

EU Botanicals Update

The European Botanical Forum (EBF) recently met with two representatives of the European Commission's DG SANCO to discuss botanicals.

The aim of the meeting was to exchange views on how best to move forward with the issue of health claims for botanicals. (Earlier in the year, the review of botanical health claims was removed from the European Food Safety Authority (EFSA)'s evaluation of Article 13.1 claims until a solution could be found to the discrepancies between the way in which they are treated under the Traditional Herbal Medicine Product Directive (THMPD), Food Supplement rules and the Claims Regulation - in particular whether traditional knowledge should be accepted in the substantiation of claims for botanical food supplements.)

A decision on the European Commission's intentions for botanicals is expected at the end of June, when the assessment of all non-botanical health claims has been completed. However, from the meeting, it would seem that the EC has not yet decided how best to balance THMPD and Food Supplement rules and work within the current legal framework.

The EBF's position in the discussion can be summarised as follows:

- Current legislation already covers the safety of botanicals.
- A negative list (based on the negative list already prepared by the EBF) under Regulation 1925/2006 on the Addition of Nutrients to Foods, which has an annex for substances with safety concerns, may be a good first step.
- The development of further lists could be envisaged based on priority issues relating to safety. This should not be a closed positive list, but an open list.
- Identification of physiological effects should be based on the principles of ECJ case law and homeostasis. EFSA opinions could be a useful source of information in this respect.
- Indications/claims should be based on traditional use.

From the discussion it was understood that the Commission's position is:

- All Article 13.1 claims will be assessed by EFSA, including botanicals. However, the advice could be that EFSA would not be able to assess them.
- A change of the terms of reference for botanicals would not be accepted by the Commission since it would discriminate against claims already assessed.
- The potential harmonisation of the use of botanicals in food supplements/foods is being discussed under the context of health claims. The Article 8 procedure (negative list) of the Regulation 1925/2006 on the addition of vitamins, minerals and other substances to foods is not the legal framework for such a potential harmonisation.

- Food Supplement legislation would therefore be the primary tool for harmonisation and dealing with both safety and claims.
- The creation of a positive list under Food Supplements Directive is probably the preferred tool, but how this would work is not yet clear.

Source: EBF