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Without a trace? New GMO labelling rules

For a number of years, EU food products containing more than 1% GMO have had to be labelled as such - a label that EU food producers and retailers have strived to avoid. New regulations, however, which come into force in April 2004, require testing and traceability. Dr John Fagan, Genetic ID, explains

There has been a fair bit of press coverage on both sides of the Atlantic concerning new European Union regulations on labelling and traceability of genetically modified (GM) food and feed. These new regulations, EC No. 1829/2003 and 1830-/2003, became effective in October 2003; both will be fully enforced starting in April 2004.

Labelling of GMOs in food is nothing new in the EU. For several years, any food product containing more than 1% GMO had to be labelled as 'containing genetically modified ingredients', a label that EU food producers and retailers have strived to avoid. Surveillance testing was used to confirm that levels of GMO in food products were at 1% or less. This policy, however, gave a free ride to highly processed food products whose processing destroyed the novel proteins or DNA sequences that indicate the presence of GMO.

The main concern that EU regulators and legislators had about the EU's old 'no GMO detected = no GMO' approach was that highly processed products could, in fact, have been made from ingredients containing GMOs, but still be declared as meeting the regulations because there was no GMO protein or DNA present in the final product. In addition, animal feed was exempted from the regulations, and over time there was increasing consumer and retailer demand for animal products that were given feed that did not contain GMOs.



Dr John Fagan, Genetic ID

As well as GMO testing, the new EU rules require traceability of food and feed ingredients back to their source materials. In cases where GMOs are present at or above levels that require labelling, labels will be required to use the EU's system of alphanumeric unique identifiers to identify each type of GMO present. Food and feed producers should also note that some previously banned GMOs are now permitted in food and feed products sold in the EU, as long as such GMOs have received a favourable risk assessment from the EU and their presence in the product is adventitious and technically unavoidable.

These new rules designate three types of GMO within the EU regulatory framework:

Approved GMOs have undergone a full evaluation procedure by the EU regulatory system. These can be present in foods at any level. This includes GMO corn (maize) varieties such as Monsanto YieldGard® (Mon 810) or AgrEvo Liberty Link® (AgrEvo T25). However, if such GMO varieties are present in foods at levels greater than 0.9%, the food product must be labelled as 'containing genetically modified organisms'.

Not approved but safety-assessed GMOs are GMOs that have not been fully approved for human food use in the EU but that have undergone a favourable safety assessment by a technical review panel. These GMOs are allowed to be present in small amounts – up to 0.5% – in a food product. Examples would be Monsanto's Roundup Ready® (GA21 and NK603) GMO corn varieties.

GMOs that are neither approved nor safety-assessed are not allowed in food products at any level in the EU. One example of this category of GMO is StarLink® corn, which did not pass a safety assessment and will not be approved for use in food. Other examples would be two new GMO varieties that were commercialised in the US this year, Monsanto's YieldGard Rootworm® (Mon 863) variety and the Dow-Mycogen-Pioneer Herculex I® (Dow 1507) variety. Both are in the process of undergoing EU safety assessment and may be approved for use in food at some point in the future under the EU labelling and traceability rules outlined above.

Discussions with representatives of many major food producers and retailers, particularly in the EU, indicate that they do not anticipate a major change in consumer sentiment regarding GMOs in the near future. Consequently they are maintaining their policies of keeping GMO levels in their products below the thresholds at which labelling is required.

It is conceivable that in the future this situation may change. However, analysts believe that this will require significant advances in the transparency of GMO development, safety testing, regulatory approval and commercialisation. Analysts also believe that another factor that may change the public's attitude toward GMOs will be the development of GMO varieties that have demonstrable health or other benefits for consumers. Such advances, however, will still need the aforementioned transparency and also have solid proof that they do not create unintended negative side effects for consumers or the environment.

Cost implications

The central cost issue is the scope of change that will be required of food and feed producers. The EU has had regulations on labelling of GMOs in food since 1998. From that date onward, most major players in the EU market and most international suppliers to the EU's food manufacturers and processors have implemented programmes for controlling the GM content of their products and keeping the level of GMOs in their products below EU thresholds for labelling. The new regulations will require some minor modifications, but significant increases in the cost of operating them are not anticipated.

The legal obligations for a producer operating within the EU are quite straightforward. EU producers need information from their suppliers identifying the specific lots of product such that traceability is maintained, and they need information stating whether or not GMOs are present in the product. EU producers are also required to maintain records of who purchased their products and the GM content of those products. In short, this is referred to as a 'one forward, one back' chain of custody and traceability system. It is simple and inexpensive.

In cases where an EU food producer is obtaining ingredients or raw materials from abroad, the first EU recipient is required to document the identify of the seller from whom they purchased the material. The first EU recipient is also required to have the supplier provide traceability back to the source of the raw material or the raw materials used in the purchased inputs, with documentation to support suppliers' claims. This is a more challenging requirement than buying and selling within the boundaries of the EU. However, the responsibility for satisfying these requirements is on the overseas supplier, not on the EU company importing the raw material or ingredient. This means that external suppliers to the EU market need to put a full traceability programme in place for products that they provide to EU food producers, manufacturers, brokers or retailers.

The stakes are high for companies working in or supplying the EU market. The actual fines for compliance violations will be relatively modest, but the cost of recalls and resulting brand damage could be considerable. Two essential elements are needed for compliance with the new EU GMO labelling and traceability regulations:

- Traceability. Traceability is the end result of an effective IP programme. If you have an effective IP programme, you will have traceability for your product from raw materials and input ingredients to final product.
- GMO testing. Rigorous GMO testing is in order to verify that levels of adventitious GM in ingredients, other process inputs and your final products are below the relevant EU thresholds (0.9% and 0.5%). These are quantitative thresholds. The testing method used to determine the amount of GMO present should be quantitative. And it should be as rigorous as the surveillance testing that regulators will be using. We recommend the use of the PCR (polymerase chain reaction) method, which is what EU regulators will be using and which is generally accepted as the gold standard for GMO detection and quantification.

Identity preservation and Certification

Testing is not enough. A Quality Control approach to keeping a product non-GMO requires constant (and expensive) testing of final products. It is much more cost effective to take a Quality Assurance approach. Integrating IP programmes into production systems has proven to be scientifically sound, cost-effective and consequently popular with food producers doing business in the EU.

Designing and implementing QA-based non-GMO Identity Preservation (IP) systems that comply with EU regulations (not to mention regulations or market specifications in other regions of the world) is not a trivial undertaking. Many food producers have found that it is much more economical to outsource the design and implementation of a practical,

cost-saving non-GMO IP system.

After a non-GMO IP system is in place, many producers have found that it also makes sense to have an independent third party organisation such as Cert ID certify that the system is delivering the desired results and is producing non-GM products. This approach provides an added layer of risk management and provides support in the event of a challenge to a non-GMO claim. Third-party certification is widely seen as a commitment to quality that gives consumers increased confidence in the product. It also provides product differentiation. Many European food manufacturers and retailers are now asking their suppliers to arrange for third-party non-GMO certification of their ingredients and products.

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