

MEMORANDUM

DATE February 3, 1970

SUBJECT: MCA-FDCC Comm
Delaney Clause

TO: FILE

Meeting of subcommittee of FDCC Committee of MCA to draft revision of Dalaney clause in FDC Act. Those present were Mr. Taylor Hanavan, du Pont, Chairman; Dr. John Zapp, du Pont, Dr. Jack Frawley, Hercules, Mr. Robert Miller, Hercules, Mr. Morgan Hoover, MCA, and the writer.

Although the Nelson bill (S3295) eliminates the GRAS (generally recognized as safe) list MCA was not asked to comment on this aspect.

Mr. Hanavan will draft the proposed reply to Mr. Creed Black, Assistant Secretary of HEW, but the appropriate content will be as follows:

(a) that the Delaney clause is not necessary by reason of the fact that the Secretary is directed not to issue a food additive regulation if a fair evaluation of the data fails to establish that the proposed use is safe.

(b) that the present wording of the clause remains substantial as a present to alleviate any fear that industry would tolerate deleterious effects for food additives, and

(c) that a proviso be added to present wording to the effect that "unless in the opinion of the Secretary sufficient evidence exists to permit the establishment of a (safe) or toxicologically insignificant level of intake for man of the substance so found to induce cancer.

It was the concensus of opinion of the group that simple deletion of the Delaney clause would be politically unacceptable.

Dr. Frawley indicated that the industry Committee of the Food Additives Committee of NAS-NRC has advocated repeal of the Delaney clause but that the NRC had contended it could not act until asked for its opinion. They have apparently now been asked and will submit comment via Dr. Handler, President of NRC-NAS.

A point of conflict; Dr. Frawley had heard that Rep. Delaney was in favor of modification where Mr. Hoover heard from Mr. Black that Rep. Delaney opposed introduction of legislation to delete.

Although the Secretary now has power to abolish GRAS list, Mr. Hanavan believes that legislation would be required to eliminate prior sanctions.

In answer to question as to what would happen if Delaney clause not deleted agreed to general answer that given right species, amount, time of administration, etc., almost any substance might be carcinogenic (i.e. not mention specific products or types of products which might be in danger of elimination).


Further Notes on Delaney Clause Meeting

(1) Zapp commented on legislative history of Act - In 1938 believed there was sharp line between poisonous and non-poisonous substances; by 1958 knew this assumption was false but believed substances were carcinogenic or not - now know that this also in error - carcinogens weak or potent.

(2) See paper by Epstein and Lijinski - Nature, January 3, 1970. Believe NaNO_2 is precursor of nitrosamines in body - these potent carcinogens - no presently known substitutes for nitrates and nitrites in curing meat - other substances do not retain red color.

Smoked meats use nitrates and other things - now smoke only few hours and after injection with needle.

(3) Du Pont feeding studies on regenerated cellulose for Lehman of FDA, then had to do a lot of additional work for Cellophane reg. because this not regenerated cellulose i.e. other things added.


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