

New recommended daily allowances: benchmarking healthy European micronutrient regulation

Let governments take care of safety and industry of health

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Summary

Reflecting on the previous articles on micronutrients published in this journal and elsewhere, we concluded that a crucial aspect invaluable to developing European regulation in this field still needed to be addressed. This concerns the nature of the so-called recommended daily allowances (RDAs); that is the average daily dietary intake level that is sufficient to meet the nutrient requirements of healthy individuals. The RDA standards have now been functioning for more than half a century, yet they are only concerned with an optimum of micronutrient consumption in relation to a known deficiency. To protect human health as perceived by the EC, maximum levels of safe upper limits (SULs) of micronutrients are now implemented into regulation. However, in order to take forward regulation that aims to enhance health rather than simply maintain 'minimum' health and safety standards through RDAs and SULs, a new RDA (nRDA) standard needs to be developed. The focus of such a nRDA is on optimum consumption of a certain micronutrient in relation to a wide range of health-enhancing long-term effects (so as to go beyond the well-known deficiency states related to vitamins and minerals only) so that regulation can actively contribute to health. This nRDA will eventually encompass a wide range of micronutrients, not just the standard vitamins and minerals.

A new scientific and regulatory route

Last year we published two papers on micronutrients and food supplements in this journal.² In these papers we established a new perspective on micronutrients, that is

vitamins, minerals, and 'other substances' as referred to in the Food Supplements Directive (FSD)³ and the Common Position (EC) No 2/2006 regarding the regulation on fortified foods (FFR; enacted as Regulation EC 1925/2006 on 20 December 2006)⁴ such as amino and fatty acids, carotenoids, and polyphenols. These compounds are all part of the human diet and apparently show interesting health-enhancing characteristics at certain doses. Moreover, we showed that the EC is being overtly and unduly precautionary in terms of its focus on risks of over-exposure to food supplements, its deliberate neglect of the risks of malnutrition caused by micronutrient-deficiencies, and its pre-empting of innovative research and markets.

In *Environment, Law & Management* we recently published an article in which we specifically focused on *intended normal use* as a simple and straightforward concept that, subject to its consistent execution and application, can serve to regulate products and to organise and harmonise relevant markets.⁵ We contended that intended normal use, ie use in terms of recommended consumption levels and fields of application, as unambiguously clarified and presented by the manufacturer on a product's packaging and accompanying information, should be the core regulatory and market ordering principle. We have shown this by means of analogy, both from the EU and the USA, and by regulatory

1 Correspondence to hjaap@xs4all.nl, tel +31(0)793460304. The authors would like to thank the International Nutrition Company BV in Loosdrecht, The Netherlands for providing a grant to carry out this review.
2 J C Hanekamp 'The Precautionary Principle: A Critique in the Context of the EU Foods Supplements Directive' [2006] 2 Env Liability 43–51; Hanekamp and A Bast 'Food Supplements and

Fortified Foods: the EC's patriarchal Precautionary Perspective on Public Health' [2006] 5 Env Liability 181–91.

3 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] OJ L183 51–57.

4 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) (24 May 2007).

5 B Schwitters and others 'The European Regulation of Food Supplements and Food Fortification. Intended Normal Use – the Ultimate Tool in Organising Level Playing Field Markets and Regulations or How to Break the Fairy Ring around "Other Substances"' (2007) 19 Env Law & Management 19–29.

content in the relevant policy fields. We have also discussed a recent and prominent regulatory proposal in the field of botanicals that portrayed the current and/or evolving EU regulatory framework as insufficient for industry and trade to differentiate, at the consumer level, between foods and medicines.⁶ We have shown this to be seriously flawed and inconsistent.

However, despite the logic of our proposals and innovations, we have simultaneously given clues (leaving aside the legal aspects we have discussed earlier), in *casu* aspects of the Public Choice School, regarding why intended normal use *tout court* seems to be difficult to embed into regulation. Nobel laureate James M Buchanan and Gordon Tullock, the two founders of the Public Choice School in economics, showed that ‘command and control’ policies seemed to be greatly favoured over such things as performance standards that allow producers instead of regulatory bodies to choose production technologies that induce cost-effective production and control.⁷ They demonstrated convincingly that ‘vested interests’ of established industry have something to gain from federally-mandated output restrictions and other constraints, such as entry and expansion of emerging and innovative industries.⁸

Bearing in mind these deliberations, in our view what is required to strengthen the proposed coherent policy of intended normal use is a ‘new’ scientific perspective on micronutrient requirements. Political choices as to the type of preferred regulation are mostly only in part related to epistemic (rational) deliberations. In the absence of relevant epistemic grounding, public policies are the object of preferred and time-framed politics. In our view, it is a new perspective on RDAs – that is, the average daily dietary intake level sufficient to meet the nutrient requirements of nearly all (97 to 98 per cent) healthy individuals in a particular life stage and gender group – that could in fact make possible an about-face in the field of food supplements and fortified foods. The RDAs and the need for n(ew)RDAs will therefore be the focus of this article.

It has become increasingly clear that the RDAs that have been used for many decades are too limited in their approach to micronutrients, partly because they are reserved only for those vitamins and minerals which cause the well-defined deficiency diseases. By definition, other

(food-endogenous) substances that seem to have health-enhancing properties, yet lack a well-defined deficiency profile, cannot have an RDA set, and will therefore, as far as regulation is concerned, be primarily approached from a safety (toxicological) point of view. This is the result of applying the principle of a ‘high level of consumer protection’ expounded in the FSD and many other regulatory documents. If the safety of those other substances cannot be guaranteed, then these substances cannot be added to the positive lists of compounds allowed on the European market. Indeed, the FSD in the preamble (3), states: ‘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 ...’.

As stated in one of our previous articles in this journal, food supplements are regarded by the FSD, albeit not explicitly, as superfluous and redundant products that are, by default, only in need of excess toxicology regulation; a varied and balanced diet is offered as a ‘guarantee’ for sufficient micronutrient consumption and thereby human health.

However, the maximising health attributes, which nowadays are rarely a matter of preventing acute deficiency diseases, seem to lie in the field of long-term benefits, such as reduced incidence of cancer, cardiovascular and inflammatory conditions, and the deceleration of premature aging. RDAs, however, do not define an optimal level of any nutrient, as they are focused on deficiency-disease prevention. They are designed to meet the needs of healthy people and do not take into account special needs arising from infections, metabolic disorders, impaired uptake, or chronic disease.⁹ These constraints have a historical background which we discuss below. We will subsequently develop a micronutrients approach focused on optimising public health, rather than on safety. As opposed to concerning ourselves with ‘minimum’ (RDAs) and maximum (ie toxic) amounts (SULs) of micronutrients, we need to focus on an optimum level of micronutrient-consumption. This optimum we envision as being defined with a nRDA.

A brief history of recommendations

It need hardly be argued that vitamins and minerals are essential. It has been known since ancient times that human

6 P Coppens and others ‘Use of Botanicals in Food Supplements. Regulatory Scope, Scientific Risk Assessment and Claim Substantiation’ (2006) 50 *Annals of Nutr & Metab* 538–54.

7 J M Buchanan and G Tullock *The Calculus of Consent* (University of Michigan Press Ann Arbor 1962).

8 BYandle ‘Public Choice at the Intersection of Environmental Law and Economics’ (1999) 8 *Eur J Law Econ* 5–27.

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

health is dependent on diet. Until recent times, the impact of diet upon health was a process of trial and error. In the more recent history of Western Europe, the first 'public' application of knowledge acquired in such a way was the prevention of scurvy at sea. In the first half of the 18th century, it was established through careful observation that scurvy was due to a lack of fresh food, particularly fruit and vegetables, and could be prevented. The publication in 1753 of Lind's treatise on the prevention of scurvy could be regarded as the landmark inauguration of the history of dietary standards.¹⁰ By 1796, the Royal Navy was providing lemon juice – known as 'lime juice' – to its sailors: the term 'limey', a slang nickname for the British which originally referred to British sailors, is derived from 'lime-juicer', referring to the Royal Navy and the mercantile fleet practice of supplying lemon juice to British sailors to prevent scurvy.

The first formal action to institute dietary recommendations was the passage of the British Merchant Seaman's Act in Britain in 1835, by which the provision of lemon juice to prevent scurvy was made compulsory in the rations of the mercantile service.¹¹ At the time, nobody knew why fresh fruits and vegetables prevented scurvy. By the mid 19th century, deficiency diseases could be correctly diagnosed (quite a feat in itself), yet could not be explained. During the succeeding 50 years, several other dietary recommendations were proposed, mainly by individual scientists or physicians. Most of these recommendations were based on the observed protein and energy intakes of working people. All the recommendation proposed prior to the early part of the 20th century, except that for citrus juice for sailors, dealt only with energy sources and protein. The nutritional importance of other components of foods in the maintenance of health was recognised only at the beginning of the 20th century.¹²

In the 1930s, two sets of dietary standards were proposed in connection with efforts to alleviate the deprivation caused by the economic depression; one by a committee of the British Medical Association (BMA) and the other by Stiebling.¹³ The BMA committee made no quantitative estimates of needs for vitamins and minerals

but recommended the inclusion of protective foods in the diet. The standard proposed by Stiebling as a guide to ensure the nutritional adequacy of diets was the first to include quantitative values for specific vitamins and minerals. The values were based on current knowledge of human requirements for nutrients.

Between 1925 and 1935, the League of Nations Health Organisation established committees and commissions and held conferences to examine many aspects of problems relating to food and nutrition, especially those resulting from the economic crisis of 1929. The Mixed Committee on the Problem of Nutrition was appointed, under the chairmanship of Lord Astor, by the Council of the League of Nations in 1935, following a resolution adopted by the Sixteenth Assembly requesting the nomination of a committee, including agricultural, economic and health experts, to submit a general report on the whole question of nutrition in its health and economic aspects. In 1937, the Mixed Committee presented its Final Report on the Relation of Nutrition to Health, Agriculture and Economic Policy to the Assembly. In 1938, Dame Janet Campbell summarised the report as follows:¹⁴

For the first time it has been clearly stated, with international authority, that the nutrition of a people is a matter of grave public concern; that it is not sufficient for doctors and scientists to lay down the requirements of an adequate dietary, but that producers of foodstuffs must be able to provide the necessary constituents in sufficient quantity at reasonable prices, and that production depends not only on the competence of agriculturists, but also on the assistance given to them to overcome economic and political difficulties outside their own control. Throughout the reports the Committee emphasises the importance to health of protective food-stuffs; the provision of an adequate supply available for all classes may involve the reorganisation of agriculture, the modification of commercial policy, financial assistance to industries or to groups of persons, and educational propaganda to persuade both producers and consumers to make full use of the knowledge and facilities placed at their disposal. For most countries this would entail far-sighted schemes of research and reform, but few who have studied the question will disagree with the conclusion that such a policy would be fully justified by the resulting improvement in national health and efficiency. The

10 J Lind *A Treatise of the Scurvy* (Edinburgh 1753).

11 I Leitch 'The Evolution of Dietary Standards' (1942) 11 *Nutr Abstr Rev* 509–21.

12 For an extensive discussion of recommended dietary allowances see E A Harper 'Evolution of Recommended Dietary Allowances. New Directions?' (1987) 7 *Ann Rev Nutr* 509–37.

13 British Medical Association 'Committee on nutrition' (1933) *Suppl 25 Br Med Journal*; H K Stiebling *Food Budgets for Nutrition and Production Programs* (US Dept Agric Miscell Publ No 183 Washington DC 1933).

14 J M Campbell 'The Nutrition Report' (1938) 17 (2) *International Affairs* 251–53.

Committee regards the malnutrition which exists in all countries as at once a challenge and an opportunity; a challenge, as it rightly thinks, to men's consciences, and an opportunity to eradicate a social evil by methods which will increase economic prosperity.

The Technical Commission of the League of Nations Health Organisation presented its report on estimated requirements for vitamins and minerals in 1937.¹⁵ Two transitions in the evolution of dietary standards can be observed between the beginning of the 20th century and 1940. First, from being recommendations for programmes to relieve starvation and illness because of economic and wartime crises, they became standards to maintain and improve the health of the population as a whole, albeit from the perspective of specific deficiency states, as dictated by the scientific knowledge which was then current. Secondly, from being observational standards based on information about the usual patterns of food consumption, they became technical standards based on scientific knowledge of human needs for essential nutrients and energy sources.¹⁶

This very concise history of diet shows that the goals to improve human health were clear-cut. Poverty and malnutrition were obvious features of existence in the 18th, 19th, and the beginning of the 20th centuries. Regulators felt impelled to improve the human condition with the aid of (nutritional) science, while making room for agriculture and industry. Moreover, and this has been the main driver for standardisation of food intake, the prospect and reality of war (WWI and II) fuelled the necessity to deliver scientific knowledge on food literally to the front lines. In 1941, the National Nutrition Conference painted the nutritional goals and needs of Americans in vivid colours:

This is a grave hour in our Nation's history. We have met here at the request of our President, to contribute our knowledge and our effort to an urgent defense task. We have been asked by our Commander-in-Chief to tell him what we can do to make America strong by making Americans stronger for whatever perilous task may lie ahead. ... In summary, our answer is that, given the national will to do it, we have the power to build here in America a nation with better morale, a more united purpose, more toughness of body, and greater strength of mind than the world has ever seen ... Yes,

*food will build a new America.*¹⁷

Standards for food consumption that enhance health, including RDAs for micronutrients, show a remarkable history of close and astute observation and spot-on scientific inquiry. However, since the 1940s, when reflecting on the character, dietary use and public relevance of the RDAs for vitamins and minerals, little has changed, despite the fact that immense research efforts have been expended within the food sector. RDAs are still related to the avoidance of deficiency states, with minor changes, when compared with significantly increased and increasing scientific insights. In 1994, this was recognised by the Food and Nutrition Board, which stated that:

The role of the RDAs at any time is to provide the best consensus of nutrition science interpreted into recommended values at that time. The FNB believes that the science of nutrition has advanced significantly, and the next edition of the RDAs will need to reflect this progress. One consideration is expanding the RDA concept to include reducing the risk of chronic disease.¹⁸

Dietary standards: standardising diet

The purpose of dietary standards shows an evolution from preventing scurvy (1753), starvation diseases (1862), feeding the army and the nation (1918), maintaining health and working capacity (1933), joining health and agriculture (1935), to maintaining perfect health (1941).¹⁹ The USA National Nutrition Conference for Defense was responsible through the National Research Council for a new charter of requirements, formulated on a new level: 'The aim is "buoyant health", "the building up of our people to a level of health and vigor never before attained or dreamed of ..."', as expressed by the Surgeon General Thomas Parran.²⁰

However, as we have already observed with reference to the Food and Nutrition Board, this 'buoyant health' cannot be achieved by using the RDAs that were set long ago, when focusing on micronutrients that may enhance human health. Indeed, even if we soldier on with the old RDA approach:

Nutrients identified as potential (deficiency) problems

15 League of Nations (1938) 'Report by the Technical Commission on Nutrition on the Work of its Third Session' (1938) 7 Bull League Nations Health Organ 461–82.

16 Harper (n 12).

17 The National Nutrition Conference (1941) 56(24) Public Health Reports 1233–55 (italics in the original).

18 Food and Nutrition Board, Institute of Medicine 'How Should the Recommended Dietary Allowances be Revised?' (National Academy Press Washington DC 1994).

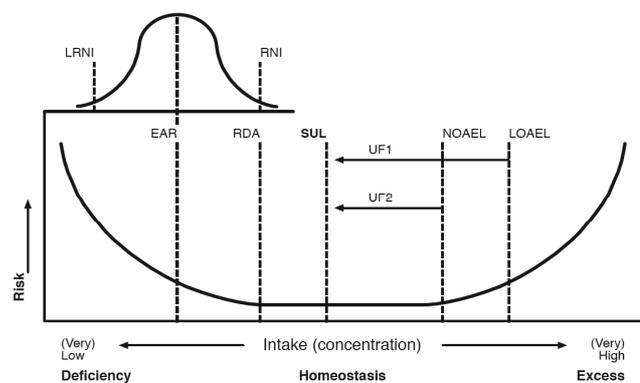
19 Leitch (n 11).

20 *ibid.*

for most gender/age groups based on comparisons to Estimated Average Requirements include vitamins A, E, and C, and magnesium. Other nutrients that may be problems only for certain segments of the population are vitamin B6 for older adult females, zinc for older adult males and females and teenage females, and phosphorus for preteen and teenage females. Vitamin K, calcium, potassium, and dietary fibre, nutrients for which no Estimated Average Requirements have been established, may also be of concern.²¹

In order to give some insight into the difficulty associated with RDAs, the procedure for determining RDAs depends on being able to set an Estimated Average Requirement (EAR): that is, a daily nutrient intake value that is estimated to meet the requirement of half the healthy individuals in a group. If the standard deviation of the EAR is available and the requirements for the micronutrient are normally distributed, the RDA is set two SDs above the EAR ($RDA = EAR + 2 SD_{EAR}$):²²

Figure 1: Generalised model for the U-shaped curve for micronutrient dose-response



The RNI (reference nutrient intake) is similar to the RDA. The lower reference nutrient intake (LRNI) is daily nutrient intake value, which is adequate for only 2.5 per cent of healthy individuals in a group. RDAs need to be derived from nutritional requirements. For that, a criterion of adequacy is selected from a scientific literature review.

Usually, a well-defined pathological condition determines the relatively short-term dose-response for which the RDA is optimised. For instance, scurvy, as a result of a lack of vitamin C consumption, develops after several weeks. To summarise, RDAs define the minimum required amount to maintain health by avoiding a specific deficiency state, below which risks will increase.

Data is sometimes examined to determine whether reduction of risk of a chronic (long-term) degenerative disease or developmental abnormality could be used as a criterion of adequacy. However, as we have shown, the available scientific evidence of chronic degenerative disease prevention as the basis for setting recommended levels of intake has not until now been taken into account. Thus, for vitamins EARs and RDAs are based on criteria related to their general function, so that the prevention of acute deficiency diseases (obviously allowing for a safety margin) is 'guaranteed'. In the scheme depicted above, micronutrients are defined within the confines of pharmacology and pathology, that is the branches of medicine that deal with the interaction of drugs with the diseased systems and processes in living organisms (human and animal), particularly the mechanisms of drug action as well as the therapeutic and other uses of the drug.

In order to establish a SUL for micronutrients (the maximum amount we mentioned earlier), the no-observed adverse effect level (NOAEL) and lowest-observed adverse effect level (LOAEL) for micronutrient exposure are divided by an uncertainty factor (UF). Safety or uncertainty factors are applied to allow for uncertainties in the use of data obtained from human or animal studies, in order to establish the amount of a particular substance that can be consumed without producing adverse effects. Applying UFs to a NOAEL (or LOAEL) will result in a value for the derived UL that is less than the experimentally derived NOAEL. The larger the uncertainty, the larger the UF and the lower the UL, which represents a lower estimate of the threshold, beyond which risks of exposure to the specific micronutrient may increase. To summarise, SULs define the maximum micronutrient exposure beyond which risks might ensue.

The methods of establishing RDAs and SULs for micronutrients described above are entrenched in the minds of policy-makers and in mainstream scientific research. However, when considering the inadequacies of the (generalised) pharmacological shape of the dose-response curve of essential micronutrients such as vitamins and minerals (and indeed other compounds), we should envisage the development of a different physiological perspective in which the issue of optimum dosages not in relation to specific acute deficiency states but to long term (chronic) disease states, can be addressed. In doing this, we have come to a

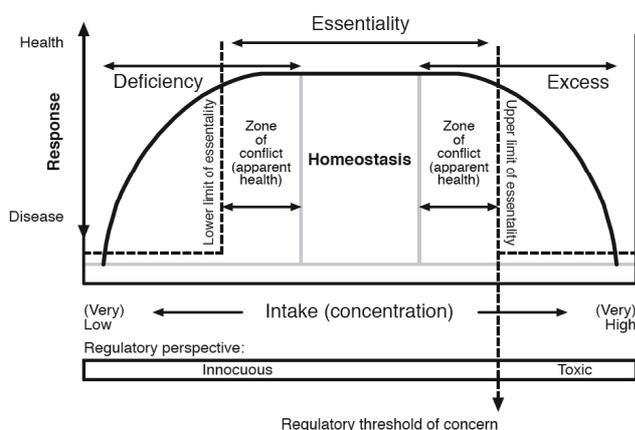
21 A Moshfeg and others 'What We Eat in America' NHANES 2001-2002: Usual Nutrient Intakes from Food Compared to Dietary Reference Intakes (USDA Agricultural Research Service 2005).

22 Institute of Medicine Dietary Reference Intakes for Thiamin, Riboflavin, Niacin, Vitamin B6, Folate, Vitamin B12, Pantothenic Acid, Biotin, and Choline. (1998) A Report of the Standing Committee on the Scientific Evaluation of Dietary Reference Intakes and its Panel on Folate, Other B Vitamins, and Choline and Subcommittee on Upper Reference Levels of Nutrients, Food and Nutrition Board (National Academy Press Washington DC 1998).

'new' model which we have summarised as the U-shaped curve in an inverted fashion. The figure does not address deficiency and excess toxicology from a regulatory or experimental point of view, but centres on the organism as it is exposed across a certain concentration range of micronutrients. For clarity, beneath the curve we have positioned the regulatory concerns in relation to the pharmacological shape of the dose-response curve:

Figure 2: The (inverted) U-shape curve of micronutrients²³

As shown, an optimum of micronutrients-exposure – that



is, the homeostatic plateau – exists, yet cannot be described with the RDA-concept, as RDAs only describe an optimum of micronutrient exposure required to avoid certain specific deficiency states. With this scheme we make a transition from pharmacology/toxicology to physiology, that is study of the functioning of living organisms, of maintaining the constancy of the *milieu interne* and of the functioning of the organism's constituent tissues or cells. The totality of this functioning operates, as Figure 2 shows, within homeostatic boundaries, that is the self-regulating process by which biological systems tend to maintain internal stability while striving for conditions that are optimal for survival. If homeostasis is successful, life continues; if unsuccessful, disease, disaster or death ensues. The stability attained is actually a complex system of dynamic equilibria, in which continuous change occurs yet relatively uniform conditions prevail. The homeostatic plateau as a result of optimal consumption of micronutrients is currently the most interesting object of scientific inquiry, as it will elucidate the actual needs of all sorts of people with different genetic and metabolic predispositions and actual health/disease

23 Taken from a lecture by Dr M Dourson and others 'Toxicology Excellence for Risk Assessment'.

states in relation to consumption patterns.

The margin between essentiality (that is, at a minimum, the prevention of deficiency) and excess (that is, at a maximum, the prevention of toxicity) can range from a few-fold for trace elements such as selenium,²⁴ to orders of magnitude for some of the B group vitamins such as biotin or pantothenic acid.²⁵ As we have stated earlier, micronutrients cannot be characterised other than by a two-sided benefits-risks profile (an (inverted) U-shaped dose-response curve that marks benefits and risks), despite the regulatory focus on excess toxicity.²⁶ In actual fact, European food-safety legislation has as its goal 'a high level of protection for human life and health' whereby *mutatis mutandis* the potentially beneficial side of micronutrients should, by definition, be the focus. This also corresponds to 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 European Commission entitled *Healthier, Safer, More Confident Citizens: a Health and Consumer Protection Strategy*.²⁷

Bearing this in mind, the following proposition will, in our view, make the change from disease prevention to health enhancement possible. To do this we need to focus on an optimum level of micronutrient-consumption; the maintenance of homeostasis with the aid of micronutrients is at the core of the proposal. This will make a transition from the 'old' RDAs to the nRDAs possible. Moreover, shifting the focus to homeostasis and optimising health, the nRDA approach enables us to include many more food-endogenous compounds than just the well-known vitamins and minerals. This makes regulation, in conformity with the principle of intended normal use, fully practicable and creates a new level playing field for industry.

N(ew)RDAs: a homeostatic advance

Scientific discoveries in the field of micronutrients will in the short- and long-term add considerably to innovation in the fields of food supplements, food fortification and conventional foods. It is quite likely that in future the effects

24 Panel on Dietary Antioxidants and Related Compounds, Subcommittees on Upper Reference Levels of Nutrients and Interpretation and Uses of DRIs, Standing Committee on the Scientific Evaluation of Dietary Reference Intakes, Food and Nutrition Board Dietary Reference Intakes for Vitamin C, Vitamin E, Selenium, and Carotenoids (National Academy Press Washington DC 2000) p 284 pp 311–18.

25 Institute of Medicine (n 22).

26 See note 2.

27 See http://ec.europa.eu/health/ph_overview/Documents/com_2005_0115_en.pdf (last accessed on 22 May 2007).

of micronutrients on reducing the risk of disease will increasingly be used to establish novel nutrient requirements.²⁸

However, as we have shown elsewhere,²⁹ policies regulating food supplements and food fortification (the FSD and the FFR) are dominated by a culture of risk-aversion which engenders policies focused exclusively on excess toxicity risks (usually strengthened with the precautionary principle), while simultaneously lecturing Europeans to 'eat a normal healthy diet'. These policies therefore avoid responsibility for the health of European citizens. The confines of innovation, although high on the agenda of the European Community, are 'a high level of protection for human life and health'.

In all fairness, the failure of many public campaigns, whether promoting the eating of more fruit and vegetables, more physical exercise, and so on and so forth, demonstrates the difficulty governments have in promoting the health of their citizens.³⁰ Enforcing food policies related to what one should consume and how will always fail. This brings us to the subtitle of this article, which to some may seem presumptuous. It is crucial to repeat the obvious: manufacturers make products (and thereby create markets). These products, from straightforward food products to highly specialised food supplements, add to the possibilities for people to choose and eat their fill or 'work' on their health through food (products). As stated as early as 1941:³¹

The leaders in food manufacturing and distribution will lend their facilities and their great influence to get the maximum distribution of those foods now most deficient in our national dietary. Greater volume will make it possible to cut processing and distribution costs. Other food industries will follow the lead of the millers and bakers in improving the nutritional value of their products.

Reiterating Dame Janet Campbell's words seems opportune here as well.³²

... that it is not sufficient for doctors and scientists to lay down the requirements of an adequate dietary, but

that producers of foodstuffs must be able to provide the necessary constituents in sufficient quantity at reasonable prices, and that production depends not only on the competence of agriculturists, but also on the assistance given to them to overcome economic and political difficulties outside their own control. ...

In order to profit from industrial potential and scientific enquiry, the RDA needs to be superseded by the nRDA in the broader long-term context of a healthy lifespan. Current scientific insights show the health-promoting effects of numerous micronutrients in a context that is much broader than that of the classic deficiency states. This is important as fortified foods, food supplements, and the 'nutraceuticals' found therein play an increasingly important role in the maintenance of human health. In the context of the 'internal market' called European Community, a significant number of judgments made by the European Court of Justice unequivocally prohibit Member States from using the RDAs as a means of setting maximum levels for vitamins and minerals. In spite of this, RDAs continue to play a role in the various discussions, but regulators, politicians, food business operators and consumers are confronted by the problem that the classic RDAs are an inadequate tool to manage a 'healthy lifespan'. A nRDA could resolve many of these issues.

A healthy lifespan-oriented nRDA necessitates the establishment of multiple physiological (homeostatic) markers. As those markers must be relevant in a very long-term (lifespan) dose-response process, they will be markers of sub-clinical and physiological events in the onset and early development of diseases such as cancer and cardiovascular dysfunction. One of those markers, genomic integrity, serves as the foremost characteristic of diet-related conditions, ranging from 'perfect' health to degenerative diseases such as cancer, chronic inflammations (arthritis), cardiovascular and neurodegenerative diseases, and diabetes. Human DNA needs constant maintenance and repair to protect against all sorts of damage stemming from 'stressors' such as carcinogenic chemicals in food, solar radiation, inadequate supply of micronutrients, and so on and so forth. When such damage to the human genome is recurrent and persistent, it results in the numerous diseases mentioned above. Diet is most likely to be the deciding factor in genomic integrity.³³ Hence, the level of genomic integrity directly correlates with certain levels of micronutrients present in the daily diet and the health-

28 A G Renwick and others 'Risk-benefit Analysis of Micronutrients' (2004) 42 *Food Chem Tox* 1903–22.

29 J C Hanekamp, A Bast 'Food Supplements and European Regulation within a Precautionary Context: A Critique and Implications for Nutritional, Toxicological and Regulatory Consistency' (2007) 47 *Crit Rev Food Sci Nutr* 267–85.

30 The national vaccination programmes, which are directly related to the minimisation or eradication of communicable diseases, and thereby add tremendously to human health, are a well-known and not to be underestimated exception.

31 See note 17.

32 Note 14.

33 M Fenech, L R Ferguson 'Vitamins/minerals and Genomic Stability in Humans' (2001) 475 *Mut Res* 1–6.

promoting effects derived thereof. Needless to say, micronutrients not only influence genomic integrity as such, but also form the substrates needed by the organism to execute the ‘instructions’ originating from the DNA.

An accompanying effect will be that the nRDAs will encompass not only the well-known micronutrients (vitamins, minerals), but may also include other food-borne health-beneficial compounds (referred to as ‘other substances’ in EU food regulations and policies) usually not defined as ‘essential’. This is a quantum leap forward in the sense that the new approach may reveal that micronutrients hitherto regarded as non-essential are in fact essential, and this will considerably facilitate regulatory efforts in this field. This will also stimulate innovative research into the health-attributes of numerous food-endogenous compounds hitherto not identified as essential.

That leaves this article with one last question. What can be the goals of a European society that has lost most of its drive to expand its intellectual horizons and is ‘fearful’ of its future to the extent that a precautionary perspective is deemed necessary in most, if not all, relevant fields of society? This perspective postulates that once we have engaged in a direction that might lead to deep errors, we will no longer be able to stop or choose the good aspects and resist the bad. 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.³⁴

The 1941 paper on food and health we referred to above was inspired by the threat and reality of war. Technical issues concerned with food were then framed in overarching perspectives of national freedom, global peace and prosperity for all, and the like. Economic parties, from within agriculture and the processing and distribution industries were seen as partners able to bring into practice the scientific knowledge painstakingly made available to all. What would now be the added value of a nRDA over the current RDA? Public choice seems a fitting answer. Command and control seem an outdated regulatory option in an increasing liberal and free market that equally spawns numerous (private) research institutes interested in generating knowledge and hoping for lucrative patents. A society with few overarching goals requires few regulations other than clear-cut safety regulations which apply to all.³⁵ Industry, when properly provided with these clear-cut safety goals, can put the scientific knowledge gained into practice.

34 G Hottois ‘A Philosophical and Critical Analysis of the European Convention of Bioethics’ (2000) 25(2) J Med Phil 133–46.

35 Schwitters (n 5).