CURRENT APPROACHES TO FOOD CHEMICAL SAFETY ASSESSMENT CAPACITY BUILDING TRAINING

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World Bank Global Food Safety Partnership

Presentation Content

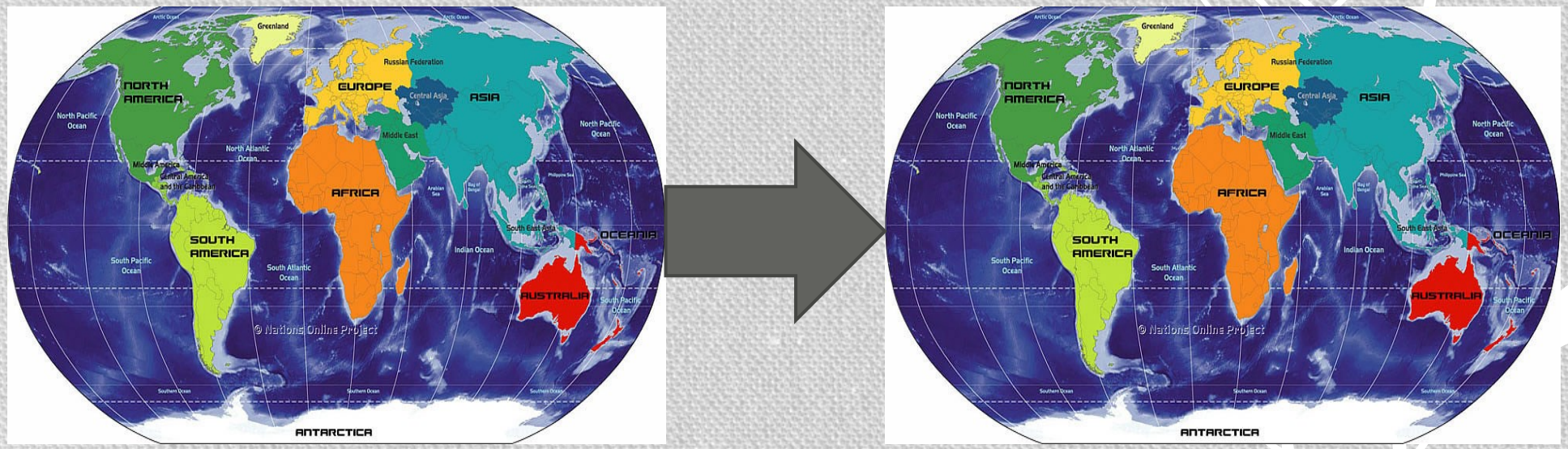
- Future Challenges for Food Safety – Importance of Food Chemical Risks
- Background to World Bank Global Food Safety Partnership Food Chemical Risk Assessment Project
- Elements of the e-Learning Module
- Logistics and Challenges
- Next Steps

Future Challenges

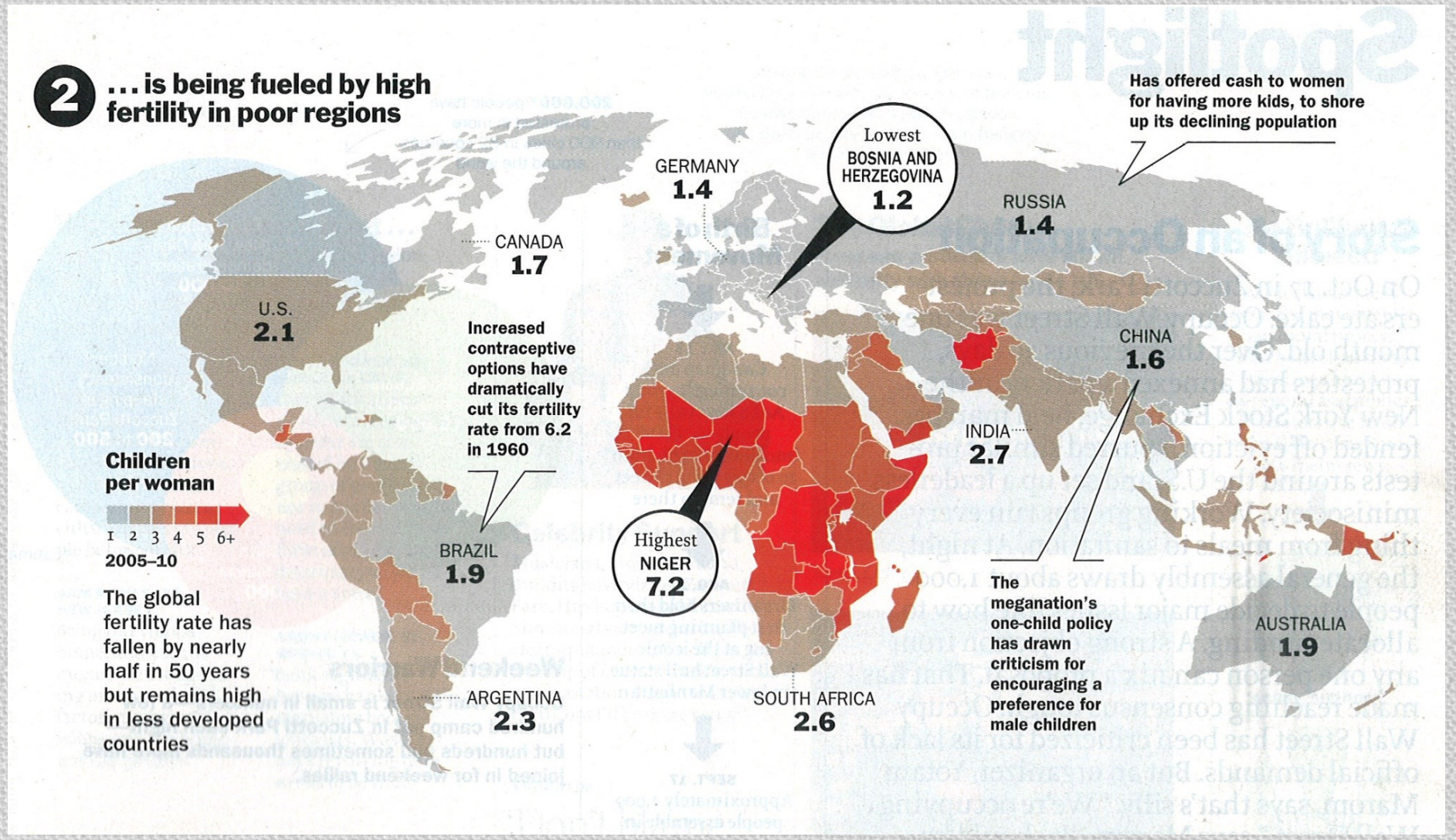
Food Supply Local

Global Food Supply

Future Challenges



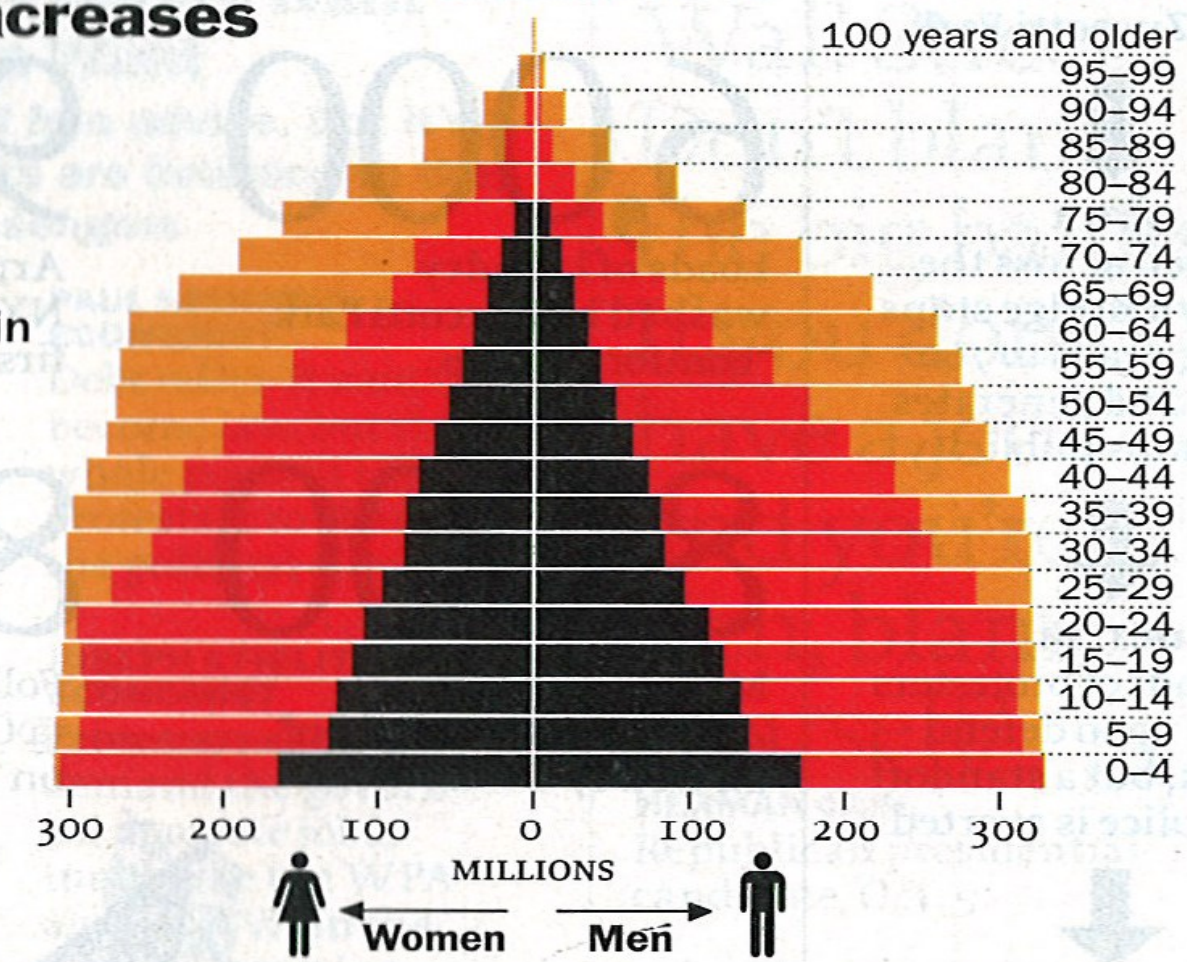

1 The massive growth in world population . . .
1 BILLION
1804
123
YEARS
TO NEXT
BILLION
2 BILLION
1927
32
3 BILLION
1959
15
13
11
13
14
18
4 BILLION
1974
5 BILLION
1987
6 BILLION
1998
7 BILLION
2011
8 BILLION
2025
9 BILLION
2043
PROJECTED
1B
2B
3B
4B
5B
6B
7B
8B
9B


2 . . . is being fueled by high fertility in poor regions
Children per woman
1 2 3 4 5 6+
2005–10
The global fertility rate has fallen by nearly half in 50 years but remains high in less developed countries
CANADA 1.7
U.S. 2.1
Increased contraceptive options have dramatically cut its fertility rate from 6.2 in 1960
BRAZIL 1.9
ARGENTINA 2.3
GERMANY 1.4
Lowest BOSNIA AND HERZEGOVINA 1.2
Highest NIGER 7.2
SOUTH AFRICA 2.6
RUSSIA 1.4
Has offered cash to women for having more kids, to shore up its declining population
INDIA 2.7
CHINA 1.6
The meganation's one-child policy has drawn criticism for encouraging a preference for male children
AUSTRALIA 1.9

3 . . . and by increases in life span

There were 12 working-age people for every person over 65 in 1950; by 2050 there will be 3

Population by age and sex



An Era of Globalization

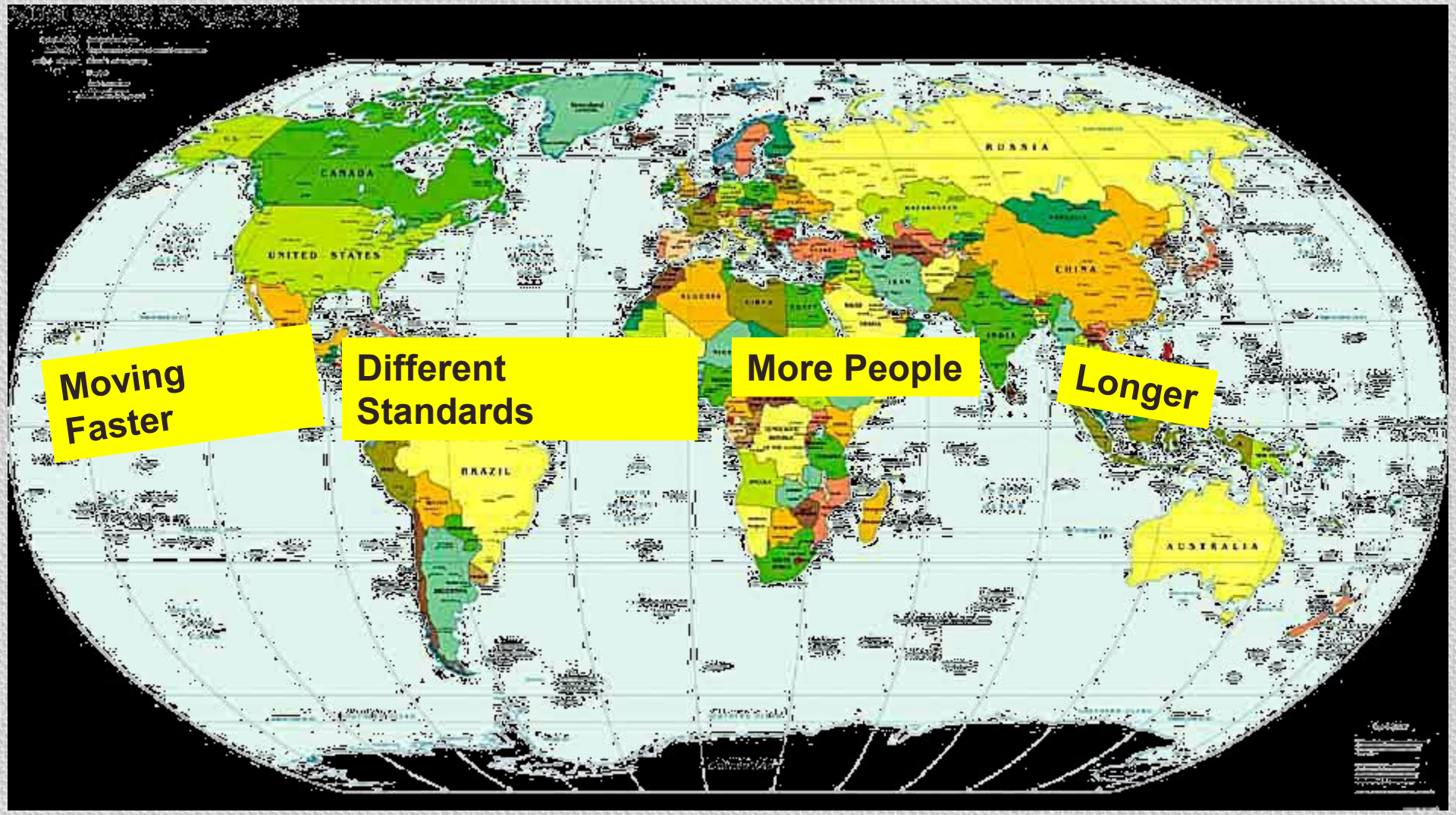
-Changes in Global Food Industry-

- The **STRUCTURE** of the global food industry is continually changing and evolving
  - Mergers, acquisitions, consolidations
  - Expansion into foreign markets
  - Strategic partnerships – Countries/regions (e.g. Asia/Pacific) are negotiating multilateral Free Trade Agreements (APEC, TPP); bilateral agreements between countries are becoming more commonplace for supply of specific food commodities.

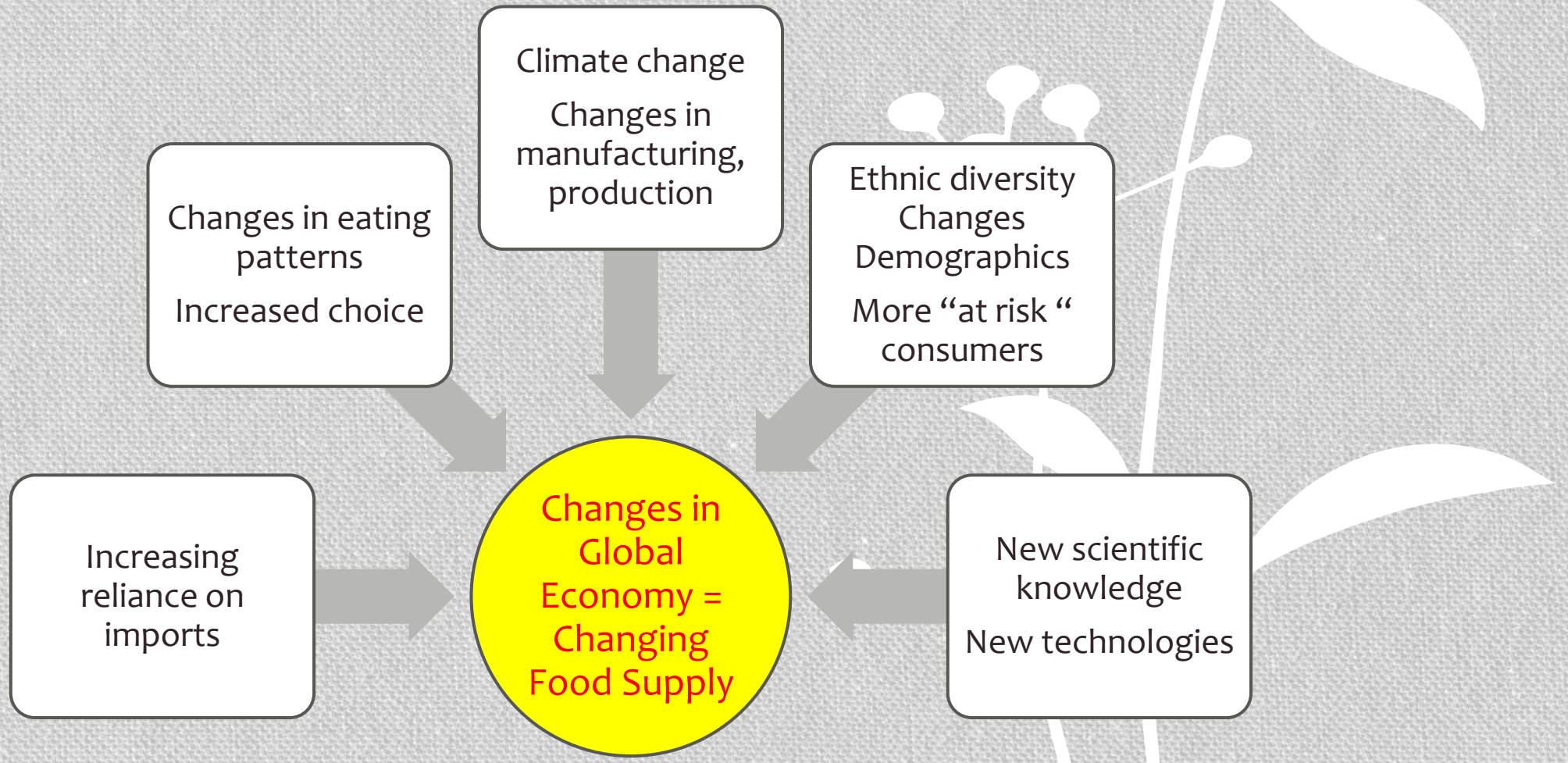
Changes in Global Economy

- Global Economy
  - The **VOLUME** of foods and ingredients in international trade is ever increasing
  - The **TYPES** of foods and ingredients
    - 1980's – primary grains and oilseeds
    - Today – processed foods, ingredients

Globalisation



More Opportunity for things to go wrong


Climate change
Changes in manufacturing, production
Changes in eating patterns
Increased choice
Ethnic diversity
Changes Demographics
More “at risk “ consumers
Increasing reliance on imports
Changes in Global Economy = Changing Food Supply
New scientific knowledge
New technologies

Food Health Risks Changing….

- **Classic Risk Factors**
  - Microbiological
  - Chemical – heavy metals, agricultural chemicals
  - Physical
  - Unknown (e.g. natural toxins)
- **Other Risk Factors**
  - New technologies
  - Changing nutrient profiles
  - Novel foods / functional foods
  - Allergenic foods
  - Food intolerances
  - Demographics
  - Changing scientific methodologies in hazard assessment and risk assessment – need to update knowledge

Traditional Food Safety Concerns

- Microbiological
  - *Salmonella* spp.
  - *Clostridium botulinum*
  - *Staphylococcus aureus*
  - *Clostridium perfringens*
- Chemical
  - Heavy metals
  - Pesticides and agricultural chemicals

- Physical
  - "Filth"
  - Foreign objects

Today's Food Safety Issues

1975-1995

- *Campylobacter jejuni*
- *Clostridium botulinum* (infant)
- *E. coli O157:H7*
- *E-coli O104:H4*
- *Listeria monocytogenes*
- *Salmonella* Enteritidis
- *Vibrio cholerae* (Latin America)
- *Vibrio vulnificus Yersinia enterocolitica*
- *Norwalk and Norwalk-like viruses*
- *Rotavirus*

- *Cryptosporidium parvum*
- *Giardia lamblia*
- *Toxoplasma gondii*
- Bovine spongiform encephalopathy prion
- Melamine
- Acrylamide
- Bisphenol A
- Pthalates
- Economically motivated adulterants – e.g. Sibutramine. Viagra in coffee, Phenolphthalein,
- Nanochemical safety
- Etc.

Changes in Scientific Knowledge

- Greater understanding of foodborne pathogens
- More and better analysis and detection methods – ppb, ppt, ppqd!!
- Creating new issues re safe but non compliant for many low level chemicals e.g. BPA, ag/vet chemicals
- Processing technology
  - Aseptic
  - High pressure
  - Nanotechnology
  - Irradiation

Emerging Food Chemical Issues

- Extensive global trade

Local Issues

National Issues

International Issues

- Governments can be frequently confronted with food chemical issues which require immediate responses.

Challenges for Responding to Food Chemical Safety Issues

- Short timeframes to respond
- Inadequate/incomplete data
- Uncertainties in data
- Perceptions
- Legal liabilities
- Political sensitivity

Food Chemical Risk Assessment Capacity Building

- Many different sources (FAO, WHO, EU, FDA, FSANZ, JIFSAN, Universities, Industry, etc, etc)
- Mostly targeted to specific clients/audiences and not always complete
- Need for a new and simple approach that can be used by a general audience, particularly food safety regulators from developing countries

THERE SEEMS TO BE A NEVER ENDING DEMAND FOR FOOD CHEMICAL RISK ASSESSMENT TRAINING!!!!!!!

Project developed and facilitated by the World Bank Global Food Safety Partnership

Provided by D. Hattis

Chemical Risk Assessment Capacity Building: *Involvement*

- Paul Brent, Chair, Expert Group and GFSP Consultant
- Manfred Luetzow, GFSP Consultant
- A/Prof Leon Brimer, GFSP Consultant
- Sonia Bradley, Senior Advisor, GFSP Secretariat
- Expert working group – internationally recognised chemical risk assessment experts
- Providers of training materials

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Contributors

The main authors of this module include:

- Dr Paul Brent, Principal Scientific Consultant, Global Food and Chemical Risk Assessment and Risk Management Solutions – Project Leader
- Dr Manfred Luetzow, Joint Secretary FAO/WHO JECFA – Project Consultant to World Bank Global Food Safety Partnership
- A/Prof. Leon Brimer, University of Copenhagen – Project Consultant to World Bank Global Food Safety Partnership

The Expert Working Group comprised of :

- Dr Angelika Tritscher, WHO JECFA Joint Secretary
- Dr Ken Hinga, USFDA
- Dr David Goldman, USDA
- Dr Djien Liem, EFSA
- Dr Clare Narrod, University of Maryland, USA
- Professor Junshi Chen, China Centre for Food Safety Risk Assessment
- Dr John Reeves, New Zealand Ministry Primary Industries
- Dr Maia Jack, US Institute for Frozen Foods
- Ms Megan Crowe, US Department Economics

Audience

This module is primarily intended to be used by developing country food regulatory agencies reviewing food chemical risk assessments, and by people preparing food chemical risk assessments for food regulatory agencies.

It is also intended to be of assistance to a broader audience seeking information about processes of food chemical risk assessment globally, including food industry scientists.

Chemical Risk Assessment Capacity Building: *Timeline*

- Project conceptualized and team formed 2013
- Expert Group formed 2013
- Consultation with potential providers of material and Expert Group during 2014
- Identified currently available training material
- Reviewed available materials and provided report and recommendations for comprehensive, globally relevant tool
- Presented draft materials/progress report in Cape Town, WB GFSP Meeting December 2014
- Preparation of e-materials by mid 2015
- Roll out mid 2015 with the ability to review and refine over course of 2015 and beyond

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Chemical Risk Assessment Capacity Building: *Final Report To WB GFSP*

- Significant materials identified
- Four ranked most highly as suitable in part, but no one set of materials suitable as GFSP global module. Few suitable for e-learning.
- University of Copenhagen (Brimer) material suitable, accessible and UC willing to engage.
- Review process assisted in refining: audience; format/content; currency; development of a GFSP module.

Project Stages - Report:
Key findings

- Most available material is front-teaching or text-book oriented
- If front-teaching, slides plus case studies with no background texts (for teachers, learners)
- Most of the material is “audience-adapted training” (created or adapted to a specific ad-hoc training

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Project Stages 1 and 2 - Report:
Development of the module

- Developed by using materials already available as identified
- If developers and owners of such material are willing and allowed to contribute, they will be invited to participate as part of the current project
- Contributions of the project were not be remunerated
- A tiered approach was applied, starting with general high level principles and drilling down to greater levels of complexity as needed to accomplish the training objectives.

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Global Food Chemical Risk Assessment Training
Suggested approach

- Food risk assessment is a scientific discipline that **historically** uses a formal approach which includes certain pre-defined terms such as “hazard”, “hazard identification”, “dietary exposure” and “risk characterisation”
- Approach to develop the concept of food chemicals risk assessment and its principles together with the participants using examples rather than just providing terms and definitions.

SAFER FOOD STRONGER ECONOMIES HEALTHIER WORLD

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Global Food Chemical Risk Assessment Training
Draft structure & contents

- Seven modules proposed
- Developed from the structure of the reviewed materials (mainly Brimer)
- Avoid too much theoretical approach, be practical
- Start from the daily work of participants and not from the risk analysis dogma

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Global Food Chemical Risk Assessment Training
Seven modules

1. General Introduction to Food Chemical Risk Assessment -What is the problem?
2. Food chemicals – their toxicity
3. Regulatory framework
4. How much of it?
5. Formalizing the process
6. Specific aspects – GMOs, novel foods
7. All together now

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Global Food Chemical Risk Assessment Training

Seven modules

Many Contemporary Examples

- BPA
- Tebuconazole
- Lead
- Phosmet
- Acrylamide
- Amoxicillin
- Mycotoxins
- GM Food Safety
- Novel Food Safety
- Safety of Nanomaterials
- New Plant Breeding Techniques
- Flavouring Agents

Global Food Chemical Risk Assessment Training

1. What is the problem?

- Understanding what food chemicals are, why they are present in food, why some of them are unsafe, what basic questions are to be answered when assessing their safety
- Develop concept of risk assessment and risk analysis using examples rather than using the scholarly traditional approach

Global Food Chemical Risk Assessment Training

2. Food chemicals – their toxicity

- Understanding the steps from intake of food chemicals, their metabolism, the toxic effects observed, assessing the severity of effects in animals and humans
- Metabolism, toxicokinetics & toxicodynamics
- Examples of chemicals and toxicity endpoints
- Dose-response observations
- Threshold vs non-threshold mode of actions

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Global Food Chemical Risk Assessment Training

3. Regulatory framework

- Understanding how regulators define acceptable risk and thereby set the framework for assessing food risks
- The role of and interaction between risk managers and risk assessors
- The notion of safety for food chemicals
- Acceptable daily intake
- Minimizing intake of unavoidable toxic substances
- Need for exposure estimates to assure that risk management measures comply with risk assessment

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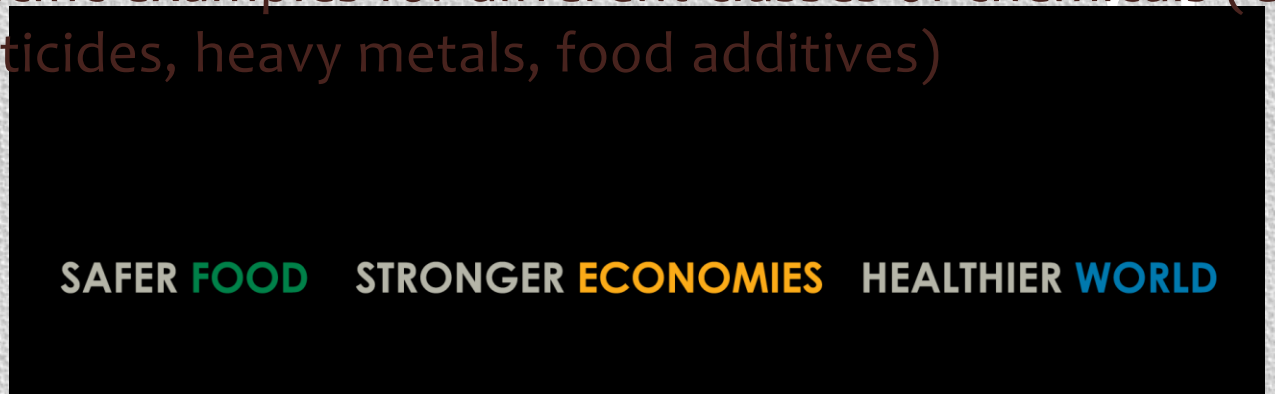
Global Food Chemical Risk Assessment Training

4. How much of it?

- Understanding the data needed to estimate intakes of food chemicals – dietary exposure modelling
- Food consumption data: what is available (national data, GEMs), how to generate them?
- Levels of chemicals on food: reliable analytical testing, increasing sensitivity of analytical systems, zero tolerance
- Intake differences between segments of the population (infants, children, adults), types of diets
- Specific examples for different classes of chemicals (e.g pesticides, heavy metals, food additives)



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On-line course

Training program on Food Chemical Risk Assessment for developing country food safety regulators and the food Industry

Module 4

How much of it?

Dietary Exposure Chapter 4

- No exposure – no risk
- Exposure via the oral route
- Exposure – what is essential
- Simple calculations – «back of the envelope»
- What is our objective
- Pesticides
- Exposure via the oral route
- Food conumption is different
- Food consumption tables
- Food balance sheets and using them
- Household surveys and individual data
- Model diets
- Food concentration data
- Uncertainty
- Total Diet Studies etc etc

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5. Formalizing the process

- Understanding how the international food safety community recommends to perform safety evaluation of food chemicals – WHO/FAO, USFDA, USEPA, EFSA, FSANZ, Health Canada etc etc
- Framework of risk analysis
- Four steps of risk assessment – the definitions
- World Trade Organization, Codex Alimentarius
- Uncertainty and data gaps

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6. Specific aspects

- Understanding how the general approach and the main principles are modified for specific classes of food chemicals
- Specific units that describe risk assessments for food chemical classes that deviate significantly
- Flavouring substances, novel foods, GMO, nano-materials, new plant breeding techniques
- Threshold of Toxicological concern (TTC)
- Food contact materials (bisphenol A, phthalates)

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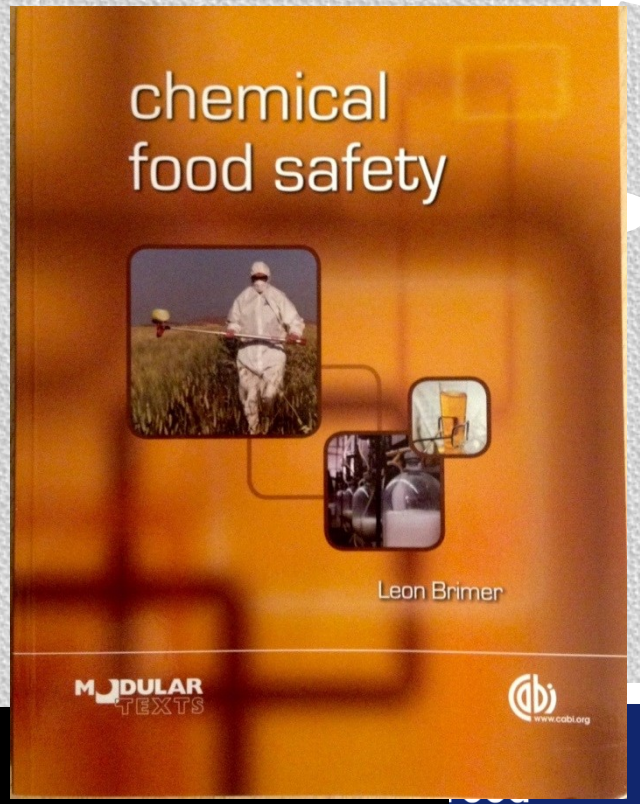
Global Food Chemical Risk Assessment Training

7. All together now

- Applying all learnt elements to a new situation
- Formulate the question
- Assess available information, search for more data
- Walk through the four steps of risk assessment for a single case
- Final discussion
- Tips and tricks (if any)

Global Food Chemical Risk Assessment Training
Current work

- Parallel work on several modules started October 2014
- Leon Brimer joined the group
- Module chapters currently being finally edited



SAFER FOOD STRONGER ECONOMIES HEALTHIER WORLD

Safety
Partnership

Module No.	Title of module Case study/excercise	Author	Objective	Content	Format	Draft 1 05.09.15	Comments/follow up	Draft 2 XX.9.15	Comments/follow up	Final XX.10.15
0_01	Welcome	LB	Explain how the module shall be used and studied [pedagogic]	Best practice how to work through the module	Presentation	Available				
1_01	What is the problem?	PB	Understanding what food chemicals are, why they are present in food, why some of them are unsafe, what basic questions are to be answered when assessing their safety	• Overview of food components present in food, added deliberately or involuntarily to food (using examples for main categories) • What is safe (discuss this term from a scientific and societal angle) • Develop the basic elements of risk assessment and risk analysis using examples rather than using the scholarly traditional approach • Food chain approach (raw materials) • "The dose makes the poison" (hazard x exposure)	Presentation Background text	Available				
1_02	Phosmet	PB	Case study		Slides	Available	Part of 1.01			
1_03	Bisphosphenol A	PB	Case study			?				
1_04	Acrylamide	LB	Case study		Presentation	Available				
2_01	Food chemicals – their toxicity	LB	Understanding the steps from intake of food chemicals, their metabolism, the toxic effects observed, assessing the severity of effects in animals and humans	• Absorption, distribution, metabolism, excretion of food chemicals • Toxicokinetics & toxicodynamics • Examples of chemicals and toxicity endpoints • Dose-response observations • BMDL • Threshold vs. non-threshold mode of actions • TTC (Structure vs activity)	Presentation Background text	Available				
2_02	Toxtree (QSAR, TTC)	LB	Excercise			?				
2_03	Example of a contaminant aflatoxin	LB	Case study		Slides	Available	Part of 2.01			
2_04	Exercise how to derive an ADI from dose response in a pivotal study (real case)	LB	Excercise			?				
3_01	Regulatory framework	ML	Understanding how regulators define acceptable risk and thereby set the framework for assessing food risks	• The notion of safety for food chemicals • Acceptable daily intake • Minimizing intake of unavoidable toxic substances • Need for exposure estimates to assure that risk management measures comply with risk assessment	Presentation	Available				
4_01	How much of it?	ML	Understanding the data needed to estimate intakes of food chemicals	• Food consumption data: what is available, how to generate them • Levels of chemicals on food: default levels (e.g. regulatory maximum concentrations), importance of reliable analytical testing at national level (method used) • Intake differences between segments of the population, types of diets • Specific examples for different classes of chemicals (e.g pesticides, food additives)	Presentation Background text	Yes				
4_02	Example of a pesticide and veterinary drug (e.g. cypermethrin – use WHO JMPR spreadsheet and vet drug model diet	ML	Excercise			Under preparation				
4_03	Example of a contaminant: aflatoxin	ML	Excercise			Under preparation				
5_01	Formalizing the process	ML	Understanding how the international food safety community recommends to perform safety evaluation of food chemicals	• Roles of risk managers and risk assessors • Framework of risk analysis • Four steps of risk assessment – the definitions • Repeating the main elements • World Trade Organization, Codex Alimentarius • Uncertainty and data gaps		Under preparation				
5_02	Discuss the ML setting process (case acrylamide) roles of risk assessment / risk management	ML	Case study			Under preparation				
6_01	Specific aspects	ML/PB/LB	Understanding how the general approach and the main principles are modified for specific classes of food chemicals	Specific units that describe risk assessments for food chemical classes that deviate significantly (contemporary thinking)	Presentation	?				
6_02	Flavouring substances	LB				?				
6_03	Novel foods	PB			Presentation Background text	Available				
6_04	GMO	PB			Presentation Background text	Available				
6_05	Nano-materials	PB			Presentation Background text	Available				
6_06	Chemicals being present not only in food	ML			Presentation	Under preparation				
6_07	Food contact materials	LB			Presentation	Available				
6_08	Upcoming issues, future challenges	PB			Presentation	?				
6_09	New technologies, new plant breeding	PB			Background text	Available				
7_01	All together now (wrap up)	LB	Applying all learnt elements to a new situation	• For e-learning: just a summary of main points • Assess available information • Formulate the question • Search for more data • Walk through the four steps of risk assessment for a single case • Final discussion • Tips and tricks (if any)	Presentation	?				

Author	Objective	Content	Format	Draft 1 05.09.15	Comments/follow up	Draft 2 XX.9.15	Comments/follow up	Final XX.10.15
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PB	Case study		Slides	Available	Part of 1.01			
PB	Case study			?				
LB	Case study		Presentation	Available				
LB	Understanding the steps from intake of food chemicals, their metabolism, the toxic effects observed, assessing the severity of effects in animals and humans	• Absorption, distribution, metabolism, excretion of food chemicals • Toxicokinetics & toxicodynamics • Examples of chemicals and toxicity endpoints • Dose-response observations • BMDL • Threshold vs non-threshold mode of actions • TTC (Structure vs activity)	Presentation Background text	Available				
LB	Excercise			?				
LB	Case study		Slides	Available	Part of 2.01			
LB	Excercise			?				

Challenges

- Tyranny of distance
  - Writers are in Australia, Switzerland, Denmark
  - Expert Group in Geneva, Parma, USA, China, New Zealand etc
- Technology/communication challenges – emails, telephone, skype, face-to-face meetings
- Discipline/timeframes – regular fortnightly/monthly teleconferences
- Competing priorities of very busy participants
- Pressure from potential users of the module – much interest to road test the module

Next Steps

- Editing and formatting the module for consistency
- Seek comments/assistance from Expert Group
- Road test module - ILSI SEA/ASEAN funding opportunity to test utility of module
  - 3-4 different countries;
- Feedback from road test
- Amend module after feedback
- Publish module on WB GFSP web site in several different languages
- USE IT?

Food laws…

The Task…

Ensure Everything They Eat is Safe… for 90 years


Thank you