Botanicals in food supplements

A step forward in usage harmonisation in the EU?

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The market for botanical-based food supplements in the European Union is highly differentiated, not only because of the great variety of the products used, but also with regard to the individual laws that govern them in each member state.

The aim of Europe-wide harmonisation of this important sector, facilitation of the free movement of goods while maintaining a guarantee of public safety, is therefore a major challenge.

Much discussion and many meetings have been organised in this respect, attracting the interest of national and European regulatory agencies, and associations of consumers and producers. The most authoritative conclusions in this regard were those laid down by the European Commission (EC) in December 2008 essentially establishing that there was no need for further harmonization of the sector due to the current European legislative arsenal.

In particular, the EC pointed out that regulations 178/2002 (general food law), 1924/2006 (health claims) and 1925/2006 (Art. 8) and the regulation of novel foods 258/97 were sufficient to give a substantial legislative framework able to support every possible decision at European level. Finally, in this context, the EC also recalled the integrative function of national laws and the principle of mutual recognition. Actually, this legislative context has arisen some criticisms as, for example, the application of the 1924/2006 on health claims. In 2010 in fact, botanicals have been removed from the claims identification procedure having pending future decisions on this matter concerning in particular a recognition of their traditional use similar to plant-derived drugs regulated by the Traditional Herbal Medicinal Products Directive (THMPD). It should be remembered also the difficult achievement of mutual recognition, that must be applied on a case by case basis due to the lack of harmonization.

In this context, the EC also had to recognise two possible scenarios within its 2012 document in reference to the future legislative developments relevant to harmonisation: the first concerns the possible maintenance of the *status quo* (with all the possible downsides mentioned above); the second refers to the ability to recognise a legislative specificity to botanical derivatives modifying some important legislative aspects. In particular, these changes should include the recognition of traditional use to achieve claims, the definition of the concepts of quality and safety and the revaluation of the bases of mutual recognition.

In our opinion, the BELFRIT project is in line with the second scenario already mentioned in the CE 2012 document. It is a detailed guide that could quickly lead to a harmonisation agreement for the free use of botanical-based products that will be selected as dietary supplements in Belgium, France and Italy. The name BELFRIT comes from BELgium, FRance and ITaly, whose competent authorities decided to share their experiences to list the eligible plants in food supplements (due to similarities in the regulatory approach for botanical-based food supplements). Scientific experts of these countries were enrolled and after a year and a half they prepared an initial common list of plants allowed for use in food supplements on the basis of safety and traditional use.

The rationale and methodology behind BELFRIT were presented at a plenary meeting held in Rome in April 2013 and a workshop at the European parliament in June 2013. More recently, in November 2013, the Belgian authorities organised a symposium in Brussels (with the presence of other Member States) where the first list of plants (Harmonized list Section A) selected by BELFRIT experts and the EC and other Member States assessments were presented.

This list, which will soon be available on the Belgian authority website, consists of the correct botanical identification of the plant or of the part used, identification of the active ingredients (if possible) and suggested cautions for use (where deemed necessary). A second list of plants (Section B, about 100 plants) is still being examined by the BELFRIT experts.

Rumours indicate the activities carried out by the BELFRIT experts were much appreciated by the EC members at the meeting: they stressed that other states could join this initiative, or at least could consider the applicability in their national contexts. In agreement with this assessment, representatives of Poland, Spain, Croatia, Romania and Germany gave positive opinions on the project results. The most critical, although favouring a wider debate, were the representatives of Sweden, the Netherlands and the UK.

In our opinion, the approach adopted by BELFRIT represents a positive step on the difficult road to European harmonisation. Some aspects still need to be addressed more comprehensively, such as those related to the definition of quality criteria and therefore of safety. For this purpose, the development of an agreement on quality control and safety data of plant-derived products, as an example, is advisable. Equally important is a proposal for general agreement on some limitations to use based, for example, either on maximum acceptable levels for some secondary metabolites or on specific people groups. Taking into account that these aspects have already been considered as relevant elements of BELFRIT, we can only send the whole team our best wishes for their work in the current year.

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