Seafood & IQ: Smart Fats, Smarter Babies: Moving FDA Formula Regulations from 8-Tracks to Claude Chats

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OPERATION STORK SPEED

2025

fda 01/09/25

FDA celebrates the life of President Jimmy Carter and his commitment to public health.

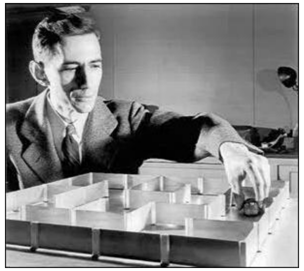
President Carter signed the Infant Formula Act into law on Sept. 26, 1980. In the ceremony pictured here, he said that the law was "designed to ensure that commercially produced and marketed infant formulas meet accepted nutritional standards and that consistent quality is maintained in their preparation."

Infant Formula Act of 1980

Hearing before the Subcommittee on Health and Scientific Research of the Committee on Labor and Human Resources, United States Senate, Ninety-sixth Congress, second session, on S. 2490 ... June 12, 1980

United States. Congress. Senate. Committee on Labor and Human Resources. Subcommittee on Health and Scientific Research

Claude



Seafood & IQ: Smart Fats, Smarter Babies: Moving FDA Formula Regulations from 8-Tracks to Claude Chats

ELSEVIER

The Journal of Nutrition

Volume 128, Supplement 11, November 1998, Pages 2059S-2293S

LSRO Report: Assessment of Nutrient Requirements For Infant Formulas

Daniel J. Raiten, John M. Talbot, Janet H. Waters

1998

- *"…clinical and basic science studies on the effects of supplementing infant formula with AA and DHA are being pursued …the Expert Panel recommended that the question of requiring the addition of specific LCPUFAs to infant formulas be reassessed within five years."*

1998+5 = 2003

2025-2003 = 22 years?

2001-2003: As promised, many studies

Randomized Trials with Polyunsaturated Fatty Acid Interventions in Preterm and Term Infants: Functional and Clinical Outcomes

Robert A. Gibson[a,*], Wenxiong Chen[b], and Maria Makrides[a]

Lipids, Vol. 36, no. 9 (2001)

11 Preterm RCT: "**mostly positive effects on CNS and vision; some negative effects on growth.**

10 Term RCT: **Results mixed, either neutral or positive**.

TERM INFANT STUDIES OF DHA AND ARA SUPPLEMENTATION ON NEURODEVELOPMENT: RESULTS OF RANDOMIZED CONTROLLED TRIALS

The Journal of Pediatrics • October 2003

Ricardo Uauy, MD, PhD, Dennis R. Hoffman, PhD, Patricia Mena, MD, Adolfo Llanos, MD, MPH, and Eileen E. Birch, PhD

14 Term RCT "meta-regression": "We conclude that there is a significant relationship between [omega-3 level]… and visual acuity measurements… ."

Long-chain polyunsaturated fatty acids in breast milk: are they essential? Gibson & Makrides *Adv Exp Med Biol*. ***2001***

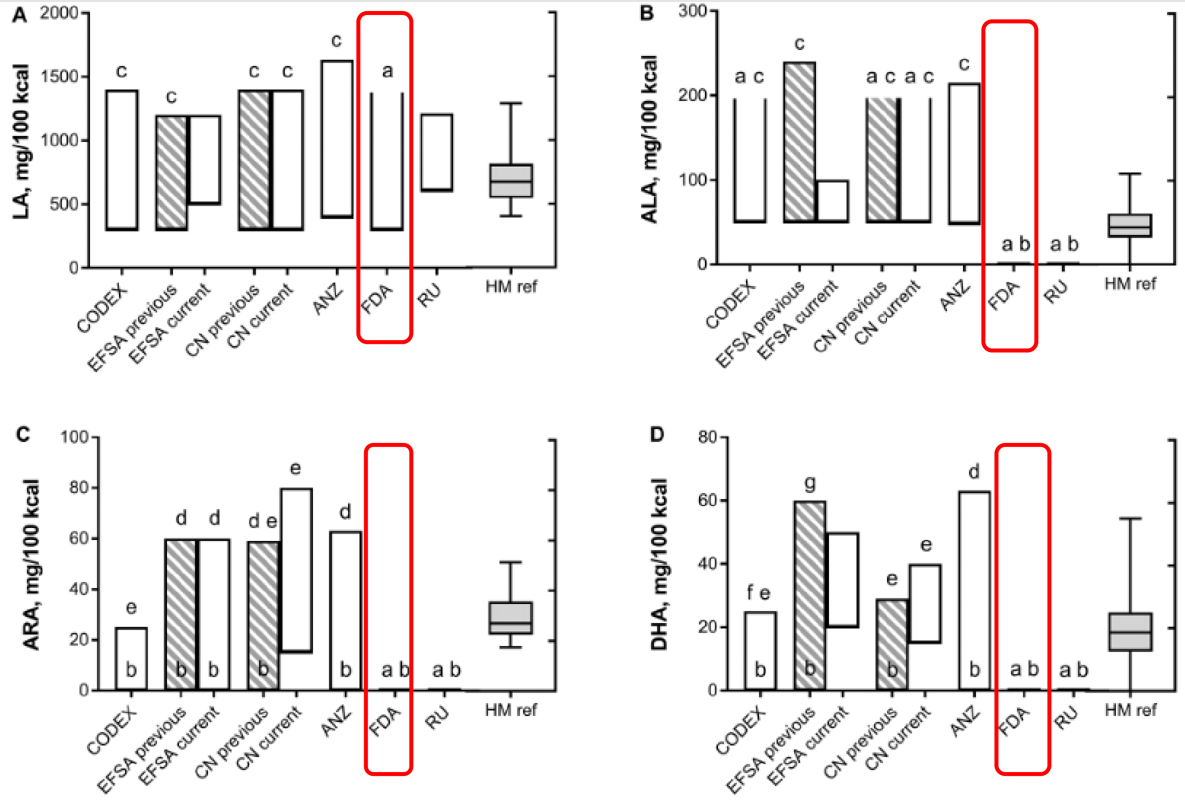
From abstract: **"Randomized clinical trials involving preterm infants have shown a clear requirement for DHA for full visual and neural development.** … However, **intervention studies with term infants** … **have not yielded consistent results.** Some randomized studies have demonstrated improved visual and developmental indices in supplemented over unsupplemented infants, others have failed to demonstrate an effect.

Advances in Nutrition

Volume 12, Issue 6, November 2021, Pages 2085-2098

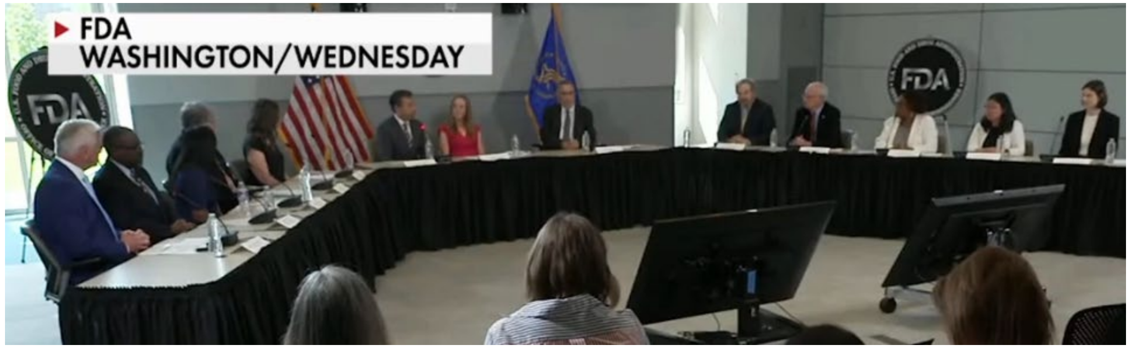
Perspective: Moving Toward Desirable Linoleic Acid Content in Infant Formula

Susan E Carlson,[1] Lidewij Schipper,[2] J Thomas Brenna,[3,4] Carlo Agostoni,[5,6] Philip C Calder,[7] Stewart Forsyth,[8] Philippe Legrand,[9] Marieke Abrahamse-Berkeveld,[2] Bert JM van de Heijning,[2] Eline M van der Beek,[2,10] Berthold V Koletzko,[11] and Beverly Muhlhausler[12,13]



- Current US regulations, and others
- Background science
- Current consensus recommended ranges for fatty acids; further considerations
  - DHA, ARA, LA, ALA
- Fatty acid sources:
  - Seed oils
  - Fruit oils
  - Cow’s milk fat
- Knowledge gaps/research recommendations

What I did on my summer vacation…



Are seed oils actually bad for your health? Here's the science behind the controversy

JULY 7, 2025 · 5:00 AM ET

Maria Godoy

npr

One researcher who has spent decades studying fatty acids is Tom Brenna of the University of Texas at Austin. He is concerned that some people may be eating too many omega-6s in their diet from seed oils, because not everyone processes omega-6s in the same way. He says emerging research suggests some people may be more susceptible to inflammation from omega-6s.

The omega-6 & omega-3 balance

Most Americans eat about 10 times more omega-6 fats than omega-3 fats. And all the nutrition researchers we spoke with agree that for better health, it's a good idea to bring that intake into better balance, although the exact ratio has not been defined, according to the National Institutes of Health.

Since most people get plenty of omega-6s in their diet, the general advice is to up your intake of omega-3s. Fatty fish like salmon, mackerel and sardines, and plants including walnuts, flaxseeds and chia seeds are all rich sources of omega-3s.

And Brenna says you shouldn't stop eating omega-6s altogether.

"Some of the influencers are talking about getting rid of all the omega-6 in the diet," Brenna says. "And that would be a terrible idea," he says. "Some omega-6 is absolutely required. The question is how much?"

Brenna says he sticks mostly to olive oil — which is a fruit oil — though he notes that if everyone only used olive oil, "there isn't enough olive oil in the world" to meet demand. And he says it's expensive.

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life but better

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RFK Jr. is investigating infant formula. Here's what's at stake

UPDATED JUN 5, 2025

By Sandee LaMotte

The update on formula is long past due, said Dr. Thomas Brenna, a professor of pediatrics, chemistry and human nutrition at the Dell Medical School at the University of Texas at Austin. Brenna is a member of the new FDA review panel on infant formula that met in Washington on Wednesday. The group has met once online, and this was the first in-person meeting.

The New York Times

June 13, 2025

The F.D.A. Is Reviewing Infant Formula for the First Time in Decades

The agency's commissioner has implied that some of their ingredients may be harmful. Is that true?

Out-of-Date Formula Standards

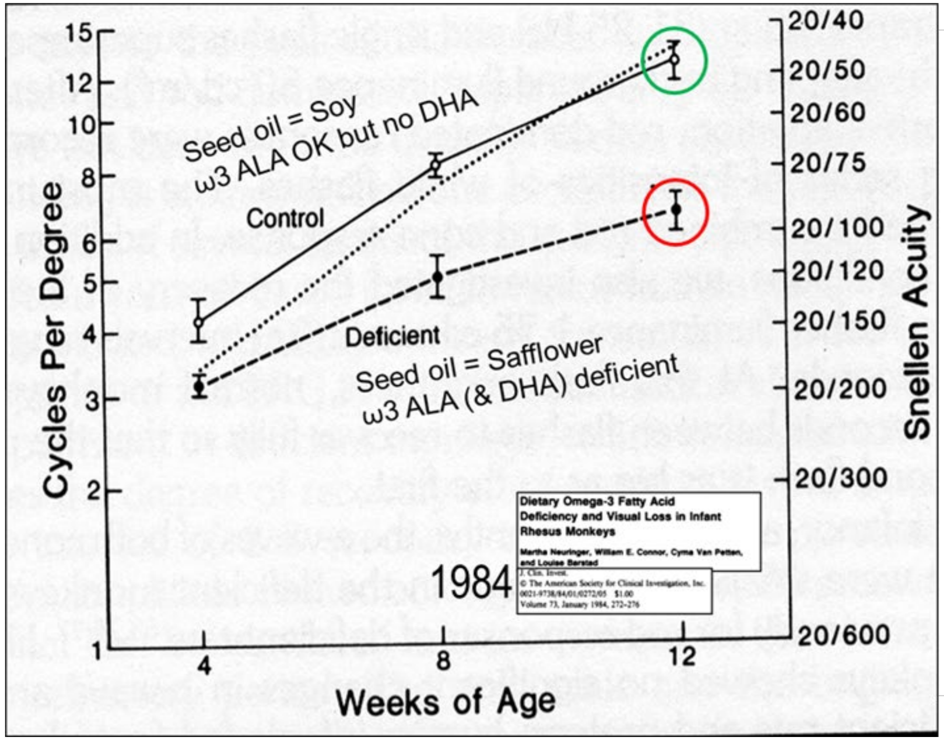
The claim: The nutrient requirements for infant formula are overdue for a review.

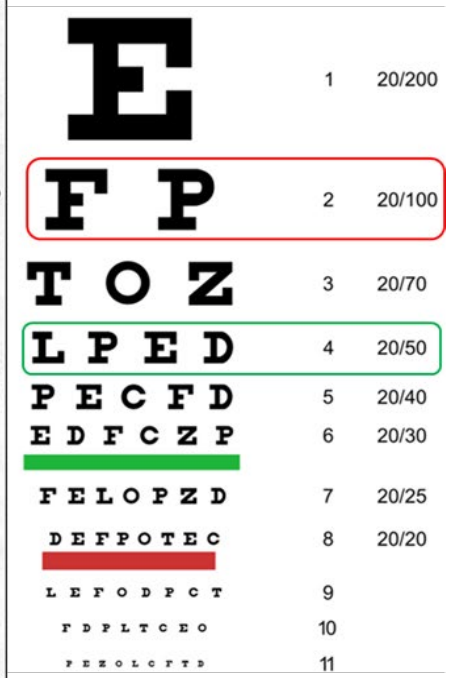
What experts say: This is true.

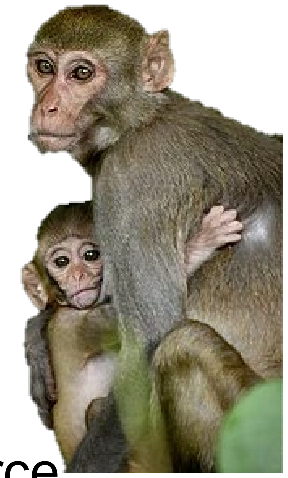
Since the nutrition standards for infant formulas were set in 1980, there have been few updates to them, said Tom Brenna, a professor of pediatrics at the University of Texas at Austin Dell Medical School who participated in the F.D.A. panel. The standards include requirements for nutrients like fat, protein, vitamins and minerals. Research since then has suggested that some of the levels should be adjusted.

And there is no F.D.A. requirement for a fatty acid called docosahexaenoic acid, or DHA, which is important for brain development, Dr. Brenna said. Most formula manufacturers have chosen to include it in their products, but not all of them add enough to be beneficial, he said, so the F.D.A. should set a minimum level.

1984, “Rapid Publication”







- Why does this matter?
- Rhesus monkey pregnant females fed as the sole source of fat
  - safflower oil (deficient)
  - soy oil (OK)
- Visual acuity, a measure of **neural** development, poorer in omega-3 deficient.
- Switch deficient neonates to soy, vision improves
- Does it work with DHA? In Humans?

DHA deficiency in infancy: induced by high LA (partially)? (1998-2005 studies)

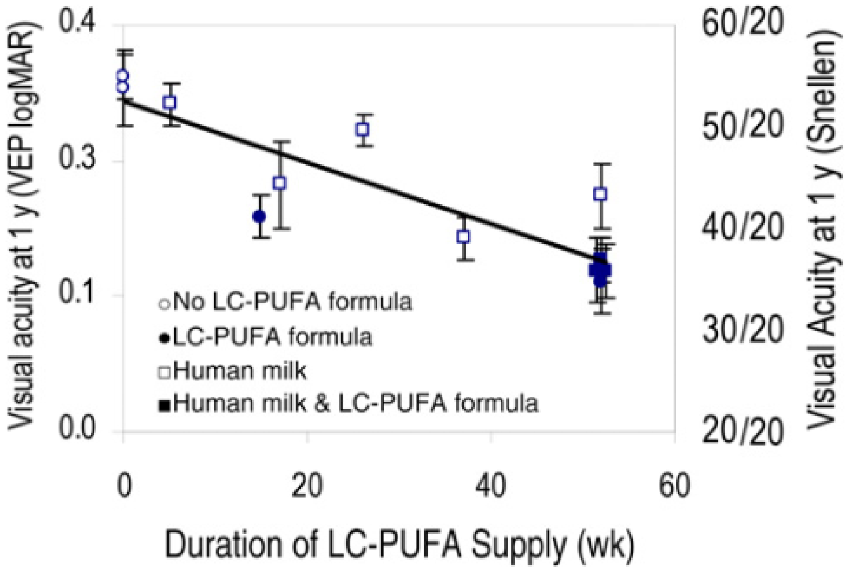


FIGURE 5 Visual acuity at 52 wk of age as measured by sweep VEP, expressed as logMAR. Data are drawn from 4 randomized controlled trials in human infants conducted in one laboratory and published 1998–2005. The

Long-chain polyunsaturated fatty acids and the preterm infant: a case study in developmentally sensitive nutrient needs in the United States[1–4]

*J Thomas Brenna** *Am J Clin Nutr* 2016;103(Suppl):606S–15S.

- The duration of DHA intake whether by infant formula or breastmilk determines visual acuity at 1 year of age.
- More DHA = better visual acuity at 1 year (formula or breastmilk)
- Visual acuity is a measure of **overall neural development**. It is not just about retina (as if that's not enough).




Birch/Hoffman/MJN studies at the Retina Foundation of the Southwest

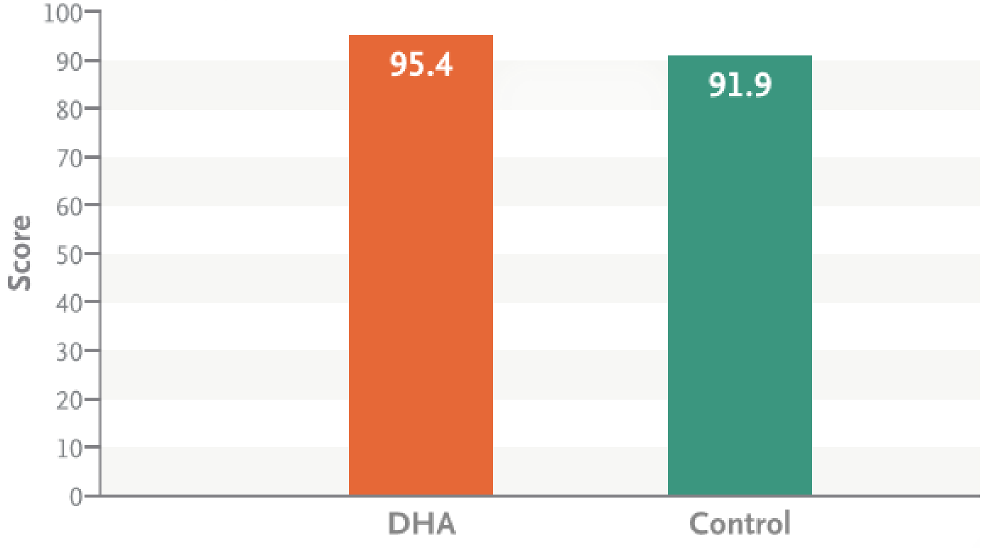
The NEW ENGLAND JOURNAL of MEDICINE
October 27, 2022
N Engl J Med 2022; 387:1579-1588

Neonatal Docosahexaenoic Acid in Preterm Infants and Intelligence at 5 Years

Jacqueline F. Gould, Ph.D., Maria Makrides, Ph.D., Robert A. Gibson, Ph.D., Thomas R. Sullivan, Ph.D., Andrew J. McPhee, M.B., B.S., Peter J. Anderson, Ph.D., Karen P. Best, Ph.D., Mary Sharp, M.B., B.S., Jeanie L.Y. Cheong, M.D., Gillian F. Opie, M.B., B.S., Javeed Travadi, D.M., Jana M. Bednarz, G.Dip., et al.

Mean FSIQ Score at 5 Years of Corrected Age

Adjusted mean difference, 3.45 (95% CI, 0.38–6.53); P=0.03



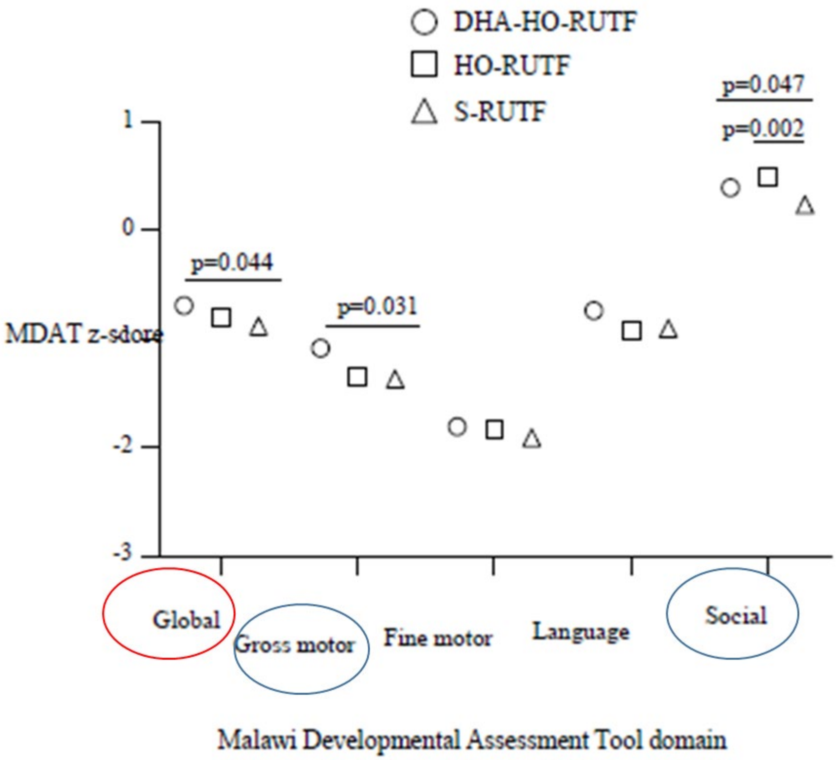
CONCLUSIONS

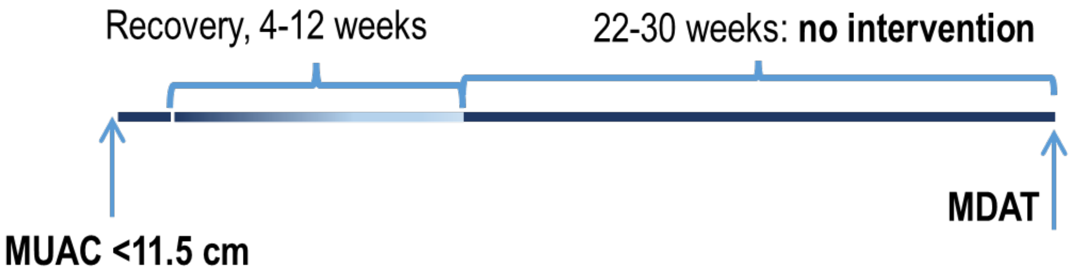
Among infants born before 29 weeks' gestation, an enteral emulsion of DHA (60 mg per kilogram per day) was associated with an FSIQ score at 5 years of age that was modestly higher than that with control feeding.

- Increase of about **3.5 IQ points** at age 5 years with DHA provision early in life
- No intervention for 5 years
- Early provision of DHA likely changed brain structures to yield a permanent improvement in neurocognitive function

DHA in toddler foods improves IQ

- Malawi Developmental Assessment Tool (MDAT) better in DHA-HO=hi DHA, low linoleic





[3 December 2021]

RUTF, per 100 kcal
- **LA <780mg**
- **ALA >110 mg**
- **DHA allowed**

Previously proposed
- LA <1,110mg
- ALA >33mg

Low linoleic acid foods with added DHA given to Malawian children with severe acute malnutrition improve cognition: a randomized, triple-blinded, controlled clinical trial

Am J Clin Nutr 2021;00:1–12.

Kevin Stephenson,[1] Meghan Callaghan-Gillespie,[2] Kenneth Maleta,[3] Minyanga Nkhoma,[3] Matthews George,[3] Hui Gyu Park,[4] Reginald Lee,[2] Iona Humphries-Cuff,[5] R J Scott Lacombe,[4] Donna R Wegner,[2] Richard L Canfield,[4] J Thomas Brenna,[4,6] and Mark J Manary[2,3,7]

Seafood is Brain food.
Brain selective nutrients

- Fat
  - Omega-3 DHA
- Minerals (absorbable)
  - Iron
  - Iodine
  - Zinc
  - Copper
  - Selenium

What's next?
The comment period ended (Sept 11)

- *"…FDA is interested in information that would help us determine whether there is a need to revise the existing nutrient requirements in 21 CFR 107.100, taking into consideration any new scientific data or information related to infant formula nutrients, including international infant formula standards."*
- *"5. What other nutrients (e.g., docosahexaenoic acid and arachidonic acid) or specifications for nutrients (e.g., ratio of linoleic acid to alpha-linolenic acid), if any, should we consider adding to 21 CFR 107.100? Please explain your rationale."*

Key Concepts

- Overhauling the regulations for infant formulas is long overdue
- Seafood omega-3 is a big part of what ought to be in formula, but isn't
- Breastfeeding remains the most reliable feeding for babies
  - Lessons learned making formula (as) great as possible (again) further implicates seafood nutrition as a nutrition machine for moms

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