Commercializing Innovative Foods

Mark Warner, PE
Founder, Warner Advisors LLC

Understanding the challenge of commercializing innovative foods will separate those that change the future of food, from others that become an asterisk in a market study. In my previous publication ***what makes scale-up of industrial bio-technology so difficult***, I expanded on the technical challenges of commercializing advanced bio-technology. While most of the scale-up lessons are directly applicable to the emerging shift to innovative foods, there are other key factors that must be considered to ensure success.

The first place to start is a discussion of what I mean by innovative food. Traditional food companies have made significant improvements over the years in the cost, nutritional value and safety of the foods we eat every day. I do not intend to ignore their progress, but there has been a recent push (backed by robust venture funding) to create a new sector of innovative foods. These are primarily proteins that traditionally come from animal farming, with the goal of producing indistinguishable products from non-animal sources. You can find a plethora of new and exciting companies making novel foods by application of advanced biotechnology such as meat, milk, eggs, cheese, fish, gelatin and other products. There are two common themes among these companies that define the sector, they are based on advanced biotechnology and their measure of success is a product that is indistinguishable from the current animal-based offering. The second item is the key. While there have been alternatives available for many years to most animal-based offerings (veggie burgers, soy milk, etc.) they are not considered indistinguishable. Consumers are aware they are not eating the "real thing", but make a choice for health, religious or other reasons. The primary goal of the innovative food industry is to provide alternatives that do not require this choice, which is both game-changing and a high bar to meet. As I look forward and outline what is necessary for this burgeoning industry to succeed, let's review how most protein products are made within biotechnology today.

The classic route of biotechnology-based protein production is by aseptic fermentation from an organism that can excrete the protein into the fermentation broth. The protein is isolated from the broth by clarification, combined with techniques such as various forms of filtration (UF, MF, TFF) then purified by chromatography. Finally, the protein is ensured to be free of pathogens and undesirable organisms by utilizing a sterile filtration process. This likely sounds familiar to those who have worked in advanced biotechnology, however if this is the starting point for an innovative food process, there are many obstacles with this approach that make it unlikely to reach commercial success in most food applications. The first concern is that while these technologies are robust and very appropriate for applications with high product values (pharmaceuticals), they seldom produce food products that are price competitive.

Secondarily and often more importantly, they do not readily fit the regulations and requirements of producing commercial food. Gaining an understanding of the applicable food safety requirements and how they constrain innovative food technology is a critical first step at the beginning of the development process. Otherwise there is a significant risk that the process developed will not reach commercial success.

The following is a summary of the key concepts of making food products and can provide a vehicle for self assessment. The intent is to outline the difference with traditional biotechnology and why a shift in thought process is required to bring a novel food to market.

"Fizz-Muh" – when I first meet with companies looking to commercialize an innovative food technology, I can often access the understanding of the task at hand by inquiring about their strategy for complying with the *food safety modernization act* (FSMA, aka "fizz-muh"). This was a major overhaul of the US food safety regulations in 2011 that governs how food is produced and what is considered safe to eat. For any food producer, FSMA is the tail that wags the dog. An understanding of the requirements of the regulation and how it impacts manufacturing operations is critical, or the company risks going down a long process development path that results in a great product that cannot be sent to market. It is important to note this regulation is different than the *generally regarded as safe* (GRAS) determination that new food products must make.

The path to safe food – another area that is often eye opening for those moving from traditional biotechnology into food applications is how food safety is managed, and more specifically how organisms are controlled. In pharma applications, the expectation is that fermentations will be clean (no foreign organisms) and the end product sterile, free of any pathogens or foreign organisms. That is not the case with food. If you look at a specification sheet for commercial food products such as flour, you will see that they are free of federally regulated pathogens (e-coli, listeria, salmonella, etc.), but have acceptable levels for other non-pathogenic organisms including mold, yeast and coliform. Pasteurization is the typical approach to controlling organisms in food, but many novel proteins that wish to maintain functionality will require an alternate method, that still meets the food safety requirements.

Think sanitation, not sterility – one of the distinct differences between traditional biotechnology and food production is the concept of cleanabililty of equipment versus the ability to sterilize it. In biotechnology, steam or chemical sterilization is the standard. Much of the equipment is rated such that it can be regularly heated to a temperature and pressure to achieve sterility. For cost and practicality reasons, that is not how food equipment is manufactured and thus, not how the food safety regulations are structured. The ability to access and clean equipment, followed by a verification of cleanliness is the backbone of a typical food safety program. This is a case where the technology being used may be robust and a great fit for biotechnology, but *it's really a square peg trying to fit into a round hole* when making food.

Proactive versus reactive – the question I get the most after reviewing the constraints above is: why does it matter, in the end I can just test my product and as long as it passes all the tests, it meets the regulations, right? Under FSMA, that is not the case. Food safety programs that rely solely on back-end quality testing are not allowed. One of the key concepts of FSMA is that there

must be adequate control points throughout the manufacturing process, with quality testing as a second line of defense, not the primary method.

Who's the boss? – in the case of food safety, from a practical perspective, it is the state or local health department. This is the entity that will issue your facility a permit to manufacture food and administer the food safety regulations. FSMA sets the guiding principles that flow down to the local level, but the group permitting and inspecting dairies, meat packers and other traditional food manufacturing facilities (and bringing that history and perspective) is the primary regulator.

The key to success in commercializing innovative foods is to bring all the brilliant people and novel technologies of advanced biotech to food applications, with the understanding they will need to figure out how to modify their square peg to fit into the round hole that is food manufacturing.

Mark Warner is a registered professional engineer with 30 years of experience in process commercialization, focusing for the last 10 years on taking first-of-a-kind-technologies from bench-top to commercial operation. He is a leader in commercialization of innovative food products, working for industry leaders such as Solazyme (TerraVia) and Impossible Foods. Mark is the founder of Warner Advisors, providing consulting services and acting in interim engineering leadership roles for advanced bioeconomy clients. He can be reached at mark@warneradvisorsllc.com or for more information, visit www.warneradvisorsllc.com.