

# “But what is it, Doc?” – Health Care Professionals under Regulation 1924/2006

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“Wine is the most healthful and hygienic of beverages”

Louis Pasteur (1822–1895), French HCP

## I. Introduction

Changes in the epidemiological profile in Western countries during the last three decades have shown an increasing trend in the development of non-transmissible chronic diseases in the adult population. Nutrition-related lifestyles have been identified as one of the main risk factors for the onset of such diseases. The reaction of some countries<sup>1</sup>, pioneered by Japan<sup>2</sup> in the early eighties, has focused on the role of nutrition for the prevention of such diseases, as the rising health care costs derived from their treatment is becoming unsustainable.

Within this framework, health care professionals (hereinafter, “HCPs”) are increasingly informed about the nutritional and physiological benefits of some foodstuffs, both when reducing a risk factor of developing a disease or coadjuvating to such end with a positive health effect on the bodily functions. Doctors themselves, sometimes moved by their deontological obligations, sometimes by other considerations, will disseminate this information to their peers, the scientific community and the general public.

Regulation 1924/2006 (hereinafter, the “HCR”)<sup>3</sup> foresaw the use of references to recommendations

and endorsements of food products by HCPs and their associations in communications intended to consumers. However, it remained silent as to the legal fate of communications addressed by food business operators to HCPs and did not address the status of other types of communications from HCPs to consumers.

The question whether information from food business operators to HCPs on the health benefits of foods have to abide by the HCR is an open debate, both among food lawyers and enforcement authorities. This article purports to shed some light on this debate from a legal point of view. It will embrace the application of an exemption, and will outline the legal basis and reasoning justifying it. According to Article 1(2) HCR, “[t]he Regulation shall apply to nutrition and health claims made in commercial communications, whether in the labelling, presentation or advertising of foods to be delivered as such to the final consumer”. A contrario, it will be argued that the HCR does not apply either to (i) *non-commercial communications* (which, according to Recital 4, include information in the press and in scientific publications<sup>4</sup>), or to (ii) *communication* on foods which are not to be delivered to the *final consumer*.

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1 See, *inter alia*, the new Chilean legislation on health claims, which identified several reduction of disease risk claims associated to non-transmissible chronic diseases such as cancer, osteoporosis, cardiovascular diseases, arterial hypertension, nutritional anemia or caries (Cf. *Normas técnicas sobre directrices nutricionales que indica, para la declaración propiedades saludables de los alimentos*. Exenta N° 764 Official Journal of 5.10.09).

2 The concept of “functional food” was nurtured by the Japanese government in the eighties because it was concerned about the

ageing of the country’s population and the resultant cost of health-care (Japanese people have the longest life-expectancy in the world) (Heasman, 1997). See *Nutritional Aspects of Food Processing and Ingredients*, Chapter 3 – Functional Foods: Prospects and Perspectives, P.J.A. Sheehy and P.A. Morrissey, pp. 45–65. Eds. C.J.K. Henry & N.J. Heppell (1998) Gaithersburg, Aspen Publishers.

3 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 (OJ L 404/9 of 30.12.2006).

4 Recital 4 states that the HCR “should not apply to claims which are made in non-commercial communications, such as dietary guidelines or advice issued by public health authorities and bodies, or non-commercial communications and information in the press and in scientific publications”.

Nonetheless, this exemption needs to be structured within the EU legal framework applying to health claims, food labelling and consumer law in general. Also, it needs to be tempered by the restrictions, such as the prohibitions of recommendations from individual doctors, to communications originating from HCPs to patients or consumers.

At a second stage, this article will delineate the legal boundaries existing at the other end of the information flow, i.e. when HCPs communicate on the nutritional or health benefits of foods. As it will be argued, in communications on the health properties of foodstuffs originating from HCPs, the promotional purpose is the key in determining their *commercial* character and the ensuing application of the HCR. Such promotional character is *per se* excluded in case of communications compiled in an *independent manner*, particularly provided for no financial consideration, but will be caught by the HCR if they are, in fact, a disguised form of advertisement.

## II. Definition of HCPs

The EU legislator has left to the Member States the competence to decide what is (and what is not) a HCP<sup>5,6</sup>.

In the HCR, “*medical, nutrition or dietetic professionals*” seem to fit under the broad category of HCPs<sup>7</sup>. However, the requirements to become a doctor, a nutritionist or a “*dietetic professional*” are laid down under national law. Directive 2001/83/EC on medicinal products<sup>8</sup> prohibits the advertising to the general public of medicinal products available

on medical prescription-only, but allows advertising them to professionals, who are defined as “*persons qualified to prescribe or supply such products*”<sup>9</sup>.

A wider interpretation, in line with the consumer protection objective of the HCR, is taken by the UK’s Food Standard Agency, according to which HCPs would include “*anyone who is presenting themselves, or is understood by the consumer, as having expertise in the field of health or nutrition*”<sup>10</sup>.

For Finland’s food safety authority, Evira, HCPs include “*persons who have been educated in the field of nutrition or in the science of clinical nutrition (nutrition therapy)*”<sup>11</sup>.

## III. HCPs as Recipients of Commercial Communications on the Health Benefits of a Foodstuff

### 1. Exclusive Application of the HCR to the Final Consumer

The HCR does not apply to information on foods which are not to be delivered to the *final consumer*. Article 2(1) HCR refers to Regulation 178/2002<sup>12</sup> for the definition of *final consumer*, which, in turn, defines it as “*the ultimate consumer of a foodstuff who will not use the food as part of any food business operation or activity*”<sup>13</sup>.

The reference to the concept of *final consumer* in Article 2(1) excludes from the scope of the HCR professionals (such as HCPs) acting within the scope of their professional activities. This dichotomy *consumer* vs. *professional* lies in the very foundation of EU consumer protection

5 See on this topic *Health law and the European Union*, TK. Hervey, J.V. McHale, Cambridge University Press, 2004.

6 For example, the different categories of HCPs recognized under Spanish law are described in Law 44/2003 on the organization of health professions. According to Article 2 thereof, health professions are organized in two main categories according to their education level. The higher education level covers those who have a license in Medicine, Odontology, Pharmacy, and Veterinary science. The lower education level covers those who earned a diploma in Nursing, Physiotherapy, Occupational therapy, Podiatry, Optics, Optometry, Speech and language Therapy, and Human Nutrition and Diet (Cf. Ley 44/2003, de 21 de noviembre, de ordenación de las profesiones sanitarias (BOE 22.11.2003). Also, food technologists working within the sanitary sector are considered HCPs.

7 Article 11.

8 Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ L 67/311 of 28.11.2001).

9 Article 88.

10 Food Standards Agency Guidance to compliance with Regulation (EC) 1924/2006 on nutrition and health claims made on foods, of April 2008 (revised).

11 Guideline for Application of Article 11 of Regulation (EC) No 1924/2006 on nutrition and health claims (8.2.2010).

12 Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 31/1 of 1.2.2002).

13 Article 3(18) of Regulation 178/2002.

law<sup>14</sup>, as has been expressly acknowledged by the scholars<sup>15</sup>.

The same principle applies to other regulated areas, such as prescription-only medicines, tobacco products or infant formulae: whilst promotion (in the form of advertising) to the general public is prohibited<sup>16</sup>, it is allowed if addressed to *professionals*<sup>17</sup>.

Furthermore, were HCPs to be caught by the HCR when acting exclusively within the scope of their professional duties, the concept of *final consumers* in Article 1(2) HCR would lose its *effet utile* (principle of effectiveness).

Finally, it is apparent from the objectives and provisions of the HCR that its remit is restricted to communications addressed to consumers, and not to professionals acting within the scope of their business activity: Recital (1) lays down the overarching objective of consumer protection of the HCR, aside from ensuring the proper functioning of the internal market: “In order to ensure a high level of protection for consumers and to facilitate their

choice, products put on the market, including imported products, should be safe and adequately labelled”. Recitals (10) and (11) justify the adoption of nutrient profiles in order to avoid misleading consumers when making choices. Recital (16) reminds that the HCR takes as a benchmark the concept of average consumer, as developed by the Court of Justice of the European Union (hereinafter, the “CJEU”). Article 5(2) provides that nutrition and health claims should be understandable by the average consumer.

This interpretation has been corroborated by the only national authority which has made their views public in this respect. Thus, for the UK’s Food Standard Agency, “[t]he Regulation only applies to claims made in communications aimed at the final consumer (Article 1) and it is the Agency’s opinion that it will not control claims made in communications within trade, to doctors or other health professionals, or to their organisations, whether the claim is in the labelling, presentation or advertising of the food. However, if the information were, at any time,

14 See to this effect Council Directive 85/577/EEC of 20 December 1985 to protect the consumer in respect of contracts negotiated away from business premises (OJ L 372/31 of 31.12.1985), Article 1(2)(a); Council Directive 90/314/EEC of 13 June 1990 on package travel, package holidays and package tours (OJ L 158/59, of 23.6.1990), Article 2(4); Council Directive 93/13/EEC of 5 April 1993 on unfair terms in consumer contracts (OJ L 95/29 of 21.4.1993), Article 2(b); Directive 97/7/EC of the European Parliament and of the Council of 20 May 1997 on the protection of consumers in respect of distance contracts (OJ L 144/19 of 4.6.1997), Article 2(2); Directive 98/6/EC of the European Parliament and of the Council of 16 February 1998 on consumer protection in the indication of the prices of products offered to consumers (OJ L 80/27 of 18.3.1998), Article 2(e); Directive 1999/44/EC of the European Parliament and of the Council of 25 May 1999 on certain aspects of the sale of consumer goods and associated guarantees (OJ L 171/12 of 7.7.1999), Article 2(a); Directive 2000/31/EC of the European Parliament and of the Council of 8 June 2000 on certain legal aspects of information society services, in particular electronic commerce, in the Internal Market (OJ L 178/1 of 17.7.2000), Article 2(e); Directive 2002/65/EC of the European Parliament and of the Council of 23 September 2002 concerning the distance marketing of consumer financial services and amending Council Directive 90/619/EEC and Directives 97/7/EC and 98/27/EC (OJ L 271/16 of 9.10.2002), Article 2(e); and Directive 2005/29/EC of the European Parliament and of the Council of 11 May 2005 concerning unfair business-to-consumer commercial practices in the internal market and amending Council Directive 84/450/EEC, Directives 97/7/EC, 98/27/EC and 2002/65/EC of the European Parliament and of the Council and Regulation (EC) No 2006/2004 of the European Parliament and of the Council (OJ L 149/22 of 11.6.2005), Article 2(a).

15 According to the scholars, the various definitions referred to in the above mentioned acts share common characteristics which can be summarized as comprising all physical persons acting outside their professional duties, who receive goods or services

for their final use or consumption, with the objective to meet personal or family needs. See, in this sense, González Vaqué, “La noción de consumidor normalmente informado en la jurisprudencia del Tribunal de Justicia de las Comunidades Europeas: la Sentencia Gut Springenbedie”, *Derecho de los Negocios*, n° 103 (April 1999), Palao Moreno, “La protección de los consumidores en el ámbito comunitario europeo” in Reyes López, *Derecho de Consumo*, Tirant lo Blanch, Valencia, 2002, pp. 39–40; Tenreiro, “Un Code de la consommation ou un Code autour du consommateur? Quelques réflexions critiques sur la codification et la notion du consommateur” in Krämer, Micklitz y Tonner, *Law and diffuse Interests in the European Legal Order – Liber amicorum Norbert Reich*, Nomos, Baden-Baden, 1997, p. 348.

16 *A fortiori*, in the case of food products, it is not prohibited, but strictly limited by the HCR.

17 Directive 2001/83 prohibits the advertising to the general public of medicinal products available on medical prescription-only, but allows advertising them to professionals (“persons qualified to prescribe or supply such products”) (Article 88). Also, whilst Directive 2003/33/EC of 26 May 2003 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the advertising and sponsorship of tobacco products (OJ L 152/16 of 20.6.2003) prohibits the advertising of tobacco products in the print media (newspapers and other publications), information society services and radio broadcasting, it can be done so in publications intended exclusively for “professionals in the tobacco trade” (Article 3). Along the same lines, Article 14 of Directive 2006/141/EC of 22 December 2006 on infant formulae and follow-on formulae and amending Directive 1999/21/EC (OJ L 401/1 of 30.12.2006) prohibits the advertising to the general public of the former type of products, but allows it in “publications specializing in baby care and scientific publications”, subject to certain conditions (e.g. such information shall not imply or create a belief that bottle feeding is equivalent or superior to breast feeding) and to the fact that it contains only information of a scientific and factual nature.

*conveyed to the final consumer within a commercial context, any claims made would need to comply with the requirements of the Regulation.*"<sup>18</sup>

Also, a number of scholars share this opinion<sup>19</sup>. On the other hand, some authors rely on a strictly literal reading of Article 1(2) of the HCR to justify the application of the HCR to HCPs. These authors believe that the phrase "*to be delivered to the final consumer*" refers to the foodstuffs themselves and not to the communications in connection thereto. According to this view, there would be no difference if the advertising aims at the final consumer or professionals (be them HCPs or sales managers) for as long as the products are delivered to the final consumer<sup>20</sup>.

This literal interpretation has the merit of being coherent with the scope of application of the Directive 2000/13/EC<sup>21</sup>, which applies to the "*labelling of foodstuffs to be delivered as such to the ultimate consumer*"<sup>22</sup>. However, it disregards the dichotomy consumer-professional enshrined in EU consumer law, and in our view, pales in the light of the arguments described above. Indeed, it is difficult to maintain successfully that the EU legislator allows the advertising to professionals of products which represent serious public health concerns (such as prescription-only medicines, tobacco products or infant formulae) without major limitations but subjects the advertising of foodstuffs to professionals to the stringent requirements of the HCR (which purports, as stated *supra*, at providing a high level of consumer protection).

Finally, it could be further argued that, since HCPs are potential consumers of the foods adver-

tised to them, the HCR would apply. However, the condition of HCPs as potential consumers is merely accidental and only secondary to their condition as professionals. Therefore, it could not be such as to trigger the application of the HCR.

In spite of the above, the minimum criteria established under Directive 2006/114/EC on misleading and comparative advertising<sup>23</sup> should be observed in any communication from the food industry to HCPs. Directive 2006/114 prohibits any form of advertising which in any way, including its presentation, deceives or is likely to deceive the persons to whom it is addressed or whom it reaches and which, by reason of its deceptive nature, is likely to affect their economic behaviour or which, for those reasons, injures or is likely to injure a competitor.

## 2. Associated Risk of Reclassification

It could also be argued that, when promoting the health benefits of their products to HCPs, food business operators could not refer to the prevention, treating or cure of human diseases (hereinafter, "*medicinal claims*"), as any reference to such properties is prohibited by Directive 2000/13 with the exception of the so-called "*reduction of disease risk claims*"<sup>24</sup>.

In fact, foods may have beneficial effects on health and even "*serve therapeutic purposes*"<sup>25</sup>, as the CJEU has acknowledged.

A product recommended or described as preventing, treating or curing a human disease is a medicinal product "*by virtue of its presentation*"

<sup>18</sup> See note 9 *supra*.

<sup>19</sup> See, for example, Holle (*Health Claims Kompakt*, 2007), who holds that the HCR is exclusively applicable to final consumers, or Teufer (ZLR 2009, 581). Meisterernst and Haber (Meisterernst/Haber, *Praxiskommentar Health&Nutrition Claims*, 2008, art. 1 margin note 64 et seq.) had in the past doubted that non-consumers were exempted from the scope of the HCR, but have since embraced the opposite view (see forthcoming publication *Health and Nutrition Claims. Commentary on the Health HCR*, Lexxion Verlagsgesellschaft, 2010).

<sup>20</sup> See Hagenmeyer (StoffR 2007, 201, 202) and Holtdorf (LMuR 2008, 84, 86).

<sup>21</sup> Directive 2000/13/EC of the European Parliament and of the Council of 20 March 2000 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs (OJ L 109/29 of 6.5.2000).

<sup>22</sup> Article 1(1). When it comes to misleading information, the core objective of consumer protection rules, Directive 2000/13 also makes clear that it is addressing the final consumers

(purchaser): "*The labelling and methods used must not: (a) be such as could mislead the purchaser to a material degree*" (Article 2).

<sup>23</sup> Directive 2006/114/EC of the European Parliament and of the Council of 12 December 2006 concerning misleading and comparative advertising (OJ L 376 of 27.12.2006).

<sup>24</sup> The HCR allows, upon prior authorization by the European Commission, the use of this type of claims in foods, which are defined as "*health claims that states, suggests or implies that the consumption of a food category, a food or one of its constituents significantly reduces a risk factor in the development of a human disease*", Article 2(6).

<sup>25</sup> See Judgment of the CJEU of 15 November 2007, Commission v Germany, Case C-319/05, ECR 2007 Page I-09811, paragraph 64: "*As the Advocate General observed, in point 60 of her Opinion, there are many products generally recognised as foodstuffs which may also serve therapeutic purposes. That fact is not sufficient however to confer on them the status of medicinal product within the meaning of Directive 2001/83*".

within the meaning of the first subparagraph of Article 1(2) of Directive 2001/83, even if it is generally regarded as a foodstuff and even if in the current state of scientific knowledge it has no known therapeutic effect<sup>26</sup>. In that context, a product is “*presented for treating or preventing disease*” when it is expressly “*indicated*” or “*recommended*” as such, possibly by means of labels, leaflets or oral representation. A product is also “*presented for treating or preventing disease*” whenever any *averagely well-informed consumer* gains the impression, which, provided it is definite, may even result from implication, that the product in question should, having regard to its presentation, have the properties in question<sup>27</sup>.

In our opinion, however, these limitations are restricted to products presented with such properties to the *final consumer*, and not to *professionals* acting within the scope of their duties.

Firstly, the ban on medicinal claims is laid down in Directive 2000/13, which, as it has just been pointed out, applies to the labelling, presentation and advertisement of foodstuffs to be delivered as such to the *ultimate consumer*, and not to professionals.

Secondly, the distinction *final consumer* vs. *professionals* is also relevant for meeting the criterion of “*medicinal product by presentation*” as developed by the CJEU case-law. The term “*presentation*” of a medicinal product must be interpreted by taking as a reference the *final consumer* of the products, and not *professionals*, in this case, HCPs. This is in line with the CJEU’s settled case-law on the matter, which has constantly interpreted the definition of “*presentation*” broadly, in order to catch not only

medicinal products having a genuine therapeutic or medical effect, but also “*those which are not sufficiently effective or do not have the effect which consumers would be entitled to expect from the way in which they are presented*”<sup>28</sup>. Directive 2001/83 thereby intends to protect consumers not only from harmful or toxic medicinal products, but also from a variety of products used instead of the proper remedies<sup>29</sup>.

Thirdly, recognition that the information which can be sent to HCPs is not strictly subjected to the prohibition on the use of medicinal claims can be found in the legislation on foods for particular nutritional purposes (PARNUTS)<sup>30</sup>, which can be applied to regular foods for the purposes of this analysis. Thus, whilst a ban on medicinal claims applies to the labelling, presentation and advertising of PARNUTS, this prohibition “*shall not prevent the dissemination of any useful information or recommendations exclusively intended for persons having qualifications in medicine, nutrition or pharmacy*”<sup>31</sup>.

Hence, the outright ban on medicinal claims should not, in principle, be applied to the communications from food business operators to HCPs provided that the former does not disclose an intention to market his products as medicinal products.

The rationale underpinning this reasoning is that HCPs should be able to recognize the true nature of a food due to their specialized education. Thanks to their knowledge, the possibility that HCPs gain the impression that foods, having regard to their presentation, have the properties of preventing, treating or curing a human disease is negligible<sup>32</sup>.

26 Judgment of the CJEU of 28 October 1992, Case C-219/91, *Criminal proceedings against Johannes Stephanus Wilhelmus Ter Voort*, ECR p.I-05485, para. 21.

27 Judgments of the CJEU of 30 November 1983, *Criminal proceedings against Leendert van Bennekom*, Case 227/82, Rec.p.3883 (para. 18); and of 21 March 1991, *Criminal proceedings against Jean Monteil and Daniel Samanni*, Case C-60/89, Rec.p.I-1547 (para. 23).

28 Judgment of the CJEU of 15 November 2007, Case C-319/05, *Commission v. Germany*, Rec.p.I-09811, para. 43. Examples on the CJEU taking the *final consumer* as the reference in order to classify a product as a medicinal product “by its presentation” can be also found in *Ter Voort*, cited in note 25 *supra*, a case in which a product was presented with therapeutic properties in a brochure which was sent to the purchaser, at his request, after sale. The CJEU made clear that the information contained in the brochure was of such a kind “as to cause the product to appear to be a medicinal product in the eyes of an averagely well-

*informed consumer who asked to receive the publication and, moreover, in the eyes of any consumers who might learn of the existence of the publication*”. See also to this effect, *Van Bennekom and Monteil and Samanni*, cited in note 26 *supra*.

29 *Ibid*.

30 Council Directive 2009/39/EC of the European Parliament and of the Council of 6 May 2009 on foodstuffs intended for particular nutritional uses (OJ L 124 of 20.5.2009).

31 Unless the European Commission grants an exception in clearly defined cases.

32 In this regard, it could be argued that medical doctors may not have specific academic background in nutrition, as this may not be usually included in their study plans. However, doctors are undoubtedly in a better position than average consumers when it comes to understanding the physiological mechanism and effects of the substances at hand, and how this effect is beneficial for human health.

#### IV. HCPs as *Originators* of Commercial Communications on the Health Benefits of a Foodstuff

Communications from HCPs are partly regulated under the HCR. When recommendations and endorsements are used in commercial communications, they have to fulfil the requirements established therein and refer exclusively to authorized claims. However, when they do not act in the remit of a *commercial communication*, they are free in their choice of words.

The difficulty lies in determining whether and under which conditions communications from HCPs on the nutrition or health benefits of foods can be considered *non-commercial*, and, thus, exempted from the application of the HCR.

##### 1. Restrictions on Recommendations and Endorsements

Recommendations and endorsements of food products by HCPs and their associations are subject to Articles 11 and 12(c) HCR. Article 11 states that “*in the absence of specific Community rules concerning recommendations of or endorsements by national associations of medical, nutrition or dietetic professionals and health-related charities, relevant national rules may apply in compliance with the provisions of the Treaty*”. Article 12(c), on its part, prohibits the use of health claims which make reference to “*recommendations of individual doctors or health professionals and other associations not referred to in Article 11*”.

A presumption exists that associations of HCPs act without any promotional intent<sup>33</sup>. This is why Article 11 of the HCR allows, in the absence of con-

trary specific Community provisions and subject to national legislation (including any deontological codes for the relevant regulated profession), recommendations or endorsements of food products by national associations of medical, nutrition or dietetic professionals and health-related charities.

The rationale remains that properly qualified HCPs such as nurses, dentists and pharmacists, nutritionists and dieticians may provide recommendations helpful to consumers regarding diet, foods and health as a means of preventing specific diseases. Their contribution in providing specialist advice is therefore welcomed<sup>34</sup>.

Both a literal reading of these provisions and the interpretation arising from their legislative *iter* point towards a restrictive approach of their scope of application. In effect, as it arises from Article 11(d) of the initial Commission legislative proposal, Article 12(c) was to ban all claims making reference to (i) “*the advice of doctors or other health professionals*”, (ii) “*their professional associations*”, and (iii) “*charities*”. Only at a later stage was the total ban relaxed, taking into account that such an outright prohibition could be too restrictive since it would prevent certain professional organizations and charities from promoting a healthier diet as a means of preventing specific diseases. Thus, it was agreed to exempt certain associations and health-related charities, and allow Member States to keep or adopt their own rules in this regard<sup>35</sup>.

Insofar as they are used in commercial communications, endorsements and recommendations by HCP, associations may only be referred to when the following cumulative conditions are fulfilled: (i) the recommendation or endorsement is carried out exclusively by associations of medical, nutrition or dietetic professionals or health-related charities; (ii) neither the rules nor the administrative practice of

33 The Opinion of the European Economic and Social Committee of 26 February 2004 on the HCR Proposal, while recognizing the benefits of healthcare professional advice and supporting the introduction of Article 11, warned that “*possible dependence [of the scientific community] on financial support or sponsorship should be monitored as they may provide endorsements for foods which are simply promotional deals not based on any set standards or open to other competing brands. Moreover, clear criteria must be developed concerning the acceptability of sponsorship*”. Opinion of the European Economic and Social Committee on the Proposal for a Regulation of the European Parliament and of the Council on nutrition and health claims made on foods (COM(2003) 424 final – 2003/0165 (COD)), section 4(7).

34 Recommendation of 29 March 2006 for Second Reading on the Council common position for adopting a regulation of the European Parliament and of the Council on nutrition and health claims made on foods (9858/3/2005 – C6-0018/2006 – 2003/0165(COD)), amendment 26.

35 The Report on the Proposal for a HCR provided by the European Parliament at 1st reading on May 12, 2005 still included the ban on claims referring to the advice of doctors or other health professionals, or their professional associations, or charities (*vid.* Amendment 42, referring to Article 11), but opened a possibility to have them authorized if scientifically substantiated and notified in accordance with the HCR.

the Member State at hand oppose the use of such endorsements; (iii) the association recommending or endorsing the product at hand has been legally established or recognized under the laws of a Member State of the EU; and (iv) the claim which the product bears fully complies with the HCR.

(i) *Endorsements by international associations*

The term “national associations” in Article 11 of the HCR relates to the requirement for the associations to be legally established or recognized under the laws of a Member State of the EU<sup>36</sup>, irrespective of the nationality of their different members or the scope of their activities, which can be national or international. Thus, most *international* associations of medical, nutrition or dietetic professionals operating in the EU are, in fact, associations legally established or recognized under the laws of a Member State (i.e. *national* associations in the sense of Article 11)<sup>37</sup>.

This interpretation has been confirmed by the European Commission and the Member States which informally agreed within the *Working Group on Nutrition and Health Claims* that international associations could be treated equally to national associations<sup>38</sup>.

Finally, as the definition of association has not been harmonized under Community law, the assessment of whether a given entity has been legally established or recognized under the laws of a Member State of the EU (i.e. it qualifies as a “national association”) must be performed on a case-by-case basis, in the light of the relevant national legislation.

To sum up, the HCR permits endorsements and recommendations of food products by *international* associations of medical, nutrition or dietetic profes-

sionals provided that these associations have been legally established or recognized under the laws of a Member State of the EU and the other conditions have been complied with.

(ii) *The specific case of partnerships with research institutes*

Communicating on partnerships between a food company and a research institution of any kind is not prohibited *per se* by the HCR. However, informing about the existence of partnerships (e.g. joint research projects) is not entirely without risks, since it may amount to an implicit endorsement or recommendation of the partner institution. Although some rules of thumbs apply (e.g. not to incorporate any health or nutrition claims in the communication or not making references to a specific product), this analysis should be performed on a case-by-case basis.

## 2. Restrictions on Recommendations by individual HCPs: The Concept of “Non Commercial” Communications

As it has been highlighted at the outset, the HCR does not apply to *non-commercial communications*, which, according to Recital 4, includes information in the press and in scientific publications. However, neither the HCR nor Regulation 178/2002 further defines the concepts of *commercial* or *non-commercial communications*.

(i) *Legal Definitions*

According to Directive 2006/123 on services in the internal market and Directive 2000/31 on certain legal aspects of information society services, in particular electronic commerce, in the Internal Market,

36 The European Parliament stressed at 1st reading that “claims referring to doctors’ or other health professionals’ opinions, or those of associations of various kinds, should be permitted only on a restricted basis, i.e. where they refer, on the basis of common criteria, to associations that have been duly recognised (at least by the Member State concerned)”. Document A6-0128/2005. The Commission subsequently confirmed that claims referring to “non recognized health professionals and other associations” remain prohibited [Communication from the Commission to the European Parliament, document COM(2006)2final].

37 For instance, the Standing Committee of European Doctors (CPME, *Comité Permanent des Docteurs Européens*) is an international organization established under Belgian law. According to Article 1 of CPME statutes, “An International Association is constituted with a philanthropic, scientific and pedagogical

object under the name: “Standing Committee of European Doctors”. This Association is formed in accordance with Title III of the Belgian Act of 27th June 1921”. Similarly, the statutes of the European Federation of Nurses Associations (EFN), a federation of national nurses associations, states that “[t]he European Federation of Nurses Associations (EFN) is governed by the Belgian law on international non-profit organizations and foundations of 27 June 1921, as amended by the law of 2 May 2002”, etc.

38 Cf. Food Standards Agency, Interested Parties’ letter: Commission Working Group on Nutrition and Health Claims, June 5, 2008 (not published): “On Article 11 and whether international (and European) associations and health-related charities could be treated in the same way as national associations, Member States and the Commission agreed that this should not present a problem”.

commercial communications are defined as “any form of communication designed to promote, directly or indirectly, the goods, services or image of an undertaking, organization or person engaged in commercial, industrial or craft activity or practicing a regulated profession”<sup>39</sup>. Similarly, Directive 89/552 concerning television broadcasting activities describes ‘audiovisual commercial communication’ as “images with or without sound which are designed to promote directly or indirectly, the goods, services or image of a natural or legal entity pursuing an economic activity”<sup>40,41</sup>.

On the other hand, “communications relating to the goods, services or image of the undertaking, organization or person, compiled in an independent manner, particularly when provided for no financial consideration do not, in themselves constitute commercial communications”<sup>42</sup>.

Commercial communications include advertising<sup>43</sup>, which is generally defined by its business connection on the one hand, and its promotional purpose on the other. Advertising is defined in Directive 2006/114 on misleading advertising as “the making of a representation in any form in connection with a trade business, craft or profession in order to promote the supply of goods or services, including immovable property, rights and obligations”<sup>44</sup>.

Whilst the HCR does not have an independent definition of ‘advertising’, other legal acts may, in view of particular public health considerations, pro-

vide for a broader definition. Thus, the definition provided in Directive 2003/33 on the advertising of tobacco products includes any direct or indirect promotional effect, irrespective of the purpose of the communications<sup>45</sup>. Further, Directive 2001/83 does not require that the advertising of medicinal products be made in a context of commercial or industrial activity, whereas Directive 2006/114 limits that definition to the marking of a representation “in connection with a trade, business, craft or profession”<sup>46</sup>.

It arises from the above definitions that:

- (i) the promotional purpose is the main criterion to differentiate *commercial* from *non-commercial communications*, irrespective of the means used to disseminate the information to the final consumers, i.e. directly by the legal entity marketing the promoted products or indirectly via a third party, or the form of appearance (e.g. a press release);
- (ii) a promotional purpose is excluded *per se* in the case of communications compiled in an independent manner particularly provided for no financial consideration. Conversely, a promotional effect does not convert *per se* communications compiled in an independent manner into *commercial communications*; and
- (iii) statements from third parties need to be made in connection with a trade, business, craft or profession to be classified as *commercial*.

39 Directive 2006/123/EC of the European Parliament and of the Council of 12 December 2006 on services in the internal market (OJ L 376/36 of 27.12.2006), and Directive 2000/31, cited in note 13.

40 Council Directive 89/552/EEC of 3 October 1989 on the coordination of certain provisions laid down by Law, Regulation or Administrative Action in Member States concerning the pursuit of television broadcasting activities (OJ L 298 of 17.10.1989), as modified by Directive 2007/65/EC of the European Parliament and of the Council of 11 December 2007 (OJ L 332 of 18.12.2007).

41 As per Directive 89/552 on Television Broadcasting, forms of audiovisual commercial communication include, *inter alia*, television advertising, sponsorship, teleshopping and product placement. See note 39 *supra*.

42 Directive 2006/123 and Directive 2000/31, cited in notes 38 and 13 *supra*.

43 According to Directive 2005/29, cited in 13 *supra*, commercial practices are “any act, omission, course of conduct or representation, commercial communication including advertising and marketing, by a trader, directly connected with the promotion, sale or supply of a product to consumers”.

44 Similarly, Directive 89/552 on television broadcasting defines television advertising as “any form of announcement broadcast whether in return for payment or for similar consideration or broadcast for self-promotional purposes by a public or private undertaking or natural person in connection with a trade, business, craft or profession in order to promote the supply of goods or services, including immovable property, rights and obligations, in return for payment”.

45 ‘Advertising’ is defined as “any form of commercial communications with the aim or direct or indirect effect of promoting a tobacco product” (our emphasis). *Vid.* Directive 2003/33 on tobacco, cited in note 13 *supra*.

46 Directive 2001/83 provides that “‘advertising of medicinal products’ shall include any form of door-to-door information, canvassing activity or inducement designed to promote the prescription, supply, sale or consumption of medicinal products”. According to the advocate general Ruiz-Jarabo Colomer, “the omission in the [Medicinal Products Directive] to reproduce the definition of advertising given in the [Directive on Misleading Advertising] and the [Directive on Television Broadcasting] (which also contains the factor of the connection with the trade or business) was wholly intentional” (Cf. Opinion of Advocate General Ruiz-Jarabo Colomer, delivered on 18 November 2008, *Frede Damgaard*, Case C-421/07).



(ii) *Applicability of the CJEU Case-Law on Third Party Statements to Foodstuffs*

In the absence of rulings on the concept of *commercial communications* in food law, reference can be made to other categories of products for which this question has been raised before the CJEU. Insofar as Directive 2001/83 on medicinal products is concerned<sup>47</sup>, the Court has clarified that claims from third parties acting on their own initiative and completely independently *de jure* or *de facto* from the manufacturer or the seller of a product would not affect the *classification* of products as medicinal since they do not disclose an intention on the part of the manufacturer or seller to market the products as medicinal products<sup>48</sup>. Such statements could nevertheless be construed as advertising, if the claims relate to a product that has already been classified as medicinal<sup>49,50</sup>.

Such a restrictive approach is justified by the particular public health considerations underlying the marketing of medicinal products, which finds its expression in a total ban on the advertising of prescription medicinal products to the general public. Thus, the advertising of medicinal products “*even where it is carried out by an independent third party outside any commercial or*

*industrial activity, (...) is liable to harm public health, the safeguarding of which is the essential aim of Directive 2001/83*”<sup>51</sup>.

Similar public health concerns justify the bans on advertisement for tobacco products<sup>52</sup>, infant formulae<sup>53</sup>, and, to some extent, alcoholic beverages<sup>54,55</sup>.

This is not the case for foodstuffs.

Firstly, because the HCR does not prohibit advertising foodstuffs with health claims, but merely subjects them to certain conditions. Secondly, because it expressly excludes from its scope of application “*non commercial communications in the press*”. Thirdly, because, unlike the definition of ‘*advertising*’ laid down in Directive 2006/114 on misleading advertising, the definition provided for in Directive 2001/83 does not require a message to be disseminated in the context of a commercial or industrial activity to be held as advertising.

(iii) *Limits: The Disguised Forms of Advertising*

As it has been just shown, communications – be they in the form of private recommendations or publications – addressed by HCPs to the final consumer of foods that have been advertised to them would not, in principle, be caught by the

47 Directive 2001/83, cited in note 16 of *supra*.

48 Judgment of the CJEU of October 28, 1992, *Ter Voort*, cited in note 25 *supra*.

49 See in particular: Ekstrand & Haagaard, *Who can Speak freely? – Can independent parties be held liable for their statements and to what extent can a company make use of third party testimonials*, European Food and Feed Law Review, 3/2009, pp. 192–195.

50 Judgement of the CJEU of April 2, 2009, *Frede Damgaard*, Case C-421/07, Rec.p.I-02629. According to paragraph 24, “[t]he situation of the author of a communication about a medicinal product and, in particular, his relationship with the company which manufactures or distributes it, are a factor which, although it may help to determine whether the communication constitutes advertising, must be evaluated together with other circumstances, such as the nature of the activity carried out and the content of the message”.

51 Judgement of the CJEU on *Frede Damgaard*, paragraph 22, cited *supra* in note 28. Recital (45) of Directive 2001/83 states: “[a]dvertising to the general public, even of non-prescription medicinal products, could affect public health, were it to be excessive and ill-considered. Advertising of medicinal products to the general public, where it is permitted, ought therefore to satisfy certain essential criteria which ought to be defined”.

52 Directive 2003/33 on tobacco advertising prohibits the advertising of tobacco products in the press, other printed publications, or in information society services that are addressed to the general public. Directive 89/552 on television broadcasting prohibits all forms of television advertising for cigarettes and other tobacco products, as well as the sponsorship of television programmes by undertakings whose principal

activity is the manufacture or sale of cigarettes and other tobacco products, or the provision of services the advertising of which is prohibited in that Directive; and teleshopping for tobacco products.

53 Article 14 of Directive 2006/141, cited in note 16 *supra*, restricts advertising of infant formulae to publications specialising in baby care and scientific publications.

54 According to consistent case-law of the CJEU, a provision that limits the possibilities of advertising of alcoholic beverages as a means of combating alcoholism responds to public health concerns (*Vid.* CJEU judgments of 10 July 1980, *Commission/France*, case 152/78, Rec.p.I- 02299, paragraph 17; of 25 July 1991, *Aragonesa de Publicidad Exterior and Publivia*, joined Cases C-1/90 and C-176/90, Rec.p.I-04151 para. 15; or 8 March 2001, *Konsumtombudsmannen v. Gourmet International Products AB*, C-405/98, Rec.p.I-01795, para. 27).

55 According to the CJEU’s settled case-law, the freedom of expression may only be limited when justified by objectives in the public interest by a pressing social need and, in particular, proportionate to the legitimate aim pursued. The possibility of such a restriction has also been raised in relation to the advertising of tobacco products. *Vid.* the Judgement of the CJEU of 12 December 2006, *Germany v European Parliament and Council of the European Union*, Case C-380/03, Rec.p.I-11573, para. 155, and additionally: the Judgments of 26 June 1997, *Vereinigte Familienpress Zeitungsverlags- und vertriebs GmbH v Heinrich Bauer Verlag*, Case C-368/95, Rec.p.I-03689, para. 26; of 11 July 2002, *Mary Carpenter v Secretary of State for the Home Department*, Case C-60/00, Rec.p.I-06279, para. 42; and of 12 June 2003 *Eugen Schmidberger, Internationale Transporte und Planzüge v Republik Österreich*, Case C-112/00, Rec.p.I-05659, para. 50.

HCR. However, this conclusion could be rebutted if these communications were, in fact, a disguised form of advertising.

Recommendations or publications by HCPs referring to health or nutritional benefits of foods would be construed as a disguised form of advertising if the HCP does not act *independently* from food business operators.

This would be the case if a food business operator provides financial or non financial inducement to the HCP, who obtains a direct or indirect, tangible or intangible benefit by communicating on the said products. The existence of remuneration would provide strong evidence that the HCP is not acting in an independent manner, as would any gain in kind, indirect or future benefit. This would also be the case if a food business operator enters in a reciprocal agreement with the HCP. Even in the absence of remuneration, the existence of an arrangement with the HCP could reflect a promotional intention.

It is worth noting in this regard that the *UK Advertising Standards Agency* has ruled on various occasions that the publication of an editorial article related to a specific product – including food supplements – had to be considered as a *commercial communication*. The main grounds for qualifying the articles as commercial were: the setting of the articles in the same visual field as an advertisement relating to the same product; overt and exclusive promotion of the product by the articles; express references in the articles to the product object of the advertisement, naming of the company's internet website and contact details in the text of the articles; and the reciprocal agreement between the company marketing the product and the journalist to publish the articles jointly with the advertisements, despite the absence of remuneration<sup>56</sup>.

For its part, *Autocontrol (Asociación para la Autorregulación de la Comunicación Comercial)*, the Spanish advertising regulatory body, considered an editorial article in relation to a medicinal product appearing in a newspaper to be of an advertising

nature despite the absence of a remuneration by the company marketing the product for its publication<sup>57</sup>. According to the jury, the advertising character of the article could be inferred from the following elements: absence of journalistic relevance (the product object of the article had not recently been launched on the market); mention of the brand instead of the generic name of the active principle or medicine; obvious laudatory tone focusing on the benefits of the product; origin of the article in a press release transmitted by the company marketing the product to the media; and simultaneous publication of a similar article in a magazine also addressed to the general public.

In sum, albeit not sufficient to convert recommendations or publications by HCPs into commercial communications, the fact that the foods object of the HCPs' communications have been previously advertised to them could lead to such a conclusion when occurring in conjunction with other elements. For instance, if the HCPs recommend the products in an unequivocally laudatory tone, if references are made to particular brands, or if several articles are published in favour of the same foods in a short period of time. If the interested food business operator refers to the HCPs recommendations or publications, the latter would fall under the prohibition of Article 12(c) HCR.

## V. Concluding Remarks

When advertising their products to HCPs, food business operators do not have to comply with the stringent requirements of the HCR. This opens a possibility to disclose information about recent studies that may or may not have a beneficial health effect, studies which, in the frame of the authorization procedures established by the HCR, may not receive the EFSA stamp of generally accepted scientific evidence. Due to their educational and professional background, HCPs are better positioned to interpret the information made available to them.

In any event, when communicating to HCPs, food business operators would have to comply with the requirements established by Directive 2006/114.

On the other hand, in communications on the health properties of foodstuffs originating from HCPs, the promotional purpose is the key to determining their *commercial* character and the ensuing application of the HCR. Such promotional character

56 ASA adjudications: *Express Newspapers and Goldshield Ltd*, August 12, 2009, (Ref. 94069); *Goldshield Ltd and Express Newspapers*, August 19, 2009 (Ref. 93309); *Express Newspapers and Orthotics Online Ltd*, August 12, 2009, (Ref. 100347); *Express Newspapers and LadyCare Lifetime Ltd*, August 12, 2009, (Ref. 100356).

57 *Autocontrol*, Sección Segunda del Jurado, Xenical, 4 de octubre de 2001.

is *per se* excluded in case of communications compiled in an independent manner, particularly provided for no financial consideration, but will be caught by the HCR if they are, in fact, a disguised form of advertisement.

The provision of financial or non financial inducement to the HCP or even the existence of a reciprocal agreement between the food business operator and the HCPs to issue a communication on a product will point the way towards the existence of a commercial communication. Several elements, when assessed in conjunction, could lead to a simi-

lar conclusion (e.g. the unequivocally laudatory tone of the article, the naming of the products or their distinctive ingredients, a simultaneous publication in several media, the absence of journalistic relevance, or the reference to the article in the food business operator's commercial communications, etc.).

A case-by-case analysis is therefore indispensable before any attempt at classification.

In sum, several and complex legal issues arise in connection with HCPs and health benefits of foods. Different interpretations may be put forward. Time (or, rather, the CJEU) will prove us right (or not).