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The HFMA is a not-for-profit organisation founded in 1965. It is the authoritative and responsible voice for the UK natural products industry. We promote and protect the general interests of members of the industry and promote high standards of product manufacture and presentation to ensure consumer safety, responsible and informative communications and compliance with applicable legislation. We represent around 125 manufacturers and suppliers of specialist health products, notably food supplements, herbal products, natural remedies, sports nutrition products, natural cosmetics and health foods. Over 75% of our members are SMEs, including many 'micro' businesses.

HFMA welcomes the European Commission's '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 and is grateful for the opportunity to offer its comments, which we understand at this stage should be confined to whether the evaluation is sufficiently comprehensive and whether the questions it poses are the right one to obtain the information the Commission is seeking.

Nutrient Profiles

HFMA considers the proposed scope of the Evaluation on nutrient profiling to be sufficiently comprehensive to obtain the information the Commission seeks, and therefore has no further comment to make at this stage of the consultation process.

Plants and their preparations used in foods

As a member of the European Federation of Associations of Health Product Manufacturers (EHPM), HFMA supports the key observations of their response, and, like EHPM, HFMA considers the proposed scope of the Evaluation in relation to Plants and their Preparations used in foods to be comprehensive and correctly focused. However, HFMA has the following additional comments to make:

i. Section B, 'Content and Subject of the evaluation' Plants and their preparations used in foods, paragraph 5.

This paragraph discusses health claim substantiation and the safety concerns of Member States on the authorisation of health claims on certain substances, '*..when no regard is given to the safety aspects of their use in foods*'. In relation to safety, an important difference between plant preparations used in food supplements and foods containing plant preparations is that, unlike most foods, food supplements are delivered in unit doses and their consumption can therefore be accurately monitored and, if necessary, restricted.

ii. Section C, Scope of the evaluation/FC Plants and their preparations used in foods, 4, Coherence

This section touches on regulatory 'borderline' issues. The great majority of plants can be used in both medicines and foods/food supplements, and, under Union law as it stands today, it is the prerogative of Member State authorities to classify relevant products as medicines. While welcoming that this important point is raised HFMA therefore questions whether the bullet points sufficiently highlight/recognise the implications of and the differences - or lack of coherence - between an EU medicinal *product* marketing authorisation, and an EU positive list of permitted plant *ingredients*. Ideally, Union law should evolve in a direction where traditional use of plant ingredients is recognised as a crucial element of a safety assessment. This is the way coherence should develop. Insofar as Member States retain a competence to classify products in either way, the principle of mutual recognition should be vigorously applied to overcome obstacles for the free movement of goods.