

# 1. Introduction

## Scope of the training package

This package was developed in this context to present a framework for the safety assessment of foods derived from recombinant-DNA plants, based on internationally accepted principles and guidance. Additionally, it introduces other issues related to the topic and provides links to useful resources. Practical information about organizing and delivering a training workshop is also included.

Several international documents are being prepared on safety assessment of genetically modified (GM) foods other than those derived from recombinant-DNA plants, and additional training materials will also be developed by FAO. This particular training package does not address the safety assessment of foods derived from other recombinant organisms (such as microorganisms and animals) or livestock feeds derived from recombinant-DNA plants, nor does it consider the ethical and socio-economic issues, and environmental risks, that may be associated with the release of recombinant-DNA plants.

## Objectives

In order to support capacity building in food safety assessment, FAO, in collaboration with many international, intergovernmental and governmental bodies, has supported the development of a standardized training programme to assist countries in implementing international documents related to the risk analysis of products containing or derived from genetically modified organisms. Specifically, the training package should be used for implementation of programmes that:

- promote a harmonized international regulatory approach to countries that have requested such guidance, to ensure consistency and uniformity in the application of international standards;
- provide regulators in the beneficiary countries with information on internationally accepted approaches to the evaluation of foods derived from recombinant-DNA plants;
- endorse a transparent, science-based approach to the safe introduction and use of foods derived from recombinant-DNA plants.

## Target audience and trainer qualifications

The target audience includes national food safety regulators, authorities, and/or scientists tasked with training others to undertake the safety assessment of foods derived from recombinant-DNA plants. While developed mainly for government agencies in developing countries, this tool may also be of use to agencies in developed countries, as well as to donor organizations and agencies supporting capacity building activities in food safety.

Expected qualifications for the trainer include a Ph.D. degree in natural sciences or an equivalent combination of education and experience, and extensive experience as a regulator or as a senior scientist active in a scientific area relevant to the safety assessment of GM foods. Examples of relevant areas include: molecular biology, plant breeding, biochemistry,

immunology, toxicology, and human or livestock health and nutrition. Experience with working in a multidisciplinary environment with people of different nationalities, ethnic and cultural backgrounds would be an asset. Proficiency in using computers, on-line communication and information retrieval is expected. The trainer is also expected to have in-depth knowledge of both public and private sector research and development, and to have excellent language, communication and presentation skills, particularly to different audiences. A publication record in the scientific literature or in dossier evaluation is required. Trainers should be selected on their personal capacities in a transparent manner. For international training courses attention should be paid to geographical and gender balance.

## Contents of the training package

The package is composed of three parts with a CD-ROM containing the visual aids and other relevant reference materials. The first part, *Principles of safety assessment of foods derived from recombinant-DNA plants*, provides guidance text for the implementation of an effective framework for safety assessment of foods derived from recombinant-DNA plants. The second part, *Tools and techniques for trainers*, offers a practical guide for preparing and delivering a workshop on the topic of safety assessment of foods derived from recombinant-DNA plants. This section includes various checklists and forms, a sample workshop agenda, sample workshop evaluation sheet, and five useful presentation modules for trainers. All forms, presentations and copies of the relevant Codex Alimentarius documents are included in the CD-ROM in electronic format. The third part, *Case studies*, presents three safety assessment dossiers that have been summarized for training purposes<sup>3</sup>. All three case studies have been developed based on the data and information submitted for the food safety assessment regulatory evaluation conducted by Governmental agencies such as Health Canada, the United States Food and Drug Administration, and Food Standards Australia New Zealand. The case studies are in-kind contributions that have been provided by Agbios, Inc., Ottawa, Canada, and the Canadian Government, represented by Health Canada<sup>4</sup>.

## Expected outcomes

Upon completion of training administered using this training tool as a guide, the audience will be able to plan and deliver GM food safety assessment training for national food safety authorities, regulators, and/or scientists in their own training programmes ●

<sup>3</sup> In order to enhance the utility of the case studies for training purposes, certain information has been summarized and the data presented in the case studies are only a subset of those actually submitted. The case studies do not reflect a complete application, nor a complete safety assessment.

<sup>4</sup> These case studies are included in this training package without any modification or enhancement by FAO. The views expressed in the case studies do not necessarily reflect the views of FAO.