The term functional foods (FF) relates to foods that exert beneficial health properties beyond those expected from their nutrients. Many international regulations lack the definition of FF. Health claims are intended to communicate relevant properties of FF to the consumer. A critical analysis on the regulatory situation on FF and health claims is presented and recommendations are established. Health claims should be based on sound scientific evidence of the beneficial effects of functional ingredients. However, the putative bioactivity may be due to a variety of compounds that may be directly or indirectly responsible for their effects. FF should demonstrate their beneficial effects when consumed as part of the diet. Consequently, in order to designate a food as FF, research must be performed at different levels, including chemical analysis, in vitro and in vivo studies that clarify mechanisms of action, and clinical assays developed to put into evidence the claimed beneficial effects. The food industry should take into consideration that the formulation of functional products does not guarantee the expected physiological effects. The diversity of current food regulations represents a series of difficulties for marketing, at a local and international level. An effort to harmonize the criteria to define FF and their validation strategies represents an urgent matter in order to establish health claims, protect the consumers and promote food innovation.