IRISH ASSOCIATION OF HEALTH STORES

EU Discussion Paper on the setting of maximum and minimum amounts for vitamins and minerals in foodstuffs.

EU Health and Consumer Protection Directorate- General

IAHS Response

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Executive Summary

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- Usage of Food Supplements in Ireland is as high as 45% and growing
- National survey data shows significant nutrient intake deficits
- There is now overwhelming evidence supporting the benefits of food supplements in enhancing health and reducing the risk of disease.
- The outstanding safety record of food supplements surpasses that of food itself

Regulation

- Regulation must be appropriate and proportionate.
- There must be a balance between consumer safety and consumer choice
- Over-regulation is counterproductive and will undermine human health.

Risk Assessment

- Risk assessments must take into account the benefits of food supplements and reflect the fact that benefits far outweigh the risks.
- Risk assessments should be based primarily on safety considerations and not derived from RDAs/PRIs.
- Of the five examples of risk assessment models given, only one (ERNA-EHPM) is appropriate to evaluate food supplements
- Key risk assessment models have been ignored (EVM, FOA/WHO)
- The setting of maximum and minimum levels must be a transparent process and follow sound scientific principles.
- There is a variety of Risk Management options which should be explored in preference to setting unnecessarily low maximum levels.
- In addition to pan-European maximum levels, Member States should be permitted to set higher levels on a national basis accompanied by advisory statements where necessary.

Introduction

The Irish Association of Health Stores (IAHS) is a professional trade association representing approximately 80% of all health stores in the Republic of Ireland. Health stores are now established in most towns and even in some villages in Ireland, and have become recognised as valuable members of the community wherever they are present. Currently, approximately 140 Small and Medium-size Enterprises (SMEs) operate at both wholesale/manufacture and retail levels in Ireland in the natural health sector. The industry estimates the sector is worth approximately €45 million annually and employs in excess of 1,000 people directly.

Health stores seek to promote better understanding of nutrition and encourages people to inform themselves on all health issues and to take responsibility for their own health.

Good nutrition is fundamental to good health, and the relationship of diet and lifestyle factors to the maintenance of good health is now well established and recognised by all health authorities. Food supplements may be utilised as an additional health promotion measure, not only to ensure adequate nutrition levels, ***but to enhance normal physiological function by ensuring optimal nutrition levels.***

All IAHS health stores are governed by a strict Code of Ethics and operate a Retail Protocol of Selling which ensures that the public make safe and effective choices when purchasing food supplements. It is a requirement of membership that member stores have fully trained staff on duty at all times.

DG Sanco Discussion Paper

As an integral part of Directive 2002/46/EC on food supplements and also of the proposed EU regulation on the addition of vitamins and minerals to foodstuffs, the Commission is required to propose maximum and minimum levels for vitamin and minerals. The Health and Consumer Protection Division of the EU Commission has produced a Discussion Paper on the setting of these levels and invites comments from interested parties.

General Comments

Although the discussion paper covers most of the relevant issues, it appears to be based on three major flaws, which rather limits the paper's usefulness:-

Flaw No1 – The false premise that high levels of vitamins and minerals are a greater risk than low levels .

Although in paragraph 13 the paper does refer to the problem of low intakes of nutrients, it appears to concentrate on the setting of maximum levels, as though they presented a much greater problem. Paragraph 14 states that:-

"With such proliferation of these products (i.e.food supplements and fortified foods) the setting of maximum levels for vitamins and minerals is becoming increasingly a pressing need for the responsible authorities to ensure that the potential sum of intakes from all sources on the market should not threaten to undermine the high level of human health which the Treaty sets as our policy objective ."

It is undeniable therefore that the Commission takes the view that high levels of vitamins and minerals present a much greater threat to human health than levels which are too low. This notion is a fallacy, as all national nutritional surveys, without exception, repeatedly show that nutritional levels are insufficient in most western countries. They also show that in countries where high dose vitamin/mineral supplements are available, safety is not an issue. Thereafter the discussion paper takes a skewed approach to risk management and highlights overly restrictive approaches to the setting of maximum levels.

Flaw No 2. Risk Assessment does not take benefits into account.

The second major flaw in the discussion paper is that when discussing risk assessment techniques, it does not refer to the need to consider the benefits to human health of the nutrients concerned. The discussion paper does not appear to recognise that vitamins and minerals are nutrients which are essential to the body, and cannot be considered in the same light as contaminants, chemical additives and other substances which have either no benefit to human health, or are inherently toxic. A risk/benefit analysis would be more appropriate for nutrients.

Flaw No 3. Existing Major Risk Assessment Studies Ignored.

The third major flaw in the document is that it ignores much of the risk assessment work which has already been carried out by various government agencies, expert groups and individuals. Some of these are major works and took years to complete. They include the following:-

- FOA/WHO. A Model for Establishing Upper levels of Intake for Nutrients and Related Substances January 2006.
- EVM. Safe Upper Levels for Vitamins and Minerals. UK Expert Group on Vitamins and Minerals . 2003.
- Hathcock JN Vitamins and Minerals: Efficacy and Safety *Am J. Clin Nutr. Vol 66,1997.*
- FNB Dietary Reference Intakes – Tolerable Upper Intake Levels.

Usage & Market

Usage of Food Supplements in Ireland

A survey carried out by Behaviour & Attitudes in August 2001 found that over 45% of Irish people now consume food supplements. Usage of supplements increases slightly with age: 50% of the 50+ age group are users, as opposed to 40% in the 15-34 age group. Perhaps most significantly, the survey found that usage has risen from 29% in 1990 to 45% in 2001, and is remarkably evenly distributed across all socio-economic groups.

By recognising the increase in (a) awareness of the role played by nutrition in determining health status and (b) the consumer's desire to self care, the growth in demand for food supplements over recent years can be readily understood.

Nutrient Deficit

Nutrient Deficit

Conventional medics, national health experts and the EU Commission consistently overplay the supposed dangers of high dosages of vitamins and minerals in an effort to justify enforcing low nutrient levels in food supplements. We are often told that a "well-balanced diet" is all that is required for optimum health. However, not everyone knows what a well-balanced diet is, and every single national survey carried out [1, 2] shows that even those who do believe that they eat a well-balanced diet, fail to get anything like the ideal intake of vitamins, minerals, essential fats and complex carbohydrates. [3, 4] It is often not possible to maintain optimal levels through diet alone, due to factors such as a hectic lifestyle, environmental pollution, stress, poor diet, consumption of junk food, and special demands made on the body by pregnancy, physical training, smoking, disease etc.

- **It is interesting to note that a smoker needs to consume 200mg vitamin C (or four times the RDA) to have the same blood level of vitamin C as a non-smoker. [5]**

While food supplements should in no way replace a varied and diverse diet, the evidence indicates that very few people actually reach basic dietary requirements, and fewer still reach optimal levels of nutrition. Still more evidence shows that, even in modern western societies, people are still suffering nutritional deficits, despite being informed as to what a "proper diet" should contain. Nutritional deficits continue to be problematical even in populations of modern well-developed countries, particularly among the elderly. [6, 7, 8, 9]

In the US, 55% of people admitted to hospital were found to be nutritionally deficient.[10] Alarmingly, malnutrition actually increased during hospitalisation, the very place where ill people should be receiving the best of nutrition. [11]

In 1990 and again in 1998 national nutrition surveys carried out in the UK have shown that that large minorities are not reaching their dietary targets for Reference Nutrient Intake (RNI).[12] [13] In 2000, the National Diet and Nutrition Survey has revealed that 91% of girls aged 4-6 years failed to reach the RNI for zinc [14]. In the same survey it was reported that 97 % of girls aged 15 to 18 years, do not reach the RNI for magnesium, 73% do not reach the RNI for zinc which is an important nutrient for the immune system, and very significantly 53 % do not reach the RNI (200mcg) for folic acid, even though an intake of 400mcg per day is recommended to reduce the risk of spina bifida.

In Ireland the North/South Ireland Food Consumption survey identified a prevalence of inadequate intake of calcium in women and of iron in women of reproductive age. The survey showed that 48% of women aged between 18-50 had inadequate iron intake. Only 2% of women aged 18-35 reached the RDA for folate. Inadequate intakes of vitamin A were identified in 20% of men and 17% of women. Inadequate intakes of vitamins D, E and riboflavin were also identified [15].

North/South Ireland Food Consumption Survey

Long-term nutrient deficits such as those listed above can lead not only to deficiency states, but also to mild symptoms of ill-health, such as fatigue, frequent infections, dry skin, mouth ulcers etc, as well as increasing the risk of chronic disease [16]. B.N. Ames of the University of California has observed that deficiencies of micronutrients can lead to DNA damage and oxidative stress leading to an increased risk of cancer. [17] Fenech has identified a similar role for vitamin B12 and folic acid. [18]

These risks may be greater in certain vulnerable sub-groups such as the elderly, the very young, or the ill and infirm. Optimal nutritional levels are those which not only protect against deficiencies but also protect against damage sustained by environmental toxins, and reduces the risk of chronic illness.[19] The application of the concept of optimal nutrition may require higher intakes of certain nutrients compared with levels considered necessary for essential needs.

The Benefits of Food Supplements

The potential benefits of food supplements are similarly ignored by most national health authorities, despite overwhelming positive evidence in the scientific literature to indicate that the use of food supplements can be a beneficial enhancement to health. At least this has been recognised by the European Commission which stated in an Explanatory Memorandum to the Food Supplements Directive that "potential health benefits may accrue from the intake of recommended or higher than recommended levels of these nutrients". [20]

The IAHS has listed well over 1,000 studies in peer-reviewed scientific literature which support the benefits of food supplements.

A 1996 study published in the *American Journal of Clinical Nutrition* which followed 11,178 people between the ages of 67 and 107 over a 10 year period concluded that the overall risk of death through these diseases was reduced by 42% for those who took higher dose supplements of vitamins C and E. [21]

It has been shown conclusively that women who take a supplement containing 400 mcg. folic acid can markedly reduce their risk (60-80%) of having babies with neural tube defects such as spina bifida .[22] In one of the largest epidemiological studies ever carried out, the Nurses Health Study, which involved over 88,000 women over 15 years, the conclusions stated that long-term use of multivitamins (including folic acid) may substantially reduce the risk for colon cancer.[23] Significantly, the North/South Ireland Food Consumption Survey, while identifying that 1 in 3 Irish women had inadequate iron intakes, it stated that : "in women aged 18-50 years who used supplements, the proportion with inadequate intakes of iron was half that of women who did not use supplements, indicating that supplements containing iron make an important contribution to the diets of menstruating women" [24]. There is also substantial evidence to support the relationship between vitamin E supplementation and reducing the risk of heart disease.[25] In epidemiological studies involving 100,000 people, long-term use of vitamin E supplements was associated with a 40 % reduction in heart disease.[26] In a clinical intervention study of coronary patients at Cambridge University Medical School, supplementation of up to 800iu vitamin E per day reduced risk of a further heart attack by as much as 75%. [27]

The Role of Supplements in reducing healthcare costs

The appropriate and widespread use of food supplements, as part of a balanced diet in addition to a healthy lifestyle, could substantially reduce general healthcare costs. Some examples are as follows:-

1. In the US, 4,600 babies were born with neural tube defects in 1992, representing hospital costs of $141 million. If all women of childbearing age used multivitamins with folic acid, it is estimated that the current incidence of neural tube defects could be reduced by at least 50%, thus creating a saving of c. $70 million per annum.[28] [29]

2. Similarly, 280,000 low birth weight babies are born in the US each year. It is estimated that average annual savings of $2.6 billion could be effected if pregnant women took a multivitamin containing zinc.[30]

3. The everyday use of multivitamin/mineral supplements could substantially improve immune function and thus reduce infectious disease.[31]

4. Supplementation with calcium plus vitamin D could reduce the rate of hip fracture by up to 20%, representing an average annual saving in the US of $1.5 to $2 billion.[32]

5. Regular use of antioxidant supplements could delay the onset of cataracts by 10 years, thereby reducing the need for cataract operations by half, providing an estimated saving of $1.75 billion.[33]

6. Long-term vitamin E supplementation can reduce the risk of heart disease by as much as 75%,[34] and in the US it is estimated that $8.4 billion could be saved if people took at least 100iu vitamin E per day.[35] .

Excellent Safety Record of Food Supplements

Safety record of Food Supplements

Food supplements have a safety record which is second to none and far surpasses that of food itself. High dose food supplements have been on sale in Ireland for almost 40 years and no deaths or serious adverse effects have ever been recorded due to food supplement use in Ireland, and worldwide the incidence is very small compared to the widespread usage. Information on the adverse effects of vitamin/mineral supplements is difficult to come by, but in the UK the Food Standards Agency reports 11 reports over the last 11 years, most of which are minor [36]. In the US in 1998 a total of 49,709 exposures to different types of vitamins were reported to the poison control centres, accounting for a total of 14 major adverse outcomes, and no deaths [37]. In a country where not only the consumption of food supplements is high, the dosages would also tend to be much higher than in most EU states, these represent a significant set of safety data. Figure 1 shows the breakdown of these reported exposures.

Vitamin	Exposures	Major Adverse Events	Deaths
Multivitamins (no F or Fe)	2,409	1	0
Multivitamins (with Fe, no F)	5,781	2	0
Paediatric Multivitamins (no F or Fe)	7,252	0	0
Paediatric Multivitamins (with Fe,no F)	16,125	0	0
Vitamin A	2,146	0	0
Vitamin B3 niacin	2,244	2	0
Vitamin B6 pyridoxine	355	5	0
Vitamin B complexes	1,439	0	0
Vitamin C	2,650	0	0
Vitamin D	192	1	0
Vitamin E	1,726	1	0

Figure 1 Breakdown of exposures reported to US Poison Control Centers in 1998
[F =fluorine, Fe = Iron]

Figure 2 overleaf shows that the risk of death from food supplements is less than the risk presented by being struck by lightening or dying by bee stings. Sources: CDC, FDA, National Poisons Center, NIH.

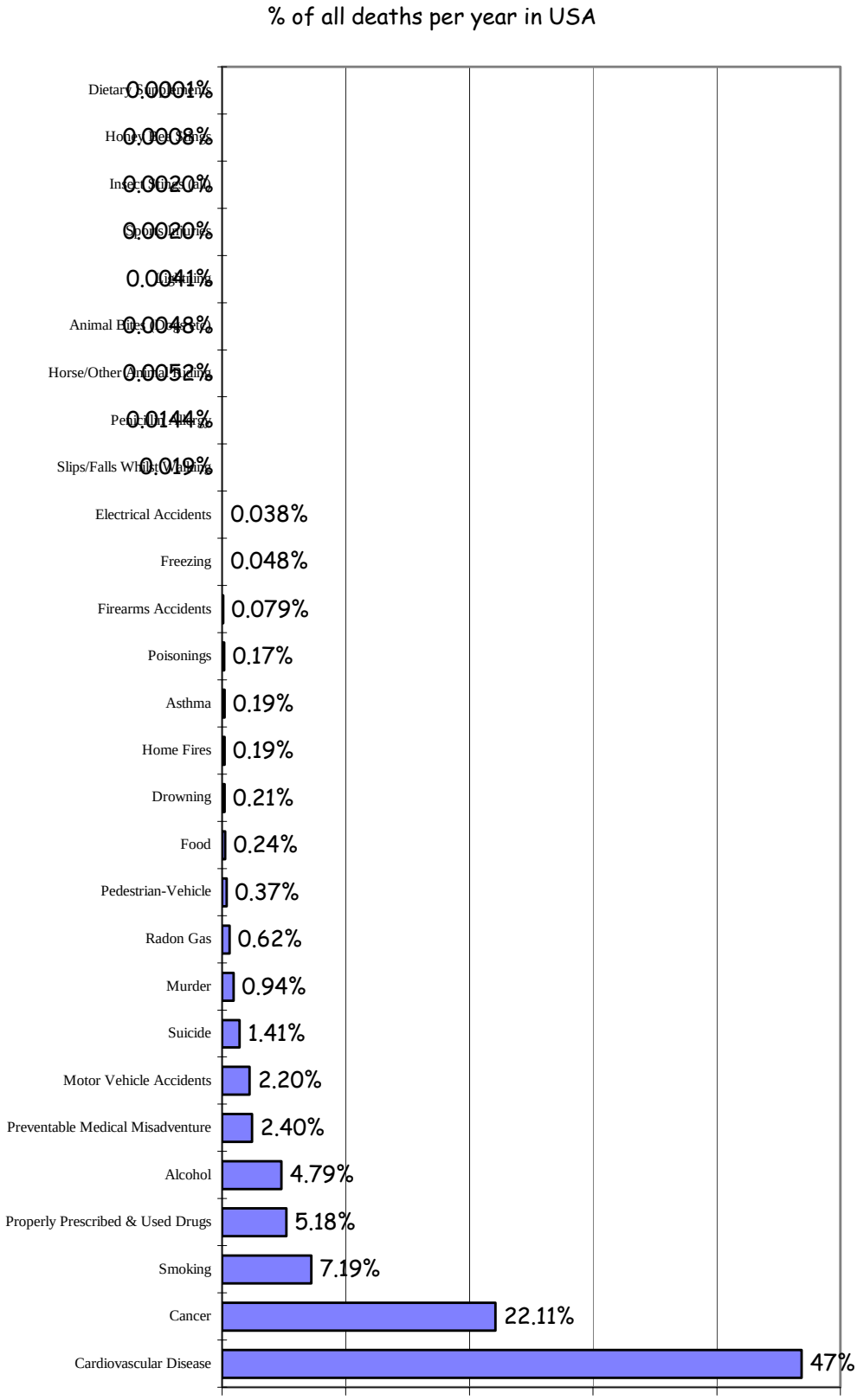

Figure 2 Statistical Risk of Death from Food Supplements (USA)

Responses to Specific Questions

Question 1

Where there is not yet a scientifically established numerical tolerable upper intake levels for several nutrients, what should be the upper safe levels for those nutrients that should be taken into account in setting their maximum levels?

Other important risk assessment work should be taken into account, such as those of the US Food & Nutrition Board, the UK EVM report. Guidance Levels issued by the latter report would be particularly useful. Opinions already released by EFSA/SCF which identifies and characterises any potential hazards of the nutrient in question should also be taken into account. The Industry already abides by a set of recommended maximum levels and these should also be taken into account.

Question 2

For some vitamins and minerals the risk of adverse effects, even at high levels of intakes, appears to be extremely low or non-existent according to available data. Is there any reason to set maximum levels for these vitamins and minerals?

No. It is not logical to set maximum safety levels where no safety issues arise. If some kind of maximum level is deemed necessary for these nutrients, the EVM Guidance Levels may be considered as a good starting point.

Question 3

Where we set maximum levels, do we inevitably also have to set maximum amounts for vitamins and minerals separately for food supplements and fortified foods in order to safeguard both at a high level of public health protection and the legitimate expectations of the various food business operators? Are there alternatives?

No, for three reasons:-

1. Maximum levels, when decided, are likely to be very conservative, will have in-built safety factors, will be determined for long term use, and will take into account daily dietary intake including that of fortified foods.
2. Nutrients taken in supplement form will differ from nutrients present in foods in terms of bio-availability, nutrient form, time of ingestion, and amount consumed.
3. The levels of nutrients added to foods are likely to only reach amounts needed to make a health claim, which are likely to be quite small. Further addition of nutrients to the foodstuff will be unnecessary, expensive and will have a negative impact on taste.

Question 4

The Commission would appreciate receiving available information on intakes of vitamins and minerals or indications of the best sources providing such data at EU level.

Question 5

If such existing data refer only to the intake in some Member states, can they be used for the setting of legitimate and effective maximum levels of vitamins and minerals at European level? On the basis of what adjustments, if any?

The posing of the above two questions would indicate that the EU Commission is not confident of their sources of information on vitamin and mineral intakes. Whereas it is widely acknowledged that dietary survey data is not very precise due to the many variables, the existing data is all there is to go on. Differences in data collection techniques and in analytical methodologies between Member States mean that the data is often not comparable. Even if dietary survey techniques were harmonised throughout the EU, there would still be marked differences in dietary habits from country to country or from region to region. Therefore the "one-fits-all" approach is not appropriate and not practical. There needs to be a degree of national flexibility to some extent in the setting of maximum levels in order to reflect any regional differences in dietary intakes which may become apparent.

Question 6

Should the intake from different population groups be taken into account in the setting of maximum levels of vitamins and minerals?

No. This would be impractical. Also, as in the EVM report the maximum levels suggested would be safe for all population groups, so there would be no need to set different levels for different population groups, except perhaps for children.

Question 7

Taking in to account all the above-mentioned considerations, how far should PRIs/ RDAs be taken into account when setting maximum levels for vitamins and minerals?

There seems to be a lot of confusion as to the precise meaning of PRIs/RDAs. Some Member States appear to consider these levels as some sort of upper safe level, which is, of course, totally incorrect. Up to quite recently it was the view of some Member Sates including Ireland, that any food supplement

containing vitamins or minerals in excess of the RDA automatically became a medicine. The arbitrary use of the RDAs, or a multiple thereof, as a level above which a supplement automatically becomes a medicine was found to be disproportionate by the European Court [38]. Yet some Member States continued to negotiate the Food Supplements Directive from standpoints which were shown to be incorrect and disproportionate.

The RDA is actually the absolute minimum amount of nutrient required to avoid a deficiency. In other words it is a **minimum amount**, and is not determined on the basis of the concept of optimal nutrition as incorrectly stated in paragraph 37, page 12 of the discussion document. As such, RDAs are irrelevant to maximum levels which are based on safety. They should only be taken into account in cases where the eccentricities of a formulaic method of determining maximum levels has produced a safety level below the RDA.

Question 8

Should the minimum amount of a vitamin or a mineral in a food to which these nutrients are added be the same as the significant amount required to be present for a claim and/or declaration of the nutrient in nutrition labelling? Should different minimum amounts be set for certain nutrients in specific foods or categories of foods? If yes, on what basis?

When a manufacturer adds a vitamin or a mineral to a food, it is usually done with a specific purpose in mind, for example to make a claim. There is little point in going to the trouble and expense of adding a nutrient if no claim can be made in respect of it. Therefore the minimum amount determined should be that at which a claim can be made.

Different minimum amounts can be can be set for specific foods of food categories provided that the minimum amount significantly enhances the amount of the nutrient ordinarily found in that food or category of food.

Question 9

Should minimum amounts for vitamins and minerals in food supplements also be linked to the significant amounts that should be present for labelling purposes or they should be sent in a different way?

Although the Food Supplements Directive states that the Nutritional labelling Directive does not apply to food supplements, the IAHS considers that for any food supplement product, it should, at the very least, contain significant amounts of the vitamins and minerals which manufacturers claim are present in that product. If a “significant amount” of a nutrient is defined as 15% of the RDA, then IAHS has no objection to that level. The problem arises, however, when no RDA has been set for a nutrient.

Comments on the Examples of Existing Models for Setting of Maximum and Minimum amounts of vitamins and Minerals

1. French Agency of Food Safety (AFSSA)

The French example as applied to food supplements is disproportionate because it uses the RDA or a multiple of the RDA as a basis for the setting of maximum levels (see ECJ cases no C-387/99 and C-150/00). It consistently refers to "nutritional need", rather than safety. It also underplays the risk of inadequacy and overplays the risk of exceeding safety limits.

2. Danish institute of Food and Veterinary Research

The Danish example is primarily concerned with the addition of vitamins and minerals to food, i.e. fortified foods. In setting maximum levels not only does the model take into account micronutrient intake from the regular diet, it also factors in intake from fortified foods as well as from food supplements. Thus the upper level (UL) established by SCF/EFSA will be diluted by consideration of the 95th percentile intake from the diet (CI95), the supplement intake (SI), the maximal allowance from fortified foods (MA), the 95th percentile energy intake (EI 95) and the fraction of foods that is available for fortification (PFF n) irrespective of whether they will in fact be fortified or not. This will lead to absurdly low maximum levels, and is therefore disproportionate.

3. German Federal Institute for Risk Assessment (BfR)

In considering the German model, the BfR attitude to food supplements should be carefully noted. On their website BfR states that "In principle, food supplements are superfluous for healthy individuals with a normal diet" [39]. It goes on to say that the body gets all it needs from a balanced diet, again ignoring overwhelming evidence that most people in the EU do not get all they need from their diet, as explained in the paragraph entitled Nutrient Deficit above. In fact BfR contradicts itself when asserting that "80 to 90% of people take far less than the recommended dose of this vitamin (folate)" [40].

As regards the risk assessment model itself, BfR introduces yet another safety factor **in addition** to those used in various derivations of upper safety levels by agencies such as the Food and Nutrition Board (FNB), the Expert Group on Vitamins and Minerals, and the Scientific Committee for Food (SCF). This extra factor is referred to as the Multi-Exposure Factor (MEF) which completely over-estimates the effect of concomitant consumption of food, fortified food and high dose food supplements. The end result of this is a totally unrealistic risk

assessment model which will reduce the maximum permitted levels to absurdly low levels.

Furthermore the model, by its own admission, is apparently not applicable to some 19 nutrients including vitamin A, beta carotene, vitamin C, iron, selenium and most of the B vitamins. Therefore it cannot be seriously considered as a practical or workable model for the derivation of maximum levels.

4. ILSI Europe

This paper appears to focus solely on setting levels for the addition of micronutrients to food and concludes that at least 15% of the EU RDA per serving can be safely added to foods for most nutrients. It would not appear to be relevant to food supplements.

5. ERNA-EHPM

This is perhaps the most realistic of the risk assessment models described by the discussion paper. In the case where there is no UL identified, or where relatively high doses pose no risk to human health, the model proposes that no maximum level be set, which is logical. Where there is a low risk of exceeding the UL, the risk model can take into account changing dietary patterns, (e,g, increased consumption of fortified foods). Where there is a potential risk of exceeding the UL the risk model takes into account the Reference Values for Nutritional Labelling, risk of deficiency and the risk of excessive intake. Precautionary risk management factors are introduced (150% for vitamins and 110% for minerals).

Thus of the five examples of risk management models, if applied to food supplements, three are unnecessarily restrictive and not solely based on safety criteria, one is irrelevant and only one is reasonable, realistic and follows basic common sense. Other risk assessment models such the EVM report [41]and the FAO/WHO model [42] are ignored.

Economic Implications

Implications of the Directive – Economic Impact

Implications for Industry

The industry estimates that the omissions of nutrients from the Positive list, will necessitate the re-formulation of approximately 85% of vitamin/mineral supplements including nearly all of the multivitamin preparations on our shelves. Moreover, the SCF opinion on just one nutrient (vitamin B6) will result in the loss of 75% of all B complex and B6 supplements from health store shelves.

Thus it can readily be seen that the Food Supplements Directive will have quite a severe impact on the range of food supplements currently being sold in health stores. As food supplements form over 50% of most of IAHS members' stock

in trade at any one time, the livelihood of many members is at stake. Although designed to remove barriers to trade, as well as to protect public health, the Directive will in fact achieve the opposite. As virtually none of the food supplements being imported from outside the EU, from countries such as the USA, Canada or Australia will comply with the Directive, these products will be barred from entering the EU. Within the EU, many of the smaller manufacturers will not have the resources to be able to comply with these requirements, and will close down, leading to loss of jobs. Remaining food supplement manufacturers will be forced to drastically reduce or re-formulate their product range, thus adding immeasurably to costs once again**.** In Ireland this will be more acutely felt because nearly all of the 120 companies involved in the industry are Small to Medium-sized Enterprises (SMEs).

Implications for the consumer

The stated purpose of the Directive is to harmonise the market, and also to protect public health. Both are laudable objectives, but the net effect of this directive will almost certainly be the removal of many food supplement products from the marketplace, not because they are unsafe, but because of overly restrictive regulations based on false premises, and utilising multiple "safety factors". This represents an unacceptable curtailment of consumer choice for no good reason. This, in turn, will lead to loss of jobs in the manufacturing, distribution and retail areas. Consumers will still want these products, so they will turn to mail order, the black market and the Internet as a source for them, where quality and safety controls are non-existent.

Unnecessarily restrictive regulation will lead to black-market conditions and Internet sales where quality and safety controls are non-existent. Therefore the directive will actually have the effect of increasing the hazard to the consumer.

Compliance costs

The compliance cost to industry is a major concern.

Re-labelling costs to industry have been calculated to be in the region of GB£300-500 (approx. €450-€750) per product by the UK Food Standards Agency (FSA). [43]

The FSA also estimate reformulation to be in the region of GB £3,000 (c. €4,500) per product.

However, the main costs to industry involve the submission of a full safety dossier to the SCF, which is estimated at between GB £80,000 (c. €120,000) and GB £250,000 (c. €375,000) **per ingredient** (not per product).

Our members rely, in the main, on products manufactured by the smaller innovative companies, as opposed to the multinational pharmaceutical companies. These smaller companies will undoubtedly suffer under the FSD due to compliance costs and other restrictions (viz. annexes).

The UK Food Standards Agency reports that "small specialist retailers (such as health stores) stand to lose significant amounts of business if a wide range of specialist products is no longer available". [44]

Conclusions

Conclusions

The IAHS considers that the data presented above show conclusively that vitamin/mineral supplements are amongst the safest products ingested. The data also demonstrates that vitamin/mineral supplements have substantial benefits to health. Moreover, the safety and benefits of vitamin/mineral supplements far outweigh any threat to human health that they may pose. The data shows that nutritional deficit is a far greater threat to human health than high supplemental levels of nutrients.

It follows therefore that rigorous risk assessment and management of vitamin/mineral supplements is, for the most part, not indicated, and if applied will contravene the sprit and purpose of the Food Supplements Directive and reduce consumer choice markedly. Certainly most of the risk assessment models reviewed by the discussion paper and the measures they entail are wholly disproportionate to the risks present by food supplements. Finally, over-regulation will encourage black market conditions where no quality or safety standards exist at all

Recommendations

Recommendations

It would appear that in the first instance the Commission requires access to higher quality intake data than currently available. Development of intake data and collection methods, terminology and interpretation of the data need to be harmonised across the EU. Risk assessment techniques need to better adapted to assessing nutritional substances taking into account benefits as well as risks, and risk management measures need to be pragmatic and reasonable in order to retain public confidence and to avoid economic damage to business.

Regulation must be appropriate to the products being regulated.

The IAHS would urge the EU Commission to consider the matter of setting of maximum levels of vitamins and minerals as applied to food supplements very carefully. The pitfalls of adopting an overly harsh risk assessment and management environment for food supplements should be clear to see. The process of setting maximum levels should be as transparent as possible using a mixture of sound scientific principles and common sense. It is important that the Commission should not bend to pressure from restrictive Member States or to vested interests, or be seen to do so.

There would seem to be a almost as many proposed models for the setting of maximum levels as there are Member States, and some Member States seem to be quite entrenched in their opinions. Also, interpretations of the data on nutrient safety appear to differ widely. Thus it may prove difficult to agree common ground between the Member States. If this proves to be the case it might be useful for the Commission to consider a more flexible procedure.

UK Food Standards Agency (FSA) Approach [45]

The UK is one of the Member States which can demonstrate a long history of the safe use of high-dose food supplements. Ireland is in a similar position, where high dose supplements have existed safely on the market for over 40 years.

In order to protect consumer choice, as well as consumer safety, the FSA approach is to support the establishment of maximum safe levels for individual vitamins and minerals across the EU for the purposes of intra-EU trade based on the recommendations from the European Food Safety Authority.(EFSA). In addition, a second tier of higher maximum levels for each vitamin and mineral could be set at a national level in individual member states where there was evidence that dietary intake levels at a national level were lower than the figure used across the EU, or a national expert opinion supported safe supplemental intakes. These additional levels would be accompanied where appropriate by additional risk management measures such as warnings labels, or advisory statements.

For example if a Member State were to permit a vitamin supplement to contain over 1,000mg vitamin C the product would be required to carry an advisory statement which would read something like :- “May cause mild stomach upset in some individuals”. For a supplement containing in excess of 25mg of vitamin B6 the advisory statement would state “Long term use may lead to mild tingling and numbness”. These risk management measures do represent a more proportionate approach, and in our view, a much more acceptable than setting a disproportionately low level.

The IAHS considers the FSA approach to be practical, pragmatic and a reasonable measure which will enable consumers in certain Member States to continue to exercise their right to choice, and at the same time ensuring consumer safety. It also has the advantage of permitting pan-EU trade in food supplement. The IAHS would strongly urge the EU Commission to give careful consideration to this approach [46].

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