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Special Topics

Understanding the Complexities of Customs Regulations for Herbal and Dietary Supplements

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With the rising popularity of dietary supplements—specifically fish oil supplements, which have been proven to be beneficial in reducing the risk for heart disease, improving vision and helpful in battling certain cases of Alzheimer's disease—we have witnessed increasing scrutiny from governmental agencies. These agencies are challenging health claims, the legality of claims made on dietary-supplement labels and whether any one agency can or should regulate the import of herbal or dietary supplements.

Among these agencies, The Bureau of Customs and Border Protection (CBP) should certainly be part of any manufacturer's or importer's considerations, especially when dealing with dietary supplements. CPB's treatment of fish oil supplements, specifically the classification or country of origin marking of fish oil supplements, serves as a bellwether for issues facing the importation of a number of other supplements and supplement ingredients.

Classification of any product imported into the United States carries with it an attendant duty rate, or "Customs duties." Customs duties are chargeable upon the importation of goods, which are generally grouped into exclusive, similar categories or classes of goods.

In the United States, bulk and unaltered fish oils have always been classified under Chapter 15 of the Harmonized Tariff Schedule of the United States (HTSUS), which provides, among other things, for animal and vegetable fats and oils (Chapter 15). The various subheadings in Chapter 15 used by Customs are dutiable, up to approximately 8% *ad valorem* in some cases, depending on the specific product. The fish oil supplements could also potentially be classified under Chapter 21 as dietary supplements, if the fish oil supplements are imported in an encapsulated or softgel form. And, if this encapsulation process takes place in either Canada or Mexico, the process of encapsulating the fish oils there "transforms" the product to make the necessary tariff shift from Chapter 15 to Chapter 21, and thus eligible for duty-free entry under the North American Free Trade Agreement (NAFTA). Although it is possible to take advantage of preferential tariff treatment under NAFTA by encapsulating the fish oils in Canada or Mexico, the more important question is: How should these fish oil supplements be classified?

There are provisions in the tariff code that would allow for the duty-free treatment of the fish oil supplements regardless of where that encapsulation process takes place and possibly whether the fish oils even undergo an encapsulation process.

In the case of *Inabata Specialty Chems. v. United States*, 29 C.I.T. 419 (Ct. Int'l Trade 2005), the Court of International Trade addressed the classification of chondroitin sulfate (CS)—processed bovine cartilage imported in a bulk powder form and that was used for therapeutic purposes such as to provide relief from osteoarthritis (OA). The court found that the evidence overwhelmingly, and essentially uncontrovertibly, established that CS was prepared for, bought and sold, and imported for "therapeutic uses." In other words, regardless of whether substantial evidence existed as to whether use of CS had a measurable, positive effect on people suffering from OA, it was undeniable that CS was being used as a treatment for that particular ailment, rather than for purposes of general health or well being.

In determining the proper classification of the CS, the *Inabata Specialty* court recognized that tariff classification relies heavily on commercial practice and understandings, not just the indications given on labels, literature, or otherwise. The court reiterated that it was not required to determine how effectively CS functioned as an OA pain reliever, but rather, found it sufficient that the marketplace, among other factors, recognized CS as a therapeutic substance. In *Inabata Specialty,* the court recognized that the classification of CS depended upon the "use" of that product and thus took into consideration each of the factors to determine what that use is in the United States at, or immediately prior to, the date of importation of CS.

The same argument that was made in *Inabata Specialty* can be made for fish oil supplements. There are provisions in the tariff for fish oil supplements that are more relevant and would allow the fish oil supplements to be imported into the United States, free of duty regardless of the country of origin or manufacture.

The industry and the commercial understanding of consumers that purchase fish oil supplements is clear—use of the fish oil supplements is intended to both treat and prevent various and specific ailments and diseases. There is a body of scientific evidence that supports the fact that fish oil supplements are prepared, bought, and sold for such purposes, and not simply for general health and well being. This is strong evidence to support the marketing and public perception of the efficacy of fish oil supplements and, concurrently, that fish oil supplements are medicaments and should be treated and classified as such. With the importation of fish oil supplements increasing from year to year, the savings in duty upon a successful appeal to Customs or, failing that, the Court of International Trade, would be substantial and may potentially result in an ocean of savings.

Although this article focuses on issues concerning fish oil supplements, there are many additional herbal and dietary supplements that may be incorrectly classified and subject to Customs duties. Manufacturers and importers would be well served to learn more about the classification and country of origin marking of herbal and dietary supplements and whether such provisions apply to their products.

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