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***"One Health is the collaborative efforts of multiple disciplines working locally, nationally, and globally to attain optimal health for people, animals, plants and our environment."***

*"One Health implementation will help protect and/or save untold millions of lives in our generation and for those to come."*

*"Between animal and human medicine there are no dividing lines--nor should there be."*

Rudolf Virchow, MD (the father of cellular pathology)

### **One Health in Action...**

## **The New United States Food and Drug Administration (FDA) Food Safety Modernization Act (FSMA)**

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Graciously provided January 23, 2013 to the One Health Initiative website by:

***Michael R. Taylor, Deputy Commissioner for Foods and Veterinary Medicine at the U.S. Food and Drug Administration, Silver Spring, MD***

January 4, 2013 was a historic day for food safety. With publication of proposed rules on produce safety and preventive controls in facilities that produce human food, we are taking an important step forward in preventing foodborne illnesses and outbreaks.

Although ground breaking, these proposed rules represent what we have known for some time—that food safety is no accident. It takes all of those involved in producing and processing food taking the right measures to prevent hazards that can cause illness at each important stage of the process.

It may sound simple when stated that way, but make no mistake—building a new food safety system whose goal is prevention and that is science- and risk-based is no easy task. Nor will it happen overnight. It will take sustained effort and continued partnerships with everyone involved.

But the public health imperative for this effort and these new rules is clear. Too often, we have seen major food-related outbreaks, with hundreds of people becoming ill. This isn't acceptable to anyone, whether you are the victim or the victim's parent or child. The burden of illness is backed up from data from the U.S. Centers for Disease Control and Prevention (CDC), which estimates that one in 6 Americans get ill each year, 128,000 are hospitalized and 3,000 die.

These outbreaks also inflict significant costs on the food industry, due to market disruptions and lost sales. Even businesses that are not at fault suffer because they produce the same product that has been implicated in an outbreak.

We would never claim that all illnesses and outbreaks will be prevented once these rules are implemented, but we are confident that the burden on public health and the economic well-being of the food system will be lessened significantly.

In many ways, the concept of preventing food safety hazards that is represented by these two rules is not new. It has been about 50 years since the U.S. National Aeronautics and Space Administration (NASA) first used preventive controls as a way to keep food safe for astronauts. Since then, many manufacturers have adopted modern preventive controls for food safety as the only acceptable way to do business. Over the past 20 years, FDA and the United States Department of Agriculture (USDA) have already set preventive control requirements for seafood, juice, eggs, meat and poultry.

But we still have a lot to do to translate these familiar concepts into regulations that can apply and work in a practical way in the large and diverse array of food production settings that comprise today's food system. This includes farms and facilities of all sizes and types producing a vast array of foods each with its own risk profile. We need rules that work to protect food safety in ways that are adaptable to this diversity. One-size-fits-all-rules won't work. The proposed rules reflect the parallel goals of food safety protection and practicality. We have worked to make the proposed requirements highly adaptable to different settings, whether you are a small organic farmer or a large multi-national corporation. We have worked to make the proposed rules risk-based, recognizing that there is no need to set requirements for produce that is not eaten raw, such as potatoes. And we propose exemptions and modified requirements that recognize the need to be sensitive to small businesses.

The two proposed rules are the first among five rules that would lay the cornerstone of a prevention-based, modern food safety system that addresses the safety of both domestic and imported product. Three additional rules will follow. The proposed rule on Foreign Supplier Verification is the central element of the new import oversight system mandated by FSMA <http://www.fda.gov/food/foodsafety/fsma/default.htm> and thus an essential component of the modern food safety system envisioned by Congress for today's global food system. It will strengthen the oversight of foods imported to the U.S. by making importers accountable for verifying that the food they import is produced in a way that achieves the same level of public health protection as required of domestic growers and processors. The proposed rule on Accreditation of Third Party Auditors would also strengthen assurances about the safety of imported food by setting standards for accreditation of private third-party auditors in foreign countries. The proposed rule on Preventive Controls for Animal food is similar to the rule for human food. Together, they complement each other in a way that reflects the **"One Health" concept**, which supports collaboration among the medical and veterinary communities and recognizes the convergence of human and animal health.

In developing all of these rules, we have made sure the public's voices have been heard, from the victims of foodborne illness, to farmers in all types of operations, to industry experts who have experience in implementing preventive controls. Our extensive outreach has included trips to farms in 14 states and various processing facilities, 500 presentations to stakeholders around the country, and we have worked closely with our colleagues at USDA, who have the most experience working with the farm community. We will continue to listen during the 120-day comment period as we schedule public meetings and briefings and as we prepare the next three rules for publication. This open and public debate is

essential to ensuring we end up with the best rules possible, and a new food safety system that works well for consumers and industry alike.

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**Comment from: One Health Initiative Autonomous *pro bono* Team:** Laura H. Kahn, MD, MPH, MPP • Bruce Kaplan, DVM • Thomas P. Monath, MD • Jack Woodall, PhD • Lisa A. Conti, DVM, MPH

We are proud to note that FDA personnel, **Dr. Bernadette Dunham**, a veterinarian and **Dr. Kathleen F. Gensheimer**, a physician are participating members of the One Health Initiative Team's Honorary Advisory Board <http://www.onehealthinitiative.com/advBoard.php>:

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