National Institute for Public Health
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Ministry of Health, Welfare and Sport

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RIVM Letter report 2020-0022
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Synopsis

Risk assessment of caffeine in food supplements

People use food supplements containing caffeine in order to be able to engage more intensely in sporting activities, to lose weight more quickly, or to increase their level of concentration. These food supplements often contain high concentrations of caffeine. As a result, people can consume more caffeine than is safe for their health. This can lead to high blood pressure, headaches, or restlessness. This is the conclusion of a study carried out by RIVM at the request of the Ministry of Health, Welfare, and Sport (VWS).

The European Food Safety Authority (EFSA) has established maximum limits to the amounts of caffeine that can be safely consumed. For adults, for example, the maximum safe daily dose is equivalent to four to six cups of coffee. Due to the use of some food supplements containing caffeine, the amount that can be safely consumed may be exceeded. This can certainly happen if a person combines these food supplements with other products that contain caffeine such as coffee, tea, and chocolate.

There is no legal limit to the maximum amount of caffeine present in food supplements in the European Union. VWS can use the results of this study to submit a request to the European Commission to regulate caffeine in food supplements at the European level.

Keywords: caffeine pills, exposure estimate

Publiekssamenvatting

Risicobeoordeling van cafeïne in voedingssupplementen

Voedingssupplementen met cafeïne worden bijvoorbeeld gebruikt om intensiever te kunnen sporten, sneller af te vallen of zich beter te kunnen concentreren. Deze voedingssupplementen bevatten vaak hoge gehaltes cafeïne. Mensen kunnen hierdoor meer cafeïne binnenkrijgen dan veilig is voor de gezondheid. Ze kunnen dan een te hoge bloeddruk krijgen, hoofdpijn, of rusteloos worden. Dit blijkt uit onderzoek van het RIVM in opdracht van het ministerie van Volksgezondheid, Welzijn en Sport (VWS).

De Europese Voedselveiligheidsautoriteit (EFSA) heeft maximale hoeveelheden cafeïne vastgesteld die veilig zijn om binnen te krijgen. Voor volwassenen bijvoorbeeld komt de veilige dagelijkse hoeveelheid overeen met vier tot zes koppen koffie. Door het gebruik van sommige voedingssupplementen met cafeïne kunnen de veilige hoeveelheden worden overschreden. Dit kan zeker gebeuren wanneer mensen deze voedingssupplementen combineren met andere producten die cafeïne bevatten, zoals koffie, thee en chocolade.

In de Europese Unie is er geen wettelijke limiet voor de maximale hoeveelheid cafeïne in voedingssupplementen. VWS kan de uitkomsten van dit onderzoek gebruiken om een aanvraag te doen bij de Europese Commissie om cafeïne in voedingssupplementen op Europees niveau te reguleren.

Kernwoorden: cafeïnepillen, blootstellingsschatting

Contents

Summary

Food supplements containing caffeine are often marketed for performance enhancement and weight loss. A high intake of caffeine can however result in adverse health effects. In response to parliamentary questions about a serious caffeine poisoning by a 20-year old man in the Netherlands, the Minister of Medical Care (Ministry of Health, Welfare and Sport; VWS) supported the inclusion of caffeine in Annex III of Regulation (EC) 1925/2006 to make it possible to set restrictions on the maximum concentration of caffeine in food supplements at a European level. This Annex contains a list of 'other substances'[1] whose use in foods is either prohibited (Part A), restricted (Part B) or under scrutiny (Part C). Member States or the Commission can initiate the procedure to ultimately place substances on Annex III. Member States can submit a request to the Commission with an assessment showing that "a potential risk to consumers is associated with the ingestion of amounts of the substance that greatly exceed those reasonably expected under normal conditions of consumption of a balanced and varied diet" and/or "a potential risk to consumers is associated with the consumption of this substance by the general adult population or other specified population group for which a potential risk has been identified". RIVM was therefore requested by VWS to perform a risk assessment for caffeine in food supplements.

An internet search identified several caffeine containing food supplements (n=40) that are available in Dutch web shops. Based on the caffeine content of these products and their recommended use, it was estimated that the intake of caffeine through these supplements varied between 16 and 500 mg for a single dose and between 16 and 1000 mg for a daily dose. For more than 25% of the supplements (n=14) the amount of caffeine per single dose and/or recommended daily dose was not clear.

To estimate the intake of caffeine from the diet (not including supplements), a chronic dietary intake assessment for the general population was performed using the Monte Carlo Risk Assessment (MCRA) calculation tool. Food consumption data of the Dutch National Food Consumption Survey (DNFCS) of 2012-2016 were used in combination with caffeine concentrations of products used in the opinion of the European Food Safety Authority (EFSA) on caffeine (EFSA, 2015). The chronic exposure to caffeine was calculated using the Observed Individual Means (OIM) model implemented in MCRA. The estimated chronic dietary intake of caffeine for adults amounted to 260 and 636 mg per person per day at the P50 and P95, respectively, corresponding to 3 and 8 mg/kg bw per day. For adolescents (13-17 years), corresponding estimated intake levels were 35 and 174 mg (1 and 3 mg/kg bw).

[1] Within the framework of this Regulation, an 'other substance' is defined as a substance other than a vitamin or mineral that has a nutritional or physiological effect.

The toxicological reference values as derived by EFSA (2015) were used in the risk assessment. For a single intake of caffeine, the reference value (RV-SI) is 200 mg. The reference value for a habitual or daily intake (RV-DI) is 400 mg for adults and 3 mg/kg bw per day for adolescents. The intake of caffeine resulting from the recommended single dose of the different food supplements is compared to RV-SI, and the recommended daily dose of supplements is compared to the RV-DI.

In addition, the caffeine intake resulting from food supplement use and from other dietary sources is compared with each other and the total intake from both sources with the RV-DI. When the RV-DIs are exceeded, adverse effects like effects on the cardiovascular system, body temperature, hydration and central nervous system cannot be excluded. It is recognized that effects on sleep latency and duration may already occur at a dose of 100 mg; however, these effects are not considered as adverse in the current report.

When consumed according to recommended use, 10 supplements led to a caffeine intake exceeding either the RV-SI of 200 mg or the RV-DI of 400 mg for adults. One of these supplements exceeded both levels. For adolescents, 20 supplements would result in a daily dose above the RV-DI of 3 mg/kg bw. Therefore, a potential risk to consumers is associated with the consumption of these supplements and possible adverse effects cannot be excluded for part of the caffeine containing food supplements available in Dutch web shops. This does not take into account the exposure to caffeine from other sources than food supplements yet.

When comparing the caffeine intake from food supplements with the dietary caffeine intake it can be concluded that the caffeine intake from food supplements is within the range of the dietary intake or much higher (up to a factor of almost 4 for adults and 28 for adolescents), depending on the supplement. For an adult consumer with a median intake of caffeine via the diet, the total daily dietary caffeine intake could exceed the RV-DI of 400 mg/day with a factor of approximately 3 when also using the food supplements with the highest caffeine dose. For consumers with a high intake of caffeine via the diet this would be a factor 4. For adolescents with a median caffeine intake from the diet, additional intake via the use of food supplements could lead to a total daily caffeine intake that exceeds the RV-DI of 3 mg/kg bw up to a factor of approximately 5. For adolescents with a high caffeine intake from the diet, this would be a factor 6.

For both Dutch adolescents and adults it can be concluded that 1) the caffeine intake via the use of food supplements with caffeine can greatly exceed the intake via the 'normal' diet and 2) that this may result in intakes that largely exceed the reference values for both adolescents and adults with a median and high intake via the diet. In addition, the caffeine intake from some food supplements may already exceed the reference values independent of other dietary intake. Hence adverse effects cannot be excluded when food supplements with caffeine available in Dutch web shops are used. As such, both requirements for the inclusion in Annex III of regulation (EU) 1925/2006 are met.

1 Introduction

1.1 Background

In 2019 the Dutch television program 'Max Meldpunt' broadcasted an episode about a 20-year old man that suffered a heavy caffeine poisoning due to a high intake of caffeine containing food supplements (caffeine pills) (Max Meldpunt, 2019). In response to this case, parliamentary questions were raised for the Minister of Medical Care about the occurrence of caffeine poisonings (Bruins, 2019). Also, questions were asked about the need for setting maximum levels for caffeine in food supplements[2]. In his response, the Minister supported the inclusion of caffeine in Annex III of Regulation (EC) 1925/2006 to set restrictions on the maximum concentration of caffeine in food supplements at a European level.

Regulation (EC) No 1925/2006 of the European Parliament and of the Council of 20 December 2006 regulates the addition of vitamins, minerals and of (ingredients containing) certain other substances to foods. Within the framework of this Regulation, an 'other substance' is defined as a substance other than a vitamin or mineral that has a nutritional or physiological effect. Annex III of this Regulation contains a list of 'other substances' whose use in foods is prohibited (Part A), restricted (Part B) or under Community scrutiny (Part C). Member States or the Commission can initiate the procedure, described in Article 8 of the Regulation, to ultimately place substances on Annex III. Member States can submit a request to the Commission with an assessment showing at least one of the following:

- "a potential risk to consumers is associated with the ingestion of amounts of the substance that greatly exceed those reasonably expected under normal conditions of consumption of a balanced and varied diet, due to the conditions under which the substance is added to food or used in the manufacture of food;
- a potential risk to consumers is associated with the consumption of this substance by the general adult population or other specified population group for which a potential risk has been identified."

RIVM was therefore requested by the Ministry of Health, Welfare and Sport (VWS) to perform a risk assessment for caffeine in food supplements to investigate if these requirements are met. This report describes an overview of food supplements containing caffeine available on the Dutch market. The caffeine intake resulting from these food supplements and from the normal diet was estimated. The potential risk of the exposure to caffeine was assessed using levels of no safety concern for caffeine derived by the European Food Safety Authority (EFSA, 2015).

[2] Food supplements are concentrated sources of nutrients (or other substances) with a nutritional or physiological effect. Such food supplements can be marketed in "dose" form, such as pills, tablets, capsules, liquids in measured doses, etc. See https://ec.europa.eu/food/safety/labelling_nutrition/supplements_en

1.2 Information on existing assessments

In 2015 the EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA) published an opinion on the safety of caffeine in which levels of no safety concern were derived. EFSA concluded that a single dose of caffeine up to 200 mg (about 3 mg/kg bw for a 70-kg adult) and a habitual caffeine intake up to 400 mg per day (about 5.7 mg/kg bw per day for a 70-kg adult) from all sources do not give rise to safety concerns for the general healthy adult population. Habitual caffeine intake is defined as a daily caffeine intake for longer periods of time, usually months or years. In addition, effects on sleep latency and duration may occur at a lower dose of 100 mg, especially when caffeine is consumed short before bedtime. This opinion is summarized into more detail in chapter 5 of this report and used in the risk assessment.

In 2015, the Norwegian Scientific Committee for Food and Environment (Vitenskapskomiteen for mattrygghet; VKM) assessed the risk of food supplements containing caffeine resulting in daily doses of 100 and 300 mg (VKM, 2015). VKM concluded that it is unlikely that a daily dose of 100 mg of caffeine from food supplements would cause adverse health effects in any of the age groups, including pregnant women and the fetus and lactating women and their breastfed infants, based on the levels of no safety concern derived by EFSA (2015). However, a dose of 100 mg per day could increase sleep latency and reduce sleep duration. A daily dose of 300 mg of caffeine from food supplements was concluded to possibly cause health effects in children, adolescents, pregnant and lactating women, the fetus and the breastfed infant. Also, when consumed in a single dose, 300 mg could cause health effects in the general adult population. However, when consumed throughout the day, no health effects were expected for healthy adults with this dose, apart from potential increases in sleep latency and a reduced sleep duration. In its assessment, VKM did not take intake of caffeine through other sources into account.

In addition, assessments on the risks of the consumption of caffeine containing energy drinks have been performed previously by the Dutch National Institute for Public Health and the Environment (RIVM) (Bemelmans et al., 2018), the German Bundesinstitut für Risikobewertung (BfR, 2019) and VKM (2019). As these assessments focused on energy drinks only, they are not discussed in this report.

1.3 Information on existing legislations

At an EU level, labelling requirements are in place as laid down in Regulation (EU) 1169/2011 on the provision of food information to consumers. Foods other than beverages to which caffeine is added with a physiological purpose (including food supplements) have to contain the following sentence on the label: 'Contains caffeine. Not recommended for children or pregnant women.' Also, the caffeine content has to be provided, expressed per recommended daily dose.

No maximum levels for caffeine in foods (including food supplements) are set at EU level. Member states can have national legislation regarding maximum caffeine content of foods. In Belgium, for example, a limit for caffeine in food supplements is in force, where the maximum

daily dose of caffeine resulting from the use of food supplements is restricted to 80 mg (FPS Public Health, Food Chain Safety and Environment, 2009). In the Netherlands, no maximum level for caffeine in food supplements has been set. There is, however, a limit for lemonade and soft drinks in which a maximum amount of 350 mg of caffeine per litre is stated in the Commodities Act (Warenwetbesluit, 2019).

2 Description of the product

2.1 Identity and nature of the source material

Caffeine (IUPAC name 1,3,7-trimethylpurine-2,6-dione; CAS number 58-08-2) is an alkaloid found in the seeds, nuts or leaves of a number of plants such as coffee and cocoa beans, tea leaves, guarana berries and kola nuts. Caffeine can be produced synthetically as well. Caffeine is added to food supplements as such, or by adding plant extracts that contain caffeine. The latter is often marketed as a natural source of caffeine (Pubchem database on caffeine; EFSA, 2015) but all include the same caffeine, chemically speaking, as depicted in Figure 1.

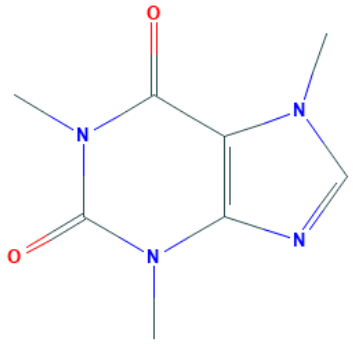

Figure 1. Chemical structure of caffeine.

2.2 Use and use levels

Food supplements containing caffeine are often marketed for performance enhancement and weight loss (EFSA, 2015).

A large number of food supplements containing caffeine available on the Dutch market was found through an internet search[3]. These supplements are listed in Table 1. The amount of caffeine per single dose and the recommended number of single doses per day are given, along with the total recommended daily dose of caffeine. Also, it is indicated if warning phrases for children and pregnant and lactating women[4] are mentioned by the web shops. It is important to note that the information provided by the internet search is limited to the available information on the websites of the products. Any additional information that might be present on the product label itself was not taken into account.

Besides food supplements, there are numerous foods that contain caffeine. These food products include chocolate, coffee, tea and products in which these products have been processed, and cola beverages and energy drinks. An overview of these products and the caffeine concentrations used for the exposure assessment in the EFSA opinion of 2015 are presented in Appendix 1.

[3] Websites were consulted in the period December 2019 till January 2020.
[4] Although a warning phrase for lactating women is not required for food supplements according to Regulation (EU) 1169/2011, many food supplements were shown to include lactating women in their warning phrases.

Certain human medicinal products contain caffeine and painkillers (tablets) are the most widely used type. These typically contain 50 mg of caffeine per tablet in combination with paracetamol and the recommended (single) dose is 1-2 tablets with a maximum of 6 tablets per day (Medicines Information Bank, Medicines Evaluation Board, 2020).

Table 1. Examples of several food supplements containing caffeine available on the Dutch market with the amount of caffeine per single dose, maximum recommended number of single doses per day, maximum recommended daily dose of caffeine and information on warning phrases for children, pregnant women and lactating women.

Name product (brand)	Amount of caffeine per single dose (mg)	Maximum recommended number of single doses per day	Maximum recommended daily dose of caffeine (mg)	Warning phrases concerning:		
				Children	Pregnant women	Lactating women
Caffeine kick (Olimp)[1]	300	1	300	N	N	N
High Caffeine 200 mg (Natrol)[2]	200	3	600	Y	Y	Y
Caffeine tabletten 200 mg (Bulk Powders)[3]	200	Not mentioned	-	Y	N	N
Caffeine 200 mg 8-hour sustained release (Puritan's Pride)[4]	200	1	200	Y	N	N
Caffeine Core Serie (Mutant)[5]	200	1	200	Y	Y	Y
Caffeine (a) (Scitec Nutrition)[6]	100	1	100	Y	Y	Y
Caffeine 200 mg (Haya Labs)[7]	200	5	1000	Y	Y	Y
Caffeine Boost (Nootropics)[8]	200	2	400	Y	Y	N
Concentrated PreWork out (Bodylab24)[9]	360	1	360	Y	Y	Y
Relentless[a] (Dedicated Nutrition)[10]	120	2	240	Y	Y	Y
Cafeine Booster[11]	250-500	3	750	N	Y	Y
Tested Cafeine (Tested Nutrition)[12]	200	3	600	Y	Y	Y
Cafeine 200 (a) (Nutrex Research)[13]	200	2	400	Y	Y	Y
Pure Cafeine (Evolution)[14]	200	3	600	N	N	N
Sis Energygel Go + Caffeine (SIS)[15]	75	Not mentioned	125*	Y	Y	N
Caffeine (c) (Allmax)[16]	200	Not mentioned	-	N	N	N
Qwin caffeine tabletten (Qwin)[17]	100	Not mentioned	-	N	N	N
Born superliquid gel cappuccino + caffeine (Born)[18]	Not mentioned	Not mentioned	-	N	N	N
Caffeine 200 (b) (Nutrex)[19]	200	2	400	Y	Y	Y
Caffeine tablets (Oxford Vitality)[20]	200	2	400	Y	N	N
Power gel (Power bar)[21]	50	1	50	Y	Y	Y
Fat Burn Extreme (Evolution slimming)[22]	Not mentioned	1	-	N	N	N

Name product (brand)	Amount of caffeine per single dose (mg)	Maximum recommended number of single doses per day	Maximum recommended daily dose of caffeine (mg)	Warning phrases concerning:		
				Children	Pregnant women	Lactating women
Born Energy Block (Born)[23]	Not mentioned	10	-	N	N	N
Allnutrition caffeine (Allnutrition)[24]	200	Not mentioned	-	N	N	N
Support energie sticks (Oenobiol paris silhouette)[25]	50	1	50	Y	Y	Y
Dagravit vitaal 50 + soepel bewegen tabletten[26]	up to 16	1	16	Y	Y	N
super groene thee vetverbrander[b] (Holland & Barrett)[27]	198,4	1	198,4	Y	N	N
Energie gels cafeine guarana (Vifit Sport)[28]	Not mentioned	Not mentioned	-	Y	Y	N
Mental focus[c] (Scitec Nutrition)[29]	50	Not mentioned	-	Y	Y	Y
Cafeïne tabletten (Perfectbody)[30]	250	1	250	N	Y	Y
CBD + cafeïne tabletten voor alertheid enconcentratie[d] (Medterra)[31]	50	2	100	N	N	N
Mutant Core Series cafeïne (Mutant)[32]	200	1	200	N	N	N
caffeine tabletten (Qwin)[33]	100	Not mentioned	400*			
High Caffeine 200 mg (Natrol)[34]	200	3	600	Y	Y	Y
Superhero[e] (Scitec Nutrition)[35]	300	Not mentioned	-	Y	Y	N
First Energy Gum (First Energy Gum)[36]	80	2	160**			
WUG Military (WUG)[37]	150	2	300	N	N	N
WUG Energy+ gum[f] (WUG)[38]	45	2	90	Y	Y	Y
Elite Kick-Start Caffeine Gum (Healthspan)[39]	100	Not mentioned	-	N	N	N
caffeine gum mint (6D Sports nutrition)[40]	50	Unclear	-	N	N	N

Y: information is present in the description found on the website.
N: information is absent in the description found on the website.
*No daily maximum number of recommended single doses was provided but the product information contained a maximum recommended daily caffeine consumption.

**The recommended daily dose was not clearly stated in the provided information on the website.

[1] https://www.bodylab.nl/caffeine-kick-60-kapseln.html?utm_source=pla-de&utm_medium=sea&utm_campaign=bodylab_shop&wkz=bl24seaplacssnl&gclid=EAIaIQobChMInv7EjaDa4wIV1Od3Ch0qBAbsEAQYAyABEgKDAPD_BwE

[2] https://www.bsnutrition.nl/training/high-caffeine-200mg-natrol.html?variation=369%3D2202&gclid=EAIaIQobChMInv7EjaDa4wIV1Od3Ch0qBAbsEAQYHCABEgLe0_D_BwE

[3] https://www.bulkpowders.nl/cafeine-tabletten.html?view=ppc&pid=2347&gclid=EAIaIQobChMI8u3SkLST5AIVxud3Ch1vSgOAEAkYASABEgLmP_D_BwE

[4] https://www.bodyenfitshop.nl/puritans-pride-caffeine-200-mg-8-hour-sustained-release/?channable=e24223.MTE3NDY&gclid=EAIaIQobChMI8u3SkLST5AIVxud3Ch1vSgOAEAkYBSABEgK-ZfD_BwE

[5] https://www.bsnutrition.nl/training/caffeine-core-serie-mutant.html?variation=552%3D1956&gclid=EAIaIQobChMItbivpbqT5AIVBETTCh0kWgD7EAkYASABEgLAEPD_BwE

[6] https://www.houseofnutrition.nl/product/afslanken-afvallen/afslank-supplementen/caffeine/?gclid=EAIaIQobChMIx7e2rrqT5AIV2vZRCh1n8Q2wEAkYASABEgLpcfD_BwE

[7] https://www.bsnutrition.nl/training/caffeine-200mg-haya-labs.html?variation=186%3D63&gclid=EAIaIQobChMI8u3SkLST5AIVxud3Ch1vSgOAEAkYDiABEgJnJPD_BwE

[8] https://nootropics-shop.nl/products/caffeine-pillen-nootropics-90-caps?variant=1300207468569&currency=EUR&utm_source=google&utm_medium=cpc&utm_campaign=google+shopping&gclid=EAIaIQobChMI8u3SkLST5AIVxud3Ch1vSgOAEAkYEyABEgLOi_D_BwE

[9] https://www.bodylab.nl/bodylab24-concentrated-pre-workout-375g.html

[10] https://www.bodyenfitshop.nl/dedicated-nutrition-relentless/?channable=e24223.NTQxMzg&gclid=EAIaIQobChMIlLKl6L-T5AIVBETTCh0kWgD7EAkYAyABEgIIZ_D_BwE

[11] https://xxlnutrition.com/nl/nld/xxl-nutrition/caffeine-booster

[12] https://www.bsnutrition.nl/training/tested-caffeine.html?variation=369%3D510&gclid=EAIaIQobChMIlLKl6L-T5AIVBETTCh0kWgD7EAkYCiABEgJ8UvD_BwE

[13] https://www.bodystore.nl/nutrex-caffeine-200.html

[14] https://www.fruugo.nl/pure-caffeine-powder-200mg-capsules-300-capsules-caffeine-supplement-evolution-slimming/p-31267738-64919267?language=en&ac=croud&gclid=EAIaIQobChMIlLKl6L-T5AIVBETTCh0kWgD7EAkYDCABEgJjePD_BwE

[15] https://www.bodyenfitshop.nl/energygel-sis-go-caffeine/?channable=e24223.NTIxNDE&variation=240%3D4410%26236%3D2387&gclid=EAIaIQobChMIlLKl6L-T5AIVBETTCh0kWgD7EAkYDSABEgK_YPD_BwE#240=4410&236=2387

[16] https://www.get-ripped.nl/sportsupplementen/slank-supplementen/slank/caffeine-allmax-100-tabletten__553/

[17] https://www.deonlinedrogist.nl/drogist/qwin-cafeine-tabletten.htm?channable=e23640.NzMyNTY&cross=0&dtext=0&dtag=0&dmenu=0&dpath=0&dafval=0&dvraag=0&drel=0&ingr=0&etk=0&gclid=EAIaIQobChMIr9qx9seT5AIVl53VCh3PKQrJEAkYBSABEgImX_D_BwE

[18] https://www.wielervoeding.nl/born-super-liquid-gel-cappuccino-+-caffeine-9-+-1-gratis,1984.html?gclid=EAIaIQobChMIr9qx9seT5AIVl53VCh3PKQrJEAkYDiABEgJ1lPD_BwE

[19] https://www.body-supplies.nl/training/caffeine/caffeine-200-now-foods.html?channable=e18450.bnV0cmV4LWNhZmZlaW5l&utm_campaign=LeGuide+NL&utm_content=&utm_source=LeGuide&utm_medium=CPC&utm_term=&variation=59%3D2907

[20] https://www.fruugo.nl/caffeine-tablets/p-23150467-50693433?language=en&ac=croud&gclid=EAIaIQobChMIr9qx9seT5AIVl53VCh3PKQrJEAkYEyABEgIvuvD_BwE

[21] https://www.bodyenfitshop.nl/powerbar-power-bar-power-gel/?channable=e24223.MTE4MjY&variation=240%3D2207%26236%3D4942&gclid=EAIaIQobChMIr6_vv9yT5AIVyOFRCh2yGAqcEAkYCiABEgIoDfD_BwE#240=2207&236=4942
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[30] https://www.bol.com/nl/p/cafeine-tabletten-200-tabletten-perfectbody-nl/9200000103525946/?suggestionType=typedsearch&bltgh=oTVaXDsTIUJqTnt-nLFGeA.1.2.ProductTitle
[31] https://www.bol.com/nl/p/cbd-cafeine-tabletten-voor-alertheid-concentratie/9200000106281042/?suggestionType=typedsearch&bltgh=oTVaXDsTIUJqTnt-nLFGeA.1.4.ProductTitle
[32] https://www.bol.com/nl/p/mutant-core-series-cafeine/9200000077028783/?suggestionType=typedsearch&bltgh=oTVaXDsTIUJqTnt-nLFGeA.1.5.ProductImage
[33] https://www.bol.com/nl/p/qwin-cafeine-90-tabs/9200000049821157/?suggestionType=typedsearch&bltgh=oTVaXDsTIUJqTnt-nLFGeA.1.6.ProductImage
[34] https://www.bodystore.nl/natrol-high-caffeine-200mg.html
[35] https://www.houseofnutrition.nl/product/pre-workout/met-caffeine/superhero/?attribute_pa_product-smaak=mango-lime&gclid=EAIaIQobChMI19b2ppzd5AIVTOh3Ch2_GgzhEAkYASABEgLoIvD_BwE
[36] https://www.firstenergygum.com/nl/shop?gclid=EAIaIQobChMIk--Fk8yt5wIVh-N3Ch2YEAPWEAAYASAAEgLUsfD_BwE
[37] https://wugum.nl/shop/nl/wug-life-night/58-wug-military-150mg-cafeine-per-kauwgom-2-gums.html
[38] https://wugum.nl/shop/nl/wug-health/68-wug-energy-15-gums.html
[39] https://www.wiggle.nl/healthspan-elite-kick-start-caffeine-gum-120-pieces/
[40] https://www.24pharma.nl/6d-sports-nutrition-caffeine-gum-mint-60-kauwgoms.html

3 Caffeine exposure: extent and duration

3.1 Intake of caffeine from food supplement use

Based on the available information on the product labels or in the product descriptions of the food supplements as given in Table 1, a single dose would lead to a caffeine intake varying between 16 and 500 mg. Based on the recommended use, the daily intake of caffeine would vary between 16 and 1000 mg, which was, as a worst case assumption, considered as a potential chronic exposure to caffeine through food supplements.

3.2 Intake of caffeine from the diet (not including supplements)

There are many foods, including beverages, that can constitute the daily intake of caffeine. To assess the expected intake of caffeine from the diet, not including supplements, a chronic dietary intake assessment for the general population was performed using the Monte Carlo Risk Assessment (MCRA) calculation tool (version 8.3; MCRA, 2019). Consumption data of foods containing caffeine were obtained from the Dutch National Food Consumption Survey (DNFCS) 2012-2016 (Van Rossum, 2018). In this DNFCS, persons aged 13 to 79 have reported what food and drinks they have consumed on two non-consecutive days. The age group 13-17 consisted of 577 persons and the adult age group of 18-79 of 2150 persons. Average caffeine values in foods were obtained from EFSA (2015; see Appendix 1).

The chronic exposure to caffeine was calculated using the Observed Individual Means (OIM) model as implemented in MCRA (De Boer et al., 2019). First, the consumed amount of each caffeine containing food item per person-day was multiplied with the average caffeine concentration. Subsequently the intakes per food were summed to obtain the total intake of caffeine per person-day. These daily exposures were averaged across the days per person which resulted in a distribution of mean daily exposures per person (OIMs). These mean daily exposures were calculated per person and per kg bodyweight. This distribution of mean daily exposures was quantified by calculating the median (P50) and 95th percentile (P95) of exposure in accordance with the EFSA opinion of 2015. This distribution of mean exposure per day reflects the chronic exposure.

The mean daily exposures were weighed for age, sex, region, education, level of urbanization, day of the week and season using weighing factors. This ensured that the estimates were representative for the Dutch population and for the entire year. All available days (including days when no foods containing caffeine were consumed) from the DNFCS were included in the exposure assessment. The results are presented in Table 2.

Because the consumption of caffeine containing food supplements by persons younger than 18 years could not be excluded, and the Netherlands Nutrition Centre (Voedingscentrum) allows for a limited consumption of caffeine containing beverages by children aged 13 or

older (Voedingscentrum, 2020), the chronic exposure to caffeine was also calculated for adolescents (aged 13-17 years) using the OIM model. The estimated chronic intake of caffeine for adults amounted to 260 and 636 mg per person per day at the P50 and P95, respectively, corresponding to 3 and 8 mg/kg bw per day (Table 2). For adolescents, corresponding estimated intake levels were 35 and 174 mg (1 and 3 mg/kg bw).

Table 2. Chronic dietary intake of caffeine for adolescents (13-17 years) and adults (18-79 years)

Age-group	**P50**		**P95**	
	Mg/day	**Mg/kg bw per day**	**Mg/day**	**Mg/kg bw per day**
13-17	35	0.6	174	2.9
18-80	260	3.3	636	7.8

3.3 Medicinal intake of caffeine

As described in section 2.2, certain human medicinal products, such as painkillers, also contain caffeine. When these painkillers are simultaneously used according to the prescription (1-2 tablets per dose with a maximum of 6 tablets per day for a prolonged period of time), an additional single and daily dose of caffeine could amount to 50-100 mg (0.7-1.4 mg/kg bw) and 300 mg (4.3 mg/kg bw), respectively (based on a bodyweight of 70 kg). This will not be further discussed in the risk assessment, but is mentioned to show that one should be aware of this additional source of caffeine intake as well.

4 Toxicological data

4.1 Toxicokinetics and toxicological data

For this risk assessment of caffeine, the toxicological reference values (RVs) as derived by EFSA (2015) were used. Below a brief summary of the toxicokinetics and toxicity of caffeine is given based on the EFSA opinion.

Caffeine is readily and completely absorbed after oral intake. It is able to cross the blood-brain barrier and the placenta. Caffeine is mainly metabolized by cytochrome P450 (CYP) 1A2, for which polymorphisms are described indicating that interindividual differences exist. Activity of CYP1A2 accounts for about 95% of the caffeine clearance. Plasma half-life is about 4 hours (range: 2-8 hours). Because during pregnancy CYP1A2 activity diminishes, the plasma half-life of caffeine is three to four times longer at the end of pregnancy leading to higher blood concentrations of caffeine (EFSA, 2015).

EFSA addressed the possible adverse health effects of caffeine for the general healthy population and relevant specific subgroups of the general population (children, adolescents, adults, elderly, pregnant and lactating women and subjects performing physical exercise). Possible interactions of caffeine with other common constituents of energy drinks, alcohol and *p*-synephrine were also addressed.

EFSA focused on the effects for which most concern was expressed in previous risk assessments, and which had been given most attention by literature. For the effects of single doses of caffeine and repeated doses of caffeine within one day, this included adverse effects on the cardiovascular system (e.g. increased blood pressure, decreased myocardial blood flow, and events occurring that are related to cardiovascular disease). Also, effects on body temperature and hydration (diuretic effects) were addressed, along with effects on the central nervous system (such as an increase of sleep latency and decrease of sleep duration, anxiety, perceived exertion during exercise and the potential 'masking' effect of caffeine on alcohol intoxication).

For the chronic effects of habitual intake of caffeine, EFSA focused on the adverse effects for which relationships with caffeine intake had been reported in scientific publications. These included effects on the cardiovascular system (such as changes in myocardial blood flow, blood pressure) related to the development of cardiovascular disease and adverse pregnancy outcomes (e.g. fetal growth retardation, small size for gestational age) in the offspring.

General healthy population
According to EFSA, *single doses* of caffeine up to 200 mg (about 3 mg/kg bw, assuming a bodyweight of 70 kg) from all sources do not give rise to safety concerns for the general healthy adult population even when consumed prior to intense physical exercise. EFSA concluded that changes in myocardial blood flow were the appropriate health

outcome upon which to base this conclusion. Doses up to 200 mg of caffeine were considered unlikely to induce clinically relevant changes in myocardial blood flow. Similarly, EFSA concluded that single doses up to 200 mg are unlikely to induce clinically relevant changes in blood pressure, hydration status or body temperature, or to lead to a reduction of perceived exertion during exercise or mask the subjective perception of alcohol intoxication when alcohol is consumed at doses up to about 0.65 g alcohol/kg bw. Since no studies were available in middle-aged/elderly subjects undertaking intense physical exercise, no conclusion could be drawn on this subgroup.

In addition, EFSA concluded that single doses of 100 mg of caffeine (about 1.4 mg/kg bw, assuming a bodyweight of 70 kg) could increase sleep latency and reduce sleep duration, particularly when consumed close to bedtime.

Habitual caffeine intake from all sources up to 400 mg per day (about 5.7 mg/kg bw, assuming a bodyweight of 70 kg) was considered not to give rise to safety concerns for healthy adults in the general population by EFSA. This was based upon the lack of health concerns expressed by other bodies in previous assessments for this level of habitual caffeine consumption in relation to acute toxicity, bone status, cardiovascular health, cancer risk or male fertility and the fact that no new studies could be identified by EFSA that would justify modification of these conclusions.

Pregnant women
Daily caffeine intakes from all sources up to 200 mg per day by pregnant women do not raise safety concerns for the fetus.
No specific conclusion was drawn on the health effects of single doses of caffeine for pregnant women due to a lack of available studies. Because of the different kinetics of caffeine in pregnant women, EFSA concluded that the level of no safety concern for general non-pregnant adults does not apply to pregnant women performing physical exercise.

Lactating women
No data was available to characterize the risk of single doses of caffeine and habitual caffeine intake for lactating women. However, EFSA concluded that singles doses of caffeine up to 200 mg and habitual caffeine consumption at doses of 200 mg per day by the mother are safe intake levels concerning risks for the breastfed infant.

Children and adolescents
For children and adolescents, no safe level of caffeine intake could be derived due to a lack of available information for these population subgroups. However, EFSA stated that the single dose of caffeine of no concern derived for acute caffeine intake by adults (3 mg/kg bw) may also apply to children based on the fact that children and adolescents have a caffeine clearance at least that of adults. Also, like for adults, caffeine doses of about 1.4 mg/kg bw may increase sleep latency and reduce sleep duration in some children and adolescents.

Concerning habitual intake of caffeine, the levels of no safety concern for adults (5.7 mg/kg bw per day) could apply to children and

adolescents, according to EFSA. However, a more conservative level of no safety concern of 3 mg/kg bw per day was proposed for habitual caffeine consumption by children and adolescents, due to uncertainty on the long-term effects of caffeine in these population subgroups.

An overview of levels not giving rise to safety concerns as derived by EFSA (2015) is given in Table 3. These RVs are used in the risk assessment.

Table 3. Levels of caffeine not giving rise to safety concerns (reference values) for different population groups as derived by EFSA (EFSA, 2015).

	Single intake		**Daily intake**	
	mg/day	**mg/kg bw per day**	**mg/day**	**mg/kg bw per day**
Adults	200[a]/100[b]	3[a]/1.4[b]	400	5.7
Pregnant women [c]	Safe level adults not applicable	Safe level adults not applicable	200	3
Lactating women [d]	200	3	200	3
Children and adolescents	No studies available	No studies available [e]	-	3

[a] the RV of 200 mg per day for adults for general health effects was also considered to apply to for single doses prior to physical exercise. No studies are available in pregnant women or middle aged/elderly subjects undertaking intense physical exercise.
[b] for effects on sleep latency and duration.
[c] concerning risk for the fetus.
[d] concerning risk for breastfed infant.
[e] according to EFSA 3 mg/kg bw per day may apply.

Interactions
EFSA addressed other substances which are likely to occur in 'energy drinks' (such as taurine and D-glucurono-γ-lactone), alcohol and *p*-synephrine since these may modify the possible adverse health effects of caffeine and/or the doses at which such adverse effects may occur. Constituents of energy drinks at typical concentrations and moderate alcohol consumption were not thought to adversely interact with caffeine at a safe single intake level of up to 200 mg or a habitual intake level of up to 400 mg. For *p*-synephrine, no conclusion could be drawn on its possible interaction with caffeine consumption due to a lack of studies (EFSA, 2015).

5 Risk assessment

The main objective of this risk assessment was to assess whether at least one of the requirements, described in Article 8 of the Regulation (EU) 1925/2006 is met for supplements containing caffeine. These requirements included:

- "a potential risk to consumers is associated with the ingestion of amounts of the substance that greatly exceed those reasonably expected under normal conditions of consumption of a balanced and varied diet, due to the conditions under which the substance is added to food or used in the manufacture of food;
- a potential risk to consumers is associated with the consumption of this substance by the general adult population or other specified population group for which a potential risk has been identified."

In the two paragraphs below, both requirements will be discussed for caffeine.

The intake of caffeine resulting from the recommended use of food supplements at one serving is compared to the RV for a single intake of caffeine (RV-SI) of 200 mg, and the daily dose is compared to the reference value for the daily intake of caffeine (RV-DI) of 400 mg per day for adults and 3 mg/kg bw per day for adolescents (see Table 3). In addition, the combined caffeine intake from food supplement use and other dietary sources will be compared to the RV-DI. It is recognized that effects on sleep latency and duration may already occur at a dose of 100 mg; however, these effects are not considered as adverse in the current report.

5.1 Caffeine intake from food supplements

Based on the caffeine content and recommended use of food supplements containing caffeine available on the Dutch market, it was estimated that a single dose could lead to a caffeine intake between 16 and 500 mg (0.2 – 7.2 mg/kg bw for adults of 70 kg and 0.2 – 8.2 mg/kg for adolescents of 61 kg[5]). The daily intake of caffeine would vary between 16 and 1000 mg (0.2 – 14.3 mg/kg bw for adults of 70 kg and 0.2 – 16.4 mg/kg bw per day for adolescents of 61 kg).

For adults, 10 supplements identified in the internet search (see Table 1), led to a caffeine intake exceeding either the RV-SI of 200 mg or the RV-DI of 400 mg when consumed according to recommended use. One of these supplements exceeded both RVs. For adolescents, 20 supplements would result in a daily intake above the RV-DI of 3 mg/kg bw. For more than 25% of the supplements (n=14) the amount of caffeine per single dose and/or the recommended daily dose was not clear, and it was not possible to determine whether the caffeine intake would exceed the respective RV.
A potential risk to consumers is associated with the consumption of part of the food supplements with caffeine available on in Dutch web shops.

[5] Based on average weight of adolescents in DNFCS 2012-2016

Possible adverse effects, including effects on the cardiovascular system, body temperature, hydration and central nervous system cannot be excluded.

5.2 Caffeine intake from food supplements in relation to dietary caffeine intake

The dietary intake estimation for the general adult Dutch population showed that the median chronic intake of caffeine was 260 mg per day and the high intake (P95) was 636 mg per day (Table 2).

Comparing the dietary intake values to the intake from food supplements (see section 5.1) showed that the caffeine intake from food supplements is within the range of the dietary intake or much higher. For an adult consumer with a median intake of caffeine via the diet, the total daily dietary caffeine intake could increase up to 384%, and for high consumers up to 157%. These intakes would exceed the RV-DI of 400 mg per day with a factor of approximately 3 for consumers with a median intake and a factor 4 for high consumers.

For adolescents, the dietary intake estimates were 35 mg per day (0.57 mg/kg bw per day) and 174 mg per day (2.9 mg/kg bw per day) for the median and high (P95) intake, respectively (Table 2). Additional intake via the use of food supplements could increase the total daily dietary intake up to 575% for adolescents with a high intake, and up to 2825% for adolescents with a median intake. In those cases, the RV-DI of 3 mg/kg bw will be exceeded by up to a factor of approximately 6 for adolescents with a high intake and 5 for adolescents with a median intake (assuming a bodyweight of 61 kg based upon data from the DNFCS 2012-2016).

For both Dutch adolescents and adults it can be concluded that 1) the caffeine intake via the use of food supplements with caffeine can greatly exceed the intake via the 'normal' diet and 2) that this may result in intakes that largely exceed the RV for both adolescents and adults with a median and high intake via the diet, and hence adverse effects cannot be excluded.

6 Conclusions and recommendations

The caffeine intake resulting from the use of food supplements available on the Dutch market was assessed to see whether the requirements for a request to include caffeine in Annex III of Regulation (EU) 1925/2006 were met. The assessment shows that the use of these food supplements could result in caffeine intakes that greatly exceed the amount of caffeine ingested from the diet for adults and adolescents, based on Dutch consumption data (DNFCS 2012-2016). In addition, both the single dose intake and the total daily intake of caffeine resulting from only the use of food supplements could already exceed the respective reference values, independent of other dietary intake. Hence, a health risk by consumption of these food supplements cannot be excluded. As such, both requirements for the inclusion in Annex III are met.

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Appendix I

Average concentration levels of caffeine in caffeine containing products, taken from EFSA (2015)

Tabel 1 Caffeine concentrations in food and beverages

Groups	**Subgroups**	**Caffeine concentration used in the intake assessment (mg/L or mg/kg)**
Chocolate	Chocolate bar	111
	Milk chocolate	168
	Chocolate snacks	168
	Cocoa beverage based on cocoa powder	168
	Cocoa beverage based on cocoa-beverage preparation powder	42
	Dark chocolate	525
Coffee	Coffee drink	445
	Cappuccino	273
	Espresso coffee	1340
	Decaffeinated and imitations	21
	Instant coffee, ready to drink	445
Tea	Black tea	220
	Green tea	151
	Tea (unspecified)	165
	Tea, decaffeinated	25
Cola beverages (caffeinated)		108
'Energy drinks'		320

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