BOTANICALS CHARACTERIZATION IN EUROPE

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Botanicals are defined as fiber , juice, oil, pulp, tissue, or other components derived from plants and used in cosmetics, food supplements, personal care products, or pharmaceuticals.

The Botanicals and all the preparations obtained from plants, algae, fungi or lichens are available as food supplements in EU.

Products like i.e. those made from *Gingko biloba*, *Allium sativum*, *Hypericum perforatum*, *Panax ginseng* are labelled as natural foods, and many claims are made concerning possible health benefits. They can be bought over the counter in pharmacies, supermarkets, specialist shops and via the Internet.

While most of these products have a long history of use in Europe, some problems exist with regard to safety and quality. These include the risk of chemical or microbiological contamination and the need to ensure that concentrations of bioactive agents are within safe limits.

With the Regulation (EC) No 178/2002, EU Commission provide a general principles and requirements for foods and create the European Food Safety Authority (EFSA).

Before, The European Medicines Agency, a decentralised agency of the European Union, responsible for the scientific evaluation of medicines developed by pharmaceutical companies for use in the European Union, in October 2010 published a "Reflection paper on stability testing of herbal medicinal products and traditional herbal medicinal products**",** accepting the tradition use and giving several definitions on:

Herbal medicinal products, Herbal substances, Herbal preparations, Markers , Active markers, Analytical markers, Specification, Traditional herbal medicinal products.

The strengths and weaknesses of the different regulatory procedures will be reviewed and evaluated as well as the current methods for quality, efficacy and safety evaluation. Also the criteria to categorize botanical products will be defined, either as foods or medicinal products. that botanical products can be regulated under the current food and medicinal regulations. Will be also examined a stepwise framework for the assessment of safety and efficacy.

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