DRAFT - TWH
2/9/70

Section 409(c)(3) 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 regulation, 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 much of a burden to industry since its enactment in 1958.

To date, the term "cancer" as used in the Amendment has been limited to tumors that matastasize (malignancies) and the mere presence of benign growths 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 special protocol for cancer testing has been devised. As a result, no such protocol has been required by FDA as part of the safety evaluation of any new additives.

The lack of significant burden on industry to date does not mean that the Delaney Amendment could not in the future result

in the imposition on industry of an unrealistic insurmountable burden which could pose a serious threat to the development of new products that would contribute to food technology and be beneficial to the food supply. The Act could be construed to include within the term "cancer" any growth regardless of malignancy. 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 to approve or 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 inadequacy of a per se approach to a scientific

question of this type. We need only point out in this regard that the 1938 Act in effect imposed a per se concept. A substance once found harmful or deleterious at some level was barred at any level of use. However, experience over the years demonstrated that such a nonscientific approach was unreasonable and unnecessary. With the Food Additives Amendment of 1958, Congress recognized the need for reasonable scientific judgment in this area by authorizing the Secretary 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 by the Delaney Amendment also at the last moment reimposed the per se concept with respect to cancer; demonstrably unworkable by past experience and again demonstrated to be unworkable by the recent cyclamate experience.

This is not to say that elimination of the Delaney Amendment automatically would authorize the Secretary to set tolerances for carcinogens. Naturally, before any such tolerance could be established, just as with any other toxic effect 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. In this regard, with few exceptions there is fairly general agreement that at least in some cases it may be 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 toxicity ~~problems pertinent~~ to food additives.

Actually, 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 Delaney 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."