How easily digestible wine and healthy chocolate tempt to seduce - recent decisions on Health Claims

Citeersuggestie: K. Verzijden, How easily digestible wine and healthy chocolate tempt to seduce - recent decisions on Health Claims, LifeSciencesenRecht.nl, LSenR 276.

Context

By 14 December 2012, food items in the European Union (EU) with a health claim on their packaging not on a permitted list will have to be removed from the shelves.[1] The so-called permitted claims list was developed on the basis of the Regulation on nutrition and health claims on foods (the Regulation)[2], which came into force in January 2007. The aim of this Regulation is to harmonise rules related to health claims on food, in order to allow the consumer to make an informed choice and to stimulate the free movement of foods. All nutritional and health claims made in commercial communication in relation to all foodstuffs, including drinks and supplements fall within its scope. With this Regulation, the Commission hopes to eliminate misleading claims and to allow only those that are clear, easily understood by consumers and supported by scientific evidence, while at the same time levelling the playing field for food product manufacturers in the EU.[3]

Classification of claims

The Regulation divides health claims into the categories of (i) general function, (ii) new function, and (iii) disease risk factor reduction claims and claims related to children's development and health[4] (hereinafter referred to as disease risk reduction and children's health claims). General function claims were subject to a mass procedure, of which a first round of selection of claims was finished on 16 May 2012, with 222 claims approved.[5] The approved claims feature on a list implemented by the so-called Permitted Claims Regulation of May 2012[6] and can also be searched in a Register[7]. The list is dynamic and food product manufacturers can continue to apply to have new claims added to it. Recently, a claim regarding the beneficial effects of cocoa flavanols on blood circulation received a favourable opinion,[8] whereas a beneficial relationship between plant sterols and cholesterol levels was deemed insufficiently substantiated.[9]

Appraisal of claims by EFSA

Under EFSA's appraisal process for new function and disease reduction factor and children's health claims[10], it is up to the applicant to formulate the claim and the dosage required to achieve the claimed effect, and to submit relevant scientific studies. It follows that when a claim is rejected, this is not necessarily due to the fact that there is no connection between the substance and the claimed benefit, but depends on the applicant's preciseness in formulating the claim, EFSA's interpretation of what is beneficial, and the applicant's thoroughness in providing scientific substantiation[11]. A lack of scientific studies can lead to rejection, but does not necessarily imply that the claim is untrue; rather, more scientific research is needed before EFSA can form a positive opinion on the matter.

Criticism

The implementation of the Regulation and the Permitted Claims Regulation has generated criticism from industry associations on the one hand and non-governmental food watchdog organisations on the

[1] http://europa.eu/rapid/pressReleasesAction.do?reference=IP/12/479

[2] Regulation (EC) No 1924/2006 of the European Parliament and of the council of 20 December 2006 on nutrition and health claims made on foods.

[3] http://ec.europa.eu/food/food/labellingnutrition/claims/index_en.htm

[4] General function claim are covered by article 13.1, new function claims by article 13.5 and disease risk reduction and children's health claims by article 14 of the Regulation.

[5] The mass procedure ran from 2006 to 2012, in which 44,000 claims from across the EU were submitted by the Member States and consolidated to 4,600. A total of 1,719 claims were rejected and a number are still in the pipeline, including claims related so-called botanical substances, of which it is unclear whether they should fall within the legislation concerning food or medicine.

[6] 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;

[7] http://ec.europa.eu/nuhclaims/

[8] EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA); Scientific Opinion on the substantiation of a health claim related to cocoa flavanols and maintenance of normal endothelium-dependent vasodilation pursuant to Article 13(5) of Regulation (EC) No 1924/2006. EFSA Journal 2012;10(7):2809.

[9] EFSA Panel on Dietetic Products, Nutrition and Allergies. Scientific Opinion on the substantiation of a health claim related to a combination of plant sterols and Cholesternorm®mix and reduction of blood LDL-cholesterol concentrations pursuant to Article 14 of Regulation (EC) No 1924/2006. EFSA Journal 2012;10(7):2810.

[10] The process consists of three consecutive questions, namely whether the substance can be sufficiently characterised, the claimed effect is physiologically beneficial, and a cause-and-effect relationship exists based on scientific evidence. EFSA has issued a number of guidance documents: www.efsa.europa.eu/en/nda/ndaguidelines.htm.

[11] In order to successfully submit a new function claim, it is realistic to expect that a minimum of two independent clinical studies will have to be submitted.

other. For instance EFSA's appraisal methods have been questioned by the Dutch Foodwatch, which has sought to undermine Unilever's Becel Pro-Activ's new function claim with regard to, *inter alia,* the lowering of LDL cholesterol.[12] It has also questioned EFSA's favourable opinion on the claim related to cocoa flavanols, alleging for instance that Callebaut's claim relied too heavily on studies commissioned by Callebaut itself or on unpublished proprietary research.[13]

Legal action

Furthermore, on 2 July 2012, The United Kingdom Health Food Manufacturer's Association (HFMA) and the Dutch association Health Food Products Netherlands ("*Natuur- & gezondheidsProducten Nederland, NPN*) have taken legal steps and lodged an action against the Commission with the European Court of Justice, seeking annulment of the Permitted Claims Regulation, or, alternatively, a declaration that the initial Regulation is void for illegality.[14] It is difficult to predict the outcome of such procedure, but at least it shows that for many the restricted list of 222 permitted general function claims represents a serious concern.

Recent cases: EU

Despite criticism and pending annulment action, at the moment the health claims Regulation is being enforced and strictly interpreted. A prime example is the recent case at the European Court decided on 6 September 2012, in which the Court upheld the prohibition on the marketing of wine as '*easily digestible*[15]'. Even though the statement was correct in principle and did not imply an improvement in health, it implied the preservation of a good state of health despite the potentially harmful consumption of alcoholic beverages in the short and long run. The Court felt that the prohibition was compatible with the fundamental rights guaranteed at an EU-level and with the principle of proportionality.[16]

Recent cases: the Netherlands

Claims on food packaging and in advertising are not only under scrutiny at the EU level, on a national level in the Netherlands, the Dutch Advertising Code Authority (*Stichting Reclame Code*) has been addressing misleading product advertisement under the self-regulatory regime of the Dutch Advertising Code. A case brought by a consumer and decided against the manufacturer under this Code in July 2012 concerned advertisement for a soft drink as '100% organic' when it was not.[17] Reference point is whether the average consumer would have made a purchasing decision based on these statements that he might otherwise not have.[18]

Conclusion

Health claims in food labelling and advertising have become vital marketing tools to attract consumers' attention and to differentiate products from competing products. On the one hand, EU consumers expect accurate information on products they buy, in particular when health claims are put forward. On the other hand, Member States, regulatory bodies and non-governmental consumer interest organisations have been given extra means to challenge these claims. The permitted health claims list is expected to have far-reaching consequences especially for the food supplement industry, as health and nutritional claims are their products' main selling point. Given the potential impact of the regulation and its permitted list for the industry, Axon Lawyers will continue to actively monitor the developments in this area, including the legal action initiated against the Commission.

Karin Verzijden[19]
www.axonlawyers.com

[12] http://foodwatch.nl/misleid/becel_pro_activ/index_nl.html.
[13] ("*Have Magnums suddenly become healthy stuff*?") foodwatch.nl/laatste_nieuws/nieuwsberichten/is_een_magnum_nu_ineens_gezond/index_nl.html
[14] http://tinyurl.com/caseT296-12
[15] In German, the original language of these proceedings, the notion of "*easily digestible*" reads "*bekömmlich*". The wine growers cooperative using this notion had argued that it did not refer to health but rather to well-being. In German this line of reasoning is indeed easier to follow than in English.
[16] HvJ EU 6 september 2012, zaak C-544/10 (Deutsches Weintor eG tegen Land Rheinland-Pfalz), LSenR 258 en via http://curia.europa.eu/juris/documents.jsf?num=C-544/10.
[17] The ingredient water, not being an agricultural product, cannot be biological.
[18] Stichting Reclame Code, 4 July 2012, https://www.reclamecode.nl/webuitspraak.asp?ID=79250&acCode
[19] The author is grateful to Jade van Parijs, intern with Axon Lawyers in August and September 2012, for her valuable contribution to this article and for the joyful cooperation at our firm.