For saccharin decision, revamp food laws

A total revision of the food safety laws has been proposed by a National Academy of Sciences report, ordered by Congress in 1977 as part of the Saccharin Study and Labelling Act. The first part of the study, released last November, concluded that saccharin is a potential, probably low-level, human carcinogen (SN: 11/11/78, p. 325). The final part now urges a more flexible food safety policy that would give the Food and Drug Administration options (besides a complete ban) for food components suspected of causing cancer. However, the NAS committee members were unable to agree on how saccharin should be handled under their proposed scheme or how it should be handled separately by Congress.

Current food regulations, according to the report, are "complicated, inflexible and inconsistent." The NAS panel proposes that the laws be simplified and made more consistent by setting a single policy for all foodstuffs, instead of differently regulating additives, contaminants and natural constituents. The group would introduce flexibility by allowing the Food and Drug Administration to consider benefits — documented and perceived — as well as risks. Such a policy would replace the Delaney clause, which now requires that cancer-causing food additives (introduced after 1958) be banned outright.

In the panel's plan, any food substance could be assigned to one of three risk categories by what panel member Clifford Grobstein of the University of California at San Diego calls a "rough qualitative judgment." The categorization would take into account both the seriousness of detrimental health effects and the probability of their occurrence. The FDA would be authorized to use discretion in regulating foods within a category. For example, a "high risk" food could be banned, restricted, required to carry a logo connoting high risk or required to bear information on risk and appropriate use.

From within the NAS panel and from without, critics have charged that giving the FDA such discretionary authority would open it to undesirable pressure from the food industry. At a press conference last week panel member Don K. Price of the John F. Kennedy School of Government responded, "It never seemed to me those pressures were absent in the present system." He said that under the current scheme, which asks for purely scientific risk judgment, regulators had to sneak in political considerations.

In further disagreement, a minority statement from seven panel members argues that direct food additives should be regulated more strictly than natural substances, which are more difficult to remove from food. The statement also says there is currently no "scientifically defensible" way to divide carcinogens, and other compounds doing irreversible damage, into different risk categories.

Saccharin, under the evaluation scheme proposed by the majority of the panel members, would fall into the high or moderate risk categories. Appropriate actions thus could range from banning the additive to identifying it with a distinctive logo.

Members of the NAS committee hold a broad spectrum of views regarding advisable saccharin actions if Congress does not revamp its food safety policy. These individual proposals range from a ban on the sweetener in packaged goods but permitting it temporarily as a "table top" sweetener (that is the current FDA position) to simply minimizing the amount of saccharin to give the current sweetness while investigating its potential benefits. "We did not pretend to tell them [Congress] what to do," said committee chairman Frederick C. Robbins.

FDA commissioner Donald Kennedy, meanwhile, says his agency will move again to ban saccharin when the 18-month moratorium expires May 13. Although the FDA itself plans to request food law changes that may relax the Delaney clause, Kennedy says any good law would ban saccharin in food. He says the NAS report is "a useful starting point for consideration of a redesign of the nation's food safety policy." □

Gene-splicing risks assessed low

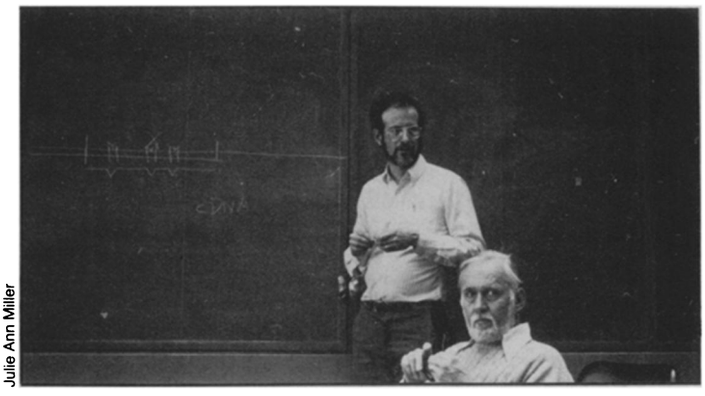
The scariest scenario from the scientists concerned about hazards of recombinant DNA depicted cancer-causing genes, inadvertantly spliced into common bacteria, creating an epidemic of cancer. Such a catastrophe would require that the harmful genes move from bacteria to mammalian cells and successfully function there.

An experiment to deliberately measure that risk was designed in 1975 and begun last year as the first research in the U.S. maximum safety facility at Fort Detrick (SN: 3/25/78, p. 180). National Institutes of Health scientists Malcolm Martin and Wallace Rowe report in the March 2 SCIENCE the basically reassuring results of initial risk assessment work. No viral infection was produced in mice fed or injected with bacteria harboring viral genes contained in recombinant DNA molecules. "We learned that our intuitive fears were exaggerated," Rowe told a press conference at NIH.

The risk assessment experiments used polyoma virus, a small DNA virus that infects mice but not people. The adult mouse reacts to infection by producing detectable antibody against the virus's coat. Because polyoma virus can cause tumors in newborn rodents, experiments are currently underway to examine whether viral genes in recombinant DNA can induce tumor formation.

Recombinant DNA alone, as well as in bacteria, was tested to see if it could cause infections. No infections resulted when only a single copy of the polyoma DNA was contained either in a ring of bacterial DNA (a plasmid) or in the DNA of a virus that infects bacteria. However, one of the recombinant DNA molecules contained two copies of the polyoma genes. Some mice injected with large doses of that molecule did produce evidence of infection. Because injections of pure polyoma DNA can cause infection, the scientists believe that in this case the polyoma DNA was released from the recombinant DNA molecule. The scientists say that pure recombinant DNA containing two copies of a virus's genes is very unlikely to arise, particularly during "shotgun" experiments, which splice uncharacterized segments of a chromosome.

The general lack of infectivity can be extrapolated to other DNA viruses contained in recombinant DNA molecules in bacteria, Rowe says. He now believes any research is safe that uses enfeebled bacteria *E. coli* K-12, except perhaps implantation of foreign genes that make toxins. Rowe cautions that risk assessment experiments will be necessary for each new recombinant DNA system biologists want to use. He says that a fungus, for example, is more likely than a bacterium to have the enzymes required to replicate an animal virus. □



Julie Ann Miller

Martin (standing) and Rowe explain that bacteria lack machinery for producing functional animal viruses from recombinant DNA.