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U.S. China Agreement on Food Safety: Terms and Enforcement Capacity

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Introduction: The Urgency to Negotiate an Agreement

In December 2007, U.S. Treasury Secretary Henry Paulson, preparing for the U.S.-China Strategic Economic Dialogue (SED), said, "Right now product and food safety is the No. 1 issue."[1] Food and product safety would take precedence even over the U.S. campaign to convince the Chinese to revalue their currency to avoid U.S. legislation against currency manipulation as an unfair trade subsidy.[2] How did product and food safety, normally a technical issue, rise to at least momentary pre-eminence in U.S.-Chinese geo-politics?

The immediate occasion of Secretary Paulson's remarks was the negotiation within the SED of an "Agreement Between the Department of Health and Human Services [HHS] of the United States and the General Administration of Quality Supervision, Inspection and Quarantine [AQSIQ] of the People's Republic of China,"[3] signed on December 11th in Beijing. The urgency to negotiate the agreement began in May 2007 when the U.S. Food and Drug Administration (FDA) advised importing companies to recall more than 150 brands of pet food products that had incorporated contaminated ingredients from China. U.S. veterinary officials estimated that 39,000 pets were sickened or died.[4]

In June, the FDA began to detain farm-raised seafood imports from China due to concerns about unsafe drug residues used in fish food. In September, a Reuters/Zogby poll of 1,000 U.S. consumers reported that a quarter of them had stopped buying food imports from China. In October, the U.S. House of Representatives held hearings that featured Congressional investigators reporting on their fact finding missions about food safety in China.[5] November saw the publication of reports on import food safety by President George Bush's Interagency Working Group (IWG) on Import Safety, and the FDA.[6] Clearly, the food safety related events of the summer and fall made the negotiation of the HHS-AQSIQ agreement an urgent U.S. policy priority.

> *"We disagree with biased, incomplete media reports and pure condemnation that are blind to the facts; and we are opposed to trade barriers set for food safety issues and politicizing the issues."* Vice-Premier Wu Yi at the High Level International Food Safety Forum: Beijing, November 27, 2007.

The issue of product and food safety was no less urgent for China, particularly because Chinese food exports to the U.S. had increased 133 percent from 2003 to $3.3 billion in 2007.[7] New U.S. import food safety requirements, if difficult to implement, might impede further export growth. Responding to the pet food and other contamination incidents, AQSIQ announced in July 2007 that it had shut down 152,000 unlicensed food producers and retailers, and had revised more than 1,800 national food standards.[8] (There are 448,000 food processing facilities in China, with 26,000 producing 72 percent of the food.[9]) In August 2007, China published a "White Paper on Food Quality and Safety" that described China's food processing industry and outlined its domestic and export food safety and quality programs.[10] According to Zhao Baoqing, a former AQSIQ official now at the Chinese embassy in Washington, "During 2004 to 2006, more that 99 percent of Chinese food to the U.S. met the U.S. safety

and quality standards," adding that "quality and safety questions are something that every country has to deal with."[11] President Hu Jintao discussed food safety measures, among other trade issues, with President Bush during the Asia-Pacific Economic Cooperation ministerial meeting in September 2007.[12]

In addition to Chinese concerns about trade and domestic food safety, there is the sensitive matter of China's international reputation, particularly as it will be profiled by world media at the Beijing Olympic Games on August 8-24. AQSIQ has announced a number of measures "so as to ensure that all athletes, officers, judges, journalists and audience from all countries and regions can eat 100% safe and reliable food products in Beijing."[13] The U.S. Olympic Committee nevertheless announced in February 2008 that its 600 delegates would eat U.S. food in their own training camp, rather than eating Chinese-produced food in the Athletes Village.[14]

In November 2007, AQSIQ helped to organize an International Food Safety Forum with 600 delegates from "42 countries and regions," resulting in the "Beijing Declaration on Food Safety" and bilateral agreements with Germany, South Korea, Canada and Brazil.[15] EU member countries and Japan are among those who have also received contaminated Chinese food and feed exports.[16] These and other food safety initiatives were part of the Chinese context for the December 11th bilateral agreement with the United States.

The purpose of this article is first to explain and contextualize the terms of the HHS-AQSIQ agreement. Then some of the challenges to its implementation in China, as assessed by U.S. Congressional investigators and other analysts, are outlined. Finally, U.S. capacity for implementing import food safety rules is summarized, on the basis of IATP's "Import Food Safety in the Twilight of the Bush Administration." (available at www.iatp.org)

Overview of the U.S.-China Food Safety Agreement

The first Article states, "The purpose of this Agreement is to establish a bilateral cooperative mechanism regarding food and feed safety." In theory, a bilateral agreement should obligate both parties reciprocally to the agreement's terms. The Agreement contains reciprocity language, for example, regarding information sharing on laws, regulations and "significant risks to public health related to product safety, manufacturing conditions, recalls" and other food safety issues that might affect public health (Article IV).

However, the stipulation of what foods and feedstuffs are covered by the Agreement, at least in its initial phase, shows that the Agreement is intended to address primarily U.S. import concerns. These terms would cover pet food/pet treats, the food and feed ingredients wheat gluten, corn gluten and rice protein, low acid canned foods and farm-raised fish (Annex. Section I.B). The definition of "feed" includes "feed ingredients, feed additives and feed that contains veterinary drugs" to address U.S. concerns about unapproved ingredients or veterinary drugs, or unsafe levels of such drugs in feed (Article 2.3). Key U.S. agricultural exports to China include soybeans, hides, cotton, poultry, wheat and feed. Only the latter U.S. export is presently covered by the Agreement. Consumer organizations have criticized the Agreement for excluding products, such as apple juice, with a history of food safety violations.[17]

A March 2008 meeting of FDA and AQSIQ officials in China resulted in a decision to focus first on farm-raised fish, the subject of the aforementioned June 2007 FDA import alert. Negotiations will begin on terms for FDA inspection of fish farms and the tracing of fishmeal to determine whether drugs in the feed are safe to consume.[18] There are compelling reasons for the U.S. focus on aquaculture exports. In the latest Centers for Disease Control survey of U.S. food-borne illness (1999), about a fifth of 76 million cases were caused by seafood. As a result of the import boom since 1999, 83 percent of U.S. seafood consumption is now imported. Given this increase, it is likely that the share of food-borne illness caused by imported seafood has risen as well.[19]

China has been the leading seafood exporter to the United States since 2004, with exports increasing 34 percent between February 2006 and February 2007. Seafood exports from China accounted for an average of 39 percent of all import refusals due to veterinary drug residues from 2003 to 2006, rising to 59 percent in 2006.[20] Yet the FDA refused only 1,786 seafood import shipments of 859,357 (0.21 percent) in 2006, in part because it collected samples for testing from only 5,071 of those shipments (1.93 percent). Insufficient paperwork or past exporter import rule violations, rather than testing results, are the most frequent reasons for shipment refusal.[21] The FDA's Science Board reported a 78 percent decline over 35 years in inspection of FDA-regulated products and production facilities, "an appallingly low inspection rate."[22]

The decline of the FDA's food safety inspection and testing programs is well-documented, and the food industry's opposition to an expansion of inspection and testing is well-known (see the section below on U.S. food safety management capacity). These factors led negotiators to a novel solution to remedy the U.S. inspection and testing deficiency while facilitating the food industry's desired boom in U.S. food imports from China. They agreed that government authorities, or the private entities the governments accredit, would certify that food processing facilities for the products covered by the Agreement meet import safety requirements. The certification of facilities as safe is intended to prevent the export of contaminated products and reduce the need for product inspection and testing at U.S. ports of entry.

The Agreement will rely on "training programs and scientific discussions or cooperation, intended to support the long-term stability and effectiveness of the registration and certification programs for Covered Products" (Article V.2). Furthermore, food safety certification programs are viewed in the FDA's "Food Protection Plan" as a way to allow the FDA to focus its inspection resources on what the agency determines as a narrow range of high risk products, such as seafood.[23]

The FDA will seek Congressional authority to have importers obtain food safety certificates for their suppliers, either from legislatively authorized government authorities or from "third-party" (neither the authorized government agency nor company) certifiers.[24] Legislation introduced in the Senate in March 2008 would allow the FDA to accredit the voluntary seafood inspection program of the National Oceanic and Atmospheric Administration (NOAA) as a food safety certifier. Certification by the NOAA could remove or circumvent present FDA import restrictions on Chinese seafood without the controversy that might result from new legislation to remove the restrictions. The FDA would delegate its statutory authority to the NOAA as a "third party." The accreditation of a U.S. government agency with a voluntary inspection program to carry out inspection duties that the FDA is required to perform does not make sense in terms of protecting consumers from harm, except if the NOAA inspects products for which the FDA either lacks resources or does not allocate resources to inspect.

The FDA is also seeking to accredit AQSIQ as a third-party certifier.[25] In private third-party certification, the certifier can be neither the exporter nor the importer. For example, TransFair U.S.A., a nonprofit organization,[26] is the third-party certifying agent for fair trade coffee imported into the U.S.[27] However, Codex Alimentarius Commission guidelines allow governments to be designated as third-party food safety and quality certifiers, subject to a number of caveats, including a lack of "conflict of interest with the commercial aspects of the consignment."[28] Codex standards and guidelines are presumptively authoritative, according to Article 3 of the World Trade Organization's Agreement on the Application of Sanitary and Phytosanitary Measures.

So as long as AQSIQ meets the Codex certification requirements, the FDA can delegate its statutory authority to AQSIQ to become a third-party certifier. The Agreement would allow AQSIQ-supplied certification information to be used to justify reduced rates of import inspection (Annex, Section II.2), a provision recommended by the Grocery Manufacturers Association.[29] A former FDA official noted that this provision would give China preferred treatment over Mexico and Canada, major agricultural exporters to the U.S. who likewise have sought such treatment.[30] Such preferential treatment could be demanded by all World Trade Organization members. The European Commission has told U.S. officials that even a voluntary use of certification to expedite trade would create a "de facto obligation" that could discriminate against some exporters.[31]

The regulatory cooperative programs outlined in the Agreement are targeted to reduce the prevalence of U.S. import safety contamination in aquaculture and feedstuffs products. One proposed program concerns the level of permitted use of veterinary drugs (Article V. 2b). Another seeks to identify the undocumented substitution of feedstuffs ingredients that would reduce the nutritional quality or inflate the value of a feedstuff (Article V.2e). The Agreement would establish an "exchange of scientific, technical, and regulatory information about compliance and enforcement programs of each Party" (Article V.2c). Because food safety regulations are only as good as their compliance and enforcement programs, the FDA and AQSIQ will likely meet many times about these programs.

One of the most sensitive issues in any bilateral food safety agreement concerns the on-site inspection of food processing export establishments. The Agreement proposes terms to develop "a streamlined process" to allow inspectors from either government to inspect each other's export establishments with or without advance notice (Article V.4). Given the products covered in the first phase of the Agreement, these inspections will be FDA inspections of Chinese production facilities, including fish farms. The FDA has announced its intention to station eight officials in China.[32] Even if they were to inspect only the 26,000 food processing establishment employing more than ten persons,[33] their task would be impossible. But if they target certain aquaculture or feedstuffs exporters, unannounced inspections, especially given the commercial consequences of inspection failure, may result in wider compliance with U.S. import rules for those products.

There are three measures by which the FDA and AQSIQ will annually and jointly review the effectiveness of the Agreement's programs in improving the safety and quality of the covered food and feed products: 1) the rate of import shipment refusal; 2) the percentage of imports that do not originate in FDA or AQSIQ registered export establishments (non-registration is a criterion for shipment refusal); 3) "the

volume, frequency and significance in terms of public health hazard of recall" of the products covered by the Agreement (Article VIII). While products may be refused entry due to inspection or testing results, the Agreement does not indicate whether the rate of refusal will include published inspection and testing data. This review will apparently involve only government officials with no opportunity for non-governmental comment or reporting. Finally, the Agreement affirms the right of both governments to take any measure they deem necessary "to protect the public health of the citizens of its respective country" (Article IX). Yet the assertion of this right does not require governments to divulge what portion of refused imports were rejected as a result of physical inspection and product testing.

U.S. Government Assessment of Chinese Food Safety

Most U.S. government assessment of Chinese food safety management capacity is recent and varies somewhat in focus according to the governmental entity making the assessment. This brief survey of these assessments is not comprehensive but illustrative, and concerns only U.S. Congressional and U.S. Department of Agriculture reports.

U.S. Congressional constituent pressure prompted the U.S. House of Representatives to send a Congressional staff delegation with members of the Democratic and Republican parties on a food and product safety fact finding mission in August to China. The delegation met with U.S., Chinese and Hong Kong officials, and multinational corporate food executives and news reporters based in China. They visited food processing facilities and government food testing laboratories, the latter which the staff found comparable to FDA laboratories. Regarding domestic food safety management controls, the delegation report concluded, "The Chinese government has minimal ability, even at the local level, to monitor food production activities in order to ensure product safety."[34] Delegation sources reported that while AQSIQ and other government agencies set high food standards, standards enforcement was largely left to local authorities, who report to Communist Party officials whose priority is to ensure low food prices and economic growth, rather than consumer safety.[35]

> *"Although there was agreement over the sincerity and scope of AQSIQ efforts, there was less confidence over the willingness of local CIQs [China Inspection and Quarantine] to follow the Central Government's dictates. And Committee staff was told that it is at the local level where the system succeeds or fails." U.S. Congressional staff delegation report. October 4, 2007.*

Because of the FDA's lack of confidence in AQSIQ's ability to keep local foods out of the export supply chain, the FDA has refused to recognize the validity of local CIQ safety certificates. Nevertheless, according to Congressional investigators, "FDA has no prohibition against the entry of food products that do not bear this certification."[36] Looking for ways to improve U.S. import safety, both the Congressional staff delegation and Congressional Research Service investigators have compared how other countries and governmental entities import food from China, particularly Japan and Hong Kong. Noting that Japan inspects about 15 percent of all food imports from China, and the Chinese administrative entity of Hong Kong inspects yet more food, compared to the FDA's one percent inspection rate, the staff concluded that the FDA could not afford the cost of rising to Japan's and Hong Kong's inspection and testing rates.[37] Furthermore, according to a Japanese household survey, because safety is

the top food concern for 70 percent of those polled, the Japanese consumer is willing to pay a premium for safety.[38]

Instead, the staff report recommends that the FDA rely on AQSIQ safety certification of food and feed exports, stating that "absence of such a certificate, however, most certainly means that the Chinese quality control has been evaded."[39] Reliance on electronic certification of food safety is a main tool of the FDA's "Food Protection Plan," but the FDA has no current regulatory authority to reject a shipment on the basis of the lack of a certificate. Given the advanced state of counterfeiting in China noted by the Congressional staff, the FDA/AQSIQ Agreement contains provisions to secure the integrity of electronic certification and to revoke certification to export on the basis of FDA inspection or testing results (Annex, Section II, C).

The USDA has analyzed Chinese food safety measures for FDA-regulated products in the context of Chinese export competitiveness with the United States and the Chinese agricultural system. The USDA notes that "[m]any of China's food safety problems can be traced back to the farm level," particularly regarding excessive use of pesticides and veterinary drugs.[40] Its analysis of production contracts provides useful insight into the problems faced by foreign investors in Chinese agriculture in terms of instituting Good Agricultural Practices that would reduce pesticide and veterinary residue levels in foods and fish.

According to the USDA, the Chinese Ministry of Agriculture has regulatory authority over farm-level food safety, which focuses on pesticides and not on the microbial pathogens in agricultural water and soil that can contaminate fish, meat, poultry and horticultural products.[41] USDA economists conclude, "China's looming threat to the U.S. [horticultural] industry is somewhat offset by high marketing costs, uneven quality, and chemical residues on Chinese fruits and vegetables. China still faces challenges in improving the quality and safety of products."[42]

U.S. Capacity for Implementing Bilateral Food Safety Agreements

The capacity of the FDA to implement the bilateral agreement with AQSIQ is based on a broader food safety management capacity. The carefully drafted Agreement, targeted at a few high risk products, should not be prejudged because of broader U.S. management problems. Nevertheless, it is hard to be sanguine about the likelihood of the Agreement's success in protecting public health. The General Accountability Office (GAO), an independent U.S. government auditor, considers overall U.S. government food safety management controls to be so weak as to merit inclusion on its "high risk" audit series.[43]

> *"As we have repeatedly reported, our fragmented food safety system has resulted in inconsistent oversight, ineffective coordination and inefficient use of resources. With 15 agencies collectively administering at least 30 laws related to food safety, the patchwork nature of the federal food safety oversight system calls into question whether the federal government can more efficiently and effectively protect our nation's food supply." GAO testimony to the U.S. House of Representatives. April 24, 2007.*

This management fragmentation and inefficient use of food safety resources did not come about as a result of the import boom of the past decade. Rather, the import boom exposed the vulnerabilities of both U.S. domestic and import food safety management, a consequence of three decades of deregulatory pressure and food safety budget cuts, particularly for inspection and testing.

The FDA Science Board review of FDA food safety programs concluded that they were "severely eroded" and that the inspection program, which is to verify that the other programs are working, suffers from "an appallingly low inspection rate."[44] A former FDA administrator testified to Congress that "for years" there were fewer than 200 fulltime FDA inspectors to "conduct entry reviews, collect samples and conduct physical examinations and investigations on all imported goods, including food and drugs" in more than 300 U.S. ports of entry.[45] As a result, for example, the U.S. inspection rate of seafood imports is about 1/20 to 1/50 of the European Union rate, depending on species.[46]

Despite the "appalling low inspection rate," food industry lobbyists told President George Bush's Interagency Working Group (IWG) on Import Safety not to increase import inspection at U.S. ports of entry, and the IWG duly outlined food safety controls that de-emphasize physical inspection and product testing.[47] The IWG report states that the FDA "Food Protection Plan" is integrated with its own "Import Safety Strategic Framework and Action Plan."[48] The FDA plan covers domestic food safety controls as well as the "approximately 189,000 registered foreign facilities [that] manufacture, process, pack, or hold food consumed by Americans."[49] How will the FDA compensate for its very small capacity to inspect the facilities, to say nothing of the import products, from the huge number of facilities under its nominal authority, given the scarce FDA food safety resources that are one result of the Bush Administration's tax cuts and huge budgetary deficit? The FDA plan will "promote increased corporate responsibility to prevent food-borne illnesses" through "the adoption of voluntary preventive controls."[50] In other words, the food industry will maintain *de facto* control over food safety management.

A new Administration may raise taxes and/or reallocate existing resources to enhance port of entry inspection and testing. But the pressure to continue the Bush Administration practice of "voluntary compliance" by the food industry with "voluntary preventive controls" to expedite trade could well continue in a new Administration. In a normal commercial and legal climate, liability for harm to consumers, in addition to loss of commercial reputation and sales, would act as sufficient deterrents to motivate compliance with import requirements. But as the lines of public and private authority are blurred with the definitions and practice of third-party food safety certification, the laws governing liability become more difficult to use. Furthermore, the Bush Administration practice of deferring prosecution of law-breaking corporations, in exchange for promises of good behavior, invites greater risk-taking by less scrupulous importing companies.[51]

Conclusion

Michael Taylor, now a health policy professor but formerly a USDA and FDA official (1991-1996) and legal advisor to Monsanto, said, "We owe China a debt of gratitude for putting food safety on the map in the United States," while suggesting that the melamine contamination of U.S. pet food imports provided the impetus to both U.S. food import and domestic safety reform.[52] Taylor was among the witnesses testifying at an April 24, 2008 U.S. House of Representatives hearing on the food provisions of the draft "Food and Drug Administration Globalization Act." FDA officials had hoped that Congress would pass legislation giving the FDA new legal powers by the end of May.[53]

Taylor's testimony is representative of the food safety regulatory "community," insofar as he affirms the primacy of the food industry in preventing food safety hazards: "The unavoidable reality is that government does not make food and government cannot make it safe. . . [M]odern regulation is clear in setting performance standards for companies and flexible in how companies can achieve the standard."[54] However, the Grocery Manufacturers Association is strongly opposed to the FDA legislation, claiming, at the same hearing, that the draft legislation's proposal on third-party certification "would be tantamount to creating a 'shadow' government."[55] The future of this complex legislation is thus not clear and its approval probably not imminent.

However, one of Taylor's recommendations merits comment because it pertains to the enforceability of parts of the bilateral Agreement. Taylor follows the GAO and the National Academy of Sciences in calling for legislation that would enable the FDA to treat "food safety as a farm-to-table, system wide problem."[56] He commends the draft legislation for including provisions on fresh produce, a major export from China to the U.S. He then recognizes that "at the farm level, systematic planning for prevention of food safety problems is in its relative infancy."[57] The "infancy," we hasten to add, is economic, as well as technical and legislative. What, if anything, can government do to induce importers to incorporate the costs of farm-level food safety measures in the prices paid to farmers for imported foods?

In terms of the bilateral Agreement, "farm-to-table" food safety measures affect farm-raised seafood exports perhaps more than any of the other products currently covered in the Agreement. The FDA can test seafood for veterinary drug residues and reject imports for excessive residues. But the FDA's and AQSIQ's ability to prevent the need for drug use by ensuring high water quality standards, high fish stock standards and good aquaculture management practices by thousands of suppliers is very limited. If the Agreement is extended to cover fresh produce imports, then AQSIQ's ability to enforce good agricultural practices, e.g. to prevent microbial contamination of produce by runoff from livestock feedlots, is likewise very limited. As noted above, the Ministry of Agriculture (MoA), and not AQSIQ, regulates domestic agriculture production and farm-level food safety. The MoA's regulation over the production of 200 million farm operations largely concerns pesticide residues and not microbial contamination. A survey of recent Chinese food safety regulations and legislation revealed little MoA regulatory activity.[58] As noted above, U.S. congressional investigators do not believe that AQSIQ has the ability to ensure that food produced under the MoA's authority would not be diverted to the export supply system. FDA-regulated food imports include about 60 percent of U.S. fruit and vegetable consumption and more than 75 percent of seafood consumption.[59] Insofar as China is the leading source of U.S. seafood imports and among the leaders of fresh produce imports, there is a

need for greater cooperation between the MoA and AQSIQ, as well as the FDA and AQSIQ to prevent farm-to-table food hazards.

The FDA's "Food Protection Plan" states, "FDA often has very limited information regarding conditions under which most food is produced in foreign countries."[60] It is remarkable that it has taken the United States more than a decade after the start of its food import boom to gather information to propose regulatory reform that aims to protect consumer health, rather than just facilitate trade. It is not at all clear whether the FDA's Plan, which relies on "increased corporate responsibility to prevent food-borne illnesses" through "the adoption of voluntary preventive controls,"[61] will reduce imports of contaminated or otherwise hazardous food and feed products. The political, regulatory, budgetary and technical challenges to fundamental reform of the FDA's domestic programs are very great. Extending the proposed FDA food safety reform to China will certainly be a far greater challenge.

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58 Claudia Nanninga. Unpublished research notes on Chinese food safety regulation and legislation during the past decade. Institute for Agriculture and Trade Policy. April 2008. On file with the author.

59 "Statement of Benjamin L. England, JD" to the Subcommittee on Oversight and Investigations, Committee on Energy and Commerce, U.S. House of Representatives. November 1, 2007. At 4.

60 "Food Protection Plan." Op cit. 9.

61 Ibid. 3 and 12-18.

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