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International Trade Agreement Provides New Framework for Food-Safety Regulation

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On April 15, 1994, after 7 years of formal negotiations, the United States and over 100 other nations signed a trade agreement completing the Uruguay Round of the General Agreement on Tariffs and Trade (hereinafter referred to as GATT). Under the agreement, agricultural trade will be brought more fully under the disciplines that have served to expand trade in manufactured products in recent decades.

Major government subsidies to agricultural production will be reduced and trade barriers to agricultural imports will be lowered. At the same time, the GATT agreement seeks to balance the benefits of reducing nontariff barriers with assurances regarding protection of consumer safety.

Several trends contribute to making food-safety regulation an increasingly contentious trade issue. The value of food products traded between countries has more than doubled during the last 20 years.

U.S. processed food exports doubled in value in only the last 10 years and now account for nearly half of U.S. agricultural exports.

As incomes grow and populations age, consumers in industrialized countries and many middle-income countries demand a higher level of food safety. Exporters, including the United States, will

need to meet safety standards in order to compete in these markets. But countries may be tempted to use safety standards to shield domestic producers from competition. The GATT agreement addresses this issue, but not in a way that will eliminate disputes immediately, so differences in food-safety regulations will continue.



The negotiated sanitary and phytosanitary provisions of the recent GATT accord assure each country's right to guard the health of its citizens, while deterring countries from using health-related regulations to bar trade.

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The GATT Agreement Addresses Food-Safety Concerns

The GATT agreement requires member nations to adhere to certain trade rules and to seek reductions in trade barriers through periodic rounds of negotiations. Conflicting food-safety regulations were recognized as barriers to trade at the onset of the Uruguay Round. The GATT agreement sets up a framework for recognizing legitimate differences among countries over food-safety regulations and for resolving disputes. However, many details specifically relating to issues of harmonization remain to be worked out.

Harmonizing the Many Regulations, Through Many Forms

Harmonization is a general term that can mean several different things in practice. It can mean that product standards, such as established legal limits for pesticide residues, are the same in two different countries.

Another type of standard requires that specific safety controls are followed in food production. For example, with the recently proposed regulation that U.S. seafood processors implement Hazard Analysis Critical Control Points (HACCP) systems in their manufacturing plants, overseas suppliers to the United States also must have such process standards.

Also, regulators require certain information to determine if a product is safe. The U.S. Environmental Protection Agency (EPA) and the Food and Drug Administration (FDA) require pesticide, food additive, and animal drug developers to provide extensive information on the potential impact of their products on human health before the pesticide, food additive, or drug can be marketed in the

United States. The harmonization issue is whether different countries require the same food-safety information to register a product for use in their countries.

Decisions on what constitutes a hazard and on the level of acceptable risk (the "risk standard") can differ widely among countries, and within countries for different hazards. For example, in the United States pesticide use on food commodities is regulated in the same way, regardless of whether the pesticide was applied before or after harvest. However, a different risk standard is sometimes applied to fresh and processed foods in certain cases. In Japan, pesticides applied after harvest are considered food additives and subjected to different risk standards than if they were applied before harvest. No differences exist for fresh and processed commodities. Differences in risk standards between countries can be challenging to harmonize.

Why "Harmonize"?

While often difficult to achieve, harmonization of food-safety regulations can provide economic benefits. For example, when different countries have the same information requirements for registering a new pesticide or food ingredient, the cost of developing new products can be spread over a larger market and unit costs are consequently lowered. As long as the harmonized regulatory process ensures safety of the new product, consumers should benefit from a wider availability of safe products at lower costs.

Another general type of economic benefit arises when producers compete to provide the required level of safety in world markets. Production can shift to where it is cheaper to attain a particular safety attribute, due to either advantageous natural resources or superior technology. For example, food production could

shift to regions where particular pest problems are fewer, and hence fewer pesticide applications might be needed. And, livestock production could concentrate in areas without endemic disease.

Food-Safety Regulation Under GATT

The new GATT agreement provides a framework for distinguishing protectionist regulations from legitimate sanitary and phytosanitary (SPS) regulations, that is, from regulations intended to protect human, animal, or plant life or health that are scientifically based and do not arbitrarily or unjustifiably discriminate between nations. The desire to harmonize such regulations is balanced with other considerations. These include concerns relating to national sovereignty, appropriate levels of protection, a scientific basis for regulations, transparency, equivalency, regionalization, and dispute resolution.

Harmonization

The GATT agreement emphasizes the desirability of "common sanitary and phytosanitary measures" among member nations. In order to promote harmonization, three international organizations are recognized as sources of scientific expertise and internationally agreed-upon standards: the Codex Alimentarius Commission (commonly referred to as the Codex), the International Office of Epizootics (IOE), and the International Plant Protection Convention (IPPC). The Codex addresses trade and food-safety issues related to food additives, pesticide residues, contaminants, animal drugs, packaging, and food standards. The IOE deals with animal health issues; the IPPC with plant pests and plant health.

The Codex works to develop standards that protect consumers everywhere, while at the same time facilitating trade in food products.

Other Trade Agreements Deal With SPS Issues

Growth in trade has also spurred a variety of less formal negotiations by the United States to "harmonize" regulations with major trading partners.

As a result of the 1989 U.S.-Canada Free Trade Agreement, the U.S. Environmental Protection Agency (EPA) and its Canadian counterpart are evaluating for registration a new pesticide, tebufenozide, that has both agricultural and forestry uses. It has potential environmental benefits from lower application rates, less persistence, and a more selective mode of action than do current alternatives. The regulatory agencies are using this process to understand how the two countries differ in their approaches to assessing the risks and benefits of agricultural chemicals. EPA is also establishing tolerances (legally allowable amounts of residues) for pesticides used on food products traded between Canada and the United States where tol-

erances exist in Canada, but not in the United States.

The United States and New Zealand are currently working toward an agreement whereby New Zealand's Ministry of Agriculture and Fisheries (MAF) would certify that selected fruit and vegetables from New Zealand are, with a high degree of confidence, in compliance with U.S. pesticide-residue tolerances. In recognition of this New Zealand Government certification, the U.S. Food and Drug Administration would offer facilitated entry/inspection procedures for the selected commodities. The arrangement is based on strict control of pesticide usage and residues throughout the production process, including pesticide usage recordkeeping and residue analyses in-field and before export. To date, kiwi fruit and strawberries are under discussion, and apples, pears, and several other commodities are being considered.

There is an eight-step process for developing Codex standards that often takes years to complete—even for measures which may be quite simple, such as the Codex rule stating peanut butter must be made from peanuts. Other Codex standards are much more complex, such as those setting maximum residue limits (called MRL's in other countries, and tolerances in the United States) for pesticides.

Where comparisons are possible, a recent Government Accounting Office (GAO) study showed that in 81 percent of the cases, the Codex standards are either similar to or are more stringent than the

U.S. standards. U.S. standards are more stringent in 19 percent of the cases. The GATT agreement will not force the United States to adopt lower international food-safety standards even in these cases.

Appropriate Level of Protection

The GATT agreement clearly states that nations have the right to choose the risk standard that applies to a particular hazard, such as carcinogenic pesticide residues or animal diseases.

Some countries may choose to accept more risk than is allowed by the international standard. This will likely occur frequently in de-

veloping countries, where achieving the same levels of safety as exist in developed countries may make the foods prohibitively expensive. Many developed countries may opt for more stringent risk standards than the international standards.

Allowing national sovereignty works against the goal of harmonization, but recognizes that individual nations are unwilling to subscribe to uniform international standards for all hazards. Thus, the agreement balances national interests with the goal of harmonization.

Scientifically Based Measures

The new GATT agreement states that all SPS measures must be based on science. Although nations have the right to choose their own risk standards, they must be established in a scientifically defensible manner. Regulations cannot impose requirements that do not have a scientific basis for reducing risk. For example, a quarantine period for live animals should be no longer than necessary to ensure a disease is not present.

Realistically, however, there may be different interpretations of what is scientifically justified. Moreover, nations can adopt provisional SPS measures on the basis of pertinent available information when there is insufficient scientific information to make an objective assessment of risks. In such cases, nations are obligated to seek additional information in "a reasonable period of time." These problems notwithstanding, movement toward basing SPS measures on a scientific basis is a major step forward in eliminating trade barriers that are specifically established without a scientific basis to favor domestic producers over foreign suppliers.

Transparency

Food-safety regulations are often unclear and can appear capricious. Therefore, the GATT agree-

ment requires nations to publish their regulations, provide a mechanism for answering questions and receiving comments from affected trading partners, and notify trading partners about any new standards.

Equivalence

Regulations may differ for institutional or historical reasons. Member nations must accept that SPS measures of another country are equivalent if they result in the same level of public-health protection, even though the measures themselves might differ. However, the burden lies with the exporting country to demonstrate that the measures provide the same level of public-health protection as the importing country's regulations.

Regionalization

The GATT agreement directs member nations to recognize the concept of pest- or disease-free areas within a country. Presently, outbreaks of certain diseases in a country may prevent exports of selected products from that country even if other regions in that country have no disease problem at all. Thus, the agreement will allow exports from a disease-free region of the exporting country to an importing country, even though the disease might be endemic in other parts of the exporting country. Exporting countries are required to provide evidence that pest- or disease-free areas likely will remain that way.

Dispute Resolution

The GATT agreement also provides a clearly defined mechanism for resolving disputes between countries in a timely manner. Disputes regarding the legitimacy of a country's regulations are to be decided by a dispute-settlement panel.

If the standards under dispute differ from the international standards accepted by the three interna-

tional organizations, then the country implementing the standards must show that they comply with the country's obligations under the agreement. For example, they must be scientifically based, transparent, and consistent. A dispute-settlement panel will not be forced to choose between two nations' scientific standards. It will be expected only to state whether the SPS measures under question have a scientific basis and if they are consistently applied. If the standards are not upheld by GATT, then the country holding such standards can retain them only if compensation (as established by the panel) is paid to the complaining trading partner.

The dispute-settlement process simply ensures that nations comply with the obligations that they have agreed to. A nation with an adverse panel finding against it is encouraged to work with the nation bringing the complaint to the GATT panel. Failure to reach a settlement results in trade retaliation at a level set by the GATT panel.

What Issues Remain?

There are concerns whether the SPS provisions of the GATT agreement can promote trade while safeguarding public health. Many specific concerns over food safety stem from the technical nature of the language of the SPS provisions of the GATT agreement.

The issue of harmonization—particularly with respect to how harmonization interacts with national sovereignty—is one that has prompted considerable debate. Some critics feel that U.S. food safety is threatened by the SPS provisions. Some wonder whether the higher U.S. standards may be challenged and eventually disallowed because they are more stringent than the international Codex standards. This criticism seems to reflect a basic misunderstanding of the GATT text.

National-sovereignty concerns have also been raised with respect to the dispute-settlement process of the new World Trade Organization (WTO), which will replace the GATT Secretariat. The WTO will provide the institutional framework for world trade in goods, services, and intellectual property rights. Some critics of the new GATT Agreement see the WTO as an entity which will diminish U.S. sovereignty through the establishment of an expanded, more powerful dispute-settlement process. However, WTO panel reports (which settle a complaint brought by one WTO member against another) essentially will be no more binding than current GATT panel findings. Individual nations will be responsible for deciding how to implement WTO decisions. Moreover, WTO findings will continue to be made by member nations and not by a new international bureaucracy.

Preemption of U.S. State and local laws is another important issue raised. National governments commit themselves under the agreement to ensure that subnational governments comply with the provisions of the law. This does not mean that State and local laws cannot be more restrictive—it means that they must be consistent with the SPS provisions. In recent years, some States have imposed food-safety standards that are stricter than Federal regulations. For example, California has passed Proposition 65 requiring labeling of potential carcinogens in food. Such measures will remain valid as long as it can be shown that they do not violate the GATT provisions.

There are some concerns about transparency—that the GATT dispute-settlement process is less transparent than it could be. Critics also have asked that there be more public information relating to WTO decisionmaking.

The GATT agreement does not recognize that SPS regulations may

be based on criteria other than safety—such as social concerns relating to animal welfare, consumer preferences, or environmental concerns. Other nations have applied or threatened to apply trade restrictions because of social concerns. For example, the European Union (EU) has recognized such concerns as legitimate grounds for banning new products or processes. In 1989, the European Community (the precursor to the EU) banned use of the recombinant bovine growth hormone (known as rbST, the product is an artificially synthesized copy of bovine somatotropin which is a naturally occurring protein hormone in cattle) believing it would favor large farms and change the current farm structure. While the EU has also considered banning of imports of products produced with the use of rbST, this prohibition has not yet been imposed. It is clear that such a measure would not be

justified under the SPS provisions of the GATT agreement.

A similar issue is that science is not the only basis for policy. The science of measuring risks relies on value judgments and on assumptions that cannot be wholly objective. The GATT agreement recognizes this inherent uncertainty by allowing national sovereignty in the choice of acceptable safety standards and by requiring consistency and equivalency in the application of standards. It is worth noting that while the agreement requires that SPS measures be scientifically based, it does not require that they be based on the "best" science or on the "weight of the evidence." It thus avoids the potential for dueling scientists. Dispute-settlement panels will not be responsible for choosing among scientific views, but will determine only whether a particular SPS measure has a scientific basis.

The GATT agreement represents important progress that could ultimately improve product safety and information for consumers in member nations. Increased international

competition should provide safety features at a lower cost. Imported and domestic goods will have to meet equivalent standards.

However, the process and impacts of harmonization and dispute resolution will evolve only over the long run. Differences in food-safety regulations and risk preferences across countries will continue to pose challenges for harmonization and food trade.

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