

Health risks of excessive energy shot intake

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So-called energy shots are a new kind of energy drinks that contain caffeine and taurine. In advertisements, these are claimed to increase concentration and capacity or physical performance. They are marketed in smaller portions (25-75 ml) than the more common energy drinks yet contain a higher concentration of caffeine and in some cases taurine per litre than energy drinks. The compositions of energy shots known to BfR vary significantly and contain between 50-200 mg caffeine and 200-1000 mg taurine per portion. In contrast to energy drinks, these energy shots are labelled with the manufacturer's suggested intake levels. All of those known to BfR thus far uniformly recommend one portion per day.

In BfR's opinion, energy shots that contain the constituents listed above pose no health risk if consumed in accordance with the manufacturer's intended use, i.e. one portion per day, and other product labels.

Health risks can result if the suggested intake level is exceeded considerably. This could mean that the constituents (caffeine and taurine) are consumed in considerably higher amounts and/or over a shorter time span than before with ordinary energy drinks. Yet the potential extent should be estimated differently due to varying amounts of caffeine and taurine in individual energy shots. Excessive doses of caffeine can lead to risks associated with known potential adverse effects. It remains to be clarified whether the interaction of caffeine with other constituents in energy drinks (e.g. taurine) or with ethanol in the alcoholic beverages consumed alongside energy shots or with physical exertion (e.g. extended, physically strenuous dancing or sports activities) could amplify the adverse effects of caffeine. An actual causal relationship between these factors has not yet been scientifically demonstrated. The extent of potential health risks depends on the intake amounts (caffeine and taurine) and the manner of intake (e.g. once, rapid intake over a short period of time, high amounts distributed over several single doses), on individual consumer sensitivity to the effects of caffeine, the usual amount of caffeine consumed daily, the amount of caffeine consumed through other sources of caffeine as well as potential parallel factors such as alcohol intake or strenuous physical/sports activity.

According to BfR, there is a risk that energy shots are not used in accordance with the manufacturer's advice for intended use. The Institute assumes that energy shots are sometimes consumed in place of energy drinks and thus consumed – like these – at the discretion of the consumer without quantitative limit. It should also be noted that consumers in night clubs may choose to increase their energy shot intake in an attempt to counteract fatigue or to reach a state of arousal. Since physical exertion also increases thirst, there is a risk that the suggested intake levels of energy shots are not adhered to.

According to BfR, the desire to improve performance produces a risk of excessive energy shot intake. As consumers can be expected to disregard the advice for intended use, thus taking in high doses of caffeine which could result in adverse effects, the Institute deems energy shots unsafe. BfR estimates that such expected consumer behaviour cannot be prevented by the manufacturer's advice for intended use.

1 Subject of the assessment

In Germany, so-called "energy shots" are to be marketed or are currently marketed as dietary supplements. Energy shots are similar to energy drinks in composition and appearance. En-

ergy drinks are non-alcoholic beverages that contain high amounts of caffeine and taurine and sometimes glucuronolactone and inositol. However, the concentration of caffeine and taurine in energy shots far exceeds the amounts allowed in energy drinks. The Federal Ministry of Food, Agriculture and Consumer Protection (BMELV) has asked the Federal Institute for Risk Assessment (BfR) to issue an opinion on the consumer health risk of these products.

At the time of the assessment, seven energy shots are known to BfR. Five of these products are labelled as dietary supplements. One product is labelled *a dietetic dietary supplement for intense muscular exertion, especially for athletes*. One other product is also intended for athletes.

The caffeine concentration in these products is 1.3-6 g/L, the taurine concentration is 4-20 g/L and portion volumes are 25-75 ml. Present information indicates that all products carry the manufacturer's advice for intended use, which uniformly state one portion per day. If used accordingly, caffeine intake is 50-200 mg/day and taurine intake is 200-1000 mg/day depending on each product. In six of the products, the caffeine concentration is provided exclusively by caffeine, in one product it is provided exclusively by guarana extract. Some of the products contain added inositol (up to 50 mg/portion) and two products have added glucuronolactone (70 mg/portion), while one product contains no information on the amounts added.

With the exception of one product, the labels indicate increased caffeine concentration and one product (200 mg caffeine/portion) carries the notice "high caffeine concentration". Five products also carry (warning) labels stating that they are not suitable for children, pregnant women and caffeine-sensitive individuals, and in some cases additional groups (breast-feeding mothers, diabetics) are named. One product (200 mg caffeine/portion) is labelled unsuitable for individuals with high blood pressure and cardiovascular disease in addition to children and pregnant and breast-feeding women.

2 Results

The compositions of energy shots assessed here vary significantly (caffeine concentrations 1.3-6 g/L, taurine concentrations 4-20 g/L). With respect to the manufacturer's advice for intended use (1 portion/day), caffeine intake ranges from 50-200 mg and taurine intake ranges from 200-1000 mg/day.

Consumer health can be at risk if the intake of the energy shots in question considerably exceeds the amount indicated on the label. In this case, the constituents (caffeine and taurine) may be consumed in much higher doses and/or over shorter periods of time than those of energy drinks have been, and the potential extent differs due to the varying caffeine and taurine concentrations of individual energy shots. Potential adverse effects commonly associated with excess caffeine intake can thus lead to risks. Furthermore, it is suspected that the interaction of caffeine with other constituents in energy drinks (e.g. taurine) or with ethanol in the alcoholic beverages consumed together with energy shots or with physical exertion (e.g. extended, physically strenuous dancing) or sports activities could amplify the adverse effects of caffeine. The extent of potential health risks depends on the intake amounts as well as the time span in which these occur (boluses, rapid intake over a time span, distribution of high intake amounts over several single doses and several hours), on individual consumer sensitivity to the effects of caffeine, the usual amount of caffeine consumed daily, the amount of caffeine consumed through other sources as well as potential parallel factors such as alcohol intake or strenuous physical/sports activity.

According to BfR, there is a risk that energy shots are not used in accordance with the manufacturer's advice for intended use. As consumers can be expected to disregard the suggested intake levels, thus taking in high doses of caffeine which could result in adverse effects, the Institute deems energy shots unsafe in terms of Article 14(1) of Regulation (EC) No 178/2002¹. BfR estimates that in the case of "energy shot" products such expected consumer behaviour cannot be prevented by the manufacturer's advice for intended use on the label. BfR therefore recommends that "energy shot" products are prohibited from being placed on the market.

3 Reasons

The following points are important for the health assessment of these products:

3.1 Caffeine

Due to its pharmacological effect, caffeine is on the one hand used for medical purposes (to temporarily counteract symptoms of fatigue; BGA, 1988; pharmaceutical product information of a caffeine monopreparation, 2008). On the other hand, the use of caffeine in the production of common stimulant beverages (e.g. cola, coffee and tea) is widely accepted. However, BfR is critical of the use of caffeine in foods consumed in the form of concentrates and not consumed in the context of common foods (e.g. in the form of stimulant beverages). This form of caffeine intake does not allow consumers to anticipate their potency based on taste as traditional stimulant beverages do.

3.1.1 Hazard potential

Caffeine stimulates the central nervous system and can affect the vegetative nervous system depending on dose. The effect of caffeine and its metabolites on these organ systems occurs through different mechanisms such as the inhibition of adenosine receptors which is especially essential for a psycho-stimulating, centrally stimulating effect, and other mechanisms including the inhibition of phosphodiesterase, increased calcium mobilisation and the antagonistic effect on benzodiazepine receptors (IOM, 2008).

The psycho-stimulating effect on the central nervous system is the main desired effect of caffeine, for which a customary single dose of 50-100 mg up to 200 mg is used (Martindale, 2009).

Acute adverse effects resulting from caffeine intake depend on individual sensitivity and the extent of the daily intake of caffeine-containing beverages. Long-term consumption of caffeine, especially in medium and higher doses, can lead to the development of a tolerance to most of its effects and side effects (BGA, 1988; pharmaceutical product information of a caffeine monopreparation, 2008). However, it is known that chronic high caffeine intake can also lead to adverse effects (Medsafe Editorial Team, 1999; Greden, 1974; Myerson et al., 2002).

The adverse effects of caffeine in adults include nervousness, irritability, insomnia, nausea, headache, tremor, increased anxiety, perceptual disturbances, diuresis, arrhythmia, tachycardia, increased respiration rate and gastrointestinal disturbances (Nawrot et al., 2003; Wechsler, 2005). Individual cases of serious poisoning with worse symptoms, such as confusional states after high intake amounts have been reported, though the tablets that were

¹ Regulation (EC) No 178/2002 of the European Parliament and of the Council laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety

taken also contained high amounts of ammonium chloride (Shaul et al., 1984). A similar case, in which caffeine in the gram range had been consumed during two previous days, reports a “grand mal” seizure and increased serum creatine kinase levels in connection with physical exercise (FitzSimmons and Kidner, 1998). Fatal cases after high caffeine intake have also been reported (e.g. Dimaio and Garriott, 1974; Alstott, 1973).

The following information is available on the use of caffeine as pharmaceutical product:

- For the indication “to temporarily counteract symptoms of fatigue”, single doses of 100 to 200 mg caffeine are used, which can be repeated if necessary, but not more than twice within 24 hours (BGA, 1988; pharmaceutical product information of a caffeine monopreparation, 2008).
- With regard to “side effects”, the information states that the appearance of side effects depends on the above named factors and that even low doses (this probably refers to 100 mg) can cause tachycardia, insomnia, apprehension and gastrointestinal disturbances, while doses over 200 mg can cause irritability, headaches and intensified physiological muscle tremors even in individuals with low sensitivity (pharmaceutical product information of a caffeine monopreparation, 2008).
- In section “special warnings and special precautions for use” patients with hyperthyroidism (may increase) and patients with cirrhosis of the liver (caffeine may accumulate) are advised to take caffeine at a low dosage (about 100 mg) and only under medical supervision (pharmaceutical product information of a caffeine monopreparation, 2008).
- “Overdosing” contains the information that symptoms of poisoning can occur at 1g caffeine and more if the amount is taken in a short time span. It also states that fatal doses of caffeine range from 3 g² and 10 g (pharmaceutical product information of a caffeine monopreparation, 2008).

However, individual data and specifications on the use of caffeine as a pharmaceutical product from the information cited above (BGA, 1988; pharmaceutical product information of a caffeine monopreparation, 2008) are not available to BfR.

Available research publications provide examples of adverse effects ranging from nausea and mild tremors to increased anxiety, nervousness, drowsiness and headaches. These symptoms occur in single doses ranging from 5 mg/kg body weight (BW) (equivalent to 300 mg at 60 kg BW) to 700 mg caffeine or when 3 x 300 mg caffeine/day is administered (Bender et al., 1997; Bonati et al., 1982; Evans and Griffiths, 1992; Kaplan et al., 1997; Charney et al., 1984; Mattila et al., 1988). As a result of the study design (sometimes coffee was eliminated before begin of the study), the validity of cited examples is limited.

The list of documents indicates that adverse effects of caffeine were observed after higher caffeine boluses. Yet these do not represent a systematic literature evaluation concerning the symptoms of acute adverse caffeine effects or thereby relevant doses. Published, systematic evaluations on this research question are not available to BfR at present. Furthermore, pharmacovigilance surveillance data of pharmaceutical products relevant to this are not publicly available. In addition, available data on acute adverse effects of caffeine administered in several single doses over a period of several hours are insufficient to derive a dose-response relationship.

The potential risks of specific groups (e.g. individuals with cardiovascular diseases or epilepsy) are referred to in Chapter 3.3.

² It is unclear whether this dose should apply to adults or children.

In reference to the potential risk group of diabetics, it must be noted that in type II diabetes, the intake of 250 mg and 375 mg caffeine in conjunction with a subsequent meal led to an adverse increase of postprandial hyperglycaemia and postprandial release of insulin (Lane et al., 2004; 2007). On the other hand, in type I diabetes, the awareness of signs of hypoglycaemia was observed to have improved after the intake of 250 mg caffeine (Debrah et al., 1996).

With regard to children, the Scientific Committee on Food (SCF, 1999) has determined that several studies show that the intake of 5 mg caffeine/kg BW increases arousal, irritability, nervousness and anxiety in several children, especially if they usually only consume low amounts of caffeine. SCF concluded that for children who usually do not consume much tea or coffee, the intake of 160 mg caffeine/day in a ten-year-old child weighing 30 kg, equivalent to a dose of 5.3 mg caffeine/kg body weight/day, can cause temporary side effects such as irritability, nervousness or anxiety (SCF, 1999).

Regarding the special risks of pregnant women, the British Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment (COT, 2008) has evaluated the intake of caffeine during pregnancy on the basis of a recent epidemiological study and the evaluation of published research studies. The Committee concluded that caffeine intake during pregnancy is associated with an increased risk of reduced foetal growth. The Committee assumed a causal relationship, yet this could not be substantiated definitively. COT was unable to identify a threshold dose, below which there would be no increased risk. However, it is probable that intake levels around 200 mg caffeine per day or even less are related to increased risk. Existing research literature indicates that caffeine intake and the occurrence of miscarriages are related, though uncertainties in this regard have not been dispelled (COT, 2008). As a result, the British Food Standards Agency recommended that pregnant women should limit their caffeine intake to less than 200 mg/day (FSA, 2008).

Concerning breastfed babies, the biological half-life of caffeine in infants during their first months is 65-100 h and considerably higher than that of adults. Caffeine passes into the mother's milk. While the infant is still breastfed, its condition and behaviour can be impaired by caffeine taken in along with breast milk (BGA, 1988; pharmaceutical product information of a caffeine monopreparation, 2008). Pharmaceutical recommendations state that if the use of caffeine is extended or higher doses are taken, the baby should be weaned.

3.1.2 Exposure

In compliance with the manufacturer's advice for intended use of these products, the daily intake of caffeine is between 50-200 mg.

The caffeine concentration in normal portions of coffee varies depending on preparation, portion size and coffee variety. In Germany, one cup of coffee (up to 125 ml) contains between 50-130 mg caffeine (400-1000 mg/L) (Unknown, 2008). For commonly available larger coffee cups (about 200 ml) this would result in caffeine intake between 80-200 mg caffeine/portion. In Great Britain, mean values of 105 mg caffeine were determined for portions of coffee, while these ranged extremely between 15-254 mg (FSA, 2004).

3.2 Taurine

The Panel on Food Additives and Nutrient Sources added to Food of the European Food Safety Agency (EFSA) has evaluated the use of taurine as constituent in energy drinks. EFSA concluded that the daily intake of up to 1400 mg taurine/day is no cause for health

concern. A NOAEL (no observed adverse effect level) for rats of at least 1000 mg/kg BW/day was assumed in this regard. The EFSA Panel evaluated taurine as single substance, but did not take interactions between caffeine and taurine into account, aside from diuretic effects that were considered improbable. The Panel did not evaluate the safety of energy drinks as such (EFSA, 2009).

In compliance with the manufacturer's advice for intended use of these products, the daily intake of taurine is between 200-1000 mg.

3.3 Combined intake of large amounts of caffeine and taurine in conjunction with the simultaneous intake of alcohol and/or sports activity

In evaluating the health risks of energy drinks or products that have large amounts of caffeine and taurine added, it is important to consider the effects of potential interactions. The adverse effects of caffeine (cardiovascular system, central nervous system, reproductive toxicity) could be amplified when these constituents interact with other energy drink constituents (e.g. taurine) or ethanol in the alcoholic beverages consumed together with energy shots. Furthermore, these effects could also be amplified if energy shots are consumed in conjunction with physical exertion or sports activities. In this respect, certain potential risk groups such as consumers with cardiovascular disease, epileptics, pregnant women and children must be examined separately. As depicted in BfR Opinion "New human data for the assessment of energy drinks" (BfR, 2008), current data are not sufficient for a comprehensive evaluation of potential health risks. The additional (warning) labels and recommendations for certain groups of consumers recommended in this Opinion remain relevant.

While the literature on this subject reports cardiovascular or other effects and complications, even unexplained deaths, after the increased intake of energy drinks usually in conjunction with sports activity, physical exertion and/or alcohol intake, causal relationships remain uncertain (e.g. SCF, 2003; Stimulant Drinks Committee, 2003; Lehtihet, 2006; BfR, 2008). This lack of a definitive causal relationship is the basis of ambiguities pertaining to the risk assessment of energy drinks described above.

The following depicts a short exemplary compilation of such reports, including reports in reference to potential risk groups listed above as well as a compilation of several clinical studies.

3.3.1 Case studies

- Case of a 23-year-old man in Greece in 2001 who suffered from a myocardial infarction after playing football while consuming energy drinks (SCF, 2003). A causal relationship is uncertain.
- Case of an 18-year-old man who presumably consumed up to 3 cans of an energy drink during a basketball tournament in Ireland and suddenly died, presumably as a result of cardiac arrhythmia (Stimulant Drinks Committee, 2003). A causal relationship is uncertain.
- Case of a 19-year-old woman who consumed about 6 drinks in one evening, which contained an energy drink (caffeine concentration 320 mg/L, taurine concentration 4 g/L) and vodka. Around 7 p.m., she consumed a meal. After midnight, she had not consumed any more food or drink and was not very intoxicated. She was found dead in her bed the following morning. The forensic medical examination revealed a blood

alcohol level of 0.87. A definitive cause of death could not be determined (Lehtihet et al., 2006; BfR, 2008).

- Case of a 31-year-old woman in 2001 who consumed drinks containing vodka and energy drinks (caffeine concentration 320 mg/L, taurine concentration 4g/L) over the course of a dance event. She collapsed during a dance and died in hospital. The forensic medical examination merely revealed a slight deposit of connective tissue in the cardiac muscle and a slight fatty liver. A definitive cause of death could not be determined (Lehtihet et al., 2006; BfR, 2008).
- Case of an 18-year-old man who consumed several cans of an energy drink (caffeine concentration 320 mg/L, taurine concentration 4 g/L) a day “in order to remain concentrated” and collapsed dead while watching television. The blood ethanol level in his thigh was 0.59, in his urine 0.80. The forensic medical examination revealed a moderate isolated deposit of connective tissue in the cardiac muscle. A definitive cause of death could not be determined (Lehtihet et al., 2006; BfR, 2008).
- Case of a 31-year-old football referee who practiced football on a regular basis. One week after participating in a 3000 m match, before which he had consumed three cans of an energy drink (caffeine concentration 320 mg/L, taurine concentration 4 g/L), he was diagnosed with rhabdomyolysis and acute kidney failure with tubular necrosis of uncertain cause (Lehtihet et al., 2006; BfR, 2008).
- Case of a 28-year-old motocross race driver who suffered from cardiac arrest during a motocross racing tournament, but survived following treatment. He had consumed 7-8 cans of an energy drink (caffeine concentration 80 mg/can) within 7 hours. The cause of the incident could not be determined. The authors presume that the excessive intake of energy drinks and strenuous physical activity could trigger potentially fatal myocardial ischaemia in predisposed individuals (Berger and Alford, 2009).
- In January and February 2008, BfR enquired at the Federal Office of Consumer Protection and Food Safety (BVL) and the German poison information centres (GIZs) on reports concerning health detriments following the intake of energy drinks. BVL had no such reports since 2005. 6 of the total 9 GIZs of the Federal Republic of Germany had information according to which a total of 91 reports (double-counting possible) of adverse effects following the intake of energy drinks emerged between 2001 and 2007 (partly shorter recording periods of individual GIZs). These effects were sometimes observed to occur following very high intake amounts of energy drinks and/or in combination with the consumption of alcoholic beverages, pharmaceutical products or drugs. Due to the recapitulating portrayal of events which lack critical details, a causal relationship can not be derived. This also applies to the death of a young adult who died before the emergency physician arrived, after he had consumed unknown amounts of energy drinks with vodka at a party. The symptoms that have been described include stomach aches, high blood pressure, tachycardia (accelerated heart rate), ventricular fibrillation, impaired vision, convulsions and myoclonus (muscle spasms).
- The sudden death of a young woman possibly related to the intake of a product referred to as “energy blast” that contained guarana and ginseng. The woman suffered from a mitral valve prolapse. The caffeine concentration of the beverage was 10 g/L; the portion size was 55 ml equivalent to a caffeine intake of 550 mg/portion (Cannon et al., 2001). The authors state that the woman received a bottle of the product and

nearly emptied it, while the Australian Adverse Drug Reactions Advisory Committee states that the intake amount is unknown (ADRAC, 2000). No additional information on product composition and ingredients that could be relevant is available. The reports state that in general the young woman did not consume great amounts of coffee. The effect of caffeine was regarded as a likely factor to have contributed to her death (ADRAC, 2000).

- Two cases of tachycardia (in one case associated with orthostatic intolerance) that were observed in connection with the consumption of energy drinks, i.e. of a beverage referred to as “speed shots”, which contained additional plant extracts besides caffeine (Nagajothi et al., 2009; Terlizzi et al., 2008) (see also EFSA evaluation below of Iyadurai and Chung, 2007).
- Case of an adult who consumed up to eight cups of espresso and an additional 6 cans of an energy drink (caffeine concentration 320 mg/L, taurine concentration 4 g/L) per day (estimated total intake of 1.3 g caffeine/day) over the course of several months and developed arrhythmia with atrial fibrillation (Myerson et al., 2002). It is known that chronic high intake levels of caffeine can induce arrhythmia (Greden, 1974).
- Iyadurai and Chung (2007) describe four patients who experienced generalised cerebral convulsions following the intake of energy drinks in high doses but not in low doses without the reported simultaneous intake of alcohol. For example, a healthy 25-year-old man twice experienced generalised cerebral convulsions with a four-month interval after consuming energy drinks in a fasted state. He had neither suffered from such a symptom previously, nor did it recur after a six-month abstinence from energy drinks. At his last exposure, he had consumed 1420 ml (2 x 24 ounces) of an energy drink 30 to 60 minutes prior to the convulsions. Two other patients who experienced convulsions after energy drink intake, generally suffered from migraine headaches, and in one case the energy drink was consumed in a fasted state, in the other case it was accompanied by the intake of pills that contained large amounts of caffeine. A fourth patient, who suffered convulsions for the fourth time, was cited to state that he only experienced convulsions after consuming more than 1420 ml of an energy drink. The authors state that none of the patients had additional convulsions after abstaining from energy drinks and previously only had convulsions after the intake of higher amounts. Neurological clarifications provided no indications for other causes. The caffeine and taurine levels in the energy drinks are not known. The products contained additional plant extracts such as guarana, ginseng, ginkgo or milk thistle. In its Scientific Opinion on taurine and glucuronolactone, EFSA (2009) stated the possibility that these effects as well as those described by Nagajothi et al. and Terlizzi et al. (see above) could be due to the known side effects of caffeine, and that there is no scientific evidence to suggest a causal relationship with the intake of taurine. On the other hand, the Panel stated that interactions between caffeine and taurine, aside from diuretic effects, have not been studied. It is known that high doses of caffeine can induce convulsions and lower the limit of the occurrence of convulsions in epilepsy patients.

3.3.2 Human study

Furthermore, though due to their design and small number of participants they can only serve as orientation, findings from human studies indicate possible cardiovascular risks that could become relevant in conjunction with physical exertion:

- 10 participants (aged 19-30 years) 30 minutes prior to maximum physical stress on a bicycle ergometer received a) nothing to drink, b) 750 ml of an energy drink (240 mg caffeine, 3000 mg taurine), c) 750 ml of an energy drink plus 0.4 g alcohol/kg BW and d) 750 ml of an energy drink without subsequent physical stress. In conclusion, the comparison of group c) with group a) revealed delayed pulse rate recovery after physical stress. A lowered heart rate variability (HRV) is regarded to indicate a reduced balance of the autonomic nervous system and is correlated with an increased risk of arrhythmia, which in turn is considered to increase the risk of sudden cardiac death. Furthermore, low-grade electrocardiogram (ECG) changes in groups b) and c) were registered before the stress test. One participant developed temporary premature atrial systole after energy drink intake, but not after simultaneous alcohol intake. The authors state that no clinically significant arrhythmia was observed. They do however hypothesise that under similar conditions (intake of energy drinks with alcohol in conjunction with physical exertion) individuals who are predisposed for arrhythmia could have an increased risk of arrhythmia (Wiklund et al., 2009).
- In an exploratory study Steinke et al. (2009) examined the cardiovascular effects of energy drinks in 15 healthy participants (average age 26 years) with low blood pressure at physical rest. After an initial examination during which blood pressure and heart rate were taken and an ECG was determined, each participant consumed 500 ml of an energy drink (2 cans), which contained a total of 160 mg caffeine and 200 mg taurine, within 30 minutes. The examinations were repeated after 30 minutes, one, two, three and four hours. Over the next five days, each participant consumed 500 ml/day, and on the seventh day, the procedure of the first day was repeated. On both days, four hours after the energy drink had been consumed, a raised mean systolic blood pressure by 9-10 mm Hg and an increased heart rate by 5-7 beats per minute were determined. Habituation after several days of intake was not observed. Over the course of the study, seven participants reported adverse effects such as "flightiness", gastrointestinal symptoms, urinary urgency or insomnia, though it should be noted that the participants usually only consumed low doses of caffeine and the study did not include a control group. Until further findings are available, Steinke et al. urged patients with cardiovascular diseases to abstain from energy drink consumption.

3.4 Risk characterisation

The energy shots available are of very heterogeneous composition. Their caffeine concentration varies between 50-200 mg/portion and their taurine concentration is between 200-1000 mg/portion.

3.4.1 Use in accordance with the requirements

If a use in accordance with the suggested intake levels is presupposed, products could pragmatically be divided into the following two groups (see 3.4.1.1 and 3.4.1.2).

3.4.1.1 Products with a caffeine concentration that clearly exceeds the concentration of previously regular 250 ml portion energy drinks (150-200 mg caffeine/portion, taurine concentration up to 1000 mg/portion) (category A energy shot)

The following points are essential with regard to these products:

- Pregnant women are advised to consume not more than 200 mg caffeine/day. Products that contain 150 mg caffeine/portion also constitute a very high intake level in this context. BfR recommends that such products are labelled as unsuitable for pregnant women.
- Since infants could be affected negatively by caffeine intake along with breast milk, BfR recommends that such products are labelled as unsuitable for breast-feeding mothers.
- With portions of 150 mg children (10 years old, 30 kg BW; SCF, 1999) reach intake levels of 5 mg caffeine/kg BW. These have been connected with the temporary appearance of arousal, irritability, nervousness and anxiety in several children (SCF, 1999). These products should therefore be labelled as unsuitable for children.
- In light of the information presented in Chapter 3.3, BfR recommends that the aforementioned products are labelled as unsuitable for caffeine-sensitive individuals until clarifying studies are available. It should be noted that patients with arrhythmia or mental illnesses, possibly also individuals with heart diseases other than arrhythmia should be considered to belong to the group of caffeine-sensitive individuals. They should therefore be considered as a risk group that potentially reacts very sensitively to the effects of energy drinks.
- BfR recommends that product labels contain adequate notices concerning the increased caffeine concentration and actual caffeine concentration per portion of these products.
- Since these products might also be consumed in combination with regular energy drinks, BfR recommends that the notice recommended for energy drinks “*if larger amounts of such drinks (i.e. energy drinks and energy shots) are consumed in conjunction with extensive sports activity or the intake of alcoholic beverages, adverse effects can not be excluded*” is adequately adopted.

3.4.1.2 Products with a caffeine and/or taurine concentration that is in the range of previously regular 250 ml portions of energy drinks (caffeine concentration rounded to 100 mg/portion; taurine concentration up to 1000 mg/portion) (category B energy shots)

If they are used in accordance with the manufacturer’s advice for intended use, this category of energy shots raises no health concerns in light of the fact that the caffeine and taurine intake levels correspond to those of regular energy drink portions, energy drinks are lawfully marketed and these products are ordinarily consumed as desired. However, the products are significant sources of caffeine. BfR recommends that a label indicates the increased caffeine concentration per portion of these products.

Since these products are also sometimes consumed in combination with regular energy drinks, BfR recommends a second label in addition to the above mentioned notice informing that “*in particular larger amounts of such drinks (i.e. energy drinks and energy shots) are not recommended for children, pregnant and breastfeeding women and caffeine-sensitive individuals*”.

3.4.2 Predictable use not in accordance with the requirements

Furthermore, health risks can result if the energy shots under consideration are not consumed in accordance with the manufacturer’s advice for intended use and considerably exceed suggested intake levels. It appears realistic that some consumers do not consume energy shots in accordance with the manufacturer’s advice, but in part as a substitute for energy drinks and – like these – consume energy shots at personal discretion without quantitative limit. This occurs in part because of the fact that energy drinks and their constituents are

advertised positively but also because consumers cannot judge the potency of this form of caffeine intake through its taste as it is possible for the traditional stimulant beverages coffee and tea.

As a result of the concentrated form with considerably higher caffeine concentrations (1.36-6 g/L in contrast to 0.32 g/L) and sometimes taurine concentrations (4-20 g/L in contrast to 4 g/L), a volume effect contributing to naturally constrained consumption of energy drinks and their constituents does not apply to energy shots. This facilitates the intake of higher amounts of caffeine and taurine over a shorter time span than by use of former energy drinks. However, the potential extent must be estimated variably due to different caffeine and taurine concentrations in the energy shots mentioned. The health risks resulting from such intake behaviour have not been adequately researched and there are considerable information gaps. Health risks depend on the intake amounts as well as the time span in which these occur (boluses, rapid intake over a short period of time, distribution of high intake amounts over several single doses and several hours), on individual consumer sensitivity to the effects of caffeine, the usual amount of caffeine consumed daily, the amount of caffeine consumed through other sources of caffeine as well as potential parallel factors such as alcohol intake or strenuous physical/sports activity.

If the suggested intake levels of energy shots are exceeded considerably, the excessive caffeine intake amounts can lead to health risks. However, at present, health risks related to intake amounts cannot be accurately determined especially in regard to the distribution over several single doses over an extended period during a day, particularly because consumer-specific factors mentioned above are also relevant. Furthermore, though the circumstances are uncertain, it is suspected that the adverse effects of caffeine (cardiovascular and central nervous system) could be amplified through the interaction with other energy drink constituents (e.g. taurine) or ethanol in the alcoholic beverages consumed together with energy shots. Furthermore, these effects could also be amplified if energy shots are consumed in conjunction with physical exertion or sports activities. In this respect, certain potential risk groups such as consumers with cardiovascular disease and epileptics must be examined separately. This possibility and the existing information gaps would become more relevant in products that can lead to higher caffeine and taurine intake amounts than the consumption of energy drinks already entails, if the suggested intake levels are exceeded considerably.

It should also be noted that consumers in night clubs may choose to increase their energy shot intake in an attempt to counteract fatigue after prolonged nightly outings or to deliberately trigger a state of arousal. Since physical exertion also increases thirst, there is a risk that the manufacturer's advice for intended use of the liquid energy shots is not adhered to. BfR is therefore of the opinion that it is likely that consumers will not always adhere to a use in accordance with the manufacturer's advice for intended use.

Sufficient data for the risk assessment of consumers with specific pathologies such as cardiovascular diseases, epilepsy and possibly diabetes are not available. The BfR opinion that individuals with high blood pressure and cardiovascular diseases are recommended to restrain their consumption of energy drinks, also applies to caffeine and taurine intake through energy shots.

For health risks of pregnant and breast-feeding women and children, refer to Chapter 3.4.1.1.

3.4 Overall assessment and measures

According to the opinion of BfR it is likely that consumers will not always adhere to a use in accordance with the manufacturer's advice. In light of these circumstances and potentially high caffeine intake levels resulting from considerably exceeded intakes with potentially adverse effects, BfR assesses the above mentioned "energy shot" products as unsafe in terms of Article 14(1) of Regulation (EC) No 178/2002. In the case of "energy shot" products, such consumer behaviour (considerably excessive intake) cannot be avoided by manufacturer's advice for intended use. BfR thus recommends that "energy shots" are prohibited from being placed on the market.

4 References

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