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TO WHOM IT MAY CONCERN

Re: Legal Interpretation of Article 4 (2) of Regulation 1924/2006/EC; Our file n° FE09528/02

This will comment on the legal interpretation of Article 4 (2) of Regulation 1924/2006/EC¹ (hereinafter NHCR) concerning the derogations from the obligation to comply with the nutrient profiles. In particular, this will analyze what would be a proper interpretation of Article 4.2 and on whether, as advocated by certain stakeholders, the provisions of Article 4 (2) (a) and Article 4 (2) (b) ought to be interpreted and enforced "in combination".

For an example of an interpretation combining the two derogations we recall that, taking a product "*reduced in salt, but still too high in salt, and too high in saturated fatty acids and sugars in comparison with the profiles*" it has been argued² that no claim would be allowed for such product on grounds that "although according to the derogation in 4 (2) (a) the salt profile does not need to be taken into account, two other profiles are exceeded, therefore, no claim is allowed, not even "salt reduced."

We strongly disagree with that interpretation. Indeed, for the reasons that are more amply discussed below it is our opinion that the provisions in (a) and (b) of Article 4 (2) have been intended by the Community legislator as constituting two absolutely distinct derogations, obeying each to their respective conditions, and must accordingly be interpreted and enforced separately and independently (meaning that in the example referred to above the claim "salt reduced" should be allowed).

We submit that any other interpretation:

- would not respect the intent of the legislator and would, as such, run afoul the principle of useful effect.
- would constitute a violation of:
 - the principle of legal certainty and the protection of legitimate expectations
 - the principle of proportionality

¹ Regulation (EC) N° 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, 30.12.2006, p.9 (as amended).

² See letter from Belgium's Service Public Fédéral Santé Publique, Sécurité de la Chaîne Alimentaire et Environnement, to the European Commission, dated 20 August 2008 regarding request clarification article 4.2 a) & b).

- would be susceptible to jeopardize the compatibility of the entire Article 4 with Community law, having regard, *inter alia*, to the legal principles above and to the Inter-Institutional Agreement of the European Parliament, of the Council and of the Commission of 22 December 1998 on common guidelines for the quality of drafting of Community legislation.³

Background

The NHCR harmonizes the provisions laid down by law, regulation or administrative action in Member States which relate to nutrition and health claims in order to ensure the effective functioning of the internal market whilst providing a high level of consumer protection.⁴ It applies to nutrition and health claims made in commercial communications, whether in the labeling, presentation or advertising of foods to be delivered as such to the final consumer.⁵ It entered into force on 19 January 2007 and has been applicable as from 1 July 2007.

Article 4 (1) NHCR provides that the European Commission should establish by 19 January 2009 specific nutrient profiles including exemptions, which food or certain categories of food must comply with in order to bear nutrition or health claims and the conditions for the use of nutrition or health claims for foods or categories of foods with respect to nutrient profiles. This is foreseen with the purpose of avoiding a situation where nutrition and health claims can result in misleading consumers by masking the overall nutritional status of the product.⁶

The NHCR foresees the possibility of granting exemptions from nutrient profiles “which may be necessary for certain foods or categories of foods depending on their role and importance in the diet of the population”.⁷

Finally, Article 4 (2) NHCR provides that, “*by way of derogation from paragraph 1, nutrition claims:*

- referring to the reduction of fat, saturated fatty acids, trans-fatty acids, sugars and salt/sodium shall be allowed without reference to a profile for the specific nutrient/s for which the claim is made, provided they comply with the conditions laid down in this Regulation;*
- shall be allowed, where a single nutrient exceeds the nutrient profile provided that a statement about the specific nutrient appears in close proximity to, on the same side and with the same prominence as the claim. This statement shall read as follows: ‘High [The name of the nutrient exceeding the nutrient profile] content.’”*

³ European Parliament, Council, Commission, Interinstitutional Agreement of 22 December 1998 on common guidelines for the quality of drafting of Community legislation, 1999/ C 73/01.

⁴ See Article 1 (1) NHCR.

⁵ See Article 1 (2) NHCR.

⁶ Preamble NHCR paragraph 11.

⁷ Preamble NHCR paragraph 12.

Discussion

I. Correct interpretation of Article 4(2) NHCR

Both paragraphs in Article 4(2) set derogations to the principle in Article 4(1) that claims (nutritional and health claims) cannot be made when the product does not meet the established nutrient profile.

Both derogations apply only to nutrition claims. No health claim can be allowed, by derogation to Article 4(1) in application of Article 4(2).

The derogations from Article 4(2) cover nutrition claims that shall be allowed in two cases as follows:

Case 1 (or numeral 4.2 (a) NHCR): The nutrition claim(s) in question refers to the reduction of key nutrient(s): fat, saturated fatty acids, trans-fatty acids, sugars and sodium/salt. In that case, the reduction claim can then be allowed even if the nutrient(s) content(s) although reduced, remain(s) higher than the profile;

Case 2 (or numeral 4.2 (b) NHCR): A single nutrient exceeds the nutrient profile; but in this case a compulsory statement is required. This derogation applies (1) to nutrition claims referring to the reduction of other nutrients than the important nutrients as expressly mentioned in numeral 4.2(a), and (2) to all other nutrition (non reduction) claims.

We consider that the structure of Article 4(2) calls for an independent reading of the two derogations; if the Community legislator had intended to regroup the two derogations into one it would, at the time of adding the second derogation⁸, have made a clear link between the two, consistent with its obligations under the Inter-Institutional Agreement of the European Parliament, of the Council and of the Commission of 22 December 1998 on common guidelines for the quality of drafting of Community legislation.

We note that the wording of Article 4(1) (a) calls for the possibility of more than one reduction claims (*...for the specific nutrient(s) for which the claim is made...*); this, we submit, suffices to eliminate the interpretation that the two derogations have to be read together. If indeed, that were to be the case, then the derogation applicable to reduction claims would only apply to one such claim, making it impossible to properly enforce the derogation in Article 4(2) (a) which has to apply, potentially, to more than one claim.

In our opinion, therefore, the derogations for reduction claims (for the listed key nutrients) are fully and autonomously regulated by paragraph (a) while derogations based on the fact that only one nutrient exceeds the nutrient profile, are fully and autonomously regulated (except for the reduction claims for the listed key nutrients) by paragraph (b). That interpretation is reinforced by the fact that the derogations were adopted at different moments within the legislative process and, additionally, they were both introduced by the Community

⁸ See infra

legislator with the intent of serving different purposes. Consequently, to apply the different derogations jointly will be contrary to the principle of effectiveness and would be against the general principles of Community law of proportionality, legal certainty and legitimate expectations.

II. The two derogations have a distinct purpose as illustrated by their respective legislative “history” and the Community’s legislator intent

A. A different legislative history

The derogation in Article 4 (2) (a) was part of the original Commission Proposal

The original proposal from the European Commission⁹ only contemplated as derogation from the nutrient profiles, the derogation ultimately established under Article 4.2. numeral (a).

Article 4 read as follows in the proposal:

“1. Within 18 months from the adoption of this Regulation, the Commission shall, in accordance with the procedure laid down in Article 23 (2) establish specific nutrient profiles which food or certain categories of foods must respect in order to bear nutrition or health claims.

The nutrient profiles shall be established, in particular, by reference to the amounts of the following nutrients present in the food:

- (a) fat, saturated fatty acids, trans-fatty acids*
- (b) sugars*
- (c) salt/sodium.*

The nutrient profiles shall be based on scientific knowledge about diet, and nutrition, and their relationship to health and, in particular, on the role of nutrients and other substances with a nutritional or physiological effect on chronic diseases. In setting the nutritional profiles, the Commission shall seek the advice of the Authority and carry out consultations with interested parties, in particular food business operators and consumer groups.

Exemptions and updates to take into account relevant scientific developments shall be adopted in accordance with the procedure referred to in Article 23 (2).

2. By way of derogation from paragraph 1, nutrition claims referring to the reduction in the amounts of fat, saturated fatty acids, trans-fatty acids and sugars,

⁹ Proposal for a regulation of the European Parliament and of the Council on nutrition and health claims made on foods, presented by the Commission, Brussels, 16.7.2003, COM (2003) 424, final, 2003/0165 (COD).

salt/sodium, shall be allowed, provided they comply with the conditions laid down in this Regulation.

This derogation disappeared at 1st reading at the European Parliament since at that stage, Article 4 was deleted altogether. However, the derogation was later reintroduced in the Council Common position (09858/3/2005).

At that stage, however, the wording has been amended to render explicit what was implicit in the Commission Proposal, i.e. that the nutrition claims referring to the reduction in key nutrients shall be allowed even if the reduction has not been sufficient for one or more nutrients to make it comply with the profile applicable to it.

The derogation took then its final form as follows:

(2) By way of derogation from paragraph 1, nutrition claims referring to the reduction of fat, saturated fatty acids, trans-fatty acids, sugars and salt/sodium shall be allowed without reference to a profile for the specific nutrient/s for which the claim is made, provided they comply with the conditions laid down in this Regulation (underline added)

The derogation in Article 4 (2) (a) was then maintained at second reading at the European Parliament.¹⁰

The derogation in Article 4 (2) (b)

The derogation under Article 4.2 (b) was only introduced at second reading at the European Parliament. On 21 March 2006 an amendment¹¹ was proposed by the Environment Committee of the European Parliament which introduced in the Recommendations for second reading a derogation reading as follows:

"By way of derogation from paragraph 1, nutrition claims shall be allowed, provided that in addition reference is made to the nutrients which do not meet the nutrient profile. This information should be of factual, non-discriminating character and clearly visible to the consumer"

That amendment was justified as follows: *"Claims should be admissible if one element of a nutrient profile is exceeded. An additional obligation to disclose nutrition information would allow consumers to make an informed choice. The details of presentation should be considered following completion of the Authority's task and within the context of the review of the Nutrition Labelling Directive 90/496/EC".*

¹⁰ Although, it did not appear in the first NHCR published version (OJ L 404 of 30 December 2006) making it necessary to publish a corrigendum (OJ L 12/3 of 18 January 2007).

¹¹ Amendment n° 17

Then, on 8 May 2006, the informal trialogue between the three institutions reflected the will of the European Parliament to add the derogation proposed at the Parliament's second reading. The report of that meeting states that *"the EP insisted on having derogation from the requirements that foods need to meet a certain nutrient profile in order to make nutrition claims. The Presidency invites COREPER to consider the following proposal as the "final" offer to settle this sensitive and crucial point"*.¹²

Article 4 (2): *"by way of derogation from paragraph 1, nutrition claims*

- a) referring to the reduction of fat, saturated fatty acids, trans-fatty acids, sugars and salt/sodium shall be allowed without reference to a profile for the specific nutrient/s for which the claim is made, provided they comply with the conditions laid down in this Regulation;*
- b) shall be allowed, where a single nutrient exceeds the nutrient profile provided that a statement about the specific nutrient appears in close proximity to, on the same side and with the same prominence as the claim. This statement shall read as follows: "High [name of the nutrient exceeding the profile] content".*

That new derogation was ultimately adopted by the European Parliament at second reading on 16 May 2006.

B. Different legislative intents

The derogation in Article 4 (2) (a) was introduced to encourage product reformulation

The rationale for that first derogation was clearly to provide an incentive to product reformulation by avoiding a situation where a product which would have been reformulated, justifying a reduction claim for one or more important nutrients, would nevertheless be prevented from claiming that reduction because it would still exceed the threshold for one or more of those specific, key nutrients. This derogation was introduced with the purpose of encouraging the food industry to engage in product reformulation. The derogation is specifically applicable only to reduction nutrition claims in relation with key nutrients (such as fat, saturated fatty acids, sugar sodium) which have been proven to cause adverse effects on health if consumed in quantities exceeding the recommended intake levels. As the Commission has recognized, it has been scientifically proven that there is a link between the high consumption of these nutrients and the incidence of chronic diseases "such as cardiovascular disease,

¹² Note from the Secretary General to the Delegations, "Consideration of the compromise amendments as discussed at the informal trialogue with the EP on 8 May 2006 with a view to reach a second reading agreement", 9.5.06 n° 9112/06

diabetes, several types of cancer, obesity, osteoporosis and dental disease.”¹³ We can say that the derogation serves a double purpose as it’s in the best interest of the Community to prevent the negative effects of these nutrients and to induce the food industry to reduce the levels of these nutrients in food.

That reading of the first derogation was already clear from the original wording (above) proposed by the Commission: “nutrition claims referring to the reduction in the amounts of fat, saturated fatty acids, trans-fatty acids and sugars, salt/sodium, shall be allowed, provided they comply with the conditions laid down in this Regulation” meaning (albeit implicitly) that this would be the case even if the reduction has not been sufficient for one or more nutrients to make it comply with the profile applicable to it. From the wording of the derogation it is clear that it applies only to nutrition claims which comply with the following conditions: it consists of nutrition claims referring to the reduction of the specific nutrients mentioned; the product fails to comply with one or more nutrients; and it complies with the conditions laid down in the NHCR. The latter condition in our opinion requires that the nutrition claim(s) must comply with the general principles and conditions established in Articles 3 and 4 NHCR, as well as the obligation to provide nutrition information (Article 7 NHCR); and with the specific conditions established in Chapter III and, in particular, whether the “reduced” claim is conformity with the criteria established in the Annex for that specific claim.

We have to stress that, contrary to what is implied in the French version of the NHCR,¹⁴ the final provisions in Article 4.2 (a) and (b) which read: “*By way of derogation from paragraph 1, nutrition claims referring to the reduction of fat, saturated fatty acids, trans-fatty acids, sugars and salt/sodium shall be allowed without reference to a profile for the specific nutrient/s for which the claim is made, provided they comply with the conditions laid down in this Regulation*” (underline added) do not mean: “*...by way of derogation from paragraph 1, nutrition claims referring to the reduction of fat, saturated fatty acids, trans-fatty acids, sugars and salt/sodium which do not refer to a profile for the specific nutrient/s for which the claim is made, shall be allowed, etc...*” as in the French version.

Rather, as outlined above, “*without reference to a profile*” means “*without having regard to a profile*”, i.e. that a reduction claim for one or more important nutrient(s) will be allowed even if the reduction for one or more nutrient(s) has not been sufficient to ensure compliance with the nutrient profile for such nutrient(s). As a matter of fact, we do not see how a nutrition “claim” could ever “refer to” a profile.¹⁵

¹³ Proposal for a regulation of the European Parliament and of the Council on nutrition and health claims made on foods, presented by the Commission, Brussels, 16.7.2003, COM (2003) 424, final, 2003/0165 (COD), page 5, paragraph 14.

¹⁴ OJ FR 04.03.08 001.001 page 12

¹⁵ However, the European Court of Justice has established that when there is divergence between the various language versions of a Community text, the provision in question must be interpreted by reference to the purpose and general scheme of the rules of which it forms part. (See Case C-372/88 Milk Marketing Board of England and Wales v Cricket St Thomas Estate, paragraph 19)

Recalling that the first publication of the NHCR had already been erroneous with regard to that very same provision (Article 4 (2) was not fully reproduced in the original publication) which required the publication of a corrigendum, we urge the Community institutions to publish a further corrigendum to correct the French version of the NHCR and in particular Article 4(2).

The derogation in Article 4 (2) (b) was introduced to reflect a proportionate approach

The derogation under Article 4.2 (b) was included to serve a different objective, which was to proportionally apply the nutrient profiles and to reasonably mitigate the rigorous effects which could derive from its application. The Community legislator clearly anticipated that the strict application of Article 4.1 could have resulted in prohibiting products from bearing claims. The purpose of the NHCR was not to ban claims to be made, but to control the marketing of products which could mislead the consumer by masking the overall nutritional qualities of the product. For that reason, the legislator introduced this derogation in order to allow a product to bear nutrition claims when it exceeds the threshold for a single nutrient only, under the particular obligation that a statement explaining the 'High nutrient content' is also included in the same field of vision and with the same prominence as the claim.

It is clear that by introducing this derogation the Community legislator wanted to reflect a proportionate approach by choosing a less restrictive approach (duly informing the consumer instead of prohibiting the use of nutrition claims). The purpose of the second derogation was not to deprive the consumer of useful and adequate information when only one threshold of the nutrient profile would be exceeded. In that situation the additional information requirement would allow the consumer to make an informed choice.

This derogation applies to any type of nutrition claim included in the NHCR's Annex and for any nutrient (unlike derogation 4.2 (a)), but only when one nutrient exceeds the nutrient profile.

In addition to purpose of the derogations, we consider that the structure of Article 4(2) calls for an independent reading of the two derogations; if the Community legislator had intended to regroup the two derogations into one it would, at the time of adding the second derogation¹⁶, have made a clear link between the two, consistent with its obligations under the Inter-Institutional Agreement of the European Parliament, of the Council and of the Commission of 22 December 1998 on common guidelines for the quality of drafting of Community legislation.

¹⁶ See infra

III. Legal interpretation of the derogations in Article 4.2 in accordance with the principle of effectiveness

In preparation to the eminent adoption of the nutrient profiles by January 2009 discussions about the correct interpretation of the derogations established in Article 4.2 have gained importance in the past month. There are two opposing views, whether derogation 4.2 (a) should be read in conjunction with derogation 4.2 (b), or whether there are two separate derogations.

It has been the standing of the European Court of Justice (ECJ) that “where a provision of Community law is open to several interpretations, preference must be given to that interpretation which ensures that the provision retains its effectiveness (see, *inter alia*, Case 187/87 *Saarland and Others v Minister for Industry, Post and Telecommunications and Tourism and Others* [1988] ECR 5013, paragraph 19).”¹⁷ Based on the well-established jurisprudence of the ECJ, the only plausible way in which Article 4.2 NHCR will retain its effectiveness is by interpreting and implementing both provisions separately as it has been clearly established that they were introduced in the NHCR in response to different purposes.

Recognising that one the objectives of the nutrient profiles is to encourage product reformulation to comply with the nutrient profiles¹⁸ (or, at least, not to discourage such reformulation) and in this way to provide an incentive for the manufacturing of healthier products,¹⁹ we note that if a joint interpretation is applied, reformulated products would not be allowed to claim that reformulation.

To follow a joint interpretation will be contrary to the Community’s legislator efforts to promote product reformulation, and consequently, to lower the intake of key nutrient which can have a negative impact on health. Why to deprive the consumer from that substantiated information about the reduction in one of the key nutrients?

In addition, a joint interpretation will run afoul of the principle of effectiveness since, as previously explained, both derogations apply to different situations. The first derogation only refers to “reduction” nutrition claims for the given specific nutrients, while the second derogation applies to any nutrition claim in relation to any nutrient or substance. If we were to apply both derogations together, it will reduce scope of application that the legislator had in mind when it adopted both separate derogations. It is clear that the purpose of the two derogations was to cover other type of nutrition claims besides reduction claims.

On the other side, while we understand that among the underlying objectives of the NHCR in general, and of the nutrient profiles, in particular, one was to avoid the use of misleading claims and to help consumers make informed choices, we note that a separate interpretation

¹⁷ See Judgment of the Court of 24 February 2000 in Case C-434/97, *Commission of the European Communities v French Republic*, paragraph 21. See also Judgment of the Court of 4 October 2001 in Case C-403/99, *Italian Republic v Commission of the European Communities*, paragraph 37

¹⁸ The preamble to NHCR recognizes that nutrient profiles should allow product innovation. See paragraph 11, Preamble NHCR.

¹⁹ Introduction to the Commission’s Working Document on the Setting of Nutrient Profiles, 2 June 2008

of the derogations would not put into question the achievement of these two objectives. On the contrary, the separate interpretation of both derogations does not run the risk of considering the claims as misleading the consumer. The conditions under which they apply are very strict. For instance, in Derogation 4.2 (a) it is required to comply with the conditions laid down in the Regulation; and in derogation 4.2 (b) it is required that a statement is added in the same field of vision where the claim will appear, in addition, any nutrition claim made will have to be in compliance with the general and specific requirements established in the NHCR. Furthermore, the separate interpretation of the derogations would allow consumer to be better informed about the products they consume and to make an informed choice of the products they buy in relation with those which have not been reformulated (Art. 4.2 (a)) or that exceed threshold levels in more than one nutrient (Art. 4.2(b)).

IV. A combined interpretation of the derogations would render Article 4 non compliant with Community law on grounds of a breach of the legal principles of proportionality, legal certainty and legitimate expectations.

Violation of the principle of proportionality

It is clearly established in the preamble of the NHCR that the nutrient profiles will be applied with the purpose of avoiding the use of claims that will result in masking the overall nutritional status of a food product which could mislead the consumer.²⁰ Nonetheless, at the same time, it has been recognized that the profiles must also allow product innovation and they should take account of the variability of dietary habits and traditions, and the importance of the individual product in the overall diet. If the derogations are interpreted and implemented in combination, it would result in a disproportionate measure as it would go beyond what is necessary to obtain the objectives of the nutrient profiles mentioned in the preamble of the NHCR.

Article 5 of the EC treaty provides that “any action by the Community shall not go beyond what is necessary to achieve the objectives of the Treaty.” In addition, the well-settled case law of the ECJ, has established that measures implemented through Community provisions must be appropriate for attaining the objective pursued and must not go beyond what is necessary to achieve it.²¹ According to the ECJ, “the lawfulness of the prohibition of an economic activity is subject to the condition that the restrictive measures are appropriate and necessary in order to achieve the objectives legitimately pursued by the legislation in question; when there is a choice between several appropriate measures recourse must be had to the least onerous, and the disadvantages caused must not be disproportionate to the aims pursued.”²² Following the criteria established by the ECJ, it is unquestionable that the joint interpretation will pass the proportionality test, even when the disproportional character will result from how Article 4.2 would be interpreted and implemented in practice, rather than from the actual text of the provision. As it has been previously argued, the objectives of the nutrient profiles can be perfectly attained if a proper interpretation of the two separate

²⁰ Preamble NHCR, paragraph 11.

²¹ Joined Cases C-453/03, C-11/04, C-12/04 and C-194/04 *ABNA Ltd et al.*, Judgment of the European Court of Justice, 6 December 2005, paragraph 68; *Swedish Match*, paragraph 47 and *Arnold André*, paragraph 45

²² Case C-331/88, *R.v. Minister for Agriculture, Fisheries and Food, ex parte FEDESA* 1990, paragraph 13

derogations is made. It is clear that a less onerous and equally effective measure would be the separate interpretation and implementation of Article 4.2 NHCR.

Breach of the principles of legal certainty and legitimate expectations

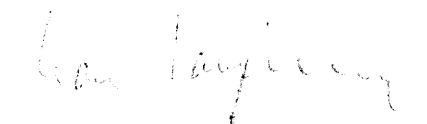
In our opinion, any interpretation that would result in the combination of the two derogations would violate the principles of legal certainty and the protection of legitimate expectation. If an expectation is created and that expectation is found to be legitimate, the ECJ will protect that expectation by making the representation that gave rise to the expectation binding on the relevant Community institutions.

In adjudicating legitimate expectation claims the ECJ follows a two step approach. Firstly it asks whether the actions by the Community institutions created a reasonable expectation in the mind of the aggrieved stakeholders. If the answer to this question is in the affirmative, the second question is whether that expectation is legitimate. If the answer to the second question is equally in the affirmative, then the ECJ will enforce the legitimate expectation.

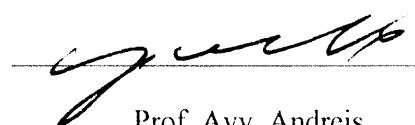
In our opinion the unequivocal text of Article 4.2 has created a legitimate expectation on the operators that the derogations are to be applied separately. As it has been amply demonstrated above, the way Article 4.2 was drafted, created a reasonable expectation that the two types of derogations would not be enforced in combination and that they both corresponded to independent situations. Therefore, the operators have had the legitimate expectation that if they engage in product reformulation activities, their products, even if they did not meet the nutrient levels established in the profile, could still bear nutrition claims which will inform consumers of the benefits of the product in relation with similar non-reformulated products. In addition, we should not underestimate that the NHCR entered into force in July 2007, therefore, there is a great likelihood that at this stage (and already foreseen the adoption of the nutrient profiles), operators had already engaged in product reformulation activities relying on any of the two derogations in Article 4.2.

The expectation that Article 4.2 is to be interpreted separately is legitimate as each derogation has its own justifications and conditions. Furthermore, neither from the text of the regulation nor from the wording of the Article can it be implied that the derogations were to be applied in combination. Absent any express provision to the contrary in the NHCR, the expectation that the derogations under Article 4.2 must be interpreted separately is a legitimate expectation which deserves legal protection.

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