ORGANOBALANCE – From Spin-Off to Successful Probiotics Producer

Probiotic bacteria have been widely discussed for a number of years, especially in Europe. They first became known as relatively unremarkable "useful bacteria" in special yoghurts with rather vague promised effects (like boosting our immune system). Now, however, they increasingly present themselves as probiotic strains with special properties, which are used for various purposes and in different forms. These include traditional dairy products – still the main application field –, dietary supplements in tablet form and cosmetic products.

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What was originally conceived as a means of promoting intestinal health is now increasingly subjected to scientific scrutiny to understand the underlying mechanisms. In some cases probiotics have been developed as a form of preventive medicine. Studies have been published showing that certain probiotic strains can be used successfully to alleviate the symptoms of the bowel disease Morbus Crohn or to alleviate cold symptoms and make colds clear up more quickly.

The New Probiotics

When ORGANOBALANCE was founded in 2001, many of today's applications of probiotic cultures as specific promoters of health still had to be explored. The word "probiotic" means simply "for life", and dates back to the early twentieth century when scientists noticed that the regular consumption of food fermented with lactic acid bacteria brought health benefits. This is what convinced ORGANOBALANCE that there was still much to be discovered about the real benefits of probiotics and that naturally occurring probiotic strains probably offer enormous potential for development and benefits for consumers.

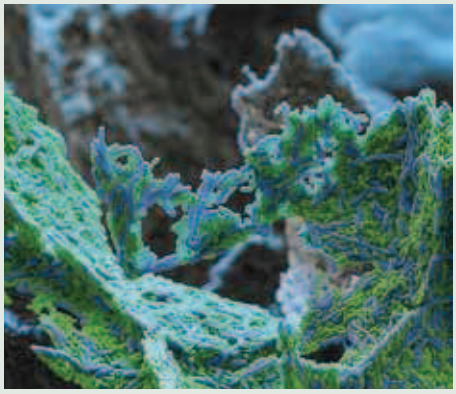
Therefore we began to evaluate the large variety of naturally occurring "good micro-organisms" systematically and built our own collection of strains of micro-organisms, specializing in food-grade lactic acid bacteria and yeasts, which has been expanded continuously for fifty years. In recent years we have used innovative screening methods and raster scans to identify new strains, characterize them and then develop them to product maturity. In some cases these efforts have led to completely unexpected and innovative applications.

As an illustration of our work in this field, we would like to present a project here whose development is already advanced. In close cooperation with BASF Future Business GmbH, ORGANOBALANCE has succeeded in identifying and describing a naturally occurring bacterium of the *Lactobacillus paracasei* species, which selectively recognizes the caries pathogen *Streptococcus mutans* and binds it. In highly sensitive screening assays developed specifically for this purpose by ORGANOBALANCE, we filtered a strain from our own collection of bacteria, which can recognize and bind the caries pathogen under the conditions that prevail in the mouth. The *Lactobacillus* cells function as molecular hooks, which attach themselves to the surface of the mutans cells. Mutans cells masked in this way can no longer adhere to the teeth as micro-aggregates, where they usually embed themselves using self-generated mutan, if sugar is present, and produce cariogenic acids. The mutans bacteria can thereby be gently and effectively removed from the mouth (for example, during teeth-brushing) without harming other oral flora.

Probiotics and the Health Claims Regulation

Consumer-protection regulation requirements mean that it is of utmost importance for this new generation of probiotics to be selected according to their function and effects if they are to be brought to market. In Europe, health-related claims made for functional components in foods must be tested and evaluated under the European Health Claims Regulation. This means that all products for which health-related claims are asserted must have proven their relevance for the health benefit in question in efficacy studies. Terminology like "supports", "regulates" or

Figure 1



Scanning EM: Photo of a co-aggregate of Lactobacillus and Streptococcus mutans (Copyright: BASF SE)

"improves the immune system" will no longer be permitted unless the relevant company can present intervention studies that prove the claim and hence the efficacy of the component concerned. The success of these complex and expensive intervention studies depends on being able to perform step-by-step selection processes during product or active ingredient development until the best candidate is found (a standard procedure in drug development). From the large number of existing strains, ONE is thereby eventually selected that exhibits the desired properties. At this stage, the candidate in question will already have proven its efficacy in in vitro studies and possibly in animal models too. ORGANOBALANCE uses this search strategy to filter out the "diamond" from a large collection of wild-type strains systematically by ever more stringent test procedures. We demonstrated in initial assays that it is possible using this method to prove conclusively the effect-related properties identified at laboratory level as an effective principle in animal studies and in studies using test subjects, thus paving the way to market maturity. As a new form of application, the active strains are also eligible for patent protection.

ORGANOBALANCE Markets and Fields of Business

Using its own collection of strains and its specially developed OASSYS® screening technology, ORGANOBALANCE has succeeded in tapping the potential of new effective micro-organisms for many areas of application.

Alongside new strains of probiotic bacteria for use in cosmetics (active agents derived from lactic acid bacteria that specifically stabilize and regenerate the protective micro-flora of the skin), our developments include strains for food applications, such as an antagonist to combat caries-generating bacteria or the stomach germ Helicobacter pylori, as well as probiotics for animal health.

ORGANOBALANCE started out as a spin-off of Technische Universität Berlin. Today, the company has 28 employees and is consciously customer-oriented. We predominantly conduct projects in the form of license models.

This makes us a reliable and innovative cooperation partner for the manufacturing industry in the field of R&D. One example is our strategic partnership with BASF, with whom we have cooperated successfully in a range of projects since 2002. We are engaged in many other development projects, some of which are at laboratory and others already at pilot stage, in close cooperation with medium-sized and large companies in Germany, Europe and North America.

In these projects, we use synergies in order to bring together the expertise and the proprietary bacterial strains of ORGANOBALANCE with the market and product know-how of our partners as effectively as possible. ORGANOBALANCE thereby also makes available its know-how in process development and formulations. Since 2007, we have also been able to offer pilot production facilities. With 150 liters of fermentation and drying capacity, we can provide product batches for testing purposes. ORGANOBALANCE is consequently well placed to begin producing its own cultures.

For the coming period, we also see great development potential for specific functional natural components or strains, especially in the fields of nutrition and preventive medicine. Micro-organisms traditionally used in foods, such as lactobacillae and yeast, which have GRAS (generally recognized as safe) or QPS (qualified presumption of safety) status, therefore have a very good chance of reaching consumers soon.

During the next twelve to eighteen months, we expect to see the first of our products ("Invented in Berlin") to come on the market – perhaps with the field of dental care taking the lead.