Executive Summary

Unbeknownst to the general public, popular infant formulas sold throughout the United States contain infinitesimally small ingredients known as engineered nanoparticles or nanomaterials. While some nanoscale ingredients may offer potential benefits, their safety remains poorly understood, and a growing body of scientific research is raising concerns about their use in food and many other consumer products. **The groundbreaking analysis of nanomaterials in baby formula presented here by Friends of the Earth is meant to inspire greater public scrutiny, industry accountability and government regulation of nanotechnology, particularly in the food sector.** This analysis builds on our 2014 nanotechnology report, *Tiny Ingredients, Big Risks: Nanomaterials rapidly entering food and farming.*

Nano ingredients pose threats to human health but are not regulated or assessed for safety before they are put on the market. In the United States, the Food and Drug Administration (FDA) is charged with ensuring baby formulas are safe, however, the FDA does not approve the safety of infant formulas before they can be marketed. The FDA requires that baby formulas meet certain nutritional requirements and are screened for pathogens, and companies must register with the FDA and provide a notice before marketing a formula. However, these rules do not include screening or safety testing of nanomaterials or other potentially toxic synthetic ingredients. Baby formulas are intended for our most vulnerable population and should be regulated with the utmost of care. A product fed to millions of infants should not be permitted to go to market if we are not certain that the ingredients it contains are safe for human consumption. All infant formulas should be thoroughly tested for safety.

To put the nanoscale in context: a strand of DNA is 2.5 nm wide, a red blood cell is 7,000 nm wide, and a human hair is around 80,000 nm wide. One nanometer is one billionth of a meter. One way to understand how incredibly tiny these particles are is to consider a tennis ball in comparison with planet Earth. On scale, a tennis ball is the same size in relation to Earth as a nanoparticle is to a tennis ball.

Major baby formula brands contain nanomaterials

This analysis by Friends of the Earth reveals the use of engineered nanomaterials in baby formulas sold throughout the United States. We commissioned independent laboratory studies with a world-class nanotechnology research facility at the Arizona State University (ASU) to learn more about the presence of engineered nanomaterials in popular baby formulas. To our knowledge, these are the first laboratory studies focused on the detection of engineered nanomaterials in baby formulas that are marketed to the public.

Friends of the Earth tested a selection of six baby formula samples gathered from retailers in the San Francisco Bay Area.

We found nano-sized structures and particles of potential concern in all six of the baby formulas tested, including: Nano-hydroxyapatite (nano HA) in needle-like and non needle-like form, nano titanium dioxide (TiO2), and nano silicon dioxide (SiO2) (the nano TiO2 and SiO2 results were inconclusive). TiO2 was tentatively identified using a scanning electron microscope (SEM) in the Similac® Advance® OptiGRO™ (liquid) product, though after purchasing a second sample several months later and using a different separation process and transmission electron microscopy (TEM) analysis, the presence of TiO2 could not be confirmed.

Nanoparticles found in popular baby formulas tested by Friends of the Earth

Baby Formula Brand	Nanoparticles Found
Gerber® Good Start® Gentle	Nano-hydroxyapatite (nano HA)
Gerber® Good Start® Soothe	Titanium dioxide and silicon dioxide (limited amount of particles detected)
Enfamil™	Nano-hydroxyapatite (nano HA) in needle-like and non needle-like form
Similac® Advance® OptiGRO™ (liquid)	Titanium dioxide (nano TiO2 laboratory results inconclusive)
Similac® Advance® OptiGRO™ (powder)	Nano silicon dioxide (laboratory results inconclusive)
Well Beginnings™ Advantage®	Nano-hydroxyapatite (nano HA)

Nanomaterials present novel risks to human health

Recent studies have found that these nanomaterials may pose risks to human health if ingested or inhaled. Especially concerning: the nanomaterials

found in the three powdered formulas we tested provide a probable inhalation hazard for babies, parents and other care givers, as well as workers involved in the manufacturing of these products.

Nanomaterials have unique properties that offer many new opportunities for food industry applications. They can be used as nutritional additives, flavoring and coloring, anti-caking agents or as antibacterial ingredients for food packaging. However, **the same properties exhibited at the nanoscale that make these materials attractive for use in the food industry may also result in greater toxicity for humans and the environment.** (See full report for summary of the latest science).

At the nanoscale, the physical, chemical, and optical properties of familiar substances differ from those of the same substances in larger particle form. Nanoparticles can be more chemically reactive and more bioactive than larger particles. Because of their very small size, nanoparticles are more likely than larger particles to enter cells, tissues and organs.

The European Union Scientific Committee on Consumer Safety (SCCS) finds that needle-like nano-hydroxyapatite — one of the nanomaterials we found in Gerber®, Well Beginnings™, and Enfamil™ formulas — is potentially toxic, could be absorbed by and enter cells, and should not be used in cosmetics such as toothpaste, teeth whiteners and mouth washes. A material that should not be used in cosmetics raises greater concern when used in food.

Nanomaterials are already used widely in the commercial sector

Nanotechnology is a rapidly expanding, multi-billion dollar industry involving manipulation of matter at the nanoscale. As of August 2008, the Project on Emerging Nanotechnologies estimated that over 800 manufacturer-identified nanotech products were publicly available, with new ones hitting the market at a pace of three to four each week.

Many nanomaterials have already entered wide-scale commercial use and can be found in hundreds of products available on supermarket shelves, including transparent sunscreens; light-diffracting cosmetics; penetration enhanced moisturisers; stain, moisture and odor repellent fabrics and clothing; long-lasting paints and furniture varnishes; anti-bacterial household appliances such as vacuum cleaners; refrigerators and air conditioners; and sporting equipment.

Beyond baby formulas, other children's products that contain engineered nanoparticles include skincare products and sunscreens, supplements, food containers, pacifiers, teethers, blankets, toys and stuffed animals, baby bottles, toothbrushes, baby carriages, bibs, baby clothing and many other products.

Nanotechnology is currently in the first generation of innovation. In coming years and decades, the next generation nanotechnology is forecast to bring more complex nanodevices, nanosystems, and nanomachines. Nanobiotechnology may be used to manipulate the genetics of humans, animals and agricultural plants at the atomic scale and to incorporate synthetic materials into biological organisms and biological materials into synthetic structures.

EU responsible technology policies

European regulators have enacted a range of precautionary policies for nanotechnologies. The European Parliament is working towards a moratorium on novel foods containing nanomaterials. France, Belgium and Denmark have implemented mandatory registries for nanomaterials, and the EU has implemented a nanofood-labeling regime.

U.S. regulatory inaction

In stark contrast to the EU, the United States has not developed any mandatory regulations or safety assessments for nanomaterials used in food or consumer products. It is important for U.S. consumers to know that manufacturers are not

required to list nanomaterial ingredients on product packaging in the United States. In our investigation, Friends of the Earth did not find any baby formulas that listed nanoparticles as ingredients, including the samples we found — via laboratory testing — to contain nanoparticles.

Nanotechnology raises ethical and social justice concerns

Serious ethical and social justice concerns must be addressed in the regulation of nanotechnology. In the case of baby formula, infants may be at greater risk of suffering health harms because of their more vulnerable physiology. Children's immune, central nervous, reproductive, and digestive systems are still developing, and at certain early stages of development, exposure to toxicants can lead to irreversible damage which can increase risk of disease later in life.

Food sector workers represent another vulnerable population as they may come into contact with nanomaterials during production, packaging, transport and waste disposal of food, food packaging and agrochemicals. As one example, the U.S. Occupational Health and Safety Administration states that nanoscale titanium dioxide, which we found in baby formula samples, is a potential occupational carcinogen.

Friends of the Earth and allied organizations demand regulatory action

In response to mounting scientific evidence on the potential harms of nanotechnology, non-governmental organizations worldwide, including Friends of the Earth, are calling for precautionary action. More than 70 groups from six continents have endorsed a guiding document published in 2007 called *Principles for the Oversight of Nanotechnologies and Nanomaterials*.

In 2011, the Center for Food Safety, along with Friends of the Earth and other organizations, filed a lawsuit calling out the FDA for failure to take action on a 2006 citizen petition to regulate nanotechnology. In response to the lawsuit, the FDA released voluntary, non-binding recommendations for industry that were finalized in 2014.

Given the potentially serious health and environmental risks and social implications associated with nanofoods, Friends of the Earth calls for a moratorium on the further commercial release of food products, food packaging, food coatings, food contact materials and agrochemicals that contain engineered nanomaterials until nanotechnology-specific safety and labeling laws are established and the public is involved in decision-making.

Friends of the Earth recommends the FDA conduct a thorough review of the nanoparticle ingredients found in baby formulas. The agency must, in the meantime, use its authority to enforce manufacturer recall of baby formulas containing engineered nanoparticles, as these ingredients may put people at risk.

We also demand greater accountability and transparency from food producers and retailers to allow consumers to make informed choices about

this novel set of technologies. If nanotechnology is to be developed safely, responsibly and transparently, there is an urgent need for further research and dissemination of information to policy makers, regulators, consumers and the scientific community.

Summary of recommendations:

For a detailed description of the following recommendations, see the full report.

What government must do:

- Enact a moratorium on new commercial nanotech products
- Assess safety of and recall baby formulas with nanoparticle ingredients
- Regulate nanomaterials as novel substances
- Extend the size-based definition of nanomaterials up to 500 nm in size
- Protect workers
- Ensure transparent, mandatory safety assessment and product labeling

What industry must do:

- Recall formula containing nanomaterials
- Remove nanomaterials from product formulas
- Create nanomaterial policies
- Ensure transparency in the supply chain

What concerned parents, individuals and organizations can do:

Until government and companies manage nanotechnology in a responsible and transparent manner, there are steps we can take to protect our health.

- Breastfeed when and if possible
- Hold government and industry accountable: Join Friends of the Earth to demand a moratorium on the use of nanotechnology in the food sector and urge policy makers to regulate and label food, food packaging and agricultural products containing manufactured nanomaterials
- Contact baby formula manufacturers and ask them to remove nanomaterials from their products

Visit our website to learn more about nanotechnology, take action and support our efforts to create a safe, just, resilient and sustainable food system. http://www.foe.org/nanotechnology

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