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Novel food, food supplements: The European regulation, its application in France. Thoughts on safety, risk assessment and health claims of food supplements

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In 2002, the European Community adopted a regulation for food supplements (European Directive 2002/46/CE June 10th). This was an important event in the regulation of food supplements. The European regulation was adopted in France, with some modifications, by decree 2006-352 of March 20th 2006. The European Regulation on food supplements and novel food is more defined than those for any other food types and is exemplary. The Regulation on addition of vitamins and minerals to food differs from the regulation on the addition of other substances such as amino acids, essential fatty acids, fibers, carbohydrates, various plant, and herbal extracts. While the Regulation includes vitamins and minerals to the positive list of supplements as well health claims, other substances are included in the negative list of supplements. According to the Regulation, substances added to food supplements must have a nutritional or physiological effect. The increased use of food supplements led to the creation of a department specialized in the safety of food supplement. The safety of food supplements is a permanent concern for sanitary authorities (EFSA, ANSES for France). Nutrivigilance is recently developed in France. These authorities have recently combined scientific methodological approaches and a collective expertise to implement and monitor simple and useful rules that insure consumer's safety. Safety laws aim to protect the consumers of food supplements.

Keywords: Safety; Adverse effects; Toxicology; Dietary supplements; Claim; Complementary and alternative medicine; Nutrivigilance; European regulation; ANSES.

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