EU-India Capacity building Initiative for Trade Development (CITD)

Lot 1: Food Safety and SPS, Technical Regulations and Standardization, and Support to Post Clearance Audit (PCA) in Customs

The European Union and Risk Assessment

F. Boccas, May 2017
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1. The European Union & its institutions
2. Key Principles
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1. The European Union & its institutions

- The EU in 2017
- Institutions
- Member States
- EFSA
The EU & its Institutions

The European Union in 2017
The EU & its Institutions

- 28 Member States (India 29 States + 7 territories)
- 22 official languages (India 22 + Hindi & English)
- 3 alphabets (Latin, Greek, Cyrillic)
- 508 million inhabitants
- 4 million km² (India 3.3 million Km²)
- 21 republics + 7 kingdoms
- 5 candidate countries (Albania, FYROM, Montenegro, Serbia, Turkey)
- 2 potential candidate countries (Bosnia-Herzegovina, Kosovo)

EU-India Capacity building Initiative for Trade Development (CITD) – Lot 1 SPS/TBT/Customs
EU is world’s largest economy
Annual Gross Domestic Product of € 16.3 trillion (18.5 trillion US$), representing about **23% of the global output**.
The EU is also the world’s top trading block.

EU is India’s 1st trading partners, and India is the EU’s 9th largest trading partner
Bilateral trade in goods topped € 77 billions in 2016 and trade in services was approximately € 23 billions. In both cases, the import/export flows are fairly balanced, with a slight advantage for India. This proves the complementarity of the two economies.
The EU & its Institutions

- EU is the largest importer of agricultural products / food in the World
  Before US, China, Japan and Russia
  Imports more agricultural products from developing countries than the USA, Canada, Australia, Japan and New Zealand altogether.
  Imports 65% of its consumption of fish and fishery products.

- The EU is the world's third largest population bloc after China and India.
  It covers over 4 million km² and has 508 million inhabitants. By surface area, France is the biggest EU MS and Malta the smallest. Germany is the most populated Member State.
The EU & its Institutions

Council of the EU

European Parliament

Financial control

Interpretation of law

European Court of Auditors

European Court of Justice

European Commission

Advisory Committees

Economic & Social Committee

Committee of the Regions

EU-India Capacity building Initiative for Trade Development (CITD) – Lot 1 SPS/TBT/Customs
2. Key Principles

- Law versus standards
- Risk Analysis in EU food control
- The EU food law
- Roles in the process of food control
- Risk Assessment at the origin of food laws & regulations
**Key Principles**

**Essential** food safety, animal health and plant health requirements

- Regulatory edification process based on risk analysis and WTO agreement on SPS Measures
  - EU food Law, Regulations, Directives, Decisions

**Other Requirements**

- Standardisation, elaboration of guides...
  - Standards, professional codes, guides, contractual arrangements

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Key Principles

Risk Analysis in EU Food Control

- Independent scientific Risk Assessment at the source of legislation
- Official controls carried out by authorities (Member States) on the basis of Risk analysis
  - Inspection frequency
  - Residue monitoring
- Risk-based decisions by FBOs (Hazard Analysis) when deploying Food Safety Management Systems
The EU Food Law

Reg. 178/2002

- **Crisis Management**
  - RASFF
  - Emergencies and crisis management

- **Key Responsibility of Food Business operators**
  - Safety
  - Responsibility
  - Traceability
  - Transparency
  - Emergency
  - Prevention
  - Co-operation

- **Separation of RA & RM**
  - Establishment of EFSA
  - Risk Management based on RA
  - Precautionary Principle
  - Transparency

**Key Principles**
Key Principles

**EFSA**
National RA inst.
Scientific Community
International RA inst.

**RISK Assessment**

**Scientific Opinions**

DG SANTE (EC)
MS Regulatory bodies

**RISK Management**

DG SANTE verifies that MS apply in uniform manner throughout the EU

FBOs apply rules and hold full responsibility for food safety

MS Control Authorities verify that FBOs apply correctly

Consumers choose and influence the regulatory edification process

Safe Food Supply

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Key Principles

JECFA, JMPR, USA, NZ, AUS, Canada, Japan...

Codex, IPPC, OIE

DG SANTE
European Commission

EU Food & Feed Law

Scientific Opinions

EU Member States’ Risk Managers

EU MS RA bodies

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3. Constituents of the food control system

- The Scientific Community
- EFSA and other RA bodies
- Consumers
- Food Business Operators
- Legal Instruments
- DG SANTE
- Member States
Constituents of the System

The Scientific Community

- **Universities and other research bodies**
  - Research on all food safety / health issues
  - Train food scientists and experts
  - Contribute to the work of national RA bodies and EFSA

- **EU Reference Laboratories (EU RL)**
  - Research on detection methods
  - Research on method validation
  - Dissemination of science at EU level (NRLs)

- **National Reference Laboratories (NRLs)**
  - Dissemination at national level
Constituents of the System

European Food Safety Agency (EFSA)

- Organises & manages Risk Assessment
  Scientific committee
  Advisory forum
  Scientific Panels

- Issues independent scientific opinions
  Plant health, plant protection, GMOs, animal feed, animal health & welfare, biological hazards, chemical contaminants, food additives, food packaging and nutrition

- Cooperates with other RA bodies worldwide
  USA, Japan, Australia, EU Member states, New Zealand, Canada, China, Chile, OIE, WHO, FAO...
Constituents of the System

Other Risk Assessment bodies

- European Centre for Disease Prevention and Control (ECDC, human aspects)
- European Medicines Agency (EMA)
Constituents of the System

Consumers

- Are informed at all stages
  - Risk assessment
  - Risk management

- Are consulted during the process of legislation edification
  - Public consultations

- Influence policies
  - Market surveillance studies
  - Dissemination of information through the media
  - Lobbying in institutions
Constituents of the System

Food Business Operators

- Have – by law - the primary responsibility of food safety
  Regulation 178/2002 food law

- Participate in the elaboration of guides of good practices
  Professional associations

- Are consulted during the process of legislation edification
  Advisory group : 45 stakeholders from all sectors
Legal instruments

- **Regulations**
  of general application binding in all Member States (MS)

- **Directives**
  directed to MS stipulates results and deadlines leaves form and methodology to MS

- **Decisions**
  applies specifically in one or more MS directly binding
Constituents of the System

DG SANTE
Directorate General for Health and Food Safety

Develops the Food legislation in consultation with EU Member States (harmonisation process)


Operates the Rapid Alert System for Food and Feed (RASFF)

Alerts

Verify the application of legislation by MS and foreign countries

Audits in EU MS and foreign Countries

Coordinates food safety crisis management at EU level

Decisions
Constituents of the System

DG SANTE
Directorate General for Health and Food Safety

- Provides training on the application of the legislation to EU MS and foreign countries
  Better Training for Safer Food (BTSF) Programme

- Provides guidance and advice to EU MS and foreign countries
  Technical Assistance such as the CITD project
Constituents of the System

Member States

➢ Participate in the risk assessment process
  National Risk Assessment systems cooperate with EFSA

➢ Participate in the elaboration of the legislation
  National experts posted at DG SANTE
  Standing Committee on Plants, Animals, Food and Feed and its 14 sections

➢ Enforce the legislation (harmonised)
  Maintain a national capacity for official control
  Implement risk-based official controls
  Report to DG SANTE
  Implement measures in case of food safety crisis
4. European Food Safety Authority (EFSA)

- Role
- Organisation
- Functioning
EFSA

- Responsible for:
  - Providing independent scientific advice and support for EU law/policies on food and feed safety
  - Providing independent, timely risk communication
  - Promoting scientific cooperation

- **NOT** Responsible for:
  - Developing food safety policies and legislation
  - Adopting regulations, authorising marketing of new products
  - Enforcing food safety legislation
  - Taking charge of food safety/quality controls, labelling or other such issues, like inspections and traceability
EFSA

- Works with
  460 permanent staff
  Annual budget of 79 million Euros (2017)

- Draws scientific knowledge from
  National food safety agencies and research organisations
  400 research institutes
  1,500 experts
  Other EU agencies
EU-India Capacity building Initiative for Trade Development (CITD) – Lot 1 SPS/TBT/Customs
Management Board

- 14 members appointed by the Council following proposal from Parliament
- 1 member representing DG SANTE
- Manages the Authority

Not involved in Scientific advice
Advisory Forum

Representatives of MS Risk Assessment bodies
DG SANTE as observer
Advise EFSA on scientific matters, work programme / priorities and emerging risks
Scientific coordination amongst all stakeholders
Avoid duplication of efforts
Scientific Committee

One Chairperson + 15 members

Develops horizontal risk assessment methodologies

Coordination of the work of panels to ensure consistency

Strategic scientific advice to management board

Assesses emerging risks
Scientific Panels

10 Scientific panels
Perform the risk assessment work:

1. Animal Health and Animal Welfare (AHAW)
2. Food Additives and Nutrients sources (ANS)
3. Biological Hazards (BIOHAZ)
4. Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF)
5. Contaminants in the Food Chain (CONTAM)
EFSA

Scientific Panels

10 Scientific panels Perform the risk assessment work:

6. Additives and Products or Substances used in Animal Feed (FEEDAP)
7. Genetically Modified Organisms (GMO)
8. Dietetic products, Nutrition and Allergies (NDA)
9. Plant Health (PLH)
EFSA Staff

- **Staff of EFSA**
  - Support the work of Panels and Scientific Committee
  - Produce dissemination tools
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**EFSA**

- Procedure for Expert selection
- Accepted mandates (Register of Questions)
- Names of panel and working group members
- Declaration of interest of experts
- Agendas of plenary meetings
- Minutes of plenary and working group meetings
- Access to data
- Open panels meetings
- Consultations
- Adopted opinions
- Press releases and web stories
A comprehensive Communication policy

General Public

Risk Assessors

Risk Managers

Policy Makers

Stakeholders
Scientists/Academics

Efsa
European Food Safety Authority

Media

Concerned Individuals
5. How it works

- Elaboration of the legislation
- Content of the legislation (salient points)
- Risk based controls
- National Residue Monitoring Plans
- Food safety crisis management

EU-India Capacity building Initiative for Trade Development (CITD) – Lot 1 SPS/TBT/Customs
# How it Works

<table>
<thead>
<tr>
<th>Who...</th>
<th>Does What...</th>
<th>How ?</th>
</tr>
</thead>
<tbody>
<tr>
<td>European Scientific Community</td>
<td>Elaborates scientific opinions</td>
<td>Within the <strong>EFSA</strong> mechanism</td>
</tr>
<tr>
<td>DG SANTE</td>
<td>Proposes legislation : ML, MRPL, MRL, control methods...</td>
<td>Officers of DG SANTE draft proposed legislation on the basis of scientific opinions of EFSA</td>
</tr>
<tr>
<td>Member States</td>
<td>Review and propose amendments</td>
<td>Standing Committee on plants, animals, food an feed</td>
</tr>
<tr>
<td>Parliament &amp; Council</td>
<td>Adopt legislation</td>
<td>Through a Co-decision mechanism</td>
</tr>
<tr>
<td>Member States</td>
<td>Enforce Legislation</td>
<td>Official Control systems</td>
</tr>
<tr>
<td>DG SANTE</td>
<td>Verifies application</td>
<td>Through Audits</td>
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“Food Law”
Regulation (EC) No. 178/2002

Regulation (EC) No. 882/2004 on Official Controls

**Hygiene**
- Reg 852/2004 food hygiene
- Reg 853/2004 hygiene rules for food of animal origin
- Reg 2073/2005 microbiological criteria & Histamine

**Residues**
- Dir 91/414/EC (pesticides modified by Dir 2007/6/EC)
- Reg 396/2005 MRLs of pesticides
- Dir 96/23/EC residues in live animals and their products
- Dec 2002/657 performance criteria for methods of analysis
- Reg 37/2010 on MRLs of pharma. active substance in FOAO

**Contaminants**
- Reg 401/2006, 178/2010... sampling and analysis for mycotoxins
- Reg 333/2007 sampling & analysis for heavy metals, PHA, tin
- Reg 1883/2006 sampling & analysis for dioxins & PCBs

**Official Controls**
- Reg 854/2004 official controls for food of animal origin
- Reg 2406/96 Organoleptic examination for FP
- Reg 2074/2005 Freshness Indicators for FP

**Labelling**
- Reg 1169/2011 general
- Dir 90/496/EEC nutritional
- Reg 1924/2006 claims
- Reg 16/2012 frozen food

**Potable Water**
- Dir 98/83/EC

**Additives**
- FOOD
  - Reg 1333/2008
  - Reg 1331/2008
- FEED
  - 1831/2003
  - 386/2009

**Misc.**
- Novel foods,
- GMOs,
- Irradiation,
- Trichinella, BSE,
- Food Contact Materials,
- Animal By-Products,
- Feed, etc.
Official Controls implemented throughout the feed and food chain *« from Field to Fork »*
The Food law Regulation (EC) No. 178/2002
Main responsibility on operators, transparency, traceability, prevention, crisis management, EFSA, RASFF

For the use of Competent Authorities
- Reg 882/2004 organisation of official controls
- Reg 854/2004 official controls for products of animal origin
- Reg 1250/2008 health certificates
- Dir 96/23 on control of authorized veterinary medicines and their residues
- Reg(333, 1883, 401, 2074...) & Decisions (2002/657...) on the application of Reg882, Reg 854 and Dir96/23 for organoleptic examination, approval of Residue Monitoring Plans, standards for testing/sampling methods, performance criteria for methods of analysis, etc.

For Food Business Operators
- Reg 852/2004 food hygiene (general principles of food hygiene)
- Reg 853/2004 specific hygiene requirements for prods of animal origin
- Dir 8/83 on drinking water
- Dir 89/107 and 95/2 on food additives
- Dir 96/22 on prohibition of hormones, steroids, anabolizing active substances...
- Dir 2000/13, Reg 104/2000, 2065/2007 and 16/2012 on labelling
- Reg 2073/2005 on microbiological criteria and histamine
- Reg 1881/2006, 165/2010, 105/2010... on permitted maximum levels of Contaminants
- Reg 2406/96 on marketing standards & Reg2074/205 for visual inspection, parasites
- Reg 37/2010 on veterinary medicines MRLs in products of animal origin
How it Works

Structure of EU food legislation

Food of non-animal origin

- Reg 882/2004 official controls

Food of animal origin

- Reg 852/2004 food hygiene
- Reg 853/2004 specific hygiene rules for food of animal origin
- Legislation on Veterinary Medicines Residues
- Reg 854/2004 specific rules for the organisation of official control

Legislation on Pesticide Residues
How it Works

Organisation of official controls

Reg. 882/2004

- Criteria for Competent Authorities (CA)
  - powers, capacities (laboratories...)
  - Coordination between units

- Functioning principles
  - delegation of control tasks
  - staff training, transparency, confidentiality
  - internal control on their efficiency

- What CAs have to do
  - inspections, checks of hygiene conditions & HACCP
  - Interviews of staff, controls, reports

- How they have to work
  - Sampling and analysis, accredited laboratories
  - Crisis management
Reg. 882/2004

Official Controls Expert Group

The Official Controls Expert Group aims to ensure informed dialogue between Member States' competent authorities and the Commission.

Covers issues related to the implementation and enforcement of food chain legislation and, in particular, of official controls along the food chain as provided by Regulation (EC) No 882/2004.

Composed of national experts. Establishment in 2010
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How it Works

Reg. 854/2004 controls of products of animal origin

- For imports and internal market
- Approval by the CA of establishments complying with Reg. 852/2004 and Reg. 853/2004
- Establishments supervised by official inspection service (list up-to-date)
- Regular checks of hygiene
- Specific provisions in Annexes:
  - Annex I: Fresh Meat
  - Annex II: Live Bivalve Molluscs
  - Annex III: Fishery products
  - Annex IV: Raw milk and dairy products
How it Works

Example

CHAPTER II: CONTROL OF RAW MILK UPON COLLECTION

1. The competent authority is to monitor the checks carried out in accordance with Annex III, Section IX, Chapter I, Part III, to Regulation (EC) No 853/2004.

2. If the food business operator has not corrected the situation within three months of first notifying the competent authority of non-compliance with the criteria with regard to plate count and somatic cell count, delivery of raw milk from the production holding is to be suspended or — in accordance with a specific authorisation of, or general instructions from, the competent authority — subjected to requirements concerning its treatment and use necessary to protect public health. This suspension or these requirements are to remain in place until the food business operator has proved that the raw milk again complies with the criteria.
Chapter II Food Business operators’ obligations

- General obligations: refers to requirements in Annex I (primary production) and Annex II (processing...)

- General and specific hygiene requirements: microbiological criteria, temperature control, maintenance of the cold chain, sampling and analysis (Reg 853/2004)

- “Food business operators shall put in place, implement and maintain a permanent procedure or procedures based on the HACCP principles”
Risk based controls

- Scheduling of controls based on risk analysis is an EU legislation requirement: article 3 of Regulation (EC) n°882/2004

- “Adequate frequency” depending on history of controls, specific risks linked to products, processes...

Risk based classification of establishments leading to scheduled inspections
How it Works

**Inspection frequency** (based on risk)
*example of France*

- **Risk category IV** ($\text{Nr} \geq 480$): $2/\text{year}$ minimum
- **Risk category III** ($480 > \text{Nr} \geq 200$): $1/\text{year}$ minimum
- **Risk categories I & II** ($\text{Nr} < 200$): $1/3 \text{ years}$ minimum
  + following inspections in case of non compliance and/or policy measures
How it Works

Risk Classification of establishments

\[ Nr = A \times b \times S \times M \]

- **A**: Theoretical risk by establishment category (10 to 40)
- **b**: Production volume (1 to 4)
- **S**: Consumer sensitivity (1 to 2)
- **M**: Grade of inspection grid (1 to 4)

Risk grade \( Nr \) defines **4 risk categories**:

- **risk category**: I (very low risk) to IV (High risk)
- adaptation of **inspection frequency**

Thresholds set at local level **except for category IV** (\( Nr \geq 480 \)) and **category III** (\( 200 \leq Nr < 480 \))
<table>
<thead>
<tr>
<th>A=10</th>
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</table>
| A=15 | – Dried meat products, shelf stable  
       – Canned meat products, shelf stable (approved establishment) |
| A=20 |  |
| A=25 | – Treated stomach, bladders and intestines  
       – Gelatine (excepted produced by bones)  
       – Canned meat products, shelf stable (farm approved establishment) |
| A=30 | – Rendered animal fats and greaves  
       – Heated meat products, not post-lethality exposed, not shelf stable (ex: deli products vacuum packed)  
       – Meat products not shelf stable, intended to be cooked before consumption (ex: chipolata sausage)  
       – Raw material collection intended to produce gelatine and collagen |
| A=35 | – Smoked/salted/dried meat products, not shelf stable, ready to eat  
       – Meat products not shelf stable, ready to eat  
       – Meat preparations |
| A=40 | – Gelatine produced by bones  
       – Meat products, post-lethality exposed, ready to eat  
       – Sliced meat products, in retail package, ready to eat  
       – Mechanically separated meat  
       – Minced meat |
Example of b Levels – Meat and Meat Products (example of France)

- **Minced meat and meat preparation (domestic ungulates)**
  - Production $\leq 100$ t/year $b = 1$
  - $100 <$ production $\leq 1,000$ t/year $b = 2$
  - $1,000 <$ production $\leq 2,000$ t/year $b = 3$
  - Production $> 2,000$ t/year $b = 4$

- **Meat products (domestic ungulates, poultry)**
  - Production $\leq 50$ t/year $b = 1$
  - $50 <$ production $\leq 500$ t/year $b = 2$
  - $500 <$ production $\leq 5,000$ t/year $b = 3$
  - Production $> 5,000$ t/year $b = 4$
How it Works

Monitoring Plans for detection of residues

- Legal base
  Dir 96/23 on measures to monitor certain substances...
  Dir 96/22 on prohibition of the use of hormones, etc.

- Dir 96/23
  Yearly reporting to DG SANTE (article 4)
  Control of adequacy by DG SANTE
  Obligation of information to the public
  Co-responsibility of operators
  Upstream control on the marketing & use of substances
  Annex I : list of substances to be monitored
  Annex II : substances to be detected by type of animal
  Annexes III & IV : Sampling methodologies
  Annex V : list of community reference laboratories

Based on Risk Analysis
How it Works

Food Safety Crisis management

➢ Legal base
Reg. 178/2002 setting RASFF, EFSA, Crisis Management.

➢ EU level
RASFF + EU RLs
Network of crisis coordinators under DG SANTE authority
Crisis cell:
Exercises EU wide & training of officials for preparedness

➢ Member State level
Adapted legal powers and system (Reg.178)
NRL (detection) + SOP (action)
Training and nation wide exercises
Any Questions?

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