Substantial Equivalence in Food Safety Assessment

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Substantial Equivalence in Food Safety Assessment

"Substantial equivalence," or SE, is an internationally recognized standard that measures whether a biotech food or crop shares similar health and nutritional characteristics with its conventional counterpart. Biotech foods that are substantially equivalent have been determined to be as safe as their conventional counterparts. Products that are not substantially equivalent may still be safe, but must undergo a broader range of tests before they can be marketed.

ASSESSING THE SAFETY OF FOODS DERIVED FROM BIOTECHNOLOGY

New foods or food components must be assessed for their safety and wholesomeness (nutritional adequacy) regardless of the method by which they are produced or processed. Safety considerations for biotech foods are essentially the same as those for products produced by traditional methods.

Many questions are routinely asked about the safety of crops derived through biotechnology, such as:

- Will the transferred gene and/or its derived product have nutritional, toxic or allergenic effects?
- Will new or novel components be produced?
- Will levels of existing components be altered?

The responsibility for addressing these questions lies with the developers of such products and government regulatory agencies. These questions are answered before biotechnology products are brought to market.

ANALYZING THE PRODUCT

Crops produced through biotechnology are analyzed in great detail with respect to the genes and gene products introduced and the composition of the host crop. Gene products are evaluated for potential allergenicity and tested for acute toxicities and major compositional components. If these tests show the expressed protein is safe, the next step is an evaluation of "substantial equivalence."

IS THE PRODUCT SUBSTANTIALLY EQUIVALENT?

Substantial equivalence evaluations are conducted to assess whether the key nutrients or anti-nutrients in the plant components used for feed or food have been changed. If a biotechnology product is found not to have any differences in the composition of nutritional or anti-nutritional components from its conventional counterpart, it is considered substantially equivalent.

In its basic form, SE is an analytical evaluation that compares the composition of the food/feed component under review with an existing food/feed or food/feed component that humans or animals already safely consume. The assessment relies on validated methods.

HOW SE ASSESSMENTS WORK

Typically, a biotech food is compared with its equivalent or counterpart crop or processed food. If no counterpart exists, additional safety considerations are warranted. The comparison is based on the normal range of composition of key groups of reference components: nutrients like essential vitamins, minerals, fatty acids, carbohydrates and amino acids; any naturally occurring toxicants, such as erucic acid and glucosinolates in canola or solanine in potato; and allergenic proteins in commonly allergenic foods like soybean and wheat. Information on the normal ranges of reference components may come from a variety of sources, including existing databases, scientific literature or data derived from parental and/or other conventional foods/feeds or food/feed components. The number of components to be compared is generally limited to those deemed necessary to ensure that the particular crop or food is substantially equivalent.

In determining substantial equivalence, health and regulatory officials consider natural levels of variation, any processing the food or ingredient may undergo, its intended use and general intake levels among the population.

WHAT SE MEANS

SE, by itself, is not a safety assessment. If a new product is determined to be substantially equivalent, then the new food or food component has been assessed to be as safe as its traditional counterpart and can therefore be regulated similarly. A determination that a biotech food or crop is not substantially equivalent does not mean the product is unsafe. However, a product that is determined to not be substantially equivalent would be subject to a broader analysis on a case-by-case basis, with the safety assessment focusing on established differences between the product and its conventional counterpart.

Additionally, two food products — such as processed food components like soybean oil - may be considered substantially equivalent even though the raw grains or varieties from which they were derived are different, such as in their ability to tolerate herbicides.

A GLOBALLY ACCEPTED STANDARD

Substantial equivalence is a globally accepted principle. Its use in food safety assessment is a concept endorsed and utilized by many national food health agencies — including the Canadian Food Inspection Agency, Japan's Ministry of Health and Welfare, and the U.S. Food and Drug Administration. International organizations that use it include the United Nation's Food and Agriculture Organization, the World Health Organization and the Organization for Economic Cooperation and Development.

If a biotech food or a derivative of a biotech food is determined to be substantially equivalent to an existing food, this determination should apply in all countries. However, the specific nutritional contribution the product would make to the dietary patterns for the population in the country intended for use should also be taken into account.

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