1992

Cheese Industry Conference 1992

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In the Continuing Education conference/program in which you have elected to participate, there are certain assumptions of risk which you engender when participating in physical activities as a part of this conference/program. You must be aware of these assumptions.

Throughout this conference/program, you will receive competent, progressive, sequential instruction and proper supervision. Every effort will be made to keep all facilities and equipment in good, safe, workable condition.

You will not be asked to do anything which is inconsistent with the conference/program or is in any way not reasonable and prudent.

However, the entire responsibility is not the activity administrator's. You, too, have a responsibility. For your own safe participation, and that of your fellow participants, you must call to the attention of the activity administrator any situation which you perceive to be a potential danger to you or your fellow participants. This would include, but should not be limited to:

- equipment that has broken or is in need of repair
- when you are not feeling well or are unduly fatigued
- when you have unusual difficulty in performing a skill

Also, you are obligated to follow the rules and regulations set down by the activity administrator for your safety. This includes the proper dress, such as tennis shoes and protective equipment, e.g., eye glass guards. If you choose not to use such protective equipment provided or requested, you must realize that you are doing so at your own peril and that injury might occur.

We all want a safe environment, but it must be recognized that accidents do occur in active participation. We want vigorous participation, but all of us, the activity administrator, you and fellow participants, must use good judgement and work together for safe participation.

Should an injury be incurred during participation in this Continuing Education conference/program, the activity administrator will make arrangements for transportation to Logan Regional Hospital or another appropriate health care facility.

The injured party is responsible for all financial obligations incurred in this process and subsequent treatment necessitated by the injury. Because of this, participants are encouraged to carry some form of health care insurance.

Please discuss with your activity administrator any known physical problems which may limit your participation in this Continuing Education conference/program.

Should you have any questions regarding this statement, please contact your activity administrator.

NOTE: The activity administrator is the authorized USU Life Span Learning Programs agent assigned to coordinate your activity program.

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SYNOPSIS

NUTRIENT CONTENT CLAIMS
(COMMONLY REFERRED TO AS "DESCRIPTORS")

INTRODUCTION

All information for this presentation has been taken from FDA's PROPOSED rules, as published in the Federal Register, Vol. 56, No.229, Wednesday, November 27, 1991, Proposed Rules, Pages 60421-60528, with the assumption that most proposals will probably be finalized as they now read. Most certainly some changes will take place between now and November 9, 1992, with consumers, industry, and state and local regulatory agencies to be held responsible for awareness of those changes. These changes or amendments affect the Code of Federal Regulations (CFR), most specifically, 21 CFR part 101.

DEFINITION

"Nutrition information in any context, and in any form of expression, implicit, as well as explicit,"....... shall be considered a NUTRIENT CONTENT CLAIM. 21 CFR 101.9(a) (Federal Register, Wednesday, November 27, 1991, page 60386)

SUPPLEMENTARY INFORMATION

"One of the main purposes of the Nutrition Labeling and Education Act of 1990 was to establish the circumstances in which claims could be made that describe the nutrient content of food." (Federal Register, Wednesday, November 27, 1991, page 60513)
BACKGROUND

America's eating habits are changing. Our method of choosing foods is based on a different set of criteria than was used 20 years ago. Many suggestions from individuals, industry, and the scientific community were received by FDA, concerning health issues and dietary concerns that would address this change in consumer buying preferences.

"These recommendations, which were published in 1980 and revised in 1985 and 1990, are based on the view that the judicious selection of foods containing low or high levels of certain nutrients as part of an overall diet is prudent on the part of all consumers, not just those with special dietary needs." (Federal Register, Wednesday, November 27, 1991, page 60421)

The Federal Register goes on to say that, "In addition, two scientific consensus reports, "The Surgeons General's Report on Nutrition and Health", (1988) (Ref.2) and the National Academy of Sciences report, "Diet and Health: Implications for Reducing Chronic Diseases Risk" (1989) (Ref.3), concluded that changes in current dietary patterns, namely reducing consumption of fat, saturated fatty acids, cholesterol, and sodium and increasing consumption of complex carbohydrates and fiber, could lead to reduced incidence of certain chronic diseases. (page 60421)

Again, quoting from the Wednesday, November 27, 1991 Federal Register, "Approximately 3500 of the over 5000 questionnaire responses also supported the need for additional descriptor definitions.............One comment stated that the terms were meaningless in the way they are now used and are primarily used as marketing tools rather than as guides for the health conscious consumer". (page 60422)
There are nine NUTRIENT CONTENT CLAIMS (descriptors) that the NUTRITION LABELING AND EDUCATION ACT OF 1990 (NLEA) mandated that FDA define and set forth in its regulations. These nine include:

1. FREE
2. LOW
3. REDUCED
4. LESS
5. FEWER
6. LIGHT (LITE)
7. MORE
8. HIGH
9. SOURCE OF

These one word descriptors may in turn have one or more synonyms. The nutrient content claims are used to describe certain nutrients. Their exact definition depends on, and changes with, each nutrient they are describing. These nutrients include:

1. CALORIES
2. FAT
3. CHOLESTEROL
4. CARBOHYDRATES
5. DIETARY FIBER
6. PROTEIN
7. SODIUM
8. VITAMINS A & C
9. MINERALS CALCIUM & IRON
'RULES OF THE GAME'

There are certain rules which must be followed in order to use these nutrient content claims on a food label.

NUTRIENT CONTENT CLAIMS-- :

1. must be made in accordance with the new regulations.
2. which appear in the "Nutrition Statement" are not considered a Nutrient Content Claim.
3. of "Low" or "Free" can only be made on altered or reformulated foods.
4. must be of a type size no larger than the "Statement of Identity".
5. must be followed in immediate proximity by the statement, "See side panel for information about fats and other nutrients".
6. that list actual amounts of nutrients must meet the requirements of either "High" or "Low" claims.
7. that make comparative claims must follow specific formats.
8. rules are in force when using the term "Modified" in the 'Statement of Identity'.
9. must follow the definition for 'meal-type' and 'nonmeal-type' products.
10. must be accompanied by an acceptable Nutrition Statement.
11. must meet the specific requirement for the specific claim.
12. have certain exemptions that apply in specific situations.
Following is FDA's explanation and clarification of the legally defined relationship between the nutrient content claim and the nutrient it may accompany. Also included is the index or section number where it will be inserted into 21 CFR (the labeling portion of the Code of Federal Regulations).

§ 21 CFR 101.54 NUTRIENT CONTENT CLAIMS FOR "SOURCE", "HIGH", and "MORE"

HIGH

A food product using the nutrient content claim "high" (or any of the prescribed synonyms), must contain 20% or more of the RDI or DRV per reference amount customarily consumed and per labeled serving size.

SOURCE

A food product using the nutrient content claim "source" (or any of the prescribed synonyms), must contain 10-19% of the RDI or DRV per reference amount customarily consumed and per labeled serving size.

MORE

A food product using the nutrient content claim "more" (or any of the prescribed synonyms), must contain at least 10% more or the RDI or DRV than the reference food that it resembles and for which it substitutes.

§ 21 CFR 101.56 NUTRIENT CONTENT CLAIMS FOR "LIGHT" OR "LITE"

A food product using the nutrient content claim "light" or "lite" must have at least a 1/3% reduction in calories compared to the reference food with a minimum reduction of 40 calories per serving size.

If a food product derives 50% or more of its calories from fat then the fat content must be reduced by 50%, with a minimum reduction of more than 3 grams of fat per serving size.

There are other rules governing the use of "light" or "lite".
§ 21 CFR 101.60 NUTRIENT CONTENT CLAIMS FOR THE CALORIE CONTENT OF FOODS

A. CALORIE CONTENT CLAIMS

FREE

A food product using the nutrient content claim "calorie free" (or any of the prescribed synonyms), must contain less than 5 calories per reference amount customarily consumed and per labeled serving size.

LOW

A food product using the nutrient content claim "low calorie " (or any of the prescribed synonyms), must contain less than 40 calories per reference amount customarily consumed and per labeled serving size.

REDUCED

A food product using the nutrient content claim "reduced calories " (or any of the prescribed synonyms), must have been specially processed to reduce the calories by 33 1/3% or more with a minimum reduction of more than 40 calories per reference amount customarily consumed and per labeled serving size from the reference food that it resembles and for which it substitutes.

FEWER

A food product using the nutrient content claim "fewer calories " must contain at least 25% fewer calories with a minimum reduction of more than 40 calories per reference amount customarily consumed and per labeled serving size from the reference food that it resembles and for which it substitutes.

B. SUGARS CONTENT CLAIMS

FREE

A food product using the nutrient content claim "sugars free" (or any of the prescribed synonyms), must contain less than .5 grams per reference amount customarily consumed and per labeled serving size.

There are other rules governing the use of the nutrient content claim "sugars free".
NO ADDED

A food product using the nutrient content claim "no added sugars" (or any of the prescribed synonyms), must have no sugars added during processing.

There are other rules governing the use of the nutrient content claim "no added sugars".

A food product using the nutrient content claim "__ less sugars " must contain at least 25% less sugars per reference amount customarily consumed and per labeled serving size than the reference food that it resembles and for which it substitutes.

§ 21 CFR 101.61 NUTRIENT CONTENT CLAIMS FOR THE SODIUM CONTENT OF FOOD

FREE

A food product using the nutrient content claim "sodium free" (or any of the prescribed synonyms), must contain less than 5 milligrams per reference amount customarily consumed and per labeled serving size, must not contain any added sodium, and if not altered during processing, must bear a statement such as, "____ - a sodium free food."

VERY LOW

A food product using the nutrient content claim "very low sodium " (or any of the prescribed synonyms), must contain 35 milligrams or less sodium per reference amount customarily consumed and per labeled serving size, and if not altered during processing, must bear a statement such as, "____ - a very low sodium food."

LOW

A food product using the nutrient content claim "low sodium " (or any of the prescribed synonyms), must contain 140 milligrams or less sodium per reference amount customarily consumed and per labeled serving size, and if not altered during processing, must bear a statement such as, "____ - a low sodium food."
REDUCED

A food product using the nutrient content claim "reduced sodium" (or any of the prescribed synonyms), must have been specially processed to reduce sodium content by 50%, with a minimum reduction of 140 mg sodium, and must bear a statement such as, "Reduced Sodium - 50% less sodium than regular _____.

LESS

A food product using the nutrient content claim "less sodium", must have 25% less sodium, with a minimum reduction of 140 mg sodium per reference amount customarily consumed and per labeled serving size than the reference food for which it substitutes, and must bear the required comparative statement.

There are other rules governing the use of sodium nutrient content claims.

§ 21 CFR 101.62 NUTRIENT CONTENT CLAIMS FOR FAT, FATTY ACID, AND CHOLESTEROL CONTENT OF FOODS

FAT CONTENT CLAIMS

FREE

A food product using the nutrient content claim "fat free" (or any of the prescribed synonyms), must contain less than 0.5 grams of fat per reference amount customarily consumed and per labeled serving size, must not contain any added ingredient that is an oil or fat, and if not altered during processing, must bear a statement such as, "_____ - a fat free food."

LOW

A food product using the nutrient content claim "low fat" (or any of the prescribed synonyms), must contain 3 grams of fat or less per reference amount customarily consumed and per labeled serving size, and if not altered during processing, must bear a statement such as, "_____ - a low fat food."
REDUCED

A food product using the nutrient content claim "reduced fat" (or any of the prescribed synonyms), must have been specially processed to reduce fat content by 50%, with a minimum reduction of more than 3 grams of fat, and must bear a statement such as, "Reduced Sodium - 50% less sodium than our regular ___ product. Fat content has been reduced from 8 grams to 4 grams per serving."

LESS

A food product using the nutrient content claim "less fat", must have 25% less fat than reference food, with a minimum reduction of more than 3 grams of fat per serving, and must bear a statement such as, "This ___ product contains 40% less fat than our regular ___ product. Fat content has been lowered from 10 grams to 6 grams of fat per serving."

___% FREE

A food product using the nutrient content claim "__ % fat free", must meet the criteria for low fat, unless the claim of 100% fat free is made, then the fat free criteria must be met.

FATTY ACID CONTENT CLAIMS

LOW

A food product using the nutrient content claim "low in saturated fat" (or any of the prescribed synonyms), must contain 1 gram or less of saturated fatty acids per reference amount customarily consumed and per labeled serving size, and not more than 15% of the calories may come from the saturated fatty acids, and if not altered during processing, must bear a statement such as, "___ - a low saturated fat food."

REDUCED

A food product using the nutrient content claim "reduced saturated fat" (or any of the prescribed synonyms), must have been specially processed to reduce the fatty acid content by 50%, with a minimum reduction of 1 gram per reference amount customarily consumed and per labeled serving size, and must bear a statement such as, "Reduced saturated fat. Contains 50% less saturated fat than national average for Non Dairy Creamers. Saturated fat reduced from 3 grams to 1.5 grams per serving."
LESS

A food product using the nutrient content claim "less saturated fat", must have 25% less saturated fat with a minimum reduction of more than 1 gram per reference amount customarily consumed and per labeled serving size, from the reference food that it resembles and for which it substitutes, and must bear a statement such as, "Brand Y crackers contains 40 percent less saturated fat than our regular Brand X crackers. Brand Y contains 6 grams saturated fat; Brand X contains 10 grams saturated fat.

There are other rules governing the use of fatty acid content claims.

CHOLESTEROL CONTENT CLAIMS

FOOD CONTAINING LESS THAN 11.5 GRAMS TOTAL FAT PER SERVING

FREE

A food product containing less than 11.5 grams total fat per serving and per 100 grams of food, using the nutrient content claim "cholesterol free" (or any of the prescribed synonyms), must contain less than 2 milligrams of cholesterol per reference amount customarily consumed and per labeled serving size, and must contain 2 grams or less of saturated fatty acids per reference amount customarily consumed and per labeled serving size, and if not specially processed or altered, must bear a statement such as, "Product - a cholesterol free food."

FOOD CONTAINING MORE THAN 11.5 GRAMS TOTAL FAT PER SERVING

A food product containing more than 11.5 grams total fat per serving and per 100 grams of food, using the nutrient content claim "cholesterol free" (or any of the prescribed synonyms), must contain less than 2 milligrams of cholesterol per reference amount customarily consumed and per labeled serving size, and must contain 2 grams or less of saturated fatty acids per reference amount customarily consumed and per labeled serving size, and if not specially processed or altered, must bear the statement, "Product - a cholesterol free food, containing 14 grams of fat per serving." If the product contains less than 2 milligrams of cholesterol only as a result of special processing or alteration, then the label must bear a statement such as,
"Cholesterol free margarine, contains 100 percent less cholesterol than butter. Contains no cholesterol compared with 30 milligrams in one serving of butter. Contains 14 grams of fat per serving."

FOOD CONTAINING LESS THAN 11.5 GRAMS TOTAL FAT PER SERVING

LOW

A food product containing less than 11.5 grams total fat per serving and per 100 grams of food, using the nutrient content claim "low cholesterol" (or any of the prescribed synonyms), must contain 20 milligrams or less of cholesterol per reference amount customarily consumed and per labeled serving size, and must contain 2 grams or less of saturated fatty acids per reference amount customarily consumed and per labeled serving size, and if not specially processed or altered, must bear a statement such as, "LOW FAT COTTAGE CHEESE, - a low cholesterol food."

FOOD CONTAINING MORE THAN 11.5 GRAMS TOTAL FAT PER SERVING

A food product containing more than 11.5 grams total fat per serving and per 100 grams of food, using the nutrient content claim "cholesterol free" (or any of the prescribed synonyms), must contain 20 milligrams or less of cholesterol per reference amount customarily consumed and per labeled serving size, and must contain 2 grams or less of saturated fatty acids per reference amount customarily consumed and per labeled serving size, and if not specially processed or altered, must bear the statement, "Product, - a low cholesterol food, containing 14 grams of fat per serving." If the product contains less than 20 milligrams of cholesterol only as a result of special processing or alteration, then the label must bear a statement, such as the following, "Low cholesterol peanut butter sandwich crackers, contains 83% less cholesterol than our regular peanut butter sandwich crackers. Cholesterol lowered from 30 mg to 5 mg per serving. Contains 13 grams of fat per serving."

FOOD CONTAINING LESS THAN 11.5 GRAMS TOTAL FAT PER SERVING
REDUCED

A food product containing less than 11.5 grams total fat per serving and per 100 grams of food, using the nutrient content claim "reduced cholesterol" (or any of the prescribed synonyms), must have been specially processed to reduce the cholesterol level by 50% or more with a minimum reduction of 20 milligrams of cholesterol per reference amount customarily consumed and per labeled serving size, and must contain 2 grams or less of saturated fatty acids per reference amount customarily consumed and per labeled serving size, and must bear a statement such as, "Reduced cholesterol beef gravy mix, contains 70% less cholesterol than our regular beef gravy mix. Cholesterol lowered from 80 mg to 24 mg per serving."

FOOD CONTAINING MORE THAN 11.5 GRAMS TOTAL FAT PER SERVING

A food product containing less than 11.5 grams total fat per serving and per 100 grams of food, using the nutrient content claim "reduced cholesterol" (or any of the prescribed synonyms), must have been specially processed to reduce the cholesterol level by 50% or more with a minimum reduction of 20 milligrams of cholesterol per reference amount customarily consumed and per labeled serving size, and must contain 2 grams or less of saturated fatty acids per reference amount customarily consumed and per labeled serving size, and must bear a statement such as, "Reduced cholesterol salad dressing, contains 65% less cholesterol than our regular salad dressing. Cholesterol lowered from 30 mg to 10.5 mg per serving. Contains 12 grams of fat per serving."

FOOD CONTAINING LESS THAN 11.5 GRAMS TOTAL FAT PER SERVING

LESS

A food product containing less than 11.5 grams total fat per serving and per 100 grams of food, using the nutrient content claim "less cholesterol", must have at least 25% less cholesterol than the reference food with a minimum reduction of 20 milligrams of cholesterol per reference amount customarily consumed and per labeled serving size, and must contain 2 grams or less of saturated fatty acids per reference amount customarily consumed and per labeled serving size, and must
bear a statement such as, "Hot Coco Mix - 30% less Cholesterol than our regular hot coco mix. Cholesterol lowered from 30 mg to 23 mg per serving."

FOOD CONTAINING MORE THAN 11.5 GRAMS TOTAL FAT PER SERVING

A food product containing less than 11.5 grams total fat per serving and per 100 grams of food, using the nutrient content claim "less cholesterol", must have at least 25% less cholesterol than the reference food with a minimum reduction of 20 milligrams of cholesterol per reference amount customarily consumed and per labeled serving size, and must contain 2 grams or less of saturated fatty acids per reference amount customarily consumed and per labeled serving size, and must bear a statement such as, "Vegetable Beef Soup Mix - 25% less Cholesterol than our regular vegetable beef soup mix. Cholesterol lowered from 140 mg to 105 mg per serving. Contains 13 grams of fat per serving."

§ 21 CFR 130.10 REQUIREMENTS FOR SUBSTITUTE FOODS NAMED BY USE OF A NUTRIENT CONTENT CLAIM AND A STANDARDIZED TERM.

"A use of nutrient content claims in which there is a great deal of both industry and consumer interest, but that is not addressed {directly} in the nutrient content claims document, is".....the use of nutrient content claims on standardized foods.

"Foods that are subject to food standards, or that substitute for foods that are subject to food standards, make up a substantial portion of the nation's food supply........FDA has promulgated approximately 300 standards of identity under section 401 of the act. These standards are codified in 21 CFR parts 131 through 169. Under the misbranding provisions of section 403 of the act, if a food resembles a standardized food but does not comply with the standard, that food must be labeled as an "imitation." (Federal Register, Vol 56, No. 229, Wednesday, November 27, 1991, Proposed Rules, Page 60513)
Using the following requirements, nutrient content claims may be used on standardized foods:

a. Description

The food product must be a standardized food as defined in 21 CFR parts 131-169, but does not comply because of deviation due to the use of a FDA defined and properly used nutrient content claim. The food product must be relevant to the standard in all other respects.

b. Nutrient addition

Nutrients shall be added so that the product is not nutritionally inferior to the standardized food.

c. Performance characteristics

The performance characteristics shall be similar, if not, the label shall bear a statement describing or warning the consumer of the difference, i.e., "not recommended for cooking."

d. Other ingredients

1. Ingredients used shall be those provided in the CFR definition, except: safe and suitable ingredients may be used
   (a) to improve texture
   (b) to add flavor
   (c) to prevent syneresis
   (d) to extend shelf life

2. Ingredients that are specifically required by the standard of identity shall not be replaced or exchanged, i.e., vegetable oil shall not replace milkfat in light sour cream.

3. An ingredient specifically prohibited shall not be added.

e. Nomenclature

The name of the food shall be the appropriate nutrient content claim and the applicable standardized term.
Label declaration

1. Each ingredient used shall appear in the ingredient statement.

2. Those not provide for shall be identified by an asterisk, and a following statement, such as:

"*Ingredient(s) not in regular product."

or

"*Ingredient(s) in excess of amount permitted in regular product."

§ 21 CFR 101.69 PETITIONS FOR NUTRIENT CONTENT CLAIMS

Petitions for nutrient content claims may be filed with the FDA and may include:

1. Petitions for new nutrient content claims.

2. Petitions for additional synonyms.

3. Petitions for the use of an implied claim in a brand name.
HEALTH CLAIMS ON FOOD LABELS

The Nutrition Labeling and Education Act of 1990
Current Status

DeJoy G. Hendricks
Utah State University
10th Biennial Cheese Conference
August 17, 1992

When the McGovern Senate Select Committee on Nutrition published the Dietary Goals for Americans in 1977 it set in motion a number of movements that played together to bring about the Nutrition Labeling and Education Act of 1990. The basis for the Dietary Guidelines was the relationship between diet and disease.

The Dietary Guidelines have been modified by the American Heart Association, the United States Department of Agriculture, and National Cancer Institute, and American Medical Association, the Surgeon General and the National Academy of Sciences into seven summary statements:

1. Eat a variety of foods.
3. Choose a diet low in fat, saturated fat and cholesterol.
4. Choose a diet with plenty of vegetables, fruits and grain products.
5. Use sugars only in moderation.
6. Use salt and sodium only in moderation.
7. If you drink alcoholic beverages, do so in moderation.

In the early 1980’s Kellogg Company began a campaign to promote All-Bran which emphasized the relationship between dietary fiber and epidemiological evidence of reduced risk of colon cancer. This action was a direct challenge to Food and Drug Administration’s (FDA) traditional ban on food product health or disease related claims.

During the 1940-1960 period FDA worked on rule making and because of the economic impact of some labeling regulations maintained a high visibility that culminated when Congress itself excused the FDA from responsibility for labeling of vitamin-mineral supplements. Food safety issues were addressed strongly in the 1950-1980 era. Projects included reviewing safety of color additives, devising standards for regulatory carcinogenic animal drug residues including Diethylstilbestrol and identification of real and potential carcinogens. A lack of compelling food safety issues in the mid 1980’s and the boldness of Kellogg’s All-Bran marketing set the stage for the FDA to again address food labeling.

The complete Nutrition Labeling and Education Act is to be reviewed by several individual speakers at this short course. Therefore, my comments will be limited to only that segment of the Act that deals with health claims.
Health Claims

FDA has held hearings on ten diet-health claims. These claims and the proposed actions are as follows:

<table>
<thead>
<tr>
<th>Claim</th>
<th>Proposed Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dietary fiber and cancer</td>
<td>Additional review</td>
</tr>
<tr>
<td>Dietary fiber and heart disease</td>
<td>Additional review</td>
</tr>
<tr>
<td>Folic acid and neural tube defects</td>
<td>Disallow</td>
</tr>
<tr>
<td>Antioxidants vitamins and cancer</td>
<td>Disallow</td>
</tr>
<tr>
<td>Zinc and immune function in elderly</td>
<td>Disallow</td>
</tr>
<tr>
<td>Omega 3 fatty acids and coronary heart disease</td>
<td>Disallow</td>
</tr>
<tr>
<td>Calcium and osteoporosis</td>
<td>Allow</td>
</tr>
<tr>
<td>Lipids and cardiovascular disease</td>
<td>Allow</td>
</tr>
<tr>
<td>Dietary lipids and cancer</td>
<td>Allow with specifications</td>
</tr>
<tr>
<td>Sodium and hypertension</td>
<td>Allow</td>
</tr>
</tbody>
</table>

The four claims which currently have favorable action are the claims which will directly affect dairy products. The two which are currently under additional review may be relevant for some dairy products or dairy mixes.

Calcium and Osteoporosis

Dairy products currently provide more dietary calcium than any other food group for all segments of the population. It has been well documented that high calcium intake results in greater bone mass at maturity. The consequence of a larger bone mass is a lower incidence of disabling osteoporosis in later life. With the use of products such as Lactaid there are very few individuals who cannot consume dairy products at levels adequate to insure calcium intake that will maximize bone mass and minimize bone loss. Fermented dairy products of foods made from milk fractions provide additional choices of available calcium sources for some individuals.
Lipids and Cardiovascular Disease

This claim will create some difficulty for dairy products as saturated fats and cholesterol are major risk factors for cardiovascular disease. Technology, however, is available to change the lipid characteristics of milk fat. A more economical approach is the development of low fat dairy products, which is currently being accomplished.

Research efforts need to be concentrated on economical methods of reducing cholesterol in milk. Again perhaps the easiest solution is the promotion of low fat dairy products which are also reduced cholesterol products.

Dietary Lipids and Cancer

Low fat dairy products will benefit from this claim. The past decade has seen a large consumer shift to low or reduced fat milk consumption. This pattern will undoubtedly continue with the allowance of this type of health claim on the low fat products.

Sodium and Hypertension

Dairy products exclusive of cheeses will qualify for this health claim.

Dietary Fiber and Cancer, Dietary Fiber and Heart Disease

Milk is a companion food to cereals, some of which may be allowed to make the health claims of the association between fiber and cancer and fiber and cardiovascular disease. The dairy industry will certainly want to collaborate with the cereal industry in promoting this type of health claim. In addition cereals and/or specific fiber components may be added into some dairy products to qualify for these claims if they are indeed allowed.

Requirements

There are a number of specific requirements in terms of nutrient content that a food must meet before qualifying for a health claim. Foods that contain more than 11.5 gms of fat per serving or per 100 gms could not qualify for any health claim. Four grams of saturated fat per serving or per 100 gms would exclude foods from health claims. Forty five milligrams of cholesterol or 360 mg of sodium per serving or per 100 gms of food would also exclude the use of any health claims. Thus, high lipid dairy products would be excluded from the proposed health claims. However, low lipid dairy products would qualify for one or more health claim.
Conclusions

If properly used the Nutrition Labeling and Education Act of 1990 health claims guidelines will assist the consumer in making food choices based on health benefits and encourage the food industry to develop food products that are healthy to eat as well as tasty. The dairy industry has already made great strides in providing healthful food products for the consuming public. The approval to openly use health claims should encourage the development of even more dairy products and their promotion for health benefits.
Another nutrition labeling issue discussed in the 1979 ANPRM was whether food manufacturers and producers either should be required to ensure that their food labels accurately reflected the nutrient composition of their products principally by analyzing individual lots of their products (which is the current policy), or should be allowed to use composite data bases for deriving appropriate nutrient values for labeling. In the 1979 ANPRM, FDA and USDA set forth the following policy concerning the use of nutrient data bases:

FDA and USDA encourage industry to develop and maintain meaningful data bases that may be useful guides for determining the nutrient values of indigenous nutrients. FDA and USDA likewise encourage industry to submit such data bases to them so that they may judge their applicability for use in nutrition labeling. The sampling plans and statistical factors to be used in developing the accuracy of the nutrient profile appearing on the label will be determined according to the food and the nutrient, for each data base. This evaluation will not constitute approval, but it will assist industry in developing and interpreting a data base for nutrition labeling.

FDA and USDA encourage the use of properly evaluated data bases for all appropriate segments of industry. Generic labels would reduce the burden associated with developing the data base and reduces the number of nutrition labels that a food retailer would need to maintain. For example, FDA has already approved a data base that allows a common label applicable to all varieties, types and geographic sources of broccoli. Additionally, this type of generic nutrition label can be developed at a lower cost by trade associations than would be the case if individual growers or packers had to develop data bases for individual varieties of produce grown in one location. The disadvantage is that the variability gives rise to a nutrition label that may understate, for example, the nutritional value of a particular variety of produce or of produce from a particular region because of the need for the label to cover industry-wide variations. Likewise, the nutritional value may be under-or overstated for produce that varies in size such as apples, oranges, and bananas.
FDA is proposing to extend mandatory nutrition labeling to fresh produce. Because of the variability problem, this proposal has the potential for imposing a significant analytic and economic burden on this segment of the food industry. Consequently, FDA also is proposing in (101.9 e 7) to exempt, under certain conditions, fresh fruits and vegetables from the agency's procedures for determining label compliance with (101.9). The conditions are: the nutrition information provided is in accordance with an FDA-approved data base, the nutrition label has been computed following FDA guidelines, and the food has been handled in accordance with good manufacturing practice to prevent nutrient loss.

FDA advises that organizations obtaining data base and nutrition on label approval, will be held responsible for continued maintenance of the data base. As already noted, if FDA surveillance activities indicate that an approved data base may no longer be appropriate, the agency's approval will be withdrawn. FDA does not intend to prohibit the use of data bases not specifically approved by the agency. If this proposal is adopted, organizations will be free to use other data bases that they believe validly reflect the nutrient contents of their products. However, labeling computed from these data bases will be subject to the compliance procedures of (101.9 e 1 through 6).

The food and Drug Administration (FDA) is proposing to amend its nutrition labeling regulations (1) to define serving and portion size on the basis of the amount of food commonly consumed per eating occasion by persons 4 years of age or older, by infants, or by children under 4 years of age (toddlers); (2) to require the use of both U.S. and metric measures to declare serving size; (3) to permit the declaration of serving (portion) size in familiar household measures; (4) to permit the optional declaration of nutrient content per 100 grams (or 100 milliliters); and (5) to define a "single serving container" as that which contains 150 percent or less of the standard serving size for the food product. FDA also is proposing to establish standard serving sizes for 159 food product categories to assure reasonable and uniform serving sizes upon which consumers can make nutrition comparisons among food products.
Since 1973 there has been support among consumer and professional groups and some manufacturers and trade associations for the standardization of serving sizes (38 FR 2125, January 19, 1973). On several occasions, FDA has stated that reasonable and uniform serving sizes should be used and has expressed its intention to develop a procedure for standardizing serving sizes. The agency in 1974 (39 FR 20887) stated that it would propose serving sizes on its own initiative if divergent serving sizes continued to be used in the marketplace.

In a view of the many comments from the recent food labeling hearings and comments made to the ANPRM about the need for more realistic consistent serving sizes, FDA has tentatively concluded that reasonable and standardized serving sizes should be established. The agency, therefore, is proposing to establish a new regulation, (101.12 21 CFR 101.12), that sets forth standard serving sizes for 159 food product categories for nutrition labeling and other food labeling purposes. FDA intends to use these standard servings sizes, if they are adopted, to evaluate whether claims on food labels, such as "low sodium" and "low cholesterol," are appropriate and not misleading to consumers.

Regulatory Approach: As stated above, the serving size is the amount of a food that is used as the basis for presenting the food's nutrient content to the public. In deciding how serving sizes should be determined, the agency considered the purposes and uses of serving sizes, as well as the comments on serving size that it received in response to the ANPRM and its experience over the past 20 years in regulating nutrition information on food products. Based on its consideration of these factors, the agency reached a set of tentative conclusions about serving sizes. Frequently, it was not possible to meet all potential goals for the purposes and uses of serving sizes. When conflicts arose, priority was given to the option that FDA considered to be most useful to consumers.

1. Reasonable Serving Sizes:

Several comments pointed out that in the absence of limits on the amount of food in a serving, manufacturers had manipulated serving sizes on their products to achieve a per serving content that would allow claims such as "low calorie" or "low sodium" that
made their products appear nutritionally superior relative to other products in light of public health concerns.

FDA agrees that serving sizes should represent reasonable average amounts that are commonly consumed. To reflect this fact, the agency tentatively concludes that the serving size for a particular food should be the amount that is commonly consumed by the population group for which the food is intended.

Comments indicated that to be a useful reference point, the serving size should be expressed in units that are readily understood by consumers. Most of the comments recommended the use of familiar units, such as count pieces, package, and household measures (e.g., cups or tablespoons). Several comments requested that manufacturers also be permitted to declare serving size by weight (e.g., oz) as well as household measures. Other comments, citing international harmonization in food labeling, recommended the use of metric units for weights and volume, with 100 grams (g) or 100 milliliters (mL) as the basis for providing nutrition information on most foods and 10 g or 10 mL on foods consumed in small amounts.

FDA recognizes that most consumers prefer the use of familiar household units such as count, pieces, cups, slices, and tablespoons. However, it quickly became clear to the agency that the variability in size and weight of various food products (e.g., lack of standardization in bread size and in thickness of slices) would mean that for many products, this approach would create compliance problems and would make it difficult for consumers to make comparisons among similar products.

FDA tentatively concludes that for most foods, manufacturers should be required to list on the label the standard serving size in U.S. units, such as oz or fluid ounces (fl oz), followed by the equivalent metric measurements (mL) in parentheses. As an example, the serving size for fluid milk should be described as "8 fl oz (240 mL)" and for bread as "2 oz (56 g)."
To be responsive to the many comments that requested that serving sizes be expressed in familiar household units. FDA also tentatively concludes that manufactures should be permitted voluntarily to declare the serving size in terms of familiar household measures, such as cups, pieces, or count. Thus, in addition to declaring the serving size for fluid milk as "8 fl oz (240 mL)," the manufacturer could add 1 cup."

FDA also tentatively concludes that nutrient declaration per 100 grams (or 100 milliliters) should not be required at this time. U.S. consumers are not as familiar with the metric system as consumers in other countries and, as stated above, have expressed strong preference for familiar units. However, because FDA wishes to support international harmonization in food labeling, FDA tentatively concludes that it will permit manufacturers to voluntarily provide nutrition information on the basis of 100g or 100 mL in addition to the required information.

2. **Standardized Serving Sizes:**

The second purpose of the serving size is to provide a means by which consumers can make comparisons between foods. Many comments pointed out that a major impediment to effective consumer use of nutrition labeling information has been the multiplicity of serving sizes, including in particular, those used on foods that are sold in obviously single-serving containers.

As a result of its consideration of these comments, the agency tentatively concludes that standardized serving sizes should be established to provide consumers with a more realistic means for making food comparisons. Standard serving sizes facilitate comparison of the nutritional values of foods that are the same types of products and that have similar uses in the diet.

3. **Conclusion:**

Therefore, FDA tentatively concludes that serving sizes should be based on the average level of consumption by the population groups for which the food is intended, be declared in both U.S. and metric measures, and be standardized based on those units.
B. Regulatory Options: FDA identified five possible options for implementing its tentative conclusions on serving sizes. These options were as follows: (1) Maintain the current system in which manufacturers develop their own serving sizes; (2) allow manufacturers to develop their own serving size using criteria and procedures established by FDA; (3) adopt a single uniform serving size for all products, e.g. 100 g (or 100 mL) or 1 oz (28 g); (4) develop standard serving sizes on a food-by-food basis that are derived from nationally representative food consumption surveys to provide a mechanism by which interested parties can add to or amend the standard serving sizes; and (5) use some combination of approaches, e.g., dual labeling of nutrition information based on two different serving size approaches.

The first option, to permit manufacturers to establish their own serving sizes, obviously provides maximum flexibility for the food industry. Most of the food industry comments preferred this approach.

The second option, to permit manufacturers to develop their own serving sizes by applying criteria established by FDA, was FDA's first choice when work began on this proposal. The agency believed that this option would provide flexibility for manufacturers and not be a particular burden for the agency.

FDA has tentatively concluded that it is not possible to develop criteria or detailed enough guidelines to ensure that manufacturers and others using the same databases and same set of instructions would necessarily come up with the same or even similar serving sizes. The third option, to adopt a uniform serving size for all products, e.g., 100g (or 100 mL) or 1 oz (28 g), has the advantage of being simple, straightforward, and easy to develop implement and monitor.

A major disadvantage of this approach is that foods are not necessarily consumed in 100 g or 1 oz quantities, and it does not respond to the strong consumer sentiment expressed to FDA that nutrition information should relate to commonly consumed amounts. Moreover a metric value (100 g), rather than 1 oz., as the basis for standardization would be confusing to many American consumers. Use of 1 oz., on the other hand, would do nothing to facilitate trade.
For all these reasons, FDA has tentatively concluded not to put forward this option. The fourth option, to have FDA develop standard serving sizes with a petition process to provide a mechanism by which interested parties could add to or amend the established serving sizes, is the basic approach incorporated in this document.

FDA is publishing as part of this regulation, proposed standard serving sizes for 159 food product categories (see proposed 101.12 b, Tables 1 and 2). These product categories cover virtually all of the foods reported as being consumed by the U.S. population in the NFCS of 1977 and 1978 (Ref. 10). FDA also has added several serving sizes for newer foods in the marketplace that were not available at the time of that survey.

A major disadvantage of this approach is that serving sizes will differ by type of product, and thus comparison of nutritional value across a broad range of products will be limited.

A fifth option to permit manufacturers to use dual declaration of nutrition information on the basis of both standard serving sizes developed by FDA and a uniform 100 g (or 100 mL) serving, is proposed in this document as an option for manufacturers. Given the large amount of nutrition information proposed for inclusion on the label, the agency has decided not to propose to make this dual declaration mandatory but requests comments on whether it should be made mandatory on some or all foods.

4. The Proposed Regulation:

Introduction: The agency is proposing in (101.9 b) to retain the current requirement that nutrition information in the labeling of food be declared in relation to a serving or, where the food is customarily not consumed directly, in relation to a portion of the food. Likewise, the agency is retaining current (101.9), redesignated as (101.9 b4), which defines standard household measures.
FDA is proposing definitions for the terms "serving" (or "serving size") and "portion" in (101.9 b1). The current definition of "serving size" states that it is "the reasonable quantity of food suited for or practicable of consumption as part of a meal by an adult male engaged in light physical activity, or by an infant or child under 4 years of age when the article supports or is represented to be for consumption by an infant or child under 4 years of age." The agency is proposing to modify the definition in two ways.

First the agency is proposing to define "serving size" as "that amount commonly consumed per eating occasion" by the target population. FDA is proposing in (101.9 b1) to modify the definition of "portion" to state that it is the amount of a food customarily used only as an ingredient in the preparation of "other foods," rather than of "a meal component."

5. Description of Serving Size

A. FDA is proposing in (101.9 b2) that a package containing 150 percent or less of the standard serving size specified in Tables 1 or 2 is a single-serving container. FDA is proposing the cutoff level of 150 percent or less based on a survey conducted by FDA in the Washington, DC area and on FDA's Food Label and Package Survey (Ref. 15).

The agency is also proposing to require that for single-serving containers, the unit of the container, e.g. bar, box, carton, dinner, package, or pouch, be declared as the serving size. Thus, the serving size should be the same as the net weight or volume of the package.

B. FDA is proposing in (101.9 b3) to permit manufacturers to voluntarily declare the serving size in familiar household measures (column 3 in Tables 1 and 2) following the required declaration in U.S. and metric units.
FDA is proposing to adopt a new regulation (101.12) that will provide a set of standardized serving (portion) sizes for 159 food product categories that food manufacturers are to use declaring nutrient content information for their products. These standardized serving sizes, presented in Tables 1 and 2, should not be interpreted as dietary recommendations. Rather, they represent commonly consumed amounts and therefore are reasonable quantities by which consumers can evaluate the nutritional content of a product.

FDA is proposing in (101.12 g) to establish, in addition to the current requirements prescribed in 21 CFR part 10, a procedure whereby interested persons may petition the agency to amend an established serving (portion) size or to establish an appropriate serving (portion) size for a product not covered in proposed (101.12 b).

FDA since 1973, has provided guidelines for deriving nutrition label values that are representative of the range of nutrients in a food. Under the guidelines, the label values are established by statistical analyses of data gathered to account for seasonal effects, growing/harvesting regions, storage, and other variables that affect nutrient content. This procedure together with FDA’s compliance standards in (101.9 e 4 ii) and (e 5) (renumbered as (101.9 g 4 II) and (g 5) in this proposal, which allow up to a 20 percent deviation for naturally occurring nutrients, permits most foods to be represented by a single label value for each nutrient, even those that are quite variable.

The agency believes that single values calculated using this procedure are more informative, and are less confusing, for consumers than are ranges of values, especially where the ranges are large. A single value also permits manufacturers to avoid frequent product analyses and label changes, and it requires that FDA take compliance action only if a label significantly misrepresents the nutrient content of a food. A revised guide, to be entitled "FDA Nutrition Labeling Manual-A Guide for Using Data Bases," will be available by the time a final rule in this proceeding is issued. The revised guide will provide a more comprehensive discussion of procedures for using a data base to develop a nutrition label. It will also discuss some suggested alternatives to current procedures. In the revised guide, the agency will provide for the use of a mean value derived from a satisfactory data base for use in nutrition labeling in conformance with (101.9 g 4 ii). In order to ensure that the data base is adequate for this purpose, a maximum coefficient of variation will be incorporated in the revised guide in addition to other requirements. The coefficient of variation is the standard of deviation (a measure
of variability) expressed as a percentage of the mean. The mean value that may be used should be derived from an acceptable data base that meets the criteria given in detail in the booklet and summarized below:

<table>
<thead>
<tr>
<th>Number of Samples</th>
<th>Maximum Coefficient of variation</th>
</tr>
</thead>
<tbody>
<tr>
<td>5</td>
<td>17</td>
</tr>
<tr>
<td>10</td>
<td>25</td>
</tr>
<tr>
<td>20</td>
<td>31</td>
</tr>
<tr>
<td>30</td>
<td>34</td>
</tr>
<tr>
<td>40</td>
<td>36</td>
</tr>
<tr>
<td>50</td>
<td>37</td>
</tr>
</tbody>
</table>

Thus, if the sampling plan is acceptable to the agency, and the above number of samples are assayed, then, if the coefficient of variation is equal to or less than the maximum coefficient of variation applicable to the number of samples as specified above, the mean value may be used for labeling purposes instead of the calculated value using the agency formula.

FDA has reviewed the written comments received on the serving size proposal, the written comments to the notice of public meeting on serving sizes, and the presentations at the public meeting.
In the 1990 proposal, FDA identified five options for regulating serving sizes: (1) Permit manufacturers to establish their own serving sizes; (2) permit manufacturers to develop their own serving sizes by applying criteria established by FDA; (3) FDA adopt a single, uniform serving size (e.g., 100 g or 100 mL); (4) FDA develop standard serving sizes with a petition process to provide a mechanism to add or amend the established serving sizes; and (5) permit manufacturers to use dual declaration of nutrition information on the basis of both standard serving sizes developed by FDA and a uniform 100 g or 100 mL, (section 2 b 1 B) direct FDA to establish standards to define serving sizes. None of the regulatory options in the 1990 proposal except, the fourth option, the one chosen by FDA, fulfills this legal requirement.

"The term 'serving' or 'serving size' means an amount of food customarily consumed per eating occasion by persons 4 years of age or older which is expressed in a common household measure that is appropriate to the food."

Because many single-serving packages exceed the proposed 150 percent level, the agency believes that it is not appropriate to lower the cutoff level for the definition of a single-serving container. Rather, in light of the evidence of the trend to larger packages, the agency believes that it is more appropriate to increase the upper limit to "less than 200 percent." This higher level, if adopted, will require that more small packages be labeled as a single-serving.

Therefore, in (101.9 b 6) of this proposal, FDA is proposing to require that manufacturers declare that there is a single-serving in a container or package that contains less than 200 percent of the reference amount proposed in (101.12 b), and that they declare nutrition information based on the total content of the container.
### Standard Serving Sizes

#### Product Category

<table>
<thead>
<tr>
<th>Dairy products and substitutes:</th>
<th>Label Statement</th>
<th>Standard</th>
<th>Voluntary Household Measures</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cheese, cottage or ricotta</td>
<td>4 oz</td>
<td>4 oz. (112 g)</td>
<td>Cup(s).</td>
</tr>
<tr>
<td>Cheese, grated hard, e.g., parmesan</td>
<td>1/3 oz</td>
<td>1/3 oz. (9 g)</td>
<td>Tbsp(s).</td>
</tr>
<tr>
<td>Cheese, all others except those listed as separate categories— includes cream cheese and cheese spread.</td>
<td>1 oz</td>
<td>1 oz. (28 g)</td>
<td>Piece(s) for distinct pieces (e.g., slices, cubes) or tbsp(s).</td>
</tr>
<tr>
<td>Cheese sauce</td>
<td>1/4 cup</td>
<td>1/4 cup (15 g)</td>
<td>Cup(s).</td>
</tr>
<tr>
<td>Cocoa</td>
<td>8 fl oz</td>
<td>8 fl oz. (240 mL)</td>
<td></td>
</tr>
<tr>
<td>Cream or cream substitute, fluid</td>
<td>2 tbsp</td>
<td>2 tbsp. (30 mL)</td>
<td></td>
</tr>
<tr>
<td>Cream or cream substitute, powder</td>
<td>2 tsp</td>
<td>2 tsp (15 g)</td>
<td></td>
</tr>
<tr>
<td>Cream, half and half</td>
<td>2 tbsp</td>
<td>2 tbsp. (30 mL)</td>
<td></td>
</tr>
<tr>
<td>Milk, condensed, undiluted</td>
<td>3 tbsp</td>
<td>3 tbsp. (45 mL)</td>
<td></td>
</tr>
<tr>
<td>Milk, evaporated, undiluted</td>
<td>1 tbsp</td>
<td>1 tbsp. (15 mL)</td>
<td></td>
</tr>
<tr>
<td>Milk, eggnog, milk-based drinks, e.g., instant breakfast, meal replacement.</td>
<td>8 fl oz</td>
<td>8 fl oz. (240 mL)</td>
<td>Cup(s).</td>
</tr>
<tr>
<td>Milk shake</td>
<td>12 fl oz</td>
<td>12 fl oz. (360 mL)</td>
<td></td>
</tr>
<tr>
<td>Sour cream or dairy-based dips</td>
<td>2 tbsp</td>
<td>2 tbsp. (45 g)</td>
<td></td>
</tr>
<tr>
<td>Yogurt</td>
<td>8 oz</td>
<td>8 oz. (224 g)</td>
<td></td>
</tr>
<tr>
<td>Desserts:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ice cream, ice milk, frozen yogurt, sherbert</td>
<td>6 fl oz</td>
<td>6 fl oz (15 g)</td>
<td>Piece(s) for individually wrapped or packaged products and cup(s) for others.</td>
</tr>
<tr>
<td>Sundae</td>
<td>1 cup</td>
<td>1 cup (45 g)</td>
<td></td>
</tr>
<tr>
<td>Custard, gelatin or pudding</td>
<td>1/2 cup</td>
<td>1/2 cup (20 g)</td>
<td></td>
</tr>
</tbody>
</table>
that is based on their use in the form purchased:

(5) Serving size should be based on the major intended use of the food (e.g.,
milk as a beverage and not as an addition to cereal); and

(6) Foods that have similar dietary usage and product characteristics that affect consumption should be grouped together (e.g., all chips and similar snacks).

(b) The following standard serving (portion) sizes shall be used for food labeling:

**TABLE 1.—STANDARD SERVING SIZES: INFANT AND TODDLER FOODS**

<table>
<thead>
<tr>
<th>Product category</th>
<th>Standard serving size</th>
<th>Label statement</th>
<th>Voluntary household measures</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>(1)</td>
<td>(2)</td>
<td>(3)</td>
</tr>
<tr>
<td>Cereal, dry instant</td>
<td>1 ounce (oz.)</td>
<td>1 oz. (14 g)</td>
<td>Tablespoon (tbsp(s)) or cup(s)</td>
</tr>
<tr>
<td>Cereal, prepared</td>
<td>4 oz.</td>
<td>4 oz. (112 g)</td>
<td>Jar.</td>
</tr>
<tr>
<td>Cottage cheese</td>
<td>3 oz.</td>
<td>3 oz. (84 g)</td>
<td>Jar.</td>
</tr>
<tr>
<td>Dinner, dessert, fruit, vegetable or soup, dry mix</td>
<td>1/4 oz.</td>
<td>1/4 oz. (7 g)</td>
<td>Jar.</td>
</tr>
<tr>
<td>Dinner, dessert, fruit, vegetable or soup, junior type</td>
<td>4 oz.</td>
<td>4 oz. (112 g)</td>
<td>Jar.</td>
</tr>
<tr>
<td>Dinner, dessert, fruit, vegetable or soup, strained type</td>
<td>3 oz.</td>
<td>3 oz. (84 g)</td>
<td>Jar.</td>
</tr>
<tr>
<td>Dinner, fruit, vegetable, stew or soup for toddlers</td>
<td>6 oz.</td>
<td>6 oz. (168 g)</td>
<td>Jar.</td>
</tr>
<tr>
<td>Egg/egg yolk</td>
<td>2 oz.</td>
<td>2 oz. (56 g)</td>
<td>Jar.</td>
</tr>
<tr>
<td>Juice, all varieties</td>
<td>4 fluid (fl) oz.</td>
<td>4 fl oz. (120 milliliters) (mL)</td>
<td>Jar.</td>
</tr>
</tbody>
</table>

1 Unless otherwise noted in the product category name, serving sizes are for the ready-to-serve (RTS) or almost ready-to-serve form of the product (e.g., heat and serve and brown and serve). If not listed separately, serving size for the unprepared form (e.g., dry cereal) is the amount required to make one serving of the prepared form.

2 Standard serving size established by the Food and Drug Administration (FDA). These values have been derived primarily from the amount of food commonly consumed per eating occasion as reported in the 1977-1978 Nationwide Food Consumption Survey conducted by the U.S. Department of Agriculture.

**TABLE 2.—STANDARD SERVING SIZES: GENERAL FOOD SUPPLY**

<table>
<thead>
<tr>
<th>Product category</th>
<th>Standard serving size</th>
<th>Label statement</th>
<th>Voluntary household measures</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>(1)</td>
<td>(2)</td>
<td>(3)</td>
</tr>
<tr>
<td>Bakery Products</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bread sticks</td>
<td>1 oz.</td>
<td>1 oz. (28 g)</td>
<td>Piece(s)</td>
</tr>
<tr>
<td>Bread (excluding sweet quick type), biscuits, rolls, crossants, muffins, bagels, toaster pastries</td>
<td>2 oz.</td>
<td>2 oz. (56 g)</td>
<td>Piece(s)</td>
</tr>
<tr>
<td>Brownies</td>
<td>2 oz.</td>
<td>2 oz. (56 g)</td>
<td>Piece(s)</td>
</tr>
<tr>
<td>Cake without icing, all varieties except cheese cake</td>
<td>3 oz.</td>
<td>3 oz. (56 g)</td>
<td>Piece(s)</td>
</tr>
<tr>
<td>Cake without icing, all varieties except cheese cake</td>
<td>2 oz.</td>
<td>2 oz. (56 g)</td>
<td>Piece(s)</td>
</tr>
<tr>
<td>Cheese cake</td>
<td>4 oz.</td>
<td>4 oz. (112 g)</td>
<td>Piece(s)</td>
</tr>
<tr>
<td>Coffee cakes, doughnuts, Danish, sweet rolls, sweet quick type breads</td>
<td>3 oz.</td>
<td>3 oz. (70 g)</td>
<td>Piece(s)</td>
</tr>
<tr>
<td>Cookies, graham crackers, or sandwich type crackers</td>
<td>1 oz.</td>
<td>1 oz. (28 g)</td>
<td>Piece(s)</td>
</tr>
<tr>
<td>Crackers, all varieties excluding graham and sandwich type</td>
<td>1 oz.</td>
<td>1 oz. (28 g)</td>
<td>Piece(s)</td>
</tr>
<tr>
<td>Croissants</td>
<td>1 oz.</td>
<td>1 oz. (28 g)</td>
<td>Piece(s)</td>
</tr>
<tr>
<td>French toast, pancakes</td>
<td>4 oz.</td>
<td>4 oz. (112 g)</td>
<td>Piece(s)</td>
</tr>
<tr>
<td>Pie crust</td>
<td>1/2 oz.</td>
<td>1/2 oz. (42 g)</td>
<td>Piece(s)</td>
</tr>
<tr>
<td>Taco shells</td>
<td>1 oz.</td>
<td>1 oz. (28 g)</td>
<td>Shell</td>
</tr>
<tr>
<td>Waffles</td>
<td>3 oz.</td>
<td>3 oz. (84 g)</td>
<td>Piece(s)</td>
</tr>
<tr>
<td>Beverages</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Carbonated and noncarbonated drinks including fruit drinks, wine cooler and mineral water</td>
<td>12 fl oz</td>
<td>12 fl oz (360 mL)</td>
<td>Cup(s)</td>
</tr>
<tr>
<td>Coffee or tea, prepared</td>
<td>8 fl oz.</td>
<td>8 fl oz (240 mL)</td>
<td>Cup(s)</td>
</tr>
<tr>
<td>Coffee, ground, dry</td>
<td>2 tbsp</td>
<td>2 tbsp (g)</td>
<td>Cup(s)</td>
</tr>
<tr>
<td>Coffee, instant, dry, or tea, instant or leaf, dry</td>
<td>2 tbsp</td>
<td>2 tbsp (g)</td>
<td>Cup(s)</td>
</tr>
<tr>
<td>Ice tea, prepared</td>
<td>12 fl oz.</td>
<td>12 fl oz (360 mL)</td>
<td>Cup(s)</td>
</tr>
<tr>
<td>Cereals and other grain products</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Breakfast cereals, ready to eat (weight - 1 oz per cup)</td>
<td>11 oz.</td>
<td>1 oz (42 g)</td>
<td>Tbsp(s) or Cup(s)</td>
</tr>
<tr>
<td>Breakfast cereals, ready to eat (weight - 1 oz but less than 2 oz per cup)</td>
<td>1 oz.</td>
<td>1 oz (28 g)</td>
<td>Cup(s) or Biscuit type</td>
</tr>
<tr>
<td>Breakfast cereals, ready to eat (weight - 2 oz but less than 3 oz per cup)</td>
<td>1 oz.</td>
<td>1 oz (28 g)</td>
<td>Cup(s) or Biscuit type</td>
</tr>
<tr>
<td>Breakfast cereals, ready to eat (weight - 2 oz but less than 3 oz per cup)</td>
<td>2 oz.</td>
<td>2 oz (56 g)</td>
<td>Cup(s) or Biscuit type</td>
</tr>
</tbody>
</table>
### Table 2.—Standard Serving Sizes.1 GENERAL FOOD SUPPLY—Continued

<table>
<thead>
<tr>
<th>Product category</th>
<th>Standard serving size</th>
<th>Label statement</th>
<th>Voluntary household measures</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Breakfast cereals, ready to eat (weigh &gt;3 oz. per cup)</strong></td>
<td>3 oz</td>
<td>3 oz (84 g)</td>
<td>Cup(s) or Piece(s) for large distinct pieces (e.g., biscuit type).</td>
</tr>
<tr>
<td>Cornflakes</td>
<td>1 tbsp</td>
<td>1 tbsp (14 g)</td>
<td>Tbsp(s) or cup(s).</td>
</tr>
<tr>
<td>Flours or cornmeal</td>
<td>1 oz</td>
<td>1 oz (28 g)</td>
<td>Tbsp(s).</td>
</tr>
<tr>
<td>Bran or wheat germ</td>
<td>1/2 oz</td>
<td>1/2 oz (14 g)</td>
<td>Cup(s).</td>
</tr>
<tr>
<td>Grains, e.g., rice, barley, dry</td>
<td>2 oz</td>
<td>2 oz (56 g)</td>
<td>Piecels(s).</td>
</tr>
<tr>
<td>Grains, e.g., rice, barley, prepared</td>
<td>1 cup</td>
<td>1 cup (8 oz)</td>
<td>Cup(s).</td>
</tr>
<tr>
<td>Hush puppies</td>
<td>2 oz</td>
<td>2 oz (56 g)</td>
<td>Cup(s).</td>
</tr>
<tr>
<td>Pastas, dry</td>
<td>3 oz</td>
<td>3 oz (84 g)</td>
<td>Cup(s).</td>
</tr>
<tr>
<td>Pastas, prepared</td>
<td>5 oz</td>
<td>5 oz (140 g)</td>
<td>Cup(s).</td>
</tr>
<tr>
<td>Pastas, dry, ready to eat, e.g., fried, canned chow mein noodles</td>
<td>1 oz</td>
<td>1 oz (28 g)</td>
<td>Cup(s).</td>
</tr>
<tr>
<td>Stuffings</td>
<td>1/4 cup</td>
<td>1/4 cup (5 g)</td>
<td></td>
</tr>
<tr>
<td><strong>Dairy products and substitutes:</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cheese, cottage or ricotta</td>
<td>4 oz</td>
<td>4 oz (112 g)</td>
<td>Cup(s).</td>
</tr>
<tr>
<td>Cheese, grated hard, e.g., parmesan</td>
<td>1 oz</td>
<td>1 oz (28 g)</td>
<td>Tbsp(s).</td>
</tr>
<tr>
<td>Cheese, all others except those listed as separate categories—includes cream cheese and cheese spread.</td>
<td></td>
<td></td>
<td>Tbsp(s).</td>
</tr>
<tr>
<td>Cheese sauce</td>
<td>1/4 cup</td>
<td>1/4 cup (5 g)</td>
<td>Cup(s).</td>
</tr>
<tr>
<td>Cocoa</td>
<td>8 fl oz</td>
<td>8 fl oz (240 ml)</td>
<td>Cup(s).</td>
</tr>
<tr>
<td>Cream or cream substitute, fluid</td>
<td>2 tbsp</td>
<td>2 tbsp (30 ml)</td>
<td>Cup(s).</td>
</tr>
<tr>
<td>Cream or cream substitute, powder</td>
<td>2 tsp</td>
<td>2 tsp</td>
<td>Tbsp(s).</td>
</tr>
<tr>
<td>Cream, half and half</td>
<td>2 tbsp</td>
<td>2 tbsp</td>
<td>Tbsp(s).</td>
</tr>
<tr>
<td>Milk, condensed, undiluted</td>
<td>3 tbsp</td>
<td>3 tbsp (45 ml)</td>
<td>Cup(s).</td>
</tr>
<tr>
<td>Milk, evaporated, undiluted</td>
<td>1 tbsp</td>
<td>1 tbsp (15 ml)</td>
<td>Cup(s).</td>
</tr>
<tr>
<td>Milk, eggnog, milk-based drinks, e.g., instant breakfast, meal replacement</td>
<td>8 fl oz</td>
<td>8 fl oz (240 ml)</td>
<td>Cup(s).</td>
</tr>
<tr>
<td>Milk shake</td>
<td>12 fl oz</td>
<td>12 fl oz (350 ml)</td>
<td>Cup(s).</td>
</tr>
<tr>
<td>Sour cream or dairy-based dips</td>
<td>2 tbsp</td>
<td>2 tbsp (1 oz)</td>
<td>Cup(s).</td>
</tr>
<tr>
<td>Yogurt</td>
<td>8 oz</td>
<td>8 oz (224 g)</td>
<td>Cup(s).</td>
</tr>
<tr>
<td><strong>Desserts:</strong></td>
<td></td>
<td></td>
<td>Cup(s).</td>
</tr>
<tr>
<td>Ice cream, ice milk, frozen yogurt, sherbert</td>
<td>6 fl oz</td>
<td>6 fl oz (170 g)</td>
<td>Piecels(s) for individually wrapped or packaged products and Cup(s) for others</td>
</tr>
<tr>
<td>Sundae</td>
<td>1 cup</td>
<td>1 cup (8 oz)</td>
<td>Piecels(s) for individually wrapped or packaged products and Cup(s) for others</td>
</tr>
<tr>
<td>Custard, gelatin or pudding</td>
<td>1 cup</td>
<td>1 cup (8 oz)</td>
<td></td>
</tr>
<tr>
<td>Custard toppings and fillings</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cake frosting or icing</td>
<td>3 tbsp</td>
<td>3 tbsp (1 oz)</td>
<td></td>
</tr>
<tr>
<td>Dessert toppings, fruits and syrups</td>
<td>2 tbsp</td>
<td>2 tbsp (1 oz)</td>
<td></td>
</tr>
<tr>
<td>Dessert toppings, nuts and sprinkles</td>
<td>1 tbsp</td>
<td>1 tbsp (1 oz)</td>
<td></td>
</tr>
<tr>
<td>Pie filling</td>
<td>3 oz</td>
<td>3 oz (84 g)</td>
<td></td>
</tr>
<tr>
<td>Whipped toppings, dairy and nondairy products</td>
<td>2 tbsp</td>
<td>2 tbsp (1 oz)</td>
<td></td>
</tr>
<tr>
<td>Egg and egg substitutes</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Egg mixture, e.g., Egg Foo Young</td>
<td>3 1/2 oz</td>
<td>3 1/2 oz (98 g)</td>
<td></td>
</tr>
<tr>
<td>Egg (all sizes)</td>
<td>2 oz</td>
<td>2 oz (56 g)</td>
<td></td>
</tr>
<tr>
<td>Egg substitutes</td>
<td>4 oz</td>
<td>4 oz (112 g)</td>
<td></td>
</tr>
<tr>
<td>Omelet or scrambled egg</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fats and oils</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Butter, margarine, oil, lard, shortening</td>
<td>1 tbsp</td>
<td>1 tbsp (1 oz)</td>
<td></td>
</tr>
<tr>
<td>Mayonnaise, sandwich spread, mayonnaise type dressing</td>
<td>2 tbsp</td>
<td>2 tbsp (1 oz)</td>
<td></td>
</tr>
<tr>
<td>Dressings for salads</td>
<td>2 tbsp</td>
<td>2 tbsp (1 oz)</td>
<td></td>
</tr>
<tr>
<td>Fish, shellfish, and meat, or poultry substitutes</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Anchovies and caviar</td>
<td>1 oz</td>
<td>1 oz (28 g)</td>
<td></td>
</tr>
<tr>
<td>Dried, e.g., jerk</td>
<td>1 oz</td>
<td>1 oz (28 g)</td>
<td></td>
</tr>
<tr>
<td>Entrees (cooked) with sauce</td>
<td>5 oz</td>
<td>5 oz (140 g)</td>
<td></td>
</tr>
<tr>
<td>Entrees (cooked) without sauce</td>
<td>4 oz</td>
<td>4 oz (112 g)</td>
<td></td>
</tr>
<tr>
<td>Fish and shellfish, canned</td>
<td>3 oz</td>
<td>3 oz (84 g)</td>
<td></td>
</tr>
<tr>
<td>Substitute for bacon</td>
<td>1 oz</td>
<td>1 oz (28 g)</td>
<td></td>
</tr>
<tr>
<td>Substitutes for luncheon meat, sandwich spread, Canadian bacon, sausage and frankfurter</td>
<td>2 oz</td>
<td>2 oz (56 g)</td>
<td></td>
</tr>
<tr>
<td>Smoked or pickled fish or shellfish</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Used as toppings, e.g., substitutes for bacon bits</td>
<td>1 oz</td>
<td>1 oz (28 g)</td>
<td></td>
</tr>
<tr>
<td>Fruits and fruit juice</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Canned or pickled</td>
<td>1 oz</td>
<td>1 oz (28 g)</td>
<td></td>
</tr>
<tr>
<td>Dehydrated/freeze-dried</td>
<td>2 oz</td>
<td>2 oz (56 g)</td>
<td></td>
</tr>
<tr>
<td>Dried</td>
<td>1 oz</td>
<td>1 oz (28 g)</td>
<td></td>
</tr>
<tr>
<td>Fruit sauce or relish, e.g., cranberry sauce or relish</td>
<td>3 oz</td>
<td>3 oz (84 g)</td>
<td></td>
</tr>
<tr>
<td>Fruit jellies or flavors, e.g., maraschino cherries, lemon lime</td>
<td>3 oz</td>
<td>3 oz (84 g)</td>
<td></td>
</tr>
<tr>
<td>Fruits used primarily as condiments, e.g., cranberries</td>
<td>1 oz</td>
<td>1 oz (28 g)</td>
<td></td>
</tr>
<tr>
<td>All other fruits, fresh, weighing 50 percent but . . . 150 percent of the standard serving size per piece</td>
<td>3 oz</td>
<td>3 oz (84 g)</td>
<td></td>
</tr>
</tbody>
</table>

1. Including examples of specific food products and their serving sizes, as well as general guidelines for labeling and household measures.
### Table 2.—Standard Serving Sizes.¹ General Food Supply—Continued

<table>
<thead>
<tr>
<th>Product category</th>
<th>Standard serving size</th>
<th>Label statement</th>
<th>Voluntary household measures</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>(1)</td>
<td>(2)</td>
<td></td>
</tr>
<tr>
<td>All other fruits, fresh, weighing &lt; 50 percent of the standard serving size per piece.</td>
<td>5 oz</td>
<td>5 oz (g)</td>
<td>10 oz (g)</td>
</tr>
<tr>
<td>All other fruits, fresh, weighing &gt; 150 percent of the standard serving size per piece.</td>
<td>5 oz</td>
<td>5 oz (g)</td>
<td>10 oz (g)</td>
</tr>
<tr>
<td>Juice or nectar</td>
<td>5 oz</td>
<td>5 oz (g)</td>
<td>10 oz (g)</td>
</tr>
<tr>
<td>Juice used as ingredients, e.g., lemon juice</td>
<td>1 tbsp</td>
<td>1 tbsp (15 mL)</td>
<td>1 oz</td>
</tr>
<tr>
<td>Watermelon</td>
<td>12 oz</td>
<td>12 oz (506 g)</td>
<td>1 cup</td>
</tr>
<tr>
<td>Legumes</td>
<td>Bean cake (bolu)</td>
<td>4 oz</td>
<td>4 oz (112 g)</td>
</tr>
<tr>
<td></td>
<td>Dry</td>
<td>2½ oz</td>
<td>2½ oz (70 g)</td>
</tr>
<tr>
<td>Prepared, plan or in sauce</td>
<td>6 oz</td>
<td>6 oz (168 g)</td>
<td>1 cup</td>
</tr>
<tr>
<td>Meal type trays.⁴</td>
<td>Breakfast trays, all varieties</td>
<td>4 oz</td>
<td>4 oz (112 g)</td>
</tr>
<tr>
<td></td>
<td>Lunch or dinner trays</td>
<td>5 oz</td>
<td>5 oz (142 g)</td>
</tr>
<tr>
<td>Cracker and cheese trays:</td>
<td>Extra helping type</td>
<td>5 oz</td>
<td>5 oz (142 g)</td>
</tr>
<tr>
<td></td>
<td>Trays for children</td>
<td>8 oz</td>
<td>8 oz (224 g)</td>
</tr>
<tr>
<td></td>
<td>Trays containing 2 items</td>
<td>8 oz</td>
<td>8 oz (224 g)</td>
</tr>
<tr>
<td></td>
<td>Trays containing 3 or 4 items</td>
<td>11 oz</td>
<td>11 oz (312 g)</td>
</tr>
<tr>
<td></td>
<td>Salad plate served as a meal</td>
<td>8 oz</td>
<td>8 oz (224 g)</td>
</tr>
<tr>
<td></td>
<td>Sandwich</td>
<td>5 oz</td>
<td>5 oz (142 g)</td>
</tr>
<tr>
<td></td>
<td>Sandwich and soup</td>
<td>11 oz</td>
<td>11 oz (312 g)</td>
</tr>
<tr>
<td>Miscellaneous products:</td>
<td>Batter mixes, bread crumbs, meat, poultry, fish coating mixes, dry</td>
<td>1 oz</td>
<td>1 oz (28 g)</td>
</tr>
<tr>
<td></td>
<td>Salt, seasoning salt (e.g., garlic salt)</td>
<td>1 g</td>
<td>1 g</td>
</tr>
<tr>
<td>Mixed dishes:</td>
<td>Appetizers, not measurable with cup, e.g., egg roll, pizza roll</td>
<td>6 oz</td>
<td>6 oz (168 g)</td>
</tr>
<tr>
<td></td>
<td>Appetizers and cocktails in sauce, measurable with cup, e.g., shrimp cocktail</td>
<td>1 cup</td>
<td>1 cup (g)</td>
</tr>
<tr>
<td></td>
<td>Entrée type, measurable with cup, e.g., stew, spaghetti, macaroni and cheese, pot pie, etc.</td>
<td>3 oz</td>
<td>3 oz (84 g)</td>
</tr>
<tr>
<td></td>
<td>Entrée type, not measurable with cup, e.g., goulash, quiche, etc.</td>
<td>6 oz</td>
<td>6 oz (168 g)</td>
</tr>
<tr>
<td></td>
<td>Oriental noodle soup based on dry</td>
<td>3 oz</td>
<td>3 oz (84 g)</td>
</tr>
<tr>
<td></td>
<td>Nuts and seeds: Nut, seed, and mixtures</td>
<td>1 oz</td>
<td>1 oz (28 g)</td>
</tr>
<tr>
<td></td>
<td>Nut and seed butter or paste</td>
<td>2 tbsp</td>
<td>2 tbsp (40 g)</td>
</tr>
<tr>
<td></td>
<td>Used primarily as ingredient, e.g., coconut, nut, and seed flour, etc.</td>
<td>1 oz</td>
<td>1 oz (28 g)</td>
</tr>
<tr>
<td></td>
<td>Potato chips and sweet potatoes</td>
<td>3 oz</td>
<td>3 oz (84 g)</td>
</tr>
<tr>
<td></td>
<td>French fries, hash browns, skins, stuffed or pancake</td>
<td>6 oz</td>
<td>6 oz (168 g)</td>
</tr>
<tr>
<td></td>
<td>Mashed, canned or with sauce</td>
<td>6 oz</td>
<td>6 oz (168 g)</td>
</tr>
<tr>
<td></td>
<td>Plan, fresh, frozen, canned, or cooked</td>
<td>4 oz</td>
<td>4 oz (112 g)</td>
</tr>
<tr>
<td>Salads (For salads served as a meal, see meal type trays.)</td>
<td>Egg, Fish or shellfish salad</td>
<td>3 oz</td>
<td>3 oz (91 g)</td>
</tr>
<tr>
<td></td>
<td>Fruit or pasta salad</td>
<td>5 oz</td>
<td>5 oz (142 g)</td>
</tr>
<tr>
<td></td>
<td>Potato salad</td>
<td>6 oz</td>
<td>6 oz (168 g)</td>
</tr>
<tr>
<td></td>
<td>Vegetable salad</td>
<td>3 oz</td>
<td>3 oz (84 g)</td>
</tr>
<tr>
<td>Sauces, gravies, and condiments:</td>
<td>Barbecue sauce, hollandaise sauce, tartar sauce, mannade</td>
<td>2 tbsp</td>
<td>2 tbsp (34 g)</td>
</tr>
<tr>
<td></td>
<td>Main entrée type sauce, e.g., spaghetti, creole, newburg, a la king, sweet and sour, etc.</td>
<td>1 cup</td>
<td>1 cup (g)</td>
</tr>
<tr>
<td></td>
<td>Used as condiments, e.g., catsup, mustard, steak sauce, salsa, etc.</td>
<td>1 tbsp</td>
<td>1 tbsp (16 g)</td>
</tr>
<tr>
<td></td>
<td>Used as topping, e.g., gravy, white sauce, cocktail sauce, etc</td>
<td>1 cup</td>
<td>1 cup (g)</td>
</tr>
<tr>
<td>Snacks</td>
<td>Chips, pretzels, extruded snacks</td>
<td>1 oz</td>
<td>1 oz (28 g)</td>
</tr>
<tr>
<td></td>
<td>Fruit-based snacks, e.g., fruit roll-ups, fruit winks, etc.</td>
<td>1 oz</td>
<td>1 oz (28 g)</td>
</tr>
<tr>
<td></td>
<td>Gram-breaded snack mix without nuts or fruits</td>
<td>1 oz</td>
<td>1 oz (28 g)</td>
</tr>
<tr>
<td></td>
<td>Gram-breaded snack mix with nuts and/or fruits</td>
<td>1 oz</td>
<td>1 oz (28 g)</td>
</tr>
<tr>
<td></td>
<td>Popcorn, popped or unpopped</td>
<td>1 oz</td>
<td>1 oz (28 g)</td>
</tr>
<tr>
<td>Sodas</td>
<td>All varieties</td>
<td>1 cup</td>
<td>1 cup (g)</td>
</tr>
<tr>
<td>Sugars and Syrups</td>
<td>Baking candies chips, etc</td>
<td>1 oz</td>
<td>1 oz (28 g)</td>
</tr>
<tr>
<td></td>
<td>Candies</td>
<td>1 oz</td>
<td>1 oz (28 g)</td>
</tr>
<tr>
<td></td>
<td>Confectioners' sugar</td>
<td>1 oz</td>
<td>1 oz (28 g)</td>
</tr>
<tr>
<td></td>
<td>Honey, jam, jelly</td>
<td>1 tbsp</td>
<td>1 tbsp (14 g)</td>
</tr>
<tr>
<td></td>
<td>Marshmallows</td>
<td>1 oz</td>
<td>1 oz (28 g)</td>
</tr>
<tr>
<td></td>
<td>Popcorn, snow cones</td>
<td>2 oz</td>
<td>2 oz (56 g)</td>
</tr>
<tr>
<td></td>
<td>Sugar</td>
<td>2 tbsp</td>
<td>2 tbsp (34 g)</td>
</tr>
<tr>
<td></td>
<td>Molasses</td>
<td>2 tbsp</td>
<td>2 tbsp (34 g)</td>
</tr>
<tr>
<td></td>
<td>Syrups</td>
<td>1 cup</td>
<td>1 cup (g)</td>
</tr>
<tr>
<td>Vegetables</td>
<td>Corn kernels</td>
<td>3 oz</td>
<td>3 oz (84 g)</td>
</tr>
<tr>
<td></td>
<td>Dehydrated or freeze dried</td>
<td>1 oz</td>
<td>1 oz (28 g)</td>
</tr>
<tr>
<td></td>
<td>Dried</td>
<td>1 oz</td>
<td>1 oz (28 g)</td>
</tr>
<tr>
<td>Product category</td>
<td>Standard serving size</td>
<td>Label statement</td>
<td>Voluntary household measures</td>
</tr>
<tr>
<td>------------------</td>
<td>-----------------------</td>
<td>----------------</td>
<td>-----------------------------</td>
</tr>
<tr>
<td>Fruit &amp; vegetable pastes</td>
<td>2 oz</td>
<td>2 oz (56 g)</td>
<td>Piece(s) or cup(s)</td>
</tr>
<tr>
<td>Pickles, relish</td>
<td>1 oz</td>
<td>1 oz (28 g)</td>
<td>Piece(s)</td>
</tr>
<tr>
<td>Vegetable plasie, e.g., tomato paste</td>
<td>3 oz</td>
<td>3 oz (84 g)</td>
<td>Piece(s)</td>
</tr>
<tr>
<td>Juice</td>
<td>6 fl oz</td>
<td>6 fl oz (180 mL)</td>
<td>Piece(s)</td>
</tr>
<tr>
<td>Olives</td>
<td>1/2 oz</td>
<td>1/2 oz (14 g)</td>
<td>Piece(s) for distinct pieces (e.g., gerkons)</td>
</tr>
<tr>
<td>Pickles, other than dill, sour, or relish</td>
<td>1 oz</td>
<td>1 oz (28 g)</td>
<td>Tbsp(s)</td>
</tr>
<tr>
<td>Vegetable sauce or puree, e.g., tomato sauce, tomato puree</td>
<td>3 oz</td>
<td>3 oz (84 g)</td>
<td>Cup(s)</td>
</tr>
</tbody>
</table>

1 Unless otherwise noted in the product category name, serving sizes are for the ready-to-serve or almost ready-to-serve form of the product (e.g., heat and serve and brown and serve). If not listed separately, serving size for the unprepared form (e.g., dry mixes, concentrates, dough, batter, raw fish and shellfish) is the amount required to make one serving of the prepared form.

2 Standard serving size established by FDA. These values have been derived primarily from the amount of food commonly consumed per eating occasion as reported in the 1977-1978 Nationwide Food Consumption Survey conducted by the U.S. Department of Agriculture.

3 In expressing the serving size on the product label, manufacturers shall first declare the standard serving size followed by the equivalent metric quantity in parentheses. Where metric quantity is left blank, manufacturers shall fill in the blank with the metric quantity specific for their product equivalent to the standard serving size specified by FDA. For unprepared products (e.g., dry mixes, concentrates, dough, raw fish), manufacturers shall provide the quantity of the unprepared product required to make one standard serving of the prepared product in (for fl oz) followed by the corresponding metric quantity in parentheses, e.g., 1 1/2 oz of milk (42 g).

4 This column lists other household measures that may be provided by the manufacturer to express the serving size in easily visualized units for the specified product. For example, for sliced bread manufacturers may provide the number of slices that is the nearest equivalent (in half slices) to 2 oz. The unit “piece” should be expressed in units of the piece descriptive of the product, e.g., slice, roll, cookie, muffin, bar, stick or a fraction such as 1/2 pizza.

5 These products are considered to be single-serving products and thus nutrition information shall be provided per piece followed by the metric quantity of an edible portion in parentheses, e.g., one large egg (50 g), one apple (140 g).

6 These products come in single-serving containers (see the definition of single-serving containers in §101.3(b)(2)) and thus nutrition information shall be provide per container followed by the metric quantity of the net content of the container in parentheses, e.g., one dinner (310 g), one sandwich (120 g), or one tray (150 g).

7 When these vegetables have been processed or prepared or otherwise offered for use as vegetable dishes, e.g., onion rings, sautéed mushrooms, or stewed tomatoes, serving size shall be the same as that of the vegetable dish, i.e., 3 1/2 oz for a vegetable dish without sauce and 4 1/2 oz for a vegetable dish with sauce.
The intent of the Nutrition Labeling and Education Act is to improve food labels by providing the consumer more relevant nutrition information. This information presumably will be utilized to make food selections which will improve the nation's nutrient status. This discussion will be limited to the nutrients proposed to be included on the food labels and labeling of nutrient supplements.

**FDA's Proposed Rules:** November 6, 1991

Federal Register V. 56 No. 229, November 27, 1991

Must be finalized November 8, 1992

May 1993 Compliance

**Mandatory Labeling**

Processed foods including:
- Fresh/frozen seafood (packaged)
- Meat and poultry (USDA)

Nutrition information:
- "As packaged"
- "As consumed" (maybe included)

**Voluntary Labeling**

Fresh produce: "As packaged"
Seafood, unpackaged or packaged at retail: "As consumed"

Information on large placards, brochures, pamphlets, videos

For 20 most frequently consumed raw fruits
For 20 most frequently consumed raw vegetables
For 20 most frequently consumed raw fish
Mandatory Nutrients

Calories
Calories from total fat
Total fat (grams)
Saturated fat (grams)
Cholesterol (milligrams)
Total carbohydrates (grams, excludes dietary fiber)
Complex carbohydrate (grams)
Sugars (grams)
Dietary fiber (grams)
Protein (grams)
Sodium (milligrams)
Vitamin A (percent of daily value)
Vitamin C (percent of daily value)
Calcium (percent of daily value)
Iron (percent of daily value)

Voluntary Nutrients
(unless claims are made about the nutrient)

Calories from saturated and unsaturated fat, total carbohydrates, protein
Unsaturated fat or amount of polyunsaturated and monounsaturated fats (grams) - (unless claim is made about fatty acid or cholesterol content)
Insoluble and soluble fiber
Protein as percent of RDI for foods other than infant foods
Potassium (milligrams)
Thiamine, riboflavin, niacin, and other vitamins and minerals as percent of RDI (unless added as a supplement)

Nutrition Profiles

RDI - Reference Daily Intakes
(protein, 26 vitamins and minerals)
DRV - Daily Reference Values
(fat, cholesterol, fiber, sodium, carbohydrate, potassium)

Under the heading "Nutrition Profile" percent of Daily Values must appear; daily values represent RDIs and DRVs
RDA's = nutrient levels for 14 sex/age groups
(Recommended Dietary Allowances)

USRDA's = maximum amounts
(U.S. Recommended Daily Allowances)

RDI's = average amounts
(Reference Daily Intakes)

EXAMPLE:

RDA for iron = 15 mg
RDI for iron = 12 mg
USRDA for iron = 18 mg

THE PROPOSED NUTRITION LABEL OF TOMORROW

<table>
<thead>
<tr>
<th>Calories</th>
<th>Dietary fiber (grams)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Calories from total fat</td>
<td>Protein (grams)</td>
</tr>
<tr>
<td>Total fat (grams)</td>
<td>Sodium (milligrams)</td>
</tr>
<tr>
<td>Saturated fat (grams)</td>
<td>Vitamin A (% of Daily Value)</td>
</tr>
<tr>
<td>Cholesterol (milligrams)</td>
<td>Vitamin C (% of Daily Value)</td>
</tr>
<tr>
<td>Total carbohydrates (grams)</td>
<td>Calcium (% of Daily Value)</td>
</tr>
<tr>
<td>Complex carbohydrate (grams)</td>
<td>Iron (% of Daily Value)</td>
</tr>
<tr>
<td>Sugars (grams)</td>
<td></td>
</tr>
</tbody>
</table>
A statement of the percent of the Daily Reference Value in a serving must be presented for the components and in the format described below:

<table>
<thead>
<tr>
<th>Food Component</th>
<th>Percent</th>
<th>Value*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total Fat</td>
<td>%</td>
<td>75 g</td>
</tr>
<tr>
<td>Saturated Fat</td>
<td>%</td>
<td>25 g</td>
</tr>
<tr>
<td>Cholesterol</td>
<td>%</td>
<td>300 mg</td>
</tr>
<tr>
<td>Total Carbohydrate</td>
<td>%</td>
<td>325 g</td>
</tr>
<tr>
<td>Dietary Fiber</td>
<td>%</td>
<td>25 g</td>
</tr>
<tr>
<td>Sodium</td>
<td>%</td>
<td>2,400 mg</td>
</tr>
</tbody>
</table>

*Based on a reference caloric intake of 2,350 calories

Vitamin and Mineral Supplements

Quantitative amount and percent of RDI
- all vitamins
- all minerals

Quantitative amount
- calories
- fat
- carbohydrates
- dietary fiber

Amount in one unit of supplement (one pill or tablet)
MARKETING CHEESE AT A MOVING TARGET

Presented at the 10th Biennial Cheese Conference
Hosted by Utah State University
Logan, UT, August 18, 1992

By Jerry Dryer, Principal, The Jerry Dryer Group
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708/559.8505

Dairy foods manufacturers and marketers have a long track record of meeting consumer needs by marketing at a moving target.

Dairy foods manufacturers and marketers have been modifying milk and milk products to meet changing consumer wants and needs since at least the turn of the century.

Sometimes dairies have been so responsive that they have generated consumer protests.

Take the days, for example, when Upton Sinclair was writing about the unsanitary conditions in the meat packing industry. The dairy industry took it upon itself to begin (1895) pasteurizing milk. That prompted consumer protests. Consumers argued that processors were tampering with a natural food -- milk. Today, we still have a vocal group of raw milk advocates and drinkers.

Homogenization (1919) also prompted similar outcries about tampering with Mother Nature's most nearly perfect food.

As World War I got underway, physical examinations for the young men being inducted into the military indicated that they were suffering from shortages of Vitamin D in their diet. Although it took a while (1932); once again, dairies came to the rescue. Milk bottlers began fortifying milk with vitamin D. Again, in the midst of some consumer protests.
By the end of the Second World War, Americans were faced with another food related challenge. They were getting too many "good" things (nutrients including calories) from their diet. By the mid-1950s, people were beginning to watch their waistline. Once again, the dairy foods business was front and center.

During the 1950s, dairy companies launched the first fat-reduced beverages and foods — lowfat dairy beverages fortified with Vitamin A and, a little later, reduced-fat cottage cheese.

This time creativity almost landed dairy processors in jail. Given the standards of identity of the day (to be labeled milk, it must contain at least 3.5 percent milk fat), dairy processors were creating and marketing 'substandard foods' in direct violation of federal and state laws.

To circumvent the law, several processors created fanciful names for their new beverages. Names like VIM, which is still available in the Chicago market, were used. In fact, I think names like VIM were a stroke of marketing genius. Unfortunately, the word marketing had not yet been introduced into the vocabulary of the dairy foods business.

Pasteurization, homogenization, vitamin fortification, fat reduction. All changes aimed at a moving target — the changing consumer.

More about this later, when I address positioning.

But first a look at the issue of reduced-fat or in this case reduced-caffeine. Yes, I know. We are in the dairy business, but I think we can learn something from our competitors in the coffee business.

The story begins almost two decades ago. The Big boys and Big girls in the coffee business were between the coffee bean and a hard place. The story of coffee is a classic for those of us in the food business. It can tell us a great deal about how consumers and companies respond to change.

We can relate coffee to changing consumer tastes. We can relate the coffee business to changes in how business is being done in the food and beverage business. We can relate coffee to new product development — the right way and the wrong way.

Caffeine — one of the "C" words like cholesterol, calories and communism — is a bitter, crystalline alkaloid.

However, for many of us it is one of the essential vitamins. The body simply does not respond to the alarm clock in the morning without the promise of caffeine. And it comes in great flavors — coffee, tea, chocolate, cola.
Anyway, eventually it became clear to a fair number of humanoids that they should avoid the alkaloids. Personally, I shifted from two pots a day to two cups a day.

But the shift was from two pots of Hills Bros. or Folgers Sisters to two cups of Victor's high octane chocolate amaretto. From two pots of $2.99 a pound coffee to two cups of $7.99 a pound coffee.

Yes, the Hills and Folgers tried to take the caffeine out — with lye — the secret ingredient in Grandma's soap. But, without the caffeine it just wasn't coffee; and with the lye residue, it just wasn't healthy.

Now, market research and forecasting had clearly demonstrated to the Hills and Folgers that caffeine was the problem. Take the caffeine out, the researchers said, and they'll buy your coffee again.

Unfortunately, the big-budget researchers at Hills and Folgers didn't ask all of the right questions or all the right people. They forgot one important element: If it doesn't taste good: Will you still drink it? If it doesn't give you that wakeup call in the morning: Will you still buy it?

But my friend Victor, on the other hand, understood taste. He didn't travel to the coffee plantations in a corporate jet. He hitch hiked there and drank real coffee with real people. He discovered several niches; niches that Mr. Hills or Ms. Folgers either did not know about or thought were too small for them.

Victor discovered people like me: I'll drink less coffee, but better coffee. A pint of Ben & Jerry's; instead of a half gallon of Jewel Foods'.

Victor discovered people who did not want to drink caffeine; but loved the flavor of coffee fortified with hazelnut or Irish creme or ...

Victor discovered people who could not drink caffeine; but were willing to switch to a hot, flavored beverage.

Which takes us to the business side of the coffee business or the food business. While the coffee business is dominated — in pounds of grounds sold — by the Hills and Folgers; guess who is making most of the money. The Victor's of the world. Not just coffee; but two dozen different flavors of coffee and another dozen flavors with the caffeine removed by the safer, although more expensive Swiss-water process.

You could paint almost the same scenario for lowfat milk. We simply took out the fat to meet the reduced-calorie needs of people. We let it go at that and milk sales have suffered because of it.
We all know the story. The numbers are there. Whole milk sales have been plunging because people are avoiding fat. But increases in lowfat milk sales have not kept up with decreases in whole milk sales.

In 1970, per capita beverage milk sales totaled 28.4 gallons; 23.6 gallons were whole milk. During 1990, sales totaled 23.7 gallons; just 9.7 gallons were whole milk.

You have all heard the story before. We lost consumption as people tried and rejected lowfat milk. But by offering lowfat milk, we had focused attention on the fact that there was fat in whole milk. Today, people believe that whole milk is 20 percent to 30 percent fat, according to consumer surveys conducted by Penn State. No wonder they are not rushing to buy and drink whole milk. It's a toxic substance.

Let's not screw up the cheese business in the same way. Let's not make the same kinds of mistakes they made in the coffee business and the dairy beverage business.

However, we certainly have the potential. Just ask Dick Fogg, group vice president of dairy foods at Land O' Lakes. Fogg noted earlier this year that lowfat cheese represents less than 10 percent of cheese sales. "Why?", he asked. "Because the stuff on the market tastes awful," Fogg responds.

I agree with Fogg. Most of the reduced-fat cheese on the market today is problematic. That is part of the reason why retail cheese sales have been below year-earlier levels during four of the past five quarters.

We promote lowfat cheese and we focus consumer attention on the fat content of traditional cheeses. That discourages consumption of traditional cheeses.

When consumers then try lowfat cheese, they are less than satisfied and we have lost retail sales.

Larry Hamm, an agricultural economist at Michigan State University, agrees with Dick Fogg and me and he elaborates.

Hamm argues that the 2 percent to 3 percent growth in cheese sales enjoyed during most of the 1980's will not reoccur. Most of that sales growth was because cheese was taking business away from red meat. Hamm thinks it is doubtful that the dairy industry can steal more demand from meat.

He notes that the issue of health is what drove people from meat to cheese. Now, dairy product sales will be hammered because of their fat content. The image of traditional dairy products is destined to be hurt. And some of the damage will be self-inflicted.
This damage to the image of traditional cheese may not be intended, but large companies such as Kraft, Beatrice and Borden are now focusing their attention on lowfat cheeses.

By telling consumers all about the health benefits of lowfat cheeses through millions of dollars worth of advertising, consumers begin to rethink the benefits of traditional products.

Even if consumers try these new products and revert back to traditional dairy products they may use less of the traditional products after being bombarded with messages about consuming less fat.

There also are a number of other forces slamming the cheese business. Publicly-held companies must keep stockholders happy. That means, among other things, these companies are forced to roll out new and improve products to come up with sales growth.

To generate still more sales growth, to maintain market share or to increase market share, cheese marketers are resorting to price cutting. They are surrendering some, if not all, of their brand equity. The cheese business is going the way of the fluid milk business -- dominated by store brands and price driven.

Price competitiveness is taking the added value out of brand names for both the manufacturer and the retailer. Consumers are viewing cheese more as a generic product than they are as individual brands.

Generic or branded, high quality lowfat cheeses are still clearly one of the options for success in the cheese business. Unfortunately, the introduction of lowfat and nonfat products has had a rocky road.

Several years ago as lowfat became a buzz word, dozens of cheesemakers decided they could simply skim some of the cream off the milk in the vat and produce a lowfat product.

Many of these cheesemakers privately conceded that it wasn't a particularly good product, but after all, how could a lowfat cheese be good.

To traditional cheesemakers, lowfat cheese was an oxymoron. Cheese is fat. If you take out the fat, you are not going to have a very good product; it is not real cheese.

The first lowfat products were destined to fail in the commercial market and they did.

Therefore, all together too many people in the cheesemaking and cheese marketing community concluded: There is no market for lowfat cheese.
In fact, product did not sell because the cheese was totally unacceptable. The flavor was terrible, the texture was terrible, the shelf life was terrible and failure in the marketplace was a certainty. In fact, much of the so-called lowfat cheese on the market today is, in the words of Dick Fogg, "awful."

As food scientist Dr. Steven Newton explained in a recent issue of Dairy Foods magazine: Making lowfat cheese is more than skimming the cream off the milk in the vat. Making lowfat cheese is very complex. It requires changing make procedures. It requires changing ingredients. It requires replacing the fat with other functional solids. It requires using flavor and texture enhancers.

As Clem Honer concluded in his "Lowfat Report Card" in Dairy Field magazine: "In the end analysis, it is clear that a market does exist for lowfat products, but that more development needs to be done to bolster flavor and other traditional product characteristics in all (dairy) product categories, particularly frozen desserts and cheese."

In deed, there is a major and growing market for lowfat cheese. The target continues to move. Consumers are continually being bombarded with the eat-less-fat message. Demand for lowfat products continues to build and there is a need that we need to fill.

Research recently conducted by the Grocery Manufacturers of America tells us a great deal about what that consumer wants.

The results look like this. Of the 1,002 grocery shoppers asked "When you decide what food and groceries to buy which of the following are most important to you? Second most important?"

Two-thirds (65 percent) of the consumers ranked nutrition either most important or second most important. Nearly half (44 percent) say nutrition is the most important consideration when they purchase food.

Price ran a distant second and taste a distant third.

I would make two additional observations about this data. First: The word nutrition reads lowfat, low calorie, low cholesterol, fresh, natural.

A new study from the Food Marketing Institute and Prevention magazine gives us an inside look at nutrition. More than two-thirds (68 percent) of the participants in the study "almost always" check the expiration date on the product because they're concerned about freshness.

Two-thirds (64 percent) "almost always" check out the amount of fat in the product. Some 70 percent say they use lowfat milk, another 50 percent say they have switched from ice cream to frozen yogurt.
More than half (54 percent) of the consumers "almost always" check for cholesterol content and another 51 percent, "almost always" check for calories and sodium.

My second observation relating to the GMA research comes from diary research which I have seen, but cannot share with you in print.

The diary research suggests that taste is much more important than the Grocery Manufacturers of America study suggests. The GMA survey asked consumers what they do; it did not measure what they actually do when setting at the table. Both the private diary research and grocery store sales numbers we track suggest that taste ranks right up there with nutrition.

Consumers are not going to give up a great deal of taste to get the nutrition they want. Instead they will simply give up the product or the category and find an alternative food -- a different snack, a new ingredient, mustard not mayo.

Research and analysis funded by The NutraSweet Company, the marketers of Simplesse, helps confirm my conclusions. Retail traditional cheese volume has declined about 7 percent during the most recent 12 months measured. About 1/3 of that lost volume shifted to "healthy" cheeses. The remainder was loss due to consumer moderation (62 percent) or the consumer abandoning the category (4 percent).

To survive, cheesemakers and cheese marketers must produce and deliver cheeses that are both healthful and tasteful. Quality is the key, but past successes in the cheese business have been based on a number of factors.

1/ I am convinced that consistent quality is reason number one for our past successes.

2/ We have served consumers a variety of products -- Cheddar, brie, Colby, natural, processed, cold pack...

3/ We have delivered convenience -- chunks, slices, shreds, strings, cubes, out of the refrigerator and onto the table, pizza. Do you realize that shredded cheese represents nearly one-third of the retail cheese sales today?

4/ We have provided consumers with a nutritional product full of protein, full of calcium, full of good things. Pizza has the four food groups. Cheese is fresh product. Cheese is natural.

5/ Cheese has been viewed as healthful until recently. Take a look at this data from the United Dairy Industry Association. They conduct an ongoing attitude and usage trends study.
Note that in 1980, 50 percent definitely agreed that "Cheese is a healthful;" but by 1988, only 40 percent. It has slipped further since then. Meanwhile, about 40 percent thought "Cheese can cause heart disease" in 1980 and by 1988, 50 percent felt that way.

A chunk of our future success clearly lies in the lowfat, reduced-fat segment of the business. Again, The NutraSweet Company analysis suggests the potential: Less than 1 percent of the "healthy" cheese volume came from new category buyers. The potential is huge.

About 1/3 of "healthy" cheese volume increase came from consumers adding more cheese to their purchase mix.

If we get our act together and start to produce more and far better lowfat cheeses, I see total cheese sales continuing to grow. If we do not take the lowfat cheese business seriously, cheese sales will continue a steady decline.

The message to consumers reads: EAT LESS FAT. They are responding in one of three ways:

1. They are eating a pint of Ben & Jerry's; not a half gallon of store brand ice cream;
2. They are eating frozen yogurt instead of ice cream or
3. They have left the frozen dessert category and now have an apple for dessert.

In my opinion, cheese faces the same future.

There will continue to be a market for really, really high quality traditional cheeses and there will be a growing and profitable market for really, really high quality lowfat cheeses.

There are a goodly number of users out there who do not need to or do not want to worry about their fat intake. There are also a number of users out there who have a preference to use less of the very best. The very best reads, high fat.

There is room in the market place for the Ben & Jerry's of cheese and, in fact, there are several of them out there right now that are enjoying good success.

There were some early entrants in this market -- Besnier and Tholstrup. Both are producing full fat products, double cream products, carving out a niche in the U.S. market.
Just about a year ago, RothKase joined the ranks and they are rolling out a full line of full fat European type cheeses. Products like gruyere, Hofbrau Kase, St. Bernard and Swedish Style Fontina. Rothkase's gruyere -- the only one made in the U.S. -- uses imported cultures, curing boards and smear.

Paul Scharfman at the Specialty Cheese Company is going after the high-end Hispanic side of the business with his La VacaRica brand of Hispanic cheeses.

The company that Paul purchased about a year ago had been producing private label Hispanic cheeses for about a dozen years. Now Paul, an ex-Kraft General Foods marketing executive, is rolling out branded high-fat cheeses targeted at very specific audiences.

The other side of the coin is really, really high quality, lowfat cheeses.

There are only a few products enjoying success in this market; but there also are some up and comers.

Here is one of the successes: Kraft FREE Singles. (Ingredient label: High moisture skim milk cheese (skim milk, cheese culture, salt, enzymes) whey, skim milk, dried corn syrup, sodium phosphate, less than 2% of: salt, buttermilk, cellulose gel, sodium citrate, natural and artificial flavor, sorbic acid as a preservative, carrageenan, cellulose gum, artificial color, vitamin A palmitate.)

Kraft Free Singles sales totalled $25 million last year, according to Adweek magazine; however, the product still had not been rolled out nationally.

Just a couple of months ago, Borden began shipping their versions: Fat FREE Singles, Fat FREE Sharp and Fat FREE SWISS Singles. (Ingredient label: Skim milk cheese (cultured skim milk, salt and enzymes), skim milk, whey, corn syrup solids, sodium phosphate, enzyme modified cheese, cellulose gel, salt, sorbic acid (preservative), carrageenan, calcium phosphate, propionic acid, cellulose gum, artificial color, Vitamin A palmitate.)

And as I speak, Beatrice's Healthy Choice's Fat Free Singles (and 29 other fat-free items) are being introduced onto the retail shelf. (Ingredient label: Unavailable)

I have not tried the Borden or the Healthy Choice product, but can attest to the quality -- flavor and texture -- and functionality of Kraft's FREE Singles. This is an excellent product.

There are a couple of other fat free items on the retail shelf. However, I will follow my mother’s advice: If you cannot say something good about somebody (something), it is best that you say nothing at all.
Meanwhile I am not quite convinced this -- Fat Free -- is where the real growth will be over the short term. I think the best potential lies in the reduced-fat, very lowfat segment, especially for natural cheese.

Here's a great product. Not consistently great during its development; but it is now coming into its own and has excellent potential. It is Cabot Farmers' Cooperative Creamery cheddar cheese produced with 75 percent less fat than regular cheese.

Cabot's 75-percent-less-fat cheese is superior to any of the one-third fat-reduced cheeses on the market. However, the Cabot/Agri-Mark merger has slowed its introduction. Now, I expect Cabot to make steady progress in the market.

White Clover has an emerging line of cheeses -- cheddar, cobly and munster -- with 50 percent less fat. *(Ingredient label: Pasteurized skim milk, whey protein concentrate (All natural Simplesse brand), cultures, salt, enzymes, calcium chloride, beta carotene).*

And during the past several months, Tillamook, Polly-O, Churny, Frigo, Beatrice and others have launched light or lowfat natural cheeses. But, interestingly, most of the new cheeses introduced during the past year have been traditional and high-fat cheeses.

The lowfat cheese market looks like this. Sales totalled nearly 10 percent of the total retail cheese market last year or about $500 million in sales.

Estimates from several authorities in the business suggest that sales will increase about 30% a year. Currently, Kraft has about a 60 percent market share, according to the best numbers I have seen.

The real growth on the lowfat side of the business will also be generated in foodservice and as an ingredient in other foods.

For fifteen years, the brightest spot in the foodservice cheese business is the lowfat cheese business: Part-skim mozzarella cheese in the pizza business. It has seen double-digit growth for more than a decade.

Now, there is a new entrant: Falbo-Lites which is an even lower fat mozzarella cheese. *(Ingredient label: Pasteurized Milk, Whey Protein Concentrate (All Natural Simplesse Brand), Culture, Enzymes, Salt.)*

It's enjoying good success in its initial markets where Chicago's Famous Home Run Inn pizzeria is positioning it as a great tasting, healthier pizza lower in cholesterol and lower in fat.

Food techies at the Institute of Food Technology Expo and restaurant operators at the National Restaurant Show waited in line to sample (and get second helpings of) this pizza.
My monitoring of consumer attitudes strongly suggests that vegetarianism is taking on major significance among American consumers. A combination of a lower fat, lowfat cheese with vegetable toppings on a pizza is a good way to merge the dairy business into this growing category of consumers -- vegetarians.

Another new entrant is Mid-America Dairymen's very lowfat process cheese aimed primarily at the foodservice business. We tried this cheese at the Institute of Food Technology show in June and it received very good reviews.

We need to use positioning to capitalize on this lowfat trend and we could learn some lessons from the positioning used by other people.

Ice milk did not work as a lowfat ice cream alternative, because that is how it was served: As a lowfat version of ice cream. In consumers minds, they were comparing it to ice cream and had ice cream expectations. Ice milk lacked the flavor and lacked the class of ice cream. It enjoyed a brief moment in the sun and then sales growth melted. Today the segment continues to shrink steadily with the arrival of frozen yogurt.

Frozen yogurt is a classic example of positive and good positioning. It is, in fact, a new category. Not many marketers positioned it as an alternative to ice cream. Instead it was positioned as a healthful, great tasting dessert and, by the way, it is lowfat.

Everything about it is premium. The packaging is classy, the product is expensive, the ingredients are upscale.

And therefore the frozen yogurt business is not cannibalizing high fat -- the traditional -- ice cream business. In fact, the very high fat ice cream business, the Ben & Jerry's and Haagan Dazs' are enjoying their best year ever.

In the cheese business, there are a couple of classic examples of positioning -- an old standard, Velveta and an upstart, Lite 50. (Ingredient label: Cheddar cheese (aged over 6 months)(milk, cheese culture, salt, enzyme), water, skim milk, microparticulated milk protein (whey protein concentrate)(Simplesse brand all natural fat substitute), reduced lactose whey, whey protein concentrate, salt, lactic acid, sorbic acid (to prevent mold), natural flavors, xanthan gum and apo-carotenal color.)

You may not eat Velveta; but some of your best friends do. Why has it been so successful? Because Kraft positioned it so that they did not compete directly with themselves; so they did not detract from Kraft naturals, from Kraft cheese. They did not call it "Kraft natural cheese that has been pasteurized and processed, then mixed with whey, other milk solids and some non-dairy stuff American cheese food".
A more recent and lowfat positioning success can be found with Lite 50. Actually this product is "Kaukauna Club's reduced-fat, reduced-cholesterol, reduced-calorie, microparticulated whey protein concentrate fortified cold pack cheese food". Sounds good? Lite 50 sounds a lot better.

They probably would not be the world's largest selling soft drink if they had decided to call Coca Cola an "artificially colored, artificially flavored, sugar-fortified, artificially carbonated water."

The Lite 50 and Velvetta positionings help keep the consumer from comparing the new product with the traditional product. Instead they taste it with no pre-set expectations other than the hype that you may have used to get it onto the shelf and then into their grocery cart.

Some cheese folks, say that Lite 50 has a slight "whey aftertaste" because of the Simplesse. Tastings by more than 100 of my lay friends has triggered almost no negatives and never a word about unacceptable aftertaste. Lite 50 is doing very well.

We also need to look at positioning our lowfat products not as cheeses but as other products. How about positioning them as snacks or desserts or appetizers. We can do those things with package sizes including single servings and we can do those things by adding other flavor ingredients whether it be peppers or garlic or herbs to our products.

In summary, I see the world like this:

The demand for high quality, traditional cheeses is here to stay

The demand for lowfat and nonfat cheeses is here to stay

The demand for taste and variety is here to stay

Therefore, we need to intensify our efforts to make and market the very best traditional, lowfat and nonfat cheeses possible.

I wish you happy making and marketing.
NEW NUTRITION LABEL FORMAT SCHEMES
AND THE DAIRY INDUSTRY

by

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THE UNIVERSITY OF UTAH

PRESIDENT, GEIGER & ASSOCIATES
FOOD LABELING & GOVERNMENT AFFAIRS CONSULTANTS
SALT LAKE CITY, UTAH

I. OVERVIEW

* INTRODUCTION
* NUTRITION LABEL FORMAT HISTORY
* RECENT RESEARCH FINDINGS
* PROPOSED FDA FORMAT REGULATIONS
* EFFECT ON THE DAIRY INDUSTRY
* RECAP
* CONCLUSIONS

II. INTRODUCTION

III. NUTRITION LABEL FORMAT HISTORY

* 1975- NUTRITION LABEL FORMAT REGULATIONS WENT INTO EFFECT
* 1978- PUBLIC COMMENT SOLICITED
* 1979- INTERAGENCY TASK FORCE DEVELOPED
* 1982- GERSIN ASSOCIATES DESIGNED NUTRITION LABEL FORMATS
* 1990- NUTRITION LABELING AND EDUCATION ACT SIGNED INTO LAW
* 1991, NOV.- NUTRITION LABELING PROPOSED REGULATIONS PUBLISHED
* 1991, MAY 20 - FDA PHASE I STUDY REPORTED
* 1992, JULY 20 - FORMAT REGULATIONS PROPOSED
NUTRITION LABELING & EDUCATION ACT-1990

THE IMPLEMENTING REGULATIONS SHALL-

REQUIRE THE REQUIRED INFORMATION TO BE CONVEYED TO THE PUBLIC IN A MANNER WHICH ENABLES THE PUBLIC TO:

1) READILY OBSERVE AND COMPREHEND SUCH INFORMATION

2) UNDERSTAND ITS RELATIVE SIGNIFICANCE IN THE CONTEXT OF A TOTAL DAILY DIET

IV. RECENT RESEARCH FINDINGS

* NFPA
* U. OF UTAH
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V. PROPOSED FDA FORMAT REGULATIONS

A. FINDINGS OF RESEARCH

B. FDA'S TENTATIVE VIEW

C. RELATIVE IMPORTANCE OF LABEL USES

D. REQUEST FOR COMMENTS ON OTHER ISSUES
(REFERENCE: FDA. FOOD LABELING: FORMAT FOR NUTRITION LABEL; PROPOSED RULE. FEDERAL REGISTER, MONDAY, JULY 20, 1992: 57(139), P.32,058 -32,089.)
FDA'S PROPOSAL

A. FINDINGS OF RESEARCH

* DO NOT IDENTIFY A CLEARLY SUPERIOR FORMAT FOR ALL USAGE SITUATIONS

B. FDA'S TENTATIVE VIEW

* INFORMATION WILL BE DISPLAYED IN A MANNER THAT IS SIMPLE AND MINIMIZES CLUTTER

* INFORMATION WILL BE PRESENTED IN A TABULAR FASHION, ALTHOUGH PERHAPS ENHANCED BY OTHER GRAPHIC DEVICES TO PROVIDE RAPID ACCESS TO, AND GREATER OBSERVABILITY OF, KEY NUTRITION INFORMATION

* THE NUTRITION INFORMATION DISPLAY WILL INCLUDE EITHER A LISTING OF THE QUANTITATIVE AMOUNT OF EACH NUTRIENT, OR A PERCENT OF THE PROPOSED RDI OR DRV, OR COMBINATION OF BOTH

* NUTRIENT INFORMATION MUST BE LINKED TO DIETARY GUIDANCE THAT IS CONSIDERED IMPORTANT TO PUBLIC HEALTH

C. RELATIVE IMPORTANCE OF LABEL USES

* MUST FACILITATE THE ACCURATE SEARCH FOR SIGNIFICANT NUTRIENT INFORMATION WITH MINIMUM EFFORT

* MUST FACILITATE DIETARY CALCULATIONS
D. OTHER REQUESTS FOR COMMENTS ON:

* USDA FORMAT AND OTHER ALTERNATIVES
* HOW LABEL CAN MEET EDUCATIONAL ROLE
* NEED FOR DRV$s ON THE LABEL
* UTILITY OF ADJECTIVAL DESCRIPTORS
* ORDERING OF NUTRIENTS
* "FOR A 2,350 CALORIE DIET. YOUR DAILY VALUE MAY BE HIGHER OR LOWER, DEPENDING ON YOUR CALORIE INTAKE"
* VOLUNTARY COMPONENTS, I.E. HIGHLIGHTING, ADJECTIVES
* EVALUATION MEASURES TO USE WHEN CONSIDERING OTHER EVIDENCE

FDA PROPOSAL DISADVANTAGES

* RESEARCH TESTING NOT WELL CONTROLLED THEREFORE VALID CONCLUSIONS CANNOT BE DRAWN
* USE OF DV$s FOR SELECTED NUTRIENTS
* ARRANGEMENT OF INFORMATION/FORMAT

FDA PROPOSAL ADVANTAGES

* USE OF DV$s
* MANDATORY LABELING OF ALMOST ALL PROCESSED FOODS
VI. EFFECT ON THE DAIRY INDUSTRY

* ADVANTAGES

* DISADVANTAGES

* HOW TO EFFECTIVELY USE THE LABEL TO MARKET YOUR PRODUCT

VII. RECAP

RESEARCH SUPPORTS:

1) NUTRITION LABEL CHANGE
2) GRAPHIC PORTRAYALS INCREASE COMPREHENSION

FINAL REGULATIONS

1) PUBLISHED BY NOVEMBER 8, 1992
2) IMPLEMENTED BY MAY 8, 1993
VIII. CONCLUSIONS

AMERICANS NEED TO LEARN HOW TO MAKE WISE FOOD
CHOICES AS PART OF A HEALTHY LIFESTYLE.
MAKING AVAILABLE ACCURATE, NON PRODUCT SPECIFIC
INFORMATION ON FOOD LABELS, ALLOWS THE CONSUMER TO
MAKE INFORMED JUDGMENTS ABOUT FOOD SELECTIONS.

COMPANIES WHO WISH TO GAIN CONSUMER ACCEPTANCE OF
THEIR PRODUCTS AND LARGER MARKET SHARE WILL PROVIDE
THIS INFORMATION:
(1) ON THE NUTRITION INFORMATION
    DISPLAY PANEL
(2) ELSEWHERE ON THE PACKAGE USING GRAPHICS
(3) THROUGH EDUCATIONAL INFORMATION
NUTRITION LABELING AND
THE DIARY INDUSTRY

10th Biennial Cheese Conference
& Nutrition Labeling Workshop
Utah State University
Logan, Utah
August 19, 1992

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I. INTRODUCTION

The passage of the Nutrition Labeling Act of 1990 (NLEA) in November of that year represents the most pervasive and far-reaching changes to the requirements for labeling foods in the U.S. since the passage of the Federal Food, Drug and Cosmetic Act in 1938 and the Fair Packaging and Labeling Act in 1966. As will be discussed today, the NLEA's mandatory nutrition labeling requirement represent a major expansion of current rules and FDA authority. The food labeling requirements found today in 21 C.F.R. Pats 101, et seq. presently require nutrition labeling only if a food contains an added nutrient, or if a nutrition claim is made for the food on the label, in labeling, or in advertising. The old rules are being phased out and the new rules are being ushered in. You must be aware of the new scheme so that you can formulate new, innovative products and promote them taking the utmost advantage of this new scheme.

II. SUMMARY

The NLEA amended the Federal Food, Drug, and Cosmetic Act (FDC Act). In summary, the most important of these changes are as follows:

- Mandatory nutrition labeling for almost all food products, including fresh produce and seafood.
- Federal regulation of nutrient content claims and health claims.
- National uniformity for several food labeling requirements.

These provisions are discussed in greater detail below.
III. MANDATORY NUTRITION LABELING

Section 2 of the NLEA added new Section 403(q) to the FDC Act concerning nutrition labeling.

A. Required Information

Except for fresh produce and seafood or exempted products (discussed in later) the label or labeling of all food products must include the following information:

- Serving size/reference amount;
- Number of servings per container;
- Amount of the following nutrients provided per serving:
  - Total calories;
  - Total calories from total fat;
  - Total fat;
  - Saturated fat;
  - Cholesterol;
  - Sodium;
  - Total carbohydrates;
  - Complex carbohydrates;
  - Sugars;
  - Dietary fiber; and
  - Total protein.

FDA may by regulation revise the list of nutrients required to be declared on the label. FDA may also prescribe a simplified format for foods that contain "insignificant amounts" of more than one-half of the nutrients that are required to be declared. With respect to vitamins and minerals within the scope of Section 411 of
the FDC Act, FDA is required to adopt regulations specifying the
nutrition labeling format "in a manner which is appropriate for
such food."

B. Exemptions From Mandatory Nutrition Labeling

1. Small Retailers

Small retailers with annual gross sales of $500,000 or less,
or annual gross food sales of $50,000 or less, are exempt from the
NLEA's nutrition labeling requirements. The practical effect of
this exemption is that small retailers do not have to provide
nutrition labeling for bulk foods, fresh produce or seafood.

2. Miscellaneous Exemptions

The following food products are exempt from the NLEA's
mandatory nutrition labeling requirements:

- Restaurant and carry-out foods;
- Infant formulas;
- Medical foods;
- Foods intended for further processing, labeling, or
  repacking;
- Foods in small packages if not labeled with any
  nutrition information;
- Foods that contain "insignificant amounts" of all
  nutrients required to be declared on the label
  (e.g., coffee), if no nutritional claims are made;
- Foods distributed principally to restaurants and
  other foodservice institutions.

C. Consumer Education

FDA is required to provide consumer education concerning the
availability and importance of nutrition information.
IV. NUTRIENT CONTENT CLAIMS AND HEALTH CLAIMS

Section 3 of the NLEA added new Section 403(r) to the FDC Act. This new section regulates nutrient content claims and health claims.

A. Nutrient Content Claims

1. A nutrient content claim is a claim that "characterizes the level of any nutrient" which is required to be declared on the label. These claims must be made using terms that have been defined by FDA; the use of other, undefined terms is not permitted. FDA is expressly required to define the following terms:

   - "Free;"
   - "Healthy;"
   - "Low;"
   - "Light" or "lite;"
   - "Reduced;"
   - "Less;" and
   - "High."

All nutrient content claims must be accompanied, prominently and in immediate proximity to the claim, with the statement: "see _____ for nutrition information," with the panel where the nutrition information is located to be identified in the blank.

The NLEA contains special, less stringent requirements with respect to nutrient content claims contained in the brand name of a food that was in use before October 25, 1989. FDA has adopted additional, more stringent requirements for claims concerning the
absence of a nutrient, cholesterol content claims, saturated fat claims, and dietary fiber claims.

2. Claims Concerning The Absence Of A Nutrient

A claim about the absence of a nutrient cannot be made unless the nutrient is usually present in the food (or in a food for which the food is a substitute, as defined by FDA regulations). To use the examples cited in the legislative history, a "no cholesterol" claim could not be made for a soft drink, but might be appropriate for margarine. FDA can also, by regulation, permit such claims if they would be useful and the statement discloses that the nutrient is not usually present in the food, e.g., "Brand X, a naturally sodium-free product."

3. Cholesterol Content Claims

The NLEA limits cholesterol claims for foods that contain "fat or saturated fat in an amount which increases to persons in the general population the risk of disease or a health related condition," as determined by FDA by regulation. For these foods, a cholesterol content claim can be made only if: (a) FDA adopts a regulation that the level of cholesterol in the particular food is substantially less than the level usually present in the food (or the food for which it is a substitute), or (b) FDA adopts a regulation that cholesterol is not usually present in the food, that the cholesterol claim would be useful to consumers, and that the label statement discloses that cholesterol is not usually present in the food. If a food qualifies for a cholesterol content claim under either of these criteria, the food's fat or saturated
fat content must be prominently disclosed in immediate proximity to the cholesterol content claim.

4. Saturated Fat Claims

Any claim concerning the level of saturated fat in a food must, if the food contains cholesterol, be accompanied by the prominent disclosure, in immediate proximity to the saturated fat claim, of the level of cholesterol in the food.

5. Dietary Fiber Claims

A food may not make a claim that it is high in dietary fiber unless: (a) the food is low in total fat, as defined by FDA, or (b) the level of total fat in the food is prominently disclosed in immediate proximity to the dietary fiber claim.

B. Health Claims

A health claim is any claim that "characterizes the relationship of any nutrient" required to be declared on the label "to a disease or health-related condition." Health claims may only be made in accordance with claim-specific regulations adopted by FDA. In adopting regulations, FDA may take into account the contribution of a particular type of food to the total diet. According to the example used in the legislative history, this provision might allow FDA to prohibit a health claim for a snack food product with a particular level of fat, while allowing a health claim for a frozen dinner with the same level of fat.

FDA may adopt regulations authorizing specific health claims only if FDA finds, based on "the totality of publicly available scientific evidence," that there is "significant scientific
agreement" among qualified experts that the claim is supported by the evidence.

In its implementing regulations, FDA must address the following areas:

- Calcium and osteoporosis;
- Dietary fiber and cancer;
- Lipids and cardiovascular disease;
- Lipids and cancer;
- Sodium and hypertension; and
- Dietary fiber and cardiovascular disease.

FDA is only required to consider these six areas; it is not required to approve claims. FDA is expressly prohibited from requiring premarket approval for any health claims.

In February 1990, FDA reproposed regulations on "health messages." The thrust of the NLEA and FDA's reproposal are very similar: Health claims would be at risk for regulatory action unless they are consistent with model claims approved by FDA. Both the NLEA and the reproposal adopt identical scientific standards for substantiating health claims, and both focus on the same six areas for permissible claims at the outset.

C. Exemptions

The new requirements on nutrient content and health claims do not apply to infant formulas and medical foods. In addition, the limitations on cholesterol, fat, and fiber content claims do not apply to restaurant food.
D. Petitions For Nutrient Content Claims And Health Claims

The NLEA expressly authorizes the submission of petitions to FDA with respect to new nutrient content claims and new health claims. FDA is required to make a final decision (including the issuance of a proposed regulation if appropriate) within 100 days after submission. With respect to petitions for nutrient content claims using terms already defined by FDA, the agency is required to make a final decision within 90 days after submission. Finally, the NLEA authorizes the submission of petitions concerning the use of implied nutrient content claims in brand names for food products. FDA is required to act on these petitions within 100 days after submission. The petition will be considered granted if FDA does not act on it within 100 days.

V. NATIONAL UNIFORMITY AND PREEMPTION

Section 6 of the NLEA added new Section 403A to the FDC Act concerning national uniformity in food labeling. National uniformity would be phased in over a period of time, depending on the particular provision of the FDC Act.

A. Existing FDA Standards Of Identity

Existing FDA standards of identity (FDC Act Sections 401 and 403(g)) were adopted as national uniform standards on November 8, 1990.
B. Imitation Labeling, Declaration Of Net Contents, Signature Line, Ingredients Statement

Federal requirements for the following food labeling requirements were adopted as uniform national standards on November 8, 1991:

- Imitation labeling requirements (FDC Act Section 403(c));
- Identification of the manufacturer, packer, or distributor (FDC Act Section 403(e)(1));
- Net contents declaration (FDC Act Section 403(e)(2)); and
- Listing of food ingredients (FDC Act Section 403(i)(2)).

C. Nutrition Labeling, Nutrient Content And Health Claims

The new requirements added by the NLEA concerning mandatory nutrition labeling (FDC Act Section 403(q)), and nutrient content and health claims (FDC Act Section 403(r)) will become uniform national standards at the time those provisions become federal law, on May 8, 1993.

D. Food Names, Deceptive Packaging, Prominence Of Labeling Information, Quality And Fill Standards, Common Or Usual Names, Declaration Of Artificial Flavors, Colors, and Preservatives

The NLEA requires FDA to commission a study of the following provisions of the FDC Act and FDA's implementing regulations, and related state and federal laws addressing the same subjects, to determine whether FDA is adequately implementing the FDC Act:

- Misrepresentation of food names (FDC Act Section 403(b));
- Deceptive packaging (FDC Act Section 403(d));
Prominence of label statements (FDC Act Section 403(f));

Standards of quality and standards of fill (FDC Act Section 403(h));

Common or usual food names (FDC Act Section 403(i)(1)); and

Declaration of artificial flavors, colors, and preservatives (FDC Act Section 403(k)).

FDA must complete this study by May 8, 1991. FDA was required to publish by August 8, 1991 its proposed conclusions concerning whether these provisions of the FDC Act are being adequately implemented; FDA's final conclusions must be published by November 8, 1992. If FDA fails to publish its final conclusions in timely fashion, the proposed conclusions will be treated as final conclusions. Those provisions that are finally listed as having been adequately implemented by FDA will become national uniform standards.

If FDA concludes that one or more provisions are not being adequately implemented, it must publish proposed revisions to its regulations by November 8, 1992. FDA must adopt final revised regulations by May 8, 1993; upon adoption, these revised regulations become national uniform standards. If FDA fails to adopt final regulations in timely fashion, the proposed regulations will be deemed to be final regulations.

E. Construction And Limitations On National Uniformity

The NLEA provides that the national uniformity provisions shall not be construed to apply to any requirement concerning food safety warnings (e.g., California's Proposition 65), and shall not
be construed to affect preemption, either express or implied, which may arise under the Constitution, other statutes, or other provisions of the FDC Act that are not amended by the NLEA.

F. Petitions For Exemption From National Uniformity

The NLEA expressly authorizes states and localities to petition FDA for exemptions from national uniformity, if the state or local requirements are consistent with federal law, would not unduly burden interstate commerce, and are intended to address particular local needs which are not met by federal law. The submission of a state or local exemption petition by May 8, 1992 could delay preemption of the particular state or local requirement, depending on the subject of the requirement.

VI. MISCELLANEOUS PROVISIONS

A. State Enforcement

Section 4 of the NLEA amended Section 307 of the FDC Act to allow a State to bring, in its own name in state court, an action to enforce the food labeling provisions of the FDC Act that are the subject of national uniformity. A State must give FDA 30 days notice before bringing an enforcement action. If FDA notifies the State within the 30 day period that it has brought an informal or formal enforcement action with respect to the food product, the State may not proceed for at least 90 days. Thereafter, the state is further precluded from bringing an enforcement action if FDA is diligently prosecuting a court proceeding, has settled that proceeding, or has settled the informal or formal non-judicial enforcement proceeding pertaining to the food product. In any such
court proceeding brought by FDA, a state may intervene as a matter of right.

B. Ingredient Declaration

Section 7 of the NLEA amended Section 403(i) of the FDC Act concerning ingredient labeling to impose three new requirements. These provisions become effective on November 8, 1991, with certain exceptions established by Public Law No. 102-108 (signed into law on August 16, 1991), as discussed below.

1. Foods Subject To Standards Of Identity

The NLEA requires the declaration of ingredients, in descending order of predominance, for all food products, including foods subject to standards of identity. At the present time, only "optional" ingredients are required to be declared on the labels of standardized foods.

With respect to this requirement, as well as the declaration of color ingredients (discussed below), Public Law No. 102-108 created a grace period for food products for which the label was printed before July 1, 1991 and the new label is attached to the food before May 8, 1993; these products are subject to pre-NLEA requirements in this area. Under Public Law No. 102-108, firms have two interim options with respect to food products for which the labels are printed after July 1, 1991. For these products, firms can comply with the literal terms of the NLEA; alternatively, they can comply with FDA's June 21, 1991 proposed rule on ingredient labeling.
2. Declaration Of Color Ingredients

The NLEA requires the specific declaration of those color ingredients that are subject to certification requirements, e.g., "Blue No. 2," "Red No. 40," in the ingredients statement. Color ingredients not subject to certification requirements, e.g., paprika and grape skin extract, can continue to be declared in the ingredients statement by a collective term.

At the present time, almost all color ingredients, regardless of whether they are subject to certification, may be declared in the ingredients statement by a collective term. By regulation, FDA has required that Yellow No. 5 be declared by name.

The same effective date requirements set forth under Section B.2. above, concerning foods subject to standards of identity, apply to the declaration of color ingredients.

C. Rulemaking Procedure For Standards Of Identity

Section 8 of the NLEA amended Section 701(e) of the FDC Act to allow standards of identity for most food products (with the exceptions discussed in the following paragraph) to be adopted, revised, and revoked through notice-and-comment rulemaking. In comparison, under prior law, these proceedings had to be carried out using a cumbersome and time-consuming formal rulemaking proceeding that provided an opportunity for a formal evidentiary hearing before an Administrative Law Judge.

The formal rulemaking procedure continues to be required for the revision or revocation of standards of identity for the following products: (1) dairy products, (2) cheese and related
products, (3) frozen desserts, and (4) maple syrup. However, new standards for these products may be adopted through notice-and-comment rulemaking.

D. Regulatory Timeframes

FDA was required to issue proposed regulations to implement the new nutrition labeling requirements by November 8, 1991, which it did. Final regulations are to issue by November 8, 1992. The final regulations must go into effect 6 months after publication. If FDA fails to issue final regulations on schedule, the proposed regulations are deemed to be final regulations on the date the final regulations are due. We understand FDA is on target for issuing the final regulations by November 8, 1992 and, in fact, may issue them in October (overly optimistic). These regulations must allow for "minor variations" in the nutritional value of a food resulting from the normal course of production or from assortments of similar foods. Thus, except with respect to fresh produce and seafood, the NLEA's nutrition labeling requirements take effect no later than May 8, 1993. If FDA finds that compliance with these requirements of the NLEA would cause undue economic hardship, it may delay application of the requirements for no more than one year. We also understand FDA is considering a nine-month extension to this compliance date, i.e., February 8, 1994.

VII. SERVING SIZES -- FDA PROPOSED RULE

FDA has proposed a rule to establish "reference amounts" (i.e., standard serving sizes) for use in determining labeled serving sizes for purposes of nutrition labeling. A final rule
based on the proposal will become effective on the uniform effective date for new requirements mandated by the NLEA.

A. Relationship to Other Labeling Proposals

The serving sizes proposal is a companion to a separate proposal on nutrition labeling. As proposed in both documents, the reference amounts would be the basis for determining a product's labeled serving size for use in declaring nutrient contents in nutrition labeling. The serving sizes proposal also is important in relation to FDA's nutrient content claims and fat, fatty acid, and cholesterol claims proposals because a claim would be required to meet FDA's definition in terms of both the reference amount and the labeled serving size. Finally, the proposal is important in regard to FDA's health claims proposals because specific levels of fat, saturated fat, cholesterol, and sodium per labeled serving size would disqualify a food from bearing a health claim.

B. Reference Amounts/Serving (Portion) Sizes

The proposal would set reference amounts for essentially all food products. The proposal lists reference amounts for 131 food product categories for adults and children four years of age and older. For some foods, reference amounts would also be established for infants and toddlers. For the most part, reference amounts are set forth in FDA's proposal in metric units of grams or milliliters. A few are set forth in terms of cups (e.g., soups), tablespoons, or other units (e.g., one egg). FDA has proposed that the appropriate reference amount for cheese is 30 grams, approximately one ounce.
Reference amounts would represent a standard, based on consumption data, from which a product's labeled serving size would be determined. The serving size declared for nutrition labeling purposes generally would be required to be declared in terms of common household measures (e.g., cup, tablespoon, teaspoon, slice, or ounces). The nutrition label declaration of serving size would be in the household measure closest to the standard reference amount. That serving size then would be followed in parentheses by the size in grams or milliliters, followed by an optional declaration in ounces or fluid ounces.

Cups, tablespoons, or teaspoons would have to be used wherever feasible. Labeled serving sizes would be expressed in 1/4 cup increments down to and including 1/4 cup. Quantities less than 1/4 cup would have to be shown in whole tablespoons down to one tablespoon. If below one tablespoon, serving size would be expressed in teaspoons to the nearest 1/4 teaspoon increment. If these measurements are not applicable, then units such as a piece, a slice, and fractions of such, would have to be used. If none of the foregoing is applicable, ounces or fluid ounces may be used, expressed in 0.5 ounce/fluid ounce increments. Rounding would be indicated by use of the term "about" (e.g., "about 0.5 ounce").

A product that is packaged or sold individually and that contains less than 200% of the relevant reference amount would be considered a single serving container. Also, small packages sold individually, that contain 200% or more of the relevant reference amount would constitute a single serving if the entire contents of
the package reasonably could be eaten at one sitting. The labeled serving size of a single serving container would be the actual contents.

The labeled serving size for packages containing several discrete units (e.g., cheese slices) would be the number of units that most closely approximates the reference amount. If a unit weighs 67% or more, but less than 200%, of the reference amount, then the serving size is one unit. If a unit weighs 200% or more of the reference amount, one unit may be declared as the serving size if it can reasonably be consumed at a sitting.

In declaring the number of servings per container, a manufacturer would have to either: (a) declare the serving size as the approximate household measure that results in a whole number of servings in the container (e.g., serving size approximately 1/2 cup; number of servings per container 10); or (b) declare serving size in exact household measure and approximate the number of servings (e.g., serving size 1/2 cup; number of servings per container approximately 10). In either case whole numbers only would have to be used for the number of servings, except for random weight products. A manufacturer would have to express the serving size of a random weight product in ounces and declare "varied" for the number of servings.

Manufacturers would be permitted to petition FDA to establish or amend a reference amount.
VIII. MANDATORY NUTRITION LABELING; RDIs AND DRVs -- FDA PROPOSED RULE

A. Mandatory Nutrition Labeling Requirements

FDA proposed that nutrition labeling be required on most processed foods, whether packaged or not. Foods that contain only "insignificant amounts" (discussed below) of all specified nutrients and that make no nutrition claim in labeling or advertising would not have to bear nutrition labeling. In addition, as discussed below, FDA proposed a number of specific exemptions.

In general, foods would have to provide nutrition information on the food label. Foods not in packaged form and some small packages would be required to use counter cards or other point-of-purchase labeling.

Unless the food qualifies for a simplified format (discussed below), the following information generally would be required, in the order listed below:

- "Nutrition information per serving" (heading)
- Serving size
- Servings per container
- Calories
- Calories from total fat
- Calories from saturated fat (voluntary)
- Calories from unsaturated fat (voluntary)
- Calories from total carbohydrate (voluntary)
- Calories from protein (voluntary)
- Total fat
- Saturated fat
- Unsaturated fat (voluntary)
- Cholesterol
- Total carbohydrate
- Complex carbohydrate
- Sugars
- Sugar alcohol (voluntary)
- Dietary fiber
- Soluble and insoluble fiber (voluntary)
- Protein
- Sodium
- Potassium (voluntary)

"Percent of Daily Value" (heading) (based on reference daily intake (RDI)):
- Vitamin A
- Vitamin C
- Calcium
- Iron

Any other vitamins or minerals listed in FDA's regulation, when added as a nutrient supplement or when a claim is made about them.

Other naturally occurring protein, vitamins, and minerals listed in FDA's regulation (voluntary).
"Nutrition Profile" (heading) (percent of daily reference value (DRV)) of:

- Total fat
- Saturated fat
- Unsaturated fat (voluntary)
- Cholesterol
- Total carbohydrate
- Dietary fiber
- Sodium
- Potassium (voluntary)

Some nutrients, such as saturated fat, cholesterol, and complex carbohydrate, would be allowed to be omitted from the listing if present only in "insignificant amounts" (discussed below). In this case, however, a statement would have to appear at the end of the nutrient list stating "Not a significant source of__".

FDA also proposed to allow use of a simplified declaration if a serving of the food contains "insignificant amounts" of at least eight of the following: calories, calories from fat, total fat, saturated fat, cholesterol, total carbohydrate, complex carbohydrate, sugars, dietary fiber, protein, sodium, vitamin A, vitamin C, calcium, and iron. The simplified format would be allowed to be presented in lines instead of vertical columns. (It appears that the long form would have to be in column form.) Depending upon a food's nutrient profile, the simplified form could include as little as serving size, number of servings per
container, calories, total fat, total carbohydrate, protein, and sodium.

FDA proposed the following compliance rules: For added vitamins, minerals, protein, carbohydrates, dietary fiber, unsaturated fat, or potassium, the amount declared would have to be present. For foods containing these nutrients naturally, at least 80% of the declared amount would have to be present. For calories, sugars, total fat, saturated fat, cholesterol, or sodium, no more than 120% of the declared amount would be permitted.

FDA proposed that an "insignificant amount" be defined as that amount which may be rounded to "0" in nutrition labeling. This is an important term as it is also used in the proposal to determine exemptions from nutrition labeling and eligibility for use of the simplified form of declaration. The proposal would establish specific definitions for declaring "0" for each of the nutrients. For example, "0" would be defined as less than 2% of the RDI (discussed below) for vitamins and minerals, less than 5 milligrams for sodium, less than 0.5 gram for protein, and less than 0.25 gram for saturated fat.

B. Exemptions From Mandatory Nutrition Labeling

FDA proposed the following exemptions from mandatory nutrition labeling:

- Food sold by small businesses with less than $500,000 gross annual sales to consumers or less than $50,000 gross annual food sales to consumers, provided no nutritional claim or information is given.

- Food sold in restaurants or other restaurant-type establishments.
• Food sold in grocery stores from self-service bars, or bakery or deli counters.

• Infant formulas.

• Medical foods (as defined).

• Bulk foods shipped for processing, repacking, or labeling.

• Food for institutional use if nutrition information is provided directly to those institutions.

• Raw fruits, vegetables, and fish, which are subject to separate guidelines.

• Foods in packages with less than 12 square inches of label space, provided that nutrition information is supplied at point of sale.

• Unit containers in a multiunit package, if the inner units are properly labeled and certain other conditions are met.

• Food sold from bulk containers, if nutrition information is supplied at the point of sale.

• Dietary supplements of vitamins and minerals (except in food form) must be labeled in accordance with a slightly different regulation, proposed § 101.36.

C. "Recommended Daily Intakes" and "Daily Reference Values"

"Recommended Daily Intake" (RDI) essentially is a term intended to replace U.S. Recommended Daily Allowances (RDAs). FDA proposed to set RDIs for all vitamins and minerals allowed to be declared in nutrition labeling. Many of the proposed RDI values are changed from current RDAs, and some use different measurements (e.g., retinol equivalents). Percentage of RDIs in nutrition labeling would be declared under the heading "Percent of Daily Value."
"Daily Reference Value" (DRV) also is a new term devised by FDA to be used in providing consumers with optimal, daily consumption levels for total fat, saturated fat, unsaturated fat, cholesterol, total carbohydrate, dietary fiber, sodium, and potassium. The proposal calls for declaration of nutrition information for those listed nutrients as a percent of DRV, followed by specification of the established DRV for the nutrient. DRV information would be declared under the heading "Nutrition Profile."

IX. FDA NUTRITION LABELING FORMAT -- FDA PROPOSED RULE

A. Summary/Discussion

On July 20, 1992, FDA proposed to adopt a "Percent DV with RV" format as the standard format for presenting nutrition information in food labeling. "DV" is an abbreviation for "daily value." A daily value represents an optimal amount of a nutrient to be consumed on a daily basis, based upon public health recommendations. The term includes both "recommended daily intakes" (RDiS) of vitamins and minerals and "daily reference values" (DRVs) for total fat, saturated fat, unsaturated fat, cholesterol, total carbohydrates, dietary fiber, sodium, and potassium.

Essentially, the Percent DV with DRV format provides three types of information in table form:

1. Absolute values of content per serving for total calories, calories from fat, total fat (g), saturated fat (g), cholesterol (mg), sodium (mg), total carbohydrate (g), complex carbohydrate (g), sugars (g), dietary fiber (g), and protein (g), and percent of daily value of vitamin A, vitamin C, calcium, and iron;
2. Daily reference value (DRV) information for total fat, saturated fat, cholesterol, sodium, total carbohydrate, dietary fiber, and protein (i.e., a label delineation of public health recommendations for maximum/minimum daily intakes of these nutrients; and

3. Percent DV (i.e., percent of DRV) that the food provides for each of these nutrients.

A statement that the daily values are based upon a standard 2350 calorie daily diet also would be included.

B. Significant Changes to This Proposal is Probable

While FDA proposes to adopt the Percent DV with DRV format, the proposal reflects that the agency may be far from resolute in its determination. FDA broadly seeks comment on the strengths and weaknesses of the proposed format, refinements that might be incorporated, strengths and weaknesses of other format alternatives previously tested, and suggestions for any alternate format. Comments and other information (e.g., ongoing industry studies) received by FDA prior to publishing a final regulation may be important in determining the nutrition labeling format ultimately adopted by the agency.

FDA, although not entirely settled upon a final format, has concluded tentatively that the final format will reflect several elements:

- Information will be displayed in a manner that is simple and minimizes label clutter.
- Information will be presented in a tabular fashion, perhaps enhanced by other graphic devices to provide rapid access to, and greater observability of, key nutrition information.
The nutrition information display will include either a listing of the quantitative amount of each nutrient in absolute terms (e.g., grams), or a listing of the amount as a percent of the proposed RDI or DRV, or a combination of both.

Nutrient information will be linked to dietary guidance that is considered important to public health.

FDA believes, based upon its evaluation of formats to date, that the Percent DV with DRV format may best incorporate these elements, but also might be improved upon.

However, FDA may agree to many major or minor refinements in finalizing its format regulation. For example, certain information might be stressed through display changes in typesize, typeface, or highlighting; graphic presentations that have proved promising might be incorporated, as might adjectival descriptors; or a statement might indicate that DVs may vary depending upon age, gender, activity level, and other factors. The spectrum of possible refinements is broad, and any ultimately adopted scheme could be either mandatory or voluntary.

X. FAT, FATTY ACID, AND CHOLESTEROL CONTENT CLAIMS --
FDA PROPOSED RULE

A. General Principles

Terms describing the fat, fatty acid, or cholesterol content of foods would be considered nutrient content claims, and would have to comply with requirements governing the use of such claims. For example, claims would have to be accompanied by a "referral statement" directing consumers' attention to nutrition labeling.
Claims for foods that inherently meet nutrient "free" or "low" definitions would have to be distinguished in wording from the unqualified claim (e.g., "peanut butter, a cholesterol free food"). "Reduced" and comparative claims (e.g., "less fat") would have to be explained. Claims, except "reduced," generally would be permitted for "meal-type products" under definitions similar to those governing single food items, i.e., a product containing ingredients from two of four food groups, and providing at least 200 calories per serving or weighing six ounces per serving.

Generally, a food product would be permitted to bear a fat, fatty acid, or cholesterol content claim only if it qualified for the claim at both the product's labeled serving size and the "reference amount" established by FDA for the relevant category of food. Certain claims for meal-type products would be defined per 100 grams of food.

FDA has proposed to permit label use of only defined fat, fatty acid, and cholesterol content descriptors. Use of undefined descriptors may constitute misbranding. Use of a defined claim triggers nutrition labeling.

B. Total Fat Claims/Descriptors

FDA proposed to define "fat free," "low fat," "reduced fat," comparative ("less fat") claims, "___% fat free," and specific synonymous descriptors. Parameters for appropriate use of these claims would include the following:

be permitted for foods that contain less than 0.5 gram of fat and no added ingredient that is a fat or oil.

2. "Low Fat": "Low fat," "low in fat," "contains a small amount of fat," "low source of fat," and "little fat" would be permitted in labeling foods that contain 3 grams or less of fat.

3. "Reduced Fat": "Reduced fat," "reduced in fat," and "fat reduced" would be permitted in labeling foods that have been specifically formulated or processed to reduce fat content by 50% or more, with a minimum reduction of more than 3 grams of fat in comparison to a reference food.

4. Comparative ("Less Fat") Claims: Comparative claims using the term "less" would be permitted in labeling foods that contain at least 25% less fat, with a minimum reduction of more than 3 grams of fat in comparison to a reference food.

5. "__% Fat Free": "__% fat free" would be permitted in labeling foods that meet the definition of "low fat." The amount of total fat per serving (expressed to the nearest gram) would have to be disclosed in immediate proximity to the claim.

C. Fatty Acid Claims/Descriptors

FDA proposed to define "low in saturated fat," "reduced saturated fat," comparative ("less saturated fat") claims, and specific synonymous descriptors. Parameters for appropriate use of these claims include the following:

1. "Low in Saturated Fat": "Low in saturated fat," "low saturated fat," "contains a small amount of saturated fat," "low source of saturated fat," and "a little saturated fat" would be permitted in labeling foods that contain 1 gram or less of saturated fat and derive not more than 15% of calories from saturated fat.
2. "Reduced Saturated Fat": "Reduced saturated fat," "reduced in saturated fat," and "saturated fat reduced" would be permitted in labeling foods that have been specifically formulated or processed to reduce saturated fat content by 50% or more, with a minimum reduction of more than 1 gram in comparison to a reference food.

3. Comparative ("Less Saturated Fat") Claims: Comparative claims using the term "less" would be permitted in labeling foods that contain at least 25% less saturated fat, with a minimum reduction of more than 1 gram in comparison to a reference food.

4. The levels of total fat and cholesterol in a food would have to be disclosed in immediate proximity to any of these defined saturated fat claims, except declaration of cholesterol content may be omitted when the food contains less than 2 milligrams of cholesterol.

D. Cholesterol Claims/Descriptors

FDA proposed to define "cholesterol free," "low cholesterol," "reduced cholesterol," comparative ("less cholesterol") claims, and specific synonymous descriptors. Parameters for appropriate use of these claims include the following:


2. "Low Cholesterol": "Low cholesterol," "low in cholesterol," "contains a small amount of cholesterol," "low source of cholesterol," and "little cholesterol" would be permitted in labeling foods that contain 20 milligrams or less of cholesterol.
3. "Reduced Cholesterol": "Reduced cholesterol," "reduced in cholesterol," and "cholesterol reduced" would be permitted in labeling foods that have been specifically formulated or processed to reduce cholesterol content by 50% or more, with a minimum reduction of more than 20 milligrams in comparison to a reference food.

4. Comparative ("Less Cholesterol") Claims: A comparative claim using the term "less" would be permitted in labeling foods that contain at least 25% less cholesterol, with a minimum reduction of more than 20 milligrams in comparison to a reference food.

5. Use of these cholesterol content claims, including "reduced cholesterol" and comparative claims, would be prohibited on foods that contain more than 2 grams of saturated fat.

6. Cholesterol claims would be permitted on foods containing more than 11.5 grams of fat only if the level of total fat is disclosed in immediate proximity to the claim.

7. Food products containing more than 11.5 grams of total fat would be permitted to claim "cholesterol free" or "low cholesterol" only if (i) the relevant cholesterol content threshold is met, and (ii) the food contains at least 25% less cholesterol, with a minimum reduction of more than 20 milligrams in comparison to a food having a "significant market share," (5% or more share) and (iii) the claim is explained.

XI. SUBSTITUTE FOODS NAMED BY COMBINING A NUTRIENT CONTENT CLAIM AND A STANDARDIZED FOOD NAME — FDA PROPOSED RULE

A. General Rule

FDA's proposed rule would permit modified foods that substitute for traditional standardized foods to be named by combining a nutrient content claim and the name of the standardized food. Proposed 21 C.F.R. § 101.30(e). The food would have to meet FDA's definition for the nutrient content claim in question.
Proposed § 101.30(a). Some deviations from the standard of identity's compositional requirements would be permitted, as discussed below. A food that meets FDA's proposed requirements would not have to be labeled with a name including the terms "substitute" or "alternate."

For example, FDA has proposed that a "reduced fat" food would have to exhibit a 50% fat reduction, with a minimum fat reduction of more than 3 grams per serving. Cheddar cheese, a standardized food, contains 10 grams fat per 30 gram serving. Under the proposal, "reduced fat cheddar cheese" would have to contain 5 grams or less fat per 30 gram serving.

The modified food would also have to include any required disclosures on the principal display panel (PDP) for the nutrient content claim in question. For example, "reduced fat cheddar cheese" would have to include a PDP statement such as "contains 50% less fat than regular cheddar cheese, fat content has been reduced from 10 grams to 5 grams per serving."

This proposal does not affect existing standards of identity that already incorporate nutrient content claims, e.g., "low fat cottage cheese."

B. Performance Characteristics

FDA proposed that a modified product bearing the standardized name would have to have similar "performance characteristics" to the traditional, standardized food. Performance characteristics include factors such as physical properties (texture, melting point, freezing point), flavor characteristics (aroma and taste),
functional properties (body, spreadability) and shelf life. If a modified product differs from the traditional standardized food in any performance characteristic, this fact must be stated on the label. Proposed § 130.10(c). For example, if a "reduced fat margarine" does not perform the same as regular margarine for use in frying, a statement such as "not recommended for frying purposes" would have to appear on the PDP, with specific proposed placement and typesize requirements.

C. Ingredients

1. Added Nutrients To Avoid Nutritional Inferiority

The proposal does not change FDA's longstanding requirement that modified foods that are nutritionally inferior to the traditional foods for which they substitute must be labeled as "imitation." However, FDA has recognized that modification of a traditional standardized food may inadvertently remove significant quantities of some nutrients. FDA proposed that any such inadvertently removed nutrients could be added to the modified product, even if not permitted by the standard of identity for the traditional food. Any added nutrients would have to be included in the ingredients statement. Proposed § 130.10(b).

For example, liquid eggs that have been modified to reduce the cholesterol content may be nutritionally inferior to traditional liquid eggs because the special processing may inadvertently remove significant quantities of Vitamin A. Under the proposal, Vitamin A could be added to "reduced cholesterol liquid eggs" even though
the liquid eggs standard of identity does not provide for the addition of Vitamin A.

2. Other "Safe And Suitable" Ingredients

FDA recognized that some product composition changes may be necessary to attain an acceptable finished product that meets the requirements of the nutrient content claim. FDA proposed in § 130.10(d)(1) that, in addition to ingredients permitted by the traditional standard, other "safe and suitable" ingredients may be used to improve texture, add flavor, prevent syneresis (e.g., prevent the separation of peanut butter), or extend shelf life so that the product is not inferior in performance characteristics to the traditional standardized food. If any flavor ingredients are added to a modified standardized product, the label must comply with FDA's existing flavor labeling regulation.

3. Ingredient Labeling

To assist consumers in differentiating between the traditional standardized food and the modified version of that food, FDA proposed that all ingredients added under the "safe and suitable" provision (proposed § 130.10(d)(1)), as well as ingredients permitted by the traditional standard that are added at levels in excess of those allowed by the traditional standard, would have to be appropriately identified as such with an asterisk in the ingredients statement. A statement such as "*Ingredients not in regular ____" or "*Ingredients in excess of amount permitted in regular ____" would be required to appear immediately following the ingredients statement. However, nutrients added to restore
nutrients inadvertently removed by special processing would not have to be identified by an asterisk in the ingredients statement. Proposed § 130.10(f)(2).

4. **Use Of Similar Ingredient**

Under the proposal, a manufacturer's ability to use "safe and suitable" ingredients not provided for by the traditional standard does not extend to substituting a similar ingredient for one required by the standard. Proposed § 130.10(d)(2). For example, the substitution of vegetable oil for milk fat to produce "cholesterol free sour cream" would not be permitted.

5. **Ingredients Prohibited By The Standard**

Some standards of identity specifically prohibit the addition of certain ingredients to those standardized foods. FDA proposed that such prohibited ingredients likewise could not be added to a modified food. Proposed § 130.10(d)(3).
Use of Biotechnology in the Food Industry

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Presented at the 10th Biennial Cheese Conference, Logan, UT.

Biotechnology is a buzz word that is used for a variety of technologies. The word biotechnology can be used in the medical industry to refer to new methods of drug production or to the use of gene therapy in humans to treat genetic diseases. In the food industry, biotechnology also has a wide definition. The same types of scientific activities used in the medical industry are used in the food industry, such as biochemistry, molecular genetics, microbiology, and process engineering. It can be said the application of these disciplines to commercially produce or improve food for consumption is biotechnology in the food industry.

Food science is inherently multidisciplinary, meaning food production draws knowledge from many areas of science to produce safe food products for consumption. So, the use of biotechnology in the food industry should not be foreign because biotechnology is also a multidisciplinary activity. Food processing and development uses protein chemistry, biochemistry, analytical chemistry, molecular genetics, animal physiology, and process engineering - some of the same technologies as biotechnology. Why then is biotechnology looked at differently when talking medicinal treatments and food processing? Biotechnology is a bag of tool that can be applied to solve problems in many areas of society, but the use and application must be safe.
The food industry has many applications for biotechnology (Table 1). Each application within the food industry has many questions that can be answered using tools from biotechnology.

<table>
<thead>
<tr>
<th>Application</th>
<th>Use of Biotechnology</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fermentation</td>
<td>yeast strain improvement, yield increase, new processing conditions, spoilage control</td>
</tr>
<tr>
<td>Baking</td>
<td>yeast and bacterial strain improvement, process control, pathogen control, spoilage control</td>
</tr>
<tr>
<td>Meat</td>
<td>bacterial strain improvement, improved preservation methods, low-fat products, pathogen control</td>
</tr>
<tr>
<td>Dairy</td>
<td>bacterial strain improvement, increased yield, antibiotic-free milk, novel uses of fat, low-fat products, cheese ripening, sanitation, probiotic products, microbial stabilizers, low cholesterol</td>
</tr>
<tr>
<td>Flavor</td>
<td>production of natural flavors</td>
</tr>
<tr>
<td>Food Crops</td>
<td>shelf life extension of fruits and vegetables, resistance to disease, tolerance to cold, reduced post-harvest enzymes, altered nutrient levels</td>
</tr>
</tbody>
</table>

Use of biotechnology by the food industry is inevitable. By the year 2000 the worldwide agriculture and food processing market is estimated to be $9.5 to $100 billion.

Biotechnology will play an ever increasing role in the production of food, and more
importantly, dairy products because production costs can be decreased, quality increased, and new products developed.

Dairy processing has used biotechnological-derived products extensively for coagulation enzymes. Due to the high cost of raw materials for production of rennet, dairy scientists began investigating alternative enzymes to clot milk. Initially, enzymes from yeast or microbes were used. These enzymes were used with varied success, each has activities that rennet does not have against milk proteins. Consequently, defects were noticed with some of the alternative coagulants. This led to the desire by many to use molecular genetics to produce chymosin (a product of cows) in another organism - recombinant chymosin was born. Recombinant chymosin produced in Escherichia coli K12 was approved for use in the US March 23, 1990 and is being sold by Pfizer, Inc. Two other organisms, both yeast, are also used to produce recombinant chymosin - Aspergillus niger var. awamori and Kluyveromyces lactis. Government approval was long in coming and required extensive documentation regarding food safety, enzyme structure, and selection methodology for Pfizer. Since the food industry is the largest user of enzymes of any industry, it is expected that recombinant enzymes will become more important and common in food processing.

Another area biotechnology has played a role is in development of bacteriophage (phage) resistant starter cultures. Todd Klaenhammer and Marshall Products (Madison, WI) disseminated a plasmid (pTR2030) encoding phage resistance into different strains of lactococci and followed the conjugal transfer using antibiotic resistance markers. Strains that received pTR2030 became phage resistant and were used in field trials with success (Sanders, 1986). These and other data provide evidence that genetic techniques are useful in making phage resistant starter cultures that retain other important characteristics for use in the dairy industry.

Other applications of biotechnology to starter cultures have been used in Europe to modify the proteolytic capabilities. All naturally produced proteinases of lactococci
have been characterized as serine proteinases which are different in only a few amino
acids (Kok, 1990). Serine proteinases of starter cultures can be divided into type PIII,
cleaving α- and β-casein, and type PI, cleaving only β-casein. Hybrid enzymes,
showing different specificities from either type, were constructed by simply cloning the
genes for these enzymes. This is significant because it opens the door for the possibility
of engineering specific types of proteinases in starter cultures. Other important areas
for the application of biotechnology to the dairy industry include flavor and texture
enhancement, accelerated ripening of cheese, production of bacteriocins and other
natural antimicrobials, polysaccharide production, control of flavor defects, probiotic
products, production of food grade enzymes and heterologous proteins, improved
cultures for low-fat dairy products, cold-sensitive yogurt starter cultures, and starter
cultures that can withstand freeze-drying.

Before biotechnological systems may be commercially applied to foods, safety of
new products and techniques must be verified and approved by the Food and Drug
Administration (FDA) and the United States Department of Agriculture (USDA). The
Federal Food, Drug, and Cosmetic Act gives the FDA the authority to demand and
enforce the production of a safe food supply. To coordinate policy and enforcement
between the many agencies of government, the Executive Office of the President, Office
of Science and Technology established the Biotechnology Science Coordination
Committee (BSCC). The committee designed a coordinated framework for the
regulation of biotechnology indicating new products, derived from biotechnology,
should be reviewed in essentially the same manner as products manufactured under
more traditional processes (USA, 1986). FDA is attempting to foster innovative
products by assuring “whole food safety” before foods from recombinant plants before
they enter the market and once in the market not requiring them to be marked
distinctively (Kessler et al., 1992).
Commercial manufacturers of dairy foods are subject to regulations from both FDA and USDA. FDA sets forth standards of identity describing and defining characteristics of individual dairy products, while USDA regulates grading of finished dairy products (USA, 1986). FDA, however, regulates production of food stuffs, therefore the organisms or products derived from biotechnology for dairy foods applications should require approval from FDA only prior to use in food (Kessler, 1992). A prime example of this is Kiwifruit, a breeding hybrid of a berry plant native to Asia that transformed.

Important questions exist for the dairy industry regarding how the agency views genetically altered microorganisms. FDA policy toward biotechnology has focused upon a case by case basis for review and approval, but it is apparent that this approach will soon become too bulky and slow for the rapidly changing biotechnology developments in the food industry. Kessler (1992) describes decision trees that put the burden on the company to show the food produced via biotechnology is safe and that the methods for production, and that the food produces the expected result in the consumer. Recombinant chymosin has various protein forms depending what organism is used to produce the protein. This was a major stumbling block for Pfizer, but it appears FDA is backing down from this because minor alterations in proteins will be allowed and will not constitute a reason to question food safety (Kessler, 1992).

The method of moving DNA between organisms is also a question. While transduction (moving DNA via phage) and conjugation (cell to cell contact) are documented physiological processes among lactic acid bacteria, natural transformation (uptake of DNA from the environment) systems in these organisms have not been identified. Transformation is usually achieved via a technique known as electroporation. This method is based on artificially imposed conditions causing physical events in the cell wall to change rather than natural cellular events. Opinion of
bacteria improved by transformation remains unknown, even if recombinant DNA molecules have not been employed in the construct.

One of the most significant discoveries in lactic acid bacteria has been that many important traits for milk fermentations are encoded by plasmid DNA. Plasmids are extrachromosomal, autonomously replicating bits of DNA that can be shifted to other bacteria. An important distinction needs to be made between the method of transferring DNA and the source of the DNA being transferred for regulatory purposes. As of yet this has not been addressed by the FDA, but it appears that the company producing the food will be responsible for investigating the DNA molecule for other possible products other than those of interest and intention. Interests of the dairy industry would certainly be served if the question of how the FDA will address intraspecific and intergeneric genetic constructs of transformed GRAS bacteria, which use whole, unaltered plasmids from other GRAS bacteria. Recently Kessler (1992) provided hope that food systems will be looked at as a "whole system" rather than a multitude of individual components, each of which must be cleared by the FDA.

The criteria for FDA review of organisms obtained through the use of recombinant DNA has been established (USA, 1986) and expounded on recently (Kessler, 1992). It remains unclear, however, whether the agency would consider a transformed GRAS organism, which contained a recombinant DNA molecule derived entirely from other GRAS bacteria, as GRAS or as a food additive. Approval of new recombinant products require considerable time and expense. Thus, GRAS affirmation may be even more laborious to a company than approval as an additive. Because of the potential expense, clarification of the FDA position is critical if biotechnology is to be accepted by the dairy industry. Although, non-clinical safety testing is being given a chance to test new foods as a whole, but it is presenting new problems in testing methodology (Kessler, 1992).
In an effort to resolve some questions and address the use of biotechnology in human food, an expert panel, The International Food Biotechnology Council (IFBC), was formed in 1988. In 1990, IFBC proposed a series of procedures to assist regulatory evaluation and safety determination of biotechnology products (IFBC, 1990). For safety evaluation of whole foods produced by microorganisms, IFBC recommended regulatory agencies first consider the origin of all nucleic acids used to make the recombinant DNA. Secondly, look for new food constituents resulting from the new construct, and finally, examine the new product for its effects to alter the intake levels of food constituents among consumers. These recommendations seem to have had a large impact because Kessler (1992) has adopted them, almost in full. Using these recommendations allows cultures constructed entirely from GRAS microbes and DNA, regardless of the technology employed in the construct, to retain GRAS status. If this is the case then, the road for biotechnology in the food industry has just been paved for a smooth ride.

References


PHARM ANIMALS: MILK AS A SOURCE OF BIOLOGICS
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The mammary gland of various farm animals (cows, sheep, goats and pigs) could serve as bioreactors for production of specific biopharmaceutical proteins. Milk as it exists today is a complex mixture of well over 50 discrete protein components, several of which have already been utilized in certain product applications (bovine immunoglobulins, lactoferrin, and lactoperoxidase). By introducing foreign genes into the germline of animals the mammary gland could produce foreign proteins in large quantities. Based on results in other species, it would be realistic to predict the production of 100 kg/year of a specific protein in the milk of a transgenic cow. Transgenic farm animals such as sheep, goats, and pigs are currently being developed to produce specific biopharmaceutical proteins in their milk. Transgenic cows represent a much longer development cycle which could be used for production of specific proteins for infant formulas or in increasing cheese yields.
CHEMISTRY OF Fe(III)-MILK PROTEIN COMPLEXES AS RELATED TO IRON-FORTIFIED CHEESE

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Iron deficiency is a major nutritional problem affecting hundreds of millions of people all over the world, and is especially prevalent in infants, young children and women of child-bearing age in the US (Dallman et al., 1984; Hurrell and Cook, 1990). Iron deficiency can be overcome by increasing iron intake, either with supplemental medicinal iron, or by fortification of the food supply. Fortification of the food is generally considered the best long-term approach for combating iron deficiency. However, a successful fortification program depends on the correct choice of food vehicle. Universality of consumption of milk and milk products makes them potentially good vehicles for delivering iron in the diet. Attempts to fortify fluid milk with iron have not been successful due to the off-flavor problems associated with it (Coccodrilli and Shaw, 1985); however, cheese with its unique physicochemical properties may be congenial for iron-fortification. To this end our laboratory has successfully developed iron-fortified Cheddar cheese by adding ferric iron sources to milk before renneting (Zhang and Mahoney, 1989a, 1989b, 1990 and 1991). Trained and lay panel of judges determined that the flavor characteristics of iron-fortified Cheddar cheese were comparable with those of unfortified control cheese; studies with rats indicated high iron bioavailability. However, for a successful commercialization of iron-fortification technology of cheese, it is essential to understand the mechanism and thermodynamics of iron-milk protein complex formation, and the functional and stability characteristics of iron-milk protein complexes. Elucidation of the mechanism would provide the information to enable the dairy processor to optimize the processing conditions for manufacturing high quality iron-fortified cheese. In this paper, we present (i) the binding of Fe(III) to \( \alpha_5 \)-casein (\( \alpha_5 \)-CN), \( \beta \)-casein (\( \beta \)-CN), \( \kappa \)-casein (\( \kappa \)-CN), \( \beta \)-lactoglobulin (\( \beta \)-LG), \( \alpha \)-lactalbumin (\( \alpha \)-LA) and bovine serum albumin (BSA) at pH 6.60,
(ii) the iron-induced conformational changes in proteins at pH 6.60, (iii) the effect of iron on renneting properties of milk, and (iv) the effect of pH and NaCl concentration on the binding of Fe(III) to \( \alpha_{s1}-CN \).

**Binding of Fe(III) to Caseins and Whey Proteins**

Binding of Fe(III) to \( \alpha_{s1}-CN, \beta-CN, \kappa-CN, \beta-LG, \alpha-LA \) and BSA was studied at pH 6.60 using diafiltration method and the binding data analyzed by Scatchard equation. Binding of Fe(III) to proteins increased with an increase in free Fe(III) concentration, but the amount bound to different proteins at a given free Fe(III) concentration varied indicating the differences in their binding affinities. Scatchard analysis of the data indicated that \( \alpha_{s1}-CN, \beta-CN, \kappa-CN \) and BSA have at least two groups of non-identical binding sites, whereas \( \beta-LG \) and \( \alpha-LA \) have single class of binding sites. It appears that first group of binding sites in both caseins and BSA are preferentially filled and have higher binding affinities compared to the second group of binding sites. Relative binding of Fe(III) to proteins follows the order: \( \alpha_{s1}-CN > \beta-CN > BSA > \kappa-CN > \beta-LG > \alpha-LA \). Free energy change \( (\Delta G = -RT \ln K) \) calculated for the binding of Fe(III) to different proteins was negative and low in magnitude indicating that the binding is instantaneous and thermodynamically favorable. Thus, both the caseins and whey proteins are capable of forming complexes with Fe(III) at pH 6.60.

**Possible Amino Acid Side Chain Groups Involved in the Binding of Fe(III) to Proteins**

Difference absorption spectra of Fe(III)-protein complexes in the visible region (350 to 650 nm) were carried out to determine the possible amino acid side chain groups involved in the binding of Fe(III) to different casein and whey protein fractions. Negative absorption bands in 420-421 nm region, and positive absorption bands in 470-471, 491-492 and 560-562 nm region were observed for \( \alpha_{s1}-CN \) and \( \beta-CN \), where as positive absorption bands in 421-424, 470-471, 491-492 and 562-568 nm region were observed for \( \kappa-CN \), BSA, \( \beta-LG \) and \( \alpha-LA \). The spectra of different model amino acid-Fe(III) complexes revealed that the negative absorption band in 420-421 nm region was due to phosphorylserine-Fe(III) complexes and positive absorption band in 560-565 nm region was due to carboxyl-Fe(III) complexes, whereas the positive absorption bands in 470-471 nm and 490-492 nm region were possibly due to a chelate site involving carboxyl, nitrogen and oxygen groups. Thus, phosphorylserines and carboxyl groups of Asp and Glu seem to play a major role in the binding of Fe(III) by \( \alpha_{s1}-CN \) and \( \beta-CN \), where as carboxyl groups of Asp and Glu seem to play a major role in the binding of Fe(III) by \( \kappa-CN \), BSA, \( \beta-LG \) and \( \alpha-LA \).
Iron(III)-Induced Conformational Changes in Proteins

Conformational changes in proteins, especially, changes in the environment of aromatic side chains in proteins as a result of binding Fe(III) were monitored by following fluorescence emission after excitation at 280nm. Addition of Fe(III) caused a decrease in fluorescence intensity together with a red shift of the emission maximum indicating that binding of Fe(III) to proteins induced conformational changes resulting in the exposure of tryptophan and tyrosine residues to a more polar environment. The Fe(III)-induced conformational changes in caseins may affect the rennet clotting behaviour of casein micelles during cheese making.

The Effect of Fe(III) on Renneting Properties of Milk

(a) Iron addition to pasteurized (cheese) milk. The kinetics of chymosin hydrolysis and rennet clotting time (RCT) as a function of FeCl₃ (0 to 0.86 mM) addition to pasteurized (cheese) milk were determined (Reddy and Mahoney, 1992). Ferric chloride did not affect the rate of enzymic reaction, but increased RCT of skim milk. Addition of FeCl₃ resulted in a slight increase in RCT of whole milk, which remained constant at all iron concentrations.

(b) Iron addition to milk before pasteurization. Addition of varying amounts of FeCl₃ to milk before pasteurization on the rate of chymosin hydrolysis and RCT were determined (Reddy and Mahoney, 1992). FeCl₃ had no effect on the rate of enzymic reaction, although it affected RCT. Rennet clotting time of both the whole and skim milk decreased with increasing concentration of FeCl₃.

Effect of pH and NaCl on the Binding of Fe(III) to αₛ₁-Casein

Because the pH of cheese decreases due to microbial action and NaCl concentration increases due to salting, the effect of pH and NaCl on the binding of Fe(III) to αₛ₁-casein (major protein in casein micelles) was evaluated (Reddy and Mahoney, 1991). Binding of Fe(III) to αₛ₁-casein was studied as a function of pH (5.6, 6.1, 6.6, 7.2, and 7.8) and NaCl concentration (0.1 and 0.5 M) using diafiltration method. Results indicated that the number of iron binding sites on the protein were not influenced by either change in pH or NaCl concentration. However, binding affinity of Fe(III) to protein increased as the pH was decreased from 7.8 to 5.6, while it decreased as the NaCl concentration was increased from 0.1 to 0.5 M. Free energy change (\(\Delta G = -RT \ln K\)) calculated for the binding of Fe(III) to αₛ₁-casein at different pHs and NaCl concentrations was negative and low in magnitude (-3.79 and -7.28 k cal M⁻¹) indicating that the binding of Fe(III) to protein is instantaneous and thermodynamically favorable. Thus, from the practical point of view,
the binding affinity of Fe(III) increases as the pH of milk is lowered by microbial action during cheese making.

Acknowledgements

The financial support of the Western Center for Dairy Proteins Research and Technology and National Dairy Promotion and Research Board is greatfully acknowledged.

References


IRON FORTIFIED CHEESE

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Iron deficiency anemia is still the most prevalent nutritional problem in the US and world today (Stoskman 1987). Infants and children, adolescents, pregnant women, women at child bearing age and the elderly are the population groups most vulnerable to iron deficiency (Baker and DeMaeyer 1979, Dallman et al. 1980). The Second National Health and Nutrition Examination Survey (NHANES II) estimated that the prevalence of iron deficiency anemia in the U.S. is at 5.7% for 1-2 year-old infants, 5.9% for 15-17 year-old girls, 4.5% for young women and 4.8% for elderly men (Dallman et al. 1984). In British Isles, 40% of the adolescents (94 out of 234) are iron depleted based on serum ferritin concentration less than 10 ng/ml (Armstrong 1989). It is hard to increase iron intake by dietary manipulation because some frequently consumed foods contain very little iron. Thus, to increase dietary iron levels, iron is fortified into various food products. Dairy products are widely consumed providing high quality proteins, vitamins and minerals except iron. Lack of iron in dairy products decreases the iron-density of diets when the proportion of dairy products in the diets increases (Farley et al. 1987). So, it is logical that fortifying dairy products with iron may increase dietary iron-density of the people who consume large amounts of dairy products. Iron fortification will promote nutritional quality of dairy products, then promote their marketing.

Three iron sources, ferric chloride, iron-casein and iron-whey protein complexes were chosen to fortify cheeses. The quality of iron fortified cheese was determined for Cheddar and process cheeses at pilot scale and for Cheddar cheese at commercial scale. Bioavailability of fortified iron has been determined using a rat model. A human study on bioavailability of iron fortified cheese is currently underway.
Iron fortified Cheddar cheese, pilot study (Zhang and Mahoney 1989a, 1990)

Iron fortified Cheddar cheeses were made in a laboratory vat from 330 pounds of milk. Thiobarbituric acid substances (TBARS), an indicator of autoxidative damage, was determined. Oxidized off-flavor and cheese flavor were determined by an expert taste panel. Iron fortification of Cheddar cheese did not significantly increase TBARS of cheese and did not change oxidized off-flavor and cheese flavor of the cheese (Table 1). To mimic market condition, iron fortified cheeses were exposed to fluorescent lights for 28 days and TBARS were determined. Compared to control cheese, TBARS of iron fortified cheese did not change during 28 days exposure (Table 2).

Iron fortified process cheese, pilot study (Zhang and Mahoney 1991)

Four batches of process cheese were made in a steam-jacketed kettle of five-pound capacity. TBARS and sensory evaluation were conducted at 10, 30 and 90 days after cheese was made. TBARS, oxidized off-flavor and cheese flavor of iron fortified cheese did not change comparing to control cheese (Table 3). Hedonic values (a score system composed of a series of scores from dislike extremely from 1 to like extremely from 1 to 9) of 94 panelists were also not significantly different among iron fortified and control cheeses (Table 4).

Iron fortified Cheddar cheese, commercial scale

Iron fortified cheese has been made from 55,000 pound of milk in a commercial vat. TBARS of iron fortified cheese did not increase significantly comparing to the control cheese. Sensory evaluation using Hedonic assay by open taste panelists has shown that cheese fortified with FeCl₃ has the same quality as control cheese. Market surveys have shown that about 80% of panelists are willing to buy FeCl₃ fortified cheese, which is similar to the percentage of people willing to buy control cheese.

Bioavailability of iron from fortified cheese using rat model (Zhang and Mahoney 1989b)

Fortified iron in Cheddar cheese was well utilized by rats. Hemoglobin regeneration efficiency (HRE) were 75, 66 and 67% for cheeses fortified with FeCl₃, Fe-casein and Fe-whey protein, respectively. Compared to a HRE of 85% for FeSO₄, a highly absorbable iron source, iron from fortified cheese will be a good dietary iron source.
Human bioavailability of iron from fortified cheese

A human study on bioavailability of iron in fortified Cheddar cheese is currently underway. From preliminary results, the iron in fortified cheese is well utilized by human subjects compared to other iron fortified products such as infant cereals.

Dietary iron contributed by iron fortified cheese

At the level of iron fortification in commercially made cheese, iron content increases significantly, which would promote cheese from a non-iron product to an iron source product (Table 5).

Cost of iron fortified cheese

At a fortification level of 60 mg/kg cheese, the cost of FeCl₃ is about 0.14 cents per pound cheese if highly purified FeCl₃ is purchased. When food grade FeCl₃ is available, this added cost would decrease.

References


### TABLE 1. TBARS values and expert taste panel scores of iron-fortified cheese

<table>
<thead>
<tr>
<th>Iron Source</th>
<th>Control</th>
<th>FIP-WP</th>
<th>Fe-casein</th>
<th>Fe-WP</th>
<th>FeCl₃</th>
<th>LSD¹</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cheese Fe, μg/g</td>
<td>1</td>
<td>39</td>
<td>40</td>
<td>39</td>
<td>42</td>
<td>---</td>
</tr>
<tr>
<td>TBARS</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>7 days</td>
<td>0.00</td>
<td>0.00</td>
<td>0.00</td>
<td>0.00</td>
<td>0.00</td>
<td>---</td>
</tr>
<tr>
<td>1 month</td>
<td>0.00</td>
<td>0.00</td>
<td>0.00</td>
<td>0.00</td>
<td>0.00</td>
<td>---</td>
</tr>
<tr>
<td>4 months</td>
<td>0.05</td>
<td>0.16</td>
<td>0.16</td>
<td>0.12</td>
<td>0.18</td>
<td>---</td>
</tr>
<tr>
<td>7 months</td>
<td>0.00</td>
<td>0.03</td>
<td>0.00</td>
<td>0.03</td>
<td>0.05</td>
<td>---</td>
</tr>
<tr>
<td>9 months</td>
<td>0.02</td>
<td>0.03</td>
<td>0.10</td>
<td>0.06</td>
<td>0.07</td>
<td>---</td>
</tr>
<tr>
<td>12 months</td>
<td>0.03</td>
<td>0.08</td>
<td>0.07</td>
<td>0.07</td>
<td>0.07</td>
<td>---</td>
</tr>
<tr>
<td>Taste panel score²</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Oxidized off-flavor</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>15 days</td>
<td>1.4ᵃ</td>
<td>4.2ᶜ</td>
<td>3.6ᶜ</td>
<td>2.0ᵃᵇ</td>
<td>3.1ᵇᶜ</td>
<td>1.5</td>
</tr>
<tr>
<td>1 month</td>
<td>3.4</td>
<td>3.0</td>
<td>4.8</td>
<td>4.0</td>
<td>2.8</td>
<td>NS</td>
</tr>
<tr>
<td>4 months</td>
<td>3.3</td>
<td>3.8</td>
<td>4.2</td>
<td>4.8</td>
<td>4.5</td>
<td>NS</td>
</tr>
<tr>
<td>7 months</td>
<td>3.2</td>
<td>3.0</td>
<td>3.8</td>
<td>5.2</td>
<td>5.3</td>
<td>NS</td>
</tr>
<tr>
<td>9 months</td>
<td>2.9</td>
<td>3.6</td>
<td>2.4</td>
<td>4.0</td>
<td>3.5</td>
<td>NS</td>
</tr>
<tr>
<td>12 months</td>
<td>3.1</td>
<td>3.4</td>
<td>5.6</td>
<td>5.7</td>
<td>4.3</td>
<td>NS</td>
</tr>
<tr>
<td>Cheese flavor</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>15 days</td>
<td>6.7</td>
<td>4.8</td>
<td>6.0</td>
<td>5.6</td>
<td>5.5</td>
<td>NS</td>
</tr>
<tr>
<td>1 month</td>
<td>5.9ᵇᶜ</td>
<td>7.7ᵃ</td>
<td>5.5ᶜ</td>
<td>6.4ᵃᵇᶜ</td>
<td>7.0ᵃᵇ</td>
<td>1.4</td>
</tr>
<tr>
<td>4 months</td>
<td>6.0</td>
<td>4.9</td>
<td>4.4</td>
<td>3.8</td>
<td>4.7</td>
<td>NS</td>
</tr>
<tr>
<td>7 months</td>
<td>5.9</td>
<td>6.1</td>
<td>5.8</td>
<td>5.3</td>
<td>4.8</td>
<td>NS</td>
</tr>
<tr>
<td>9 months</td>
<td>5.4ᵇᶜ</td>
<td>4.4ᶜ</td>
<td>7.2ᵃ</td>
<td>4.8ᵇᶜ</td>
<td>5.6ᵇ</td>
<td>1.2</td>
</tr>
<tr>
<td>12 months</td>
<td>6.5</td>
<td>6.5</td>
<td>5.6</td>
<td>4.0</td>
<td>6.2</td>
<td>NS</td>
</tr>
</tbody>
</table>

ᵃ,ᵇ,ᶜ Means with the same superscripts are not significantly different (P>0.05).

¹ Least significant difference values were calculated when F was larger than F₀.₀₅ (P < 0.₀₅). NS means not statistically significant (P>0.₀₅).

² Taste panel scores were set from 1 to 10. For oxidized flavor, the higher score indicated a stronger flavor. For cheese flavor, the higher score indicated a better quality. Each value is a mean of 10 panelists.
TABLE 2. Increase in TBARS in the surface layer of iron fortified cheese exposed to fluorescent lights for 28 d

<table>
<thead>
<tr>
<th>Cheese</th>
<th>0 d</th>
<th>3 d</th>
<th>7 d</th>
<th>14 d</th>
<th>28 d</th>
</tr>
</thead>
<tbody>
<tr>
<td>Control</td>
<td>0.00</td>
<td>0.01</td>
<td>0.06</td>
<td>0.09</td>
<td>0.08</td>
</tr>
<tr>
<td>FIP-WP</td>
<td>0.03</td>
<td>0.01</td>
<td>0.06</td>
<td>0.13</td>
<td>0.07</td>
</tr>
<tr>
<td>Fe-casein</td>
<td>0.00</td>
<td>0.01</td>
<td>0.06</td>
<td>0.12</td>
<td>0.09</td>
</tr>
<tr>
<td>Fe-WP</td>
<td>0.03</td>
<td>0.06</td>
<td>0.06</td>
<td>0.12</td>
<td>0.09</td>
</tr>
<tr>
<td>FeCl₃</td>
<td>0.05</td>
<td>0.01</td>
<td>0.06</td>
<td>0.12</td>
<td>0.08</td>
</tr>
</tbody>
</table>

1 Cheeses aged 6 months were cut into about 0.4 kg blocks, re-vacuum packaged in polyethylene bags, and then exposed continuously to fluorescent lights at 1280 lux in a room at 10°C. The first 2 mm from the surface exposed to the lights was cut for TBARS assay.

TABLE 3. Iron contents and qualities of iron fortified process cheddar cheese

<table>
<thead>
<tr>
<th>Process cheese</th>
<th>Control</th>
<th>Fe-casein</th>
<th>Fe-WP</th>
<th>FeCl₃</th>
<th>LSD, a=0.05</th>
</tr>
</thead>
<tbody>
<tr>
<td>Iron content, mg/kg</td>
<td>2</td>
<td>41</td>
<td>39</td>
<td>39</td>
<td>---</td>
</tr>
<tr>
<td>Moisture, %</td>
<td>37.3</td>
<td>37.2</td>
<td>37.2</td>
<td>37.3</td>
<td>---</td>
</tr>
<tr>
<td>Fat, %</td>
<td>32.2</td>
<td>33.6</td>
<td>33.6</td>
<td>34.6</td>
<td>---</td>
</tr>
<tr>
<td>TBARS</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>10 d</td>
<td>.05</td>
<td>.07</td>
<td>.06</td>
<td>.11</td>
<td>---</td>
</tr>
<tr>
<td>30 d</td>
<td>.09</td>
<td>.10</td>
<td>.09</td>
<td>.09</td>
<td>---</td>
</tr>
<tr>
<td>90 d</td>
<td>.08</td>
<td>.10</td>
<td>.12</td>
<td>.08</td>
<td>---</td>
</tr>
<tr>
<td>Taste panel score¹</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Oxidized off-flavor</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>10 d (8)²</td>
<td>2.8</td>
<td>2.4</td>
<td>3.0</td>
<td>3.1</td>
<td>NS</td>
</tr>
<tr>
<td>30 d (9)</td>
<td>2.3</td>
<td>2.1</td>
<td>1.9</td>
<td>1.9</td>
<td>NS</td>
</tr>
<tr>
<td>90 d (8)</td>
<td>2.1</td>
<td>2.6</td>
<td>2.2</td>
<td>1.9</td>
<td>NS</td>
</tr>
<tr>
<td>Cheese flavor</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>10 d (8)</td>
<td>7.2</td>
<td>7.1</td>
<td>6.6</td>
<td>6.4</td>
<td>NS</td>
</tr>
<tr>
<td>30 d (9)</td>
<td>6.4</td>
<td>7.0</td>
<td>6.1</td>
<td>6.8</td>
<td>NS</td>
</tr>
<tr>
<td>90 d (8)</td>
<td>6.5</td>
<td>5.9</td>
<td>5.5</td>
<td>6.6</td>
<td>NS</td>
</tr>
</tbody>
</table>

¹ Taste panel scores were set from 1 to 10. For oxidized flavor, the higher score indicated a stronger flavor. For cheese flavor, the higher score indicated a better quality.
² The value in the parenthesis is the number of the panelists.
TABLE 4. Open taste panel scores for iron-fortified process cheese

<table>
<thead>
<tr>
<th></th>
<th>Control</th>
<th>Fe-casein</th>
<th>Fe-WP</th>
<th>FeCl₃</th>
<th>LSD²</th>
</tr>
</thead>
<tbody>
<tr>
<td>Texture</td>
<td>6.3</td>
<td>6.1</td>
<td>5.9</td>
<td>6.0</td>
<td>NS</td>
</tr>
<tr>
<td>Flavor</td>
<td>6.2</td>
<td>6.0</td>
<td>5.6</td>
<td>6.0</td>
<td>NS</td>
</tr>
<tr>
<td>Overall</td>
<td>6.1</td>
<td>5.9</td>
<td>5.7</td>
<td>6.0</td>
<td>NS</td>
</tr>
</tbody>
</table>

¹ Taste panel scores were hedonic scores set from 1 to 9 for which 1 was "dislike extremely" and 9 was "like extremely." Each value is a mean of 94 volunteer lay subjects.

² LSD means least significant difference values which would be calculated when F was larger than F.05 (P < .05). NS means not statistically significant (P > .05).

Table 5. Iron contents of foods

<table>
<thead>
<tr>
<th></th>
<th>Fresh basis (mg/kg)</th>
<th>Dry basis (mg/kg)</th>
<th>Energy basis (mg/1000 kcal)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Beef*</td>
<td>32</td>
<td>108</td>
<td>24</td>
</tr>
<tr>
<td>Spinach*</td>
<td>31</td>
<td>333</td>
<td>119</td>
</tr>
<tr>
<td>Cheese**</td>
<td>1-2</td>
<td>2-3</td>
<td>0.25-0.5</td>
</tr>
<tr>
<td>Iron fortified cheese**</td>
<td>75</td>
<td>120</td>
<td>19</td>
</tr>
</tbody>
</table>

*The iron values are from Handbook 8 (1).
**Determined value.
FORECASTING THE PRICES OF DAIRY PRODUCTS

A VALUABLE TOOL FOR AN INDUSTRY GROWING IN SOPHISTICATION AND SIZE

by

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Presented at the
10th Biennial Cheese Industry Conference
Utah State University
Logan, Utah
August 18, 1992
I. INTRODUCTION

There is no need to spend much time on observing how much the American dairy industry has changed in the past ten years due to economic, political and technological influences and on the whys and wherefores of those influences. Just the fact that the number of cheese plants is now down to 630 or less from 950 while the production of cheese has increased from 5.3 billion pounds to 6.5 billion pounds (even with a drop in cottage cheese production) suggests there is growing sophistication in the financial affairs of the industry. More important, the evolution toward more free market conditions in the American dairy business indicate that more sophisticated handling of its financial affairs is essential. In a sense, this means that "dairy" must catch up with the rest of American agriculture or agribusiness.

One of the notable differences between the dairy sector and the rest of agriculture is that the former has relatively little involvement with the forecasting of prices, while the latter absolutely relies on it. It is true that reason for this is that dairy products are not traded in futures markets that have the most direct need for forecasting. It is also true that the price support program, in giving "stability" to the markets for dairy products, prevented the kind of volatility in the primary products prices we have seen for the past three or four years. However, manufacturers and buyers of cheese and other dairy products can use forecasts as much as commodities traders can and the more information the dairy industry has as to what is likely to happen to prices of its products and why, the more likely orderly price behavior is to evolve.

This paper describes the first and only regular dairy products price forecasting service of its kind in the world and how it is being used. This service was first developed for whey powder prices ten years ago this past Spring when the price should have been going up but was going down. Then WPC and lactose were added to the list because whey products prices seemed to behave independently of the prices...
of the primary products, cheese, milk and NFDM. When government surpluses of cheese and NFDM dropped to a level low enough to suggest the free market nature of the business was reasonably close at hand, the prices of these products were added to the list. Casein prices were added despite the sense that two or three major producers and decisions on subsidies by the EC controlled them. Finally, the M-W milk price was added in January 1990 at the request of several clients.

Since there is more at stake with primary products, we will start with those after explaining how the forecasting is done.

II. HOW DOES THE FORECASTING WORK?

The forecasting is done by computer using a proprietary model that can include as many as 25 different factors, some of which are the obvious ones of production and stocks of the product of direct concern (the primary fundamentals) and many of which come from outside the industry. The model, which was developed by Dr. James Kneafsey, a commodities trader and forecaster with 15 years of experience in agricultural commodities, foreign exchange rates, etc., is illustrated in Figure 1 in terms of its main elements. Figure 2 lists some of the factors which make up these elements.

The importance of each main element can vary with time. For instance, dairy industry factors (and especially the primary fundamentals and one or two closely related prices) usually account for roughly 40% of the overall weight of all the factors in the model. However, extreme economic conditions can cause the macroeconomic factors to dominate in reality as well as in the forecasts. For example, when the model was first developed for whey powder prices in the Spring of 1982 after I was challenged by certain whey processors to explain why the price was going down when it should have been rising, Jim Kneafsey had the immediate explanation. We were in a recession and all prices were going down. We think the current recession, while not sinking the whey powder price, has helped to keep it from going through wilder swings.

The most important technical factor can be the so-called parametric behavior of the price of concern. This is the history of movement of the price, a seemingly obvious factor, but one that is less important if there is little or no movement in the price for a long period. A point to remember is that forecasting relies on movement. No movement makes things difficult. It is the long stretches with no changes that keeps us from forecasting the price of butter (along with the large government involvement with very large surpluses).
Figure 1. Major Components in the Cambridge Commodities Corporation's Proprietary Longer-Term Forecasting Model
## Fundamental Indicators

- **Industry Factors** (40%)
  - Production (by group)
  - Stocks
  - Price/demand relationship
  - Exogenous programs, etc.
- **Domestic Macroeconomic Factors** (20%)
  - Real GNP growth
  - Interest rates
  - Money supply
  - Capacity utilization, etc.
- **International Financial Variables** (10%)
  - Foreign exchange rates
  - Capital flows
  - Trade-weighted dollar value, etc.

## Technical Parameters

- CRB Index
- Momentum indices
- Moving average indicators
- Stochastics
- Price/time relationship

### Figure 2. Factors Making Up the Components in Cambridge Commodities Corporation's Longer-Term Model and Their Approximate Relative Importance
Another technical factor of importance in the longer term is the Commodities Research Bureau (or CRB) Index. This gives a collective outlook for 32 commodities, many of which are agricultural ones, including the grains and oilseeds that affect feed prices. Jim Kneafsey has traded in soy products and has an excellent grasp of this factor in the total picture. If there was sufficient budget, the elements going into the CRD Index could be adapted to the historic regional concentration of cheese production in the North Central States or to the newer Western regional production.

Referring to Figure 2 again, the macroeconomic factors already have been mentioned with regard to their varying overall influence.

Finally, we see from Figure 2 that there are international factors which cannot be ignored despite the generally apparent self-contained nature of the U.S. dairy industry. The importance of these vary with the product, the whey products having more of a tic because of the larger role free market exports play than with cheese and NFDM. The strength or weakness of the U.S. Dollar is prominent here and there have been times during the past two years when the weakness has seemed to us to have played a role in making our forecasts more accurate because of the stimulus on exports of whey products and the buoyant effect that this has had on the prices.

Before we leave the explanation of what goes into the forecasting model, we should mention that this is the longer-term model that looks out 13 months by month. We also make weekly short-term forecasts when a price is highly volatile. The model for these has only two or three factors, one being the parametric price behavior, the second being the CRB Index and the third, if present, being any highly correlated price of another dairy product.

We also make long-term forecasts of up to five years out in which selected macroeconomic factors play more important roles.

III. CHEESE PRICES

The cheese price we forecast is the 40-lb Block price as quoted on the National Cheese Exchange. The Barrel price would key directly off this and we have found by analysis the that average Mozzarella price, despite occasional appearances otherwise, still could be keyed off it reliably (at least through this past Spring when we made the test).
We started forecasting the Block price at the end of 1987 after we had requests and, as mentioned in the introduction, felt that there was enough of a free market condition. Mock forecasts showed that accuracy should be excellent. Of course, according to the law of the relative of Murphy, Quagmire O'Dairy, the price then took off and it took some time for the longer-term model to calibrate the volatility. The model tends to lag and we found that this lag was consistent, so that good accuracy looking three to six months out has been attained by applying the lag factor during surges. The root cause of the lag is the timing of the availability of production and stocks data. They are six weeks behind when the longer-term forecasts are issued on the 10th or 11th of each month.

By the beginning of the current cycle, the forecasting model had picked up the extreme volatility of past cycles and so our forecast in April expected another nearly symmetrical up and down as shown in Figure 3. If we applied the lag factor, this forecast would have been very accurate indeed until events such as the unusually long milk flush in the M-W states helped to slow down the climb. Of course, the subsequent monthly forecasts have changes as new data become available and that is the point of updating every month.

Missing from our model is a real demand-side factor, not the quarterly commercial disappearance data. We have ideas of how to develop this and we would be pleased to talk in detail to those who see the merits of forecasting.

IV. WHEY PRODUCTS

Before going on with the primary products, I thought we might look very quickly at the whey side of the cheese/whey complex.

When we started with whey powder and it was cycling between 10¢ and 20¢ per lb, we could forecast out up to a year with an accuracy of ±1% or 2% while calling as many as three turns ahead. Then, as seen in Figure 4, the price went into a different mode in 1986 and in 1987 it broke to a record at 30¢, or 50¢ higher than past high peaks. The volatility until 1990 is illustrated in Figure 4. We did call the muted behavior in 1990 well ahead.

The question now is whether the whey powder price will stay in a new higher range of highs and lows.

Figures 5 and 6 are presented simply to show how dramatically the behavior of the 34% WPC and edible lactose prices differ from that of whey powder and each other.
Figure 3.

CHEDDAR CHEESE PRICES
40# BLOCKS

NATIONAL CHEESE EXCHANGE LAST WEEK PRICE

PRICE (IN U.S. $/LB)

MONTH

J 83 84 85 86 87 88 89 90 91 92 93

MET 1/10/92 PREPARED BY CGC/IMI
WHEY POWDER PRICES

Figure 4.

FORECAST

ACTUAL OVERALL MON. AVERAGE

MONTH

85 86 87 88 89 90 91 92 93

07/18/89 PREPARED BY CCC/NN
Figure 5. WHEY PROTEIN CONCENTRATE PRICES

AVERAGE OF MONTHLY RANGE FOR LAST 3K OF MONTH

MONTH

65 66 67 68 69 70 71 72 73 74 75

PRICE (IN U.S. $/LB)

07/15/82 PREPARED BY COC/HH
Figure 6.

LACTOSE PRICES

- Actual Avg of Mostly Range for Last Wk of Month (solid line)
- Actual Overall Monthly Average (broken line)
- Forecast (dotted line)

Price (in U.S. $/lb.)

10-36

10-37

10-38

10-39

10-38

10-37

10-36

10-35

10-34

10-33

10-32

10-31

10-30

10-29

10-28

10-27

10-26

10-25

10-24

10-23

10-22

10-21

10-20

10-19

10-18

10-17

10-16

10-15

10-14

10-13

10-12

10-11

10-10

10-9

10-8

10-7

10-6

10-5

10-4

10-3

10-2

10-1


84  85  86  87  88  89  90  91  92  93

07/18/82 PREPARED BY OCO/HE
This has made forecasting most interesting indeed, especially when you consider that the WPC price has not had any really repetitive cycles and that the lactose price has broken the record high set back in 1981.

V. NFDM

Going back to the primary products takes us first to the Extra Grade NFDM price, which we started forecasting in October 1989 as it was moving to a record high. See Figure 7. We have seen lags similar to those with the Block price.

A highlight has been the call of the flat behavior at the start of 1991. One producer client called in September 1990 to ask whether to hold or sell a large amount of stock. We advised selling because we did not think that falling prices would rebound upward into another sharp cycle that within the next six months would carry it above the price the client was offered. We don't know whether the client followed our advice, but he seems happy. We will point out this access feature of the service below.

We note that for our cheese industry, the price of NFDM is high enough to encourage its substitution in certain cheeses by other milk protein products including UF milk protein concentrates. The question is whether it will remain high. The government seems to be doing all it can to encourage that it will via the DEIP and other export programs which are clearing the CCC warehouses. In any case, our cheese industry needs to consider what will happen to the world price and the strength of the U.S. Dollar to evaluate if and when NFDM exports without government backing might become as active as they were in 1989.

When the Grade A and Extra Grade NFDM prices are combined next month, we will be prepared to forecast the single value.

VI. M-W MILK

I have left the primary product, milk, to last. This may be a case of "fools rush in where angels (and smart people) fear to tread". We started forecasting the M-W milk price in January 1990 just after the wild ride up to a record peak at $14.93 the previous month. See Figure 8. As a result, the forecasts were haywire for several months. We have subsequently found lags similar to those for the Block and NFDM prices and we have also found that the model has calibrated the past wild swings too well in the last few months, as it did for the driving factor, Blocks.
Figure 7. NON-FAT DRY MILK PRICES -- EXTRA GRADE
IN DOLLARS PER POUND

ACTUAL AVERAGE FOR LAST WEEK OF MONTH

PRICE (IN U.S. $/LB)

MONTH

86 87 88 89 90 91 92 93
Figure 8. M-W MILK, 3.5% FAT

FORECAST

ACTUAL MONTHLY AVERAGE

PRICE (IN U.S. \$/CWT)

MONTH

84 85 86 87 88 89 90 91 92 93

07/15/93 PREPARED BY CCC/HII
A highlight of forecasting the M-W milk price has been calling the slow-down and the more orderly turn going into 1991.

We have studied the alternatives proposed for the M-W price series and we think we can construct a model based on the pieces that will make up the new series. We will go to work on that in earnest when a firm date for adopting the new series is established by the USDA.

VII. HOW DOES THE CHEESE INDUSTRY BENEFIT FROM FORECASTING?

After seven years of providing the service, we have found that there is a range of benefits to producers, buyers and traders of dairy products. Some of these benefits can be measured quite rigorously in dollar terms. A short list follows:

- Plan pricing in the marketing/sales departments and evaluate different pricing scenarios when budgeting for profitability and expenditures in the financial department. We have found that the forecasting service is valued very highly when it is not used in isolation by "marketing" only.

- Help negotiate contracts with buyers or suppliers depending on which side you are on. Having an independent scientific view has been acknowledged by several clients to be very helpful in agreeing on prices over periods ranging from three to twelve months.

- Get hedging advice for sell-or-buy decisions. This is the largest single benefit and the one most clearly measured in terms of the worth of the service.

- For buyers in the food industry using dairy products as ingredients, plan variances with an independent scientific set of projections and the underlying explanations.

In general, the benefits are realized in improved financial management, improved selling or buying activities and improved profits.

VIII. WHAT IS INCLUDED IN THE SERVICE?

Finally, the service is a monthly forecast letter which projects the price out 13 months by month and explains how the main correlated factors are affecting the price and the forecasted price. The service also includes the access to Dr. Kneafsey, as mentioned earlier. There are also supplemental weekly short-term forecasts issued when the price is highly variable.
There are clients in their sixth year of subscribing to the service and we think this speaks well for the contribution it can make as an added tool in projecting prices within your own companies and cooperatives.
Willow Vale Rd
Gerringong
NSW 2534
11 August, 1992

Dr Bart Weimer
Dept. of Nutrition and Food Sciences
Utah State University
Logan, Utah 84322-8700

Dear Bart,

I would be delighted to be met at the airport. I am not keen to grapple with driving on the right hand side. Thank you also for ordering the book, James to hip pocket grateful! I trust my paper has arrived.

See you in Salt Lake City, and looking forward to it.

Sincerely,

Peter M. Linklater
MILK AND DAIRY BEEF QUALITY ASSURANCE PROGRAM:
WHERE ARE WE NOW?

G. M. Jones
Assistant Director, Extension Agriculture & Natural Resources
Virginia Tech, Blacksburg, Virginia

Recent reports in the public media and results of two Food and Drug Administration (FDA) surveys, as well as a congressional hearing and a General Accounting Office (GAO) report, have created considerable criticism and public outcry over the presence of animal drug residues in milk. The GAO study suggested that FDA was unable to assure the American consumer that milk was free from potentially harmful drug residues. It claimed that FDA has not determined safe milk residue levels for many of the drugs used extra-label. One farm magazine has stated that "the public can have little faith in FDA’s claim that milk is safe..."

In 1984, it was estimated that antibiotic contaminated milk cost the U.S. dairy industry $50 million. The consumers' perception that milk has not been contaminated with drugs is important, and is second only to their concerns over herbicides and pesticides. Besides this concern, another problem with drugs includes capability for them to markedly interfere with the manufacture of cultured dairy products and cheese. There also has been speculation that 5-10% of the human population could have an allergic reaction when exposed to low concentrations of drugs, especially penicillin. This has been shown to be true for parental administration; however, it has not been documented for the presence of drugs in food products.

10 Point Quality Assurance Program

There is an urgent need for the dairy industry to develop a plan which reduces the presence of drug residues in milk and dairy beef. Such a program has been developed by the American Veterinary Medical Association and the National Milk Producers’ Federation. This ten-point quality assurance program is a sound, practical approach to minimizing the chance that drugs will contaminate either milk or meat. The ten points included in this program are:

1) Practice healthy herd management, which includes housing and sanitation, nutrition, reproduction, vaccination and parasite control, as well as introduction to disease and mastitis prevention.

2) Establish a valid veterinarian/client/patient relationship.

3) Use only FDA approved over-the-counter or prescription drugs.

4) Make sure all drugs have labels that comply with state and/or federal labeling requirements.
5) Store all drugs correctly.

6) Administer all drugs properly and identify all treated animals.

7) Maintain and use proper treatment records on all treated animals.

8) Use drug residue screening tests.

9) Implement employee/family awareness of proper drug use to avoid marketing of adulterated products.

10) Complete the quality assurance checklist annually.

Questions and Concerns

The Quality Assurance Program was introduced in 1991 at six regional "Train the Teacher" workshops. Since its introduction, there have been some problems or concerns. These include the following:

1) **Misconception about when a veterinarian and farmer should sign the certificate** if the farmer has attended a training meeting. The intention is that the program will be discussed between the two parties on the farm where drug inventories can be conducted, labels checked, records reviewed, and herd management practices evaluated.

2) **Lack of accurate cow-side residue tests.** There has been some distrust that has developed for tests and their use on individual cows. Research from California has suggested that three cows experimentally infected with coliform mastitis (to evaluate somatic cell counts to 12 million) showed a false positive reaction to many of the tests, although untreated. Of great concern also must be the possibility that treated cows retain drugs longer than the label withholding time. Studies on treated cows at Virginia Tech found that only 64% of cows treated for clinical mastitis were clean at the end of the recommended withholding time, while 73% of cows treated intramuscular were negative. It has been suggested that lactoferrine or lysozymes cause the positive test. Would the same be true for those cows treated for foot rot? We must remember that label withholding times were established before today's more sensitive tests were developed. It also has been shown that diseased cows retain the drug longer than normal cows, which often are used for establishing label discard times.

Recent studies of 32 clinically mastitic cows in the Virginia Tech herd showed that only two were positive. It seems ill advised to ignore the possibility that these drug screening tests are detecting actual drugs present in milk of cows although label would suggest that they are clean.

3) **Confusion over state and federal requirements.** Apparently there is some concern over which products must be labeled, such as vaccines and biologics. This
is spelled out in the Quality Assurance Program producer manual. Of greater concern is the lack of clarity regarding the suspension of grade A permits when a herd is found in violation. It is not clear whether this first violation will cost the dairy farmer two days lost milk production or a suspension of two days after the farm’s milk has been found to contaminate a truck load of milk (or four days’ milk shipment).

4) Some claim that record keeping of drug use on the farm is too difficult. The producer manual provides two charts which simplify drug record keeping. One is an inventory of drugs which allows farmers to determine if labels are correct, and if the drugs are stored properly. It also inquires of the accuracy of the drug residue test being used on the farm. The second record is a permanent treatment record for cows that have received drugs for any reason. In too many situations, dairy farmers do not keep permanent records and have no way to check on a cow’s treatment history.

5) It takes too much time to complete the Quality Assurance Program. In my experience, it takes a little over an hour to go through the program with a dairy farmer. This includes time to discuss some of the problems we had identified. This also was true in studies conducted in Minnesota. However, studies with violator herds in Wisconsin found that approximately three hours were needed to complete the certification with these herds. In my experience, we found problems with labelling or storage, separation of treated cows, and assumed ability of tests to detect all drugs.

There are other areas of concern or problems associated with implementation of this program. It is a voluntary program, except for herds found with drug residues. When dairy farmers and milkers have attended extension programs which explained the ten points, they often identified sources of problems on their farms, and were able to take corrective action. The intention of the "Train the Teacher" program was that either milk coops/plants, veterinarians, or extension agents would provide educational meetings for farmers and milkers. The most logical and perhaps effective means to do this is a coordinated, cooperative effort between industry, veterinarians, inspection, and extension where changes in the PMO can be discussed and the ten-point program can be reviewed in detail. It is not adequate to discuss the program in a five- to ten-minute producer annual meeting or Extension program. Our experience has been that we need a minimum of two hours, and when specific quality assurance educational programs have been provided, and milk coops, veterinarians, and extension have adequately promoted these programs, attendance has been outstanding. This would be an excellent example of where an integrated approach has addressed an issue or need. This type of program is recommended for much of the dairy industry. It provides an opportunity for dairy farmers to understand where problems can develop and how they can prevent them in the future. It also allows interaction between farmer and farmer, or farmer and industry. Although it may raise more questions, it is a step in the decision-making process.

The Quality Assurance Program provides sound, useful management information. Failure of any group, milk coop or plant, veterinarian, or extension, to participate is a serious disregard for the needs of the dairy industry.
Microbes in Raw Milk and Their Control

Mansel W. Griffiths,
University of Guelph, Guelph, Canada N1G 2W1

The microflora of raw milk changes with production practices. Since the introduction of on-farm refrigerated storage, the dominant spoilage organisms have become Gram-negative, psychrotrophic bacteria. The most important group of these organisms are the pseudomonads. Various methods have been proposed to limit the growth of psychrotrophic bacteria in milk prior to processing. These have included heat-treatment at sub-pasteurization temperatures (thermization), use of CO₂, "natural" preservatives such as lactoperoxidase, and addition of lactic acid bacteria. Whereas all are effective, the procedure to be adopted, to a certain extent, depends on the product to be made from the milk.

There have also been changes in the diseases associated with consumption of milk. No longer is tuberculosis considered a threat, although there is evidence of the re-emergence of this disease. Organisms such as Listeria monocytogenes have attracted a great deal of attention as emerging pathogens. In the main, these organisms are not heat-resistant and should be destroyed by adequate pasteurization. However, there is increasing evidence that psychrotrophic Bacillus spp. can survive pasteurization and produce toxins in milk during growth at low temperature.

Large outbreaks of foodborne illness due to the consumption of milk have been reported and these have been attributed to contamination of the product post-pasteurization. Management techniques, including HACCP, can help reduce the risk of contamination but adequate hygiene monitoring schemes must be in operation. Methods have been described for assessing the cleanliness of surfaces and rinse washes in 5 to 10 minutes. Research is being carried out on rapid methods to detect microbial contamination of foods.
RAW MILK QUALITY AND MILK PROCESSING

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ABSTRACT

The objective of this discussion has been to develop a greater awareness, appreciation and understanding of the relationship between high raw milk quality and food safety and the "real" quality and public image of finished dairy products. Milk products can be no better (and safer) than the quality of the raw materials from which they are made. The most relevant quality tests (parameters) for inclusion in quality assurance monitoring programs for raw milk and cream were reviewed. For each milk quality parameter, appropriate test values or standards have been recommended. Specific quality premiums (or penalties where applicable) per hundredweight of milk have been offered for inclusion in progressive milk quality incentive (bonus) payment programs (QUIPPs). Emphasis was placed on the inclusion of these tests: sensory (flavor) quality, low count limits for somatic cells, preliminary incubation (PI) tests, and psychrotrophic bacilli (spores). In the author's view, the requirements for consistently achieving excellent results indicative of high raw milk quality generally exceed the efforts needed to attain public health safeguards. Hence, when superior raw milk quality is attained--then a safe milk supply is assured.
"Quality is the key to success!" W. Edwards Deming. One of the earliest statements that I recall (and retained) from an early dairy chemistry class was "A Milk Product Can Be No Better Than the Quality of the Raw Materials From Which They Were Made!" I have since viewed this important statement to be The First Rule of Quality Assurance.

The wholesomeness, freshness and quality of dairy ingredients do far more to determine the eating quality and shelf life of dairy foods than any other factors. In the industry we sometimes get so "caught up" with the milk fat content, the formula, the specific flavoring, manufacturing techniques, the overrun content, or the right package, etc. that we tend to forget that we are working with a most delicate and sensitive biological system in the case of milk. The freshness of milk or cream and other positive quality dimensions are most critical in determining the pleasant sensory properties (flavor and body/texture) of market milk, cheese, and other dairy foods.

An important prerequisite of a thorough milk quality assurance program is careful, discriminating flavor evaluation of all milk, cream and concentrated milk sources. This implies the need for a "screening" of all dairy ingredients for possible off-aroma, off-taste, body/texture and color/appearance shortcomings. We must reject any objectionable off-flavored milk and cream sources if high quality, acceptable dairy foods are to be produced and marketed on a consistent basis.

Raw milk and cream as dairy food ingredients

Quality incentive payment (bonus) programs (QUIPP's) are an excellent approach for helping obtain and insuring higher quality raw milk for processing. High raw milk quality enhances product flavor profiles, extended product shelf life, higher cheese yields, and increased sales. The quality parameters that should be incorporated into relevant milk quality bonus programs include:

- flavor (odor and/or taste) evaluation
- freedom from antibiotics, drug and chemical residues
- no added water
- low sediment content
- appropriate temperature history (rapid cooling and ≤ 40°F [4.4°C] storage)
- rigorous bacterial standards (low total aerobic bacteria [SPC] and Preliminary Incubation [PI] counts)
- low bulk tank somatic cell counts (target ≤ 200,000 SCC/ml)

Suggested standards and test values for a progressive milk quality incentive payment program (QUIPP) are summarized in Table 1. Oregon (1987) and California (1990) have already
promulgated rigorous maximum somatic cell counts for Grade A raw milk; they are ≤ 750,000 and ≤ 600,000 SCC/ml, respectively. Ontario, Canada has promulgated an aggressive somatic cell count program over a period of years.

Raw milk analysis for psychrotrophs (cold growing spoilage bacteria) and heat-resistant sporeformers (Bacillus spp.) is somewhat unique within the series of milk quality tests presented for consideration in Table 1. However, these two parameters of raw milk quality are most important for helping assure reasonable shelf life, minimizing the occurrence of sweet curdle and/or bitter off-flavors in the more perishable milk products, and reduction of cheese yield or cheese flavor characteristics.

**FLAVOR IS "THE VOICE" OF MILK AND MILK PRODUCTS**

Dairy product flavor is the key to consumer acceptance and repeat dairy product sales. The art (and science) of competent detection of undesirable flavors and/or odors in raw milk supplies is an invaluable, but often under used quality assurance tool. The correct diagnosis of the nature and cause of a dairy ingredient flavor quality problem is absolutely necessary before remedial measures can be undertaken by quality assurance and production personnel.

**Milk flavor evaluation techniques**

The actual tasting of raw milk or cream samples is certainly not advised for food safety reasons. However, there is an answer to this dilemma: laboratory pasteurize any raw milk samples at ≥ 155°F (68°C) for ≥ 10 minutes. Then cool the pasteurized samples to 55°-65°F (13°-18°C) before determining flavor characteristics. Evaluation of milk or cream for flavor quality is not as effective when sample temperatures are below 50°F (10°C). Any potential off-odor or off-taste is more readily detected after sample tempering to 60°F ± 5°.

Proper flavoring technique calls for briefly swirling the lab pasteurized milk (or cream) sample and then taking a full "whiff" of the air and noting possible volatile constituents from within the container headspace. For raw milk samples, an alternative technique is to temper samples to 80°-90°F (~30°C). The higher temperature more completely volatizes potential off-odors and facilitates their detection by focusing on possible "off" aromas.

**How to respond to milk off-flavors**

The most difficult decisions about sensory quality involve those "borderline" cases of marginal flavor quality, when outright rejection of a questionable milk or cream source can be difficult. As a rule these cases of marginal milk off-flavor tend "to get worse before they get better." To be forewarned is to be better prepared. If the person(s) responsible for milk and cream ingredient reception has any doubt or question about the acceptability of a given tanker load of milk or cream, then a second or third opinion from other competent personnel should be obtained about the flavor properties of the ingredient(s) in doubt. It is most helpful if quite discriminating and self-confident persons in sensory perception are available and willing to take appropriate action at this point.
Table 1. A Progressive Milk Quality Incentive Payment Program (QUIPP) with Suggested Bonuses or Penalties as $/Cwt. Milk.

<table>
<thead>
<tr>
<th>Quality Parameter</th>
<th>Regulatory Standard</th>
<th>Suggested Standard</th>
<th>Bonus/ Penalty</th>
<th>Cwt.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Flavor/Odor</td>
<td>Okay or Satisfactory</td>
<td>Not Satisfactory</td>
<td>0¢</td>
<td>-25¢</td>
</tr>
<tr>
<td>Temperature</td>
<td>≤45°F (≤7.2°C)</td>
<td>&lt;40°F (≤4.4°C)</td>
<td>0¢</td>
<td>-25¢</td>
</tr>
<tr>
<td></td>
<td>≥50°F (≤10°C)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Antibiotics/Drugs</td>
<td>Negative</td>
<td>Negative</td>
<td>0¢</td>
<td>-25¢</td>
</tr>
<tr>
<td></td>
<td>Positive</td>
<td></td>
<td>-25¢ to -50¢</td>
<td></td>
</tr>
<tr>
<td>Added Water</td>
<td>Negative</td>
<td>Negative</td>
<td>0¢</td>
<td>-25¢</td>
</tr>
<tr>
<td></td>
<td>Positive</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fresh Raw Milk</td>
<td>≤80,000</td>
<td>≤10,000</td>
<td>10¢</td>
<td></td>
</tr>
<tr>
<td>SPC/ml</td>
<td>or</td>
<td>≥20,000</td>
<td>-5¢</td>
<td></td>
</tr>
<tr>
<td></td>
<td>≤100,000</td>
<td>≥80,000</td>
<td>-25¢</td>
<td></td>
</tr>
<tr>
<td>Preliminary</td>
<td>20-50,000</td>
<td>20-50,000</td>
<td>0¢</td>
<td></td>
</tr>
<tr>
<td>Incubation Count</td>
<td>(PI)/ml</td>
<td>≥50,000</td>
<td>-5¢</td>
<td></td>
</tr>
<tr>
<td>Somatic Cell</td>
<td>≤750,000</td>
<td>≤100,000</td>
<td>20¢</td>
<td></td>
</tr>
<tr>
<td>Count/ml</td>
<td>or</td>
<td>101-200,000</td>
<td>-10¢</td>
<td></td>
</tr>
<tr>
<td></td>
<td>≤600,000</td>
<td>201-300,000</td>
<td>-15¢</td>
<td></td>
</tr>
<tr>
<td></td>
<td>or</td>
<td>301-500,000</td>
<td>-15¢</td>
<td></td>
</tr>
<tr>
<td></td>
<td>≤1,000,000</td>
<td>501-600,000</td>
<td>-50¢</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>601-750,000</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>≥750,000</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Psychrotrophic</td>
<td>≤10</td>
<td>10-99</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Heat-resistant</td>
<td></td>
<td>≥100</td>
<td>-10¢</td>
<td></td>
</tr>
<tr>
<td>Bacilli*</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Oregon SCC/ml max.; July 1, 1987  
California SCC/ml max.; January 1, 1990  
USPHS/FDA PMO (Federal) SCC/ml max; July 1, 1987  
Flavor quality essential for consumer acceptance

Consumers more readily identify with the flavor characteristics of milk and milk products than with any other measures or parameters of product quality (i.e., bacteria counts, composition, etc.). The progressive dairy processor that applies available quality assurance tests can minimize consumer complaints and maximize customer goodwill and thus maintain or increase dairy product sales. Quality assurance personnel of progressive processors must be more familiar with and more sensitive to possible product off-flavors than the firm’s most discriminating customer. Perhaps nothing is more embarrassing for a dairy processor than to have a consumer be the first one to recognize and react to a serious milk product off-flavor, which originated from the dairy ingredients. Application of The First Rule of Quality Assurance can do much to guarantee success. "Dairy products are only as good as the dairy ingredients from which they are made!"

THE BENEFITS OF A QUIPP PROGRAM

Appropriately developed and conducted milk quality incentive payment (bonus) programs (QUIPP's) can serve to financially reward producers for performing their critical role in producing high quality milk as an ingredient for flavorful dairy foods. Some of the more progressive dairy cooperatives in the U.S. have heightened their focus on raw milk quality by introducing an economic penalty (e.g., as much as 25¢ to 50 ¢/cwt) if certain quality test parameters are not met.

What are the best milk quality monitoring tools?

The U.S. dairy industry doesn't always use or apply the most relevant tests for monitoring milk quality. What should be the "battery" of raw milk quality assessment tests for determining real milk quality? How do we interpret these tests? What procedures should be in an affective, aggressive Quality Incentive Payment Program (QUIPP)?

The best tests (parameters) for determining raw milk quality

1. **Flavor: Odor, Taste, Mouthfeel, and Occasionally Color and Appearance.** Undoubtedly, flavor is the most important yardstick for consumer acceptance of milk. Moderate and serious off-flavors in milk at the farm bulk tank level must be avoided. Taste and odor (plus shelf life) are the only "yard sticks" that consumers employ to evaluate milk quality.

2. **Farm Inspection (Visual Observations):** This consists of an organized set of visual observations conducted by a trained and experienced sanitarian (regulatory agency), industry field representative or an extension dairy specialist of the management practices related to milk harvesting, transferring, storage and overall sanitation, drug and antibiotics storage and use, and housekeeping. This can be most informative in ascertaining potential milk quality. An official inspection
Evaluating raw milk quality from a microbiological standpoint

3. **Standard Plate Count (SPC):** A highly standardized procedure and media is used to estimate the total aerobic, viable bacterial cell count of an aseptically collected fresh, raw milk sample. The SPC concerns itself with: (1) total live aerobic bacteria, but (2) not necessarily the kinds of bacteria present and is historically required for (3) public health reasons (official). SPC is conducted on samples ≤ 36 hrs old and involves plate incubation for 48 ± 3 hr at 32°C (90°F). Regulatory SPC count maximums are 80,000 to 100,000 cfu/ml (depending on the state). SPC counts of less than 20,000 cfu/ml are highly desirable. For some QUIPP programs the target is as low as ≤ 5,000 or ≤ 10,000 cfu/ml.

4. **Preliminary Incubation (PI) Count:** This is simply another approach for conducting the Standard Plate Count. A raw milk sample (producer or milk tanker) is held for 18 hours (+20 minutes) at 12.8°C (55°F) [A preliminary incubation condition to "stress" the milk sample under "borderline refrigeration"]. Then the sample is subjected to a SPC. This is an effective procedure for indicating presence of psychrotrophic bacteria (spoilage type) and, hence, provides good evidence of sanitation and/or cooling shortcomings in milk production and storage.

In essence, we could say that the PI count is a "measure of 'lasting' quality," since it "shows up" the presence of unwanted spoilage bacteria. Most unfortunately, these cold-loving bacteria often produce proteolytic enzymes (proteases) that can survive pasteurization and subsequently limit fluid milk shelf life or adversely affect cheese yield or flavor quality. Whenever PI counts exceed more than 3 or 4 times the fresh raw SPC, or when the PI exceeds 50,000 cfu/ml, the "trouble spots" or contamination source(s) need close inspection.

5. **Laboratory Pasteurization Count (LPC):** Raw milk samples are essentially subjected to a simulated vat (or batch) pasteurization procedure in a laboratory waterbath. LPC results in excess of 500 (or 300) cfu/ml (industry standards) indicate the presence of bacteria that most likely would survive the pasteurization process (thermodurics). Due to the prevalence of HTST pasteurization this procedure has lost some favor in recent years since it mimics vat pasteurization. Other microbiological tests may be more relevant today.

6. **Heat-Resistant (Sporeforming) Psychrotrophs (HRSP) Test:** This more recently introduced test is a modification of the LPC that identifies thermodurics that are also able to grow at refrigeration temperatures (psychrotrophs). This test is based on heat-treating the raw milk sample to 80°C (176°F) for 10 min (optionally 75°C [167°F] for 20 min), quickly cooling the sample, then SPC plating, and incubation for 10 d at 7.2°C (45°F). An HRSP
(spore) count $\geq 10$ cfu/ml is indicative of potential shelf life problems or reduced cheese yields. HRSP counts in the range of 0-10/ml are preferred, 10-100 cfu/ml are "borderline," and $>100$ cfu/ml often lead to "sweet curdle" and/or bitter off-flavored milk. No spore count at all would be most ideal, but is probably a rare occurrence.

7. **Coliform (Plate) Count:** A differential media is used to enumerate this group of Gram negative bacteria that originate from the intestinal tract of warm-blooded animals (*Escherichia coli* and *Aerogenes* spp). The coliform count is a basic "index of the level of sanitation." An occasional standard applied to raw milk is $<100$ coliforms/ml. This test is infrequently applied to raw milk (e.g., it is more applicable to pasteurized products $\leq 10$/ml).

8. **Direct Microscopic Bacteria Count (DMC):** The DMC can be a good screening test since the results are obtained rapidly. The DMC often provides an indication of the cause of the sanitation problem, since a trained and experienced technician can ascertain the general types and/or range of bacteria present when a Gram stain is used. However, this method is only effective for relatively, "high count" milk ($\sim 300,000$ cfu/ml). New technologies appear to be on the horizon to facilitate rapid ($\leq 15$ min @ $\sim 10^6$ cfu/ml level) microbial assessments at plant reception.

9. **Other Microbial Procedures:** Previously, procedures were employed to "indirectly" estimate the bacterial population of raw milk samples; this was done most often by measurement of the "dye reduction" capability of a given sample. Dye reduction tests such as methylene blue and resazurin (reduction times) and crystal violet or tetrazolium salts have been employed. Other approaches have involved measurements of catalase, oxidase, pyruvate or/and ATP production, electrical impedance measurements of media (Bactometer), color reflectance (Omnispec 4000), and bioluminescence/ATP measurement schemes (Lumac, Biotrace M3, and Promega). The latter instruments are typically automated, computer controlled and display/print results.

**Other raw milk quality tests**

10. **Antibiotics and Drug Residues:** Numerous laboratory methods have been developed to determine the presence or absence of antibiotics and drug residues in milk. Currently, the *Bacillus subtilis* and/or *B. stearothermophilus* plate disk test and the Charm II test are "official" methods for detecting approximately 0.02-0.03 I.U. of penicillin (or other beta-lactam forms of antibiotic). Other methods for drugs detection are the: (a) Delvo-Test P/SP (colormetric); (b) Charm I and Charm Farm (radioactive basis); (c) Penzyme Test III (colormetric) (d) the Cite Probe Test (e) LacTek; (f) the BR test; (g) EZ-Screen; and (h) the Signal test. Any source of antibiotic positive milk can pose serious human health, economic and aesthetics/public image problems.

11. **Somatic Cells (SCC):** One of the best indicators of normal milk composition is measurement of the somatic (body) cells in milk from a given herd (bulk tank). Somatic
cell counts in excess of ~260,000/ml may be indicative of some degree of mammary system(s) infection by pathogenic microorganisms (mastitis). Elevated somatic cell counts in milk can lead to: (a) lost milk production (Table 2), (b) reduced cheese yields, (c) flavor deterioration, and/or (d) product shelf life reduction.

**TABLE 2. Potential Production Losses Due to Elevated SCC's.**

<table>
<thead>
<tr>
<th>SCC/ml</th>
<th>Potential Milk Loss Lbs Per Cow/Year</th>
<th>% Loss</th>
</tr>
</thead>
<tbody>
<tr>
<td>100,000</td>
<td>0</td>
<td>--</td>
</tr>
<tr>
<td>200,000</td>
<td>400</td>
<td>3</td>
</tr>
<tr>
<td>400,000</td>
<td>800</td>
<td>6</td>
</tr>
<tr>
<td>600,000</td>
<td>1000</td>
<td>8</td>
</tr>
<tr>
<td>800,000</td>
<td>1200</td>
<td>12</td>
</tr>
</tbody>
</table>

12. **Freezing Point Determination:** The most consistent physical property of milk is the freezing point (< -0.30°C [≤31.5°F]). The cryoscope is a quite precise instrument for determining the addition of water to milk (unethical and illegal). Each 0.006°C increase in freezing point of milk is indicative of ~1% added water, whether accidental or purposeful.

13. **Titratable Acidity (% T.A.) and pH:** The buffering components of milk exhibit a "baseline acidity" and a slightly acidic pH of 6.6-6.8. Delayed or inadequate milk cooling often permits the growth of lactic acid bacteria and formation of lactic acid (which is responsible for sour taste and possible milk coagulation). This can be detected by the T.A. test. Normal fresh milk (depending on the breed and the milk solids content) exhibits an "apparent acidity" of 0.14-0.17% acidity (as lactic acid). A milk T.A. of 0.20% or higher can generally be detected by taste. When T.A.'s are less than 0.135%, we should be suspicious of alkali producers (i.e. psychrotrophs or spoilage bacteria).

14. **Sediment Content:** The amount of unwanted extraneous material (soil residues) in milk can be objectively quantitated by the disk filtration method. The disks (with any possible filtered, insoluble sediment) are compared to standards and assigned an appropriate grade number (No. 1, 2, 3, and 4 [unlawful]). Only sediment grades of 1 or 2 are acceptable for Grade A milk and for milk quality incentive programs.

15. **Temperature:** "LIFE BEGINS AT 40!" --- 40°F (4.2°C) that is, for the growth of spoilage (psychrotrophic) bacteria. Legal standards require that milk be cooled to 50°F (10°C) within 1 hour after completion of milking and to 45°F (7.2°C) within 2 hours after milking. The preferred quality standards for milk cooling are: to 45°F within 1 hr after herd milking completion and to 40°F or less within 2 hrs; and no bulk tank blend temperatures above 45°F. Rapid cooling and holding of raw milk at 35-38°F is critical
for optimizing milk quality and potential shelf life. This limits the outgrowth of any potential psychrotrophic bacteria. Recording thermometers effectively monitor critical temperatures of milk in farm bulk tanks and indicate that tank cleaning was performed.

IMpACT OF MILK QUALITY ON PROCESSING

Tests for milk quality are necessary primarily because the numerous practices and phases of milk production, storage, transport, and processing are not performed ideally. The better the job of performance, the greater the likelihood of high raw quality, and the less the need for quality assurance tests. Significant economic impact derives from conversion of raw milk and cream into final products. Hence, characterization of available raw materials through relevant, state-of-the-art test methodologies is mandatory—for both food safety and quality assurance reasons.

When raw milk supplies do not measure up against our "quality yardsticks" (standards), final product quality, shelf life, and/or yields (cheese especially) suffers. Elevated somatic cell counts (good evidence of abnormal milk as a result of mastitis) can markedly affect milk composition and reduce cheese yields (Table 3), as well as quality. Occasionally, off-flavors result from the altered milk production when somatic cells exceed 300,000 SCC/ml (Table 4). This is partially due to increased enzymatic activity in higher SCC/ml milk (Table 4).

**TABLE 3. Factors That Adversely Impact Cheese Yield**

<table>
<thead>
<tr>
<th>Factor</th>
<th>Value</th>
<th>Impact</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>SCC/ml*</td>
<td>≤ 106,000 cells/ml</td>
<td>100% cheese yield efficiency</td>
<td>Opt. C% TP</td>
</tr>
<tr>
<td></td>
<td>≥ 127,000 cells/ml</td>
<td>96% cheese yield efficiency</td>
<td>&lt; C% TP</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>&gt; Fat &amp; protein in whey</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>&gt; H₂O in cheese</td>
</tr>
<tr>
<td>Milk age*</td>
<td>5 days @ 4°C</td>
<td>&gt; Make time</td>
<td>&gt; Protease &amp; plasmin activity</td>
</tr>
<tr>
<td></td>
<td></td>
<td>&gt; Starter amount</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>&gt; Ripening time</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>&lt; H₂O in cheese</td>
<td></td>
</tr>
<tr>
<td>Psychrotroph levels</td>
<td>&gt; 1 X 10⁶/ml</td>
<td>&lt; Cheese yield</td>
<td>&gt; Casein denaturation</td>
</tr>
<tr>
<td></td>
<td></td>
<td>&gt; Cheese off-flavors</td>
<td>&gt; Protein in whey</td>
</tr>
</tbody>
</table>

TABLE 4. Influence of Somatic Cell Count on the Quality of Herd Milk.

<table>
<thead>
<tr>
<th>SCC/ml</th>
<th>ADV</th>
<th>Flavor Characteristics</th>
<th>% Fat</th>
<th>Lipase Activity</th>
</tr>
</thead>
<tbody>
<tr>
<td>250,000</td>
<td>0.85</td>
<td>Okay</td>
<td>3.45</td>
<td>---</td>
</tr>
<tr>
<td>400,000</td>
<td>1.07</td>
<td>Sl. rancid</td>
<td>---</td>
<td>1.49 units</td>
</tr>
<tr>
<td>700,000</td>
<td>1.21</td>
<td>Mod. rancid</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>&gt;1,000,000</td>
<td>1.60</td>
<td>Pron. rancid</td>
<td>3.20</td>
<td>1.73 units</td>
</tr>
</tbody>
</table>

* ADV = Acid Degree Value

Wisconsin Dairies Co-Op

Good, quality conscious dairymen today, strive to control mastitis by a combination of proper management practices, effective sanitation, and environment control (e.g., mastitis prevention). Non-judicious use of antibiotics and drugs for mastitis control/treatment are not as effective for production of herd milk with low somatic cell counts. Furthermore, avoidance of antibiotics residues in milk is constantly a challenge for dairymen who "treat instead of prevent."

SUMMARY

When we examine the word QUALITY it is a neutral noun. It needs an appropriate adjective or modifier to better describe it if we want to accentuate the positive. All personnel in the dairy industry should never be too content unless all of our milk products can consistently be classified as superior or supreme quality. The expense of achieving excellent quality are frequently less than it seems because many of the practices that serve to enhance quality also improve efficiency in our production activities.

It is absolutely essential that the quality of raw milk and cream be determined by relevant tests for: (1) sensory characteristics, (2) microbial profiles, (3) physico-chemical properties (composition), (4) abnormal properties, (5) shelf-life potential (6) yield potential, and (7) possible adulterants.

It is helpful to always bare in mind the First Rule of QA: "A MILK PRODUCT CAN BE NO BETTER THAN THE QUALITY OF THE RAW MATERIALS FROM WHICH THEY WERE MADE!" When high quality dairy products are consistently manufactured through progressive quality assurance programs--then food safety is practically insured.

"The Dairy Industry -- if it is to reach and maintain its proper goal in the present economy, must direct every effort towards the marketing of quality products."

James R. Welch - 1974
Klenzade, A Service of Ecolabs, Inc.


ABSTRACT

Monitoring Fluid Milk Shelf-Life
David K. Bandler
Professor of Food Science
Cornell University
Ithaca, NY

“How times have changed -- we now send the bad milk to the bottler.”
Anon.

Maintaining a strong demand for milk and dairy products is dependent on proper production practices and constant quality assurance. In addition to meeting regulatory standards, milk must taste good throughout the shelf-life period and satisfy the consumer perception at any time until the product is consumed. The research and extension program sponsored by the New York State Milk Promotion Board and Cornell University has enabled the industry to improve the quality and reliability of dairy products.

In the past year, 77 samples of commingled raw milk were collected from milk storage tanks of New York State processors. Over 50% of the samples tested had excellent SPCs, (less than 50,000) while 18% had counts in excess of 300,000 -- the legal limit for commingled milk. The manufacture of quality dairy products requires that they be made from raw ingredients which are free from defects.

Conventionally heat processed (HTST) milk accounts for over 99% of fluid sales in the Northeast. Milk of New York processors is regularly monitored to determine the point of spoilage under a project conducted at Cornell University. Known as the “Voluntary Shelf-Life (VSL) Program”, every commercial fluid milk processing plant is visited by extension staff at least 3 times a year. Samples of each product line are collected and subjected to 10 quality tests on day 1 and then re-evaluated for SPC, coli, ADV and flavor on days 7, 10 & 14 while kept at a controlled storage temperature of 43°F (6.1°C). Results are communicated
immediately. On-site audits and recommendations for remedial action to improve plant practices are made where necessary. Currently, upstate New York plants have sell-by dates averaging 12.9 days compared to 10.7 days at program start in 1983. Regular HTST processing along with improved filling equipment design and sanitation programs makes shelf-life expectancy of 21 days an achievable goal.

In addition to the individual attention each processor receives, the Milk Quality Improvement Project is also involved in programs to further educate dairy personnel. Superintendents from each plant attend an annual seminar where the results of these studies are presented with further encouragement for quality improvement. Additional workshops related to dairy product quality are presented to meet the needs of the industry.

Vitamin fortification continues to be a concern. Low fat and skim milk must contain added Vitamin A at a level of 2,000 International Units per quart. In 1989, over two thirds of the samples of New York State milks tested for Vitamin A were outside the range of good manufacturing practices. Companies involved were informed and corrective action suggested. Generally, milks with more than the required amount had a “vitamin” off-flavor.

The mishap involving over-fortification of Vitamin D which occurred in New England is a reminder of the importance of correct fortification. Guidelines for vitamin fortification have been updated and distributed with expert support to improve management in this area of processing. Copies of the “Milk Quality Improvement Project, 1992 Annual Report” and “Vitamin Fortification of Fluid Milk” will be available at the conference.
MILK QUALITY IMPROVEMENT PROJECT

1992 ANNUAL REPORT

Program Supported by:

New York State Milk Promotion Order
and
Cornell University
Department of Food Science
College of Agriculture and Life Sciences
Cornell University

MILK QUALITY IMPROVEMENT PROJECT

1992 Annual Report
For the Period April 1, 1991 to March 31, 1992

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R. A. Ledford
SECTION I
MILK QUALITY IMPROVEMENT -- PRODUCER PROGRAM

Manufacture of quality dairy products requires that they be made from raw ingredients which are free from defects. Raw milk may be susceptible to reduced quality from both a bacteriological and chemical/flavor standpoint. Bacterial contamination and growth can occur in raw milk on the farm, during transit and at the dairy plant. Chemical/flavor defects can develop in milk relative to the health and nutrition of the dairy cow or through poor handling of milk such as excessive agitation or temperature abuse. It is important to assess the quality of commingled raw milk before processing to prevent production of an inferior product.

Once processing begins, raw milk may be subjected to a clarifier/separator which removes certain particulate matter from the milk. Constituents such as somatic cells, sediment and bacteria are thrown by centrifugal force to the outside of the separator bowl. This material becomes concentrated into a "sludge" which is either removed from the clarifier by manual cleaning or by automatic discharge. Clarifier/separator may be located on the raw or pasteurized side of processing. Clarifier/separator sludge from raw milk may contain large numbers of bacteria which if handled incorrectly can become environmental contaminants. Of concern is the potential consolidation of pathogenic bacteria which have been shown to be present in some raw milk. Release of these bacteria into the dairy plant environment could lead to disaster.

Maintaining raw milk quality begins at the farm. It takes true commitment from the producers to supply the dairy industry with a raw product free from defects. Educational seminars and materials are available which can help them achieve this goal. The Pro-Dairy Program is available to all dairy farmers in the state, providing information to help them "manage for success" which includes producing a quality product. Currently of concern is the prevention of drug residues in milk. New York State is actively engaged in a program to help educate the dairy industry on the importance of preventing contamination of milk.

PRODUCER PROGRAM -- RESULTS AND ACCOMPLISHMENTS

Commingled Raw Milk

During 1991 77 samples of commingled raw milk were collected from bulk milk storage tanks of New York State processors. The percentage of milks with Standard Plate Counts within specified ranges are shown in Figure 1. Over 50% of the samples tested in 1991 had excellent SPCs, less than 50,000 while 18% had counts in excess of 300,000 – the legal limit for commingled milk. The source of these high counts needs to be determined by the processors so they can be prevented in the future.
Acid Degree Values (ADV), a measure of rancidity, should be less than 1.0 before processing. An ADV of 1.4 or greater has the potential for being rancid. In 1991 96% of the commingled raw milks tested had ADVs of less than 1.4 which compares favorably to only 84% of the samples from 1990.

Clarifier Sludge

When milk is clarified in the raw state, the potential for high numbers of bacteria being concentrated in the sludge exists. When clarified post-heating the numbers of bacteria are not as significant. This is shown in Table 1. Concentration of bacteria is the nature of the beast. To relate the total bacteria counts of the sludge to the overall quality of the raw milk is not practical. However, the fact that the bacteria are concentrated in the sludge raises the concern of potential pathogens within the environment of the plant. Currently pathogen testing is not allowed within the Food Science Facilities. A pathogen laboratory designated for this type of work is in the planning and development stage.

Table 1. Comparison of Clarifier Sludge, Raw and Post-Heating.

<table>
<thead>
<tr>
<th></th>
<th>Raw Milk Sludge</th>
<th>Post-Heat Sludge</th>
</tr>
</thead>
<tbody>
<tr>
<td>Average SPC</td>
<td>225,000,000</td>
<td>4,800</td>
</tr>
<tr>
<td>Average Coliform</td>
<td>2,100,000</td>
<td>1</td>
</tr>
</tbody>
</table>
SECTION II

MILK QUALITY IMPROVEMENT -- FLUID PROCESSOR PROGRAM

The Voluntary Shelf-Life Program for fluid milk has been the heart of the Milk Quality Improvement Project since its conception. The primary goal of the program has been to evaluate product quality and shelf-life and give guidance to the processor as to where and how improvement is warranted. In conjunction with the shelf-life program additional projects have been completed over the years which were designed to meet the needs of the industry. Projects in the past included a program to reduce ADVs in the raw milk supply, extensive studies on the influence of somatic cells on dairy product quality, evaluation of methods for determining raw and finished product quality as well as evaluation of processing equipment in relation to keeping quality of milk. Current issues which the program is addressing include continued concerns related to product quality, correct vitamin fortification of dairy products, prevention of drug residues in milk and dairy product safety.

To evaluate fluid milk, a complete range of tests have been selected to best measure the critical parameters related to product quality and regulatory standards. A summary of the testing done for the Shelf-Life Program and a discussion of the results for 1991 follows. This summary has been distributed to each processor as a guide to better understand the test results so they can be used to improve the quality program of their plant.

Each fluid milk plant involved in the program was sampled three times in 1991 which is a 50% increase over previous years. The increase in plant sampling serves as a more frequent reminder of the importance of a continuing quality program and also allows Extension Personnel more direct contact with the industry. Reports of the results from the initial testing and shelf-life studies are sent to each processor in a timely manner. Comments are included with each report pointing out test results which indicate a need for improvement. Additional guidance is always offered to assist the processor in preventing or minimizing quality defects.

In addition to the individual attention each processor receives, the Milk Quality Improvement Project is also involved in programs to further educate dairy personnel. Superintendents from each plant attend an annual seminar where the results of our studies have been presented with further encouragement for quality improvement. Additional workshops related to dairy product quality are currently being developed to meet the concerns of the industry.

Vitamin fortification continues to be a concern to the dairy industry in New York and the rest of the nation. The mishap involving over-fortification which occurred in New England has reminded us of the importance of correct fortification. Guidelines for vitamin fortification have been updated and distributed with support to improve management in this area of processing.
Sample Storage Temperature and Testing Schedule

Collected samples are transported to the Milk Quality Laboratory in coolers kept below 40°F. Initial testing begins within 48 hours of collection. After arrival to the Milk Quality Laboratory the samples are split into four sterile 500 mL bottles. One bottle is used for Initial Day testing while the remaining bottles are stored at 43°F for testing at 7, 10, and 14 days. Ideally, dairy products should be stored at temperatures less than 40°F (without freezing) to achieve the maximum shelf-life and freshness of the product. However, temperatures in the marketplace and in household refrigerators are commonly above "ideal". The temperature chosen (43°F) for the VSL program was selected based on a survey of supermarket display cases conducted in the early 1980's. It is felt that this temperature gives a reasonable indication of the shelf-life of a product which is handled under less than "ideal" conditions.

The testing schedule and analyses performed are:

<table>
<thead>
<tr>
<th>Initial Day</th>
<th>Day 7, Day 10 and Day 14</th>
</tr>
</thead>
<tbody>
<tr>
<td>Standard Plate Count (SPC)</td>
<td>SPC</td>
</tr>
<tr>
<td>Coliform Count</td>
<td>Coliform Count</td>
</tr>
<tr>
<td>Flavor Analysis</td>
<td>Flavor Analysis</td>
</tr>
<tr>
<td>Acid Degree Value (Homo &amp; Raw only)</td>
<td>ADV (Homo only)</td>
</tr>
<tr>
<td>Antibiotic (Delvo)</td>
<td></td>
</tr>
<tr>
<td>Freezing Point</td>
<td></td>
</tr>
<tr>
<td>Vitamin A</td>
<td></td>
</tr>
<tr>
<td>Butterfat</td>
<td></td>
</tr>
<tr>
<td>Lab Pasteurization Count (Raw Milk)</td>
<td></td>
</tr>
<tr>
<td>Rapid Psychrotroph Count (Raw Milk)</td>
<td></td>
</tr>
<tr>
<td>Aerobic Spore Count (Raw Milk)</td>
<td></td>
</tr>
</tbody>
</table>

The following is a brief discussion of the testing procedures performed with suggestions on how to interpret the results.

**Bacteriological Testing Procedures**

**Standard Plate Count (SPC) - Initial Day:**

*SPC - Pasteurized Milk -- Standard Limit of 20,000/mL*
*SPC - Raw Milk, Commingled -- Not to Exceed 300,000/mL*

The Standard Plate Count is an estimate of the total number of aerobic (grow in presence of oxygen) bacteria present in a sample that are capable of growth on SPC media when incubated at 32°C (89.6°F) for 48 hours. The theory behind the Standard Plate Count is that individual bacteria (or tight groups of) will multiply and grow on SPC media to form a visible, countable colony. Colonies counted on an SPC plate are expressed as the number of bacteria per milliliter (mL). There are 946 mL in a quart of milk.
Standard Plate Count

Legal standards for Standard Plate Counts for fluid milk are less than 20,000 per mL for as long as the milk is offered for sale. The percentage of Voluntary Shelf-Life (VSL) samples which satisfied the standard are shown in Figure 2. Nearly all samples had SPCs below 20,000 at day 1 of testing which is when milks are normally tested for compliance. However, the percentage of samples which were less than 20,000 dropped dramatically after 7 days storage at 43°F. The data for 1991 shows an improvement over the previous years in the number of samples which are less 20,000 after 7, 10, and 14 days. This is illustrated in the trend lines in Figure 3. SPCs below 20,000 after 10 and 14 days is a good indication of an successful quality program.

FIGURE 2

Percentages of All VSL Samples SPC Less Than 20,000/ml

1992 Data - January to March 23
In New York State approximately 23% of the dairy plants process 82% of the milk. In most, but not all cases, the milks processed by these "large" plants have a longer shelf-life, better flavor scores and lower bacteria counts than the "small" plants. This is most likely due to more up to date processing equipment, rigorous maintenance and sanitation programs, in-house laboratory control, and better training and management of personnel. However, there are "large" plants whose quality is generally poor while there are "small" plants that have excellent quality records, demonstrating that size does not define quality.

The SPC over shelf-life can be used as one indicator of the quality control program of a plant. Figures 4 & 5 break down the SPC information in Figure 2 into "large" and "small" plants. The percentage of samples with SPCs less than 20,000 has been significantly higher for the "large" plants over the past four years when compare to the "small" plants.
FIGURE 4

Percentage of VSL Samples
SPC Less Than 20,000/ml
Large Plants

Day

Day 1  Day 7  Day 10  Day 14

Large Plants - 23% plants accounting for ca. 82% production on Oct. 1990

FIGURE 5

Percentage of VSL Samples
SPC Less Than 20,000/ml
Small Plants

Day

Day 1  Day 7  Day 10  Day 14

Small plants represented 77% of the plants processing approx. 18% of the milk in Oct. 1990.
Coliform Bacteria Counts

Coliform bacteria in pasteurized milk are indicators of post-pasteurization contamination. Legal standards are less than 10 coliform per mL though the detection of any coliform is unacceptable. Coliform are not always at detectable levels immediately after processing, but may show up later in shelf-life. Table 2 shows the percentage of samples with coliform less than 10 per mL throughout shelf-life. A modest increase in percentage of samples without coliform suggests that plant sanitation procedures are improving.

<table>
<thead>
<tr>
<th></th>
<th>Day 1</th>
<th>Day 7</th>
<th>Day 10</th>
<th>Day 14</th>
</tr>
</thead>
<tbody>
<tr>
<td>1992*</td>
<td>99</td>
<td>83</td>
<td>79</td>
<td>80</td>
</tr>
<tr>
<td>1991</td>
<td>96</td>
<td>76</td>
<td>73</td>
<td>73</td>
</tr>
<tr>
<td>1990</td>
<td>95</td>
<td>77</td>
<td>69</td>
<td>65</td>
</tr>
</tbody>
</table>

* 1992 Data - January to March 23

Flavor Scores

The most significant test for consumer acceptability of fluid milk is its taste. Average milk flavor scores are shown in Figure 6. Scores for 1991 tend to be slightly higher than previous years for milks stored for 7, 10, and 14 days, though the overall scores are in need of improvement. The first quarter of 1992 however is not promising dramatic changes. The trend in flavor scores is a reflection of the SPC data which suggests that a higher percentage of the milks tested were not subject to microbial spoilage.
Rancid Flavor - Acid Degree Value

Acid degree value (ADV) is a measure of the free fatty acids in milk and correlates with the development of rancid off-flavors. For most people, an ADV of 1.4 or higher is the threshold for off-flavor. The percentages of homogenized milks with ADVs less than 1.4 are shown in Figure 7. This data suggests a significant improvement of ADVs after 7, 10 and 14 days for 1991 and first quarter 1992.

FIGURE 7
Percentage of Homogenized Milk Samples ADV Less Than 1.4
Vitamin A

Vitamin fortification of milk continues to be a concern of the dairy industry. In 1991 a Massachusetts dairy overdosed its fluid milk with Vitamin D to the extent that it allegedly caused the death of an elderly woman. Currently the Milk Quality Improvement Project is only testing for levels of Vitamin A. Low fat and skim milk must contain added Vitamin A at a level of 2000 International Units per quart "within the limits of good manufacturing practices". New York State accepts milks which contain Vitamin A in the range of 1600 to 2400 IU per quart. The percentage of samples tested which fall within this range are shown in Figure 8 along with the percentage of milks which were over and under fortified. Included are results from a FDA survey which are similar to the results for New York State indicating a national problem.

**FIGURE 8**

Vitamin A Content Over/Under By 20% of Declared Amount

The percentage of samples found to be in compliance has been fairly constant over the last four years with approximately one third of the samples falling within the acceptable range. Again, the "large" plants have had a greater percentage of samples in compliance when compared to the "small" plants. Most larger operations use vitamin feed pumps versus manual addition. Feed pumps if maintained and used correctly will accurately fortify milk products. Some smaller operations have or are installing these pumps in response to growing concern over vitamins in milk. The results for the first quarter of 1992 suggest a dramatic improvement in the percentage of samples in compliance. This improvement can be expected to continue as dairy management becomes more involved in assuring proper vitamin fortification of milk.
VITAMIN FORTIFICATION OF FLUID MILK

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February, 1992

Program Supported by:

New York State Milk Promotion Board
and
Cornell University
INTRODUCTION

Low fat and skim milk must contain added vitamin A at a level of 2,000 International Units (IU) per quart within limits of good manufacturing practices. Under NY State regulations, the acceptable range for fortification of milk with vitamin A is 1,600 - 2,400 IU/quart.

In 1988 and 1989 approximately two-thirds of the samples tested were out of this range with a higher percentage underfortified (<1,600 IU). Companies involved were informed and corrective action suggested.

The results for 1990 and 1991 did not show a major improvement in the percentage of samples within the acceptable range of vitamin A fortification, although less samples are underfortified. The information that follows should prove useful if your plants' vitamin A addition is not in compliance. Please contact the Extension staff at Cornell if we can provide assistance.

LOW FAT AND SKIM MILK WITH VITAMIN A ADDED
Percentage in Each Range

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It is essential that milks be fortified as indicated on the product label and according to Federal and State regulations. Federal regulations for vitamin fortification are summarized below.

**Federal Requirements and Options**

The Code of Federal Regulations, Title 21 states:

"Section 131.110 Milk
(a) Description. Milk......................
(b) Vitamin addition. (Optional). (1) If added, vitamin A shall be present in such quantity that each quart of the food contains not less than 2000 International Units thereof within limits of good manufacturing practice. (2) If added, vitamin D shall be present in such quantity that each quart of the food contains 400 International Units thereof within limits of good manufacturing practice.

SECTION 131.135 Lowfat Milk.
(a) Description..............................
(b) Vitamin addition. (1) Vitamin A shall be present in such quantity that each quart of the food contains not less than 2000 International Units thereof within limits of good manufacturing practice. (2) Addition of vitamin D is optional. If added, vitamin D shall be present in such quantity that each quart of the food contains 400 International Units thereof within limits of good manufacturing practice.

SECTION 131.143 Skim Milk.
(a) Description..............................
(b) Vitamin addition. (1) Vitamin A shall be present in such quantity that each quart of the food contains not less than 2000 International Units thereof within limits of good manufacturing practice. (2) Addition of vitamin D is optional. If added, vitamin D shall be present in such quantity that each quart of the food contains 400 International Units thereof within limits of good manufacturing practice."

To meet the requirements of the Code of Federal Regulations, good manufacturing practices require that the vitamin A & D levels not be less than 2000 International Units per quart of vitamin A and 400 International Units of vitamin D, and that they not exceed a 20% over fortification level; not greater than 2400 International Units per quart of vitamin A and 480 International Units per quart of vitamin D. New York State allows underfortification to 20%; not less than 1,600 IU per quart of vitamin A and 320 IU per quart of vitamin D.
Types of Concentrates Available

A number of different types of concentrates are available. All contain vitamin D, and/or vitamin A palmitate with a carrier consisting of any of the following: butter oil, corn oil, evaporated milk, non-fat dry milk, polysorbate 80, propylene glycol and glycerol monooleate. It is best to store vitamin concentrates as recommended by the manufacturer, generally avoiding heat and light. If stored under refrigeration, viscous concentrates should be brought to room temperature before addition.

Problems Involved With Fortification

Natural Levels. Milk and milk products which contain a large proportion of fat are relatively good dietary sources of vitamin A, but as is the case with other natural foods, the vitamin D content of unfortified milk is quite low. As with other milk components, vitamin A and D levels are affected by breed, season, diet, lactation and in the case of vitamin D, animal exposure to sunlight.

In general when cows are transferred from pasture to winter rations in the fall, a decline in the vitamin A and D levels can be expected in the raw milk. This occurs slowly through the winter season until the cows are once more on pasture in the spring. With proper selection of feed and diet concentrates this effect can be kept to a minimum. Natural levels of vitamin A range from 400 I.U. in winter to 1200 I.U. in summer, and vitamin D, 5 I.U. in winter to 40 I.U. in summer. These are approximate ranges to indicate possible seasonal variations.

Because of seasonal and other variations in natural vitamin levels it is necessary to monitor the level of fortification to assure that levels are within good manufacturing practices. Most commercial concentrates are prepared to fortify milks with 2,000 IU per quart vitamin A and/or 400 IU per quart vitamin D.

Vitamin D is very stable in homogenized whole milk and is not affected by pasteurization or other processing procedures. Vitamin D in fortified homogenized whole milk will remain constant with little or no loss of vitamin potency during long periods of proper storage. No loss of vitamin D will be experienced under normal shelf-life periods.

Vitamin A and D fortified skim milk products are subject to decreases in vitamin A, because the vitamin is no longer protected by fat as it is in whole milk. In fluid skim or low fat milk added vitamin A deteriorates gradually during normal storage of the milk at 4.40 C (40° F) in the dark but is destroyed rapidly when the milk is exposed to sunlight or fluorescent light in transparent glass bottles or transparent plastic containers. The photo destruction of added vitamin A is dependent on the intensity and wave length of light and milk source. The use of amber or brown glass bottles, pigmented plastic containers formulated with specific light barriers and paper cartons retard this destruction. Vitamin A losses in 2% milk from five dairy plants ranged from 8% to 31% when they were exposed to 200 foot candles of fluorescent light for 24 hours in clear plastic containers.
pigmented containers or gold shields over fluorescent tubes practically eliminated these losses.¹

Problems associated with natural levels, loss of vitamin A during storage and the problems with the mechanical addition discussed in the following section of this guideline indicate the difficulty in providing a product that will have proper potency levels.

Process/Methods of Addition

Vitamin fortification has been accomplished by the addition of vitamins at many different points in the processing system. These have ranged from addition to the raw tanker before unloading, to the silo tank, to the pasteurizing vat (when vat pasteurization is used), to the HTST balance tank, and directly into the milk line. Federal regulations require that vitamins be added to milk prior to pasteurization. Both batch addition and addition with metering pumps have been used. The batch procedure requires accurate measurement of the volume of milk to be fortified, accurate measurement of the vitamin concentration and proper mixing.

The problem of under fortifying is often related to the point in the system where fortification takes place. Vitamin A and D are both fat soluble and will gradually become more concentrated in the milk fat portion of the milk. Both oil and water base vitamins may be susceptible to this migration problem. However, water soluble vitamin concentrates are available which minimize this problem.

If vitamins are added before separation and standardization in the proper amount, and the product is then separated and standardized, the low fat product will tend to be under fortified and the high fat product over fortified. To reduce this effect, it has been found that if the vitamin concentrate is in a water soluble carrier, the separation of the vitamins to the fat or cream phase is minimized. Processors who use this procedure should perform confirmatory assays to insure proper fortification levels of each product.

Many HTST systems are now being used with in-line fat standardization which also makes possible switching without stopping from products requiring fortification with vitamin D to those requiring both A and D. These systems require metered injection of the proper vitamins at a point after standardization and before pasteurization. Sanitary positive displacement pumps are available for this purpose.

There are two types available, one is a piston type positive displacement metering pump without valves. It is equipped with a micrometer, which allows accurate and reproducible amounts of vitamins to be added which are calculated based on the rate of product flow through the system.

The other type metering pump is also a positive displacement (peristaltic) pump which offers precise control, (volume can be controlled by the size of tubing used as well as pump speed) and ease of cleaning (only the tube is in contact with the vitamin concentrates). These pumps also have a history of reproducibility and reliability. All metering pumps should be designed specifically to conform with the 1989 Grade A Pasteurized Milk Ordinance recommended by the U.S. Public Health Service for equipment employed in sanitary applications.

The best point for injection of the vitamin is ahead of the homogenizer which in most cases is a point of low pressure. This allows the homogenization process to distribute the vitamin throughout the milk. A positive displacement type pump must be used. Negative pressures at the point of injection can create problems unless a positive displacement pump is used. A small vacuum can result in relatively large volumes of vitamin concentrate to be drawn into the milk system in a very short time period.

Simple, single speed HTST systems running one product (for example, homogenized vitamin D milk) would work very well with one metering pump. More complex systems having two or more operating speeds and running products requiring both vitamin D and vitamins A and D may use more than one pump and a valving arrangement; see Figure 1.

To avoid the need for two pumps or constant adjusting of pumps where both vitamin D and vitamin A and D concentrates are used in the same HTST systems, the vitamin D concentrate can be diluted with water or skim milk so that it can be fed into the system at the same rate as the vitamin A and D concentrate. (Regulatory personnel should be notified for their approval if this procedure is used.) Provision should be made to keep these solutions at 40°F (4.4°C) or less during fortification process. Extreme care should be taken to make precise measurements. Small errors in measurements and calculation can have a major effect on the final concentration in the finished product. Containers and equipment used for dilution should be cleaned and sanitized daily or more frequently if necessary.

Essential to proper results are the following:

1) Management must be committed to proper fortification and be concerned with both over and under levels.

2) Design the system correctly for proper addition in which concentrate is added after standardization and before pasteurization is completed.
3) Use an accurate, sanitary, positive displacement metering pump with a scheduled cleaning procedure after use.

4) Use a check valve on the injection line to prevent milk from being pushed back into the line. This depends on pump displacement.

5) Check meter calibration regularly by determining delivery rate accuracy.

6) Keep accurate records of vitamins used and products produced, checked daily against theoretical use. Care should be taken that adequate fortification of small run products like skim milk is not masked by much larger volumes of 2% or other partly skimmed milk products.

7) Use insulated vessels such as thermos jugs for holding diluted concentrates to maintain temperatures of 40°F (4.4°C) and below. A regular systematic cleaning and sanitizing schedule must be maintained for these vessels.

8) Check finished products regularly. Results should be reported in International Units (I.U.)/Quart. Because of the sensitivity and difficulty in performing these tests, it is necessary to procure the services of a competent laboratory, one that is familiar with the handling and testing of vitamin fortified dairy products.

9) **Protect from light!** Vitamin A concentrates are susceptible to daylight, bright fluorescent and mercury vapor lights.

**Testing Methods**

The Association of Official Analytical Chemists (AOAC), recommends a liquid chromatography method for vitamin D. The Carr-Price Method is recommended by AOAC for vitamin A. Other methods for vitamin A include fluorescent spectrophotometry (see Journal of Dairy Science Volume 58, page 558) and liquid chromatography methods. Most plant quality control laboratories are not equipped to perform these analyses.

Limited testing at Cornell may be available to help plants get started. Contact the Extension Office for more information. (607-255-3027).
Two speed system - 2 pumps, no pump adjustment, just change valves

Either D or A & D at either speed

1/8" plastic tubing, plastic valves, stainless steel check valves. FMI (Fluid Metering Inc.) pumps

*Recommend use of sanitary check valve-valves to separate milklines from vitamin concentrates and to keep all milk contact surfaces of sanitary design - easy to clean and available for inspection.

REFERENCES:


Theory and Practice of Vitamin D. Fortification of Milk. K. G. Weckel.
Modified Atmosphere Packaging:
Technological and Safety Considerations

Joseph H. Hotchkiss
Cornell University
Stocking Hall
Ithaca, NY 14853

Controlled/modified atmosphere packaging (C/MAP) can be defined as the alteration of the gases surrounding a packaged food. This is undertaken for two reasons; first, to slow the respiration for fruits and vegetables, and secondly, to inhibit or alter the growth of microorganisms in non-respiring products. The objective is to extend shelf life. In nearly all cases, C/MAP products are refrigerated.

The scientific literature and commercial practice have both demonstrated that controlled/modified atmosphere packaging (C/MAP) extends shelf life and maintains quality of refrigerated foods including cheeses and other dairy foods. The quality of perishable refrigerated foods can also be improved over conventionally packaged and stored products. Limitations to C/MAP include increased capital equipment and materials costs, potential consumer resistance to packaging, and concerns over safety.

C/MAP is more complex than conventional packaging. Variables which must be controlled in C/MAP include product composition and quality, gas composition and volume, package form and barrier properties, storage and abuse conditions, and the type and reliability of the packaging equipment. Both the barrier properties and design of the package are important considerations in C/MAP. The barrier has to be sufficient to maintain desired gas mixtures during the desired shelf life. In most cases the package must be designed with sufficient headspace to act as a reservoir for the gas mixture. Several types of equipment are available for C/MAP of foods. The type of equipment chosen depends on speeds needed type of product and cost.

Many microbiological safety questions remain unanswered. Particularly important is the relationship between spoilage and pathogenicity. In some cases, C/MAP has the potential to inhibit spoilage that would lead to consumer unacceptability while allowing growth of pathogenic bacteria such as Listeria monocytogenes. There is also a need to develop improved barrier materials and for a better understanding of safety. Research into the use of bacteriocins which will inhibit pathogen growth and/or inoculations with microorganisms which would render products unacceptable are also needed.

We have demonstrated the use of C/MAP as tool to extend the shelf life of cottage cheese to 45 to 60 days. CO₂ was dissolved directly into the cream dressing before addition of the curd. The
cheese was then packaged in polystyrene tubs and over wrapped with high barrier heat shrinkable film. Gram negative bacteria and mold development was inhibited in the MAP product compared to conventional product. The shelf life of the cottage cheese approached 60 days.

We have also investigated the effects of this packaging system on the growth of *Clostridium sporogenes* and *Listeria monocytogenes* when inoculated into creamed cottage cheese. Cheese was packaged with and without CO₂ in polystyrene tubs and over wrapped with high-barrier heat shrink film and stored at 4, 7 and 21°C for up to 63 days. *C. sporogenes* failed to grow in any sample but *L. monocytogenes* grew in the conventionally packaged cottage cheese from an inoculum level of 10⁴ to 10⁷ cfu/g after lag times of 7 and 28 days at 4 and 7 °C. *L. monocytogenes* failed to grow in cottage cheese packaged with CO₂ and stored at 4°C and increased from 10⁴ to 10⁵ cfu/g in product to which CO₂ had been added and stored at 7°C. This indicates that the addition of CO₂ to cottage cheese to extend shelf life does not represent an increased listeria or botulism hazard. It also seems to suggest that listeriosis could occur as a result of eating contaminated cottage cheese.
CONCERNS FOR "LIGHT" DAIRY PRODUCTS

Craig J. Oberg, Weber State University

Presented at the 10th Biennial Cheese Conference, August 18-20, 1992, Logan, Utah.

I. FAT CONTRIBUTIONS TO CHEESE

A. Cheese firmness
   1. Physical state of the fat (proportion of solid to liquid fat)

B. Adhesiveness

C. Elasticity
   1. Ratio of fat to solids-not-fat (rigidity of globules)
   2. Interaction between fat globule membrane and protein matrix
   3. Size distribution of fat globules
   4. Extent of unsaturation in fatty acids

D. Flavor
   1. Free fatty acids
   2. Reservoir for fat-soluble flavors
   3. Fat-water interface for flavor reactions
   4. Bacteria congregate at fat-protein interface

E. Color

F. Mouthfeel, smoothness, creaminess

G. Frozen products; controls release of flavors, freeze/thaw stability, shrinkage, and melt-down quality

H. Carrier for fat-soluble vitamins

II. WAYS TO LOWER FAT IN CHEESE

A. Reduce Fat and Increase Other Milk Components
   1. Increase moisture level, lower cooking temperatures
   2. Increase Protein Level (condensed skim milk, NFDM, skim milk)
      a. problem - high levels of lactose - pH drops too low
   3. Ultrafiltration - incorporate undenatured whey proteins
   4. Standardization of Milk to Proper C/F Ratio

B. Partial or Total Fat Replacement with Substitute
   1. Fat Mimetics
      a. provide the same mouthfeel
      b. do not heat well, used in frozen, creamed products
      c. limited use in semi-soft and hard cheese
      d. types
         starch-based (cold-pack cheeses, cheese food products)
         protein-based (widest use in hard cheeses)
         cellulose-based
2. Fat Substitutes
   a. same chemical properties as fats
   b. no application presently
3. Gums and Emulsifiers
   a. bind water
   b. disadvantages - inhibit starter/rennet activity, cause pastiness during ripening, side fermentations
   c. use in frozen dairy products shows promise
C. Cholesterol Removal

III. PROBLEMS WITH LOWFAT CHEESES
A. Flavor Defects
   1. Meaty-brothy flavor (very common)
      often due to changes in microflora
   2. Astringency
   3. Bitterness - bitter peptides
   4. Unclean flavors
   5. Less flavor intensity
   6. Acidic
B. Texture/Body Defects
   1. Corky/rubbery body
   2. Poor shred
   3. Soft body
   4. Decreased melt
   5. Gas defects - slits, blown-up packages
C. Other Defects
   1. Loss of Vitamin A
   2. Glossy appearance - removal of fat affects light reflection
   3. Shorter storage time - deterioration of body
   4. Regulatory problems - "Standards of Identity", use of the term "imitation"

IV. POSSIBLE SOLUTIONS TO IMPROVE LOWFAT CHEESE
A. Increase Flavor Intensity
   1. Decrease moisture level in cheese
      a. improve flavor development, long term storage
   2. Ripen at higher temperatures
      b. often get slightly different flavors
      c. low fat cheese prone to off-flavors
   3. Select proper starter cultures (peptidolytic activity)
   4. Culture adjuncts
   5. Add emulsifying agents (gums)
   6. Add enzyme-modified cream
   7. Homogenization
   8. Swiss cheese, heat-treated L. helveticus cultures
B. Off Flavors
   1. Culture adjuncts
   2. Reduce microflora/secondary flora
   3. Different type of starter cultures
   4. Select cultures - alpha-dicarbonyl production (meaty, brothy)

C. Body/Texture Problems
   1. Increase moisture and reduce acid level - increase softness
   2. Use gums to restore textural properties
      ex. carrageenan - slicing improvement
      locust gum - spreadability
      carboxymethyl cellulose
   3. Lower moisture levels by adding more solids
   4. Raise the salt level to bind more water

D. Too Much Acid
   1. Wash curd during manufacture

E. Loss of Vitamin A
   1. Change "standards of identity" so it can be added to cheese

F. Calcium Lactate Crystal Formation
   1. good tight packaging (problem with high moisture cheeses)

Best is a total systems approach - combination of ideas - flexibility.

V. LOWFAT CHEESE MANUFACTURING CONSIDERATIONS (Cheddar Cheese)


A. MILK PASTEURIZATION AT 180°F (vs 164°F)
   Effects: Increases set time slightly.
             Increases moisture and sugar concentration.
             Results in lower pH.
             Decreases protein breakdown.

B. RAISE INOCULUM LEVEL TO 2% (vs 0.5%)
   Effects: Difficult to control acid production.
             Final pH too low.
             Acid flavor, mealy body.
             More intense flavor during aging.

C. RENNEN LEVELS
   Effects: 1.5 months - 4.6 oz./1000 lbs best
             3 months - 3.45 oz./1000 lbs best
             6 months - 1.15 oz/1000 lbs best
             Increased rennet levels decrease shelf life.

D. WHEY DILUTION (remove 20% whey and replace with 10% water)
   Effects: Less flavor, more off flavors, poorer texture
E. DRAIN pH
Effects: High drain pH gives higher moisture levels. Higher drain pH, then at 3 months - More flavor intensity, less off flavors. More calcium retained.

F. MILL pH
Effects: Higher mill pH results in higher moisture level, more flavor intensity, better body.

G. CURD WASHING
Effects: Less flavor intensity, mushy body, more off flavors, shorten shelf life. Increase in moisture if wash curd to 72°F.

IDEAL MAKE SCHEDULE
Milk skimmed to 1.75 to 1.8% milkfat.
Use slow starter to get 2:45 to 3:30 make time.
High drain pH - 6.45 (whey) or 6.35 (curd).
High mill pH - 5.8 to 5.9.
No stir-out time.
Age cheese at least 3 months.

VI. LOWFAT CHEESE CULTURES
"Cultures/media for full-fat cheese are not optimal for low-fat cheeses..."

A. Selection of Lowfat Cultures
1. Less proteolytic
2. Slower acid producers
3. Have enough peptidolytic activity to breakdown bitter peptides
4. Does not overproduce alpha-dicarbonyl compounds (meaty-brothy flavors)
5. Flavor intensity (adjuncts)

B. Problems with Cultures
1. Many accentuate flavor defects.
2. Increased inoculum levels (since the cultures are less active) make it difficult to control acid development.
3. Higher moisture levels
   a. Lower cook temperatures lead to increased cell numbers and increased cell activity - pH can get too low (below 5.0 at 24 hr)
   b. Salt in moisture decreases and allows cultures to continue acid production.
C. Culture Adjuncts
   1. *Leuconostoc* in mesophilic starters
   2. *Lactobacillus casei* cultures

VII. LOWFAT CHEESE ECONOMICS

1. Competition for shelf space.
2. Price of excess milkfat, NDM, etc.
3. Premium pricing required, so flavor and texture must be optimal.

REFERENCES:


Snook, R. 1991. Manufacture of cheese with Simplesse. pg 111 in Proc. 28th Annu. Marschall Italian Cheese Sem., Madison, WI.
NON-STARTER FLORA AND REDUCED FAT CHEESE

Mark E. Johnson
Center for Dairy Research
University of Wisconsin - Madison

INTRODUCTION

There are two categories of microorganisms found in cheese; those that are deliberately added as starter and non-starter species. Non-starter species either survive the heat-treatment given to milk prior to cheesemaking or occur as contaminants in milk and cheese during manufacture. By statute, all reduced fat cheese made in Wisconsin must be manufactured from pasteurized milk. This effectively eliminates over 90% of the indigenous raw milk flora.

The gram negative psychrotrophic bacteria, particularly Pseudomonas but also the Enterobacteriaceae (coliforms) are by far the most common organisms in raw milk comprising perhaps 90% of raw milk isolates (4). The gram positive organisms including Streptococcus, Leuconostoc, Bacillus, Clostridia, Enterococci, Lactobacillus and the coryneform group make up less than 10% of the raw milk flora. The gram negative bacteria do not survive milk pasteurization nor do most of the non-spore forming gram positive bacteria. The predominant bacteria in pasteurized milk are the Bacillus and the coryneform bacteria. With few exceptions Lactobacilli do not survive pasteurization (1, 6, 8) yet this group of bacteria becomes the dominant flora of cheese, especially of aged cheese (7,8).
It has been determined that the dairy plant environment is the source of the Lactobacilli ultimately becoming the dominant non-starter flora in cheese (5). Lactobacilli are contaminants in raw and pasteurized milk gaining access to the milk or cheese through soiled equipment, air, and even human contact.

Although it is recognized that defects occurring in cheese have been attributed to a variety of microorganisms, this presentation will concentrate on the ubiquitous Lactobacilli and the undesirable affects they can have in cheese.

**GAS FORMATION**

Several microorganisms have the potential to cause gas accumulation in cheese: lactobacillus, clostridium, coliforms, yeasts, propionibacterium, bacillus, leuconostoc, and lactococci (diacetylactis). To determine the organism responsible for the gassy defect selective media or variations in conditions of growth or isolation are employed. We examined 22 cases of gassy defects in cheese including sweet holes, slits, cracks, and blown packages. The causitive agent in 18 cases was determined to be CO₂ producing heterofermentative lactobacilli. The CO₂ is produced from the metabolism of sugar; lactose or galactose. Of the four remaining cases, two cheese had high clostridia numbers and two cases remain unresolved.

**CALCIUM LACTATE CRYSTALLIZATION**

Starter bacteria produce only L(+) lactic acid. Racemization (conversion) of L(+) lactic acid to DE(-) lactic acid always precedes calcium lactate crystallization. Racemization is concomitant with an increase in non-starter lactic acid bacteria,
particularly lactobacilli (2). Manufacturing procedures, packaging and storage conditions also play a major role in the development of crystals (3).

UNCLEAN FLAVORS

Lactobacilli can produce chemical compounds that give cheese flavors described as unclean. Bob Lindsay (U.W.-Madison) has identified these compounds as microbial metabolites of aromatic amino acids. Phenylalanine gives rise to phenethanol (rosey flavor), tyrosine to p-cresol (barny, utensil) and tryptophan to indole and skatole (lingering unclean). The increased aqueous phase and lower fat levels in reduced fat cheese undoubtedly play a key role in the taste response evoked by these compounds. They normally partition to the fat phase, but under the high moisture/low fat environment are increasingly found in the aqueous phase.

CONTROL OF LACTOBACILLI

Pasteurization is the first means of defense against lactobacilli. Most lactobacilli (especially heterofermentative) are easily killed by pasteurization. The effectiveness of pasteurization is enhanced by high quality raw milk with low levels of lactobacilli contamination. Since lactobacilli found in cheese are most likely to be contaminants from the processing area strict adherence to sanitation is mandatory. Rapid cooling of cheese will help control growth but the best storage conditions can be for naught if during distribution the temperature of the cheese rises above 45°F.
Cheese composition can also affect the growth of lactobacilli. High moisture, low salt, high pH and low lactic acid levels can result in an increase in the growth and metabolism of the lactobacilli as well as other undesirable microorganisms.
Thermal Destruction of Lactobacilli

Numbers of Lactobacilli Remaining in Heated Milk

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<td>10,000</td>
<td>Y100</td>
<td>Y100,000,000</td>
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Y10 = 1 per 10 ml of milk

Temperature °F
Time Constant at 16 sec
REFERENCES


At the 1988 Conference I described the computer system we designed and built to monitor and control cheese making. In this paper I will outline an investigation of syneresis and show how this relates, at a fundamental level, to the control of cheese making. I will conclude by speculating about future developments in controlling cheese making.

The inherent difficulty in measuring syneresis is that the separation of curd from whey causes it to collapse under its own weight. This causes a systematic error in measuring curd moisture. The only way to overcome this problem is to measure syneresis without separating curd from whey. Various attempts have been made to add known amounts of tracer to curd and whey mixtures and measure the progressive dilution of the tracer as more whey is expressed from the curd. All the tracers which have been used have adsorbed to the curd surface, so invalidating the method. The first requirement was for a reliable method to measure syneresis to provide an accurate quantification of the process.

Method of measurement of syneresis.

The measurements were carried out in scaled down cheese vats. Nine stainless steel boxes, 90 mm on each side and fitted with a water proof lid were rotated in a horizontal plane at 13 RPM in a frame in a water bath held at 30°C, or at any required temperature. Each box provided one sample to measure syneresis at suitable intervals. Skim milk powder was reconstituted to 10% w/v and left to equilibrate for 1 hour. Aliquots of 500 ml were measured into each box in a water bath at 30°C and left to reach the setting temperature. Sufficient rennet was added to each box to give coagulation in 12 to 15 minutes. Later the curd was cut with miniature curd knives into 8 mm cubes. The lid was clipped to the boxes and these were then fastened in the frame which rotated the boxes in a large water bath. The slowly rotating boxes imparted a tumbling motion to the curd and provided suitable stirring without shattering the curd. At intervals a box was removed and an accurately measured volume of whey was removed from the box, care being taken to keep the whey level well above the level of the curd. A known volume of distilled water was added and the curd was stirred gently to ensure thorough mixing. A sample of the diluted whey was removed within 15 seconds. Two ml samples of both undiluted and diluted whey were mixed with 2 ml of 2.5% w/v sodium tripolyphosphate. The optical density of both samples was measured in a spectrophotometer at 600 nm. The following is deduced from Beer's law.

\[ V_w = V_a \cdot \frac{OD \text{ diluted}}{OD \text{ undiluted} - OD \text{ diluted}} \]

where
- \( V_w \) = volume of whey remaining in box after removal of whey sample.
- \( V_a \) = volume of water added.

The total volume of whey \( V_t = V_w + V_r \), where \( V_r \) is the volume of the removed whey.

The greater the volume of undiluted whey removed initially, the more accurate is the final result, always provided that the curd particles are not exposed. Soon after cutting, only about 10 ml of whey could be removed without exposing the curd, up to 200 ml could be removed after two hours. The reproducibility of the whey dilution method of measuring syneresis is demonstrated in the results of 3 separate experiments shown in Figure 1. The error bars show the range in the results. The coefficient of variation for the 3 experiments was 1.3%. The method proved to be well suited for an
examination of the effect of various conditions on syneresis. The only specialized equipment required is the boxes and the frame to rotate them in the water bath.

Results.
The effect of temperature on syneresis.

The results of measuring syneresis in curd set, cut and syneresed at 30°, 33°, 36° and 39°C are shown in Figure 2. Each curve is the mean of duplicate runs. Care was taken at 39°C to prevent the curd particles matting together. There was the expected increase in syneresis at higher temperatures. The increase in temperature increased the rate and extent of the initial rush of whey from the curd, but not the duration of that initial rush. After this initial period there were no obvious differences in the slopes of the curves, and thus in the rate of syneresis. There is a smaller difference in syneresis between the 33° and 36°C curves, but the reason for this is not known. The steady state temperature results at 30° and 36°C may be compared in Figure 3 with the increase from 30° - 36°C immediately after cut. In curd raised to 36°C immediately after cut there was increased syneresis, but it took longer to reach the equilibrium rate of syneresis. Similar results are shown in Figure 4 in which the temperature was ramped to 39°C. Once again syneresis in the curd ramped to 39°C reached the same level as in the curd held at 39°C throughout. These results show that the lower temperature at set and cut had no significant effect when the temperature was raised shortly after cut.

The effect of pH on syneresis.

The natural pH of the reconstituted skim milk was pH 6.65. Aliquots of milk were adjusted by dropwise addition of 4N HCl into vigorously stirred milk at 5°C. This was left for 1 hour to equilibrate. The syneresis of milk at pH 6.65, 6.3 and 6.01, all at 30°C, is shown in Figure 5. There is general similarity between these curves and those obtained at different temperatures. There was a slightly greater initial rush of whey from the curd at pH 6.01 immediately after cutting than from curd at 39°C. However the duration of this rush seemed to be similar, and the rate of syneresis then decreased to a constant rate which was similar at all 3 levels of pH.

The effect of cut size on syneresis.

Miniature curd knives were constructed to give 4 mm and 16 mm cubes of curd. The milk was renneted at 30°C and subsequently cut into 4, 8, or 16 mm cubes. The temperature was maintained at 30°C. The results in Figure 6 are the average of duplicate runs. There was again an initial rush of whey which progressively increased with each reduction in cut size. This rush lasted for about the same time in all 3 treatments and then syneresis reached the same rate in all treatments. The effect on the 3 mm and 16 mm cut sizes of a ramp increase in temperature to 39°C after cut is also shown. The initial rush of whey in the 8 mm curd particles was considerably faster, but the 8 mm and 16 mm cubes both reached equilibrium syneresis rates at about the same time. These results show, as expected, that the smaller cut size produced more syneresis but the increased syneresis was not proportional to the increase in surface area.

The effect of cut time on syneresis

Curd was cut at different multiples of the catch time. The catch time is the time at which the first sign of coagulation is visible. The curd was cut at 1.5, 2.5 and 3.5 times the catch time. The curd cut at 1.5 times the catch time was soft, but did not shatter. Special care was taken to avoid smashing the softest curd because smashing does increase syneresis. The results are shown in Figure 7. There is no discernible difference in the rate of syneresis between the 3 treatments.
The effect of stirring on Syneresis

The control conditions used only the tumbling action of the curd in the rotating boxes. The other 3 conditions included a small bar, a small baffle or a large baffle attached to the lid to increase stirring intensity. The results are shown in Figure 8. The most vigorous stirring produced the largest initial rush of whey from the curd, but the duration of this critical rush was approximately constant for all treatments. The rate of syneresis in the next phase was then approximately equal in all treatments. This suggests that the stirring of the curd immediately after cut has a significant effect on the moisture level. The quantitative measurement of syneresis shown in Figure 8 can be interpreted as evidence of forces external to the particle driving the process of syneresis. However the results do not show how those external forces act on the curd particles. The crucial importance of the role of external forces is shown in the fact that curd which is not cut and stirred synereses only very slowly.

The study of the kinetics of syneresis has shown that physical factors such as pH and temperature have a profound effect on the initial rate of syneresis. These factors did not influence the rate of syneresis in the period after the initial rush of whey. Cut size has no influence on the physical chemistry of the curd, but smaller curd sizes led to more syneresis. Further measurement of the effect of these or other variables on syneresis would only provide more information on the effect of the driving force on syneresis, not the driving force itself. It was concluded that a study of the structural changes in curd during syneresis might explain the driving force.

Electron Microscopy.

It was not considered likely that artefacts from chemical fixation would affect the gross morphology of curd preparations. The network structure was significantly larger than the artefactual results associated with fixation. It is this network structure which we sought to relate to syneresis. The syneresis measurements described above were carried out on reconstituted skim milk. A preliminary examination by scanning electron microscopy of sections of curd prepared from both reconstituted milk and fresh whole milk showed similar three dimensional networks linked together to form strands. The fat globules did not appear to be involved in the network and are present in the spaces between the strands. It was concluded that the structural changes involved in syneresis could be investigated with reconstituted skim milk.

Milk was set with rennet at 30°C, cut after coagulation and then cooked at 39°C. Samples were taken at intervals for fixing and subsequent examination in the electron microscope. At cut time the gel network appeared diffuse and the strands were not well defined. After 15 minutes the strands were less diffuse and the micelles appeared to be more tightly packed. At the end of 2 hours the edge of the curd was tightly packed and formed a skin. The centre of the curd formed a comparatively loose open network.

Reconstituted skim milk was set at 30°C, cut and then syneresed at this temperature. One hour after cut a curd sample was taken for examination by transmission electron microscopy. Another batch was set at 39°C and maintained at this temperature throughout. A sample was taken 1 hour after cut and examined by the same technique. The curd set, cut and cooked at 39°C was more open than the curd at 30°C. Syneresis is faster at 39°C. In both samples the surface of the curd particles had compacted to form a skin.

The electron microscope images showed that the micelles are packed into strands at cut, and that the strands become more compact as stirring
progresses. The arrangement of micelles in relation to one another did not change, they merely moved closer together. It was not expected that the arrangement of micelles within the strand would change because this would involve breakage of existing intermicellar bonds. Moisture in the strands was reduced as it joined the free volume whey in the particle. This qualitative assessment of the changes involved in syneresis emphasised the need for a quantitative measurement of strand consolidation. Scanning electron microscopy gives a 3 dimensional view of the curd. The large and variable depth of field made quantitative analysis of the image impractical. Transmission electron microscopy of thin sections also presents problems. Each field covers only a very small area and the network is highly variable within the field. Many fields are needed to obtain valid results. Another problem is that the high resolution of transmission electron microscopy causes the strands to be poorly defined, since only the micelles are visible. This is a special problem at cut when the strands have not consolidated into an easily identifiable network. It is not feasible to measure the strand thickness on such images. It was concluded that the lower magnification and lower resolution of light microscopy was more suitable for quantification of the changes in curd.

Light microscopy and image analysis.

A decisive advantage of light microscopy was the availability of computer-based image analysis which was not available for electron microscopy. Samples suitable for this technique required rigorous standardisation of sampling and specimen preparation. This ensured that the dimensions of the features of interest in the sections varied only in response to changed vat conditions.

Sims (1974) has reported that glycol methacrylate is suitable for routine preparation of sections of 1-2 μ thickness. Curd particles were fixed overnight in 2% glutaraldehyde in 0.2M pH 6.7 phosphate buffer at 4°C. They were then cut in two with a sharp scalpel and dehydrated in a graded alcohol series with 2 final steps in 100% acetone. The particles were embedded in JB-4 glycol methacrylate embedding resin (Polysciences). When the resin manufacturer's instructions were followed the specimen was damaged by heat produced by polymerisation and the blocks were too soft. Solution A consisted of 0.45 g catalyst (benzoyl peroxide) in 120 ml of glycol methacrylate monomer. The particles were infiltrated with 3 changes of Solution A. Polymerisation was initiated by adding 0.3 ml of solution B (ethylene glycol) to 30 ml of solution A. Oxygen was excluded by layering liquid paraffin on the top of the reaction mixture. The blocks were left overnight at 0°C. When the polymerisation was complete the blocks were held at 60°C in an air oven for 2 hours. Sections were cut to 2μ thickness on a Leitz 1512 microtome and stained with 0.5% acidified carbol fuchsin and destained with 10% ethanol.

The Zeiss Microvideomat was used for image analysis. Four parameters were derived for each field. These were the average projection length of the features, the circle diameter assigned to the average feature area, the average chord length of the features and the average distance of the features from one another. From the latter the strand thickness can be determined. These parameters were recorded and averaged for each of 10 fields. The results for strand thickness are shown in Fig 9 for curd set, cut and then syneresed at 30°C and 39°C. The curd set and cut at 39°C has a lower initial strand thickness than the curd set and cut at 30°C. There was a smaller difference in strand thickness after 120 minutes. There is a progressive reduction in strand thickness as the casein micelles consolidate and pockets of free whey were visible in the section. In the early stages of syneresis the curd was the continuous phase, but later in the process the porosity of the network increased and the free space became the continuous phase. This caused some problems with the Microvideomat 11.
program because it is designed to measure the parameters on a discrete phase embedded in a continuous phase, that is, discrete particles which are not connected. These problems were eliminated in the next experiments by direct measurement of area density from the grey area results. The open spaces in the curd are termed "free area" and defined by a suitable setting of the grey level.

Syneresis and free area.

The aim of this section of the work was to test the proposition that the free area in the curd is a major determinant of syneresis rate. Free area was measured in unsyneresed curd at various temperatures and pH values at intervals up to 120 minutes. Syneresis was measured in curd cut and stirred under similar conditions. The free area measurements could then be related to syneresis.

The results of measuring syneresis in curd cut and stirred at 30°, 33°, 36° and 39°C are shown in Figure 10. In the same figure are the measurements of free area in curd held at the same temperature and not cut or stirred. There is a progressive increase in syneresis and free area as the temperature rises from 30° to 33°, 36° and 39°C.

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*Free area was measured in uncut, unsyneresed curd

In a similar experiment the syneresis and free area in unsyneresed curd was measured for normal milk, pH 6.65, and for milk adjusted for pH 6.3 and pH 6. Syneresis of these milks was measured at 30°C. The free area in uncut and unsyneresed curd at these values was also measured. The results of syneresis and free area measurement are shown in Figure 11. The free area and syneresis increase at the lower pH values. Two different samples of low heat skim milk powder, regarded as identical by the
supplier, were compared in a similar experiment. The 2 reconstituted milks
were set and cut at 30°C. Both were at pH 6.65. Syneresis and free area
were measured by the standard procedures. The results in Table 1 show that
Batch A, which syneresed more, also had a greater free area than Batch B.

All the data from the experiments discussed above are shown in Table 1.
In addition some experiments in which either calcium, magnesium or sodium ions
were added at an ionic strength of 8.25X10^-3 are included. The same results
are shown in Fig 12 which shows a clear relationship between syneresis in cut
and stirred curd and free area in the uncut curd. These results of
measurements 15 minutes after cut are the 4 lowest syneresis values. The
remaining data include measurements at 60 minutes and 120 minutes.

A reappraisal of syneresis mechanisms.

There are 2 distinctly different phases of syneresis. The first is
characterised by an open curd structure and a very high rate of flow of
whey from the curd particle which eventually declines as syneresis enters
the second, the constant rate phase. The results described above allow the
formulation of some new hypotheses about the mechanisms controlling
syneresis.

The coagulation of milk proceeds until the curd is firm enough to cut.
During this time casein micelles associate and then casein strands begin to
form and these gradually express whey into the free volume inside the curd
particle visible as free area with the light microscope. The essentially
two dimensional free area in the section prepared for microscopic
examination equates to the three dimensional free volume in the curd
structure. The amount of strand consolidation and hence of free area is
increased by higher temperature, lower pH and the addition of calcium ions.

Syneresis begins when the curd is cut and the mechanical action of
stirring on the outside of the curd helps to squeeze the whey out of the
curd. At this point the rate of syneresis is high, determined by the free
volume, or porosity of the curd structure. It is also at this time that
starter and fat are released from the curd through the open structure. The
more open the original curd structure, that is curd showing a high
percentage of free area, the better the outer layers compact to form a
skin. It is envisaged that the whole curd particle, retaining its original
shape, undergoes three dimensional shrinkage with the greatest shrinkage at
the surface where a skin rapidly forms. Clearly the skin prevents any
further loss of starter or of fat. The rate of syneresis declines and
eventually reaches a constant value. This marks the beginning of the second
phase of syneresis. The constant rate phase eventually ends and syneresis
essentially stops.

The key to understanding the mechanism involved in this phase is a
clear statement of the problem. The curd particle continues to expel whey
slowly. It must be reducing in volume as it does so. This required three
dimensional shrinkage of the particle. However, by this time the outer skin
is well formed and offers significant resistance to further shrinkage. It
is important to understand that the flow of a small volume of whey through
the comparatively large surface area of the particle would involve forces
small by comparison with those required to shrink the outer skin. This
skin, while not incompressible, is inherently difficult to shrink because
the outside skin has to rearrange itself to accommodate the reduced surface
area. It is analogous to shrinking an orange with an outer skin and a soft
inner core. The rate-limiting step in this second phase is the required
contraction in the skin, not the permeability of the skin to whey.

At the end of the vat phase the curd particle has a well defined
moisture gradient, increasing from the outside skin to the highest level at
the centre. Syneresis has been taken to its practical limit in the vat
after about 2 hours. The next stage of the cheese-making process involves
the removal of the curd from the whey. Once out of the whey the curd no
longer has to undergo three dimensional shrinkage but instead can be flattened between two planes and can retain the same surface area as the whey flows out of the curd. Some of the curd is inevitably fractured by mechanical action and releases more whey.

The significance of the syneresis results to cheese making.

Cheese makers in Australia have always had difficulty in controlling the moisture level of cheddar cheese. Figure 13 shows the pattern of the moisture loss from curd in one Australian factory. There are 2 separate stages to be considered here. The first is the vat stage, which ends at pump when the curd is separated from the whey. The second is the period from pump to dry when the moisture content in the curd drops sharply in a short time.

Syneresis in the vat is determined to a significant extent by the free volume in the curd, equivalent to the free area in Table 1. This is demonstrated by the effect on free area of calcium ions added to milk. Higher temperatures and lower pH have a similar effect on free area. The general effect of these variables on syneresis is well accepted, but there has been no suitable method of measuring those effects. The methods reported here give reproducible, objective results. They can be applied to cheese milk and certainly the syneresis measurements can be done in the factory when variation in the milk warrants it. The difference in syneresis between milk sample A and milk sample B in Table 1 at 120 minutes illustrates the kind of variation in syneresis between different milks referred to above. Judicious addition of calcium and higher setting temperature would give syneresis in milk B equal to milk A. The significant issue is that measurement of syneresis and free area give results which show how much calcium and what temperature to use to standardise syneresis in the vat.

Cheese makers have long known that stirring rate influences syneresis but Figure 8 shows that careful, vigorous stirring increases the initial rush of whey immediately after cut. The current methods of stirring large vats tend to produce shattering of the curd with fast agitation speeds immediately after cut. It might be possible to design a stirring system for large vats which could produce more syneresis at that stage, without shattering the curd. Workers in Holland developed a slowly rotating cylindrical drum with baffles to stir freshly cut curd for Edam cheese. It depended on a tumbling action to stir the curd and the principle might have previously unrecognised advantages for Cheddar cheese.

The second stage to be considered in Figure 13 is pump to drain. A large amount of moisture is released from the centre of the curd when the curd particles are flattened and some are fractured. If curd handling between pump and dry removed the whey effectively, cheese would have a uniform moisture level throughout the block. Data from our laboratory which are typical of Australian conditions are shown in Table 2. Blocks of twenty kg cheese were divided into 8 sections by cutting in halves in each plane. Two of the sections, diagonally opposite each other were further subdivided into 27 samples of about 100g. Each sample was minced, mixed and the moisture determined by the standard method. The range in moisture averaged 1.76% for the 7 cheeses. It is not this variation itself which is the issue here, it is the conditions which cause it. When the curd is flattened, the whey which comes out needs to drain away freely. The conception of flow described in the previous section means that separation of whey at dry requires highly efficient drainage. Samples of curd taken from mechanised belts and allowed to cheddar in small tubes with adequate drainage gave lower moisture levels at mill than the curd cheddar in commercial equipment. Freely drained curd would have a more uniform moisture composition. Australian equipment for draining and cheddaring curd traps large amounts of whey in the curd mattress because drainage is inadequate.
This contributes significantly to the variation in moisture levels reported in Table 2.

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</table>

It is time to reexamine the methods used to drain the curd. Equipment should fracture and flatten the particles and then give free drainage. If the physical condition of the curd particles minimises fusion, then drainage will be maximised.

An alternative method of producing lower moisture curd at the end of the vat stage would be to cut the curd into smaller particles. The resulting larger surface area would ensure drier curd. This does not seem feasible with the methods now used to cut curd. It is worth considering new methods of cutting the curd. An alternative concept might be possible with cold renneting. This involves adding rennet to cold milk and completing the enzymatic phase of coagulation at low temperature. The milk will not coagulate at the low temperature, but it does coagulate immediately it is warmed. This process has not been a commercial success. It might be possible to coagulate cold renneted milk into small particles and eliminate cutting. For example, continuous coagulation on a warmed teflon surface would give a large thin sheet of coagulum which would break easily into small pieces. There is an alternative concept which would use an immiscible fluid as a heat exchange medium. It might be possible to drop cold renneted milk into warm butterfat and form small spherical curd particles. There are no doubt better liquids to use as a heat exchange medium.

The techniques developed for this investigation have provided fresh insights into syneresis and suggested some new ways to deal with moisture control in cheese making. There is much to be done before the process is fully understood. The work reported here on syneresis and microscopy has not been published elsewhere and is available in the thesis by Smith (1985).

References
Temperature 30°C
pH 6.63
Milk held for two hours before setting with rennet.

FIGURE 1
Reproducibility of the Whey Dilution Method
FIGURE 2
The Effect of Temperature on Syneresis.
The milk was set and cut at the temperatures indicated.
FIGURE 3
A COMPARISON BETWEEN THE SYNERESIS KINETICS OBTAINED FOR STEADY STATE TEMPERATURE CONDITIONS OF 30°C & 36°C AND A TEMPERATURE RAMP FROM 30°C TO 36°C INTRODUCED AT CUT TIME.
FIGURE 4
A Comparison Between the Syneresis Kinetics Obtained for Steady State Temperature Conditions of 30°C & 39°C and a Temperature Ramp From 30°C to 39°C Introduced at Cut Time
FIGURE 5
The Effect of pH on Syneresis.
The milk was set and cut at 30°C at the pH indicated.
FIGURE 6
The Effect of Different Cut Sizes on Syneresis as Measured by the Whey Dilution Method.
Figure 7: The Effect of Curd Tension on Syneresis.
The milk was set and cut at 30°C, pH 6.65.
FIGURE 8
The Effect of the Rate of Stirring on Syneresis
The milk was set and cut at 30°C, pH 6.63.
FIGURE 10
Kinetics of Syneresis for Steady State Temperature Conditions and the Mean Free Curd Area of Undisturbed Curd Set at the Same Temperatures.
The mean free area of the curd was measured after 60 and 120 minutes. The pH of the milk was the natural pH.
FIGURE 11
The Effect of pH on Syneresis and Percentage Free Area of the Curd.
The curd was set at 30°C at the pH indicated.
Figure 12. Free area in unsyneresed curd and syneresis in cut and stirred curd.
Figure 13
Factory 012 Pattern of moisture loss

Moisture Content (%) vs. Elapsed time from addition of rennet (mins)

- Cut
- Heat on
- Heat off
- Pump Dry
- Mill
- Salt

Ex-Press

40 80 120 160 200 240 280
MEMBRANE PROCESSING
WAYNE G. GEILMAN, Ph.D.
10th Biennial Cheese Conference
Utah State University - August 20, 1992

INTRODUCTION

During the last two decades, the amount of research performed on the use of membrane processing in the dairy industry has been impressive. A complete review of the literature is not practical in this paper. Some publications regarding basic membrane processing and cheese production using membrane technology are cited.

Membrane Separation

To understand membrane processing, some basic concepts and definitions must be reviewed. Membrane processing involves the physical separation of solutes, colloids and solvents using a pressure gradient across a semi-permeable membrane (17). Selection of proper membranes allows this process to effect a molecular sieving of solvents solutes and particles.

In conventional dead-end filtration, solids are collected and removed from the solvent by directing the flow of the feed stream into the filtration medium at a perpendicular angle. Solids accumulate on the filter interface, in a layer that increases in depth and density until the removal of the solvent is impeded. Filtration stops and the solids are removed. In
most membrane filtration processes, the flow of feed stream is tangential to the filter medium. Although a secondary or polymerized layer is formed on the membrane surface (10, 17, 46), the tangential flow of the feed stream curtails the development of this layer (49, 129). The system may thus be used for long periods of time before development of this layer is sufficient to impede flux, or flow, across the membrane (47). The layer accumulated on the membrane is composed of low molecular weight salts, peptides (10, 17, 46, 47, 90, 121) and/or complex carbohydrates, microorganisms and other nitrogenous compounds (91).

When accumulation of this layer restricts solvent removal, the system can be cleaned and the layer is removed. If substances become strongly attached to the membrane, usually through chemical interactions, they cannot be removed with normal cleaning. When this happens, the membrane becomes fouled and must be replaced.

While the tangential flow of the feed stream retards the development of the secondary membrane, the transmembrane pressures (which is the difference in pressure between the feed stream and the solvent removal side of the membrane) result in filtration. The degree to which solvents, solutes and particles are separated is determined primarily by the size of the openings, or pores, in the membrane. Substances that are too large to pass through the pores of the membrane are rejected, retained, and concentrated. Those that are small enough to move across the membrane are removed with the solvent. The ability of
substances to pass through the membrane can also be influenced by factors such as charge, shape, and hydrophobicity. The characteristics of the feed stream determine the type of membranes, flow rates, processing times, temperatures, and configuration of the system used. The processing pressure used is dependant upon the configuration of membrane system and viscosity of the feed stream (12, 17, 57, 80). Membrane separation is a dynamic system, in which change of any of the processing parameters may affect other factors. The effect of shear, resulting from system configuration (pumping, flow dynamics and control of pressure gradients with valves), should be closely evaluated because it may change feed stream and finished product attributes.

The portion of the mixture that is removed is called permeate; that which is retained is called retentate (8). Retentate contains larger particles and molecular weight moieties. These substances are concentrated in respect to the original volume of solvent. It is common to refer to retentates according to the volumetric reduction. Thus, a retentate that is reduced to half the original volume is a 2X retentate. Because concentration of specific substances is dependant upon the amount present in the feed stream, volumetric concentration factors may lead to erroneous assumptions concerning the percent of the substance in the retentate. A more accurate method to express concentration is based on the concentration of individual moieties.
Definitions of Processes

Membrane processes have been named according to the size of substances that are in the retentate. Terms used to describe different processes often overlap. New names are constantly being developed as researchers try to describe and distinguish individual processes. Nanofiltration and leaky RO are examples of descriptions that have entered membrane processing vernacular. Some names have received general acceptance and are defined in the following paragraphs.

Microfiltration (MF) refers to a process where the pore size of the membrane is greater than 100,000 nanometers. Filtration with these membranes can be accomplished with low transmembrane pressures (5-100 psi) and particles, bacteria, fat globules, viruses and large colloids are removed from the permeate (17). MF can be used for "cold pasteurization" (17), fat removal, and separation of fruit pulps.

Ultrafiltration (UF) uses membranes with a pore size of 1 to 100 nanometers. Transmembrane pressures needed to force separation with these membranes is 10 to 100 psi. Proteins and other large molecules are separated and concentrated with this process (51, 80). Production of protein concentrates is the main application of UF in the food industry.

Reverse osmosis (RO), often called hyperfiltration (127), requires membranes with even smaller openings (.1 to 1 nanometers). As the size of the opening decreases, pressure needed to effect separation increases. Therefore, pressures in
excess of 100 psi are required for this operation. RO can effect the separation of ions from aqueous solutions. Water purification and concentration of all solids can also be accomplished (2, 51).

Two other membrane processes should be mentioned. In electrodialysis, a charge is placed on the membrane. The charge enhances separation by repulsing similarly charged substances. This process is useful for the separation of acids and other charged particles. Permevaporation is used to separate volatiles from liquids (17). Membranes are used in this process are not porous, but are selective for specific molecules that can be transported across the membrane. Transmembrane pressure is maintained using reduced pressure gases or vacuum. Although these two processes have potential to improve product quality and create new products, they have not been widely accepted in the food industry.

Types of Membranes

At least 18 different polymers have been used to produce commercial membranes. Membranes have been manufactured from cellulose acetate, polycarbonate, polyethylene, polysulfones and other polymeric compounds (17). Composite membranes can be made by casting the polymeric structure a microporous sublayer of another fibrous material. Asymmetric membranes are composed of the same material throughout, although one surface forms the active layer containing small pores. Thin layer composite
membranes (TLC) have two layers of polymeric material in lieu of one. The second layer increases filtration efficiency by providing a smooth surface. Mineral membranes, which use a thin layer of metallic oxide (such as zirconium oxide) to form the filtration surface and a strong ceramic support structure are resistant to chemical degradation, can withstand temperatures of 400°C and extreme pressures (17, 81, 127). These are the most rigorous of the membranes and they are also the most expensive.

Polymeric membranes can be manufactured with a wide range of surface configurations. Membrane properties, such as molecular weight exclusion, hydrophobicity, surface charge, polarity, pore density, and membrane configuration, influence the development of the secondary membrane and consequently filtration.

Membrane Systems

The selection of the type of membrane and the physical configuration of the system (pumps, piping, valves, etc.) is dependant upon the material being processed (36). The types of products being made from the retentate should also be considered when determining the system design. The importance of shear, resulting from prolonged pumping and control of pressure differentials, should not be discounted (9, 48). Four basic hardware configurations of UF systems are currently in use.
Plate and Frame

Short et al. (115) evaluated a plate and frame systems. Flat sheets of membranes are compressed between rigid support frames. The feed stream is introduced between the membranes and permeate is removed through the support frames. Replacement of leaky membranes is simple. Only moderate filtration surface area to floor space ratios are obtained. Plate and frame systems usually use high processing pressures, which require several pumps. The frames are expensive to install and maintain, which is a disadvantage. The expansion of this configuration has been slow because of these considerations.

Tubular

In a tubular system the membrane is cast on a tube or straw of porous support material. The straws have a diameter of 2.5 to 5 mm. Membranes or straws are placed in stainless steel tubes which give them strength and support. These, in turn, are arranged in a collection vessel. The feed stream is introduced to the inside of the membrane straw and permeate is collected in the surrounding vessel. Because of the large inside annular diameter, viscous products can be processed with this system. Pressure and pumping requirements are low and several modules can be supplied by one pump. Tubular systems have low membrane area to floor space ratios and installation costs are quite high.
Hollow Fiber

Tube diameter of the flow channel in hollow fiber systems is .5 to 2.0 mm. These are asymmetric membranes with the support and filtration structure being made from the same polymer. Hundreds of small diameter tubes can be placed in a collection vessel, resulting in good membrane surface to floor space ratios. Hollow fiber systems operate at low pressures and have low pump requirements. Because the membrane is not laminated to the support material, back-flushing to remove foulants can be performed (17).

Spiral Wound

Spiral wound membranes have the highest membrane area per floor space ratio. Hardware for this system is relatively inexpensive and membranes are easily changed. Spiral wound modules consist of two flat sheets of membrane separated by a porous mesh support material. Sheets are sealed on three sides, with the fourth side being attached to a permeate collection tube. A second mesh spacer, which allows space for the feed stream to pass over the membrane, is placed on top of the membrane. The entire stack is then rolled to form a spiral, and placed in a pressure vessel. Spiral wound systems require moderate pressures, are very economical, and therefore are the most common (127).
Cleaning of Ultrafiltration Plants

The construction of UF systems can create cleaning problems. Cleaning of membrane surfaces, porous structures and pressure vessels require special attention. Cleaning and sanitation is limited to approved chemicals, and then only at certain concentrations (115, 116, 117, 118, 122). Flow of cleaning compounds through the system is critical (107, 119, 120, 131).

Applications

Membranes have been used in non-food applications to concentrate chemicals used in tanning, painting (8, 127), paper processing and sizing of textiles. Separation of oily waste waters, reduction of BOD and COD in water streams and retention of cells in bioreactors are some other uses (17). Membranes are used in the food industry to remove bacteria (126, 127) and enzymes (52) from solutions. Sugar solutions, fruit juices, egg whites, vegetable and dairy proteins are concentrated with membranes (17, 108, 127).

MEMBRANES IN DAIRY PROCESSING

Initially, membrane processing was used in the dairy industry to recover whey proteins (1, 2, 5, 12, 47, 51, 80, 130). Approximately 20% of the milk protein and some milk fat are not retained in cheese. Recovery of whey proteins as whey protein concentrates has been very successful, however inclusion of them in cheese would be more profitable. RO (6, 7, 17, 49, 51), and
UF (3, 17, 18, 27, 28, 29, 43, 44, 67, 68, 80, 86, 87, 125) concentration of milk prior to cheese production has been proposed. Studies on reduction of shipping costs by UF concentration of milk on the farm may also offer an economic advantage (34, 66, 79, 85, 103).

Reverse Osmosis (RO)

Cheese has been made using RO (6, 7, 9, 37), although use of cellulose acetate membranes (17), which are difficult to clean and require high processing pressures (which may lead to lipolysis) (9) have limited the use of this process. New advances in membrane technology may require a re-evaluation of this process.

Ultrafiltration

Cheryan (17) provides a good historical review of the development of UF in the dairy industry. Dejmek (24), as well as de Rham and Chanton (25), developed economic models to estimate savings that could result from using UF in cheese making. The cheese yield derived from these predictions were never obtainable because of difficulties in processing of the retentate. Even with lower yields, the application of UF for cheese production deserves careful evaluation.

Production of Retentate Using Ultrafiltration

Production of retentate can be influenced by quality of substrate, type of equipment, retention rate of components, and
type of membrane used. Empirical models can be used to estimate retention rates of various components (25). Retention of milk protein (caseins, serum proteins, enzymes and membrane fractions) varies from 93 to 100% (35, 51). Fat retention is almost 100% (35, 38, 39). Minerals partition across the membrane according to their solubility (11, 20, 35, 36). Transition metals (Mo, Fe, Cu, P, and Zn), associated with enzymes and minerals in the micelle (Ca, P, Na, K, Mg, Fe), are concentrated, depending upon the speed at which they equilibrate with the soluble minerals (11, 15, 36, 38, 41, 60, 77, 128). Soluble minerals remain in a state of equilibrium in the aqueous phase across the membrane. The amount of calcium and phosphorus in retentate can be adjusted by altering the pH of the feed stream prior to concentration (28, 36, 39, 40, 41, 104, 124, 125). Lactose remains in solution and is removed from retentate with the permeate. Lactose levels can be reduced by adding water to the feed stream and diluting the concentration of lactose in it. Lactose is then removed in the permeate and reduced in the concentrate. This process is called diafiltration (8, 17).

To optimize efficiency of the UF process, temperatures of 45-50°C are required. These temperatures favor growth of bacteria contamination. Therefore, thermalization, subpasteurization or other forms of heat treatment may be required to insure retentate quality (17, 85, 132).

Because microbes and other contaminates (69) are concentrated in the retentate, the microbial quality of the feed
stream is very important (36, 44, 62, 75, 100, 110). Zottola et al. (133) and others (98) have even demonstrated that phage are concentrated in retentate. Concentration of these particles could affect the development of acid in cheese made from retentate.

**Cheese from Retentate**

Concentration of dairy proteins affect their physicochemical properties. Rennet coagulation of retentate is rapid (29, 36, 40, 44, 123), which probably results from the proximity of the proteins to each other. The dehydration of the protein may also play a role in protein coagulation. The coagulum is firmer, coarser, cooks faster and may display a grayish color.

Cheese made from retentate is firmer, does not melt or stretch well, and does not age at a normal rate (36, 89). The body may be dry, crumbly and corky, despite higher moisture levels. Nutritional quality of UF cheese may be slightly different because of the removal of some nutrients during filtration (20).

Analyses of UF cheese whey indicates that not all whey and casein proteins are captured in the curd (70). Loss of solids results from poor coagulation, shattering of the curd during the cutting step and subsequent mechanical agitation. Ernstrom (27) and Sutherland (124) proposed the use evaporation as a means to decrease losses.
Cultures

Identification of bacterial cultures, capable of pH reduction in retentate, is important (19, 36, 39, 68, 88, 80, 92, 101, 105, 109). Not all cultures grow and produce acid in retentate (36). To overcome problems encountered when cultures grown in standard media are introduced to concentrated retentate, the use of retentate as a starter media has been proposed (93, 94, 95, 96, 99).

Cheese Production

Retentate has been used to make variety of processed and natural cheeses (16). A partial listing of cheeses made from retentate include: Cheddar cheese (5, 6, 23, 38, 40, 42, 58, 61, 65, 72, 74, 78, 105, 113, 125), low-fat Cheddar cheese (14, 89), cheese base (27, 28, 29, 30, 68, 124, 125), Mozzarella cheese (21, 30, 31, 32, 33, 50, 53, 76), Gouda (50), Edam (36), Brick (13), Colby (13), Feta (45, 50, 106, 111, 126), Havartii (50), soft white cheeses (86, 87, 88), Dominati (4, 112), Queso Blanco (82), Cottage cheese (7, 22, 36, 54, 59, 64, 76, 83, 84, 90, 102, 104), and Ricotta (80).

Cheese made from retentates share several characteristics. They are firmer, contain higher moisture, do not age as rapidly, may develop off flavors, do not melt well and usually have higher yields than normal cheese. Although many of these attributes may be viewed as defects, they could be used to improve characteristics of many products.
Other Dairy Products Made using UF

UF has been used to make whey protein concentrates that have unique functional properties. Production of whey proteins has been a major breakthrough in dairy processing. Originally intended as an substitute for non-fat-dry-milk, it was soon recognized that functionality of the concentrate could be altered by controlling processing conditions. Whey proteins for specific uses are now manufactured and command a premium price.

The development of spray-dried milk retentates (26, 55, 56) with reduced lactose and increased protein content is also possible. Using membrane processing, powdered dairy products can be produced to meet special consumer requirements. Membranes have also been used to make low-lactose cultured products, such as quarg, yogurt and buttermilk (50, 54, 63, 73). Production of retentate cream may offer an alternative to mechanical separation and produce products which could help displace more milk fat (114). Ice cream, permeate drinks, and concentrated milks have also been made. These products were designed to fill market niches that cannot be satisfied with conventional dairy processing.

CONCLUSION

Membrane processing is a simple and efficient way to concentrate solids. The energy requirements are lower than conventional concentration methods, since water does not undergo phase conversion. Applications of membrane processing has been
successfully used to produce whey protein concentrates. Membrane processing of cheese has been slow to develop. Increases in cheese yield have not met anticipated levels. Cheeses from membrane processes have unique properties that may be considered as defects by some, but could result in development of specialized value-added products. Membrane processing can help create new products and markets for the dairy industry.
REFERENCES


Bacteriocins as Natural Food Preservatives.

by

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The bacteria used to ferment dairy foods produce a number of metabolic compounds which are antagonistic to other microorganisms. Combined, these products create an environment within the fermented food that strongly inhibits the growth of pathogenic and spoilage microorganisms. Examples of these antimicrobial compounds include organic acids such as lactate, acetate and propionate, and other compounds such as diacetyl, ethanol, hydrogen peroxide and proteinaceous bacteriocins. The variety of physical and inhibitory properties found among the latter compounds has generated considerable interest toward their potential for food preservation.

Some of the potential applications for bacteriocins in foods include:

1. Bacteriocin-producing starter cultures engineered to combat specific spoilage organisms in fermented foods.
2. Preparations of species- or genera-specific bacteriocins to inhibit spoilage lactobacilli in processed high acid foods.
3. Improve the probiotic properties of Lactobacillus or Bifidobacterium strains used in health-oriented dairy foods.
4. Self-selective genetic markers for food grade cloning vectors.

Bacteriocin production is widespread among both Gram-positive and
Gram-negative genera. In general, the bactericidal effect of these molecules is limited to closely related species of bacteria. Some bacteriocins produced by Gram-positive bacteria, including those used in dairy fermentations, exhibit a much broader spectrum of antagonism. These bacteriocins act not only against related species but also against completely unrelated, pathogenic and spoilage bacteria or even fungi. Bacteriocin production has now been demonstrated in every genera of lactic acid bacteria and also in Propionibacterium spp. Because of their proteinaceous nature, bacteriocins are degraded by stomach enzymes when consumed as part of a fermented food. This feature, combined with useful physical and inhibitory properties, has facilitated the application of two of these compounds, nisin and Microgard™, as preservatives for processed dairy foods.

Lactic bacteriocins with relatively narrow spectra of activity may also be useful for food preservation. Several of these compounds have been identified within the genus Lactobacillus, which contains species important to both food fermentation and spoilage. Bacteriocins inhibitory only to lactobacilli may be useful in high acid products where spoilage by these microorganisms is predominant.

At present, processors that use nisin or Microgard™ rely upon commercial preparations that are added directly to processed foods. Although food preservation with bacteriocins has focused on applications in processed foods, similar applications clearly exist in fermented dairy products if the starter cultures synthesize a bacteriocin or are able to grow in its presence. Through biotechnology, dairy microbiologists now aim to engineer starter cultures for which will produce bacteriocins known to combat the unique spoilage organisms associated with a particular product.
Several laboratories have cloned and sequenced genes associated with nisin production. Genes for other lactic bacteriocins have been located on plasmid or chromosomal DNA and a few have subsequently been cloned and sequenced. In addition, a few bacteriocin genes reside on conjugative plasmids or transposons, which facilitates their distribution to other lactic acid bacteria. Through gene transfer, heterologous expression of the pediococcal bacteriocin Pediocin A has been achieved in *Lactobacillus reuteri*, and expression of the *Lactobacillus acidophilus* bacteriocin lactacin F has been obtained in *Lactobacillus gasseri* and in *Leuconostoc gelidium*. Our laboratory has used gene transfer to construct nisin-producing variants from fast acid-producing strains of *L. lactis* ssp. *cremoris*, the organism most commonly used to manufacture Cheddar-type cheeses. We have also introduced and expressed genes for nisin immunity in strains of *Streptococcus salivarius* ssp. *thermophilus*. These results demonstrate that potential exists for the development of starter cultures that specifically inhibit spoilage or pathogenic microorganisms associated with a particular product. This strategy should provide an effective mechanism to enhance product safety and stability without any compromise in product quality. Widespread and specific application of these natural food preservatives may be envisioned as additional bacteriocins and the genes which control their synthesis are identified, isolated and characterized.
Automated Microbiology for Cheese Laboratories

by

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Presented at the 10th Biennial Cheese Industry Conference

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20 Aug 1992

INTRODUCTION

The most economical and precise methods for microbiological quality testing of milk involve the use of bioactivity monitors (1). At the last conference I reported on the potential for using reflectance colorimetry because of significant savings and seemingly unlimited versatility. Today we share field success using the Omnispec™ 4000 (OS). The OS combines a sophisticated colorimeter installed in an incubator chamber, a computer-controller, and modern software. The more than 650 steps associated with running the Standard Plate Count (SPC)(3) are reduced to only 16 for running reflectance colorimetry, and only 8 if an automatic sampler is installed (1).

MILK QUALITY TESTING FOR THE CHEESE INDUSTRY

Quality assurance managers in the dairy industry tell me that they are interested in more information than is provided in the traditional SPC. But most new developments make the SPC easier to run but do not improve the value of the data obtained. In order to obtain more information about the types of numbers present the quantitation of coliforms is considered valuable. The problem is that numbers or counts do not relate to any useful product parameter. Conversely, bioactivity monitors can help provide information on biochemical changes that produce product spoilage or loss. In the cheese industry the SPC might help us estimate whether raw milk has been temperature abused but it has not demonstrated value in measuring conditions during farm production. It remains relevant if high numbers of any or all types of organisms are used as indicators of poor quality.

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control during production. A more useful value would provide an estimate of the psychrotrophs that produce enough proteolytic activity in raw milk to cause product yield losses and/or off flavors. This kind of information is economically provided through modern bioactivity monitors or SMART instruments as described by Dr. Anthony Sharpe (3). He defined a SHARP instrument as one that provides, "Sequential Measurements until Amplitude Reaches Threshold." The threshold relates to product unwholesomeness, a more desired value than almost meaningless "initial numbers."

**BIOACTIVITY MONITORS VS. PLATE COUNTING**

Plate counting provides estimates of the initial cfu/mL in the milk sample under certain controlled conditions. That value alone has not proven as helpful to the dairy industry as desired. On the other hand, bioactivity monitors or SMART instruments provide estimates of initial numbers, estimates of spoilage potentials, estimates of inhibitors or stimulants in samples, estimates of specific spoilage types, and correlations to parameters of unwholesomeness to consumers (3). They can also estimate specific pathogens. The data is therefore far more indicative of the values desired in quality control programs.

**IMPEDEANCE METHODS FOR RAW MILK**

The Bactometer™ has been approved and available for years to provide raw milk quality information. Darigold, Inc., Seattle, WA, has used Bactometers™ for three years and currently uses four ovens routinely for a capacity of 512 raw milk samples daily. The samples undergo Selective Preliminary Incubation (SPI) at 13°C for 18 h and are then introduced into the instrument operating at 32°C. The SPI encourages sufficient selective outgrowth and activity of psychrotrophs to make the instrumental data more precise and available 15 h after instrument startup. The precision allows estimates down to 10,000 cfu/mL, or log 4, with excellent accuracy, but more importantly, the data correlates better to spoilage estimates of pasteurized milk products. This is because it relates to actual potential changes in flavor, color, viscosity, or similar parameters of unwholesomeness. Bioactivity monitors provide an economical and earlier indication of spoilage potential than the 7 to 9-day Moseley or the 10-day psychrotrophic bacteria count. The correlation between the OS and the SPC was 0.94 therefore \(0.94^2 = 0.884 \times 100 = 88\%\) of all observations were associated with the calibration line.

The above instrumentation has been useful in establishing an effective milk quality incentive program. The Spiral Plater (SPPLC) is also used in these laboratories to...
provide SPC estimates. Fourteen hundred member patron samples are sampled at about 6,500 weekly. Maximum payment is received when samples test <10,000 SPPLC. Less is received for samples testing between 10,000 and 30,000 and assessments are made when counts are over 100,000 SPPLC cfu/mL. This system is enthusiastically supported by the cooperative members who are continually looking for more accurate and modern results that tell them more and cost less to conduct.

An OS was evaluated in this environment and found to provide acceptable precision estimates down to log 3 cfu/mL. An one mL sample was blended with 0.2 mL reagent in a 48-well microtest plate. The R = 0.90 indicating 81% of samples were associated with the calibration line. Additionally coliform estimates with similar precision were possible down to 10 cfu/mL. Both tests could be conducted simultaneously. As a result of these studies two OS instruments have been ordered for their laboratories and will replace the SPPLC. It was estimated that the savings per test would allow payback of the instrument cost at $35,000 in 22 months.

At Smith's Food King, in Layton, UT, an OS is providing shelf life estimates and coliform estimates on pasteurized products. Similar studies are soon to be reported by Rusty Bishop and colleagues who have been conducting research with an OS.

REFLECTANCE COLORIMETRY IN THE CHEESE INDUSTRY

For one and one half years Avonmore West, Richfield, ID, has used reflectance colorimetry for estimating total microbial loads in raw milk samples and used the data in an effective incentive payment program. These industry leaders did not wait for AOAC approval to apply the savings associated with reflectance colorimetry. Even though the method was not "regulatory" all producer samples are run on the OS two times each week. This involves an average of 600 tests per week but only involves six micro test plates instead of 600 petri plates. The ability to run this many tests per week was not possible before OS technology. The few samples found above the control point of 50,000 cfu/mL are plate loop counted to provide pre-approval back up data. Thus the SPC load has been effectively reduced by 97% and the number of monthly tests have increased 800%. Technicians were eager to see the OS back in operation after lightning silenced the computer and they were forced to use plating methods. They enjoy working with the OS and dread the day they may need to return to plate counting.
A producer incentive program provides 50¢/cwt for samples that are below 50,000 cfu/mL and have low somatic cell counts. Instrument results are available on the same day of testing thus making rapid field response possible.

Correlations above 0.9 have been found routinely between the OS and the SPC. Monitoring of coliforms has also been conducted. Plate loop count costs were estimated between $1.50 to 2.00 per sample. Avonmore technicians prepare their own reagents so the per sample OS costs for labor and supplies are estimated below 20¢ per sample. Savings of $1.75/test under the present program would pay for the instrument in less than 10 months. Automated samplers are being evaluated that will further reduce the number OS preparatory steps involved, provide additional savings, and pay for themselves in a similar time interval.

OMNISPECTM REGULATORY STATUS

A collaborative study involving seven OS instruments and 23 collaborators and analysts was completed and submitted to AOAC early this year (2). The instrument demonstrated better precision than the SPC conducted in each laboratory. It was evident that better precision was possible even when the OS was operated by untrained technicians. The percentages of samples associated with the calibration curve were only 35 through 92% for the SPC but were from 92 to 99% for the OS data. Favorable response has been received from members of the AOAC committee evaluating this technology. We anticipate full committee official action at the annual AOAC meetings in Cincinnati, Ohio in September. OS technology has been included in the 16th edition of Standard Methods for the Examination of Dairy Products, expected to be in print this Fall.

CONCLUSIONS

The dairy industry can obtain a better estimate of milk microbiological quality using bioactivity monitors or SMART instruments than using plate counting because the data generated relates more to the principles of unwholesomeness sought by such testing. Bioactivity monitors are more precise than plate count methods, even when used by untrained technicians. The per sample costs associated with OS technology provide unusually rapid instrument pay back when compared to plate counting. Users rapidly develop reluctance to return to plate counting after working with OS technology for a few days. Regulatory action appears very positive for the application of bioactivity monitors in dairy industry laboratories. Current users of OS technology are convinced that this
type of anlysis is superior to plate counting in that it is more accurate and precise in estimating parameters of significance and the results are more reliable and easier to guarantee.

ACKNOWLEDGEMENTS

We appreciate the continued financial support of Wescor, Inc. in providing the Omnispec™ instrumentation and media.

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