

Food Supplements and Fortified Foods: a Scientific and Managerial Rejoinder to EC Policies

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1. 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.² The *DP* denotes two regulatory instruments, a Directive and a Regulation, that both 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*).³ In the *DP*, the EC invites stakeholders to provide answers to questions it primarily has with regard to the execution of Article 5 of the *FSD* we will cite below and of the similarly worded Article 6 of the *FFR*. In both articles, the EC has set itself the task of setting minimum and maximum levels of vitamins and minerals for fortified foods and food supplements by way of risk management that follows and is separated from risk assessment. These key articles state a number of issues we will address with the aid of the following questions, as formulated in the *DP* (we have numbered the question for ease of reference):

- (1) ‘Where there is not yet a 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 be taken into account when setting maximum levels for vitamins and minerals?’

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² See:

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 (last accessed on the 28th of September 2006).

³ See:

[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) (last accessed on the 28th of September 2006).

Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements (2002) L183 O J Eur Comm 51–57.

In order to have the proper perspective in relation to the questions of the *DP* and the answers we will put forward in this paper, we will first address the implementation possibilities of a food supplements policy and elucidate some key inconsistencies. This will clarify the embedded presuppositions behind the questions asked in the *DP*. Subsequently, we will propose a novel policy approach in view of current scientific knowledge. In this article, when using the term micronutrients, this refers not only to vitamins and minerals but also to ‘other substances’ (as referred to in the *FSD* as well as in *FFR*) such as amino- and fatty acids, carotenoids, and the well-known 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 minerals), consumption may well be advantageous in terms of long-term health benefits (e.g. in relation to the incidence of cancer, inflammatory responses and aging).

2. 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.⁴ We define food supplements in a similar fashion as 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 (13) below). Safety in the *FSD* and the *FFR* is, roughly, defined in terms of trying to prevent, by way of risk management, overexposure 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, i.e. 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.’⁵

‘Maximum levels’ resulting from a scientifically based risk assessment are defined as SULs (or Tolerable Upper Intake Levels). These ‘maximum levels’ are provided by the EFSA. ‘Maximum levels’ resulting from the ensuing politically oriented risk management process will be set by the EC as the ‘maximum levels’ for the actual micronutrient content in products, such as food supplements and fortified foods. The setting of the latter mentioned maximum levels intends to provide a framework in which consumers can make informed decisions about intake, having confidence that harm will not ensue. 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’. Below, we cite some of the relevant parts from the *FSD* and highlight the pertinent passages 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.

⁴ See note 3.

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

(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 that we need from a balanced diet only holds if we in fact eat such a balanced diet consistently. The perspective here expounded by the EC therefore is tautological: adequate is by default adequate. How this adequacy can be achieved, and what that adequate diet would actually be like remains undiscussed. Moreover, factors impinging on the individual nutritional status are only partly related to the dietary intake on which the EC has its focus. Malabsorption (genetic or otherwise) and increased nutritional requirements (e.g. during a disease period) also 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 presumes average physiological health of the individual (population) concerned.

The EC's opinion furthermore presumes 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 for all necessary nutrients. The question then is whether this European diet *is* or *is not* a sufficient source of all necessary nutrients. The relevance thereof is clear as the opinion expressed in (3) entails 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):⁶

'(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 See Common Position (EC) No 2/2006, note 3.

Is it the case that the EC, 4 years after having issued the *FSD*, is confident that a varied diet now *guarantees* intake of all necessary nutrients? Yet, in stark contrast with this newest conviction, the closing line of (7) states that 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.⁷ What's more, dietary–habits of the lower socio–economic classes are known to be of a lower nutritional standard than on average would be required for a diet intended to provide the basis for a healthy life.⁸ Food selection is constrained by economic and socio–cultural considerations, whereby healthy eating patterns will be necessarily compromised, resulting in nutritional inadequacies. For most micronutrients, amplification of the cost–constraint results in a progressive decrease in nutrient density of the diet.⁹ Moreover, as a recent survey in the Netherlands shows, under–nourishment in hospitals and other care institutions is high, suggesting that even in professional environments, the maintenance of an ‘adequate and varied diet’ is quite problematical.¹⁰

The final sentence (in italics) of (8) reveals the issue we addressed in the previous article on food supplements published in this journal.¹¹ It has become increasingly clear that RDAs are too restrictive an approach to micronutrients. Their maximising health attributes, which are not only a matter of preventing the well known acute deficiency diseases, more importantly seem to lie in the field of long–term benefits such as reduced cancer and cardio–vascular incidences and decelerating premature aging. Reiterating, RDAs do *not* define an optimal level of any nutrient, as they are focussed on deficiency–disease prevention. They are furthermore designed to meet the needs of healthy people and do *not* take into account special needs arising from infections, metabolic disorders, or chronic disease.¹² These are important constraints to consider in any policy focussed 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 need to be taken account, *ergo* need 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) that lacks the force of law, does contain a list of allowed micronutrients, but their content–levels in different types of fortified foods still need to be established. In

⁷ MRC Vitamin Study Group. 1991. ‘Prevention of neural tube defects: results of the Medical Research Council vitamin study’ (1991) 338 *Lancet* 131–137.

See further: M. Lucock ‘Is folic acid the ultimate functional food component for disease prevention?’ (2004) 328 *Brit Med J* 211–214.

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* 686–691.

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* 3764–3771.

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

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.

¹² Devlin, T.M (ed.) ‘Textbook of Biochemistry with Clinical Correlation’ (2002) Wiley–Liss, New York, p. 1137–1165.

paragraph 28 of the *DP*, the Commission comments on the complexities created by the task to simultaneously set 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.’

3. *Slippery-slopes*

The approach chosen by the EC to establish maximum levels (not SULs!) for food supplements, in which other sources of micronutrient intake (food, including fortification) are balanced in relation thereto, is hampered by a number of problems of which the regulatory dilemma mentioned above is only of minor concern. *Firstly*, when maximum levels for food supplements need to be correlated to the total overall intake of food and food products, this generates a slippery-slope situation. Will 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 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 in the past hundred years at least!), in which micronutrient content specifically is enhanced then also come into regulatory focus. When one looks at the state-of-art research on the optimisation of nutrients in whole foods and its beneficial health effects,¹³ 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 precautionary principle, generates an open-ended compulsorily regulatory structure relating to all food-products, not just food supplements and fortified foods. Indeed, few could resist expanding on the exigencies of public health if given official normative powers and unrestrained license to define.

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.¹⁴ So, although total intake, according to the *FSD* and the *FFR*, should be balanced in the derivation of maximum levels of micronutrients in food supplements, the actual possibilities to do so are severely hampered for lack of data.

¹³ V.M. Ursin ‘Modification of Plant Lipids for Human Health: Development of Functional Land-Based Omega-3 Fatty Acids’ (2003) *J Nutr* 4271–4274.

F. Fumagalli and others ‘From Field to Health: A Simple Way To Increase the Nutraceutical Content of Grape As Shown by NO-Dependent Vascular Relaxation’ (2006) *J Agric Food Chem* 5344–5349.

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) *Phys Plantarum* 398–406.

I.L.F. Nielsen and others ‘Bioavailability Is Improved by Enzymatic Modification of the Citrus Flavonoid Hesperidin in Humans: A Randomized, Double-Blind, Crossover Trial’ (2006) *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* 2331–2337.

As stated in this article: ‘Genetic enhancement of valuable dietary components in plant foods, such as specific flavonoids in tomatoes, may allow us to optimize 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.

¹⁴ See the *DP*, 32, note 2.

Secondly, the *FSD/FFR*–approach is pre–occupied with risk of excess although risks in relation to the intake of micronutrients are on both side of the equation. This aspect we dealt with in our previous article on the *FSD*.¹⁵ Micronutrients differ from other chemical substances in foods in that they are essential/beneficial for the human physiology, so that different 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’. Said *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 these must be understood within a precautionary context).¹⁶ For instance: does *high* mean ‘no risk’ (that is guaranteeing absolute safety)?;¹⁷ is *high* defined in terms of the in environmental legislation widely used MTR (Maximum Tolerable Risk level of, say, 1 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 certain potential risk does not exceed the MTR level, generally no further policy action is required.¹⁸ Considering the limited regulatory capabilities, regardless of the available public funding, this would certainly be a sensible approach towards micronutrients. Parenthetically, an MTR–approach applied in the context of the *FSD/FFR*–construct, would most likely instigate regulatory action to try to ameliorate the deficiency–section of the micronutrients–equation instead of the excess–section.

Fourthly, a focus on the risks of excess of micronutrient intake could shy away the public from health–enhancing diets, which could well include fortified foods and supplementation considering the uncertainties connected to 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 stands in stark contrast with the present regulatory focus.¹⁹ Through the implementation of the *FSD* and *FFR*, the existing bias for negative information about possible health risks of products or activities could well be enhanced, which is counter to the maxim of a ‘high level of protection for human life and health’.²⁰ In conclusion: stringent regulation of micronutrient levels in food supplements and fortified foods has opportunity costs. Striving to guarantee public safety in relation to excess toxicity, the foregone opportunity is the cost–effective reduction of micronutrient deficiencies and its concomitant short–*and* long–term health effects.

4. An unmanageable succession of events

A deeply embedded presupposition of quite some EC regulation, including the *FSD* and *FFR* discussed here, is related to the perspective the EC has on citizenship and economic activities deployed within the Community. The implied distrustful perspective the EC has on techno–science,²¹ as an articulation of both

¹⁵ See note 11.

¹⁶ 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 (2002) L32 O J 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 See for the problems of the proof of safety: I.D. Bross, ‘Why Proof of Safety Is Much More Difficult Than Proof of Hazard’ (1985) 41 *Biometrics* 785–793.

¹⁸ See: ‘Nuchter omgaan met risico’s’ (2003) RIVM rapport 251701047/2003, Bilthoven, The Netherlands. [‘Coping rationally with risks’]

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 Anal* 199–206.

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

See: J. Mokyr ‘The Gifts of Athena. Historical Origins of the Knowledge Economy’ (2002) Princeton University Press, Princeton.

individuals and (economic and knowledge) institutions, is that the complex of science, technology and industry could very well lead us irreversibly to fatal and unmanageable consequences. This dystopic premise is widespread in EC regulation. (A dystopia is a society considered to be objectionable, for any of a number of reasons.) Indeed, the European Environment Agency, in their well-known yet deeply flawed report on the precautionary principle, even states with regard to new technology that ‘their very novelty might be taken as a warning sign’.²² This dystopic outlook is usually addressed with the aid of the precautionary principle as a way out of the perceived techno-science conundrum. We criticised the precautionary approach on other occasions, including our previous paper in this journal.²³ The eminent Belgium 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.’²⁴

As Hottois points out, the subtle yet overarching influence of the ‘slippery slope’ argument ‘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’, raises serious doubts about the EC’s perspective on the value of knowledge, information, education, ethics, responsibility and the individual’s capability of judging freely. The gross underestimation of the value of available knowledge makes it prone to a selection of knowledge in accordance with e.g. ‘worst-case’ scenarios, which Hottois pinpoints as one of the main drivers to impose definitive and massive prohibitions. Regulatory risk management consequently is carried out in line with the 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.²⁵ The fact that excess toxicity is the predominant consideration in the *FSD* and the *FFR* is a typical example thereof.

When the EC is developing policies in order to regulate, for the benefit of European citizens, the micronutrient content of all food sources, as is implied by the *FSD* and the *FFR*, then a ‘true value’ of human health and the means to acquire it through a varied and adequate diet is assumed, and subsequently laid down in regulation. A ‘true value’ of health, however, carries utopian overtones that are paternalistic and even

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

²³ See also: I. Forrester, J.C. Hanekamp ‘Precaution, Science and Jurisprudence: a Test Case’ (2006a) 9(4) *J Risk Res* 297–311. J.C. Hanekamp ‘Precaution and Cholera: A Response to Tickner and Gouveia-Vigeant’ (2006b) 26(4) 1013–1019.

²⁴ G. Hottois ‘A Philosophical and Critical Analysis of the European Convention of Bioethics’ (2000) 25(2) *J Med Phil* 133–146.

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 See Hanekamp (2006b), note 23.

anti-humanist, as it cannot, if taken seriously by the EC, be challenged or ignored.²⁶ Indeed, a ‘true value’ can anything but adhered to.

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

Peculiarly, the EC itself believes to have immunity against and overseeing capability of the ‘irresistible concatenation of actions’, against which individuals and economic parties, with the aid of the precautionary principle, needs to be protected. In what way the EC actually obtained this ‘immunity’ and overseeing capability is a mystery. Indeed, ‘one may wonder what direction is perfectly ‘safe’ and ‘pure’ and what choice is totally free from ambiguities and ambivalent possible consequences’, as Hottois poignantly remarks. The illusion of guidance towards safety is supposed to be supported by precaution, yet it will fail to do so, as it condemns the very steps it requires. The regulation that the principle requires always give rise to risks of its own – and hence the principle bans what it simultaneously authorizes.²⁹

Politically, however, precaution does give guidance to the implementing governmental bodies, as it best addresses secondary risk–management strategies.³⁰ 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 human health of European citizens. Intoxication as a result of food supplements intake is a considerably more visible albeit infrequent phenomenon, upsurged by the bias for negative information about possible health risks of products or activities,³¹ compared to deficiency diseases that are not and cannot be related to any regulatory activities.

With the above–sketched background of European policy–making, we now turn to the *DP* questions and will subsequently propose a novel approach to micronutrients regulation.

5. A rejoinder to the European Commission

The overarching perspective we choose in relation to any type of (newly discovered) micronutrient is the actual ‘mandatory’ amount of micronutrients for the human organism that maximizes a healthy lifespan (which, parenthetically, in a number of cases of the classical micronutrients appears to be higher than the amount needed to prevent acute deficiency diseases).³² Policies in relation to food supplements should primarily be focused on health–enhancement. 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 also is along the lines of the Healthy Life Years (HLY) Structural Indicator (that is the number of years a person can expect to live in good health) as put forward in the Communication from the Commission titled *Healthier, safer, more*

²⁶ H. Achterhuis. ‘De erfenis van de utopie’ (1998) Ambo, Amsterdam. [‘The legacy of utopia’]

²⁷ See Hanekamp (2006b), note 23.

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

²⁹ C.R. Sunstein ‘Laws of Fear: beyond the precautionary principle’ (2005) Cambridge University Press, Cambridge, U.K.

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

³¹ See note 20.

³² M. Fenech ‘Recommended dietary allowances (RDAs) for genomic stability’ (2001) 480–481 Mut Res 51–54.

*confident citizens: a Health and Consumer protection Strategy.*³³ 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–behaviour in relation to both fortified foods and food supplements. As a seemingly forthright numerical approach, trying to balance the micronutrient–content of food supplements and food fortification in relation to ‘average’ conventional food consumption of the European populace will be unable to direct 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 shall also be presented, provided that SULs are available and if so, only when specific and serious safety concerns have been demonstrated.³⁴ 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.³⁵ 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 straightforwardly regarding the micronutrient in question that, at a specific consumption level, could pose below–RDA (deficiency) or above–SUL (adverse effects) health risks in relation to his/her entire consumption habits. This leaves the consumer to decide how much of which food (supplement) product he or she should consume. This approach will inform consumers about SULs on a ‘Total Dietary Intake’ basis and it will leave consumers free to make their own choices how to ‘add up’ levels of micronutrients consumed in combination with their own individual choices of conventional foods.

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 will offer guidance in relation thereto. Things are a lot more complicated when considering ‘other substances’, for which limited scientific knowledge is available, and RDAs and SULs, and thereby maximum and minimum levels, are not readily obtainable. As these substances are usually not defined as essential, although they might add demonstrably to human health, deficiency cannot be established as is done with vitamins and minerals. It seems then that future regulatory demands will increase when ‘other substances’ will come into focus. Below, we propose a novel regulatory framework for micronutrients that include other substances. As

³³ See: http://ec.europa.eu/health/ph_overview/Documents/com_2005_0115_en.pdf (last accessed on the 28th of September 2006).

³⁴ See: J.C. Hanekamp and others ‘Chloramphenicol, food safety and precautionary thinking in Europe’ (2003) 6 *Env Liab* 209–219.

³⁵ See: http://www.europarl.europa.eu/meetdocs/2004_2009/documents/pa/553/553919/553919en.pdf (last accessed on the 28th of September 2006).

we did not elaborate on the maximum and minimum levels of micronutrients in the recommendations in response to the *DP*, we will address this issue in the broader context of the rejoinder below.

6. 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 shouldn't have on newly developed products that come to market and/or products that are already on the market currently lacking publicly available scientific knowledge. 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-born chemicals have their own specific nutritional benefit(s) – toxicological profile, both individually and interactively (e.g. 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 etceteras, and will slow innovation (no-data-no-market). Even if scientific knowledge on risks of food-endogenous compounds is available –the 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 life 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 crisp breads. 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 fruits and vegetables.³⁶ This is probably the correct approach.

However, when it comes to food supplements, individuals consciously and voluntarily make a choice to consume these supplements, contrary to being unconsciously and involuntarily exposed 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.³⁷ Food supplements and fortified foods that come to market need to be safe e.g. 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 thereof, how then should micronutrients best be regulated, if at all?

In terms of excess exposure risks, a recent analysis in the Netherlands by the RIVM suggests that, on average, there seems to be no need for concern about too high intakes of vitamins or minerals³⁸ (which, in any case, is dwarfed by drug toxicity).³⁹ When the 'high level of protection for human life and health' is taken seriously, *firstly*, the breadth and depth (in other words integrity) of scientific knowledge in this field 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.⁴⁰ *Secondly*, therefore, a realistic regulatory

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 1232–1238.

³⁸ M.C. Ocké and others 'Dietary supplement use in the Netherlands. Current data and recommendations for future assessment' (2005) RIVM report 350100001/2005, Bilthoven, The Netherlands.

See also: B.N. Ames "The Metabolic Tune-Up: Metabolic Harmony and Disease Prevention' (2003) 133 J Nutr 1544S–1548S.

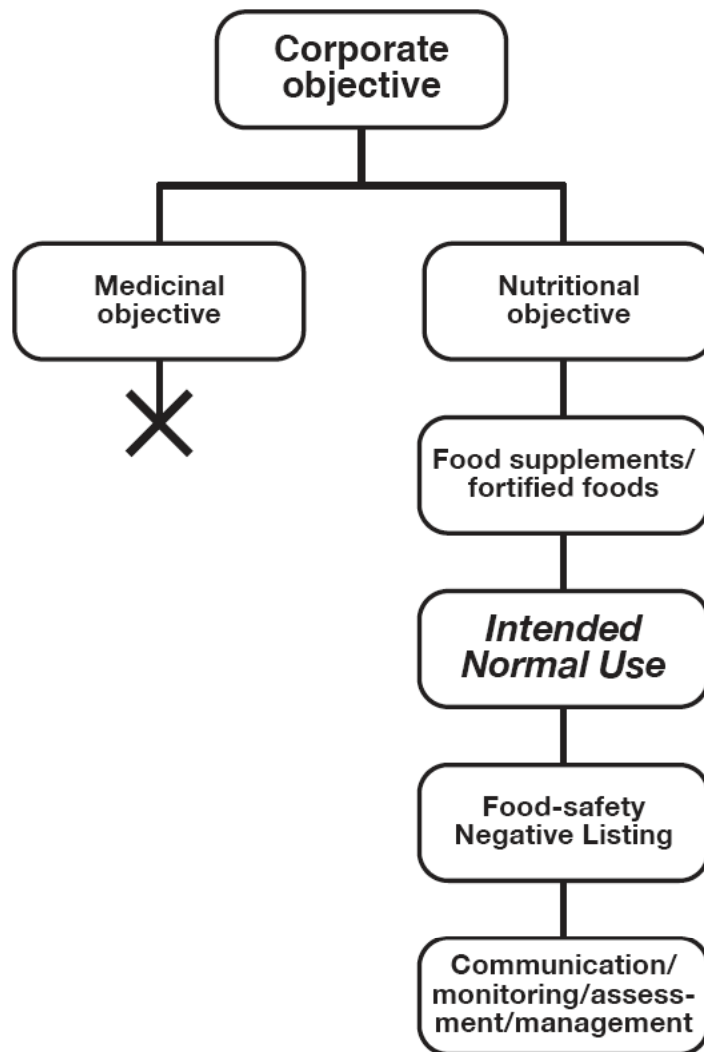
³⁹ J. Lazarou and others 'Incidence of Adverse Drug Reactions in Hospitalized Patients. A Meta-analysis of Prospective Studies' (1998) 279(15) JAMA 1200–1205.

⁴⁰ R.C. Barnard 'Scientific Method and Risk Assessment' (1994) 19 Reg Tox Pharm 211–218.

approach of micronutrients cannot be founded on precautionary thinking as understood by the European Commission. *Thirdly*, any rational regulatory approach has to decide on which level public intervention is justified: risks, benefits, and policy intervention potential need to be balanced therein.

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). A following flow–chart is descriptive for 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.⁴¹ 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 rising switch from

⁴¹ See for a study on herbal medicinal products e.g.: E. Ernst ‘Risks of herbal medicinal products’ (2004) 13 *Pharmacoepi drug safety* 767–771.

prescription-only-medication (POM) to OTC medicines, and this development is likely to continue.⁴² The global trend is towards the encouragement of increased self-care, not only in the treatment of minor ailments, but also of 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 above-presented scheme concerns micronutrients that are explicitly intended by the prospective producer to be presented for use as 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 of the fact that until now risks of overexposure to micronutrients seems limited.⁴³ In fact, when merely considering the issue of household economics, people in general will not be capable or indeed willing to personally 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.

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 shall 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 role of science and the history of safety that has been established as a result of long-term widespread use (tacit knowledge)⁴⁴ are different yet complementary and need to be internalised and/or explicated by the producer, whether through experimental scientific research, literature desk-top studies, or both. We envision products' quality, purity (when applicable), consistency and stability guaranteed through GMP (good manufacturing practice) and/or other industry standards that match today's safety requirements and concerns. This is an important aspect in the safety-guarantee producers need to assess, manage and communicate. In addition, compounds with a long-standing wide-spread use –whether within or outside the EU–⁴⁵ could in principal be generally regarded as safe (GRAS). Tea, as an example, has been consumed literally for thousands of years, and it is this long record of tea consumption that makes the potentially beneficial compounds, present in tea, an attractive target for research and marketing.⁴⁶

In order to stimulate a level-playing field and innovative developments within the field of food, we propose this *ex post* approach of micronutrient compounds, whereby the aspect of safety is not tackled on the basis of politically dominated precautionary thinking,⁴⁷ but rather on the basis of prevention, i.e. on the basis of objective, verifiable scientific data concerning safety. Contrary to the precautionary approach, such an

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) (last accessed on the 28th of September 2006).

⁴³ See note 38.

See also: A. Shao and others 'Risk assessment for creatine monohydrate' (2006) 45 Reg Tox Pharm 242–251.

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 289–298.

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 that have 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 note 21.

⁴⁵ Regulation (EC) No 258/97 of the European Parliament and the Council of 27 January 1997 concerning novel foods and novel ingredients. (1997) L43 O J Eur Comm 1–7.

In fact, this regulation defines a novel food or ingredient as novel when it is without a history of use in the EU (*sic*)!

⁴⁶ See e.g.: 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.

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 market–entrance, and –continuance. 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’.⁴⁸ As mistrust in science is widespread (see e.g. the discussion of Hottois, above), scientific knowledge is hardly deemed to be sufficient to overcome the knowledge–barrier, so any precautionary ban will have an ‘enduring temporality’.⁴⁹ An effective opposite therefore would comprise of a preventive negative list of compounds proven to be damaging to public health.⁵⁰

Analogously, as is feared with the implementation of the European REACH chemicals policy (an acronym that stands for ‘Registration, Evaluation, and Authorization of Chemical Substances’), consistent regulatory *ex ante*–demands on new chemical products economically could hamper small– and medium–sized businesses significantly, as full–fledged toxicological research requires considerable funding.⁵¹ 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 manufactures need to be sure of their product food–safety 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.⁵² The HOI is the highest level of intake observed or administered as reported within studies of acceptable quality.⁵³ 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 both of interest to governments as to 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 would 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 subsequently became 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 as of yet not 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 view of the state–of–art scientific knowledge, necessitates a new–RDA approach in which the ‘survival’ approach of prevention of deficiency (as in the current RDAs) is transformed into a ‘health’ approach, that is the optimisation of a healthy life–span. In our view, the 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. So, it is not so much new regulation that is required in the field of

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

⁴⁹ See Forrester, note 23.

⁵⁰ See note 34.

⁵¹ L. Bergkamp, J.C. Hanekamp ‘The Draft REACH Regime: Costs and Benefits of Precautionary Chemical Regulation’ (2003) 5 *Env Liab* 167–180.

B. Durodié ‘The True Cost of Precautionary Chemicals Regulation’ (2003) 23(2) *Risk Anal* 389–398.

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 note 43.

food supplementation and fortification. What is needed are governments that delegate to citizens freedom to make choices and economic parties to freely create new markets in which responsibility for health and safety is taken seriously.⁵⁴ 'True (regulatory) perspectives' on health and safety dampen down innovative insights both scientifically and democratically.

⁵⁴ See : B.M. Friedman 'The Moral Consequences of Economic Growth' (2005) Alfred A. Knopf, New York.