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EXCESSIVE "PRECAUTION" THREATENS FOOD CONSUMERS AND FOREIGN TRADE

by

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The "precautionary principle" is steadily making its way toward the highest levels of international trade and food safety policy — and shows few signs of faltering. The negotiation of the Cartagena Protocol on Biosafety in January 2000 first drew international attention to the principle's regulatory leap from environmental risk assessment to food safety regulation. Since that time food industry organizations, food safety regulators, and international trade officials have watched as the precautionary principle emerged in the deliberations of the Codex Alimentarius Commission (Codex), the legislation of the European Union (EU), the negotiation of international trade, and the food safety regulations of developing countries. Without a concerted effort on the part of industry and government around the world, the precautionary principle may soon be integrated into the international trade agreements that form the backbone of the World Trade Organization (WTO). If this misapplication of the precautionary principle is permitted, it could result in severe consequences for the science-based regulation of food safety and the global food market.

THE EMERGENCE OF THE PRECAUTIONARY PRINCIPLE

The concept behind the precautionary principle was introduced in Europe in the early 1970's as a "precautionary approach." The precautionary approach was intended to provide environmental risk managers with a tool for decision-making with regard to extraordinary environmental threats. It has since been inserted into a variety of environmental regulatory schemes and is now embedded in the regulations of the EU, the legislation of Canada, and several international environmental agreements.

Precaution in general is certainly integral to responsible business practices and serves as a foundation for most contemporary health and environmental regulation. The activities of risk assessment and risk management are inherently precautionary in character and in situations where science cannot yet provide a full or appropriate response to concerns about the significant or irreversible impacts of a certain activity or technology, precautionary action is still appropriate. However, the misapplication or misinterpretation of precaution can adversely impact society by unnecessarily depriving whole populations of potential improvements in human health, environmental quality, and quality of life.

THE MISAPPLICATION OF THE PRECAUTIONARY PRINCIPLE

In fact, there is a distinct difference between the use of precaution in risk analysis and the "precautionary principle." Over the past two years, the EU has ignored this distinction and adopted the principle as a focal point in their food safety policy and in related international negotiations, including those at the Codex Committee on General Principles (CCGP). The EU has pointed to both the Sanitary and Phytosanitary (SPS) Agreement of the WTO and the Rio Declaration on Development and the Environment

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(Rio Declaration) as the basis for its insertion of the precautionary principle into food safety regulation. Article 5.7 of the SPS Agreement does provide for the use of precaution, specifying that where scientific evidence is "insufficient" to establish safety, members may adopt provisional measures. Likewise, Principle 15 of the Rio Declaration on Development and the Environment states that "lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation. However, in its February 2000 Communication on the Precautionary Principle, the EU melded the mention of precaution in risk analysis in the SPS Agreement, and the international environmental approach to precaution in the Rio Declaration to inappropriately expand the concept of "lack of full scientific certainty" to food safety policy.

But the application of the precautionary principle to environmental risk assessment is not necessarily analogous to the use of precaution in the safety assessment of food and food ingredients. The principle has been used historically as a standard for managing environmental risks. Unlike many environmental risks, the risks associated with food products and food ingredients are well known, usually minimal in nature and scope, and not persistent in duration. The focus of food safety assessment should be on the occurrence of severe and quantifiable adverse conditions and effects, and such decisions should be made on the basis of proper scientific evaluation, rather than political concerns motivated by unsubstantiated fears or biases.

THE ROUTE TO THE WORLD TRADE ORGANIZATION

The Cartagena Protocol on Biosafety. As noted earlier, the negotiation of the Cartagena Protocol on Biosafety first introduced much of the food industry to the concept of the precautionary principle and the implications of its use. The Protocol is significant in that it establishes the precautionary principle as a viable component of an international covenant. And as the only international mechanism currently governing trade in living modified organisms (LMOs) utilizing a precautionary approach, the Protocol is likely to have significant influence on international decisions regarding trade in seeds, bulk commodities, and finished foods that contain or are derived from genetically modified organisms (GMOs).

The inclusion of the principle within the Protocol, in conjunction with the EU's subsequent release of its communication regarding the concept, has raised the debate over the application of the principle to the highest levels of international decision-making. The EU communication crystallizes the vague treatment of the principle within the Protocol into an increasingly clear directive for international decision-making. Specifically, the EU communication concludes that decisions regarding the use of LMOs should be based on science, but that, "the appropriate response in a given situation is thus the result of a political decision, a function of the risk level that is 'acceptable' to the society on which the risk is imposed." In other words, if a relationship between LMOs (which includes biotech commodities) and an adverse event is suspected, but has not been demonstrated, decision-makers have the right to act or not to act. This position clearly leaves open the opportunity for parties to refuse entry to LMOs on the basis of criteria other than science-based risk assessment, and thus paves the way for international trade disputes waged before the WTO.

The Protocol's inclusion of the precautionary principle in its risk assessment of LMOs also increases the pressure on relevant international organizations such as Codex to fast-track the development of guidelines and standards for foods containing or derived from GMOs. In fact, Codex is currently wrestling with the explicit introduction of the precautionary principle into its *Working Principles for Risk Analysis*. Following last year's meeting in Paris, the Codex Committee on General Principles (CCGP) returned the *Proposed Draft Working Principles for Risk Analysis* to Step 3 of the Codex Procedure for government comment. Specifically, the CCGP requested comment on the application of precaution in risk management, as addressed in paragraphs 34 and 35 of the draft document. CX 4/10 CL 2000/12-GP. Paragraph 34 contains square bracketed language setting forth the conditions under which risk managers may appropriately apply "precaution" in evaluating a potential food hazard. In addition, Paragraph 34 contains an important footnote, indicating that "some Members refer to [the concept outlined in Paragraph 34] as the 'precautionary principle.'"

Paragraph 35 of the *Draft Working Principles* elaborates the criteria that should be taken into account in the exercise of precaution, in order to ensure the consistency of the decision process. Seven separate criteria

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are outlined and, for the most part, the criteria are unobjectionable. However, the first and fourth criteria pose potential concerns, in that they provide clear openings for the entry of the precautionary principle in Codex risk assessment principles.

The first criteria permits the application of precaution where "there is evidence to suggest that a risk exists, but the cause or extent of any negative effects are unknown due to gaps or uncertainty in the available scientific data." The ambiguity of this language is problematic, as "gaps or uncertainty in the available scientific data" will exist in almost any risk assessment, no matter how rigorous. The application of these criteria paves the way for the entrance of the precautionary principle (explicitly introduced in Paragraph 34) whenever there is the slightest amount of uncertainty regarding any aspect of risk. The novelty of biotech foods and relative youth of the body of scientific information regarding their effects makes the risk assessment of biotech products particularly susceptible to the application of the precautionary principle. Without an explanation within this criteria of the nature or extent of uncertainty that is sufficient to trigger "precaution," virtually any country that wishes to exercise the precautionary principle to restrict trade in biotech products may do so, as some level of scientific uncertainty is likely to be found in any preliminary risk assessment.

The ambiguity of the language in the fourth criteria is problematic as well. Here, the draft requires that any decisions taken under the risk analysis be "the least trade restrictive necessary to achieve protection of the health of consumers," without further elaboration. Again, this criteria provides members with no guidance or constraints in determining what constitutes "the least trade restrictive necessary." The criteria does not refer to any international trade conventions or delimit the factors that constitute health, whether environmental, biological, ecological, or economic. The ambiguity here serves as an open invitation to member countries wishing to use an undefined precautionary principle to prohibit trade when a science-based rationale for regulating the product is not available.

The Sanitary and Phytosanitary Agreement. The potential that the precautionary principle is included in a Codex standard or guideline also raises questions concerning the interpretation of WTO Agreements, particularly in the case of trade disputes. By accepting the Agreement Establishing the World Trade Organization (WTO Agreement), WTO member governments agree to be bound by the rules in all of the multilateral trade agreements attached to it, which includes both the SPS Agreement addressing food safety. Codex texts are particularly relevant to the application of the SPS Agreement because the agreement specifically directs member governments to utilize Codex texts in taking decisions under it.

When disputes arise between member governments regarding the application of agreements such as the SPS, parties have recourse to dispute settlement procedures under the 1994 Dispute Settlement Understanding (DSU). Article 3 of the DSU outlines the dispute settlement system's function, which is to preserve the rights and obligations of Members under the covered agreements and to clarify the existing provisions of those agreements in accordance with customary rules of interpretation of public international law. Thus, the source of law under consideration in dispute settlement is the texts of the agreements themselves, including any explicit references to Codex standards, guidelines, or recommendations.

While the WTO itself is not responsible for developing food safety standards, it does have the authority to place restrictions on the use of food safety measures as unjustified or disguised barriers to trade. The WTO accomplishes this task primarily through the SPS Agreement. The role of Codex standards and guidelines in the application of SPS measures is referred to several times throughout the agreement, perhaps most important of these agreements being Article 3, which addresses the harmonization of phytosanitary standards. International standards, guidelines, and recommendations for food safety are further defined in Annex A to the SPS Agreement as "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."

In addition, the SPS Agreement indicates that the standards and guidelines of the relevant international organizations are to be utilized in the application of risk assessment techniques. Article 5.1

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requires that Members ensure "that their sanitary or phytosanitary measures are based on an assessment, as appropriate to the circumstances, of the risks to human, animal, or plant life or health, taking into account risk assessment techniques developed by the relevant international organizations." As noted earlier, Codex standards and guidelines would play a role in the appropriate exercise and definition of precaution, as elaborated in Article 5.7 of the agreement. Thus, it is critical that Codex standards, guidelines, and recommendations addressing the use of precaution in risk analysis reflect the scientific, food safety-oriented aims of the organization.

COSTS TO THE CODEX PROCESS AND INTERNATIONAL TRADE

The Codex Alimentarius Commission has established that its standards and guidelines are to be based on the principle of sound scientific analysis and evidence, allowing for other legitimate factors relevant for the health protection of consumers and the for the promotion of fair practices in food trade. Codex standards and guidelines must be based on sound science and where appropriate, other legitimate factors (yet to be defined) relevant for health protection and fair practices in the food trade. The "precautionary principle" does not meet either of these criteria for inclusion in a Codex standard.

The presumption that supports the precautionary principle in its current form is that *hazards* and *risks* are somehow synonymous — but we need to recognize the distinction. Where evidence on a substance obtained through accepted scientific procedures demonstrates a reasonable certainty that it is not harmful, the presumption must favor its authorization, and we must avoid the adoption of principles that would sanction prohibiting the substance's authorization on the basis of speculation or political expediency.

Given that one of the Codex Alimentarius Commission's missions is to create a framework by which the WTO can effectively and expeditiously resolve disputes over trade in food, it is vital that we collectively seek to ensure that all of its activities are based on, and informed by, recognized food safety standards. All members of Codex should recognize clearly that the standards, guidelines, and recommendations established by Codex have a profound and permanent impact not only on food safety, but on international trade by virtue of Codex's unique role in the WTO dispute resolution process.

Such standards, guidelines, and recommendations should be consistent with, and not take precedence over, proper scientific risk assessment, recognizing that science by its very nature cannot ensure certainty. To insist on such outcomes, by establishing a redundant and insupportable global principle espoused by one region, especially when member countries already have at their disposal the right and the capacity to employ precaution in their regulatory processes, would do irreparable harm to the integrity of the SPS Agreement, not to mention the continued effectiveness of the WTO, upon which all nations depend as the guarantor of the principles of free trade in the twenty-first century's global economy.

All countries actively engaged in international trade should support the use of sound science as the basis for cost-effective, risk-based precautionary measures that are protective of health and environmental standards. In addition, countries should support cooperative international efforts involving both the public and private sectors to develop and share scientific data that would improve the accuracy and relevance of risk assessments and harmonize methodology and quality assurance. If international standards-setting agencies like Codex embark on a path toward adoption of "principles" instead of insisting that scientific standards be applied with appropriate diligence, the safety of the world's food supply would not have been improved in any quantifiable manner at the conclusion of the process. Instead, member states will be denied the means of access to technological innovations in food science like biotech foods that carry with them the potential to feed a growing global community, as well as access for their food exports to the markets of other member states.

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