

# Food supplements and fortified foods: the EC's patriarchal precautionary perspectives on public health

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## Rejoinder context

In a 'Discussion Paper on the Setting of Maximum and Minimum Amounts for Vitamins and Minerals in Foodstuffs' (DP), issued in June 2006, the European Commission (EC) seeks advice on micronutrients added to food and present in food supplements.<sup>2</sup> The DP looks at two regulatory instruments, a directive and a regulation, both of which address the use of vitamins, minerals and 'other substances' as supplements to conventional diets: the Common Position (EC) No 2/2006 regarding the Regulation on Fortified Foods (FFR) and the 2002 Food Supplement Directive (FSD).<sup>3</sup> In the DP, the EC invites stakeholders to provide answers to its questions, in particular regarding the execution of Article 5 of the FSD and the similarly worded Article 6 of the FFR. In both articles, the EC has undertaken the actual management of risk (the separate and further step to risk assessment) by setting minimum and maximum levels of vitamins and minerals for fortified foods and food supplements. These key articles concern a number of issues which we will address with the aid of the following questions, as formulated in the DP. We have numbered the questions for ease of reference:

1. Where there are not yet scientifically established numerical tolerable upper intake levels for several nutrients, what should be the upper safe levels for those nutrients that should be taken into account in setting their maximum levels?
2. For some vitamins and minerals the risk of adverse effects, even at high levels of intakes, appears to be extremely low or non-existent according to available data. Is there any reason to set maximum levels for these vitamins and minerals?
3. Where we set maximum levels, do we inevitably also have to set maximum amounts for vitamins and minerals separately for food supplements and fortified foods in order to safeguard both a high level of public health protection and the legitimate expectations of the various food business operators? Are there alternatives?
4. Taking into account all the above-mentioned considerations, how far should PRIs/RDAs (population reference intakes/recommended daily allowances) be taken into account when setting maximum levels for vitamins and minerals?

To put the questions asked by the DP and the answers we put forward in this paper in perspective, we will first address the implementation possibilities of a food supplements policy and show some key inconsistencies generated by the precautionary perspective the EC usually takes on regulation. This will clarify the embedded presuppositions behind the questions asked in the DP. We then propose a new approach to policy in view of current scientific knowledge. In this article, the term micronutrients refers not only to vitamins and minerals but also to 'other substances' (as referred to in the FSD as well as in the FFR), such as amino and fatty acids, carotenoids, and polyphenols, that are all part of the human diet. Although bioactive food compounds such as polyphenols are usually not categorised as micronutrients, and although they are not placed within the framework of the classical deficiency symptoms (as is the case with vitamins and certain

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2 [http://ec.europa.eu/food/food/labellingnutrition/supplements/discus\\_paper\\_amount\\_vitamins.pdf#search=%22%22Discussion%20Paper%20on%20the%20setting%20of%20maximum%20and%20minimum%20amounts%20for%20vitamins%20and%20minerals%20in%20foodstuffs%22%22](http://ec.europa.eu/food/food/labellingnutrition/supplements/discus_paper_amount_vitamins.pdf#search=%22%22Discussion%20Paper%20on%20the%20setting%20of%20maximum%20and%20minimum%20amounts%20for%20vitamins%20and%20minerals%20in%20foodstuffs%22%22) (28 September 2006).

3 [http://europa.eu.int/eur-lex/lex/LexUriServ/site/en/oj/2006/ce080/ce08020060404en00270042.pdf#search=%22Common%20Position%20\(EC\)%20No%202%2F2006%22](http://europa.eu.int/eur-lex/lex/LexUriServ/site/en/oj/2006/ce080/ce08020060404en00270042.pdf#search=%22Common%20Position%20(EC)%20No%202%2F2006%22) (28 September 2006). Council Directive 2002/46/EC of 10 June 2002 on the Approximation of the Laws of the Member States Relating to Food Supplements [2002] OJ L183 51–57.

minerals), consumption may well be advantageous in terms of long-term health benefits (eg in relation to the incidence of cancer, inflammatory responses and ageing).

### Inconsistencies in the DP, FSD and FFR

The FSD, the oldest (10 June 2002) of the two regulatory instruments addressed here, concerns food supplements marketed as foodstuffs and presented as such for the purpose of supplementing the human diet.<sup>4</sup> We define food supplements similarly to the FSD. By definition, food supplements are marketable finished products that are explicitly presented to the public for supplementation of the diet. Food supplements cannot be presented as medicines or as substitutes for medicines. The recommended dosages of the micronutrients contained in food supplements may or may not exceed the average intake of food-endogenous micronutrients.

As the DP shows, the central issues revolve around safety (see also FSD (13) below). Safety in the FSD and the FFR is, roughly, defined in terms of trying to prevent, by way of risk management, over-exposure to micronutrients and ‘other substances’ by taking into consideration safe upper limits (SULs) previously established by way of risk assessment. SULs are doses of vitamins and minerals that potentially susceptible individuals could take daily on a life-long basis in reasonable safety, without medical supervision. The European Food Safety Authority (EFSA) defines the SUL as the ‘tolerable upper intake level’. In EFSA terminology, this means:

The maximum level of total chronic daily intake of a nutrient (from all sources) judged to be unlikely to pose a risk of adverse health effects to humans. ‘Tolerable intake’ in this context connotes what is physiologically tolerable and is a scientific judgment as determined by assessment of risk, ie the probability of an adverse effect occurring at some specified level of exposure. It is an estimate of the highest level of intake which carries no appreciable risk of adverse health effects.<sup>5</sup>

These ‘maximum levels’ are provided by the EFSA, and the ensuing politically-oriented risk management process established by the EC will set these ‘maximum levels’ for the actual micronutrient content in products, such as food supplements and fortified foods. These maximum levels are

intended to provide a framework within which consumers can make informed decisions about safe intake limits. Separation of assessment (EFSA) and management (EC), as a basic approach of European regulation, governs the broader context of the FSD/FFR construct against the background of what is presented as an ‘adequate and varied diet’. Some of the relevant parts from the FSD are cited below and pertinent passages are highlighted in italics:

- (3) *An adequate and varied diet could, under normal circumstances, provide all necessary nutrients for normal development and maintenance of a healthy life in quantities, which meet those established and recommended by generally acceptable scientific data. However, surveys show that this ideal situation is not being achieved for all nutrients and by all groups of the population across the Community.*
- (5) *In order to ensure a high level of protection for consumers and facilitate their choice, the products that will be put on to the market must be safe and bear adequate and appropriate labelling.*
- (9) Only vitamins and minerals normally found in, and consumed as part of, the diet should be allowed to be present in food supplements although this does not mean that their presence therein is necessary. Controversy as to the identity of those nutrients that could potentially arise should be avoided. Therefore, it is appropriate to establish a positive list of those vitamins and minerals.
- (13) Excessive intake of vitamins and minerals may result in adverse effects and therefore necessitate the setting of maximum safe levels for them in food supplements, as appropriate. Those levels must ensure that the normal use of the products under the instructions of use provided by the manufacturer will be safe for the consumer.
- (14) When maximum levels are set, therefore, account should be taken of the upper safe levels of the vitamins and minerals, as established by scientific risk assessment based on generally acceptable scientific data, and of intakes of those nutrients from the normal diet. Due account should also be taken of reference intake amounts when setting maximum levels.

The reference to an adequate and varied diet as a primary source of *all necessary nutrients* in (3) is intriguing. The truism that we can obtain everything we need from a balanced diet only holds if we eat such a balanced diet consistently. The point made here by the EC is tautological: adequate is by default adequate. How this adequacy can be achieved, and what such an adequate diet would consist of, are not discussed. Moreover, factors impinging on individual nutritional status

<sup>4</sup> Council Directive 2002/46/EC (n 3).

<sup>5</sup> Scientific Committee on Food Scientific Panel on Dietetic Products, Nutrition and Allergies ‘Tolerable Upper Intake Levels for Vitamins and Minerals’ (European Food Safety Authority 2006) p 9.

are only partly related to the dietary intake on which the EC has its focus. Malabsorption (genetic or otherwise) and increased nutritional requirements (eg during a period of disease) greatly affect the nutritional status of individuals. However, these aspects are not considered in the FSD. So, the EC's reference to an adequate and varied diet erroneously assumes average physiological health in the individual (population) concerned.

The EC's opinion also assumes some kind of natural (or traditional) 'true background value' optimised for healthy living in an otherwise undefined ideal diet that encompasses ideal quantities of 'all necessary nutrients' in bio-available qualities. However, it is unlikely that such a 'true background value' actually exists. Conversely, the phraseology of (3) implies that even this adequate and varied diet could well be an insufficient source of all necessary nutrients. The question then is whether this European diet is or is not a sufficient source of all necessary nutrients. The relevance of this is clear, as the opinion expressed in (3) implies that fortified foods and/or food supplements are superfluous against the background of this 'EU-diet'. In this context, the FFR makes for noteworthy reading (*italics added*):<sup>6</sup>

- (7) An adequate and varied diet *can*, under normal circumstances, provide all necessary nutrients for normal development and maintenance of a healthy life in quantities as those established and recommended by generally acceptable scientific data. However, surveys show that this ideal situation is not being achieved for all vitamins and minerals and by all groups of the population across the Community. *Foods to which vitamins and minerals have been added appear to make an appreciable contribution to the intake of these nutrients and as such may be considered to make a positive contribution to overall intakes.*
- (8) Some nutrient deficiencies, although not very frequent, can be demonstrated to exist at present in the Community. Changes in the socio-economic situation prevailing in the Community and the life styles of different groups of the population have led to different nutritional requirements and to changing dietary habits. This in turn has led to changes in the energy and nutrient requirements of various groups of the population and to intakes of certain vitamins and minerals for these groups that would be below those recommended in different Member States. *In addition, progress in scientific knowledge indicates that intakes of some nutrients for maintaining optimal health and well-being could be higher than those currently recommended.*

6 Common Position (EC) no 2/2006 (n 3).

Is it the case that the EC, four years after issuing the FSD, is confident that a varied diet now *guarantees* intake of all necessary nutrients? Yet, in stark contrast to this newest conviction, the closing line of (7) states that the addition of micronutrients to food rendered a positive contribution to overall intakes, which thus seem to be lower than required when considering an 'adequate and varied' diet lacking this fortification. The EC seems to be aware of the fact that in relation to, for instance, pregnancy, an adequate and varied diet does not provide micro-nutritional sufficiency when folic acid is considered.<sup>7</sup> In addition, the diet of the lower socio-economic classes is known to be of a lower nutritional standard on average than would be required for a diet intended to provide the basis for a healthy life.<sup>8</sup> Food selection is constrained by economic and socio-cultural considerations, compromising healthy eating patterns and resulting in nutritional inadequacies. For most micronutrients, amplification of the cost-constraint results in a progressive decrease in the nutrient density of the diet.<sup>9</sup> Moreover, as a recent survey in the Netherlands shows, the incidence of under-nourishment in hospitals and other care institutions is high, suggesting that even in professional environments, maintaining an 'adequate and varied diet' can be a problem.<sup>10</sup>

The final sentence (in *italics*) of (8) reveals the issue we addressed in our previous article on food supplements in this journal.<sup>11</sup> It has become increasingly clear that RDAs are too restrictive an approach to micronutrients. The long-term effects of micronutrients, such as reducing cancer and cardiovascular incidences and decelerating premature ageing, seem to be more important than their role in preventing the well-known acute deficiency diseases. To reiterate, RDAs do not

7 MRC Vitamin Study Group 'Prevention of Neural Tube Defects: Results of the Medical Research Council Vitamin Study' (1991) 338 *Lancet* 131–37. See further M Lucock 'Is Folic Acid the Ultimate Functional Food Component for Disease Prevention?' (2004) 328 *Brit Med J* 211–14.

8 S Shohaimi and others 'Residential Area Deprivation Predicts Fruit and Vegetable Consumption Independently of Individual Educational Level and Occupational Social Class: A Cross Sectional Population Study in the Norfolk Cohort of the European Prospective Investigation into Cancer (EPIC–Norfolk)' (2004) 58 *J Epidemiol Community Health* 686–91.

9 N Darmon and others 'A Cost Constrained Alone Has Adverse Effects on Food Selection and Nutrient Density: An Analysis of Human Diets by Linear Programming' (2002) 132 *J Nutr* 3764–71.

10 J Meijers and others 'Prevalentie van Ondervoeding: de Landelijke Prevalentiemeting Zorgproblemen' ['Prevalence of Under-nourishment: the National Prevalence Survey Care Problems'] (2005) 60(1) *Nederlands Tijdschrift voor Diëtisten* 12–15.

11 J C Hanekamp 'The Precautionary Principle: A Critique in the Context of the EU Foods Supplements Directive' [2006] 2 *Env. Liability* 43–51. See this article for further references.

define an optimal level of any nutrient, as they are focused on the prevention of disease caused by nutritional deficiencies. Furthermore, they are designed to meet the needs of healthy people and do not take into account special needs arising from infections, metabolic disorders, or chronic disease.<sup>12</sup> These are important constraints to consider in any policy focused on public health.

In relation to the to-be-established maximum levels for food supplements, intake of micronutrients from dietary sources other than food supplements needs to be taken into account, therefore needs to be known. Article 5 of the FSD states the following (see also (14) above):

1. Maximum amounts of vitamins and minerals present in food supplements per daily portion of consumption as recommended by the manufacturer shall be set, taking the following into account:
  - (a) upper safe levels of vitamins and minerals established by scientific risk assessment based on generally accepted scientific data, taking into account, as appropriate, the varying degrees of sensitivity of different consumer groups;
  - (b) intake of vitamins and minerals from other dietary sources.

This then must include fortified foods as a source of micronutrients. However, the regulation on fortified foods, which is still a draft (proposal) lacking the force of law, does contain a list of allowed micronutrients, although their content-levels in different types of fortified foods still need to be established. In paragraph 28 of the DP, the Commission comments on the complexities created by the task of simultaneously setting maximum amounts for two different food sources of micronutrients, knowing full well that the setting of a maximum in one category of products will work as a variable in the other and vice versa. So, the Commission writes (*italics added*):

Although food supplements and foods to which vitamins and minerals are added are covered by different measures the considerations for setting maximum levels for vitamins and minerals are inevitably interrelated. In particular, the distribution of these nutrients in the two broad categories of food products, food supplements and fortified foods, *have to be considered together* if we are to have a clear picture of the overall food offering.

<sup>12</sup> T M Devlin (ed) *Textbook of Biochemistry with Clinical Correlation* (Wiley-Liss New York 2002) pp 1137–65.

## Slippery slopes

The approach chosen by the EC to establish maximum levels (not SULs!) for food supplements, in relation to which other sources of micronutrient intake (food, including fortification) are balanced, is hampered by a number of problems, among which the regulatory dilemma mentioned above is only of minor concern. First, when maximum levels for food supplements need to be correlated to the total overall intake of food and food products, this can generate a slippery slope situation. Does this approach imply that other sources of micronutrients, including conventional fresh and processed foods (and their fortified variants), need to be regulated as well? Micronutrient-intake as such, in the view of the FSD and the FFR, needs to be capped, implying (perhaps unwittingly) that all food and food-products need to be regulated. Modern plant-breeding technology (developed over the past hundred years at least!), in which micronutrient content is specifically enhanced, also then comes into regulatory focus. When one looks at the latest research on the optimisation of nutrients in whole foods and its beneficial health effects,<sup>13</sup> the FSD/FFR construct seems to generate a legislative culture of full-blown regulatory control of all food-sources. Consequently, even conventional foods rich in micronutrients become a regulatory target. These dilemmas are not clarified in the DP. The FSD/FFR approach, with the aid of the precautionary principle, generates an open-ended compulsory regulatory structure relating to all food-products, not just food supplements and fortified foods. This unrestrained licence to define is created by the fact that the FSD and FFR embrace the whole of micronutrient intakes from all foods in order to regulate food supplements and fortification.

<sup>13</sup> V M Ursin 'Modification of Plant Lipids for Human Health: Development of Functional Land-based Omega-3 Fatty Acids' (2003) *J Nutr* 4271–74. F Fumagalli and others 'Form Field to Health: A Simple Way To Increase the Nutraceutical Content of Grape As Shown by NO-Dependent Vascular Relaxation' (2006) 54 *J Agric Food Chem* 5344–49. J A Napier and others 'Progress Towards the Production of Very Long-chain Polyunsaturated Fatty Acid in Transgenic Plants: Plant Metabolic Engineering Comes of Age' (2006) 126 *Phys Plantarum* 398–406. I L F Nielsen and others 'Bioavailability Is Improved by Enzymatic Modification of the Citrus Flavonoid Hesperidin in Humans: A Randomised, Double-Blind, Crossover Trial' (2006) 136 *J Nutr* 404–408. D Rein and others 'Transgenic Flavonoid Tomato Intake Reduces C-Reactive Protein in Human C-Reactive Protein Transgenic Mice Than Wild-Type Tomato' (2006) *J Nutr* 2331–37. As stated in this article: 'Genetic enhancement of valuable dietary components in plant foods, such as specific flavonoids in tomatoes, may allow us to optimise human food composition and may help to reduce the burden of cardiovascular disease.' See also: 'Boosting Vitamin C Content in Blackcurrants' (2006) July *BBSRC Business* 12–13.

As the Commission itself has observed, the regulatory call for insight into the intake of micronutrients in Europe is complicated by the fact that survey costs are high and the reliability and accuracy of the estimates of intake vary widely. As surveys are expensive they are not conducted frequently, and they have become available only in a limited number of Member States. Moreover, when they are available, they can be obsolete and may not reflect current intakes of vitamins and minerals.<sup>14</sup> So, although intake of micronutrients from food supplements and fortification should be balanced, by means of maximum limits with the intake from conventional diets, the actual possibilities of doing so are severely hampered for lack of data.

Secondly, the FSD/FFR approach is preoccupied with the risk of excess, although the risks in relation to the intake of micronutrients are on both side of the equation. We dealt with this in our previous article on the FSD.<sup>15</sup> Micronutrients differ from other chemical substances in foods in that they are essential/beneficial to the human physiology, so that various adverse (toxicological) effects can result from intakes that are too low (the typical acute deficiencies or chronic diseases) as well as too high. Therefore, with its focus on excess toxicity, the FSD contradicts its own legal basis of public health regulation; a 'high level of protection for human life and health'. This FSD/FFR construct lacks the overarching scope required to weigh deficiencies (minimum levels) and excess toxicity (maximum levels) even-handedly.

Thirdly, the terms 'high' and 'protection' are not defined, although they must be understood within a precautionary context.<sup>16</sup> For instance, does 'high' mean 'no risk' (that is guaranteeing absolute safety)?<sup>17</sup> Is 'high' defined in environmental legislation in terms of the widely-used MTR (maximum tolerable risk level of, say, one extra case of morbidity or mortality within a population of 1,000,000)? 'Protection' against what and to what extent? In Dutch policy, when a potential risk does not exceed the MTR level, generally no further policy action is required.<sup>18</sup> Considering the limited

regulatory capabilities, regardless of the public funding available, this would certainly be a sensible approach towards micronutrients. Parenthetically, an MTR-approach applied in the context of the FSD/FFR construct would be likely to instigate regulatory action to try to ameliorate the problems caused by micronutrient deficiency rather than excess.

Fourthly, a focus on the risks of excessive micronutrient intake could frighten the public away from health-enhancing diets, which might well include fortified foods and supplements, considering the uncertainties about the nutritional adequacy of a diet consisting of conventional foods. Indeed, the need to educate the public about the crucial importance of nutrition and the potential health benefits of a simple and affordable daily multivitamin/mineral supplement contrasts starkly with the present regulatory focus.<sup>19</sup> Through the implementation of the FSD and FFR, the existing bias towards negative information about the possible health risks of products or activities could well be increased, which is counter to the maxim of a 'high level of protection for human life and health'.<sup>20</sup> In conclusion, striving to guarantee public safety from excess toxicity through the stringent regulation of micronutrient levels in food supplements and fortified foods may adversely affect the opportunity to reduce cost-effectively the short and long-term health problems caused by micronutrient deficiencies.

### An unmanageable succession of events

The EC has a tendency to regard techno-science<sup>21</sup> with suspicion, as something that could potentially lead to disastrous consequences. This dystopic premise is widespread in EC regulation, including the FSD and FFR discussed here. (A dystopia is a society where everything is as bad as possible.) The European Environment Agency, in its well-known yet deeply flawed report on the precautionary principle, states with regard to new technology that '[its] very novelty might be taken as a warning sign'.<sup>22</sup> The precautionary principle is

14 See the DP 32 (n 2).

15 Hanekamp (n 11).

16 Regulation (EC) 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 [2002] L32 OJ Eur Comm 1–24. This regulation on the establishment of the European Food Safety Authority specifically refers to the precautionary principle as a guiding principle of law.

17 For the problems of proving safety see I D Bross 'Why Proof of Safety Is Much More Difficult Than Proof of Hazard' (1985) 41 *Biometrics* 785–93.

18 'Nuchter omgaan met risico's' ['Coping Rationally with Risks'] (2003) RIVM rapport 251701047/2003 Bilthoven The Netherlands.

19 B N Ames and others 'Are Vitamin and Mineral Deficiencies a Major Cancer Risk?' (2002) 2 *Nature* 694–704.

20 M Siegrist and others 'Better Negative than Positive? Evidence of a Bias for Negative Information about Possible Health Dangers' (2001) 21(1) *Risk Analysis* 199–206.

21 The word techno-science contracts the terms *techné* – instructional or prescriptive ('how') knowledge usually applied in devising and constructing machines – and *epistémé* – propositional ('what') knowledge about natural phenomena and regularities usually applied to in science. I take this term from the Belgian philosopher Gilbert Hottois (see below).

See J Mokyr *The Gifts of Athena. Historical Origins of the Knowledge Economy* (Princeton University Press Princeton 2002).

22 P Harremoës, D Gee, M MacGarvin, A Stirling, J Keys, B Wynne, S Guedes Vaz *Late lessons from early warnings: the precautionary principle 1896–2000* Environmental Issue Report No 22 (European Environment Agency 2001) p 170.

frequently used to address this perceived danger. We have criticised the precautionary approach on other occasions, including in our previous article in this journal.<sup>23</sup> The eminent Belgian philosopher Gilbert Hottois, in his critique of the Convention for the Protection of Human Rights and Dignity of the Human Being with Regard to the Application of Biology and Medicine, describes this dystopic vision as follows:

This argument postulates that once man has engaged in a direction that *might* lead to deep errors, he will no longer be able to stop or choose the good aspects and resist the bad. This argument is deeply antihumanist, for it supposes that individuals lose their capability to judge and decide freely, after reflection and deliberation, as soon as they have made one – fatal – step in a direction that might lead to evil. One may wonder what direction is perfectly ‘safe’ and ‘pure’ and what choice is totally free from ambiguities and ambivalent possible consequences. The ‘slippery slope’ argument, according to which individuals are forced into an irresistible concatenation of actions (succession (of actions); authors) . . . , is anti-humanist . . . . It is the belief in irresistible concatenations, entailing the negation of human freedom and of any positive contribution of rational analysis that leads the supporters of the ‘slippery slope’ argument to want to impose definitive and massive prohibitions. Such absolute prohibitions suppress, from the very beginning, freedom of choice . . . , since this suppression of freedom is thought to be the only way to prevent future wrong uses of freedom.<sup>24</sup>

As Hottois points out, the subtle yet far reaching influence of the ‘slippery slope’ argument ‘that once man has engaged in a direction that *might* lead to serious errors, he will no longer be able to stop or choose the good aspects and resist the bad’, raises serious doubts about the EC’s perspective on the value of knowledge, information, education, ethics, responsibility

and the individual’s capacity for independent judgment. Its underestimation of the value of available knowledge makes it prone to assuming ‘worst-case’ scenarios, which Hottois pinpoints as one of the main drivers to impose definitive and massive prohibitions. Regulatory risk management is consequently carried out in line with this dystopic worldview, generating by default a precautionary-biased outcome in terms of preferred hypotheses and selected underpinning data. Implementation of the principle, consequently, is self-evident.<sup>25</sup> The fact that excess toxicity is the predominant consideration in the FSD and the FFR is a typical example of this.

When the EC is developing policies to regulate the micronutrient content of all food sources for the benefit of European citizens, as is implied by the FSD and the FFR, it assumes a ‘true value’ of human health and the means to acquire it through a varied and adequate diet, and this is subsequently laid down in regulation. The idea of a ‘true value’ of health, however, carries utopian overtones that are paternalistic and even anti-humanist, as it cannot, if taken seriously by the EC, be challenged or ignored.<sup>26</sup> Indeed, a ‘true value’ cannot be anything but adhered to, as disagreement is by definition regarded as irresponsible.

The subsequent danger is that part of society, primarily assembled within Europe’s bureaucracy, defines its concept of human health and the maintenance thereof and then imposes this concept on others, with selective reference to scientific research and its results.<sup>27</sup> Although the FSD specifically refers to facilitating the choice of consumers in (5), the reference to and understanding of ‘a high level of protection’ demonstrates that the EC does not feel comfortable with consumer freedom. This consumer freedom has effectively been curbed through politicisation of the European consumer. Through the institutionalisation of mistrust, regulation of an essentially free and deregulated market is established. The insistence, with the aid of the precautionary principle, on advance proof that products are safe galvanises consumer suspicion even further.<sup>28</sup>

Peculiarly, the EC believes itself to be immune from and able to oversee the ‘irresistible concatenation of actions’, from which individuals and economic parties need to be protected, with the aid of the precautionary principle. It is a mystery how the EC obtained this ‘immunity’ and overseeing capability. Indeed, ‘one may wonder what direction is perfectly “safe” and “pure” and what choice is totally free from ambiguities

23 See also I Forrester, J C Hanekamp ‘Precaution, Science and Jurisprudence: a Test Case’ (2006a) 9(4) J Risk Res 297–311. Hanekamp ‘Precaution and Cholera: A Response to Tickner and Gouveia-Vigeant’ (2006b) 26(4) Risk Analysis 1013–19.

24 G Hottois ‘A Philosophical and Critical Analysis of the European Convention of Bioethics’ (2000) 25(2) J Med Phil 133–46. The quote does not end there. Hottois adds the following thoughts: ‘Once again, we are not saying that the fears suggested through the “slippery slope” discourse have no psychological or sociological relevance at all. On the contrary, the unconscious is very real. But what must be clearly stated is that when one is claiming to have an ethical position, one should not support solutions imposing dogmatic prohibitions in reaction to irrational temptations (in Freudian terms: the repression of the unconscious – the id – by the superego), but solutions encouraging the slower and more difficult work of developing the conscious self: the personal ability to decide in an enlightened and deliberate way.’

25 Hanekamp (2006b) (n 23).

26 H Achterhuis *De erfenis van de utopie [The Legacy of Utopia]* (Ambo Amsterdam 1998).

27 Hanekamp (2006b) (n 23).

28 A Burgess ‘Flattering Consumption. Creating a Europe of the Consumer’ (2001) 1(1) J Consumer Culture 93–117.

and ambivalent possible consequences', as Hottois poignantly remarks. The illusion of guidance towards safety is supposed to be supported by precaution, yet precaution will fail to do so, as it condemns the very steps the guidance requires. The regulation required by the principle gives rise to risks of its own; hence the principle bans what it simultaneously authorises.<sup>29</sup>

Politically, however, precaution does give guidance to the implementing government bodies, as it best addresses secondary risk-management strategies.<sup>30</sup> The increasingly dominant regulatory culture of risk-aversion engenders micronutrient policies primarily focused on excess toxicity risks, while simultaneously lecturing Europeans on 'an adequate and varied diet'. Therefore, the FSD/FFR construct avoids responsibility for the health of European citizens. Toxicity as a result of intake of food supplements, encouraged by the bias towards negative information about the possible health risks of products or activities,<sup>31</sup> is a considerably more visible, if infrequent, phenomenon, than deficiency diseases that are not and cannot be related to any regulatory activities.

We now turn to the DP questions, and propose a novel approach to the regulation of micronutrients.

### A rejoinder to the European Commission

Our view in relation to any (newly discovered) micronutrient is that the recommended amount should maximise a healthy lifespan (which in the case of a number of the classical micronutrients appears to be higher than the amount needed to prevent acute deficiency diseases).<sup>32</sup> Policies in relation to food supplements should primarily be focused on enhancing health. This is in line with state-of-the-art scientific knowledge, and addresses the basic European precautionary policy tenet of a 'high level of protection for human life and health', which is habitually and erroneously understood in the negative. It is also along the lines of the Healthy Life Years (HLY) Structural Indicator (ie the number of years a person can expect to live in good health), as put forward in the Communication from the Commission entitled 'Healthier, Safer, More Confident Citizens: a Health and Consumer Protection Strategy'.<sup>33</sup> Therefore, in view of the above, and to keep regulation as simple as possible:

*Within the perspectives we outline in this paper, the setting of maximum levels in food supplements and/or fortified foods for micronutrients that have barely any adverse effects irrespective of known dose is superfluous, as it does not contribute to the protection of public health. Question 2 therefore can be answered in the negative.*

Bearing in mind the problems of setting maximum micronutrient levels for supplements and fortification in the context of total dietary intake and the RDA/PRI (recommended daily allowances/population reference intakes) addressed in questions 3 and 4, it is obvious that European regulation cannot control, through the FSD/FFR construct, individual consumption in relation to both fortified foods and food supplements. As a seemingly forthright numerical approach, through the setting of maximum levels, trying to balance the micronutrient-content of food supplements and food fortification in relation to the 'average' conventional food consumption of the European populace will not control individual food consumption. Indeed, as stated above, the limited availability and value of surveys will make the balancing exercise exceedingly difficult, if not impossible.

Nevertheless, RDAs are habitually presented on the labels and/or packaging of food supplements and foods containing added micronutrients. In view of this practice, we propose that SULs should also be presented, where these are available and only when specific and serious safety concerns have been demonstrated.<sup>34</sup> This is in conformity with the observations made in the Draft Opinion by Alexander Stubb on the proposal of the European Parliament and of the Council for a regulation on the addition of vitamins and minerals and of certain other substances to foods.<sup>35</sup> When SULs are mentioned on food labels and/or packaging, these can best be presented in absolute numbers (x mg or µg per day) *unrelated* to the food (supplement) product in question. The consumer will thus be informed that the micronutrient in question, at a specific consumption level, could pose health risks – either of deficiency under the RDA or adverse effects above the SUL – in relation to his/her entire consumption habits. This allows the consumer to decide how much of which food (supplement) product he or she should consume. This approach informs consumers about SULs on a 'total dietary intake' basis, and leaves consumers free to choose how to 'add up' levels of micronutrients consumed in combination with their own individual choices of conventional foods.

29 C R Sunstein *Laws of Fear: Beyond the Precautionary Principle* (Cambridge University Press Cambridge 2005).

30 M Power *The Risk Management of Everything. Rethinking the Politics of Uncertainty* (Demos UK 2004).

31 Siegrist (n 20).

32 M Fenech 'Recommended Dietary Allowances (RDAs) for Genomic Stability' (2001) 480–81 *Mut Res* 51–54.

33 [http://ec.europa.eu/health/ph\\_overview/Documents/com\\_2005\\_0115\\_en.pdf](http://ec.europa.eu/health/ph_overview/Documents/com_2005_0115_en.pdf) (28 September 2006).

34 J C Hanekamp and others 'Chloramphenicol, Food Safety and Precautionary Thinking in Europe' [2003] 6 *Env Liability* 209–19.

35 [http://www.europarl.europa.eu/meetdocs/2004\\_2009/documents/pa/553/553919/553919en.pdf](http://www.europarl.europa.eu/meetdocs/2004_2009/documents/pa/553/553919/553919en.pdf) (28 September 2006).

On a product, the SULs should be presented next to the RDAs, so that consumers can easily calculate the 'total dietary intake' bandwidth between RDA and SUL. In brief, our recommendation is as follows:

*RDAs should play a primary role in the presentation next to SULs with specific and serious safety concerns on the packaging of both food supplements and fortified foods. Both the RDAs and SULs should be presented in x mg or µg per day.*

When considering the future of the FSD and FFR, it seems that the well-known vitamins and minerals do not pose a major regulatory problem. Scientific knowledge of risks and benefits is readily available, and can be used for guidance. Things become a lot more complicated when considering 'other substances' for which limited scientific knowledge is available, and for which RDAs and SULs, and thereby maximum and minimum levels, cannot readily be obtained. As these substances are usually not defined as essential, although they might demonstrably improve human health, deficiency cannot be established as in the case of vitamins and minerals. It seems then that future regulatory demands will increase when 'other substances' come into focus. Below, we propose a novel regulatory framework for micronutrients that include other substances. As we did not elaborate on the maximum and minimum levels of micronutrients in the recommendations in response to the DP, we address this issue below.

### The broader context of the rejoinder

Question 1 has to do with the perspective – in terms of innovation and public health – that regulation should or should not have on newly developed products that come to market and/or products that are already on the market but about which few scientific facts are publicly available. Food is chemistry, and the mixture of chemicals that food represents is estimated to consist of many hundreds of thousands of different chemicals. All these food-borne chemicals have their own specific nutritional benefit(s) and toxicological profile, both individually and interactively (eg synergism and antagonism). Ongoing scientific research will augment our knowledge of ever-increasing numbers of bioactive food-endogenous chemicals.

An unremitting regulatory imposition of full toxicological assessment of increasing numbers of micronutrients (both as food supplements and fortification in foods) that will come to market, in combination with positive lists, will prove to be prohibitive in terms of cost, limited (toxicological oriented) research facilities and resources, scientific and public interests, and so on, and will slow innovation (no-data-no-

market). Even if scientific facts on the risks of food-endogenous compounds are available – scientific knowledge of the health impact of a growing number of all sorts of food-endogenous chemicals will undoubtedly increase considerably during the coming years – the inescapability of such compounds contextualises such knowledge. Whether consciously or not, people have always been exposed to a certain degree of chemical risk in their daily lives through the intake of food-endogenous compounds, of which acrylamide has gained quite some notoriety. Acrylamide, a non-nutrient, is present in foods that are fried or baked at a high temperature, such as potato chips, French fries, and crispbreads. Acrylamide is known to cause nerve damage and is a suspected human carcinogen at certain exposure levels. However, most regulatory agencies are reluctant to ban the processing of starchy foods in which acrylamide is generated. Many agencies simply alert the public and suggest a balanced and varied diet including plenty of fruit and vegetables.<sup>36</sup> This is probably the correct approach.

However, individuals make a choice to consume food supplements, rather than being unconsciously and involuntarily exposed to them as they are to food-endogenous compounds such as acrylamide. Therefore individuals making a conscious purchase of food supplements and to a lesser degree of fortified foods, expect those products to be safe, and rightly so.<sup>37</sup> Food supplements and fortified foods that come to market need to be safe eg in terms of carrying clear and simple indications for normal recommended intake. Even without the present regulatory context, this is a crucial exigency that food business operators and other economic parties must take seriously in view of issues of trust, liability, product safety and consumer protection. In view of this, how should micronutrients best be regulated, if at all?

In terms of risks of excessive exposure, a recent analysis in the Netherlands by the RIVM suggests that, on average, there seems to be no need for concern about high intakes of vitamins or minerals<sup>38</sup> (which, in any case, are dwarfed by drug toxicity).<sup>39</sup> When the 'high level of protection for human life and health' is taken seriously, first, the breadth and depth (in other words integrity) of scientific knowledge in this field

36 T Kasamatsu and others 'Balancing Risks' (2006) 46 Reg Tox Pharm 100–104.

37 C Starr 'Social Benefit Versus Technological Risk' (1969) 165 Science 1232–38.

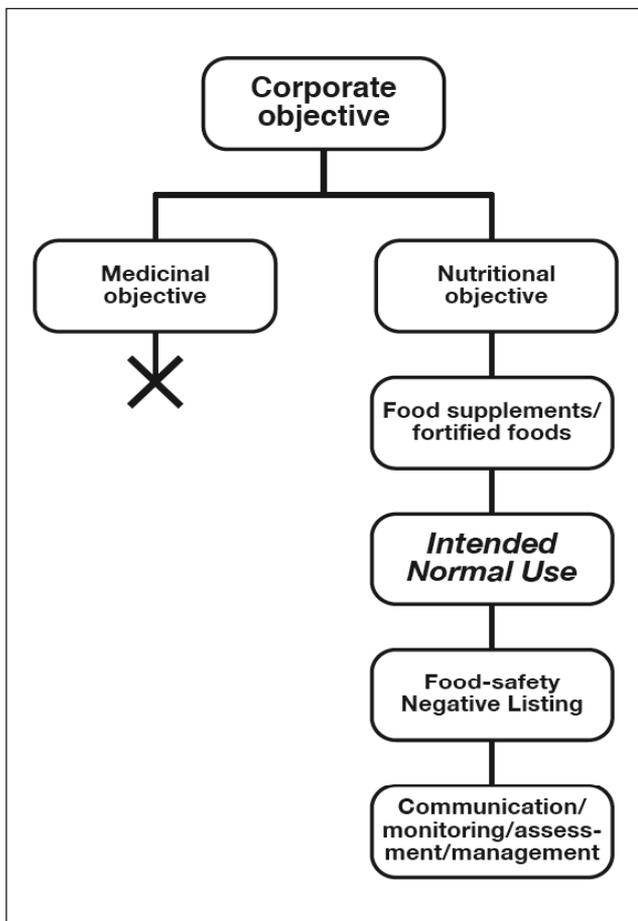
38 M C Ocké and others *Dietary Supplement Use in the Netherlands. Current Data and Recommendations for Future Assessment* RIVM report 350100001/2005 (Bilthoven The Netherlands 2005). See also B N Ames 'The Metabolic Tune-Up: Metabolic Harmony and Disease Prevention' (2003) 133 J Nutr 1544S–1548S.

39 J Lazarou and others 'Incidence of Adverse Drug Reactions in Hospitalised Patients. A Meta-analysis of Prospective Studies' (1998) 279(15) JAMA 1200–05.

needs to be taken seriously both by governments and economic parties. This is in line with a full-weight-of-evidence approach, ideally expounded in well-balanced risk-benefit assessment procedures, as a result of which a precautionary bias towards excess toxicity is eliminated. Not following this balanced approach is, in our view, contradictory to the scientific method.<sup>40</sup> Secondly, therefore, a realistic regulatory approach to micronutrients cannot be founded on precautionary thinking as understood by the European Commission. Thirdly, any rational regulatory approach has to decide on the level of public intervention that is justified: risks, benefits, and policy intervention potential need to be balanced.

We propose the following tenets to compose a realistic policy for marketable food supplements: (i) cost-benefit context; (ii) *ex post* orientated; (iii) benefit orientated, (iv) innovation oriented, and (v) market oriented (level playing-field). The flow-chart below describes the policy-direction we envision:

**Figure 1: Flow-chart for food supplements and food fortification regulation**



When micronutrients are projected to be presented for medicinal use, then these products automatically fall outside the scope of our proposed policy format.<sup>41</sup> It is noteworthy, however, that over-the-counter (OTC) medicines – medication that can be obtained without a doctor’s prescription, yet has been authorised through the proper regulatory authorities – have traditionally been used to treat self-limiting minor ailments. These medicinal compounds need only be taken for a limited amount of time and are easy to obtain and relatively safe. The scope for treating such self-diagnosed conditions has been broadened by the trend away from prescription-only medication (POM) to OTC medicines, and this is likely to continue.<sup>42</sup> The global trend is towards the encouragement of increased self-care, not only in the treatment of minor ailments, but also in the self-management of long-term conditions. Ironically, these policies, which encourage consumers to take and demonstrate their responsibility for health, is altogether counter to the approach taken in the FSD/FFR.

The scheme presented above concerns micronutrients that are explicitly intended by the prospective producer to be used for supplementation of the diet and/or as additions to conventional foods. We stipulate that the term ‘micronutrient’ must be understood in the broadest possible way (see above). A priori, the scheme places all these micronutrients, including vitamins and minerals, in an *ex post* approach. In this approach, the essential ordering principle is the intended normal use (INU, the recommended daily dosage), as unambiguously clarified and presented by the manufacturer on the product’s packaging. This approach is borne out by the fact that, until now, the risk of over-exposure to micronutrients has seemed limited.<sup>43</sup> In fact, taking into consideration the issue of household economics, people in general will not be capable of or indeed willing to invest in food supplements containing excessive quantities of micronutrients, as the costs would be prohibitive. Maximum levels therefore are superfluous in view of the fact that risks are minimal.

41 For a study on herbal medicinal products see eg E Ernst ‘Risks of Herbal Medicinal Products’ (2004) 13 *Pharmacoepi Drug Safety* 767–71.

42 ‘Over-the-counter Medication’ (2005) British Medical Association Board of Science. This report can be downloaded from [http://www.bma.org.uk/ap.nsf/AttachmentsByTitle/OTC0505/\\$FILE/OTC0505.pdf](http://www.bma.org.uk/ap.nsf/AttachmentsByTitle/OTC0505/$FILE/OTC0505.pdf) (28 September 2006).

43 See (n 38). See also A Shao and others ‘Risk Assessment for Creatine Monohydrate’ (2006) 45 *Reg Tox Pharm* 242–51. J N Hathcock and others ‘Risk Assessment for Carnitine’ (2006) *Reg Tox Pharm* doi:10.1016/j.yrtph.2006.06.007.

A Shao and others ‘Risk Assessment for the Carotenoids Lutein and Lycopene’ (2006) 45 *Reg Tox Pharm* 289–98.

40 R C Barnard ‘Scientific Method and Risk Assessment’ (1994) 19 *Reg Tox Pharm* 211–18.

We therefore propose that through the system of intended normal use (INU) of micronutrients, as established and presented by the relevant food business operator, food supplements and fortified foods should be allowed on the market without setting maximum and/or minimum levels. RDAs, if applicable, should play a primary role in the presentation next to SULs with specific and serious safety concerns. The roles played by science and the history of safety, established as a result of long-term widespread use (tacit knowledge),<sup>44</sup> are different yet complementary and need to be internalised and explicated by the producer, whether through experimental scientific research, desk-top studies, or both. We envision that the quality, purity (when applicable), consistency and stability of products will be guaranteed through GMP (good manufacturing practice) and/or other industry standards that match today's safety requirements and concerns. This is an important aspect of the safety-guarantee that producers need to assess, manage and communicate. In addition, compounds of long-standing widespread use – whether inside or outside the EU<sup>45</sup> – could in principle be regarded as generally safe (GRAS). Tea, for example, has been consumed for literally thousands of years, and it is this long record of tea consumption that makes the potentially beneficial compounds which it contains an attractive target for research and marketing.<sup>46</sup>

In order to stimulate a level playing-field and innovative developments within the field of food, we propose this *ex post* approach to micronutrient compounds, whereby the aspect of safety is not tackled on the basis of politically dominated precautionary thinking,<sup>47</sup> but rather on the basis of prevention, ie on the basis of objective, verifiable scientific data concerning safety. Contrary to the precautionary approach, such an approach to safety would support and sustain innovative industry and thus, eventually, public health and the economies of the Member States and the Community

at large. Positive listing through the no-data-no-market strategy will counteract innovation, as increasing regulatory demands, fuelled by precautionary deliberations, will hinder entry to the market, and continuing presence in it. This is illustrated in the EC communication on the precautionary principle, which states that the provisional nature of precautionary measures, which is usually a ban, 'is not bound up with a time limit but with the development of scientific knowledge'.<sup>48</sup> As mistrust in science is widespread (see eg the discussion of Hottois, above), scientific knowledge is hardly deemed sufficient to overcome the knowledge-barrier, so any precautionary ban will have an 'enduring temporality'.<sup>49</sup> An effective way of counteracting this, therefore, would consist of a preventive negative list of compounds proved to be damaging to public health.<sup>50</sup>

Analogously, as is feared with the implementation of the European REACH chemicals policy (an acronym that stands for Registration, Evaluation, and Authorisation of Chemical Substances), consistent regulatory *ex ante* demands on new chemical products could hamper small and medium-sized businesses significantly, as fully-fledged toxicological research requires considerable funding.<sup>51</sup> There are evidently good reasons to take a preventive regulatory approach with regard to safety, when confronted with products with only a very limited local or traditional use, and of which limited if any (scientific) knowledge is available. This reflects the overall approach, that manufacturers need to be sure of the food-safety of their product in relation to the recommended dosage (INU).

In the absence of RDAs and/or SULs, issues of safety can, for instance, be tackled by the highest observed intake (HOI) approach, when there are no known adverse effects.<sup>52</sup> The HOI is the highest level of intake observed or administered, as reported within studies of acceptable quality.<sup>53</sup> Monitoring of public health in relation to the intake of micronutrient food supplements (analogous to the pharmaco-vigilance system for pharmaceuticals) is a further part of the proposed scheme. This is of interest to both governments and

44 Tacit knowledge, opposite to *codified* (usually scientific) knowledge, is part and parcel of our daily lives and is transmitted through interpersonal contact, not through schoolbooks or scientific publications. Skills and traditions formed in laboratories, for instance, are utilised extensively, yet are not part of the codified output, such as journal publications and books. Therefore, even scientific knowledge in the public domain needs to be found, interpreted by specialists, and reprocessed for actual use. See n 21.

45 Council Regulation (EC) 258/97 of 27 January 1997 concerning Novel Foods and Novel Ingredients [1997] L43 OJ Eur Comm 1–7. In fact, this regulation defines a novel food or ingredient as novel as one without a history of use in the EU (*sic*).

46 See eg D S Wheeler and others 'The Medicinal Chemistry of Tea' (2004) 61 Drug Dev Res 45–65.

47 J C Hanekamp and others 'The Historical Roots of Precautionary Thinking: the Cultural Ecological Critique and "The Limits to Growth"' (2005) 8(4) J Risk Res 295–310.

48 Communication from the Commission on the Precautionary Principle (Commission of the European Communities Brussels 2000) p 11.

49 Forrester (n 23).

50 Hanekamp (n 34).

51 L Bergkamp, J C Hanekamp 'The Draft REACH Regime: Costs and Benefits of Precautionary Chemical Regulation' [2003] 5 Env Liability 167–80. B Durodié 'The True Cost of Precautionary Chemicals Regulation' (2003) 23(2) Risk Analysis 389–98.

52 'A Model for Establishing Upper Levels of Intake for Nutrients and Related Substances' (2006) Report of a Joint FAO/WHO Technical Workshop on Nutrient Risk Assessment (WHO Headquarters Geneva Switzerland 2–6 May 2005).

53 See n 43.

manufacturers, as it will reveal patterns of intake, potential benefits and associated risks. Assessment and management options remain wide open to governments and producers if monitoring studies reveal potential risks associated with intake of micronutrient food supplements (beyond a certain level). Communicating benefits and risks within this context is a viable strategy.

In view of the growing knowledge of food components other than vitamins and minerals that have subsequently become and will become available as food supplements and/or as components of fortified foods, issues of benefits and risks are becoming increasingly important. However, bioactive food compounds such as certain polyphenols that may well be advantageous in terms of long-term health benefits, are not as yet placed within the framework of the classical deficiency symptoms (as is the case with vitamins and certain minerals), and thereby lack RDAs. This then, in the light of the latest scientific knowledge, necessitates a new approach to the RDA, in which the 'survival' approach of the prevention of deficiency (as in the current RDAs) is transformed into a 'health' approach, that is the optimisation of a healthy lifespan. In our view, a switch from the current deficiency-related RDA, limited to vitamins and minerals, to a health-related RDA, extended to other substances known to have beneficial effects on health, is essential in order to understand and address the optimisation of the public's nutrient requirements. To reiterate, RDAs do not define an optimal level of any nutrient. The proposed switch will simultaneously address issues of safety, as new RDAs will give guidance to consumers in terms of beneficial consumption levels, both with regard to supplements, fortified foods, and, ultimately, conventional foods. It is not so much new regulation that is needed in the field of food supplementation and fortification, but governments that delegate to citizens the freedom to make choices, and to economic parties the freedom to create new markets in which responsibility for health and safety is taken seriously.<sup>54</sup> 'True (regulatory) perspectives' on health and safety dampen down innovative insights, both scientifically and democratically.

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54 B M Friedman *The Moral Consequences of Economic Growth* (Alfred A Knopf New York 2005).