MCA MANUFACTURING CHEMISTS ASSOCIATION
1825 CONNECTICUT AVENUE, N. W. • WASHINGTON, D. C. 20009 • (202) 483-6126

January 20, 1971
GRC-19-1

MINUTES
GOVERNMENT RELATIONS COMMITTEE
EXECUTIVE CHAMBER NUMBER THREE
THE MADISON HOTEL
15TH AND M STREETS, N.W.
WASHINGTON, D.C.
JANUARY 18, 1971

PRESENT

Myron V. Anthony	Stauffer Chemical Company
J. Warden Cunningham	Air Reduction Company, Inc.
Kimball Firestone	Firestone Tire & Rubber Company
Francis D. Flanagan	W. R. Grace & Co.
Don A. Goodall	American Cyanamid Company
Richard M. Hunt	National Lead Company
J. J. Kenney (for Morse Dial)	Union Carbide Corporation
Frederick B. Lee	Olin Corporation
Wilbur C. Lowrey	Shell Chemical Company
Mike Manatos	The Procter & Gamble Mfg. Company
Charles T. Marck	The Dow Chemical Company
Donald O. Opstad	3M Company
Lester G. Shapiro	Engelhard Minerals & Chemicals Corp.
Carstens Slack	Phillips Petroleum Company
James G. Morton, Director Government Relations	Manufacturing Chemists Association
Hugh M. Robinson	Manufacturing Chemists Association
David C. Williams	Manufacturing Chemists Association
William M. Stover, Secretary	Manufacturing Chemists Association
Brian D. Forrow (guest)	Allied Chemical Corporation

ABSENT

Carroll W. Hayes, Chairman	Celanese Corporation
Sam Pickard, Vice Chairman	Monsanto Company
E. Bruce Harrison	Freeport Sulphur Company
Robert F. Kelly	E. I. du Pont de Nemours & Company

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WILLIAM J. DRIVER
PRESIDENT

January 21, 1971

Hearing Clerk
Department of Health, Education,
and Welfare
5600 Fishers Lane
Rockville, Maryland 20852

Dear Sir:

The Manufacturing Chemists Association submits the following comments in reply to the Notice of Proposed Rule Making which appeared on pages 18623 and 18624 of the December 8, 1970 Federal Register under the heading "Eligibility of Substances for Classification as Generally Recognized as Safe in Food."

The Manufacturing Chemists Association is a nonprofit trade association of 173 United States company members representing more than 90% of the production capacity of basic industrial chemicals within this country.

Qualified Experts

The proposed rule making, as we understand it, implies that determination of GRAS should be the unilateral decision of FDA. However, under the statute, the responsibility for such a decision is not so limited. Rather, such decision must reflect the opinion of qualified experts both within and without FDA.

Consequently, we feel it should be made clear that the proposed regulation is interpretive only, and merely reflects the agency's opinion as to what substances are generally recognized by qualified experts as safe for food use. For the same reason, we also see no justification for the implication that in certain cases GRAS promulgation is "required," as stated in proposed Section 121.3(b)(2).

In order to eliminate any possible ambiguity as to FDA's role in the GRAS status question, we suggest the addition of the following sentence to proposed Section 121.3(a):

> "Of course, where a substance has been generally recognized as safe by qualified experts, its GRAS status may be affirmed by FDA as proposed herein."

For additional clarification, proposed Section 121.3(b)(1) should be written as "for which no affirmation by FDA is necessary" instead of "for which no promulgation is required."

New Use of GRAS Substance

Proposed Section 123.3(b)(3)(i) provides that any food substance intended for human consumption which has no history of safe use under the proposed conditions is not eligible for GRAS listing and therefore requires a food additive regulation.

We are in firm agreement with the principle that substances without any history of safe use can be cleared only through an appropriate food additive regulation. However, the language of this section would recognize no possibility of GRAS acceptance for a new use of a substance already recognized as GRAS for established uses, regardless of the new usage level proposed and regardless of the opinion that qualified experts might have concerning the safety of the proposed new use. While we concur that any new use of a food substance, even a GRAS substance, should be carefully reviewed, we feel that it would b needlessly restrictive and improper to require that all such new applications be cleared via a food additive regulation. The effect of this section in its present form would be to arbitrarily fix the GRAS list, thus preventing extension of GRAS coverage to new usages for traditionally GRAS substances.

We therefore propose that the language in proposed Section 121.3(b)(3)(i) be modified in such way as to permit the ext n-sion of GRAS coverage to new applications of GRAS substances, providing qualified experts consider such new applications to be GRAS.

Total Intake Limitations

Under the proposed Section 121.3(b)(3)(ii), a substance would not be eligible for inclusion as GRAS if "total intake

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We therefore propose that the language in proposed Section 121.3(b)(3)(i) be modified in such way as to permit the extension of GRAS coverage to new applications of GRAS substances, providing qualified experts consider such new applications to be GRAS.

Total Intake Limitations

Under the proposed Section 121.3(b)(3)(ii), a substance would not be eligible for inclusion as GRAS if "total intake

limitations must be imposed to assure safe use."

We do not question the desirability of establishing total intake limits where necessary to assure safety. However, where such an intake limit is established for a particular substance, we do question the conclusion that such substance should automatically be ineligible for GRAS status under any level of use below such intake limit. A conclusion such as this would seem to be in direct conflict with the definition of food additive in Section 201(s) of the statute, which excepts a substance that may be GRAS by qualified experts under the conditions of its intended use (emphasis added). The term "under conditions of its intended use" would seem to authorize a conclusion by qualified experts as to the GRAS status of a substance, which under the conditions of its use would be added to a food in an amount below an established total intake level.

Therefore, since the proposed Section 121.3(b)(3)(ii) and Section 201(s) of the statute seem to be in conflict on this question, we suggest that this proposed section be deleted with decisions in this area being resolved on a case-by-case basis in a manner consistent with the statute.

Processing

Proposed Section 121.3(b)(1)(ii) provides that any food substance which is acceptable as GRAS without formal listing, under basic criteria set forth in Section 121.3(b)(1)(i), will also be accepted when "... modified by conventional processing" which is in accord with current good manufacturing practices. However, the only guidance provided as to what processing will be considered "conventional" is found in Section 121.3(b)(2)(i). This section, in effect, stipulates that food substances otherwise considered GRAS without formal listing will require "individual review of pertinent data" in order to qualify for formal GRAS listing if they have been modified by processes introduced after January 1, 1958.

We are seriously concerned over this introduction of processing procedures as a criterion of GRAS status in a way which is, in our opinion, completely arbitrary. In short, the date at which a processing technique is introduced has nothing

whatever to do with the safety of the food substance involved. The influence of a processing procedure on the GRAS status of a food substance must be assessed based upon the fundamentals of the processing. The key question is whether or not a processing method alters the composition of a food substance in such a manner as to adversely affect its safety.

Under the present wording of these sections of the proposal, food substances processed into a unique physical form by freeze drying (a process which has relatively recently come into commercial use) could be disqualified from their inherent GRAS status merely because they had been prepared by a process introduced since January 1, 1958. Furthermore, future changes in traditional processes, such as new procedures for size classification of wheat flour fractions, could foreclose historically accepted food substances from their traditional GRAS status. This would have the effect of discouraging otherwise desirable technological advances.

We therefore strongly urge that proposed Section 123.3(b)(2)(i) be deleted, and proposed Section 121.3(b)(1)(ii) be revised to recognize the general principle that any processing applied to a food substance must not adversely affect its safety.

Prior Announcement

We note that the portion of the proposal pertaining to Section 121.3(d) makes no provision for prior announcement of a change of status or a statement of reasons therefor. However, Section 121.3 as now in effect does provide for such notice. For this reason we would propose that the last sentence of proposed Section 121.3(d) be revised to provide that "no status change will be made without prior announcement and a statement of reasons therefor."

Sincerely,

W. J. Driver