

rather that it should be evaluated on the basis of its own unique composition. The WHO report (9) provides guidelines for determining substantial equivalence and provides case studies that may serve as examples of the kinds of analyses needed to establish the safety of food products from transgenic plants.

Safety assessment to gain regulatory approval for commercialization of potatoes with transgenic resistance to the Colorado potato beetle (10) concentrated on demonstrating that newly introduced proteins not found in the parental cultivar were safe and that transgenic tubers were substantially equivalent to the parental cultivar with regard to 23 other key components, including total solids, sugars (dextrose and sucrose), proximate composition (total protein, fat, carbohydrate, total dietary fiber, calories, and ash), vitamins (vitamin C, thiamin [vitamin B1], pyridoxine [vitamin B6], folic acid, niacin [vitamin B3], riboflavin [vitamin B2]), minerals (calcium, copper, iodine, iron, magnesium, phosphorus, sodium, potassium, and zinc), and natural glycoalkaloid toxicants (solanins and chaconines).

Nutritional analyses are needed to satisfy requirements for nutritional information that must be presented in the labeling (the label is called "Nutrition Facts" in the United States) on foods marketed in some nations of the world. These analyses are a part of the quality assessment aspect of agronomic performance, which may be reserved until final line selections are made for commercialization.

Other qualities assessed in the final stages of selection will depend on the crop and the importance of the quality. Additional qualities we assess in the final stages of transgenic potato development include incidence of hollow heart, brown center, internal brown spot, potato leaf roll virus-induced net necrosis, and other internal tuber defects, susceptibility to blackspot bruise, French fry color for tubers stored at 4.5 and at 7.3°C, incidence of sugar end, and severity of sugar end.

4. Notes

1. A strong root system is achieved in potatoes transplanted to flats from in vitro cultures by watering the plantlets with a 1:250 dilution of a soluble 15-30-15 nutrient solution.
2. For potatoes, we find that hand planting hundreds of small plots is faster and neater, and less subject to error than using a transplanter. Potato hills are established and side-dressed with fertilizer, using a standard potato planter. Holes for transplanting are punched by hand with a 40-mm diameter, thin-walled plastic pipe, and 250 mL of 1:125 dilution of the fertilizer described above is applied to the roots of each plantlet soon after it is transplanted.
3. In practice, the stringency imposed on type and yield conformity will be determined arbitrarily and will depend on many economic factors. Certainly, a loss equivalent to the cost of current disease control measures, plus the cost of current disease losses, should be tolerated.