



A Forced Evolution?

**The Codex Alimentarius Commission, Scientific
Uncertainty and the Precautionary Principle**

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Introduction¹

Once upon a time, the Codex Alimentarius Commission was an obscure scientific body busily conducting its affairs far from the public eye on issues of little concern to the public at large. No more. This paper surveys the major trends that have transformed this body into a highly politically charged forum, which is attracting ever-greater scrutiny.

The paper begins by laying out the key problem for Codex – scientific uncertainty – and describes the forces that aggravate that problem. It then turns briefly to a summary description of the precautionary principle – the appropriate response to uncertainty. It finishes by proposing a number of evolutionary steps that Codex might take to function better in the changed world in which it finds itself.

While the Codex may no longer be obscure, neither is it widely studied. Therefore, the paper starts with a brief introduction to the organization and its objectives.

The Codex Alimentarius Commission

The Codex Alimentarius Commission was established in 1962 as a joint effort of the U.N. World Health Organization and the U.N. Food and Agricultural Organization. Its current membership is over 160 countries. Its official mandate is to implement the Joint FAO/WHO Food Standards Programme, among the aims of which are:

- “To protect the health of consumers and to ensure fair practices in the food trade;
- To promote coordination of all food standards work undertaken by international governmental and non-governmental organizations;
- To determine priorities and initiate and guide the preparation of draft standards through and with the aid of appropriate organizations;
- To finalize standards.”²

¹ This paper has benefited from two earlier drafts, and the generous comments provided by IISD’s Trade and Investment team and others. The previous drafts were presented at “*Standardization and Certification: Strategies for Growing and Social Responsibility*,” a conference organized by the Instituto Argentino de Normalización (IRAM), May 10 – 11, 2000, Buenos Aires, and at “*Globalization and Democratic Governance*,” at the Hubert Humphrey Institute, University of Minneapolis Campus, June 13 – 14, 2000, Minneapolis.

² Codex Alimentarius Commission. *General Requirements (Food Hygiene)*. Codex Alimentarius (Supplement to Volume 1B). Rome: FAO/WHO, 1997.

The major work of the Commission is to compile the Codex Alimentarius, a 13-volume tome of internationally accepted voluntary food safety standards.³ Codex standards address the hygienic and nutritional quality of food (including microbiological norms), food additives, pesticide residues, contaminants, labelling and presentation, and methods of analysis and sampling. The Codex also includes provisions of an advisory nature: codes of practice, guidelines and other recommended measures. The Commission, served by a six-person Secretariat based in Rome at FAO, meets every two years to adopt new standards, guidelines and recommendations, and to assign new work to its Committees. Over two hundred non-governmental organizations have observer status with the Commission. Most of these are industry representative groups, but there are a handful of public interest groups as well.⁴

The Committees of the Codex do the work of preparing proposed draft standards. Codex produces two types of standards: commodity standards, applicable to specific commodities (for example, processed fruits and vegetables, or fish and fisheries products); and general standards, which are crosscutting and applicable to all types of food, such as food labelling, food additives and food hygiene. For this latter type of standard there are nine “general subject” or “horizontal” Committees, each hosted by a member country responsible for administration, chairing and financial support. The Food Labelling Committee is hosted by Canada, for example, and France hosts the Committee on General Principles. For product-specific standards there are 16 “commodity” or “vertical” Committees, again hosted by member countries. There may be as many as 20 Committee meetings in one year. There are also five regional Committees working on regional standards, and three *ad hoc* intergovernmental task forces with Committee-like responsibilities.

The Committees submit proposed draft standards to the Commission for its consideration.⁵ The Commission then decides whether to adopt them as draft standards. Draft standards go through a consultation procedure with member countries and interested international organizations, involving specified steps

³ Each volume covers a specific area, for example, fish and fisheries products, or methods of analysis and sampling. As well as standards, each volume may also contain general principles, definitions, codes, methods and recommendations. The Codex as a whole contains 237 food standards for commodities, 3274 pesticide residue limits, 41 codes of hygienic or technological practice, 25 guidelines for contaminants and evaluations of 185 pesticides, 1005 food additives and 54 veterinary drugs.

⁴ For a complete listing of observer status groups, see

http://www.fao.org/waicent/faoinfo/economic/esn/CODEX/Manual/org_list.htm.

⁵ The Codex procedural manual uses “standards” as a shorthand for the various products of the Codex Alimentarius Commission, including general and commodity standards, guidelines, principles, recommendations, etc.

(ranging from 5 – 8, depending on the circumstances) and usually lasting several years. If the process is successful, the draft standard becomes a Codex standard and is added to the Codex Alimentarius. Even after adoption, Codex standards are voluntary, though most countries choose to accept most standards.

The Codex takes great pains to focus its work on a foundation of scientific inquiry.

“The food standards, guidelines and other recommendations of Codex Alimentarius shall be based on the principle of sound scientific analysis and evidence, involving a thorough review of all relevant information, in order that the standards assure the quality and safety of the food supply.”⁶

Codex members rely on outside help in this regard. There are two standing expert groups that feed the Codex process: the Joint FAO/WHO Expert Committee on Food Additives and the Joint FAO/WHO Meeting on Pesticide Residues, established in 1955 and 1963 respectively. On standards not related to these two areas, Codex convenes expert consultations on an *ad hoc* basis. Both the expert groups and the consultations make recommendations to Committees on proposed draft standards.⁷

The Problem of Uncertainty

Despite its expert mechanisms, the Codex increasingly faces a critical problem: scientific uncertainty. This basic problem is not new; mankind has been making policy decisions under uncertainty in one form or another for as long as we have existed. Since nothing can be definitely proven by science – we merely operate on the hypothesis that best fits the facts at any given time – any standard setting or regulatory body makes such decisions on a regular basis.⁸ This paper argues, though, that the problem is getting worse, and that it may be bad enough to warrant institutional change.

There are at least four trends that are aggravating the problem for Codex:

1. Growth of new technologies
2. Increasing environmental degradation, and public concern
3. Explosive growth in world trade

⁶ Decision of the 21st Session of the Commission, 1995.

⁷ On matters related to dairy products, recommendations are made by the International Dairy Federation.

⁸ Abstract sciences such as mathematics can, in fact, prove hypotheses. Physical sciences are not similarly capable.

4. Institutional change brought on by the WTO's SPS Agreement

Growth of new technologies. The last decade has seen enormous growth in new technologies and products of interest to standard setters, particularly in the biotechnology and chemicals sectors. The speed of that growth has been such that we have not been able to assess the human health and environmental implications of a number of the new innovations on which we now rely. Of the 70,000 chemicals in commercial use in the United States in 1995, only 2% had been fully tested for human health effects, with 70% not tested for health effects of any kind.⁹ And testing on synergistic effects – the effects of more than one chemical encountered in combination – are almost non-existent. Neither have the food products of biotechnology begun to be rigorously tested, particularly in the US where they are assumed to be substantially equivalent to the unmodified varieties. The result is a widening gap between the progress of innovation and the progress of assessment. The larger the gap, the larger the degree of uncertainty with which the regulatory and standard-setting bodies will have to deal in discharging their responsibilities.

Increasing environmental degradation: The most recent UNEP survey of the global environment confirms that on almost every indicator of environmental quality we have made little progress in slowing the continuing degradation of the natural environment.¹⁰ This has led to increasing public concern about both the state of the environment and human health implications. These trends translate into increased demands on standard-setters and regulators to protect the public interest.

But the environment is, in most of its manifestations, too complex for science to yield certainties as the basis for regulation or standard setting. Climate change is an excellent example: despite the diligent efforts and years of work by what may be the largest collective scientific effort in human history, including but not confined to the 200 member Intergovernmental Panel on Climate Change, we still have no hope of fully understanding the complexities of the interactions of the atmosphere, the oceans and greenhouse gases. This type of complexity is the rule, rather than the exception, in ecosystems. An increasingly urgent need for action in the area of the environment, then, forces regulators and standard setters to increasingly deal with uncertainty.

Explosive growth in world trade: Since 1950, the gross world product has increased by a factor of five, while world trade in that time has increased by a

⁹ *Rachel's Environment and Health Weekly*. Environmental Trends, Issue #613, August 27, 1998.

¹⁰ United Nations Environmental Programme. *Global Environmental Outlook 2000*. UNEP: Paris, 1999.

factor of fourteen. So internationally traded goods constitute a larger and larger portion of our economies. In a globalized world, the importance of national level standards is intensified. In the context of sustainable development, those whose PPM-based standards are lower than others are suspected of creating pollution havens to attract investments, and those whose standards are higher are suspected of using standards as a strategic barrier to trade, unfairly protecting domestic producers. As trade volumes grow, the commercial implications of any standards decision become that much greater.

The WTO's SPS Agreement: The World Trade Organization was created in 1995, taking under its umbrella the various agreements existing around the General Agreement on Tariffs and Trade, and various new agreements resulting from the Uruguay Round of multilateral negotiations. One of these new agreements was the Agreement on Sanitary and Phytosanitary Measures (SPS). In this agreement, Codex was named as one of five recognized bodies for setting international standards. With the stroke of a pen, in an agreement not of its own making, the Codex was thus fundamentally changed.

The SPS Agreement places a number of restrictions on domestic standards to protect human, plant and animal life and health. The measures in question should not be more trade-restrictive than necessary to achieve their objectives, nor should they be applied so as to create arbitrarily different treatment for comparable situations, either domestically or between countries. They should not be applied in such a way as to create disguised barriers to trade and, with limited exceptions for interim measures, must be based on scientific principles and not maintained without sufficient scientific evidence. This is a tough list of requirements, but the SPS Agreement allows that it can be completely avoided by countries that follow international standards – in this case, Codex standards.¹¹

For this reason, the language in the SPS 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 by many to be a useful floor,¹² but the WTO language in effect made Codex standards more like a ceiling, beyond which onerous requirements are in effect. Such standards cannot be

¹¹ "Sanitary or phytosanitary measures which conform to international standards, guidelines or recommendations shall be deemed to be necessary to protect human, animal or plant life or health, and presumed to be consistent with the relevant provisions of this Agreement and of GATT 1994." WTO SPS Agreement, Article 3 (2).

¹² "In October 1960, the first FAO Regional Conference for Europe crystallized a widely held view when it recognized: 'The desirability of international agreement on *minimum food standards* and related questions (including labelling requirements, methods of analysis, etc.).'" Quoted in FAO, *Understanding the Codex Alimentarius*, in explaining the origins of the Codex. (emphasis added)

called fully voluntary, nor are they fully mandatory, falling into an area in between which looks like voluntarism under duress. The instant effect was to transform standard setting in the Codex into a highly charged political exercise; all countries knew that the standards they were debating might subsequently be the subject of WTO dispute settlement, and acted accordingly.

It would be a mistake for those in other standard setting bodies to think that this particular driving factor only applies to the Codex. It will undoubtedly manifest itself in other contexts as well. For example, it is likely that some governments in the process of greening their procurement practices will simply rely on existing regimes, such as national level ecolabel schemes or ISO 14001, instead of establishing their own standard, certification and verification practices.¹³ Such standards would, in that case, no longer be completely voluntary – they would become government-mandated conditions of sale for a substantial portion of the markets in question. They would be voluntarism under duress.

In summary, the basic problem of uncertainty has been aggravated for Codex, first by the advent of new technologies and the rise of environmental concern, which ensure that the Commission will deal increasingly with uncertain science, and second by the language of the SPS and the explosion of international trade, which raise the stakes in any such dealings.

The Precautionary Principle

IISD and others have argued that the proper response to uncertainty is precaution.¹⁴ This is an easy enough prescription to recommend, but a devilishly difficult one to implement, as many are now discovering. In the first quarter of the year 2000 alone, there was a torrent of precedent-setting initiatives aimed at operationalizing aspects of the principle. The Codex itself is now considering draft working principles for risk analysis, in which there is text on the precautionary principle.¹⁵ It has formed an Ad Hoc Task Force on Foods Derived from Biotechnology, after failing to reach consensus on the labelling of food containing LMOs.¹⁶ The European Union released its draft interpretation of the precautionary principle.¹⁷ The OECD, on instruction from the G-8 heads of state,

¹³ Most likely would be a reliance on the standards laid out by a particular certification scheme, rather than an outright requirement that an importer be certified. The pressures on the standard-setters would be the same in either case.

¹⁴ See IISD, 1994, *Trade and Sustainable Development Principles*, esp. the section on science and precaution.

¹⁵ See Codex Alimentarius Commission document CL 2000/12-GP.

¹⁶ See “Codex Biotech Task Force Sets Work Programme,” *Bridges*, March 2000, p. 10.

¹⁷ Commission of the European Communities, “*Communication from the Commission on the Precautionary Principle*,” COM(2000)1, Brussels February 2, 2000.

convened a meeting in Scotland in February to consider the scientific and health aspects of food safety (and recommended the creation of an international consultative panel on GM foods)¹⁸ and has produced two compendia describing national and international food safety systems and activities respectively.¹⁹ The national compendium includes specific sections on how governments apply precaution. The WTO's SPS Committee released a non-binding set of guidelines in March for the implementation of Article 5.5, on achieving consistency in the regulation of different types of risks.²⁰ And the Cartagena Protocol on Biosafety, signed in January, is basically an operationalization of the precautionary principle in the context of traded LMOs.²¹

What exactly is the precautionary principle? A standard formulation, given in the Rio Principles, reads as follows,

“Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation.”²²

This formulation calls on nations to apply the principle widely “according to their capabilities,” adding a too-often missed development dimension to the approach. The problem is that, like the term sustainable development, it means many things to many people. Nonetheless, it has been used and described in enough contexts that it is possible to draw out common themes, some of which are more relevant than others to the work of standard setting bodies such as Codex.²³ The most common are:

- (i) *Preventative anticipation*: We should be willing to take action (regulatory or fiscal measures) in advance of full scientific proof of its necessity.
- (ii) *Room for error*: Because we are dealing with complex systems, a deliberate margin for error should be left open.

¹⁸ See the OECD reports from the meeting at

<http://www.oecd.org/subject/biotech/edinburgh.htm>.

¹⁹ Available on line at http://www.oecd.org/subject/biotech/g8_docs.htm.

²⁰ See “WTO Works out New SPS Guidelines without Legal Status,” *Inside U.S. Trade*, April 7, 2000.

²¹ See Aaron Cosbey and Stas Burgiel, “The Cartagena Protocol on Biosafety: An analysis of results,” International Institute for Sustainable Development: Winnipeg, 2000. Available on line at <http://www.iisd.org/pdf/biosafety.pdf>.

²² Rio Declaration on Environment and Development. Principle 15. The Rio Declaration was one of the products of the 1992 United Nations Conference on Environment and Development.

²³ See, for example, Carolyn Raffensperger and Joel Tickner (eds.), *Protecting Public Health & the Environment: Implementing the Precautionary Principle*. Washington, D.C.: Island Press, 1999; and D. Freestone and E. Hey (eds.), *The Precautionary Principle in International Law*. Kluwer, 1996.

(iii) *Proportionality of response*: The cost of proposed measures must not be out of proportion with the expected benefits (which include costs avoided).

(iv) *Onus of proof*: The onus of proof should be on the proponent of any new product, project or technology, to provide an adequate level of evidence of its safety.

(v) *A search for greater certainty*: Any precautionary measures taken must be accompanied by a search for greater scientific certainty, and periodic re-evaluation of the measures in light of new evidence.

(vi) *Openness of process*: There must be transparency in the process of decision-making, timely distribution of information, and mechanisms for input from all those affected.

(vii) *Emphasis on finding alternatives*: If alternative products or technology exist that have the same valuable qualities without the same risks of negative effects, the alternatives are to be preferred.²⁴

The precautionary principle is solidly founded in the theory of social welfare economics, where it is used to deal with the problem that future costs -- even catastrophically large ones -- become insignificant to the calculations of the present generation when they are subjected to normal rules of discounting and risk.²⁵ And some have argued that it is now an accepted principle of international law, being enshrined in agreements such as the Maastricht Treaty, the Rio Declaration and the Cartagena Protocol, among others.²⁶ But the problem lies in putting the principle into practice. It involves balancing the risks of inaction against the costs of action, continually striving to improve scientific certainty in the knowledge that such certainty is impossible, and making policy that reflects all of the above.

The Cartagena Protocol on Biosafety breaks the approach down into two distinct steps: risk assessment and risk management. Risk *assessment* is the practice of applying scientific inquiry as rigorously as possible, to produce what answers can be found about the risks involved. Good risk assessment should also tell us something about how uncertain its calculations are, and about how sensitive its

²⁴ This guideline is not as applicable in the context of standard setting as it is in the context of domestic permitting where the decision is whether or not to approve a project or a new product.

²⁵ See Charles Perrings, 1997, "Reserved Rationality and the Precautionary Principle: Technological Change, Time and Uncertainty in Environmental Decision-making," in Charles Perrings, *Economics of Ecological Resources*, Edward Algar: Cheltenham, UK.

²⁶ See James Cameron, "The Status of the Precautionary Principle in International Law," in Timothy O'Riordon and James Cameron, 1994, *Interpreting the Precautionary Principle*, London: Earthscan. Also see the submission of the European Union in the Appellate Body Report, WTO Beef-Hormone case, AB-1997-4, para. 16. Note that there is not international consensus on this argument.

results are to changing the assumptions used. The Codex also stresses the separation of the two processes in its *Statements of Principle Relating to the Role of Food Safety Risk Assessment*: "There should be a functional separation of risk assessment and risk management, while recognizing that some interactions are essential for a pragmatic approach."²⁷

Risk assessment, however, has something of a bad name among some scientists and most environmentalists, based on its inappropriate and clumsy application in practice. Santillo, Johnston and Stringer, for example, argue that,

In practice, risk assessment tends to employ simplistic and subjective assumptions about ecosystem structure and the flows of energy and matter that characterize them. Frequently they lack the breadth and quality of data necessary to facilitate prediction of impacts. Uncertainties and indeterminacies arising from ecosystem complexity are rarely made explicit.²⁸

More pointed is the assertion by a respected environmental analyst: "Risk assessment is the most powerful intellectual tool that the poisoners and destroyers of the planet have ever invented. ... It provides "cover" for just about any damaging activity that anyone might want to undertake."²⁹

The discussions and recommendations on risk assessment in this document refer (perhaps naively) to risk assessment properly practiced. Even Santillo *et al.* qualify their arguments by noting that "Scientific analyses and deductions undoubtedly serve policy makers with valuable information, and this can be used to identify hazards and to prioritize and guide decisions of a more precautionary nature."

Risk *management* is the overall exercise of policy making, which some define as including the risk assessment process. It builds on the results of risk assessment by making policy – for example, setting standards or enacting regulations. Risk management is, in the end, a political exercise -- all the costs, benefits, and probabilities that feed it are uncertain estimates. The resulting final policy

²⁷ Decision of the 22nd Session of the Commission, 1997.

²⁸ David Santillo, Paul Johnston and Ruth Stringer. "The Precautionary Principle in Practice: A Mandate for Anticipatory Preventative Action," in Raffensperger and Tickner (eds.), 36 - 50, *supra* at 16. For documented examples of shockingly shoddy risk assessment in the practice of regulatory approval of GMOs, see Chuck Benbrook and Steve Suppan. "Applying the Precautionary Principle in Assessing Transgenic Corn Technologies in the U.S.," paper presented at the conference "Globalization and Democratic Governance," Hubert Humphrey Institute, Minneapolis, June 13 - 14, 2000.

²⁹ *Rachel's Environment and Health Biweekly*. Modern Environmental Protection (Part 3), Issue #706, August 17, 2000.

involves the balancing of interests between present and future generations, among interest groups in the present, and among national economies. The problem from a trade perspective is that this process must involve giving domestic level policy makers a certain amount of discretion to make decisions based on the balancing of competing public interests, and on judgments about risk aversion. But the system of multilateral trade rules is more or less about trying to *remove* discretion from national level policy makers, since it is assumed that such discretion will be eventually used for protectionist purposes.

Two examples might help illustrate the difficulties of operationalizing the precautionary principle. The WTO dispute that dealt most clearly with the precautionary principle to date is the so-called beef-hormones case.³⁰ It is common practice in the U.S. and elsewhere to treat livestock with hormones in order to promote growth and enhance milk production. Public outcry surrounding some initial studies linking the hormones used in meat production to various forms of cancer, declining male fertility and early onset of puberty in children, led to a European Community law³¹ strictly regulating the use of certain types of hormones, and banning intra-European and import trade in such hormone-treated beef. This ban came into effect January 1, 1989, effectively blocking beef imports from the U.S. and Canada. In April 1996, the U.S. requested a dispute settlement panel, and Canada followed suit in October.

The EU argued in part that its ban was based on the precautionary principle, since some studies had indeed suggested that the hormones involved might be harmful.³² Canada and the U.S. argued in part that the EU measure was not based on scientific principles; not enough research had been done to warrant the ban. The EU lost both the dispute panels and the appeals in this case but, because of widespread public concern over food safety in the Community, it has not yet complied with the WTO rulings handed down in January 1998, and is awaiting the results of new research.

Shortly after the ruling, Codex attempted to set standards for the use of beef hormones. It failed in this task, as might be expected.³³ With the U.S. and the

³⁰ Formally known as: European Community - Measures Concerning Meat and Meat Products, 1997.

³¹ Council Directive 85/649,28 Prohibiting the Use in Livestock of Certain Substances Having a Hormonal Action. O.J. Eur. Comm. (no. L382) 228, 1985.

³² It is interesting to note that the EU chose not to defend its actions using Article 5.7 of the SPS, which allows for provisional measures in the absence of sufficient scientific evidence. Rather, it argued that the available evidence was in fact sufficient to warrant the ban.

³³ "The 22nd Session of the Codex Alimentarius Commission suspended the consideration of the adoption of the MRLs for Bovine Somatotropins (BST) pending the re-evaluation of scientific data by JECFA and the CCRVDF and the examination of the application of the 'other legitimate

EU embroiled in high-stakes litigation over the safety of these substances in the WTO setting – the U.S. government estimates that the EU law costs its livestock industry \$145 million per year – who would imagine that they could possibly come to a negotiated consensus in a setting such as Codex?

An issue with even larger stakes is raised by the case of trade in genetically modified livestock and fish, and foods that are produced from, or that contain, genetically modified organisms such as tomatoes, grains or oil. The issue here is whether and how to label such products, as distinct from the labels required of the non-genetically modified equivalents. Trade in such goods is huge and increasing, and trade frictions intense. The EU, again on the grounds of precaution, has restricted access to its markets for a number of strains of genetically modified food commodities, including corn and soy.³⁴ The financial implications are enormous; U.S. exports of soybeans to the EU plummeted from 11 million tons in 1998 to 6 million tons in 1999, while American corn shipped to Europe dropped from 2 million tons in 1998 to 137,000 tons in 1999, with a combined loss of nearly one billion dollars in sales for US agriculture.³⁵ And in countries all around the world, disparate labelling regimes are springing up to cover GMOs and products thereof.³⁶

Again, the Codex has attempted to set standards in this area. Its Committee on Food Labelling was unable to reach consensus on recommendations for the labelling of processed foods containing genetically modified organisms, and in March 2000 created the afore-mentioned Ad Hoc Task Force on Foods Derived from Biotechnology, with a four year mandate. Again, the inability to come to such an agreement is not surprising, given the large commercial interests at stake. GMO producers and processors claim that their products are substantially equivalent to unmodified varieties, and that discriminatory labels will mislead consumers into thinking differently. As well, labelling regimes for GM products will cause producers to either segregate their GM and non-GM products – a costly proposition – or label them all as possibly containing GM elements, which would probably result in loss of market share and lower prices.

factors' in relation to BST by the Committee on General Principles." ALINORM 99/21 Part 1, Addendum 2, May 1999.

³⁴ All GM corn (maize) and soy must be labelled as such, according to regulation 1139/98. And, since June 1999, there has been an effective moratorium on approvals for new GMOs.

³⁵ Brian Halweil, "Portrait of an Industry in Trouble", Worldwatch News Brief, 17 February 2000. <http://www.worldwatch.org/alerts/000217.html>.

³⁶ For an excellent summary of the various current international initiatives, see Simonetta Zarrilli, *International Trade, Human Health, and Environmental Protection: Some Concerns from the Developing World Related to International Trade in Genetically Modified Organisms*. Geneva: UNCTAD (forthcoming).

The Evolution of Codex?

Both of these cases are examples of uncertainty of science, aggravated by the trends listed previously, plaguing the normal workings of a standard setting body. It was previously suggested that they are not isolated examples, but rather the warning shots from an approaching armada of difficulties. These trends argue for an evolution of the Codex, based in part on some of the most relevant elements of the precautionary principle:

1. A focus on risk assessment and guidelines, as opposed to risk management.
2. An ongoing search for greater scientific certainty.
3. A reversal of the onus of proof.
4. A greater degree of openness.

To suggest the types of changes outlined below is not to underestimate the substantial resistance they would meet in Codex's members and in the Secretariat. Nonetheless, the argument made here is that the Codex should choose constructive voluntary change now, to spare itself painful involuntary change later.

1. A focus on risk assessment and guidelines, as opposed to risk management.

The beef hormones case is an excellent example of the difficulties Codex will face if it attempts to conduct risk management – which includes the setting of standards – in the context of uncertain science and high stakes trade. Risk management is a political task, and even given the same basic data it will result in different outcomes in different countries with different social priorities and traditions of science assessment.³⁷ The U.S., for example, is unique in that it has a public policy of accepting “zero risk” of carcinogens.³⁸ The European Union, for its part, must respond to a public with a particularly poignant concern over food safety issues. Similarly, while the human health risks of leaded gasoline have been known by all governments for decades, individual governments decided at very different times that those risks warranted removing lead (some still have not done so).

Codex would play a more useful role if, instead of trying to set standards in such cases, it provided support for risk management, leaving final judgments up to

³⁷ See Konrad von Moltke, “The Precautionary Principle, Risk Assessment and the World Trade Organization,” Winnipeg: International Institute for Sustainable Development, *forthcoming*.

³⁸ Originally inserted into the U.S. Food Additives Amendment of 1958 (and amended in 1996 to exclude pesticides), the operative legislation – the “Delaney Clause” – read: “No additive shall be deemed to be safe if it is found to induce cancer when ingested by man or laboratory animals or if it is found, after tests which are appropriate for the evaluation of the safety of food additives, to induce cancer in man or animals.”

national-level authorities. Given that any standards it sets are now forced voluntarism, such a role fits more closely with Codex's original mandate to serve those with limited technical capacity for standard setting. An agreement to disagree (if even only temporary) would mean that countries wanting to exercise precaution would not be forced by WTO rules to justify exceeding internationally agreed upon standards, as none exist.³⁹

The Codex has taken tentative steps in this direction. Its Committee on General Principles is now considering a draft set of working principles for risk analysis.⁴⁰ As defined in the draft, risk analysis includes risk assessment, risk management and risk communication. Granted, the principles are designed to give guidance to the Codex in setting standards, something that this paper argues against, but they might also be of use to domestic-level policy makers. Note that it is not clear whether the draft principles will survive –they may deal too directly with the notion of precaution for some countries, and the U.S. is facing strong industry pressures to withdraw its support for the draft.⁴¹

The need for such an approach in any particular case could be defined by Codex as the inability to achieve consensus after a given number of attempts by prescribed means.

2. An ongoing search for greater scientific certainty.

Should the Codex Commission take the course advised above, it will eventually have a list of areas in which it has declined (for the time being) to set standards, but is instead offering support to domestic level risk managers. One key feature of that support should be the continuing search for greater scientific certainty. It was noted above that one of the themes common to most approaches to the precautionary principle is the implementing of interim-type measures that respond to the results of ongoing research. The WTO's SPS Agreement, for example, states

In cases where relevant scientific evidence is insufficient, a Member may provisionally adopt sanitary or phytosanitary measures on the basis of available pertinent information, including that from the relevant international organizations as well as from sanitary or phytosanitary measures applied by other Members. In such circumstances, Members shall seek to obtain the additional information necessary for a more

³⁹ Countries would, of course, still be bound by the strictures of the SPS Agreement, but the inability of Codex to reach agreement on an international standard might conceivably give a WTO member a slightly stronger argument to back its precautionary measures.

⁴⁰ See Codex Alimentarius Commission document CL 2000/12-GP.

⁴¹ See "U.S. Split on Approach to Precautionary Principle in Codex," *Inside US Trade*, Vol. 18, No. 17 - April 28, 2000.

objective assessment of risk and review the sanitary or phytosanitary measure accordingly within a reasonable period of time.⁴²

This is, however, a limited approach to the necessary ongoing search, since it assumes that the “right” answer will be found by scientific endeavour “within a reasonable period of time.” The basic assumption propelling the need for an ongoing search is that there can never be a “right” answer, and that measures taken pursuant to the precautionary principle will need to be continuously revisited in light of new evidence.

The search for additional information – in essence an ongoing exercise in risk assessment – might be carried out by the Codex’s Joint FAO/WHO Expert Committees. The stated goal of such actions should be to contribute to attempts to reach consensus within Codex. As such, there would need to be mechanisms whereby special issues of contention could be revisited as new and significant scientific evidence became available.

3. A reversal of the onus of proof

Another theme common to most approaches to operationalizing the precautionary principle is some sort of reversal of the onus of proof. In the Cartagena Protocol on Biosafety, for example, the party proposing to export a living modified organism can be asked by the potential importing party to undertake and finance risk assessment studies.

There are a number of ways in which this approach might be adopted in the Codex process, beginning with its adoption in the draft working principles for risk analysis, where it does not currently appear. It might be applied, for example, in the question of labelling for GM livestock and fish, and processed foods derived from GM products. There is currently debate about whether these foods should in fact be labelled as such at all, with opponents arguing that they pose no health or environmental risks not posed by their unmodified equivalents. A reversed burden of proof would force those so arguing to offer convincing evidence to this effect, rather than demanding evidence of harm.

4. A greater degree of openness.

Openness comprises two elements: timely availability of documents and information, and mechanisms for public input in the decision-making processes. It is not, of course, necessary to preach the virtues of openness to most standard setting bodies; they have for many years granted special status to non-governmental organizations such as consumer groups. But it is worth briefly

⁴² See SPS Agreement, Article 5.7.

recapping the arguments for openness, if only because the Codex has traditionally been less open than other such bodies.⁴³

Openness serves two major purposes. First, it improves the quality of the decisions that incorporate it. This may be particularly true in the context of decisions that involve negotiations among politically motivated parties, who will typically bring to the table only that portion of the available scientific evidence that supports their positions.

Second, it gives the results of the process legitimacy in the public eye. This will be particularly important for food safety issues where precaution is deemed warranted, as these are typically issues about which the public has strong opinions. Institutions ignoring these types of opinions run a serious risk, as we have seen in the experience of the OECD's failed MAI negotiations, the WTO's failed Seattle Ministerial, and the failure to gain fast track negotiating authority in the U.S.

Conclusions

There is currently no international body operationalizing the precautionary principle in the area of food safety. The need for such a body is shown by the difficulties Codex has faced in cases such as beef hormones and the labelling of foods derived from biotechnology. This paper has argued that such cases are only the beginning of an increasing number of high stakes cases of uncertain science to be faced by bodies such as Codex.

The job, then, is open. The question is whether Codex wants it, given that it will involve the types of institutional evolution described above: a move away from standard setting and toward support for risk management at the national level; an ongoing search for greater scientific certainty; a reversal of the burden of proof; and greater openness of process. It is difficult to imagine an alternative to taking the job, if the analysis here is correct and such cases become more and more frequent. The Commission will quickly lose credibility if it allows itself to be torn apart repeatedly by political fighting that produces no results. That said, institutional change of such a fundamental nature is difficult to effect.

If it does choose to evolve, Codex would be well advised to do so quickly, without waiting to be moved by a crisis. In the words of one analyst:

⁴³ See Natalie Avery, Martine Drake and Tim Lang, *Cracking the Codex: An Analysis of Who Sets World Food Standards*. London: National Food Alliance, 1993.

“Nothing could be worse than to undertake the necessary debate [over how to operationalize the precautionary principle] at the international level in the context of a specific decision. That creates a situation in which one party wins while another loses – distributive bargaining – whereas there is urgent need for a framework that all concerned can recognize as contributing to some important policy goal.”⁴⁴

Codex is not alone in facing the thorny issues of uncertainty in standard setting and regulation. Other standard setting bodies will come up against the same basic issues, reshaped by their particular circumstances. The purpose of presenting this example is to give those bodies a warning, perhaps thereby contributing to timely and productive institutional change.

⁴⁴ See Konrad von Moltke, *supra* at 37.