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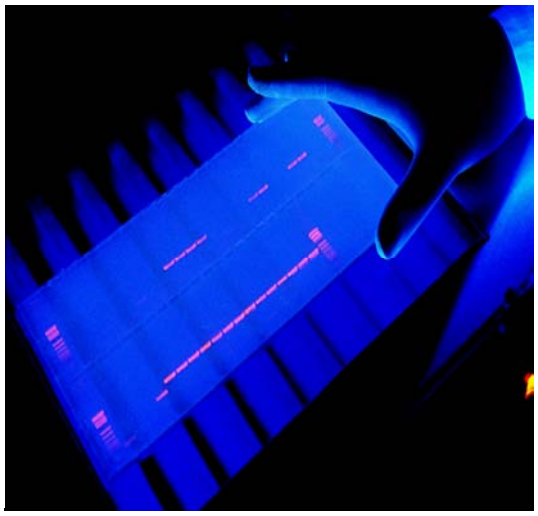
# Genetically Modified Organisms (GMO) Technical Sheet

Testing for bioengineered crops, also referred to as Genetically Modified Organisms (GMOs), has become a necessity in light of legislation imposed in member countries of the European Union, Japan, South Korea, Australia, New Zealand, and in an increasing number of other countries. They established labeling laws for approved bioengineered crops, while prohibiting the import of unapproved varieties. For approved varieties, commonly tolerance thresholds are established below which a product does not have to be labeled as containing or derived from GMOs.



Threshold levels vary for each legislation. Since 2004, the labeling threshold for food products in the European Union is 0.9%. Current EU regulations demand control through analysis and traceability. Food and feed products that contain or are derived from GMOs must be labeled. For products that are highly refined, documentation of their conventional, non-biotech source material is now required. The labeling threshold in Japan is 5%, South Korea 3%, and Australia and New Zealand 1%.

**WHAT ARE GMOs?**

A Genetically Modified Organism (GMO), for all purposes relevant herein, is considered to be an organism that contains recombinant DNA elements, i.e., that has been altered genetically by insertion of foreign DNA sequences in the organism's genome by means of modern biotechnology. In a food-related context, GMOs are currently limited almost exclusively to agricultural plants. They are also referred to as transgenic, bioengineered, or biotech crops.

The major transgenic plants in the market include corn, soybeans, canola (rapeseed), and cottonseed. Other varieties in the market include potato, sugar beet, tomato, papaya, watermelon, zucchini, and squash. No commercialized wheat or rice varieties exist yet, but release of transgenic rice varieties in the US is forecasted for the foreseeable future.

**METHODS AVAILABLE**

Two different categories of analytical methods are used to detect GMOs. One is Polymerase Chain Reaction (PCR). It is based on the detection of genetic material (DNA). It is most versatile for detection of biotech crops and therefore the method of choice for many applications. The alternative is Enzyme-Linked Immunosorbent Assay (ELISA). It detects foreign protein(s) which most bioengineered crops contain as a result of the insertion of bioengineered gene(s). As compared to PCR, ELISA is more restricted in its applicability but can be very useful in certain raw commodities.

**PCR**

There are different types of PCR methodologies, ranging from customary applications where the final reaction products are examined by gel electrophoresis, all the way to advanced PCR applications where fluorescent reaction components together with sophisticated optical instrumentation produce real-time data while the reactions are in progress.

A particular real-time PCR application which is preferably used for detection of biotech crops is often referred to as "TaqMan® PCR". It is currently the method of choice to obtain quantitative results in addition to qualitative results. Eurofins GeneScan has a wide variety of such quantitative PCR tests. Please contact our experts for more information about the most appropriate quantitative test for your sample.

A commonly recommended or required approach is to screen for any biotech crop or material derived thereof by the detection of genetic elements that are shared between virtually all commercialized agricultural GMOs. The two best-

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known examples are the 35S promoter from Cauliflower Mosaic Virus (CaMV) and the NOS terminator from Agrobacterium tumefaciens. These are widely used, well-characterized elements, which direct the expression of the biotechnology genes they reside in.

Testing for the 35S promoter in combination with the NOS terminator will detect all commercial corn and soy transgenic varieties, as well as most other agricultural biotech crops. This method is widely accepted as the most efficient way to screen for GMOs. Additional screening tests may be advisable for different commodities and ingredients. A variety of screening tests besides 35S promoter and NOS terminator are available at Eurofins GeneScan. Please contact our experts for more information about devising the best testing strategy for your product.

Additionally, PCR can be used to identify particular commercialized biotechnology varieties one at a time. The insertion of a biotech DNA sequence into a particular locus of a plant cell's genome is a unique event during the creation of a new biotech plant variety. All cells and whole plants which are progeny of this one cell carry the same biotech DNA in the same locus of their genomes and are collectively referred to as an "event". Tests that are specific for one event only may be required in some situations, for example to verify that a product does not contain any events that are unapproved in an export destination country.

**ELISA**

Enzyme-Linked Immunosorbent Assay (ELISA) detects the protein product of a biotech gene. The protein is detected by specific antibodies. These are coupled to an enzyme, which catalyzes a color-reaction with a substrate. Positive, negative, and quantitative results are determined by detecting the color change in the reaction.

Unlike PCR, ELISA is restricted to one single protein type, and cannot be used for comprehensive GMO screens encompassing several varieties at once, nor can it distinguish between specific events expressing the same protein. The conformation of the protein is usually crucial for its detection by the antibodies. Since extreme conditions (i.e. temperature, pH) affect the confirmation of proteins, ELISA is not applicable to most processed food or feed matrices. Furthermore, ELISA does not detect those GMO events which lack a distinguishable novel biotech protein.

Although we recommend PCR for most applications, ELISA methods are a useful alternative for raw soybeans and some pure soy products, and for the detection of StarLink™ corn in corn kernels or corn flour. Despite restrictions, ELISA has a cost/time advantage.

**LFS**

A further immunoassay application, referred to as lateral flow strips (LFS) or 'dip sticks', is commonly used for detection of certain biotech crops early in the food chain (e.g. harvest, grain elevators, etc). Compared to PCR and ELISA, these tests are easy to perform and typically do not require a sophisticated laboratory setting or scientific personnel.

The PCR and TaqMan® processes are covered by patents and patent applications issued to Hoffmann-La Roche AG and applicable in certain countries.