

# Guidance for food business operators on food supplements containing caffeine

Guidance and advice for businesses that manufacture, process, distribute or sell food supplements containing caffeine.

## Caffeine in food supplements

Caffeine is a substance that is found naturally in many products such as tea and coffee and it is one of the most widely consumed stimulants worldwide.

Caffeine is commonly added to food supplements, and it is often marketed with physiological effects such as increased focus and performance enhancement. Caffeine is not a vitamin or mineral, but it does fit the definition of a substance with a physiological effect, and it can therefore be used as an ingredient in food supplements.

Caffeine food supplements can often contain high levels of caffeine, sometimes from multiple ingredients which may themselves be a source of caffeine intake (for example kola nuts, guarana, certain tea leaves such as black tea). As caffeine is rapidly absorbed into the bloodstream, stimulatory effects may begin 15 to 30 minutes after ingestion and may last for a number of hours exerting physiological effects or leading to side effects (for example headaches and nausea).

## Forms of food supplements containing caffeine

Caffeine is found in a variety of food supplements, including:

- 100% caffeine powder, which is the most concentrated form of caffeine that can be found on the UK market
- caffeine supplements which contain caffeine and other ingredients and are sold dose in form
- food supplements in which caffeine is not specified in the name of the product but is listed in the ingredients, for example, pre-workout supplements
- food supplements in which caffeine is not listed as an ingredient on the packaging but contains an ingredient with a significant amount of caffeine, for example, guarana

## Recommended caffeine levels to be used in food supplements

Please take account of recommended caffeine levels to be used in food supplements and consider this information when assessing the safety composition of your product. The [European Food Safety Authority \(EFSA\) opinion on caffeine](#) advises that single doses of caffeine up to 200mg and a total daily caffeine consumption of up to 400mg are considered safe for the general healthy adult population, except for pregnant women.

The EFSA opinion notes that single servings of caffeine of 200mg are also of no concern for children and that a safe level of intake of 3mg/kg body weight for habitual consumption for children and adolescents does not pose any safety concerns. This opinion is supported by other safety authorities including the FSA, Canadian Government, and the Norwegian Scientific Committee.

The [National Health Service \(NHS\) Website](#) advises to not consume over 200mg of caffeine a day during pregnancy. The EFSA opinion advises that 'Habitual caffeine consumption up to 200 mg per day by pregnant women does not give rise to safety concerns for the foetus. Single doses of caffeine and habitual caffeine intakes up to 200 mg consumed by lactating women do not give rise to safety concerns for breastfed infants.'

## Side effects of high intake of caffeine

The EFSA opinion advises that for most individuals, caffeine intakes of up to 400mg per day are unlikely to cause adverse effects. However, individuals who are sensitive to caffeine at low doses and/or individuals with underlying health conditions may experience some side effects such as jitteriness, anxiety or difficulty concentrating.

Short term adverse effects of an excessive consumption of caffeine in children and adults include interrupted sleep, anxiety and behavioural changes. Longer term consumption of excess caffeine has been linked to cardiovascular issues i.e. effects on the heart and blood vessels.

High exposure of caffeine is associated with increased tension, nervousness, anxiety, irritability, nausea, pins and needles sensation, tremor, - sweating, palpitations (racing irregular heartbeat), restlessness and possibly dizziness. These effects may be more severe in individuals who are caffeine sensitive and/or have underlying health issues such as heart disease or high blood pressure, and effects may occur at lower doses.

Excessive caffeine consumption is associated with a number of serious adverse effects such as rapid heart rate, abnormal heart rhythms and seizures, which have been observed at intakes of approximately 1.2 grams (1,200 mg) of caffeine. Excessive consumption of caffeine during pregnancy has been associated with an increased risk of stunted foetus development.

Caffeine intakes of above 10-14 grams (10,000 mg – 14,000 mg) have been reported to be fatal, although smaller doses can also be life-threatening to sensitive populations. These cases have occurred where pure caffeine has been measured incorrectly.

## Legislation and registration requirements

In the UK, food supplements are required to be regulated as foods and are subject to the provisions of food law. Food law is a comprehensive, wide catalogue of legal requirements that a Food Business Operator (FBO) must comply with. There are [specific requirements](#) for food supplements in addition to the General Food Law Regulation (EC) No 178/2002 and to other legislation that may also be applicable. In Northern Ireland, food supplements are regulated by [EU legislation](#) as well as domestic legislation.

Food supplements themselves do not require a licence or government approval to be sold in the UK. However, anyone producing, importing, or selling food supplements must [register as a Food Business Operator](#) with their local authority and ensure that they are adhering to food safety laws. Compliance with these laws will be checked at food safety inspections and it is the responsibility of the Food Business Operators selling these products to ensure compliance.

Further information regarding food supplements and what you need to do as a business to sell them can be found on the Food Standard Agency's Food supplements webpage as well as on the Department of Health and Social Care's [Food supplement use and labels webpage](#). If your business is based in Scotland, you can find information on starting a business on the Food Standards Scotland's [Guidance on starting a new food business webpage](#).

In the UK, there is no maximum legal limit for caffeine when used within food supplements.

There are, however, maximum permitted limits for caffeine set in legislation when used as a flavouring in certain foods or drinks found in [assimilated Regulation \(EC\) No 1334/2008](#). There are also specific labelling requirements for food and drink containing caffeine which can be found in Annex III of [Regulation \(EU\) No 1169/2011 on the Provision of Food Information to Consumers](#) in Northern Ireland as well as Annex III of the [assimilated Regulation \(EU\) No.1169/2011](#) in GB. Further information regarding labelling requirements for products containing caffeine can be found on [Food labelling: giving food information to consumers](#).

Important

It is your responsibility to ensure food supplements you sell are safe for human consumption. It is an offence under the Food Safety Act 1990 to render food injurious to health.

Under the Food Safety Act 1990 food which fails to comply with food safety requirements may be seized and destroyed, at the expense of the food business operator.

The factors which determine whether food is "unsafe" or "injurious to health" are set out in article 14 of Regulation (EC) 178/2002.

## Nutrition and Health claims

A nutrition claim is a claim that states, suggests or implies that a food has beneficial nutritional properties, such as "low fat" or "high in fibre". A health claim is any claim which states suggests or implies that health benefits can result from consuming a given food, such as "helps build strong bones", "maintains healthy cholesterol levels". There are currently no approved nutrition or health claims for caffeine in the [Great Britain Nutrition and Health Claims Register](#) and the [EU Register of Health Claims](#), which is applicable in Northern Ireland. There are however, 'on hold claims' which may continue to be used until a decision is made regarding their approval. Further guidance on nutrition and health claims made on foods is available on the Department of Health and Social Care [Guidance on nutrition and health claims on foods webpage](#).

Voluntary nutrition or health claims must comply with the requirements of assimilated European Regulation (EC) No 1924/2006 on nutrition and health claims made on food.

## Advice for Food Business Operators

**Ensure you comply with regulatory standards** to protect consumers and maintain the reputation of your business. Failure to comply with applicable legislation can lead to legal repercussions and damage to your brand's reputation. For further details on relevant legislation, please refer to the section 'Legislation and Registration Requirements'.

**Ensure that the caffeine used in your products is from reputable suppliers** who are registered as a business with their local authority and provide fully referenced invoices and receipts.

**Ensure you provide accurate information about the amount and composition of ingredients in your product.** It is unlawful to provide inaccurate information, such as advertising lower or higher caffeine levels than are actually present. This will mislead consumers and, in cases of under reporting caffeine levels, increases the risk of adverse effects due to overconsumption.

**Ensure you display the correct warning statement.** Food supplements containing in a proportion in excess of 150 mg/l of caffeine, which is added for a physiological purpose, are legally required to display a specific warning on their labels to ensure consumer safety. The label must clearly state "**Contains caffeine. Not recommended for children or pregnant women**" in the same field of vision as the name of the food supplement, followed by a reference in brackets to the caffeine content per portion as recommended for daily consumption. This requirement aims to inform consumers about the potential risks associated with caffeine consumption, and protect vulnerable groups such as children and pregnant women.

**Provide clear dosage guidance:** Caffeine food supplements must declare the caffeine content per portion/serving as recommended for daily consumption. Ambiguity or lack of clarity in dosage instructions may result in consumers misusing your products, leading to adverse health effects or dissatisfaction. Clearly communicate recommended serving sizes and precautions not to exceed the recommended number of servings to minimise the risks.

**Make sure you comply with legal labelling requirements:** Ensure the caffeine dose stated on the label is accurate. EFSA's 2015 opinion recommends 'single doses of no more than 200mg per a single serving or over a total of 400mg a day'. Doses containing a higher recommended daily consumption level higher than 400 mg may lead to negative side effects.

**Ensure accuracy of provided measuring devices:** If you sell a powdered or liquid form of a supplement, make measuring dosages accessible and accurate to consumers by providing a measuring device such as a scoop. Inaccurate or unreliable measuring devices included with your supplements can compromise consumer safety and satisfaction. Conduct regular quality control checks to verify the precision of measuring instruments and provide adequate training for staff responsible for packaging to minimize errors.

**Share information online responsibly:** While online platforms (i.e. websites, commercial apps, social media etc), can be valuable for marketing and customer engagement, disseminating inaccurate or misleading information about your products can damage trust and credibility. Ensure that any information shared online is accurate, transparent, and compliant with regulations to maintain consumer confidence.

**Encourage consumer engagement with healthcare professionals:** Promote responsible usage of your supplements by advising consumers to seek guidance from healthcare professionals before starting any new dietary regimen. Emphasise the importance of informed decision-making and the potential risks associated with improper usage.

## Reporting a Food Safety Incident

If you believe a food supplement containing caffeine which has been supplied is either harmful to health, unfit for people to eat or does not meet legal requirements, you should report the issue to your Local Authority, Primary Authority or District Council. The Local Authority, Primary Authority or District Council will [report a food safety incident to the Food Standards Agency](#) in England, Wales or Northern Ireland.

If you are located in Scotland, they will [report a food safety incident to Food Standards Scotland](#).