

**PRIVILEGED AND CONFIDENTIAL ATTORNEY-WORK PRODUCT**

**MEMORANDUM**

TO: Council for Responsible Nutrition

FROM: Sidley Austin LLP

RE: WTO Analysis of EU Health Claims Regulation

DATE: April 25, 2011

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**I. EXECUTIVE SUMMARY**

1. In this Memorandum, we consider whether the European Union’s regime for regulating health claims made on food in commercial communications is consistent with the EU’s obligations under the World Trade Organization (“WTO”) Agreements. In particular, we examine the text 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*,<sup>1</sup> including any amendments thereto (collectively referred to as the “EU Health Claims Regulation” or the “Regulation”), as well as the implementation of that Regulation.
2. We conclude that the EU Health Claims Regulation, as applied, appears to violate several obligations under the *WTO Agreement on Technical Barriers to Trade* (“TBT Agreement”). In particular, while the text of the EU Health Claims Regulation, itself, does not appear to violate the *TBT Agreement* as such, it is the *application* of that Regulation by the European Food Safety Authority (“EFSA”) and the European Commission that we anticipate would be found to violate the EU’s obligations under Articles 2.2 and 5.1.2 of the *TBT Agreement*.
3. Specifically, the application of the EU Health Claims Regulation appears to violate Article 2.2 of the *TBT Agreement*, because it is more trade restrictive than necessary to achieve the EU’s objective of preventing misleading health claims on food products, and it

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<sup>1</sup> *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, 30.12.2006, p. 9.

creates an unnecessary obstacle to international trade. Furthermore, the procedures established to assess the conformity of health claims with the substantive requirements of the Regulation also appear to be inconsistent with Article 5.1.2 of the *TBT Agreement*, because they are applied more strictly than necessary to prevent the use of misleading health claims on the EU market.

4. We caution that a WTO challenge to the European Health Claims Regulation as applied by the EFSA and the European Commission can be advanced only once the EU adopts legally binding measures prohibiting the use of specific health claims, based on negative EFSA opinions. Until that point, the EFSA opinions as such would likely be viewed as advisory opinions with no legal effect. As detailed herein, implementation of various aspects of the EU Health Claims Regulation are subject to several transition periods that extend the time during which entities may continue to make use of their health claims on foods.

5. Assuming that the European Commission follows the lead of the EFSA opinions, an economist has estimated that the EU market for food supplements not containing vitamins or minerals, for example, “[...] may decrease in size by about 25% (€645 million at the ex-production facility level or €1,031 million at retail level) and result in a 30% loss of gross profitability (€242 million)” as a result of implementation of the EU Health Claims Regulation.<sup>2</sup> This would appear to impact both importers and domestic producers of such supplements.

6. In Section II of this Memorandum, we provide an overview of the relevant aspects of the EU Health Claims Regulation, and the implementation thereof. In Section III, we then provide our analysis of the WTO violations that appear to result from the application of the Regulation.

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<sup>2</sup> Graham Brookes, *Economic Impact Assessment of the European (EU)'s Nutrition & Health Claims Regulation on the EU food supplement sector and market* (“Impact Assessment Brookes”), September 2010, p. 5, available at: <http://www.ehpm.org/userfiles/file/Impact%20Assessment/Impact%20Assessment%20FINAL.pdf>. The impact assessment was commissioned by the European Health Claims Alliance (“ECHA”).

## II. OVERVIEW OF THE EU HEALTH CLAIMS REGULATION

7. Adopted in December 2006, the EU Health Claims Regulation sets out a legal framework regulating the use of nutrition and health claims made on, or relating to, food products. The Regulation requires that all such nutrition and health claims comply with the Regulation's requirements. In particular, nutrition claims can only be used when they are listed in the Annex to the Regulation,<sup>3</sup> while health claims must be authorized in accordance with the Regulation and included in one of the lists of permitted claims.<sup>4</sup> Only health claims that have been assessed and authorized in accordance with the Regulation will be permitted on the EU market.

8. Although the Regulation has been applied since July 1, 2007, it provides for transitional measures allowing the continued use of certain nutrition and health claims prior to their assessment and authorization in accordance with the Regulation.<sup>5</sup> However, a number of these transitional periods have now lapsed and applications for authorization of any existing claims must already have been submitted.

9. Given the importance of the Regulation and its application in practice, we first discuss in detail its background and objectives. We next consider the overall scope of the Regulation, the requirements imposed by the Regulation, and the implementation of the Regulation by the EFSA and the European Commission.

### A. Background and Objectives of the Regulation

10. Prior to the Regulation, the use of nutrition and health claims was subject to general food labeling legislation as laid down in *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*, as amended ("General Food Labeling Directive") and implemented by EU Member States in their domestic legislation.<sup>6</sup>

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<sup>3</sup> EU Health Claims Regulation, Article 8(1).

<sup>4</sup> EU Health Claims Regulation, Article 10(1).

<sup>5</sup> EU Health Claims Regulation, Article 28.

<sup>6</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, 6.5.2000, p. 29. We note that the European Commission has proposed a Regulation on the provision of food

11. The General Food Labeling Directive, *inter alia*, prevents labeling methods which “could mislead the purchaser to a material degree [...] as to the characteristics of the foodstuff [or] by attributing to the foodstuff effects or properties which it does not possess [or] by suggesting that the foodstuff possesses special characteristics when in fact all similar foodstuffs possess such characteristics”.<sup>7</sup>

12. The EU Health Claims Regulation indicates that it is intended to “complement the general principles in [the General Food Labeling Directive] and lay down specific provisions concerning the use of nutrition and health claims concerning foods to be delivered as such to the consumer”.<sup>8</sup> Its stated objective is to “ensure the effective functioning of the internal market as regards nutrition and health claims whilst providing a high level of consumer protection”.<sup>9</sup>

13. When the EU notified the Regulation to the WTO TBT Committee, at the stage that it was a proposal, it listed the following main objectives:

- to achieve a high level of consumer protection by providing further voluntary information, beyond the mandatory information foreseen by EU legislation;
- to increase legal security for economic operators;
- to ensure fair competition in the area of foods;
- to promote and protect innovation in the area of foods.

The proposed rules ensure that foods bearing nutrition and health claims are labelled and advertised in a truthful and meaningful manner. Consumers will be able to make informed and meaningful choices. This also contributes to a higher level of protection of human health. It gives the economic operators legal security and a more predictable environment.<sup>10</sup>

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information to consumers which, if adopted, will repeal and replace the General Food Labeling Directive. The adoption of the proposed Regulation, in its current form, would not affect our analysis set out in this Memorandum.

<sup>7</sup> General Food Labelling Directive, Article 2(a).

<sup>8</sup> EU Health Claims Regulation, Preamble, para. 3.

<sup>9</sup> EU Health Claims Regulation, Preamble, para. 36. *See also* paras. 10, 14 and 16.

<sup>10</sup> Notification of the European Communities to the WTO Committee on Technical Barriers to Trade, G/TBT/N/EEC/33, 29 August 2003. The European Commission’s Explanatory Memorandum accompanying the draft Regulation specified a fourth objective: “to improve the free movement of goods within the internal market”.

14. Thus, the Regulation aims to inform consumers and protect them against misleading health claims. This is also reflected in the following paragraph of the Regulation's preamble: "[i]t is important that claims on foods can be understood by the consumer and it is appropriate to protect all consumers from misleading claims".<sup>11</sup>

## B. Scope of the Regulation

15. The Regulation applies to "nutrition claims" and "health claims" made in "commercial communications" regarding "foods".<sup>12</sup>

16. A "health claim" is defined by the Regulation as "any claim that states, suggests or implies that a relationship exists between a food category, a food or one of its constituents and health".<sup>13</sup> "Food" includes "any substance or product, whether partially processed or unprocessed, intended to be, or reasonably expected to be ingested by humans".<sup>14</sup> The definition of "food" covers drinks, chewing gum and any substance (including water) intentionally incorporated into the food during its manufacture, preparation or treatment.<sup>15</sup> It does not include (a) feed, (b) live animals unless they are prepared for placing on the market for human consumption, (c) plants prior to harvesting, (d) medicinal products, (e) cosmetics, (f) tobacco and tobacco products, (g) narcotic or psychotropic substances, and (h) residues and contaminants.<sup>16</sup>

17. Although the focus of this Memorandum is on "health claims" for foods, we note that a "nutrition claim" is defined in Article 2(4) of the Regulation as "any claim which states, suggests or implies that a food has particular beneficial properties due to: (a) the energy (calorific value) it (i) provides; (ii) provides at a reduced or increased rate; or (iii) does not provide; and/or (b) the nutrients or other substances it (i) contains; (ii) contains in reduced or increased proportions; or (iii) does not contain".

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<sup>11</sup> EU Health Claims Regulation, Preamble, para. 16.

<sup>12</sup> EU Health Claims Regulation, Article 1(2).

<sup>13</sup> EU Health Claims Regulation, Article 2(5).

<sup>14</sup> Article 2(1)(a) of the EU Health Claims Regulation refers to the definition of "food" in Article 2 of *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, 1.2.2002, p. 1.

<sup>15</sup> Regulation (EC) No 178/2002, Article 2, as referenced by EU Health Claims Regulation, Article 2(1)(a).

<sup>16</sup> Regulation (EC) No 178/2002, Article 2, as referenced by EU Health Claims Regulation, Article 2(1)(a).

18. The Regulation 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 consumer, including to restaurants, hospitals, schools, canteens and similar mass caterers.<sup>17</sup>

19. A trade mark or brand name which can be construed as a nutrition or health claim may be used in the labeling, presentation or advertising of a food without having been approved through the authorization processes established by the Regulation, provided that “it is accompanied by a related nutrition or health claim [...] which complies with the provisions of this Regulation”.<sup>18</sup> The grandfathering of trademarks or brand names in existence prior to 2005 is particularly lengthy, as Article 28(2) provides that such marks and brand names “may continue to be marketed until 19 January 2022 after which time the provisions of this Regulation shall apply”.

### C. Core Requirements Imposed by the Regulation

20. Subject to the transition periods, only nutrition and health claims that comply with the Regulation’s requirements can be used in the labeling, presentation and advertising of food products placed on the market in the EU. The Regulation sets forth four core sets of requirements that must be satisfied before nutrition and/or health claims may be used on foods.

21. **First**, the Regulation prohibits several different classes of health claims. Article 3 of the Regulation prohibits the use of nutrition and health claims that

- a) are 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 (although derogations are possible);

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<sup>17</sup> EU Health Claims Regulation, Article 1(2).

<sup>18</sup> EU Health Claims Regulation, Article 1(3). Pursuant to Article 1(4), a derogation from Article 1(3) can be adopted for generic descriptions “which have traditionally been used to indicate a particularity of a class of foods or beverages” and which could imply an effect on human health.

- 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.

22. Article 12 specifically prohibits the use of health claims that “suggest that health could be affected by not consuming the food”, “make reference to the rate or amount of weight loss”; or “make reference to recommendations of individual doctors or health professions and other associations” not referred to in specific European Union or Member State rules. Article 4(3) provides that beverages containing more than 1.2% alcohol by volume shall not bear health claims.

23. With respect to this list of prohibitions, we did not identify any WTO inconsistency, either in terms of the Regulation itself or the application thereof.

24. **Second**, Article 10(2) of the Regulation mandates that health claims be accompanied by certain affirmative statements about the food, including (i) “a statement indicating the importance of a varied and balanced diet and a healthy lifestyle”; (ii) “the quantity of the food and pattern of consumption required to obtain the claimed beneficial effect”; (iii) “where appropriate, a statement addressed to persons who should avoid using the food”; and (iv) “an appropriate warning for products that are likely to present a health risk if consumed to excess”.

25. Again, on these requirements, we did not find anything inconsistent with WTO obligations. The inconsistency arises in the application of the third and fourth core requirements for the use of health claims.

26. **Third**, Articles 5 and 6 of the Regulation impose a number of general requirements with which nutrition and health claims must comply. Most importantly, all such claims must be “based on and substantiated by generally accepted scientific evidence”<sup>19</sup>. In addition, any food business operator making a claim on a product must be able to justify the use of it, and the person placing a product with a health claim on the EU market should have all supporting data available to demonstrate compliance with the Regulation.<sup>20</sup>

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<sup>19</sup> EU Health Claims Regulation, Article 6(1). See Codex Alimentarius, *Guidelines for the use of nutrition and health claims*, CAC/GL 23-1997, as amended in 2010, section 7.1.1.

<sup>20</sup> EU Health Claims Regulation, Article 6(2) and (3).

27. The Regulation permits nutrition and health claims only on food for which “generally accepted scientific evidence” has established that “the presence, absence or reduced content [...] of a nutrient or other substance in respect of which the claim is made [has] a beneficial nutritional or physiological effect”.<sup>21</sup>

28. Furthermore, the substance must be present in a significant quantity, not present, or present in a reduced quantity in the final product in order to produce the claimed nutritional or physiological effect, and be in an immediately consumable form. The reasonably expected quantity of the product to be consumed must provide a sufficient quantity of the substance to which the claim relates to produce the claimed effect. And the average consumer must be expected to understand the beneficial effects expressed in the claim. The claim must refer to the food ready for consumption in accordance with the manufacturer’s instructions.<sup>22</sup>

29. Food products bearing a nutrition or health claim must also comply with specific nutrition profiles and conditions of use to be established by the European Commission. These nutrition profiles were originally supposed to be finalized by January 19, 2009, but they have not yet been established.<sup>23</sup>

30. **Fourth**, the Regulation requires that nutrition and health claims be affirmatively authorized in accordance with the Regulation, subject to transition periods. Specifically, *health claims* must undergo an assessment by the EFSA and be included in a list of authorized claims in order to remain (or be introduced) on the EU market.<sup>24</sup> Nutrition claims can be used only if they are listed in the Annex to the Regulation and are otherwise in conformity with the Regulation.<sup>25</sup>

31. The Regulation sets out three different assessment and authorization procedures, based on the type of health claim at issue. In particular:

- **Article 13(1) Health Claims Covered by Commission’s Initial List of Approved Claims:**  
These are health claims *other than* those referring to

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<sup>21</sup> EU Health Claims Regulation, Article 5(1)(a) (emphasis added).

<sup>22</sup> EU Health Claims Regulation, Article 5(1) - (3).

<sup>23</sup> EU Health Claims Regulation, Article 4.

<sup>24</sup> EU Health Claims Regulation, Articles 10(1), 13-18.

<sup>25</sup> EU Health Claims Regulation, Article 8(1). In addition, Article 9 of the Regulation imposes specific requirements regarding comparative claims.

the reduction of disease risk and to children's development and health.

- **Article 13(5) Health Claims Not Initially Covered by Commission List:** These are health claims (*other than* those referring to the reduction of disease risk and to children's development and health) that entities attempt to add to the Commission List after it has been released.
- **Article 14 Health Claims Related to Reduction of Disease Risk and Children's Development and Health:** The Regulation defines “reduction of disease risk claim” in Article 2(6) as “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”.<sup>26</sup>

The rules related to each type of claim are detailed below.

#### **1. Article 13(1) Health Claims Covered by Commission's Initial List of Approved Claims**

32. Article 13(1) claims include claims referring to (a) the role of a nutrient or other substance in growth, development and the functions of the body, (b) psychological and behavioral functions, or (c) slimming, weight-control, and appetite-control. They must be (1) based on generally accepted scientific evidence and (2) well understood by the average consumer.<sup>27</sup> They are distinguished from Article 14 claims in that they are not related to reduction of disease risk, or children's development and health.

33. EU Member States were required to submit a list of such claims, together with background information, to the European Commission by January 31, 2008.<sup>28</sup> After consulting the EFSA, the European Commission was supposed to adopt a list of permitted claims by January 31, 2010.<sup>29</sup> However, such a list has not yet been adopted.

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<sup>26</sup> For such claims, the labeling, or in the absence thereof, the presentation or advertising, must bear a statement “indicating that the disease to which the claim is referring has multiple risk factors and that altering one of these risk factors may or may not have a beneficial effect.” EU Health Claims Regulation, Article 14(2).

<sup>27</sup> EU Health Claims Regulation, Article 13(1).

<sup>28</sup> EU Health Claims Regulation, Article 13(2)

<sup>29</sup> EU Health Claims Regulation, Article 13(3).

34. Initially, the European Commission intended to adopt partial lists of permitted claims, as the EFSA adopted various batches of opinions on the proposed health claims. However, in response to concerns expressed by industry about the effects of such an approach, the European Commission announced on September 27, 2010 that it will instead adopt a single list with all permitted claims (other than “botanicals”) only after the EFSA has finalized all of its pending opinions on such claims.

35. If a health claim is on the Commission’s list, then entities may make those health claims without going through any additional procedures or review, as long as they are “based on generally accepted scientific evidence” and “well understood by the average consumer”.<sup>30</sup> If they are not on this initial list, then they must go through the procedures specified by Article 13(5), as detailed below.

## **2. Article 13(5) Health Claims, Not Initially Covered by Commission List**

36. For health claims falling within the scope of Article 13(1), but not included in the Article 13(3) list of permitted claims (once adopted), potential users must attempt to add them to the Commission’s list pursuant to the procedures discussed in Article 13(5). In particular, an application for an addition to the Article 13(3) list must be submitted to a competent authority of an EU Member State which will inform the EFSA.<sup>31</sup> The EFSA must then prepare an opinion on the health claim and verify in particular whether (1) the health claim is substantiated by scientific evidence, and (2) the wording of the health claim complies with the criteria laid down in the Regulation.<sup>32</sup>

37. If the EFSA issues an opinion in favor of the inclusion of the health claim in the Article 13 list of permitted claims, the European Commission must take a decision on the application, taking into account the EFSA opinion, EU law and “other [relevant] legitimate factors”, and after having consulted the Member States.<sup>33</sup>

38. However, if the EFSA opinion does not support inclusion of the health claim in the Article 13 list of permitted claims, the European Commission must adopt a final decision in

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<sup>30</sup> EU Health Claims Regulation, Article 13(1).

<sup>31</sup> EU Health Claims Regulation, Articles 13(5) and 18.

<sup>32</sup> EU Health Claims Regulation, Article 16.

<sup>33</sup> EU Health Claims Regulation, Article 18(4).

accordance with the so-called regulatory procedure with scrutiny.<sup>34</sup> In short, that procedure involves a committee of representatives of the EU Member States giving an opinion on the draft decision, and provides the European Parliament and the Council of the EU with an opportunity to block adoption of the draft decision.<sup>35</sup>

### **3. Article 14 Health Claims Related to Reduction of Disease Risk and Children’s Development and Health**

39. A separate list of permitted claims will be prepared for Article 14 claims, which are claims related to reduction of disease risk, and to children’s development of health. These claims are subject to a systematic authorization procedure, similar to the procedure for Article 13(5) claims. An application must be submitted to a competent authority of an EU Member State, and EFSA will prepare an opinion on the health claim and verify whether (1) the health claim is substantiated by scientific evidence, and (2) the wording of the health claim complies with the criteria laid down in the Regulation.<sup>36</sup>

40. In addition, the European Commission must then submit a draft decision on the particular Article 14 claims to its Standing Committee on the Food Chain and Animal Health (“SCFCAH”), taking into account the EFSA’s opinion, EU law and other relevant legitimate factors.<sup>37</sup> The final decision is adopted in accordance with the regulatory procedure with scrutiny (described above), even if the draft decision is in accordance with the EFSA opinion.<sup>38</sup>

41. Health claims included in the Article 13 or Article 14 permitted claims lists can be used by any food business operator, except to the extent data protection restrictions apply.<sup>39</sup>

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<sup>34</sup> EU Health Claims Regulation, Article 18(5).

<sup>35</sup> The regulatory procedure with scrutiny is set out in Article 5a of Council Decision 1999/468/EC of 28 June 1998. Pursuant to Article 12 of Regulation (EU) No 182/2011, which repeals Council Decision 1999/468/EC, “the effects of Article 5a of Decision 1999/468/EC shall be maintained” for existing legislation making references thereto.

<sup>36</sup> EU Health Claims Regulation, Articles 15 and 16.

<sup>37</sup> EU Health Claims Regulation, Articles 17(1) and 23(2).

<sup>38</sup> EU Health Claims Regulation, Article 17(3).

<sup>39</sup> EU Health Claims Regulation, Article 17(5). Data protection restrictions can be included in the European Commission decision authorizing an Article 13 or 14 claim if the decision is adopted in accordance with a slightly different procedure set out in Article 5 of Regulation (EU) No 182/2011: if the European Commission proposes to restrict the use of the claim in favor of the applicant, it can adopt a draft decision to that effect if a committee of Member States representatives supports the proposal by a weighed qualified majority. However, if the committee delivers a negative opinion, the European Commission cannot adopt the decision. The

#### **D. Implementation of the Regulation**

42. As is apparent from the description of the Regulation, the EFSA plays a crucial role in the assessment and authorization process for health claims. The European Commission's decision to propose the authorization of a health claim in almost all cases depends on whether the EFSA adopts a positive or negative opinion on the health claim concerned.

##### **1. Implementing Regulation and Terms of Reference**

43. The European Commission provided the EFSA with specific Terms of Reference for its review of Article 13(1) claims that may be included in its initial list of permitted health claims.<sup>40</sup> The Terms of Reference instruct the EFSA to focus in particular on:

1. whether the information supplied adequately characterizes the food pertinent to the beneficial effect;
2. whether the beneficial effect of the food on the function is substantiated by generally accepted scientific evidence by taking into account the totality of the available scientific data, and by weighing the evidence; and
3. the specific importance of the food for the claimed effect, especially for functions affected by a large number of dietary factors (*i.e.*, is a reference to a single food scientifically pertinent).

44. In addition, the Terms of Reference instruct the EFSA to consider the claimed effect on the identified function, and advise the Commission on the extent to which:

1. the claimed effect of the food on the identified function is beneficial;
2. a cause and effect relationship has been established between consumption of the food and the claimed effect in humans and whether the quantity of the effect is related to the quantity consumed;
3. where appropriate, the effect on the function is significant in relation to the quantity of the food proposed to be consumed and if this quantity could reasonably be consumed as part of a balanced diet;
4. the specific study group(s) in which the evidence was obtained is representative of the target population for which the claim is intended;
5. the wordings used to express the claimed effect reflect the scientific evidence and complies with the criteria laid down in the Regulation.

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authorization will be valid for 5 years, after which a new decision authorizing the claim, without the restriction on the use of proprietary data, must be adopted in accordance with the regulatory procedure with scrutiny. See Articles 17(3), 18(5) and 21 of the Regulation.

<sup>40</sup> The Terms of Reference can be found here: <http://www.efsa.europa.eu/en/ndaclaims13/docs/ndaart13tor.pdf>.

45. A background note accompanying the Terms of Reference clarifies that the beneficial effects “should be significant i.e. satisfactorily demonstrate to beneficially affect identified functions in the body in a way which is relevant to health”.<sup>41</sup>

46. With respect to Article 13(5) and Article 14 claims, rather than terms of reference, the European Commission adopted a distinct Regulation establishing implementing rules for applications for authorization of such claims.<sup>42</sup> The Implementing Regulation provides a detailed overview of the information that must be included in an application. Some of the key elements are:

- a) all scientific data that are pertinent to the claim must be included, whether in favor of the claim or not;
- b) the supporting evidence for a claim must consist primarily of studies in humans;
- c) the evidence must demonstrate:
  - i. whether the claimed effect of the food is beneficial for human health;
  - ii. a cause and effect relationship between consumption of the food and the claimed effect in humans;
  - iii. whether the quantity of the food and pattern of consumption required to obtain the claimed effect could reasonably be achieved as part of a balanced diet;
  - iv. whether the specific study group(s) in which the evidence was obtained is representative of the target population for which the claim is intended;
- d) detailed information must be given regarding the characteristics of the food or food constituent.<sup>43</sup>

## 2. EFSA Implementation

47. As a result of the EFSA’s strict application of the Regulation, in the first two batches of published opinions on Article 13(1) claims, the EFSA has rejected more than 95% of potential health claims relating to food supplements not containing vitamins or minerals.<sup>44</sup>

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<sup>41</sup> Terms of Reference, p. 3 (emphasis added).

<sup>42</sup> Commission Regulation (EC) No 353/2008 of 18 April 2008 establishing implementing rules for applications for authorisation of health claims provided for in Article 15 of Regulation (EC) No 1924/2006 of the European Parliament and of the Council, OJ L 1009, 19.4.2008, p. 11, as amended (“Implementing Regulation”).

<sup>43</sup> Implementing Regulation, Article 5(a) and Annex.

<sup>44</sup> Impact Assessment Brookes, pp. 4, 8, 21.

Moreover, by May 2010 all but one Article 13(5) claim and about 75% of Article 14 claims had been rejected.<sup>45</sup>

48. The EFSA has set out its interpretation of the Regulation in two briefing documents: the first briefing document is addressed to EU Member States and the European Commission, and applies only to Article 13(1) claims.<sup>46</sup> The briefing document for stakeholders is an updated and expanded version of the briefing document for the EU Member States and the European Commission, and applies to Article 13(1), 13(5) and 14 claims.<sup>47</sup>

49. In the Briefing Document for Stakeholders, the EFSA indicates that it will consider a claim to be substantiated only if its assessment of all three criteria set out in the Terms of Reference is positive. In other words, only if

1. the food constituent is defined and characterized;
2. the claimed effect is defined and is a beneficial physiological effect; and
3. a cause and effect relationship is established between the consumption of the food/constituent and the claimed effects;

will the EFSA consider a claim substantiated. Notably, if no human studies pertinent to the claim (meaning, studies using the food/constituent and with appropriate outcome measures in a group that is representative of the target group for the claim) are submitted, the EFSA will conclude that the third criterion has not been fulfilled.<sup>48</sup>

50. It is clear from the Briefing Document for Stakeholders that the EFSA examines in detail whether studies submitted as evidence are pertinent, *i.e.*, studies from which scientific conclusions can be drawn for the substantiation of the claim. In particular, the studies must be carried out with the food/constituent concerned, under conditions of use that can

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<sup>45</sup> Impact Assessment Brookes, p. 8.

<sup>46</sup> EFSA, *Briefing document for Member States and European Commission on the evaluation of Article 13.1 health claims* (“Briefing Document for Member States”), EFSA Journal 2009, 7(11):1386.

<sup>47</sup> EFSA, *Draft Scientific Report of EFSA - Briefing document for stakeholders on the evaluation of Article 13.1, 13.5 and 14 health claims* (“Briefing Document for Stakeholders”), available at: <http://www.efsa.europa.eu/en/events/event/nda100601.htm>. Note that the document is referred to as a “draft”. It was discussed with stakeholders in June 2010 and the European Commission’s website indicates that a final version is under preparation.

<sup>48</sup> Briefing Document for Stakeholders, p. 4.

reasonably be expected in real life, and on a study group representative of the relevant population or from which the results can be extrapolated to the relevant population.<sup>49</sup>

51. The EFSA also scrutinizes in detail whether the food or food constituent concerned has been sufficiently defined and characterized to establish that evidence provided in support of a claim is pertinent, and to allow the definition of appropriate conditions of use. The Briefing Document for Stakeholders specifies what studies are required for specific formulations, constituents and combinations of constituents.<sup>50</sup>

52. In order to demonstrate that a claimed effect is beneficial, the EFSA requires that the claimed effect is “sufficiently defined to establish that the studies identified for substantiation of the claim were performed with (an) appropriate outcome measure(s) of that claimed effect”.<sup>51</sup> Moreover, the claimed effect must refer to a specific health claim: it “needs to be specific enough to be testable and measurable by generally accepted standards”.<sup>52</sup>

53. The EFSA has indicated that it adopts one of three standard conclusions for each health claim:

1. A cause and effect relationship has been established between the consumption of the food/constituent and the claimed effect;
2. The evidence provided is insufficient to establish a cause and effect relationship between the consumption of the food/constituent and the claimed effect (*i.e.*, there is supporting evidence, but it is not conclusive); or
3. A cause and effect relationship has not been established between the consumption of the food/constituent and the claimed effect (*i.e.*, there is no or, at most, limited scientific evidence).<sup>53</sup>

#### **E. Current Status and Legal Effects of the Regulation**

54. Claims related to the role of a nutrient or other substance in growth, development and the functions of the body (per Article 13(1)(a)) can continue to be used until the adoption of a European Union list of permitted claims under Article 13(3), provided that they comply with

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<sup>49</sup> Briefing Document for Stakeholders, p. 8.

<sup>50</sup> For example, for a food category the supporting data must sufficiently address “the variability between individual foods for those characteristics considered pertinent to the claimed effects” (Briefing Document for Stakeholders, p. 9). For a manufacturing process, the submitted data must “show consistency in the final product for those characteristics pertinent to the claimed effect” (Briefing Document for Stakeholders, p. 10).

<sup>51</sup> Briefing Document for Stakeholders, p. 11.

<sup>52</sup> Briefing Document for Stakeholders, p. 11.

<sup>53</sup> Briefing Document for Stakeholders, pp. 6-7.

the requirements set out in the Regulation.<sup>54</sup> As indicated above, the European Commission has not yet adopted such a list, and will only propose such a list after the EFSA has published opinions on all the claims that were submitted by Member States by January 31, 2008, except claims relating to botanicals.<sup>55</sup>

55. Other types of health claims listed in Article 13(1) (*i.e.*, psychological and behavioral functions; and slimming, weight- and appetite-control claims), as well as reduction of disease risk claims covered by Article 14, are also subject to grandfather clauses. If such health claims were used before the entry into force of the Regulation, and either (a) an application for those claims was submitted by January 2008 or (b) those claims previously had been subject to the evaluation and authorization of a Member State, they can continue to be used until six months *after* a decision by the Commission refusing to authorize those claims.<sup>56</sup>

56. There is a lengthier grandfather provision for products “bearing trade marks or brand names existing before 1 January 2005 which do not comply” with the Regulation, as they may continue to be marketed until January 19, 2022 before having to comply.<sup>57</sup>

57. To date, the European Commission has adopted five Commission Regulations, authorizing twelve Article 14 claims, and one Commission Decision authorizing one Article 13(5) claim.<sup>58</sup> The European Commission has so far rejected thirteen Article 13(5) claims and thirty-nine Article 14 claims.<sup>59</sup> Thus, despite the voluminous set of EFSA opinions (over 300 opinions covering more than 2000 claims), the current impact has been small compared to what will be the case once the initial Article 13(3) list of permitted claims is approved, particularly if that list omits, as expected, the health claims that have been rejected by the EFSA.

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<sup>54</sup> European Health Claims Regulation, Article 28(5) and (6).

<sup>55</sup> European Commission press release, *Food: Commission reviews the progressive adoption of the list of permitted health claims*, IP/10/1176, September 27, 2010.

<sup>56</sup> European Health Claims Regulation, Article 28(6).

<sup>57</sup> European Health Claims Regulation, Article 28(2).

<sup>58</sup> The following Commission Regulations were listed in the EU’s Register of nutrition and health claims made on foods on April 15, 2011: No 384/2010; No 983/2009 as amended by No 376/2010; No 1024/2009; and No 957/2010. In addition, the European Commission authorized an Article 13(5) claim by means of Commission Decision 2009/980/EU as amended by Commission Decision 2010/770/EU.

<sup>59</sup> The following Commission Regulations were listed in the EU’s Register of nutrition and health claims made on foods on April 15, 2011: No 957/2010; No 384/2010; No 983/2009; No 1167/2009; No 1162/2010; No 1024/2009; No 1161/2010; No 958/2010; No 375/2010; No 382/2010; No 383/2010; No 984/2009; 1025/2009; and No 1168/2009.

58. Therefore, despite the many negative EFSA opinions that have been published so far, most health claims concerned can still be used on food products.<sup>60</sup> This situation will rapidly change as the EFSA opinions result in a short Community list of permitted health claims under Article 13(3).

### **III. THE EU HEALTH CLAIMS REGULATION, AS APPLIED, VIOLATES THE EU'S OBLIGATIONS UNDER THE WTO TBT AGREEMENT**

59. The WTO *TBT Agreement* sets out the disciplines that apply to measures such as the EU Health Claims Regulation, *i.e.*, measures that appear to fulfill a legitimate objective but that do so in a manner that disrupts international trade in goods. Specifically, the *TBT Agreement* applies to technical regulations, standards and conformity assessment procedures, as defined in Annex 1 thereto. Essentially, it requires WTO Members to ensure that their national regulations comply with specific rules aimed at preventing unnecessary obstacles to international trade.

60. The rules set out in the *TBT Agreement* are legally binding on all WTO Members, including the European Union and each of its Member States. Notably, if a WTO Member believes that another Member is violating the *TBT Agreement*, it may choose to initiate WTO dispute settlement proceedings. If a WTO dispute settlement panel (and/or the WTO Appellate Body) were to find that the EU Health Claims Regulation, as such or as applied, violated the TBT Agreement, then the EU would be required to withdraw or modify the measure, or face the possibility of authorized trade retaliation by the complaining Member.

61. Pursuant to WTO dispute settlement, a measure may be challenged "as such", "as applied", or in both ways.<sup>61</sup> The starting point for an analysis of an "as such" challenge is the measure on its face (to the extent the measure is a written measure), with the inquiry focusing on whether the text of the measure, itself, violates WTO rules. By contrast, an "as applied" challenge can be brought against measures where the text itself might be consistent with

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<sup>60</sup> Regulation, Article 28(5) and (6). See European Commission press release, *Food: Commission reviews the progressive adoption of the list of permitted health claims*, IP/10/1176, September 27, 2010.

<sup>61</sup> See, e.g., WTO Appellate Body Report, *US-Carbon Steel*, paras. 156: "We note, first, that, in dispute settlement proceedings, Members may challenge the consistency with the covered agreements of another Member's laws, as such, as distinguished from any specific application of those laws." See also WTO Appellate Body Report, *US – 1916 Act*, para. 75; WTO Appellate Body Report, *US – Corrosion-Resistant Steel Sunset Review*, para. 82.

WTO rules, but their application in practice is not. Or, a Member may choose to challenge a measure both “as such” and “as applied”.

62. With respect to the EU health claims regime, we believe that it is the *application* of the Regulation, rather than the text of the measure, as such, that violates the disciplines of the *TBT Agreement*. The strength of our arguments depends, therefore, to a large extent on the factual evidence available to demonstrate that the EU’s application of the Regulation is inconsistent with the *TBT Agreement*. In addition, we note that a WTO challenge against the Regulation as applied can only be brought to the extent the Regulation’s application results in legally binding decisions, such as a prohibition on the use of certain health claims.<sup>62</sup>

63. In the sections below, we explain why the EU Health Claims Regulation and elements thereof fall within the scope of the *TBT Agreement*, and we detail the violations of the *TBT Agreement* that result from application of the Regulation by the EFSA and the European Commission, assuming that the European Commission will generally follow the EFSA opinions. This memorandum does not address the compatibility with WTO law of the EU’s treatment of nutrition claims.

**A. The Regulation, As Applied, is Inconsistent with Article 2.2 of the *TBT Agreement***

64. There are credible claims that the manner in which the Regulation is applied is inconsistent with Article 2.2 of the *TBT Agreement*. Article 2.2 provides as follows:

Members shall ensure that technical regulations are not prepared, adopted or applied with a view to or with the effect of creating unnecessary obstacles to international trade. For this purpose, technical regulations shall not be more trade-restrictive than necessary to fulfil a legitimate objective, taking account of the risks non-fulfilment would create. Such legitimate objectives are, *inter alia*: national security requirements; the prevention of deceptive practices; protection of human health or safety, animal or plant life or health, or the environment. In assessing such risks, relevant elements of consideration are, *inter alia*: available scientific and technical

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<sup>62</sup> Opinions of the EFSA are not legally binding and under the EU Health Claims Regulation do not themselves result in authorizations or prohibitions. It is only when the opinions lead to an EU measure prohibiting (or not authorizing) the use of the health claims concerned that a WTO challenge can be brought.

information, related processing technology or intended end-uses of products.<sup>63</sup>

65. Based on a review of the text, there are four elements necessary to prove a claim under Article 2.2 of the *TBT Agreement*.<sup>64</sup> First, the measure of concern must be a “technical regulation” within the meaning of the *TBT Agreement*. Second, the stated objective must be “legitimate”, although it does not necessarily need to qualify as one of the types of objectives listed in the third sentence of the provision. Third, there must be an actual link between the measure and the declared legitimate objective, *i.e.*, the measure must contribute to the advancement of the declared objective. Fourth, in light of the legitimate objective, one must determine whether the impact of the measure on international trade is more trade-restrictive than necessary to fulfill the legitimate objective. Each of these elements is addressed below.

### **1. The EU Health Claims Regulation is a “Technical Regulation”**

66. The EU Health Claims Regulation is a “technical regulation”, as defined in Annex 1, paragraph 1 of the *TBT Agreement*, and therefore subject to the disciplines of the *TBT Agreement*. Indeed, the EU has previously acknowledged that the Regulation is a “technical regulation” and notified the draft Regulation pursuant to the *TBT Agreement*, and the notification was circulated under the auspices of the WTO TBT Committee.<sup>65</sup>

67. Annex 1, paragraph 1 of the *TBT Agreement* provides the following definition of a “technical regulation”:

Document which lays down product characteristics or their related processes and production methods, including the applicable administrative provisions, with which compliance is mandatory. It may also include or deal exclusively with terminology, symbols, packaging, marking or labelling requirements as they apply to a product, process or production method.

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<sup>63</sup> Underlining added.

<sup>64</sup> WTO panels and the WTO Appellate Body interpret the treaty text pursuant to the customary rules of international law codified in the *Vienna Convention on the Law of Treaties 1969* (“Vienna Convention”). The interpretation begins with Article 31.1 of the *Vienna Convention*, which provides that “A treaty shall be interpreted in good faith in accordance with the ordinary meaning to be given to the terms of the treaty in their context and in the light of its object and purpose”.

<sup>65</sup> WTO, Notification of the European Communities to the Committee on Technical Barriers to Trade, G/TBT/N/EEC/33, August 29, 2003.

68. The WTO Appellate Body has clarified that a measure must be examined “as a whole” to determine its proper legal character.<sup>66</sup> To meet the definition of a technical regulation (1) a measure must set forth “product characteristics”, (2) “compliance” with these product characteristics must be “mandatory”, and (3) the measure must be applicable to an “identifiable” product or group of products.<sup>67</sup>

69. The EU Health Claims Regulation satisfies each prong of this definition, beginning with the fact that it sets forth “product characteristics” that are mandatory. The definition of a “technical regulation” indicates that a regulation may “deal exclusively with terminology, symbols, packaging, marking or labelling requirements”, leading the WTO Appellate Body to conclude that product characteristics may include “not only features and qualities intrinsic to the product itself, but also related ‘characteristics’, such as the means of identification, the presentation and the appearance of a product.”<sup>68</sup>

70. In this case, the Regulation imposes specific requirements regarding the labelling, presentation and advertising of all food products, which fall into the scope of “product characteristics” covered by the definition of a technical regulation.<sup>69</sup> In particular, it is clear that the Regulation provides that nutrition and health claims can be used in the labelling, presentation and advertising of food products placed on the EU market only if they comply with a variety of requirements set out in the Regulation.<sup>70</sup> For example, Article 3 indicates that compliance with all of the Regulation’s requirements relating to product characteristics is mandatory, stating that “[n]utrition and health claims may be used in the labelling, presentation and advertising of foods . . . *only if they comply* with the provisions of this Regulation”.<sup>71</sup>

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<sup>66</sup> WTO Appellate Body Report, *EC – Asbestos*, para. 64.

<sup>67</sup> WTO Appellate Body Report, *EC – Asbestos*, paras. 66-70. *See also* WTO Appellate Body Report, *EC – Sardines*, para. 176.

<sup>68</sup> *See* WTO Appellate Body Report, *EC – Asbestos*, para. 67.

<sup>69</sup> That labeling requirements can qualify as a technical regulation for the purposes of the *TBT Agreement* can be seen from the WTO Appellate Body Report in *EC – Sardines* (paras. 174, 187-195). *See also* WTO Panel Report, *EC – Trademarks and Geographical Indications*, paras. 7.448-7.452.

<sup>70</sup> The WTO Appellate Body held in *EC – Asbestos* that a technical regulation “may provide, positively, that products *must possess* certain ‘characteristics’, or the document may require, negatively, that products *must not possess* certain ‘characteristics’”. In both cases, the legal result is the same: the document ‘lays down’ certain binding ‘characteristics’ for products, in one case affirmatively, and in the other by negative implication”. WTO Appellate Body Report, *EC – Asbestos*, para. 69.

<sup>71</sup> Emphasis added.

71. The final element of the definition of a “technical regulation” requires that a measure be applicable to an “identifiable” product or group of products. In *EC – Asbestos*, the WTO Appellate Body confirmed that this requires “identification of the product coverage of a technical regulation”.<sup>72</sup> It is clear from the Regulation, particularly Articles 1(2), 3 and 5(1), that it applies to “foods”.<sup>73</sup> Therefore, the Regulation applies to an identifiable group of products: “food” as defined in Article 2 of Regulation (EC) No 178/2002.

72. Thus, the Regulation is a “technical regulation” in the sense of Annex 1 to the *TBT Agreement*.

## **2. The Regulation Aims to Satisfy a “Legitimate Objective” Within the Meaning of Article 2.2 of the *TBT Agreement***

73. The Regulation’s main objective is to inform consumers about food products and protect consumers against misleading health and nutrition claims. In addition, the Regulation is aimed at (1) increasing legal security for economic operators, (2) ensuring fair competition in the area of foods, and (3) the promotion and protection of innovation in the area of foods.<sup>74</sup>

74. The Regulation’s objective of protecting consumers against misleading claims arguably falls within the scope of two “legitimate objectives” listed in Article 2.2 of the *TBT Agreement*: “the prevention of deceptive practices” and “protection of human health or safety”. We note, however, that the Regulation’s other objectives (informing consumers; increasing legal security; ensuring fair competition; promoting and protecting innovation) are not set forth in the illustrative, non-exhaustive list of legitimate objectives.

75. A WTO Member has the right to declare that its technical regulation is linked to a particular “legitimate objective” not listed in the illustrative list of Article 2.2.<sup>75</sup> It would be very difficult to successfully challenge a Member’s characterization of the objective of its

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<sup>72</sup> WTO Appellate Body Report, *EC – Asbestos*, para. 70.

<sup>73</sup> Article 2(1)(a) of the Regulation refers to the definition in Article 2 of 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, 1.2.2002, p. 1, as amended. See the text of Article 2 of Regulation (EC) No 178/2002 for the full definition.

<sup>74</sup> See paras. 10 - 14 above.

<sup>75</sup> WTO Appellate Body Report, *EC – Sardines*, para. 286: “[...] given the use of the term ‘*inter alia*’ in Article 2.2, the objectives covered by the term ‘legitimate objectives’ in Article 2.4 extend beyond the list of objectives specifically mentioned in Article 2.2.”

own Measure, absent persuasive factual evidence demonstrating that it is not accurate. In this case, there do indeed not appear to be strong arguments to challenge the stated objectives of the Regulation, or whether those objectives are “legitimate”.

76. The crux of the violation is not related to the legitimacy or accuracy of the objectives of the EU Health Claims Regulation, but rather whether the application of the Regulation makes a contribution to the declared “legitimate” objectives that balances the interests of international trade.

**3. The Application of the Regulation is More Trade Restrictive than Necessary for the Achievement of the Regulation’s Objective(s)**

77. The EU Health Claims Regulation, as applied, appears to violate Article 2.2 of the *TBT Agreement* because it results in an “unnecessary obstacle to international trade” in the sense that it is “more trade-restrictive than necessary” to fulfill its objective. This is demonstrated, in part, by showing that the European Union could satisfy the same objectives with alternative, less trade-restrictive measures.

**a. *The Regulation’s Application Has a Severe Trade-Restrictive Impact***

78. As we noted above, the EFSA has been applying the Regulation in a very restrictive manner. If the European Commission follows the EFSA recommendations, this will ultimately lead to a prohibition on the use of many health claims, including about 95% of all health claims relating to food supplements not containing vitamins or minerals.<sup>76</sup> Moreover, based on the information submitted by CRN members, it appears that a significant number of products that would be affected by the Commission’s actions are imported into the EU. Accordingly, the restrictive impact on trade in goods is likely to be severe.

79. A review of the EFSA opinions published so far reveals that many rejections mainly result from an overly restrictive application of the requirements in the Regulation and the Terms of Reference. For example, the Regulation, the Terms of Reference and the Implementing Regulation all specifically indicate that the EFSA should assess claims by “taking into account the totality of the available evidence” and by “weighing the evidence”,

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<sup>76</sup> Impact Assessment Brookes, pp. 4, 8.

which provides the EFSA with significant discretion in how it chooses to consider the application and the accompanying evidence.<sup>77</sup>

80. Nevertheless, the EFSA often classifies submitted evidence as “not pertinent” and fails to even consider it.<sup>78</sup> For example, the EFSA has systematically rejected studies that were not done on the general population, *e.g.*, because it considers that the evidence concerned did not establish that patients were representative of the general population.<sup>79</sup> The EFSA’s refusal to consider a large number of scientific studies is not consistent with its task to “tak[e] into account the totality of the available evidence”.

81. The EFSA’s opinion on lutein provides a clear example.<sup>80</sup> Considerable evidence was submitted demonstrating that lutein has a beneficial effect on eye health. However, instead of weighing *all* the evidence before it, the EFSA focused on human intervention studies, of which it rejected a significant number, *e.g.*, because it considered that the results of studies in patients could not be extrapolated to the general population.<sup>81</sup> Even though the EFSA recognized that epidemiological studies consistently supported a beneficial role for lutein in vision, it concluded that this was not supported by the *weight of evidence* from 44 pertinent human intervention studies.<sup>82</sup> In other words, instead of looking at the overall support for the claim in both epidemiological studies and human intervention studies, the EFSA applied a weight of evidence approach only with regard to the latter studies.

82. The EFSA opinion relating to anti-oxidant properties provides another example of the overly restrictive approach to reviewing health claims.<sup>83</sup> While anti-oxidative properties have

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<sup>77</sup> Regulation, Preamble, para. 17. Terms of Reference, p. 5. Implementing Regulation, Annex, para. 3 of the “General Principles for the Scientific Substantiation”.

<sup>78</sup> See the concerns expressed by the European Federation of Associations of Health Product Manufacturers (“EHPM”): <http://www.ehpm.org/EHPM-comments-on-claims.aspx>. See in particular EHPM, *Comments in relation to the second batch of Article 13(1) claims opinions*, May 2010, p. 2.

<sup>79</sup> See, *e.g.*, EFSA, *Scientific Opinion on the substantiation of health claims related to glucosamine alone or in combination with chondroitin sulphate and maintenance of joints (ID 1561, 1562, 1563, 1564, 1565) and reduction of inflammation (ID 1869) pursuant to Article 13(1) of Regulation (EC) No 1924/2006*, EFSA Journal, Volume 7, Issue 9:1264. See EHPM, *Comments in relation to the first batch of Article 13(1) claims opinions*, October 2009, p. 2.

<sup>80</sup> EFSA, *Scientific Opinion on the substantiation of health claims related to lutein and maintenance of vision (ID 1603, 1604, 1931) pursuant to Article 13(1) of Regulation (EC) No 1924/2006* (“EFSA Opinion on lutein”), EFSA Journal, Volume 8, Issue 2:1492.

<sup>81</sup> EFSA Opinion on lutein, p. 6.

<sup>82</sup> EFSA Opinion on lutein, p. 8.

<sup>83</sup> EFSA, *Scientific Opinion on the substantiation of health claims related to various food(s)/food constituent(s) and protection of cells from premature aging, antioxidant activity, antioxidant content and antioxidant*

generally been acknowledged as providing important beneficial effects for public health, as well understood by consumers, the EFSA summarily concluded that there is no or very limited support for the related claims (*e.g.*, for tea and grape seed extracts). Despite support for the claims in animal and *in vitro* studies, the EFSA appears to have based its conclusion on the absence of, in its view, pertinent human intervention studies.<sup>84</sup> Notably, the EFSA’s conclusion is inconsistent with, for example, the general recommendation to consume fruit and vegetables.<sup>85</sup>

83. Moreover, instead of applying different standards to different claims, a review of the EFSA’s published opinions reveals that it has been subjecting all or most claims to the evidentiary standards for the “extreme end of the claims spectrum”: reduction of disease risk claims. This is not only inappropriate but also an impossible standard to meet for many health claims.<sup>86</sup>

84. A recent economic impact assessment found that as a result of the EFSA’s current approach the EU market for food supplements not containing vitamins or minerals “[...] may decrease in size by about 25% (€645 million at the ex-production facility level or €1,031 million at retail level) and result in a 30% loss of gross profitability (€242 million)<sup>87</sup>. Furthermore, it has been estimated that the “additional costs associated with, for example, stock and packaging write-offs and changes, would likely add €291 million, resulting in total short term losses equal to two-thirds of annual gross profits in the ‘other substances’ market and 41% of total gross profits in the broader market, including vitamins and minerals”<sup>88</sup>.

85. Information supplied by CRN Members confirms the significant trade impact of the Regulation as applied by the EFSA: it is estimated to impact up to €260 million in trade of individual companies and is anticipated to lead to decreases in revenue of 25% or more.

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*properties, and protection of DNA, proteins and lipids from oxidative damage pursuant to Article 13(1) of Regulation (EC) No 1924/2006 (“EFSA Opinion on protection of cells”), EFSA Journal, Volume 8, Issue 2:1489.*

<sup>84</sup> EFSA Opinion on protection of cells, p. 7.

<sup>85</sup> See, *e.g.*, EHPM, *Comments in relation to the second batch of Article 13(1) claims opinions*, May 2010, p. 13.

<sup>86</sup> EHPM, *Comments in relation to the second batch of Article 13(1) claims opinions*, May 2010, p. 5.

<sup>87</sup> Impact Assessment Brookes, p. 5.

<sup>88</sup> Impact Assessment Brookes, p. 5.

86. There can therefore be no doubt that the Regulation, as currently applied, has a severe trade-restrictive impact. We note that the Regulation’s trade restrictions need not be high to render the measure “more trade restrictive than necessary” within the meaning of Article 2.2 of the *TBT Agreement*. There is no *absolute* amount of trade that needs to be impacted in order to succeed in a claim.

**b. *Less-Trade Restrictive Alternatives Would Fulfill the Regulation’s Legitimate Objectives***

87. To successfully claim that the manner in which the Regulation is currently applied violates Article 2.2, one must demonstrate that the resulting trade-restrictive impact is greater than any contribution the strict EFSA reviewing standard makes to the specified objectives.

In this regard, the WTO Appellate Body has reasoned as follows:

In order to determine whether a measure is “necessary” [...] a panel must assess all the relevant factors, *particularly the extent of the contribution to the achievement of a measure’s objective and its trade restrictiveness*, in the light of the importance of the interests or the values at stake. If this analysis yields a preliminary conclusion that the measure is necessary, this result must be confirmed by comparing the measure with its possible alternatives, which may be less trade restrictive while providing an equivalent contribution to the achievement of the objective pursued.<sup>89</sup>

Although the WTO Appellate Body made this statement in the context of interpreting Article XX(b) of the *General Agreement on Tariffs and Trade 1994* (“*GATT 1994*”), these criteria for assessing the “necessity” of a trade measure linked to a particular objective are fully applicable to the parallel determination of necessity in Article 2.2 of the *TBT Agreement*. Specifically, while Article XX(b) of the *GATT 1994* allows for Members to take measures “necessary to protect human, animal or plant life or health”, Article 2.2 of the *TBT Agreement* states that the technical regulation must “not be more trade-restrictive than necessary to fulfil a legitimate objective”.<sup>90</sup>

88. As discussed below, the trade-restrictive effect of the Regulation as currently applied is far greater than any positive contribution that this high level of scrutiny by EFSA could

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<sup>89</sup> WTO Appellate Body Report, *Brazil – Retreaded Tyres*, para. 156 (emphasis added).

<sup>90</sup> Emphases added.

make to any of the specified objectives. We recall that the estimated impact of the EFSA's current application of the Regulation is a 25% decrease in size of the EU market for the food supplements concerned, leading to a 30% loss of gross profitability. The EFSA has rejected the vast majority of all health claims it has reviewed so far. Particularly affected are food supplements not containing vitamins or minerals: as explained above, if the EFSA maintains its current approach, close to 95% of all health claims relating to these products will be rejected.

89. While this high percentage of rejections could arguably contribute to the Regulation's main objective of protecting consumers against misleading health claims -- in the simple sense that when there are no health claims there necessarily are no misleading health claims -- its trade-restrictive impact far outweighs the contribution to the objective. Many of these health claims have been used for years on food products in the EU market. For most of them, there is no indication that they are in fact misleading or deceptive, even though regulators had every right to challenge those health claims based on, for example, the General Food Labeling Directive, as implemented by the Member States.<sup>91</sup> Indeed, as the EFSA acknowledges, there is supporting evidence for many of the very health claims that it has rejected, although such evidence has not been considered conclusive by the EFSA.

90. While the EU Health Claims Regulation, itself, acknowledges that the use of misleading information on the labelling or in advertising of food products was already prohibited in the EU prior to the adoption of the Regulation by Directive 2000/13/EC, it alleges that despite Directive 2000/13/EC:

There is a wide variety of claims currently used in the labelling and advertising of foods in some Member States relating to substances that have not been shown to be beneficial or for which at present there is not sufficient scientific agreement.<sup>92</sup>

In other words, the European Union argues that despite Directive 2000/13/EC, there are many health claims on the EU market of unknown reliability. Establishing a positive assessment

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<sup>91</sup> As discussed above, Article 2 of the General Food Labeling Directive prohibits misleading food labeling practices. Under EU law, Member States are obliged to implement this prohibition in their national legislation and are responsible for enforcing the prohibition.

<sup>92</sup> EU Health Claims Regulation, Preamble, para. 14.

and authorization process could arguably ensure that there are no misleading or deceptive health claims on the EU market.

91. However, the Regulation as it is currently applied has a different effect: it prevents the use of health claims that have not been shown to be misleading or deceptive, and for which there is supporting evidence of their veracity. These claims are being rejected because, instead of applying a “weight of evidence” approach, the EFSA is, *inter alia*, rejecting large numbers of scientific studies that are not randomized controlled trials (“RCTs”), normally required for pharmaceutical products, and requiring evidence that unequivocally and conclusively supports a health claim.

92. The Regulation’s contribution to the other declared objectives of (1) increasing legal security for economic operators, (2) ensuring fair competition in the area of foods, and (3) the promotion and protection of innovation in the area of foods, is also minimal.

93. We understand from, *inter alia*, CRN Members that the Regulation has so far led to *insecurity* and *uncertainty* for industry. The manner in which the EFSA has applied the Regulation’s requirements appears inconsistent, applying different standards to food supplements containing vitamins and minerals as compared to other food supplements not containing vitamins and minerals.<sup>93</sup> Furthermore, we understand that Member States are acting on the EFSA opinions and imposing restrictions on the use of health claims, even though the final step of the assessment and authorization process have not yet been completed. Lastly, as exemplified recently, even if the EFSA issues a favorable opinion on a health claim, industry still is not certain that the European Parliament or the Council will not block the authorization of the health claim.<sup>94</sup>

94. The Regulation also does not contribute to the objective of fair competition or the objective of promoting and protecting innovation in the area of foods. In particular, the

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<sup>93</sup> EHPM, *Comments in relation to the first batch of Article 13(1) claims opinions*, October 2009, p. 3.

<sup>94</sup> See, e.g., <http://www.europarl.europa.eu/nl/pressroom/content/20110314IPR15477/html/DHA-in-baby-food-Environment-Committee-opposes-health-claim>. On March 16, 2011 the European Parliament’s responsible committee voted against a health claim for which the EFSA had adopted a favorable opinion and which the European Commission had proposed to authorize. Despite the favorable EFSA opinion, the European Parliament’s committee argued that there is no scientific consensus on the claim. While the European Parliament narrowly rejected the committee’s motion on April 6, 2011 this remains a good example of the uncertainty created by the system.

different standards applied to food supplements containing vitamins and minerals, as compared to food supplements not containing vitamins and minerals, will likely lead to the rejection of 95% of all claims relating to the latter category. This will not only affect competition between these food supplements but will also stifle innovation, because it will be more difficult for industry to market products in the latter category, such as probiotics, which heavily rely on health claims.

95. We note that in assessing whether a measure is more trade restrictive than necessary, Article 2.2 of the *TBT Agreement* requires a government to take account of the “risks non-fulfilment [of its objective] would create”. (To be clear, Article 2.2 does not impose an obligation to perform a risk-benefit analysis with respect to a product, but is rather focused on the risk of non-fulfillment of the policy objective of the government implementing the regulation.) Furthermore, in assessing such risks, it also states that the intended end-uses of the products may be taken into account. In this case, a less trade-restrictive approach on the assessment of health claims, *i.e.*, permitting the use of health claims for which there is scientific support, even if not unequivocal, would not lead to significant risks for consumers of the food including those claims.

96. It should be recalled that pursuant to Article 4(1) of the Regulation, nutrition profiles and conditions for the use of health claims will be established. Furthermore, a less trade-restrictive approach to the assessment of claims would not change the fact that the Regulation prohibits misleading and deceptive claims.<sup>95</sup> Moreover, all food products are already subject to the EU’s food safety legislation.

97. In considering the “intended end-uses of” the regulated product, pursuant to Article 2.2 of the *TBT Agreement*, it must also be kept in mind that the Regulation relates to the use of health claims on food products, and not on pharmaceutical products. The overly restrictive approach adopted by the EFSA leads to an unnecessary and inappropriate medicalisation of foodstuffs that brings the treatment of food claims much closer to the evaluation and authorization of pharmaceutical products. False claims about pharmaceutical products (which can be the difference between life and death of a particular patient) will naturally have far greater negative implications than false health claims about foods, making it clear that

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<sup>95</sup> EU Health Claims Regulation, Article 3.

“the risk non-fulfilment would create” for pharmaceuticals is generally much more grave than the risk for food. In addition, the process and testing required to get a pharmaceutical product authorized requires a significant investment, which can be recouped once the product has been authorized. However, recoupment of investment is not as easy for food products bearing health claims. Health claims are aimed at informing consumers about food products and allowing them to supplement their diet, not at preventing, treating or curing diseases. This difference should be reflected in the EFSA’s assessment of health claims.<sup>96</sup>

98. The foregoing illustrates that a less restrictive EFSA approach to the assessment of health claims, taking account of the Regulation’s requirement to apply a “weight of evidence” approach with regard to *totality* of the evidence, would not lead to any significant risk. The Regulation already provides sufficient safeguards in the form of nutrition profiles, conditions of use, and a prohibition on misleading and deceptive claims. Although EFSA’s strict standards or requirements might be appropriate in the context of evaluating claims about the effectiveness and use of pharmaceutical products, the nature of the food is quite different than the nature of pharmaceuticals. Again, this type of consideration is specifically incorporated into Article 2.2 of the *TBT Agreement*. It is indeed our understanding, based on information received from CRN Members, that no other jurisdiction in the world evaluates health claims based on standards applicable to pharmaceutical products.

99. In case the European Union does not consider these safeguards sufficient, it could, e.g., adopt a complementary requirement providing that the labeling of a food product bearing a health claim for which there is scientific support, but no consensus, specifies that there is a lack of consensus. Indeed, we understand based on information received from CRN Members that this is the approach adopted by the United States.<sup>97</sup>

100. In conclusion, the above analysis demonstrates that the application of the EU Health Claims Regulation by the EFSA, to the extent their opinions are followed by the European

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<sup>96</sup> See, e.g., EHPM, *Comments in relation to the second batch of Article 13(1) claims opinions*, May 2010, p. 6.

<sup>97</sup> See U.S. Department of Health & Human Services, U.S. Food and Drug Administration, *Guidance for Industry: FDA’s Implementation of ‘Qualified Health Claims’: Questions and Answers; Final Guidance*, available at

<http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodLabelingNutrition/ucm053843.htm> (last visited 15 April 2011).

Commission, is “more trade-restrictive than necessary to fulfil a legitimate objective”, within the meaning of Article 2.2.

**c.      *The Regulation’s Application Creates “Unnecessary Obstacles to International Trade”***

101. The foregoing also suggests that the EU has failed to “ensure” that its technical regulation is “not prepared, adopted or *applied* with a view to or *with the effect* of creating unnecessary obstacles to international trade”, in violation of the first sentence of Article 2.2 of the TBT Agreement.<sup>98</sup>

102. As discussed above, the Regulation, as currently applied, will prevent a significant number of food products from being marketed with health claims, even though such health claims have not been shown to be either misleading or deceptive, and for which there is scientific support. Indeed, most of the health claims rejected by the EFSA are allowed in many other major markets. The result is a significant decrease in the size of the EU market for food supplements and considerable revenue losses for industry, including with respect to imports of food products into the European Union.

103. As detailed above, the obstacle to international trade created by the Regulation as currently applied is not “necessary”, because there are less trade-restrictive alternatives available to prevent misleading or deceptive health claims from being used on food products in the European Union. Preventing misleading or deceptive claims does not require a prohibition of all health claims for which there is significant scientific support but no complete consensus. For the foregoing reasons, the Regulation as currently applied violates Article 2.2 of the *TBT Agreement*.

**B.      *The Regulation is Inconsistent with Article 5.1.2 of the TBT Agreement***

104. The EU Health Claims Regulation, as applied, also appears to violate Article 5.1.2 of the *TBT Agreement* for many of the same substantive reasons discussed above with respect to Article 2.2. Article 5 of the *TBT Agreement* disciplines the “procedures for assessment of conformity by central government bodies”, as initially reflected by the heading to Article 5. Article 5.1.2 specifically provides, in pertinent part, as follows:

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<sup>98</sup> Emphases added.

5.1 Members shall ensure that, in cases where a positive assurance of conformity with technical regulations or standards is required, their central government bodies apply the following provisions to products originating in the territories of other Members: [...]

5.1.2 conformity assessment procedures are not prepared, adopted or applied with a view to or with the effect of creating unnecessary obstacles to international trade. This means, *inter alia*, that conformity assessment procedures shall not be more strict or be applied more strictly than is necessary to give the importing Member adequate confidence that products conform with the applicable technical regulations or standards, taking <sup>99</sup> account of the risks non-conformity would create.

105. Thus, for a measure to fall within the scope of Article 5.1.2, it must be a “conformity assessment procedure” aimed at ensuring that imported products conform with an applicable “technical regulation”. Rather than focusing on the overall EU Health Claims Regulation, as does Article 2.2 of the *TBT Agreement*, Article 5.1.2 considers the manner in which the relevant authorities determine whether a suggested health claim conforms with the terms of that Regulation.

**1. The EU Health Claims Regulation Establishes Conformity Assessment Procedures Within the Meaning of Article 5 of the *TBT Agreement***

106. Annex 1, paragraph 3 of the *TBT Agreement* provides the following definition of a “conformity assessment procedure”:

Any procedure used, directly or indirectly, to determine that relevant requirements in technical regulations or standards are fulfilled.

107. An explanatory note in Annex 1 clarifies that such procedures include, among others “procedures for sampling, testing and inspection; evaluation, verification and assurance of conformity; registration, accreditation and approval as well as their combinations.”

108. As described above, Articles 13 and 14 of the Regulation establish assessment and authorization procedures that all health claims must undergo before they can be used on the

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<sup>99</sup> Emphases added.

labelling of, or in presentations or advertisements relating to, food products marketed in the European Union. In general, before a health claim can be used on, or in relation to a food product, the EFSA must first adopt a favorable opinion on the health claim, following which the health claim will be added to a list of permitted health claims through an EU legislative procedure initiated by the European Commission.

109. The assessment procedures set out in Articles 13 and 14 of the Regulation are, therefore, aimed at ensuring that all health claims used on, or in relation to, food products marketed in the EU comply with the substantive requirements imposed by the Regulation. Food products bearing health claims cannot be marketed in the EU unless the health claims concerned have been assessed by the EFSA and authorized by the EU legislature.<sup>100</sup> These procedures can therefore be considered conformity assessment procedures within the meaning of the *TBT Agreement*.

**2. The Conformity Assessment Procedures Related to the EU Health Claims Regulation Are Inconsistent with Article 5.1.2 of the *TBT Agreement***

110. Having found that the Regulation establishes conformity assessment procedures aimed at ensuring that the labeling, presentation and advertising of food products complies with the substantive requirements imposed by the Regulation, we now examine whether the conformity assessment procedures are inconsistent with Article 5.1.2.

**a. *The Requirements Applicable to Conformity Assessment Procedures***

111. Article 5.1.2 requires that conformity assessment procedures “are not prepared, adopted or applied with the view or effect of creating unnecessary obstacles to international trade”. To be consistent with this requirement, such procedures must “not be more strict or applied more strictly than is necessary to give the importing Member adequate confidence that products conform with the applicable technical regulations or standards”. In making this determination, account must be had “of the risks non-conformity would create”.

112. The requirements of Article 5.1.2 have not previously been interpreted in WTO dispute settlement proceedings. However, it is clear that they are very similar to the

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<sup>100</sup> EU Health Claims Regulation, Article 3.

requirements imposed by Article 2.2 of the *TBT Agreement*. Therefore, much of our analysis of the consistency of the Regulation with Article 2.2 applies here as well.

**b. The Objective of the Conformity Assessment Procedures**

113. We recall that the main objective of the Regulation as a whole is to inform consumers and protect them from misleading nutrition and health claims.<sup>101</sup> The EU established the conformity assessment procedures set out in Articles 13 and 14 of the Regulation to ensure that all health claims used on, or in relation to, food products on the EU market conform with the substantive requirements imposed by the Regulation.<sup>102</sup> In particular, the conformity assessment procedures are aimed at ensuring that health claims are “based on and substantiated by generally accepted scientific evidence”.<sup>103</sup>

114. Notably, the Regulation intentionally sets forth three different conformity assessment procedures for different health claims.<sup>104</sup> As we explained above, function claims are assessed and authorized in accordance with Article 13 of the Regulation, while reduction of disease risk claims and claims referring to children’s development and health are subject to the procedure set out in Article 14. Health claims falling within the scope of Article 13, but not included in the lists submitted by EU Member States nor in the Article 13 list of permitted claims (once adopted), must follow the Article 13(5) assessment procedure.

115. The Regulation, the Terms of Reference and the Implementing Regulation all indicate that the EFSA must assess the conformity of health claims with the substantive requirements imposed by the Regulation by “taking into account the totality of the available scientific evidence” and by “weighing the evidence”.<sup>105</sup>

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<sup>101</sup> See paragraph 14 above.

<sup>102</sup> See, e.g., the Terms of Reference.

<sup>103</sup> EU Health Claims Regulation, Article 6(1).

<sup>104</sup> EU Health Claims Regulation, preamble, paragraph 26: “Health claims other than those referring to the reduction of disease risk and to children’s development and health, based on generally accepted scientific evidence, should undergo a different type of assessment and authorisation.”

<sup>105</sup> EU Health Claims Regulation, preamble, para. 17. Terms of Reference, p. 5. Implementing Regulation, Annex, para. 3 of the “General Principles for the Scientific Substantiation”.

**c.      *The EFSA's Application of the Conformity Assessment Procedures***

116. As described above, a review of the opinions published by the EFSA reveals that it applies the conformity assessment procedures in a manner that is stricter than what is required by the Regulation, the Implementing Regulation and the Terms of Reference. In particular, instead of “taking into account the totality of the available scientific evidence” and “weighing the evidence”, as it is required to do, the EFSA often rejects scientific evidence submitted in support of health claims as “not pertinent”.<sup>106</sup>

117. The EFSA explained in its Briefing Document for Stakeholders how it determines whether studies are “pertinent” for the substantiation of a health claim. It assesses, *inter alia*, whether submitted studies have been carried out with the food/constituent concerned, under conditions of use that can reasonably be expected in real life, and on a study group representative of the relevant population or from which the results can be extrapolated to the relevant population.<sup>107</sup>

118. The EFSA’s strict application of these elements has resulted in the rejection, without consideration as part of “the totality of the available scientific evidence”, of large numbers of scientific studies submitted in support of health claims.<sup>108</sup> Notably, the EFSA categorically refuses to adopt favorable opinions for claims not supported by *human* studies that are not RCTs or otherwise considered pertinent.<sup>109</sup> As indicated above, the EFSA’s approach leads to an unnecessary and inappropriate medicalisation of foodstuffs, and by doing so fails to properly take “account of the risks non-conformity would create” pursuant to Article 5.1.2 of the *TBT Agreement*. Again, the EFSA fails to appreciate that while a high level of scrutiny may be appropriate for pharmaceutical products in view of the risks of misleading claims that could result, it need not apply a similarly high standard for health claims about food, for which the risk of non-conformity is relatively low.

119. Moreover, the EFSA has been inappropriately subjecting all claims to the evidentiary standards for the “extreme end of the claims spectrum”: reduction of disease risk claims. Yet,

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<sup>106</sup> EHPM, *Comments in relation to the second batch of Article 13(1) claims opinions*, May 2010, p. 2. See also the example in paragraph 80 above.

<sup>107</sup> Briefing Document for Stakeholders, p. 8. See, e.g., EFSA Opinion on lutein, discussed above.

<sup>108</sup> EHPM, *Comments in relation to the second batch of Article 13(1) claims opinions*, May 2010, p. 2.

<sup>109</sup> Briefing Document for Stakeholders, p. 4. See, e.g., EFSA Opinion on protection of cells, discussed above.

“normal functions of the body can benefit from the intake of certain food components without showing a decrease or increase of a parameter”.<sup>110</sup> In fact, it is impossible “for many health contributions to show improvements of health within the boundaries of normality in the way EFSA expects”.<sup>111</sup>

**d.      *The Conformity Assessment Procedures are Applied More Strictly than is Necessary***

120. The foregoing summary of the EFSA’s application of the conformity assessment procedures established by Articles 13 and 14 of the Regulation supports the conclusion that the conformity assessment procedures are applied more strictly than is necessary.

121. The trade-restrictive impact of EFSA’s application of the conformity assessment procedures is severe. It is expected that 95% of health claims relating to food supplements not containing minerals or vitamins will be rejected. The expected result is a 25% decrease in size of the relevant EU market and a 30% loss of gross profitability for industry.<sup>112</sup>

122. We recall that the overall objective of the Regulation is to protect consumers against misleading claims used on or in relation to food products. The EFSA’s application of the conformity assessment procedures goes far beyond ensuring that health claims are supported by generally accepted scientific evidence and preventing misleading claims from being used on food products in the EU. It is preventing products from being marketed in the EU with health claims for which there is scientific support, and most of which are permitted in all other major markets without any evidence of widespread consumer deception or harm.

123. For the foregoing reasons, the conformity assessment procedures established by Articles 13 and 14, as applied by the EFSA, violate Article 5.1.2 of the *TBT Agreement*, because their application has the effect of creating unnecessary obstacles to international trade.

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<sup>110</sup> EHPM, *Comments in relation to the second batch of Article 13(1) claims opinions*, May 2010, p. 5.

<sup>111</sup> EHPM, *Comments in relation to the second batch of Article 13(1) claims opinions*, May 2010, p. 5.

<sup>112</sup> Impact Assessment Brookes, p. 5.