



## MEETING

# GENETIC BASIS OF UNINTENDED EFFECTS IN MODIFIED PLANTS

14-15 January 2014

Lord Elgin Hotel  
100 Elgin Street  
Ottawa, Canada

Co-sponsored by:

Canadian Food Inspection Agency (CFIA)  
HESI Protein Allergenicity Technical Committee (PATC)  
ILSI International Food Biotechnology Committee (IFBiC)  
ILSI Research Foundation  
CropLife International

## BACKGROUND AND OBJECTIVES

As transgenic (GM) products worthy of commercialization became available, procedures were instituted to ensure that these plants were as safe for food, feed, and environmental release as their conventional counterparts. These procedures addressed the two types of changes that could be considered in a GM food / feed / environmental release safety assessment.

Of these two possible types of changes, one is referred to as "intended." This type of change in a new product is brought about by the introduced transgene. Because many transgenes express a known and characterized protein, procedures can be developed that directly assess the protein for toxicity and allergenicity, as well as measure levels of metabolites that may be associated with the protein's function.

The other type of change is referred to as "unintended." This potential change could materialize as a consequence of gene insertion or from random mutations that take place during the transformation and tissue culture process. Because the nature of unintended changes is unknown, there is no direct test for them. However, the potential for an unintended change to present a food or feed hazard is currently assessed through compositional analyses and agronomic studies. Some regulatory authorities may also require animal feeding tests.

Thus far, no adverse unintended changes have materialized. Consequently, a reevaluation of the original premise is merited.

The objectives of this meeting are to explore current knowledge and data gaps on unintended effects and discuss how this information can inform and improve risk assessments. The meeting will feature presentations on the molecular basis for unintended changes, a hypothesis-driven look at unintended effects in conventional and GM crops, and the consequences of unintended effects from a safety assessment perspective. Finally, a panel of experts will discuss the extent to which unintended or unexpected changes are hazardous.