UNIVERSIDAD DEL VALLE DE GUATEMALA

Facultad de Ingeniería

"DESARROLLO DE UNA MARGARINA FORTIFICADA CON OMEGA-3 Y CALCIO".

Trabajo de investigación presentado por
OLY MARIANELLA VARGAS PELLECER
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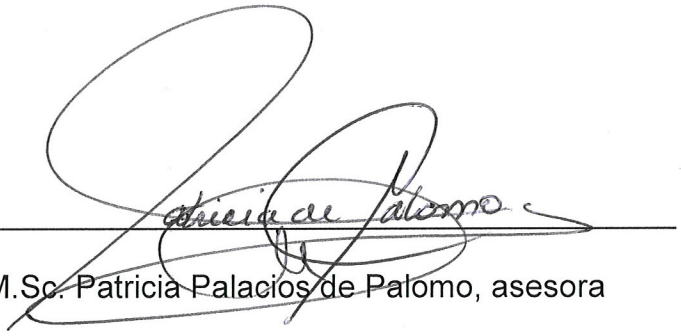

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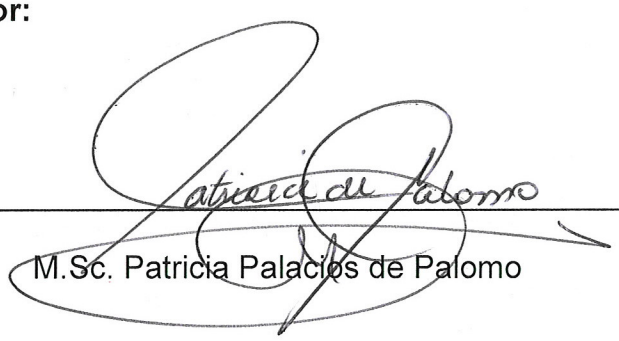

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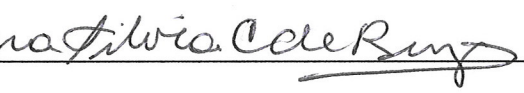

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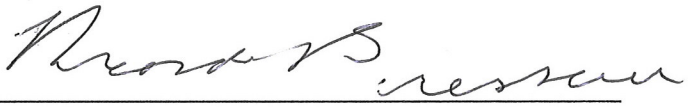

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Dr. Ricardo Bressani

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AGRADECIMIENTO

Este trabajo no habría sido posible de llevarse a cabo sin la ayuda de Dios que siempre me acompaña en mi camino; así como la confianza que me brindó la empresa OLMECA, S.A., el Departamento de Ingeniería en Ciencias de Alimentos de la Universidad del Valle de Guatemala, mi familia, amigos.

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La autora.

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RESUMEN

La margarina es un producto que tiene diversos usos, tanto en la industria alimentaria como dentro de la vida cotidiana de los consumidores debido a que se puede consumir directamente o aplicada en otros alimentos.

En el mercado guatemalteco actualmente se observan margarinas fortificadas con Omega-3 las cuales son importadas y ninguna de ellas se encuentra fortificada con calcio, lo cual crea una oportunidad para los productores guatemaltecos de grasas y aceites para que desarrollen y produzcan una margarina como está con la que puedan competir y brindar a su mercado un producto que sea atractivo y que presente una ventaja para la salud.

Al realizar la fortificación de la margarina se mejora el producto ya existente debido que actualmente se encuentra fortificada con vitamina A y D, y es elaborada con aceite de soya el cual por naturaleza cuenta con 0.92g de Omega-3 por cucharada. La adición de Omega-3 ayudaría a que la margarina sea una fuente significativa de Omega-3 y la adición de calcio haría que exista una interacción con la vitamina D que mejoría la absorción del calcio.

La margarina fortificada con Omega-3 y calcio representará una opción de compra para el guatemalteco con ventaja sobre otros productos semejantes ya que con su consumo mínimo de aproximadamente 43.33 g/día estará satisfaciendo alrededor del 0.5% RDA de omega-3 (DV = 1300 mg/día) y el 0.38% RDA de calcio (DV = 1000 mg/día) sobre una dieta de 2000 calorías.

Es decir que el objetivo principal de realizar esta tesis es desarrollar una margarina guatemalteca que sea funcional y de beneficio para la salud del consumidor guatemalteco.

I. INTRODUCCIÓN

En 1970, profesionales de la investigación de alimentos, sugerían que los cambios en la dieta de las personas coincidían con el aumento significativo en el número de infantes, niños y adolescentes que sufrían problemas de comportamiento. Lo importante aquí era la idea que los aditivos alimentarios, y los colorantes en particular, pudieran tener alguna relación con la hiperactividad, entonces este tema despertó mayor interés y bastante controversia. A continuación una serie de estudios científicos llevados a cabo aún a la fecha, no han demostrado que haya relación alguna entre los aditivos alimentarios, incluidos los colorantes, y los problemas de comportamiento o la hiperactividad. Además de no existir en la actualidad pruebas científicas publicadas que apoyen que el uso de dietas de eliminación puedan ser la terapia principal para tratar problemas de comportamiento.

A continuación se presenta el estudio de una margarina fortificada con Omega 3 y Calcio, en el cual se expone que la misma tiene diferentes usos, este estudio es presentado como parte la tesis de grado de Licenciatura en Ciencias de Alimentos de la Universidad del Valle de Guatemala.

Se espera exponer la importancia de la margarina definida esta como un aditivo alimentario que normalmente se consume como alimento, sin embargo se pretende cambiar el uso que se le pueda dar como ingrediente característico en la alimentación y que agregue cantidades proporcionales de Omega-3 y calcio al ser humano que lo consuma para que agregado a subproductos se convierta en un componente de dichos productos alimenticios. Siendo el calcio un mineral que está concentrado en más del 90%, en los huesos y dientes, este reviste importancia porque reduce la presión arterial alta, el cáncer, sirve también en porcentajes elevados, para la coagulación sanguínea y para el insomnio.

El cuerpo humano es capaz de producir todos los ácidos grasos que necesita, excepto dos: el ácido linoléico (LA), un ácido graso Omega-6, y el ácido alfa-linolénico (ALA), un ácido graso

Omega-3, que deben ingerirse a través de la alimentación y que por ello se conocen como "ácidos grasos esenciales". Ambos son necesarios para el crecimiento y la reparación de las células, y además pueden utilizarse para producir otros ácidos grasos (como el ácido araquidónico (AA) que se obtiene del LA). Sin embargo, como la conversión en ciertos ácidos grasos es limitada, se recomienda incluir fuentes de ácido eicosapentanoico (EPA) y ácido docosahexanoico (DHA). El LA y el ALA se encuentran en los aceites vegetales y de semillas. Aunque en general la cantidad de LA sea muy superior a la de ALA, el aceite de colza y el de nuez son excelentes fuentes de este último. El EPA y el DHA se encuentran en el pescado graso (Ej. salmón, caballa, arenque). El ácido araquidónico puede obtenerse de fuentes animales como la carne y la yema de huevo.

Las margarinas son grasas semisólidas con aspecto similar a la mantequilla que se obtienen mediante procedimientos industriales a partir de grasas insaturadas de origen vegetal o bien a partir de grasas de origen animal y vegetal mezcladas.

La presentación de este trabajo pretende agregar componentes importantes para el buen desarrollo del consumidor, enfocado principalmente en Omega-3 y calcio. También se pretende demostrar que los avances tecnológicos han permitido reducir significativamente, hasta una tercera parte, en algunos casos, la proporción de ácidos grasos trans, además del contenido total de grasas de media, el 60% en la actualidad cuando en el pasado alcanzaban a tener hasta un 80% y por lo tanto demasiadas calorías.

II. JUSTIFICACIÓN

Parte de los productos que consume un adulto guatemalteco en su dieta cotidiana se encuentra la margarina ya que la puede consumir directamente o acompañada con una variedad de productos como lo pueden ser productos de panificación, repostería, confitería y productos culinarios como salsas y sopas.

Es por ello que hoy en día se observa en el mercado la importación de este producto con modificaciones de mejora en beneficio para la salud del consumidor, como por ejemplo actualmente se observa que se encuentra fortificada con Omega-3 que es un ingrediente que ayuda a prevenir enfermedades cardiovasculares y se considera grasa benéfica para la salud del ser humano. Este trabajo lo que se busca es dar mejoría a una margarina nacional a la cual se le desea también fortificar con Omega-3 y calcio.

Por otra parte no solo se busca atender la necesidad de la salud del consumidor guatemalteco sino también la necesidad de quien produce este tipo de producto que desea poder competir con una margarina que se clasifique también como alimento funcional; debido a que se contaría con la presencia de Omega-3 y el calcio que son considerados como componentes que tienen evidencia científica que ayudan a prevenir enfermedades, al igual que la margarina en si ya que ella se considera como funcional debido a que posee fitoesteroles que ayudan a reducir el riesgo de enfermedades coronarias y a reducir los niveles de colesterol.

Por lo tanto la margarina nacional que se desea desarrollar tiene como objetivo ser un producto funcional.

III. OBJETIVOS

3.1. General

- Desarrollar una margarina fortificada con Omega-3 y calcio dirigido a la población adulta del mercado guatemalteco.

3.2. Específicos

- Mejorar la funcionalidad de una margarina vitaminada a través de una fortificación con Omega-3 y calcio.

- Evaluar sensorialmente una margarina fortificada con Omega-3 y calcio.

- Determinar la estabilidad de una margarina fortificada con Omega-3 y calcio a través de vida acelerada.

IV. HIPÓTESIS

Es posible desarrollar una margarina nacional fortificada con Omega-3 y calcio.

V. ANTECEDENTES

Hoy en día los alimentos funcionales se consideran importantes debido a que cuentan con uno o varios componentes que brindan un beneficio a la salud del consumidor que superior al de los nutrientes básicos.

Los cambios de estilo de vida también han creado oportunidades de desarrollo y mercado para los alimentos funcionales, debido a que el consumidor se caracteriza por contar con poco tiempo para preparar sus alimentos, se preocupa más por su salud y alimentación.

La margarina es un producto que surgió por la necesidad de crear un alimento económico como sustituto de la mantequilla y se caracteriza por ser un alimento funcional que contiene como componente activo fitoesteroles que ayudan a prevenir enfermedades coronarias y a reducir los niveles de colesterol; la adición de Omega-3 y calcio en una margarina ayudaría a prevenir enfermedades como la osteoporosis y también a reducir el riesgo de enfermedades como la osteoporosis y también a reducir el riesgo de enfermedades coronarias.

Al evaluar una margarina reológicamente se busca que tenga untabilidad, dureza y que se comporte como un fluido no Newtoniano; mientras que al evaluarla sensorialmente que su sabor, olor y color sean característicos a la de una margarina. Las propiedades reólogicas de una margarina dependen mucho de su proceso industrial que comprende el pesaje de los ingredientes, mezclado, homogenización, enfriamiento, cristalización, extracción, corte y empacado del producto.

5.1. Alimento funcional.

El programa de ciencia de alimento funcional de Europa fue fundado por la Unión Europea y por el Instituto Internacional Ciencias de Vida (ILSI), el cual define a un alimento funcional como: Un alimento puede ser considerado como "funcional" si este es satisfactoriamente demostrado que afecta benéficamente uno o más funciones objetivas en el cuerpo, más allá de los efectos nutricionales adecuados de tal manera que es pertinente, ya sea a un mejor estado de salud y bienestar y / o reducción del riesgo de enfermedad.

Ejemplo de alimentos con un potencial benéfico para la salud

Alimento	Ingrediente funcional	Beneficio potencial para la salud
Tomates	Licopeno	Reducir riesgo de cáncer
Pro-activo, Benecol, margarina	Fitoesterol	Reducir riesgos de enfermedades coronarias y reducir los niveles de colesterol.
Yakult	Bacteria proviótica	Ayuda a la salud gastro-intestinal.
Pescado	Ácidos Omega-3	Reducir riesgos de enfermedades coronarias.

Un alimento funcional puede ser un alimento natural, también puede ser un alimento donde lo natural de uno o más componentes han sido modificados, o un alimento en el cual la bioavilidad de uno o más componentes ha sido modificado o ninguna combinación de estas posibilidades.

5.2. Alimentos funcionales y los consumidores

Los alimentos funcionales son considerados como una entidad que se encuentran en algún lugar en medio de la medicina y productos de alimentos convencionales, pero no

hay una definición común de alimentos funcionales. Japón tiene su propia legislación para Alimentos de uso específico para la Salud, las cuales se conocen como FOSHU en la cual los alimentos funcionales son claramente considerados como productos alimenticios que son comidos como parte de una dieta ordinaria.

5.3. Enfermedad coronaria

La enfermedad coronaria es una condición en la cual las principales arterias ya no se encuentran en condiciones para suministrar suficiente sangre y oxígeno al músculo del corazón (miocardio). Lo cual causa una reducción del flujo que es acumulado en las plaquetas y en la partes más intimas de las arterias; este tipo de problema se le denomina aterosclerosis. Está es una enfermedad que progresa lentamente y usualmente empieza en la infancia pero usualmente no se manifiesta sino hasta la edad adulta.

Existe un número de factores que predispone a un individuo a esta enfermedad como lo es: la edad, el sexo, la raza y el historial familiar; estos factores pueden ser modificables, como la hiperlipidemia (altos niveles de lípidos en la sangre), hipertensión (alta presión en la sangre), obesidad, fumar cigarro y falta de ejercicio. Y estudios han revelado que el 50% de la variabilidad de está enfermedad es debido a factores genéticos y el resto asociado con la influencia del medio con las dietas, el fumar y la vida sedentaria.

Los PUFAs de la serie n-3 (ácido eicosapentanoico (EPA) y ácido decosahexaenoico (DHA)) han mostrado reducir los niveles del plasma TAG y reducir la trombosis cuando son adicionados a una dieta pero no en su totalidad al igual que sucede con los niveles de LDL que son reducidos pero no es su totalidad.

5.4. Osteoporosis

La osteoporosis es una enfermedad del metabolismo del hueso caracterizado por la disminución de la masa ósea (osteopenia) y la disminución de la densidad mineral del hueso (BMD), la implicación de esto es producir huesos porosos y frágiles, los cuales incrementan el riesgo de fracturas. Existen diferentes etiologías de osteoporosis pero la más común y universal es la que depende de la edad y se presenta comúnmente en la edad adulta. Los que influyen en la osteoporosis son: la genética, nutrición, estilo de vida y factores endocrinos. El rol de los factores genéticos es ilustrado por las diferencias en la densidad mineral del hueso en medio de la raza, sexo y familias similares. La nutrición está influida por la baja ingesta de calcio, alta consumo de alcohol, cafeína y sodio. Los factores de estilo de vida que contribuyen a la osteoporosis incluyen fumar cigarro y baja actividad física. Un importante factor endocrino es la deficiencia de estrógeno (postmenopausia en la mujer).

La osteoporosis en los afroamericanos es generalmente baja debido a que tiene una alta densidad mineral en los huesos, mientras que la de los norteamericanos e hispanos es baja aunque la de los asiáticos es aun más baja debido a que su constitución esquelética es diferente debido a que por ejemplo tienen caderas más cortas y estatura más baja.

Como regla general, alrededor del 20% - 30% de la dieta de calcio se absorbe y la mayoría del calcio se absorbe a través a través de la vía de la vitamina D. Existen otras formas de adquirir el calcio como lo son los suplementos de calcio y los alimentos fortificados con calcio.

5.5. El papel de la salud en la elección de alimentos

La salud es un factor común que influye en el pensamiento de los consumidores en el momento que realizan la elección de sus alimentos.

Los consumidores tienden a tener ideas acerca del valor nutricional de los productos. Además de la información acerca de la grasa y contenido de vitaminas tienden hacer generalizada. Así como también en las características sensoriales los consumidores asumen cosas como por ejemplo los alimentos bajos en grasa tiene un sabor diferente a las del producto original. También para muchos consumidores las adiciones de componentes como aditivos alimenticios son consideradas como riesgo potencial para la salud.

Es decir que la salud es claramente un criterio esencial en la decisión de los consumidores al seleccionar sus alimentos la cual también depende de la educación que ha recibido el consumidor.

Los claims tienen que estar basados en evidencias científicas, lo cual significa que el efecto debe ser probado con estudios clínicos. Los estudios deben dar el suficiente soporte para evidenciar que el producto produce beneficios con las porciones que son ingeridas en una dieta normal.

5.6. Margarina

La margarina es una emulsión de agua en grasa, empleada como sustituto de la mantequilla según la idea de su inventor, un farmacéutico francés llamado Mége-Mouriés en 1870, como respuesta a un encargado de Napoleón III para encontrar un sustituto económico e igualmente nutritivo de la mantequilla.

En un principio la margarina se preparó a partir de sebo de buey o carnero que al fundir y mezclar con agua daba la *oleo-margarina*. A partir de 1930, fecha en que aparecieron industrialmente los aceites hidrogenados, empezaron a utilizarse estos aceites vegetales endurecidos por hidrogenación. Hoy día se utilizan aceites vegetales endurecidos por el proceso llamado hidrogenación.

Hoy en día existe una variedad de margarinas como lo son la regular, líquida, de dieta, spread, para panificación, para restaurantes, las cuales son empacadas en diferentes presentaciones. Las margarinas son elaboradas a partir de una variedad de grasas y aceites, incluyendo la soya, palma, maíz, canola y algodón. Las margarinas pueden atender los requerimientos de los diferentes consumidores: servicios de comida, procesadores de alimentos, etc.

El enfoque nutricional en las margarinas surge alrededor de 1923 cuando la marca de margarina Nucoa fue la primera en fortificar con vitamina A. Estas prácticas empezaron a ser universales en varios productos alimenticios alrededor de 1937. Un notable científico, Dr. Anton J. Carlson, testifico que las grasas en la margarina Nucoa y la mantequilla son igualmente digestibles pero que la margarina tiene más ácidos grasos poliinsaturados como el ácido alfa linolenico el cual se ha establecido como ácido graso esencial para el crecimiento normal y mantención de la piel. A raíz de esto en 1941 la FDA reconoce a la margarina como un alimento con valor y no un sustituto de la mantequilla.

Desde 1951 la fuente de aceite más importante para la elaboración de la margarina ha sido el aceite de soya debido a que es económico y posee un alto contenido de ácidos grasos poliinsaturados en comparación de otros aceites.

5.7. Fases de una margarina

- ***Fase grasa:*** El objetivo es producir una mezcla de grasa con un índice elevado de grasa solida de manera que el producto se mantenga firme en el refrigerador y se derrita fácilmente en la boca, para ello debe existir la formación de cristales beta (β).

- ***Fase acuosa:*** Esta fase comprende hasta el 20% de la margarina. Tradicionalmente esta fue de leche vaca, pero hoy en día puede ser agua con o sin algún componente de proteína comestible. En el agua se adicionan las sales y preservantes que son solubles y han de formar la fase acuosa.

- ***Emulsificación.*** El sistema de emulsificación une la fase acuosa con la fase grasa para impartir una forma específica al producto final.

5.8. Aditivos en margarinas

- *Emulsionante:* por ser una emulsión se necesita una sustancia que favorezca la unión de los dos componentes impidiendo su separación, la sustancia utilizada es la "lecitina" que es obtenida de la soja.

- Se utiliza la lecitina porque se ha reconocido como un producto GRAS (Generalmente Reconocido como Seguro, por sus siglas inglés).

- *Espesante:* es preciso añadir sustancias de este tipo, para que la emulsión no se rompa sobre todo en épocas calurosas.

- Sabores: la sal que es el cloruro de sodio, es adicionado para dar sabor y preservar la margarina. Además también se adiciona diacetil para impartir el sabor característico de la margarina.

- La percepción del sabor es influenciado por la boca, la cual determina el sabor por medio de la porción de margarina que se funda en ella. La boca siente y controla las características de esta porción de margarina y determina la textura y el sabor de la misma.

- *Conservador*: para impedir el crecimiento de microorganismos. Los conservadores más comúnmente utilizados son: ácido sorbico y ácido benzoico en sus sales de sodio y calcio. El ácido benzoico es más activo como contra las bacterias mientras que el ácido sorbico es más activo contra mohos y levaduras.

- *Aromas:* normalmente se añaden sustancias del tipo de diacetilo para imitar el sabor de la mantequilla.

5.9. Valor nutritivo

Es muy parecido al de la mantequilla, ya que es un 80% grasa y un15% de agua. Las grasas pueden ser animales (incluso de ballena o de cerdo) o vegetales (manteca de palma o aceite de algodón, de soya, de girasol, de maíz).

Se suele añadir también parte de los productos de la leche, o vitaminas y sal. Y puede contener también sustancias que permitan una buena emulsión. En cuanto a calorías se encuentra al mismo nivel que la mantequilla, ya que 80 de cada 100 gramos, son grasas. Esos 100 g aportan alrededor de 720 calorías. Es, pues, un alimento fundamentalmente energético.

5.10 Pruebas analíticas para grasas y aceites.

Existen dos manuales que establecen la los métodos analíticos estándar para aceites y grasas. Los cuales son:

- D. Firestone, ed. Official Methods and Recommended Practices of the American Oil Chemists Society, 4th ed. AOACS, Champaign IL, 1990.
- C. Paquot and A. Hautfenne, eds. IUPAC Standard Methods for the Analysis of Oils, Fats and Derivatives, 7^{th} ed. Blackwell Scientific Publications, Oxford, London, UK, 1987. A. Dieffenbacher and W.D. Pocklington, eds., 1st Supplement, Blackwell, 1992.

5.10.1 ***Pruebas físicas y químicas:*** *Índice de grasa Sólida/Content.* El índice de grasa sólida (SFI) y el contenido de grasa sólida (SFC) relaciona el porcentaje de shortening que es sólido a varias temperaturas. Esta curva puede tener una variedad de formas; para la mantequilla de cocoa es jorobada, pero algunas otras son más rectas en su mayor parte, con empinamiento o menor pendiente. La curva no puede ser predicha de una determinación hecha a una temperatura; los SFI o SFC de la curva requieren un orden para ser comprendidas las propiedades del shortening a diferentes temperaturas. (4)

La funcionalidad una grasa plástica depende no solamente del contenido de sólidos, sino también del punto de SFI/C que se encuentre en la curva. Conociendo un SFI/C especifico implica que el valor para un batch particular debe ser este el valor usado y no corresponde para otro tipo de batch, y este es un punto muy importante que se debe cuidar en la elaboración de margarinas y shortening.

El método original para la estimación del porcentaje de sólidos en un grasa se baso en la dilatometría y los números obtenidos son los que se refieren al índice de grasa sólida.

- *Punto de fusión.* El punto de fusión usualmente se refiere a la temperatura a la cual un componente puro cambia de la fase sólida a la fase líquida. En el caso de la grasa comercial, la cual es una mezcla de triglicéridos (y fase de monogliceridos y otros emulsificantes) no ocurre cambios de forma. Este también se puede definir como el punto de fusión Wiley que es la temperatura, bajo las condiciones de esta prueba, en la que la muestra de disco asume una forma esférica y está, nos da un índice de la temperatura a la que se funde la muestra.
- *Estabilidad oxidativa.* Resistencia a la autoxidación es importante en las grasas y aceites, especialmente en algunas aplicaciones como los son la fritura. Para la medición de esta resistencia el aceite es calentado en presencia de oxigeno, y el período de tiempo necesario para el valor de peróxido alcanza un nivel específico que lo determina.

Método de actividad de oxígeno (AOM): La estabilidad oxidativa de la grasa es medida por la AOM> El aire es burbujeado a través del aceite o la grasa a un temperatura de alrededor de 97.8°C. Periódicamente, las muestras de aceite son retiradas y el valor del

peróxido es determinado. El tiempo requerido para el desarrollo a una concentración de peróxido de 100 meq/kg es el AOM que es la estabilidad oxidativa de la muestra.

Índice de estabilidad del aceite (OSI): EL punto final para la estabilidad del aceite es medido automáticamente en esta prueba. El aire es burbujeado a través de aceite caliente, y uno de los productos es desglosado (ácido fórmico) es cargado por vacío de aire dentro de una celda de agua destilada. La maquina monitorea la actividad del agua continuamente. El tiempo al cual sube bruscamente es al final del punto de determinación. La proporción de la reacción de autoxidación es exactamente el doble de cada 10 grados Celcius que se incrementa la temperatura. Y el aparato es usualmente operado a 110°C en un corto período de prueba.

Bomba de oxigeno: La muestra es sellada en un contenedor adjunto al lugar del medidor de la presión. La bomba es presurizada con oxígeno a 100 psi, después es puesto en un baño de agua. El punto final es el tiempo cuando la muestra empieza absorber oxigeno rápidamente y forma gotas de presión. Esto es reportado a la bomba de oxígeno y los resultados corresponden a la vida útil del producto.

- *Sensorial.* Color: Los aceites difieren inherentemente por su color y esto depende de la fuente de la cual provengan. Como siempre un aceite refinado que provenga de una fuente específica es de color oscuro. El color es usualmente medido utilizando el Tintometro Lovibond; en el cual el aceite es colocado en un tubo de mediciones estándares y es comparado con vidrios de color estándar, que usualmente son rojos y amarillos. Los analistas intentan una combinación de vidrios estándares hasta que obtienen un match. Los

resultados son usualmente expresados cono los números de los vidrios estándares.

Sabor y olor: Evaluación organoléptica del aceite con un prueba empírica lo cual no sustituye la experiencia del analista. Los factores negativos significan rancidez oxidativa, reversión de sabores. La reversión de sabores se produce muchas veces porque los aceites son almacenados después de la refinación. Por ejemplo el aceite desarrolla un sabor afrijolado y el aceite de palma un sabor metálico. El olor que desarrollan los aceites es el de rancidez oxidativa y son causados primordialmente por el aldehído que es volátil y los compuestos cetónicos del desglose de los peróxidos de ácidos grasos. La evaluación es mejor cuando se utilizan aceites que han sido calentados alrededor de 40-50°C en un baño de agua.

- *Índice de yodo.* El índice de yodo es una medida de la insaturación de ácidos grasos y es expresada en términos del número de centigramos de yodo absorbido por gramo de muestra (% yodo absorbido).

Aplicación: aplicable para todas las grasas y aceites normales que no contengan enlaces dobles conjugados.

- *Acidez titulable.* Este método determina los ácidos grasos libres existentes en la muestra, es aplicable a todos los aceites vegetales crudos y refinados, aceites marítimos y grasas animales.

- *Índice de peróxido.* Este método determina todas las sustancias, en términos de miliequivalentes de peróxido por 1000 gm de muestra, que oxidan el ioduro

de potasio bajo las condiciones de la prueba. Generalmente se asume que las sustancias son peróxidos yu otras sustancias similares que oxidan la grasa.

Este método es aplicable a todas las grasas y aceites normales, incluyendo margarina. Este método es altamente empírico y cualquier variación en la prueba puede provocar variaciones en los resultados.

- *Cromatografía de gases:* La cromatografía de gases (CG) es una técnica de separación que ha revolucionado la química analítica. James y Martin la idearon en 1952. No tardó en aplicarse tanto a compuestos orgánicos como inorgánicos, y cuando fines de 1954 aparecieron en el comercio los primeros instrumentos, esta técnica empezó a utilizarse en grado creciente. En 1980 se estima en más de 200, 000 el número de cromatógrafos de gases en el mundo y en más de 30, 000 de publicaciones sobre el tema.

La cromatografía es método físico de separación basado en la distribución de la muestra entre dos fases. Una fase es lecho estacionario de extensa superficie empacada apretadamente dentro de una columna. Esa es la fase estacionaria y puede ser un sólido o una delgada película líquida que reduce al sólido. La otra fase consiste en un gas o líquido que percola sobre la fase estacionaria y alrededor de la misma. Esta fase se denomina fase móvil. (13)

En la cromatografía de gases, la fase móvil se denomina gas portador, ya que es un gas inerte cuya finalidad es transportar las moléculas de la muestra a través de la columna. (13)

- *Determinación de calcio:* El calcio en una solución de muestra reducida a cenizas puede ser determinado por:

  - *Determinación de calcio por precipitación como oxalato.* El calcio es precipitado como oxalato insoluble de sus soluciones amoniacales. En este método, pueden interferir un exceso de magnesio y fosfatos, por lo que es necesaria una estricta adhesión al método.

  - *Determinación de calcio por espectrofotometría de absorción atómica.* El residuo de las cenizas se trata con HCI diluido y se realizan diluciones de la muestra. La muestra posteriormente, se lleva al espectrofotómetro donde se determina la cantidad de calcio presente comparando con una curva estándar de él.

- *Análisis proximal:* El propósito principal de un análisis proximal es determinar, en un alimento, el contenido de humedad, grasa, proteína y cenizas. Estos procedimientos químicos revelan también el valor nutritivo de un producto y como puede ser combinado de la mejor forma con otras materias primas para alcanzar el nivel deseado de los distintos componentes de una dieta. Es también un excelente procedimiento para realizar control de calidad y determinar si los productos terminados alcanzan los estándares establecidos por los productores y consumidores.

5.11. Calcio (Huesos y sistema nervioso)

Su fórmula es Ca. Es una sustancia blanquecina que los huesos y dientes acaparan y conservan para asegurar el crecimiento y mantener la solidez del esqueleto, que es nuestra arquitectura interna. Puede asegurarse que el 90% de todo nuestro calcio está

precisamente formando parte de los huesos y que sólo el 10% restante está distribuido por los músculos, el cerebro, la sangre, el corazón. Su papel es tan importante que, sin él, ni los nervios podría cumplir correctamente su misión, ni dl corazón podría latir. Una disminución de calcio en sangre puede tener consecuencias graves.

Una de sus funciones más curiosas es la de frenar la excitabilidad del sistema nervioso y muscular. Se logra gracias al calcio contenido en la sangre, cuya cifra es de 1.000 mg/L. Para mantener esta cifra vital constante, el organismo tiene sus reservas si falta, es cuando echa mano de los huesos y de allí lo toma. Si sobra, lo devuelve a las piezas óseas. Otra de sus funciones es el desarrollo del esqueleto, sobre todo del niño. Cuando falta, es por raquitismo o por desmineralización. En el adulto la falta de calcio podría llevar al proceso de osteoporosis, es decir, la pérdida de masa ósea. Por otra parte el calcio facilita el paso del influjo nervioso a través de las conexiones neuromusculares, normaliza el sueño, la tensión sanguínea, el equilibrio del hígado, la coagulación de la sangre y otras muchas funciones fisiológicas.

La Organización Mundial de la Salud recomienda una ingestión diaria de al menos 300 miligramos de calcio, subiendo hasta los 700-800 si se trata de una mujer gestante o un individuo en período de crecimiento. Como es sabido, los alimentos más ricos en calcio son la leche y todos los derivados lácteos. El pan, la carne, los tomates, las patatas y algunos pescados también contienen calcio.

Funciones: Es un constituyente de la dentadura y de los huesos, regula el sistema nervioso y muscular, el sueño y la tensión sanguínea.

Deficiencia: Raquitismo, osteoporosis, palpitaciones, calambres musculares, insomnio. Es componente de: Huesos, dentadura, uñas, sangre, corazón y piel.
Fuente alimenticia: Leche y productos lácteos, pan, carne, patatas, sardinas, salmón. Etc.

Los niveles de calcio en el suero son regulados cuidadosamente por la homeostática de la glándula paratiroidea y la vitamina D. Los cambios en la concentración del suero del calcio son dirigidos por la distribución en el funcionamiento del sistema nervioso, el corazón y otros músculos. En el caso de la disminución de la concentración del calcio, la absorción de tracto gastrointestinal se incrementa o los enlaces del calcio del esqueleto son movilizados hacia la circulación sanguínea.

- Influencia de la retención de calcio a partir de otros nutrientes: *a) Proteína*: Una alta ingesta de proteína resulta incremento en la perdida de calcio a través de la orina. (11) b) *b) Proporción de calcio y fósforo:* Numerosos estudios, particularmente de animales deficientes en vitamina-D han mostrado que la proporción de calcio/fósforo ha de ser un factor determinante para evaluar los requerimientos de calcio. Las dietas del ser humano consisten especialmente de productos vegetales donde es casi invariable el contenido de fósforo y calcio, lo cual indica que la retención de calcio no se ve afectada por los niveles de fósforo. (11) *c) Minerales y trazas de elementos:* Los niveles de calcio en el dieta puede interferir con la absorción de otros minerales divalentes tales como: magnesio, hierro, zinc y cobre. Las cantidades de calcio en la dieta son inversamente proporcionales a la absorción de otros minerales y trazas de elementos.

- Las pérdidas de calcio a través del cuerpo se producen de la siguiente forma:
  - 15 a 20 mg/ día en condiciones normales sedentarias

- 100 a 350 mg/día son excretados.
- En la orina depende de la cantidad de proteína ingerida.
- 130 mg/día de las células del tejido epitelial y de la secreción digestiva dentro del tracto intestinal. (11). El consumo de calcio varía enormemente en el mundo, oscilando entre 800 mg/día o más en los países industrializados y 200-300 mg/día en los países en desarrollo. Paradójicamente, la osteoporosis es más frecuente en los países industrializados.
- Dosis: 150 mg (15%) por porción

- Alegación de salud (Health Claim)

La baja ingesta de calcio es un factor de riesgo para la osteoporosis, una condición de la disminución de masa ósea o densidad. A largo de toda la vida una adecuada ingesta de calcio ayuda a mantener la salud ósea. Alimentos típicos: Bajo en grasa y leche descremada, yogurt, tofu, enriquecido con calcio cítricos bebidas, y algunos suplementos de calcio.

Requisitos: complementar la alimentación para que sea "alto" en calcio y no deben contener más fósforo que calcio. Las reclamaciones deben citar otros factores de riesgo; estado la necesidad de que el ejercicio regular y una dieta saludable; que explicar una cantidad de calcio adecuada temprana en la vida y ayuda a reducir el riesgo de fractura reclamaciones por productos con más de 400 mg de calcio por día debe indicar que es sobre una ingesta diaria de 2000mg.

Reclamación muestra: "El ejercicio regular y una dieta saludable con suficiente calcio ayuda a los adolescentes, adultos jóvenes blancos, asiáticos y a la mujer a mantener una buena salud ósea y reducir el alto riesgo de osteoporosis.

5.12. Ácidos grasos omega-3

Son ácidos grasos que tienen su doble enlace en medio del 3° y 4° átomo de carbono, el nombre de Omega se le atribuye a Holman debido a que el diseño este sistema de nomenclatura, el cual proviene del alfabeto griego. El sistema Omega implica empezar contar desde el metil que se encuentra al final de la cadena de la molécula del ácido graso hasta llegar al primer doble enlace de la molécula del ácido graso el cual debe encontrarse en el 3° átomo de carbono contando de atrás hacia delante hacia delante.

Son sustancias de las cuales se sabe que reducen el riesgo de las enfermedades cardiovasculares, a partir del siglo XX nutricionalmente se sugirió introducirlas en la dieta de las grasas para proveer energía y proporcionar grasa que beneficiara la salud del ser humano. Estos ácidos grasos no son solo relevantes para prevenir el riesgo de las enfermedades cardiovasculares sino también para el desarrollo y funcionamiento del cerebro.

- Ácidos grasos esenciales poliinsaturados : w-6 y w-3. El ácido linolénico o ácido alfa linolénico es encontrado en los cloroplastos de las hojas verdes de los vegetales como la espinaca, semillas de lino, linaza, nueces etc. El ácido eicosapentaenoico (EPA) y el ácido decosahexaenoico (DHA) se encuentran en pescado. Este ácido es convertido a través de una serie de desaturación y pasos de elongación en ácido araquidónico y ácido alfa linolenico en EPA y DHA. La elongación y desaturación del ácido alfa linolénico a EPA y DHA ocurre en los leucocitos del ser humano e hígado del ser humano y roedores (ratas). Los ácidos w-3 y w-6 compiten por las enzimas de la desaturación. Pero ambas enzimas desaturasas 4 y 6 (enzimas que están implicadas en a desaturación) prefieren al ácido w-3 que al ácido w-6. La retroconversión de DHA y ácido araquidónico a

los ácidos de cadena corta ha sido mostrado que ocurre por la beta (β) –oxidación en humanos.

- Dosis: De 2 g a 3 g por día.

Clase de aceite de soya	Gramos por cucharada		Relación de omega-6 a omega-3
	Omega-6	Omega-3	
Aceite básico de soya (aceite para cocinar o para ensaladas)	6.94	0.92	8:1
Mayonesa, aceite de soya	5.20	0.69	8:1
Alimentos para untar, 70% de aceite vegetal (soya y aceites de soya *hidrogenados)*	2.06	0.22	9:1
Margarina, barra dura, aceite de soya *hidrogenado*	2.74	0.21	13:01
Aceite de soya bajo en ácido linolénico (1%)	7.62	0.14	56:1
Aceite de soya para todo propósito, *parcialmente hidrogenado*, industrial	1.17	0.03	39:1
Manteca vegetal, para freír, trabajos pesados, *hidrogenada* <1% linoleico	0.03	0.01	3:1

Fuente: ESHA food processor SQL software; Iowa State University.

(31)

- Alegación de Salud (Health Claim)

La Administración de Alimentos y Medicamentos (FDA) anunció la disponibilidad de una alegación cualificada para la reducción de riesgo de cardiopatía coronaria (CC) en alimentos que contienen ácido eicosapentaenoico (EPA) y ácido docosahexaenoico (DHA), ácidos grasos Omega-3. Normalmente, la EPA y DHA Omega-3 los ácidos grasos contenidos en los pescados grasos como el salmón, la trucha e

lago, el atún y el arenque. Estos ácidos grasos no son esenciales para la dieta, sin embargo, la evidencia científica indica que estos ácidos grasos pueden ser beneficiosos en la reducción de las enfermedades del corazón. "Enfermedad coronaria es un importante problema de salud que causa 500.000 muertes al año en los Estados Unidos", dijo el Dr. Lester M. Crawford, Comisionado de la FDA Actuación. "Esta nueva reclamación de la salud calificados ácidos grasos Omega-3 debería ayudar a los consumidores a medida que trabajamos para mejorar su salud mediante la identificación de los alimentos que contienen estos compuestos importantes."

Una calificada declaración de propiedades saludables en los alimentos deben ser apoyadas por pruebas científicas. Sobre la base de una evaluación sistemática de los datos científicos disponibles, como se indica en la FDA "interino Procedimientos para Calificados de Salud de Reclamaciones en el etiquetado de los alimentos convencionales Humanos y Humanas suplementos dietéticos", la FDA está anunciando una alegación cualificada para la EPA y DHA grasos Omega-3 ácidos. Si bien esta investigación no es concluyente, la FDA tiene intención de ejercer su facultad discrecional de aplicación con respecto a la alegación de propiedades saludables cualificada siguientes: "De apoyo pero no concluyentes de la investigación muestra que el consumo de EPA y DHA ácidos grasos Omega-3 puede reducir el riesgo de enfermedad coronaria.

En 2000, la FDA anunció una reclamación de salud calificado suplementos dietéticos que contengan EPA y DHA Omega-3 ácidos grasos y la reducción del riesgo de cardiopatía coronaria. La FDA recomienda que los consumidores no excedan más de un total de 3 gramos por día de EPA y DHA Omega-3 ácidos grasos, con no más de 2 gramos por día de un suplemento dietético.

5.13. Evaluación funcional física de la margarina

- ***Untabilidad:*** Las características de untabilidad ha sido predichas por medio de penetrómetros de cono por medio de la siguiente expresión:

$$p_a = \frac{mg}{d^n}$$

Donde:

Pa = fuerza para superar la resistencia a la penetración del cono en el material. El cual se denomina "valor de cedencia para el flujo (yield value)."

Mg = peso del cono más el peso de otras partes movibles del penetrómetro.

□ = constante con un valor de aproximadamente 2.

d = profundidad a la que el cono penetra en la muestra.

k = $1/\square \cos^2$ a cot a. En donde a es la mitad del ángulo del cono.

Haighton demostró que la untabilidad de la margarina y de otros materiales tipo manteca pueden predecirse a partir de valores de Po, siempre y cuando las pruebas se realicen bajo condiciones controladas de temperatura. El índice de untabilidad de Haighton está definido como:

$$U.I. = p_0 - 0.75\,(p_0 - p_t)$$

Donde Po y Pt son, respectivamente los valores de cedencia para el flujo de la muestra antes y después de ser trabajada. El "trabajo" (working) se logra pasando la muestra a través de un pequeño orificio, como en el caso de un extrusor o de una moledora de carne. El "trabajo" destruye la red entrelazada que existe entre los cristales de grasa. Posteriormente, durante el almacenamiento, ocurre reoganización de la estructura destruida previamente. Esta destrucción y reoganización de la margarina sucede a tasas distintas. Para explicar este comportamiento, se ha sugerido que la red entrelazada de los cristales de grasa está compuesta por dos tipos de uniones, "primarias" y "secundarias". Las uniones "primarias" son muy fuertes y no se rompen fácilmente, pero una vez rotas no se reorganizan durante el tiempo que dura el experimento. Su origen se desconoce realmente, pero se ha sugerido que son debidos a poderosas fuerzas de atracción existentes entre cristales de grasa. Las uniones "secundarias" son fuerzas de atracción de van der Waals entre los cristales de grasa, las cuales son débiles y fácilmente rotas, pero también son fácilmente reorganizables. Consecuentemente, uniones "secundarias" y en menor proporción las uniones "primarias" son destruidas durante el "trabajo" pero tan solo las uniones "secundarias" se reorganizan durante el almacenamiento subsecuente.

La relación uniones ("primarias" "secundarias") influye en la plasticidad. Cuando la relación es muy alta la margarina es muy dura y frágil. Mientras que cuando esta relación es muy baja, el producto es fluido. De allí que sea importante el obtener una

relación correcta. Los cambios en las propiedades reológicas se pueden estudiar durante el "trabajo" y el subsecuente almacenamiento con mayor detalle.

Cuadro 1
Características de untabilidad de la margarina y de productos grasos en general

Valor de cedencia para el flujo, po (g.cm-2)	Características de la untabilidad
<50	Muy suave, fluible
50-100	Muy suave, pero no untable
100-200	Suave pero untable
200-1000	Sastisfactoriamente untable
>1000	Muy dura, no untable

- ***Fluido no Newtoniano (Plástico):*** Los fluidos plásticos son aquellos que no fluyen hasta que son sometidos a un esfuerzo cortante límite determinado, llamado esfuerzo de deformación plástica, umbral de fluencia o límite de fluencia, g0. En el caso de los fluidos plásticos de Bingham, una vez que se supera el valor del umbral de fluencia, la velocidad de deformación es proporcional al esfuerzo, como en el caso de los fluidos newtonianos. Estos fluidos exhiben propiedades de líquido a esfuerzos superiores al umbral de fluencia por lo tanto pueden ser clasificados tanto como líquidos como sólidos. (23)

El producto plástico ideal es el descrito por el modelo de Bingham:

$$g = g0 + M' \acute{y}n$$

Donde:

$g_{0=}$ es el umbral de fluencia y M es la viscosidad plástica. El umbral de fluencia puede ser consecuencia de un entrelazado de moléculas o

partículas debido a su gran tamaño, ramificaciones o forma irregular. También puede ser debida a la formación de redes provocadas por las interacciones entre moléculas o partículas.

Entre los alimentos típicamente plásticos se encuentran el puré de patata y la nata batida, el chocolate fundido y algunas grasas como margarinas y mantequillas. El modelo de Bingham ha sido también utilizado por algunos autores para describir el comportamiento reológico de pastas de fécula de mandioca, suero de puré de albaricoque a gradientes de deformación bajos de geles de pectina y de algunos zumos naturales de manzana.

- ***Dureza :*** Las margarinas deben tener una cierta estructura cristalina para mantener una consistencia semisólida a temperatura ambiente y a la temperatura de frigorífico. Se requiere que se derritan rápidamente a la temperatura corporal, por lo que la margarina se derretirá rápidamente en la boca sin dejar una sensación pegajosa.

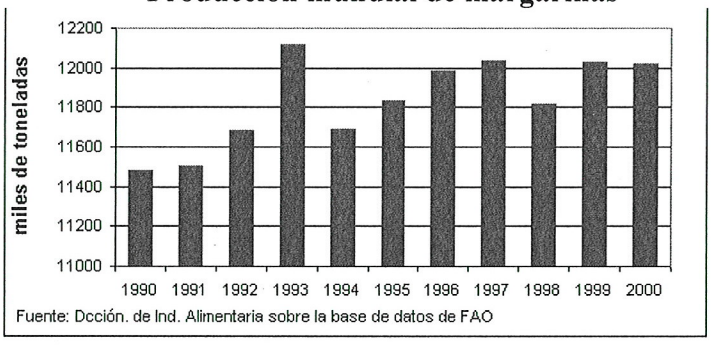
La grasa de la margarina es polimórfica, es decir, es capaz de formar varios tipos diferentes de cristales. Los cristales *a* son los más pequeños, originan un cristal liso pero inestable. Los cristales b ' tienen un tamaño medio, y siguen siendo los deseados para las margarinas porque proporcionan una **textura lisa, son bastante estables y aseguran la plasticidad del producto.** Los cristales de mayor tamaño son los de tipo b, que son estables y granulados, y generalmente indeseables. Además, la forma b se convierte fácilmente en una estructura dura y quebradiza.

5.14. Producción mundial de margarinas

- La producción mundial de margarinas en el año 2000 superó los 12.000.000 de toneladas.
- Entre 1990 y 2000 el crecimiento anual promedio de la producción fue de 0,5 %. En el período 1990 - 1995 la tasa de crecimiento alcanzó 0,6% mientras que entre 1996 y 2000 se evidenció una desaceleración llegando solo al 0,15 %.
- Los principales países productores fueron Estados Unidos (29 %) y Paquistán (12 %) e India (8%).
- La 6° ubicación a nivel mundial la ocupa Brasil.

Gráfica1

Producción mundial de margarinas

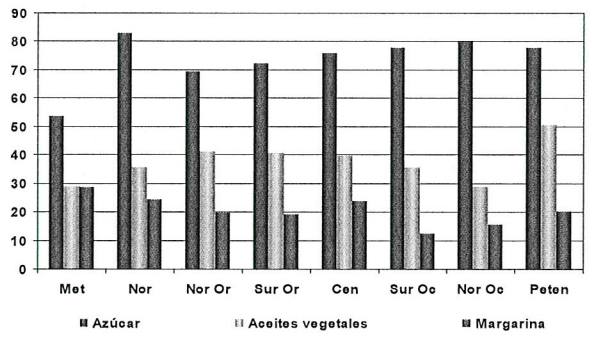


Fuente: Dcción. de Ind. Alimentaria sobre la base de datos de FAO

5.15. El consumo de alimentos en Guatemala

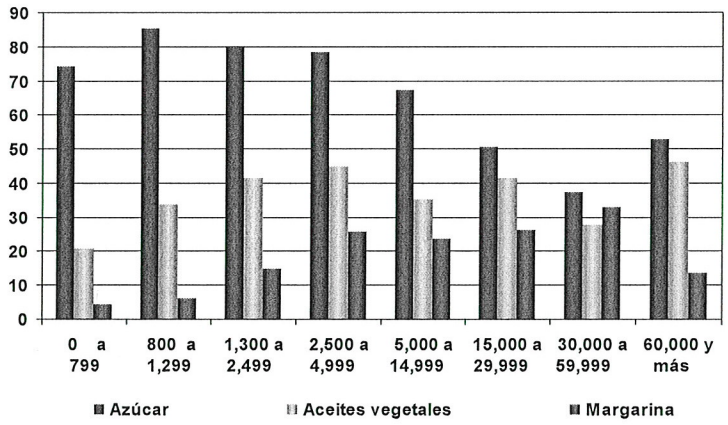
Gráfica 2

Patrón de consumo de azúcar, aceite vegetal y margarina, por regiones (Porcentaje de hogares)



Gráfica 3

Patrón de consumo de azúcar, aceite vegetal y margarina, por nivel de ingreso (% hogares) Banguat



VI. METODOLOGÍA

A. Materiales

- **Materia Prima**
  - Agua
  - Sal
  - Suero dulce
  - Ácido cítrico
  - Benzoato de sodio
  - Sorbato de potasio
  - Sabor crema
  - Grasa vegetal
  - Lecitina de soya
  - Emulsificantes
  - Vitamina D
  - Vitamina A
  - Sabor mantequilla
  - Calcio
  - Omega-3

B. Equipo de Laboratorio y Reactivos

- Análisis de Grasa
  - Unidad de destilación " Soxhlet"
  - Balanza Analítica
  - Espátula
  - Éter dietílico

- Análisis de Proteína
  - Aparato de digestión Labconco
  - Aparato de destilación kjeldahl
  - Balanza Analítica
  - Balones Kjeldahl de 100 ml.
  - Acido Sulfúrico Concentrad
  - Óxido de Mercurio (grado reactivo)
  - Sulfato de Sodio Anhidro (grado reactivo)
  - Solución de Ácido clorhídrico 0.1 N
  - Solución de hidróxido de sodio 10 N
  - Solución indicadora de rojo de metilo
  - Acido bórico al 4% (p/v) en agua
  - Tiosulfato de sodio al 8% (p/v) en agua
- Análisis de humedad
  - Horno Fisher Scientific Isotemp® 500 series
  - Desecadora
  - Balanza Analítica
  - Cápsulas y tapa de aluminio
- Determinación de Calcio
  - Mufla Thermolyne 62700
  - Mechero
  - Balanza Analítica
  - Campana de extracción
  - Crisoles de porcelana
  - Espectrofotómetro de Absorción Atómica

- Determinación de pH
  - Ph metro
  - Pizeta
  - Beakers
  - Solución Buffer pH 4.00
  - Solución Buffer pH 7.00
  - Agua destilada
- Punto de Fusión (Wiley)
  - Alcohol etílico
  - Agua
  - Probeta de 100 ml
  - Aire
  - Termómetro
  - Plato de acero de aproximadamente 10mm de espesor y 150mm por lado.
  - Beaker de 1000 ml
- Índice de yodo
  - Erlenmeyer de 250 ml con tapón
  - 3 pipetas de 5, 20 y 25 ml
  - Pinzas de buerta y soporte
  - Balanza analítica
  - Yoduro de potasio
  - Solución wijs
  - Tiosulfato de sodio
  - Yoduro
  - Tetracloruro de carbono

- Dicromato de potasio
- Solución soluble de almidón
- Agitador electromagnétio

– Acidez
  - Erlenmeyer de 250 ml
  - Soporte
  - Pinzas para bureta
  - Agitador electromágnetico
  - Balanza analítica
  - Alcohol etílico
  - Fenolftaleína
  - Hidróxido de sodio

– Índice de peróxido
  - Balanza analítica
  - Erlenmeyer de 250 ml
  - Soporte y pinza para buretas
  - Agitador electromágnetico
  - Ácido acético
  - Cloroformo
  - Ioduro de potasio
  - Almidón
  - Tiosulfato de sodio
  - Dicromato de potasio

– Cuantificación de ácidos grasos
  - Papel filtro Whatman No. 44
  - Beaker de 100 ml

- Balón aforado de 25 ml
- Pipetas Pasteur
- 3 Pipetas serológicas de 5 ml
- Cromatógrafo de gases
- Estufa
- Integrador PE NELSON
- Solución de hidróxido de sodio: 20gm en 1000 ml de metanol
- Trifloruro de boro
- Heptano
- Solución de cloruro de sodio saturada
- Sulfato de sodio anhidro

– Vida de anaquel

- Agua desmineralizada
- Beaker de 500 ml
- Tubos de ensayo de plástico y vidrio con tapón
- Pipetas Pasteur
- Aparato OSI

C. DIAGRAMA DE FLUJO DE ESPECÍFICACIONES

PROCESO A NIVEL DE LABORATORIO

- Ingredientes

Tabla 1

Orden de adición de los ingredientes

FORMULACION:	
No.	INGREDIENTES
1	Grasa vegetal
2	Lecitina de soya
3	Emulsificante
4	Omega-3
5	Vitamina A
6	Vitamina D
7	Calcio
8	Sabor mantequilla
9	Agua
10	Sal
11	Suero dulce
12	Acido cítrico
13	Benzoato de sodio
14	Sorbato de potasio
15	Sabor crema

Tabla 2

Equipo para realizar los ensayos a nivel de laboratorio

No.	Equipo
1	Recipiente cilíndrico largo de acero inoxidable con capacidad de 1 kg
2	4 Beakers de 500 ml
1	Espátula
1	Varilla de agitación
1	Un recipiente para baño de agua fría
1	Un agitador eléctrico

Procedimiento:

I. Pesar la grasa vegetal.

II. Derretir la grasa en el recipiente cilíndrico de acero inoxidable.

III. Pesar en un beaker los ingredientes del 2 al 8 que se mencionan en la tabla No.1.

IV. Pesar en un beaker el agua.

V. Pesar en un beaker los ingredientes del 10 al 15 que se mencionan en la tabla No.1

VI. Mezclar los ingredientes del paso No. V con el agua hasta que esté homogénea la mezcla.

VII. Mezclar los ingredientes del paso No. III con un poco de la grasa vegetal hasta que este homogénea la mezcla.

VIII. Mezclar en el recipiente cilíndrico de acero inoxidable las mezclas del paso VI y VII.

IX. Calentar y agitar la mezcla final a una temperatura que no exceda los 45°C.

X. Colocar agua y un poco de hielo en el recipiente para baño agua fría e introducir el recipiente cilíndrico del paso No. IX .

XI. Agitar por 15 minutos hasta obtener la cristalización del producto y dejar que se solidifique.

Especificaciones del producto

Fisicoquímicas		Organolépticas
COLOR	R 4.7 A 70 máx	
ACIDEZ (%FFA)	0.050 máx	SABOR BUENO
PEROXIDO (meq/kg)	1.0 máx	OLOR BUENO
PTO FUSION (°C)	43.0 - 44.0	
ÍNDICE DE YODO	42.0 - 44.0	
HUMEDAD (%)	15.50	
ACEITE (%)	81.00	

Tabla 3

Equipo utilizado durante el proceso industrial

No.	Equipo
1	Pesaje
2	Tanque de Mezclado
3	Homogenizador
4	Túnel de enfriamiento
5	Cristalización
6	Formación del producto por extrusión
7	Corte y Empaque
Nomenclatura	Te = Temperatura de Entrada Ts = Temperatura de Salida t = tiempo F = Flujo V = Velocidad Tagua = Temperatura del agua T frío = Temperatura fría

D. Metodología

El desarrollo del presente trabajo se realizara en 7 etapas:

I. ***Conseguir muestras de Omega -3 y calcio.*** Solicitar muestra por medio de proveedores.

II. ***Diseñar la formula de margarina con Omega-3 y calcio***. Realizar ensayos para obtener la formula final de la margarina fortificada con Omega-3 y calcio.

III. ***Evaluar la calidad de la margarina a través de análisis fisicoquímicos y microbiológicos.*** Establecer parámetros de calidad para el proceso de elaboración de la margarina fortificada con Omega-3 y calcio.

IV. ***Realización de análisis proximal*** Para determinar el contenido nutricional del producto.

V. ***Vida de anaquel*** Se realizará un estudio de vida de anaquel en condiciones de vida acelerada para definir el tiempo de vida útil del producto final.

VI. ***Evaluación sensorial*** Se realizara una prueba hedónica para determinar la aceptabilidad y el impulso de compra de la margarina fortificada con Omega-3 y calcio.

VII. ***Evaluación de costo del producto.*** Se realizara un análisis de costo para determinar el precio del producto final de la margarina fortificada con Omega-3 y calcio.

VII. DATOS Y RESULTADOS

7.1 Análisis fisicoquímicos (AOCS)

7.1.1 Contenido de Grasa Sólida (NMR)

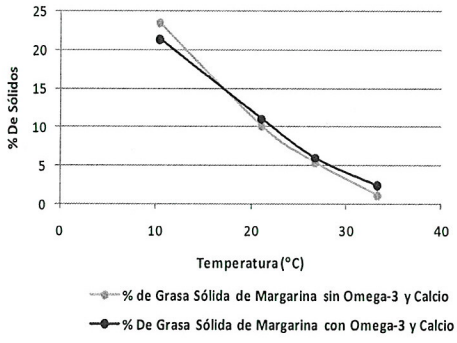
Tabla 4

Porcentaje de grasa sólida para margarina con (W-3 y Ca) y sin (W-3 y Ca)

Temperatura (°C)	Contenido de grasa sólida (NMR) de margarina:	
	sin (w-3 y Ca)	con (w-3 y Ca)
	Porcentaje de sólidos	Porcentaje de sólidos
10.5	23.5	21.39
21.1	10.15	11.04
26.7	5.44	5.96
33.3	1.16	2.37

Gráfica 4

Porcentaje de grasa sólida para una margarina



7.1.2 Parámetros fisicoquímicos

Tabla 5
Parámetros fisicoquímicos para una margarina con (W-3 y Ca) y Sin (W-3 y Ca

	Margarina	
	Sin w-3 y Ca ± 0.5	Con W-3 y Ca ± 0.5
Color: Lovibond	A = 70, R = 2.4	A= 70, R = 2.2
Peróxido (meq/Kg)	0.2	0.2
Acidez (%FF)	0.22	0.22
Punto de Fusión Wiley (°C)	35.6	36
Índice de Yodo (Wijs):	Prom. 97.24	Prom. 98.70
Humedad (%)	25.32	24.01
Residuo (%)	2.98	3.8
Aceite (%)	71.7	72.2
Sal (%)	1.2	1.5
Vida Útil	8 Meses	7.5 Meses

7.2 Evaluación Sensorial

7.2.1 Resultados de Evaluación Sensorial Hedónica

Tabla 6
Resultados de prueba Hedónica de una margarina sin W-3 y Ca.

Control	Sabor	Cremosidad	Olor	General
Promedio	8	7	7	8
Desviación Estándar	1	1	1	1
Mediana	7	8	7	8
Moda	7	8	7	7
n	24	24	24	24

Tabla 7
Resultados de Prueba Hedónica de una Margarina con W-3 y Ca.

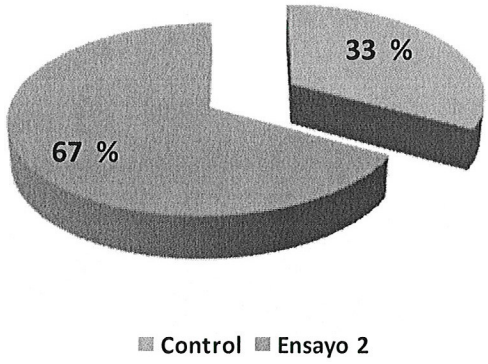
Ensayo 2	Sabor	Cremosidad	Olor	General
Promedio	7	7	7	7
Desviación Estándar	2	2	2	2
Mediana	7	7	7	7
Moda	7	7	7	7
n	24	24	24	24

7.2.2 Resultados de evaluación sensorial de preferencia

Tabla 8
Resultados de prueba de preferencia para una margarina con y sin W-3 y Ca.

Margarina		%	Frecuencia	Comentarios
Control	A	33	8	La muestra se caracterizó por tener buena cremosidad, sabor, olor y apariencia apetecible
Ensayo 2	B	67	16	La muestra se caracterizó por tener buen sabor, olor, buen color, apariencia en general, ser menos salada y más apetecible.
	Nulo	0	0	N/A
	Total	100	24	

Gráfica 3
Evaluación sensorial de prueba de margarina

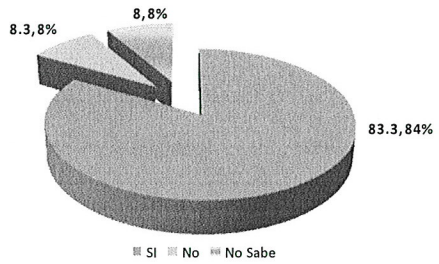


7.3 Evaluación de intención de compra

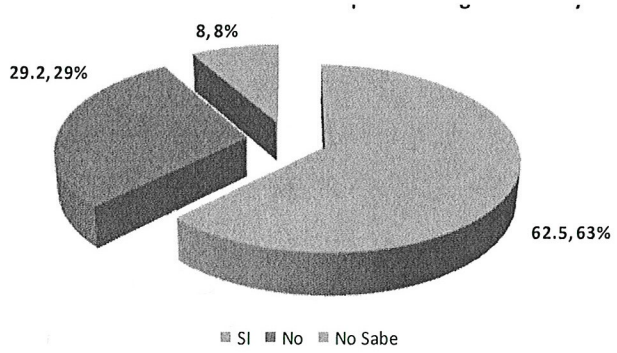
Tabla 6
Evaluación de Intención de compra para una Margarina con y sin W-3 y Ca.

Intención de compra	Sí	No
Control	Sí lo comprarían porque tiene buen sabor, buen color, buena cremosidad y buena textura.	No la comprarían porque le hace falta sabor y sal.
Ensayo 2	Sí la comprarían porque tiene rico sabor, buen olor, buena cremosidad, buen color y textura característicos de una	No la comprarían porque le falta sabor, olor, cremosidad y sal.

Gráfica 4
Intención de compra de margarina control



Gráfica 11
Intención de compra de margarina
(Ensayo 2)



7.4 Cálculos

7.4.1 Cálculo 1: Determinación de calcio

Cantidad de Ca obtenido en 100g de muestra: $\frac{44.35mg}{100g}$

Porción o cantidad de referencia para una margarina: 14 g

Valor Diario según (VD) FDA: 1000 mg

Valor de Referencia del Nutriente (VRN) según CODEX: 800 mg

$$14g * \frac{44.35mg}{100g} * \frac{100\%}{1000mg} = 0.62\% \leq 2\%VD$$

$$14g * \frac{44.35mg}{100g} * \frac{100\%}{800mg} = 0.76\% \leq 5\% VRN$$

- Valor de calcio obtenido por absorción atómica

Sol. D = 1 ml de la Sol. C diluida en 10 ml

Sol. C = muestra de ceniza preparada en 25 ml

$$\frac{6.10mgCa}{1000mlSol.D} * \frac{10mlSol.D}{1mlSol.C} * \frac{25mlSol.C}{3.4379gMDEMARG} * 100\% = \frac{44.35mgCa}{100gmuestra}$$

7.4.2 Cálculo 2: Determinación de Omega 3.

- Porción o cantidad de referencia para una margarina: 14 g
- Cantidad de Omega-3 en muestra patrón: 550 mg
- Cantidad de Omega-3 en muestra de margarina:

Por cromatografía:

- Área de muestra parón: 70376400
- Área de muestra de margarina: 13349400
- Cantidad de mg de Omega-3 en la muestra de margarina

$$13349400A * \frac{550mg\omega - 3}{70376400A} = 104.327mg\omega - 3$$

Cantidad de Omega-3 en 100 g de muestra: $\frac{104.327 mg\omega - 3}{100 gMuestra}$

Porcentaje de Omega-3 obtenido en la muestra:

$$104.327 mg\omega - 3 * \frac{100\%}{550 mg\omega - 3} = 18.97\%$$

- Valor a declarar en el etiquetado nutricional

$$14 g * \frac{104.327 mg\omega - 3}{100 g} * \frac{100\%}{550 mg\omega - 3} = 2.66\%$$

7.4.3 Cálculo No. 3: Determinación de vida útil

- Índice de Estabilidad del Aceite (OSI) en tiempo (hrs): 45.8 hrs OSI
- Factor de corrección de hrs OSI a hrs AOM (Método de Oxígeno Activo): 0.985
- 45.8 hrs OSI * 0.985 = 45.113 hrs AOM
- Factor de conversión de hrs AOM a días: 5

$$45.113 \text{ hrs AOM} * 5 = 225.565 días * \frac{1 mes}{30 días} = 7.5 meses$$

7.4.3 Cálculo 4:

Tabla No.

Costo de producto

FASE ACUOSA	COSTO POR Kg (Q /Kg)	%	g	Kg	COSTO (Q)
AGUA (%)	Q0.28	23.0420	92.1680	0.0922	Q0.03
SAL (%)	Q1.65	1.6000	6.4000	0.0064	Q0.01
SUERO DULCE (%)	Q7.35	1.4000	5.6000	0.0056	Q0.04
ÁCIDO CÍTRICO (%)	Q8.17	0.0400	0.1600	0.0002	Q0.00
BENZOATO DE SODIO (%)	Q33.15	0.0500	0.2000	0.0002	Q0.01
SORBATO DE POTASIO (%)	Q12.70	0.0500	0.2000	0.0002	Q0.00
CALCIO	Q60.00	0.5000	2.0000	0.0020	Q0.12
SABOR CREMA (EMCA) (%)	Q115.22	0.0150	0.0600	0.0001	Q0.01
FASE GRASA					
Carga H2 (100%oleina II) (%)		19.4250			
Aceite Crudo de Palma (%)		3.3670	155.0000	0.1550	
Estearina III (%)		3.1080			
Aceite de Soya RBD (%)		44.1000	264.0000	0.2640	
TOTAL BASE MARGARINA					
LECITINA DE SOYA (%)	Q23.35	0.5000	2.0000	0.0020	Q0.05
LIPODAN GRINSTED PBS 201 (%)	Q52.96	0.8000	3.2000	0.0032	Q0.17
MYVEROL 18-04K (%)	Q36.19	0.1000	0.4000	0.0004	Q0.01
OMEGA 3	Q1,000.00	1.8560	7.4240	0.0074	Q7.42
PREMEZCLA VITAMÍNICA D3 NJ 07054 (%)	Q817.33	0.0050	0.0200	0.0000	Q0.02
SABOR MANTEQUILLA IFF SN 456741(%)	Q251.70	0.0400	0.1600	0.0002	Q0.04
BETACAROTENO (%)	Q1,384.34	0.0020	0.0080	0.0000	Q0.01
TOTAL		100.0000	400.0000	0.4000	Q7.94
Empaque					0.33
CIF					0.33
TOTAL					**Q8.60**

Q17.50	COSTO DE MERCADO
Q12.25	30% WALT-MART
Q8.60	30% OLMECA

7.5 Diseño de fórmula

	Ensayo 2	
FASE ACUOSA	%	g
AGUA (%)	23.04	92.17
SAL (%)	1.60	6.40
SUERO DULCE (%)	1.40	5.60
ÁCIDO CÍTRICO (%)	0.04	0.16
BENZOATO DE SODIO (%)	0.05	0.20
SORBATO DE POTASIO (%)	0.05	0.20
CALCIO	0.50	2.00
SABOR CREMA (EMCA) (%)	0.02	0.06
FASE GRASA		
Carga H2 (100%oleina II) (%)	19.43	
Aceite Crudo de Palma (%)	3.37	155.00
Estearina III (%)	3.11	
Aceite de Soya RBD (%)	44.10	264.00
TOTAL BASE MARGARINA		
LECITINA DE SOYA (%)	0.50	2.00
LIPODAN GRINSTED PBS 201 (%)	0.80	3.20
MYVEROL 18-04K (%)	0.10	0.40
OMEGA 3	1.86	7.42
PREMEZCLA VITAMÍNICA D3 NJ 07054 (%)	0.01	0.02
SABOR MANTEQUILLA IFF SN 456741(%)	0.04	0.16
BETACAROTENO (%)	0.00	0.01
Total	100.00	400.00

VIII. DISCUSIÓN DE RESULTADOS

Hoy en día los alimentos funcionales se consideran importantes debido a que cuentan con uno o varios componentes que brindan un beneficio a la salud del consumidor que es superior al de los nutrientes básicos. Los cambios de estilo de vida han creado oportunidades de desarrollo y mercado para los alimentos funcionales, debido a que el consumidor se caracteriza por contar con poco tiempo para preparar sus alimentos, se preocupa más por su salud y alimentación.

La margarina por naturaleza se caracteriza por ser un alimento funcional que contiene como componente activo fitoesteroles que ayudan a prevenir enfermedades coronarias y a reducir los niveles de colesterol.

La adición de calcio en la margarina presenta como resultado que es un mineral que ha de aportar 0.62% del VD (1000 mg) según FDA y 0.76 % VRN (800 mg) según CODEX en la nutrición del ser humano. Es decir que con base a la norma de etiquetado de la FDA la margarina únicamente ha de considerarse como un alimento que ayude a cumplir el VD en la dieta del ser humano y que debe declararse dentro del etiquetado nutricional como menor o igual al 2% del VD.

El valor diario de calcio obtenido en la margarina no permite que se pueda colocar una alegación de salud en el alimento que diga "fortificado con calcio" o "ayuda a prevenir la osteoporosis" ya que para poder declarar una alegación de salud como éstas la FDA exige que el alimento presente un valor que sea 10 % DV/RC. Con base al etiquetado del CODEX la normativa también exige que el alimento contenga 15 %

VRN/100 g para poder realizar una alegación de salud y a la vez indica que para el etiquetado nutricional el mineral debe declararse como > 5% del VRN.

La razón de no obtener un mayor porcentaje del VD o porcentaje VRN del calcio en la margarina para que pueda ser considerada como un alimento funcional por este mineral y declarase en su etiquetado una alegación de salud que de un valor agregado al producto en beneficio tanto para el consumidor como desde el punto de vista de mercadeo es debido a que a una mayor adición de calcio en el diseño de fórmula se pierden las propiedades organolépticas características de la margarina como lo son el sabor y el olor ya que durante la experimentación se percibió un sabor amargo y un olor diferente que iban hacer que el producto no fuera preferido o aceptado por el consumidor.

Al adicionar Omega-3 a un producto alimenticio hay que aclarar que aún no existe un VD o VRN definido por la FDA o CODEX ya que aún no existen estudios que confirmen cual es exactamente el VD o VRN para este compuesto activo; sin embargo existen productos que con base a la alegación de salud realizada por la FDA en el año 2000 y estudios realizados han tomado como referencia un VD de 500-1000 mg de ALA (Ácido Alfa Linolénico); además dependiendo de la cantidad de mg de Omega-3 que presente el producto así también colocan una alegación de salud que le da un valor agregado desde el punto de vista de mercadeo al producto como también beneficio nutricional al consumidor tal es el caso de la margarina **I Can't Believe It's Not Butter! de Unilever.** Entonces si se toma como referencia un VD de 550 mg de ALA la margarina realizada presenta 104.327 mg de ALA lo cual permite que se pueda colocar una alegación de salud que mencione que es una "buena fuente de Omega-3"; se hace énfasis también que este resultado se obtuvo tomando como muestra patrón un producto de Omega-3 de GNG para poder realizar el análisis cromatográfico. Otra razón por la

cual se puede colocar la alegación de salud de "buena fuente de Omega-3" en el producto es debido a que dos de sus ingredientes son ricos en Omega-3 los cuales son: el aceite de soya y el Omega-3 adicionado de origen vegetal proveniente de la linaza.

La margarina realizada se considera fortificada con Omega-3 y a la vez como alimento funcional debido a que ha de aportar un beneficio en la salud del consumidor, como lo es la prevención de enfermedades cardiovasculares.

Los resultados fisicoquímicos que se presentan en las tablas No.1 y 2 , indican que la adición de calcio y Omega-3 no afectaron los parámetros fisicoquímicos para la margarina ya que son similares o cercanos a los establecidos; los resultados están basados en la metodología de la AOCS. Al ser similares o cercanos los resultados obtenidos a los establecidos permiten que sea factible la elaboración de la margarina con Omega-3 y calcio a nivel industrial debido a que no se debe cambiar, adicionar o quitar alguna parte del proceso que se maneja actualmente dentro de la industria de aceites y grasas.

Los resultados de evaluación sensorial obtenidos en las tablas No.3, 4, 5 y 6 y gráficas No. 2, 3, 4 y 5 indican que la margarina elaborada con Omega 3 y calcio tiene una aceptación de 7 puntos que representa una aceptabilidad de (me gusta moderadamente) y una preferencia del 67%, es decir que organolépticamente la margarina se caracterizo por tener buen sabor, olor, cremosidad y aparencia en general. Además se determinó que la intención de compra de la margarina es 62.5% siendo un porcentaje alto que confirma que el producto si es ha de ser aceptado por los consumidores dentro del mercado.

La elaboración de una margarina con Omega-3 y calcio sí es posible de realizarse a nivel nacional dentro de la industria de aceites y grasas debido a que su proceso no se ve afectado; y únicamente puede considerarse como alimento funcional por la adición de Omega-3 debido a que la adición de calcio no contribuye significativamente para que se considere como fortificada con este mineral.

IX. CONCLUSIONES

- Sí es posible desarrollar una margarina fortificada con Omega-3 dirigida a la población adulta del mercado guatemalteco, sin embargo fortificada con calcio no debido que a una mayor adición de este mineral se pierden propiedades organolépticas características de la margarina como el sabor.

- Se mejoró la funcionalidad de la margarina vitaminada con la adición de Omega-3 debido a que permite que la margarina se considere como alimento funcional y buena fuente de este compuesto activo mientras que la adición de calcio ha de dar un aporte mínimo a la salud del consumidor guatemalteco.

- Se evaluó sensorialmente la margarina realizada con Omega-3 y calcio y presentó una buena aceptación, preferencia e intención de compra ante la margarina control o característica.

- Se determinó por vida acelerada que la estabilidad de la margarina con Omega-3 y calcio es de 7.5 meses.

- Se estima que el costo de la presentación de margarina de 400g fortificada con Omega-3 y calcio es de Q 8.60 para obtener un precio de venta de Q 17.50.

X. RECOMENDACIONES

- Se recomienda que para el desarrollo de la margarina con Omega-3 y calcio la adición de Omega-3 sea en la fase grasa y el calcio en la fase acuosa para que se produzca una buena homogenización en el proceso.

- Se recomienda colocar dentro del etiquetado nutricional el valor diario de calcio según la norma de etiquetado de FDA o CODEX y esto depende del destino en el que se comercialice el producto ya que el % de valor diario se declara en diferente cantidad para cada caso.

- Se recomienda realizar la declaración de Omega-3 fuera del etiquetado nutricional debido a que aún no se tiene definido un % de VD por parte de la FDA o CODEX y se puede tomar como ejemplo la margarina **I Can't Believe It's Not Butter! de Unilever.**

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ANEXOS

NOMBRE: _____ No. Panelista

DEPARTAMENTO: _____ [ ]

FECHA: _____

POR FAVOR LEA LAS INSTRUCCIONES

INSTRUCCIONES: A continuación se le presenta una muestra de: **Margarina**
Pruébela e indique que calificación le da en una escala de 1 a 9 de lo que se le pide a continuación.

Características a evaluar	Me disgusta muchisimo	Me disgusta mucho	Me disgusta	Me disgusta poco	Ni me gusta ni me disgusta	Me gusta poco	Me gusta	Me gusta mucho	Me gusta Muchisimo
Sabor	1	2	3	4	5	6	7	8	9
Olor	1	2	3	4	5	6	7	8	9
Cremosidad	1	2	3	4	5	6	7	8	9
General	1	2	3	4	5	6	7	8	9

LO COMPRARIA ? SI [ ] NO [ ]

POR QUÉ? _____

_____

Hoja de Contro de Posiciones Prueba de Preferencia

Producto Evaluado: **Margarina**

Fecha: _____

Identificacion de Muestras

A = _____

B = _____

1	A	B	
2	B	A	
3	A	B	
4	B	A	
5	A	B	
6	B	A	
7	A	B	
8	B	A	
9	A	B	
10	B	A	
11	A	B	
12	B	A	
13	A	B	
14	B	A	
15	A	B	

16	B	A	
17	A	B	
18	B	A	
19	A	B	
20	B	A	
21	A	B	
22	B	A	
23	A	B	
24	B	A	
25	A	B	
26	B	A	
27	A	B	
28	B	A	
29	A	B	
30	B	A	

NOMBRE: _____ No. Panelista

DEPARTAMENTO: _____ ☐

FECHA: _____

POR FAVOR LEA LAS INSTRUCCIONES

INSTRUCCIONES: A continuación se le presenta dos muestras de: **Magarina**
Pruébelas de izquierda a derecha tomando un sorbo de agua entre cada muestra. Señale que muestra le gusta más y porque. **Evalué Sabor, Cremosidad y Apariencia en general.**

¿ Que muestra le prefiere o cual le gusta más?

Muestra # ☐ Muestra # ☐

¿Por qué? _____

_____

Observaciones: _____

_____

¡Muchas Gracias!

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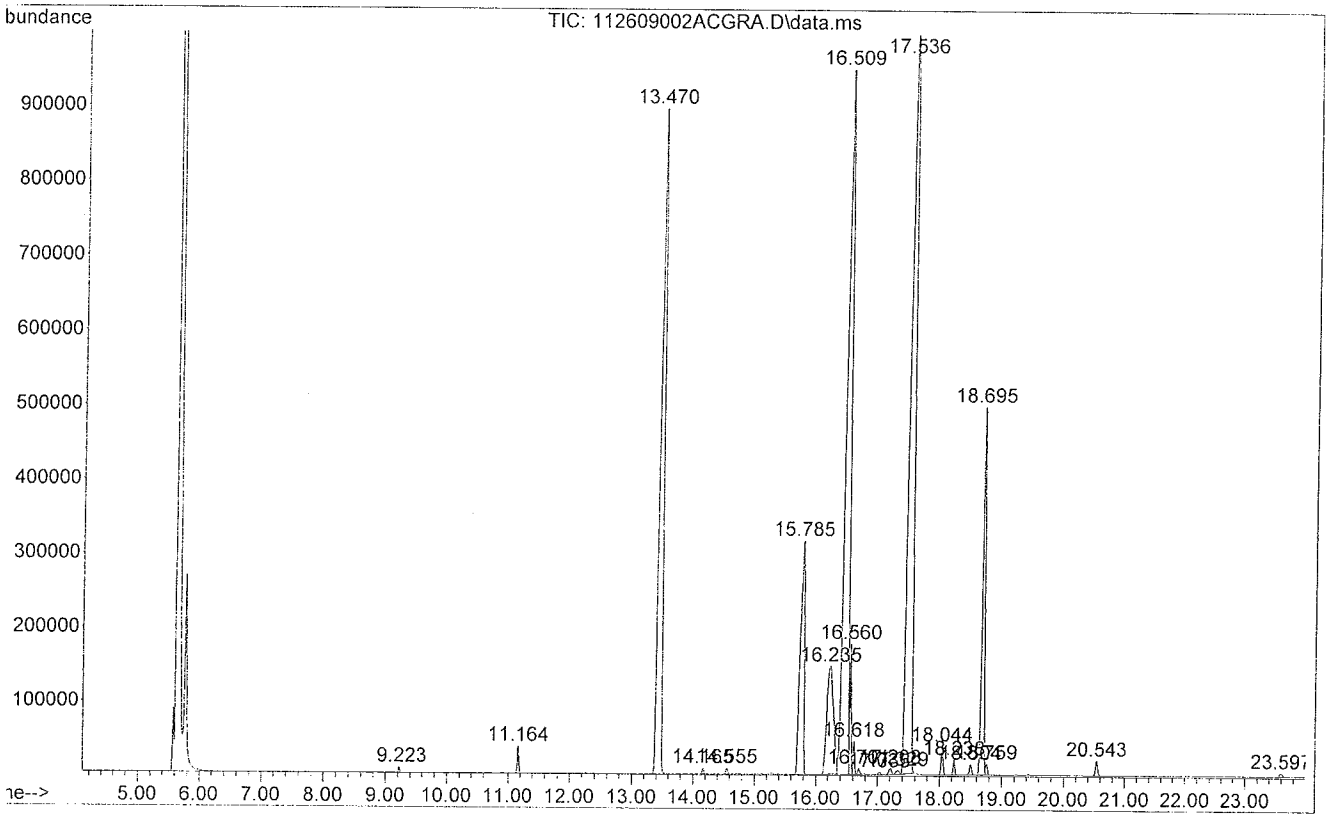
Number: 1



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erator : AdeM
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known Spectrum: Apex
tegration Events: ChemStation Integrator - events.e

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9.222	0.06	C:\Database\NIST05a.L			
		Decanoic acid, methyl ester	47245	000110-42-9	72
		Undecanoic acid, methyl ester	57095	001731-86-8	64
		Nonanoic acid, methyl ester	37542	001731-84-6	56
11.165	0.34	C:\Database\NIST05a.L			
		Methyl tetradecanoate	86750	000124-10-7	95
		Methyl tetradecanoate	86752	000124-10-7	91
		Methyl tetradecanoate	86753	000124-10-7	90
13.471	19.61	C:\Database\NIST05a.L			
		Hexadecanoic acid, methyl ester	105644	000112-39-0	97
		Pentadecanoic acid, 14-methyl-, me thyl ester	105662	005129-60-2	95
		Hexadecanoic acid, methyl ester	105639	000112-39-0	95
14.167	0.07	C:\Database\NIST05a.L			
		3-Pentenal, 4-methyl-	3127	005362-50-5	11
		Cyclohexylmethyl formate	18945	002888-49-5	10
		Cyclohexanemethanol, 4-methyl-, tr ans-	12246	003937-49-3	10
14.553	0.10	C:\Database\NIST05a.L			
		Hexadecanoic acid, 15-methyl-, met hyl ester	114867	006929-04-0	83
		Methyl cyclohexanepropionate	36099	020681-51-0	38
		4-Nonanol, 4-methyl-	28366	023418-38-4	12
15.786	7.39	C:\Database\NIST05a.L			
		Octadecanoic acid, methyl ester	123709	000112-61-8	99
		Octadecanoic acid, methyl ester	123700	000112-61-8	98
		Octadecanoic acid, methyl ester	123708	000112-61-8	97
16.236	5.82	C:\Database\NIST05a.L			
		9-Octadecenoic acid (Z)-, methyl e ster	122321	000112-62-9	99
		9-Octadecenoic acid, methyl ester, (E)-	122326	001937-62-8	93
		9-Octadecenoic acid (Z)-, methyl e ster	122323	000112-62-9	93
16.509	26.44	C:\Database\NIST05a.L			
		9-Octadecenoic acid, methyl ester, (E)-	122326	001937-62-8	99
		9-Octadecenoic acid (Z)-, methyl e ster	122323	000112-62-9	98
		9-Octadecenoic acid (Z)-, methyl e ster	122321	000112-62-9	98
16.559	1.56	C:\Database\NIST05a.L			
		9-Octadecenoic acid (Z)-, methyl e ster	122321	000112-62-9	99
		9-Octadecenoic acid (Z)-, methyl e ster	122323	000112-62-9	99

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known Spectrum: Apex
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		9-Octadecenoic acid, methyl ester, (E)-	122326	001937-62-8	98
16.618	0.44	C:\Database\NIST05a.L			
		9-Octadecenoic acid (Z)-, methyl e ster	122321	000112-62-9	95
		9-Octadecenoic acid (Z)-, methyl e ster	122323	000112-62-9	91
		Cyclopropaneoctanoic acid, 2-hexyl -, methyl ester	113415	010152-61-1	91
16.700	0.08	C:\Database\NIST05a.L			
		1-Pyrroline, 3-ethyl-	2922	1000073-06-0	11
		Cyclohexanemethanol, 4-methyl-, tr ans-	12246	003937-49-3	10
		10-Undecen-4-one, 2,2,6,6-tetramet hyl-	74475	042565-49-1	10
17.037	0.04	C:\Database\NIST05a.L			
		1-Dodecyne	33486	000765-03-7	47
		1-Dodecyne	33489	000765-03-7	43
		Cyclohexane, methylene-	2823	001192-37-6	38
17.210	0.14	C:\Database\NIST05a.L			
		cis-7-Dodecen-1-ol	45993	020056-92-2	72
		1-Pentadecyne	63039	000765-13-9	56
		6-Dodecyne	33495	006975-99-1	53
17.328	0.10	C:\Database\NIST05a.L			
		Spiropentane, propyl-	5776	006191-88-4	53
		Cyclohexane, methylene-	2822	001192-37-6	49
		Cyclohexane, methylene-	2823	001192-37-6	47
17.537	29.28	C:\Database\NIST05a.L			
		10,13-Octadecadienoic acid, methyl ester	121100	056554-62-2	99
		9,12-Octadecadienoic acid (Z,Z)-, methyl ester	121106	000112-63-0	99
		9,12-Octadecadienoic acid (Z,Z)-, methyl ester	121105	000112-63-0	99
18.042	0.44	C:\Database\NIST05a.L			
		Eicosanoic acid, methyl ester	140312	001120-28-1	97
		Hexadecanoic acid, 15-methyl-, met hyl ester	114867	006929-04-0	87
		Octadecanoic acid, methyl ester	123709	000112-61-8	87
18.238	0.22	C:\Database\NIST05a.L			
		9,12,15-Octadecatrienoic acid, met hyl ester, (Z,Z,Z)-	119876	000301-00-8	87
		11,14,17-Eicosatrienoic acid, meth yl ester	137080	055682-88-7	87
		cis,cis,cis-7,10,13-Hexadecatriena	81217	056797-43-4	72

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known Spectrum: Apex
tegration Events: ChemStation Integrator - events.e

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		9,12,15-Octadecatrienoic acid, met hyl ester, (Z,Z,Z)-	119876	000301-00-8	91
		cis,cis,cis-7,10,13-Hexadecatriena	81217	056797-43-4	72
		11,14,17-Eicosatrienoic acid, meth yl ester	137080	055682-88-7	59
18.697	7.18	C:\Database\NIST05a.L			
		9,12,15-Octadecatrienoic acid, met hyl ester, (Z,Z,Z)-	119876	000301-00-8	91
		11,14,17-Eicosatrienoic acid, meth yl ester	137080	055682-88-7	87
		9,12,15-Octadecatrien-1-ol, (Z,Z,Z)-	101506	000506-44-5	86
18.761	0.17	C:\Database\NIST05a.L			
		9-Octadecenoic acid (Z)-, methyl e ster	122321	000112-62-9	90
		Cyclopropaneoctanoic acid, 2-hexyl -, methyl ester	113415	010152-61-1	59
		7-Hexadecenoic acid, methyl ester, (Z)-	104151	056875-67-3	59
20.544	0.26	C:\Database\NIST05a.L			
		Docosanoic acid, methyl ester	154653	000929-77-1	96
		Docosanoic acid, methyl ester	154652	000929-77-1	96
		Heneicosanoic acid, methyl ester	147951	006064-90-0	87
23.596	0.09	C:\Database\NIST05a.L			
		1,2,3,4-Hexadecanetetrol, [2R-(2R* ,3S*,4S*)]-	118465	136953-06-5	9
		Aminoguanidine	846	000079-17-4	7
		Aminoguanidine	845	000079-17-4	7

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9.223	BB	0.023	107089	9.161	9.274
11.164	BV	0.027	633041	11.098	11.227
13.470	PV	0.053	36450474	13.334	13.546
14.165	BV	0.026	123426	14.114	14.202
14.555	PV	0.032	177500	14.499	14.617
15.785	PB	0.060	13743028	15.600	15.880
16.235	BV	0.093	10810061	16.017	16.347
16.509	VV	0.066	49151539	16.347	16.538
16.560	VV	0.026	2890923	16.538	16.590
16.618	VV	0.029	822490	16.590	16.662
16.701	VV	0.030	142022	16.662	16.758
17.035	VV	0.029	73644	16.995	17.087
17.208	PV	0.048	252494	17.122	17.258
17.329	VV	0.052	186460	17.258	17.378
17.536	PV	0.070	54417120	17.378	17.595
18.044	BV	0.035	826437	17.935	18.101
18.238	BV	0.032	404340	18.169	18.340
18.504	PB	0.039	360459	18.367	18.582
18.695	BV	0.041	13349400	18.604	18.734
18.759	VV	0.033	308652	18.734	18.820
20.543	BB	0.037	479491	20.420	20.628
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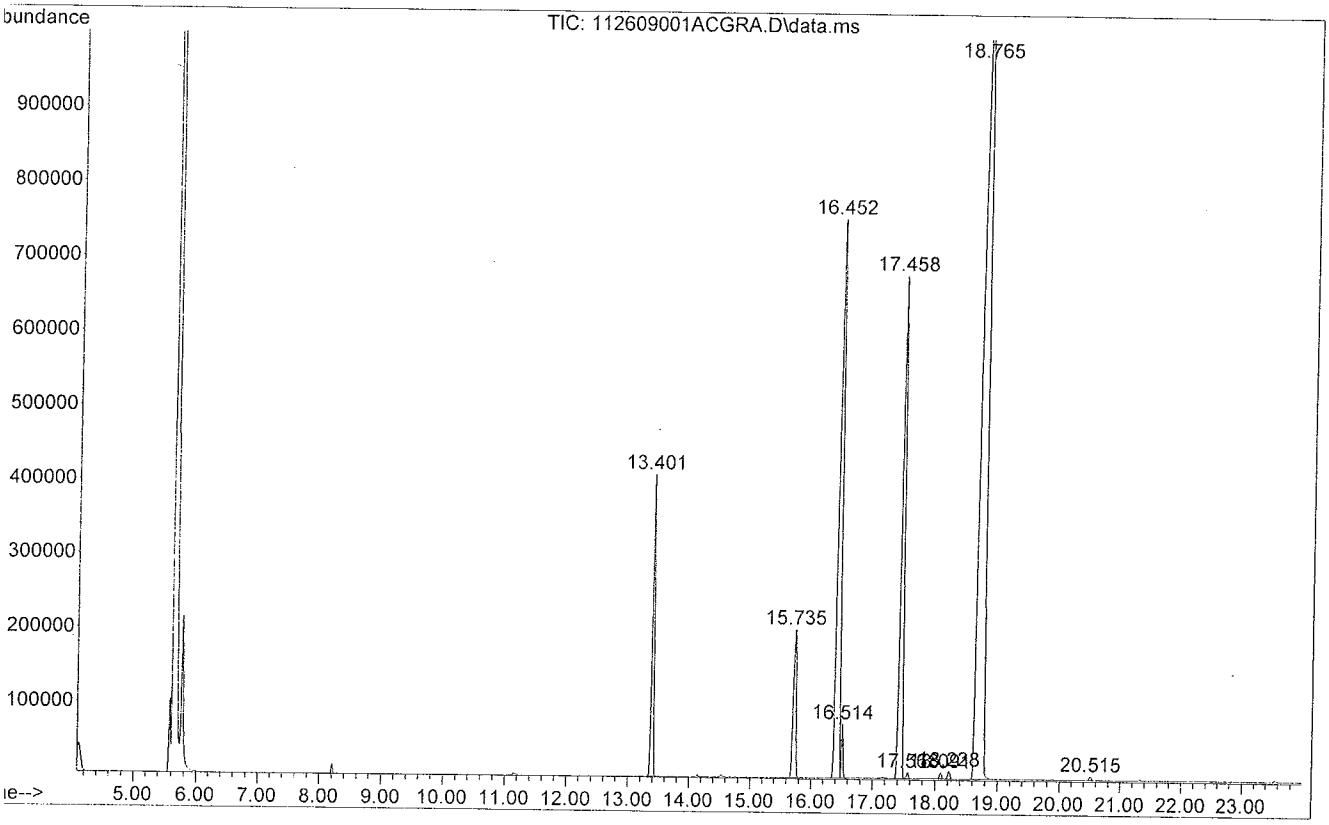

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		Pentadecanoic acid, 14-methyl-, me thyl ester	105662	005129-60-2	97
		Hexadecanoic acid, methyl ester	105644	000112-39-0	96
		Hexadecanoic acid, methyl ester	105646	000112-39-0	94
15.736	4.67	C:\Database\NIST05a.L			
		Octadecanoic acid, methyl ester	123709	000112-61-8	99
		Octadecanoic acid, methyl ester	123700	000112-61-8	98
		Octadecanoic acid, methyl ester	123708	000112-61-8	94
16.455	20.31	C:\Database\NIST05a.L			
		9-Octadecenoic acid, methyl ester, (E)-	122326	001937-62-8	99
		9-Octadecenoic acid (Z)-, methyl e ster	122321	000112-62-9	99
		9-Octadecenoic acid, methyl ester, (E)-	122328	001937-62-8	94
16.514	0.94	C:\Database\NIST05a.L			
		9-Octadecenoic acid (Z)-, methyl e ster	122321	000112-62-9	95
		9-Octadecenoic acid (Z)-, methyl e ster	122323	000112-62-9	94
		14-Octadecenoic acid, methyl ester	122314	056554-48-4	91
17.460	15.59	C:\Database\NIST05a.L			
		9,12-Octadecadienoic acid, methyl ester	121093	002462-85-3	99
		9,12-Octadecadienoic acid (Z,Z)-, methyl ester	121105	000112-63-0	99
		10,13-Octadecadienoic acid, methyl ester	121100	056554-62-2	99
17.569	0.11	C:\Database\NIST05a.L			
		Bicyclo[2.2.1]heptane, 2-methyl-	5855	015185-11-2	58
		Bicyclo[2.2.2]octane, 2-methyl-	10368	000766-53-0	53
		Cyclohexaneethanol, acetate	36087	021722-83-8	53
18.092	0.13	C:\Database\NIST05a.L			
		Hexadecanoic acid, 15-methyl-, met hyl ester	114867	006929-04-0	72
		4-Nonanol, 4-methyl-	28366	023418-38-4	17
		Aminoguanidine	846	000079-17-4	9
18.229	0.19	C:\Database\NIST05a.L			
		11,14,17-Eicosatrienoic acid, meth yl ester	137080	055682-88-7	90
		1,3-Cyclooctadiene	5270	001700-10-3	58
		(Z)6,(Z)9-Pentadecadien-1-ol	74468	077899-11-7	40
18.765	51.21	C:\Database\NIST05a.L			
		9,12,15-Octadecatrienoic acid, met hyl ester, (Z,Z,Z)-	119876	000301-00-8	91

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tegration Events: ChemStation Integrator - events.e

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		9,12,15-Octadecatrienoic acid, met hyl ester, (Z,Z,Z)-	119875	000301-00-8	90
		9,12,15-Octadecatrienoic acid, met hyl ester, (Z,Z,Z)-	119877	000301-00-8	90
20.517	0.08	C:\Database\NIST05a.L			
		Hexadecanoic acid, 15-methyl-, met hyl ester	114867	006929-04-0	9
		Aminoguanidine	845	000079-17-4	7
		N-Nitrosodimethylamine	766	000062-75-9	7

dar

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1	13.401	BV	0.035	9306307	13.315	13.467
2	15.735	BV	0.047	6412326	15.634	15.802
3	16.452	BV	0.051	27917404	16.304	16.484
4	16.514	VB	0.028	1292393	16.484	16.603
5	17.458	PV	0.047	21430892	17.289	17.532
6	17.568	VV	0.030	147415	17.532	17.608
7	18.091	BV	0.033	177510	18.033	18.154
8	18.228	PV	0.034	257312	18.154	18.292
9	18.765	BV	0.082	70376400	18.578	18.886
0	20.515	BV	0.039	115145	20.466	20.570

NRD 1:

SORBANCE:
0.072 0.072 0.072

(STD APPLIED):

2.00 SD: 0.0003 RSD(%): 0.47
COEF.: 1.0000 SLOPE: 0.0360

NRD 2:

NCENTRATION:
3.91 3.94 3.87

(STD APPLIED):

3.98 SD: 0.0317 RSD(%): 0.81
COEF.: 0.9996 SLOPE: 0.0353

NRD 3:

NCENTRATION:
5.75 5.79 5.88

(STD APPLIED):

5.93 SD: 0.0653 RSD(%): 1.13
COEF.: 0.9990 SLOPE: 0.0346

NRD 4:

NCENTRATION:
7.81 7.88 7.76

STD APPLIED):

7.91 SD: 0.0616 RSD(%): 0.79
COEF.: 0.9992 SLOPE: 0.0342

NRD 5:

NCENTRATION:
9.81 9.63 9.77

STD APPLIED):

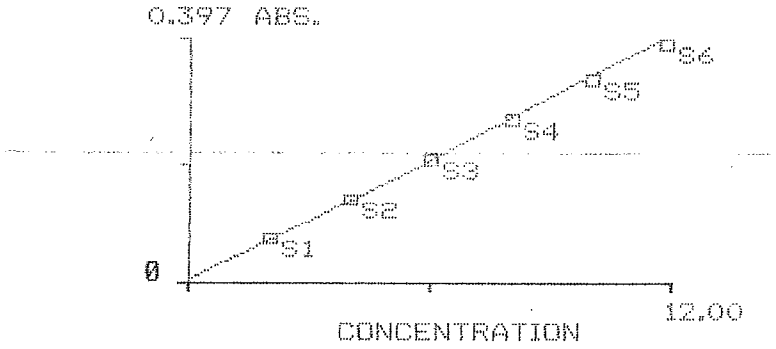
9.85 SD: 0.0948 RSD(%): 0.97
COEF.: 0.9991 SLOPE: 0.0338

RD 6:

ICENTRATION:
11.72 11.75 11.84

STD APPLIED):

11.86 SD: 0.0630 RSD(%): 0.54
COEF.: 0.9993 SLOPE: 0.0335



CENTRATION:

Sample conc. > than highest standard.

Sample conc. > than highest standard.

Sample conc. > than highest standard.

Sample conc. > than highest standard.

28.70 SD: 0.1270 RSD(%): 0.44

CENTRATION:

Sample conc. > than highest standard.

Sample conc. > than highest standard.

Sample conc. > than highest standard.

Sample conc. > than highest standard.

29.02 SD: 0.1301 RSD(%): 0.45

CENTRATION:

Sample conc. > than highest standard.

Sample conc. > than highest standard.

Sample conc. > than highest standard.

Sample conc. > than highest standard.

14.60 SD: 0.0193 RSD(%): 0.13

CENTRATION:

Sample conc. > than highest standard.

Sample conc. > than highest standard.

Sample conc. > than highest standard.

Sample conc. > than highest standard.

13.99 SD: 0.0822 RSD(%): 0.59

CENTRATION:

6.13 6.14 6.03

6.10 SD: 0.0613 RSD(%): 1.00

CENTRATION:

5.71 5.74 5.67

5.71 SD: 0.0379 RSD(%): 0.66

HENRY LAMOTTE OILS GmbH

GEGR. 1925

REVISADO 19 JUN. 2008

Bremen, 16.06.2008

Certificate of Analysis - *KEY BRAND*

LINSEED OIL, PRESSED
BP 2008,Ph.Eur.6, 2008
Lot: ***0113650***

Analysis results:

Parameter		Result
Specific gravity (20 degree C)		0,928
Refractive index (20 degree C)		1,480
Acid value		0,9
Peroxide value		complies
Iodine value		183
Saponification value		192
Unsaponifiable Matter		1,3 %
Water		0,09 %
Colour gardner		9,8
Fatty acid composition		
Laurin acid	C 12:0	<0,05 %
Myristic acid	C 14:0	<0,05 %
Myristoleic acid	C 14:1	<0,05 %
Palmitic acid	C 16:0	5,34 %
Palmitoleic acid	C 16:1	0,07 %

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Lot: ***0113650***

Margaric acid	C 17:0	0,06 %
Heptadecic acid	C 17:1	<0,05 %
Stearic acid	C 18:0	3,95 %
Oleic acid	C 18:1	21,49 %
Linoleic acid	C 18:2	17,28 %
Linolenic acid	C 18:3	51,13 %
Octadecatetraen acid	C 18:4	<0,05 %
Arachidic acid	C 20:0	0,16 %
Eicosenoic acid	C 20:1	0,20 %
Eicosanedienoic acid	C 20:2	<0,05 %
Eicosanetetraenoic acid	C 20:4	<0,05 %
Behenic acid	C 22:0	0,14 %
Erucic acid	C 22:1	0,08 %
Lignoceric acid	C 24:0	0,10 %
Nervonic acid	C 24:1	<0,05 %
Other		0,05 %
Cadmium		<0,01 mg/kg
Identity		complies
Purity		complies

he compliance with the regulations of VO (EG) No. 1881/2006 concerning the determination of the maximum ontents of certain contaminants in food with respect to polycyclic aromatic hydrocarbons (PAH) and dioxins are uaranteed by suitable monitoring examinations.

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BP 2008,Ph.Eur.6, 2008
Lot: ***0113650***

Residual solvents: The pharmaceutical raw material (as an excipient) meets the requirement of Ph.Eur.5.0:5.4, the food regulations are also fulfilled.

This product in question is not affected by the GMO problem. Therefore this product does not need to be labelled regarding any genetic modification as per the new GMO regulations 1829/2003 and 1830/2003.

TSE/BSE risk: This raw material is of pure vegetable origin. During production, storage and transport there is no contact with any animal material and a cross contamination is excluded.
Therefore the requirements of Comm.Direc. 1999/82/EEC, CPMP/BWP/1230/98, Ph.Eur.Suppl.2000:5.2.8 are not applicable.

HENRY LAMOTTE OILS GMBH

Computer edited certificate - valid without signature

Alimentos

Propiedades reológicas de emulsiones alimenticias

Vernon Carter E.J.*, Torreblanca Roldán A.**, y Lever García C.A.***

Resumen

Se revisan en forma general algunos conceptos relacionados con el comportamiento reológico y estabilidad de emulsiones, y se presentan algunos modelos matemáticos propuestos para representar el flujo de derivados lácteos.

I. Introducción

Una gran variedad de productos alimenticios son emulsiones, entre las que se encuentran la mayoría de los derivados lácteos tales como leche, mantequilla, crema, yogurt, helados, queso, etc., algunas emulsiones cárnicas y algunos otros productos como mayonesas y margarinas. Es conveniente que se efectúen mediciones de las características reológicas de estos productos por varias razones (Sherman):[1]

- Tener un control de calidad sobre las materias primas o ingredientes que son empleados en la fabricación del producto.
- Tener un control sobre el proceso de fabricación y sobre el producto final.
- Evaluar la influencia de los ingredientes en la estructura del producto y sus características texturales.
- Suplementar la información obtenida por medio de grupos de jueces acerca del comportamiento de un producto en usos prácticos e incluso el llegar a sustituir las evaluaciones de jueces especialmente entrenados con mediciones reológicas apropiadas.

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** Instituto Nacional de la Nutrición y Universidad Iberoamericana.
*** Universidad Iberoamericana.

II. Definición de una emulsión

Una emulsión es la integración de dos fases inmiscibles, donde una está dispersa en la otra en la forma de gotas de tamaño microscópico. La estabilidad contra la coalescencia es lograda mediante la presencia de un agente emulsificante que es adsorbido alrededor de las superficies de las gotas. El mecanismo de estabilización se verá más adelante en el inciso III. C.

Generalmente, las dos fases líquidas que constituyen una emulsión son el agua y el aceite. Una de las principales razones por las que se usa aceite en la forma de una emulsión y no en su estado natural, es que se puede lograr un intervalo mayor de características de flujo y consistencia. Es importante revisar los tipos de flujo existentes y la teoría asociada con ellos antes de presentar la información relativa a algunos alimentos específicos.

III. Teoría de la reología de los fluídos

A. *Flujo Newtoniano*

El comportamiento de flujo de algunas emulsiones muy diluídas puede ser caracterizado por un solo parámetro, la viscosidad Newtoniana, la cual está definida como:

$$\eta = \frac{\tau}{\dot{\gamma}} \qquad (1)$$

donde existe una relación lineal entre el esfuerzo cortante *(shear stress)*, τ, y la tasa o rapidez de corte *(shear rate)*, $\dot{\gamma}$.

El flujo Newtoniano de fluídos en general se puede ilustrar con el siguiente modelo. Imagínese que un espacio entre dos planos paralelos que se encuentran separados una distancia x y está lleno con un líquido. Si aplicamos una fuerza F al plano superior A (Fig. 1), mientras que el plano inferior B se mantiene estacionario, A se moverá con una velocidad constante u. El líquido que se encuentra entre los dos planos no se mueve a la misma velocidad. La rapidez con que se mueve este líquido varía de acuerdo a su distancia del plano A; la velocidad máxima ocurre en la capa adyacente al plano A y es cero en la capa adyacente al plano B. La rapidez de cambio o tasa en la velocidad del fluído está dada por la relación du/dx. Esta relación representa la tasa de corte, $\dot{\gamma}$, del líquido, mientras que la fuerza por unidad de área aplicada al plano A representa el esfuerzo cortante, τ.

Como la viscosidad del líquido, η, está dada por la relación $\tau/\dot{\gamma}$, y ésta se mantiene constante, η puede ser determinada con una sola medición independientemente de la magnitud de τ ó $\dot{\gamma}$. Sin embargo, el comportamiento de flujo de la mayoría de las emulsiones alimenticias y, en general, de alimentos líquidos y semisólidos no puede ser caracterizado con una viscosidad constante, y tienen que ser caracterizados por lo menos

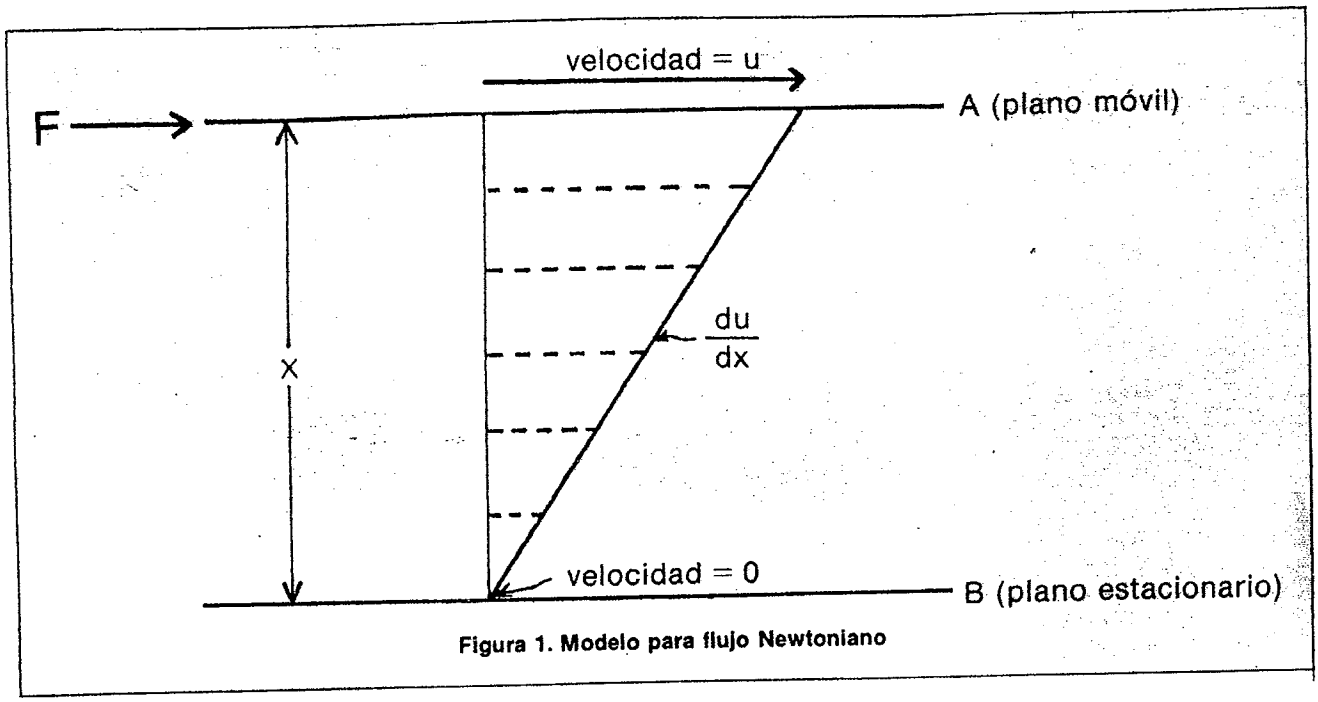

Figura 1. Modelo para flujo Newtoniano

con dos parámetros y con modelos más complejos. A los materiales que muestran una desviación del comportamiento de flujo Newtoniano se les conoce generalmente como fluídos no-Newtonianos.

B. *Flujo no-Newtoniano*

En flujo no-Newtoniano la viscosidad varía conforme se cambia la tasa de corte. Es decir, el esfuerzo cortante, τ, y la tasa de corte $\dot{\gamma}$, no están relacionadas linealmente, y en la práctica la relación entre éstos dos parámetros puede seguir en tres formas distintas (Sherman).[2,3]

1. *Flujo pseudoplástico*

El esfuerzo cortante y la tasa de corte están relacionados en forma no lineal, con la pendiente de la curva disminuyendo conforme se aumenta la tasa de corte (Fig. 2). A altos valores de la tasa de corte la relación se vuelve finalmente lineal. Además, el flujo comienza tan pronto como se aplica un esfuerzo cortante y, por lo tanto, la curva pasa por el origen de la gráfica.

2. *Flujo plástico*

El esfuerzo cortante y la tasa de corte están relacionados en forma no lineal como en el caso del flujo pseudoplástico. Sin embargo, para que el flujo comience es necesario el aplicar un esfuerzo cortante considerable (Fig. 2); a este esfuerzo cortante crítico requerido para que se inicie el flujo se le conoce como el "esfuerzo mínimo para el flujo" (*lower yield value*). Se pueden medir otros dos valores del esfuerzo que se aplican a materiales plásticos. Estos son el "esfuerzo superior para el flujo" (*upper yield value*), que es el esfuerzo cortante en el cual se lleva a cabo la transición de la relación lineal entre el esfuerzo cortante y la tasa de corte, y el "esfuerzo extrapolado para el flujo" (*extrapolated yield value*) que se deriva de la ordenada al origen en el eje del esfuerzo cortante por la extrapolación de la parte lineal de la gráfica.

La pendiente de la parte lineal de la gráfica de esfuerzo cortante contra la tasa de corte para materiales pseudoplásticos o plásticos representa la viscosidad mínima para ese material, ya que se ha destruído toda su estructura interna.

3. *Flujo dilatante*

Existen dos formas posibles para el flujo dilatante, dependiendo en si se requiere un esfuerzo cortante para iniciar el flujo o no. Cuando el flujo comienza con la aplicación de un esfuerzo cortante mínimo el comportamiento de flujo es el contrario de aquel observado en pseudoplasticidad, es decir, que el esfuerzo cortante y la tasa de corte están relacionados no linealmente, pero la curvatura aumenta conforme se aumenta la tasa de corte. Cuando es necesario el esfuerzo cortante finito para iniciar el flujo, el comportamiento de flujo es lo contrario del observado en plasticidad. La representación matemática de la relación no lineal entre el esfuerzo cortante y la tasa de corte en flujo no-Newtoniano fue propuesta por primera vez por Ostwald[4] y De Waele.[5] Estos autores propusieron una relación de la forma de la ecuación (2):

$$\dot{\gamma} = \frac{1}{\eta^*} (\tau)^n \qquad (2)$$

donde η^* es un parámetro que corresponde a la viscosidad y n es una constante. En el caso de flujo plástico el "esfuerzo mínimo para el flujo", τ_0, se incorpora lo que nos da la siguiente ecuación:

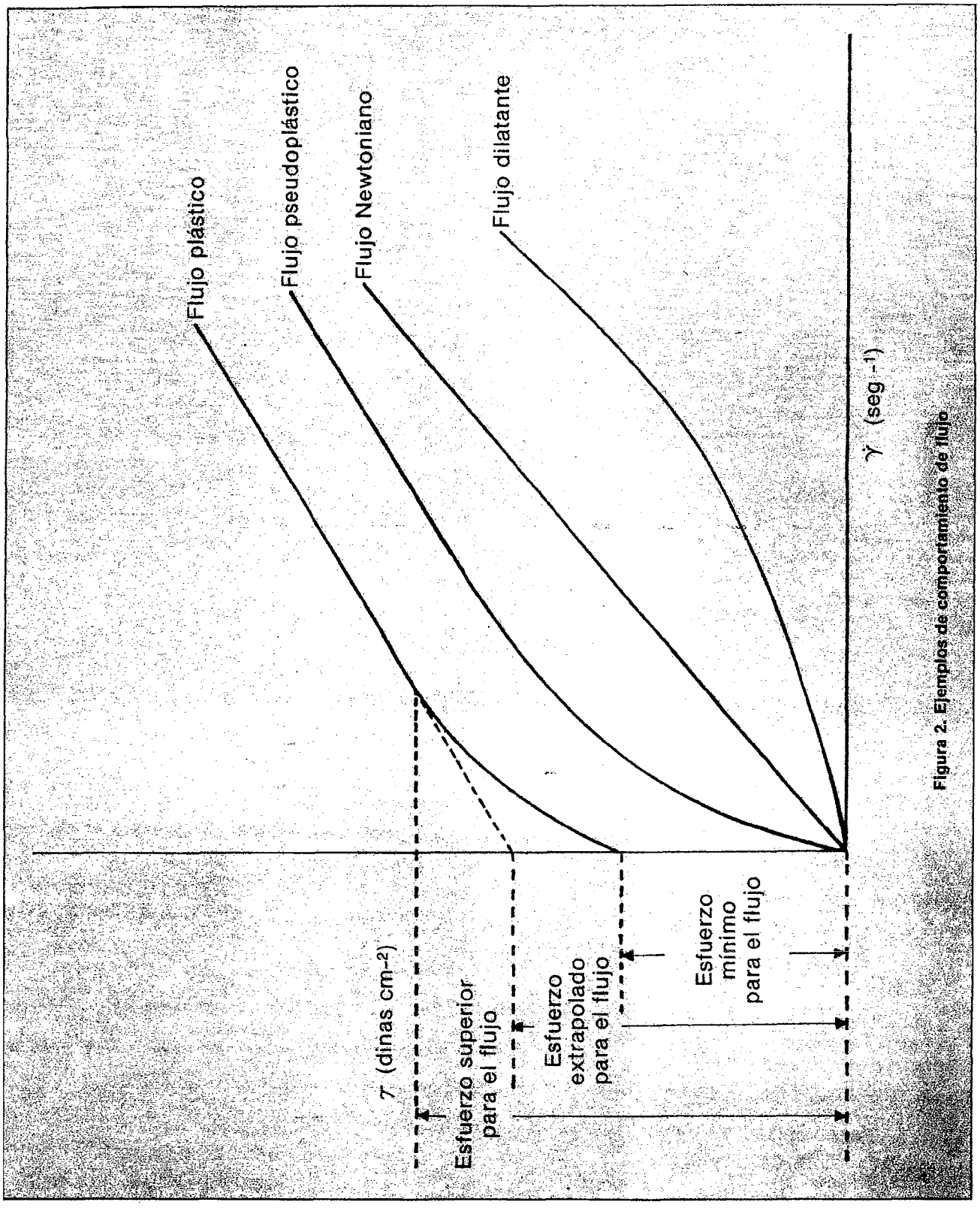

Figura 2. Ejemplos de comportamiento de flujo

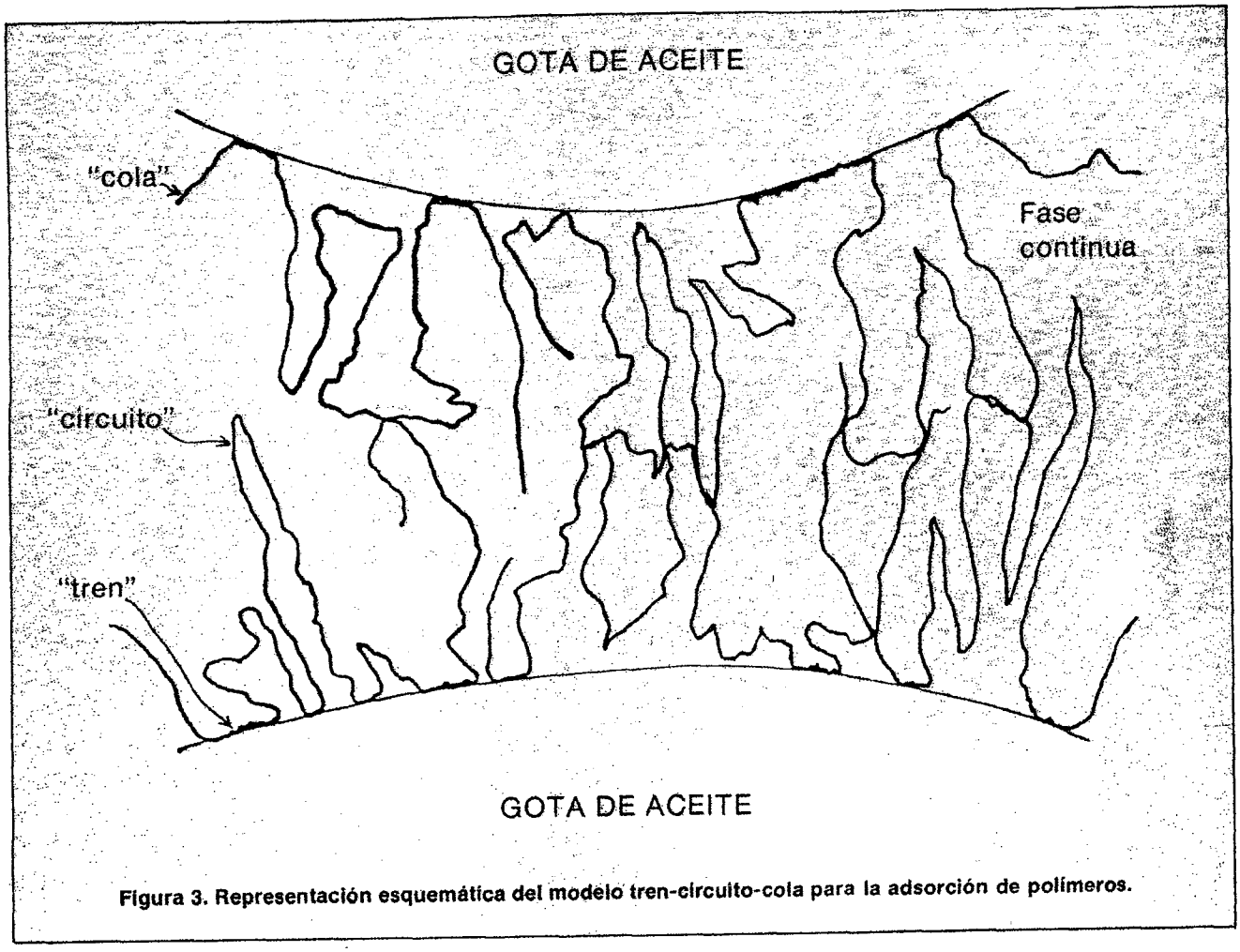

Figura 3. Representación esquemática del modelo tren-circuito-cola para la adsorción de polímeros.

$$\dot{\gamma} = \frac{I}{\eta *} \quad (\tau - \tau_0)^n \qquad (3)$$

Si los datos del flujo se ajustan a las ecuaciones (2) ó (3) entonces una gráfica logarítmica del esfuerzo cortante contra la tasa de corte da una línea con una pendiente n.

Además, cuando $n < 1$ las ecuaciones describen flujo plástico o pseudoplástico, cuando $n > 1$ el flujo es dilatante y cuando $n = 1$ el flujo es Newtoniano.

La validez de las ecuaciones (2) y (3) ha sido cuestionada en base a su dimensionalidad y ha sido propuesta una forma alternativa para superar esta crítica:

$$\tau = k\,(\dot{\gamma})^n \qquad (4)$$

donde k es un índice de consistencia (Rha;[6] Holdsworth[7]).

C. *Viscoelasticidad. La influencia de la floculación de las gotas en la reología de emulsiones.*

Durante el almacenamiento las gotas de una emulsión tienden a flocularse. Esto da origen a una estructura interna caracterizada por la formación de agregados en donde parte de la fase continua es atrapada en los espacios existentes entre las gotas floculadas. Cada agregado se comporta como si tuviese un volumen mayor que aquel dado por la suma de las gotas individuales del cual está constituido (Sherman[2]). Uno de los factores que influye en la estabilidad de las emulsiones contra la floculación es el tipo de agente emulsificante empleado. En el caso de emulsiones estabilizadas con compuestos de bajo peso molecular, tales como los electrólitos o las sustancias tensoactivas tipo detergentes, la tasa de floculación está influenciada por las fuerzas de atracción de London-van der Waals y por la repulsión electrostática entre las dobles capas de igual signo existentes en las superficies de las gotas (Derjaguin y Landau;[8] Verwey y Overbeek[9]). Sin embargo, en el caso de emulsiones estabilizadas con agentes macromoleculares como lo son las proteínas y las gomas, que es el caso de las emulsiones alimenticias, la tasa de floculación se ve afectada por factores de tipo estérico.

Estos polímeros no son adsorbidos en su totalidad en la superficie de las gotas y solo segmentos de la molécu-

a son adsorbidos, los que se denomi-an "trenes" (*trains*), mientras que el esto de la molécula es proyectada entro de la fase continua formando lo que se le llama "circuitos" (*loops*) Fig. 1). Los segmentos terminales ibres del polímero adsorbido son co-ocidos con el nombre de "colas" *tails*) (Jenckel y Rumbach[10]; Gra-am y Phillips[11]). Al flocularse las mulsiones, los "circuitos" partici-an en la formación de enlaces entre as moléculas de gotas adyacentes, evando eventualmente a la forma-ión de una red estructurada muy arecida a aquella de geles. Esta red structurada da origen al comporta-iento viscoelástico de las emulsio-es, el cual puede ser expresado en érminos de la relación deformación/ sfuerzo (*creep compliance*), J(t), on el tiempo t durante el cual se plica un esfuerzo constante (Sher-an;[1,3] Barry[12]):

$$J(t) = J_0 + \sum_{i=1}^{n} J_i[1 - \exp(-t/\tau_i)] \cdot t/\eta_N \qquad (5)$$

onde

J_0 es la relación $\left[\frac{\text{deformación}}{\text{esfuerzo}}\right]$ elástica instantánea;

$\sum_{i=1}^{n} J_i$ es la suma de un número discreto, i, de relaciones $\left[\frac{\text{deformación}}{\text{esfuerzo}}\right]$ elásticas de retardo, J_i;

τ_i son los tiempos de retardo, y

η_N es una viscosidad Newtoniana

mbién,
$J_0 = 1/E_0$, $J_i = 1/E_i$, $\tau_i = J_i \eta_i = \eta_i/E_i$

nde

E_0 es el módulo de elasticidad instantánea,

E_i representa los módulos de elasticidad de retardo, y

η_i son las viscosidades asociadas con J_i.

Cuando las fuerzas de origen estérico son las principales responsables de la floculación, la energía total de interacción está dada por (Napper;[13] Ottewill[14]):

$$V_T = V_R + V_A + V_S \qquad (6)$$

donde

V_S es el potencial debido a las fuerzas de origen estérico,

V_R es el potencial de repulsión, y

V_A es el potencial de atracción.

La contribución al módulo elástico. E_P, por las interacciones poliméricas en las superficies de las gotas está dado por (van Vliet *et al*[15]):

$$Ep = \frac{B\ \Gamma N_{AV}}{H\ M} \cdot kT \cdot \frac{3\phi}{2} \qquad (7)$$

donde:

B es una medida de la efectividad en la formación de enlaces por las moléculas poliméricas adsorbidas,

Γ es la concentración de polímero adsorbido por unidad de área superficial de las gotas,

N_{AV} es el número de moléculas adsorbidas en la superficie de la gota,

M es el peso molecular del polímero,

H es la distancia entre las superficies de las gotas,

ϕ es la fracción volumétrica de la fase dispersa, y

$\frac{BN_{AV}}{H\ M}$ es la concentración numérica de redes efectivamente entrelazadas.

Ep es el máximo contribuyente de E_0 en emulsiones estabilizadas estéricamente. Muchas emulsiones alimenticias contienen mezclas de agentes emulsificantes y su comportamiento viscoelástico dependerá en gran proporción en las relaciones en que estos se encuentren. Varios estudios han señalado que existe una relación crítica entre los agentes emulsificantes a la cual la emulsión exhibe una mayor viscoelasticidad y a cualquier variación de esta relación disminuye el valor de los parámetros viscoelásticos descritos por la ecuación (5) (Boyd *et al*;[16] Benton y Sherman[17]).

D. *La influencia de la coalescencia de las gotas en la reología de emulsiones*

Cuando una emulsión se deja reposar por un periodo prolongado las gotas se floculan y forman agregados. Dentro de estos agregados ocurre cierto grado de coalescencia, resultando que el número de gotas por unidad de volumen disminuye y el tamaño promedio de las gotas aumenta. Al proceso global de la floculación seguida por la coalescencia se le denomina coagulación (Sherman[3]).

La coalescencia de las gotas resultan en la disminución de los parámetros viscoelásticos E_0, Ei, η_i y η_N (Sherman[18]).

Esto es de esperarse ya que a ϕ constante, $E_0 \alpha 1/D^3$ como lo demuestra la siguiente expresión (Sherman[19]):

$$E_0 = \frac{\phi\,(1 + 1 \cdot 828\,\nu)\,A}{36\,\pi\,D^3\,H^3} \qquad (8)$$

en donde ν es el volumen total de las fase continua atrapada en los espacios entre las gotas en el estado agregado.

Luego pues, existe la siguiente situación: cuando las gotas floculan continuamente, los parámetros viscoelásticos aumentan, mientras que la coalescencia de ellas disminuye su valor. El efecto global resultante dependerá en cuál de los dos procesos es el predominante (Vernon Carter y Sherman[20]).

4. *Algunos modelos matemáticos propuestos para representar el flujo de derivados lácteos*

a). Leche. La leche es una emulsión

de grasa en agua. A pesar de su gran importancia como alimento, ha resultado difícil el definir su viscosidad con la ecuación propuesta por Einstein,[21] que relaciona la viscosidad de la emulsión con la viscosidad de su fase continua, η_0, y el volumen de su fase dispersa, ϕ:

$$\eta = \eta_0 (1 + 2.5\,\phi) \qquad (9)$$

Randhahn,[22] analizó un gran número de muestras de leche indicando que la viscosidad se puede relacionar con el contenido de grasa (F) por medio de la siguiente ecuación:

$$\eta = A_1 + A_2F + A_3S + A_4F^2 \qquad (10)$$

en donde, A_1, A_2 A_3 y A_4 son unas constantes y S es la concentración de sólidos en la leche exceptuando la grasa.

La leche debido a su bajo contenido de grasa exhibe flujo Newtoniano a temperatura ambiente, sin embargo a temperaturas más bajas su comportamiento se transforma en no-Newtoniano (Fernández Martín[23]).

b). *Crema.* La crema tiene un contenido de grasa mayor que el de la leche y exhibe flujo no-Newtoniano el cual sigue la ley de la potencia (Prentice[24]):

$$\eta\,ap = \eta_1 (\dot{\gamma})^{\beta} \qquad (11)$$

donde:

η ap es la viscosidad aparente a una tasa de corte seleccionada,

η_1 es la viscosidad aparente a una tasa de corte unitaria, y

β es un "coeficiente de anormalidad", y para fluídos Newtonianos, $\beta = 0$.

Algunas cremas con un contenido de grasa hasta del 50% en peso exhiben flujo Newtoniano dentro de un intervalo de temperatura de 40-80°C (Phipps[25]). En estos casos la viscosidad está relacionada al porciento en peso de grasa ε por:

$$\eta = \eta_0 \exp[3.07(\varepsilon + \varepsilon^{5/3})] \qquad (12)$$

A tasas de corte bajas y a temperatura ambiente, el comportamiento de la crema es no-Newtoniano y sigue la ecuación (4) (Prentice[26]). La crema exhibe comportamiento viscoelástico cuando es sometida a esfuerzos constantes muy pequeños y la viscoelasticidad aumenta con el contenido de grasa (Randhahn y Reuter[27]).

c. *Yogurt.* La consistencia del yogurt es frecuentemente evaluada con penetrómetros. Sin embargo, la evaluación por tal método ha sido problemática debido a la facilidad con que la estructura del producto es destruida.

La técnica del módulo de rigidez de geles, es apropiada para examinar las propiedades reológicas del yogurt (Atkin y Sherman[28]), el cual es viscoelástico cuando son aplicados esfuerzos constantes pequeños.

La viscoelasticidad cambia cuando el yogurt incluye pedazos de fruta.

d. *Helado.* El helado es una emulsión de grasa en agua congelada (aunque no completamente) que tiene gran contenido de aire, y un contenido de grasa no muy elevado. Sus propiedades reológicas han sido investigadas por medio de estudios de deformación esfuerzo contra tiempo indicados en la sección III. C, usando un viscoelastómetro de placas paralelas (Shama y Sherman[29]). Tales estudios indican que los parámetros viscoelásticos están influenciados por el contenido de grasa, el contenido de aire, por la temperatura del producto. Es decir, que tanta agua está en la forma de hielo, y el tamaño de sus cristales.

e. *Mantequilla y margarina.* Estos dos productos son emulsiones de agua en grasa parcialmente solidificadas y sus propiedades reológicas se ven muy influenciadas por la relación de grasa cristalizada grasa líquida (Parkinson *et al*[30]).

Las características de untabilidad han sido tradicionalmente predichas a partir de estudios con penetrómetros de cono por medio de la siguiente expresión (Sherman[3]):

$$p_i = \frac{mg^r}{d_p^n} \qquad (13)$$

donde:

p_0 es la fuerza para superar la resistencia a la penetración del cono en el material, el cual se denomina "valor de cedencia para el flujo" (*yield value*).

mg es el peso del cono más el peso de otras partes movibles del penetrómetro,

n es una constante con un valor de aproximadamente 2,

d_p es la profundidad a que el cono penetra en la muestra, y

$k = \frac{1}{\pi} \cos^2 a \cot a$. En donde a es la mitad del ángulo del cono.

Haighton[31] demostró que la untabilidad de la margarina y de otros materiales tipo manteca pueden predecirse a partir de valores de p_0, siempre y cuando las pruebas se realicen bajo condiciones controladas de temperatura. En el Cuadro I presentamos la clasificación que se les asignó a dichos materiales según su desempeño práctico.

El "índice de untabilidad" está definido por Haighton,[32] como:

$$U.I. = p_0 - 0.75\,(p_0 - p_1) \qquad (14)$$

donde p_0 y p_1 son, respectivamente, los valores de cedencia para el flujo de la muestra antes y después de ser "trabajada". El "trabajo" (*working*) se logra pasando la muestra a través de un pequeño orificio, como en el caso de un extrusor o de una moledora de carne.

El "trabajo" destruye la red entrelazada que existe entre los cristales de grasa. Posteriormente, durante el almacenamiento, ocurre cierta reorganización de la estructura destruida previamente. Esta destrucción y reorganización de la estructura de la mantequilla y la margarina sucede a tasas distintas. Para explicar este comportamiento, se ha sugerido (van den Tempel[33]) que la red entrelazada de los cristales de grasa está compuesta por dos tipos de uniones, "primarias" y "secundarias". Las uniones "primarias" son muy fuertes y no se

)mpen fácilmente, pero una vez ro- ıs no se reorganizan durante el tiem- o que dura el experimento. Su ori- :n se desconoce realmente, pero se a sugerido que son debidos a pode-)sas fuerzas de atracción existentes ıtre los cristales de grasa. Las unio- es "secundarias" son fuerzas de :racción de van der Waals entre los 'istales de grasa, las cuales son débi- s y fácilmente rotas, pero también)n fácilmente reorganizables. Con- :cuentemente, uniones "secunda- as" y en menor proporción las unio- :s "primarias" son destruidas du- nte el "trabajo" pero tan solo las ıiones "secundarias" se reorgani- n durante el almacenamiento sub- cuente.

La relación uniones ("primarias" secundarias") influye en la plastici- ıd (Naudet *et al*[34]). Cuando la rela- ón es muy alta, la mantequilla o argarina es muy dura y frágil. ientras que cuando esta relación es uy baja, el producto es fluído. De í que sea importante el obtener una lación correcta. Los cambios en las opiedades reológicas se pueden es- diar durante el "trabajo" y el subse- ente almacenamiento con mayor talle, por medio de estudios de vis- elasticidad aplicando esfuerzos nstantes muy pequeños en pruebas compresión o con el viscoelastó- :tro de placas paralelas (Shama y erman[35]).

Cuadro 1 Características de untabilidad de la margarina y de productos grasos en general.

Valor de cedencia para el flujo, po ($g.cm^{-2}$)	Características de la untabilidad
< 50	Muy suave, fluible
50 - 100	Muy suave, pero no untable
100 - 200	Suave, pero untable
200 - 1000	Satisfactoriamente untable
> 1000	Muy duro, no untable

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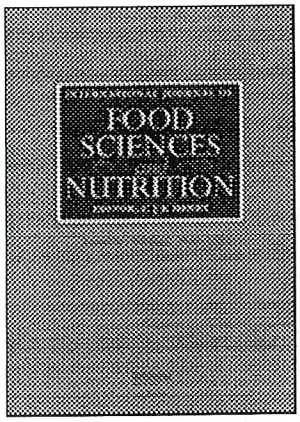

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The Nutritional Qualities of Margarine

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The Nutritional Qualities of Margarine

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Scientific Adviser to Van den Berghs Limited

IF THE HUMAN digestive system were no more than a fully automated arrangement of chemical processes, whose purpose with fats was to store them economically and burn them efficiently, it would be simple indeed to show that most fats — whatever their origin and however they were offered for human consumption — would serve that purpose. And there would be no more to nutritional requirements than that.

But we know in fact that these requirements vary in kind as one grows through childhood to maturity and, furthermore, that the digestive system is subject to emotional stresses and strains which affect its efficiency. So fat is not just so many calories of energy. One still recalls with distaste how once, in the pursuit of scientific knowledge, one ate — with others — 50 g red palm oil neat every day for a period. We all prefer our fat to be dispersed throughout the diet for we can stomach it more readily that way. So we take more than half our requirements in such a form that we are not consciously aware of it as we eat — in natural food, in processed food and in baked food — the invisible fat as it is called. And the remainder we like to be as palatable as possible, and as well spread as possible, for fat — more so than protein or carbohydrate — is apt to produce a feeling of nausea when taken neat.

It is the fat we spread that we are concerned with here. We depend on it for a large part of the fat-soluble trace nutrients which are vital to growth and health, and margarine more so than butter is used deliberately as a vehicle for those nutrients. It would be idle, and indeed foolish, to obscure the fact that margarine was devised as a substitute for butter; or that it was not wholly successful until the trace nutrient qualities of butter were recognised. It would be equally foolish to correlate the quality margarines of today with the well-conceived but primitively-formulated product of Mege-Mouries.

The present-day manufacturer of margarine — in his own interests — must satisfy himself that his products are nutritionally adequate. To some extent he is bound by Government regulations to make them so. The housewife — by selection — produces meals to appease family hunger. Through ignorance, she may not always achieve nutritional adequacy, but she must not be misled into thinking she has. Beyond that, it is to the manufacturer's advantage to produce something both attractive and palatable since these qualities —as we have indicated — cannot be wholly divorced from digestibility in the human system. It is indeed palatability which initiates the flow of gastric juices necessary to digestion.

Let us consider then the vitaminisation of margarine. We have celebrated last year the centenary of the birth of Sir Frederick Gowland Hopkins, whose discovery of vitamins pinpointed a vital difference between butter and the margarine of that time, and set manufacturers a major problem in solving it: two problems, in fact: one, to find sources of the vitamins in concentrated form; two, to overcome the unpalatability of vitamin A sources.

What we call the vitamin A potency of butter is compounded of true vitamin A and carotene, which is convertible *in vivo* to vitamin A. What the vitamin A equivalent of carotene is for man is anyone's guess, and one guesses low to be on the safe side. The point is that the human system is lazy and, given enough vitamin A, will ignore the carotene. Limited to carotene, it will convert it inefficiently and so requires a gross excess to maintain a satisfactory

balance. Hence one tends to view carotene more as a useful colorant and attach only a modest vitamin A potency to it.

Pre-formed vitamin A therefore is the more important nutritional factor, and the problem facing margarine manufacturers at the outset was that the only abundant source of vitamin A was fish liver oil, which was highly unpalatable, even at the low levels of addition required. They used cod liver oil, and made the best of a bad job by concentrating the vitamin into the unsaponifiable portion of the oil, which they then dissolved in a bland oil and deodorised. The discovery of enormous reserves of vitamin A in whale liver eased the problem slightly for, being of mammalian origin, whale liver oil was not so unpalatable as fish liver oil.

The second world war intensified the problem. Not all margarines had been vitaminised by then, and it was made compulsory as a nutritional precaution. But the supply of whale liver oil dwindled, while that of cod liver oil was not equal to the demand.

One turned, of necessity, to the rapidly growing U.S. and Canadian shark and dogfish liver oil industries for help. Research into methods of refining was intensified and two large-scale processes were developed — molecular distillation in the U.S. and chromatographic adsorption in this country — which largely eradicated the problem of the fishy flavour. They were helped by a Government regulation fixing the serum pH on the alkaline side. Its purpose was to extend the storage life of the margarine but, unknowingly, it helped to prevent fishy flavour reversion.

But acid sera are more palatable and, with the easing of restrictions after the war, there was a general move to reintroduce them, and we were in difficulty again. It was with a sigh of relief therefore that we witnessed — and indeed joined in — the final stages of development of synthetic vitamin A, helping to demonstrate its biochemical identity with the natural material, and establishing conditions for stability in margarine.

When cod liver oil was used as a source of vitamin A, vitamin D was concomitant. Neither whale, shark nor dogfish liver oil contain it to any significant extent, however, and it was possible to use them only because a manufactured source of vitamin D (irradiated ergosterol) became available. It presents no flavour problem. The primary interest in vitamin D in the present context is that the level is fixed far higher than that of butter, to ensure that children are not dependent upon the fortuitous conversion of skin sterols, by the action of atmospheric untraviolet light, for an adequate supply of the vitamin.

The other important post-war innovation was the introduction of the votator for making margarine. Superficially this may seem no more than a matter of technical engineering, or — at best — a means of improving hygiene by eliminating all handling stages; but in fact, its versatility has made possible quite important strides in the control of texture, which influences both the palatability of the margarine and its flavour. We like margarine — and butter — to be cool on the palate, not too fatty, and to release its flavour quickly. What may not be so readily realised is that behind it all — so far as margarine is concerned — lies a considerable amount of research into the physical chemistry of glycerides, their polymorphism, their patterns of crystallisation, and liquid/solid matrices.

Margarine manufacturers have an advantage here that, with a wide range of natural oils to select from, they can maintain a closer control on the texture of their product. At the same time they can ensure that the margarine contains reasonable reserves of essential fatty acids, that is, those acids — like linoleic acid — which the body needs for growth but cannot synthesise. We will not elaborate on this to any great extent for, although the presence of essential fatty acids is considered a good

and necessary thing, it would seem that the average diet contains sufficient for normal requirements.

Finally it is worth enlarging a little on flavour which plays perhaps a more subtle role than other factors in determining digestibility. There are flavours one likes, which aid digestion, and off-flavours most of us don't like. Fresh butter has a pleasant well-rounded flavour, which nevertheless varies surprisingly in character from type to type. Badly stored or aged butter develops a rancid off-flavour, unpleasant to most. A few people — strangely — seem to like it.

Margarine fats have native flavours which may not be unpleasant as such but count as foreign to the manufactured product. The art of the oil refiner then is to remove these native flavours in such a manner that the oil remains bland in taste for at least the normal shelf life of the finished product. The manufacturer can then impart desirable flavours without fear that their effect will be nullified by residual or developing off-flavours. But the total flavour of margarine is a combination of fat and serum flavour*, and it is here that texture becomes important. One can have good flavour in both the fat and the *serum**, but unless they are released together on the palate their effect is limited. A well-textured margarine will have a well-rounded flavour because it does just that.

So we see that, while the value of margarine as a food lies in the energy it will provide, and the growth and health it will promote, its palatability depends upon the technical skill with which texture and flavour are created; and the overall nutritional quality of margarine is a sum of all these contributory factors.

*Serum is the total aqueous phase of margarine (or butter). It contains salt, water soluble acids and proteinaceous material.

Nutritional Survey in the Cook Islands

BY JUDITH D. WALKER

Nutritionist, South Pacific Health Service

IN 1960 A NUTRITION survey was carried out in conjunction with a New Zealand Medical School investigation of blood cholesterol levels and the incidence of coronary disease amongst Polynesians living in the Cook Islands. Two groups of people were studied. These included villagers eating the traditional 'native' diet in which more than 90 per cent. of the dietary fat came from the coconut, and a group of families eating 'westernised' diets in which less than 25 per cent. of the fat came from the coconut.

The families were selected from the islands of Mitiaro and Atiu for high coconut diets, and from the Island of Rarotonga for low coconut diets. These three islands are in the southern part of the Cook Islands.

Mitiaro is a small low-lying island with a population of approximately 300. The island mainly consists of barren rocky land with a small area of volcanic soil where the food for the island is cultivated. The staple foods are green bananas varied with breadfruits and small amounts of root vegetables (taro, tapioca and yams). Other foodstuffs eaten in large quantities are coconuts and sea-foods such as crabs, shellfish, fish, a type of eel and chestnuts (*Indocarpus edulis*) when in season. The only export from the island is copra. Ships

eat right. American Dietetic Association

Shop Smart — Get the Facts on Food Labels

Become a smart shopper by reading food labels to find out more about the foods you eat. The Nutrition Facts panel found on most food labels will help you:

- Find out which foods are good sources of fiber, calcium, iron, and vitamin C
- Compare similar foods to find out which one is lower in fat and calories
- Search for low-sodium foods
- Look for foods that are low in saturated fat and trans fats

A Quick Guide to Reading the Nutrition Facts Label

Start with the Serving Size

- Look here for both the serving size (the amount for one serving), and the number of servings in the package.
- Remember to check your portion size to the serving size listed on the label. If the label serving size is one cup, and you eat two cups, you are getting twice the calories, fat and other nutrients listed on the label.

Check Out the Total Calories and Fat

Find out how many calories are in a single serving and the number of calories from fat. It's smart to cut back on calories and fat if you are watching your weight!

Let the Percent Daily Values Be Your Guide

Use percent Daily Values (DV) to help you evaluate how a particular food fits into your daily meal plan:

- Daily Values are average levels of nutrients for a person eating 2,000 calories a day. A food item with a 5% DV means 5% of the amount of fat that a person consuming 2,000 calories a day would eat.
- Remember: percent DV are for the entire day— not just for one meal or snack.
- You may need more or less than 2,000 calories per day. For some nutrients you may need more or less than 100% DV.

The High and Low of Daily Values

- 5 percent or less is low – try to aim low in total fat, saturated fat, cholesterol, and sodium
- 20 percent or more is high – try to aim high in vitamins, minerals and fiber

Limit Fat, Cholesterol and Sodium

Eating less of these nutrients may help reduce your risk for heart disease, high blood pressure and cancer:

- Total fat includes saturated, polyunsaturated and monounsaturated fat. Limit to 100% DV or less per day.
- Saturated fat and trans fat are linked to an increased risk of heart disease.
- Sodium – high levels can add up to high blood pressure.
- Remember to aim low for % DV of these nutrients.

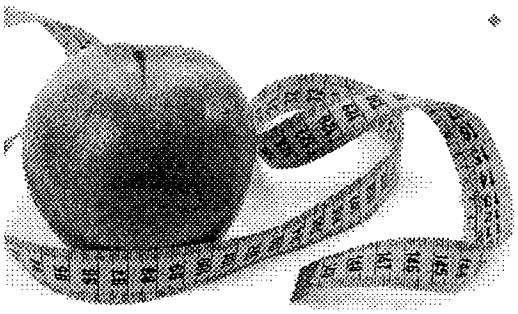
Nutrition Facts

Serving Size 1 cup (228g)
Servings Per Container 2

Amount Per Serving	
Calories 250	Calories from Fat 110
	% Daily Value*
Total Fat 12g	18%
Saturated Fat 3g	15%
Trans Fat 1.5g	
Cholesterol 30mg	10%
Sodium 470mg	20%
Total Carbohydrate 31g	10%
Dietary Fiber 0g	0%
Sugars 5g	
Protein 5g	
Vitamin A	4%
Vitamin C	2%
Calcium	20%
Iron	4%

* Percent Daily Values are based on a 2,000 calorie diet. Your Daily Values may be higher or lower depending on your calorie needs:

	Calories:	2,000	2,500
Total Fat	Less than	65g	80g
Sat Fat	Less than	20g	25g
Cholesterol	Less than	300mg	300mg
Sodium	Less than	2,400mg	2,400mg
Total Carbohydrate		300g	375g
Dietary Fiber		25g	30g



Get Enough Vitamins, Minerals and Fiber

- Eat more fiber, vitamins A and C, calcium, and iron to maintain good health and help reduce your risk of certain health problems such as osteoporosis and anemia.
- Choose more fruits and vegetables to get more of these nutrients.
- Remember to aim high for % DV of these nutrients.

Additional Nutrients

Carbohydrates – There are three types of carbohydrates----sugars, starches and fiber. Select whole-grain breads, cereals, rice and pasta plus fruits and vegetables.

Sugars – Simple carbohydrates or sugars occur naturally in foods such as fruit juice (fructose), or come from refined sources such as table sugar (sucrose) or corn syrup.

Check the Ingredient List

Foods with more than one ingredient must have an ingredient list on the label. Ingredients are listed in descending order by weight. Those in the largest amounts are listed first. Effective January 2006, manufacturers are required to clearly state if food products contain any ingredients that contain protein derived from the eight major allergenic foods. These foods are milk, eggs, fish, crustacean shellfish, tree nuts, peanuts, wheat and soybeans.

What Health Claims on Food Labels Really Mean

FDA has strict guidelines on how certain food label terms can be used. Some of the most common claims seen on food packages:

- Low calorie – Less than 40 calories per serving.
- Low cholesterol – Less than 20 mg of cholesterol and 2 gm or less of saturated fat per serving.
- Reduced -- 25% less of the specified nutrient or calories than the usual product.
- Good source of – Provides at least 10% of the DV of a particular vitamin or nutrient per serving.
- Calorie free – Less than 5 calories per serving.
- Fat free / sugar free – Less than 1/2 gram of fat or sugar per serving.
- Low sodium – Less than 140 mg of sodium per serving.
- High in – Provides 20% or more of the Daily Value of a specified nutrient per serving.
- High fiber – 5 or more grams of fiber per serving.

FDA also sets standards for health-related claims on food labels to help consumers identify foods that are rich in nutrients and may help to reduce their risk for certain diseases. For example, health claims may highlight the link between calcium and osteoporosis, fiber and calcium, heart disease and fat or high blood pressure and sodium.

For a referral to a registered dietitian and for additional food and nutrition information visit www.eatright.org.

eat right.

The American Dietetic Association is the world's largest organization of food and nutrition professionals. ADA is committed to improving the nation's health and advancing the profession of dietetics through research, education and advocacy.

Means of Delivering Recommended Levels of Long Chain n-3 Polyunsaturated Fatty Acids in Human Diets

M.L. Garg, L.G. Wood, H. Singh, and P.J. Moughan

ABSTRACT: n-3 Polyunsaturated fatty acids (n-3PUFA) of marine origin have been shown to be essential for brain development and cognitive function. In addition to their essentiality, the scientific literature is full of evidence to suggest that regular consumption and/or dietary supplementation with long chain n-3PUFA give several health benefits including: prevention of cardiovascular diseases, inflammatory diseases, dyslexia, and depression. Long chain n-3PUFA intake in the Western countries, including Australia, has been shown to be inadequate. This is largely due to the fact that the Western populations do not eat seafood on a regular basis because of its cost and availability, and many individuals do not like the flavor/taste/odor of seafood. Foods fortified with long chain n-3PUFA could play an important role in meeting the demands for optimal health. Marine n-3PUFA are not likely to compete with saturated, monounsaturated, and n-6PUFA as a major source of dietary fat; however, increasing the intake of foods containing marine n-3PUFA is an important strategy for the prevention of chronic illnesses. Recent developments in food technology allow fortification of foods, such as bread, dairy products, eggs, pasta, biscuits, margarines, and other spreads, without the undesirable fish odor/taste and with reasonable shelf life. There is a need to increase the amount of long chain n-3PUFA consumed per serve and optimize their bioavailability. This article reviews the foods fortified with marine n-3PUFA and their role in meeting daily requirements, and highlights the need for further research in this important area of functional foods.

Keywords: n-3 fatty acids, eicosapentaenoic acid, docosahexaenoic acid, fish oil, functional foods

Introduction

The human diet contains polyunsaturated fatty acids (PUFA) belonging to the n-6 and n-3 fatty acid families. Major dietary n-6PUFA include linoleic (18:2), γ-linolenic (18:3), and arachidonic (20:4) acids, whereas major dietary n-3PUFA include α-linolenic (18:3), eicosapentaenoic (20:5), docosapentaenoic (22:5), and docosahexaenoic (22:6) acids. Linoleic, γ-linolenic, and α-linolenic acids are present in large quantities in foods of plant origin, such as corn or maize oil, sunflower seed oil, cottonseed oil, soybean oil, linseed oil, evening primrose oil, and canola oil. Arachidonic acid originates from muscle and organ meats, or alternatively may be synthesized within the body via successive desaturation and chain elongation of linoleic acid. The longer chain n-3PUFA are found mainly in foods of marine origin or are synthesized via desaturation and chain elongation of α-linolenic acid within the human body. Recent evidence suggests that lean meat contributes significantly to the longer chain n-3PUFA content of the Western diet (Sinclair and others 1982; Meyer and others 2003; Li and others 2005). When present in equimolar concentration, linoleic acid and α-linolenic acid compete for conversion to their respective longer chain products, arachidonic acid and eicosapentaenoic acid (Contreras and Rapoport 2002). Recent studies have demonstrated that, for maximum conversion of α-linolenic acid to eicosapentaenoic acid and a maximum reduction in the formation of arachidonic acid, the α-linolenic acid should be supplemented with saturated fatty acids (SFA) rather than n-6PUFA (Garg and others 1989; MacDonald-Wicks and Garg 2004).

Saturated, monounsaturated, and n-6PUFA will continue to form a majority of the fatty acids present in the human diet. n-3PUFA, particularly the longer chain fatty acids of marine origin, constitute a small proportion of the total fat intake. For individuals or populations who consume no seafood or muscle or organ meats, such as vegetarians, α-linolenic acid is the only potential source of n-3PUFA. However, recent studies have demonstrated that the extent of conversion of α-linolenic acid to longer chain n-3PUFA is modest, and it is uncertain as to whether meaningful amounts of conversion occur to support normal growth and development. Emken and others (1994) found 15% conversion, whereas Pawlosky and others (2001) reported 0.2% conversion; both reported that the conversion to docosahexaenoic acid was much less than that to eicosapentaenoic acid and docosapentaenoic acid. However, the longer chain n-3PUFA that accumulates in tissue membranes is docosahexaenoic acid. Therefore, in some individuals, supplementation of the diet using fish oil capsules or foods fortified with fish oil fatty acids may be the only option to supply the recommended levels of longer chain n-3PUFA. As the dose of marine n-3PUFA required to achieve targeted health benefits is much higher than the recommended levels for maintenance of general health, it becomes even more challenging to meet the required amount of these fatty acids in order to minimize the risk of chronic disease.

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Dietary Intakes and Recommendations for Long Chain n-3PUFA

The dietary intake of total n-3PUFA has been estimated from a large dietary survey in the United Kingdom to be 2000 mg for men and 1410 mg for women (Gregory and others 1990), but these estimates do not distinguish between plant and marine n-3PUFA. In the United States, the dietary intake of total n-3PUFA has been reported to be 1600 mg/d, of which 100 to 200 mg/d is 20:5n-3 and 22:6n-3 (Kris-Etherton and others 2000). A recent study reported an average daily intake of 189 mg of marine n-3PUFA (20:5, 22:5, and 22:6 at 56, 26, and 106 mg/d, respectively) (Meyer and others 2003) in the diets of Australians. The major food sources contributing to n-3PUFA intakes include seafoods (71%), meats (20%), and eggs (6%). This study indicated that Australians are failing to meet the recommendations as outlined in the draft document of the new Australian Nutrient Reference Values (previously known as Recommended Dietary Intakes) in which adequate intake has been set at 190 mg/d. The paper also highlighted the need for strategies to increase the availability and consumption of foods enriched with long chain n-3PUFA. In contrast to these Western diets, Japanese eat about 80 g of fish and shellfish per day, providing approximately 1000 to 2000 mg/d of 20:5n-3 and 22:6n-3 (Sugano and Hirahara 2000). This high fish consumption is believed to contribute to the reduced incidence of coronary heart disease (CHD) in this population (Lands and others 1990).

A host of health agencies and professional organizations worldwide have issued recommendations on the intake of long chain n-3PUFA (Table 1). A number of recommendations to increase marine oil intake in people with or at risk of cardiovascular disease (CVD) have been made. These recommendations are based on evidence derived from sound clinical trials linking dietary deficiency of long chain n-3PUFA with cardiovascular events, and a recent meta-analysis of 13 cohort studies including more than 220,000 individuals followed for CHD mortality rates for an average of 12 y (He and others 2004). The British Nutrition Foundation Task Force recommends a daily intake of 500 to 1000 mg/d of long chain n-3PUFA, which is equivalent to 1 to 2 portions of oily fish per week (British Nutrition Foundation 1992). In contrast, the U.K. Department of Health recommends a daily intake of 200 mg of 20:5n-3 and 22:6n-3 (Department of Health 1994). Sweden recommends that the ratio of n-6PUFA to n-3PUFA be 5:1 (Nordic Working Group on Diet and Nutrition 1996). The World Health Organization recommends 1 to 2 servings of fish per week, each containing 200 to 500 mg of 20:5n-3 and 22:6n-3 (Kris-Etherton and others 2002). The American Heart Association (AHA) recommends that people with no CVD should eat oily fish twice/week and foods rich in α-linolenic acid (walnuts, canola, soy, and flaxseed). However, those with documented CVD should eat approximately 1 g of 20:5n-3 and 22:6n-3 per day, preferably from oily fish but also in supplement form. The AHA further recommends that, for triglyceride-lowering effects, 2 to 4 g of n-3PUFA should be consumed per day as a supplement under a physician's care (Kris-Etherton and others 2003). The International Society for the Study of Fatty Acids and Lipids (ISSFAL) recommends adequate 18:2n-6 intake as 2% energy, healthy 18:3n-3 intake as 0.7% energy, and, for cardiovascular health, a minimum of 500 mg of 20:5n-3 and 22:6n-3 per day (ISSFAL 2004). The expert panel supported by the National Institutes of Health recommends 300 mg of docosahexaenoic acid per day for pregnant or lactating females (Simopoulos and others 1999). The Joint FAO/WHO Expert Consultation on Fats and Oils in Human Nutrition made no specific recommendations for n-3PUFA, but recommended that individuals with linoleic-to-linolenic acid ratio in excess of 10:1 should be encouraged to consume foods rich in n-3PUFA, such as green leafy vegetables, legumes, fish, and other seafood (FAO/WHO Consultation on Fats and Oils 1994).

In summary, dietary recommendations for long chain n-3PUFA supplementation are still a matter of debate. Recommendations vary depending on desired disease prevention: daily ranges for 20:5n-3 and 22:6n-3 begin at 180 mg (for healthy adults) to 500 mg (decrease in heart disease) to 1000 mg (decrease in mental illness) (Ruxton and others 2004).

It is also recommended that the ratio of n-6PUFA to n-3PUFA should not exceed 4 to 1 in order to optimize the bioavailability, metabolism, and incorporation into membrane phospholipids (Garg and others 1988c, 1990; Volker and Garg 1996). There are three possible ways to achieve this: (1) simply increasing long chain n-3PUFA consumption in the diet; (2) keeping the SFA, monounsaturated fatty acids (MUFA), and long chain n-3PUFA content constant and decreasing n-6PUFA in the diet (however, taking a whole-diet approach and in the light of general dietary advice to decrease the proportion of SFA in the diet, to concomitantly decrease n-6PUFA will encourage a low-fat intake which has the potential to reduce the level of circulating high density lipoprotein (HDL) cholesterol (Katan 1998; Terpstra and others 2000)); (3) maintaining the level of long chain n-3PUFA, decreasing total n-6PUFA and making up the shortfall in dietary fat intake with MUFA and/or SFA (this will improve the n-6PUFA-to-n-3PUFA ratio without reducing the fat content in the diet and will therefore avoid the detrimental effects of a reduction in circulating HDL cholesterol level). Whether either of the last two options is suitable to optimize the n-6PUFA-to-n-3PUFA ratio without adverse effects on the plasma lipid profile remains to be established.

Health Benefits and Mechanisms of Action of n-3PUFA

Epidemiological and experimental evidence suggests that consumption of marine n-3PUFA is associated with a reduced risk of CVD, certain types of cancer, inflammatory disease (rheumatoid

Table 1 — Recommended Daily Intake of Long Chain n-3 Polyunsaturated Fatty Acids

Organization	Recommended daily dose of 20:5n-3 plus 22:6n-3 (mg)	Population
National Health and Medical Research Council (Australian Nutrient Reference Values)	190	General population
British Nutrition Foundation Task Force	500–1000	People at risk of CVD
U.K. Department of Health	200	General population
European Academy of Nutritional Science	200	General population
ISSFAL	650	General population
AHA	1000	People at risk of CVD
	Oily fish (twice/week)	General population
	>3 g/d	To reduce triglyceride levels
NIH	300	Pregnant and lactating females

arthritis, asthma, lupus, and ulcerative colitis), diabetes mellitus, multiple sclerosis, and clinical depression (Ruxton 2004; Wang and others 2004). It is noteworthy that, if the population under study already has a high overall intake of fish, eating more fish is not associated with increased health benefits. These effects are mediated by alterations in circulating lipid levels, eicosanoids, cytokines, and physico-chemical properties of the cellular membranes. n-3PUFA are pleiotropic molecules with a broad variety of different biological actions, including hypotriglyceridemic, anti-aggregatory, anti-inflammatory, and anti-arrhythmic responses. Long chain n-3PUFA have been shown to reduce the size of the chylomicrons synthesized in the intestinal mucosa and released into the thoracic lymph following consumption of foods containing fats (Chan and others 2003). They have also been shown to reduce circulating levels of triglyceride and to reduce secretion of very low density lipoprotein (LDL) from the hepatic tissue (Parks and others 1990; Ikeda and others 2001). Dietary supplementation with long chain n-3PUFA has been shown to inhibit delta-6 desaturase activity, and reduce plasma and tissue levels of arachidonic acid (20:4n-6) (Garg and others 1988a, 1988b). Dietary 20:5n-3 and 22:6n-3 have also been shown to compete at the cyclo-oxygenase and lipo-oxygenase levels with 20:4n-6 to reduce the formation of series-2 eicosanoids (von Schacky and others 1985; Kurlandsky and others 1994; Nordoy and others 1994). Consumption of long chain n-3PUFA has also been associated with a reduction in plasma levels of pro-inflammatory cytokines (interleukins and tumor necrosis factor) (Endres and others 1994; Wallace and others 1995; Wachtler and others 1997; Seljeflot and others 1999). Dietary supplementation with fish oil high in long chain n-3PUFA is accompanied by a reduction in fibrinogen content and down regulation of the expression of adhesion molecules such as VCAM-I and ICAM-I (Gans and others 1988; Collie-Duguid and Wahle 1996; Hughes and others 1996; Vanschoonbeek and others 2004). Dietary long chain n-3PUFA are incorporated into the platelet phospholipids and concomitantly reduce platelet aggregation (Skeaff and Holub 1988; Chen and others 2000). Recent studies have demonstrated that dietary supplementation with long chain n-3PUFA improves vascular compliance and favorably modifies blood pressure (Cobiac and others 1992; Appel and others 1993; McVeigh and others 1994; Geleijnse and others 2002). Incorporation of long chain n-3PUFA into the membrane phospholipids can alter the physico-chemical properties of the membrane and influence membrane-associated functions, such as hormone binding, ion channels, enzyme activities, and so on. (Clandinin and others 1991).

The U.S. Food & Drug Administration has granted a qualified health claim for dietary n-3PUFA supplements: "Consumption of Omega-3 fatty acids may reduce the risk of CHD. FDA evaluated the data and determined that, although there is scientific evidence supporting the claim, the evidence is not conclusive" (US Food & Drug Administration 2004). The United Kingdom has become the first country outside the United States to grant an n-3 fish-oil health claim that manufacturers throughout Europe have begun applying to their products. The claim, issued by the Joint Health Claims Initiative, made up of consumer protection groups, food law enforcers, and members of the food industry, states: "Eating 3 g weekly, or 0.45 g daily, long chain n-3PUFA, as part of a healthy lifestyle, helps maintain heart health." (Joint Health Claims Initiative 2005).

Given that most Western populations fall well short of recommended oily fish servings per week, food formulators are working hard to develop other ways of increasing fish oil intake, and a wide range of products including eggs, breads, crackers, milks, cheeses, and juices are expected to carry the claim in the near future. Apart from well-informed health seekers, the majority of the consumers in Australia and New Zealand display poor understanding of omega-3 fatty acid types and sources (Patch and others 2005a, 2005b). Moreover, for a vast majority of consumers, improved heart health remains the health benefit most readily linked with n-3PUFA intake/supplementation.

Safety concerns relating almost exclusively to the administration of large doses of LCn-3PUFA have been expressed by some experts. Subjects reported a higher incidence of belching and unpleasant taste (Belluzzi and others 1994) when taking fish oil capsules as supplements, but not experienced by those who increased their n-3PUFA intake purely by dietary means. Since LCn-3PUFA are known to exert a dose-related increase in bleeding time, concerns have been raised about the possibility of increase in blood loss during labor or during surgical operations. However, there are no documented cases of abnormal bleeding even when high dosages of LCn-3PUFA were supplemented along with anticoagulant medications. High doses of LCn-3PUFA have the potential to increase LDL cholesterol levels and/or increase oxidizability of LDLs; however, clear evidence and clinical relevance of these findings remain unclear. People who bruise easily, have a bleeding disorder, or take blood thinning medications are advised to take LCn-3 supplements under the supervision of a healthcare provider.

Food Sources of n-3PUFA

Common plant sources of n-3PUFA (in the form of α-linolenic acid) include canola oil, soybean oil, walnuts, and flaxseed (linseed) oil. However, plant biologists are removing α-linolenic acid from these sources by genetic manipulation and/or by chemical hydrogenation to improve the shelf-life stability and cooking qualities (Robert and others 2005). Enriched eggs, produced by the addition of fish meal or canola/linseed oil to chicken feed, are also a good source of long chain n-3PUFA (Scheideler and others 1997; Smuts and others 2003; Bourre 2005a). However, concerns with cholesterol present in yolk prohibit frequent consumption of eggs. It is also possible to enrich poultry and pig meat with long chain n-3PUFA by supplementing the feed with fish meal or canola/linseed oil (Metcalf and others 2003; Bourre 2005b). Food sources of long chain n-3PUFA (20:5n-3 and 22:6n-3) include seafoods, fish oils such as cod liver oil, menhaden oil, and herring oil, lipid extracts from fungi, and algae of marine origin. With increased consumption of seafood and impure marine oils, concerns have been raised about the toxins, such as parachlorobenzoic acid, DDT, dioxin, and methyl mercury, that may be present in these foods (Mahaffey 2004; Melanson and others 2005).

Regardless of the source, all long chain n-3PUFA are highly susceptible to oxidation, which leads to unpleasant off-flavors and taste in the final product (Nawar 1996; Watkins and German 1998). The oxidative instability of long chain n-3PUFA is markedly higher than that of oleic acid (18:1n-7) and linoleic acid (18:2n-6). Exposure to high temperatures and air during processing and storage can cause rapid deterioration of these fatty acids. Another problem is the residual "fish" aroma and taste that often remain in the product even if n-3 oils are properly processed and stored. These problems can often be minimized by refining and deodorizing the oil, and packaging in an inert gas like nitrogen to prevent oxidation. Natural and synthetic antioxidants such as tocopherols and ascorbyl palmitate are commonly used to help prevent oil oxidation (Frankel and others 1994; Huang and others 1994; Chen and Ho 1997). However, the effectiveness of antioxidants depends on several factors, such as pH, temperature, polarity and concentration of antioxidants, and the physical properties of the food system. Consequently, great variations can be seen in different food systems.

Microencapsulation of oil can be used to delay or inhibit oxidation and allow the manufacturer to handle and incorporate oil in

Table 2—Examples of Some Commercially Available Microencapsulated n-3 Powder Products

Company/Product	Product description	Ingredients
BASF/Dry n-3 18:12	Microencapsulated fish oil rich in EPA and DHA, light yellow	Gelatin and sucrose matrix, coated in starch, sodium ascorbate (E310), ascorbic acid (E300), tocopherol (E306), tricalcium phosphate (E341)
BASF/Dry n-3 5:25C	Microencapsulated fish oil high in DHA, light yellow	Caseinate and sucrose matrix, coated in starch, ascorbyl palmitate (E304), sodium ascorbate
Nu-Mega/Driphorm Hi-DHA 50	Powder containing 48% Hi DHA tuna oil, bland taste	Tuna oil, sodium caseinate, dextrose monohydrate, dried glucose syrup, sodium ascorbate (E301), mixed natural tocopherols, lecithin, dl-alpha tocopherol (E307), ascorbyl palmitate (E304)
Salkat/Vana Sana EPA/DH, A Rich Powder, 50A 070	Powder, typical taste	Natural fish oil concentrate, carbohydrates, antioxidants, free flowing agent

food products (Kolanowski and others 1999; Klinkesorn and others 2005). The microencapsulation process can also help mask undesirable fishy odors and flavors in the final product. A number of companies, including BASF, Roche, Clover, and Ocean Nutrition, manufacture and sell microencapsulated fish oil powders for use in food products (Table 2). Moreover, several patents on microencapsulation technologies for the protection and encapsulation of fish oil exist. Most of these encapsulated n-3 oil products are based on the formation of fish oil emulsions using proteins, polysaccharides, lecithin, and other low molecular weight emulsifiers, individually and in various combinations. The emulsions are then spray-dried to form microcapsules. However, the amount of oil that can be delivered in these formats varies from 1% to 30%. During spray-drying, a significant proportion of the oil can migrate into the surface of the powder particle, which readily oxidizes and can cause off-flavors in food products. To improve the oxidative stability of the microencapsulated product, antioxidants can be added to either the oil or the powder, or both. Microemulsification has added advantages, such as long shelf life, masking of the taste and flavor of fish, and improved bioavailability of the n-3PUFA. However, particular attention needs to be paid to the material used for microencapsulation for maximum bioavailability. These technologies have allowed the fortification of frequently consumed foods, such as breads, biscuits, soups, fruit juices, and spreads with reasonable consumer acceptability. However, the levels of incorporation that can be achieved with existing technologies are very low and the amounts of long chain n-3PUFA required to meet recommended allowances are impractical in most cases. Further work in this area needs to concentrate on the development of convenience foods, suitable for fortifying with larger amounts of n-3PUFA per serve, in a palatable format.

Facts about Foods Fortified with Long Chain n-3PUFA

There is a constantly growing range of foods enriched in n-3PUFA available to the consumer (Table 3). One of the limitations of currently available foods fortified with long chain n-3PUFA is that they need to be consumed in large quantities to meet a dietary recommendation of 200 mg/d for healthy adults, or even in larger amounts to meet a dietary recommendation of 1000 mg/d of long chain n-3PUFA for people at high risk of CVD. Australian food examples include:

- Dairy Farmers (Farmers Best) milk provides at most 31.2 mg of 20:5n-3 and 22:6n-3 per 250 mL serving, which is no more than 15% of what is needed per day to benefit heart health, and less than 3% of the recommended dose for people at high risk of CVD.
- Brownes (Heart Plus) milk drink has been specially formulated to improve the performance of the heart and cardiovascular system as part of a balanced diet with regular physical activity. This product does better. One serve (250 mL) contains about 75% of our daily requirement of long chain n-3PUFA, but still needs to be consumed at a dose of over 1.5 L to meet a dietary recommendation of 1000 mg/d of long chain n-3PUFA for people at high risk of CVD.
- Coles (High Top) bread provides only 37 mg of 20:5n-3 and 22:6n-3 per serve (2 slices). Buttercup (Wonder White) DHA bread contains only 34 mg of 20:5n-3 and 22:6n-3 in 2 slices. Both breads contain per serve less than 15% of what is needed for good heart health and less than 3% of the recommended dose for people at high risk of CVD.
- AP Foods (Seachange) omega-3 spread contains 600 mg of long chain n-3PUFA per 100 g. Approximately 35 g/d of this spread must be consumed for a healthy heart and 175 g/d would need to be consumed to obtain sufficient long chain n-3PUFA to benefit those at high risk of CVD.
- Biomedical Laboratories (IQ3 Brainstorm) cereal bars in the United Kingdom are made using Nu-Mega's Driphorm powdered fish oils. The fruit-flavored bars, containing 150 mg of 20:5n-3/22:6n-3, are marketed as a way to improve children's performance at school. This appears to be a good way of supplying long chain n-3PUFA in the diets of children.

Conclusions

Clearly, there is a need to develop foods that can deliver the recommended level of long chain n-3PUFA in convenience foods consumed on a regular basis. n-3PUFA, particularly of marine origin, will continue to be a minority of all the fatty acid classes present in the human diet, even after making a recommendation of 2 to 3 servings of fish and seafood per week. It is not likely that we will

Table 3—Examples of Some Commercially Available Foods Fortified with n-3 Polyunsaturated Fatty Acids

Product	20:5n-3/22:6n-3	% of daily dose (general population)	% of daily dose (for those at high risk of CVD)	Country
Dairy Farmers (Farmers Best) milk	31.2 mg per 250 mL serve	15	3	Australia
Brownes (Heart Plus) milk	150 mg per 250 mL serve	75	15	Australia
Coles (High Top) bread	37 mg per serve of 2 slices	16	3.2	Australia
AP Foods (Seachange) omega-3 spread	200 mg per 35 g serve	100	20	Australia
Fish oil capsules (most brands)	300 mg per 1 g capsule	150	30	Australia
Cereal bars (Biomedical Laboratories)	150 mg per bar	75	15	United Kingdom

start eating fish on a daily basis just because the n-3PUFA are beneficial to health. If everyone in the world starts consuming even 2 to 3 servings of fish per week, the supply of fish will run out very quickly. Innovative methods of providing required amounts of long chain n-3PUFA are needed. Species of algae and fungi have been isolated and cultured for mass production of long chain n-3PUFA free of the toxins that are typically found in some fish. Efforts are being made to insert genes in plants and animals to enable endogenous synthesis of long chain n-3PUFA. Until such gene manipulations are successfully implemented and their safety established, it is imperative that the delivery and the bioavailability of n-3PUFA are optimized. There is some evidence to suggest that the bioavailability of long chain n-3PUFA can be improved by providing n-3PUFA in a food matrix that accelerates their entry into the mucosal cells. Some important points to optimizing the benefits from n-3PUFA supplements, such as fish oil capsules, include the following:

1. Keep n-6PUFA in the diet as low as possible.
2. Consume n-3PUFA supplements with a background diet rich in MUFA.
3. Consume supplements with the meal.
4. Ensure that sufficient preformed long chain n-3PUFA foods are consumed, rather than relying on foods containing the parent 18:3n-3.
5. Prefer microencapsulated fish oil capsules over normal capsules.

Research Needs

It is evident from the information presented in this article that there is a need to develop functional foods that can provide the recommended levels of long chain n-3PUFA, including for those who have already had a cardiovascular event and those at a high risk of developing CHD. It is noteworthy that although foods fortified with higher levels of long chain n-3PUFA need to be developed, the total fat content, particularly the level of SFA, must not exceed the dietary guidelines. The fortified food must be convenient, palatable, with no fishy odor/flavor and no fishy eructation following consumption. The food matrix should provide minimum or no resistance for release of long chain n-3PUFA in the gastrointestinal tract to ensure maximum bioavailability. Particular attention needs to be paid to the material used for microemulsification, as this may be an important criterion for the bioavailability of long chain n-3PUFA. Quantitative data on bioavailability of long chain n-3PUFA from the n-3PUFA enriched foods is lacking in the literature, although acute and chronic effects of consuming these foods on n-3PUFA incorporation have been extensively reported. Other factors, dietary or physiological, which might affect the bioavailability of long chain n-3PUFA also merit further investigation. Perhaps, long chain n-3PUFA can be combined with other nutrients in a single food to optimize their health benefits. One such ideal combination may be the synergistic effects of long chain n-3PUFA and plant sterols on plasma lipids. Plant sterols are known to reduce plasma and LDL cholesterol, while the triglyceride lowering properties of long chain n-3PUFA are well established. The combination of the two may be ideal to achieve overall lipid-lowering effects from a single food. Similarly, long chain n-3PUFA can be combined with other dietary ingredients, such as carotenoids, in order to maximize the anti-inflammatory effects for the prevention of rheumatoid arthritis, asthma, and inflammatory bowel disease. The development of functional foods enriched with larger amounts of long chain n-3PUFA and testing for bioavailability, biological and clinical effects require a concerted team effort, including food scientists/technologists, human/clinical nutritionists, and food producers. Some of these aspects of long chain n-3PUFA are under active investigation in our research laboratories.

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ALIMENTOS FUNCIONALES: UNA HISTORIA CON MUCHO PRESENTE Y FUTURO

FUNCTIONAL FOODS: A HISTORY WITH A LOT OF PRESENT AND FUTURE.

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RESUMEN

La evolución de los hábitos nutricionales ha sido muy variable a través del tiempo, pero siempre soportada con el criterio básico de mantener la salud. Cada día las exigencias de los consumidores se dirigen más a la búsqueda de nuevos productos con propiedades funcionales que puedan proporcionar además del valor nutritivo, otros componentes con actividad fisiológica que permitan un mejor estado tanto físico como mental, reduciendo así el riesgo de enfermedades y alargando la vida al mismo tiempo que manteniendo su calidad. Esta revisión describe aspectos importantes de alimentos e ingredientes con características funcionales, a través del pasado, presente y futuro.

Palabras clave: alimentos funcionales, ingredientes funcionales, componentes fisiológicamente activos.

ABSTRACT

The evolution of nutritional habits has experienced many changes through the time, but it has always been supported with the basic criterion to maintain the health. Every day the exigencies of the consumers go more to the search of new products with functional properties that can provide in addition to the nutritious value, other components with physiological activity that allow a better physical and mental state, reducing therefore the risk of diseases and extending the life at the same time that maintaining its quality

This review describes an overview about the most important aspects of the foods and ingredients with functional characteristics through the past, present and future.

Keywords: functional foods, functional ingredients, physiologically active components.

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INTRODUCCIÓN

La Academia Nacional de Ciencia de los Estados Unidos ha definido los alimentos funcionales como "cualquier alimento o ingrediente alimenticio modificado, que pueda proporcionar un beneficio a la salud superior al de los nutrientes tradicionales que contiene" (1). Muchas otras definiciones en el mismo sentido se pueden encontrar (2, 3, 4, 5, 6). A lo largo del tiempo se han utilizado muchos términos para identificar los alimentos funcionales, tales como alimentos de diseño, productos nutracéuticos, alimentos genéticamente diseñados, farmalimentos, vitalimentos, fitoalimentos/fitonutrientes, alimentos de alto rendimiento, alimentos inteligentes, alimentos terapéuticos, alimentos de valor añadido, alimentos genómicos, prebióticos/probióticos, alimentos superiores, alimentos hipernutritivos, alimentos reales (3,7). La tabla 1 resume alguna de estas definiciones.

Tabla 1. Definiciones relacionadas con los alimentos funcionales

Término	Definición	Bibliografía
Alimento Funcional	Cualquier alimento o ingrediente que proporcione un beneficio para la salud superior al que aportan los nutrientes tradicionales que contenga.	1
Quimiopreventivo	Componente alimenticio, con función nutritiva o no, que se ha comprobado científicamente que posee potencial inhibitorio, preventivo frente al cáncer primario y secundario.	8
Alimento de Diseño	Alimento procesado al que se le han añadido ingredientes naturales ricos en sustancias preventivas de enfermedades.	9
Nutracéutico	Cualquier sustancia que pudiera considerarse alimento, o parte de él, que proporcione beneficios médicos o para la salud, incluyendo la prevención y el tratamiento de enfermedades.	10, 11
Fitoquímico	Sustancias que se encuentran en frutas y verduras comestibles, que se ingieren diariamente en cantidades importantes por los humanos, y que poseen el potencial de modular el metabolismo de forma positiva en la prevención del cáncer.	8, 12

El sistema regulatorio japonés, FOSHU (Alimentos de uso exclusivo para la salud), describe 11 categorías de ingredientes con actividad fisiológica (3):

- Fibras alimentarias.
- Oligosacáridos.
- Alcoholes derivados de azúcares.
- Ácidos grasos poliinsaturados.
- Péptidos y Proteínas.
- Glucósidos, Isoprenoides y Vitaminas.
- Alcoholes y fenoles.
- Colinas (lecitina).
- Bacterias del ácido láctico.
- Minerales.
- Otros.

El poder funcional de los alimentos sobre la salud es de origen milenario, principalmente a lo largo de la historia de la cultura oriental, donde los alimentos y la medicina son considerados igualmente importantes en la prevención y curación de enfermedades. La relación alimento-medicina es conocida por la cultura china hacia el año 1000 AC. El "Yellow Emperor's Internal Classic" es probablemente el primer libro clásico de medicina china (745-221 AC) donde se encuentran diversas prescripciones de dietas médicas (7). Muchos productos, desde la antigüedad, han sido utilizados como alimentos, y como medicina, tales como el jengibre, la menta, el ajo, el azafrán. La filosofía del "alimento como medicina" es la que soporta el paradigma de los alimentos funcionales (13).

Una de las primeras menciones históricas de incorporación de nutrientes en los alimentos data del 400 DC, en el que el médico persa Melanpus sugirió que la adición de limaduras de hierro al vino en campañas bélicas tenía un efecto fortalecedor y de aumento en la resistencia en los soldados que lo consumían. Ya en el año 1831 el médico francés Boussingault impulsó la adición de yodo a la sal para prevenir el bocio.

La cultura occidental durante la historia ha creado una barrera entre la alimentación y el trata-

miento farmacológico que hoy en día está desapareciendo. En 1942, la caseína parcialmente hidrolizada como una fuente proteica fue utilizada en pacientes pediátricos con desórdenes gastrointestinales y alergias. Hacia 1950 fue desarrollada para los astronautas una fórmula completamente hidrolizada para disminuir los desechos durante el vuelo (11).

Durante la primera mitad del siglo XX, las vitaminas fueron objeto de especial atención en el campo de la nutrición, por parte de la comunidad científica; es la época del descubrimiento de 13 vitaminas esenciales (13). El paradigma de la época establecía que los alimentos deberían ser abundantes, sin contaminación ni adulteración, sanos y nutritivos (14).

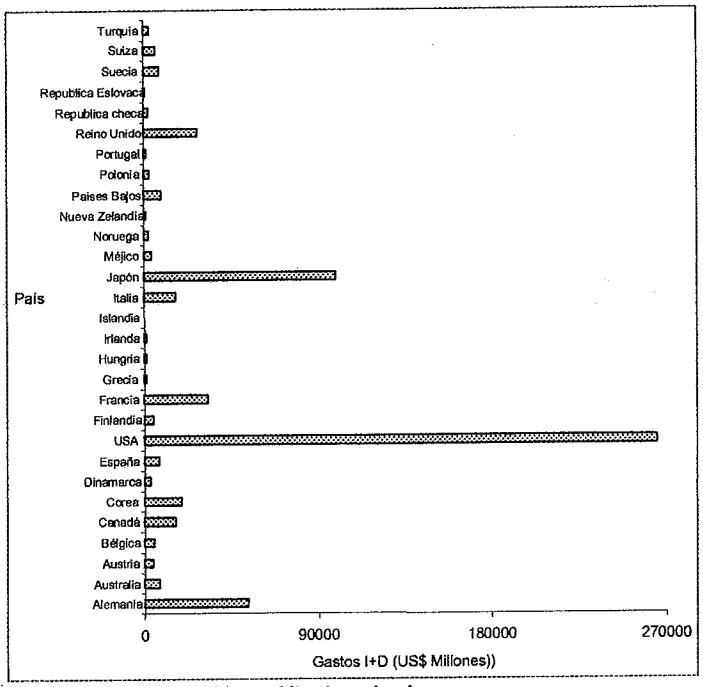
La llegada de las dos Guerras Mundiales provocó hambruna en la población, y esto impulsó a los diferentes gobiernos a establecer verdaderos programas de enriquecimiento de alimentos con toda clase de nutrientes esenciales, con la finalidad de corregir o prevenir las deficiencias alimenticias que sufría un sector muy amplio de la población. Se promovió la mejora del conocimiento de la composición nutricional de los alimentos y el desarrollo de proyectos de restauración de nutrientes en aquellos alimentos que los habían perdido durante los procesos de manipulación y transformación industrial. Así se establecieron como prácticas de fabricación la adición de yodo a la sal, las vitaminas A y D a la margarina, la vitamina D a la leche, y las vitaminas B1, B2, niacina y el hierro a las harinas y al pan (15).

Existe un interés muy especial de muchos países, comunidades académicas y científicas, por explorar en el campo de los alimentos funcionales dado que cada día la cultura hacia una alimentación sana y con mayores beneficios va en aumento. El objetivo del presente documento es el de ilustrar sobre aspectos generales de los alimentos funcionales, analizar la situación actual y las tendencias en un futuro próximo. La revisión fue realizada en la base de datos de la Sciencedirect (ELSEVIER) en el periodo de los últimos 15 años, en libros y tesis de posgrado específicos de alimentos funcionales editados en los últimos 5 años.

Situación actual

El concepto de los alimentos funcionales fue desarrollado en Japón durante la década de 1980, como una necesidad para reducir el alto costo de los seguros de salud que aumentaban por la necesidad de proveer cobertura a una población cada vez de mayor en edad (16). Con el paso del tiempo se han identificado componentes fisiológicamente activos o bioactivos en los alimentos (17, 18, 7), soportados con un aumento en las evidencias científicas en que se apoyan los efectos fisiológicos o los beneficios para la salud; al mismo tiempo aumenta el interés de los consumidores, la industria y los legisladores por este tipo de alimentos.

El éxito actual de la industria alimentaría depende de la capacidad de adaptación e innovación de productos de calidad que satisfagan las expectativas y además respondan a las necesidades sociales de los consumidores. La importancia de la innovación, y especialmente su transferencia y evolución, debe extenderse a la comunicación, búsqueda de información, ayudas de los gobiernos, las sociedades, las alianzas. Además, para conseguir una política de innovación, la empresa puede optar por el desarrollo interno de tecnología o bien por la transferencia de la misma (19). Según el informe de tecnología e innovación en España, COTEC 2003 (www.cotec.es/publica/publicaciones.html), el gasto de Investigación y Desarrollo (I+D) se interpreta como la verdadera inversión que prepara la futura capacidad competitiva de los países y de las empresas (Figura 1). Los países que van a la cabeza en inversiones en I+D, igualmente corresponden a los de avances más significativos en el desarrollo de alimentos funcionales: USA, Japón, Alemania, Francia y el Reino Unido.



Fuente: www.cotec.es/publica/publicaciones.html.
Fecha de consulta: Agosto 2003.

Figura 1. Situación internacional actual de inversiones en I+D.

En el mercado actual se encuentran una serie de productos que ayudan a favorecer un adecuado crecimiento y desarrollo del individuo, interesante para las mujeres durante la gestación, el desarrollo fetal, el crecimiento y desarrollo del lactante y del niño. Hay alimentos enriquecidos en hierro y folatos (cereales de desayuno), yodo (sal yodada), calcio (lácteos y bebidas), vitamina D (lácteos y grasas), nutrientes específicos en la infancia (fórmulas infantiles), etc. Uno de los alimentos que contiene estas propiedades es la leche enriquecida con calcio, vitaminas A y D. El lanzamiento de estos productos en la gama desnatada y semidesnatada se ha impulsado bajo la restauración de las vitaminas liposolubles A y D, que la leche pierde al eliminar la grasa. El objetivo del calcio en estos productos es ayudar a la formación y el mantenimiento de una masa ósea y dientes fuertes y sanos (20). La leche, junto con los derivados lácteos tiene su principal valor nutricional en su alto contenido en calcio y su consumo es tan imprescindible que su exclusión o bajo consumo impediría el aporte dietético de calcio adecuado.

Alimentos que ayudan al metabolismo de sustancias, con bajo contenido energético, bajos en grasas o en azúcares, enriquecidos en ácidos grasos omega-3 o en fibra, bebidas y productos para deportistas, contribuyen a mantener un peso adecuado, controlar el nivel de azúcar en sangre o las tasas de colesterol y triglicéridos plasmáticos, o permiten un adecuado rendimiento en la práctica de actividad física. En estos productos se sustituye el azúcar común por otro tipo de edulcorantes no calóricos (sacarina, ciclamato, espártame, etc.) o bien se reduce o sustituye cierta cantidad de grasas por otros componentes menos calóricos (almidones, etc.). Algunos ejemplos son: mermeladas con edulcorantes no calóricos, patés, margarinas y mayonesas *light*, bebidas con sacarina u otros edulcorantes acalóricos, etc.

Se han desarrollado productos que favorecen la defensa contra el estrés oxidativo; funcionan como una barrera frente al efecto nocivo de los radicales libres sobre el ADN, las proteínas y los lípidos de nuestro cuerpo. Éstos contribuyen a reducir el riesgo de enfermedades cardiovasculares, degenerativas e incluso de cáncer. Entre las sustancias antioxidantes más destacables se encuentran las vitaminas E y C, los carotenoides, el zinc, el selenio, los polifenoles y compuestos de azufre. Se destaca la presencia en el mercado en forma creciente de los jugos de fruta o de bebidas de leche y jugo, que incluyen entre sus ingredientes una o varias sustancias antioxidantes. La actividad antioxidante de la vitamina E quizás la hace una de las más importantes; existe evidencia científica de que la vitamina E puede ayudar a prevenir ciertas formas de cáncer (21) especialmente cáncer de próstata (22). Algunos autores apuntan un carácter preventivo de la angina (23), la preclancia (24), la enfermedad de Alzheimer (25), la artritis reumatoidea (26), cataratas (27) y a tratamientos de infertilidad (28). Es importante tener en cuenta que altas dosis pueden provocar el efecto contrario, es decir, pueden resultar prooxidantes (29, 30, 31).

Algunos aceites vegetales tienen una variedad de componentes fisiológicamente activos que son obtenidos por procesos de refinado y son de uso medicinal, tales como: la vitamina E, los ácidos grasos como el ácido γ-linolénico y el ácido ricinoleico, los fosfátidos como la fosfatidilcolina y la fosfatidilserina, los carotenoides como el β-caroteno, los fitosteroles como el β-sitosterol, el estigmasterol o sus formas saturadas (estanoles), el γ-oryzanol, quinonas como la coenzima Q_{10} (CoQ_{10}) y las vitaminas K_1 y K_2 (32). En Japón algunos aceites comestibles con altos niveles de vitamina E y β-sitosterol han recibido la aprobación según el FOSHU y la tendencia actual hacia los aceites refinados fortificados es similar a la fortificación de la harina de trigo que empezó en USA durante los años 1940. Todos estos componentes tienen un gran potencial en el desarrollo de nuevos productos funcionales.

La oficina de Food and Drug Administration (FDA) recientemente aprobó el uso de esteroles y estanoles en margarinas para ayudar a disminuir el nivel de colesterol y su demanda a nivel mundial se ha incrementado después de su aprobación; desafortunadamente el costo del producto enriquecido es 3 veces mayor que el de una margarina normal (33). De igual manera, el Comité Científico de Alimentación Humana en la Unión Europea aprobó recientemente el enriquecimiento en fitosteroles de margarinas y yogur líquido. Ensayos recientes han confirmado que alimentos de diferentes matrices, enriquecidos en fitosteroles reducen el LDC-colesterol sin alterar el HDL-colesterol o los triglicéridos en general (34). En el mismo sentido, el desarrollo de una mayonesa que ayuda a reducir el colesterol, utilizando γ-Oryzanol puede contribuir igualmente a incrementar la demanda de este componente en el futuro (35).

El consumo habitual de ácidos grasos omega-3 (ácido eicosapentanoico (EPA) y ácido docosahexanoico (DHA)), contribuye a reducir las tasas de colesterol y triglicéridos sanguíneos y a reducir el riesgo de formación de trombos o coágulos y de enfermedades cardiovasculares (36). La leche desnatada enriquecida con omega-3 y huevos con DHA son un ejemplo particular de estos productos.

Otros alimentos funcionales son los probióticos que son aquellos que contienen microorganismos vivos que al ser ingeridos en cantidades suficientes, ejercen un efecto positivo en la salud más allá de los efectos nutricionales básicos (37, 38, 39). En esta denominación se incluyen, además de los microorganismos del yogur (*Lactobacillus bulgaricus y acidophillus*), los de otras leches fermentadas de nueva generación (*Bifidobacterium y Lactobacillus casei inmunitas*, etc.). Las bacterias ácido-lácticas ejercen similares acciones saludables en el organismo: equilibran la flora intestinal y potencian el sistema de defensas o inmunológico (40).

Los prebióticos son sustancias de los alimentos que resisten la digestión en el intestino delgado y son susceptibles de ser fermentadas por la flora bacteriana del intestino grueso, ejerciendo un efecto favorable sobre la misma e indirectamente sobre nuestro cuerpo. Entre los prebióticos hay diferentes tipos de fibra: soluble, lignina y oligosacáridos no digeribles, por ejemplo los fructooligosacáridos, que se añaden a productos como leche, yogures, flanes y margarinas. Estos compuestos son sustrato de las bacterias que colonizan el intestino grueso, originando ácido láctico y ácidos grasos de cadena corta, que estimulan el crecimiento de las bifidobacterias y equilibran la flora intestinal (37,38).

Otros productos que favorecen las funciones psicológicas y de conducta, que están relacionadas con el apetito y la sensación de saciedad, el rendimiento cognitivo, el humor o tono vital y el manejo del estrés son los alimentos enriquecidos en fibra, con sustancias excitantes (cafeína, ginseng, etc.) o tranquilizantes extraídas de plantas, etc. (7,3, 41).

El mercado actual de los alimentos funcionales es estimado en el orden de 33 billones de dólares. USA es el mercado más importante y dinámico con un consumo estimado mayor del 50% de la cantidad global (42,43), donde los alimentos funcionales representan aproximadamente un total del 2% del mercado total de los alimentos (44).

Otro mercado importante es el japonés. El informe de la Japan Health Food & Nutrition Food Association, del 26 de enero de 1998, estableció que desde la entrada en vigor de la regulación hasta el año 1998 solamente 126 productos recibieron la aprobación FOSHU y estos productos representaron en ventas aproximadamente 1 billón de dólares. En febrero del 2000, el número de productos con la aprobación FOSHU fue 174 y sus

ventas en el mercado representaron alrededor de 2 billones de dólares, sin embargo aproximadamente mil productos adicionales han sido introducidos en el mercado japonés como alimentos saludables sin la aprobación de FOSHU (45).

Marco legislativo

Con el espectacular aumento en la comercialización y el uso de suplementos dietéticos y alimentos enriquecidos y fortificados que el mercado ha experimentado, se hace cada vez más necesario un marco legislativo que proteja a los consumidores de las atribuciones de propiedades falsas o confusas y que además pudiera responder a las necesidades de la industria en cuanto a innovación en el desarrollo de productos, su comercialización y su promoción.

Japón a partir de 1991, es el único país que tiene un proceso regulador específico para la aprobación de alimentos funcionales, conocidos como el sistema FOSHU, que está amparado por la nueva ley de regulación de mejora nutricional según ordenanza ministerial No. 41, de julio de 1991, enmendada por la ordenanza ministerial No. 33, de mayo 25 de 1996) (46). Los alimentos con la aprobación FOSHU están soportados por informes de seguridad, evidencias científicas sobre el efecto en los humanos y la composición o un análisis nutricional correspondiente. De acuerdo a los japoneses, un alimento funcional debe cumplir 3 condiciones (2):

1. Estar constituido por ingredientes naturales.
2. Se debe consumir como parte de una dieta diaria.
3. Ser un alimento que al consumirse presente una particular función en el cuerpo humano, como:
   - Mejoramiento en los mecanismos de defensa biológica.
   - Prevención o recuperación de algunas enfermedades específicas.
   - Control de las condiciones físicas y mentales.
   - Retardo del proceso de envejecimiento.

En la Unión Europea (UE), en la actualidad no existe una legislación armonizada sobre las discusiones de salud, y por lo tanto las cuestiones relativas a dichas discusiones se resuelven a nivel nacional (3). El reto en los estados miembros de la UE es conseguir, bajo el marco regulador existente, que los mensajes que se comunican no hagan ninguna referencia a que dichos alimentos puedan reducir el riesgo de padecer enfermedades, incluso aunque existan pruebas científicas que avalen dichas afirmaciones. La legislación europea relativa al etiquetado prohíbe atribuir a los alimentos propiedades preventivas, terapéuticas o curativas, y la referencia a dichas propiedades. En ausencia de una directiva relativa a alegaciones de salud, los estados miembros de la UE han aplicado diferentes interpretaciones de la actual legislación sobre etiquetado. A su vez, la opinión generalizada es que las alegaciones de salud deben estar adecuadamente corroboradas para proteger al consumidor, fomentar el comercio justo y potenciar las investigaciones y la innovación en la industria alimentaria.

En Estados Unidos se permite desde 1993 que se aleguen propiedades "que reducen el riesgo de padecer enfermedades" en ciertos alimentos. Solo se autoriza una declaración de beneficio para la salud en el etiquetado de productos regulados por la administración para alimentos y medicamentos (FDA), siempre que existan evidencias científicas públicamente disponibles que demuestren la validez de la relación descrita en esa declaración (47). Según la FDA, las discusiones pueden basarse también en "declaraciones autorizadas" de Organismos Científicos Federales, como los Institutos Nacionales de la Salud (National Institutes of Health) y los Centros para la Prevención y el Control de Enfermedades (Centres for Disease Control and Prevention), así como de la Academia Nacional de las Ciencias (48).

DESARROLLO DE ALIMENTOS FUNCIONALES

Criterio para la selección del alimento portador.

Uno de los factores más importantes para el éxito de cualquier programa de incorporación de nutrientes a los alimentos lo constituye la elección del alimento portador. En primer lugar es necesario conocer los gustos y las necesidades nutricionales de la población a la que van destinados estos productos. Se espera con su consumo mejorar el estado alimenticio y de salud de la población en su conjunto, por lo que las características organolépticas

del alimento fortificado deberán ser del agrado y aceptación del consumidor. Esto hace que no cualquier alimento pueda ser fortificado, aunque técnicamente sea posible. Además no todos los nutrientes pueden ser adicionados, puesto que su estabilidad dentro de la matriz del alimento, así como sus efectos sobre la naturaleza y calidad del mismo, tienen la última palabra en la viabilidad del proceso y en la aceptación por el consumidor. Así pues, la selección del alimento deberá garantizar las siguientes consideraciones:

- Control de calidad.
- Estabilidad y biodisponibilidad de los nutrientes bajo condiciones de uso y almacenamiento.
- Las características organolépticas no deben sufrir cambios significativos.
- Ser económicamente viable a través de un proceso industrial.
- No toxicidad debido a un exceso de la dosis empleada o por interacciones con otros componentes originales del alimento.
- El alimento seleccionado debe ser consumido regularmente y en cantidades predecibles por la población.

Metodologías de fabricación

- **Ingeniería genética**

El desarrollo biotecnológico ha permitido obtener productos con cambios perdurables en el tiempo y de características especiales a partir de modificaciones genéticas. Arroz con b-caroteno y un mayor contenido en hierro (49, 50), soja rica en ácido oleico y pobre en ácidos grasos saturados (51) y cambios en el valor nutricional de la patata (52) son ejemplos de estos productos.

- **Técnicas en cultivo y cría**

Modificaciones en las técnicas de cultivos vegetales y cría de animales pueden generar mejoras en los productos finales. Huevos enriquecidos con ácidos grasos omega-3 (53, 54, 55), leche y carne de vaca enriquecidas con ácido linoleico (56), son algunos ejemplos.

- **Incorporación a granel**

Es ésta la tecnología más utilizada en los programas de fortificación y enriquecimiento. En general, implica la obtención de una mezcla homogénea que contiene los nutrientes a adicionar en las cantidades deseadas. Las cantidades agregadas dependerán en gran medida de la fase del procesamiento seleccionada para la adición, pues siempre se deberán tomar en consideración todos aquellos factores de industrialización capaces de causar pérdidas de los nutrientes incorporados, tales como tratamientos térmicos, operaciones mecánicas, procesos de enfriamiento que reduzcan la disolución de la premezcla en el producto, etc. Los alimentos formulados más comercializados siguiendo el método de mezclado son el azúcar, las harinas, productos lácteos, los aceites vegetales, la margarina, las bebidas y los alimentos líquidos.

- **Ingeniería de matrices. Impregnación a vacío (IV).**

El proceso de impregnación a vacío ha sido descrito (57,58) a través de la acción del mecanismo hidrodinámico (HDM), como un proceso de transporte de materia en un sistema sólido poroso-líquido. La técnica de impregnación a vacío (IV) ha sido aplicada para introducir líquidos con componentes fisiológicamente activos en la estructura porosa de diferentes frutas, cambiando la composición del producto y sus propiedades físicoquímicas (59,60). Esta técnica se presenta como una alternativa de la aplicación en la industria alimentaria para la producción de nuevos alimentos funcionales por las siguientes ventajas (61):

- Cinéticas de transferencia de masa rápidas.
- Mayor ganancia de solutos en tiempos cortos.
- Mejor conservación del color y mejora del mismo en algunos productos.
- Conservación del sabor y aroma del producto fresco, al permitir trabajar a bajas temperaturas sin incrementos importantes de tiempo de proceso.

La impregnación a vacío está afectada por diversos factores (61, 62):

- Composición del tejido.
- Estructura del tejido (tamaño y distribución de poros).
- Tiempo de relajación de la matriz sólida, que depende de las propiedades mecánicas del alimento.
- Velocidad de flujo del gas y del líquido durante la acción del HDM, que a su vez depende de la estructura del tejido y de la viscosidad de la disolución.
- Tamaño y forma de la muestra.

Mecanismos de acción

Las acciones básicas implicadas en las distintas técnicas de obtención de alimentos funcionales se simplifican en:

- Extracción: se extrae o neutraliza la acción de algún componente no deseado, presente en el alimento, por ejemplo agentes tóxicos o mutagénicos.
- Reemplazo: se procede a una sustitución parcial o total de un componente negativo por uno positivo, sin modificar de manera notable las propiedades del alimento (ejemplo: sustituir materia grasa de origen animal por hidratos de carbono de cadena larga).
- Aumento: se aumenta el contenido de un componente beneficioso para la salud, preexistente en el alimento (ejemplo: la adición de fibra).
- Adición: se añade un ingrediente que el alimento previamente no contenía y que supone una ventaja para el consumidor (ejemplo: adición de vitaminas, minerales u otros micronutrientes).

Fases de desarrollo

Las fases más importantes en el proceso de desarrollo y obtención de alimentos funcionales son (63):

1) Selección y definición clara de los componentes fisiológicamente activos.
2) Desarrollo de las técnicas adecuadas para identificar y valorar la actividad de dichos ingredientes en la materia prima y en el producto terminado.
3) Estudio experimental de las propiedades físicas, químicas y biológicas del alimento.
4) Estudio de los procesos de absorción y de metabolización del ingrediente con actividad fisiológica por el organismo.
5) Estudio, mediante procedimientos acelerados, de la estabilidad del constituyente activo en la fórmula final, en distintas condiciones.
6) Valoración extensa de los hipotéticos efectos beneficiosos en un modelo animal, preparándose para los ensayos clínicos.
7) Realización de estudios de toxicidad aguda y crónica, en modelos animales adecuados.
8) Establecimiento de las dosis mínimas y máximas en adultos y en niños sanos, así como en enfermos y en personas mayores (si en ellos tuviera indicación el principio activo).
9) Experimentación clínica siguiendo el protocolo científico adecuado, en adultos sanos.

FUTURO DE LOS ALIMENTOS FUNCIONALES

Las principales tendencias para el desarrollo futuro de los alimentos funcionales están relacionadas con los siguientes hechos:

- Los cambios en las expectativas y las actitudes de los consumidores.
- El crecimiento del conocimiento sobre la relación dieta-procesos fisiológicos.
- Los avances en la ciencia y tecnología de los alimentos
- Los cambios en las políticas reglamentarias.

Los principales desafíos tecnológicos a los que se enfrenta el desarrollo de nuevos alimentos funcionales son: la mejora de la estabilidad de los componentes con actividad fisiológica, la problemática de cuantificación y análisis, las dosis máximas, la realización de más estudios clínicos que avalen de manera rigurosa los efectos beneficiosos que se atribuyen a los distintos componentes, así como también cumplir con las nuevas expectativas de los consumidores y los aspectos de mercado y legislativos que se vayan generando.

Las frutas son alimentos cuya mayor parte de la producción mundial está destinada al consumo en fresco, y diseñar nuevos productos funcionales a partir de éstas, con mayor tiempo de vida útil, abre nuevas puertas al crecimiento de la agroindustria y a la satisfacción de las exigencias del consumidor actual. El enriquecimiento de frutas con componentes fisiológicamente activos puede ser un efectivo camino para combatir deficiencias y, en este sentido, las frutas son clave como vehículo portador por su elevado consumo mundial. Si éstas se enriquecen a niveles del consumo diario recomendado (CDR) pueden contribuir a un mejor estado nutricional de la población.

Las mejores perspectivas del futuro las tiene la expresión de genes que codifican proteínas de alto valor añadido en la glándula mamaria de algunos mamíferos. Como consecuencia se produce una leche enriquecida en determinados productos, como el activador del plasminógeno o el

factor antihemofílico (12). Claramente la ingeniería genética es una nueva tecnología en expansión que va a cambiar la oferta alimentaria en los próximos años.

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Motivations and cognitive structures of consumers in their purchasing of functional foods

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Abstract

The present study initially fulfils a two-fold aim: first, to identify the functional foods most frequently purchased by a homogeneous group of well-educated consumers; and second, to define the most important functional food attributes that affect consumers' purchasing decisions when examined in two separate age groups (young adults and early-middle-aged). By employing the MEC analysis methodology, the study further fulfils two additional aims: third, to obtain insights into the functional food-related buying motives of consumers; and fourth, to design a MEC hierarchy of consumption-relevant cognitive structures per age group in order to explain their functional food-related purchasing behaviour. The results of the study highlight health enhancement and health risk prevention through appropriate dietary choices as the most important motives of functional food purchasing for the two age groups, respectively. A special interest in eating enjoyment that results from functional food consumption and in trust that must surround those foods also emerge from both age groups. Moreover, some differences among the two age groups are prominent, such as that the early-middle-aged consumers show a great interest in knowing the origin of the functional product; while the young adults emphasize on functional foods' convenience and (low) price. These results lead to the conclusion that functional foods should deliver their health benefits above and beyond the standard (high) perceived quality required by consumers from any common food product.

Keywords: Functional foods; Means-end chains; Purchasing motives; Cognitive structures; Greece

1. Introduction

In order for some foods to be connected with healthy nutrition, they should usually be related with food elements such as fat, salt, dietary fibres or vitamins (Urala, 2005). Apart from this rather conventional perception of what constitutes a nutritious food, there are many food products that have special beneficial effects on the human organism, usually referred to as "nutraceuticals", "pharma foods", "nutritional foods", "medical foods", "designer foods", "super foods" and also as "functional foods" (Childs & Poryzees, 1997). The basic idea behind functional foods is summarized in the following Hippocrates' saying: "*Let your food be your medicine, and your medicine be your food*" (Jonas & Beckmann, 1998, p. 11).

Nowadays, an internationally acknowledged definition of functional foods is still lacking. According to Margaret (2002): "*... a food can be regarded as functional if it is satisfactorily demonstrated to beneficially affect one or more target functions in the body beyond adequate nutritional effects in a way that is relevant to either an improved state of health and well-being and/or to a reduction of risk of disease...*" (Margaret, 2002, p. 5). Furthermore, functional foods must maintain their nutritional nature and they should easily become part of daily nutrition: "*Functional foods must remain foods, and they must demonstrate their effects in amounts that can normally be expected to be*

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consumed in the diet. They are not pills or capsules, but part of a normal food pattern" (Margaret, 2002, p. 5).

By implementing a Means-end Chains (MEC) analysis methodology, the present study attempts to identify which functional foods' attributes affect consumer's choice, to understand the motives behind the purchasing of a functional food and to explore consumers' cognitive structures by linking consumers' knowledge about functional food product attributes to knowledge about themselves. The paper begins with a literature review of consumer behaviour towards functional foods. The methodology part that follows refers to the objectives of the research and describes its two stages (exploratory and main stage). The analysis and results are presented in the third part of the paper, while the discussion section examines the degree to which the objectives of the study have been fulfilled. Finally, the conclusions section summarizes the most important points of the research and presents some useful managerial insights for the functional food industry.

2. Consumer behaviour towards functional foods

The lack of an official definition is one of the main constraints for the analysis and monitoring of functional food markets (Menrad, 2003), as well as for their growth (Castellini, Canavari, & Pirazzoli, 2002). However, consumers rarely prefer or dislike a food on the basis of business or scientific terms describing its healthiness or nutritional value (Lähteenmäki, 2004). On the contrary, functional foods are often regarded as a food type that responds to any health-relevant consumer requirements. According to Schmidt (2000), consumers who receive the "message" of functional foods and feel in control of their health condition know that certain food ingredients can help to reduce the risk of a disease or improve their health status. As a result, this particular food category seems to have many growth prospects in the short run (Lähteenmäki, 2004).

Irrespective of their growth potential, functional foods constitute a type of product with high diversity. Seen from the consumer's point of view, functional foods are not a homogenous category; consumers' attitudes thus affect the purchasing intention for different functional products differently (Urala & Lähteenmäki, 2004, 2007). The most important criteria of functional foods' acceptance include perceived functional product characteristics such as their naturalness and overall quality image as opposed to the hedonic perception that results from their consumption (Urala, 2005). Moreover, consumer characteristics, such as demographic backgrounds; personal motivations to engage in health preservation behaviours; and type of and trust in health-related information, also play an important role.

Referring to this latter category of functional food acceptance criteria, consumers' socio-demographic characteristics, such as gender, education and age, are among the most important. The literature shows that female consumers are a more promising target group for functional foods than men (Urala, 2005), partly because they show more interest in healthy food consumption and health in general (Bogue & Ryan, 2000; Childs & Poryzees, 1997). Moreover, functional food users are often more educated (Anttolainen et al., 2001;de Jong et al., 2004). Concerning age, Poulsen (1999) mentions that relatively older participants in his research (i.e. older than 55 years) showed a greater intention to buy functional foods. On the contrary, earlier results by Childs and Poryzees (1997) implied that the elderly show less intention to buy a food that prevents a disease compared to younger consumers. Bhaskaran and Hardley (2002) further suggest that individuals of older age show different attitudes with regard to health claims and the type of "functionality" compared to younger consumers. Urala (2005) also supports that elderly consumers put more emphasis on the results of food consumption relevant to the prevention of a disease compared to younger consumers. This fact is also supported by the study of Bogue and Ryan (2000), according to which elderly consumers pay greater attention to health claims relevant to a decreased probability of cancer development, while younger consumers pay more attention to claims about increased energy levels. The above often contradictory findings suggest that there should not be a generalization in the demographic profile of functional food consumers: gender, age, as well as education are important factors that affect the consumption of functional foods, but the differences between different kinds of these foods are prominent (de Jong, Ocké, Branderhorst, & Friele, 2003). According to Urala (2005); Dagevos (2005), consumer demographic characteristics are only partially correlated with the acceptance of functional foods. Moreover, Verbeke (2005) mentions that consumer attitudes towards functional foods do not depend on their socio-demographic characteristics.

Another important motive for the consumption of functional foods is the preservation of good health status (Urala, 2005) and how much consumers perceive functional foods to contribute to this aim. European consumers consider food healthiness to be an important factor affecting their overall nutrition choices (Lappalainen, Kearney, & Gibney, 1998). The research by van Kleef, van Trijp, and Luning (2005) shows that the relation between the health condition of a consumer and the type of a product's health claim affects the intention to buy the product. Furthermore, Verbeke (2005) reports that the existence of a family member with a specific health problem affects positively the acceptance of functional foods. However, de Jong et al., 2003 show that less than 40% of the Dutch participants in their study consider the consumption of particular functional foods as an easy way to preserve their health. In a follow-up piece of research, de Jong et al., 2004 found that 19% of the participants with high levels of cholesterol used relevant drugs, another 11% of the participants used a relevant functional food, while only 5% combined both approaches. The above findings show that consumer health issues do not necessarily support the consumption of functional foods.

The type of and trust in the information about the effect of a particular product on health constitute additional factors of functional foods' success (Urala, 2005). According to Tuorila and Cardello (2002), information about the health benefits of a food can increase the likelihood of its consumption. Results can differ between different effects on health, however, with claims related to improved physical and mental alertness being more likely to motivate consumption of functional foods like a fruit juice (Tuorila & Cardello, 2002). Furthermore, confidence in functional foods and the resulting acceptance by consumers is largely the result of consumers' knowledge on the particular issue. Wansink, Westgren, and Cheney (2005) demonstrate that a person's knowledge of the characteristics of a functional food is not enough to stimulate consumption. The purchasing likelihood of that food is proven to increase only when the consumer combines the functional characteristics with the consequences of their consumption. In this way, it is proven that consequence-related knowledge about the functional food (e.g. the product contributes to the preservation of bone health) increases the likelihood of consumption at a larger extent than the attribute-related knowledge (e.g. existence of extra calcium). Apart from trust in the health claims and the means by which relevant information is communicated, Urala (2005) supports the view that trust in functional foods is affected by the type of base product (carrier) whose attributes have been improved. Bech-Larsen and Grunert (2003) agree that the type of the base product contributes to how much the consumers perceive the functional foods to be healthy. Moreover, van Kleef et al., 2005 add that the potential buyers tend to trust the health claims more when the basic carrier has a positive overall image, as well as a "history" in health claims (e.g. yogurt, juices, etc.).

The criteria that are related to consumer perceptions about functional foods' characteristics are also important. A general concern that functional foods could be less natural compared to conventional foods emerges often in the literature (e.g. Cox, Koster, & Russell, 2004; Frewer, Scholderer, & Lambert, 2003). This concern is not always unjustified: the development of functional foods usually demands modern technology, since it is necessary to add, remove or modify ingredients (Urala, 2005). Although the alterations in the naturalness of functional foods can vary according to the base product, its functional attributes and their combination (Poulsen, 1999), consumers' reaction to the use of modern technology in the production of functional foods has been stressed in the literature. For instance, Jonas and Beckmann (1998) showed that the Danish participants in their research are negative towards the fortification and modification of foods, perceiving such food products to be non-natural and impure. However, the same authors supported the view that the perceived naturalness of a functional food can vary across cultures. For example, de Jong et al., 2003 conclude that the Dutch participants in their research can clearly distinguish between functional foods and drugs and prefer a functional food to a drug with the same benefit.

Furthermore, organoleptic attributes – especially taste – are some of the most important factors that affect consumers' choice of functional foods (Jonas & Beckmann, 1998; Urala, 2005; Verbeke, 2006). Adding, removing or modifying food ingredients could have negative consequences in taste and other organoleptic attributes of functional foods; thus taste could be inversely related to functional food consumption choice (Tuorila & Cardello, 2002). Even if the increase in the "functionality" of a food does not affect its organoleptic attributes, the enhancement of foods with bioactive or natural ingredients can still result in saltiness, bitterness, or sourness (Verbeke, 2006). Consumers have early expressed particular discomfort about the mediocre taste of functional foods (e.g. Jonas & Beckmann, 1998). Later surveys (e.g. Tuorila & Cardello, 2002) also mention that the off-flavour severity of a functional product decreases the consumption probability of the product, in spite of any persuasive claims about the advantages of its consumption. It is therefore obvious that functional foods must not be perceived as inferior in taste when compared with their conventional counterparts.

3. Methodology

3.1. Research aims

The present study employs the MEC analysis methodology on a homogeneous group of consumers in terms of their socio-demographic profile (e.g. high educational level, younger age) with the following aims:

(a) To identify the most frequently purchased functional food products;
(b) To define the most important attributes of functional foods;
(c) To gain insights into consumers' functional food-related buying motives; and
(d) To model consumers' functional food selection-relevant cognitive structures, i.e. the way that functional food consumption-relevant knowledge is stored and organized in consumers' memories.

Presenting a clear image of the functional food market in Greece is beyond the scope of this study; the identification, however, of some frequently purchased functional food types and their most important attributes through aims (a) and (b) will offer a valuable insight into functional food preferences. Regarding aims (c) and (d), the main criteria for evaluating the usefulness of their outcomes will be to what extent users of the results feel that they have achieved a better understanding of consumers that gives them inspiration and helps them make better business decisions. In parallel with the above-described aims, the study will further attempt to offer an indication about the degree of functional market fragmentation. Therefore, the sample

will be divided in two separate groups with very "thin" differences in their profiles (i.e. well-educated young adults and the well-educated early-middle-aged) in order for the functional attributes' importance, purchasing motives and overall cognitive structures to be identified for each group.

To achieve its objectives, the present study uses a homogeneous sample of consumers who are at least university graduates, aged between 25 and 44 years, and responsible for food buying in their household. This sample is divided in two analogous age groups: the 25–34 age group (young adults) and the 35–44 age group (early-middle-aged). The need for sample homogeneity is imposed by the nature of the MEC analysis methodology. For instance, Grunert and Grunert (1995) suggest that only when ladders are obtained from a group of *homogeneous* respondents, they together will yield an estimate of this group's cognitive structure with predictive validity. Moreover, Vannoppen, Verbeke, Van Huylenbroeck, and Viaene, 2001 add that criteria for sample inclusion in a laddering study should include to what extent respondents are able and prepared to "speak out" and whether they know the product under examination and its market channels well.

To achieve aims (a) and (b), an exploratory research phase is undertaken first. The results of this study supplement the main MEC phase of the research to achieve aims (c) and (d).

3.2. Exploratory phase

In order to achieve objectives (a) and (b), an exploratory phase with a homogeneous sample of $n = 60$ consumers (30 for the n_1 = young adults, 25–34 years old group and n_2 = the early-middle-aged, 35–44 years old group) is executed first. The requirements for participation in the sample were a person's high educational level (university graduate or higher) and suitable age (columns 1 and 2, Table 1). S/he also had to have purchased a functional product during the month prior to the implementation of the pilot study (January 2006). Furthermore, the informant should actively participate in the food buying decision of the household. The recruitment was organised by a private agency. Based on the criteria described above, potential respondents have been selected among the agency's data base in the areas of central, south-east and south-west Athens. Trained personnel visited respondents who agreed to participate at their place at day and time arranged through prior telephone communication at the participants' convenience. During these visits, the participants filled in a short questionnaire during a personal interview that lasted no more than 10 min.

The questionnaire first included a list of 18 of the most important functional food brand names in the Greek market from the following food categories: dairy products, spreads, fruit juices, snack and bakery products and eggs. The participants were asked to indicate the brands usually consumed in their household. The second section of the questionnaire included a master list of 58 functional food attributes, covering seven concrete and abstract categories of a hypothetical functional product's marketing mix: (perceived) quality attributes; appearance and package attributes; functionality-related attributes; hedonic attributes; and label, price and brand name attributes. This master list has been developed based on the literature described in previous sections, but also on past MEC applications on various types of foods (e.g. wine, vegetable oils, and organic food) (Table 2). The participants were asked to evaluate each attribute on a five-point Likert-type importance scale with end-points 1: "not important at all" to 5: "very important". The attributes scoring 4 and 5 on the 1–5 scale by at least two-thirds of the participants were selected to create a shortlist of attributes per age group that were shown for subsequent evaluation to the participants of the MEC study (see following section).

Table 1
Socio-demographic profile of the samples (pilot $n = 60$ and main sample $N = 40$), %

	Pilot study 25–34 years ($n_1 = 30$)	Pilot study 35–44 years ($n_2 = 30$)	Main study 25–34 years ($N_1 = 20$)	Main study 35–44 years ($N_2 = 20$)
Gender				
Male	50	36.7	50	30
Female	50	63.3	50	70
Educational level				
University student	30	0	15	0
University – Polytechnic graduate	53.3	80	55	75
Postgraduate/ Ph.D.	17.7	20	30	25
Marital status				
Single	80	83.3	75	20
Married	20	16.7	25	80
Age (mean)	29.7	40.9	30.3	41.0

3.3. Application of the MEC analysis phase

The implementation of the MEC analysis in examining consumer perceptions about functional foods is not unseen in the relevant literature (e.g. Jonas & Beckmann, 1998; Morris, McCarthy, & Reilly, 2004; Urala & Lähteenmäki, 2003). For implementing the MEC phase in the present case, a homogeneous sample of $N = 40$ consumers is used (young adults $N_1 = 20$, 25–34 years old group and early-middle-aged $N_2 = 20$, 35–44 years old group). The requirements for participation to the MEC sample are similar to the exploratory study (university degree or higher, suitable age, purchasing of a functional product during the month prior to the implementation of the MEC study (March 2006), and active participation to household food buying decisions). The recruitment was organised by a private agency. Potential respondents have been approached by trained personnel during their purchases in three outlets

Table 2
Source of food attributes selected for inclusion in the pilot attribute master list

Authors	Attributes chosen for the pilot questionnaire
Padel and Foster (2005)	*Label information*: Country of origin *Functional attributes*: Removed dangerous ingredients
Sorenson and Bogue (2005)	*Brand name attributes*: Familiarity with the brand *Functional attributes*: Better digestion, enforces body defence
Morris et al. (2004)	*(Perceived) Quality attributes*: Pure product *Label information*: Health claims and functionality *Functional attributes*: Strong bones, vitamin C
Urala and Lähteenmäki (2003)	*(Perceived) Quality attributes*: Safe food, healthy food, natural product *Appearance – package*: Package size, practical size *Organoleptic attributes*: Nice taste *Functional attributes*: Added functional ingredients (e.g. vitamins fibre, calcium *Price*: Price
Krystallis and Ness (2003), Fotopoulos et al., 2003)	*Label information*: Quality assurance (e.g. ISO/HACCP), best before date, packaging date *Price*: Value for money
Jonas and Beckmann (1998)	*Functional attributes*: Antioxidant ingredients, calcium, high fibre food, keep cholesterol level low
Bech-Larsen, Nielsen, Grunert and Sorensen (1996)	*(Perceived) Quality attributes*: Economical in use *Appearance – package*: Environmentally sound package, nice package *Organoleptic attributes*: Specific (strong, neutral, poor) colour and odour, nice taste

of a major food retail chain in central, south-east and south-west Athens, respectively. Subjects who had purchased any type of functional food were questioned about their willingness to participate in the MEC phase. Among them, final participants have been selected based on the criteria discussed previously. The laddering interview took place at participants' place, at day and time arranged by them through telephone communication with the agency, in order to make the participants feel comfortable and to induce a positive mood conducive to open communication during the interview. The socio-demographic profile of the MEC sample can be seen in columns 3 and 4 of Table 1.

The laddering interview process began with a small introduction: the interviewee was informed about the purpose of the interview, whilst to ensure common understanding of the term "functional" a reference was made to the functional food definition by Margaret (2002) described in the beginning of the present paper. Next, the consequences and values elicitation phase began. In the first step, the interviewee was asked to consider the event of buying a functional food. In this respect, the corresponding to a participant's age functional food type as identified in the exploratory phase was mentioned by the interviewer as an exemplary functional product to facilitate the participant's cognition retrieval process. Then, the interviewee was handed the shortlist with the most important functional food attributes that correspond to his/her age group, as determined by the exploratory phase. After that, s/he was asked to evaluate each attribute in terms of its importance when buying a functional food on the same importance scale as in the exploratory phase. In a final step, the attributes deemed most important by the interviewee were used as laddering starting points.

Based on these attributes and after the question "*why is this important to you*" being repeatedly asked by the interviewer, each interviewee was called to subconsciously connect product attributes with consequences and/or his/hers personal values. The time necessary for the completion of the task varied between 40 and 60 min, according to the ability of the interviewee to express him/herself and his/hers conscious involvement in the functional food purchasing process.

4. Analysis and results

4.1. Analysis and results of the exploratory phase

As mentioned before, identification of the most frequently purchased functional food products was based on a list of 18 of the most well-known brand names in the Greek market. The first group of young adults showed a clear preference for a functional orange juice brand (with enhanced vitamin content). The early-middle-aged consumers, however, clearly preferred three functional margarine brands (all with reduced cholesterol risk).

The most important functional food attributes according to the results of the exploratory phase are presented in columns 1 and 2 of Table 3. Overall, the particularly important attributes appointed (scoring 4 or 5 by at least two-thirds of the pilot sample) belong to the categories label information, brand name, (perceived) quality and, mainly, functionality. It should be mentioned that there was a general agreement trend between the two age groups in terms of the importance assigned to most of the attributes examined (26 for the young adults and 33 for the early-middle-aged group), with some notable exceptions found in the functionality-related attribute category. However, given the importance of the functionality attributes for the present survey, the complete category was included in both age groups irrespective of the importance assigned to each functionality attribute during the exploratory phase. The total number of attributes to be evaluated was thus increased to 37 for the young adults (26 important from the exploratory phase plus 11 functionality attributes) and 40 for the early-middle-aged (33 important from the exploratory phase plus 7 functionality attributes).

4.2. Means-end chain analysis and results

As explained above, a list of 37 attributes was presented to the young adult group, whereas the same list with 3

Table 3
Master list of important attributes for the pilot study (columns 1 and 2) and resulting short list of important attributes for the main study (columns 3 and 4)

Attributes[a]	Pilot study 25–34 years ($n_1 = 30$)	Pilot study 35–44 years ($n_2 = 30$) (%)	Main study 25–34 years ($N_1 = 20$) (%)	Main study 35–44 years ($N_2 = 20$) (%)
Perceived quality attributes				
1. Pure product	90[b]	96.7	20[c]	45
2. Safe food	93.3	100	20	15
3. Trust in brand name	80	83.3	60	45
4. Economical in use	56.7	56.7	–	–
5. Quality product	96.7	96.7	15	40
6. Part of daily nutrition	76.7	76.7	15	20
7. Healthy product	96.7	100	60	50
8. High technology product	23.3	50	–	–
9. Natural product	80	96.7	40	15
Appearance – package				
10. Package size	20	23.3	–	–
11. Environmental friendly package	50	60	–	–
12. Nice package	43.3	33.3	–	–
13. Practical package	86.7	70	35	10
14. Different package than the conventional product	16.7	20	–	–
15. Aluminum can package	3.3	23.3	–	–
16. Package made of glass	16.7	33.3	–	–
17. Plastic package	3.3	20	–	–
18. Paper package	13.3	26.7	–	–
Organoleptic attributes				
19. Strong aroma	3.3	13.3	–	–
20. Neutral aroma	10	20	–	–
21. Light aroma	36.7	23.3	–	–
22. Nice taste	90	90	70	40
23. Neutral taste	13.3	10	–	–
24. Specific texture	26.7	40	–	–
25. Specific colour	13.3	20	–	–
Label attributes				
26. Information about health/functionality claims	80	86.7	20	15
27. Nutritional value	86.7	86.7	15	20
28. Quality assurance (e.g. ISO/HACCP)	83.3	90	15	20
29. Best before date	100	100	75	70
30. Packaging date	100	80	25	15
31. Country of origin	56.7	86.7	–	60
Functionality attributes				
32. Antioxidant ingredients	43.3	63.3	5	15
33. Removed dangerous ingredients	86.7	86.7	5	15
34. Fortified ingredients	56.7	63.3	0	0
35. Added calcium	70	80	5	15
36. Added vitamins and minerals	86.7	63.3	45	15
37. Added fibre	53.3	80	10	15
38. Added phosphor	56.7	60	0	0
39. Added functional ingredients	40	43.3	0	0
40. Low cholesterol level	43.3	86.7	15	55
41. Low saturated fatty acids content	40	70	0	30
42. Necessary for personal well being	73.3	83.3	5	15
43. Enforces body defense	90	96.7	40	55
44. Reduces cardiovascular disease risk	63.3	83.3	5	60
45. Provides more energy	80	70	55	15
46. Provides proved health claims	90	90	15	20
47. Contains probiotics	33.3	60	5	15
48. Contributes to digestion improvement	60	86.7	0	40
49. Contributes to vision improvement	40	53.3	0	5
50. Contributes to good physical condition	93.3	96.7	20	60
51. Contributes to osteoporosis prevention	76.7	86.7	10	40
Price				
52. Value for money	100	93.3	50	15
53. Same price with conventional products	60	73.3	–	5

Table 3 (*continued*)

Attributes[a]	Pilot study 25–34 years ($n_1 = 30$)	Pilot study 35–44 years ($n_2 = 30$) (%)	Main study 25–34 years ($N_1 = 20$) (%)	Main study 35–44 years ($N_2 = 20$) (%)
54. Price higher than the conventional product	26.7	56.7	–	–
55. Price lower than the conventional product	63.3	70	–	0
Brand name attributes				
56. Promotion campaign	36.7	43.3	–	–
57. Known producing company	76.7	76.7	20	15
58. Familiarity with the brand name	80	76.7	15	20

[a] Importance scale: 1 = "not important at all" to 5 = "very important".
[b] Attributes deemed important when a score 4 or 5 is given by at least 66.7% of the sample in the pilot study.
[c] Atributes deemed important when a score 4 or 5 is given by at least one of the participants (5%) in the main study.

additional attributes was presented to the early-middle-age group. The 3 additional attributes were "country-of-origin", "same price as conventional products" and "lower price than conventional products". Consumers of both age groups were thus asked to evaluate those attributes in terms of their importance when buying a functional food in general, whereas a functional fruit juice and a functional spread were offered (to the young adult and early-middle-aged groups, respectively) as examples to facilitate consumers' cognition retrieval process. The most important attributes were finally used as starting points of the laddering interview per respondent.

The answers given during the interviews by the 40 consumers of both groups were then coded: answers of the same meaning were categorized into common categories of attributes, consequences and values (A-C-Vs). In this way, a group of codes was created per abstraction level A-C-V that embodied all the information elicited from the participants. Overall, 18 consequence codes and 8 value codes were elicited from the young adult group, while exactly the same codes were used for coding the consequences and values emerged from the early-middle-aged group, with the addition of one extra value code. The coding process was based on corresponding codes of past functional and other food-related MEC studies, as described in Table 4. In total, the average number of codes elicited per consumer was approximately 43 for the young adults, forming 9.2 ladders on average. On the contrary, more codes were elicited form the early-middle-aged (approximately 48 per consumer), also forming more ladders on average (10.6 per consumer).

After coding, the analysis continued with the use of the MEC Analyst software, which provides an interactive system of data importation where multiple A-C-V ladders per participant are inserted in the form of relevant codes. After every ladder is input and the classification of codes is completed, data analysis is conducted for the creation of a tree diagram (Hierarchical Value Map, HVM) where the cognitive structures referring to functional foods are illustrated for each age group. Initially, MEC Analyst constructed an aggregate Implication Matrix. The Implication Matrix represents all the links between the A-C-V constructs which emerged from the interviews by demonstrating how many times they were brought about in the laddering interviews. The number of relations which emerged between two elements shows the strength of the particular connection. For the creation of the HVM the links from the Implication Matrix that are to be mapped should be defined. For this reason, every relation is compared to a cut-off level. In the present case, the chosen cut-off level is five, meaning that a certain connection appears in the HVM if it is mentioned once or more times by at least five participants (25% of each age group $N_1$and N_2) during the laddering interviews.

The last stage of the analysis was the drawing of the HVM. The HVM of the young adult group represents 68% of the direct links reported by at least 5 persons in the Implication Matrix, while the HVM of the early-middle-aged group presents 76% of the relevant links (Figs. 1 and 2). The main A-C-V links of the two HVMs are presented in Table 5.

5. Discussion

5.1. Functional food products and important product attributes

As mentioned previously, the results of the exploratory phase show that young adult consumers have a clear preference in the functional fruit juice category (a brand of fruit juice enhanced with vitamins). Moreover, there is a great difference in preference between the first product and those which follow. The second (older) group shows more balanced results in relation to its most preferred functional food brands. However, the clear preference in three functional spreads (substitute brands of spread with decreased cholesterol risk) highlights the specific functional food category as the favourite of this age group. Thus it seems that a small variation in consumers' socio-demographic profile (e.g. 10 years of age on average) is enough to direct their preferences towards different types of functional food and functionality-related benefits, indicating the possibility of fragmentation in the functional food market.

Despite their preferences in different functional food products, however, the two age groups share certain findings in relation to the most important attributes of func-

e 4
of consequences – values codes elicited per age group of the main sample ($N = 40$) and relative literature examples

es	25–34 years age group ($N_1 = 20$)	35–44 years age group ($N_2 = 20$)	Literature examples
sequences			
ctional			
ody needs	<5[a]	<5[a]	1. Body needs (Urala & Lähteenmäki, 2003)
asy to choose–use	9	<5	2. Easy to buy/use (Jonas & Beckmann, 1998)
ating–living healthy	18	20	3. Eating healthy (Padel & Foster, 2005)
hysical appearance	<5	<5	4. Physical appearance (Morris et al., 2004)
hysical health	20	13	5. Physical well-being (Jonas & Beckmann, 1998)
mprovement	<5	11	6. Will buy/use (Jonas & Beckmann, 1998)
roduct choice –			
onsumption	<5	8	
Bones' health promotion	20	20	8. Promotes health (Urala & Lähteenmäki, 2003)
Health promotion			
chological			
Eating enjoyment	14	14	9. Eating enjoyment (Morris et al., 2004)
Economic efficiency	14	<5	10. Monetary considerations (Morris et al., 2004)
. Feeling good	19	17	11. Feel good (Padel & Foster, 2005)
. Performance	17	15	12. Improved performance (Urala & Lähteenmäki, 2003)
improvement			
. Knows what to get	<5	<5	13. Knows what to get (price-quality) (Urala & Lähteenmäki, 2003)
(price/quality)			
. Need – desire satisfaction	19	<5	15. Quality of life (Krystallis & Ness, 2003)
. Quality of life	<5	<5	16. Socialize (Gutman, 1982)
. Socialization [b]	6	–	17. Time saving (Jonas & Beckmann, 1998)
. Time saving	9	<5	18. Trust (Morris et al., 2004)
. Trust	14	16	
alues			
nstrumental			
9. Tradition [b]	–	<5	19. Tradition (Schwartz, 1992)
erminal			
0. Belonging	6	<5	20. Belonging (Gutman, 1982; Kahle et al., 1986)
1. Good health and long life	<5	<5	21. Good health and long life (Jonas & Beckmann, 1998)
2. Inner harmony	6	11	22. Inner harmony (Zanoli & Naspetti, 2001)
3. Hedonism	13	14	23. Pleasure (Krystallis & Ness, 2003; Fotopoulos et al., 2003) Hedonism (Schwartz, 1992)
24. Psychological satisfaction	<5	9	24. Psychological satisfaction (Krystallis & Ness, 2003)
25. Security	10	16	25. Security (Schwartz, 1992)
26. Self confidence	19	<5	26. Self-esteem (Gutman, 1982), Achievement (Schwartz, 1992)
27. Self fulfilment	<5	<5	27. Self fulfilment (Zanoli & Naspetti, 2001)

[a] Number of times a benefit/value is mentioned at least once per respondent, cut-off level = 5.
[b] Psychological consequence "socialization" is a code of only the 25–34 age group and instrumental value "tradition" is a code of only the 35–44 age group.

tional foods that affect their purchasing decisions. More specifically, the exploratory phase shows that both groups consider extremely important for the functional foods' buying choice a number of perceived quality-related attributes (see Table 3, columns 1 and 2), such as, indicatively, the product being "pure", "safe", "healthy" and of a high "quality". The two groups also attach great importance to label information-related attributes, such as the "best before" and "packaging" dates, and the type of "health/functionality claims", "quality assurances" and "nutritional value". The same is the case for price attributes (e.g. "value for money") and brand name attributes (e.g. "familiarity with the brand").

The significance of these four attribute categories highlights the fact that functional foods remain foods, even if they are perceived as a special food category. Consumers should be certain about functional food quality and have at their disposal all the relevant information to evaluate the product before they proceed to the evaluation of its functional benefit, which is complementary to the product's expectedly high quality. However, this line of argumentation is not justified in the case of the appearance – package and the organoleptic attribute categories, where the only attributes that are deemed important to the consumers of both groups concern the "practical package" and the "nice taste". This is possibly the case because the attribute mas-

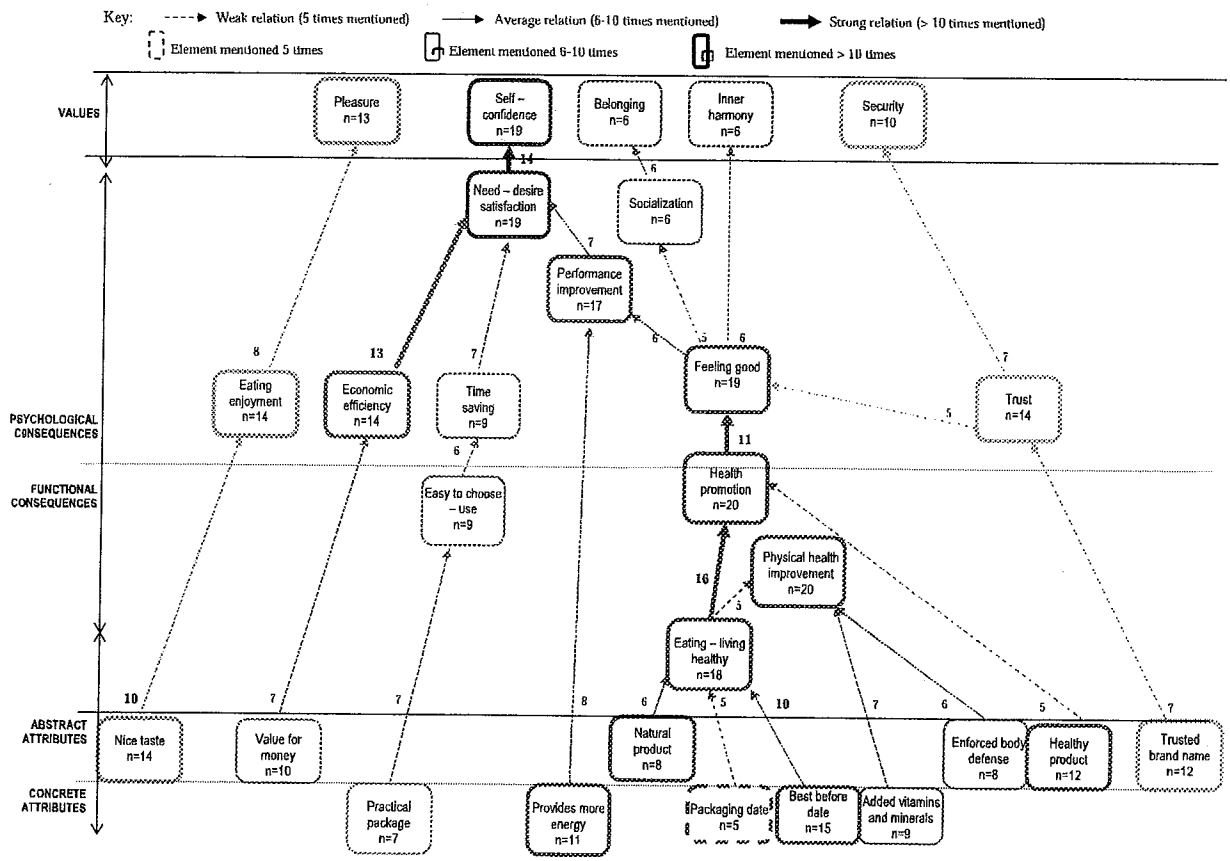

Fig. 1. Hierarchical Value Map of Functional Food Consumers of 25–34 years of age (cut-off level: 5, $N = 20$).

terlist refers generally to functional foods and not to certain products, thus downplaying the importance of more "subjective" product characteristics, such as organoleptic attributes, in the absence of a concrete buying example. Nevertheless, the greatest interest of the exploratory results lies in the category of functionality-related attributes, where both groups share a substantial interest in some general attributes, such as the "enforcement of body defence", the "contribution to good physical condition", the "provision of proved health claims" and the "removal of dangerous food ingredients".

Regarding differences between the two exploratory age groups, the "country of origin" and the "price same/lower than the conventional product" are recorded as important attributes only for the young adult group. However, the greatest differences between the two age groups in perceived importance are encountered in the functionality-related attribute category, where the early-middle-aged consumers underline the importance of overall more attributes than the younger consumers (13 vs. 9 functionality attributes, respectively). Thus, apart from 8 functionality attributes that are important for both groups, the young adults consider the "added vitamins and minerals" an important functional food attribute. On the contrary, the early-middle-aged assign importance to 5 additional attributes, such as "low cholesterol level", "contribution to digestion improvement", "reduced cardiovascular disease risk", and "low saturated fatty acid content". Overall, the observation that the young adults are more interested in energy enhancement attributes, such as added vitamins and minerals, while the early-middle-aged emphasize more on disease prevention attributes, such as lower cholesterol and cardiovascular diseases risk reduction is among the most important of this research. It should also be mentioned that the results of the exploratory phase indicate that consumers are not willing to sacrifice taste or convenience, to risk in trusting unknown brands or to spend more money in order to purchase foods with functional characteristics.

Finally, it is worth comparing the number and type of attributes that are deemed important by the exploratory sample ($n = 60$) as opposed to the MEC sample ($N = 40$), given that both samples are directly comparable in terms of their socio-demographic profiles (columns 1–2 vs. columns 3–4, Table 3). Taken as a whole, it is clear that the 20 attributes important for more than 25% of the main sample (5 attributes commonly important for both age groups plus 6 attributes important for the young adults

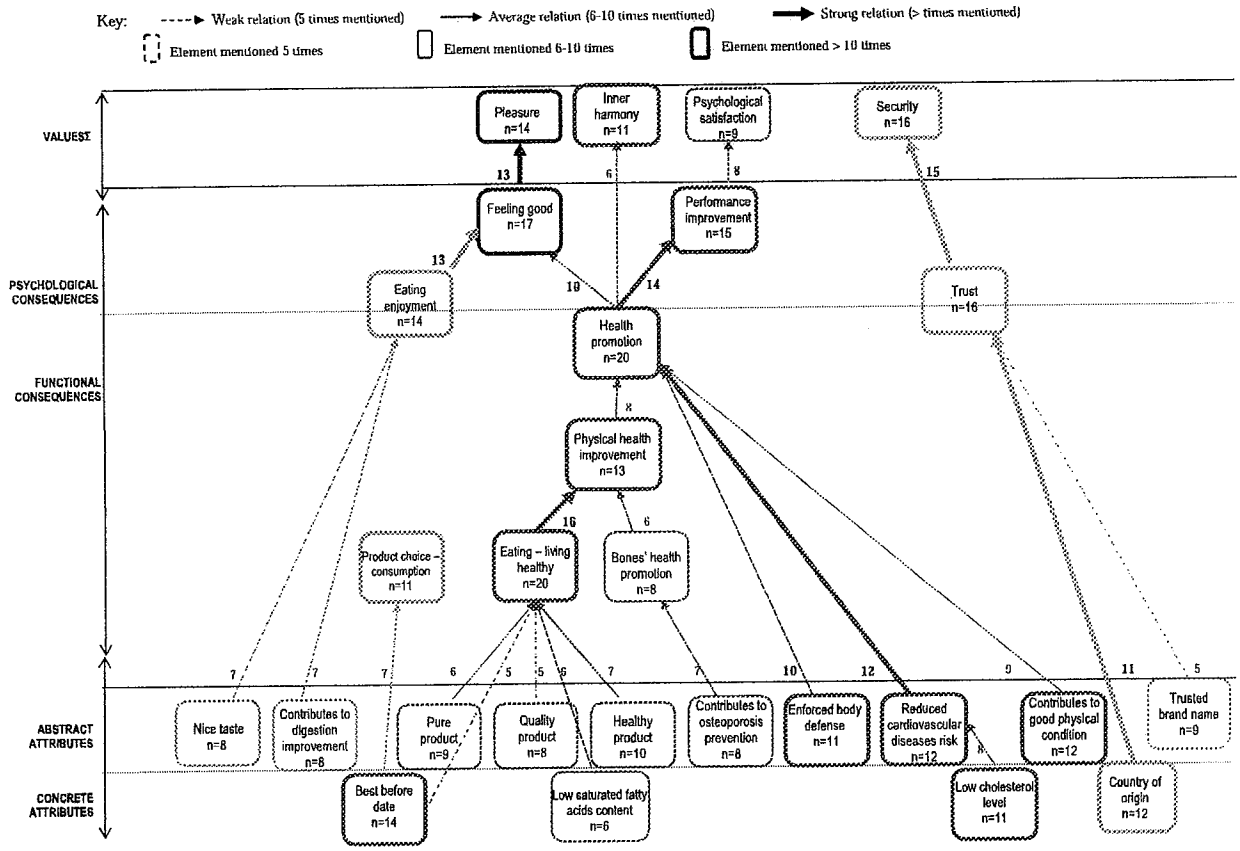

Fig. 2. Hierarchical Value Map of Functional Food Consumers of 35–44 years of age (cut-off level: 5, $N = 20$).

and 9 attributes important for the early-middle-aged) correspond to a great extent to the results for the same attributes from the exploratory phase. This trend is especially evident in the functionality-related attribute category, where 9 out of 14 attributes important for the exploratory phase are also important for the MEC study.

However, there are also a number of attributes for which the results between the two phases of the research diverge (usually attributes important for the exploratory sample but not for the MEC sample), mainly in relation to the category label information (health claims, quality assurance), perceived quality (safe, natural product) and brand name (known company, familiar brand name). This finding is possibly due to the fact that consumers in the MEC phase have been advised to keep in mind a specific functional food product per age group (fruit juice and spread, respectively) when responding to the laddering interviews, whereas this was not the case for the exploratory phase. It is thus justified that the type of base product (carrier) whose attributes have been improved plays a major role in consumers' evaluations of a functional product, as suggested in the literature (Bech-Larsen & Grunert, 2003; Urala, 2005; van Kleef et al., 2005), mostly with respect to attributes expected from any quality food product.

5.2. Consumer motives and cognitive structures related to functional foods

In order to obtain insights in relation to the functional food-related buying motives of consumers and the way that functional food consumption-relevant knowledge is stored and organized in consumers' cognition, the discussion further focuses on the main outcome of the study: the HVMs of the two age groups of the main sample. Eleven attributes are seen on the HVM of the young adults (attributes deemed important by at least 5 respondents or 25% on N_1). These attributes are divided into 5 concrete and 6 abstract attributes. In the Hierarchical Value Map of the early-middle-aged, 14 attributes are present (again, attributes deemed important by at least 5 respondents, or 25% on N_2), most of which (10) are abstract.

Based on the number of links represented, the most important cognitive construct of the HVM in the young adult age group consists of elements that together form the area of consumers' concern about the *enhancement of their health status* (109 direct links in total or 54.5% of the links appearing in the HVM above cut-off level, see Tables 4 and 5 and Fig. 1). This area is built around a number of health promotion-related benefits from the consumption of a functional food, such as "health promotion", "physical

Table 5
Links of attributes – consequences – values of the hierarchical value maps mentioned by more than 10 respondents of each age group of the main sample($N_1 = 20$ and $N_2 = 20$)

	Connection frequency[a] (%)	Cognitive area of each connection
Main links of 25–34 years age group		
1. Attribute "*Best before date*" is connected with consequence "*Eating–living healthy*"	10/109 (9.1)	*Health enhancement*
2. Consequence "*Eating–living healthy*" is connected with consequence "*Health promotion*"	16/109 (14.6)	*Health enhancement*
3. Consequence "*Health promotion*" is connected with consequence "*Feel good*"	11/109 (10.0)	*Health enhancement*
4. Consequence "*Need – desire satisfaction*" is connected with value "*Self confidence*"	14/149 (9.3)	*Health enhancement, Economic efficiency, Practicality*
5. Consequence "*Economic efficiency*" is connected with consequence "*Need – desire satisfaction*"	13/20 (65)	*Economic efficiency*
6. Attribute "*Nice taste*" is connected with consequence "*Eating enjoyment*"	10/18 (55.5)	*Eating hedonism*
Main links of 35–44 years age group		
1. Attribute "*Enforces body defence*" is connected with consequence "*Health promotion*"	10/143 (6.9)	*Health risk prevention*
2. Attribute "*Reduces cardiovascular diseases risk*" is connected with consequence "*Health promotion*"	12/143 (8.3)	*Health risk prevention*
3. Consequence "*Eating – living healthy*" is connected with consequence "*Physical health improvement*"	16/143 (11.1)	*Health risk prevention*
4. Consequence "*Health promotion*" is connected with consequence "*Performance improvement*"	14/143 (9.7)	*Health risk prevention*
5. Consequence "*Health promotion*" is connected with consequence "*Feeling good*"	10/143 (6.9)	*Health risk prevention*
6. Consequence "*Feeling good*" is connected with value "*Pleasure*"	13/170 (7.6)	*Health risk prevention, Eating enjoyment*
7. Consequence "*Eating enjoyment*" is connected with consequence "*Feeling good*"	13/27 (48.1)	*Eating enjoyment*
8. Attribute "*Country of origin*" is connected with consequence "*Trust*"	11/31 (35.4)	*Trust*
9.Consequence "*Trust*" is connected with value "*Security*"	15 (48.3)	*Trust*

[a] Connection expressed as a number per total number of connections (%) in the relevant cognitive area.

health improvement", and "eating–living healthy". The consumers between 25 and 34 years of age thus take advantage of a variety of product attributes including functionality-related attributes ("provides more energy", "added vitamins and minerals" and "enforces body defence"), health-related perceived quality attributes ("natural", "healthy" product) and health-related label information attributes ("packaging date", "best before date") in the pursuit of their health status promotion. The satisfaction of the particular need drives the "feel-good" psychological consequence. This is a key knob in young adults' cognition, since it relates their preference for health-related food attributes – including functionality – with central personality constructs of higher abstraction, such as the values of "inner harmony" (directly), "belonging" (through the "socialisation" psychological consequence) and "self confidence" (through "performance improvement" and "need – desire satisfaction" psychological consequences).

Apart from the health-related cognitive construct, the HVM of the 25–34 age group includes additional constructs of lesser importance. For instance, the area of *eating hedonism* (18 direct connections overall or 9% of the links appearing in the HVM above cut-off level) is centred on the benefit of "eating enjoyment" that results from the consumption of a food with a "nice taste" and it is the result of consumers' pursuit of "pleasure". The cognitive structure of the younger consumers is completed with the constructs of *trust* (19 direct links or 9.5% of the links appearing in the HVM above cut-off level): a trusted brand name creates trust that satisfies the pursuit of security; *economic efficiency* (20 direct connections or 10% of the links appearing in the HVM above cut-off level): a value for money-priced product translates into economic efficiency that fulfils needs and desires, a fact that in turn leads to self-confidence; and *practicality* (20 direct connections or 10% of the links appearing in the HVM above cut-off level): a practically packaged product means an easy to choose/use product that leads to time saving, a fact that in turn fulfils needs and desires and creates self-confidence.

The most important cognitive construct of the early-middle-aged HVM consists of the area of consumers' concern about the *prevention of risks threatening their health status*(143 direct links in total or 66.8% of the links appearing in the HVM above cut-off level, see Tables 4 and 5 and Fig. 2). This area is built around the same central health promotion-related benefits from the consumption of a functional food found in the 25–34 age group, meaning "health promotion", "physical health improvement", and "eating–living healthy", with the addition of the "bones' health promotion" benefit. The consumers between 35 and 44 years of age also take advantage of a variety of product attributes, which include functionality attributes related to health risk prevention ("low saturated fatty acids content", "contribution to osteoporosis prevention", "body defence enforcement", "cardiovascular diseases' risk reduction", "low cholesterol level", and "contribution to good physical condition"). A number of health-related perceived quality attributes ("pure", "healthy", "quality" product), and health-related label information attributes ("best before date") in the pursuit of their health status maintenance are also included. In this respect, the direct link between the "cardiovascular diseases risk reduction" attribute and the "health promotion" benefit is among the most powerful links of the whole cognitive structure.

The satisfaction of this particular need drives both the "feeling good" and – mainly – the "improved performance" psychological benefits, forming the core link of the early-middle-aged consumers' cognition. This link relates consumers' preference for health-related food attributes – including functionality – with personality constructs of higher abstraction, such as the values of "pleasure", "inner harmony" and "psychological satisfaction".

Apart from the health-related cognitive construct, the HVM of the early-middle-aged includes additional constructs of lesser importance, as was the case with the young adults. Thus, the area of *eating hedonism* (27 direct connections overall or 12.6% of the links appearing in the HVM above cut-off level) is again present, this time centred around the link between the "eating enjoyment" and "feeling good" benefits that result from the consumption of a food with both a "nice taste" and that "improves digestion". The overall cognitive construct is still driven by the pursuit of "pleasure" values. The cognitive structure of the early-middle-aged is completed with the clear-cut construct of *trust* (31 direct links or 14.4% of the links appearing in the HVM above cut-off level): choice of a trusted functional brand name, but mainly of a functional food product with known country of origin, creates trust that satisfies the need for feeling secure.

From the above it is clear that, through functional foods, the consumers of both age groups try to satisfy mainly the need for improvement or preservation of their health status, thus seeking quite similar benefits from the consumption of these products. But the fact that these benefits steam from the selection of quite different functionality attributes indicates that the consumers of both groups may perceive functional foods' ideal marketing mix differently. Highly educated young adults and early-middle-aged consumers appear to pay attention to different marketing elements, but which lead to analogous results in terms of consumers' health improvement or preservation. At the same time, young adult consumers seem to rely on attributes more typical to "common" food products (e.g. practical use, fair price, nice taste, high perceived quality guaranteed through a trusted brand name). The early-middle-aged consumers, on the other hand, rather perceive a functional food product more like a combination of food and medicine. Nevertheless, the consumers of both age groups do not appear willing to compromise taste and overall eating enjoyment for the health benefit of functional foods, irrespective of its type (enhancement or maintenance), whereas the demand for a trustworthy functional food production process also remains strong.

The results of the research are also in agreement with previous studies on functional food purchasing motives. For instance, Bhaskaran and Hardley (2002) maintain that the health-related characteristics of functional foods do not affect to a great extent the younger ages that pay more attention to attributes such as taste and price. The older ages explain their purchasing intentions mainly from the disease prevention point of view. Furthermore, Bogue and Ryan (2000) showed that older consumers are more interested in health claims about a decrease in the possibility of a disease, while younger consumers are more interested in claims about an increase in energy levels.

6. Conclusions – Managerial implications

The present study employs the MEC analysis methodology to identify the most frequently purchased functional foods for a homogeneous consumer sample, define the most important functional food attributes that affect purchasing decisions and explore the degree of functional food market fragmentation through the identification of potential differences in functional attributes' importance assigned by the same consumers when examined in two separate age groups (young adults and the early-middle-aged). The study further aims at obtaining insights into the functional food-related buying motives of consumers. The final objective of the study is to design a MEC hierarchy of consumption-relevant cognitive structures and explain functional food-related purchasing behaviour by specifying how parts of the cognitive structure will be retrieved and used to guide behaviour.

Consumers are difficult to differentiate on the basis of age using only on the criterion of importance assigned to various functional food attributes, since their evaluation presents too many similarities between the two age groups examined. Attributes of great importance for both are those that typically affect the choice of a "common" food product, such as information on the label, price, convenience, perceived quality characteristics and brand name. There is even a general agreement in functionality-related attributes that concern consumers' overall health status. The noticeable difference, however, lies in the fact that the young adults are more interested in functional foods that improve their physical condition and energy levels; a 10 years average age difference, however, appears enough to divert consumers' interest towards more health risk prevention benefits of functional foods' consumption, despite the fact that those benefits are initiated by the same functional attributes.

The results of MEC analysis should promote strategic thinking by providing creative solutions in problems of product positioning (Reynolds, Dethloff, & Westberg, 2001). Each of the HVMs' orientation could be seen as a potential product positioning strategy (Gengler & Reynolds, 1995). More specifically, HVM presents many alternative choices for the development of a strategic placement like the increase/decrease in the importance of an element on the map, the creation/deletion of a connection among the elements, the strengthening/weakening in a connection between a brand and an element or the creation of a new element in the map (Reynolds et al., 2001).

Such an occasion is clearly presented in the HVM of the young adult group: one can observe that no functionality attributes are connected to the "eating–living healthy" and "health promotion" link, which is the most important

link of the overall HVM (also see Table 5). On the other hand, two functionality attributes are weakly related to the "physical health improvement" benefit, which in turn is not connected to the central benefit of "health promotion". Consequently, a positioning option would be the appearance of more functionality-related attributes in the map that will create stronger connections to the core benefits of the health enhancement cognitive area. The result would be a strategic placement that could communicate to young adults that "*they could promote their overall health status* (functional consequence) *through the improvement of their physical performance* (functional consequence) – 'new' link that is currently missing – *by consuming foods with improved level of vitamins and minerals than enhance their organism's natural defence*" – an intensification of the existing link.

At the same time, the appearance of the eating enjoyment cognitive area in both HVMs is a hint for the food industry that well-educated consumers will not accept products that could have a positive effect on their health but present worse organoleptic attributes compared to conventional ones. Finally, the demand for fairly-priced functional foods by the young adults could be an indication for the companies in favor of development of more tailor-made pricing policies per functional product types, targeting different consumer segments.

Despite the fact that the reference made by the interviewee in the beginning of the laddering interviews to a relevant-per-age-group functional product has been made simply to facilitate the flow of speech during the interview, it is possible that it stimulated the retrieval of unintended constructs from consumers' sub-consciousness. This may have biased the outcome of the research to a certain extent, since it is not absolutely clear which is the main source of the variation appearing in the HVMs, that is the different carrier, the truly different cognition of the two age groups, or both. However, what has been essentially evaluated here is the list of functional food-related attributes as emerged from the exploratory phase, similar to a large extent for the two age groups. Therefore, all consumers evaluated the "same" functional product, as emerged from the exploratory phase. It is from that point on that differences start appearing, and not earlier: consumers in different groups assigned importance to different functionality attributes of essentially a "common" product. Nevertheless, future research must overcome this limitation by comparing the HVMs derived for two functional products by each age group (e.g. fruit juice and spread HVMs for both young adults and early-middle-aged). Finally, as with any MEC study, the outcomes presented here should not be unquestionably generalised; a wider-scale quantitative research is needed to validate the results of the MEC research presented here.

The success of functional foods is related to how well they satisfy frequently complementary consumer needs. The successful development of new functional products should take into account the opportunities that are presented through consumer sciences. Food manufacturers should monitor consumer behaviour towards functional foods in order to ensure that these products match consumer needs and expectations and that their health claims are promoted by means of honest information dissemination in an attractive way.

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trategies for Improving Calcium Nutriture f the U.S. Population

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ABSTRACT: Despite more than 20 y of awareness of the importance of calcium to health, U.S. calcium intakes remain suboptimal. Fortification of foods with shortfall nutrients is probably the optimal strategy for dealing with widespread nutrient deficiencies, as it has the best chance of reaching the population segments most at risk, as contrasted with attempts at changing individuals' food choices or relying on voluntary supplement taking. Given the wide array of potential calcium fortificants and fortification levels, there is not much to guide manufacturers interested in improving the nutritional value of their products. In this review, we assemble the calcium salts/complexes that have been used or proposed for use as fortificants and describe certain of their measured characteristics that relate to incorporation into foods, particularly what is known of their absorbability. The calcium salts most commonly used as supplements or fortificants exhibit similar absorbability when tested in pure chemical form. Choice of salt will depend mainly upon cost, compatability with the manufacturing process, and consumer acceptability. However, interaction with food, tablet, or beverage matrices can degrade intrinsic absorbability substantially. As a consequence, each product must be explicitly tested to establish the degree to which its calcium is available to consumers.

Keywords: absorption, bioavailability, calcium, deficiency, fortification

Introduction

1982, the American Society for Bone and Mineral Research held ress conference on osteoporosis, calling the public's attention protective role of a high calcium intake. Media coverage of that erence led in the mid-late 1980s to what *Newsweek* Magazine d "The Calcium Craze." "Craze" apart, the underlying science ound, and no less than 3 subsequent NIH Consensus Devel- nt Conferences recommended increased calcium intakes for age groups in the population, precisely to lower the risk of porosis.

despite more than 20 y of awareness of the importance of m to health, U.S. calcium intakes remain suboptimal. As re- as 2004 the U.S. Surgeon General, in his report on bone health HHS 2004) stated that calcium has been singled out as a ma blic health concern today because it is critically important to health and the average American consumes levels of calcium far below the amount recommended.

America's chief health educator, the Surgeon General gives cans the best scientific information available on how to im- their health and reduce the risk of illness and injury. Earlier, the urgeon General's Report on Nutrition and Health (USDHHS had suggested that calcium be considered for food fortifica- oday calcium intake is recognized to be important not only for ealth but also for lowering the risk of a host of other disorders ranging from hypertension to colon cancer to obesity.

ong the earliest studies of calcium metabolism and bone (and one of the longest running, continuously supported projects in NIH history) is the Omaha Nuns Study conducted by the Creighton Univ. Osteoporosis Research Center. Begun in 1967 and continuing to the present, 40 y later, the project studies calcium metabolism in the population at risk for osteoporosis before and after manifestation of the bone disorder occurs.

The Omaha Nuns study literally "wrote the book" on the operation of the calcium economy in mid-life women. Its findings have provided the principal scientific basis for the NIH recommendations for adult calcium intake. The project has also established the gold-standard measurement of calcium absorption using a radioactive tracer method. Absorption of calcium from over 50 foods, beverages, supplements, and fortificants has subsequently been measured in human subjects at the Creighton Univ. Osteoporosis Research Center.

The Need for Calcium Fortification of Foods and Beverages

The principal reason for fortifying modern diets is the decline in per capita calorie expenditure in the industrialized nations and the corresponding need to reduce energy intake. This fact, coupled with an increase in energy-dense, nutrient-poor foods, results in substantial shortfalls of many key nutrients in contemporary diets, in contrast with the diets of just 2 generations ago.

Fortification of foods with nutrients is probably the optimal strategy for dealing with wide-spread nutrient deficiencies, as it has the best chance of reaching the population segments most at risk, as contrasted with attempts at changing individuals' food choices or relying on voluntary supplement taking. Successful instances of fortification-induced eradication of disease include the conquest of pellagra in the United States by niacin fortification of white flour, the virtual elimination of goiter by iodination of salt, and the reduction of neural tube defects by folate fortification of cereal grain products. Two of these involved mandatory fortification, while iodination of mandatory fortification seems unlikely at the present time. It took the FDA 24 y to require folate fortification after the 1st request to do so from the Natl. Academy of Sciences. Hence the emphasis for calcium will likely remain on voluntary fortification, with food manufacturers confronting an absence of standards and a multiplicity of options, both for calcium source and for level of fortification.

Early efforts of food manufacturers in the 1980s included such notable examples as Procter & Gamble's "Citrus Hill Plus Calcium" and Continental Baking's "Wonder Calcium" (both subsequently withdrawn, though for quite different reasons). Similar examples appeared on supermarket shelves through most of the 1990s, but few lasted long. Then, beginning in 1999, calcium-fortified brands appeared in large numbers and have, for the most part, been apparent commercial successes. Over 1100 calcium-fortified products (Clark 2006) were introduced in a recent 5-y period (more than two-thirds of these in the beverage and snack categories). Whatever their commercial success, several of these products are what must be judged fortification failures (Heaney and others 2005a, Heaney and Rafferty 2006) and need reformulation.

Moreover, fortification has only partially penetrated most major food categories, taking all brands into consideration. Thus, in the category of ready-to-eat cereals, many of General Mills™ breakfast cereals are now fortified with calcium, whereas those produced by Kellogg's™ and Post™, for example, are not. Continental Baking has reintroduced a calcium-fortified Wonder Bread™ (though at a lower level than its earlier attempt), but many breads remain unfortified. Thus, population penetration remains spotty.

The importance of calcium to the consumer is reflected in consumer attitudes and beliefs, if not in food choices. A survey of consumer preferences for minerals in beverages (Rokosh 2005) reveals:

- The general public rates the claim "*Good Source of Calcium*" as most important when choosing fortified beverages
- 70% have consumed fortified beverages
- 23% once per day or more
- 24% 1 to 6 times per week
- 30% believe such beverages are vital to health
- 67% see themselves as deficient in calcium, magnesium, iron, zinc, and/or potassium
- 69% consider calcium one of the most important ingredients in fortified beverages, necessary for maintaining a healthy lifestyle

Given the wide array of potential fortificants and fortification levels, there is not much to guide manufacturers interested in improving the nutritional value of their products. In this review, we assemble the calcium salts/complexes that have been used or proposed for use as fortificants and describe certain of their measured characteristics that relate to incorporation into foods, particularly what is known of their absorbability. We also call attention specifically to instances of fortification failures that should, if possible, be avoided in future attempts at fortification.

Absorbability: Meaning and Importance

With respect to absorbability, it should be noted at the outset that, while for disorders such as osteoporosis, absorption is of paramount importance, unabsorbed calcium in the gut exerts useful functionality in its own right (blocking absorption of potentially harmful by-products of digestion) (Heaney 2003a). Hence emphasis on absorbability as the *primary* criterion of a desirable fortificant may not always be pertinent. Absorbed and unabsorbed calcium are both important. A calcium-rich diet supports both. from the blood into the lumen in the form of digestive secretions and sloughed mucosal cells. The first, *gross* absorption, is a feature of the calcium source and is the most relevant measure to use in characterizing fortificants and fortified foods. The second, *net* absorption, is heavily dependent upon host factors and is the measure of greatest nutritional relevance to the individual.

Absorption of calcium, as for many divalent cations, is relatively inefficient. In healthy adults, at typical calcium intakes, gross absorption averages in the range of 25% to 35% of typical ingested calcium loads, while net absorption averages about 10% to 12%. Additionally, absorption is a function of load size, varying inversely as the logarithm of the test load (Heaney and others 1990a). For loads as small as 10 to 20 mg, gross absorption will exceed 80% of the ingested load, while for the same source, at a load size of 1000 mg, gross absorption will typically average about 20%. These numbers illustrate an often misunderstood feature of absorption. Eighty percent (80%) would seem to be clearly better than 20%. However, 80% of a 20 mg load means that only 16 mg is transported from the gut lumen into the blood, while 20% of a 1000 mg load results in 200 mg calcium actually entering the blood stream. It is the *amount* absorbed, not the *fraction (or percent)* absorbed that has nutritional significance.

It is beyond the scope of this review to describe methods of measuring absorption, but it is necessary here to point out that the isotopic tracer methods, when correctly implemented, directly measure gross absorption *fraction*, while the pharmacokinetic and intestinal balance methods reflect, instead, the net absorbed *quantity*. The distinction is important because different sources may require different methods, and to compare sources it is necessary not only that they be tested at the same load size but by the same method as well. When the emphasis is on the calcium source (that is, the fortificant or the fortified food) as in this review, gross absorption fraction will be the preferred measure.

Methods

Literature search

Medline was searched for all studies of calcium absorption in humans, with primary emphasis on the absorbability of specific sources. A total of 45 articles were found. After deciding whether they met the inclusion criteria (see below), these were combined with 31 studies performed in the authors' laboratory and in that of TNO Nutrition and Food Research Inst., Zeist, the Netherlands. Several of these provided data for multiple salts. Some few of these had, themselves, been previously published (but most of which had previously appeared only in project reports or internal communications to sponsors).

Inclusion criteria

We included in this study primarily studies in which gross absorption was measured from a chemically defined calcium load. This allowed both quantitative estimation and comparison of the absorbability of various calcium salts, and estimation of the effect of incorporating the salt into various food/supplement matrices. In studies in which a reference material such as milk or precipitated calcium carbonate was used, the absorbability of a test calcium source was also expressed relative to that of the referent in the same test participants (that is, a quotient was calculated for the absorbability

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st 2 sources, and several up to 4 sources. We excluded 1 study ploying the gastrointestinal lavage method, 4 using recovery of er solely from fecal collections, 3 in which the only measurement of urine calcium, 3 biodynamic studies measuring only change erum parathyroid hormone, 1 study measuring whole body cal- n retention, 2 studies in children, and 1 study involving patients n liver disease. This makes a total of 14 studies not yielding us- e data. Additionally, there were 6 studies using pharmacokinetic hods that while useful for comparing products, produce results t cannot be straightforwardly converted to fractional absorption ues. These studies were used only to the extent that they con- ed a referent allowing expression of absorption relative to the rent. Finally, 2 papers consisted of meta-analyses that, of course, tained no original data.

tudies involving fecal recovery of calcium tracers were elimi- ed because such studies measure net rather than gross absorp- , and because, when properly executed, such studies require onged fecal collections for accuracy, and most such reports did meet this criterion. Although a method exists (Heaney 2003b) converting data from pharmacokinetic studies into fractional orption values, this method has not been validated across large ges of load size, and hence studies involving pharmacokinetic ntestinal methods were included only when comparisons were le between sources, permitting calculation of relative values n a suitable referent material had been included in the study. pharmacokinetic studies were excluded because serum calcium surements were obtained for fewer than 5 h. In all, 18 published orts were included in this analysis (Recker 1985; Smith and others ; Miller and others 1988; Heaney and others 1989, 1990a, 1999,), 2001, 2003, 2005b; Andon and others 1996; Nickel and others ; Weaver and others 1996, 2002; Martin and others 2002; Brink others 2003; Rosado and others 2005; Heaney 2006).

n this respect, the word "test" is used to designate an individual surement in a single individual, and the word "study" to des- te a group of individual tests on the same calcium source as of a single investigative protocol. If more than 1 calcium source evaluated in a single protocol, we counted them as separate ies.

lytical methods

or the 30 studies performed in the authors' laboratories and previously published in the scientific literature, the test proce- followed published methods (Heaney and Recker 1985, 1988), h, briefly, were as follows. All tests were performed in healthy ts; all studies had been approved by the Institutional Review ds of Creighton Univ. or TNO Nutrition and Food Research and all subjects gave written consent. All tests were carried n the morning after an overnight fast, usually with the test cal- source being ingested in the middle of a light breakfast meal. hose studies in which the protocol required that the substance gested without food, on an empty stomach, the results were gated and separately analyzed because of the previously es- hed fact that calcium absorption for many sources tends to be nced in the presence of food (Heaney and others 1989). (This effect probably relates to the influence of food on gastric emp- . rather than to any feature of the calcium source itself.) When st method was pharmacokinetic in character, multiple blood les were taken over a 9- to 24-h period following ingestion of Recker 1985, 1988).

For tracer-labeled experiments, the source was generally intrinsically labeled by addition of a suitable calcium isotope to a solution of the chemical salt concerned, prior to its precipitation and formulation into a specific dosage form (for example, capsule, tablet, food fortificant). This method ensured uniform distribution of the tracer through the carrier atoms of the calcium source. In beverages in which the calcium salt was in solution, extrinsic labeling was implemented by direct addition of a suitable quantity of the tracer to the source, allowing equilibration for 17 h at 4 °C before dosing. As the protocols for several studies called for different ingested calcium load sizes, fractional absorption values were normalized to a 300 mg load by using the following equation

$$AdjAbsFx = MeasAbsFx - 0.0964 * \ln(300/load) \quad (1)$$

derived from a study of the effect of load size on absorption fraction (Heaney and others 1990a). In this equation, $AbsFx$ = gross absorption fraction, and load = the calcium load of the test source in milligrams.

Statistical analysis

As the purpose of this analysis was primarily descriptive, simple summary statistics were computed using the routines in Microsoft Excel (Microsoft Corp., Redmond, Wash., U.S.A.). For studies of the same calcium salt, means and standard deviations for each report and/or study arm were pooled to develop an aggregate estimate of the results across all of the studies concerned, with weighting for sample size. Where quotients were available for contrasting absorbability from a particular source and that of a referent, a single-sample t-test was used to evaluate whether the ratio departed significantly from a value of 1.0 (= equivalent absorbability).

Comparison of Calcium Salts

Our comparative analysis examines 11 calcium salts tested in various configurations as single salts, compound/combination salts, pure salts, salts prepared as pharmaceutical formulations, and/or salts within a food/beverage matrix. Some tests were conducted without food on an empty stomach, and others were co-ingested with a standardized meal. Roughly half of the tests include a milk comparator and 20%, a precipitated calcium carbonate comparator.

Table 1 sets forth the various calcium salts studied under either the tracer or pharmacokinetic methods of measurement, together with test conditions, number of subjects, and subject characteristics. Roughly 70% of the over 2100 individual tests were carried out in premenopausal women. Calcium carbonate accounts for the majority mainly because $CaCO_3$ was often chosen as the referent in a crossover study design. In cases where both men and women have been tested on the same salt, both tend to exhibit similar absorption values. Similarly, the data show that there is little difference in the absorption efficiency of pre- and postmenopausal women. Hence, in presenting the results that follow (Table 2 to 5), we aggregate studies of the same salt from men and both pre- and postmenopausal women.

Table 2 sets forth the mean absorbability values of 9 salts that have been tested either in pure form (that is, without excipients and without prior incorporation into a food or beverage matrix) standard deviations around the respective means, and the second is the standard deviation for the aggregate of all the component study means. (With 1 salt, calcium glycerophosphate, for which there was only a single study, only the within-study SD is shown.) Had all the studies been random samples of a single population of absorption values, the SD of the means (that is, the between-study SD) would be predicted to be smaller than the within-study SD, by a factor of $1/N$. In the case of $CaCO_3$ (in matrix), however, the between-study SD is *not* smaller but is substantially larger than the within-study DS, indicating the presence of substantial heterogeneity among the sample means.

This effect is most apparent for a single salt (for example, calcium carbonate) and suggests either (1) differences in the absorptive performance of the various test participant panels or (2) differences in test conditions (for example, with and without a test meal) or (3) matrix effects on inherent absorbability. Figure 1 captures the mean values for 25 studies of calcium carbonate and shows 2 points very clearly: (1) absorption from an empty stomach is less efficient than that from the same salt fed with a light breakfast; and (2) there is a 2-fold spread of fractional absorption values for calcium carbonate once the salt is incorporated into various food, supplement, or beverage matrices, with mean absorbability values ranging from 0.21 to 0.42. The highest value was for a product fully as well absorbed as the pure salt, while the lowest was for a product less than half as well absorbed. Much of this variability must reflect interaction of food, study SD for many of these salts is smaller than for calcium carbonate, indicating that the different matrices did not appreciably alter the absorbability of the noncarbonate salt concerned (Table 2).

These discordances in calcium bioavailability highlight the reality that bioavailability cannot be predicted based on the current chemical knowledge of the source, but must be directly tested. Nor can bioavailability of a salt in 1 matrix be extrapolated to other untested matrices.

The ideal model for testing calcium bioavailability is a crossover design in which the source calcium in question is tested against a referent calcium source such as dairy milk. Within a subject, calcium absorption efficiency is highly consistent (Heaney and others 1990b) and the milk (or other) comparator effectively eliminates the interindividual variation. Testing calcium absorption against a consistent comparator such as milk or precipitated calcium carbonate standardizes the test and allows for credible conclusions (that is, comparing "apples" to "apples"). Table 3 sets forth calcium absorbability not as absolute fractional absorption ($AbsFx$) but as a quotient relative to milk, and Table 4 does the same for a precipitated calcium carbonate referent. Absorption equal to that of the referent calcium has a value of 1.0. The following conclusions may be drawn:

- Most calcium salts ingested under *fasting* conditions show reduced absorbability relative to the same salt ingested with food, with the exception of calcium lactate, which, in a single study, demonstrated better absorption from a fasting than from a fed state.

Table 1 – Numbers of individual tests by salt and by test conditions.

Salt	Subjects tested				Test conditions		
	n	Pre-meno	Post-meno	Men	Pure salt[b]	No meal	w/meal
Calcium carbonate	927	683	234	10	112	137	790
Tricalcium phosphate	137	116	10	11	10		137
Dicalcium phosphate	36	36					36
Calcium citrate	116	17	89	10	44	7	109
Calcium sulfate	34	34			9	9	25
Calcium lactate	30		30		30	10	20
Calcium citrate malate	558	434	124		10		558
Calcium hydroxide	42	18	24				42
Bisglycinocalcium	13	13			13	13	
Calcium glycerophosphate	24	24					24
Combination salts[a]	184	94	46	44	10		184
Total	2101	1469	557	75	238	176	1925

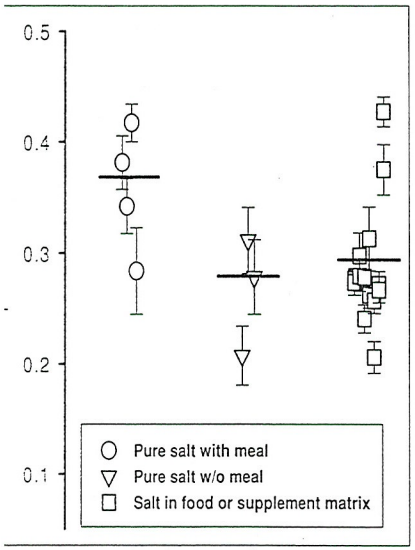
[a]CaLactate Gluconate; CaLactate MCP/DCP/TCP; Ca/P/K/Mg/Na; Ca/P/K/Citrate.
[b]"Pure salt" means the salt ingested in a gelatin capsule, not incorporated into a food-like matrix, and irrespective of co-ingested food.

Table 2 – Fractional absorption of various salts co-ingested with a low-Ca test meal.

Salt[a]	*N* (studies)	*N* (subjects)	Weighted *adj absFx*[b]	Within-study SD	Between-study SD
Calcium carbonate – pure salt	5	71	0.3682	0.0981	0.0565
Calcium carbonate – in matrix	22	557	0.2580	0.0752	0.1094
Calcium citrate – in matrix	3	37	0.3817	0.0848	0.0029
Tricalcium phosphate – in matrix	7	137	0.2429	0.0975	0.0212
Dicalcium phosphate – in matrix	2	36	0.2610	0.0774	0.0178
Calcium sulfate – in matrix	2	25	0.4002	0.1009	0.0577
Calcium lactate – in matrix	3	30	0.3300	0.0906	0.0708
Calcium glycerophosphate – in matrix	1	24	0.2714	0.0720	–
Calcium hydroxide – in matrix	2	18	0.2916	0.0344	0.0236
Calcium citrate malate – in matrix	17	508	0.3380	0.0909	0.0355

[a]"Pure salt" means the salt ingested in a gelatin capsule, not incorporated into a food-like matrix, and irrespective of co-ingested food. "In matrix" refers to incorporation of the salt into a food during its preparation or to admixture of the salt with the components commonly encountered in nutritional supplement tablets or capsules, in both cases prior to fabrication of the final ingested form; weighting is by sample size.
[b]Where load size in tests concerned differed from the standard load of 300 mg, resulting values adjusted to 300 mg (see text).

beverage industry may engage the challenge of identifying food or beverage vehicles that preserve the pure salts' absorbability characteristics.



ure 1—Mean values for absorption fraction from 25 udies of calcium carbonate absorption. Point plot of ean (± 1 SEM) absorbability values for the pure salt co-ested with a meal (left column), for the pure salt with-t any co-ingested food (middle column), and for the salt ricated into various food, supplement, or beverage ma-ces (right column). (Copyright, Robert P. Heaney, 2007. ed with permission.)

ble 3—Comparative salt absorbability—salt-to-milk otient.

	N (subjects)	All subjects
e salts, fasting without meal		
alcium carbonate	41	0.999
alcium citrate	7	0.935
alcium lactate	10	1.466[a]
alcium sulfate	9	0.985
e salts, co-ingested meal		
alcium carbonate	34	1.116[a]
ricalcium Phosphate	10	0.789[a]
alcium lactate	20	1.033
alcium citrate malate	10	1.007
alcium lactate gluconate	10	1.092
ts in food supplement matrix, o-ingested meal		
alcium carbonate	168	0.987
ricalcium Phosphate	137	0.834[a]
alcium Phosphate	36	0.965
alcium sulfate	25	1.094
alcium citrate malate	228	1.114[a]
omb. (Ca Lactate MCP/ DCP TCP)	84	0.864
omb. (Ca, P, K, citrate)	33	0.817

nificantly different from 1.0.

- Among the 12 calcium salts co-ingested with a meal, none of the 6 exhibiting improved absorption (that is, quotients > 1.0) contained a calcium phosphate salt, while 5 of the 6 exhibiting reduced absorption (that is, quotients < 1.0) had phosphate as a component of the salt. Although it is beyond the scope of this analysis to explore the totality of the calcium economy, this less efficient absorption of the phosphate salts is not necessarily a negative consideration. Calcium absorption is just 1 component in the calcium economy. Calcium is retained in bone as a calcium phosphate salt and the total nutrient intake of phosphorus is critical for the accumulation of bone mineral. Though phosphorus is less likely to be as severely underconsumed as calcium in adults, certain segments of the population, such as elderly women taking bone-building medications, may benefit from the phosphorus contained in the calcium phosphate fortificants.
- Overall, while a few salts seem to stand out (for example, CCM, calcium lactate, and $CaSO_4$ on the high side, and TCP on the low side), most salts exhibit roughly similar bioavailability and tend to fall within ± 10% of the absorbability of milk calcium.

Clearly, what is true for pure calcium salts cannot be extrapolated or generalized to the same salts tested as calcium supplements or food fortificants. The pharmaceutical formulation, which includes a broad range of factors such as excipients (flavorings, coatings, sugars, starches, lubricants), encapsulation, and granulation, can result in great differences in bioavailability. The effect of various tableting formulations on calcium bioavailability both from test products and from marketed calcium supplements is extreme, resulting in a reduction in absorbability of from 7.5% to 39% in a tableted $CaCO_3$ preparation, relative to the pure $CaCO_3$ salt.

Another source factor that may influence bioavailability is the presence of enhancers or inhibitors in the source itself. This is particularly significant in the instance of calcium added as a fortificant to foods natively absent any calcium. For example, calcium-citrate-malate as a fortificant in fruit juice shows superior absorbability in an apple juice matrix compared to the same complex salt in an orange juice matrix when tested in the same individuals, and poorer absorbability when tested as a pure salt in water (Table 5). In an animal model (not included in the studies examined here), Mehansho and others (1989) found good absorbability for CCM calcium in orange

Table 4—Comparative absorbability—salt-to-calcium carbonate (pure $CaCO_3$) quotient.

Salt/product	Quotient—all subjects	*N*
Research $CaCO_3$ product A	0.611	26
Research $CaCO_3$ product B	0.787	16
Commercial $CaCO_3$ product A	0.880	26
Commercial $CaCO_3$ product B	0.941	24
Commercial calcium citrate product	0.925	24

Table 5—Comparative absorbability—calcium-citrate-malate (CCM) in various beverage matrixes.

Beverage matrix	Mean *absFx*	*N*
CCM in water	0.2784	10
CCM in orange juice	0.3424	57
CCM in apple juice	0.4024	57

previously cited (USDHHS 2004), a substantial shortfall was noted between prevailing and recommended calcium intakes. The report stressed the need to do a better job of applying what we know toward the goal of improving the calcium nutriture of the U.S. population. Food fortification is a way to improve intake of a nutrient with generally recognized effectiveness. Hence better and more widespread utilization of this option for calcium by food manufacturers would seem to be indicated. Some barriers to effective fortification can be identified and need to be addressed. None would seem to be insuperable.

First there is the evident variation in bioavailability between products, highlighted in Table 2 and Figure 1. This can be solved in several ways, but preferably by developing a better understanding of the matrix factors that alter bioavailability. Additionally, bioavailability needs to be tested for each product, as it is difficult to predict, especially for calcium carbonate which, in most other respects, would appear to be a highly desirable fortificant.

The choice of a salt will inevitably depend to a great extent on compatibility with the manufacturing process, on taste effects, and on product stability characteristics. If these factors should dictate choice of a less bioavailable salt, confirmed by testing, the relatively lower absorbability can generally be offset by the simple device of fortifying to a higher level. The focus in all such fortification strategies should be on the quantity of the fortificant *absorbed*, not the quantity *added*. Initially, this may create some regulatory problems, but it seems to us that no other approach makes sense.

Related to this matter of bioavailability is another quality-related issue. In beverages, such as soy "milk" and some fortified orange juices, it has been shown that the fortificant tends to settle to the bottom of the carton (Heaney and others 2005a, Heaney and Rafferty 2006). Even vigorous shaking was not sufficient to resuspend the calcium salt in some products. Here bioavailability is moot, as it is ingestion itself that is compromised. In all such instances, the labeled content, while technically accurate, is irrelevant and will likely be misleading to consumers.

Second, and of some contemporary interest, is the issue of whether or not the added calcium will confer a net benefit. The report from the Women's Health Initiative (WHI) of a small increase in kidney stones in women receiving large calcium supplement doses (Jackson and others 2006) has resulted in some cooling of consumer interest in calcium. That reaction is almost surely inappropriate, but needs addressing nonetheless. It is important to understand that the character of the stones reported in WHI has not been identified and that stones were not a planned outcome variable in WHI. Hence, the observation may well be spurious. It is important also to recall that calcium intakes in WHI, in the supplemented arm, were nearly twice currently recommended values, while the purpose of any proper fortification strategy would be to bring individuals up from low intakes to recommended levels, not to exceed them. Finally, it is important also to view the WHI report in the context of the totality of the evidence. In the only published randomized controlled trial of calcium intake in stone-formers, a diet providing calcium at recommended levels resulted in 50% fewer stones than did a calcium-restricted diet (Borghi and others 2002). This finding is concordant with other data showing reduced stone risk as calcium intake rises from low to currently recommended levels (Curhan and others 1993). (The reason is simply that unabsorbed calcium in the

Finally, it should be noted that a significant nonsource factor affecting calcium absorption is the vitamin D status of the individual. It has long been recognized that vitamin D is necessary for the active transport of calcium across the intestinal mucosa. Only recently, however, has the vitamin D status that fully optimizes calcium absorption been identified and quantified. Serum 25-hydroxyvitamin D concentration (25OHD) is the accepted functional indicator of vitamin D status. Heaney has shown that intestinal calcium absorption improved by 68% when serum 25OHD was raised from 50 to 80 nmol/L in postmenopausal women (Heaney and others 2003). While both values fall within the current laboratory reference range for "normal" serum 25OHD status, these results indicate that improving vitamin D status up to repletion is important for fully optimal calcium absorption efficiency.

Recently, it has been realized that vitamin D status of the U.S. population is at least as insufficient as that of its calcium intake, and hence there is beginning to be interest in vitamin D fortification of suitable foods, as well. While fortification with vitamin D seems a sound strategy for many reasons, the added vitamin D is biologically inactive and does not produce an acute calcium absorptive enhancement effect. Dietary vitamin D must first be absorbed, and then undergo a series of hydroxylations, first in the liver and second in the kidney, to produce the active form of the vitamin that is the regulator of calcium absorption. Vitamin D, as an additional fortificant to a calcium-fortified food or beverage, while doubtless contributing to the improvement or maintenance of the recipient's serum 25OHD status, does not itself directly influence the absorption of the calcium contained in the product. Vitamin D does not, therefore, have to be present in the calcium source in order to insure calcium absorption.

Additional Notes about Effective Calcium Fortification

As already stated, the decision about which calcium source to use in a food or beverage formulation is related to ease of use in that application, taste effects, and stability in the finished food or beverage. But also the decision is based on overall cost and desired health claims. In regard to health claims, in general, calcium is best absorbed by the body when consumed in smaller amounts, taken several times throughout the day. Therefore, added calcium is probably most effective at fortification levels up to 30% DV (daily value), that is, 300 mg per serving. The associated health claims are:

- Foods containing 10% of the calcium DV, when compared to a standard serving size of a similar food, can say they are "Calcium Enriched," "Calcium Fortified," or have "More Calcium."
- Foods containing 10% to 19% of the calcium DV can say "Contains Calcium," "Provides Calcium," or is a "Good Source of Calcium."
- Foods containing 20% or more of the calcium DV can be listed as "High in Calcium," "Rich in Calcium", or an "Excellent Source of Calcium."

In regard to ease of use in an application, calcium carbonate is often used in items where clarity or dry and chalky mouthfeel would likely not be noticeable, such as food bars and cereal. Because calcium carbonate is the least costly calcium source, opaque meal replacement beverages and soy beverages also become a vehicle for this salt, especially in its micronized forms. This approach, however, works best when stabilizers and ingredients to reduce interaction with protein (when present) are employed to keep this insoluble

r a calcium that either can be soluble at a certain pH, such as calum citrate, or be soluble in a broad pH and concentration range. ne latter functionality moves the calcium choices primarily into ctate, lactate gluconate, and gluconate salts of calcium because her highly soluble forms of calcium, such as calcium chloride, ave undesirable taste acceptance at usages over 10% DV. Calcium marate would appear to be useful for clear beverages for taste and lubility, but dissolution is significantly slower than the lactate or ctate-gluconate salts, and solubility in cold water is lower as well. nally, concentrated slurries or syrups are difficult or impossible ith calcium fumarate while achievable with lactates and lactate uconates.

Conclusions

Despite more than 25 y of awareness of the importance of calcium to health, and 2 decades of U.S. manufacturers' launching calcium fortified foods, the mean U.S. calcium intakes remain boptimal. More widespread food fortification with calcium, well ecuted, offers the promise of effectively dealing with that problem virtually no cost and essentially no risk.

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Food Antioxidant Capacity

T. SUN AND S.A. TANUMIHARDJO

ABSTRACT: Many methods are available for determining food antioxidant capacity, which is an important topic in food and nutrition research and marketing. However, the results and inferences from different methods may vary substantially because each complex chemical reaction generates unique values. To get a complete and dynamic picture of the ranking of food antioxidant capacity, relative antioxidant capacity index (RACI), a hypothetical concept, is created from the perspective of statistics by integrating the antioxidant capacity values generated from different *in vitro* methods. RACI is the mean value of standard scores transformed from the initial data generated with different methods for each food item. By comparing the antioxidant capacity of 20 commonly consumed vegetables in the U.S. market that were measured with 7 chemical methods, we demonstrated that the RACI correlated strongly with each method. The significant correlation of RACI with an independent data set further confirmed that RACI is a valid tool to assess food antioxidant capacity. The key advantage of this integrated approach is that RACI is in a numerical scale with no units and has consistent agreement with chemical methods. Although it is a relative index and may not represent a specific antioxidant property of different food items, RACI provides a reasonably accurate rank of antioxidant capacity among foods. Therefore, it can be used as an integrated approach to evaluate food antioxidant capacity.

Keywords: antioxidant capacity, electron transfer, hydrogen atom transfer, vegetables

Introduction

Antioxidants and antioxidant capacity of food, nutraceuticals, botanicals, and other dietary supplements have recently attracted the attention of the industry, scientists, and consumers because of potential health benefits (Verlangieri and others 1985). Antioxidants in food include several classes: (1) simple phenols and phenolic acids, (2) flavonoids, and (3) others such as β-carotene, lutein, α-tocopherol, and ascorbic acid. Each class of antioxidants has its own unique chemical properties. Phenolic compounds have an aromatic ring with one or more hydroxyl substituents, or functional derivatives (for example, esters, methyl ethers, and glycosides). Flavonoids include anthocyanidins, flavonols, flavones, isoflavones, catechins, and flavanones (Herrmann 1988). The characteristic structure of a flavonoid is a diphenylpropane (C_6-C_3-C_6) (Hertog and others 1992). In nature, flavonoids usually occur as glycosides with the 3rd position of the C ring commonly connected to the glycosyl group (Finotti and Di Majo 2003). Carotenoids, for example, β-carotene and lutein, are pigments found in many fruits and vegetables. α-Tocopherol, or vitamin E, is a fat-soluble vitamin found in plant oil. Ascorbic acid, or vitamin C, is a water soluble antioxidant found in citrus fruits.

Many evaluation methods for antioxidant capacity have been developed. The merits and disadvantages of these methods have been fully discussed in several reviews (Halliwell and others 1995; Frankel and Meyer 2000; Prior and others 2005; Roginsky and Lissi 2005; MacDonald-Wicks and others 2006). According to the chemical reaction used, methods to measure antioxidant capacity can be mainly grouped into 2 classes: hydrogen atom transfer (HAT) and electron transfer (ET) based methods (Huang and others 2005). HAT methods measure the ability of an antioxidant to quench free radicals by hydrogen donation. In most HAT methods, antioxidants and a probe compete for thermally generated peroxyl radicals and the quantitation is derived from the kinetic curves after monitoring the competitive reaction kinetics. HAT methods include oxygen radical absorbance capacity (ORAC), total radical-trapping antioxidant parameter (TRAP), and inhibition of auto-oxidation of induced low-density lipoprotein (LDL). ET methods measure the ability of a potential antioxidant to transfer 1 electron to reduce radicals, metals or carbonyls, which use the color change of the oxidant as the endpoint indicator. Examples of ET methods include 2, 2′-azinobis-(3-ethylbenzothiazoline-6-sulfonic acid) (ABTS), ferric reducing antioxidant power (FRAP), 2, 2′-diphenyl-l-picrylhydrazyl (DPPH), and cupric reducing antioxidant capacity (CUPRAC) methods (Huang and others 2005).

Because multiple reaction mechanisms and different phase locations are usually involved in measuring the antioxidant capacity of a complex food system, there is no simple universal method by which "total antioxidant capacity" can be measured accurately and quantitatively (Frankel and Meyer 2000; Niki and Noguchi 2000; Niki 2002; Sanchez-Moreno 2002; Huang and others 2005; Prior and others 2005; MacDonald-Wicks and others 2006). Because many methods are available and are being used by different research groups, it is difficult to compare the results of food antioxidant capacity between studies. The food and nutraceutical industries cannot perform strict quality control on antioxidant products. Reviews or critiques to standardize methods or point out problems have been published (Frankel and Meyer 2000; Niki 2002; Sanchez-Moreno 2002; Prior and others 2005; MacDonald-Wicks and others 2006). The consensus is that multiple methods, based upon different reaction mechanisms, should be used. Given the diversity of food antioxidants and complex reactions involved in the measurement of antioxidant capacity, multiple methods are suggested as "standard" to evaluate food antioxidant capacity. However, the

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July 11, 2006

FDA Allows Third Nutrient Content Claim Notification for Specific Omega-3 Fatty Acids Under FDAMA Authoritative Statement Procedure

Between 2004 and 2006, companies filed three notifications with FDA regarding nutrient content claims for the omega-3 fatty acids docosahexaenoic acid (DHA), eicosapentaenoic acid (EPA) and alpha-linolenic acid (ALA) in the labeling of conventional foods and dietary supplements.[1] These claims are based upon authoritative statements by the Institute of Medicine (IOM) of the National Academy of Sciences (NAS), and have been allowed under the notification provision established by the FDA Modernization Act of 1997 (FDAMA). The claims are now available for any product meeting the criteria set forth in the notifications, as described below.

I. Basis for Notifications

FDAMA amended the Federal Food, Drug, and Cosmetic Act (FDCA) to allow manufacturers and distributors to use health claims or nutrient content claims in food and dietary supplement labeling if such claims are based on current, published, authoritative statements from certain federal scientific bodies, as well as from the NAS. Before such claims may be used in labeling, a notification must be submitted to FDA demonstrating that the statement upon which the claims rely is an authoritative statement meeting the criteria set forth in the FDAMA amendments. If FDA does not object to the notification within 120 days, the claims are deemed authorized. The submitter and any other manufacturer or distributor may then use the claims in accordance with the criteria set forth in the notification. FDA can subsequently overturn the claim, but must issue a regulation or obtain a court order to do so.

While all three notifications were based upon authoritative statements made by the IOM in its September 5, 2002 report, *Dietary Reference Intakes: Energy, Carbohydrate, Fiber, Fat, Fatty Acids, Cholesterol, Protein and Amino Acids* (IOM Macronutrients Report), each proposed slightly different claims and qualifying criteria, which are summarized below.

II. ALA

Both the Three Seafood Companies Notification and the Martek Notification addressed ALA claims, delineating criteria for "Good source," "Excellent source," and "More" claims.[2] For ALA, the claims criteria under the Three Seafood Companies Notification are more lenient.

[1] The first notification was submitted on January 16, 2004, by Alaska General Seafoods, Ocean Beauty Seafoods, Inc., and Trans-Ocean Products, Inc. (Three Seafood Companies Notification). The second was submitted on January 21, 2005, by Martek Biosciences Corporation (Martek Notification). The third was submitted on December 9, 2005 by Ocean Nutrition Canada, Ltd. (Ocean Nutrition Notification).

[2] Under all three Notifications, established synonyms for "good source," "excellent source," and "more" may be used.

A. Three Seafood Companies Notification[3]

The Three Seafood Companies Notification was based on a population-weighted average adequate intake (AI) level for ALA of 1.3 g/day, and established the following claim criteria:

- Good source is between 130 and 260 mg ALA per RACC;
- Excellent source is 260 mg or more ALA per RACC; and
- More is at least 130 mg more ALA per RACC than the reference food.

All claims must state "omega-3" before or after "ALA", or in parentheses, such as "(an omega-3)". Good source and excellent source claims must be accompanied by one of the following statements:

"Contains [x] mg of ALA per serving, which is [x]% of the Daily Value for ALA (1.3 g)."

or

"Contains [x]% of the Daily Value for ALA per serving. The Daily Value for ALA is 1.3g."

"More" claims must be accompanied by:

"[x]% (10% or greater) more of the Daily Value of ALA per serving than [reference food]. This product contains [x] mg ALA omega-3 per serving, which is [x]% of the Daily Value for ALA omega-3 (1.3 g). [Reference food] contains [x] mg ALA omega-3 per serving."

B. Martek Notification

The Martek Notification was based on an AI for ALA of 1.6 g/day, which is the AI for adult males set forth in the IOM Macronutrients Report. The Martek Notification established the following claim criteria:

- Good source is between 160 and 320 mg ALA per RACC;
- Excellent source is 320 mg or more ALA per RACC; and
- More is at least 160 mg more ALA per RACC higher than the reference food.

It is not necessary to use the term "omega-3" in these claims. Good source and excellent source claims must be accompanied by one of the following statements:

"Contains [x] mg of ALA per serving, which is [x] % of the 1.6g Daily Value for ALA."

"More" claims must be accompanied by:

"Contains [x] % more of the Daily Value of ALA per serving than [reference food]. This product contains [x] mg ALA, which is [x] % of the Daily Value for ALA (1.6 g)."

[3] The Three Seafood Companies Notification was described in detail in Covington & Burling LLP's July 28, 2004 client alert.

III. DHA

Both the Three Seafood Companies Notification and the Martek Notification addressed DHA, and both established only "excellent source" claims for this nutrient. For DHA, the claims criteria under the Martek Notification are more lenient.

A. Three Seafood Companies Notification

The Three Seafood Companies Notification relied upon an AI for DHA of 130g/day, and required products to contain at least 130 mg DHA per RACC – the entire AI for DHA – in order to bear "excellent source of DHA" claims. This approach differs from FDA regulatory requirements for excellent source claims generally, which permit such claims to be made on products containing 20% of the Daily Value (DV), per RACC, of the nutrient for which the claim is made.

All claims must contain "omega-3" before or after DHA, or in parentheses, such as "(an omega-3)". The claims must be accompanied by one of the following statements:

"Contains [x] mg of DHA per serving, which is [x]% of the Daily Value for DHA (130 mg)."

or

"Contains [x]% of the Daily Value for DHA per serving. The Daily Value for DHA is 130 mg."

B. Martek Notification

The Martek Notification established a qualifying level for "excellent source of DHA" of at least 32 mg DHA per RACC. This is based on 20% of a 160 mg/d DHA AI, and therefore follows the traditional FDA regulatory requirement for "excellent source" claims.

All claims must contain "omega-3" before or after DHA, or in parentheses, such as "(an omega-3)". Excellent source claims must be accompanied by the following statement:

"Contains [x] mg of DHA per serving, which is [x] % of the 160 mg Daily Value for DHA."

IV. EPA

Only the Three Seafood Companies Notification addressed claims for EPA alone, and established criteria for only "excellent source of EPA" claims. As with DHA claims under this Notification, "excellent source of EPA" claims are based upon an AI for EPA of 130g/day, and products must contain at least 130 mg EPA per RACC – the entire AI for EPA – in order to bear these claims.

All claims must contain "omega-3" before or after EPA, or in parentheses, such as "(an omega-3)". The claims must be accompanied by one of the following statements:

"Contains [x] mg of EPA per serving, which is [x]% of the Daily Value for EPA (130 mg)."

or

"Contains [x]% of the Daily Value for EPA per serving. The Daily Value for EPA is 130 mg."

V. DHA and EPA in Combination

Only the Ocean Nutrition Canada Notification addressed claims for DHA and EPA in combination[4]. That Notification established only excellent source claims for this combination, with a qualifying level of at least 32 mg EPA and DHA combined per RACC.

All claims must contain "omega-3" before EPA and DHA. Excellent source claims, such as, "Excellent source of Omega 3 EPA and DHA," must be accompanied by the following statement:

> "Contains [x] mg of EPA and DHA combined per serving, which is [x] % of the 160 mg Daily Value for a combination of EPA and DHA."

* * *

General criteria for nutrient content claims must also be satisfied when using any of the foregoing claims. Covington & Burling LLP is happy to provide counsel on the use of these nutrient content claims for specific omega-3 fatty acids.

* * *

This information is not intended as legal advice, which may often turn on specific facts. Readers should seek specific legal advice before acting with regard to the subjects mentioned herein.

If you have any questions concerning the material discussed in this client alert, please contact the following members of our Food & Drug practice group:

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[4] Under the Three Seafood Companies Notification, where a product contains enough DHA and EPA to make individual "excellent source" claims for each nutrient, it appears plausible to combine the claims into one statement. That is, where the product contains 130 mg DHA and 130 mg EPA, it seems possible to make claims such as "High in DHA and EPA omega-3s" and "Contains [x]% of the Daily Value for DHA and [x]% of the Daily Value for EPA per serving. The Daily Value for DHA and EPA is 130 mg each."

CODEX ALIMENTARIUS

Directrices sobre Etiquetado Nutricional

CAC/GL 2-1985

Paola Juárez
Guatemala, 23 septiembre de 2009

Nutrientes a declarar en todos los alimentos

- Voluntario
  - Valor energético, proteínas, carbohidratos disponibles y grasas
- Obligatorio
  - Nutriente-propiedad declarada
    - Carbohidratos Cantidad/tipo azúcares, almidón, fibra dietética
    - Ácidos grasos/ Colesterol AGS, AGM, AGP y colesterol La legislación nacional puede exigir *-trans*
  - Nutriente importante para mantener un buen estado nutricional Legislación o directrices dietéticas nacionales
    - Vitaminas y Minerales RDI, > 5 % RDI por porción, 100 ml o g y/o nutricionalmente importantes a nivel nacional
    - Producto/norma de Etiquetado Codex tendrá precedencia sin contradicción

- Valor energético kJ y kcal
- Carbohidratos disponibles y grasas g
- Proteína (% N * 6.25) g Opcional: % VRN
- Vitaminas y Minerales Sistema Métrico y/o % VRN

→ 100 g ó 100 ml ó envase (1 porción) + por porción (No. de porciones/envase

→ Solamente por porción (No. de porciones/envase

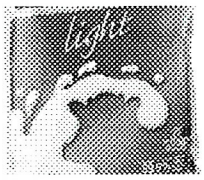
Ácidos grasos

Contenido total de grasa		...	g
de las cuales	ácidos grasos saturados	...	g
	ácidos grasos – trans	...	g
	ácidos grasos monoinsaturados	...	g
	ácidos grasos poliinsaturados	...	g
Colesterol		...	mg

Valores de referencia de nutrientes

[illegible]	(g)	50
[illegible]	(µg)	800[a]
[illegible]	(µg)	5[b]
[illegible]	(mg)	60
[illegible]	(mg)	1.4
[illegible]	(mg)	1.5
[illegible]	(mg)	10[c]
[illegible]	(mg)	2
[illegible]	(µg)	200
[illegible]	(µg)	1
[illegible]	(mg)	800
[illegible]	(mg)	300
[illegible]	(mg)	14
[illegible]	(mg)	15
[illegible]	(µg)	150[d]
[illegible]	valor no establecido	
[illegible]	valor no establecido	

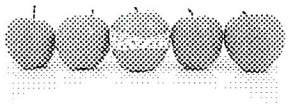
Declaraciones de propiedad respecto al contenido de nutrientes



Paola Juárez
Guatemala, 30 de septiembre de 2009

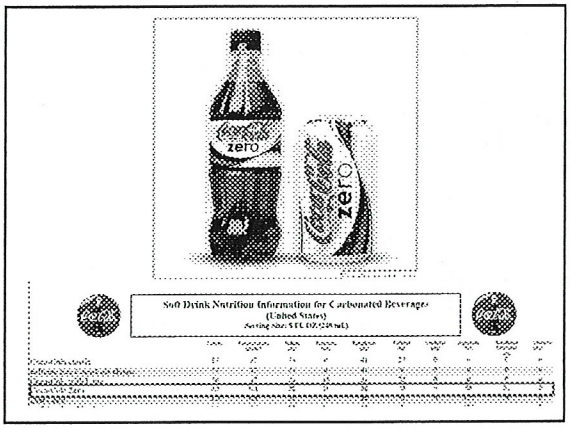
Respecto al contenido de nutrientes
Nutrient Content Claims

Nivel de nutrientes en los alimentos
No están permitidas otras declaraciones



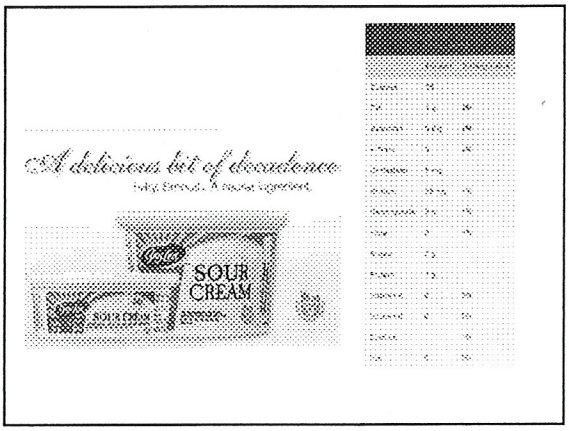
FREE, "zero", "No", "Without", "Trivial source of", "Negigible source of", "Dietarily Insignificant source of"

Nutriente	FDA	CODEX "Exento" "libre de" (No más de)
Calorías	< 5 cal/CR y porción, "No Salt Added", "Unsalted"	4 kcal/100 g
Grasa Total	< 0.5 g/CR y porción	0.5 g/100 g ó ml
Grasa saturada	< 0.5 g AGS, AGT/CR y porción	0.1 g/100 g ó ml
Colesterol	≤ 2 mg/CR y porción	0.005 g/100 g ó ml, 1.5 g AGS/100 g, 0.75 g AGS/100 ml y 10 % de energía de grasa saturada
Sodio	< 5 mg/CR y porción	0.005 g/100 g
Azúcares	< 0.5 g/CR y porción	0.5 g/100 g ó ml



LOW "Litle", "Few" for calories, "Contains a small amunt of", "Low Source of"

Nutriente	FDA	CODEX (No más de, Comparativas)
Calorías	≤ 40 cal/CR y 50 g/ CR es pequeña	Bajo contenido → 40 kcal/100 g ó 20 kcal/100 ml
Grasa Total	≤ 3 g/CR y 50 g/CR es pequeña "_% Fat Free"	Bajo contenido → 3 g/100 g ó 1.5 g/100 ml
Grasa saturada	≤ 1 g/CR y 15 % cal AGS	Bajo contenido → 1.5 g/100 g ó 0.75 g/100 ml y 10 % de energía
Colesterol	≤ 20 mg/CR y 50 g/CR es pequeña	Bajo contenido → 0.02 g/ 100 g ó 0.01 g/100 ml
Sodio	≤ 140 mg/CR y 50 g/CR es pequeña "Very low sodium": ≤ 35 mg/CR y 50 g/CR es pequeña	Bajo contenido → 0.12 g/100g Contenido muy bajo → 0.04 g/100 g

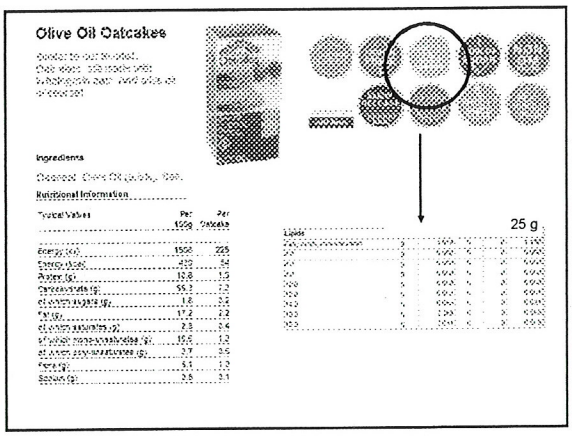


REDUCED/LESS "Lower", "Fewer" for calories, "Modified" statement of identity

25 %/apropiada CR en relación al alimento de referencia

Reference food may not be "Low Calorie, ..."

CODEX reducido ≡ ligero



Comentarios

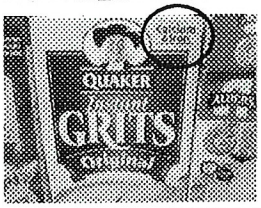
Nutriente	FDA
Calorías	Light o Lite ≥ 50 % grasas/50 % de apropiada RC, <50 % grasas/50 % de apropiada RC o 1/3 de RC
Grasa Total	Light
Grasa saturada	> 2 mg colesterol/RC ó > 3 g de GT ó 0.5 g GT /RC "Sat Fat Free" →declarar al lado declaración
Colesterol	2 g AGS/RC →declarar al lado GT si 13 g/RC
Sodio	"Light" (para productos reducidos en sodio) → "Low calorie" + "Low Fat" + sodium reduced 50% "Light in sodium", "Lightly salted → Reducido 50 %/RC
Azúcares	"No Added Sugars", "Without Added Sugars", "Unsweetened", "No Added Sweeteners"→ si no se agregaron durante el proceso Las declaraciones no incluye a los polialcoholes
Cuando los niveles exceden	→ 13 g GT, 4 g ACS, 60 mg Col, 480 Na/RC, porción, RC pequeñas, 50 g Ej. "See nutrition information for _ content"

"High", "Rich In", "Excellent Source Of"

≥ 20 % DV/RC

"Good Source", "Contains", "Provides"

10-19 % DV/RC

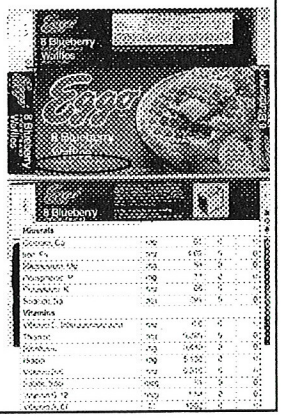


CODEX

Proteína	Contenido básico	10% VRN/100g, 5% VRN/100 ml 5% VRN/100 kcal, 10% VRN/porción
	Contenido alto	2 x Contenido básico
Vitaminas y Minerales	Contenido básico	15 % VRN/100 g, 7.5 % VRN/100 ml 5 % VRN/100 kcal, 15% VRN/porción
	Contenido alto	2 X Contenido básico

"More", "Fortified", "Eriched", "Added", "Extra", "Plus"

≥ 10 % DV/RC→ Vitaminas, minerales, proteína, fibra dietética y potasio.



LEAN Mariscos → ≤ 10 g GT, 4.5 g AGS, 95 mg Colesterol/RC y 100 g y por porción

EXTRA LEAN Mariscos → < 5 g GT, 2 g AGS, 95 mg Colesterol/RC y 100 g y por porción

High Potency

→Vitaminas o Minerales 100% RDI/RC

Modified

"Modified cheesecake contains, 35 % less fat than our regular cheesecake"

Saludables

Health

CODEX Directrices Dietéticas o Regímenes Saludables

Reducción de riesgos de enfermedades,

No. Dx., cura,mitigación o Tx. de una enfermedad

Es necesario que la FDA las evalúe

- Calcio y osteoporosis
- Sodio e Hipertensión
- Grasa dietética y Cáncer
- Grasa saturada dietética y colesterol y riesgo de enfermedad coronaria
- Fibra contenida en granos, frutas y vegetales y cáncer
- Frutas, vegetales y granos que contienen fibra, particularmente fibra soluble y riesgo de enfermedades coronarias
- Frutas y vegetales y Cáncer
- Folato y Defectos del Tubo Neural
- Carbohidratos no cariogénicos dietéticos edulcorantes y Caries dentales
- Riesgo de enfermedades coronarias
- Proteína de soya y riesgo de enfermedades coronarias
- Esteroles de plantas y riesgo de enfermedades coronarias
- Alimentos con granos enteros y riesgo de enfermedades cardíacas y ciertos cánceres
- Potasio y riesgo de presión alta
- Agua fluorada y reducción del riesgo de caries dentales
- Grasa saturada, colesterol y grasa *Trans* y reducción de riesgo de enfermedades cardíacas

Declaraciones saludables cualitativas

- Nueces & enfermedad cardíaca
- Omega-3 & Enfermedad coronaria
- Ácidos grasos monoinsaturados del aceite de oliva & enfermedad coronaria
- Té verde & cáncer
- Tomates y/o salsa de tomate & Cánceres de Próstata, Ovarios, Gástricos y Páncreas
- Ácidos grasos insaturados del aceite de canola y reducción del riesgo de enfermedades coronarias
- Aceite de maíz y productos que contengan aceite de maíz y Reducción del riesgo de enfermedades cardíacas

CFSAN/Office of Nutrition, Labeling, and Dietary Supplements
April 2008

Guidance for Industry

A Food Labeling Guide

XIV. Appendix F: Calculate the Percent Daily Value for the Appropriate Nutrients

Contains Nonbinding Recommendations

There are two sets of reference values for reporting nutrients in nutrition labeling: 1) Daily Reference Values (DRVs) and 2) Reference Daily Intakes (RDIs). These values assist consumers in interpreting information about the amount of a nutrient that is present in a food and in comparing nutritional values of food products. DRVs are established for adults and children four or more years of age, as are RDIs, with the exception of protein. DRVs are provided for total fat, saturated fat, cholesterol, total carbohydrate, dietary fiber, sodium, potassium, and protein. RDIs are provided for vitamins and minerals and for protein for children less than four years of age and for pregnant and lactating women. In order to limit consumer confusion, however, the label includes a single term (i.e., Daily Value (DV)), to designate both the DRVs and RDIs. Specifically, the label includes the % DV, except that the % DV for protein is not required unless a protein claim is made for the product or if the product is to be used by infants or children under four years of age. The following table lists the DVs based on a caloric intake of 2,000 calories, for adults and children four or more years of age.

Food Component	DV
Total Fat	65 grams (g)
Saturated Fat	20 g
Cholesterol	300 milligrams (mg)
Sodium	2,400 mg
Potassium	3,500 mg
Total Carbohydrate	300 g
Dietary Fiber	25 g
Protein	50 g
Vitamin A	5,000 International Units (IU)
Vitamin C	60 mg
Calcium	1,000 mg
Iron	18 mg
Vitamin D	400 IU
Vitamin E	30 IU
Vitamin K	80 micrograms µg
Thiamin	1.5 mg
Riboflavin	1.7 mg
Niacin	20 mg
Vitamin B_6	2 mg
Folate	400 µg
Vitamin B_{12}	6 µg
Biotin	300 µg
Pantothenic acid	10 mg
Phosphorus	1,000 mg
Iodine	150 µg
Magnesium	400 mg
Zinc	15 mg
Selenium	70 µg
Copper	2 mg
Manganese	2 mg
Chromium	120 µg
Molybdenum	75 µg
Chloride	3,400 mg

order to calculate the % DV, determine the ratio between the amount of the nutrient in a serving of food and the DV for the nutrient. That is, divide either the actual (unrounded) quantitative ıount or the declared (rounded) amount (see next section) by the appropriate DV. When deciding whether to use the unrounded or rounded value, consider the amount that will provide the eatest consistency on the food label and prevent unnecessary consumer confusion. The nutrients in the table above are listed in the order in which they are required to appear on a label in cordance with 21 CFR 101.9(c). This list includes only those nutrients for which a DRV has been established in 21 CFR 101.9(c)(9) or a RDI in 21 CFR 101.9(c)(8)(iv).

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XVI. Appendix H: Rounding the Values According to FDA Rounding Rules

Contains Nonbinding Recommendations

The following table provides rounding rules for declaring nutrients on the nutrition label or in labeling:

Nutrient	Increment Rounding	Insignificant Amount
Calories Calories from Fat Calories from Saturated Fat	< 5 cal - express as 0 ≤50 cal - express to nearest 5 cal increment > 50 cal - express to nearest 10 cal increment	< 5 cal
Total Fat Saturated Fat *Trans* Fat Polyunsaturated Fat Monounsaturated Fat	< .5 g - express as 0 < 5 g - express to nearest .5g increment ≥5 g - express to nearest 1 g increment	< .5 g
Cholesterol	< 2 mg - express as 0 2 - 5 mg - express as "less than 5 mg" > 5 mg - express to nearest 5 mg increment	< 2 mg
Sodium Potassium	< 5 mg - express as 0 5 - 140 mg - express to nearest 5 mg increment > 140 mg - express to nearest 10 mg increment	< 5 mg
Total Carbohydrate Dietary Fiber	< .5 g - express as 0 < 1 g - express as "Contains less than 1 g" or "less than 1 g" ≥1 g - express to nearest 1 g increment	< 1 g
Soluble and Insoluble Fiber Sugars Sugar Alcohol Other Carbohydrate	< .5 g - express as 0 < 1 g - express as "Contains less than 1 g" or "less than 1 g" ≥1 g - express to nearest 1 g increment	< .5 g
Protein	< .5 g - express as 0 < 1 g - express as "Contains less than 1 g" or "less than 1 g" or to 1 g if .5 g to < 1 g ≥1 g - express to nearest 1 g increment	< 1 g
When declaring nutrients other than vitamins and minerals that have RDIs as a % DV	express to nearest 1% DV increment	< 1% DV
Vitamins & Minerals (express as % DV)	< 2% of RDI may be expressed as: (1) 2% DV if actual amount is 1% or more (2) 0 (3) an asterisk that refers to statement "Contains less than 2% of the Daily Value of this (these) nutrient(s)" (4) for Vit A, C, calcium, iron: statement "Not a significant source of _____ (listing the vitamins and minerals omitted)" ≤10% of RDI - express to nearest 2% DV increment > 10% - 50% of RDI - express to nearest 5% DV increment > 50% of RDI - express to nearest 10% DV increment	< 2% RDI
Beta-Carotene (express as % DV)	≤10% of RDI for vitamin A- express to nearest 2% DV increment > 10% - 50% of RDI for vitamin A- express to nearest 5% DV increment > 50% of RDI for vitamin A- express to nearest 10% DV increment	

express nutrient values to the nearest 1 g increment, for amounts falling exactly halfway between two whole numbers or higher (e.g., 2.5 to 2.99 g), round up g., 3 g). For amounts less than halfway between two whole numbers (e.g, 2.01 g to 2.49 g), round down (e.g., 2 g).

hen rounding % DV for nutrients other than vitamins and minerals, when the % DV values fall exactly halfway between two whole numbers or higher (e.g., 2.5 2.99), the values round up (e.g., 3 %). For values less than halfway between two whole numbers (e.g., 2.01 to 2.49), the values round down (e.g., 2%).

REFERENCE AMOUNTS CUSTOMARILY CONSUMED PER EATING OCCASION: INFANT AND TODDLER FOODS[1 2 3 4]

Product Category	Reference amount	Label statement[5]
Cereals, dry instant	??	1/3 cup (13 g)
Cereals, prepared, ready-to-serve	??g	———cup(s) (——— g)
Other cereal and grain products, or ready to eat e.g., ready to eat cereals, cookies, teething biscuits, and toasts.	7g for infants and 20g for toddlers for ready-to-eat cereals; 7g for all others.	(———cup(s) (———g) for ready-to-eat cereals; — piece(s) (——— g) for others
Dinners, desserts, fruits, vegetables, or soups, dry mix	15 g	——— tbsp(s) (——— g) or ———cup(s) (——— g)
Dinners, desserts, fruits, vegetables, or soups, ready-to-serve, junior type.	110 g	
Dinners, desserts, fruits, vegetables, or soups, ready-to-serve strained type.	60 g	———cup(s) (———g)
Dinners, stews or soups for toddlers, ready-to-serve	170 g	———cup(s) (———g)
Fruits for toddlers, ready-to-serve	125 g	———cup(s) (———g)
Vegetables for toddlers, ready-to-serve	70g	———cup(s) (———g)
Eggs/egg yolks, ready-to-serve	55 g	———cup(s) (———g)
Juices, all varieties	120 mL	4 fl oz (120 mL)

[1] These values represent the amount of food customarily consumed per eating occasion and were primarily derived from the 1977—1978 Nationwide Food Consumption Surveys conducted by the U. S. Department of Agriculture.
[2] Unless otherwise noted in the Reference amount column, the reference amounts are for the ready-to-serve or almost ready-to-serve form of the product (i.e., heat and serve, brown and serve). If not listed separately, the reference amou for the unprepared form (e.g., dry cereal) is the amount required to make one reference amount of the prepared form. Prepared means prepared for consumption (e.g., cooked).
[3] Manufacturers are required to convert the reference amount to the label serving size in a household measure most appropriate to their specific product using the procedures in 21 CFR 101.9(b).
[4] Copies of the list of products for each product category are available from the Division of Nutrition (HFF-260), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 200 C st. SW., Washington, DC 20204.
[5] The label statements are meant to provide guidance to manufacturers on the presentation of serving size information on the label, but they are not required. The term "piece" is used as a generic description of a discrete unit. Manufactu should use the description of a unit that is most appropriate for the specific product (e.g., sandwich for sandwiches, cookie for cookies, and bar for frozen novelties).

TABLE 2

REFERENCE AMOUNTS CUSTOMARILY CONSUMED PER EATING OCCASION: GENERAL FOOD SUPPLY[1 2 3 4]

Product Category	Reference amount	Label statement[5]
Bakery *Products*		
Biscuits, croissants, bagels, tortillas, soft bread sticks, soft pretzels, corn bread, hush puppies.	55 g	——— piece(s) (———g)
Breads (excluding sweet quick type), rolls	50 g	——— piece(s) (———g) for sliced bread and distinct pieces (e.g., rolls); 2 oz (56 g/ —-inch slice for unsliced bread
Bread sticks—see crackers		
Toaster pastries—see coffee cakes		
Brownies		
Cakes, heavy weight (cheese cake, pineapple upside-down cake, fruit, nut, and vegetable cakes with less than 35 percent of the finished weight as fruit, nuts, or vegetables; light weight cake with icing; Boston cream pie; cupcake; éclair; cream puff)[7].	40 g	——piece(s) (———g) for distinct pieces; fractional slice (——g) for bulk
	80 g	——piece(s) (———g) for distinct pieces (e.g., sliced or individually packaged products); ———fractional slice (———g) for large discrete units.
Cakes, light weight (angel food, chiffon, or sponge cake without icing or filling)[8]	55 g	——— piece(s) (———g) for distinct pieces (e.g., sliced or individually packaged products); ———fractional slice (———g) for large discrete units
Coffee cakes, crumb cakes, doughnuts, Danish, sweet rolls, sweet quick type breads, muffins, toaster pastries.	55 g	———piece(s) (———g) for sliced bread and distinct pieces (e.g., doughnut); 2 oz (56g/visual unit of measure) for bulk products (e.g., unsliced bread)
Cookies	30 g	——piece(s) (———g)
Crackers that are usually not used as snack, melba toast, hard bread sticks, ice cream cones	15 g	——piece(s) (———g)
Crackers that are usually used as snacks	30 g	——piece(s) (———g)
Croutons	7 g	——tbsp(s) (——g) or ——cup(s) (—— g);
French toast, pancakes, variety mixes	110 g prepared for french toast and pancakes; 10 g dry mix for variety mixes.	——piece(s) (——g) for large pieces
Grain-based bars with or without filling or coating, e.g., breakfast bars, granola bars, rice cereal bars	40 g	——piece(s) (——g); ———cup(s) (——g); for dry mix
		——piece(s) (——g)

pastries	123 g	——piece(s) (——g) for distinct pieces; ——fractional slice (——g) for large discrete units
Pie crusts	1/6 of 8 inch crust; 1/8 of 9 inch crust	1/6 of 8 inch crust (——g); 1/8 of 9 inch (——g)
Pizza crust	55 g	——fractional slice (——g)
Taco shells, hard	30 g	——shell(s) (——g)
Waffles	85 g	——piece(s) (——g)
Beverages		
Carbonated and noncarbonated beverages, wine coolers, water	240 mL	8 fl oz (240 mL)
Coffee or tea, flavored and sweetened	240mL prepared	8 fl oz (240 mL)
Cereals and Other Grain Products		
Breakfast cereals (hot cereal type), hominy grits	1 cup prepared; 40 g plain dry cereal; 55 g flavored, sweetened cereal	——cup(s) (——g)
Breakfast cereals, ready-to-eat, weighing less than 20 g per cup, e.g., plain puffed cereal grains.	15 g	——cup(s) (——g)
Breakfast cereals, ready-to-eat weighing 20 g or more, but less than 43 g per cup; high fiber cereals containing 28 g or more of fiber per 100 g.	30 g	——cup(s) (——g)
Breakfast cereals, ready-to-eat, weighing 43 g or more per cup; biscuit types.	55 g	——piece(s) (——g) for large distinct pieces (e.g., biscuit type); ——cup(s) (——g) for all others
Bran or wheat germ	15 g	——tbsp(s) (——g) or ——cup(s) (——g)
Flours or cornmeal	30 g	——tbsp(s) (——g) or ——cup(s) (——g)
Grains, e.g., rice, barley, plain	140 g prepared; 45 g dry	——cup(s) (——g)
Pastas, plain	140 g prepared; 45 g dry	——cup(s) (——g); ——piece(s) (——g) for large pieces (e.g., large shell) or 2 oz (56 g/visual unit of measure) for dry bulk products (e.g., lasagna or spaghetti noodles)
Pastas, dry ready-to-eat, e.g., fried canned chow mein noodles	25 g	——cup(s) (——g)
Starches, e.g., cornstarch, potato starch, tapioca, etc.	10 g	1 tbsp(8 g) for cornstarch; 1 tbsp (10 g) for tapioca; 1 tbsp (——g) for others
Stuffing	100 g	——cup(s) (——g)
Dairy Products and Substitutes		
Cheese, cottage	110 g	½ cup (105 g) for small curd; ½ cup (113 g) for large curd, low fat, or with fruit added; ½ cup (——g) for others
Cheese used primarily as ingredients, e.g., dry cottage cheese, ricotta cheese.	55 g	1/3 cup(48 g) for dry curd cottage cheese; ¼ cup (62 g) for ricotta cheese
Cheese, grated hard, e.g., Parmesan, Romano	5 g	1 tbsp(s) (5 g)
Cheese, all others except those listed as separate categories—includes cream cheese and cheese spread.	30 g	——piece(s) (——g) for distinct pieces; ——tbsp(s) (——g) for cream cheese and cheese spread; 1 oz (28 g/visual unit of measure) for bulk
Cheese sauce—see sauce category		
Cream or cream substitutes, fluid	15 mL	1 tbsp (15 mL)
Cream or cream substitutes, powder	2 g	1 tsp (2 g)
Cream, half & half	30 mL	2 tbsp (30 mL)
Eggnog	120 mL	½ cup (120 mL) or 4 fl oz (120 mL)
Milk, condensed, undiluted	30 mL	2 tbsp (30 mL)
Milk, evaporated, undiluted	30 mL	2 tbsp (30 mL)
Milk, milk-based drinks, e.g., instant breakfast, meal replacement, cocoa.	240 mL	1 cup (240 mL) or 8 fl oz (240 mL)
Shakes or shake substitutes, e.g., dairy shake mixes, fruit frost mixes	240 mL	1 cup (240 mL) or 8 fl oz (240 mL)
Sour cream	30 g	2 tbsp (30 g)
Yogurt	225 g	1 cup (——g)
Desserts		
Ice cream, ice milk, frozen yogurt, sherbet: all types, bulk and novelties (e.g., bars, sandwiches, cones).	½ cup-includes the volume for coatings and wafers for the novelty type varieties.	——piece(s) (——g) for individually wrapped or packaged products; ½ cup (——g) for others
Frozen flavored and sweetened Ice and pops, frozen fruit juices: all types, bulk and novelties (e.g., bars, cupso.	85 g	——piece(s) (——g) for individually wrapped or packaged products; ½ cup (——g) for others
Sundae	1 cup	1 cup (——g)
Custards, gelatin or pudding	½ cup	——piece(s) (——g) for distinct unit (e.g., individually packaged products); ½ cup (——g) for bulk
Dessert Toppings and Fillings		
Cake frostings or icings	35 g	——tbsp(s) (——g)
Other dessert toppings, e.g., fruits, syrups, spreads, marshmallow cream, nuts, dairy and nondairy whipped toppings.	2 tbsp	2 tbsp (——g)
Pie fillings	85 g	——cup(s) (——g)
Egg and Egg substitutes		
Egg mixtures, e.g., egg foo young, scrambled eggs, omelets	110 g	——piece(s) (——g) for discrete pieces; ——cup(s) (——g)

TABLE 2 ----Continued

REFERENCE AMOUNTS CUSTOMARILY CONSUMED PER EATING OCCASION: GENERAL FOOD SUPPLY[1 2 3 4]

Product Category	Reference amount	Label statement[5]
Eggs (all sizes)(9)	50 g	1 large, medium, etc. (—— g)
Egg substitutes	An amount to make 1 large (50 g) egg	—— cup(s) (—— g)
Fats and Oils		
Butter, margarine, oil, shortening	1 tbsp	1 tbsp (14 g) for butter, margarine, or oil; 1 tbsp (9 g) for whipped butter or margarine; 1 tbsp (13 g) for shortening
Butter replacement, powder	2 g	—— tsp(s) (—— g)
Dressings for salads	30 g	2 tbsp (—— g)
Mayonnaise, sandwich spreads, mayonnaise-type dressings	15 g	1 tbsp (14 g) for mayonnaise; 1 tbsp (15 g) for imitation mayonnaise, mayonnaise-type dressings or sandwich spread
Spray types	0.25 g	About —— seconds spray (—— g)
Fish, Shellfish, Game Meats[10], and Meat or Poultry Substitutes		
Bacon substitutes, canned anchovies,[11] anchovy pastes, caviar	15 g	—— piece(s) (—— g) for discrete pieces; —— tbsp(s) (—— g) for others
Dried, e.g., jerky	30 g	—— piece(s) (—— g)
Entrees with sauce, e.g., fish with cream sauce, shrimp with lobster sauce.	140 g cooked	—— cup(s) (—— g); 5 oz (140 g/visual unit of measure) if not measurable by cup
Entrees without sauce, e.g., plain or fried fish and shellfish, fish and shellfish cake	85 g cooked; 110 g uncooked[12]	—— piece(s) (—— g) for discrete pieces; —— cup(s) (—— g); —— oz (—— g/visual unit of measure) if not measurable by cup[13]
Fish, shellfish, or game meat[10], canned[1]	55 g	—— piece(s) (—— g) for discrete pieces; —— cup(s) (—— g)
Substitute for luncheon meat, meat spreads, Canadian bacon, sausages and frankfurters	55 g	—— piece(s) (—— g) for distinct pieces (e.g., slices, links); —— cup(s) (—— g); 2 oz (56 g/visual unit of measure) for nondiscrete bulk product
Smoked or pickled[11] fish, shellfish, or game meat[10]; fish or shellfish spread	55 g	—— piece(s) (—— g) for distinct pieces (e.g., slices, links); —— cup(s) (—— g); 2 oz (56 g/visual unit of measure) for nondiscrete bulk product
Substitutes for bacon bits—see miscellaneous category		
Fruits and Fruit Juices		
Candied or pickled[11]	30 g	—— piece(s) (—— g)
Dehydrated fruits—see snacks category		
Dried	40 g	—— piece(s) (—— g) for large pieces (e.g., dates, figs, prunes); —— cup(s) (—— g) for small pieces (e.g., raisins)
Fruits for garnish or flavor, e.g., maraschino cherries[11]	4 g	1 cherry (—— g)
Fruit relishes, e.g., cranberry sauce, cranberry relish	70 g	—— cup(s) (—— g)
Fruits used primarily as ingredients, avocado	30 g	See footnote 13
Fruits used primarily as ingredients, others (cranberries, lemon, lime)	55 g	—— piece(s) (—— g) for large fruits; —— cup(s) (—— g) for small fruits measurable by cup[13]
Watermelon	280 g	See footnote 13
All other fruits (except those listed as separate categories), fresh, canned, or frozen	140 g	—— piece(s) (—— g) for large fruits; —— cup(s) (—— g) for small fruits measurable by cup[13]
Juices, nectars, fruit drinks	240 mL	8 fl oz (240 mL)
Juices used as ingredients, e.g., lemon juice, lime juice	5 mL	1 tsp (5 mL)
Legumes		
Bean cake (tofu)[11], tempeh	85 g	—— piece(s) (—— g) for discrete pieces; 3 oz (84 g/visual unit of measure) for bulk products
Beans, plain or in sauce	130 g for beans in sauce or canned in liquid; 90 g for others	½ cup (—— g)
Miscellaneous category		
Baking powder, baking soda, pectin	1 g	¼ tsp (—— g)
Baking decorations, e.g., colored sugars and sprinkles for cookies, cake decorations	¼ tsp or 4 g if not measurable by teaspoon	—— piece(s) (—— g) for discrete pieces; ¼ tsp (—— g)
Batter mixes, bread crumbs	30 g	——tbsp(s) (—— g) or —— cup(s) (—— g)
Cooking wine	30 mL	2 tbsp (30 mL)
Drink mixers (without alcohol)	Amount to make 240 mL drink (w/out ice)	——fl oz (—— mL)
Chewing gum(9)	3 g	—— piece(s) (—— g)
Meat, poultry and fish coating mixes; seasoning mixes, dry, e.g., chili seasoning mixes, pasta salad seasoning mixes.	Amount to make one reference amount of final dish	——tsp(s) (—— g) or ——tbsp(s) (—— g)
Salad and potato toppers, e.g., salad crunchies, salad crispins, substitutes for bacon bits.	7 g	——tbsp(s) (—— g)

Salt, salt substitutes, seasoning salts (e.g., garlic salt).....	1 g.....	——tsp(s) (—— g); ——piece(s) (—— g) for discrete pieces (e.g., individually packaged products)
Spices, herbs (other than dietary supplements).....	¼ tsp or 0.5 g if not measurable by teaspoon	¼ tsp (—— g); —— piece(s) (—— g) if not measurable by teaspoons (e.g., bay leaf)
Mixed Dishes.....	.....	
Measurable with cup, e.g., casseroles, hash, macaroni and cheese, pot pies, spaghetti with sauce, stews, etc..	1 cup.....	1 cup (—— g)
Not measurable with cup, e.g., burritos, egg rolls, enchiladas, pizza, pizza rolls, quiche, all types of sandwiches.	140 g. add 55 g for products with gravy or sauce topping, e.g., enchilada with cheese sauce, crepe with white sauce[14].	—— piece(s) (—— g) for discrete pieces; ——fractional slice (—— g0 for large discrete units
Nuts and Seeds.....	.....	
Nuts, seeds, and mixtures, all types: sliced, chopped, slivered, and whole.	30 g.....	—— piece(s) (—— g) for large pieces (e.g., unshelled nuts); —— tbsp(s) (—— g) or —— cup(s) (—— g) for small pieces (e.g., peanuts, sunflower seeds)
Nut and seed butters, pastes, or creams.....	2 tbsp.....	2 tbsp (—— g)
Coconut, nut and seed flours.....	15 g.....	—— tbsp(s) (—— g)
Potatoes and Sweet Potatoes/Yams.....	.....	
French fries, hash browns, skins, or pancakes	70 g prepared; 85 g for frozen unprepared french fries	—— piece(s) (—— g) for large distinct pieces (e.g., patties, skins); 2.5 oz (70 g/ —— pieces) for prepared fries; 3 oz (84 g/ —— pieces) for unprepared fries
Mashed, candied, stuffed, or with sauce.....	140 g.....	—— piece(s) (—— g) for discrete pieces; —— cup(s) (—— g) for sliced or chopped products
Salads.....	.....	
Gelatin Salad.....	120 g.....	½ cup (120 g)
Pasta or potato salad.....	140 g.....	—— cup(s) (—— g)
All other salads, e.g., egg. Fish, shellfish, bean, fruit, or vegetable salads.	100 g.....	—— cup(s) (—— g)
Sauces, Dips, Gravies and Condiments.....	.....	
Barbecue sauce, hollandaise sauce, tartar sauce, other sauces for dipping (e.g., mustard sauce, sweet and sour sauce), all dips (e.g., bean dips, dairy-based dips, salsa).	2 tbsp.....	2 tbsp (—— g)
Major main entrée sauces, e.g., spaghetti sauce.....	125 g	½ cup (—— g)
Minor main entrée sauces (e.g., pizza sauce, pesto sauce), other sauces used as toppings (e.g., gravy, white sauce, cheese sauce), cocktail sauce.	¼ cup.....	¼ cup (—— g)
Major condiments, e.g., catsup, steak sauce, soy sauce, vinegar, teriyaki sauce, marinades.	1 tbsp.....	1 tbsp (—— g)
Minor condiments, e.g., horseradish, hot sauces, mustards, worcestershire sauce.	1 tsp.....	1 tsp (—— g)
Snacks.....	.....	
All varieties, chips, pretzels, popcorns, extruded snacks, fruit-based snacks (e.g., fruit chips,) grain-based snack mixes.	30 g.....	—— cup(s) (—— g) for small pieces (e.g., popcorn) —— piece(s) (—— g) for large pieces (e.g., large pretzels; pressed dried fruit sheet); 1 oz (28 g/visual unit of measure) for bulk products (e.g., potato chips)
Soups.....	.....	
All varieties.....	245 g.....	1 cup (—— g)
Sugars and Sweets.....	.....	
Baking candies (e.g., chips).....	15 g.....	—— piece(s) (—— g) for large pieces; —— tbsp(s) for small pieces; ½ oz (14 g/visual unit of measure) for bulk products(e.g., potato chips)
Hard candies, breath mints.....	2 g.....	—— piece(s) (—— g)
Hard candies, roll-type, mini-size in dispenser packages.....	5 g.....	—— piece(s) (—— g)
Hard candies, others.....	15 g.....	—— piece(s) (—— g) for large pieces; —— tbsp(s) (—— g) for "mini-size" candies measurable by tablespoon; ½ oz (14 g/visual unit of measure) for bulk products
All other candies.....	40 g.....	—— piece(s) (—— g); 1 ½ oz (42 g/visual unit of measure) for bulk products
Confectioner's sugar.....	30 g.....	¼ cup (30 g)
Honey, jams, jellies, fruit butter, molasses.....	1 tbsp.....	1 tbsp (—— g)
Marshmallows.....	30 g.....	—— cup(s) (—— g) for small pieces or —— piece(s) (—— g) for large pieces
Sugar.....	4 g.....	1 tsp (—— g); —— piece(s) (—— g) for discrete pieces (e.g., sugar cubes, individually packaged product)

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XII. Appendix D: Qualified Health Claims

Contains Nonbinding Recommendations

FDA will exercise enforcement discretion for qualified health claims when the claim meets all general requirements of 21 CFR 101.14, *except* for the requirements that the claim meet the significant scientific agreement standard and that the claim be made in accordance with an authorizing regulation. Other factors that FDA will consider in exercising enforcement discretion are listed in the following qualified health claim table.

Qualified Health Claims	Eligible Foods	Factors for Exercising Enforcement Discretion	Claim Statements
0.8 mg Folic Acid & Neural Tube Birth Defects Docket No. 1991N-100H 10/10/2000 enforcement discretion letter 04/03/2001 clarification letter ***Note:*** *there also is a folic acid/neural tube defect health claim authorized by regulation (see 21 CFR 101.79).*	Dietary supplements containing folic acid	The disclaimer (i.e., FDA does not endorse this claim...) is placed immediately adjacent to and directly beneath the claim (i.e., 0.8 mg folic acid ...), with no intervening material, in the same size, typeface, and contrast as the claim.	0.8 mg folic acid in a dietary supplement is more effective in reducing the risk of neural tube defects than a lower amount in foods in common form. FDA does not endorse this claim. Public health authorities recommend that women consume 0.4 mg folic acid daily from fortified foods or dietary supplements or both to reduce the risk of neural tube defects.
B Vitamins &	Dietary supplements	The disclaimer (i.e.,	As part of a well-

Vascular Disease Docket No. 1999P-3029 11/28/2000 enforcement discretion letter 05/15/2001 clarification letter	containing vitamin B6, B12, and/or folic acid	FDA evaluated the above claim...) must be immediately adjacent to and directly beneath the first claim (i.e., As part of a well-balanced diet...) with no intervening material that separates the claim from the disclaimer, and the second sentence must be in the same size, type face and contrast as the first sentence. Products that contain more than 100 percent of the Daily Value (DV) of folic acid (400 micrograms), when labeled for use by adults and children 4 or more years of age, must identify the safe upper limit of daily intake with respect to the DV. The folic acid safe upper limit of daily intake value of 1,000 micrograms (1 mg) may be included in parentheses. The claim does not suggest a level of vitamins B6, B12, and/or folic acid as being useful in achieving the claimed effect. Dietary supplements containing folic acid must meet the United States Pharmacopeia (USP) standards for disintegration and	balanced diet that is low in saturated fat and cholesterol, Folic Acid, Vitamin B6 and Vitamin B12 may reduce the risk of vascular disease. FDA evaluated the above claim and found that, while it is known that diets low in saturated fat and cholesterol reduce the risk of heart disease and other vascular diseases, the evidence in support of the above claim is inconclusive.

		dissolution, except that if there are no applicable USP standards, the folate in the dietary supplement shall be shown to be bioavailable under the conditions of use stated on the product label.	
Selenium & Cancer Docket No. 2002P-0457 02/21/2003 enforcement discretion letter 04/28/2003 clarification letter	Dietary supplements containing selenium	The disclaimer (i.e., Some scientific evidence suggests...) is placed immediately adjacent to and directly beneath the claim (i.e., Selenium may reduce the risk), with no intervening material, in the same size, typeface, and contrast as the claim itself The supplement does not recommend or suggest in its labeling, or under ordinary conditions of use, a daily intake exceeding the Tolerable Upper Intake Level established by the National Academy of Sciences/Institute of Medicine for selenium (400 micrograms per day). Paragraph 101.14(d)(2)(vii) requires that the dietary supplement bearing the claim meet the nutrient content claim definition for high (i.e., 20% or more of the daily value (DV) per RACC). 20% DV for selenium is 14 micrograms.	(1) Selenium may reduce the risk of certain cancers. Some scientific evidence suggests that consumption of selenium may reduce the risk of certain forms of cancer. However, FDA has determined that this evidence is limited and not conclusive. *or,* (2) Selenium may produce anticarcinogenic effects in the body. Some scientific evidence suggests that consumption of selenium may produce anticarcinogenic effects in the body. However, FDA has determined that this evidence is limited and not conclusive.

Antioxidant Vitamins & Cancer Docket No. 1991N-0101 04/01/2003 enforcement discretion letter	Dietary supplements containing vitamin E and/or vitamin C	The disclaimer (i.e., ...evidence is limited and not conclusive) is placed immediately adjacent to and below the claim, with no intervening material, in the same size, typeface, and contrast as the claim itself. The supplement does not recommend or suggest in its labeling, or under ordinary conditions of use, a daily intake exceeding the Tolerable Upper Intake Levels established by the Institute of Medicine for vitamin C (2000 mg per day) or for vitamin E (1000 mg per day). Paragraph 101.14(d)(2)(vii) requires that the food bearing the claim meet the nutrient content claim definition for *high* (i.e., 20% or more of the daily value (DV) per RACC). 20% DV for vitamin C is 12 mg; 20% DV for vitamin E is 6 IU.	(1) Some scientific evidence suggests that consumption of antioxidant vitamins may reduce the risk of certain forms of cancer. However, FDA has determined that this evidence is limited and not conclusive. *or,* (2) Some scientific evidence suggests that consumption of antioxidant vitamins may reduce the risk of certain forms of cancer. However, FDA does not endorse this claim because this evidence is limited and not conclusive. *or,* (3) FDA has determined that although some scientific evidence suggests that consumption of antioxidant vitamins may reduce the risk of certain forms of cancer, this evidence is limited and not conclusive.
Phosphatidylserine & Cognitive Dysfunction and Dementia Docket No. 2002P-0413 02/24/2003 enforcement discretion letter	Dietary supplements containing soy-derived phosphatidylserine	The disclaimer (i.e., Very limited and preliminary scientific research...) is placed immediately adjacent to and directly beneath the claim (i.e., Phosphatidylserine may reduce...), with no intervening material, in the same size, typeface,	(1) Consumption of phosphatidylserine may reduce the risk of dementia in the elderly. Very limited and preliminary scientific research suggests that phosphatidylserine may reduce the risk of dementia in the

05/13/2003 clarification letter 11/24/2004 updated letter		and contrast as the claim itself. The claim does not suggest a level of phosphatidylserine as being useful in achieving the claimed effect. The soy-derived phosphatidylserine used is of very high purity.	elderly. FDA concludes that there is little scientific evidence supporting this claim. *or,* (2) Consumption of phosphatidylserine may reduce the risk of cognitive dysfunction in the elderly. Very limited and preliminary scientific research suggests that phosphatidylserine may reduce the risk of cognitive dysfunction in the elderly. FDA concludes that there is little scientific evidence supporting this claim.
Nuts & Heart Disease Docket No. 2002P-0505 07/14/2003 enforcement discretion letter	(1) *Whole or chopped nuts* listed below that are raw, blanched, roasted, salted, and/or lightly coated and/or flavored; any fat or carbohydrate added in the coating or flavoring must meet the 21 CFR 101.9(f)(1) definition of an insignificant amount. (2) *Nut-containing products* other than whole or chopped nuts that contain at least 11 g of one or more of the nuts listed below per RACC. (3) Types of nuts eligible for this claim are restricted to	***Whole or chopped nuts*** Whole or chopped nuts do not need to comply with the total fat disqualifying level in 21 CFR 101.14(a)(4). Only walnuts do not need to comply with the requirement in § 101.14(e)(6) that the food contain a minimum of 10 percent of the Daily Value per RACC of vitamin A, vitamin C, iron, calcium, protein, or dietary fiber. Where the claim is used on whole or chopped nuts, the	Scientific evidence suggests but does not prove that eating 1.5 ounces per day of most nuts [such as *name of specific nut*] as part of a diet low in saturated fat and cholesterol may reduce the risk of heart disease. [See nutrition information for fat content.] *Note: The bracketed phrase naming a specific nut is optional. The bracketed fat content disclosure statement is applicable to a claim made for whole or chopped nuts, but not a claim*

	almonds, hazelnuts, peanuts, pecans, some pine nuts, pistachio nuts, and walnuts. Types of nuts on which the health claim may be based is restricted to those nuts that were specifically included in the health claim petition, but that do not exceed 4 g saturated fat per 50 g of nuts.	disclosure statement (see nutrition information...) must be placed immediately adjacent to and directly beneath the claim, with no intervening material, in the same size, typeface, and contrast as the claim itself. Nuts bearing the claim must comply with the 21 CFR 101.14(a)(4) saturated fat disqualifying level (4 g saturated fat per 50 g nuts). ***Nut-containing products*** Nut-containing products bearing the claim must comply with all the 21 CFR 101.14(a)(4) disqualifying levels which are 13 g total fat, 4 g saturated fat, 60 mg of cholesterol, and 480 mg of sodium per RACC. The claim applies only to types of nuts that do not exceed the 21 CFR 101.14(a)(4) disqualifying nutrient level for saturated fat (4 g saturated fat per 50 g nuts). Nut-containing products bearing the claim must comply with the 21 CFR	*made for nut-containing products.*

		101.62(c)(2) definition of a *low saturated fat food* and the 21 CFR 101.62(d)(2) definition of a *low cholesterol food.* Nut-containing products bearing the claim must comply with the 21 CFR 101.14(e)(6) requirement that the food contain a minimum of 10 percent of the Daily Value per RACC of vitamin A, vitamin C, iron, calcium, protein, or dietary fiber prior to any nutrient addition.	
Walnuts & Heart Disease Docket No. 2002P-029 03/09/2004 enforcement discretion letter	Whole or chopped walnuts	Walnuts do not need to comply with the total fat disqualifying level in 21 CFR 101.14(a)(4). Walnuts do not need to comply with the requirement in § 101.14(e)(6) that the food contain a minimum of 10 percent of the Daily Value per RACC of vitamin A, vitamin C, iron, calcium, protein, or dietary fiber. The disclosure statement about total fat content (i.e., See nutrition information for fat content) is placed immediately following the claim, with no intervening material, in the same	Supportive but not conclusive research shows that eating 1.5 ounces per day of walnuts, as part of a low saturated fat and low cholesterol diet and not resulting in increased caloric intake, may reduce the risk of coronary heart disease. See nutrition information for fat [and calorie] content. *Notes: The bracketed phrase "and calorie" is optional in that FDA does not intend for the presence or absence of such phrase to be a factor in whether it considers enforcement discretion for the use*

		size, typeface, and contrast as the claim itself.	*of the qualified health claim. FDA considered this additional information beneficial to consumers to heighten their awareness of the caloric contribution from walnuts and encourages companies to include it in product labeling.*
Omega-3 Fatty Acids & Coronary Heart Disease Docket No. 2003Q-0401 09/08/2004 enforcement discretion letter - Wellness Petition 09/08/2004 enforcement discretion letter - Martek Petition	Conventional foods and dietary supplements that contain EPA and DHA omega-3 fatty acids.	Dietary supplements should not recommend or suggest in their labeling a daily intake exceeding 2 grams of EPA and DHA **Total fat content** Dietary supplements that weigh 5 g or less per RACC (RACC for dietary supplement is labeled serving size) are exempted from the total fat disqualifying level, but if dietary supplements that weigh 5 g or less per RACC exceed the total fat disqualifying level (13.0 g per 50 g) the disclosure statement (i.e., "See nutrition information for total fat content") must be placed immediately adjacent to the health claim. Dietary supplements that weigh more than 5 g per RACC must not exceed the total fat	Supportive but not conclusive research shows that consumption of EPA and DHA omega-3 fatty acids may reduce the risk of coronary heart disease. One serving of [Name of the food] provides [ ] gram of EPA and DHA omega-3 fatty acids. [See nutrition information for total fat, saturated fat, and cholesterol content.] *Note: Dietary supplements may declare the amount of EPA and DHA per serving in "Supplement Facts," instead of making the declaration in the claim.*

			disqualifying level (13.0 g per RACC and per 50 g if RACC is ≤ 30 g or ≤ 2 tbsp). (See "Qualified Health Claims Subject to Enforcement Discretion, Omega-3 Fatty Acids and Coronary Heart Disease" and the enforcement discretion letter for Omega-3 Fatty Acids and Coronary Heart Disease) Fish (i.e., "products that are essentially all fish") may not exceed 16.0 g total fat per RACC. Fish with a total fat content greater than 13.0 g per RACC must include "See nutrition information for total fat content" with the health claim. The "products that are essentially all fish" include fish without any added ingredients and fish with a small amount of added fat or carbohydrate that meets the definition of an insignificant amount in 21 CFR 101.9(f)(1). Examples of these products are raw fish, boiled fish, and broiled fish. **Conventional foods** other than fish may not exceed the total fat disqualifying levels. For individual foods,	

			the total fat disqualifying level is 13.0 g per RACC and per 50 g if RACC is ≤ 30 g or ≤ 2 tbsp. The total fat disqualifying level is 26.0 g per label serving size for meal products and 19.5 g per label serving size for main dish products. **Saturated fat content** Dietary supplements must meet the criterion for low saturated fat with regard to the saturated fat content (≤ 1 g per RACC) but not with regard to the no more than 15 percent calories from saturated fat criterion. Fish may not exceed the saturated fat disqualifying level of 4.0 g per RACC (or 4.0 g per 50 g if RACC is ≤ 30 g or ≤ 2 tbsp). Conventional foods other than fish must meet the criteria for low saturated fat (≤ 1 g per RACC and no more than 15 percent of calories from saturated fat for individual foods, ≤ 1 g per 100 g and less than 10 percent calories from saturated fat for meal products and main dish products). There is an error in the enforcement discretion		

letters in the section of "low saturated fat," stating that meal products and main dishes meet all criteria specified for the "low saturated fat" criteria (21 CFR 101.62(c)(2)). The CFR number should be (21 CFR 101.62(c)(3)).

Cholesterol content

Dietary supplements that weigh 5 g or less per RACC are exempt from the cholesterol disqualifying level (60 mg per 50 g), but those that exceed the cholesterol disqualifying level must include "See nutrition information for cholesterol content" with the qualified health claim. Dietary supplements that weigh more than 5 g per RACC must meet the criterion for low cholesterol (≤ 20 mg per 50g).

Fish must meet the extra lean criterion with regard to cholesterol content (< 95 mg per RACC and per 100 g, whichever is greatest), but not with regard to saturated fat content. Fish with cholesterol content greater than 60 mg per RACC must include "See nutrition

information for cholesterol content" with the qualified health claim.

Conventional foods other than fish must meet the low cholesterol criterion (21 CFR 101.62(d)(2)). See 21 CFR 101.62(d)(2) for the low cholesterol criterion specific for individual foods, meal products, and main dish products.

Sodium

All conventional foods and dietary supplements must meet the sodium disqualifying level (≤ 480 mg per RACC and per 50 g if RACC is ≤ 30 g or ≤ 2 tbsp for individual foods, ≤ 960 mg per label serving size for meal products, ≤ 720 mg per label serving size for main dish products).

The 10 percent minimum nutrient requirement

All conventional foods must meet the 10 percent minimum nutrient requirement (Vitamin A 500 IU, Vitamin C 6 mg, Iron 1.8 mg, Calcium 100 mg, Protein 5 g, Fiber 2.5 g per RACC), prior

		to any nutrient addition. The 10 percent minimum nutrient requirement does not apply to dietary supplements (21 CFR 101.14(e)(6)).	
Monounsaturated Fatty Acids From Olive Oil and Coronary Heart Disease Docket No. 2003Q-0559 11/01/2004 enforcement discretion letter	All products that are essentially pure olive oil and labeled as such (see * for definitions) Dressings for salads (i.e. salad dressings) that contain 6 g or more olive oil per Reference Amount Customarily Consumed (RACC), are low in cholesterol (21 CFR 101.62(d)(2)), and do not contain more than 4 g of saturated fat per 50 g. Vegetable oil spreads that contain 6 g or more olive oil per RACC, are low in cholesterol (21 CFR 101.62(d)(2)) and do not contain more than 4 g of saturated fat per RACC. Olive oil-containing foods that contain 6 g or more olive oil per RACC, are low in cholesterol (21 CFR 101.62(d)(2)), contain at least 10% of either vitamin A, vitamin C, iron, calcium, protein or dietary fiber. If the	Olive oil, vegetable oil spreads, dressings for salads, shortenings and olive-oil containing foods do not need to comply with the total fat disqualifying level in 21 CFR 101.14(a)(4). The requirement that the food comply with the 50 gram-criterion of the saturated fat disqualifying level (21 CFR 101.14(e)(3)) does not apply to olive oil, vegetable oil spreads, and shortenings. The requirement that the food contain a minimum of 10 percent of the Daily Value per RACC of at one of the following: vitamin A, vitamin C, iron, calcium, protein, or dietary fiber per RACC (21 CFR 101.14(e)(6)) does not apply to olive oil, dressings for salads, and shortenings. When the total fat disqualifying level is exceeded in vegetable oil spreads, dressings for salads, shortenings, or olive-oil containing	Limited and not conclusive scientific evidence suggests that eating about 2 tablespoons (23 grams) of olive oil daily may reduce the risk of coronary heart disease due to the monounsaturated fat in olive oil. To achieve this possible benefit, olive oil is to replace a similar amount of saturated fat and not increase the total number of calories you eat in a day. One serving of this product contains [x] grams of olive oil. *Note: The last sentence of the claim "One serving of this product contains [x] grams of olive oil." is optional when the claim is used on the label or in the labeling of olive oil.* *(1) Olive oil means virgin olive oil, or blends of virgin olive oil and refined olive oil; where virgin olive oil is the oil resulting from the first pressing of olives and is suitable

	RACC of the olive oil-containing food is greater than 30 g the food cannot contain more than 4 g of saturated fat per RACC and if the RACC of the olive oil-containing food is 30 g or less the food cannot contain more than 4 g of saturated fat per 50 g. Shortenings that contain 6 g or more olive oil per RACC and are low in cholesterol (21 CFR 101.62(d)(2)) and do not contain more than 4 g of saturated fat per RACC. Meal products (21 CFR 101.13(l)) or Main dish products (21 CFR 101.13(m)) are not eligible for the claim.	foods the disclosure statement (i.e., See nutrition information for saturated fat content) must be placed immediately following the claim, with no intervening material, in the same size, typeface, and contrast as the claim itself. When the food does not meet the definition of low saturated fat (21 CFR 101.62(c)(2)) the disclosure statement (i.e., See nutrition information for saturated fat content) must be placed immediately following the claim, with no intervening material, in the same size, typeface, and contrast as the claim itself. If both of the above two conditions are met the disclosure statements for total fat and saturated fat can be combined (i.e., See nutrition information for total and saturated fat content).	for human consumption without further processing and refined olive oil is the oil obtained from subsequent pressings and which is suitable for human consumption by refining processes which neutralize the acidity or remove particulate matter. (2) Vegetable oil spread means margarine (21 CFR 166.110) and margarine-like products. (3) "dressings for salads" means dressings for salads formulated to contain olive oil. (4) "shortenings" means vegetable oil shortenings, formulated to contain olive oil. (5) Olive oil-containing foods means foods, such as sauces or baked goods, excluding olive oil, vegetable oil spreads, dressings for salads, and shortenings.
Green Tea & Cancer Docket No. 2004Q-0083	Green tea and conventional foods and dietary supplements that contain green tea	*Green tea* does not exceed the disqualifying nutrient levels for total fat, saturated fat, cholesterol, and	(1) Two studies do not show that drinking green tea reduces the risk of breast cancer in women, but one

06/30/2005 enforcement discretion letter		sodium specified in 21 CFR 101.14(a)(4). FDA intends to consider the exercise of its enforcement discretion for qualified health claims for green tea and breast cancer and for green tea and prostate cancer to be used on the label or in the labeling of *green tea-containing foods* when the food does not exceed any of the disqualifying nutrient levels for fat, saturated fat, cholesterol, and sodium. FDA intends to consider the exercise of its enforcement discretion for *green tea* that does not meet the 10% minimum nutrient content requirement in 21 CFR 101.14(e)(6). FDA does not intend to consider the exercise of its enforcement discretion for *green tea-containing foods* that do not meet the requirements of 21 CFR 101.14(e)(6).	weaker, more limited study suggests that drinking green tea may reduce this risk. Based on these studies, FDA concludes that it is highly unlikely that green tea reduces the risk of breast cancer. *or,* (2) One weak and limited study does not show that drinking green tea reduces the risk of prostate cancer, but another weak and limited study suggests that drinking green tea may reduce this risk. Based on these studies, FDA concludes that it is highly unlikely that green tea reduces the risk of prostate cancer.
Chromium Picolinate & Diabetes Docket No. 2004Q-0144 08/25/2005 enforcement discretion letter	Dietary supplements containing chromium	Dietary supplement containing chromium must meet or exceed the requirement for a "high" level of chromium as defined in 21 CFR 101.54(b) (i.e., 24 mg or more per RACC under the current regulation) for	One small study suggests that chromium picolinate may reduce the risk of insulin resistance, and therefore possibly may reduce the risk of type 2 diabetes. FDA concludes, however,

		FDA to exercise enforcement discretion.	that the existence of such a relationship between chromium picolinate and either insulin resistance or type 2 diabetes is highly uncertain.
Calcium and Colon/Rectal Cancer & Calcium and Recurrent Colon/Rectal Polyps Docket No. 2004Q-0097 10/12/2005 enforcement discretion letter	Dietary supplements containing calcium	The dietary supplement must meet or exceed the requirement for a "high" level of calcium as defined in 21 CFR 101.54(b) (i.e., 200 mg or more calcium per RACC) The calcium content of the dietary supplement must be assimilable (i.e., bioavailable) (21 CFR 101.72(c)(ii)(B)), and meet the United States Pharmacopeia (U.S.P.) standards for disintegration and dissolution applicable to their component calcium salts. For dietary supplements for which no U.S.P. standards exist, the dietary supplement must exhibit appropriate assimilability under the conditions of use stated on the product label (21 CFR 101.72(c)(ii)(C)).	**Colon/Rectal Cancer:** Some evidence suggests that calcium supplements may reduce the risk of colon/rectal cancer, however, FDA has determined that this evidence is limited and not conclusive. **Recurrent Colon Polyps:** Very limited and preliminary evidence suggests that calcium supplements may reduce the risk of colon/rectal polyps. FDA concludes that there is little scientific evidence to support this claim.
Calcium & Hypertension, Pregnancy-Induced Hypertension, and Preeclampsia Docket No. 2004Q-0098	Dietary supplements containing calcium	The dietary supplement must meet or exceed the requirement for a "high" level of calcium as defined in 21 CFR 101.54(b) (i.e., 200 mg or more calcium per RACC)	**Hypertension:** Some scientific evidence suggests that calcium supplements may reduce the risk of hypertension.

10/12/2005 enforcement discretion letter		The calcium content of the dietary supplement must be assimilable (i.e., bioavailable) (21 CFR 101.72(c)(ii)(B)), and meet the United States Pharmacopeia (U.S.P.) standards for disintegration and dissolution applicable to their component calcium salts. For dietary supplements for which no U.S.P. standards exist, the dietary supplement must exhibit appropriate assimilability under the conditions of use stated on the product label (21 CFR 101.72(c)(ii)(C)).	However, FDA has determined that the evidence is inconsistent and not conclusive. **Pregnancy-Induced Hypertension:** Four studies, including a large clinical trial, do not show that calcium supplements reduce the risk of pregnancy-induced hypertension during pregnancy. However, three other studies suggest that calcium supplements may reduce the risk. Based on these studies, FDA concludes that it is highly unlikely that calcium supplements reduce the risk of pregnancy-induced hypertension. **Preeclampsia:** Three studies, including a large clinical trial, do not show that calcium supplements reduce the risk of preeclampsia during pregnancy. However, two other studies suggest that calcium supplements may reduce the risk. Based on these studies, FDA concludes that it is

			highly unlikely that calcium supplements reduce the risk of preeclampsia.
Tomatoes and/or Tomato Sauce & Prostate, Ovarian, Gastric, and Pancreatic Cancers Docket No. 2004Q-0201 11/08/2005 enforcement discretion letter - American Longevity Petition 11/08/2005 enforcement discretion letter - Lycopene Heath Claim Coalition Petition	(1) Cooked, Raw, Dried, or Canned Tomatoes (2) Tomato Sauces that contain at least 8.37 percent salt-free tomato solids		**Tomatoes and/or Tomato Sauce and Prostate Cancer:** Very limited and preliminary scientific research suggests that eating one-half to one cup of tomatoes and/or tomato sauce a week may reduce the risk of prostate cancer. FDA concludes that there is little scientific evidence supporting this claim. **Tomato Sauce and Ovarian Cancer:** One study suggests that consumption of tomato sauce two times per week may reduce the risk of ovarian cancer; while this same study shows that consumption of tomatoes or tomato juice had no effect on ovarian cancer risk. FDA concludes that it is highly uncertain that tomato sauce reduces the risk of ovarian cancer. **Tomatoes and Gastric Cancer:** Four studies did not

			show that tomato intake reduces the risk of gastric cancer, but three studies suggest that tomato intake may reduce this risk. Based on these studies, FDA concludes that it is unlikely that tomatoes reduce the risk of gastric cancer. **Tomatoes and Pancreatic Cancer:** One study suggests that consuming tomatoes does not reduce the risk of pancreatic cancer, but one weaker, more limited study suggests that consuming tomatoes may reduce this risk. Based on these studies, FDA concludes that it is highly unlikely that tomatoes reduce the risk of pancreatic cancer.
Unsaturated Fatty Acids from Canola Oil and Reduced Risk of Coronary Heart Disease Docket No. 2006Q-0091 10/06/2006 enforcement discretion letter	Canola oil (see * for definitions) Vegetable oil spreads, dressings for salads, shortenings, and canola oil-containing foods that contain 4.75 g or more of canola oil per RACC, are low in saturated fat (21 CFR 101.62(c)(2)), are low in cholesterol (21 CFR 101.62(d)(2)),	Canola oil, vegetable oil spreads, dressings for salads, shortenings and canola-oil containing foods do not need to comply with the total fat disqualifying level in 21 CFR 101.14(a)(4). The requirement that the food contain a minimum of 10 percent of the Daily Value per RACC of at one of the	Limited and not conclusive scientific evidence suggests that eating about 1 1/2 tablespoons (19 grams) of canola oil daily may reduce the risk of coronary heart disease due to the unsaturated fat content in canola oil. To achieve this possible benefit, canola oil is to replace a similar

	and meet the saturated fat, cholesterol, and sodium disqualifying levels (21 CFR 101.14(a)(4)). Vegetable oil spreads and canola oil-containing foods must also meet the 10% minimum nutrient content requirement (21 CFR 101.14(e)(6)).	following: vitamin A, vitamin C, iron, calcium, protein, or dietary fiber per RACC (21 CFR 101.14(e)(6)) does not apply to canola oil, dressings for salads, and shortenings. When the total fat disqualifying level is exceeded in vegetable oil spreads, dressings for salads, shortenings, or canola-oil containing foods, the disclosure statement (i.e., See nutrition information for total fat content) must be placed immediately following the claim, with no intervening material, in the same size, typeface, and contrast as the claim itself.	amount of saturated fat and not increase the total number of calories you eat in a day. One serving of this product contains [x] grams of canola oil. *For the purposes of this qualified health claim: (1) "Canola oil" means products that are essentially pure canola oil and are labeled as such. (2) "Vegetable oil spread" means margarine (21 CFR 166.110) and margarine-like products, formulated to contain canola oil. (3) "Dressings for salads" means dressings for salads formulated to contain canola oil. (4) "Shortenings" means vegetable oil shortenings, formulated to contain canola oil. (5) "Canola oil-containing foods" means all other foods, such as sauces or baked goods, formulated to contain canola oil, excluding canola oil, vegetable oil spreads, dressings

			for salads, and shortenings.
Corn Oil and Corn Oil-Containing Products and a Reduced Risk of Heart Disease Docket No. 2006P-0243 3/26/2007 enforcement discretion letter	Corn oil (see * for definitions) Vegetable oil blends and shortenings that contain 4 g or more corn oil per RACC, are low in cholesterol (21 CFR 101.62(d)(2)), meet the cholesterol and sodium disqualifying levels (21 CFR 101.14(a)(4)), and do not contain more than 4 g of saturated fat per RACC. Dressings for salads (i.e. salad dressings) that contain 4 g or more corn oil per RACC, are low in cholesterol (21 CFR 101.62(d)(2)), meet the cholesterol and sodium disqualifying levels (21 CFR 101.14(a)(4)), and do not contain more than 4 g of saturated fat per 50 g. Vegetable oil spreads that contain 4 g or more corn oil per RACC, are low in cholesterol (21 CFR 101.62(d)(2)), meet the cholesterol and sodium disqualifying levels (21 CFR 101.14(a)(4)), contain at least 10% of either vitamin A, vitamin C, iron, calcium, protein	Corn oil, vegetable oil blends, vegetable oil spreads, dressings for salads, shortenings and corn-oil containing foods do not need to comply with the total fat disqualifying level in 21 CFR 101.14(a)(4). The requirement that the food comply with the 50 gram-criterion of the saturated fat disqualifying level (21 CFR 101.14(e)(3)) does not apply to corn oil, vegetable oil blends, vegetable oil spreads, and shortenings. The requirement that the food contain a minimum of 10 percent of the Daily Value per RACC of at one of the following: vitamin A, vitamin C, iron, calcium, protein, or dietary fiber per RACC (21 CFR 101.14(e)(6)) does not apply to corn oil, vegetable oil blends, dressings for salads, and shortenings. When the total fat disqualifying level is exceeded in vegetable oil spreads, dressings for salads, shortenings, or corn-oil containing foods, the disclosure statement (i.e., See	Very limited and preliminary scientific evidence suggests that eating about 1 tablespoon (16 grams) of corn oil daily may reduce the risk of heart disease due to the unsaturated fat content in corn oil. FDA concludes that there is little scientific evidence supporting this claim. To achieve this possible benefit, corn oil is to replace a similar amount of saturated fat and not increase the total number of calories you eat in a day. One serving of this product contains [x] grams of corn oil. (1) "corn oil" means products that are essentially pure corn oil and are labeled as such (2) "vegetable oil blends" means a blend of two or more vegetable oils formulated to contain corn oil (3) "vegetable oil spread" means margarine (21 CFR 166.110) and margarine-like products formulated

	or dietary fiber, and do not contain more than 4 g of saturated fat per RACC. Corn oil-containing foods that contain 4 g or more corn oil per RACC, are low in cholesterol (21 CFR 101.62(d)(2)), meet the cholesterol and sodium disqualifying levels (21 CFR 101.14(a)(4)), contain at least 10% of either vitamin A, vitamin C, iron, calcium, protein or dietary fiber. If the RACC of the corn oil-containing food is greater than 30 g, the food cannot contain more than 4 g of saturated fat per RACC, and if the RACC of the corn oil-containing food is 30 g or less, the food cannot contain more than 4 g of saturated fat per 50 g.	nutrition information for total fat content) must be placed immediately following the claim, with no intervening material, in the same size, typeface, and contrast as the claim itself. When the food does not meet the definition of low saturated fat (21 CFR 101.62(c)(2)), the disclosure statement (i.e., See nutrition information for saturated fat content) must be placed immediately following the claim, with no intervening material, in the same size, typeface, and contrast as the claim itself. If both of the above two conditions are met, the disclosure statements for total fat and saturated fat can be combined (i.e., See nutrition information for total and saturated fat content).	to contain corn oil (4) "dressings for salads" means dressings for salads formulated to contain corn oil (5) "shortenings" means vegetable oil shortenings formulated to contain corn oil (6) "corn oil-containing foods" means all other foods, such as sauces or baked goods, formulated to contain corn oil, excluding corn oil, vegetable oil blends, vegetable oil spreads, dressings for salads, and shortenings.