Food

This section aims at updating readers on the latest developments of risk-related aspects of food law at the EU level, giving information on legislation and case law on various matters, such as food safety, new diseases, animal health and welfare and food labelling.

Provisional Findings by EFSA on the Safety of Caffeine and the Possible Implications on Caffeine Health Claims and Energy Drinks

*Blanca Salas and Bruno G. Simões**

I. Introduction

In January 2015, the European Food Safety Authority (hereinafter, EFSA) published its draft Scientific Opinion on the safety of caffeine,[1] which was subsequently subject to a public consultation. Inter alia, EFSA provisionally found that single doses of caffeine of up to 200 milligrams (mg) and daily intakes of up to 400 mg do not raise safety concerns for adults in the European Union (EU). EFSA's final findings stand to have an important impact on various fronts, including in relation to the caffeine health claims that the European Commission (hereinafter, Commission) failed to adopt in 2012. The findings in the draft Scientific Opinion also look poised to have some bearing on a variety of schemes, such as labelling requirements, sales bans and taxation schemes, that several governments have adopted or may be considering to adopt in relation to energy drinks and food supplements that contain caffeine.

Caffeine, which is a stable alkaloid, is present in various plants such as coffee and cocoa beans, tea leaves, guarana berries and the kola nut, and has a long history of human consumption. It is contained in ingredients added to a variety of foods, such as baked goods, ice creams, soft candy and soft drinks. Caffeine is also an ingredient of energy drinks and it is sometimes present in combination with synephrine[2] in a number of food supplements marketed for weight loss and sports performance, among others.

II. Background

In recent times, concerns have been raised by the public and various non-governmental organisations (hereinafter NGOs) in relation to caffeine consumption in a number of circumstances and age groups, notably: (i) caffeine consumption during pregnancy and lactation, and any potential adverse health effects on the foetus; (ii) acute and long-term effects of caffeine consumption on the central nervous system (e.g., sleep, anxiety and behavioural changes) in adults, adolescents and children; (iii) long-term adverse effects of caffeine consumption on the cardiovascular system in adults; (iv) acute effects of caffeine consumption in energy drinks and the risk of adverse health effects in adolescents and adults involving the cardiovascular and central nervous systems, particularly when consumed within short periods of time, at high doses, and in combination with alcohol and/or physical exercise; and (v) acute effects of caffeine in combination with synephrine on the cardiovascular system.

Following a request from the Commission, EFSA's Panel on Dietetic Products, Nutrition and Allergies (NDA) delivered a draft Scientific Opinion[3] on the safety of caffeine, in particular on a daily intake of caffeine, from all sources, that does not give rise to concerns about harmful effects on health for the general population and for specific population sub-

* The authors are Associates at *FratiniVergano – European Lawyers*, a law firm with offices in Brussels and Singapore that specialises in international trade and food law (www.fratinivergano.eu). An earlier version of this article appeared in *Trade Perspectives*©, Issue 2 of 23 January 2015.

1 EFSA NDA Panel (EFSA Panel on Dietetic Products, Nutrition and Allergies), 2015. Draft Scientific Opinion on the safety of caffeine, available at http://www.efsa.europa.eu/en/consultations/call/150115.pdf (last visited on 31 March 2015).

2 Although this combination is banned in certain jurisdictions, e.g. Finland.

3 EFSA's draft Scientific Opinion was adopted on 23 April 2015.

groups. In addition, the Commission requested that possible interactions between caffeine and other food constituents (such as alcohol or substances found in energy drinks), caffeine and synephrine, and caffeine and physical exercise, be addressed.

III. Comment

In its draft Scientific Opinion, EFSA found, in relevant part, that for the general adult population (i.e., 18-65 years), single doses of caffeine from all sources of up to 200 mg (corresponding to about 3 mg/kilogram of bodyweight (kg bw) for a 70 kg adult) do not raise safety concerns, even if said doses are consumed less than two hours prior to intense physical exercise. Single doses of 100 mg of caffeine may increase latency (i.e., the amount of time it takes to fall asleep) and reduce sleep duration in some adults, particularly when consumed soon before falling asleep. Caffeine intakes from all sources up to 400 mg per day do not raise safety concerns for adults in the general population, except for pregnant women. EFSA also found that other common constituents of energy drinks (e.g., taurine and D-glucurono-γ-lactone) or alcohol are unlikely to present a risk to health when combined with caffeine.

According to EFSA, caffeine intakes from all sources up to 200 mg per day by pregnant women do not raise safety concerns for the foetus; and single doses of caffeine up to 200 mg and caffeine doses of 400 mg per day consumed by lactating women do not raise safety concerns for breastfed infants. For children and adolescents, EFSA considered that the information available is insufficient to base a safe level of caffeine intake. However, EFSA estimated that caffeine intakes of no concern derived from acute consumption in adults (i.e., 3 mg/kg bw per day) may serve as a basis to derive daily caffeine intakes of no concern for children and adolescents.

Caffeine consumption has been a contentious issue in recent years. In 2011, EFSA evaluated a number of health claims on caffeine (relating to improved concentration, increased alertness, endurance capacity, endurance performance and reduction in the rated perceived exertion/effort during exercise)[4] were evaluated by EFSA, which resulted in a positive outcome. These claims were subject to specific conditions of use, including that caffeine be consumed one hour prior to exercise (at doses of 3 mg/kg bw for claims on endurance capacity and performance, and at doses of 4 mg/kg bw for claims on reduction in the rated perceived exertion/effort during exercise). However, despite EFSA's favourable opinion, the Commission did not include the relevant health claims on caffeine in the positive list of general function claims approved in the EU.[5]

Indeed, it appears that, in the context of the relevant discussions aimed at the claims' approval between the Commission and EU Member States, some EU Member States raised concerns that health claims related to caffeine may cause an increase in the consumption of certain products, especially highly-caffeinated soft drinks. In this sense, EFSA's provisional findings may be of some relevance inasmuch as they highlight that, given the most common concentration of caffeine in energy drinks (320 mg/litre (l)) and the most common format (250 ml/can), about 14% of adult energy drink consumers and 11% of adolescent consumers may exceed caffeine intakes of 200 mg during a single athletic session.

Additional concerns[6] were reportedly raised in relation to the validity and appropriateness of the total daily intake for the general population that the Commission proposed in the conditions of use for the claims (i.e., 300 mg per day), which is based on the conclusions for pregnant women of a 1999 report of the Scientific Committee on Food (SCF, i.e., EFSA's predecessor).[7] In relevant part, the SCF report concluded that the contribution of energy drinks to the total caffeine consumption of adults[8] did not appear to be a cause for concern (assuming that energy drinks replace other sources of caffeine). However, the SCF found that certain daily intakes of caffeine

4 The health claims at hand were, specifically, "caffeine helps to improve concentration", "caffeine helps to increase alertness", "caffeine contributes to a reduction in the rated perceived exertion/effort during endurance exercise", "caffeine contributes to an increase in endurance performance", and "caffeine contributes to an increase in endurance performance capacity".

5 The list of permitted health claims is included in Commission Regulation (EU) No 432/2012 of 16 May 2012 establishing a list of permitted health claims made on foods, other than those referring to the reduction of disease risk and to children's development and health, OJ 2012 L 136/1.

6 European Commission, Summary Report of the Standing Committee on the Food Chain and Animal Health held in Brussels on 10 December 2012 (Section General Food Law).

7 SCF (Scientific Committee on Food), 1999. Opinion on Caffeine, Taurine and D-Glucurono - γ - Lactone as constituents of so-called "energy" drinks.

8 Excluding pregnant women.

may bring about temporary changes in behaviour (such as increased excitability, irritability, nervousness or anxiety) in children, and noted that it was advisable for pregnant women to moderate their caffeine consumption.

Most recently, the relevance of daily caffeine intakes was highlighted by a 2014 study published by researchers of the World Health Organisation (WHO),[9] which concluded, inter alia, that health risks associated with the consumption of energy drinks primarily relate to their high caffeine content. In particular, the study reported that a caffeine overdose may lead to serious health problems such as palpitations, hypertension, nausea, convulsions and, in extreme cases, heart failure.[10]

Arguably, the findings and conclusions highlighted above have had some impact on the recent legislative activity in relevant jurisdictions, where concerned authorities have used their regulatory power to consider (and, in some instances, adopt) schemes to tackle concerns related to caffeine consumption.

In the EU, for instance, the so-called Food Information Regulation[11] requires that, as of 13 December 2014, beverages with high caffeine content[12] carry, in the same field of vision as the name of the beverage and followed by a reference in brackets to the caffeine content expressed in mg per 100 ml, the warning message "High caffeine content. Not recommended for children or pregnant or breast-feeding women". The final text of the Food Information Regulation, including this and other requirements, arguably reflects concerns rooted in a number of EU Member States, some of which had been already addressed by national governments.

By way of example, in May 2014, Lithuania, which adopted stricter health warnings on energy drinks already in 2013, established a total ban on the sale of high-caffeine energy drinks to minors. In relevant part, the Lithuanian legislation[13] prohibits the sale, purchase or otherwise transfer of energy drinks to children under 18 years of age, and enables energy drink sellers to request identity documents from their customers. The definition captured in the country's law is an ample and all-encompassing one (i.e., "[e]nergy drink is a non-alcoholic beverage containing more than 150 mg/l of caffeine (regardless of the source), or containing more than 150 mg/l of caffeine and one or more other stimulants of the central nervous system like glucuronolactone, inositol, guarana, ginsenosides, ginkgo extract and taurine. Energy drink may contain carbohydrates, vitamins, minerals, amino acids, food additives, fruit juices and plant extracts"), where the list of "other stimulants of the central nervous system" is an open one and could therefore include substances not expressly listed.

Along the same lines, an excise tax on energy drinks went into effect in France on 1 January 2014, although it was declared unconstitutional only a few months later.[14] The discrepancy between the formulation of the Lithuanian and French measures, as well as their unequal success in the domestic legal frameworks, is only a small sample of the much more dramatic implications that a multiplication of this type of schemes could have on the EU's internal market. In particular (regardless of Lithuania's ban being arguably justifiable),[15] the proliferation of restrictive measures affecting energy drinks could ultimately lead to a fragmentation of the EU's internal market

9 João Joaquim Breda, Stephen Hugh Whiting, Ricardo Encarnação *et al.*, "Energy drink consumption in Europe: a review of the risks, adverse health effects, and policy options to respond", Public Health, 14 October 2014, doi: 10.3389/fpubh.2014.00134. Available on the Internet at: http://journal.frontiersin.org/Journal/10.3389/fpubh.2014.00134/full#B10 (last visited on 31 March 2015).

10 Ignacio Carreño, "Energy Drinks: Stricter Health Warnings on Caffeine Content in the EU and Sales Bans to Minors and New Excise Taxes" 4 *European Journal of Risk Regulation* 2014, pp. 543 *et sqq.*, at p. 547.

11 Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers, amending Regulations (EC) No 1924/2006 and (EC) No 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004, OJ 2011 L 304/18.

12 Except beverages based on coffee, tea or their extracts where the name of the food includes the term '*coffee*' or '*tea*', and which: (i) are intended for consumption without modification and contain caffeine, from whatever source, in a proportion in excess of 150 mg/l; or, (ii) are in concentrated or dried form and after reconstitution contain caffeine, from whatever source, in a proportion in excess of 150 mg/l.

13 Law No. XII-885 amending the Food Law No. VIII-1608.

14 In September 2014, France's Constitutional Council declared the tax scheme unconstitutional (with effect from 1 January 2015) by ruling that it failed to observe the principle of equality vis-à-vis other beverages with the same caffeine content.

15 Article 36 of the Treaty on the Functioning of the European Union (TFEU) provides that restrictions on grounds of human life and health (inter alia) are allowed as an exception to the prohibition of quantitative restrictions and measure having an equivalent effect set out in Articles 34 and 35 TFEU, provided that certain conditions are met.

of these products, in violation of the most basic principles and freedoms.

IV. Conclusion

As part of the public consultation on its provisional findings on the safety of caffeine (which concluded on 15 March 2015), EFSA held a meeting at the beginning of March with relevant stakeholders to exchange views on its assessment. Interested parties highlighted, inter alia, inconsistencies between EFSA's provisional findings and the conclusions of other authoritative bodies[16] with respect to, in relevant part, the interaction between caffeine and alcohol, and between caffeine and physical exercise.

Against this background, it remains to be seen what will be the precise impact of EFSA's draft Scientific Opinion, including in relation to the status of health claims on caffeine in the EU, which will surely need to be put in the wider context of the new findings. Arguably, any possibility of approval of the relevant health claims will depend, at least partially, on whether EU Member States are convinced by the assessment, as well as on whether they are satisfied with the eventual regulatory space that the EU framework grants to national governments. In parallel, EFSA's provisional findings look poised to fuel the ongoing debate on the adequacy of labelling requirements, taxation measures, or even sales bans to minors, enacted to address concerns that health claims related to caffeine may cause an increase in the consumption of highly-caffeinated energy drinks by minors (in particular in view of EFSA's preliminary finding that alcohol is unlikely to present a risk to health when combined with caffeine).

16 Such as the French ANSES (*Agence nationale de sécurité sanitaire de l'alimentation, de l'environnement et du travail*) and the German BfR (*Bundesinstitut für Risikobewertung*).