

Proceeding Paper

# Surveillance of Unregulated Caffeine Health Claims on Coffee and Other Foods—A Market Analysis <sup>†</sup>

Katharina Höfflin, Veronika Kurz, Yvonne Köder, Kristina Schmied, Verena Bock, Ann-Kathrin Kull and Dirk W. Lachenmeier \* 

Chemisches und Veterinäruntersuchungsamt (CVUA) Karlsruhe, Weissenburger Strasse 3, 76187 Karlsruhe, Germany; katharina.hoefflin@cvuaka.bwl.de (K.H.); veronika.kurz@cvuaka.bwl.de (V.K.); verena.bock@cvuaka.bwl.de (V.B.); ann-kathrin.kull@cvuaka.bwl.de (A.-K.K.)

\* Correspondence: lachenmeier@web.de

<sup>†</sup> Presented at the International Coffee Convention 2024, Mannheim, Germany, 17–18 October 2024.

**Abstract:** Caffeine is an alkaloid belonging to the methylated xanthine family. It is found in various foods of plant origin, including tea leaves, guarana berries, and coffee beans. Due to its stimulating effect on the central nervous system and the associated increase in alertness and reduction in tiredness, caffeine is specifically added to some foods, such as food supplements. Claims about the positive physiological effects of caffeine are health claims within the definition of the European Union (EU) Health Claims Regulation and must be authorised before use. Despite a positive opinion from the European Food Safety Authority, regulation of the authorisation of caffeine claims was rejected due to a veto by the European Parliament. As a result, health claims are currently not regulated for caffeine in all EU member states, and the transitional on-hold status also no longer applies for most claims. Therefore, products with health claims regarding caffeine are still observed within the context of governmental food-control activities. To investigate how these are currently used on the market, internet research (n = 188) was carried out. The sample included foods that naturally contain caffeine or to which it is frequently added, namely coffee, tea, non-alcoholic soft drinks and mixed drinks, as well as food supplements, including sports nutrition products. Furthermore, the labelling of official samples that were conspicuous in relation to caffeine in the years 2019–2023 (n = 136) was included in the evaluation. The products most frequently advertised with unregulated health claims for caffeine were food supplements (31% of 135 products). On the other hand, health claims were least frequently used for coffee (4% of 77 products) and tea (18% of 33 products). For all product groups, health claims were mainly made regarding improved concentration and performance/energy. The individual effects the health claims referred to differed between the product groups. In the case of coffee and tea, the advertised effects are mainly limited to increased energy and performance in the form of a “kick” or “boost”. A wider range of different health claims are used for food supplements and alcohol-free beverages, including claims relating to stamina and alertness. In general, the tendency was observed for health claims to be advertised more frequently on the internet than on the product labelling itself. This study exposes a critical issue: while scientific evidence supports some health claims for caffeine, they still remain unregulated, complicating enforcement and creating public confusion. Prompt regulatory revision is needed to align these claims with scientific validations, ensuring both accuracy and regulatory compliance.



**Citation:** Höfflin, K.; Kurz, V.; Köder, Y.; Schmied, K.; Bock, V.; Kull, A.-K.; Lachenmeier, D.W. Surveillance of Unregulated Caffeine Health Claims on Coffee and Other Foods—A Market Analysis. *Proceedings* **2024**, *109*, 20. <https://doi.org/10.3390/ICC2024-18172>

Academic Editor: Steffen Schwarz

Published: 8 August 2024



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**Keywords:** caffeine; health claims; EU regulations; food labelling; market survey; coffee; consumer protection; food control

## 1. Introduction

Caffeine is an alkaloid from the methylated xanthine family and occurs naturally in various foods of plant origin such as tea, guarana, and coffee. Due to its stimulating effect on the central nervous system and the associated increase in alertness and reduction

in the feeling of tiredness, caffeine is also deliberately added to some foods [1]. In the European Union (EU), claims about the physiological effects of caffeine are treated as so-called health claims within the definition of Regulation (EC) No. 1924/2006 (Health Claims Regulation) [2]. These claims must be approved prior to use on food labels or in advertising. Despite a positive opinion from the European Food Safety Authority, the approval regulation for four caffeine claims was withdrawn due to a veto by the European Parliament. The primary reason for the rejection was the concern that the use of health claims about caffeine would encourage the consumption of energy drinks by adolescents, which are characterised by high levels of both sugar and caffeine [3]. Indeed, the presence of health claims regarding caffeine and the declaration of caffeine content may encourage consumption [4]. For example, the average caffeine intake via natural sources from coffee and tea is already very high, estimated at about 240 mg per day for German consumers [5]. This is already more than half of the 400 mg/day considered safe by the European Food Safety Authority (EFSA) for healthy adults [1]. In a small proportion of young adults (less than 5%), the maximum recommended caffeine intake is consistently exceeded [6], so there might be some justification for the standpoint of the European Parliament not to further decrease the safety margin with health-based advertising.

At present, no health claims for caffeine are approved, and most of the transitional measures for certain on-hold health claims no longer apply. As products with caffeine health claims had repeatedly come into focus in the course of previous official food control measures, an internet search was carried out to investigate how these are currently used on the market. Samples examined for official control purposes, which were conspicuous in connection with caffeine analytically and/or in the labelling, were also retrospectively taken into account.

## 2. Materials and Methods

In the search for products with health claims related to caffeine, the product categories beverages and food supplements, including sports nutrition, were considered. Within beverages, the focus was on coffee, tea, non-alcoholic soft drinks, and mixed drinks, as these often contain caffeine.

The research was conducted exclusively online, employing both a targeted and a non-targeted search strategy. In the targeted search strategy, well-known brands associated with caffeine were examined for the presence of health claims. In order to achieve this, the websites of the brands were searched for any caffeine-related claims. In the event that the brands in question did not possess their own website with an online store, the search was conducted on retailer websites. In certain instances, the manufacturers themselves advertised sales on alternative platforms, such as by using hyperlinks. In the non-targeted search strategy, caffeine health claims and product categories were searched for individually or in combination in various search engines. The objective was to identify brands with lower sales, in order to ensure that they would not be overlooked due to the limited awareness of them. In the event of conspicuous hits, the product groups and/or the associated brands were subjected to further examination.

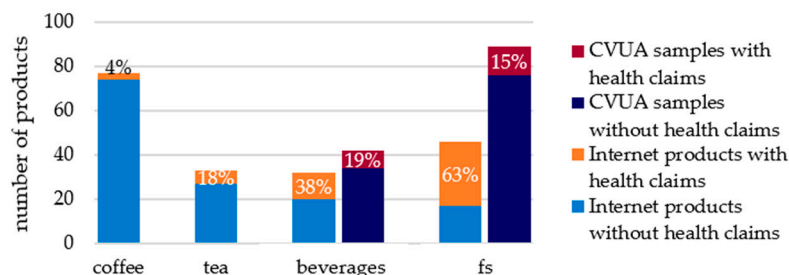
Furthermore, the CVUA Karlsruhe laboratory information system (LIMS) database was queried to identify samples that were analysed for caffeine and were objected to in relation to caffeine between the years 2019 and 2023. The labelling of those samples was subsequently reviewed with a view to identify any health claims regarding caffeine. In order to achieve this, both the archived product images and the websites that were saved at the time of the sampling were subjected to examination.

## 3. Results and Discussion

### 3.1. Prevalence of Caffeine Health Claims across Product Categories

Within the product groups evaluated, health claims for caffeine were most frequently used for food supplements, including those intended for sports nutrition, and beverages (Figure 1). Among the internet products evaluated, food supplements were significantly

more affected (63%) than beverages, where the proportion of products with health claims for caffeine was 38%. In the food supplements and beverages analysed for caffeine between the years 2019 and 2023 (n = 136), the proportion of samples advertised with health claims was similar in both product groups at 15% and 19%, respectively.

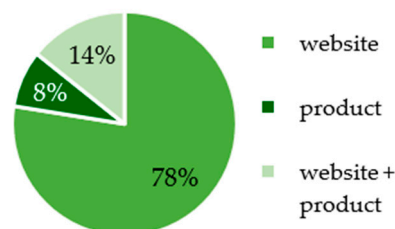


**Figure 1.** Percentage of samples evaluated for caffeine health claims. fs: food supplements.

For coffee and tea, health claims for caffeine were less common. Among internet products (n = 188), 18% of tea products and 4% of coffee products were promoted with health claims. Between 2019 and 2023, only one coffee and four tea samples of the CVUA samples analysed for caffeine were objected to in relation to caffeine. The number of samples was too small to make a representative statement. Therefore, those samples were not evaluated for health claims.

### 3.2. Distribution of Caffeine Health Claims: Product Labels vs. Websites

In the internet samples where the product label was fully visible on the internet pages, it is notable that health claims were more frequently stated exclusively on the websites (14%) than exclusively on the products (8%); see Figure 2. In 78% of the products, health claims regarding caffeine were advertised on the product itself and on the websites. It can be concluded that websites serve as a significant platform for the promotion of products with health claims.

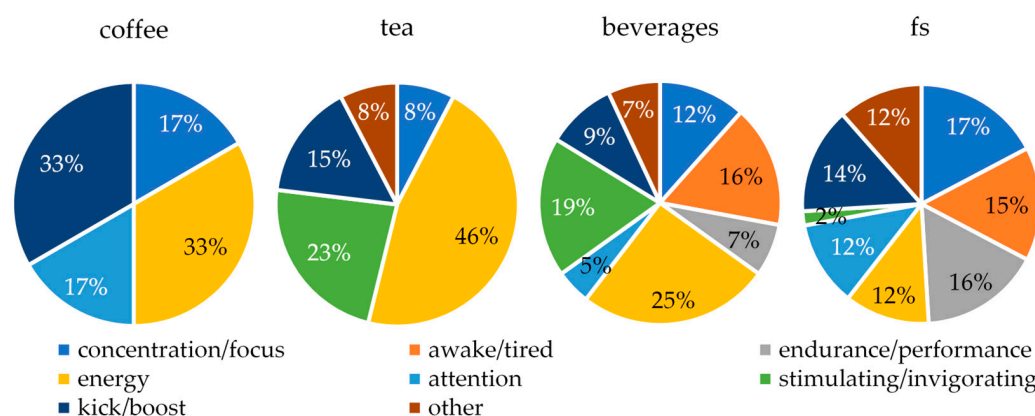


**Figure 2.** Placement of advertising with health claims for caffeine in the products from the internet search.

### 3.3. Categories and Frequency of Caffeine-Related Health Claims

The health claims relating to caffeine can be differentiated according to the type of health claim in question. The relative proportions of the identified categories of health claims per product group are illustrated in Figure 3. In the case of coffee and tea products, health claims are predominantly employed to promote energy (33% of health claims for coffee products, 46% for tea products) and energy-related parameters, such as a “kick” or “boost” (33% of health claims for coffee products, 15% for tea products). A greater variety of health claims are identified in the advertising of beverages and food supplements, which are represented in similar proportions. In the case of beverages, the largest proportion of health claims relate to energy, accounting for 25% of all claims. In the case of food supplements, the largest proportion of health claims relate to concentration and focus, accounting for 17% of all claims. In the case of tea products, beverages, and food supplements, health claims were also made that do not fall into the areas of concentration, performance, or

energy. These claims extend beyond the scientifically confirmed effects of caffeine, such as the promotion of fat burning.



**Figure 3.** Types of health claims for caffeine identified in the products evaluated. fs: food supplements.

### 3.4. Evaluation of the “On-Hold” Status of Caffeine Health Claims

The objective of the Health Claims Regulation is to establish a unified legal framework for nutrition and health claims within the EU, with the aim of protecting consumers from misleading or false claims. The positive nutritional or physiological effects must be proven for all nutrition and health claims on the basis of generally recognised scientific evidence. In consequence of the considerable number of health claims submitted by the Member States that were required to be evaluated by EFSA, a list was compiled in 2012 comprising more than 2000 health claims on botanicals. The aforementioned health claims may continue to be used under certain conditions as on-hold claims under the purview of the food business operators until a final decision is made regarding their status. The use of the claims is contingent upon compliance with the Health Claims Regulation and national provisions. The evaluation of further health claims for botanicals has been temporarily halted [7].

On-hold claims must comply with the requirements set forth by the Health Claims Regulation, as outlined in Article 28(5). In particular, the evidence must be based on generally accepted scientific principles. It is the responsibility of the food business operator to prove their case. In accordance with the ruling of the Court of Justice of the EU on 10 September 2020 (C-363/19), the food business operator may rely on the evidence contained within the dossiers submitted to EFSA [8]. Therefore, a positive assessment by EFSA, such as for the claims ‘caffeine contributes to an increase in endurance performance’ and ‘caffeine contributes to an increase in endurance capacity’, may be used as evidence of beneficial effects. On the other hand, claims with a negative opinion from EFSA will be placed on the non-authorized list and the on-hold status will no longer apply [9].

In accordance with Article 28(6) of the Health Claims Regulation, health claims regarding psychological and behavioural functions and claims regarding slimming or weight-control or a reduction in the sense of hunger (Article 13(1) b and c) may only be used as on-hold claims if their use was permitted prior to the entry into force of the Health Claims Regulation, or if an application was made before 19 January 2008. It is necessary to consider the legislation of the individual countries. Prior to the Health Claims Regulation, there were no health claims in accordance with Article 13(1) b and c that were permitted in Germany. Consequently, the on-hold status does not apply to health claims with a psychological function reference or for weight reduction in Germany, because the transitional period for these health claims under Article 28(6) of the Health Claims Regulation has expired.

Taking into account the requirements for the authorisation of health claims and the utilisation of the on-hold status, the authors agree with Meyer and Baumgärtner [3] and Sadler [9,10] that the claims about physical performance may still be on hold, while the authors do not agree that the mental performance claims are still on hold. This illustrates the lack of clarity surrounding the categorisation of health claims that have been placed

on hold. Therefore, the Appendix A Table A1 presents a comprehensive list of all health claims pertaining to caffeine, accompanied by their status within the EU register, the information whether they were rejected, and the status of the evaluation conducted by the EFSA. Additionally, the authors have provided their assessment of whether they consider the claim to be still on hold (last column of Table A1).

### 3.5. Comparison to Previous Studies

In 2015, a total of 43 food supplements and sports nutrition products containing caffeine were evaluated. At that time, 5 of the 17 (12%) objected samples were objected to due to deficiencies in relation to unauthorised health claims in general [11]. The proportion of complaints is comparable to the proportion of food supplements with caffeine health claims in the samples from 2019 to 2023 (15%). It should be noted that only the claims ‘caffeine contributes to an increase in endurance performance’ and ‘caffeine contributes to an increase in endurance capacity’ are potentially permitted as on-hold.

## 4. Conclusions

Despite the legal uncertainty surrounding the use of health claims relating to caffeine in advertising, such claims are frequently used for the promotion of numerous products. Such claims are employed with greater frequency in the case of products containing added caffeine than in the case of products naturally containing caffeine. The type of health claims made vary according to the product group. In the context of distance selling, health claims are employed with greater frequency on websites than on the product itself.

Although some caffeine health claims are scientifically supported, they are still not regulated, which makes them difficult to communicate and enforce under food law. The considerable number of caffeine claims identified in the products under review, coupled with the wide range of different types of claims, indicates that this is a prevalent advertising strategy, despite the absence of regulatory approval. A prompt revision of European regulations is required to guarantee a high level of consumer protection based on scientifically validated and approved caffeine claims.

**Supplementary Materials:** The following supporting information can be downloaded at: <https://www.mdpi.com/article/10.3390/ICC2024-18172/s1>, poster file (in PDF format) presented at ICC 2024.

**Author Contributions:** Conceptualisation, D.W.L.; methodology, Y.K. and K.S.; formal analysis, K.H., V.K., Y.K. and K.S.; investigation, K.H., V.K., Y.K. and K.S.; data curation, K.H., V.K., Y.K. and K.S.; writing—original draft preparation, K.H. and V.K.; writing—review and editing, D.W.L., V.B., A.-K.K., Y.K. and K.S.; visualisation, K.H. and V.K.; supervision, D.W.L., V.B. and A.-K.K.; project administration, D.W.L. All authors have read and agreed to the published version of the manuscript.

**Funding:** This research received no external funding.

**Institutional Review Board Statement:** Not applicable.

**Informed Consent Statement:** Not applicable.

**Data Availability Statement:** The raw data supporting the conclusions of this article will be made available by the authors on request.

**Acknowledgments:** The laboratory teams of the plant-based foods and beverages departments at CVUA Karlsruhe are thanked for excellent technical assistance. The authors would like to acknowledge the assistance of DeepL (<https://www.deepl.com/>) for providing support in German-English translation and English language improvement.

**Conflicts of Interest:** The authors declare no conflicts of interest.

### Appendix A

**Table A1.** Overview of Health Claims Related to Caffeine and Caffeine-Containing Foods in the EU Register and the Open European Food Safety Authority (EFSA) Database, Including Their Current Status (as of 26 June 2024).

EFSA Question No.	EFSA Opinion Ref.	ID EU Register/Dossier No.	Nutrient Substance, Food, or Food Category	Claim <sup>1</sup>	Status EU Register [12]	Status Per EU Regulation	Status Open EFSA (Positive/Negative Opinion) [13]	Status On-Hold <sup>2</sup>
Q-2008-2221	[14]	1484	Caffeine	Contributes to the mobilisation of fat stores. Contributes to the stimulation of fat release. Helps to increase fat burning. Contributes to the oxidation of stored fats. Helps generate a negative energy balance. Contributes to increased calorie burning.	non- authorised	n/a	published (negative)	no
Q-2008-2226	[15]	1489	Caffeine	Enhances physical performance. Provides a performance edge. Can delay the onset of fatigue. Can increase exercise intensity/work rate.	non- authorised	n/a	published (negative)	no
Q-2008-2224	[14]	1487	Caffeine	Caffeine can increase resting metabolic rate. Caffeine supports thermogenesis and energy oxidation.	non- authorised	n/a	published (negative)	no
Q-2013-00399	[16]	0393_UK	Caffeine	Caffeine helps to increase alertness (>40 mg, <75 mg). <sup>3</sup>	non- authorised	EU Regulation 2016/1411 [12]	published (negative)	no
Q-2008-1522	[14]	735	Caffeine (from tea/coffee/chocolate or added in pure form)	Contributes to the mobilisation of fat stores. Contributes to the stimulation of fat release. Helps to increase fat burning. Contributes to the oxidation of stored fats. Helps generate a negative energy balance. Contributes to increased calorie burning.	non- authorised	n/a	published (negative)	no
Q-2008-1524 Q-2008-2223	[15]	737, 1486	Caffeine (from tea/coffee/chocolate or added in pure form)	Improves physical performance. <sup>4</sup> EFSA proposed wording: Caffeine contributes to an increase in endurance performance.	non- authorised	n/a	published (positive)	possibly on hold <sup>6</sup>
Q-2008-1330	[17]	543	Caffeine and carbohydrate	Helps increase carbohydrate availability during endurance exercise. Combination of caffeine and carbohydrate improves endurance performance.	non- authorised	n/a	published (negative)	no
Q-2008-2764	[18]	2031	CoffeeSLENDER® tablets made from an extract from green coffee beans (Svetol®) the active principle of which is: 5-caffeoylquinic acid (chlorogenic acid) = 45%, caffeine = 2%, 3-caffeoylquinic acid = 10%	As an aid to weight loss and weight control as part of a calorie-controlled diet. Acts by reducing absorption of sugar (glucose) from the digestive tract.	non- authorised	n/a	published (negative)	no
Q-2008-2533	[19]	1800	Epigallocatechin gallate (ECGC) + caffeine	Increases burning of calories. Stimulates your metabolism to burn calories. Stimulates your body to enhance the calorie burning process. Stimulates your metabolism. Three servings per day have been shown to increase calorie burning by approximately 106 calories.	non- authorised	n/a	published (negative)	no



Table A1. Cont.

EFSA Question No.	EFSA Opinion Ref.	ID EU Register/Dossier No.	Nutrient Substance, Food, or Food Category	Claim <sup>1</sup>	Status EU Register [12]	Status Per EU Regulation	Status Open EFSA (Positive/Negative Opinion) [13]	Status On-Hold <sup>2</sup>
Q-2008-2668	[20]	1935	L-Theanine	Caffeine antagonist.	non-authorised	n/a	published (negative)	no
Q-2008-1400	[21]	613	Taurine	It supports proper metabolism (uptake of glucose/caffeine).	non-authorised	n/a	published (negative)	no
Q-2008-3884	[18]	3152	Coffee	Antioxidants in coffee helps protect our cells against free radicals.	non-authorised	n/a	published (negative)	no
Q-2008-1838	[18]	1099	Coffee	Coffee is a major dietary source of antioxidants. Antioxidants from dietary sources: protect you from free radicals. Protect your cells and tissues from oxidation. Antioxidants help strengthen our body's natural defences against oxidative stress.	non-authorised	n/a	published (negative)	no
Q-2008-1839	[18]	1100	Coffee	Coffee contributes to healthy blood glucose levels.	non-authorised	n/a	published (negative)	no
Q-2011-00783	[22]	n/a	Coffee C21	Regular consumption of Coffee C21 contributes to the maintenance of DNA integrity in cells of the body.	non-authorised	n/a	published (negative)	no
Q-2014-00624	[23]	n/a	Coffee C21 (coffee standardised by its content of caffeoylquinic acids, trigonelline, and N-methylpyridinium)	Regular consumption of Coffee C21 contributes to the maintenance of DNA integrity in cells of the body.	non-authorised	EU Regulation 2016/1411 [12]	published (negative)	no
Q-2019-00423	[24]	0487_DE	Coffee C21, a blend of pure Arabica roast coffees ( <i>Coffea arabica</i> L.) without any non-coffee ingredients	Regular consumption of Coffee C21 contributes to the maintenance of DNA integrity in cells of the body.	non-authorised	n/a	published (negative)	no
Q-2010-00254	[18]	4301	Coffee, not covered by specific food legislation	Coffee naturally contains antioxidants that may support the body's natural cell defences. Coffee is a major dietary source of antioxidants. Antioxidants from dietary sources: protect from free radicals, which cause cell damage. Protects body tissues, lipids, cells and DNA from oxidative damage. Help strengthen the body's natural defences against oxidative stress.	non-authorised	n/a	published (negative)	no
Q-2008-2225	[15]	1488	Caffeine	Supports exercise performance (reduction in perceived exertion, improve time to exhaustion and exercise capacity). <sup>4</sup> EFSA proposed wordings: Caffeine contributes to an increase in endurance capacity. Caffeine contributes to a reduction in the rated perceived exertion/effort during exercise.	not listed	n/a	published (positive)	possibly on-hold <sup>6</sup>
Q-2008-2228	[14]	1491	Caffeine (with or without carbohydrates)	Enhances mental performance. Enhances focus, alertness and concentration. Enhances reaction time. Stay sharper for longer. <sup>5</sup> EFSA proposed wordings: Caffeine helps to increase alertness. Caffeine helps to improve concentration.	not listed	n/a	published (positive)	no <sup>7</sup>

Table A1. Cont.

EFSA Question No.	EFSA Opinion Ref.	ID EU Register/Dossier No.	Nutrient Substance, Food, or Food Category	Claim <sup>1</sup>	Status EU Register [12]	Status Per EU Regulation	Status Open EFSA (Positive/Negative Opinion) [13]	Status On-Hold <sup>2</sup>
Q-2008-2222	[14]	1485	Caffeine (from tea/coffee/chocolate or added in pure form)	Contributes to mental performance. Helps maintain and improve alertness. Aids concentration. Helps make you feel more energetic. Helps revive you. Helps keep you alert. <sup>5</sup> EFSA proposed wordings: Caffeine helps to increase alertness. Caffeine helps to improve concentration.	not listed	n/a	published (positive)	no <sup>7</sup>
Q-2008-1926	[14]	1187	Coffee drink/caffeine	Coffee helps you stay alert. Coffee invigorates.	not listed	n/a	published (negative)	no
Q-2008-2227	[15]	1490	Caffeine (with or without carbohydrates)	Reduces the perception of effort. <sup>5</sup> EFSA proposed wording: Caffeine contributes to a reduction in the rated perceived exertion/effort during exercise.	not listed	n/a	published (positive)	no <sup>7</sup>
Q-2008-1523	[14]	736	Caffeine (from tea/coffee/chocolate or added in pure form)	Contributes to mental performance. Helps maintain and improve alertness. Aids concentration. Helps make you feel more energetic. Helps revive you. Helps keep you alert. Helps improve how you feel. <sup>5</sup> EFSA proposed wordings: Caffeine helps to increase alertness. Caffeine helps to improve concentration.	not listed	n/a	published (positive)	no <sup>7</sup>
Q-2008-1840	[14]	1101	<i>Coffea arabica</i> L. and other spp. (common name: coffee)	Cognitive and physical performance.	not listed	n/a	published (negative)	no
Q-2008-4914	n/a	4204	Food supplement green tea extract rich in EGCG, vitamin C, caffeine, carnitine	Helps to slim body by fat burning.	not listed	n/a	application withdrawn	no
Q-2008-4913	n/a	4203	Food supplement green tea extract rich in EGCG, vitamin C, caffeine, carnitine	Helps promote thermogenic effect.	not listed	n/a	application withdrawn	no
Q-2008-1908	n/a	1169	Energy drinks containing 0.032% caffeine, 0.4% taurine, and 0.24% glucuronolactone	Contains natural caffeine to stimulate your mind. Delivers fresh physical energy while enhancing performance, endurance and concentration.	not listed	n/a	application withdrawn	no
Q-2008-2010	[25]	1272	Caffeinated carbohydrate containing energy drinks	Enhances mental performance, reaction time, alertness, focus, and memory. Energises. Gives you an energy boost. Enhances mental energy. Enhances alertness quickly.	not listed	n/a	published (negative)	no
Q-2010-00376	n/a	4423	<i>Ilex paraguariensis</i> -mate-leaves	Invigorating action due to polyphenols, catechins, theobromine, caffeine, and mate content. <sup>5</sup>	not listed	n/a	intake	no <sup>7</sup>
Q-2008-1843	[20]	1104	<i>Camelia sinensis</i> (common name: tea)	Tea helps refresh body and mind. Tea helps to revive you. Tea helps keeping you alert.	not listed	n/a	published (negative)	no



Table A1. Cont.

EFSA Question No.	EFSA Opinion Ref.	ID EU Register/Dossier No.	Nutrient Substance, Food, or Food Category	Claim <sup>1</sup>	Status EU Register [12]	Status Per EU Regulation	Status Open EFSA (Positive/Negative Opinion) [13]	Status On-Hold <sup>2</sup>
Q-2008-2871	n/a	2138	standardised Guarana extract PC102 Dry extract from seeds of <i>Paullinia cupana</i> H. B. et Kunth, drug-to-native extract ratio (4.5–7):1, solvent of extraction ethanol/water, 11.0–13.0% caffeine	For mental performance. <sup>5</sup>	not listed	n/a	intake	no <sup>7</sup>
Q-2010-00487	n/a	4534	<i>Cassia angustifolia</i> folium, <i>Camellia sinensis</i> folium (senna leaves, tea bush leaves)	Maintain weight control because of anthraquinone, catechins, polyphenols and caffeine, constituents present in this plants combination. <sup>5</sup>	not listed	n/a	intake	no <sup>7</sup>
Q-2008-4915	n/a	4205	Food supplement green coffee extract rich in chlorogenic acids, vitamin B8, chromium, green tea extract	Helps promote weight loss.	not listed	n/a	application withdrawn	no
Q-2008-1944	n/a	1206	Food supplement of plants (meadowsweet, birch, green tea, green coffee, yerba mate), concentrated fruits juices, and pectin	Three-in-one slimming action, adopt the slimming action, relax. Specially formulated for those who wish to refine their thighs, cuts and hips. Product plants: Meadowsweet and birch support the hydric elimination of the kidneys. Green tea helps in weight control. Yerba mate is traditionally used to contribute to lipid degradation.	not listed	n/a	application withdrawn	no

Abbreviations: EGCG, epigallocatechin gallate; n/a, not available; EU, European Union; EFSA, European Food Safety Authority. <sup>1</sup> Submitted wording. <sup>2</sup> Judgment based on the authors’ expert opinion and interpretation of available data, considering commentaries for classification of claims according to Regulation (EC) No 1924/2006 [26,27]. <sup>3</sup> The caffeine content was too low for substantiation of the health claim. <sup>4</sup> Health claim within the definition of Article 13(1)(a) of Regulation (EC) No 1924/2006 related to the role of a nutrient or substance in bodily functions (authors’ judgement). <sup>5</sup> Health claim within the definition of Article 13(1)(b) and (c) of Regulation (EC) No 1924/2006 related to psychological functions and weight management (authors’ judgement). <sup>6</sup> Transitional measures for certain on-hold health claims under Article 28(5) of Regulation (EC) No 1924/2006, potentially possible pending further review. <sup>7</sup> Transitional period for these health claims under Article 28(6) of Regulation (EC) No 1924/2006 has expired as neither the Member States’ communication of claims by 31 January 2008, nor the Commission’s subsequent decision-making process, were completed as stipulated; additionally, there were no national provisions for caffeine-related claims for psychological functions and weight management in Germany prior to the regulation’s entry into force.

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