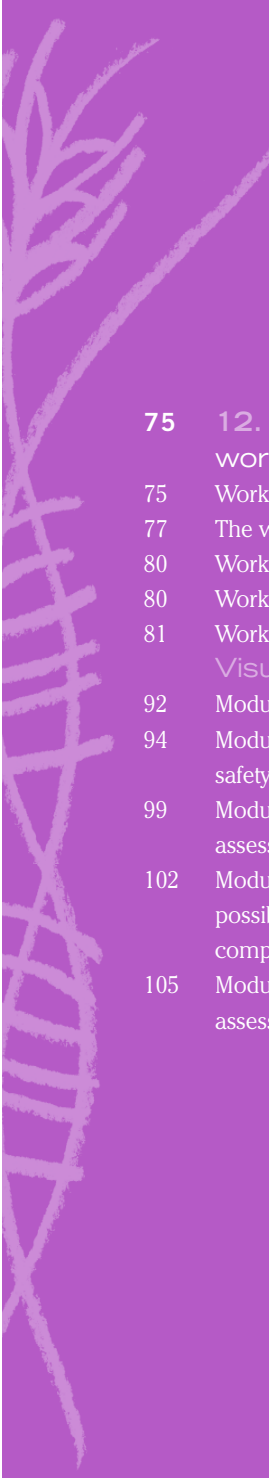


Part Two
Tools
and Techniques
for trainers





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12. Preparing and delivering a workshop

Workshop preparation

The success of a workshop typically reflects the effort that went into its preparation. Below are some of the key activities that workshop organizers may wish to consider during the preparatory period.

1. Confirm that the required financial resources will be provided and accessible when required. Obtain the necessary institutional and administrative support to manage the workshop, including realistic budgeting and cost-control measures to avoid corruption and written agreements on auditing and cost-control measures.
2. Identify the goal(s) of the workshop. These may take the form of a statement of purpose or objectives, an agenda and/or a discussion paper that sets out key issues, and references or resources with which the participants may wish to familiarize themselves in preparation for the workshop. The goals of the workshop may include:
 - Introduction of participants to the concepts and principles used to frame the pre-market safety assessment of foods derived from recombinant-DNA plants.
 - Introduction of participants to types of information and data that they may be tasked with evaluating as safety assessors, using case studies of products approved for human consumption in a number of countries.
 - Emphasizing the multidisciplinary nature of the safety assessment of foods derived from recombinant-DNA plants using practical, hands-on exercises designed to simulate the team effort required.
3. Determine how many people can be accommodated at the trainers' workshop. The number of people invited will partly determine the process that is most appropriate for the stated purpose. Safety assessment workshops are most successful when they are iterative and the

Form 12.1. Terms of reference for participant selection

Checklist for desired profile

- Experience as a regulator or scientist active in agricultural biotechnology or a discipline relevant to the safety assessment of GM foods. Examples include molecular biology, plant breeding, biochemistry, immunology, toxicology, and human or livestock nutrition.
- Experience working in a multidisciplinary environment with people of different nationalities, ethnicity and cultural backgrounds.
- Familiarity with use of computers, on-line information communication and information retrieval.
- Experience of both public and private sector research and development.
- Publication record in both the scientific literature and more general interest press.
- Communication and presentation skills, particularly to different audiences.
- Advanced university degree in biological/agricultural sciences or an equivalent combination of education and experience.
- Excellent spoken/written [language]

participants are given group activities or exercises to carry out, rather than being passive recipients of information through a more typical seminar or lecture format. To maximize the effectiveness of such training it is suggested that the number of participants should be limited to approximately 20.

4. Participant selection is key to the success of a GM food safety assessment workshop and therefore it is very important to identify carefully those best to invite with reference to the workshop objectives. It may be possible to invite individual regulators/scientists to the workshop directly, but often, because of protocol considerations, letters of invitation must be sent to a director or senior administrator of a specific institution inviting them to select one or more delegates to participate in the workshop. In order to assist this person in selecting the appropriate participant(s), it is helpful to provide terms of reference that clearly describe the education and professional expertise that is required. A template for this is provided in Form 12.1.
5. Determine the appropriate way to invite participants to the workshop, whether in writing or by telephone, directly or via someone more senior in their organization. This will probably be determined by such factors as:
 - a. decisions the workshop organizers make regarding the focus of the workshop;
 - b. the organizational level from which the organizers wish to attract participants;
 - c. the relationship the organizers may or may not have established already with potential participants;
 - d. the extent to which invitees themselves are in a position to decide whether or not to attend.
6. Allow sufficient time between receipt of an invitation and the actual event to avoid conflicts with other previously scheduled commitments. Time is also required to make appropriate travel arrangements, including applications for entry visas, which for some countries can take several months.
7. Provide any relevant background material for review in advance. This might include:
 - Codex Principles for the Risk Analysis of Foods Derived from Modern Biotechnology (Appendix 1);
 - Codex Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants (Appendix 2);
 - selected case studies;
 - key references, especially those pertinent to the country/region in which the workshop is being given.
8. Identify a suitable location and venue for the workshop. If participants must travel to the location, the venue should be in close proximity to adequate lodging. Other issues to consider when selecting a venue are listed below.
 - a. If small-group work is an important part of the agenda, the venue should have sufficient separate rooms.
 - b. The group-work rooms should all have flip-chart stands, paper and markers to facilitate the small-group work/discussions.
 - c. The plenary room must have the necessary “hardware” to accommodate the presenters. Typically this includes an LCD-type projector or overhead projector and a large screen.
 - d. Depending on the size of the group, microphones for speakers and mobile “floor microphones” may be necessary to allow participants to ask questions and hear answers.
 - e. Ideally, the seating arrangement in the plenary room should have all participants sitting around smaller tables for interaction during and after presentations. This is particularly important if break-out rooms are not available and small-group work must take place in the plenary room.

The following is a sample checklist that organizers may wish to use and/or adapt as they prepare for a workshop.

Form 12.2. Workshop preparation checklist

- Identify appropriate funding sources for the workshop and prepare written agreements on the objectives, size and structure of the workshop. All financial and administrative matters must be clarified in writing, including how the financial resources will be managed.
- Ensure that proper auditing will be performed and specify exactly what type of expenses will be covered by the workshop budget. Most often, a full-time position is required to take care of all practical matters starting at least 2 months prior to the workshop.
- Conduct pre-workshop meetings during which you will:
 - identify key collaborators and their contributions (host institute, sponsors, etc.);
 - identify facilitator(s);
 - generate a list of potential participants;
 - select a date for conducting the workshop;
 - decide on a list of potential speakers for each session for which a speaker is required.
- Estimate workshop costs and cost-sharing across partners if appropriate.
- Send invitations at least three weeks before the event for national workshops. For international workshops, 2 months' notice is the absolute minimum. If the travel costs will be covered by the organizers, clear and written instructions of the fare class, maximum costs and cost documentation must be provided.
- Identify and reserve a workshop location that (ideally) has:
 - a plenary room large enough for the number of participants;
 - break-out rooms, or a room large enough for small groups to work in the same room without disturbing each other;
 - on-site accommodation.
- Make arrangements with a food and beverage supplier for lunch and breaks. Take into account food needs/preferences for international workshops in which cultural and religious considerations may specify food choices.
- Finalize the agenda and confirm presenters, and clarify in writing their financial support (travel, accommodation, honorarium, etc.).
- Hold a training meeting for small-group facilitators 1 week prior to the workshop if small-group sessions are to be included.
- Collect necessary equipment and materials prior to the workshop:
 - notebooks and pens for participants;
 - pads of flip-chart paper and markers;
 - name tags;
 - copies of all handouts to be distributed.
- Obtain overhead and LCD projectors, including spare equipment, and ensure the availability of technical assistance prior to and during the workshop.

The workshop facilitator

A workshop facilitator acts as a guide for the entire workshop and as such should have excellent organizational and leadership skills. In the case of GM food safety assessment training workshops, the workshop organizer is often required to take on the role of facilitator as well. The following are some practical tips for facilitating workshops.

- Participants appreciate a meeting that starts and ends on time. Ensure that sufficient time is allotted for registration at the beginning of the workshop so that this activity can be completed before the workshop opens. Similarly, participant assessment or evaluation forms should be provided before the close of the workshop and enough time provided so that the attendees can complete these and hand them in before the workshop ends.
- Ensure that there is a registration table to assist participants as they arrive. Provide a sign-in sheet that lists name, organization, region of work and contact information for each person. Distribute name tags.
- Ensure that a list of participants is compiled and distributed by the end of the workshop. Consider asking participants to verify the accuracy of the information before they leave.
- Keep presenters and participants informed of the point they are at on the agenda. If the

Form 12.3. Sample agenda for 3-day workshop

GM Food Safety Assessment Workshop Agenda

Venue _____

Date _____

Day 1

8.00	Registration	
9.00	Opening, welcome	
Workshop Introduction		
9.15	Presentation 1: Workshop overview	Presentation Module 1
9.30	Introduction of the participants and trainers	
Part I: Concept of GM Food Safety Assessment and International Perspectives		
9.45	Presentation 2: Concepts and principles of GM food safety assessment, key international initiatives	Presentation Module 2 Ch. 2
10.30	<i>Coffee break</i>	
11.00	Introduction of three case studies <ul style="list-style-type: none"> • GM insect-resistant corn event MON 810 • GM high oleic acid soybeans • GM herbicide tolerant soybean 	
12.00	Assigning working groups	
12.30	<i>Lunch</i>	
Part II: Approach and Framework, Identification of Required Information		
13.30	Presentation 3: The comparative approach and the framework for the safety assessment of GM foods	Presentation Module 3 Ch. 3–4
14.30	Working Group Session 1: Using case studies, identify the description and review the sufficiency of the information on: <ul style="list-style-type: none"> • description of the recombinant-DNA plant • description of the host plant and its use as food • description of the donor organism(s) • description of the genetic modification(s) 	
15.30	<i>Coffee break</i>	
16.00	Plenary Session 1: Report back and discussion for WG Session 1	
17.30	Summary and Conclusions of Day 1	

(Continued)

Form 12.3. (cont.)

Day 2

Part III: Possible Toxicity & Allergenicity and Compositional Analysis		
9.00	Presentation 4: Characterization of the genetic modification(s), assessment of possible toxicity & allergenicity, and compositional analysis of key components	Presentation Module 4 Ch. 5–8
10.00	Working Group Session 2: Using case studies, evaluate possible toxicity	
10.30	<i>Coffee break</i>	
11.00	Working Group Session 2, cont.	
12.00	<i>Lunch</i>	
13.00	Plenary Session 2: Report back and discussion for WG Session 3	
14.00	Working Group Session 3: Using case studies, evaluate possible allergenicity	
15.30	<i>Coffee break</i>	
16.00	Plenary Session 3: Report back and discussion for WG Session 4	
17.30	Summary and Conclusions of Day 2	

Day 3

9.00	Working Group Session 4: Using case studies, identify and evaluate the compositional analysis	
10.30	<i>Coffee break</i>	
11.00	Plenary Session 4: Report back and discussion for WG Session 5 and overall WG sessions	
12.30	<i>Lunch</i>	
Part IV: Risk Communication		
13.30	Presentation 5: Risk communication and safety assessment decisions	Presentation Module 5 Ch. 10
14.30	Working Group Session 5: Using case studies: <ul style="list-style-type: none"> • strategize the meaning of risk communication • prepare a decision document for the general public 	
15.30	<i>Coffee break</i>	
16.00	Plenary Session 5: Report back and discussion for WG Session 6	
17.30	<ul style="list-style-type: none"> • Workshop evaluation • Handing out certificates • Concluding comments • Closing workshop 	



workshop takes place over two or more days, announce the daily programme at the start of each day.

- Ensure that all presentation materials are available and ready to be used. In the case of PowerPoint or similar presentations, ensure that these are loaded and saved on a computer before the start of each day's presentations.
- Provide an overview of a particular segment of a workshop before asking participants to begin their small-group or workbook work.
- Move from group to group to get the flavour of discussions and to help clarify any questions participants may have. Depending on the number of workshop participants, it may be helpful also to involve others as small-group facilitators.
- Keep an eye on the clock and give participants advance notice of when they need to complete a segment of their work.
- Ensure that there is enough time allocated to discussion. Participants may often learn more from each other than from the lecturers!

The facilitator does not need to have all the answers; however, participants will look to the facilitator for guidance in exploring a question in order to arrive at an appropriate response. Facilitators must be prepared in advance for this. There should be a moderator for each session to facilitate and guide the discussion.

Workshop agenda

Creating an effective agenda is an important element of a productive workshop. The agenda communicates information regarding:

- topics of discussion;
- the presenter for each topic;
- the time allotted to each topic;
- the focus of the meeting.

Presentations and break-out sessions should be based on the safety assessment processes, including:

- description of the recombinant-DNA plant;
- description of the host plant and its use as food;
- description of the donor organisms(s);
- characterization of the genetic modification(s);
- safety assessment:
 - expressed substances (non-nucleic acid substances)
 - compositional analysis of key components
 - evaluation of metabolites
 - food processing
 - nutritional modification
 - other considerations.

A sample agenda is provided in the Form 12.3. Organizers may wish to use and/or adapt as they prepare for a workshop.

Workshop evaluation and certificates

Evaluation

It is important to get feedback on participants' experiences during the workshop and their plans for using the information. A workshop evaluation form should be distributed before the close of the workshop. A sample evaluation form is provided in the Form 12.4. Organizers may wish to use and/or adopt as they prepare for a workshop.

Box 12.1. Creating an effective agenda

1. Develop an agenda for your workshop that involves:
 - 20 participants with different levels of expertise;
 - lectures presenting the safety assessment principles and criteria based on the Codex Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants;
 - group activities/exercises providing hands-on experience in the food safety assessment of these products using case studies.
2. Select appropriate case studies for your workshop.
 - Suitable for training?
 - Select a clear, simple example;
 - Feasible for the time frame of the workshop?
 - at least 15 minutes are needed for explanation of the case study at the beginning of the workshop
 - a break-out group discussion session usually takes at least 1 hour
 - a report-back session also takes at least 1 hour.

Box 12.2. Developing a workshop evaluation

1. Write down your key objectives for your workshop.
2. Establish measures (ratings, response options, open-ended questions) to assess whether the objectives have been achieved.
3. Develop questions using 1 and 2, noting the following:
 - an appropriate number of questions is 5 to 10;
 - always provide a space for comments;
 - consider providing 15 minutes to fill out and 5 minutes to collect the forms.

TIP: In order to ensure that everyone fills out an evaluation, organizers may consider awarding certificates of participation for workshop attendees. Participants receive their certificate once they have completed and handed in their evaluation form. It is important that the evaluation is done prior to the end of the programme.

Certificates

Certificates can be used as a positive reinforcement to certify that the trainee completed the workshop and to encourage active participation in the workshop.

The one-page certificate should contain brief information about the organizer (not FAO), date and duration of the course, location, course topics and the full name of the participant. The certificate should note that the person attended the training course and be signed and stamped as appropriate.

Workshop presentations

Visual aids

Visual aids should be clear, simple and necessary to the presentation. It is important to refer to slides/transparencies during the course of the presentation; the audience should be guided through the key points on each visual aid. Transparencies or slides that do not serve a legitimate purpose should be discarded. The use of too many visual aids may detract from the talk by distracting the audience from the presenter.

Training modules

The sample presentations may be useful for organizers/facilitators/trainers when preparing for a workshop (pages 86–102). A CD-ROM provides the modules in electronic format together with other relevant reference materials ●

Form 12.4. Sample Workshop Evaluation Form

Workshop Evaluation Form

Workshop name _____

Venue _____

Date _____

Your cooperation in completing this questionnaire is greatly appreciated. The information you provide will be useful in planning future events and will help the organizers and presenters to improve their materials and presentations.

Overall rating

In general, how would you rate this course?

- Excellent
- Good
- Average
- Fair
- Poor

Workshop objectives

The objectives of this workshop are listed below. Please indicate, on a scale of 1 to 5, if you believe these objectives have been achieved. A rating of 1 means the objective has not been achieved and 5 means the objective has been achieved fully.

Objective 1: [Type the objective here]

- 1 2 3 4 5

Objective 2: [Type the objective here]

- 1 2 3 4 5

Objective 3: [Type the objective here]

- 1 2 3 4 5

Form 12.4. (cont.)

Topics

In this section we would like you to rate the content, usefulness, supporting aids (e.g. slides, handouts, etc.) and time management of each presentation. When rating content, you should consider such factors as the rigor of the material (theory, soundness and methodology). With regard to usefulness, rate the topic in terms of its applicability/relevance to the workshop objectives. Factors to consider in assessing presentation include clarity, logical structure, good use of visual aids, etc. Please place a check in the box that most accurately represents your opinion of these factors.

	<i>Content</i>					<i>Usefulness</i>					<i>Presentation</i>					<i>Time management</i>					
	<i>Excellent</i>	<i>Good</i>	<i>Average</i>	<i>Fair</i>	<i>Poor</i>	<i>Excellent</i>	<i>Good</i>	<i>Average</i>	<i>Fair</i>	<i>Poor</i>	<i>Excellent</i>	<i>Good</i>	<i>Average</i>	<i>Fair</i>	<i>Poor</i>	<i>Excellent</i>	<i>Good</i>	<i>Average</i>	<i>Fair</i>	<i>Poor</i>	
Day 1																					
Presentation 1 (type title)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Presentation 2 (type title)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Presentation 3 (type title)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Activity 1 (type title)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Activity 2 (type title)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<hr/>																					
	<i>Content</i>					<i>Usefulness</i>					<i>Presentation</i>					<i>Time management</i>					
	<i>Excellent</i>	<i>Good</i>	<i>Average</i>	<i>Fair</i>	<i>Poor</i>	<i>Excellent</i>	<i>Good</i>	<i>Average</i>	<i>Fair</i>	<i>Poor</i>	<i>Excellent</i>	<i>Good</i>	<i>Average</i>	<i>Fair</i>	<i>Poor</i>	<i>Excellent</i>	<i>Good</i>	<i>Average</i>	<i>Fair</i>	<i>Poor</i>	
Day 2																					
Presentation 1 (type title)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Presentation 2 (type title)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Presentation 3 (type title)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Activity 1 (type title)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Activity 2 (type title)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

Form 12.4. (cont.)

Strengths and weaknesses

Please list what you consider to be three main strengths of the course.

1.

2.

3.

Please list what you consider to be three main weaknesses of the course.

1.

2.

3.

Form 12.4. (cont.)

Additional topics

What additional topics should have been included in this course?
 - and what topics should be excluded to allow this?

Logistical arrangements

Pre-meeting support	<input type="checkbox"/> Excellent	<input type="checkbox"/> Good	<input type="checkbox"/> Average	<input type="checkbox"/> Fair	<input type="checkbox"/> Poor
Accommodation	<input type="checkbox"/> Excellent	<input type="checkbox"/> Good	<input type="checkbox"/> Average	<input type="checkbox"/> Fair	<input type="checkbox"/> Poor
Meals	<input type="checkbox"/> Excellent	<input type="checkbox"/> Good	<input type="checkbox"/> Average	<input type="checkbox"/> Fair	<input type="checkbox"/> Poor
Organization and management	<input type="checkbox"/> Excellent	<input type="checkbox"/> Good	<input type="checkbox"/> Average	<input type="checkbox"/> Fair	<input type="checkbox"/> Poor

Other comments

Please write down any additional comments or suggestions you may have.



Visual aids

Module 1

Workshop overview

GM food safety assessment

Presentation module 1

Workshop overview

Food and Agriculture
Organization
of the United Nations



GM food safety assessment



Workshop objectives

- **Assist in implementing internationally accepted principles and guidelines**
- Share many **countries' experiences of regulation and safety assessment methods**



Module 1 / slide 2

GM food safety assessment



Scope of the workshop

Train experts (training of trainers) to deliver workshops to

- **improve the capability of regulatory authorities**
- **to assess, manage and communicate** the potential risks associated with foods derived from recombinant-DNA plants

Module 1 / slide 3

GM food safety assessment



Presentations

- Concepts and principles of safety assessment
- Approach and frameworks of safety assessment
- Assessment of possible toxicity, possible allergenicity, and compositional analysis
- Risk communication and public policy issues

Module 1 / slide 4

GM food safety assessment



Working group sessions

- Break-out sessions with case studies will give participants hands-on exercises on preparing and conducting training workshops
- Case studies include:
 - MON 810 corn
 - GTS 40-3-2 soybeans
 - High oleic acid soybeans



Module 1 / slide 5

GM food safety assessment



Expected outcomes

Workshop provides:


- an overview of the international perspectives on safety assessment of foods derived from r-DNA plants (Codex and FAO/WHO)
- theoretical and practical experience in safety assessment methodology
- practical information on organizing and delivering training workshops

Properly trained regulators can:

- enhance the safety of foods, thereby not only improving the health of consumers but also ensuring the safety of foods entering international trade

Module 1 / slide 6

Visual aids Module 1 (cont.)

GM food safety assessment 

Agenda: day 1 morning

9.15 **Presentation 1.** Workshop overview

9.30 Introduction of the participants and trainers

9.45 **Presentation 2.** Concepts and principles of GM Food safety assessment, key international initiatives (Codex, FAO/WHO, OECD, etc.)

10.30 *Coffee break*


11.00 Introduction of three case studies

- GM Insect Resistant Corn Event MON 810
- High Oleic Acid Soybeans
- GM Herbicide Tolerant Soybeans

12.00 Assigning working groups

12.30 *Lunch*

Module 1 / slide 7

GM food safety assessment 

Agenda: day 1 afternoon

13.30 **Presentation 3.** The comparative approach and the framework for the safety assessment of GM foods

14.30 **Working group session 1.** Using case studies, identify the description and review the sufficiency of the information on:


- description of the recombinant-DNA plant
- description of the host plant and its use as food
- description of the donor organism(s)
- description of the genetic modification(s)

15.30 *Coffee break*

16.00 **Plenary session 1.** Report back and discussion for WG Session 1

17.30 Summary and Conclusions of Day 1

Module 1 / slide 8

GM food safety assessment 

Agenda: day 2

9.00 **Presentation 4.** Characterization of the genetic modification(s), assessment of possible toxicity & allergenicity, and compositional analysis of key components

10.00 **Working group session 2.** Evaluate possible toxicity

12.00 *Lunch*

13.00 **Plenary session 2.** Report back


14.00 **Working group session 3.** Possible allergenicity

15.30 *Coffee break*

16.00 **Plenary session 3.** Report back

17.30 Summary and Conclusions of Day 2

Module 1 / slide 9

GM food safety assessment 

Agenda: day 3

9.00 **Working group session 4.** The compositional analysis

10.30 *Coffee break*

11.00 **Plenary session 4.** Report back

12.30 *Lunch*

13.30 **Presentation 5.** Risk communication

14.30 **Working group session 5.** Using case studies: strategize the meaning of risk communication; prepare a decision document for the general public

15.30 *Coffee break*

16.00 **Plenary session 5.** Report back

17.30 Workshop evaluation, certificates, concluding comments, workshop close

Module 1 / slide 10

Visual aids

Module 2

Concepts and principles of GM food safety assessment

GM food safety assessment

Presentation module 2

Concepts and principles of GM food safety assessment

Food and Agriculture Organization of the United Nations



GM food safety assessment

Presentation objectives

- Introduce the definitions, concepts and principles currently applied for the safety assessment of GM foods
- Introduce internationally agreed texts, guidelines and recommendations required for the safety assessment procedure

Module 2 / slide 2

GM food safety assessment

Definition: modern biotechnology

- The application of:
 - *in vitro* nucleic acid techniques, including r-DNA and direct injection of nucleic acid into cells or organelles,
- or
- fusion of cells beyond the taxonomic family, to overcome natural physiological reproductive or recombinant barriers and using techniques not used in traditional breeding and selection

(Cartegena Protocol on Biosafety)

Module 2 / slide 3

GM food safety assessment

Modern biotechnology

- Broadens the scope of genetic changes
 - Should not result in foods that are less safe than those produced by conventional techniques (OECD, 1993)
- ↓
- A new or different standard of safety is not required
 - Previously established principles for assessing food safety still apply

Module 2 / slide 4

GM food safety assessment

International efforts

- Concerted efforts made internationally
- Key international consultations addressing the safety assessment of GM foods:
 - FAO/WHO
 - IFBC
 - ILSI
 - OECD
 - CAC
 - etc.
- The criteria used to assess the safety of GM foods are generally consistent from one country to another (World Bank, 2003)
- Countries may differ in statutory and non-statutory approaches to regulating GM foods

Module 2 / slide 5


GM food safety assessment

Key considerations

- International discussions between OECD countries, and within the United Nations FAO/WHO expert consultations, have resulted in a consensus on the specific safety issues that should be considered when evaluating a novel food

Module 2 / slide 6

Visual aids Module 2 (cont.)


GM food safety assessment 

General principles

- The following are used internationally in safety assessment of r-DNA foods:
 - conventional foods are generally considered to be safe, if provided prepared and handled
 - novel foods, including r-DNA foods, are required to undergo mandatory pre-market safety assessment in some jurisdictions (e.g. Japan, Canada, Australia and New Zealand, UK, EU)
 - an explicitly cautious approach is applied to foods, such as r-DNA foods, with no history of safe use

(cont.)

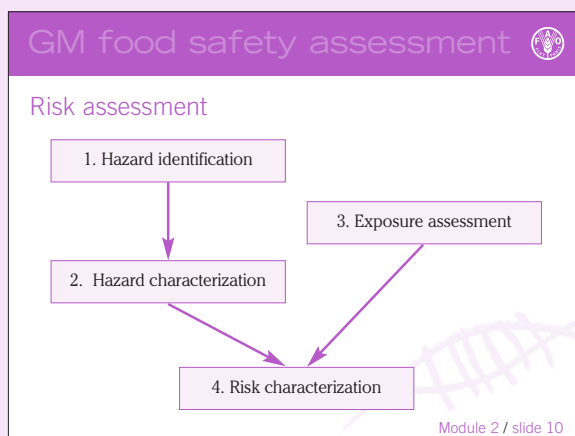
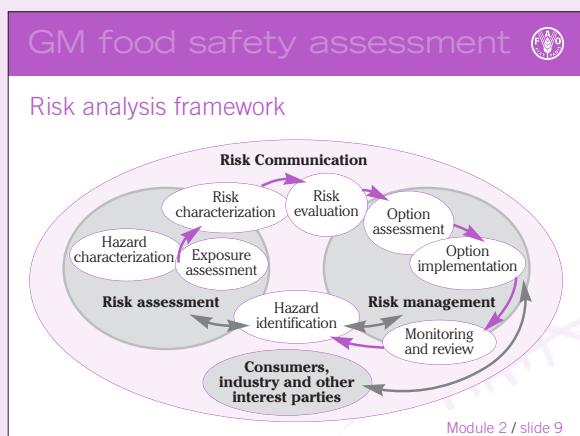
Module 2 / slide 7


GM food safety assessment 

General principles (cont.)

- Safety assessments of r-DNA foods are undertaken according to key principles:
 - Safety assessments use scientific, risk-based methods.
 - Safety assessments are conducted on a case-by-case basis.
 - Both intended and unintended effects of genetic modification are considered.
 - Where appropriate, comparisons are made with conventionally produced foods.
- Decisions with respect to safety are based on the totality of the evidence

Module 2 / slide 8




GM food safety assessment 

1. Safety assessments use scientific, risk-based methods

- Risk assessment** is the process of determining as accurately as possible the actual likelihood and consequences of the risks presented by exposure to identified hazards
- The objective is to **identify the potential for adverse effects** that r-DNA foods may pose for human health
- Use a modified **hazard identification scheme** referred to as a safety assessment to identify whether a hazard is present in the whole food

Module 2 / slide 11

GM food safety assessment 

2. Safety assessments conducted on a case-by-case basis

- Applied to a food commodity, for the food and food products derived from that modified commodity e.g. corn (kernels, corn flour, corn syrup, oil); canola (oil); cotton (oil and linters)
- Foods derived from a commodity (e.g. soybeans) that have been modified with different traits are assessed separately
- Any subsequent use of modern biotechnology requires a separate safety assessment

Module 2 / slide 12

Visual aids

Module 2 (cont.)

GM food safety assessment

3. Consideration is given to both intended and unintended effects

Safety considerations apply to all aspects of the r-DNA food. Conducted in two phases:

1. Identification of similarities and differences

- traditional vs novel sources of donor DNA/genes
- molecular characterization – new genes, proteins, genetic stability
- compositional analysis

(cont.)

Module 2 / slide 13

GM food safety assessment

3. Consideration is given to both intended and unintended effects (cont.)

2. Identified differences are subjected to further scrutiny

- toxicity/allergenicity of any new protein
- safety of any transferred antibiotic resistance genes
- safety, nutritional impact and pattern of any compositional changes

Module 2 / slide 14

GM food safety assessment

4. Comparisons are made with conventionally produced foods

- r-DNA food variety compared with conventional counterpart food with history of safe use
- Comparison used to identify differences in levels of naturally occurring allergens, toxins, nutrients and antinutrients, or the ability to promote typical growth or well-being
- Significant differences (r-DNA vs conventional) assessed for biological significance and potential adverse health effects

Module 2 / slide 15

GM food safety assessment

Safety considerations

1. Description of the host organism that has been modified, including information on nutrient composition, known antinutrients, toxicants and allergenic potential, and any significant changes in these that may result from normal processing.
2. A description of the donor organism, including any known associated toxicity and allergenicity, and the introduced gene(s).
3. Molecular characterization of the genetic modification, including a description of the modification process and the stability of the introduced trait.

(cont.)

Module 2 / slide 16

GM food safety assessment

Safety considerations (cont.)

4. Identification of the gene products, including a description of the characteristics of the inserted gene.
5. Evaluation of the safety of expected new substances in the food, including an evaluation of any toxins produced directly by the modification.
6. Assessment of the new food's potential allergenicity.

(cont.)

Module 2 / slide 17

GM food safety assessment

Safety considerations (cont.)

7. Evaluation of the unintended effects on food composition, including:
 - a) assessment of the changes in the concentration of nutrients or naturally occurring toxicants
 - b) identification of antinutrient compounds that are significantly altered in novel foods
 - c) evaluation of the safety of compounds that show a significantly altered concentration.

Module 2 / slide 18

Visual aids Module 2 (cont.)


GM food safety assessment 

Key initiatives:
to identify and address future needs

OECD task force for safety of novel foods and feeds

- consensus documents that provide guidance on critical parameters (e.g. key nutrients) of food safety and nutrition for each food crop
- documents for those products that have already been approved, as well as for commodities that are likely to be approved in the future
- http://www.oecd.org/document/63/0,2340,en_2649_34391_1905919_1_1_1_1,00.html

Module 2 / slide 19


GM food safety assessment 

Key initiatives:
to identify and address future needs

Codex ad hoc intergovernmental task force on foods derived from biotechnology

- general principles for the risk analysis of foods derived from recombinant DNA plants
- guideline for the conduct of safety assessment of foods derived from recombinant DNA plants and microorganisms
- and more...
- http://www.fao.org/ag/agn/agns/biotechnology_codex_en.asp

Module 2 / slide 20


GM food safety assessment 

Codex guideline

Codex guideline for foods derived from recombinant DNA plants

- The safety assessment of a food derived from a recombinant-DNA plant follows a stepwise process of addressing relevant factors including:
 - description of the r-DNA plant
 - description of host plant and its use as food
 - description of donor organism(s)
 - description of the genetic modification(s)
 - characterization of the genetic modification(s) *(cont.)*


Module 2 / slide 21

GM food safety assessment 

Codex guideline *(cont.)*

- Safety assessment
 - expressed substances (non-nucleic acid substances): assessment of potential toxicity and assessment of possible allergenicity (proteins)
 - compositional analyses of key components
 - evaluation of metabolites
 - food processing
 - nutritional modification
 - other considerations (e.g. marker genes)

Module 2 / slide 22

GM food safety assessment 

Key initiatives:
to identify and address future needs

FAO/WHO expert consultations

- Safety aspects of genetically modified foods of plant origin (June 2000)
- Allergenicity of genetically modified foods (January 2001)
- Safety assessment of foods derived from genetically modified microorganisms (September 2001)
- Safety of food derived from transgenic fish (November 2003)

(cont.)

Module 2 / slide 23

GM food safety assessment 

Key initiatives:
to identify and address future needs *(cont.)*

- Safety of food derived from biotechnology
- FAO capacity building project to assist countries in implementing international standards related to the risk analysis of products derived from biotechnology
- http://www.fao.org/ag/agn/agns/biotechnology_en.asp

Module 2 / slide 24

Visual aids

Module 2 (cont.)

GM food safety assessment

Conclusions

- Concepts and principles developed by OECD, FAO/WHO and Codex have been practically applied by countries assessing the safety of foods derived from modern biotechnology
- Internationally conducted evaluations of r-DNA plant products have demonstrated that the concepts can be applied effectively in the safety assessment and approval of foods derived from modern biotechnology

(cont.)

Module 2 / slide 25

GM food safety assessment

Conclusions (cont.)

- The approach to the safety assessment of foods derived from modern biotechnology is continually evaluated, elaborated and expanded upon in international fora
- Participating countries contribute to the process and adopt updated approaches into their respective regulatory systems

Module 2 / slide 26

Visual aids

Module 3

The approach and framework for safety assessment of GM foods

GM food safety assessment

Presentation module 3

The approach and framework for the GM food safety assessment




Food and Agriculture Organization of the United Nations

GM food safety assessment

Presentation objective

- Introduce the concept of “comparative approach” and the reasons why the approach is used for safety assessment of GM foods
- Introduce the concept of “substantial equivalence (SE)”, examples of tests using SE, issues regarding SE application, and background to adaptation of the concept
- Introduce Codex framework
- Explain stepwise approach and specific data requirements



Module 3 / slide 2

GM food safety assessment

Comparative approach

- Based on **the principle**: the products can be compared with conventional foods
- **Objective**: to determine if the GM food presents any new/altered hazard in comparison with its conventional counterpart
- **Goal**: not to establish an absolute level of safety, but rather the relative safety of the new products and that there is a reasonable certainty that no harm will result from the intended uses

Module 3 / slide 3

GM food safety assessment

Focuses


- Safety assessment is based on a comparison of an r-DNA organism to a counterpart or control with a history of safe use
- The focus of the comparison is to determine similarities and differences

Module 3 / slide 4

GM food safety assessment

Key concept

- If a new or altered hazard, or nutritional or other safety concern (noting that not every hazard is new, as many are present in the existing food) is identified, the risk should be characterized for its relevance to human and livestock health



Module 3 / slide 5

GM food safety assessment

Familiarity and determination

- **Familiarity** is defined as knowledge of the characteristics of a species and experience with the use of that species
- The **determination** is based on scientific literature and practical experience with the organism and similar varieties/lines

Module 3 / slide 6

Visual aids

Module 3 (cont.)

GM food safety assessment

Identifying unintended effects

- New products with intentionally altered nutritional profiles challenge the ability to assess unintended consequences
- Examples:
 - GM low-glutelin rice (decrease in glutelin levels was associated with an unintended increase in levels of prolamins)
 - GM Golden Rice (intentionally increased levels of beta-carotene, but unexpectedly found the modification accompanied by higher levels of xanthophylls)

Module 3 / slide 7

GM food safety assessment

Substantial equivalence

- First described in an OECD publication in 1993
- 60 experts, 19 countries, more than 2 years discussing how to assess the safety of GM foods
- Substantial equivalence was further endorsed by FAO/WHO joint expert consultation in 1996
- The concept of familiarity was the progenitor of the concept of “substantial equivalence”, an approach developed by some jurisdictions as part of the risk assessment process

Module 3 / slide 8

GM food safety assessment

Key concept

- Substantial equivalence is one of many tools in the regulatory process for making decisions about particular characteristics of an r-DNA organism compared with its unmodified counterpart (e.g. a parent or host or donor)
- The concept should be used as a starting point to determine the safety of the differences found in the thorough analysis of an r-DNA organism, and not as a final decision step



Module 3 / slide 9

GM food safety assessment

Subject of debate

The appropriate use of the concept of substantial equivalence has been the subject of much debate by many expert bodies

- OECD, FAO/WHO, Codex
- Institute of Food Technology, 2000
- NZ Royal Commission on Genetic Modification, 2001
- Canadian Royal Society Report, 2001
- US NAS, 2002
- UK Royal Society, 2002
- Society of Toxicology Position Paper, 2002
- American College of Nutrition, 2002
- UK Government Report, 2003

Module 3 / slide 10

GM food safety assessment

Adoption of the concept

- The **OECD** and some other international organizations recognize it as a valid concept that “contributes to a robust safety assessment framework”
- The **Codex Task Force** continues to work with the concept of substantial equivalence in safety and nutritional assessment and to speculate about alternative strategies
- The **Codex Guideline** includes reference to substantial equivalence (paragraph 13) as a key step in the safety assessment process, not a safety assessment in itself

Module 3 / slide 11


GM food safety assessment

Limitations of substantial equivalence

- Requires sufficient analytical data to be available in the literature, or be generated through analysis
- Dependence on a comparator and on the information that is available, or can be generated for the comparator
- The choice of comparator is crucial to effective application of the concept
- An appropriate comparator must have a well-documented history of use

Module 3 / slide 12


Visual aids Module 3 (cont.)

GM food safety assessment 

Remarks on the comparative approach

- **Whole food vs individual substances** (additives, pesticides, etc.)
 - safety assessments require different approaches
 - whole foods from many crops sometimes contain natural toxicants, antinutrients – may be important to the plant but may be harmful to humans
- **Codex Guideline** recommends that a **comparative assessment** be used to determine the safety of GM food (as safe as conventional counterpart)
 - paragraphs 13–17


Module 3 / slide 13

GM food safety assessment 

Codex framework

- “Principles for the risk analysis of foods derived from modern biotechnology” (2003)
- “Guideline for conduct of food safety assessment of foods derived from recombinant-DNA plants” (2003)


Module 3 / slide 14

GM food safety assessment 

Stepwise approach

- Guideline **paragraphs 18–21**
- **Goal:** to examine the intentional and unintentional consequences of the specific modification on food components, in comparison with a counterpart food that has a history of safe use


Module 3 / slide 15

GM food safety assessment 

Specific data requirements


- Description of the recombinant-DNA plant (paragraph 22)
- Description of the host plant and its use as food (paragraphs 23–25)
- Description of the donor organism(s) (paragraph 26)
- Description of the Genetic Modification(s) (paragraphs 27–29)

Module 3 / slide 16

GM food safety assessment 

Working group assignment

- Using case studies, **identify** the following:
 - description of the recombinant-DNA plant
 - description of the host plant and its use as food
 - description of the donor organism(s)
 - description of the genetic modification(s)
- Then **review** the sufficiency of information for the above items



Module 3 / slide 17

Visual aids

Module 4


Characterization of GM, assessment of possible toxicity, possible allergenicity and compositional analysis

GM food safety assessment

Presentation module 4


Characterization of GM, assessment of possible toxicity & allergenicity and compositional analysis

Food and Agriculture Organization of the United Nations 


GM food safety assessment 

Presentation objectives

- Explain the methodology of characterization of the genetic modification(s)
- Introduce methodology of toxicity assessment including animal studies
- Introduce methodology of potential allergenicity assessment including important parameters
- Introduce methodologies of compositional analysis, evaluation of metabolites, food processing and nutritional modification




Module 4 / slide 2

GM food safety assessment 

Characterization of the Genetic Modification(s)

- Codex Guideline paragraphs 30-33
 - Molecular analysis
 - Randomly generated plant transformation events
 - Transgene detection using event-specific primers
 - Extent of refinement at the current level of the technology


Module 4 / slide 3

GM food safety assessment 

Toxicity

- Codex Guideline paragraphs 34-40
- Key considerations:
 - protein expression product(s) of the inserted gene(s)
 - effects resulting from disruption of gene expression due to insertion of donor DNA into the host genome
- Intention to determine safety: as safe as the conventional counterpart
 - e.g. conventional soybean has the potential to affect endocrine functions – GM soybean with an equivalent composition would have the same potential


Module 4 / slide 4

GM food safety assessment 

In vitro studies

- Novel proteins (as opposed to other chemicals)
 - predictable metabolic fate in the human/animal gut
 - *in vitro* digestibility assay – indicates the likelihood of a protein having characteristics unusual for dietary proteins
- If a protein is shown to be resistant to typical digestive fluid: significant for proteins with potentially adverse biological activities (toxicity or allergenicity)
- Proteins that exhibit toxicity generally exert their effect in a short time frame – acute toxicity tests are considered adequate

Module 4 / slide 5


GM food safety assessment 

Animal studies

- Major element of the safety assessment of many compounds: pesticides, pharmaceuticals, chemicals, food additives, etc.
- Substance: known purity, no nutritional value
- Codex Guideline paragraphs 10–12 and 53
- Difficulties: foods are complex mixtures of compounds in composition and nutritional value – identifying potential adverse effects in animal studies without appropriate control treatments is extremely difficult

Module 4 / slide 6

Visual aids Module 4 (cont.)


GM food safety assessment 

Allergenicity (proteins)

- Codex Guideline paragraphs 41–43
- True food allergies may involve several types of immunological responses
- Most common types: allergen-specific immunoglobulin E (IgE) antibodies

(cont.)


Module 4 / slide 7

GM food safety assessment 

Allergenicity (proteins) (cont.)

- True food allergies may also include cell-mediated reactions
- Codex has adopted a list of the most common allergenic foods associated with IgE-mediated reactions
- GM food crops can introduce potential allergenicity into the human diet
- Codex recommends that an integrated, stepwise, case-by-case approach be used in the assessment of possible allergenicity of GM food


Module 4 / slide 8

GM food safety assessment 

Assessment strategy

- 1st step – the determination of:
 - the source of the introduced protein
 - any significant similarity between the amino acid sequence of the protein and that of known allergens
 - its structural properties
- No single test can predict the likely human IgE response to oral exposure
- Isolation of any newly expressed proteins from the r-DNA plant in order to characterize the protein
- Important to establish whether the source is known to cause allergic reactions


Module 4 / slide 9

GM food safety assessment 

Important parameters

- Source of the protein
- Amino acid sequence homology
- Pepsin resistance
- Specific serum screening

Module 4 / slide 10


GM food safety assessment 

Remarks on toxicity and allergenicity assessment

- **Quality assurance**
 - It is very important that the organizational process and the conditions under which lab studies are planned, performed, monitored, recorded & reported are according to the principles of GLP
 - Toxicology studies: it is important to establish the relationship of changes in physiological parameters measured to the dose levels of the tested compound

(cont.)

Module 4 / slide 11

GM food safety assessment 

Remarks on toxicity and allergenicity assessment (cont.)

- **Other methods & tools**
 - As scientific knowledge and technology evolve, other methods and tools may be considered in assessing the allergenicity potential of newly expressed proteins

Module 4 / slide 12

Visual aids

Module 4 (cont.)

GM food safety assessment

Compositional analysis

- Both beneficial and harmful components in the human diet:
 - nutrients
 - bioactive non-nutrients
 - antinutrients
 - toxicants
 - contaminants
 - other potentially useful and dangerous elements
- It is important to decide which nutrients/elements to focus the evaluation on
- Codex Guideline paragraphs 44–46

Module 4 / slide 13

GM food safety assessment

Food processing

- Codex Guideline paragraph 47
- Processing methods can cause a significant variation in the nutrient content of a food
- Modern separation techniques (milling, centrifugation, pressing, etc.) change the nutritional content
- Heating techniques may reduce the content of many heat-labile nutrients (vitamins, phytochemicals, etc.)

Module 4 / slide 14

GM food safety assessment

Nutritional modification

- Codex Guideline paragraphs 48-53
- For r-DNA plants that were intentionally developed to have altered nutrients, the aim of the nutritional evaluation is to demonstrate that there are no unintentional changes (bioavailability etc.)
- The compositional differences are likely to be greater – thus current methods for safety assessment may be found limiting, due to that nutritionally modified crops will not be substantially equivalent to their conventional counterparts, and share fewer compositional values for comparison

Module 4 / slide 15

GM food safety assessment

New analytical methods

- Further improvement of methodologies and more sensitive techniques allow detection of unintended alterations in the composition that were once undetectable
- The utility and applicability of the non-targeted techniques for risk assessment need further exploration in validating the relevance to food safety of observed changes
- Profiling methods are not yet suitable for risk assessment purposes, but if validated they may be useful to confirm and supplement other data

Module 4 / slide 16

GM food safety assessment

Working group assignments

- Using case studies:
 - **identify** the toxicity studies, and **evaluate** the possible toxicity
 - **identify** the allergenicity studies, and then **evaluate** the possible allergenicity
 - **identify** the description of compositional analysis, and then **evaluate** the analysis



Module 4 / slide 17

Visual aids

Module 5

Risk communication and safety assessment decisions

GM food safety assessment

Presentation module 5

Risk communication and safety assessment decisions



Food and Agriculture Organization of the United Nations

GM food safety assessment

Presentation objectives

- Introduce risk communication in the context of risk analysis (Codex)
- Explain what risk communication should and should not be
- Explain the patterns of risk perception and trust
- Introduce a food safety-related communication strategy
- Introduce FAO/WHO expert consultation recommendations



Module 5 / slide 2

GM food safety assessment

Risk communication in the context of risk analysis

- Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius (2003): general orientation on risk analysis
- Communication linked to the risk analysis process
- Embedded in risk assessment and risk management
- Active at the start of the risk analysis process – not an add-on at the end
- Everyone's responsibility

Module 5 / slide 3

GM food safety assessment

Working principles: general aspects

- **Risk analysis process:**
 - applied consistently
 - open, transparent and documented
 - **the three components of risk analysis to be documented fully and systematically in a transparent manner**
 - **effective communication and consultation with interested parties throughout risk analysis**
- **Structured approach:**
 - Risk assessment, risk management and risk communication, each of the three components being integral to the overall process and applied in an overarching framework

Module 5 / slide 4

GM food safety assessment

Codex definition of risk communication

- The interactive exchange of information and opinions throughout the risk analysis process concerning risk, risk-related factors and risk perceptions, among risk assessors, risk managers, consumers, industry, the academic community and other interested parties, including the explanation of risk assessment findings and the basis of risk management decisions

Module 5 / slide 5

GM food safety assessment

Risk communication should:

- promote awareness and understanding of the specific issues under consideration
- promote consistency and transparency in formulating risk management options and recommendations
- provide a sound basis for understanding the risk management decisions proposed
- improve the overall effectiveness and efficiency of the risk analysis

(cont.)

Module 5 / slide 6

Visual aids

Module 5 (cont.)

GM food safety assessment

Risk communication should *(cont.)*:

- strengthen the working relationships among participants
- foster public understanding of the process, so as to enhance trust and confidence in the safety of the food supply
- promote the appropriate involvement of all interested parties
- exchange information in relation to the concerns of interested parties about the risks associated with food

Module 5 / slide 7

GM food safety assessment

Risk communication involves...

- a two-way process
- understanding people's perception of risk
- opportunities for public involvement in decision making
- timely and accurate information
- internal communication

Module 5 / slide 8

GM food safety assessment

Risk communication is not...

- just about communicating risk
- simply selling decisions to the public
- a crisis-related process
- the sole responsibility of communication specialists

Module 5 / slide 9

GM food safety assessment

Major function of risk communication

- To ensure that all information and opinion required for effective risk management is incorporated into the decision-making process
- Should include a transparent explanation of:
 - the risk assessment policy
 - the assessment of risk
 - including the uncertainty

Module 5 / slide 10

GM food safety assessment

As an important part of biosafety procedure

- To ensure public acceptance of food derived from recombinant-DNA plants
 - communicate and interact with the public about the specific risks and actions taken
 - a mechanism that builds confidence among the stakeholders in a gradual manner moving along with the different phases of the development of the r-DNA plant and foods derived from it

Module 5 / slide 11

GM food safety assessment

Two components of risk communication

- **technical components**, which generally concern the scientific hazards evaluated in the **risk assessment** and **management options** arising out of the assessment
- **non-technical components**, which include the **administrative** protocols, and the **cultural** and **ethical** issues in the society dealt with by the regulatory agencies during the process of risk analysis

Module 5 / slide 12

Visual aids

Module 5 (cont.)

GM food safety assessment

Regulatory risk communication

- Codex principles paragraphs 22–24
 - explain both how and why decisions are taken
 - acknowledge any concerns raised by stakeholders
 - explain how these concerns have been addressed
- A number of countries have adopted OECD measures for information dissemination
 - inviting public comments on safety evaluation reports
 - disclosure of data used in safety assessments
 - publication of results of meetings of safety assessment bodies

Module 5 / slide 13

GM food safety assessment

Risk communication as a two-way process

- Regulatory risk communication
 - providing information about the regulatory framework and processes
 - gathering input and feedback
- Credibility is built into the communication process by providing technical reviews on the process in simple language
- Two questions that need to be answered - raise the issue of choice and knowing what foods from r-DNA plants may be in the marketplace:
 - are foods from r-DNA plants safe?
 - what foods have been genetically modified?

Module 5 / slide 14

GM food safety assessment

Perception of risk

- We all see the world differently (mindsets)
- People of similar backgrounds tend to perceive risk in a similar way
- Some gender differences
- People with less control over their lives tend to see greater risk
- Evidence-based perception of risk: **RISK=HAZARD**
- Consumer perception of risk: **RISK=HAZARD+OUTRAGE**

Module 5 / slide 15

GM food safety assessment

Consumers' perceptions of levels of risk

- Media coverage can often be alarmist
- Stakeholders concerned about balancing health messages with potential risks
- Applies to many contaminants in food issues
- The acceptable level of risk differs between countries and communities

Module 5 / slide 16

GM food safety assessment

Trust

- Public confidence in the safety of the food supply
- Trust in industry and government regulators to ensure safe food
- Hard to regain trust once it is lost
- Not a level playing field
- Negative events are more noticeable than positive events
- Sources of bad news are seen as more credible
- The media is attracted to bad news
- Special interest groups are skilful in using the media

Module 5 / slide 17

GM food safety assessment

Information release

- Early release is the key
 - story will leak anyway – loss of trust/credibility
 - people entitled to information affecting lives
 - sets pace for resolution of issue
 - better control of accuracy of information
 - less work to release than respond to inquiries
 - less chance of public becoming angry
 - less chance public will over-estimate risk
 - more time for public involvement

(Adopted from New Jersey Department of Environmental Protection, 1987)

Module 5 / slide 18

Visual aids

Module 5 (cont.)

GM food safety assessment

Communication strategy

Risk	Perceived risk	Examples	Strategy
Low	Low	Allowed level of contaminants	Passive
Low	High	GM foods , dioxins, mercury in fish	Responsive
High	Low	Microbial contamination	Educative
High	High	BSE	Proactive

(cont.)

Module 5 / slide 19

GM food safety assessment

Communication strategy (cont.)

- Identify audiences – segment stakeholder groups (don't forget internal audiences)
- Prepare messages – normally three key messages and separate messages to each audience
- Select communication tools

Module 5 / slide 20

GM food safety assessment

Media

- Press, radio and television
- Establish working relationships and credibility in non-crisis times
- Know what messages you want to convey
- Be open and honest... and available
- Be helpful
- Understand how the media works

Module 5 / slide 21

GM food safety assessment

FAO/WHO: useful considerations in risk communication

- Know the audience
- Involve the scientific experts
- Establish expertise in communication
- Be a credible source of information
- Share responsibility
- Differentiate between science and value judgement
- Assure transparency

Module 5 / slide 22

GM food safety assessment

Risk communication in safety assessment

- Creation of better information about the regulatory system
- Creation of a centralized information body
- Increase public awareness and engagement

Module 5 / slide 23

GM food safety assessment

Working group assignments

Using case studies:

- **strategize** the methods of risk communication
 - involving all the stakeholders?
 - having a good relationship with the media?
 - building credibility?
- **prepare** a decision document for the general public



Module 5 / slide 24