

The precautionary principle: a critique in the context of the EU Food Supplements Directive

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Setting the micronutrient stage

In this article we will critically analyse the European Food Supplements Directive 2002/46/EC,¹ and will show an alternative and balanced perspective on (micro)nutrients and food supplements. The European Food Supplements Directive (the Supplements Directive) concerns food supplements marketed as foodstuffs and presented as such. We define food supplements, as does the directive, as capsules, tablets, pastilles, lozenges and other similar forms of embodiment, such as sachets, ampoules, dispensing bottles to provide controlled dosages of liquids and powders containing (micro)nutrient food compounds, irrespective of their ways of manufacturing. Some (micro)nutrient food compounds are isolated or extracted from natural materials; others are produced by way of fermentation or chemical synthesis. By definition, food supplements are marketable finished products that are explicitly presented to the public for supplementation of the diet, and are therefore not presented for medicinal purposes. Food supplements may or may not exceed the loads of intake of (micro)nutrient food compounds present in the consumed diet, resulting in higher exposures (concentrations).

The Supplements Directive does not apply to medicinal products as defined by Directive 2001/83/EC.² Medicinal products are defined as any substance or combination of substances presented for treating or preventing, or making a medical diagnosis, or for restoring, correcting or modifying physiological functions in human beings. Botanical products – products that are attracting increasing public and regulatory attention – are usually regarded as medicinal in character,

although some products are close or even identical to food, while others indeed come close to or are in fact medicines, especially when presented for (implied) medicinal purposes.³

Nowadays there is an increasing market for food supplemental products with perceived *and* real health benefits. This development, combined with the consumer's general perception that 'natural equals safe' or 'natural equals healthy', results in a tendency for increased use of supplemental (micro)nutrient and botanical products, not only as bioactive ingredients in primarily food supplements but also as herbal teas. Most food supplements embody micronutrients in their isolated forms, in forms that are synthetically produced ('fine chemicals') and in dosages that may exceed dietary level Recommended Daily Allowances (RDAs). In the field of botanicals, a long history of traditional use of botanical preparations does not per se guarantee safety; botanical preparations may, for example, contain individual ingredients known to be genotoxic and carcinogenic.⁴ The Supplements Directive consequently was implemented in order to safeguard human health in view of the potential toxicity of excess intake of micronutrient food supplements.

However, (micro)nutrient food compounds differ from other chemical substances in foods in that they are essential for the human physiology, so that different adverse (toxicological!) effects can result from intakes that are too low as well as too high. Nevertheless, the focus of the directive is solely on the toxicology of excess. (Micro)nutrient food compounds usually refer to vitamins and minerals, which are required by all living organisms in minute amounts, usually as part of an endogenous enzyme, a cell-produced catalytic

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1 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.

2 Council Directive 2001/83/EC of 6 November 2001 on the Community code relating to medicinal products for human use [2001] OJ L311/ 67–128.

3 A Bast and others 'Botanical Health Products, Positioning and Requirements for Effective and Safe Use' (2002) 12 Environmental Toxicology and Pharmacology 195–211.

4 For example, see IMCM Rietjens and others 'Flavonoids and Alkenylbenzenes: Mechanisms of Mutagenic Action and Carcinogenic Risk' (2005) 574 Mutation Research 124–38. For the issue of consumption of herbal products and health (although this touches more on the medicinal aspect not addressed here), see JL Nortier and others 'Urothelial Carcinoma Associated with the Use of a Chinese Herb (*Aristolochia fangchi*)' (2000) 342 New England J Medicine 1686–92.

protein. Commonly required minerals include, for instance, copper, zinc, molybdenum, manganese, selenium and iodine. Vitamins cannot be synthesised in the body in amounts sufficient to meet physiological needs and therefore must be obtained from the diet or from some synthetic sources. For this reason, vitamins and minerals are called *essential* nutrients. If a vitamin or mineral is absent from the diet or is not properly absorbed by the body, a specific deficiency disease usually develops; scurvy in the case of vitamin C,⁵ rickets in the case of vitamin D.⁶ For that reason, RDAs have been established for several essential nutrients in order to prevent deficiency diseases (acute toxicity of deficiency). The RDA is the average daily dietary intake level that is sufficient to meet the nutrient requirement of nearly all (97 to 98 per cent) healthy individuals in a particular life stage and gender group.

There is, on the other hand, increasing scientific evidence that apart from the well-known essential micronutrients (vitamins and minerals) for which RDAs were established, there are many constituents of edible plant products that form part of the human diet, which may well support health over long terms of the human life-span (referred to in the Supplements Directive as ‘other substances’). The best known of these plant compounds – polyphenols – may either help to prevent disease or may act as disease-inhibitors at an early disease stage.⁷ Although some polyphenols are, under experimental conditions,⁸ mutagenic, this chemical group as a whole is perceived as having a wide range of overriding positive biological effects, including antioxidant, anti-mutagenic and anti-inflammatory properties that indicate long-term benefits and *mutatis mutandis* long-term risks when humans consume these compounds below a certain level. Although these bioactive compounds are usually not categorised as micronutrients, and no classical deficiency

symptoms may be observed, as is the case with vitamins and minerals, consumption may be advantageous in terms of long-term health benefits (for example, in relation to the incidence of cancer, inflammatory responses and aging). We will therefore take account of these bioactive compounds (such as polyphenols) within the food area, and when using the term micronutrients refer to ‘other substances’ such as polyphenols as well.⁹

Furthermore, RDAs currently used for micronutrients are based on the prevention of diseases of deficiency only (short-term issues). This is still the dominant perspective on micronutrients. Numerous papers, however, have dealt with the issue of increased intake of fruit and vegetables and the reduction of cancer incidence and cardiovascular mortality (long-term issues), intrinsically or explicitly addressing the role of micronutrients.¹⁰ Diets rich in fruits and vegetables are known to be protective against, for example, cardiovascular diseases and cancer.¹¹ Evidence suggests that chronic DNA damage as precursory to, for example, cancer and aging, occurs at levels above the level that causes acute and specific RDA-related micronutrient deficiency diseases. Established RDAs, and this is the emerging paradigm, may in fact have become obsolete in that they are insufficient to prevent long-term DNA damage, resulting in, for example, cancer and aging.¹² In summary, the perspective materialising from state-of-art scientific research in relation to any type of

5 K Akhilender Naidu ‘Vitamin C in Human Health and Disease is Still a Mystery? An Overview’ (2003) 2 Nutrition J 7.

6 SA Abrams ‘Nutritional Rickets: An Old Disease Returns’ (2002) 60(4) Nutrition Reviews 111–15.

7 For example, see DL McKay and JB Blumberg ‘The Role of Tea in Human Health: An Update’ (2002) 21 J American College of Nutrition 1–13.

8 NN Barotto and others ‘Quercetin Enhances Pretumorous Lesions in the NMU Model of Rat Pancreatic Carcinogenesis’ (1998) 129 Cancer Letters 1–6; MA Pereira and others ‘Effects of the Phytochemicals, Curcumin and Quercetin, upon Azoxymethane-induced Colon Cancer and 7,12-dimethylbenz[a]-anthracene-induced Mammary Cancer in Rats’ (1996) 17 Carcinogenesis 1305–11. The study of Barotto and others cited here used 10g quercetin/kgbw, which, in terms of human diet exposure ranges reported on, is unrealistically high. See the paper of Ames and Gold discussing the issue of the maximum tolerated dose approach in cancer research, and the flurry of responses generated by this paper: BN Ames and LS Gold ‘Too Many Rodent Carcinogens: Mitogenesis Increases Mutagenesis’ (1990) 249 Science 970–71.

9 For scientific articles dealing with regulatory approaches for (micro)nutrient compounds (including botanical food compounds) within the food area, see HM Meltzer and others ‘Risk Analysis Applied to Food Fortification’ (2002) 6 Public Health Nutrition 281–90; B Schilter and others ‘Guidance for the Safety Assessment of Botanicals and Botanical Preparations for Use in Food and Food Supplements’ (2003) 41 Food and Chemical Toxicology 1625–49; R Kroes and R Walker ‘Safety Issues of Botanicals and Botanical Preparations in Functional Foods’ (2004) 198 Toxicology 213–20. For a recent framework of risk assessment for nutrients and other substances, see *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 (2–6 May 2005 WHO Headquarters Geneva Switzerland).

10 For example, see WC Willett ‘Diet and Health: What Should We Eat?’ (1994) 264 Science 532–37; C Borek ‘Dietary Antioxidants and Human Cancer’ (2004) 3 Integrative Cancer Therapies 333–41.

11 For example, see KA Steinmetz and JD Potter ‘Vegetables, Fruit, and Cancer Prevention: A Review’ (1996) 96 J American Dietetic Association 1027–39; AR Ness and JW Powles ‘Fruit and Vegetables and Cardiovascular Disease: A Review’ (1997) 26 Intl J Epidemiology 1–13.

12 BN Ames and P Wakimoto ‘Are Vitamin and Mineral Deficiencies a Major Cancer Risk?’ (2002) 2 Nature 694–704; BN Ames, H Atamna and DW Killilea ‘Mineral and Vitamin Deficiencies Can Accelerate the Mitochondrial Decay of Aging’ (2005a) 26 Molecular Aspects of Medicine 363–78; BN Ames ‘Increasing Longevity by Tuning Up Metabolism’ (2005b) 6 EMBO Rep S20–S24.

micronutrient is that the actual ‘mandatory’ amount of micronutrients for the human organism that maximises a healthy lifespan, in a number of cases turns out to be considerably higher than the amount needed to prevent acute deficiency diseases.¹³ It seems increasingly clear that RDAs are too restrictive an approach to micronutrients and their health attributes, which are not only a matter of preventing deficiency diseases but, more importantly, lie in the field of long-term benefits such as reduced cancer and cardiovascular incidences and decelerating aging.

Micronutrient food supplements: the directive’s inner workings

The Supplements Directive has formulated a number of ground rules and ordering principles in relation to micronutrient food supplements and their safety,¹⁴ among others:

- a high level of consumer protection based on the precautionary principle
- food ubiquity and availability
- Safe Upper Limits (SULs) through conventional risk assessment methodology and the development of Maximum Permitted Levels
- reference average dietary intake
- risk assessment prior to market entrance of (micro) nutrient food compounds not yet listed on positive lists (the no-data–no-market approach)
- ways of presenting micronutrients to the public (labelling and health claims).

These ground rules and principles carry distinct overtones of precaution, whereby the directive has a regulatory preoccupation with market failure. Indeed, micronutrient food supplements will only be allowed on the market when placed on so-called ‘positive lists’, which in turn is meant to imply to regulators that their safety has been, in some way or another, established. Supplement compounds, even ones that have been legitimately marketed in one or more Member States, in full accordance with the relevant national safety regulations, will now only be placed on the EC’s positive list(s) when an appropriate (characterised by us as precautionary) risk characterisation is performed and presented.

In 2003, the UK Expert Group on Vitamins and Minerals (EVM) produced a report in which a normative methodology is developed and described for the well-known vitamins and minerals.¹⁵ The normative concept produced by the committee is the SUL, mentioned above, which is described by the committee as:

the determination of doses of vitamins and minerals that potentially susceptible individuals could take daily on a life-long basis, without medical supervision in reasonable safety. The setting of these levels provides a framework within which the consumer can make an informed decision about intake, having confidence that harm should not ensue.¹⁶

Already a dispute has evolved around the UK SULs on account of a number of German studies.¹⁷ These reports, compiled by the German Federal Institute for Risk Assessment (BfR), propose structurally and significantly lower recommended maximum permitted levels than those implied in the UK EVM report. Both major reviews choose a concentration approach in their respective studies more or less linked to physiology and/or standardised (average) diet exposure combined with toxicological data and conventional modelling. Nevertheless, the conclusions vary widely. For example, the BfR’s report proposes a 225 mg maximum for vitamin C (EVM – 1000 mg), a 5.4 mg maximum for vitamin B6 (EVM – 10 mg) and 9 µg for vitamin B12 (EVM – no maximum).

In the Supplements Directive, micronutrient food supplements are regulated from an excess toxicity perspective, although, as shown above, straightforward consistency of safety standards for micronutrients seem to be more complicated than the available data would suggest. Whether or not supplements might add to the overall health of European citizens is, from a regulatory point of view,

15 *Safe Upper Levels for Vitamins and Minerals* (2003) Report of the Expert Group on Vitamins and Minerals. This report can be downloaded from <http://www.food.gov.uk/multimedia/pdfs/vitmin2003.pdf> (last accessed 7 March 2006).

16 *ibid* p 6.

17 *Verwendung von Vitaminen in Lebensmitteln Toxikologische und ernährungsphysiologische Aspekte, Teil I* (2004) Bundesinstitut für Risikobewertung. This report can be downloaded from: http://www.bfr.bund.de/cm/238/verwendung_von_vitaminen_in_lebensmitteln.pdf (last accessed 7 March 2006). See also *Verwendung von Mineralstoffen in Lebensmitteln. Toxikologische und ernährungsphysiologische Aspekte. Teil II* (2004) Bundesinstitut für Risikobewertung. This report can be downloaded from: http://www.bfr.bund.de/cm/238/verwendung_von_mineralstoffen_in_lebensmitteln_bfr_wissenschaft_4_2004.pdf (last accessed 7 March 2006).

13 M Fenech ‘Recommended Dietary Allowances (RDAs) for Genomic Stability’ (2001) 480–481 *Mutation Research* 51–54; M Fenech ‘Micronutrients and Genomic Stability: A New Paradigm for Recommended Dietary Allowances (RDAs)’ (2002) 40 *Food and Chemical Toxicology* 1113–17.

14 Note 1.

regarded as irrelevant. Thereby, the Directive assumes what actually should be proven, namely, that the health effects of an over-regulatory excess toxicity approach would be superior to alternatives. The concomitant assumption is that there are no health detriments from proposed (over)regulation. A choice is presented between health and money (economy), or even health with no loss at all, as a peripheral presumption is that the market will find a better and a cheaper as well as a safe way. Something (health) is gained with nothing lost (no adverse health effects from over-regulation).¹⁸ The burden of proof of safety corresponding to excess toxicity subsequently lies firmly with the marketing parties.

The problematical precautionary paradigm

Although we mention the precautionary principle as one of the main drivers of the Supplements Directive, the principle is not mentioned therein. However, with the installation of the European Food Safety Authority the principle was specifically referred to, and hence it takes prime position in the development of European regulation within the food area.¹⁹ The main gist of precautionary thinking is best captured in the Rio definition that is considered the most authoritative among the many formulations of the precautionary principle that can be found nowadays:²⁰

Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation.

The principle is presented as a way of handling modern risks and is said to promote prevention rather than cure. In essence, the precautionary principle seeks to advance the timing and tighten the stringency of *ex ante* regulation. On these sliding scale dimensions, regulation is 'more precautionary' when it intercedes earlier and/or more rigorously to preclude uncertain future adverse consequences of particular human activities.²¹ The axiom put forward by the precautionary

principle is that implementation regarding risks to human health and/or the environment singularly results in the reduction or elimination of those risks, which is required by the EC when it states its goal: 'a high level of protection for human life and health'.²²

A common characterisation of the precautionary principle holds that it seeks to impose timely protective measures to prevent uncertain risks, that is, risks as to which there is little or no data on their probability and magnitude. Uncertainty is a key element. Indeed, the precautionary perspective on knowledge is that scientific research needs to be focused on guaranteeing safety, which has become a strategic requirement for new products and processes. As the European Commission states in its communication on the precautionary principle:²³

Countries that impose a prior approval (marketing authorisation) requirement on products that they deem dangerous *a priori* reverse the burden of proving injury, by treating them as dangerous unless and until businesses do the scientific work necessary to demonstrate that they are safe.

This approach of innovation is usually defended with the quote that 'Absence of evidence of harm is no evidence of absence of harm',²⁴ which, however, is a meaningless truism.²⁵

The precautionary principle therefore typically shows strong scepticism with regard to scientific claims. With the reversal of the burden of proof it can never be completely proven that micronutrient food supplements do *not* pose any risks to consumers. Examples for the impossibility of proving a negative can be generated at random and ad infinitum. This scepticism, however, is only one side of the precautionary culture. Reflecting a profound ambiguity, the other side of the precautionary attitude towards what science can and should offer is optimistic to the same extent that it is pessimistic. One can only believe that this objective is achievable if one has a strong belief in science's ability to identify risks and offer means for their prevention.

The aspiration to prevent uncertain risks is, however, unachievable due to a problem common to all formulations of the precautionary principle. From a logical point of view

18 A Wildavsky *But is it True? A Citizen's Guide to Environmental Health and Safety Issues* (Harvard University Press Cambridge 1997).

19 Council Regulation (EEC) 178/2002 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] OJ L31/1–24.

20 JD Graham 'Decision-analytic Refinements of the Precautionary Principle' (2001) 4 J Risk Research 127–141.

21 JB Wiener 'Precaution in a Multi-Risk World' (Duke Law School Public Law and Legal Theory Working Paper Series Working Paper No 23 2001).

22 Note 19.

23 Communication from the Commission on the Precautionary Principle COM (2000) 1 final 5.

24 T Christoforou 'The Regulation of Genetically Modified Organisms in the European Union: the Interplay of Science, Law and Politics' (2004) 41 Common Market Law Review 637–709.

25 On the issue of the scientific method and risk assessment, see FA Seiler and JL Alvarez 'The Scientific Method in Risk Assessment' (1994) 331A Technology: J Franklin Institute 53–58.

the Rio definition, as the most authoritative of definitions, is meaningless, because the lack of scientific certainty – which is propounded to be unsolvable by the scientific method – deprives us of the possibility to calculate the costs and benefits of precautionary measures.²⁶ What is more, the problem with the precautionary principle is that it does not provide any guidance whatsoever. As Sunstein explains:²⁷

The real problem with the Precautionary Principle ... is that it is incoherent; it purports to give guidance, but it fails to do so, because it condemns the very steps that it requires. The regulation that the principle requires always give rise to risks of its own – and hence the principle bans what it simultaneously mandates.

Analysed at this fundamental and logical level, the precautionary principle engenders an impossible arrangement: to decide on a 'safe course' results in the formation of other and new risks, which, by definition, evokes a secondary precautionary response, ad infinitum. To break this infinite regress the application of precaution needs to be limited. Precaution therefore demands choice. One cannot be cautious on all fronts, as this would completely stifle any type of activity, including precautionary policy itself. By randomly selecting some target risk and focusing exclusively on that risk in a regulatory setting and only secondarily in a scientific setting (it has been argued elsewhere that the choices that are made in relation to the implementation of the precautionary principle are guided primarily by the so-called 'cultural ecological critique' ideology²⁸), regulators can construct a decision as to the proper course of action. Application of the precautionary principle 'guided' by this approach results in policies that are blind to the negative external effects thereby created. As a result thereof, precaution empowers bureaucracy: the regulatory exigency to intervene, although underpinned with scientific research, nevertheless, as a result of the diminution of scientific standards (the scepticism we pointed at above), is driven by other than scientific deliberations.²⁹ The precautionary

principle therefore, is not so much *anti*-scientific; it is *ante*-scientific. Within the precautionary perspective, scientific research generates by default a precautionary-biased outcome in terms of preferred hypotheses and selected underpinning data. Implementation of the principle, consequently, is self-evident.

This brings us back to the issue of food supplements and the decision to regulate excess toxicity while ignoring the essentiality of micronutrients consumption, and, more importantly, disregarding the issue that the risks of deficiency exceed those of excess. Micronutrient deficiency is a well-known historic phenomenon; a broad range of food products, including and especially fruits and vegetables, have been available to almost all social groups in the Western world only in the last couple of decades. Indeed, health risks due to micronutrients are habitually and historically related to *deficiencies* in the diet and not excess. This is so because minerals and the majority of vitamins are water-soluble and are readily eliminated by excretion as well as metabolism,³⁰ the exceptions being vitamins A and D, which are lipid-soluble. The Supplements Directive in the preamble (3), states, however:

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.

Therefore, in view of this statement in the Supplements Directive, food supplements are regarded as superfluous products that are, by default, only in need of excess toxicology regulation; a varied diet is more or less a guarantee for sufficient micronutrient consumption and thereby human health. Parenthetically, the term 'normal diet' begs the question of what exactly a normal diet is.

Our contention is that within the precautionary context described above, the Supplements Directive is primarily focused on secondary risk management. Regulators and (scientific) experts in the main are being made increasingly accountable for what they do and thereby are becoming increasingly preoccupied with managing their own risks. Particularly, secondary risks to reputation are becoming as significant as the primary risks for which policies should in

26 FB Cross 'Paradoxical Perils of the Precautionary Principle' (1996) 53 Washington and Lee Law Review 851–925.

27 CR Sunstein *Laws of Fear: beyond the precautionary principle* (Cambridge University Press Cambridge UK 2005).

28 For the issue of precautionary choices in a cultural and historical perspective, see JC Hanekamp SW Verstegen and G Vera-Navas 'The Historical Roots of Precautionary Thinking: The Cultural Ecological Critique and "The Limits to Growth"'

(2005) 8 J Risk Research 295–310. See also CG Turvey and EM Mojduzka 'The Precautionary Principle and the Law of Unintended Consequences' (2005) 30 Food Policy 145–61.

29 F Furedi *Culture of Fear. Risk-taking and the Morality of Low Expectation* (Continuum London 2002).

30 J De Vries (ed) *Food Safety and Toxicity* (CRC Press New York 1997) 93. MC Ocké et al 'Dietary Supplement Use in the Netherlands. Current data and recommendations for future assessment' RIVM Report 350100001/2005, Bilthoven, The Netherlands.

fact be devised.³¹ The increasingly dominant regulatory culture of risk-aversion therefore engenders a food supplements policy singularly focused on excess toxicity risks, while simultaneously lecturing the Europeans to 'eat a normal healthy diet'. Therefore, the directive avoids responsibility for the human health of European citizens. Toxicity as a result of food supplements intake is a considerably more visible phenomenon, increased by the bias for negative information about possible health risks of products or activities.³² In comparison, deficiency diseases are not (and cannot be) related to any regulatory activities, as European regulators are not responsible for the individual dietary habits of European citizens, yet deficiencies have a far greater impact on public health. To accentuate this last point, it has been calculated that folic acid fortification is associated with annual economic benefit of US\$312 million to US\$425 million.³³ The cost savings (net reduction in direct costs) were estimated to be in the range of US\$88 million to US\$145 million per year. The US economic burden due to vitamin D insufficiency from inadequate exposure to solar UVB irradiance, diet, and supplements was estimated in 2004 at US\$40–56 billion, whereas the economic burden for excess UV irradiance was estimated at \$6–7 billion. These results suggest that increased vitamin D through UVB irradiance, fortification of food, and supplementation could reduce the health care burden in the United States, UK, and most likely elsewhere.³⁴

As a concluding observation, in line with the above, the Supplements Directive institutionalises mistrust within the consumer culture.³⁵ Through the politicisation of the consumer in Europe, on account of the introduction of accountability as the market was deregulated in the 1980s with the obvious loss of governmental and political power,

EU governments re-established their legitimacy. By means of this institutionalised mistrust, regulation of an, in essence, deregulated market can be established. The insistence on advance proof – with recourse to the precautionary principle we criticise above – that products (in this case micronutrient supplements) pose no risk to human health, galvanizes consumer suspicion even further.³⁶

Of court cases, science and the pre-empting of the European market

Despite all the above-mentioned and other publicised critical comments on precaution,³⁷ a recent court case ruling (Joined Cases C–154/04 and C–155/04) on the Supplements Directive explicitly refers to the precautionary principle as the discerning criterion.³⁸ As stated in the relevant paragraphs:

67 The information provided by the claimants in the main actions in their written observations about certain vitamin or mineral substances not included on the positive list in Annex II to Directive 2002/46 is not such as to cast doubt on the merits of that explanation. It is apparent from it that at the time when the directive was adopted those substances had not yet been evaluated by the Scientific Committee on Food or that, at the very least, the committee continued to entertain serious doubts, in the absence of adequate and appropriate scientific data, regarding their safety and/or their bioavailability.

68 In those circumstances and in view of the need for the Community legislature to take account of the precautionary principle when it adopts, in the context of the policy on the internal market, measures intended to protect human health ... the authors of Directive 2002/46 could reasonably take the view that an appropriate way of reconciling the objective of the internal market, on the

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

32 M Siegrist and G Cvetkovich 'Better Negative than Positive? Evidence of a Bias for Negative Information about Possible Health Dangers' (2001) 21 *Risk Analysis* 199–206. For an explanation of negative bias, see SE Taylor 'Asymmetrical Effects of Positive and Negative Events: The Mobilization-Minimization Hypothesis' (1991) 110 *Psychological Bulletin* 67–85. For a cultural-sociological perspective on risk selection, see M Douglas and A Wildavsky *Risk and Culture. An Essay on the Selection of Technological and Environmental Dangers* (University of California Press Berkeley 1982).

33 SD Grosse and others 'Re-evaluating the Benefits of Folic Acid Fortification in the United States: Economic Analysis, Regulation, and Public Health' (2005) 95 *American J Public Health* 1917–22.

34 WB Grant and others 'Comparisons of Estimated Economic Burdens due to Insufficient Solar Ultraviolet Irradiance and Vitamin D and Excess Solar UV Irradiance for the United States' (2005) 81 *Photochemistry and Photobiology* 1276–86. See further, CF Garland and others 'The Role of Vitamin D in Cancer Prevention' (2006) 96 *American J Public Health* 252–61.

35 A Burgess 'Flattering Consumption. Creating a Europe of the Consumer' (2001) 1 *J Consumer Culture* 93–117.

36 See further, GB Gori 'Science, Imaginable Risks, and Public Policy: Anatomy of a Mirage' (1996) 23 *Regulatory Toxicology and Pharmacology* 304–11; GB Gori 'The Costly Illusion of Regulating Unknowable Risks' (2001) 34 *Regulatory Toxicology and Pharmacology* 205–12.

37 G Conko 'Safety, Risk and the Precautionary Principle: Rethinking Precautionary Approaches to the Regulation of Transgenic Plants' (2003) 12 *Transgenic Research* 639–47; RW Hahn and CR Sunstein 'The Precautionary Principle as a Basis for Decision Making' (2005) 2(2) *The Economist's Voice Article* 8 1–9.

38 See <http://curia.eu.int/jurisp/cgi-bin/form.pl?lang=en&Submit=Submit&alldocs=alldocs&docj=docj&docop=docop&docor=docor&docjo=docjo&numaff=C-154%2F04&datefs=&datefe=&nomusuel=&domaine=&mots=&resmax=100> (last accessed 7 March 2006).

one hand, with that relating to the protection of human health, on the other, was for entitlement to free movement to be reserved for food supplements containing substances about which, at the time when the directive was adopted, the competent European scientific authorities had available adequate and appropriate scientific data capable of providing them with the basis for a favourable opinion, whilst giving scope, in Article 4(5) of the directive, for obtaining a modification of the positive lists by reference to scientific and technological developments.

69 It is also necessary to state in that regard that, by virtue of Article 7 of Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ 2002 L 31/1), the Community legislature is entitled to adopt the provisional risk management measures necessary to ensure a high level of health protection and may do so whilst awaiting further scientific information for a more comprehensive risk assessment, as is stated in the 10th recital to Directive 2002/46.

70 Contrary to the contention of the claimants in Case C-154/04, a negative list system, which entails limiting the prohibition to only the substances included on that list, might not suffice to achieve the objective of protecting human health. Reliance in this instance on such a system would mean that, as long as a substance is not included on the list, it can be freely used in the manufacture of food supplements, even though, by reason of its novelty for example, it has not been subject to any scientific assessment apt to guarantee that it entails no risk to human health.

This central quote of the ruling shows a number of things. First, precaution is only regarded within the context of the internal market and the protection of human health, where of course human health should prevail over economy. However, this view on micronutrients and the presumed risks involved a priori selects for scientific knowledge in league with the precautionary principle with its institutionalised mistrust and secondary risk management tendencies. More importantly, it ignores one of the basic tenets of European regulation, which in the case of micronutrients seems all the more ironic: ‘a high level of protection for human life and health’. As micronutrients cannot be characterized other than by way of a two-sided symmetrical benefits–risks profile (risk and benefits are on both sides of the micronutrients equation),

the benefits of micronutrients must be an integral factor in the regulatory equation.

Secondly, the subsidiary and paradoxical role and functioning of science is highlighted in this quote. On the one hand, science should give definitive answers in relation to the issues of safety when a (new) micronutrient food supplement is brought to market. How this could be done when the precautionary principle is one of the basic principles is quite obscure. Indeed, how safe is safe enough, and what scientific results would be deemed sufficient? As said, and this cannot be emphasised enough, it can never be proven that micronutrient food supplements do *not* pose any risks to any consumers. As it is possible to prove that a particular risk exists, yet impossible to prove that any and all possible risks are absent, the precautionary principle is prone to generate a *probatio diabolica*, which is impossible and thereby unlawful. To make matters worse, the EC in its communication states that ‘measures adopted in application of a precautionary principle when the scientific data are inadequate, are provisional ...’ and that ‘the provisional nature is not bound up with a time limit but with the development of scientific knowledge’.³⁹ This in fact means – considering, as said, that it is not possible to prove the absence of any and all possible risks – that precautionary measures could well have a *permanent temporary* status. Justice delayed is justice denied.

Conversely, with the no-data – no-market approach, market parties will be required to carry out research into the absolute safety of their products. In view of the exponentially growing knowledge on food-endogenous compounds – the number of characterised polyphenols is over eight thousand!⁴⁰ – this will be, as is our contention, an insurmountable task. Cramer, Ford and Hall already remarked in 1978 in their seminal paper on this issue:

Safety evaluation is caught in a frustrating circle. It is neither possible nor sensible to try to obtain the information needed to assess every imaginable toxic risk associated with every substance, and pursuit of greater safety therefore demands the setting of priorities as well as sensible limits for investigation. To do this with confidence requires possessing the very information that is lacking and that can be won only slowly on a few substances at a time, with significant uncertainty and at considerable cost. This requires priorities, and completes the circle of frustration.⁴¹

39 COM (2000) 1 final (n 23) 11.

40 L Bravo ‘Polyphenols: Chemistry, Dietary Sources, Metabolism and Nutritional Significance’ (1998) 56 Nutrition Rev 317–33.

In other words, unremitting assessment of increasing numbers of micronutrients (or other chemicals for that matter) that will come to market, in part as the result of increasing knowledge of the health impact of all sorts of food-endogenous chemicals, will prove to be prohibitive in terms of cost, limited research facilities and resources, scientific and public interests, etcetera. More importantly, many of the issues which arise in the course of the interaction between science (or technology) and society – for example, the beneficial or deleterious side effects of technology (micronutrient food supplementation) – hang on the answers to questions which can be asked of science and yet which cannot be answered by science.⁴² Issues of health and safety can be structured in the language of science, as questions of fact, yet cannot be answered by science; they transcend science. These issues are trans-scientific as they, among other things, refer to value judgments. We do not take this to be a shortcoming of science as such, but an overstatement of the possibilities of science in relation to the normative issues of health and safety.⁴³ Within the field of micronutrients the following value judgments could for instance be stated: How safe is safe enough?,⁴⁴ Focus on risks or benefits of micronutrients?, Focus on market – or government – failure?, etcetera. Facts and values, within the specific framework of the justification phase of science, however, need to be separated.⁴⁵ The ‘logic to regulate’ once toxicology elucidates a certain risk is occasioned by a value judgment, which, as said, is not scientific but trans-scientific.

The reference made in the court case ruling (paragraph 135) ‘that vitamins and minerals affected by the prohibition are those which are not normally found in, or consumed as part of, the diet.’ is baffling in the context of the above. To place this matter into context: food products as a whole are estimated to consist of many hundreds of thousands of different chemicals. All these food-content chemicals have their own specific pharmaco-toxicological profile, both individually and interactively (synergism and antagonism). There is scant knowledge of all these different compounds,

and science will have its hands full to characterise a mere fraction of those compounds. Parenthetically, does the above reference imply that any chemically synthesised micronutrient could not be part of the normal diet, whereby by definition it is prohibited? This would be an absurd conclusion, yet this is not excluded in the ruling or indeed the Supplements Directive.

Thirdly and finally, the Supplements Directive with its implicit recourse to precaution, pre-emptively innovative economic parties. Scientific research done by an innovative market party can still be deemed insufficient by the European regulatory bodies, which therefore hold total rights to shape the market as they choose. As precaution does not require credible scientific information to ban a certain product (see, for instance, the issue of phthalates)⁴⁶ economic parties are from a procedural and substance point of view left in the dark. This will obstruct a level playing field, and will deprive economic parties from their rights freely to enter the European market.

Conclusion

Policies directed at human health should, by definition, be wary of the set goals and the possibilities science and regulation have to offer. The Supplements Directive has as its fundamental goal the ‘high level of protection for human life and health’, which, however, is specifically translated in an asymmetric precautionary fashion; only excess toxicity is addressed. This then immediately shows the critical flaw, as risks are on all sides of the regulatory equation. For that reason, the precautionary principle, apart from our own reservations and critiques uttered by others elsewhere, has no place in the regulatory field of micronutrient food supplements – or in any other field for that matter. Focus on the risks of excess toxicity with recourse to the general acceptability of precaution generates the precautionary paradox: the caution that ‘should’ give us pause causes harm, which we should pause before permitting to occur.⁴⁷

From a risk management perspective the Supplements Directive, in our view, first and foremost caters for secondary risk management inclinations (liability and reputation) by

41 GM Cramer, RA Ford and RL Hall ‘Estimation of Toxic Hazard – A Decision Tree Approach’ (1978) 16 Food and Cosmetic Toxicology 255–76.

42 AM Weinberg ‘Science and Trans-Science’ (1972) 10 Minerva 209–22.

43 B Durodié ‘Limitations of Public Dialogue in Science and the Rise of New “Experts”’ (2003) 6 Critical Review of International Social and Political Philosophy 82–92.

44 For example, see A Wildavsky *Searching for Safety* (Transaction Publishers New Brunswick 1991).

45 M Stenmark *How to Relate Science and Religion. A Multidimensional Model* (Wm B Eerdmans Publishing Co Cambridge 2004). Religion, here, is referred to in the wider context as worldviews.

46 European Union Risk Assessment Report 1,2–Benzenedicarboxylic Acid, di–C8–10–Branched Alkyl Esters, C9–Rich and di–“Isononyl” Phthalate (DINP) (2003) European Commission–Joint Research Centre Institute for Health and Consumer Protection European Chemicals Bureau (ECB) Brussels Publications Office; MA Babich and others ‘Risk Assessment of Oral Exposure to Diisononyl Phthalate from Children’s Products’ (2004) 40 Regulatory Toxicology and Pharmacology 151–67.

47 J Harris and S Holm ‘Extending Human Lifespan and the Precautionary Paradox’ (2002) 27 J Medicine and Philosophy 355–68.

explicitly referring to the ‘normal diet’ as a sufficient source of the required micronutrients. In so doing, micronutrient food supplementation is implicitly regarded as superfluous. Therefore, the directive openly avoids responsibility for the human health of European citizens: intoxication toxicity as a result of food supplements intake is an infinitely more ‘visible’ phenomenon, increased by the bias for negative information about possible health risks of products or activities. By comparison, deficiency diseases are not (and cannot be) related to any regulatory activities, yet they have a far greater impact on public health. Ames is quite adamant when he states that:

A metabolic tune-up through an improved supply of micronutrients is likely to have great health benefits, particularly for those with inadequate diets, such as many of the poor, young, obese and elderly. The issues discussed here highlight 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. Tuning up metabolism to maximize

human health and lifespan will require scientists, clinicians and educators to abandon outdated models and explore more meaningful ways to prevent chronic disease and achieve optimum health. It is becoming clear that unbalanced diets will soon become the largest contributor to ill health, with smoking following close behind.⁴⁸

In view of the above, it seems clear that the European Commission is ‘infected’ with an over-regulatory zeal, enhanced by the precautionary principle. And as said, precaution empowers bureaucracy. It therefore may be prudent to recapitulate the words of John Stuart Mill:

Nevertheless, when there is not a certainty, but only a danger of mischief, no one but the person himself can judge of the sufficiency of the motive which may prompt him to incur the risk: in this case, therefore, (unless he is a child, or delirious, or in some state of excitement or absorption incompatible with the full use of the reflecting faculty,) he ought, I conceive, to be only warned of the danger; not forcibly prevented from exposing himself to it.⁴⁹

48 Ames 2005b (n 12).

49 JS Mill *On Liberty* (1859). Cited from <http://www.utilitarianism.com/ol/five.html> (last accessed 7 March 2006).