



More possibilities in relation to the substances that can be used in the manufacturing of food supplements

Royal Decree 130/2018, of 16 March, amending Royal Decree 1487/2009, of 26 September, regarding food supplements

Background

On 28 March 2018, the Royal Decree 130/2018, of 16 March, amending Royal Decree 1487/2009, of 26 September, regarding food supplements, came into force. The purpose of the new Royal Decree is to update and clarify the regulatory framework applicable to food supplements in Spain. The main aspects regulated by this new regulation are the ones indicated below.

Nutrients and other substances

According to the applicable regulation, both in the EU and Spain, substances used in the manufacturing of food supplements are classified as “nutrients” and “other substances”.

The concept of “nutrients” is fully harmonized at European level, as there is a list applicable to the entire EU in which it is specifically stated which are the nutrients (understood as vitamins and minerals) that can be used to manufacture food supplements.

On the other hand, the concept of “other substances” is not harmonized in the European Union and, so far, has not been defined by Spanish legislation either. The new Royal Decree puts an end to this situation and incorporates a list of which are the “other substances” that may be used to manufacture food supplements in Spain. Moreover, such list contains moreover certain safety warnings with respect to such “other substances” that must be included in the labeling of such supplements.

Mutual recognition

The new Royal Decree expressly foresees the mutual recognition principle already contained in the European law which aims to guarantee the free circulation of food supplements in the EU market.

Such principle provides that if there are food supplements legally manufactured or marketed in an EU Member State it should be allowed for them to be marketed in Spain, regardless of the fact that they contain substances (other than nutrients) not specifically included in the new Royal Decree.

From our point of view, it would be desirable that the Spanish authorities provide a flexible interpretation of the new Royal Decree so that:

- (i) it is allowed that food supplements which are legally marketed in other Member States enter into the Spanish market, and
- (ii) national producers have the possibility to market in Spain food supplements containing substances not expressly included in the new Royal Decree, as long as such producers can prove that there is another food supplement with the same composition as the one that is intended to be marketed in Spain, which is being legally marketed in another Member State.