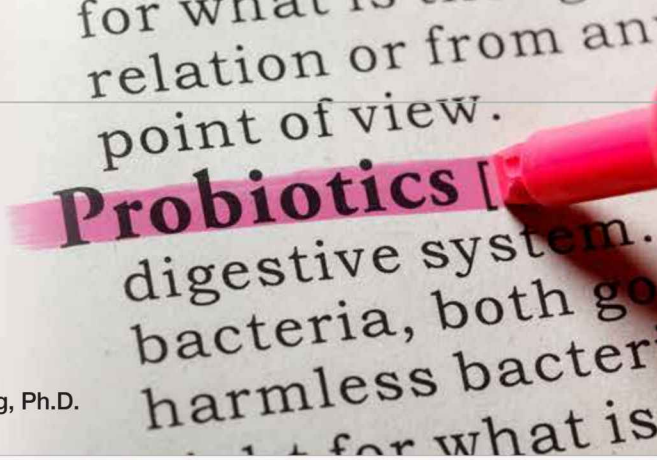

Advancing probiotic innovation with science and advocacy

by Andrea Wong, Ph.D.

INSIDER's take

- Manufacturers are tasked with creating products that meet standards—but those standards should bring clarity, not confusion, to consumers.
- FDA should allow probiotic supplement brands to label quantities in CFUs rather than requiring them to list the ingredients by weight.
- In 2019, the California State Assembly presented legislation that was inconsistent with FDA's current probiotic policy and regulation.

The supplement aisles of local retailers and the expo halls of industry trade shows offer an excess of product innovation in the probiotics space. These live organisms are being incorporated into a wide array of supplement and food products, providing consumers with more purchasing options than ever before. Consumers can find probiotics in traditional dietary supplement delivery forms like powders, capsules and gummies, as well as in food products, like chips or cheese puffs.

As probiotics continue to trend in the dietary supplement industry, and consumers continue to seek alternative delivery forms, the industry has a heightened responsibility for creating products with high-quality and reliable standards to ensure trust and dependability for consumers.

Labeling updates

In September 2018, FDA issued a draft guidance titled, "Policy Regarding Quantitative Labeling of Dietary Supplements Containing Live Microbials: Guidance for Industry," that announced its intent to exercise enforcement discretion to allow supplement companies to use colony-forming units (CFUs) when declaring the quantity of live microbials on a Supplement Facts label. While encouraging, the draft guidance also stated that the label must also list the quantitative amount by weight, as is required by current regulation for dietary ingredients. The Council for Responsible Nutrition (CRN) submitted comments in response to the draft guidance, commending FDA for recognizing the appropriateness of CFUs for describing probiotic quantity, but expressing concern with the agency's position that supplement labels should also list the quantity of probiotic ingredients by weight. It is not possible to accurately correlate probiotic quantity in both weight and CFUs on a consistent basis. Therefore, the recommendations in the draft guidance cannot be implemented in a manner that is not potentially misleading to consumers.

Noting a lack of action since the draft guidance was issued last year, CRN sent a letter to FDA in August, reiterating its request for FDA to eliminate the condition that

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live microbial quantity must be listed in terms of weight, in addition to quantity in CFUs, and to formally exercise enforcement discretion when marketers declare quantity of probiotic ingredients in CFUs only so that manufacturers and marketers of probiotic products could provide consumers with accurate and meaningful label information. CRN is still waiting for a response from FDA.

State legislation concerns

Earlier this year, the California State Assembly presented legislation concerning the labeling of dietary supplement products containing live microorganisms, including probiotics. The introduced Assembly Bill AB 1178 required probiotic dietary supplements to label ingredients by genus, species and strain, and to identify quantity at end of shelf life by CFU. The bill's requirements are inconsistent with FDA's current policy and regulation, putting industry in a difficult position and potentially causing confusion among consumers.

To foster innovation in this sector and to maintain a responsible market, it's important that industry continues working to ensure proper labeling, regulation and research of this category.

CRN worked to have the CFU requirements removed from the Senate version of the bill, leaving only the genus, species and strain requirement. While the requirement created a state-imposed labeling obligation in addition to federal requirements, it was not conflicting with current federal regulation.

The bill did not progress out of committee before the legislative session ended in mid-September, giving the responsible industry the opportunity to continue working with the bill's author—California Assemblyman Bill Quirk (D-Hayward)—to find compromise language should the bill be reintroduced in next year's legislative session, since he had not agreed to the Senate revision.

Many Americans rely on probiotics as part of their health and wellness regimens. To foster innovation in this sector and to maintain a responsible market, it's important that industry continues working to ensure proper labeling, regulation and research of this category.

Andrea Wong, Ph.D., is the senior vice president, scientific and regulatory affairs, of the Council for Responsible Nutrition (CRN), a trade association for the dietary supplement and functional food industry.