



**TO: Food and Drug Administration Transition Team**  
**FROM: Consumers Union**  
**RE: FDA Food Safety Responsibilities**  
**DATE: December 15, 2008**

Consumers Union (CU) is very concerned about the erosion in FDA's ability to protect the consumer, which has been highlighted by the recent melamine scare and the summer outbreak of illness due to salmonella in peppers, among many other problems. While CU is deeply concerned about FDA's drug safety role, and has already provided input to the transition team on the subject, this memo focuses on FDA's food safety responsibilities.

Overall, the agency is clearly in need of a major overhaul including new authority to deal with imports and a budget increase to effectively manage its responsibilities to ensure the safety of the nation's food supply. It must significantly increase inspections of imported foods beyond the current level of 1 percent, increase inspections of domestic food-processing facilities from once every 10 years on average to something approaching annual inspections, and be equally tough on foreign facilities. It needs to update its computer systems and make sure all of its partners – including state and local agencies – can communicate properly with each other and with the FDA.

However, a number of issues within FDA's existing purview need immediate attention. The most urgent include the following:

**1. Mercury in fish advisory.** FDA should not relax its 2004 advice on consumption of mercury in fish for women of childbearing age and young children. Changes to this advice are currently circulating in interagency review. Certain high-mercury species of fish pose serious hazards to fetuses and young children. Women and children can get the benefits of eating fish by eating low-mercury fish. FDA therefore should not relax its existing warnings.

**2. Melamine in infant formula and other food products.** FDA has so far set a safe level based only on the toxicity of melamine. However, melamine alone is not the only concern. The problem with pet food two years ago showed that melamine *in combination with* one of its derivatives, cyanuric acid, is far more toxic than melamine alone. The two in combination form stones in the kidney, which is what was lethal to thousands of pets, and caused six deaths of infants in China earlier this year. A small FDA test program of infant formula made in the US this fall— 74 samples —found one sample positive for melamine and one sample positive for cyanuric acid. FDA should immediately conduct a much wider testing program — probably thousands of samples — and set a safety level for melamine in infant formula based on the



effects of melamine and cyanuric acid combined. FDA should also warn caregivers of the remote but possible danger of feeding infants a combination of the contaminated formulas.

3. **BPA.** The chemical bisphenol-A is used in linings of canned food, baby bottles, and other plastic that comes in contact with food. FDA has established a safety standard for BPA that its own science advisory board criticized this fall as inadequate. FDA should immediately develop a new, more stringent, safety standard for BPA based on the advice of its scientific advisors, and should ban its use as a food contact substance.

4. **Animal drugs.** Although FDA in July decided to ban certain off-label uses of cephalosporin drugs on livestock and poultry, in November it cancelled the ban just five days before it was to go into effect. The ban was originally imposed because of concerns about growing resistance to this drug due to consumption of animals and animal feed treated with it during processing. Cephalosporin drugs are highly valuable in human medicine, and their overuse is a significant public health concern. The ban should be allowed to take effect as planned.

Important pending issues that FDA can address on a slightly longer timetable, but that should be addressed as soon as possible, include:

5. **Labeling of cloned and genetically engineered animals.** FDA in the last year issued a risk assessment indicating that cloned animals are safe to go into the food supply. It also issued a guidance saying that it would review the safety of genetically engineered animals as new animal drugs. In both cases, it indicated that it would not require labeling of either type of animal in the food supply. We believe that both types of animals are fundamentally different from their conventional counterparts, and that this is a "material fact." FDA should initiate rulemaking to require labeling.

6. **Produce safety and traceability.** There are a number of things FDA should do to increase the odds that we will not see problems similar to the spinach and the tomato/pepper contamination problems of the last two years. FDA should consider making the Guidance it has issued for leafy green production and processing a mandatory regulation. More immediately, however, following up on two hearings it recently held on traceability, FDA should require unique identifiers for all produce in commerce, and require electronic recordkeeping so that it can be traced back to the grower. This should greatly shorten the time it takes to figure out where contaminated produce is coming from when an outbreak occurs.

7. **Nanotechnology.** New products containing nanoparticles are rapidly being introduced into consumer products. Recent testing by Consumer Reports shows that all brands of sunscreen that used titanium dioxide or zinc oxide contained these minerals in nanoparticle form. Scientists

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are united in the view that the safety of such products used on or in the body should be assessed. FDA has held several hearings on these issues but has taken no definitive action. FDA should immediately issue a rule or guidance that would indicate when and under what circumstances companies using nanoparticles in food or cosmetics should inform FDA, and what safety questions need to be answered.

8. **Shell eggs.** Several years ago, FDA developed a shell egg regulation designed to prevent salmonella in eggs. The rule would have accomplished this by requiring sound and stringent sanitation at egg production facilities. The rule was never made final, and was recently withdrawn after being sent to OMB. FDA should not wait any longer to finalize the rule as proposed.