Perceived risks associated with unintended effects of transgene insertion provide the impetus for an array of regulatory requirements for GM crops including environmental safety studies. Insertional mutagenesis, creation of cryptic reading frames, and perturbation of endogenous pathways are among the theoretical phenomena commonly cited as having the ability to cause unintentional adverse effects. The theoretical underpinnings of these phenomena are compared with similar risks for non-transgenic breeding methods, and empirical data are reviewed. It is concluded that these risks are higher for non-transgenic breeding methods compared with transgenic methods, and that the long history of safety with traditionally bred crops supports a similar level of regulatory oversight for GM crops. The value of assessing indirect effects of superior pest control within crop fields is also questioned based on the merits of raising pests or weeds within crop fields as a means to support desired non-target species.

Keywords: unintended effects, regulation, insertional mutagenesis