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Review of COM 671 – European Commission proposal for a regulation of the European Parliament and of the Council on the addition of vitamins and minerals and of certain other substances to food

Prepared for the European Parliament Committee on Environment, Public Health and Consumer Policy

INTRODUCTION

This review has been prepared under the terms of a contract between EASAC and the Committee on Environment, Public Health and Consumer Policy, for the provision of scientific advice in the area of Environment, Public Health and Food Safety. The task assigned to EASAC is to give expert, independent comments on the scientific aspects of the Commission document; it is not our intention to deal with economic, social or internal market aspects.

EASAC identified four independent experts through the network of the member Academies of EASAC to review the Commission document COM 671, briefing them about the task and collating their individual reviews into a single document. The process of collation is intended to produce a coherent, comprehensive and authoritative review while respecting any divergence of opinion among the reviewers. The experts whose reviews are collated in this report come from Eire, Italy, the Netherlands and the UK, and their expertise covers food science, nutrition, clinical medicine, public health.

The names of the individual reviewers remain confidential and, in keeping with normal EASAC practice, the reviewers were not paid for their reviews. All reviewers were asked to disclose any interests that might be judged to affect their ability to review the Commission document impartially. None disclosed any such interests.

SUMMARY

In this Proposal, the Commission recommends a Regulation to harmonise divergent national rules on the voluntary addition of vitamins and minerals (and certain other substances) to foods.

The reviewers varied in their views on the significance of the issues covered and the extent to which the science base was well established. Two reviewers did not find the Proposal controversial and felt that the document was balanced and the conclusions reasonable. Others were more critical of the principle underlying the voluntary fortification of food and were concerned about whether the Regulation would be effective with regard to the selection of foods that should not be allowed to be fortified. While there was a

strong case to be made for the regulation of the market for fortified foods, there was also need to ensure that any new Regulation was well aligned with the currently proposed Regulation on Health Claims.

Reviewers generally wanted more scientific detail, for example relating to measurement and calculation of nutrient intakes, labelling and exemplification of the 'certain other substances', so that the measures could be better focused. They also thought it particularly important for the Commission to do more to support research to measure food intakes in the EU and to evaluate the impact of intakes on health and well-being.

BACKGROUND

The Commission document notes that manufacturers add nutrients to foods either voluntarily or because it is compulsory under national or Community rules. They often add nutrients voluntarily in order to restore what is lost during food processing, in order to produce foods nutritionally equivalent to an important food item or to enrich foods with particular nutrients or other substances having a nutritional or physiological effect. The nutrients most commonly added to foods for these purposes are vitamins and minerals.

The practice of adding vitamins and minerals has attracted increasing attention because of increasing scientific evidence about the relationship between diet and health. Manufacturers have developed more products to which vitamins and minerals are added and they tend to promote those as products that would confer a health benefit on consumers. This has led to authorities being increasingly concerned about the practice and its consequences for public health, and to attempts to regulate it at the Member State level. The resultant national rules on the voluntary addition of nutrients vary widely. The Commission wishes to act to harmonise them. The proposed Regulation does not affect existing Community rules on the addition of nutrients and is not intended at this stage to harmonise existing national rules on compulsory addition of nutrients to food (dictated by public health considerations at the national level). The task of regulating food supplements is the responsibility of the approved Regulation 2002/46/EC, and regulating health claims the responsibility of the to-be-approved Regulation 2003/xx/EC.

As the Commission observes, there are two important elements in considering the impact of the proposed rules: (i) the addition of these substances is practised on a voluntary basis, so no such addition is imposed on the food manufacturers; and (ii) products to which nutrients or other substances are added are perceived by the consumer and promoted by the manufacturer as being of 'better' nutritional quality. In consequence, the Commission claims that the proposed rules will have a substantial positive impact on both:

- manufacturers – who will benefit from the establishment of common rules and the opening of those national markets currently severely restricted by strict national rules; and
- consumers – who can make an informed choice because of the specific labelling requirements and who are reassured that the products when consumed under normal conditions and as part of a varied diet will pose no risk to health.

Thus, in summary, the proposed Regulation aims to harmonise divergent national rules concerning the addition of vitamins and minerals and of certain other substances to food in order to ensure a high level of consumer protection. The Regulation defines the purposes for which additions are allowed, lists the permitted vitamins and minerals, provides for certain restrictions regarding foods that can be supplemented, sets the criteria for establishing maximum and minimum levels, provides for rules on labelling, presentation and advertising and enables Member States to require the notification of marketing of these products in order to facilitate their monitoring.

EVIDENCE BASE

The EASAC reviewers varied in their judgement on the extent to which the science was controversial. Two of the researchers advised that the science was relatively well established and not controversial, and saw the proposal as providing a thorough and balanced account and analysis of the evidence. From this perspective, the conclusions were supported by the evidence, and the available evidence was judged sufficient to enable action. Overall, the need for regulation of the market for fortified foods was strong.

One reviewer was significantly more critical in referring to the Basic Impact Assessment paragraph 1, which states 'The majority of these substances or ingredients are used on the basis of adequate scientific data supporting a demonstrated or plausible beneficial effect and have permitted the food industry to put forward innovative products for an increasingly health conscious and demanding consumer'. This reviewer advised that the Commission's assessment diverged sharply from the opinion of other independent experts who had generally felt that the scientific support for these 'innovative' additions was weak to non-existent. The reviewer questioned that if this represented the Commission's evaluation of what constituted adequate scientific data then that did not bode well for the quality of the health claims to be accredited under the proposed (separate) Regulation on Health Claims (now also before Parliament).

One other reviewer also found undemonstrated inferences in the reasoning that assumed increasing levels of nutrients would result in better health status. Both the FAO/WHO Expert Consultation of Vitamins and Mineral Requirements (2001) and the US-RDA (2001) reviewed the recommended level of intakes without finding any scientific evidence of significant positive outcome in the health status of populations or individuals for levels exceeding those recommended (with the possible exception of calcium). Even for nutrients such as vitamin K, for which recent evidence indicated that the optimum level for an activity (on osteocalcin) was greater than that needed for the optimal vitamin status indicator (coagulation) used to define the recommended intake, the conclusion was that in the absence of further evidence (on metabolic role), it would be unwise to recommend raising the recommended intake. Moreover, even if it were to be demonstrated that consumers of fortified food were in better health than non-consumers, this was not evidence for cause-and-effect because such consumers might be more health conscious in other ways (for example, with regard to physical exercise, smoking). Multivariate analysis of the evidence base would be necessary.

This reviewer also noted that there were (at least) four levels of intervention to meet nutritional needs. First, and most important, was a balanced diet. But the relative role of the other three strategic approaches – pharmacological prescription, nutrient supplements, fortified foods – was not yet clear, nor was the extent to which they were interchangeable.

DESIRABLE NUTRITION PROFILE (Explanatory memorandum point 14)

One reviewer queried whether manufacturers should be allowed to make foods with an 'unhealthy' nutrition profile look better through addition of vitamins (for example, 'doughnuts with added vitamin C'). The reviewer advised that the issue should not be delegated to the Regulation on Health Claims because manufacturers could circumvent the claims rule (for example using communication channels not subject to regulation). From this perspective, where there was a public health need, it was the responsibility of national

governments to mandate fortification of foods; but if foods could not bear health claims then they should not be allowed to be fortified.

In this context, the present proposal contains no restrictions on which foods may be enriched, apart from alcoholic beverages even though the Basic Impact Assessment (paragraph 4) argues that 'There are some restrictions concerning certain foods to which vitamins and minerals may be added that may be perceived as having a negative impact for some operators. Such restrictions are based on health considerations like the increasing obesity and of other chronic diseases for which diet is emerging as a very important factor'. The reviewer asked why, if the Commission felt that addition of vitamins to certain foods would promote obesity, it would nevertheless want to allow such additions. These issues for relevance and coherence were also highlighted in Article 5 'Additional foods or categories of foods to which vitamins and minerals may not be added may be determined'. This was vague in potentially permitting the exclusion of 'unhealthy' foods from fortification without identifying the scientific or public health basis.

This concern was reinforced by another reviewer who predicted confusion at both consumer and producer levels by the application of two different Regulations linking food characteristics to health claims. The present Regulation in principle allows nearly any fortified food, whereas the Regulation on Health Claims allows fortification only when the criteria of 'correct' nutritional profile are met.

However, two of the reviewers noted that in the Explanatory memorandum paragraph 14, reference was made to the fact that consumers might switch to fortified foods because of their perceived benefit, whereas paragraph 11 indicated that this switching in preference was not supported by the evidence. The relative importance of the benefit from fortification versus price and other parameters was never mentioned. Fortification was not the major determinant of consumer choice – value, price, taste, habit being far more important. Furthermore, no reference was made in the document to data on the proportion of consumers who made food choices based on nutrition labels – this evidence exists and shows a very low impact. If consumers did not increase their use of fortified foods (above the 1-6% stated) then it was questionable that any fortification strategy could succeed at the population level.

One reviewer specifically addressed the proposal's comment that change in lifestyle brought new requirements for food fortification. Increased sedentary behaviour was the main determinant of the reduction in energy intake in western countries in the last decade and this conceivably may result in the population not meeting recommended nutrient intakes unless nutrient density is increased. However, there was lack of scientific evidence to advise on whether the reduction in physical activity and energy intake is also accompanied by proportional reduction in need for some nutrients (linked to energy metabolism, for example B vitamins), although not others.

INTAKE DATA (Explanatory memorandum point 19)

One reviewer observed that paragraph 19 sought to require that account be taken of all sources of vitamins and minerals – fortification, supplementation – and, thus, new national food survey data would have to be collected. But data on intake from additives would be difficult to obtain. At present, for food safety purposes, intake estimations erroneously made the conservative assumption that if an additive may be legally used in specific foods then it would always be present (see also the next section). Moreover, this conservative method also erroneously assumed that the additive (as a vitamin) would be present at the maximum legal level –

taking this approach would lead to overestimates of exposure (as revealed by probabilistic modelling of food additive intakes in the 5th Framework Programme project www.tchpc.tcd/montecarlo).

Several reviewers made points relating to the necessity to evaluate the effect of the introduction of the Regulation on the market – a stated goal of the Commission. While desirable, this would be a major task because comprehensive and independent food intake surveys (comparable to US-NANES) have not yet been established at the European level, nor seem likely to be within the 6.5 years envisaged by the Commission. Moreover, to be able to track changes in nutrient intake, the situation at the beginning of the period to be considered should be assessed with the same method and accuracy and this, presumably, is not feasible.

SETTING NUTRIENT LEVELS

One reviewer advised that invoking the nutrient profile was counterproductive in the area covered by Article 7 (4): 'When the maximum levels referred to in paragraph… are set for vitamins and minerals whose reference intakes for the population are close to the upper safe levels, the following will also be taken into account… the nutrient profile of the product'. This might be taken to mean, for example, that only expensive soft margarines may be fortified with vitamin D while cheap hard margarines may not. The issue here was not the promotion of unhealthy foods but, rather, excessive intakes of vitamins when too many foods were fortified (subject to the qualification discussed in the preceding section). The reviewer proposed that the remedy was to restrict fortification to foods with a narrow range of intake such as bread or salt. Restriction to 'healthy' foods would not work in limiting intake because consumers could still eat large amounts of a range of 'healthy' foods and, thereby, receive excess of the nutrient.

In this general context, the other reviewers introduced additional points about identifying specific populations. In the Explanatory memorandum point 6, reference is made to the fact that '…there exist one or more population groups with intakes well below the recommended levels'. By definition 2.5% of the population – the top 2.5% on the requirement distribution – are not catered for in setting reference intakes. Point 9, in stating that '….some nutrient deficiencies, although not very frequent, can be demonstrated to exist today in the community', masks a lack of consensus on the evidence base. One reviewer emphasised that, among women, one in three had inadequate iron status and one in thirty had iron deficiency anaemia as defined by the World Health Organisation. On the whole, however, reviewers advised that there were no risks of micronutrient deficiencies apart from those treated by compulsory national and Community addition rules (and these remained outside the scope of the present Regulation).

The reviewers stressed the importance, as new evidence emerged, either quantitative (for example on vitamin requirements) or qualitative (for example, on effects on different biological processes or even the discovery of new essential nutrients), of having a fast-track review procedure in place so that the Regulation could be modified accordingly.

LABELLING

Generally, reviewers commented that the specification of Article 8, labelling and advertising, needed to be made coherent with the Regulation on Health Claims proposal.

The proposal was regarded as ambiguous on whether the labelling details applied to that which had been added or that which was present. Should the label describe exogenous or total (ie exogenous plus endogenous) substances? The latter would be more useful to the consumer and to nutritionists who were monitoring the intake of essential nutrients (see previous points). Furthermore, when would the specified concentrations on the label apply – at the time of addition or at the end of the shelf-life? In this context, the definition of 'fresh' needed to be considered carefully: the reductions of vitamin concentrations during storage needed to be brought into the discussion.

ADDITION OF CERTAIN OTHER SUBSTANCES

The Explanatory Memorandum point 21, together with Articles 10 and 11 on addition of certain other substances, was regarded as very vague and incomplete. Annex III also referred to such components but gave no examples. If the Commission felt it too complicated properly to regulate these components at the present time, then it should state so and plan for a separate Regulation. There was a danger that the present proposed Regulation may suddenly ban food components that had been used in foods for many years.

CONTINUING NEED FOR EPIDEMIOLOGICAL RESEARCH

The suggestion of a community register of fortified foods (Explanatory memorandum point 22) was thought to be potentially ineffective. A vast effort would be required to provide the data and none of it would answer the key question: 'Has fortification led to an imbalanced diet?' Several reviewers agreed that the only way to answer this question was to require the European Food Standards Agency to organise a survey of food (and supplement) intake along common lines across the EU. Furthermore, reviewers emphasised that the aims relating to better nutritional quality of the food supply to the European population would be achieved only if research efforts were made to demonstrate the impact of nutrients, food and diets on health and well being.

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