, 2013).

The globalization of commerce brings both benefits and risks to consumers—the promise that goods are available at any time of the year, such as mangos in the winter, and the risk that when something comes from another country, its safety and quality are more difficult to ensure. At every step in the path to market, from raw materials to manufacture, storage, and distribution, a product can be contaminated, diverted, counterfeited, or adulterated. Language barriers, time differences, and distances multiply these risks, and the internet can exacerbate the problem by providing a veil of anonymity to dishonest sellers.

Regulators are mobilizing to address the risks that come with globalization, and a recent FDA-commissioned Institute of Medicine (IOM) study titled *Ensuring Safe Foods and Medical Products Through Stronger Regulatory Systems Abroad* examines the challenges that many low- and middle-income countries (LMIC) face in doing this (IOM, 2012). It discusses the major gaps in these systems and offers remedies in the form of recommendations. The IOM study also identifies the core elements that all regulatory systems should have in order to protect the public's health (see Figure 1 in the Annex). One of these elements is a strong regulatory workforce, yet the IOM study identified a number of gaps in this area. To address these, it made a major recommendation—a call for the development of a standing global curriculum of fundamental regulator competencies.

> *IOM Recommendation 6-3: The FDA should facilitate training for regulators in developing countries. The purpose is workforce training and professional development through an ongoing, standing regulatory science and policy curriculum….* (IOM, 2012, p. 204).

[1] Participants in the dissemination meeting for the IOM report *Ensuring Safe Foods and Medical Products through Stronger Regulatory Systems Abroad*.

This recommendation was the focus of a multi-stakeholder meeting[2] convened at the IOM on September 19, 2012. The goal of the meeting was to disseminate the IOM study findings, initiate dialogue, obtain expert input, and catalyze a long-term strategy for development of a global curriculum. The purpose of this paper is to synthesize the authors' views of that discussion. This paper introduces key ideas related to regulatory systems strengthening and workforce development and proposes next steps for advancing the topic.

## KEY IDEAS

The September 19, 2012, meeting on developing a global curriculum of fundamental regulator competencies covered important ground. It began with an explanation of the need for a more systematic and effective approach to building competencies in LMIC regulatory authorities, while recognizing that this is a generational goal, requiring long-term commitment.

### The Rationale for a Global Curriculum

The IOM study found that the regulatory workforce is one of nine main gaps in LMIC regulatory systems,[3] and that many factors contribute to this gap, including a lack of manpower, difficulties with staff retention, and inadequate technical training (IOM, 2012). On the subject of manpower, there are simply not enough people to fill most regulatory agencies. For example, the IOM study noted that in LMICs, environmental health inspectors frequently serve as food safety inspectors, and the positions in food and medical product quality laboratories are often not occupied. This is part of a larger problem of health worker shortages in LMICs, especially since regulators tend to come from other professions such as pharmacy, medicine, and law. There is already a shortage of such professionals for various reasons.

There are also numerous challenges to retaining staff. In countries with a robust private sector, personnel frequently leave for better-paying jobs in industry. In less developed countries, trained staff commonly find work on donor projects or in nongovernmental organizations (NGOs) where the salaries are higher. The politics of regulatory decision making can lead to firings or damage morale and cause staff to quit, further exacerbating the challenge to retain staff. Corruption presents another challenge, and is both a cause and effect of retention difficulties. In such a negative environment, there can be a lack of *esprit de corps*. The absence of a formal credentialing system to guide career progression adds to this problem.

A lack of technical training is another critical problem, especially given the rapid pace of innovation, and the need to stay abreast of the science that underpins these products. The dearth of training in risk assessment, risk management, risk communication, and inspections is complicated by a need for training in basic science, protocols, and probabilities. The IOM study found that some inspectors have only reached middle school, and their scientific understanding is rudimentary at best. Another problem is that the regulatory curricula often used by LMICs borrow heavily from high-income countries, and this may not be helpful if these curricula have little applicability to LMIC situations. Such technical deficits are at the root of inadequate regulatory systems in many LMICs, and often, regulators' inability to ensure product safety and

[2] The meeting was attended by more than 30 people from different stakeholder groups and featured presentations as well as a roundtable discussion.

[3] The others gaps include problems with adherence to standards; control over supply chains; infrastructure deficits; legal foundations; fragmentation; postmarket surveillance; communications; and political will (IOM, 2012).

quality stem from the lack of appropriate training. It is difficult to develop, implement and evaluate science-based standards, or define systems for approving foods and drugs, if the people who are involved do not have a good sense of the conceptual basis for why regulations are put in place or the technical expertise to implement them.

Gaps in workforce development are partly due to a lack of investments in regulatory systems and the regulatory workforce by LMICs. With so many challenges and so few resources, it is understandable why LMICs have focused on developing other parts of their health systems before the regulatory workforce. However, the need to ensure quality and safety in the face of trends such as globalization of the medical products supply and the scale-up of medicines in LMICs are highlighting the importance of workforce development more than ever before.

Donors are also recognizing the importance of workforce development. Although they have been successful in providing substantive trainings, the donor approach is also limited. Training priorities offered by donors do not necessarily cater to the specific needs of the regulatory authority, they can be ad hoc, and occur without a follow-up system in place. Additionally, the training opportunities tend to favor the donor's timetable. Further, the IOM study found that when training opportunities involve travel, senior regulators are rewarded before junior regulators who may be most in need for such skills building.

**Solutions for Strengthening the Regulatory Workforce: A Global Curriculum**

The IOM study put forward specific models for programs to address these problems, ranging from a standing regulatory science college to a train-the-trainer approach and apprenticeship programs. It also emphasized the importance of academic partnerships to these endeavors and suggested specific examples that have proven successful. Academic partnerships are especially important in building long-term, local capacity and helping to ensure a sustainable workforce.

The IOM study also proposed the idea of a predictable, standing global curriculum of fundamental regulator competencies. The intent of such a curriculum is to teach minimal skills that apply universally, whether a regulator works in a small authority or a large one. Although a curriculum will not necessarily address the manpower shortage, it may enhance retention through an improvement in *esprit de corps* and the sense that regulators are part of a recognized and respected profession. It will undoubtedly help to build the science, policy, and regulatory expertise that are at the core of current deficits. Further, when a curriculum is delineated, it will enable countries to better understand the needs of a regulatory workforce, and to develop their workforce strategies. For donors, a curriculum will provide a framework for competency building within a broader system.

In the face of globalization, a universal curriculum should be favored by all countries. As an increasing number of products are imported across expanding global supply chains, their safety and quality depend on the expertise and skills of other regulators. FDA, for example, has developed a globalization strategy. The broader goal of FDA's efforts is to weave a global product safety net, where regulators, industry, and other organizations can come together to prevent unsafe products from entering the market, no matter where they come from or where they are consumed. This implies that many regulators' skills need to be strengthened to participate effectively.

Although strengthening the regulatory workforce is important to FDA, this is not within the agency's mission or budget. The IOM study recognized this and appropriately described

FDA's role as a facilitator in establishing a global curriculum. Indeed, FDA is interested in helping to catalyze the development of a global curriculum given the potential for stronger regulatory systems and supply chains, and the need to enable both countries and donors to better understand regulatory competencies and target future resources.

## Key Considerations for Developing a Global Curriculum

One of the most important themes of the September 19 stakeholder meeting was that regulatory systems are at the nexus of economic development, trade, and public health. The director of COFEPRIS, the Mexican regulatory authority, gave several examples of this. The measures of the success of Mexico's regulatory investments (market value of applications approved, costs to industry in application delay, number of additional patients treated as a result of generic product approvals) reflect economic development, trade, and public health principles (see Box 1-1). Many LMICs are likely to think about regulatory issues in much the same fashion, and these are important considerations for designing a global curriculum.

The importance of country context was another major meeting theme on September 19. The World Health Organization's (WHO's) presentation of its approach to regulatory systems capacity building emphasized the value that assessments[4] bring to determining context. Assessments point to areas for improvement and help to illuminate priorities that are based on countries' specific needs. WHO then works to build regulatory capacity in steps that reflect these country priorities. Therefore, where clinical trials are prevalent but oversight is weak, clinical trials capacity should be strengthened. Similarly, where the prevalence of substandard and falsified medicines is high but regulatory capacity for market control, supply chain security, and pharmacovigilance is weak, WHO prioritizes these areas. A global curriculum should be similarly tailored to local needs. It should also have the flexibility to be implemented in a step-wise fashion. WHO called this a "modular approach."

[4] The PAHO/WHO assessment tool is a 500+ indicator tool, which asks questions about the basic legal foundations, processes, and standards of a regulatory system, on domains such as marketing authorization, inspections, clinical trials, and pharmacovigilance, for example.

**BOX 1-1**
**A Case Study on the Importance of Regulatory System Strengthening from Mexico**

The case for regulatory system strengthening was made in the plenary session by Mikel Arriola, the Commissioner of COFEPRIS. Like many emerging economies, Mexico's desire for regulatory reform is in part rooted in the need to embrace trade and economic development imperatives in Mexico. Dr. Arriola's presentation was organized to show how Mexico is addressing specific IOM recommendations.

Dr. Arriola affirmed the characteristics of successful regulatory systems put forward by the IOM, including rapid and appropriate response based on risk analysis, swift adjustment to innovative scientific discoveries and ideas, consistent application of regulations to all economic agents, and independence from external influences. He said Mexico has made great strides in these areas and cited a recent Pan American Health Organization (PAHO) assessment of its regulatory system, which accorded it their highest level of functionality—level IV, a regulatory system of "regional reference." The assessment helped Mexico understand which parts of the regulatory system needed further strengthening and investment.

Some of the policy changes that led to these improvements included reforms on reliance (where countries use the regulatory information and decisions of other countries), third-party auditing, and deregulation. For example COFEPRIS now recognizes the good manufacturing practice certificates of the Australian, Brazilian, Canadian, European Union, Japanese, and United States drug regulatory agencies. On one-way equivalence (a form of reliance), it recognizes medical devices approved in the United States, Canada, and Japan. Regarding third-party audits, third parties are now allowed to do pre-verification of administrative paperwork on drugs and devices. Finally, the deregulation of medical devices means that 1,700 products no longer meet the definition of a medical device and thus do not need regulatory scrutiny.

The subsequent results of these policies are dramatic. There have been large savings in administrative costs and a decrease in the regulatory burden. Pre-verification has reduced Mexican application waiting times from 1 year to less than a month. Each day the end of an administrative process is delayed, the costs to industry are between $4,000 and $5,000. Therefore, the 11,618 authorizations issued promptly between March 2011 and August 2012 saved industry close to $1.8 billion. The policies have also increased registrations by 7,645 percent since 2010. This speeding of approvals has seen the release of 157 new generic medications and 31 innovator drugs. With the savings derived from the strategy to liberate generics, COFEPRIS estimates that an additional 750,000 patients can be treated over 4 years.

SOURCE: Arriola Peñalosa, 2012.

Problems are often similar among regions, and a representative from the New Partnership for Africa's Development shared a concrete example of a regional approach to capacity building in Africa called the African Medicines Regulatory Harmonization initiative (AMRH). As there are many different product registration standards in African countries, and there are common needs for a speedier pathway to market and consistency of science-based approaches, AMRH uses regional economic communities to collaborate toward more harmonized registration standards. AMRH is a variation on an emerging concept in the field of regulatory systems strengthening that uses work sharing in regional groupings to make more efficient use of resources. The program uses work-sharing in regional networks to make more efficient use of resources. For example, an agency that has expertise in inspections can share that expertise with other regulators in the network. Such an arrangement may be more efficient than building up all capabilities within individual country regulatory agencies. A global curriculum should take into account the skills that will be necessary to implement and sustain such regional models.

The curriculum frameworks put forward by the Regulatory Affairs Professional Society (RAPS) and the International Food Protection Training Institute (IFPTI) (see Figures 2 and 3 in

the Annex), provide highly evolved examples of competencies for regulating food and medical products. Each framework is divided into four professional development levels, in ascending order of experience: entry, journey, technical expert, and leadership. At each level, there are specific competencies and knowledge/skills to be gained. As the frameworks illustrate, the competencies are numerous, and require significant resources to fulfill them.

When authorities have resource constraints or are very small, WHO suggested generalist training in which staff learn high-level tasks that span the needed duties, rather than specialize in one technical area versus another. To illustrate this point, WHO outlined a model staffing structure for dossier review, requiring a head of registration unit, a microbiology assessor, a toxicology assessor, a bioequivalence assessor, a pharmaceutical chemistry assessor, a statistical assessor, and a clinical reviewer. However, in low-income countries where there are very few health workers, let alone health workers devoted to regulatory issues, there would be great difficulty in filling these different areas of technical expertise.

The scenario of a product crisis in a low-income country further illustrates this point. If the agency responsible had five people, it would need broad competencies in areas such as crisis management, risk communication, public relations, and stakeholder outreach. They would also need general scientific competencies. During the September 19 meeting, RAPS and IFPTI noted that underlying all of their frameworks are competencies in risk assessment, decision making, crisis management, regulatory science, communication within an organization, and communication with other organizations. The overlap of these competencies with what is required in this scenario suggests a possible skeleton structure for a global curriculum going forward.

## The Process of Developing a Global Curriculum

Participants' discussion at the September 19 meeting of the process flow, from designing competencies and curricula to implementing certification schemes, illustrates what must be done to develop a global curriculum. Because their organizations do extensive work in this domain, IFPTI and RAPS led a discussion of the methods and approaches used to define those elements, with IFPTI focusing on foods, and RAPS concentrating on medical products.

A coherent approach to curriculum development flows easily from the premise that regulators are professionals. Like other professions, the job of a regulator has an identifiable scope of work and thus a defined body of knowledge. Having a defined body of knowledge implies the existence of core competencies. Competencies provide the basis for training program learning objectives, exams, job descriptions, and career recruitment/retention. In general, competencies are developed through an iterative process that involves defining domains, job tasks, and responsibilities.

RAPS, for example, brings together an expert group of professionals from industry and regulatory agencies, and uses a psychometrician to guide them through the development of an outline of minimal competencies for the practicing professional. The outline is validated with extensive input from a large number of practicing professionals, and the results are then used to define professional competencies. Such an approach ensures that the defined competencies address not just what is learned in the classroom, but also what must be done on the job.

An important feature of the IFPTI framework is that it maps their full inventory of 800 U.S.-based food safety training courses to their core competencies. In order to link these competencies to curricula and thus training, IFPTI inventories the existing courses, analyzes the

alignment of jobs and training, develops courses, trains instructors, and delivers the final training. Some courses are taught online, but this can be a problem in regions where internet access is poor. RAPS is also using its curriculum framework and competency definitions as a basis for training.

RAPS and IFPTI have implemented quality-control measures for their educational activities, including review of individual courses, and an instructor development process. RAPS has also implemented certification exams, another quality measure, because if regulators are passing exams on material related to their jobs, it can be assumed that educational programs are effective. RAPS develops a number of certification exams and its inventory includes tests that are based on regulations for the United States, Canada, and the European Union. It has also developed an exam with a global focus, covering the International Standards Organization as well as those of important global harmonization bodies. A certification exam similar to the RAPS global exam could be linked to a proposed global curriculum.

## NEXT STEPS

In summary, the September 19 meeting featured important dialogue on (1) the rationale for a global curriculum; (2) key considerations for developing a curriculum (such as the nexus of economic development, trade, and public health; assessments; the modular approach; networks; and the generalist concept); and (3) the actual curriculum development process. Although the details of the curriculum are yet to be fleshed out, participants expressed general support, and recognized the tremendous value it could have. After the meeting, stakeholders formed a small ad hoc working group to consider possible options and strategies toward achieving the goal going forward.

The scope of a global curriculum will be diverse and wide-ranging, because there are many kinds of regulators, from inspectors to laboratory experts to reviewers. Similarly, there are many kinds of products to regulate, from medicine to foods to radiological devices. For the purposes of this proposed global curriculum, the scope will likely first cover food and medical products. It will also focus on training government regulators.

Critical issues that remain include how the curriculum will be developed, who will develop it, how it will be validated and kept relevant within the context of a complex and rapidly changing regulatory environment, how it will be financed, and identifying stakeholders that can lead such an initiative. Key principles are emerging—the curriculum should be generated in consultation with a broad range of stakeholders, and there should be platforms to make it widely available, free of charge. Other organizations can then use it as a framework for designing educational programs. Another principle is that the curriculum must be accepted and embraced by LMICs as an important group of users.

Once the curriculum has been developed, it will need to be piloted. There are a variety of options for piloting, including regional programs like AMRH and PAHO's Pan American Network for Drug Regulatory Harmonization, which is currently in the process of planning a training strategy for the Americas. The Caribbean is another possibility, as there have been discussions of competency building for workforce needs in the context of developing a regional regulatory system. Wherever piloted, collaboration and leveraging the collective resources of participating stakeholders will be essential to cementing its uptake in key countries/regions and establishing it as a framework for global competency-building efforts going forward.

## ANNEX

**FIGURE 1** Core Elements of A Food and Medical Products Regulatory System

Government is the foundation for a strong regulatory system. As the national standard-setting body, governments:

- use science and risk as a basis for developing policy;
- participate in international cooperation and harmonization of standards;
- make ethical decisions; and
- recognize, collect, and transmit evidence when breaches of law occur.

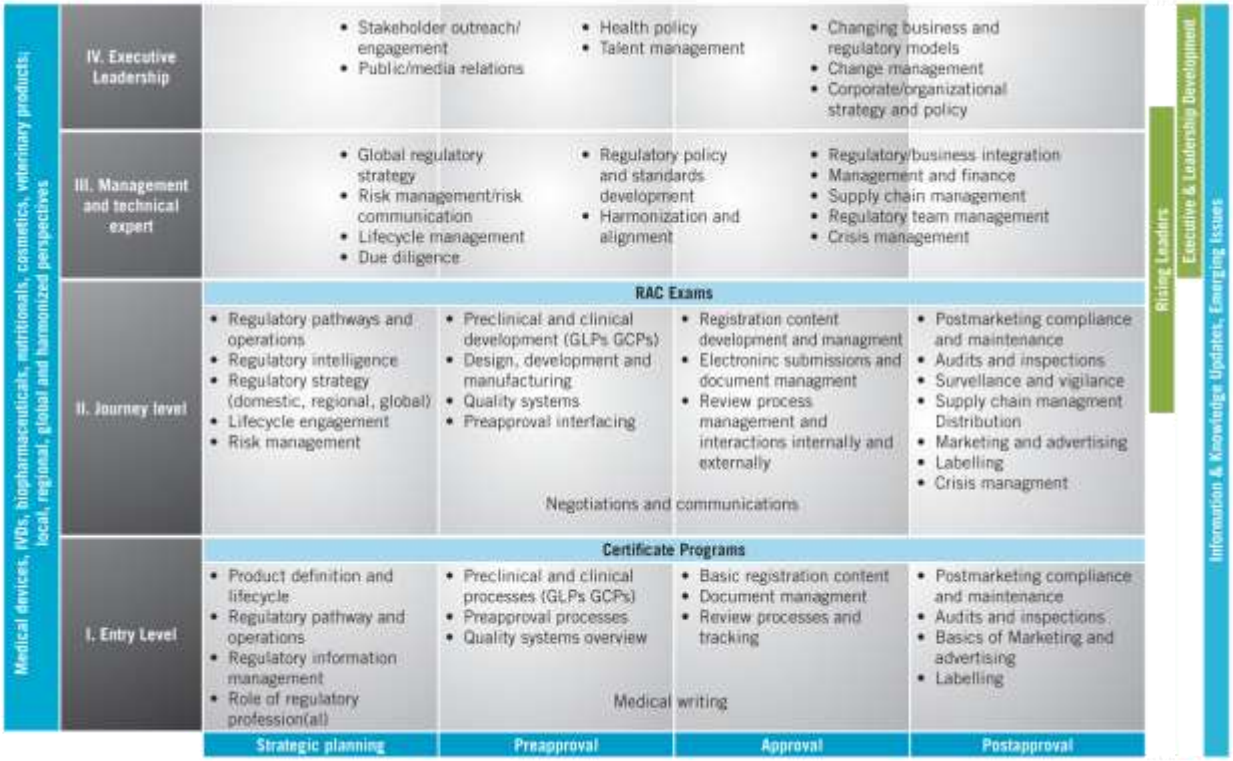
A food and medical product regulatory system integrates:

- product safety through good manufacturing, clinical, laboratory, and agricultural practices;
- staff development and training for employees;
- monitoring and evaluation of product quality using laboratories;
- inspection and surveillance of products throughout the supply chain;
- risk assessment, analysis, and management; and
- emergency response.

Protecting the public's health is crucial in a food and medical product regulatory system. The system needs to quickly communicate information to the public in emergencies to ensure the public's safety.

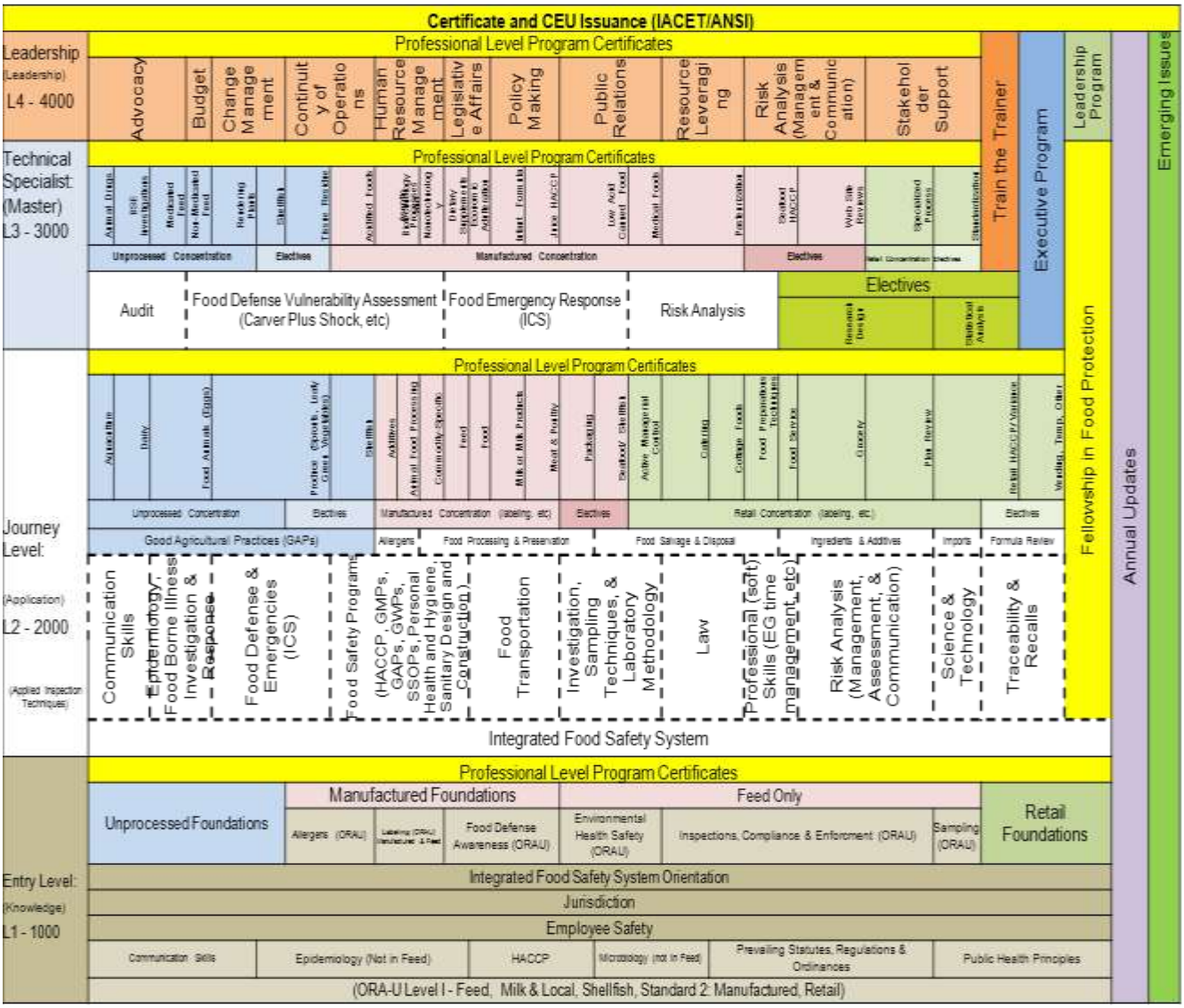
SOURCE: IOM, 2012.

**FIGURE 2** RAPS Regulatory Curriculum Framework




SOURCE: Keramidas, 2012.

**FIGURE 3** IFPTI Regulatory Curriculum Framework




SOURCE: Bradsher and Wojtala, 2012.

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