Health Claims and Botanicals: How to Proceed with European Harmonisation?

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The European Commission is currently evaluating what public authorities, the business community and other stakeholders want to do with the claims for botanicals – on hold since 2010 – in order to make a proposal on how applications for health claims for botanicals should be assessed and, moreover, whether the use of botanicals in foods must be regulated separately. It is a great challenge to find a legally robust and politically feasible solution for the current situation.

I. Preceding Events

If health claims are used for foods, they must comply with the Claims Regulation1. This regulation sets out general and specific conditions for making nutrition and health claims. It also lays down that the European Food Safety Authority (EFSA) assesses claim applications and that the European Commission authorises their use.

In 2010, the EFSA evaluated some of the claims applications for botanicals in accordance with the current standards for assessing health claims. Not one of the submissions was given a positive assessment. While medical claims for traditional herbal medicines were permitted on the basis of traditional data, traditional data for the substantiation of health claims were found to be insufficient. This discrepancy led to the European Commission ceasing the assessment for health claims of botanicals and starting a review of the matter.

In addition to the need to assess botanical claims, there was a call for harmonisation of substances to be used in food supplements. Vitamins and minerals are subject to European legislation2, which clearly regulates which vitamins and minerals may be used in food supplements. No arrangement has yet been made for other ‘different’ physiologically active nutrients, but European regulation thereof is to be provided for in the Food Supplements Directive. Article 8 of Regulation 1925/20063 does provide for a harmonised procedure which member states must follow in the event of doubt regarding the safety of such a ‘different’ nutrient. There are differing opinions in the member states regarding what substances are to be permitted in what quantities.

II. Consultation

In 2012, the Commission carried out a survey among the member states regarding their preferred solution for the ‘on hold’ situation of botanical health claims. The member states were highly divided on the matter. A number were of the opinion that claims on botanicals must also be reviewed in accordance with the current EFSA standards for the assessment of health claims. What is sauce for the goose is sauce for the gander. Others felt that separate legislation should be established for such claims and that said legislation, in addition to the health claims, should harmonise the use of botanicals in food, including food supplements, at European level.

III. Claims Regulation: Fit for Purpose?

As of this autumn the European Commission will take another look at the claims legislation for botan-
icals. There was great resistance to sending the current Claims Regulation back to the drawing board. In the framework of REFIT, the European *Regulatory Fitness and Performance Programme*, a programme for assessing existing European legislation where necessary and possibly making it more suitable and simplified for the intended purpose, a way was found to modify the current Claims Regulation. At present the Commission is again examining how best to proceed with the claims for botanicals.

**IV. The Current Situation Disrupts the Level Playing Field**

The discrepancy between the assessment of medical claims and health claims regarding the use of traditional data was the reason to pause the assessment of the submitted claims for botanicals. Companies can use the botanical claims already submitted, but not yet assessed or authorised, in their communication. National rules apply to this use and, in the Netherlands, self-regulation applies. However, this creates inequality with regard to the use of the other claims, the approved or rejected health claims. Companies cannot use unauthorised claims in their commercial communication, while *on hold* claims for botanicals may be used. This disrupts the level playing field.

For companies which sell botanicals and want to communicate about this, this may be a favourable situation, but for other supplements which contain *non-botanicals*, this situation can distort competition. In the past few years this led to two court cases against the European Commission, seeking to rectify this situation. Both cases were declared inadmissible at first instance, but one of the two must be heard now and this puts pressure on the Commission.

The use of *on hold* claims raises a lot of questions in practice, too. There is ambiguity regarding the terms and conditions under which the claims may be used. In the Netherlands self-regulatory agreements were made in this respect, but monitoring and enforcement of the proper use of these claims is very difficult because this is not laid down in legislation. An imbalance arises between a pre-market surveillance of statements and a post-market enforcement of agreements.

**V. Differences between Member States**

The big problem in finding a solution for the *on hold* claims is to obtain sufficient support for a proposal. A legislative proposal in which not only the traditional health claims but also all kinds of other aspects, such as safety and quality of the use of botanicals in or as foods, should be regulated. It seems virtually impossible to lay down all these different aspects in one harmonising regulation, in particular because of the big differences in permitted application of botanicals in food supplements across the member states. Then, the question arises whether such a regulation is truly necessary.

The limited European harmonisation of ingredients to be used in food supplements has led to differences in legislation in the member states. These national rules differ both in scope and in set-up. Some member states work with positive lists of permitted ingredients, while other member states use negative lists of prohibited ingredients. Some countries have extensive legislation with maximum quantities, while other countries have elaborated on this very summarily.

In addition, member states have the right to classify individual products as drugs or foods on a case-by-case basis. Incidentally, the chance that an individual product will be seen as a food in one member state and a comparable product will be seen as a drug in another member state is very small, given the extensive legislation and criteria laid down in European case law in the area of ‘distinction foods – drugs’.

**VI. Mutual Recognition**

The differences between the member states in the use of botanicals as foods cause problems in the trade among countries. This restricts the free movement of goods, one of the most important principles in the European Union.

Member states are obliged to apply the principle of mutual recognition. This principle asserts that a

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4 Opinion of Advocate-General Bobek 25 April 2017, in joined cases C-596/15 P (Bionorica SE) and C-597/15 P (Diapharm GmbH & Co. KG) vs. European Commission.

5 CJEU 15 January 2009, C 140/07 (Hecht-Pharma GmbH/Staatsliches Gewerbeaufsichtsamt Lüneburg), ECLI:EU:C:2009:3.
product that is legally on the market in one member state must, in principle, be able to be sold in all member states. A member state can only prohibit putting a product on the market if it can demonstrate that the product will entail a risk for the consumer in that country. Because the member states are prone to ride roughshod over this principle, in 2008 the European Commission prepared a regulation\(^6\) in which it laid down procedures which member states must follow in the event they wish to impose trade impediments. Member states nevertheless continue to breach the principle, usually to protect their own market or their existing rules and habits.

Also, the fact that it is up to a member state to determine whether a product is a drug can be a problem for the mutual recognition of food supplements.

VII. Hecht-Pharma Guidelines in the Grey Zone between Food supplement and Drug

We have seen that a product can be a food supplement in one member state, while a comparable product is put on the market as a drug in another member state. These products, both herbs and other supplements, are virtually never assessed in accordance with the criteria laid down in legislation and case law, which thus leads to disparities. Member states that want harmonisation would like to see legislation with lists of permitted compounds with a permitted quantity for use in supplements. In some countries, like Belgium and France, this is already common practice. In Belgium they apply the rule that if a substance occurs in drugs, the substance may only be used in food supplements up to a maximum of 80% of the minimum dosage in drugs.

However, the interface between supplements and drugs is more complicated than that. When assessing whether a product is a drug, not only the active ingredient, but all characteristics of the product have to be reviewed to determine whether the product falls under the food legislation or under the drug legislation. In the Hecht-Pharma case\(^7\) the European Court of Justice presented a list of characteristics which must be reviewed in particular, such as the composition, the pharmacological properties to the extent to which they can be established in the present state of scientific knowledge the manner in which it is used, the extent of its distribution, its familiarity to consumers and the risks which its use may entail.

The review must also be exerted in a transparent and verifiable way, so that it is clear to market players how the opinion was reached.

In addition to composition and pharmacological properties, the method of use and concomitantly the intended use are important features: what is the intention of the use of the product, preservation of health or application in the event of illness?

It is up to the member state to assess whether a product must be deemed a drug, and thus subject to the assessment of at least all of the above mentioned characteristics. In practice governments do not properly carry out this review, or do not wish to carry it out in full. Often, only the ingredients and dosage are reviewed. The review is not simple, there is hardly any case law on the execution of the review as to the various features and how these relate to the final opinion.

On the basis of the Hecht-Pharma case it is not possible to make a list of a maximum of quantities of a substance to be used in a supplement, above which quantity this substance should be classified as a drug. Substances are not end products, and the CJEU explicitly stipulated that all characteristics of the individual end product must be reviewed to ultimately be able to form an opinion on the status of that one product. Creating a list of herbs which may be used in supplements below certain quantities and which above those quantities turn the product in which they are processed into a drug, is simply not possible. A maximum dosage of a substance can only be determined on the basis of the safety criterion.

Member states that want European harmonised legislation for botanicals (substances) in order to regulate the interface between food supplements and drugs differently, must realise that such legislation is contrary to the ‘case-by-case ’ product assessment prescribed in the Hecht-Pharma case, requiring assessment of all features of the product. Substances miss most of those features, so that food-drug assessment of substances is not possible.


\(^7\) See note 5.
VIII. Harmonisation of Use of Ingredients

If we wish to harmonise the use of substances, other than vitamins and minerals, in food supplements, this is possible with a positive list – a list of permitted compounds – or with a negative list – a list of prohibited substances.

A list, positive or negative, must be assessed. All substances which are to be permitted by means of a positive list must be assessed as to safety and biological availability. This is an enormous task with regard to herbs. The safety thereof is often determined on the basis of long-term use, after which scientific assessments no longer take place. If that is imposed as the standard, an enormous clear-out will arise and it will not do justice to the current practice, where hardly any problems occur in this area due to the fact that there is already sufficient legislation and regulation in the area of safety of food supplements and other foods.\(^8\)

When determining a negative list, substances are assessed on the basis of unsafety or a justified suspicion thereof. The Netherlands has legislation with such a negative list for herbs. This could be introduced into a ‘European negative list’ since European legislation already has the framework in which the unsafe substances can be placed. The supplements regulation has a negative list system.\(^9\) Application of the procedure laid down in this article automatically leads to a list of prohibited substances that also applies to food supplements.\(^10\) It seems easy to use the current legislation to regulate the harmonisation of herbs by means of this procedure and not to come up with new legislation; something that is far from easy, if not outright impossible in the current European political climate.

Harmonisation of the use of botanicals in food supplements seems the most feasible with a law which makes use of a procedure resulting in a list of prohibited substances. Given the large differences in the EU member states, gradual harmonisation can be effected with such a system. The botanicals on the ‘negative list being compiled’ can be prohibited in any event. At the same time member states – during a transition period – can also keep possible national positive lists.

Another advantage of this form of harmonisation is the less inhibitive effect on innovation. For example, adding a new source of folic acid to the positive list of vitamins and minerals turned out to be a(n) (overly) long process.

IX. Traditional Use

Traditional use is based on experience in medical or nutrition practice and not on scientific proof. It is knowledge that has been developed ‘on the job’, as it were. If a use exists longer than a generation, some 25 years, it is usually deemed traditional. Food is, by definition, already as old as humankind, and most of the food we eat every day is traditional. That food has long had a relationship with health, growth, development and illness should be clear. In addition, in the past, no firm distinction was made between illness and health. This strict distinction was created by legislation.

As previously indicated, at present, a substantiation of an effect on the basis of data on long-term use is treated differently. In the Medicinal Products Directive\(^11\) these data are permitted to substantiate a medical claim while in the Claims Regulation, data on traditional use to protect or benefit health are currently found too insubstantial for the substantiation of a health claim.

This unequal treatment of equivalent evidence in health claims and medical claims forms the basis of the decision of the European Commission to halt the assessment of health claims for botanicals and to review how to deal with this inequality.

Unequal treatment in similar situations is thus the problem that must be resolved. This is a problem relating to the assessment of claims. In essence, this applies to all claims and the unequal treatment is not reserved for the claims for botanicals. The precedent for permitting claims on the basis of traditional data is laid down in the European directive on traditional herbal medicinal products, but is not limited to the health claims for botanicals.

If the European Commission proposes another treatment of claims for just botanicals, it is again introducing an inequality, i.e. in the assessment of claims for botanicals and claims for non-botanicals.

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10 See note 3.
This seems difficult to shape within the Claims Regulation. If separate legislation were to be established for botanicals, which also regulates the claims for botanicals, the inequality may be less clear, but it will still be present.

X. Conditions for Traditional Data to Substantiate Claims

When considering the assessment of traditional data to substantiate health claims, the question arises when the traditional use is such that the perceived health effect can be deemed substantiated. In this respect, criteria which are already laid down in the Medicinal Products Directive can be reviewed.

Those criteria are: bibliographic proof and/or proof provided by an expert of the traditional use during a period of at least 30 years, of which at least 15 years are in the internal market, which meets the standard of biologically plausible, according to recognised experts in the area of the specific use. The relationship between the substance and the effect on health must be consistent with existing biological and medical knowledge.

Bibliographic proof, drawn up by experts in the field, play a crucial role in this regard. The integrity of the authors of the bibliographic data is relevant in this respect.

XI. Traditional Use as Substantiation for Other Substances

If within the claims regulation traditional use can serve as substantiation for a botanicals claim, logically this also applies to the health claims for other substances which can present traditional use as substantiation. Must the entire process of assessment of already authorised or rejected claims be reviewed again? Not necessarily. Suppose that in the framework of the REFIT programme, the claims regulation offers scope for substantiation with traditional data, new submissions can then use this new substantiation. Apart from botanicals, a few dozen applications in this field are expected, including submissions for substances such as probiotics, prunes, brewer’s yeast or linseed. With probiotics, where there is a lot of proof on health effects, the scientific world was put out by the rejection of all submitted claims. There is much information relating to long-term use. If for these substances, too, traditional data as substantiation of claims are permitted, possibly supported by modern scientific research into the working mechanism, things are kept equal.

XII. Conclusion

Inequality in the assessment of traditional data in the evaluation of health claims and medical claims can be eliminated by allowing traditional data in the assessment of health claims. Not only for botanicals but for all foods. What is sauce for the goose is sauce for the gander. That is a robust legal position.

The EU member states want a harmonised European situation for use of botanicals in foods. Consequently, attention has been paid to separate legislation for botanicals in which both the use of botanicals and claims to be communicated are regulated. But the wishes of member states and their methods of market regulation vary enormously. It will be an almost impossible task to agree on new legislation for botanicals due to the large political differences.

The “on hold” situation with the claims for botanicals finds its origin in a fault in the claims regulation. The simplest solution can therefore be found in a modification of the claims regulation. By changing the claims legislation within the REFIT programme, claims based on traditional data can be permitted, eliminating the need for new legislation for botanicals in foods. The use of allegedly unsafe botanicals can be prohibited within existing European statutory frameworks; no new legislation is required for this. This makes it a feasible and simple solution that fits within the goals of Euro Commissioner Timmermans for better regulation and less European regulatory pressure.