

Position Paper

of the
German Pharmaceutical Industry Association
(BPI) e.V.

concerning the

Evaluation and Fitness Check (FC) Roadmap

„Evaluation of a) Regulation (EC) No. 1924/2006 on nutrition and health claims made on food with regard to nutrient profiles and health claims made on plants and their preparations and of b) the general regulatory framework for their use in foods”

Background:

In 2006, with the publication of the Health Claims Regulation (EC) No. 1924/2006, the EU Commission created a European framework regulating health claims concerning foods, with the intention of protecting consumers from unfounded claims and to give the industry clarity with regard to the legality of particular statements. Citing the large number of health claims submitted, the EU Commission informed the public in a press release¹ on September 27, 2010 that there would be a progressive adoption of the list of permitted health claims and that the assessment of health claims associated with „botanicals“ would be undertaken later. However, the same press release also stated that the evaluation of health claims for botanical substances would continue after the publication of Regulation (EU) No. 432/2012 (list of permitted claims). **To date, the Commission has failed to fulfil this obligation.**

At the end of July 2012, the EU Commission presented the member states with a discussion paper proposing two options for the further evaluation of health claims associated with foods containing botanical substances. The majority of the member states were either explicitly in favour of continuing the evaluation of botanicals according to the Health Claims Regulation or saw obstacles to creating a new regulatory framework.² **Despite this, the assessment process has not been restarted.**

In October 2015, the Commission published a roadmap for a consultation procedure to again clarify the further process concerning the assessment of health claims for botanical substances and the nutrient profiles. This is surprising, as the Commission clearly stated its intention to continue the assessments in 2010 and, in 2012, the member states themselves also declared to be in favour of proceeding according to the Health Claims Regulation. The fact that this new consultation is to include only a subset of the affected industry is particularly disconcerting. **The consultation procedure only includes the food industry and excludes the manufacturers of phytopharmaceuticals and health products who are also affected.**

¹ See press release of the European Commission dated 27.09.2010, available here:
<http://europa.eu/rapid/pressReleasesAction.do?reference=IP/10/1176&format=HTML&aged=0&language=EN&guiLanguage=en>

² See presentation of the Unit Head of the responsible Directorate in the European Commission, Basil Mathioudakis at a conference on 18.04.2014:
http://www.salute.gov.it/imgs/C_17_EventiStampa_163_intervisteRelatori_itemInterviste_8_fileAllegatoIntervista.pdf (page 2).

The German Pharmaceutical Industry Association (BPI) e.V. demands the further assessment of health claims concerning botanicals:

- The Health Claims Regulation is the valid legal framework for all health claims concerning foods and does not differentiate between chemical and botanical substances. It also does not foresee delays in the assessments.
- The creation of new regulatory rules is not necessary, as
 - the current Reg. (EC) No. 1924/2006 already defines the framework for health claims,
 - the Reg. (EC) No. 1925/2006 regulates the permitted ingredients for food supplements (although not used for botanicals thus far),
 - Article 8 of Reg. (EC) No. 1925/2006 allows the adoption of a negative list of substances for foods and
 - the Reg. (EC) No. 258/97 defines procedures for the authorisation of novel foods.
- The declared goal of consumer protection must finally be achieved by the full implementation of the Health Claims Regulation, ending the misleading of consumers through unqualified health claims.
- The endangerment of the entire Health Claims Regulation and the resulting increased costs for both manufacturers and regulators must be prevented.
- Phytopharmaceuticals, whose safety, quality and efficacy have been demonstrated in national or European marketing authorisation or registration procedures, must be clearly differentiated from foods in the future.

Drawing on 65 years of experience, the German Pharmaceutical Industry Association (BPI) e.V. represents a broad spectrum of the pharmaceutical industry on both national and international levels. More than 240 companies with more than 73.000 employees are members of the BPI. One focus of the association's activities lies in the area of self-medication with over-the-counter medicinal products, which include phytopharmaceuticals and health products from other regulated areas such as food supplements.