THE MARKET FOR PRE- AND PROBIOTIC INGREDIENTS

(Excerpts from the full paper delivered at the IFT Short Course in June 2002)

Introduction

This paper is based on several market studies carried out by GIRACT in the period 2000-2002.

The three regions considered in this paper are Japan, the USA and West Europe.

The major product groups considered are # *(text suppressed)*. Other foods are of marginal relevance except # *(text suppressed)*.

Definitions

It is important to distinguish between probiotic, prebiotic and synbiotic ingredients:

Probiotic: Live microbial strain(s) fed by mouth which beneficially affect(s) the host animal by improving its intestinal microbial balance

Prebiotic: A non digestible food ingredient that beneficially affects the host by selectively stimulating the growth and/or activity of one or a limited number of bacteria in the colon

Synbiotic: A mixture of pro- and pre- biotics which beneficially affects the host by improving the survival and implantation of selected live microbial strains in the gastrointestinal tract

Legislation

Considering legislation, the primary issues are as follows.

- Whether the product to be marketed is considered to be a drug or a food
- What is the clinical evidence that can be presented to support appropriate claims
- Which is or are the competent authority(ies) in a country or region who will accept or reject a claim proposed by a manufacturer

Certainly there is currently a lack of coherence across countries and regions of the world concerning all of these points.

International

At international level, the Codex Alimentarius is the on-going attempt to harmonise legislation in the food sector across countries into a coherent structure thus reducing the friction in inter-country trade.

Within the Codex Alimentarius, some microorganisms are identified in the fermented milk sector, but there is no reference to the concept of prebiotics.

The Draft Standard for Fermented Milks by IDF for the Codex Committee on Milk and Milk Products (A-11, 3/2000) defines the specific micro-organisms that must be used in certain fermented milk products. The draft also requires these specific micro-organisms to be present in the final product at concentrations of at least 10^7 cfu/g ; while any additional micro-organism(s) declared on the label must be in concentrations of at least 10^6. The following table lists the specific micro-organisms required to be present according to the draft's standards.

Fermented Milk Product	**Specific Micro-organisms**
Acidophilus Milk	*Lactobacillus acidophilus*
Kefir	Starter cultures prepared from kefir grains, *Lactobacillus kefiri,* species of the genera *Leuconostoc , Lactococcus* and Acetobacter. Kefir grains constitute both lactose fermenting yeasts (*Kluyveromyces marxianus*) and non-lactose-fermenting yeasts (*Saccharomyces omnisporus, Saccharomyces cerevisae* and *Saccharomyces exiguus*)
Kumys	*Lactobacillus delbruekii* subsp. *Bulgaricus* and *Kluyyveromyces marxianus*
Yoghurt	Symbiotic cultures of *Streptococcus thermophilus* and *Lactobacillus delbruekii* subsp. *bulgaricus*

Though organisms are listed in this case which have recognisable probiotic character to the initiate, there is no discussion of the enhanced character of a probiotic strain, as opposed to any other lactobacillus, for example.

Japan

A very different situation is found in Japan, where both pre and probiotic functionalities are well recognised. The regulatory authority is the Ministry of Health and Welfare. Work has been done in this area since initial evidence was presented by YAKULT in the 1930's.

 # (text suppressed)

USA

Of the three regions considered in this chapter, the complete antithesis of the Japanese situation is seen in the USA. The structure of US legislation is largely set by the food and drug administration, the FDA.

Three main Acts are likely to apply in this area. *# (text suppressed)*.

As far as probiotic products are concerned, yoghurts in the US, yoghurts must contain L. bulgaricus and S. thermophilus. Declaration of "starter cultures" is, however, sufficient to cover these.

The National Yoghurt Association has established and is trying to encourage manufacturers to carry out voluntary labelling with a 'Live active culture' on the yoghurt products. There is only a minimal live bacteria count required in States other than California and Oregon.

As far as the prebiotic sector is concerned, in only dietary fibre is an allowable claim in the food sector. For an ingredient to be termed an oligosaccharide, it must have less than ten repeating units.

Any supplement that had been on the market before 1994 requires no GRAS clearance by the FDA. Although GRAS affirmation is still possible for supplements, the FDA does have the opportunity post-marketing of challenging a food manufacturer's view of what he might claim.

W. Europe

In between these two extremes lies W. Europe, and here we shall consider just the European Union.

The primary regulatory authority is the European Commission.

However this interacts with and sometimes contradicts individual member state legislation, whether it be prior to the introduction of EU-wide legislation or outside its reach altogether.

 # (text suppressed)

Interestingly, France has very recently permitted one particular prebiotic ingredient with a "bifidogenic" claim, and GIRACT believes that this slow acceptance of individual claims for both pre and probiotics will grow with time providing a sufficiently well developed dossier of support information for particular claims is presented to the appropriate EU scientific authorities.

End Use Markets

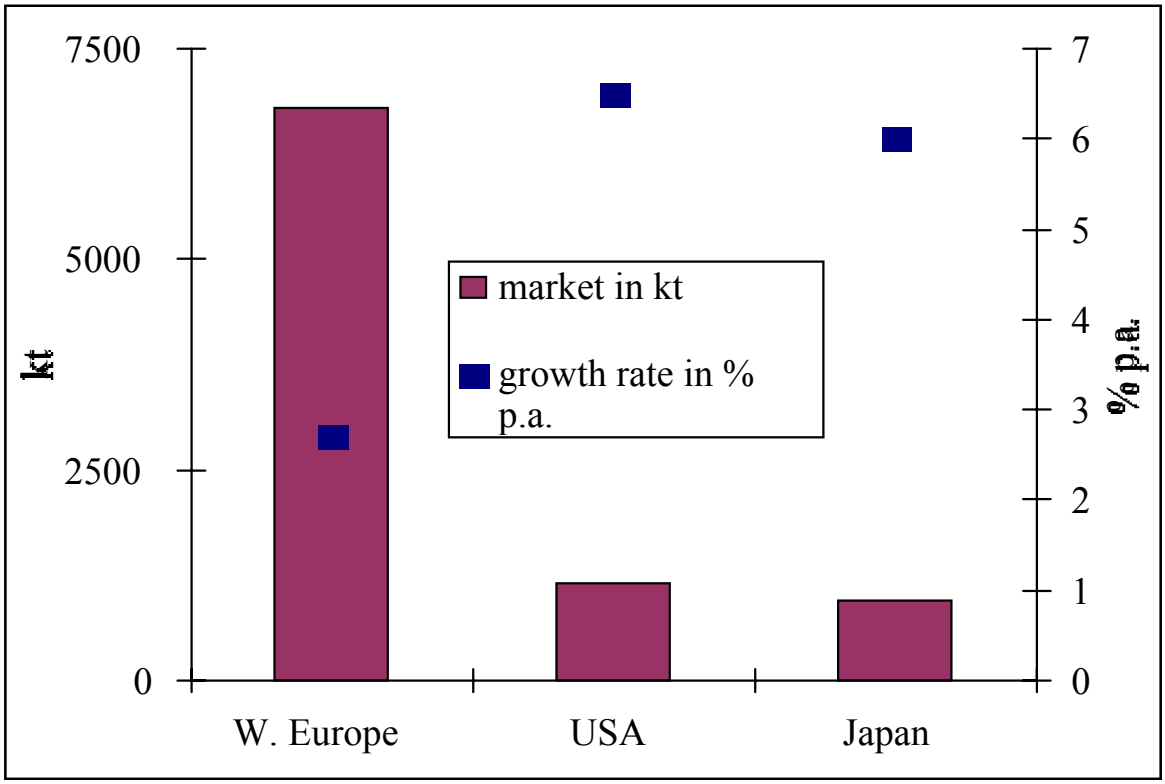
In all regions *# (text suppressed)* is the most significant of the foods, followed by *# (text suppressed)*.

There are other foods with pre and probiotic ingredients to be found, *# (text suppressed)*.

Finally there are significant *# (text suppressed)*.

Yoghurt and Soured Milk Market

The figure below shows the relative sizes of the total market and growth rates for the three regions.



The Western European market is thus # *(text suppressed)*.

The leading players differ by # *(text suppressed)*.

Supplements

The other major area is supplements, and the next figure gives an indication of the relative sizes of the food supplements markets.

 # (graph suppressed)

Here the US and Japan markets *# (text suppressed)*.

Prebiotics

The main prebiotics species are oligosaccharides, though not all indigestible oligosaccharides are necessarily prebiotics.

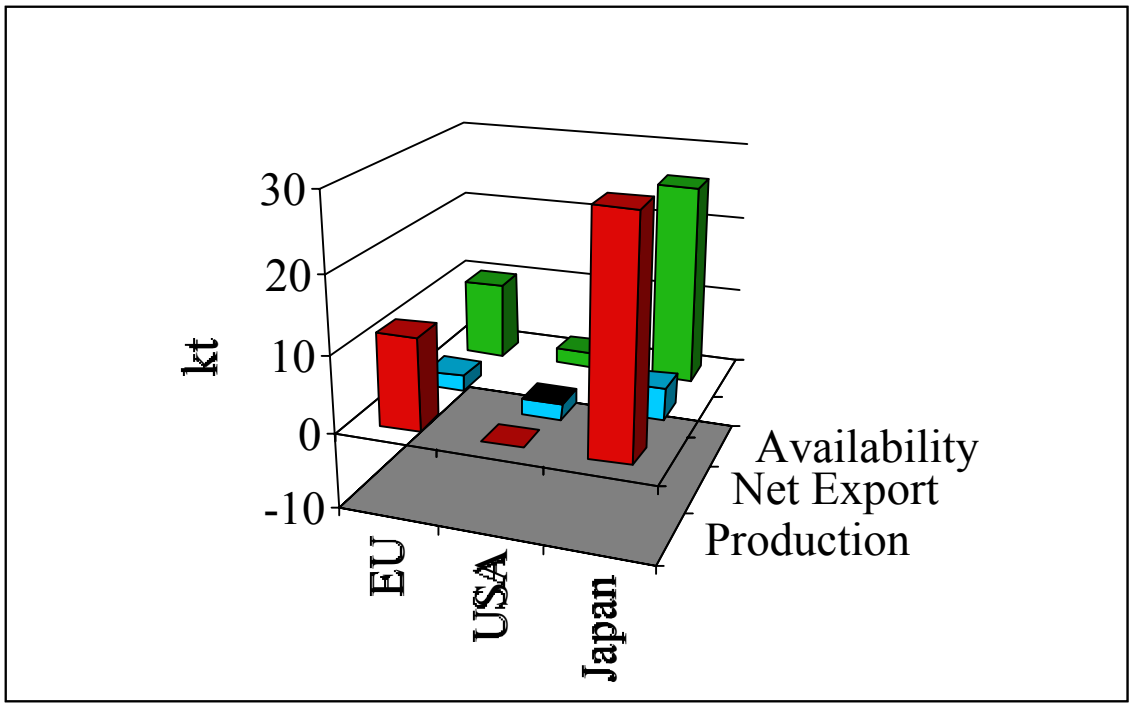
In general the term 'oligo' applies to molecules with two-four sugar units, but Fructo-oligosaccharides are an exception since, especially in Europe, there is a large subsector of inulin breakdown products which may contain twenty or more replicated units.

The other source of Fructo-oligosaccharides is a synthetic route from sucrose yielding a short chain product with a narrow range of repeating units.

Inulin and the two Fructo-oligosaccharide subsets represent the vast majority of prebiotic compounds found in the US and Western Europe.

The other major product in these regions are Galacto-oligosaccharides, whilst a significant number of other products are found largely in Japan, including Isomalto-, Xylo-, Lacto-, Agaro-, Soy-, oligo compounds and Lactulose and Raffinose are also considered prebiotics.

The next figure shows the size and shape of supply and demand of all prebiotic species across the three regions.



It is immediately evident that Japan dominates the market in both production and consumption. The EU is in comfortable second place, whilst the US is a very small player.

Looking in more detail at the types of product most used, Japan has a history of a thousand years of using red seaweed, which is a source of oligosaccharides. The next figure shows that Isomalto-oligosaccharide is dominant, followed by Galacto- and Fructo- products.

 # (graph suppressed)

The EU has a different pattern, shown in the next Figure.

 # (graph suppressed)

The very high figures for Inulin/FOS relate to the anomaly driven by the Common Agricultural Policy in which chicory production and fructose extraction was encouraged by the ban on the manufacture of classic high fructose syrups from starch origin. ORAFTI, COSUCRA and SENSUS are the three producers in this category.

The major supplier of the synthetic Fructo-oligosaccharide is BEGHIN MEIJI, whilst the Galacto product is largely in the hands of BORCULO DOMO.

 # (text suppressed). The reason for this is shown in the next figure:

(graph suppressed)

The large volume of isomalto-oligosaccharide in Japan is at least in part explained by # *(text suppressed)*.

Demand for Prebiotics

It is necessary to consider the quite different demands for each of the three regions.

In the US, demand # *(text suppressed)*.

In Europe the situation is quite different. The next figure illustrates the demand both for FOS 2 /Inulin and FOS 1, where # *(text suppressed)*.

(graph suppressed)

It should be noted that the claim is often limited to that of dietary fibre, and the sectors in which products were actually found across Western Europe are shown in the table below.

(table suppressed)

In Japan the situation is, as already noted, different, and again the table gives an indication of the sectors in which these prebiotic products are often found.

Probiotics

Probiotic species are generally of the Lactobacteriaceae family, though consequently Gram positive, non-spore forming, and have largely been isolated from species present in the human intestine. A number of the species apparently have most impressive health claims, though in making a selection the ability of the specie to survive, to reach and multiply in the gut, is the key.

The criteria used for the selection of a strain are the following:

- Non-pathogenic activity
- Desired technological and organoleptic properties
- Resistance to gastric acid and bile salts

- Biological efficiency on humans including studies on adhesion to human intestinal epithelial cells
- Interaction with enteropathogenic bacteria
- Stimulation of the immune system

A quite impressive range of health benefits have been claimed for probiotic microorganisms, and they are as follows:

- Recolonisation of gut post antibiotic treatment
- Anti diarrhoea
- Irritable bowel syndrome alleviation
- Infection resistance
- Anti-tumour
- Improved immune status
- Cholesterol reduction
- Improvement of vaginal flora
- Eczema reduction
- General digestive tract prophylaxis

A selection of the species found in the food and supplement sector in GIRACT's study are shown below covering lactobacillus.

 # (table suppressed)

The bifidobacteria species considered were:

 # (table suppressed)

Other genera are also occasionally found, including Enterococci, Lactococci, Streptococci, and Causido cultures.

The supply of probiotic cultures is of one of four types - captive production by the end user, by such companies as NESTLE and YAKULT; production for captive use under licence from a licence holder, such companies as VALIO and MORINAGA; supply by traditional culture manufacturers, which will include RHODIA, CHR. HANSEN, SKW, and LALLEMAND; and finally, the supply of frozen or freeze dried products from new supplement producers.

In order to make coherent estimates of the volumes of cultures consumed in the regions and sectors, a model was derived considering the quantity of probiotic in the end product, the growth, if any, from the moment of inoculation to that of evaluation in the finally packaged product; the degree of attenuation between point of packaging and the end of shelf-life; and the density of each organism leading to an assessment of the freeze-dried equivalent in tons of each product.

When the supplement sector was considered, the model was slightly simpler, since the product is present as a stable freeze-dried powder, and the assessment was largely one of the weight of culture present in the average dose for each region.

The final figure shows the demand shares of probiotic strains in yoghurt, dairy based drinks, other food and supplements across the three regions studied.

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 # (text suppressed)

GIRACT is expecting tighter control on health claims in this sector in the coming decade, and so volumes will increase for those products with the best support for their product claims.

Conclusions

Looking forward, it is probable that acidophilus and bifidus species will remain dominant, especially in food. Heavy marketing, supported by quality scientific evidence will be required to establish any other specie whilst in the supplement sector entry will be easy, but products may well be more ephemeral. New markets can also give new opportunities, such as those in S. Korea, Australia, China, the latter of which must have enormous potential.

It is a promising, evolving and complex market, characterised by different sectors of penetration and potential in each of the three regions.

In Europe the market is # *(text suppressed)*.

In the US # *(text suppressed)*.

In Japan the market is first # *(text suppressed)*.

In the prebiotic sector, oligosaccharides have other functions than just those of prebiotic nature; this includes opportunities in animal feed, as bulking agent in carriers, and as dietary fibre per se.

The attraction of the prebiotic is # *(text suppressed)*.

Price will continue to be a primary selection factor for prebiotic ingredients, and growth will parallel developments in probiotic claims.

The above presentation was drawn from several of our multi-client studies including the two studies on Prebiotic and Probiotic ingredients For further information please contact GIRACT at info@giract.com