OBAMA-BIDEN TRANSITION PROJECT

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MEMO

To: **Sustainable Agriculture Transition Team**
From: **Margaret Mellon, Director, UCS Food and Environment Program**
Subject: **Recommendations on Biotechnology and Overuse of Antibiotics in Animal Agriculture**
Date: **December 22, 2008**

Below are recommendations to the transition team in two areas relevant to sustainable agriculture—biotechnology regulation and antibiotic use in food animal production

PROBLEM I: Lax oversight of genetically engineered crops and animals
Twenty-five years after its beginning, genetic engineering remains a controversial technology whose products promise benefits but also pose risks to food safety, the environment, and trade. Strong regulation is essential to protect the food system and the environment and ensure consumer confidence in the technology.

SOLUTIONS:

1. **Stop the issuance of the USDA final rule on genetically engineered organisms[1] and its accompanying environmental impact statement. Initiate a process to review and strengthen the rule.**

The USDA is in the final phases of issuing a broad rule governing genetically engineered (GE) crops and other organisms under the Plant Protection Act. As proposed, the rule dramatically reduces the rigor of oversight of genetically engineered crops, especially those engineered to produce pharmaceutical and industrial compounds (pharma crops).

The features of the rule most in need of strengthening are:

- Scope: The proposed scope gives the regulated industry unprecedented say in whether its products will be regulated and should be revised to bring most GE organisms to the agency under a flexible scheme that adjusts the intensity of review to the level of risk the products pose.
- Definition of noxious weeds: The proposed definition of noxious weeds fails to include many serious ecological harms and should be revised to allow the agency to respond to such concerns.
- Pharma crop oversight: The proposed rule would allow pharma crops (GE crops engineered to produce drugs and industrial chemicals) to contaminate the food supply and should be revised to include a ban on all outdoor production of pharma food crops.

2. **Abandon the current policy employing the drug provisions of the Federal Food, Drug and Cosmetic Act to regulate GE animals. Seek new legislative authority empowering the FDA to require mandatory pre-market safety approvals of GE and cloned animals used as food.**

The Federal Food, Drug and Cosmetic Act (FFDCA) does not confer obvious authority on the FDA to require the pre-market safety approvals of any foods not deemed food additives. Absent such authority, the agency has based its GE animal program upon a tortured interpretation of the drug provisions of the FFDCA, that is, the FDA is treating GE animals as drugs. Although the drug laws have the advantage of providing a mandatory review of safety aspects of GE animals, their requirements for secrecy throughout the review and approval process make them inappropriate for oversight of GE animals. Such extreme

[1] See USDA's proposed rule: 73 *Fed. Reg.* 60008-48 (October 9, 2008); online at http://edocket.access.gpo.gov/2008/pdf/E8-23584.pdf.

Food and Environment Program
1825 K St NW · Ste 800 · Washington, DC 20006
Phone 202-223-6133 · Fax 202-223-6162
www.ucsusa.org/food_and_agriculture

Union of Concerned Scientists
Citizens and Scientists for Environmental Solutions

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secrecy will exacerbate, not allay, concerns about the safety of GE foods. The agency should seek explicit Congressional authority for a transparent, mandatory pre-market review of GE and cloned animals.

3. Initiate a process to update the twenty-year-old Coordinated Framework for the Regulation of Biotechnology.

In the mid-1980's the Reagan Administration initiated the production of the Coordinated Framework for Biotechnology,[2] which has overseen the first wave of agricultural biotechnology products. Now, two decades later, the Coordinated Framework needs to be updated to address a new generation of more complex biotechnology products and fill an important gap in the original version—the regulation of GE animals. As before, the White House should establish and lead a multi-agency task force to reevaluate and revise the framework.

PROBLEM II: Overuse of medically important antibiotics in animal agriculture exacerbates the antibiotic-resistance public heath crisis

Antibiotic resistance leads to more illnesses and greater severity of illnesses as antibiotics become less effective. Seventy percent of all antibiotics used in the United States are estimated to be used as feed additives for chickens, hogs, and beef cattle. Scientific evidence points to this massive agricultural use of antibiotics as a significant contributor to antibiotic resistance in the general human population.

SOLUTIONS:

FDA's Center for Veterinary Medicine (CVM) should move aggressively to reduce feed additive uses in poultry and livestock of those antibiotics, like penicillin and tetracycline, that are important in human medicine. UCS recommends the following highest-priority steps:

- Review drugs currently used in both human and animal medicine for their resistance implications
  CVM should set a timetable to review all drugs currently used in both human and animal medicine for their resistance implications and, where the reviews indicate that drugs are no longer safe from a resistance standpoint, initiate cancellation proceedings for non-essential uses.
- Reissue the ban on extra-label use of cephalosporins
  CVM should reissue the ban that it withdrew early in December 2008 at industry's behest.
- Implement and strengthen requirements on veterinary drug use data collection and reporting
  CVM should begin implementing the data collection and reporting program as required under 2008 drug user fee legislation.
- Request increased funding for antimicrobial resistance surveillance through the National Antimicrobial Resistance Monitoring System (NARMS)
  CVM should seek to substantially bolster the funds available for NARMS to develop a robust national surveillance system for resistant diseases, and especially to address the animal sources of methicillin-resistant *Staphylococcus aureus* (MRSA).

For further information, please contact:
Margaret Mellon
Union of Concerned Scientists
202-331-5432
mmellon@ucsusa.org

[2] 51 *Fed. Reg.* 23302-93 (June 26, 1986)