Food Safety
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Statement of the Scientific Committee
of the Food Safety Authority of Ireland

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Risk management options related to the use of botanicals in food supplements

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Statement

Botanicals, and derived preparations made from plants, algae, fungi or lichens, have become widely available on the EU market in the form of food supplements. Such products are typically labelled as 'natural foods' and a variety of claims are made regarding their possible health benefits. These products can be bought in pharmacies, supermarkets, specialist shops and online via the internet. Some concerns exist about their safety and quality, including the risk of chemical or microbiological contamination and the need to ensure that concentrations of these substances are within safe limits.

As the EU does not have a centralised authorisation procedure for the use of botanicals and derived preparations in food, other than that the use of botanicals and derived preparations in food has to comply with the general requirements of food law in the EU, there is a requirement to develop a basis for risk management of these botanicals on the Irish market.

A few years ago, Belgium, Italy and France started the BELFRIT (BELgium, FRance, ITaly) project to develop a common standard for botanicals. The result is a list of about 1,000 herbal substances, which were assessed and approved by a scientific committee, and the list was adopted by all three countries, albeit to differing degrees.

This Statement addresses a "Request for Advice" from the Food Safety Authority of Ireland (FSAI) Scientific Committee entitled, "A scientific review of the BELFRIT approach to risk assessment of botanicals and its applicability in Ireland".

In particular, the "Request for Advice" comprised the following two questions:

1. Is the safety risk assessment approach used for the botanical species on the BELFRIT list robust and suitable for potential adoption for risk management purposes of these botanicals on the Irish market?*

2. Are there any scientific concerns or considerations that the FSAI should be aware of when considering possible adoption of the BELFRIT list of botanicals and its associated warnings?

**The Scientific Committee was advised to review existing European Food Safety Authority (EFSA) publications, such as the "Guidance on safety assessment of botanicals and botanical preparations intended for use as ingredients in food supplements" and the EFSA Botanicals Compendium, as part of its discussions concerning the robustness and suitability of the BELFRIT safety risk assessment approach.*

In considering this request, the Scientific Committee reviewed the current legislative situation relating to botanicals used in food supplements, including the Regulatory Fitness and Performance (REFIT) programme evaluation of Regulation (EC) No 1924/2006 on nutrition and health claims made on foods in relation to plants and their products; the work of EFSA on safety assessment of botanicals; the issue of use of botanicals in herbal medicinal products and in food supplements; and the approach by Member States to regulation of botanicals in food supplements, including the BELFRIT project.

Food supplements containing substances, other than vitamins or minerals, are foodstuffs within the meaning of Article 2 of *Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety*. The aforementioned Article 2 explicitly excludes from the definition of a foodstuff, a series of product categories, including medicinal products within the meaning of *Directive 2001/83/EC of the European Parliament and of the Council on the Community code relating to medicinal products for human use*. Regulation 178/2002 puts the onus on food business operators not to place unsafe food on the market.

Since Community law does not include specific provisions on the use of substances other than vitamins or minerals in food supplements, the free movement of such products is governed by Articles 28 to 30 of the EC Treaty and can be subject to national restrictions or bans only within the limits laid down by Article 30. Despite the overall positive approach of Member States towards this principle of “mutual recognition”, application of this principle appears to be problematic in a number of countries and has resulted in cases being brought to the European Court of Justice since, under the current EU rules, it is possible for a Member State to classify a product as food or as medicine depending on its presentation and claimed effect.

Attempts to indirectly harmonise the use of botanicals and their conditions of use in food supplements by regulating health claims have not been successful, due to divergent views on the level of scientific evidence required to assess such claims.

EFSA has published a Guidance Document for the safety assessment of botanicals and botanical preparations intended for use as ingredients in food supplements, and a Compendium of Botanicals intended to facilitate hazard identification relating to plants. However, EFSA has not been able to assess health claims made for plants and their preparations used in food nor to undertake scientific risk assessments for specific botanicals.

The most recent initiative undertaken to bring clarity to this area has been implemented in 2015 through the Regulatory Fitness and Performance programme (REFIT) evaluation of Regulation (EC) No 1924/2006 on nutrition and health claims made on foods.

This evaluation was to focus on nutrient profiles and health claims on plants and their preparations added to foods. With regard to the latter, specifically the evaluation is to establish whether the current rules concerning health claims on plants and their preparations used in foods are adequate, and how the use of such claims interacts with the current applicable food regulatory framework on plants and their preparations used in foods. To date, the evaluation has not been finalised.

In the absence of harmonised Community rules, several Member States, particularly Belgium, France and Italy, through the BELFRIT project, and other EU countries through their classification system for plants and parts of plants to be used in foods, have developed approaches to regulate or provide advice on the use of botanicals for use in food supplements. This includes implementation of legislation, such as is the case in Belgium, France and Italy, or through non-regulatory reference lists providing guidance. Even in the case of the BELFRIT list, the final adoption into legislation differs in the three countries, with differing numbers of substances covered, or additional restrictions on use having been implemented. Furthermore, the evidence base underlying these approaches is not entirely transparent, with strong evidence available for some substances whereas for others the information is limited and sometimes it appears to have been based on the “history of safe use” principle and/or based on expert judgement.

With regard to the questions contained in the Request for Advice, the Scientific Committee considers that the BELFRIT list(s) of botanical species is not suitable for potential adoption for regulatory risk management purposes for botanicals on the Irish market, due to a lack in transparency in the risk assessment approaches used. However, the BELFRIT list, together with other Member State’s resources, in tandem with the EFSA Guidance Document and Compendium of Botanicals, are useful tools to be included in the risk assessment and management of botanicals in food supplements available on the Irish market.

The Scientific Committee further noted that there is a compelling need for a harmonised approach to be taken on this topic across the EU. Until such time as this is achieved, risk management of botanicals on the Irish market will need to be carried out on a case-by-case basis.

However, efforts by the FSAI should particularly focus on substances where:

- Evidence on potential toxicity is emerging
- Questions on the authenticity of substances have arisen
- Fraudulent claims have been made
- Products are likely to have been spiked deliberately with unlabelled substances (e.g. Weight loss products, performance enhancing substances)
- Products are likely to be contaminated for economic gain (e.g. Use of unauthorised colours to mimic use of colourful herbs/spices)

The Scientific Committee noted that EFSA's work in this field aims to provide any organisation assessing the safety of botanical ingredients with a science-based approach. It provides the criteria that should be taken into account when establishing the safe use of botanicals or derived preparations. The toolkit is composed of a:

- Guidance document identifying the data needed to assess the safety of botanicals and describing a science-based approach for the safety assessment
- Report with a number of examples illustrating how to apply the proposed scientific approach
- Compendium of botanicals that have been reported to contain substances that may be of a health concern when used in food or food supplements. This compendium has been subject to regular updates.

Finally, the Scientific Committee noted that a considerable wealth of information exists which could be utilised by manufacturers of food supplements containing botanicals when assessing the potential risk associated with the use of certain substances.

In this regard, it is recommended that the FSAI support food business operators by providing an information resource which might consist of signposting the various different information sources available

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