
Robert E. Shank Papers

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RADIO-TV THANK YOUS

Thank you letters have been sent to all radio and television stations for all their cooperation in the Heart Fund Campaign. If you requested to receive these letters in bulk, you should have received your allotment by this time. Enclosed in the letter is an extra self-addressed log to enable us to estimate the value of the time we received. After we analyze these logs, we will return those from your state to you.

THE PUBLIC BEAT (News of Public Policy and Government Affairs of Interest to AHA)
by Dolph Chianchiano

CHANGING FAT COMPOSITION OF ANIMAL PRODUCTS

The National Research Council Food and Nutrition Board (the group which sets Minimum Daily Requirements for nutrients) held a two-day conference on the "Changing Fat Composition of Animal Products" December 12 and 13, 1974, in Washington, D.C. The announcement suggested that the symposium would be concerned with the desirability of reducing the fat content of foods for health, economic and management purposes. A basic assumption, it appeared, was that the American public needs beef in its diet because it is an important source of zinc, iron and niacin. Thus, it was postulated that decrease in total consumption of dietary fat would best be accomplished by reducing the size of beef portions and/or their percentage of fat, or by reducing the amount of vegetable fat in the diet.

On the other hand, it soon became clear that without additional direction, agricultural economics and consumer preference will dominate decisions about food composition. For example, the cattle producers and processors will probably change growing cycles to reduce the trimable fat on beef. Feed grain and transportation, it was explained, cost too much to allow the luxury of a ribbon of fat. Furthermore, surveys indicate that most consumers now throw away such fat and are annoyed at having to pay high prices for such waste.

But there seems to be less likelihood that the percentage of fat in the grain will be measurably altered. The industry is convinced that the consumer wants a good deal of fat because it associates it with juiciness, tenderness and flavor. Consumer panels seem to prefer hamburger and processed meats that are 22 to 27 percent fat. (It was pointed out that a low-fat frankfurter attracted very few sales when test-marketed in 1973.)

One ray of hope was nevertheless presented. New studies seem to show that alterations in methods of refrigerating carcasses after slaughter and changes in cooking methods, will enhance tenderness and juiciness, thus permitting consumer acceptance of beef with lower fat content.

HEART ACT EXTENSION

The National Heart, Blood Vessel, Lung and Blood Act of 1972 expires on June 30, 1975. Dr. Rapaport is scheduled to testify before the Senate Health Subcommittee on March 17 to urge its extension. Heart Associations will be provided the complete text of his remarks soon thereafter.

SMOKING

Dr. Jeremiah Stamler taped a television interview with Senator Frank Moss (D., Utah) about the needs for new public initiatives to reduce cigarette consumption in this country. The Senator indicated that he would be interested in new public policy proposals in this area. Meanwhile, the Clearinghouse on Smoking has issued its latest annual report which contains much new information about health dangers related to smoking. The Report is available from the U.S. Government Printing Office, Washington, D.C. 20402, for $1.60. The title is, "The Health Consequences of Smoking, 1974." Ask for DHEW Publication Number (CDC) 74-8704.

Dr. Shank

REHABILITATION HEW has published regulations implementing the programs and activities authorized under the Rehabilitation Act of 1973. These appeared in the Dec. 5, 1974 issue of the Federal Register. Copies may be obtained from the Rehabilitation Services Administration, 330 "C" Street, S.W., Washington, D.C. 20201.

HYPERTENSION AND REVENUE SHARING On Dec. 23, 1974, President Ford vetoed H.R. 14214, the Health Revenue Sharing and Health Services Act of 1974. This measure included authorization for $35 million in grants to state health departments for hypertension control programs during the current fiscal year. Mr. Ford said that he decided to veto the health services bill because it conflicted with his strong commitment to American taxpayers to hold health programs, the President's action was not specifically directed at heart disease.) The President noted that the bill authorized appropriations which exceeded his recommended budget for the current fiscal year by $1 billion, and that authorizations for the following year were double and triple the levels he believes appropriate.

GRANTSMANSHIP POSSIBILITIES Not only are government sources for funding social service programs getting tight...The Ford Foundation, the nation's wealthiest philanthropic institution, announced in the middle of December that it was cutting its grants in half, from $208 million to $100 million. This is on top cuts that it has been gradually making since 1967 when Ford Foundation awards were running at the level of $300 million a year. McGeorge Bundy, the Foundation's president, said that the cirtical factor in this decision was the desire of the trustees to move away from the practice of using a portion of the Foundation's capital assets for annual grants. Still, the economic climate was probably an important consideration and many fear that many other foundations will follow Ford's example in these hard times.

CHEESE Americans have drastically reduced their consumption of some dairy products in recent years but have stepped up their cheese eating markedly in the same period. Since 1955, we are drinking 26.6 per cent less whole milk and using 41.7 per cent less cream and 46.7 per cent less butter. On the other hand, sales of American cheese are up 64.7 per cent and consumption of all other cheeses (except cottage cheese) has gone up 128 per cent. These facts would seem to validate our interest in "filled cheese" over the past year! ("Filled cheese" is made with vegetable oil substituted for butter fat.)

EGGS The Federal Trade Commission has decided to appeal the decision of the U. S. District Court in Chicago denying a request for a temporary injuction against the advertisements of the National Commission on Egg Nutrition. The notice of appeal was filed on Nov. 20, 1974. Briefs are due Jan. 6, 1975.

jw

National Association
of Broadcasters
Code Authority
Advertising Guidelines

Effective January 15, 1974

Vegetable Oils, Margarines

The Radio Code Board, at its November 2, 1973 meeting and the Television Code Review Board, at its October 10-12, 1973 meeting, revised the Code Authority's current policy regarding the advertising on radio and television of such foods as vegetable oils and margarines.

The new policy was arrived at following an extensive review of representative attitudes held by government, health association and Code Authority Medical and Science Advisory Panelists toward cholesterol, saturated fats and related health issues.

The Guidelines for the Advertising of Vegetable Oils, Margarines and Related Products apply to advertisements in which direct or indirect reference is made to fats (saturated or unsaturated) or cholesterol specifically, or health or health-related matters generally. Products affected by the Guidelines include, but are not necessarily limited to, vegetable oils, margarines, egg substitutes, modified dairy products, substitute dairy products and modified meat products.

As a result of comments received by the Code Authority on the Guidelines initially issued by the Radio Code Board and the Television Code Review Board, some changes have been made in those Guidelines. The revised, final Guidelines for the Advertising of Vegetable Oils, Margarines and Related Products:

1. Allow appropriately qualified, precise references to cholesterol in such advertising.

2. Require that any references to serum cholesterol or possible benefits be related to a total dietary program in which more than one aspect must be changed.

3. Disallow any indication that an individual food will help lower serum cholesterol levels.

4. Allow a properly qualified reference to coronary heart disease solely in relationship to the three major controllable risk factors —cigarette smoking, high blood pressure, and serum cholesterol levels.

5. Exhort advertisers to reference the risk factors of cigarette smoking and high blood pressure when referencing the risk factor of serum cholesterol.

6. Encourage advertisers to include a copy line directing potential dieters to first seek the advice of doctors.

7. Disallow any specific health benefits claims (e.g., longevity, protection from coronary heart disease) as stemming from any single practice or food substance.

The Guidelines become effective January 15, 1974. The Code Authority will serve as central clearance for all commercials affected by the Guidelines. Advertisers/agencies should submit any commercial, current or proposed, affected by the Guidelines to the Code Authority's New York office, 485 Madison Avenue, Room 1900.

Council on Foods and Nutrition

Composition of Certain Margarines

BOTH kind and amount of dietary fat are receiving considerable attention, chiefly because of evidence of possible relationships between dietary fat and atherosclerosis. In some instances, physicians may wish to advise a change in the amount and kind of fat in the diet of certain patients. "Special" margarines have been developed which differ significantly in fatty-acid composition from the more conventional types. These products are intended to supply larger quantities of polyunsaturated fatty acids than do ordinary margarines. They contain a greater percentage of liquid unhydrogenated, or very lightly hydrogenated, oils but they are prepared in a way similar to that used for the making of ordinary margarines.

The composition of margarines is regulated by the Federal Food and Drug Administration under a specific Standard of Identity.[1] This standard requires a minimum fat content of 80%. Some form of milk is required, such as whole milk, skimmed milk, or a mixture of non-fat dry milk and water. Nearly all margarines contain either fresh, liquid or skimmed milk or reconstituted, non-fat, milk solids. Optional ingredients are allowed, including provitamin A (carotene), vitamin A, vitamin D, salt (sodium chloride), sodium benzoate or benzoic acid not to exceed 0.1% of the weight of the finished product, as well as lecithin or mono- and diglycerides (or both) not in excess of 0.5% of the weight of the finished product. The following preservative and flavoring components are also permitted in limited amounts: citric acid, isopropyl citrates, stearyl citrate, artificial flavoring, and diacetyl.

The manufacture of margarine entails the combination of an aqueous phase, composed of milk and other water-soluble components, and fat and fat-soluble components to produce a water-in-oil emulsion.

The milk phase is cultured by inoculating the pasteurized milk component with a culture of lactic-acid-producing organisms. This process, commonly called ripening, helps produce the characteristic flavor of the margarines.

Several techniques are employed to produce a stable water-in-oil emulsion having acceptable texture and flavor. Generally, the oil and water phases are mixed and agitated vigorously at a temperature slightly above the melting point of the oil. When the emulsion is formed, it is chilled and crystallized to produce a firm product suitable for packaging and handling. The type of oil in the product controls, to a great extent, the spreading and melting properties of the margarine. These properties, however, are also influenced by the emulsifying and chilling processes.

Special margarines differ from regular margarines in having a higher polyunsaturated fatty-acid content. This difference may be attributed to manufacturing techniques which permit the use of relatively high proportions of unhydrogenated, or only lightly hydrogenated, oils. These margarines are prepared by (1) blending liquid hydrogenated oils with significantly hardened oils, or (2) combining lightly hydrogenated oils with hardened oils.

There is no uniformity in the composition of special margarines. They vary widely in their content of linoleic acid and saturated fatty acids, as well as in the relative proportions of cis and trans oleic acids. The significance of the trans forms has not been established in human nutrition.

A comparison of the regular and of 6 special margarines is given in the table. Values are expressed as ranges of those products indicated in the footnote. The average linoleic acid content of the 6 special margarines is 27 gm. per 100 gm. of margarine. The polyunsaturated fatty acid content of special margarines is considerably greater, in most instances more than double that of the conventional margarines. There is little difference in the saturated fatty acid content of the 2 types of margarines.

The nutritional significance of the increased amount of linoleic acid in the special margarines has not been well established. On the basis of the average per capita consumption of margarine, the extra amount of linoleic acid made available by the use of special margarine is not very great.

The iodine value of the fats in these margarine products is not necessarily a good indication of either the saturated or the polyunsaturated fatty acid content, since this value is also affected by the monounsaturated acid content. In product promotion, considerable attention has been directed to the kinds of oils used in the preparation of the margarines. The impression given is that corn oil is the oil of choice. There is no acceptable evidence that the kind of oil (i.e., cottonseed, corn, soya bean, or safflower) used has any therapeutic significance, since each of these oils can serve as a source of polyunsaturated fatty acids.

This information is given to inform the physician about a class of food products. The statement in no way suggests that the many claims and implications connected with the products mentioned are clinically sound.

Ranges of Composition in Grams of Fatty Acid, as Glyceride Ester, per 100 Gm. Margarine

	Iodine Value	Linoleic Acid (Polyunsaturated)	Oleic Acid (Monounsaturated)	Saturated	Ratio of Linoleic to Saturated Acids
"Special" Margarines	92-100	22-34	18-42	14-28	1.2 -1.7
Regular Margarines*	75-82	7-15	45-53	17-22	0.48-0.91

* Analysis of 10 brands.

The Council has authorized publication of the above statement.
PHILIP L. WHITE, SC.D., Secretary

The Council on Foods and Nutrition wishes to thank the following companies for making available the analyses of their "special" margarine products: Best Foods (Mazola); J. H. Filbert, Inc. (Mrs. Filbert's Corn Oil Margarine); Lever Brothers Co. (Golden Glow); Pitman-Moore Co. (Emdee); Standard Brands, Inc. (Fleischmann's Unsalted); Swift and Company (Award).

Reference

1. Code of Federal Regulations, Title 21, Food and Drugs, Part 45, Oleomargarine: Definitions and Standard of Identity, revised 1955, pp. 182-184.

Robert W. Harkins
Director, Scientific Affairs

March 11, 1975

Robert E. Shank, M.D.
Chairman, Nutrition Committee
American Heart Association
Department of Preventive
Medicine and Public Health
School of Medicine
Washington University
St. Louis, Missouri 63110

Dear Dr. Shank:

You will be pleased to know we have shared your letter of February 17 with more than sixty members of the GMA Technical Committee for Food Protection at last week's meeting.

We hope your letter will encourage those companies who may be on the fence to contribute their corporate data to the National Nutrient Data Bank. We, that is, industry, government, and third-party users of the Data Bank, still have a selling job to do to convince companies to support the Data Bank. For too many companies, the Bank is still viewed as something to be considered whenever they get the time.

I understand that Dr. Robert Rizek has also or will shortly respond to your letter of encouragement and support, plus provide materials you requested.

Sincerely,

Robert W. Harkins

Robert W. Harkins, Ph.D.
Vice President
Scientific Affairs

RWH/fb

cc: Robert L. Rizek, Ph.D.

UNITED STATES DEPARTMENT OF AGRICULTURE
AGRICULTURAL RESEARCH SERVICE
NORTHEASTERN REGION

Consumer and Food Economics Institute
Hyattsville, Maryland 20782

March 10, 1975

Dr. Robert E. Shank
Washington University
School of Medicine
4566 Scott Avenue
St. Louis, Missouri 63110

Dear Dr. Shank:

I am sending under separate cover 10 copies of the data form being used for the data bank. We are, of course, accepting data in many ways. The data form outlines the data needed ideally to have a comprehensive data bank.

You asked if there were any specific suggestions I might have regarding how you might advance the program. As I indicated, I know that any support given to the program by the Heart Association would be of great benefit. Over the past 2 years, we have been working quite closely with the Heart and Lung Institute, National Institute of Health, in developing lipid data through a review of the literature. I am enclosing a copy of a paper that outlines the status of our work. From this review, we have found that there are a number of gaps in the data. If possible, the Association might consider supporting the research that is needed to obtain these data.

If I can be of further assistance, please call on me.

Sincerely,

Robert L. Rizek
Chairman

Enclosures

"Separate Cover"
ARS Form 200 (10)

Copies to
Mrs. Weinstock
Dr. Ruth Brenner

UNITED STATES DEPARTMENT OF AGRICULTURE
AGRICULTURAL RESEARCH SERVICE
NORTHEASTERN REGION
Consumer and Food Economics Institute
Hyattsville, Maryland 20782

March 3, 1975

Dr. Robert E. Shank
Chairman, Nutrition Committee
American Heart Association
Washington University
St. Louis, Missouri 63110

Dear Dr. Shank:

Dr. Harkins, GMA, informed me of your interest in the Nutrient Data Bank that we are developing here in the Department.

I am enclosing a copy of a talk I gave last summer on the Data Bank that outlines in general what we are doing. The computer system is nearing completion and we are starting to enter the data we have been receiving from industry.

We would certainly appreciate any assistance that your organization could give us, whether it be moral or by encouraging industry and others to cooperate.

Sincerely,

Robert L. Rizek

Robert L. Rizek
Chairman

Enclosure

UNITED STATES DEPARTMENT OF AGRICULTURE
AGRICULTURAL RESEARCH SERVICE
NORTHEASTERN REGION
Consumer and Food Economics Institute
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March 3, 1975

Dr. Robert E. Shank
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We would certainly appreciate any assistance that your organization could give us, whether it be moral or by encouraging industry and others to cooperate.

Sincerely,

Robert L. Rizek

Robert L. Rizek
Chairman

Enclosure

MEMORANDUM

Inter-Society Commission for Heart Disease Resources

SUITE 316
44 EAST 23rd STREET
NEW YORK, N. Y. 10010
Tel. 212-737-7800

March 3, 1975

TO: See Below

FROM: Donald T. Fredrickson, M.D.

SUBJECT: FTC Proposal on Advertising

In his research for the revised ICHD report on prevention of atherosIcerotic diseases, Dr. Podell has learned of a proposed rules change under consideration by the FTC. An explanation of this action is contained in his memorandum. Because of its potential significance, I believe this deserves our immediate consideration. In addition to our own Panel we are alerting others who may be interested in responding.

Time limits prevent an official action by the ICHD on this issue. Dr. Podell feels, however, that a strong individual endorsement of a statement would be helpful and, possibly, influential. Therefore, I would appreciate it if you would carefully review the attached materials and let me have your response within a week. Specifically, we need your reaction to the following: (1) Do you think this or a similar letter should be sent, (2) Do you have any changes to suggest, and (3) Can we include your name on the letter?

DTF:im
Enclosures

Henry W. Blackburn, M.D.
Jack Bryant, M.D.
Dolph Chianchiano
William E. Connor, M.D.*
Kurt Deuschle, M.D.
Joseph T. Doyle, M.D.*
Charles Fisch, M.D.(President, American College of Cardiology)
Samuel J. Fomon, M.D.*
Richard Gorlin, M.D.
Howard Hiatt, M.D.
Richard E. Hurley, M.D.
Howard Jacobson, M.D.
C. David Jenkins, Ph.D.*
William B. Kannel, M.D.*
Ancel Keys, Ph.D.
Lewis H. Kuller, M.D.*
Norman Lasser, M.D.
Jean Mayer, ~~M.D.~~ Ph.D
Elizabeth Munvies, ~~M.D.~~ Ph.D
William D. Nelligan
Elliot Rapaport, M.D. (President, American Heart Association)

George Reader, M.D.
Anne R. Somers
Jeremiah Stamler, M.D.*
Frederick J. Stare, M.D.
Eugene Stead, M.D.
Paul Stolley, M.D.*
Mary Winston
Ernest L. Wynder, M.D.

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*Member, ICHD Atherosclerosis Study Group

MEMORANDUM

Inter-Society Commission for Heart Disease Resources

SUITE 316
44 EAST 23rd STREET
NEW YORK, N. Y. 10010
Tel. 212-737-7800

March 3, 1975

TO: Atherosclerosis Review Panel

FROM: Richard N. Podell, M.D.

SUBJECT: Federal Trade Commission (FTC) Proposals to Limit the Advertising of Foods Low in Cholesterol and Saturated Fat

The FTC staff has proposed regulations which would severely limit the advertising and marketing of foods based on compatibility with a cholesterol lowering diet. The rationale is that it would be misleading to suggest in any way that lowering blood cholesterol is desirable in order to prevent heart disease. Therefore, ads are to be limited to showing a picture or a statement of the actual label of the food.

While food advertising should be regulated so that it is honest and not misleading, the current proposals might well have a catastrophic impact on the availability of many low cholesterol-low saturated fat food products. It would certainly obliterate the health education impact of current advertising efforts.

Fortunately, the Commissioners and certain elements of the staff are concerned about the possible harmful effects of the proposals. They are especially fearful that by limiting advertising the ability to market new low cholesterol-low saturated fat foods will be handicapped to the degree that these will no longer be available on the market. The effect of the even more restrictive regulations of the 1960's and the proliferation of new products in response to their liberalization in 1971 stands as evidence.

The FTC staff, therefore, is actively soliciting our opinion. Evidently, few medical organizations have commented on the proposals thus far. The FTC staff assures me that the issue is sufficiently fluid at this point so that a powerful statement would very likely influence the outcome.

Attached is a letter I drafted in response to the specific questions proposed by staff. You will see that judgments of a political and regulatory nature are required as well as strictly medical ones. Fortunately, the 1970 ICHD report

provides fairly clear guidelines in each of these areas, and I think that that approach remains consistent with our present views.

Unfortunately, the deadline for comments is a short one, probably April 1, 1975. Therefore, I don't think it will be possible to meet on this as a group. Instead I think we should solicit support for our position from ourselves and our consultants, as individual committee members rather than as the ICHD committee itself. For example, I could sign the letter, and those endorsing its position could signify on the support petition.

Because of the time problem, Don will be canvassing your opinion by telephone. If you have any questions on the technical aspects, please call. I think we have a rare opportunity to influence a very major policy decision.

RNP:im

NOTE: A fire in a telephone company switching facility has interrupted telephone service in our building for an indefinite period. Therefore, I will have to have your response by mail.

DTF

(FTC Staff's Proposed Section Regarding Cholesterol, Fat and Fatty Acid Content Claims)

§437.9 - FAT, FATTY ACID AND CHOLESTEROL CONTENT CLAIMS.

(a) An advertisement shall not contain any representation regarding the fat, fatty acid or cholesterol content of an advertised food, unless such food meets the criteria set forth in 21 CFR §1.18 and carries a nutrient label in compliance with that Regulation. If such food meets the criteria set forth in 21 CFR §1.18 and carries a nutrient label in compliance with that Regulation, an advertisement may contain only those representations which are permitted under 21 CFR §1.18.

(b) An advertisement shall not contain any representation that consumption of an advertised food or a serving thereof will prevent, mitigate or cure, or in any way contribute to the prevention, mitigation or cure of, heart or artery disease or any attendant condition.

(c) An advertisement shall not represent that consumption of an advertised food or a serving thereof will not cause or help cause, or will not increase or help increase the likelihood or risk of, heart or artery disease or any attendant condition.

§437.10 - HEALTH AND RELATED CLAIMS.113/

(a) An advertisement shall not contain a representation that:

(1) A food, because of the presence or absence of certain vitamins and/or minerals, is adequate or effective in the prevention, cure, mitigation, or treatment of any disease or symptom.

(2) A balanced diet of ordinary foods cannot supply adequate amounts of nutrients.

(3) The lack of optimum nutritive quality of a food, by reason of the soil on which that food is grown, is or may be responsible for an inadequacy or deficiency in the quality of the daily diet.

113/ See 21 CFR 51.17(i).

(Analysis)

§ 437.9 FAT, FATTY ACID AND CHOLESTEROL CONTENT CLAIMS.

The Food and Drug Administration's nutrient labeling program strictly regulates the making of label claims regarding the fat, fatty acid and cholesterol content of foods. FDA prohibits any claim linking the consumption of a food to the prevention of coronary disease or to positive effects on existing coronary conditions. It is the Commission's understanding that the intent of the FDA regulations in this area is to eliminate any label representation which, in the absence of medical advice, would tend to confuse or mislead consumers about the relationship between cardiovascular disease and the consumption of foods which contain or do not contain fat, fatty acid and cholesterol. FDA's regulation embodies the view that a consumer's physician--not the consumer alone--should make the judgment as to what, if any, dietary changes should be made to reduce the risk of heart or artery disease or related conditions. The staff would propose a rule consistent with FDA's provision on this subject (see Staff Statement of Fact, Law and Policy). The Commission is concerned that this approach when applied to advertising may prevent the making of certain limited claims which are both accurate and beneficial, and the questions raised below are intended to explore whether or not this concern is justified.

* * * * * * * * *

ISSUES

What claims, if any, concerning food and heart or artery disease or any attendant conditions or the fat, fatty acid or cholesterol content of food, which are forbidden by 21 CFR §1.18 to be made in food labeling, should be permitted in advertising? Why should such claims be permitted in advertising but not in labeling? Is any such claim, even if literally true, likely to carry with it any additional implication(s) which would be deceptive or unfair?

2. Is there any claim concerning food and heart or artery disease or any attendant condition which is not forbidden by 21 CFR §1.18 and which should be allowed in food advertising?

* * * * * * * * *

Inter-Society Commission for
Heart Disease Resources
44 East 23 Street
New York, New York 10010
March 10, 1975

Mr. William D. Dixon
Special Assistant for Rulemaking
Federal Trade Commission
Washington, D.C. 20580

Dear Mr. Dixon:

We the undersigned are physicians, nutritionists, and epidemiologists who are specialists in the preventive aspects of atherosclerotic diseases. We are members of the atherosclerosis review panel of the Inter-Society Commission for Heart Disease Resources. We wish to comment on the Federal Trade Commission staff proposals for trade regulation rule 16 C.F.R. 437.9 (Fat, Fatty Acids and Cholesterol Claims).

The Inter-Society Commission shares with the Federal Trade Commission the concern that food advertising be non-deceptive and that it promote rather than diminish the public health. We have studied the staff proposals carefully. We support the F.T.C. in its conclusion that there should be regulation in this area of food advertising. However we are deeply concerned that staffs' recommendations as now written and interpreted are overly restrictive. We fear that if implemented in the present form the result would be to mislead the consumer, to inhibit the development and marketing of low cholesterol, low saturated fat food options and to contribute adversely to medical and governmental efforts to fight premature heart disease and stroke.

For your convenience we will address our remarks to the 13 questions sent us by the F.T.C. staff.

Question 1: Should all representations in advertising concerning the relationship between fat and/or cholesterol and heart disease be banned (except content statements) following F.D.A. regulations 21 C.F.R. section 1.18?

We are firmly convinced that certain statements about fat and/or cholesterol and heart disease are essential to the public interest. The question should be not whether statements should be allowed but how they should be formulated so as to best serve the interests of fairness and the public health. Possible formulations are considered in answers to later questions. The case that(sub)statements be permitted is detailed below. In brief, it rests on the following arguments:

1. Advertising is different from labeling in purpose and practice: therefore advertising and labeling should be governed by different rules.

2. New information has become available since the F.D.A. prepared 21 C.F.R. 1.18. This information provides a firmer basis for statements about diet and heart disease.

3. Staff's proposals would discourage advertising based on valid health attributes in favor of advertising based on other appeals for example; taste, group conformity pressures.

4. Staff's proposals would discourage marketing of attractive low cholesterol, low saturated fat alternatives to favorite high cholesterol, high saturated fat foods. This would effectively limit range and quality of choice available to the consumer.

5. Staff's proposals would have the objective effect of encouraging the continued intake of the high cholesterol, high saturated fat diet, which is almost unique to this country, at incalculable cost to the public health.

6. The number of persons at risk because of elevated blood lipids represents a large majority of the adult population of the country.

7. Staff's recommendation to restrict all advertising statements except as in 21 C.F.R. 1.18 is in opposition to the spirit of the positions taken by the major American Scientific and Medical Authorities who have considered the relationship between the American diet and the incidence level of heart disease.

These arguments will be considered at this point:

1) Advertising is different from labeling

Food labeling serves primarily to identify a product and its contents. Advertising has always served in a broader role. Advertising must draw a customer's attention to a product and motivate the potential customer by acquainting him with the product by virtues from the customer's point of view. We recognize that there have been cases in which the advertising message has been unfair or deceptive. We note also that much of advertising technology is directed toward the creation of a dramatic rather than an intellectual appeal. However, since the F.T.C. allows legitimate health related claims to be made in the advertising of over the counter drugs and most food products and since great latitude is given to food advertisers in promoting the taste, texture and other qualities of foods, it seems inconsistent that only foods which are low in cholesterol and saturated fat should be deprived of the opportunity to employ the full power of honest and non-deceptive but dramatic and aggressive advertising to persuade the customer to buy the product.

2) Important new information has become available since The Food and Drug Administration regulation 1.18 was fully considered

F.D.A. regulation 1.18 reflects the comments received on proposals published on June 15, 1971 (36 FR 11521). The major research by F.D.A. staff would have taken place prior to publication. Presumably most of the outside comments were received within a year after the proposals were published. Therefore, regulation 1.18 would not have received the full benefit of recent advances with an important bearing on statements to be made in relation to diet and heart disease. Most important the Federal Trade Commission regulations should take into account two publications:

1. Miettinen's study demonstrating a lower heart disease rate among Finnish mental hospital patients treated for twelve years with a cholesterol lowering diet. (Miettinen, M., et.al., Effect of Cholesterol lowering diet on mortality from coronary heart disease and other causes, Lancet 2:835, 1972)

2. The statement on Diet and Coronary Heart Disease of The American Medical Association Council on Foods and Nutrition and The Food and Nutrition Board of The National Academy of Sciences-National Research Council

(J.A.M.A., Dec. 25, 1972), which set forth the rationale for advocating a change of diet for most Americans.

Miettinen manipulated the diets of a thousand men and a thousand women in two mental hospitals during a period of twelve years. For the first six years hospital "N" served a cholesterol lowering diet and hospital "K" served the standard Finnish diet, which like ours is high in cholesterol and saturated fat. During the next six years the diets were reversed. Among men the total coronary death rate was lowered by half during the low cholesterol, low saturated fat treatment period. This difference was highly significant statistically. Among women the diet group had a 33% lower coronary mortality rate, a substantial difference, but one, which owing to the lower coronary mortality rate among women, did not reach statistical significance. Miettinen's study is well designed and greatly strengthens previous evidence that long term lowering of cholesterol and saturated fat levels by diet will reduce the incidence of early atherosclerosis and death.

The American Medical Association-National Academy of Science statement is of special importance because of the attempts which have been made to invoke the physician's opinion and the doctor-patient relationship by those seeking to restrict the marketing of low cholesterol-low saturated fat foods.

We quote from the A.M.A.-National Academy of Science statement:

"In summary, the average level of plasma lipids in most American men and women is undesirably elevated...The evidence now available is sufficient to discourage further temporizing with this major national health problem... Americans should be advised to maintain a desirable body weight by an appropriate combination of physical activity and calorie intake. In "risk categories" (defined in the text as a cholesterol of 220 mgs % and above) it is important to decrease substantially the intake of saturated fat and to lower cholesterol consumption...since the foregoing recommendation will be effective only if they can be accomplished with relative ease modified and ordinary foods useful for this purpose (should) be readily available on the market reasonably priced and easily identified by appropriate labeling. Any existing legal and regulatory barriers to the marketing of such foods should be removed." (Emphasis ours) The complete text of the statement is attached.

3) Staff's proposals would discourage advertising based on a food's valid health virtues.

One of the reasons for consumer support of nutritional labeling was to provide food manufacturer's an incentive to emphasize good nutrition in their product development and marketing strategies more so than was true in the past. One hope was that food manufacturer's might compete by stressing and improving the nutritional virtues of their products as well as the traditional ones such as taste. It was hoped that in this way the free market would serve to educate the consumer while at the same time enhancing the nutritional characteristics of the food from which he must choose. If a particular advertising strategy (e.g. emphasis on the low cholesterol, low saturated fat virtues of the food) is to be severely restricted while other claims (e.g. sweetness) are allowed the full range of modern advertising technique. Then inevitably advertising will focus on the less restricted strategies. The opportunity for health education will be lost. Yet, more important, the incentive of the manufacturer to improve the nutritional qualities of the product would have been negated. Instead he will have every incentive to develop his product to fit a less severely regulated marketing strategy, and there will be no penalty, competitive

or otherwise, if health and nutrition interests are sacrificed in the process.

4) Closely related to the above, staff's proposals would discourage the development and marketing of attractive low cholesterol, low saturated fat alternatives to favorite high cholesterol, high saturated fat food.

The development and marketing of a new food product from the laboratory to national marketing may cost many millions of dollars. The food industry is competitive and management's interest is legitimately to seek profit and to minimize the risk of loss. Therefore any regulation which substantially inhibits the ability to successfully market a particular kind of food, or which casts doubt on the probability that such food can be marketed successfully will, profoundly diminish the probability that a rational manager will commit his company to the risk inherent in introducing such foods. Each food product needs a major selling point that will bring it to the consumer's attention. The major selling point for low cholesterol, low saturated fat foods is obviously the desirable effect of lowering blood cholesterol and the probable long term benefit to cardiovascular health. Realistically, low cholesterol, low saturated fat food products may not taste as good as high cholesterol, high saturated fat alternatives. They may be more expensive or less convenient to prepare. Indeed to the extent that "flavor", and "richness" are provided by fat content, low fat products may be inferior in taste. Is it reasonable to ask the producer of a low cholesterol, low saturated fat food to restrict his dramatic advertising to such appeals as taste, texture, and cost? Obviously not, as it is precisely these virtues which his potential customer must often sacrifice to some degree to obtain the greater virtue of a prudent diet. If the competitor's dramatic representation of satisfaction with the "creamy texture" and "full bodied richness" cannot be balanced by an honest and dramatic explanation of the importance of a cholesterol lowering eating style, then foods for which low cholesterol and saturated fat content is the major virtue will be severely handicapped in the competitive market. The probable result will be the relative unavailability of useful and important technologically feasible low cholesterol/low saturated fat foods.

During the 1960's, when government regulation was most restrictive, industry failed to develop to the point of national marketing many foods which were good alternatives to low cholesterol and low saturated fat food products. We know that the technology for production was available, because these foods were used in scientific studies of diet and heart disease throughout the decade. However, only with the liberalization of labeling and advertising regulations in 1973 did we find many of these products reaching the market. It is our fear and our prediction that if staff proposals are accepted without amendment that the promotion of low cholesterol, low saturated fat foods will be uniquely handicapped. Result we fear will be a loss of these products from the market, a limitation in the ability of the consumer to choose attractive but low cholesterol, low saturated fat foods, and therefore a deterioration of the effort to promote the public's cardiovascular health.

5) Staff's proposals are cast in the language of "neutrality" or "even handedness" however, objectively their effect would be to support our continued intake of diets high in cholesterol and saturated fat.

Except for Finland, the United States' diet is about the worlds highest in terms of saturated fat and cholesterol. This is also true of our rate of atherosclerotic heart disease among persons in their 40's, 50's and 60's.

Long-time habits and government regulation have for decades worked to make any alternative dietary style sufficiently inconvenient or otherwise unattractive so as to be unrealistic for anyone except individuals with a most fervent commitment.

There is a long history of government policy geared to the promotion of high cholesterol and high saturated fat eating styles. Until 1973 even a statement of the cholesterol content of a food on its label was forbidden. The Filled Milk Act forbade interstate shipment of a vegetable oil substituted milks until 1972. The Filled Cheese Act, while a minor nuisance, remains on the books. Mellarine, a low saturated fat alternative to ice cream, remains illegal in many states. Few low cholesterol, low saturated fat alternatives to our major sources of saturated fat and cholesterol are available in the nation's restaurants and cafeterias, much less in the burgeoning "fast-food" chains. This, despite the fact that perhaps a third of all meals are served away from home. Indeed, only last year the Secretary of Agriculture urged the American people to consume more beef.

Therefore, it is (unnecessarily) very difficult to maintain a low cholesterol, low saturated fat diet which is attractive, convenient and reasonably priced. To do so requires more than trivial effort. One of the few balances to the multiple incentives to eat high cholesterol, high saturated fat has been the ability to advertise aggressively and honestly the importance of diets low in cholesterol and saturated fat. Staff's proposals would take away the ability to advertise the importance of low cholesterol, low saturated fat eating. It would continue to permit the advertising of foods on the basis of their "richness" or "creaminess". It would leave untouched the tremendous extra governmental incentives to the maintenance of a high cholesterol and high saturated fat diet.

There are few sources of information and few whose interest is to promote low cholesterol low saturated fat eating. There are many sources of information, and many whose deep interest it is in promoting high cholesterol, high saturated fat intake. To remove from the field of battle one of the very few natural allies of cardiovascular preventive medicine would in our view be deleterious to the health and well being of the public. To remove this ally under the guise of fairness and evenhandedness strikes us as bizarre irony at best.

6) The number of persons "at risk" for high cholesterol is very large.

The justification for severe restriction on the advertising of low cholesterol, low saturated fat food products might have greater validity if the "at risk" population were a tiny minority of the American public. However, the opposite is the case. Using the American Medical Association-National Academy of Sciences cut-off of 220 mg % we find the "at risk" population among middle aged Americans to be about two-thirds of the population in those age groups. The mean blood cholesterol among American men, aged 45-54 was found by the National Health Survey to be 230.5 mg %. Among women it was 236.8 mg %. In contrast, although blood cholesterol levels are not available from representative samples in most other countries reviews of the literature suggests that typical values in Italy, Greece and Yugoslavia are below 200 mg % and among rural Japanese 150 mg % or less.

7) Finally the staff contends "(Federal Register November 11, 1974, page 39850) that the F.D.A. regulations embodies the view that "a consumer's physician not the consumer alone should make the judgment as to what if any dietary changes should be made to reduce the risk of heart or artery disease or related conditions". We heartily concur in urging that all individuals seek the advice

> of their physician as to the nutritional quality of their diet. However this recommendation cannot reasonably be interpreted to deny that there is enough medical authority in this country already on record supporting a general lowering of cholesterol and saturated fat levels to justify statements to this effect in honest and regulated advertising.

The situation is to some degree analogous to that with the two other great heart disease risk factors: hypertension and cigarette smoking. In both instances we urge the individual to consult with his physician. Nevertheless, it is permitted, and indeed in part it is federal government policy to encourage that advertising and education directed toward the general public be done to persuade individuals to not smoke, to have their blood pressure checked and to not drop out of therapy. In both cases the profound and pervasive adverse effects of the risk factors justifies government action. Such action in no way infringes on the privileges or prerogatives of the medical profession. Indeed, the profession supports the assistance of government and private enterprise in promoting good health habits in these areas.

Realistically each individual ultimately makes his own choice to smoke or not to smoke, to stay in blood pressure therapy or not, to consume a diet generally high in cholesterol and saturated fat or low in cholesterol and saturated fat. To suggest that all Americans should eat a diet high in fat and cholesterol unless they have specific medical advice to do otherwise is analogous to saying that all should smoke unless their physician specifically indicates otherwise. As physicians we hope all persons will consult us about their diet. We would like to obtain blood lipid values and provide nutrition counseling to all of them. However, realistically we know that many perhaps a majority will for a variety of reasons not enter into a comprehensive discussion of their nutrition with their physician. Indeed for 50 million American families to enter into such discussions with their physicians periodically would be physically impossible. To negate the value of honest health educational advertising on the grounds that health education must be done only by an individual physician perverts the physician's position. Indeed in some respects staff's interpretations of the position of the medical profession is "more Catholic than that of the Pope". While advocating transferring the full responsibility for nutritional health of the nation to the practicing physician may have a certain superficial appeal, we view it as at best an evasion of a difficult public policy issue and at worse means of justifying in the name of healths and medicine actions actually taken for other reasons.

A brief recapitulation of the medical professions's position is in order. First we must recognize that there is no officially constituted body governmental or non-governmental which is totally authoritative or totally representative of the views of the health professionals on health related public policy matters. However, a number of bodies which are widely representative and generally respected have made policy statements (see attached). Perhaps most important is the joint statement of the Council on Foods and Nutrition of the American Medical Association and the Food Nutrition Board of the National Academy of Sciences-National Research Council. This has been discussed and clearly indicates a recommendation for the majority of Americans to decrease their dietary intake of cholesterol and saturated fat.

In 1971 the national heart and lung institute published the report of its Task Force on Atherosclerosis. The task force consisted of 15 emminent authorities on heart disease from outside the federal government and 5 high level participants from the heart and lung institute. They concluded:

> "The average North American has higher than optimal lipid levels...depending on confirmation by appropriate diet or drug trials, it therefore would appear prudent to the American people to follow a diet aimed at lowering serum lipid concentrations. For most individuals this can be achieved by lowering

serum lipid concentrations. For most individuals this can be achieved by lowering intake of calories, cholesterol and saturated fat".

The Inter-Society Commission for Heart Disease Resources published a report "Primary Prevention of the Atherosclerotic Diseases" December, 1970, revised April, 1972. The ISHD report was the result of more than a years deliberation by twelve emminent authorities in the fields of cardiology and epidemiology. At that time the Commission recommended that a strategy of primary prevention of premature atherosclerotic diseases be adopted as long term national policy for the United States and to implement this strategy that adequate resources of money and manpower be committed to accomplish:

...changes in diet to prevent or control hyperlipidemia,obesity, hypertension and diabetes

...elimination of cigarette smoking

...pharmacological control of elevated blood pressure

"The commission recommends the following modification of diet for the general public, and particularly for individuals with marked increase in risk of premature atherosclerotic diseases.

1. Caloric intake be adjusted to achieve and maintain optimal weight.

2. Reduction of dietary cholesterol to less than 300 mg per day.

3. Substantial reduction of dietary saturated fats."

Others from the medical profession who have endorsed the position that the general level of blood cholesterol is undesirably elevated and should be modified by dietary means include: the National Heart Association, The American Health Foundation, and the Medical Boards of the nations of Norway and Finland.

It is important to recommend a physician consultation about nutrition and heart disease. Indeed such a consultation should be a recommendation to nearly all Americans in order to determine the cardiovascular risk. However since the majority of adults in this country are indeed at high risk, the sense of the resolutions of the various medical and scientific organizations is that medical consultation should occur in conjunction with rather than as a precondition to limiting dietary cholesterol and saturated fat. Indeed from a health point of view one might well recommend a greater need for physician consultation among those choosing a high cholesterol, saturated fat diet, and compulsory cholesterol saturated fat labeling for all food, as recommended by the American Medical Association House of Debates in 1974. However for the purpose of todays discussion the case is sufficiently clear. The weight of medical opinion falls with those who would permit discussion of heart disease and diet and not with those who would eliminate it. While it may be appropriate to restrict statements on a food label which is a small face serving primarily to identify the product, neither private medical authority nor government authority including the National Institutes of Health or the Food and Drug Administration, has indicated the desirability of uniquely handicapping the advertising and marketing low cholesterol, low saturated fat product.

2. If claims, in your opinion, should be permitted, what kinds of claims are permissible, and what qualifications if any should be required?

Most important, advertisers should be permitted to make factually correct statements

of current understanding of the relationship between the diet and heart disease. In doing so they should be permitted to a cite recognized medical authority, for example, to quote directly from the statement of the American Medical Association Council on food and nutrition. Second, the advertiser must be allowed to indicate that his food (if qualified--criteria discussed below) is consistent with recommendations for a diet low in cholesterol and low in saturated fat.

We agree with the staff's opinion that no single product should be allowed to claim that it is by itself effective in lowering blood cholesterol. Narrowly construed certain foods such as oils or special margarine substituted for butter, or chicken substituted for beef will by themselves have a significant effect on the blood cholesterol level. However to rely on single products in lowering blood cholesterol is subject to potential abuse. We are especially concerned that the consumer not view low cholesterol, low saturated fat eating as a "quick fix". The low cholesterol, low saturated fat diet is most satisfying and most effective as part of a total dietary plan for lowering blood cholesterol. Therefore it should be presented in advertising as part of a total plan only. Thus, an individual food may be represented as consistent with or an important part of cholesterol lowering diet but should not be represented as sufficient by itself. Particularly, we do not recommend at this time that food advertising be based solely on a food's content of polyunsaturated fatty acids, but only on its relative or absolute lack of saturated fatty acids and cholesterol.

Comparisons among foods according to the criteria discussed below, should be specifically permitted. The essence of a low cholesterol, low saturated fat diet is the substitution of low cholesterol/saturated fat foods for their high cholesterol, high saturated fat alternatives. There are two distinct kinds of substitutions. First there are products, many of which are of recent development, which simulate the taste and texture of favorite high cholesterol, high saturated fat foods. The low cholesterol egg products, polyunsaturated fat substituted cheeses, and vegetable protein simulations of meats are examples. If the premise is granted that honest and educational advertising should be allowed, then the case for comparing these low cholesterol, low saturated fat products with the standard version would follow readily.

More important from the point of view of practical nutrition, is the substitution of traditional foods which are low cholesterol, low saturated fat foods in the diet for other foods which serve a similar functional role. A most important example is the substitution of chicken, fish or natural vegetable protein for hamburger, steak or pork. Thus, the virtue of chicken is that eating it is of itself a good, but that it is an excellent protein source which lacks the high saturated fat content of its competitor's pork and beef. Thus the recommendation to eat chicken is plausible only in so far as its use as compared tothat of an alternative and functionally analogous food.

That we have chosen certain examples from food products whose labeling regulations are the responsibility of the Department of Agriculture is deliberate. Advertising regulations should cover all food products, whether or not their labeling is regulated by the F.D.A. The role of meat as a contributor to the diet's saturated fat content is too important. Similarly, if one chicken advertiser notes the "golden yellow" (i.e. fat) content of his chickens, should not another be allowed to indicate why it is important to the consumer that his are lower in golden yellow fat?

Advertisers should be permitted although not required to indicate that the dietary prevention of heart disease is only one of several aspects and that attention should be given to other aspects such as cigarette smoking and high blood pressure and that the individual should periodically evaluate his health status with the physician.

Finally, as it is impossible to anticipate all eventualities, particularly in science, where new information is continually being sought, we recommend that a medical-legal review board monitor advertising related to diet and heart disease to assure compliance with the intent of honest and informative health based food advertising.

3. Does an ad which mentions that a food is "low in cholesterol" or "low in saturated fat" overemphasize the role that food plays in reducing blood serum cholesterol levels and therefore its role in mitigating heart disease? Consider for example the role of margarine and vegetable oil in the average diet.

This question should be answered at two levels. First, a relatively small number of foods do contribute a major proportion of the cholesterol and saturated fat to the American diet. For example, in our 1972 report the ISHD recommended the reduction of dietary cholesterol to less than 300 mg per day. We noted that the average American daily cholesterol intake was approximately 600 mg per day. A single egg yolk however contains 250 mg cholesterol, by itself nearly the daily allowance. We further recommended an intake of less than 10% of total calories to be obtained from saturated fat. Assuming a caloric intake of 2500 calories per day the average American should take in no more than 250 calories or less than 27 grams of saturated fat per day. One cup of whole milk contains 5 grams saturated fat. One cup of ice cream contains 8 grams; six ounces of ham approximately 8 grams. These are very substantial portions of the maximum recommended allowance for a day. Therefore the contribution of indivudal foods to the cholesterol and saturated fat intake in the diet can be highly significant. Furthermore numerous studies prove that free living individuals can lower their blood cholesterol levels while using a diet similar to that recommended by the Inter-Society Commission.

The second reason for emphasizing the individual food is because the whole remains the sum of it's parts, i.e. it is only through individual choices that one creates an overall dietary pattern. Elimination of advertising of low cholesterol/low saturated fat foods on the grounds that each mouthful is insignificant would be reductio ad absurdum, reduced, indeed, to absurdity. Ads should state that cholesterol lowering is only effective when part of a total dietary plan, but each element of the plan remains essential.

4. Is the substitution of some foods low in cholesterol or saturated fat for others insignificant so that ad claims would be deceptive i.e., margarine or butter? Should some claims be permitted for certain foods and others banned?

On the basis of our answer to question 3 we conclude that to indicate that a food such as margarine or chicken is preferable to butter or beef as part of a comprehensive diet low in saturated fat and cholesterol is not deceptive. Indeed to indicate anything but the preferability of these products from a cholesterol point of view would result in deception by omission of information, a fault which has properly been deplored by the F.T.C. and staff (39 FR 39855- 39859). Several studies in which free living individuals did indeed lower their blood cholesterol level on this kind of diet are listed in the answer to question 9.

5. Should a food low in cholesterol but high in saturated fat be allowed to make "low in cholesterol" claims? What standard should be set up to evaluate the fat and cholesterol content of food to prohibit such claims?

6. When is a food high, medium or low in cholesterol? Saturated fats? Should the F.T.C. rules set up standard governing "low in cholesterol/fat" claims?

Questions 5 and 6 will be answered together.

There should be a major, but not an absolute overlap between criteria for "low cholesterol" and for "low saturated fat" claims. In addition there should be criteria for comparison claims between foods.

Dietary cholesterol and saturated fat are distinct contributors to blood cholesterol levels. Certain foods which are highly recommended are very low in one element, but only moderately low in the other. For example, chicken and fish are recommended as major protein sources because they are low in saturated fat, especially in comparison to the alternatives beef or pork. However, the cholesterol content of chicken and fish is only marginally less than that of meat and pork. Therefore, there needs be some distinction between the criteria for low saturated fat and low cholesterol claims.

In contrast, we do not wish to encourage products so out of balance that the advantage gained from one aspect of the substitution is outweighed by a disadvantage resulting from another aspect of the substitutions. This caveat applies not only to imbalances related to fat and cholesterol, but to caloric and protein content as well.

While the precise numbers must be considered tentative, we suggest that criteria for low cholesterol/low saturated fat claims take the following lines:

I. To claim "low in cholesterol"
   A typical portion should contain:
   A. $<$25 mg cholesterol, and
   B. $<$2.5 mg saturated fat, or a P/S ratio $\geq$1.0.

This would admit claims for such foods as yogurt, skim milk, egg white, soft margarine, and unprocessed vegetable products. It would not allow claims for chicken or fish.

II. To claim "low in saturated fat"
   A typical portion should contain:
   A. $<$2.5 mg saturated fat, and
   B. $<$10% of calories from saturated fat, and
   C. $<$80 mg cholesterol

This would allow claims for chicken and fish, as well as <u>most</u> vegetable products.

III. To claim a "lower in cholesterol" <u>comparison</u>

   A. The advertised food must serve the same usual purpose in the diet (e.g. main dish,dessert) as the compared food, <u>and</u>
   B. The advertised food must have the same or fewer calories per portion as the compared food, <u>and</u>
   C. If the advertised and compared foods are a "main dish", then the quality and quantity of protein in the advertised food must be generally comparable or superior to that in the compared food, <u>and</u>
   D. The advertised food must contain less than 25 mg cholesterol in a portion <u>and</u> less than 50% of the cholesterol content in a portion of the prepared food, <u>and</u>
   E. The advertised food must have 80% or less the content of saturated fat and a P/S ratio no lower than in the compared food.

IV. To claim a "lower in saturated fat" comparison

   A. Criteria A, B and C of III apply, <u>and</u>

B. The advertised food must contain <2.5 gm saturated fat per portion and < 50% of the saturated fat content per serving and a P/S ratio no lower lower than that of the compared food, and
C. The advertised food must contain less than 50% of the per portion cholesterol content of the compared food.

Consideration should also be given to indicating the advertised foods content of cholesterol and saturated fat in terms of "recommended maximum allowances" for example, 300 mg per day cholesterol and 250 (10%) of calories saturated fat.

7. What evidence is there that diet resulting in high cholesterol and fat levels in the blood contributes to heart disease?

This question has been reviewed exhaustively. We will briefly recapitulate the case for primary prevention of heart disease. The initial stimulus linking high cholesterol high saturated fat diet resulted from the striking correlation of heart disease rates with the affluence of nations both geographically and temporally, in the light of the famines which occurred in Europe after World War I and World War II. The long term study of single populations such as that of Framingham, Massachusetts established the blood cholesterol level as an import predictor of heart disease. Such studies did not and were not designed to demonstrate the causal relationship between the blood cholesterol and heart disease or the ability of dietary changes to prevent the development of heart disease. The Framingham work was extended and Angel Keyes in his monumental Heart Disease in Seven Countries. Keyes found in 22 populations a striking correlation between the dietary intake of saturated fat, the blood cholesterol levels and the development of heart disease, strengthening the circumstantial evidence favoring the lipid hypothesis. On a pathological basis the fact that lesions of atherosclerosis are primarily made up of cholesterol further increased the suspicion that blood cholesterol levels was the link between diet and heart disease. Indeed international comparison of autopsies demonstrated that Americans develop more atherosclerosis and at a younger age than do individuals in countries with a diet that is lower in cholesterol and saturated fat.

Thus far, however, the evidence is suggestive only. Direct proof comes from two sources. First many investigators have succeeded in reproducing lesions similar to that found in human atherosclerosis in primates fed diets which are high in cholesterol and saturated fat. Such lesions do not occur on standard diets. Recently controlled studies demonstrated that monkeys fed a typical American diet had more atherosclerosis than monkeys fed a so called "prudent" low cholesterol, low saturated fat style diet. Furthermore monkeys switched to a low cholesterol diet after a period on the high cholesterol, high saturated fat diet showed less atherosclerosis than monkeys on the high cholesterol, high saturated fat diet for the same duration of time, suggesting a regression in atherosclerosis caused by the adoption of the prudent diet.

The relevant human evidence concerns primary prevention. Thus far there have been published only three controlled studies in primary prevention of heart disease using a low cholesterol, low saturated fat diet. In each there was a sizeable decrease in the incidence of new coronary events in the experimental compared with the control groups. Although it is possible to criticize each study on devil's advocate technical grounds, these remain the most relevant trials of primary prevention published to date.

Obviously studying large populations of free living individuals over many years is difficult. Indeed the United States government rejected as too expensive a proposal to fund a definitive study on the effect of diet and heart disease. Thus we are forced to weigh the evidence and to conclude on the basis of a preponderance of evidence rather than on unequivocal proof. Nevertheless the preponderance of evidence has been sufficient for the A.M.A. council on Food and Nutrition, the American Heart Association, the Food and Nutrition Board of the National Academy of Science, the Inter-Society

Commission for Heart Disease Resources, and the Atherosclerosis Task Force of the National Heart and Lung Institute of N.I.H. Each report concluded that there is probably a causal and treatable relationship between the diet and an individuals chance of developing premature heart disease. The bibliography is attached.

8. In your opinion should the average American lower his or her cholesterol/fat intake?

We recommend that the average American lower his or her dietary cholesterol/fat intake.

9. What studies are available which indicate that a lowering of the dietary intake of cholesterol and saturated fat results in the lowering of serum cholesterol levels?

There are many studies. The most important study of the effect of diet on cholesterol levels was the national diet heart study whose report was published in supplement number one to the March, 1968 edition of Circulation. The national diet heart study established conclusively that in a free living situation motivated and educated individuals could adhere to a diet restricted in saturated fat and cholesterol which would result in a substantial lowering of blood cholesterol levels. A recent view of the literature on cholesterol lowering diets was conducted by Anderson J. et. al. in the Journal of the American Dietetic Association, Volume 62, page 133-142, February, 1973.

10. Do you agree or disagree with the proposed provisions section 437.9 B and C?

We submit that these sections should be clarified to widen the interpretation beyond that allowed in the staff discussion. Thus, section B should specifically allow a statement that food meeting criteria is consistent with recommendations for a low cholesterol, low saturated fat diet. It should require a statement that a lowering cholesterol should be undertaken as part of a total diet plan. It should require a statement urging the individual to seek the advice of his personal physician. It should allow a statement of what a balanced low cholesterol, low saturated fat diet would entail. It should allow a statement that a comprehensive program of heart disease prevention should include other measures such as treating high blood pressure and reducing or eliminating cigarette smoking. Specific comparisons between foods should be allowed. Regulation of advertising should be extended to include the regulation of claims about those foods in which labeling is regulated by the Department of Agriculture.

Section C should be interpreted (or amended) to mean that "An advertisement shall not represent that consumption of an advertised food by itself or a serving thereof will not cause or help cause, or will not increase or help increase the likelihood or risk of, heart or artery disease or any attendant condition".

11. Is there any benefit to consumers to permitting an advertiser to disclose in the ad the total fat content of the advertised food in terms of the total calories provided by fat? In terms of the amount of saturated and polyunsaturated fats present in the food? In terms of the saturated to polyunsaturated fat ratio?

All measures are useful. The first two are essential, the last, convenient, but optional, if the first two are provided.

12. Is the proper way to measure "fat" content the absolute amount of saturated and unsaturated fat, calculated independently or a ratio of saturated to unsaturated fats? Should advertising claims comparing the fat content of foods

be permitted? If no, should the comparison be on the basis of the absolute ratio of saturated/unsaturated of each product. If comparisons were limited to "significant" differences only, what, in your opinion would be significant differences in fat levels between two foods?

Both absolute amounts of saturated fats and P/S ratios are useful, the former being more informative.

Comparisons should be allowed because the entire rationale of the cholesterol lowering diet is based on the substitution of relatively low cholesterol, low saturated fat foods for relatively high cholesterol, high saturated fat foods. Criteria for comparisons are discussed in the answer to question #6. These should reflect both absolute amounts and ratios of fats as well as other nutritional considerations. "Significant" differences should mean reductions of at least 20% and preferably 50% in the cholesterol or saturated fat content.

13. The opinion of the major bodies of medical opinion is clear, in its recommendation for typical American adults.

There should be a reduction of cholesterol and saturated fat and one's physician should be consulted. However, there is not the slightest suggestion anywhere that a high cholesterol-high saturated fat diet is preferable for anyone. In no case does the recommendation to consult a physician suggest that one should choose a high cholesterol, high saturated fat diet unless specifically directed by a physician. To suggest as in 39 F.R. 39850 that physicians recommend a high cholesterol-high saturated fat diet for adults is a gross misinterpretation of the opinion of the medical profession. To quote the Council on Food and Nutrition of the American Medical Association:

> "The average level of plasma lipids in most American men and women is undesirably elevated...The evidence now available is sufficient to discourage further temporizing with this major national health problem. In "risk categories" (defined in the statement as cholesterol level of $\geq$ 220 mg %, thus including most adult Americans) it is important to decrease substantially the intake of saturated fat and to lower cholesterol consumption." (Parentheses ours) - J.A.M.A. December 25, 1972

Clearly there is sufficient medical opinion to justify a change in diet for most Americans. While we hope all Americans will seek nutritional advice and lipid evaluation, such advice is to be viewed as supplementary to rather than as a pre-condition for the dietary restriction of cholesterol and saturated fat.

Finally, we note that our case is directed toward reducing cholesterol and saturated fat. We have not specifically recommended a major increase in poly-unsaturated fatty acid consumption, which is controversial. In addition we are withholding our recommendations as to the diet of infants and small children.

We thank you for this opportunity to comment. If you have questions on our comments or would like us to give oral testimony or consultation we would be happy to do so.

Yours truly,

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Council on Foods and Nutrition

Diet and Coronary Heart Disease

A Council Statement

Coronary heart disease is the major public health problem in the United States and in many other countries. In 1970, for example, some 666,000 Americans, of whom about 171,000 were under the age of 65, died of coronary heart disease (CHD) and many more were disabled by the same disorder. It is particularly disturbing that many relatively young Americans in their most productive years are killed or incapacitated by this disease.

Epidemiologic, experimental, and clinical investigations have identified a number of "risk factors" associated with susceptibility to CHD that can be manipulated. These include an elevation in plasma lipids, especially plasma cholesterol, high blood pressure (hypertension), heavy cigarette smoking, obesity, and physical inactivity. The evidence is not sufficient to quantitate the benefits that may be expected to come from modifying these various risk factors, but the seriousness of the situation demands that all reasonable means be used to reduce the conditions that contribute to risk of CHD.

There is abundant evidence that the risk of developing CHD is positively correlated with the level of cholesterol in the plasma. This risk, independent of other risk factors mentioned above, is relatively small at levels less than 220 mg/100 ml but increases progressively with each increment in plasma cholesterol above this level. Approximately one-third of American men, and a less definitely known proportion of women, consuming their usual diets maintain plasma cholesterol levels at or below 220 mg/100 ml. There is extensive evidence that the level of cholesterol in the plasma of most people can be lowered by appropriate dietary modification. Generally, such lowering can be achieved most practicably by partial replacement of the dietary sources of saturated fat with sources of unsaturated fat, especially those rich in polyunsaturated fatty acids, and by a reduction in the consumption of foods rich in cholesterol. Preliminary evidence suggests that faithful and continued consumption of a cholesterol-lowering diet over a period of years can reduce the coronary attack rate in middle-aged men. As would be expected in dealing with a chronic disease of this kind, early intervention appears to be more effective than intervention after the disease is evident.

Elevation of other plasma lipids (plasma triglycerides) also imposes an increased risk of CHD. The elevation of plasma triglycerides is often, but not always, associated with an elevation of plasma cholesterol. Plasma triglycerides can also be modified by dietary intervention. Although there are as yet no satisfactory epidemiologic data to support the conclusion that triglyceride-lowering diets can reduce the occurrence of CHD in persons with hypertriglyceridemia, the inference from clinical studies that such a reduction can be anticipated is strong.

In summary, the average level of plasma lipids in most American men and women is undesirably elevated. The importance of lowering the plasma cholesterol in any individual depends in large part upon his usual plasma cholesterol concentration.

The evidence now available is sufficient to discourage further temporizing with this major national health problem. Therefore the Food and Nutrition Board and the Council on Foods and Nutrition recommend that:

(1) Measurement of the plasma lipid profile, particularly plasma cholesterol, become a routine part of all health maintenance physical examinations. Such measurements should be made in early adulthood, when coronary heart disease is still rare, and repeated at appropriate intervals. The potential impact of other risk factors should also be periodically assessed.

(2) Persons falling into "risk categories" on the basis of their plasma lipid levels be made aware of this and receive appropriate dietary advice. Such advice may vary somewhat with the nature of the blood lipid profile.[1-4] As indicated above, Americans should be advised to maintain a desirable body weight by an appropriate combination of physical activity and calorie intake. In "risk categories" it is important to decrease substantially the intake of saturated fat and to lower cholesterol consumption. In practice, this entails substituting polyunsaturated vegetable oils for part of the saturated fat in the diet.

(3) Care be taken to assure that the dietary advice given does not compromise the intake of essential nutrients. Desirable intakes of nutrients are indicated in the recommended dietary allowances found in the National Academy of Sciences publication 1694 (1968).

(4) Since the foregoing recommendations will be effective only if they can be accomplished with relative ease, modified and ordinary foods useful for this purpose be readily available on the market, reasonably priced, and easily identified by appropriate labeling. Any existing legal and regulatory barriers to the marketing of such foods should be removed.

(5) High priority be given to the conduct of studies that will determine reliably the extent to which the modification of plasma lipids, by dietary or other means, as well as modification of other risk factors, can reduce the risk of developing coronary artery disease.

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4. American Health Foundation: Position statement on diet and coronary heart disease. *Preventive Med* 1:255-286, 1972.

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UNITED STATES DEPARTMENT OF AGRICULTURE
Agricultural Research Service

NUTRIENT DATA BANK

Robert L. Rizek, Elizabeth Murphy, and Susan Gebhardt
Consumer and Food Economics Institute

With the adoption of nutritional labeling, there has been a resurgence of interest in research relative to food composition. This renewed interest has focused attention on the Nutrient Data Bank (NDB) of the Department of Agriculture. The NDB will serve as an international repository of analytical data on all food and beverage products and their ingredients. It will provide a storehouse of information useful to nutritionists, food scientists, dietitians, doctors, and consumers. One immediate and direct utilization of the data bank will be the use of the data in the revision and updating of the next edition of Agriculture Handbook No. 8 (AH-8).

The Department's interest in food composition data is not new. In fact, USDA, through its Consumer and Food Economics Institute and predecessor groups, has developed food composition data for over 80 years. It was in 1896 that the Department published Dr. Atwater's extensive table of food values, the first such table in the United States.

Since then, tables on food composition have been expanded to include additional foods and data for many nutrients now known to be important to man. The Department's basic publication, AH-8, last revised in 1963, contains data on six minerals, five vitamins, calories, proximate composition, cholesterol, and fatty acids. In addition, tables have been published which contain data on amino acids, food yields, and three additional B-vitamins. An updated cholesterol table was published in 1972. A new handbook, No. 456, now in final preparation, will give values for most of the nutrients in AH-8, in terms of common household and market units of foods.

Since the USDA has had in reality a nutrient data bank for many years, what is new and worthy of attention today? The answer is a greatly accelerated program, with active participation and far greater input from industry. The amount of data to be made available and the speed with which data will be released will be increased greatly; moreover, data will be in a form suitable for computer use.

One might question this development of the NDB in view of the fact that the FDA has indicated that representative data from sources such as USDA AH-8 are not now sufficient to be a basis for nutritional labeling.

Talk by Robert L. Rizek at the 27th Annual Reciprocal Meat Conference of the American Meat Science Association, June 19, 1974, Texas A & M University, College Station, Texas.

FDA representatives have pointed out that for each product, it is essential that representative data be checked by analysis of individual lots at least until more complete food composition data are available on an industry wide, regional, and manufacturing basis. However, they, as well as USDA officials, have said that in time, as the Nutrient Data Bank is developed so that it includes data on individual analyses, methods of analyses, and the standard errors of the data, these data, backed up by periodic analytical spot checks, can be used for nutritional labeling.

There is one use of AH-8 in nutrition labeling which until recently has been overlooked. That use is to determine in a product those nutrients unlikely to occur in labelable amounts. Review of representative data for a specific product may indicate that only two or three of the nutrients in it may be expected to reach 2 percent or more of the U.S. RDA. A profile analysis for all of the nutrients would not be necessary, and under these circumstances a food company might request analyses only for those nutrients that are likely to be present at 2 percent or more of the U.S. RDA.

In 1971, the Department was approached by industry regarding the possibility of expanding our efforts in this major area of concern. Since that time, considerable progress has been made. The nutrients to be included in the data bank have been specified, and a format for submitting data for the bank and updating previously submitted data has been developed, pretested and sent to participating trade associations, companies, universities, laboratories, etc. Through the cooperation of the FDA, a contract has been completed to develop a coding system for identifying foods. We are now in the process of letting a contract with the cooperation of the FDA to develop the necessary software for the NDB.

The NDB will include substantially more data than that is now available from the USDA--primarily AH No. 8. In fact, the NDB can be reviewed as three different data bases--each of which will be of interest to different users.

Data Base I will consist of the individual analytical values for each food analyzed and supplied to the NDB--from industry, universities, or government. Also included in this data base will be the entire sample description, i.e., date of analysis, method of analysis, variety, breed, maturity, location of production, etc. Each scientist doing work in food composition will have at his fingertips the results of all analyses that have been completed on the food or product he is concerned with.

Data Base II will provide composite values, as well as the standard errors, by breed, variety, maturity, location of production, method of cooking. etc. This data base will be of interest to research scientists as well as those concerned with nutritional labeling.

Data Base III will consist of nationwide composite representative values for each food--quite similar to that data now available in AH-8, except that the number of foods and the nutrients included will be considerably expanded.

One immediate and direct utilization of the NDB will be the publication of the next edition of AH-8. Except for the change in form--it will be published in looseleaf form--and an expansion in the number of foods and nutrients covered, the revised AH-8 will continue primarily as it has in the past--giving representative nationwide values for the nutrients in foods. In addition, the new edition will include, whenever practical, the standard errors of the overall composite values, and the composite values and standard errors by variety, stage of maturity, etc.

A review of the data submission form (ARS Form 200) which has been developed jointly by industry and government for use with the NDB will help in understanding the scope and content of the effort underway. The form is divided into two general sections. One is for providing a detailed description of the sample analyzed and other information needed to evaluate and code the data. The other is for posting of data on approximately 100 nutrients and related compounds of foods as well as for reporting analytical methods used in their analysis. Included are proximate components, minerals, and fat soluble vitamins, water soluble vitamins, amino acids, and lipids.

Since the development of Form 200 and its distribution to potential contributors, it has been suggested that its complexity has discouraged participation. Let me assure you that this was not its intent. On initial inspection it is complex. However, it must be realized that the form was designed to cover every possible nutrient for any food that might be analyzed. It is not expected that any one food will include values for all or even for most of the nutrients specified. We know that initially, analyses will only be completed for a limited number of nutrients. The nutrient data, as well as that data requested for sample description is the ideal--that which is needed for a truly complete data bank.

The question has also been raised as to whether or not it is necessary to use Form 200 in submitting data to the NDB. The answer to this is "no." If data are available in machine readable form or on company's internal forms, etc., they are perfectly acceptable. It is essential, however, that the data be accompanied by as much of the descriptive information about the product analyzed as is available. In our discussion with a number of companies that either are submitting data or are planning to submit data, it is evident that in the past they have not obtained and/or retained sufficient data on sample description. They are finding, however, that little additional effort is required to maintain a data system that will provide all of the information that is essential for the data bank.

Sample Description

Careful identification of the food sample is essential for evaluation of the data and for proper coding. Consequently, considerable information is required related to the description and identification of the food items. To assist the data supplier in providing adequate descriptive details of the food item, a comprehensive checklist has been included to ease the task of describing the sample and to call attention to the kinds of information that can be given.

Information needed includes such things as the generic and scientific names of the food, geographic location and target market for which the item was prepared, ingredients and directions for use, and any standards of compliance or identity which the product meets.

Product and processing information asked for includes treatments applied to the food, such as bleaching, curing, and pickling; processing techniques--canning, freezing, dehydration, and milling; method of cooking; physical state of the food; portion of the food analyzed; and class, grade, variety, or species.

In addition to the descriptive information about the food product and its nutrient contents, it is essential that the methods of sample preparation and analyses be provided. In most instances, these will probably be standard methods such as those of the Association of Official Analytical Chemists. Reference to the chapter and paragraph numbers in a publication such as AOAC is satisfactory. Reference only to the edition is not sufficient as there is more than one method for determining some nutrients in some foods. In referring to looseleaf publication on analytical methods, methods should be identified by date as well as by method number.

For mineral element determinations, certified samples of orchard leaves and beef liver are available from the National Bureau of Standards. Laboratories may want to analyze one of these standard samples along with their food samples, as a measure of the accuracy of their analytical procedures.

Nutrients

Proximate Composition: The initial nutrient section of the form is for entering data on the energy-yielding components of foods--protein, fat, and carbohydrate--as well as data on specific carbohydrate fractions, dimensions and weight of specified portions, and refuse.

Protein values are to be calculated by multiplying the nitrogen content of the food, measured by the Kjeldahl method, by suitable specific factors. Such factors are given in Table 8, page 161, AH-8. The general factor, 6.25, should not be used where more specific factors are available, such as 6.38 for milk and milk products, or 5.71 for

soybeans. For food mixtures the approximate proportion of total nitrogen coming from the different ingredients should be specified and used as weights with appropriate factors for converting nitrogen to protein.

The Atwater calorie factors will be used for estimating food energy in the NDB. For carbohydrates, these factors were developed for use with values derived by difference between the weight of total solids and the sum of the weights of protein, fat, and ash. Therefore, it is necessary to have information on total solids (or on the converse--moisture) and total ash content for each food.

Furthermore, crude fiber, which is included in total carbohydrate used in calculating energy values by the Atwater factors, should not be subtracted from the total carbohydrate value submitted for the data bank. For some foods, such as fruit juice and preserves, the Brix reading is used in calculating total solids and is included in the first nutrient section of the form. Starch is also included, as are five specific sugars--sucrose, glucose, fructose, lactose, and maltose. These nutrients, although not required for nutritional labeling, are receiving increasing attention from nutritionists. As their specific roles in nutrition are worked out through research, the need for data on their contents in foods may become critical.

Mineral Elements and Fat Soluble Vitamins: In the second nutrient section of the data submission form, 17 mineral elements are included. They are split into two groups--a group usually found in macro or semi-micro amounts and a group of trace elements. The two groups are:

Macro		Trace	
Calcium	Chlorine	Chromium	Cobalt
Iron	Magnesium	Copper	Fluorine
Phosphorus	Potassium	Iodine	Manganese
Zinc	Sulfur	Molybdenum	Selenium
Sodium			

Listed on the same pages with the mineral elements are the fat-soluble vitamins: Preformed vitamin A, beta-carotene, alpha-tocopherol, and vitamin D. Space has been provided in an addendum so that data on the various carotene and tocopherol fractions can be reported. Data on carotene fractions are especially needed because retinol equivalents, to be accurately calculated, require data on a larger number of carotene fractions and their various stereoisomers than have been available in the past.

Water Soluble Vitamins: The water soluble vitamins included in the third section of the form are:

Vitamin C	Vitamin B_6
Thiamin	Biotin
Riboflavin	Folacin
Niacin	Vitamin B_{12}
Pantothenic Acid	

For vitamin C, space is provided for recording dehydroascorbic acid as well as reduced ascorbic acid. For many foods, of course, amounts of dehydroascorbic acid are negligible and can be ignored. However, in some foods, certain frozen foods for example, dehydroascorbic acid is present in significant amounts.

In some instances, it is necessary to make corrections in reporting the vitamin content of foods. Thiamin should be calculated as thiamin chloride hydrochloride. Pantothenic acid should be corrected if necessary for calcium in calcium pantothenate, the standard commonly used in analyses for this vitamin. For vitamin B_6 or its fractions, correction should be made for the hydrochloride part of the standards used in its determination.

Vitamin B_6 is generally determined as the total vitamin. Occasionally, however, it is separated into its three principal forms--pyridoxine, pyridoxal, and pyridoxamine--with each fraction determined separately. Provision has been made in the data submission form for providing data on the separate fractions and the sum of these fractions, as well as for data on total vitamin B_6 obtained without separation into its component parts.

Niacin will be included as preformed niacin, which is specified by the Food and Drug Administration for use in nutritional labeling, and as niacin equivalents.

Amino Acids: The fourth area of nutrient information relates to amino acids. Those included are:

Tryptophan	Threonine	Isoleucine
Leucine	Lysine	Methionine
Cystine	Phenylalanine	Tyrosine
Valine	Arginine	Histidine
Alanine	Aspartic acid	Glutamic acid
Glycine	Proline	Serine

Only total amino acids are to be included. Free amino acids, which are of importance to flavor and quality, are not important to determining nutritional content. Available amino acids are not suitable for use in nutrient composition tables at this time, either, since little is yet known about the amounts present in various foods, or factors affecting those amounts.

Lipids: The lipid components included are:

Lipid Fractions	Individual Fatty Acids	
	Saturated	Unsaturated
Cholesterol	Butyric 4:0	Oleic 18:1
Total glycerides	Caproic 6:0	Linoleic 18:2
Phospholipids	Caprylic 8:0	Linolenic 18:3
Glycolipids	Capric 10:0	Arachidonic 20:4
Total trans fatty acids	Lauric 12:0	Docosahexanoic 22:6
Polyunsaturated fatty acids	Myristic 14:0	
Saturated fatty acids	Palmitic 16:0	
	Stearic 18:0	
	Arachidic 20:0	

The FDA has specified the analytical methods for total polyunsaturated and saturated fatty acids which will be used in determining compliance with labeling requirements. For individual fatty acids and other lipid components, data for the NDB may be obtained by usual methods such as gas-liquid chromatography.

As I indicated, a contract was let last year by FDA to develop a coding and data retrieval system. The Department has worked with the FDA, the food industry, and others in this endeavor so that the system will be of maximum value to all users. The objectives of the system are to uniquely identify each food item or ingredient in the NDB; provide information on the characteristics of each item included in the bank, including the method and date of analysis, and provide a highly efficient retrieval system. The system has been designed to allow for the addition of new foods as they are developed.

Food Code

The food identification code for entry and retrieval of food items from the Nutrient Data Bank will consist of two parts--a food term and qualifiers.

The food term will be a four character alpha code.

Food Term

Character	Meaning
1	Major Food Group
2	Subgroup
3	Preferred Term
4	Specific Term

The first character will identify the food item as belonging to one of the 21 major food groups which have been developed by grouping foods with similar commodity characteristics.

21 Major Food Groups

A. Meat (other than poultry)
B. Dairy Products
C. Poultry, Reptiles, their Eggs and Insects
...
...
G. Sausages and Luncheon Meats
...
T. Seasonings and Condiments
U. Leavening Agents and Additives
V. Baby Foods

Character 2 designates the food item as belonging to a subgroup of one of the major food groups. The subgroups for meat are:

A. Meat (other than poultry)

a) Beef
b) Veal
c) Pork
d) Lamb and Mutton
e) Goat
f) Other Meat
g) Mixtures of Meats

Subgroups are further divided into preferred term or specific term which provide a more detailed description of the subgroup. The preferred and specific terms for cuts of meat were taken from the standard (list of names) published by the National Livestock and Meat Board.

Expanded and more complete specificity in the use of the food code is made possible by the use of qualifiers, which will use an alpha/numeric code. Approximately 2,600 qualifying terms have been identified for further specifying the food items. They include: Processing terms, cooking methods, grades, auxiliary components, packaging materials, and other information needed to describe the production, processing, and analysis of the food items.

An example is the complete identification code for a choice grade, broiled, porterhouse steak, lean with visible fat analyzed which would be AAHC D022, F019, J009. This is formed as follows:

Food Identification Code

Food Term	Qualifiers
AAHC	D022, F019, J009
A Meat group	D022 Choice
A Beef	F019 Broiled
H Loin	J009 Lean with visible fat
C Steak, porterhouse	

Data Needs for Meat

Meats contribute significant amounts of nutrients to the national diet. Therefore, it is essential to have reliable up-to-date information concerning their nutrient composition.

Improving the present data for raw and cooked meats requires carefully planned coordinated studies. For beef and other meats there is very little information on paired samples of raw and cooked cuts from the same animal. Mostly the available data are from unrelated sources and hence of dubious value for comparative purposes.

The appropriate relationship among cuts of meat from different parts of the same carcass needs to be preserved; a random selection of market samples would not provide this relationship. The cuts need to be described in terms meaningful to the consumer as well as the research worker--this includes grade of the meat and proportions of separable lean and separable fat and bone for cuts with bone. In addition to information on proximate composition and energy values, data are needed for vitamins, minerals (including trace elements) and lipid components, including cholesterol.

To be of maximum usefulness, it is essential that studies be designed to show the effects of customary production, processing and preparation practices. For instance, hogs have been genetically improved to produce leaner animals, but we do not have nutrient information to reflect this change. Processed meat products--such as sausages containing several types of meat and products in which soy or other meat extenders are used--is another area where analyses are needed. Also values for variety meats, widely used in ethnic dishes, are scarce.

Data are needed to answer the question of what happens during cooking to the vitamins, minerals, and lipid components of meat cooked by various methods at different temperatures and to varying degrees of doneness.

Summary

At the initiation of a major project, such as the NDB, it is difficult to predict when it will be completed. Completion will depend to some extent on the inflow of data in terms of quality, quantity, and speed. Indeed, it could be argued that the NDB will never be completed as it is a living repository of analytical data. However, stages of development have been outlined which will give an indication of availability of the data.

Initial releases of the NDB will include the individual analytical values for each food which have been screened and appear to be acceptable. These data, in all likelihood, will be released by food groups in the following order: Meat and meat products, cereals, dairy

products, and fruits and vegetables, with the first group being made available within the next 2 years. The derivation of representative values which consumes considerable time, will be delayed until a large portion of the data are received, evaluated as to reliability, and made available through the computer data bank.

It is hoped that the computer data bank will be fully operational with most individual and representative values and standard errors available to the public within 3 years. The new edition of Agriculture Handbook 8 should follow shortly after that.

Both the computer data bank and the successor of AH-8 will be updated on a continuing basis as new data are obtained for nutrients in the foods already included in the NDB or as industry develops new food products. In this way, users will have the latest, most complete data that are available.

The NDB will be available to anyone who may have need for this type of data. Although plans have not been finalized, the computer data tapes probably will be made available for purchase through a private contractor, similar to the way the tape for AH-8 is now handled. In addition, the software programs developed by the Department for the NDB as well as for use in Departmental research programs will also be made available. The new edition of AH-8 will be handled through the regular government publication process. A listing of those obtaining either of the two systems will be maintained so that they can receive any revised or new data as they are released.

February 21, 1975

Dr. Jean Mayer
Department of Nutrition
Harvard School of Public Health
677 Huntington Avenue
Boston, Massachusetts 02115

Dear Jean:

This is written to invite you to attend the meeting of the Nutrition Committee of the American Heart Association on March 20, 1975. The Committee will meet in Suite C of the Biltmore Hotel in New York City. You will be our guest and the AHA will be responsible for the costs of your travel.

As discussed in our telephone conversation, we would like to hear your thoughts and counsel concerning possible new roles for the AHA and this Committee in attempting to get information concerning diet to the public and making these efforts more effective. Several items on the agenda of the upcoming meeting pertain to this subject. Your suggestions would, therefore, be helpful and carefully considered.

The Committee will meet at 9:00 a.m. and I shall save the time from 11:00 a.m. to 1:00 p.m. for this discussion. Come at a time convenient to you.

We look forward to seeing you again.

Sincerely,

Robert E. Shank, M. D.

cc:Mrs. Mary Winston, AHA

February 17, 1975

Dr. Robert W. Harkins
Director of Scientific Affairs
Grocery Manufacturers of America
Washington, D.C. 20005

Dear Dr. Harkins:

The Nutrition Committee of the American Heart Association is concerned with education of the public in best food choices for purposes of health and avoidance of heart disease. The Committee desires to launch new educational programs which will take advantage of new food labeling information. Moreover, it has in the past developed informational materials for use by physicians in assisting patients in modifying diets for health purposes. A major limitation in these efforts is the incompleteness of currently available tables of food composition. We therefore are sincerely interested in the program under your direction to develop a Data Bank.

The American Heart Association and its Nutrition Committee would like to advise the food industries that this is an undertaking which will serve a very useful purpose and will do much to advance the health interests of Americans. We would like to offer our encouragement and support and would appreciate any specific suggestions you might like to offer us for our participation and involvement.

I would be very grateful, also, if you could provide me any materials which are available describing the Data Bank and the procedures utilized in compiling this information.

Very sincerely yours,

Robert E. Shank, M. D.
Chairman, Nutrition Committee
American Heart Association

cc:Mrs. Mary Winston

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Robert E. Shank, M. D.
Chairman, Nutrition Committee
American Heart Association

cc:Mrs. Mary Winston

LIPIDS IN FOODS: PROBLEMS AND PROCEDURES IN COLLATING DATA

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NUTRIENT DATA COLLECTION

The promulgation of nutritional labeling (*Federal Register,* March, 1973) has reemphasized the need for additional and more complete quantitative data on the nutrient components of all foods. The urgency for such information is universally appreciated, and the Nutrient Data Research Center of Consumer and Food Economics Institute at USDA has been and is actively soliciting, collecting, and tabulating nutrient data (Murphy et al., 1973; Watt et al., 1974). Most data are obtained from published literature (bulletins and research reports) and private communications. A pronounced increase in analyses of food composition by industry, agricultural experiment stations, universities, and government laboratories is anticipated. These analyses should provide a more reliable base from which comprehensive food tables can be assembled because in contrast to many publications, their primary objective is quantification of nutrient components in composite samples of foods.

The need for nutrient information has accelerated the establishment of a Nutrient Data Bank (NDB) (Rizek and Murphy, 1973). This computerized system provides a mechanism whereby incoming food composition data from industry, various laboratories, and literature publications will be appropriately coded and individually entered into a computer bank. From this bank it will be possible to calculate nationwide representative composite values and ranges for various nutrients in a food and to correlate specific compositional differences with variety, season, processing method, cooking regime, etc. The descriptive information is coded to facilitate retrieval by any of several designations, according to ingredient, target market, food standards, or particular nutrient.

This data bank will be a repository for all food composition data, both domestic and foreign, obtained from various plausible sources, viz., research reports, contract work, and continuous literature screening. It will include all known nutrients, essential and nonessential. When in

*On leave from Cornell University, Department of Food Science, Ithaca, N.Y.

operation, this bank will significantly expand the ability to rapidly handle (collection, tabulation, averaging, correlation) and retrieve information on food composition.

As a valuable information source the data bank will be used by consumer groups, medical epidemiologists, nutritionists, dieticians, food scientists, researchers, teachers, food processors, quality control and product development personnel, and biostatisticians.

Because of its inherent flexibility, facilitating the continual addition of data from current literature, the data bank will be up-to-date. Cumulating data will eventually permit the precise quantification of the effects of various production (breeding, genetic selection, variety), processing, cooking, and storage parameters on individual nutrients. It will facilitate the derivation of more universally valid conversion factors and ultimately enable the formulation of a completely balanced diet from specified foods.

To expedite the submission of useful data and recording of literature data and to ensure uniformity in criteria and tabulation, a comprehensive food composition form (ARS 200) was produced (Watt et al., 1974). This form is arranged in two sections. The first section is purposefully designed to ensure a complete detailed description of the sample analyzed, and the second provides organized sections for the orderly tabulation of approximately 100 nutrients. This form is available from USDA, and its use by all personnel involved in nutrient analyses, food composition, and research is encouraged because it provides a ready check list of the information required and a format for its tabulation.

The NDB will be very useful in the revision and expansion of Handbook No. 8 (Watt and Merrill, 1963) presently underway. For those familiar with the multitude of problems encountered in compilation of nutrient data, Handbook No. 8 represented an historical, monumental achievement. The history, rationale, approaches, methodology, problems, and limitations of food tables have been discussed in several papers (Watt and colleagues, 1962, 1970, 1974; Murphy et al., 1973; Corden, 1972; Widdowson, 1967; McMasters, 1963; Harris, 1962; Leung, 1962; Mayer, 1960). Data in Handbook No. 8 were derived to represent national averages, and these values have been universally used in many other compilations. The tables need to be expanded to include all nutrients, especially the 40 or so essential nutrients, the major carbohydrate components of foods, and the fatty acids. The tables should also indicate the range of variation in nutrients and, if possible, provide information on the presence of antinutrients in certain foods, e.g., oxalic acid or phytates, which may reduce the availability of minerals, such as calcium.

Some of the general problems involved in compilation of nutrient data have been enumerated (Watt and Murphy, 1970; Murphy et al., 1973). Information on all nutrients is being continually recorded at the Nutrient Data Research Center (USDA). Although the collection of data is random and uncertain except when directly obtained by contract, close screening and examination of literature often reveal useful data, facilitate definition of needs, and provide justification for analyses of foods for particular nutrients.

STATUS OF LIPIDS AND FATTY ACIDS

Because of the lack of collated quantitative information, the requirements for reliable data in conjunction with nutritional labeling, and the expressed need by medical/nutritional personnel conducting epidemiological surveys to assess the suspected correlation between dietary fatty acids and the incidence of vascular/coronary problems, a group was formed at NDRC in 1973 to assemble all available data on lipid and fatty acid content of the food supply.

A subsequent thorough survey of the world literature resulted in the perusal of about 5,000 articles concerning lipids in specific foods. Approximately 45% of the articles contained potentially useful data. There are many shortcomings associated with screening of literature as a source of usable nutrient data on lipids, and many of these emanate from the fact that nutrient data information was not a primary objective of many reported analyses. Problems, some common, some unique, are invariably encountered, and these include: poor definition (proximate analysis) or lack of description of item or sample analyzed (maturity, variety, raw or cooked, whole fish or fillets, extent of processing, storage, etc.); use of inefficient extractants, e.g., using hexane to extract lipids from a high moisture food; inferior methodology in analyses of lipids and fatty acids; and failure to provide appropriate gravimetric data and needed conversion factors.

TABLE 1

Some Factors Which Influence the Lipid Content, Extractability, and Composition of Primary and Processed Foods

A. Production Conditions
1. Animals, poultry, and fish: breed, species, sex, age, nutrition, season, environment
2. Plant/vegetable: variety, maturity/ripeness, season, climate
3. Ingredients used in formulated, imitation, manufactured foods

B. Processing
1. Handling prior to processing: crushing, bruising
2. Types of treatments and methods of processing: aging, blanching, bleaching, canning, curing, defatting, degerming, drying, freezing, hydrogenation, milling, nutrification, salting, winterizing

C. Storage and Packaging Conditions: frozen, ambient temperature, relative humidity, packaging

D. Physical State: intact, cut, diced, flaked, ground, milled, minced, mashed, powdered, puffed, shredded, sliced, condensed, concentrated, dry, moist, dilute, batter, dough, etc.

E. Cooking Method: cooking medium, water/oil, baking, boiling, broiling, braising, deep-fat frying, oven frying, breading and cooking, microwave, etc.

F. Designation of Portion/Cut Analyzed
1. Plant portion: flowers, leaves, stems, roots, pulp with/without seeds, pod with/without seeds, seeds, kernels, kernels plus testa, kernels with/without bran layer, etc.
2. Animal, poultry, and fish: meat cut – typical cuts of beef, pork, sheep (as listed in Anon., 1973. Uniform retail meat identity standards manual) with extent of trimming; poultry portion – light/dark meats, with/without skin and/or adipose, deboned portions, etc.; fish – whole/fillet, shellfish with/without shell, etc.

FACTORS INFLUENCING LIPIDS IN FOODS

Among the principal drawbacks to proper evaluation and use of literature data is omission or inadequate description of the sample analyzed. This includes failure to provide information concerning pertinent production and processing factors which affect lipid content and composition. The more common factors, viz., production, processing, storage and cooking, which influence the content and availability of nutrients in foods have been discussed recently (Hollingsworth and Martin, 1972; Chichester, 1973; Hollingsworth, 1970; Bender, 1966; Campbell and Morrison, 1966). However, these reviews are characterized by the paucity of data concerning the variability of lipids in foods. Such information is essential for proper evaluation of published results during compilation of nutrient data tables, and it should also be carefully considered by those involved in nutrient analyses both present and future.

Some of the factors, frequently overlooked, which affect the lipids of foods, i.e., their extractability and analyzed composition, are listed in Table 1. Because many of these descriptions are not standardized, some effort to define them in more exact quantitative terms is desirable. Examples of the manner in which these parameters can influence lipids and lipid analyses are discussed throughout this paper.

A. Production Factors

Several production conditions may influence the content and composition of lipids in animals and plants, and these should be recognized and recorded by the analyst.

1. Animal, Poultry, Fish Products

Meats: The content and composition of lipids of various species of animals vary significantly, especially between ruminants and nonruminants. They also vary significantly among ferous and domesticated species of ruminants (Crawford et al., 1970). It is well known that lipid differences in species affect food quality of meats from these animals, e.g., firmness of meat and susceptibility to rancidity, and also the properties of their rendered fats – tallow, lard, and mutton fat.

Breed apparently does affect the fat content and perhaps composition of animals (Thrall, 1969; Rumsey et al., 1972; Sumida et al., 1972). Wood (1973) and Wood and Lester (1973) reported that Pietran breed had 5% more unsaturated fatty acids

in their tissues than had Large White pigs. Kauffman et al. (1968) reported that there was significant breed difference in marbling content of longissimus dorsi muscles. In beef marbling ranged from 6.5 to 8.1 in Red Poll and Angus; in pork the Duroc breed had a marbling score of 5.5 and eight breeds had scores ranging from 2.2 to 2.8. An increase in 1 score point corresponds to about 1 and 1.5% increase in extractable lipid in beef and pork, respectively. However, many studies purportedly showing such breed differences did not analyze animals with identical life histories; hence, it is difficult to ascribe observed differences solely to breed. The trend toward using a particular breed for specific commercial purposes tends to minimize breed as a factor influencing lipids in commercial meats and animal products.

Sex, through the influence of hormones, does affect meat composition and quality (Hedrick et al., 1967). Analyses of lipids from longissimus dorsi show that generally heifers are fatter than steers or bulls, and boars have less fat than gilts or barrows (Hood and Allen, 1971; Allen et al., 1967).

Age may have an influence on lipids of meat, other factors being constant. Generally, as animals age, the ratio of fat and lean to bone increases (Guenther, 1967; Hedrick et al., 1967). The fat content of bovine muscle tends to increase with age, but this can be quite variable (Lawrie, 1961). An increased content of unsaturated fatty acids in muscle and subcutaneous fat of beef up to 20 months was observed by Hecker et al. (1973). Age is not a factor in pigs, for the preponderance of animals are killed at 5 to 7 months.

Both the amount and composition of dietary fat can have a marked effect on the lipids of animal products, and generally this is more pronounced in nonruminant animals. Thus, pigs easily assimilate dietary fat and deposit it in adipose and muscular fat, which becomes more or less saturated depending on the diet (Brooks, 1971; Koch et al., 1968; Nordstrom et al., 1972; Chung and Lin, 1965).

Because of the rumen hydrogenation of dietary lipids, commercial ruminant meats have a more constant lipid composition despite dietary variations. However, Crawford et al. (1970) found significant differences between lipids and fatty acids from meats of domestic and wild ruminants which they attributed to diet and selection. Some recent research, in which dietary polyunsaturated lipids were protected from hydrogenation in the rumen by encapsulation, resulted in concurrent changes in milk, muscle, and adipose lipids of ruminants so that these lipids resembled the dietary lipids (Scott et al., 1971; Bitman et al., 1973). However, diets containing unusual fats and fatty acids are not currently used for production of products of commercial importance.

Although seasonal variation in lipids of animals is mostly attributable to dietary factors, environmental temperature can modify lipid composition. More unsaturated fats are deposited in the adipose, especially the outer subcutaneous layers, of both beef and pork animals raised at low ambient temperatures (Thrall and Cramer, 1971; MacGrath et al., 1968; Fuller et al., 1974). Chacko and Perkins (1965) reported a relationship between location of body fat and the degree of saturation; i.e., the more internal fats of beef, pork, and sheep contained greater amounts of saturated fatty acids.

Milk: The fat content and fatty acid composition of milk are affected by several factors, particularly by diet (both by physical state and chemical composition of the diet) and also by season and by breed and stage of lactation of the milk-producing animal (Kurtz, 1974; Patton et al., 1960; Stull and Brown, 1964; Boatman et al., 1965; Scott et al., 1971; Bitman et al., 1973; Storry, 1970). With the exception of season (Kurtz, 1974), the effects of these factors on the composition of the commercial milk supply are usually negligible.

Poultry: The lipid content and composition of chicken meats are quite variable (Tables 2 and 3), depending on the amount and composition of dietary fat (Mickelberry et al., 1966; Marion and Woodroof, 1963; Leveille and Sauberlich, 1963; Schuler and Essary, 1971), dietary protein (Marion and Woodroof, 1966; Marion et al., 1967), sex and age of bird, i.e., broiler, roaster, or stewing (Sugano et al., 1966; Chung et al., 1967; Marion and Miller, 1968; Edwards et al., 1973). However, with most large-volume commercial items these variables are usually quite constant, and hence chicken lipids are expected to be rather similar from batch to batch. Unfortunately, few researchers have done reliable quantitative analyses of the typical commercial sample. Most published data are usually concerned with examining more abnormal or exotic parameters.

The lipids from the subcutaneous fat of chickens (layers) maintained at low temperatures (21°C,

TABLE 2

The Influence of Dietary Fat on Lipid Content of Broiler Tissue

Portion	Dietary fat: Low fat (< 1%)	Corn oil (10%)	Lard (10%)	Hydrogenated coconut oil (10%)
	Lipid content (g/100 g tissue)			
Breast	0.9	1.1	2.3	0.8
Thigh	4.4	7.6	7.5	6.6
Liver	2.8	3.1	3.6	3.0
Skin	27.9	36.0	37.5	32.0
Abdominal fat	72.1	82.0	84.1	76.4

From Mickelberry, W. C., Rogler, J. C., and Stadelman, W. J., *Poult. Sci.*, 45, 313, 1966. With permission.

TABLE 3

Data Showing Effects of Dietary Fat on the Percentage Fatty Acid Composition of Lipids from Hen's Thigh

Fatty acid	Fatty acid composition of thigh lipids: Dietary lipid: Normal[a] (5%)	Corn oil[b] (10%)	Hydrogenated coconut oil (10%)[b]
C 12:0	–	–	9.4
C 14:0	–	1.0	5.7
C 16:0	22.3	20.0	21.6
C 16:1	5.6	2.9	4.0
C 18:0	5.8	7.7	8.9
C 18:1	39.6	33.2	31.6
C 18:2	24.6	31.5	16.1
C 20:4	–	1.4	0.8
Others	2.1	2.3	1.8

[a]From Rogler and Carrick (1964).
[b]From Chung et al. (1967).

0°C) contain a significantly higher level of polyunsaturated acids (Fisher et al., 1962).

Eggs: Breed, age, and nutrition of the hens affect composition of eggs. Edwards (1964) showed differences in lipid content and fatty acid composition of eggs from different White Leghorns and Rhode Island strains. Marion et al. (1966) reported that both breed and age of laying hens influenced lipid composition of eggs. Older hens lay larger eggs with a higher percentage of yolk. Although the lipid content as a percent of the yolk remains fairly constant (Kline et al., 1965), the saturated fatty acids and arachidonic acid decrease while the oleic and linoleic levels increase with age (Marion et al., 1966).

Dietary fat markedly influences egg lipids, particularly the fatty acids associated with the glycerides (Chen et al., 1965). Pankey and Stadelman (1969) quantified the fatty acid changes associated with inclusion of various oils in layers' feed. Safflower, corn, and soybean caused an increase in linoleic acid levels at the expense of palmitic and oleic acid; olive oil boosted the oleic acid levels; and coconut oil increased the lauric and myristic acid content. Grain sorghum caused a decrease in the linoleic acid content of eggs even when safflower oil was included in the layer's diet (Chavez et al., 1966). Commercial layers are normally fed a balanced laying ration, and hence the lipid components are assumed to be relatively constant in commercial eggs.

The composition of eggs is not measurably influenced by management (battery, deep litter, or free range) of layers, other conditions being similar (Tolan et al., 1974).

Fish: Analogous variables apply to fish samples; i.e., species, sex, age, nutrition, and environment all influence lipids to varying extents, and these have been detailed in extensive reviews and papers by Ackman (1973, 1974), Stansby (1967a, 1967b, 1969, 1973), Saddler et al. (1972), Taarland et al. (1958), and Gruger et al. (1964).

Seasonal fluctuation is a variable that must be recognized in tabulating fish data. Lean fish (Stansby, 1973) demonstrate little seasonal varia-

TABLE 4

Variation in Lipid Content of Mackerel Caught Off Northeast and Northwest Atlantic

	Lipid content (%)				
Month/season	Northeast fillet/whole	Fillet	Northwest light meat	Dark meat	Ref.
January (late)	19.1	–	–	–	Hardy, 1972
March (late)	8.7	–	–	–	Hardy, 1972
"Spring"	–	8	–	–	Ackman, 1971
"Spring"	5.4	–	–	–	Taarland, 1958
May (early)	6.3	–	–	–	Hardy, 1972
May (late)	–	–	2.2, 2.3	8.7	Ackman, 1971
June (early)	–	–	3.2, 4.9	–	Mannan, 1961
June (mid)	3.9, 7.6 9.1	–	–	–	Hardy, 1972
June (mid)	–	–	2.2, 3.3	8.9, 12.8	Ackman, 1971
July (early)	9.9	–	–	–	Hardy, 1972
July	–	–	4.6, 7.2	11.1, 14.6	Ackman, 1971
August (early)	14.3	–	–	–	Hardy, 1972
August (late)	–	–	7.6	18.3	Ackman, 1971
September (early)	11.2	–	–	–	Hardy, 1972
September	–	8.6	–	–	Ackman, 1971
October (early)	15.7	–	–	–	Hardy, 1972
October (early)	–	–	10.2	14.4	Ackman, 1971
October (late)	19.2	–	–	–	Hardy, 1972
"Fall"	20.2	–	–	–	Taarland, 1958
"Fall"	–	22	–	–	Ackman, 1971
November	–	12.9	–	–	Gruger, 1964
November	–	25.5	–	–	Ackman, 1971
December (early)	23.4	–	–	–	Hardy, 1972
December (early)	–	–	12.6, 18.8	–	Mannan, 1961
December (mid)	21.6, 24.1	–	–	–	Hardy, 1972
December (late)	16.1	–	–	–	Hardy, 1972

tion in the lipid content of flesh because the liver is the principal site of lipid storage; e.g., cod fillets contain 0.6 to 0.7% lipid, mostly phospholipids, whereas cod liver may contain from 15 to 75% lipid (mostly triglyceride) depending on the time of year the fish are caught (Jangaard et al., 1967). Fatty fish, which store triglycerides in their flesh, show wide seasonal variation and, according to Stansby (1973), attain a maximum amount of triglyceride in summer and a minimum in late winter. However, in assembling the literature data, exceptions to this were observed, e.g., Atlantic mackerel from separate geographic locations (Table 4). These data indicate that lipids decrease to a low by late spring and then gradually increase to a high in December.

TABLE 5

Oil Content and Fatty Acid Composition of Germ Oil from Several Strains of Corn

Strain	Lipid content of corn	Fatty acid composition of corn germ oil			
		C 16:0	C 18:0	C 18:1	C 18:2
		(%)			
IHO	16.3	13.4	1.8	39.0	45.8
RHO	9.2	13.0	1.8	37.2	48.0
Wf 9 × OH 43	4.6	15.9	2.0	26.1	56.1
RLO	2.3	14.0	0.9	20.4	64.8
ILO	0.8	16.6	1.6	14.4	67.4

From Curtis, P. E., Leng, E. R., and Hageman, R. H., *Crop Sci.*, 8, 689, 1968. With permission.

2. Plant and Plant Products, Cereals, Vegetables, Nuts, Oilseeds

Production conditions are probably more pronounced in their effects on the lipids of plant products, and some typical, though by no means exhaustive, examples are cited below.

Variety/Strain/Selection: Species and variety exercise a marked influence on lipid content and composition of plants, and this is particularly noticeable among the cereals and oilseeds (Weber, 1973; Marguard, 1973). This important subject was reviewed at a symposium recently (Anon., 1972), at which the variations in plant genotypes, which provide the geneticist with the capability of altering fat content and fatty acid composition, were discussed.

Hymowitz et al. (1972) assembled data showing the variations among soybean species with respect to lipid and protein content. Lipids ranged from 6 to 21%, the highest being found in *Glycine max*, the domestic commercial species. The varieties of *Glycine max* grown in the USA have relatively constant lipid content (21 to 23%) and fatty acid composition (Lundberg, 1972; Gutierrez and Kocelj, 1971).

Curtis et al. (1968) showed the tremendous variation in fat content and fatty acid composition of strains of corn (Table 5). There was a positive correlation between fat and oleic acid content of corn and a negative correlation between fat and linoleic acid. Flora and Wiley (1972) reported a wide range (i.e., 5 to 18%) in lipid contents of several corn varieties, most of which were experimental mutants.

Wheat varieties contain varying levels of lipids; i.e., hard red winter, soft red spring, hard red spring, and durum have 1.8, 2.0, 2.2, and 2.5% lipids, respectively (Watt and Merrill, 1963; Mecham, 1971; Weber, 1973).

Two of the more dramatic and commercially important examples of genetic variation, resulting from careful selection, are the 0 erucic acid strains of rapeseed now widely propagated in Canada and the high oleic acid safflower oil now in commercial production in California. Information concerning these was reviewed by Downey (1971), Applequist and Ohlson (1972), Knowles (1965, 1969), and Fuller et al. (1967).

The fatty acid composition of cottonseed oil is influenced by the variety (Bailey et al., 1966), and it appears that the selection of glandless cottonseed oil was accompanied by an increase (approximately 10%) in oil content (Jacks et al., 1973).

Virginia spreading-type peanuts tend to have more linoleic acid than do the Spanish bunch types, which tend to contain slightly more oil. The effects of strain and seasonal effects on peanut characteristics were studied by Holley and Hammons (1968) and on fatty acids by Worthington et al. (1972, 1973). However, compared with those of other oilseeds, fat content and fatty acid composition of peanuts from around the world are quite constant (Sekhon et al., 1972).

Maturity or Ripeness: Lipids change markedly with degree of ripeness or maturity of the plant. Corn, which may be harvested at different times depending on its mode of utilization, e.g., canning or corn-on-the-cob, generally has an increasing lipid content with stage of maturity, but this may vary with strain (Table 6).

TABLE 6

Changes in Lipids and Fatty Acids in Maturing Corn

Strain	DAP[a]	Total lipids (mg)	Fatty acid (mg/100 kernels) C 16:0	C 18:0	C 18:1	C 18:2	C 18:3
H 51	20	58.2	2.8	0.3	3.3	7.0	0.6
	45	947.1	127.8	10.7	226.4	342.1	7.1
	75	1142.4	160.6	12.9	294.5	445.9	9.2
	85	1141.7	162.2	13.8	286.6	444.1	14.7
K 6	15	60.0	2.5	0.2	3.3	9.6	1.1
	45	684.2	59.5	6.1	124.7	309.0	9.7
	75	424.0	39.7	3.5	67.3	200.4	6.7

[a]DAP: Days after pollination.

From Weber, E. J., *J. Am. Oil Chem. Soc.*, 46, 485, 1969. With permission.

Both the lipid content and fatty acid composition of soybeans increase during maturation (Rubel et al., 1972; Privett et al., 1973), but the changes in percentage fatty acid distribution are small during the last 2 or 3 weeks.

Lipids increase during the maturation of peanuts, and there is a relatively more marked increase of oleic acid than of linoleic acid (Young et al., 1972).

Temperature: Numerous workers have shown the effect of growing temperatures on oil content and fatty acid composition of plant products, particularly oilseeds. Canvin (1965) indicated that oilseeds grown at lower temperatures contained more oil. Most seeds have higher levels of linoleic acid when grown at lower temperatures (Marguard, 1973; Applequist and Ohlson, 1972; Sietz, 1969).

The temperature effects in corn vary with the genotype (Thompson et al., 1973). When grown at lower temperatures, oats, wheat, and barley (particularly oats) produce more fat (Lindberg et al., 1964).

The effects of variety, season, and growing conditions on the lipids of some important plant foods have been reviewed by Marguard (1973).

In many plant seeds and oilseeds studied there appears to be a very consistent negative correlation (-0.85 to -0.95) between oleic acid and linoleic acid content, and in rapeseed between oleic acid and erucic acid. Of the various plant fats, cocoa butter (*Theobroma cacao*) is remarkably consistent in fatty acid composition irrespective of geographic origin (Woidich, 1970). This may well be attributed to its simple fatty acid composition which is almost devoid of di- or polyunsaturated acids.

Pesticide and herbicide treatments have negligible effects on the lipids of oilseeds, e.g., soybean, peanut, cottonseed, (Johnson and Jellum, 1972; Worthington and Smith, 1973; Wilkinson and Hardcastle, 1971); virus infections do not affect soybean lipids (Harris et al., 1970).

3. Fat-added Foods

Several pieces of information are necessary to classify manufactured foods, particularly those for which no legal standards exist. Foods which contain added fats present a recurring problem in evaluation of food lipid data. A significant source of fat consumed is derived from a variety of baked goods, and the variations in fat content of these epitomize some of the problems we encounter in compiling data on lipid and fatty acid composition. The fat content of baked goods shows marked variations even for similar items (Tables 7

TABLE 7

Range of Fat Levels Reported in Baked Goods

Commodity	Fat content (%)
White bread	2–4
Hard rolls	approx. 3
Cakes	12–30
Cookies	6–31
Pie crust	8–23
Doughnuts	18–27
Danish pastry	22–24

TABLE 8

Observed Variations in the Fatty Acid Composition of Plain Cake

Shortening source	Total fat (%)	Fatty acids (g/100g cake)				
		Saturated			Polyunsaturated	
		C 16:0	C 18:0	C 18:1	C 18:2	C 18:3
Corn oil	12.0	1.8	0.3	3.4	5.8	0.1
Hydrogenated shortening	12.4	1.9	1.3	4.8	2.6	0.2
Vegetable shortening	13.9	4.0		8.0	1	–
Unknown fat	16.8	2.1	2.0	8.0	2.2	–
Margarine	12.4	2.0	1.0	5.4	3.3	–
Butter	12.7	7.0		4.0	1	–

TABLE 9

Fatty Acid Content of Cookie Mix Containing Different Shortening Sources

Fatty Acid	Shortening					
	Lard (100%)	Lard (10%) Soybean oil	Lard (25%) Soybean oil	Lard (25%) H. soybean	Soybean oil shortening	Lard (50%) Butter
C 16:0	3.7	3.4	2.8	3.2	1.5	6.5[a]
C 18:0	2.0	1.9	1.7	2.0	2.6	1.5
C 18:1	6.0	7.0	6.1	7.7	6.6	5.7
C 18:2	1.4	1.9	3.3	1.5	3.7	0.7
C 18:3	0.2	0.2	0.4	–	–	–

[a]Includes 2.7 g short chain fatty acids; H. soybean = Hydrogenated soybean oil. Fatty acids expressed as g/100 g mix.

and 8). This is because different amounts and types of shortening are added by different manufacturers. Furthermore, the source of the shortening used markedly influences the nature of the fatty acids present (Table 8). It is not sufficient to stipulate shortening as animal or vegetable fat, and the term hydrogenated (or the more recent euphemistic term, slightly processed) is quite meaningless for indicating the fatty acid composition.

The consumer, nutritionist, and dietician need to know the amount of each fatty acid in any food item, and personnel at Nutrient Data Bank are required to derive an average value for each food commodity. In this context, indicating that a cookie was made with hydrogenated shortening is of little value. Several fats may be used as shortening for cookies, viz., lard, hydrogenated vegetable oil, butter, or various proportions of these. Assuming a cookie mix contained 15% fat, then its fatty acid composition would vary depending on the source of shortening used (Table 9). These data clearly reveal the difficulty in providing an average value for the individual fatty acid content of a cookie mix and dramatize the need for more descriptive information.

Thus, in manufactured products, the particular ingredients and source of fat markedly affect lipid composition. The increased tendency to use substitute/imitation fats in various simulated products presents another dilemma; e.g., chocolate coatings on candies and cakes alter the fatty acids depending on whether hydrogenated coconut/palm kernel/cottonseed fat was used (Ryberg, 1970; Dallow, 1974).

Standardized products reveal extreme variations in component fatty acids, e.g., filled milks, even those with the same brand name (Table 10). The changing fatty acid ratios reflect the use of different fats. This was more clearly shown in the

TABLE 10

Variation in Saturated:Unsaturated Fatty Acids and Fat Content of Filled Milks Over a 6-Month Period

	Product[a]				
Month	A	B	D	G	H
1	72:28	24:76	98:2	98:2	22:78
2	68:32	26:74	97:3	99:1	20:80
3	73:27	23:77	97:3	20:80	25:75
4	66:34	30:70	98:2	20:80	24:76
5	79:21	19:81	99:1	12:88	96:4
6	72:28	18:82	98:2	55:45	43:57
Fat content (%)	3.23	3.51	3.31	3.34	3.33

[a]A, B, D, G, and H denote same brand names sampled at different periods.

From Horvath, R. A., Brown, W. H., and Stull, J. W., *Am. J. Clin. Nutr.*, 24, 397, 1971. With permission.

recent fatty acid analyses of imitation milks by Filsoof et al. (1973).

Comparable variations are observed for infant formulas where a variety of fats, i.e., coconut, corn, lard, tallow, palm oil, or olive oil may be added (Hughes et al., 1963; Herting and Drury, 1969). The more contemporary products tend to have higher levels of polyunsaturated acids.

The lipid content of soup may range from 0.4 (vegetable soup) to 9% (cream soups). The source of fat used in cream soups (chicken fat, lard, soybean oil) markedly affect their essential fatty acid content; e.g., cream of potato, with approximately 2.0%, and cream of mushroom, with 8.7% fat, could have polyunsaturated to saturated ratios of 0.34 and 1.73, respectively.

These selected data demonstrate the difficulty in providing average data for the faty acid composition of manufactured foods.

B. Processing

Information concerning handling and the type and extent of processing should be provided with all analyses.

Handling prior to processing, especially where it might alter the nutrients, should also be described. Bruising, cutting, or breaking of vegetables, fruits, and oilseeds can activate lipase (s) and/or lipoxidase, which may alter the lipids. Injury to these items can also facilitate autoxidation of lipids and permit microbial contamination with subsequent nutrient alteration. Whether or not a vegetable had been blanched could affect the changes cited above.

Several processes markedly affect the lipid content and composition of foods. Defatting by pressing or solvent extraction may decrease fat content to varying degrees. Thus, in manufacture of cocoa powder, the product may have a 8 to 25% range of fat content (Minifie, 1970), and oilseed and fish meals vary in fat content according to degree or efficiency of extraction.

Shortenings and margarines have widely differing fatty acid compositions because of variations in type and extent of hydrogenation and because of the conditions of hydrogenation, i.e., selectivity, catalysts, pressure, agitation, temperature (Swern, 1964; Jones et al., 1965; Koritala and Dutton, 1969; Swindells, 1970). Since processed vegetable oils, approximately 75% of which are soybean oil, are a major source of dietary fats and essential fatty acids, it is very important to have more reliable information on the effects of hydrogenation on the fatty acid composition, i.e., polyunsaturated acid content, positional and geometric isomers, and saturated fatty acids. Fortunately, the selectivity of hydrogenation and the accompanying processes involved in manufacture of margarines and shortenings are being continually improved to retain more linoleic acid in these products. Thus, the average level of linoleic acid in modern margarines (stick) is around 30% compared with 10% 15 years ago, and many of the reputable soft margarines (tub) have around 40% linoleic acid. With plastic shortenings the linoleic acid level averages around 25%. These data are generally true for the reputable brand name producers; however, our calculations have revealed great variations between brand names of margarines even though fat was purportedly from the same source. The data (Table 11) of Beare et al. (1967) clearly show the lack of any useful relationship between the label claim and the essential fatty acid content of margarines. Corn oil based margarines may range from 10 to 30% polyunsaturates. The average polyunsaturated content of 68 American margarines was 22 g per 100 g margarine (range 6 to 48). The average *cis,cis* (w 6 1,4-pentadiene) content of soft margarines runs about 85% of the polyunsaturates and higher for the newer soft margarines.

TABLE 11

The Content of *cis*-Methylene-interrupted Polyunsaturated Fatty Acids in Some Canadian Margarines

Label claim	*cis,cis* Polyunsaturated acids (%) June	October
Vegetable oil 100%	26.5	22.2
Contains liquid corn oil, high polyunsaturates	16.5	10.0
Made from 100% pure corn oil	4.8	6.0
Made from 100% pure corn oil	19.7	19.1
Polyunsaturated – made from 100% vegetable oil	9.0	6.0
Vegetable oil 100%, 80% liquid oil	11.0	9.6

From Beare, J. L., Heroux, C., and Murray, T. K., *Can. Med. Assoc. J.*. 96, 1575, 1967. With permission.

Several attempts have been made to closely correlate the precise fatty acid composition with the selectivity and extent of hydrogenation of edible vegetable oils (Jones et al., 1965; Beare-Rogers, 1970; Swindells, 1970). Such a correlation is feasible under experimental conditions and, despite some difficulties, should be possible under carefully controlled industrial conditions. However, at present, wide variations in fatty acid composition and in *cis* and *trans* isomer contents are obtained for oils with similar iodine values. If reliable nutrient data are to be kept current, either the producers or government laboratories must continually monitor the fatty acid composition of processed vegetable oils. However, if nutritional claims are made, printing of the fatty acid composition on the label by the producer is mandatory.

Winterization enhances the polyunsaturated fatty acid content and more specifically the content of linoleic acid when applied following selective hydrogenation of soybean oil. Directed rearrangement or interesterification alters the fatty acid composition of fats depending on nature of fat added or removed.

The effects of processing, e.g., milling and fractionation, can suitably be exemplified by cereal grains. While cereal lipids occur in low quantities, they are of nutritional significance because of the presence of large amounts of linoleic acid and tocopherols. The fat content and fatty acid composition of common cereal grains are shown in Table 12. The lipid is most concentrated in the germ in all of the grains except rice, where it is concentrated in the bran layer. Any processing treatment which removes the germ or bran layer will alter lipid composition (and tocopherols) of cereal grains. Recording literature values on rice has been difficult because of lack of information as to whether whole rice, brown rice, or polished rice was analyzed. The effect of milling and fractionation on alteration of lipids and fatty acids in hard red winter wheat is summarized in Table 13.

Pasteurization and homogenization do not significantly alter composition of lipids of milk (Boatman and Hammond, 1964), but processing

TABLE 12

Averaged Lipid Content and Fatty Acid Composition of Cereal Grains[a]

Cereal grain	Lipid content	Handbook No. 8 value	Fatty acids (%) C 16:0	C 18:0	C 18:1	C 18:2	C 18:3	Lipid location concentration
Wheat	2.5	2.2	18	2	14	61	5	Germ (10%)
Rye	1.9	1.7	18	–	14	58	10	Germ (19%)
Barley	2.7	–	22	2	10	57	6	–
Oats	6.5	–	16	2	36	43	3	Germ (30%)
Corn	4.8	3.9	15	2	35	47	1	Germ (30%)
Rice[b]	2.4	1.9	–	–	–	–	–	Bran (20%)
Rice[c]	1.3	0.4	20	2	38	37	2	

[a]Fatty acid distribution was taken from: Burkwall and Glass, 1965; Lindberg et al., 1964; Skarsaune et al., 1972; Bracco et al., 1967; Beringer, 1966; Jellum et al., 1973; Beadle et al., 1965.
[b]Brown rice.
[c]Milled rice.

TABLE 13

Distribution of Lipids in Wheat Fractions

Milling fraction	Percent of whole grain	Fat content (%)	Percent of total lipid	Fatty acid distribution				
				C 16:0	C 18:0	C 18:1	C 18:2	C 18:3
Whole wheat	100	2.5	100	18.0	1.0	12.6	63.4	5.0
Flour	72	1.7	49.0	19.4	1.0	10.2	64.6	4.0
Germ	1	10.9	4.4	17.3	0.6	14.2	59.0	8.2
Bran	14	4.4	24.6	16.4	1.2	16.0	60.0	5.2
Shorts	9	6.1	22.0	17.8	0.8	15.3	59.2	6.4
Red dog	4	4.3	6.9	18.0	0.9	14.5	60.8	5.1

From *Millfeed Manual*, Miller's National Federation, Chicago, 1967. With permission.

treatments result in rather obvious changes in lipids of foods; e.g., the manufacture of cheese results in a marked (approximately tenfold) concentration of the milk fat in the final product, and the manufacture of butter from cream causes a twofold concentration of fat.

Canning can markedly alter both fat content and composition depending on whether water or oil is used and on the composition of the oil. Tuna, canned in oil and drained before analysis, has 12 to 15% fat compared with 1% when canned in brine (Bonnet et al., 1974), and smoked herring canned in oil may contain up to 30% fat compared with 12% in the natural state (Taarland et al., 1958).

C. Storage

The duration of storage, temperature, moisture, availability of oxygen, and light can influence the state and composition of lipids in foods via lipolysis and oxidation/polymerization. The net effect could be lower extractability of fat and/or an altered fatty acid spectrum.

During storage of cereals prior to their being milled, lipid hydrolysis may occur, depending on the moisture content and relative humidity (Acker and Becker, 1971).

Extensive hydrolysis of fish lipids can occur during frozen storage, and the implications of this have been discussed in several papers (Olley et al., 1962; Bligh and Scott, 1966).

Nagy and Nordby (1970) studied changes in neutral lipid and polar lipid components of pasteurized, aseptically "cold-filled" bottled orange juice as a function of storage time and temperature. Hydrolysis, primarily of phospholipids, resulted in a threefold and an eightfold increase in free fatty acids at 40°F and 85°F, respectively, with a concurrent decrease in phospholipid concentration to 30.4% of its original value after 16 weeks of storage.

Negligible changes occur in the lipids of eggs during storage at low temperatures (Evans et al., 1967; Marion and Woodroof, 1968). The lipids in meat undergo some oxidation during storage at low temperature, and this usually results in loss of some of the polyunsaturated fatty acids, especially those associated with the phospholipids (Keller and Kinsella, 1973).

D. Physical State

The physical state of a food as such does not affect the lipids; however, information describing the physical state is important in evaluating published data because physical state of food can markedly influence efficiency of lipid extraction. Furthermore, this information is needed for calculation of lipid content per edible portion; e.g., milk or soups may be powdered, concentrated, or ready-to-serve.

E. Cooking Method

Method of cooking can have a marked effect on the lipid content and composition of foods, being decreased by some methods, e.g., broiling, and increased by others, e.g., deep-fat frying (Smith et al., 1972; Standal et al., 1973; Schuler and Essary, 1971; Chung et al., 1966).

In a study of cooking methods, Smith and Vail (1963) showed that oven frying causes a greater loss in lipids than does skillet frying, whereas deep-fat frying results in fat absorption. Roasting also causes loss in fat (Mickelberry et al., 1964).

TABLE 14

Influence of Type of Meat, Skin, and Cooking on the Lipids of Chicken (g/100 g)

	Light meat		Dark meat	
	With skin	Without skin	With skin	Without skin
Raw	3.9	1.5	6.3	3.8
Cooked (fried)	9.9	6.1	13.6	9.3

The presence or absence of skin has a marked effect on the lipid content of analyzed poultry meats (Table 14), and it also significantly affects the absorption of lipids during cooking (Nagy, 1971). Thus, chicken fried with skin, without skin, and without either skin or cooking fat contained 10, 7.8, and 3.6 g fat per 100 g edible portion, respectively; stewing hen, turkey, and duck cooked either with or without skin contained 22.8, 8.9, and 9.6 or 6.1, 38.1, and 10.9 g fat per 100 g edible meat, respectively. Breading and composition of the breading mix, the duration of frying, and the composition of frying oil all influence the lipid content and composition of deep-fried poultry meats and other products (Smith and Vail, 1963; Kilgore and Luker, 1964; Kilgore, 1966, Bennion, 1967; Phillips and Vail, 1967; Heath et al., 1971; Smith et al., 1972).

Deep-fat frying markedly alters the fat content and composition of other products; e.g., the lipids of potato chips on frying increase from 2 to approximately 35% by weight, doughnuts, depending on type and composition, can increase from about 6 to 26% fat, following deep-fat frying. Whereas mild cooking methods causing loss of lipids from meats result in minor changes in fatty acid distribution, deep-fat frying markedly alters the fatty acid composition of the final product which tends to simulate that of the frying oil (Smith et al., 1972; Robertson et al., 1972; Heath et al., 1971).

It is generally concluded that negligible changes occur in lipids during baking (Phillips, 1966). Boiling of foods is associated with extraction of some lipid, as every soupmaker or pork-and-cabbage practitioner appreciates. Schiller et al. (1973) found negligible changes in egg lipids when eggs were cooked in conventional and microwave ovens.

Much research designed to quantify the precise alterations occurring in nutrients (including alterations in lipids) during cooking by various methods is still needed. Foods of defined composition with graduated ranges of the different components of interest should be cooked systematically by different methods (varying times, temperatures, moisture, pressure) and the changes in nutrients quantified in relation to their original concentration. The effects of cooking on lipids of meats should be studied by using raw cuts and the corresponding cuts from the contralateral side as cooked sample. The temperature of cooking and internal temperature of cooked sample should be given, and proximate analysis should be done on both samples to calculate cooking yields.

F. Designation of Portion Analyzed

Inadequate descriptive information is a major problem in evaluating usefulness and reliability of published and unpublished nutrient data. Examples are myriad; a few typical types are cited below.

The grade of meat analyzed is rarely given, though it is generally assumed to be choice. The extent of trimming of meat cuts or the inclusion or exclusion of skin on poultry meats can markedly alter the fat content and fatty acid spectrum; lack of this information is a recurring problem in evaluating literature data. The term trimming requires some standardization whereby it might be quantifiable from laboratory to laboratory. Similarly, the degree of marbling needs standardized measurement to aid comparison and evaluation of data. Grading provides some index of marbling, but this is a qualitative assessment at best.

Although there are ample data on various muscles of beef and pork and on the more popular meat cuts, limited information exists concerning the lipids in the samples of meat consumed; i.e., how much and what portion of cooked cut was actually eaten? These are the data needed for nutrient tables. Stipulation of whether a sample was raw or cooked and the manner of cooking is

necessary, though such information is occasionally omitted. Fat content of raw and of cooked bacon and chipped beef illustrates the differences cooking can make. Cooked bacon has 20% less fat after being fried, and chipped beef has 6% fat when raw and 10% when cooked and creamed.

Description of poultry meat should state whether light or dark meat with or without skin was analyzed, and if the meat was cooked, the cooking method should be described. All these factors significantly influence the lipid content and composition of the ready-to-eat item (Table 14).

Published analytical data concerning the lipids in fish are fraught with uncertainty because of the inadequate description. The description should answer the questions: Were whole fish or only fillets analyzed? Was dark muscle included or excluded when authors referred to white meat? Was liver included in whole fish? Was the sample of meat taken from the anterior or posterior region of the fish? For canned fish (tuna, salmon, smoked herring, sardines, etc.), these questions should be answered: Do data represent total contents of can or drained solids? Were the fish canned in water or oil?

With plant products it is necessary to stipulate the portion analyzed, whether flowers, leaves, stems, roots, etc. This is perhaps most important with respect to seeds which normally contain reserves of fat. It is significant to know whether the seeds were included or excluded in analyses of fruits. For cereals the inclusion or exclusion of the germ and bran affects the lipid content and composition (Table 12), and for rice it is important to state whether or not the bran layer was included. Similarly with seeds, it should be clearly stated whether whole seed or kernel was actually analyzed; e.g., whole safflower seeds have approximately 36 to 38% oil, whereas the kernels alone may contain 55 to 60% oil (Knowles, 1972).

The need for full, accurate description of the commodity being analyzed is particularly important for processed foods; e.g., green olives have about 13% fat, mission olives have around 20%, and Greek-style olives (oil coated) have approximately 36% fat (Watt and Merrill, 1963).

With increasing consumption of processed prepared foods and food mixtures which are not standardized, it is imperative that a clear quantitative description of that food is given because rarely do supposedly similar items with different brand names have identical composition. Also, it is necessary to indicate whether a sample is an experimental or a typical commercial item because this may determine whether the data are useful or not.

The foregoing discussion reveals the numerous factors which influence food lipids, and it cogently demonstrates the need to include all appropriate information on history and description of product being analyzed. Inclusion of necessary information is facilitated by using the format organized in ARS form 200 (Food Composition Data).

ANALYTICAL FACTORS

A. Extraction Method

In addition to the parameters listed above, the method of lipid extraction can markedly influence the final analyzed composition. A multitude of methods have been used for the extraction of lipids, and the heterogeneity of methods and practices vitiates the reliability of literature data. The method of extraction directly governs the amount and composition of extracted lipids, which vary with the type of foods and the amount and disposition of fat in the foods. Generally, the higher the fat content of a food commodity, the smaller the variability in extractability. The difference between an apolar solvent alone and an apolar plus polar solvent extractant is ascribed to the superior ability of the latter to remove the more polar structural lipids from the foodstuff. Mixtures of solvents of varying polarity have been used to extract lipids for many years. Bloor (1914) introduced the alcohol ether mixture that combined the penetrating power of alcohol with the solvent power of ether. This idea was improved by Folch et al. (1951, 1957) and Bligh and Dyer (1959), who utilized chloroform methanol mixtures.

In foods there has been a traditional tendency to use particular methods for different commodities, e.g., butanol:water for cereals (Mecham, 1971); petroleum ether, diethyl ether, ethanol ammonia (Roese/Gottlieb, Mojonnier) for dairy products; and the Bligh and Dyer (1959) method for fish. Refluxing with apolar solvents (hexane, diethyl ether), i.e., Soxhlet method, is very prevalent for dry materials, and acid hydrolysis (Werner-Schmidt, AOAC, 10th ed., 1965) is the official method advocated by FDA in compliance with nutrient labeling.

Numerous studies have been directed toward finding the most efficient method and solvent system for extracting the lipids of particular foods. This is important to achieve because in many instances, especially with low-fat foods, the essential fatty acids which are associated with the polar lipids may not be quantified when less efficient methods are employed. Although the acid hydrolysis method (AOAC, 10th ed., 1965) for quantifying total fat is very efficient and reliable, the optimum solvent extraction methods need to be established, also. The advantage of direct solvent extraction is that it is fast and efficient and generally does not alter the lipid components. Furthermore, by using this method, the various components of the lipids and lipid classes can be subsequently quantified. Such quantification is important for composition studies and for studying changes with processing, cooking, and/or deterioration. In contrast, the acid hydrolysis method yields partially hydrolyzed lipids depending on concentration of acid and duration of digestion.

Several methods have been employed for extraction of meat lipids. Petroleum or diethyl ether is inefficient, particularly for lean meats which may contain from 5 to 20% phospholipids. The method of Bligh and Dyer (1959) was shown by Ostrander and Dugan (1962) to be the best procedure for extracting the lipids from raw and cooked meat tissue. Subsequent studies by Hagan et al. (1967) and Marchello et al. (1968) showed that chloroform-methanol invariably gave best extraction of lipids from lean meats. Furthermore, Hagan et al. (1967) indicated that it was the best method for most foods, especially those with low fat content.

Bligh and Dyer (1959) demonstrated the superiority of their extraction method over several others and showed that it compared closely with the method of Folch et al. (1957) for extraction of lipids from lean fish cod muscle. Generally apolar extractants are less efficient; e.g., 2.3 and 5.2% lipids were extracted from the crab (*Cancer magister*) by ether/Soxhlet and chloroform/methanol, respectively (Giese, 1966). Because of the variation in efficiency of extraction methods, Lee et al. (1966) compared several methods for extracting lipids from fish meal. Briefly, they consistently found that the lengthy AOAC acid hydrolysis method was only slightly better than a rapid modified Bligh and Dyer (1959) method, which in turn was much superior to the Mojonnier method, the alkaline saponification procedure, and to diethyl ether extractions.

With cereals and other products containing relatively low amounts of lipids, some of which are "bound" as lipoproteins or complexed with starch, polar extractants are required. McKillican and Sims (1964) found that some 50% of the lipids in whole wheat flour are bound. Nonpolar solvents (ether, hexane, benzene) are inadequate, and hence many data (in the literature) obtained by using these solvents are incomplete. Furthermore, the fatty acid distribution of the extracted lipids is quite different for the various cereal grains (Table 15). The ether extract or fat of wheat, as presented in proximate analyses, may be 50% too low. It is known that the solvent methods presently employed do not remove all of the lipids from cereals because subsequent acid hydrolysis extracts still more of the tightly bound lipids (Acker et al., 1968; Inkpen and Quackenbush, 1969; Burkwall and Glass, 1965). Water-saturated butanol extracts appreciable amounts of nonlipid components which must be removed before subsequent quantification of the lipids (Nelson et al., 1963; Flora and Wiley, 1972). For quantifying total fatty acids, the acid hydrolysis method (AOAC, 10th ed., 1965) is used, and for quantitative extraction of intact lipids for subsequent compositional analysis, warm, water-saturated butanol is advocated (Acker and Becker, 1971).

Fruits and vegetables are most easily and efficiently extracted in the freeze-dried state. When moisture content is high (i.e., fresh fruit), extractability is poor if hexane alone is employed. Thus, with avocados, 37 and 98% of the lipids were extracted with hexane at moisture levels of 65 and 2%, respectively (Montano et al., 1962). In extracting dried fruits and vegetables with apolar solvents, milling or grinding to a fine particle size is advocated. When extracting fresh samples, homogenization and a mixture of polar/apolar solvents give best results.

Apolar solvents are adequate for removing the preponderance of the lipids from materials with high fat contents. However, Jacks et al. (1970, 1973) showed that the inclusion of approximately 2% water in a hexane-acetone (31:20 v/v) extractant achieved a greater (approximately 6%) yield of lipids from flaked cottonseed, and more polar solvents, e.g., chloroform: methanol:water, ex-

TABLE 15

The Variation in Lipids and Fatty Acids of Some Cereals as Affected by Extraction Methods

Solvent	Lipid content (%)	Fatty acids (%)			
		C 16:0	C 18:1	C 18:2	C 18:3
Wheat[a]					
Petroleum ether	1.8	15.7	21.5	49.3	7.7
Water-saturated butanol	3.0	17.0	17.1	56.2	5.4
Rice (polished)[b]					
Petroleum ether	–	25.1	42.6	28.3	0.9
Chloroform methanol	–	23.3	31.1	36.2	1.3
Corn endosperm[c]					
Petroleum ether	–	12.0	33.4	50.0	1.3
Chloroform: Methanol (1:1)	–	15.5	26.2	52.3	2.4
Petroleum ether: methanol (2:1) and acid hydrolysis	–	19.3	20.4	54.0	2.9

[a]From Klopfenstein and Pomeranz (1968).
[b]From Lee et al. (1965).
[c]From Jellum (1971).

tracted about 9% more lipid material than apolar solvents.

The diversity of modifications to published methods, where every investigator has his own procedure, presents a recurring problem in evaluating published data. For nutrient data determination, each researcher should provide a check for accuracy assessment to ensure validity of the analytical data. In order to avoid as much variation as possible, the FDA is recommending the Werner-Schmidt acid hydrolysis method (FDA, Interim Methodology Instruction #1, March 1973). FDA will accept comparable methodology if details of accuracy are provided. Thus, it may be assumed that the methods of Folch et al. (1957) or Bligh and Dyer (1959) are acceptable. In fact, these latter methods generally give higher values (weights) of lipid content because they extract the intact lipid molecules, whereas the acid hydrolysis method may cause extensive hydrolysis of the lipids and yield mostly fatty acid, depending on acid concentration, time, and temperature of extraction. Where it is desired to determine the various lipid classes in foods, the acid hydrolysis method is unacceptable.

Finally, researchers and analysts should recognize that factors other than solvent(s) may affect lipid extractability of foods. These include moisture content and particle size of foods, temperature of extractants, solvation ratios, and the duration of extraction.

B. Conversion Factors

In surveying the literature we frequently find reports with excellent analyses of lipids and fatty acids of edible items which unfortunately fail to include the actual fat content of the sample analyzed. This is usually because analyses were incidental or concerned with other objectives. However, occasionally even in papers on chemical analysis for nutrient data this necessary information is omitted.

Because the objective of nutrient tables on food lipids is to provide data on the actual content of each fatty acid per 100 g food, it is not only necessary to provide reliable data on fat content and total fatty acid composition (percent) but also to use appropriate conversion factors to calculate the actual quantity of each fatty acid. For example, salad oil is 99.6% fat of which 95.6% is fatty acids; hence, 100 g salad oil actually contains 95.2 g fatty acids, and a conversion factor of 0.952 may be used for salad oils. Unfortunately, the conversion factor is rarely provided in the

TABLE 16

Fatty Acid Content of Various Cereal Products

Product	Total lipid	Total fatty acid g/100 g product	Conversion factor
Flour, all purpose	1.5	1.13	.753
Whole wheat	3.5	2.74	.783
Wheat flake cereal	2.43	1.92	.790
Hamburger rolls	7.85	6.32	.805
White bread	5.53	4.66	.843
Shredded wheat cereal	2.54	2.17	.854
Biscuit mix	14.2	12.22	.861
White bread (Continuous process)	5.08	4.42	.870
Whole wheat bread	6.94	6.33	.912
Doughnuts	26.57	24.62	.926

From Inkpen, J. A. and Quackenbush, F. W., *Cereal Chem.*, 46(5), 580, 1969. With permission.

literature. Appropriate factor(s) can be obtained by direct determination of the fatty acid content of the total lipid extract via saponification or by quantifying of the individual lipid classes and using individual conversion factors to calculate an average factor.

Direct determination of the fatty acids in the total lipid extract (by saponification, extraction of nonsaponifiable matter, acidification of soaps, and extraction of the fatty acids) is the better method because it is simple, rapid, and accurate. Conversion factors vary depending on the quantitative composition of the total lipid extract and the average molecular weight of component fatty acids (Table 16). The higher the triglyceride content of the extracted fat, the higher the conversion factor. As phospholipid content of total lipid extract increases from 0 to 30%, the conversion factor declines from 0.95 to 0.83. Fats with significant quantities of low moleculer weight fatty acids have lower conversion factors; e.g, butterfat is 0.94, lard is 0.95. Whereas the statement (Mayer, 1960) that to calculate the fatty acids in foods it is necessary only to multiply the amount of fat in a food by the value of each fatty acid may be acceptable for approximating the fatty acids in high fat foods, it is not advocated for calculating data for the Nutrient Data Bank. Accurate experimentally determined conversion factors should be used for each food item.

Fisher et al. (1966) determined the fatty acid content in flour lipids at 72.8% (range 69 to 76), and Burkwall and Glass (1965) reported values of 72.0, 62.0, and 82.0% for whole wheat, flour, and bran, respectively. The data of Inkpen and Quackenbush (1969) demonstrate the relationship between fat content and conversion factors for bakery products (Table 16). Conversion factors are rarely provided in the current literature. However, when a detailed composition of lipid classes is provided, a conversion factor can be approximated. Thus, wheat flour contains 48, 26.4, and 22.7% neutral lipids (mostly glycerides), glycolipids, and phospholipids, respectively (MacMurray and Morrison, 1970). Assuming an average molecular weight of 270 for each fatty acid, these lipid classes contain approximately 95.6, 50, and 72% fatty acids by weight; i.e., 100 g of flour lipids have 45.9, 13.2, and 16.3 g fatty acids in neutral lipids, glycolipids, and phospholipids, respectively; hence, the conversion factor is 0.754.

In calculating the content of each fatty acid in eggs, a typical conversion factor was derived from lipid composition data of Privett et al. (1962). Egg lipids constantly have about 65, 23, and 5% triglycerides, lecithin (phosphatidylcholine), and cephalin (phosphatidylethanolamine), respectively. These lipid classes have 95.6, 70.8, and 75.6% fatty acids, and the conversion factor is 0.822. Thus, when the quantities of the various lipid classes are given, a generally applicable conversion factor can be derived.

When sample description and total lipid extraction are adequate and fatty acid analysis is reliable, one can calculate the weights of the fatty acids in some fish by using conversion factors derived from

TABLE 17

Representative Conversion Factors for Calculating the Fatty Acid Content of Fish Lipids of Varying Composition

Total lipid Content	Glycerides %	Phospholipids[a] %	Conversion factor
0.65	–	92.3	0.665
0.70	7.1	85.7	0.685
0.80	18.8	75.0	0.720
0.90	27.8	66.7	0.746
1.00	35.0	60.0	0.767
1.25	48.0	48.0	0.804
1.50	56.7	40.0	0.830
1.75	62.9	34.3	0.848
2.00	67.5	30.0	0.861
2.50	74.0	24.0	0.880
3.00	78.3	20.0	0.893
3.50	81.4	17.1	0.901
4.00	83.8	15.0	0.909
4.50	85.6	13.3	0.914
5.00	87.0	12.0	0.918

[a]Assuming: Phospholipid content was 0.6 g per 100 g, sterols (cholesterol) 0.05 g/100 g edible portion, and conversion factors of 0.956 and 0.72 were used for triglycerides and phospholipids, respectively.

the knowledge of the lipid composition of the same or a closely related species. Thus, for low fat fish, e.g., cod, catfish, haddock (Stansby, 1973), if total lipid content is known and if it can be assumed that they contain an average 0.6 g phospholipid (Olley et al., 1962) and 0.05 g cholesterol (Feeley et al., 1972) per 100 g edible tissue, generally applicable conversion factors can be derived for a range of lipid levels (Table 17). For animal, avian, and fish lipids, when the major lipid classes are mostly glycerides and phospholipids and when the proportions of these are known, a reasonable conversion factor can be estimated by using the knowledge that the glycerides and phospholipids contain 95.6 and 72% fatty acid, respectively. Thus, if the total lipid of a food contains 95 and 5% glyceride and phospholipid, respectively, a conversion factor of 0.94 (95 X 95.6) + (5 X 0.72) is applicable.

C. Fatty Acid Analysis

The distribution of the fatty acids should be determined when the total fatty acid content has been calculated. Gas-liquid chromatography (GLC) is the method of choice for determining fatty acid composition. In compilation of data for NDB this is the accepted method, though data obtained by other methods are tabulated if appropriate gas-liquid chromatographic determinations are not available. The determination of polyunsaturated acids of common foods and fats by the alkali-isomerization method gives very acceptable data but does not provide complete data on all fatty acids in a food (Zmachinski et al., 1966; Alfin-Slater and Melnick, 1964; Beadle et al., 1965). The procedures, problems, precautions, and limitations of GLC for the complete analysis of fatty acids have been discussed (Stoffel et al., 1959; Ackman et al., 1967; Ackman and Eaton, 1971).

GLC is now routinely used, and, when conditions are standardized, reproducibility and accuracy are excellent (Herb and Martin, 1970). Literature data are generally good because in most instances standard mixtures or internal standards are used for calibration. Furthermore, with availability of authentic standards of various methyl esters and improved knowledge of column characteristics and behavior of specific fatty acids, misidentification of fatty acid peaks is now less of a problem. The standard method for GLC of food fatty acids proposed by FDA is essentially that published in AOAC, 11th edition (1970). The weight of each fatty acid in the food sample is calculated by multiplying the weight of total fatty acids in 100 g food by the percent fatty acid as determined by GLC. Only those fatty acids occur-

ring in excess of 0.1 g per 100 g food warrant tabulation at this time for nutrient tabulation.

With the advent of nutritional labeling, supplemental information on the quantity and nature of food fatty acids will be necessary. Thus, the various geometric and positional isomers of unsaturated acids will ultimately require determination. This will apply particularly to edible oils, spreads, margarines, shortenings, mayonnaise, i.e., to oils that have been subjected to hydrogenation, as these are principal sources of essential fatty acids in contemporary American diets. Thus, it is expedient to determine the *cis, cis* 1,4-pentadiene content and conceivably in time to quantify all the isomers present. The separation of unsaturated fatty acid isomers (positional and geometric) by GLC requires a much higher number of theoretical plates than are found in conventional GLC columns currently in use. However, narrow bore (0.5 mm ID) long capillary columns (35 to 60 m) coated on the inner surface with an appropriate liquid phase can effectively separate positional and geometrical isomers of fatty acids. These columns require small amounts of very clean samples and demand greater technical skill. They are not yet in routine use in quality control labortories.

Since there is no routine method for measuring all of the fatty acid isomers and because the critical polyunsaturated components are composed mostly of the essential fatty acids, the lipoxidase method for quantifying the *cis, cis* 1,4-pentadienes, i.e., linoleic, linolenic, arachidonic acids, has been adopted (FDA, Interim report #1, 1973). This method is based on the original report of MacGee (1959) and has been in official use in Canada since 1968. The parameters affecting this method were examined in detail by MacGee (1959). The method is based on the ability of lipoxygenase (lipoxidase), usually from soybean, to catalyze the conjugation of *cis, cis* methylene interrupted double bonds in fatty acids, thereby increasing the absorption at 233 nm. The enzyme is specific for *cis, cis* structures and almost exclusively specific for acyl chains with initial double bond at the sixth carbon from the methyl group (n 6). Thus, the enzyme favors those fatty acids with the essential fatty acid structure, e.g., linoleic acid (*cis,cis* n 6,9). The reaction must be carried out under conditions where oxygen and lipoxidase are in excess compared with the substrate (5 to 100 μg), and the reaction must have sufficient time to go to completion. The FDA interim lipoxidase method is similar to that of the Canadian Food and Drug Directorate Method (1968). The method is amenable to routine analyses and has given excellent results (Zmachinski et al., 1966; Beare et al., 1967). Swindells (1970) showed this method to be reproducible and used it to show that nonselective hydrogenation ensured greater retention of the essential fatty acids in soya, rape, and sunflower oils than did selective conditions. As previously demonstrated by Beare et al. (1967), there were wide variations in essential fatty acid content of edible oil and fat products bearing similar labels. Waltking and Zmachinski (1970) used lipoxidase to monitor the destruction of essential fatty acids in frying oils under commercial conditions.

PRESENT STATUS AND SPECIFIC NEEDS

The literature survey has been productive and in addition has indicated the particular areas for which additional data are required on lipids.

Within the major food groups new and/or corroborative data are needed for many items. This is particularly true for monitoring the effects of processing, cooking, and storage on a wide variety of food items. Many of the present data on raw and cooked items are derived from separate analyses of different samples by different workers. In future analyses, representative samples of the same batch of food or cut of meat should be analyzed before and after cooking or processing so that more reliable data are obtained. In studying the changes in fatty acids of foods with processing or cooking, the use of an internal standard is advocated because mere normalization of GLC peaks may yield erroneous data (for discussion, see Waltking and Zmachinski, 1970).

Additional data are needed on cultured dairy products, e.g., sour cream, cultured buttermilk, kefir, koumiss, and yogurt, and continual updating of composition of imitation dairy products is advised.

There is an abundance of data on fat and relative composition of fatty acids of meats but a marked lack of quantitative data or appropriate conversion factors to enable calculation of needed data. Furthermore, many data are of dubious values because of inadequate description of samples (age, diet, extent of trimming, grade, extraction efficiency). Because of the important function of nutrient tables, it may be expedient to

carefully and systematically determine the fatty acid content and composition of various cuts of commercial grade meats in order to confirm the present data calculated from random sources and to provide new data for several items. There is a definite need for information quantifying the changes occurring during processing and cooking (meats and all other foods). For studies of this nature, it is necessary to analyze identical samples from a common representative source at appropriate stages (before and after) of the processing or cooking treatment. It is not recommended to analyze raw samples and then analyze cooked samples from a different source or batch and ascribe differences to the effects of cooking. It is essential to obtain data that accurately reflect the actual portion of meat that is consumed. Most data in the literature were obtained from studies designed to compare relative proportions of fatty acids as a function of some specific experimental treatment and as such are of limited value for nutrient data tables for which accurate quantitative data based on the actual edible portion are needed.

Lipids in fish vary as a function of season, geographic origin, prevailing temperature, freshwater/marine, type of tissue analyzed (whole or fillets), processing/cooking history, and method used for lipid extraction and analysis (Stansby, 1967a, 1967b, 1969, 1973; Ackman, 1973, 1974). Available information on the more important commercial fish are subject to reservations because of lack of uniformity of extraction methods, failure to designate and adequately define cuts of fish studied, and absence of information on season and location of catch. There is an abundance of data on the relative distribution of fatty acids in fish and shellfish, but these data are of limited value for compilation of nutrient tables because it is not possible to accurately calculate actual weights per unit edible portion because of lack of conversion factors. Furthermore, many data represent a single sample of whole fish or a fillet. There are very few data describing changes in fatty acids with processing or cooking, and such data are essential in a nutrient table. Thus, analyses of lipids and determination of conversion factors of many edible fish (fresh, processed, and canned), edible crustaceans, mollusks, aquatic animals, seafood products, and fish eggs are needed.

There is limited information available on the fat content of foods containing added fats or oils and fat-based commodities. These foods, e.g., bakery goods, cake mixes, cookies, pie crusts, pastries, confectioneries, margarines, shortenings, and mayonnaise, tend to have quite a variable fat content and a still more variable fatty acid composition depending on the manufacturer and formulation, source of shortening, and extent and type of processing of the shortening. Because of these variations, it is difficult to obtain a generally correct composition for fatty acids of foods containing processed fats or oils. Thus, current data are needed for most bakery goods, confections, breakfast cereals, snack foods, and pasta products.

The pervasive use of substitute cocoa butters prepared from various other fats and hydrogenated oils has rendered it difficult to derive reliable data from the literature on cocoa and chocolate-based goods.

In conclusion, it should be recognized in relation to lipids that the primary objective is to determine content of individual fatty acids of foods. Several criteria must be fulfilled to ensure calculation of useful valid data. An adequate number of well-described, representative samples should be analyzed; proximate composition should be determined on all samples; extraction method should be consistent and its efficiency checked routinely; the fatty acid content of the extracted lipids should be determined to obtain a correct conversion factor; the fatty acids associated with the total lipids should be analyzed by gas-liquid chromatography. By using these data, the content of each fatty acid present in excess of 0.1 g (i.e., g/100 g food) should be calculated. When the triglycerides amount to more than 95% of the total fat for fats and oils, the conversion factor of 0.95 is applicable except for butterfat, where the conversion factor is 0.945. The fatty acid content can be determined directly by GLC for simple fats, shortenings, salad oils, etc. by using an internal standard (Mason et al., 1964; Waltking and Zmachinski, 1970).

Adherence to the requirements which are conveniently listed in ARS form 200 should measurably expedite the establishment of a comprehensive nutrient data bank and facilitate revision of Handbook No. 8.

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FORM APPROVED
OMB NO. 40R-3861

UNITED STATES DEPARTMENT OF AGRICULTURE
AGRICULTURAL RESEARCH SERVICE

FOOD COMPOSITION DATA

ARS FORM 200
MAY 1973

FOOD COMPOSITION DATA

1a. GENERIC NAME & SIMPLE DESCRIPTION *(e.g., casein; frozen carrots, pureed; cake mix; malt; modified food starch).*

2. CODE NO. ASSIGNED TO COMPANY/INSTITUTION

3. FOOD CODE *(CFEI)*

1b. BRAND NAME *(recording Brand Name is optional)*

4. DATE RECEIVED IN NDRC

5. SCIENTIFIC NAME *(e.g., Phaseolus limensis, lima beans; Triticum durum, Durum wheat; Reinharditus hippoglossoides, Greenland turbot)*

6. DIRECTIONS FOR USE OF PRODUCT *(from label)*

7. INGREDIENTS *(specify in descending order* **all** *ingredients)*

8. ANALYSIS OF SAMPLE MADE BY FOOD MFG. ☐ YES ☐ NO

IF "NO", SPECIFY LABORATORY OUTSIDE THE COMPANY

9. GEOGRAPHIC LOCATION FOR WHICH ITEM WAS PREPARED *(check one)* ☐ USA ☐ CANADA ☐ BOTH

MAIN TARGET MARKETS FOR WHICH ITEM WAS PREPARED *(check* **all** *applicable)*

10. ☐ BABY FOOD, STRAINED

11. ☐ JUNIOR FOOD

12. ☐ CONSUMERS *(families, individuals)*

13. ☐ LARGE QUANTITY FOOD SERVICE OPERATIONS

14. ☐ LOW-SODIUM DIETS

15. ☐ CARBOHYDRATE-CONTROLLED DIETS

16. ☐ OTHER SPECIAL DIETS *(explain):*

17. ☐ ETHNIC GROUPS *(specify):*

18. ☐ INGREDIENT FOR USE BY FOOD MANUFACTURER IN — *(specify):*

19. ☐ OTHER *(explain):*

STANDARDS OF COMPLIANCE *(specify Standard, if any, by number and cite sources and date)*

20. FEDERAL STANDARDS OF IDENTITY

21. MILITARY SPECIFICATIONS

22. FEDERAL PURCHASE SPECIFICATIONS

23. STATE OR PROVINCE STANDARD *(if diff. from federal)*

24. OTHER *(including company specifications)*

25. CHECKLIST OF PRODUCT AND PROCESSING VARIABLES *(check all applicable)*

A. TREATMENT APPLIED

- ☐ Aged
- ☐ Blanched *(specify method):*
- ☐ Bleached
- ☐ Cured
- ☐ Defatted
- ☐ Partially defatted
- ☐ Degermed
- ☐ Homogenized
- ☐ Hydrogenated
- ☐ Nutrients added
- ☐ Nutritive sweetener added
- ☐ Non-nutritive sweetener added
- ☐ Phosphate
- ☐ Pickled
- ☐ Ripened
- ☐ Salted
- ☐ Sulfured
- ☐ Winterized
- ☐ Other *(describe):*

B. PRESERVING TECHNIQUE

- ☐ None

Commercially processed

- ☐ Bottled
- ☐ Canned
- ☐ Dehydrated
- ☐ Dehydro-frozen
- ☐ Frozen
- ☐ Pasteurized
- ☐ Refrigerated
- ☐ Smoked
- ☐ Other *(describe):*

Home processed

- ☐ Canned
- ☐ Dried
- ☐ Frozen
- ☐ Other *(describe):*

- ☐ Other *(describe):*

C. PROCESSING TECHNIQUE

Canning

Method

- ☐ Acidified heat processed
- ☐ Aseptic
- ☐ Continuous agitating retort
- ☐ Discontinuous agitating retort
- ☐ Flame sterilizer
- ☐ Hot-fill-hold
- ☐ Hydrostatic retort
- ☐ Still retort
- ☐ Other *(describe):*

Type of Pack

- ☐ Juice
- ☐ Light syrup
- ☐ Heavy syrup
- ☐ Extra heavy syrup
- ☐ Oil
- ☐ Vacuum
- ☐ Water
- ☐ Dietetic *(explain):*
- ☐ Other *(describe):*

Dehydration

- ☐ Air convection
- ☐ Drum
- ☐ Freeze-dried
- ☐ Puff
- ☐ Spray
- ☐ Sun dried
- ☐ Vacuum
- ☐ Other *(describe):*

Freezing

- ☐ Forced air
- ☐ Still air
- ☐ Contact – plate freezing
- ☐ Immersion *(specify medium):*
- ☐ Other *(describe):*

Milling or Refining

- ☐ Air classified
- ☐ Bolted
- ☐ Conditioned
- ☐ Dry milled
- ☐ Wet milled
- ☐ Roller milled
- ☐ Stone milled
- ☐ Extraction rate *(describe):*
- ☐ Pearled
- ☐ Purified *(explain):*
- ☐ Resifted *(explain):*
- ☐ Screw-pressed
- ☐ Solvent-extracted
- ☐ Tempered
- ☐ Whole ground

For wheat

- ☐ Durum
- ☐ Hard
- ☐ Soft
- ☐ Other *(specify):*

☐ **Other Processing Technique** *(describe):*

D. COOKING METHOD

☐ **No cooking**

Cooked by conventional methods

Without added water or fat

- ☐ Baked
- ☐ Partially baked
- ☐ Broiled
- ☐ Browned
- ☐ Heated
- ☐ Popped
- ☐ Roasted
- ☐ Toasted
- ☐ Other *(describe):*

With water, steam

- ☐ Boiled
- ☐ Parboiled
- ☐ Braised
- ☐ Poached
- ☐ Precooked
- ☐ Simmered
- ☐ Steamed
- ☐ Steamed with pressure
- ☐ Stewed
- ☐ Other *(describe):*

With added fat or fat from item

- ☐ Deep fat fried
- ☐ Oven fried
- ☐ Pan fried
- ☐ Other *(describe):*

With other ingredients

- ☐ Breaded
- ☐ Candied
- ☐ Creole
- ☐ Scalloped with cheese
- ☐ Other *(describe):*

☐ Other conventional method *(describe):*

☐ **Cooked by microwave** *(Give details):*

Continued on next page

25. CHECKLIST OF PRODUCT AND PROCESSING VARIABLES – CONTINUED *(check all applicable)*

E. PHYSICAL STATE

- ☐ Chips
- ☐ Cut
- ☐ Cubed
- ☐ Diced
- ☐ Flakes
- ☐ French Cut
- ☐ Granulated
- ☐ Ground
- ☐ Milled
- ☐ Minced
- ☐ Mashed
- ☐ Pieces
- ☐ Powdered
- ☐ Puffed
- ☐ Sections
- ☐ Shredded
- ☐ Sliced
- ☐ Split
- ☐ Sticks
- ☐ Wedges
- ☐ Whole
- ☐ Concentrated
- ☐ Condensed
- ☐ Evaporated
- ☐ Fluid
- ☐ Juice
- ☐ Paste
- ☐ Puree
- ☐ Rehydrated
- ☐ Diluted – with water *(amount specified on container)*
- ☐ Diluted – with milk *(amount specified on container)*
- ☐ Batter
- ☐ Dough
- ☐ Ready-to-heat-and-eat
- ☐ Baby food – strained
- ☐ Baby food – junior
- ☐ Other *(describe)*:

F. DESIGNATION OF PORTION ANALYZED

Grain, Fruit, Vegetable and Other Groups of Plant Origin

- ☐ Heads
- ☐ Leaves
- ☐ Leaves – with stems
- ☐ Stems
- ☐ Pulp – with skin
- ☐ Pulp – with skin and seeds
- ☐ Pulp – with seeds w/o skin
- ☐ Juice – strained
- ☐ Juice – not strained
- ☐ Nectar
- ☐ Peel
- ☐ Pod – with seeds
- ☐ Pod – without seeds
- ☐ Seeds
- ☐ Kernels – with skin
- ☐ Kernels – without skin
- ☐ Other *(describe)*:

Dairy, Meat, Fish and Other Groups of Animal Origin
(check all applicable in **each column***)*

GROUP	PART OR CUT	DESCRIPTION
☐ Beef	☐ Breast	☐ Whole fish
☐ Chicken	☐ Chuck	☐ Whole cut
☐ Eggs	☐ Drumstick	☐ Light meat
☐ Fish *(specify kind)*:	☐ Eggs – whole	☐ Dark meat
	☐ Egg whites	☐ Bone removed
☐ Lamb	☐ Egg yolks	☐ Shell removed
☐ Mutton	☐ Fillet	☐ Separable fat
☐ Pork – fresh	☐ Ham	☐ Separable lean
☐ Pork – cured	☐ Heart	☐ Skin
☐ Shellfish *(specify kind)*:	☐ Gizzard	☐ Skin removed
	☐ Leg	☐ Specially trimmed *(describe)*:
☐ Turkey	☐ Liver	
☐ Veal	☐ Rib	☐ Solids – with bone and liquid
☐ Other *(specify)*:	☐ Roe	☐ Drained solids – with bone
	☐ Shoulders	☐ Solids and liquids
	☐ Tongue	☐ Drained solids
	☐ Other *(specify)*:	☐ Drained liquid
		☐ Other *(describe)*:

G. PACKAGING *(specify size of container by weight or volume of contents)*

- ☐ All metal –
- ☐ Fiberboard –
- ☐ Flexible foil laminate –
- ☐ Glass –
- ☐ Paper bag –
- ☐ Plastic –
- ☐ Plastic boil-in-bag –
- ☐ Pressurized metal container –
- ☐ Metal container –
- ☐ Other *(describe)*:

H. CLASS, GRADE, VARIETY, SPECIES *(specify)*:

I. COMMENTS

DETAILED VERBAL DESCRIPTION OF SAMPLE

(Include when applicable and if known information on factors and conditions such as suggested below.)

26. AGRICULTURAL PRODUCTION: Breed; Sex; Feeding practices of animals; Age; Area of country or location where produced; Variety, Maturity; Degree of ripeness; Time or season of year produced; Fertilization; Other growing conditions.

27. HANDLING AND MANUFACTURING PROCESSES: Treatment and time interval from harvest to beginning of processing; Kind and degree of refinement; Parts removed; Type and method of processing; Treatments as lye dip, type of blanching, use of antioxidants; Form prepared for distribution; Type and size of packing; Conditions and length of storage.

28. SAMPLING: Samples reported *(check)*: ☐ Composites ☐ Individual Samples. Describe the "total" that was sampled and how sampling was conducted.

29. If samples reported herein were analyzed as part of a plan to measure EFFECT of specified condition(s) *(e.g. studies on extent of milling, length and/or condition of storage, kind or degree of processing, other variables)*, give details. If data being reported herein are part of a continuing study, please give below location and information about additional data.

Mfg. Prod. No.	Date	Type of Analysis	Details of Study *(Indicate matching of samples to determine effect(s) measured.)*

CODE NO. ASSIGNED TO COMPANY/INSTITUTION	FOOD CODE (CFEI)

DATA ON EDIBLE PART OF PRODUCT:

KIND OF MEASUREMENT	PRINCIPAL ADDED SOURCE(S) OF COMPONENT(S)	CALORIE FACTOR	UNIT OF MEASUREMENT	MO./DAY/YR. MFG. PROD. NO.	MO./DAY/YR. MFG. PROD. NO.	MO./DAY/YR. MFG. PROD. NO.	MO./DAY/YR. MFG. PROD. NO.	MO./DAY/YR. MFG. PROD. NO.
	A	B	C	D	1 E	2 F	3 G	4 H	5 I
* 201 Solids, total 1/ 2/			gram						
* 202 Nitrogen, total 3/			gram						
* 203 Protein (N x _____) 4/		7/	gram						
* 204 Fat (total lipid)		7/	gram						
* 205 Carbohydrate, total (by diff.) 5/		7/	gram						
206 Fiber			gram						
* 207 Ash, total 6/			gram						
* 208 Energy value 7/			Calories						
209 Starch			gram						
210 Sucrose			gram						
211 Glucose			gram						
212 Fructose			gram						
213 Lactose			gram						
214 Maltose			gram						
215 Brix			degrees						
* 216 Weight of specified portion 8/			gram						
217 Dimensions or volume of specified portion from line 216 8/									
218 Weight of refuse, if any 9/			gram						
219 Addendum 10/			gram						

* Measurement needed for nutrient labeling regulations.

1/ If water in any form — i.e., brine, steam, other — has been added, indicate on line 201, column B.

2/ In column P state conditions, as time, temperature, for determining total solids. If other determinations as anhydrous citric acid, water-insoluble solids, or soluble solids were made, make appropriate entries under Addendum.

3/ Excluding nitrate/nitrite. If N is from several ingredients, specify in column P approximate portion of total N from foods of (1) Gelatin; (2) Other animal sources; (3) Cereals; (4) Other plant sources; (5) Other *(specify)* sources as yeast, amino acids. If N in addition to that measured by Kjeldahl is determined, enter data under Addendum.

4/ Calculate protein from nitrogen using factors from Table 8, page 161 of AH No. 8. For chocolate and cocoa use total N x 4.7 but calculate carbohydrate by difference using total N x 5.63. Calculate protein in mushrooms as 2/3 N x 6.25; yeast as 4/5 N x 6.25; coffee as negligible. Enter factor used in blank.

5/ The figure for Total Carbohydrate (by difference) includes fiber.

6/ In column B specify added salt (NaCl), seasoning et cetera other than added carbohydrate sweeteners; in column P specify approximate amounts of added salt, seasonings et cetera in 100 grams of product. Specify iodized if iodized salt is used.

CONTENT PER 100 GRAMS OF FOOD

If data as shown measure EFFECT of a variable (e.g. lot sampled before and again after storage), give details on a separate sheet and attach here.

MO./DAY/YR. MFG. PROD. NO.	MO./DAY/YR. MFG. PROD. NO.	MO./DAY/YR. MFG. PROD. NO.	MO./DAY/YR. MFG. PROD. NO.	MO./DAY/YR. MFG. PROD. NO.	CITATION TO METHODS OF SAMPLE PREPARATION AND ANALYSIS EMPLOYED	SUPPLEMENTARY INFORMATION	
6 J	7 K	8 L	9 M	10 N	O	P	
							201
							202
							203
							204
							205
							206
							207
							208
							209
							210
							211
							212
							213
							214
							215
							216
							217
							218
							219

7/ Compute calories with factors from columns D, G, J on page 160 of AH No. 8, or 4, 7, 10 on page 25 of AH No. 74 (rev. 1973) for grams of protein, fat, carbohydrate; apply 6.93 to grams of alcohol and factor for glucose (3.68) to sorbitol. List and include information for alcohol, sorbitol under Addendum. Enter calorie factors used in column C.

8/ Determine and report weight in grams and dimensions in cm. or mm. or volume in ml. of specified portion of the product analyzed. In column P express the measure or unit in consumer terms such as 1 cup. If product is composed of two or more parts that are edible, describe or specify parts in column P and state proportions by weight of each part. Enter unit of measure used for line 217 under column D.

9/ Describe in column P any inedible part or parts present that were included in the weight of the portion weighed.

10/ Enter data for additional measurements here, including specific sugars not listed above; sorbitol, groups of carbohydrate, such as reducing sugars; non-nutritive components, such as pectin; organic acids; alcohol.

CODE NO. ASSIGNED TO COMPANY/INSTITUTION	FOOD CODE (CFEI)		DATA ON EDIBLE PART OF PRODUCT:					CONTENT PER 100 GRAMS OF FOOD					If data as shown measure EFFECT of a variable (e.g. lot sampled before and again after storage), give details on a separate sheet and attach here.	
			MO./DAY/YR.	MO./DAY/YR.	MO./DAY/YR.	MO./DAY/YR.	MO./DAY/YR.	MO./DAY/YR.	MO./DAY/YR.	MO./DAY/YR.	MO./DAY/YR.	MO./DAY/YR.		
MINERAL ELEMENTS OR FAT-SOLUBLE VITAMINS	PRINCIPAL ADDED SOURCES OF MINERAL ELEMENTS OR FAT-SOLUBLE VITAMINS 1/	UNIT OF MEASUREMENT	MFG. PROD. NO.	MFG. PROD. NO.	MFG. PROD. NO.	MFG. PROD. NO.	MFG. PROD. NO.	MFG. PROD. NO.	MFG. PROD. NO.	MFG. PROD. NO.	MFG. PROD. NO.	MFG. PROD. NO.	CITATION TO METHODS OF SAMPLE PREPARATION AND ANALYSIS EMPLOYED	SUPPLEMENTARY INFORMATION 2/
			1	2	3	4	5	6	7	8	9	10		
A	B	C	D	E	F	G	H	I	J	K	L	M	N	O
301 Calcium		mg												
302 Chlorine		mg												
303 Iron		mg												
304 Magnesium		mg												
305 Phosphorus		mg												
306 Potassium		mg												
307 Sodium		mg												
308 Sulfur		mg												
309 Zinc		mg												
310 Chromium		mcg												
311 Cobalt		mcg												
312 Copper		mcg												
313 Fluorine		mcg												
314 Iodine		mcg												
315 Manganese		mcg												
316 Molybdenum		mcg												
317 Selenium		mcg												
318 Vitamin A, total value		I.U.												
319 Preformed, expressed as *(check one)*: ☐Alcohol ☐Acetate ☐Palmitate		mcg												
320 Provitamin A 3/		mcg												
321 Beta-carotene		mcg												
322 Alpha-carotene		mcg												
323 Alpha-tocopherol 3/		mg												
324 Vitamin D		I.U.												
325 Addendum														

1/ Specify source(s) and approximate amounts of each mineral element or fat-soluble vitamin contributed and included as part of the total figures shown in columns D through M.

2/ Give details in column O if National Bureau of Standards or other certified sample was analyzed at the same time.

3/ Specify under Addendum additional forms determined that are not listed and enter data.

CODE NO. ASSIGNED TO COMPANY/INSTITUTION	FOOD CODE (CFEI)		DATA ON EDIBLE PART OF PRODUCT:					CONTENT PER 100 GRAMS OF FOOD						
			MO./DAY/YR.	MO./DAY/YR.	MO./DAY/YR.	MO./DAY/YR.	MO./DAY/YR.	MO./DAY/YR.	MO./DAY/YR.	MO./DAY/YR.	MO./DAY/YR.	MO./DAY/YR.		
WATER-SOLUBLE VITAMINS	PRINCIPAL ADDED SOURCES OF WATER-SOLUBLE VITAMINS 1/	UNIT OF MEASUREMENT	MFG. PROD. NO.	MFG. PROD. NO.	MFG. PROD. NO.	MFG. PROD. NO.	MFG. PROD. NO.	MFG. PROD. NO.	MFG. PROD. NO.	MFG. PROD. NO.	MFG. PROD. NO.	MFG. PROD. NO.	CITATION TO METHODS OF SAMPLE PREPARATION AND ANALYSIS EMPLOYED	SUPPLEMENTARY INFORMATION
A	B	C	1 D	2 E	3 F	4 G	5 H	6 I	7 J	8 K	9 L	10 M	N	O
401 Vitamin C:		mg												
402 Reduced Ascorbic Acid		mg												
403 Dehydro Ascorbic Acid 2/		mg												
404 Thiamin 3/		mg												
405 Riboflavin		mg												
406 Niacin (nicotinic acid) preformed		mg												
Niacin equivalent from tryptophan: 407 Determined tryptophan 4/		mg												
408 Estimated tryptophan 5/		mg												
409 Total niacin equivalent [406 + 407 or 406 + 408]		mg												
410 Pantothenic acid 6/		mg												
Vitamin B_6 411 Pyridoxine (alcohol form)		mg												
412 Pyridoxal (aldehyde form)		mg												
413 Pyridoxamine (amine form)		mg												
414 Vitamin B_6 from sum of 411, -12, -13 7/		mg												
415 Vitamin B_6 8/		mg												
416 Biotin		mcg												
417 Folacin		mcg												
418 Vitamin B_{12}		mcg												
419 Addendum														

If data as shown measure EFFECT of a variable (e.g. lot sampled before and again after storage), give details on a separate sheet and attach here.

1/ Specify source(s) and approximate amount of each vitamin contributed and included as part of the total figures shown in column D through M.

2/ If dehydro form has not been determined because it has previously been found to be negligible, state "not applicable" in column O.

3/ Report on the basis of thiamin chloride hydrochloride [$C_{12}H_{17}ClN_4OS \cdot HCl$].

4/ If amino acid, tryptophan, is determined, report data and details of analysis on line 501. Calculate niacin equivalent from tryptophan by dividing milligrams of tryptophan by 60. Record results on line 407, this page.

5/ If tryptophan is not determined directly, calculate tryptophan using content of nitrogen, line 202, and either (1) the tryptophan values per gram of nitrogen from table 1 of Home Economics Research Report No. 4 "Amino Acid Content of Foods;" or (2) the tryptophan values of 90 mg per gram of nitrogen for milk and eggs, 75 mg per gram of nitrogen for meat and fish, and 60 mg per gram of nitrogen for cereals and legumes. State in column O which alternative was used. To obtain niacin equivalents, divide calculated values for milligrams of tryptophan by 60. Enter figures on line 408.

6/ Report as pantothenic acid, correcting if need be for calcium in calcium pantothenate.

7/ Enter data on line 414 only if data are available for all three components and shown on line 411, 412, and 413.

8/ Enter data on line 415 from method for determination of total vitamin B_6 only.

CODE NO. ASSIGNED TO COMPANY/INSTITUTION	FOOD CODE (CFEI)

	AMINO ACIDS 1/	PRINCIPAL ADDED SOURCES OF AMINO ACIDS 2/	UNIT OF MEASUREMENT	DATA ON EDIBLE PART OF PRODUCT:				
				MO./DAY/YR.	MO./DAY/YR.	MO./DAY/YR.	MO./DAY/YR.	MO./DAY/YR.
				MFG. PROD. NO.	MFG. PROD. NO.	MFG. PROD. NO.	MFG. PROD. NO.	MFG. PROD. NO.
				1	2	3	4	5
	A	B	C	D	E	F	G	H
501	Tryptophan		mg					
502	Threonine		mg					
503	Isoleucine		mg					
504	Leucine		mg					
505	Lysine		mg					
506	Methionine		mg					
507	Cystine		mg					
508	Phenylalanine		mg					
509	Tyrosine		mg					
510	Valine		mg					
511	Arginine		mg					
512	Histidine		mg					
513	Alanine		mg					
514	Aspartic acid		mg					
515	Glutamic acid		mg					
516	Glycine		mg					
517	Proline		mg					
518	Serine		mg					
519	Ammonia		mg					
520	N recovered		mg					
521	Addendum							

1/ Data for total amount of each amino acid present are to be reported. Do not report data for either free amino acids or available amino acids.

2/ Specify source(s) and approximate amount of each amino acid contributed and included as part of the total figures shown in columns D through M.

CONTENT PER 100 GRAMS OF FOOD							
MO./DAY/YR.	MO./DAY/YR.	MO./DAY/YR.	MO./DAY/YR.	MO./DAY/YR.			
MFG. PROD. NO.	MFG. PROD. NO.	MFG. PROD. NO.	MFG. PROD. NO.	MFG. PROD. NO.	CITATION TO METHODS OF SAMPLE PREPARATION AND ANALYSIS EMPLOYED	SUPPLEMENTARY INFORMATION	
6	7	8	9	10			
I	J	K	L	M	N	O	
							501
							502
							503
							504
							505
							506
							507
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							520
							521

If data as shown measure EFFECT of a variable (e.g. lot sampled before and again after storage), give details on a separate sheet and attach here.

CODE NO. ASSIGNED TO COMPANY/INSTITUTION	FOOD CODE (CFEI)		DATA ON EDIBLE PART OF PRODUCT:					CONTENT PER 100 GRAMS OF FOOD						
			MO./DAY/YR.	MO./DAY/YR.	MO./DAY/YR.	MO./DAY/YR.	MO./DAY/YR.	MO./DAY/YR.	MO./DAY/YR.	MO./DAY/YR.	MO./DAY/YR.	MO./DAY/YR.		
LIPIDS 1/ 2/	PRINCIPAL ADDED SOURCES OF LIPIDS 3/	UNIT OF MEASUREMENT	MFG. PROD. NO.	MFG. PROD. NO.	MFG. PROD. NO.	MFG. PROD. NO.	MFG. PROD. NO.	MFG. PROD. NO.	MFG. PROD. NO.	MFG. PROD. NO.	MFG. PROD. NO.	MFG. PROD. NO.	CITATIONS TO: SAMPLE PREPARATION, SOLVENT(S) USED, METHOD OF ANALYSIS	SUPPLEMENTARY INFORMATION
A	B	C	1 D	2 E	3 F	4 G	5 H	6 I	7 J	8 K	9 L	10 M	N	O	
601 Cholesterol 2/		mg													601
602 Total Glycerides		gram													602
603 Phospholipids		gram													603
604 Glycolipids		gram													604
605 Total trans fatty acids		gram													605
Fatty acids *(as acids)*: 3/															
606 Saturated: 4/		gram													606.
607 Butyric 4:0		gram													607
608 Caproic 6:0		gram													608
609 Caprylic 8:0		gram													609
610 Capric 10:0		gram													610
611 Lauric 12:0		gram													611
612 Myristic 14:0		gram													612
613 Palmitic 16:0		gram													613
614 Stearic 18:0		gram													614
615 Arachidic 20:0		gram													615
616 Unsaturated: 4/		gram													616
617 Oleic 18:1		gram													617
618 Linoleic 18:2 2/ 5/		gram													618
619 Linolenic 18:3 2/ 5/		gram													619
620 Arachidonic 20:4		gram													620
621 Docosahexanoic 22:6		gram													621
Data for Food Labeling *(as triglycerides)*: 6/															
622 Polyunsaturated		gram													622
623 Saturated		gram													623
624 Addendum															624

If data as shown measure EFFECT of a variable (e.g. lot sampled before and again after storage), give details on a separate sheet and attach here.

1/ Data requested are for total amounts, e.g. total amount of cholesterol or total amount of each fatty acid per 100 grams of food. Do not report data if a portion of the particular lipid occurs in bound form and only the free form has been determined.

2/ Under Addendum, list and enter data on content in 100 grams of food for other lipids determined, e.g. other sterols, total unsaponifiable matter, fatty acids such as 22:0, 16:1, 20:1, 22:1, 24:1, total 18:2, total 18:3, 20:5, 22:5 and others not already listed, including positional and geometric isomers.

3/ Specify source(s) and approximate amount of each lipid contributed and included as part of the total figures shown in columns D through M.

4/ Leave blank.

5/ Enter data only for **all** -cis forms.

6/ Determine by the methodology specified in the regulations published in the Federal Register, vol. 38, no. 49, March 14, 1973, Report data as triglycerides per 100 grams of food.

MEMO FROM

Mary Winston

3/7/75

Dear Dr. Shank:

Please note that this entire packet was mailed to the Nutrition Committee members on this date, in Mrs. Winston's absence.

Yours truly,

Sharon Borahove

(Secy to Mrs. Winston)

American
Heart
Association

Dr. Shank

Memorandum

7 March 1975

TO: Members of the Nutrition Committee

FROM: Sharon Borakove
Secretary to Mrs. Winston Sharon Borakove

SUBJECT: Enclosed Materials for Meeting

Please review the enclosed information prior to our March 20 & 21, 1975 meeting. To avoid unnecessary duplication of materials, please bring this packet with you to the meeting.

Also, please note that the time of the March 21st meeting has been slightly changed. The revised schedule is as follows:

March 20 - 9:00 A.M. - 5:00 P.M.
March 21 - 9:00 A.M. - 3:00 P.M.

The continental breakfast in the meeting room March 21st has been canceled. The meeting will begin at 9:00 A.M. on that date.

See you soon.

MW:svw

(Written in Mrs. Winston's absence)

For Your Information
Dr. Shank

To Get, Customer Must Demand

By BEN L. KAUFMAN
Enquirer Reporter

Don't expect supermarkets to tell customers much about nutrition so long as no one demands this data, a Kroger executive warned Wednesday night.

J. Patrick O'Connor said advertising promotes the "convenience and taste" of food and there will be no massive switch to nutrition-based advertising until the public demands it, no matter how many people are going hungry.

O'Connor, regional manager for Kroger public affairs, described the food industry's understanding of the need for better public education on nutrition at the annual meeting of the Metropolitan Area Religious Coalition of Cincinnati (MARCC) at Wesley Chapel United Methodist Church.

HE CONCEDED industry tactics are geared to customer demand and much food sold has little nutritive value. Moreover, he said, malnutrition is common but so is obesity:

"Even stadium seats are being built three inches wider today."

Still, there is also confusion and disagreement among nutritionists and with this situation, there is an "open season rationale" about food advertising and sales "among food manufacturers."

O'Connor urged MARCC to organize a lobby on behalf of better nutrition education because none exists and "we know all too little about the foods we eat and about food processing."

MARCC LAST year elevated malnutrition/hunger to a top priority, along with problems in the schools.

O'Connor refused to accept the blame for poor nutrition counseling for the industry. He said public schools, welfare agencies and churches do little and they, too, are in daily contact with people who most need help planning their meals.

Kroger, for instance, has not done much because no one has asked, he said, but rather than wait for the company to change its ways, he suggested someone ask Kroger to help.

Hilda Gilbert, executive assistant and co-ordinator of public relations for the Hamilton County Welfare Department, asked O'Connor if Kroger would put out quality programs meant to reach the poor and others on commercial television, teaching basic nutrition and how to use money, food stamps, etc, to achieve a better diet.

O'CONNOR DID NOT respond to her challenge, but to the general tone of the questions. He defended his firm, saying, "We've never been asked before. . . because the public doesn't know what to demand."

Kroger has the money and talent, he added, to help: "They're there; they can be responsive."

MARCC also passed its 1975 budget, at $60,474 less than $3000 more than last year. It is funded by 14 specific religious groups/organizations and a few smaller donors.

Cincinnati Enquirer

2/6/75

WASHINGTON UNIVERSITY

SCHOOL OF MEDICINE
ST. LOUIS, MISSOURI 63110

DEPARTMENT OF PREVENTIVE MEDICINE
AND PUBLIC HEALTH
4566 SCOTT AVENUE
(314) 454-2467

March 5, 1975

Mr. Robert L. Rizek
U. S. Department of Agriculture
Agricultural Research Service
Northeastern Region
Consumer and Food Economics Institute
Hyattsville, Maryland 20782

Dear Mr. Rizek:

I am very grateful to you for your letter of March 3 and its information concerning the Nutrient Data Bank. The Nutrition Committee of the American Heart Association is interested in encouraging and supporting all efforts to update and make more useful the data on food composition. I would appreciate it very much if you could provide me with a copy of the data form for NDB, or if the request is not excessive - 10 copies. These would be distributed to members of the Committee for their information. Our Committee meets on March 20 and 21. Could I possibly have copies prior to those dates?

If you have specific suggestions concerning positions or activities to be taken by the Committee or the Heart Association which might advance the program of the data bank, it would be helpful for us to have them.

Very sincerely yours,

Robert E. Shank

Robert E. Shank, M. D.

UNITED STATES DEPARTMENT OF AGRICULTURE
AGRICULTURAL RESEARCH SERVICE
NORTHEASTERN REGION
Consumer and Food Economics Institute
Hyattsville, Maryland 20782

March 3, 1975

Dr. Robert E. Shank
Chairman, Nutrition Committee
American Heart Association
Washington University
St. Louis, Missouri 63110

Dear Dr. Shank:

Dr. Harkins, GMA, informed me of your interest in the Nutrient Data Bank that we are developing here in the Department.

I am enclosing a copy of a talk I gave last summer on the Data Bank that outlines in general what we are doing. The computer system is nearing completion and we are starting to enter the data we have been receiving from industry.

We would certainly appreciate any assistance that your organization could give us, whether it be moral or by encouraging industry and others to cooperate.

Sincerely,

Robert L. Rizek
Chairman

Enclosure

UNITED STATES DEPARTMENT OF AGRICULTURE
Agricultural Research Service

NUTRIENT DATA BANK

Robert L. Rizek, Elizabeth Murphy, and Susan Gebhardt
Consumer and Food Economics Institute

With the adoption of nutritional labeling, there has been a resurgence of interest in research relative to food composition. This renewed interest has focused attention on the Nutrient Data Bank (NDB) of the Department of Agriculture. The NDB will serve as an international repository of analytical data on all food and beverage products and their ingredients. It will provide a storehouse of information useful to nutritionists, food scientists, dietitians, doctors, and consumers. One immediate and direct utilization of the data bank will be the use of the data in the revision and updating of the next edition of Agriculture Handbook No. 8 (AH-8).

The Department's interest in food composition data is not new. In fact, USDA, through its Consumer and Food Economics Institute and predecessor groups, has developed food composition data for over 80 years. It was in 1896 that the Department published Dr. Atwater's extensive table of food values, the first such table in the United States.

Since then, tables on food composition have been expanded to include additional foods and data for many nutrients now known to be important to man. The Department's basic publication, AH-8, last revised in 1963, contains data on six minerals, five vitamins, calories, proximate composition, cholesterol, and fatty acids. In addition, tables have been published which contain data on amino acids, food yields, and three additional B-vitamins. An updated cholesterol table was published in 1972. A new handbook, No. 456, now in final preparation, will give values for most of the nutrients in AH-8, in terms of common household and market units of foods.

Since the USDA has had in reality a nutrient data bank for many years, what is new and worthy of attention today? The answer is a greatly accelerated program, with active participation and far greater input from industry. The amount of data to be made available and the speed with which data will be released will be increased greatly; moreover, data will be in a form suitable for computer use.

One might question this development of the NDB in view of the fact that the FDA has indicated that representative data from sources such as USDA AH-8 are not now sufficient to be a basis for nutritional labeling.

Talk by Robert L. Rizek at the 27th Annual Reciprocal Meat Conference of the American Meat Science Association, June 19, 1974, Texas A & M University, College Station, Texas.

FDA representatives have pointed out that for each product, it is essential that representative data be checked by analysis of individual lots at least until more complete food composition data are available on an industry wide, regional, and manufacturing basis. However, they, as well as USDA officials, have said that in time, as the Nutrient Data Bank is developed so that it includes data on individual analyses, methods of analyses, and the standard errors of the data, these data, backed up by periodic analytical spot checks, can be used for nutritional labeling.

There is one use of AH-8 in nutrition labeling which until recently has been overlooked. That use is to determine in a product those nutrients unlikely to occur in labelable amounts. Review of representative data for a specific product may indicate that only two or three of the nutrients in it may be expected to reach 2 percent or more of the U.S. RDA. A profile analysis for all of the nutrients would not be necessary, and under these circumstances a food company might request analyses only for those nutrients that are likely to be present at 2 percent or more of the U.S. RDA.

In 1971, the Department was approached by industry regarding the possibility of expanding our efforts in this major area of concern. Since that time, considerable progress has been made. The nutrients to be included in the data bank have been specified, and a format for submitting data for the bank and updating previously submitted data has been developed, pretested and sent to participating trade associations, companies, universities, laboratories, etc. Through the cooperation of the FDA, a contract has been completed to develop a coding system for identifying foods. We are now in the process of letting a contract with the cooperation of the FDA to develop the necessary software for the NDB.

The NDB will include substantially more data than that is now available from the USDA--primarily AH No. 8. In fact, the NDB can be reviewed as three different data bases--each of which will be of interest to different users.

Data Base I will consist of the individual analytical values for each food analyzed and supplied to the NDB--from industry, universities, or government. Also included in this data base will be the entire sample description, i.e., date of analysis, method of analysis, variety, breed, maturity, location of production, etc. Each scientist doing work in food composition will have at his fingertips the results of all analyses that have been completed on the food or product he is concerned with.

Data Base II will provide composite values, as well as the standard errors, by breed, variety, maturity, location of production, method of cooking. etc. This data base will be of interest to research scientists as well as those concerned with nutritional labeling.

Data Base III will consist of nationwide composite representative values for each food--quite similar to that data now available in AH-8, except that the number of foods and the nutrients included will be considerably expanded.

One immediate and direct utilization of the NDB will be the publication of the next edition of AH-8. Except for the change in form--it will be published in looseleaf form--and an expansion in the number of foods and nutrients covered, the revised AH-8 will continue primarily as it has in the past--giving representative nationwide values for the nutrients in foods. In addition, the new edition will include, whenever practical, the standard errors of the overall composite values, and the composite values and standard errors by variety, stage of maturity, etc.

A review of the data submission form (ARS Form 200) which has been developed jointly by industry and government for use with the NDB will help in understanding the scope and content of the effort underway. The form is divided into two general sections. One is for providing a detailed description of the sample analyzed and other information needed to evaluate and code the data. The other is for posting of data on approximately 100 nutrients and related compounds of foods as well as for reporting analytical methods used in their analysis. Included are proximate components, minerals, and fat soluble vitamins, water soluble vitamins, amino acids, and lipids.

Since the development of Form 200 and its distribution to potential contributors, it has been suggested that its complexity has discouraged participation. Let me assure you that this was not its intent. On initial inspection it is complex. However, it must be realized that the form was designed to cover every possible nutrient for any food that might be analyzed. It is not expected that any one food will include values for all or even for most of the nutrients specified. We know that initially, analyses will only be completed for a limited number of nutrients. The nutrient data, as well as that data requested for sample description is the <u>ideal</u>--that which is needed for a truly complete data bank.

The question has also been raised as to whether or not it is necessary to use Form 200 in submitting data to the NDB. The answer to this is "no." If data are available in machine readable form or on company's internal forms, etc., they are perfectly acceptable. It is essential, however, that the data be accompanied by as much of the descriptive information about the product analyzed as is available. In our discussion with a number of companies that either are submitting data or are planning to submit data, it is evident that in the past they have not obtained and/or retained sufficient data on sample description. They are finding, however, that little additional effort is required to maintain a data system that will provide all of the information that is essential for the data bank.

Sample Description

Careful identification of the food sample is essential for evaluation of the data and for proper coding. Consequently, considerable information is required related to the description and identification of the food items. To assist the data supplier in providing adequate descriptive details of the food item, a comprehensive checklist has been included to ease the task of describing the sample and to call attention to the kinds of information that can be given.

Information needed includes such things as the generic and scientific names of the food, geographic location and target market for which the item was prepared, ingredients and directions for use, and any standards of compliance or identity which the product meets.

Product and processing information asked for includes treatments applied to the food, such as bleaching, curing, and pickling; processing techniques--canning, freezing, dehydration, and milling; method of cooking; physical state of the food; portion of the food analyzed; and class, grade, variety, or species.

In addition to the descriptive information about the food product and its nutrient contents, it is essential that the methods of sample preparation and analyses be provided. In most instances, these will probably be standard methods such as those of the Association of Official Analytical Chemists. Reference to the chapter and paragraph numbers in a publication such as AOAC is satisfactory. Reference only to the edition is not sufficient as there is more than one method for determining some nutrients in some foods. In referring to looseleaf publication on analytical methods, methods should be identified by date as well as by method number.

For mineral element determinations, certified samples of orchard leaves and beef liver are available from the National Bureau of Standards. Laboratories may want to analyze one of these standard samples along with their food samples, as a measure of the accuracy of their analytical procedures.

Nutrients

Proximate Composition: The initial nutrient section of the form is for entering data on the energy-yielding components of foods--protein, fat, and carbohydrate--as well as data on specific carbohydrate fractions, dimensions and weight of specified portions, and refuse.

Protein values are to be calculated by multiplying the nitrogen content of the food, measured by the Kjeldahl method, by suitable specific factors. Such factors are given in Table 8, page 161, AH-8. The general factor, 6.25, should not be used where more specific factors are available, such as 6.38 for milk and milk products, or 5.71 for

soybeans. For food mixtures the approximate proportion of total nitrogen coming from the different ingredients should be specified and used as weights with appropriate factors for converting nitrogen to protein.

The Atwater calorie factors will be used for estimating food energy in the NDB. For carbohydrates, these factors were developed for use with values derived by difference between the weight of total solids and the sum of the weights of protein, fat, and ash. Therefore, it is necessary to have information on total solids (or on the converse--moisture) and total ash content for each food.

Furthermore, crude fiber, which is included in total carbohydrate used in calculating energy values by the Atwater factors, should not be subtracted from the total carbohydrate value submitted for the data bank. For some foods, such as fruit juice and preserves, the Brix reading is used in calculating total solids and is included in the first nutrient section of the form. Starch is also included, as are five specific sugars--sucrose, glucose, fructose, lactose, and maltose. These nutrients, although not required for nutritional labeling, are receiving increasing attention from nutritionists. As their specific roles in nutrition are worked out through research, the need for data on their contents in foods may become critical.

Mineral Elements and Fat Soluble Vitamins: In the second nutrient section of the data submission form, 17 mineral elements are included. They are split into two groups--a group usually found in macro or semi-micro amounts and a group of trace elements. The two groups are:

Macro		Trace	
Calcium	Chlorine	Chromium	Cobalt
Iron	Magnesium	Copper	Fluorine
Phosphorus	Potassium	Iodine	Manganese
Zinc	Sulfur	Molybdenum	Selenium
Sodium			

Listed on the same pages with the mineral elements are the fat-soluble vitamins: Preformed vitamin A, beta-carotene, alpha-tocopherol, and vitamin D. Space has been provided in an addendum so that data on the various carotene and tocopherol fractions can be reported. Data on carotene fractions are especially needed because retinol equivalents, to be accurately calculated, require data on a larger number of carotene fractions and their various stereoisomers than have been available in the past.

Water Soluble Vitamins: The water soluble vitamins included in the third section of the form are:

Vitamin C	Vitamin B_6
Thiamin	Biotin
Riboflavin	Folacin
Niacin	Vitamin B_{12}
Pantothenic Acid	

For vitamin C, space is provided for recording dehydroascorbic acid as well as reduced ascorbic acid. For many foods, of course, amounts of dehydroascorbic acid are negligible and can be ignored. However, in some foods, certain frozen foods for example, dehydroascorbic acid is present in significant amounts.

In some instances, it is necessary to make corrections in reporting the vitamin content of foods. Thiamin should be calculated as thiamin chloride hydrochloride. Pantothenic acid should be corrected if necessary for calcium in calcium pantothenate, the standard commonly used in analyses for this vitamin. For vitamin B_6 or its fractions, correction should be made for the hydrochloride part of the standards used in its determination.

Vitamin B_6 is generally determined as the total vitamin. Occasionally, however, it is separated into its three principal forms--pyridoxine, pyridoxal, and pyridoxamine--with each fraction determined separately. Provision has been made in the data submission form for providing data on the separate fractions and the sum of these fractions, as well as for data on total vitamin B_6 obtained without separation into its component parts.

Niacin will be included as preformed niacin, which is specified by the Food and Drug Administration for use in nutritional labeling, and as niacin equivalents.

Amino Acids: The fourth area of nutrient information relates to amino acids. Those included are:

Tryptophan	Threonine	Isoleucine
Leucine	Lysine	Methionine
Cystine	Phenylalanine	Tyrosine
Valine	Arginine	Histidine
Alanine	Aspartic acid	Glutamic acid
Glycine	Proline	Serine

Only total amino acids are to be included. Free amino acids, which are of importance to flavor and quality, are not important to determining nutritional content. Available amino acids are not suitable for use in nutrient composition tables at this time, either, since little is yet known about the amounts present in various foods, or factors affecting those amounts.

Lipids: The lipid components included are:

Lipid Fractions	Individual Fatty Acids	
	Saturated	Unsaturated
Cholesterol	Butyric 4:0	Oleic 18:1
Total glycerides	Caproic 6:0	Linoleic 18:2
Phospholipids	Caprylic 8:0	Linolenic 18:3
Glycolipids	Capric 10:0	Arachidonic 20:4
Total trans fatty acids	Lauric 12:0	Docosahexanoic 22:6
Polyunsaturated fatty acids	Myristic 14:0	
Saturated fatty acids	Palmitic 16:0	
	Stearic 18:0	
	Arachidic 20:0	

The FDA has specified the analytical methods for total polyunsaturated and saturated fatty acids which will be used in determining compliance with labeling requirements. For individual fatty acids and other lipid components, data for the NDB may be obtained by usual methods such as gas-liquid chromatography.

As I indicated, a contract was let last year by FDA to develop a coding and data retrieval system. The Department has worked with the FDA, the food industry, and others in this endeavor so that the system will be of maximum value to all users. The objectives of the system are to uniquely identify each food item or ingredient in the NDB; provide information on the characteristics of each item included in the bank, including the method and date of analysis, and provide a highly efficient retrieval system. The system has been designed to allow for the addition of new foods as they are developed.

Food Code

The food identification code for entry and retrieval of food items from the Nutrient Data Bank will consist of two parts--a food term and qualifiers.

The food term will be a four character alpha code.

Food Term

Character	Meaning
1	Major Food Group
2	Subgroup
3	Preferred Term
4	Specific Term

The first character will identify the food item as belonging to one of the 21 major food groups which have been developed by grouping foods with similar commodity characteristics.

21 Major Food Groups

A. Meat (other than poultry)
B. Dairy Products
C. Poultry, Reptiles, their Eggs and Insects
...
...
G. Sausages and Luncheon Meats
...
T. Seasonings and Condiments
U. Leavening Agents and Additives
V. Baby Foods

Character 2 designates the food item as belonging to a subgroup of one of the major food groups. The subgroups for meat are:

A. Meat (other than poultry)

a) Beef
b) Veal
c) Pork
d) Lamb and Mutton
e) Goat
f) Other Meat
g) Mixtures of Meats

Subgroups are further divided into preferred term or specific term which provide a more detailed description of the subgroup. The preferred and specific terms for cuts of meat were taken from the standard (list of names) published by the National Livestock and Meat Board.

Expanded and more complete specificity in the use of the food code is made possible by the use of qualifiers, which will use an alpha/numeric code. Approximately 2,600 qualifying terms have been identified for further specifying the food items. They include: Processing terms, cooking methods, grades, auxiliary components, packaging materials, and other information needed to describe the production, processing, and analysis of the food items.

An example is the complete identification code for a choice grade, broiled, porterhouse steak, lean with visible fat analyzed which would be AAHC D022, F019, J009. This is formed as follows:

Food Identification Code

Food Term		Qualifiers	
AAHC		D022, F019, J009	
A	Meat group	D022	Choice
A	Beef	F019	Broiled
H	Loin	J009	Lean with visible fat
C	Steak, porterhouse		

Data Needs for Meat

Meats contribute significant amounts of nutrients to the national diet. Therefore, it is essential to have reliable up-to-date information concerning their nutrient composition.

Improving the present data for raw and cooked meats requires carefully planned coordinated studies. For beef and other meats there is very little information on paired samples of raw and cooked cuts from the same animal. Mostly the available data are from unrelated sources and hence of dubious value for comparative purposes.

The appropriate relationship among cuts of meat from different parts of the same carcass needs to be preserved; a random selection of market samples would not provide this relationship. The cuts need to be described in terms meaningful to the consumer as well as the research worker--this includes grade of the meat and proportions of separable lean and separable fat and bone for cuts with bone. In addition to information on proximate composition and energy values, data are needed for vitamins, minerals (including trace elements) and lipid components, including cholesterol.

To be of maximum usefulness, it is essential that studies be designed to show the effects of customary production, processing and preparation practices. For instance, hogs have been genetically improved to produce leaner animals, but we do not have nutrient information to reflect this change. Processed meat products--such as sausages containing several types of meat and products in which soy or other meat extenders are used--is another area where analyses are needed. Also values for variety meats, widely used in ethnic dishes, are scarce.

Data are needed to answer the question of what happens during cooking to the vitamins, minerals, and lipid components of meat cooked by various methods at different temperatures and to varying degrees of doneness.

Summary

At the initiation of a major project, such as the NDB, it is difficult to predict when it will be completed. Completion will depend to some extent on the inflow of data in terms of quality, quantity, and speed. Indeed, it could be argued that the NDB will never be completed as it is a living repository of analytical data. However, stages of development have been outlined which will give an indication of availability of the data.

Initial releases of the NDB will include the individual analytical values for each food which have been screened and appear to be acceptable. These data, in all likelihood, will be released by food groups in the following order: Meat and meat products, cereals, dairy

products, and fruits and vegetables, with the first group being made available within the next 2 years. The derivation of representative values which consumes considerable time, will be delayed until a large portion of the data are received, evaluated as to reliability, and made available through the computer data bank.

It is hoped that the computer data bank will be fully operational with most individual and representative values and standard errors available to the public within 3 years. The new edition of Agriculture Handbook 8 should follow shortly after that.

Both the computer data bank and the successor of AH-8 will be updated on a continuing basis as new data are obtained for nutrients in the foods already included in the NDB or as industry develops new food products. In this way, users will have the latest, most complete data that are available.

The NDB will be available to anyone who may have need for this type of data. Although plans have not been finalized, the computer data tapes probably will be made available for purchase through a private contractor, similar to the way the tape for AH-8 is now handled. In addition, the software programs developed by the Department for the NDB as well as for use in Departmental research programs will also be made available. The new edition of AH-8 will be handled through the regular government publication process. A listing of those obtaining either of the two systems will be maintained so that they can receive any revised or new data as they are released.

EXHIBIT G

FEDERAL TRADE COMMISSION
WASHINGTON, D. C. 20580

BUREAU OF
CONSUMER PROTECTION

January 13, 1975

Mr. Dolph Chianchiano
Public Policy and Government
Affairs
American Heart Association
44 East 23rd Street
New York, New York 10010

Dear Mr. Chianchiano:

Enclosed is our revised list of questions concerning several of the issues raised in regulating cholesterol and fat content claims. These questions may help focus your attention on those issues which appear salient to us, but, of course, they are by no means all inclusive.

We encourage the AHA to prepare a comment for submission to the Commission. We also would welcome any comment on any other part of the proposed Rule and the additional staff proposals on an affirmative disclosure scheme and regulation of natural, organic and health food claims.

Any formal comment should be addressed to William D. Dixon, Special Assistant for Rulemaking, Federal Trade Commission, Washington, D. C. 20850. Presently the deadline for comment is February 5, 1975. I will call to let you know if, as is now anticipated, that deadline is extended.

If my colleagues or I can be of any assistance, do not hesitate to call. Our numbers are Stewart Block (202)962-4414; Judith Niebrief (202)962-4441; Thomas J. Donegan, Jr. (202) 962-4165; William S. Busker (202)962-4604; and Lois Dimore (202)962-4738.

Sincerely,

Stewart A. Block

Stewart A. Block
Attorney

Enclosure

QUESTIONS

§437.9 - Fat, Fatty Acid and Cholesterol Content Claims

1. Should all representations in advertising concerning the relationship between fat and/or cholesterol and heart disease be banned (except content statements), following the FDA regulations 21 CFR §1.18? Why or why not?

2. If claims, in your opinion, should be permitted, what kinds of claims are permissible and what qualifications, if any, should be required?

3. Does an ad which mentions that a food is "low in cholesterol" or "low in saturated fat" overemphasize the role that food plays in reducing blood serum cholesterol levels, and therefore, its role in mitigating heart disease? Consider, for example, the role of margarine and vegetable oil in the average diet?

4. Is the substitution of some foods low in cholesterol or saturated fat for others insignificant so that ad claims would be deceptive i.e. margarine for butter, other examples? Should some claims be permitted for certain foods and others banned?

5. Should a food low in cholesterol but high in saturated fats be allowed to make "low in cholesterol" claims? What standards should be set up to evaluate the fat and cholesterol content of foods to prohibit such claims?

6. When is a food high, medium, or low in cholesterol? saturated fats? Should the FTC rule set up standards governing "low in cholesterol/fat" claims.

7. What evidence is there that diet resulting in high cholesterol and fat levels in the blood contributes to heart disease?

(Attach a bibliography)

8. In your opinion, should the average American lower his or her cholesterol/fat intake?

9. What studies are available which indicate that a lowering of the dietary intake of cholesterol and saturated fat results in the lowering of serum cholesterol levels?

10. Do you agree or disagree with the proposed provisions §437.9(b) and (c). (Page 72 of the double-spaced rule?). Why?

11. Is there any benefit to consumers to permitting an advertiser to disclose in the ad the total fat content of the advertised food in terms of the total calories provided by fat? In terms of the amount of saturated and polyunsaturated fats present in the food? In terms of the saturated to polyunsaturated fat ratio?

12. Is the proper way to measure "fat" content the absolute amount of saturated and unsaturated fats, calculated independently or a ratio of saturated to unsaturated fats? Should advertising claims comparing the fat content of foods be permitted? If so, should the comparison be on the basis of the absolute amounts of saturated (or unsaturated) fats or between the ratio of saturated/unsaturated of each product? If comparisons were limited to "significant" differences only, what, in your opinion would be significant differences in fat levels between two foods?

13. Should the general consumer attempt to reduce his or her intake of cholesterol or saturated fat without first obtaining the advice of a physician?

American
Heart
Association

Memorandum

January 3, 1975

TO: Drs. Albrink, Gotto, Mueller, Rapaport, Shank

FROM: Dolph Chianchiano

SUBJECT: Federal Trade Commission Regulations on Food Advertising

This is a follow-up on my memorandum of 12 December 1974 concerning the Federal Trade Commission's proposed regulations on food advertising. It will comprise the issues and questions which arose during discussion with the FTC attorneys during lunch in Washington the following day.

The rules on advertising claims concerning fat and cholesterol originally proposed by the FTC staff would only allow a statement of the weight of these items per serving or per package. Representations that a particular product would promote health or prevent disease because of its fat composition would be banned. Furthermore, it would not even be permissible to mention that a product was "low" in fat or cholesterol. This is much more restrictive than what is presently legal to advertise.

The governing body of the Federal Trade Commission (the "Commission") refused to go along with this proposal. FTC staff speculated that the Commission believes a more liberal policy is necessary to encourage food processors to develop and market new products. The Commission would like to see regulations which would strike a balance between this goal and the elimination of misleading claims, such as the one that Gablinger's beer is low in fat content. Accordingly, the FTC staff is looking for alternative regulatory schemes and/or support from disinterested groups for their original position.

Among the alternatives which the FTC attorneys raised were:

1- Allow health claims but require a statement that hyperlipidemia is only one risk factor in heart disease.

2- Allow health claims but require a statement that no one food can effect lower total cholesterol intake or lower blood-fat levels.

3- Prohibit health claims but allow representation that a product (or competing product ?) is high, low or medium in cholesterol.

The attorneys seemed to have the most problem with the third alternative. Among the drawbacks they cited were:

(a) what constitutes "high", "low", or "medium" ? (A claim could be made that a single pat of butter is"low" in cholesterol.) Put another way, how do you measure that one

product is significantly lower in cholesterol or saturated fat?

(b) The third alternative does not solve the situation where a product may be low in cholesterol but high in saturated fat or triglycerides.

The FTC attorneys asked you to consider other potential approaches to food advertising which impacts on heart disease. Specifically:

1- In view of the AHA position on balanced diet and overall lowering of caloric intake, should calorie disclosure be required in all advertising?

2- In the draft regulations already printed, no food shall be represented in advertising to be a substitute or replacement for another food when the advertised food contains a higher fat content unless " the total fat content is clearly and conspicuously disclosed". (Section 437.4(b)(4)).

a) should a more restrictive prohibition be imposed?

b) is "fat content" the proper operative phrase--i.e., should a distinction be made between saturated and unsaturated fat, and/or cholesterol?

3- Section 437.5 proposed to regulate claims that foods are "nourishing", "wholesome", "nutritious", or have similar qualities...Should this section be amended to include a consideration of fat content, e. g., if more than "x" per cent of a food's calories are fat calories, it could not be advertised as being "good for you".

On reviewing these questions, it seems that a conference call may be necessary. The FTC attorneys would like us to comment on the November 11 regulations by the end of this month.

cc: William W. Moore
Mary Winston
Charles L. Plante

P.S. At the conclusion of our meeting, I brought the Advertising Guidelines of the National Association of Broadcasters for vegetable oils and margarines to the attention of the FTC attorneys. (You will find a copy enclosed.) I commend these to you as a possible basis for an alternative approach to this situation.

Encl.

FEDERAL TRADE COMMISSION
WASHINGTON, D. C. 20580

BUREAU OF
CONSUMER PROTECTION

January 13, 1975

Mr. Dolph Chianchiano
Public Policy and Government
Affairs
American Heart Association
44 East 23rd Street
New York, New York 10010

Dear Mr. Chianchiano:

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Any formal comment should be addressed to William D. Dixon, Special Assistant for Rulemaking, Federal Trade Commission, Washington, D. C. 20850. Presently the deadline for comment is February 5, 1975. I will call to let you know if, as is now anticipated, that deadline is extended.

If my colleagues or I can be of any assistance, do not hesitate to call. Our numbers are Stewart Block (202)962-4414; Judith Niebrief (202)962-4441; Thomas J. Donegan, Jr. (202) 962-4165; William S. Busker (202)962-4604; and Lois Dimore (202)962-4738.

Sincerely,

Stewart A. Block

Stewart A. Block
Attorney

Enclosure

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13. Should the general consumer attempt to reduce his or her intake of cholesterol or saturated fat without first obtaining the advice of a physician?

FEDERAL TRADE COMMISSION
WASHINGTON, D. C. 20580

BUREAU OF
CONSUMER PROTECTION

December 10, 1974

Mr. Dolph Chianchiano
Public Policy and Government
Affairs
American Heart Association
44 East 23rd Street
New York, New York 10010

Dear Mr. Chianchiano:

This will confirm our meeting time, scheduled for Friday, December 14, at 12 Noon at 21st Street and Constitution Avenue, Washington, D.C.

As I discussed with you yesterday, the FTC has published for expert and public comment a staff proposal which would eliminate all claims that eating a particular food (for example a food low in cholesterol or saturated fats) will help reduce the risk of heart and artery disease. In particular, the staff's proposal would permit an advertisement for a food to give only an accurate statement of the cholesterol and/or fat content. The staff's proposal also would require a statement that the information on cholesterol and/or fat content of the product is provided for those persons who are reducing their total dietary cholesterol or fat intake on the advice of a physician.

The FTC's staff is particularly interested in the American Heart Association's opinion of whether this proposed regulation goes too far in eliminating claims that a particular advertised food which is low in cholesterol or saturated fats can help reduce the risk of heart attack or related diseases. Some of the questions we are anxious to have your views on are:

1. Are there any claims for foods which are low in cholesterol or saturated fats which could be made to the general public without being deceptive?

2. Should the general consumer attempt to reduce his intake of cholesterol or saturated fat without first obtaining the advice of a physician?

3. Is there a level of cholesterol or saturated fat which would be generally recognized by experts to be "low", "moderate" or "high"? What would be the factors considered in judging a food to be "low", "moderate" or "high" in cholesterol or saturated fat?

4. Would it be accurate to state that a food product is "high" in polyunsaturates if it also contained "moderate" or "high" amounts of cholesterol or saturated fats?

5. Would an advertisement which pointed out the low cholesterol and/or fat level for a particular food, or its high polyunsaturated level, over-emphasize the role of that particular food in the diet in the reducing or mitigating the risk of heart disease and related conditions?

The text of the staff's proposed regulation governing claims concerning cholesterol and saturated fat appears on page 39862 of the Federal Register Volume 39, No. 218 part II, published on November 11, 1974. The purpose and analysis of this provision is discussed on page 39850 of the document. Enclosed is an additional copy of that document for your files. Also included in this document are:

(1) A proposed Rule approved by the Commission (pps. 39842-39845).

(2) An explanation of Proceeding and Analysis and Statement of Issues by Section, approved by the Commission (pps. 39845-39851).

(3) A Staff Statement of Fact, Law and Policy (pps. 39852-39860).

(4) A Staff Proposal for Affirmative Disclosure in Food Advertising [not adopted by the Director of the Bureau of Consumer Protection or the Assistant Director for National Advertising] (pps. 39860-39862).

(5) Staff proposed provisions on

(a) Natural and Organic Food Claims

(b) Health and Related Claims (p. 39862).

I hasten to stress that the cholesterol and fat provisions noted for your specific attention have not been included by the Commission as part of the Commission's formal proposed Rule. Rather, they were included in the published materials because the Commission wished to obtain further expert and public comment in these matters. As a result, your thoughts on this matter can play a very significant role in the approach ultimately adopted by the Commission.

As you requested, I am also enclosing a copy of §1.18 of the Food and Drug Administration's regulations governing label statements regarding cholesterol and fat.

If you have any questions concerning any part of the proposed Rule, please feel free to call me at (202) 962-4414. If I am out, my colleagues Bill Busker, (202) 962-4604, or Tom Donegan, (202) 962-4165, will be able to help you.

Thank you for your cooperation. I look forward to meeting you on Friday.

Sincerely,

Stewart A. Block

Stewart A. Block
Attorney

Enclosures

§ 100.10 Fortified ready-to-eat breakfast cereals.

(a) In order to be eligible to bear the guideline statement set forth in § 100.1 (b), a ready-to-eat breakfast cereal described in paragraph (d) of this section shall contain the following vitamins and minerals in the amounts prescribed:

Nutrient	Per serving	
	Amount	Percent U.S. RDA
Protein (grams)	6.5	10
Vitamin A (IU)	1,250	25
Thiamine (milligrams)	.38	25
Riboflavin (milligrams)	.26	15
Niacin (milligrams)	5.0	25
Calcium (milligrams)	150	15
Iron (milligrams)	4.5	25
Vitamin B6 (milligrams)	.5	25
Folic acid (μg)	.1	25
Magnesium (milligrams)	100	25
Zinc (milligrams)	3.8	25

(b) A serving shall be 1 ounce, except that a serving for a single service container shall be the amount in the container. A serving of milk with ready-to-eat breakfast cereal shall be 4 fluid ounces.

(c) Protein, magnesium, and zinc are optional nutrients for fortification. If they are added, the total quantities present in the food shall be at least at the levels specified in paragraph (a) of this section.

(d) Protein content shall not be listed when the protein efficiency ratio (PER) is less than 20 percent of the PER of casein.

(e) The cereal products subject to this regulation are those manufactured for use as ready-to-eat breakfast cereals. For the purposes of this section the term "cereal" includes food products made from the seeds of grains and similar plants and from oilseeds.

(f) A ready-to-eat breakfast cereal which meets this guideline may bear the term "fortified" as part of its name.

(g) A ready-to-eat breakfast cereal that contains any nutrient at a level which falls within the dietary supplement range established in § 80.1 of this chapter is subject to the requirements of § 80.1 and is not subject to this section. Any such product shall conform to the labeling requirements of § 1.17(c) and shall comply in all other respects with the requirements of § 80.1.

(h) When the dual declaration of nutrient content of cereal plus milk, provided in § 1.17(d)(2) of this chapter, is used in the nutrition labeling of a product which meets this guideline, the percentage of the U.S. RDA for protein provided by the cereal plus milk mixture shall be the sum of the percentage of the U.S. RDA for protein provided by the cereal alone and the percentage provided by the milk alone.

(i) The provisions of this section are not applicable to a ready-to-eat breakfast cereal product represented as an infant cereal.

Interested persons may, on or before August 13, 1974, file with the Hearing Clerk, Food and Drug Administration, Rm. 6-86, 5600 Fishers Lane, Rockville, MD 20852, written comments (preferably in quintuplicate) regarding this proposal. Comments may be accompanied by a memorandum or brief in support thereof. Received comments may be seen in the above office during working hours, Monday through Friday.

Dated: June 7, 1974.

A. M. SCHMIDT,
Commissioner of Food and Drugs.

[FR Doc.74-13472 Filed 6-13-74;8:45 am]

IMPORTANT

[21 CFR Part 100]

GENERAL PRINCIPLES GOVERNING THE ADDITION OF NUTRIENTS TO FOODS

Notice of Proposed Rule Making

The Commissioner of Food and Drugs has promulgated a series of regulations related to the nutritional quality of foods in recent months. The regulations have included nutrition labeling under § 1.17 (21 CFR 1.17), fat, fatty acid, and cholesterol labeling under § 1.18 (21 CFR 1.18), imitation foods under § 1.3(e) (21 CFR 1.3 (e)), special dietary foods under Part 125 (21 CFR Part 125), nutritional quality guidelines under Part 100 (21 CFR Part 100), dietary supplements of vitamins and minerals under § 80.1 (21 CFR 80.1), and amino acid addition to foods under § 121.101 (21 CFR 121.101). Other existing standards of identity permit or require addition of vitamins, minerals, and protein to foods in order to improve the nutritional quality of the product, e.g., enriched flour under § 15.10 (21 CFR 15.10).

During the development of regulations related to nutrition, it became apparent that there is a need to define and publish the principles governing the addition of vitamins, minerals, and protein to food.

The Commissioner concludes that a separate standard of identity for each food to which a vitamin, mineral, and/or protein may properly be added is neither practicable nor appropriate. The Commissioner has also determined that a single standard of identity listing all foods to which a vitamin, mineral, and protein may properly be added, is unnecessarily inflexible in light of developing knowledge about nutrition. Accordingly, in the FEDERAL REGISTER of January 19, 1973 (38 FR 2153) the Commissioner announced his intention to hold in abeyance the portion of the 1968-1970 special dietary food regulation hearings relating to vitamin- and mineral-fortified foods, identity, and label statements, under § 80.2, pending experience under nutritional quality guidelines.

The general principles for the establishment of such nutritional quality guidelines were proposed in the FEDERAL REGISTER of December 23, 1971 (36 FR 24822) and promulgated in the FEDERAL REGISTER of March 14, 1973, (38 FR 6969). The Commissioner has concluded that it is now appropriate to establish general principles governing the addition of vitamins, minerals, and protein to food, which will serve as the basis on which the Food and Drug Administration will permit such nutrient addition in the future.

The addition of vitamins and minerals to foods was first undertaken as a public health measure to prevent the development of deficiency diseases that afflicted large segments of the public. As the causes of such diseases as goiter and rickets were identified, the addition of specific nutrients to food was recommended. The success of this program has been widely recognized and acclaimed. The addition of iodine compounds to salt over fifty years ago, which has ended a widespread goiter problem, is a good example of consumer benefits from this type of program.

The addition of nutrients to foods has been evaluated by many public health and nutrition authorities. It is generally concluded that such programs have provided a safeguard in national diets and have been effective in reducing the prevalence of deficiency diseases in many countries. Such programs remain valuable today, provided sufficient information is available to identify the nutrition problem, to define affected population groups, and to designate suitable foods to act as vehicles for the added nutrients.

The basic principle that dietary deficiency disease can be prevented by appropriate addition of nutrients to foods has been best described in "Improvement of Nutritive Quality of Foods," a joint policy statement by the Food and Nutrition Board of the National Academy of Sciences-National Research Council (NAS/NRC) and the Council on Foods and Nutrition of the American Medical Association (AMA) published in the *Journal of the American Medical Association*, 205:868-869, Sept. 16, 1968. This statement has been retained in the more recent report, "Improvement of the Nutritive Quality of Foods, General Policies" of the Council on Foods and Nutrition, published in the *Journal of the American Medical Association*, 225:1116-1118, August 27, 1973, and in the statement, "General Policies in Regard to Improvement of Nutritive Quality of Foods," prepared by the Food and Nutrition Board of the NAS/NRC, released on August 23, 1973. Copies of these statements are on file with the Hearing Clerk. The practical application of the principles stated by these two groups is given in the following quotation from the 1968 statement:

> The availability and low cost of nutrients produced industrially and the advances in food technology have enhanced the potential for the improvement of existing foods and for the formulation of new foods. Enrichment, fortification, and restoration of nutritional value of certain foods have been endorsed by the Council on Foods and Nutrition and the Food and Nutrition Board: Specifically, the following practices in the United States continue to be endorsed: The enrichment of flour, bread, degerminated corn meal, corn grits, whole grain corn meal, and white rice (with thiamine, riboflavin, niacin, and iron); the retention or restoration of thiamine, riboflavin, niacin, and iron in

...ssed food cereals; the addition of vita... D to milk, fluid skim milk, and nonfat ... milk; the addition of vitamin A to mar... fluid skim milk, and nonfat dry milk; ... the addition of iodine to table salt. The ...tective action of fluoride against dental ...ies is recognized and the standardized ...ition of fluoride to water is endorsed in ...as in which the water supply has a low ...oride content.

The Commissioner is aware that permitting the addition of nutrients to foods solely on the basis of an identified deficiency disease, or of the probability that ... will develop because of a basic nutrient deficiency in the food supply, would be unduly restrictive. With the increased use of convenience foods, fabrication of foods from new ingredients, and substitute foods, there is a need to maintain the nutritional quality of diets when there are changes in food patterns. When evidence of a substantial change in food consumption patterns has occurred which results in a less satisfactory nutrient intake in the population, consideration must be given to application of the principles of fortification to improve ...diet.

...80.2, to establish a standard ... all vitamin- and mineral-fortified ... was published in the FEDERAL REGISTER on June 18, 1966 (31 FR 8521). The order was subsequently stayed because of objections and requests for public hearings in an order published December 14, 1966 (31 FR 15730). A further order was subsequently published in the FEDERAL REGISTER of April 8, 1967 (32 FR 5736), amending § 80.2 to add additional classes of food. A hearing was convened in May 1968 and continued for two years, closing in May 1970. Extensive oral and documentary evidence was presented with respect to the food fortification policy enunciated in § 80.2.

In December 1969, a White House Conference on Food, Nutrition and Health was convened. The Report of the Conference reflected a consensus that nutrition information and food consumption patterns are too dynamic to be written down in, or governed by, inflexible rules, but that the Food and Drug Administration should establish standards of nutritional quality for all foods used as a significant part of the diet to assure a minimal nutrient content in the diet.

After reviewing the portion of the special dietary food hearings concerning fortified foods and the recommendations of the White House Conference on Food, Nutrition and Health, the Commissioner concluded that it would be in the public interest to develop regulations for fortified foods utilizing the approach of establishing nutritional quality guidelines for certain classes of foods, including those to which vitamins, minerals, and protein may be added, in lieu of establishing standards of identity as originally adopted in § 80.2. The Commissioner therefore added a new Part 100 for nutritional quality guidelines for foods, and established the first nutritional quality guidelines for precooked frozen convenience "heat and serve" dinners.

The Commissioner has also considered the relation of "imitation" foods to nutritional quality. In the FEDERAL REGISTER of January 19, 1973 (38 FR 2138), a proposal was published to define "imitation" food in terms of nutritional content. The proposal stated that nutrients could be added to substitute foods in order to achieve nutritional equivalence. The Commissioner published an order in the FEDERAL REGISTER of August 2, 1973 (38 FR 20702), establishing § 1.8(e) which defined "imitation" and established the criteria for determining nutritional equivalence. The preamble to the order stated that vitamin and mineral additions to substitute foods would be permitted in order to achieve nutritional equivalence but cautioned against excessive fortification.

The Food and Nutrition Board of the NAS/NRC and the Council on Foods and Nutrition of the AMA have also discussed the need for restoring vitamins and minerals to replace those lost in the processing of foods. The August 23, 1973, statement from the NAS/NRC states in part:

> The appropriate selection of a wide variety of conventional foods is important in assuring adequate intake of all essential nutrients. It is, of course, desirable that foods having undergone some form of post-harvest processing contain the variety and amounts of essential nutrients that were present at significant levels in the raw, preprocessed food. A significant level of a nutrient is considered to be 5 percent or more of the RDA of that nutrient in an average serving. Restoration of nutrients lost in the processing of foods has been recognized for many years as an appropriate method for improving their nutritional value. Under circumstances where restoration is undertaken through the addition of nutrients as specific chemical entities, it is important that all essential nutrients present at significant levels in the original preprocessed food be restored to the extent that is technically feasible. The nutrient level achieved through restoration should be 1.0–1.5 times preprocessed levels. The principle of extensive restoration is of special importance when a label claim for the content of an added nutrient is made.

The basic concept adopted by both organizations is to restore significant nutrient levels of processed foods to the levels present in the fresh unprocessed food. An uncontrolled restoration could result in the addition of trivial amounts of nutrients, giving rise to misleading promotional claims but providing no significant benefit to consumers.

The Canadian Food and Drug Directorate, in its "Trade Information Letter" No. 351, April 23, 1971, proposed a procedure to allow controlled restoration of nutrients lost in the course of manufacturing, similar to the approach proposed by the AMA and the NAS/NRC. It states that vitamins, minerals and protein added to traditional foods should be present in amounts related to the purpose of the addition, e.g., to replace those nutrients lost in the course of good manufacturing practice, if the amount originally present provided at least 10 percent of the daily requirement of these nutrients in a reasonable daily intake of the food, the amount added should compensate for that lost in processing. The Canadian government has been applying this guideline since 1971.

The concept of adding nutrients to foods when such nutrients are lost in processing, only when the foods are recognized as significant sources of the nutrients, appears to be one acceptable approach.

However, the Commissioner concludes that restoration of measurable nutrient loss for any processed food is more reasonable and has adopted this approach in the proposal. The use of nutrition labeling under § 1.17 requires that vitamin and mineral levels be listed at 2-percent intervals between 2 and 10 percent of the United States Recommended Daily Allowance (U.S. RDA) for each nutrient. The level of 5 percent of the U.S. RDA proposed by the AMA Council on Foods and Nutrition and the NAS/NRC Food and Nutrition Board to determine if a food is a significant source of a nutrient falls outside the labeling increments. Because 2 percent of the U.S. RDA is sufficiently important to justify labeling increments at this level, the Commissioner proposes 2 percent of the U.S. RDA as the minimum loss of a nutrient during processing if restoration is to be permitted. Thus, restoration of trivial amounts of nutrients will not be permitted, since such a practice would be misleading and deceptive.

The Commissioner also proposes to permit the addition of nutrients to certain classes of foods if addition of the nutrient is necessary to raise the nutritional quality of the food up to the nutritional level appropriate for that class of food based upon the best available scientific data on food consumption, nutrition needs, and dietary habits.

The White House Conference on Food, Nutrition and Health recommended vitamin and mineral fortification based on caloric content. The NAS/NRC Committee which developed the initial nutritional quality guideline reports also suggested that nutrient levels in some foods should be related to the caloric contribution of the food. Following such a pattern, nutrient additions would be controlled by restricting the level of any added nutrients to the percentage of the U.S. RDA equal to the caloric contribution of the food to a daily calorie standard. The Commissioner proposes to set the daily calorie standard at 2800 kilocalories. Thus, a food which contributes 280 kilocalories per serving (10 percent of the daily calorie standard) could have vitamins, minerals, and protein added per serving to a level equal to 10 percent of the U.S. RDA. This approach will prevent irrational fortification or fortification to unduly high levels or levels which would make the products dietary supplements. The AMA Council on Foods and Nutrition, in its statement of August 27, 1973, outlined its position as follows:

> Nutrient density is an expression of nutrient content in terms of caloric value of a serving of food as related to a standard such as the RDA * * * for nutrients and calories. For example, a serving containing 230 kilocalories might be referred to a calorie standard of 2,300 kilocalories/day. In this instance, the food represents 10 percent of the calorie

value of the standard and should be expected to contain this percentage of each of the nutrients in the standard. If a given nutrient is naturally present in an amount equal to three quarters or more of that percentage, no further adjustment is needed.

A similar concept has been proposed using protein content as the food component for establishing the role of the food in the diet. The mechanism for control of vitamin and mineral additions would be similar to that when calorie content is used as a basis for control. When protein is used, protein-free products are eliminated from consideration, even when they provide significant caloric contributions, and no basic standard is provided for the addition of protein to a food. However, when calories are used as the basis for comparison, protein can be considered as a nutrient and added when appropriate.

The Commissioner proposes that the concept of relating vitamin, mineral, and protein content to caloric contribution either for the addition of nutrients to foods, or for establishing nutritional quality, be included in the general regulation regarding the addition of nutrients to foods. A careful review of the procedure as proposed by the White House Conference and the NAS/NRC Committee developing the nutritional quality guidelines and in the AMA Council on Foods and Nutrition statement indicates that it can be used not only in controlling the addition of nutrients to foods, but also as a means for establishing a basic concept of nutritional quality for fabricated foods.

Thus, the Commissioner proposes to allow the addition of nutrients to foods using the "balanced" concept of adding nutrients in relation to calories. Such nutrient addition would not be appropriate, however, where the desirable nutrient addition or composition of the food has already been established by a nutritional quality guideline or a food standard, and the proposal therefore excludes these foods from this form of fortification. Thus, white bread would be required to be enriched pursuant to the existing food standard, if any nutrients are added, and could not be fortified under the balanced nutrient approach. Manufacturers wishing to use the balanced nutrient approach to fortification must carefully consider the criteria established in the regulation. Where appropriate, consumers or manufacturers may also petition the Commissioner to establish a nutritional guideline or a standard of identity.

For the purposes of nutrient addition to achieve "balanced" nutrition, the Commissioner proposes that a caloric level of 2800 kilocalories be set as a daily standard, and that the vitamin and mineral levels be those established under § 1.17(c)(7)(iv). The protein levels will be the same as those established under § 1.17(c)(7)(ii)(a). The protein levels to be used to calculate the protein per 100 kilocalories would be 65 grams for protein with a protein efficiency ratio (PER) less than casein but more than 20 percent that of casein and 45 grams for protein with a PER equal to or greater than that of casein. The PER shall be determined by the appropriate method in "Official Methods of Analysis of the Association of Official Analytical Chemists," 11th edition, (1970).[1] A table giving the nutrient levels per 100 kilocalories included in the proposal is as follows:

Nutrient	Unit of measurement	Adults and children over 4 yr	
		U.S. RDA	Per 100 kcal
Protein	Grams	[1] 65.0	2.32
Do	do	45.0	1.61
Vitamin A	IU	5,000.0	178
Vitamin C	Milligrams	60.0	2.14
Thiamine	do	1.5	.054
Riboflavin	do	1.7	.061
Niacin	do	20.0	.72
Calcium	Grams	1.0	.036
Iron	Milligrams	18.0	.64
Vitamin D	IU	400.0	14.3
Vitamin E	do	30.0	1.07
Vitamin B$_6$	Milligrams	2.0	.071
Folic acid	do	.4	.014
Vitamin B$_{12}$	μg	6.0	.21
Phosphorus	Grams	1.0	.036
Iodine	μg	150.0	5.36
Magnesium	Milligrams	400.0	14.3
Zinc	do	15.0	.54
Copper	do	2.0	.071
Biotin	do	.3	.011
Pantothenic	do	10.0	.357

[1] If the protein efficiency ratio of protein is equal to or better than that of casein, U.S. RDA is 45 g.

In the past, the addition of a vitamin or mineral to a food has resulted in the food being defined as a "special dietary food." This approach was adopted to ensure that such foods would contain specific label information about the particular nutrient(s) involved, pursuant to regulations promulgated in 21 CFR Part 125. Virtually all of the foods previously categorized as special dietary foods for purposes of requiring nutrient labeling have been intended for consumption by the general population and not by any particular small segment of it. With the development of nutrition labeling under § 1.17, it is no longer necessary to regulate nutrient labeling of these general purpose foods under the provisions of the law relating to special dietary foods.

For some products, general nutrition labeling under § 1.17 is inappropriate and very specific special dietary food labeling under 21 CFR Part 125 has been retained. These foods were exempted from § 1.17 in the final regulation. Such exempted foods include certain infant foods for which separate labeling has been promulgated in § 125.5; dietary supplements of vitamins and minerals, subject to a standard of identity in § 80.1; any food intended for use as the sole item of the diet, for which specific special dietary food labeling, including in some cases amino acid composition, is appropriate under 21 CFR Part 125; and foods represented for use solely under medical supervision to meet nutritional requirements in specific medical conditions, such as foods for the dietary management of inborn errors of metabolism, for which specific special dietary food labeling is also more appropriate under 21 CFR Part 125. In each of these instances, the broad approach adopted for nutrition labeling, which is clearly desirable for general consumer use, is inappropriate because of the need for more detailed and specific information and because the type of product involved is more readily susceptible to precise quality control of the nutrient levels.

Thus, the addition of a vitamin, mineral, or protein to food, unless included in one of the above exemptions, will not result in that food being considered a special dietary food for labeling purposes. Such addition of a nutrient will instead require full nutrition labeling under § 1.17.

Over the years, several terms have been used to describe the different purposes for addition of nutrients to foods, i.e., enrichment, restoration, and fortification.

The term "enrichment" usually is defined as the addition of one or more nutrients to a food in order to increase the consumption of those nutrients by the general population or a defined segment of the population. The nutrients added to the food are higher levels of those nutrients already present in the food. The best example of enrichment is bread and flour. The term enrichment has often been incorporated into the name of the food to which the nutrients have been added, e.g., "enriched bread," "enriched flour."

"Restoration" is the addition of nutrients to conventional foods in order to restore nutrients lost during processing. The level of the restored nutrient is approximately the same as is present naturally in the product.

"Fortification" has been used to denote the addition of one or more nutrients to a food whether or not they are naturally present. The terms "vitamin added" or "with added vitamins and minerals" as well as the term "fortified" have, at times, been used to identify fortified products. This definition overlaps that given to "enrichment," and would permit the same food to be labeled as "enriched" or "fortified." This could result in consumer confusion.

The Commissioner proposes to limit the use of the word "fortified" to those situations where nutrients are added to a food which does not naturally contain those nutrients. Since the addition of several nutrients to a food can occur, the addition of any one nutrient, not naturally present in the food, shall require that the term "fortified" be used even if other nutrients are added which are naturally present in the food.

While the terms stated above ("enriched," "restored," "fortified") can be defined so they have specific meanings, they have often been used interchangeably and thus the consumer probably accepts all as indicating simply that the nutritional quality has been improved by the addition of a nutrient.

The Commissioner proposes to define these terms as set forth above so that

[1] Copies may be obtained from: Association of Analytical Chemists, P.O. Box 540, Ben Franklin Station, Washington, DC 20044.

...ey will be used properly in labeling and interested persons will be able to distinguish between them.

The Commissioner emphasizes that the publication of this proposed regulation on the addition of nutrients to foods is not intended to encourage the industry to put vitamins, minerals, or protein into every food. The addition of a nutrient to a food must conform to the principles in the proposed regulation, and provide consumers with reasonable benefit without misleading them into believing that the food with added nutrients will ensure a complete diet. The proposed regulation, therefore, provides that, if the addition of a nutrient(s) to a food is contrary to the regulation, the food to which the nutrient(s) is added is required to bear a prominent statement that the nutrient(s) added has been determined by the U.S. Government to be unnecessary and inappropriate.

The Commissioner also proposes to amend § 100.1 to provide that any food which would otherwise be required to be labeled with the statement specified in § 100.1(f) will not be required to be so labeled if the nutrient(s) is added to the product in accordance with § 1.8(e) of this chapter to avoid being an imitation.

In order to prevent labeling claims for the addition of measurable amounts of nutrients to foods which do not reach the level of substantial nutritional "significance," the Commissioner proposes to prohibit claims concerning the addition of any nutrient for purposes of enrichment, fortification, or restoration, or the balanced nutrition concept unless such addition is equal to or in excess of 10 percent of the U.S. RDA per serving. Also, in order to prevent labeling claims which might result in a substitute food being represented as superior to the food which it resembles because of nutrients added to prevent nutritional inferiority, the proposed regulation prohibits labeling claims concerning the addition of nutrients to such foods.

These two prohibitions apply only to claims relating directly to the addition of nutrients, and in no way prohibit claims on the total nutrient content of the food itself. Thus, the label for a product to which less than 10 percent of the U.S. RDA of a nutrient is added could not declare the product to be "fortified" or "enriched" or "restored," or otherwise state or imply that nutrients have been added. On the other hand, there would be no prohibition for label statements on such products which accurately claim that the product contains a specified amount of the nutrient, e.g., "contains 6 percent of the U.S. RDA of _____".

In order to make it possible to make nutrient claims for foods which do contain at least 10 percent or more of the U.S. RDA of nutrients added for the purposes of enrichment, restoration, or fortification, the Commissioner proposes to amend paragraph (d) to allow claims to be made on the labels of foods which comply with the guidelines established in Subpart B.

The section on general principles of the regulations on nutritional quality guidelines, § 100.1 (21 CFR 100.1), does not state specifically whether nutritional quality guidelines apply only to nonstandardized foods or to standardized foods as well. In the preamble to the proposal to establish a nutritional quality guideline for breakfast beverage products, published elsewhere in this issue of the FEDERAL REGISTER, it is stated that a breakfast beverage product which meets the vitamin C requirements of an applicable standard of identity may bear the guideline statement provided in § 100.1 (b).

In order to prevent misinterpretation of the applicability of nutritional quality guidelines to standardized foods, the Commissioner proposes to amend § 100.1 (b) and (c) to provide that a food which contains a vitamin(s) or mineral(s) added for nutritional purposes, in accordance with the provisions of a standard of identity, may bear the statement provided in § 100.1(b). When the provisions for vitamin or mineral content of a standard of identity differ from the nutrient levels of an applicable nutritional quality guideline in Subpart B of Part 100, a proposal to amend the standard of identity to conform with the nutritional quality guideline will be published for comment.

Pertinent background information to which reference has been made as well as other information on which the Commissioner relies to support this proposal is on public display at the office of the Hearing Clerk.

Therefore, pursuant to provisions of the Federal Food, Drug, and Cosmetic Act (secs. 201, 403, 701(a), 52 Stat. 1040–1042 as amended, 1047–1048 as amended, 1055 (21 U.S.C. 321, 343, 371(a))) and under authority delegated to him (21 CFR 2.120), the Commissioner proposes to amend Subpart A of Part 100 in § 100.1 by revising paragraphs (b), (c), (d), and (f) and by adding new paragraphs (g), (h), (i), and (j), to read as follows:

§ 100.1 General principles.

* * * * *

(b) Labeling for a product which complies with all of the requirements of the nutritional quality guideline established for its class of food or of a food standard promulgated under section 401 of the act that prescribes the nutrient additions to the food may state "This product provides nutrients in amounts appropriate for this class of food as determined by the U.S. Government", except that the words "this product" are optional. This statement, if used, shall be printed on the principal display panel and may also be printed on the information panel, in letters not larger than twice the size of the minimum type required for the declaration of net quantity of contents by § 1.8b of this chapter. Labeling of noncomplying products may not include any such statement or otherwise represent, suggest, or imply the product as being, in whole or in part, in compliance with a guideline.

(c) A product bearing the statement provided for in paragraph (b) of this section, in addition to meeting the requirements of the applicable nutritional quality guideline or food standard, shall comply with the following requirements:

(1) The label of the product shall bear the common or usual name of the food in accordance with the provisions of the guideline and §§ 1.8 and 102.1 of this chapter and of any applicable food standard promulgated under section 401 of the act.

(2) The label of the product shall bear nutrition labeling in accordance with §§ 1.8d and 1.17 of this chapter and all other labeling required by applicable sections of Part 1 of this chapter.

(d) No claim or statement may be made on the label or in labeling representing, suggesting, or implying any nutritional or other differences between a product to which nutrient addition has or has not been made in order to meet the guideline, except that a nutrient addition shall be declared in the ingredient statement, and except as provided for in guidelines established in Subpart B of this part or in any applicable food standard promulgated under section 401 of the act.

* * * * *

(f) A product within a class of food for which a nutritional quality guideline has been established and to which has been added a discrete nutrient either for which no minimum nutrient level or nutrient range or other allowance has been established as appropriate in the nutritional quality guideline, or at a level that exceeds any maximum established as appropriate in the guideline, shall be ineligible to bear the guideline statement provided for in paragraph (b) of this section, and such a product shall also be deemed to be misbranded under the act unless the label and all labeling bear the following prominent and conspicuous statement: "The addition of _____ to (or "The addition of _____ at the level contained in) this product has been determined by the U.S. Government to be unnecessary and inappropriate and does not increase the dietary value of the food", the blank to be filled in with the common or usual name of the nutrient(s) involved. If the nutrient(s) is added to the product in accordance with § 1.8(e) of this chapter to avoid being an imitation, this paragraph shall not apply.

(g) The following principles shall govern the addition of a vitamin(s), mineral(s), and/or protein to food:

(1) A vitamin, mineral, or protein, as listed in paragraph (g)(3)(v) of this section, may be added to a food which is not naturally a significant source of such nutrient, as defined in § 1.17(c)(7)(v) of this chapter, if all of the following conditions are met:

(i) The intake of the nutrient is below a desirable level in the diets of a significant number of people.

(ii) The food to which the nutrient is added is generally consumed by a significant segment of the population in need.

(iii) The amount of the nutrient added makes a significant contribution to the diet of the population in need.

(iv) The added nutrient is stable in the food under customary conditions of storage and use.

(v) The added nutrient is physiologically available from the food.

(vi) There is a reasonable assurance that an excessive intake which could reach a toxic level will not occur.

(2) A vitamin, mineral, or protein, as listed in paragraph (g)(3)(v) of this section, may be added to a food if addition of the nutrient is necessary to raise the nutritional quality of the food up to the nutritional level appropriate for that food, based upon the best available scientific data on food consumption, nutrition needs, and dietary habits.

(3) Vitamins, minerals, and protein may be added to a food to balance the calorie contribution of the food if all the following conditions are met:

(i) A normal serving of the food contributes at least 55 kilocalories to the diet, i.e., 2 percent of the daily kilocalorie standard of 2800 kilocalories.

(ii) Use of the food reduces the nutritional quality of the total diet when consumer without such added nutrients.

(iii) The added nutrients are physiologically available from the food.

(iv) The food is not the subject of a nutrition quality guideline established in Subpart B of this part or a food standard that prescribes the nutrient additions to the food promulgated under section 401 of the act.

(v) The food with added nutrients, as prepared and eaten by the consumer, contains all of the following nutrients per 100 kilocalories based on 2800 kilocalories per day:

Nutrient	Unit of measurement	Adults and children over 4 yr.	
		U.S. RDA	Per 100 kcal
Protein	Grams	[1] 65.0	2.32
Do	do	45.0	1.61
Vitamin A	IU	5,000.0	178
Vitamin C	Milligrams	60.0	2.14
Thiamine	do	1.5	.054
Riboflavin	do	1.7	.061
Niacin	do	20.0	.72
Calcium	Grams	1.0	.036
Iron	Milligrams	18.0	.64
Vitamin D	IU	400.0	14.3
Vitamin E	do	30.0	1.07
Vitamin B$_6$	Milligrams	2.0	.071
Folic acid	do	.4	.014
Vitamin B$_{12}$	µg	6.0	.21
Phosphorus	Grams	1.0	.036
Iodine	µg	150.0	5.36
Magnesium	Milligrams	400.0	14.3
Zinc	do	15.0	.54
Copper	do	2.0	.071
Biotin	do	.3	.011
Pantothenic acid	do	10.0	.357

[1] If the protein efficiency ratio of protein is equal to or better than that of casein, U.S. RDA is 45 g.

(4) A vitamin, mineral, or protein, as listed in paragraph (g)(3)(v) of this section, may be added to a food which is naturally a source of such nutrient if addition of the nutrient is necessary to restore a nutrient shown by adequate scientific documentation to be lost in processing a measurable amount, i.e., at least 2 percent of the U.S. RDA per serving, if the following conditions are met:

(i) The nutrient is shown by adequate scientific documentation to be present in the food prior to processing in a quantity equivalent to at least 2 percent of the U.S. RDA in a normal serving of food.

(ii) Good manufacturing practices cannot avoid a measurable loss in such nutrient during processing.

(iii) The food is not the subject of a nutrition quality guideline established in Subpart B of this part or a food standard that prescribes the addition of nutrients to the food promulgated under section 401 of the act.

(h) Any food to which any vitamin, mineral, or protein has been added shall be deemed to be misbranded under the act unless the label and all labeling bears the prominent and conspicuous statement, "The addition of _____ to (or "The addition of _____ at the level contained in) this product has been determined by the U.S. Government to be unnecessary and inappropriate and does not increase the dietary value of the food" (the blank to be filled in with the common or usual name of the nutrient(s) involved), except for the following:

(1) Any infant food which simulates human milk or is suitable as a complete or partial substitute for human milk and which complies with § 125.5 of this chapter.

(2) Any dietary supplement which complies with § 80.1 and Part 125 of this chapter.

(3) Any food represented for use as the sole item of the diet.

(4) Any food represented for use solely under medical supervision to meet nutritional requirements in specific medical conditions.

(5) Iodized salt.

(6) Any food conforming to a standard of identity promulgated under section 401 of the act.

(7) Any food conforming to a nutritional quality guideline established in Subpart B of this part.

(8) Any food with a vitamin, mineral, or protein restored to preprocessing levels as defined in paragraph (g)(4) of this section.

(9) Any food with a vitamin, mineral, or protein added pursuant to § 1.8(e) of this chapter so that it is not nutritionally inferior to the food for which it substitutes and which it resembles.

(10) Any food fortified in compliance with paragraph (g)(3) of this section.

(11) Any food the composition of which is defined by other regulations or statutes.

(i) The following principles shall govern claims or statements on labels or in labeling:

(1) No claim or statement may be made on the label or in labeling that any vitamin, mineral, or protein has been added to a food, either in general terms, e.g., "fortified", or in specific terms, e.g., "_____ added", if it is added pursuant to § 1.8(e) of this chapter, except that a nutrient addition shall be declared in the ingredient statement.

(2) No claim or statement may be made on the label or in labeling that any vitamin, mineral, or protein has been added to a food, either in general terms, e.g., "fortified", or in specific terms, e.g., "_____ added", unless such vitamin, mineral, protein has been added at a level equal to or in excess of 10 percent of the U.S. RDA in a serving (or portion) of the food, except that a nutrient addition shall be declared in the ingredient statement.

(3) A food with a vitamin(s), mineral(s), or protein restored to preprocessing levels as defined in paragraph (g)(4) of this section may be labeled as "_____ restored" with the blank filled in with the vitamin(s), mineral(s), or protein restored if such vitamin(s), mineral(s), or protein has been added at a level equal to or in excess of 10 percent of the U.S. RDA in a serving (or portion) of the food.

(4) The label of a food to which vitamins, minerals, and protein have been added in accordance with paragraph (g)(3) of this section may bear the statement "Contains vitamins, minerals, and protein in proportion to its caloric content".

(j) For the purposes of food labeling, the following definitions shall apply:

(1) "Enriched" or "enrichment" means the addition to a food or one or more vitamin(s), mineral(s), or protein(s) which are naturally present in lesser amounts in the food in order to increase the consumption of such nutrient(s) by the general population or a specific segment of the population.

(2) "Restoration" means the addition of one or more vitamin(s), mineral(s), or protein(s) to a processed food in order to restore such nutrient(s) lost during processing to the level naturally present in the unprocessed food.

(3) "Fortification" or "fortified" means the addition to a food of one or more vitamin(s), mineral(s), or protein(s) not naturally present in the food in order to increase the consumption of such nutrient(s) by the general population or by a specific segment of the population. When the added nutrients include at least one nutrient not naturally present and one or more nutrients naturally present, the term "fortification" or "fortified" applies.

Interested persons may, on or before August 13, 1974, file with the Hearing Clerk, Food and Drug Administration, Rm. 6-86, 5600 Fishers Lane, Rockville, MD 20852, written comments (preferably in quintuplicate) regarding this proposal. Comments may be accompanied by a memorandum or brief in support thereof. Received comments may be seen in the above office during working hours, Monday through Friday.

Dated: June 7, 1974.

A. M. SCHMIDT,
Commissioner of Food and Drugs.

[FR Doc.74-13463 Filed 6-13-74;8:45 am]

Nutrition information provided by ufacturer or distributor directly to sionals (e.g., physicians, dietitians, tors) may vary from the require- of this section but shall also con- or have attached to it the nutrition mation exactly as required by this on.

The location of nutrition infor- on on a label shall be in compliance § 1.8d.

The following foods are exempt this section or are subject to special labeling requirements:

(1) Except where expressly covered by § 125.5 of this chapter, infant, baby, and junior-type foods marketed and promoted for children under 4 years of age shall include nutrition information on the label and in labeling in compliance with this section except that the term "serving" shall mean that reasonable quantity of food suited for or practicable of consumption by an infant or child under 4 years of age and that the U.S. RDA levels for infants and children under 4 years of age contained in § 125.1(b) of this chapter shall be used in lieu of the U.S. RDA levels contained in paragraph (c)(7)(iv) of this section. For the purposes of labeling these foods with a percent of the U.S. RDA for protein, a value of 20 grams of protein shall be the U.S. RDA value for protein with a protein efficiency ratio (PER) equal to or greater than casein, and 28 grams if the PER of the protein is less than the PER of casein but greater than 20 percent of casein.

(2) Dietary supplements, the nutrients of which consist solely of vitamins and/or minerals, shall be labeled in compliance with §§ 80.1 and 125.3 of this chapter, except that the labeling of a dietary supplement in food form, e.g., a breakfast cereal, shall conform to the labeling established in paragraph (c) of this section, including the order for listing vitamins and minerals established in paragraph (c)(7)(iv) of this section, in lieu of the labeling established in § 80.1 (i)(1) of this chapter.

(3) Any food represented for use as the sole item of the diet shall be labeled in compliance with Part 125 of this chapter.

(4) Foods represented for use solely under medical supervision in the dietary management of specific diseases and disorders shall be labeled in compliance with Part 125 of this chapter.

(5) Iodized salt shall be labeled in compliance with § 3.87 of this chapter and when used in a food does not subject that food to labeling under this section if it is declared in the ingredient statement by me (iodized salt) and neither iodine odized salt is otherwise referred to e label or in labeling or advertising.

A nutrient(s) included in food for technological purposes may be red solely in the ingredient state- without complying with this sec- the nutrient(s) is otherwise not d to on the label or in labeling dvertising.

A standardized food containing an nutrient(s), e.g., enriched flour, and included in another food as a component may be declared in the ingredient statement by its standardized name, without compliance with this section, if neither the nutrient(s) nor the component is otherwise referred to on the label or in labeling or in advertising.

(8) Food products shipped in bulk form for use solely in the manufacture of other foods and not for distribution to consumers in such bulk form or container.

(9) Food products containing an added vitamin, mineral, or protein, or for which a nutritional claim is made on the label or in labeling or in advertising, which are supplied for institutional food service use only: *Provided*, That the manufacturer or distributor provides the nutrition information required by this section directly to those institutions on a current basis.

(i) A food labeled under the provisions of this section shall be deemed to be misbranded under sections 201(n) and 403(a) of the act if its labeling represents, suggests, or implies:

(1) That the food because of the presence or absence of certain dietary properties, is adequate or effective in the prevention, cure, mitigation, or treatment of any disease or symptom.

(2) That a balanced diet of ordinary foods cannot supply adequate amounts of nutrients.

(3) That the lack of optimum nutritive quality of a food, by reason of the soil on which that food was grown, is or may be responsible for an inadequacy or deficiency in the quality of the daily diet.

(4) That the storage, transportation, processing, or cooking of a food is or may be responsible for an inadequacy or deficiency in the quality of the daily diet.

(5) That the food has dietary properties when such properties are of no significant value or need in human nutrition. Ingredients or products such as rutin, other bioflavonoids, para-aminobenzoic acid, inositol, and similar substances which have in the past been represented as having nutritional properties but which have not been shown to be essential in human nutrition may not be combined with vitamins and/or minerals, added to food label in accordance with this section, or otherwise used or represented in any way which states or implies nutritional benefit. Ingredients or products of this type may be marketed as individual products or mixtures thereof: *Provided*, That the possibility of nutritional, dietary, or therapeutic value is not stated or implied (e.g., their labeling does not state that their usefulness in human nutrition has not been established and does not otherwise disclaim nutritional, dietary, or therapeutic value).

(6) That a natural vitamin in a food is superior to an added or synthetic vitamin, or to differentiate in any way between vitamins naturally present from those added.

Effective date. All labeling ordered after December 31, 1973, unless extended by the Commissioner on petition for good cause shown, and all labeling used for products shipped in interstate commerce after December 31, 1974, shall comply with this regulation. (Secs. 201, 403, 701(a), 52 Stat. 1040–1042 as amended, 1047, 1055; 21 U.S.C. 321, 343, 371(a).)

Dated: March 7, 1973.

CHARLES C. EDWARDS,
Commissioner of Food and Drugs.

NOTE: Incorporation by reference provisions approved by the Director of the Federal Register, January 15, 1973.

[FR Doc.73-4671 Filed 3-13-73;8:45 am]

PART 1—REGULATIONS FOR THE ENFORCEMENT OF THE FEDERAL FOOD, DRUG, AND COSMETIC ACT AND THE FAIR PACKAGING AND LABELING ACT

Labeling of Foods With Information on Cholesterol and Fat and Fatty Acid Composition

In the FEDERAL REGISTER of January 19, 1973 (38 FR 2132), the Commissioner of Food and Drugs published a regulation relating to labeling foods with information on cholesterol and fatty acid composition. The regulation reflected the comments received on proposals published on June 15, 1971 (36 FR 11521), concerning cholesterol and fatty acid labeling. Thirty days were provided for additional comments on technical corrections or modifications. The Commissioner received more than 20 additional comments on the published regulation.

The comments from manufacturers were directed toward the triggering of nutrition labeling when fatty acid labeling was provided, the restrictions on label statements other than those provided for in the regulation, and the analytical procedures to be used for determining compliance. Other comments received from manufacturers included a request to allow products with less than 2 grams of fat in a serving to be labeled with fatty acid informaton; a request to delete the words "fatty acid" from the required heading (i.e., "Polyunsaturated fatty acid") and to use the word "fat" instead; a request to delete the statement of the percent of calories from fat and definition of servings; and a request to delete the required statement which makes reference to physicians advising the use of diets.

Two comments were received stating that the proposed labeling for fat was derogatory that no lower limit for fat content was proposed, suggesting that fat was not a valuable ingredient. It was suggested that the Commissioner establish a standard for the percent of calories from fat so that a food could state what percent of this daily fat standard it contained in a manner similar to that permitted for protein.

Comments received from consumers or consumer representation gave strong support to the cholesterol and fatty acid labeling. Their comments include a request that complete nutrition labeling be required whenever cholesterol content was stated, that the ratio of polyunsaturated to saturated fatty acids be listed (P/S ratio), and that servings be defined.

After considering all comments and suggestions for change submitted, the Commissioner has concluded to make a number of technical modifications to the final regulation, as outlined in the following discussion.

I. CHOLESTEROL LABELING

1. The suggestion that cholesterol labeling also require nutrition labeling was based on the contention that products listing a lower cholesterol content than usually found for that product class should disclose total nutritional value. The Commissioner concludes that there is merit in this suggestion, in that it would provide consumers with the same total information for both fatty acids and cholesterol. In reviewing products for which cholesterol labeling would provide consumers with useful information, primarily foods from those classes which are major contributors to dietary cholesterol of fabricated substitutes, it appears that nutrition labeling would serve a useful purpose. The regulation has therefore been changed in this respect.

The combining of cholesterol and nutrition labeling results in several additional technical changes to make the provisions of nutrition labeling apply to this section. In this issue of the FEDERAL REGISTER, the Commissioner is also publishing technical modifications to the nutrition labeling regulations of § 1.17 (21 CFR 1.17) reflecting the additional comments received on that regulation. Several of the proposed changes in cholesterol and fatty acid labeling are discussed in the preamble to that document and are incorporated into that regulation. These include provisions for using portions as well as servings, a partial exemption for institutional food products, and a provision for providing information to health and education professionals.

2. The suggestion was made that cholesterol content be declared in 5-milligram increments. While it does not appear that permitting actual values for cholesterol content would cause any problem, a more uniform statement of cholesterol content, in 5-milligram increments, would afford consumers a more uniform method of comparison. The regulation has therefore been modified to require cholesterol content to be stated in the nearest 5-milligram increment.

3. One manufacturer requested that a series of names be established for low, reduced, or cholesterol-free products. The Commissioner does not at this time propose to attempt to establish any common names of this type on his own initiative. Manufacturers with products which might be labeled with a common or usual name incorporating such statements may submit an appropriate petition under new Part 102, which establishes a procedure for adopting a common or usual name for a food, and which is published elsewhere in this issue of the FEDERAL REGISTER. Such names may not be false or misleading, and will be required to provide sufficient information to consumers that they can easily identify the product.

II. FAT AND FATTY ACID LABELING

1. The Food and Drug Administration (FDA) did not intend to suggest that the fat portion of the diet was unimportant. However, the Commissioner concludes that there is no good reason at this time for FDA to establish a U.S. Recommended Daily Allowance (U.S. RDA) for fat. There appears to be no deficiency of fat in the American diet. If there is a need for a standard for the quality of fat in the diet, it would be more appropriate to request that the Food and Nutrition Board of the National Academy of Science consider establishment of such a standard.

With respect to establishing a lower compliance limit for fat content, the Commissioner has concluded that no exact minimum figure is needed for determining compliance with the label declaration of fat. Manufacturers will be expected to follow good manufacturing practices in the production of products, and the label declaration of fat, carbohydrates, and calories will reflect such practices.

2. Several manufacturers and associations requested that the term "fatty acid" be dropped from the required declaration, on the basis that this term would confuse consumers. In addition, it was pointed out that the calculation of the fatty acid class was in fact made on the basis of the triglycerides, not the fatty acids, and therefore should not be referred to as "fatty acids." Comments were also received asking that the class "other fatty acids" be deleted.

With respect to the use of the term "fatty acids," it is probably true that consumers recognize "polyunsaturated" and "saturated" in relation to fat-modified diets, and the more technically correct term "fatty acids" could be confusing. The Commissioner agrees that the deletion of the term "fatty acids" will not result in any misunderstanding of the label by consumers, and has therefore changed the regulation.

In regard to deletion of the term "other fatty acids" there is only limited comment either supporting deletion or requesting retention of this statement. With the deletion of the term "fatty acid," the word "other" no longer can be easily understood, and might be misunderstood to mean that the "other" category has some special value. The original intent was to provide a means for identifying the total fat content, but it appears that this is less important than reducing the danger of consumer confusion. Thus, the category of "other fatty acids" has been deleted.

3. Two comments were received asking that the statement on the percent of calories from fat be deleted. A comment was received supporting retention of this provision. In the preamble to the published regulation, reference was made that percent of calories from fat was considered useful. No evidence was submitted that this would create any hardship. Accordingly, no change is made in the regulation in this respect.

4. A major objection related to the restrictions on any other statements on cholesterol and fatty acids content on the label or in labeling. Manufacturers felt that such restrictions were unreasonable, and that they had a right to provide such information if it was true and not misleading. Their concern was that consumers would not be able easily to identify products that might be useful in low cholesterol or fat-modified diets.

The Commissioner concludes that unrestricted statements on the principal display panel highlighting the cholesterol or fatty acid content overemphasize these components and could mislead consumers into believing that the medical basis for a fat-modified diet has been firmly established. However, the Commissioner also recognizes the need to identify a product on the shelf of the food store, and consideration has therefore been given to how this best can be done. For purposes of identifying a product which has cholesterol or fatty acid information on the label, a statement has been included in the revised regulation which can appear on the principal display panel. This will be a standard statement, to avoid the possibility that every manufacturer would use a different statement, thus further confusing the consumers. The restriction on other statements is retained.

5. The Commissioner discussed in the preamble to the January 19, 1973, regulation, the need for limiting fatty acid labeling to foods which made a reasonable contribution to the total daily fat intake. The requirement that a product provide at least 2 grams of fat in a serving is reasonable. No valid reasons or data were provided to support changing this limit, and it has been retained in the regulation.

6. A request was received to permit, in fatty acid statements, the content of fatty acid to be rounded off to the nearest gram. It was the intent of the Commissioner that this be done, and this change has been incorporated into the regulation.

7. Another request was made to require the polyunsaturate/saturate content ratio (P/S ratio) to be placed on the label. This was fully discussed in the preamble to the regulation as published on January 19, 1973. The Commissioner had concluded that stating the content of polyunsaturated and saturated fatty acids is adequate. Thus no change is made in this aspect of the regulation.

8. The deletion of mandatory nutrition labeling when fatty acid information is provided was requested by manufacturers and trade associations. They were particularly concerned with the inclusion of full nutrition labeling on products such as vegetable oils and shortenings where the product contains only fat and the label would show positive values for only calories and fat, and

zero for all other nutritional components.

The Commissioner considered this problem prior to publishing the final regulations on January 19, 1973, and concluded that the consumer needs full nutrition labeling in order to evaluate products bearing fatty acid labeling. The provision for nutrition labeling is therefore retained unchanged.

9. Several manufacturers requested deletion of the required statement regarding physicians advising individuals to use modified diets, as they contended that this statement would be misunderstood by consumers. A comment strongly supporting the statement was received from a consumer organization which felt that individuals considering the special information provided by fatty acid and cholesterol labeling should be reminded that major diet changes should be carried out under medical direction. The Commissioner concludes that it is essential that consumers understand that a modified diet should be undertaken only with the advice and guidance of a physician and only as a total program. The required label statement has been retained in the final regulation.

10. Many manufacturers objected to the use of the Canadian Food and Drug Directorate Method FA-59 for determining the level of cis,cis-methylene-interrupted polyunsaturated fatty acid as part of the compliance program. The concerns expressed by those manufacturers were essentially the same as those stated in response to the proposal published June 15, 1971. In the preamble to the January 19, 1973, regulation, the Commissioner stated in the discussion of this question that FDA had modified the procedure so that it could be applied to products covered by this regulation. Copies of these modifications will be made available to interested parties upon request to the Bureau of Foods, Food and Drug Administration, 200 C Street SW., Washington, DC 20204. The principal reason for using the method adopted for cis,cis-methylene-interrupted polyunsaturated fatty acids is to eliminate interference from trans forms of the polyunsaturated fatty acids. Use of the Association of Official Analytical Chemists (AOAC) methods for polyunsaturated fatty acids determinations will also be acceptable where trans forms are not present. The Commissioner has also stated in the regulation that alternative methods of analysis may be submitted to FDA for determination of their acceptability, and he encourages manufacturers to use this route to handle specific problems of analysis on individual food products. The reference to methods for analysis in the regulation has therefore been retained.

Accordingly, having considered the additional comments received and other relevant information, the Commissioner concludes that new § 1.18 as promulgated in the FEDERAL REGISTER of January 19, 1973 (38 FR 2132), should be repromulgated to reflect the technical modifications discussed above.

Therefore, pursuant to provisions of the Federal Food, Drug, and Cosmetic Act (secs. 201, 403, 701(a), 52 Stat. 1040–1042 as amended, 1047–1048 as amended, 1055; 21 U.S.C. 321, 343, 371(a)) and under authority delegated to the Commissioner (21 CFR 2.120), § 1.18 as promulgated on January 19, 1973 (38 FR 2132), is amended to read as follows:

§ 1.18 Labeling of foods in relation to fat, fatty acid, and cholesterol content.

(a) Implicit or explicit claims for the value of food in preventing or treating heart or artery disease can be misleading to consumers. However, a significant segment of the medical community is recommending that individuals modify their total diet by eliminating certain foods or by replacing certain foods with others in order to effect changes in the levels of blood components. Although there have been no definitive studies which have demonstrated beyond doubt that extensive changes in the consumption of fat and cholesterol by the general public are desirable, it is nevertheless appropriate to provide for informative labeling which will help individuals to identify foods for inclusion in fat-modified diets recommended by physicians. It is also appropriate to prohibit label statements which misrepresent specific foods as being, of themselves, of value in the control of the levels of these blood components or in the control of heart or artery disease.

(b) A food label or labeling may include a statement of the cholesterol content of the food: *Provided*, That it meets the following conditions:

(1) The food is labeled in compliance with the provisions of § 1.17.

(2) The following information is included in the following order, in accordance with the provisions of § 1.17(c)(6)(ii):

(i) The cholesterol content, stated to the nearest 5-milligram increment per serving.

(ii) The cholesterol content, stated to the nearest 5-milligram increment per 100 grams of the food.

(iii) The statement required by paragraph (d) of this section.

(c) A food label or labeling may include information on the fatty acid content of the food: *Provided*, That it meets the following conditions:

(1) The food contains 10 percent or more fat on a dry weight basis and not less than 2 grams of fat in an average serving. Any food containing less than 10 percent total fat on a dry weight basis and/or containing less than 2 grams of fat in a serving is not suitable for use by man as a means of regulating the intake of fatty acids.

(2) The food is labeled in compliance with § 1.17 and the following information is included in the following order in accordance with § 1.17(c)(6)(ii):

(i) The total fat content in terms of the percentage of the total calories in the food provided by fat with the heading "Percent of calories from fat."

(ii) The amount of fatty acids, calculated as the triglycerides, shall be stated in grams per serving to the nearest gram in the following two categories, stated with the following headings, in the following order, and displayed in equal prominence:

(*a*) *Cis, cis* - methylene - interrupted polyunsaturated fatty acids, stated as "Polyunsaturated";

(*b*) The sum of lauric, myristic, palmitic, and stearic acids, stated as "Saturated"; and

(iii) The statement required by paragraph (d) of this section.

(d) A food labeled in accordance with paragraph (b) or (c) of this section shall display the following statement on the label: "Information on fat (and/or cholesterol, where appropriate) content is provided for individuals who, on the advice of a physician, are modifying their total dietary intake of fat (and/or cholesterol, where appropriate)."

(e) Compliance with this section shall be determined as follows:

(1) A collection of primary containers or units of the same size, type, and style produced under conditions as nearly uniform as possible, designated by a common container code or marking or, in the absence of any common container code or marking, a day's production, constitutes a "lot."

(2) The sample for analysis shall consist of a composite of 12 subsamples (consumer units), taken one from each of 12 different randomly chosen shipping cases, to be representative of a lot.

(3) Composites shall be analyzed for fat and saturated fatty acids by the methods of the Association of Official Analytical Chemists (AOAC). The methods for fat, fatty acids, and cholesteral will be those of the Association of Official Analytical Chemists (AOAC), or other reliable and appropriate methods. Alternative methods of analysis may be submitted to the Food and Drug Administration to determine their acceptability. The determination of cis,cis-methylene-interrupted polyunsaturated fatty acids will be the Canadian Food and Drug Directorate Method FA-59[1] for cis,cis-methylene-interrupted fatty acid.

(4) A food with a label declaration of cholesterol content shall be deemed to be misbranded under section 403(a) of the act if the content of the composite is greater than 20 percent in excess of the value for the cholesterol content declared on the label.

(5) A food with a label declaration of fat content shall be deemed to be misbranded under section 403(a) of the act if the content of the composite is greater than 20 percent in excess of the value for the fat content declared on the label or less than required by good manufacturing practices.

(6) A food with a label declaration of fatty acid content shall be deemed to be

[1] Copies of the method may be obtained by writing to Division of Nutrition, BF-124, Bureau of Foods, Food and Drug Administration, 200 C Street SW., Washington, DC 20204.

misbranded under section 403(a) of the act if the content of the composite is greater than 20 percent in excess of the value, or less than 80 percent of the value, for the fatty acid content declared on the label.

(f) Label statements made in accordance with paragraphs (b), (c), or (d) of this section shall comply with the requirements of § 1.8d, but in no case may they be printed in larger than the minimum size type required by the provisions of § 1.8b for the declaration of net quantity of contents.

(g) No label or labeling may contain a claim indicating, suggesting, or implying that the product will prevent, mitigate, or cure heart or artery disease or any attendant condition. The principal display panel of the label may state "cholesterol (fat) information appears _____," the blank to be filled in with a phrase stating where the information is contained. The statement shall appear in one-sixteenth-inch type size or in the alternative in a type size no larger than one-half the minimum type size required for the declaration of net quantity of contents by the provisions of § 1.8b of this chapter.

(h) Any label or labeling containing a statement on cholesterol and fatty acid content not in conformity with this section shall be deemed to be misbranded under sections 201(n) and 403(a) of the act.

Effective date. All labeling ordered after December 31, 1973, and all labeling used for products shipped in interstate commerce after December 31, 1974, shall comply with this regulation.

(Secs. 201, 403, 701(a), 52 Stat. 1040–1042 as amended, 1047–1048 as amended, 1055; 21 U.S.C. 321, 343, 371(a))

Dated: March 7, 1973.

CHARLES C. EDWARDS,
Commissioner of Food and Drugs.

NOTE: Incorporation by reference provisions approved by the Director of the Federal Register, January 15, 1973.

[FR Doc.73-4672 Filed 3-13-73;8:45 am]

COMMON OR USUAL NAMES FOR NONSTANDARDIZED FOODS

In the FEDERAL REGISTER of June 22, 1972 (37 FR 12327), the Commissioner of Food and Drugs proposed a procedure for the establishment by regulation of common or usual names for foods. The Commissioner also proposed to establish a common or usual name for seafood cocktails, to include the percentage of the characterizing seafood ingredient(s).

Seventy-nine comments were received in response to the proposal. Forty-eight comments (including two consumer comments bearing, respectively, 132 and 50 signatures) endorsed the proposal. Of these, 21 suggested additional requirements. Twelve comments were in opposition to the proposal. Nineteen expressed neither endorsement nor opposition, but requested modification, clarification, specific exemptions, or additional requirements.

The Commissioner has evaluated all the comments. The points raised and the Commissioner's responses are as follows:

1. Twenty-eight requests were made that the proposal be expanded to include additional labeling requirements such as the percentage of all ingredients for all foods; the percentage of primary ingredients for all foods; the percentage of fats, carbohydrates, and proteins; the vitamin and mineral content; and the specific source of ingredients.

The Commissioner concludes that percentage labeling of ingredients should be restricted to situations where this information has a material bearing on price or consumer acceptance of the food, or where such information may prevent deception. Labeling the percentage of all ingredients would be extremely costly and would provide no proven benefits to consumers. A mechanism for estalishing a regulation requiring labeling of the percentage of all "primary" ingredients that have a material bearing on the price or consumer acceptance is provided for in this regulation.

Since receipt of the comments relating to this matter, the Commissioner has published regulations in the FEDERAL REGISTER of January 19, 1973 (38 FR 2125), relating to nutrition labeling. Labeling the specific source of ingredients is still under consideration and is not the subject of this regulation.

2. Several objections were made on the ground that authority for establishing the common or usual name does not exist outside of section 401 of the act. The objections were as follows:

a. There is no legal basis for the application of section 201(n) of the act to the establishment of common or usual names.

b. A product containing a substantial and adequate quantity of a characterizing ingredient does not need the amount disclosed, since this is not a "material fact" within the meaning of section 201(n).

c. The proposal establishes, with no authority, a new method of promulgating standards of identity.

d. The proposal is contrary to congressional intentions that the common or usual name shall be established only under section 401 with safeguards of section 701(e) of the act.

The Food and Drug Administration (FDA) has, in the past, determined the name of a specific product, and required the percentage labeling of specific ingredients under sections 201(n), 403, and 701(a) of the act (e.g., 21 CFR 1.10(d), 3.6, 3.34, and 3.70, of which the latter three are revoked by this order and transferred to new Part 102). After reviewing all comments, the Commissioner concludes that the statutory provisions contain ample authority for the establishment of common or usual names that may or may not include the percentage of any characterizing ingredient(s), and that the regulation is well within the congressional intent.

The Commissioner does not agree that the disclosure of the amount of a characterizing ingredient is not a "material fact" within the meaning of section 201(n). Disclosure of this fact is often necessary for the consumer to choose between two competing products when the amount of the ingredient is important to the value of the food.

The Commissioner agrees that a name may be determined by regulation through the establishment of a standard of identity under section 401 of the act, and proposes to continue utilizing this alternative method whenever appropriate. Section 401 does not, however, preclude the establishment of a common or usual name under other sections of the act.

In response to several objections that there are no provisions in the proposal for formal hearings, the Commissioner notes that no hearing is required by the Federal Food, Drug, and Cosmetic Act or the Administrative Procedure Act for regulations promulgated pursuant to section 701(a) of the Federal Food, Drug, and Cosmetic Act. The Commissioner concludes that there is sufficient opportunity for public participation in the development of regulations establishing a common or usual name. Any interested person may submit a petition to establish a common or usual name. Any proposal published in the FEDERAL REGISTER will allow at least 60 days for comment. Interested persons may submit counterproposals, or may discuss any proposal with FDA officials, or may request an informal hearing, which may be granted if good cause is shown. The regulation establishing the common or usual name for Greenland turbot was published after such an informal hearing. All information that could be produced at a formal hearing can be submitted in comments, and the requirement of a formal hearing would serve only to delay new regulations. The Commissioner concludes that neither a formal hearing nor an informal hearing in every case would be in the public interest.

3. Several comments argued that there is no need for new regulations establishing the common or usual name of foods, because this can be done through a standard of identity. The Commissioner concludes that standards of identity are appropriate and useful, and will continue to be promulgated, where there is a need to prescribe the entire compositional requirements for a food, in addition to the name of the food. Often, however, there is a need simply to establish a uniform and informative name for a food without the compositional aspects of a food standard and, in these instances, a food standard is inappropriate.

4. Many industry representatives recommended that the proposal, if adopted, be amended to include clarification regarding the intended application of the regulation. The matters suggested for clarification may be stated as follows:

AMERICAN COLLEGE OF CARDIOLOGY

The following comments are submitted in reply to questions raised by the Federal Trade Commission in correspondence dated January 9, 1975 with Dr. Henry D. McIntosh, President of the College:

1. All representations in advertising concerning the relationship between fat and/or cholesterol and heart disease should not be banned. Qualified references to coronary heart disease should be allowed in relationship to the three major risk factors, namely, elevated serum cholesterol, hypertension and cigarette smoking. It is not practicable and not necessary to require reference to each of these three factors on every occasion where one is mentioned. For example, it is not practicable to require a reference to hypertension and cigarettes in every instance where cholesterol as a risk factor is mentioned.

2. A claim should be allowed that an elevated serum cholesterol is a risk factor for coronary artery disease. With regard to diet, a claim should be allowed that a diet with a high ratio of polyunsaturated: saturated fat or with a reduced intake of cholesterol tends to lower the serum cholesterol. I would not allow any specific health benefit claim, for example, that a lowered risk of arteriosclerosis or of coronary artery disease, could result from changing one single food or dietary factor. I would require a statement that no one food can be expected to raise the p/s ratio or lower the total cholesterol intake in the diet, or alter the cholesterol level in the blood, unless it is used as part of an overall diet program.

3. This question is answered in reference to question #2, i.e., the low cholesterol or high p/s ratio food should be used as part of an overall diet program.

4. This question is also partially answered in question #2. Margarine, vegetable oil and low fat dairy products can be part of an overall diet program. The contribution of one single food item, for example peanut butter, to the overall diet would depend upon how much of that particular food was consumed. This obviously would vary considerably from one person to another. The important concept is the relationship of the food to the overall diet plan.

5. It is misleading for food high in saturated fat to make a low cholesterol claim since the high saturated fat content would tend to elevate the blood cholesterol. The important point, it seems to me, is to have accurate labeling in terms of both p/s ratio and cholesterol content. This is of greater importance than the designation of high, low or medium content of cholesterol. It is difficult to identify for the public foods which are low in cholesterol and high in saturated fat, for example, coconut oil.

6. It is very difficult to designate foods as low, medium or high in cholesterol without reference to the overall nutritional program. A cholesterol intake of less than 300 mg per day, 300-500 mg moderate, and over 500 mg as high. This grouping conceivably could be used to indicate various categories. It would seem very difficult to define all foods with a single cutoff point with respect to cholesterol, total fat or saturated fat. For example, a meat product containing 10% fat would be considered "low fat", while milk would be "low fat" only if it had less than 2%. Thus, no overall guidelines could be given with respect to fat content but would have to be specified for for the individual food. Other factors that would have to be taken into account would include the quantity of a normal serving, the frequency with which the food is eaten, the accuracy and reproducibility of food analysis and the variation of content at different times of the year. Because of these complexities, accurate labeling of p/s ratio and cholesterol content would seem to be the most important information to be conveyed to the consumer. Some statement comparing the cholesterol content with that of the natural food should be allowed. For example, if an egg substitute has 0 mg of cholesterol as compared to 250-300 mg in an average egg yolk, such a statement should be allowable.

7. There is extensive evidence from epidemiologic and animal studies that a high level of serum cholesterol is an important risk factor for coronary artery disease. Perhaps the best documentation is from the Framingham Study where the risk of developing coronary disease was increased in young men by as much as five and one-half times by an elevated serum cholesterol.[1]

8. In my opinion, the average American should lower his cholesterol and attempt to substitute polyunsaturated for saturated fats. This view is consistent with recommendations of the American Heart Association, of the American Medical Association Council on Foods and Nutrition, and of the Food and Nutrition Board of the National Research Council of the National Academy of Science. There have been many dietary studies[2,3,4,5] demonstrating the effect of the increase in p/s ratio of the diet on the serum cholesterol. Fewer studies have been done in which solely the cholesterol intake was examined apart from the p/s ratio but a reference to those of Connor is included. The work of Keyes suggested that on a quantitative basis the p/s ratio was more important than the total intake of cholesterol as a determinant of the level of blood cholesterol. I disagree with the two proposed rule changes, B and C. As stated above, I would not allow a specific health benefit claim from one single factor, food or serving, but would allow reference to the food as part of an overall diet program aimed at decreasing an individual's risk of developing coronary artery disease.

10. While it is helpful to give caloric content, if it were required for the manufacturer to do this in addition to providing the cholesterol and p/s ratio and content, it might discourage cooperation with the voluntary labeling act. It would be of benefit to consumers to have the quantity of saturated and polyunsaturated fat in the food and their ratio.

11. It is helpful to have both the content of polyunsaturated and saturated fats as well as the ratio, since many people will not understand how to calculate the ratio. For radio and television advertising it is more important to give the ratio. On the labeling both the ratio and the content of polyunsaturated and saturated fat should be given. A separate designation should be given to monounsaturated fats since they do not count in the calculation as either polyunsaturated or saturated fats. In comparing one food to another, it is the ratio of polyunsaturated to saturated fat that should be considered. As to the contribution of this food to the diet, obviously, if the total quantity of fat in the food is very low, its contribution would be insignificant. However, it would seem unlikely that a manufacturer would go to the expense of advertising the p/s ratio of a food if it actually had very little fat. A significant difference in p/s ratio would be a difference of 0.5, i.e., an increase from 0.3 to 0.5.

12. The general consumer should be encouraged to check with his doctor before undertaking a diet and, in particular, before starting a weight reduction program. The potential danger of a severely fat restricted diet would be the possibility of developing serious deficiencies of fat soluble vitamins in the very young and the very old, particularly in the lower socioeconomic groups. Nutritional surveys have already indicated deficiencies of Vitamin A and borderline calcium deficiencies in such groups.

GENERAL COMMENTS

The recent regulations of the Food and Drug Administration providing for labeling of foods with their fat composition (including saturated fat, polyunsaturated fat and cholesterol content) represent a potentially valuable advance long sought by the American College of Cardiology and all those concerned to curb the severe epidemic of premature heart attacks in the United States. Food labeling--as provided by these regulations--needs to be widely implemented as soon as possible. At the same time, a sustained and extensive process of professional and public education is needed so that the meaning of the labeling is widely and well understood. Only in this way will the potential value of this labeling for the improved nutrition and health of the American people be realized. The essentiality of this mass education effort was appropriately emphasized by the White House Conference on Nutrition and other responsible bodies before and since the FDA regulations were promulgated. The American College of Cardiology reaffirms and reemphasizes the importance of this educational effort. It pledges the resources of its organization and membership to it. American cardiologists are in their practices already widely educating their patients on the role of improved nutrition in the effort to achieve the primary and secondary prevention of coronary heart disease, and will continue to do so. The College as an organization is contributing--and will continue to contribute--to the community-wide and nation-wide professional and public education effort to aid the American people to improve their

nutrition by reducing high levels of intake of saturated fats, cholesterol and calories.

For this effort to be optimally effective it must be as widespread, sustained, accurate and popular as possible. Professional, voluntary and public health organizations all should be encouraged to help with this educational undertaking. So also should the several sectors of the food industry.

Towards this end, the College urges that government regulatory agencies (Food and Drug Administration, Federal Trade Commission, Federal Communications Commission, etc.) adopt a positive--rather than a restrictive--approach to food industry advertising of products low in saturated fat and cholesterol. Companies should be encouraged to aid the needed mass education effort by disseminating sound scientific information about such products through advertising and other means. Such communications should put the facts about the composition of a specific product and its significance in proper context: the product is useful because of its low saturated fat and cholesterol content in aiding consumers to achieve an <u>overall</u> reduction in saturated fat and cholesterol intake; it is useful as part of a general improvement in pattern of food intake for lowering saturated fat and cholesterol ingestion, and thereby safely reducing serum cholesterol levels. Emphasis should also be given in advertising to the well-established data linking risk of heart attack to <u>three</u> major risk factors--not only diet-dependent elevated serum cholesterol,

but also cigarette smoking and high blood pressure. In this way federal regulatory agencies can encourage the food industry to make a positive contribution, based on well-established scientific evidence, to the effort to curb the coronary epidemic.

Recently data have become available indicating that at long last death rates from coronary heart disease are beginning to decline for young adults and middle-aged American men. In all likelihood, this positive development reflects the years-long many-sided efforts of cardiologists, physicians generally, the entire heart movement to turn the flank of this modern-day epidemic. Every encouragement is needed to broaden and intensify these efforts. The American College of Cardiology and its membership are pledged to do all they can. The federal regulatory agencies are called upon to do their part as well.

Mary Winston

CNI Weekly Report
Community Nutrition Institute

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FTC Proposes New Restrictions On Food Advertising

The Federal Trade Commission (FTC) this week published its long-awaited proposed trade regulation rule for food advertising but withheld approval from a staff recommendation that all food advertisements be required to provide brand-specific nutrition information.

The 20-page document, which was published in the November 11 Federal Register, represents a compromise between the FTC's "upper staff" -- Thomas Rosch, director of the Bureau of Consumer Protection, and Richard B. Herzog, assistant director for national advertising -- and the "lower staff," headed by James H. Cohen, assistant deputy director for national advertising. While not approving the lower staff's recommendations for mandatory nutritional disclosure, Rosch allowed the lower staff's proposal to be published for comment along with the officially-approved FTC package. (For background, see CNI Vol. IV:40.)

The FTC rule goes beyond current regulations in proposing that food advertisers who assert that their products have nutritional value must meet minimum standards of quality and make extensive disclosures of important ingredients. However, the key issue the Commission must face is whether this limited form of regulation will lead to better advertising or will simply drive food manufacturers to promote their products solely on the basis of "taste, appearance, and association with social pleasures," to quote from the lower staff's alternative proposal. The lower staff argued that, without mandatory nutritional disclosure, "massive food advertising may well undermine or even defeat the purpose of nutrient labels" (see box).

One advertising industry spokesman told the New York Times, "I don't think there'll be any nutritional claims made whatsoever" if the current FTC proposal is allowed to stand.

As expected, the FTC also abandoned earlier efforts to control the advertising of heavily-sweetened foods. Instead, the agency released a letter addressed to Alexander Schmidt, commissioner of the Food and Drug Administration (FDA), expressing strong support for FDA efforts to resolve the sugar issue and offering any assistance the FTC could provide. The FTC said it would consider "what steps, if any, it should take to regulate the advertising of foods which contain sugar in amounts and/or forms which may be deleterious to the health of consumers" upon completion of FDA's review of available scientific evidence.

Four Categories

In narrowing the proposed rule to advertisements that make nutritional claims about a product, the FTC divided types of claims into four categories: emphatic nutrition claims, nutrient comparison claims, nourishment claims, and claims for food intended to be combined with other foods.

Under the FTC definition, an emphatic claim (such as "packed with vitamins") would only be permitted if the nutrient advertised contains at least 35 percent of the U.S. Recommended Dietary Allowance (RDA) and the identity and percentage of RDA of the nutrient is "clearly and conspicuously disclosed in the advertisement.

This 35 percent threshold for "emphatic" claims represents the FTC's major departure from the FDA's nutritional labeling standards. There is no counterpart in the FDA regs for the "emphatic claim" standard; the FTC proposals otherwise mesh closely with FDA standards. For example, the proposed ad rule follows the 10 percent RDA threshold for nutritional significance set forth in the FDA regulations.

(Continued on next page)

In dealing with nutrient comparison claims, the FTC proposed that such claims may not be made unless the comparison is with an equal-sized serving of a commercially-available food and (1) the identities of the advertised and compared foods are "clearly and conspicuously disclosed;" and (2) the advertised food and the compared food "normally serve the same purpose in the diet;" and (3) the same nutrients are compared and the name of each compared nutrient is disclosed.

Nutrition comparisons would also be subject to restrictions relating to calorie content, protein quality and the availability of nutrients other than those advertised.

Nourishment claims ("wholesome," "nutritious," etc.) for a product could not be made unless the food provided at least four nutrients, including protein, in nutritionally significant amounts per 100 calories and a serving of the food provides at least one nutrient in a significant amount, or more than 2 percent of the RDA.

Labeling Threatened

"Without advertising disclosure, massive food advertising may well undermine or even defeat the intended purpose of nutrient labels. Massive food advertising, which avoids the subject of brand-specific nutrition information -- and instead attempts to sell food products solely for such factors as taste, appearance, and association with social pleasures -- has the capacity or tendency to obscure the importance of nutrition and to reduce the importance or relevance of nutrient labels to consumers. It is highly pertinent to this point that the architects of the nutrient labeling program at FDA do not view that program as a panacea for problems of malnutrition but see other steps, including information in advertising, as necessary adjuncts to the elimination of ignorance and deception...

"A study on the effects of nutrient labeling on food purchasing found that, in the absence of information to the contrary from an authoritative source, consumers believe that heavily advertised name brands are good products, high in nutrient value. This assumption can vitiate the impact of nutrient labeling on many prospective purchasers and thus decrease its effectiveness."

-- from the FTC staff recommendation for mandatory nutritional disclosure.

The final major category is claims for foods intended to be combined with other foods (e.g., breakfast cereal and milk). An advertised food may claim that when combined with other foods it provides a designated percent of the RDA for certain nutrients, but it may not claim that the advertised food alone contains the amount of nutrients found in the combination. Also, if more than 50 percent of the RDA of any nutrient named in the advertisement is derived from the added food, the ad must disclose that fact.

Finally, the FTC would require advertisers who speak of "energy" or "food energy" to indicate that they mean nothing more than calories. Advertisements could not represent that consumption of any food, by itself, will produce "health, general vigor, sustained energy or alertness."

Advertisements for products designed for weight control would have to comply with FDA regulations and state the number of calories. Advertisements for foods containing artificial sweeteners would have to provide a comparison of calories in the advertised product and calories in an equal-sized serving of the same food with nutritive sweeteners.

Impact Uncertain

The FTC invited comments but did not advance proposals on natural and organic food claims; fat, fatty acid and cholesterol content claims; and health and related claims. The FTC's Rosch noted at a news conference that his agency had decided for the moment not to "follow blindly" FDA policies on cholesterol.

The impact of the proposed regulations is difficult to assess. Except for breakfast cereals and some fruit products, only a small amount of food advertising makes nutritional claims. Rosch made the point that the FTC proposal would have little or no impact on food prices, since the only advertisers affected would be those who already have performed considerable research in order to meet FDA and USDA nutrient label guidelines.

In addition to raising a host of nutritional issues, the FTC proposal leaves unclear what is meant by "clear and conspicuous disclosure" of information in advertisements. After the agency has analyzed comments on these issues, it will hold one or more hearings and publish a final version of the trade rule sometime later. Since this final version could be challenged in the courts, effective regulation appears at least two years away.

Written comments on the proposals are due by February 5, 1975. Copies of the package may be obtained by writing the Office of Legal and Public Records, Federal Trade Commission, 6th and Pennsylvania N.W., Washington, D.C. 20580.

Consumer Groups Ask For New Grade of Beef

A coalition of national consumer organizations joined by Rep. Peter Peyser (R-N.Y.) last week called for a major revision of beef grading standards that would result in an entirely new grade of beef.

USDA in September proposed moving the top third of beef currently labeled "choice" up to the "prime" grade while moving the top third of the current "good" grade up to "choice" (see CNI Vol. IV:37). "Prime" and "choice" beef contains more fat marbling than "good" beef, which comes from grass-fed cattle.

At a press conference the consumer advocates contended that the USDA plan would result in shoppers being charged "choice" prices for "good" beef that is cheaper to produce. Congressman Peyser declared that "all that would happen here is that the public would be ripped off buying a lesser grade of beef for more money."

The consumer advocates said they wanted the cattle industry to pass along savings obtained by bringing meat heretofore labeled "good" to market two weeks earlier. They said the leaner beef costs 8 percent less to produce and could produce savings of as much as 11 cents per pound.

"Target the Price Break"

Marcia Cohen, an attorney for Consumers Union, said the new grade proposed by the coalition would "target the price break" and pass it on to the consumer. The coalition recommended that the new grade be clearly designated as such and that USDA conduct extensive consumer education to explain it to the public.

Ellen Haas, acting director of the National Consumers League, said the consumer proposal was gathering support from some cattle industry spokesmen ("They are concerned with a marketable product"), some restaurateurs and officials of several retail food chains, including Kroger and Jewell. (In Washington, D.C., Safeway supermarkets are already experimenting with grass-fed beef labeled "calf-good." Managers of two stores selling the beef for 10 to 60 cents less per pound than comparable cuts told a Washington Post reporter they can hardly keep up with the demand.)

Haas noted that most of the objections to the "new grade" proposal had come from meat packers, who claim consumers would not be able to understand the new beef classification.

Richard Lyng, president of the American Meat Institute, which represents meat packers, said the new grade would be "confusing to shoppers."

The public has until December 10 to submit comments to USDA on the beef grading proposal.

FCC Sets Policy For Children's TV

The Federal Communications Commission (FCC) last week published a policy statement declaring that all television stations must provide a reasonable amount of programming for children and that a significant amount of it must be educational.

However, the agency rejected the request of Action for Children's Television (ACT), the Boston-based activist group, that it adopt specific rules banning advertisements on children's programs and requiring specific amounts of programming at specific times. The FCC policy statement, which was published in the November 6 Federal Register, was the fruit of an investigation launched in 1971 at the request of ACT.

"It's a cop-out," responded Peggy Charren, ACT co-founder. "Twenty years of self-regulation of children's television has shown us that the only way to get real change is with a rule."

ACT had hoped for rules that would ban all commercials from children's television shows, require stations to broadcast 14 hours per week of children's programming aimed at various age groups, eliminate all mention of brand names from children's shows and ban commercials by the hosts or characters on the program.

The FCC defended its decision not to impose specific rules as consistent with its historic role of imposing only general affirmative duties on broadcasters in return for their right to use the airwaves.

CNI Weekly Report

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San Francisco Gets City-Wide Breakfasts

by Suzanne Vaupel

(Ms. Vaupel, former school breakfast coordinator for the Food Research and Action Center in New York City, currently works for the Children's Rights Group in San Francisco.)

Last year San Francisco was the largest school district in the nation with no district-sponsored school breakfast programs. Today, 36 schools city-wide are serving breakfast. By Christmas or soon thereafter, all 125 San Francisco schools -- both elementary and secondary -- will operate the program; each school will be funded under the "especially needy" funding formula provided in the Child Nutrition Act.

This transformation came about as the result of a well-organized and determined community effort. As late as a year ago, the San Francisco school board was maintaining stubborn opposition to school breakfasts. Before that it took three years of conversation, negotiation, and confrontation for the Mission Rebels -- a strong-willed and successful community organization -- to win the right to serve breakfasts in a select few San Francisco schools. The Rebels offered a good breakfast program but received no school district support at all, not even custodial services. However, the Rebels' persistent efforts set the stage for the present district-wide program.

Citizen Coalition

A major source of opposition to school breakfasts was the city's director of school food services. Engulfed in the problems facing every school district, the cafeteria division was not eager to start another program. As if soaring food prices, high union wages, lack of storage space, unavailability of commodities, a restricted budget, and low school lunch participation were not problems enough, the cafeteria division was faced with the closing of several of its satellite kitchens under the Field Act, which requires all California schools to be "earthquake proof." Schools that fail to meet minimum earthquake standards must be closed and reconstructed.

Late last fall, however, a group of very determined community leaders began to discuss the school breakfast program seriously. They represented such key organizations as the Conference on Religion, Race, and Social Concerns; the Coalition for Effective Schools; PTA; Western Addition Youth Council; League of Women Voters; Social Justice Commission of the San Francisco Archdiocese; Council of Churches; Council on Early Childhood Education; San Francisco Dental Society; and the San Francisco Medical Society. They won the support of the unions: American Federation of Teachers; San Francisco Central Labor Council, AFL-CIO; Local 400 - Civil Service Employees; California Classroom Teachers' Association; and the San Francisco Joint Council of the International Longshoremen's and Warehousemen's Union. Eventually, over 40 community organizations endorsed a resolution calling for the school breakfast program in every school.

The coalition named itself the Children's Rights Group, Health and Nutrition Committee, and chose California Assemblyman Willie Brown and State Senator Milton Marks as co-chairmen. Staff employees were selected for their knowledge of the school breakfast program and the San Francisco schools. Ed Polk of the Youth Law Center was appointed director. He was assisted by Joyce Ream of the PTA, an expert on the San Francisco schools; Douglas Blake and Chester Ng from the California Nutrition Action Committee; and by this writer.

The coalition kicked off its campaign at a press conference in early spring. Assemblyman Brown and Senator Marks announced the goal: a school breakfast program in every San Francisco school by the fall of 1974.

Feasibility Study

After the press conference, the work of the coalition was low-key but persistent. Work began on assessing the problems of a district-wide school breakfast program. At a regular meeting of the school board's budget and finance committee, the Children's Rights Group requested that the superintendent's staff conduct a feasibility study of the breakfast program to be completed within 30 days. The Children's Rights Group offered its staff for legal and technical expertise. The recommendation passed.

Over the next 30 days the Children's Rights Group worked closely with Associate Superintendent Milton Reiterman in conducting the study. Advice from citizens at this point proved crucial in helping the school district uncover potential problems. Such important issues as the scope of the program, types of meals to be served and the inclusion of nutrition education were hammered out at these meetings. Basic to all these issues were funding problems; the Children's Rights Group tried to guide the school district to the funding sources.

While the staff of the Children's Rights Group was working on the feasibility study, school breakfast supporters were busy talking up the program with school board members and key administration people. In mid-May the school board unanimously approved a resolution directing the school super-

intendent to "implement a plan for the provision of hot, nutritious breakfasts for all school children... in cooperation with the Mission Rebels, at the earliest possible date, with provision for a no cost or reduced price breakfast."

One week after adopting the resolution, the board accepted Associate Superintendent Reiterman's feasibility study as the plan to be implemented.

Up to this point the school food services director had maintained her opposition to school breakfasts. Once the board had approved plans for the program, however, the director submitted her resignation. Her assistant, a school breakfasts supporter, was appointed acting director.

The summer months were spent getting ready for the new program. The Children's Rights Group worked closely with the cafeteria division at every step. Discussions were held with the transportation office, the paraprofessional office and custodian office as well as with the elementary, junior high and high school divisions. Scheduling, supervision, menus, clean-up, storage space and warehousing were just a few of the problems to be worked out.

"Especially Needy" Designation

The cost of producing a breakfast in San Francisco is extremely high. Labor comes to 10 cents per meal (direct labor - 7 cents; transportation labor - 3 cents) and supervision adds another 2.8 cents. Food costs are also high. Milk alone costs the district 12 cents per serving. To meet these high costs the district is able to rely on a unique combination of funding sources.

The most significant aspect of this funding is the "especially needy" designation of every school. Since its inception, the national school breakfast program has included a provision for higher-than-normal funding in "circumstances of severe need where the rate per meal established by the Secretary is deemed by him insufficient to carry on an effective breakfast program in a school" (Child Nutrition Act, section 4(d); 42 U.S.C. §1773). Designated schools presently receive 45 cents for each free breakfast they serve and the regular 8.75 cents for each "paid" breakfast. (Regular reimbursement rates are 30.75 cents, 25.25 cents, and 8.75 cents.)

Since "circumstances of severe need" is so hard to define, the provision of the law is used much less than Congress had anticipated when it was passed. USDA recommends to states that each school be 75 percent "needy" in order to qualify, according to the national guidelines for free and reduced price meals. Since each state can set its own standards, however, these criteria vary from state to state. New Jersey, for instance, defines the standard as 30 percent "needy" enrollment, since that figure produces approximately 75 percent "needy" participation in the lunch and breakfast programs.

In designating the San Francisco schools as especially needy, the state used a combination of factors as suggested by the regulations (7 C.F.R. §220.9(b-1)). The criteria under which various schools qualified included:

1. An especially high percentage of free and reduced price breakfasts, determined to be 75 percent of the total average daily participation being free and reduced price meals; or

2. Unusual costs required to provide breakfast in the school despite the observance of good management practices.

However, the San Francisco school district found in the law and regulations at least six criteria to guide the school food services director in selection of expecially needy schools. These are:

- Schools drawing attendance from areas in which poor economic conditions exist. (42 U.S. C.A. 177c(c))

- Schools in which a substantial proportion of children must travel long distances daily. (42 U.S.C.A. 1773(c)

- Schools in which there is a special need for improving the nutrition and dietary practices of children of working mothers and children from low-income families. (42 U.S.C.A. 1773(c))

- Schools in which the regular reimbursement in insufficient to carry on an effective breakfast program.(42 U.S.C.A. 1773(d))

- Schools where there is a need to serve an especially high percentage of free and reduced price breakfasts. (7 C.F.R. § 220.9 (b-1))

- Schools where there are unusual costs required to provide a breakfast despite observance of good management practices. (7 C.F.R. § 220. 9 (b-1))

The school district submitted a letter to the state office documenting the qualification of San Francisco schools under each category. In addition, the district noted that all its schools are involved in racial desegregation plans that have resulted in the integration of children from different economic classes. "Refusing to certify our schools as especially needy," the district argued, "will have

(Continued on page 8)

New Congress Will Force Compromises

by Altigula

(Altigula -- Latin for "Deep Throat" -- is the pseudonym of a veteran legislative observer who will contribute articles to CNI on a regular basis.)

Many of President Ford's worst fears about the elections were realized last week, but his campaign warnings about a "legislative dictatorship" will not come true.

The more likely result is that he will have to compromise on legislation that provides more government involvement in the economy and more consumer and environmental protection than this conservative President would like. He will veto bills and have some vetoes overridden, but he may actually have less trouble than if the Republicans had been victorious in the 1974 elections.

The fact is that even if the Democrats had scored many more successes than they did, the threats of a "veto-proof Congress" and a "legislative dictatorship" would still have been sheer campaign nonsense. In modern times, neither party in Congress has had the power or the inclination to initiate its own total program of legislation. Parties have initiated some individual bills, but they have possessed neither the staffs, the public attention nor the cohesive unity necessary to serve as real alternatives to the President in power.

No Competition Likely

Like its recent predecessors, the incoming 94th Congress will probably react to the President's proposals; it would feel lost without them. It will continue to take back some of the powers which previous Congresses lost to strong Presidents, particularly to Richard Nixon. It will hardly rubber-stamp the President's policies, but it is not likely to be a competitor in the initiation of policy either.

The Democrats' political situation supports this outlook. Will Rogers' quip ("I am not a member of any organized political party; I am a Democrat") still fits. Democratic legislators tend to be more varied, less disciplined and answerable to more diverse and conflicting constituencies than Republicans. They split and fight among themselves more often.

Also, the House and Senate Democratic leadership has been weak in recent years. It attempts to lead more by agreement than by the exercise of its power. Sometimes it does not lead at all. Great outcries for strong leadership are often heard from Democratic Members of Congress.

Actually, these legislators want weak leadership. Each member of the House or Senate wants the effective use of leadership power to back his own legislative goals, but he does not want that discipline used against him.

The fact that the members of the 94th Congress will be younger and more educated than those of previous sessions makes continued weak leadership even more likely. The political hacks of the 1930s, whose service to the local political party was rewarded with terms on Capitol Hill, were used to taking orders. They fully understood Speaker Sam Rayburn's dictum, "To get along, go along." But the well-educated and ambitious 25, 30 or 40-year olds who were elected last week are unlikely to wait on their elders until they get seniority.

The liberal Democrats in the House will probably increase the use of the party caucus to coordinate Democratic policies and strategies as well as to prod conservative Southern chairmen and the leadership. Even with the increased number of liberals, however, the caucus will have trouble translating its decisions into actual legislation.

Democrats' Quandry

For example, many of the newly-elected Democrats come from areas that usually vote Republican. Their election -- often by narrow margins -- was a reaction to the GOP's past performance rather than the "mandate" to which Democratic leaders aspire. Since these new Members want to increase their currently tenuous job security, they will be especially careful to cater to what they think their constituents want rather than to a Democratic policy.

The Democrats' quandry is further complicated by their desire to maintain good relations with their new-found farm, suburban and conservative supporters while, at the same time, meeting the legislative aspirations of such traditional adherents as liberals, labor and minorities. Maintaining this delicate balance is essential if the Democrats are to succeed in pyramiding their 1974 victories into even more important victories in 1976.

An instance of this problem will occur within a few weeks when the Senate considers a trade bill in the lame duck session. Liberals support the bill for ideological reasons; farmers support it to maintain their big export markets, but labor bitterly opposes it because of fear of exporting jobs.

Other legislation facing the lame duck session, which begins Monday, will pose similar but lesser problems. Congress will spar on economic legislation, tax reform and other major issues but probably do little other than pass the remaining appro-

priation bills and left-over measures with deadlines. Some less controversial economic bills, such as aid for the unemployed, job creation and housing could pass, but the liberal Democrats will probably seek to put off final action on major controversial measures until the 94th Congress.

The new Congress is likely to pass next year -- perhaps over Presidential vetoes -- such long discussed proposals as national health insurance and the consumer protection agency. On most issues, compromises will be worked out between the President and Congressional Democrats after each side has sharply delineated its position.

Congressional Democrats are unlikely to attempt major new economic or social reforms other than ones which have crystalized politically, such as health insurance. But even if they do, the Presidential veto will continue to be a great obstacle, as President Eisenhower demonstrated to the huge Democratic majority of the 1959-60 Congress.

Human Needs Votes

The Coalition for Human Needs and Budget Priorities, a Washington-based coalition of labor, religious, public interest and other organizations, has published a "Human Needs Voting Record" that rates each member of the 93rd Congress on a wide range of anti-poverty, consumer, defense and other issues.

Votes on food stamps for strikers and SSI recipients, on Older Americans training programs and on legal services back-up centers are included in the compilation. Copies of the voting record are available from the Coalition at 2030 M St., N.W., Washington, D.C. 20036.

Some of the most bitter political fights may result from action on Presidential appointments. The Democrats will probably unite to win political points and embarrass the Ford Administration after scrutinizing the backgrounds of Ford nominees. Nelson Rockefeller and some other proposed government officials are likely to be defeated or have their nominations withdrawn because of revelations made during the confirmation process.

Yet, overall, the President has reason to be secretly pleased with the election results. In view of the national economic problems and the government efforts needed to meet them, the adversary Democrats may be easier for him to deal with than a Congressional majority or near-majority of conservative Republicans. Even though members of his party more accurately reflect President Ford's own views, they would probably hinder the spending and intervention policies that he must implement to handle the economic crisis. In addition, the overwhelming Democratic majority in Congress provides the President with a convenient whipping boy for many of the government actions that he will be forced to take. Succeed or fail, he can blame the Democrats.

Nader Group Renews Attack on Red No. 2

With the Food and Drug Administration (FDA) moving toward removal of impediments to the use of Red. No. 2, the controversial food dye, Ralph Nader's Health Research Group (HRG) has renewed a plea made in 1971 to ban the coloring outright.

Red No. 2 is used to color red lipsticks, soft drinks, gelatine desserts, baked products, candy, breakfast cereals, gum, pet foods, pill coatings and many other products. More than 900,000 pounds of the dye were certified for use in about $10 billion worth of products last year. Red No. 2 has been on "provisional" status since 1960 and under review since 1971, when FDA announced that it intended to cut back on allowed uses of the dye (see CNI Vol. I:45).

In a letter to FDA, the HRG's Sidney M. Wolfe said Red No. 2 "has no place in the American food supply" because of possible carcinogenic effects and possible toxic effects on unborn fetuses. The letter cited several unpublished studies conducted by the agency since 1951 that, according to the HRG, "strongly indicate that Red No. 2 does cause cancer" and noted conflicting results of studies on fetotoxicity. The HRG said its calculations showed that a 110-pound woman could safely ingest only about one-third of a can of soft drink daily while a child should drink no more than a "couple of gulps."

An FDA spokesman replied that the "theoretical calculations" that the HRG used to demonstrate carcinogenicity are "invalid, both statistically and toxicologically."

"Dr. Wolfe totally ignores more extensive studies which are statistically valid and have not shown carcinogenicity," the FDA spokesman continued. He added that a special ad hoc committee of toxicologists and health experts will report favorably on the safety of the additive, possibly before the end of this year.

The HRG's Wolfe acknowledged that some of the statistics he used were abstractions but contended that the FDA had ignored or misinterpreted negative findings so as to "whitewash" charges of fetal toxicity and sidestep the cancer issue.

School Breakfasts ...

the unintended but disastrous effect of punishing some children by denying them a nutritious breakfast because -- and only because -- they have sought enforcement of their constitutionally guaranteed rights to equal educational opportunity."

California law provides for a special tax solely for the purpose of providing additional funds for meals for needy pupils. Local school districts are allowed to levy a district tax of up to 5 cents per $100 of assessed evaluation. Since these funds can be used only for meals for needy pupils, the lunch and breakfast programs are not thrown into competition with other school programs for this money.

State legislation recently signed into law will provide additional state funds to the school lunch and breakfast programs. Some 5 cents will be provided for every school lunch and breakfast served. This legislation was authored by State Senator George Moscone, chairman of the Senate Subcommittee on Nutrition and Human Needs.

Enthusiastic Support

At present the San Francisco school breakfast program has all the earmarks of success. "It is one of the finest programs we've ever had," says Edward Borup, principal of San Miguel School. Richard Farrar, acting food service director, has enthusiastically devoted himself and his staff to the huge task of implementing a district-wide program. The depth of citizen support became evident recently as voters approved a local proposition authorizing the building of a central kitchen facility.

However, many ideas have yet to be realized. The original feasibility study placed much importance on a recommendation for the coordination of a nutrition education program with the school breakfast program. The district has not yet acted on this recommendation. A committee of community experts was to be formed to assist in implementing and evaluating the program. A tasting panel of students was to be organized to decide on the products to be purchased and served.

Implementation of such ideas in a large school district takes time. The possibilities for success are good. If the present enthusiasm for the program in the school district continues, San Francisco may well become a national model for urban district-wide school breakfast programs.

New Food Stamp Coupons

The days of 50¢ and $2 food stamp coupons are about to end. USDA has announced that after March 1, 1975 food stamps will be issued in $1, $5, and $10 denominations.

Food stores will be allowed to make change with loose $1 food stamp coupons just as they now give out loose 50¢ coupons. "Scrip" or tokens will be given for change of 99¢ or less.

USDA is also redesigning the coupons, but don't look for any stylistic breakthroughs. Seized, perhaps, by the Bicentennial spirit, USDA has chosen to decorate the coupons with the American flag, the Liberty Bell, a scene depicting the Declaration of Independence, and various Presidential portraits.

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Wichita, KS 67218

West Virginia University | MEDICAL CENTER
MORGANTOWN, WEST VIRGINIA 26506

School of Medicine
Department of Medicine
304-293-4121

January 15, 1975

Mary Winston
Nutritionist
American Heart Association, Inc.
44 E. 23rd St.
New York 10010

Dear Mary:

I have studied all the material which you recently sent to me concerning advertising of food products and the relationship of such advertising to be food labeling laws.

My overall impression is that the Federal Trade Commission would like to control advertising so that it is consistent with the labeling laws regarding fat and cholesterol contents of food, but that the food industry believes that these regulations are too restrictive. The chief restrictive regulation is that health claim for foods low in cholesterol and/or saturated fat or high in unsaturated fat are not permitted.

The enormous force of the food industries through advertising is made very clear in this document. My chief fear in permitting health claim would be that mentioned in Mr. Chianchiano's letter of January 3rd, that "the Federal Trade Commission believes a more liveral policy is necessary to encourage food processors to develop and market new products". I believe such emphasis will lead to increased consumption of polyunsaturated fat rather than a reduction in total fat or saturated fat intake. The striking increase in cheese consumption and the allusion to "filled cheese" could lead to a real explosion in intake of polyunsaturated fats. I would rather see the emphasis on reduction of saturated fats than on increase in polyunsaturated fats. It is the basic medical policy that I am concerned about. Enough in the way of possible dangers from too high an intake of very unsaturated fat has appeared in the literature to make me feel quite cautious about recommending more than modest increases.

With regard to some of the specific issues raised by Mr. Chianchiano's letter of January 3rd, I certainly do agree that foods should be labled with content of cholesterol, saturated fat and polyunsaturated fat, as outlined on page 39862 of the Federal REgister of November 11, 1974. I am quite leary about permitting advertising claims of benefits for the above reasons - that obviously the big swing in industry will be towards filled products and increased intake of calories (albeit low cholesterol polyunsaturated). It does seem to me that item 3 in his letter, some representation that a product is high, low or medium in

cholesterol, would be helpful. This could possibly be related to low, medium or high total daily intakes of cholesterol. Thus, under 200 mg. a day could be low, 200-700 could be medium and over 700 could be high. Whether an individual item was low or high could be related to its total caloric content, its protein content, or its fat content. I do not believe it would be appropriate to say that a food product is high in polyunsaturates if it also contains moderate or high amounts of cholesterol or saturated fats.

As I stated at our December meeting on food endorsement, I think we need to think carefully about what we as a committee would like the food industry to do. I would be much more interested in seeing emphasis on decreased total caloric intake, increased exercise, development of meat products with lower fat (i.e. range beef rather than grain fed beef for instance), and the move away from "empty calories". I would not like to see the food industry encouraged further to increase the availability of polyunsaturated fat because I think the overall results would be increased caloric intake.

In short, other than some indication about whether a food is high, medium or low in cholesterol or saturated or unsaturated fat content, I do not think that health claims should be made in advertising items for which information concerning fat content appears on the label.

Too much of total education is now carried out by industry through advertising. What we need is not more education by industry, but more education by disinterested groups such as the American Heart Association.

I though the regulations about advertising "natural and organic foods" were good (page 39862, November 11th, Federal Register).

Sincerely yours,

Margaret

Margaret J. Albrink, M.D.
Professor of Medicine

MJA/ac

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ANTONIO M. GOTTO, JR., M.D.
Department of Medicine

January 14, 1975

To: Mary Winston

From: Antonio M. Gotto, Jr., M.D. AMG

Re: Letter of December 10 from Federal Trade Commission on Regulations of Food Advertising

With regard to the questions raised by the FTC attornies and the various alternatives, my views are as follows:

a. I would allow a qualified reference to coronary disease in relationship to the three major risk factors, elevated serum cholesterol, hypertension and cigarette smoking. It may not be practicable to require reference to cigarette smoking and high blood pressure as risk factors in each instance where cholesterol as a risk factor is also mentioned.

b. I would not allow any specific health benefit claims such as decreased risk from coronary disease as resulting from any single factor or food substance.

c. I would require a statement that no one food can expect to lower total cholesterol intake or lower the levels of cholesterol or triglyceride in the blood unless it was used as part of an overall diet program.

With regard to alternative #3, it is more important to have accurate labeling in terms of PS ratio and cholesterol content, than it is to have claims concerning the high, low or medium content of cholesterol. It should be noted that it is difficult to identify to the public foods which are low in cholesterol and high in saturated fat, for example, coconut oil.

Question #2: Based on recommendations of the AHA, the AMA Council on Foods and Nutrition, and the Food and Nutrition Board of the National Research Council, there is justification in recommending to the general public a reduction in the intake of saturated fat and in cholesterol. The potential dangers from such recommendations would include the following: Some individuals have high blood triglyceride or diabetes and may require a somewhat different diet, although it is quite feasible to incorporate the essentials of the Prudent Heart Diet with a hypertriglyceridemia or diabetic diet recommendations. The Ten State Nutrition Survey shows the existence of deficient serum levels and/or dietary intake of Vitamin A in certain ethnic and socioeconomic groups, particularly in the Mexican American, and also to a greater extent in the very young and very old.

If severe fat restriction were practice by such groups, the likelihood of a more serious deficiency of Vitamin A, and possibly of other fat soluble vitamins may occur. Other nutritional surveys have shown borderline calcium deficiencies, but this might be expected to occur more frequently in the elderly. A reduction in the intake of Vitamin D enriched milk and the failure to at least use skim milk, could contribute to calcium deficiency and osteoporosis in the elderly.

Question #3 relates to the level of cholesterol and saturated fat which would be recognized as low, moderate or high, and the factors involved in determining whether a particular food fell into this category with respect to cholesterol or saturated fats. Again, the food has to be considered as a total nutritional program. A daily cholesterol intake of less than 300 mg. could be considered low, 300-500 mg moderate, and over 500 mg. as high. Similarly, a PS ratio of overall diet of 2 or greater could be considered as high, 1 as moderate, and 0.3 or less as low. Therefore, total consumption of cholesterol and of saturated fat in the diet have to be taken into account. With respect to saturated fat, the PS ratio grouping above could conceivably be used to indicate the various categories. Categories of food would have to be defined with respect to cholesterol and fat levels on an individual basis and this would seem impracticable. One cutoff point could not be used for all foods. For example, a low fat chesse might contain 8% butterfat or less, frozen dessert 1% or less, meat product 10% fat or less and milk 2% or less. No overall guidelines could be given but would have to be defined for the individual food. Factors to be considered in judging a food to be low, moderate or high in cholesterol and saturated fat would include the following: (a) amount in a normal serving; (b) source of fat; (c) PS ratio; (d) frequency a particular food is eaten; (e) accurate reproducible analysis; (f) variation of the food, for example, cereal products are generally low in cholesterol and saturated fat; however, certain new grain cereals (granolas) may contain hydrogenated fat and coconut fat. To the best of my knowledge no set of definitions currently exists.

The answer to question #4 is related to #3. The important factor is the PS ratio. The content of polyunsaturated and saturated fat should be given. Many foods which are high in cholesterol have a low PS ratio; however, this is not true of fish. If the PS ratio is not used, it would be misleading to say a food is high in polyunsaturated fat. It could be misleading because the food could be equally high in saturated fat.

Question #5 has been answered above. It is the total food intake that is important. One could expect little change in lipids from using egg beaters if he continued to eat 14 eggs per week. "Promise" margarine could scarcely affect the PS ratio of the diet if shortening, cream and bacon continue to be used, possibly in larger amounts.

With regard to the other specific questions raised at the January 3 meeting with the FTC lawyer, I make the following suggestions:

1. While it is desirable to give calorie intake, if this is required in addition to the cholesterol and PS ratio, it may discourage the manufacturer from cooperating with the voluntary labeling act.

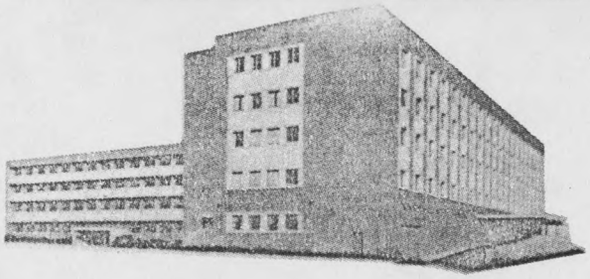
2. The "total fat" is not the proper operative phrase. The PS ratio and cholesterol content are the information that should be given.

3. It is difficult to define a specific percentage of food content of fat, carbohydrate or protein that correlates with such vague terms as "nourishing, wholesome or nutritious". I would not recommend adding any further specific

definitions with regard to this point.

With regard to other points raised, I would allow a properly qualified precise reference to cholesterol and PS ratios. I would encourage individuals to check with their doctor before undertaking a diet and in particular before starting a weight reduction program. I think that it is a mistake to require the manufacturers to give full food composition in order to comply with the Voluntary Labeling Act. This discourages participation of the manufacturer so that information is available about PS ratio and cholesterol content on fewer foods. I think that in the long run nutritional labeling should require manufacturers to list cholesterol, fat source and PS ratio on all food products. We generally receive only about 50% return from manufacturers contacted when we try to obtain this information. Without this information it is not possible to determine if a particular food can be used on cholesterol restricted, low saturated fat diet. With complete information on the label it is the responsibility of nutritionists and physicians to educate patients and the public as to how to use it wisely.

AMG/ja



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DEPARTMENT OF INTERNAL MEDICINE
John F. Mueller, M.D., Director
(303) 892-1207

January 7, 1974

Mrs. Mary Winston
American Heart Association
44 East 23rd Street
New York, New York 10010

Dear Mary:

I am responding to your memo of December 6, 1974, as well as the memos from Dolph Chianchiano dated December 12, 1974 and January 3, 1975. All of this material concerns the proposed regulations by the Federal Trade Commission on food advertising, particularly as it relates to the problems of fat, fatty acid, and cholesterol advertising.

Let me begin with the general statement that I support in principle the Commission's attitude toward regulating food advertising in the U.S. This must of necessity be somewhat arbitrary in its application and, therefore, can be controversial. However much of this controversy is "nit-picking," and I cannot really disagree with its substance.

As far as the matters relating to fat and cholesterol advertising, this is the matter which I discussed to some extent with the Committee at its last meeting. As you recall, I have been a member of the Code Authority for the National Association of Broadcasters Scientific Panel for sometime. We have wrestled with the matters under discussion and have developed the advertising guidelines which were reproduced and distributed by Dolph. I might say that I was not in complete agreement with these guidelines, particulary in one respect noted below, but feel that it is a rational kind of approach which most people can live with. The matter which was in the original guidelines and was removed concerned the attempts to define a "significant contributor" to cholesterol intake. More out of desperation than for any other reason, an attempt to define certain foods as significant contributors and the amounts of dietary cholesterol that would be necessary to identify such a food, led to the abandonment of any such definition. This indeed does represent a difficulty, but one which I was not willing to admit was hopeless. It seems clear to me that egg is a significant contributor to cholesterol intake as an example. One must, of course, be arbitrary in any such definition as the FTC has been in regards to other nutrient intakes. Therefore, I see no reason why we could not define a significant contributor as any food which contributes in a serving more than the arbitrary figure of 100 mg of cholesterol. At any rate I would support such an attempt.

Let me now move on to answer some of the specific questions raised in Dolph's letter of December 10, 1974:

1) I believe strongly that we should stay away from allowing any

specific claims for individual foods, but should insist that claims be presented which incorporate the food in an overall dietary plan.

2) Of course, it would be best to have any type of change in a dietary plan done under or with the advice of a physician, however this is not practical, and I do subscribe to the idea that modest changes in consumer intakes of cholesterol and saturated fat can be made without the specific direction or advice of a physician.

3) This question I have alluded to in the above paragraphs. I think our diet-heart statement states clearly the levels for cholesterol and saturated fat that we feel are optimal, and therefore, define those which would be considered low or high. In terms of food contributions, as I have stated above, they have to be considered in terms of the overall dietary intake and must, of fact, be arbitrary, but I believe this can be done.

4) This question is semantics. One should not be allowed to state that a product is "high" in polyunsat's unless information concerning the remainder of its fatty acid content is not also given. I would support the FTC's determination to prohibit the use of emphatic or excessive claims.

5) Again, the use of the advertised food in an overall dietary plan must be emphasized and the extent to which this food is used in such a dietary plan should be identified, also.

In response to Dolph's questions in his memo dated January 3, 1975, I would make the following comments:

I would agree that health claims should be allowed but require a statement that it is only one of many risk factors in heart disease, and also that no one food can in and of itself have any health significance, but that it must be looked at in light of an overall dietary pattern.

I think the advertising claims for cholesterol content of a food should be related 1) to the food that it is replacing, and 2) to the significance of the total cholesterol intake that that food represents.

In terms of the other questions that they asked, I do not believe that calorie disclosures are necessary in all food advertising, however, when that advertising is used for the purpose of weight reduction, then obviously calorie disclosures are essential.

In response to the questions relating to the use of food for substitute or replacement for other foods, it seems to me, here, that the matter depends upon the nature of the food product and its advertising claim. I would agree, in general, that "fat content" is an improper designation and a distinction should be made between saturated and unsaturated and cholesterol. I would not support the suggestion that in terms of wholesome nourishing foods that a consideration of the fat content is essential.

Again, one has to take into account the total contribution of that product to the overall dietary intake, and the decision concerning this matter is based on that fact.

It is not easy to respond to such a voluminous amount of material in a clear and concise manner. I hope these comments are of some value and will serve more as points for discussion when this matter is, presumably, taken up either at our next meeting or, if necessary, by telephone conference.

Sincerely yours,

Jack

John F. Mueller, M.D.
Director

JFM/sh

The F.D.A. position with regard to food labeling is not in the public interest. The decision that a physician rather than a consumer should make the decision with regard to dietary modification is a bad one and is probably based on the following assumptions:

1. Such dietary modification is hazardous to certain people.
2. Physicians have expert knowledge about nutrition.
3. There is little evidence that dietary modification is effective except for some people.
   A) There is no evidence that a reduction in the amount of fat and cholesterol in the diet is hazardous to individuals, including children.
   B) Physicians probably know less about nutrition than many lay individuals. Few medical schools give courses in nutrition, even fewer have Nutrition Departments. The idea that an individual must see a physician in order to receive dietary consultation serves only to needlessly increase the utilization of medical services and medical care costs.
   C) To require an individual to see a physician in order to begin a nutrition program is a major limitation for any public health or preventive medicine program.

There is solid evidence that dietary intake of fat and cholesterol is the major factor in the development of atherosclerosis. Studies in animals and humans clearly show this relationship. Changes in dietary intake of cholesterol and fat or an increase in ratio of unsaturated to saturated fat in the diet will result in a change in the serum cholesterol level. In certain overweight individuals, caloric restriction is also necessary.

The unanswered question is whether an individual who has around 40-45% of calories from fat and a high ratio of saturated to unsaturated fat can reduce his risk of a heart attack by dietary modification.

In order to collect such adequate data, a long-term National Dietary Heart Study would be needed. No such study is currently being done or planned for immediate implementation.

The consumer should have the right to decide whether to try and reduce the fat and cholesterol content of their diet. In order to do this they must have information about:

1. The caloric content of foods.
2. The fat content as percent of calories and grams per serving.
3. The cholesterol content.
4. The type of fat, saturated or unsaturated, not only in the raw product but after processing as well.

Criteria should be established for classifying certain foods as "low fat", "low cholesterol" or "high in polyunsaturated fats".

Advertisements should be able to state that:

1. People with a lower cholesterol have lesser risk of heart attacks.
2. Eating a low fat, low cholesterol diet will reduce serum cholesterol levels.

Whether advertisers can claim that a reduction in serum cholesterol levels by dietary modification reduces the risk of heart attack is open to serious debate. Many other accepted medical and nutritional theories are based on much flimsier evidence.

The other area of major concern to the Heart Association relates to weight reduction and "caloric content of foods". My primary concern with the labeling relates to the measurement of "portions" and "servings". I doubt whether many

people know what a one-ounce or three-ounce serving is. Perhaps a better method of classifying is needed, such as "tablespoon", "teaspoon", or "cup" calories per serving and then defining number of servings per can, package, etc. I think that a group of nutritionists interested in obesity and atherosclerosis should perhaps work on an improved labeling strategy.

Finally, the basis of the other nutritional labeling as listed in the Federal Registry Statement (RDA's) is based on weaker evidence than that for fat, cholesterol and obesity. The problems of atherosclerosis, obesity and hypertension are of far greater magnitude to the American people than slight decreases in the RDAs.

Lewis H. Kuller, M.D., Chairman
The Department of Epidemiology

LHK/ms

THE OHIO STATE UNIVERSITY

January 14, 1975

Ms. Mary Winston
Nutrition Committee
American Heart Association
44 East 23rd Street
New York, N. Y. 10010

Dear Ms. Winston:

I have read the FTC statement in the Federal Register. As a new member of the Nutrition Committee I am not sure of just what I am to do. The following are my comments.

Much of this document is concerned with truth in advertising which is needed. The section on form, content, and methods of disclosure beginning on page 39842 causes me to question whether the accuracy recommended is feasible for a food processor. The accuracy impresses me as much more than is needed for a consumer.

Our objective in the matter of labelling is to insure that persons on prescribed diets can determine from the label the content of nutrients and certain information about their composition. To this end I would want the number of calories per portion or serving and the proportions of protein, fat and carbohydrates. The protein portion also expresses the PER. There is no mention I could find of expressing carbohydrates as complex and simple sugars. The desirability of this should be discussed by the committee. The methods of disclosure of protein, carbohydrates and fat recommended appears to be grams. Expression as percent of total calories in a serving or portion would be much better. Again, the degree of analytical accuracy being recommended appears to be much greater than can reasonably be expected of a processor and is needed by a consumer.

With regard to vitamins, minerals and trace metals, the recommendation appears more than adequate with an exception I will state shortly. I fear that small containers will disappear from the market as these have insufficient space in which to print all this stuff. Much of what is recorded is of little interest to the consumer or physician. Our greatest concern in this area is sodium content; a subject I do not see discussed in the FTC tome. Labelling for sodium content would be of rather little value to the consumer as he is

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not accustomed to gauging his intake in milligrams per meal or day. Foodstuffs containing more than some prescribed amount of sodium per serving or portion could be labelled "not recommended for persons on low salt diets".

Disclosure of fat content and composition is not dealt with in the FTC statement. They discuss at length prohibition of advertising claims for heart disease cure or prevention which certainly is correct. Persons on prescribed low fat and cholesterol diets must be able to determine from a label the fat and cholesterol content of a serving or portion. Fat expressed as percentage of calories I feel is understandable to the average person. He would avoid those foods providing more than 40% of calories from fat or adjust other foodstuffs so that total daily calories from fat could remain below this or some prescribed percentage. Cholesterol can be expressed as milligrams per serving or portion, because most diets attempt to limit the daily intake to some figure for cholesterol expressed in milligrams. Fatty acid composition should be expressed as the percentage of saturated and unsaturated fatty acids in the final product. Whether this should be expressed as saturated and polyunsaturated or saturated, monounsaturated, and polyunsaturated should be discussed.

By and large the present document from FTC does not address itself to our primary concerns for helping patients adhere to prescribed diets by adequate disclosure on prepared foods of their composition.

Sincerely,

Jack C. Geer, M.D.

JCG/lcb

Jack C. Geer, M. D.

American
Heart
Association

Dr. Shank

Memorandum

TO: Members of the Nutrition Committee 6 Dec 74

FROM: Mary Winston, Nutritionist Mary Winston/dlw
Division of Education and Community Programs

SUBJECT: Federal Register, November 11, 1974, Part II, Food Advertising

We will appreciate it if you would review the FTC regulations on food advertising which were mailed to you sometime last week. In order to be meaningful, the document must be read in its entirety. I agree it is a formidable and time consuming task, but one that needs to be done. Since the regulations have implications for the American Heart Association, we feel that your response is vital.

Please send your comments to Mary Winston by January 15, 1975.

Best wishes for a happy holiday season.

MW:Th2:yy

Attachment: FTC Announces Food Advertising Rules

THE PUBLIC BEAT (News of Public Policy and Government Affairs of Interest to AHA) by Dolph Chianchiano

FTC ANNOUNCES FOOD ADVERTISING RULES

The Federal Trade Commission published a proposal relating to unfair methods of competition and unfair or deceptive acts or practices in food advertising in the Nov. 11, 1974 Federal Register. Comments will be accepted up to Feb. 5 next year. The draft regulations cover "nutrients", "protein" and "calorie" claims but seem to avoid the issue of advertising relating to cholesterol and saturated fat. The proposal will be studied in detail by the AHA Nutrition Committee whose analysis will form the basis for a public policy position.

FETAL RESEARCH

The Biomedical and Behavioral Research Training Act (Public Law 93-348) reaffirmed the authority of the National Institutes of Health to support research training in response to Mr. Nixon's decree that all such programs should be terminated. It also created the National Advisory Council for the Protection of Subjects of Biomedical and Behavioral Research. That Commission will have its first meeting in Washington, D.C., Dec. 3 and 4. It is expected that the first substantive item on the agenda will be the question of fetal research.

LEGAL PROBLEMS OF EMERGENCY CARE

The AHA is one of the official co-sponsors of the First National Conference on the Medicolegal Implications of Emergency Medical Care. This conference will be held in Washington, D.C., June 8-10, 1975. Our President, Elliot Rapaport, M.D., will be the principal luncheon speaker on June 9.