Pub - Processed Flavors

MEMORANDUM

TO: FEMA Board of Governors
FEMA Expert Panel
SECC
Process Flavors Committee

FROM: G. Burdock

DATE: 12 Sept 91

SUBJ: Progress report summarizing the current activities of the various committees at work on process flavors.

THE FEMA/FDA TASK FORCE

The Analytical Methodology Group

The charge to this group is to develop an easily reproducible methodology for the detection of heterocyclic amines (HCAs). Four laboratories are participating: Nestle and Givaduan in Switzerland, the FDA and a consulting laboratory, Lawrence Livermore in California.

Nestle (Dr. Gross) has developed a method that utilizes HPLC for detection of heterocyclic amines (MeIQx and diMeIQx) following a tandem column clean-up. (A description of the methodology is available on request.) A collaborative study among the participants is underway following the July 30th meeting to confirm the accuracy of the method.

Once the method is validated, the methodology group will be examining a model process flavor spiked with a combination standard. Once this is mastered, the methodology group will be working on realistic, but not commercially marketed process flavors.

As you may know, there are 20+ heterocyclic amines found in foods. Initially, the methodology group was only working on the detection of MeIQx and diMeIQx as marker substances for the presence of all heterocyclic amines, but the decision was made to go to a new combination standard which also includes IQ, MeIQ and PhiP. This five substance combination includes a sample of the HCA occurring in highest amounts (PhiP) and some of the most biologically active (IQ, MeIQ, DiMeIQx). The reasons for using a combination are (1) to confirm that

we are looking at a representative sample of HCAs in foods and; (2) we will be able to determine if different reaction conditions or ingredient combinations significantly influence the ratio of the substances in the final product.

We will soon be requesting process flavor manufacturers to submit realistic samples of non-commercialized process flavors which have never been marketed. These candidate flavors will be distributed to the methodology group for analysis. Selection of flavors will be made on the basis of relative amounts of substance produced according to reaction conditions described by the Process Flavors Survey. That is, more samples would be taken from those categories that reported the greatest poundage.

We expect to be well on our way to completion of the analysis of the sample process flavors by the time the FEMA group meets with the FDA again in mid-November. Although the FDA is pleased with the quality of progress to date, they would like to move at a more rapid pace.

Following the meeting with the FDA and if the method is reproducible between labs, the method will be published. Publication will allow FEMA members to employ the method in their own labs.

Timetable

The current timetable for this activity calls for completion of all work by mid-winter.

The Process Flavors Survey

A confidential survey of process flavors was requested by the FDA to determine the amount of process flavors in commerce and, roughly, the conditions of manufacture. The survey was to consist of three parts:

(1) the initial survey of FEMA members and those companies that were thought to produce process flavors,

(2) a verification survey to determine if the first survey captured a majority of producers and,

(3) an expanded survey to include all participants in the NAS survey on food additives.

The initial survey and the verification survey were completed and the results were reported to the FDA, and to FEMA members at the 1991 Safety Breakfast. Because of the extensive participation in the survey by FEMA members, the FDA concluded that the third part of the survey (solicitation of information from all participants in the NAS survey) was unnecessary.

Timetable.

The survey portion of the project is at an end. A formal report will be written and

circulated.

EXPERT PANEL ACTIVITIES

In 1985, the Panel members received their first briefing on process flavors. Lately, with the renewed interest by the FDA and European regulators, the Panel has been asked to expand their activities in the process flavor area.

To date, the Panel has visited two process flavor producers and have been extensively briefed on the products and processes involved by member company experts.

The Panel formed a Process Flavor Working Group consisting of Drs. Munro, Portoghese and Wagner. This Working Group has developed an action plan to meet the following goals:

- determine the full range of practices involved in the manufacture of process flavors,
- determine the composition of process flavors,
- conduct a review and evaluation of the toxicological data on microcontaminants of process flavors, and
- compile and analyze data on consumption of process flavors.

Determining the full range of practices.

The Panel is aware that the technology of process flavor production is a rapidly evolving field involving biotechnology and other new food technologies. Therefore, the Panel has decided to avail itself of the services of a consulting food technologist, in conjunction with knowledgeable industry scientists, to prepare a report on the state of the art of processed flavor production.

Determining the composition of process flavors.

Considerable scientific literature exists on microcontaminants in cooked food, but much of it was developed from model systems and it is unclear how these systems relate, if at all, to current industrial practices for process flavors. The literature will be extensively researched by the Panel.

A potential source of pertinent information on microcontaminants will be developed by the Analytical Methodology Group cited above. The information provided by this group will be important because as it will be produced by an accepted and reproducible detection methodology from a defined system representative of commercially available products.

Reviewing and evaluating the toxicological data on microcontaminants resulting from cooking processes.

The substantial literature on microcontaminants has not been compiled in any

comprehensive manner that would permit an assessment of the effects of these substances.

The Panel considers it essential to develop methodology to assess the potential health impact from microcontaminants from both process flavors and foods. This will require knowledge of structure activity relationships in relation to toxicity, and the development of new methodologies to deal with the safety evaluation of these complex mixtures.

The Panel will first focus on the five aminoimidazoazaarenes (AIA) identified by the Analytical Methodology Group, that is, MeIQx, DiMeIQx, IQ, MeIQ and PhiP. These five substances represent those substances occurring in highest amounts (PhiP), the most biologically active (IQ, MeIQ, DiMeIQx) and those currently under study by government laboratories (PhiP, MeIQ and MeIQx). The Panel will also examine representative members of the carboline family of heterocyclic amines Trp-P-1, Trp-P-2, Glu-P-1 and Glu-P-2. The carbolines are also biologically active, but are formed under slightly different conditions than the AIA.

Compilation and analysis of data on consumption of process flavors.

The Panel considers it essential to obtain data on the consumption of process flavors and relate this to the dietary load of microcontaminants formed during the cooking process.

There are a number of ways of approaching this problem including disappearance data, estimates of per capita intake based on production figures or more refined analyses using the MRCA food consumption data base. Of these, the most accurate is the MRCA data base, which will also provide the amount of home cooked products which contain microcontaminants. This information will permit estimation of a "consumption ratio" of microcontaminants consumed via processed flavors, versus that provided via home cooking processes.

Timetable

The Panel expects to have the consultants on board and working on a review document by mid-September. Analysis of data will take place during the fall and winter months. A final report by the Panel is expected in late spring of 1992.

FINANCIAL

All of this activity will predictively have a financial impact. A rough estimate of activity and cost was presented to the membership late last year. The industry responded in a responsible manner.

Now that the Panel is more focused and has a greater appreciation of the scope of the issues, it will be necessary to review the Panel component of the budget. There is no reason to believe that quantum changes will be made to the original overall program budget, but we will reserve further comment until the final numbers are generated.

If you have any questions or comments on this report or the project, please feel free to contact Dr. George Burdock at the FEMA office (202) 293-5800.