

# Client Alert

FDA and Life Sciences

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## European Court of Justice Restricts Advertising for Food with Botanicals

On April 30, 2025, the Court of Justice of the European Union (CJEU) has ruled that advertising food products containing botanicals with health claims is not permitted until the European Commission has granted the permission based on the examination of health claims relating to botanical substances by EFSA (Novel Nutriology, case file C-386/23). An exception exists, if the health claim is covered by the transition provisions of the EU Health Claims Regulation.

The CJEU clarifies the previously uncertain legal situation which primarily affects the food supplement industry and all health-related foods. The court has ruled that health claims are not permitted, except for those included in Regulation (EU) No. 432/2012, referred to as “list”, and those covered under the transition provisions.

All other health claims are now banned.

### BACKGROUND

According to Article 10 of the EU Health Claims Regulation (EC) No 1924/2006 (“HCR”), health claims may only be used on foods, if they have been scientifically assessed by the European Food Safety Authority (EFSA) and authorized by the European Commission by including them into the “list” provided by Regulation (EU) 432/2012 in accordance with the HCR.

For reasons of unequal treatment and capacity, the Commission has ordered EFSA to suspend the assessment of health claims for botanical substances in the year 2010. Health claims for botanicals are currently not assessed by EFSA and cannot be authorized by the European Commission. Therefore, it is currently not possible for a food business operator to obtain a permitted health claim for botanicals.

Since health claims for botanicals have not been included in the lists of authorized health claims, these claims are not permitted according to article 10 (1) and (3) of the regulation.

This means, that only health claims which have been submitted by the Member States of the EU to the European Commission within the timelines provided by the HCR within the year 2008, can be used if meeting the general requirements of the HCR, since these health claims are covered by transition provisions of the HCR. Since these claims are duly submitted by the EU Member States in time, but put “on-hold” by EFSA after the order from the Commission, these claims are called “on-hold claims”, and they are covered by the transition provisions of the HCR. Health claims for botanicals submitted later must not be assessed by EFSA since 2010, and they cannot be authorized by the European Commission.

In the EU many manufacturers of food products containing botanicals argued when using health claims, that the claims need to be considered as on-hold claims, or that the HCR may not apply in these cases, since the Commission stopped the evaluation of health claims by EFSA in 2010.

The CJEU was requested by the German Federal Supreme Court (“BGH”) for a preliminary ruling concerning a food supplement of the German company Novel Nutriology. In the case the ingredients “saffron extract” and “melon juice extract” were advertised as mood enhancing, improving in emotional balance and reducing of stress and fatigue.

The BGH asked the CJEU, if food products may be advertised with health claims relating to botanicals without these claims being authorized under the HCR. The transition provisions of the HCR do not apply.

The key argument of the manufacturer of the food product to be advertised is being hurt in his fundamental rights under the German Constitution and under the Charter of Fundamental Rights of the EU.

#### **CJEU RULES: HEALTH CLAIMS FOR BOTANICALS ARE BANNED, UNLESS...**

The CJEU ruled that Article 10 (1) of regulation No. 1924/2006 contains a fundamental ban on health claims. Advertising with health claims is prohibited unless they are authorized and part of the “list” or unless they are covered by the transition provisions. The CJEU denied any violation of fundamental rights of the manufacturer.

#### **IMPACT**

The ruling supports consumer protection and restricts opportunities to market botanical substances. The ban applies until the Commission decides to proceed examining the claims. Since the health claims on botanicals must not be assessed since 2010, it is unclear, if or when the Commission is going to proceed. This impacts companies in the food supplement industry as it limits the options to advertise food supplements and will further result in a decline of innovation in the market for food supplements.

#### **TAKE AWAY FOR THE FOOD INDUSTRY**

The ruling of the CJEU has a significant impact on the options to advertise health claims for food products containing botanicals. The manufacturers should

- create advertising claims which are not considered as “health claims” in accordance with the HCR
- create advertising messages which may focus on different aspects than the health component.

King & Spalding has significant expertise in creative support of companies not to violate the HCR also after the new ruling.

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