EDWARDS LOCKS 80-80 RULE INTO NUTRITIONAL LABELING

Food and Drugs Commissioner Edwards has indicated that the 80-80 rule in his agency's proposed nutritional labeling regulations is not negotiable (See Story, Page 31).

In a speech before the Grocery Manufacturers of America June 19 at White Sulphur Springs, W. Va., Edwards said "there can be no token labeling designed for promotion more than for buyer information." Referring to the proposed rule, under which at least 80% of the units of a product must meet nutritional levels, the Commissioner said:

> " . . . The initiation fee may come high for some, especially those who deal in foods with high nutrient variability. But the 80% rule controlling variation is the maximum we can tolerate. And the analytical burden for conforming to this rule must be borne by industry.
>
> "I recognize you may have certain problems with the program, but it has great potential and I am hopeful you will decide in favor of participation."

Noting FDA's reliance on "the will of the marketplace" for enforcement of the "voluntary" nutritional labeling, Edwards said: "As yesterday's public would reject a product for poor taste, tomorrow's will reject a product for poor nutrition. Empty calories will be hard to sell."

The Commissioner criticized some of the comments his agency has received on its proposals to limit PCBs (See FOOD CHEMICAL NEWS, June 5, Page 10). He said:

> "The paper industry . . . has responded with protests that the proposal is 'unfair, unrealistic, and unreasonable' - - hardly a favorable recognition of changing consumer values. While voicing strenuous protest, there have been no concurrent offers of reasonable alternatives. This is reaction at the one extreme. It's the old, old view that any regulation is too much regulation, and if industry can just hold out long enough, it will go away.
>
> "At the other extreme - - with an equally limited point of view - - are certain consumerists. They object to PCBs and to FDA's control program. They live in the world of the ideal where choices are never gray and science is absolute."

Edwards staked out "somewhere in between the two extremes" as the "proper place for FDA." He said the agency is "trying to listen to all sides," including "the feed manufacturers and the interdepartmental PCB task force." Noting voluntary cooperation from Monsanto, the Commissioner said FDA will "continue to monitor

the field," and that "we feel that the program now evolving will provide reasonable control within present FDA abilities."

The speaker emphasized that "no existing regulatory authority will guarantee against PCBs entering the environment," putting in a plug for the Nixon Administration's pending Toxic Substances bill.

Meanwhile, in more comments filed with FDA on the PCB proposal, the comments of the American Feed Manufacturers Association were endorsed by Central Soya, Domain Industries, Nutrena Feeds, H. K. Webster Co., Hubbard Milling, John W. Eshelman & Sons, Southern States Cooperative, BP Feed, and Moorman Mfg.

Noting that legislation is pending on Capitol Hill for mandatory labeling of all food ingredients, Edwards hinted that it might not really be needed. "Meaningful voluntary action at this point in time may eliminate the need for more governmental regulation," he said.

However, he put in a pitch for legislation to require food processors' registration with FDA, saying this "is essential." "At present, our inventory of plants and products is incomplete," Edwards said, adding: "We get most of what information we have from FDA inspectors, from cooperating State officials, and from consumer complaints. Not only is this hit-or-miss method inadequate, it is inequitable." He urged GMA "advice and cooperation in helping achieve passage of a sound law to remedy this gap in regulatory law."

Conceding that "general standards for plant sanitation in far too many cases have slipped" - - as was alleged in a recent General Accounting Office report - - the Commissioner said FDA intends "to take prompt and vigorous action to assure good housekeeping in food plants . . . " He continued:

> "It is not necessary that we find actual adulteration to take action under the insanitary food provision of the law. With the hiring of an additional 300 inspectors and with special funds just approved by Congress, it is our purpose to end violations wherever and whenever they are found. We do not, however, intend to make this added effort at the expense of our number one priority - - microbiological problems."

Edwards praised GMA's "support of a special $8 million advance funding for strengthening the industry surveillance program," saying this "reflects the enlightened view that sound enforcement of reasonable regulations can only increase consumer confidence - - in both government and in industry."

Stressing industry responsibility, the Commissioner added "this admonition: Even if FDA had enough personnel to inspect every food plant twice a year, there would still be 363 days when every plant would be on its own. So it all comes back to . . . the basic responsibility for safe and wholesome food, and for consumer confidence, rests first of all with you in industry, not with government. It can be no other way."

0239874

In a lengthy discussion of the consumer movement, Edwards was more kind to consumer advocates than he has been in some speeches in the past. He placed the onus for current discontent on "the reality that we have today more products than quality, more promises than progress, and more concern for reaping profits than for earning them." Edwards continued:

> "To be sure, there are a number of activists who have helped arouse and focus consumer expectations, but . . . I would submit . . . that Ralph Nader did not create today's consumer movement; although he and others plead its case, they would never have gotten off page 34 of yesterday's newspaper were not the movement's roots deep in disappointments of the past.
>
> "All of this has created a vicious cycle of consumer discontent. A frustrated consumer turns first to industry, then to Congress; Congress in turn mirrors consumer discontent in new and tougher laws. The burden is then passed on to the regulatory agencies, and, finally, comes back to you - - through recalls, court actions and through more restrictive regulation.
>
> "In my judgment, the circle can only be broken where it began - - namely with industry."

The Commissioner praised "the leadership of the food industry" for its "growing understanding of the need for public accountability," lauding combined FDA-industry efforts regarding PCBs, nutritional labeling, self-certification, the salmon program, and in the National Canners Association's proposed quality control program. He called these "examples of the kind of initiatives needed to break the circle of consumer disaffection."

FD

However, Edwards said "there are still too many in industry who bury their heads in the sand and hope their consumer problems will somehow go away - - that consumerism is nothing more than a fad." The Commissioner alleged that some people "see hope for relief from regulation in the halls of Congress."

Expressing confidence that the pending reorganization bills in Congress would strengthen - - not weaken - - FDA (See Story, Page 44), Edwards said:

> "I suggest that you not be fooled by a few misguided members of the press who walk about dismantling or destroying the FDA. There is, to be sure, debate in Congress over bureaucratic structure and location. But there is no debate, no sentiment, no proposal to do other than strengthen the functions of the FDA. No one in Congress today talks about a weaker FDA. When the year is out, the FDA may operate under a new name, but it will not operate with less purpose, fewer resources, or less law."

0239875

Calling his administration of FDA "without question the most active in the history of the agency," the Commissioner said "we recognize that action for action's sake in the regulatory field is neither in the interest of the consumer nor the regulated industries." He said that "major actions" have averaged "about one per week thus far this year," calling them "responsible actions aimed at reasonable regulation and at restoration of public confidence in both industry and government."

Listing accomplishments of his agency, Edwards noted the "unprecedented doubling of the FDA's budget," and that under his reorganization "we have an agency that in my judgment is as well managed as any in government."

The agency "for the first time in FDA history" has "nearly 300 of the nation's finest scientists and physicians advising" it, Edwards said. He also stated that, "We now meet monthly with major consumer groups and while we disagree on issues, we have established an environment in which issues can be discussed with minimum emotion and maximum exchange of facts."

Noting that it had been said that "FDA could never get the cooperation of the industries it regulates without being the captive of them," Edwards said: "The cooperation we are receiving from industry today is greater than it has been in the history of the agency. And in my judgment, consumer protection, while still imperfect, has never been more prevalent. Meaningful dialogue with consumers and industry will continue to be a major goal of this administration."

The Commissioner concluded his speech by stating that "the goal of the FDA is to be a half step ahead of the future, not a half step behind the past."

o

FDA TO SURVEY "MEAL REPLACEMENT" PRODUCTS

The Food and Drug Administration plans to survey "meal replacement" products and products designed to either supplement a meal or supply supplementary energy between meals.

The field survey, to begin Aug. 1 and to be completed by Oct. 31, has a dual purpose. In part it will be to check quality control procedures, and in part it will be to check the nutritional adequacy of the products as it relates to label claims and the nutrient content of the products.

Included will be 900-calorie type products in liquid and powder forms, pastry products, candy-type high-nutrient products, and cereals if they supply more than 10 grams of protein in a serving. The survey is expected to cover 22 plants.

FDA issued instructions to inspect all presently known manufacturers of these classes of products, and the products themselves will be sampled. These samples will be analyzed by the Division of Nutrition's National Center for Nutrient Analysis. Inspection reports also will be submitted to the Division of Nutrition for evaluation in conjunction with the analytical results.

o