

Microbeads Banned in Cosmetics and Toothpaste

Cosmetics and toothpaste manufacturers must reformulate to eliminate use of plastic microbeads by July 2018 under new federal legislation.

On December 18, 2015, Congress passed H.R. 1321 — the “Microbead-Free Waters Act of 2015” — and presented it to President Obama on December 22, 2015. H.R. 1321 will become law when signed by the President, which is expected to occur soon after the first of next year.¹

Section 301 of the Federal Food, Drug and Cosmetic Act (FFDCA) lists prohibited acts. H.R. 1321 adds to that list the

“manufacture or the introduction or delivery for introduction into interstate commerce of a rinse-off cosmetic that contains intentionally-added plastic microbeads.”²

H.R. 1321 indicates that “rinse-off cosmetic” includes “toothpaste” as well as any “drug” that also is a “cosmetic”. It phases in the ban on such products containing intentionally-added plastic microbeads as follows:

- **July 1, 2017**: Ban on *manufacture* of rinse-off cosmetics that are not “drugs”.
- **July 1, 2018**:
 - Ban on introduction or delivery for introduction into interstate commerce of rinse-off cosmetics that are not “drugs.”
 - Ban on manufacture of rinse-off cosmetics that are “drugs.”
- **July 1, 2019**: Ban on *introduction or delivery for introduction into interstate commerce* of rinse-off cosmetics that are “drugs.”³

H.R. 1321 pre-empts all state laws, including those already in force, that impose “restrictions with respect to the manufacture or introduction or delivery for introduction into interstate commerce of rinse-off cosmetics containing plastic microbeads” that are not “identical” to those under H.R. 1321. This pre-emption provision indicates Congressional intent to avoid burdening industry by limiting compliance obligations to only one federal law instead of the current situation of many, differing state laws. As discussed below, however, H.R. 1321 — due to its simplicity in wording and structure — leaves interpretive ambiguities which not only will create compliance challenges, but also may allow states to regulate certain types of products containing plastic microbeads that fall outside of H.R. 1321’s scope.

Ambiguities In Scope

H.R. 1321 is a simply worded, one-page law that bans manufacture and introduction and distribution into commerce of

- (a) a “rinse-off cosmetic” to which
- (b) “plastic microbeads” are
- (c) “intentionally-added”.

Several key terms are not defined in the law or elsewhere in the FFDCA which the law amends. This situation results in certain ambiguities discussed below that may require FDA rulemaking and/or guidance to resolve and that may result in compliance challenges and enforcement vulnerabilities in the meantime.

The law defines “plastic microbead” as

“any solid plastic particle that is less than five millimeters in size and is intended to be used to exfoliate or cleanse the human body or any part.”⁴

A plain language reading indicates that this definition requires the “solid plastic particle” to have been intentionally-added so that the product will “be used to exfoliate or cleanse the human body or any part.” Under such a reading, if the “solid plastic particle” is being intentionally-added so that the product will be “used” for some other reason — such as, for example, to lubricate and fill crevices in the skin for a more pleasing visual appearance — then H.R. 1321 arguably may not apply to ban such a product.

Another potential ambiguity is created by the term “plastic” which H.R. 1321 does not define and neither does the FFDCA. The House report on the law specifically mentions polyethylene and polypropylene and refers to plastic microbeads as being “synthetic plastic particles,” however, the word “synthetic” does not appear in H.R. 1321. Under the circumstances, it is unclear whether H.R. 1321 covers “naturally derived,” more readily biodegradable materials that function as plastics, such as polymers made from vegetative matter. Arguably, if concerns about bioaccumulation of microbeads in the environment are behind H.R. 1321 (see next section below for more information) then biodegradability should be a factor in determining whether a particular material qualifies as a “plastic” covered by the law .

H.R. 1321 also provides no definition of “rinse-off cosmetic.” FFDCA defines “cosmetic” as (1) articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance, and (2) articles intended for use as a component of any such articles; except that such term shall not include soap.” So, H.R. 1321, in essence, adds the term “rinse-off” to this definition. It seems clear that a “rinse-off cosmetic” would include various items specifically mentioned in the House report that are applied to the human body and intended to be washed off with water, such as face wash, body wash and toothpaste. Other items, however, may fall into a grey zone or be excluded, such as, for example, a mouth rinse that is swished around the mouth and then spit down the drain, but is never “rinsed off”.

State Regulation and Pre-emption

H.R. 1321 aims to address the concern that plastic microbeads pass through through wastewater treatment plants, into waterways, and into the bodies of fish and other aquatic organisms, resulting potentially in environmental harm, such as blocking of fish digestive systems, replacement of nutrient-

laden food with the plastic microbeads, and concentration in fish of toxics such as polyaromatic hydrocarbons (PAHs) and polychlorinated biphenyls (PCBs), which adhere easily to the plastic.⁵

In recent years, a number of state already have imposed bans or restrictions on plastic micro-beads to address this concern, creating a difficult patchwork of regulations for industry to negotiate. To solve this problem for industry, H.R. 1321 pre-empts any state laws that are “not identical,” including state laws which regulate “indirectly.”⁶ The House Report for H.R. 1321 indicates the bill’s purpose is as much to give manufacturers certainty through pre-emption of state laws as to prevent microbeads from getting into waterways.⁷

Despite the clear Congressional intent to pre-empt state regulation, the ambiguities in H.R. 1321 discussed above create uncertainties as to whether states may be able to regulate in situations clearly or possibly excluded by H.R. 1321. Indeed, environmental and consumer protection groups may continue to advocate for state regulation if they believe the scope of the federal law is too narrow, and this could lead to litigation over whether new state regulations are pre-empted.

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Endnotes

- ¹ Microbead-Free Waters Act of 2015, H.R. 1321, 114th Cong. (2015), *available at* <https://www.congress.gov/bill/114th-congress/house-bill/1321/text>. No veto is anticipated. The bill was passed by voice vote in the House and by unanimous consent in the Senate.
- ² *Id.* § 2(a) (to be codified at 21 U.S.C. § 331(ddd)).
- ³ *Id.* § 2(a).
- ⁴ *Id.* § 2(a).
- ⁵ *See, e.g.*, Personal grooming products may be harming Great Lakes marine life, *Scientific American* (June 25, 2013) *available at* <http://www.scientificamerican.com/article/microplastic-pollution-in-the-great-lakes/>.
- ⁶ H.R. 1321, 114th Cong. § 2(c).
- ⁷ H. Rept. 114-371, at 2 (2015) *available at* <https://www.congress.gov/congressional-report/114th-congress/house-report/371/1>.