Alar Five Years Later

by Kenneth Smith

This special report was written for the American Council on Science and Health by Kenneth Smith, Editorial Writer of *The Washington Times* as a follow-up to the two previous reports: *Alar One Year Later* and *Alar Three Years Later.*

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"As a pediatric surgeon, as well as the nation's former surgeon general, I care deeply about the health of children — and if Alar ever posed a health hazard, I would have said so then and would say so now. When used in the regulated, approved manner as Alar was before it was withdrawn in 1989, Alar-treated apple products posed no hazard to the health of children or adults."

— C. Everett Koop, M.D.

Executive Summary

In early 1989, this country suffered the public relations equivalent of a natural disaster, one that most scientists now believe should never have occurred. It concerned a little-known chemical called Alar,* [*Alar is the registered trade name of the Uniroyal Chemical Company] a growth regulator that farmers had used successfully for over 20 years to improve the quality and appearance of apples. But a high-profile environmental group and a popular television show conspired to use Alar to set off a prime-time food scare. That chemical, said the Natural Resources Defense Council (NRDC) and the commentator Ed Bradley on *60 Minutes* , was the most potent cancer-causing substance in the food supply.

Panic set in overnight and, fed by an orchestrated public-relations campaign, quickly got out of control. Parents poured apple juice down the drain. Stores pulled apple products from their shelves. Apple growers suffered losses estimated at hundreds of millions of dollars. "Usually," boasted one of those who helped set off the panic, "it takes a significant natural disaster to create this much sustained news attention for an environmental problem."

There has been less news coverage of the fact that study after study has since found that Alar was neither an environmental health problem nor a cause for panic. To date, there is no mainstream, peer-reviewed research to suggest that trace exposures to Alar, of the sort consumers could expect from eating apples or drinking apple juice, have caused so much as a single additional case of cancer.

But five years later, the fallout from this man-made panic still lingers. Growers have never recovered the money they lost. The public remains wary of man-made chemicals, which, ironically, have generated the higher crop yields which now help feed the world. The controversy also distracted Americans from genuine risks of cancer, such as cigarette smoking.

This paper summarizes the politics and science surrounding Alar over the last two decades. On this, the fifth anniversary of the scare, the American Council on Science and Health calls for the NRDC to withdraw the report that set off the scare and for *60 Minutes* to admit that the scientific evidence does not support the position of their "A is for Apple" report. These admissions would vindicate the use of a valuable agricultural chemical and emphasize the importance of sound science.

'Completely Specious'

Five years after a *60 Minutes* episode on killer apples set off a nationwide panic and devastated growers, some people have a hard time believing the whole thing really happened. Robert Beckel, a veteran Washington insider, told listeners on Pat Buchanan's November 17, 1993, radio program that there was no real debate over the inaccuracy of the CBS broadcast. "Listen..." he said, "I think the people who did that have admitted they were wrong."

No, as a matter of fact, they haven't. The truth is that both *60 Minutes* officials, who produced the February 26, 1989, program "A is for Apple," and the NRDC, which helped orchestrate it, continue to defend their indictment of Alar to this day. At various times, they have attempted to declare victory and get out of the controversy. But they remain haunted by their highly publicized triumph. Today their handiwork is under attack in a variety of legal, scientific and even journalistic forums, where coverage of more recent NRDC campaigns is qualified with unfriendly reminders of the apple scare.

"Only four years ago," wrote *New York Times* correspondent Keith Schneider in the June 1993 issue of *ECO* magazine, "the NRDC and *60 Minutes* teamed up to cause a food scare by attacking Alar, a chemical growth regulator used on apples, as the single greatest cancer threat to children in the food supply. That conclusion has since been described as completely specious by university, federal and state health experts across the country."

When a reporter for *The New York Times*, a publication long sympathetic to environmental causes, turns skeptical, it's a bad sign for the NRDC. Given that kind of reporting, perhaps Mr. Beckel can be forgiven his assumption that the organization had acknowledged its errors. To his surprise and perhaps to that of others, Alar lives on, not as the plant growth regulator produced by Uniroyal, but as a proxy in political debates over the regulation of man-made chemicals.

"When used in the approved regulated fashion, as it was, Alar does not pose a risk to the public's health. In matters of health, good science, not misplaced fears, must drive public policy."

— Ralph R. Reed, M.D. of the AMA

Toxic Data

Prior to February 26, 1989, there was little reason to suspect that Alar, a formulation containing the active ingredient daminozide, would someday set off a panic. Producers counted on it to slow the growth of certain apples that tended to drop off the tree — and rot — as soon as they ripened. Using Alar to harvest the crop all at once meant lower productions costs, less waste, more attractive produce, lower prices and, ultimately, happier, healthier consumers.

Moreover, the compound had been on the market for the better part of two decades without being linked to any health risks. In 1966, Dr. Bernard Oser had conducted carcinogenicity tests of Alar on rats for the Food and Drug Administration. After two years of high-dose feeding, no tumors were found in any of the 32 tissues subsequently examined. Thus, the 1968 registration of Alar by the FDA was not done without evidence of its safety.

By 1973, however, there were some highly controversial and purely hypothetical risks associated with Alar, according to Bela Toth, D.V.M., of the Omaha, NE-based Eppley Institute for Research in Cancer. Dr. Toth found that 1,1-dimethylhydrazine (UDMH), a byproduct of Alar, caused blood vessel, lung, kidney and liver tumors in mice. This finding was of interest to federal

regulators because Alar contains about 50 parts per million (ppm) UDMH, mammals convert about one percent of Alar to UDMH, and about five percent of the Alar residue on apples converts to UDMH during processing of applesauce and apple juice. In 1977, Dr. Toth a found high tumor incidence in mice fed Alar.

These findings set off a special Environmental Protection Agency (EPA) review in 1980, which was canceled and then ultimately reinstated following a NRDC lawsuit in 1984. But, as recounted by Rutgers University scientist Joseph D. Rosen, Ph.D., in the fall 1990 edition of *Issues in Science and Technology*, a publication of the National Academy of Sciences, scientists sitting on an EPA Science Advisory Panel (SAP) in 1985 found the data flawed. The problem was that Toth had treated the rodents to such high doses — 29 milligrams per kilogram of body weight per day — that toxicity could have caused the tumors.

Reported the panel: "The data available are inadequate to perform a qualitative risk assessment. The Toth Alar studies do give rise to concern over the potential oncogenicity [tumor formation] of daminozide. The panel feels that the other studies are equivocal. None of the present studies is considered suitable for quantitative risk assessment." The SAP was equally critical of other UDMH findings: "The recent inhalation studies provide some evidence of potential oncogenicity. However, these studies also present a number of discrepancies which require further clarification." In the *Federal Register* for January 16, 1987 (vol 52, p. 1913), the EPA repudiated the studies by Toth and Hahn, another careless investigator, as unsuitable for regulatory purposes. The EPA later reversed its position without comment on September 7, 1989 (*Fed Reg.* vol 54, pp. 37278-37286) by using extraordinarily high doses to make hypothetical projections of the carcinogenicity of UDMH and Alar.

The agency declined to ban Alar on the basis of the Toth data. It subsequently ordered Alar manufacturer Uniroyal to conduct a new round of testing, which turned up negative, both for Alar and UDMH. Even mice treated with UDMH at the so-called maximum tolerated dose (MTD) — above which the dose becomes toxic (2.9 mg / kg / day for males and 5.8 mg / kg / day for females) — showed no tumors. The dose for males was almost 35,000 times greater than the highest estimated daily intake of UDMH by pre-schoolers.

"It was only when mice were given doses of UDMH above the accepted toxicity threshold," wrote Dr. Rosen, "that tumors appeared. In one of [Uniroyal's] studies, one mouse out of a group of 45 receiving UDMH for one year at 11.5 mg / kg / day had a lung tumor. Blood vessel (both benign and malignant) and lung (benign only) tumors also were observed in 11 of 52 mice that had received a hefty 23 mg / kg / day dose of UDMH. In fact, the dose was so high that 80 percent of the male mice died prematurely because of extreme toxicity."

It was this "toxic data" — generated by doses almost as high as those in the Toth studies dismissed by the SAP — on which EPA would base a decision to phase out the chemical by July 31, 1990. The agency conceded some people might get the idea that such high doses had simply poisoned the rodents, making them particularly poor models for human cancer risks. In a February 1989 press release EPA said, "it may be argued that the deaths are the result of excessive toxicity, which may compromise the outcome of the study." Dr. Rosen argued exactly that in his paper.

But on February 1, 1989, the agency went ahead and ordered Uniroyal to phase out Alar by the 1990 deadline anyway. Extrapolating from the toxic rodent doses cited by Dr. Rosen, EPA said continued use of Alar would mean a hypothetical lifetime risk of 45 cancers per one million exposed humans. Its standard for such chemicals is one hypothetical cancer per million.

Anatomy of a Scare

A 1990 phase out, unwarranted as it was, still wasn't enough for the NRDC, which stood to profit from a prime-time scare campaign to ban Alar immediately. Or so David Fenton, the media consultant NRDC officials hired to run that campaign, explained to them.

How? First and most important, an Alar scare might foster interest in the group's languishing regulatory agenda. Longtime converts to the crusade against synthetic chemicals in general and pesticides in particular, NRDC officials had nonetheless failed to make believers of lawmakers or the public. Neither group seemed particularly troubled about trace pesticide exposures, and press conferences and lawsuits notwithstanding, the NRDC couldn't get their attention. The specter of killer apples could change all that. "The symbolic appeal of the thought of apples as a threat to children," cited by Mr. Fenton in the summer 1989 issue of *Propaganda Review*, would make that agenda an easier sell.

Second, the group wanted to raise money. "The campaign was designed so that revenue would flow back to NRDC from the public," Mr. Fenton told *Propaganda Review*. More money meant more support for its anti-pesticide dogma.

Third, the NRDC wanted to punish the apple industry for continuing to use Alar: "The idea was for the 'story' to achieve a life of its own, and continue for weeks and months *to affect policy and consumer habits*," (emphasis added) Mr. Fenton said in a May 22, 1989 press release. Changing those habits (*i.e.*, discouraging apple consumption) might send a message to other growers and other industries dependent on synthetic chemicals.

To achieve these goals and to publicize the NRDC report, "Intolerable Risk: Pesticides in Our Children's Food," Mr. Fenton designed a fairly simple strategy: "Usually public interest groups release similar reports by holding a news conference, and the result is a few print stories," he said in the May 22 press release. "Television coverage is rarely sought or achieved.... Our goal was to create so many repetitions of NRDC's message that average American consumers, (not just the policy elite in Washington, DC) could not avoid hearing it — from many different media outlets within a short period of time."

With that in mind, months before the scare began, Mr. Fenton shrewdly negotiated a deal with *60 Minutes* to break the story of killer apples, arranged follow-up interviews with a variety of morning talk shows, magazines and other print media and helped Hollywood personalities like Meryl Streep form "Mothers and Others for Pesticide Limits," which would generate a whole new round of news stories on Alar's alleged hazards. Mr. Fenton even sent Ms. Streep to convince *Newsweek* not to run an advance story on Alar that might jeopardize the embargo giving *60 Minutes* the right to break the story. Although she failed to stop *Newsweek*'s account, the NRDC warned scientists who had received an advanced copy of "Intolerable Risk" not to speak to *Newsweek* about it. Such are the lengths to which Mr. Fenton went to manipulate the press.

> "The Alar scare of three years ago shows what can happen when science is taken out of context or the risks of a product are blown out of proportion. When used in the approved, regulated fashion, as it was, Alar does not pose a risk to the public's health."
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> — M. Roy Schwarz, M.D., senior vice president of the AMA

In the end, it paid off. "The most potent cancer-causing agent in our food supply," said a concerned-looking Ed Bradley on the February 26, 1989, *60 Minutes*, "is a substance sprayed on apples to keep them on the trees longer to make them look better." According to "Intolerable Risk," which he called the "most careful study yet on the effect of daminozide and seven other cancer-causing pesticides on the food children eat," one out of about 4,000 pre-schoolers with a lifetime exposure to those eight compounds would develop cancer. For those who didn't get the picture, *60 Minutes* filled the screen with a graphic of an apple with a skull and crossbones.

It was a sensational report, and just as Mr. Fenton predicted, most of the media fell for the scare. *USA Today* wondered, "Are we poisoning our children?" Yes, said Phil Donahue: "Don't look now but we're poisoning our kids. I wouldn't lie to ya." *Family Circle* magazine warned of "Forbidden Fruit." After another food scare on tainted Chilean grapes occurred,*Time* magazine couldn't help but ponder, "Is anything safe?"

No Apples a Day

Not surprisingly consumers wanted nothing to do with killer apples. One parent even chased down a school bus because she had naively packed the forbidden fruit in her child's lunch box. Schools removed apples from the menu. Apple markets collapsed overnight. For some growers, the scare would be the last straw, the one that would force them out of business. Said an official for one Virginia cooperative, "Business dropped 100 percent. It killed us."

Faced with criticism from the American Council on Science and Health (the publisher of this report), which took out a full-page advertisement in April 1989 calling the scare baseless, and unfriendly print reporting on Mr. Fenton's manipulations, *60 Minutes* agreed to air a second program on Alar on May 14, 1989. Mr. Bradley, however, used the program primarily to try to challenge the credibility of his critics and to give even greater exposure to persons promoting hysteria over trace chemical exposures.

Uniroyal subsequently withdrew Alar from the market, and withdrawn it remains to this day, a monument to NRDC's scare. From the environmental group's point of view, the scare was a complete success.

First, it gained worldwide attention for the group's anti-pesticide agenda, attention usually reserved for a "significant natural disaster," according to Mr. Fenton's press release. "Passage of (new, tougher pesticide) legislation is now much more likely than before this campaign," he said.

Second, the scare enriched the NRDC. "A modest investment by NRDC repaid itself many-fold in tremendous media exposure and (substantial, immediate revenue for future pesticide work)," Mr. Fenton said in the release.

Third, it peeled the apple industry apart. The "market was really being damaged," Mr. Fenton boasted to *Propaganda Review*. "The price of apples fell enormously. The stock of Alar's manufacturer, Uniroyal, dropped considerably. Consumer buying habits changed overnight. Lines started forming in health food stores. The sales of organic produce soared. All of which we are very happy about."

For public consumption, NRDC officials tried to tell growers they weren't really all that happy about damaging the apple market: Growers weren't supposed to be the target; went the argument, pesticides were. Privately, however, the organization could hardly contain its glee. As panic set in and growers stood by helplessly, NRDC Executive Director John Adams congratulated Mr. Fenton in a March 10, 1989, letter for a scare well done: "I want you to know how pleased we are with the job you've done so far," he wrote. He concluded by saying, "We look forward to continuing to work with you on this and other issues."

There was no sign of regret for the economic toll the scare took on growers. Assessments of the damage vary. According to estimates from the U.S. Department of Agriculture cited in the October 4, 1991, issue of *Science* magazine, the scare cost growers $120 million. An Apple Institute official told the Virginia Horticultural Society in January 1990 that the figure was $250 million for growers and another $125 million for the processing industry. Growers in Washington state estimate they alone lost $200 million.

NRDC spokesmen have attempted to downplay such damages, saying apple growers did well in the following years. Perhaps those who survived the scare did do well. But in a November 1, 1990 editorial in *Science* magazine, Daniel E. Koshland Jr. dismissed that argument: "That is like an embezzler justifying embezzlement by saying the banking industry continues to survive."

Growers Fight Back

On November 28, 1990, angry growers in Yakima County, Washington, filed a lawsuit against CBS, the NRDC and Fenton Communications, charging that the defendants "disparaged the plaintiffs' red apples by communication or publication of false, misleading and scientifically unreliable statements about red apples, with reckless disregard of the truth or falsity of such statements," resulting in "serious economic loss" to growers. They sued for more than $250 million in damages.

But in September 1993, U.S. District Court Judge William Fremming Nielsen dismissed the suit, saying the apple growers hadn't proven the *60 Minutes* report wrong. By putting the legal burden of proof on the plaintiffs, the judge, in essence, required that the apple growers prove that Alar was not a carcinogen. While this may be legitimate in legal parlance, scientifically, there is no way to prove a negative. Even if 100 reputable studies showed that there was no carcinogenic risk from a chemical, critics could challenge the conclusion with one poorly done study or charge that the next study might show otherwise.

But even if the *60 Minutes* segment was proven false, it wouldn't have mattered, according to the judge. CBS was protected against the suit because its report relied in part on EPA studies. "A news reporting service is not a scientific testing lab and these services should be able to rely on a scientific government report when they are relaying the report's results," Judge Nielsen said.

In fact, CBS and the NRDC relied very little on EPA reports. "Intolerable Risk" was based on the Toth data. EPA findings weren't. "Intolerable Risk" used a model that accounted for age at the time of Alar exposure. EPA did not. "Intolerable Risk" counted on exposure data from a small 1985-86 Department of Agriculture survey of apple and apple product consumption by 2,000 people. EPA relied on a large 1977-78 USDA study of 30,000 people for its exposure data. Not surprisingly, their risk estimates were wholly different: 45 cancers per million persons exposed, according to the EPA; as many as 910 cancers per million persons exposed, according to "Intolerable Risk."

Although the EPA considered Alar a probable carcinogen, it did not consider it an imminent hazard. In a May 1989 letter to James A. Wylie, a Uniroyal vice president, Victor J. Kimm, EPA's acting assistant administrator for Pesticides and Toxic Substances wrote, "We disagree strongly with the recent reports appearing on television and in the newspapers and magazines concerning the analysis developed by the NRDC which created the impression that there is a massive and imminent public health problem as the result of pesticide residues in food and particularly from Alar residues in apples and apple products. This is simply untrue. We believe that the NRDC report presents a misleading picture of the risk of pesticides in the diet."

Asked whether Alar is a known carcinogen for either adults or children, then-acting EPA administrator Dr. John Moore wrote in the May/June 1989 issue of *EPA Journal*, "The answer is no. Scientists do not have direct evidence in humans that traces actual cancer cases to Alar exposure."

In a March 9, 1992, letter to Elizabeth Whelan, Sc.D., M.P.H., president of the American Council on Science and Health, Assistant EPA administrator Linda Fisher sounded a similar theme, saying that: "We did not believe [Alar] posed an imminent hazard or warranted a panic."

The growers intend to appeal Judge Neilsen's ruling.

"One of the most comprehensive reviews of the epidemiologic literature ever conducted concluded that synthetic chemicals are not a significant cause of human cancer, except in isolated instances of occupational exposure. Nothing has appeared in the scientific literature since publication of this review to modify or qualify that conclusion."

— American Medical Association's Council on Scientific Affairs

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Scientists Smell a Rat

EPA and the *60 Minutes* / NRDC team had this much in common: They relied heavily on highly controversial rodent tests and animal-to-man extrapolations to reach their conclusions. They had to. As noted above by Dr. Moore, there was and is no direct evidence that exposure to Alar causes cancer in humans. Mr. Bradley could not show mothers grieving over children lost to killer fruits and veggies on his program because not one such case exists.

The NRDC acknowledged as much in a more recent report, "After Silent Spring." In that document, the careful reader discovers the pesticidal toll that wasn't: "Today, the total health risks presented by pesticide residues in our food supply remain unknown.... Due to the obvious difficulties, no epidemiological studies have ever been conducted to determine the link between pesticide residues in food and human illness.... Given the difficulty of determining the true risks posed by pesticides in food, being conservative in regulating their presence is especially critical." [p. 22]

Thus when an organization like the NRDC said Alar has a lifetime risk of 910 cancers per million exposed children, one can't compare it to a real risk like riding a motorcycle (2,000 deaths per 100,000 at risk) or fire fighting (80 annual deaths per 100,000). The latter figures are based on real victims and real actuarial risks. Lacking flesh-and-blood victims of Alar, the NRDC and EPA had to make them up. Using animal testing and animal-to-man extrapolations, they created hypothetical graves filled with hypothetical victims.

The theory behind this methodology is that exposing animals to test compounds may help predict human carcinogenicity without actually exposing humans to the compounds. Critics, of whom there are many, would say such testing is an attempt to predict human carcinogens without knowledge of their effects in humans and without any means to determine whether those predictions are accurate. It is guesswork and enormously complicated guesswork at that, easily frustrated by a host of variables like diet, age, sex and metabolism.

For these and others reasons, the extrapolation of findings from animals to humans remains controversial in the scientific community. One may argue that in certain, highly controlled circumstances, it can be useful. That is, if a substance causes tumors in two or more species, if it causes those tumors at exposure levels similar to those humans might experience, if it causes tumors that do not occur spontaneously in those species, all other factors being constant, the substance may pose a risk to humans.

But in the hands of government regulators, a single animal test — in a species prone to spontaneous tumor formation at doses a thousand or million times higher than human exposures — may qualify a substance as a possible or even probable human carcinogen. The implicit assumption here is that man is basically a very large mouse susceptible to the same compounds and tumors, that there is a linear relationship between the compound's effects at high doses and low doses and that the compounds and the tumors are causally related.

Many scientists refuse to make such assumptions, which are the only basis for declaring Alar a carcinogen. Just months before the NRDC issued "Intolerable Risk," Professor Lester Lave of Carnegie Mellon and his colleagues questioned the value of animal studies in *Nature.* "Extrapolating from one species to another is fraught with uncertainty... [the rodent bioassay] is rarely the best approach for deciding whether to classify a chemical as a human carcinogen."

In 1990, EPA released a report, "Reducing Risk" which challenged the same animal testing EPA had used to label Alar a carcinogen. Said one report panel headed by Dr. Arthur Upton, director of the Institute of Environmental Medicine at New York University: "Although the database on dose-response relationships for carcinogens that has been obtained from both animal and human studies is comparatively strong,*there is considerable uncertainty on how to extrapolate from high doses to low doses and from animals to humans...*" (emphasis added)

Part of the uncertainty is that high-dose animal tests may be measuring something other than

the potency of the suspect compound. According to Drs. Bruce Ames and Lois Gold, "Chronic dosing at the [maximum tolerated dose] often causes chronic cell death, which leads to chronic cell division in neighboring cells that replace the dead cells. High doses can interfere with cell-cell communication, which also stimulates cell division. Thus, chronic dosing of chemicals at the MTD can increase cancer incidence in animals." (*Phantom Risk*, p. 156)

Another problem is that the high doses often used in animal testing have no relation to the doses that humans experience. A National Cancer Institute official once complained that in one pesticide study, "the amount in pounds required for a lifetime study (bioassay) in the rodent exceeded the amount available from a manufacturer in his total annual production" (*The Apocalyptics*, p. 248). As pointed out earlier, the MTD dose for UDMH cited by Dr. Rosen is 35,000 times the highest estimate of the daily intake of UDMH by pre-schoolers. If pre-schoolers consume tens of thousands of times less UDMH, what exactly does the animal test prove?

Too Conservative

Given the questionable value of extrapolations from animals to man and from high to low doses, relying on these extrapolations to identify and eliminate suspect compounds from the environment overestimates the risks of such compounds and confounds the regulatory standards needed to deal with them. Proponents of the practice, like the NRDC and the EPA, tend to justify such estimates on moral rather than scientific grounds. In a November 29, 1991 letter to *Science*, the EPA's Victor Kimm explained, "Characterizing risk is not an exact science: Uncertainty is inherent in the estimation of risk regardless of the methodology used. Deciding how to deal with that uncertainty — and thus which animal models, exposure scenarios and means of extrapolation to use — is ultimately a matter of making value judgments as well as doing science." Typically that means being overly cautious, overly conservative in regulating a compound in case somebody someday proves it really is dangerous.

Just how conservative, Robert Schuplein, director of the Office of Special Research Skills at the Food and Drug Administration, explained in the *EPA Journal*. Suppose, he said, that the regulatory agency for which you worked asked you to provide an estimate for the average height of a person:

> Getting the data on all the people in the world is impractical, but unless you do, you can't really give a figure without including some certain error. And the size of the error is also impossible to obtain. So in order to be absolutely clear and correct in your response, you decide to give a worst-case estimate: 'The average height of a man will in no case exceed....'
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> This is a very strong statement, so to hedge your bet and to be sure you're right, you will have to make conservative assumptions. One you might make is that the average height of a person will in no case exceed the tallest person in the world. This contains the inherent reliability one likes to have when called upon to defend the regulatory decision against tall activists. Now the tallest people you know about from your research are all less than 8 feet. But there may be giants somewhere, and there is some anecdotal evidence. (Remember the stories about 'Bigfoot.') Let's assume you find a record of a 12-foot giant now deceased. On the possibility that he might have left living relatives, you assume a maximum height of 15 feet, because there is plenty of data indicating that better nutrition over the last 50 years has increased the average body size by about 20 percent. So your official response, supported by several pages of data, reads: 'The average height of a person will in no case exceed 15 feet.'
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> This statement has all the required regulatory qualities needed for the *Federal Register*. It is impeccably correct. It will withstand any legal challenge. It is prudent and does not underestimate the height. It also has at least two undesirable qualities. It is not very helpful. And it discriminates against short people. (Translation: The recasting of a regulatory problem away

from *probable risk* [average height] to *worst-case risk* results in the under appreciation of risk-lowering factors.

The linear extrapolation of rodent bioassay data embodies the regulator's credo ('It's better to be safe than sorry') far more than it does the scientist's ('It's better to be right than wrong'). Currently, the regulatory objective is often fulfilled at the expense of the scientific one.

Asked whether Alar is a known carcinogen for either adults or children: "The answer is no. Scientists do not have direct evidence in humans that traces actual cancer cases to Alar exposure."

— Past acting EPA administrator John Moore, Ph.D.

Real Science

What scientists have discovered and regulators have obscured is that trace exposures to the likes of Alar simply are not a serious health hazard. Consider how they compare to other causes of cancer.

The most famous study on cancer causation was done by epidemiologists Dr. Richard Doll and Richard Peto of Oxford University and appeared in the *Journal of the National Cancer Institute* in 1981. According to their review of epidemiological data, about one third of U.S. cancers are related to tobacco use. Another third are associated with diet and nutrition. Roughly three percent are related to alcohol, seven percent with reproductive and sexual behavior, three percent with "geophysical factors" such as ultraviolet radiation, ten percent with infection, one percent with food additives, two percent with pollution, one percent with "industrial products," one percent with medicine and medical procedures and four percent with occupation. According to the study, "there is no evidence of any generalized increase [in U.S. cancer rates] other than that due to tobacco."

Or consider how exposure to man-made chemicals compares to that of natural chemicals. In *Science* magazine articles published in 1987 and 1992, Drs. Ames, Gold and others found that humans consumed far more natural pesticides than man-made ones. "We are ingesting in our diet," they wrote in 1987, "at least 10,000 times more by weight of natural pesticides than of man-made pesticide residues." In 1992, they constructed a Human Exposure/Rodent Potency index known as HERP, which found that whether someone is consuming an apple or apple juice with trace amounts of Alar, he is still subject to a lower lifetime cancer risk than someone eating a stalk of celery (which contains a rodent carcinogen known as caffeic acid). "What one can say," they concluded, "is that when ranked on an index that compares human exposure to rodent potency, the synthetic pesticides and water pollutants rank at the bottom."

The theories of Ames and Gold and Doll and Peto are now a matter of scientific consensus that "A is for Apple" and the NRDC did nothing to shake. As the American Medical Association's Council on Scientific Affairs reported in a January 11, 1993, article published in the *Archives of Internal Medicine*: "One of the most comprehensive reviews of the epidemiologic literature ever conducted concluded that synthetic chemicals are not a significant cause of human cancer, except in isolated instances of occupational exposure. *Nothing has appeared in the scientific literature since publication of this review to modify or qualify that conclusion*." (emphasis added)

The AMA Council, relying on the work of Drs. Ames and Gold, also attempted to put the risk of synthetic pesticides and natural pesticides in perspective:

It has been calculated, based on Food and Drug Administration data, that the average intake of man-made pesticides per person per day in the United States is 0.09 mg. About half this exposure (0.04 mg) is due to four chemicals that were not carcinogenic in high-dose rodent bioassays. Hence, the maximum exposure to carcinogenic pesticide residues is 0.05 mg per person per day (assumes that all the remaining residues are of pesticides that are carcinogenic in rodents, an unlikely assumption.)

In contrast, Americans consume about 1.5 g of natural pesticides per person per day, more than 15,000 times the level of synthetic pesticides. Moreover... [several] of these natural pesticides are known carcinogens...

It should also be pointed out that stress often increases the levels of natural pesticides in plants. For example, psoralens (light-activated mutagen-carcinogens) are present in unstressed celery at a concentration of about 0.8 ppm. However, celery stressed by insect attack exhibits much higher psoralen levels — levels of 25 ppm have been reported....

The foregoing should not be taken to suggest that exposure to natural pesticidal carcinogens is too high.... *But by comparison, the levels of synthetic pesticide residues in food seem so low as to be [trivial]. That is the point of the argument*. (emphasis added)

For more evidence of the scientific consensus on man-made carcinogens, consider the book*Genes and the Biology of Cancer* by Dr. Harold Varmus, a 1989 Nobel prize winner and the newly appointed director of the National Institutes of Health, and Dr. Robert Weinberg: In a box entitled "A Cancer Epidemic?" (p. 51), the authors downplay fears of synthetic compounds: "Taken together, the data suggest — perhaps unexpectedly — a relatively minor role in human carcinogenesis for the environmental pollutants that have increased substantially over the past half-century."

One can explain the minor role in part by using the basic rule of toxicology that the dose makes the poison. Consumers are exposed to tiny amounts of synthetic chemicals at the dinner table, which makes for a correspondingly smaller hypothetical health risk from them. In the May-June 1993 issue of *Journal of the Association of Official Analytical Chemists*, FDA officials Norma Yess and her colleagues reported the results of extensive government monitoring of pesticide residues: "Most infant foods and adult foods eaten by infants / children... had residue levels well below EPA tolerances or FDA action levels. In relatively few instances... residues were found for which there was no tolerance for that particular commodity. Overall, the findings corroborate results presented in earlier reports that indicate the safety of the food supply relative to pesticide residues."

Likewise Gelardi and Mountford, writing in *Regulatory Toxicology and Pharmacology*, found that infant formulas are more than safe relative to pesticide residues: "Data presented here demonstrate the absence of detectable levels of pesticides in infant formula."

Thank You, Pesticides

Ironically, scare tactics waged against useful synthetic chemicals pose health risks of their own. Writing in the August 2, 1991, issue of *Science*, Zilberman warned that without substitutes, "pesticide bans result in reduced production levels and higher prices, a substantial loss of discretionary income to consumers and a redistribution of income among agricultural producers."

Testifying before a House Agricultural subcommittee, Resources for the Future fellow Leonard P. Gianessi told lawmakers that non-chemical alternatives to pest and disease control generally aren't as effective as synthetic chemicals: "For example, in Northeastern apple orchards the cost of pesticides for an organic apple orchard is about $248 / acre while for standard conventional apple production the cost is $95 / acre. The conventional apple grower is estimated to apply 26 lbs / acre of pesticides while the organic grower has to use 101 lbs / acre of organically approved natural compounds."

Dr. John Graham, director of the Harvard Center for Risk Analysis, warned lawmakers "the

loss of a pesticide may cause direct harm to public health as a result of consumer exposure to the fungi that thrive without the pesticide."

A 1993 National Academy of Sciences report on "Pesticides in the Diets of Infants and Children" advocated regulatory changes regarding pesticide usage and expanded collection of data relating to it. But in the first paragraph of the report, it also said the following: "Chemical pest control has contributed to dramatic increases in yields for most major fruit and vegetable crops. Its use has led to substantial improvements over the past 40 years in the quantity and variety of the U.S. diet and thus in the health of the public." [p. 13]

Pieces such as *60 Minutes*' "A is for apple" not only discourage pesticide use, they also deter consumption of fruits and vegetables that dietary experts consider critical to good health. Indeed, just days after the *60 Minutes* broadcast on killer apples, the National Research Council released a three-year, 1,400-page study detailing the work of 19 scientists who reviewed almost 6,000 studies without finding any evidence that pesticides or natural toxins in food contribute significantly to cancer risk in the United States. If anything, health experts were calling on Americans to consume more fruits and vegetables, not fewer. A March 2, 1989, front-page *Washington Post* headline read: "Experts Agree: Eat More Fruit, Vegetables."

That assessment hasn't changed in the years following the scare. J. Routt Reigart, M.D., representing the 45,000-member American Academy of Pediatrics, told a House Agriculture subcommittee in July 1993, "The American Academy of Pediatrics believes, given the available information on the risks of pesticides in the diet, that it is prudent to recommend that infants and children be provided a diet rich in fruits and vegetables. No known risk from pesticides presently outweighs the benefits of this healthful diet."

Please Pass the Alar

If mainstream science has vindicated pesticides in general, it has also vindicated Alar in particular. In 1989, the same year Uniroyal felt compelled to withdraw Alar from the market:

- The California Department of Food and Agriculture found that "Intolerable Risk" relied on "inappropriate residue values and exposure models to reach invalid conclusions."
- A 1989 study by experts from the World Health Organization and the Food and Agriculture Organization concluded that "daminozide was not oncogenic in mice." The experts also said that because UDMH was present in the studies as either a contaminant or breakdown product, "both compounds had been adequately bioassayed." The experts met again recently to review additional UDMH data and came away more convinced than ever that Alar and UDMH were not the risks they had been portrayed as.
- A 1989 study by the British government concluded that "even for infants and children consuming the maximum quantities of apples and apple juice, subjected to the maximum treatment with daminozide, there is not risk from UDMH."

And exonerations of Alar continue to appear in the scientific literature. In a 1993 paper, Hasegawa,*et al*. reported findings that "Daminozide was considered not to be carcinogenic." In a 1991 paper Cabral*et al*. reported, "Benomyl, Daminozide and Folpet gave negative results."

Drs. Varmus and Weinberg highlight the work of Drs. Gold and Ames in their treatment of Alar: "[They calculate] that the carcinogenic hazard of a glass of apple juice contaminated with the now-banned Alar (a chemical used to prevent premature ripening of apples) is 1/18th that of a peanut butter sandwich (having traces of the natural mold aflatoxin), 1/50th that of a mushroom, or 1/100th that of a glass of beer (containing alcohol and natural fermentation products)."

In 1993 the Center for Media and Public Affairs surveyed 400 members of the American Association of Cancer Research members on alleged health hazards. Only six percent of those polled

thought Alar was a serious cancer risk.

Under the circumstances, it's not surprising that a number of health experts have personally stepped forward to criticize the Alar scare.

- Said Dr. C. Everett Koop in a 1991 letter to Dr. Whelan, "As a pediatric surgeon, as well as the nation's former surgeon general, I care deeply about the health of children — and if Alar ever posed a health hazard, I would have said so then and would say so now. When used in the regulated, approved manner as Alar was before it was withdrawn in 1989, Alar-treated apple products posed no hazard to the health of children or adults."

- Dr. Richard Adamson of the National Cancer Institute told *The Washington Times* in a March 2, 1992, interview that the risk of eating an apple with trace amounts of Alar is "certainly less than the risk of eating a well-done hamburger" and about the same risk as eating a peanut butter sandwich.

- Dr. M. Roy Schwarz, senior vice president of the American Medical Association released the following statement on February 26, 1992, the third anniversary of the Alar scare: "The Alar scare of three years ago shows what can happen when science is taken out of context or the risks of a product are blown out of proportion. When used in the approved, regulated fashion, as it was, Alar does not pose a risk to the public's health."

- Said Dr. Michael Gough, molecular biologist and risk-assessment specialist at the Congressional Office of Technology Assessment in the June 1993 issue of *ECO*: "John Adams and the NRDC ignore the highest proven risks to health, like smoking and fat in the diet, and focus their energies on risks that are tiny in comparison. It's a campaign designed to attract donations, not to improve public health."

NRDC on the Defensive

Keith Schneider's assessment of that campaign in *ECO* is equally blunt:

> The NRDC's campaign, taken up by sympathetic members of the media, cast chemical companies as willful violators of the public trust, evil villains who pollute without remorse. The NRDC also asserted with great success, and not much scientific evidence, that exposure to tiny traces of chemicals in food and water was causing a 'cancer epidemic' in the U.S.
>
> The group's efforts were rewarded by growing membership lists and rising donations from foundations....

But that kind of campaign can generate resentment, he reported: "Having successfully used scare tactics over the last 25 years to push their concerns to the top of the political agenda — and to build multi-million dollar organizations — the NRDC and other groups are reluctant to change what's worked. But faced with growing public resentment, some of Mr. Adams' colleagues in the movement are beginning to criticize the old methods." And the general public isn't alone in its resentment. President Clinton showed "obvious reluctance" to tap officials from the NRDC and other environmental groups for top policy posts in his administration, Schneider reported, as former President Bush did. It's another sign they are out of the political and scientific mainstream.

NRDC officials have attempted to restore their credibility, albeit not by using peer-reviewed findings to defend "Intolerable Risk." Instead they have launched attacks on critics like the American Council on Science and Health, saying its industry funding compromises its science. But such name-calling is hardly a response to the broad scientific consensus ACSH cites in challenging

animal-to-man and high dose-low dose extrapolations critical to classifying Alar a carcinogen. Nor is it a response to the science that places pesticides low on the list of human carcinogens.

60 Minutes has problems of its own, most obviously in court, where growers say they will press ahead with an appeal in their product disparagement case against the program. On another, lower-profile level,*60 Minutes* producer Don Hewitt promised ACSH that he would air a third program on Alar if Dr. Whelan obtained a statement from either the EPA or the National Cancer Institute that the chemical was "safe." Given the regulatory constraints on EPA requiring high-dose animal tests on suspected carcinogens, nothing, not even peanut butter sandwiches, which have trace amounts of a natural carcinogen known as aflatoxin, can be "safe" from its perspective.

NCI, meanwhile, cannot prove the negative, that is, that Alar will never pose a risk. It can and did say that the lifetime risk of eating an apple with Alar is less than that of eating a well-done hamburger. That may not be enough for Mr. Hewitt. However, it helps put the risks of Alar in perspective when one understands that the newsworthiness of "A is for apple" ranks somewhere down there with "H is for hamburger."

"We did not believe [Alar] posed an imminent hazard or warranted a panic."

— Assistant EPA administrator Linda Fisher

End of a Scare

Five years after*60 Minutes* and the NRDC launched their food scare, it's clear that the episode has cost both organizations considerable credibility. Whether one talks to a layman like Robert Beckel, a journalist like Keith Schneider, a scientist like Dr. Bruce Ames or a government official like Dr. Richard Adamson, one hears that the risks of Alar were blown out of proportion. The allegations against Alar were "completely specious." And they continue to distract EPA regulators and laymen alike from the real risks of cancer as determined by experts: cigarette smoking, over exposure to sunlight and currently unidentified dietary factors.

In light of this, ACSH requests that the NRDC withdraw "Intolerable Risk" and end the disinformation campaign associated with it. ACSH also calls on*60 Minutes* to air a program that puts the risks of trace exposures to man-made chemicals like Alar in perspective for its audience. These organizations should not take such actions only in the interest of setting the record straight. They should do so in the interest of promoting public health.

Chronology

1966 Alar tested for carcinogenicity in rats. No tumors found.

1968 Alar registered for use on food crops.

1973 Bela Toth finds UDMH, a byproduct of Alar (daminozide), responsible for blood vessel, lung, kidney and liver tumors in mice when given at several times the maximum tolerated dose (MTD).

1977 Toth finds Alar itself responsible for high tumor incidence in mice when given at several times the MTD.

1984 EPA initiates a special review of Alar.

1985 A scientific panel authorized by the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), completes special review of Alar and concludes that the Toth data are too flawed to assess the risks of Alar.

1986 EPA orders Uniroyal to conduct additional tests exposing animals to Alar at high doses and to provide more residue data.

1989 Based on tumors found in mice exposed to enormous doses of Alar, EPA reports that it would hold proceedings to determine whether to ban it after July 31, 1990. In a February 1 press release, the agency says that "it may be argued that the [mice] deaths are the result of excessive toxicity..."

On February 26, *60 Minutes* devotes a segment to the NRDC report, *Intolerable Risk*, which predicts one additional case of cancer for every 4,200 pre-schoolers exposed to Alar. The report, promoted by a public relations campaign, sets off a national panic.

On March 1, *The Washington Post* reports the National Research Council urges greater consumption of fruits and vegetables, saying, there is "no evidence that pesticides or natural toxins contribute significantly to cancer risk in the United States.

In May, a California Department of Food and Agriculture analysis of *Intolerable Risk* finds no health risk from Alar.

On May 14, *60 Minutes* gives critics of the first report a chance to appear on a second Alar segment. But it was actually no more balanced than the initial one. Mr. Bradley questioned the motives of scientists, including Elizabeth Whelan and Bruce Ames, who said that fears about Alar were overblown. The critical reviews of the NRDC and the propaganda campaign of Fenton Communications were never mentioned.

In June, under pressure, Uniroyal withdraws Alar from the market.

In December, the British government finds "no risk to health" from the small amounts of Alar and UDMH found in food.

A United Nations panel, comprising experts from the World Health Organization and The Food and Agriculture Organization, conclude that Alar is "not oncogenic in mice."

1990 In the fall 1990 issue of *Issues in Science and Technology*, Dr. Joseph Rosen challenges the credibility of the NRDC.

The October issue of *Reader's Digest* publishes one of the first articles for a lay audience to expose the politicized science behind "The Great Alar Scare."

On November 28, Washington apple growers file suit against CBS, the NRDC and Fenton Communications.

1991 On October 4, *Science* magazine reports that EPA, while still considering Alar and UDMH to be carcinogens, finds they are only half as potent as it reported in 1989. Many interpret this as halving the risk of an already hypothetical risk.

On November 1*Science* magazine makes a thinly veiled critique of CBS and the NRDC when it reports that "A clearly dubious report about possible carcinogenicity by a special interest group was hyped by a news organization without the most simple checks on its reliability or documentation."

In a letter dated December 20, former U.S. Surgeon General C. Everett Koop, M.D., states that Alar posed no health hazard before it was withdrawn.

1992 On June 5, a U.S. District Judge eliminated NRDC and Fenton Communications from the apple growers suit.

NRDC issues a press release on calling the court decision "A crushing rebuke to the misguided fringe group campaign to harass, harm, and silence the environmental movement," and "a complete vindication of our position."

EPA continues to insist that Alar was a serious hazard. The agency stated in a September 30 press release that "EPA's recalculation of the dietary risk [of Alar] has confirmed the position taken by the Agency in 1989 [on] the risk to public health. The risks remain significant...."

1993 In June, Keith Schneider reports in*ECO* magazine that, "the NRDC and*60 Minutes* teamed up to cause a food scare by attacking Alar, a chemical growth regulator used on apples, as the single greatest cancer threat to children in the food supply. *That conclusion has since been described as completely specious by university, federal and state health experts across the country*."

On September 13, the judge dismisses the suit against CBS, finding that the issue of Alar's carcinogenicity is unresolved and placing the burden of proof on the plaintiffs.

NRDC releases report accusing ACSH of spreading misinformation and claiming vindication yet again.

On September 23, EPA issues a reregistration eligibility decision document on daminozide for non-food uses.

1994 On the fifth anniversary of the initiation of the Alar/apple scare, the American Council on Science and Health calls on the NRDC to end its disinformation campaign against Alar and other synthetic pesticides and calls on *60 Minutes* to air a program that puts the risks of trace exposures chemicals such as Alar in perspective.

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