Superior Health Council

ADVISORY REPORT OF THE SUPERIOR HEALTH COUNCIL No. 8689

"The use of caffeine in foodstuffs"

12 January 2012

1. INTRODUCTION AND REQUEST

Following an advisory report issued by the Superior Health Council (SHC) on energy drinks (SHC 8622, 2009), the Council received a request for advice from the FPS Public Health, Food Chain Safety and Environment regarding the use of caffeine in foodstuffs, including food supplements and soft drinks (letter of 9 September 2010).

Amongst other things, the request aims at finalising regulatory provisions regarding the presence of caffeine in food supplements (both liquid and solid) by adapting the Ministerial Decree of 19 February 2009 regarding the manufacture and marketing of food supplements that contain substances other than nutrients and plants or plant preparations.

More particularly, the Council's advice is requested on the following issues:

1. "assessment of the intake of caffeine through food other than food supplements (e.g. via coffee, tea, cola beverages and energy drinks) by the general population as well as specific population groups such as children, teenagers and young adults;"
2. "description of the adverse effects and risks attendant upon the ingestion of caffeine (ratio dose ingested/response);"
3. "the tolerable Upper intake level (UL), if necessary depending on the different sensitivities of various population groups"
4. " the current margins between levels of exposure and tolerable upper intake level (UL)"
5. "assessment of the risks to the general population and specific population groups linked to the ingestion of caffeine through food supplements (liquid or solid) when
   (a) these food supplements are taken instead of the "habitual" foodstuffs, such as e.g. energy drinks and
   (b) these food supplements are taken in addition to the "habitual" foodstuffs, for food supplements with a caffeine content of 50, 60, 70, 80, etc. mg of caffeine per serving or recommended daily quantity;"
6. "assessment of the risks to the general population and specific population groups linked to the ingestion of caffeine through other foodstuffs such as chewing gum (or others mentioned in the CRIOC study in the appendix), when
   (a) these other foodstuffs are taken instead of the "habitual" foodstuffs and/or food supplements and
   (b) these other foodstuffs are taken in addition to the "habitual" foodstuffs and/or food supplements"
7. "assessment of the current limit that authorises flavoured non-alcoholic beverages to contain 320 mg of caffeine per litre, more precisely the need to maintain this limit, modify it or abolish it;"
8. "assessment of the impact on the risks to the general population and to specific population groups of the following potential measures:

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(a) setting conditions or limits on the use of caffeine-containing products;
(b) setting the upper caffeine content in, amongst others, the foodstuffs mentioned above;
(c) determining the mandatory warnings on the labels of these products."

In addition, the inquirer draws the Council's attention to several provisions that it might want to take into account whilst drawing up its advisory report. The most important are the following:

1. the "energy shots" (which contain the same active substances as energy drinks, but within a smaller liquid volume) meet with the definition of food supplements, which sheds doubt on the applicability of the 320 mg/l legal limit for caffeine in flavoured non-alcoholic beverages. Moreover, some of these energy shots are legally marketed in other EU Member States as food supplements;"
2. "all specific national regulations shall be motivated by the need to protect consumer health and shall therefore be underpinned scientifically by a risk analysis in keeping with current legislation (General food law);"
3. "as regards food supplements, European case law does not allow for specific substances to be simply prohibited if the consumer can be warned about the potential hazards they entail through ad hoc labelling;"
4. "the caffeine content can only be limited on the basis of a scientific risk analysis, which, amongst other things, takes into account
   - the tolerable Upper intake level (UL) set on the basis of generally accepted scientific data, considering the different sensitivities of various population groups;
   - the intake through other food sources."

Observation regarding the terminology used:
The inquirer uses the notion "tolerable Upper intake level" (UL). According to a generally accepted definition, this concerns the highest daily nutrient intake level that entails no risk of adverse health effects for most individuals in the general population. It should be pointed out that this terminology is not necessarily used as such in some of the works that have been taken into account to draw up this advisory report. As a result, and so as to avoid any false generalisations, the terminologies used in these publications are mentioned as such in this report.

In order to respond to these questions, the permanent NHFS (Nutrition and Health, including Food Safety) working group was tasked with this dossier.

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2. CONCLUSIONS AND RECOMMENDATIONS

First of all, the Superior Health Council (SHC) finds that the data on the intake of caffeine by different population groups in Belgium are somewhat scarce. The most recent can be found in the 2004 food consumption survey, on the basis of which the average intake of caffeine by Belgian adults (men or women) can be assessed to range between approximately 2.2 and 2.3 mg/kg/day, with significant individual variation. For an average body weight of 70 kg, this amounts to a daily intake of 150 to 160 mg of caffeine by adults. Recent observations indicate that these values are now considerably underestimated, especially due to the increased consumption of energy drinks in the last decade, and, more recently, energy shots. There are no age distribution data available for this increased consumption.

As regards the description of the risks and adverse effects linked to the use of caffeine, the SHC finds that the data from the extensive review by Nawrot et al. (2003) still constitute a reference base. They indicate that there is a great deal of evidence that shows that a moderate intake of caffeine of 400 mg/day in adults is not linked to any adverse effects such as general toxicity, cardiovascular effects, altered behaviour, increased incidence of cancer or effects on male fertility. The same holds for the bone status and/or the calcium balance, provided that the calcium intake is sufficient.
However, women of childbearing age (who wish to become or are pregnant) constitute an at-risk group in which the intake of caffeine should not exceed 300 mg/day. The same is true for children (especially preadolescents), who are liable to suffer from behavioural effects (including anxiety) and in whom the development of the nervous system could be altered. It follows that the intake of caffeine should not exceed the upper limit of 2.5 mg/kg/day.
Finally, there are a number of more recent reports that tend to reduce these values to 200, or even 100 mg/day for pregnant women.

As regards a potential upper safety limit for caffeine exposure, the SHC considers that the following values, taken from the literature (Nawrot et al., 2003), are appropriate:

- For healthy adults, most authors indicate that a moderate exposure to caffeine of 5.7 mg/kg/day (400 mg/day for a 70 kg adult) is not linked to any adverse effects such as general toxicity, cardiovascular effects, altered behaviour, increased incidence of cancer and effects on male fertility. Still, the SHC is aware of the fact that in some publications, this value is set at 3 mg/kg/day (210 mg/day for 70 kg males), which is the limit above which increased anxiety can be observed.
- For children, including preadolescents, the upper intake level is 2.5 mg/kg/day, which is looked upon as the limit above which altered behaviour is liable to appear, including anxiety as well as a potentially altered development of the nervous system.
- For women of childbearing age, it is advised that the maximum daily intake should not exceed 300 mg/day, or even 200 mg/day.

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These limit values and the caffeine intake estimated on the basis of the 2004 Belgian consumption data have made it possible to calculate how many male and female caffeine consumers exceed the maximum daily intake of 3 and 5.7 mg/kg/day. It turns out that:

- for around one quarter of the adult Belgian population (aged between 19 and 74), the daily intake exceeds the 3 mg/kg threshold beyond which there is an observable increase in anxiety. Conversely, only a very small fraction of the same population (less than 5%) exceeds the maximum daily intake of 5.7 mg/kg/day.
- the caffeine consumption of teenagers aged between 15 and 18 poses but very few problems.

These same data have also made it possible to assess how many caffeine consumers exceed the maximum daily intake by ingesting randomly fixed additional quantities of caffeine. It turns out that for a maximum daily intake set at 3 mg/kg/day, an additional intake of 60 to 80 mg/day causes the proportion of individuals whose exposure is above the upper value to almost double and that this concerns up to 50% and over of the population (between 36 and 56% of adult men or women). Such an intake can be reached by consuming a single energy drink unit. The New Zealand Food Safety Authority, which has made a similar but more detailed assessment, draws conclusions that are along the same lines. According to this assessment, around 70% of children, 40% of teenagers and 60% of young adults who consume caffeine exceed the 3 mg/kg/day limit by consuming a single energy drink unit or energy shot unit.

The SHC was requested to express an opinion on the appropriateness of the current limit that authorises flavoured non-alcoholic beverages to contain 320 mg of caffeine per litre, and, more precisely, on the need to maintain this limit, modify it or abolish it. The SHC finds that this limit is too high in terms of consumer health protection. The SHC advises to lower this limit to 150 mg/l (European regulations regarding product labelling), which would be a reasonable precautionary measure (article 7.1 of EU Regulation 178/2002). Such a limit also applies to energy drinks.

The SHC recommends that the amount of caffeine provided by any solid or liquid caffeine-containing **food supplement** (including the energy shots) or **any other product to which caffeine has been added** should be limited to 80 mg per daily serving.

Moreover, the labels of these products should carry a warning aimed at limiting the number of units consumed on a daily basis, e. g. “do not consume more than X units/day” (X to be defined according to the 80 mg/day limit value).

Finally, if the recommended daily serving reaches the 80 mg caffeine limit, the label should mention that the product: “is not suitable for children, pregnant and lactating women and individuals sensitive to caffeine”.

More generally, the SHC takes the view that sufficiently recent food consumption data are essential to carry out scientific risk assessments. The last national food consumption survey was conducted in 2004. The SHC therefore advises that this survey be repeated on a regular basis and that it should not only concern the adult population, but also children and teenagers.

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3. FURTHER DETAILS AND ARGUMENTATION

List of abbreviations used

CRIOC:	*Centre de Recherche et d'Information des Organisations de Consommateurs*
EFSA:	European Food Safety Authority
EU:	European Union
FPS:	Federal Public Service
FSA:	British Food Standards Agency
LOAEL:	Lowest Adverse Effect Level
NOAEL:	No Observed Adverse Effect Level
RPE:	Ratings of Perceived Exertion
SCF:	Scientific Committee on Food
SHC:	Superior Health Council
UL:	tolerable Upper intake Level
WIV-ISP	*Institut Scientifique de Santé Publique* (Scientific Institute for Public Health)

3.1. Methodology

This advisory report is based on expert reports and on advisory reports from public health authorities, as well as on scientific articles from the international literature and experimental research reports, which were selected by means of databanks for bibliographic research.

3.2. Further details

The different questions will be discussed separately.

3.2.1. Assessment of the intake of caffeine through food other than food supplements (e.g. via coffee, tea, cola beverages and energy drinks) by the general population as well as specific population groups such as children, teenagers and young adults.

As is the case in other countries, the intake of caffeine in Belgium is mainly due to the consumption of coffee, tea, cocoa and food that contains these ingredients. Caffeine can also be added to a whole series of beverages, including energy drinks, energy shots (same active substances as energy drinks, but within a smaller volume), soft drinks such as cola beverages, and alcoholic beverages. The intake of caffeine through these latter sources should not be neglected, especially since it has increased significantly these past few years as a result of aggressive marketing. It should be pointed out from the start that the data on the intake of caffeine in Belgium are scarce.

The most recent can be found in the results of the **food consumption survey conducted in 2004** by the FPS Public Health and the Belgian Scientific Institute for Public Health (WIV-ISP). An analysis of the results carried out in co-operation with the WIV-ISP made it possible to draw up the following table, based on the hypotheses and calculations found in appendix 1 of this report. The first part of the table contains the data on men, whereas the second focuses on women.

Table 1: Dietary baseline exposure estimate for caffeine (mg/kg/day) in 2004 for various population groups in Belgium (Appendix 1)

Consumption per age group among men (mg/kg/day)				
	Aged 15-18	Aged 19-59	Aged 60-74	Aged >74
Mean	1.2	2.2	1.9	1.8
Standard deviation	0.8	1.3	1.4	1.2
P95	2.7	4.5	4.7	4.1
P97.5	3.1	5.2	5.5	4.8

Consumption per age group among women (mg/kg/day)				
	Aged 15-18	Aged 19-59	Aged 60-74	Aged >74
Mean	0.9	2.3	2.2	1.8
Standard deviation	0.7	1.8	1.4	1.2
P95	2.1	5.8	4.8	4.0
P97.5	2.3	7.2	5.5	4.6

We can therefore conclude that in 2004, **the average intake of caffeine among Belgian adults (men or women) was estimated to be close to 2.2 to 2.3 mg/kg/day**, with significant individual variation. For an average body weight of 70 kg, these data amount to a daily intake of **150 to 160 mg of caffeine by adults**.

With the data from other countries available, a comparison can be made. In this respect, a very comprehensive report was recently published by the New Zealand Food Safety Authority. The latter provides a risk profile that addresses the potential risk of consuming caffeine from energy drinks and energy shots. It was drawn up by the Institute of Environmental Science and Research Limited, ESR (New Zealand Food Safety Authority, 2010b) and compiles a whole series of data on caffeine as well as original research that makes it possible to assess the risk linked to the intake of caffeine. Amongst other things, it mentions the baseline exposure to caffeine calculated for seven population groups based on two food consumption surveys which, unfortunately, are rather old, one having been conducted in 1997 (for adults) and the other in 2002 (children). The table below contains the baseline exposures to caffeine for different age groups assessed on the basis of the consumption of caffeine-containing foodstuffs (tea, coffee, chocolate, cola beverages). As these food consumption surveys are relatively old (1997 and 2002), they only provide an imperfect picture of the current situation.

Table 2: Dietary baseline exposure estimates for caffeine (mg/day) for various New Zealand population groups (*New Zealand Food Safety Authority*, 2010b).

	Children 5-12 yrs	**Teenagers 13-19 yrs**	**Young males 19-24 yrs**	**Adults 20-64 yrs ***	**Older people 65+ yrs**	**Females 16-44 yrs***	**Females 16-44 yrs pregnant**
Mean	20	82	277	236	156	226	125
Median	7	41	148	180	140	149	57
Min	<1	<1	<1	<1	<1	<1	<1
Max	644	2664	2220	3785	1998	3256	795
P5	1	1	1	22	33	8	0
P95	74	294	1080	666	354	623	479

P5=5th percentile and P95=95th percentiles, representing low and high consumers respectively.
* excluding pregnant women

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These same baseline consumption values can be expressed in terms of mg/kg/day (frequently used format), except for pregnant women.

Table 3: Dietary baseline exposure estimates for caffeine (mg/kg/day) for various New Zealand population groups (*New Zealand Food Safety Authority*, 2010b).

	Children 5-12 yrs	**Teenagers 13-19 yrs**	**Young males 19-24 yrs**	**Adults 20-64 yrs ***	**Older people 65+ yrs**	**Females 16-44 yrs***	**Females 16-44 yrs pregnant**
Mean	0.6	1.2	3.5	3.5	2.3	3.4	NA
P95	2.0	4.5	14.4	9.1	5.3	9.6	NA

NA=not available because of changing weight during pregnancy.
P95=95th percentile and represents a high consumer.
* excluding pregnant women

The report also compiles the different exposures to caffeine in a series of other countries. A table in the appendix to the report provides a significant number of figures, the most important of which are mentioned below (references in: *New Zealand Food Safety Authority*, 2010b). The average caffeine consumption in the United States and Canada varies from 0.4 to 1 mg/kg/day for children, and 1.8 to 3 mg/kg/day for adults. In Argentina, the average intake is around 1 mg/kg/day for children, 3 mg/kg/day for teenagers and up to 5 mg/kg/day for adults, with high consumers possibly ingesting up to 13 mg/kg/day. The average consumption of caffeine in Brazil is 2.7 mg/kg/day for population groups aged between 10 and 60. In Denmark, the average intake for children and older teenagers (aged 15-19) is 0.6 and 2.1 mg/kg/day, respectively. On average, Danish adults consume around 8 mg/kg/day, with high consumers reaching up to 18 mg/kg /day. According to estimates from the United Kingdom in 1988, children and teenagers consume 2 mg/kg/day and adults about 4.5 mg/kg /day, with high consumers reaching up to 8 mg/kg/day.

As regards the contribution of the different foodstuffs consumed in New Zealand to the overall intake of caffeine, a more detailed analysis shows that for children (aged 5 to 12) and younger teenagers (aged 13 to 15) , the intake of caffeine was mostly from tea and cola beverages, with coffee contributing to a lesser extent. For older teenagers (aged 15 to 19) and all adults, the main contributor was coffee, followed by tea. The following table mentions the contributions of the different foodstuffs to the overall intake of caffeine.

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Table 4: Percentage contributions of caffeine-containing foods to caffeine dietary exposure for various New Zealand population groups (*New Zealand Food Safety Authority*, 2010b).

Food	Children 5-12 yrs	Teenagers 13-15 yrs	Teenagers 15-19 yrs	Young males 19-24 yrs	Adults 20-64 yrs*	Older people 65+ yrs	Females 16-44 yrs*	Females 16-44 yrs pregnant
Biscuits, cakes, pastries	11	6	1	<1	<1	<1	<1	1
Cereal	<1	<1	<1	<1	<1	<1	<1	<1
Choc desserts	1	<1	<1	<1	<1	<1	<1	<1
Chocolate confectionary	6	4	1	<1	<1	<1	<1	1
Cocoa & choc drinks	7	4	1	1	<1	<1		<1
Coffee	**10**	**23**	**73**	**83**	**75**	**61**	**76**	**57**
Energy drinks	2	3	<1	1	<1	<1	<1	<1
Soft drinks	**30**	**32**	**13**	**10**	3	0	3	2
Tea	**32**	**29**	**10**	5	**20**	**38**	**19**	**39**

Those food groups contributing 10 or more percent to total caffeine exposure are bolded.
* excluding pregnant women

A recent report shows that around 75% of US children (Nebraska) consume caffeine. Amongst these children, 5-7 year-olds consume an average 52 mg/day, whereas 8-12 year-olds are exposed to an average 109 mg/day (Warzak et al., 2010). The authors find that this report fills a 10 year-old gap as regards exposure data for a fairly young population. They also express surprise about the fact that these values are rather high, in contrast to the Canadian recommendations according to which, under ideal circumstances, the intake of caffeine should not exceed 62 and 85 mg/day, respectively, for these two age groups.

Another recent report assesses the risk linked to the intake of caffeine among children and teenagers in the Nordic countries, i.e. in Denmark, Finland, Iceland, Norway and Sweden (Meltzer et al., 2008). For all of these countries, the report mentions an average intake of caffeine via soft drinks (cola) between 0.3 and 0.5 mg/kg/day for children aged 4 to 6. As regards teenagers, the consumption varies significantly from one country to another, ranging between 0.3 and 0.6 mg/kg/day up to 1.3 mg/kg/day. Some teenagers are exposed to over 3 mg/kg/day, through soft drinks alone. This report adds that this consumption does not take into account the intake via coffee or chocolate. Moreover, these data are based on food consumption surveys conducted between 2000 and 2002. As the authors point out, they only provide an imperfect picture of the current intakes, especially since the latter appear to have increased considerably since the appearance of energy drinks. Among the data found in this report, the following figures show the evolution of the soft drink (cola) consumption in the Nordic countries and compare this consumption with that in various other countries, including Belgium. Please note that the source of these data is not mentioned.

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Figure 1: Evolution of the soft drink consumption in the Nordic countries (Meltzer et al., 2008)

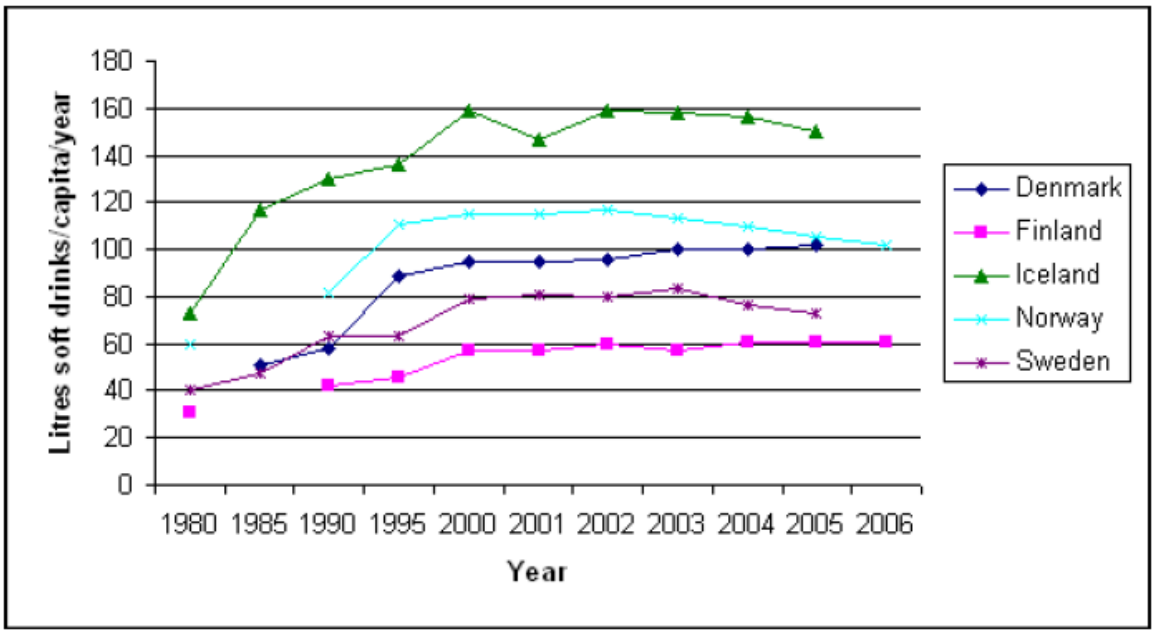
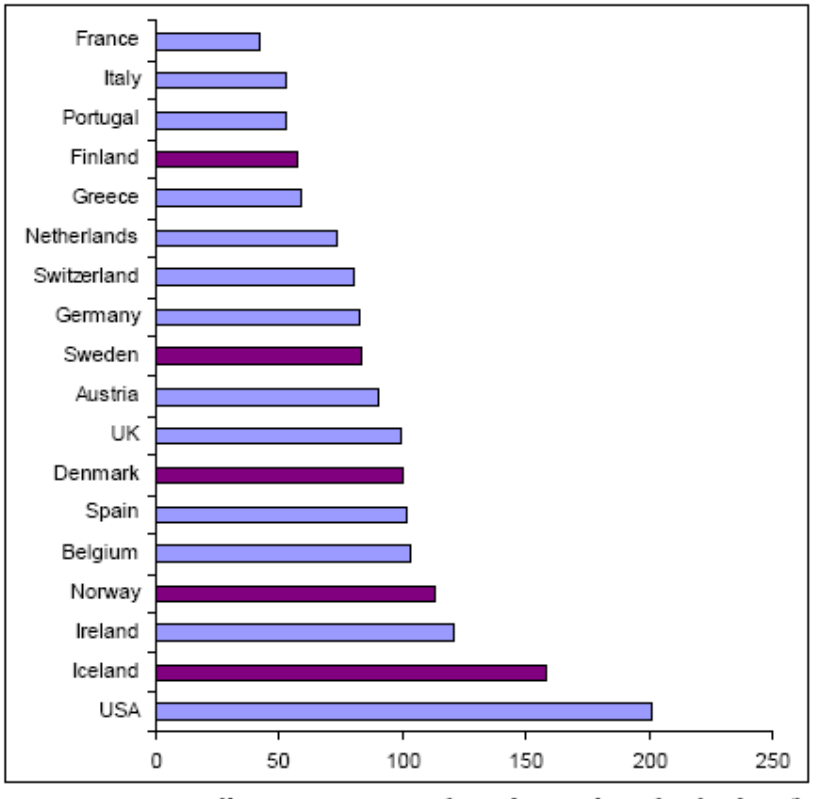


Figure 2: Overall soft drink consumption (litres/capita/year) in various countries (Meltzer et al., 2008)



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Aside from foodstuffs that naturally contain caffeine as well as the traditional cola beverages, the population can also consume beverages or food supplements that contain this substance, such as energy drinks and energy shots, which can then be major contributors to the intake of caffeine. As regards Belgium, the FPS Public Health has provided a non-exhaustive list with the different preparations of the energy shot-type that are commercially available under the status of food supplement and are found on the Belgian market as a result of the free movement of goods in the EU. The following table provides the data on the energy shots:

Table 5: Description of the energy shots available on the Belgian market (non-exhaustive list)

Company	**Name**	**Presentation**	**Caffeine content per unit**
Coca Cola	Burn Energy Shot	50 ml bottle	80 mg
Red Bull	Red Bull Energy Shot	60 ml bottle	80 mg
Supergroup	Fluelcell Tropical Twist Fluelcell wild berries Flavour	60 ml bottle	100 mg
Monster	Monster Energy Shot	90 ml bottle	140 mg
Pietercill	Quick Energy (orange)	59 ml bottle	175 mg

Moreover, the following preparations are said to be available in this country as potential sources of caffeine:

- "Lemonades", very often presented as 25 or 33 cl cans;
- Chewing gums, 3 tablets of which are believed to amount to 80 mg of caffeine;
- Effervescent tablets, which, as they are intended to be dissolved in water, should not provide over 320 mg of caffeine per litre (see lemonades);
- Syrups, which should also provide no more than 320 mg/l caffeine after having been thinned down with water.

A report from the *Centre de recherche et d'information des organisations de consommateurs* (CRIOC, 2010), which was also made available to the SHC, provides some additional information, the most important of which can be found below. Some of this information forms the basis of that provided by the Administration:

- Among the energy drinks commercially available in Belgium are those belonging to the following brands: Red Bull, Atomic, Nalu, Burn, Rodeo, Monster, Virus, Boosted, Hell, Taurine Force and Energy. They usually contain 320 mg/l caffeine. The most frequently found types of packaging are 250 ml cans (80 mg of caffeine), but 500 ml cans are also said to be available (160 mg of caffeine). There are wide discrepancies as regards the information that is potentially provided on the labels as regards the maximum quantities that should be consumed: if any, the advice given ranges from 2 to as much as 4 cans a day.
- The chewing gums called "Black Rhino" contain caffeine and 3 of these tablets provide the same amount of caffeine as one energy drink can.
- There are also "energy" pills available in pubs, night clubs and parties, which are labelled as food supplements. Some are available in devices that look like chewing gum dispensers. There are also caffeine-containing effervescent tablets available (presented in metal cases similar to those used for pain medicine), as well as syrups intended to be thinned down, and powders.

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More recently, the attention of the SHC was drawn to tablet dispensers found in the lavatories of a large Belgian university. By inserting money into these dispensers, it is possible to obtain tablets of the brand XK1, which are labelled as “food supplements with vitamins and minerals” and contain 50 mg of caffeine per dose unit.

The issue of energy drinks (80 mg caffeine/unit) has been discussed in detail in a recent report of the SHC (SHC 8622, 2009). In this report, the SHC regretted having no concrete data on these beverages at its disposal, especially as far as their consumption in Belgium is concerned. This gap has been partially filled since. Indeed, a recent note (with limited circulation) from the EFSA - *European Food Safety Authority*, 2010) reviewed the potential emergent risk from an increased consumption of caffeine and other ingredients in energy drinks, especially for children and young adults. This note emphasises the fact that the consumption data in various countries are relatively scarce (they are said to be available for Austria and Ireland only). Still, it reports on the data collected by "*Euromonitor International* “ (EFSA, 2010), which concern the consumption of energy drinks in all European countries from 1997 to 2009. In Belgium, this consumption, expressed in million litres of energy drinks per year, rose from 2.4 in 1997 to 19.3 in 2009. This would amount to saying that every Belgian (all age groups) drinks around 2 litres of energy drinks each year. These figures are anything but precise, but they do provide a clear picture of the significant increase in the consumption of these beverages within just a few years.

3.2.2. Description of the adverse effects and risks attendant upon the ingestion of caffeine (ratio dose ingested/response).

Preliminary observation regarding the effects of caffeine: caffeine is an alkaloid of the methylxanthine family, and is naturally found in many plants or plant preparations such as coffee, tea, cocoa, cola, guarana, maté, etc. Its great popularity is linked to its stimulating effects on the central nervous system. Taken in the form of common beverages such as coffee, tea and certain soft drinks, it reduces drowsiness and enhances alertness, which accounts for its great popularity. As a result, caffeine has become the most widely used psychoactive substance worldwide, whilst remaining perfectly legal. The amount of caffeine contained in one serving of coffee ranges between 40 and 150 mg depending on the nature and origin of the coffee and the manner in which it is prepared; it lies between 30 and 50 mg for a serving of tea, is close to 35 mg for soft drinks and ranges between 10 and 30 mg for a bar of chocolate. Still, due to its high consumption, not only in the form of common beverages or foodstuffs, but also as energy drinks or energy shots (80 mg per serving), medicines or various food supplements (see above), scientists' attention has been drawn to its potential adverse effects on human health when it is consumed in excessive amounts or by specific population groups. Many studies have therefore been published on this subject, including on its mode of action and on the mechanisms of its potential toxicity. Discussing these studies in detail would go beyond the scope of this advisory report, but they can easily be found in the scientific literature, including in many of the references in this report.

Published a few years ago, the **report from Nawrot et al.** (2003) provides an excellent overview of the knowledge gleaned until then and still valid today on the effects of caffeine on human health. Generally speaking, these authors point out that there is a broad consensus that daily intakes of caffeine doses over 500-600 mg (4 to 7 cups of coffee or 7 to 9 cups of tea) entail a significant health risk and can therefore be regarded as “abuse”. “Caffeinism” (sustained abuse of caffeine) can result in a whole series of symptoms such as restlessness, anxiety, irritability, agitation, muscle tremor, insomnia, headache, increased diuresis, sensory disturbances (e.g. tinnitus), cardiovascular symptoms (e.g. tachycardia, arrhythmia) and gastrointestinal complaints (e.g. nausea, vomiting, diarrhoea). Excessive caffeine intake (>400 mg/day) increases the risk of unstable bladder development in women. For those with pre-existing bladder instability, even a moderate caffeine intake (200–400 mg/day) may increase this risk.

From a more specific point of view and as regards the cardiovascular effects, a moderate intake of caffeine (4 cups or less/day or ≤ 400 mg caffeine/day) does not appear to have a significant effect on cardiovascular health. Conversely, an increased risk has been observed at intakes of five or more cups of coffee per day (≥ 500 mg caffeine/day). As regards bone health, the results of the studies suggest that caffeine intakes of < 400 mg/day do not significantly affect the bone status and calcium balance, provided that the individuals concerned ingest at least 800 mg calcium per day. If this is not the case, caffeine may adversely affect bone development. A higher daily caffeine intake (> 400 mg/day) may affect bone density, especially in women, and increase the risk of fracture, especially if the calcium intake is low (low milk consumption). As regards the effects on mood and performance in adults, the evidence for the potential beneficial effects (alertness and vigilance, memory, mood) is rather contradictory and concerns acute consumptions. Moderate chronic consumption of caffeine in adults has not been associated with any major adverse effects on mood or performance, but caution is advised for individuals suffering from anxiety. There is insufficient evidence to show that long-term caffeine use may result in the development of caffeine dependence.
However, caffeine cessation induces withdrawal symptoms (headaches, tiredness, etc) which may last for up to a week. The intensity of these symptoms may be dose-dependent and may even occur at low doses (100 to 300 mg/day), but the results of these studies are inconsistent. A small number of studies have been devoted to children, and, once again, their results are somewhat inconsistent. This research is especially concerned with caffeinated beverages of the soft-drink type. Anxiogenic effects have been reported, but they are difficult to interpret. In this age group, however, it does seem important to take into account the immaturity of the nervous system, which is still developing in children. As regards any carcinogenic effects, it appears that caffeine intakes below 500 mg/day have been found to be safe. There is no reliable evidence that there are any links between the consumption of coffee and cancer of the urinary tract and pancreas. Concerning the effects on reproduction and development, and thus on conception and pregnancy, it is generally acknowledged that caffeine intakes over 300 mg/day are liable to reduce fecundability in fertile women, increase the risk of spontaneous abortion and impair foetal growth (lower birth weight and intrauterine growth retardation). The latter effects are particularly significant in women who smoke or consume alcohol. Intakes over 400 mg/day can result in reduced motility and viability of the spermatozoa, without, however, affecting overall male fertility. Finally, a moderate intake of caffeine (≤ 300 mg/day) by pregnant or lactating women does not appear to adversely affect post-natal development.

In the conclusion to their extensive review, Nawrot et al. (2003) point out that there is a great deal of evidence that shows that a moderate intake of caffeine of **400 mg/day** in **adults** is not linked to any adverse effects such as general toxicity, cardiovascular effects, altered behaviour, increased incidence of cancer or effects on male fertility. The same holds for the bone status and/or calcium balance, provided that the calcium intake is sufficient. However, the results show that **women of childbearing age** (who wish to become or are pregnant) constitute an at-risk group in which the intake of caffeine **should not exceed 300 mg/day**. The same holds for **children** (especially preadolescents) who are liable to suffer from behavioural disorders (including anxiety) and in whom the development of the nervous system could be altered. It follows that these authors take the view that it is advisable that the **intake of caffeine should not exceed 2.5 mg/kg/day**. This amounts to e.g. a daily intake of 50 mg/20 kg, 75 mg/30 kg, 100 mg/40 kg or 125 mg/50 kg. The data on teenagers are too scarce to fix a level that should not be exceeded.

Amongst the **other data of interest** or more recent data on the risks linked to caffeine exposure, the following publications are worth mentioning:

A recent report from the Committee on Toxicity, an independent scientific advisory organism, provides another review of the situation as regards the potential toxicity of caffeine in pregnant women and states, with a great deal of caution, that it is likely that caffeine affects foetal development even with daily intakes of 200 mg (*Committee on Toxicity of Chemicals in Food*, COT, 2008). At such levels, the effects could be observable in no more than 2% of children. They

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are believed to include low birth weight and spontaneous abortion. Yet in its previous report (2001), this upper intake level was believed to be 300 mg/day, which was identical to the intake level previously mentioned in the Nawrot report. Following this report, the *British Food Standards Agency* has recommended that pregnant women should limit their caffeine intake to less than 200 mg/day (FSA, 2008). The authors of the CARE study (*CARE study group*, 2008) have recently reported on an increased risk of intrauterine growth retardation in mothers consuming between 200 and 299 mg of caffeine per day. They acknowledge that it is difficult to set an upper level above which the risk is significantly higher, but observe that the risk is lowest in women whose caffeine intake is below 100 mg/day. As a result, they advise pregnant women to stop drinking coffee altogether, or to drink considerably less.

The report from the New Zealand Food Safety Authority mentioned above (2010b) seeks to clarify the situation as regards the dose-response effects of caffeine. The data are not fundamentally different from those in Nawrot et al., 2003. These are the main points:

Fatalities are usually associated with ingestion of caffeine in excess of 5 g, although recovery after ingestion of 30 g has been reported (Nawrot et al., 2003; Kerrigan and Lindsey, 2005).
Caffeinism, or caffeine intoxication, may occur with doses greater than 250 mg and can result in symptoms of anxiety (restlessness, nervousness, facial flushing) and diuresis (increased urine production). In a comprehensive review Nawrot et al. (2003) concluded that for the healthy adult population, moderate daily caffeine intake at a dose up to 400 mg/day was not associated with adverse effects such as general toxicity, cardiovascular effects, effects on bone status and calcium balance (so long as enough calcium is consumed) behavioural changes, cancer and male fertility. The implication is that habitual daily use of more than 500-600 mg (four to seven cups of coffee or seven to nine cups of tea) is a health risk for healthy adults. However, clinical data concerning health effects of persistent, high caffeine intakes is lacking.

Increased anxiety levels in children (8-12 years) at doses of 2,5 mg/kg bw/day and at 3 mg/kg bw/day in 70 kg adults have been reported in a limited number of studies (Bernstein et al., 1994; Nickell and Uhde, 1994).

Positive mood effects, such as feelings of increased energy, imagination, efficiency, self-confidence, alertness, motivation and concentration were associated with low doses of caffeine (20-200 mg/day) (Smith et al., 2000; Stimulant Drinks Committee, 2002).

A reduced ability to sleep, for some people, at doses of 100 mg (1,4 mg kg bw/day in 70 kg adults) at bedtime has been reported (Smith et al., 2000).

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Finally, the EFSA (2011a and b) has very recently published two reports on the assessment of health claims usually attributed to caffeine.

In a first report on physical activity (EFSA 2011a), the European Authority concludes that there is no scientific evidence in support of a link between the consumption of caffeine and an increase in physical performance during short-term high-intensity exercise. Conversely, the EFSA considers that a relationship has been established between the consumption of caffeine and (1) endurance performance and (2) an increase in endurance capacity (reduction in perceived exertion, improved time to exhaustion and exercise capacity). The European Authority adds that these effects are felt if the caffeine is consumed at doses of 3 mg/kg one hour prior to exercise in a target population of adults performing endurance exercise. Similarly, the EFSA considers that a relationship has been established between the consumption of caffeine and perceived exertion/effort during exercise (RPE scale: Ratings of Perceived Exertion). The European Authority adds that this effect is felt if the caffeine is consumed at doses of 4 mg/kg one hour prior to exercise in a target population of adults performing endurance exercise.

In a second report that focuses on the reduction in body fat mass, body weight, increased alertness and attention (EFSA, 2011b), the European Authority concludes that there is no scientific evidence in support of a relationship between the consumption of caffeine and increased body fat oxidation as well as increased energy expenditure, both of which could lead to a reduction in body mass. However, the EFSA does consider that a relationship has been established between the consumption of caffeine and increased alertness and attention, and that this could be expressed in the following terms: “cognitive” and/or “mental” “performance” or “function”. The Authority considers that this claim corresponds to an intake of caffeine of at least 75 mg per serving for adults. However, it adds that for children, the consumption of a dose of 5 mg/kg could result in transient behavioural changes, such as increased arousal, irritability, nervousness or anxiety. Similarly, it points out that it is advisable for pregnant and lactating women to have a moderate caffeine intake.

As regards the risks linked to exposure to caffeine through the consumption of **energy drinks**, the following reports and research should be mentioned. Some of these data have been taken from the previous report of the SHC on energy drinks (SHC 8622, 2009) and are therefore only mentioned briefly.

At the European level, the SCF (Scientific Committee on Food, 1999) issued a first opinion on caffeine in energy drinks in 1999 and concluded that a daily intake of 160 mg caffeine/day in the form of cans containing up to 320 mg/l amounts to a considerable contribution to the total daily caffeine intake. This intake is, however, comparable to that of most other drinks, such as tea or coffee, with a caffeine content ranging between 100 and 400 mg/l. If energy drinks are really consumed instead of other caffeinated drinks, including tea and coffee, the consumption of these beverages does not appear to cause any problems in adults (with the exception of pregnant women). In children, who usually do not drink tea or coffee, substituting energy drinks for both cola beverages (brown drinks on the basis of plant extracts) and other soft drinks can significantly increase their daily caffeine consumption (SHC 8622, 2009).

The German Federal Institute for Risk Assessment (BfR, 2008) reports having explicitly re-assessed the potential risks linked to consuming energy drinks containing up to 320 mg/l of caffeine. It expresses its reservations on this subject and makes the following recommendations: (a) adverse effects should not be excluded when large quantities of these beverages (higher than the limits mentioned above) are consumed whilst exerting intense physical effort or in combination with alcoholic beverages and (b) such beverages, especially when consumed in large quantities, are not recommended for children, pregnant or lactating women, or caffeine-sensitive people (patients with arrhythmia or mental disorders) (SHC 8622, 2009).

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In 2010, this same institute re-examined the potential health risks linked to the excessive consumption of energy shots (BfR, 2010). The experts conclude that consuming energy shots that contain 50 to 200 mg of caffeine per serving pose no health risk provided that no more than one serving is consumed per day. Still, this report provides a very detailed and comprehensive discussion of all the potential risks associated with these drinks in the event that they are consumed in amounts in excess of those recommended. On the whole, the data in this report concerning the risks associated with the consumption of caffeine are consistent with those mentioned previously (Nawrot et al., 2003). Additionally, the report provides some interesting information on the use of caffeine as a pharmaceutical product. It is said that single doses of 100 to 200 mg caffeine may be used temporarily to counteract symptoms of fatigue and may be repeated if necessary, but not more than twice within 24 hours. As regards the side effects that are expected for this use, doses of 100 mg are said to be liable to cause tachycardia, insomnia, apprehension and gastrointestinal disturbances, whilstoses over 200 mg can cause irritability, headaches and intensified muscle tremors in caffeine-sensitive individuals. Moreover, special precautions are recommended for individuals with hyperthyroidism and with cirrhosis of the liver. These individuals are advised to take caffeine at a low dosage (100 mg) and under medical supervision. Finally, the section on overdosing mentions that symptoms of poisoning can occur at doses of 1,000 mg caffeine and more and that fatal doses of caffeine range between 3 and 10 g (BfR, 2010).

Based on an assessment of the risks linked to the consumption of caffeine, the New Zealand Food Safety Authority (2010) advises in its 2010 report that energy drinks and energy shots that contain caffeine should not be targeted at children or young teenagers. These recommendations are based only on existing data, which were mentioned above. According to this Authority, children and teenagers who already ingest caffeine through tea, coffee or cola beverages, are liable to be exposed to short-term side effects when consuming energy drinks and energy shots. It therefore takes the view that these drinks should carry a warning that they are not recommended for children (nor lactating women and caffeine-sensitive individuals). Finally, it regrets that there is a lack of data on the consumption of energy drinks and energy shots, e.g. as concerns the type of consumers, products and the amounts consumed.

Very recently, Seifert et al. (2011) published a review on the effects of energy drinks on children, teenagers and young adults in *Pediatrics*. In the United States, 30 to 50% of teenagers and young adults are said to drink these beverages. Because of their high caffeine content and the lack of regulations on these caffeine concentrations, the consumption of these drinks has resulted in severe adverse effects, including epileptic seizures, diabetes, heart anomalies or mood alterations and behavioural disturbances. Out of the 5,448 caffeine overdoses that were reported in the United States in 2007, 46% concerned youths under the age of 19. Since 2010, a specific code has been attributed to energy drinks in the United States, which allows for more precise reporting of their adverse effects. In this context, a report published in 2011 in the same American journal, viz. *Pediatrics* (*Committee on Nutrition and the Council of Sports Medicine and Fitness*, 2011), concludes that energy drinks entail potential health risks, that they are not suitable for children and teenagers and that these population groups should never consume them.

More specifically for **Belgium** and as pointed out in its previous report on energy drinks (SHC 8622, 2009), the SHC issued an unfavourable advisory report in 1995 on a request to use a caffeine content of 320 mg/l in beverages, whereas the Belgian legislation only authorised the addition of 150 mg/litre in lemonades of the soft drink (cola) type. In 1996, two Belgian experts raised the question of inspections for certain caffeinated products in a scientific publication (Lafontaine & Noirfalise, 1996). In 1997, the SHC received an inquiry regarding the broader issue of "Smart Drinks/Drugs", which include energy drinks with high caffeine content. It expressed its concern over these preparations and pleaded for concerted action by the competent European Authorities.
More particularly as regards the health risks linked to the consumption of energy drinks, the Council pointed out in its recent report on energy drinks (SHC 8622, 2009) that it is indeed the

caffeine that remains the main cause of concern, as has been confirmed by a recent American study (Clauson et al., 2008).

Other authors (Reissig et al., 2009) stress that consuming these drinks may lead to caffeine intoxication as well as caffeine dependence and withdrawal symptoms.
Along the same lines, Miller et al. (2008) established a connection between the consumption of energy drinks and risk behaviour in young people who consume a great deal of energy drinks (more than 6 times a month). They are believed to run a higher risk of growing addicted to nicotine, alcohol, but also cannabis. Two studies also note that there is a very clear tendency for young people to consume these drinks in combination with alcohol, which reduces the symptoms of alcohol intoxication, as well as their awareness of this state. This in turn results in a rise in accidents and an increased likelihood of becoming addicted to alcohol (Oteri et al., 2007; Malinauskas et al., 2007).
Similarly, O'Brien et al. (2008) show that a survey on American campuses has revealed that combining energy drinks with alcohol increases the alcohol consumption and alters its consequences.
Finally, these facts have been confirmed by a very recent study that finds that consuming energy drinks increases the risk of alcohol addiction (Aria et al., 2011).

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3.2.3. The upper intake level, if necessary depending on the different sensitivities of various population groups.

The report from the New Zealand Food Safety Authority (2010b) correctly points out that there is currently no acknowledged reference value as regards the exposure to caffeine. The experts therefore refer to various papers and to exposure limits mentioned for different population groups. Thus, the data below provide values which the SHC also considers relevant for this advisory report:

- For the general population, the values from Nawrot et al. (2003) still constitute a reference. They indicate that for healthy adults, a moderate exposure to caffeine **of 5.7 mg/kg/day** (**400 mg/day** for a 70 kg adult) is not linked to any adverse effects such as general toxicity, cardiovascular effects, altered behaviour, increased incidence of cancer and effects on male fertility. Still, the authors set this value at **3 mg/kg/day** (**210 mg/day** for 70 kg males), which is the limit above which increased anxiety can be observed.

- For children, the data gleaned by Nawrot et al. (2003) still hold, viz. an upper intake level of **2.5 mg/kg/day**, which is looked upon as the limit above which altered behaviour can appear, including anxiety as well as a potentially altered development of the nervous system. It is on this basis that the Canadian Ministry of Health recommended that the daily caffeine intake should not exceed 2.5 mg/kg/day for children aged 12 or less. Meltzer et al.'s (2008) report assessing the risks linked to the consumption of caffeine, which focuses on children and teenagers in the Nordic countries, led to the following values: a NOAEL (*No Observed Adverse Effect Level*) of 0.3 mg/kg/day for caffeine tolerance development, and an LOAEL (*Lowest Adverse Effect Level*) of 1-1.25 mg/kg/day for tolerance development, 2.5 mg/kg/day for anxiety development and 1.4 mg/kg/day for sleep disturbance.

- For women of childbearing age, the recommendations are those already mentioned above, viz. a maximum daily intake of either 300 mg/day (Nawrot et al., 2003), or even 200 mg/day (FSA, 2008).

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3.2.4. Current margins between levels of exposure and maximum daily intake

As regards the level of exposure of the Belgian population and following assessments carried out on the basis of the data from the 2004 food consumption survey (appendix 1), it can be posited that the average intake for the adult male or female population aged 19 -50 is around **2.3 mg/kg/day**. At that time, the corresponding value for teenagers aged 15-18 would have been around **1.1 mg/kg/day.**

The following table, calculated on the basis of these data, mentions the proportion of consumers whose caffeine intake exceeds the maximum daily intake of 3 and 5.7 mg/kg/day for adults (men and women) (see above for the meaning of these values).

Table 6: Percentage of caffeine consumers in Belgium with estimated daily caffeine intakes over 3 and 5.7 mg/kg/day

	Aged 15-18	Aged 19-59	Aged 60-74	Aged >74
Men (%)				
> 3 mg/kg/day	3	22	19	14
> 5.7 mg/kg/day	0	2	2	1
Women (%)				
> 3 mg/kg/day	0	25	24	14
> 5.7 mg/kg/day	0	5	2	1

Following the analysis of this table, it may be concluded on the basis of the results of the 2004 food consumption survey (see appendix 1) that **for around one quarter of the adult Belgian population (aged 19-74), the caffeine consumption exceeds the maximum daily intake of 3 mg/kg/day** above which increased anxiety may be observed. Conversely, only a very small fraction of the same population (less than 5%) exceeds the maximum daily intake of 5.7 mg/kg/day. Finally, it appears that the caffeine consumption of teenagers aged between 15 and 18 poses but very few problems.

By means of comparison, the following table, taken from the report from the New Zealand Food Safety Authority (2010b), mentions the proportion of consumers whose caffeine intake exceeds the value of 3 mg/kg/day or 200 mg/day for pregnant women solely through the usual dietary sources, excluding energy drinks and energy shots (as well as other caffeinated food supplements). Thus, it appears that between 2% and 38% of caffeine consumers has a baseline exposure to caffeine above adverse effect levels.

Table 7: Proportion (%) of caffeine consumers with estimated daily exposures to caffeine greater than caffeine adverse effect levels for different New Zealand population groups (*New Zealand Food Safety Authority*, 2010b).

	Children 5-12 yrs	**Teenagers 13-19 yrs**	**Young males 19-24 yrs**	**Adults 20-64 yrs ***	**Older people 65+ yrs**	**Females 16-44 yrs***	**Females 16-44 yrs pregnant**
% consumers >adverse effect level **	2	11	35	37	27	38	25
%respondents >adverse effect level **	2	8	28	35	26	35	22

* excluding pregnant women

** An adverse effect level of 3,0 mg/kg/day was applied (Smith et al., 2000) for all population groups except for pregnant females where an adverse effect level of 200 mg/day was applied.

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3.2.5. Assessment of the risks to the general population and specific population groups linked to the ingestion of caffeine through food supplements (liquid or solid) when (a) these food supplements are taken instead of the "habitual" foodstuffs such as e.g. energy drinks and (b) these food supplements are taken in addition to the "habitual" foodstuffs, for food supplements with a caffeine content of 50, 60, 70, 80, etc. mg caffeine per serving or recommended daily quantity.

As regards the Belgian population, assessments were carried out on the basis of the results of the 2004 food consumption survey mentioned above by calculating the proportion of caffeine consumers who exceed the maximum daily intake of 3 and 5.7 mg/kg/day for men and women, in the event that they consume additional amounts of caffeine randomly set at 60, 80, 100, 120, 140 and 160 mg of caffeine.

Table 8: Proportion (%) of the Belgian population with caffeine intakes greater than 3 and 5.7 mg/kg/day depending on additional intakes of caffeine ranging between 60 and 160 mg/day.

		Aged 15-18	Aged 19-59	Aged 60-74	Aged >74
Men (%)					
> 3 mg/kg/day	Baseline intake	3	22	19	14
	+ 60 mg	18	44	36	35
	+ 80 mg	25	51	42	44
	+ 100 mg	34	59	48	51
	+ 120 mg	46	67	55	59
	+ 140 mg	58	74	62	68
	+ 160 mg	72	82	69	76
> 5.7 mg/kg/day	Baseline intake	0	2	2	1
	+ 60 mg	1	4	5	3
	+ 80 mg	1	5	6	4
	+ 100 mg	2	7	8	5
	+ 120 mg	2	9	10	7
	+ 140 mg	4	12	12	9
	+ 160 mg	5	15	15	12
Women (%)					
> 3 mg/kg/day	Baseline intake	0	25	24	14
	+ 60 mg	14	47	47	38
	+ 80 mg	21	56	54	47
	+ 100 mg	31	65	61	55
	+ 120 mg	44	73	69	64
	+ 140 mg	61	81	76	73
	+ 160 mg	78	88	82	81
> 5.7 mg/kg/day	Baseline intake	0	5	2	1
	+ 60 mg	0	9	7	3
	+ 80 mg	1	11	9	5
	+ 100 mg	1	13	12	7
	+ 120 mg	2	17	15	10
	+ 140 mg	3	21	19	13
	+ 160 mg	5	25	23	18

This table shows that for a maximum daily intake set at 3 mg/kg/day, **an additional intake of 60 to 80 mg/day** causes the proportion of individuals whose exposure is above the upper value to almost double and that **this concerns up to 50% and over of the population** (between 36 and 56% of adult men or women). Such an intake can be reached by consuming a single energy drink unit or a single energy shot, which usually contain over 80 mg/unit. Conversely, for a maximum

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daily intake of 5.7 mg/kg/day, the proportion of adults who exceed this value remains very moderate (around 10% at most).

By means of comparison, the New Zealand Food Safety Authority (2010b) mentions that it assessed the effects of consuming energy drinks or energy shots on the basis of various data available in that country regarding these types of beverages, which are liable to increase the caffeine intake within concentration limits that range between 10 and 300 mg per unit consumed. The calculations are made for 3 age groups (children, teenagers, young males) by taking into account the consumption of 1 to 4 units of all energy shots or energy drinks available in New Zealand:

Table 9: Daily baseline caffeine exposures (mg/kg/day) and additional exposures for various New Zealand population groups in the event of 1-4 units of energy drinks or energy shots being consumed (*New Zealand Food Safety Authority*, 2010b).

	Children 5-12 yrs		**Teenagers 13-19 yrs**		**Young males 19-24 yrs**	
	Mean	P95	Mean	P95	Mean	P95
Baseline	0.6	2.0	1.2	4.5	3.5	14.4
Baseline + 1 retail unit	4.4	9.1	3.2	6.9	5.1	16.9
Baseline + 2 retail units	8.3	17.2	5.2	10.3	6.8	18.1
Baseline + 3 retail units	12.2	25.3	7.2	14.0	8.4	19.7
Baseline + 4 retail units	16.0	33.6	9.2	17.8	10.0	22.1

This table was used to calculate the proportions (%) of individuals whose exposure is greater than 3 mg/kg/day, which is looked upon as the level beyond which adverse effects are liable to occur:

Table 10: Proportion (%) of individuals with caffeine intakes above 3 mg/kg /day for various New Zealand population groups in the event of 1 to 4 units of energy drinks or energy shots being consumed (*New Zealand Food Safety Authority*, 2010b).

	Children 5-12 yrs	**Teenagers 13-19 yrs**	**Young males 19-24 yrs**
Baseline	2	11	35
Baseline + 1 retail unit	68	42	62
Baseline + 2 retail units	89	77	84
Baseline + 3 retail units	94	89	92
Baseline + 4 retail units	95	93	95

Thus, it turns out that around 70% of children, 40% of teenagers and 60% of young adults who consume caffeine, exceed the 3 mg/kg/day limit, which is looked upon as an adverse effect level, by consuming a single energy drink unit or shot unit.

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Quantitative data regarding the other caffeinated supplements available on the Belgian market are too scarce to allow for clear conclusions to be drawn. However, table 8 does provide some insight into the risks at the intake levels considered (additional intakes between 60 to 160 mg).

3.2.6. Assessment of the risks to the general population and specific population groups linked to the ingestion of caffeine through other foodstuffs such as chewing gum (or others mentioned in the CRIOC study in the appendix), when (a) these other foodstuffs are taken instead of the "habitual" foodstuffs and/or food supplements and (b) these other foodstuffs are taken in addition to the "habitual" foodstuffs and/or food supplements.

The lack of data regarding the description and consumption of the "other foodstuffs" makes it difficult to make a specific assessment of this issue, other than that on the basis of table 8. It should be noted that these "other foodstuffs" could provide up to 180 mg of caffeine per serving.

3.2.7. Assessment of the current limit that authorises flavoured non-alcoholic beverages to contain 320 mg of caffeine per litre, more precisely the need to maintain this limit, modify it or abolish it.

The current Belgian legislation states explicitly in a Royal Decree on additives in foodstuffs (RD of 1 March 1998) that the authorised maximum caffeine content in flavoured non-alcoholic beverages is 320 mg/l. In addition, the Federal Minister of Public Health clearly adds that in Belgium, caffeine falls under the legislation on additives until matters have been standardised at the European level and that this standardisation will occur within another framework than the legislation on additives. Caffeine also falls under the European legislation on flavourings. Finally, a European regulation, which entered into force on 1 July 2004, states that the labels of beverages that contain over 150 mg of caffeine per litre shall contain the message "high caffeine content" in the same field of vision as the name under which the product is sold and that this message shall be followed by the caffeine content (expressed in mg/100 ml) to warn the consumers of possible health risks (Directive 2002/67/EC). The European legislation (Directive 2002/67/EC) does not make any provisions for particular warnings, e.g. as regards potential high-risk groups.

Based on the data in this report and those from the 2004 food consumption survey (the limitations of which are well known), the SHC takes the view that the 320 mg/l limit for caffeine in **flavoured non-alcoholic beverages** is too high in terms of consumer health protection. The SHC advises to set this limit at a lower value, viz. 150 mg/l (European regulations regarding product labelling), which would be a reasonable precautionary measure (article 7.1 of EU Regulation 178/2002).[1] Such a limit also applies to energy drinks.

[1] In *specific cases in which an assessment of the available information shows that adverse health effects are possible, despite remaining scientific uncertainty, provisional risk management measures, which are required to ensure the high level of health protection aimed at by the Community, may be implemented whilst awaiting further scientific information that will make it possible to make a more comprehensive assessment of the risk.*

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3.2.8. Assessment of the impact on the risks to the general population and to specific population groups of the following potential measures: (a) setting conditions or limits on the use of caffeine-containing products; (b) setting the upper caffeine content in, amongst others, the foodstuffs mentioned above; (c) determining the mandatory warnings on the labels of these products.

The Australian and New Zealand legislation holds that all beverages or liquid food supplements that contain over 145 mg/l should bear the following warning on the label: "not suitable for children, pregnant or lactating women or individuals sensitive to caffeine." Similarly, the Finnish food safety authority takes the view that the simple statement "high caffeine content" required by the European directive does not suffice and advises that the same statement should be used as that imposed by the New Zealand Authority on beverages with a caffeine content over 150 mg/l (*New Zealand Food Safety Authority*, 2010b).

The SHC recommends that the amount of caffeine provided by any solid or liquid caffeine-containing **food supplement** (including the energy shots) or **any other product to which caffeine has been added** should be limited to 80 mg per daily serving.

Moreover, the labels of these products should carry a warning aimed at limiting the number of units consumed on a daily basis, e. g. "do not consume more than X units/day" (X to be defined according to the 80 mg/day limit value).

Finally, if the recommended daily serving reaches the 80 mg caffeine limit, the label should mention that the product: "is not suitable for children, pregnant and lactating women and individuals sensitive to caffeine".

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5. APPENDIX

Appendix 1: Assessment of the caffeine intake in Belgium via non alcoholic beverages (2004 survey)

The assessment of the caffeine intake through beverages is grounded on the database from the Belgian food consumption survey conducted in 2004 with adults and teenagers (aged ≥ 15) (Vandevijvere, 2004). Coffee, tea, soft drinks and energy drinks were included in the calculations. The products on which the statement "without caffeine" was explicitly mentioned were excluded, as well as flavoured waters, fruit juices and coffee substitutes. As regards tea and coffee, a maximum caffeine content of 320 mg/l was taken into account. As for soft drinks and energy drinks, they were attributed a maximum caffeine content of 150 mg/l or 320 mg/l depending on the brand. Brands that were known to be caffeine-free were excluded.

Only participants with 2 full 24-hour recalls were considered in the analyses (n = 3083). The individual caffeine intake through a specific beverage was calculated as follows:

$$y_i(mg/kgbw/day) = \frac{c_i \times x_i}{bw_i}$$

where y_i = caffeine intake through a specific beverage in individual i (mg/kg body weight per day), c_i = caffeine content in this particular beverage (mg/kg), x_i = the consumption of this particular beverage by individual i and bw_i = the body weight of this individual i. The total caffeine intake was calculated by adding the caffeine intakes through the various beverages per person and per

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day. The habitual caffeine intake was then calculated using the Nusser method (Nusser, 1996) and the C-SIDE software (Dodd, 1996). This method makes it possible to eliminate intra-individual variance and to introduce corrections for the distribution of the Belgian population according to age and gender as well as day of the week and season.

The average caffeine intake for men lies between 1.21 and 2.16 mg/kg body weight per day (table 1), depending on the age group, whereas for women, it ranges between 0.91 and 2.33 mg/kg body weigh per day (table 2).

Table 1. Caffeine intake per age group among men (in mg/kg body weight per day)

	Aged 15-18	Aged 19-59	Aged 60-74	Aged >74
Mean	1.21	2.16	1.94	1.81
Standard deviation	0.79	1.28	1.42	1.19
P95	2.68	4.49	4.65	4.05
P97.5	3.11	5.19	5.49	4.77

Table 2. Caffeine intake per age group among women (in mg/kg body weight per day)

	Aged 15-18	Aged 19-59	Aged 60-74	Aged >74
Mean	0.91	2.33	2.15	1.77
Standard deviation	0.65	1.81	1.40	1.18
P95	2.06	5.76	4.76	3.97
P97.5	2.32	7.16	5.48	4.57

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6. COMPOSITION OF THE WORKING GROUP

All experts joined the working group *in a private capacity.* The names of the members and experts of the Superior Health Council are indicated with an asterisk*.

The following experts were involved in drawing up this advisory report:

BRASSEUR Daniel *	Paediatric nutrition	ULB
CARPENTIER Yvon *	Nutrition, pathological biochemistry	ULB
DE BACKER Guy *	Preventive medicine, public health, epidemiology	UGent
DESTAIN Jacqueline *	Industrial microbiology, technology	Gembloux Agro-Bio Tech
FONDU Michel	Chemistry, additives, contaminants	ULB
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This working group was chaired by Mr. Yvon CARPENTIER, the scientific secretary was Ms. Michèle ULENS

About the Superior Health Council (SHC)

The Superior Health Council is a federal body that is part of the Federal Public Service Health, Food Chain Safety and Environment. It was founded in 1849 and provides advisory reports on public health issues to the Ministers of Public Health and the Environment, their administration, and a few agencies. These advisory reports are drawn up on request or on the SHC's own initiative. The SHC takes no decisions on the policies to follow, nor does it implement them. It does, however, aim at giving guidance to political decision-makers on public health matters. It does so on the basis of the most recent scientific knowledge.

Apart from its 25-member internal secretariat, the Council draws upon a vast network of over 500 experts (university professors, members of scientific institutions), 200 of whom are appointed experts of the Council. These experts meet in multidisciplinary working groups in order to write the advisory reports.

As an official body, the Superior Health Council takes the view that it is of key importance to guarantee that the scientific advisory reports it issues are neutral and impartial. In order to do so, it has provided itself with a structure, rules and procedures with which these requirements can be met efficiently at each stage of the coming into being of the advisory reports. The key stages in the latter process are: 1) the preliminary analysis of the request, 2) the appointing of the experts within the working groups, 3) the implementation of the procedures for managing potential conflicts of interest (based on the declaration of interest, the analysis of possible conflicts of interest, a referring committee) and 4) the final endorsement of the advisory reports by the Board (ultimate decision-making body). This coherent set of procedures aims at allowing the SHC to issue advisory reports based on the highest level of scientific expertise available whilst maintaining all possible impartiality.

These advisory reports are submitted to the Board. Once they have been endorsed, they are sent to those who requested them as well as to the Minister of Public Health and are subsequently published on the SHC website (www.css-hgr.be), except as regards confidential advisory reports. Some of them are also communicated to the press and to target groups among healthcare professionals.

The SHC is also an active partner in developing the EuSANH network (*European Science Advisory Network for Health*), which aims at drawing up advisory reports at the European level.

In order to receive notification about the activities and publications of the SHC, you can send an e-mail to info.hgr-css@health.belgium.be .

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