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Health claims on food products: a few clues for greater clarity

Until the adoption of Community Regulation 1924/2006[1], the assessment of health claims in relation to the labeling, presentation or advertising of food products was most of the time carried out *a posteriori*.

In France, the *Direction Générale de la Concurrence, Consommation et de la Répression des Fraudes* (General Directorate for Competition Policy, Consumer Affairs and Fraud Control or hereinafter "DGCCRF") would assess, after a product had been launched on the market, whether the health claim relating to such product complied with the general obligation of non-misleading advertising set forth in Article L.121-1 of the French Consumer Code.

Now, since the adoption of Regulation 1924/2006 (that entered into force on July 1, 2007), the assessment is carried out *a priori*, i.e. before the launch of the product. As such, health claims must be imperatively and expressly authorized by the European Commission and registered on a list of authorized claims before being effectively used.

What health claim and for what assessment?

Article 2 of Regulation 1924/2006 defines a health claim as "*any claim that states, suggests or implies that a relationship exists between a food category, a food or one of its constituents and health*".

The applicable assessment procedure depends on the "nature" of the relevant health claim:

- If the claim tends to be a "general function health claim", it must be included on the pre-established list of authorized general function health claims[2] that includes, to date, 4,637 claim entries; it should be specified that the European Food Safety Agency ("EFSA") expects to complete the evaluation of the general function health claims prioritized by the European Commission by the end of June 2011.

For this type of health claim, the food business operator does not need to file an individual application for authorization but must respect the exact name of the authorized claim and, as the case may be, the conditions

for use prescribed by the European Commission.[3]

- If the health claim relates to child development and health or to disease risk reduction, the food business operator must file an individual application for authorization that will be examined in the framework of a much more complex procedure, the outcome of which is particularly uncertain.

The procedure governing applications for authorization

The authorization procedure involves several national and EU authorities, e.g. for France: the DGCCRF, the EFSA and the European Commission.

The DGCCRF examines the admissibility of the application

Before transmitting the application to the EFSA, the DGCCRF must ensure that the application file is complete and:

- regarding the form, that the application meets the format requirements imposed by European authorities (5 parts and 3 Annexes A, B, C) and that it is accompanied by all necessary supporting elements;
- regarding the content, that the application only concerns one health claim, that such claim relies on the relevant provisions of Regulation 1924/2006 and that the risk of disease and the target group are clearly identified.

The application is forwarded to the EFSA only if it satisfies all of these formal and substance requirements.

The EFSA examines the application on the basis of scientific criteria only

The authorization of a health claim is granted exclusively on the basis of the scientific evidence produced in support thereof.

To orient food business operators on the nature and scope of required scientific evidence, several tools have been created: the EFSA notably adopted in 2007 a document relating to the scientific guidance for the preparation and the presentation of the application for health claim authorization; Commission Regulation 353/2008[4] provides further key elements concerning admissible scientific evidence. Even though the EFSA has been rendering decisions in relation to health claim authorizations only for a few years, a careful review of the issued opinions provide valuable information on the high level requirements applied by the EFSA for the admissibility of scientific evidence.

As examples of what is required, it should be noted that EFSA considers that:

- *"journal abstracts and articles published in newspapers, magazines, newsletters or handouts that have*

not been peer-reviewed" as well as *"books or chapters of books for consumers or the general public"* shall "*not be cited*[5]*";*

- studies on animals or in vitro studies, articles published in specialized magazines, articles published by scientists on the Internet, etc. are not sufficient unless they support studies conducted on men which constitute scientific evidence par excellence[6].

The EFSA has already issued thousands of opinions in relation to general function health claims but only 73 – most of them negative – on health claims concerning disease risk reduction or child development and health.

While it is unfeasible to make a summary of all negative opinions issued by the EFSA, it is possible and useful to identify the main reasons that led to the dismissal of the applications for authorization.

After a review of such negative opinions, it appears that the EFSA's assessment is based on three main questions that must be answered positively to maintain hope that the relevant authorization will be granted:

1. **Are the nutriment or the substance concerned by the claim and the alleged effect identifiable?** This requirement is met if the nutriment is sufficiently characterized with respect to its manufacturing process, origin, composition, etc.
2. **Is the alleged effect beneficial?** The proof of a beneficial effect is difficult to establish as it supposes that the scientific study has sufficiently isolated the substance/nutriment within the overall composition, to be able to ensure that the alleged effect can be attributed exclusively to this or that particular agent of the tested substance or nutriment. Producing such proof is not easy since the substance/nutriment is often made up of several agents that might be hard to isolate from each other.
3. **Is it possible to establish from the scientific elements supporting the application the existence of a cause and effect relationship between the consumption of this nutriment or substance and the alleged effect (for the target group and in the conditions of use prescribed by the applicant)?**

In the majority of applications, the most complex challenge is to establish the existence of a cause and effect relationship (c):

- the group of persons used for the scientific studies must be sufficiently representative of the group targeted by the alleged health claim[7];
- the scientific study must strictly relate to the compositional specifications of the food product for which an application for authorization of a health claim has been filed[8];
- the results must be significant, failing which the EFSA will rule that no scientific conclusions may be drawn.

The European Commission makes the final decision

Since the opinions issued by the EFSA are non-binding, the final decision to authorize – or to refuse – a health claim is vested with the European Commission (Standing Committee on the Food Chain and Animal Health or « SCFCAH »).

In practice, however, the European Commission most often follows the opinions rendered by the EFSA.

The sanctions

Pursuant to Decree n°2009-532[9], the provisions of Regulation 1924/2006 constitute the enforcement measures referred to in Article L 214-1 of the French Consumer Code that relates to conformity and safety of products and services.

Consequently and pursuant to Article L214-2 of the French Consumer Code, "*breaches of Regulation 1924/2006 that are not to be confused with any fraud or falsification provided for under Articles L. 213-1 to L. 213-4 and L. 214-1 (§7), shall be punished as third-class petty offences*" (i.e. fines up to EUR 450).

The question is how to distinguish breaches of Regulations 1924/2006 that constitute falsification offences under Article L.213-1 of the French Consumer Code (and that, as such, are punishable by a EUR 3,700 fine and two years of imprisonment maximum) and breaches of Regulation 1924/2006 that are considered as third-class petty offences?

The distinction between these two categories of offences lies in the existence of an intentional element. If there is no intentional element, the offense shall be considered as a third-class petty offence.

As such, a food business operator that would produce in support of his application for authorization biased or purposely truncated scientific studies could be charged with the offense of falsification since in such circumstances, the existence of an intentional element is established. Similarly and insofar as Regulation 1924/2006 only authorizes the use of expressly approved health claims, the use of any claims other than the adequate one could be considered as deceitful advertising (as per Article L.121-1 of the French Consumer Code), an offense punished by Article L.213-1of the French Consumer Code.

In cases where the intentional element is more difficult to establish, breaches of Regulation 1924/2006 would probably be sanctioned by a third-class fine (it being specified that the amount of the fine can be multiplied by the number of committed offences).

Because Regulation 1924/2006 has strengthened the assessment of health claims, food business operators must ensure that this constraint is duly taken into account in their food marketing policy, well upstream of the launch of the product.

Any contemplated health claim must be subject to a series of very serious scientific studies, which may entail heavy financial investments (several thousand Euros for clinical trials). In addition, the contemplated health

claim must be carefully drafted. It must be clear and legible for the average consumer.

In any event, any food business operator wishing to add a health claim on its products must proceed with caution. It is always possible and preferable to withdraw an insufficiently complete application for authorization rather than meeting a refusal that is not subject to appeal[10].

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

[2] General function health claim means any claim that refers to the role of a nutrient or substance in (i) growth, development and body functions, (ii) psychological and behavioral functions, (iii) slimming and weight control, satiety or reduction of available energy from the diet.

[3] Provided that the claim is not based on newly developed scientific evidence and/or for which protection of proprietary data is not requested. In such a case, an application for authorization is required.

[4] Commission Regulation (EC) No 353/2008 of 18 April 2008 establishing implementing rules for applications for authorization of health claims as provided for in Article 15 of Regulation (EC) No 1924/2006 of the European Parliament and of the Council.

[5] Art. 7 of Annex to Regulation 353/2008.

[6] Question n° EFSA-Q-2009-00751, opinion adopted on July 9, 2010: negative opinion because of the absence of human intervention studies.

[7] For an opinion related to the Kinder Chocolate, in which the Authority considered that the studies were not performed in the target population (children and young adults) since there were performed either in a specific group not representative of the general population of children (ie lactose intolerant subjects) and in groups mainly adults (Question n° EFSA-Q-2008-283, opinion adopted on January 22, 2009).

[8] For a health claim related to a combination of *Bifidobacterium bifidum*, *Bifidobacterium breve*, *Bifidobacterium infantis*, *Bifidobacterium longum, the EFSA specified that the study must imperatively relate to this combination of bacteria (*Question n° EFSA-Q-2009-00224, opinion adopted on December 4, 2009).

[9] Decree n°2009-532 of May 12, 2009 implementing the provisions of the French Consumer Code in respect of nutrition and health claims on foods and the addition of vitamins and minerals and of certain other substances to foods.

[10] It should be noted that it is always possible to withdraw an application for authorization as long as the

EFSA has not adopted an opinion (for this purpose, a request must be filed with the DGGCCRF (cf. Article 7 of Regulation 353/2008)).

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