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United States Senate

COMMITTEE ON
AGRICULTURE, NUTRITION, AND FORESTRY
WASHINGTON, DC 20510-6000

March 24, 1993

The Honorable Vice President Al Gore
The White House
1600 Pennsylvania Avenue, N.W.
Washington, D.C. 20501

Dear Mr. Vice President:

It was good talking with you and I wanted to add further thoughts on a national biotechnology policy.

History is full of examples of technology preceding without adequate controls--and then becoming mired in public opposition. While we are reforming our food safety laws we must make sure that we do not make the same mistake with biotechnology that we made with pesticides.

I am particularly concerned with the impacts of biotechnology on agriculture.

To give you a better idea of some of my concerns, I am including copies of the speech I gave at the Public Voice conference on food safety, my floor statement introducing S. 1916, the Herbicide Reduction Act of 1991, a letter I sent to Secretary Madigan on the USDA proposal to change APHIS biotechnology regulations, and letters to Secretary Espy and the General Accounting Office on the potential impacts of bovine somatotropin.

I look forward to working with you on these issues over the coming years.

Sincerely,

Pat

PATRICK J. LEAHY
Chairman

PJL/mdf
enclosures

United States Senate

COMMITTEE ON
AGRICULTURE, NUTRITION, AND FORESTRY
WASHINGTON, DC 20510-6000

March 16, 1993

Ms. Eleanor Chelimsky
Assistant Comptroller General
Program Evaluation and Methodology Division
United States General Accounting Office
Washington, D.C. 29548

Dear Ms. Chelimsky:

The Food and Drug Administration, (FDA) recently announced that it will convene its Veterinary Medicine Advisory Committee on March 31, 1993, in Gaithersburg, Maryland. The purpose of the meeting is to discuss whether the increased incidence of mastitis in dairy cows treated with bovine somatotropin presents a human health risk as a result of the increased use of antibiotics. The FDA encourages interested individuals to present data, information or views on the issue.

I wish to ensure, to the extent possible, that the full range of views and concerns relevant to this question are presented at this meeting. We must make certain that any decision reached by the FDA is based on all the relevant information.

For this reason, I request that the General Accounting Office present at this meeting a summary of the concerns that were raised in your report titled Recombinant Bovine Growth Hormone: FDA Approval Should Be Withheld Until the Mastitis Issue is Resolved.

Please contact me or Tom Hebert of my staff (224-5207) if you have any questions concerning this request.

Sincerely,

PATRICK LEAHY
Chairman

PJL/jmc

United States Senate

COMMITTEE ON
AGRICULTURE, NUTRITION, AND FORESTRY
WASHINGTON, DC 20510-6000

December 22, 1992

The Honorable Edward Madigan
Secretary of Agriculture
U.S. Department of Agriculture
14th Street and Independence Avenue, S.W.
Washington, D.C. 20250

Dear Secretary Madigan:

I would like to submit comments on USDA's proposed rule to ease regulations governing planned introductions of genetically engineered plants (Docket No. 92-156-1).

Unfortunately, this proposed rule appears to be one more example of an Administration that values deregulation above all else. Under the guise of promoting the biotechnology industry, USDA has effectively abandoned all federal oversight of the introduction of genetically engineered plants. This time, however, even industry groups think that the Administration has gone too far.

They recognize what the Department does not -- that the success of their products ultimately relies on consumer acceptance. Consumer acceptance, in turn, depends on a reasonable and consistently applied set of federal regulations to ensure that new products are safe for consumers and the environment.

I am particularly concerned by the provision that would allow researchers to bypass the current permit procedure for virtually any proposed field trial if "after prior consultation with the Director of BBEP, an appropriate State regulatory official, or an appropriate Institutional Biosafety Committee, the researcher has determined that the introduction of the regulated article is unlikely to pose a greater risk as a plant pest in the test environment than the unmodified plant from which it was derived."

The wording of this provision essentially allows researchers to determine for themselves whether a planned introduction qualifies for the new notification procedure. There is, for example, no description of what would constitute an acceptable "consultation." By failing to specify what form this consultation should take, this provision threatens to circumvent existing requirements for public participation and notification. I cannot allow these decisions to be made behind closed doors, out of the public eye.

This provision also appears to introduce a new regulatory standard -- that the planned introduction is "unlikely to pose a greater risk" -- without providing scientific criteria for assessing that risk. Allowing researchers themselves, or Institutional Biosafety Committees not qualified to make these judgements, to determine what poses an unreasonable risk is unacceptable.

By authorizing the Biotechnology Risk Assessment program in the 1990 Farm Bill, this Committee recognized the critical need for risk assessment research. In the absence of reliable scientific data and until the results of research supported by this program are available, it is premature to assume that release of genetically engineered organisms poses no risk to the public or the environment.

With this proposed rule, the Department has effectively handed over its authority to regulate introductions of genetically engineered plants to state and local authorities. At the same time, the Department seeks to preempt state and local policies that are in conflict with the rule. If USDA wishes to retain its authority over the introduction of genetically engineered plants, it must accept its responsibility to regulate the process.

Finally, I caution the Department against making any attempts to finalize this rule before the new Administration has taken office. A last-minute effort by the outgoing Administration to substantially deregulate the release of genetically engineered plants would be inappropriate. Decisions of this magnitude should be left to officials of the new Administration.

Sincerely,

Patrick Leahy

PATRICK J. LEAHY
Chairman

United States Senate
COMMITTEE ON
AGRICULTURE, NUTRITION, AND FORESTRY
WASHINGTON, DC 20510-6000

March 22, 1993

The Honorable Mike Espy
Secretary of Agriculture
U.S. Department of Agriculture
14th and Independence Avenue, S.W.
Washington, D.C. 20250

Dear Mr. Secretary:

The Food and Drug Administration (FDA) is expected soon to issue a ruling on the use of supplemental bovine somatropin (bST) in the dairy industry. I am writing to ask that you explore the options available to you to ensure that any negative effects of bST approval for the dairy industry are prevented or minimized.

Some experts within the industry are concerned that even modest rates of adoption of bST could lead to large increases in milk production, depressing milk prices, and increasing Commodity Credit Corporation (CCC) net removals of dairy products. This could mean higher government costs and larger assessments on dairy producers. Such effects could be seriously exacerbated if the introduction of bST results in a weakening of consumer demand for milk and other dairy products. Johanna Farms has estimated that the combination of a 3 percent increase in supply and a 5 percent reduction in demand could result in a $320 million increase in CCC outlays and a $0.63 per hundredweight increase in producer assessments in 1995.

FDA approval of bST is expected in less than two months. In such a short time it is not possible to enact legislation to deal with the problems created by bST approval for dairy farmers, the industry and the government. For this reason, I ask that you examine the authorities currently available that would allow you to take actions to address these issues.

Please contact me once you have examined the options available to you so that we can explore possible courses of action. As always, call me if you have any questions concerning this request, or if there is anything that I can do to assist you in this matter.

Sincerely,

PATRICK J. LEAHY
Chairman

PJL/trh

New Directions in Food Policy
Senator Patrick Leahy
March 22, 1993

Change at USDA:

I have said many times that the Department of Agriculture needs to face the realities of the 21st Century. All of American agriculture needs a new vision for a new World.

When USDA was created, over half the U.S. population lived and worked on farms. President Lincoln called USDA the "people's Department" for just that reason. Today, less than two percent live on farms.

Traditional farm interests have dominated USDA's thinking for decades. These interests are important -- but now USDA's non-farm responsibilities are much broader.

There are 250 million consumers in the United States; over 40 million Americans receive some type of USDA food assistance; while only 5 million Americans live on farms.

Unless USDA changes, it runs the risk of becoming less and less relevant to a changing America. But I am not promoting change for the sake of change. For years USDA has been managing programs, to address yesterday's problems.

For the first 100 years of its existence the major policy question was: "What can USDA do FOR farmers?"

Now, environmentalists, food safety experts, conservationists and the American public are asking: "What are farmers doing TO us?"

USDA must focus more on food policy, instead of farm policy. USDA must help farmers produce what consumers want -- fresher, more nutritious, and safer foods in greater varieties. USDA must help farmers balance their responsibility as producers with their responsibility as resource managers and stewards of the land. USDA should focus on meeting tougher world competition in the face of a technological revolution. USDA must meet its moral responsibility to eliminate hunger in America. And, USDA must focus on all rural Americans, not just farmers.

Food Safety:

Secretary Espy realizes these points. He has done more in his first two months regarding food safety, than USDA has done in the last ten years. His proposed reforms will revolutionize meat and poultry inspection, and protect consumers.

The Secretary is changing the dynamic, because he is concentrating first and foremost on consumers -- on families that buy food. He has declared a "war" on deadly pathogens. He has not accepted the industry argument that all you have to do is cook it thoroughly.

I agree with the Secretary. Proper cooking is important. But that should be our last line of defense against foodborne illnesses -- it should not be America's only line of defense.

People make mistakes -- restaurants undercook hamburgers, and parents undercook hamburgers -- but the death penalty is too strong a punishment.

I applaud Secretary Espy's efforts to develop a scientifically based inspection system that looks at microbiological contamination from the farm to the dinner table.

I want to mention another food safety issue -- fish inspection. I have said for years that consumers should not have to guess whether the fish they eat is safe.

Several of America's best restaurants are refusing to buy fish from U.S. waters -- they believe, and their lawyers agree, that it is much safer to buy imported fish. For example, a well-known Washington restaurant purchases its salmon from aquaculture operations in Chile so they can be certain of its quality.

This trend will continue until America wakes up. We continue to dump hazardous wastes into our waters and then wonder why our children may be at risk. I will be working with the new administration to create a comprehensive, mandatory fish inspection program.

Pesticides and Sustainable Agriculture:

One food safety area that the Department cannot handle by regulation is pesticides.

Recent court decisions state that the Delaney Clause means what it says -- no residues of a cancer causing chemicals are permitted on processed foods. The Secretary has stated that legislative action will be needed this year.

I have said many times that the problem with our pesticide laws is that they leave the public in the dark, and the farmer on the hook. The public is in the dark because safety studies on many pesticides, currently in use, have not been completed.

The public will not have confidence in a system of pesticide regulation that says absolutely no pesticide residues are allowed on some foods, but on other foods even the government's safety standards can be exceeded on economic grounds.

Consumers will not be satisfied with our food safety laws if it takes years for EPA to take pesticides off the market, even when it decides they are unsafe.

The present system also does not work for farmers. It leaves them on the hook. As new health data comes to light they do not know from year to year whether they will be able to use a pesticide or not. This year we must reform our pesticide laws based on scientifically sound standards.

There are some who want a health-based system that can be bent if it hurts one industry or another. That will not work for the public or the food industry as a whole. We need to choose one scientifically based safety standard and make everyone play by the rules.

While we are reforming our food safety laws we must make sure that we do not make the same mistake with biotechnology that we made with pesticides.

Biotechnology:

We started using pesticides, and then set up a regulatory system to decide whether they were safe. That was backwards. We must understand the food safety consequences of new biotechnology products before we use them widely.

As biotechnology has evolved, the Federal government has attempted to massage old laws to fit this new technology. As a result, several agencies, including EPA, USDA, FDA, and NIH regulate biotechnology. The system needs to be rationalized and streamlined.

Tomorrow I will call Vice President Gore to let him know that I believe we need a comprehensive biotechnology policy.

The public needs to be sure that if a new biotechnology product is introduced -- it is safe. Entrepreneurs large and small need to know that their considerable financial risks are worth taking.

History is full of examples of technology preceding without adequate controls--and then becoming mired in public opposition. Both pesticides and nuclear power never fulfilled their promise because an adequate regulatory system was not developed and broad public acceptance was never achieved.

The great promise of biotechnology -- to cure cancer and AIDS, to reduce hunger, and much, much more -- must not be lost because we have not faced these issues and resolved them.

Labeling:

USDA should take the lead in helping farmers reduce their use of pesticides, rather than promoting such use with cosmetic grade standards. American consumers should decide if they want to buy an orange grown with fewer pesticides, even if it has a few more blemishes.

I have been worried for some time that current farm programs encourage chemical-intensive agriculture by discouraging crop rotations and limiting diversity. That is one reason I pushed for the organic labeling provisions and the sustainable agriculture provisions in the farm bill. USDA should take the lead and show farmers alternative ways to do business. Farmers should be informed how to break their chemical dependency.

Also the labeling of biotechnology products needs to be explored. Consumers may demand the labeling of foods produced even if scientists think they are safe.

Science can tell us about risks -- but science cannot tell us how much value to assign to competing interests. Labels can help consumers decide for themselves how to resolve those issues.

Circle of Poison:

This relates to another matter -- the "Circle of Poison." Circle of Poison is a fight between chemical companies and consumers, and I still expect the consumers to win.

In neighborhood supermarkets, millions of Americans buy food grown overseas that has been sprayed with pesticides so dangerous that EPA refuses to

let our farmers use them in the U.S. One-fourth of the produce we eat is imported. I will ask the new Administration to join with me in attempting to break this circle of poison.

Nutrition and health:

For far too long USDA has ignored the important link between nutrition and health. Rather than leaving nutrition on the back burner -- Secretary Espy has already announced plans to put USDA in the forefront of nutrition policy.

One source of the problem has been the management of commodity programs by the prior Administration. USDA offers schools tons of surplus commodities that they do not want.

Under a proposal I am advancing, schools would be offered a wide variety of low-fat dairy products. Better yet, the proposal will not cost taxpayers a dime and will improve the nutritional health of children.

The school lunch program must set a good example.

Nutrition labeling is another area that is important to me -- I believe that Americans have the right to know what they are eating. We should take confusion out of labels -- they should be easy to read, and explain the nutrient content of the food.

Hunger in America:

I have spoken many times about how hunger is a moral issue, not a political issue. Our nutrition programs are a vital defense against hunger. But I agree with the President -- the best line of defense, for those who are able, is jobs.

The recession has put record numbers of Americans on food stamps -- over 40,000 a week have come onto the program during the last Administration. That is 40,000 more a week for the last four years.

Americans need jobs -- and the President's proposals are designed to put America back to work.

One new direction in food policy can be simply stated -- USDA must give a new priority to its nutrition programs.

I conducted a survey last year regarding TEFAP -- The Emergency Food Assistance Program. That program, which provide bags of groceries to needy families, has become a first line of defense against hunger. I sent letters to every

state last year and found out that most States needed major increases in TEFAP foods. For example, Missouri needed a 600% increase to keep up with demand. Eleven states needed DOUBLE the amount to feed these hungry families.

We need better coordination at USDA so that domestic needs for food and agricultural interests are better balanced.

Conclusions:

In these important areas of food policy I will continue to work with Public Voice. They have been an important force for reform.

At the same time, I am looking forward to working with the new Administration. It is refreshing to finally be working with the Administration, rather than against the Administration.

United States of America

Congressional Record

PROCEEDINGS AND DEBATES OF THE 102d CONGRESS, FIRST SESSION

Vol. 137 WASHINGTON, TUESDAY, NOVEMBER 5, 1991 No. 162

Senate

HERBICIDE REDUCTION ACT OF 1991

Mr. LEAHY. Mr. President, I am concerned about the Department of Agriculture's continued funding of herbicide resistant plant development and research. I should tell you, Mr. President, I feel the Department of Agriculture should help farmers develop safer growing techniques instead of helping chemical companies sell more pesticides. The funding of herbicide resistant plant research is a shortsighted, misguided policy.

The reason chemical companies like herbicide resistant plants is clear: Once commercially licensed, these plants will encourage greater pesticides use, not less. This is not what the public nor farmers want.

The American public is demanding safer food and groundwater. Farmers are worried about prolonged exposure to pesticides that place them and their families at risk. A poll of Iowa farmers showed that 78 percent of Iowa farmers believe that modern farming relies too heavily on pesticides.

The United States is the world leader in biotechnology research and should continue to be, but leadership means funding the right projects in the right areas; herbicide resistant plants are neither.

Instead of herbicide resistant plants, we should be looking at disease, drought, or frost resistant plants.

The United States' food supply is one of the safest in the world. At a time when we are toughening food safety and environmental standards, it makes no sense for the administration to be funding research that will encourage greater chemical herbicide use.

USDA is not the only one developing herbicide resistant plants. The chemical industry is spending millions of dollars on similar research. The companies will not disclose how much they are spending on their research, but their motives are clear. Once approved for commercial use, the annual U.S. market for these plants is estimated to exceed $300 million by the year 2000. The world market will be even larger.

The administration should not be spending precious tax dollars on research that primarily benefits the profit margins of the chemical industry.

The primary beneficiaries of this research are not farmers or consumers, but rather the large chemical companies getting the benefits at the American taxpayers' expense.

I support continued research in biotechnology. And despite the protests from the chemical industry, this legislation is neither antitechnology nor anitbiotechnology. USDA research funding would not be reduced. Instead, Federal funds spent on developing herbicide resistance plants would be shifted to other biotechnology and sustainable weed control research.

Biotechnology should, and will, play a significant role in agriculture. But as with any other technology, there are appropriate and inappropriate uses. An application that will increase the

use of chemical herbicides is inappropriate.

Because of USDA bookkeeping procedures, no one knows for sure the exact amount the administration spends on herbicide resistant plant research. The Senate Agriculture Committee has uncovered at least $8.4 million in spending. Two examples of federally funded herbicide resistant plant research include:

USDA is spending $103,000 on developing plants resistant to 2,4-D, a known carcinogen that is a close relative of the defoliant agent orange. A study of Kansas farmers showed that farmers exposed to 2,4-D as few as 20 days had a six times greater chances of developing non-Hodgkins lymphoma. In addition, the Food and Drug Administration found increased incidence of malignant tumors, breast tumors, and malignant blood cell tumors in laboratory animals.

USDA is also spending $705,000 on developing plants resistant to atrazine, a pesticide labeled by the Environmental Protection Agency as a class C possible carcinogen. Atrazine also contaminates groundwater. A 1989 U.S. Geological Survey study found atrazine in 98 percent of the examined streams, 56 percent of which had levels higher than the EPA's health advisory level. Atrazine is currently undergoing a second review by EPA because of serious "potential oncogenic risk * * * and concern about widespread contamination of ground water."

Groundwater contamination is a threat nationwide. Over 95 percent of rural America relies on this same groundwater for drinking water.

Herbicide resistant plants will not solve the problem of reducing chemicals in our farming systems. They will not protect the American farmer and farmworker. They will not maintain the highest possible standards of food quality. They will not preserve our precious groundwater supplies. They will not protect our beleaguered natural resources.

We must stop funding herbicide resistant plant research and start funding research that will help ensure the continued preeminence of American agricultural products in a global marketplace that is becoming more and more environmentally conscious. Now is the time to act.