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CODEX ALIMENTARIUS, BIOTECHNOLOGY AND TECHNICAL BARRIERS TO TRADE

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As controversial food trade issues, such as biotechnology, occupy the interests of consumers and regulators throughout the world, the work of the Codex Alimentarius Commission (Codex) has assumed vital importance. With this increased prominence has come the accompanying risk that free trade might be compromised for less than scientific objectives.

Key words: biotechnology; Codex; food and agriculture; Technical Barriers to Trade (TBTs); trade barriers.

Although the Codex Alimentarius Commission has functioned as part of the United Nations Food and Agriculture Organization (FAO) since 1962, its activities have been of little more than occasional interest to the international food industry until recent years. However, with the advent of the World Trade Organization (WTO) and the establishment of the North American Free Trade Agreement (NAFTA) and other regional trading blocs, the deliberations of Codex have become significantly more important to the international trade interests of government and industry groups alike. Increased interest in the elaboration of Codex standards, guidelines, and recommendations may be attributed to increased international awareness of two very practical functions of the Codex Commission and its numerous committees.

First, lesser developed countries lacking both the expertise and financial resources to fully develop food regulatory structures adequate for the protection of public health and the free flow of goods within their own borders, have become aware that the guidance and information needed to fill in these regulatory gaps is often made available in the Codex activities and deliberations of delegates from more industrialized nations. Second, multinational corporations and trade associations have become aware of the role that Codex has been given in the WTO Agreements as the means by which disputes over trade in food products may be resolved.

Increased awareness of the practical functions of Codex activities in shaping national legislation and establishing international trade standards appears to have strengthened Codex's role as the focal point of efforts to achieve internationally harmonized food standards. However, as the Commission's work has continued in recent years, many international regulatory gaps show signs of being filled by legislation that imposes burdens on industry without demonstrable benefits to public welfare. In their most troublesome manifestations, some of these measures, especially recent regulations concerning

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biotechnology food labeling, could be viewed as technical barriers to trade. For example, two Codex committees are currently reviewing draft language that, if ultimately adopted in its present form, could significantly impact the United States' (US) foreign trade interests with regard to food and food ingredients derived from modern biotechnology. The draft documents, which are under consideration within the Codex Committee on General Principles (CCGP) and the Codex Committee on Food Labeling (CCFL), raise important questions regarding the appropriate application and definition of the risk management principles used to evaluate biotechnology foods in the global market and the implications of formalizing mandatory international labeling requirements for biotechnology foods. A brief look at the trade implications of just one of these proposals, the draft guidelines for labeling of foods derived from biotechnology, will demonstrate the potential for such a proposal to be used as a technical barrier to trade and a roadblock to any potential WTO case brought on such a basis.

Labeling Options

At the CCFL meeting in May 2000, the issue of labeling for foods derived from modern biotechnology was given over to a drafting group charged with fast-tracking the development of a Codex guideline on biotechnology food labeling. The revised draft reportedly attempts to integrate two proposed options for labeling included in square brackets under Section 5 of the Draft Recommendations (Codex Alimentarius Commission [Codex], 2000); a section intended to address mandatory labeling requirements. In brief, Option 1 of these recommendations would only require that biotechnology food be labeled in cases where the biotechnology food is not substantially equivalent to its conventional counterpart in composition, nutritional value, or intended use. Labeling would also be required under Option 1 in cases where the biotechnology food contains an allergen transferred from a product recognized by Codex as causing hypersensitivity, or where the biotechnology food contains an ingredient derived from pork fat, beef fat, or lard that is not present in the foods' conventional counterpart. In large part, Option 1 is consistent with the United States Food and Drug Administrations' (US FDA) 1992 policy addressing the labeling of foods derived from new plant varieties (United States Food and Drug Administration [FDA], 1992).

Option 2, however, would impose mandatory labeling for any food or food ingredient that is composed of, or contains, a genetically modified organism (GMO), even if the biotechnology food is substantially equivalent to its conventional counterpart in composition, nutrition, and intended use. In addition, Option 2 would require labeling where the food or food ingredient is produced from, but does not contain, a genetically engineered organism if the food contains protein or DNA resulting from gene technology, or is not substantially equivalent to its conventional counterpart.

In effect, the integration of Options 1 and 2 would require that all foods or food ingredients containing genetically modified organisms be labeled, regardless of their characteristics or equivalence to existing foods. In addition, labeling would be extended to foods that are simply produced from, but do not contain, genetically modified organisms. Adoption of a hybrid of these two distinct options within Codex would result in a major policy shift away from the regulation of food and food ingredients based upon the scientific evaluation of the foods' characteristics and toward the regulation of food and food ingredients based categorically upon the process used for production. It is worth noting that a third option, proposed by Norway, India, and Consumers International, would mandate process-based labeling; in other words, any time DNA recombination occurs, regardless of effect, or lack thereof, the food would be accordingly labeled.

Labeling, Trade And Non-Tariff Barriers

The potential for the creation of a technical barrier to trade through the adoption of such a guideline may best be seen by looking to the emerging labeling requirements of a particular country, such as

Saudi Arabia. Under the pending (now suspended until December of this year) Saudi proposal for biotechnology labeling, the following scenario could well arise: On January 1, 2002, Company X may export a shipment of packaged food products bound for Saudi Arabia. Upon arrival, the Saudis may request, on the basis of CCFL decisions regarding biotechnology labeling, that Company X provide a certificate of GM-free status, test results supporting the status determination, or the appropriate "contains GM" label or stickers for each affected ingredient.

If Saudi Arabia were also to rely on pending decisions with the Codex committees on General Principles, Food Hygiene, and Food Import and Export Certification, this information would be required in addition to a certificate or label information regarding ingredient quantities or percentages; a certificate or label information regarding the country of origin of one or more components of the product; a general certificate of safety for consumption; a certificate attesting to the safety of the food packaging used; a certificate attesting to the safety or Hazard Analysis and Critical Control Point (HACCP) status of the processing and packaging establishment; and a certificate attesting to the microbiological analysis of the product.

Such an outcome, while admittedly farfetched in its entirety, would cause severe trade dislocation, even if effected on a piecemeal basis. As matters stand today, manufacturers already are bedeviled by a maze of conflicting, counter-intuitive, and often useless regulatory certification documents in the more than 150 jurisdictions around the globe that serve to do little more for food safety than provide at great cost, time, and expense that which the worlds' food manufacturers already do on their own initiative—test and self-certify the safety of their products. They are bound by an enforcement mechanism far more effective than the disapproval of one regulatory agency or another—strict liability in tort[1] for harms resulting from misbranded, mislabeled, or unsafe food products. Rather than add additional layers of meaningless certification, Codex and its constituent members would do better to work with industry toward the development of reliable and seamless self-certification or third-party certification mechanisms designed to provide real, tangible evidence of proper production and handling of food to consumers.

Codex And The WTO

In such a context, the economic and trade implications of the adoption of a Codex guideline or recommendation on biotechnology food labeling are numerous, given the questions of scope, application, traceability, and documentation that are to be addressed by the drafting group. However, the controversy surrounding many of these issues and the corresponding likelihood of trade disputes arising based on labeling concerns is not limited to the possible creation of non-tariff barriers to trade. The elaboration of new Codex guidelines and recommendations may also impact the application of international food safety agreements, such as the WTO Agreement on the Application of Sanitary and Phytosanitary (SPS) Measures.

For example, 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, including the SPS Agreement and the Agreement on Technical Barriers to Trade (TBT). Codex texts are particularly relevant to the application of the SPS and TBT agreements because the agreements specifically direct member governments to utilize texts in taking decisions under the agreements.

Should disputes arise between member governments regarding the application of agreements, such as the SPS or TBT, parties have recourse to the procedures for dispute settlement under the 1994 Dispute Settlement Understanding (DSU) (General Agreement on Tariffs and Trade [GATT], 1994). Article 3 of the DSU outlines the function of the dispute settlement system, 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 guidelines, standards, 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, although the TBT Agreement also addresses food quality requirements and other food safety issues not covered by the SPS Agreement. As noted earlier, the trade implications of the development of Codex guidelines or recommendations on biotechnology labeling depend in part on the referenced role of Codex guidelines in the relevant international food safety agreements.

The role of Codex standards, guidelines, and recommendations in the application of SPS measures is referred to several times throughout the Agreement. Perhaps most importantly, in Article 3, which addresses the harmonization of phytosanitary standards, the SPS reads as follows,

> (1) To harmonize sanitary and phytosanitary measures on as wide a basis as possible, Members shall base their sanitary or phytosanitary measures on international standards, guidelines, or recommendations where they exist, except as otherwise provided for in the Agreement, and in particular, paragraph 3.[ ]
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> (2) Sanitary or Phytosanitary measure which conform to international standards, guidelines, or recommendations shall be deemed necessary to protect human, animal, or plant life or health, and presumes to be consistent with the relevant provisions of this Agreement and of GATT 1994. 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 drugs and pesticide residues, contaminants, methods of analysis and sampling, and codes and guidelines of hygienic practice." (World Trade Organization, 1994).

Thus, if Codex were to adopt the hybrid draft biotechnology labeling guidelines, all Member nations would be given license to adopt the same or similar standards as national law and implement those standards, without risk of violating either the SPS or TBT Agreements. As a result, any dispute over market access resulting from rejection of biotechnology labeled product or prohibition from entry into a given country must be decided in favor of the government that mandates labeling, as the WTO will almost certainly rule in accordance with Codex labeling guidelines or recommendations in any potential dispute settlement proceeding.

Concluding Comments

The implications for producers, consumers, and member nations of misconceived Codex guidelines or standards relating to the labeling of biotechnologically enhanced foods would be negative and far-reaching, not only for the agricultural biotechnology industry, but for future innovations that might be the subject of precautionary, non-science based international food standards.

All of the foregoing is worth keeping in mind as we approach the next round of Codex sessions on General Principles and Food Labeling, where the shape of future standards in a number of critical areas may well be decided, for better or for worse. Regulatory fig leaves may provide convenient short-term political relief; they are neutral at best and profoundly dangerous in the worst case, as guarantors of a safe food supply, easily accessible, and readily affordable to the worlds' consumers.

Endnotes

[1] Tort liability for food divides into two theories—one of "negligence" and one of "strict liability." Defendants will typically argue for the judge to apply negligence liability, because it allows them to refer to the industry standard of care, which may be deemed enough "care" to warrant denial of the claim. Strict liability generally divides into "defect liability" (the product's design or manufacture created a hazard), and "failure to warn" of a known risk, where a product is designed properly and made properly, but still poses risks that require a warning to certain users. Failure to warn of such risk by a food manufacturer could result in liability for harm. Food allergens fall into the "failure to warn" group under current food safety law.

In the case of "strict liability" it is hard to generalize about its use in relation to the manufacture of food products. Some legal cases have used a negligence standard in some situations. In such cases, it is harder for plaintiffs to recover damages. For example, if victims of bovine spongiform encephalopathy (BSE) brought a case against food manufacturers they might have to prove that the BSE prion was known to be present in hamburgers at the time that they were manufactured and sold, and that a failure to warn was the cause of the ingestion of BSE prions. Plaintiffs always prefer to use strict liability for ease of recovery (of damages)—foods containing foreign objects or contaminated with chemicals are easy strict liability cases. An exception is the failure to warn of pesticide risks, which US federal law preempts in many cases under the United States Environmental Protection Agency's Federal Insecticide, Fungicide, and Rodenticide Act (or FIFRA).

Perversely, regulatory "precaution" toward GMOs could increase liability for food companies if the rDNA process is found to have set the highest standard of care for the design of foods (Redick, 2000). Negligence liability arises from a company's failure to meet the basic standard of due care for avoiding harm to others. Strict liability is applied to cases where there is a design defect or a failure to warn of risks, without regard for the seller's knowledge of lack of care in selling the product. For example, transgenic corn can reduce the formation of mycotoxins in some areas of the world, under some environmental conditions; if negligence applies, meeting the industry standard of care for reducing mycotoxins might suffice as a defense. Since mycotoxins arguably are natural, not added by humans, they might be treated under negligence in some jurisdictions. Other states in the US might find these carcinogens to be grounds for strict liability, and the failure to test and warn, regardless of industry practice, could lead to liability.

The advent of rDNA breeding could also lead to "design defect" product liability (*ibid*.), which presents its own unique problems for defendants (food companies). For example, if genetic engineering (rDNA) methods are developed which allow the precise deletion of genes for allergic proteins, then a food company failing to "design" its food in such a way would expose it to design defect strict liability. A similar "design" argument might be made by a creative plaintiffs' attorney who considers a mycotoxin prone food to be poorly designed, arguing by analogy that a car that used rust-prone steel is poorly designed, or grain riddled with preventable rat feces is poorly stored.

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