

Being practical over carcinogens

Is the Food and Drug Administration's (FDA) decision on lead acetate a precedent-setting move for all regulatory agencies? That remains to be seen. But it is certainly the first attempt by an agency to deal practically with a substance that has been labelled carcinogenic.

Tests with animals indicate that high doses of ingested lead will lead to excess numbers of cancers among the animals. The approach for agencies in the environmental and occupational health field has been to put restrictions on the substances and lower the allowable exposure to the lowest possible level.

As with vinyl chloride, those agencies have been known to consider practicality in reaching limits. But in the consumer area, the answer to exposure limits has usually been absolute. The archetypal rule is the Delaney amendment, which bans any carcinogens from food additives, ignoring the fact that some

foods contain carcinogens naturally.

But now the FDA has decided that since humans receive 100 to 500 micrograms of lead daily from food sources and another 20 to 400 micrograms from airborne sources each day, the 0.5 micrograms of lead acetate that might be absorbed through the scalp from use of hair dyes is not significant. The agency plans to approve the use of lead acetate as a color additive in hair dyes. The petition for the white lead crystalline compound has been pending since 1973.

"By any reasonable standard, lead acetate must be regarded as safe for hair dye use," says FDA. Whether reasonable standards will be the rule rather than the exception for regulatory agencies dealing with alleged carcinogens remains to be seen. But the FDA action could be a precedent that will make it easier for others to follow.

Clusters of pesticides; the EPA way to registration

There are over 38,000 pesticide products now registered with the Environmental Protection Agency (EPA). And, according to the amended Federal Insecticide, Fungicide and Rodenticide Act, EPA is supposed to review each and every one of them.

That's a monumental task that the agency proposes to handle by clustering the active ingredients in the pesticides by similar uses and then, if that doesn't make the cluster manageable enough, they intend to break the groups down even further by sites on which they are applied.

But clustering is only the first step. The whole idea here is to rank these pesticides so that the over-worked EPA can decide where to start. The ranking will be based on such factors as production and exposure. The agency has developed a simple equation, with its own internal complexities, to give point values to each of the more than 600

active ingredients that go into the pesticides.

It was in December of 1979 that EPA first proposed that it would review the products based on their active ingredients, so that products with the same active ingredients can be registered under the same standard. Despite all this planning and prioritizing, EPA estimates that it may take 15 years for review of all registered pesticides.

First come, first reviewed

Under the EPA scheme, a cluster is a group of chemicals and a group of sites that are related. For examples, the 10 insecticides registered for use on citrus and grapes make up a cluster.

But even before this kind of grouping, the agency made some use categories. Chemicals were divided into insecticides, herbicides, growth regulators, and preservatives for example. But, while growth regulators was a small group, insecticides, herbicides, and fungicides

were too many to place in a single cluster. Eventually, EPA decided on clusters of one to 26 chemicals, with most clusters limited to less than 20 chemicals.

EPA has proposed 13 groupings of insecticides, from 23 chemicals used on cotton, soybeans, peanuts, wheat and tobacco to 13 for miscellaneous uses, such as diamidfos and methyl trithion. There are 10 herbicide groups, including 15 chemicals used on sorghum, rice and small grains. There are also 10 groups of fungicides. And 15 other groups round out the categories. There are 48 clusters all together.

But designing the clusters is only the first step in EPA's effort to schedule the pesticides for review. To assign point values to chemicals within each cluster, the agency has developed an equation in which the rating $X = (2E_1 + E_2) / (P)$; E_1 is human exposure, E_2 is fish and wildlife ex-

posure and P is production of the chemical. EPA didn't include a risk factor in the equation because they didn't have enough toxicity data and because they say they found it didn't make any difference because exposure was so highly weighted.

EPA is proposing to assign number values in the equation based on a variety of factors. For example, high production (over 1 million lbs/year) ranks a 5, medium a 3, and low (under 25,000 lbs/year) a 1. Similarly, exposure numbers depend on persistence data, method of application and use.

EPA says the system appears to work. That remains to be seen. Even EPA qualifies the system by reserving the right to move on other chemical pesticides that may grab the public limelight. For now, they are just trying to get a handle on what appears to be almost a lifetime job of reviewing the existing pesticide registrations.

Biotechnology into profits: Some first and second thoughts

The matter of splicing genes to manufacture biological entities never before produced to accomplish tasks never before done (or done as well) is still stirring up some interesting business arrangements.

Allied Chemical has bought a 10% interest in Bio Logicals, a one and one-half year old Toronto-based biotechnology firm.

Genentech, one of the hottest new stock issues last year, has an agreement with Fluor, the engineering and construction firm, to examine applications of genetic engineering to process and plant construction.

The first British biotechnology firm has been formed with \$30 million in investments from private and public interests.

But while all this maneuvering is going on to take advantage of the financial potential of genetic engineering, Harvard University is having second thoughts about getting too involved (ICN, December 1980).

The equity Allied will put into Bio Logicals reportedly will be used to fund research into the uses of biotechnology in the production of industrial specialty and agricultural chemicals. It is all part of Allied's "long range plan to accelerate and direct research and development into high technology areas," says Richard Ashley, president of Allied's Chemicals Company. Bio Logicals specialty is the application of genetic engineering techniques to yeasts. It has yet to produce a commercial product.

Also with no products of its own, Genentech will explore with Fluor

the process engineering applications of genetic transfer techniques. Fluor will supply Genentech with data on the economics of new plant construction, including estimates of capital and operating costs, market potential and financing alternatives. The two companies will, together, assess application of bioengineering developments resulting from Genentech's technology.

Celltech, the first British biotechnology company, has an agreement with the Medical Research Council that provides the company with a "framework" to give it access to research the lab is carrying on. The new company also has an arrangement with the National Research Development Corp., the public corporation that is the repository for all patent rights for research done at university and public labs in the United Kingdom.

The company will be owned 44% by the public corporation the National Enterprise Board. The remainder of the shares will be divided equally between the Prudential Assurance Co., the Midland Bank, British and Commonwealth Shipping and TDC, a venture capital firm.

The concern over the environmental ramifications of genetic engineering has now taken the back seat to a new concern. Can universities maintain their positions in society while pursuing the potential profits from the research they are sponsoring? It is an old question but it has received a new emphasis by the great potential of genetic engineering. Nevertheless, the answer from the universities appears to be no go.



EPA plans to cluster groups of pesticides to ease the burden of performing safety tests, such as this analysis of blood samples from test animals, on the 38,000 pesticides currently registered.

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Cover

Computer chips, a revolution in chemical analysis

For analytical chemistry, the introduction of microelectronics has caused revolutionary changes in the manner, speed and depth of chemical analysis. And the revolution is still going on. Improved micro-processor-based instruments for chemical analysis are lowering costs, and improving capabilities and ease of operations.

Patent rights: When does an employee own an invention?

The rights of employer and employee to an invention made by an employee during employment gives rise to some prickly problems. Was a contract entered into between the parties assigning inventions from employee to employer? If not, was the employee specifically "hired to invent," or was the employee merely a general employee? If a general employee, did he make the invention on company time, using company materials or labor? The issues are examined in this piece by a noted patent attorney.

Chemical lab safety: Some sets of rules

All the public turmoil over occupational and environmental effects from chemical hazards appears now to be filtering down to the laboratory level. OSHA is preparing a set of criteria for safe operation of chemical labs, including guidelines for controlling exposure to carcinogens. And the NRC has prepared a new report that offers detailed practices for all types of laboratories where chemicals are used.

18 Crystal ball sees Washington boosting R&D, blasting regulation

How will the new Reagan administration impact on the life of the industrial chemist? This analysis of the new administration's expected policies toward research and development spending and regulatory reform contains some good news and some bad news.

20 Why does the U.S. lag in innovation?

The results of a Conservation Foundation study examining a perceived lag in technological innovation in U.S. industry are presented here. The study lays the blame partly on government regulation and recommends regulatory reforms and information gathering.

15 Hazardous wastes at Love Canal: What are the effects?

This presentation of a study done by a panel appointed by New York state to review the scientific studies of the health effects of a chemical waste dump at Love Canal contains some criticisms of government agencies and the original studies which conclude that the chemical dump adversely affected the health of some Love Canal residents.

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