

Why RDAs and ULs Are Incompatible Standards in the U-Shape Micronutrient Model: A Philosophically Orientated Analysis of Micronutrients' Standardizations

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Risk assessments of micronutrients are carried out in the customary deficiency-excess model. It is regarded as straightforward and unambiguous. Nevertheless, it is a problematic amalgamation of two different and to a certain extent contrasting perspectives on risk and science that we will criticize in this contribution. Our critique is framed in a conceptual scheme of opposing perspectives highlighted by the rival characteristics of RDAs and SULs and the role of science therein. The one part of our scheme holds the typically modern approach that centers on risks that can be scientifically assessed more or less confidently. Subsequent policies are aimed at preventing major health problems that affect the majority of the population from early on in life. The RDAs are the ideal type-case here. The other part of our scheme holds a much more postmodern approach in which health risks are explicitly recognized as "uncertain." Dealing with those risks has little to do with major health problems from early on in life. Here, we encounter the scientific quandary of disentangling complex factors and impacts that may relate to some extra quality of life later on in life. SULs are exemplarily thereof. We will show that RDAs originally spawned from the scientific aim of securing objective knowledge "to lay down the requirements of an adequate" diet. SULs, conversely, are the upshot of generating acceptable outcomes driven by ever-increasing safety requirements. This shift from securing objective knowledge to generating acceptable outcomes will be addressed in relation to precautionary culture.

KEY WORDS: Deficiency-excess micronutrient model; precautionary culture; principle of preferring inaction; RDAs; safety-driven acceptability; securing objective knowledge; SULs

1. STANDARDIZING FOOD: FOOD STANDARDS AND SCIENCE

Setting scientific and policy standards that benchmark the benefits and risks of foods is of great

consequence for industry, policymakers, and consumers. In Europe, the core regulatory framework in food law is Regulation 178/2002/EC.⁽¹⁾ According to this Regulation, "food" (or "foodstuff") denotes "any substance or product, whether processed, partially processed or unprocessed, intended to be, or reasonably expected to be ingested by humans." The scope of Regulation 178/2002/EC concerns "all stages of the production, processing and distribution of food" and its general objective is to provide "a high level of protection of human life and health and the protection of consumers' interests, . . .". This Regulation thus sets general rules for all products

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that are brought to market. To that effect, the general requirements of this Regulation deal with food safety, presentation, traceability, and related responsibilities of food business operators. Importantly, the Regulation also constitutes the European Food Safety Authority (EFSA) and defines the Authority's task and fields of competence and authority.

Within this context, setting toxicity levels not only for *micronutrients* (vitamins and minerals), but also for "other substances," in view of the growing market for food supplements, is now a foremost regulatory topic in Europe. "Other substances" are defined as food-endogenous substances with a nutritional or physiological effect other than the forms of vitamins and minerals approved for use in food supplementation and food fortification. Examples are amino acids and fatty acids, carotenoids, and polyphenols.⁽²⁾ The European Food Supplements Directive (Directive 2002/46; FSD) regulates food supplements marketed as foodstuffs and presented as such for the purpose of supplementing the human diet.⁽³⁾ Regulation 1925/2006/EC (Food Fortification Regulation (FFR)) sets requirements for "the addition of vitamins and minerals and of certain other substances to foods."⁽⁴⁾ These laws complement the principles of general food law laid down in Regulation 178/2002/EC. For clarity, health-related data of micronutrients characteristically are *not* considered in setting regulatory safety standards for food-products.⁽⁵⁾

The customary model to assess micronutrients in general and SULs (safe upper limits) in particular is the deficiency-excess model⁽⁶⁾ derived from the underlying physiological model (Fig. 1). We will analyze the deficiency-excess model in this contribution.

At the left part of this model's scale, where the levels of exposure *decrease* and the levels of deficiency *increase*, the organism will become exposed to increasing risk of harm. Here we find the so-called recommended dietary allowances (RDAs), which principally are advisory tools aimed at preventing deficiencies. At the right part of the model's scale, where the levels of exposure *increase*, the organism incurs an increasing risk of harm by excess intake. Here we find the so-called (safe) upper limits (SULs or, more generally, ULs), which are derived from no observed adverse effect levels (NOAELs) or lowest observed adverse effect levels (LOAELs) divided by some uncertainty factor (UF). SULs operate as regulatory tools implemented at the level of the food industry. Within the bandwidth of deficiency and toxicity a physiological optimum is assumed (homeostasis), which may vary for different micronutrients, various individuals, and populations.

Although this model is regarded and applied as a straightforward and unambiguous risk assessment and regulatory tool, it nevertheless is a problematic amalgamation of two different and to a certain extent competing perspectives on science. To the best of our knowledge, these shortcomings have not been addressed previously. We will formulate a critique with reference to the use of the two in our view incompatible standards in this model, namely, the SUL and the RDA.

We will frame our critique in a scheme that opposes two contrasting perspectives on risk that will highlight the rival characteristics of the RDAs and the SULs, respectively, and the role of science therein. The one part of the scheme holds the typically *modern* approach that centers on risks that can

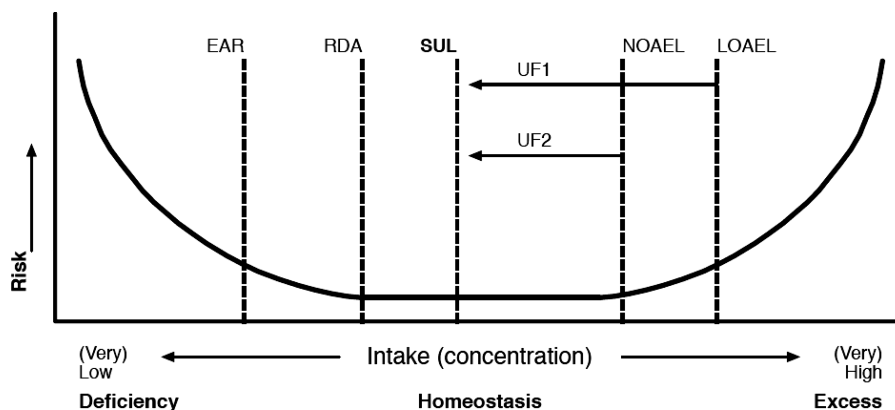


Fig. 1. Deficiency-excess model for micronutrients.

be assessed more or less confidently with the aid of science. Subsequent policies based on these scientific risk assessments are aimed at preventing major health problems that affect the majority of the population from *early on* in life. The RDAs are the ideal type-case here. The other part of our conceptual scheme holds a much more *postmodern* approach in which health risks are quite explicitly recognized as “uncertain.” Dealing with those risks has little to do with major health problems from early on in life. Here, we encounter the scientific quandary to disentangle complex factors and impacts, which may relate to some extra quality of life at the *end* of our lifetime. Here, the SULs are the ideal type-case in point.

In this contribution, with the aid of the above-presented scheme, we will show that RDAs originally spawned from the scientific *aim* of securing objective knowledge “to lay down the requirements of an adequate dietary” driven by poverty and war.⁽⁷⁾ SULs, conversely, are the upshot of the scientific objective of generating *acceptable* outcomes driven by ever-increasing safety requirements: “How safe is safe enough?”⁽⁸⁾ This shift from securing objective knowledge to generating acceptable outcomes will be addressed in relation to the rise of precautionary culture, with which we will set off our contribution.

2. SCHEMATIZING OPPOSING VIEWS ON SCIENCE AND RISK IN A CAUTIOUS CULTURE⁽⁹⁾

Worldviews shape and influence the process of scientific inquiry. Clearly, good science is worldview neutral, that is to say that it is not aligned to, or does not support, any particular ideology, religion, or worldview *over another*.⁽¹⁰⁾ Indeed, theories, hypotheses, and concepts should be accepted in light of considerations that involve transparent and reproducible empirical evidence,⁽¹¹⁾ other (accepted) theories, and overt *epistemic* values such as consistency, simplicity, integrity, and descriptive, explanatory, and predictive power only.⁽¹²⁾ These epistemic values are essential as no theory or hypothesis can ever be verified completely. A scientist is rationally entitled to hold his/her beliefs in relation to the theories at hand with a commitment that surpasses the strength of the evidence (for *or* against).⁽¹³⁾ “Progress requires that most scientists get themselves in the grip of a theory which they aim to develop and defend, and without simply trying to dispose of it as fast as possible.”⁽¹⁴⁾ Securing objective knowledge therefore does not abide by the

expectations, wishes, and demands of the *global audience*—citizens, NGOs, economic parties, governments, and etceteras. Science does not easily accommodate majority consensus views, or minority views for that matter.

With this *modern* use of science, risks can be, and in fact are, assessed as a result of which public policies are constructed that add measurably to public health and safety.⁽¹⁵⁾ The 20th-century problems of poverty-induced undernourishment on account of economic depressions and war proved to be powerful drivers for scientists to develop one of the first food standards—namely, the RDAs for vitamins and minerals—that improved public health decisively. The value of *food security* is expressed in this research development from which we still profit today.⁽¹⁶⁾

Then again, with the rise of *precautionary culture*, the role of science as a means to secure objective knowledge has noticeably changed. In modern Western societies, as material needs are met for most people, the logic of wealth distribution that has shaped the Western world loses its immediate relevance,⁽¹⁷⁾ subsequently assenting to the logic of risk distribution.⁽¹⁸⁾ A society in which citizens are privileged to enjoy and value their health, wealth, safety, security, and longevity paradoxically becomes gripped by the hazards and potential threats unleashed by the exponentially growing wealth-producing forces that mark the later stages of the modernization process.⁽¹⁹⁾ Previously, during the early stages of modernity, these hazards were not prioritized because coping with and surmounting poverty, hunger, and disease were, unsurprisingly, the overriding societal interests. As Beck asserts: “The driving force in the class society can be summarized in the phrase: *I am hungry!* The collective disposition of the risk society, on the other hand, is expressed in the statement: *I am afraid!*”⁽²⁰⁾ Therefore, in contemporary *postmodern* society the goal of affluence yields to that of life-term (indeed intergenerational) safety.⁽²¹⁾

Concomitantly, in economically and industrially highly developed societies, diverse regulation of a mainly precautionary nature⁽²²⁾ has found its way into many areas.⁽²³⁾ Societies’ shift to a culture of precaution galvanizes citizens’ insistence on *advance proof* that activities and products pose no risk to human health, especially in the long term.⁽²⁴⁾ SULs are exemplarily of this development as they are defined as “doses of vitamins and minerals that potentially susceptible individuals could take daily on a life-long basis, without medical supervision in reasonable

safety.”⁽²⁵⁾ Scientific research and regulation caters for this “risk management of everything.”⁽²⁶⁾ Lest we forget, there *is* a strong desire among mass-public citizens in the Western world to believe that they live, and need to live, in a world made predictable by science. There is an equally strong desire among elite citizens working in the media, business, and government to appear to be doing the right thing by ritualistically consulting *seemingly au fait* analysts and consultants (technocratic, scientific, religious, or otherwise) from well-known institutes in order to “grasp the future.”⁽²⁷⁾ Science as a result has become heavily politicized and commercialized. The increasing public and political focus on safety, security, and predictability propels scientific research in growing and disparate fields toward *acceptable* outcomes, as opposed to objective knowledge.⁽²⁸⁾ *Food safety*, superseding food security, is now one of the dominant public values, and the precautionary regulatory context creates a substantial and growing “scientific market” for safety research.

Still, scientists are quite aware of the limitations of scientific knowledge. As stated earlier, within science verification is beyond our capabilities. Indeed, examples abound in which science comes up with surprising new insights overturning old ideas and concepts. In the celebrated BBC documentary *The Ascent of Man*, Jacob Bronowski memorably assessed what science in fact *is*.

Science is a very human form of knowledge. We are always at the brink of the known; we always feel forward for what is to be hoped. Every judgement in science stands on the edge of error and is personal. Science is a tribute to what we *can* know, *although* we are fallible. In the end, the words were said by Oliver Cromwell: ‘I beseech you, in the bowels of Christ, think it possible you may be mistaken.’

When we expand our demands for safety, as precautionary culture does, into a by definition *unknown* distant future, the confines of even our best scientific knowledge will surface progressively more poignantly. Here, we enter the realm of uncertainty, and cross-over from modernity to postmodernity:

Because we don’t drop dead [because of the implementation of a technology; *authors*], we allow ourselves to draw our boundaries of consideration much narrower than they should be. *Boundaries over space and time* are nearly always much narrower than the boundaries that include the cause. When the boundaries are made appropriately larger, they embrace more of our ignorance and more ambiguity.⁽²⁹⁾

Those who seriously entertain the conviction that science (“the boundaries of consideration”) should transgress its fundamental confines of space and time in order to address the many perceived long-term risks need quite a robust belief in what science *can* and *must* deliver. On the one hand, they can find obvious support in the fact that Western world citizens *have* experienced increasing wealth, safety, security, and longevity *on account of* science and technology. On the other hand, however, a high level of confidence regarding what science is supposed to deliver is offset by a high level of scepticism with regard to what science cannot and should not do. In modern society, scepticism about science’s capacity to secure objective knowledge, illustrated by the erosion of the idea(1) of autonomous knowledge and autonomous law,⁽³⁰⁾ lent aid to the shift to the notion of *inter-subjective* knowledge.⁽³¹⁾ It is merely a matter of degree to claim that all knowledge is related to interests and power.⁽³²⁾ “Finding the truth” has throughout the 20th century been to some degree replaced by “winning the power struggle.”⁽³³⁾ New knowledge always carries the potential risk that it will upset agreed upon concepts, policies, and power structures based on “established” scientific knowledge.

Science thus finds itself between Scylla and Charybdis. On the one hand, it is looked at as the discerning field of authority and advice, and not without cause. On the other hand, it is regarded as being the all-pervasive origin of many risks that might materialize in a distant future. Part of the scientific community has sought to respond to and thereby helped shape the approach of *acceptability*.⁽³⁴⁾ Particular directions in scientific and social inquiry, because of their likely positive social and environmental outcomes, for instance, should be favored.⁽³⁵⁾ Put differently, scientific inquiry, at the same time, should be explanatory, normative, practical, and self-reflexive. Ideally, the acceptability approach should empower people with capacities to reason critically and to assess sharply the conflicting (scientific) argumentations that play an important role in their lives.⁽³⁶⁾ The U.K. government’s inquiry into the purported adverse health effects of mobile phones, for instance, concluded that in future “non-peer reviewed papers and anecdotal evidence should be taken into account” as part of the process for reaching decisions on these matters.⁽³⁷⁾

What we have very briefly sketched here is a development in which the modern role of science as a means of securing objective knowledge has transformed, up to certain level, into a postmodern

means to generate acceptable outcomes for a society whose safety and security is thought to be continually threatened by numerous known and unknown dangers. A culture of fear has emerged.⁽³⁸⁾ The modern approach centers on risks that can be assessed more or less confidently and policies that aim at preventing major health problems will include the majority of the population from *early* on in life. Conversely, the more postmodern approach deals with health risks that are much more explicitly viewed as uncertain. Dealing with those risks has little to do with major health issues that most people will encounter from early on in life, but is focused on risks that might (or might not) materialize at a far later stage in life. This scheme we will explicate subsequently with a focus on micronutrients and their advisory and regulatory boundaries.

3. FROM SHORT-TERM ADEQUACY TO LONG-TERM OPTIMIZATION—RDAs AND SCIENCE IN ACTION

Below we summarize the generalized *physiological* dose-response curve of essential micronutrients such as vitamins, minerals, and other compounds on which the assessment model is based (Fig. 2). This scheme centers on the organism as such as it is exposed across a certain load of micronutrients. For clarity, beneath the curve we have positioned the regulatory concerns of the dose-response curve.

In the history of food standards, the upper limits of exposure did not come into vogue until recently, as undernourishment was dominant, and of course still is in quite some parts of the world. The 1930s, the time of the Great Depression, in which food *security* was the dominant issue, is effectively captured by Boudreau: “delegates to the League of Nations, together with League officials, launched what came to be known as the world food movement, *designed to release the economic jam by emphasizing that adequate diets were essential to human health, . . .*”⁽³⁹⁾

Enhancing health through adequate diet was the 20th-century driver to gain factual scientific knowledge of food requirements. Focusing on micronutrients, the overarching research efforts have, among other things, culminated in RDAs for micronutrients, defined as the average daily dietary intake level that is sufficient to meet the nutrient requirement of nearly all (97–98%) healthy individuals in a particular life stage and gender group. The original concept of RDA was a “goal” or “floor” for intake below which risks of inadequacy begin to significantly increase. RDAs, based on a specific *criterion of adequacy*, were designed to serve as dietary standards for the planning of food supplies for population groups. They were originally formulated as reference standards for use by qualified individuals who have the responsibility for assuring that food distributed to large groups of people would be nutritionally

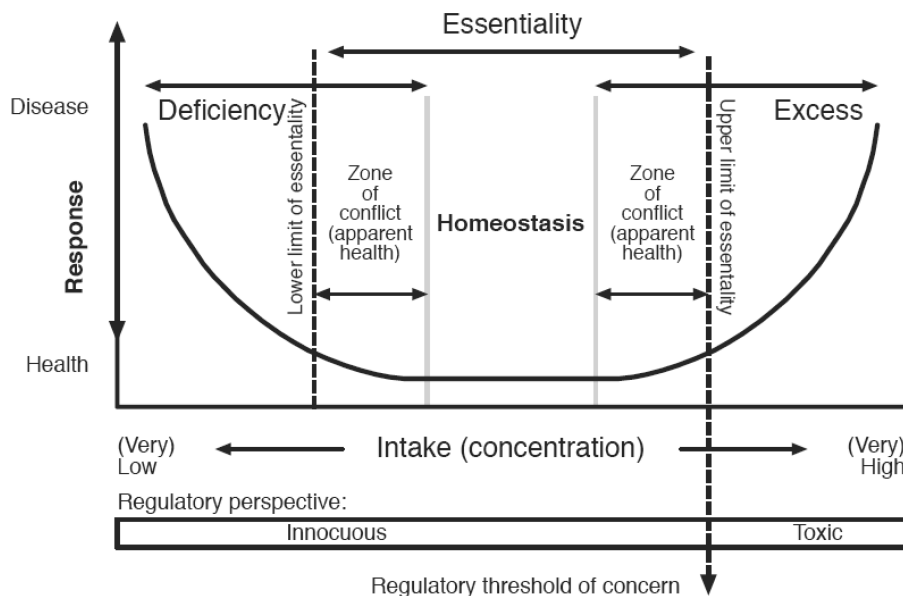


Fig. 2. Physiological dose-response model for micronutrients.

adequate.⁽⁴⁰⁾ With this objective knowledge about the interaction between food and human health in hand, research institutes and governments addressed the *primary* risks of undernourishment: starvation, disease, and infant mortality, and quite effectively so. RDAs, however, do *not* take into account special needs arising from infections, metabolic disorders, or chronic disease, and thereby do *not* define an *optimal* level of any nutrient.

With the rise of precautionary culture long-term diseases related to micronutrients *have* come to the fore, however, within the format of securing objective knowledge. For instance the Food and Nutrition Board (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.”⁽⁴¹⁾ Despite advancing knowledge concerning the role of food components in the prevention of more subtle metabolic damage resulting in degenerative diseases, current RDAs do not reflect this progress.⁽⁴²⁾

Nevertheless, diet is now regarded as a key factor in maintaining genomic integrity, i.e., protecting DNA from deleterious damage through cellular mechanisms such as prevention, repair, or apoptosis.⁽⁴³⁾ Degenerative diseases such as cancer as well as the process of aging are partly caused by DNA damage.⁽⁴⁴⁾ There is accumulating scientific evidence that higher levels of some micronutrients may be necessary for various DNA maintenance reactions, and that the current RDAs for some micronutrients seem inadequate to protect against genomic instability.⁽⁴⁵⁾ The need to set micronutrient requirements to minimize DNA damage seems a way forward.⁽⁴⁶⁾ This also might result in the inclusion of other substances for which there is accumulating evidence that they add to a healthy lifespan, such as the polyphenolic antioxidants that have, in scientific studies, been implicated to contribute notably to healthy aging.⁽⁴⁷⁾

Expanding RDAs beyond their original intent, both in terms of degenerative diseases and range of food components, highlights the issue of *uncertainty* in the existing RDAs—currently offered in single numbers as a seemingly conclusive expression of comprehensive scientific insight—from the viewpoint of *optimal* intake and the availability of scientific knowledge that could act to establish an all-inclusive RDA.⁽⁴⁸⁾ Vitamin D might serve here as a good example. The basic effect of vitamin D on human health is generally regarded as the mainte-

nance of a healthy skeleton. For adults, bone mineral content (BMC), bone mineral density (BMD), and fracture risk, in combination with serum 25(OH)D and PTH (parathyroid hormone) concentrations, are considered to be the most useful indicators of optimal vitamin D status.⁽⁴⁹⁾ Over a range of life stages a suitable RDA has been derived based on these markers. However, in the 1970s and 1980s, nuclear receptors for the active metabolite of vitamin D, $1\alpha,25(\text{OH})_2\text{D}_3$, were discovered in a variety of tissues *not* directly involved in calcium homeostasis. Numerous proteins are now known to be regulated by $1\alpha,25(\text{OH})_2\text{D}_3$, including several oncogenes that are inhibited by $1\alpha,25(\text{OH})_2\text{D}_3$. The classical limits of vitamin D regulated calcium homeostasis are thus far exceeded.⁽⁵⁰⁾ It has been suggested that a daily intake of 25 μg of vitamin D₃, which is substantially higher than the current RDA, may well lower the risk of developing different cancers substantially.⁽⁵¹⁾ This is open to further scientific scrutiny yet underscores the current limitations of RDAs in light of scientific developments.

The inherent uncertainty in the RDAs is an expression of scientific progress, considering the growing knowledge base of micronutrients vis-à-vis long-term health issues. The evidence generated is as of yet deemed to be insufficient to upgrade RDAs to incorporate long-term effects *in casu* genomic integrity and “other substances” as well. Evidently, disagreement abounds within this scientific (and any other) discourse, but if that is the case, the dispute is about whether some information truly provides a ground for everyone to believe that RDAs can in fact incorporate long-term perspectives.⁽⁵²⁾ This issue brings us to the other side of the U-shape curve and the opposite side of our scheme. Here, uncertainty *factors* (UFs) are explicitly introduced, as a result of the so-called lack of scientific knowledge, in order to formulate SULs so as to protect the public from excess toxicity.⁽⁵³⁾ Uncertainty about long-term risks cannot be effectively elucidated by science, necessitating safeguarding procedures as to “embrace more of our ignorance and more ambiguity” (see above), or so the precautionary tale goes.

4. SAFE UPPER LIMITS—BASIC OUTLINES

In order to establish SULs, standard toxicological approaches have been chosen despite the obvious U-shape of the dose-response curve. Historically, NOAEL, that is, the highest dose that in its adverse effects does not differ significantly from the

control, has been used to establish human equivalent reference doses for potentially harmful effects of substances.⁽⁵⁴⁾ Applying methods of risk assessment, the NOAEL (or LOAEL) levels for micronutrient exposure are divided by an UF. UFs are used to allow for uncertainties in the data obtained from human or animal studies in order to establish the amount of a particular substance that can be consumed without harm. The larger the uncertainty, the larger the UF and the lower the SUL, which represents a lower estimate of the threshold beyond which risks of exposure to the specific micronutrient may increase. In the application of UFs the derived UL should not be lower than the recommended intake. Carotenoids intake, for instance, is some 2 mg/day, with a RDA of 0.4–1 mg/day, while the ATBC and CARET studies showed an increased lung cancer risk in current smokers given 20 mg/day β -carotene and 30 mg/day β -carotene plus retinol supplementation, respectively.⁽⁵⁵⁾ If these levels are considered to be a LOAEL, then setting a UF to establish a SUL is critical in relation to the RDA, not to mention the actual daily intake.

Even so, different SULs are proposed by different organizations. The reports compiled by the German Federal Institute for Risk Assessment (BfR), for instance, propose structurally and significantly lower recommended maximum permitted levels than those reported in the U.K. EVM study.⁽⁵⁶⁾ Both choose a similar approach in their respective studies more or less derived from a physiology-based and/or standardized (average) diet exposure combined with toxicological data and conventional modeling, yet the conclusions vary noticeably. For example, the BfR's report proposes a 225 mg maximum for vitamin C (EVM—1,000 mg), a 5.4 mg maximum for B6 (EVM 10 mg), and 9 μ g for B12 (EVM—no maximum). In relation to vitamin A, the EVM does not state a NOAEL, while the FNB states a NOAEL of 4.5 mg/day. The EVM proposes that dosages beyond 1.5 mg/day may be inappropriate (they do not formally establish a SUL), while the FNB opts for a SUL of 3 mg/day. Assessing new food-endogenous compounds, the “other substances” as mentioned in the FSD and the FFR, and determining their SULs seems even less clear-cut, yet will become increasingly important in order to develop the required negative lists on which unauthorized—unsafe—ingredients for food supplements will be notified.⁽⁵⁷⁾

Some SULs are set to food supplements alone and some for the intake from both food and sup-

plements, explaining at least some disparity. However, setting different NOAELs and LOAELs, or even disagreeing to set a NOAEL, LOAEL, or none at all, is related to expert judgments with no universally agreed upon procedure. This holds for the establishment of UFs as well. There is no algorithm or decision rule that a scientist can follow when making such decisions. In making a scientific judgment, the scientist needs, ultimately, recourse to the epistemic values mentioned above. It makes the risk assessment procedure, straightforwardly presented by the EFSA, considerably less straightforward.⁽⁵⁸⁾ It needs to be remembered that even scientific knowledge needs to be interpreted by specialists and processed for actual use.⁽⁵⁹⁾ These steps are far from formalized and hold both epistemic and nonepistemic valuations.

Indeed, no prior probability of certain consequences of a certain activity or product is ever assigned *in vacuo*. Researchers cannot, in reality, be concerned with testing every possible consequences of a given activity or product. Science can only deal with plausible consequences. Prior probabilities are assigned subjectively and therefore do not reflect factual data by themselves, hence creating a wide distribution of prior probabilities among a scientific community. Varying nonepistemic values, corresponding to a given socioeconomic and ideological context, set off this distribution.⁽⁶⁰⁾ One such nonepistemic value is precaution,⁽⁶¹⁾ among others explicated in European regulation. Here, the opposing perspectives on science and risk collide most evidently, as we will see in our concluding paragraphs.

5. PARTITIONING THE MICRONUTRIENTS ASSESSMENT MODEL—RDAs VERSUS SULS

So, to what degree do SULs protect or add to public health and do they equate with RDAs in terms of the science applied? “Chemicals, unlike persons, are not innocent until proven guilty but suspect until proven innocent. So the burden of proof shifts, and it is now up to the industrialists to dispatch it.”⁽⁶²⁾ Indeed, the current European policies on food safety like the FSD solely deal with risks of excess exposure in order to guarantee the precautionary “high level of protection of human life and health and the protection of consumers’ interests, . . .”⁽⁶³⁾ Precaution, as a primary nonepistemic value underlying risk assessment and management, is deemed to be the way forward when considering new technology such

as industrial food-products:⁽⁶⁴⁾ “[N]ovelty might be taken as a warning sign.”⁽⁶⁵⁾ Precaution, as one of the main drivers, is not mentioned in the FSD. With the installation of the European Food Safety Authority precaution *is* specifically referred to as a key principle in food regulation.⁽⁶⁶⁾

To try to answer the question posed at the beginning of this paragraph, a recent analysis in the Netherlands by the RIVM in Bilthoven suggests that, on average, there seems to be no need for concern about too high intakes of vitamins or minerals,⁽⁶⁷⁾ which, in any case, is dwarfed inestimably by drug toxicity.⁽⁶⁸⁾ Yet, it hardly needs emphasizing that adverse effects as a result of food supplements intake is a more “visible” phenomenon, keeping in mind the bias for negative information about possible health risks,⁽⁶⁹⁾ compared to deficiency diseases that are not, and cannot be, related to any regulatory activities other than advising the populace “to eat healthy,” a less than successful *and* naïve strategy.⁽⁷⁰⁾ The naivety and unsuccessfulness of such “risk management strategies” has been recognized in a DG Sanco (the European Health and Consumer Protection Directorate) requested but subsequently ignored report on the future of scientific advice on food and public health. It is striking that in this report by James *et al.*, nutrition, health, and economic status jointly are addressed.⁽⁷¹⁾

To have scientific analysis on a European basis is important because currently many policy makers simply consider that the answer to tobacco problems is to “educate” the individual consumer not to start smoking. This naïve approach is evident in many other dimensions of public health, e.g. those relating to inappropriate diets in pregnancy; the substantial problems of low birth weight babies; the continuing challenge of iodine deficiency within the EU; the widespread anaemia in children and adult woman; the major issues relating to the health of Asians and other immigrant communities within the EU; the challenge of coping with escalating rates of adult chronic diseases and the huge and growing impact of the poor health of Europe’s elderly. In societal terms the health impact of societal deprivation, social exclusion and poverty is now becoming a major European issue which requires much more objective scientific analyses than are currently available.

Within the context of the *then* projected but never established European Food and Public Health Authority, James *et al.* describe the major issues plaguing human health from early on in life, of which food-consumption inadequacies are high on the list. Science can and has elucidated these risks and proposed ameliorating strategies (RDAs), yet with the actual

formation of the European Food Safety Authority these risks have been taken out of the equation. Precautionary culture requires an altogether different risk management, of which SULs are primary tools within the field discussed in this contribution. The U-shape curve is in actual fact *partitioned* to accommodate precautionary demands (see below), despite the *continuous* nature of the U-shape curve of micronutrients, as well as “other substances” when making scientifically allowances for protection from chronic disease.

The right part of the curve is deemed to require regulation only *without* any evidential suggestions that this will contribute measurably to public health. Consequently, this partitioning is the corollary *not* of epistemic deliberations, as James *et al.* demonstrate quite clearly, on the contrary. Ames, in a similar vein, adds 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. . . . Tuning up metabolism to maximize human health and life-span will require scientists, clinicians and educators to abandon outdated models and explore more meaningful ways to prevent chronic disease and achieve optimum health.⁽⁷²⁾

Precaution, conversely, as the primary *nonepistemic* risk assessment and management value, does not render any straightforward clarification either for focusing on excess-toxicity. The claim of Rolston that “it is moral to err on the safe side and that business has the responsibility to argue that the risks are minimal, not to presume so and chance the damage,”⁽⁷³⁾ is not being applied in a straightforward and encompassing manner to the benefit of the European public. Focus on the risks of excess toxicity with recourse to the general acceptability of the value of precaution at once generates the precautionary paradox: the caution (of excess exposure) that “should” give us pause causes harm (of deficiency), which we should pause before permitting to occur.⁽⁷⁴⁾ The artificial disjuncture between health and safety is introduced for reasons *other* than epistemic values or the nonepistemic value of precaution.

Indeed, opposing the common understanding and European regulatory practice of focusing on excess toxicity, micronutrients’ regulation *does* necessitate, especially from a precautionary point of view, a toxicologically symmetrical approach of micronutrients as opposed to a focus on excess toxicity. The EC’s Healthy Life Years Structural Indicator (that

is, the number of years a person may expect to live in good health) seems to underscore this point.⁽⁷⁵⁾ Without the symmetrical approach, the quest for safety by European regulators ignores the negative health impact of the diet of the lower socioeconomic groups. The dietary habits of these societal classes are known to be of a lower nutritional standard than on average would be required for a diet intended to provide a healthy life.⁽⁷⁶⁾ Food selection is constrained by economic and sociocultural considerations, whereby healthy eating patterns will be necessarily compromised, resulting in nutritional inadequacies and declining health.⁽⁷⁷⁾ This is especially relevant in view of the consumption (or rather the lack of it) of micronutrients and “other substances” with beneficial characteristics.⁽⁷⁸⁾ Despite the fact that precaution is brought to the fore as a clear-cut argument in support of the focus on excess toxicity and the establishment of SULs, a *hidden* nonepistemic value is the main driver thereof nevertheless. Here, we need to return to our schematics of so-called modern and postmodern perspectives on science and risk.

6. SUBVERTING THE AIM OF SECURING OBJECTIVE KNOWLEDGE—THE SEARCH FOR SAFETY IN STASIS

As we have seen above, the scientific effort to secure objective knowledge in precautionary culture is transformed into the goal of *acceptability* and strategies of, e.g., safety through governance as to include all involved from a democratic point of view are followed. The reason for that is simple: at this juncture science cannot secure objective knowledge as we are dealing with remote probabilities that might (or might not) materialize in a distant future.

Even if one were to agree to *acceptability* as democratically laudable and worthy of effort, given the wide divergence of audiences and participants *not sharing* a common interest,⁽⁷⁹⁾ resolving an argument’s validity on the basis of acceptability of premises and acceptable inferential links embedded in a given value-based context could unduly favor the stronger of the “disputants” and place the weaker at a decided disadvantage.

Such recourse to audiences and to their own standards of acceptance raises not only the specter of relativism . . . but the more serious problem of allowing what intuitively seems impermissible when we look beyond the restricted interests of specific audiences. . . . Are we committed to finding acceptable the statements of

the racist when his like-minded audience approves of them? When an audience does not see the sleight of hand involved, or raises no objections, should we allow the questionable reasoning of an arguer? These questions point to a serious problem . . . The point is itself implied by the reference to “questionable reasoning”, because to whom is it questionable? If we are prepared to extend to individual audiences *carte blanche* authority to set the standards of acceptability, then we fall prey to the vicissitudes of popularity . . . , primarily in the form of *ad populum* arguments.⁽⁸⁰⁾

The tendency to suspend judgment about *truth* by lending primacy to the approach of *acceptability* paradoxically reestablishes the very anti-democratic practices that this “dialogue approach,” as explained in the many governance initiatives, is thought to avoid.⁽⁸¹⁾ More importantly, raising *acceptable* benchmarks in the context of guaranteeing safety, and strongly connecting argument appraisal with audience adherence and contexts, subverts the aim to secure objective knowledge. It is always possible to assume that a particular risk exists and subsequently project more stringent policies, yet *impossible* to prove or assume that any and all possible risks are *absent*. As a case in point for the latter, Weinberg pointed out that a study designed to detect an increased mutation frequency of about 0.5% following low dose radiation (at a 95% confidence level) would involve an experiment requiring 8 billion mice.⁽⁸²⁾ Thus, the search for *acceptable* levels of exposure related to a high level of safety results in regulatory itineraries that persistently drive ever-increasing scientific input and output and additional and more stringent regulation. This development, in our view, fuels “doubt beyond reasonable proof,” licensing open-ended policy structures.⁽⁸³⁾

We have thus moved into a realm in which all the major risks have been identified (albeit not solved all) and are subsequently striving to drive out *all* risks, including accidents. Being mistaken about outcomes of human activities, interventions, and products that could be detrimental to humans and/or the environment, even accidents, should be minimized up to the point of eradication. A *British Medical Journal* editorial states that “most injuries and their precipitating events are predictable and preventable. That is why the *BMJ* has decided to ban the word accident.”⁽⁸⁴⁾ In a similar vein, it is noted elsewhere that “[t]he goal for replacing the term *accident* must be that the event be understood as the consequence of a causal chain of facts and circumstances in which the subject always can intervene to avoid its occurrence

or to mitigate its consequences. That is, as a *preventable fact*.”⁽⁸⁵⁾

The *commitment* to precaution therefore seems to surpass a mere pragmatic adherence. This simultaneously means that “belief in precaution” is truth-conducive, that is to say related to the professed factual beneficial workings thereof.⁽⁸⁶⁾ Consequently, precaution can only be justified epistemically, signifying that the endorsement of precaution must be related exclusively to factual knowledge of reality and not to, e.g., a preferred worldview.⁽⁸⁷⁾ Practical arguments—e.g., power, wealth, worldviews—cannot leave any traces in belief formation, and they must lead to belief (if at all) without the believer being aware thereof. Consequently, practical arguments cannot form an overt part of the commitment to precaution, and therefore do so in a *hidden* manner,⁽⁸⁸⁾ as is revealed by the contradictory setting of precaution in the field of micronutrients.

The hidden nonepistemic value underneath the debate on risk and precaution seems to be “*preferring inaction*” through, say, a principle of preferring inaction (PPI).⁽⁸⁹⁾ The PPI is an additional assumption in no way entailed by precaution itself and may actually result in violations thereof should inaction turn out to be more damaging than action, as the debate on micronutrients illustrates. Proponents of the value of precaution have yet to adopt clearly or defend at all the PPI.⁽⁹⁰⁾ In view of its hidden character, this is unlikely to happen. Actually, science and technology, and their innovative character, are advanced in terms of “more robust, diverse and adaptable . . . to minimize the costs of surprises and maximise the benefits of innovation” by exactly the proponents of the value of precaution.⁽⁹¹⁾

Inaction is *sustained* through governance. When involved in decision making, the public can no longer claim that “science and technology” is a realm outside its responsibility. The public seems to be offered a chance to speak out, but as a consequence will be under the cloud of the decisions made, often not by the public itself but by those who claim to serve the public’s interests. Focusing on safety as a publicly acceptable governance strategy allows authorities to abdicate responsibility and leadership. Public dialogue with recourse to the value of precaution permits the authorities openly to claim that “all” were consulted should things go wrong in the future, so public dialogue deflects blame from those whom we ought to *hold* accountable.⁽⁹²⁾ Small wonder that such a policy will tend to prohibit *any* new technology. The value of precaution is therefore predisposed

toward *safety in stasis*, as expounded by the PPI.⁽⁹³⁾

Trading the aim of securing objective knowledge for an acceptability requirement simultaneously sanctions a shift from primary to 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 fact be devised.⁽⁹⁴⁾ The “risk management of everything” reflects the efforts of organizational agents formerly engaged in the collectivization and pooling of social and economic risks of a primary nature—that is, in this case to separate from *and* reindividualize their own personal risk of a secondary nature. Secondary risk management enhances the predisposition to attain “safety in stasis.” The result is a potentially catastrophic downward spiral in which expert judgment shrinks to a meaningless form of defensible compliance.⁽⁹⁵⁾ This might also indicate the reason why in the establishment of new RDAs the incorporation of scientific knowledge on chronic disease and aging is lagging. RDAs fall outside the range of governance, with its focus on acceptability, as securing objective knowledge is compulsory to ascertain the factual relationship between chronic disease and micronutrients. It needs not emphasizing that the democratic possibilities of scientific research with the aim of securing objective knowledge are to all intents and purposes nonexistent.

7. IMMANENT AND FUTURE CHALLENGES—A CONCLUSION

In this contribution, we believe that we have successfully challenged the accepted wisdom in relation to micronutrients’ regulation and its foremost assessment tool.⁽⁹⁶⁾ Marrying SULs and RDAs in one model is a problematical exercise that can only be uncovered when considering the respective research goals. We have shown that different scientific and cultural traditions collide in this model. We have also shown that RDAs from their inception tried to address real and contemporary risks from early on in life related to the quality and quantity of food consumption, while SULs do not address current risks of food products’ consumption *at all*. Long-term risks with unknown potentials are projected to be covered by SULs, and thereby express quite eloquently Beck’s observation that contemporary

society is “afraid,” paradoxically within the context of an abundant and long life.

A more novel attempt to address micronutrients’ safety is the Population Safety Index (PSI). The PSI is calculated by dividing the SUL minus the mean highest intake to which is added the potential intake from water, with the RDA. The PSI thus provides a process “by which quantitative and qualitative data can be used to allocate the nutrients into three categories of risk. The proposed risk management model is also used as an aid to the setting of maximum levels of vitamins and minerals in fortified foods and food supplements.”⁽⁹⁷⁾ Having numerically characterized the safety of each vitamin and mineral, the risk manager must decide at what PSI risk management measures are required.

Searching for safety, as we have seen, is not a mathematical exercise as “no single all-purpose number . . . expresses ‘acceptable risk’ for a society. Values and uncertainties are an integral part of every acceptable problem. As a result, there are no value-free processes for choosing between risky alternatives. The search for an ‘objective method’ is doomed to failure and may blind the searchers to the value-laden assumptions they are making . . . Not only does each approach fail to give a definitive answer, but it is predisposed to representing particular interests and recommending particular solutions. Hence, choice of a method is a political decision with a distinct message about who should rule and what should matter.”⁽⁹⁸⁾ The PSI is a flawed proposal as it basically misunderstands the different components of the equation and the slanted precautionary drive toward safety in stasis of especially a secondary nature. The PSI could perhaps be saved if the RDAs would be given a “precautionary uncertainty factor” of some sort to balance the equation with respect to the UF of the SULs. However, this would be a grave misunderstanding of the scientific tradition of securing objective knowledge, which generated the RDAs in the first place.

Incontrovertibly, the most critical and most volatile problems cannot be solved without the effective marshalling of expert scientific knowledge and judgment. Securing objective knowledge about safety, health, and the like, despite the inherent and attendant value judgments, preeminently remains a scientific task, and a challenge for the future. This is attainable only if the scientific community is perceptive of its own values and frames, and is not aligned to a particular worldview *over* another. This is not to say that science has a monopoly of some sort or an-

other, far from it. “Science is tentative, exploratory, questioning, largely learned by doing. One of the world’s leading physicists was famous for opening his introductory classes by saying that it doesn’t matter what we cover, but what we discover, maybe something that will challenge prevailing beliefs if we are fortunate.”⁽⁹⁹⁾

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