

JJH: JOL: TGG: RF

XF: MURIATIC ACID

TO: Betsy Meyer, Wayne Hilgers, Jim Gibson

FROM: T. G. Grumbles
DATE: August 24, 1984

Interoffice
Communication

SUBJ: IFAC MEETING REGARDING PROPOSED FDA GRAS
REVOCATION OF BY-PRODUCT MURIATIC

VISTA

The subject meeting was held in Washington on August 21. The International Food Additives Council has agreed to represent interested producers of muriatic acid, including non-members, in commenting to FDA on this issue. Enclosed are the following:

1. an attendance list from the meeting
 2. draft copy of the revised Food Chemicals Codex (FCC) Hydrochloric Acid Monograph
 3. 1981 FCC survey of organic contaminants in by-product acid
 4. background information on the IFAC, just in case you were wondering.
- A. It is clear to most people who have had conversations with the FDA regarding this proposed action that FDA is under political pressure to take action on various food additives issues, particularly those dealing with contaminants. In particular recognized carcinogenic or suspect carcinogenic contaminants. As a result of this FDA has over reacted to FCC's third edition monograph on Muriatic, which dropped the specific prohibition of by-product acid from any chlorinated hydrocarbon pesticide process.
- Further, they were aware of FCC's efforts to publish a new Hydrochloric monograph with specific contaminant limits but were not satisfied with this effort for two reasons. The first is they felt FCC was taking too long to do this, creating an interim period of risk from undefined contaminants. Secondly, FDA did not feel that the organic contaminant survey (Attachment 3) from which FCC based their work was comprehensive. This is somewhat understandable since only six producers responded.
- B. All present agreed that the basic objection to the proposed rule is the precedence of regulation by process rather than placing specific contaminant

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levels on food grade acid. Regulation by process is not unprecedented but is rare. Also FDA is assuming "on-purpose" acid would have no organic contaminants, and there appears to be no data to support this assumption.

- C. I was the only one at the meeting who had seen FDA's Threshold (economic) Assessment. This was reviewed, and those present confirmed the feeling that FDA underestimated the economic impact of this proposal. They only considered the potential price increase for "on-purpose" acid.

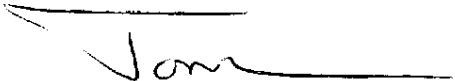
If the impact can be shown to exceed \$100MM then a complex series of administrative procedures is necessary. The agency obviously wanted to avoid this.

- D. The IFAC will develop a survey questionnaire for those producers present, and others that have expressed interest, to generate comprehensive data regarding the potential organic contaminants in by-product acid and typical levels.

It is felt that if we can convince the FDA that FCC's organic contaminant list was comprehensive, they will be more willing to accept the FCC recommended contaminant levels as described in the attached draft (Attachment 2).

- E. The current deadline for comments is September 25. There is little chance that this will be extended.
- F. IFAC is aware that acid users, in particular the corn syrup producers, are preparing extensive comments. These comments should deal with potential levels in finished foods.

Under separate cover, I will be distributing proposed action steps for Vista. Basically, we should proceed with our plans to comment.



Thomas G. Grumbles

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Attachments

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**INTERNATIONAL FOOD ADDITIVES COUNCIL
SOME QUESTIONS AND ANSWERS**

WHAT IS THE INTERNATIONAL FOOD ADDITIVES COUNCIL?

The International Food Additives Council is a trade association of companies engaged in the manufacture, sale, reformulation, and commercial use of food additives. The Council now numbers among its member companies many of the largest, most diversified, food additive manufacturers in the world.

WHY WAS IT FORMED?

Food additives have for some time been a target of overzealous government regulators, publicity-seeking scientists, uninformed media and confused consumers. This unstable environment has led to restrictive regulation and proposed regulation related to the manufacture and use of food additives and, in some cases, all out attacks on the safety of particular substances. In the past, manufacturers and users found it necessary to form splinter groups of larger organizations, to address their specific problems, often losing the broad support of those organizations and rendering their activity ineffective. Additionally, broad issues in the food industry frequently have specific impact upon the manufacture of food additives, different than the effects upon food processing in general. These differences frequently were not addressed properly in the past.

An industry trade publication editor described the International Food Additives Council as "an association for a group of manufacturers that desperately need it -- a group of manufacturers who are regulated more strictly than almost any group in the food industry; and a group of manufacturers who face an alarming confidence gap with the public."

WHAT ARE THE OBJECTIVES OF THE COUNCIL?

The Council has three major objectives:

- 1) To provide and encourage open communication about food additives in order to assure the development of objective and useful regulation in the interest of both the public and private sectors.

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- 2) To serve as an information resource for food additives, in general, and for specific food additives, including direct and indirect additives.
- 3) To conduct and monitor scientific research, conferences and reviews for the continuing evaluation of food additives, including their manufacture, application and safe and efficacious use.

ARE THESE OBJECTIVES BEING SERVED BY THE COUNCIL?

Most definitely! The Council has structured its activities along two approaches. The umbrella approach provides an opportunity for food additive manufacturers to address, from their perspective, those larger issues affecting the food industry. For example, issues like overall food safety, product labeling, Good Manufacturing Practice and unfavorable consumer perceptions about food additive safety and efficacy are of concern to all members. Problems related to specific substances are handled through committees comprised of the affected firms. However, unlike some other organizations, these committee activities have the full support of all of the Council's members, who realize that important and pervasive scientific and regulatory precedents and consumer perspectives are often established in resolving a controversy related to a particular additive.

WHAT HAS BEEN ACCOMPLISHED?

First and foremost, a communications conduit has been firmly established to alert member companies to developing problems and activities which have or will have an effect on their operations. The Council monitors, on a worldwide basis, scientific, regulatory and media activity affecting food additives and continually updates the membership. The Council, in operation since early 1980, has already established itself as an information resource and spokesgroup to a variety of publics. Communications from and to regulatory agencies worldwide, scientific and technical organizations, the media, and associations and various collective third-party groups, are regularly handled by the Council's professional staff.

Among the more significant accomplishments IFAC has achieved are:

- Food Safety

The Council is now involved in working toward a favorable revision of U.S. food safety policy. Consideration of industry and government proposals and appropriate response to FDA, the White House Subcabinet Council's Working Group on Food Safety, and various legislative influentials are among our activities in this area.

- Priority Based Assessment of Food Additives

The Council has developed position papers dealing with various aspects of FDA's planned Priority Bases Assessment of Food Additives (PAFA, formerly the Cyclic Review) program and has met with agency personnel to discuss the program parameters. The Council has let the agency know that food additive manufacturers do not feel that FDA's contemplated chemical structure activity evaluation and population consumption data (based upon current sources) are acceptable for prioritizing food additives for FDA's planned required testing.

- Food Chemicals Codex

The Council reviewed and offered acceptable modifications to many of the draft monographs subsequently published in the Third Edition of the Codex. The Council also prevailed in its argument that maximum limits on minor constituents of substances should be based upon safety data instead of the sensitivity of the analytical method. Additionally, the Council achieved a favorable modification of the Codex treatment of "Added Substances." The Council now continues to work closely with the Codex on its ongoing revisions. Further, the Council is actively engaged in tracking and providing input to other important programs of the National Academy of Sciences.

- Phosphates

A massive survey of over one thousand commercial users of phosphates to establish current use parameters was completed and utilized to substantiate the Council's submittal to FDA calling for elimination of the practice of establishing use restrictions for substances affirmed as "Generally Recognized As Safe" (GRAS) for current use and as may be reasonably expected for use in the future. FDA has stated the IFAC position likely will be adopted as their future policy on all such "GRAS" substances.

- Carrageenan

The Council has established an ongoing communication with FDA on carrageenan, providing significant new data and expert scientific evaluation to address concerns raised in conjunction with the GRAS review program. Additionally, IFAC submitted a comprehensive scientific monograph to the FAO/WHO Joint Expert Committee on Food Additives that resulted in continuing the Codex Committee on Food Additives endorsement of carrageenan in various food standards. The Council is also working with the U.S. Pharmacopeia on resolving purity specifications for carrageenan that are unnecessarily restrictive. IFAC also now serves as a clearinghouse for carrageenan information.

- Sulfites

A proposed rule of the Food and Drug Administration concerning sulfiting agents, called for removing sodium sulfite from the list of generally recognized as safe (GRAS) substances since the agency did not have evidence or sufficient information on this substance's use in foods. IFAC was successful in obtaining an extension of the comment period from FDA to allow the Council adequate time to survey and collect data from the manufacturers of certain of these sulfiting agents. The Council collected use data from manufacturers and submitted this information to FDA, thereby supplying the agency with evidence that sodium sulfite is currently being used as a direct human food ingredient. Because of new developments about sulfites and asthma and FDA's broad reevaluation of sulfites, the Council has undertaken a program on sulfites involving regulatory interface, analytical investigation and scientific evaluation.

- International Regulatory and Scientific Liaison

International regulatory bodies are not only growing in scope, but increasing in numbers as well. Through meetings and other communications, the Council has established itself as a contact point for information on food additives with the FAO/WHO Joint Expert Committee on Food Additives, the Codex Alimentarius Commission Committee on Food Additives, the International Programme on Chemical Safety, and other important international organizations. Representatives of the Council have attended and will continue to attend and participate in these various meetings since the regulation, monitoring and scientific review of food additives are major topics for discussion. IFAC has also provided to these organizations appropriate written comments on specifications for identity and purity of certain substances, on sampling plans for determination of contaminants and on other subjects which impact directly upon the bulk ingredient manufacturer.

- Consumer Education

An informational handbook entitled Food Additives has been developed by the Council. The brochure deals with the purpose, history, consumption, labeling, safety, testing, regulatory approval and benefits of food additives. Copies have and are being distributed to industry, trade publications, newspapers, magazines, food and health columnists, newsletters, associations, libraries, county extension agents, home economists, nutritionists, dieticians, grocery consumer specialists, academicians and consumers. This effort is part of a general public information effort to make the environment more favorable for food additives.

BUT, WHAT ARE THE BENEFITS OF MY COMPANY'S PARTICIPATION
IN THE INTERNATIONAL FOOD ADDITIVES COUNCIL?

- Most importantly, you will help to assure the continuation and expansion of programs necessary to the preservation of food additive availability with unnecessary regulatory restriction and a favorable environment for new food additive approval and use. In other words, you will have business interruption insurance in force.
- You will have an umbrella under which specific issues can be resolved as they come about without the necessity of forming a special organization or ad hoc group.
- You will have an experienced advocate for your food additive interests with federal agencies and other national, state and local government bodies without increased company visibility and risk.
- You will have an opportunity to provide input into the decision-making process of the Council to assure your interests are not overlooked or sacrificed.
- You will have a source of assistance on matters of a sensitive nature concerning food additives. The Council talks to media on behalf of industry and, occasionally, responds to consumer inquiries for member companies.
- You and your company will be kept up-to-date on all matters relevant to the safety and use of food additives on a regular basis. The Council utilizes frequent written member updates and bulletins and participatory meetings, so you stay informed.

SOUNDS LIKE EVERYTHING IS UNDER CONTROL? WHY DOES THE
COUNCIL NEED OUR COMPANY'S PARTICIPATION?

- The current Presidential administration has been characterized as pro deregulation, or at least anti-regulation. However, extensive support within Federal agencies remains for continuing regulation of industries where health and safety considerations are involved.
- Former President Nixon's 1969 Executive Order to evaluate the safety of all food additives classed as "Generally Recognized As Safe" serves as a reminder of potentially troublesome regulatory actions by even a conservative administration. Today's climate, in which many former, liberal, elected and appointed officials have returned to consumer activist organizations, remains opportune for regulatory evaluation and restriction of food additives.
- Activities of significant impact at the Federal level continue to receive scrutiny and important consideration. These include among others, overall food safety legislation, completion

of the GRAS review, the Priority Based Assessment of Food Additives and sodium and potassium labeling. A plethora of state regulatory proposals related to foods and food additives is emerging. The National Academy of Sciences has underway reviews on risk assessment, on criteria for toxicological evaluation of chemicals, and on microbiological contamination of food and food additives. The World Health Organization intends to pursue more tenaciously than ever, food safety review through its International Programme on Chemical Safety. More and more international organizations are taking an increased role in food additive safety evaluation.

- Yes, the programs and actions of the International Food Additives Council are working and have resulted already in an improved environment for food additives. But, the adversaries, in both the public and private sectors, continue to impugn food additives and work toward their removal from the food supply. The maintenance and expansion of the Council's programs are critical to the future sales and use of food additives as important ingredients in your sales and profits formula. The International Food Additives Council requires broad-based support from all those who benefit from its activities.

IF I HAVE ADDITIONAL QUESTIONS OR WANT TO DISCUSS
MEMBERSHIP, WHO SHOULD I CONTACT?

Richard Cristol, Robert Gelardi or any staff member at Council headquarters will be glad to hear from you. Phone or write them at:

International Food Additives Council
5775 Peachtree-Dunwoody Road
Suite 500-D
Atlanta, Georgia 30342
(404) 252-3663

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INTERNATIONAL FOOD ADDITIVES COUNCIL
Hydrochloric Acid Meeting
August 21, 1984 - Ramada Renaissance
Washington, D.C. - 1:00 P.M.

Members

ATTENDEES

Ray Feder	Allied Chemical
Gabriel Paci	Cabot Corporation
Tom Bohnert	The Dow Chemical Company ✓
Wayne Sander	Kelco, Division of Merck & Company, Inc. ✓
Robert Campbell A. J. Batla	Mobay Chemicals Corporation
James Fike John Brokars	Pennwalt Corporation
Nic Stufano	Standard Chlorine Chemical Company, Inc.
James Elfstrum	Stauffer Chemical Company ✓
Thomas Grumbles	Vista Chemical Company
Bob Odle	Vulcan Materials Company
Clausen Ely	Covington & Burling
Richard E. Cristol Jane MacDonald	International Food Additives Council

✓ member companies

FCC Survey of ?

ORGANIC COMPOUNDS REPORTED IN BY-PRODUCT HCl

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FLA

COMPOUND	PPM	ROUTE TO
		NO. MANUFACTURERS* REPORTING
Acetylene	4	1
Benzene	0 - 1.9	1
Benzyl chloride	0 - 0.2	1
Carbon tetrachloride	0.9 - 5	4
Chlorodifluoromethane	10 - 30	1
Chloroform	0.2 - 2.5	4
Chlorotoluene	0 - 0.6	1
Dichlorobenzene	0 - 0.2	1
Dichlorodifluoromethane	10 - 30	1
1,1 - Dichloroethane	0.1 - 1	2
1,2 - Dichloroethane	0.5 - 7	1
Dichlorofluoromethane	10 - 30	1
Dichlorotoluene	0.05 - 0.1	1
Ethyl chloride	0.2 - 0.6	1
Ethylene dichloride	0.4	1
Methyl chloride	0.1 - 2	2
Methylene chloride	0.1 - 3.3	2
Monochlorobenzene	0 - 3.5	1
Perchloroethylene	0.1 - 1	2
Propylene dichloride	1.7	1
Toluene	0 - 2	1
Trichlorofluoromethane	10 - 30	2
Trifluoromethane	5 - 30	1
Vinyl chloride	0.1 - 0.2	1
(24 Total)	(5 > 10 ppm)	

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* Nine manufacturers of by-product HCl were identified; six are represented here; three did not respond in time.