

Global Food Safety Monitor May 21, 2009

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Risk and communication

According to the bureaucratic paradigm of risk analysis, scientists assess the risks of a particular product or ingredient in response to tasks set by risk managers, i.e., high-level regulatory officials. Once a risk has been assessed (as a number if possible, e.g., humanly "tolerated" parts per million of a toxin), risk managers develop policy, which is communicated by government and industry officials to the public. In practice, and particularly during a public health emergency, the paradigm breaks down and risk communication takes many forms.

In this *Monitor*'s articles, the extent of risks and the channels for its communication both intersect with and fall outside the paradigm. For example, the World Health Organization (WHO) has been criticized for communicating too soon and in the form of a pandemic alert the risk data that it gathered from governments on the H1N1 influenza virus. The technical definition of pandemic refers to the prevalence and rapidity with which an illness spreads. With 40 countries reporting 9,830 confirmed cases of H1N1 to WHO as of May 19, the data justified WHO's decision to issue the "imminent pandemic" alert on April 29. Despite 79 deaths reported globally as of May 19 from this H1N1 outbreak, critics say that WHO "cried wolf," and that its risk communication unnecessarily damaged the global pork industry.

Recent reviews of EU, U.S. and Mexican regulations on genetically modified organisms offer different opportunities for risk communication. For the U.S., the regulatory review is part of a larger strategy to support private and public investments in GMOs as the chief technology through which to ensure global food security by 2050. (Based on computer-modeled assumptions about population growth, agricultural crop yields and natural resource constraints, institutions such as the World Bank and FAO attempt to forecast the amount of agricultural production needed by 2050 to meet food security needs, usually defined in calorie intake per person. Though projections so far in the future cannot be verified empirically, their quantification and policy scenarios are used to solicit immediate public investments in GMOs and other agricultural technologies.) The review is an opportunity

to reaffirm the safety of GMOs that has been assumed since the first U.S. regulatory framework for commercializing GMOs was established in 1986, originally under the aegis of former Vice President Dan Quayle's Competitiveness Council. The European Commission's (EC) campaign to legalize the planting of GMOs is part of a broader strategy premised on the belief that EU member states otherwise cannot grow sufficient feed grains for the EU meat and dairy industry.

Communicating about favorable European Food Safety Authority risk assessments and providing technical assistance to make GMOs "co-exist" in the field and food supply chain is part of EC risk communication. For federal government and industry officials in Mexico, approval of legislation to commercialize GMOs, despite widespread popular opposition, is justified not only in terms of conforming to WTO obligations, but also to make national growers competitive in the transnational corporate trading system. For these officials, risk communication is a tool not simply to assert the public health and environmental safety of the product, but also to enhance national competitiveness.

Historically, risk communication practice has resulted from negotiation among government and agribusiness officials, advised by academics, most of them going in and out of government service. However, consumers, often regarded as irrational by both governments and industry in assessing and communicating risk, have some options when neither governments nor companies are able to trace back the sources of contamination in food products to communicate risks to the public. As a resource note below shows, as food supply chains grow longer, traceability challenges grow so great that companies don't know where their ingredients come from. The response of some food companies to an inability to ensure the safety of their products has been to shift liability for unsafe products on to consumers, e.g., through detailed cooking instructions. Apparently, the cost of out-of-court settlements for sickening consumers is less than the cost of shortening and simplifying the supply chain. Apart from not buying anything from those companies, and advising friends not to do so, consumers can and do intervene in the regulatory process to prevent risky products from getting to market.

Sources: Andrew Jack. "WHO moots ratings rethink amid criticism on swine flu alerts." Financial Times. May 8, 2009; "Influenza a (H1N1) - update 20." World Health Organization. May 7, 2008; Stephen Clapp. "OIG report urges USDA biotech export strategy." Food Chemical News. April 6, 2009; Jamie Strawbridge. "EU Poised to Unveil New Standard for Detecting Trace GMO Presence." Inside U.S. Trade. January 23, 2009; Michael Moss. "For Frozen Entrees. 'Heat and Eat' Isn't Enough: Food Giants Shifting Onus for Safety to Consumer." The New York Times. May 15, 2009.

True but misleading: what's not in a name

U.S. officials, in a coordinated effort to protect the pork industry from an industry estimated \$7 million a day in lost anticipated sales, continually remind reporters that it is not "swine flu" but "H1N1," a virus with human, avian and porcine genetic material. WHO issued a May 2 statement, with the World Trade Organization, the World Animal Health Organization (OIE), and the UN Food and Agriculture (FAO) organization, that there was no scientific justification for the import bans on pork products that have spread to more than a dozen countries. The National Pork Producers Council cites this statement in support of its message, "The bottom line is pork is safe to eat and handle." Mexico reiterated this message in its May 5 report to the WTO, following the April 23 Mexican Ministry of Health announcement of the presence of the H1N1 virus in Mexico. Mexico told WTO members that based on work undertaken since 2008, "We are able to announce THE ABSENCE OF ANY OUTBREAK OF SWINE INFLUENZA (capitals in the original)" and that all Mexican pork was safe to eat.

But Dr. Joergen Schlundt, the director of WHO's food safety program, provided this caveat to these statements in an email response to Reuters: "Meat from sick pigs or pigs found dead should not be processed or used for human consumption under any circumstances . . . there are no data available on the survival of Influenza A/H1N1 on meat nor any data on the infectious dose for people." The first part of the caveat is commonsensical: don't trade or eat meat from sick pigs or pigs that have died prior to slaughter. More troubling is the second part of the caveat-that there is no risk relevant data about H1N1 on meat on the basis of which an import ban could be justified. True, H1N1 has not been isolated yet in the hogs that a laboratory employed by the Smithfield Corporation has selected for testing from the Granjas Carroll Confined Animal Feeding Operations (CAFOs) it co-owns with a Mexican agribusiness firm. On May 14, Smithfield chief executive officer Larry Pope announced in a letter to employees that lab tests confirmed that the "H1N1 influenza affecting humans did not originate" from the Granjas Carroll facility near La Gloria, Veracruz. Samples of the lab tests were sent to Mexican authorities.

Granjas Carroll manages a CAFO located about 5 miles from La Gloria where the first case of H1N1 was diagnosed on April 2. Sixteen Granjas Carroll CAFOs in Perote Valley produce about 1.2 million pigs annually, of about 15 million slaughtered annually in Mexico. Smithfield established the first CAFO in the Perote Valley in 1993, in anticipation of the trade benefits of the North American Free Trade Agreement. The stench and other environmental health problems from the CAFOs have resulted in popular opposition to the facility. Granjas Carroll has sued activists for defamation and some of the activists have reported receiving death threats. In February, two children in La Gloria died of what Mexican health authorities called "acute respiratory infection" that they said had nothing to do with the environmental health conditions at Granjas Carroll. A private risk assessment firm Veratect, had warned WHO's regional office in early April of a respiratory illness affecting more than 600 people in La Gloria. On May 7, Mexican food safety and animal health authorities said that during their visit to the Granja Carroll facilities, they observed neither sick pigs nor sick workers.

Yet a narrow claim about the apparent absence of H1N1 in one CAFO can mislead if the claim is used to distract the public from public health officials' concerns that CAFOs are a probable factor in the emergence of H1N1, which as of May 17 had killed 66 persons in Mexico. According to Dr. Michael Greger, "A preliminary analysis of H1N1 from human cases in Texas and California reveals that six of the eight viral segments arose from North American swine flu strains circulating since 1998, when a new strain was first identified on a factory farm in North Carolina." Dr. Robert Webster, a leading researcher in flu virus evolution, ascribes the emergence of H1N1 in 1998 to the adjacent location of swine and poultry CAFOs employing common personnel. La Gloria is surrounded by both swine and poultry CAFOs. Literature cited by Dr. Greger noted that close confinement predisposes pigs to infection and locating swine CAFOs in close proximity to one another increased the odds for testing positive for swine flu by 16.7 times.

The close confinement that makes CAFOs economically viable is a recognized vector for virus mutation and transmission. In 2006, the U.S. National Institutes of Health (NIH) stated that because CAFOs "concentrate large numbers of animals close together, they facilitate rapid transmission and mixing of viruses." In March 2003, *Science* reported the concerns of molecular virologists that swine, as "mixing vessels" for swine, human and avian influenzas, now had co-evolved an "extremely promiscuous" virus that could infect humans. Science also reported that the U.S. Department of Agriculture did not then have an official surveillance system for swine flu.

According to *The Wall Street Journal*, the USDA has just begun a pilot program for swine flu surveillance but hasn't yet tested any of the 65 million U.S. swine. Nor are farmers required to report cases of swine flu. The USDA was pressured by the Centers for Disease Control to create the program after it reported that a worker had been infected by H1N1 in 2005 after exposure to freshly slaughtered pigs. Despite the concerns of the virologists, swine flu has been a low priority disease for USDA. In late May, the OIE will debate whether its 172 member governments should report swine flu outbreaks to the organization, whose standards enable livestock, meat and dairy product trade. If OIE members vote to require such reporting, perhaps there will be more public health pressure to investigate the causes of epidemic-scale hog deaths, such as those reported at Smithfield's CAFO in 2007 in Cenei, Romania. While Smithfield maintains that "it is impossible to know" why thousands of pigs died, it is seeking \$11.5 million from the European Union to pay for killing and disposing of the afflicted animals.

In Mexico, where the first H1N1 deaths occurred, the Center for Economic Studies of the Private Sector said that the epidemic exposed the breakdown of the general public health system and lack of Mexican capacity to diagnose and promptly treat patients afflicted by the virus. Further complicating diagnosis and treatment, five strains of influenza have been circulating in Mexico and some of the H1N1 patients did not have a fever, a typical symptom and screening criterion. The head of Mexico's National Institute for Respiratory Illnesses warned that hospitals had only seen "the point of the pyramid" of the epidemic, anticipating that many cases of H1N1 would be identified before patients became gravely ill. Mexico's Ministry of Health will present a proposal to the World Health Assembly, meeting May 18-27 in Geneva, that a fund be established to compensate those countries that report to WHO "in an opportune manner" disease outbreaks of international scope.

Despite the transmission of H1N1 to 39 countries, on May 13, Smithfield Foods chief executive officer Larry Pope told a meeting of agribusiness stock analysts, "This thing [H1N1]'s been way overblown-way overblown . . . For the impact it had relative to the news media coverage, it's absolutely crazy. And even the two deaths that happened in the U.S. . . . I feel sorry for those people, but those people had complicated medical issues that they were dealing with. And so this is really not a big deal."

Hopefully, WHO's declaration of an "imminent pandemic" has triggered adequate public health preparation, including having sufficient anti-virals to treat the disease, whose impacts have largely been mild outside of Mexico. But if H1N1 evolves further to become rapidly lethal, the truths about pork consumption and the semantic parsing of the disease will be rapidly forgotten. The accusations that WHO "cried wolf" and the denials that CAFO practices had anything to do with the pandemic will be attributed to somebody else.

Sources: Rod Smith. "Pork losing \$7m daily." Feedstuffs. May 11, 2009; Steve Lewis and Amber Healy. "Flu epidemic hits pork industry, debilitates Mexico's food sector." Food Chemical News. May 4, 2009; "Pork Safe To Eat, Handle,' Says Pork Industry." National Pork Producers Council press release. May 3, 2009; "Information on Outbreaks of A/H1N1 Human Influenza Virus on Mexican Territory." World Trade Organization Committee on Sanitary and Phytosanitary Measures. May 5. 2009; "WHO warns against H1N1 tainted pork." Food Chemical News. May 11, 2009; Steve Fainaru. "Mexicans Blame Industrial Hog Farms: But Health Officials Have Found No Link to Recent Flu Outbreak." The Washington Post. May 10, 2009; Riaz Tayob. "WHO monitoring swine flu, response and preparedness." SUNS. May 6, 2009; Tom Johnston. "Smithfield completes testing on Mexican pigs, awaits results." Meatingplace.com. May 5, 2009; Tom Johnston. "Smithfield says its Mexican hogs test negative for H1N1 flue." Meatingplace.com. May 15, 2009; "A food system that kills: Swine flu is meat industry's latest plague." GRAIN. April 28, 2009; Scott Kilman. "U.S. Testing for Flu in Pigs Less Stringent Than for Mad Cow, Bird Flu." The Wall Street Journal. May 5, 2009; Doreen Carvajal and Stephen Castle. "Meat Packer Puts Stamp on Europe." The New York Times. May 7, 2009; Michael Greger. "CDC Confirms Ties to Virus First Discovered in U.S. Pig Factories." Humane Society of the United States. May 3, 2009; Bernice Wuetrich. "Chasing the Fickle Swine Flu." Science. Vol. 299. March 7, 2003; AP Newman et al. "Human case of swine influenza A (H1N1) triple reassortant virus infection, Wisconsin." Emerging Infectious Diseases. September 2008; "Las cifras;" Enrique Méndez

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Deregulating GMOs: It's all legal now

On March 6, a presidential decree ended the 10-year Mexican moratorium against the planting of genetically modified maize. In practice, the moratorium had been violated at least since 2001, when the Mexican government first recognized that maize landraces had been contaminated with GMOs. The moratorium was established because the environmental health effects of GMOs on maize landraces were not (and continue not to be) studied. In 2004, the North American Commission on Environmental Cooperation published a study in which it recommended that U.S., Mexican and Canadian governments evaluate the effects on human health of consuming genetically modified maize, since Mexicans consume far more maize per capita than do U.S. and Canadian citizens. However, no such study has been undertaken.

With the end of the moratorium, it is expected that Monsanto will be able to sell its genetically modified seed to commercial growers in the northern tier states of Sonora, Sinaloa, Tamaulipas and Chihuahua. In September 2008, Greenpeace Mexico discovered that U.S. seed imports sold as conventional hybrids were in fact genetically modified and planted on about 25,000 hectares in Chihuahua. On April 14, Greenpeace Mexico filed criminal charges against President Felipe Calderón and his ministers for authorizing GM maize planting in his presidential decree.

Global civil society has responded to the presidential decree and to the government's request for comments on applications from Monsanto, DuPont-Pioneer and Dow toward commercializing 25 genetically modified varieties (eight of them unapproved in the U.S.), nearly all of them maize. On May 13 the Mexican Network in Defense of Maize presented to regulatory authorities a sign-on letter that has gathered the support of 768 organizations from 56 countries, in addition to 2433 individuals. The letter will also be presented at the June 1-5 meeting of the International Treaty of Plant Genetic Resources for Food and Agriculture. The letter, signed on to by IATP, characterizes the presidential decree as a crime against humanity, insofar as Mexico is the primary center of maize origin and diversity, and the affect of contaminating Mexican landraces is unstudied and unknown. The letter also repudiates the industry claim that GMOs yield more than conventional varieties and denounces government spying on peasant farmers to ensure that company patents on seeds developed from peasant-developed germ plasma are protected.

In the United States, where officials have allowed commercialization of GMOs without pre-market safety testing since at least 1996, civil society and farmer organizations have more modest goals than those of the Mexican Network. In a March 20 letter to the U.S. Department of Agriculture, approximately 80 U.S. organizations, including IATP, petitioned the USDA to release a final Environmental Impact Assessment (EIS) on GMOs that is required under the National Environmental Protection Act. The USDA undertook the EIS in 2004 as part of its plan to revise the regulatory framework for GMOs. (In the semi-annual review of U.S. federal regulatory activity,

published May 11, the Obama administration did not forecast when the new USDA biotechnology regulation framework would be published. The new framework will revise the original 1987 one.) The petitioners also asked USDA Secretary Tom Vilsack, a strong supporter of GMOs while governor of Iowa, to withdraw a rule proposed by the Bush administration that would allow companies to determine when rules governing the presence of "low level" GMO contamination would trigger regulatory action. While the U.S. government has largely allowed self-regulation by GMO developers, petitioners argue this particular proposed rule would negate USDA's legal responsibilities under the Plant Protection Act. Until the USDA issues new rules on GMOs, the petitioners call for a freeze on all GMO commercialization applications. Meanwhile, at the G-8 agricultural ministers meeting April 18-19 in Italy, Secretary Vilsack supported a G-8 commitment to expand GMO use and free trade in the name of eradicating global hunger.

Because the U.S. government believes that GMOs pose no more risks to public health or the environment than do conventional seeds and foods, it has opposed work on biotech labeling at the Codex Alimentarius Commission's committee on food labeling (CCFL) for nearly two decades. The World Trade Organization regards Codex standards as conforming to WTO agreements. For the U.S., any labeling of GMO products would be "true but misleading" since products so labeled would be distinguished from conventional foods. During the May 4-8 CCFL meeting, the U.S. again tried to stop all Codex work on biotech labeling but failed, supported "perhaps" by only Mexico, according to the head of the U.S. delegation. Michael Hansen, representing Consumers International at the meeting, said that U.S. intransigence could be explained by State Department officials' fears of a WTO dispute on biotech labeling.

In the European Union, the GMO regulatory divide between the European Commission and the EU member states continues to widen. At a late March meeting of EU agricultural ministers, nine countries indicated support for a Dutch proposal that each EU member state be allowed to decide whether or not to plant biotech crops, while following EC rules on the importing of GMOs. Four member states opposed the proposal in the belief that EC internal market rules would be undermined if states were allowed to determine whether or not to allow GMO planting. In April, Germany became the sixth EU member state to ban planting of EC-approved GMOs. Spain, Portugal, Romania, Poland, Slovakia and the Czech Republic grow transgenic crops on a very small percentage of the EU's arable land. The EC has sought to mollify member state concerns through a non-binding recommendation on rules for preventing contamination of organic and conventional crops by GMOs. The EC has created a European Co-existence Bureau to provide technical assistance to member states that seek to implement the recommendation.

Sources: Ana de Ita. "Por decreto transgénico." La Jornada. March 21, 2009; "Mensajes cruzados, prácticas obscuras." GRAIN Biodiversidad. May 2009; Red en Defensa del Maíz. Press release. May 13, 2009; "No to transgenic maize!"; "Denuncia Greenpeace a Calderón. Cardenas y Elvira por infringer leves sobre OGM." April 14, 2009; Center for Food Safety Press release. March 20, 2009; "No end in sight for USDA biotech regulatory overhaul." Food Chemical News. May 18, 2009; "G-8 Ag Ministers Support for Biotech and Free Trade Undermines Steps to Eradicate Hunger."

Institute for Agriculture and Trade Policy press release. April 21, 2009; Stephen Clapp. "U.S. aims to stop further Codex work on biotech labeling." Food Chemical News. April 13, 2009; "EU farm ministers consider re-nationalizing biotech approvals." Food Chemical News. March 30, 2009; "Germany readies ban on biotech corn cultivation." Food Chemical News. April 20, 2009; "Commission publishes new report on national strategies to ensure coexistence of genetically modified crops with conventional and organic farming." European Commission press release. April 2, 2009,

Resources

<u>"Traceability in the Food Supply Chain."</u> Office of the Inspector General. U.S. Department of Health and Human Services. March 2009.

This is the first Inspector General (IG) report in eight years to review compliance with Food and Drug Administration (FDA) food safety rules. Because the ability to trace back or trace forward the source of food contamination or adulteration is crucial to preventing food emergencies and mitigating those that occur, the topic of this report couldn't be more timely or appropriate. IG auditors selected 40 foods (beverage, dairy, grain and horticulture products in equal number) under FDA authority and purchased them for trace back from U.S. retail food establishments to farms. The IG interviewed managers at 103 of 118 facilities (processing, storage, distributing and retailing) that the FDA requires to keep traceability records. If the managers could not provide contact information for the food supply chain sources of its food, the IG considered the facility to have failed. Following this methodology, the IG was able to trace 5 out of 40 foods at each step of the supply chain. For 31 remaining products, the IG could identify facilities that likely handled the products. Given these results and the fact that only half of retail food managers interviewed were aware of FDA record-keeping requirements, the IG makes recommendations that the FDA propose new legislation to strengthen traceability. Farms are currently exempt from FDA record-keeping rules. The IG identifies the lack of traceability for raw food products mixed from numerous farms as a "serious vulnerability" in U.S. food safety.

"Food Safety: Report by the Secretariat." April 16, 2009 and "Medium Terms Strategic Plan: 2008 (Strategic Goal 9 on Food safety, food security and nutrition)." May 2009.

"Proposal Program Budget 2010-2011: Financial Tables." May 2009

World Health Organization for the Sixty-Second World Health Assembly.

This set of documents, prepared for the intergovernmental World Health Assembly (May 18-22 in Geneva), gives an overview of WHO food safety objectives and resources in the near to medium term. The Secretariat report divides the food safety analysis from medium-term strategic objectives in which food safety, food security and nutrition are joined to fulfill UN Millennium Development Goals. This division makes it difficult to analyze what part of WHO's budget is directed to food safety, compared to that dedicated to food security and nutrition programs that are carried jointly with the UN Food and Agriculture Organization. Nevertheless, the Secretariat report states, "Food safety and food-borne diseases are a growing public health problem," with food-borne and waterborne diarrheal diseases killing an estimated 2.2 million people annually, about 1.9 million of them children. "Many or most new human infectious diseases over recent decades have originated from animals and that transmission has also been through food." As a result, WHO is focusing on surveillance of diseases transmitted from animals to humans to aid with "forecasting, alert and response mechanisms."

Strategic objective nine is "to improve nutrition, food safety and food security, throughout the life course, and in support of public health and sustainable development." The bundling of food safety with food security and nutrition follows the recognition that those most vulnerable to food-borne disease are the undernourished. The Strategic Plan states, "nutrition and food safety are not sufficiently prominent in national development plans," noting that "only 0.7 percent of the World Bank's total assistance to developing countries is for nutrition and food

security." National and international budgetary commitment to food safety and nutrition has been historically low, despite the economic damage caused by food-borne disease to both trade and development. Whereas in 2008, WHO estimates that 30 of 193 member countries had integrated strategies on food safety, nutrition and food security, by 2011 it aims to have 70 member countries with such strategies; WHO proposes to spend about \$19 million in 2010-2011 to achieve that and related objectives. The total proposed budget to achieve all program goals for strategic objective nine is about \$120 million, about a fifth of which is spent by the headquarters and the rest in regional WHO offices. But perhaps the most alarming statistic in the financial tables is that \$18.7 million, less than a sixth of the WHO proposed budget for food safety, food security and nutrition programs, comes from member country dues. The remainder of the budget will depend on "voluntary contributions" from member countries, foundations and companies, usually given for specific purposes. Whether these contributions will be forthcoming during a global economic crisis is very uncertain.

The *Global Food Safety Monitor* is a periodic newsletter published by the Institute for Agriculture and Trade Policy and edited by Steve Suppan, Ph.D.

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