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CONSUMER AND INDUSTRY PLAFORM

Proeuhealth –workshop, 16 March, 2-5 pm, Sitges

The report will first describe the aim and structure of the combined platform session, then give the main points brought forward by contributors, and thirdly go through issues and viewpoints raised by consumer representatives for the general discussion.

Description of the workshop

The aim of the combined industry and consumer platform session was to discuss what should be taken into consideration when new (food) products or applications for promoting gut health are developed, both from the industry and consumer point of view. Special attention was given to consumer expectations and concerns related to these new applications. The platform provided a forum for manufacturers and consumers to bring forward their viewpoint on issues related to functional foods in general, and especially to probiotic products.

The discussion started with nine short viewpoints from the industry and consumer representatives. The presenters and their titles are presented in table below.

Table. Prepared viewpoints in the order of presentations

Presenter	Organisation	Title
B. Kettlitz	BEUC, Belgium	Awareness and expectations of consumers in relation to so-called functional foods and gut health
J van Loo	Orafti, Belgium	Prebiotics
C. Shortt, B. Degeest	Yakult, UK	Towards generic claims for probiotic lactic acid bacteria
J-M. Antoine	Danone, France	Probiotics - a challenging opportunity for science, industry and consumer
G. Trigueros	OCU, Spain	Consumer concerns related to probiotic and prebiotic products
A. Ledeboer	Unilever, the Netherlands	Probiotic research: What is needed? A view from industry
C. Cavadini	Nestlé, Switzerland	Challenges to the extension of the probiotic concept to different food product categories . An industry point of view
R. Mitchell	EFCCA, Europe	European Federation of Crohn's and Colitis Associations (EFCCA … and Probiotics
E.Laulund	Chr. Hansen, Denmark	Safety in post genomics era
Chaired by C. Daly and L. Lähteenmäki		

The participants in the panel discussion were (from left to right in the picture):
1. Rod Mitchell, EFCCA, United Kingdom
2. Esben Laulund, Chr. Hansen, Denmark
3. Aat Ledeboer, Unilever, Netherlands
4. Colette Shortt, Yakult, United Kingdom
5. Jean Michel Antoine, Danone, France
6. Christoph Cavadini, Nestlé, Switzerland
7. Gemma Trigueros, Technical Department OCU, Spain
8. Beate Kettlitz, BEUC, Belgium
9. Jan van Loo, Orafti, Belgium (not in the picture)
10. Bart Degeest, Yakult, United Kingdom (not in the picture)

Summaries of prepared viewpoints

As the first viewpoint, **Beate Kettlitz (BEUC, Belgium)** brought forward expectations and concerns consumers have related to so-called functional foods. The functional foods are on the on the border of food and medicines, and traded on a global basis which raises the question how consumers can judge the truthfulness of the information and how the link between individual food products and overall diet can be interpreted. According to Ms. Kettlitz the results from BEUC member organizations suggests that improvements are needed in labelling and quality assurance to ensure that the products contain what they claim to do and that the information given on the label is sufficient to make informed choices. Ms. Kettlitz also raised many questions about the efficiency of the products, defining the adequate dose, possible effects of too large doses and how the food matrix impacts the effects. Furthermore one question that is crucial from nutrition point of view is that what is the impact of functional foods in overall diet; perhaps functional products replace other beneficial products or adding them into diet is regarded as sufficient for heath in otherwise not so wholesome diet.

Jan van Loo (Orafti, Belgium) told about the potential beneficial effects of prebiotics which are compounds that support the growth of beneficial bacteria. This means that prebiotics have to meet three criteria: they are 1) non-digestible, 2)fermented by the bacteria in the colon and 3) fermented selectively. While fermented they are converted into compounds that are biologically active (e.g. acetate, propionate, butyrate and lactic acid). In their fermentation they stimulate some, mainly probiotic groups of bacteria in the colon, and at the same time they suppress other groups of bacteria. Based on several human trials, the possible health benefits of prebiotics include improved bowel habit (prebiotics reduce constipation and reduce diarrhoea), modulated lipid metabolism, increased absorption of minerals, modulation of immune system and anticarcinogenic properties. According to Dr. van Loo the big challenge for nutritional research in the future in the field of prebiotics will be to elucidate mechanisms, and to directly demonstrate the health effects.

Colette Shortt (Yakult, United Kingdom) raised the issue of whether generic claims should be allowed for probiotic lactic acid bacteria. Generic claims can assist the consumer in making wise food choices and could impact consumers` willingness to try new products. In addition, generic claims in the area of nutrition increase consumers awareness of the link between diet and health. However, at the moment most of the probiotic scientific data available relate to the efficacy of specific strains. New scientific results will increase our knowledge of the fundamental basis for probiotic effects and may provide the basis for generic claims or may show that these are not tenable. There are many challenges - the activity of probiotics is dependent on the host, the definition of a healthy microbiota is difficult and within a population there is great inter- and intra-individual variability. Furthermore, more specific biomarkers are needed. Despite the long history of consumption of probiotic LAB and bifidobacteria further effort is needed to establish that probiotic lactobacilli and/or bifidobacteria are gut friendly bacteria and beneficial in the diet.

The title of presentation given by **Jean-Michel Antoine (Danone, France)** was "Probiotics - a challenging opportunity for science, industry and consumers". Antoine acknowledged the long tradition of use of probiotics and their beneficial effect to human health. Probiotics should be living and active in the gut, e.g. producing metabolites which actively interact (communicate) with the mucus. In his talk Dr. Antoine emphasised the challenge of looking for mechanisms of the activity of probiotics and their ability to talk to the cells in the gut wall and/or to the existing gut microbiota (cross-talk). To justify any claims human feeding studies are needed as products will be ingested by humans and global integrated effects should be reported. Dr. Antoine also presented a new concept "corpsotic" when discussing about the stability of the probiotic products and incidence of dead cells e.g. in heat treated products. Probiotic products should contain active, living bacteria and to avoid confusion the products that contain only dead bacterial cells should be named differently.

Gemma Trigueros (Technical Department OCU, Spain) presented the viewpoint of consumer concerns. The aggressive advertising gives consumers ideas about the products and their health claims. However, many times the clinical trials are made with higher amounts of active bacteria than is alive in the end-product. In future the critical consumer wants products which are safe, risk-free and have true health claims based on clinical trials with real amount of active bacteria in the product. Ms. Trigueros also presented questions related to the specificity of strains and industrial viewpoint on legislation on health claims.

Aat Ledeboer (Unilever Research, The Netherlands) stated that at the moment industry wants the same as consumer. Since there still are no hard proofs on functionality and mechanisms of probiotic products, there is a need for new and often fundamental knowledge on mechanisms of action, and survival of probiotic strains under harsh conditions such as dry and semi-dry products during storage or in the gut after ingestion. According to Dr. Ledeboer, for studying probiotics a holistic approach is needed with co-operation of scientists from different disciplines. Dr. Ledeboer stated that probiotics have multiple food options and product extensions (also outside Western society) which can be achieved e.g. by exploring different functionalities, mixed strains, dose response and optimal physiological state.

Christoph Cavadini (Nestlé, Switzerland) discussed in his presentation (1) stability of the probiotics preparations and (2) questions related to the transfer of the probiotic concept to other product categories. Although the shelf life stability in many products has been solved, future work is required especially for producing shelf-stable products with intermediate moisture levels: These products may be exposed to high temperatures during distribution and storage. In addition, investigating the production of probiotic biomass, its down stream processing as well

as effects of the food matrix on probiotic functionality are required to better standardise and guarantee quality and functionality of probiotic cultures. Optimal fermentation and down stream processing, development of specific delivery systems as well as confirmation of probiotic functionality at lower concentrations and within the target population are according to Dr. Cavadini questions that need to be studied.

Rod Mitchell (EFCCA, United Kingdom) as the current Chairman of European Federation of Crohn's and Colitis Associations (EFCCA) provided an IBD (inflammable bowel disease) patient perspective to the meeting. In year 2004 EFCCA estimates that there are more than 1 million patients throughout Europe diagnosed with either Crohn`s disease or colitis and the numbers are still rising especially among young people. European Federation of Crohn's and Colitis Associations is currently concerned with problems associated with compliance to therapies, the safety and efficacy of the treatments and more comprehensible patient information. According to Mr. Mitchell, IBD patients are aware that certain probiotics or food supplements containing friendly bacteria may be able to positively change the balance of the wide-range of bacteria found in the intestine, without being harmful to patient, or producing negative side effects found in many drug treatments. Open questions still are e.g. how the use of probiotics may affect the use of other single or combination drug therapies in the treatment of Crohn´s and colitis. Patients also need to be assured about the benefits, safety and right doses of probiotic treatments.

In his viewpoint**, Esben Laulund (Chr. Hansen, Denmark)** brought forward the use of genomics as a way to assess the safety of probiotics. Preparation of guidelines and methods for the safety assessment of probiotics as well as other food micro-organisms is an ongoing task in several committees and organisations, including European Food & Feed Cultures Association. One of the main criteria discussed in these groups is the safety question related to antibiotic resistance pattern of selected bacterial species/strains. However, other criteria like virulence factors, immune stimulation, production of toxins and compounds like bacteriocins and biogenic amines are included in the evaluations. Parallel to this work European Food & Feed Cultures Association has established a list of "Micro-organisms with a documented history of use in food". Dr. Laulund stated that the genomic tools can provide an important way to secure a holistic approach in the safety assessment and provide a rational risk management of the safety aspects of probiotics. However, a proper risk assessment based on the genomics approach of the probiotic strains needs to be evaluated together with the history of use and the observed performance in the actual product.

Questions raised by consumer and patient organisations for discussion

Below are some questions raised by the consumer and patient organisations and responses given by industry representatives and audience. These responses present viewpoints of single scientists or professionals, and thus cannot be regarded as the best truth commonly shared by scientific community. However, the discussion illuminates the diverse issues that have to be taken into account when consumer concerns are approached. There are no simple answers to the complicated issues and also consumers take a wide viewpoint when weighing their opinions.

Have the claimed health effects been proved?

The nature of the claims raised several comments: what kind of evidence is required and do we need to understand the mechanisms through which the products affect the physiological

functions? Prof. Blaut emphasised that our scientific understanding of some mechanisms is relatively good, but some of the data are obtained from animal models and the correspondence to humans has been assumed but not always proved. The validity of these models in humans has not been proved.

The need of controlled, scientifically sound clinical experiments was emphasised in several comments. The products should be tested in different consumers groups so that the results can be generalised and if necessary, the messages can be targeted to those consumer groups that benefit from the use of a product. However, consumers' need to know about the physiological mechanisms was not regarded as essential by some industrial discussants. Ms. Trigueros, on the other hand, stated that consumers are willing and able to understand, if not the detailed physiological mechanisms the connection between the component and its effects. She regarded the consumer education in these matters important. Consumers should be able to understand what the functional benefits are and how they may improve their health.

Mr. Mitchell brought forward the question of variation among individuals: can one promise that the same probiotic is beneficial for all or should one make clear that the efficacy may vary from one person to another. If this viewpoint is ignored, too much may be promised to an individual consumer.

Are the messages comprehensible to the consumers?

The current information about health effects is strain specific and therefore rather complicated for consumers who may find it difficult to differentiate between strains. The idea was put forward about more simple but generic claims: if scientists can find a consensus of certain effects being common to all probiotic or all lactic acid bacteria, then generic claims on these benefits would be easier for consumers to understand.

Consumer representatives underlined that claims need to be proven. The industry should not promise too much. According to legislation the phrase "preventing disease" is not allowed, but the "reduction of a risk factor" is allowed. Consumers' ability to understand these claims should not be underestimated. The field is strongly under progress and consumers will learn new links between ingredients and their effects in the body.

The consumer representatives emphasised that consumers need simple sentences about the amount of active and alive bacteria in the product. This means that the portion size required to achieve the effect should always be mentioned in connection to the claims.

Do the products contain probiotic bacteria in quantities that are sufficient to produce the promised effects?

The viability of probiotic bacteria in the end product is a technological problem. Some studies have shown that the bacteria do not always survive in the quantities promised in the package. For consumer trust it is essential that the end product contains what has been promised in labelling. Therefore legislation for making claims is crucial as it allows interference with misleading messages and unsubstantiated claims.

A common understanding was that consumers have a right to know how many living bacteria the end product contains. Someone suggested further that the claims should announce on what kind of number of bacteria they are based on.

Prof. Knorr reminded that the technology for keeping the strains alive in products is challenging task as each strain behaves differently in identical conditions and targeted technologies are required.

Safety of probiotics to ordinary consumers?

As a consumer representative, Beate Kettlitz was happy that the issue of safety was brought forward. Probiotics are generally regarded as safe and by definition they should be beneficial to consumers. Although the safety record is good, when applying new strains the safety issues need to be evaluated. The possible antibiotic resistance is one cause of concern and should be investigated further. Furthermore, the short term safety record is good but there is little information about the long-term use of probiotics. The industrial participants emphasised that safety is the first criterion for food manufacturers.

In addition to the discussion on the sufficient amount of probiotics, also the possibility of overdose was brought forward. However, if eaten as a food product, getting too many bacteria is unlikely.

Probiotics for treatment of Crohns and colitis patients: are they safe and effective?

Mr. Rod Mitchell brought forward questions whether probiotics will be an alternative way to treat Crohns or colitis patients in the future and whether the safety and suitability to all patients can be assured in these products. **Francisco Guarner** (Spain) commented on the clinical aspects of probiotics starting with issue of safety. So far only low side-effects with the products have been reported. Guarner stated that at the moment it is difficult to answer whether probiotics should be classified as drug or food and more demonstration about the health effects is needed. According to Guarner, in the case of IBD patients, consulting with patient's own medical doctor is essential before including probiotics in the diet or changing the diet in other ways.