Before the

COMMITTEE ON HEALTH, EDUCATION, LABOR AND PENSIONS
UNITED STATES SENATE

Statement of

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On

International Food Safety Standards

Tuesday, December 4, 2007

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About Waters Corporation

For 50 years, Waters has developed innovative analytical science solutions to support scientists around the globe who focus on meeting the stringent laboratory demands for food safety regulation and analysis.

Waters Corp., a publicly traded corporation (NYSE:WAT) headquartered in Milford, Massachusetts, holds worldwide leading positions in three complementary analytical technologies — liquid chromatography, mass spectrometry, and thermal analysis. Specifically, the company designs, manufactures, sells and services ultra performance liquid chromatography (UPLC), high performance liquid chromatography (HPLC), chromatography columns and chemistry products, mass spectrometry (MS) systems, thermal analysis and rheometry instruments.

In addition to providing solutions in food safety, Waters creates business advantages for laboratory-dependent organizations by delivering sustainable scientific innovation to enable advancement in healthcare delivery, environmental management, and water quality. Waters products are used by pharmaceutical, life science, biochemical, industrial, academic and government organizations working in research and development, quality assurance and other laboratory applications.

Waters Corp. employs approximately 4,700 employees worldwide, operating in 27 countries.

Summary of Statement

The global trade in food is increasing significantly, such that governments no longer have direct control over the production standards employed for much of the food consumed by their citizens. While governments do have a responsibility to promote and permit international trade, they also have a responsibility to protect the health of their citizens from the presence of potentially harmful contaminants in the food supply.

The Codex Alimentarius Commission was set up in 1963 by the Food and Agriculture Organisation (FAO) and the World Health Organisation (WHO) with the aim of developing harmonized food standards and guidelines. Codex therefore acts as a central point of reference with respect to food standards; however, it is generally believed that the current Codex standards lack sufficient scope to be either universal or comprehensive. Also, the implementation/enforcement of standards varies significantly from one country to another.

As a consequence, governments have been compelled to develop mechanisms to ensure that imported food and feed does not pose a hazard to the health of humans or animals.
These systems prove to be most effective when they involve collaboration of numerous bodies and organisations. This includes collaboration between governments and collaboration between regulatory authorities, producer organisations and technology providers (such as Waters Corporation) working together, ensuring that solutions are effective, robust and cost effective.

FDA currently regulates domestic food production, but has little control over the production standards employed for imported food. The European Union (EU) concluded that relying on voluntary compliance did not afford adequate assurances of protection and adopted an approach of licensing third countries and the individual food producing establishments therein. This involves frequent inspection audits of each country, examining the food safety regulations and the implementation of those regulations, to ensure that food destined for the EU is produced under rules that afford equivalent guarantees to those afforded by EU regulations. Compliance with these requirements is monitored through the implementation of an import testing programme, which includes, documentary checks (ensuring that food comes from an EU approved establishment), physical checks and laboratory examination. Non-compliance can result in withdrawal of permission to export to the EU.

In response to complaints from consumer organisations in 2002 regarding the presence of contaminants in imported food, the Japanese Government reviewed and revised The Food Safety Basic Law and the standards set for food safety. Initially the Japanese Government did not adopt a policy of third country approval/licensing, but rather placed the onus on the importers to ensure that imported food was compliant with the new Japanese food safety standards. Additionally, the new regulations imposed a mandatory requirement on importers to have new food imports tested to demonstrate that it met the standards. Compliance with these standards is assured by a high level of laboratory testing for a very wide array of chemical contaminants, which is carried out by the Japanese Government during importation. More than 10% of all Japanese food import consignments undergo laboratory testing. Subsequently the Japanese Government has begun licensing foreign establishments for some high-risk commodities.

Faced with the differing import requirements of each country/region, exporting producers tend to focus on meeting the demands of their chosen market. In the absence of exacting and robustly enforced import requirements, the United States (US) faces a real risk of receiving product deemed unsuitable for markets with more stringent controls.

Background on International Food Safety Standards

Article 20 of the **General Agreement on Tariffs and Trade (GATT)** allows governments to act on trade in order to protect human, animal or plant life or health, provided they do not discriminate or use this as disguised protectionism.

The Agreement on the Application of Sanitary and Phytosanitary **Measures (SPS)** permits governments to set their own standards, but requires them to apply measures only to the extent required to protect human health. It does not permit Member Governments to discriminate by applying different requirements to different countries where the same or similar conditions prevail, unless there is sufficient scientific justification for doing so. It is indeed a basic precept of this agreement that there should be a sound scientific basis for food safety regulations. However, it does permit application of the precautionary principle when risks can not be quantified.

The Agreement on Technical Barriers to Trade (TBT) seeks to ensure that technical regulations and standards and analytical procedures for assessing conformity with technical regulations and standards do not create unnecessary obstacles to trade.

Both the SPS and TBT Agreements acknowledge the importance of harmonizing standards internationally to minimize or eliminate the risk of sanitary, phytosanitary and other technical standards becoming barriers to trade.

The General Principles of the Codex Alimentarius states:
The publication of the Codex Alimentarius is intended to guide and promote the elaboration and establishment of definitions and requirements for foods to assist in their harmonization and in doing so to facilitate international trade.

Codex And The Ethics Of International Trade

Codex Alimentarius Commission also encourages food traders to adopt voluntarily ethical practices as an important way of protecting consumers' health and promoting fair practices in the food trade. To this end, the Commission has published the ***Code of Ethics for International Trade in Food***. A principal objective of this code is to stop exporting countries and exporters from dumping poor-quality or unsafe food on to international markets.

National Food Safety Standards

Harmonization of food safety standards may indeed be a very worthy cause, however, it is generally accepted that Codex standards currently lack sufficient scope to be comprehensive. Neither does Codex address substances for which acceptable daily intakes (ADI) have not been established. These include (but are not limited to) residues of nitrofuran group of compounds and the antibiotic chloramphenicol. Disputes over the presence of these substances in food have caused the largest disruptions to international food trade, resulting from contamination, in recent years. As a consequence, many countries have developed a complete set of independent food safety regulations (albeit ensuring conformity with Codex standards whenever possible).

Given the significant growth in global food trade in recent years, many countries are currently in the process of revising (or in many cases completely overhauling) their food safety legislation with regard to both domestic production and importation.

The European Union system

In 2002, the European Union made major changes to the way food safety legislation is developed and implemented, when it passed Council Regulation 178/2002 into European law. This regulation established The European Food Safety Authority, an independent body with responsibility for risk analysis, but devoid of risk management responsibility. This ensured that risks would be evaluated independently from the effect any legislation may have on trade, or on the management of the risk (testing). It also ensured that the requirements of the SPS agreement would be met in establishing a scientific basis for the legislation.

This regulation also established the Rapid Alert System for Food and Feed (RASFF), whereby when violative food contaminants are detected either at market or at a Border Inspection Port (BIP) information relating to the product, the nature of the violation, the country of origin and the notifying country is published on a weekly basis, shared among the relevant competent authorities within the EU member states for action if necessary (recalls, increased vigilance etc) and simultaneously put into the public domain. Additionally, this legislation put in place an absolute requirement for traceability at all stages, from production, through processing, distribution and retailing.

In the same year, legislation was introduced which specified the criteria which must be applied when validating the analytical techniques used for detection of chemical contaminants in food. The EU Commission has chosen not to prescribe analytical techniques, instead allowing regulatory laboratories to develop their own methods utilizing the latest advances and technological innovations to improve sensitivity, throughput and cost effectiveness. This is considered a significant factor in allowing laboratories in EU member states to respond rapidly to food safety issues and to keep pace with scientific advances. However, in Commission Decision 2002/657 validation criteria were laid down to ensure that laboratories demonstrate that analytical techniques are fit for purpose and suitably robust when detecting contaminants at the level of interest. The EU Commission demands that violative results be confirmed using an unequivocal, confirmatory technique and lays down the identification criteria that must be met in this Decision. The use of a confirmatory technique is required to ensure that producers are not unfairly disadvantaged from the reporting of "false positive results" that can occur when screening tests are employed. This legislation also mandated that regulatory laboratories must be accredited under the international standard ISO 17025, ensuring that all laboratories are working to acceptable standards.

The European Union ensures the safety of domestic food production through the implementation of a comprehensive raft of food safety legislation, regulating the use of veterinary drugs in product of animal origin (POAO) and of pesticides in both POAO and non-POAO. Compliance with this legislation is monitored through a comprehensive testing programme the level of testing of which is based on a percentage of annual production. These testing programmes are funded from a levy imposed on producers (for example, a levy per head of animals slaughtered in the case of POAO). The EU Commission has fixed the minimum levels of this levy depending on the species.

It is noteworthy that for substances where the risk is established, but not quantified, the EU applies the precautionary principle. A significant number of contaminants are known to be carcinogenic and/or genotoxic, however the risk has not been quantified and they are seldom likely to generate acute conditions which can serve as signals of frequent violation. In these cases the EU has imposed a complete ban on their presence and requires laboratory analysis to demonstrate compliance.

How the EU treats imports

Accepting that global trade in food is increasing year on year and that EU is probably the largest single market in the world, the EU Commission does not adopt the view that trading partners will automatically become food safety partners. Instead the EU makes the latter a precondition to becoming the former.

The EU Commission maintains lists of approved countries and establishments within those countries, which are approved by commodities. Therefore, as an example, China must be named on an approved list for the export of seafood before any product will be permitted entry into the EU. Additionally, individual establishments within China are maintained on an approved list for the export of seafood and only those establishments are permitted to export product to EU. This system is similar to that operated by the USDA for meat and poultry, but in 2004 the EU extended this to make provision for not just POAO, but for any foods which may constitute a risk (Council Regulation 882/2004).

A requirement for remaining on these lists includes the annual submission of details of control programmes which are in place regulating the safety of food produced for the EU including the results of regulatory monitoring. The underlying premise is that third countries must be able to offer assurances that food exported to EU is produced under a series of controls that offer at least the same guarantees of safety as is offered by European regulations. There must be a legal basis for enforcement of these regulations. Therefore, although the EU can not enforce its legislation on third countries, it does demand *equivalence*.

An additional prerequisite for remaining on these approved lists involves permitting regular inspection of competent authorities, production, processing, traceability and the laboratories involved in regulatory monitoring (including checking the efficacy of methods of analysis employed). The aim of these inspections is verification of the assurances given and the inspections are carried out by the staff of the Food and Veterinary Office (FVO) with the assistance of scientific “national experts”. If a significant number of non-compliances are observed during an inspection mission, it can (and does) result in an establishment, or entire country being de-listed and therefore forfeiting the ability to export a given commodity to the EU.

In 2001, a World Health Organisation (WHO) committee examining coordination and harmonization of food safety control systems concluded that whilst it is not possible to test our way to safe food, a robust monitoring system is vital to ensure compliance with regulation controlling food production. The EU Commission has determined that no consignment from a third country should be permitted to enter the EU without being subject to veterinary checks and that fixed percentages must undergo physical checks (Commission Decision 97/78). In practice, based upon assurances offered by

third countries, a derogation regarding the level of these physical checks may be negotiated on a country-by-country basis.

A mechanism for recovery of costs associated with carrying out the import monitoring has been described in Council Regulation 882/2004. This legislation lays down minimum charges per consignment that must be applied, but makes provision for recovery of the full economic cost of inspection and any laboratory analysis. The importer or their agent is responsible for these charges. A significant level of violation detected during this import monitoring may result in 100 % of product undergoing laboratory analysis before it is permitted to enter the EU. If the violation is deemed to constitute a significant risk then it may result in the country being de-listed for that commodity.

The Japanese system

Japan is one of the least self-sufficient developed countries in the world, importing more than 60% of its food. Therefore, Japan has traditionally relied heavily upon the regulatory systems in the exporting countries for ensuring food safety. However, in 2002 a number of consumer organisations carried out surveys that found high concentrations of certain agricultural chemicals were present in imported crops. Many of the detected chemicals were banned from use in domestic Japanese production. This prompted a complete overhaul of the Food Safety Basic Law (the main statutory instrument regulating food safety in Japan). Central to this was the establishment of the Food Safety Commission, an independent body with responsibility for risk analysis. Additionally, the Specifications for Food and Food Additives was revised to include many more chemicals than had been previously addressed. This creation of the so-called Japanese Positive List (listing 799 agricultural chemicals) was prompted by the fact that the licensing of agricultural chemicals differs from one country to another. Prior to the creation of the positive list, when chemicals not licensed in Japan were identified in imported food, each violation was dealt with on a case by case basis. The maximum residue levels (MRLs) in the positive list are based on internationally accepted values where available, but a uniform limit of 10 parts per billion (ppb) is applied for substances for which safe levels had not been established.

It is worth noting that Japan does not demand equivalence in terms of analytical testing, since domestic produce is not tested for the full range of chemicals detailed in the positive list, but accepts that local legislation effectively controls the use of unlicensed chemicals. In addition, the change in Japanese legislation did not make provision for maintenance of approved lists of countries and establishments, for the purposes of import. Instead, the onus for ensuring compliance was placed on the importer combined with heavy penalties for violation. When violations are detected, subsequent consignments must undergo voluntary testing in Japanese laboratories, paid for by the importer, before the consignment can be released. If the violation rate exceeds 5% of consignments from an establishment (or country) then a complete ban on importation may result.

For substances not permitted to be present at any concentration (so-called Not Detect or ND), the challenge is ensuring that all laboratories are capable of offering the same assurances. EU does this by specifying a minimum required performance level (MRPL) that laboratories must demonstrate. Japan has adopted a different approach in

prescribing methods that must be used by Japanese regulatory laboratories. It appears to be generally accepted by the Japanese scientists that this author has spoken to, that this is too restrictive and limits the ability of the laboratories to employ recent technological advances, such Ultra Performance Liquid Chromatography (UPLC, developed by Waters Corporation) to increase throughput and improve cost effectiveness.

Although the Japanese government does not maintain approved lists for all commodities, when recurrent violations are detected, Japanese scientists may be dispatched to the offending country to offer technical assistance in a bid to correct the problem. The Japanese Government has subsequently introduced approved lists, but only for spinach imports. However, there is speculation that this may be extended to other foods.

Differences between the EU, Japan

Whilst Japanese legislation appears similar to EU regulations, there are fundamental differences in the implementation. Whereas, EU demands equivalence in terms of legislation and levels of monitoring, Japan places the onus for compliance on the importer and ensures compliance through a very high level of import monitoring. The result is that Japanese importers will typically demand certification of compliance with Japanese regulations prior to dispatch.

Despite this high level of testing of produce destined for Japan, the Japanese authorities ensure compliance by carrying out laboratory analysis for a very large number of contaminants at import (around 10% of all imported food consignments undergo laboratory analysis) and publish the results of violations detected. It is interesting to note that a frequently used level of testing is designed to detect a 1% violation rate with reasonable efficacy (that is to say, if 1 consignment out of every 100 is violative for a particular substance then there is a 95% chance that violations will be detected), yet the dramatic changes in Japanese legislation were prompted by the discovery of a 0.4 % violation rate across all commodities and chemical contaminants. It should also be noted that even a 10% inspection rate does not in itself constitute a significant level of protection. Rather, it serves as a monitoring tool to ensure compliance.

Export food safety testing

It might be reasonable to assume that such a high level of interest in food safety from a number of very large food importers would itself create a harmonized set of standards resulting in the food safety equivalent of "herd immunity." In some instances, this may be the case. For example, the Thai Department of Fisheries has submitted a list of recommended establishments to the US FDA which is very similar to the approved list maintained by the EU, but it is noted that use of these establishments by US importers is voluntary and that some recent FDA refusals (October 2007) came from establishments not on the recommended list.

It is also noted that whilst only 4 countries appear to have submitted lists of recommended establishments for seafood to the US, 95 have done so to the EU (where it is mandatory). One assumes that this arises because the standards are not

harmonized internationally and the requirements are very different from one market to another. Therefore, in practice, exporting countries tend to focus on separate schemes depending on the intended recipient. This is borne out by the observation that many establishments on the FDA refusals list are not on approved lists for the EU and therefore would not be permitted to export to the European Union. This should not be interpreted as an indication that they are necessarily producing substandard goods, but rather that they may be focused on markets not requiring advanced approval.

Conclusion

It is clear that any food safety system which relies on voluntary compliance will be inherently risky, since even the very stringent systems employed by both the EU and Japan continue to give rise to a significant number of cases of violative food contamination (as published by each authority). Countries without unequivocal regulations governing the production of imported food run the risk of inviting the delivery of sub-standard products. This author has examined a seafood export action plan which clearly stated that seafood found to be in violation of EU regulations could be sold into markets where the regulations were less stringent. In the absence of comprehensive, internationally applied standards, imported food safety can only be ensured through the application of unambiguous legislation in combination with a robust enforcement and monitoring programme.