Comments from the NATURAL RESOURCES DEFENSE COUNCIL on the Federal Trade Commission's Proposed, Revised Green Guides,

16 CFR Part 260,
Project No. P954501

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The Natural Resources Defense Council (NRDC) appreciates this opportunity to comment on the Federal Trade Commission's (FTC's) Proposed, Revised Green Guides. NRDC is a national, non-profit organization of scientists, lawyers, and environmental specialists dedicated to protecting public health and the environment.

NRDC's Health and Environment program focuses on reducing human exposure to toxic chemical pollutants in air, water, food, shelter, the workplace, and our homes. The Program has worked for many years to identify endocrine disrupting chemicals (EDCs) and has led efforts to reduce exposure to EDCs found in consumer products such as phthalates found in toys and air fresheners, bisphenol A (BPA) in food cans, "antibacterial" chemicals in hand soaps and flame retardants in home furnishings and electronics.

Endocrine Disrupting Chemicals are Toxic at Low Levels

The endocrine system is a complex network of glands and hormones that regulates many of the body's functions, including growth, development and function of organ systems. The endocrine glands -- including the pituitary, thyroid, adrenal, thymus, pancreas, fat tissue, ovaries, and testes -- release carefully-measured amounts of hormones into the bloodstream where they act as natural chemical messengers. These hormones control and adjust many essential life functions including reproduction, lactation, energy balance, and growth and development of nearly every organ system in the body, including the brain and nervous system.

For many decades, scientists have recognized that synthetic chemicals are capable of interfering with the action of hormones produced within the body. This interference scrambles the body's key signaling pathways resulting in a phenomenon known as endocrine disruption. Endocrine disruption was first described in the 1990's when environmental chemical contamination was associated with numerous wildlife abnormalities including observations of male fish with female characteristics, impaired reproduction in birds, and alligators with small penises.[1] Subsequent

[1] Colborn T, vomSaal FS, Soto AM. Developmental effects of endocrine disrupting chemicals in wildlife and humans. Environ Health Perspect 1993;101:378–84.

laboratory animal studies have confirmed that exposure to some endocrine-disrupting chemicals, especially during development, can result in a wide range of adverse effects including birth defects of the genitals, changes in sex hormone levels, infertility or increased time to pregnancy, cancer, and altered development of the brain and nervous system. The effects described in wildlife and laboratory animals coupled with observations of an overall decline in sperm counts in adult men, increased rates of infertility in couples, increased rates of birth defects of the genitals including malformed penises and undescended testicles in infant boys, and increased rates of testicular and other hormone-dependent cancers raised concern that endocrine disrupting chemicals were not only affecting wildlife, but also could be harming human health.

There is a substantial amount of scientific proof that when exposure to EDCs occurs at the same time that organs or systems (such as the organs of the immune system, reproductive system, and nervous system) are developing, even transient, low-dose exposures can cause irreparable harm.[2,3] That is, the timing of exposure may actually be more critical than the dose. Exposures to EDCs during critical windows of development have been shown to have permanent effects.[4] Some of these effects, such as infertility or cancer, may not be obvious until adulthood even though the exposure occurred during fetal or neonatal life.[5]

The Guidelines Should Not Encourage Risk Trading

Section 260.9(b) states that a claim that a product is free of a substance may be deceptive if the product "contains or uses substances that pose the same or similar environmental risks as the substance that is not present…."

This section needs be clarified in two ways. First, this provision should include both health and environmental risks. Claims that products are free a substance would likely be interpreted by consumers to indicate both that it is therefore safe for health and safe for the environment. It is important that products claiming to be free of one substance not contain a substitute that poses the same or similar health risks, in addition to environmental risks, as the original substance.

Second, we support preventing manufacturers from substituting equally problematic substances into products to be able to make a free-of claim. However, we are concerned that this section will encourage risk-trading and expose consumers and the environment to other equally dangerous but "different" risks. For example, a producer claiming "BPA-free" is likely appealing to consumers who are worried about the endocrine-disrupting activity of BPA. However, if BPA is replaced with a substance that is not an endocrine disrupter, but is carcinogenic, it is not clear that the claim would be deceptive because endocrine disruption and

[2] Colborn T. 2006. A case for revisiting the safety of pesticides: a closer look at neurodevelopment. *Environ Helath Perspect* 114(1):10-17. Review.
[3] Colborn T. 2004. Commentary: setting aside tradition when dealing with endocrine disruptors. *ILARJ* 45(4):394-400. Review.
[4] Colborn T. 2004. Neurodevelopment and endocrine disruption. *Environ Health Perspect* 112(9):944-49. Review; Crain DA, et al. 2008. Female reproductive disorders: the roles of endocrine-disrupting compounds and developmental timing. *Fertil Steril* 90(4):911-40. Review; Main KM, Skakkebaek NE, and Toppari J. 2009. Cryptorchidism as part of the testicular dysgenesis syndrome: the environmental connection. *Endocr Dev* 14:167-73.
[5] Grandjean P, et al. 2008. The Faroes statement: human health effects of developmental exposure to chemicals in our environment. *Basic Clin Pharmacol Toxicol* 102(2): 73-75.

carcinogenicity may not be considered "the same or similar" risks. However consumers would likely expect that a product that is free of an EDC is also safe and free of any substances that are harmful to health and the environment. Therefore, we suggest that this section be clarified such that a truthful claim that a product is free of a deleterious substance still be considered deceptive if the contains or uses substances that pose any health or environmental risk.

Products containing "de minimis" amounts of a substance should not be considered "free of" that substance.

Section 260.9(c) states that "Depending on the context, some no, free-of, or does-not-contain claims may be appropriate even where a product, package, or service contains or uses a de minimis amount of a substance." The guidelines provide an example where insulation may be marketed as "formaldehyde free" even though it emits trace amounts of formaldehyde.

First, NRDC is specifically concerned about this example. Formaldehyde is a known human carcinogen and there is no assumed "safe" level of exposure for a consumer who is exposed to many different low level sources of formaldehyde in their daily lives. Therefore, we do not believe that a *de minimis* amount of formaldehyde should be allowed in any product claiming to be "formaldehyde free."

More broadly, NRDC is concerned that the FTC would allow any – even *de minimis* – levels of a substance into a product and still allow a free-of claim be made. This is particularly important for chemicals like EDCs that cause adverse effects for human health and the environment at very low levels. Circulating levels of naturally occurring human hormones are found in the parts per billion (ppb) to parts per trillion (ppt) range. A large body of scientific evidence has found levels of synthetic, hormonally-active chemicals circulating in the human body in the parts per billion range and many of these exposures occur as result of exposure form consumer products. These levels may be considered "*de minimis*" or "trace," yet still have devastating effects on development in humans and wildlife.

We urge the FTC to adopt a scientifically-valid, health-protective approach to chemicals in consumer products by not allowing the free-of claim to apply to even *de minimis* amounts of chemicals that are present in a consumer product.

If FTC allows a *de minimis* exemption in free-of claims, there should be restrictions on the use of that exemption

Considerations for allowing a de minimis exemption

If, despite the concern identified above, the FTC does decide to allow free-of claims to be made on products that contain *de minimis* concentrations of a substance, the amount that qualifies as *de minimis* must be set in a scientifically valid method. The proposed revised guideline notes "that the determination of whether an amount is *de minimis* depends on the substance at issue and requires a case-by-case analysis." NRDC agrees that allowing an exemption must be based on a case-by-case analysis.

The following restrictions should apply to the *de minimis* exemption. First, it should not apply to persistent, bioaccumulative, and toxic chemicals, carcinogenic, mutagenic, or reproductive toxins, endocrine disruptors, or other classes of compounds known to be harmful in very small

amounts. Second, the exemption should not permit aggregate exposure at levels above any applicable state or federal law or regulation. Third, the *de minimis* amount allowed should provide a margin of safety for exposure to chemicals that are active at low doses that is at least as protective as the margins provided by standard risk assessments based on uncertainty factors. And finally, the FTC should require that a producer seeking to make a free-of claim for a particular substance first prove that the *de minimis* level does not pose a threat to human health or the environment.

De minimis should be based on testing

Free-of claims should be substantiated based on whether the substance can be found in the product using validated detection methods with limits of detection that are within the range of currently established human exposures. Where possible, the assay should be validated for detecting the substance at least in the ppb range. Furthermore, to substantiate free-of claims, companies should clearly and prominently qualify their claims. For example, a notation on the label could direct consumers to a website that identifies the assay used and the detection limit for the substance tested. Making this information publicly available would be an important factor for substantiating the claim for consumers.

These testing results should guide the determination of whether a *de minimis* concentration is present in the product, rather than relying on the marketer's intent. In some cases, manufacturers may intentionally choose not to add a substance into its product, but manufacturing, processing or packaging practices could cause the substance to be unintentionally incorporated into the product. For example, the chemical BPA is found in canned food and infant formula because the cans themselves are lined with a resin that contains BPA. The chemical migrates and contaminates the contents of the can, although the producers did not intentionally add it to the product. Despite a marketer's intention, the product could still contain a significant amount of BPA, which is important to consumers. As such, whether or not the producer intended to add the chemical to its product should not determine whether a "free of "claim can be made. Unintentional, but detectable, contamination of a product with a chemical should render it ineligible for a "free of" claim.

Conclusion

NRDC is pleased that the FTC provides guidelines to marketers to discourage greenwashing. For the free-of and non-toxic claims, the FTC should consider the special qualities of endocrine disrupting chemicals that can cause adverse health and environmental effects at seemingly trace levels. Clarifying these guidelines with endocrine disrupting chemicals in mind can help consumers avoid unwittingly buying products that are harmful to their health or to the environment.

Respectfully submitted,

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