Omega-3s in infant formula: time for a close look

The FDA just announced that it is planning to research health claims on infant formulas such as "supports brain and eye development." The FDA wants to:

- assess women’s understanding of and response to various statements on infant formula labels. The study results will be used to help the Agency to understand the role that certain types of statements on infant formula labels have in influencing formula choice. The study will focus on purchase choice, perceived similarity of the formula to breast milk, and perceived likelihood that the formula has certain health benefits.
Translation: the FDA thinks that claims for omega-3 fatty acids—DHA, in this case—on infant formulas mislead mothers into thinking the formulas are better than breast milk.

Despite lack of evidence for benefits, infant formula makers have been so successful in marketing the addition of these omega-3 fatty acids that you can hardly buy a formula without them.

I was in Ecuador a few months ago and saw this sign:

![Sign in Ecuador promoting omega-3 fatty acids](image)

The idea? Omega-3’s will make your kid smart.

My book, *What to Eat*, has a chapter on infant formula and baby food. Here are some relevant excerpts:

Infant formulas cause controversy and are endlessly contentious for three important reasons. Formulas are (1) largely unnecessary (most mothers can breast feed their infants), (2) not as perfect as breast milk for feeding babies, and (3) more expensive than breast feeding.

Breast milk is nutritionally superior to formula, but from a marketing standpoint it has one serious disadvantage: it is free. Beyond one-time purchases of breast pumps, storage bottles, or special clothing, nobody makes money from it.

For mothers who cannot, should not, or do not want to breast feed, formula is a socially and nutritionally acceptable substitute. But formula companies do not only promote formulas to mothers who must use formula. In subtle and not-so-subtle ways, they promote the use of formulas to all pregnant women and new mothers.

I go on to explain that because formula is the sole food for infants, its composition is highly regulated. Therefore, all infant formulas have the same composition, and all virtually indistinguishable.
Competition for market share explains why formula companies want to put distinctive nutrients in their formulas—especially nutrients considered “conditional.” A conditional nutrient is one that might have some benefits under some circumstances. Even if the health benefits are minimal or questionable, they can be used in advertising.

That is the principal reason why so many formulas now have fatty acids added—omega 6 arachidonic acid (ARA) and omega-3 docosahexaenoic acid —the same one that is in fish oil. These two fatty acids are normally present in breast milk, and there is some evidence, weak and questionable as it may be, that they support infant brain development and vision.

Formula makers got the FDA to agree that ARA and DHA are normal components of food (which they are) and, therefore, are Generally Recognized As Safe (GRAS). This means that companies could add ARA and DHA to infant formulas without having to prove that either of them really did anything useful or beneficial.

I then explain that the FDA apparently agreed to the GRAS petition with some reluctance, as indicated by its answer to the question, “What is the evidence that addition of DHA and ARA to infant formulas is beneficial?”

The scientific evidence is mixed. Some studies in infants suggest that including these fatty acids in infant formulas may have positive effects on visual function and neural development over the short term. Other studies in infants do not confirm these benefits. There are no currently available published reports from clinical studies that address whether any long-term beneficial effects exist.

My interpretation of the proposed research study is that the FDA thinks the addition of ARA and DHA may discourage mothers from breastfeeding and may unnecessarily cause them to buy more expensive formula.

If you agree, tell the FDA you think the study is a great idea, and the sooner it gets going, the better.


The perils of food and nutrition research

I write a monthly (first Sunday) Food Matters column for the San Francisco Chronicle. Today’s is about the difficulties of doing nutrition research. The Chronicle headline writer titled it, “Be skeptical of food studies.” Oops.

I’m not skeptical about Food Studies—the capitalized field of study—at all. My NYU department started undergraduate, master’s, and doctoral programs in Food Studies in 1996 and they have
flourished ever since.

The column is about small-letter food studies, meaning nutrition and food research studies:

Q: You were quoted saying that you didn’t believe newspaper reports linking diet sodas to an increased risk of stroke and heart disease. How do you decide whether research is good or bad?

A: This one was easy. I didn’t think it made sense. Mind you, I’m no fan of diet sodas. They violate my rule never to eat anything artificial. And I don’t like the taste of artificial sweeteners.

Whenever a study comes out claiming harm – or benefits – from eating a single food or ingredient, I get skeptical. That’s why I also questioned these recent study results: high-fructose corn syrup (HFCS) makes rats gain weight faster than sucrose (table sugar); zinc supplements prevent symptoms of the common cold; and pomegranate juice has greater health benefits than any other kind of fruit.

When I read about single-factor studies, I want to know three things: Is the result biologically plausible? Did the study control for other dietary, behavioral or lifestyle factors that could have influenced the result? And who sponsored it?

**Plausibility:** The diet soda study used a self-reported questionnaire to find out how often people reported drinking diet sodas. Nine years later, people who reported habitually drinking diet sodas had a 60 percent higher rate of stroke and heart attacks. The rate was somewhat lower when controlled for age, sex, race, smoking, exercise, alcohol, daily calories and metabolic syndrome.

Leaving aside the unreliability of self-reported dietary intake, the study raises a more important question. Was it designed to investigate the link between diet sodas and stroke or was this just an accidental finding? The questionnaire undoubtedly asked hundreds of questions about diet and other matters. Just by chance, some of them could be giving results that look meaningful. And the increase in stroke risk seems surprisingly high for something not previously known to be a stroke risk factor.

Mostly, I can’t think of a biological reason why diet sodas might lead to cardiovascular disease unless they are an indicator for some other stroke risk factor such as obesity, high blood pressure or binge drinking. It would take a study designed to test this idea specifically – and a good biological explanation – to convince me that diet sodas cause strokes.

The plausibility issue also rises in the HFCS study. Again, I’m not a fan of HFCS – we would all be healthier if we ate less sugar – but from a biochemical standpoint, HFCS and table sugar are pretty much the same. They have similar amounts of glucose and fructose, are digested as quickly and are metabolized the same way. Even the average amounts consumed are about the same. That soda companies are replacing HFCS with sucrose is strictly about marketing, not health.

**Controls:** The zinc-and-colds study was a comprehensive review (a “meta-analysis”) of previous studies done since the first one in 1984. Eleven studies have showed some benefit; seven have not. All of them were placebo controlled, double-blind. This meant that half the participants were given a dummy pill, and neither participants nor investigators were supposed to know who was taking what.

But in some studies, the zinc takers complained about the taste of the pills, hinting that they knew what they were.
I’ve heard this before. In the early 1970s, National Institutes of Health investigators did a study of vitamin C and the common cold. They got about 300 NIH employees to take either vitamin C or a placebo, double-blind. The tantalizing result: People taking vitamin C reported fewer colds and milder symptoms than people taking placebos.

Alas, many participants withdrew from the study before it ended. When asked why, they admitted tasting the pills. The investigators reanalyzed the results. Bingo! No matter what pill the participants actually took, those who thought they were taking vitamin C reported fewer colds and milder symptoms.

If the studies were not really blinded, the zinc results are questionable. I have no doubt that many people feel better when they take zinc supplements, but I’m not sure whether that’s because of something zinc really does or just its placebo effect.

**Sponsorship:** Vested interests influence the design and interpretation of studies. The best-designed studies control for factors that might influence results. Even so, their results require interpretation. Interpretation requires interpreters. Interpreters bring their own biases into the interpretation.

I mention pomegranate juice because one of its major producers sponsors studies to hype its benefits. Yes, pomegranates are delicious, but antioxidant powerhouses? So are most fruits. Pomegranates may have high antioxidant activity, but compared with what? Its maker does not say. Sponsored research is also about marketing, not health.

Nutrition research is hard to do, which makes study design and interpretation particularly challenging. Nutrition is a thinking person’s field, requiring careful analysis at every step. When you hear a result that sounds too good to be true, it usually is.

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**Update on organics**

On March 02, [USDA announced](https://www.usda.gov/newsroom/press-releases/2018/03/02/usda-revokes-accreditation-two-certifying-agencies) that it was revoking its accreditation of two certifying agencies, Certified Organic, Inc. (COI) and Guaranteed Organic Certification Agency (GOCA).

USDA says COI failed to

- Communicate with hired inspectors about proper procedures or ensure they were adequately trained
- Adhere to internal procedures according to their operational manual
- Keep confidentiality agreements on file for all employees with knowledge about certification applicants or operations
- Indicate on certificates the effective dates for organic certification,
- Ensure adequate training for employees about the regulations
- Provide clients with cost estimates including inspection fees
- Clearly identify the company’s responsibility to pay for any required pre- or postharvest testing

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8 comments

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Tags: Research
Mar 5 2011
• Verify organic system plans against the actual practices of their certified operations

GOCA’s problems had to do with “persistent noncompliance,” including such things as “failure to require clients to use defined boundaries and border zones as required by the organic standards.” This may all sound absurdly bureaucratic but it means the certifiers could be overlooking producers’ violations of organic standards.

You can track down the records of such things on the USDA’s website, and see the handful of other such enforcement actions at the National Organic Program’s site.

I’d say this is progress. Organic producers are supposed to follow the rules of the National Organic Program, and to be inspected to make sure they do. If the inspectors aren’t doing their job diligently, you won’t be able to tell whether the organic foods you buy are worth the premium prices.

This is a key point of a recent FoodNavigator story on the market for organics. The U.S. industry is expected to go from $21.1 billion in 2010 to $36.8 billion in 2015. How come? Because of “the government’s monetary and regulatory support and increasing acceptance of organic food in the country.”

People will pay more for organics if they think the producer is credible. Organics are about credibility. That is why the USDA needs to fiercely enforce organic certification. Doing so protects the industry. The more of this sort of thing, the better.

NOAA’s new aquaculture policy

The National Oceanic and Atmospheric Administration (NOAA) has proposed the nation’s first aquaculture policy, which it says it did in response to consumer demand for local, safe, sustainably produced seafood (FoodNavigator.com has a good summary).

Ah yes. Seafood. The wild west of the food industry. Safe and sustainable sounds good, but the statistics are not reassuring.

As NOAA explains, U.S. aquaculture – meaning farmed – currently only accounts for about 5% of our seafood. Get this: an astonishing 84% of U.S. seafood is imported. Of this, half is farmed.

Worldwide, farmed seafood exceeded catches of wild seafood for the first time in 2009.

NOAA guesses that with wild fish stocks depleting rapidly, we will see plenty more fish and shellfish farming.

NOAA quotes the depressing Food and Agriculture Organization report on world fisheries and aquaculture. This says that worldwide per capita fish availability is about 17 kg per year, and supplies more than 3 billion people with at least 15% of their average animal protein intake. No
wild fish stock can keep up with that kind of demand.

NOAA’s yawn-inducing recommendations (edited):

- Enable sustainable aquaculture…in harmony with healthy, productive, and resilient marine ecosystems
- Ensure agency decisions to protect wild species and coastal and ocean ecosystems
- Advance scientific knowledge concerning sustainable aquaculture
- Make timely and unbiased aquaculture management decisions
- Support aquaculture innovation and investments that benefit the nation’s coastal ecosystems, communities, seafood consumers, industry, and economy.
- Advance public understanding of sustainable aquaculture practices
- Work with our federal partners to provide resources and expertise needed to address aquaculture challenges
- Work internationally to learn from aquaculture practices around the world

It’s going to take a lot more than that to fix the fish situation.

Way to go GAO! A single food safety agency

Thanks to FoodSafetyNews for the heads up on the latest Government Accountability Office (GAO) attempt to get Congress to consolidate federal food safety functions on one agency.

The GAO’s latest 345-page report on how the federal government can save money lists its proposals in alphabetical order by area. Agriculture comes first and, therefore, so does food safety. You have to love the way GAO titles its sections: “Fragmented food safety system has caused inconsistent oversight, ineffective coordination, and inefficient use of resources.”

GAO has been saying this for 20 years. In 1990, for example, it published reports on who does what in the federal government about food safety and the inconsistencies in oversight.

As I wrote in Safe Food: The Politics of Food Safety (2010),

Today, an inventory of federal food safety activities reveals a system breathtaking in its irrationality: 35 separate laws administered by 12 agencies housed in six cabinet-level departments….

At best, a structure as fragmented as this one would require extraordinary efforts to achieve communication let alone coordination, and more than 50 interagency agreements govern such efforts.

Among the six agencies with the broadest mandates, all conduct inspections and collect and analyze samples, and at least three—though not necessarily the same ones—have something to do with regulating dairy products, eggs and egg products,
fruits and vegetables, grains, and meat and poultry.

Until recently, the system had no mission statement (for whatever such statements are worth) and it still does not have consistent rules, clear lines of authority, a rational allocation of resources, or standards against which to measure success.

With such a system, some issues—such as use of animal manure to fertilize food crops—inevitably fall between the cracks and are governed by no rules whatsoever.

Not much has changed in the subsequent 20 years, as this new report attests. As is inevitably the case, some of the areas of overlap are simply absurd:

The 2008 Farm Bill assigned USDA responsibility for catfish, thus splitting seafood oversight between USDA and FDA. In September 2009, GAO also identified gaps in food safety agencies’ enforcement and collaboration on imported food.

Specifically, the import screening system used by the Department of Homeland Security’s Customs and Border Protection (CBP) does not notify FDA’s or FSIS’s systems when imported food shipments arrive at U.S. ports.

But the worst is the situation with shell eggs, seemingly unfixable, given the 2010 recall of 500 million eggs:

FDA is generally responsible for ensuring that shell eggs, including eggs at farms such as those where the outbreak occurred, are safe, wholesome, and properly labeled and FSIS [USDA] is responsible for the safety of eggs processed into egg products.

In addition, while USDA’s Agricultural Marketing Service sets quality and grade standards for the eggs, such as Grade A, it does not test the eggs for microbes such as Salmonella.

Further, USDA’s Animal and Plant Health Inspection Service helps ensure the health of the young chicks that are supplied to egg farms, but FDA oversees the safety of the feed they eat.

I repeat. This is not a new issue. The hope was that the food safety act passed in January would pave the way to establish a single food safety agency. The GAO report, while urging its creation, doubts that it will cut costs.

But it might save lives.

2 comments

Like

Tags: FDA, Food safety, GAO, USDA
Mar 1 2011

Oh those Brits: now breastmilk ice cream

FoodQualityNews reports that the British Food Standards Agency (FSA) is all upset about ice cream made from breast milk.
Eeks. It might violate food safety standards!

The Baby Gaga breastmilk ice cream is sold by a London firm called The Icecreamists. The company has been forced to withdraw Baby Gaga in response to complaints that it might not be safe for human consumption.

The milk comes from 15 moms. It is screened prior to sale, in part because breast milk can pass on things like hepatitis.

But nowhere in this account does it say whether the milk was pasteurized or how the ice cream tastes. I want to know!

Should the FDA allow HFCS to be renamed “corn sugar”? I vote no.

A colleague pointed out to me today that I am listed nine times on the Corn Refiners Association website as supporting its petition to the FDA to change the name of High Fructose Corn Syrup (HFCS) to corn sugar.

When the idea first came up, I didn’t think it mattered much. But as I had to add more and more postscripts to my post on the issue, and as I read the comments on it, I was persuaded otherwise. On balance, the arguments against changing the name outweigh the idea that it doesn’t matter (it matters to the Corn Refiners of course).

The FDA is collecting comments on the name change on its website. I filed this comment today:

The FDA should deny the Corn Refiners petition to change the name of High Fructose Corn Syrup (HFCS) to corn sugar.

I understand that the Corn Refiners Association uses my comments on its website to support its position. The website quotes comments I have made to the effect that HFCS is biochemically equivalent to sucrose. It is. But I do not believe that biochemical equivalence is a good reason for the FDA to agree to a name change at this point.

It is highly unlikely that public misunderstanding of nutritional biochemistry and the differential physiological effects of glucose vs. fructose will be addressed and corrected by changing the name of HFCS to corn sugar.

Therefore, the name change is not in the public interest. Its only purpose is to further the commercial interests of members of the Corn Refiners, and that is not one the FDA should be concerned about.

If you have thoughts about the petition, nothing could be easier than telling the FDA what you think:
1. Click on this link.

2. Look on the left side of the page “Results,” “Corn Refiners Association – Citizens Petition,” and on the right side a link that says “Submit a Comment.”

3. Click on “Submit a Comment.” Fill out the form with your name and affiliation. Type in your comment. If a box comes up saying that you are taking too long, click OK and it will give you more time.

My understanding is that there is no particular deadline but rumors are that the FDA will consider all comments submitted by the end of this week.

17 comments

Tags: FDA, HFCS

Feb 26 2011

**USDA recalculates distribution of food dollar**

USDA has changed the way it reports the country’s annual expenditures on the food system. It has just released the Economic Research Service’s [new food dollar report](#). As the report explains, it is designed to answer the question “For what do our food dollars pay?”

The USDA has a nifty way of presenting this information. The first illustration identifies the distribution of the U.S. food dollar between farm and marketing shares. The farm share is what goes to the farmer. The marketing share is everything else that happens to a food between harvest and consumption.

What surprised me about this was the 15.8% farm share. For those of you who keep track of such things, it was 19% in 2006.

But the USDA changed the methods for computing this figure. Using the new methods, 15.8% is a 4% increase since 2006. However this is calculated, less than 20 cents of a dollar spent on food
is for the food itself.

The second illustration explains the distribution of the food dollar among ten industry groups involved in the supply chain.

Looking at the actual data series this way, farm and agribusiness accounts for only 11.6% of the dollar. The big sectors are food processing (18.6%) and food service (33.7%).

From a health and sustainability standpoint, isn’t there something wrong with this picture?

14 comments

UK health agency: limit red and processed meats to 3 ounces a day

The UK Department of Health issued a warning today to eat less red and processed meat.

- Red meat means beef, lamb and pork as well as minced meat and offal from these animals.
- Processed meat means ham, bacon, luncheon meat, corned beef, salami, pâté, sausages and burgers.

The warning is based on a new report from the independent Scientific Advisory Committee on Nutrition (SACN). Its report evaluated the effects of iron on health. Because red meat is a primary source of dietary iron, the committee looked at evidence on the links between red meat and processed meats and bowel cancer.

The report concludes that the link “probably” exists and that:

Adults with relatively high intakes of red and processed meat (around 90 g/day or more) should consider reducing their intakes. A reduction to the UK population average for adult consumers (70 g/day cooked weight) would have little impact on the proportion of the adult population with low iron intakes.
How much is 90 grams? It is only three ounces of cooked meat.

The UK Health Department advises:

- People who eat a lot of red or processed meat – around 90g or more of cooked weight per day – are at greater risk of getting bowel cancer;
- Cutting down to the UK average of 70g a day can help reduce the risk; and
- This can be achieved by eating smaller portions or by eating red and processed meat less often.

The Department points out that cooked meat weighs about 70% of its uncooked weight (it has less water). So 3 ounces of cooked meat is equivalent to about 4 ounces of uncooked meat.

Expect to hear lots of reactions like “red meat can still be enjoyed in moderation as part of a healthy balanced diet.”

And where are the US Dietary Guidelines on the subject of red and processed meats? Buried in euphemisms, alas:

- Choose lean meats
- Choose seafood instead of some meat
- Reduce calories from solid fats

No wonder Americans are confused about diet and health.

**Closure (?) on Salmonella Saintpaul**

The *New England Journal of Medicine* has just published a CDC report bringing the Salmonella Saintpaul outbreak of 2008 to an apologetic close (for a quick rundown on the history of this incident, see my previous posts).

The investigation of this outbreak first implicated tomatoes, with devastating effects on the tomato industry. As the paper concludes:

> Although an epidemiologic association with raw tomatoes was identified early in this investigation, subsequent epidemiologic and microbiologic evidence implicated jalapeño and serrano peppers. This outbreak highlights the importance of preventing raw-produce contamination.

Yes it does. Jalapeño and serrano peppers turn up in salsas and guacamoles. These are mixtures of many ingredients that are often eaten with chips or prepared foods. People have a hard time remembering whether they ate peppers or not, particularly when the peppers are chopped fine. As the investigators explained:

> This outbreak investigation highlights the recurring challenges of epidemiologic
identification of ingredients in foods that are commonly consumed, rapid identification and investigation of local clusters, the need to continue exploring hypotheses during an ongoing outbreak, and produce tracing in the supply chain.

Traceback issues such as commingling, repacking, varying degrees of product documentation throughout the supply chain, difficulty in linking incoming with outgoing shipments to the next level in the distribution chain, and the complexity of the distribution chain continue to hinder product-tracing efforts….

In addition, an understanding of the mechanisms and ecologies that can lead to contamination of produce on farms and the institution of additional control measures from the source throughout the supply chain are critical for preventing similar outbreaks in the future.

In other words, we badly need farm-to-table safety controls for all foods, no exceptions.

But, as the accompanying editorial by Michael Osterholm explains,

The new law has a major shortcoming: dollars. There was no appropriation approved by the Congress for the act or authorization in the bill for the FDA to assess fees on the companies that it inspects. The Congressional Budget Office estimated that implementing this legislation would require $1.4 billion between 2011 and 2015….

Recent reports in the media calling this act “historic legislation” must be tempered by the reality that without the necessary resources, requiring the FDA to carry out the law’s required activities will be like trying to get blood out of a rock.

Blood out of a rock? The House just passed a bill that would CUT the FDA’s food safety budget by $241 million.

Of course the FDA doesn’t need the funds. After all, only 21% of the 1,500 people known to have gotten sick with Salmonella Saintpaul had to be hospitalized, and only 2 died. And Salmonella Saintpaul is in foods that real Americans don’t eat anyway, like peppers with funny foreign names and alfalfa sprouts.

I used to say that Congress would never move on food safety until a close relative of a senior Senator became seriously ill with food poisoning. Now I have to include a senior House member.

4 comments

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Tags: Food safety, Salmonella

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Next public appearance
San Francisco: Public Health Heroes Award Ceremony

I am the 2011 recipient of the National Public Health Hero Award given by the UC Berkeley School of Public Health, and will make brief remarks. Yerba Buena Center for the Arts, 6:00 reception.

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