

Harvard Business Review

November-December 1981



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Monsanto's 'early warning' system

John W. Hanley

How a major
chemical company manages
the risks and benefits in
technological progress

Interviewed by
David W. Ewing and
Millicent R. Kindle

Few potential conflicts between business and society have created so much public concern as the risks inherent in scientific and technological advance.

One leading corporation that has sought to reduce this area of conflict is Monsanto. At various stages in the development of a new material or chemical product, it brings together knowledgeable scientists and engineers to "blow the whistle" on a new product concept that may introduce unacceptable hazards to users.

Monsanto has organized task forces to analyze the role and effects of so-called "devil's chemicals"—that is, product and process chemicals that may cause cancer. Moreover, with scientific advances taking place every day, the company seeks to develop a realistic, up-to-date philosophy about the trade-offs between risks and benefits in technical progress.

Perhaps no one at Monsanto supports such efforts more vigorously than does its chairman and chief executive officer, John W. Hanley, the subject of the main interview in this article. Formerly executive vice president at Procter & Gamble, Mr. Hanley came to Monsanto as chief executive in 1972. He is also a director of Citicorp and May Department Stores, in addition to serving on various government boards concerned with foreign trade.

Following the interview with Mr. Hanley are short interviews with three Monsanto executives who are intimately involved with efforts to assess the potential hazards in new and existing products. Curtis Elmer, manager of environmental staff information, describes a massive ongoing project to collect data on the impact of chemicals on the health of the company's 45,000 domestic and 20,000 overseas employees. Dexter Sharp, director of environmental sciences research for agricultural products, discusses efforts to assess possible carcinogenic and other toxic effects of herbicides. And Dr. Roger Folk, director of the environmental health laboratories, discusses his group's philosophy and approach in testing the effects of the company's products on health and the environment.

The four interviews were conducted by David W. Ewing, managing editor of HBR, and Millicent R. Kindle, manuscript editor. Photographs courtesy of Monsanto Company.

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Interview with John W. Hanley

HBR: What does it feel like to be chief executive of a giant chemical company during a period when the word "chemical" has come to mean "cancer maybe" in the minds of much of the public?

Mr. Hanley: I don't sense any appreciable difference in my role from that of other chief executive officers of reasonably complex companies. Because Monsanto and the entire chemical industry are in the public eye, we're perhaps more sensitive to certain societal issues than some of my counterparts. But I don't see that as unproductive; rather, I regard it as quite appropriate. The facts are that Americans don't have a very good perception of the risks and the benefits of chemicals.

Our whole society is moving to address itself to a range of problems and opportunities, and the chemical industry has perhaps a disproportionate share of those opportunities at the moment, but that doesn't bother me. I think we recognize an obligation to help educate the public, which is the solution to the problem.

It must be hard to counter the popular impression of chemical companies as risky places to work.

The trouble is, there are a few schlock operators—complete with leaky valves and dripping pipes—on the economic margins of the industry. Rightly or wrongly, they believe that they can't afford to have a safe process or a safe place to work. But for the vast majority of the industry, that's a seriously distorted perception.

Many observers believe that Monsanto has developed an effective approach to anticipating and handling the risks of new product development, especially the potential hazards to health and the environment. How does this work?

We try to eliminate all of the possible surprises, and that's easier to do with new than existing projects. At every major stage of research and development, we formally assess the possible hazards of a new material or process. We look at things like the known or expected impurities of a new product, its expected toxicity (what technical people call "acute" and "chronic" toxicity), foreseeable dangers in disposal, and the ability of cus-



tomers to use the material properly and safely. So these are our preliminary assessments of the hazards—any effects on the health of workers, users, the public at large, the natural environment, the chain of life.

If the new product passes these early tests and goes into development, we hold technology risk reviews. This means that we bring together the most knowledgeable people we can find—doctors, industrial hygienists, chemists, biologists, safety experts, epidemiologists, animal toxicologists, and anyone else who is technically qualified to see how, where, and when that material or process might cause trouble. What might go wrong? What exposure levels might cause what risks?

If the experts see potential hazards, the question becomes, "Can those dangers be managed?" For example, can we change the production methods to recycle the hazardous dust? Can we eliminate the risk by a special valve or some other safeguard? If the answer is yes, we go ahead, assuming that the project makes economic sense; if it is no, then we stop work on the project.

Do these experts—the "early whistle-blowers"—come from your own staff?

Many of them do, but not all. It depends. We don't claim to be the fountain of all knowledge, and so we contact experts outside the company in universities and other organizations in the United States—in organizations all over the world, in fact. For instance, we may have a product that raises a question about the effect of zinc in the metabolic system. We don't have experts here on zinc metabolism, but we know where they are and we call on them; Dr. Bert Vallee at the Harvard Medical School is one. So we would ask him to come in and help us assess the risk with a zinc metabolite.

What happens if the experts don't agree?

Then we are forced to take the most conservative posture possible. If the product would pose substantial risk in the judgment of one or more of the best qualified experts, we can't take a chance on it. If there is uncertainty, we'll go out and try to get more data on the questions raised—and then more judgments either refuting or confirming the experts' concern.

People here understand that if a project ought to be stopped because of environmental risks, the earlier it is stopped, the better off we all are. What really hurts is going all the way through much of the research and development and then

finding something that invalidates all of that prior work.

Is it a problem to keep this conservatism on potential health and environmental risks from dampening enthusiasm for research and new product development?

The conservatism I'm talking about is not in venturesomeness; it's in being realistic about a product's ultimate acceptability. We want researchers and developers to do their homework before new products are put to the market test. The goal is to make health and environmental concerns an integral part of our business thinking just as raw material and transportation costs, return on investment, and other considerations are part of our thinking. Instead of being a deterrent to innovation, I see our approach as a stimulant, for it means that we can proceed confidently in the development and marketing of a new product because we know it passes strict medical and environmental tests.

It is true that when we put our internal review systems in place a number of years ago, they met with resistance here. But those doubts have long since dissipated. New product developers know that if it weren't for the internal checks and balances, they would be rolling the dice every time they committed time and money to a new product introduction.

How new is this early warning approach at Monsanto?

In recent years we have expanded and formalized it, and I believe we practice it more thoroughly than ever before, but the basic concept isn't new. For instance, in the mid-1960s we developed a new organo-phosphate insecticide, which promised to be very effective in controlling certain insects in cotton. After we tested this product, trademarked COLEP, in our labs, we did some limited field testing under scientific supervision. The tests of acute toxicity made by the medical department showed that the toxicity was too difficult to control; there were too many circumstances in which the user could make a small mistake and subject himself or herself to an unacceptable risk. So the product was dropped, the project was killed.

In other words, the principles we're working on aren't new. I think that what is new is the comprehensiveness of our approach now. The reviews are more analytical and systematic, they begin earlier, more experts are brought in.

Why is the risk assessment process easier for new products?

As I mentioned, environmental and health risk studies are implicit in the development of every new product. The existing products, however, have the potential for unexpected findings because when many of them were developed years ago, what is today a normal, thorough range of studies was not done. And we are in fact taking our newfound knowledge and looking retrospectively at these older businesses.

A well-known Monsanto example is PCBs, or polychlorinated biphenyls. We made this class of beneficial chemicals for nearly 40 years, only to learn in the late 1960s that they were bio-accumulating in the environment. Long before we understood the possible consequences, we voluntarily withdrew from PCB applications where we felt their discharge into the environment would be hard to control. And in 1977 we ceased production entirely because of the public's increasing perception that these chemicals presented an unacceptable level of risk.

How successful has the early-whistle-blower approach been in eliminating unpleasant surprises after a new product is launched?

Technically, it has been very successful, aborting numerous projects that were tempting because of the needs they could fill. Most of those projects I couldn't even tell you about because they were killed in early stages by our technical staff.

Politically, however, we have had one well-known disaster—the Cycle-Safe bottle. We must have spent more than \$100 million on this pioneering, recyclable plastic beverage bottle. You could grind it up and make another bottle out of it. We were even testing a version that could be washed out and refilled. People thought it would help to solve the nation's litter problem.

At every main step we asked the experts—both in and out of government—for their judgments on all the data that could be gathered about Cycle-Safe. We asked, "Do you agree it's safe?" At every point they said they did. If there had been much negative opinion, we would not have proceeded. We even organized a scientific symposium in Boston that brought together both those who opposed the concept of a plastic beverage bottle and those who supported the idea. We went as far as a company could go in encouraging scientific peer review and criticism. I think it's fair to say that the scientific community considered our approach a model of what should be done. Officials of both the FDA and the EPA congratulated us on our profile of test data.

But a couple of years after Cycle-Safe went on the market, it was banned in 1977 by the

FDA. The bottle became the victim not of valid health and environmental concerns but of extreme, unforeseeable, and inflexible government restrictions and interpretations fueled by the intense political pressures and emotions of the time. We said then, and we still believe, that the action forcing this highly innovative product out of the marketplace was unfair, unwarranted, and not in the public interest.

The disappointment from the ban on the Cycle-Safe bottle was enormous—to say nothing of all those who lost their jobs.

It was unbelievable. It is unbelievable. We gnashed our teeth and moaned and groaned and cried a lot; and then we said, "Okay, we've got to pursue this thing through the court to demonstrate to the regulatory agencies that they cannot make capricious moves without being called to task." We still don't have a reasoned, rational response from the FDA despite the fact that its basis for the ban was neither scientific nor proper and that it had to reconsider what it did to us.

But we're out of that market now. The new plastic bottles you see on the shelves today are made from polyester and cannot be recycled or refilled.

I'm still angry because it was a very large, important opportunity for Monsanto and, when the whole story is written, it will be proved beyond the shadow of a doubt that there was no scientific basis for the ban. It was a mistake made by the FDA. So what we want to do through our legal pursuit of the matter is; in effect, to put a sign up on the bulletin boards of the regulatory agencies saying: "Be careful. Make sure you're right before you make these moves."

What is Monsanto doing to overcome the setbacks caused by the ban?

On a broad scale, we've worked with the Carter administration and now the Reagan administration to try to bring some sensible guidelines into the relationship between industry and government. I personally have played a modest role in helping the new administration address the pivotal issues in the regulatory process.

Within our company itself, there are some people who feel that their whole existence has been frustrated by the government's unwarranted action against Cycle-Safe. We've reassigned them; we've tried to help them understand that we want to make something positive out of all this. We emphasize that even if the FDA doesn't think of Cycle-Safe as a success, we do. But I'm sure there

are wounds that have not yet healed—that will not heal—as a result of this unfortunate problem.

Do you make contingency plans when a new project goes into production, or do you have special teams of investigators ready to go into action if something goes wrong?

I can't think of a situation today where we would have contingency plans for a new product as it enters production. By that time, we would have reviewed environmental constraints to the point that the possibility of a surprise is almost eliminated.

But we're ready in case a possible, unexpected problem arises that involves one of our products or processes, and we'd investigate the allegations and develop our data or work with other producers to develop industry data. Then we'd make one of three decisions: to defend the product, to change our methods even though production costs may increase, or to drop the product.

As part of our overall corporate approach, we established our environmental policy staff and the environmental policy committee, both headed by a senior vice president, in 1977. These new organizations provide corporate leadership and initiative for managing Monsanto's impact on the environment. They also serve as checks and balances to eliminate crises as new projects go forward; they act as a "watchdog" internally and an early warning system externally.

We've been talking mostly of new products and materials. What about investigating the risks in products that are already being marketed?

Existing products need to be tested for two reasons. First, some of them have been around for a long time, and when they came out they were not subjected to modern testing methods. Monsanto studies a few such products—formaldehyde is a recent example—but usually, because the products are produced by many companies, they are assigned for testing to the Chemical Industry Institute of Toxicology, which is funded by the industry as a whole.

Another reason is that new evidence may come to light indicating a health or environmental problem not suspected before. For example, some of our people are the world's leading experts on the genetic and other possible effects of acrylonitrile on animals and humans. When we learn something new about acrylonitrile—or any other subject of research—we'll test any of our products on the market that contain the chemical.

Benzene is another example that has been around forever. Yet in the last ten years some toxicological data on benzene suggest that in certain circumstances it can be troublesome to humans. Monsanto is the world's largest user of benzene, I believe, and we are going to be testing this chemical for quite some time.

So surprises can come from new knowledge—new analytic capabilities—and we really don't know what all of that knowledge means.

Discussions of chemical hazards sometimes center on "devil's chemicals." What are these?

Devil's chemicals are contaminants—usually highly toxic or carcinogenic—that are inadvertently formed in trace amounts during production. Examples include the nitrosoamines, the bioxins, and the furans.

You have indicated that many uncertainties exist about devil's chemicals. Does this fact complicate Monsanto's job?

Yes. During the last two decades our national ability to measure and quantify has taken quantum leaps forward, and this has changed much of our thinking and added a whole range of questions. A couple of decades ago we could measure chemical impurities fairly accurately in the range of parts per million. If something was not detected in this range, we considered the impurity nonexistent, zero. But today we can measure many trace contaminants in parts per trillion. To give you an idea of this technical achievement, one part per trillion is roughly the equivalent of a single grain of sugar in an Olympic-size swimming pool.

Our increasing analytic capability has permitted us to measure things way beyond our ability to understand what the data mean. And with this greater measuring ability, society is beginning to realize that there's no such thing as zero in this business of impurities. Even fresh water has impurities, we now know.

Whose job is it to identify and analyze devil's chemicals—the government's, the corporation's, or both?

Both. At Monsanto we have spent millions of dollars in this effort. We are not required by law to do so, but like other industry leaders, we consider it our job. Our so-called devil's chemicals project is looking for trace contaminants in existing products, and we have now examined most of them. We have found no product contain-

ing trace amounts even close to the levels that medical and toxicological scientists believe could cause harm. As for government, organizations like the FDA, EPA, and OSHA spend large sums assessing devil's chemicals, and their staffs work in continuous contact with us.

Is your devil's chemicals project related to the early-whistleblower approach?

The two are independent of each other except when a new product or process is being examined. Then the presence or absence of a devil's chemical could enter into the decision whether to continue development of the product.

How do you square the enormous effort and expenditure Monsanto is making to analyze devil's chemicals with the fact that you have lawsuits on your hands like the one filed in March 1981—a \$1.7 billion claim by a group of Monsanto workers in West Virginia who allege that they were exposed to paraminobiphenyl and dioxin?

Maybe this suit proves that there's no way to do your job in this industry without having some brickbats thrown at you. PAB was used from the mid-1940s to the mid-1950s in the Nitro, West Virginia plant to produce certain raw materials. In the mid-1950s, studies began suggesting that prolonged exposure to PAB could cause bladder cancer. Once this was confirmed, we halted the use of PAB and put all employees who had been exposed to it on a long-term health monitoring program.

That program, by the way, continues to this day. Monsanto's response was described in the medical literature as a model for other companies and occupational medicine departments. I don't want to minimize the misfortune of those who may have become victims of PAB exposure. But it was the company that blew the whistle in this case, not a government agency—and certainly not the employees.

How can society take these uncertainties into account when it sets standards for health and safety?

If we go looking for a trace amount of something, chances are we're going to find it in some minuscule amount at least. When we do find it, we must be prepared to take some action or be convinced that no action is needed. Again, what has happened is that our ability to detect substances in many cases has outstripped our ability to understand what, if anything, their presence means. A growing body of evidence suggests that there's a

threshold for all carcinogens—a level of use below which they are not hazardous—but that theory is not universally held. So we are far from hearing the last words on the significance of trace chemicals. In the meantime, what we've got to do is strike the best balance we can between possible risks and known rewards.

In the media there are many accusations and much debate about the hazards of chemical products. Is all this debate simply a result of the scientific uncertainties you have mentioned?

Only some of it, and sometimes only a small part of it. The trouble is our tendency to confuse risk assessment with risk acceptance. They are two very different things, separate parts of the equation. Risk assessment is primarily a scientific exercise. It is an attempt at quantification—that is, determining that material X at exposure level Y presents Z degree of risk to animals or human beings. Risk acceptance is quite different. This is a judgment call, not a scientific measurement. It is a judgment that the risk, high or low, is acceptable or unacceptable.

Who are the experts in assessing risks as opposed to those who decide whether to accept the risks?

Risk assessment is the job of experts—toxicologists, analytic chemists, environmental specialists, doctors, and epidemiologists. Risk acceptance, on the other hand, is not for experts but society at large. It depends on the public's general feelings about risk as well as the credibility of the risk assessors, the role and influence of activist organizations like the Sierra Club and antinuclear groups, the activity of legislators, the reputation of regulatory agencies, and so forth. As a result of all these influences, risk acceptance becomes inconsistent at times, with high risks like cigarette smoking being accepted and low risks, despite scientific assurances, being rejected.

One of the most intimate links I know between science and society is this bridge from risk assessment to risk acceptance. However, this link is the subject of a lot of confusion.

Where do you see risk assessment and acceptance being confused?

All over. For example, a couple of summers ago the saccharin issue came bubbling up again. Well, before the scientific data were in on risk assessment, the question of acceptance was being debated on Johnny Carson's "Tonight" show,

in Congress, on the front page of the *New York Times*, and in lots of other places. That's cockeyed. You can't reach a sound decision on acceptance until the scientific data are properly structured and analyzed. The data are in on smoking, penicillin, and many pesticides, but for an enormous number of products there are still no guidelines; or whatever guidelines that do exist are under repair or advisement.

Let me give you another example.

Regularly our plants are visited by a group of world-famous pathologists who bring their expertise to bear on the question of what further improvements might be made in the environment here. Sometimes I sneak into the back of the room and listen to their discussions but, frankly, their discussions are generally too technical for me; they go right over my head. One time I got them together at the end of a meeting and said: "You know, we think our plants are a safe place to work, but we're terribly concerned about health and safety and we want to do everything we can to make them better. What can I do?" And they told me: "Outlaw smoking. Its danger to health is higher than everything else."

So I talked about this with my associates and discussed whether I should write a letter to every employee sharing this scientific perspective. We decided we should be very careful about any step like that. The data measuring the risks of smoking are one thing, but the acceptance of those risks is another. Employees have the right to make that kind of decision themselves, except when smoking is hazardous because of working conditions. You see "no smoking" signs in many areas of the plants but not in offices.

How does Monsanto ensure the safety and health of the public at hand—the employees?

We have an in-house medical and environmental health department, which keeps close tabs on employees' health and safety through a computerized medical and environmental health system that we call MEHI. And detailed epidemiological studies on Monsanto employees show they are healthier than a comparable sample of the general population. Beyond that, three or four pathologists visit our plants regularly and advise us on how we could further improve plant safety for our employees.

Overall, we've set a new all-time safety record. It's kind of a theme; you see signs all over our plants about "the great safety race." In fact, National Safety Council data for 1979 show the U.S. chemical industry second of 43 industries in safety performance—more than ten times safer than non-military government service! And a recent study

comparing some 3,700 male Du Pont chemists with more than 19,000 male Du Pont nonchemists in the same salary categories found a somewhat lower cancer mortality rate among the chemists.

During the last few years the media have been giving much attention to problems in chemical waste disposal. Is the early-whistleblower approach a way to head off that problem too?

Yes and no. The technical reviews are useful in determining if a proposed product or process can be modified to avoid creating any hazardous waste, and ease of modification will be one of the factors in deciding whether to go ahead with the product. But the reviews don't deal directly with existing waste streams created by chemicals. Those streams are the subject of another effort under way. A hazardous waste study team is getting answers to such questions as: Where are our waste streams? What are the existing treatment and disposal methods? What do projections show about likely increases or decreases in dangers? This team will take another year to get the answers, and then we will complete a ten-year plan for handling hazardous wastes. We may even develop a network of regional facilities for disposal of wastes created by plants in different areas.

Does this mean Monsanto won't have to worry about creating "Love Canals"?

We can't take anything for granted. Is there a warehouse somewhere filled with drums of chemical waste left over from some company operation of many years ago? We've been in business for 80 years. We have surveyed all old closed waste sites, and we don't think any of them could become a hazard. Nevertheless, it is conceivable that some site was used before the development of modern record keeping that we know nothing about. So we live with a certain risk from the past, just as other generators of hazardous waste do.

As for the future, I'm confident that technology is the country's answer. Scientists in every right-thinking company in our industry are being challenged to make products in such a way that they don't produce undesirable by-products. I think that 25 years from now there no longer will be processes that generate large quantities of hazardous waste; the existing processes that do that will be phased out in favor of new systems that won't. When I see people recoiling from technology because of pollution and hazardous side effects, I want to tell them: "The solution to those problems is also rooted in technology. We've got to give scientists a chance to go to work."

Could you tell us some of the ways Monsanto is trying to improve public awareness of the chemical industry's efforts to safeguard health and the environment?

We started back around 1975 with a program of public education, if you will, called "The Chemical Facts of Life" which, we think, has helped people see chemicals in their broadest perspective. On a more personal level hundreds, maybe thousands, of our employees are spokesmen for this public awareness effort. We cover everything from symposia and workshops to Rotary Club meetings, and there are an enormous number of these smaller gatherings. Monsanto encourages managers up and down the organization to speak out in their areas of expertise—to help explain our operations, our positions, and our policies—and also to be available to answer the tough questions and the allegations when they are posed.

Do you view educating the public, then, as an opportunity to correct illusions about the dangers of chemicals?

We go further than that. We try to point out as clearly as we can the risks and the benefits of specific chemicals manufactured by Monsanto—and then we show that life in total is made up of chemicals and no chemical is completely safe all the time, everywhere. We want people to understand that. The problem has been largely the media's focus on the risks without quite recognizing that we really can't live in a contemporary way without the contributions of chemicals. Yet people tend to want to isolate the risks, and that can't be done.

What has been the impact on the chemical industry in general of this widespread public concern over environmental and health hazards from chemicals?

I don't think the public's concern has curbed the basic entrepreneurial spirit of the people in our industry at all, nor do I sense any reluctance on the part of young people to come in and cast their lot with us in terms of career development. They want to come in, and they understand that problems are solved through human effort.

As I have said, our ability to identify trace materials and their effect on human and environmental health has developed very rapidly, almost astronomically. And with those skills we've been restudying what we do, what we make, how it's used—and there are enormous opportunities to improve the safety and efficiency of our products

and processes and our contribution to safeguarding the environment.

Is it difficult to instill and maintain this philosophy in new employees?

No, it isn't difficult at all. These men and women come from a social atmosphere—particularly evident on college campuses—in which environmental concerns are part and parcel of life. And they bring this attitude with them.

We find more difficulty in getting a few of our longer-term employees to appreciate the importance and integral nature of environmental matters. They have done business for so long in an atmosphere that did not place very great emphasis on these areas that some of them now have difficulty changing the ways they do things—even the ways they think about things.

We periodically monitor attitudes within the corporation, and surveys over the past few years indicate that we are making progress on environmental awareness. But there will always be room for improvement.

You have stated that government agencies have made a confusing tangle out of the business of risk assessment. Do you see any signs that government agencies are trying to untangle the mess that's been made?

Yes, I'm an optimist, and there are signs of reason and rationality returning to the Potomac. The learning process of our whole society is continuing to advance, and people are realizing that there has to be an evaluation of all the factors involved—the benefits as well as the risks. For example, chest X rays pose a risk of cancer, but since the benefits for detecting disease are great, most people accept that risk. When you start looking at products involving more potent carcinogens, the trade-off gets more debatable, but even in these cases society sometimes accepts the risks if it believes the benefits are worth the trade-offs. Aflatoxin—a naturally occurring substance—is one of the most potent carcinogens known, yet it is tolerated in foods by both consumers and federal regulators at levels that cause liver cancer in rodents. So I think people are beginning to see that life is a series of trade-offs.

If society and government regulation are so inconsistent, does it make sense to have much regulation at all?

I don't have any trouble accepting regulation of suspected carcinogens and limiting

exposure to them as much as possible. My plea is only to avoid snap judgments, or our way of life is going to be threatened. We've got to make the best judgment calls we can make, and that means advancing our scientific knowledge. For instance, does aflatoxin cause liver cancer in humans? We don't know yet.

Different species can be affected very differently by particular chemicals, and we lack direct correlations between cancer in animals and cancer in humans. We're working on that problem at Monsanto, but Monsanto can't do it alone. The work is going to have to come from industry, government, the universities, and other groups all working together.

Regulation also makes sense in view of the fact that risk assessment is a judgment call. For example, if a very toxic pesticide is tightly controlled in the workplace, with workers thoroughly educated in handling it, the health risk is small. But the hazards of that pesticide are obviously greater and maybe unacceptable if much of the public is using it without the expert knowledge of how to handle it.

Do you view Monsanto's testing approach as proactive or reactive to government regulation?

We take the lead in testing. The existence or nonexistence of federal and state regulatory agencies has no relevance at all to the need for our testing programs. We consider them a responsibility of being in this business.

Are there cases where Monsanto's standards are higher than those of government regulatory agencies?

There are such instances in the United States, and outside the United States there are dramatic examples of this kind. In many foreign countries where we operate, we have the same standards for worker health and safety as in St. Louis, even though the governments of those nations do not require such standards.

Because of testing, is the chemical industry getting so expensive that small companies won't be able to compete?

In some areas it's getting to be very difficult for a small, young company. Take herbicide testing, for instance—all the tests required to determine how the chemical affects the food chain and ultimately human metabolism. It would be very unusual if the three of us could develop a

miracle herbicide in a garage tomorrow and have enough resources to pass the testing regimen required by the government. I think we've got to be careful about squashing the little guy by setting up requirements that aren't necessary, putting up hurdles that are unnecessarily high. Today's entrepreneurs who can create tomorrow's Monsantos are important to the country.

We understand that since the environmental policy staff was organized, the company has benefited in lots of ways.

At the federal level, we have seen our suggestions affect the Clean Water Act amendments, the OSHA labeling regulation, certain EPA air pollution regulations, and others. And as environmental regulation moves from the federal to the state level or even lower, we have been effective in influencing regulations in a number of areas, principally waste treatment and workplace laws and regulations. We don't try to unnecessarily weaken laws or regulations but rather to achieve a better balance among government, industry, and the public.

Let me take the Toxic Substances Control Act, a piece of legislation that was debated for several years before enactment. The chemical industry was advising the legislators on the kind of legislation that would respond to the problem, and the law is now passed with the full blessing of most members of Congress. We were heavily involved in it and think it's potentially very good. Now, that the law is in place, a whole range of regulations needs to be enacted to implement it. The existence of our environmental policy group allows us to deal constructively with the regulators, and that process is ongoing. Our data base of information regarding effects of our processes and products on the environment and health is helpful to the regulators and so, quite properly, industry and government are partners in developing regulations designed to accomplish whatever the law calls for. So we now have much more of a collaborative than an adversary relationship.

You have mentioned some of the promising opportunities for joint ventures between industry and university research groups. Do you see this type of collaboration as ongoing?

Yes. So much of the scientific community is in the academic world that we have to be interested in what's going on there. In the past, business has had little incentive to develop the discoveries made on U.S. campuses. For example, say that a scientist at the University of Idaho develops

something relevant to caffeine in the metabolic system. He makes a worthwhile discovery, publishes, and it goes on the shelf. But General Foods and Procter & Gamble have little interest because that professor was funded by the government and so his invention, if it's patented, cannot be granted on an exclusive basis. Industry won't take on the commercial development job because, for every dollar scientists spend getting to the invention, it'll take 10 or 100 dollars to get it to a practical application. So because they don't have an exclusive shot at that invention, companies don't pursue it.

Now we're trying to change that. We've tried to have a coupling of interests where we could mix skills and aspire to genuine synergism. We agreed to take on the developmental responsibilities with Harvard Medical School right at the outset in exchange for some kind of proprietary interest in the joint discoveries. Right now we happen to be studying the nature of molecular messengers, which trigger the metabolic system and can feed tumors and start cancerous growths.

If we can demonstrate that such collaboration can be profitable for the industrial partner, we may encourage a whole series of like relationships around the world and thereby change that fumbling, incomplete process which involves the transfer of academic research into products and processes that benefit society.

Do you, then, see private companies supplementing the government by bankrolling campus scientists?

Yes, I do. The government is clearly curtailing the nature of its investment in research and development, and I don't quarrel with that as part of getting our budgetary process back into some balance. But there is going to be a void, and I hope that the kind of experimentation going on will be so successful as to encourage other people, other industries to come in and help fill that need. The Harvard-Monsanto experience is only one degree on a circle of 360 degrees.

Interview with Curtis Elmer

HBR: How long has Monsanto been collecting employee health information?

Mr. Elmer, manager of Environmental Staff Information: We've just started formalizing collection of this data over the past few years with our MEHI—medical and environmental health information—system, but we've been working in that area for 40, 50 years.

We are just beginning to use MEHI. The first step, to get a system and start it working, is over. Now we're on the second step of feeding the system data, and that will be ongoing. The third step of getting the data out so we can issue meaningful reports is still in the future. We have 45,000 Monsanto employees in the United States to deal with and 20,000 more outside the United States. So you can imagine that the job of data collection and input is significant.

Do you have safeguards to protect the privacy of employee information once it's entered into the MEHI computerized system?

Most definitely. The process for medical data entry starts at a plant clinic where a doctor or nurse fills out two-part forms to record employee health information. On the top line goes the employee's name; on the second, the social security number and birth date. When that form is completed, it's torn off below the top line, so the only thing that shows on the form that gets mailed to us is the social security number and birth date. Somebody who might accidentally open the envelope can't tell much by that. And when it gets entered into the computer, the programmer uses a specific program that scrambles the original into a totally meaningless jumble of letters and numbers. When the information is withdrawn, it has to go through that same program to unscramble the letters and numbers. It's a tough code to break. Furthermore, only physicians can receive output with a person's name on it.

Do you monitor for possible health effects from specific chemicals?

Yes. We do studies for very specific purposes, either in a certain plant or for a certain chemical wherever it is used or made. Ten years ago, our study data were less efficiently collected.



All we knew was that someone was either exposed or not. For example, we had an accident at one of our plants in the late forties that exposed a few hundred workers to potentially hazardous levels of the chemicals being used at the time. The health status of those workers has been carefully monitored ever since. We followed this particular group of employees—not because any government regulation required it—but rather because we had no previous experience with that kind of exposure and didn't know what, if any, the long-term health effects might be. As it turned out, we learned much later that the highly toxic contaminant, TCDD or dioxin, was one of the substances involved in the accident. Back in the forties, dioxin hadn't even been chemically identified.

Dioxin is one of the devil's chemicals, isn't it?

Right—and it's much in the news lately because of the Agent Orange controversy and other incidents. We're one of the few companies with documented exposure records with it. Now we don't know exactly how much the people were exposed to during the accident because the science of industrial hygiene was not very sophisticated 30 years ago. But we do know who was exposed and what their symptoms were. We've recently conducted follow-up epidemiology studies on this group of workers and found no apparent excess in cause of death as a result of exposure some 30 years ago. We're able to do studies like this with a great deal more detail now because we know more about the specific effects of exposures on people, both what and how much. This is the kind of information we are putting into our MEHI system—any noticeable effects on the health of Monsanto employees that might be relevant to workplace exposure.

Do you think the FDA sometimes overreacts when devil's chemicals are found as product contaminants in very small amounts?

The FDA's concern is not necessarily limited to the presence of devil's chemicals. The Delaney Amendment to the Food & Drug Act gives the FDA special problems and rigid guidelines. This amendment states specifically that nothing man-made can be added to foods that has been shown to cause cancer in any test, of animals or people, at any level. On the other hand, the FDA permits naturally occurring carcinogens in our food supply. Take aflatoxin, a potent human carcinogen. It is a naturally occurring mold that's formed on peanuts and other grain crops consumed by humans. The

FDA allows aflatoxins in U.S. foodstuffs, albeit at very low levels, because it has concluded that the benefits outweigh the risks. We simply feel that this same sort of rationale should be permitted with man-made ingredients.

Do the regulators think there are no safe levels for suspected carcinogens?

This is certainly the prevailing attitude in the FDA. Other agencies like OSHA and the EPA are continually striving to reduce exposures to the lowest possible levels. There is a substantial body of evidence that says there are safe levels for carcinogens. We know that many nutrients, essential for health and even life itself, have caused tumors when fed to rats at relatively high levels. Typically the regulators react to a high-dose animal test by issuing a new standard, let's say at 30 parts per million. Then another test comes along that shows a carcinogenic reaction at a lower dose level and they'll say, okay, let's reduce exposure to 10 ppm and if 10 is good, 2 ppm would be even better and so on.

Well, every time they go down another increment it raises the costs, sometimes tremendously. And their reasons for what they do are not always rational or clear. To reduce exposure in a workplace from 10 ppm to 2 ppm on a particular substance may be justified. But if such a decision is based on unrealistic judgments, the net effect can be millions of dollars in additional costs to us and no real benefit to our workers. When this happens, we're faced with a real dilemma. Is it worth it, or do we just fold up our tent and get out of the market—denying the consumer a benefit and some workers their jobs. With MEHI we hope to build a case based on hard data to counter the regulators' arguments.

Interview with Dexter Sharp

HBR: We're interested in Monsanto's concept of early whistleblowing—that is, the organization of checks and balances designed to eliminate the possible hazards in a new project long before it ever goes on the market. Could you give us an example of how your section plays this role?

Mr. Sharp, research director, Environmental Science, Monsanto Agricultural Products: Let's take Monsanto's well-known Roundup herbicide. Roundup was first formulated as a dimethylamine salt, a formulation different from the product sold commercially now. Dimethylamine is a secondary amine and can form a nitroso compound, or nitrosoamine. We blew the whistle, pointing out that we would have had very serious problems defending the use of that product because of the remote chance that nitrosodimethylamine—a known carcinogen in animal tests—might form in the environment. So we developed a new formulation using isopropylamine, which is a primary amine that cannot form a nitroso compound. And that is the formulated product that we know today.

Nitrosoamines have a bad reputation. Would the Environmental Protection Agency have refused to register the first version of Roundup if you hadn't made that change?

At the time this happened, not many people knew about the hazards of nitrosoamines. We were not sure at all what the EPA's position would be. It may not have had that information then, though of course it does today. So what we did—like what we do today—was not only to anticipate what the EPA *might* do if it had the information we had but, more important, to avoid placing on the market a potentially hazardous product.

If the scientists hadn't been able to come up with the alternative formula using isopropylamine, what would have happened?

Our scientists would have continued their research until a suitable formulation was found. The work on Roundup would not have been stopped. The potential benefits of Roundup to agriculture were too great to have done otherwise, and we would have developed some other kind of formulation.



When you have to put so much emphasis on the possible risks as opposed to the likely benefits, is an atmosphere of excessive caution likely to be created?

Naturally we try to avoid such an atmosphere, but carcinogenicity is only one part of the equation. For a chemical to be a problem, the public as well as our employees have to be exposed to it. If, using initiative and imagination, we can find ways to produce and use that product so that the potential for exposure is remote, we would go ahead with it. Also, by determining to the fullest extent possible the ultimate fate of a chemical throughout the environment, we gain the broadest technical base for assessing safety.

Could you give an example of how Monsanto reduces the risk of exposure?

Suppose you use water in the manufacture of a new product, and you pump that water into the Mississippi. After the discovery and product development work—a dozen or so stages going from the research idea through synthesis, biological evaluation, research field tests, environmental chemistry, residue studies, and others—we ask if that water is so free of chemicals that there's no problem in simply returning it to the river. If the studies show chemicals, then we ask how the water might be cleaned up, and treatments will be developed to remove the chemicals. And we may find that we can even put the water back into the Mississippi cleaner than when we took it out.

Or suppose we find that a chemical gets into the air when a pesticide is made. We measure the quantities in the air, then talk to the people involved in production: "You've got to tighten up your system. You can't have an open vat there; put a lid on it." So Manufacturing devises controls or modifies equipment to eliminate that air emission.

You use animals for testing. How confident are you that tests of a cancer hazard on animals can be extrapolated to humans?

I think these extrapolations are reasonable. They have built-in safety factors that allow for variations when the product is used by humans. Most people don't realize that there are plenty of natural products out there that are tumor inducers, and if it were the other way around—if those natural products were tested on animals first—they mightn't be allowed in food or animal feed.

For example, reportedly somebody has tested on animals a natural substance in sassafras tea and found it carcinogenic. Sassafras tea won't

be banned because of this, yet that substance may end up being banned in man-made chemicals. In fact, now that testing methods have improved so much, natural products such as caffeine and other substances in plants are being looked at very critically for chemical manufacture even though they occur naturally in various foods. Such manufactured natural products may have useful properties beneficial to humans as food preservatives, for example.

Doesn't all this testing delay launching a pesticide product on the market?

Oh, yes. It may take $4\frac{1}{2}$ to 5 years to complete all the studies—toxicology (including carcinogenicity), identification of metabolites, effect of residues on crops, fate in the environment, and so on. All these data go into a petition to the EPA to establish residue tolerances in support of food or feed use and to grant a label, that is, precise directions for use. The data may be enormous—for Roundup, for example, the first label petition comprised 19 volumes stacked two feet tall. And then it takes the EPA from 18 months to 2 years to review all of the information. In parallel with the tests, there is still more work to do—the stages of process and product chemistry, engineering design, and manufacturing plant construction before actual production and marketing. And sales can't start until the EPA accepts our supporting data, establishes tolerances, and grants a label for the pesticide. Altogether we may be talking about 8 to 10 years or so from conception to manufacture and sales.

Can this lengthy process really pay off?

Yes, if we have found a new chemical that has unique biological effects and can solve a major agricultural problem, the process pays off. Furthermore, if we can define the fate of this newly created molecule in complete terms—what happens when it is consumed or leached into the soil or changed by sunlight—we're going to be a lot better off. We need that information to defend the product uses and effectively communicate our knowledge if people begin to worry about the product.

Interview with Dr. Roger Folk

HBR: What is the aim of the Environmental Health labs?

Dr. Folk, director, Environmental Health Laboratories: First, we want to make sure that every product made by the company is safe for users. Second, we want to make sure that company workers exposed to different chemicals in testing and manufacturing are safe.

When you say "safe," do you mean in compliance with government regulations?

We try to go a lot farther than that. We could never keep the scientists here motivated if we saw our job as just checking out new products according to standard protocols. That would be mesmerizing; it would be like putting hubcaps on the assembly line in Detroit. If we said, "We've got to weigh all those test animals and do it just like this, at the expense of other observations," we'd be trapped.

How much farther can you go, then?

We want to fully understand the data we generate. We have more data on our materials and products than anyone else has, and we want to make sure we know what those data are saying, regardless of whether the government or anyone else is concerned.

Let's say we see something in the data that is a little bit different from what we expected. We don't pass it off and say, "We don't have to worry about that." We're interested because we're scientists and our training makes us interested in apparently minor discrepancies. The discrepancies may turn out to be the most important thing about a whole study.

Also, we're interested because such an approach will produce better risk analyses for the company. Finally, we're interested because we're professionals. I can attract better people to the labs if we foster a spirit of inquiry here. There's always a big piece of every scientist that has to hold onto the inquisitive attitude learned in school, and I want to encourage that innovative and entrepreneurial spirit.

Do these extremely talented people cause administrative problems?



Well, we can't put up with too many geniuses! Most managers, including myself, are just not smart enough to manage them. But we've got to have very good scientists—some of the best ones are mavericks—and this can cause administrative problems. I'm like a conductor. I make sure that all the pieces play in harmony without restricting individual talents.

What are some of the major disciplines represented in these labs?

We have toxicologists. Some are concerned with the effects of compounds given to test animals in their food, others with the effects of compounds in the air they breathe. The studies conducted by toxicologists range from short, single-dose experiments to lifetime administration of a compound to rats or mice. The latter is one of the most expensive kinds of study. It costs about \$500,000 to do a lifetime feeding study to determine the potential of a compound to cause cancer in experimental animals.

We have pathologists, clinical chemists, and histologists who analyze the test animal's blood to determine red cell counts, white cell counts, and so on—everything you would have done if you went in for a complete physical examination. We have pharmacologists who analyze what happens to a compound after it gets into the test animal's body—how long it stays there, how it is excreted, how it is distributed among the organs.

We have a genetic toxicology group. These people study the potential of a compound to change the DNA in the nucleus and produce mutations. The genetic toxicology group also studies the potential effects of products on reproduction and the development of the fetus—a discipline we call teratology.

And we have our own computer group that captures and manages reams and reams of data. For instance, one of our standard studies is a 90-day feed or inhalation study. This one study will involve 160 rats or mice and will generate in excess of 40,000 pieces of data—and that's fairly small, by our standards.

This is just a beginning—I could go on and on.

Is there a cutoff point on toxicity—that is, some level above which a new product is considered too dangerous and dropped?

Yes, but there are no rigid criteria because everything has some degree of toxicity if given in large enough doses. We start with large doses and short-term effects, working up to smaller

doses given over long periods. We start drawing blood samples for the longer studies and stage by stage the study intensifies. In each major stage we want to see some toxicity, because anything you can think of—sugar, milk, vitamins—is toxic if a large enough dose is given.

If the toxicologists see no adverse effects at all, they feel very uneasy with the data. Was something done incorrectly? They're not comfortable until they know the no-effect levels and the levels at which toxicity occurs and compare the latter with the highest levels any human user can get exposed to—and see if there is a good margin of safety. But there is no number or ratio or formula that is applied to give a go or no-go decision, because toxicity isn't a simple matter. ▽

The open society, the unrestricted access to knowledge, the unplanned and uninhibited association of men for its furtherance—these are what may make a vast, complex, ever growing, ever changing, ever more specialized and expert technological world, nevertheless a world of human community.

J. Robert Oppenheimer
Science and the Common Understanding, 1953

The wildness of science

The essential wildness of science as a manifestation of human behavior is not generally perceived. As we extract new things of value from it, we also keep discovering parts of the activity that seem in need of better control, more efficiency, less unpredictability. We'd like to pay less for it and get our money's worth on some more orderly, businesslike schedule. The Washington planners are trying to be helpful in this, and there are new programs for the centralized organization of science all over the place, especially in the biomedical field.

It needs thinking about. There is an almost ungovernable, biologic mechanism at work in scientific behavior at its best, and this should not be overlooked.

The difficulties are more conspicuous when the problems are very hard and complicated and the facts not yet in. Solutions cannot be arrived at for problems of this sort until the science has been lifted through a preliminary, turbulent zone of outright astonishment. Therefore, what must be planned for, in the laboratories engaged in the work, is the totally unforeseeable. If it is centrally organized, the system must be designed primarily for the elicitation of disbelief and the celebration of surprise.

Moreover, the whole scientific enterprise must be arranged so that the separate imaginations in different human minds can be pooled, and this is more a kind of game than a systematic business. It is in the abrupt, unaccountable aggregation of random notions, intuitions, known in science as good ideas, that the high points are made.

The most mysterious aspect of difficult science is the way it is done. Not the routine, not just the fitting-together of things that no one had guessed at fitting, not the making of connections; these are merely the workaday details, the methods of operating. They are interesting, but not as fascinating as the central-mystery, which is that we do it at all, and that we do it under such compulsion.

I don't know of any other human occupation, even including what I have seen of art, in which the people engaged in it are so caught up, so totally preoccupied, so driven, beyond their strength and resources.

Scientists at work have the look of creatures following genetic instructions; they seem to be under the influence of a deeply placed human instinct. They are, despite their efforts at dignity, rather like young

animals engaged in savage play. When they are near to an answer their hair stands on end, they sweat, they are awash in their own adrenalin: To grab the answer, and grab it first, is for them a more powerful drive than feeding or breeding or protecting themselves against the elements.

It sometimes looks like a lonely activity, but it is as much the opposite of lonely as human behavior can be. There is nothing so social, so communal, so interdependent. An active field of science is like an immense intellectual anthill; the individual almost vanishes into the mass of minds tumbling over each other, carrying information from place to place, passing it around at the speed of light...

There is nothing to touch the spectacle. In the midst of what seems a collective derangement of minds in total disorder, with bits of information being scattered about, torn to shreds, disintegrated, reconstituted, engulfed, in a kind of activity that seems as random and agitated as that of bees in a disturbed part of the hive, there suddenly emerges, with the purity of a slow phrase of music, a single new piece of truth about nature...

It is instinctive behavior, in my view, and I do not understand how it works. It cannot be prearranged in any precise way; the minds cannot be lined up in tidy rows and given directions from printed sheets. You cannot get it done by instructing each mind to make this or that piece, for central committees to fit with the pieces made by other instructed minds. It does not work this way.

What it needs is for the air to be made right. If you want a bee to make honey, you do not issue protocols on solar navigation or carbohydrate chemistry, you put him together with other bees (and you'd better do this quickly, for solitary bees do not stay alive) and you do what you can to arrange the general environment around the hive. If the air is right, the science will come in its own season, like pure honey.

From
"Natural Science," in *The Lives of a Cell*
by Lewis Thomas.
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Originally appeared in the *New England Journal of Medicine*.
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