



E. I. DU PONT DE NEMOURS & COMPANY
INCORPORATED

WILMINGTON, DELAWARE 19898

LEGAL DEPARTMENT

March 16, 1970

Mr. Morgan M. Hoover, Secretary
Food, Drug, and Cosmetic Chemicals Committee
Manufacturing Chemists Association
1325 Connecticut Avenue, N. W.
Washington, D. C. 20009

Dear Morgan:

As promised per phone last Friday, I have given some thought to the drafting question which should wrap up this matter.

As a frame of reference, I should point out that in addition to the quoted sections of the Delaney Act in the draft statement, there is a further proviso expressly exempting feed for animals raised for food production where no residues of an additive are found in edible portions. The full proviso therefor reads as follows:

"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 the safety of food additives, to induce cancer in man or animal, except that this proviso shall not apply with respect to the use of a substance as an ingredient of feed for animals which are raised for food production, if the Secretary finds (i) that, under the conditions of use and feeding specified in proposed labeling and reasonably certain to be followed in practice, such additive will not adversely affect the animals for which such feed is intended, and (ii) that no residue of the additive will be found (by methods of examination prescribed or approved by the Secretary by regulations, which regulations shall not be subject to subsections (f) and (g)) in any edible portion of such animal after slaughter or in any food yielded by or derived from the living animal;"

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Apart from the question of drafting technique, the first question to be resolved is whether our proposed proviso should go before or after the animal feed exemption which I recall was obtained by the Animal Health Institute as a result of substantial legislative activity. Frankly, I concur with Ken Mulford's position that the proviso should probably come before the animal feed exemption, and I think this can be done without disturbing the Animal Health Institute position.

After the words "to induce cancer in man or animal", we would add the following "except that the foregoing provisions of this proviso shall not apply where 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 substances so found to induce cancer; and except, further, that the foregoing provisions of this proviso shall not apply", etc., (pick up the language in the Animal Health Institute exemption).

Turning to the Color Additive Amendment, we have a substantially similar problem though the language differs in some minor respects. The Delaney Amendment language with respect to color additives reads as follows:

"(B) A color additive (1) shall be deemed unsafe, and shall not be listed, for any use which will or may result in ingestion of all or part of such additive, if the additive is found by the Secretary to induce cancer when ingested by man or animal, or if it is found by the Secretary, after tests which are appropriate for the evaluation of the safety of additives for use in food, to induce cancer in man or animal, and (ii) shall be deemed unsafe, and shall not be listed, for any use which will not result in ingestion of any part of such additive, if, after tests which are appropriate for the evaluation of the safety of additives for such use, or after other relevant exposure of man or animal to such additive, it is found by the Secretary to induce cancer in man or animal; Provided, That clause (1) of this subparagraph (B) shall not apply with respect to the use of a color additive as an ingredient of feed for animals which are raised for food production, if the Secretary finds that, under the conditions of use and feeding specified in proposed labeling and reasonably certain to be

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followed in practice, such additive will not adversely affect the animals for which such feed is intended, and that no residue of the additive will be found (by methods of examination prescribed or approved by the Secretary by regulations, which regulations shall not be subject to subsection (d)) in any edible portion of such animals after slaughter or in any food yielded by or derived from the living animal."

Again, I would suggest that our proviso precede the animal feed exemption. Beginning with the words "Provided, That", it would read "Provided, That clauses (i) and (ii) of this subparagraph (B) shall not apply where in the opinion of the Secretary, etc.,". The Animal Health Institute exemption could then follow with an "and provided, further," type lead-in. However, this exemption should still be limited to clause (i) of subparagraph (B) just as it is now so limited in the statute.

An amendment similar to the language and approach we have suggested for food additives would also be needed for section 512(d)(1)(H) of the new animal drug section of the Act added by the Animal Drug Amendments of 1968.

In answer to Ken Mulford's question in the last paragraph of his March 9 letter to me and for the record so that there will be no misunderstanding among those receiving a carbon copy of that letter, it is our intention that NCA's legislative liaison man, a Mr. Morgan, will arrange an informal meeting with Mr. Creed Black of HEW, who had informally related Finch's inquiry to NCA. Morgan will orally pass on the substance of NCA's views and at the same time provide a copy of the statement. It is understood, of course, that while NCA has been asked in confidence by HEW to provide our views, if any, and while it is expected that any NCA views transmitted to HEW will be maintained as confidential, there is no way to preclude HEW from disclosing any part of or releasing the statement in toto to any source that might suit its purpose.

Sincerely,

TW
Taylor W. Hanavan

TWH:ema

cc: J. P. Frawley
W. A. Knapp
R. M. Miller
K. E. Mulford
J. A. Zapp, Jr.