Intelligence in Enzyme Regulation: Promoting Consumer Confidence

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The "novel foods" regulation initially approved by the Europeasn Union (EU) Council of Ministers in October 1995, and now awaiting the approval of the European Parliament, does not apply to enzymes—whether produced through genetic modification or not. This, we believe, is as it should be. Since the overwhelming majority of enzymes are simply food processing aids and have no role in the final food product, clearly most are neither "novel foods" nor "novel food ingredients." Three notable exceptions—which would be regulated as additives—are lysozyme (which acts as a preservative in cheese), invertase (a stabilizer), and glucose oxidase (which will serve as an antioxidant, if approved).

There are some people, however, who would include as a novel food any enzyme produced through the involvement of genetic modification. This would almost certainly cause serious confusion among food processors who use enzymes, and among consumers, as well, as it could be seen as discrimination against enzymes from genetically modified organisms. Like every participant in the food chain, AMFEP (Association of Manufacturers of Fermentation Enzyme Products, Brussels), which represents the enzyme producers of Europe, is sensitive to the need for consumer confidence in the safety of the food they eat. The association is certainly not against regulation of enzymes per se. Indeed, we have become convinced of the need for the regulation of enzymes at the European level to ensure confidence in our products and the growing role they play in the food chain. However, that regulation should be "intelligent." There are several facets to this "intelligence."

For a start, regulations should be harmonized within the EU. Currently, there are important and potentially confusing differences in the way EU member states regulate and even classify enzymes. As food products increasingly cross borders, these differences pose problems for consumers, enzyme producers and users, and even for regulators themselves.

Within that harmonized regulation, all enzymes should be considered in the same way, whether produced by classical means or with the involvement of genetic modification. The reason for this is compelling: Nearly all enzymes produced through the use of genetic modification are identical to those found in nature; thus, it is extremely difficult, if not impossible, to distinguish their origins. How could regulators "police" the sources of enzymes? For uses in animal feed, there is already a common EU regulatory regime that encompasses all enzymes. Appropriate parallel measures for food uses would help complete the regulatory picture.

The task of regulation is to ensure that enzymes used in food processing are safe. In this regard, AMFEP believes that extensive testing—including animal testing—for every new enzyme production method or every new application can sometimes be counterproductive. Regulators, the food industry, and consumers already have a great deal of experience in the use of enzymes. AMFEP believes that such experience should be used in drawing up two distinct "positive" lists: one of microorganisms proven to be safe for use in producing food enzymes, and a second list of enzymes that are currently permitted in food processing. Specific regulatory approval would be required if either the enzyme or the producer microorganism appeared on the respective lists.

Then there is the question of transparency: Regulations should recognize that consumers have a right to information about what is in a product and how it is made. Information about the use of enzymes can be given in many ways, and labeling is but one of these ways. However, product labeling—if it is done—should not be the only source of information: It should be accompanied by other details explaining the information on the label itself. The enzyme industry has an open information policy and will inform its customers as to whether an enzyme has been produced using genetically modified organisms, enabling our customers to further inform the end consumers. Additionally, we tell consumer organizations and other interested parties how we produce our enzymes.

Readers of *Bio/Technology* already know that enzymes provide important benefits to food processors, consumers and the environment. They replace chemicals in many processes; they are completely biodegradable; they work at moderate temperatures, thereby reducing energy use in manufacturing processes; they reduce waste from manufacturing processes and from other industrial and municipal sources.

Using genetically engineered organisms to produce enzymes offers further advantages: It raises production efficiency and thus less use of energy and raw materials and less waste; it makes available enzyme products which, for economic or other reasons, would not otherwise be available; and it can increase the specificity and purity of enzyme products.

Rather than erecting regulatory barriers, the EU should be looking at ways to encourage an industry which European companies dominate. A regulatory regime that treats all enzymes uniformly regardless of means of production would be an important step in the right direction. ///