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# The Nutraceuticals Industry and the Food Supplements' Legislation

Human **health** and diet are strictly intertwined, as proved by strong scientific evidence, and showed by consumer choices. In this panorama the concept of nutraceuticals fits well. The definition has been coined by Stephen L. DeFelice in 1989 as: *'a food (or part of a food) that provides medical or health benefits, including the prevention and/or treatment of a disease'*. In practice, "nutraceutical" means a product containing one or more substances usually found in foodstuffs but made available in a pharmaceutical packaging (e.g., tablets, capsules, drops) in a concentrated and purified form, which aims to **prevent and treat diseases**. The global trend is moving towards foods that specifically address long- term preventative health, looking at few facts: non-communicable diseases are considered the main threat of our generation, the rising of healthcare costs and the increased mistrust in conventional medicine.

Despite the lack of attention given on the topic by the national and European legislator, according to the Italian Trade Agency, the Italian nutraceutical industry is the **largest** in Europe, with a market share of 27%. In 2019 in Italy the revenues amounted to € 3.6 billion, and in 2018 exports amounted to €735 million, values projected to grow in future, following the consumer trend. From a consumer perspective according to latest available data of FederSalus, 82% of nutraceutical products consumed, are recommended by doctors and pharmacists, leading to the outcome that 18 million Italian citizens consume them on a regular basis, of which 65% are between 25 and 64 years old and 74% consider that such products have beneficial health effects.

The products on the market range from probiotics to omega-3 as better identified in the following table.

Top 10 nutraceuticals (and omega-3) sold in Italy between April 2017 and April 2018	
Product	Value (million €)
Probiotics	385.2
Mineral supplements	232.6
Tonics	179.2
Hypercholesteremic based on monacolin	129.1
Multivitamin- Multimineral supplements	119.5
Intestinal function	106.3
Vitamins	103.1
Cough (suppressants, expectorants, etc.)	98.7
Joints (joint health, anti-arthritis etc)	93.3
Sleep and calm (stress-reducing and sleep-inducing products, sedatives etc.)	91.6
Antiacid, anti-heartburn and anti-acid reflux	88.6
Omega- 3	39.6

Source: FederSalus with data from New Line Ricerche di Mercato and IRI, April 2018

From a legal point of view, nutraceuticals can be placed in a grey area between medicines and food with nutritional purposes. Since nutraceuticals are not defined by any legal provision, neither at European nor at International level, their natures' categorization is particularly challenging.

Nutraceuticals' nature falls within the category of food, as defined in Regulation (EC) No. 178/2002, article 2 which excludes medicinal products from its application. Indeed, the discipline of pharmaceutical products is retrievable from Directive 2001/83/EC. Since nutraceuticals play a key role in preventing nutrition-related diseases, being placed beyond the diet but before medicines, they shall be intended as a foodstuff.

Few scholars consider nutraceutical products as functional foods, which are food part of a diet, being consumed on a regular basis, with the characteristic to have beneficial effects on health beyond the nutritional value. However, nutraceuticals products are more closely to a pharmaceutical preparation rather than a daily consumed food.

On the other side, nutraceuticals are in the practice classified as food supplements, as defined by art. 2 of Regulation (EC) No. 1925/2006, despite the existence of some differences between these two products' categories.

The main difference is to be found in their function. Indeed, while nutraceutical foods aim at preventing and treat diseases, promoting human well-being, **food supplements** aim at complement daily diets ensuring nutrients intake.

Following market practice, nutraceuticals are marketed as food supplements, and therefore they shall comply, at national level with the Legislative Decree 2004 no. 169, and at the European level with Regulation (EC) No. 1170/2009 which modifies the Directive 2002/46/EC and the Regulation (EC) No. 1925/2006.

However, even if in the practice nutraceuticals are marketed as food supplements, they constitute a different product, which is part of a **new share** on the market. Their nature is still vague, and doubts over the interpretation of such legislative framework remain. In conclusion, since globally the revenue of 2018 is expected to **grow** at a 7.8% annual growth rate from 2018 to 2023, a regulatory intervention is desirable and necessary to fill the legislative gap thus adapting the legislation to new market needs, and properly sell and advertise such products.

Industries need to be aware of the need to support and foster an evidence-based approach. Indeed, to bear on the label the beneficial effects of the nutraceutical products is necessary a strong scientific evidence based on human clinical studies of such benefit, to obtain the authorization by EFSA.

As a final remark, looking at the fact that nutraceuticals bring together the world of food and pharma, the cooperation within these two industries has the potential to boost such market, enriching each other's experience in the field.

The LCA team has significant experience in the functional foods and nutraceuticals sector and offers specialist advice by supporting its clients - including manufacturers, suppliers and leading multinational companies - in all relevant aspects and issues related to this sector. In particular, the Firm supports companies in the context of industry contracts and regulatory compliance procedures.

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