FDA proposes sweeping new food safety rules

By Neela Banerjee and Alana Semuels, Los Angeles Times

The Food and Drug Administration has proposed sweeping rules to curtail food-borne illnesses that kill thousands of Americans annually — and, in the process, to transform itself into an agency that prevents contamination, not one that merely investigates outbreaks.

The rules, drafted with an eye toward strict standards in California and some other states, enable the implementation of the landmark Food Safety Modernization Act that President Obama signed two years ago in response to a string of deadly outbreaks of illness from contaminated spinach, eggs, peanut butter and imported produce.

The first proposed rule would require domestic and overseas producers of food sold in the U.S. to craft a plan to prevent and deal with contamination of their products. The plans would be open to federal audits. The second rule would address contamination of fruit and vegetables during harvesting.

One in six Americans suffers from a food-borne illness annually, a "substantial burden" on the country, according to the FDA. Of those who get sick, about 130,000 end up hospitalized and 3,000 die.

A salmonella outbreak in peanut butter last fall prompted the FDA to shut down a New Mexico production facility of Sunland Inc. and initiate a mass recall from retailers such as Trader Joe's. A listeria outbreak in several states last year also killed dozens of people.

"The FDA Food Safety Modernization Act is a common-sense law that shifts the food safety focus from reactive to preventive," Health and Human Services Secretary Kathleen Sebelius said Friday in releasing the proposals.

The outbreaks of the last several years pushed consumer advocates and much of the food industry to back more stringent standards.

Many welcomed the proposed rules, although consumer advocates pointed out that the standards were delayed in the White House a year past their congressionally mandated due date, giving rise to concerns that the Obama administration sought to avoid any political fallout in an election year.

The 2011 food safety act, the most comprehensive overhaul of the food industry in 70 years, was to be built on three sets of regulations, not just the two issued Friday, said Caroline Smith DeWaal, food safety director at the Center for Science in the Public Interest, a Washington consumer advocacy group.

The third rule, which has yet to be issued, would establish how food importers would verify that the products they bring in meet U.S. standards.

Last year more than 800 cases of illness were caused in the U.S. by contaminated imported tuna flakes, cantaloupes, mangoes and ricotta cheese, DeWaal said, citing data from the Centers for Disease Control and Prevention.

"It's supposed to be a three-legged stool in terms of consumer protection," DeWaal said, "and one leg is still missing."

The FDA said developing the complex new rules took time as it consulted "consumers, government, industry, researchers and many others," and "studied, among many other sources, the California leafy greens marketing agreement." Additional rules will "follow soon," the agency said.

The California Leafy Green Products Handler Marketing Agreement, formed in 2007 after an E.coli outbreak tied to

spinach crops, mandates that farmers fund government audits of their food safety processes. Melon growers in California have a similar agreement and last year made it mandatory, said Stephen Patricio, president of Westside Produce in Firebaugh which grows, packs and ships melons.

"California has the most stringent requirements," Patricio said. "It's the culture of food safety that is important, and California farmers have been working on the culture of food safety for a decade."

As a result, the proposed federal regulations aren't expected to force substantial changes in the way many crops in California are handled. Melons in the state also have a mandatory code on every box that is shipped that would allow authorities to track where the fruit came from and when it was harvested, a policy that was proposed in the new regulations.

Eric Hanagan already has implemented some of the policies suggested in the proposed guidelines.

Hanagan's 1,500-acre farm, which grows melons and vegetables in the Rocky Ford area of Colorado, was hit hard when a nearby farm was blamed for a 2011 listeria outbreak that killed 25 people. In response, Hanagan and other farmers adopted rules that they hoped would restore the region's reputation.

His vegetables are now shipped with codes that allow them to be tracked, and every winter he and other regional farmers go to classes about food safety. Hanagan's farm is inspected twice a year by the state, one of the inspections unannounced. Inspectors talk to each worker individually and regulate what kind of shoes, clothes and jewelry they can wear.

Hanagan estimates that the regulations cost medium-sized farms about \$5,000 to \$7,500 a year, which includes the cost of time for training workers and attending classes. But, he said, it's worth every penny.

"We need to have safe food, because if you get a consumer sick, you're done," he said. Jensen Farms, the Colorado farm blamed for the listeria outbreak, filed for bankruptcy in May.

The FDA will gather public comment for 120 days before finalizing the rules. Large farms would have 26 months to comply with most of the new requirements after the final rules are published; smaller farms would have longer.