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Or. Eng.

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OVERVIEW OF CURRENT FOOD SAFETY ISSUES

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Or. Eng.

OVERVIEW OF CURRENT FOOD SAFETY ISSUES[1]

I. INTRODUCTION

1. It is difficult to read a newspaper or listen to a news report without being exposed to some new concern about food or how it is produced. Consumer and environmental interest groups are focused on the food chain with numerous high-level conferences, investigations and regulatory reviews on various aspects of food safety. Governments see emerging food safety concerns as a priority issue. Domestically, many have commissioned internal regulatory reviews and restructured, or created new, food safety agencies. Internationally, the potential for trade barriers resulting from food safety regulations is expected to become a major issue in the upcoming round of trade talks.

2. Civil society concerns go well beyond basic human health. The quality of food and how it is produced, animal welfare, modern biotechnology, the environment and ethical and cultural differences all feature prominently in the public debate. This paper identifies the issues as seen by the various stakeholders, briefly describes the OECD response to these concerns, and issues three challenges to the agricultural knowledge system.

II. FOOD SAFETY CONCERNS: WHAT THE STAKEHOLDERS SAY

3. The OECD held a meeting with over 50 non-governmental organisations (NGOs) on November 20, 1999 at its Paris headquarters to hear and to understand the views of NGOs on biotechnology and other aspects of food safety. Business, trade union representatives and scientists also participated and stressed that they shared many of the same concerns expressed by the consumer and environmental groups, although they held many different views. A summary of the main themes and messages from this consultation provides a useful review of the current issues related to food safety as expressed by the full range of stakeholders.

The issue is more than health and safety…

4. Concerns over biotechnology and food safety go beyond the matter of human health and safety. There are economic, social and ethical issues (Box 1). Effects on food quality, animal welfare and biodiversity were just some of the areas where many felt information was inadequate. Many participants questioned if and how the “non-scientific” concerns should be addressed in the context of national and international regulatory frameworks. Maintenance of national sovereignty in the area of food safety and quality was seen as essential, but working towards harmonisation of standards is equally important. There was general agreement that it was useful to separate the safety and non-safety issues as the problems and possible solutions were quite different. For farmers, the significant concentration of the biotech industry could mean excessive dependence on products and techniques controlled by a handful of multinationals.

[1] Paper prepared by Wayne Jones, Principle Administrator in the OECD Directorate for Food, Agriculture and Fisheries, and Secretary to the OECD Ad Hoc Group on Food Safety.

Box 1. Modern Biotechnology: Why Food is Different

The use of modern biotechnology, or genetic engineering, in the production of food has become a central safety issue.[1] The health and food sectors are both struggling to absorb the flood of new knowledge and data. However, these advances have also underlined some key differences between the two sectors. Health care is a highly regulated domain whose products address often life-threatening situations in a context where risks and benefits must be balanced; a context which imposes ethical imperatives on the medical practitioner, the drug industry and the regulatory authority to equip themselves with the latest knowledge.

The food sector also deals with biological phenomena – the growth of plants and animals; their protection against infection and disease; the transformation and distribution of resulting products; safeguarding these against microbial or other contamination; fine tuning their taste, quality, and acceptability to the consumer; and studying nutritional and other effects. The new knowledge and techniques are no less available to the food industry, and genome projects on the main agro-food plants and animals are ongoing.

But thereafter several differences emerge. Food is familiar, and comforting in its familiarity: we need to eat every day, and because we are creatures of habit the latest innovations are not necessarily what we want. Furthermore, unlike the medicines we use, most of what we eat has never been the object of specific regulation. Innovation may raise suspicions, which regulation may intensify rather than dissipate. Thus in the public mind, novelty in food is a more sensitive issue than advances in health care.

Worries about genetically modified foods fall under three general headings:

- Human health: there are concerns about the possible adverse affects on human health of introducing genetic material from a wide variety of sources into foodstuffs, both in the short and long run (e.g., allergic reactions, resistance to antibiotics).
- Environmental risks: there are concerns that transgenic plants could generate negative effects on the environment either directly or through interaction between existing and new genes (e.g., introduction of new plants, creation of super weeds through “out-crossing”, loss of biodiversity).
- Ethical considerations: there are concerns about the use and patenting of genetic materials linked to issues of intellectual property rights, implications for developing countries, dietary intake and religious convictions (e.g. crossing species boundaries, terminator seeds, excessive industrial concentration). The valuation of acceptable levels of different types of risks is also part of the ethical considerations involved in the determination of the acceptability of GM foods.

[1] Genetic engineering refers to a set of technologies that artificially move functional genes across species boundaries to produce novel organisms. The resultant organisms can have new combinations of genes--and therefore new combinations of traits--that are not found in nature and, not possible through natural mechanisms. Such a technology is radically different from traditional plant and animal breeding.

Source: OECD Policy Brief, Modern Biotechnology and the OECD, May 1999

Consumers want the right to choose…

5. Many NGOs said they did not believe science has at this point satisfactorily addressed their concerns over the effects of GM foods on human health or environment. Consumers were not uniformly lined up in opposition to GM foods, but they were adamant about the "right to choose" food in their local markets. They felt that consumers have the right to know what they are eating, no matter what their reasons may be - health, ethical, religious or other. Environmentalists argued that it is necessary to regulate the

very processes of modern biotechnology in order to avoid unforeseen longer-term impacts on the environment and human health. Product regulation is too short term and insufficient for these groups.

6. Most environmental NGOs invoked the "Precautionary Principle" as a means of giving a "breathing space" while the long-term impacts of GM foods were more closely assessed (Box 2). The current and potential benefits in the use of products of biotechnology were emphasised by a number of participants, especially industry groups from a number of regions. Scientists themselves were not promoting GM foods one way or the other. They recognised that all science, all progress, carries risks or hazards and that historically this has always been the case. Modern science produces sophisticated technologies that require analysis and action in terms of assessing "probabilities" and improving risk management tools.

Consumers want labelling requirements…

7. Several consumer organisations present demanded responsible international oversight and international guidelines on labelling. They felt that labelling is essential for ascertaining the origin of foods, and in particular for separating GM from non-GM foods; for monitoring possible adverse effects of ingredients; and for the security of the public in the long term. Rules for product labelling and advertising must, according to these organisations, be backed by sound monitoring and reporting, with provision for reviews and appeals of decisions related to permits and licensing. It was stated that food safety cannot be a field for voluntary guidelines, and that safety measures should not be left to the private sector. A number of participants felt that governments therefore have a clear role in developing risk management tools such as mandatory labelling, transparent approval processes for novel foods, and regular, systematic environmental impact analyses as part of risk assessment.

A framework of sustainable development…

8. Many agreed with the sentiment that new biotechnologies need to be assessed within a framework of sustainable agriculture, encompassing both economic and resource sustainability. There was considerable discussion about the actual benefits of biotechnology and genetically modified (GM) crops in particular. Anecdotal evidence and scientific studies were referenced both supporting and questioning the benefits in terms of yields, costs and environmental impacts. Producer groups generally reported favourable results but experience is not widespread and local climatic conditions may make a difference. Organic farmers, who represent a small but rapidly growing segment of agriculture, expressed concerns about potential damage from GM crops to neighbouring farms and raised questions about measures of protection and liability. Farm groups felt they should be protected by legislation against liability for any damage caused by GM products if codes of practice are followed.

Food safety is also a trade issue…

9. It was pointed out that different food safety regulations reflecting different national evaluations of acceptable risk can be accommodated in international trade agreements so long as such regulations are based only on scientific risk assessment. But several groups argued that science is not able to assess unquantifiable risks, and consequently, they urged precaution. The possibility of trade disputes increases when economic, social and ethical considerations are superimposed on the science-based approach, but at the same time the concerns of consumers must be respected.

10. Harmonisation or mutual recognition of regulations was seen as a means of reducing costs to industry and consumers while increasing trade. Countries should seek consensus on regulatory approaches by working through international bodies. It was suggested by some that the WTO take a lead role in

addressing these issues by updating the Sanitary and Phytosanitary Agreement (SPS), including a clarification of the precautionary principle. Others felt strongly that many of these issues were best dealt with under the UN Biosafety Protocol initiative. There were also those who do not want the SPS or Technical Barriers to Trade (TBT) agreements to be tampered with for fear of an increase in non-tariff barriers to trade.

Box 2. How Safe is Safe? -- The Precautionary Principle

Many consumer and environmental interest groups, promoting a "better safe than sorry" approach, argue that the Precautionary Principle should be applied to food safety risk management. According to the Precautionary Principle, measures should be taken to avoid injury in circumstances of scientific uncertainty at the time. The role of the Precautionary Principle is currently being debated in several OECD countries and at the international level but there is neither agreement on the definition of the principle nor how it should be applied.

A precautionary approach is recognised in several international agreements including the WTO Sanitary and Phytosanitary Agreement. Article 5.7 of the SPS Agreement indicates that "In cases where relevant scientific evidence is insufficient, a Member may provisionally adopt sanitary or phytosanitary measures on the basis of available pertinent information, including that from the relevant international organisations as well as from sanitary or phytosanitary measures applied by other Members. In such circumstances, Members shall seek to obtain the additional information necessary for a more objective assessment of risk and review the sanitary or phytosanitary measure accordingly within a reasonable period of time.

However, provisions of the SPS Agreement regarding precaution, are much more restrictive than what some consumer groups often mean when they invoke the "precautionary principle", suggesting that there may be a fundamental ambiguity between the expectations of certain groups in society and practical measures.

Most industry representatives believe it is essential that risk assessment remain separate from risk management in order to maintain the credibility of a science-based risk analysis process. The views of many are reflected in a statement by the EU Committee of the American Chamber of Commerce, "Many of the controversial issues surrounding effective risk management, including application of the Precautionary Principle, would be more easily resolved in the context of an established, comprehensive risk analysis process in which communication, transparency, and stakeholder participation are integral elements from the beginning of the process.

[1] The EU Committee of the American Chamber of Commerce, EU Committee Position Paper on a Comparative Risk Analysis Process, September 9, 1999, Brussels. p.4.

Greater focus on developing countries…

11. While most saw modern biotechnology as an important tool in assuring increased food supplies for the world's growing populations, no one considered it as the only, or even the most important, avenue for achieving greater food security. Such technologies are seldom designed for or accessible to, the small landholders in developing countries. Poverty, political conflict, production inefficiencies and imbalances in the world trade system were viewed as greater constraints on food security. However, experiences from Mexico, for example, suggested there is a potential for modern biotechnology to contribute to sustainable agricultural systems while improving international competitiveness. The seeds industry indicated technology transfer to the South is occurring to some extent but many participants agreed that greater effort is required to enhance traditional crops, protect indigenous plant varieties and foster local knowledge of

farmers in developing countries, as these could contribute to long-term economic and environmental sustainability.

Science has its limits…

12. Most NGOs felt that sound science and a transparent and predictable regulatory process are essential if an approval system is to have legitimacy in the eyes of the public (Box 3). There was general agreement that risk assessment should be science-based and transparent; that governments rather than industry should set regulations; that such regulations should be mandatory where human, animal or environmental safety were in question; that regulatory agencies should be independent; and that enforcement and compliance must be assured. According to some of the groups present, however, science should not be considered as the only basis for decision, for two reasons.

13. First, science has limits. It can provide answers only in probability terms - it is essential to acknowledge what we don't know and the tentative nature of some things we do know. Second, food policy decisions require subjective choices derived from social values, not merely scientific facts. Many consumers today believe that GM foods are different because the process of genetic modification is fundamentally new and different – therefore untested. They request that the process be identified in the label of all commercial goods derived from GMOs. Yet, scientists and regulators argued that the process itself does not tell us much about the safety of the final product. This is the reason why in most current legislation, the emphasis is on regulating the product rather than the process.

Research must continue…

14. Virtually all participants agreed that research in modern biotechnology should continue. However concerns were expressed about the shift in both basic and applied research from the public to the private sector as well as the privatisation of public research. Many called for greater government or non-profit organisations involvement in research on agricultural applications of biotechnology. A major issue is the introduction of such crops and products into the food chain and the environment. It was suggested that research should increase but only under carefully controlled conditions with regular monitoring. And not all research was seen as beneficial. For example, development of the terminator gene uniquely for patent protection reasons was strongly rejected by the majority of participants.

15. In reference to patenting and plant breeders' rights, it was recognised that firms need some assurance of a reasonable return on large investments in research. However, the rights of farmers to reuse seed from their own crops must also be respected. The possibility of patenting life forms was also a point of debate with no clear-cut consensus emerging. In advanced countries development of non-food uses of crops, such as biodegradable plastics and biofuels could breathe new economic life into rural communities. Some suggested that the industrial uses of agricultural biotechnology would be quite important in the not too distant future.

Box 3. The Changing Focus of Safety Assessment

For two decades the OECD has been addressing the problems and contradictions of regulating for safety, clarifying the issues and encouraging the international sharing of experience and diffusion of best practices. Enormous experience has accumulated in sectors such as food safety, plant breeding, pesticides and agricultural quarantine. Safety assessment should build on existing knowledge of the organism to which changes have been made, providing clear information about the changes introduced and the intended use.

One significant criterion is familiarity with the organism – whether in the industrial fermentation tank, the farmer's field or in food consumption habits, a long history of safe use is a reassuring and practical starting point. Thus the initial focus on the new technology of recombinant DNA and the genetic modification of organisms shifted by the end of the 1980s to focus on the organisms themselves, the specific changes, and the intended use. The responsibility for safety assessment lay with the various agencies concerned, dealing with such matters as live vaccines, gene therapy and environmental impacts of agricultural crop plants and food safety.

Traditionally, regulatory oversight in the food sector had focused on such matters as residues, contaminants, processing aids, packaging materials, labelling – everything, in short, except the main elements of the food itself. The various plant, animal and other products by which our ancestors and we have met our needs for carbohydrate, fats, proteins and vitamins had generally not been subject to regulation.

Only as modern or novel technologies, such as food irradiation or the use of explicitly identified enzyme additives, became available, did public interest and regulatory attention begin focusing on the main food elements themselves and the technological processes to which they have been subjected. This poses a fundamental and central question: given that we have not regulated the bulk of the foodstuffs we eat, raw or processed – many of which have entered human diet only in recent years – by what rationale should we start regulating the latest innovations in products or processing methods? What should be the trigger for new regulation?

To help solve these problems, the principle of substantial equivalence for assessing the safety of novel foods, including those derived through modern biotechnology, has become current practice in many countries. The concept of substantial equivalence was first described in an OECD publication in 1993, *Safety Evaluation of Foods Derived by Modern Biotechnology: Concepts and Principles*, produced by some 60 experts from 19 OECD countries. It stresses that an assessment should show that a GM variety is as safe as its traditional counterparts. Since the concept of substantial equivalence was first described, a number of new foods have been assessed and knowledge has accumulated on how to use the concept. This includes work on assessment methodologies when substantial equivalence can not be applied, as well as efforts to identify the critical nutrients and toxicants found in major crop plants, as a focus for the demonstration of substantial equivalence.

Source: OECD Policy Brief, Modern Biotechnology and the OECD, May 1999

More information, more dialogue wanted…

16. Greater emphasis on sound science was seen as critical for risk assessment, risk management and communication. Too often unsubstantiated claims, anecdotal stories and biased reporting have served only to cloud the issues. Scientific studies should always be subject to peer reviews prior to public release. Governments, industry and NGOs all have a responsibility to get the facts straight and make this information available to the general public. The scientific community stressed that there was still much that was unknown and much research to be done. All stakeholders want to be consulted in the regulatory process from planning to implementation. This process must be analytically sound, objective, credible, transparent and accountable if it is to instill public confidence.

III. FOOD SAFETY CONCERNS: CHALLENGES FOR THE OECD

17. The OECD's challenge is to offer more effective assistance to governments as they develop approaches to biotechnology, particularly as it relates to food safety and genetically modified organisms and trade. The OECD and other international fora must address the interaction of three elements:

- Science: findings on the implications of the technologies for human health and the environment need to be presented clearly and underpin policy considerations, while acknowledging that scientific evidence is often incomplete and equivocal.
- Regulation: regulations need to be consistent with scientifically defined risks to health and the environment; and the similarities and differences in regulation across countries need to be analysed in relation to rigorously defined standards.
- Public information: governments and the scientific community must be transparent in presenting findings on risks and in putting in place measures to address the risks.

18. Related to this, the organisation will work to enhance international co-operation in research analysis, safety standards and regulatory frameworks and increase the efficiency of the safety assessment process by helping to avoid the duplication of effort for government and industry.

19. Following recent mandates from OECD government ministers, and in view of the request from leaders of the G-8 industrial countries, the OECD is now intensifying its work in the areas of biotechnology and food safety. Three new initiatives should be of particular interest to the AKS community:

Response to the G8 Request

20. The G8 Heads of State and Government meeting in Cologne, June 1999 invited the OECD Working Group on Harmonisation of Regulatory Oversight of Biotechnology and the OECD Task Force for the Safety of Novel Foods and Feeds to undertake a study of the implications of biotechnology and other aspects of food safety. The Task Force will focus on science-based principles for risk assessment while the Working Group will focus environmental considerations relayed to modern biotechnology. In developing the response to the G8 request, the OECD Council also decided to set up an Ad Hoc Group on Food Safety in order to procure further Member country guidance and involvement in the definition of other work on food safety. The Ad Hoc Group's initial responsibility will be to develop a compendium of current and planned food safety systems and activities.

OECD Conference on GM Food Safety

21. The OECD will to hold a major international scientific conference in Edinburgh early next year with a view to taking forward the scientific debate on food safety aspects of biotechnology and genetically modified organisms (GMOs). The conference will bring together leading experts from OECD Governments, consumer and other interest groups, industry, international organisations and developing countries to debate the scientific and human health issues surrounding GM food. The primary focus of the conference will be the science of GM food. But there will be an opportunity to address related issues such as public perception and consumer confidence, consumer information and choice and environmental concerns.

OECD Schemes for Seed Certification

22. The *OECD Schemes for Seed Certification* were developed to regulate international trade in seed as well as counter seasonal multiplication of seed between the northern and southern hemispheres. The Schemes have been implemented by a total of forty-six Member and non-member countries across all continents. A new activity of the Seed Schemes addresses some of the "other aspects of food safety" identified in the G8 request such as risk assessment and management, consumer information as well as mutual recognition instruments. The OECD Seed Schemes, in response to a World Seed Federation Initiative, will examine the feasibility of the special identification of GM seeds and the establishment of harmonised threshold schemes. The Advisory Group of the Schemes will review information to be given by the seed industry on existing assessment technologies for the separation or tolerance levels of transgenic seed of maize and soybean and a timetable for discussing and developing varietal identity and purity thresholds.

The Co-operative Research Programme on Biological Resource Management for Sustainable Agriculture Systems

23. The programme's aim is to intensify fundamental research in biotechnology, with new emphasis on research integrating socio-economic and scientific concerns as well as risk assessment. Almost all OECD Member countries participate in this programme, which seeks to reinforce international scientific co-operation and to facilitate the exchange of information on current research, in particular that of value to developing countries. The proposed new activity for the period 2000-2004 with an enlarged scope is under review within the OECD. The expanded themes would be:

- new agricultural products for sustainable farming and industry
- quality of animal products and safety of food
- enhancing environmental quality in agricultural systems
- connecting scientific progress to sustainable and integrated agro-food systems.

IV. FOOD SAFETY CONCERNS: CHALLENGES FOR THE AKS

24. This paper has identified the major food safety concerns and some of the key challenges taken up by the OECD. There are similarly important contributions that could be taken up by the AKS. In the discussions to follow about the implications of current and emerging food safety concerns for the AKS, participants may wish to consider the following challenges:

Redefining the roles of the AKS in food safety

25. As noted above, civil society is concerned about the shift from public to private sector research as well as the privatisation of public research, with calls for greater government involvement. Member country submissions on food safety for this conference agreed that close co-operation between the research and education/extension components of the AKS was vital to a successful food safety programme. They also indicated that two-way communication was required, with safe food practices coming from the AKS and input on stakeholder needs and priorities going to the AKS. (See the companion conference document by Dr. William Wagner, *Comparative Analysis of AKS Approaches in Addressing Problems Related to Food Safety in OECD Member Countries).*

Assessing the benefits and costs of GM foods

26. During the NGO consultation referred to in the first part of this paper, the discussion about GM foods kept returning to the questions of what real benefits did these products provide and what real dangers did they impose. Unsubstantiated claims, anecdotal evidence and questionable scientific studies abound, which serve only to cloud the debate. Much is still unknown. More independent research is required, backed up by documentation of on-farm results. The AKS could play an increasingly significant role in the collection, co-ordinations, and distribution of analytical and objective information on GM foods.

Connecting science and policy

27. Connecting science and policy was the theme for an OECD Conference on Biological Resource Management held in Paris 29-31 March 1999. The government, science, NGO and media participants addressed such issues as:

> "Are the most urgent concerns of society being taken account in agricultural research?"
>
> "Is agricultural research sufficiently connected with other research fields (health, ecology, etc.)?"
>
> "Are the results of research expressed in ways understood by competent authorities? the public?"
>
> "How can policy-makers reconcile scientific advice with pressures from civil society?"

From these discussions, a number of needs were identified. The need to improve co-ordination of agricultural research internationally; the need to strengthen relations between the "hard and soft" sciences (economic, social, ethical); and the need to improve the dialogue with all stakeholders, including those in developing countries.