



## Health Claims: *Queisser and B-Vitamins*

CJEU, 30.01.2020, C-524/18 and BGH, 25.06.2020, I-ZR 162/16

November 4<sup>th</sup> 2021

Dr. Levke Voß | meyer.rechtsanwalts GmbH





„Queisser / B-Vitamins II“

Ginkgo + B-Vitamine + Cholin  
40 Kapseln

33% mehr Inhalt  
33% mehr Inhalt



aktiv

Ginkgo  
+ B-Vitamine + Cholin



aktiv

Kapseln mit Cholin, B-Vitaminen,  
Zink und Ginkgoextrakt  
Nahrungsergänzungsmittel

**Zusammen:**  
Cholinatrat, Ginkgo-Blatt-Extrakt (10,3 %),  
Celatine, Beistärke, Füllstoff Cellulose,  
Calcium-D-pantothenat, Festigungsmittel  
Silbernanopartikel, Trennmittel Calciumlactat von  
Speisefettsäuren, Zinkoxid, Vitamin B<sub>12</sub>,  
Vitamin B<sub>9</sub>, Ferbitarfolat, Titandioxid, Eisenoxide  
und Eisenhydroxide, Folsäure, Vitamin B<sub>1</sub>.  
Bitte inleghende Gebrauchsinformation  
beachten.

**Wichtige:**  
Die angegebene empfohlene tägliche  
Verzehrmenge darf nicht überschritten  
werden. Nahrungsergänzungsmittel sind kein  
Ersatz für eine ausgewogene und  
abweichlungsreiche Ernährung und nicht  
gesunde Lebensweise. Für kleine Kinder  
unzugänglich aufbewahren.

**Hersteller:**  
40 Kapseln = 22,2 g  
Münchener Hofapotheke  
GmbH, 80333 München, Deutschland

B-Vitamine und Zink für  
Gehirn, Nerven, Konzentration  
und Gedächtnis  
1x täglich

B-Vitamins and zinc for brain,  
nerves, concentration  
and memory

40 Kapseln

Fol  
saure  
B<sub>12</sub>  
B<sub>9</sub>  
B<sub>1</sub>

Vitamin B1 and Vitamin B12  
contribute to normal energy-yielding  
metabolism, to normal functioning of  
the nervous system [...]

Vitamin B<sub>1</sub> und Vitamin B<sub>12</sub> tragen zum normalen Energie-  
stoffwechsel bei. Sie unterstützen die normale Nervenfunktion  
und leisten einen Beitrag zur normalen Funktion der Psyche.  
Vitamin B<sub>12</sub> spielt wie Vitamin B<sub>1</sub> eine Rolle im normalen  
Energistoffwechsel und für die normale Nervenfunktion.

Das Spurenelement Zink leistet einen Beitrag zu einer normalen  
kognitiven Funktion und trägt dazu bei, die Zellen vor  
oxidativem Stress zu schützen.  
Cholin ist Bestandteil von Phospholipiden, den Haupt-  
bestandteilen der Zellmembranen. Cholin wird in Nerven und  
Gehirn zu den Neurotransmittern Acetylcholin und GABA  
umgewandelt. Neurotransmitter sind Botenstoffe, die die  
Nervenzellen untereinander und mit den Muskelzellen  
verbinden.

Zinc contributes to normal cognitive  
function and to the protection of cells  
from oxidative stress [...]

Für Gedächtnis, Konzentration und die Fähigkeit die  
Herausforderung der täglichen Bewältigung, spielen  
B-Vitamine eine Rolle. Der Stress hat auf eine gute  
Gehirnfunktion einen negativen Einfluss.

Die Kapseln von Doppelherz aktiv enthalten  
B-Vitamine und das Spurenelement Zink. Zusätzlich enthalten  
sie Ginkgo-Blatt-Extrakt.

Stress zu schützen.

Folsäure spielt eine Rolle für die normale Funktion der Psyche.  
Darüber hinaus hat Folsäure eine Funktion bei der Zellteilung.

Pantothensäure leistet einen Beitrag zur normalen geistigen  
Leistungsfähigkeit und trägt wie Folsäure und Vitamin B<sub>12</sub>  
zur Erhaltung der Nervenzellen bei.

Der Ginkgo-Baum ist  
föhrlich. In Asien ist er

## Proceedings

**Plaintiff (Schwabe):** Information on the front of the outer packaging "*B vitamins and zinc for brain, nerves, concentration and memory*" violates

- Articles 3, 5, 6 and 10 of Regulation (EC) No. 1924 / 2006
  - general food law and
  - competition law prohibitions on misleading people.
- 
- **12.07.2018:** Decision of Federal Court of Justice (BGH – I ZR 162/16)  
request for a preliminary ruling under Article 267 TFEU  
*“B-Vitamins”*
  - **30.01.2020:** Judgment of the ECJ (Case C-524/18)  
*“Schwabe/Queisser Pharma”*
  - **25.06.2020:** Judgment Federal Court of Justice (BGH - I ZR 162/16)  
*“B-Vitamins II”*

## Art. 10 (3) HCR

### Art. 10 Abs. 3 HCR:

Reference to **general, non-specific benefits** of the nutrient or food for **overall good health** or **health-related well-being** may only be made

**if accompanied by a specific health** claim included in the lists provided for in Article 13 or 14.

- German Federal Court of Justice (17. 1. 2013 – I ZR 5/12 – Medicinal mushrooms / „Vitalpilze“)
  - ✓ **unspecific** = in which the statements refer to the health well-being to be **supported or increased** by taking the agent („vitalizing“)
  - ✓ **specific** = which express or suggest "**promoting functions of the body**"



*B-Vitamins and zinc for brain, nerves, concentration and memory?*



- German Federal Court of Justice (12.07.2018):

For the distinction between special and non-specific health claims, it depends on whether the claim creates a **direct causal relationship** between a food category, a food or one of its components and a function of the human organism, the **scientific validation of which can be checked in an authorization procedure**.

**Federal Court of Justice (BGH), 12.07.2018: Request for a preliminary ruling**

1. Is a reference to general, **non-specific health-related benefits** “**accompanied**” within the meaning of Article 10(3) of Regulation No 1924/2006 by specific health claims in accordance with one of the lists provided for in Article 13 or 14 of that regulation, even if that **reference is situated on the front** and the **authorised claims are situated on the back of an outer packaging** and, in the perception of the public, although the claims are clearly related to the reference in terms of content, the reference does not contain a clear indication, marked with an asterisk, for example, to the claims on the back?
2. Does **evidence** within the meaning of Article 5(1)(a) and Article 6(1) of Regulation No 1924/2006 also need to be provided in the case of reference being made to general, non-specific benefits within the meaning of Article 10(3) of that regulation?

## Scientific evidence for unspecific claims?

### Art. 5 para 1 lit. a HCR:

The use of nutrition and health claims shall only be permitted if the following conditions are fulfilled:

the presence, absence or reduced content in a food or category of food of a nutrient or other substance in respect of which the claim is made has been shown to have a beneficial nutritional or physiological effect, as **established by generally accepted scientific evidence**

### ECJ:

*„It follows that **Article 10(3)** must be interpreted as meaning that a ‘general’ health claim within the meaning of that article, such as that at issue in the main proceedings, must satisfy the evidential requirements laid down by that regulation.”*

*However, **it is sufficient**, for that purpose, that references to general, non-specific benefits of a nutrient or food on the general state of health and health-related well-being **be accompanied by specific health claims that are supported by generally accepted scientific evidence** which has been verified and authorised, provided that the latter claims are included in the list provided for in Article 13 or Article 14 of that regulation.*

**ECJ, 30.01.2020, C-524/18 + Verbatim adoption of Federal Court of Justice (25. 06. 2020, I ZR 162/16)**

*„Accordingly, the concept of ‘accompanying’ within the meaning of that article, must be interpreted as including **both a substantive and a visual dimension**..“*

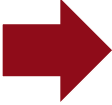
### **Substantive dimension:**

this concept of ‘accompanying’ requires that **content** of the ‘general’ health claim and the specific health claim **match**, implying, in substance, that the former is fully supported by the latter.

### **Visual dimension:**

**the immediate perception** by the average consumer, reasonably well informed and reasonably attentive and circumspect, **of a direct visual link** between the reference to general, non-specific health benefits and the specific health claim, which requires, in principle, **spatial proximity or immediate vicinity between the reference and the claim.**

## Conclusion

- 
- Unspecific health-claims need to be accompanied by specific, authorised claims
  - content of the ‘general’ health claim and the specific health claim must match (**Substantive dimension**)
  - immediate perception by the average consumer (**visual dimension**)
    - Spatial proximity or
    - immediate vicinity between the reference and the claim
    - **Exception:** explicit reference, such as an asteriks



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## Health Claims: *Beauty Claims*

BGH, 14.05.2020, I ZR 142/19

November 4<sup>th</sup> 2021

Christina Schröck, LL.M. | meyer.rechtsanwalts GmbH

## Beauty claims in case law

- Beauty claims = advertising relating to aesthetics and outward appearance
- Often reference to hair, nails, and/or skin

### → health claims?

#### **BGH, 07.04.2016, I ZR 81/15 – “Repair capsules”**

- Authorised health claims for normal skin, hair and nails

### → health relation

- Great skin, full hair, hard nails + product name “repair” = unauthorised health claims, as a repair effect is claimed which goes beyond “normal”



### Other inadmissible claims:

- LG Waldshut-Tiengen, 14.09.2017, 3 O 11/16 KfH
  - increase the collagen content and elasticity of the skin
  - reduce the wrinkle depth
- OLG Bamberg, 20.10.2017 – 3 U 117/17; LG Aschaffenburg, 08.05.2018 - 1 HK O 118/17
  - „nutrition of the skin“
  - „promoting the support structure of our skin“
- OLG Karlsruhe, 13.03.2019 – 6 U 90/17
  - “firm skin” as a result of a positive influence on the connective tissue as a support structure of the skin



- Product in question: **collagen drink**
- Advertising included:
  - „fewer visible wrinkles“
  - “firmer skin”
  - “a youthful look”
  - “strong hair”
  - “healthy nails”
  - “activate the body’s own production of collagen and hyaluronan”
  - “improve the collagen structure in the lower dermal layers as well as skin hydration”
- Short decision (dismissing appeal of non-admission):  
→ Verdict of the OLG Hamm was correct, no need for an appeal

- All claims are health-related
- Many of the claimed effects suggested that ingesting the advertised product would improve the structure of the skin
- Claiming a positive effect on hair, nails and skin is a reference to specific bodily functions within the meaning of Art. 13 NHCR. This view is supported by the fact that the list of authorised claims contains statements about the condition of hair, nails and skin.
- Not just about aesthetics but specific changes of bodily functions

## Takeaway for your marketing

- Most if not all claims concerning the condition of hair, skin, and nails are health-related
- Use authorised claims for specific substances, not the product (e.g. zinc)
- Be careful with the wording
- Ask a lawyer



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# Updates on health claims in France

Health Claims – The Food law Cast by meyer.

4<sup>th</sup> November 2021

[Gaëlle Saint-Jalmes](#), Qolumn

Little case law to comment on but  
the sector is still highly controlled  
by the authorities



# As a reminder : who are the competent authorities in France?

At the national level



Direction générale de la concurrence,  
de la consommation et de la répression des fraudes

At the local level



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Direction Départementale  
de la Protection  
des Populations

# The sanctions



In case of **unfair commercial practice** , the main sanctions are :

- 2 years imprisonment maximum
- For an individual: maximum fine of €300,000
- For a legal entity: maximum fine of €1,500,000

=> The amount of the fine may be increased, depending on the benefits derived from the infraction:

- to 10% of the average annual turnover of the last 3 years, or
- 50% of the expenses incurred for the realization of the advertising or the practice constituting this infraction.



# The sanctions



The authorities can also impose a **5th class fine** (€1500) per offending product (sanctions for product compliance – Art. R.451-1 Consumer code).

Ex: **Cour de cassation (Ch. Crim), 20 October 2020 (19-81.207)**

=> confirmation of the sentencing of a food supplements importer to 390 fines of 100 euros.

Unauthorized health claim for the product Calori Light "*Capture 50% of the fat*". Discussion around the notion of Food business operator : the Court confirms that the importer (sourcing from Monaco) was responsible for the claims and had to verify them before marketing the product.

# National Investigation Program 2020



The priorities of the DGCCRF are divided into 6 orientations, the 4th being dedicated to food products and consumer goods.

*"The DGCCRF will reinforce its controls on the fairness of European and national claims and mentions (organic, labels, appellation of origin, made in France, nutritional and health claims,...) [...]"*

# Monitoring of online stores selling “miracle products”

BILAN D'ACTIVITÉ

2020

## Activity report 2020:

- Numerous inspections of online stores offering COVID-19 related products.
- These controls concerned in particular **food supplements** .
- A coordinated action of the control authorities of each European country set up by the European Commission has led to several notifications of fraud.
- In France, about twenty websites presented misleading claims such as therapeutic claims.

# Control of nutritional and health claims on food supplement websites - 2020



Verification of the loyalty of claims by the DGCCRF

95 controls of food supplement websites in 2020

**Average rate of non-compliance of 76% :**

- the use of unauthorized health claims or used in a non-compliant manner (64% of the controlled sites concerned)
- the use of prohibited therapeutic claims (49% of the controlled sites)
- the use of so-called "general" claims not associated with authorized health claims (23% of the controlled sites)

*"Compliance with regulations is low, regardless of the size of the company"*

[Link](#)

# Focus on algae - based food supplements July 2021



Investigation started in 2018.

Objectives of the investigation:

- To verify that the nutrition or health claims used were authorized and justified.
- To verify the absence of therapeutic claims.

In short:

- Almost **one out of three** food supplements in anomaly
- **Three criminal reports** , including one for the use of prohibited therapeutic claims, and one for the use of unauthorized health claims and prohibited therapeutic claims.

+ **32 injunctions and 32 warnings** have been established by the DGCCRF investigators, for breaches related to the claims used and the labelling.

[Link](#)

# Focus on certain products with health claims - June 2021

Investigation conducted in 2019 on infusions, teas, chocolates, cereals, honeys...

More than 300 establishments controlled

Conclusion: still a lot of non-compliant health claims on food, especially on the internet.

**Anomaly rate of 44%**

60 warnings, 71 injunctions and 17 fines



[Link](#)

# Focus on certain products with health claims

- Presence of therapeutic claims

For example:

"to fight against anemia"; "used during a cold"; "used in the treatment of certain dermatoses such as acne, eczema, psoriasis".

- Presence of unauthorized health claims, not included in the positive lists of authorized claims

For example:

"Coconut helps digestion"

"Biotin helps maintain normal nails"

[Link](#)



# Focus on certain products with health claims

- Non-compliant claim wording that changes the meaning of the authorized claim

For example:

"Vitamin C increases the immune system" instead of the authorized claim

"Vitamin C contributes to the normal functioning of the immune system"

- General Claim not accompanied by an authorized claim

For example:

"Superfruit"

"Detox"



[Link](#)



Food and Products Lawyers

Thank you

# Gaëlle Saint-Jalmes

## Partner

**Gaëlle Saint-Jalmes** has been practicing for more than fifteen years in the field of product law, for French and international clients. She offers her knowledge of the consumer sectors and their challenges to her clients, both in consulting and litigation.

As a lawyer and then in-house counsel, Gaëlle Saint-Jalmes has developed significant expertise in food law and regulation (nutritional and health claims, labeling, food supplements, crisis management, etc.).

She also has solid experience in the regulation of cosmetic and health products (particularly medical devices), as well as in sustainable development issues applied to consumer products.

Her expertise in consumer law covers unfair commercial practices, e-commerce, sales promotion and advertising, in particular with respect to regulated products (alcohol and tobacco).



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# "Turn Products Law into a pillar of business"

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HEALTH CLAIMS FOR  
BOTANICALS –  
THE MEZINA-CASE

*Webinar on health claims – Meyer rechtsanwälte*

GULLIKSSON



## COMPETENT AUTHORITIES AND COURTS IN SWEDEN

- Food agencies
    - Swedish Food Agency (national)
    - Local food agencies (municipalities)
  - Deals with all regulatory issues including labelling and in-store activities in direct vicinity to the product.
  - Appeals to decisions are filed with the Administrative Courts
  - Consumer Agency/  
Consumerombudsman
  - Deals with all advertising issues with the support of the Swedish Food Agency.
  - Appeals to the Patent- and Market Court which is also the court where competitors file their law suits.
-





## CASE PROCEDURE

- Normally initiated with a letter or report from either agency stating the issue and inviting the operator to respond
- The operator responds and the Agency delivers its decision.
- At this point it is possible to make the matter go away by simply complying.
- The Consumer Agency/Consumerombudsman may take cases with precedential value to court despite compliance.
- The agencies will expect compliance. If not they may issue prohibitive injunctions conditioned on fines or other appropriate measures.
- If "lives are not a stake" transitional periods" of 3-6 months to implement changes are often granted.
- If a food agency's decision is appealed unless the decision explicitly states that the decision has immediate effect the product can stay as is on the market during the appeals process.



## CONSUMEROMBUDSMAN V. MEZINA AB CASE NO. PMT 11229-17

- Mezina AB (Mezina) is a company that is active in development, documentation, research and marketing of herbal medicines, medicines and dietary supplements.
  - Mezina markets on the website [www.wellvita.se](http://www.wellvita.se) i.a. the following food supplements containing plants or plant extracts (so-called botanicals):
    - **Movizin complex** containing ginger, rosehip and boswellia,
    - **Macoform** containing artichoke and dandelion, and
    - **Vistavital** containing blueberries.
  - Mezina made health claims for these products
-



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Måndag-fredag  
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Klimakterie

Skönhet och hår

Ögon

Mage

Macoform

Mage i balans

Gestomax

Få fart på matsmältningen

Inulax

Hjälper dina tarmar att fungera normalt

Hjärta

Munhygien

Immunförsvar

Minne

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Energi

Sport

er du hjälp?

INGER NILSSON:

# -Ömma leder hindrar inte mig!



JUST NU  
**149<sup>00</sup>**  
HALVA PRISET



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MACOFORM

## Bra för din mage!



BURET TILL DIG  
**149<sup>00</sup>**  
HALVA PRISET



## Bevara ett vackert och fylligt hår







## THE CONSUMEROMBUDSMAN'S CLAIMS

- The Consumerombudman's claimed prohibitive injunction for 12 different claims in the marketing among others:
    - "Movizin complex - för dina leder".
    - "Ingefära kan hjälpa till med att bevara rörligheten i lederna och bidra till energi och vitalitet". (Movizin)
    - "Nypon kan hjälpa till med att bevara rörligheten i lederna",
    - "Nypon som kan hjälpa mig att bevara mina leder och bidra till ledernas fortsatta styrka".
    - "Kronärtskocka kan bidra till en normal matsmältning och stödja magens komfort".
-



## THE COMPLETE LIST OF CLAIMS SUBJECT TO THE LAWSUIT

- “Movizin - for the joints”
  - "Rosehip can help maintain joint mobility",
  - “Rosehip that can help me preserve my joints and contribute to the joints continued strength ”.
  - “Ginger can help maintain joint mobility and contribute energy and vitality ”.
  - 'Boswellia - The resin from this tree has long been used in India, among other places to support the natural mobility and flexibility of the joints ',
  - “I always make sure to take a daily dose of Movizin, where Boswellia helps with keeping the joints comfortable ”.
  - “Macoform – stomach in balance”
  - “Artichoke can contribute to a normal digestion and support the stomach comfort".
  - “Dandelion can support the physiological pH balance and contribute to a normal intestinal function ”.
  - "Vistavital - maintain normal vision".
  - “Blueberries promote blood supply to the eye and retinal function and contribute to maintain the normal function of the eye ",
  - "Blueberries - Helps maintain the normal function of the retina".
-



## THE PARTIES AGREE...AND NOT

- The parties agreed that the claims concerned a specific substance and and fell within the definition of health claims in Regulation 1924/2006
- The parties disagreed on whether or not claims which did not refer to a specific substance - e.g. Movizin – for your joints – should be defined as article specific health claims or non-specific health claims (art 10.3)





## BOTANICALS

- 2010 the Commission would not assess claims on botanicals.
- Applications filed which hadn't been assessed were put on hold
- The transitional rule in article 28.5:
  - Health claims as referred to in Article 13(1)(a) may be made from the date of entry into force of this Regulation until the adoption of the list referred to in Article 13(3), under the responsibility of food business operators provided that they comply with this Regulation and with existing national provisions applicable to them, and without prejudice to the adoption of safeguard measures as referred to in Article 23.

**The Consumerombudsman asked that the question of the application of 27.5 was to be referred to the ECJ to which the Swedish Court agreed.**

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## THE ECJ – C-363/19

- Article 5(1), Article 6(1) and (2), Article 10(1) and Article 28(5) of Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods, as amended by Regulation (EC) No 107/2008 of the European Parliament and of the Council of 15 January 2008, must be interpreted as meaning that,
  - under the transitional arrangements provided for in the latter provision, the burden of proof and standard of proof in respect of the health claims, which requires the food business operator concerned to be able to justify, by means of generally accepted scientific evidence, the claims which it uses.
  - Those claims must be based on objective evidence which has sufficient scientific agreement.
  - The use of the expression ‘**generally accepted scientific evidence**’ means that such evidence should not be limited to beliefs, hearsay derived from popular wisdom, or the observations or experiences of persons outside the scientific community.



## THE SWEDISH PATENT- AND MARKET COURT'S DECISION... (APRIL 2021)

- Mezina has argued that the company has the right to make the health claims as long as they have been notified to the European Commission on the basis of the scientific evidence submitted in connection with the applications.
  - But the Court said that's not enough...
  - The judgment of the European Court of Justice states that it is Mezina who must prove,
    - on the one hand, that it has been proven that the nutrients have a favorable nutritional or physiological effect according to generally accepted scientific evidence (Article 5), and
    - secondly, that the claims are more generally based on and can be substantiated with the help of generally accepted scientific evidence (Article 6 (1)).
-



## MEZINA HADN'T MET ITS BURDEN OF PROOF

- Mezina had relied on a list of documentation submitted to the European Commission in connection with applications.
  - The list consists of a number of articles, etc. from various magazines.
  - There is no investigation in the case which shows that this documentation is to be regarded as accepted scientific evidence within the meaning of the Regulation.
  - The fact that the claims were used in other Member States had no bearing on the case
-



“MOVIZIN COMPLEX - FOR YOUR JOINTS ”,  
“MACOFORM - STOMACH IN BALANCE  
”AND“ VISTAVITAL - MAINTAINING NORMAL VISION ”

- Non-specific?
  - No, specific!
  - According to the court, Mezina's health claims in this part are also to be regarded as specific health claims.
  - Unlike the general health claims, Mezina's claims refer to a specific product.
  - The health claims can only be construed by an average consumer that there is a proven effect between the products mentioned in the claims and on the human joints, stomach or sight.
-



## CONCLUSION

- The Court issued a prohibitive injunction conditioned on a fine of SEK 500.000 (appr. EUR 50.000) per claim.
- If Mezina resumes its use of the claims payment of the fine can be ordered for each transgression.
- The other sanction available in cases like this is a market disturbance fee up to SEK 10.000.000. This is used primarily by the Consumerombudsman as the fee falls to the Government.
- Competitors can sue for damages and destruction of the materials containing the prohibited claims. Damages is the more common of the two.

# THANK YOU FOR YOUR ATTENTION!

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