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24 Highbury Crescent, London N5 1RX, UK

Tel: (+44) 20 7226 6663 Fax: (+44) 20 7354 0607 Email: consint@consint.org

The Need to Complete and Apply a Coherent Set of Principles **for Managing Food Safety Risks in All Nations**

SUMMARY

Consumers International supports the development of comprehensive “working principles for risk analysis,” to support transparent food safety decision-making processes at both the international and national levels. Consistent, harmonized principles offer the promise of ensuring a high standard of health protection and food safety for consumers in all parts of the world, while avoiding creating unjustified trade barriers. The Codex Alimentarius Commission and several of its subsidiary bodies are currently developing consensus principles for risk analysis, and completion of that work is an urgent priority. Many opportunities for further progress in advancing risk management through sound principles are identified in this paper. They include spelling out more detailed principles for risk management of specific food safety problems, and expanding the Codex principles to make them useful as guidelines for national governments. A broader consensus is needed on clear principles for the application of precaution and on the roles of science and non-scientific other factors in food safety risk management. And the scientific advisory system on which Codex and many national governments rely for risk assessments needs to be expanded and improved, to increase the quantity and quality of risk assessments to keep pace with demand.

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INTRODUCTION

Broadly speaking, risk management describes the work engaged in by all food safety regulators. Within the conceptual framework of risk analysis, risk management is the broadest, overarching activity. Risk managers are responsible for identifying the existence of a hazard, commissioning a risk assessment, selecting and implementing the appropriate options for managing or responding to the risk, and ensuring that good risk communication is maintained with all interested parties at all stages of the process.

The risk managers with whom Consumers International and its members most often interact include food safety agency officials in the 120 or so countries where our 270 members are based, and Codex committees that set international food safety standards.

Consumers International has two general goals concerning risk management at both the national and international level:

- (1) Risk analysis (and its risk-management component) should be based on sound, consistent, and transparent principles. The rules by which food safety decisions are reached should be spelled out clearly and widely adhered to, so that all concerned parties can know the basis for decisions.
- (2) Organizations representing consumers should be able to participate in the risk management process in appropriate ways, in all countries and at the international level.

Consumer participation issues are addressed in a separate paper. The remainder of this paper focuses on principles for risk management.

PRINCIPLES FOR RISK MANAGEMENT: CURRENT STATUS

Many national governments have adopted food safety legislation, and some have also elaborated principles for the conduct of food safety risk analysis, and for its primary components: risk assessment, risk management, and risk communication. Essentially all national and international approaches to risk management share a commitment to base decisions on a scientific risk assessment, and recognize that determining how much risk is acceptable depends not only on science but also on more subjective economic, social and cultural considerations.

Because of such non-scientific “other factors,” risk managers in different situations faced with similar problems may decide to tolerate more or less risk than other governments have chosen to do, and may set standards that differ from one another. Such differences are unavoidable and recognized as legitimate, but there are also significant benefits from the effort to harmonize food safety standards internationally. Harmonization is essential to promote more equal and effective protection of consumers in all nations from food-borne hazards, and as we all know, it tends to facilitate trade in foods.

Needless to say, consumers want harmonization to elevate the food safety capabilities and standards of less developed countries, so that all consumers may enjoy the highest level of protection. Consumers look to the food safety leaders of the world to avoid “downward harmonization,” i.e. lowest-common-denominator safety standards that would facilitate trade by lowering the level of protection currently enjoyed by some countries.

One way to facilitate harmonization of food safety standards among nations is to develop consensus international working principles for risk analysis. Such principles, if adopted by most governments, would help to promote consistency and transparency of standards, prevent or remove unjustified barriers to trade, and ensure public health protection.

The Codex Alimentarius Commission has, for nearly a decade, been working to develop a consensus international approach to Risk Analysis. The first phase of this work consisted of several expert

consultations, including one on Risk Analysis, one on Food Safety Risk Management, and one on Risk Communication. The second phase, now nearing completion, is the elaboration of some “Working Principles for Risk Analysis” by Codex committees. One very important document is (it is to be hoped) now in nearly final form, and will be considered at the April 2002 meeting of the Codex Committee on General Principles. If adopted as scheduled by the Commission in 2003, these principles will provide an internationally agreed framework that defines accepted approaches to the conduct of food safety risk analysis.

The Codex Working Principles for Risk Analysis, as currently drafted, describe risk analysis by Codex committees; they do not attempt to address all the concerns that risk managers in national governments must weigh. However, if adopted, Codex principles could serve as a model for national agencies and may enhance the coherence of national approaches to risk management.

To produce the current Working Principles draft, CCGP has held lengthy discussions of many complex issues and difficult concepts. The adoption of these principles will be a major milestone for Codex, but it will also be just another step in a continuing process. Much of the hard work still lies ahead.

RISK MANAGEMENT PRINCIPLES: THE CHALLENGES AHEAD

Applying Codex Principles at the National Level. The issue of how Codex principles can be applied to national food safety risk management by member governments is complex. Codex member governments want such advice and would like to follow agreed rules, but they are also cautious about agreeing to any “principles” that might restrict their rights or, in particular, adversely affect their food trade interests. Consequently, the CCGP has not yet determined how and when it will be able to develop guidance based upon the Codex “Working Principles” to support food safety decisions made by member governments. Discussion of this important objective will continue at the April 2002 CCGP meeting.

Need for More Detailed Principles in Specific Food Safety Areas. The current Codex Working Principles are very general, and do not address in detail specific considerations that arise in any specialised field of food safety risk management, such as the control of foodborne pathogens or the regulation of pesticide residues in foods. Codex committees active in those and other specialised areas (principally, the Codex Committees on Food Hygiene, Pesticide Residues, Residues of Veterinary Drugs in Foods, Food Additives and Contaminants, Good Animal Feeding Practices, and Foods Derived from Biotechnology) thus need to develop their own, more detailed, working principles for risk analysis their subject area. This work has progressed to different degrees in the different committees; for example, CCFH and CCRVDF have elaborated several excellent documents, some of which have been adopted by the Commission. Other committees are at less advanced points in the process, but moving ahead with the task.

Collectively, this is an enormous amount of work for Codex, but it is very important work. It will define and explain the basis for Codex risk management decisions, and should also offer models for emulation by national regulators facing the same types of problems. This work may occupy a significant part of many Codex committees’ agendas for the next three to five years.

Precaution: An Especially Important and Difficult Task. All governments (and several Codex committees) occasionally will encounter a need to manage a risk on which there is insufficient scientific evidence to provide a conclusive assessment of the exact nature and magnitude of the hazard. Consumers expect, and there is essentially universal agreement among regulators, that governments should take action to protect public health in such circumstances, rather than wait for more definitive scientific evidence. There is a broad consensus among governments that actions taken in such cases should be based on the available scientific information, proportional to the possible risk, consistent with other measures taken to deal with similar risks, non-discriminatory, should consider a range of risk-management options, and should be reviewed in a timely manner as new scientific evidence emerges to support a better risk assessment.

The international community has also agreed, for example at the Melbourne Conference in 1999, that precaution is an essential element of food safety risk analysis, at both the national and international levels. Yet, despite broad agreement that precautionary food safety decisions are legitimate, and despite a general consensus about the conditions that should apply to such decisions, the international community (working primarily through the Codex Committee on General Principles) has to date failed to agree on any statement of principles governing the application of precaution in food safety decisions. The most obvious obstacle to agreement has been that numerous governments, fearful that some “precautionary” food safety standards might be unjustified disguised trade barriers, have opposed adoption of *any* principles related to precaution by the Codex Commission. In July 2001, the Codex Commission agreed that Codex itself should not adopt standards, but might consider other kinds of measures, when scientific data are insufficient. But this agreement offered no guidance for appropriate use of precaution at the national level.

Consumers International calls upon this assembly of the world’s food safety leaders to address this challenge head-on. It is time for CCGP to assert that the business of Codex is the protection of public health, with sensitivity to trade concerns—not the reverse. It is essential, to maintain consumer confidence in the Codex system, that Codex both affirm the legitimacy of precautionary food safety standards, and spell out clear principles that define the appropriate use of precaution to safeguard health, which national governments can apply to their own decisions. Transparent principles for the application of precaution are, in fact, the strongest protection against the misuse of food standards to restrict trade; governments that oppose adoption of sound principles for the use of precaution are in fact working against their own trade interests.

CI believes that one way to progress the international debate on precaution would be to hold a workshop in which national food safety officials compare their experiences with the application of precaution. We believe such a collection of case studies would amply demonstrate, to the satisfaction of sceptical trade officials, that precaution is a familiar tool that has been widely and wisely used by food safety regulators, generally without creating unjustified trade barriers. Case studies would provide a robust basis for deriving principles that define appropriate uses of precaution, and identify any occasional misuses. We believe the Global Forum of Food Safety Regulators would be an ideal venue for such a workshop. If the impasse over precaution within the Codex system persists, Consumers International urges this Forum to compare case studies, at its next opportunity.

Role of Science and “Other Legitimate Factors.” One of the most complex discussions within the Codex work defining principles for risk management addresses the roles of science and non-scientific “other legitimate factors” in decisions. Last July, the Codex Commission adopted some general guidelines describing the appropriate use of “other factors” in Codex decisions. Additional work remains, to spell out detailed guidelines for the integration of factors in addition to science in risk management decisions by Codex committees in specialised food safety areas. Consumers International believes it would also be very valuable for each national food safety authority to spell out its own working principles for decision-making. In general, the manner in which health risks, economic costs, and social and political considerations are integrated in risk management is one of the most complex and least transparent aspects of decision-making. It would both help improve the soundness of decisions and increase public support for decisions if clear, consistent principles were spelled out and followed by governments at all levels.

Need to Improve the Quantity and Quality of Risk Assessments. While there is an almost universal agreement that a sound scientific risk assessment is an essential part of the basis for any food safety risk management decision, meeting the need for competent, timely and independent risk assessments presents a considerable challenge. The number of food safety hazards whose risks need assessing is large, and expanding. The nature of adverse health effects associated with food contaminants expands as scientific research develops additional ways to measure harm. Good risk assessments are needed internationally and at the national level, and the latter need to be informed by exposure and susceptibility data specific to national situations. The number of experts capable of carrying out such assessments is limited, and the experts who are asked to do food safety risk assessments have not always

been as competent, as unbiased or as free of financial conflicts of interest as they must be to inspire public confidence in their work.

Currently, risk assessments for Codex committees are done by three joint FAO/WHO expert bodies, which are in turn supported by data and experts drawn for the most part from national governments. Many observers now agree that the current system is overwhelmed, and cannot meet projected needs. FAO and WHO are working with dedication to meet the need for risk assessments. The agencies have also strengthened their procedures for seeking nominations, in an effort to recruit a broader and more diverse cross section of the world's scientific community, and they have improved procedures for identifying and excluding experts with conflicts of interest. All of these steps have been necessary and appropriate, but collectively, much more still needs to be done. In particular, the depth and breadth of scientific participation in risk assessment panels needs to be expanded, to meet the need for more assessments that cover new and emerging forms of toxicity, such as endocrine disruption and effects on developmental processes in infants and children. More scientists from developing countries need to participate, and more scientific data on exposures and health effects related to food-related hazards in the less developed countries need to be incorporated into international risk assessments.

Consumers International urges all governments to support the WHO and FAO in their efforts to expand and improve the international expert advisory system, by seriously considering committing additional resources for this task. Without scientifically sound, credible risk assessments, neither national nor international food safety risk managers can ensure consumers the level of health protection they need and expect.

In summary, Consumers International is gratified by progress in the development of international approaches to food safety risk management since about 1990. At the same time, we recognize that continued hard work lies ahead, to raise the world's food safety systems to where they need to be. We welcome the creation of this forum and commend the governments who are participating. We support your ongoing efforts to protect our food supply and our health, and thank you for your attention to these concerns.