

BOTANICAL CLAIMS - ON HOLD

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Effective communication of the unique features of your products to consumers is crucial for successful marketing. Strong claims that convince consumers to choose your products above other options are essential. Working with claims can be challenging, especially due to the strict European regulations that must be followed. Botanical claims have their own specific status within these regulations. This whitepaper offers insight into the exceptional situation of "Botanicals on hold."

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INTRODUCTION

Nutritional and health claims on supplements play a very important role in communication with both therapists and consumers. Because a user does not have the ability to observe active ingredients or functionality in supplements, these properties must be communicated. Without this crucial information, it is almost impossible for a user to find the right product for a specific need.

The European Claims Regulation (EC 1924/2006) provides a clear framework for the use of claims. However, the current transitional provisions for botanical claims make the field of claims quite complex. On the one hand, the transitional provisions lack clear guidelines and details on which claims are allowed under what conditions. On the other hand, there are differences in implementation between member states of the European Union. Although the regulation is harmonized at the European level, it is the responsibility of the member states to ensure compliance with the regulation. Sometimes, member states use additional national legislation for this purpose. In addition, decisions by the European Court of Justice shape the landscape for making botanical claims.

The result of the above situation is that claims on supplements are made in a very broad spectrum ranging from "clearly prohibited claims" to "meeting the strict requirements for making claims". As a result, a consumer may see products with a multitude of promises, while other producers limit themselves to statements that are specifically allowed. It is clear that a so-called "level playing field" is healthier for the entire product group and that exceptional situations are undesirable in order to maintain the reliability of claims in general and claims on supplements in particular as high as possible.

To be able to make claims on botanicals as a producer in the transitional provisions, there are a number of steps to be taken. If you as a producer get the details in order, claims on botanicals are perfectly possible. This regulation also gives you as a producer the opportunity to distinguish yourself professionally.

CLAIMS. THE BASIS

In a previous whitepaper, I discussed the field of claims and how we can work within it. Keep these principles in mind when working with Botanical claims:

1. Don't use claims just as a marketing slogan.

Let your claims be a supporting part of your brand identity. Using a claim just as a quick marketing slogan does not add long-term value.

2. Be open and honest. Prevent to be misleading.

Difficult because you have to attract attention on the shelf in the market. Always provide open and honest communication and make sure temptation does not turn into deception.

3. Watch how the market responds to your products.

Some products get extra attention from consumers. Research the sensitivities of your product group and take these considerations into account when applying claims.

4. Familiarize yourself with the European claims regulation.

The rules provide the framework for working with claims. As always, details determine the final result, take the time for all the details for the best result.

EU CLAIMS REGULATION

The European Claims Regulation has several goals: to protect the consumer, improve the free movement of goods in the internal market, and promote and protect innovation in the field of food. EC 1924/2006 is designed for making nutrition claims and health claims.

The basis of the regulation is that no nutrition or health claim is allowed unless a claim is specifically listed on a list of allowed claims. This list is managed by the European Commission, while the EFSA (European Food Safety Authority) is called upon to assess the scientific basis behind a claim.

BOTANICALS ON HOLD SITUATION

At the start of the claims regulation, a large number of files were submitted for approval by the member states in 2008. 44000 files were submitted by various countries, and this list was reduced to 4637 unique files that describe a relationship between an ingredient and a health benefit. The EFSA has given an opinion on many of these files as to whether there is indeed a claim that is supported by scientific evidence. Of the 2758 reviewed (Art 13.1) files, EFSA gave a positive opinion on 229.

In the process with the EFSA, there is a category of claims that has not yet been reviewed, namely claims on food products with botanicals (herbs). The assessment of 1548 botanical claims was suspended in 2010. This means that to this day, no decision has been made on the position of botanicals in the claims regulation. In fact, the problem is that the claims regulation for food and supplements is stricter than for medicines. In the medicines regulation, there is a special category of products with effects based on "traditional use". In addition, there are international differences between herbal preparations. In one country, these products are seen as medicines, in another country as health products.

Until a decision has been made on the botanicals, a temporary solution is in use: a large number of claims that were submitted in 2008 may still be used. This is the transitional provision, also known as the "Botanicals - on hold situation".

HOW TO START WITH BOTANICAL CLAIMS?

The starting situation is that the product with the on hold claim always meets the general conditions that apply to all nutrition and health claims. So always keep an eye on EC 1924/2006.

A number of steps can be taken to determine whether an on hold claim on your product is possible. The steps are quite laborious and, for example, require access to Access. Because the on hold situation is temporary, it is not expected that this process will become easier in the future. I am happy to help if you get stuck anywhere.

Step-by-step plan

1. Search for a claim or ingredient in the [Access database](#) and note the ID that belongs to your claim
2. Check whether the conditions match the daily dose of your product
3. Check whether the ID is still on hold according to [the EC's list](#)
4. Use the Dutch indicative list of allowed wording of the claim

Ad 2: You can find the conditions (Conditions of Use) by clicking on 'print' in the Access database and entering the ID number. A new screen with information about this claim will now appear.

Ad 4: Since the claims have not yet been reviewed by the EFSA, it is difficult to choose the correct claim wording yourself. Use the indicative list of the Keuringsraad as a guide. Keep your claim close to the application area given in the claims file as submitted (Access database details).

This step-by-step plan is valid for the Netherlands, where this self-regulatory method of working has been agreed upon. Other member states have different requirements for the use of "on hold" claims, which are often much less flexible. In the Netherlands, you are allowed to use the Indicative List of the Keuringsraad. You are also required to include a disclaimer with "on hold" claims for the Dutch market. The Reclame Code Commissie considers it misleading if an "on hold" claim is used in the same way as an authorized claim. Therefore, the advertiser must include a disclaimer about the provisional approval of the claim. A list of example disclaimers is available.

If, after following these steps, you conclude that you want and can make an "on hold" claim, it is important to remember that an "on hold" claim can only be used until a final EU decision has been made. You should also ensure that there is evidence based on generally accepted scientific evidence for the use of this claim, especially for the amount of the claimed substance used.

The use of claims in a product name is worth a whitepaper in itself. You can also use an "on hold" claim in a product name. However, it is important to keep in mind that if a decision is made on "on hold" botanicals, a claim may no longer be used. This can be inconvenient for a product name.

Overall, it appears from this step-by-step plan that working with "on hold" claims is not easy. However, do not let this discourage you. Make sure you pay attention to the details to avoid any problems with your claims. Regulatory agencies such as the NVWA in the Netherlands also struggle with this complex issue. Therefore, make sure that your claims are always honest and transparent, without trying to mislead your consumers. Credibility is a characteristic of strong brands that consumers trust.

RECOMMENDATIONS

Keep an eye on the market.

Because the rules surrounding the temporary on-hold situation are not clear, problems sometimes arise in the market. Some supplement producers are testing the limits and sometimes exceeding them. If a producer is checked by the NVWA, they may face fines, but in the meantime, claims have been made that put the credibility of the supplements industry as a whole under pressure. Don't be this exception in the market.

Beware of medical claims

Pay special attention to the boundary between health claims and medical claims. Even though the goal of supplements is to prevent or help with conditions, never mention specific illnesses. Medical claims are specifically not allowed, and if you do use those claims, this will no longer be covered by the claims regulation, but by pharmaceutical regulations, with significantly higher fines. For example, "inflammation" in your claim is already a word to avoid.

Accept the limitations of claims

Botanicals on hold is difficult. You want to communicate about the therapeutic effects of supplements, because the consumer cannot deduce this themselves, while the claims regulation only allows this if the EFSA concludes that it is undeniably scientifically proven. Although strict, at least the regulation applies to every producer.

Don't struggle alone

There are several allies that can help with this topic. Are you, for example, affiliated with a trade association such as the [NPN](#) or [EHPM](#)? Definitely also check with the [Keuringsraad](#) (NL), they regularly post tips on their website. Of course, you can also quickly get me excited, especially if you want to set up a good internal system for claims.

REFERENCES/SOURCES

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DISCLAIMER

The information in this whitepaper is provided as general guidance and should not be relied upon as legal or specific professional advice. Claims is a field where details make up the final result. Using claims responsibly is done in consultation.

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Frans van der Sman is an interim consultant in the field of regulatory affairs and nutrition. His expertise focuses on claims, food choice logos, portfolio analyses, and product improvement.

His passion and dedication to nutritional issues, combined with a high level of integrity, allow him to strengthen the strong brands of his clients in a trusted partnership.