MANUFACTURING CHEMISTS ASSOCIATION
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February 24, 1970

To: FOOD, DRUG, AND COSMETIC CHEMICALS COMMITTEE

Subject: MCA Position re Delaney Clause

Gentlemen:

I attach a draft dated February 24 of the subject statement developed by a task group appointed by your chairman. The task group consisted of Taylor Hanavan as chairman, Bill Knapp, and Jack Frawley. The statement has the approval of Bob Miller and John Zapp who assisted the task group. Your chairman is also in agreement.

If you have any basic disagreement, it is important that you let me know by Friday, February 27.

Sincerely yours,

M. M. Hoover, Secretary
Food, Drug, and Cosmetic
Chemicals Committee

MMH:gr

Attachment

Distribution "C"

Section 409(c)(3) of the Federal Food, Drug, and Cosmetic Act states that "No such regulation shall issue if a fair evaluation of the data before the Secretary -

> (A) fails to establish that the proposed use of the food additive, under the conditions of use to be specified in the regulations, will be safe."

There follows a proviso, the so-called Delaney Amendment, which states,

> "Provided, That no additive shall be deemed to be safe if it is found to induce cancer when ingested by man or animal, or if it is found, after tests which are appropriate for the evaluation of food additives, to induce cancer in man or animal;..."

Other than the recent application by FDA of the Delaney Amendment to cyclamates, the Amendment has not been a serious impediment to intelligent regulation since its enactment in 1958.

To date, the term "cancer" as used in the Amendment has been limited to malignant tumors and the mere presence of non-malignant tumors has not resulted in application of the Amendment. Moreover, in spite of the efforts of various scientific groups including a special FDA advisory committee, no reliable and practical protocols for cancer testing have been devised. As a result, testing by such protocols has not been a routine requirement by FDA as part of the safety evaluation of new additives.

The lack of significant interference to date does not mean that the Delaney Amendment could not in the future become an

unrealistic insurmountable burden which could pose a serious threat to the development of new products which would contribute to food technology and quality of the food supply. The Act could be construed to include within the term "cancer" any tumor regardless of its pathologic description. New protocols may be proposed which go beyond what is scientifically reasonable and the economic parameters of new product development. Most significant, however, is that with today's analytical procedures, almost any substance in some quantity is capable of detection by highly refined analytical equipment and methods sensitive to parts per billion and even parts per trillion. Coupled with this is the fact that our biological scientists have developed unique toxicological testing techniques that given the right species, dosage form, timing and method of administration, almost any substance can be found to induce a tumor of some type whether benign or malignant - a result which, however meaningless, might require the Secretary to refuse approval or to ban the additive involved.

The Act as presently constituted imposes a per se concept so that the Secretary by statute is precluded with respect to cancer from exercising any reasonable scientific judgment on the question of toxicologically significant hazard or risk to man. Yet the legislative history of the Act and experiences thereunder demonstrate the fallacy of a per se approach to a scientific question

of this type. The 1938 Act in effect imposed a per se concept that a substance which was found harmful or deleterious at some level was prohibited from use at any level. However, experience over the years demonstrated that such a non-scientific approach was unreasonable and unnecessary. With the Food Additives Amendment of 1958, Congress recognized the need for reasonable scientific judgment in the evaluation of safety by authorizing the Secr tary to establish safe limits of a substance for man even where such substance was found to cause in animals a chronic or acute toxic response at a higher level or levels. Yet in 1958, Congress reimposed the per se concept with respect to cancer; despite the fact that past experience had demonstrated it to be unworkable. The recent cyclamate experience confirms the unworkable nature of the Amendment, if it is interpreted in a literal or strict sense.

Elimination of the Delaney Amendment automatically would not authorize the Secretary to set tolerances for carcinogens. As with any other toxic effect before any such tolerance could be established, the Secretary as a matter of scientific judgment would have to conclude from the scientific evidence available whether a threshold limit could be established for a suspected carcinogen. There is general agreement that in some cases it is possible to set such threshold limits. Yet the Delaney Amendment as phrased precludes any scientific judgment - the same

scientific judgment which Congress entrusted to the Secretary for the safeguarding of the public health with respect to all other toxic effects which can be produced in experimental animals.

There is no reasonable justification for continuing the Delaney Amendment in any form. However, it would be difficult from a legislative enactability point of view to accomplish outright repeal. For this reason, it is suggested that the Amendment be revised to restore to the Secretary the right and obligation of exercising scientific judgment in the area of carcinogenicity. To this effect, we would suggest that the semicolon and the word "or" be deleted from the last sentence of the so-called Delan y Amendment and the following language added:

> "... unless in the opinion of the Secretary sufficient evidence exists to permit establishment of a safe or toxicologically insignificant level of intake for man of such substance so found to induce cancer."