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NEW REGULATION FOR THE USE OF PROBIOTICS IN CHILE

Recently, the Public Health Institute ("ISP" for its acronym in Spanish) issued Resolution No. 3435, according to which it establishes the control regime applicable to, "products in pharmaceutical oral forms prepared with Latobacilus spp., Bifidobacterium spp. and other specific bacillus", also known as "probiotics".

In the ISP's resolution sets forth that the control regime applicable to products that include Latobacilus spp., Bifidobacterium spp. and other specific bacillus, which are commercialized in pharmaceutical oral forms (e.g. capsules and tablets) and are aimed at **maintaining the balance of the intestinal flora, the intestinal transit and stimulating the immune system, corresponds to the one applicable to foods**. Hence, these products shall comply with the regulations applicable to foodstuff products in Chile, especially with the provisions of the Sanitary Foods Regulations –Decree No. 977 of 1997–, and with Decree No. 860 of 2017 which sets forth Technical Standard 191 on the guidelines applicable to the declaration of healthy properties of foods.

The resolution also provides that those products that have **any purpose other than maintaining the balance of the intestinal flora, the intestinal transit and stimulating the immune system, or that are aimed at maintaining the balance of the bacterial flora in any part of the human body, other than the intestine, shall be subject to the application of the regime applicable to pharmaceutical products**. Therefore, these products cannot be distributed in Chile without the corresponding health registration, in compliance with the provisions of Decree No. 3 of 2011 which approves the Regulations for the National Control System of Pharmaceutical Products for Human Use.

Insofar as the aforementioned health registration is not obtained, products that qualify as pharmaceutical by the resolution **must be recalled from the market by the distributor or seller**, notwithstanding any applicable health responsibilities.

Please bear in mind that, as mentioned above, this resolution of the ISP is applicable only to products that are commercialized in "pharmaceutical oral forms".

The complete text of Resolution No. 3435 is available here.

If you have any questions regarding the matters discussed in this memorandum, please contact the following attorneys or call your regular Carey contact.

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