**ALA3.1 Interpretation of operation characteristic curves for GM testing**

**Prerequisites**

Understanding of:

1. Sources of error in marker data development
2. Approaches to minimize errors in marker data development
3. Testing procedures for genetic modifications

**Purpose**

Provide understanding that GM testing has to satisfy conflicting interests: those of GM seed providers, and the general public. GM testing procedures have to balance the risk to both parties, and are constrained by legislation (GM threshold) and technical capabilities of GM assays.

**Background**

Authorization of GM events depends on the legislation in a country, and involves a thorough study of the impact of GM events on health and ecology, among others. Countries that allow cultivation or utilization of GM crops, have established legislation on acceptable % of GM seed in supposedly GM free varieties used for sowing (usually 0%) or for feeding (such as GM maize and soybean in European countries: 0,9%). Those countries perform tests for GM% in seed lots, often in public or contracted certified laboratories. The problem is, that destructive tests required for DNA isolation make it impossible to determine the true GM% in a seed lot (would also be too expensive to test large numbers of kernels). Thus, proper sampling strategies have to be developed to estimate GM% of seed lots. Due to sampling error, GM% can be over- or underestimated.

**Tasks**

Suppose that the criteria involve sampling and testing 500 individual seeds, and to reject the lot if more than 1% of the seeds test positive for a transgenic trait.

1. Based on the set criteria, operating characteristic (OC) curves in Figures A and B (two curves: dotted, solid line) below were obtained. For each OC curve describe the implications to seed producers and consumers (general public), and compare with Figure 6 in eModule 3.
2. Figures A and B are based on the assumptions, that marker assays used for GM detection are free of error. How are OC curves and respective testing procedures affected, if marker-assays have a) 10% false positive, and b) 10% false negative detection rates ?
3. Given sampling and laboratory error, consider the optimal testing procedure in case of a 0 (zero) GM tolerance, as discussed in European countries.

**Figure A**



Figure B

**Tentative answers** (can differ, based on context / assumptions made)