

## CRN State Regulation Update

2020 challenges remain high priority in the New Year By Amanda Darlington, director, government relations, CRN

In 2020, the dietary supplement and functional food industry faced challenging legislation and regulation around the country. Specifically, three big issues arose over the past year: age restriction legislation on weight management and sports nutrition dietary supplements; hemp-CBD legalization and regulation efforts; and sustainability issues in the form of single-use plastics packaging legislation in California. CRN will continue to combat these troublesome regulations that place unnecessary burdens on the industry in 2021.

### Age Restriction Legislation

Nearly identical legislation was introduced in the 2020 legislative cycle in California, Illinois, Massachusetts, New York State and New York City that proposed age restriction and limited access requirements to two broad categories of dietary supplements and functional foods—sports nutrition and weight management products.

This legislation, although well intentioned, would have significant negative impacts on all consumers and limit their access to safe and beneficial products without a scientific or legal basis to do so. At the same time, the legislation would also place unreasonable compliance and economic burdens on retailers in these states.

Last year, CRN worked with state chambers of commerce, retail associations and various industry trade associations to assemble a unified coalition of opposition and educate legislators and businesses about the negative impacts of these bills. Moreover, as CRN anticipates the re-introduction of these bills in 2021 state legislative cycles, we plan to reignite our allies and continue in our education efforts to legislators and stakeholders around the country. With states in budget shortfalls, due to the consequences of the COVID-19 pandemic, CRN will be closely monitoring how this legislation will take flight next year, as legislators focus on COVID-19 relief and conservative spending efforts.

### Hemp-derived CBD Legislation

More than two years after the 2018 Farm Bill has passed, legalizing hemp-derived cannabidiol (CBD), the industry continues to face regula-

ry uncertainty about the inclusion of hemp-derived CBD in dietary supplements. In the absence of a single federal framework of regulation for CBD products, CRN remains concerned of the possibility of inconsistent and perhaps conflicting state requirements on the regulation of hemp-derived CBD products, including dietary supplements that contribute to a patchwork of state laws that make simultaneous compliance with anticipated federal regulations difficult, if not impossible.



States imposing their own requirements and restrictions have the opportunity to model these regulations after the federal requirements for dietary supplements. By creating a consistent, harmonized framework, states will encourage companies to develop high quality products that can be sold interchangeably from state to state. Near the end of 2020, CRN issued a position paper calling for a consistent, harmonized framework for state CBD regulation.

While a state may allow for the sale of CBD in dietary supplements within that state, companies must still consider how federal law applies to the sale of their products within a particular state, as well as how any limitations or specific requirements (such as labeling, testing, manufacturing and registration) affect the sale of CBD products within the state. For instance, hemp-derived CBD is still illegal in the state of California. While industry initiatives have been aggressive following the 2018 Farm Bill and particularly strategic during the last months of legislative session, in collab-

oration with Governor Newsom's office, corporations and trade associations around the country were unable to get a legalization bill in 2020.

CRN continues to work with Congressional leaders to support passage of federal legislation H.R. 8179, the Hemp and Hemp-Derived CBD Consumer Protection and Market Stabilization Act of 2020. This legislation, if enacted, will direct that CBD be recognized as a lawful dietary ingredient irrespective of any other definitional hurdles in the federal Food, Drug & Cosmetic Act, regulated under the U.S. Food and Drug Administration (FDA), and will require that these CBD-containing products adhere to the same legal requirements for manufacturing, labeling, promotion and usage as any other dietary supplement. It will provide a clear legal pathway to market for dietary supplements containing hemp-derived CBD and will help protect the health and safety of consumers by addressing many of the concerns that currently exist from an untamed market.

We expect Congress to entertain this legislation early in the 117th session and strongly encourage states looking to adopt their own hemp-related regulatory structures to fashion ones that would be consistent with that federal framework. CRN will also continue to monitor and submit comments on state regulation of hemp-derived CBD products. We have submitted comments to Kentucky, Iowa, Texas, Utah and Virginia and will be submitting comments in New York in January 2021.

It is critical that FDA open the dietary supplement lane to CBD, so that companies manufacturing and marketing CBD products are subject to the comprehensive range of dietary supplement laws and regulations. CRN members include manufacturers and suppliers that sell hemp-derived CBD dietary supplements around the country and therefore have a vested interest in having hemp-derived CBD dietary supplements consistently regulated by current federal standards.

### Single-use Plastics Packaging Legislation

Single-use plastics packaging is an issue that impacts countless consumers,

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health problems when they arise.

Another analysis explored the commitment of consumers in relation to food and drink products with a digestive health positioning. It found that 44 percent intended to seek out such products on a shopping trip and 36 percent were willing to pay a premium for food and drink products with a digestive health positioning.

## Consumers Want to See the Proof

Another trend that has appeared to have gathered pace during the pandemic is demand for claims backed by evidence. Half (49 percent) of global consumers say they now want more information about the nutritional benefits of products, while two thirds (64 percent) say they will now pay more attention to claims.

Scientific substantiation is particularly important in the probiotic space, because not all strains are created equal. Many products on the market don't live up to the hype, and when it comes to wellness benefits, there are huge differences between strains. It's hard to overstate the importance of using a probiotic supported by high-quality research, especially when consumers are increasingly savvy and are being advised to engage with the science supporting the products they buy. The International Scientific Association for Probiotics and Prebiotics, for example, urges them to "hunt a little" for "scientific evidence of probiotic health benefits."

## New Evidence of a Role in Protein Digestion

One probiotic strain that certainly does meet the demand for scientific substanti-

ation is *Bacillus coagulans* GBI-30, 6086. It is supported by more than 25 published papers demonstrating benefits in areas such as immunity, as well as digestive health. And in 2020, new evidence emerged of the role it plays in another area of increasing concern to consumers.

The ability of our bodies to use protein is critical to many functions, but it can be influenced by factors like aging, stress and the rigors of physical activity. Since the rate of protein absorption can decline with age, it's particularly important for seniors to be able to efficiently utilize the protein they consume. Meanwhile, sportspeople and active lifestyles at all levels are seeking the muscle-building and recovery benefits of protein. Finally, wellness-focused consumers generally are increasingly identifying protein utilization support as a desired functional benefit in their everyday foods and beverages.

Ensuring healthy protein absorption and utilization starts with meeting dietary needs. This can be difficult but adding certain probiotics to a healthy diet can help, as demonstrated by new research. Published in *Nutrition & Metabolism*, the double-blind randomized, controlled crossover study added to the body of research demonstrating that the strain can increase amino acid absorption into the bloodstream.

Thirty men and women between the ages of 18 and 55 ingested 25g of milk protein concentrate with or without 1 billion CFUs (colony-forming units) of *Bacillus coagulans* GBI-30, 6086 daily for two weeks. Blood samples were taken at regular intervals and analyzed for concentrations of 22 amino acids. Significantly

greater quantities of amino acids were found in the blood of participants who consumed the strain than those in the control group. They also had higher maximum concentrations of 10 amino acids.

## GanedenBC30 for Consumer Needs

This is a happy example of probiotic research keeping pace with the needs of consumers. As they develop new needs, such as protein utilization, science delivers more evidence that some probiotic strains can meet them. However, the key word here is some. The positive findings of a study that looks at a particular strain and its impact on health cannot be used to support that of another. The strain used in this study was GanedenBC30, (*Bacillus coagulans* GBI-30, 6086) Kerry's patented spore-forming probiotic ingredient. Supported by over 25 papers, and hardy enough to be used in a wide range of food and beverage applications, it's the ideal strain for constantly evolving consumer needs. **NIE**



John Quilter, Kerry vice president and general manager, leads the development and growth of Kerry's ProActive Health technologies. He holds a bachelor of agriculture science from University College Dublin (UCD), a master of food science from UCD and a professional diploma in strategy, innovation and change from UCD Michael Smurfit Graduate Business School.

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businesses, state and local governments and policy initiatives and environmental infrastructure throughout the country. National and California-based associations and organizations galvanized in August in opposition to the California Circular Economy and Plastic Pollution Reduction Act, that would set goals to reduce waste from single-use packaging and products and set standards for single-use plastics packaging classification as reusable, recyclable and compostable.

While the environmental impacts of plastics usage and disposal is a global

issue, the California legislation places an undue burden on manufacturers and defers overly broad authority to the California Department of Resources Recycling and Recovery (CalRecycle). This broad authority is particularly troublesome because the bill directs CalRecycle to determine whether packaging or priority single-use products are reusable, recyclable or compostable. This definition-setting authority would presumably lead to arbitrary criteria, constraining the ability of the industry to comply. Moreover, this exemplifies the lack of infrastructure that exists in the state, and country for that matter, for an intended program like this to be effective. There

are a few of the many observations that the opposition coalition emphasized to the legislature killing the bill during the final stretch in the midnight hour of this year's legislative session.

CRN continues to be at the forefront of these issues in state legislatures and regulatory agencies around the country, advocating on behalf of our member companies and the dietary supplement and functional food industry overall.



Amanda Darlington is the director, government relations of the Council for Responsible Nutrition.