Training workshop
Codex Alimentarius: Risk analysis and risk assessment procedures

National Institute of Nutrition (NIN)
Hyderabad, Andhra Pradesh
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Report

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Accomplished work

1. A training workshop was held by the reporting consultant Manfred Lützow under the title *Codex Alimentarius: Risk Analysis and Risk Assessment Procedures* from November 27 to December 1. The meeting venue had been provided by the National Indian Institute for Nutrition at Hyderabad, Andra Pradesh; the local organisation was the responsibility of Dr T. Longvah, Deputy Director, and his collaborators. Although the organizers were informed rather late, their organization and the provided meeting facilities were excellent in all aspects; in summary they met the agreed contractual obligations of the hosting government.
2. Fifteen participants out of invited 23 were able to attend – from their affiliation and background they reflected the complex central and federal political structure and the importance of independent bodies dealing with specific commodities (see Appendix 1).
3. Following several discussions with Dr E. Boutrif (FAO; STDF) the reporting consultant modelled the training workshop's structure and content along the outlines of the recently finalized but not yet published *Food Safety Risk Analysis - A Guide for National Food Safety Authorities* (FAO/WHO, Rome, 2006; in press). The workshop was split into six modules of which the four central ones and their presentations were based on this document (see Appendix 2):

Module 1	*Introduction to Seminar and Topic*
Module 2	*Introduction to risk analysis, international trends - current status in India*
Module 3A	*Risk Management (preliminary steps)*
Module 4	*Risk assessment*
Module 3B	*Risk Management (continued)*
Module 5	*Risk Communication*

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Module 6 Benchmark and conclusions

4. Presentations had been prepared in advance for all six modules, however, these were adapted and fine tuned according to the progress the workshop made; in addition the following case studies and special trainings sessions were prepared *ad hoc* in response to issues and topics proposed by the participants of the workshop during the first two days:

   The natural sweetener Stevia (food additive, novel food, dietary supplement)

   Exposure assessment: the pesticide endosulfan (general and specific issues)

   Codex vs national standards: MRLs for pesticide residues – why are there differences?

   Case study: methyl mercury in fish

   Sudan red: a food additive without risk assessment

   Chloramphenicol: risk assessment of a banned veterinary drug

5. The program contained also a number of working group exercises, ad hoc discussions and interventions. Participation during lectures, discussion and working groups was very active; all participants raised issues and contributed. The following working groups were organized:

   Elements of a national food safety system

   Preliminary risk management steps: three case studies

   SWOT Analysis of the current Indian system – three important things to change

   The results from the third working group exercise on the strengths and weaknesses of the present food safety system were consolidated in a final discussion of the workshop and agreed upon (see Appendix 3).

6. One topic of discussion was what national food safety systems should be studied by Indian officials before framing the necessary elements under the new food safety act. According to the discussions and observations made, more input for the specific Indian situation may require the study of systems with a strong federal component such as Germany and Switzerland. It may also be helpful to visit countries that have just recently started to introduce changes (e.g. Thailand) or implemented those (e.g. Cyprus).

Recommendations

7. Following a request from the audience, the reporting consultant identified in the final discussion of the workshop from his view spontaneously the following three areas of priority to improve the food safety in India:

   Improve the involvement of technical experts who understand the specific food safety issues (irrespective of seniority and representation "by office") - India has many good experts and should use that expertise more efficiently and encourage regular and frequent horizontal exchange of information.

   Expose experts more internationally in a systematic way by encouraging, permitting their participation in international expert committees such as JECFA, JMPR, and related activities such as Codex Alimentarius.

   India's probably biggest food safety problem is the deficiency in education and knowledge about very basic hygiene issues among those who prepare and eat the food (cf. recently completed NIN study). Beside all WTO & trade issues it should not be forgotten that a sustainable change requires an involvement and participation of all sectors of society including consumers (as an example: Thailand). Activities in the area of education at primary school but also of adults should be a priority.

These points express a personal view after four days of discussion and certainly do not reflect an in depth understanding of the specific Indian situation. They do not substitute a corresponding analytical study to arrive at more validated recommendations.

8. With respect to the objective of the workshop and its desired output the number of participants may not be sufficient to achieve more than providing a first brief to a small number of Indian experts; Food Safety Risk Analysis as lectured and discussed in this training workshop should become part of the curricula of those faculties which contribute significantly to scientific and regulatory food safety discussions. Comprehensiveness and degree of complexity of should be adjusted to the academic level.
9. The low level of organization of the food sector is another area that should be addressed since it would severely limit the shift of responsibility and the implementation of self-control mechanisms. Certification schemes issued by food producer or manufacturers organizations could encourage cooperatives, companies, single vendors to join sector organizations.
10. However, among the participants the level of understanding was partially astonishing good; for such experts working at central or federal institutions training is probably not so much about teaching but rather framing and improving the already available knowledge and broadening their horizon.

Debriefing

11. The reporting consultant met on December 4 at Delhi representatives of the Department of Commerce (Jayant Dasgupta, Joint Secretary; Mr Sanjay Kumar, Deputy Director), the Ministry of Health (Mr Rajesh Bhushan, Director) and the National Institute for Nutrition (Dr. T. Longvah, Director) for de-briefing on the results. Topics of discussion focussed mainly on the above mentioned recommendations and the strengths and weaknesses identified by the participants; Mr Rajesh pointed out that several activities to improve the infrastructure of laboratories, monitoring and surveillance, and training had started, partially in a five year project supported by the World Bank.

Follow up

12. The participants will receive within four weeks a questionnaire asking for their assessment of the training workshop's overall program, the presentations, the case studies and the provided documentation. The answers will be summarized and results shall be communicated to WTO and the Department of Commerce.
13. Participants were invited to raise any issues or questions related to the topics of the workshop with the reporting consultant by e-mail during the coming months. They will also be notified about the availability of the publication which was used as a basis for the training workshop's program.
14. The reporting consultant will provide the presentations in a generic version and more detailed comments about the food risk analysis guide to Mr E. Boutrif for further possible use by FAO.

Proposed further activities

15. General training on food safety risk analysis should be provided in India systematically not only to government officials at federal and state level, but also to experts who work at research institutions, officers from commodity boards and export/import agencies, and staff from the private sector involved in food safety issues.

16. For this purpose the workshop's program as it was held in Hyderabad could be adapted and similar workshops could be organized at locations to be proposed by the Indian government. Additional time should be given for the preparation of these workshops; specifically participants should be invited to raise issues of interest and proposals for case studies.
17. STDF is invited to use this workshop as a standard/template for training in other developing countries that are seeking capacity building in food safety risk analysis according to internationally recognized and updated procedures.

Thanks

18. The reporting consultant expresses his gratitude to Dr T. Longvah and his team for their hospitality, the organization of the event and the delicious food provided at the institute's guest house.

Neuenhof, 8 January 2007

Appendix 1: List of participants

Sh. V.D. Sattigeri Scientist E-II Central Food Laboratory C/o Central Food Technological Research Institute, Mysore-570013
Sh. S.P. Chaudhari Jr. Scientific Officer Central Food Laboratory Stavely Road, Pune Cantonment, Water Works Campus, Behind St. Mary Church Pune-411001
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Shri Rajiv Sharma, Technical Assistant Food Research and Standardization Laboratory, Navyug Market, Ghaziabad-200101
Shri.T.Longvah Deputy Director National Institute of Nutrition (ICMR) Jamia Osmania PO Hyderabad
Dr.V.Sudershan Rao Senior Research Officer National Institute of Nutrition (ICMR) Jamia Osmania PO Hyderabad
Dr.K.Bhaskarachary Research Officer National Institute of Nutrition (ICMR) Jamia Osmania PO Hyderabad
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Shri M.N. Patankar, Assistant Commissioner Aurangabad. Food & Drugs Administration(M.S.) 341, Bandra Kurla Complex, Madhursudan Kalelkar Marg, Bandra (East), Mumbai.
Shri. Amitabh Chandra Commissioner Food & Drugs Administration (M.S.) 341, Bandra Kurla Complex, Madhursudan Kalelkar Marg, Bandra (East), Mumbai.

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Appendix 2:

Workshop schedule and program

	Mon	Tues	Wed	Thus	Fri
9.00-10.30		**Module 2** India's food safety systems Discussion	**Module 4** Risk Assessment Part II	**Module 3B** Risk Management After the risk assessment Working Group Exercise	**Module 6** India Working Group Exercise
10.30-10.45		Morning Break	Morning Break	Morning Break	Morning Break
10.45-12.30		**Module 3A** Risk Management The first steps	**Module 4** Risk Assessment Working Group Exercise	**Module 5** Risk Communication Working Group Exercise	**Module 6** Final presentations Plenary discussion What next?
12.30-14.00	Lunch	Lunch	Lunch	Lunch	Lunch
14.00-15.30	**Opening** **Module 1** Introduction National Regime on Codex Standards (Kumar)	**Module 3A** Risk Management The first steps Working Group Exercise	**Module 4** Risk Assessment Working Group Exercise	**Module 5** Risk Communication	
15.30-15.45	Afternoon Break	Afternoon Break	Afternoon Break	Afternoon Break	
15.45-17.00	**Module 2** Background / WG Codex Alimentarius Risk Analysis	**Module 4** Risk Assessment Part I	**Module 3B** Risk Management After risk assessment	**Module 5** Risk Communication Working Group Exercise	

Module 1 - Introduction to Seminar and Topic

Layout of seminar, introduction of program

- Rules and proposed approach to joint work

Introduction of speakers and participants

- Expectations
- Objectives
- Follow-up

Module 2- Introduction to risk analysis, international trends - current status in India

Food Safety Risk Analysis: the background

- The changing food safety environment.
- Evolving food safety systems
- An abundant array of hazards
- Increasing demands on national food safety authorities

Codex Alimentarius

- Primer on Codex Alimentarius: history, main aspects, relation to SPS/WTO
- What do you know about the Codex Alimentarius?

Risk analysis: an introduction

- Components of risk analysis
- Carrying out risk analysis
- Risk analysis at the international and national levels
- Essential characteristics of risk analysis
- Benefits for national governments of using food safety risk analysis

Food Safety: current affairs and recent developments in India

- Presentation by Mr. Sanjay Kumar, DOC

Discussion

- Proposed way of working
- Establishment and briefing of working groups

Module 3A - Risk Management

This module shall provide a comprehensive overview of the management of food-borne risks to consumers. A generic risk management framework (RMF) will be discussed in some detail. The RMF consists of four steps: i) preliminary risk management activities; ii) identification and selection of risk management options; iii) implementation; and iv) monitoring and

review. Where necessary and feasible, a risk assessment is commissioned within the RMF as a functionally separate exercise (Module 4). Most stages of risk management require extensive communication, coordination and collaboration, both between risk managers and risk assessors, and with external stakeholders (Module 5). Application of each step in the RMF is illustrated by at the national and/or international levels.

Introduction

- Perspectives on risk

A generic risk management framework

Understanding risk management

Preliminary risk management activities

Step 1: Identify and describe the food safety issue
Step 2: Develop a risk profile
Step 3: Establish broad risk management goals
Step 4: Decide whether a risk assessment is necessary
Step 5: Establish a risk assessment policy
Step 6: Commission the risk assessment

Module 4 - Risk assessment

Risk assessment is the scientific foundation of risk analysis. This modules takes a broad view of risk assessment methodologies and their essential characteristics. The four steps in the Codex risk assessment system are fully explored, together with risk ranking and epidemiological approaches. The responsibilities of risk managers in commissioning and administering a risk assessment are discussed and differences between risk assessment approaches for chemical compared with microbiological hazards are illustrated. The relative merits of qualitative and quantitative approaches are examined, as are recent approaches using probabilistic models of risks.

Introduction

- Risk assessment and the WTO SPS Agreement
- Relative positions of risk assessment and risk management

Scientific approaches for assessing risks

- Risk assessment
- Use of ranking tools
- Epidemiology
- Combinations of approaches

Responsibilities of risk managers in commissioning and administering a risk assessment

- Forming the risk assessment team
- Specification of purpose and scope
- Questions to be addressed by risk assessors
- Establishing risk assessment policy
- Specification of form of the outputs

- Time and resources

General characteristics of risk assessment

- Objectivity and transparency
- Functional separation of risk assessment and risk management
- Structured process
- Basis in science
- Dealing with uncertainty and variability
- Peer review

Risk assessment methodology

- Basic components of a risk assessment
- Qualitative or quantitative?
- Risk assessment for chemical hazards
- Risk assessment for biological hazards
- Biotechnology risk assessment
- Sensitivity analysis
- Validation
- Establishment of "targets" in the food chain as regulatory standards

Integrating risk assessment and economic assessment

Module 3B - Risk Management (continued)

Preliminary risk management activities (continued)

Step 7: Consider the results of the risk assessment
Step 8: Rank food safety issues and set priorities for risk management

Selection of risk management options

Step 1: Identify available management options
Step 2: Evaluate the identified management options
Step 3: Select a risk management option(s)

Implementation of the risk management decision

Monitoring and review

Module 5 - Risk Communication

Introduction

Understanding risk communication

Key communication elements of food safety risk analysis

- Identifying a food safety issue

- Developing a risk profile
- Establishing risk management goals
- Developing a risk assessment policy
- Commissioning a risk assessment
- During the conduct of a risk assessment
- When the risk assessment is completed
- Ranking risks and setting priorities
- Identifying and selecting risk management options
- Implementation
- Monitoring and review

Some practical aspects of risk communication

- Goals of communication
- Communication strategies
- Identifying "stakeholders"
- Methods and media for communication

Module 6 - Benchmark and conclusions

Working group exercise: gap analysis, strengths and weaknesses of Indian risk analysis approach

Groups to characterize further India's risk analysis process on food.

Issues to consider:

- How transparent is the system?
- How timely/responsive is the system?
- Does the system have regard to international standards?
- Are standards mandatory or voluntary?
- Strengths and weaknesses of food safety control systems?
- Driving forces in setting the pace?

Summary of Risk Analysis

- Final wrap up

The steps of Risk Management

- Take home lessons

Resources and links

Follow up? Follow up!

Appendix 3: SWOT Analysis & Three things to change

Codex Alimentarius: Risk Analysis and Risk Assessment Procedures

NIN, Hyderabad, AP – 27.11 - 1.12.2006

Consolidated result of a working group exercise:

SWOT Analysis & Three things to change

Strengths

1. Availability of large expertise and man power
2. Broad variety of optional or alternate food stuffs (India is not dependent on few staple foods)
3. New *Food Safety and Standards Act* as one integral act for management supported by stakeholders such as BIS, Agmark, FPO, etc
4. Increased recent participation in CODEX and WHO, WTO etc
5. A well organized food control system exists
6. Subcommittee of CCFS has the representative from various relevant fields (vertical integration)
7. Increasing consumer awareness to food safety, food issues

Weaknesses

1. Different eating habits region to region – challenge to the system by the complex food supply
2. Approach towards hygiene and cleanliness in food handling, at most stages of the food chain
3. Socio – political factors influence
4. Lack of indigenous studies and data
5. Inadequate monitoring and surveillance systems for contaminants
6. Inadequate food borne disease surveillance
7. Food producing sector is to a large extent not organized

Opportunities

Knowledge of interaction (English language!)

By over coming our weaknesses, we will be able to

- Provide safe food with in the country
- To be a reliable exporter of food products

Threats

Change of the environment for food production and distribution due to globalization

If Indian situation is not improved i,e. measures re not implemented,

- India may become a dumping ground for unsafe food
- Affect the image of the country, and lead to decline in exports

The first three things you would like to change

1. High dependence on international data.
2. Advance Training for the up gradation of skills of researchers (RA)
3. Advance Training for the up gradation of skills of Administrators and Regulators (RM)
4. Regular Monitoring and Surveillance system for contaminants
5. Establishing a system for Food borne disease surveillance
6. Improvement of necessary infrastructure for analysis of contaminants