

European probiotics industry fears regulations will scuttle market for health-promoting or disease-preventing foods

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The European probiotic food industry may be frozen out of the consumer market as a result of new European Union nutrition and health regulations requiring proof that health benefits accrue from adding live microorganisms such as lactic acid bacteria and yeasts to fermented products such as yogurt.

The industry has long maintained that consumption of probiotics has a beneficial effect on humans because they inhibit the reproduction of pathogens that cause intestinal inflammatory diseases, some forms of diarrhea and urogenital infections.

But regulations introduced in 2007 to protect consumers against misleading or false advertising now require industry to submit all food and supplement health claims to the European Food Safety Authority (EFSA) for scientific evaluation prior to their use in the European Union, the world's largest and most advanced market for so-called "functional foods," i.e., ones which are said to have health-promoting or disease-preventing properties.

The safety authority has subsequently rejected wave after wave of probiotic health claim dossiers. To date, it has rejected every submitted claim. The industry says the dossiers are often rejected on the basis of technicalities rather than a lack of evidence. Once rejected, products must be withdrawn from the market within six months, on pain of prosecution.

Within that context, scientists and industry will meet at an International

Probiotic Conference workshop on Friday to discuss strategies for weathering the storm.

"It's a mess and we're all trying to work our way through it with little or no guidance from EFSA," says Dr. Elinor McCartney, director of Pen & Tec Con-

stantiate their health claims to the European Union member state of their choice. That evidence was consolidated and passed along to the EFSA for evaluation.

After the EFSA rejected claims regarding the gut, immunity and other health benefits of probiotics, the European Food and Feed Cultures Association slammed the authority for failing to communicate expectations or publish guidelines on how much or what type of evidence efficacy panels require.

"We actually do not know how EFSA is evaluating probiotic claims," says Caroline Herody, a representative for both the association and the Danish food-production company Danisco, which makes excipients (inactive substances which are carriers for the active ingredients of a medication).

EFSA hasn't been transparent with industry about what they're looking for, adds Dr. Gregor Reid, director of the Canadian Research and Development Centre for Probiotics. "They've made it unnecessarily difficult for companies to know what information to provide in order to gain approval, and where there has been guidance it's invariably come too late."

In 2008, the European Commission issued guidance that indicated the authority would reject outright any scientific health claims dossier that didn't contain human clinical data.

The instructions came too late for many probiotic food companies who were already in the process of submit-



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Yogurt is the most common product into which live microorganisms are added and then promoted as having health benefits.

sulting and chair of the regulatory workshop. "They're just throwing out claims. We've all been surprised by how rigid an approach they've taken to probiotics."

Under the new regulations, companies were asked to submit whatever evidence they felt necessary to sub-

ting their claims, as human studies can take three or more years to complete.

EFSA's insistence on evidence derived from the gold standard of randomized clinical trials is ill-suited to demonstrating the supportive function that live microorganisms play in human health, critics say.

"Probiotics are not drugs and they're not nutrients: they fall somewhere in between," says McCartney. "EFSA is taking a pharmaceutical approach, but the standards of evidence that go along with that approach are too high, particularly if we're looking at healthy populations."

As it can take 10–15 years for a disease to develop, and the study participants are free of disease at the baseline, it's not surprising or particularly informative to see no benefits after several years of supplementation, she adds. "It's pulling probiotics out of context and treating them like drugs, which no one is claiming they are. It's also not taking into consideration nutrition science in its entirety."

But the absence of data from clinical trials hasn't been the only problem. Many industry claims were made before companies realized that the authority was requiring them to include strain characterization for all microorganisms. That, in turn, led to many EFSA rejections on the grounds of incomplete dossiers rather than insufficient evidence of efficacy.

Many claims were thrown out because EFSA deemed the strains were insufficiently characterized, says Dr. Yolanda Sanz, an EFSA panel expert on nutrition, dietetic products and aller-

gies. In those cases, the authority did not scrutinize the gut health, immunity and other health benefit data contained in the dossiers.

According to McCartney, EFSA's failure to communicate its assessment process has left many companies in limbo, unwilling to develop new products or resubmit claims for fear of further rejection and adverse publicity.

France-based industry leader-Danone has twice withdrawn health claims applications for probiotic yogurts Activia and Actimel.

"There are serious financial and health implications to EFSA's approach," says Reid. "If EFSA doesn't start communicating what they want, food companies will eventually give up on the expensive claims application process and, in turn, will likely give up on putting the money into researching and selling probiotic products."

The probiotic food market was estimated to be worth approximately €10 billion in 2008 and holds an estimated 10% of the global functional food market, but the industry is only as strong as its health claims.

"EFSA is in danger of killing public confidence in probiotics, and that would mean a smaller health food industry in Europe, reduced spending on research and development, jobs lost, billions of dollars drained from the economy and studies killed," Reid says. "The worst that could happen is if probiotics became no longer available and the consumer was left with no options."

For its part, EFSA insists that holding probiotics to the gold standard of clinical trials is necessary to guarantee

that public confidence in probiotics is based on true health benefits.

"Food are not drugs ... but the science behind [probiotics] should be sound in any case," says Sanz. "This is contrasted with the previous situation in which nothing was regulated and that is why criteria seem to be so strict."

EFSA is organizing a fall workshop to address concerns about these criteria. Meanwhile, industry legal teams are preparing court challenges.

"There's only two ways around EFSA in this situation: you either do the work or you change the law," says McCartney. "In the short term, industry will have to reduce their claims to deal with simple things like improved fecal consistency, but obviously those claims won't be amenable to creative marketing."

Another alternative for companies is to resubmit rejected claims under different articles of the health claims regulations. But that would require them to meet a higher standard of evidence.

The June 18 regulatory workshop was part of the week-long International Scientific Conference on Probiotics and Prebiotics held in Kosice, Slovakia.

"This really is an international issue, because the world looks to Europe as a leader in probiotics," Reid says. "I think it's not unreasonable to expect to see these kinds of regulations exported elsewhere in the world."

Canada currently doesn't regulate what bugs can be called a probiotic or what health claims can be made about probiotic foods. — Lauren Vogel, *CMAJ*

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