

Troubles with Thresholds

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Introduction

For decades, national seed certification procedures have been largely harmonized to facilitate international trade of seed. Adventitious amounts of foreign material and genetic off-types are always present in seed lots and most certification standards specify the acceptable levels for seed purity and genetic purity. Seed production procedures such as isolation distances and previous field history have been developed over time to achieve a balance of maximum levels of purity in a practical and cost effective manner.

Actual adventitious levels from numerous sources vary by crop kind due to the biology of the species. Within the existing international seed certification standards it is not uncommon to have genetic purity levels of 99 - 98% or a standard of 1-2% for adventitious genetic impurity.

As the acreage of unconfined commercial production increases, one must assume that the percentage of adventitious material from genetically modified (GM) sources is directly related to the percentage acreage planted to GM crops.

The assessment and approval of a GM event assumes that, with release into unconfined commercial production, the adventitious GM material can be expected to be present in seed lots and other food and feed shipments at the same level as traditional non-GM material.

Even though all certified seed production procedures have been met, it is highly likely that a GM crop has been grown on the seed production field in some previous year and the neighbouring commercial fields beyond the required isolation distances are planted to GM crops and detectable levels of pollen can still be carried into seed production fields.

For the crop year 2000, Canada's 12 million acres of canola is estimated to be 55% GM varieties. Argentina's soybean crop is estimated at 95% GM. This means that the threshold levels for adventitious GM varieties can be equivalent to the current levels allowed in traditional non-GM seed production. Commercial production of seed is the first step in a chain of production, handling and processing procedures leading to manufactured food product.

Thresholds set for food products must consider the capability of the food production chain to economically meet that standard.

Thresholds Defined

The seed industry refers to the numbers published in seed regulations as the "standard" and the tolerance is a measure of the standard deviation. The standard can be set at a level where 80 % of lots being grown using certification procedures could be approved. If the buyer or regulatory authority later retested the lot and found that the result exceeded the standard, then the tolerance is applied.

The initial "official test" is generally conducted in the originating country at the seller's expense. The initial test results must meet or exceed all contract specifications and is used as the basis for contract settlement. If the buyer or regulatory authorities want to challenge the initial test, any further "official test" results can only be accepted if they exceed the standard plus the tolerance. For example, a contract figure for germination of 90% has a tolerance of 6. If the lot was re-tested at destination and resulted it 87%, the lot must be accepted because it is within tolerance.

There are times when a standard of zero could apply to purity such as weed seeds. In this case a zero percent standard can still have a tolerance of 0.2.

Threshold is defined as a combination of the standard plus tolerance. For example, if the average level of adventitious GM in non-GM crops is determined to be 1% with a tolerance of 2% the threshold would be 3%.

Thresholds and Post Harvest Retesting

Let us assume that we have extensively sampled certified seed lots of a selected species and determined that the average purity was 99% or 1% for adventitious material. If the threshold was set at 1%, this means that if 100 lots of seed were sold and all lots were retested at a later time for regulatory or verification purposes, one would expect 50% of all shipments to be rejected at random.

The threshold should be set at a level that, having used accepted certification or segregation procedures, the lots being tested will be accepted 98 - 99% of the time.

This means that if the average adventitious material in a product being traded is found to be 1%, the threshold for regulatory or verification purposes must be considerably higher, perhaps 4-5 %.

The other option is to amend the seed production procedures to meet an average level of adventitious material of 0.1% in order for 98% of lots, if retested, to meet a 1% threshold. Subsequent Identity Preservation and segregation procedures would need to be amended to maintain the same threshold level. Keep in mind that when an event is approved for unconfined commercial release, it has met requirements for food, feed or environmental safety. Therefore the additional cost, which could be substantial, is solely for purposes of offering consumer choice.

Production practices are amended to a more costly level if a lower threshold is required for safety reasons. However, amendments to more costly production and handling procedures for reasons of offering consumer choice should not incur more cost than the consumer is willing to pay.

What is the Right Threshold for Seed?

An International Seed Network Initiative (ISNI) has been formed to evaluate methods available to detect adventitious amounts of GM on non-GM varieties. The ISNI is seeking international validation of the methods for use in international trade. This means that the seller of seed would know, prior to the sale, what the threshold is and the test method to be used to verify the threshold level. More important, if the buyer or a regulatory authority wished to retest the seed, the same methods and procedures would be required to be used.

International harmonization of national seed certification schemes is under the auspices of the OECD Seed Scheme. Recently there has been a series of OECD meetings attempting to negotiate an international threshold rather than ad hoc or unknown standards for each country. The EU position was based of a desire to meet an arbitrarily chosen standard of 1% in food. The EU position argued for a maximum threshold for seed of 0.5% or less.

Countries with large commercial production of GM crops are now able to evaluate the amount of adventitious GM material that may be found in non-GM crops. Preliminary results of testing the level of adventitious GM material found in non-GM seed lots suggest an average level of just under 1%. Canada, United States, Argentina and the International Seed Trade Federation's (FIS) position argued that anything less than 1% would be not be achievable.

Therefore, accepting a threshold at less than 1% or letting the talks fail and continuing to meet a standard of 0.5% or less will result in the same outcome. The October OECD Seed Scheme meeting failed to reach a consensus. We can not trade seed of certain species to countries with a threshold less than 1%.

Traders of commodities, food ingredients and manufactured foods would be advised to heed the findings in the seed industry and the status of negotiations.

Approved Versus Unapproved Events

An important development of the OECD Seed Scheme negotiations resulted in a distinction between threshold levels for approved and unapproved events. To date, none of the other international discussions such as Biosafety or Codex labeling have addressed this issue.

Regulatory authorities have implicitly stated that the threshold level for unapproved events is zero.

The implications of this are profound. While the seed industry will be primarily concerned with the international trade of varieties from countries of similar climatic adaptation, food manufacturers will want to source ingredients, and food retailers will want to import manufactured foods, from all parts of the world.

For example, if a GM event is approved in a tropical species and gains widespread commercial production in that tropical country, adventitious levels of the GM event must be expected in all other non-GM products that are grown in the area or handled in the same facilities. Canadian food manufacturers who import non-GM ingredients of tropical foods, or manufactured foods that contain tropical food ingredients, have a high probability that their imported products will contain a detectable level of an adventitious GM event and, if unapproved, the shipment will have a zero threshold.

This means that the regulatory authorities of every country must consider a means to “approve” every event that any country has approved for unconfined commercial production. Without some form of harmonized data and regulatory approval requirements among countries, consider the regulatory capacity and cost of doing this for perhaps hundreds of new events per year?

The recent case of non-GM canola seed shipments to the EU that subsequently tested positive for adventitious GM confirmed the application of a zero threshold. This makes the debate to establish an international labeling threshold a mute issue if countries maintain a moratorium on an approval process or refuse to approve any events due to overzealous use of the “precautionary principle”.

If commercial production of unrestricted GM crops are widely grown and seed, commodities, food ingredients or manufactured foods are to be internationally traded, trade will be severely affected due to a zero threshold for unapproved events if countries, such as the EU, refuse to offer a science based approval process.

For some interest groups, this is a desired outcome.

Validated Test Methods

The ISNI will be studying appropriate testing methods that could be used to verify the adventitious presence of GM in non-GM varieties. If the test is to be used to verify the content of a truckload of grain being delivered to a grain elevator or a shipment of an ingredient about to be unloaded at a food manufacturer, the test must be easy to conduct and affordable with results available in minutes.

“Negative Testing” is a major challenge. Rather than conducting a single test to confirm the presence of a specific event, a separate test would, in theory, need to be done to detect the presence for each approved and unapproved event. A single test could be used to detect a protein or DNA segment that is common to most approved events. However, if a new event is approved that does not share the common protein or DNA fragment, then further tests may be required. Further, other non-GM material could contain the same protein or DNA fragment and cause a “false positive” test result.

Negative testing is a challenge because the choice of test that can meet the above requirements often has limited detection levels. For example, an ELISA test may be limited to a 1% detection level. A negative ELISA test means that “no protein associated with certain GM events has been detected”. Product promotion people and politicians often convert this awkward statement into more absolute terms such as “GMO FREE” which is not correct. Users of Polymerase Chain Reaction (PCR) claim detection levels as low as 0.001 percent. By targeting a single event, hundreds of samples can be tested over several weeks at a cost of tens of thousands of dollars and a positive test can be produced. Where does that leave the claim of “GMO FREE” if the event is unapproved with a zero tolerance?

If the validated test method to be used for international trade is an ELISA test, the conditions of using this test include an understanding and acceptance of the detection limits. Without validated test methods for commercial trade, a seller can be using an ELISA test and confidently reporting that there is no detectable adventitious GM only to have a third party retesting the shipment using PCR at a much higher level of sensitivity and reporting a positive test. This can be devastating to a seller if the shipment is going to a country that has not approved the event and is applying an absolute zero threshold.