
International Regulatory Capacity Building Global Curriculum Project



Factors Driving Food Safety Change

- Global food supply
- New Regulations – FSMA, SFCA
- Changing science
- New Threats
- Media influence
- Consumer expectations



FSMA - Focus on Imports

- Certification for high risk foods
- Foreign supplier verification program
- Voluntary qualified importer program
- Third party certification
- Authority to deny entry
- Foreign regulatory capacity-building



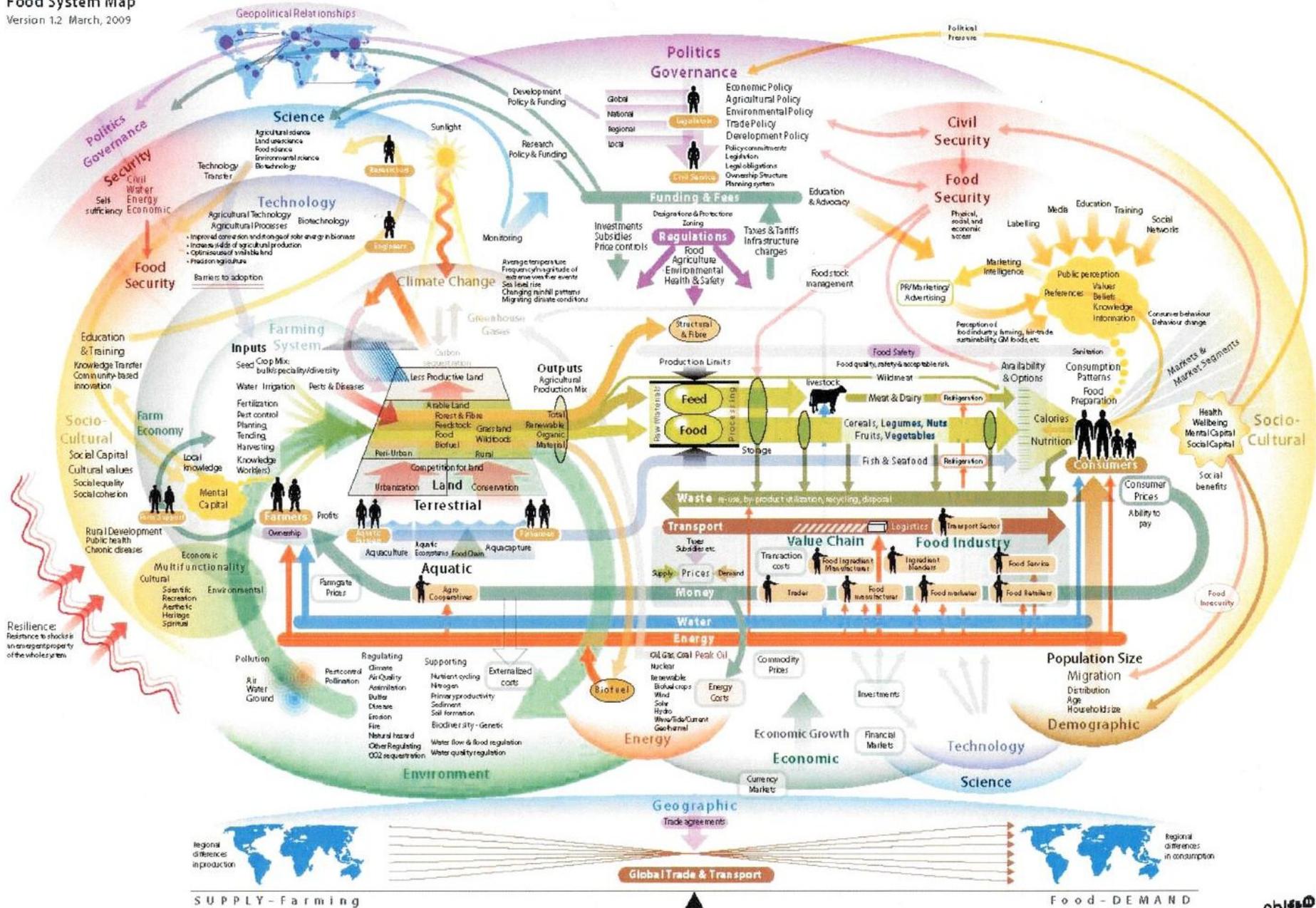
Global Food Supply Influences

- Climate
- Politics
- Energy
- Waste
- Supply Chains
- Socio-cultural
- Regulations
- Science + Technology
- Economies
- Education + Training
- Water
- Environment



The Global Food System

Food System Map
Version 1.2 March, 2009



Food Risk Matrix

The *Cause* leading to the *Effect* of Adulteration

Food Quality	Food Fraud	Motivation Gain: Economic
Food Safety	Food Defense	Harm: Public Health, Economic, or Terror
Unintentional	Intentional	
Action		

Spink, John, & Moyer, Douglas C. (2011b). Defining the Public Health Threat of Food Fraud. *Journal of Food Science*, 76(9), R157-162.

Imported Foods in U.S.

- Over 250,000 foreign registered firms
- Imported through over 300 ports
- 80% of Seafood
- 50% of fruit and vegetables
- Major reliance on spices, chemicals, preservatives
- 40% of finished drugs
- Rising trends



By 2050

- World's population will reach 9.1 billion – 34% increase
- Food production must increase 70%
- 70% of world's population will be urban – 49% today
- Developing countries net imports of cereals will more than double



Agri-Food Sector Capacity Building

■ Private Sector

- Private Standards
 - BRC
 - FSSC 22000
 - IFS



Capacity building

- GFSI Toolkit
- Training

■ Public Sector

- Regulation
 - CODEX
 - EFSA
 - US FDA



Capacity building

- Training System for Regulatory Personnel

■ Education

- Undergraduate
- Graduate Degrees



Capacity building

- Science degree programs
- Certificates

Trade

Economic Development

Public Health

Complexities of the Global Supply Chain

- Lack of visibility
- Multiple interconnections
- Incomplete records
- Challenging tracking
- Maintaining cold chain



Supply Chain Risks

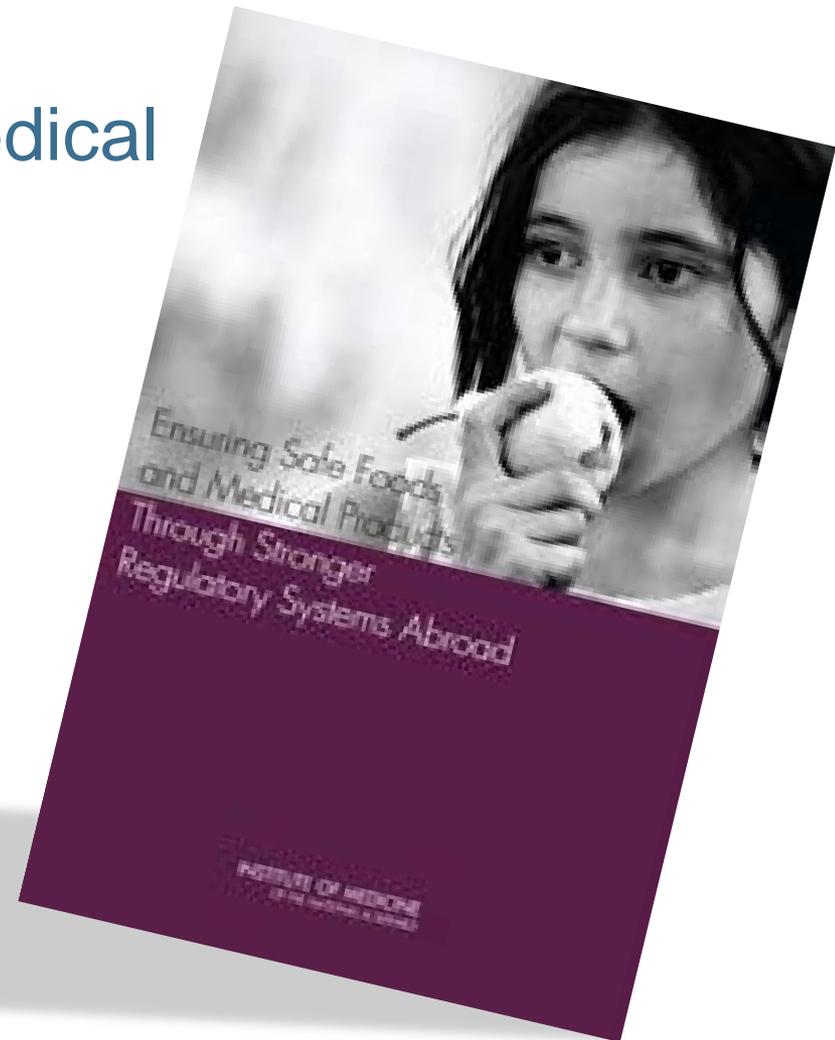


Supply Chain Risks



2012 Institute of Medicine Report

Ensuring Safe Food and Medical
Products Through Stronger
Regulatory Systems Abroad



Core Elements of a Food Regulatory System

- Product safety through GMPs, GAPS
- Staff development and training
- Monitoring products using laboratories
- Inspection and surveillance throughout the supply chain
- Risk assessment, analysis, and management
- Emergency response



Critical Issues Faced By Regulators

- Adherence to international standards
- Controlling supply chains
- Infrastructure
- Laws
- Workforce
- Fragmentation
- Surveillance
- Communication
- Political will

Critical Issues Facing Regulators Identified by IOM Committee

Nine Problems Facing Product Safety Systems in Developing Countries

1. Adherence to international standards
2. Supply chain problems
3. Infrastructure deficits
4. Lack of/ confusing regulatory laws
 - Neglected
 - Unequally applied
 - Non existent product liability laws



Nine Problems Facing Product Safety Systems in Developing Countries

5. Regulatory responsibilities scattered across agencies
6. Poor public health/ food safety surveillance systems
7. Poor communication
 - Within a regulatory authority
 - Across government agencies that share regulatory responsibilities
 - Between government and the regulated industry
 - Between government and the public
 - With counterpart agencies in other countries
8. Lack of accountability/ public will

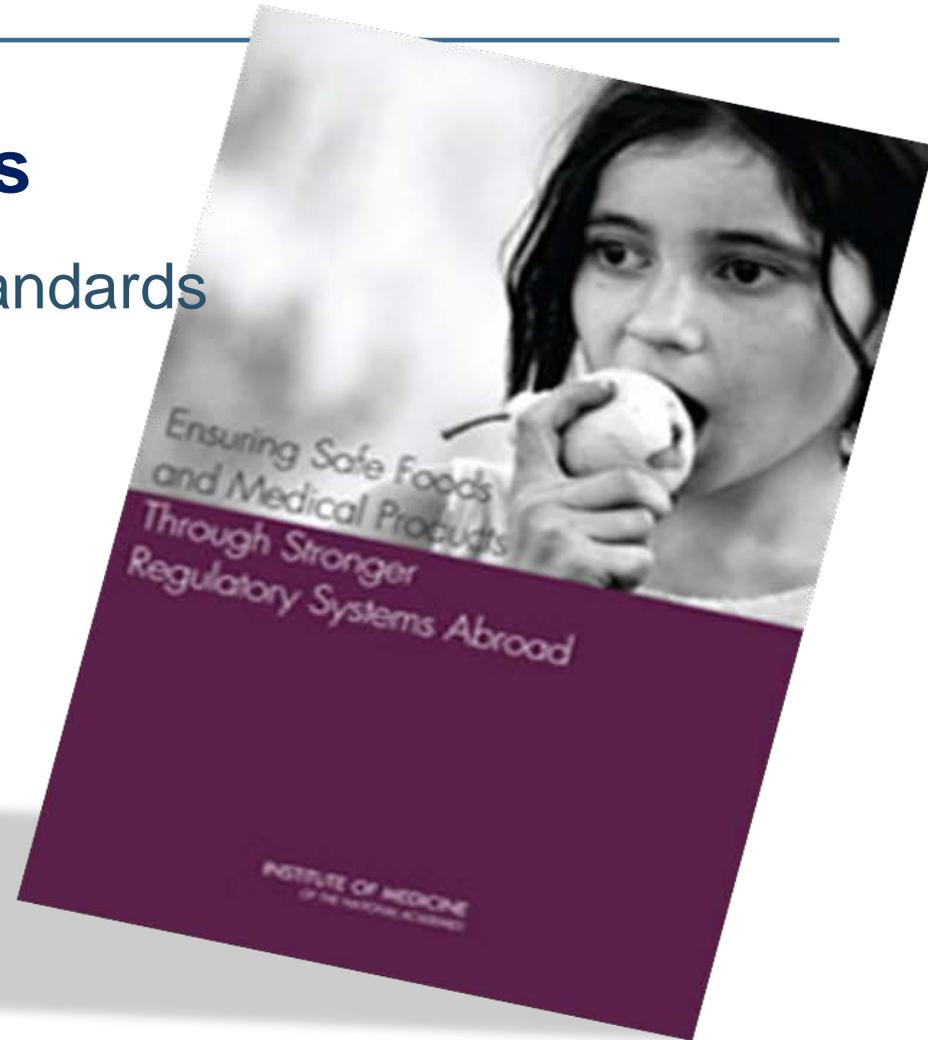
9. Regulatory workforce

- Insufficient
- Retention problems, low pay
- Lack of training / lack of academic curricula
- Poor morale
- Corruption is a cause and effect
- Undue political influence
- Fragmentation



IOM Recommendations

- Adherence to International Standards
- Controlling Supply Chains
- Infrastructure Deficits
- Strong Legal Foundation
- Workforce
- Fragmentation
- Surveillance
- Communication
- Political Will
- Enterprise Risk Management



FSMA

International Regulatory Capacity Building

FDA Office of International Programs - led effort

- Training is the first step
- Build a global regulatory curriculum
- Needs/ gap analysis tools
- Donor agencies assurance
- World Bank –
Global Food Safety Partnership



Global Curriculum Project

FDA Office of International Programs



Global Curriculum Project

Scope

- Food & medical products
- Training government regulators



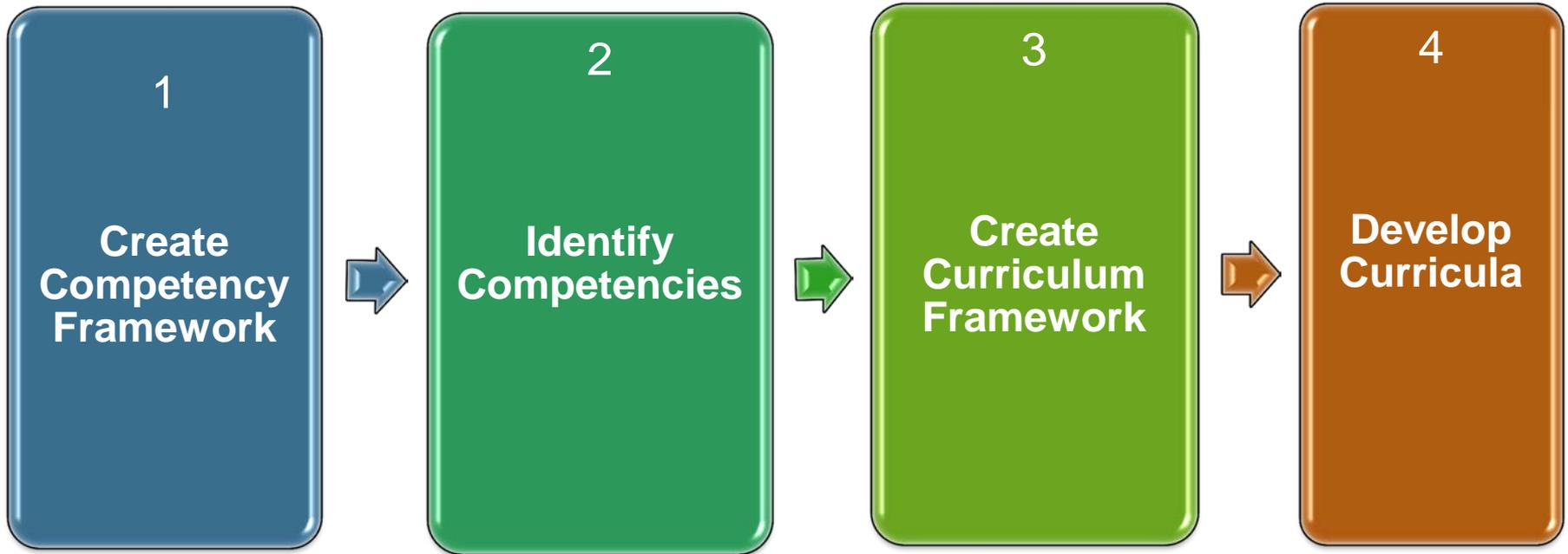
Global Curriculum Project - Phase I Outcomes

October 2014

1. Define the minimal core competencies of a regulatory professional
2. Develop a curriculum framework for educating and training the regulatory workforce
3. Develop a gap assessment tool to be used by low-middle income countries



Competency-Based Curriculum Framework Development Process



Competency-Based Curriculum Framework Development Process

Step 1

Create Competency Framework

(identify domains and professional levels)

Competency Framework

- **Model** that defines the blueprint for ‘**excellent**’ performance within an organization or sector.
- **Contains competencies**, which can be generically applied to a broad number of roles within the organization or sector.
- **Benchmark** against which the performance can be assessed.

Competency Framework

International Food Protection Training Institute
U.S Regulatory Food Protection Professional
Competency Framework

	Technical Competency	Programmatic Competency	Communications Competency	Leadership Competency
Leadership				
Technical Specialist				
Journey				
Entry				

Competency-Based Curriculum Framework Development Process

Step 2

Identify Competencies

(combination of knowledge, skills, abilities, and behaviors required to accomplish the desired outcome)

Competencies - Definition

- Ability or skill
- Personal attributes or inputs (knowledge, skills, and abilities) that individuals must have, or must acquire, to perform work tasks effectively

Identify Competencies

<p style="text-align: center;">Inspector (Comprehension)</p>	<p>information gathering skills.</p> <p>IC2. Apply active listening skills and adapt to different communication styles.</p> <p>IC3. Apply tactical communication skills in potentially confrontational situations.</p> <p>IC4. Write and present clear, concise, and accurate reports of inspection findings.</p>	<p>professional manner according to CFIA expectations.</p> <p>IG2. Explain a decision made in relation to job responsibilities.</p> <p>IG3. Establish positive relationships.</p> <p>IG4. Identify and analyze problems.</p> <p>IG5. Collect, record, analyze, interpret, and explain data.</p> <p>IG6. Use effective organizational skills.</p>	<p>decisions and actions taken.</p> <p>IL2. Employ collaboration skills in teams.</p> <p>IL3. Use persuasive techniques accomplish objectives.</p> <p>IL4. Confidently express concerns.</p>	<p>vision, mission, and values statement to day-to-day activities.</p> <p>IO2. Explain agency role in relation to other federal/ provincial partners, industry partners, and stakeholders.</p> <p>IO3. Use agency organizational structure to interact with internal functions.</p> <p>IO4. Explain agency regulatory authority and program delivery.</p>	<p>inspection process.</p> <p>IT2. Explain compliance, noncompliance, and enforcement measures.</p> <p>IT3. Describe inspection policies, guidance, and laboratory results.</p> <p>IT4. Describe production and processing systems and preventive control plans.</p>
<p style="text-align: center;">Trainee (Knowledge)</p>	<p>TC1. Apply written and verbal directions.</p> <p>TC2. Accurately record observations.</p> <p>TC3. Discuss ideas and concepts logically and succinctly.</p> <p>TC4. Describe good communication skills.</p>	<p>TG1. State the role of professional conduct.</p> <p>TG2. Identify appropriate decisions.</p> <p>TG3. Define cultural awareness.</p> <p>TG4. Describe the importance of good</p>	<p>TL1. Recognize the importance of policies dealing with ethical behaviour.</p> <p>TL2. Express the importance of Public Service.</p> <p>TL3. Indicate a desire to pursue professional growth.</p>	<p>TO1. Describe agency vision, mission, and values.</p> <p>TO2. Distinguish agency role in relationship to other federal/ provincial partners.</p> <p>TO3. Describe agency organizational</p>	<p>IT1. Describe regulations pertinent to the agency.</p> <p>IT2. Describe hazards and risks within the scope of inspection.</p> <p>IT3. Describe inspection procedures.</p>

Competencies Identification

- “Strawman” based on US, UK, & Canadian models
- Expert Panel
- Validation using broad international group

Competency-Based Curriculum Framework Development Process

Step 3

Create Curriculum Framework

(key content areas relevant to profession)

Curriculum Framework – Definition

- **Guide** for the **systematic acquisition** of competencies
- Model that defines content to be learned
- Part of a **outcome-based** training system
- The curriculum (sequenced coursework) is **aligned** to the framework

What is the Curriculum Framework?

- A platform/system to catalog/organize courses
- Framework is like a library
- Courses are like the books – each categorized and in sections (content areas)



Regulatory Curriculum Framework

Regulatory																																																												
Certificate and CEU Issuance																																																												
Leadership (Leadership) L4 - 4000	Professional Level Program Certificates																																																											
	Advocacy	Budget	Change Management	Continuity of Operations	Food Systems and Sustainability	Human Resource Management	Legislative Affairs	Policy Making	Public Relations	Resource Leveraging	Risk Analysis (Management & Communication)	Stakeholder Support	Instructor Development	Executive Programs	Integrated Food Safety System Implementation																																													
	Professional Level Program Certificates																																																											
Unprocessed Concentration	Electives	Manufactured Concentration						Electives	Retail Concentration	Electives																																																		
Technical Specialist: (Master) L3 - 3000	Professional Level Program Certificates																																																											
	Audit	Food Defense Vulnerability Assessment (Carver Plus Shock, etc)				Food Emergency Response (ICS)			Risk Analysis		Electives		Instructor Development	Executive Programs	Integrated Food Safety System Implementation																																													
	Professional Level Program Certificates																																																											
<table border="1"> <tr> <td>Unprocessed Concentration</td> <td>Electives</td> <td colspan="6">Manufactured Concentration (Labeling, etc.)</td> <td>Electives</td> <td colspan="2">Retail Concentration (Labeling, etc.)</td> <td>Electives</td> </tr> <tr> <td colspan="2">Good Agricultural Practices (GAPs)</td> <td>Allergens</td> <td colspan="3">Food Processing & Preservation</td> <td colspan="2">Food Salvage & Disposal</td> <td>Formula Review</td> <td>Imports</td> <td colspan="2">Ingredients & Additives</td> </tr> <tr> <td colspan="2">Communication Skills</td> <td colspan="2">Epidemiology, Foodborne Illness Investigation & Response</td> <td colspan="2">Food Defense</td> <td colspan="2">Food Emergencies (ICS)</td> <td colspan="2">Food Transportation</td> <td colspan="2">Investigation, Sampling Techniques, & Laboratory Methodology</td> <td>Law</td> <td colspan="2">Preventive Controls</td> <td colspan="2">Professional (soft) Skills (EG time management, etc)</td> <td colspan="2">Risk Analysis (Management, Assessment, & Communication)</td> <td colspan="2">Science & Technology</td> <td colspan="2">Traceability & Recalls</td> </tr> </table>																Unprocessed Concentration	Electives	Manufactured Concentration (Labeling, etc.)						Electives	Retail Concentration (Labeling, etc.)		Electives	Good Agricultural Practices (GAPs)		Allergens	Food Processing & Preservation			Food Salvage & Disposal		Formula Review	Imports	Ingredients & Additives		Communication Skills		Epidemiology, Foodborne Illness Investigation & Response		Food Defense		Food Emergencies (ICS)		Food Transportation		Investigation, Sampling Techniques, & Laboratory Methodology		Law	Preventive Controls		Professional (soft) Skills (EG time management, etc)		Risk Analysis (Management, Assessment, & Communication)		Science & Technology	
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Journey Level: (Application) L2 - 2000 (Applied Inspection Techniques)	Professional Level Program Certificates																																																											
	Practicum																																																											
	Unprocessed Foundations					Manufactured Foundations					Retail Foundations																																																	
Entry Level: (Knowledge) L1 - 1000	Allergens	Communication Skills	Employee Safety	Environmental Health Safety	Epidemiology	Food Defense Awareness	HACCP	Inspections, Compliance & Enforcement	Integrated Food Safety System Orientation	Jurisdiction	Labeling	Microbiology	Prevailing Statutes, Regulations & Ordinances	Public Health Principles	Sampling	Future Leaders Programs	Annual Updates	Emerging Issues																																										
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CFIA Inspectorate

Canadian Food Inspection Agency
Inspectorate

Curriculum Framework

Leadership (Synthesis and Evaluation)		Certificates																				Skills Training		Language	
Area Chief Inspector	Regional Chief Inspector																					English	French	Level 1/2	Level 3/4
Manager	Supervisor																					Level 1/2	Level 3/4	Level 5/6	Level 7/8
Specialist		Sector Specifics										General Specifics										English		French	
Senior Compliance Officer (Analysis)		Food Concentration										Animal Concentration										Level 5/6		Level 7/8	
Compliance Officer (Application)		Food Concentration										Animal Concentration										Level 5/6		Level 7/8	
Inspector (Comprehension)		Food Concentration										Animal Concentration										Level 5/6		Level 7/8	
Trainee (Knowledge) PREP		Certificates																				Level 5/6		Level 7/8	

Food & Feed Laboratories

Senior Administrative Level	Certifications & Certifications																		Clean Management	Emerging Issues	Human Resources Management	International Organization for Standardization [ISO] [Section 4]	Leadership/Executive Program	Public Relations	Instructor Development	Project Management	Integrated Food Safety System [IFSS] Implementation	Future Leaders	Annual Update								
	Management	Budget	Quality of Operations	Facility Management	Legislative Affairs	Organizational Culture	Pulling Making	Program/Grant Management	Stakeholder Management	Stakeholder Support	System Analysis																										
Supervisor/ Manager Level	Certifications & Certifications																		Clean Management	Emerging Issues	Human Resources Management	International Organization for Standardization [ISO] [Section 4]	Leadership/Executive Program	Public Relations	Instructor Development	Project Management	Integrated Food Safety System [IFSS] Implementation	Future Leaders	Annual Update								
	Advanced Chromatography						Microbiology						Coastal Regulation and Medicine		Incident Command Systems [ICS]		Regulation													Risk Communication Introduction							
Expert Level	Certifications & Certifications																		Clean Management	Emerging Issues	Human Resources Management	International Organization for Standardization [ISO] [Section 4]	Leadership/Executive Program	Public Relations	Instructor Development	Project Management	Integrated Food Safety System [IFSS] Implementation	Future Leaders	Annual Update								
	Food			Food			Skill/Fisk			Animal Health			Food			Food														Skill/Fisk							
	Validation Methods									Validation Methods																											
Mid-level	Certifications & Certifications																		Clean Management	Emerging Issues	Human Resources Management	International Organization for Standardization [ISO] [Section 4]	Leadership/Executive Program	Public Relations	Instructor Development	Project Management	Integrated Food Safety System [IFSS] Implementation	Future Leaders	Annual Update								
	Reconstituted Foods	Allergens	Evidence-based Decision Making	Grant Writing	Internal Audit	Labeling	Measurement Uncertainty	Method Modification/ Development	Microbiology			Risk Analysis			Real Case Analysis			Validation Methods																			
	Animal Health	Dairy	Food	Food	Skill/Fisk			Animal Health			Food			Food			Skill/Fisk																				
Entry Level	Certifications & Certifications																		Clean Management	Emerging Issues	Human Resources Management	International Organization for Standardization [ISO] [Section 4]	Leadership/Executive Program	Public Relations	Instructor Development	Project Management	Integrated Food Safety System [IFSS] Implementation	Future Leaders	Annual Update								
	FDA Food Emergency Response Network [FERN] Methods		Gas Chromatography-Mass Spectrometry [GCMS]		Hazardous Material Shipping		Inductively Coupled Plasma Mass Spectrometry [ICPMS]		Liquid Chromatography-Mass Spectrometry [LCMS]		Advanced Molecular Toxicology		Diagnostics Level 3		Food Emergency Response Network [FERN] Methods		Infection Agent Shipping													Laboratory Response Network [LRN] Methods		Patent Methods					
	Critical Thinking		Epidemiology, Foodborne Illness Investigation, & Response		Evidence Management		FDA Regulatory Training Methods		Food and Food Emergencies		Laboratory Networks		Legal Proceedings		Public Speaking		Technical Writing Skills													Transferability		USDA Regulatory Training Methods					
Entry Level	Integrated Food Safety System [IFSS]																		Clean Management	Emerging Issues	Human Resources Management	International Organization for Standardization [ISO] [Section 4]	Leadership/Executive Program	Public Relations	Instructor Development	Project Management	Integrated Food Safety System [IFSS] Implementation	Future Leaders	Annual Update								
	Animal Health Certification		Dairy Certification		Environmental		Food		Food		Skill/Fisk Certification		Radiological		Animal Health Certification		Dairy Certification													Environmental		Food		Food		Skill/Fisk Certification	
	Animal Health		Dairy		Environmental		Food		Food		Skill/Fisk		Radiological		Animal Health		Dairy													Environmental		Food		Food		Skill/Fisk	
	Basic Chromatography			Basic Mass Spectrometry			Chemical Food Feed			Separation Techniques			Analytical Techniques		Basic Microbiology		Basic of Enzyme-Linked Immunosorbent Assay [ELISA]													Basic Polymerase Chain Reaction [PCR]		Diagnostics Clinical		Culture			
Basic Communication Skills	Basic Laboratory Statistics	Basic Laboratory Techniques [Lab]	Chain of Custody	Evidence	Incident Command Systems [ICS]	Inspection Sampling	Integrated Food Safety System [IFSS] Orientation	International Organization for Standardization [ISO] Accreditation	Laboratory Information Management System [LIMS]	Public Health Principles	Quality Assurance	Reference Method Reference	Regulatory Programs	Safety	Serial Dilution	Waste Management																					

High School Framework

12th grade	Capstone Project																											
	Aquaculture	Consumers	Food Animals	Herbicides	Organic	Produce	Venues/ Distribution	Emergency Response	Epidemiology	Foodborne Illnesses	HACCP Plans	Inspection	Pathogens	Role of Laboratories	Sampling	Tracebacks	Commercialization	Cost Analysis	Development Plan	Shelf Life / Quality	Specifications	Trends	Environmental / Health Influences	Marketing Analysis	Package Cost	Packaging Requirements	Shelf Life / Quality	Trends / Market Research
	Local Food Production						Food Safety						Business/Research - Product Development						Business - Food Marketing/Packaging									
	Food Business Basics				Good Agricultural Practices (GAPS)				Good Manufacturing Practices (GMPs)				Hazard Analysis Critical Control Point (HACCP)				Law		Marketing		Regulations							
11th grade	Capstone Project																											
	Basic Food Chemistry	Energy	Ions	Water	Food Science Related Careers	Mixtures	Research	Separation Techniques	Additives	Food Analogs	Micronutrients	Phytochemicals	Fermentation	Food Safety	Current Trends	Dehydration and Concentration	Thermal Preservation	Complex Carbohydrates	Enzymes	Lipids	Proteins	Sugar	Food Science	Scientific Evaluation	Sensory Evaluation			
	Basic Chemistry				Complex Food Systems				Food Chemistry				Food Microbiology		Food Preservation and Packaging				Organic Chemistry				Science of Food					

Phase II – Next Steps

- Curriculum
 - Development
 - Validation
 - Widely available & free
- Pilot Regions
- Platforms

