was that there was very little representation from industry. These are public meetings. Those of you who are interested in these new consumer concepts that are going to be affecting your industry should be sure to have representation at these meetings.

What's going to happen now? FDA will have hearings on these subjects, most likely scheduled for summer or early fall. I feel very strongly that prior to these hearings we should have a public policy forum on food nomenclature where we can have industry, consumers and the government officials sit down and discuss these issues. We must discuss the trade offs, find out what the new labeling programs will mean, what they will cost, and whether they are in the consumers best interest.

Finally I would like to mention just one other piece of important legislation: the new bill to set up a national consumer nutrition information act of 1978. This is a bill that is now before the subcommittee on Domestic, Consumer and Nutrition Services of the House Agricultural Committee. It is a bill that will unify nutrition education in the government. It will set up a nutrition council.

In the proposed legislation, the makeup of the council is very heavily weighted with government officials and has a very small number of consumers and industry representatives. This council will set the overall nutrition education policy for the government. The lead agency according to the bill as it stands right now is the Department of Agriculture with the person to chair that council from the Department of Agriculture. Health, as it relates to diet, is very very important. Where is HEW? Are they going to be given a cochairmanship of that committee or are they going to be just sort of an adjunct?

This legislation is going to be very important to all of you because it will be setting the new nutrition education guidelines for this country.

As you can see, there is indeed a great deal of emphasis in Washington on the consumer and on consumer legislation.

Toxins, aflatoxins, natural toxicants and antinutrients in foods. Safety data required for food additives.

Dr. R. Hall, Vice President, Science and Technology, McCormick and Co.

To deal effectively with food additives and safety requirements for them, there must be a constructive relationship between the flavor industry and the legislators. But that is not enough. The attitudes of the more vocal members of the community have had a good deal to do with regulatory and legislative principles under which we operate. We are not going to change those principles without changing some of the underlying attitudes. To achieve this, some new perspectives will be necessary.

Most people manage to go for very long times without thinking about natural toxicants. But it may be useful to look at them to see whether they can provide the perspectives for coping with risk in our environment, and specifically in our food supply.

I suspect it shatters some illusions of many people to hear, or worse yet, to understand, that there are "bad things" nature puts in our food. We have abroad the impression that the bad things have been put there purposely or inadvertently by humans and that nature is beautiful. This is a distorted perspective. In order to pursue this we need to settle on some definitions.

Toxicity is the capacity of a substance to produce injury. The term includes, of course, the capacity to induce teratogenic, mutagenic, and carcinogenic effects. It could be very well defined as chemical disruption of living systems or organisms.

Hazard is the probability that injury will result from the use of the substance in the proposed quantity and manner. Hazard, therefore, links toxicity (the inherent capacity to cause harm) and quantity. The amount of a substance present will determine if the potential for harm will, in fact, be realized.

Safety is the practical certainty that injury will not result from the substance when it is used in the manner and the quantity proposed for its use. In many definitions it is customary to add the phrase, "within the lifetime of the individual," as for some types of risks it would be a matter of time. If one could live to be 150 years old, one would incur risks that would not have accumulated to a significant extent in a normal lifetime.

Exposure or quantity of use is a major factor in

determining the extent to which the capacity of the substance to produce injury will, in fact, be translated into actual risk.

Safety can never be demonstrated directly, only indirectly. Safety is simply the apparent absence of harm based on observation. One can no more prove a substance safe than one can prove that he or she is honest. If someone has done something wrong and evidence of that can be obtained, then one can show that person was not honest—at least under those circumstances. But evidence of honesty, like evidence of safety, is simply the absence of adverse indications—presumbly after a very thorough look.

Safety therefore, is always implied, never explicit; relative, never absolute. A *toxicant* is a substance which displays a degree or kind of toxicity which renders it worth of note. *Toxin* is often synonomous with toxicant but it also has the more limited or more precise meaning of a toxic protein capable of producing antibody production and produced usually by a microorganism. Thus we speak of toxin produced by a snake or a spider or a bacterium.

Food toxicants are significant first simply because food itself is of interest—it is a biological necessity, a cultural expression, an esthetic experience, and a means of social interchange. Beyond nutrition, even without a thought for nutrition in most cases, we choose our food because we like it. The major factors in choice are esthetics, basis of expense, and to some extent on the basis of convenience.

While we are increasingly aware of nutritional and safety aspects, I suspect that except for a small dedicated group, very few people actually make their meal to meal food choices on the basis of nutrition and food safety. And I suspect further, on the basis of a long time of watching people in stores and the space given to divided bins in the supermarket, that most of the nutrition and safety based choices are based on misinformation. This includes fad diets, the impression that natural vitamin C is better than artificial, and other similar misapprehensions.

There are some special reasons for interest in this topic today. Food toxicants have been and still are real. In earlier times they were a far greater risk. Food processing, among other things, has done a great deal to reduce these risks.

N. H. Steorts and R. Hall

Secondly, natural toxicants pose some fascinating chemistry and biochemistry which we simply can't consider here.

Third, these substances provide us with some essential perspectives on food safety. Through this window we can gain some insight as to why we take some of the risks we do, the safety factors that are appropriate, the ways in which we manage these risks.

Actual Hazards

Order of Priority

1. microbiological
2. nutritional
3. environmental contaminants
4. natural toxicants
5. pesticide residue
6. food additives

The sources of food hazard have been identified in rank by Dr. Schmidt, previous FDA commissioner, and Dr. Virgil Wodika. Most of you are familiar with that listing. The chart does an injustice because the first two hazards are far and away greater than the next two. The statistics from the Center for Disease Control and our obvious burden of obesity and obesity-related physical disabilities testify to that.

Next come the environmental contaminants which represent a real hazard though, fortunately, a very infrequent one. They are well dramatized when they occur. The polybrominated biphenyls, and rare cases of mercury poisoning are examples of that sort of thing.

Then come the natural toxicants, some of which we will discuss later. These are probably the least known of the hazards as far as most people are concerned. Then significantly below those in terms of any known or demonstrable ill effects, are pesticide residues and food additives. I say that with full awareness that there is probably someone in the audience who thinks Dr. Feingold's ideas are wonderful, or who is very much concerned with pesticide residues. But in terms of known effects, measured by the available facts rather than by the fears of some, they belong very definitely at the bottom.

It is ironic and frustrating, therefore, that a great many people tend to look at those hazards almost in inverse and perverse order of importance, rating the food additive and pesticide residues very high, giving increasing attention to the nutritional but very little attention to the microbiological risk.

The increasing attention being paid to nutrition comes from a very vocal, a very concerned group of consumers but they are a small minority of the total. If you don't believe that, just look at the statistics on body weight in the popula-

tion.

The information by which we judge toxicological risks and safety comes largely from two sources. First, of course, are animal studies. We can't discuss in detail here the procedures, values and pitfalls of toxicology and epidemiology. However, note that animal tests are difficult, hard to reproduce, and subject to a variety of major uncertainties. Yet they are often the only game in town—the only real source of information on how the substance may affect humans. We try to allow for all these problems with large safety factors when we interpret the results, but we can never be absolutely sure. For all their weaknesses they remain a very valuable source of insight.

Human experience, though it involves the species with which we are most concerned, is usually ambiguous. It is ambiguous in that it does not directly connect cause with effect. It is frequently insensitive, as it takes a very rare adverse reaction to be noticed. If the adverse effects are expressed in terms of a type of illness or a disease that is already common, then it takes large swings of incidence for it to be noticed. Furthermore, the consequences may be long delayed and therefore remain unnoticed for many years. Epidemiological work is risky and uncertain, yet obviously of great potential value.

Last, of course, is informed scientific judgment in interpreting the results of all of these. This, of course, is something of which we need a great deal more. One of our current problems is the tendency to do toxicology at home for fun and profit, amateur interpretation of extremely complex and uncertain data. We can't forbid it, we can't prevent it, we can merely try to make people a little more aware of the pitfalls, a little less ready to accept the latest crisis statement, or to believe the ready interpretation of unpublished data by a biased or unqualified source.

Anyone who follows media reports of congressional interest or consumer advocate concern, might reasonably conclude we are in the grip of two phobias. One, of course, is the fear of chemicals, and the other is the fear of anything new. We are not going to remove those today. The fact is the world is chemical, you and I are bundles of chemicals, and the new isn't necessarily hazardous and the old isn't necessarily safe. Very often we are simply unaware of the near misses from hazards of which we are ignorant. Perhaps the natural toxicant area helps us look at that.

We can look at toxicants by origin, how they get to us. Are they actively biosynthesized by the source or are they passively passed to us through the food chain? We can look at them in terms of pharmacological effects, such as carcinogenicity, mutagenicity, or respiratory enzyme interference. There are natural toxicants in the food we eat every day that are capable of exhibiting these effects. We can look at them in terms of narrow margins of safety or serious and unusual toxicity. Finally we can view them in terms of how to manage the hazard. What can we do about the poisons that are naturally in our food? We can deal with them (1) by reducing our exposure to them, (2) by monitoring, when we can't directly control them, (3) by disregarding the hazard, and (4) often by simply being unaware of the hazard.

From these general comments, we will move to some specific hazards. Here we face a problem of choice. The field is enormous because everything is poisonous. This is not an original thought. Paracles said it about 400 years ago and then he went on to say something very perceptive, "Only the dose makes the poison." This was his way of referring to what we now know is the relationship between dose and response. The exposure, the intake determines in fact how hazardous a toxic substance will be.

We are not going to deal with all natural toxicants. We will leave out all the major nutrients, although some of them can be tolerated only at very low multiples of our normal intake. We will leave out the very difficult subject of allergens. Almost every food ingredient is allergenic to someone under some circumstances. We will not discuss rare foods that are only consumed by a small minority of people. And we will ignore the food toxicity caused by inborn errors of metabolism, of which there are over 100 now recognized. These cause us to be unable to manage or deal with certain normally harmless foods and food ingredients.

We will begin with the potato. As many of you know, it, like all members of the nightshade family, biosynthesizes glyco alkaloids. The alkaloid in potato is solanine. This glycoside is a neuro toxin that inhibits transmission of nerve impulses, an action somewhat similar to the action of the phosphorous pesticides and the nerve gases. Solanine is located near the skin of the potato right along with the vitamin C.

We manage this hazard in several ways. First is dietary choice. We just don't eat potatoes as much as people used to. Solanine poisoning in Europe was quite common in the early years of this century, particularly where a lot of potatoes were eaten. Processing is another means by which we reduce the exposure by removing the skin from pre-cooked and processed potatoes. We also breed potatoes with an eye to the solanine content. One promising variety of potato was kept off the market because its solanine content was too high.

This hazard is intrinsic, that is, the potato produces solanine naturally and the safety factor is less than 10. For new potatoes the safety factor is only about 8.

The second natural hazard is in that staff of life in much of the world, rice. In the tropical

areas, it is particularly difficult to dry rice to the point where mold growth will be inhibited. Molds, particularly of the penicillium family, grow on moist rice and produce a group of metabolites, usually colored, which leads to the name "yellow rice." One of these natural contaminants is islanditoxin. It is a toxin with a very curious structure, a polypeptide. We can control this risk partly through sanitation and by improved processing. Mechanical drying would be a most important contribution to public health from the fairly common illness caused by this rice toxin.

Another class of toxins found widely in nature are the cyanogenetic glycosides. These normal constituents produce hydrogen cyanide and cyanide ion during food preparation, or even when the tissues are bruised as when chewing the food. There are many cyanide producing plants, including bamboo shoots, most seeds of the cherry family, the cassava plant from which we get tapioca.

It is noteworthy that the carbohydrate sources which are the food mainstay in most of the developing countries are major sources of food toxicants and are serious sources of human illness in the developing countries where food processing has not developed enough to handle the problem.

One of the most common sources of cyanide in our culture is the lima bean. There never was a lima bean grown that did not produce cyanide. We breed lima beans in this country with a low cyanide content so this really is not a hazard to us, although it does kill people in other parts of the world. Indeed, even in this country, people with bizarre diets (and this is a significant number of people in this country), or those who are unwise enough to be taking amygdalin or laetrile, and who also eat heavily of lima beans or bamboo shoots, would probably be taxing their body beyond its ability to detoxify cyanide.

We deal with the problem through food processing, by plant genetics, and usually by simply ignoring the problem. We don't worry about cyanide poisoning. The safety factor runs between 2 and 15 depending on our diet. People who are particularly fond of those foods which contain cyanide may well be getting very close to their level of tolerance.

It was quite a surprise some year ago to find in the carrot and some other members of the carrot family, a substance now called carotatoxin. It has a remarkable structure; it is a diacetylenic compound. So far we simply disregard this toxin, although it is a very potent neural toxin. At this point, there is no evidence that eating carrots will do anything worse than turn you yellow.

Now potatoes, carrots, lima beans and rice are certainly very common items in the diet. Let me mention one which is more obscure.

One of the very earliest references to toxicity

is found in verses 31-33 of the 11th Chapter of the Book of Numbers. It tells of an incident that occurred while the Israelites were wandering in the desert. Quoting from the New English Bible, "Then a wind from the Lord sprang up; it drove quails in from the west, and they were flying all round the camp for the distance of a day's journey, three feet above the ground. The people were busy gathering quail all that day, all night, and all next day, and even the man who got least gathered ten homers. They spread them out to dry all about the camp. But the meat was scarcely between their teeth, and they had not so much as bitten it, when the Lord's anger broke out against the people and He struck them with a deadly plague. That place was called Kibroth hattaavah (the 'graves of greed') because there they buried the people who had been greedy for meat." The meat was scarcely between their teeth and they had not so much as chewed it when the plague struck. Now *that* is acute toxicity. It certainly made an impression on the children of Israel for the story is recounted almost word for word in the 78th Psalm.

We call these "green quail." These quail winter in Africa. When it is a bad year and they don't have much to eat or their usual nutritional sources, some of them feed on the seed of the hemlock. The toxin in hemlock is coniine, of which quail are quite tolerant. When the quail started the long trip back across the Mediterranean to Europe for the summer, they were blown off course by the wind from the west. They were absolutely exhausted and barely able to fly a few feet above the ground. Their tissue stores were depleted and the coniine concentrated and that's how this tragedy took place. Today we simply, through dietary choice, do not eat green quail or we disregard the hazard.

We not only get our toxins from the land and from the air but also from the sea. We are all familiar with shellfish poisoning due to saxitoxin. In this instance, we monitor the hazard. We can't control it, but we do count the population density of the organisms that cause it, and we bioassay the seafood we eat.

Another food around which a great deal of myth has revolved is honey. If you haven't been in healthfood stores, you would be amazed at the variety of honey that is available. Most of it of course is unfiltered and unpasteurized, and is called with unconscious irony, "pure." Honey both historically and today is itself a source of toxins. Bees, who do not share our ideas of toxicity or aesthetics, but are programmed for sweetness, will pick up many toxins. There are areas in Oregon where we have to be careful about the honey.

In New Zealand, tutin and hyenanchin are frequently found in honey. Tutin comes from the tutu tree. This tree does not have nectar in its flowers. The passion vine hopper, an aphid, feeds on the leaves of the tree. It leaves its sweet excrement on the leaves on which it feeds. Bees gather this sweet "honeydew." In the stomach of the bee, the tutin from the tree is partially hydroxylated to hyenanchin.

These few examples of natural toxins are only a tiny portion of those that we know, and those that we know about are certainly only a small portion of those that must exist and that are gradually being discovered. Now this is said not in despair, but in realistic appraisal. If hazards are, as indeed they are, inescapable, we should improve our opportunities for successful survival by careful appraisal, by choice, and by providing sensible priorities for investigation and research. We should pay the most attention to the greatest hazards and the least attention to the least hazards but try not wholly to neglect any.

If we contrast our attitudes toward natural toxicants and our attitudes to food additives, we find they are poles apart. We are widely ignorant of the natural hazards and we run surprisingly large risks with these natural toxicants, which we either don't know about or don't care about.

On the other hand, we are virtually paranoid about food additives. This is reflected in our laws and in our regulations.

I think you are all familiar with the provisions of the regulations concerning food additives. They require full disclosure of the identity of the substance, the conditions of proposed use, the relevant physical, chemical and technical aspects of the substance, the effect it is intended to produce, a description of practical methods of analysis in food so that if a tolerance is required the use level may be checked to make certain that it is within that tolerance, and full reports of investigations made with respect to safety.

The problem with statutory requirements in such detail is that they are rarely exactly right. They are insufficient for dealing with some types of risk and wholly excessive for dealing with low levels of risk. The governmental mechanisms are not a finely tuned device for the management of risk. One of the reasons is the popular pressure resulting from fear of the artificial, concern for tampering with the food supply, and the fear of food additives.

We find the same kind of dichotomy in the Delaney clause which puts a tolerance of zero or a safety factor of infinity on added carcinogens, but which is absolutely silent on the naturally occurring ones.

The concern by this vocal minority has pressured Congress and the Food and Drug Administration and other regulatory agencies into a position where the nominal requirements of the law and regulations and their actual requirements are poles apart. The practical result is that no new chemical entity will receive food additive approval from the FDA in the foreseeable

future.

We see evidence of this by looking at the recent past. In 1960 eleven non-flavor food additives were approved that year. For the following few years, FDA was clearing up the backlog of approvals resulting from the food additivies amendment. The approvals dropped late in the 1960s with a few flavor materials in 1973 which are actually nature-identical. In the case of non-flavor additives, there was a rapid dropoff from the sixties with two approved in 1971, two in 1972; for 1974, 1975, and 1976 the figures are zero in each year.

So there is essentially no possibility of a new chemical entity being approved as a food additive unless the public attitude and Congressional attitude, and therefore regulatory agency attitude, change.

This is not unusual. Everyone who works for a large organization, public or private, knows that one will never be criticized for the unrealized benefit, but only for the recognized risk. It is a simple matter in safety evaluation to ask new questions that take a long time and enormous funds to answer. This seems to be the pattern which will continue unless we can change it.

I think there is some hope because of the Food Safety Council. The Council is a broadly based organization with both consumer and independent expert participation. It is taking a very broad-based look at what is appropriate in terms of safety in order to be able to say conscientiously, "We have looked at the greatest probable risks, with the greatest feasible effort, and yet we have not wasted resources unnecessarily." Its strength lies not only in its technical competence, but also in the high level of consumer representation in it. The consumers entered into it with grave misgivings, but I have seen some very enthusiastic and effective participation by them.

I think this kind of activity represents the only possibility for changing the climate of opinion in a way that will permit legislation and regulations to change.

A single incident like the saccharin problem is useful as it dramatized one of the issues. However, it is very unusual and not typical of the usual kind of problem we face. Even the consumer reaction, violent though it was, would probably not be sufficient to change the statute. We must have a sound scientific rationale for that change, and broad public support for that rationale. We are fortunate that the Food Safety Council has been working on this problem for some time.

We do have to learn to live with risk. Risk is a reality we all accept in the areas where we are familiar but which we are very, very reluctant to accept in areas where we feel insecure, or when we feel the risk is an imposed risk. There is a big difference between our acceptance of risks

we can choose like smoking and not wearing seat belts, and the risks that we feel we have no control over, such as those in the food supply. As Chauncey Starr observed, "We are loath to let others do unto us what we happily do to ourselves."

Perhaps a broadly participatory approach in defining what are acceptable criteria for safety will give us a way out of what, otherwise, looks like an inescapable morass.

Part III. The State of the Art

Flavorist's point of view

J. Broderick, Vice President, Flavor Division, H. Kohnstamm and Co.

Flavor formulation is, to a large extent, an art. Its development is dependent on the skill of its artisans, the techniques and materials available. The demand for the artists' products influences the number of people who can afford to practice but does not, at least in a positive way, affect the quality of the art. Hardship often allows fewer to practice but can create better artists.

To see where we are at this time it is helpful to see how we got here. When we go back in time and bring ourselves to the present it is also tempting to extrapolate into the future. Based on current trends I see a number of roads open that could affect the industry and its individuals in different ways. I must warn you that my comments are one individual's views.

Flavor chemists, or flavorists, as we prefer to be called, are a relatively recent development. Prior to World War I it would be difficult to find a resident American who would meet the job description of a flavorist. The United States had many "flavor" firms but these were principally extract houses that extracted vanilla beans, made alcoholic dilutions and emulsions of essential oils, perhaps a few simple compounds, as well as dilutions of flavor bases purchased from basic houses. The few basic houses, domestically owned, were in reality essential oil houses. Usually they represented European houses for perfume and flavor bases and specialties. At the extract house the American flavor chemist generally was the batch maker or the owner who gleaned enough knowledge by experience and from sales representatives to produce relatively unsophisticated flavors for the local trade. He probably had little or no technical training. The technically trained chemist at the basic house was only a part time flavorist. His main function was either essential oils, quality control, organic chemistry, fragrances, or perhaps all of these. Our part time flavorist's most complex task was likely to be simple compounds of oils, or oils and aromatics, to produce flavors such as root beer or sarsparilla that are not used in Europe; or to blend imported bases; or to make simple adjustments to European bases.

World War I was largely responsible for the development of the chemical industry in the U.S., for it cut off many of our European sources of supply. German owned firms in the U.S. severed their connections with their home bases and became American owned firms. Aromatic chemical houses were formed or were opened by European firms after World War I. Many European trained flavor, fragrance, essential oil, and related technical people were attracted to the U.S., and post World War I flavor development was largely an extension of European pre World War I technology. We saw some firms grow in the U.S. whose products reflected the methodical approach of the related German firm. French technology was more fragrance oriented and reflected the attitude that whatever the good Lord made could be improved upon. Nothing is that black and white, but German companies did become more scientific and aromatic chemical oriented whereas French firms tended towards "natural" materials and blends. In Holland and Switzerland a happier amalgam of these approaches took place. The practical English, with a built-in market in the Commonwealth, tended to be more sales oriented, and developed a worldwide market for simple, effective compounds. The competitive advantage they had in the Commonwealth, and thus the lack of real competition, resulted, as time went by, in too little emphasis on research and product improvement. English flavor compositions have suffered quality wise in the last few decades. A major effort to improve followed their entry into the Common Market.

Secrecy was the byword for the immigrant chemist who often brought processes and formulations with. A few Americans were trained, some learned by observation or came up through manufacture; but training was largely a father-son (or other close relatives') legacy. Outsiders found employment in key positions in the flavor industry exceedingly difficult prior to World War II.

During the period between the two world wars the home industry grew but looked to Europe for the better flavors, the newer chemicals (often purposely mislabeled), and improved technology. Post World War II saw a tremendous demand for U.S. flavored products (our industry was intact) and this was reflected