

they present a reasonable certainty of no harm. But under the Dole-Johnston proposal, the language of the Delaney reform is carried over to the general standard for food safety. FDA would be required to approve additives that caused only a negligible or insignificant risk of harm—in other words, instead of the current law standard of no harm, the proposal would establish a weaker standard of not too much harm.

Perhaps this change is inadvertent. It certainly is unjustified and unneeded. Perhaps, in aiming at the Delaney clause on cancer-causing substances, the sponsors mistakenly hit the general food safety standard too. Or perhaps the food industry lobbyists saw their chance and took it—to get out from under the Delaney clause, and get out from under the general food safety standards too.

It is a long way from no harm to not-too-much harm, and before we travel down that road we had better be very sure we know the consequences.

The amendment I will offer when we return to the bill, in addition to dealing with the Delaney clause, will also delete the provision weakening the general food safety standard. The provision seems to be a gratuitous weakening of a standard that is working well in current law and does not need reform. If a change in this important law is not necessary, it is necessary not to change it.

The bedrock food safety standard in current law should not be discarded lightly. Any legislation in this area must reflect the care and deliberation due a subject as important as whether the citizens of this country, especially infants and children, are now to be exposed to a higher risk of cancer and other diseases in the food they consume.

Madam President, toward the conclusion of my remarks I remind the Senate once again what has been happening to cancer incidence in the American population. It has increased by 48 percent since 1950. This is excluding cancers of the lung and the stomach.

Here we see what has been happening. We have seen the treatment of a number of these, particularly childhood cancers, have gotten much better. So the burden among the children in this country in many instances has been increasingly hopefully beneficial in terms of the treatment.

But when we see the continued increase in the incidence of cancer, and the danger that brings, why should we be out here flying in the face of a National Academy of Sciences' study which has recommended how we can protect children, and throwing that recommendation, which represents the best in terms of scientific information, over our shoulder and throwing it to the winds? I fail to understand the logic of that position.

Everyone knows what is going on here. Food industry lobbyists are trying to stampede Congress into hasty action on the Delaney clause that will

have drastic long-term consequences for the safety of the food supply of 250 million Americans. I have never heard any consumer say that they think food is too safe.

Those who vote for this amendment go on the record in support of prompt but responsible Delaney reform and against any tampering with the general food safety standard.

The Delaney clause may have outlived its usefulness, but it deserves a decent burial. It deserves to be replaced by a modern safety standard that strikes the right balance between the needs of industry and the health of our children. And the general food safety standard deserves to remain intact.

REGULATORY REFORM AND FOOD SAFETY STANDARDS

Mr. HATCH. Mr. President, contrary to what opponents of S. 343 allege, enactment of our bill would neither undermine the existing standard for food safety nor needlessly expose our citizens—man, woman, or child—to carcinogenic substances.

Although we are today considering the Bosnian arms embargo issue, since the issue of the Delaney clause has arisen, I wanted to take this brief opportunity to respond to some inaccuracies that were propounded in this Chamber today.

I will limit my remarks now to two criticisms raised today: that S. 343 lessens the safety standard for all foods; and that the bill is defective in that it lacks a definition of negligible or insignificant risk.

I plan to defer the rest of my remarks on Delaney clause issues for our continued consideration of S. 343.

As my colleagues are aware, the three Delaney clauses contained within the Federal Food, Drug and Cosmetic Act to ban a limited group of substances—food additives, color additives, and animal drugs—if they are found in whatever quantity to produce cancer in laboratory animals.

This inflexible zero risk standard in the law is outdated scientifically, as my colleague, Senator KENNEDY, noted earlier.

Some have alleged that the Delaney clause modification language of S. 343 somehow fundamentally undermines our Nation's food safety laws. That simply is not the case. It is unfortunate that some of my colleagues are relying on the interpretation of lawyers at the Food and Drug Administration who apparently cannot read the law—and this is not the first time those in this Chamber have had that experience.

So that this is perfectly clear to my colleagues, I want to walk through this issue so that you can see how the language contained in S. 343 continues to protect the public health.

The Delaney clause modification language in S. 343 states:

The Secretary of Health and Human Services and the Administrator of the Environmental Protection Agency shall not prohibit

or refuse to approve a substance or product on the basis of safety, where the substance or product presents a negligible or insignificant foreseeable risk to human health resulting from its intended use.

This provision of S. 343 harmonizes the safety standard of the three Delaney clause provisions with the safety standard long applied by FDA under the other safety provisions contained within the Food, Drug and Cosmetic Act.

In other words, there are substances which could be present in food, or added to food, or indeed, used on or in the human body, which are not subject to the Delaney clause language. To single out these three Delaney clause substances for treatment other than that accorded a broader group of substances used for virtually identical purposes is senseless, especially in view of the fact that FDA has a well-established safety standard for those substances which does incorporate the negligible risk standard.

For the edification of my colleagues, I will list these substances: pesticide residues that do not concentrate in processed food; food substances that are not classified as additives because they are generally recognized as safe or were approved by FDA or USDA during the period 1938 to 1958; dietary supplement ingredients; constituents of food additives; constituents of color additives; environmental contaminants in the food supply; cosmetic ingredients; undetectable animal drug residues; and ingredients in nonprescription and prescription drugs, biologics, and medical devices.

To make a distinction in the safety standard for these substances versus food additives, color additives, or animal drugs, is, at best, irrational.

My colleague from Massachusetts has expressed the concern that in amending section 409(c)(3) of the Food, Drug and Cosmetic Act, the language of S. 343 eliminates the safety standard for all foods from the law.

Specifically, 409(c)(3) says:

No regulation [food additive approval] shall issue if a fair evaluation of the data before the Secretary—

(A) fails to establish that the proposed use of the food additive, under the conditions of use to be specified in the regulation, will be safe: *Provided*, that no additive shall be deemed to be safe if it is found to induce cancer when ingested by man or animal. . . [Delaney language].

It is my understanding that my colleague is concerned that the way in which S. 343 was drafted, that is, modifying all of 409(c)(3) instead of just the proviso containing the Delaney language, eliminates entirely the existing safety standard.

I believe the implication is that the modification should be made to the proviso only.

I simply do not believe that is an accurate reading of the law, when the totality of the Food, Drug and Cosmetic Act provisions with respect to food safety are read together.

I want to assure my colleagues that that was not our intent. In fact, I do

not recall ever hearing any one suggest that that should be the case, in any discussions I have had on the Delaney clause.

There exist a number of safety standards which apply to food under the Federal Food, Drug and Cosmetic Act. Some of these standards overlap—that is, more than one standard may apply to a food or food ingredient or constituent, depending on the particular circumstances.

First, there is the general adulteration standard under section 402(a)(1) of the FD&C Act. This section, which applies to food generally, says that a food is deemed to be adulterated (that is, unsafe) if:

It bears or contains any poisonous or deleterious substance which may render it [the food] injurious to health; but in case the substance is not an added substance such food shall not be considered adulterated under this clause if the quantity of such substance does not ordinarily render it injurious to health.

This safety standard has two parts. For poisonous or deleterious substances added to food, the food is adulterated if the substances may render the food injurious to health. For substances which are not added, that is, they are inherent or not the result of human activity, the adulteration standard is ordinarily injurious to health.

These two principal adulteration standards have been bulwarks in the legislative and regulatory scheme to ensure the safety of food for decades. Indeed, numerous courts have had occasion to interpret these provisions, for example, in *U.S. v. Boston Farm Center, Inc.* (590 F.2d 149 (4th Cir. 1979) and *United States vs. Anderson Seafoods, Inc.*, 622 F.2d 157, (5th Cir. 1980).

These standards remain unamended in S. 343 and would continue to guarantee the safety of our food supply.

Second, it is important to note that the adulteration standards found in section 402(a)(1) are independent of the requirement that such food ingredients as food or color additives be shown to be safe. Or put more simply, any legislative change to section 409 dealing with food additives, for example, would not affect the adulteration standards in section 402(a)(1).

In fact, FDA has used the 402(a)(1) standard to permit quantities of substances, including recognized carcinogens such as aflatoxin—a naturally occurring toxicant from mold which particularly affects peanuts—to be in food. In such a case, FDA has typically employed risk assessment to determine the level of the carcinogenic poisonous or deleterious substance that presents only an insignificant risk.

Third, numerous other safety standards are set forth in section 402 of the FD&C act. One of the principal additional standards provides that a food is adulterated if it contains a poisonous or deleterious substance which is unsafe within the meaning of section 346.

Section 346 provides that a food containing a poisonous or deleterious sub-

stance is unsafe for purposes of section 402, and thus is adulterated unless the substance is required in the production of the food or cannot be avoided by good manufacturing practice.

It is under the principals of section 346 that FDA has regulated environmental contaminants, including such substances as PCBs, a particularly toxic group of chemicals once widely used in industrial production, and PBBs, a flame retardant that was mistakenly applied to food in Michigan.

FDA has implemented this section through the use of action levels and tolerances, which are announced levels of the toxic substance that will be permitted in food.

As Professor Richard Merrill observed in "Regulating Carcinogens in Food: A Legislator's Guide to the Food Safety Provisions of the Federal Food, Drug and Cosmetic Act," (77 Mich L.Rev. 171 (1978), "Most notably section 406 . . . does not unequivocally preclude the marketing of food that contains an added carcinogenic substance." Professor Merrill adds that "FDA has taken the position that it may establish a tolerance for a contaminant shown to be carcinogenic—and thus 'approve' its presence in food in quantities below the tolerance."

As is the case with respect to section 402(a)(1), the legislative language contained in S. 343 has no effect on the important safety standard found in the interplay between sections 402(a)(2)(A) and section 406.

Fourth, section 402 contains numerous other standards related to the safety of food, including those that pertain to food that contains filthy, putrid or decomposed substance, that has been prepared under unsanitary conditions, that contains unlawful pesticide residues, or if the package of the food contains a poisonous or deleterious substance that may render the food injurious to health, (the same standard as set for in section 402(a)).

The second point on which I would like to comment is the contention that not defining insignificant or negligible risk in legislation language is a bad idea.

I take vigorous exception to the idea that the Congress should define these terms in law. Imposition of the zero risk standard by legislative fiat is what led to the Delaney dilemma in the first place.

When Congress first enacted a Delaney amendment in 1958, scientists were not able to detect potentially carcinogenic substances at the parts per million, or parts per billion, levels as they are today. Does this mean that we should lock into the law a one in a million lifetime risk of cancer standard? I think not. What our bill does is allow the agencies to make these definitions. This will allow the law to grow with the science.

In closing, Mr. President, let me reiterate my continued commitment to Delaney reform which both protects the public health and is consistent

with sound scientific and regulatory principles. This is long overdue.

CONCLUSION OF MORNING BUSINESS

The PRESIDING OFFICER. Morning business is now closed.

BOSNIA AND HERZEGOVINA SELF-DEFENSE ACT OF 1995

The PRESIDING OFFICER. Under the previous order, the Senate will now resume consideration of S. 21, which the clerk will report.

The assistant legislative clerk read as follows:

A bill (S. 21) to terminate the United States arms embargo applicable to the Government of Bosnia and Herzegovina.

Mr. LIEBERMAN. Madam President, I rise to speak in favor of the proposal which I am privileged to cosponsor with the distinguished majority leader and many others of both parties, which would finally lift the arms embargo and do some justice in the former Yugoslavia, by replacing a policy of inaction or half actions that has failed to stem the conflict, has failed to stop aggression, and has failed to protect the victims of that aggression, whose pain we see each night on our television sets.

Madam President, this is a genuinely bipartisan or nonpartisan effort, as it should be, as American foreign policy has traditionally been at its best—above party consideration.

Senator DOLE and I began this effort in 1992 when the incumbent in the White House happened to be a Republican, President Bush. We have continued in 1993, 1994, and 1995, with President Clinton in the White House.

Sadly, each time that we have raised this question of lifting the arms embargo and using allied air power selectively, we have been met with different excuses. A defense, not even really so much a defense of the existing policy, but criticisms, complications, unintended results, that might occur if the arms embargo was lifted.

In that, I think, and I will get to that in a moment or two, we have failed not only to see what was happening on the ground, but to listen to the victims of the aggression. The Bosnians have said repeatedly, over and over again, "We don't want American soldiers on Bosnian soil. We don't need American soldiers on Bosnian soil. We have troops on Bosnian soil, they are Bosnians—in excess of 100,000. They are motivated, understandably, to fight to defend their country, their communities, their families, themselves. Just give us the weapons with which to defend ourselves."

Madam President, we rise again, a bipartisan group. Several tries at lifting the arms embargo having failed, this time we act with some sense of hope that we will be able to achieve, perhaps