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June 9, 1989

VIA TELECOPIER

Mr. Thomas G. Grumbles
Vista Chemical Company
15990 North Barker's Landing Road
Houston, Texas 77224

Re: Options for Obtaining Appropriate FDA Status for Byproduct HCl

Dear Tom:

Following up on the telephone conversation that Holly Foley and I had with you today, the purpose of this letter is to provide you with a brief summary of the alternatives available for establishing appropriate Food and Drug Administration (FDA) status for Vista's hydrochloric acid (HCl) produced as a byproduct of linear alkyl benzene production. As we understand it, chlorine is used as a catalyst in this process with HCl being produced as a byproduct. You have already generated a large amount of information on residual benzene levels in the HCl but do not yet have a complete impurity profile on the acid.

As we discussed, it is difficult to predict at this stage what the best alternative will ultimately be for establishing to FDA's satisfaction the safety of Vista's byproduct HCl for use in direct food additive applications. The existing alternatives, however, may be broken down into the following: (1) a data submission to FDA demonstrating, if possible, that the byproduct HCl is essentially equivalent, in terms of the nature and levels of impurities, to the acids which the Agency is currently willing to consider generally recognized as safe (GRAS); (2) submission of a GRAS Affirmation Petition specifically for HCl produced as a byproduct of the Vista process; and (3) submission of a Food Additive Petition (FAP) for the acid.

The first two options would both have the objective of ensuring explicit inclusion of byproduct HCl from the Vista process in the final GRAS Affirmation Regulation for hydrochloric acid which the Agency has been working on for the past five years. The third option would request promulgation of a separate Food Additive Regulation specifically clearing the use of the Vista acid in food additive applications.

The best approach to take in submitting data to FDA on Vista's byproduct HCl will depend largely on the outcome of your additional analytical work on possible impurities present in the acid. If the analytical data demonstrate that the HCl is at least as pure as the acid that is currently considered by FDA to be GRAS--an unlikely outcome at this point--it may not be necessary to prepare more than an informal, informational submission of the data to the Agency. If the impurities found in Vista's acid differ from those found in direct process HCl but are clearly innocuous at the levels found, a GRAS Affirmation Petition may be indicated. Finally, if relatively high levels of impurities are detected, or if any carcinogens are present in measurable quantities, it probably will be necessary to submit the data in the form of a Food Additive Petition.

To provide you with some indication of the types of information needed and the necessary format to follow depending upon the type of submission chosen, we are enclosing herewith copies of §§ 170.35 and 171.1 of the Food Additive Regulations, which set forth, section-by-section, the information requirements established by FDA for GRAS Affirmation Petitions and Food Additive Petitions, respectively. With specific regard to the byproduct HCl, whether a GRAS Affirmation or Food Additive Petition is ultimately determined to be the most appropriate option, the following types of information will be needed:

- A description of the manufacturing process leading to the formation of byproduct HCl, including any steps taken to purify the acid;
- Specifications applied by Vista to HCl that will be sold into the food processing industry, copies of analytical methods used to ensure compliance with the specifications, and data from several (3 to 5) production lots demonstrating compliance of the acid with your internal specifications.
- Specifications for the raw materials used in the process and methods for ensuring compliance with the same;

- The identities of possible impurities in the HCl based upon the manufacturing process and purity of the starting materials;

- Results of analyses on a number of production lots encompassing at least a several week manufacturing period showing the measured levels of detectable impurities in the acid and the lower detection limit for any anticipated impurities that are not detected;

- Data validating the reliability of the analytical procedure for impurities and demonstrating the claimed lower detection limits;

- All available toxicological data on the impurities (with the exception of compounds, such as benzene, the safety of which FDA has already evaluated);

- A description of the food processing applications in which Vista's byproduct HCl is used, and a rough breakdown of the percentages of the total quantity of HCl produced by Vista that are used in the various applications;

- If possible, data demonstrating the fraction of HCl used in ion exchange resin regeneration that may remain in the resin and, in turn, may be added to corn syrup that is processed through the ion exchange column. (The latter information will be used to determine how much of the measured quantities of impurities in the HCl may ultimately become a component of food when the HCl is used in this "secondary" direct additive application.)

In addition to this information specific to the production and use of the byproduct HCl, a GRAS Affirmation Petition or Food Additive Petition will need to include an Environmental Assessment (EA) discussing the possible environmental impact of the use of byproduct HCl produced specifically by the Vista process. A description of the general types of information needed to complete an EA for either a Food Additive or GRAS Affirmation Petition is set forth in 21 C.F.R. § 25.31a, "Environmental assessment for proposed approvals of FDA-regulated products-Format 1" (copy enclosed). We can provide you with more specific details of the EA requirements when and if you decide to file a petition for the acid.

While it is premature to predict the type of submission to FDA that will best fit the circumstances once additional analytical data are developed, it appears likely that either a Food Additive Petition or GRAS Affirmation Petition will prove to be the best route for establishing appropriate status for Vista's byproduct HCl. However, in the event that the additional analytical data demonstrate that the acid is essentially identical to HCl produced by the fused silica or burner acid procedures, both of which are considered by FDA to be GRAS, or if the analytical data are equivocal and do not clearly indicate that a petition is called for, it may prove wise to prepare an informal submission of data to the Agency and meet with the appropriate FDA officials to discuss the significance of the data and the appropriate course to take from that point. Such a submission should contain most of the information outlined above for inclusion in a petition but may be compiled in a more informal way and contain less detail on subjects other than the identities and levels of impurities in the acid. Regardless of the form taken by the submission, it will be essential to document with as much specificity as possible the composition of the acid and the procedures utilized to identify and quantify the impurities.

As we discussed, while the information requirements for a GRAS Affirmation or Food Additive Petition and the FDA review process are well defined, it is difficult to predict with any confidence the duration of the review process and timing of publication of a responsive regulation. The uncertainty of the timing that is typical when dealing with FDA is exacerbated here by the fact that the Agency is in the process of preparing a rulemaking affirming as GRAS direct-process HCl. For this reason, if the data permit, it will probably be preferable to submit a GRAS Affirmation Petition for Vista's HCl rather than filing a Food Additive Petition since the acceptance for filing a GRAS Affirmation Petition will permit the immediate marketing of the byproduct HCl during the pendency of the GRAS petition review.

In other words, the short-term goal of submitting a GRAS Affirmation Petition is simply to obtain acceptance of the Petition for filing; if FDA's initial review of the data lead to this acceptance, your marketing efforts need not be disrupted while awaiting completion of the petition review process. On the other hand, if a Food Additive Petition proves to be the only realistic alternative for submitting data on byproduct HCl to FDA, it will be necessary to await completion of the review and promulgation of a responsive Food Additive Regulation before marketing the acid for direct food additive

Timing

use. In this case, considering the rate at which the FDA staff typically operates, a responsive regulation for the acid is unlikely to issue before 12 months from the date of submission, and may well take 18 to 24 months.

Once you have had a chance to review the information provided above, we will be happy to discuss with you in more detail the available options for moving forward to establish appropriate FDA status for the acid and, in particular, the analytical data that will be needed regardless of the specific alternative chosen. At that time, we will be pleased to discuss with you and your technical associates details of the analytical procedures that are most likely to yield the types of data needed as well as suitable analytical sensitivities for the various prospective impurities based on their relative toxicities. We look forward to hearing from you and stand ready to assist in any way possible.

Cordially yours,

Peter

Peter L. de la Cruz

Enclosures

cc: William L. McClain, Esq.

File-376

To: Distribution

From: M. A. Fishbein
Date: February 21, 1991

nteroffice
:ommunication

VISTA

Subject: **FOOD GRADE MURIATIC ACID UPDATE**

This letter will bring you up to date on recent activities by the International Food Additives Council (IFAC) and the Food Chemicals Codex (FCC) Revisions Committee with regards to food grade muriatic acid. Joe Gregg and I attended an IFAC Ad Hoc Hydrochloric Acid Committee meeting in January. Please see the minutes from this meeting (Attachment 3).

Highlights of the current situation are as follows:

FCC HCl Monograph
Revising the specifications for food grade muriatic acid is still on the agenda of the FCC Revisions Committee. However, a revised HCl monograph is not expected for another year.

IFAC Action Plan
The Ad Hoc HCl Committee will agree on a revised HCl monograph and submit the proposal to the FCC Revisions Committee in 1991. The proposal will be submitted along with the data on "by-product" and "on-purpose" food grade muriatic acid which was specifically requested by the Revisions Committee.

VISTA Action Plan
Last year we agreed to delay completing a risk assessment evaluation of Vista's muriatic acid until a decision is reached on a Pacol at Baltimore. If this decision is that Baltimore will continue to produce by-product muriatic acid, I recommend that we begin to take independent steps to get our muriatic acid approved by the FDA. This recommendation is based on indications that Vista's HCl is one of the least contaminated by-product muriatic acids available on the market, and that "on-purpose" muriatic acid is not as pure as once thought.

The above items as well as the background on the food grade muriatic acid issue are discussed in greater detail in Attachment 1.

The next meeting of the Ad Hoc HCl Committee is planned for May 2, 1991 at IFAC headquarters in Atlanta.

Mitchell A. Fishbein
Senior Process Engineer
Baltimore Chemical Plant

/mw
attachments
Distribution:
LRB, JOGi, JPW, DLM, JOGr, BJM (Baltimore)
THH, TGG, RB, MFC, GEH, RES (Houston)

Background

Vista along with seven other suppliers of food grade by-product muriatic acid are participating on an Ad Hoc Committee of IFAC, in an effort to maintain the Generally Recognized As Safe (GRAS) status of by-product muriatic acid sold to the food industry. The Food and Drug Administration (FDA) has not accepted the current FCC HCl monograph. They are considering eliminating the GRAS status of by-product muriatic acid, unless the monograph is revised and is acceptable to them. If the GRAS status of by-product acid is eliminated, each supplier would need to independently get the FDA to approve their muriatic acid. This can be both a costly and a multiple year process. See Attachment 4 for an overview of the various relationships with regulating food grade muriatic acid.

FCC HCl Monograph

Revising the specifications for food grade muriatic acid is still on the agenda of the FCC Revisions Committee, although a revised HCl monograph is not expected for another year. A revised HCl monograph was not included in the third supplement to the third edition of the Food Chemicals Codex, which was issued for public comment last month. Instead, the Revisions Committee is planning to revise the HCl monograph in the fourth edition, which is due out in 1992.

In their effort to revise the HCl monograph, the Revisions C mmittee has requested that the Ad Hoc HCl Committee of IFAC submit to them any available data on "by-product" as well as "on-purpose" food grade muriatic acid. Specifically, they are interested in contaminants and their levels, toxicity data, and the production and use of HCl for food processing. The Ad Hoc Committee is still in the process of gathering this data for submission to the FCC.

IFAC Action Plan

The action plan for the Ad Hoc HCl Committee is to agree on a revised HCl monograph and to submit the proposal along with the data specifically requested by the FCC Revisions Committee in 1991.

The IFAC representative on the Ad Hoc HCl Committee is Dr. Ebert, a toxicologist, who also happens to be a member of the FCC Revisions Committee. Dr. Ebert has recommended that th best approach for industry to maintain the GRAS status of by-product HCl is for the Ad Hoc Committee to submit a proposed HCl monograph with tighter limits on contaminants to the FCC Revisions Committe . The Ad Hoc committ e has agreed with this approach, alth ugh the Committee is having trouble r aching consensus on a n w monograph.

T date, there is tentative agreement to reduce limits for total organic compounds from 5 ppm to 2 ppm and for heavy metals as lead from 5 ppm to 1 ppm. However, for other individual compounds there is not agreement. In fact, some represented companies will not even agree with the current limit for benzene, 50 ppb.

In an effort to reach consensus on a new monograph, a confidential survey was completed. Individual companies reporting high levels for contaminants of interest, ppm range, were asked if they could support a much lower level, such as 50 ppb, and if not, what level they could meet. For the results from this survey see Attachment 2.

Vista was asked if we would be agreeable to limits of 50 ppb benzene and 1 ppm heavy metals, as lead. Since these are our current specifications, we did not object. In fact, Vista would be able to meet all of the limits proposed to the individual suppliers of by-product muriatic acid.

VISTA Action Plan

In June of 1989, the Business Area, Environmental, and the Baltimore Plant jointly developed a plan to complete a risk assessment evaluation of Vista's muriatic acid. The evaluation would determine which further course of action to pursue, such as, applying for a food additives petition or possibly exiting the food grade market. It was subsequently decided at a Business Area/Manufacturing meeting in January of 1990, to delay the risk assessment evaluation until a decision is reached on a Pacol at Baltimore.

If the outcome of the Pacol at Baltimore decision is that the Baltimore Plant will continue to produce by-product muriatic acid, we should begin to take independent steps to get our muriatic acid approved by the FDA. Through our participation on IFAC's Ad Hoc HCl Committee, we have learned that Vista's muriatic acid is one of the least contaminated by-product muriatic acids on the market.

The AD Hoc Committee is now in the process of gathering data on the impurities in "on-purpose" muriatic acid made by burning hydrogen with chlorine. The FDA had originally concluded that the "on-purpose" burner acid was the least contaminated food grade muriatic acid available, and thus considered eliminating all by-product acid from food applications. We hear on the Ad Hoc Committee that the FDA now realizes that "on-purpose" burner acid is not as pure as once thought.

I xpect to hear before the next Ad Hoc HCl Committee meeting in May 1991 what the contaminant levels are in "on-purpose" burner acid. If the contaminant levels in burner acid are found to differ not significantly from Vista's by-product muriatic acid, this will support Vista taking independent action to get our muriatic acid approved by the FDA.

Mitchell A. Fishbein
Senior Process Engineer
Baltimore Chemical Plant

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ATTACHMENT 2

Results of IFAC/HCL
Committee Survey
July 6, 1990

COMPOUND	QUESTION	CONSENSUS
Carbon Tetrachloride	0.05 PPM Limit	Mixed-Several Agreed Max 1.0 PPM
Chloroform	0.05 PPM Limit	No One Agreed Max 2.0
Chlorofluorocarbons	Reduce 25 PPM	10 PPM Total a possibility.
Heavy Metals	1 PPM Limit	Unanimous Agreement
Methyl ne Chloride	0.05 PPM Limit	"No" Max 2.0
Benz ne	0.05 PPM Limit	Mixed-Some Agreed
Chl rob nzene (r Dichlorobenzene)	0.05 PPM limit	"No" 0.7 PPM Limit
T luen	0.05 PPM Limit	"No" (IRIS/RFD is 10PPM)
Sp cific Fluorocarbons		
Chl r difluoro		10
Dichlor fluoro		10
Dichlorodifluoro		4
Trichl rofluoro		10 (Total)

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INTERNATIONAL
Food
Additives
Council

ATTACHMENT 3

February 6, 1991

TO: Ad Hoc Hydrochloric Acid Committee

RE: Minutes - Ad Hoc HCL Committee Meeting - January 15, 1991

Attached are the Minutes of the Ad Hoc HCL Committee Meeting held on January 15, 1991 at The Madison Hotel, Washington, D.C.

Please note those action items, indicated by an *, where you have agreed to an action item and plan.

If you have questions and comments, please do not hesitate to call.

Sincerely,

A. G. Ebert

A. G. Ebert, Ph.D.
Executive Director

AGE/nwn
Attachment

VEU-143763

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INTERNATIONAL FOOD ADDITIVES COUNCIL
Ad Hoc Hydrochloric Acid Committee Meeting
January 15, 1991 - The Madison Hotel
Washington, DC - 10:00 a.m.

Minutes

I. CALL TO ORDER

The meeting was called to order and self-introductions were completed. The Kellen Company Antitrust Guidelines were available and their contents briefly reviewed.

II. LIST OF ATTENDEES

A list of attendees is attached to and made a part of these minutes.

III. REVIEW OF PREVIOUS MINUTES

The minutes of the June 7, 1991 meeting were approved as drafted.

It was noted that additional follow-up action is required specifically the potential need for filing an FOI request on the matter of constituent assays of high fructose corn sweeteners.

IFAC Council agreed to follow-up on this matter*.

IV. CPI CONSULTING ASSOCIATES REPORT

A copy of a CPI letter to Mr. Talbot was circulated to members. A copy is attached to the master book copy of these minutes. Several committee members reported that they are subscribing to a soon-to-be-published SRI study on the Hydrochloric Acid business. The subscribers agreed to review the SRI study on receipt, supplement the CPI data, and send additional information to IFAC headquarters for potential submission to FDA and the FCC.

V. REVIEW OF CONSTITUENT DATA

Results of the IFAC/HCL Survey of July 6, 1990 were discussed in the aggregate and a copy of the consensus data circulated. A copy of the report is sent to non-attending committee members and is attached to the master book copy of these minutes. Following discussion, participants agreed in a straw vote that a limit of 2mg/kg for total organic compounds could be proposed to FCC. This is a marked reduction from the 5mg/kg limit established in FCC III, 2nd supplement.

Participants also agreed to retention of the 25mg/kg total fluorinated organic compounds limit based on the adequate safety database that has been established for the fluorocarbons. Participants also informally agreed to a 1mg/kg heavy metals limit. Therefore, staff agreed to draft a suggested revised monograph for review by the HCL Committee.*

Noting the FCC's on-going interest in on-purpose acid, several participants whose companies produce on-purpose acid agreed to complete constituent assays for their product. Several committee members remarked on-purpose acid is not necessarily marketed for food use. Nevertheless, participants agreed to increase the Committee's database and have the constituent data made available to IFAC. Approximately six weeks will be required for completion of these assays.* These minutes further request that constituent data be identified as coming from on-purpose acid marketed for food use - or not.

As a result of the re-emerging interest in on-purpose acid, it was suggested that several producers of this product be contacted and their membership on the IFAC Ad Hoc HCL Committee be solicited. Committee members agreed to provide names and addresses for IFAC staff for follow-up.*

VI. DISCUSSION OF AVAILABLE TOXICOLOGY DATA

Noting that there were several review articles on various toxicologic constituents, either available or in preparation, it was the sense of the Committee to anticipate the collection of no additional toxicology data at this time.

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VII. DRAFT SUBMISSION TO FOOD CHEMICALS CODEX

Staff agreed to prepare for Ad Hoc Committee review the following:*

- A suggested draft FCC Monograph for Hydrochloric Acid.
- A revision of the draft reply dated May 18, 1990 to Dr. Bigelow sent to Committee members - but not submitted to FCC. The revised reply will include:
- Information on HCL production and use from the CPI Report - to be supplemented by the SRI Report.
- Information on constituents and levels, thereof, as called for in the Bigelow letter of March 2, 1990 Paragraph 2.
- Information on constituents in on-purpose acid - to be provided.
- Additional information felt to be appropriate. Decision will be based on informal discussion of HCL at the FCC Winter meeting.

VIII. PLAN OF ACTION

The Committee agreed:

- Informal discussion on HCL will continue at the Winter FCC meeting and, if needed, elsewhere.
- Data on constituents in on-purpose acid will be acquired and circulated in the aggregate to each Ad Hoc HCL Committee members.
- The CPI Report will be supplemented by the SRI data.
- The draft response to Dr. Bigelow's March 2, 1990 letter will be sent to the Committee for review.
- The Committee will meet again in Atlanta at IFAC headquarters on Thursday, May 2, 1991 (tentative, subject to confirmation).

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IX. FINANCIAL STATUS

A summary of expenditures incurred in 1990 was circulated. Staff pointed out that the treasury was now depleted. The proposed 1991 budget as indicated on a handout, attached to the master copy of these minutes was discussed and approved. With anticipated participation of eight companies, pro-rata invoices to fund the 1991 budget will be mailed. It was further agreed to increase the treasury by adding funds from new members as they join the organization.

X. ADJOURNMENT

There being no further business, the meeting adjourned at 12:16 p.m.

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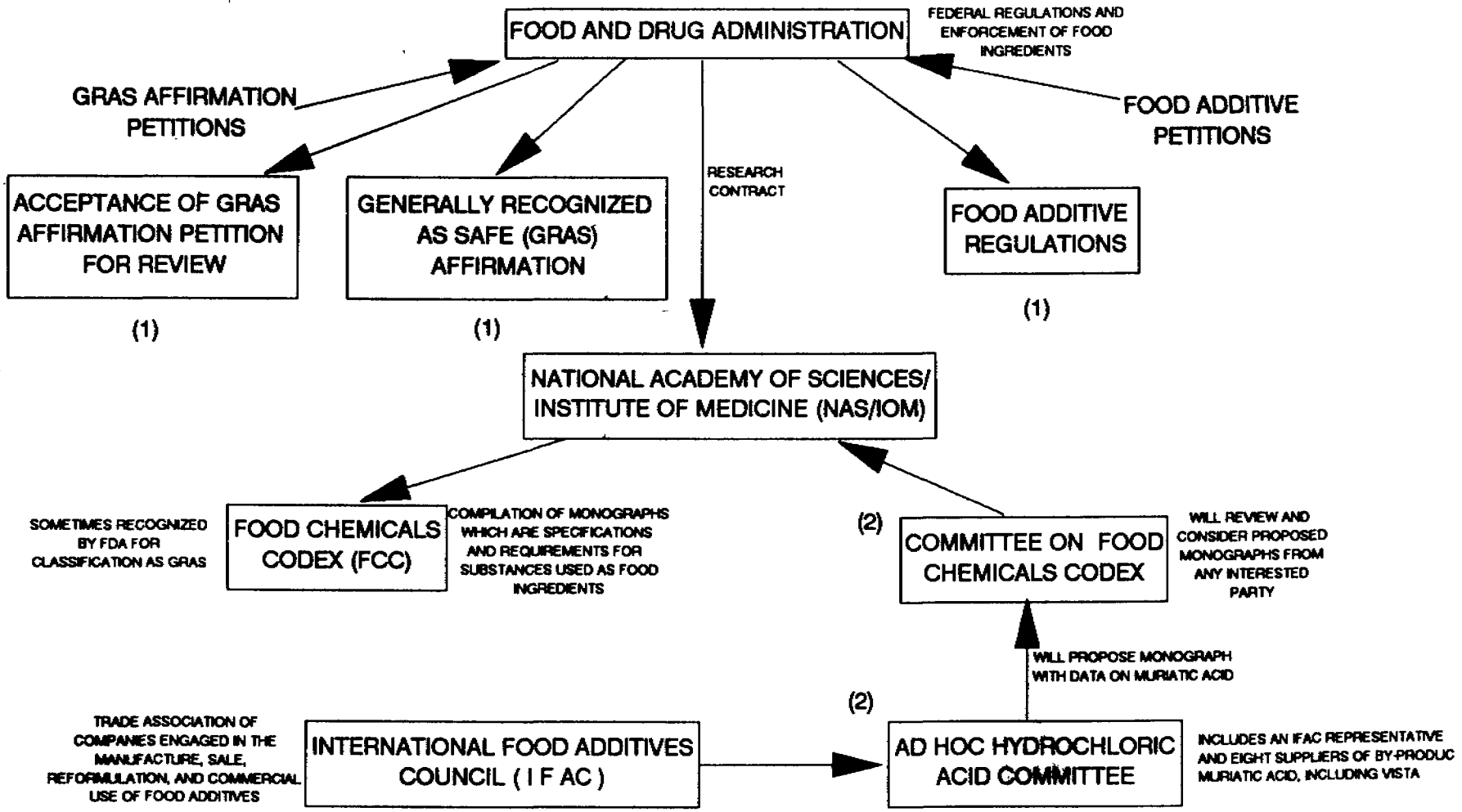
INTERNATIONAL FOOD ADDITIVES COUNCIL
HYDROCHLORIC ACID COMMITTEE MEETING
THE MADISON HOTEL - WASHINGTON, D.C.
TUESDAY, JANUARY 15, 1991

LIST OF ATTENDEES

Robert Buccafusco	Allied-Signal, Inc.
John Reid Judy Brunton	Atochem North America
Phillip Armstrong	BASF Corporation
Donald Naragon Jim Joyce Randy Childers	Mobay Corporation
David Guenther Evert Talbot	Reagent Chemical & Research
Mitch Fishbein Joe Gregg	Vista Chemical Company
George Butler	Vulcan Chemicals
Clausen Ely	Covington & Burling
Andrew Ebert	International Food Additivies Council

ATTACHMENT 4

OVERVIEW OF RELATIONSHIPS WITH REGULATING FOOD GRADE MURIATIC ACID



(1) ONE OF THESE ACTIONS BY THE FDA WILL BE NEEDED TO CONTINUE MARKETING VISTA BY-PRODUCT MURIATIC ACID FOR FOOD APPLICATIONS ,IF THE CURRENT GRAS STATUS OF BY-PRODUCT ACID IS ELIMINATED.

(2) THE IFAC REPRESENTATIVE AND LEADER OF THE AD HOC HYDROCHLORIC ACID COMMITTEE IS ALSO ONE OF THE FOURTEEN MEMBERS OF THE FOOD CHEMICALS CODEX REVISIONS COMMITTEE.