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The Codex Alimentarius and Environment-related Food Safety: the Functioning of the Global Standards[1]

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Acronyms used

BP	Biosafety Protocol
CAC	Codex Alimentarius Commission
CBD	Convention on Biological Diversity
CCGP	Codex Committee on General Principle
GM	genetically modified
ICGMA	International Council of Grocery Manufacturers Associations, Washington, DC
LMO	living modified organism
MEA	multilateral environmental agreement
SPS (WTO)	Agreement on the Application of Sanitary and Phytosanitary measures
TFFBT	Task Force on Foods Derived from Biotechnology
TBT (WTO)	Agreement on Technical Barriers to Trade
UNEP	United Nations Environment Programme

You are what you eat
Tiny Tim

Abstract

This paper focuses on a neglected area of multilateral environmental regulation, namely environment-related food safety through the Codex Alimentarius. This body is the implementing arm of the FAO-WHO Food Standards Programme, and it is an important organism with over 160 member states. Created in 1961, it has received a much increased significance through the conclusion of the Uruguay Round because two WTO agreements (TBT and SPS) recognize and specify it as their reference point in the WTO's dispute settlement function. Thus it has become the world's most important standard regarding food quality and safety. The dynamics of the multilateral negotiations administered by the Codex Alimentarius Commission is characterized by its conflicting double mandate of assuring food safety on one hand, and of facilitating international trade on the other hand. Its functioning is very decentralized thanks to the fact that it is based on about twenty Committees and ad hoc Task Forces which are hosted by different member states. The fundamental doctrine guiding the Codex's activities is the scientificity of its risk assessment principles and procedures. The key unresolved debates revolve around the question whether an importing country may use precautionary measures to justify import restrictions in the face of scientific uncertainty and around the modalities of food labeling. Precautionary measures - as an integral part of science-based risk assessment - are defended primarily by the European Union, and they are opposed primarily by the U.S.

1. The Institutional Context of the Codex Alimentarius

This paper represents an exploratory overview of an intergovernmental organization that is not normally associated with international environmental affairs, namely the Codex Alimentarius. The Codex is, nevertheless, at the heart of multilateral negotiations dealing with an environmental issue that is attracting more and more attention, namely *environment-related food safety*. The focus of the present analysis on environment-related food safety can claim to be reasonably original in the context of the study of international ecopolitics or international environmental law but it is not entirely new, for instance the much cited *Institutions for the Earth* (Haas, Keohane and Levy, 1993) contains a section on the Codex Alimentarius (Paarlberg, 1993:314).

The Codex Alimentarius, as its name implies, is responsible for elaborating internationally valid standards, guidelines, and recommendations regarding food safety. We shall focus our attention here largely onto those two specific issues within the Codex's purview that are considered to be of an environmental nature in the most direct sense, namely pesticide residues levels in the food, and living modified organisms (LMOs). The term 'LMOs' is in many instances synonymous with the more widely used and more comprehensive term 'genetically modified (GM) food,' but the Cartagena Protocol on Biosafety to the Convention on Biological Diversity[3] uses exclusively the term LMOs for its subject matter. The reason is that processed food products are not included in that agreement. We shall use both terms in order to be able to distinguish between the two meanings. The term LMOs is often more pertinent for our discussion than the term GM food because we are particularly interested here in the interface between environment and food safety. Most GM food products on the other hand have been processed in such a way that they are not living anymore, i.e. self-reproducing when planted in the soil, and they are therefore not dangerous to biodiversity.

One should keep in mind, furthermore, that the Codex and the Biosafety Protocol (BP) are not addressing exactly the same subject matter (Boisson de Chazournes, Thomas et al. 2000). The Codex deals with the safety of all food products, whether living or not (chocolate), whereas the BP deals with all LMOs whether edible or not (cotton). Nevertheless, there is a very important overlap, especially in the large and commercially very important sector of genetically modified living food commodities, such as soy beans, corn, or grains, which may represent a threat to biodiversity when they are used purposely or inadvertently as seeds. It should be noted also that in developing countries even grains imported as foodstuff are often used as seeds by farmers, especially in a crisis situation (Pythoud, 2002).

Pesticides and LMOs used as seeds represent the most important environment-related food safety concerns because they have the potential to change the ecosystem for a very long time. They both raise the double concern of environmental degradation such as reduced soil fertility and biodiversity, and potential health risks such as cancer or allergies. At the Codex they are dealt with in two specialized entities:

- the *ad hoc* Codex Intergovernmental Task Force on Foods Derived from Biotechnology,
- the Codex Committee on Pesticide Residues.

That is why it is justified to put these two categories of food and food-related products regulated by the Codex into the context of international environmental affairs. It should be pointed out, furthermore, that strictly speaking we are dealing here not only with food safety but more generally with food standards. Some people may orient their choices toward organic food or fair trade food products independently of their taste or of scientific evidence that they are healthier, but simply because they wish to support less mechanized agricultural methods and maybe also in the wider sense the cultural aspects of those production systems which make it possible to find these food varieties on the market.

[3] Adopted in Montréal on 29 January 2000
http://www.biodiv.org/biosafety/protocol.asp

The development of LMOs, which has been added to other human intrusions into the state of nature such as the application of pesticides and fertilizers, has stimulated over the past few years an increased interest for environment-related concerns regarding food safety, not to mention food production and food security. To the extent that agrochemicals and GM seeds promote the expansion of larger and larger monocultures (Halweil, 2000:15) with less and less germplasm diversity, they are at the center of these questions both from environmental and from food safety view points. One should not confuse the variety of genetically modified plants with the variety of genes because genes cannot be created:

> Timothy Swanson, an economist at University College in London, estimates that plant breeders still return each year to landraces and their wild relatives for about 6 percent of the germplasm lines used in their breeding. (The remainder are advanced breeding lines and established commercial varieties)
> (Tuxill,2000:31).

At first the Green Revolution introduced the large-scale application of agrochemicals, mechanization and large capital requirements, and now the international commercialization of GM food is providing an additional impetus for these concerns. It is clear that the Codex Alimentarius is not considered to be a multilateral environmental agreement (MEA) since it does not regulate a sector of the environment such as forests, deserts or the climate. Nevertheless, the dynamics of those Codex negotiations which are of direct concern for the regulation of pesticides and LMOs can only be understood if they are seen as a related part of the wider negotiation framework that is called 'trade and environment,' and which at the multilateral level deals mostly with the relations between the WTO and MEAs (Perrez 2000). The Convention on Biological Diversity (CBD), administered by the UN Environment Programme (UNEP), is one of the most important MEAs. It should be stressed, however, that this framework has very limited ambitions and a narrowly defined framework. The multilateral debates administered by the WTO's Committee on Trade and Environment are at this point in time only non-binding discussions that are in no way comparable to the regular binding trade negotiations. Furthermore, they are strictly limited to the potential impact that trade-related environmental measures might have on the trade of goods, services and on intellectual property rights, but they do not include a debate on the opposite dynamics, namely the impact of trade on various aspects of the ecosystsem.

The most significant overlap between the Codex Alimentarius and the Biosafety Protocol consists probably in the area of labeling or identification of genetically modified food products. The CBD's Biosafety Protocol which is closely related to trade policy and to the trading rights that members acquire through the ratification of the WTO Agreement deals in Article 18 with some aspects of the thorny question of labeling LMOs destined for international trade. It specifies that those aspects which have not been concluded yet shall be resolved "no later than two years after the date of entry into force of this Protocol." The labeling issue has been a major stumbling block until the last moment in the tortuous negotiations of the BP which peaked in a "deal-breaking battle at the very end of the Montreal conference (Gupta, 2000:29)." The tension between the LMO exporters and most other countries was resolved by stipulating mandatory labeling for LMOs intended to be released into

the environment (mostly seeds), and by dealing with the more important commercial commodities later within this specified time frame.

Thus we can observe a tight interconnection between four different types of multilateral agreements:

- the food safety standards of the Codex Alimentarius,[4]
- the trade agreements SPS and TBT including the wider WTO
- framework,
- the MEA Convention on Biological Divesity,
- the BP which is "neither a pure environmental nor a pure trade agreement (Falkner, 2000:312)"

The tight intertwining of these different kinds of agreements shows clearly that one needs to see the two streams of environment-related food safety negotiations of pesticide residues and of GM food products within the Codex regulatory framework as an important part of the wider trade and environment negotiations. It should be pointed out, however, that in the ongoing debate of trade and environment issues the Codex normally is still not included. It is to be hoped that this analysis will contribute to an inclusion of the Codex Alimentarius in these discussions and negotiations at least as an important related consideration.

The Codex Alimentarius is an unusual kind of organization in many ways. To complicate matters, like many regulatory frameworks, it may be categorized both as an organization or an agreement depending on the thrust of the analysis. It should be noted furthermore that in legal terms the Codex is not considered as an intergovernmental organization in the customary sense because it is not an autonomous international legal entity but rather a subsidiary body, more precisely it is the implementing arm of the Joint FAO/WHO Food Standards Programme. Its origins go back to 1961 when the FAO Conference decided to establish the Codex Alimentarius Commission. Two years later the Joint FAO/WHO Food Standards Programme was established through the institutionalized cooperation of the FAO Conference and the WHO's World Health Assembly.[5]

A quick look at its "charter," namely the 170 page *Procedural Manual,*[6] will show immediately that we are dealing here with a major and highly complex intergovernmental instrument. This manual represents the "The legal base for the Commission's operations and the procedure it is required to follow...."[7] Thus even though the Codex is not strictly speaking a multilateral agreement it can base its global legitimacy on the fact that the various editions of its *Procedural Manual* (the 12th presently) are the result of extensive multilateral consultations at different levels: working groups of the Codex Committee on General Principles (CCGP), the CCGP plenary negotiations, the Codex Alimentarius Executive Committee, and the Codex

[4] Some lawyers do not consider these food standards as multilateral agreements and prefer to stick to the term 'codex.' In view of the fact, however, that they have been elaborated through numerous tightly structured large multilateral negotiations open to over 160 national delegations governed by United Nations rules and procedures we shall look at them as agreements.

[5] *Understanding the Codex Alimentarius,* 1999. Rome: FAO and WHO, 35 p. (7). This is the official publication explaining to a wider public the purpose and functioning of the Codex Alimentarius and its Commission. http://www.fao.org/docrep/w9114e/w9114e00.htm

[6] *Procedural Manual* of the Codex Alimentarius Commission, 12th edition, 2001. Rome: FAO and WHO, 174 p. ftp://ftp.fao.org/codex/manual/Manual12ce.pdf

[7] *Understanding the Codex,* 1999*, op. cit.* p. 13.

Alimentarius Commission which has to adopt all major decisions. All these negotiations of course benefit from the support of the Secretariat. As is to be expected in all multilateral regulatory bodies, developing countries are very strongly underrepresented at all levels. Changes are usually achieved by consensus, a vote is rarely necessary. It is unavoidably very complex because its mandate, i.e. the multilateral negotiation of food safety standards, is not only very complex from a scientific standpoint, but also fraught with political tensions and cultural traditions which are not easily amenable to global harmonization, one of the Codex's key objectives.

The Codex Alimentarius has managed to stay out of the limelight in spite of a mandate that concerns all of us, and in spite of the fact that it is not a recent creation. It is hardly ever in the news and generally speaking it receives not much attention by experts and scholars of international law and international relations. One may hypothesize that this hidden nature of the Codex can be explained to some extent by the difficulty of categorizing it. First of all, it can be considered a hybrid food safety - trade agency. Secondly, in spite of the fact that it is not an autonomous intergovernmental organization, it administers multilateral negotiations among its member countries that are as dynamic, complex and far-reaching as any negotiations taking place in intergovernmental organizations. Thirdly, both of its parent organizations are specialized UN agencies, but the Codex is a quite unique body because of its very lean and original organizational constellation. The Joint Programme shows a very modest budget of only about $2.5 million per year, of which FAO supplies at least 75% and WHO the rest.[8] The solution to this organizational riddle lies in its decentralized nature. It has about 20 permanent committees and a couple of task forces with a specific mandate limited to a few years, and which are all hosted and paid for by different countries. Canada for instance hosts the Codex Committee on Food Labeling, France the one on General Principles, the Netherlands the one on Pesticide Residues, and Japan hosts the *ad hoc* Codex Intergovernmental Task Force on Foods Derived from Biotechnology. This loose structure and the heavy financial burden shouldered by the committees' host countries allow the organization to function with a budget that is exceedingly modest in the face of its heavy and complex mandate.

The Codex's hidden nature may, however, change over the coming years for two reasons. First of all the there are increasing concerns, at least in the industrialized countries - particularly in Europe - that major food suppliers are compromising food safety in order to improve their economic benefits. These suppliers of course are more and more under competitive pressures in a world that increasingly opens itself up to international trade. The fact that these competitive pressures which affect just about all industries are felt in the food sector also is not particularly surprising as such, but the level of quality and safety standards is undoubtedly a much more immediate concern here than in most other very competitive industries such as textiles or furniture. As a result we have particularly detailed government regulations at the national and often at the sub-national levels, and an extensive interaction among standards of exporting and importing countries. A related important point to consider is a relatively high level of politicization, because

[8] Report on the Financial Situation of the Joint FAO/WHO Food Standards Programme for 2000/01 and 2002/03, ALINORM 01/5, May 2001, 8 p.

our health and well-being, not to mention in some cases our cultural identity (Echols, 2001),[9] are directly affected by what we eat and drink.

The second important reason why the Codex is likely to increase its profile lies in the fact that its mandate and its visibility have been given an enormous boost through the conclusion of the Uruguay Round: the WTO, which is notoriously choosy about the organizations it deals with at an institutionalized level, has explicitly adopted the Codex Alimentarius as *the* reference point for the settlement of disputes within the categories of its assigned subject matter. This reference point is stipulated most importantly in the SPS agreement:

> SPS Agreement, Annex A - Defintions
>
> 3. *International standards, guidelines and recommendations*
>
> a) for food safety, the standards, guidelines and recommendations established by the Codex Alimentarius Commission relating to food additives, veterinary drug and pesticide residues, contaminants, methods of analysis and sampling, and codes and guidelines of hygienic practice.[10]

This paragraph needs to be placed into the context of the other provisions of the SPS Agreement, and of course of the whole WTO agreement. The SPS Agreement specifies under which conditions an importing country may restrict or ban the importation of certain goods for sanitary and phytosanitary reasons. In other words, its provisions represent exceptions to the trade regime's doctrine of non-discrimination[11] and of non-protectionism.[12] It implies that the WTO puts the burden of proof for the justification of such trade measures onto the importing country because an exporter whose products are in conformity with the Codex standards is assumed to fulfill the requirements of a WTO-compatible internationally accepted standard. This does not mean that an importing country is prevented from insisting on more demanding standards, but if it wants to do so it has to prove that its import standards or conditions are *necessary* for the protection of public health. More specifically, it has to show that the determination of its import regulations is the result of a process which is based on scientific methods and practices. The Codex does not define the terms science or the scientific method but it does provide rather exceptionally explicit definitions for those terms which characterize – in the framework of the Codex Alimentarius - risk analysis for food safety (Annex No. III).

The SPS Agreement takes precedence over the TBT Agreements in its domain of application, i.e. in import restrictions of a biological or medical nature. Nevertheless, the TBT Agreement is also important with regards to the Codex, especially with regards to the thorny and unresolved issue of the rights an importing country may have to insist on the mandatory labeling of GM products. The TBT agreement refers to the Codex in a generic way:

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[9] For an in-depth treatment of food as culture, food as commerce, and risk analysis in the Codex-WTO framework see: Echols, Marsha A. 2001. *Food Safety and the WTO – The Interplay of Culture, Science and Technology.* New York, The Hague: Kluwer Law International.

[10] *The Results of the Uruguay Round of Multilateral Trade Negotiations - The Legal Texts*, 1995. Geneva: WTO, 559 p. Also available at www.wto.org

[11] GATT Article I *General Most-Favored-Nation Treatment,* WTO, http://www.wto.org/english/docs_e/legal_e/legal_e.htm

[12] GATT Article III *National Treatment,* WTO, *Ibid.*

> TBT Agreement, Article 1.1 *General Provisions*
>
> General terms for standardization and procedures for assessment of conformity shall normally have the meaning given to them by definitions adopted within the United Nations system and by international standardizing bodies taking into account their context and in the light of the object and purpose of this Agreement.[13]

The WTO's institutional linkage has given the Codex what Romi (2001:204) calls "cette importance stratégique." This elevation to a new and far more powerful status occurred a few years ago with the WTO agreements' entry into force on January 1, 1995, and with it the explicit elevation of the Codex norms to a WTO-compatible framework. One may note that the full realization of this fact and of its economic, legal, political and even societal ramifications is a slowly spreading process. It is fair to say that so far neither the media nor the academic research community has paid a great deal of attention to the Codex. However, the struggle between the US and the EU in the cases of beef hormones and the unfettered introduction of GM food products in international markets, as well as the various highly mediatized food scandals in Europe over the past few years indicate quite clearly that the issue of food safety is of increasing importance. One may safely predict that especially the different perspectives on GM food in the US and Europe will attract far more attention to the Codex in the very foreseable future.

To conclude this section let us look briefly at the larger picture of the politically tense issue area that is usually called “non-trade issues” at the WTO. Its 1996 Ministerial Conference has decided that social issues shall be dealt with by the International Labor Organization, and there has been no significant change in this position with the exception of facilitated access to certain pharmaceuticals for developing countries. As far as the environment is concerned, the WTO has received, for the first time, a mandate from its governing body at the November 2001 Doha Ministerial Conference to start certain negotiations on MEAs (Doha Declaration Article 31).[14] Furthermore, in Article 32 the Doha Declaration gives some instructions to the WTO's Committee on Trade and Environment, but here it does not mention MEAs at all except for making a reference to the previous Article. This could indicate more flexibility at the WTO regarding discussions and negotiations of environmental issues other than MEAs, which might leave the door open for a more comprehensive approach toward trade and environment problems.

That would be a positive and overdue trend because the multilateral trade and environment debate which is essentially centered on WTO, UNEP, and UNCTAD as far as intergovernmental organizations are concerned has generally been too much fixated on MEAs and has not given enough considerations to other aspects of the far wider relationship between trade policies and the environment. For instance one may point out in the case discussed here that trade policies such as the WTO agreements governing the application of sanitary and phytosanitary measures in the areas of pesticide residues or GM food standards have an important impact on the expansion of large monocultures and their negative environmental consequences. These kinds of issues are not receiving enough attention in the trade and environment debate.

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[13] WTO, *Ibid.*

[14] Doha Ministerial Declaration, 2001, http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_e.htm

As we can see, the Codex is not only an unusual institution, it is also particularly interesting from the standpoint of the development of public international law because as a joint subsidiary body of the FAO and the WHO with an important overlap with UNEP's CBD and with explicit linkages to the WTO's SPS and TBT agreements it is situated right at the center of the UN-WTO relationship. The study of these issues requires an integrated approach towards the interface between the sciences of ecology on one hand and economics on the other hand. In order to facilitate this integrated approach, and in order to help reconciling diverging priorities I am proposing to use the term *ecolomics* which I consider to be very useful for achieving a better balance in many such situations, particularly in the trade and environment dialogue.

2. The Functioning of the Codex Alimentarius

The Codex Alimentarius is defined as "a collection of international food standards that have been adopted by the Codex Alimentarius Commission (CAC)." It is open to all member nations of FAO and WHO, and it claims to be - correctly, without a doubt - "the most important international reference point in matters concerning food quality."[15] The notion of *international reference point* is very pertinent because it expresses, perhaps better than the more common term 'standard,' the Codex's real nature: Governments and intergovernmental organizations *refer* to the Codex in many ways with regards to international aspects of food safety. It may also be considered as a legal threshold of contamination, for instance in those cases where an importing country is entitled - under WTO law - to ban or restrict the importation of a food product that contains more than the limit of a toxic substance which is specified by the Codex.

The reason why the Codex may be considered as a reference point rather than a standard lies in the fact that the adoption of its food safety threshold values as well as its testing and other laboratory procedures are voluntary for all countries, whether they are members or not, whereas the term standard is often used in the sense of a compulsory benchmark. In other words, it is a voluntary standard, at least as far as the Codex itself is concerned. The fact that especially the negotiators of the SPS Agreement, and also of the TBT Agreement, then went ahead and decided to use these voluntary standards as their decisive criterion to judge whether an importing country's trade-restrictive sanitary or phytosanitary measures are based on science and are therefore justified, or whether such a justification is not fulfilled and therefore the measure is of a discriminatory or protectionist and therefore illegal nature according to WTO law - well, the Codex considers that this is not really its problem. The fact of the matter is, as Cosbey (2000:3) points out, that the WTO connection has very much politicized the Codex:

> ...the language of the SPS has completely changed the character of the Codex. The Commission was originally designed to act as a consensus shop on voluntary standards, which would serve as guidelines to those in need of technical assistance. Its standards were thought to be a useful floor. But the SPS language in effect made Codex standards more like a ceiling, beyond which onerous requirements are in effect. Such standards cannot be called fully voluntary, nor are they fully mandatory, falling into an area in between which looks like voluntarism under duress. The instant

[15] *Understanding the Codex*. 1999, *op cit.,* back cover

> effect was to transform standard setting in the Codex to a highly charged exercise; all countries knew that the standards they were debating might subsequently be the subject of WTO dispute settlement, and acted accordingly.

In legal terms, the Codex is established as a dependent body under Article VI of the Constitution of the FAO (Herwig, 2001:259). This seems clear enough but it doesn't say anything about the legal responsibilities which a government accepts by becoming a member. Law professor Raphaël Romi (2001, p. 205 & 208 considers that its standards, not to mention its guidelines and recommendations, are "normally optional (normalement facultatives)." Indeed, international harmonization which is promoted by the Codex represents only a goal, and it is still far from being accomplished. There is a considerable spectrum of legal constraints in the Codex texts which include, in addition to the standards, other directives such as principles, guidelines, recommendations, or obligations. Romi situates the Codex at the interface between two different sets of rules which he calls legal and technical. He considers this situation as temporary and ambivalent as well as ambiguous, and he admonishes lawyers to accept this reality and to deal with it as it is, as long as major changes are not instituted.

The nature of the Codex negotiations prior to the establishment of the WTO has often been characterized as resembling a Gentlemen's club debating issues of a not very political, essentially scientific nature. The key in understanding the essence of this voluntary nature of a standard which forms the basis of the everything but voluntary SPS Agreement resides in the fact that if an exporting country uses Codex standards as a benchmark for goods its wants to export, it has good reasons to assume that they would successfully overcome a dispute by the importing country due to sanitary or phytosantary concerns. The importing country on the other hand would be hard pressed to challenge the WTO compatibility of goods that meet Codex Alimentarius standards, in fact so far there has never been a case where the WTO's Dispute Settlement Body has ruled against standards based on the Codex although there are no guarantees that this could not happen.

A certain degree of uncertainty remains mainly due to the fact that the Codex not only produces science-based standards but it assumes also an important role in the process of endorsing or sanctioning scientific expertise. The problem here is that the role of the Codex with regards to the ways and means how scientific expertise is brought to bear onto the decision-making process of the Panels of the WTO's Dispute Settlement Body is neither clearly defined nor transparent. This opacity has been (and still is!) playing a very important role in the dispute over beef hormones between the US and the European Commission (Christoforou, 2002 and 2000).

The development of a Codex draft standard is a highly complex process. Proposals for a standard may be initiated either by a national government or by a subsidiary committee of the Codex Commission after discussions by the Codex Alimentarius Commission, or by its Executive Committee. A draft of the proposed standard is then circulated to member governments for comments, and if all goes well, the CAC will adopt the draft which it receives from the responsible subsidiary body. Subsequently, however, procedures become even more technical. The draft is sent to governments a number of times following a process consisting of eight distinct "steps" (Annex I), and steps may be repeated (an accelerated 5-step procedure is also possible). Most standards thus take several years to develop.

Once the negotiation of a standard has been finalized through its acceptance by the Codex Alimentarius Commission, the process of standardization is still far from concluded. The process through which a member country formally accepts a Codex standard – once the negotiation process to establish the standard has been finalized – is also very complex:

> ...in practice it is difficult for many countries to accept Codex standards in the statutory sense. Differing legal formats and administrative systems, varying political systems and sometimes the influence of national attitudes and concepts of sovereign rights impede the progress of harmonization and deter the acceptance of Codex standards.[16]

The acceptance of a Codex standard represents a carefully scripted process which is situated at the very core of the Codex's functioning. It provides a considerable amount of flexibility by leaving member countries some options with regards to the conditions and criterions of adherence. The Codex distinguishes between three levels of *acceptance* of a standard which are summarized as follows:

- 'free distribution' means that products conforming with a Codex commodity standard may be distributed freely insofar as matters covered by the Codex are concerned;
- 'full acceptance' means that products not complying to the Codex standard will be subjected to restrictions;
- 'acceptance with specific deviations' means that the declaration of acceptance contains some detailed reservations made by the importing country.[17]

The Codex does have a medium-term plan for the period of 2003-2007 (Annex II), but it is very doubtful whether even a reasonably effective implementation of the six objectives mentioned will make this situation of ambivalence and ambiguity clearer. The leitmotif of these six points can be summarized as an effort to push forward with the harmonization of food safety standards on a scientific basis. It is very doubtful, however, that Romi's reservations will be alleviated in the near future.

I can see the best chance for the elaboration of a clearer profile or role in the area of the Codex's *legal ambiguity* which results from the Statutes and from the Rules of Procedures of the CAC[18] that don't clearly spell out member countries' rights and obligations. The linkages to the SPS and TBT Agreements are not of much help either because they only enter into force once a dispute is brought to the WTO Dispute Settlement Body. It should certainly be possible to flesh out more clearly, through negotiations in the Codex Committee on General Principles, what exactly the legal implications of the various kinds of directives consist of, i.e. the difference between standards, guidelines, principles and recommendations.

On the other hand I think that it is unavoidable in the final analysis that the Codex in its present form has and will continue to present a considerable degree of *political ambivalence* because of its contradictory mandate of assuring food safety and of facilitating trade:

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[16] *Understanding the Codex*, 1999, *op. cit.* p. 17.

[17] *Procedural Manual.* 2001, eleventh edition, *op. cit.*, p. 32.

[18] See *Procedures Manual, op. cit.,* p. 4-17.

> The highest priority of the Codex Alimentarius Commission, as stated in Article 1 of its statutes, is to protect the health of consumers and ensure fair practices in the food trade. [19]

> Through harmonization, they (The officials and experts... who... determined the direction of ...the Codex Alimentarius) envisaged fewer barriers to trade and a freer movement among countries...[20]

It seems obvious that no matter how the Codex might be transformed, it will always be of an ambivalent nature, some kind of a conceptual oxymoron, as long as it retains this double mandate. As Professor Romi (2001:207) points out, the fulfillment of one of the two objectives will have to be carried out at the expense of the other one. The only alternative would be to limit its mandate to the international harmonization of food safety standards, and to leave the task of trade facilitation in the hands of other organizations. In fact - why shouldn't food safety be its only mandate? Wouldn't the Codex as the UN agency for food safety be more credible and legitimate if it left trade facilitation to other bodies such as obviously WTO, or UNCTAD, or FAO which has a long tradition of facilitating trade in food products? Does it really make sense to put the regulation and the promotion of any important public issue under the same hat? It is obvious that in this scenario the Codex Secretariat would have to be centered primarily at WHO. The fact of the matter is, however, that the international community does not seem to be concerned about these legal and political ambiguities and ambivalences. The thinking seems to be that member countries are aware of these uncertainties, and if it comes to a dispute, well, then let the chips fall where they may.

3. The Management of Scientific Uncertainty

The core business of the Codex Alimentarius resides in the management of risk based on scientific principles and processes in the area of food safety. In other words, it tries to manage something that is inherently very difficult to manage, namely scientific uncertainty. It has undoubtedly managed, in its forty year long history, to impose itself as *the* global authority in this field. It has thus elaborated clearly the most detailed presentation of the risk analysis process that a multilateral organization has ever produced. (Annex III). These definitions give the impression that risk assessment, risk management, and risk communication are essentially separate and distinct components of the wider concept of risk analysis. In reality, however, things are more complex. The key distinction that needs to be made here is that risk assessment refers to the scientific sphere, whereas risk management refers to the political and legal one. The challenge for the Codex lies in managing the relationship between the two.

Without going here into a lengthy discussion of this very complex relationship which has been analyzed in much detail and with real insight and originality by Noiville and de Sadeleer (2001), one may summarize their findings as follows: Assessment and management are by no means two distinct phases of the wider

[19] *Understanding the Codex op. cit. p. 19.*

[20] *Understanding the Codex op. cit. p. 23.*

notion of risk analysis but rather, they are dynamically overlapping in a constant back-and-forth process. Furthermore, the extent to which assessment and management of risk are separated reflects the philosophy of government policy with regards to how the relevant ministries assume their responsibilities with regards to food safety either in a proactive way, or else passively hoping that nothing unplanned will be happening. In a proactive management of risk the ultimate decision makers will make sure that they control the process.

It is fundamental for the understanding of the Codex Alimentarius' risk management process to realize that the Codex is by no means a scientific body carrying out risk evaluations in the various food categories. Instead, it can be considered as a multilateral regulatory agency that *commissions* such evaluations (and, as mentioned, at the same time it promotes freer trade of these same products). The actual risk assessment is carried out by independent experts who are appointed by FAO and WHO, and who are not part of the staff of Codex, FAO, or WHO. The findings and conclusions of these experts represent the foundation of the Codex standards which in turn represent the point of reference for the WTO in adjudicating whether a certain food safety regulation of an importing country is justified, because it is based on science, or whether, to the contrary, its scientificity is questionable and therefore the regulation is considered to be a WTO-illegal protectionist measure.

It is obvious from this method of managing scientific uncertainty that the work carried out by these experts is of the greatest importance in assuring food safety worldwide. This is particularly true since we live in a world in which food is not only more and more traded between countries and continents, but with the conclusion of the Uruguay Round and the WTO's Agreement on Agriculture and the SPS Agreement, food has become subject to essentially the same trade disciplines as any other product as long as it is considered to be safe for consumption based on scientific criteria. The Codex therefore goes to great length in asserting the independence and the qualifications of the experts in charge of scientific risk evaluation. In the case of GM food for instance a call for submission of applications for a roster of experts mentions:

> In the light of the importance of the issues to be addressed by the expert consultations, FAO and WHO attach great value to the technical quality and independence of the participating experts as well as to the transparency of the selection process.
> ...
> Interested applicants should indicate any potential conflict of interest that may affect their independence as experts including: employment (past or present) by any commercial enterprise or private or civil sector association active in the field of biotechnology; recipient of research or other study grants from such enterprises or associations; shareholdings in commercial enterprises active in the field of biotechnology; membership of private or civil sector associations active in the field of biotechnology. Experts appointed to the joint roster will be asked to make such a declaration in writing, and these declarations will be made publicly available.[21]

Nevertheless, in their much-cited *Rapport au Premier Ministre*, Kourilsky and Viney (2000: 164) have concluded that it would be desirable to review the expert

[21] Call for submission of applications for a roster of experts
http://www.who.int/fsf/GMfood/Biocall%20for%20expert.pdf

system of the Codex because it continues to lack transparency, it is not conforming to the scientific principles of independence and of objectivity, and it does not provide opportunities for debates among scientists on controversial issues. The last point is particularly serious because scientific research is characterized to a large extent by controversy and by debates among peers over contentious and contested procedures and results. Since the Codex does not provide information on its extensive web site about *how it manages scientific controversies*, one has to simply take its conclusions for granted without being able to assess to what extent they may be contested in a peer review, and how minority views among these experts are dealt with. In democratically governed countries such practices would not be tolerated at the national level, but these same countries apparently see no major problem with these practices at the multilateral level.

In evaluating food safety, the Codex uses what it calls "A Code of scientifically sound standards.[22]" The term scientifically sound is not as harmless as it may appear, in fact it embodies a fundamental difference of perceptions between competing world views with regards to foods safety, and these views tend to clash with each other in intergovernmental negotiations concerning food safety. On the one side we have the United States, and usually Canada, Argentina and Australia, often joint by some politically less influential countries, who insist that risk assessment is a strictly scientific practice which will yield clear results that deserve the full confidence of the public. In this perspective the results must be used for binding regulations and standards regarding the rights a of country to ban or restrict food imports based on criteria such as the levels of pesticide residues, the percentage of GM food ingredients, or the right of a country to ban domestic as well as imported GM food altogether. This approach is often considered to be based on the notion of "sound science" by its advocates with the result that this term has become a code word in a political sense. It conveys the notion that scientists have fully understood and explained in a neutral fashion their object of investigation. It should be noted, however, that the WTO legal texts don't use any such terms, and in fact it doesn't have any concrete meaning other than maybe diplomatic and political rhetoric.

There are also nuances in the way the word “sound” is used in this context. On one hand we find the very wide and comprehensive notion of “sound science” which implies that all the socio-economic, political and institutional aspects of the scientific process are “sound,” whatever that means. On the other hand there is the more specific term of “scientifically sound standards”[23] which is used by the Codex, and which only refers to a proper scientific process that was used in elaborating the standards without giving any automatic authority or credibility to its wider context. The “sound science” concept covers the complete area of risk analysis including assessment, management and communication, whereas the focus on “scientifically sound standards” seems to be limited to the scientific method used in risk assessment. The Codex Alimentarius does not carry out risk assessment on its own but its realm includes responsibility for risk management and risk communication which may explain this often overlooked difference in the terms used.

The European Union and its member countries (most vigorously probably Germany) defend a different approach to risk assessment. That approach is also based on scientific methodologies but it recognizes that there are cases where the scientific expertise is either strongly divided, or where the level of generally

[22] *Understanding the Codex Alimentarius, op. cit.* p. 3.

[23] *Ibid.*

recognized knowledge is not yet adequate to draw inferences which are solid enough to serve as a criterion on which one can base rulings about the justification of sanitary or phytosanitary trade-restricting measures. In these cases the EU defends the notion that an approach based on the precautionary principle must be an option that a country can adopt. This is a politically sensitive issue over which especially the US and the EU have been and are regularly clashing in different forums such as multilateral negotiations over biosafety regulations, food safety, or the toxicity of chemical products and of hazardous wastes.

The right of a country to take import-restricting precautionary measures in those cases where the results of scientific risk assessment leave important questions unanswered has received a strong support from the adoption of the Biosafety Protocol in January 2000. It does not mention the term 'precaution' except in the preamble and in the introductory objective, but it contains in two operational articles the following language:

> Lack of scientific certainty due to insufficient relevant scientific information and knowledge ... shall not prevent that Party (i.e. the LMO importer) from taking a decision, ... in order to avoid or minimize such potential adverse effects.[24]

The potential decision a country may take which this text refers to of course is nothing else than the application of sanitary or phytosanitary measures which restrict or ban the importation of LMOs. In the often somewhat simplifying political debate we now have a clash over two positions which are often called, perhaps in an unduly stereotyping way, 'sound science' versus 'precaution,' but the fact of the matter is that both approaches are based on medical, biological, chemical and very generally scientific procedures and techniques. It is not exaggerated to say that scientific rigor and precaution are two sides of the same coin, namely dealing with uncertainties concerning the materialization of certain risks to public health of the environment. The difference is simply that the European approach takes explicitly into account that science provides no answers or unsatisfactory answers to certain questions, and it attempts to integrate this incomplete state of knowledge into the regulatory decision-making process. The US approach, on the other hand, tends to assume or to claim that sound science has fully adequate answers to deal with the management of risk, and that the precautionary approach is nothing but a protectionist stratagem. This stance is contradicted, however, by domestic policies in the US which also use precautionary measures to protect public health and the environment.

Scientific rigor and precaution are by no means contradictory or conflicting perspectives or strategies, rather they complement each other. The application of precautionary measures in the EU's tradition of risk management is clearly built upon scientific foundations and is advocated only when and where the inadequate state of scientific knowledge calls for such an approach. No precautionary language has been introduced into the Codex so far due to US resistance, but it is to be expected that the EU will continue to try to make the Codex coherent with the BP in this regard.

Another notion which also looks pretty harmless is the term 'coherence,' but as a result of this conflict, it has become another politically loaded code word in the Codex negotiations, and not surprisingly, it again primarily pits the US against the EU, although it should be stressed that the US is often benefiting from strong support on this issue from developing countries. The US evidently fears that coherence

[24] Cartagena Protocol on Biosfety, *op. cit.,* Articles 10.6 and 11.8.

among multilateral agreements will result in the introduction of precautionary measures into the Codex, and that insufficiencies in the state of knowledge about the impact of GM food on human health will be used by European importing countries to ban or restrict them, or at the very least to make labeling mandatory, which in turn may deter European customers from buying these food products. Those US fears are not unfounded, especially with the present generation of GM crops which on the whole do not offer the consumer any advantage whatsoever except possibly a very minor price advantage. The European public's general rejection of GM products might change, however, once the biotech industry introduces products which provide clear advantages to the consumer, such as prettier looks, better taste, a more convenient shape or whatever (a Mango that is as easy to eat as an apple...). Then again, if the public should become more aware of the potential environmental aspects of GM crops, then the consumers' behavior will be even more difficult to predict.

This struggle over the concept of coherence has entered the negotiations over the most recent amendments of the Procedural Manual. It contains an appendix "General Decisions of the Commission" dealing in condensed form with principles concerning *the role of science* in the Codex decision-making process, and it addresses the extent to which factors other than food safety may be taken into account. At the 24th Session in Geneva in July 2001 a proposed amendment was submitted to delegates containing among other proposals nine points to be added to this appendix.[25] The 7th point, in brackets, read as follows:

> [albeit not within the mandate of the Codex, certain factors may be taken into account, if recommendations of relevant multilateral intergovernmental organizations exist. Codex standards should avoid having a negative impact on the application of such internationally agreed recommendations].

The text of this proposed amendment could be interpreted in the sense, for instance, that the precautionary articles of the BP should be reflected in future changes to the Codex in order to achieve a better coherence with the BP, and especially in order to avoid that the Codex might have a negative impact on the implementation of the BP. This point, however, was the only one out of the nine drafted amendments that was deleted due to strong opposition from the US delegation. This opposition was certainly in tune with the intentions of ICGMA, one of the major lobby groups of the food industry, who argued as follows:

> The specific insistence on the inclusion of "other", non-science factors, or factors unrelated to food safety "not within the mandate of Codex" in the discussion of standards and guidelines setting can only reflect a desire to broaden Codex's criteria in the interest of promoting agendas other than food safety.[26]

The ICGMA is undoubtedly quite correct in its interpretation of this proposed amendment. The intention of the drafters of this paragraph might indeed have been to achieve a common strategy in protecting both biodiversity and food safety through coherent policy measures. Then again - what is wrong with this? In fact it would seem

[25] ALINORM 01/10, dated May 2001, "Consideration of Proposed Amendments to the Procedural Manual of the Codex Alimentarius Commission," 8 p.

[26] International Council of Grocery Manufacturers Associations (ICGMA), Washington, DC, comments faxed 06/20/01, annexed to Codex cover sheet LIM-9 dated June 2001.

that the objectives of biosafety and of food safety are at least as compatible as the objectives of food safety and of trade, which as mentioned are the two objectives that the Codex Alimentarius is quite able to accept as its joint and compatible mandates. This example is an illustration of the difficulties the EU is facing in introducing seemingly obvious concepts like precaution, and coherence with other multilateral agreements, into the Codex Alimentarius. It may also serve as an indicator of the lopsided balance between trade and food safety interests.

4. Conclusions and Outlook

As we have seen in our discussion, the Codex Alimentarius is a very complex mechanism and has become highly politicized recently. Its work in the elaboration of food safety standards which serve as reference points for international trade policy is of great and direct significance to everybody. We shall conclude by looking briefly at a recurring theme in the analysis of the Codex's functioning, namely transparency and balance in the organization's composition and structures.

The Codex Alimentarius has developed procedures for the admission of International NGOs with observer status.[27] It is important to realize, however, that in the context of the Codex negotiations the notion of 'non-governmental' is used very literally and not in the traditional sense of civil society organizations without a profit motive; the NGOs who participate at the Codex negotiations as observers are in their large majority industry associations such as the Biotechnology Industry Organization or the International Organization of the Flavour Industry, and only a handful of "real" NGOs in the usual sense of the term such as Consumers International or Greenpeace. The list of the participating NGOs is included in the List of Participants of the meetings as is usually done for the major meetings of UN bodies.[28] It should be pointed out, furthermore, that many delegations include industry representatives.

There is clearly a problem here, and it is not clear whose fault it is. The active participation of industry representatives is not surprising; however, the scant representation of "real" NGOs who are often considered watchdogs over an organization's transparency is indeed striking, especially in light of the concerns over a lack of transparency which were expressed above. It is not clear, however, whether the Codex makes it difficult for the “real” NGOs to attend the meetings as observers because they have to demonstrate their international nature or - more likely, I suspect - whether civil society has not discovered and realized yet the importance of the stakes being negotiated here. Be that as it may, this very uneven NGO representation is indeed very much part of the Codex's organizational culture and it may explain at least partially the ambiguities and the lack of transparency with regard to the execution of its role as the scientific arbiter in food trade.

Perhaps the most worrisome aspect in the Codex's operations is the general impression that trade interests are given more importance than food safety concerns. In the short or medium term it has to be assumed that a major realignment of these priorities is very unlikely given the constraints of realpolitik. Nevertheless, there is no

[27] Principles concerning the Participation of International Non-Governmental Organization in the Work of the Codex Alimentarius Commission (Procedural Manual 11th Edition, FAO and WHO, 2000). http://www.codexalimentarius.net/Manual/ingos.htm#E9E4

[28] Report of the 24th Session, Geneva, 2-7 July 2001:

ftp://ftp.fao.org/codex/alinorm01/al01_41e.pdf

reason why one should not be able to arrive at a better balance between the two conflicting spheres. That improved balance would at the very minimum require an equal financial participation of FAO and WHO, and with it obviously a considerably strengthened input of WHO, including at least equal participation in the secretariat activities. Such a financial balance of course would not *per se* achieve a better equilibrium between trade and food safety priorities, but it is certainly a precondition. In fact it would represent a precondition which would be relatively easy to achieve in comparison with the more structural modifications outlined above.

WHO officials explain that they have difficulties in allocating substantially increased contributions to the Codex in view of their numerous other mandates and tight budgets, and that in any case a correspondingly increased input in the decision-making process would not be assured. Without quarrelling over the WHO's hierarchy of priorities, it is obvious that the amounts that would be required represent a very small expenditure for the Codex member countries in relation to the wide ramifications and stakes of these food standards. Just 5 million dollars per year would triple the budget of the Codex Alimentarius' secretariat which seems rather incredible in view of the increasing threats to public health arising from the rapidly increasing world-wide trade in food products. The present imbalance is clearly a result of political forces and not of genuine financial constraints. *As long as the WHO is only the junior partner in this joint programme, it will be difficult for the Codex to make a credible claim that it takes a balanced approach between trade and food safety concerns!* In view of the entrenched trade-oriented US position in other intergovernmental forums, even where the US participates only as observers, the outlook is unfortunately not very bright for significant modifications in the foreseeable future.

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Annexes

Annex No. I

UNIFORM PROCEDURE FOR THE ELABORATION OF CODEX STANDARDS AND RELATED TEXTS
Procedural Manual, 2000:21-23
ftp://ftp.fao.org/codex/manual/Manual12ce.pdf

Steps 1, 2 and 3

(1) The Commission decides, taking into account the "Criteria for the Establishment of Work Priorities", to elaborate a World-wide Codex Standard and also decides which subsidiary body or other body should undertake the work. A decision to elaborate a World-wide Codex Standard may also be taken by subsidiary bodies of the Commission in accordance with the above mentioned criteria, subject to subsequent approval by the Commission or its Executive Committee at the earliest possible opportunity. In the case of Codex Regional Standards, the Commission shall base its decision on the proposal of the majority of Members belonging to a given region or group of countries submitted at a session of the Codex Alimentarius Commission.

(2) The Secretariat arranges for the preparation of a proposed draft standard. In the case of Maximum Limits for Residues of Pesticides or Veterinary Drugs, the Secretariat distributes the recommendations for maximum limits, when available from the Joint Meetings of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Core Assessment Group on Pesticide Residues (JMPR), or the Joint FAO/WHO Expert Committee on Food Additives (JECFA). In the cases of milk and milk products or individual standards for cheeses, the Secretariat distributes the recommendations of the International Dairy Federation (IDF).

(3) The proposed draft standard is sent to Members of the Commission and interested international organizations for comment on all aspects including possible implications of the proposed draft standard for their economic interests.

Step 4

The comments received are sent by the Secretariat to the subsidiary body or other body concerned which has the power to consider such comments and to amend the proposed draft standard.

Step 5

The proposed draft standard is submitted through the Secretariat to the Commission or to the Executive Committee with a view to its adoption as a draft

standard.[29] In taking any decision at this step, the Commission or the Executive Committee will give due consideration to any comments that may be submitted by any of its Members regarding the implications which the proposed draft standard or any provisions thereof may have for their economic interests. In the case of Regional Standards, all Members of the Commission may present their comments, take part in the debate and propose amendments, but only the majority of the Members of the region or group of countries concerned attending the session can decide to amend or adopt the draft. In taking any decisions at this step, the Members of the region or group of countries concerned will give due consideration to any comments that may be submitted by any of the Members of the Commission regarding the implications which the proposed draft standard or any provisions thereof may have for their economic interests.

Step 6

The draft standard is sent by the Secretariat to all Members and interested international organizations for comment on all aspects, including possible implications of the draft standard for their economic interests.

Step 7

The comments received are sent by the Secretariat to the subsidiary body or other body concerned, which has the power to consider such comments and amend the draft standard.

Step 8

The draft standard is submitted through the Secretariat to the Commission together with any written proposals received from Members and interested international organizations for amendments at Step 8 with a view to its adoption as a Codex standard. In the case of Regional standards, all Members and interested international organizations may present their comments, take part in the debate and propose amendments but only the majority of Members of the region or group of countries concerned attending the session can decide to amend and adopt the draft.

[29] Without prejudice to any decision that may be taken by the Commission at Step 5, the proposed draft standard may be sent by the Secretariat for government comments prior to its consideration at Step 5, when, in the opinion of the subsidiary body or other body concerned, the time between the relevant session of the Commission and the subsequent session of the subsidiary body or other body concerned requires such action in order to advance the work.

Annex No. II

Excerpt from the Strategic Framework
Addendum II to the Report of the 24th Session, Geneva, 2-7 July, 2002, pp. 82-86.
http://www.codexalimentarius.net/cac24/alinorm0141/appiie.htm#E10E26

STRATEGIC OBJECTIVES AND PRIORITIES

1. The fundamental objective of the Codex Alimentarius Commission is to establish sound internationally agreed guidelines for national food control systems based on the criteria of consumer health protection and fair practices in trade and taking into account the needs and special concerns of all countries. All of the objectives listed below are considered to be equally important to the overall achievement of the strategic vision.

Objective 1:
Promoting Sound Regulatory Framework

1. In many countries, effective food control is undermined by the existence of fragmented legislation, multiple jurisdictions and weaknesses in surveillance, monitoring and enforcement. Sound national food control and regulatory systems are essential to assuring the health and safety of domestic population as well as assuring the safety and quality of foods entering international trade. While the establishment of regulatory framework is fundamentally a national responsibility, the CAC and its parent bodies, the FAO and WHO, have a strong interest in promoting national regulatory systems that are based on international principles and guidelines and address all components of the food chain. The development of sound food control and regulatory infrastructure including human resources is particularly important for developing countries as they seek to achieve higher levels of food safety and nutrition and will require high level political and policy commitment as highlighted in the report of the 1999 Melbourne Conference on International Food Trade Beyond 2000. [Report of the Conference on International Food Trade beyond 2000:Science based Decisions, Harmonization, Equivalence and Mutual Recognition, Melbourne, Australia, 11-15 October,1999, Appendix 1, p.29.] An effective food control system is critical in enabling all countries to assure the safety of their foods entering international trade and to ensure that imported foods conform to national requirements. Successful negotiation of bilateral mutual recognition and/or equivalence also depends on the ability of countries to assure each other of the integrity of national regulatory systems.

2. The priorities for the CAC in the development of international standards and related texts will be to:

• provide essential guidance for member countries through the continued development of international standards and guidelines relating to food safety and hygiene, nutrition, labeling and import/export inspection and certification systems and for the practical application of the concepts of equivalence and mutual recognition ; and

• promote the development of national food control systems based on international principles and criteria for the reduction of health risk along the entire food chain.

Objective 2:
Promoting Widest and Consistent Application of Scientific Principles and Risk Analysis

1. The CAC will promote and further strengthen its capacity to include health considerations in its standards and guidelines through the widest possible application of risk analysis based on Codex principles. Risk analysis as it applies to food, is an emerging discipline and will require ongoing and sustained inputs from the Commission, its parent organizations and national governments to promote

conceptual development and application at the international and national levels. Risk Communication will be vital to this process. The early implementation of the CAC Action Plan on Risk Analysis by the Commission and member governments is essential to:

• promoting the consistent application of risk analysis principles throughout all of the work of Codex system;

• achieve strengthened international capacity for risk assessment including those related to microbiological hazards and dealing with emerging pathogens;

• improving understanding of risk analysis concepts, principles and application at the national level especially for developing countries through targeted technical assistance and cooperation,

• promoting greater transparency of the whole risk analysis process;

• improving understanding of how precaution and scientific uncertainty are factored and taken into account in the risk analysis process;

• strengthening risk communication; and

• promoting the collection of data from developing countries and from all regions of the world so that the risk analysis is based on global conditions and requirements.

2. The CAC will also need to accord high priority to ongoing development of concepts and principles and the establishment of sound working principles for the application of risk analysis both at international and national levels. It should also promote better understanding of risk analysis through technical assistance programmes. A strengthened expert scientific evaluation structure for addressing chemical, microbiological hazards and emerging pathogens will also be critical to support and underpin the Codex standards development processes.

3. Consistent with the Statements of Principle, adopted by CAC in 1995, the Commission will need to have due regard, where appropriate, to other legitimate factors relevant to health protection of consumers and for the promotion of fair practices in food trade when developing standards and guidelines. International consensus on the scope and application of other legitimate factors in Codex decision making will be essential for their sound and consistent application right across the Codex system.

Objective 3:
Promoting Linkages/ between Codex and other Multilateral Regulatory Instruments and Conventions

1. The CAC does not and cannot operate in isolation. It needs to work closely with other relevant international standards setting and regulatory bodies to promote close cooperation and dialogue on matters of common interest. As the WTO-recognized international body for establishing food safety standards the Commission has a clear obligation to establish international food standards for the protection of consumers' health and ensuring fair practices in food trade, and these standards may be used by Member countries in both domestic regulation and international trade. At the same time the Commission needs to interact closely with related international bodies. and take due account of international regulatory initiatives and developments thereby promoting coordination of all food standards work undertaken by international governmental and nongovernmental organizations. Such cooperation is also important to minimize duplication of effort. Food safety and issues such as biotechnology are of global interest and are the subjects of debate and discussion in a number of multilateral institutions. The CAC has, by virtue of its lead role in international food standards, a strategic interest in working closely with relevant multilateral institutions and conventions to provide its technical input and expertise and contribute to building international consensus on contemporary food standards and regulatory policy matters.

Objective 4:
Enhance Capacity to Respond Effectively and Expeditiously to New Issues, Concerns and Developments in the Food Sector

1. With the rapid development of technology and emergence of food safety as a major issue of public policy, there is a need to enhance the capacity of Codex to respond to members' needs in a way that maintains confidence in its ability as the international organization for food standards. There are a number of important considerations in this context. A major issue for Codex is the length of time it takes to establish standards. Codex processes are too protracted and are not responsive to current expectations and public policy imperatives. Governments around the world are having to grapple with significant regulatory challenges and Codex, as the global food standards setting body, needs to be able to respond effectively and expeditiously through the development of internationally harmonized solutions to food safety and international trade matters. A refocusing of the manner in which the Commission and its subsidiary bodies produce outcomes must be a strategic priority. The key functions of a refocused Commission would be to:

• provide strategic oversight, direction and cross coordination of the work programmes of all subsidiary bodies;

• initiate new work and adopt standards and related texts against defined time frames;

• provide a forum for discussion of selected contemporary food safety and regulatory policy issues;

• make appropriate use of information technologies; and

• promote consensus-based decision-making.

2. At the subsidiary body level, major improvements can be achieved through the establishment of time-limited procedures and through a review of the current step procedure. Timely development of standards will also require improved alignment of the timing and frequency of meetings of commodity and general subject committees.

3. As noted in the introductory sections, the parent bodies of the Commission accord high priority to food safety and international standards development programmes. Host governments also provide significant financial support. Ultimately, however, the ability of Codex to fulfil its mandate and respond to the growing needs and expectations of its members will depend on the availability of additional resources. Codex meetings and related activities already represent a heavy workload and further intensification of work will require additional financial and human resources.

Objective 5:
Promoting Maximum Membership and Participation

1. Full participation by all Codex Members and other interested parties in the work of the CAC and its subsidiary bodies is now more important than ever. The participation of all members and relevant intergovernmental and non governmental organizations is critical to sound decision-making and ensuring that Codex standards and related texts take account of the full range of interest and viewpoints. Since the early nineties there has been a significant increase in the membership of Codex with developing countries now constituting a significant proportion of total membership. Notwithstanding this growth in membership many countries are still faced with serious financial and human resource constraints to effective participation in Codex activities. Achieving the objective of maximum participation will require specific and ongoing action to address the following:

• Resource constraints- Early action is required to facilitate the effective participation of developing countries in Codex standards development activities, including financial assistance from extrabudgetary resources where possible;

• Capacity building -There is a continuing need to invest in capacity building programmes, especially in developing countries aimed at strengthening national Codex administrative and consultative structures (e.g., Codex Contact Point and National Codex Committee) and provide for enhancing national capacity for technical analysis and participation in international standards development activities by all interest groups. This requires bilateral or multilateral technical assistance and should include training.

2. In addition to actions to promote participation of member countries, the CAC also needs to continue its efforts to promote and facilitate the participation of consumers and public interest groups in its processes at the international leveland encourage governments to take action at the national level. Given the strong public interest in food safety and regulatory issues, the involvement and input of consumers and non governmental groups at the international and national levels is essential to build public confidence in international standards and assure the strong public input, acceptance and support for Codex standards, guidelines and recommendations as a basis for domestic regulation and trade.

Objective 6:
Promoting Maximum Application of Codex Standards

1. As the pre-eminent international standards setting body for food, the CAC has a clear and strategic interest in promoting the maximum use of its standards both for domestic regulation and international trade. International harmonization based on Codex standards, guidelines and recommendations is essential to promoting a global approach to consumer health protection (including systems for the reduction of food-borne risks) and minimizing the negative effects of technical regulations on international trade. This will require sustained commitment and effort in the following key directions:

• The Statements of Principle on the Role of Science in the Codex Decision-Making and the Extent to which Other Factors are Taken into Account [Codex Alimentarius Commission, Procedural Manual, Eleventh Edition, p.180.] which provide the essential criteria for decision making in Codex, will require strong support and commitment by all countries if the statements are to become operationally effective both at international and national levels;

• Codex must continue to promote the application of sound science and the principles of risk analysis on a consistent basis throughout its work as envisaged in the Commission's Action Plan on Risk Analysis [Codex Alimentarius Commission, Report of 23rd session, Rome, 28 June-3 July 1999, p.10-11.] ;

• Codex processes must be inclusive and transparent and provide for participation and input from all interested groups both at the national and international level. This is particularly important given the interest and concern among Codex members to assure that Codex processes take due account of scientific uncertainties and the element of precaution. Transparency of the criteria and process of risk assessment and decision making will be paramount to achieving this objective;

• The Commission must complete the strategic shift, first signaled at the 1991 FAO/WHO International Conference on Food Standards, Chemicals in Food and Food Trade, towards performance-based standards and guidelines for broad application across a range of commodities and focus on provisions essential for health protection of consumers and for the promotion of fair practices in food trade;

• Codex must ensure that its standards and guidelines reflect the needs and special concerns of the developing world without compromising on the health of consumers;

• Codex decisions should be based on consensus to the maximum extent possible;

• The Codex Alimentarius Commission, whilst acknowledging that food safety standards cannot be compromised, should, when elaborating and deciding upon Codex standards and any related texts, take into consideration the special needs of developing countries including infrastructure, resources, technical and legal capabilities. Codex standards and related texts should not have the effect of creating unnecessary, unjustified or discriminatory obstacles to the exports of developing countries; and

• Codex standards for food quality and safety, including labeling aspects, should be carefully prepared to ensure that they are not over-prescriptive and not more restrictive than necessary.

Implementation of the Strategic Vision and Objectives

1. The strategic objectives described in this document will require a plan of action and implementation strategy. These matters will be addressed within the framework of the Medium Term Plan for 2003-2007.

Annex No. III

Procedural Manual of the Codex Alimentarius Commission: 12th edition, 2001, pp. 43-44.
ftp://ftp.fao.org/codex/manual/Manual12ce.pdf

DEFINITIONS OF RISK ANALYSIS TERMS RELATED TO FOOD SAFETY[30]

Hazard: A biological, chemical or physical agent in, or condition of, food with the potential to cause an adverse health effect.

Risk: A function of the probability of an adverse health effect and the severity of that effect, consequential to a hazard(s) in food.

Risk Analysis: A process consisting of three components : risk assessment, risk management and risk communication.

Risk Assessment: A scientifically based process consisting of the following steps: (i) hazard identification, (ii) hazard characterization, (iii) exposure assessment, and (iv) risk characterization.

Hazard Identification: The identification of biological, chemical, and physical agents capable of causing adverse health effects and which may be present in a particular food or group of foods.

Hazard Characterization: The qualitative and/or quantitative evaluation of the nature of the adverse health effects associated with biological, chemical and physical agents which may be present in food. For chemical agents, a dose-response assessment should be performed. For biological or physical agents, a dose-response assessment should be performed if the data are obtainable.

Dose-Response Assessment: The determination of the relationship between the magnitude of exposure (dose) to a chemical, biological or physical agent and the severity and/or frequency of associated adverse health effects (response).

Exposure Assessment: The qualitative and/or quantitative evaluation of the likely intake of biological, chemical, and physical agents via food as well as exposures from other sources if relevant.

Risk Characterization: The qualitative and/or quantitative estimation, including attendant uncertainties, of the probability of occurrence and severity of known or potential adverse health effects in a given population based on hazard identification, hazard characterization and exposure assessment.

[30] These Definitions are proposed on an interim basis: they are subject to modification in the light of developments in the science of risk analysis and as a result of efforts to harmonize similar definitions across various disciplines.

Risk Management: The process, distinct from risk assessment, of weighing policy alternatives, in consultation with all interested parties, considering risk assessment and other factors relevant for the health protection of consumers and for the promotion of fair trade practices, and, if needed, selecting appropriate prevention and control options.

Risk Communication: The interactive exchange of information and opinions throughout the risk analysis process concerning hazards and risks, 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.

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