

## MINERAL FORTIFICATION IN FOOD AND SUPPLEMENTS

W. Europe, USA and Japan

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### ABSTRACT

*While the need for mineral fortification is no longer contested, many related issues are still debated. These include such complex areas as bioavailability, dosage, choice of salts, interaction with other components, etc. In spite of such uncertainties, potential opportunities are apparent in the increasing demand for supplements and fortification of foods with calcium, magnesium, iron and zinc.*

### Introduction

The market for *nutraceuticals* has changed significantly in the last few years. With the consumer becoming more aware of the need for minerals and their general deficiency in minerals in many diets, a quiet revolution is taking place in the food industry in terms of new products and technologies. The increasing number of conferences and trade shows which include this area as a central theme is a clear indicator of the growing importance of the subject in the west.

Of the four more popular minerals, calcium is of particular interest because of its association with osteoporosis, and it has received substantial support from worldwide medical circles.

Magnesium requirements are generally much lower and medical insufficiency is rare. The ion is implicated in the electro-neurological system and is heavily promoted as an “anti-fatigue/recuperation” supplement in Europe, USA and Japan. Calcium/magnesium balance issues have implications for fortification using blends, as well as giving the opportunity for a ‘natural’ claim in Japan where dolomite is promoted (the original rock having the desirable CA/Mg ratio).

Iron fortification is especially associated with women's health and there is again a very large measure of support for such incorporation. The problems lie in achieving a satisfactory load without unacceptable taint and with adequate bioavailability. There have been recent technological advances – claims are linked to bioavailability, chelating, phytate restriction of absorption, etc.

Zinc deficiencies are typically related to inadequate diets and traumas associated with, e.g. severe burns.

The present article is based on GIRACT's seminal market report covering mineral fortification of food and as supplements in the three regions of USA, W. Europe and Japan.

### **Definitions**

The term **enrichment** means restoring the level of vitamins and minerals in a food to those approximating the levels found in the unprocessed material.

**Fortification** on the other hand means increasing the amount of micronutrients to a level greater than that found in the unprocessed food.

The two terms are often used interchangeably even within the food industry.

There are some other factors such as Reference Daily Intake (RDI), and bioavailability, around which the industry is still searching for legal and technical consensus.

### **Legislation**

In the **USA**, the FDA is the key Body. It sets much stricter regulations for foods than for supplements.

The FDA's policy neither encourages the indiscriminate addition of nutrients to foods nor considers it appropriate to fortify fresh products, meat, poultry or fish products, sugars or snack foods such as candies or carbonated beverages. However, food manufacturers have the option to add nutrients to enhance the marketability of a product as long as the content is accurately identified and the level is considered safe.

The NLEA Act (1990) requires labels to carry nutrient content descriptors and permits modified labels of standardised foods as well as certain health claims.

The only direct acceptable claims concerning minerals is that “calcium reduces the risk of osteoporosis”.

Companies must petition the FDA to obtain approval before making a health claim that is not listed.

Some softening of the FDA position is occurring since the FDAMA (1997) - the Modernization Act. This permits companies to try to launch products with the FDA having only 120 days to comment before the launch date.

In the case of supplements, the DSHEA (1994) has given companies much more freedom to make less clearly supported health (but not cure/prevention) claims; they must only inform the FDA within 30 days of launch.

In the EU, work is progressing on legislation to reconcile nutritional claims, novel foods, but meanwhile the relevant current legislation is:

for foods:

- Miscellaneous Additives (95/2/EC) in general
- Nutritional Products, 90/496/EEC and 96/8/EC (setting minimum quantities for the minerals to be found in the respective food)
- Infant Formulae and Infant Food 96/5/EC, limiting the anions which may be used

for supplements:

No clear legislation and uncertainty concerning claims

for medicines:

Full registration requirements via the EMEA, tend to freeze formulations.

**Japan** has been the most successful in introducing a cogent and widely-accepted regulation system in this sector though by Western standards, some anomalies are observed.

It does specifically regulate a list of chemical additives whilst largely approving 'natural' ingredients. This approach has given opportunities for such products as oyster shell, dolomite, haem iron, ... to be particularly valued.

The FOSHU (Foods for Specified Health Use) classification has improved consumer confidence in these products in general and thus has given a significant boost to the demand for mineral salts. The number of FOSHU approved products increased significantly from only 55 in 1996 to an impressive 182 by March 2000.

The number of mineral-based products with FOSHU approval account for about 6% of the total approved products.

### **Supply**

GIRACT has considered the various mineral salts in three groups:

- inorganic salts
- organic salts
- exotic salts.

The choice of salt is driven by a number of factors including:

- cost effectiveness of cation delivery
- solubility
- taste/smell
- colour
- 'protection' such as chelation
- claims regarding bioavailability.

Identification of suppliers specifically for food fortification purposes is not always evident. The most valuable guide to players comes from GIRACT's interview sources. However, much distribution is carried out by fine chemical companies offering a wide range of suitable salts.

No clear identification of volumes produced nor of imports/exports of each salt for food fortification/enrichment alone exists. Availability data is thus deduced to be equivalent to total demand for each salt.

A new generation of products such as CCP (calcium phosphopeptide), CCM (calcium citrate malate) and soluble fibres such as inulin are already seen in the market as calcium absorption promoters. This is likely to increase the current debate on absorption and bioavailability of various mineral salts in the human system.

### **Prices**

The price per cation is naturally dependent on the cation load, and varies significantly across salts and regions. Thus, the exotic mineral salts, particularly in Japan, are very expensive in delivering a particular level of cation enrichment.

Choice of a specific mineral salt would be according to application. For example, for calcium, the first choice is a low cost mineral (carbonates, sulphates, chlorides, quoted at less than US\$ 0.1-0.8/kg). If these low cost minerals cannot fulfil technical requirements, phosphates would be the next choice (at US\$ 1.2/kg). Finally, the more expensive organic salts would be used for special requirements (e.g. a lactate is priced at US\$ 3.5/kg).

The "exotic" products - frequently with claims of high bioavailability or "ultra-natural" provenance - are high-priced and used where a particular claim is made - mostly in supplements in the US and W. Europe, while their use in foods is increasing in Japan.

Both organic and exotic salts command a premium based on their label-friendly marketing appeal.

### **Demand**

GIRACT has estimated the market for the four mineral salts in the food fortification/supplement sector in the three regions to be over \$400 mio. In minerals such as magnesium, the supplement sector is the major contributor, while the compulsory addition in flour in certain countries makes this sector very important for iron.

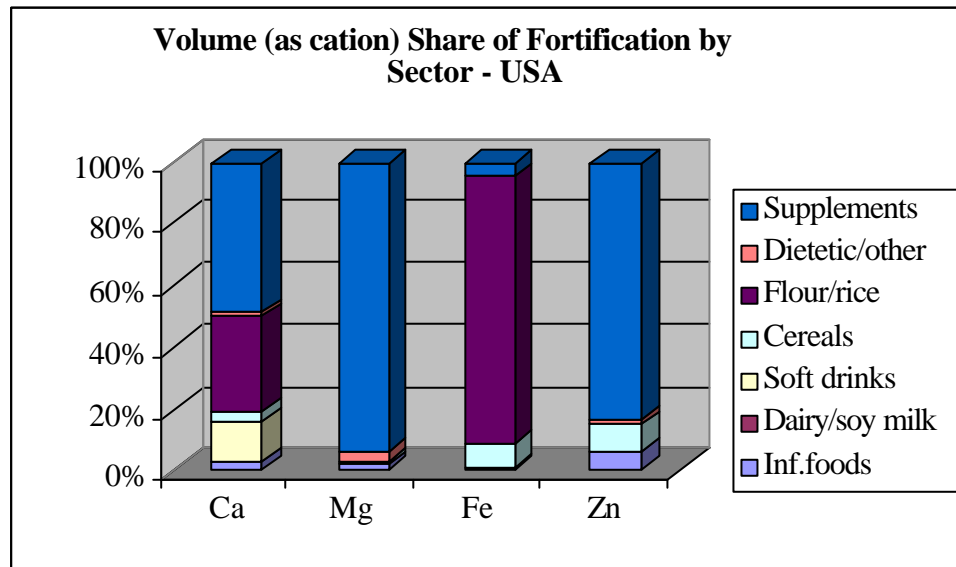
In view of a complete lack of secondary data in this area, a special methodology was devised to estimate demand in each of the sectors

First, the mineral load per defined weight of the end-product was estimated through a combination of interviews and shop-checks, which provides the target and the possible addition of the various salts. The next step was to determine the total load of each cation across anions. This was followed by an estimation of the penetration of individual cation/anion combinations. Finally, based on the above, a demand estimate was calculated for that particular sector. This result was analysed and further discussed with the industry leaders in order to sharpen the focus of these estimates.

The total demand for calcium is much higher than any other. This is reinforced by the relatively good understanding of the need for calcium fortification in the three regions.

The important food end-use sectors include infant foods, soft drinks, dairy, cereals, flour/rice, etc.

For example, the share of fortification, measured as the cation only, by sector in the USA is given in the graph below.



Source: GIRACT

Products such as scallop shell powder and milk calcium are much more easily accepted in the Japanese market than the other two regions studied.

Growth rates are impressive for many sectors, and with the increasing marketing and R&D spend in this area, GIRACT's forecasts for 2005 have taken into account the following factors:

- growth rates of the end-use sectors, in turn dependent on such factors as population growth, awareness of mineral needs, changes in legislation, etc.
- possible changes in the dosage of the minerals in the end-products
- possible increase in the penetration of mineral salts in any given sector.

### **Conclusions and Forecasts**

The total food fortification/supplement market for the relevant mineral salts in the three regions is expected to grow at an annual rate of around 4% to about \$ 450 mio in 2005 (at 1999 price). The major obstacle to growth will continue to be the severe restrictions in the health claims that can be made, particularly in W. Europe and the USA. While the Japanese authorities are less strict about the claims, GIRACT believes that the overall legislative situation is more cogent and clear in this market, thereby helping the market to grow faster.

There are significant opportunities for the suppliers of mineral salts in all three regions, but a serious scientific effort needs to be made in solving such key issues as bioavailability and RDI, and obtaining a scientific consensus across markets.

Perhaps there is a lesson to be learnt from such companies as DANONE, NESTLÉ, VALIO and YAKULT, which have relentlessly persisted in obtaining scientific credibility for probiotics, and are thus currently reaping significant commercial benefits.

In fact, awareness of the benefits of minerals is already reasonably high amongst consumers, but any attempt at cutting corners and rushing to the market place with ‘half’ claims and counter claims can only be at the peril of a growing, long-term market. These and many other related issues were discussed recently in Giract's 2<sup>nd</sup> Mineral Fortification Conference in February 2001.

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