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EFSA (Parma, Italy) is considered the biggest hurdle in obtaining EU health claims today. The EU scientific advisor routinely rejects health claim petitions, often citing a lack of scientific data—and immune-support health claims are no exception.

But a new EU project could improve the scientific standards by which immune-health ingredients are studied.

In December 2011, the EU approved the FibeBiotics research initiative, its latest financial investment in the food ingredients sector. Now underway, the €6 million, 4.5-year project is focusing on nondigestible polysaccharides, from traditional fibers and other foods, for gut- and immune-health research.

Nondigestible polysaccharides represent one of the more intriguing areas of immune-health research today, but scientific understanding of this class of ingredients is largely specific to each individual type of polysaccharide. Without using standardized practices, protocols, and analytical methods across the category, resulting data can be largely inconsistent.

And so, FibeBiotics is enlisting four universities, five research institutes, and eight ingredient companies in a team effort to standardize analytical methods, validated biomarkers, and clinical endpoints, and conduct clinical trials on three nondigestible polysaccharides intended for immune support: a yeast beta-glucan, an oat beta-glucan, and arabinoxylan from wheat.

“To the best of our knowledge, this is the first project of this scale and scope, specifically in the immune-health category and ending with human studies,” says Don Cox, PhD, senior vice president of R&D for Biothera (Eagan, MN), whose proprietary baker’s yeast beta-glucan ingredient Wellmune WGP will be a focus of the project.

Cox says that the project could even serve as a sort of blueprint for how to go about designing research plans for successful outcomes in other ingredient categories.

Food Applications

Part of FibeBiotics will involve looking at immune-health ingredient bioactivity once the ingredient is placed into a food application. Since certain food matrices and processing may affect bioactivity of ingredients, investigating how active ingredients are thereafter exposed to immune cells and taken up in the blood is warranted. Such research is needed to substantiate the effects an ingredient may have in realistic human delivery systems (i.e., functional foods).

While Biothera’s own research indicates that the Wellmune WGP mechanism is unaffected by various food and beverage matrices, Cox warns that “there are some compounds for which this isn’t always the case, wherein even the processing temperatures of a certain food matrix can impact an ingredient’s efficacy.”

In fact, the food matrix may even *increase* the bioactivity of some of these polysaccharides. Just take it from Swedish Oat Fiber (Bua, Sweden), another partner in the study, whose OatWell oat bran—rich in oat beta-glucans—will be another project focus.

“As for most former studies involving OatWell, our ingredients will be incorporated into real food matrices to see how different processing may impact the bioactivity relevant to end-consumers,” says Frédéric Prothon, R&D manager for Swedish Oat Fiber. “For instance, we have previously demonstrated that extrusion, performed in a controlled way, does significantly increase the bioactivity of oat beta-glucan. We do not exclude that such effects may also be achieved in the scope of this project.”

State-of-the-Art Technology

Tests will employ commonly available laboratory technologies to investigate each ingredient's influence on direct immune effects, changes in gut flora, and the metabolites formed once these ingredients are ingested. Additional data will come from the use of innovative, state-of-the-art technologies, including a simulated model of the human digestive system—SHIME by developer ProDigest (Gent, Belgium)—and GA-map technology from Genetic Analysis AS (Oslo, Norway), which is capable of documenting human gut flora profiles, flora changes as a result of food (ingredient) consumption, and correlations of flora profiles to health-condition prognoses.

Technologies employed in FibeBiotics should provide a better understanding of what biomarkers are best for validating a beneficial immune response with nondigestible polysaccharides. Beyond simulated digestive tracts and other *in vitro* research, FibeBiotics will employ a series of human pilot trials on immune-health ingredients. Those demonstrating significant effects are expected to ultimately move on to a large clinical trial. Clinical trials will focus on the elderly, a population perhaps best suited to immune-health research because of generally reduced immune efficiency at this stage of life.

The benefit of FibeBiotics is as much its sole benefit to the involved beta-glucans and arabinoxylan as it is the program's crossover potential into other ingredient science. In fact, a number of other immune-health ingredients are projected to be involved in pilot trials—including shiitake mushroom beta-glucan, apple pectin, and exopolysaccharides from fermented milk. Some of the tools and technologies employed in the project can be used for studying these and other ingredients.

Probiotics, Too

While the main scope of FibeBiotics is to focus on nondigestible polysaccharides and a handful of other ingredients with prebiotic potential, probiotics have understandably found their way into the workplan, too, via probiotic developer Winclove Bio Industries (Amsterdam). Project manager Isolde Besseling-van der Haart explains the role of probiotics in the project:

*Probiotics, by themselves, have an effect on the gut and immune system, but can also work synergistically when stimulated by certain prebiotics. Since polysaccharides also have a prebiotic effect, there might be an interesting opportunity to combine the probiotics with nondigestible polysaccharides to further enhance the effects on the human host. By diverse *in vitro* and *ex vivo* analyses, more insight will be gained on the interaction between nondigestible polysaccharides and probiotics and whether and how they work synergistically. Finally, combining the nondigestible polysaccharides with the probiotics will be one of the options to develop a functional food aimed at beneficially influencing the human gut and immune system.*

Future Influence

FibeBiotics is expected to offer a benchmark for better understanding of immune-health biomarkers on the whole, but the program will also serve as a model for how other ingredient sectors might want to consider approaching scientific data collection to back up health claims. The aim of FibeBiotics, after all, is to hopefully submit an EFSA claim for one or several of these ingredients.

“To our knowledge, this is the first large EU project where researchers work together with the industry and aim to develop end-products that might be able to pass EFSA claim evaluation and do this by using the EFSA guidelines in the area for support of gut and immune function,” says Jurriaan Mes, PhD, FibeBiotics project coordinator.

According to Mes, FibeBiotics beat out 30 other projects on bioactive compounds and functional products that were petitioned to the EU. Two additional projects—fashioned like FibeBiotics but focusing on other compounds—are expected to receive EU approval in November 2012.



- [2] <http://www.nutritionaloutlook.com/category/topics/baked-goods>
- [3] <http://www.nutritionaloutlook.com/category/supplier-categories/ingredients/specialty-ingredients/beta-glucan>
- [4] <http://www.nutritionaloutlook.com/taxonomy/term/1746>
- [5] <http://www.nutritionaloutlook.com/category/topics/efsa>
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