USDA

U.S. DEPARTMENT OF AGRICULTURE

OFFICE OF THE SECRETARY

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FAX COVER SHEET

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FROM:
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MESSAGE:

DEPARTMENT OF AGRICULTURE
OFFICE OF THE SECRETARY
WASHINGTON, D.C. 20250

June 17, 1998

Honorable Jacob J. Lew
Acting Director
Office of Management and Budget
252 Old Executive Office Building
Washington, D.C. 20503

Dear Jack:

I am writing to ask for your help in resolving two issues which would alleviate some of the pressure on the Department of Agriculture's (USDA) fiscal year (FY) 1999 appropriations bills. As you said in your June 11, 1998 letter to Senator Stevens, the Senate version of our appropriations bill does not adequately fund a number of our most important initiatives and reduces or eliminates funding for a number of key mandatory programs. For instance, the Senate bill eliminates funding to administer the mandatory Fund for Rural America and the Conservation Farm Option Program and reduces funding for the Emergency Food Assistance Program. The House bill goes even further in cutting mandatory programs, eliminating funding for the Initiative for Future Agriculture and Food Systems. If these bills were to become law in their present form, they would render meaningless all the effort we have just invested in providing for key rural development and research needs in the research reauthorization bill now awaiting signature by the President.

The first issue has to do with decisions by the Office of Management and Budget (OMB) concerning unobligated balances of previous programs which were transferred to and merged with the new Rural Community Advancement Program (RCAP) and Rural Housing Assistance Grants (RHAG) in our FY 1998 appropriations act. RCAP and RHAG replace individual rural development programs which were previously funded by the Congress on an annual basis. Language in the FY 1998 appropriations act provided that the remaining balances of these programs, totalling $186 million, were to be transferred to and merged with the new programs. Funds for the RCAP and RHAG are provided on the basis that they are available until expended. The Department's interpretation of Congress' views is that merging these balances into the RCAP and RHAG appropriations means these balances take on the characteristics of the RCAP and RHAG funds, thereby extending their availability. Your office has indicated that this is not the case, effectively eliminating $186 million from helping to fund FY 1999 initiatives, which would be extremely valuable in the current situation.

The second issue has to do with the scoring of the discretionary programs in our appropriations bill by OMB and by the Congressional Budget Office (CBO). We are advised that the CBO believes that our appropriations bill will cost $190 million more than OMB's estimate. I know that OMB staff works with CBO to resolve scoring issues, and I would appreciate whatever your staff can do with CBO to try to lower their estimate of the cost of our bill. Any progress along these lines would of course be very helpful as we move further through the appropriations process.

I look forward to working with you as we work our way through the FY 1999 process, and I will greatly appreciate any help you can give us on these issues.

Sincerely,

Dan

DAN GLICKMAN
Secretary

Jack - The first item is really important. We need your help.
Thanks

UNITED STATES DEPARTMENT OF AGRICULTURE
FOOD SAFETY INITIATIVE
(Dollars in Thousands)

	1998 Approp.	1999 President's Budget	1999 Senate Committee	1999 House Committee	Senate Change from Budget	House Change from Budget
A. EARLY WARNING SYSTEM FOR PUBLIC HEALTH SURVEILLANCE						
1. Enhance/Expand active foodborne disease surveillance program						
Economic Research Service (ERS)	$32	$285	$32	$32	-$253	-$253
Food Safety and Inspection Service (FSIS)	1,500	1,500	1,500	1,500	0	0
DEPARTMENT SUBTOTAL, A	1,532	1,785	1,532	1,532	-253	-253
B. RISK ASSESSMENT						
1. Establish a Risk Assessment Consortium						
Economic Research Service (ERS)	33	686	33	471	-653	-215
Office of the Chief Economist (OCE)	3	3	3	3	0	0
2. Develop better data and modeling techniques to assess exposure to microbial and chemical contaminants, including animal drug residues, through the food supply						
Agricultural Research Service (ARS)	4,498	4,818	4,498	4,598	-320	-220
Cooperative State Research, Education, and Extension Service (CSREES)	150	1,962	150	250	-1,812	-1,712
Office of the Chief Economist (OCE)	51	149	51	149	-98	0
3. Develop dose-response assessment models (also called hazard characterization) for use in risk assessment						
Office of the Chief Economist (OCE)	6	6	6	6	0	0
4. Identify control measures for reducing foodborne illness losses in agricultural production and processing.						
Food Safety and Inspection Service (FSIS)	0	1,000	0	1,000	-1,000	0
AGENCY SUBTOTAL, B (ARS)	4,498	4,818	4,498	4,598	-320	-220
AGENCY SUBTOTAL, B (CSREES)	150	1,962	150	250	-1,812	-1,712
AGENCY SUBTOTAL, B (ERS)	33	686	33	471	-653	-215
AGENCY SUBTOTAL, B (FSIS)	0	1,000	0	1,000	-1,000	0
AGENCY SUBTOTAL, B (OCE)	60	158	60	158	-98	0
DEPARTMENT SUBTOTAL, B	4,741	8,624	4,741	6,477	-3,883	-2,147

UNITED STATES DEPARTMENT OF AGRICULTURE

FOOD SAFETY INITIATIVE (Continued)

(Dollars in Thousands)	1998 Approp.	1999 President's Budget	1999 Senate Committee	1999 House Committee	Senate Change from Budget	House Change from Budget
C. BIOSCIENCE RESEARCH						
1. Improved detection methods						
Agricultural Research Service (ARS)	11,115	12,815	11,115	11,565	-1,700	-1,250
Cooperative State Research, Education, and Extension Service (CSREES)	1,260	2,258	1,260	1,360	-998	-898
2. Understanding antimicrobial resistance						
Agricultural Research Service (ARS)	508	808	508	608	-300	-200
Cooperative State Research, Education, and Extension Service (CSREES)	500	740	500	500	-240	-240
3. Understanding antibiotic drug resistance						
Agricultural Research Service (ARS)	92	892	92	292	-800	-600
4. Prevention techniques: pathogen control, reduction, and elimination						
Agricultural Research Service (ARS)	29,710	38,810	29,890	31,460	-8,920	-7,350
Cooperative State Research, Education, and Extension Service (CSREES)	3,810	5,940	3,810	3,960	-2,130	-1,980
5. Food handling, distribution, and storage						
Agricultural Research Service (ARS)	8,926	10,676	8,926	10,076	-1,750	-600
Cooperative State Research, Education, and Extension Service (CSREES)	680	1,500	680	830	-820	-670
6. Test samples of fruits and vegetables for microbial pathogens						
Agricultural Marketing Service (AMS)	0	6,257	0	0	-6,257	-6,257
AGENCY SUBTOTAL, C (AMS)	0	6,257	0	0	-6,257	-6,257
AGENCY SUBTOTAL, C (ARS)	50,351	64,001	50,531	54,001	-13,470	-10,000
AGENCY SUBTOTAL, C (CSREES)	6,250	10,438	6,250	6,650	-4,188	-3,788
DEPARTMENT SUBTOTAL, C	56,601	80,696	56,781	60,651	-23,915	-20,045

UNITED STATES DEPARTMENT OF AGRICULTURE
FOOD SAFETY INITIATIVE (Continued)

(Dollars in Thousands)	1998 Approp.	1999 President's Budget	1999 Senate Committee	1999 House Committee	Senate Change from Budget	House Change from Budget
D. INSPECTIONS						
1. Enhanced Federal-State inspection partnerships						
Food Safety and Inspection Service (FSIS)	565	8,412	565	565	-7,847	-7,847
DEPARTMENT SUBTOTAL, D	565	8,412	565	565	-7,847	-7,847
E. EDUCATION						
1. Improve consumer education						
Cooperative State Research, Education, and Extension Service (CSREES)	1,115	3,461	1,115	1,645	-2,346	-1,816
Economic Research Service (ERS)	420	420	420	420	0	0
Food Safety and Inspection Service (FSIS)	0	500	0	0	-500	-500
Office of the Chief Economist (OCE)	28	28	28	28	0	0
2. Improve retail, food service, and institutional education						
Cooperative State Research, Education, and Extension Service (CSREES)	900	2,799	900	1,330	-1,899	-1,469
Office of the Chief Economist (OCE)	10	10	10	10	0	0
Food and Nutrition Service (FNS)	0	2,000	2,000	2,000	0	0
3. Improve veterinary and producer education						
Cooperative State Research, Education, and Extension Service (CSREES)	350	1,105	350	525	-755	-580
Food Safety and Inspection Service (FSIS)	0	2,000	0	1,341	-2,000	-659
AGENCY SUBTOTAL, E (CSREES)	2,365	7,365	2,365	3,500	-5,000	-3,865
AGENCY SUBTOTAL, E (ERS)	420	420	420	420	0	0
AGENCY SUBTOTAL, E (FNS)	0	2,000	2,000	2,000	0	0
AGENCY SUBTOTAL, E (FSIS)	0	2,500	0	1,341	-2,500	-1,159
AGENCY SUBTOTAL, E (OCE)	38	38	38	38	0	0
DEPARTMENT SUBTOTAL, E	2,823	12,323	4,823	7,299	-7,500	-5,024

UNITED STATES DEPARTMENT OF AGRICULTURE
FOOD SAFETY INITIATIVE (Continued)

(Dollars in Thousands)	1998 Approp.	1999 President's Budget	1999 Senate Committee	1999 House Committee	Senate Change from Budget	House Change from Budget
AGENCY TOTAL (AMS)	0	6,257	0	0	-6,257	-6,257
AGENCY TOTAL (ARS)	54,849	68,819	55,029	58,599	-13,790	-10,220
AGENCY TOTAL (CSREES)	8,765	19,765	8,765	10,400	-11,000	-9,365
AGENCY TOTAL (ERS)	485	1,391	485	923	-906	-468
AGENCY TOTAL (FNS)	0	2,000	2,000	2,000	0	0
AGENCY TOTAL (FSIS)	2,065	13,412	2,065	4,406	-11,347	-9,006
AGENCY TOTAL (OCE)	98	196	98	196	-98	0
SUBTOTAL, USDA	$66,262	$111,840	$68,442	$76,524	-$43,398	-$35,316
FOOD AND DRUG ADMINISTRATION	$124,576	$174,576	$124,576	$131,574	-$50,000	-$43,002
TOTAL, AGRICULTURE BILL	$190,838	$286,416	$193,018	$208,098	-$93,398	-$78,318

a) Includes redirection of $420,000 provided in 1998 for National Academy of Sciences Food Safety Study to other research.
b) Includes $1 million for expanded research to maintain the safety and quality of fresh fruits and vegetables.
c) Excludes $1 million add-on for cooperative research with Perdue University at the National Institute for Food Safety Engineering in detection and prevention of chemical and mirobial contaminants.

17-Jun-98

UNITED STATES DEPARTMENT OF AGRICULTURE
FOOD SAFETY INITIATIVE

(Dollars in Thousands)

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17-Jun-98

Food Safety budget '98

THE WHITE HOUSE
WASHINGTON

From the Office of:

The Domestic Policy Council

Elena Kagan
Deputy Assistant to the President
for Domestic Policy

TO: Tom Freedman

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PAGES: 2

MESSAGE:

Please call (202) 456-5584 if there are any problems with the transmission.

Food Safety

Meat and Poultry Packers Defeat Move To Allow Civil Penalties in the Industry

By DAVID ROGERS
Staff Reporter of THE WALL STREET JOURNAL

WASHINGTON—Meat and poultry packers narrowly defeated a White House-backed initiative to give the Agriculture Department authority to impose civil penalties for food-safety violations in the industry.

The 25-19 vote came as the House Appropriations Committee approved a $56.1 billion agriculture bill that also rejects the Clinton administration's request to impose more than $570 million in new industry user fees to help pay for inspections.

To fill the gap, the Appropriations Committee leadership was forced to shift funds from elsewhere in the budget to ensure support for the Food and Inspection Service. About $609 million is provided for the fiscal year beginning Oct. 1, but to find these funds, the committee was forced to take funds from an agriculture research initiative only recently passed by Congress.

The revised Inspection Service budget is big enough to provide a modest $20.5 million increase over the current year. But the total program level is less than the president requested, and Mr. Clinton would get only a fraction of the $96 million he wanted for his larger food-safety initiative in the Agriculture Department and the Food and Drug Administration.

Yesterday's debate over civil penalties came on an amendment offered by Rep. Nita Lowey (D., N.Y.) and backed by Agriculture Secretary Dan Glickman and a coalition of consumer and labor organizations. Any new fines would be capped at $100,000 per violation, and Ms. Lowey argued that the new power would give the department greater flexibility in disciplining violators without having to shut plants down. However, the packing industry lobbied against the plan.

The department already has the authority to seek criminal penalties. But in some cases, such as when a plant fails to keep accurate records, civil fines could be a more appropriate and timely response from the administration's standpoint.

The Republican opposition, led by Reps. Jack Kingston of Georgia and Tom Latham of Iowa, argued that the new penalties were excessive and would fall hardest on smaller processors. But the issue clearly split the GOP, which lost four members in the vote. And Ms. Lowey might even have triumphed but for the poor attendance by fellow Democrats.

Meanwhile, the Appropriations Committee approved a $20.6 billion spending bill supporting federal energy and water programs for the coming year. Total funding is less than the current year, and the panel would terminate federal funding for the Tennessee Valley Authority—cutting the administration's entire $76.8 million request for the agency.

Aetna Managed-Care Unit Won't Cover Viagra Drug

By a WALL STREET JOURNAL *Staff Reporter*

NEW YORK—Aetna Inc.'s Aetna U.S. Healthcare managed-care unit told New York state regulators it doesn't plan to cover the impotence medication Viagra as part of its regular prescription-drug coverage, a spokesman for the New York State Department of Insurance said.

Employers that want Viagra included as a prescription-drug benefit will have to pay more for extra coverage, the Hartford, Conn., health-insurance company told the state in a recent letter. The state requested that insurers provide information on whether they planned to cover Viagra, sold by New York drug maker Pfizer Inc. Aetna is the only company so far that has refused to include Viagra as part of normal coverage, the state spokesman said.

An Aetna U.S. Healthcare spokeswoman said she couldn't comment on the specifics of the letter but said the company's Viagra policy "has not changed and the company is continuing to evaluate its coverage of Viagra. In the interim, it is not a covered benefit." The company said it hopes to reach a final decision on Viagra coverage soon.

Judge Lifts Ban By FDA on Imports Of a Special Rice

By a WALL STREET JOURNAL *Staff Reporter*

SALT LAKE CITY—In a setback for the Food and Drug Administration's push to regulate dietary supplements, a federal judge lifted the agency's ban on imports of a special Chinese rice used to make a popular cholesterol-reducing capsule.

U.S. District Judge Dale Kimball in Salt Lake City late yesterday granted a preliminary injunction sought by Pharmanex Inc., the maker of the supplement. The judge said the company could be forced out of business if the FDA's ban remained in place, and he noted that the agency doesn't consider the supplement, marketed as Cholestin, to be dangerous.

Last month, the agency had concluded that Cholestin, made from red yeast rice from China, is actually an unapproved drug. It contains lovastatin, which occurs naturally in the Chinese rice and is the same active ingredient in an approved prescription drug, Merck & Co.'s Mevacor, which has been on the market since 1987.

In his order, Judge Kimball said Pharmanex has "raised substantial and serious questions regarding the lawfulness of FDA's interpretation" of the 1994 Dietary Supplement Health and Education Act. That interpretation, he added, "merits further careful consideration."

William McGlashan, Pharmanex president, said the court's action will prove "very important" to the dietary supplement industry. "It shows that the FDA cannot arbitrarily declare a drug from something that is clearly a food," he said.

Pharmanex can now import 10 tons of red yeast rice to its Farmington, Utah, factory, which churns out as many as 90,000 capsules a day. After that, the Simi Valley, Calif., company can import as much as six tons of the rice every three months.

Judge Kimball's decision followed arguments Monday from attorneys representing each side. Pharmanex had sued the FDA last year after the agency had banned the imports of the special rice. The dispute is the first challenge to the FDA's powers under the 1994 Dietary Supplement Health and Education Act.

An FDA spokeswoman said the agency will review the court order thoroughly and pursue the case on its merits.

Tom — what happened here? Could you do something for the weekly on this and the approps. battles generally, with some ideas about how to get the President into this issue and turn things around? Thanks.
Elena
cc: Bruce

THE WALL STREET JOURNAL
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