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Authorized Health Claims Pursuant to Regulation (EC) No 1924/2006: The Difficulty of Producer-Consumer Communication

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Authorized Health Claims pursuant to Regulation (EC) No 1924/2006: the difficulty of producer-consumer communication

Luis González Vaqué[1]

"Si nosaltres callem, qui parlarà?"
Miquel Martí i Pol (1929 – 2003)

I. Introduction

Consumer information is one of the most important and *popular*[2] tools in consumer policy and protection, and will be for the foreseeable future. It is "important" because of its role in correcting imbalances in communication (whether of a commercial nature or not), and enabling consumers to make transactional decisions based on their own preferences and needs. And it is "popular"[3] because consumer information is usually seen as the least meddling kind of administrative requirement, even when mandatory. It gives business operators a certain degree of autonomy and in many cases renders unnecessary the enforcement of other consumer protection laws, such as those dealing with the structure or composition of products[4].

There is no need to dwell here on the importance and need for information about the food we purchase and consume. Already by the end of the 1970s the Community legislator considered that "the prime consideration for any rules on the labelling of foodstuffs should be the need to inform and protect the consumer" (see the sixth recital of Directive 79/112/CEE[5]).

This statement of purpose has been confirmed, at times almost literally, by successive community regulations:

● "The prime consideration for any rules on the labelling of foodstuffs should be the need to inform and protect the consumer" (the sixth recital of Directive 2000/13/CE,[6] still in force).

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[2] See HELBERGER, N., "Form matters: informing consumers effectively", Institute for Information Law (IViR), University of Amsterdam, 2013, p. 4 (text available in the following Internet page, consulted on 15 November 2013: http://741513.websites.xs4all.nl/publications/helberger/Form_matters.pdf

[3] *ibid*, also at p. 4.

[4] According to SWINDELLS, J. A., such product regulations "…either obstruct market development and innovation, are soon overtaken by technological changes, do not serve their intended purpose, or are impossible to obey..." (see SWINDELLS, J. A., "¿Etiquetado o información alimentaria?: Más de lo mismo...", *Gaceta del InDeAl*, Vol. 10, No. 4, 2008, 23-24).

[5] Council Directive 79/112/EEC of 18 December 1978 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs for sale to the ultimate consumer (OJ L 33, 8.2.1979, p. 1) was the first community directive that regulated *horizontally* the information that could or should be given to consumers where no specific legislation was applicable (vertical rules).

[6] 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, 6.5.2000, p. 29). Text of the consolidated version available in the following Internet page, consulted on 1 October 2013: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:2000L0013:20110120:ES:PDF [In regard to this Directive see BUREAU, J. C. and VALCESCHINI, E., "European food-labeling policy: successes and limitations", *Journal of Food Distribution Research*, Vol. 34, No. 3, 2013, 70-74; CHEFTEL, J. C., "Food and nutrition labelling in the European Union", *Food Chemistry*, Vol. 93, No. 3, 2005, 531–550; LUCAS-

● "Consumers demand more and *better* information on labels and are interested in clear, simple, comprehensive, standardised and authoritative information" (see section 2 of the Explanatory Memorandum of the "Proposal for a Regulation of the European Parliament and of the Council on the provision of food information to consumers"[7]).

● "The proposal harmonises the regulatory framework for the horizontal provisions regarding food labelling and thus contributes to consumer protection by ensuring that consumers receive appropriate information to enable them to make informed, safe, healthy and sustainable choices. The proposed measures are sufficient in terms of reaching the objectives of ensuring consumers are enabled to make informed choices and to securing the smooth functioning of the internal market. At the same time they do not impose an excessive or unjustified burden." (*Ibidem*, section 3).

● "In order to achieve a high level of health protection for consumers and *to guarantee their right to information*[8], it should be ensured that consumers are appropriately informed as regards the food they consume. Consumers' choices can be influenced by, inter alia, health, economic, environmental, social and ethical considerations." [Third recital of Regulation (EU) No 1169/2011,[9] partially enforceable from 13 December 2014[10]].

Following on from the above, two further points are worth noting:

- according to 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

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PUGET, A. S., "Les allégations sur les produits alimentaires de consommation courante: Quelques questions d'actualité", *Les Petites affiches*, Vol. 395, No. 103, 2006, 4-16; PRZYREMBEL, H., "Food labelling legislation in the EU and consumers information", *Trends in Food Science & Technology*, Vol. 15, No. 7–8, 2004, 360–365; and PUOTI, P., "Etichettatura dei prodotti agroalimentari: aspetti problematici", *Diritto comunitario e degli scambi internazionali*, No. 3, 2004, 613-648].

[7] COM (2008) 40 final of 30 January 2008. On this Proposal, see CHARLIER, C. and NGO, M-A., "Informer les consommateurs au détriment de la libre circulation des marchandises. Un dilemme pour le Parlement européen", *Économie rurale*, No. 323, 2011, 71-76; and LINDNERA, L. F., "Regulating food safety: the power of alignment and drive towards convergence", *Innovation - The European Journal of Social Science Research*, Vol. 21, No. 2, 2008, 133-143).

[8] Emphasis added by the author.

[9] 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 Text with EEA relevance (OJ L 304, 22.11.2011, p. 18). On this Regulation see: COSTATO, L., BORGHI, P. and RIZZIOLI, S., "Compendio di diritto alimentare", CEDAM, 2013,220-233; BREMMERS, H., "An Integrated Analysis of Food Information to Consumers: Problems, Pitfalls, Policies and Progress", *Proceedings in Food System Dynamics*, 2012, 614–627 (available at http://131.220.45.179/ojs/index.php/proceedings/article/view/262/243 , last accessed on 27 February 2013:); FERRO, M. and IZZO,.U., "Diritto alimentare comparato", Il Mulino, 2012, 126–131; and NIHOUL, P. and VAN NIEUWENHUYZE, E., "L'étiquetage des denrées alimentaires: une pondération réussie entre intérêts contradictoires?", *Journal de droit européen*, Vol. 20, No. 192, 2012, 237-243.

[10] See: "The New European Regulation on Food Labelling: Are we Ready for the 'D' day on 13 December 2014?", EFFL, No. 3, 2013, 158-167.

and laying down procedures in matters of food safety[11] *it is a general principle of food law to provide a basis for consumers to make informed choices in relation to food they consume and to prevent any practices that may mislead the consumer*; 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[12] *covers certain aspects of the provision of information to consumers specifically to prevent misleading actions and omissions of information*.

Of course, of all the consumer information which can or must be provided through the labelling of foodstuffs the most crucial concerns health. As article 3.1 of Regulation No 1169/2011[13] states: "The provision of food information shall pursue a high level of protection of consumers' health and interests by providing a basis for final consumers to make informed choices and to make safe use of food, with particular regard to health, economic, environmental, social and ethical considerations". What this provision foresees is articulated in article 4.1 of said Regulation:

> "Where mandatory food information is required by food information law, it shall concern information that falls, in particular, into one of the following categories:
>
> […]
>
> (b) information on the protection of consumers' health and the safe use of a food. In particular, it shall concern information on:
>
> (i) compositional attributes that may be harmful to the health of certain groups of consumers;
> (ii) durability, storage and safe use;
> (iii) the health impact, including the risks and consequences related to harmful and hazardous consumption of a food;
> iii) los efectos sobre la salud, incluidos los riesgos y las consecuencias relativos al consumo perjudicial y peligroso de un alimento;
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> (c) information on nutritional characteristics so as to enable consumers, including those with special dietary requirements, to make informed choices."

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[11] OJ L 31, 1.2.2002, p. 18 [on this Regulation see "Objetivo: la seguridad alimentaria en la Unión Europea (el Reglamento (CE) n. 178/2002)", *Gaceta Jurídica de la UE*, No. 223, 2003, 59-71; FOURGOUX JEANNIN, M. V., "La construcción europea de la autonomía del Derecho alimentario" en BOURGES, L., *Sociología y Derecho alimentarios*, Aranzadi, 2013, p. 76; and HAGENMEYER, M., "Modern food safety requirements: according to EC Regulation no. 178/2002", *Zeitschrift für das gesamte Lebensmittelrecht*, Vol. 29, No. 4, 2002, 443-459].

[12] OJ L 149, 1.5.2005, p. 22 (on this Directive see: "La Directiva 2005/29/CE relativa a las prácticas comerciales desleales en materia de protección de consumidores: entre el objetivo de una armonización total y el *enfoque de plena armonización*», *Derecho de los negocios*, No. 181, 2005, 5-18; "La mise en oeuvre de la directive 2005/29/CE sur les pratiques commerciales déloyales : Les consommateurs vulnerables sont-ils suffisamment protégés?", *Revue du droit de l'Union Européenne*, No. 3, 2013, 471-490; BOURGES, L., "La discutible elección de un nivel de armonización adecuado y eficaz en el ámbito del Derecho del Consumo de la UE: ¿armonización máxima, total o completa?", *Gaceta del InDeAl*, Vol. 8, No. 3-4, 2006, 10-12; and HOWELLS, G., "Unfair Commercial Practices Directive – A Missed Opportunity?" en *The Regulation of Unfair Practices under EC Directive 2005/29*, Hart Publishing, 2007, 103-114.

[13] See footnote 9.

As regards information which is voluntarily provided, the basic principle applied since 1978[14] has been that "…the rules on labelling should also prohibit the use of information that would mislead the purchaser or attribute medicinal properties to foodstuffs"[15].

However the adoption of 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[16] (OJ L 404, 30.12.2006, p. 9), largely in response to business needs, has meant an exception that has been introduced into EU legislation covering the labelling of foodstuffs. It is this controversial Community Regulation which I shall be focussing on in the rest of this paper, and in particular the difficulties faced by consumers in understanding *health claims* so far authorised within the framework of its procedures, without of course neglecting the restrictions imposed on business operators when it comes to conveying properly the information in question.

II. 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[17]

1. *From functional claims to health claims*

Much has already been written about Regulation (EC) No 1924/2006[18], so I will limit myself here to recalling that in its White Paper on food safety [final COM (99) 719 of 12 January 2000], the Commission proposed to examine whether specific provisions should be introduced in EU law to govern "functional claims " (for example claims related to beneficial effects of a nutrient on certain normal bodily functions). Six years later, this proposal finally materialised in the form of Regulation (No 1924/2006) which "… harmonises the provisions laid down by law, regulation or administrative action in Member States which relate *to nutrition and health claims*[19] in order to ensure the effective functioning of the internal market whilst *providing a high level of consumer protection*[20]" (article 1.1).

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[14] See article 2.1(b) of Directive 79/112/CEE, quoted in footnote 5: "Furthermore, Article 2 (1) (b) of Directive 2000/13/EC […] prohibits the attribution of preventing, treating and curing properties to foods" [see paragraph 1 of the Explanatory Memorandum of 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 document of 16 July 2003, available at: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2003:0424:FIN:ES:PDF (last accessed on 16 November 2013)

[15] See recital no. 20 of Regulation No. 1169/2011, mentioned at footnote 9.

[16] See the extensive bibliography on Regulation No. 1924/2006 at http://derechoconsumo.blogspot.com.es/2007/02/etiquetado-reglamento-n-19242006.html (last accessed on 16 November 2013)

[17] The last consolidated version of this Regulation is available at http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:2006R1924:20121129:ES:PDF (last accessed on 16 November 2013)

[18] See footnote 16.

[19] Emphasis added by the author.

[20] *Idem*.

The Community legislator included the following definitions (amongst others) in the Regulation:

- "*claim* means any message or representation, *which is not mandatory under Community or national legislation*[21], including pictorial, graphic or symbolic representation, in any form, which states, suggests or implies that a food has particular characteristics" [article 2.2(1) of Regulation No 1924/2006]; and

- "*health claim* means any claim that states, suggests or implies that a relationship exists between a food category, a food or one of its constituents and health" [*ibidem*, article 2.2(5)].

Likewise article 2.2(6) provides that "*reduction of disease risk claim* means any health claim 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".

2. *Consumer "understanding" and its importance in relation to the authorization and use of health claims*

Recital No. 16 of Regulation No 1924/2006 clearly states that "it is important that claims on foods can be understood by the consumer[22] and it is appropriate to protect all consumers from misleading claims," while article 5.2 2 expressly provides that "the use of nutrition and health claims shall only be permitted *if the average consumer can be expected to understand the beneficial effects as expressed in the claim*[23]".

It is therefore evident that the *intelligibility* of the claims in question is a *sine qua non* condition of their authorization and use.[24]

Elsewhere, article 3 of the Regulation ("General principles for all claims") provides the following:

> "Without prejudice to Directives 2000/13/EC[25] and 84/450/EEC[26], the use of nutrition and health claims shall not:

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[21] *Idem*.

[22] The Community legislator refers to "the average consumer, who is reasonably well-informed and reasonably observant and circumspect, taking into account social, cultural and linguistic factors, as interpreted by the Court of Justice" (recital No. 16 of Regulation No 1924/2006). See also article 13.1(ii); as well as "La notion de 'consommateur moyen' selon la jurisprudence de la Cour de justice des Communautés européennes", Revue du droit de l'Union Européenne, No. 1, 2004, 69-92, and in particular "Las nociones 'consumidor medio' y 'miembro medio de un grupo particular de consumidores' en el Reglamento n° 1924/2006 (declaraciones nutricionales y de propiedades saludables en los alimentos)", *Gaceta jurídica de la UE*, No. 247, 2007, 9-19.

[23] Emphasis added by the author.

[24] See MARTÍNEZ PORRERA, E. and VIDRERAS PÉREZ, C., "¿Todos contra el Reglamento (UE) nº 1924/2006 relativo a las declaraciones nutricionales y de propiedades saludables en los alimentos?", *BoDiAlCo*, No. 3, 2013, 8-9.

[25] See footnote 6.

[26] Repealed and substituted by Directive 2006/114/EC of the European Parliament and of the Council of 12 December 2006 concerning misleading and comparative advertising (OJ L 376, 27.12.2006, p. 21).

(a) be false, ambiguous or misleading;

(b) give rise to doubt about the safety and/or the nutritional adequacy of other foods;

(c) encourage or condone excess consumption of a food;

(d) state, suggest or imply that a balanced and varied diet cannot provide appropriate quantities of nutrients in general. Derogations in the case of nutrients for which sufficient quantities cannot be provided by a balanced and varied diet, including the conditions for their application, and designed to amend non-essential elements of this Regulation by supplementing it may be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 25(3), taking into account the special conditions present in Member States;

(e) refer to changes in bodily functions which could give rise to or exploit fear in the consumer, either textually or through pictorial, graphic or symbolic representations."

It is worth adding that in order to ensure consumers *adequately* understand the above statements article 10 ("Specific conditions") provides *inter alia* that

2. Health claims shall only be permitted if the following information is included in the labelling, or if no such labelling exists, in the presentation and advertising:

(a) a statement indicating the importance of a varied and balanced diet and a healthy lifestyle;

(b) the quantity of the food and pattern of consumption required to obtain the claimed beneficial effect;

(c) where appropriate, a statement addressed to persons who should avoid using the food; and

(d) an appropriate warning for products that are likely to present a health risk if consumed to excess."

3. Some examples…

Brevitatis causae, I will refrain from discussing the complex procedures laid down in Regulation No 1924/2006 for the authorization of health claims at the request of the interested party[27]. These procedures are covered in detail by articles 15, 16 and 17 of the Regulation, and suffice to say that it has been the subject of much criticism, with requests often ending up being unreasonably refused.

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[27] See for example the EFSA guidelines in "Opinion of the Panel on dietetic products, nutrition and allergies (NDA) on a request from the Commission related to scientific and technical guidance for the preparation and presentation of the application for authorisation of a health claim" available at http://www.efsa.europa.eu/EFSA/Scientific_Opinion/nda_op_ej530_guidance_%20health_claim_en.pdf.pdf (last accessed on 21 November 2013)

It is nevertheless worth mentioning that authorised health claims are entered *ex officio* onto the Community Register[28], as provided for by article 20 of Regulation No 1924/2006. Here are some randomly chosen examples of such claims[29]:

- "*Carbohydrates*[30] contribute to the maintenance of normal brain function"[31].

- "*Barley beta-glucan*[32] has been shown to lower/reduce blood cholesterol. High cholesterol is a risk factor in the development of coronary heart disease."[33].

- "*Activated charcoal*[34] contributes to reducing excessive flatulence after eating"[35].

- "*Sugar-free chewing gum*[36] helps neutralise plaque acids. Plaque acids are a risk factor in the development of dental caries."[37]

- "*Docosahexaenoic acid (DHA)*[38] intake contributes to the normal visual development of infants up to 12 months of age."[39].

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[28] The Community Register can be viewed at: http://ec.europa.eu/nuhclaims/

[29] The examples are in fact taken from a paper entitled "¿Es posible que el consumidor medio entienda las declaraciones de propiedades saludables que, en virtud del Reglamento (UE) nº 1924/2006, pueden incluirse en el etiquetado alimentario?". The editor of the paper, NOBELLAR, O., claims to have chosen the claims at random i.e. he chose neither the most difficult nor the easiest ones to *interpret*…

[30] The italics are used to show which claim each nutrient, substance, food or food category refers to.

[31] See Commission Regulation (EU) No 1018/2013 (OJ L 282, 24.10.2013, p. 43), which sets out the following conditions of use in the case of this claim: "In order to bear the claim, information shall be given to the consumer that the beneficial effect is obtained with a daily intake of 130 g of carbohydrates from all sources. The claim may be used for food which contains at least 20 g carbohydrates which are metabolised by humans, excluding polyols, per quantified portion and complies with the nutrition claim LOW SUGARS or WITH NO ADDED SUGARS as listed in the Annex to Regulation (EC) No 1924/2006."

[32] See footnote 30.

[33] See Commission Regulation (EU) No 1048/2012 (OJ L 310, 9.11.2012, p. 38) which sets out the following conditions of use in the case of this claim: "Information shall be given to the consumer that the beneficial effect is obtained with a daily intake of 3 g of barley beta-glucan. The claim can be used for foods which provide at least 1 g of barley beta- glucan per quantified portion."

[34] See footnote 30.

[35] See Commission Regulation (EU) No 665/2011 (OJ L 182, 12.7.2011, p. 5) which sets out the following conditions of use in the case of this claim: "The claim may be used only for food which contains 1 g of activated charcoal per quantified portion. In order to bear the claim information shall be given to the consumer that the beneficial effect is obtained with 1 g which should be taken at least 30 minutes before and 1 g shortly after the meal".

[36] See footnote 30.

[37] See Commission Regulation (EU) No 432/2012 (OJ L 136, 25.5.2012, p. 1) which sets out the following conditions of use in the case of this claim: "Information shall be given to the consumer that the beneficial effect is obtained with chewing of 2-3 g of sugar-free chewing gum for 20 minutes, at least three times per day after meals".

[38] See footnote 30.

[39] See Commission Regulation (EU) No 432/2012 (OJ L 136, 25.5.2012, p. 1), which sets out the following conditions of use in the case of this claim: "Information shall be given to the consumer that the beneficial effect is obtained with a daily intake of 100 mg of DHA. When the claim is used on follow-on formula, the food shall contain at least 0.3 % of the total fatty acids as DHA."

These and other claims lend themselves to many readings. Firstly, they appear to be a very heterogeneous set of statements or suggestions. But then again, is it not the case that the food industry itself is varied and heterogeneous?

It has also been said that health claims are not useful because there is not enough space to put them on labels – forgetting that in principle they may be used in the labelling, presentation and advertising of foods. Likewise it seems that some producers have refused to include certain duly authorized claims in the labelling of products which are traditionally consumed for their taste, on the grounds that the consumer might be misled by the labelling into thinking such foods are of a dietary or even *medicinal* nature[40].

Much could be written about the criticisms which have been and no doubt will continue to be levelled at the application of Regulation No 1924/2006, but here I do not seek to play the role of an *inquisidor*, especially as throughout my career I have been known as someone who tries to find solutions rather than cause problems.

In my opinion the most problematic aspect of health claims is the difficulty consumers face in understanding them, and equally the difficulty for business operators face in adapting them in a way that enables their message to reach the final consumer[41] without undermining the intentions of the Community legislator in authorising them and imposing ever stricter conditions of use.

III. Seeking *flexibility* in the way food business operators express health claims

1. *The Commission attempts to make the interpretation and application of Regulation No 1924/2006 easier*

By now the reader barely needs reminding that Regulation No 1924/2006 is as complex as it is problematic[42]. As a consequence it has already been subject to many changes, to the extent that in 2007 the Commission felt it necessary to publish its "Guidance on the implementation of Regulation N° 1924/2006 - Conclusions of the Standing Committee on the Food Chain and Animal Health" (see http://ec.europa.eu/food/food/labellingnutrition/claims/guidance_claim_14-12-07.pdf)[43].

This document was drawn up after the Commission's Health and Consumer protection Directorate General set up a Working Group with experts from Member States in order to examine a series of issues concerning the implementation of the Regulation No 1924/2006, notably on the classification of claims. The Guidance

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[40] See the paper mentioned at footnote 29, p. 8.

[41] See MARIOTTI, F., KALONJI, E., HUNEAU, J.F. and MARGARITIS, I., "Potential pitfalls of health claims from a public health nutrition perspective", *Nutrition Reviews*, Vol. 68, No. 10, 2010, 624–638.

[42] See the paper mentioned at footnote 29, 2-3.

[43] In the light of the large number of interpretative documents which the Commission's DG SANCO has published in recent years to accompany its directives and regulations, SWINDELLS, J., asks ironically whether the DG's original regulations «… indescribably wrong from the standpoint of legislative practice, should when adopted come with an *instruction* manual…» (my italics). (in "Los dirigentes de la DG SANCO ¿se olvidaron de cómo se conjuga el verbo dimitir", *Gaceta del InDeAl*, Vol. 15, No. 1, 2013, 23-32)

aims to help interested stakeholders understand the Regulation better and apply it correctly and consistently. However, the document itself stresses that it "has no formal legal status and in the event of a dispute, ultimate responsibility for the interpretation of the law lies with the Court of Justice".

Thus the Guidance throws little light upon the issue at hand, although it does contain some interesting information about the interaction with Community provisions laid down in Directive 89/398/EEC and Directives adopted relating to foodstuffs for particular nutritional uses; comparative claims that are governed by Article 9 of the Regulation; borderline cases between "function claims" and "reduction of disease risk, etc.[44].

2. *Guidelines for the implementation of specific conditions for health claims laid down in Article 10 of Regulation No 1924/2006*

To address the difficulties had in *effectively* communicating the information contained in the statements discussed in this paper, the Commission adopted Commission Implementing Decision 2013/63/EU of 24 January 2013 adopting guidelines for the implementation of specific conditions for health claims laid down in Article 10 of Regulation (EC) No 1924/2006 of the European Parliament and of the Council (OJ L 22, 25.1.2013, p. 25).

This Decision was adopted because both national control authorities and food business operators had raised questions about the implementation of paragraphs 2 and 3 of Article 10 of the Regulation No 1924/2006. It has a basis in Article 10(4) of the Regulation, which provides for a possibility to adopt guidelines for the implementation of that Article on specific conditions for health claims, and its purpose is to propose directions aimed at ensuring that articles 10.2 and 10.3 of the Regulation are applied consistently and thus "…facilitate the work of the control authorities and ensure greater clarity and certainty for economic operators…" (see the second recital of the Decision).

Surprisingly enough, it appears that the *obligatory nature* of the guidelines is actually confirmed by the third recital of Commission Implementing Decision 2013/63/EU[45] where it states that "The guidelines set out in the Annex to this Decision *should be taken into account*[46] by the national control authorities and food business operators". [47]

Therefore said Annex needs to be examined in some detail. In the Introduction it explains that "the following guidelines are addressed to the national control authorities and food business operators as regards the implementation of Article 10 of Regulation (EC) No 1924/2006 […]". It is worth noting here that the guidelines do not apply *only* to the competent authorities but also to business operators.…

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[44] See HABER, B. and MEISERENRST, A., "Health and Nutrition Claims", Lexxion, 2010, 245-246.

[45] See the paper mentioned at footnote 29, p. 9.

[46] Emphasis added by the author.

[47] The French version reads "*Il convient que les autorités de contrôle nationales et les exploitants du secteur alimentaire tiennent compte* des orientations figurant en annexe de la présente décision" (emphasis added by the author), and the Spanish one provides that "Las autoridades nacionales de control y los explotadores de empresas alimentarias *deben tener en cuenta* las directives establecidas en el anexo de la presente Decisión" (emphasis also added by the autor).

The Commission then refers to Article 10 of the Regulation and other Community legislation, before stating that "it is important to note that even authorised health claims may not be used unless their use fully complies with all the requirements of the Regulation [No 1924/2006]": "accordingly, even where a claim is authorised and included in the lists of permitted health claims, national authorities should take action if its use does not comply with all the requirements of the Regulation"[48].

This is unhelpfully repetitive, as is section 1 of the Annex, which is devoted to the prohibition of unauthorised health claims and of health claims the use of which does not comply with the Regulation [Article 10(1)]. Section No. 2 ["Mandatory information accompanying authorised health claims – Article 10(2)] is of more interest insofar as the Decision *distinguishes* several pieces of information which must be provided in order to implement Article 10(2) of the Regulation No 1924/2006:

> "In order to comply with the Regulation, Article 10(2) requires two, or where appropriate, four pieces of mandatory information to be provided to the consumer when using a health claim. *The information laid down in points (a) to (d) of Article 10(2) must be given in the labelling of the food, or in its presentation and advertising if no such labelling exists*[49]. This provision should be understood in the light of the objective of the legislator to ensure a high level of consumer protection by providing accurate and truthful information to help consumers make an informed choice."

It is in this context that Commission Implementing Decision 2013/63/EU reminds us that "*Labelling*, is defined in point (a) of Article 1(3) of Directive 2000/13/EC[50] and point (j) of Article 2(2) of Regulation (EU) No 1169/2011 of the European Parliament and of the Council[51]": "that definition states that ""labelling" means any words, particulars, trademarks, brand name, pictorial matter or symbol relating to a food and placed on any packaging, document, notice, label, ring or collar accompanying or referring to such food". Furthermore, "in the Union law there is a definition of *advertising*[52], but no definition of *presentation*, which should therefore be understood in the light of the explanation provided for in point (a) of Article 2(3) of Directive 2000/13/EC and point (b) of Article 7(4) of Regulation (EU) No 1169/2011".

The Commission notes that

- "a health claim can be made on the *labelling* which can mean more than just the label, since it encompasses all the information to the consumer about the food which it accompanies or refers to" (the distinction between "labelling" and "advertising" is that "labelling" is concerned with the delivery of the food

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[48] The Commission recognises that "it would be easier to achieve compliance with the provisions of the Regulation and in particular Article 10, if the food business operator is able to demonstrate due diligence and steps taken to comply with each part of the Regulation [No. 1924/2006]".

[49] Emphasis added by the author.

[50] See footnote 6.

[51] See footnote 9.

[52] Directive 2006/114/EC of the European Parliament and of the Council of 12 December 2006 concerning misleading and comparative advertising (OJ L 376, 27.12.2006, p. 21) states: "*advertising* means 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".

to the final consumer, while "advertising" is about the promotion of the supply of food by the food business operator);

• "in order to comply with Article 10(2) [of Regulation No 1169/2011], it is necessary to include the mandatory information in the labelling of the food for which the health claim is made;

• "a health claim can be made on the *labelling* which can mean more than just the label, since it encompasses all the information to the consumer about the food which it accompanies or refers to" (the distinction between "labelling" and "advertising" is that "labelling" is concerned with the delivery of the food to the final consumer, while "advertising" is about the promotion of the supply of food by the food business operator);

• "where no *labelling* exists, the mandatory information shall be given in the *advertising* and *presentation*" of the food for which the health claim is made" [for example, where a health claim is used in a generic advertising for a food (e.g. olive oil, dairy, meat, etc.) which does not link it to a specific product which would have "labelling", then the mandatory information must also be given in the "advertising" and "presentation" of that food];

• "Article 12 of Regulation (EU) No 1169/2011 establishes a principle that the consumer should always have the mandatory information when making a decision about a purchase of a food" (special mention must be made as regards Article 14 of Regulation No 1169/2011 on distance selling: "Mandatory information shall be available to the consumer before purchase and in the cases of distance selling where access to the *labelling* is restricted, mandatory information must be included in the presentation and advertising of the food, in the material supporting the distance selling whether this is a website, a catalogue, a leaflet, a letter, etc."); and

• "an exemption exists in Article 1(2) of the Regulation for non-prepacked foodstuffs put up for sale to the final consumer or to mass caterers and foodstuffs packed at the point of sale at the request of the purchaser or pre-packed with a view to an immediate sale [that exemption means that the mandatory information listed in points (a) and (b) of Article 10.2(a) and 10.2(b) is not required: "On the contrary, where appropriate, the information required under points (c) and (d) of Article 10(2) is always required"[53].

Finally, paragraph 2.2 of Commission Implementing Decision 2013/63/EU mentions that Regulation No 1924/2006 allows food business operators certain *flexibility* as regards how to express mandatory information… Specifically, the Commission states that:

"While allowing certain flexibility to food business operators as regards how to express *mandatory information*[54], the Regulation foresees that the following four pieces of information must be provided when a permitted health claim is used:

(a) *A statement indicating the importance of a varied and balanced diet and a healthy lifestyle*

[53] See the paper mentioned at footnote 29, 10-11.

[54] Emphasis added by the author.

The purpose of this provision is *to help the consumer understand the specific beneficial effect of the food bearing the health claim*[55]. It underlines that consumers should be made aware that consumption of this particular food should be part of a varied and balanced diet and not eaten excessively or against good dietary practice (recital 18) in order to achieve healthy outcomes and that consumption of the food bearing the health claim in the context of a varied and balanced diet is only one aspect of a healthy lifestyle;

(b) *The quantity of the food and pattern of consumption required to obtain the claimed beneficial effect*

The provision relates to the information that a food business operator should provide, based on the composition of the food, to ensure that the claimed effect can be delivered. The way the food is consumed is important and communicating that to the consumer may also be a requirement of the specific conditions of use set for health claims by the Commission when authorising and listing them in the Union Register[56]. However, that provision must ensure that for all health claims the consumer is fully informed of how much of the food is required and how it should be consumed during the day. For example, information should be given whether the claimed effect is likely to be achieved by consuming the food just once or several times over the course of the day. In addition, that information must not encourage or condone excess consumption of a food as provided in point (c) of the second paragraph of Article 3. Where that is not possible, the health claim should not be made;

(c) *Where appropriate, a statement addressed to persons who should avoid using the food*; and

(d) *An appropriate warning for products that are likely to present a health risk if consumed to excess*.

Some claims may be authorised with restrictions on their use, or in the case of some substances other provisions specific to categories of foods may foresee additional labelling requirements. All such requirements are *cumulative*[57] and operators should respect all the relevant provisions applying to foods and claims. *However, food business operators should assume their responsibilities under general food law and comply with the fundamental requirement to market food which is safe and not harmful to health and utilise such statements on their own recognisance*[58]."

Space does not permit me to discuss section No. 3 here in detail. In relation to general, non-specific health benefits this section states that "Article 10(3) allows the use of easy, *attractive*[59] statements which make reference to general, non-specific benefits of a food for overall good health or health-related well-being, without prior authorisation, subject to specific conditions".

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[55] *Idem*.

[56] See footnote 28.

[57] Emphasis added by the author.

[58] *Idem*.

[59] *Idem*.

I fully agree that the use of such statements could be helpful to consumers, as they would convey more consumer-friendly messages. However, the Commission's view is that "they could be easily misunderstood and/or misinterpreted by consumers, possibly leading to imagine other/better health benefits of a food than those that actually exist": "For this reason, when referring to general, non-specific health benefits, it is required to accompany such references by a specific health claim from the lists of permitted health claims in the Union Register. The aforementioned section 3 specifies that for the purposes of the Regulation No 1924/2006, the specific authorised health claim accompanying the statement making reference to general non-specific health benefits, should be made "next to" or "following" such statement.

IV. Conclusion

It is somewhat disappointing that the Commission has not used Commission Implementing Decision 2013/63/EU to confirm that food business operators are entitled to a degree of flexibility when they include authorised health claims. I refer of course to the wording of such claims, for clearly if there is greater flexibility in the ways health claims can be presented then consumers will find them easier to understand.

On the other hand however, some consumer associations have criticised business operators for allegedly – and in their view somewhat cunningly - *cutting information out* of authorised claims, by for example omitting the ingredient which a particular claim refers to so as to give the impression that the property in question is a property of the *foodstuff which contains that ingredient*[60]…

The basic rule which should be applied here is that the *version* of any health claim which appears on labelling or advertising should not take away from or falsify the actual authorised text. It is true that there are many Community regulations which support and confirm this rule. But it is equally true that because there are many ways to replace/rephrase the original text of the claim, so it is important to specify the ways this basic rule should be applied (given it's somewhat general, unspecific and even ambiguous nature).

I am not sure whether this paper will have dispelled all the reader's doubts – or even my own for that matter. Many unresolved questions remain, such as how and whether allergens whose inclusion is not compulsory can be included as part of voluntary labelling. As such there are more than enough reasons to return to this topic when the opportunity next arises.…

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[60] See the paper mentioned at footnote 29, p. 9.