LEVEL, ON HEALTH AND AGRICULTURE

Mexico City, D.F., Mexico, 21–22 April 2005

Provisional Agenda Item 8

RIMSA14/INF/3 (Eng.) 12 April 2005 ORIGINAL: ENGLISH

CURRENT STATUS OF GENETICALLY MODIFIED FOODS

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SUMMARY

- 1. One of the new developments in food production has been the introduction of methods for development of new traits through the use of biotechnology. Based in this technology over the latest ten years genetically modified (GM) plants have been introduced in a number of countries all over the world. GM strains of maize, soybeans, rape and cotton have been marketed internationally in several areas. In addition, GM varieties of papaya, potato, rice, squash, sugar beet and tomato have been released. It is estimated that GM crops cover almost 4% of total global arable land.
- 2. The development of GM organisms (GMOs) offers the potential of increased agricultural productivity or improved nutritional values that can contribute directly to enhancing human health and development. The use of GMOs may also involve potential risks for human health and development. To provide international consistency in the assessment of GM foods, Codex Principles1 now present an international framework for the health risk assessment of GM foods. GM foods currently available on the international market have passed risk assessments and are not likely to, nor have been shown to, present risks for human health.
- 3. In the future the assessment of human health and environmental risk needs to be supplemented with evaluations of benefit; socioeconomic factors ethical aspects. International harmonization in all these areas is a prerequisite for the prudent, safe and sustainable development of the potential of any new technology, including the use of biotechnology to produce food.

INTRODUCTION

- 4. Food safety is an important part of public health linking health to agriculture and other food production sectors. Developments in food production and control have contributed to food safety systems in most developed countries perceived by many to be efficient in the prevention of disease and other problems related to food production. This perception has come under serious attack in recent years.
- 5. Whereas human health issues related to food have not been the focus of attention in most parts of the world up through the seventies and eighties, this picture has changed dramatically over the most recent decade. Some credit the heightened attention to food safety issues to a number of public scares related to food that seems to have shaken the confidence of consumers in our food safety efforts, at least in some parts of the world. While the influence of media-focus on scares should not be underestimated, several other developments in this area are likely to have had an even more important influence in the new public and political attention to this area.

¹ Codex Alimentarius Commission. *Principles for the risk analysis of foods derived from modern biotechnology*. FAO/WHO, Rome, 2003.

- 6. One of the new developments has been the introduction of biotechnology in food production. By the use of this technology over the latest ten years genetically modified (GM) plants have been introduced in a number of countries all over the world. This introduction has been met with different attitudes and different public perception in different parts of the world. In spite of these seeming differences the regulatory evaluation of GM foods has actually been comparable in most parts of the world, thus enabling international agreement on Codex Principles for the Risk Analysis of foods derived from biotechnology.
- 7. Conflicting assessments and incomplete substantiation of the benefits, risks and limitations of GM food have added to existing controversies. During a famine situation in southern Africa in 2002, the reluctance among several recipient countries to receive GM food aid was not primarily linked to health or environment issues, but to socioeconomic, ownership and ethical issues. Such controversies have not only highlighted the wide range of opinions within and between Member States, but also the existing diversity in regulatory frameworks and principles for assessing the benefits and risks of GM food. In addition many developing countries cannot afford to build the separate capacities required for effective regulation of GM foods, which again underlines the benefits that could be derived from international work for broader evaluations of GM food applications.
- 8. In many countries, social and ethical considerations may cause resistance to modifications which interfere with genes. These conflicts often reflect deeper issues related to the interaction of human society with nature, issues that should taken seriously in any communication effort. Problems of assuring equal access to genetic resources, sharing benefits on a global level, and avoiding monopolization exist for GM food as for other uses of gene technology.
- 9. Several international Organizations, including WHO, are now looking into the possibilities of expanding the evaluation of the potential introduction of GM foods to a broader area of important consequences. This new trend acknowledges the need for risk assessment relative to human health and the environment before introduction of GM plants, as has been performed in the past, but also suggests the addition of evaluation of benefits, socio-economic concerns, intellectual property rights and ethical considerations.

BACKGROUND - THE NEW RISK ANALYSIS FRAMEWORK

10. Whereas considerations related to human health risk have of course always guided safety assessment, it is also characteristic that a number of issues related to the management of food safety has often in the past focused primarily on the hazard in the food and therefore not extended to direct risk considerations. Evolution in a number of food safety areas through the nineties resulted in more focus on actual risk to human health, not only presence of hazard in the food. This was one of the reasons for the development of the Risk analysis concept in food safety.

- 11. Risk can be defined as 'a function of the probability of an adverse effect and the magnitude of that effect, consequential to a hazard(s) in food' (FAO/WHO, 1995).
- 12. Risk analysis comprises Risk assessment, Risk management and Risk communication (FAO/WHO, 1995). The Risk analysis process is typically initiated by governmental authorities, and although important parts of the process can be developed in international co-operative frameworks the full Risk analysis is at present primarily a national initiative.
- 13. The initiating part of Risk analysis is typically Risk management. In Codex terminology Risk management is the process of weighing policy alternatives in the light of the results of risk assessment and, if required, selecting and implementing appropriate control options, including regulatory measures (FAO/WHO, 1996). Risk Communication is the exchange of information and opinions concerning risk and risk-related factors among risk assessors, risk managers, consumers and other interested parties (FAO/WHO, 1999). Risk Assessment provides a scientific description of foodborne risks related to the occurrence of hazards in the food chain (FAO/WHO, 1995).
- 14. While the development of risk analysis principles in relation to food safety stems back from Codex discussions as early as 1991, some other key developments have influenced this area. The new international trade agreements: World Trade Organisation (WTO) puts emphasis on scientifically based risk assessment and the WTO SPS agreement (Article 2, paragraph 2) establishes that sanitary measures should be based on scientific principles and should not be maintained without sufficient scientific evidence.
- 15. The FAO/WHO risk analysis framework and principles are in the process of being implemented in different national and international settings. The Joint FAO/WHO Food Standards Programme is the basis for the Codex Alimentarius Commission (Codex), and food safety standards, guidelines and recommendations established by Codex are generally recognised as the basis for harmonisation of sanitary measures.
- 16. The new Risk analysis framework will enable all interested parties or stakeholders in food safety, including producers and consumers, to be more actively involved in the management and communication process. Therefore the assessment and management parts of risk analysis are sometimes presented as floating in a sea of risk communication, which thus provides the basis for interaction between all the players, including consumers, producers and other stakeholders (Figure 1).

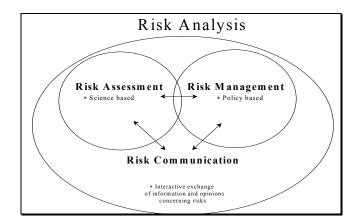


Figure 1. The WHO/FAO Risk analysis framework

17. Risk perception seems to converge a combination of scientific and cultural perspectives. Such sociological perspectives suggest that risks from technological developments have become important concerns in the social consciousness. A recognition is emerging of the need to include social dimensions of the debate over new technologies in the continued development of the risk analysis framework (Lomax, 2000).

CURRENT SITUATION - THE USE OF GENETICALLY MODIFIED PLANTS

- 18. Biotechnology is likely to have enormous potential to address a broad range of food-related problems, from food security and nutrition to food safety, and many of these issues are directly related to crop-protection strategies. On the other hand, biotechnology has created a large public concern with regard to its potential effects on human health and the environment, as well as on the right of consumers to choose what they eat.
- 19. The genetically modified (GM) crops which are presently on the international market mainly aim towards an increased level of crop protection by introducing resistance against insects, viruses or herbicides.
- 20. The insect resistant GM-crops currently are modified in such a way that they produce the toxin of the bacterium Bacillus thuringensis (Bt) which has been confirmed safe for human beings but toxic to certain insects. Crops that permanently produce Bt toxin have been shown to require less use of additional insecticides in specific situations, such as in areas with a high level of pest pressure. In some situations potential environmental risks, such as the detrimental effect on beneficial insects or a faster induction of resistant insects have been identified and monitoring strategies for the control of these risks are under development.
- 21. Virus resistance is typically achieved through incorporation of a gene coding for a virus protein, conveying to the crop resistance to the specific virus. For some constructs the probability that the viral constructs used in the crops could interact with wild type

viruses and result in new plant pathogens is a potential risk that needs further investigation. Improved mechanisms for virus resistance such as the enhancement of natural resistance mechanisms are under development.

- 22. Herbicide tolerant crops enable a more targeted approach to weed control. Under certain agro-ecological situations such as a high weed pressure the use of herbicide tolerant crops has resulted in a reduction in quantity of the herbicides used. In other local situations the potential detrimental consequences for plant bio-diversity, wild life and a decreased use of the important practice of crop rotation could represent potential drawbacks and need further investigation.
- 23. At present, only a few food crops are permitted for food use and traded on the international food- and feed-markets. These include herbicide- and insect-resistant maize (BT maize), herbicide-resistant soybeans, rape (canola) oilseed and insect- and herbicide-resistant cotton (primarily a fibre crop, though refined cottonseed oil is used as food). In addition, several government authorities have approved varieties of papaya, potato, rice, squash, sugar beet and tomato for food use and environmental release. The latter crops however are currently grown and traded only in a limited number of countries, mainly for domestic production. The regulatory status of GM crops varies among the countries that permit their use and updates can be found on various web sites, including those of the Organisation for Economic Co-operation and Development (OECD, 2005) and the International Centre for Genetic Engineering and Biotechnology (ICGEB, 2005).
- 24. In 2003, the estimated global area of commercially grown transgenic or GM crops was 67.7 million hectares or 167 million acres, grown by 7 million farmers in 18 developed and developing countries. Six main countries grew 97% of the global transgenic crop area in 2004 (see Table 1).

Country	2001		2002		2003		2004	
United States of America	35.7	68%	39.0	66%	42.8	63%	47.6	59%
Argentina	11.8	23%	13.5	23%	13.9	21%	16.2	20%
Canada	3.2	7%	3.5	6%	4.4	6%	5.4	6%
Brazil	-	-	-	-	3.0	4%	5.0	6%
China	1.5	1%	2.1	4%	2.8	4%	3.7	5%
South Africa	0.2	0.5%	0.3	1%	0.4	1%	0.5	1%
Total (world)	52.6	100%	58.7	100%	68.1	99%	78.4	97%

Table 1. Global GM crop area^a

Source: (James, 2004).

FUTURE TRENDS IN GM CROPS

- 25. The commercial introduction of transgenic crop plants with agronomic traits is often referred to as the first generation of transgenic plants. Further development of GM crops with agronomic traits is continuing, and production of a range of GM crops with enhanced nutritional profiles is also under way (Pew Initiative, 2001). Various novel traits are currently being tested in laboratories and field-tests in a number of countries. Many of these second generation GM crops are still in the development stage and are unlikely to enter the market for several years. Some key areas of research and development in plants are outlined below.
- 26. Pest- and disease-resistance. In the next 3–5 years, most newly commercialized GM crops will continue to concentrate on agronomic traits, especially herbicide-resistance (HR) and insect-resistance (IR) and, indirectly, yield potential (Pew Initiative, 2001).
- 27. Virus-resistance. Virus-resistance could be extremely important to improving agricultural productivity (Thompson, 2003). Field tests of the following virus-resistant crops are currently being conducted in various parts of the world: sweet potato (feathery mottle virus); maize (maize streak virus); African cassava (mosaic virus). These crops may be available for commercialization within the next 3–5 years.
- 28. Vitamin A rice. The best-known example of a GM crop conferring enhanced nutritional properties is rice containing a high level of beta-carotene a vitamin A precursor (so-called "golden rice") (Potrykus, 2000). Vitamin A is essential for increasing

^a Million hectares and percentage of global area, by country.

resistance to disease, protecting against visual impairment and blindness, and improving the chances of growth and development. Vitamin A deficiency is a public health problem that contributes to severe illness and childhood mortality and increases the burden of disease on the health systems of developing countries (WHO, 2003).

- 29. "High iron" rice. Prevalence of iron deficiency is very high in those parts of the world in which rice is the daily food staple (FAO, 2004). This is because rice has a very low iron content. GM rice seeds with the iron-carrier protein ferritin from soy were found to contain twice as much iron as seeds of non-transformed rice (Gura, 1999).
- 30. Removing allergens and antinutrients. Cassava roots naturally contain high levels of cyanide. As they are a staple food in tropical Africa, this has led to high blood-cyanide levels which cause harmful effects. Application of modern biotechnology to decrease the levels of this toxic chemical in cassava would reduce its preparation time.
- 31. Altered starch and fatty acid profile. In the quest to provide healthier foods, there is an effort to increase the starch content of potatoes so that they absorb less fat during frying (Pew Initiative, 2001). To create healthier fats, the fatty acid composition of soy and canola has been altered to produce oils with reduced saturated fats. Research and development is currently focusing on GM soybean, oilseed rape and oil palm (Pew Initiative, 2001).
- 32. Increased antioxidant content. The lycopene and lutein content of tomatoes have been increased as have isoflavones in soy (Pew Initiative, 2001). These phytonutrients are known to improve health or prevent disease. Research in this area is at a relatively early stage of development, as knowledge of phytonutrients is limited and not all phytonutrients are beneficial.

ASSESSMENT OF THE IMPACT OF GM FOODS ON HUMAN HEALTH

- 33. The Codex Alimentarius Commission adopted the following texts in July 2003: Principles for the risk analysis of foods derived from modern biotechnology; Guideline for the conduct of food safety assessment of foods derived from recombinant-DNA plants; and Guideline for the conduct of food safety assessment of foods produced using recombinant-DNA microorganisms. The two latter texts are based on the Principles and describe a methodology for conducting safety assessments for foods derived from recombinant-DNA plants and microorganisms, respectively (Codex, 2004).
- 34. The premise of the Principles dictates a premarket assessment, performed on a case-by-case basis and including an evaluation of both direct effects (from the inserted gene) and unintended effects (that may arise as a consequence of insertion of the new gene). The Codex safety assessment principles for GM foods require investigation of:

- (a) direct health effects (toxicity);
- (b) tendency to provoke allergic reactions (allergenicity);
- (c) specific components thought to have nutritional or toxic properties;
- (d) the stability of the inserted gene;
- (e) nutritional effects associated with the specific genetic modification; and
- (f) any unintended effects which could result from the gene insertion.
- 35. Codex principles do not have a binding effect on national legislation, but are referred to specifically in the Agreement on the Application of Sanitary and Phytosanitary Measures of the World Trade Organization (SPS Agreement), and often used as a reference in case of trade disputes.
- 36. The difficulties of testing whole foods, as opposed to the targeted chemical analyses approach have resulted in the development of alternative approaches for the safety assessment of GM foods. A series of FAO/WHO expert consultations held in 2000, 2001 and 2003 recognized that animal studies can be of help but that there are practical difficulties in obtaining meaningful information from conventional toxicology testing especially with whole-food studies in laboratory animals (where the appropriate diet for the animals needs to be assured). The consultations also noted that very little is known about the potential long-term effects of any foods. There is at present no conclusive information available on the possible health effects of modifications which would significantly change the nutritional characteristics of any food, such as nutritionally enhanced foods (FAO/WHO, 2000; FAO/WHO, 2001a; FAO/WHO, 2001b; FAO/WHO, 2003).
- 37. Unintended effects such as elevated levels of antinutritional or toxic constituents in food have been characterized in conventional breeding methods e.g. glycoalkaloid levels in potatoes. It has been argued that random insertion of genes in GMOs may cause genetic and phenotypic instabilities (Ho, 2001), but as yet no clear scientific evidence for such effects is available. In fact a better understanding of the impact of natural transposable elements on the eukaryotic genome may shed some light on the random insertion of sequences. To enhance and improve the identification and analyses of unintended effects, profiling methods have been suggested. It still remains to be seen which of these techniques (once validated) would be useful for routine risk assessment purposes.
- 38. Natural genetic transformation has been found to occur in different environments, e.g. in food (Kharazmi et al., 2003). This has led to the discovery that food-ingested DNA is not necessarily completely degraded by digestion, and that small fragments of DNA from GM foods can be found in different parts of the gastrointestinal tract (Van den Eede, 2004). FAO/WHO expert panels have discussed the potential risks of horizontal gene transfer from GM foods to mammalian cells or gut bacteria. These panels have suggested that it may be prudent in a food safety assessment to assume that DNA fragments survive in the human gastrointestinal tract and can be absorbed by either the gut microflora or somatic cells lining the intestinal tract. The FAO/WHO expert panels concluded that

horizontal gene transfer is a rare event that cannot be completely discounted, and that the consequences of such transfer should be considered in a safety assessment (FAO/WHO 2001b).

39. Allergic reactions to traditional foods are well known. The major food allergens are proteins in and derived from eggs, fish, milk, peanuts, shellfish, including crustacea and molluscs, soy, tree nuts (e.g. almonds, Brazil nuts, cashews, hazelnuts/filberts, macadamia nuts, pecans, pine nuts, pistachios and walnuts) and wheat. Whereas the groups of main allergens are well known and advanced testing methods have been elaborated, traditionally-developed foods are not generally tested for allergenicity before market introduction. The application of modern biotechnology to crops has the potential to make food less safe if the newly added protein proves to cause an allergic reaction once in the food supply. An FAO/WHO expert panel (FAO/WHO 2001a) has established protocols for evaluating the allergenicity of GM foods on the basis of the weight of evidence.

PERCEPTION AND COMMUNICATION IN A RISK ANALYSIS FRAMEWORK

- 40. Studies on conventional foods show that in many regions of the world, people have specific attitudes to food. Food is a part of cultural identity and societal life, and also has some religious features. Food is derived from nature, and consumers therefore often assume that food is safe. In many countries, people's interaction with nature, often correlated with religious perspectives, causes social and ethical resistance to modifications that interfere with genes. Investigations of public perception in areas of the world with relatively high resistance against GM foods indicate that lack of information is not the primary reason (Marris et al., 2001). The public is not for or against GMOs per se, people discuss arguments both for and against GMOs, and are aware of contradictions within these arguments. Also, people do not demand zero risk. They are quite aware that their lives are full of risks that need to be balanced against each other and against the potential benefits. People may also discriminate in their perception of different technologies where a general positive perception can be observed for applications with a clear benefit for society, e.g. for modern medicines.
- 41. The opposition to GM crops and foods seems to have as much to do with social and political values as with concerns about health and safety. GMOs are emblematic of the powerful economic fears that globalization inspires. In certain regions, hostility to GMOs is symbolic of a broader opposition to the encroachment of market forces. These are perceived to be creating a world in which money rules with little consideration for historical traditions, cultural identities and social needs (Gaskell et al, 1999).

SOCIOECONOMIC AND ETHICAL CONCERNS

42. Socioeconomic consequences arising from the adoption of GMOs in agriculture require an analysis of consequences for specific groups and interests in society. It has been claimed that there are benefits for large-scale farming as opposed to small-scale farming,

as a result of better adoption of practices associated with GMOs by large-scale farmers, as well as an ability to deal with intellectual property rights. Social scientists often discuss the importance of a shift from rural areas with labour-intensive working places, to areas with high-tech industry. Such shifts could also potentially take place as a result of the introduction of GMOs. An example here could be whether the economies of tropical oil-producing countries could be affected if GM alternatives to palm and coconut oils are engineered and production then moved to other countries.

43. The risks of biotechnology, the problems of interfering with nature, evolution and creation, and ethical considerations are of increasing importance in the civil society debate on the development and introduction of GMOs. Ethical committees are more frequently established and consulted to provide answers to issues beyond the scope of scientific committees. International agreements related to nature and food production are summarized in a report by FAO on ethical issues in food and agriculture (FAO, 2001).

CONCLUSIONS

- 44. To provide international consistency in the assessment of GM foods, Codex Principles now present an international framework for the health risk assessment of GM foods. This framework was developed and agreed between 170 Member States within a very short timeframe of four years. The framework can help ensure that future GM foods are assessed on a case-by-case basis using the most updated safety assessment methodology. GM foods currently available on the international market have passed risk assessments and are not likely to, nor have been shown to, present risks for human health.
- 45. However, at the international level, in all fifteen (15) legally-binding instruments or nonbinding codes of practice address some aspect of GMOs. Such sector-based regulations increase the already overstretched capacity of developing countries, and present challenges to develop a fully coherent policy and regulatory framework for modern biotechnology. In the future the assessment of human health and environmental risk needs to be supplemented with evaluations of benefit; socioeconomic factors and ethical aspects. International harmonization in all these areas is a prerequisite for the prudent, safe and sustainable development of the potential of any new technology, including the use of biotechnology to produce food.

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